Ontario

Regulation respecting X-ray Safety - made under the Occupational Health and Safety Act

Revised Statutes of Ontario, 1990
Chapter O.1 as amended

R.R.O. 1990, Reg. 861
(including a Technical Guide to the Regulation)

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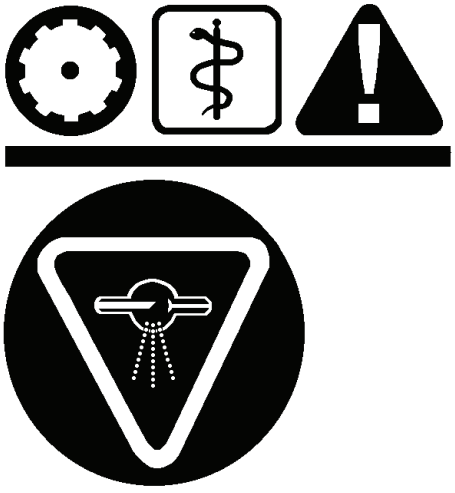

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REGULATION 861

X-RAY SAFETY

1. In this Regulation,

"absorbed dose" means the mean energy per unit mass imparted by ionizing radiation to matter;

"air kerma" means the sum of the initial kinetic energies per unit mass of all the charged particles liberated by uncharged ionizing radiation in air;

"Director" means the Director of the Health and Safety Support Services Branch of the Ministry of Labour;

"dose equivalent" means the product of absorbed dose and a quality factor where the quality factor is a measure of the biological effectiveness of the radiation, and is assigned the value 1.0 for X-rays;

"failsafe design" means a design in which any failure of safety indicators or components that can reasonably be anticipated causes the production or emission of X-rays to cease;

"gray" means,

(a) a unit of absorbed dose, and is realized when one joule of energy has been imparted per kilogram of material, or

(b) a unit of air kerma, and is realized when one joule of energy has been liberated per kilogram of air;

"redundant", when used with reference to a light, means a light with two or more separate and equivalent bulbs so designed that the failure of one bulb will not affect the operation of the other bulb or bulbs;

"shield" or "shielding" means radiation absorbing material or materials used to reduce the absorbed dose or absorbed dose rate imparted to an object;

"sievert" means a unit of dose equivalent, and for X-rays the dose equivalent measured in sieverts is numerically equal to the absorbed dose measured in grays;

"X-ray machine" means an electrically powered device, the principal purpose of which is the production of X-rays;

"X-ray source" means any device, or that portion of any device, that emits X-rays, whether or not the device is an X-ray machine;

"X-ray worker" means a worker who, as a necessary part of the worker's employment, may be exposed to X-rays and may receive a dose equivalent in excess of the annual limits set forth in Column 4 of the Schedule;

"X-rays" means electrically-generated electromagnetic radiation of maximum photon energy not less than 5,000 electron volts. R.R.O. 1990, Reg. 861, s. 1.

2. Subject to section 3, this Regulation applies to every owner, employer, supervisor and worker at a workplace where,

(a) an X-ray machine is present or used; or

(b) an X-ray source that is not an X-ray machine is present or used, if the X-ray source is capable of producing an air kerma rate greater than 1.0 microgray per hour at any accessible point outside its surface. R.R.O. 1990, Reg. 861, s. 2.

3. (1) This Regulation does not apply to an X-ray source that is licensable under the *Atomic Energy Control Act* (Canada).

(2) Sections 5, 6, 7 and 8 of this Regulation do not apply in respect of an X-ray machine the installation, registration or operation of which is

subject to the *Healing Arts Radiation Protection Act*. R.R.O. 1990, Reg. 861, s. 3.

4. Except as permitted under the *Healing Arts Radiation Protection Act*, an X-ray source shall not be operated for the irradiation of a worker. R.R.O. 1990, Reg. 861, s. 4.

5. (1) An X-ray source shall not be used at a workplace unless the employer who has possession of the X-ray source is registered with the Director.

(2) An application for registration under this section shall be in Form 1 and shall be filed with the Director.

(3) An employer who was registered under Ontario Regulation 263/84 or Regulation 855 of the Revised Regulations of Ontario, 1980 or a predecessor thereof shall be deemed to be registered under this section if the registration was subsisting at the end of the 29th day of October, 1986.

(4) If an employer who is registered under this section ceases to have possession of an X-ray source, the employer shall forthwith give a notice to the Director advising the Director of that fact.

(5) An employer's registration under this section terminates when the employer notifies the Director that the employer no longer has possession of any X-ray sources. R.R.O. 1990, Reg. 861, s. 5.

6. (1) An X-ray source shall not be installed or used in a permanent location and an X-ray source that is designed for portable or mobile use shall not be installed or used regularly in one location unless an application for review, together with plan location drawings, of the installation have been reviewed by and are acceptable to an inspector.

(2) Subsection (1) does not apply to an X-ray source that,

(a) was in use in a permanent location before the 27th day of April, 1984, if it has remained continuously in that location since that time and so long as it remains in that location; or

(b) was installed after the 26th day of April, 1984, if the installation was made in compliance with Ontario Regulation 263/84 and there was compliance with that Regulation until the end of the 29th day of October, 1986.

(3) An application mentioned in subsection (1) shall be in Form 2 and shall be accompanied by the plan location drawings mentioned in that subsection, in duplicate.

(4) Plan location drawings mentioned in subsection (1),

(a) shall bear the name of the applicant and the address of the location;

(b) shall be on a legible scale that is not less than 1:100 and that is suitable for microfilming;

(c) shall indicate the direction north;

(d) shall show the proposed location of the X-ray source and, where applicable, the range of its motion;

(e) shall show the proposed location of the X-ray control panel, if the location of the control panel is different from that of the X-ray source;

(f) shall indicate the use of rooms or areas that are adjacent, both horizontally and vertically, to the proposed location;

(g) shall indicate the type and thickness of the shielding installed or to be installed on the boundaries of the proposed location; and

(h) shall indicate the type and location of the safety devices such as warning lights, interlocks and cut-off switches.

(5) An application under this section shall be filed with the Director.

(6) Where an application under this section or a predecessor of this section has been found acceptable by an inspector, the X-ray source to which the application relates shall not be installed except in accordance with the application and the plan location drawings as accepted by the inspector.

(7) An X-ray source to which subsection (1) applies or that is described in subsection (2) shall not be used, if after the installation of the X-ray source there is a change in,

(a) the installation or use of the X-ray source;

(b) the use of rooms or areas adjacent, horizontally or vertically, to the X-ray source; or

(c) any shielding of the X-ray source,

that may result in an increase in the exposure of a worker to X-rays unless the change has been reviewed by and is acceptable to an inspector.

(8) An employer shall request a review of a change described in subsection (7) by giving the request to the Director. R.R.O. 1990, Reg. 861, s. 6.

7. (1) Where an employer comes into possession of an X-ray source that is designed for portable or mobile use and that is so used, notice thereof shall be given to the Director.

(2) The notice required by subsection (1) shall be in writing and shall include,

(a) the name and address of the employer;

(b) the employer's registration number, if any, under section 5;

(c) the location where the X-ray source will normally be stored;

(d) the purpose for which the X-ray source will be used;

(e) the make, model and serial number of the X-ray source; and

(f) the maximum operating voltage and current of the X-ray source. R.R.O. 1990, Reg. 861, s. 7.

8. An employer shall designate a person, for each X-ray source, who is competent because of knowledge, training or experience in the use and operation of X-ray sources and in radiation safety practices, to exercise direction over the safe use and operation of the X-ray source, and shall advise the Director in writing of the name of the person designated. R.R.O. 1990, Reg. 861, s. 8.

9. (1) An employer who employs a person as an X-ray worker shall, at the time that employment begins,

(a) inform the worker in writing that the worker is employed as an X-ray worker;

(b) inform the worker of the limits imposed by subsection 10 (1) on the dose equivalent that may be received by the worker; and

(c) if the worker is female, inform her of the dose equivalent limit mentioned in subsection 10 (2) applicable to a pregnant X-ray worker.

(2) An employer shall maintain a list of all X-ray workers in the employment of the employer. R.R.O. 1990, Reg. 861, s. 9.

10. (1) The dose equivalent received or that may be received by a worker shall be as low as is reasonably achievable, and in any case,

(a) an X-ray worker shall not receive a dose equivalent in excess of the annual limits set out in Column 3 of the Schedule; and

(b) a worker who is not an X-ray worker shall not receive a dose equivalent in excess of the annual limits set out in Column 4 of the Schedule.

(2) Despite subsection (1), an employer shall take every precaution reasonable in the circumstances to ensure that the mean dose equivalent received by the abdomen of a pregnant X-ray worker does not exceed 5 millisieverts during the pregnancy. R.R.O. 1990, Reg. 861, s. 10.

11. The following measures and procedures shall be carried out in a workplace where an X-ray source is used:

1. X-ray warning signs or warning devices shall be posted or installed in conspicuous locations.

2. Every X-ray source capable of producing an air kerma rate greater than 5 micrograys per hour at any accessible point shall be labeled at its operating controls as a source of X-rays.

3. Where the air kerma in an area may exceed 100 micrograys in any one hour, access to the area shall be controlled by,

   i. locks or interlocks if the X-ray source is one to which subsection 6 (1) applies or is described in subsection 6 (2), and

   ii. barriers and X-ray warning signs if the X-ray source is portable or mobile and is being so used.

4. To ensure that the dose equivalent limits mentioned in section 10 are not exceeded,

   i. structural or other shielding shall be installed as is necessary, and

   ii. diaphragms, cones and adjustable collimators or other suitable devices shall be provided and used as are necessary to limit the dimensions of the useful X-ray beam. R.R.O. 1990, Reg. 861, s. 11.

12. (1) An employer shall provide to each X-ray worker a suitable personal dosimeter that will provide an accurate measure of the dose equivalent received by the X-ray worker.

(2) An X-ray worker shall use the personal dosimeter as instructed by the employer.

(3) An employer shall ensure that the personal dosimeter provided to an X-ray worker is read accurately to give a measure of the dose equivalent received by the worker and shall furnish to the worker the record of the worker's radiation exposure.

(4) An employer shall verify that the dose equivalent mentioned in subsection (3) is reasonable and appropriate in the circumstances, and shall notify an inspector of any dose equivalent that does not appear reasonable and appropriate.

(5) An employer shall retain an X-ray worker's personal dosimeter records for a period of at least three years. R.R.O. 1990, Reg. 861, s. 12.

13. Where a worker has received a dose equivalent in excess of the annual limits set out in Column 4 of the Schedule in a period of three months, the employer shall forthwith investigate the cause of the exposure and shall provide a report in writing of the findings of the investigation and of the corrective action taken to the Director and to the joint health and safety committee or health and safety representative, if any. R.R.O. 1990, Reg. 861, s. 13.

14. Where an accident, failure of any equipment or other incident occurs that may have resulted in a worker receiving a dose equivalent in excess of the annual limits set out in Column 3 of the Schedule, the employer shall notify immediately by telephone, telegram or other direct means the Director and the joint health and safety committee or health and safety representative, if any, of the accident or failure and the employer shall, within forty-eight hours after the accident or failure, send to the Director a written report of the circumstances of the accident or failure. R.R.O. 1990, Reg. 861, s. 14.

15. (1) This section applies only to X-ray machines used for industrial radiography or industrial fluoroscopy but does not apply to an X-ray machine to which section 17 applies.

(2) No X-ray machine to which this section applies shall be used except by or under the supervision of a competent person.

(3) In addition to any other requirements of this Regulation, the following requirements apply with respect to every X-ray machine to which this section applies:

1. The control panel of the X-ray machine shall have a plainly visible warning light to indicate when X-rays are being produced in the X-ray tube.

2. The X-ray machine, if installed in a permanent location or if designed for portable or mobile operation but used regularly in one location, shall be contained in an enclosure.

