National Diagnostic Reference Levels

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Introduction

Purpose

The purpose of this document is to introduce the national references in order to identify and establish the National Diagnostic Reference Levels (NDRLs) for different diagnostic ionizing radiation applications, as well as to clarify the SFDA's requirements in applying these references. These references protect patients from medical radiation doses that may exceed the approved limits and levels, which may be unjustified, without affecting the image's quality and its diagnostic characteristics.

Scope

This national reference is applied to radiology department that have the following imaging modalities:

- Computed Tomography (CT) devices.
- General X-Ray devices.
- Mammography devices.

Background

SFDA has issued this document in reference to the following:

- Royal Decree No. (60057) dated 9/11/1441 AH, approving Saudi Health Council Resolution No. (3/88), which stated that healthcare provider Which stated that the health care provider shall comply with the national diagnostic reference level issued by the SFDA.
- Article (26) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H stipulated that “The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices in diagnosis and treatment”.
- Item (3) within section (D) of "Requirements for the Safe Use of Medical Devices and Supplies in Healthcare Facilities" (MDS REQ3) stipulated that all departments operating radiology and medical imaging devices shall "Apply National Diagnostic Reference Level (NDRL) published on the SFDA website and keep all relevant records."
- The SFDA has formed and chaired a national committee to determine the NDRLs across the kingdom. This committee is responsible for supervising the establishment the NDRLs as it reviews them periodically. Annex (3) lists the names of the committee members based on its last formation.

Requirements

1. Apply the NDRLs for radiological devices as stated in Annex (2).
2. Medical devices and supplies used in medical imaging equipment and supplies ought to automatically record dosages, protocol data, and patient information such as age, gender, and weight, using defined formats.
3. The dosage data must be collected either automatically or manually and sent periodically to the authority via email (NDRL@SFDA.GOV.SA), using the forms published on its website, as follow:
    - Data Collection Sheet for CT Scan
    - Data Collection Sheet for General Radiology
    - Data Collection Sheet for Mammography

Annexes

Annex (1): National Diagnostic Reference Levels

1. CT	A. Adult Patients (20 ± 70) Kg		
	Body part	CTDIvol (mGy)	DLP(mGy-cm)
	Head	55	1026
	Abdomen and pelvis	14	706
	Chest	12	430
	B. Pediatric Patients (Head)		
	Age	CTDIvol (mGy)	DLP(mGy-cm)
	(0-5 Y)	28	482
	(6-15 Y)	42	697
	C. Routine CT imaging protocols listed in NDRL		
	Head	Abdomen and pelvis	Chest
	CT Brain w/ Contrast	CT Abdomen & Pelvis w/ Contrast	CT Chest w/ Contrast
	CT Brain w/o Contrast	CT Abdomen & Pelvis w/o Contrast	CT Chest w/o Contrast
2. General X-Ray	Body Part – Adult		DAP(Gy.cm^2)
	Abdomen AP		2.13
	CHEST PA CHEST AP		0.49
3. Mammography	Com. Thickness (40-50) mm		MGD (mGy)
	2D-CC		1.44

Annex (2): National Diagnostic Reference Level Committee

Member	Organization
Engr. Ali Aldalaan	Saudi Food & Drug Authority - Riyadh
Dr. Yusuf AlKadhi	King Faisal Specialist Hospital & Research Centre - Riyadh
Dr. Abdulaziz Alsugair	King Faisal Specialist Hospital & Research Centre - Riyadh
Dr. Belal Moftah	King Faisal Specialist Hospital & Research Centre - Riyadh
Dr. Mohammed Alshabnah	King Faisal Specialist Hospital & Research Centre - Riyadh
Dr. Sarah Albahiti	King Abdulaziz University Hospital - Jeddah
Kostas Chantziantoniou	Johns Hopkins Aramco Healthcare - Dhahran
Dr. Abdulaziz Almosabihi	Ministry of Health - Riyadh
Dr. Abdullah Aldosari	Ministry of Health - Riyadh
Dr. Abdulrahman Almutairi	King Fahad Specialist Hospital - Dammam
Dr. Noor Alnaimy	King Fahad Specialist Hospital - Dammam
Dr. Maryam Alhashem	King Fahad Specialist Hospital - Dammam
Dr. Abdulrahman Alnaeem	King Fahad Medical City - Riyadh
Dr. Abdulrahman Alkhalifa	Prince Sultan Military Medical City - Riyadh
Dr. Abdulrahman Algeer	Armed Forces Medical Services - Riyadh
Dr. Tarek Momenah	Prince Sultan Cardiac Centre - Riyadh
Dr.Saeed Alahmari	Prince Sultan Cardiac Centre - Riyadh
Engr. Nasser Alaboudi	Saudi Food & Drug Authority - Riyadh
Engr. Fahad Alatheem	Saudi Food & Drug Authority - Riyadh
Engr. Abdulrahman Alswayeed	Saudi Food & Drug Authority - Riyadh
Ms. Alanood Alshamsi	Saudi Food & Drug Authority - Riyadh

Annex (3): Definitions and Abbreviations

SFDA	Saudi Food and Drug Authority
NDRL	National Diagnostic Reference Level
Medical Device	Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Supply	A medical substances and products used in diagnosis, treatment, prosthetics, orthotics, or in disability cases or other medical uses for humans, including medical gases.
Healthcare Provider	Any government or private establishment that provides healthcare services.
CT	Computed Tomography.
CTDIvol	Volume Computed Tomography Dose Index.
DLP	Dose Length Product.
MGD	Mean Glandular Dose.
DAP	Dose Area Product.
mGy mGy-cm Gy.cm²	Units used to measure the amount of ionizing radiation.
2D-CC	2 Dimension - Bilateral Craniocaudal (One of the mammogram screening protocols).
Abdomen AP CHEST PA CHEST AP	Protocols of general radiography.