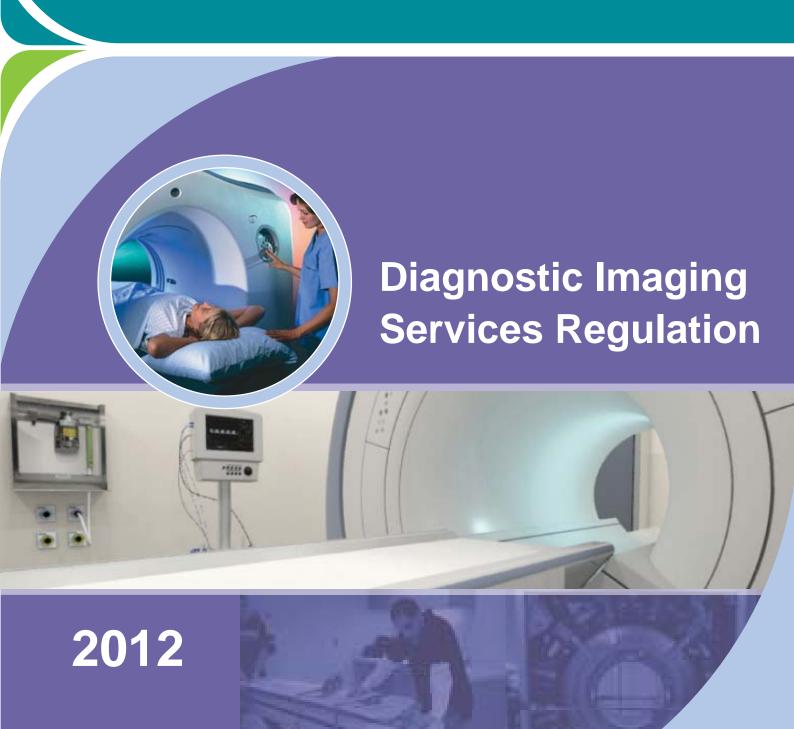




## Health Regulation Department







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#### Acknowledgment

Dubai Health Authority (DHA) is pleased to present the DHA Diagnostic Imaging Services Regulation which represents a milestone towards fulfilling the DHA strategic objectives in providing "A world class integrated health system that ensures excellence in health and healthcare for the Emirate of Dubai and promotes Dubai as a globally recognized destination for healthcare".

This Regulation is intended to be used as the base to develop radiology and diagnostic imaging standards to enable the Health regulation department to assess the facilities' compliance to the Regulation. It will assist Diagnostic Imaging Facilities in developing their quality management systems and in assessing their own competence to ensure compliance with DHA regulatory requirements and the United Arab Emirates (UAE) federal laws.

Moreover, the Diagnostic Imaging Services Regulation places an emphasis on facility design and services criteria with a focus on quality and safety of patients based on the local and federal laws in addition to the international accreditation standards.

The Diagnostic Imaging Services Regulation was developed by the Health Regulation Department (HRD) in collaboration with Subject Matter Experts whose contributions have been invaluable. The Health Regulation Department would like to acknowledge those professionals and to thank them for their dedication to quality in health and their assistance in undertaking such a complex task.

The Health Regulation Department Dubai Health Authority





#### I. Scope

This regulation applies to all health facilitates providing radiology and diagnostic imaging services (including: Radio-Diagnostic Centers, Hospitals, Day Surgical Centers, Polyclinics, Specialty clinics, General and Dental clinics) and subject to licensure under the Dubai Health Authority (DHA) establishment law, including governmental, semi-governmental, private and health facilities operating in free zone areas.

DHA has the right to amend the Diagnostic Imaging Services Regulation stipulated herein without prior notice; the latest version of the regulation shall be published in the DHA website www.dha.gov.ae

#### II. Purpose

The DHA is the sole responsible entity of ensuring that all health facilities and healthcare professionals in the Emirate of Dubai provide the highest level of safety and quality patient care at all times, through the development, establishment, and enforcement of regulation for radiology and diagnostic imaging services.

It is the responsibility of the health facility management to read, understand, and follow this regulation. The DHA uses mandatory language, such as shall, must, and require, when referring to regulatory requirements. And uses non-mandatory language, such as should, may, can, and recommend when referring to guidance.

#### **III. Definitions**

**Addendum** shall mean additional report that includes the corrections or new findings after the approval of original report.

**Computed Radiology (CR)** shall mean the use of special plate technology, scanning and computer processing to produce a digital image of a patient's organ or body part.

Computed Tomography (CT) shall mean the technique of employing ionizing radiation to produce axial (cross section) body section images. Data obtained by X-ray transmission through the patient are computer analyzed to produce these images. The series of sectional, planar images may be manipulated to produce different planar or volumetric view of the areas of interest and eliminate overlying structures such as bone. Manipulations of data allows for the selective view of either dense tissues such as bones or diffuse tissues such as the heart, brain, or lung. CT is used for both head and body imaging and is applicable to diagnosis, biopsy, and therapy planning.

**Contrast media** (or **contrast agent**) is a substance used to enhance the contrast of structures or fluids within the body in medical imaging.

**Contrast reaction** shall means mild or sever reactions to contrast media which may include nausea and/or vomiting; scattered to extensive urticaria, hypertension (isolated) with compensating tachycardia, cardiovascular collapse, convulsion and seizure.





Conventional Radiography (General Radiology) shall mean images of the skull, chest, abdomen, spine, and extremities produced by the basic radiographic process.

**Diagnostic Imaging Services** shall mean the medical service that utilizes imaging examinations with or without ionizing radiation to affect diagnosis. Techniques include radiography, tomography, fluoroscopy, ultrasonography, mammography, interventional radiography (IR), computed tomography (CT), Positron emission tomography (PET) Scan and Nuclear Medicine.

**Diagnostic Imaging Facility** shall mean any health facility in which a radiology and diagnostic imaging system(s) is used for the purpose of diagnosis or visualization, including but not limited to: Radio-Diagnostic Centres, Hospitals, Day Surgical Centres, Polyclinics, Specialty clinics, General and Dental clinics as well as mobile radiology services.

**Digital Radiography:** shall mean the capture or conversion of radiographic images in a digital format.

**Disabled People** shall mean people with personal condition or situation that could make it difficult for them to participate fully in their health care. It includes individuals with disabilities such as (physical, intellectual or sensory), age affected (either elderly or very young), affected by trauma or affected by medications/drugs.

**Fluoroscopy** shall mean the technique used to produce a real time motion in either an instantaneous or stored fashion.

**Healthcare professional** shall mean healthcare personal working in health care facilities and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

**Interventional Radiology (IR)** shall mean the clinical subspecialty that uses fluoroscopy, CT and ultrasound to guide percutaneous procedures such as performing biopsies, draining fluids, inserting catheters, or dilating or stenting narrowed ducts or vessels.

**Licensure** shall mean issuing a license to operate a health facility to an individual, government, corporation, partnership, limited liability company, or other form of business operation that is legally responsible for the facility's operation.

**Local Rules** shall mean set of instruction for handling specific radiation equipment to ensure the maximum protection from unnecessary radiation.

**Mammography** shall mean a modality utilizing ionizing X-ray imaging for breast examinations.

**Medical Complaint** shall mean expressions of dissatisfaction or concern about a health care service made by patients, or their relatives.

**Nuclear Medicine** shall mean the branch of medicine that deals with the use of unsealed radioactive substances in the diagnosis and treatment of disease.

**Patient** is any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.





**Positron Emission Tomography** (**PET scan**) is a technique that produces a three-dimensional image or picture of functional processes in the body. The system detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide (tracer), which is introduced into the body on a biologically active molecule. Three-dimensional images of tracer concentration within the body are then constructed by computer analysis. In modern scanners, three dimensional imaging is often accomplished with the aid of a CT X-ray scan performed on the patient during the same session, in the same machine.

**Picture Archiving and Communication System (PACS)** shall mean the digital capture, transfer and storage of diagnostic images. A PACS system consists of workstations for interpretation, image / data producing modalities, a web server for distribution, printers for file records, image servers for information transfer and holding, and an archive of off-line information. A computer network is needed to support each of these devices.

**Quality assurance** shall mean the planned and systematic actions that provide adequate confidence that a diagnostic facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel. The determination of what constitutes high quality will be made by the facility producing the images. Quality assurance actions include both "quality control" techniques and "quality administration" procedures.

**Quality Control** shall mean ongoing and periodic evaluation procedures of equipment to ensure continued, reliable performance.

**Radio-Diagnostic Centre** is an independent health facility providing one or more of radiology and diagnostic imaging services with one or more radiologists working in a permanent basis.

**Risk Management** shall mean a logical and systematic method of establishing the context, identifying, analyzing, evaluating, treating, monitoring and communicating risks associated with any activity, function or process in a way that will enable organizations to minimize losses and maximize opportunities.

**Sentinel Event** is defined as an unanticipated occurrence involving death or major permanent loss of function unrelated to the nature course of the patient illness or underlying condition; while Adverse Event is defined as unanticipated, undesirable or potentially dangerous occurrence in a health care organization.

System of Work shall mean a set of rules governs day-to-day the practice of using ionizing radiation equipment

**Teleradiology** shall mean transmission of diagnostic images and the related data from one location to another for the purposes of interpretation and/or consultation.

**Ultrasound** shall mean high frequency sound waves are utilized to determine the size and shape of internal organs based on the differential rates of reflection. In addition, images can be observed in real time to reveal motion, and can include coloration of arterial and venous blood flow. Cyst aspiration and fluid removal are also procedures done with the ultrasound modality.





#### IV. Acronyms

ACLS: Advanced Cardiac Life Support
ALARA: As Low As Reasonably Achievable

BLS : Basic Life Support

CPR : Cardiopulmonary Resuscitation

CT : Computed Tomography
CGO : Clinical Governance Office
DHA : Dubai Health Authority

DICOM: Digital Imaging and Communications in Medicine

DM : Dubai Municipality

DED : Department of Economic Development FANR : Federal Authority for Nuclear Regulation

HRD : Health Regulation Department LLC : Limited Liability Company

MOH : Ministry of Health

MRI : Magnetic Resonance Imaging

PACS : Picture Archiving and Communication System

PET : Positron Emission Tomography

PM : Preventive Maintenance

RN : Registered Nurse QC ; Quality Control

WHO: World Health Organization





## CHAPTER ONE: LICENSURE AND ADMINISTRATIVE PROCEDURES





Diagnostic imaging services can be provided in different type of health facilities. Either as an independent service called "Radio-Diagnostic centre" or as part of another facility services such as hospitals, Clinical Laboratory (Diagnostic Centre with two specialties) and polyclinics.

#### 1. Independent Radio-Diagnostic Centre Licensure Procedures

- 1.1 A person or entity must obtain a license from Dubai Health Authority (DHA) to operate an <u>independent Radio-Diagnostic Centre</u> in the Emirate of Dubai. This also applies to governmental and semi governmental, private health facilities and facilities operating in free zone areas.
- 1.2 Submission of an application to the Health Regulation Department (HRD) is a requirement for licensure in order to establish a new Radio-Diagnostic Centre in the Emirate of Dubai. The application to operate the facility shall be according to the applicable laws regarding this issue. For further information <u>click here</u> to see article 4 and 5 of the Federal Law number 2/1996 concerning Private Health Facilities.
- 1.3 Radio-Diagnostic Centre application in free zone area shall comply with applicable free zone laws and regulations.
- 1.4 In case of building a new Radio-Diagnostic Centre, the application file shall include both the preliminary and final architectural plans with specifications showing the proposed general location, accessibility, physical features of the site, medical equipment, furniture and other utilities i.e. medical waste storage area. The land plot allocated for the new facility must be approved for commercial use by Dubai Municipality (DM).
- 1.5 In case of operating the Radio-Diagnostic Centre in existing villa or flat, the premises must be approved for commercial use by DM.
- 1.6 Upon receipt of a completed applicant's file, the HRD will conduct a detailed review of the submitted material to determine compliance and suitability for further processing.
- 1.7 The HRD shall issue an <u>Initial Approval</u> letter for the Radio-Diagnostic Centre, with defined services and restrictions particular to the applicant request.
- 1.8 This letter will be required to complete the centre licensing procedures by local and federal authorities including but not limited to:
  - 1.8.1 The Department of Economic Development (DED) in Dubai or equivalent licensing bodies (i.e. free zones authorities).
  - 1.8.2 Federal Authority Nuclear Regulation (FANR).
- 1.9 In case of application rejection, a detailed list of issues will be provided for corrective action and the applicant is required to re-submit a new application with applicable fees.

For further details regarding the application form, ownership, licensure procedures, application fee and design re-submission fee please <u>click here</u> or visit the Health Regulation on the DHA website <u>www.dha.gov.ae</u>

#### 2. Facility Trade Name

2.1 During the initial registration process, the name of the Radio-Diagnostic Centre will be tentatively under the owner's name, till applicant is issued the health facility trade license





- 2.2 Each health facility shall be designated by a permanent and distinctive name which must not be changed without prior notification.
- 2.3 Name of the health facility shall not tend in any way to mislead the public as to the type or extent of care provided by the facility.

