IUPESM-HTTG Workshop on Radiological Equipment Maintenance Issues:
Radiation Safety Considerations

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IUPESM

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International Union for Physical and Engineering Sciences in Medicine

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IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

BSS

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General Safety Requirements Part 3

No. GSR Part 3

IAEA
International Atomic Energy Agency

2014

European BSS

Directive Published in the Official Journal of the European Union 17 January 2014

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation [1]. The Directives have been revised several times, most recently by Council Directive 96/29/Euratom [2] which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom [3], Council Directive 89/618/Euratom [4], Council Directive 90/641/Euratom [5] and Council Directive 2003/122/Euratom [6] cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety

[1] OJ L 11, 20.2.1959, p. 221.
[2] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.6.1996, p. 1).
[3] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).
[4] Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (OJ L 357, 7.12.1989, p. 31).
[5] Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas (OJ L 349, 13.12.1990, p. 21).
[6] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (OJ L 346, 31.12.2003, p. 57).

IBSS 3.15. Registrants and licensees:

(i) Shall ensure that adequate maintenance, testing and servicing are carried out as necessary so that sources* remain capable of fulfilling their design requirements for protection and safety throughout their lifetime;

* Includes equipment

EBSS Annex IX: Indicative list of information for licence applications

(g) Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

EBSS

Article 78

Information on equipment

1. Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level which is as low as reasonably achievable.

Radiological Hazards

Workers - Public - Patients

Principles of Radiation Protection

Occupational & Public	*Medical Exposure*
Justification of Practices	
Does the benefit to the exposed individuals or to society outweigh the radiation detriment?	Generic & Individual. Consider benefits and risks of available alternative techniques that do not involve ionizing radiation
Dose Limitation	
For occupational and public exposure	Not applicable to patient exposure
Optimization of Protection	
ALARA	Management of the radiation dose to the patient commensurate with the medical purpose

Radiological Equipment Output Control

- Radioactive Sources (Teletherapy & Brachytherapy)
  - Timers

Main risk: Source exchange

- Electrical Machines
  - Setting Radiation Parameters – Manual Control
    - Potential, current, time…
    - Collimator, table, gantry motions…
  - Setting Pre-established Protocols - Automatic
    - At the control console
    - Through the network
  - Activating Automatic Exposure Circuits
    - Radiography (ion chamber signal)
    - Fluoroscopy (adjusting kV, mA, pulse width, filter…)

High Risk
Teletherapy Unit Source Exchange

Source Transport Container

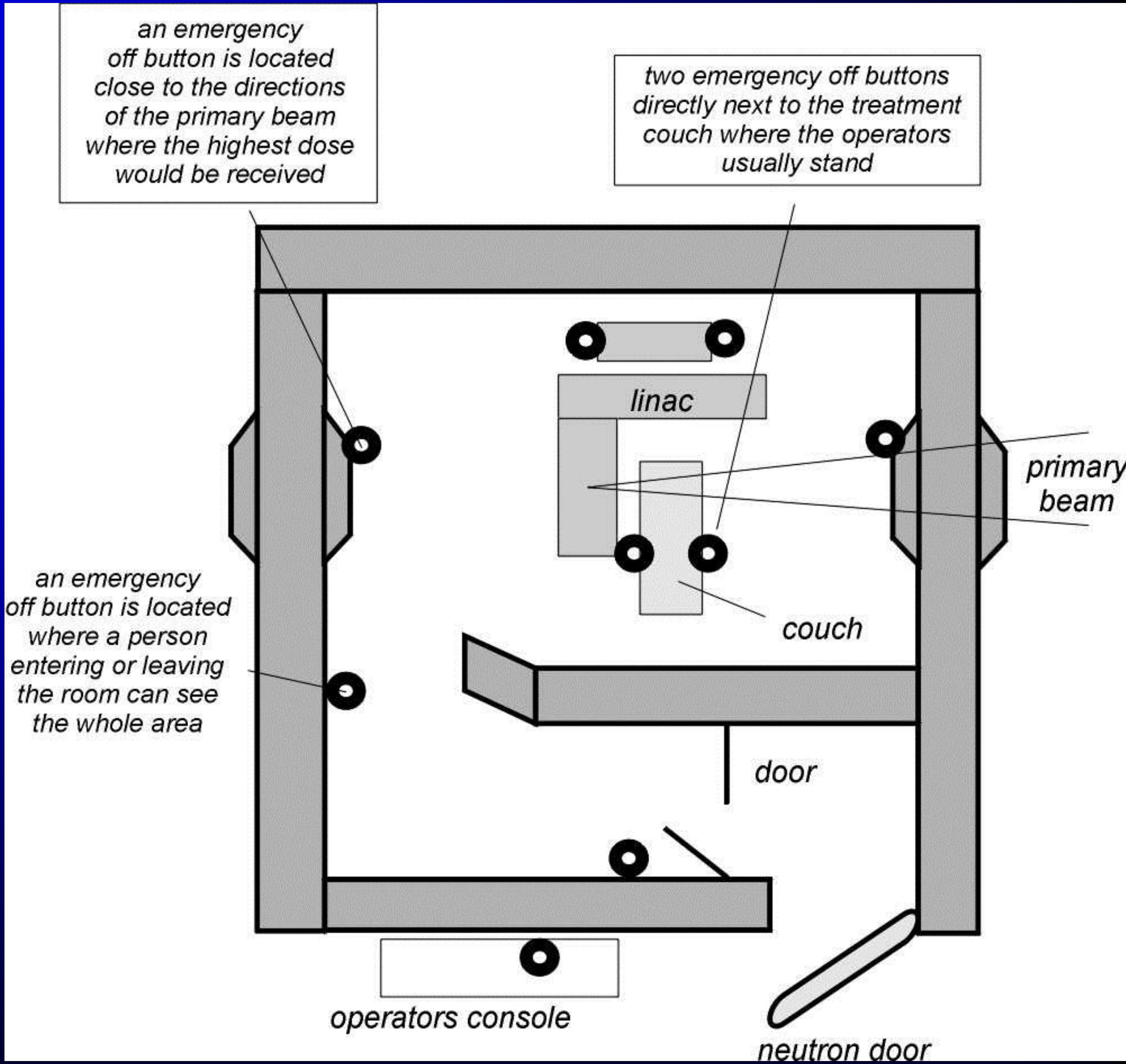
Treatment Unit Head

Photograph of a Co-60 Source Change

High energy radiotherapy equipment

i. have at least **two independent 'fail to safety' systems** for **terminating the irradiation**; and

ii. be provided with **safety interlocks** or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;



the design of safety interlocks be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys

BSS 1996

Operation Screens

▲ **Clinical mode**

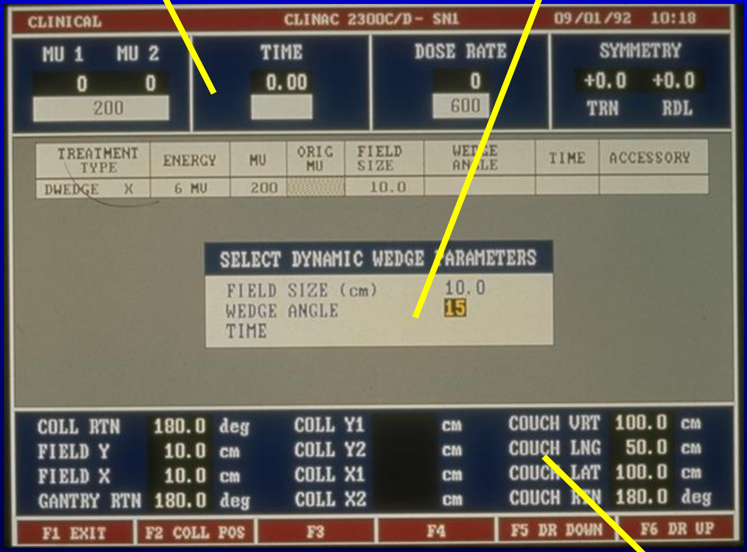
▲ **Service mode**

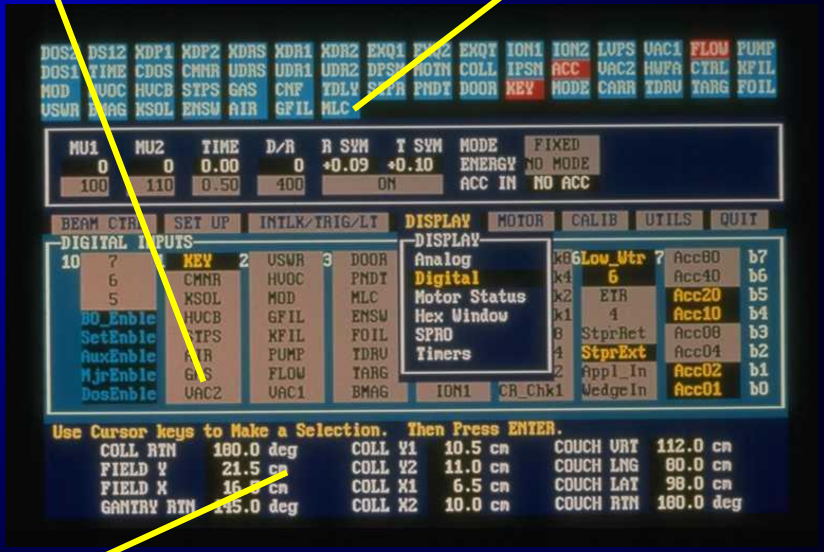
Simple choices

Dose and time

More options

Interlocks





Set-up parameters

Incorrect Repair Linac, Spain, 1990

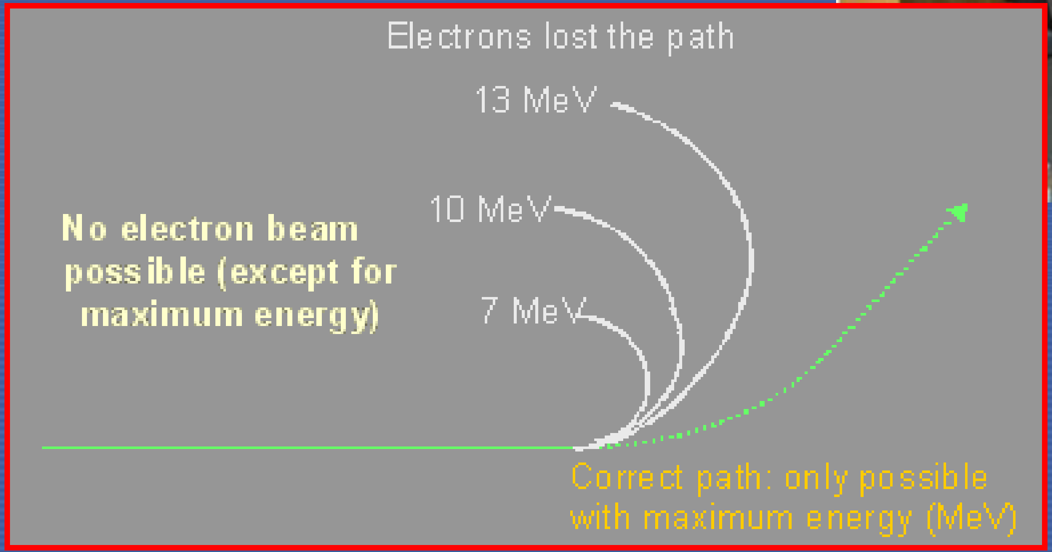
- Sagittaire linac stopped working
- GE tech working on a ^{60}Co nearby called to repair it
- He "repaired" it – Beam energy 36 MeV
- For treatments operators selected 7, 10, 13 MeV
- They assumed energy dial was "stuck" – the true energy must be the selected one