3. No person shall be permitted in the enclosure required by paragraph 2 while X-rays are being produced.

4. The enclosure required by paragraph 2 shall be provided with,

    i. reliable locks or interlocks to prevent any person from entering a radiation enclosure during an exposure and, where an exposure is terminated by an interlock, it shall only be possible to restart the exposure from the control panel, and

    ii. conspicuous warning lights of failsafe or redundant design near each entrance to the enclosure that indicate when X-rays are being produced,

    and paragraph 3 of section 11 does not apply.

5. If the enclosure required by paragraph 2 is of such a size or is so arranged that the operator cannot readily determine whether it is unoccupied, it shall be provided with,

   i. suitable audible or visible pre-exposure warning signals within the enclosure that shall be actuated for not less than ten or more than thirty seconds immediately before the initiation of an X-ray exposure,

   ii. suitable audible or visible warning signals within the enclosure that shall be actuated during the X-ray exposure, and

   iii. a suitable exit to enable any person to leave the enclosure without delay and without having to pass through the primary X-ray beam or an effective means, within the enclosure, that,

      A. prevents or interrupts an X-ray exposure,

      B. cannot be reset from outside the enclosure, and

      C. can be reached without having to pass through the primary X-ray beam.

6. An X-ray machine shall be operated, and, where an enclosure is required by paragraph 2, the enclosure shall be shielded in such a manner that,

   i. an X-ray worker is not likely to receive an effective dose equivalent in excess of 1 millisievert per week, and

   ii. a worker who is not an X-ray worker is not likely to receive an effective dose equivalent in excess of 100 microsieverts per week.

7. The employer shall ensure that a direct reading dosimeter of a suitable type is provided to each X-ray worker who in the course of his or her work may be exposed to an air kerma rate in excess of 100 micrograys per hour.

8. An X-ray worker provided with a direct reading dosimeter shall use it and shall determine the amount by which its reading has increased during each work day and record that amount at the end of the work day.

9. The employer shall retain the direct reading dosimeter records of each X-ray worker provided with such a dosimeter for a period of at least three years.

10. At least one radiation survey meter of a suitable type shall be provided for each portable or mobile X-ray machine and it shall be calibrated at least once every twelve months and kept in good working order. R.R.O. 1990, Reg. 861, s. 15.

16. In addition to any other requirement of this Regulation, the following requirements apply to every X-ray machine used for the diagnostic examination of animals:

1. Where practicable, radiographic procedures shall be performed in a room designed for the purpose of performing X-ray examinations of animals.

2. The air kerma due to leakage radiation from the X-ray tube housing or from an attached beam-limiting device shall not exceed 1 milligray in one hour at a distance of 1 metre from the focal spot of the X-ray tube.

3. Exposure duration shall be controlled by a preset timing mechanism and shall be initiated by a switch that requires positive action by the operator to continue the exposure and that allows the operator to remain at least 2 metres from the tube housing.

4. To the extent practicable, the dimensions of the useful beam shall be restricted to not more than those of the film.

5. The film cassette shall not be held by hand during an exposure.

6. The animal being X-rayed shall be restrained or supported by mechanical means where practicable.

7. If an animal is required to be restrained or supported by hand, a protective apron and gloves, providing shielding equivalent to at least 0.5 millimetre of lead, shall be worn by any person providing the restraint or support.

8. A record of radiographic exposures, including the date, kilovoltage, tube current and duration of each exposure, shall be maintained and kept for at least one year. R.R.O. 1990, Reg. 861, s. 16.

17. In addition to any other requirements of this Regulation, where an employer is in possession of an X-ray source in which the X-ray source, the object or the portion of the object being exposed to X-rays and the detection device are enclosed in a cabinet that, independent of existing structures, provides radiation attenuation and prevents access to the X-ray beam, the employer shall comply with the following requirements:

1. A warning device that indicates when X-rays are being produced shall be mounted on or near the cabinet in such a way as to be conspicuous from any position from which the cabinet can be opened.

2. Access doors and sample ports shall be interlocked with the X-ray source or with an adequately shielded shutter of failsafe design and, where operation has been interrupted by an interlock, it shall be possible to resume operation only from the control panel after the interlock has been reset.

3. The cabinet shall be so arranged and shielded as to prevent the air kerma rate from exceeding 5 micrograys per hour at

any accessible point 5 centimetres from the external surface, under all possible operating conditions.

4. Cabinet X-ray equipment that is intended to permit the entry of a person shall also be provided with,

   i suitable audible or visible warning signals within the cabinet that shall be actuated for at least ten seconds immediately prior to the initiation of X-ray production after the closing of any door that is designed to permit human access into the cabinet,

   ii suitable audible or visible warning signals within the cabinet that shall be actuated during X-ray production, and

   iii effective means within the enclosure to prevent or interrupt the production of X-rays, that cannot be reset from outside the enclosure and that can be reached without having to pass through the primary X-ray beam. R.R.O. 1990, Reg. 861, s. 17.

18. In addition to any other requirements of this Regulation, where an employer is in possession of an X-ray source that consists of analytic X-ray equipment to which section 17 does not apply and that is primarily used to determine the structure or composition of a sample of a material, the employer shall comply with the following requirements:

1. The control panel shall have an indicator, in close proximity to the X-ray "ON/OFF" switch, that clearly indicates when X-rays are being produced in the X-ray tube.

2. A warning light shall be mounted near each X-ray tube in such a way as to be clearly visible from any direction from which the tube can be approached, that indicates when X-rays are being produced.

3. The condition of each shutter, open or closed, shall be clearly indicated at or near the X-ray tube.

4. Each port shall be designed in such a way that the X-ray beam can emerge only when a camera or other recording device is in its proper position, wherever practicable.

5. At least one of the warning or safety devices mentioned in paragraphs 1 to 4 shall be of failsafe design.

6. A guard or interlock which prevents entry of any part of the body into the primary beam path shall be used, wherever practicable.

7. A shield shall be provided to absorb the primary beam at the nearest practicable position beyond the point of intersection of the beam and the sample that it is intended to irradiate.

8. All unused ports shall be secured in such a way as to prevent inadvertent opening. R.R.O. 1990, Reg. 861, s. 18.

19. In applying this Regulation, a procedure or device may vary from the procedure or device prescribed in this Regulation if the protection afforded thereby is equal to or greater than the protection afforded by the procedure or device prescribed. R.R.O. 1990, Reg. 861, s. 19.

SCHEDULE

PART OF BODY IRRADIATED	EXPOSURE CONDITIONS AND COMMENTS	DOSE EQUIVALENT ANNUAL LIMIT (millisieverts)	
		X-RAY WORKERS	OTHER WORKERS
Column 1	Column 2	Column 3	Column 4
Whole body or trunk of body	Uniform irradiation	50	5
Partial or non-uniform irradiation of body	The limit applies to the EFFECTIVE DOSE EQUIVALENT defined in Note (a)	50	5
Lens of eye	Irradiated either alone or with other organs or tissues	150	50
Skin	The limit applies to the mean dose equivalent to the basal cell layer of the epidermis for any area of skin of 1 square centimetre or more	500	50
Individual organs or tissues other than lens of eye or skin	The limit on effective dose equivalent applies, with an overriding limit on the dose equivalent to the individual organ or tissue	500	50

Notes to the Schedule:

(a) The EFFECTIVE DOSE EQUIVALENT, H_E, is determined by the following formula:

$$H_E = \Sigma_T W_T H_T$$

where:

(i) T is an index for tissue type;

(ii) H_T is the annual dose equivalent in tissue T;

(iii) W_T is a weighting factor which has the following values:
0.25 for the gonads,
0.15 for the breast,
0.12 for the red bone marrow,
0.12 for the lungs,
0.03 for the bone surfaces,
0.03 for the thyroid,
0.06 for each of the five other organs or tissues receiving the highest dose equivalents, but excluding the skin, extremities and eye lenses. The exposure of all other remaining tissues can be neglected. When the gastro-intestinal tract is irradiated, the stomach, small intestine, upper large intestine and lower large intestine shall be considered as four separate organs; and

(iv) $\Sigma_T W_T H_T$ is the sum of the $W_T H_T$ values for all irradiated tissues which receive more than 1 millisievert in a given year.

(b) The annual limits do not include any dose equivalent received by a worker from background sources or received as a patient undergoing medical diagnostic or therapeutic procedures.

(c) The annual limits include any dose equivalent received by a worker, as a consequence of his or her occupation, from all sources of ionizing radiation.

R.R.O. 1990, Reg. 861, Sched.

Form 1

Occupational Health and Safety Act

APPLICATION FOR REGISTRATION

Ontario Ministry of Labour	Radiation Protection Service	Registration No._____

Note: Insert "X" in all applicable boxes.

The undersigned, as employer ☐ or as agent for the employer ☐ applies for registration with the Radiation Protection Service of the Ministry of Labour.

A. The employer is:

Name _____ Telephone No._____

Business Address _____

City _____ Postal Code_____

B. The person to whom correspondence should be addressed is as at "A" ☐ , or is:

Name _____ Telephone No._____

Position or Title_____

Address _____

City _____ Postal Code_____

C. The general nature of the employer's business is (check one category only):
   ☐ Industrial and Commercial
   ☐ Veterinarian
   ☐ Research and Development
   ☐ Education and Training
   ☐ Other (Please specify) _____

D. As of the date of this registration, the employer is in possession of the following X-ray sources at the locations indicated (for portable or mobile units indicate where normally stored):

MAKE	MODEL	LOCATION (Room, Building, Street, City)	DATE INSTALLED

Dated at _____, this _____ day of _____, 20 _____

_____ _____

Signature of Applicant Name (please type or print)

R.R.O. 1990, Reg. 861, Form 1.

Form 2

Occupational Health and Safety Act

APPLICATION FOR REVIEW OF PERMANENT X-RAY LOCATION

Ontario Ministry of Labour	Radiation Protection Service	Registration No._____

Note: Insert "X" in all applicable boxes.

PART A: GENERAL

The undersigned, as

employer ☐ owner ☐ contractor ☐ architect ☐ engineer ☐ agent ☐

applies for review of a permanent X-ray location. The application covers a total of ___ X-ray sources in ___ rooms. It is accompanied by related floor plans in duplicate and by one completed Part B for each X-ray source for which review is sought.

1. The name of the X-ray facility for which review is sought is:
   _____

2. The employer is:

   Name _____ Telephone No. _____

   Number, Street _____

   City _____ Postal Code _____

3. The employer's registration number is _____ OR the employer is not registered □.

4. This application is submitted for the following reason:

   □ Opening of a new facility
   □ Relocation of sources
   □ Replacement of old sources in existing facilities
   □ Additional sources
   □ Acquisition of existing facility from:
   Previous owner's name _____
   Registration No. _____
   □ Change of shielding provisions, structure, or safety devices
   □ Compliance with Inspector's direction

   Operation is expected to commence on the following date:
   _____ 20___.

5. The X-ray source(s) will be (or are at present) located as at 2 □ , or at:

   Number, Street _____

   City _____ Postal Code _____

6. The person who exercises (or will exercise) direction over the safe use and operation of the X-ray source at the above location is the employer □ , or is:

   Name _____ Telephone No. _____

   Position _____

   Relevant Qualifications _____

7. The drawings and specifications were prepared by:

   employer □ architect □ other (specify) □ _____

Name _____ Telephone No. _____

Number, Street _____

City _____ Postal Code _____

8. The information set out in this application and in each Part B accompanying this application is accurate to the best of my knowledge.

Dated at _____, this _____ day of _____ , 20_____

_____ _____

Signature of Applicant Name (please type or print)

PART B: SPECIFIC

Please note: One copy of Part B is required for each X-ray source for which review is sought.

1. This sheet refers to X-ray source number _____ of _____ X-ray sources located in the room designated as _____ and so marked on the accompanying drawings.

2. This X-ray source is used for _____

   It is identified by:

   Make/Model _____ Serial No. _____ and has the following operating characteristics:

   (a) the maximum rated tube voltage is _____ kilovolts;

   (b) the maximum rated tube current is _____ milliamperes;

   (c) the anticipated maximum workload is _____ milliampere-minutes per week.