#### 3. Final Inspection and Issuing the License

- 3.1 After preparation/construction is completed and prior to any use of the Radio-Diagnostic Centre, the Health Regulation Department shall conduct an on-site pre-operating assessment visit (final inspection). The purpose of the visit is to survey the facility and to confirm fulfillments of the DHA requirements.
- 3.2 To obtain the DHA Radio-Diagnostic Centre license, the applicant must meet the following:
  - 3.2.1 Appoint a Medical Director who should be a DHA licensed Radiologist.
  - 3.2.2 Employ a sufficient number of qualified and licensed consultant/specialist radiologists, radiographers and other healthcare professionals to satisfy the requirements of this regulation and to meet patient and facility needs for all procedures performed at the facility.
  - 3.2.3 Install and operate imaging equipments required for provision of the services in accordance with manufacturer specifications.
  - 3.2.4 Meet the space requirements for the service provided in the facility
  - 3.2.5 Provide evidence of FANR license to use the ionizing radiology equipments in the facility or FANR registration number.
  - 3.2.6 Provide documented policies and procedures for the following:
    - 3.2.6.1 Infection control measures and hazardous waste management
    - 3.2.6.2 Medication management
    - 3.2.6.3 Patient health record
    - 3.2.6.4 Patient transfer and emergency action plan
    - 3.2.6.5 Radiation Safety
  - 3.2.7 Engage a Medical Physicist or other qualified professionals to survey radiology equipments oversee the equipment-related quality assurance practices of the facility, and provide the facility with quality reports on radiology equipment.
  - 3.2.8 Maintain Charter of Patients' rights and responsibilities noticeably posted on the premises at least in two languages (Arabic and English).
  - 3.2.9 Maintain adequate lighting and utilities, including temperature controls, water taps, sinks and drains, electrical outlets and communications;
  - 3.2.10 Keep floors, work surfaces, and other areas clean and neat;
  - 3.2.11 Clearly display the hours of operation of the facility as well as the type of services available:
  - 3.2.12 Clearly displayed hazardous signs aimed to restrict access for the safety of patients, visitors and staff





- 3.2.13 Diagnostic imaging facilities performing MRIs, must adhere to the ventilation requirements for cryogen locations as determined by the manufacturer of the equipment;
- 3.2.14 Designate secured areas for the direct placement of shipments of radioactive or otherwise hazardous materials;
- 3.2.15 Provide a sufficient number of toilets for patients, their families, and staff.
- 3.2.16 Ensure that the facility is accessible for handicapped and disabled individuals;
- 3.2.17 Access for disabled toilet within the same building is required for all new Radio Diagnostic centre;
- 3.3 Based on the result of the onsite assessment and after meeting the DHA requirements and recommendation (if any), a DHA license will be issued by the Health Regulation Department.
- 3.4 The Radio Diagnostic centre license is valid for one year.
- 3.5 Every license shall state the name and address of the facility, the DED license number, the period of licensure validity, the specific service(s) that the facility is licensed to deliver.
- 3.6 The facility license shall be visibly posted on the premises.

#### 4. Outpatient Care Facilities Radiology Service Licensure Procedures

- 4.1 Diagnostic imaging services can be provided in different types of health facilities. Hospitals, Day Surgical Centre and Diagnostic Centre with two specialties (Radiology and Clinical laboratory services) must provide diagnostic imaging services while other Outpatient Care facilities (e.g. polyclinics, specialty and dental clinics) may provide certain diagnostic services to meet their patient needs.
- 4.2 All diagnostic imaging facilities providing ionizing radiology services: the use of ionizing radiation and radioactive materials in health facilities must comply with FANR laws and regulations and shall meet the X-ray room surfaces and shielding thicknesses, for further information regarding FANR shielding thicknesses requirements please visit FANR website www.fanr.gov.ae.
- 4.3 For provision of diagnostic imaging services within an Outpatient Care facility, the facility management shall fill Changing/Adding New Specialty section in the Health Facilities Licensing application form and submit it to HRD office, the fee set by the DHA shall accompany the submitted application.

For further information regarding adding services please visit the Health Regulation site in DHA website <a href="https://www.dha.gov.ae">www.dha.gov.ae</a>

#### 5. Management Responsibilities

Upon obtaining the Radio-Diagnostic Centre license or the approval for adding diagnostic imaging service, the management of the diagnostic imaging facility has certain licensure responsibilities they must fulfill, which include, but not limited:

- 5.1 Comply with all federal and local laws and regulations.
- 5.2 Take necessary measures to distribute new DHA circulars and announcements among all facility professionals.





- 5.3 Cooperate with HRD inspectors and/or any duly authorized representative and provide requested documentation or files.
- 5.4 Avoid giving misleading information and false statements which may lead to legal action against professionals or the health facility.
- 5.5 Settling of any violation fines related to professionals or the health facility.
- 5.6 Maintain an active FANR license for using ionizing radiology equipments in the facility
- 5.7 Maintaining malpractice insurance for all licensed healthcare professionals as per article 25 and 26 of the UAE Federal Law number 10/2008 concerning Medical Liability.
- 5.8 Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the facility.
- 5.9 Obtain prior approval from the Ministry of Health (MOH) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOH website <a href="https://www.moh.gov.ae">www.moh.gov.ae</a>

#### **6.** Compliance Review

- 6.1 At any time and upon reasonable cause, HRD may conduct random inspection to audit the diagnostic imaging facility to determine the centre compliance with the DHA regulations, and take appropriate action if required.
- 6.2 The HRD inspectors and/or any duly authorized representative shall conduct regular onsite inspections to ensure compliance with the relevant DHA regulations.
- 6.3 The onsite inspections may be scheduled or un-announced

#### 7. Application for License Renewal

- 7.1 Application for renewal of the Radio-Diagnostic Centre license must be submitted in <u>not less than 30 days</u> prior to expiration of the license and shall conform to all renewal requirements. For further details regarding health facility license renewal procedures visit Health Regulation site in DHA website <a href="www.dha.gov.ae">www.dha.gov.ae</a>
- 7.2 The applicant's failure to file the renewal licensing application within the given time shall result in expiration of the current license on its last effective date. In such cases, the Radio-Diagnostic Centre will be subjected to financial penalties and may lead to null and void of the facility license.
- 7.3 DHA Radio-Diagnostic Centre license will be renewed for a period of one year after fulfilling the HRD requirements for re-licensure assessment.

#### 8. Temporary Suspension of the License

- 8.1 If identified that any Radio-Diagnostic Centre poses an imminent risk to the safety of patients, employees or visitors of the facility; HRD shall assess the facility operations or specific service.
- 8.2 HRD may recommend to the Director General of Dubai Health Authority the temporary suspension of the facility license or specific services.
- 8.3 The Director General shall form an investigative committee and may issue a decree of temporary suspension.





#### 9. Voluntary Cancellation of the License

- 9.1 Should a facility wish to cease its services, a <u>voluntary cancellation request</u> shall be signed by the owner of the facility and must be submitted at least (30) days before closure of the facility.
- 9.2 The management of the facility shall comply with existing DHA regulations regarding cancellation of the health facility license.

#### 10. Null and Void License

- 10.1 As per the UAE Federal Law number 2/1996 concerning Health Facilities, the health facility license is considered null and void by force of law in the following conditions:
  - 10.1.1 Transferring the health facility ownership to a different individual, corporation, Limited Liability Company (LLC), etc.
  - 10.1.2 Closure of the facility for a period of six months without presenting a valid and justified reason(s).
  - 10.1.3 The health facility is not operating for a period of six consecutive months from the date of issuing the facility license.
  - 10.1.4 Cancellation or liquidation of health facility Corporation, partnership or LLC

#### 11. Changes/Modifications Required DHA Approvals

- 11.1 Diagnostic imaging facility management shall obtain prior approval from the HRD for the following changes or modifications, this includes but not limited to:
  - 11.1.1 Ownership
  - 11.1.2 Medical Director
  - 11.1.3 Facility trade name
  - 11.1.4 Facility location
  - 11.1.5 Introducing new radiology service(s) or teleradiology services
  - 11.1.6 Voluntary permanent or temporary closure of the facility
  - 11.1.7 Relocation of existing imaging services.
  - 11.1.8 Major construction or renovation work in the facility
  - 11.1.9 Adding an extension or annex to the existing health facility building

#### 12. Renovations and Additions to the Facility Building

- 12.1 In case of renovation or addition to the existing diagnostic imaging facility building, the management must submit an application file including both the preliminary and final architectural plans with specifications showing the proposed renovation or addition to the existing facility.
- 12.2 Any alterations or additions to the existing facility building shall comply with the construction standards and building codes of the Dubai Municipality (DM) and meet the DHA Health Facilities Guidelines: Planning, Design, Construction and Commissioning.





For further information regarding the DHA Health Facilities Guidelines please <u>click here</u> or visit the Health Regulation site in DHA website <u>www.dha.gov.ae</u>





# CHAPTER TWO: IMAGING SERVICES DESIGN REQUIREMENTS





#### 13. General Design Considerations

- 13.1 Diagnostic imaging procedures may be performed in several areas e.g. hospital, polyclinic. Portable radiographic and fluoroscopic equipment may be used in selected instances for imaging of patients.
- 13.2 Patient convenience and accessibility should be an integral part of the planning and design of the Radiology Department
- 13.3 Diagnostic imaging services performs examinations and produces images from non-invasive or minimally invasive procedures performed on patients in specially equipped examination rooms. The imaging modalities associated with the diagnostic imaging services include medical applications of ionizing and non-ionizing radiation.
- 13.4 <u>Non-Ionizing Imaging</u> includes: Magnetic Resonance Imaging (MRI), Ultrasound.
- 13.5 Ionizing Imaging includes:
  - 13.5.1 **Diagnostic Radiology** applications which includes:
    - 13.5.1.1 Radiography: Film Radiography, Computed Radiography (CR), Digital Radiography (DR)
    - 13.5.1.2 Mammography
    - 13.5.1.3 Bone Densitometry
    - 13.5.1.4 Dental X-rays: Intra-Oral X-rays, Panoramic X-rays, Cephalometric X-rays and I-CAT Scanner
  - 13.5.2 **Fluoroscopy**-Based applications includes:
    - 13.5.2.1 Diagnostic Fluoroscopy (Diagnostic Imaging)
    - 13.5.2.2 Interventional Cardiology (Cath Lab),
    - 13.5.2.3 Interventional Radiology
    - 13.5.2.4 Lithotripsy
  - 13.5.3 Computed Tomography (CT) Scanning
  - 13.5.4 **Nuclear Medicine** includes:
    - 13.5.4.1 Nuclear Imaging
    - 13.5.4.2 Radionuclide Therapy (Treatment of Thyroid Cancer and non-malignant Thyroid Diseases such as hyperthyroidism)
  - 13.5.5 **Radiotherapy** includes:
    - 13.5.5.1 Radiation Treatment of Cancer
    - 13.5.5.2 Teletherapy: External Therapy
    - 13.5.5.3 Intra-Cavitary Therapy
    - 13.5.5.4 Interstitial Therapy
  - 13.5.6 **In-Vitro Applications** includes laboratory analysis of patient's biological samples by means of low-level radioactivity





- 13.6 The Federal Authority for Nuclear Regulation (FANR) is exclusively responsible for licensing the use of ionizing radiation and radioactive materials in health facilities, Radiation safety protection requirements shall be incorporated into the specifications and the building plans and must comply with FANR laws and regulations.
- 13.7 Every health facility providing ionizing radiation services shall take all necessary steps to restrict as far as reasonably practicable the extent to which his employees or other persons are exposed to ionizing radiation.
- 13.8 To meet the FANR requirements; in certain diagnostic imaging services (e.g. Nuclear medicine, Radiotherapy) the health facility needs a certified physicist or a qualified expert to specify the type, location, and amount of radiation protection to be installed in accordance with the final approved layout and equipment selections.

#### 14. Independent Radio-Diagnostic Centre

- 14.1 Radio-Diagnostic Centre can be located in an independent villa or in a flat in a commercial building; if the facility located in first floor or higher at least one lift accommodate wheelchair must be present in the building.
- 14.2 Wheelchair access must be available in the building.
- 14.3 Building corridors and doors shall be wide and accommodate wheelchair (at least 90 cm for doors and 120 cm for corridors width).
- 14.4 The centre shall provide patients reception area with separate waiting area for males and females.
- 14.5 Consultation area or office for radiologist(s) must be provided (at least 9 square meters), office shall include provisions for patient consultation, viewing and charting of radiological films.
- 14.6 Diagnostic imaging services room(s) shall meet the specific building requirements outlined in this document. (see below)
- 14.7 Patient gowning area with safe storage for valuables and clothing shall be provided (At least this area shall be 1.5 meters x 1.2 meters); the space should be large enough for staff-assisting dressing.
- 14.8 Toilets (Minimum of two) one for males and the other for females (based on the radiology services, but one toilets preferably shall be located next to or with direct access from the radiology room).
- 14.9 Designated medical records / files area.
- 14.10 Storage facilities shall be provided for film and equipment, and shall be provided with proper ventilation.
- 14.11 All Radio-Diagnostic centres shall provide parking and emergency ambulance pick-up area in the facility premises.
- 14.12 Meeting the Civil Defence fire and safety requirements (e.g. Fire extinguisher, emergency exits) are mandatory requirements to obtain DHA approval.





