# Federal and Provincial Regulations for X-Ray Emitting Equipments

C. Janicki MUHC

2004

# Outline

Radiation Emitting Device (RED) Act & Regulations Canada Safety Codes Provincial dose limits for X-Rays Provincial (Quebec) Regulations for X-Rays Radiological Issues X-Ray exposure and pregnancy Dose reduction in fluoroscopy Dose reduction in CT

The *Radiation Emitting Devices (RED) Act* governs the sale, lease and import of certain radiation emitting devices used for medical and industrial purposes or by consumers.

The Act sets safety performance standards for the sale, lease, import, labelling, packaging, and advertising of radiation emitting devices to ensure that workers and the public are not placed at risk.

Manufacturers and importers are required to notify the Minister if a device does not comply with the regulations or creates a risk to any person.

In addition, a series of voluntary safety codes that apply to radiation emitting devices in the workplace have been developed to provide guidance to employers.

The Radiation Emitting Devices Regulations prescribe safety performance and labeling that govern the design, construction and functioning of certain classes of radiation emitting devices.

All radiation emitting devices must meet the general provisions of the *Radiation Emitting Devices (RED) Act*, regardless whether or not they are subject to specific regulations.

The text of the *RED Act* and RED Regulations can be found on the Web site of the Department of Justice Canada at http://laws.justice.gc.ca/en/R-1

## Consolidated Statutes and Regulations Enabling Statute: Radiation Emitting Devices Act **Radiation Emitting Devices Regulations (C.R.C., c. 1370)**

- RADIATION EMITTING DEVICES REGULATIONS
  - SHORT TITLE
  - INTERPRETATION
  - PRESCRIPTION OF CLASSES OF RADIATION EMITTING DEVICES AND STANDARDS THEREFOR
  - DETENTION OF SEIZED DEVICES
  - DISPOSITION OF FORFEITED DEVICES
  - SCHEDULE I (s. 3)
  - SCHEDULE II (s. 3)
  - PART I TELEVISION RECEIVERS
  - PART II DENTAL X-RAY EQUIPMENT WITH AN EXTRA-ORAL SOURCE
  - PART III MICROWAVE OVENS
  - PART IV BAGGAGE INSPECTION X-RAY DEVICES
  - PART V DEMONSTRATION-TYPE GAS DISCHARGE DEVICES
  - PART VI PHOTOFLUOROGRAPHIC X-RAY EQUIPMENT
  - PART VILLASER SCANNERS
  - PART VIII DEMONSTRATION LASERS
  - PART IX LOW ENERGY ELECTRON MICROSCOPES
  - PART X HIGH INTENSITY MERCURY VAPOUR DISCHARGE LAMPS

- PART XI SUNLAMPS
- PART XII DIAGNOSTIC X-RAY EQUIPMENT
- TABLE TO PARAGRAPH 6 (K) MINIMUM HALF-VALUE LAYER OF ALUMINUM
- TABLE TO SUBSECTION 8(1) NON-MAMMOGRAPHY EQUIPMENT
   MAXIMUM ALUMINUM EQUIVALENT OF INTERPOSITIONED OBJECTS
- TABLE TO SUBSECTION 8(2) MAMMOGRAPHY EQUIPMENT --MAXIMUM ALUMINUM EQUIVALENT OF INTERPOSITIONED OBJECTS
- TABLE TO SUBSECTION 23(2) MAXIMUM DEVIATION OF LOADING FACTORS
- TABLE TO SUBSECTION 24(3) MAXIMUM VARIATION IN OPTICAL DENSITY
- TABLE TO SUBSECTION 28(1) MAXIMUM AIR KERMA OR EXPOSURE RATE OF RADIOSCOPIC EQUIPMENT, OTHER THAN WHEN IT IS RECORDING IMAGES
- PART XIII ULTRASOUND THERAPY DEVICES
- PART XIV ANALYTICAL X-RAY EQUIPMENT
- PART XV CABINET X-RAY EQUIPMENT
- PART XVI

## RED Regulations Part XII : Diagnostic X-ray Equipment

Information radiation safety procedures, maintenance instructions, X-Ray tube specifications (focal spot sizes, cooling curves, ratings, operating ranges, etc ...

#### Labelling

X-ray warning symbol, X-ray generator and tube (name, manufacturer, model, serial, date, country, filtration in mm of Al)

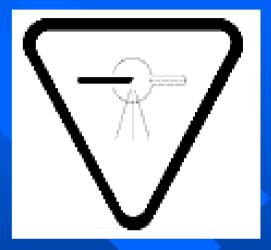
#### **Construction Standards**

Control panel (warning lights, exposure control indicator, mechanism to initiate and terminate irradiation, emergency stop switch, radiation filters, beam limiting devices, etc ...

**Functioning Standards** 

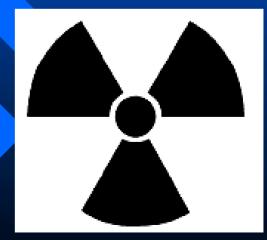
## The X-ray warning symbol must

(a) be displayed in two contrasting colours;
(b) be visible and identifiable from a distance of 1 m;
(c) be at least 2 cm high and at least 2 cm wide;
(d) bear the words "CAUTION: X-RAYS —
ATTENTION : RAYONS X"; and
(e) conform to
(i) the following diagram:



or

(ii) symbol 03-03 in the report of the International Electrotechnical Commission entitled *Graphical symbols for electrical equipment in medical practice*, Publication 878, 1988, illustrated as follows:



#### MINIMUM HALF-VALUE LAYER OF ALUMINUM

	Column 1	Column 2	Column 3
Item	Operating Range for Normal Use (kV)	X-ray Tube Voltage (kV)	Half-value Layer of Aluminum (mm)
1.	50 or less	(a) 30	0.3
		( <i>b</i> ) 40	0.4
		( <i>c</i> ) 50	0.5
2.	50 or more but not more than 70	(a) 50	1.2
		( <i>b</i> ) 60	1.3
		( <i>c</i> ) 70	1.5
3.	70 or more	(a) 70	2.1
		( <i>b</i> ) 80	2.3
		( <i>c</i> ) 90	2.5
		( <i>d</i> ) 100	2.7
		( <i>e</i> ) 110	3.0
		(f) 120	3.2
		( <i>g</i> ) 130	3.5
		( <i>h</i> ) 140	3.8
		( <i>i</i> ) 150	4.1