3. The composition of the boundaries of the room, including windows and doors, are (give material types and thicknesses):

   Floor _____

   Ceiling_____

   Walls: North _____

   East _____

   South_____

   West _____

	Occupancy (See Note 1)		Usage Factor (See Note 2)
Direction	Type	Per Cent	Per Cent
Down	.....	.....	.....
Up	.....	.....	.....
North	.....	.....	.....
East	.....	.....	.....
South	.....	.....	.....
West	.....	.....	.....

Note 1: Occupancy type is the nature of use of the area in the indicated direction relative to the X-ray source (e.g., office, waiting room, parking lot, etc.). Occupancy percent is the fraction, expressed as a percentage, of the time the area will be occupied while the source is on (omit if unknown).

Note 2: The use factor is the fraction of the time the beam will be pointed in the direction indicated, as a percentage of the total time the source is on. For uncollimated, panoramic or multiple beams, the sum may exceed 100 per cent.

The information given in this Part must correspond with that given on the accompanying floor plans.

R.R.O. 1990, Reg. 861, Form 2.

R-25

A TECHNICAL GUIDE

TO THE

X-RAY SAFETY REGULATION

UNDER THE OCCUPATIONAL HEALTH AND SAFETY ACT

Radiation Protection Service
Ministry of Labour

December 1986

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INTRODUCTION

The purpose of this guide is to provide information and advice to persons in workplaces that are subject to the X-ray Safety Regulation under the Occupational Health and Safety Act of Ontario. It explains the basis for the requirements contained in the regulation, and gives guidance on how to comply with them.

X-rays are one type of ionizing radiation. Other common types are alpha particles, beta particles, gamma rays and neutrons. The property common to all of these is that when they interact with matter, electrons are removed from atoms to form ions. In living tissue, the ionization of atoms may lead to biological changes, and some of these changes may result in adverse health effects. The effects of ionizing radiation on human health are reviewed in Chapter 3 of this guide.

Both X-rays and gamma rays are also forms of electromagnetic radiation. The spectrum of electromagnetic radiation includes radio waves, microwaves, infrared radiation, visible light and ultraviolet radiation. The only characteristic that distinguishes X-rays and gamma rays from these other forms of electromagnetic radiation is that they have more energy, and are therefore able to produce ionization. There is no difference in the properties of X-rays and gamma rays; only their origins are different. Gamma rays are emitted by the atomic nuclei of some radioactive substances. X-rays are produced when an electron loses energy.

In Canada, human exposure to gamma rays and other nuclear radiations is regulated by the federal government under the *Atomic Energy Control Act* and regulations. The agency responsible for the enforcement of this legislation is the Atomic Energy Control Board (AECB), and any questions concerning protection from nuclear radiation should be directed to officials of the AECB.

X-ray safety is a provincial concern. In Ontario, enforcement of the X-ray Safety Regulation is the responsibility of the Ministry of Labour. Occupational X-ray safety inspections are conducted by staff of the Radiation Protection Service, Occupational Health and Safety Branch, Operations Division. Any telephone inquiries concerning occupational X-ray safety and the enforcement of the legislation may be made to the Radiation Protection Service at (416) 235-5922. Written inquiries and applications for registration or plan review under the regulation should be sent to:

Director,
Occupational Health and Safety Branch,
c/o Radiation Protection Service,
Ministry of Labour,
655 University Ave., 14th Floor,
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This guide has no legal force. Any question of satisfactory compliance can only be answered by reference to the *Act* and regulation. Disagreement between officials of the Ministry of Labour and an affected person concerning the application of the legislation may ultimately be resolved by the courts.

1. EXPLANATION OF THE REQUIREMENTS OF THE REGULATION

This chapter gives a section-by-section discussion of the regulation with background information and advice on compliance with the requirements. Subsections and paragraphs whose meaning and intent are obvious are not discussed.

Section 1: Definitions

Many of the definitions are of the quantities and units used in radiation protection, and these are described in Chapter 2. Of the remaining definitions, the following deserve some elaboration:

"X-ray source" - This is a more general term than "X-ray machine". It includes X-ray machines and all other devices that may produce X-rays even though not designed or intended to do so. Some examples of X-ray sources that are not X-ray machines are electron-beam welders, high-voltage vacuum tubes, electron microscopes.

"X-ray worker" - An important element of this definition is that the potential for X-ray exposure must be a necessary consequence of the job and not unrelated to it. For example, a secretary who happens to work near an X-ray room would not be included in this definition of X-ray worker. It is sometimes difficult to evaluate the possibility that a worker may receive a dose equivalent in excess of the Column 4 limits in the Schedule. As a general guide, the Ministry will normally consider the possibility to exist in the following situations:

- the worker works in close proximity to an unenclosed primary X-ray beam, e.g., veterinary radiology, X-ray diffraction device with open beam, medical fluoroscopy;

- the worker works in an area where the air kerma rate may exceed 0.1 mGy in one week, e.g., some industrial radiography operations;

- the worker services and tests X-ray sources; or

- the workplace has a record of dosimeter results with doses in excess of 50 per cent of the limits given in column 4 of the Schedule.

These workers should be classified as X-ray workers by the employer. The consequences of a worker being so classified are:

- an employer must inform an X-ray worker of his/her classification and of the applicable dose limits, and must maintain a list of the classified X-ray workers in the workplace (section 9);

- an X-ray worker is subject to higher X-ray dose limits than other workers (section 10); and

- an X-ray worker must be provided with a suitable personal dosimeter by the employer (section 12).

With these few differences, the provisions of the regulation afford protection to <u>all</u> workers who may be exposed to X-rays.

"X-rays" - For the purposes of this regulation, the term "X-rays" is limited to include only X-rays that are electrically generated and that have a maximum photon energy of at least 5,000 electron volts (5,000 eV or 5 keV). The electron volt is a unit of energy; it is the amount of energy an electron receives by acceleration through a potential difference of one volt. Thus, only electric devices in which there is a voltage of at least 5,000 volts between conductors in a vacuum are capable of producing X-rays that are subject to this regulation.

Section 2: Application

The regulation applies to every workplace where an X-ray machine is present. It also applies to a workplace where an X-ray source other than an X-ray machine is present if the X-ray source is capable of producing an air kerma rate greater than 1.0 μGy/h (an exposure rate of more than 0.115 mR/h) at any accessible point. This condition effectively excludes devices such as cathode-ray tubes and electron microscopes. If an excluded device is damaged or modified in such a way as to increase the air kerma rate above 1 μGy/h, it then becomes subject to the regulation.

Section 3: Exemptions

An X-ray source operating at very high energies is capable of inducing radioactivity in materials exposed to the X-rays. Such a source is subject to licensing under the *Atomic Energy Control Act (Canada)* and is exempt from this regulation. Radioactivity is unlikely to be induced at X-ray energies below about 10 MeV, so sources operating up to this energy are subject to the regulation. (subsection 3 (1))

The *Healing Arts Radiation Protection (HARP) Act* applies to X-ray machines used for the diagnosis or therapy of human patients by physicians, dentists, chiropractors and podiatrists. For such machines, the *HARP Act* requires registration with, and installation approval by, the Ministry of Health. The *HARP Act* also requires the designation of a radiation protection officer for each X-ray facility. Since sections 5, 6, 7 and 8 of the X-ray Safety Regulation impose similar requirements, X-ray machines subject to the *HARP Act* are excluded from these sections. This avoids unnecessary duplication of requirements. (subsection 3 (2))

Section 4: Prohibition

The *HARP Act* establishes the conditions under which a person may be legally exposed to X-rays. Any other deliberate exposure of a worker is illegal.

Section 5 and Form 1: Registration

Note that it is the employer who is registered, not the X-ray source or location. An employer is required to register the first time any X-ray source comes into his/her possession and before it is put into use. Registration does not need to be repeated if additional sources are acquired. An employer "in possession" of an X-ray source has discretionary authority over its use; the source may be owned, leased or borrowed. (subsection 5 (1))

To apply for registration, the employer or his/her agent must complete and sign Form 1, Application for Registration, and submit it to the Director at the address given in the Introduction. Upon receipt of the application by the Ministry, the employer is assigned a registration number and an X-ray safety file is opened. (subsection 5 (2))

Blank copies of Form 1 are obtained by writing to the Director or by telephoning the Radiation Protection Service at (416) 235-5922.

An employer who had registered under previous Ontario X-ray safety regulations, and whose registration was active at the time the present regulation came into force, is not required to register again. (subsection 5 (3))

When an employer sells, trades in, loans, scraps or otherwise disposes of an X-ray source subject to this regulation, he/she must notify the Director of that fact. Employers are requested also to indicate the means of disposal and the name of the recipient, if any. (subsection 5 (4))

If an employer disposes of all X-ray sources in his/her possession, and so notifies the Director, that employer's registration is then terminated and his/her file is closed. If such an employer again comes into possession of an X-ray source, he/she must re-register with the Director. (subsection 5 (5))

Section 6 and Form 2: Plan Review

This section applies to X-ray sources used in a permanent location, including those sources designed for portable or mobile use but that are used regularly in one location (e.g., in one room). Such X-ray sources must not be installed or used before an application for plan review has been accepted by an inspector of the Ministry. (subsection 6 (1))

If an X-ray source was in use in a permanent location before April 27, 1984, and it has remained in that same location since then, an application for plan review is not required. An X-ray source that came into use in a permanent location after April 26, 1984, and for which the plan was reviewed and accepted under Ontario Regulation 263/84, is also exempt from this requirement. (subsection 6 (2))

An application for plan review must include a completed Form 2 (Application for Review of Permanent X-ray Location) and two copies of plan location drawings (i.e., floor plans). The drawings must meet the requirements listed in subsection 6 (4). The application is made to the Director, at the address given in the Introduction. Blank copies of Form 2 may be obtained by writing to the Director or by telephoning the Radiation Protection Service at (416) 235-5922. (subsections 6 (3) (4) (5))

Once an application has been reviewed and found acceptable by a Ministry inspector, one copy of the plan location drawings will be stamped and returned to the applicant. The X-ray installation must conform to the accepted application and plan location drawings. (subsection 6 (6))

If, after the preceding requirements have been satisfied, there is a change made to the X-ray source, its manner of use or its location, and the change may result in an increase of a worker's exposure, then the change must be reviewed and accepted by an inspector before the source is used. A request for a review of such a change must be submitted to the Director. Some examples of changes that may require a review are:

- an increase in the operating voltage or workload of the X-ray source;
- a decrease in the shielding of an X-ray room;
- an increase in the occupancy of areas adjacent to an X-ray room; or

- a change in the orientation of the X-ray beam. (subsections 6 (7) (8))

Form 2 is divided into Part A: General, and Part B: Specific. One completed Part A is required for each building or mailing address for which review is sought. Each Part A must be accompanied by the corresponding floor plans in duplicate. Legally, it may be necessary to apply for plan review before applying for registration. However, if the employer was not previously registered, it is usually simpler to submit both applications at the same time. The person designated in item 6 of Part A is the person mentioned in section 8 of the regulation (see below).

One completed Part B of Form 2 must be submitted for each X-ray source for which review is sought. If two or more X-ray tubes are powered by the same high-voltage supply, one Part B must be submitted for each tube.

For item 2 of Part B, the use of the source should be given in general terms, e.g., veterinary radiology, X-ray diffraction. The maximum rated tube voltage and current are the highest values at which the source is designed to operate. For X-ray sources other than X-ray tubes, the electron accelerating voltage should be entered for "tube voltage", and the electron beam current should be entered for "tube current". Where the maximum voltage and current cannot be attained at the same time, the maximum voltage should be entered and the maximum current at that voltage should be given. The workload is a measure of the cumulative X-ray output of the source. To calculate the maximum workload in the units specified on the form, multiply the maximum tube current (b) by the maximum number of minutes that the source may be operating in any one week.

Example 1. Pulse type X-ray machines.