#### 15. Diagnostic Imaging Service in Outpatient Care Facilities

- Outpatient Care facilities may provide specific range of diagnostic imaging services within the premises, such as ultrasound, conventional radiography (general radiology), Computer Tomography (CT), or Magnetic Resonance Images (MRI)
- 15.2 The facility shall meet design and building requirements for the specific diagnostic imaging service.
- 15.3 Sharing reception, waiting area and support areas for diagnostic imaging services (e.g. toilets, medical records / files area, etc.) are permitted.
- 15.4 If the facility is providing any diagnostic imaging service where contrast media may be used; the facility must provide easy access for parking and emergency ambulance pick-up area within the premises.

#### 16. Conventional Radiography

- 16.1 Conventional radiography room size shall be at least 15 square meters. Room entrance shall not be less 1.20 cm and 2 meters height with shielded door.
- 16.2 At least one designated patient gowning area for patient changing with safe storage for valuables and clothing shall be provided. At least this area shall be 1.5 meters x 1.2 meters with immediate access to the conventional radiography room.
- 16.3 Wall finish shall be general paint. Floor Finish: Vinyl Composition Tile
- 16.4 Shielded viewing window from the Control Area to the conventional radiography room should be provided.
- 16.5 Minimum X-ray room surfaces and shielding thicknesses shall comply with FANR requirements, (see appendix 1 for general information X-ray room surfaces shielding thicknesses) for further specific information regarding FANR shielding thicknesses requirements please visit FANR website www.fanr.gov.ae.
- 16.6 Fluorescent lights will provide higher illumination level up to 50 FC during patient transfer on and from the table, equipment setting, room cleaning, and equipment maintenance.
- 16.7 If film systems are used, a darkroom shall be provided for processing films (at least 2 meters square) with water basin, table, benches, film holder and Safe light1.
- 16.8 When daylight processing is used, the darkroom shall be permitted to be minimal for emergency and special uses.
- 16.9 Film processing shall be located near the procedure rooms and to the quality control area.
- 16.10 Contrast media preparation:
  - 16.10.1 If contrast media are used, this area shall include provision of sink, counter, and storage area for medication and crash cart.
  - 16.10.2 Provision for central oxygen or oxygen cylinder
  - 16.10.3 Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medication

<sup>&</sup>lt;sup>1</sup> Unless the processing equipment normally used does not require a darkroom for loading and transfer





- 16.10.4 One preparation room, if conveniently located, shall be permitted to serve any number of rooms.
- 16.10.5 Where pre-prepared media are used, this area shall be permitted to be omitted, but storage shall be provided for the media.
- 16.11 Convenient clerical offices/spaces as per the facility demand.
- 16.12 Hand-washing stations shall be provided within each procedure room unless the room is used only for routine screening such as chest X-rays where the patient is not physically handled by the staff.
- 16.13 Radiology equipment and supplies include but not limited to:
  - 16.13.1 X-ray machine with X- Ray table with wall block.
  - 16.13.2 Lead aprons.
  - 16.13.3 Gonad shields
  - 16.13.4 Immobilizer.
  - 16.13.5 Cassette and grids.
  - 16.13.6 Emergency trolley.
  - 16.13.7 Working table with bench.
  - 16.13.8 X-ray viewer.
  - 16.13.9 Foot step to help Patients to step in to X-ray table.
  - 16.13.10 Computed Radiography (CR).
  - 16.13.11 Lead apron hanger.
  - 16.13.12 Computer work station.
- 16.14 Green/Red warning light sign indicating when the X-ray beam is OFF/ON.
- 16.15 X-ray caution sign on the tube housing.
- 16.16 Designated supply storage and housekeeping area.

#### 17. Radiography/Fluoroscopy, Tomography

- 17.1 Combined Radiography and Fluoroscopy space requirement is at least 20 square meters
- 17.2 Separate toilets with hand-washing stations shall be provided with direct access from each fluoroscopic room so that a patient can leave the toilet without having to re-enter the fluoroscopic room.
- 17.3 Rooms used only occasionally for fluoroscopic procedures shall be permitted to use nearby patient toilets if they are located for immediate access.
- 17.4 Patient gowning area with safe storage for valuables and clothing shall be provided in the facility. At least one space should be large enough for staff-assisted dressing.

#### 18. Ultrasound

18.1 Ultrasound room shall be not less than 7 meters square space providing that at least one examining bed is a valuable.





- 18.2 Patient toilet shall be accessible within the ultrasound room with nursing call system
- 18.3 Lighting: Fluorescent lights will provide illumination level up to 40 FC during patient transfer on and from the table, equipment setting, room cleaning, and equipment maintenance

#### 19. Computerized Tomography (CT) Scanning

- 19.1 CT scan room space requirement is at least 24 square meters<sup>2</sup>.
- 19.2 The room shall be sized to allow a minimum clear dimension of 91.44 centimetres (3 feet) on three sides of the table for access to the patient and to facilitate transfer
- 19.3 The door swing shall not encroach on the equipment, patient circulation, or transfer space
- 19.4 Patient gowning area with safe storage for valuables and clothing shall be provided in the facility. At least one space should be large enough for staff-assisted dressing.
- 19.5 A control room shall be provided that is designed to accommodate the computer and other controls for the equipment.
- 19.6 A view window shall be provided to permit full view of the patient.
- 19.7 The angle between the control and equipment shall permit the control operator to see the patient's head.
- 19.8 The control room shall be located to allow convenient film processing (if such method is used).
- 19.9 A patient toilet shall be provided. It shall be close to the procedure room (directly accessible to the scan room is recommended so a patient can leave the toilet without having to re-enter the scan room).
- 19.10 Emergency Power Off pushbutton station.
- 19.11 Door switch with NO/NC contacts Connect to CT system control circuit. CT should shut-off upon opening of the entrance door.
- 19.12 Magnetic door interlock with CT controller to prevent interruption of scanning procedure
- 19.13 Warning light with wording "CT IN USE, DO NOT ENTER". Provide interface with CT controller via interface relay.
- 19.14 CT warning light interface relay with low voltage power supply to match CT equipment requirements
- 19.15 Radiation warning signs should be posted on the entrance door of CT scanner room

#### 20. Mammography

20.1 Mammography room space requirement is at least 9 square meters with patient gowning area with safe storage for valuables and clothing shall be immediately accessible to the room.

<sup>&</sup>lt;sup>2</sup> Space layouts should be developed in compliance with manufacturer's recommendations because area requirements may vary from machine to machine.





- 20.2 Door mammography room should be with interlock to prevent interruption of scanning procedure.
- 20.3 Warning light with wording "X-RAY IN USE, DO NOT ENTER".
- 20.4 Each X-ray room shall include a shielded control alcove. For mammography machines with built-in shielding for the operator, the alcove shall be permitted to be omitted if approved by FANR.

#### 21. Magnetic Resonance Imaging (MRI)

- The MRI room shall be permitted to range from 325 square feet (30.19 square meters) to 620 square feet (57.60 square meters), depending on the vendor and magnet strength.
- 21.2 A control room shall be provided with full view of the MRI
- 21.3 Patient gowning area with safe storage for valuables and clothing shall be provided. At least one space should be large enough for staff-assisted dressing.
- 21.4 A patient holding area shall be provided.
- 21.5 Hand-washing stations shall be provided convenient to the MRI room, but need not be within the room
- 21.6 A computer room
- 21.7 Cryogen storage shall be provided.
- 21.8 Equipment installation requirements:
  - 21.8.1 Power conditioning shall be provided.
  - 21.8.2 Magnetic shielding shall be provided.
  - 21.8.3 For super-conducting MRI, cryogen venting and emergency exhaust must be provided in accordance with the original equipment manufacturer's specifications.
  - 21.8.4 Adequate space for Coils storage based on the on these anatomic applications.
  - 21.8.5 Magnetic door interlock
  - 21.8.6 MRI Warning light and signs
  - 21.8.7 Compatible MRI medical equipments including but not limited to sphygmomanometer, wheel chair and injector.

#### 22. Interventional Imaging Facilities

- 22.1 Interventional Radiology (IR) can be performed only in hospital base diagnostic setting.
- 22.2 The IR and /or cardiac catheterization laboratory is normally located in a separate suite, but location in the diagnostic imaging area can be permitted provided the appropriate sterile environment is provided.
- 22.3 Space requirements shall meet the following:
  - 22.3.1 Procedure rooms
    - 22.3.1.1 The number of procedure rooms shall be based on expected utilization.





- 22.3.1.2 The procedure room shall be a minimum of 400 square feet (37.16 square meters) exclusive of fixed cabinets and shelves.
- 22.3.2 Prep, holding, and recovery rooms. The size of the prep, holding, and recovery areas shall be based on expected utilization.
- 22.4 Electrophysiology labs. If electrophysiology labs are also provided in accordance with the approved functional program, these labs may be located within and integral to the catheterization suite or located in a separate functional area proximate to the cardiac care unit.
- 22.5 Support areas for the IR suite/ cardiac catheterization lab:
  - 22.5.1 Scrub facilities with hands-free operable controls shall be provided adjacent to the entrance of procedure rooms, and shall be arranged to minimize incidental splatter on nearby personnel, medical equipment, or supplies.
  - 22.5.2 Patient prep, holding, and recovery area or room.
  - 22.5.3 A patient preparation, holding, and recovery area or room shall be provided and arranged to provide visual observation before and after the procedure.
  - 22.5.4 Control room or area. A control room or area shall be provided and shall be large enough to contain and provide for the efficient functioning of the x-ray and image recording equipment. A view window permitting full view of the patient from the control console shall be provided.
  - 22.5.5 Electrical equipment room. An equipment room or enclosure large enough to contain x-ray transformers, power modules, and associated electronics and electrical gear shall be provided.
  - 22.5.6 Viewing room. A viewing room shall be available for use by the cardiac catheterization suite.
  - 22.5.7 A clean workroom or clean supply room shall be provided.
  - 22.5.8 A soiled workroom shall be provided.
  - 22.5.9 Film file room shall be available for use by the cardiac catheterization suite.
  - 22.5.10 Housekeeping closet shall be provided.
- 22.6 Support areas for staff clothing and change area(s) shall be provided and arranged to ensure a traffic pattern so that personnel can enter from outside the suite, change their clothing, and move directly into the cardiac catheterization suite.

#### 23. Nuclear Medicine Facility

- 23.1 Nuclear medicine procedure room(s) shall accommodate the equipment specified in the functional program of the hospital providing the services, a stretcher, exercise equipment (treadmill and/or bicycle), and staff work space.
- 23.2 **Space Dimensions**: Reasonable size room and space for:
  - 23.2.1 Imaging ( $\approx 6 \text{ m x 7 m}$ )
  - 23.2.2 Processing and Analysis ( $\approx 2$  m x 2m , it can be included within the imaging room)





- 23.2.3 Dispensing Laboratory ( $\approx 2 \text{ m x 3 m}$ )
- 23.2.4 Injection room
- 23.2.5 Waiting Room: Injected Female Patients
- 23.2.6 Waiting Room: Injected Male Patients
- 23.2.7 Waiting area: Non-injected Patients
- 23.3 The minimum Nuclear Medicine facility requirements are as follows:
  - 23.3.1 Imaging Room:
    - 23.3.1.1 Gamma Camera and Imaging Table,
    - 23.3.1.2 Gamma Camera Computer workstation,
    - 23.3.1.3 Lead Screen Barrier
    - 23.3.1.4 Radiation Survey Monitor (one portable monitor shall be enough for small Nuclear Medicine facilities)
  - 23.3.2 Radiation Dispensing Laboratory:
    - 23.3.2.1 Radioactive Generator (Mo/Tc) and its Extra Shielding / Supply of Radiopharmaceuticals,
    - 23.3.2.2 Dose Calibrator,
    - 23.3.2.3 Shielding Tools and Containers (for vials, syringes, L-shape shield for dose labeling area, radioactive storage and waste, etc)
    - 23.3.2.4 Clean and Smooth working surface,
    - 23.3.2.5 Protective clothing (Gloves, Lab coat, etc)
    - 23.3.2.6 Absorbent tissues,
    - 23.3.2.7 Radiation Signs for labeling,
    - 23.3.2.8 Radiation warning Signs for controlled Area,
    - 23.3.2.9 Pregnancy radiation warring signs in the waiting areas.
    - 23.3.2.10 Radio pharmaceutical labeling Quality Control requirements,
    - 23.3.2.11 Syringes and needles,
    - 23.3.2.12 Ventilated fume hood for handling large doses of Iodine-131 solution,
    - 23.3.2.13 Decontamination Kit,
    - 23.3.2.14 Radiation Survey Monitor (one portable monitor shall be enough for small Nuclear Medicine facilities; for imaging area and lab)
    - 23.3.2.15 In case of using I-131 liquid form (for labeling): Alkalizing solution to be used in case of I-131 spills (such as: 25 g of sodium thiosulphate plus 2 g of sodium iodide in 1 liter of 0.1N sodium hydroxide, with a small amount of detergent added.)
    - 23.3.2.16 Stable iodine handy to block the thyroid uptake in case of significant personal contamination with I-125 or I-131. A pharmacy should be able to supply potassium iodide tablets (KI).





#### 23.3.3 Injection Room:

- 23.3.3.1 Injection chair
- 23.3.3.2 Spill tray lined with absorbent paper
- 23.3.3.3 Shielded radioactive waste container.
- 23.3.4 Patient gowning area with safe storage for valuables and clothing shall be provided. At least one space should be large enough for staff-assisted dressing.