- Except that the linac had a scanning electron beam, where the current of the scanning magnet had to match the selected electron energy
- When a transistor short-circuited, the beam stopped
- To get a beam, the tech adjusted all the energies at the maximum, 36 MeV

The Sagittaire accelerator

Travelling wave guide

Gantry and treatment head



Images courtesy of Rune Hafslund

Incorrect Repair Linac, Spain, 1990

- As the electron energy was at the maximum, the deflection in the scanning magnets was too small and the field thus became concentrated in the center
- This increased the energy fluence and therefore the dose.
- For 7 MeV, the absorbed dose was ≈ 9 times the intended.
- This increase in dose was smaller for higher energies
- During the 10 days of faulty operations, 27 patients were treated using electrons with the equipment
- Of these 27 patients, 15 died as a consequence of the overexposure (most of them within 1 year)
- Two more died with radiation as a major contributing factor

Safety

- Source safe key-lock
- Radiation warning light
- Emergency source-retract button
- Emergency source hand crank
- Dummy source positioning control

From a manufacturer of HDR units

Indiana, PA, USA, Iridium-192 Incident

An 82-year-old woman was diagnosed with anal cancer and treated with high dose rate brachytherapy at Indiana Regional Cancer Center, Indiana, Pennsylvania, on 16 November 1992. High-intensity ^{192}Ir brachytherapy was begun, but one source was not retracted afterwards and remained in place for 4 days until it dislodged. Hospital staff ignored warning signals, believing that safety equipment was giving a false alarm, and the source was not discovered until it was transferred to a medical incinerator. The patient died 5 days after the exposure with dose rates to the rectum of 84 Gy per hour.

Medical Imaging - Today

X Rays

Planar Projection Imaging

- **Radiography**

  (Film or Digital: CR / DR)
  - General
  - Mammography
  - Dental
  - Bone Densitometry
- **Fluoroscopy**

  (Image Intensifier or Flat Panel)
  - Diagnostic
  - Interventional

Volume (3D) Projection Imaging

- **Computed Tomography (CT)**
- **Digital Tomosynthesis**

Imaging in Radiotherapy (IGRT)

Non-Ionizing Radiation

- **Magnetic Resonance (MR)**
  - MRA
  - MRS
  - fMRI
- **Ultrasound (US)** incl Doppler

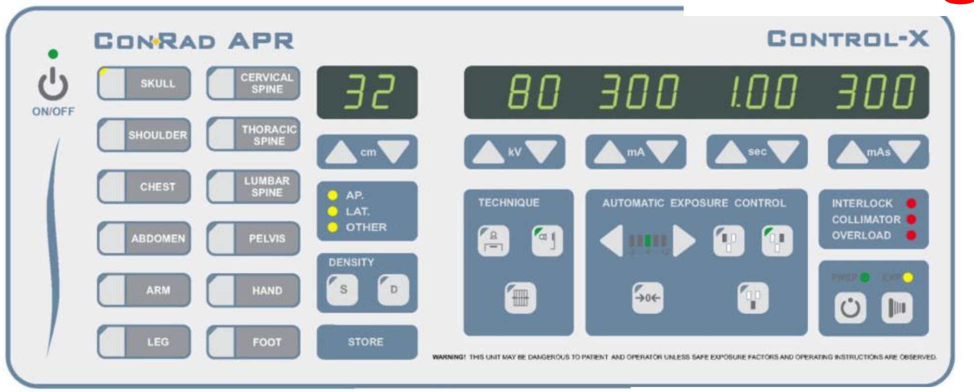
Nuclear Medicine

- Gamma Camera
- SPECT
- PET

Hybrid Systems

- SPECT/CT
- PET/CT
- PET/MR
- MR/US
- MR/Optical

Radiography



AEC

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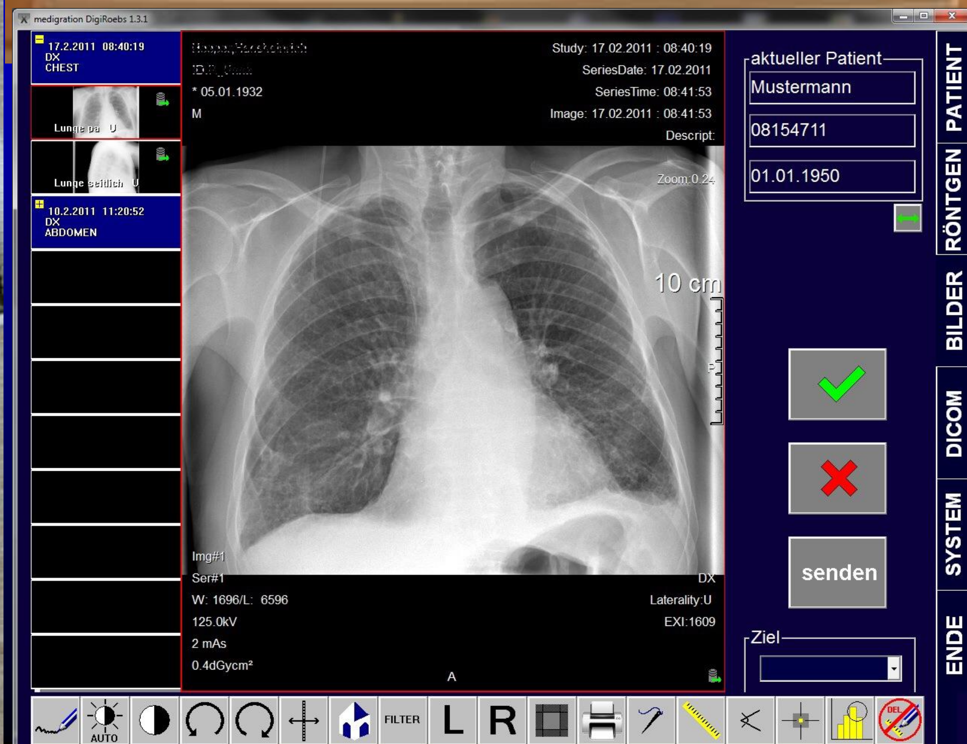


