Certification Requirements for Medical Radiation Facilities

Executive Administration for Radiological Health

Medical Devices Sector
A. GENERAL REQUIREMENTS

Each Radiology Unit at any Health Facilities having or intend to acquire a radiation emitting devices or radioactive sources used for medical applications shall:

1. Register as New Facility to obtain a valid account and a corresponding Facility ID number.

2. Choose a single person at each facility to be the contact person (it is preferable that person is the radiation safety officer/representative). The contact person is able to update information regarding their facility.

3. Submit a written letter to the SFDA requesting registration and detailing date of opening, aims and your plan to install and operate facility. Also the location, type and number of unit(s) in the facility.

4. Submit a written Authorization letter by the Facility to a representative (the contact person) for completing the Medical Radiation Facility Registration.

5. Complete and submit documents required by the Medical Radiation Facilities Registration Form accordingly to its practice and list each unit (s) at the facility. Medical Radiation Facilities Registration Forms as follow:
   a. Diagnostic X-ray facilities Form.
   b. Nuclear Medicine facilities Form.
   c. Radiotherapy facilities Form.

6. For new facility(s) or radiation unit (s) cannot be operated prior to registration and, if applicable, certification. A facility’s unit(s) must be registered prior to the completion of installation of the unit(s) at the new location.

7. Multi-Location facilities will need to register 'A' and 'B' facilities in “location type facility”.

8. For Relocation facility(s) or radiation unit (s) the applicant shall:
a. Submit a written letter requesting cancellation of your old registration number for the facility(s) or the radiation unit.
b. Submit disassembly reports.

9. For Closing facility(s) or radiation unit(s) the applicant shall:
   a. Submit a written letter requesting cancellation of your old registration number for the facility(s) or the radiation unit.
   b. Submit disassembly reports.

10. Prior to construction new facility/unit or significantly modified facility/unit, the applicant shall consult a qualified expert for radiation protection concerning room design, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations.

11. Acceptance testing and commissioning are the process of testing a new unit, or significantly modified unit, to establish the performance characteristics and to ensure that the machine meets the product specifications and the purchase agreement.

12. The SFDA may, after applying for registration and before certification, require further information to enable the SFDA to determine whether the request will be granted or denied.

13. Medical devices in general and ionizing radiation machines or sources in particular, including their equipment and accessories, should be purchased only from authorized vendors.

14. Members of the SFDA are free to visit the medical radiation facilities at any point, and to seek appropriate implementation of regulations. Failure to comply may result in cancellation of certification.

15. Registrant or applicant in specific co-operation with vendors shall ensure that all medical devices are registered and licensed by SFDA.
16. Each registrant or applicant shall develop, document, and implement a Radiation Safety Program sufficient to ensure an adequate level of protection to patients, workers and the public.

17. The registrant or applicant shall use, radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

18. All and any personnel operating on the facility shall be qualified and has prior training.

19. The registrant or applicant shall review the Radiation Safety Program content and implementation at intervals not to exceed 12 months.

20. Each record required by the SFDA shall be retained and cannot be disposed of without first notifying SDFA. The registrant shall maintain adequate safeguards against tampering with and loss of records.

21. The registrant shall maintain following records:
   a. Names of persons involved, in operate and maintain the facility.
   b. The daily workload resulting from the operation of the equipment.
   c. Personnel dosimetry results.
   d. Details of incidents involving the facility equipment.
   e. Purchases and transfers of the facility equipment.
   f. Records of the tests and safety and warning devices.
   g. The radiation surveys reports.
   h. Doses received workers, patients, during planned special exposures, accidents, and emergency conditions.
   i. Inventory of the facility equipment including radiation devices and sources.
   j. Leakage test results.
   k. Decommissioning results.