#### 24. Radiotherapy Suite

- 24.1 Space requirements:
  - 24.1.1 Rooms and spaces shall be provided as necessary to accommodate the functional program.
  - 24.1.2 Simulator, accelerator, and cobalt rooms shall be sized to accommodate the equipment and patient access on a stretcher, medical staff access to the equipment and patient, and service access.
- 24.2 Radiation protection requirements. Cobalt, linear accelerators, and simulation rooms require radiation protection.
  - 24.2.1 Layouts shall be designed to prevent the escape of radioactive particles.
  - 24.2.2 Openings into the room, including doors, ductwork, vents, and electrical raceways and conduits, shall be baffled to prevent direct exposure to other areas of the facility.
- 24.3 Construction requirements:
  - 24.3.1 Flooring shall be adequate to meet load requirements for equipment, patients, and personnel.
  - 24.3.2 Provision for wiring raceways, ducts, or conduit shall be made in floors and ceilings.
  - 24.3.3 Ceiling-mounted equipment shall have properly designed rigid support structures located above the finished ceiling.
- 24.4 Support areas for the radiotherapy suite shall be provided. Sharing of these areas between the radiotherapy suite and other areas is permitted if required by the functional program of the health facility:
  - 24.4.1 Exam rooms for each treatment room. Each exam room shall be a minimum of 100 square feet (9.29 square meters), and equipped with a hand-washing station.
  - 24.4.2 A stretcher hold area located adjacent to the treatment rooms screened for privacy, and combined with a seating area for outpatients
  - 24.4.3 Patient gowning area with safe storage for valuables and clothing shall be provided. At least one space should be large enough for staff-assisted dressing.
  - 24.4.4 Reception/control area
  - 24.4.5 Darkroom should be convenient to the treatment room(s) and the quality control area. Where daylight processing is used, the darkroom may be minimal for emergency use. If automatic film processors are used, a receptacle of adequate





size with hot and cold water for cleaning the processor racks shall be provided either in the darkroom or nearby<sup>3</sup>.

- 24.4.6 Film file area
- 24.4.7 Film storage area for unprocessed film.
- 24.4.8 Housekeeping room equipped with service sink or floor receptor and large enough for equipment or supplies storage.

<sup>3</sup> Due to the variation of the image quality, dark room processing is not a recommended by DHA. Facilities providing such processing techniques should work to phase-out this process.

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## CHAPTER THREE: DIAGNOSTIC IMAGING SERVICES STANDARDS





The intent of this chapter is to be used as a skeletal framework in order to meet the DHA requirements in supporting standardization of healthcare and fulfilling the Dubai Strategic Plan 2015 objective in improving the quality of health and health status of the population of the Emirate of Dubai. The standards have been grouped into <u>eight main clusters</u> as follows:

#### **CLUSTER ONE: PATIENT CARE**

#### 25. Patient Assessment

- 25.1 Health facilities providing diagnostic imaging services shall maintain a system for the services to meet the patient needs and clinical services offered in the facility including services required for emergencies.
- 25.2 Diagnostic imaging procedures shall be undertaken only where there is an identified clinical need and:
  - 25.2.1 Upon receipt of a request from a licensed physician requesting the services; or
  - 25.2.2 Where the physician interpreting the image is permitted to self determine the service.
- 25.3 The written or electronic request for diagnostic imaging services should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation
- 25.4 A sample of requests or records documenting the clinical need for the diagnostic imaging procedures shall be maintained at the health facility.
- 25.5 Prior to a diagnostic imaging procedure being rendered, except in cases of emergency, the diagnostic imaging practice must ensure that:
  - 25.5.1 Patients have access to information about the diagnostic imaging procedure, such information shall be available at the health facility
  - 25.5.2 Risks are advised to the patient or substitute decision maker;
  - 25.5.3 Patient's health status and relevant information about individual patient risk factors are obtained; this includes but limited to asthma, previous exposure to intravenous contrast, allergies, medical conditions such as diabetes, kidney disease or heart disease, thyroid disease, multiple myeloma-hypercoagulable state, bleeding tendency, pregnancy status, breastfeeding, medications such as metformin hydrochloride, medical devices and implanted devices such as intracranial aneurysm clips, cardiac pacemaker, coronary stents, intra ocular foreign bodies and cochlear implants.
  - 25.6 Prior to MRI scanning, all patients should be screened for possible contraindications which include, but are not limited to: the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, certain cochlear implants, and certain other ferromagnetic foreign bodies or electronic devices. Possible contraindications should be listed on a screening questionnaire.
  - 25.7 Policies and procedures on imaging pregnant females or females of child bearing age should be available.
  - 25.8 Diagnostic imaging facility using ionizing radiation must ensure that patient radiation exposure is kept As Low As Reasonably Achievable (ALARA) by selecting equipment





and techniques for diagnostic imaging procedures sufficient to provide the required clinical information. A technique chart, consistent with the ALARA principle, for each unit of radiographic equipment shall be maintained. The facility local rules shall be followed.

#### 26. Ethical Considerations

Healthcare professionals working in the outpatient care facility should be aware of their ethical responsibilities and comply with the ethical code of conduct which is governed by the principle of patient centeredness where the patient is the center of all activities.

- 26.1 Healthcare professionals should maintain patient's information confidentiality at all times.
- 26.2 Referring physicians are strongly prohibited from taking any commission for referring patient to specific diagnostic imaging service provider.
- 26.3 Patients shall be informed about any relationships between the referring physician and the outside diagnostic imaging services provider. A written approval of the patients shall be documented in this case
- 26.4 Unnecessary diagnostic imaging investigations <u>must</u> be avoided as they pose serious health implications and a financial burden to the individual and community.

#### 27. Medications Management

- 27.1 The diagnostic imaging facility must ensure that medication risks are managed by developing and implementing a policy describing the procedures for:
  - 27.1.1 Correctly and safely storing, preparing and disposing of medications in accordance with manufacturer's guidelines;
  - 27.1.2 Identifying patients at risk from adverse reactions;
  - 27.1.3 Administering medication safely and actively monitoring the effects of medication:
  - 27.1.4 Healthcare professionals capable of providing timely and appropriate care in the event of an adverse reaction to medication; and
  - 27.1.5 Reporting, investigating and responding to incidents arising from adverse reactions or medication mismanagement.
- A documented policy which identifies procedures for managing of medication adverse reactions; including the use of resuscitation equipment and associated drugs by qualified and certified healthcare professionals in Cardiopulmonary Resuscitation (CPR) or Basic Life Support (BLS).

#### 28. Anaesthesia

- 28.1 Some diagnostic procedures require administration of light, moderate sedation or even general anesthesia, such procedures necessitate close monitoring. Such procedures shall be conducted only in hospital based diagnostic imaging services provider
- 28.2 Consultant/Specialist anesthetist licensed by DHA shall be available during the provision of anesthetic care.
- 28.3 Registered Nurse (RN) assisting in the anesthetic care should be competent in:





- 28.3.1 Insertion of Intravenous (IV) lines.
- 28.3.2 Assessment and monitoring patients under sedation.
- 28.3.3 Pain assessment and management.
- 28.3.4 Medicine preparation and administration which includes understanding of pharmacology of the agents that are administered, as well as the role of pharmacological antagonists for opioids and benzodiazepines.
- 28.4 Physicians and nurses providing anesthetic care shall hold an active Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS) training if dealing with adults or Pediatric Advanced Life Support (PALS) if dealing with children.
- 28.5 Documentation of patient care shall be performed by the supervising anesthetist administering the sedative or general anesthesia agents.
- 28.6 There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to patients and all monitoring equipment. For anesthesia care provision the following equipment shall be provided:
  - 28.6.1 Reliable oxygen source with back up tank
  - 28.6.2 Airway equipment: appropriate sized oral airways, endotracheal tubes, laryngoscopes, normal masks and laryngeal masks
  - 28.6.3 Defibrillator
  - 28.6.4 Double tourniquets if the practice performs Bier blocks
  - 28.6.5 Pulse oximeter
  - 28.6.6 Electrocardiographic (ECG) monitor
  - 28.6.7 Temperature monitoring system for procedures lasting more than 30 minutes
  - 28.6.8 Blood pressure apparatus with different size cuffs
  - 28.6.9 Suction apparatus
  - 28.6.10 Emergency crash cart

#### 29. Dental Radiology Services

- 29.1 Radiographic procedures used in general and specialist dental practice play an essential part in dental health practice. Dental radiographic procedures includes: Intra-oral radiography: periapical, bitewing and occlusal views, Panoramic radiography, Cephalometry, Radiography using specialised dental CT equipment, Other forms of radiography of the complete skull or certain parts of the dentomaxillofacial region
- 29.2 Operator of dental X-ray modalities must receive full training on machine operation and dental radiation safety principles.
- 29.3 Operator of dental X-ray equipment must ensure that radiological examinations are carried out properly at all times during the course of dental treatment. This responsibility covers the following components of the examination:
  - 29.3.1 Determination of clinical need for the examination
  - 29.3.2 Selection of the most appropriate method of examination





- 29.3.3 Optimising radiographic techniques and ensuring radiation protection
- 29.3.4 The use of optimal film or electronic image processing techniques
- 29.3.5 Interpretation of dental radiographs
- 29.3.6 Maintenance of radiographic records
- 29.4 Dental hygienists and dental assistants can perform Intra-oral radiography' periapical, bitewing and occlusal views
- 29.5 Equipment designed for intra-oral radiography must not be used for any other type of radiographic examination. Radiography of the mandible, including temporomandibular joints, must be conducted only on general purpose medical X-ray equipment or on special purpose equipment designed for such examinations unless otherwise authorized by the Health Regulation Department.

#### 30. Referral and Self-Referred Patients

- 30.1 In cases where patients are referred for radiographic examination, the referrer must provide clinical notes. These notes must contain both the reason for the radiographic examination as well as an adequate history
- 30.2 Some patients are self-referred, such as for mammography, or are referred by a third party, such as an insurer or employer. In such cases Information about the results of the diagnostic imaging procedure must be documented.
- 30.3 Radiologist should recognize that performing imaging studies on self-referred patients establishes a doctor-patient relationship that includes responsibility for communicating the results of imaging studies directly to the patient and arranging for appropriate follow-up.
- 30.4 Results of the examinations should be communicated to a designated physician; Radiologist has an ethical responsibility to ensure communication of unexpected or serious findings is communicated to the patient either by the designated physician or the third party physician.

#### 31. Emergency Management and Transfer

- At minimum each diagnostic imaging Facility shall have provision for basic emergency management for occurred for patient during diagnostic procedure
- 31.2 Emergency drugs, devices, equipment and supplies must be available for immediate use in the emergency area for treating life-threatening conditions.
- 31.3 List of emergency medical equipment required in the diagnostic imaging service provider:
  - 31.3.1 Defibrillator
  - 31.3.2 Emergency Cart with Emergency medicines
  - 31.3.3 Resuscitation Kit + Cardiac board + Oral airways
  - 31.3.4 Diagnostic set
  - 31.3.5 Patient trolley with IV stand
  - 31.3.6 Nebulizer





- 31.3.7 Refrigerator for medication storage
- 31.4 Registered Nurse (RN) providing services in the diagnostic imaging service shall be trained and competent to provide the emergency care needed. Examples of emergency nurse competencies are:
  - 31.4.1 Patient Triage
  - 31.4.2 ECG Recording
  - 31.4.3 Pulse Oxymetry
  - 31.4.4 Oxygen Administration
  - 31.4.5 Intravenous cannulation
  - 31.4.6 Medication administration
- 31.5 List of Emergency medication required by diagnostic imaging Facility is available in *appendix* 2
- 31.6 Storage areas for general medical, emergency supplies, medications and equipments shall be under staff control and out of the path of normal traffic.
- 31.7 The diagnostic imaging facility should maintain a documented process for patient emergency transfer which shall ensure appropriate and timely transfer of patients to another health facility in case of emergency.
- 31.8 The Radiologist shall be responsible for the timely transfer, and to provide appropriate information from the facility to the receiving healthcare facility.
- 31.9 Mode of transport and who should accompany the patient should be decided based on the following:
  - 31.9.1 Condition of the patient,
  - 31.9.2 The physician evaluation,
  - 31.9.3 The availability and competence of the ambulance team.





#### **CLUSTER TWO: PATIENT SAFETY**

#### 32. Patient Safety Solutions

- 32.1 In line with the Patient Safety Solutions published by the World Health Organization (WHO) the diagnostic imaging facility must ensure that all patients provided with safe care and services by focusing efforts on reducing harm to patients and staff; including but not limited to:
  - 32.1.1 Patient identification (minimum two identifiers)
  - 32.1.2 Performance of correct procedure at correct body site
  - 32.1.3 Improving hand hygiene to prevent health care-associated infection
  - 32.1.4 Communication during patient hand-over
  - 32.1.5 Single use of injection devices
- The diagnostic imaging facility must develop and implement a policy to ensure that all patients are correctly identified when rendering a diagnostic imaging service by:
  - 32.2.1 Matching a patient to their request; at least two ways to identify a patient, such as the patient's name, identification number, birth date, a bar-coded wristband, or other ways from the time the patient presents and through all stages of the diagnostic imaging service and when transferring responsibility of care;
  - 32.2.2 Correctly matching patients with their intended diagnostic imaging service and the anatomical site and side (if applicable) of the diagnostic imaging procedure; and
  - 32.2.3 Reporting, investigating, and responding to patient care mismatching events when they occur and implementing changes, where relevant, to reduce the risk of future incidents.