Digital Radiography

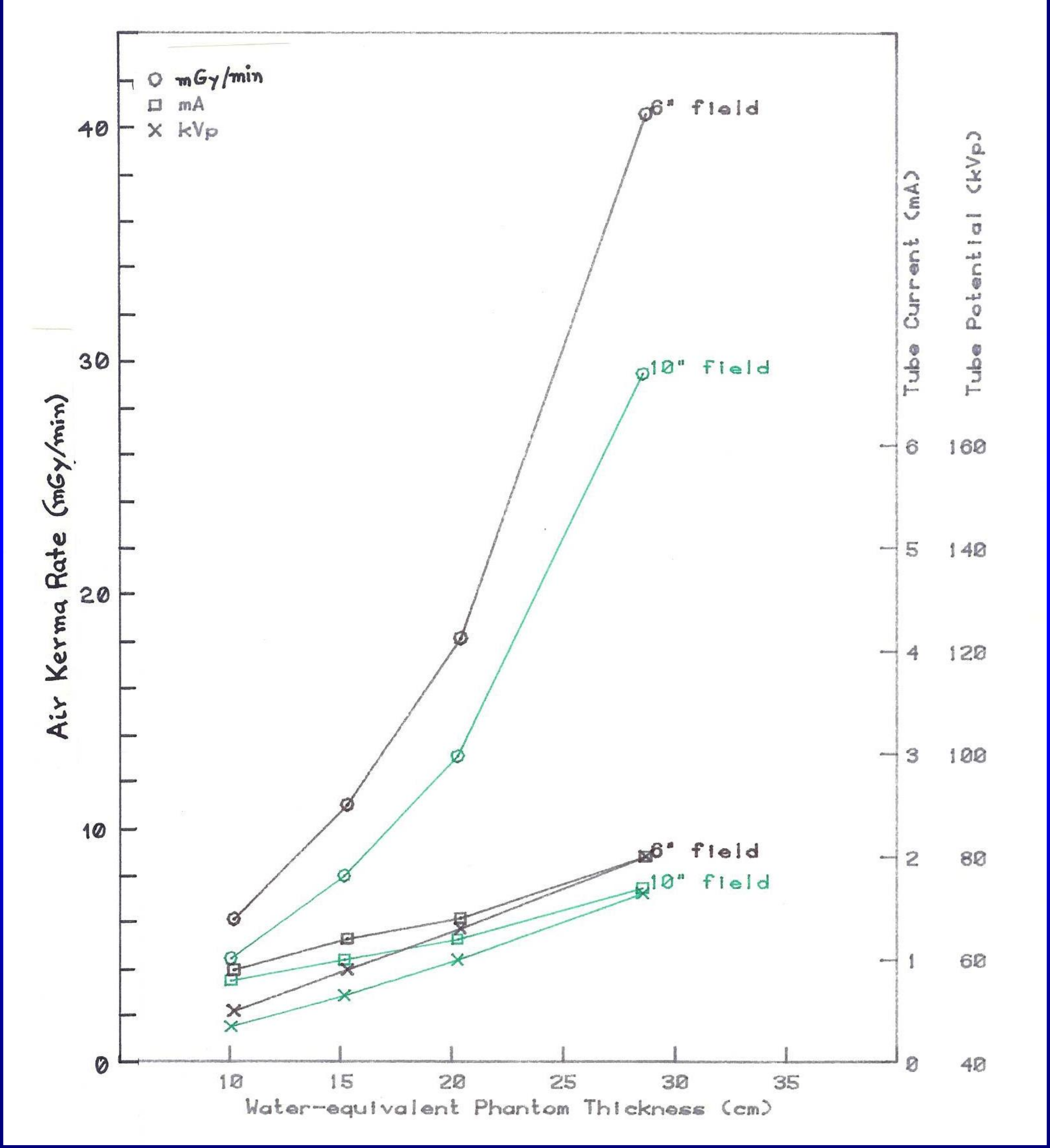
Approximate EI Values vs. Receptor Exposure

Manufacturer	Symbol	50 μGy	100 μGy	200 μGy
Canon (Brightness =16, contrast = 10	REX	50	100	200
IDC (S_T = 200)	F#	-1	0	1
Philips	EI	200	100	50
Fuji, Konica	S	400	200	100
Kodak (CR, STD)	EI	1700	2000	2300
Siemens	EI	500	1000	2000

….. The need for a standard clearly evident

JA Seibert 2010

In fluoroscopy, automatic exposure rate control is achieved by regulating the x-ray kerma rate incident on the image detector



