

SFDA Requirements for Radiological Health

Safe practice in health facilities

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Introduction

The Saudi Food & Drug Authority (SFDA) intend to regulate radiation emitting devices that affect human health as indicated in the royal decree was issued on Feb. 13, 2007 to establish the law of the SFDA. For ensuring that safety regulations are followed in all medical operations involving radiation emitting devices in the country. All regulatory requirements are based on the SFDA Medical Devices Interim regulation, which are issued by Saudi Food & Drug Authority Board of Directors Decree number 1-8-1429 and dated 27 Dec 2008.

The SFDA covers all medical regulatory aspects of ionizing and non-ionizing radiation for all practices and intervention requirements. Users of medical ionizing and non-ionizing radiation sources shall apply to these basic requirements to their own particular practices.

Justification, optimization and limitation are the core and basics of radiation protections and safety. The typical exposure to a patient shall be limited, thus to ensure that both the total effective dose and total equivalent dose to the related body parts are maintained below the related dose limit.

These regulations shall be implemented within each healthcare provider. The goal of this document is to ensure and promote the efficiency of the radiation protection program, and to minimize the radiation risks. Thus, healthcare providers shall comply with these regulations.

Terms and Definitions

‘ALARA’ means as Low as Reasonably Achievable.

‘CT’ means Computed Tomography Scan.

‘CTDI’ means Computed Tomography Dose Index.

‘DXA’ means Dual Energy X-ray Absorptiometry.

‘Healthcare Provider’ ‘HCP’ means any hospital, center or clinic that uses medical ionizing or non-ionizing radiation.

‘Ionizing and Non-Ionizing Radiation’ means any radiation that has enough energy to move atoms in a molecule around or cause them to vibrate, but not enough to remove electrons, is referred to as "non-ionizing radiation. And any radiation that falls within the ionizing radiation" range has enough energy to remove tightly bound electrons from atoms, thus creating ions.

‘IT’ means Information Technology.

‘KERMA’ means Kinetic Energy Released in Matter (Air).

‘MDMA’ means Medical Devices Marketing Authorization.

‘MI’ means Mechanical Index.

‘MOI’ means the Ministry of Interior.

‘mSv’ means milli Sievert is a derived unit of ionizing radiation dose in the International System of Units.

‘OSL’ means Optically Stimulated Luminescence.

‘QA’ means Quality Assurance.

‘QC’ means Quality Control.

‘MRSO’ means Medical Radiation Safety Officer.

‘SFDA’ means Saudi Food and Drug Authority.

‘TI’ means Thermal Index.

‘TLDs’ means thermoluminescent dosimeter is a type of personal radiation dosimeter.

Chapter 1\ Radiation Protection Related Responsibilities

1.1 Healthcare Provider

The healthcare provider is totally responsible for implementing the radiation safety program within the facility in order to protect staff, patients, and the public from unintended hazards of ionising radiation. The main responsibility of the healthcare provider is to comply with SFDA regulations and requirements of radiation safety that are applicable to the service provided. The healthcare provider should assign qualified personnel to be in charge for this liability. The number of assigned staff depends on the workload of radiation departments within the facility. The following subheadings illustrate their duties.

1.2 Medical Radiation Safety Officer (MRSO)

MRSO shall be assigned to undertake the job of assessing the radiation protection program and to ensure the quality and continuity of this program within the facility; to share the program information with the staff and assure their compliance with its parameters. This responsibility should cover all radiation protection aspects that include requirements for personnel safety, equipment and products safety, and facility security. The MRSO shall have a qualification within the field of radiology, nuclear medicine and in some cases within medical physics or health physics and certified as MRSO. Also, shall attain refreshment courses regularly.

The MRSO shall be responsible for:

1. Liaise with SFDA for new facilities requirements.
2. Assessment of radiation safety during the planning for new installation which includes any new construction or modification within the facility.
3. To establish a generic radiation protection program, according to the national and international standards of radiation safety and shall be reviewed annually.
4. Carry out a periodic inspection of the facility complies with SFDA and Ministry of Interior radiation protection requirements.
5. Monitor the compliance with the radiation protection program and report any breach.
6. Assessment the radiation safety program regularly and update them if needed.

7. Instruct staff who is operating radiological equipment with appropriate radiation safety practices.
8. Determine minimum hours of training for newly employed personnel, trainees, volunteers, and any authorized person involved to work within radiation department.
9. Assure the availability of radiation survey devices, should perform quality test and calibrated at a reference/accredited lab.
10. Keep radiation survey records, including any incident report and its corrective action.
11. Keep records of all personnel readings, report and inform if any person has exposed to an excess dose of radiation.
12. Ensure that each person has registered with the national dose registry within SFDA.
13. Strictly assure that each worker at any radiation department wear a personal dosimeter during their work within the department.
14. Conduct an investigation in the case of any worker or patient has exceeded the set limit of radiation dose; and takes a corrective action to prohibit its recurrence.
15. Full and comprehensive understanding of radiation safety program.
16. Continuous learning of any new aspects of radiation safety.
17. Overseeing and implementing the operational aspects of the radiation protection program.
18. Meet all SFDA requirements as well as procedures of the license issued during the performance of all radiation safety activities.
19. Review and approve any changes in the radiation protection program before implementation.
20. Find and investigate on radiation safety issues in the workplace
21. Initiate, recommend, or provide corrective actions for safety problems that have been found.
22. Verify and perform the corrective actions.
23. Stopping any unsafe procedures.
24. Notify management of corrective actions, unsafe operations, and radiation safety problems.
25. Serve as a member of the radiation safety committee, if applicable, and attends the meetings.
26. Provide a link between the radiation safety committee and the users of ionizing radiation.
27. Provide contact between the regulatory agencies and the licensee (SFDA and MOI).

28. Being available to be contacted from the staff as required in the regulations.
29. The MRSO shall sign a sealed-source leak tests every 6 months and the sealed source inventories, per regulation.

1.3 Practitioner

The justification of radiation procedure is the main liability of the practitioner. Moreover, the practitioner must:

1. Own qualifications that are essential to practice diagnostic or therapeutic radiation program.
2. Obtain refresher-training courses within the field of national and international radiation regulations as well as SFDA requirements and standards.
3. Find, if applicable, any examination that could be utilized in the field of ionizing radiation.
4. Be aware of the risks that are linked to ionizing radiation.

1.4 Health Informatics Specialist

Due to the innovation and development in medical IT in imaging management and the digital processing of medical images, the medical facilities require qualified and well-trained personnel specialized in Bioinformatics or Health Informatics. The Bioinformatics or Health Informatics Technologist shall:

1. Be qualified and well trained in health informatics or relevant specialty.
2. Receive training from manufacturers regard their system, e.g. picture archiving and communication system, hospital information system (HIS), laboratory information system, clinical information system (PACS), etc.
3. Be knowledgeable of networking concepts and medical device technologies.
4. Comprehend the significant role of quality assurance of the bio - info system, this to ensure obligation to the rules of good data quality to supervise monitor calibration, system stability, and system performance. In addition, the physicist can use these data to help drive quality improvement initiatives.

5. Evaluate the clinical information systems for potential weaknesses, areas requiring constant maintenance and failure modes. Update other staff regards any changes to the system, either hardware or software.

1.5 Biomedical / Clinical Engineer Responsibilities

The responsibility of biomedical / clinical engineer is to undertake the pre-purchasing medical device evaluation, technology assessment, and ensure that SFDA regulations and requirements have been met. Manage medical devices and their related clinical systems, repair and the maintenance of software and hardware on medical device imaging units and their systems. The biomedical engineer shall:

1. Have a qualification in biomedical or clinical engineering or any relevant specialty.
2. Receive training from manufacturers regard their system.
3. Receive training in radiation protection programs.
4. Assure that the status of the equipment is matching the manufacturer specifications and comply with SFDA regulations.
5. Take into account the manufacturer's instructions for corrective and preventive maintenance.

1.6 Clinical Medical Physicists

Medical physicists in a radiology department shall contribute in planning the location of the department. Their major responsibilities and contributions as follow:

1. Delineating of the radiology department.
2. Optimizing the radiology department procedures.
3. Participating in planning the radiology department resources.
4. Participating in the educational and training programs.
5. Involving in public education.

Chapter 2\ Facility and Medical Radiation Emitting Devices Requirements

2.1 General Requirements

2.1.1 General Facility Requirements:

The most important criteria are to make sure that any person within the proximity of the radiological department is exposed to a level of radiation that meets with the international dose limit (Table 2.1.1).

Table 2.1.1: Summary of dose limits.

	Occupational exposure	Apprentices of 16 to 18 years of age, who are in training for employment and students of 16 to 18 years	Public exposure
Effective dose	20 mSv per year ** averaged periods over 5 years, with no single year exceeding 50 mSv	6 mSv in a year	1 mSv in a year;
Equivalent dose to the lens of the eye	20 mSv per year	20 mSv per year	15 mSv per year
Equivalent dose to the extremities (hands and feet) or the skin*	500 mSv per year	150 mSv per year	50 mSv per year

*The equivalent dose limits for the skin, apply to the average dose over 1 cm² of the most highly irradiated areas of the skin

** The dose to the embryo/fetus for pregnancy worker should not exceed about 1 mSv during the remainder of the pregnancy.

Table 2.1.1 shows:

- In a controlled area, where staff is working, the radiation level received by the worker shall not exceed 20 mSv/year.
- In an uncontrolled area, the radiation level received by any person shall not exceed 1 mSv/year.
- In a sensitive area, for example, pediatric wards, the radiation level of 0.30 mSv/year should be implemented.

2.1.2 Staffing

- (a) A suitable qualifications for all working staff shall be:
- A degree that is suitable for the field that approved by registered education as well as examining institutions, as per the country's requirements, and authentication by relevant boards and societies.
 - Attend medical radiation protection courses for which the teaching institution, methodology and contents are accepted by the SFDA.
 - For the training for jobs that are overseen by qualified and experienced professionals, as per the country's requirements before working independently.
- (b) All members of staff should be registered with the Saudi Commission for Health Specialist. The MRSO need to acquire a certification from SFDA or any other approved institute by SFDA.
- (c) The healthcare provider should offer radiation-monitoring badges to enhance safety for any member of staff, which might exposed to 10% of the public dose limit during his/her work.
- Two personal dosimeter shall be assigned to each worker (primary and secondary).
 - Each worker shall wear a personal dosimetry when the worker expected to receive a does that exceeds the limit of (1 mSv/year).
 - When extremities are expected to receive high doses of radiation, additional personal dosimeter shall be worn on an extremity.
 - MRSO shall perform a risk assessment to determine the expected yearly dose limit of the workers in a location where a high risk of radiation is expected (e.g. Radiology department, radiation dental practices, operation room, and emergency room). If this limit exceeds 1 mSv/year, personal dosimeter shall be provided.
 - Personal dosimetry shall be read periodically (max three months).
 - Each worker shall wear the second personal dosimetry while primary personal dosimetry is being handled for reading.
 - HCP shall keep a dosimetry record for each worker in the facility.
 - The MRSO is required to inform the workers about the results of radiation monitoring.
 - When dressed in lead apron, badges shall be worn under the apron.
 - Personal dosimetry shall be read by an SFDA approved party.

