SFDA Certification
Diagnostic X-ray Facilities

Executive Administration for Radiological Health

Medical Devices Sector

A. General Information about Health Facility

Name of Health Facility		
Location (Province)		☐ Riyadh ☐ Madinah ☐ Tabuk ☐ Qasim ☐ Baha ☐ Jouf ☐ Eastern ☐ Makkah ☐ Najran ☐ Jizan ☐ Asir ☐ Hail ☐ Northern Border
A.1	**Type of Facility**	☐ Hospital ☐ Clinic ☐ MOH ☐ KFSH&RC ☐ University/college ☐ MODA ☐ NGHA ☐ SFH ☐ Private Sector Commercial Registration ____ Expiry Date ____ Provide a copy Commercial Registration ☐ ☐ Other *(Please specify)* *Note: (MOH=Ministry of Health, KFSH&RC =King Faisal Specialist Hospital and Research Centre, MODA=Ministry of Defense & Aviation, NGHA=National Guard Health Affairs, SFH=Security Forces Hospital)*
A.2	**Total Number of Beds**	
Address of Facility	City Address	
Manager/Supervisor	Name Job Title Nationality Contact Number E-mail	
A.3	**Does the facility obtain JCI or CBAHI accreditation?** *(JCI=Joint Commission International, CBAHI=Central Board of Accreditation for Healthcare Institutions)*	☐ JCI ☐ CBAHI ____/____/____ If No, what are Radiation Protection and Safety Procedures that department followed?
A.4	**Type of Certification**	Certification Name Certification No. Certification Date

B. Staffing

B.1	*(Please indicate numbers)*	**Total number of Staff**
B.2	**Responsible Doctor**	☐ check if the contact person
	Name	
	Job Title	
	Nationality	
	Contact Number	
	E-mail	
B.2.1	**Saudi Commission for Health Specialties Registration Info.**	
	SCFHS Registration No.	
	Specialty	
	Category	
	SCFHS Expiry Date	
B.3	**Radiation Safety Officer info.**	☐ check if the contact person
	Name	
	Job Title	
	Nationality	
	ID Number	
	ID expiry date	
	Contact Number	
	E-mail	
B.3.1	**Saudi Commission for Health Specialties Registration Info.**	
	SCFHS Registration No.	
	Specialty	
	Category	
	SCFHS Expiry Date	
B.3.2	**Radiation Safety Officer License Info** (provide Copy of RSO practice license ☐)	
	Practice License Type	
	Practice License No.	
	Expiry Date	

B.4	Worker(s)	☐ check if the contact person
	Name	
	Job Title	
	Nationality	
	ID Number	
	Contact Number	
	E-mail	
B.4.1	**Saudi Commission for Health Specialties Registration Info**	
	SCFHS Registration No.	
	Specialty	
	Category	
	SCFHS Expiry Date	

B.4	Worker(s)	☐ check if the contact person
	Name	
	Job Title	
	Nationality	
	ID Number	
	Contact Number	
	E-mail	
B.4.2	**Saudi Commission for Health Specialties Registration Info**	
	SCFHS Registration No.	
	Specialty	
	Category	
	SCFHS Expiry Date	

B.4	Worker(s)	☐ check if the contact person
	Name	
	Job Title	
	Nationality	
	ID Number	
	Contact Number	
	E-mail	
B.4.3	**Saudi Commission for Health Specialties Registration Info**	
	SCFHS Registration No.	
	Specialty	
	Category	
	SCFHS Expiry Date	

C. Facility Unit(s)

C.1	**IMAGING UNIT (S)**			
C.2	Unit Type (i.e. General X-ray, CT…)			
C.3	**Is the device** *(At time of purchasing)*	☐ New	☐ Used	☐ Refurbished
C.4	Manufacturer		Model	
	Year of Manufacture		Date of installation *(anticipated date for new)*	
	Maximum (kVp) in practice *(kVp=Kilovoltage)*		Maximum (mA) in practice *(mA=milliampere)*	
	Type of device *(C=Conventional orD=Digital)*		Total number of examination per week	
C.5	Tube Identification:			
C.6	**Provide a list of specifications and SN of all major parts**			☐
C.7	**Dees the unit licensed by SFDA?** (visit https://mdma.sfda.gov.sa/ListedProducts.aspx)	☐ No	☐ Yes >> MDMA Authorization No.	
C.8	**Does it connect to PACS?**			☐ Yes ☐ No
C.9	**The maximum Workload** **Provide a table of the maximum Workload against examinations type**			☐
C.10	**How many lead aprons available in the room?** **Do you test the lead aprons for shielding integrity?** **Provide a copy of the test result**			☐ Yes ☐ No ☐