Air Kerma Rate Measurements

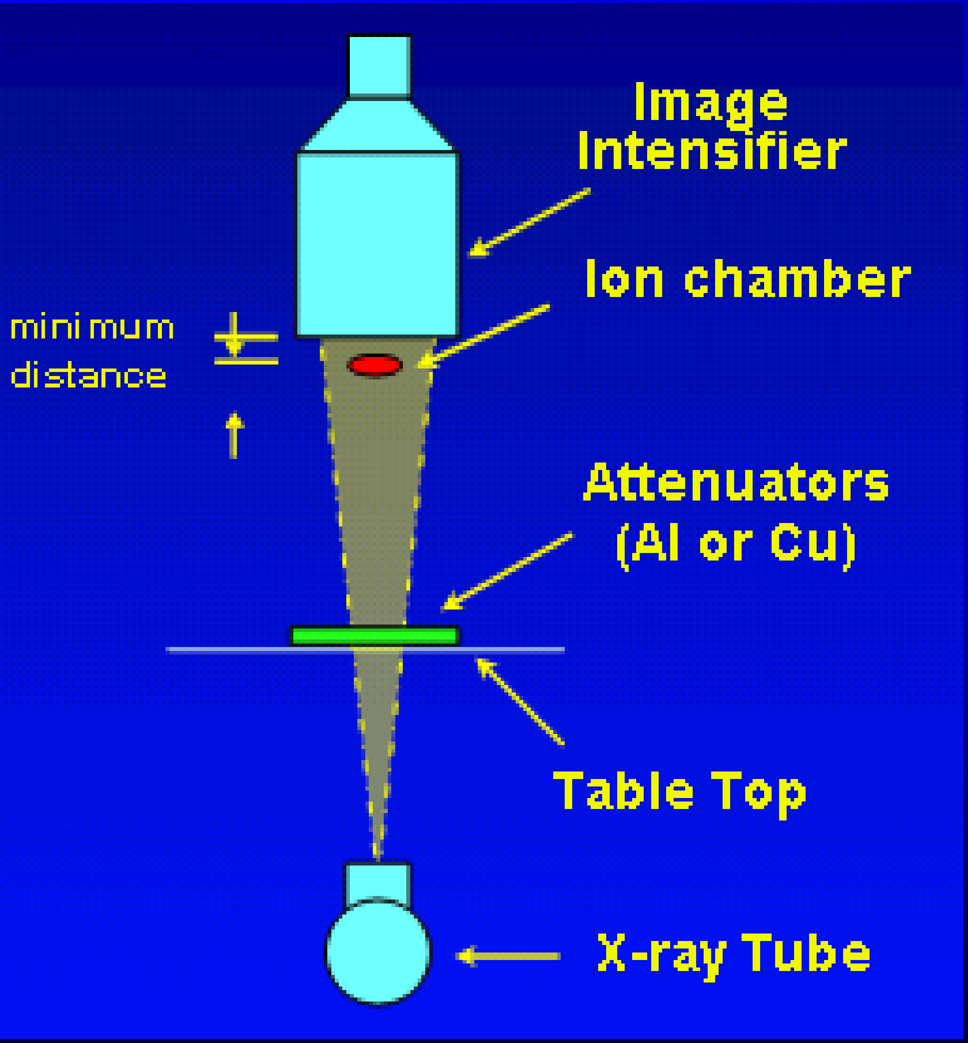
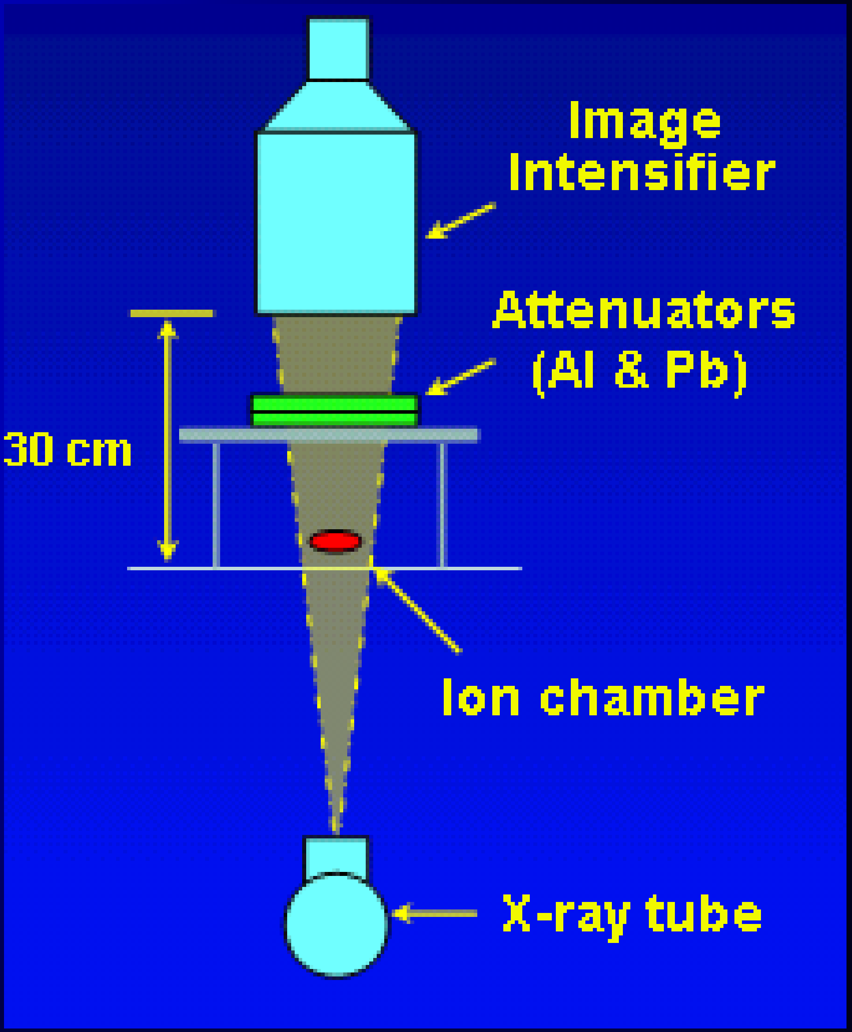