Suppose that the tube is operated at a maximum of 30 mAs (300 mA for 1/10 second) and that up to 20 exposures may be taken per week. Then the maximum workload is:

$$\frac{30 \text{ mAs/exposure} \times 20 \text{ exposures/week}}{60 \text{ seconds/minute}}$$

$$= 10 \frac{\text{mA-minutes}}{\text{week}}$$

Example 2. Continuous-beam X-ray machines.

Suppose that the tube is operated at a maximum current of 5 mA for 10 hours per week. Then the workload is:

$$5 \text{ mA} \times 10 \frac{\text{hours}}{\text{week}} \times 60 \frac{\text{minutes}}{\text{hour}} = 3000 \frac{\text{mA-minutes}}{\text{week}}$$

The use of maximum values may lead to an over-estimate of shielding needs, but it helps to ensure that dose limits will not be exceeded. This may also be considered to be a practical application of the ALARA principle, discussed under section 10.

Item 3 of Part B is mainly applicable to X-ray rooms in which open-beam X-ray equipment is operated. For cabinet-type X-ray equipment, to which section 17 applies, the information requested is not relevant. Instead of providing this information, it is sufficient to indicate that the source satisfies the requirements of section 17. For other types of X-ray source, item 3 must be completed in full to permit a review to be done. Incomplete forms, and drawings which do not meet the requirements of subsection 6 (4), will be returned to the applicant as unacceptable.

Section 7: Information Concerning Portable or Mobile X-ray Sources

Whenever an employer comes into possession of a portable or mobile X-ray source, he/she must notify the Director in writing and provide the information listed in subsection 7 (2). Note that this section applies only to those sources that will be used primarily in a portable or mobile mode; those that will be used regularly in one location are subject to section 6.

Section 8: Designation of Contact Person

The person designated by the employer under this section will serve as the primary contact for the Ministry in matters of X-ray safety, such as inspections, complaints, enquiries, etc. Normally, it is most effective to designate one person to exercise direction over the safe use of all X-ray sources at one location. In addition to being technically competent in X-ray safety, the designated contact person should:

- be able both to represent the employer and to commit funds and worker time to comply with the requirements of the regulation and any orders issued by a Ministry inspector;

- be a member of the joint health and safety committee, if there is one; and

- co-ordinate all applications for plan review for X-ray sources in the employer's workplace.

An employer may designate himself/herself as contact person if he/she is technically competent. The name of the contact person must be entered in item 6 of Form 2, Part A, when an application for plan review is submitted to the Director. The Director must also be notified if a new contact person is designated.

Section 9: Information to X-ray Workers

Once a position or job has been classified as that of an X-ray worker according to the definition in the regulation, any person who is hired or transferred into that position or job must be informed of the classification and of the corresponding dose limits. Female X-ray workers must also be informed of the special dose limit for pregnant X-ray workers given in subsection 10 (2). (subsection 9 (1))

There are also general requirements in the Occupational Health and Safety Act that the employer "provide information, instruction and supervision to a worker to protect the health or safety of the worker" (clause 14 (2) (a)), and that the employer "acquaint a worker ... with any hazard in the work and in the ... use ... of any ... article, device, equipment or a ... physical agent" (clause 14 (2) (c)). For X-ray sources, all workers must be informed of the hazards associated with X-rays and the particular sources that they may be using or that they may be close to. They must also be informed of the safety precautions to be taken.

An up-to-date list of all classified X-ray workers must be kept available in the workplace for review by a Ministry inspector. (subsection 9 (2))

Section 10 and Schedule: X-ray Dose Limits

An explanation of radiation quantities and units may be found in Chapter 2 of this guide. The annual dose limits for X-ray workers, set out in Column 3 of the Schedule, are those recommended by the International Commission on Radiological Protection (ICRP) in their publication 26.

The limits on the whole-body dose equivalent and on the effective dose equivalent are intended to limit the risk of cancer and genetic damage. Because these two health effects of X-rays are assumed not to have a threshold dose (see Chapter 3), it is impossible to set a dose limit that will ensure that the effects will not occur. Instead, the approach of the ICRP has been to recommend limits that would result in an average worker risk that is comparable to the risk of fatality in industries generally considered safe (i.e., with an average annual fatality rate not greater than 1 per 10,000 workers). The annual limits based on this approach are therefore not considered to be absolutely "safe" limits. Rather, they are considered to be annual doses above

which no worker should be exposed because the risk of health effects becomes unacceptably high.

In addition to the limits, the ICRP recommends that all doses be kept as low as reasonably achievable, economic and social factors being taken into account. This is the so-called "ALARA" principle, and it has been included in this section of the regulation. Since there is assumed to be a risk of health effects associated with doses below the limits, these doses should be minimized. As measures are taken to reduce doses, the cost of each additional decrease will be higher. A stage will be reached where any further time and money would be more effectively spent reducing the risk of other occupational health and safety hazards. At this stage, doses have become as low as reasonably achievable according to the approach used by the ICRP.

A detailed cost-benefit analysis to determine whether doses have reached the ALARA level is not practical or appropriate for all workplaces. A simpler approach is to compare the doses received by X-ray workers in the workplace under consideration with those received by X-ray workers doing similar jobs in other workplaces. If the comparison shows that doses are substantially and systematically higher in the workplace under consideration, then it is likely that these doses could readily be reduced. Examples of possible dose-reduction measures are increased shielding, reduced beam size, improved operating procedures, restricted access to radiation areas and the use of protective equipment and garments.

The Schedule also specifies dose limits for the lens of the eye, the skin and other individual organs or tissues. These limits are set at annual values which will ensure that a worker will not receive more than a threshold dose for tissue damage over the course of a working lifetime. In most practical cases of X-ray exposure, the limits on whole-body dose and on effective dose equivalent will be more limiting than the individual organ dose limits. An exception is exposure to low-energy X-rays, which do not penetrate very deeply into the body. In this case, the dose to the skin or the eyes may be the limiting factor.

Workers who are not classified as X-ray workers are subject to lower dose limits, which are set out in Column 4 of the Schedule. These are equal to the limits recommended by the ICRP for individual members of the public. They have been adopted for this regulation because personal monitoring is not

required for non-classified workers and because exposure to X-rays is not a necessary part of their jobs.

Compliance with the dose limits for an X-ray worker will normally be demonstrated by the personal dosimeter readings. These readings will be assumed to be representative of the dose received by the monitored part of the body unless there is evidence that they are not. For a non-classified worker, compliance with the dose limits can usually be verified on the basis of an X-ray survey of the workplace. If there remains some uncertainty, the worker should be either classified as an X-ray worker and provided with a personal dosimeter or moved to a different work location.

Note (b) to the Schedule gives the sources of ionizing radiation doses that are not to be included in the annual limits. Everyone is exposed to natural background sources of ionizing radiation. These include cosmic rays and naturally radioactive material in the environment. The average effective dose equivalent due to these sources is about 2 mSv per year, but it varies widely depending on geology, altitude, building materials and other factors. There are also manufactured sources of low-level background radiation, such as radium-dial watches and clocks, smoke detectors and some optical glass. Since doses from background radiation are not within the control of the employer and are received by everyone, they are not included in the occupational dose limits.

Also excluded are doses received by a worker who undergoes medical diagnostic or therapeutic procedures as a patient. These include medical and dental X-rays, fluoroscopy, nuclear medicine procedures, and radiation therapy for cancer and other disease. These exclusions are based on the premise that the patient will receive some direct benefit from undergoing the procedures. It is the responsibility of the professionally qualified person who prescribes the procedure to establish that the benefit to the patient outweighs the risk associated with the radiation exposure. In Canada the average annual effective dose equivalent from medical diagnosis is about 1 mSv.

Note (c) to the Schedule states that the annual dose limits include any dose received by a worker from all occupational sources of ionizing radiation. If a worker is exposed to radiation other than X-rays as a part of his/her occupation, the dose from this radiation must be added to any dose from X-rays for comparison with the limits. For example, an X-ray worker who has

received a whole-body dose of 20 mSv from gamma rays since the start of the year may not receive more than 30 mSv from X-rays that year without exceeding the annual limit.

There is a special dose limit for a pregnant X-ray worker. This limit, 5 mSv mean dose to the abdomen during the full term of pregnancy, is intended to prevent developmental defects due to X-ray exposure of the embryo or fetus and to minimize the potential risk of childhood cancer (see Part D of Chapter 3). The choice of this limit was based on the following additional considerations:

- an unborn child should not be permitted to receive a dose in excess of the annual limit recommended by the ICRP for a member of the public, 5 mSv; and

- the limit is the same as that used in the United States, and it is the lowest such limit in use anywhere in the world.

There is obviously a potential for exposure of an embryo during the time between conception and the time the woman realizes she is pregnant. This period is unlikely to be more than two months, and it is most unlikely that an X-ray worker would receive an abdominal dose greater than 5 mSv during this period. To ensure compliance with the dose limit, it may be necessary to estimate the dose received by the abdomen during the period of unknown pregnancy. This can usually be done on the basis of past dosimetry records and by promptly sending in the woman's personal dosimeter for reading when the employer is advised of the pregnancy. The estimated dose is then subtracted from 5 mSv to determine the limit for the rest of the pregnancy.

If the pregnant worker continues to work as an X-ray worker, then, of course, her abdominal dose (usually taken to be equal to the whole-body dose) must be monitored with a personal dosimeter. It is recommended that a pregnant worker <u>not</u> be issued with a personal dosimeter on a more frequent reading schedule than that used before her pregnancy. This is likely to result only in a less sensitive measure of the dose she receives since doses of less than 0.2 mSv per dosimeter are not recorded.

Section 11: General Safety Requirements

This section presents X-ray safety measures and precautions that are applicable to all workplaces where X-ray sources are used.

The first precaution is to ensure that workers are aware of the presence of X-rays. This may be done by posting warning signs or installing warning devices in conspicuous locations. This section does not specify the particular type of sign or warning device because no one arrangement is suitable for all types of X-ray source. Whatever is chosen, it must provide an adequate and appropriate warning to workers using the X-ray source or working in proximity to it. (paragraph 1)

A label must be affixed to the control panel of every X-ray source capable of producing an air kerma rate greater than 5 μGy/h (an exposure rate of more than 0.575 mR/h) at any accessible point. The label must identify the device as a source of X-rays, and it should caution against unauthorized use. Most new X-ray equipment is supplied with a suitable warning label. (paragraph 2)

Access to high radiation areas must be controlled, both for fixed and for portable or mobile X-ray sources. A high radiation area is one in which the air kerma may exceed 100 μGy in any one hour (equivalent exposure: 11.5 mR).

For permanent installations (those subject to section 6), all doors, panels and gates giving access to the high radiation area must be provided with locks or interlocks. If locks are used, the operator of the X-ray source will be responsible for ensuring that the area is vacated and that the locks are engaged before energizing the source. Interlocks must be designed so that the source cannot be energized until all interlocks are engaged and so that the source is adequately shielded or the production of X-rays is stopped if an interlock is opened during operation of the source.

If an X-ray source is being used in a portable or mobile mode, access control is achieved by erecting barriers and posting warning signs to delimit the high radiation area. The barriers and signs must be conspicuous and their meaning clear. In addition, the operator should maintain continuous visual surveillance of the high radiation area to ensure that it is kept clear of workers (and members of the public) during X-ray production. (paragraph 3)

There are two measures that may be necessary or desirable to ensure that the dose limits of section 10 are not exceeded. One is to provide shielding, either as a part of the X-ray source or as a part of the surrounding structure or both. Structural shielding is subject to review and acceptance by the Ministry of Health if the X-ray installation is subject to the *HARP Act*; otherwise it is subject to review and acceptance by the Ministry of Labour under section 6. The second measure is to limit the lateral dimensions of the useful or primary X-ray beam. This measure will reduce the amount of scattered radiation and, in some situations, it will also reduce the chance of accidental exposure to the primary beam. (paragraph 4)

Section 12: Personal Dosimetry

The "suitable" personal dosimeter that an employer is required to provide to X-ray workers is one that provides a measure of the dose received by the exposed part of the body. It must respond to X-rays in the energy range to which the workers may be exposed. The wearing position is discussed in Chapter 2.