2.1.3 Service and Maintenance

The departments of clinical engineering are in charge of managing, servicing and maintaining REDs up to manufacturer recommendation in a professional manner. They have to ensure that any radiological device shall have a medical device marketing authorization (MDMA) certificate prior to installation.

Medical physics shall apply all necessary tests that related to radiation protection liaising with clinical engineer. The HCP clinical engineering shall make sure that maintenances (corrective, preventive and emergency) are performed properly. All maintenance procedures should be incorporated into the quality assurance program based on the frequency recommended by the radiation medical device's manufacturer as well as the appropriate professional association. The clinical engineer should keep a descriptive maintenance report for each device.

The clinical engineer required to establish a medical device management system that includes manufacturer, distributor and importer information. Medical device information, history, maintenance report and spare parts being installed and used quality management program which include:

- Final acceptance test for the device(s) during installation.
- Mechanical as well as electrical safety tests during installation time.
- Appropriate temperature and humidity control.
- Corrective, preventative and emergency maintenance.

2.1.4 Quality Assurance Program

The medical physics department should develop a comprehensive QA program for any radiation medical device. QA program should not be lower than the SFDA minimum requirements:

- (a) A set of appropriately identified individuals assigned responsibility for performing the QA checks and the QC tests.
- (b) Quality control (QC) activities will include:
 - QC Tests to be conducted along with each test frequency.
 - A set of test equipment will be required.
 - Acceptability restrictions for all tests conducted.
 - Description of the procedure of each QC test.

- Periodic QC survey for medical physicists.

(c) Policies and procedures for:

- Protecting patients, user and public from unintended hazards of ionising radiation exposure.
- Pregnant patients or worker.
- Gonadal shielding.
- Orientation plan for CT equipment, fluoroscopic and other radiographic operators, including the program timing and content.
- Personal protective equipment that are needed; e.g. lead aprons, gloves and goggles.
- Personnel radiology monitoring.
- Radiation safety survey of the surroundings over newly installed X-ray equipment.
- Responsibilities for radiation safety.

(d) Corrective maintenance plan that will include:

- Processes to be implemented when the X-ray equipment requires calibration, service or repair.
- Actions to be implemented when the processor requires servicing or repair.

(e) Data management system or keeping records that will include:

- Recent records, the last year in particular, for the QC tests that the registrant performed.
- Earlier records for the medical physicist's QC survey alongside with the latest two QC surveys.
- Preventive, corrective and emergency maintenance records.
- Records for personnel monitoring.
- Records for protective clothes.

(f) Reference of QA manuals and storing methods.

2.1.5 The Design of Facility

At the beginning of the designing stage of a medical X-ray facility, three steps should be considered in order to provide a sufficient shielding. This will achieve and fulfil the necessary level of radiation protection:

- Facility Plan Preparation.
- Room Design and Layout.

- Structural Shielding Parameter.

2.1.5.1 Facility Plan Preparation

During this step, the preparation of the floor plan is required and the following aspect shall be determined and considered:

- The shape and the dimensions of the location (X-ray room). In addition, the position of the windows and doors should be considered so that they do not affect the level of radiation protection.
- The movement of the X-ray tube should be visualized to help plan the X-ray equipment.
- The location of the control area and the image processing rooms.
- The locations of the neighboring rooms, including the rooms below and above the facilities (what are they used for and who occupy them?).
- These rooms should be classified wither they are considered as controlled area, uncontrolled area or radiation sensitive area.
- The materials were walls, floor, ceiling, and the control area is constructed from and their thicknesses which may use as radiation barriers.
- The installation of the protective shielding.

2.1.5.2 Room Design and Layout

During this step, in order to properly design the layout of the medical X-ray facility, the following SFDA requirements shall be considered:

- General X-ray rooms should have an automatic closing door.
- General X-ray rooms shall have hard material pregnancy and radiation warning signs in both Arabic and English languages.
- When an X-ray room is being used (irradiation), it is not allowable for anyone to go inside the room without the permission of the operator.
- Pay extra attention to the direction of the X-ray beam (primary beam). Sufficient shielding shall be provided, in particular behind the wall-mounted.
- The control area and its viewing window shall be properly shielded to ensure that the operator does not receive more than 20 mSv annually.

- Whenever possible, the X-ray beam has to scatter at least twice before entering the control area.

2.1.5.3 Structural Shielding Parameters

The following parameters shall be considered, since these parameters are subjected to change in the future, conceding an allowance is recommended.

- The maximum X-ray Workload (W):
Which referred to the operational time. In another word, how long the X-ray equipment has been used.
- The occupancy factor (T):
Which referred to the fraction of time when an individual is occupying the area of interest while it is operating.
- The use factor (U):
Which referred to the fraction of the workload when the X-ray beam is directed toward the area of interest.

2.1.5.4 Warning Signs, Lights and Locking of Rooms

A sign should be placed at each entry point to the radiography room to indicate the existence risk of radiation. Additionally, a sign indicating that the X-ray room is a controlled zone. The doors that lead to radiography facilities should carry a hard material warning post about the dangers of radiation in Arabic and English languages. If warning lights are close to or over the entrance that lead to the facilities, then such lights should be:

- A yellow or white to indicate if the X-ray device is on and ready to be used; this light should bear the words “*DEVICE OPERATIONAL*”.
- A red light to indicate if the radiological machine is producing radiation, this light should bear the word “*NO ENTRY*”.



Figure.2.1.9.a: samples of radiation warning signs.



Figure.2.1.9.b: sample of radiation pregnancy warning signs.

2.1.6 Availability of Records

Keeping of records is critical for future reference. The following records should be kept at least for the last 5 years.

- The drawing records of the accepted shielding, in addition to its calculations.
- Construction justifying the installed shielding.
- Survey reports.
- Information on changes.
- Subsequent survey reports after changes.
- Personnel dosimetry.
- Area survey outcome.

- Rejected images and films.
- Installation documents, including conditions of power as well ventilated.
- Service manuals.
- Operating instructions.
- In-service training offered.
- Preventative maintenance reports.
- Emergency maintenance reports.
- Corrective maintenance reports.
- Electrical safety reports.
- Lead apron tests for shield integrity.

2.1.7 Emergency Plans

- Written emergency strategy within the department rooms.
- The written emergency strategy should be reviewed and updated periodically.
- Any adverse case should report to the SFDA.
- Actions of preventing any adverse cases in future.

2.2 Diagnostic X-ray Facility

Any new establishment of diagnostic or therapeutic facility, SFDA approval and certificate of such practice will be mandatory.

2.2.1 General

The requirements for the integration of safety and protection aspects are effectively developed when the facility is being designed (X- ray rooms alongside with other associated rooms). The three components (shielding, distance and duration) need to be considered for dose reduction as required by SFDA. The safety features are outlined below:

- a. All medical devices utilized within the department should have the SFDA MDMA.
- b. The room design should be isolated in a manner that the X-ray beam does not point to an unprotected area; e.g. waiting area and corridor.

- c. The X-ray room ought to be designed in a way that it prevents the direct incident of the X-ray beam on access doors. The doors should be designed to function as protective barriers for dispersed radiation and should be closed if the X-ray beam is ON.
- d. The operator should have clear observation of the patient during the X-ray diagnostic procedure.
- e. The patients' waiting area should be in appropriate distance from the operational room.

2.2.2 Structural Shielding

The new facility should have approval from the SFDA in order to assure that the shielding design meets SFDA requirements in order to protect staff and end-users as well as the public.

- The room shielding should revolve around a part of the yearly dose limit. It should not exceed 5 mSv annually for the radiation staff as proposed for regulated areas.
- The yearly limit of efficient dosage to members of the public, the SFDA propose a protective design objective of about 1 mSv annually for unrestricted areas.

Table 2.2.2: Suggested minimum distances to the vital organs of an occupant in an adjoining area.

Boundary	Minimum distance to occupant in adjoining area
Walls	0.3 m
Ceilings	0.5 m from the floor above
Floors	1.7 m from the floor below

The material variations that can be utilized for providing radiation shielding comprise:

- Lead sheet and lead fabricated products.
- Concrete products.
- Barium plaster.
- Brick.
- Gypsum wallboard.
- Leaded glass.
- Leaded acrylic.

- Other materials, for instance, steel alongside with wood for low energy equipment such as mammography.

The shielding specification should be dependent on the maximum voltage, which will be used within the X-ray device, the biggest radiation beam's field size in conjunction with the largest approximated workload for the device. Researches have indicated that 3 mm of lead (300 mm of concrete or 350 mm of brick is used mostly for shielding the direction of the radiation beam (primary beam). In directions that are affected solely by leakage or scattered radiations 2 mm of lead (200 mm of concrete or 250 mm of brick) is sufficient. In general, the shields over the walls, which are solely affected by leakage or scattered radiations, extend below 2 m in terms of height.

2.2.3 Size of Rooms

- The practical conditions of radiological protection are dependent on the medical roles the room has been developed for, and the workload as well as adjacent occupancy.
- From the perspective of radiation protection, it may be imperative that the size as well as plan of X-ray room is in line with their function.
- It is necessary that the room should be spacious enough to enhance the examination of bedridden patients and accommodation of peripheral devices as well as operation kit.
- It may not always be easy to leave the room when examinations and fluoroscopy is underway. However, in such instances, the people conducting the operation as well as others present in the area should be capable to move away to a safe distance or have protection in a different shield.
- The designing of the rooms should provide a certain consideration for the size of the room. The operator should have the ability of observing the patient during the entire period of the X-ray diagnostic procedure.
- X-ray rooms ought to have a size, which allows unlimited access as well as ease of motion around the device, the patient table together with the operator's console.
- The variation in the room size will be largely dependent on the space, cost and modality.
- Mammography rooms, complex Interventional rooms and general X-ray rooms shall be in sizes of not less than 15, 50 and 33 m² respectively.
- General X-ray rooms that have X-ray tubes mounted on the ceiling should have 3.1 m between the level of the floor and the underside of the ceiling board in terms of minimum height. A

height of 2.4 m for conventional ceiling should be sufficient for dental as well as dual energy X-ray absorptiometry (DXA) rooms.

- Patient doors ought to be adequately big for easier passage of beds as well as trolleys.
- For general X-ray rooms, the approximate lead for the door is mainly 2 mm at 150 kV. However, doors of approximately 3-4 mm lead at 150 kV and more might be needed for angiography suites in conjunction with multiple slice CT.

Table 2.2.3: Transmission through lead at 75 kVp, and lead equivalent thickness of various materials.

Lead Thickness (mm)	Transmission at 75kVp	Steel (mm)	Barium plaster (mm)	Concrete (mm)	Brick (mm)	Plate glass (mm)	Gypsum (mm)	Wood (mm)
1	6.9E-4	7	11	88	123	102	263	879
1.32	1.5E-4	10	14	117	157	131	446	1340
1.8	1.6E-5	13	19	162	207	173	446	1340
2	6.1E-6	15	21	181	228	191	491	1454
2.24	2E-6	17	23	205	253	212	545	1591
2.65	2.9E-7	20	27	244	295	248	638	1824
3	5.8E-8	23	31	278	332	279	717	2024
3.15	2.9E-8	24	32.4	293	344	292	751	2109
3.55	4.4E-9	27	36.6	332	385	328	841	2336
4	5.4E-10	31	41	375	435	367	943	2592

2.2.4 Rooms Used for Radiation Medical Activities

2.2.4.1 General X-ray Room and Chest X-ray Room

- Generally, the rooms consist of a console area with protective viewing screen that allow the operator to observe and interact with the patient in this area.
- The rooms shall be large enough to minimize the radiation intensity from the operator's viewing and barriers (Figure 2.2.4.1).