#### MAXIMUM DEVIATION OF LOADING FACTORS

	Column 1	Column 2		
Item	Loading Factor	Maximum Deviation from the Selected Value		
1.	X-ray tube voltage of mammography equipment	5%		
2.	X-ray tube voltage of non-mammography equipment	10%		
3.	Irradiation time	10% plus 1 ms		
4.	X-ray tube current	20%		
5.	Current time product	10% plus 0.2 mAs		



# MAXIMUM AIR KERMA OR EXPOSURE RATE OF RADIOSCOPIC EQUIPMENT, OTHER THAN WHEN IT IS RECORDING IMAGES

	Column 1	Column 2	Column 3
Item	Feature	Maximum Air Kerma Rate	Maximum Exposure Rate
1.	Not equipped with an automatic intensity control	50 mGy/min	5.75 R/min
2.	Equipped with an automatic intensity control	100 mGy/min	11.5 R/min
3.	Equipped with both an automatic intensity control and a high-level irradiation control when the latter is activated	150 mGy/min	17.25 R/min

**29.** (1) The **leakage radiation** from the X-ray source assembly of diagnostic X-ray equipment **must not exceed** an air kerma rate of **1.0 mGy/h** or an exposure rate of **115 mR/h** when the equipment is operated at the nominal X-ray tube conditions of loading that correspond to the maximum specified energy input in one hour.

# **Canada Safety Codes**

# Safety Codes and Guidelines within the x-ray and non-ionizing sections

•Safety Code 6. Limits of Human Exposure to Radiofrequency Electromagnetic Fields in the Frequency Range from 3 kHz to 300 GHz, 1999, 75 p.

•Safety Code 20A. X-Ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use, 1980, 101 p.

•Safety Code 23. Guidelines for the Safe Use of Ultrasound: Part I - Medical and Paramedical Applications, 1989, 62 p.

•Safety Code 24. Guidelines for the Safe Use of Ultrasound: Part II - Industrial and Commercial Applications, 1991, 44 p.

•Safety Code 25. Short-Wave Diathermy Guidelines for Limited Radiofrequency Exposure, 1983, 19 p.

•Safety Code 26. Guidelines on Exposure to Electromagnetic Fields from Magnetic Resonance Clinical Systems, 1987, 20 p.

•Safety Code 27. Requirements for Industrial X-Ray Equipment Use and Installation, 1987, 51 p.

•Safety Code 28. Radiation Protection in Veterinary Medicine, 1991, 38 p.

•Safety Code 29. Requirements for the Safe Use of Baggage X-Ray Inspection Systems, 1993, 25 p.

# Safety Codes and Guidelines within the x-ray and non-ionizing sections

•Safety Code 30. Radiation Protection in Dentistry, 1994, 86 p.

•Safety Code 31. Radiation Protection in Computed tomography Installations, 1994, 43 p.

•Safety Code 32. Safety Requirements and Guidance for Analytical X-Ray Equipment, 1994, 33 p.

•Safety Code 33. Radiation Protection in Mammography, 1995, 85 p.

Diagnostic X-Ray Equipment Compliance and Facility Survey, 1994, 98 p. Price: \$12.95
Radiation Safety for Baggage X-Ray Inspection Systems (Manual), 1994, 81 p. Price: \$15.95

•National Guidelines for Environmental Noise Control, 1989, 82 p.

Consumer and Clinical Radiation Protection Bureau at http://www.hc-sc.gc.ca/hecs-sesc/ccrpb/index.htm



# CAUTION

## RADIOFREQUENCY RADIATION

- Area of Unrestricted Occupancy
- Minor Injury Possible from Misuse

# WARNING RADIOFREQUENCY RADIATION

- Area of Restricted Occupancy (RF Workers Only)
- Serious Injury Possible from Misuse

# DANGER

# RADIOFREQUENCY RADIATION

- Area of Denied Occupancy
- Critical Injury or Death Possible

Safety Code 6

# **Ultrasound Radiation Warning Sign**

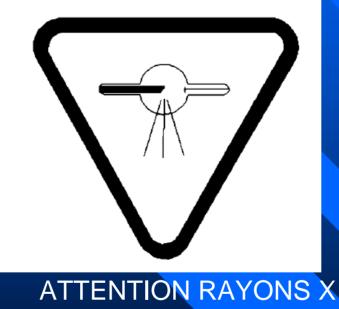
### ULTRASOUND



Safety Code 23

# X-Ray Radiation Warning Sign

## **CAUTION X-RAYS**



Safety Code 20A

- 1.0 OWNER: There *must* always be a conscious effort to reduce patient exposures to the lowest practical levels and to eliminate "unnecessary" exposures.
- 3.1 OWNER: The owner is ultimately responsible for the radiation safety of a diagnostic x-ray facility. The owner may delegate this responsibility to staff. One or more persons *must* be designated to carry out the roles described below.

#### (a) Responsible User

There *must* be at least one person designated as the responsible user to undertake responsibility for:

- ensuring that the equipment is maintained properly and functions correctly;
- (ii) ensuring that the equipment is used and maintained only by competent personnel;
- (iii) ensuring that the equipment is used correctly;
- (iv) establishing safe operating procedures for the equipment and ensuring that operating staff are adequately instructed in them;
- (v) promulgating rules of radiation safety and ensuring that staff are made aware of them;
- (vi) investigating any high x-ray exposures received by personnel;
- (vii) ensuring that radiation levels outside controlled areas are below the maximum permissible limits given in Appendix I; and
- (viii) ensuring that the Radiation Protection (Safety) Officer and all operators receive, or at least have access to, a copy of this Safety Code.