An "accurate" measure of the dose is given by a dosimeter supplied by a dosimetry service that meets the Ministry of Labour standard for X-ray dosimetry services. This standard imposes requirements on accuracy and precision under a variety of conditions of use. It also requires the dosimetry service to establish a detailed quality assurance program to ensure the continued accuracy of dosimetry results. Devices such as direct-reading dosimeters and electronic alarming dosimeters are not considered to be adequate for personal dosimetry. (subsection 12 (1))

In order for the dosimeter results to be valid, the dosimeter must be used correctly. It is the employer's responsibility to instruct the worker on the correct manner of use, and it is the worker's responsibility to follow that instruction. (subsection 12 (2))

To ensure that a personal dosimeter is read accurately, the employer must return it to the dosimetry service at the end of the period for which it was issued. When the results are received from the dosimetry service, each worker to whom a dosimeter was provided must be notified of the indicated dose, even if it is nil. The notification procedure is up to the employer and workers to arrange. (subsection 12 (3))

The employer is responsible for verifying that the reported dosimeter reading is reasonable. This verification is based on his/her knowledge of the conditions in which the dosimeter was used. A reported dose that is significantly higher or lower than expected must be brought to the attention of a Ministry inspector. (subsection 12 (4))

Dosimeter results must be retained by the employer for a minimum of three years. They must be kept in a readily accessible location at the workplace to ensure that they will be available for review by a Ministry inspector during an X-ray safety inspection. Lifetime dose records for all radiation workers in Canada are kept in the National Dose Registry, which is maintained in Ottawa by Health Canada. (subsection 12 (5))

Section 13: Investigation Level

The average annual X-ray dose received by Ontario X-ray workers is well below the limits given in Column 3 of the Schedule. It is therefore unusual for an X-ray worker to receive a dose that is a large fraction of the annual limit.

This section requires that an employer investigate all cases of workers receiving, in a period of three months, a dose that exceeds the annual limits in Column 4 of the Schedule. This means that, for workers on a quarterly dosimeter issue, any dosimeter reading in excess of 5 mSv for whole-body dose or 50 mSv for skin dose will initiate an investigation. For workers on a more frequent dosimeter issue, the level applies to any three-month period. The results of the employer's investigation, and any action taken to prevent a recurrence, must be reported in writing to the Director and to the joint health and safety committee or health and safety representative, if any.

Section 14: Overexposure Incidents

If a worker receives a dose that is known or believed to be in excess of the limits in Column 3 of the Schedule as a result of an accident, equipment failure or other incident, the employer must immediately notify the Director and the joint health and safety committee or health and safety representative, if there is one. This immediate notification is required to enable the Director to order a prompt investigation by a Ministry inspector. The purpose of the investigation is to:

- estimate the dose(s) received by the worker(s) involved (especially important if dosimeters were not used);
- determine the cause of the incident;
- ensure that action is taken to prevent a recurrence; and
- ensure that suitable medical attention is provided.

In addition to the immediate notification by telephone, telegram or other direct means, the employer must send a written report of the incident to the Director within 48 hours.

Section 15: Industrial Radiography

For the purposes of this section, the terms "industrial radiography" and "industrial fluoroscopy" refer to the use of X-rays for nondestructive testing of manufactured objects. They do not include applications such as security checks or the examination of art, foodstuffs or natural materials. However, if these other applications employ similar techniques to those of industrial radiography or fluoroscopy, a Ministry inspector may require the use of similar safety precautions. Also excluded from the provisions of this section are cabinet-type X-ray devices that come under section 17. (subsection 15 (1))

The "competent person" mentioned in subsection 15 (2) is considered by the Ministry to be one who has been certified to Level 1 Industrial Radiography under the Canadian General Standards Board Standard 48GP-4M. Alternative standards or qualifications may be specified by the Ministry as they become available.

Detailed safety requirements for industrial radiography are listed in subsection 15 (3). The requirements of paragraph 4 are intended to prevent a worker from entering an X-ray room while the machine is on, and those of paragraph 5 are intended to prevent a worker from being accidentally left in an X-ray room when an exposure is started. The suitability of the warning devices is determined by the nature of the workplace. Illumination, noise levels, obstructions, etc. should all be taken into account.

Industrial radiography often requires that X-rays be produced at high energies and high intensities, resulting in a greater risk of worker exposure than most other applications. A special design or operational limit for the weekly dose received by a worker is therefore specified. This is intended to help ensure that annual dose equivalents are maintained well below the limits. A weekly design limit also simplifies shielding design and evaluation, which are based on the maximum anticipated weekly workload. (paragraph 6)

A direct-reading dosimeter (DRD) is one that a worker wears and can read directly to obtain an immediate indication of his/her short-term exposure. Such a dosimeter must be provided to any X-ray worker who may be exposed to an air kerma rate of more than 100 μGy/h (an exposure rate of more than 11.5 mR/h). A suitable DRD will be sensitive to X-rays of the energy range to be used and will have a full-scale reading of not more than 2,000 μGy air kerma (or 200 mR exposure) or the equivalent. The most common DRD is the pocket ionization chamber, which is held up to a light to read. Electronic DRDs, which usually have audible warning signals as well, may also be used if they have adequate sensitivity. (paragraph 7)

Many DRDs, especially the pocket ionization chambers, have a tendency to accumulate an exposure reading while not in use. It is therefore important to take readings at the beginning and end of each work day and to record the difference as the reading for the day. (Alternatively, the DRD could be zeroed at the beginning of each work day.) The record of daily readings must be retained by the employer for at least three years. This is to permit a Ministry inspector to review the records and to compare them with the personal dosimeter records for consistency. (paragraphs 8, 9)

For portable or mobile industrial radiography, a suitable survey meter must be provided for each X-ray machine in use. A suitable survey meter is one that will permit the operator to verify that the requirements of this regulation are met. Many survey meters that are designed and used for gamma radiography are not suitable for X radiography because they are very inaccurate at typical X-ray energies. This is especially true of most survey meters that use a Geiger-Mueller tube. Ionization-chamber-type survey meters are usually much better, but they are also more expensive and fragile. Whatever survey meter is used, it must be calibrated at suitable X-ray energies so that its accuracy (or calibration factor) is known. If a survey meter is initially calibrated to both X-ray and gamma-ray (e.g., Cs-137 or Co-60) energies so

that the relative response is known, then subsequent calibrations (required annually) may be done with gamma rays alone to verify the long-term constancy of the instrument response. The relative response to different energies is unlikely to change unless the instrument is damaged or modified. The names of laboratories equipped to do an X-ray calibration are available from the Radiation Protection Service. (See also the paragraph on survey meters in Chapter 2.) (paragraph 10)

Section 16: Veterinary Radiology

This section contains additional requirements specific to the use of X-rays for the diagnostic radiology of animals.

Whenever possible, X-ray procedures should be done in a room designed for the purpose. The room must be adequately shielded for the type and number of procedures to be done. It should be arranged so as to prevent access during X-ray exposures by anyone except those involved in the procedure. A suitable X-ray warning sign should be posted at each entrance to the X-ray room; wording such as "Caution, X-rays" is recommended. An X-ray room may also be used for other purposes, provided that they do not result in the presence of unnecessary additional persons in the room during an X-ray exposure. (paragraph 1)

The metal housing around an X-ray tube and the attached cone or collimator must be designed and maintained to keep X-ray leakage below 1 mGy air kerma (115 mR exposure) at 1 m in one hour. The limit applies to the maximum kV and output of which the X-ray machine is capable without exceeding its design specifications. (paragraph 2)

The duration of all X-ray exposures must be controlled by a pre-set timer. The switch that starts the exposure must be of the "deadman" type that requires continuous pressure for the duration of the exposure. It should also be of a design that cannot easily be actuated accidentally. The location of the switch must permit the operator to remain at least two metres from the X-ray tube. If the switch is on a cable, the cable must be long enough to permit this distance. The purpose of this requirement is to enable the operator to reduce his/her exposure when it is not necessary to support or restrain the animal. Exposure durations should depend linearly on timer settings to within ± 10%. For

example, increasing the timer setting by a factor of 2 should increase the exposure duration by a factor within the range 1.9 - 2.1. (paragraph 3)

Any portion of the primary X-ray beam that does not intersect the animal and the film is producing scatter but no diagnostic information. To the extent practicable, the dimensions of the X-ray beam must be restricted to those of the film and should be restricted to include only the anatomy of interest. Verification that this has been achieved is provided by evidence of the edges of the X-ray field on the developed film. In addition to improving X-ray safety, this practice will improve image quality, which is adversely affected by scattered X-rays.

The recommended way to limit the beam size is by using a continuously-variable-field-size collimator with dual controls and a visible light field to show the location of the X-ray beam. The positions of the edges of the light field and the X-ray field should coincide to within ± 2 cm at the usual cassette distance. This may be easily checked by setting the collimator to a suitable field size, placing coins on top of a loaded cassette to mark the edges of the light field, then exposing the cassette and developing the film. The images of the coins should lie along the edges of the X-ray field.

Some X-ray machines, especially older units, are provided with a cone and a set of interchangeable diaphragms to produce different field sizes. The diaphragms must be marked with the field size they produce at a given distance, e.g., 20 x 25 cm at 75 cm (or 8" x 10" at 30"). The X-ray tube must be firmly mounted at the correct distance from the cassette. Some means should be provided to permit the cassette to be reproducibly positioned in the X-ray field, e.g., masking tape on the table-top. (paragraph 4)

For radiology with a lateral beam, common in large-animal practice, the cassette must not be held directly by hand, even if protective gloves are worn. The employer must provide either a stand for the cassette or a cassette holder that permits the person supporting the cassette to keep his/her hands off it. The cassette holder should hold the cassette tightly to prevent damage to the cassette through dropping and to avoid rattles that might alarm the animal. (paragraph 5)

If an animal is sedated or anaesthetized before radiology, it should be restrained or supported mechanically rather than by hand during the exposure. Low-density supports (e.g., Styrofoam) and rope ties may be used for this purpose. The operator may then leave the room or stand well away from the X-ray machine during the exposure. (paragraph 6)

If mechanical means of restraint or support cannot be used, protective garments must be worn, both by those persons restraining or supporting the animal and by any other staff whose presence is required during the exposure. Protective aprons must be worn by all staff in the X-ray room, and gloves or mittens must be worn by those holding the animal or the cassette holder. All protective garments must provide protection equivalent to 0.5 mm of lead. An X-ray worker in veterinary radiology who wears a lead apron should wear a personal dosimeter in the collar region to monitor the dose to the head since most of the body will be well protected by the apron. (paragraph 7)

A radiography log giving the date of each exposure and the technique factors (kV, mA, s) used for it is required. This is to enable an inspector to evaluate the work load of the machine and determine the normal range of technique factors that are used. Such a log may also help the veterinary staff to improve the quality of radiographs. (paragraph 8)

In addition to ordering compliance with the requirements given in this section of the regulation, an inspector may make some recommendations as a result of an inspection. Such recommendations may include:

- a technique chart should be developed for each machine, since X-ray output varies from one machine to another;

- film should be processed in accordance with the manufacturer's recommendations, using a fixed time and temperature process;

- chemicals for film processing should be kept fresh and clean, and should be replaced every three months;

- for any machine setting used, the reproducibility of X-ray output in a series of exposures should be such that the ratio of maximum to minimum does not exceed 1:4; and

- X-ray output should increase in proportion to the tube current setting to within ± 10%.

These recommendations are intended to help improve the quality of radiographs and to reduce the need for repeats. They indirectly contribute to preventing unnecessary worker exposure.