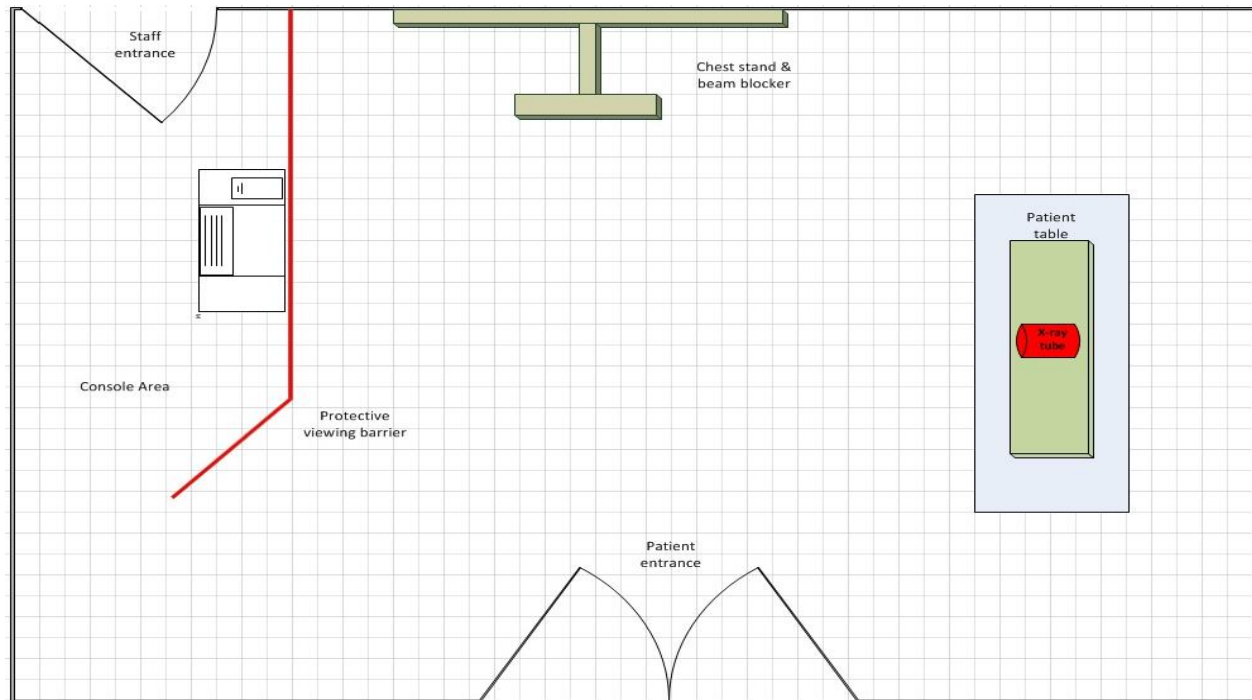


Figure 2.2.4.1: suggested general X-ray room and chest X-ray room layout.

- An area of about 33 m² is recommended for general X-ray systems. The barriers in various occupational areas such as the protective viewing screen, window frames, windows, ceiling, floor, door frames, doors and walls all should be shielded.
- Typically, this condition can be fulfilled using 2 mm of lead or other similar high Z material. Another lead beam segment might be needed behind the chest stand or vertical Bucky. The additional shield should be extended over the length of probable tube motions when it faces the wall.

More considerations:

- Reasonable door width of (≥ 1.2 m).
- Automatic interlock door.
- Leaded glass window(s).
- More than 3 m distance between the control area and the X-ray tube.
- Adequate lead aprons available within the X-ray room.

2.2.4.2 Fluoroscopy X-ray Room

Fluoroscopy allows real-time imaging to be done continuously and in some cases, it is utilized in complex studies and treatments that require some employees to be closer to the patient during the scanning procedure. Such procedures may take a long period and contain high doses in the presence of the patient.

- Shielding mechanisms should be provided at the table. In view of this, the ceiling mounted shielding screens as well as table mounted lead curtains should be installed (Figure 2.2.4.2).

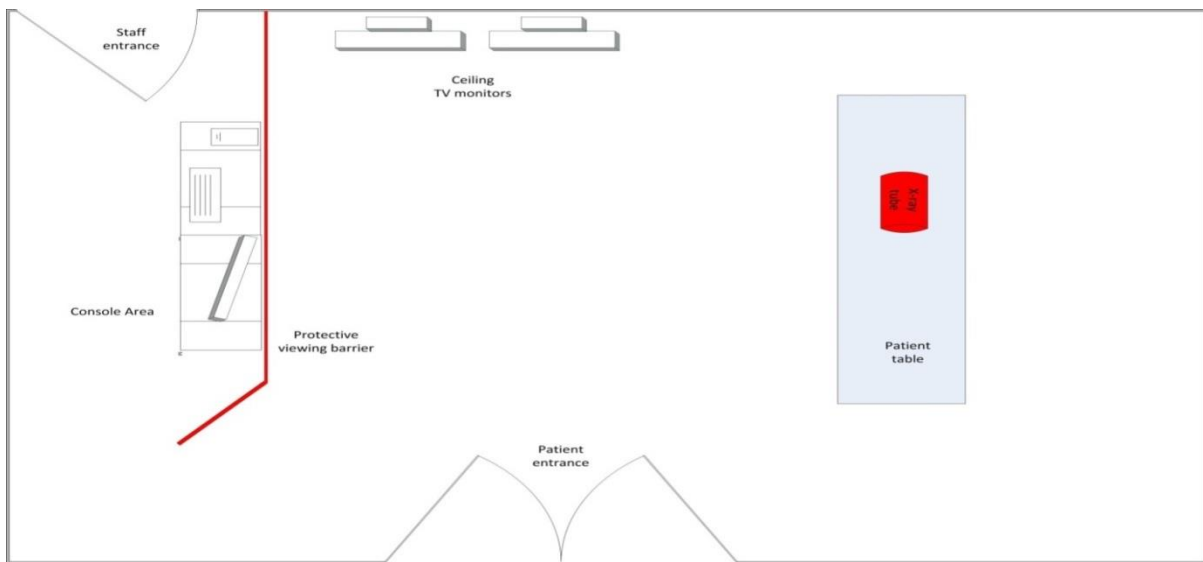


Figure 2.2.4.2: suggested fluoroscopy X-ray room layout.

- The room is similar to the general X-ray room. However, in this room the operator's viewing screen is longer because additional staff may be required during the procedures.
- The length of the screen ranges from 2.5 – 3 m, but this depends on the size of the room as well as use.
- Fluoroscopy systems might have an over the couch or an under couch tube. They may have maximum levels of radiation and are operated from the control area.
- A spacious control area is needed for fluoroscopy remote control equipment and suitable place for examination area.

- Under couch tube-systems contain lower dose levels for employees from the scattered, and are linked to additional staff operating within the room.
- Exposure controlled foot switch near the tableside should be monitored.
- Clear audiovisual indicators should be activated when the X-ray system is switched ON to prevent employees and patients from inadvertent exposure.
- A TV display mounted on the ceiling shall be placed in the control area to enable the operator to see live radiography images during the close contact with the patient.
- A combined mobile shield (such as, ceiling mounted screen, table mounted borders) might be installed on the building or project equipment.
- A personal protective kit such as lead aprons and thyroid collars should be stored properly in a suitable place that can be accessed easily within the control area.
- A toilet with direct access for patient should exist in the room that can be used especially for barium operations. In addition, changing rooms with other facilities shall be close to each other.

Radiation shielding calculations for fluoroscopy systems should consider scattered radiation. In the modern fluoroscopy unit, the major amount of the primary beam is interrupted by an imaging receptor. Fluoroscopy rooms commonly have another installed over couch tube that may be utilized, for instance, to make lateral X-ray views in barium procedures. In such instances, the room considers as a general room from X- ray and shielding should be taken into account.

2.2.4.3 Computed Tomography (CT) Scanner

CT scanner provides inter-sectional imaging that was initially taken from “single snapshot” for the body parts. The new CT systems take multi-slices, which provide 3D images, and provide a real-time monitoring of body parts. The systems have extensively increased the clinical significance of CT and allowed for comprehensive rapid scanning of patients. Therefore, the CT rooms are heavily occupied which mean that the workload is high, so the radiation levels are higher compared to modalities of other imaging systems. The following SFDA requirements shall be considered:

- Staff should not be present when a patient is being examined, thus the procedures for radiological protection consist of the operator protective screen alongside with the dimension of room techniques stated earlier.
- The works that are accommodated within the operator space are extensively spacious and comprise of direction as well as evaluation of the procedure by the radiologist, as well as observing the outcomes by the clinical team.
- The operator's room shall be used effectively for consultation, reporting, analysis role and shall cover a huge area.
- Operator's console room shall have a panoramic window with a door that connects this area to the CT room.
- The layout of a CT room shall be designed by basing on the double corridor model indicated in figure 2.2.4.3.
- The single door approach can be adopted by changing the staff entrance towards the opposite wall.
- CT rooms shall comprise a patient waiting area, changing cubicles as well as toilets.
- The console area shall be able to be used for various purposes such as consultation, teaching, reporting and processing of images and this should be considered when choosing the dose limits that will be used.
- It shall be covering the area of a single wall containing lead glass shielding that provides a scenic view.
- Operator area can be used to control on two CT units or a CT unit and MRI.
- During the procedure, an intercom shall be used for communication between the patients and control area.
- In the CT procedure room, the scanner shall be arranged in an oblique way to provide a clear view of the patient from the operator area during the examination.
- This shall enhances the movement of staff, trolleys, wheelchairs and patients within the room.
- This also shall enhances the storage of protective kit such as aprons, which shall be available and accessible.
- There are huge differences in the shielding conditions of various CT systems. Increased examination by using modern multiple slices and spiral CT systems may

lead to increase the amount of scattered radiation within the room, and thus, higher radiation shielding is necessary.