### **General requirements**

- Warning Signs The x-ray control panel must bear a permanent and conspicuous sign warning that hazardous x-radiation is emitted when the equipment is in operation and prohibiting unauthorized use.
- Markings All controls, meters, lights and other indicators relevant to the operation of the equipment *must* be readily discernible and clearly labelled or marked as to function.
- Indicator Lights There must be readily discernible, separate indicators on the control panel that respectively indicate:
  - (i) when the control panel is energized and the machine is ready to produce xrays, and
  - (ii) when x-rays are produced. When more than one x-ray tube is controlled by one control panel, there *must* be clear and visible indication, at or near the tube housing and on the control panel, of which tube is connected and ready to be energized.

- Focal Spot The location of the focal spot must be clearly and accurately marked on the tube housing.
- 5. Filtration The external surface of the x-ray tube housing must bear a permanent mark or label which sets out the minimum permanent inherent filtration in the useful beam, expressed as millimetres of aluminum equivalent at a specified peak tube potential. The total permanent filtration in the useful beam must be equivalent to at least the following thicknesses of aluminum:
  - 0.5 millimetre of aluminum, for machines designed to operate with x-ray tube potentials below 50 kilovolts peak;
  - (ii) 1.5 millimetres of aluminum, for machines designed to operate with x-ray tube potentials from 50 kilovolts peak to 70 kilovolts peak, and Devices Regulations applicable to that class of machine, as required to comply with the standards in effect at the time of replacement.
  - (iii) 2.5 millimetres of aluminum, for machines designed to operate with x-ray tube potentials above 70 kilovolts peak;

- 6. Mechanical Stability The x-ray tube must be securely fixed and correctly aligned within the tube housing. Also, the tube housing must maintain its required exposure position or movement without excessive drift or vibration during operation. The x-ray tube housing must be supported by mechanical means. It must not be hand-held during operation.
- 7. Exposure Control There must be an exposure switch, timer, or other device to initiate and terminate x-ray production. This control must automatically terminate the exposure after a preset time, product of current and time, or exposure has elapsed. Where an exposure switch is provided, the exposure switch must:
  - (i) require continuous pressure by the operator to produce x-rays (i.e., "dead man" type);
  - (ii) if in the form of a footswitch, be so constructed that if overturned inadvertent exposures do not result;
  - be so located that convenient operation outside of a shielded area is not possible, (except for exposure switches used in conjunction with mobile xray equipment, with spot film devices, in fluoroscopy and with certain special procedures), and
  - (iv) for mobile x-ray equipment, be equipped with a cable at least three metres long.

- 8. Indication of Technique Factors For x-ray machines having adjustable technique factors, the control panel *must* incorporate electrical meters or other indicators that enable determination of the x-ray tube potential (kilovolts), tube current (milliamperes) and time (seconds), or combinations of these. For equipment having non-adjustable technique factors, permanent marks or labels may be used to indicate these parameters. The actual peak kilovoltage *should* correspond to the selected or indicated value to within 5% of the selected or indicated value.
- 9. *X-Ray Tube Shielding* The x-ray tube *must* be enclosed in a shielded housing. The shielding of the housing *must* be such that, at each rating specified by the manufacturer for that tube, the leakage radiation, measured at a distance of one metre in any direction from the focal spot of the x-ray tube, does not exceed 0.1% of the exposure rate at the same distance along the central axis of the useful beam. For radiographic equipment designed specifically for mammography, the leakage radiation, measured at a distance of 5 cm from the housing and averaged over a detection area of 100 square centimetres, *must not* exceed two milliroentgen per hour (516 nC/kg per hour).

The following guidelines from Safety Code 20A identify those who may operate radioscopic (fluoroscopic) equipment:

#### A. Sec 3.1

- (a) "There **must** be at least one person designated by the owner as the responsible user to undertake responsibility for:
  - ii) ensuring that the equipment is used and maintained only by competent personnel;
  - iii) ensuring that the equipment is used correctly;
  - iv) establishing safe operating procedures for the equipment and ensuring that operating staff are adequately instructed in them."

#### B. Sec 3.2 X-ray Equipment Operators

"All operators should be certified according to a recognized standard, such as that of the CAMRT, and must possess qualifications required by any relevant Federal and Provincial regulations and statues."

Sec 3.2.3 "All operators **must** have a thorough understanding of their profession, of safe working methods and of special techniques."

#### C. Sec 8.1 General Recommendations

- 12) "X-ray equipment must only be operated by, or under the direct supervision of, qualified individuals." (See Sec 3.2 and 3.2.3 above)
- **D. Sec 9.1.10** "Medical practitioners should not operate x-ray equipment or be responsible for the use of such equipment."
- E. Sec 9.5.3(2) "Fluoroscopy must only be carried out by, or under immediate supervision of, a radiologist or physician properly trained in fluoroscopic procedures."

# **Provincial dose limits for X-Rays**

#### CLASS II NUCLEAR FACILITIES AND PRESCRIBED EQUIPMENT REGULATIONS

"Class II nuclear facility" means any of the following nuclear facilities:

(*a*) a particle accelerator with a beam energy of less than 50 MeV that is capable of producing nuclear energy; or

(b) a facility prescribed by paragraph 19(c) of the General Nuclear Safety and Control Regulations. (installation nucléaire de catégorie II)

"Class II prescribed equipment" means

(a) an irradiator that uses more than  $10^{15}$  Bq of a nuclear substance;

(b) an irradiator that requires shielding which is not part of the irradiator and that can deliver a dose of radiation at a rate exceeding 1 centigray per minute at 1 m;

(c) a radioactive source teletherapy machine;

(d) a particle accelerator with a beam energy of less than 50 MeV that is capable of producing nuclear energy; or

(e) a brachytherapy machine. (équipement réglementé de catégorie II)

X-ray equipment not capable of producing nuclear energy (nuclear reactions) does not fall under the CNSC jurisdiction.

## REGULATORY LIMITS

Occupational exposure to X-rays fall under jurisdiction of provincial governments in most cases. Exposures to radiation from nuclear transmutations are under the jurisdiction of the Canadian Nuclear Safety Commission (CNSC).