For further information regarding Patient Safety Solutions <u>click here</u> to access the WHO published nine Patient Safety Solutions.

#### 33. Infection Prevention and Control

Diagnostic imaging facilities must have an infection control and prevention program to identify and reduce the risks of acquiring and transmitting infections among patients, healthcare personnel, and visitors.

- 33.1 Infection control policy in the diagnostic imaging facilities shall be available and shall address the specific infection risks and hazards, covering all aspects of infection control, including but are not limited to:
  - 33.1.1 The basic measures for infection control and risk reduction and management such as proper hand hygiene/hand washing<sup>4</sup>, restriction of jewelry, nail polish and false nails, etc.
  - 33.1.2 Use of standard precautions.
  - 33.1.3 Needle stick management

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<sup>&</sup>lt;sup>4</sup> The WHO five moments for hand hygiene are as follows: 1) Before touching the patient, 2) Before Clean/aseptic procedure, 3) After body fluid exposure risk, 4) After touching a patient and 5) After touching patient surroundings.





- 33.1.4 Exposure prevention to blood-borne pathogens and post exposure management.
- 33.1.5 Safe handling and disposal of sharps, including the provision of medical devices incorporating sharps protection
- 33.1.6 Environmental cleaning,
- 33.2 Requirements for proper hand hygiene shall include but not limited to:
  - 33.2.1 Conveniently located hand wash basins, used only for washing purpose with hands free operating taps.
  - 33.2.2 Wall mounted non-refilling liquid soap dispenser next to each hand wash basin
  - 33.2.3 Wall mounted paper towel in use
  - 33.2.4 Staff education on hand washing technique.
  - 33.2.5 Regular audits of hand hygiene compliance.
- 33.3 Use and safe storage of antiseptics and disinfectant solutions must be according to manufactures instructions.
- 33.4 Material Safety Data Sheets (MSDS) shall be available for all chemical agents and disinfectants solutions used in the facility.
- 33.5 Equipment storage, cleaning disinfection and sterilization methods are appropriate for the type of instrument/equipment used in the facility
- As per the Federal Law number 27/1981 concerning the Prevention of Communicable Diseases, physicians must report to DHA the reportable communicable disease in case of suspicion or diagnosis of a communicable disease, reporting shall be carried out by using the DHA Infectious Diseases Notification Service.

For further information regarding the communicable disease reporting <u>click here</u> to see the DHA policy on Reporting of Infectious Diseases.

#### 34. Falls Management Program

- 34.1 The incidence of falls and fall injuries shall be minimized through a falls management program.
- 34.2 Falls prevention information shall be provided to staff, patients and patient's family/patient representative
- Patients at risk of falls shall be identified. Patients 'at risk' include but not limited to: pediatric patients, elderly, orthopedic patients, patients undergoing invasive procedures.





#### **CLUSTER THREE: PATIENT AND FAMILY RIGHTS**

#### 35. Patient's Rights and Responsibilities

- All health facilities shall ensure the Charter of Patients' Rights and Responsibilities is communicated and displayed in at least two languages Arabic and English in all patient care and waiting areas and posting on the Facility's website (If any). Additional languages may be used if required based on patients' cultural and linguistic diversity and backgrounds.
- 35.2 Patients shall have the right to full disclosure of health services cost. Cost information can be displayed in the form of price leaflet/brochure or any other form feasible for the Outpatient Care facility.
- 35.3 The Charter of Patients' Rights and Responsibilities must comply with local and federal regulations regarding Patient Rights and Responsibilities, for further information regarding this subject please <u>click here</u> or visit the Health Regulation in DHA website.
- 35.4 The diagnostic imaging facility shall ensure that patients are aware and understand their responsibilities regarding their treatment and their financial obligations.
- 35.5 Patients have the right to an interpreter services when needed.
- Patients should be given the opportunity to participate in decisions involving their healthcare when such participation is not contraindicated.
- Patients have the right to request information about the treating healthcare professionals including their scope of practice and license.
- Patients or legal guardian should be provided information concerning the patient's diagnosis, evaluation, treatment options, and prognosis.
- 35.9 Patients have a right to obtain a copy of their personal medical records.
- 35.10 Patients have the right to refuse treatment; he or she shall be advised of the medical consequences of that refusal. The refusal for treatment shall be signed by the patient and documented in the health record of the patient.
- 35.11 The diagnostic imaging facility must have an effective program for handling of patient complaints. Complaints made by a patient or by patient's family should be investigated, documented including the resolution of the complaint.
- 35.12 Medical complaints shall be reported to Clinical Governance Office (CGO) in HRD.
- 35.13 The patient and the diagnostic imaging facility have the right to change or transfer the patient care responsibility from one healthcare professional to another with clear justification.
- 35.14 Patients and their family have the right for knowledge and health education in order to assist them to participate in care and take decisions about their health status.
- 35.15 Patient satisfaction surveys may be carried out regularly by the diagnostic imaging facility management.





# 36. Disabled People Rights

- 36.1 In compliance with the federal law number 29 for 2006 regarding Disabled People Rights, all health facilities shall be made accessible to accommodate disabled individuals. The following disability requirements are mandatory:
  - 36.1.1 Wheelchair ramps within the Outpatient Care facility building
  - 36.1.2 Accessible consultation and treatment rooms.
  - 36.1.3 Accessible restrooms to disabled patients in the Outpatient Care facility or within the same building.





### CLUSTER FOUR: REPORTING & HEALTH INFORMATION MANAGEMENT

## 37. Reporting and Communication of Diagnostic Imaging Findings

- 37.1 Communication is a critical component of the art and science of medicine and is especially important in Diagnostic imaging. It is incumbent upon radiologists and the departments in which they work to ensure that the results of diagnostic. The final product of any consultation is the submission of a report on the results of the consultation.
- 37.2 Radiologists are encouraged to communicate with referring physician directly and insist on requesting clinical data with each consultation request.
- 37.3 All communication should be performed in a manner that respects patient confidentiality. Medical images and reports constitute confidential patient information and must be treated accordingly.
- 37.4 The Diagnostic imaging services provider shall defines the time period for reporting diagnostic radiology and diagnostic imaging study results
- 37.5 The final report should be transmitted to the referring physician or healthcare professional who is responsible for the clinical follow-up, and also shares in the responsibility of obtaining the results of imaging studies ordered.
- 37.6 The timeliness of reporting any imaging examination varies with the nature and urgency of the clinical problem. The written final report should be made available in a clinically appropriate, timely manner.
- 37.7 The final report should be proofread carefully to avoid typographical errors, accidentally deleted words, and confusing or conflicting statements, and should be authenticated by the reporting radiologist, whenever possible.
- 37.8 Electronic and rubber-stamp signature devices, instead of a written signature, are acceptable if access to them is secure. In any case, the name of the dictating radiologist must appear as such on the report.
- 37.9 Should the radiologist signing the report differ from the radiologist who dictated the report, this should be clearly indicated. Whenever possible, the dictating radiologist should sign his/her own reports. Proxy signing is not desirable, should be done only by another radiologist, and only in circumstances when the dictating radiologist is not available.
- 37.10 In certain cases and after issuing the final report an addendum can be added to the report; addendum content should not contradict with original report
- 37.11 If there was a significant discrepancy between the preliminary report and the final report, this should be documented and the referring physician notified of the change in cases where the change may alter immediate patient management.
- 37.12 Voice recognition systems are not foolproof and methods should be in place to allow detection and correction of program generated errors.
- 37.13 Final reports may be transmitted by paper, fax, and/or email, provided appropriate security and confidentiality measures are in place.





- 37.14 A copy of the final report should be archived by the imaging facility as part of the patient's health record (paper or electronic) and be retrievable for future reference.
- 37.15 Retention of these records should be in accordance with DHA regulations in this regard.
- 37.16 The report should include the following parts:
  - 37.16.1 **Demographics** which includes
    - 37.16.1.1 Name of patient, gender, identification number, etc.
    - 37.16.1.2 The facility or location where the diagnostic image study was performed.
    - 37.16.1.3 Name of referring (attending) physician (s).
    - 37.16.1.4 Name or type of examination.
    - 37.16.1.5 Date and time of examination.
    - 37.16.1.6 Date of dictation.
  - 37.16.2 **Body** of the report should be short and precise and includes:
    - 37.16.2.1 Clinical history, indication or clinical question may be inserted at the beginning of the report
    - 37.16.2.2 A description of the examinations and/or procedures performed and any contrast media medications, any known significant patient reaction or complication should be recorded.
    - 37.16.2.3 Limitations factors that can limit the sensitivity and specificity of the examination such factors patient anatomy (e.g. dense breast pattern), and limitations of the technique e.g. (e.g. the low sensitivity of a chest X-Ray for pulmonary embolism)
    - 37.16.2.4 Findings using precise anatomical, radiological and pathological terminology to describe the findings accurately. Abbreviations should be avoided to avoid ambiguity and risk of miscommunication.
  - 37.16.3 Unless the report is brief, each report should contain an impression (conclusion or diagnosis) section and includes;
    - 37.16.3.1 A specific diagnosis should be given when possible with a differential diagnosis should be rendered when appropriate.
    - 37.16.3.2 Follow-up or additional diagnostic studies to clarify or confirm the impression should be suggested when appropriate.
    - 37.16.3.3 Any significant patient reaction should be reported.
- 37.17 A preliminary report may precede the final report in certain circumstances and contains limited information relevant to immediate patient management.

# 38. Reporting by Non-Radiologist

38.1 In order to contribute to patient management, accuracy of image interpretation is crucial. The types of investigation which may be suitable for primary reporting by healthcare professionals without a medical degree in radiology are those where there is a single organ investigation, with a single suspected pathology and a yes/no answer.





- 38.2 Licensed Consultant/Specialist physicians<sup>5</sup> can perform ultrasound limited to their specialty scope only if they hold specialized certificate/training course in ultrasound<sup>6</sup>, e.g. cardiologist can provide Echocardiography services if he or she completed a successful program or dedicated training courses in Echocardiography
- 38.3 Consultant/Specialist physicians cannot provide radiology reports independently. Only DHA licensed radiologist is authorized to issue written radiology reports;
- 38.4 If the ultrasound diagnosis performed by Consultant/Specialist physicians carries the chance of intervention or surgery, the ultrasound report should be countersigned by licensed Consultant/Specialist Radiologist.
- 38.5 Licensed physicians as General Practitioners cannot provide ultrasound services.
- 38.6 Licensed radiographers can perform ultrasound procedures independently; he or she cannot report or interpret ultrasound images.
- 38.7 Professionals authorize to interpret plain X-ray images shall meet the following criteria:
  - 38.7.1 Consultant/Specialist physicians can interpret plain X-ray images limited to their specialty scope only.
  - 38.7.2 General Practitioners can interpret chest and extremities plain X-ray images only, they are not permitted to interpret and report other diagnostic images.
  - 38.7.3 DHA licensed Osteopath and Chiropractor practitioners can interpret plain X-ray images for osteopathy or chiropractic purposes.

### 39. Informal and Verbal Communication

- 39.1 Occasionally, radiologist may be asked to give opinion that does not result in a formal report but may be used to make treatment decisions. These opinions may be given without adequate patient history or comparison studies.
- 39.2 Informal communication carries inherent risk and often the clinician's documentation of the informal communication is the only written record of the informal communication. Radiologists who may provide such types of consultations with the intent of improving patient care should document their interpretation and note the circumstances under which they were given.
- 39.3 In some circumstances, Radiologists may require direct communication of unusual, unexpected or urgent findings to the referring physician in advance of the formal written report.
- 39.4 Telephone or verbal communications must be documented immediately by the healthcare professional that receives the order and should be authenticated within 24 hours by the healthcare professional that is responsible for ordering or evaluating the service furnished

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<sup>&</sup>lt;sup>5</sup> Licensed physicians as General Practitioners cannot provide ultrasound services.

<sup>&</sup>lt;sup>6</sup> Acceptable training courses shall be conducted in academic institute with clear structure and competency, the course shall in physicians speciality area and shall include different training modules such as basic practical physics and artefacts, probe manipulation techniques, scanning protocols and clinical cases.





# 40. Outsourcing Diagnostic Imaging Services

- 40.1 Diagnostic imaging services and/or reporting and interpreting services may be provided within the Diagnostic imaging premises, or by written agreement with outside provider.
- 40.2 Outsourced diagnostic imaging services provider shall be convenient for the patient to access, and reports are received in a timely way that supports continuity of care. The outsourced facility shall meet the following:
  - 40.2.1 A contractual agreement (or similar) shall be available.
  - 40.2.2 The image and report shall be transferred in way to ensure the diagnostic image quality of confidentiality of the report, a variety of technologies, such as picture archiving and communication systems (PACS) or teleradiology, may be required to augment service provision.
  - 40.2.3 Individual patient records must be maintained by both the initiating and providing sites and exchanged within clinically relevant timeframes.

