SFDA Certification
Radiotherapy 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 a Copy of RSO practice license ☐)	
	Practice License Type	
	Practice License No.	
	Expiry Date	

C. Facility Unit(s)

	FACILITY INFO	
	Facility type Facility Name Total number of Staff Total number of unit (s) Address	
	Room Location Number of unit(s) in the room	

	RADIOTHERAPY UNIT			
	Unit Type (i.e. General X-ray, CT…)			
	Is the device *(At time of purchasing)* ☐ New ☐ Used ☐ Refurbished			
	Manufacturer		Model	
	Year of Manufacture		Date of installation *(Please indicate the year)*	
	List specifications and SN of all Major parts ☐			
	The maximum Workload			
	Provide a table of the maximum Workload against examinations type ☐			
	Is there an In-house (On-site) engineer? ☐ Yes ☐ No			
	Is the device registered? ☐ No ☐ Yes **Provide evidence** ☐			

	INSTALLATION *(RADIOTHERAPY UNIT)*
	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

	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** _____

	FACILITY INFO	
	Facility type Facility Name	
	Room Location Number of unit(s) in the room	

	IMAGING UNIT (S)			
	Unit Type (i.e. con beam X imaging, CT…)			
	Is the device *(At time of purchasing)* ☐ New ☐ Used ☐ Refurbished			
	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	
	Tube Identification:			
	List specifications and SN of all Major parts ☐			
	Is the medical device registered with the SFDA? ☐ No ☐ Yes >> MDMA Authorization No. (visit https://mdma.sfda.gov.sa/ListedProducts.aspx			
	Is the device connected to PACS? ☐ Yes ☐ No			
	The maximum Workload **Provide a table of the maximum Workload against examinations type** ☐			
	How many lead aprons available in the unit room? **Do you test the lead apron for shielding integrity?** ☐ Yes ☐ No **Provide a copy the lead apron for shielding integrity test?** ☐			

	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

	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** _____

	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)? **If Yes, is it Leaded Glass Window(s)?**	☐ Yes ☐ No ☐ Yes ☐ No
	Is the room provided with Radiation Warning Sign (Light)? *(Outside the room)*	☐ Yes ☐ No
	Is the room provided with Radiation Signs written in (English & Arabic) languages	☐ Yes ☐ No
	Is the room provided with Audio Intercommunication System?	☐ 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 installation or any modification? **Provide Copy of safety assessment by qualified person**	☐ Yes ☐ No ☐
	Did you preform radiation area survey for the unit room? **Do you have a record of the radiation area survey results?** >> Where _____ **Provide Copy of Radiation Area Survey report?**	☐ Yes ☐ No ☐ Yes ☐ No ☐ ☐
	Provide a copy Unit Room layout shows: ○ The dimensions and shape of rooms. ○ The location where the radiation unit and the possible range of movement. ○ 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	

	RADIATION PROTECTION PROGRAM
	Provide a copy of the radiation protection program ☐

	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** _____

	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 Film Badge)?	☐ Inside facility ☐ Outside facility *(Please specify)* ☐
	Specify intervals reading of Personnel dosimeters in one year ☐	**Date of last report** ☐
	Provide a copy of personal radiation dose records for each employee? ☐	

	RADIATION DETECTION *(Personnel Dosimeters)*	
	Detector type *(i.e Dose Calibrator, Portable Survey Meters..)*	
	Intend of use:	
	Manufacturer	
	Year of manufacture	
	Model	
	S/N:	
	Last Date of calibration	
	List of calibration/QC sources *(used with the unit)*	
	Is the device *(At time of purchasing)*	☐ New ☐ Used ☐ Refurbished
	Is the device connected to computer system?	☐ Yes ☐ No

	RADIATION DETECTION *(Personnel Dosimeters)*	
	Detector type *(i.e Dose Calibrator, Portable Survey Meters..)*	
	Intend of use:	
	Manufacturer	
	Year of manufacture	
	Model	
	S/N:	
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	List of calibration/QC sources *(used with the unit)*	
	Is the device *(At time of purchasing)*	☐ New ☐ Used ☐ Refurbished
	Is the device connected to computer system?	☐ Yes ☐ No

	RADIATION DETECTION *(Personnel Dosimeters)*	
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	Intend of use:	
	Manufacturer	
	Year of manufacture	
	Model	
	S/N:	
	Last Date of calibration	
	List of calibration/QC sources *(used with the unit)*	
	Is the device *(At time of purchasing)*	☐ New ☐ Used ☐ Refurbished
	Is the device connected to computer system?	☐ Yes ☐ No

	RADIOACTIVE SOURCES *(used within the facility)*	
	Radionuclide:	
	Radiation Activity:	
	Intend of use *(type of examination and relevant devices):*	
	Purpose of use: *(Diagnostic, therapeutic or calibration)*	
	Quantity *(used by the facility within one year)*	
	Is there a solid waste require exporting?	☐ Yes ☐ No

	RADIOACTIVE SOURCES *(used within the facility)*	
	Radionuclide:	
	Radiation Activity:	
	Intend of use *(type of examination and relevant devices):*	
	Purpose of use: *(Diagnostic, therapeutic or calibration)*	
	Quantity *(used by the facility within one year)*	
	Is there a solid waste require exporting?	☐ Yes ☐ No