The National Dose Registry (NDR) is a centralized radiation dose record system, operated by the Radiation Protection Bureau (RPB) of Health Canada. It contains the occupational radiation dose records of all monitored radiation workers in Canada from the 1940's to the present.

#### REGULATORY LIMITS

Occupational exposure to X-rays fall under jurisdiction of provincial governments in most cases. Exposures to radiation from nuclear transmutations are under the jurisdiction of the Canadian Nuclear Safety Commission (CNSC).

- CNSC
- Alberta
- British Columbia
- Manitoba (not available at this time)
- New Brunswick
- Newfoundland and Labrador
- Northwest Territories (not available at this time)
- Nova Scotia
- Nunavut (not available at this time)
- Ontario
- Prince Edward Island
- Quebec (not available at this time)
- Saskatchewan
- The Yukon Territory

# REGULATORY LIMITS OF THE CANADIAN NUCLEAR SAFETY COMMISSION

This brief summary is not an official version of the regulations. For more information contact the CNSC. Click here to access their web site.

#### **Effective Dose Limits**

Nuclear Energy Worker	50 mSv /1-yr period 100 mSv /5-yr period			
Pregnant Nuclear Energy Worker	4 mSv for remainder of pregnancy			
Equivalent Dose Limits				
Lens of an Eye	150 mSv /1-yr period			
Skin	500 mSv /1-yr period			
Hands and Feet	500 mSv /1-yr period			

#### REGULATORY LIMITS OF ALBERTA

This brief summary is not an official version of the regulations. For more information contact the province. Click here to access their web site.

Whole Body50 mSv /yr<br/>100 mSv /5-yr periodAbdomen (Pregnant Worker)2 mSv for remainder of pregnancyLens of the Eye150 mSv /yrSkin500 mSv /yrHands500 mSv /yr



#### REGULATORY LIMITS OF BRITISH COLUMBIA

This brief summary is not an official version of the regulations. For more information contact the province. Click here to access their web site.

Whole Body20 mSv /yrAbdomen (Pregnant Worker)4 mSv for remainder of pregnancyLens of the Eye150 mSv /yrSkin500 mSv /yr

Hands and Feet

500 mSv /yr

# REGULATORY LIMITS OF NEWFOUNDLAND AND LABRADOR

This brief summary is not an official version of the regulations. For more information contact the province. Click here to access their web site.

#### **Dose Limits to Radiation Workers**

Bone Marrow	30 mSv /quarter
Whole Body, Gonads	30 mSv /quarter 50 mSv /year
Hands, Forearms, Feet, Ankles	380 mSv /quarter 750 mSv /year
Skin, Bone, Thyroid	150 mSv /quarter 300 mSv /year
Other Organ	80 mSv /quarter



# REGULATORY LIMITS OF NEWFOUNDLAND AND LABRADOR

#### Additional Dose Limits to Pregnant Workers

Abdomen and Pelvis

5 mSv for remainder of pregnancy

Other Organ

80 mSv /quarter 150 mSv /year

#### Additional Dose Limits to Female Radiation Workers not Known to Be Pregnant, but in the Child-bearing Years

Abdomen and Pelvis

13 mSv /quarter 50 mSv /year

Other Organ

8 mSv /quarter 150 mSv /year

Notes:

For easy comparison with other jurisdictions, units have been converted from rads found in the web site.

The terms "quarter" and "year" correspond to periods of 13 and 52 consecutive weeks on the web site.

#### REGULATORY LIMITS OF NOVA SCOTIA

#### Limits for Whole Body Dose

**Radiation Workers** 

12.5 mSv /quarter 50 mSv /year

Radiation Workers, under 18 Years of Age 15 mSv /year

(No Occupational Exposure is permitted below the Age of 16 Years.)

Female Radiation Worker of Reproductive Capacity:

13 mSv / period of 13 weeks

#### Limits for Organ Doses

Abdomen (Pregnant Worker)

15 mSv for remainder of pregnancy

Lens of the Eye

300 mSv /year

Head and Trunk; Active Blood-Forming Organs; Lens of Eyes; or Gonads

Hands and Forearms; Feet and Ankles

12.5 mSv /calendar quarter

187.5 mSv /calendar quarter

Skin of Whole Body

75 mSv /calendar quarter

#### REGULATORY LIMITS OF ONTARIO

This brief summary is not an official version of the regulations. For more information contact the province. Click here to access their web site.

Whole body

50 mSv /yr

Abdomen (Pregnant Worker) 5 mSv for remainder of pregnancy

Lens of the Eye

Skin

150 mSv /yr

500 mSv /yr

Other Organs

500 mSv /yr

#### REGULATORY LIMITS OF PRINCE EDWARD ISLAND

This brief summary is not an official version of the regulations. For more information contact the province.

Whole Body50 mSv /yrPregnant Worker5 mSv for remainder of pregnancy

Lens of the Eye

150 mSv /yr

#### National Dose Registry

#### REGULATORY LIMITS OF SASKATCHEWAN

This brief summary is not an official version of the regulations. For more information contact the province. Click here to access their web site.

Whole Body

50 mSv /y 100 mSv /5y period

#### National Dose Registry

#### REGULATORY LIMITS OF THE YUKON TERRITORY

This brief summary is not an official version of the regulations. For more information contact the territory.

Whole Body 30 mSv /quarter 50 mSv /year

Skin, Bone, Thyroid

150 mSv /quarter 300 mSv /year

Hands, Forearms, Feet, Ankles

380 mSv /quarter 750 mSv /year

Pelvis, Abdomen (Female Workers not Known to Be Pregnant but in the Child-Bearing Years)

13 mSv /quarter 50 mSv /year

Pelvis, Abdomen (Pregnant Workers)

1 mSv /mo. for remainder of term

Other Organs

80 mSv /quarter 150 mSv /year

# Provincial Regulations for Radiology Laboratories (Quebec)

# **Provincial Regulations (Quebec)**

(Quebec Government)

c. L-0.2, r.1

Regulation respecting the application of the Public Health Protection Act

An Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, ambulance services and the disposal of human bodies

(R.S.Q., c. L-0.2, s. 69)

This Act was formerly entitled :"Public Health Protection Act". The title of the Act was replaced by section 149 of chapter 60 of the statutes of 2001.