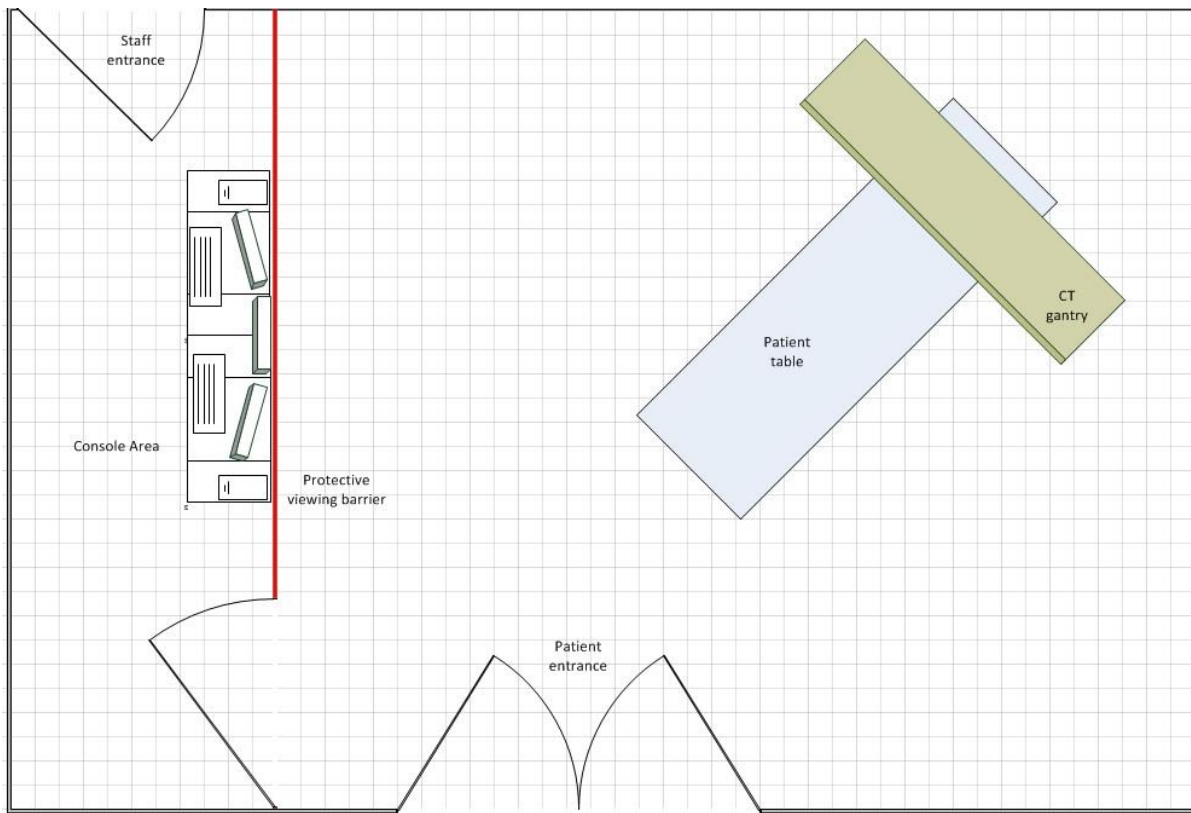


Figure.2.2.4.3: suggested Computed Tomography (C.T.) Scanner room layout.

Compared to fluoroscopy rooms, the spread of scattered radiation from the subject in the CT room is clearly outlined and fixed because the gantry location is static, thus allowing the radiography tube to follow the same oscillation path for all exposures. The isodose curves for all scanners can be obtained from the manufacturer and these may be utilized in determining the shielding requirements by considering the local mechanism. Generally, the shielding conditions for modern multiple slices CT scans contain 3-4 mm lead. However, individual shielding evaluations that are dependent upon actual loads, room sizes as well as occupancy of adjacent areas are critical to the facilities, thus should be conducted by the MRSO.

More considerations:

- Reasonable door width of (≥ 1.2 m).
- Automatic Interlock Door.

- Leaded Glass Window(s).
- The distance between the control panel and the X-ray tube ≥ 3 m.
- Lead aprons present in the radiography room.
- Presence of CTDI indicator (CTDI=Computed Tomography Dose Index).

2.2.4.4 Mammographies X-ray Devices

Mammography rooms might have smaller sizes compared to other radiography rooms, and the shielding conditions are few because low radiography energy is used (Figure 2.2.4.4).

- Normal construction materials, for instance, gypsum wallboard can offer enough attenuation.
- If the current approach is applied, and the room is changed for another radiological function, total re-shielding shall be implemented.
- When evaluating shielding conditions, only scattered radiation should be taken into account because mammography equipment is mainly designed in a manner that the image receptor blocks the primary beam.
- When designing the room, an appropriate shielding solution may require positioning the equipment in such a way that the entrance to the room will be within the wall but behind the patient, because the patient will absorb all radiation. Additionally, this procedure may enhance the patients' privacy.

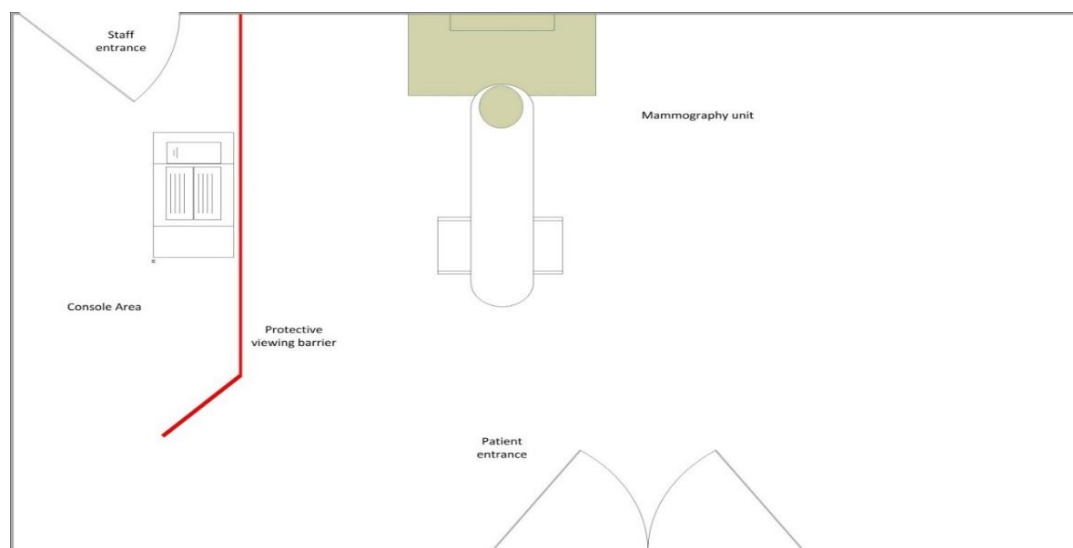


Figure 2.2.4.4: suggested Mammography X-ray room layout.

2.2.4.5 Fluoroscopy X-ray Devices (C-arm unit) (Conventional, Angiography /Interventional and Cath. Lab. Units)

Figure 5 shows a suggested layout for the Interventional fluoroscopy room. This forms part of the suite with recovery, preparation alongside with other appropriate areas. This kind of suite is mainly used for surgery, vascular, cardiology and radiology among other disciplines. The suites, which support Interventional operations,

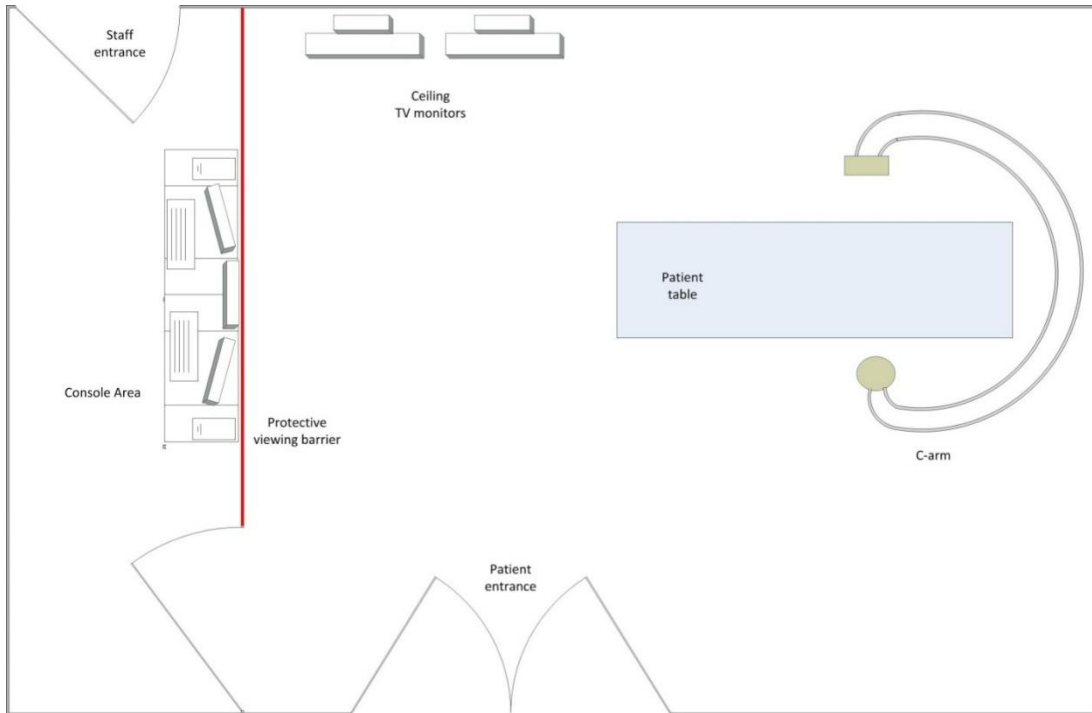


Figure 2.2.4.5: suggested fluoroscopy room layout (designed for special and Interventional radiology procedures).

- Should be developed with the intention of meeting operational theatre standards, both hygienically as well as suite design. Most of the rooms have sophisticated radiography equipment suspended from the ceiling with a C-arm configuration.
- In some instances, two installations of that nature are integrated into a room that provides “biplane” radiography imaging facilities.
- Swing-labs which are suitable for cardiac procedure may be developed, thus requiring more shielding between tables, usually formed by vertical lead blinds.

- Huge number of staff may involve frequently and should have access to patient and other areas such as the console area, and room.
- Console area serves two functions, namely teaching and consultation area.
- This entails consideration of the applied dose limits.
- Room size ought to be spacious enough with a range of 38 to 50 m².
- The console area covers the size of a single wall with a lead glass shield offering a scenic view.
- An integrated mobile shielding (for example, ceiling mounted and table mounted lead barriers) need to be included in the building or project equipment as required.
- This is critical to this kind of facility, and it should be installed in a manner that adapts well to the operations stipulated for the room.
- A personal protective equipment such as lead aprons, protective cap, thyroid collars, etc. Should be stored properly and should be adequately available and accessed easily in the control area.
- An Interventional room shall need direct access to special areas such as patient preparation, anesthetics and recovery.
- Several Interventional investigations shall require a patient to be sedated whereas other will entail general anesthetic, thus the reason of creating a recuperation room/ward as well as additional space within the radiography room for auxiliary monitoring equipment.
- Staff and patient changing areas and water cycle shall be within a close distance to be availed.
- The scattered radiation from fluoroscopy is extremely high inside Interventional rooms because of the lengthy procedure, long acquisitions as well as the high radiation dosage. Shielding conditions may be more than (2.24 mm) of lead in certain instances.
- Radiation shielding surveys are critical for such facilities and shall be conducted in conjunction with the MRSO.

2.2.4.6 Mobile X-ray & Fluoroscopy Devices (Portable)

- The device licensed by SFDA.
- Quality Control tools for mobile X-ray device.
- Dedicated place (and space) for parking as well as charging.
- Lead aprons available with the device with suitable hanging method.
- Cable length of exposure switch ≥ 3 m.

2.2.4.7 Dental Units

a. Intraoral Dental X-ray Devices (Fixed/Mobile)

The installation of intraoral X-ray might place in a designated radiography room or operation room. Within the latter scenario, the operation might not be utilized for other aims, or act as a pathway, when an X-ray procedure is underway. The surgery that accommodates the equipment should be developed in conjunction with the MRSO for the provision of a safe setting.