### 41. Teleradiology

- 41.1 If used appropriately teleradiology provides a significant support to healthcare and allows a continuous education beside an instant interpretation of the images and a possibility for a second opinion. Teleradiology is not appropriate if the available teleradiology system does not provide images of sufficient quality to perform the indicated task
- 41.2 To use teleradiology services in Dubai, the Diagnostic imaging facility management shall file a request to the Director of Health Regulation Department with evidence meeting the standard requirements.
- 41.3 The use of teleradiology shall not compensate radiologist shortage or absence from the diagnostic imaging facility.
- 41.4 Teleradiology transmitting site should comprise of at least one full time radiologist, one radiographer and a system manager with informatics certification.
- 41.5 The types and specifications of the transmission elements should be documented by the transmitting site. Diagnostic loss in the images should not be acceptable at the receiving site. Patient demographics, site information, labels and measurement data should all be transmitted without errors. The selection of the images that will be transmitted is the responsibility of the radiologist at the transmitting site
- 41.6 Equipment guidelines cover two basic categories of teleradiology
  - 41.6.1 Small matrix size (e.g., CT, MRI, ultrasound, nuclear medicine, digital fluorography, and digital angiography). The data set should provide a minimum of 512 x 512 matrix size at a minimum 8-bit pixel depth for processing or manipulation with no loss of matrix size or bit depth at display
  - 41.6.2 Large matrix size (e.g., digital radiography and digitized radiographic films). These images should be digitized to a matrix size corresponding to 2.5 lp/mm or greater measured in the original detector plane. These images should be digitized to a minimum 10 pixel byte depth.
- 41.7 Acquisition or Digitization equipment can either:





- 41.7.1 Direct image acquisition: All the data set including the image matrix and pixel byte depth that is obtained by a digital modality should be transferred to the teleradiology system. DICOM standard should be used.
- 41.7.2 Secondary image capture
  - 41.7.2.1 Small matrix images. Each individual image should be digitized to a matrix size as large or larger than that of the original image by the imaging modality. The images should be digitized to a minimum of 8 bits pixel depth. Film digitization or video frame grab systems conforming to the above specifications are acceptable.
  - 41.7.2.2 Large matrix images. These images should be digitized to a matrix size corresponding to 2.5 lp/mm or greater, measured in the original detector plane. These images should be digitized to a minimum of 10 bits pixel depth
- 41.8 The system must include annotation capabilities including patient name, identification number, date and time of examination, name of facility or institution of acquisition, type of examination, patient or anatomic part orientation (e.g., right, left, superior, inferior), and amount and method of data compression. The capability to record a brief patient history is desirable.
- 41.9 The type and specifications of the transmission devices used will be dictated by the environment of the studies to be transmitted. In all cases, for official interpretation, the digital data received at the receiving end of any transmission must have no loss of clinically significant information. The transmission system shall have adequate error-checking capability
- 41.10 Teleradiology receiving site should employ radiologist licensed in the country the service is provided. Such radiologists should be certified in teleradiology and have to be given user tuition.
- 41.11 Monitors: The specification of the receiving site monitors used for the interpretation should meet the aims of teleradiology
- 41.12 Both sites should hire information technologists and technicians who will be responsible for the computer systems and infrastructure.
- 41.13 The quantifications of the personnel in the receiving site should be identical to those of the transmitting site. All the quantifications should be documented.
- 41.14 Data compression may be used to increase transmission speed and reduce storage requirements. Several methods, including both reversible and irreversible techniques, may be used under the direction of a qualified physician, with no reduction in clinically significant diagnostic image quality. The types and ratios of compression used for different imaging studies transmitted and stored by the system should be selected and periodically reviewed by the responsible physician to ensure appropriate image quality. The radiologist at the receiving site should have the option to access the uncompressed or lossless images as needed

# 42. Health Records

42.1 The "health record" is a legal document that should accurately outline the total needs, care and management of patients. It facilitates communication, decision making and





- evaluation of care and protects the legal interests of the patient, clinician and the health facility. The term "health record" includes "radiographs and other images produced in the course of radiological examinations.
- 42.2 Health records refer to all clinical and non-clinical records, both electronic and paper-based.
- 42.3 Radiology health records can be hard or soft copy and shall include:
  - 42.3.1 A unique identifier for health records
  - 42.3.2 A system to alert staff to patients of the same name
  - 42.3.3 The identity of the healthcare professional that made the record entry and the patient it relates to.
  - 42.3.4 Complete, legible notes of diagnostic procedure and contrast media used, including contrast reaction (if any).
  - 42.3.5 Diagnostic test results and a record of when results were received.
  - 42.3.6 Copies of signed informed consent given by the patient or his/her relatives up to the fourth degree (in case of invasive diagnostic procedure).
- 42.4 Complete reports of the results of diagnostic imaging examinations must be kept in health records or the PACS (if the system is digital) for not less than <u>two</u> years and a copy must be filed in the patient's record.
- 42.5 Magnetic tapes containing the digital versions of MRI or CT studies are not permanent "health records" and do not have to be retained for the statutory or recommended retention periods as long as a hard copy of the image is placed in the patient's permanent file."
- 42.6 All information relevant to a patient should be readily available to authorized healthcare professionals or in the event that a patient is transferred.
- 42.7 Patient information should be treated as confidential and protected from loss, tampering, alteration, destruction, and unauthorized or inadvertent disclosure.
- 42.8 The diagnostic imaging facility management shall be responsible for retention of patient health records.

For further information regarding health records completion, retaining, and destruction <u>click</u> <u>here</u> to view the DHA Health Records Guidelines or visit the Health Regulation section in DHA website <u>www.dha.gov.ae</u>

### 43. Informed Consent

- 43.1 As per article (7) of the Federal Law number 10/2008 concerning Medical Liability and the Cabinet Decision No. (33) of 2009 promulgating the bylaw of the medical liability law, Informed Consent shall be obtained by the treating physician prior to procedure/surgery and/or interventions (excluding emergency cases), after discussing the complication, risks, benefits and alternatives.
- 43.2 The diagnostic imaging facility must develop a list of procedures and/or interventions requiring informed consent. Consent documentation shall be maintained in the patient's health record





43.3 If the patient lacks the full capacity (e.g. less than 18 years old) informed consent shall be obtained from their relatives up to the fourth degree or the legal guardian prior to the performance of a procedure and/or treatment

For further information regarding the Federal Law number 10/2008 concerning Medical Liability and the Cabinet Decision No. (33) of 2009 <u>click here</u> or visit the Health Regulation in DHA website <u>www.dha.gov.ae</u>

# 44. Information Management

Information management systems include records management, collection, use and storage of information, data management and Integration of information and communication technology

- 44.1 Each facility must maintain health records and reports in a manner to ensure accuracy and easy retrieval.
- 44.2 Health records shall be maintained in the custody of the health facility and shall be available to a patient or his/her designated representative through the attending healthcare professional at reasonable times and upon reasonable notice.
- 44.3 The facility shall ensure that each patient is allocated a specific unique identifier, and where multiple records for the patient exist they are cross-referenced
- 44.4 Clinical classification shall be undertaken for all patient diagnosis in accordance with the International Classification of Disease 10 (ICD10).
- 44.5 The facility shall maintain a record management policy and system that ensure:
  - 44.5.1 The secure, safe and systematic storage of data and records
  - 44.5.2 Timely and accurate retrieval of records stored on or off-site
  - 44.5.3 Patient privacy when information contained in records is released or communicated for care
  - 44.5.4 Retention and destruction of records shall be in compliance with relevant DHA regulations and guidelines (incinerating or shredding for hard copy records, wiping disks clean or the disks physically destroyed for electronic records).

### 45. Data Collection

- Each licensed health facility shall submit to the Health Data and Information Analysis Department in DHA the following data at least on a <u>quarterly basis</u>:
  - 45.1.1 The total number of patients attending the facility based on International Classification of Diseases (ICD-10) and by nationality, gender and age group.
  - 45.1.2 The total number of registered manpower in the heath facility by nationality, gender and age group.
  - 45.1.3 Total number of Radiology diagnostics procedures performed by type, patient nationality, gender and age group (if applicable).
- 45.2 The Health Regulation Department may at anytime request for additional data as deemed necessary.









## CLUSTER FIVE: QUALITY CONTROL AND ASSURANCE PROGRAMS

## 46. Quality Control

- 46.1 Radiographic units exist in a wide variety of configurations, quality begins with proper equipment selection, equipment must be appropriate in terms of its ability to deliver the quality necessary for a particular diagnostic imaging task at a cost to both patient and facility that is reasonable in terms of radiation dose, cost, and downtime.
- 46.2 Each licensed Diagnostic Imaging Facility shall maintain a documented quality control program for monitoring and evaluating the effective management, safety, and proper performance of all imaging equipments. and shall comply with minimum frequencies of testing as defined by the written facility policies and procedures of the facility and with the manufacturers' guidelines when appropriate;
  - 46.2.1 Equipment performance should be monitored by a qualified medical physicist or a qualified technologist
  - 46.2.2 Daily/ Weekly quality control testing shall be conducted and reviewed on a quarterly or annual basis, as directed, by a Medical Physicist and/or radiologist;
  - 46.2.3 The interpreting physician shall perform quality control testing and compliance testing upon the installation of all new equipment, and at specified times thereafter:
  - 46.2.4 Controls, policies and procedures relating to radiology procedures shall be included in the overall quality control and improvement program

For further details about some recommended quality control/assurance procedures for diagnostic imaging equipments, please refer to *appendix 3* 

- 46.3 Each licensed Diagnostic Imaging Facility shall have a process in place for:
  - 46.3.1 Educating its employees about medical errors and their prevention; and
  - 46.3.2 Using information gained as a result of medical error analysis as part of its quality improvement program.
- 46.4 Each facility shall establish a system to collect and review outcome data for all radiology services performed, including follow-up on the disposition of all positive results and correlation of pathology results with the interpreting radiologist report.
- 46.5 Each licensed facility shall incorporate protocols for imaging services provided to High Risk Patients, as appropriate, to determine the risks and clinical benefits involved with ionizing radiation exposure to these Patients.

## 47. Quality Manual

- 47.1 The diagnostic imaging facility governance structure should be effective and comprehensive to ensure the delivery of safe, quality of the services. A documented quality <u>manual</u> should be available which includes diagnostic imaging policies and procedures related to:
  - 47.1.1 Governance structure (mission, vision, organization structure, etc.)
  - 47.1.2 List of radiology and diagnostic imaging services and equipment provided





- 47.1.3 Radiation safety and radiographic technique charts
- 47.1.4 Infection control
- 47.1.5 Access to (or copy of) FANR radiation polices. Along with radiation system of work and facility local rules.
- 47.1.6 Provision of diagnostic imaging services and reporting and recording image findings
- 47.1.7 Consumer information and leaflets
- 47.1.8 Patient identification and procedure matching
- 47.1.9 Medication management
- 47.1.10 Complaints management.
- 47.1.11 quality control and assurance programs
- 47.1.12 Copy of the following document shall be maintained:
  - 47.1.12.1 DHA health facility license;
  - 47.1.12.2 All licensed healthcare professionals in the facility including radiologists, radiographers, nuclear medicine technologists, nurses or others.
  - 47.1.12.3 Copy of FANR license for uses of ionising radiation diagnostic services.

### 48. Reporting Sentinel Events and Major Incidences

- 48.1 Each Diagnostic Imaging Facility shall develop a written sentinel event policy.
- 48.2 The facility <u>shall report to the HRD any sentinel event</u> and major incidents which occur on the premises, this includes but not limited to the following:
  - 48.2.1 Any incident of patient death inside the facility.
  - 48.2.2 A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
  - 48.2.3 Serious criminal acts or suicide attempt of a patient inside the facility premises.
  - 48.2.4 Full or partial evacuation of the facility for any reason.
  - 48.2.5 Fire on the facility.
- 48.3 Sentinel events and major incidents shall be reported immediately and not later than three (3) working days after event occurrence.
- 48.4 Means of reporting sentinel events and major incidents shall include a written official letter to the Director of HRD either by courier or by hand delivery. Reporting should be consistent with applicable patient confidentiality.
- 48.5 The facility management shall prepare a written evaluation of its response to the sentinel event or a thorough and realistic root cause analysis with action plan. The response should be submitted to the Director of HRD either by hand or by courier within 45 calendar days of the event or of becoming aware of the event.
- 48.6 In support of DHA mission to continually improve the safety and quality of health care provided to the public, the HRD may conduct reviews of the facility activities in response to sentinel event or major incident.





### **CLUSTER SIX: HUMAN RESOURCES AND STAFFING**

In recent decades, diagnostic imaging services has experienced a technological revolution, the effectiveness of diagnostic imaging services is greatly dependent on the quality of the health care provided, the existences of well-trained healthcare professionals, as well as the implementation of quality assurance programs, are essential for obtaining accurate diagnoses

### 49. Human Resources Practices

- 49.1 The Diagnostic Imaging Facility shall maintain accurate and complete personnel records for all employees, including training records. Such records shall be maintained and kept confidential.
- 49.2 Learning and development of healthcare professionals and other staff shall ensure advancement of skills and competence and shall be relevant to their allocation and responsibilities.
- 49.3 Continuing Professional Development (CPD) activities shall be documented for all healthcare professionals.