# **Provincial Regulations (Quebec)**

2. Definitions: In this Regulation, unless the context indicates a different meaning, the following words and expressions mean:

(t) «general diagnostic radiology laboratory»: a laboratory where every kind of diagnostic radiology examination is carried out;

(u) «specific diagnostic radiology laboratory»: a laboratory where only diagnostic radiology examinations specifically related to the exercise of the profession of the permit holder are carried out;

(v) «x-rays»: electromagnetic ionizing radiation produced by the interaction of electrons with a heavy metal target;

An Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, ambulance services and the disposal of human bodies (R.S.Q., c. L-0.2, s. 69)

CHAPTER I: RETURNS OF BIRTH, MARRIAGE AND DEATH

CHAPTER II : DISEASES

CHAPTER III : CONDITIONS OF PREPARATION, EMBALMING, CREMATION, OR INCINERATION OF DECEASED PERSONS, THE PERSONS WHO MAY CONDUCT SUCH OPERATIONS AND THE PLACES WHERE THEY MAY BE CARRIED ON

CHAPTER IV : DISINFECTION, CONTAGION IN BODIES

CHAPTER V : DETERMINATION OF CERTAIN PREMISES, FOREST CAMPS OR TEMPORARY INSTALLATIONS AT PLACES WITHOUT ACCESS TO INSTITUTIONS WHERE CURRENT HEALTH SERVICES MUST BE RENDERED

CHAPTER VI : TERMS AND CONDITIONS OF ISSUE OF AUTHORIZATIONS FOR THE TRANSPORTING OF DECEASED PERSONS

CHAPTER VII : CONDITIONS FOR ISSUANCE OF PERMITS

CHAPTER VIII : STANDARDS GOVERNING THE EQUIPMENT, TECHNICAL OPERATION AND SANITARY CONDITION OF LABORATORIES AND THE QUALIFICATIONS OF THE STAFF EMPLOYED THEREIN

CHAPTER IX : STANDARDS GOVERNING THE EQUIPMENT, OPERATION AND FUNCTIONING OF AMBULANCE SERVICES, THE PREMISES IN WHICH SUCH OPERATIONS ARE TO BE CONDUCTED AND THE QUALIFICATIONS OF THE STAFF EMPLOYED

# An Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, ambulance services and the disposal of human bodies (R.S.Q., c. L-0.2, s. 69)

#### **DIVISION II**

#### **DIAGNOSTIC RADIOLOGY LABORATORY**

143. For the purposes of this Division, the following words and expressions mean:

(a) «person directly assigned to work under x-rays»: a person who works in a controlled zone;

(b) «staff»: every person working in a diagnostic radiology laboratory;

(c) «person not directly assigned to work under x-rays»: a person who, exposed in the course of professional activities to x-rays, does not usually work in a controlled zone;

(d) «physicist»: a person holding an undergraduate degree in physics or the equivalent and competent in radiation protection;

(e) «controlled zone»: those zones of the laboratory within which workers are liable to receive dose equivalents superior to the maximum permissible dose equivalents established in Schedule 8 for persons not directly assigned to work under x-rays.

R.R.Q., 1981, c. P-35, r. 1, s. 143.

#### § 1. Equipment

144. The equipment utilized in a diagnostic radiology laboratory must be kept in good operating condition to ensure the protection of the patient and staff at all times.

R.R.Q., 1981, c. P-35, r. 1, s. 144.

145. An equipment file must be opened and contain the following information with respect to each x-ray machine:

(a) identification of the machine: the name of the manufacturer, the serial number and the number of x-ray tubes;

(b) identification of the image recording devices;

(c) a plan of the laboratory indicating the shielding specifications of the walls, floors, ceiling, doors and windows as well as the location of the controlled zone, the control booth, the image recording devices, the cassette pass-boxes, the doors and the windows;

(d) a plan of the rooms above, below and adjacent to the laboratory as well as the nature of occupancy and use of such rooms and of neighbouring rooms;

(e) the primary beam orientations used and the total filtration of the x-ray tubes;

(f) the date of the inspections provided for in sections 146, 147 and 149, the results obtained, the signature of the **physicist** who carried out the inspections and the report contemplated in section 150.

**146.** When an x-ray machine is installed, a notice containing the name of the manufacturer, the model designation and the serial number of such machine must be forwarded to the Minister. Moreover, the shielding and the machine must be inspected by a physicist before operating such machine.

**147.** When there is an **alteration made in the shielding**, in the x-ray machine or in the latter's use, **the shielding and the machine must be inspected by a physicist** before operating such machine.

**148.** When there is an alteration made in the shielding, in the x-ray machine or in the latter's use, the equipment file prescribed in section 145 must be updated and indicate the alterations made.

149. An inspection of the shielding, the calibration of each x-ray machine and the safety of the installations must be carried out every 2 years by a physicist.

However, the said inspection must be carried out every 3 years in the case of a specific diagnostic radiology laboratory in dentistry.

150. A **physicist** who, during an inspection carried out under section 146, 147 or 149, observes that the shielding, the controlled zone, the x-ray machine or the installation, calibration or use of the latter is **not in conformity with this Division must immediately advise thereof the holder of the permit.** The latter must advise the staff if there is any danger that they may be exposed to dose equivalents greater than those fixed in Schedule 8 and take the necessary corrective measures immediately.

Within 5 days of such inspections, the physicist must forward a written report of his observations to the holder of the permit.

#### § 4. Protection of staff

180. The holder of a permit must delimit a controlled zone around a radiation source. Access to this zone must be indicated by a signalling system.

181. The holder of a permit must ensure that every person directly assigned to work under x-rays sign, prior to being assigned to such work, a document by which that person agrees to work in controlled zones.

182. The holder of a permit must make available to a **person directly assigned to work under x-rays** a **dosimeter which enables the monitoring of the cumulative xray doses** to which he is exposed.