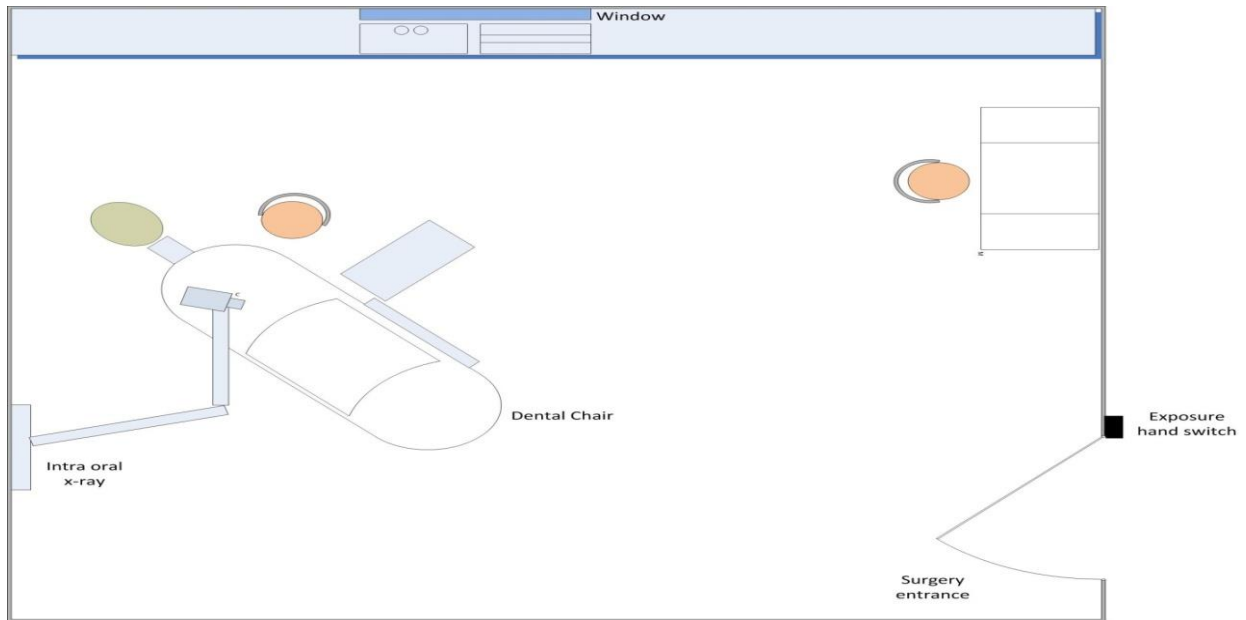


Figure 2.2.4.7.a.: suggested intra-oral dental unit layout installed in a surgery room.

- For the intraoral X-ray, the patient should be the main interceptor for the primary beam.
- The X-ray unit has to set up in order to prevent the useful beam from shifting toward unshielded barriers such as windows or doors. The intraoral X-ray

should be implemented with a long enough cable to the exposure switch or an exposure switch that is located separately to prevent the operator from coming closer to the patient's head or radiography tube.

- The distance should maintain at over 2 m between the user and the source.
- The area denoted by various points in 2 m from the head of the patient is called "controlled area".
- The MRSO need to ensure that all barriers namely (walls, windows and doors) within 2 m of the patient's head during radiography investigation offers enough protection of meeting the dose limit design.
- The MRSO's shielding evaluation should consider the anticipated workloads, distance to barriers, beam positions, barrier materials as well as occupancy for the adjoining areas, and over and under the operation rooms.
- The shielding structure would be irrelevant in the operation when the number of X-ray examination is ≤ 20 films weekly, and the space between the patient and other barrier is about 2 m.
- Wherever possible, the exposure switch need to be in the operation room, however, the switch should be outside the controlled area.
- In a situation whereby the exposure switch is sited outside the room within a public setting, it need to be secured in the lockable box for prevention of unauthorized people from unintended exposures.

b. Extraoral dental X-ray unit and combined intraoral and extraoral X-ray clinics

- For modern design, extraoral radiography unit should be sited in the designated X-ray room.
- A suggested area of 12 m² is recommended for panoramic dental X-ray.
- A slight increase in the area can accommodate both intraoral and extraoral X-ray equipment (Figure 2.2.4.7.b).

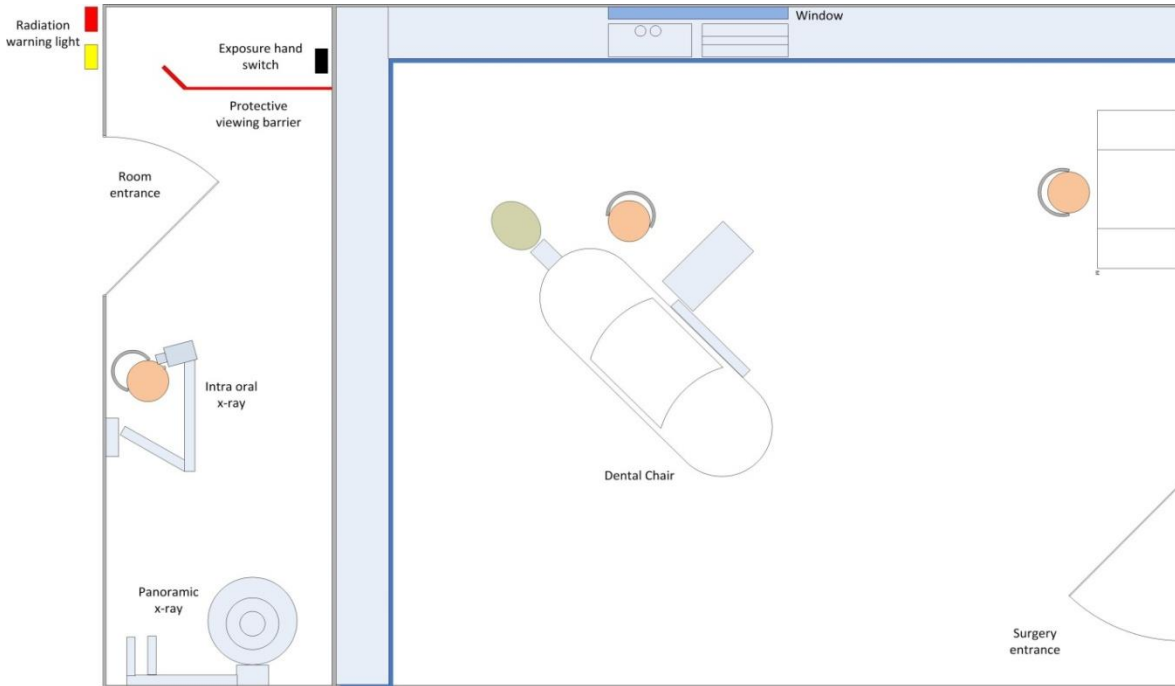


Figure 2.2.4.7.b: suggested dental radiography suite layout with several items of equipment.

- A protected operator's console indicated by Figure 2.2.4.7.b may come in handy depending on quantity of work. It is advisable to have it located in the room, particularly for children or special needs patients.
- A protective operator screen is required, however, because of the limited size in many dental clinic, it might not be possible to install it.
- A different solution entails, locating the exposure switch outside the radiography room and provide a door with small shielded glass for viewing.
- The exposure switch need to be placed within a secured box and all other switches should be labelled for identification of the units they operate.
- It is recommended that control panels should be placed at different site.
- A 1mm lead equivalence will function efficiently for shielding purposes.
- This can be coupled with the overall protection level that should be established in conjunction with the MRSO, and largely rely on the usage or occupancy of adjacent areas, room geometry and workload.

2.3 Nuclear Medicine Facility

2.3.1 General Requirements:

- Stored radioactive materials must be secured from unauthorized individuals.
- Radioactive material not in storage must be monitored and securely controlled.
- The work environment must be kept at a higher level of Hygiene and tidiness.
- All access to the department and within the department must be labelled with radiation caution signs.
- Containers of radioactive materials must be labelled appropriately (based on packaging standards).
- Containers of radioactive materials must be shielded appropriately (based on packaging standards).

2.3.2 Waste Disposal:

At least one of the followings:

- By transfer to an authorized recipient.
- By decay in appropriate storage with the implementation of proper guidelines.
- By release in sewages within the specific limits.

2.3.3 Equipment:

The department shall have an adequate amount of the following devices and services:

- Passive personnel dosimeters (TLD).
- Active (direct reading) personnel dosimeters.
- Updated TLD readings.
- TLD readings to be read by a licensed service provider of TLD readings.
- Contamination monitoring instruments.
- Radiation field monitoring instruments.
- Radiopharmacy sensitive radiation monitors.
- Decontamination kit.

2.3.4 Records:

The recording quality assurance program for the nuclear medicine facility shall include the following information:

- Records of All individual preparations for patient administration, including the patient's name, radiopharmaceutical used, activity and date.
- Records for all workers within nuclear medicine department.
- Records of planned special exposures.
- Records to ensure that doses are at least maintained ALARA and within the dose limits.
- Logbook of radioactive sources.
- Record of receipt and delivery of radioactive materials.
- Records of the disposal of radioactive materials.
- Record of quality control testing of the radionuclide calibrator.
- Record of area and hot laboratory monitoring.
- Written Local radiation safety rules and procedures.
- Written Emergency plan.
- Frequent updating of emergency plan.
- Reports of adverse events and the corrective action of such event.
- Records of corrective actions undertaken to prevent these events in future.
- Records of all acceptance tests for all equipment within the department.

2.3.5 Department Design and Layout:

- Must have controlled access to the department.
- All surfaces should be non-absorbent and easy to clean and decontaminate.
- The facility meets the shielding requirements in each room where any nuclear operation is carried out (1-2 mm lead equivalence).
- Layout of the department should be designed to isolate the administration rooms from the nuclear procedures rooms with an appropriate distance.

2.3.6 Personnel:

- Licensed medical radiation safety officer.
- Qualified staff in relevant specialty.
- Well-trained and aware staff of the radiation protection program and safety rules.

2.4 Radiotherapy Facility

2.4.1 General Requirements for Radiotherapy Facility

- a. Limiting the exposure to the area of interest.
- b. As low as reasonably achievable (ALARA), the scattered radiation or leakage radiation outside the treatment area shall not exceed the annual dose limits. Although, lowering the amount of leakage radiation, even way below the annual limits as possible is more preferable (ALARA).
- c. In compliance with the IEC and ISO standards regarding the ‘accompanying documents’, including but not limited to Medical device therapy efficiency, effectiveness, performance specifications, operating, protection, safety and maintenance instructions shall be given to the user. In addition, provide an Arabic translation of these documents, when appropriate, to the users.
- d. The main console shall be placed outside the treatment area, and should be locked when not in use.
- e. In order to insure that only the selected settings on the main console are used, safety interlocks or other measures shall be installed to prevent the use of any other setting.
- f. In order to terminate the treatment, minimally two separated ‘fail to safety’ systems shall be installed.
- g. The rooms housing radiation machine should be well sealed and locked in order to prevent unauthorised entry.
- h. During irradiation, visual and audible warning signs shall be automatically turned on at the entrances of the treatment area.
- i. To insure that the entrance doors are locked before the beginning of the treatment, interlocks shall be installed.