# 50. Healthcare Professionals Staffing Minimum Requirements

- Only healthcare professionals with proper qualifications and experience shall perform diagnostic imaging studies, interpret and report the results.
- 50.2 All healthcare professionals <u>must</u> hold an active DHA professional license and work within their scope of practice
- 50.3 The facility management shall ensure that availability of appropriate and sufficient numbers of healthcare professionals on duty to plan, supervise and perform the diagnostic imaging procedures.
- 50.4 In Independent Radio-Diagnostic Centre, healthcare professionals allocation <u>shall</u> meet the following:
  - 50.4.1 At least one full time licensed Consultant/Specialist radiologist shall be available to supervise and manage the diagnostic imaging services provided.
  - 50.4.2 At least one full time qualified and DHA licensed radiographer shall be in the facility.
  - 50.4.3 If Mammography services provided, a female radiographer must be licensed and employed in the facility.
  - 50.4.4 If diagnostic imaging with contrast media use is provided in the facility, at least one full time Registered Nurses (RN) on duty to provide and supervise patient care during contrast provision.
  - 50.4.5 When radiation therapy or other special services are provided, they are under the direction of appropriately licensed and qualified healthcare professionals.
- 50.5 In Outpatient Care facilities healthcare professionals allocation shall meet the following:
  - 50.5.1 If only **Ultrasound** and/or **Conventional Radiography** service available, at least one licensed Consultant/Specialist Radiologist must supervise the services on part time or full time basis <u>and</u> at least one full time DHA licensed radiographer.





- 50.5.2 Where **CT/MRI** services are provided <u>in Outpatient Care facilities</u>, the following shall be met:
  - 50.5.2.1 At least one licensed Consultant/Specialist Radiologist must be available to supervise the services on full time basis and to provide reports.
  - 50.5.2.2 At least one full time licensed radiographer with training in CT/MRI must be available in the facility to provide and assist in the services provision.
  - 50.5.2.3 A Registered Nurse (RN) or a physician with contrast media administration competencies. (if provided)
- 50.6 If <u>Mobile Radiology Services</u> such as Ultrasounds, Mammography, healthcare professionals allocation shall meet the following
  - 50.6.1 At least one licensed Consultant/Specialist Radiologist must be available onsite to supervise the mobile services, to discuss radiological findings and provide reports.
  - 50.6.2 At least one licensed radiographer shall be available to assist in the diagnostic mobile services provision (excluding ultrasound services). If Mammography provided as mobile services, the licensed radiographer must be a female radiographer.
  - 50.6.3 The reporting of mobile radiology reports shall be conducted by licensed radiologist.
  - 50.6.4 Radiation protection shall meet FANR requirements; the mobile unit shall be licensed by FANR.

For further information regarding the DHA Mobile Health Facility Guideline please <u>click here</u> or visit the Health Regulation site in DHA website <u>www.dha.gov.ae</u>

## 51. Specific Training and Certifications Requirements

- 51.1 MRI safety training shall be provided to all healthcare professionals and staff involved in patient management inside the MRI area.
- 51.2 A designated healthcare professional as "radiation safety officer" shall be responsible for radiation safety program in the facility. The Radiation Safety program shall include but not limited to the use and monitoring of personal protective devices in accordance with FANR applicable laws and regulations.
- 51.3 At least one licensed healthcare professionals (Radiologist/radiographer) must maintain valid training/certification in basic Cardiopulmonary Resuscitation (CPR) or Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS), He or she shall be available during diagnostic imaging services provision till the patient leave the facility.

# 52. Pregnant Healthcare Professionals

- Pregnant healthcare professionals may continue to work in a Diagnostic Imaging Facility, with the following recommendations:
  - 52.1.1 Pregnant healthcare professionals should not remain in examination rooms during scanning;





52.1.2 Pregnant healthcare professionals may opt out of all scan room work during the first trimester.





### **CLUSTER SEVEN: FACILITY MANAGEMENT**

## 53. Diagnostic Imaging Equipments

- All equipment used to conduct diagnostic imaging studies shall be regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities
- 53.2 Equipment used to acquire or print images for diagnostic imaging procedures must be safe and appropriate for its intended use. All equipments shall be installed and operated in accordance with manufacturer specifications.
- 53.3 Health Facilities providing radiology and diagnostic imaging services must maintain a current equipment inventory. A current equipment inventory should include information relating to name of item, manufacturer, and serial number.
- 53.4 The diagnostic imaging facility shall maintain effective Preventive Maintenance (PM) as per the manufacturer recommendations; the PM shall include both preventive and corrective aspects, preventive maintenance procedures are:
  - 53.4.1 visual inspection of the mechanical and electrical characteristics of the diagnostic equipments covering such things as checking conditions of cables, watching the tomographic unit for smoothness of motion, assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom, listening for unusual noises in the moving parts of the system
  - 53.4.2 Following the manufacturer's recommended procedures for cleaning and maintenance of the equipment, and regular inspection and replacement of switches and parts that routinely wear out or fail. Electrical safety testing for patient related equipment.
  - 53.4.3 Each piece of equipment has a checklist for its maintenance schedule, failure incidence, repairs done.
  - 53.4.4 A written policy to perform inspection on all new equipment prior to operational use.
- 53.5 A radiology and diagnostic imaging equipment management program should include calibrating and maintaining equipment. The program includes also monitoring and follow-up.
- 53.6 A copy of operator and safety manuals of all medical equipment and inventory list with equipment location shall be maintained.
- 53.7 A written policy for tagging medical equipment shall be maintained which include:
  - 53.7.1 PM with testing date and due date
  - 53.7.2 Inventory number
  - 53.7.3 Safety checks
- 53.8 A written policy on removal of equipment from service shall be available.
- 53.9 Elimination of the use of extension cords shall be implemented
- 53.10 Healthcare professionals (radiologist, radiographers and nurses) shall be trained to operate the medical equipment assigned to them and the hazards attached to it.





- 53.11 Records of Staff training certificates on any X-ray modalities must be maintained properly.
- 53.12 Reporting of medical equipment incidents and corrective actions taken shall be maintained in the health facility.
- 53.13 Each Diagnostic imaging facility shall implement sufficient hardware and software security measures to ensure that patient information stored in and transmitted by its computer system, handheld or other devices will be protected from inappropriate external and internal disclosure.
- 53.14 Electronic data and information management systems shall meet the diagnostic imaging facility needs and support the delivery of quality care and service; it shall ensure the timely availability of diagnostic imaging study results.

## 54. X-ray film and other supplies

- 54.1 The organization should identify cassettes, films, chemicals and other supplies necessary to regularly provide radiology and diagnostic imaging services to its patients.
- 54.2 A process to order or to secure essential films, chemicals, and other supplies should be effective.
- 54.3 All supplies are stored and dispensed according to defined procedures that incorporate the manufacturers' recommendations.
- 54.4 The periodic evaluation of reagents according to manufacturers' recommendations ensures accuracy and precision of results.

## 55. Radiation Protection and Safety Programs

- 55.1 Diagnostic imaging services include all medical applications of ionizing and nonionizing radiation and can be classified in two main group as follows
- The Federal Authority for Nuclear Regulation (FANR) is exclusively responsible for licensing all use of radiation in the United Arab Emirates (UAE), the use of ionizing radiation and radioactive materials in health facilities must comply with FANR laws and regulations. The Federal Law by Decree No 6 of 2009, Article 25, lists regulated activities that must be licensed by FANR. These activities form the basis for developing national regulations. For further information regarding FANR regulations and requirements please read FANR Regulation No. 24; visit FANR website www.fanr.gov.ae
- 55.3 FANR must be formally informed of any new, old or replaced or shifted X-ray modality.
- Non-Ionizing diagnostic imaging service doesn't require the Federal Authority for Nuclear Regulation (FANR) license and approval.
- 55.5 Health facilities providing diagnostic imaging shall has an active radiation safety program that includes all components of the diagnostic imaging services provided by the facility; (including radiation oncology and the cardiac catheterization laboratory).
- Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to





- society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)
- 55.7 A radiation safety program that addresses potential safety risks and hazards encountered in the facility shall be available. The program addresses safety practices and prevention measures for radiology and diagnostic imaging staff, other staff, and patients.
- 55.8 All radiation employees should be trained regularly on radiation safety.
- 55.9 Radiation safety program requirements includes:
  - 55.9.1 Written radiation policies and procedures that support compliance with all applicable local and federal regulations.
  - 55.9.2 Written policies and procedures for handling and disposal of infectious and hazardous materials. A register shall be kept on the safe disposal of all radioactive waste
  - 55.9.3 Identified radiation safety risks are addressed by specific processes or devices that reduce safety risks (such as lead aprons, radiation badges, etc).
  - 55.9.4 Radiology and diagnostic imaging staff are oriented to safety procedures and practices and receive education for new procedures and hazardous materials.

# 56. General Safety and Security Management

- 56.1 Diagnostic imaging facility shall ensure that the health care environment is safe. A safety management system shall be developed and implemented in the facility include fire safety, hazardous waste, emergencies, security, facility
- 56.2 The facility shall establish a fire safety plan for early detection, confining, extinguishment, rescue, evacuation and alerting the Dubai Civil Defense
- 56.3 The facility shall maintain fire extinguishers and fire protection equipments and devices as per the Dubai Civil Defense requirements
- 56.4 There should be <u>evacuation maps</u> posted in the facility to indicate current locations marked with "You are here" to provide information regarding Escape routes and Fire exits.
- 56.5 The facility staff shall be aware about the following:
  - 56.5.1 Location and use of fire hose reel/cabinets/blankets
  - 56.5.2 Assembly points
  - 56.5.3 Fire alarms/ call points break glass / pull station.
  - 56.6 Security personnel (if available) should be educated and provided with information in relation to security risks and responsibilities and oriented on their scope of work, fire safety and emergency codes.
- 56.7 There should be a written policies on the following that includes but not limited to:
  - 56.7.1 Safe keeping of patient belongings.
  - 56.7.2 Lost and found items
  - 56.7.3 How to contact the local police, in case of need





- 56.8 Hazards that might lead to slipping, falling, electrical shock, burns, poisoning, or other trauma should be eliminated
- 56.9 Employees dealing with hazardous substances (if available) shall have protective clothes or equipment as required.
- 56.10 Proper storage and containers for disposing clinical and general waste material shall be maintained.
- 56.11 Contracting with a specialized company to transport and destroy medical waste materials shall be according to the conditions issued by Public Health Department in Dubai Municipality.
- 56.12 Staff should be educated and provided with information on waste management, fire safety, hazardous substances and their responsibilities.





# Appendix 1: Minimum X-ray Room Surfaces and Shielding Thicknesses

Main X-ray Applications	Minimum Required Surface	Recommended Structural Shielding Material (Walls) <sup>7</sup> and Doors	Minimum Shielding Thickness and Height
Conventional radiography	15 m <sup>2</sup>	Walls: Lead Doors: Lead	Walls: 1.5 mm Doors: 1.5 mm Height: 1.80 m
Combined Radiography and Fluoroscopy	20 m <sup>2</sup>	Walls: Lead Doors: Lead	Walls: 1.5 mm Doors: 1.5 mm Height: 1.80 m
Computed Tomography (CT)	24 m <sup>2</sup> (Length: 6 m Width: 4 m)	Walls: Lead Doors: Lead	Walls: 1.5 mm Doors: 1.5 mm <u>Height</u> : <b>from floor to</b> ceiling
Mammography	9 m <sup>2</sup> (3m x 3m)	Walls: Stone Wall Board Doors: hard wood or <u>steel</u>	Walls: normal <b>stone</b> wall (2.5 cm min) Doors: 1 mm <b>Steel</b> or 2.5 cm of hard wood
Dental	6 m <sup>2</sup> (2m x 3m)	Walls: Stone Wall Board Doors: normal door	2.5 cm stone wall
Panoramic and Cephalometric	2m x 3m	Walls: Stone Wall Board	Walls: normal <b>stone</b> wall (2.5 cm min And 1mm Lead behind cassette holder
Bone Densitometry	2m x 3m	Walls: Stone Wall Board	Normal wall
Chiropractic X-rays	15 m <sup>2</sup>	Walls: Lead Doors: Lead	Walls: 1 mm lead Door: 1 mm Lead

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<sup>&</sup>lt;sup>7</sup> Walls shall be 6 inches thick made of Ferro concrete or 9 inches if made of blocks and if the block are hollowed out then it shall be placed with lead or shall be cover with barium, the double main entrance and the developing room shall be provided with lead, affix red alarming lights over the main entrance and tag some warning notes at the proper places.





# **Appendix 2: Diagnostic Imaging Facility Mandatory Emergency Medications**

No.	Description	Qty <sup>8</sup>	Remarks
1	Inj. Adrenaline 1:1000	5	Anaphylaxis or acute angio-oedema
2	Inj. Atropine 600mcg	10	Bradycardia, Organophosphate and
	v 1	10	Carbamate overdose
3	Inj. Amiodarone 50mg/Ml	2	Tachyarrhythmia, cardiac arrest
4	Inj. Dextrose 50%, 50ml	2	Hypoglycaemia
5	Inj. Chlorpheniramine 10mg/Ml	5	Adjunctive treatment in anaphylaxis
6	Inj. Furosemide 20mg/2ml	3	Relief of pulmonary oedema
7	Inj. Hydrocortisone 100mg/2ml	3	Acute asthma attack and post anaphylaxis
8	Inj. Dopamine 200mg/5ml	2	Hypovolaemic shock cardiogenic shock, CHF
9	Inj. Aminophylline 250mg/10ml	2	Bronchospasm
10	Inj. Salbutamol 500mcg/Ml	2	Bronchospasm
11	Inj. Glucagon 1mg	2	Hypoglycaemia
12	Salbutamol Aerosol Inhalation Nebules	1 Box	Asthma attack
13	Regular insulin	1 Box	For the treatment of Hyperglycaemia
14	Nitroglycerine and	1 Box	First line treatment for chest pain.
-		1 Box	First line treatment for chest pain.
15	Clopidogel		This fine treatment for chest pain.
16	Aspirin 325mg tablets	10	
17	Adenosine	6	Supraventricular tachycardia (SVT)
	IV Fluids such as Ringer Lactate,	5	
18	Dextrose Water, Dextrose Saline,	each	For hypovolemia
	Normal Saline.		
19	Water For Injection	1 Box	To mix hydrocortisone inj, etc.
20	Water for injection	1 Box	To mix hydrocortisone inj, etc.
	Epinephrine (Auto-Injectors)	2	
22	Normal Saline 10 ml	10	For flushing after Adenosin etc

<sup>&</sup>lt;sup>8</sup> The quantities listed cannot be exceeded and the patient should not be charged for more than the published current federal price list.