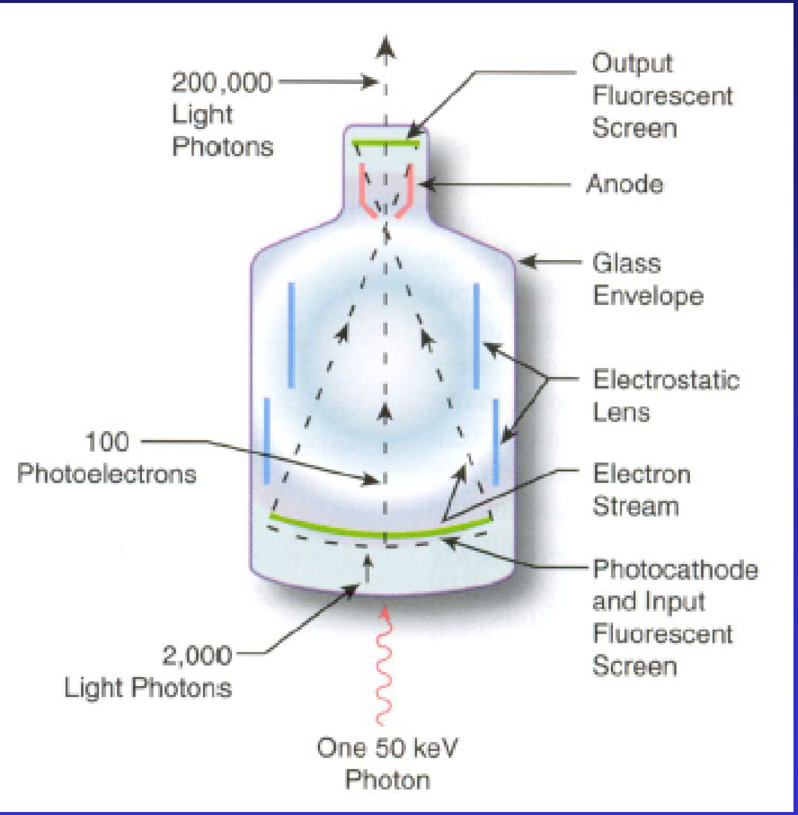
Image Detector Input



Patient Entrance

II Gain Factors

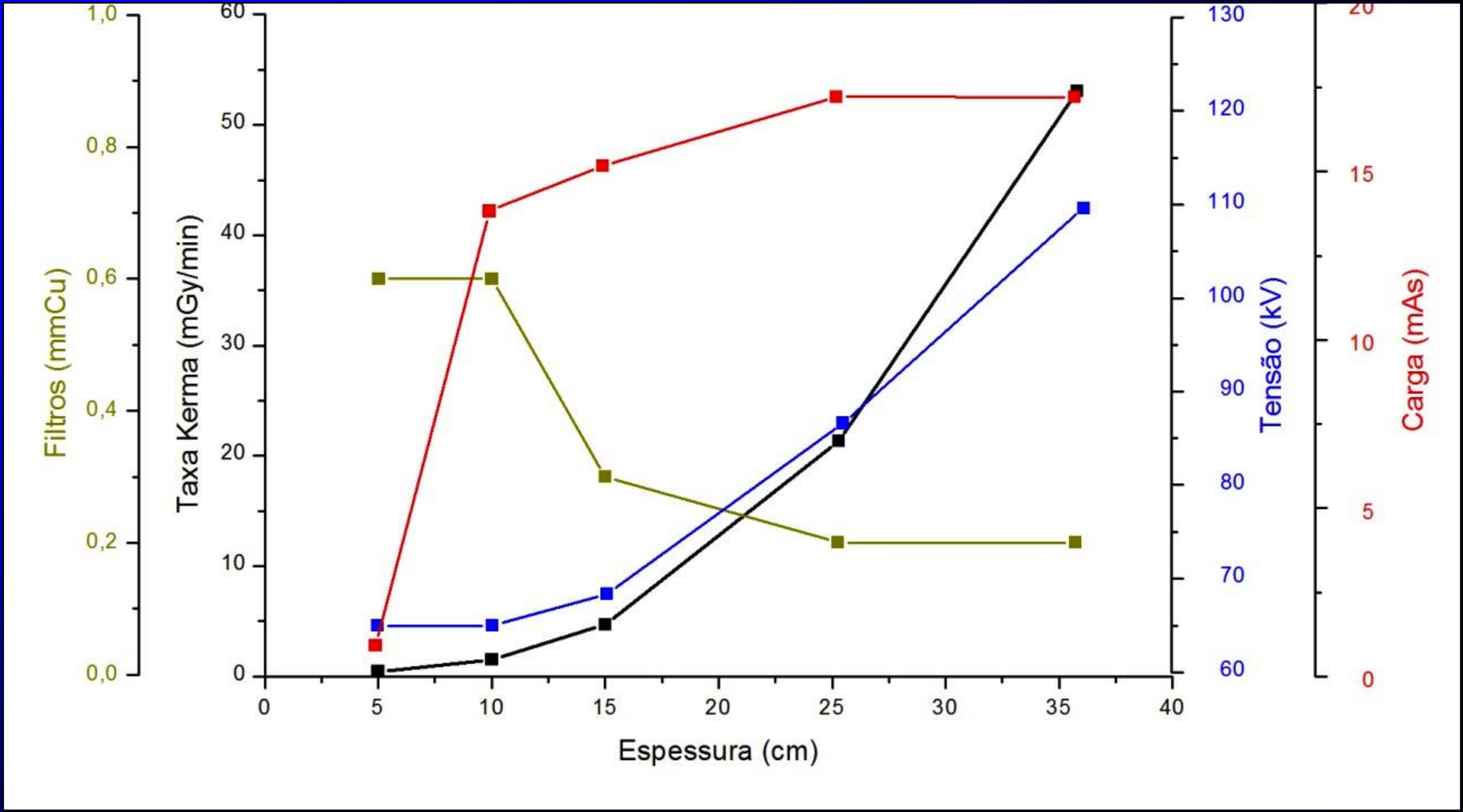
- Flux Gain (FG)
  - Increase no. light photons emitted from output phosphor compared to input phosphor; 50 - 100 typical
- Minification Gain (MG)
  - (dia. Input/dia. Output)^2
  - e.g., 23 cm to 2.5 cm => 85
- Brightness Gain
  - = FG × MG
  - Typical overall gain 5,000:1
  - BIG advantage of II over FD is brightness gain factor
  - FD uses pixel binning and image frame averaging to reduce noise