83. The cumulative x-ray dose equivalents received by the staff **must not exceed those set out in Schedule 8**.

184. When a staff member receives x-ray dose equivalents of 25 millirems or higher per week, the holder of a diagnostic radiology laboratory permit must see to it that a study be carried out in order to determine the causes of such exposure and ensure that it is lowered.

#### § 5. Protection of persons examined by means of x-rays

193. Except in dental radiography, the operator of an x-ray machine must ensure that **lead shields protect the gonads of persons of an age of reproductive capacity** unless such shields interfere with the primary purpose of the examination. Except in dental radiography, the operator of an x-ray machine must ensure that the cone of the radiation beam protects the epiphyses of children and the gonads of persons of an age of reproductive capacity.

194. In **dental radiography**, the operator of an x-ray machine must ensure that the person exposed to radiation is **covered with a protective apron** in conformity with the specifications of subparagraph *a* of section 186.

**195.** A diagnostic radiology laboratory must be designed and equipped, the walls, floor, ceiling, doors and windows of such laboratory must be shielded in a manner so that:

(a) a person who is directly assigned to work under x-rays shall not experience an exposure rate of more than 100 millirems per week; and

(b) a person who is not directly assigned to work under x-rays shall not experience an exposure rate of more than 10 millirems per week.

Such shielding is calculated in accordance with the method prescribed in Schedule 9.

**196.** When shielding is installed, the holder of a diagnostic radiology laboratory permit must ensure that a **physicist** verifies such shielding before the sealing of the barriers of the laboratory.

**197.** The shielding of the walls, floor, ceiling, doors and windows of a diagnostic radiology laboratory must constitute an uninterrupted protective screen.

198. Radiographic films must not be exposed to irradiation greater than 0,2 milliroentgens during the storage period.

Such shielding is calculated in accordance with the method prescribed in Schedule 9.

#### MAXIMUM PERMISSIBLE DOSE (MPD) EQUIVALENTS (Quebec)

per (MP	imum missible dose D) equivalents rems
Whole body, gonads, red bone marrow, lens of eye	Per year 0,5
Bone, skin Thyroid	3
a) persons under 16 years of age	1,5
b) persons 16 years of age and o	ver 3
Any tissue of the hands, forearms, feet and ankles	7,5
Other single organs or tissues	1,5

Table 1: Maximum permissible radiation dose (MPD) equivalents, excluding doses received for medical and paramedical purposes and natural background radiation, for:

1) persons of 16 and 17 years of age directly assigned to work under x-rays;

2) persons not directly assigned to work under x-rays;

3) members of the public.

#### MAXIMUM PERMISSIBLE DOSE (MPD) EQUIVALENTS (Quebec)

Organ or tissue	p) (1	aximum ermissible dose MPD) equivalents n rems
Whole body, gonads,	Quarterly	Yearly
red bone marrow, lens of eye	3	5
Bone, skin, thyroid	15	30
All tissue of the hands, fore-arms, feet and ankles	s 38	75
Other single organs or tissues	8	15

Table 2 : Maximum permissible dose (MPD) equivalents of radiation for persons of 18 years of age and over who are directly assigned to work under x-rays excluding doses received for medical and para-medical purposes and natural background radiation.

#### MAXIMUM PERMISSIBLE DOSE (MPD) EQUIVALENTS

Organ or tissue	-	nissible dose )) equivalents
Whole body, gonads, red bone marrow, lens	Quarterly	Yearly
of eye	1,3*	5*
Bone, skin, thyroid All tissue of the hands,	15	30
fore-arms, ankles and feet Other single organs or	t 38	75
tissues	8	15
* The does to the abdomen over a 2-week period and, such dose must not exceed	if the woman	is pregnant,

Table 3 : Maximum permissible dose (MPD) equivalents of radiation for women of reproductive capacity assigned to work under x-rays excluding doses received for medical and para-medical purposes and natural background radiation.

#### **CNSC Effective Dose Limits vs Provincial limits (Quebec)**

	Column 1	Column 2	Column 3	Qc X-Ray
Item	Person	Period	Effective Dose (mSv)	workers
1.	Nuclear energy worker, including a pregnant nuclear energy worker	<ul><li>(a) One-year dosimetry period</li><li>(b) Five-year dosimetry period</li></ul>	50 100	50 NA+
2.	Pregnant nuclear energy worker	Balance of the pregnancy	4	NA++
3.	A person who is not a nuclear energy worker	One calendar year	1	5

\*NEW or Radiation (X-Ray) workers

+dose to the abdomen must not exceed 2 mSv over a 2-week period ++ dose to abdomen must not exceed 15 mSv per year

#### CNSC Equivalent Dose Limits vs Provincial limits (Quebec)

	Column 1	Column 2	Column 3	Column 4	Quebec
-	Organ or	-		Equivalent Dose	X-Ray workers
Item	Tissue	Person	Period	(mSv)	Workere
1.	Lens of an eye	(a) Nuclear energy worker	One-year dosimetry period	150	50
		(b) Any other	One calendar	150	30
		(b) Any other person	year	15	5
2.	Skin	(a) Nuclear energy worker	One-year dosimetry		
			period	500	300
		(b) Any other person	One calendar year	50	30
3.	Hands and feet	<ul><li>(a) Nuclear</li><li>energy worker</li></ul>	One-year dosimetry		
			period	500	750
		(b) Any other	One calendar		75
	· ·	person	year	50	

\*NEW or Radiation (X-Ray) workers

### FORM TO BE SIGNED BY THE FEMALE STAFF OF A DIAGNOSTIC RADIOLOGY LABORATORY, SECTION 189

I acknowledge having taken cognizance of the limits of exposure to x-rays as provided for in Table 3 of Schedule 8 reproduced below.

These MPD exclude doses received for medical and para-medical purposes and natural background radiation.

\* The dose to the abdomen must not exceed 0,2 rem over a 2-week period and, if the woman is pregnant, such dose must not exceed 1,5 rem per year.