Section 17: Cabinet X-ray Equipment

Cabinet X-ray equipment to which this section applies may be found in a variety of applications, such as radiography, security, fluoroscopy and materials analysis. Standards for new equipment of this type are set by federal legislation, specifically the Radiation Emitting Devices Regulation, Part XV. The agency responsible for the enforcement of this legislation is the Bureau of Radiation and Medical Devices of Health Canada. The requirements of this section of the X-ray Safety Regulation apply to new and old cabinet X-ray equipment and are compatible with the federal legislation. An X-ray cabinet that meets the federal standards will also meet the Ontario standards.

The warning device required by paragraph 1 is most commonly a red light, but an alternative device may be satisfactory if it provides an equivalent warning. The shielding standard given in paragraph 3, 5 μGy/h air kerma rate at 5 cm, is equivalent to 0.575 mR/h exposure rate at 5 cm.

If a cabinet is large enough and so arranged as to permit a person to enter it, some additional safety features are required to ensure that no one is inside the cabinet when X-rays are produced. This requirement is more restrictive than that for industrial X-ray rooms (section 15) because a suitable standard for training of cabinet X-ray operators has not been established.

Section 18: Open Analytic X-ray Equipment

The most common type of equipment to which this section applies is X-ray diffraction devices that are not fully enclosed in a cabinet. Standards for new equipment of this type are set by the federal Radiation Emitting Devices Regulation, Part XIV. Equipment that meets the federal standards will also satisfy the requirements of this section.

Most recent X-ray diffraction equipment has a dual warning light immediately below the shutter to show when it is open. Older equipment may provide only a mechanical indicator; this is satisfactory provided that it is sufficiently conspicuous and provides a positive indication that the shutter is open. (paragraph 3)

To make it easier to bring older equipment into compliance with paragraphs 1 to 4, the option is given of making any one (or more) of the warning or safety devices failsafe. Users of the equipment must be made aware of which of them is failsafe so that undue reliance is not placed on non-failsafe devices. (paragraph 5)

No portion of the primary beam path should be left open. Air kerma rates in the primary beam are very high (up to about 100 Gy/s near the port), and injury to the skin or eye can result from a very brief exposure. Where the design or use of the equipment precludes enclosing the full beam path, some form of enclosure around the equipment is recommended. In addition, the primary beam must be intercepted by a suitable beam stop as near as practicable to the point where it has served its intended purpose. (paragraphs 6, 7)

Any beam ports that are not used must be secured to prevent inadvertent opening. If the equipment design does not provide adequate protection (e.g., the simultaneous activation of three separate devices before a beam will emerge), the shutter should be fastened shut by mechanical means or a blank plate should be secured to the tube housing. (paragraph 8)

Section 19: Alternative Means of Protection

It is impossible to anticipate all of the types of X-ray equipment to which the regulation will apply. It is also impossible to take into account all of the future technological changes that may occur. Consequently, section 19 makes provision for the "better idea". If someone wants to use a procedure or device different from that specified in the regulation, he/she may do so provided that the Ministry is satisfied that the alternative approach is at least as safe as that required by the regulation.

2. MEASUREMENT OF X-RAYS

Quantities and Units

Before discussing the measurement of X-rays and their effects on health, it is important to establish clearly the quantities and units to be used. A "quantity" is a physical property to be measured or calculated, and a "unit" is a standard amount of a quantity. For example, length is a quantity that may be measured in units of metres, kilometres, feet, miles, etc. Similarly, time is a quantity that may be measured in units of seconds, hours, years, etc. The X-ray Safety Regulation uses the international system of units called SI (Système International), which is the Canadian national standard. All units in the regulation can be expressed in terms of the four base units: metre, kilogram, second and ampere.

The quantity air kerma is formally defined in the regulation as "the sum of the initial kinetic energies per unit mass of all the charged particles liberated by uncharged ionizing radiation in air" (section 1). This definition is related to the fundamental interactions of radiation with matter, and is not easy to explain without going into a lot of detail. It is simpler to consider the way air kerma is used and its relationship to another, more familiar quantity.

Air kerma is a quantity that expresses the intensity of an X-ray field at some point. It is not necessary to specify the composition or geometry of material around that point when stating the air kerma. It is very similar to another quantity used previously for this purpose: the exposure, measured in roentgens (abbreviated R). The primary reason for changing from exposure to air kerma is that the SI unit for exposure (the coulomb per kilogram) is inconvenient to use. Recognizing the problem, the International Commission for Radiological Protection (ICRP) recommends the use of air kerma, measured in units of joule/kg. When used in radiation protection, this unit is given the special name

"gray" (abbreviated Gy). The relationship between the old and new quantities and units is:

1 Gy air kerma = 115 R exposure,

or 1 mGy air kerma = 115 mR exposure.

In terms of rate quantities, this becomes

1 mGy/h air kerma = 115 mR/h exposure

or 1 mR/h exposure = 0.0087 mGy/h air kerma

= 8.7 μGy/h air kerma.

(Here, "m" is the symbol for "milli" and "μ" is the symbol for "micro".)

The next quantity of interest is the absorbed dose. A beam of X-rays carries energy with it. When the beam strikes an object, some of the energy will be reflected (scattered), some may be passed right through (transmitted) and the remainder will be deposited in the object (absorbed). The absorbed dose to an object is the energy absorbed by the object divided by its mass. The unit for this quantity is therefore the joule/kg or gray, the same unit as for the air kerma. (The old special unit for dose was the rad: 1 Gy = 100 rads.)

Unlike the air kerma, the absorbed dose cannot be specified unambiguously without also giving the composition and geometry of the exposed object and the conditions of exposure or measurement. (If the dimensions of an object are large relative to the penetrating ability of the incident X-rays, then the dose will change with location inside the object.) For example, to say that "the absorbed dose was 0.5 Gy" means nothing unless it is also specified that this was the average absorbed dose received by a person's hand.

There is a theoretically well-defined relationship between the air kerma to which a person is exposed and the absorbed dose (or absorbed dose distribution) that he/she receives. This relationship may be difficult to determine in practice because it depends on the energy and direction of the incident X-rays and on the shape, size and composition of the exposed part of the body, not all of which may be accurately known. However, the

relationship can be measured in the laboratory for specific exposure conditions or calculated by using a computer model with simplifying assumptions. In the simplest case of a small mass of tissue surrounded by air, an exposure to 1 Gy of air kerma will result, for X-rays with energies in the range of 0.1 to 10 MeV, in an absorbed dose of about 1 Gy.

Equal absorbed doses of different types of ionizing radiation do not necessarily produce the same degree of human health effect. For example, an absorbed dose from neutrons will produce health effects similar to those from a substantially larger absorbed dose of X-rays. To account for these differences when setting limits on exposure to all types of ionizing radiation, a quantity called the dose equivalent is defined. The dose equivalent is equal to the absorbed dose multiplied by a quality factor, which is a measure of the biological effectiveness of the radiation producing the absorbed dose. For an absorbed dose measured in grays, the special unit for the dose equivalent is the sievert (Sv); the quality factor is a pure number and has no units. (The old special unit for dose equivalent was the rem: 1 Sv = 100 rems.) In the case of X-rays, the quality factor is set to be exactly 1.0, so the dose equivalent in sieverts is numerically equal to the absorbed dose in grays. The only reason for introducing dose equivalent in this regulation is for consistency with other legislation, particularly with the Atomic Energy Control Regulation of Canada. It should be noted that, while absorbed dose can apply to any material, dose equivalent can be used only for human tissue.

In the interests of brevity, the word "dose" is used in this guide to mean "dose equivalent".

The last quantity to describe is the effective dose equivalent, which is defined in Note (a) to the Schedule. This quantity is a weighted sum of dose equivalents received by tissues and organs in the body. The weighting factors have been derived by the ICRP from the relative risks of cancer mortality or serious genetic injury resulting from the tissues and organs receiving the same dose. The effective dose equivalent is therefore proportional to the risk of health effects arising from low dose, partial-body exposures. When a large fraction of the body is uniformly exposed, the effective dose equivalent becomes equal to the average dose equivalent to the exposed portion. An advantage of the use of the effective dose equivalent is that it permits the addition of doses from partial and whole-body exposures in a logically consistent way. For occupational X-ray safety, this quantity is important in

cases where part of the body was shielded from exposure in a well-defined way (e.g., by wearing a protective garment).

Approaches to X-ray Measurement

X-rays may be detected and their properties measured by using a wide variety of techniques based on many different physical principles. These will not be discussed here; the interested reader is referred to the bibliography for a selection of a few of the many works available on the subject. Instead, this section will describe the general approaches to X-ray measurement for the purpose of demonstrating compliance with the requirements of the regulation.

The dose received by a worker as the result of occupational X-ray exposure is best measured by using a personal dosimeter. This is a small, light-weight device that is attached to the worker's body or clothes at all times when occupational X-ray exposure is possible. If the dosimeter is intended to measure the dose to the whole body or to the major portion of the body, it is attached to the clothing on the front of the trunk at waist or mid-chest level. If it is likely that the worker will receive a significantly higher dose to the head or extremities, dosimeters may be obtained to attach to the collar or to a finger, wrist or leg. The dosimeter is worn for a predetermined time interval, ranging from two weeks to three months, and is then sent to the dosimetry service that supplied it. There, it will be read out, and the X-ray dose that was received during the wearing period will be reported to the users. For further information, see the item under the heading "Section 12: Personal Dosimetry" in Chapter 1 of this guide.

It is sometimes desirable to measure the intensity of an X-ray field for various locations around an X-ray source and under various operating conditions. This is done by using a survey meter, an electronic device designed to provide an immediate measure of the X-ray intensity at the position of the meter. Normally, survey meters are small and light enough to be easily carried by hand, but they are too bulky to attach to clothing. Most survey meters currently in use that are designed to measure X-rays (or gamma rays) have a meter or display that gives the quantity exposure rate in units of mR/h. In order to compare the measured values with the air kerma rates stipulated in the regulation, the dial reading should be divided by 115 to get the air kerma rate in mGy/h. A simple approximation is to divide by 100; the air kerma rate will be overestimated by 15 per cent, but this will provide an added measure

of safety when compared directly to the limits in the regulation. Since the uncertainty in the reading of the survey meter may be 15 per cent or more, this procedure will also help to ensure that levels are kept below the legal limits. (To get the air kerma rate in μGy/h using this approximation, multiply the dial reading in mR/h by 10.)

Another approach to X-ray measurement is the use of area monitors. These are electronic X-ray detectors used to provide a continuous indication of the X-ray field at a specific location, such as inside an X-ray exposure room. Often, the detector part of the device that measures the X-ray intensity will be connected by a long cable to the part that shows what the intensity is. This permits remote readout of the X-ray intensity, without human exposure, in an area where the intensity may be very high. In addition, area monitors are usually equipped with warning lights or sirens that provide a warning that the X-ray intensity at the detector has exceeded a preset level. They are a valuable safety feature in an X-ray facility where fields of high intensity and long duration are produced.

3. HEALTH EFFECTS OF X-RAYS

Soon after the discovery of X-rays in 1895 it was observed that high doses to human tissue damage that tissue and produce adverse health effects. A great deal of information has since been accumulated on the effects of ionizing radiation on human health. Despite this wealth of information, some uncertainties remain, especially concerning the effects of low doses. This chapter will give a brief summary of the present understanding of the health effects of ionizing radiation in general and X-rays in particular. Four categories of effect will be described: cancer induction, genetic damage, tissue damage and effects on the irradiated embryo or fetus.

A. Cancer Induction

Persons who have received a large dose of ionizing radiation are known to have a higher probability of developing some types of cancer than persons who have not been exposed. Since the cancers that occur are indistinguishable from cancers due to other causes, knowledge of the connection between radiation exposure and cancer is based solely upon statistical comparisons of groups of people that have been exposed with similar groups that have not. The comparisons are made more difficult by the fact that there is a delay, or latent period, between the time of exposure and the first symptoms of cancer, which may be from 2 to 50 or more years. They are also frequently complicated by the difficulty in finding a suitable, unexposed control group for comparison with exposed groups such as the survivors of nuclear bombings or patients who have received radiation therapy.