Carlton, Adler 4th ed fig 40-2

Geisler, 2007

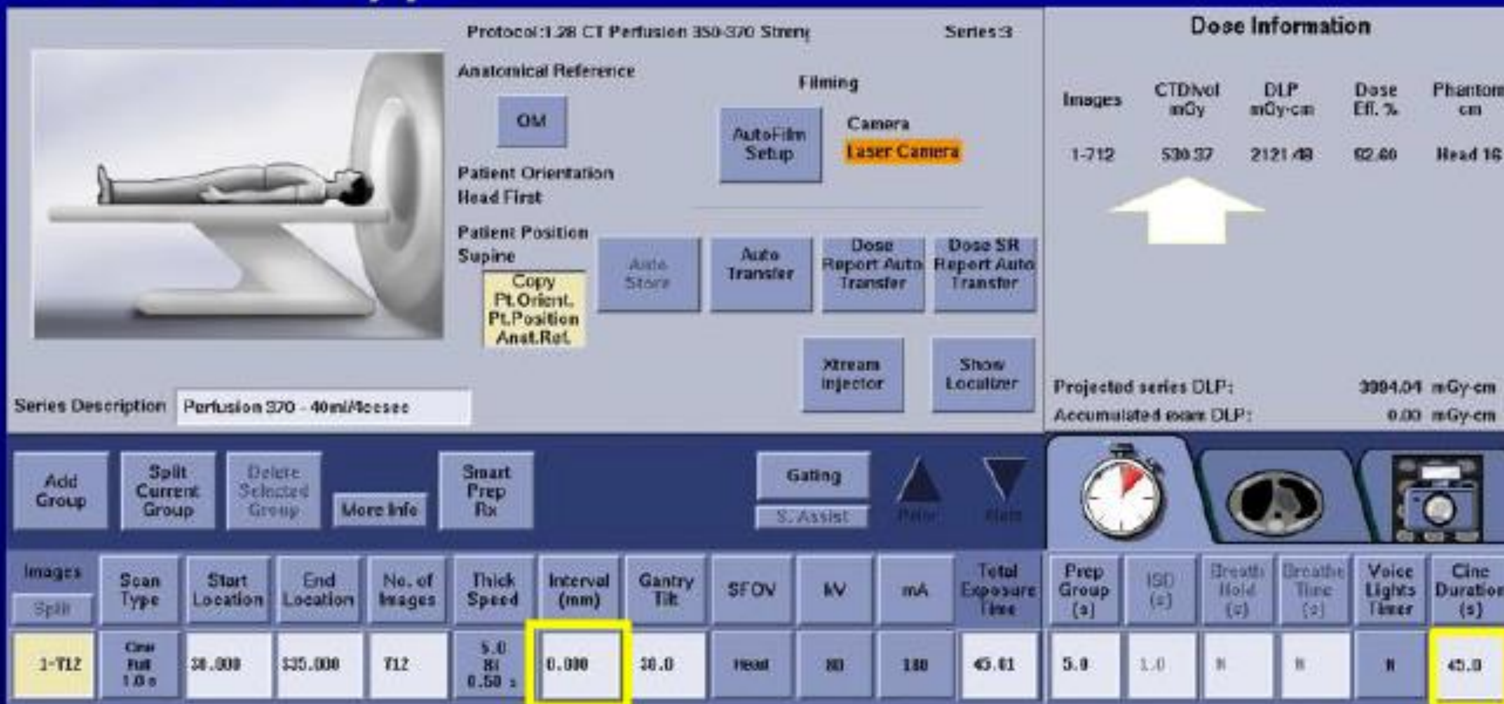
Philips Allura FPD Fluoro (Recife, Brazil)



For fluoroscopy with flat panel detectors (FPD), the charge amplifier gain is fixed. There is no control at installation or during maintenance.

GE Healthcare: Scan Mode

Cine Scan Type



In Cine Mode, Cine Duration defines how long the x-ray is on for a given location. If the interval is 0, the table does not move and the full duration is at the prescribed location, as in CT Perfusion imaging.

Humboldt Online

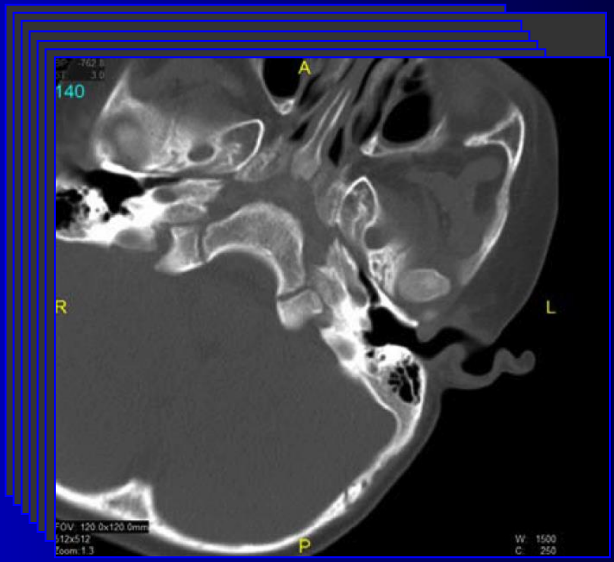
Get the News... Not the Paper

Radiation Overdoses Point Up Dangers of CT Scans

Written by Humboldt Online Editor on 16 October 2009

New York Times Raven Knickerbocker, then an X-ray technologist at Mad River Community Hospital in Arcata, Calif., activated a CT scan 151 times on the same area of the head of 2 ½-year-old Jacoby Roth, investigators concluded.

January 2008



150 CT scans to the same slice

~7 Gray peak skin dose!!

California hospital fined $25,000 for pediatric CT radiation overdose

By Cynthia E. Keen
AuntMinnie.com staff writer
March 24, 2009

Parents sue California hospital over pediatric CT radiation overdose

By Cynthia E. Keen
AuntMinnie.com staff writer
November 20, 2008

A rural California hospital is being sued by parents of a child who underwent a CT exam during an emergency department visit for a neck injury. The parents allege that their 23-month-old boy received radiation burns and has permanent chromosomal damage due to excessive radiation exposure from the CT scan, which took over an hour to perform.