I undertake to advise the permit holder or any pregnancy.

name of employee
signature of employee
date

name of permit holder ..... signature of permit holder ..... date .....

This form must be filed with the employee's record.

#### Table 3 of Schedule 8

Organ or tissue	-	issible dose ) equivalents
Whole body, gonads, red bone marrow, lens	Quarterly	Yearly
of eye	1,3*	5*
Bone, skin, thyroid	15	30
Any tissue of the hands, fore-arms, ankles and feet	t 38	75
Other single organs or tissues	8	15

#### c. S-5, r.3.01

Organization and Management of Institutions Regulation

#### An Act respecting health services and social services

(R.S.Q., c. S-5, ss. 7, 18.1, 18.2, 70, 70.1, 71.3, 94, 102, 130 and 173 par. a, b, c, c.1, e, f, i, j, j.1, k, l, q and r)

O.C. 1320-84; S.Q., 1992, c. 21, s. 375.

#### DIVISION II

#### HYGIENE AND SAFETY

11. An **institution using appliances emitting radiation** shall put into practice methods of controlling the use of appliances, **such as those** prescribed by the **Regulation respecting the application of the Public Health Protection Act (c. P-35, r. 1)**.

An institution using **radioactive substances** shall comply with the **Atomic Energy Control Regulations** (C.R.C., c. 365).

#### What to do when dose limits are exceeded (Quebec)?

#### For workers (technologists, nurses, ...):

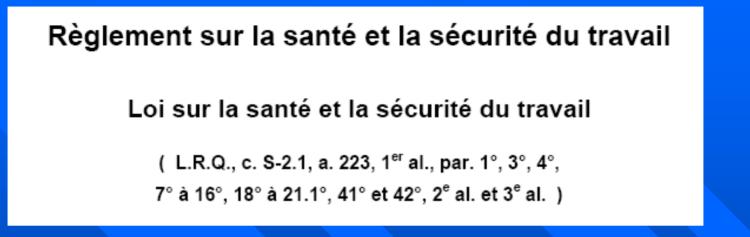
Commission de la santé et de la sécurité au travail (CSST) can remove worker from work

For professionals (doctors):

**CSST** regulation applies

Hospital Professional Service Directorate can issue summons and review work practices (Hospital Internal policies)

In private clinics, Health Ministry can revoque permits



144. Rayonnements ionisants : Les travailleurs susceptibles d'être exposés à des rayonnements ionisants doivent être surveillés par dosimétrie.

En cas de surdose, les travailleurs ainsi exposés doivent subir des examens médicaux à intervalles plus ou moins fréquents, selon la durée de l'exposition.

#### Québec 🔠

© Éditeur officiel du Québec Ce document n'a pas de valeur officielle.

> Dernière version disponible À jour au 31 octobre 2004

#### L.R.Q., chapitre S-2.1

#### LOI SUR LA SANTÉ ET LA SÉCURITÉ DU TRAVAIL

Personne à son propre compte.

**7.** Une personne physique faisant affaires pour son propre compte, qui exécute, pour autrui et sans l'aide de travailleurs, des travaux sur un lieu de travail où se trouvent des travailleurs, est tenue aux obligations imposées à un travailleur en vertu de la présente loi et des règlements.

#### Obligations.

De plus, elle doit alors se conformer aux obligations que cette loi ou les règlements imposent à un employeur en ce qui concerne les produits, procédés, équipements, matériels, contaminants ou matières dangereuses.

1979, c. 63, a. 7.

Radiological Issues: X-ray Exposure and Pregnancy

Radiation source	Average dose (mGy)	Radiation source	Average dose (mGy)
Dental	<0.01*	Barium meal (upper Gl) (Fluoroscopy)	1.1
Chest	<0.01	Barium enema (Fluoroscopy)	6.8
Mammography	<0.05*	Head (Computed tomography)	<0.005
Pelvis	1.1	Chest (Computed Tomography)	0.06
Abdomen	1.4	Lumbar Spine (Computed Tomography)	2.4
Lumbar spine	1.7	Abdomen (Computed Tomography)	8.0
Natural background radiation (entire pregnancy)	0.5*	Pelvis (Computed Tomography)"	25

Average Radiation Dose to an Unborn Child from X-ray Procedures http://www.hc-sc.gc.ca/english/iyh/medical/x\_rays.html

#### Table 5 Continuing a Pregnancy after Radiation Exposure as a Function of Gestational Age and Dose

	Fetal Absorbed Dose			
Gestational Age	<5 rad (<50 mGy)	5-15 rad (50-150 mGy)	>15 rad (>150 mGy)	
<14 d (<2 wk)	Recommended	Recommended	Recommended	
14-56 d (2-8 wk)	Recommended	Maybe consider termina- tion (in presence of other severe risks)	Maybe consider termina- tion (in presence of other risks)	
57-105 d (8-15 wk)	Recommended	Maybe consider termina- tion (in presence of other risks)	Higher risk conditions exist, but termination is not necessarily rec- ommended	
>105 days (15 wk to term)	Recommended	Recommended	Recommended	

Source.—Adapted from reference 2.

RadioGraphics 1999; 19:1289-1302

#### Table 6 Effects of Radiation Exposure on Prenatal Development

	Days after	after Fetal Dose		
Gestational stage	Conception	rad	mGy	Observed Effect
Preimplantation	0-14	5-10	50-100	Animal data suggest possibility of prenatal death
Major organogenesis	8-56	20-25	200-250	Animal and NBS data suggest that this is the most sensitive stage for growth retardation
	14-105			NBS data indicate small head size; those exposed before 8 wk did not display any intellectual deficit even with small head; most sensitive time for induction of childhood cancer
Rapid neuron development and migration	56-105	>10	>100	Small head size, seizures, decline in IQ points: 25 points/100 rad (1 Gy)
After organogenesis and rapid neuron	105 to term	>10	>100	Associated with increased frequency of childhood cancer
development		>50	>500	Severe mental retardation observed at 16-25 wk

Note.—NBS = nuclear bombing survivor from Hiroshima and Nagasaki.