- j. Safety interlocks shall be designed in a way that during maintenance bypassing the safety interlocks shall be performed only under the supervision of the maintenance personnel by providing access code or keys.
- k. An observation and communication system shall be installed in order to allow the operator to visually observe and communicate with the patient during irradiation.
- l. High doses of radiation shall be declared with audio sirens (alarm) that must go off for at least a minute. The facility must incorporate visual signs as well in order to facilitate disabled individuals.
- m. Providing an adjustable or interchangeable beam limiting devices is crucial. At the normal treatment distance, the transmitting of these devices shall not exceed 5% of the useful beam. To comply with this requirement the useful beam's neutron component may not be included.
- n. The primary barriers shall be adequately shielded. The primary beam shall only be blocked by primary barriers. Therefore, electrical or mechanical interlocks shall be installed to prevent the primary beam from hitting any secondary barriers where the shielding are not adequate.
- o. The building's blue prints must be updated after the installation of a radiation machine in order to ensure that updated information is available to authorities to deal with any emerging situations.
- p. SFDA and local rescue services must be appraised of the presence, quantity and quality of the on hand radiation sources.
- q. Electronic signs should be integrated with the building's fire protection system to ensure that fire fighters are aware of the presence of radioactive sources;
- r. For devices that use filter systems such as wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters, irradiation shall not be permitted unless a filter has been selected first. Clearly identifying any removable filter. Documentation shall describe the filter including drawing, dimensions and construction materials.
- s. Radiation leakage
 - 1. to the patient area:
 - i. New equipment shall meet the following requirements:

- a) In radiotherapy, the dose generated from the maximum radiation leakage for any radiation particle must not exceed 0.1% of the main dose exiting from the machine and measured at the patient table where the central axis of the beam hits. Additionally, the dose of leakage radiation must be measured at any point within a circle of 2 m radius centered by the isocenter and in a distance from the aperture equals the normal treatment distance, also to be measured outside the field of radiation beam. The measurement taken for each radiation particle except neutrons must be measured within an area of 100 cm² at maximum, while the measurement of radiation leakage dose of neutron particles shall be measured over an area of 200 cm² at maximum.
- b) The licensee shall receive from the manufacturer the magnitude of the leakage radiation dose for each equipment measured at the positions mentioned [i-a] of this subsection. The licensee shall keep these records for at least 5 years.
 - ii. Each radiological equipment exists in a radiotherapy facility shall obey to the following requirements:
 - a) The absorbed dose that generated from leakage radiation in normal operating condition must not exceed 0.1% of the main dose that measured 1 meter away from the source and on a circular field of 2 m radius centered by the central axis of the beam, where the central axis is perpendicular to the circular field. These measurements must be taken within an area of 100 cm² at maximum.
 - b) The licensee shall keep all the records of the dose from leakage radiation measured at the positions mentioned in subsection [ii-a] in normal operating condition. These records shall be kept for at least 5 years.

2. outside patient area for new equipment:

- a) The absorbed dose generated from leakage radiation should not exceed 0.1% for leakage from X-ray source nor 0.5 for leakage from the neutron source compared to the main absorbed dose of radiation beam that measured at the isocenter intersection with the circular plane mentioned in subsection [1-i-a] in normal operating condition. This absorbed dose from radiation leakage must be measured

at 1 m away from the main path of the radiation beam, also must be measured before the charged particles hit the window or the target.

- b) The licensee shall keep the manufacturer records of absorbed dose generated from leakage radiation at normal operating conditions and at the same positions as mentioned in subsection [1-i-a]. These measurements must be taken over an area not more than 200 m² for all radiation particles.

2.4.2 Specific and Technical Requirements

2.4.2.1 Shielding and Safety Design Requirements

- a. A qualified person in radiation protection shall review the room design before the construction stage. This includes shielding specifications and equipment arrangement of new installations, or modifications of existing installations.
- b. Each medical radiation facility shall provide primary and secondary barriers in order to ensure that the dose does not exceed the dose limits specified in the table above (relating to dose limits for individual).
- c. To obtain the SFDA approval (including technical advice and evaluation) on the shielding installation requirements, the following information must be submitted;
 1. Plans shall include the following:
 - i. The typical location of the radiation system port; the locations of doors, windows or any other openings; the location of operator's booth and the control panel location.
 - ii. The composition, structure and thickness of all walls, doors, floor and ceiling of the designated room.
 - iii. The dimensions of the designated room;
 - iv. Details of the surrounding areas and show distance to the closest area that individuals may be present.
 - v. The details of the equipment that will be used in the designated room including the energy waveform (single phase, three phase, etc.).
 - vi. The examination or treatment type, which will be executed with the equipment in that room.

2. Workload information (i.e. mA-minutes per week).
3. Calculations of the dose rate at all access points in the area surround the machine room.

2.4.2.2 Control Area Design Requirements

a. Structural requirements:

1. The operator shall be working on unobstructed floor space in the control room.
2. The barrier walls in the control room shall be fixed, at least 3 m high.
3. The shielding specifications shall meet with the dose limits for individual members of professionals.
4. The console shall be constructed and shielded in a way that ensure no scattered radiation could reach to the operator.
5. The door of the console or any portable panel, used as a part of the console, shall be provided with interlock system in order to prevent any exposure while the door or the portable panel is not locked.

b. Radiation control panel placement:

Control panel shall be installed inside the console, and:

1. Shall be located 2 m away from any point that may expose to radiation, whether primary beam, scatter, or leakage.
2. The console room shall be provided with a clear view that enable the operator to view all room accesses except for linear accelerator and brachytherapy room.

c. Viewing system requirements:

1. Every console room shall have a viewing system that shall:
 - Be designed in a way that ensure that the operator could view the patient while receiving radiation.

- Be designed in a way that permit operator to view any occupancy within the room and all room accesses.
2. If the console has an electronic viewing system:
- The camera shall be installed in order to achieve the requirement [c.1] in this section.
 - An alternative viewing system shall be provided within the room in order to back up the primary viewing system.
 - In case of occurrence of any failure within the viewing system, any radiation process shall be stopped until finishing the repair of the viewing system.

2.4.2.3 Control and Interlock System

- a. All facilities possessing a medical device radiation machine shall display easily observable signs outside the room. These signs should be automated so that whenever radiation therapy is in progress the signs warn people outside.
- b. All readouts systems within the console shall be easily identified and recognized,
- c. Entrances to the radiotherapy rooms shall be controlled by interlocks that lock the door immediately with any exposure within the room.
- d. All interlocks shall be made to prevent any exposure within the room in case of failure of the interlock system.
- e. In case of failure of interlocking system, the radiation process is resumed only by a manual reset of the interlock system from interlock itself and at the operation console.
- f. There shall be an electrical cutoff switch, which is needed to be clearly identified. This switch shall have a manual reset in order to ensure that the machine cannot be restarted from the control panel unless the cutoff switch is reset.

2.4.2.4 Quality Assurance Program

- a. Every radiotherapy facility shall have a quality assurance program in order to keep the safety standards of radiation protection for patients, staff, and public.

- b. The facility experts shall develop a comprehensive QA program for all radiotherapy equipment with a detailed test procedure.
- c. The quality assurance program for radiotherapy machines shall include the followings:
 - 1. All the equipment specifications that shall include performance characteristics and tolerance limits.
 - 2. Detailed acceptance test procedures in order to assure its compliance with manufacturer specifications.
 - 3. Equipment commissioning, which guarantee that all data are satisfactory and available in order to use the machine according to its intended purposes.
 - 4. A record for machine testing and performance evaluation against the machine commissioning data. Any tolerance limits or incident action shall be predefined.
 - 5. Initiating a preventive maintenance program to document operating conditions and faults.
 - 6. Consider performing tests after repairs to include a degree of independence between personnel responsible for repairing and for verification.
 - 7. Adequate documentation during the equipment lifespan.
 - 8. Conducting Staff training in the safe clinical use of the equipment.
 - 9. Creating an adequate quality audit for internal and external procedures.
 - 10. Ensuring proper quality assurance program or procedures for all equipment and accessories.
 - 11. Safe decommissioning and disposal procedures according to SFDA and manufacturer recommendation is required.
 - 12. Electronic communication should follow open industry standards.
 - 13. Meeting with all regulatory mandates.
- d. The recording quality assurance program for the radiotherapy facility shall include the following information:
 - 1. Test procedures.
 - 2. Test frequency.
 - 3. The name of personal performing tests.
 - 4. A copy of test results, records such as logbook or other recording format.
 - 5. The followed procedures during malfunctions.

6. The schedule of equipment QA program, including any requirement for performance checks.
7. Policies of reviewing and updating manuals and procedures in relation to operating experience and modifications circumstances.
8. Indicate a person responsible for reviewing and updating these documents.

2.4.2.5 Records and Documents Required

- a. Each record either electronic system or document required by the SFDA regulations, shall be maintained against tampering with or goes through the specified period. In addition, records cannot be disposed of without first notifying the SFDA.
- b. The policies and procedure records should be existing for inspection.
- c. Records shall be original or a clear copy of the original, and authenticated by authorized personnel. Records could be stored electronically in a system with the ability of acquiring a clear copy of the records.
- d. Letters, drawings, and specifications, records should show all related information, such as stamps, initials, and signatures.
- e. Each licensee or registrant shall unify used units on the records. It is highly recommended using the SI units Becquerel, Gray, Sievert and coulomb per kilogram.
- f. The licensee facility shall maintain following records:
 1. Names of persons involved, in operate and maintain radiotherapy facility.
 2. The daily workload resulting from the operation of the equipment.
 3. Personnel dosimetry results.
 4. Details of incidents involving radiotherapy facility equipment.
 5. Purchases and transfers of radiotherapy facility equipment.
 6. All tests of safety and warning device records.
 7. Radiation surveys.
 8. Radiation Doses records of the following:
 - Individuals who are expected to receive a dose that needs to be monitored.
 - The doses received accidentally, or in case of emergency.

9. Inventory of radiotherapy facility equipment including calibrations and repairs of that equipment.
10. Records of the radiation protection program, and shall be retained until the SFDA terminates each pertinent license or registration requiring the record. Any audits and other reviews of program content and implementation shall be retained for at least 5 years after the record is made.
11. Leak test results.
12. Decommissioning results.