## **Appendix 3: Recommended Quality Control procedures**

The following are Quality Control procedures for some Diagnostic imaging equipments as recommended by the American Association of Physicists in Medicine and The American College of Radiologists "ACR"

- 1. Quality Control for radiographic units
  - 1.1 Daily Visual Checks
  - 1.2 **X-ray Tubes and Collimators**; test all the following parameters at least annually:
    - 1.2.1 Beam Quality
      - 1.2.1.1 Light Field/X-ray Field Alignment (Congruence)
      - 1.2.1.2 X-Y Scale (Field Size Indicator) Accuracy
      - 1.2.1.3 Positive Beam Limitation System (PBL)
      - 1.2.1.4 X-ray Beam–Bucky Alignment
      - 1.2.1.5 Focal Spot Size
    - 1.2.2 X-ray Generators
      - 1.2.2.1 Kilovoltage Calibration
      - 1.2.2.2 Exposure Timer
      - 1.2.2.3 Beam Quantity (mR/mAs)
      - 1.2.2.4 Automatic Exposure Control (AEC)
    - 1.2.3 **Grids** The performance of the grid needs to be checked at least annually.
      - 1.2.3.1 Artifacts
      - 1.2.3.2 X-ray Beam Grid Alignment and Timing
    - 1.2.4 Electrical Safety
    - 1.2.5 Cassettes, Screens, Films, and Chemicals
      - 1.2.5.1 Screen-Film-Cassette Speed Matching
      - 1.2.5.2 Screen-Film Contact
      - 1.2.5.3 Screen Cleanliness
      - 1.2.5.4 Cassettes and Cassette Identification
    - 1.3 Quality control of Conventional Tomography units: The performance parameters to be tested are identical to those listed in radiographic unit QC in addition to the following:
      - 1.3.1 Motion
      - 1.3.2 Tomographic Exposure Angle Accuracy
      - 1.3.3 System Spatial Resolution
      - 1.3.4 Accuracy of Cut Level
      - 1.3.5 Section Thickness
    - 1.4 Quality control of Portable X-ray systems
      - 1.4.1 High Frequency Systems
        - 1.4.1.1 X-ray Tube and Generator
        - 1.4.1.2 Radiation Output During Extended Use





- 1.4.2 Capacitive Discharge Systems
  - 1.4.2.1 kV Calibration
  - 1.4.2.2 Leakage Radiation
  - 1.4.2.3 Beam Quantity
- 1.4.3 Additional Tests

## 1.5 Quality control of Fluoroscopic equipment

- 1.5.1 Daily
- 1.5.2 Monthly or More Frequently If Indicated
- 1.5.3 Fluoroscopic Mode: Tested Annually or More Frequently If Indicated
  - 1.5.3.1 Typical Exposure Rates
  - 1.5.3.2 Maximum Exposure Rates
  - 1.5.3.3 Image Quality
- 1.5.4 Radiographic Mode: Tested Annually or More Frequently If Indicated
  - 1.5.4.1 Kilovoltage Calibration
  - 1.5.4.2 Radiation Quality (HVL)
  - 1.5.4.3 X-ray Anti-scatter Grid
  - 1.5.4.4 Collimation
  - 1.5.4.5 Image Intensifier Input Exposure Rate (IIIER)
  - 1.5.4.6 Acceptance Testing

## 1.6 Quality control for Darkrooms, Processors, Film, and Cassettes

- 1.6.1 Daily
- 1.6.2 Weekly
  - 1.6.2.1 Darkroom Cleanliness
  - 1.6.2.2 Cassettes
- 1.6.3 Monthly
  - 1.6.3.1 Film Storage
  - 1.6.3.2 Darkroom Conditions

## 1.7 Quality Control for Computed Tomography

All computed tomography (CT) equipment shall be evaluated upon installation and subsequently monitored at least annually or more often if required

## 1.7.1 PERFORMANCE EVALUATION

Performance monitoring must be performed on each CT unit at least annually. This evaluation should include, but not be limited to, the following:

- 1.7.1.1 Alignment light accuracy
- 1.7.1.2 Alignment of table to gantry
- 1.7.1.3 Table/gantry tilt
- 1.7.1.4 Slice localization from scanned projection radiograph (localization image)





- 1.7.1.5 Table incrementation accuracy
- 1.7.1.6 Slice thickness
- 1.7.1.7 Image quality
  - a. High-contrast (spatial) resolution
  - b. Low-contrast sensitivity and resolution
  - c. Image uniformity
  - d. Noise
  - e. Artifact evaluation
- 1.7.1.8 CT number accuracy, linearity, and homogeneity
- 1.7.1.9 Display devices
  - a. Image display monitor(s)
  - b. Hard-copy display unit(s), if available
- 1.7.1.10 Dosimetry
  - a. CT dose index (CTDI)
  - b. Patient radiation dose for representative examinations
- 1.7.1.11 Safety evaluation
  - a. Visual inspection
  - b. Work load assessment
  - c. Scatter and stray radiation measurements (if work load and other related parameters have changed since acceptance testing or if CT fluoroscopy is routinely performed)
  - d. Audible/visual signals
  - e. Posting requirements
- 1.7.1.12 Monitoring Required after Replacement or Repair of a Major Component
- 1.7.1.13 Patient Radiation Dose

## 1.7.2 **QUALITY CONTROL PROGRAM**

A continuous quality control (QC) program shall be established for all CT units, the QC program should include, but not be limited to, the following:

- 1.7.2.1 Alignment light accuracy
- 1.7.2.2 Slice thickness
- 1.7.2.3 Image quality
  - a. High-contrast (spatial) resolution
  - b. Low-contrast sensitivity and resolution
  - c. Image uniformity
  - d. Noise
  - e. Artifact evaluation
- 1.7.2.4 CT number accuracy and homogeneity
- 1.7.2.5 Digital display fidelity

# 1.7.3 **ACCEPTANCE TESTING**

Initial performance testing shall be performed upon installation and should be completed before clinical use.





# 1.7.4 FOLLOW-UP PROCEDURES AND WRITTEN SURVEY REPORTS

## 1.8 Quality control for MRI equipment

### 1.8.1 **PERFORMANCE EVALUATION**

The performance of each MRI unit should be evaluated at least annually. This evaluation should include, but not be limited to, the following tests:

- 1.8.1.1 Magnetic field homogeneity.
- 1.8.1.2 Slice position accuracy.
- 1.8.1.3 Slice thickness accuracy.
- 1.8.1.4 Radiofrequency (RF) calibration for all coils.
- 1.8.1.5 Frequency and gain/attenuator verification (prescan values).
- 1.8.1.6 Image signal-to-noise ratio (SNR) for all coils.
- 1.8.1.7 Intensity uniformity for all volume coils.
- 1.8.1.8 Phase stability and image artifact assessment for all coils.
- 1.8.1.9 Softcopy (monitor) fidelity.
- 1.8.1.10 Evaluation of quality control (QC) program.

## 1.8.2 **QUALITY CONTROL PROGRAM**

A continuous QC program shall be implemented for all MRI units. The program should be established with the assistance of a medical physicist/MR scientist. The QC program should include, but not be limited to, the following: following:

- 1.8.2.1 Setup and positioning accuracy (mechanical inspection).
- 1.8.2.2 Central frequency.
- 1.8.2.3 Transmitter gain or attenuation (head coil RF calibration).
- 1.8.2.4 Geometric accuracy (gradient calibration).
- 1.8.2.5 High-contrast spatial resolution.
- 1.8.2.6 Low-contrast detectability.
- 1.8.2.7 Image artifact assessment.
- 1.8.2.8 Film processor QC.
- 1.8.2.9 Hardcopy fidelity.

### 1.8.3 **ACCEPTANCE TESTING**

The acceptance testing protocol should include an evaluation of all coils.

## 1.9 Quality Control for Ultrasound

All ultrasound equipment must be evaluated upon installation (acceptance testing) and routinely thereafter to ensure that it is functioning properly.

### 1.9.1 **PERFORMANCE EVALUATION**





Ultrasound system performance evaluations must be performed at least annually, in addition to routine quality control (QC) as described below. The following performance evaluation tests must be performed at least annually on all machines and transducers:

- 1.9.1.1 Physical and mechanical inspection.
- 1.9.1.2 Image uniformity and artifact survey.
- 1.9.1.3 Geometric accuracy.
- 1.9.1.4 Contrast resolution.
- 1.9.1.5 Fidelity of the ultrasound scanner electronic image display(s).
- 1.9.1.6 System sensitivity.

## 1.9.2 **QUALITY CONTROL PROGRAM**

A continuous QC program is essential to assure the proper functioning of all ultrasound equipment. Routine QC is typically performed by appropriately trained sonographers or equipment service engineers. Transducers are a weak link in the ultrasound imaging chain since they are easy to drop, their cables may be easily kinked and stressed, and the active elements are relatively fragile.

All scanners and all transducers in routine clinical use should be tested quarterly, but must be tested at least semiannually. This should allow problems to be identified before the diagnostic utility of the equipment is significantly impacted. These tests must include:

- 1. Physical and mechanical inspection.
- 2. Image uniformity and artifact survey.
- 3. Geometric accuracy (only for mechanically scanned transducers).

All transducer ports on each scanner should be tested using at least 1 transducer. Electronic image displays, both those on the ultrasound equipment and those used for primary interpretation (e.g., workstation displays), should be tested \

### 1.9.3 **ACCEPTANCE TESTING**

The performance of all ultrasound imaging equipment must be evaluated at the time it is acquired.

### 1.9.4 WRITTEN SURVEY REPORTS AND FOLLOW-UP PROCEDURES

## 1.10 Quality Control for Mammography Equipment

- 1.10.1 A structured quality control program must be employed to monitor the performance of mammography equipment and to provide a record in case of machine failure. The procedures must be performed regularly and require careful, consistent record keeping.
- 1.10.2 For film screen mammography equipment, the following should be checked and documented regularly
  - 1.10.2.1 Processing:
  - 1.10.2.2 Film Density





- 1.10.2.3 Image Contrast
- 1.10.2.4 Entrance Skin Exposure (ESE) (free in air\
- 1.10.2.5 Radiation Output: The mR/mAs for a standard kVp and distance should be measured
- 1.10.2.6 Half value layer
- 1.10.2.7 Screens

Test or Procedure	Frequency F	Performed by
Processing quality control (sensitometry, temperature)	Every operational day	y Technologist
Uniform phantom image and contrast test	Weekly	n
Patient entrance exposure and tube output	Every six months and upon alteration or servicing of the machine	Physicist
AEC parameters including operation of back-up timer	п	н
Collimation	н	"
Half-value layer, kilovoltage	н	п
Screens: cleaning unifom phantom contact	Meekly Monthly Every six months	Technologist

Table 1Quality Control Procedures For Film-Screen Mammography

- 1.10.3 For mammography systems with image receptor modalities other than screenfilm, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer
- 1.11 Quality control for Digital Subtraction Angiography (DSA) systems.
  - 1.11.1 Daily
  - 1.11.2 Annually or More Frequently If Indicated
    - 1.11.2.1 Fluoroscopic System Evaluation
    - 1.11.2.2 Radiographic System Evaluation
    - 1.11.2.3 Spatial Resolution
    - 1.11.2.4 Contrast Resolution
    - 1.11.2.5 Detector Sensitivity
  - 1.11.3 At Acceptance and As Needed





# 1.12 Quality Control for Nuclear medicine unit

All nuclear medicine imaging equipment shall be tested upon installation and monitored at least annually by a Qualified Medical Physicist or other qualified individual to ensure that it is functioning within manufacturer specifications and accepted performance standards

### 1.12.1 **PERFORMANCE EVALUATION**

The following characteristics shall be evaluated for the equipment to which they apply on at least an annual basis.

- 1.12.1.1 Planar image quality
  - a. System uniformity and intrinsic uniformity, if possible
  - b. Spatial resolution (intrinsic or system)
  - c. Spatial linearity
  - d. Energy resolution
  - e. Sensitivity
  - f. Multiple window spatial registration
  - g. Count rate capability
  - h. Collimator integrity
- 1.12.1.2 Tomographic image quality
  - a. Uniformity and noise
  - b. Spatial resolution
  - c. Contrast
- 1.12.1.3 Safety features and interlocks
- 1.12.1.4 Estimates of Organ Dose from Radiopharmaceuticals

## 1.12.2 ACCEPTANCE TESTING

Initial performance testing of imaging equipment shall be performed upon installation and should be completed before clinical use.

- 1.12.3 FOLLOW-UP PROCEDURES AND WRITTEN SURVEY REPORT
- 1.12.4 RADIATION SAFETY





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