For these and other reasons, it is very difficult to determine accurately the probability that a given dose of radiation will eventually result in a cancer that would not otherwise have occurred. Most of the studies that have been conducted involved persons who had received high doses (1 Sv or more) at

high dose rates. These studies have produced fairly consistent estimates of the risk of many types of cancer from exposure in the high dose range. There are no good data on the cancer risk from the lower doses and dose rates more typical of occupational radiation exposure. The fundamental difficulty is that, at low doses, a very large number of persons would be required in both the study and the control groups in order to determine a reliable risk factor. Such a study would be long and very difficult.

Nonetheless, it is important to estimate the cancer risk at low doses in order to be able to establish appropriate dose limits. To do this, it is necessary to make some assumptions, based on the current understanding of radiation effects and on considerations of safety. The three main assumptions that are commonly accepted for purposes of radiation protection are:

- there is no dose below which the probability of cancer induction is zero;

- the probability of cancer induction is linearly proportional to the dose received; and

- the probability of cancer induction is independent of the rate at which the dose is received.

Those assumptions make up what is often called the non-threshold, linear dose-effect hypothesis. On the basis of this hypothesis, the risk factors calculated from high-dose studies are taken to apply to low-dose situations, that is, the risk per Sv is a constant for all doses. Most scientists believe that this approach will not underestimate the cancer risk, so that dose limits based on it will err on the safe side.

The risk factor for whole-body exposure that is generally accepted today is best illustrated by a specific example. If 10,000 people each receive a whole-body dose of 0.1 Sv, there will occur among them an additional 20 - 40 cancer cases, of which about half will be fatal. Because of the long latent period for cancer induction, most of these cancers will appear many years after the radiation exposure. Of a similar group of 10,000 people who do not receive this dose, 1,600 - 1,700 will die from cancer due to other causes. Thus, the radiation-induced cancers represent an increase of about one per cent over the number that would otherwise have occurred. These numbers

illustrate the difficulty, mentioned earlier, of conducting studies to determine the risk of cancer at low doses.

These risk factors are necessarily averages over people of different sex, age, race and culture. The effect of most factors on individual risk is not known. It is therefore inappropriate to apply the average risk factors to estimate the probability that a given radiation dose has induced cancer in a specific individual.

B. Genetic Damage

When there is an exposure of the reproductive organs (testes, ovaries) to ionizing radiation, it may result in changes (mutations) to the genetic information contained in the germ cells (sperm, egg cell) produced by the organs. If a mutated germ cell subsequently contributes to a conception, the genetic errors will be transmitted to the child. Some types of genetic errors are so serious that the child will die before birth or before reaching adulthood. Less serious errors may result in developmental defects or disease in the offspring. Still other errors may produce no observable effect in the first-generation offspring, but may result in health effects in the second and subsequent generations.

Most of what is known about the risk of genetic damage comes from experiments with laboratory animals, and it is not certain to what degree the animal results apply to the human situation. The available data on humans indicate that the genetic risk is not higher than that for animals.

As with radiation-induced cancer, there is nothing distinctive about genetic damage produced by radiation: the same effects can be produced by many other agents (mutagens). So, again, it is a matter of trying to detect a statistical increase in genetic defects in large numbers of children of radiation-exposed individuals relative to those of unexposed individuals.

Also in common with radiation-induced cancer, it is assumed for the purposes of radiation protection that the risk of genetic damage is linearly proportional to the gonadal dose, with no threshold dose, and that it is independent of dose rate. Unlike cancer induction, however, only the dose received by a subgroup of the population (persons who subsequently become parents) contributes to producing genetic damage.

Based on animal experiments and genetic theory, it is possible to estimate risk factors for genetic damage. Using a similar example to that given for cancer induction, if 10,000 future parents receive an average gonadal dose of 0.1 Sv, it is estimated that there would be about 10 serious health effects in the first two generations and an additional 10 serious health effects in all subsequent generations. This result should be considered in the context of the "normal" (i.e., not due to radiation) rate of genetic abnormalities, which is about 10 per cent of all live births.

C. Tissue Damage

Effects in this category result when an organ or tissue receives an X-ray dose that is high enough that a large fraction of the cells in that organ or tissue cannot continue to function normally. These effects have the following characteristics:

a) There is a threshold dose below which no one will suffer the effect. The threshold dose depends on the rate at which the dose is received; the lower the dose rate, the higher the threshold dose.

b) The higher the dose is, above the threshold dose, the greater will be the number of people who will suffer the effect and the more severe will be the effect.

c) At some sufficiently high dose all exposed persons will suffer the effect. This dose may be only a factor of two or three higher than the threshold dose.

d) There is usually a delay between the radiation exposure and the appearance of the effect. The length of the delay ranges from minutes to years, and depends on the size of the dose received and the particular effect. The greater the dose is, the shorter the delay will be.

All organs and tissues in the body will be damaged by sufficiently high doses, but some organs and tissues are more sensitive than others and are therefore of greater importance for occupational X-ray safety. These will be discussed in some detail.

Skin

The most sensitive layer of the skin is the basal cell layer which lies at a depth of 0.02 to 0.4 mm from the surface, depending on the location on the body. A dose of 6 to 8 Sv to this layer in a single brief exposure will produce reddening of the skin (erythema) within one to two days. Higher doses will produce reddening more quickly. The initial reddening will last for about a week and then fade. It may then return about two to three weeks after the exposure and last for 20 to 30 days before fading. There may be several additional cycles of reddening and fading. Progressively higher doses will produce peeling and ulceration. In this last case, if the ulcer fails to heal, skin grafts or amputation become necessary.

Following the short-term effects, there may be long-term changes in the skin. These include a change in the colour, reduced thickness and greater sensitivity to injury.

The severity of the effect depends on the area of skin exposed. For a given dose, a large exposed area will produce a more severe reaction than will a small one.

Another effect of skin irradiation is loss of hair (epilation). Temporary hair loss occurs after a skin dose of 3 to 5 Sv in a single exposure, and a dose of about 7 Sv will result in permanent hair loss.

Eyes

The part of the eye that is most sensitive to X-ray exposure is the lens, and the effect of concern is the formation of cataracts. A threshold dose of 2 Sv to the lens in a single exposure will produce small opacities in some persons after a delay of two to three years, but these opacities do not usually interfere with vision. Cataracts that will interfere with vision result from acute doses greater than about 5 Sv. For doses received at low rates over a period of years, the threshold for opacities is in the range 6 to 14 Sv.

Reproductive Organs

The testes and the ovaries are very sensitive to radiation, and temporary or permanent sterility may result from exposure of these organs to X-rays.

Irradiation of the testes to acute doses as low as 0.08 Sv may result in a reduced sperm count after a delay of 30 to 60 days. Temporary sterility may result from a minimum dose of 0.15 Sv to both testes. Normal fertility will return after several months after such a dose, but it may take several years after higher doses. At low dose rates the threshold for sterility is increased: it appears that a dose rate of 1 mSv per day can be tolerated indefinitely without loss of fertility. A single dose of 5 to 6 Sv will cause permanent sterility in most men.

An acute dose of 0.65 to 1.5 Sv to both ovaries will produce prompt, temporary sterility in women. Permanent sterility may result from single doses of 3.2 to 10 Sv, with a lower threshold in older women than in younger women. At low dose rates, the threshold dose for permanent sterility increases to 6 to 20 Sv.

Bone Marrow

The active bone marrow is the site of blood cell production. Blood cells in circulation have a limited lifetime and must be replaced by new cells from the bone marrow. Exposure of the bone marrow to X-rays may reduce or stop production of blood cells, so that the number in circulation will decrease. Because the active bone marrow is widely distributed in the body, only a whole-body exposure is likely to result in a critical reduction in blood-cell production.

An average whole-body dose of 0.5 to 1.0 Sv received in a single exposure will produce a temporary reduction in the number of blood cells. In this dose range, the bone marrow soon recovers and the blood cell count returns to normal after a few months.

Higher doses result in a more rapid and severe decline in the blood cell count. The lack of white blood cells makes the body more susceptible to infection, and the lack of platelets may result in bleeding. Doses greater than about 2 Sv may lead to death from complications within about six weeks of exposure. The dose at which 50 per cent of exposed persons are expected to die, in the absence of medical treatment, is in the range of 2.5 to 5 Sv. Possible medical treatment includes isolation to prevent infection, antibiotics, transfusions and bone-marrow transplants (if a suitable donor is available), and may permit a person to survive a whole-body dose of up to about 12 Sv.

For chronic exposure at low dose rates, the bone marrow is able to recover and the threshold dose for a serious reduction in the blood cell count is much higher. It is estimated that a dose of 0.4 Sv per year, received at a low dose rate, would not produce a measurable drop in the blood cell count.

D. Effects on the Irradiated Embryo or Fetus

A special concern of many people is the possible health effects on a child resulting from the exposure of its mother to radiation during pregnancy. There are two types of health effects that may result: developmental defects and childhood cancer.

Developmental defects depend both on the dose received and on the stage of pregnancy. There are two main stages: the embryonic stage, lasting to about 50 days after conception, and the fetal stage, lasting for the rest of the pregnancy. In the embryonic stage, the major organ systems are being formed. A dose to the embryo in excess of 0.5 Sv may produce any of a wide range of developmental defects, including malformations, growth retardation and cataracts.

The human brain is different from other organs in that its development begins in the embryo and continues throughout the fetal stage. There is evidence that the brain is most sensitive to radiation during the period between the 8th and the 15th weeks of pregnancy, inclusive. A fetal dose as low as 10 mSv received during this period may result in mental retardation.

Apart from damage to the brain, irradiation of the fetus does not appear to result in developmental defects.

It should be realized that the rate of spontaneous congenital malformations (from causes other than radiation) is about 1 in 20 live births. A small increase in risk due to irradiation of the embryo may therefore be difficult to detect.

Some studies of children who were exposed to X-rays prior to birth have found an association with an increased rate of childhood cancer. Other studies have found no such association. Therefore, cause and effect relationship of fetal irradiation and childhood cancer has not been conclusively proven. If it is assumed to exist, then the risk factor is a maximum of about 5 fatal childhood cancers for 10,000 children who received an average dose of 10 mSv before birth. The normal incidence of childhood cancer is about 1.25 per 10,000 children per year.

4. BIBLIOGRAPHY

A very large number of books, reports and journal articles relevant to X-ray safety have been published. This bibliography is not meant to be in any way comprehensive, but is intended to present a representative selection of the literature available from technical libraries, booksellers and organizations. Notes following each reference provide an indication of the level of the publication and its content, where this is not apparent from the title. The level designations are assigned as follows:

Introductory - suitable for those with scientific or technical knowledge at the secondary school level.

Intermediate - suitable for those with the equivalent of one or two years of university science education.

Advanced - intended for specialists in the field, usually with a minimum educational background equivalent to university graduation in science.

American National Standards Institution

Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment

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- A comprehensive compilation of articles on fundamentals and applications written by experts in the field.

Bureau of Radiation and Medical Devices

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Health and Welfare Canada, Environmental Health Directorate publication 84-EHD-111, 1984.

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Hughes, D.

Notes on Ionizing Radiation: Quantities, Units, Biological Effects and Permissible Doses.

London: Science Reviews Ltd., 1982 (Occupational Hygiene Monograph No. 5.)

- Introductory: general audience.
- Title describes contents.

International Commission on Radiological Protection (lCRP).

Series of publications on a range of topics in radiation protection.

Published by Pergamon Press, Oxford, as the Annals of the ICRP.

- Introductory to advanced: Publications may include recommendations, advice, physical and biological data.

Recent relevant publications include:

- Publications 15 and 21: Protection against Ionizing Radiation from External Sources and Data for Protection against Ionizing Radiation from External Sources.

- Publication 26: Recommendations of the ICRP.

- Publication 28: Principles and General Procedures for Handling Emergency and Accidental Exposures of Workers.