#### RadioGraphics 1999; 19:1289-1302

Radiological Issues: Dose reduction in CT

### Ref. : American Journal of Roentgenology 2001:176;303-306 1500 Children Die Every Year From CT Scans

Abstracted from USA Today

Each year, about **1.6 million** children in the USA get CT scans to the head and abdomen - and about **1,500 of those will die later in life of radiation-induced cancer**.

What's more, CT or computed tomography scans given to kids are typically **calibrated for adults**, so children absorb **two to six times** the **radiation** needed to produce clear images. Radiologists could turn down the X-rays without losing quality, and thus expose the children to less potentially cancer-causing radiation.

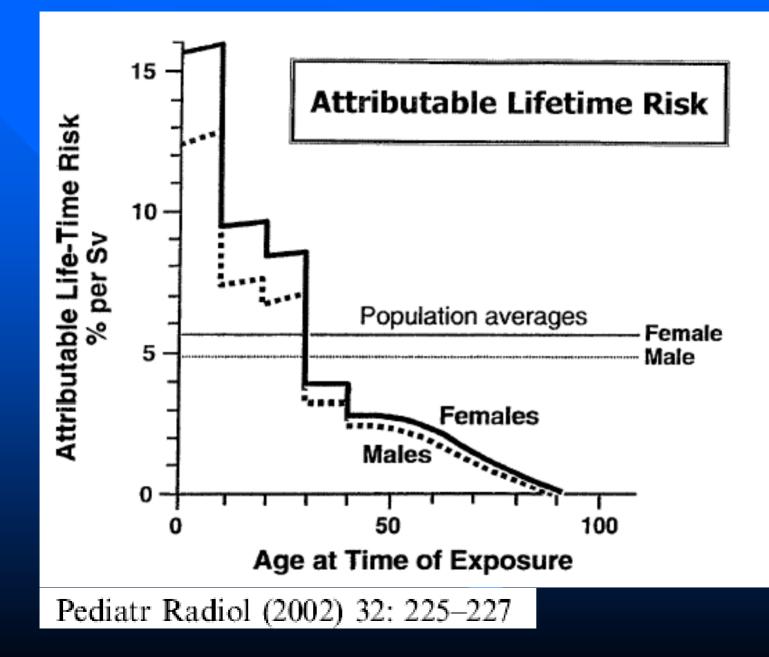
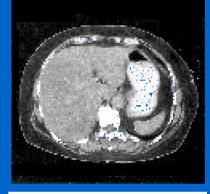


Table 1. Typical patient radiation dose			
Procedure	kVp	mAs	RAD DOSE (cGy)
Adult body Pediatric body Adult head Pediatric head	120 120 120–140 120	100–300 If same 350–560 If same	1.5–3.5 2.9–6.8 6.0–11.5 7.8–15.2

Pediatr Radiol (2002) 32: 250-260

# Image Quality and Dose

 ideal image quality high spatial resolution - low noise - narrow slice width ideal radiation input



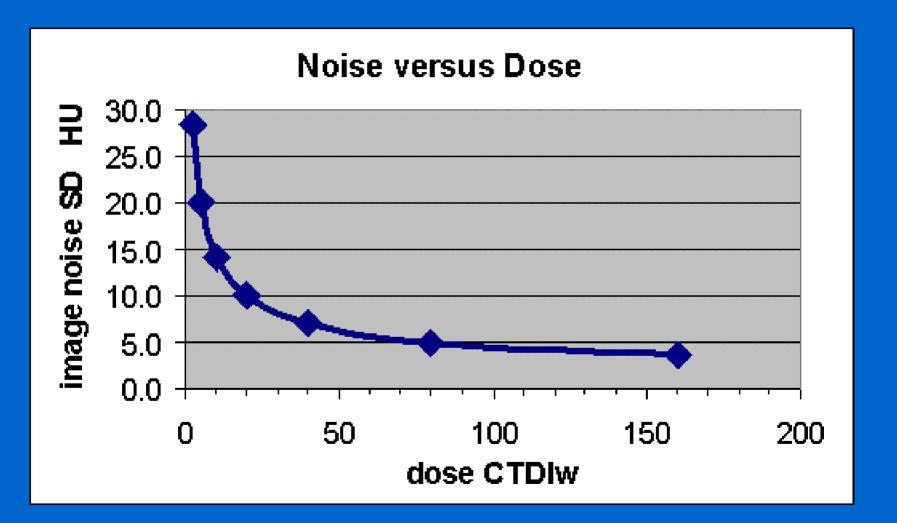


-low dose

in reality there are compromises

ImPACT Day 2001

# Optimisation of Noise and mAs



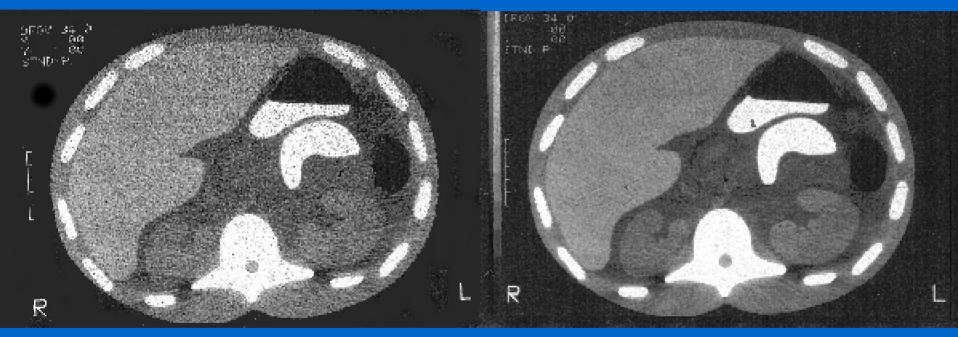
Ψ.

### noise $\alpha$ 1/sqrt(dose)

ImPACT Day 2001

# Dose and Image Quality

### Scan Plas Anthropomorphic Phantom



### 40 mA > 3 times more dose $\rightarrow$ $\leftarrow$ noise x 2 eg 20 HU -> 40 HU ImPACT Day 2001