C.11	**INSTALLATION**			
	Did you perform the Acceptance Test of the device(s) at the time of installation?			☐ Yes ☐ No
	Do you have a record of the Acceptance Test results?	☐ No	☐ Yes >> Where	
	The Acceptance Test performed by: (Please check all that apply) ☐ **Representative from the Vendor** ☐ **In-house Medical Physicist** ☐ **In-house Biomedical Engineer** ☐ **Third Party** ☐ **Other** _____			
	Did you perform other Tests at the time of installation	☐ No	☐ Yes >> list below	

C.12	**ROOM LAYOUT**			
	Is the room designed to be used for this unit?			☐ Yes ☐ No
	Please indicate the dimensions:	Length _____ m	Width _____ m	
	How many entry door(s) in the room?			_____ Door(s)
	Is the door width reasonable? *(≥ 1.2 m)*			☐ Yes ☐ No
	Is the room door(s) provided with Door Automatic Interlock? **If No, What is the alternative access that be used to close the door during exposure?**			☐ Yes ☐ No
	Does the Room contain any external window(s)?			☐ Yes ☐ No

	If Yes, is it Leaded Glass Window(s)?	☐ Yes ☐ No
C.13	**Is the room provided with Radiation Warning Sign (Light)?** *(Outside X-ray room)*	☐ Yes ☐ No
	Is the room provided with Radiation Signs written in (English & Arabic) languages	☐ Yes ☐ No
	Is the department layout and shielding approved responsible entity? **Provide Copy of previous official layout approve**	☐ Yes ☐ No ☐
	Did you perform a safety assessment for layout and shielding by qualified person prior to any modification? **Provide Copy of safety assessment by qualified person**	☐ Yes ☐ No ☐
	Did you apply radiation area survey for the unit room? ☐ Yes ☐ No **Do you have a record of the results?** ☐ Yes ☐ No >> Where ☐ **Provide Copy of Radiation Area Survey report** ☐	
	Provide a copy Unit Room layout shows: ☐ ○ The dimensions and shape of the room. ○ The location where the X-ray equipment and the range of movement of the X-ray tubes. ○ the patient's waiting area ○ The location, use, occupancy level and accessibility of adjacent rooms, as well as rooms above and below the facility ○ The designation of the adjacent rooms, whether to be designated as a controlled or uncontrolled area. ○ The location where image processing is performed, i.e., location of darkrooms, film storage area, computer workstations. ○ The planned and existing materials used to construct the walls, floor, ceiling, and the control booth, and their thicknesses including additional materials currently being used, or planned for use, as radiation shielding barriers.	

C.14	**SERVICE AND MAINTENANCE**
	Do you perform any type of Maintenance >>> ☐ **Corrective Maintenance** ☐ **Preventative Maintenance** ☐ **Emergency Maintenance** **Do you keep a record of Maintenance results?** ☐ No ☐ Yes >> Where ☐ **The Preventative Maintenance performed by: (Please check all that apply)** *(PM Interval* ☐ *)* ☐ **Representative from the Vendor** ☐ **In-house Medical Physicist** ☐ **In-house Biomedical Engineer** ☐ **Third Party** ☐ **Other** _____

C.15	**RADIATION SAFETY PROGRAM**
	Provide a copy of the Radiation Safety Program ☐ **Provide a copy of procedure manual and department policy** ☐

C.16	QUALITY ASSURANCE PROGRAM
	Do you have a written Quality Assurance Program? ☐ Yes ☐ No
	Does the QA Programme contain periodic QC checks? ☐ Yes ☐ No
	Do you have a record of the routine QC Testing results? ☐ Yes ☐ No
	>> Where ☐
	Provide a list of type, frequencies and last Date of the routine QC Testing ☐
	The routine QC Testing performed by: (Please check all that apply) ☐ **Representative from the Vendor** ☐ **In-house Medical Physicist** ☐ **In-house Biomedical Engineer** ☐ **Third Party** ☐ **Other** _____

C.17	RADIATION MONITORING *(Personnel Dosimeters)*	
	Personnel dosimeters available at facility	☐ OSL *(Optically Stimulated Luminescence)* ☐ TLD *(Thermoluminescent Dosimeter)* ☐ Film Badge ☐ Direct Reading Dosimeter ☐ Other *(Please specify)* ☐
	Where do you read the TLD (or OSL)?	☐ Inside facility ☐ Outside facility *(Please specify)* ☐
	Specify intervals reading of Personnel dosimeters in one year ☐	**Date of last report** ☐
	Provide copy of personal radiation dose records for each employee ☐	

Filled by:.....**Signature** ....