Chapter 3\ Non Ionizing Radiation

3.1 MRI Facility Requirements

1. The facility must maintain updated written policies & procedures pertaining to MRI safety, in compliance with pertinent international standards.
2. All MRI-related adverse events must be reported to SFDA and evaluated internally for improvement opportunities.
3. All new facilities must comply with zoning standards recommended by the *American College of Radiology*, as illustrated in (Fig 3.1.a). All standing MRI facilities must demonstrate approved structural plans to comply with these standards before 2020.
4. All MR personnel (or other staff individuals who are) assigned to work within zones III or IV must be screened for any implanted devices or internal foreign bodies that would preclude them from working safely within the MRI environment. They must also complete documented instruction in MRI safety procedures, as approved by SFDA, and updated every two years. All individuals who do not fulfil this requirement shall be considered as “non-MR personnel”.
5. All patients and non-MR personnel must undergo a screening process prior to entering zone III, which should be conducted by authorized MR personnel. This must include the following:
 - a. Completion of an approved individual patient MRI safety questionnaire.
 - b. This should be complimented by the use of approved ferromagnetic detector systems (conventional metal detectors are not acceptable alternatives). However, these systems do not replace the need for a direct screening process/questionnaire.
 - c. The removal of all metallic personal belongings and electronic devices.
 - d. Full identification of any implanted devices or foreign bodies within patients or personnel must be pursued by all available methods, including the use of other medical imaging techniques. Once positively identified, implanted devices should be evaluated for MRI compatibility by reference to the website: <http://www.mrisafety.com>

- e. Screening for pregnancy. If a patient is found to be pregnant, the supervising radiologist must conduct a risk-benefit assessment before allowing the patient to enter the scanning room. The assessment shall take in consideration the potential use of other nonionizing imaging techniques or the availability to postpone the procedure to after delivery period. However, if the benefit is deemed to outweigh the risk, then the scan may be performed.
6. All non-MR personnel who are allowed to enter zone III must be under the direct supervision of an authorized MR personnel member at all times.
7. All patient care related equipment used within zones III or IV must be appropriately evaluated and labelled as either being 'MRI-safe' (clearly non-metallic nor electrically conductive) or 'MRI-conditional' (objects not attracted by a hand-held magnet of >1000 Gauss, but of unknown composition). This includes patient monitoring devices, anesthesia equipment, trolleys & wheelchairs, infusion pumps, oxygen cylinders, and resuscitation equipment. All other portable objects that could potentially be brought into zone IV should also receive similar labeling, or be labelled as 'MRI-unsafe' (if attracted by a hand-held magnet > 1000 Gauss); including firefighting equipment, chairs, cleaning equipment, etc. The recommended labels are illustrated in (Fig 3.1.b).

MRI Functional Diagram

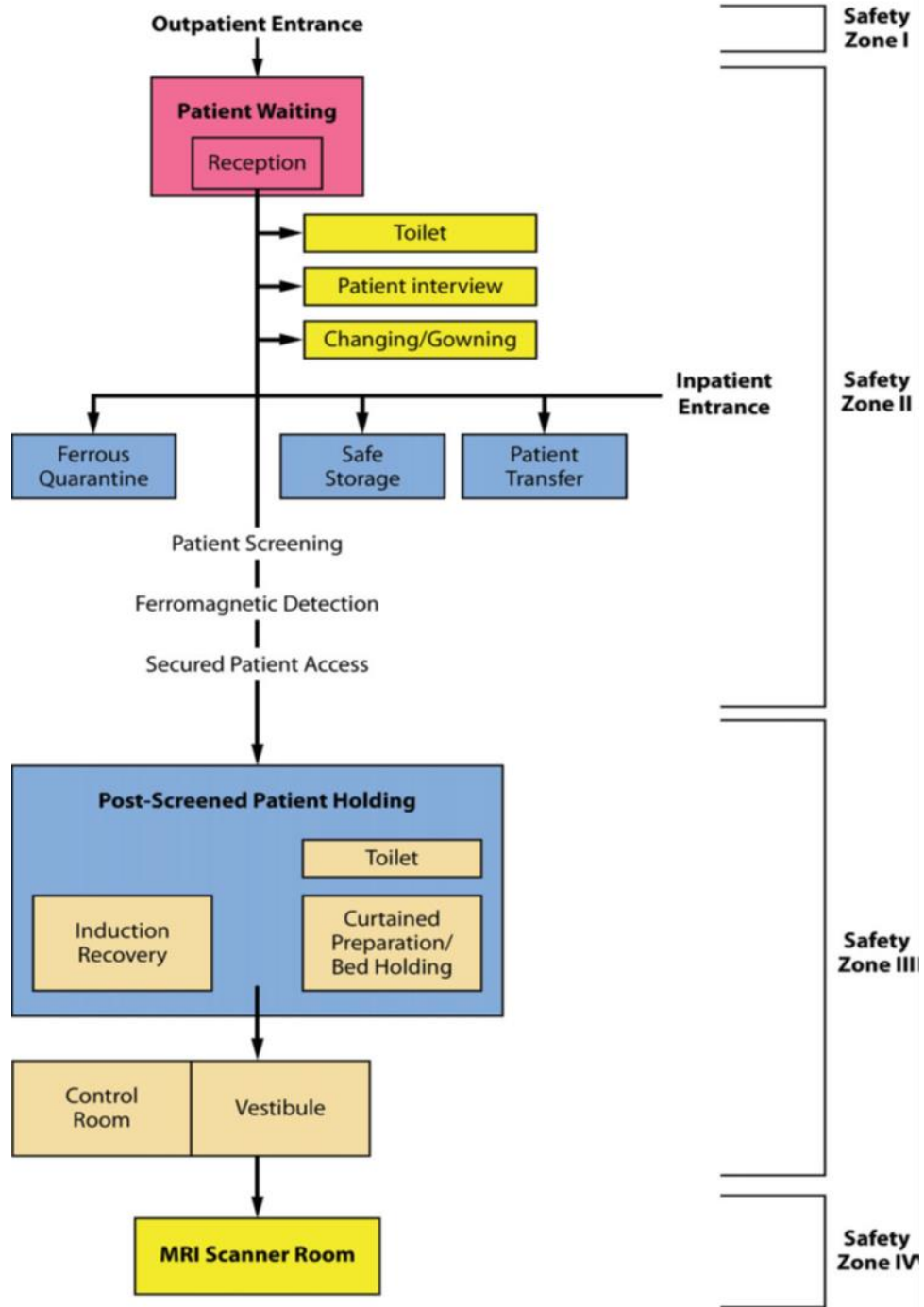


Figure 3.1.a: recommended MRI zoning standards.



MRI-safe



MRI- conditional



MRI-unsafe

Figure 3.1.b: recommended labels for MRI area.

3.2 Ultrasound Safety

Ultrasound is an imaging system which is used in different medical diagnostic applications. Diagnostic ultrasound devices have not been shown to pose any significant radiation-related risks to patients or to personnel, including pregnant women and children. However, the new modules of ultrasound that come with higher acoustic output levels can lead to some hurtful effects.

Output has to be regulated and monitored. The technologist (Ultrasound operator) should be aware and responsible about applying the requirements and risk assessment that assure the safety during the procedures as well as having a minimum knowledge about dealing with the device and its settings. The safe use of diagnostic ultrasound devices depends on output power and scanning time. Ideally, the output power should be low and the scan time should be short in accordance with ALARA principle.

There are two indicators in ultrasound that can show the biological effects which could be caused by ultrasound beam to the technologist (Ultrasound operator). They are thermal index (TI) and mechanical index (MI)

Thermal Index shows the level of risk that could be coming from the ultrasound beam by raising the temperature during the examinations. Mechanical Index shows any biological effects that could be coming from the ultrasound beam by non-thermal mechanism.

There are three forms of the TI:

1. The thermal index for soft tissue (TIS).
2. The thermal index for bone (TIB).
3. The thermal index for cranial bone (TIC).

All staff must insure caution during ultrasound examination to ensure the safety of all procedures specifically with modes and techniques that have potential higher wave levels.

The technologist (ultrasound operator) shall be taking the responsibility for:

- Minimizing dose and be aware about the biological effect that could be caused by ultrasound.
- The risks could be happened from ultrasound equipment.
- Other hazards could be caused by the application.

- Recent conditions that recommend to not use some types of equipment.
- Current guideline limits.
- The replacement of ultrasound equipment guidelines.
- The pregnant women shall be scanned only for medical needs.
- The operator shall aim to stay within SFDA recommended scanning times, detailed in (Figure 3.2). The technologist (ultrasound operator) shall follow the ALARA principle when there is a need to go over the scanning times that were recommended by the SFDA.

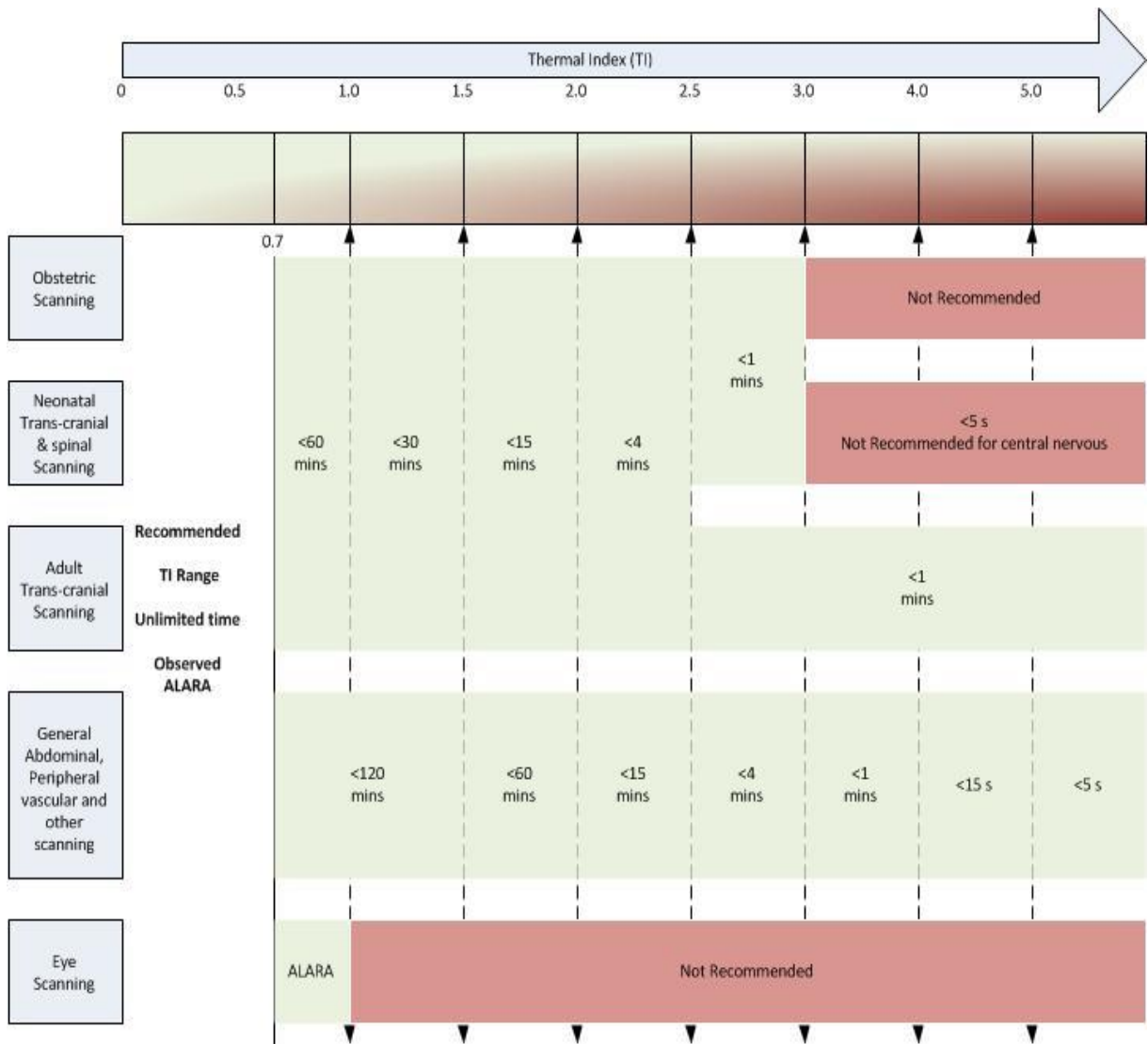


Figure 3.2: recommended maximum scanning times for different examinations conducted with different displayed thermal indices (TI).