Roth family

Seibert 2011

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CT Scan Protocols

Purpose | FDA Award | Questions | Role of the QMP | CT Dose-Check | Protocols | Lexicon | Education Slides

Available Protocols

Adult Protocols

- **Lung Cancer Screening CT** (added 06/19/2014) [**Give Feedback**]
- **Routine Adult Chest-Abdomen-Pelvis CT** (added 02/20/2014) [**Give Feedback**]
- **Routine Adult Chest CT** (added 11/20/2012) [**Give Feedback**]
- **Routine Adult Abdomen/Pelvis CT** (added 10/17/2012) [**Give Feedback**]
- **Routine Adult Head CT** (added 06/01/2012) [**Give Feedback**]
- **Routine Adult Brain Perfusion** (updated 05/22/2012) [**Give Feedback**]

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The New York Times

THE RADIATION BOOM

After Stroke Scans, Patients Face Serious Health Risks

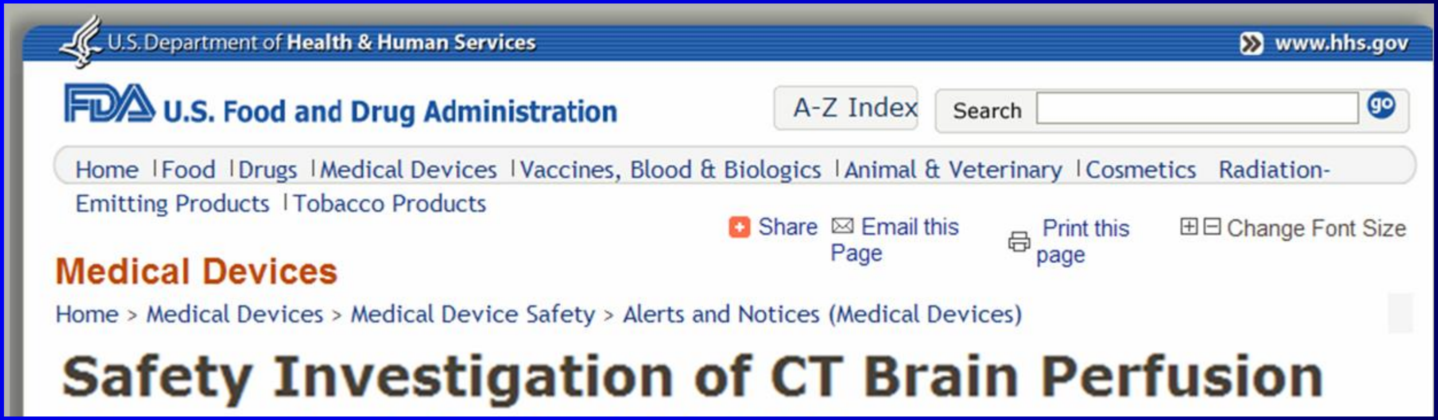
By WALT BOGDANICH

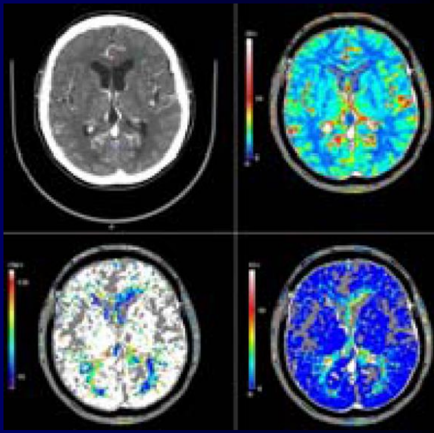
Published: July 31, 2010

When Alain Reyes's hair suddenly fell out in a freakish band circling his head, he was not the only one worried about his health. His co-workers at a shipping company avoided him, and his boss sent him home, fearing he had a contagious disease.

Only later would Mr. Reyes learn what had caused him so much physical and emotional grief: he had received a radiation overdose during a test for a stroke at a hospital in Glendale, Calif.

Other patients getting the procedure, called a CT brain perfusion scan, were being overdosed, too — 37 of them just up the freeway at Providence Saint Joseph Medical Center in Burbank, 269 more at the renowned Cedars-Sinai Medical Center in Los Angeles and dozens more at a hospital in Huntsville, Ala.





2009

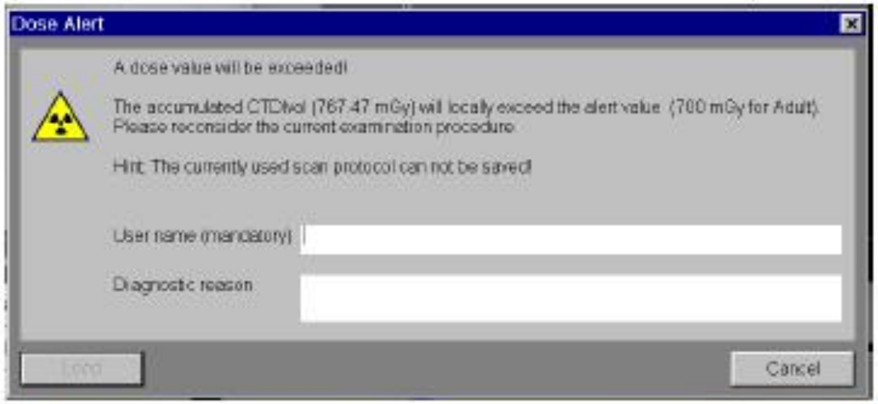
Cedars-Sinai, L.A.

CT Perfusion in Alabama

Notification vs Alert

	Notification	Alert
Values Checked	$CTDI_{vol}$ and/or DLP	Cumulative $CTDI_{vol}$ per PT location and/or Cumulative DLP
Context	Current scan	Current patient
Required before proceeding	Confirmation Comments (optional)	Confirmation Operator's name Password (if configured) Comments (optional)
Audit trail recorded	Date/Time Unique Study ID Values exceeded Corresponding dose index value Comments	Date/Time Operator's name Unique Study ID Values exceeded Corresponding dose index value Comments

From Rich Mather presentation



From Rich Mather presentation