- Publication 33: Protection Against Ionizing Radiation from External Sources Used in Medicine.

- Publication 41: Nonstochastic Effects of Ionizing Radiation.

Johns, H.E. and Cunningham, J.R.

The Physics of Radiology. 4th Ed.

Springfield, IL: Charles C. Thomas, 1983.

- Intermediate: for radiologists and medical physicists.
- Includes radiation production, interactions, dosimetry, radiotherapy planning, protection, radiobiology, diagnostic radiology.

Kase, K.R., Bjarngard, B.E. and Attix, F.H., Eds.

The Dosimetry of Ionizing Radiation, Vol. 1.

Orlando, FL: Academic Press, 1985.

- Advanced.
- Includes dosimetry and microdosimetry theory, photon and electron dosimetry, nuclear particle dosimetry, environmental dosimetry, internal dosimetry.

Kase, K.R. and Nelson, W.R.

Concepts of Radiation Dosimetry.

New York: Pergamon, 1978.

- Advanced.
- Includes detailed treatment of fundamental energy transfer processes, dose calculation for various source geometries, cavity chamber theory.

Kathren, R.L.

Radiation Protection. (Medical Physics Handbooks 16.)

Bristol: Adam Hilger Ltd., 1985.

- Intermediate: intended for medical physicists.
- Includes fundamentals and applications, a discussion of hormesis, history, facility design.

Kereiakes, J.G. and Rosenstein, M.

Handbook of Radiation Doses in Nuclear Medicine and Diagnostic X-ray.

Boca Raton, FL: CRC Press, 1980.

- Advanced: reference volume.
- Provides computed data to permit the estimation of doses received by patients undergoing nuclear medicine or diagnostic X-ray procedures.

Knoll, G.F.

Radiation Detection and Measurement.

New York: John Wiley & Sons, 1979.

- Intermediate.
- Describes in detail techniques and devices for the measurement of all types of ionizing radiation.

Laws, P.W.

X-rays: More Harm than Good?

Emmans, PA: Rodale Press, 1977.

- Introductory: general public.
- Explores the risks and benefits of medical X-rays, and describes ways to minimize doses.

Martin, E.B.M.

A Guide to the Safe Use of X-ray Diffraction amd Spectrometry Equipment.

Middlesex: Science Reviews Ltd., 1983. (Occupational Hygiene Monograph No. 8, Assoc. of University R.P.O.s.)

- Introductory.
- Includes basic physics, biological effects, safety devices and procedures. U.K. orientation.

Mettler, F.A. and Moseley, R.D.

Medical Effects of Ionizing Radiation.

Orlando, FL: Grune & Stratton, Inc., 1985.

- Advanced: mainly for physicians.
- Detailed, with many references to original work.

Moore, T.M., et al Eds.

Radiation Safety in X-ray Diffraction and Spectroscopy.

DHEW Publication No. (FDA) 72-8009 (Proc. conf. Jan. 6-7, 1970, Philadelphia.)

- Intermediate.
- Includes papers on wide range of related topics, e.g., biological effects, safety devices, instrumentation, etc.

Morgan, K.Z. and Turner, J.E., Eds.

Principles of Radiation Protection.

New York: John Wiley & Sons, 1967.

- Intermediate.
- University-level radiation protection text book.

Mould, Richard F.

Radiation Protection in Hospitals.

Bristol: Adam Hilger Ltd., 1985.

- Introductory.
- Includes basic physics, protection in diagnostic and therapeutic radiology and in nuclear medicine.
- Aimed at hospital personnel with a wide spectrum of backgrounds. U.K. perspective.

National Council on Radiation Protection and Measurements (NCRP)

Series of reports on a wide range of topics in radiation protection. Available from: NCRP Publications, 7910 Woodmount Ave., Ste. 1016, Bethesda, MD 20814, USA.

- Introductory to advanced: Reports may include recommendations, procedures, literature reviews, physical and biological data.

Recent relevant reports include:

- Report 35: Dental X-ray Protection (1970).

- Report 36: Radiation Protection in Veterinary Medicine (1970).

- Report 48: Radiation Protection for Medical and Allied Health Personnel (1976).

- Report 49: Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays Up to 10 MeV (1976).

- Report 53: Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women (1977).

- Report 57: Instrumentation and Monitoring Methods for Radiation Protection (1978).

- Report 82: SI Units in Radiation Protection and Measurements (1985).

Noz, M.E. and Maguire, G.Q.

Radiation Protection in the Radiologic and Health Sciences. 2nd Ed. Philadelphia: Lea and Febiger, 1985.

- Intermediate: intended for post-secondary students and practising medical professionals.
- Includes fundamentals and applications.

Parsons, D.F., et al.

Handbook of X-ray Safety for Electron Microscopists.

Electron Microscopy Society of America, 1973.

- Introductory: specific to electron microscopes.
- Includes basic principles, reported X-ray leaks, monitoring equipment, leakage testing.
- Somewhat dated: the suggested precautions appear excessive for recent equipment.

Pochin, E.

Nuclear Radiation: Risks and Benefits.

Oxford: Clarendon Press, 1983.

- Introductory.
- Includes: sources of radiation, measurement, biological effects, comparison of risks.

Profio, A.E.

Radiation Shielding and Dosimetry.

New York: John Wiley & Sons, 1979.

- Intermediate.
- Emphasis on shielding calculations and design; includes some dosimetry and radiation biology.

Scheele, R.V. and Wakley, J.

Elements of Radiation Protection.

Springfield, IL: Charles C. Thomas, 1975.

- Introductory: intended for physicians and medical technologists.

- Includes basic physics and radiation biology, U.S. regulations, X-ray and nuclear medicine safety.

Shapiro, J.

Radiation Protection: A Guide for Scientists and Physicians. 2nd Ed. Cambridge, MA: Harvard U. Press, 1981.

- Intermediate.
- Includes wide range of information relevant to radiation protection; a good introduction.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

Sources and Effects of Ionizing Radiation.

United Nations, New York, 1977.

- Intermediate.
- Extensive, detailed review of information available on sources of human exposure to radiation and on low-level biological effects.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

Ionizing Radiation: Sources and Biological Effects.

United Nations, New York, 1982.

- Intermediate.
- Review of information on sources of human exposure and on genetic and non-stochastic effects of radiation.

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Regulation respecting X-ray Safety

Section

Regulations made under the *Occupational Health and Safety Act* Revised Statutes of Ontario, 1990, Chapter O.1 as amended.

May 1, 2005

A. Safety Regulations

Construction Projects:	O. Reg. 213/91, as amended by O. Reg. 631/94, O. Reg. 143/99, O. Reg. 571/99, O. Reg. 145/00 O. Reg. 527/00, O. Reg. 85/04.
Industrial Establishments:	R.R.O. 1990, Reg. 851, as amended by O. Reg. 516/92, O. Reg. 630/94, O. Reg. 230/95, O. Reg. 450/97, O. Reg. 144/99, O. Reg. 284/99, O. Reg. 528/00, O. Reg. 488/01.
Mines and Mining Plants:	R.R.O. 1990, Reg. 854, as amended by O. Reg. 583/91, O. Reg. 584/91, O. Reg. 171/92, O. Reg. 384/92, O. Reg. 571/92, O. Reg. 693/92, O. Reg. 60/94, O. Reg. 779/94, O. Reg. 68/96, O. Reg. 272/97, O. Reg. 236/99, O. Reg. 486/99, O. Reg. 174/01, O. Reg. 251/01, O. Reg. 291/02, O. Reg. 31/04.
Window Cleaning:	R.R.O. 1990, Reg. 859, as amended by O. Reg. 523/92.
Critical Injury Defined:	R.R.O. 1990, Reg. 834.
Training Requirements for Certain Skill Sets and Trades:	O. Reg. 572/99, as amended by O. Reg. 42/02, O.Reg. 76/05
Diving Operations:	O. Reg. 629/94, as amended by O. Reg. 155/04.
Firefighters-Protective Equipment:	O. Reg. 714/94, as amended by O. Reg. 449/97, O. Reg. 80/02.
Health Care and Residential Facilities:	O. Reg. 67/93 as amended by O. Reg. 142/99.
Oil and Gas-Offshore:	R.R.O. 1990, Reg. 855.
Roll-Over Protective Structures:	R.R.O. 1990, Reg. 856.

Teachers:	R.R.O. 1990, Reg. 857.
University Academics and Teaching Assistants:	R.R.O. 1990, Reg. 858.

B. Designated Substances

Acrylonitrile:	R.R.O. 1990, Reg. 835, as amended by O. Reg. 507/92, O. Reg. 101/04.
Arsenic:	R.R.O. 1990, Reg. 836, as amended by O. Reg. 508/92, O. Reg. 102/04.
Asbestos:	R.R.O. 1990, Reg. 837, as amended by O. Reg. 509/92, O. Reg. 598/94 , O. Reg. 386/00, O. Reg. 103/04.
Asbestos on Construction Projects and in Buildings and Repair Operations:	R.R.O. 1990, Reg. 838, as amended by O. Reg. 510/92, O. Reg. 104/04.
Benzene:	R.R.O. 1990, Reg. 839, as amended by O. Reg. 511/92, O. Reg. 387/00, O. Reg. 105/04.
Coke Oven Emissions:	R.R.O. 1990, Reg. 840, as amended by O. Reg. 512/92, O. Reg. 106/04.
Ethylene Oxide:	R.R.O. 1990, Reg. 841, as amended by O. Reg. 515/92, O. Reg. 107/04.
Isocyanates:	R.R.O. 1990, Reg. 842, as amended by O. Reg. 518/92, O. Reg. 108/04.
Lead:	R.R.O. 1990, Reg. 843, as amended by O. Reg. 519/92, O. Reg. 389/00, O. Reg. 109/04.
Mercury:	R.R.O. 1990, Reg. 844, as amended by O. Reg. 520/92, O. Reg. 390/00, O. Reg. 110/04.
Silica:	R.R.O. 1990, Reg. 845, as amended by O. Reg. 521/92, O. Reg. 391/00, O. Reg. 111/04.
Vinyl Chloride:	R.R.O. 1990, Reg. 846, as amended by O. Reg. 522/92, O. Reg. 392/00, O. Reg. 112/04.

C. General

Biological or Chemical Agents, Control of Exposure to:	R.R.O. 1990, Reg. 833, as amended by O. Reg. 513/92, O. Reg. 597/94, O. Reg. 388/00, O. Reg. 100/04, O. Reg. 16/05, O. Reg. 77/05, O. Reg. 177/05.
Hazardous Materials Inventories:	R.R.O. 1990, Reg. 850, revoked by O. Reg. 397/93.
Workplace Hazardous Materials Information System:	R.R.O. 1990, Reg. 860, as amended by O. Reg. 36/93.

D. Hazardous Physical Agents

X-Ray Safety:	R.R.O. 1990, Reg. 861.

E. Regulations that Directly Affect/Impact the Act

Training Programs:	O. Reg. 780/94.
Unilateral Work Stoppage:	O. Reg. 243/95.
Inventory of Agents or Combinations of Agents for the Purpose of Section 34 of the Act:	R.R.O. 1990, Reg. 852, as amended by O. Reg. 517/92.
Joint Health & Safety Committees-Exemption from Requirements:	O. Reg. 385/96, as amended by O. Reg. 131/98.

NOTE:

For a complete reference to the Regulations made under the Occupational Health and Safety Act, please see the Table of Regulations which is published in print form in *The Ontario Gazette* every January and July, and is published on the e-Laws website [http://www.e-laws.gov.on.ca] under Reference Tables. The website edition is frequently updated.

Ministry of Labour
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Radiation Protection Service

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(416) 235-5922
Fax (416) 235-5926

For inquiries please contact the Ministry of Labour office nearest to you. Consult the blue pages under "Health and Safety" in your local telephone directory for additional information.

NOTE: Spills Action Centre (SAC) for After-Hours Health and Safety Emergencies: (416) 325-3000 or (800) 268-6080.

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R.R.O. 1990, Reg. 861

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