MI>0.7 should be used with caution in the presence of contrast agents.

3.3 Laser Safety

3.3.1 Laser Classes

- Class I meant to cover all devices that emit ultraviolet, visible, and infrared light, which their emission will not have any biological effect.
- Class IIa covers all products that produce visible rays within the limit of Class I but for emission not more than 1000 seconds, and its intended purpose must not be for viewing, for example supermarket scanner.
- Class II cover every product that have a visible emission within the range of 400 to 700 nm and for an emission duration more than 0.25 seconds. The products that have emission within this range constitute a risk for eyes if the exposure takes a long time.
- Class IIIa the products within this class have an emission of visible spectrum and have a radiant power that is less than 5 mW. An example of products within this class is helium-neon lasers.
- Class IIIb this class covers all products that have an emission of ultraviolet, visible, and infrared spectra. Also, include laser products that their power ranging from 5 to 500 mW within the visible spectrum. Products classified under this class constitute a risk for eyes in case of direct exposure, and at higher levels of this class could cause risks for the skin.
- Class IV it covers the products that go beyond class IIIb limits and considered risky as its scattering radiation has similar risk as direct exposure.

3.3.2 Laser Safety Procedures in clinics

- Any medical device shall obtain Medical Device Marketing Authorization (MDMA) this is to make sure that the devices are safe and perform at high level of quality.
- Patient shall sign a consent form that acknowledge procedure hazards and declare patient's history and physical state, and it should be updated in each visit.
- Operators shall be trained on laser emergency incidents, laser safety training and operating laser equipment.
- Quick operating procedures for using laser equipment shall be posted in each clinic
- The nominal hazard zone (NHZ) should be identified to prevent unintentional exposure to the laser beam.

- The NHZ should be occupied by authorized personnel.
- Personnel in NHZ should be aware of all laser safety precautions.
- Warning laser signs in Arabic and English should be placed at all entrances to warn on-lookers of potential hazard
- Doors in NHZ should remain closed and windows covered.
- Everyone in NHZ should wear appropriate eyewear (eyewear wavelength shall match and cover the device wavelength) approved by LSO (Laser safety officer).
- The operator shall stop using broken eyewear.
- Patient's eyes and eyelids should be protected by wet eyepads, laser protective eyewear, eyeshields, etc.
- High filtration surgical masks, Wall suction units with in-line filters, and Smoke Evacuator units.
- All persons in the laser treatment area should be protected from laser beam exposures to their skin and other non-targeted tissues.
- All persons in the laser treatment area should be protected from flammability hazards associated with laser usage.
- All personnel should be protected from electrical hazards associated with laser use.
- Personnel working in NHZ should demonstrate competency commensurate with their responsibilities.

3.3.3 Laser Safety Officer (LSO)

The Laser Safety Officer (LSO), will be responsible for the knowledgeable evaluation and control of laser hazards, and has the authority to monitor the use of laser equipment and to enforce regulations for the control of laser hazards.

The LSO shall be responsible for:

- Evaluate possible hazards and institute appropriate control measures and training
- Ensure evaluation of the Nominal Hazard Zone (NHZ) for each laser system
- Evaluate a pre-op and post-op safety checklist for each laser procedure
- Establish guidelines for safety eyewear and other safety equipment and assure proper selection and usage for each laser system.
- Ensure all lasers are used according to hospital standards.

- Monitor quality control procedures and conduct radiation safety audits
- Establish Maximum Permissible Exposure (MPE) for personnel compliance standards for health care personnel.

3.3.4 Performance Requirements

All laser products must have a protective housing. This housing must be secure to prevent any access to the radiation of laser that exceeds class I limits. Therefore, the human access to any laser radiation that exceeds these limits must be justified by the manufacturer. In general, protective housing must enclose and adjoin the laser source. In addition, the protective housing should be made to be strong enough in order to prevent any access to the laser that caused by any distortion due to product aging.

3.3.4.1 Warning signs

A proper labeling by Laser-Type should be posted on the door and laser product. Additionally, a sign indicating that the laser room is a controlled zone. The signs should be in Arabic and English languages (Figure 3.3.4.1).



Figure 3.3.4.1: some recommended labels.

3.3.4.2 Safety interlock requirements

The safety interlocks should be used for any class of laser systems. These safety interlocks must inhibit any opening or access to the protective housing while the system is operating or under maintenance. In case of safety interlock defeat there must be an audible and visible alarm, also in this case the housing must not be closed.

In class IIIb and IV, a remote interlock connector is needed in order to allow the user control the access interlock remotely. Furthermore, for class IIIb and IV there should be a key control that allows user to control any laser operation. This key should be impossible to remove if it is in ON position.

For classes II, IIIa, IIIb, and IV there should be an indicator that points out laser emission. In class IIIb and IV, the indicator should start indication prior to the emission process for a sufficient time in order to inform workers and others that the device is energized in order to avoid the exposure.

Beam attenuator is considered a requirement for classes II, IIIa, IIIb, and IV. The function of beam attenuator is to block any access during laser irradiation that exceed class I limits without switching off the laser.

3.3.4.3 Labeling Requirements

For all laser products that classified as class II, IIIa, IIIb, and IV there should be a warning label. The warning label should state the type of the emission if it is visible or invisible, and state the type of the spectrum if it is ultraviolet, infrared, etc. For classes II and IIIa laser products, the warning label should state the word “CAUTION” if the emission does not exceed 2.5 mW/cm². Also, for laser products that are classified as class IIIa if its emission exceeds 2.5mW/cm² the word DANGER should be stated on the label, also this applies for all class IIIb and IV laser products. The warning label should include the following information:

- Maximum output,
- Pulse duration, if pulsed,
- Laser wavelength,
- The manufacturer certifying that the product complies with its specific reference to the regulation where the device complies.

Moreover, the laser products that have protective housing, which is removable, and not safety interlocked need a warning label. The warning label must be put on the device in a way to be clearly visible. For class I and IIa, the aperture should be labelled, and should specify if there is a possibility of emitting invisible, electromagnetic, and x-rays. In addition, on all laser products there should be an identification label, this label should include:

- Name and address of the manufacturer,
- Place and date of manufacture.

All labels must permanently fix and readable.

Informational Requirements:

Each laser product should include information about:

- User manual for operation and maintenance, this manual shall include:
 - Relevant warning to avoid exposure,
 - Radiation specifications,
 - A listing of controls and adjustments,
 - Information about safety procedures during device operation or maintenance.
- Purchasing information such as brochures and specification sheets,
- Service manual,
- The service should include the following information:
 - Service procedures,
 - Maintenance schedule in order to maintain device quality,
 - A list of controls that might level up the accessible radiation,
 - A list of the removable parts of the protective housing,
 - Safety instruction during service,

3.4 Ultraviolet Safety

3.4.1 Introduction:

- UV is non-ionizing form of radiation which is invisible to the eye in the (100 - 400 nm) wavelength region of the electromagnetic spectrum.
- UV radiation is divided into:
 - UV-A (315 nm - 400 nm): highest penetration among the UV groups and it may damage the skin and cataract formation.
 - UV-B (280 nm - 315 nm): the greatest damaging form of UV and it can cause erythema and corneal burn.
 - UV-C (100 nm - 280 nm): very low damage can be detected, cannot penetrate the skin dead layer; however, it can produce corneal burn.
- Nearly all repeatedly exposed workers to ultraviolet radiation in the spectral region between (180 - 400 nm) shows no adverse health effects.

3.4.2 Working Safety Requirements:

- Adequate steps must be taken to the individuals that may be exposed to harmful amounts and wavelengths of UV in order to protect themselves and in some cases minimize the time length of exposure.
- All individuals in the room must wear personal protective equipment while the UV device is operating. PPE must protect the skin and eyes. PPE shall include UV resistant face shield, gloves and lab coat with no gap between the cuff and the glove.
- Access to UV rooms must be controlled by closing the door while the device is in use.
- Some drugs can increase susceptibility to UV harm by increasing the individual's photosensitivity. For under medication worker around UV radiation, the medicine should be checked to avoid the increment of photosensitivity.
- Work with UV radiation device should have adequate UV safety training and should be familiar with UV safety work practices and procedures.

3.4.3 Hazards on human body:

- UV radiation affects mainly on the cornea and lens of the eyes.
- UV radiation is recognized as cancer-causing agent for human skin. Additionally, skin aging and erythema are possible effects of UV skin exposure.

3.4.4 Limits recommended for UV radiation occupational exposure:

- It is important to avoid unnecessary occupational UV skin exposures as substantial radiation from the sun will be received during daily outdoor activities.
- Limits for UV-A exposure to the eye and skin should not go beyond:
 - 1.0 mW/cm² for periods greater than 1000 seconds for the UV-A or near ultraviolet spectral region (315 - 400 nm).
 - 1.0 J/cm² for exposure times less than 1000 seconds.
- For UV-B, limits are 3.4 mJ/cm² at 280 nm and 500 mJ/cm² at 313 nm.
- For UV-C, limits are 250 mJ/cm² at 180 nm and 3.1 mJ/cm² at 275 nm.
- Additional exposure limits apply to the amount of UV light exposure to the skin and the eyes.
- The amount of dose an individual can receive on their eyes or skin in the period of 8-hours varies with the wavelength of the UV radiation.
- The time of exposure to an intensity of 100 uW/cm² at wavelength 254 nm not exceed 60 seconds. When averaged over 8-hours, this value is 0.2 uW/cm².
- Blacklight (320-400 nm) is not representing a noticeable hazard.

3.4.5 Control and Interlock System

- a. All facilities possessing a medical device radiation machine shall display easily observable signs outside the room. The warning sign should include Caution: “High Intensity Ultraviolet Energy. Protect Skin and Eyes”. These signs should be automated so that whenever UV is in progress the signs warn people outside (Figure 3.4.5.1).



Figure 3.4.5.1: some recommended labels.

- b. UV-A & UV-B Devices shall be controlled by interlock switches which deactivates the UV lamp when the fluorescent lamp is activated, however, personnel must ensure that the UV light is off prior to working at the cabinet.
- c. UV is simply shielded by opaque materials such as cardboard, wood, metal and polycarbonate material
- d. UV exposure can be decreased by limiting exposure time, increasing the distance between person and the UV source and prevention of unauthorized individuals from entering the UV radiation area.
- e. There shall be an electrical cutoff switch, which is clearly identified. This switch shall have a manual reset in order to ensure that the machine cannot be restarted from the control panel unless the cutoff switch is reset.

Chapter 4\ Procedures for Minimizing Radiation Exposure to Patients

To comply with SFDA regulation to reduce unnecessary radiation exposure from Medical Imaging Devices. “SFDA required the Medical Imaging Device manufacturers as well as healthcare providers to ensure that their equipment is/are capable of automatically recording patient dose, the protocol data, and patient information such as age, gender and weight in standardized formats”

(National dose) (will developed by the Radiation Protection National Committee) (Best practice)

Introduction

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