X-RAY SAFETY MANUAL

A manual of guidance, policies and procedures specific to the use of x-rays in Diagnostic Imaging, Winnipeg Regional Health Authority.

WRHA X-ray Safety Committee

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1.0 INTRODUCTION

1.1 Purpose of the Manual

The Winnipeg Regional Health Authority (WRHA) X-Ray Safety Committee (XRSC) has undertaken the development of this manual to provide a common basis for information about x-ray safety and the x-ray safety procedures within the hospital facilities in order that:

- the use of all x-ray sources under WRHA control is done in such a way that health and safety of all staff, patients and the environment are protected; and

- compliance with all relevant federal and provincial regulations concerning x-ray is ensured by adhering with the procedures and recommendations included in this manual.

Adherence to legislative requirements

The main Regulations the WRHA uses of ionizing radiation are:

- The Manitoba X-ray Safety Regulations 341/88R
- The Radiation Emitting Devices Act

Information and guidance is contained in:

- Health Canada “Safety Code 35”

As a general approach, the main purpose of this manual is in the control of radiation exposures to ensure that all exposures are justified; that any necessary exposures are kept as low as is reasonably achievable (ALARA); that the doses received do not exceed certain specified limits; and that allowance is made for future developments.

The technologies of x-ray imaging have advanced and so have their applications. For example, the extent to which fluoroscopically guided interventional procedures are being used by clinical staff not trained in radiology has increased. So has the use of “live-time” CT procedures in which staff is present for part of or the full duration of the scan. It is therefore the hope of the XRSC that this document will be available to all x-ray users and will be of value to them in the course of their work.
1.2 **Definition of Policy**

A policy is a statement of fact or action that is accepted by the XRSC as necessary in order that consistency in the use of facilities or practices may prevail.

1.3 **Fulfillment of Policy**

Overall responsibility for advising the Chief Executive Officer that commitments made in this policy are actively carried out will be taken by the X-ray Safety Committee and the Radiation Safety Council.

1.4 **Definition of Procedure**

A procedure is a set of steps to accomplish an action by which a policy will be fulfilled.

1.5 **Definition of Terminology**

The words “**must**” and “**should**” in this manual have been chosen with purpose. The word “**must**” indicates a recommendation that is essential to meet the current accepted standards of protection. The word “**should**” indicates an advisory recommendation that is highly desirable and that is to be implemented where applicable.

1.6 **Definition of “X-ray Worker”**

Any person whose occupation requires him or her to use or operate an X-ray machine or regularly to enter an X-ray area where the X-ray machine is in use.

2.0 **WRHA RADIATION SAFETY ORGANIZATION**

2.1 **Organization of Radiation Safety in the WRHA**

   a) **Reporting and Accountability Chain**

   A tiered system of safety responsibility and reporting has been developed within WRHA from staff to executives. Individual workers have the first level of safety responsibility, followed by named persons in designated successive technical and management levels. The Medical Director of Diagnostic Imaging has the delegated responsibility for the total radiation safety program. He/she reports to the WRHA Executive on the implementation and needs of the program. The Chief Executive Officer is ultimately responsible to the Board of Directors for the program.

   b) **Allocation of Responsibilities**

   Ultimate responsibility for compliance with radiation safety legislation rests with the WRHA Board and, in particular, the Chief Executive Officer.
c) Medical Physics Experts (MPEs)

The WRHA has appointed MPEs for three main areas of ionizing radiation work:

- Diagnostic radiology (including interventional radiology)
- Nuclear medicine (including therapeutic nuclear medicine)
- Radiotherapy

Involvement of the appropriate MPE in issues of radiation optimisation - including patient dosimetry and quality assurance is required by the forthcoming Manitoba X-ray Safety Regulations.

d) Managerial Controls: Roles of Administrative Managers, Medical Managers and Line Managers

Local managerial control is crucial to the implementation of this policy. It should always be clear at local level which manager takes lead responsibility for each specific legal and operational issue. The differing sizes and complexities of individual areas of the WRHA may make it inevitable that slightly different roles may be allocated respectively to (a) Administrative Managers and Medical Managers and (b) Section Leaders (Line Managers). There must however always be a clear understanding throughout each area (and among all staff) as to exactly where key responsibilities lie. General guidance as to how particular responsibilities may be divided is as follows:

a. Administrative Managers and Medical Managers

- Ensuring that procedures are in place and are reviewed (preferably annually but at least once every three years).
- Ensuring that adequate training is made available to all staff working with radiation – and that accessible records are kept of such training.
- Ensuring that information about radiation, radiation procedures and radiation risks is readily available to all staff working with radiation.
- Ensuring that an inventory is kept of radiation equipment, that this equipment is properly maintained and that an appropriate replacement program is in place.
- Ensuring that arrangements are in place to permit safe, indemnity-covered, use of any equipment on trial, demonstration or testing.
- Ensuring that all equipment used for monitoring radiation levels in controlled or supervised areas is tested at appropriate intervals by an appropriate competent person.
- Ensuring that an investigation is carried out in the event of any staff member receiving an actual or suspected radiation exposure exceeding any local investigation level. Guidance will be given by the Radiation Protection Department of CCMB.
- Ensuring that any incident potentially requiring notification to an external inspectorate is immediately reported to the Radiation Protection Department of CCMB.
- Ensuring that staff working with radiation are appropriately trained for the actual work they carry out.
• Ensuring that risk assessments are in place for all aspects of radiation work – and that these assessments are kept up to date (usually via annual review).
• Ensuring that special measures to restrict staff doses (e.g. in the case of a pregnant member of staff) are implemented and observed.

e) Tiered Committee Structure

Two formal levels of committee structures have been established to review and report the radiation safety programs. The structure is illustrated in Figure 1.

![Committee Structure for the Organization of Radiation Safety in the WRHA](image)

**Figure 1.** Committee Structure for the Organization of Radiation Safety in the WRHA

The terms of reference of the X-Ray Safety Committee (XRSC) are provided in Section 2.3. This committee reports to the Radiation Safety Council (RSC), chaired by the Medical Director, Diagnostic Imaging. The XRSC provides an annual report to the WRHA executive through the Chair of the Radiation Safety Council.

2.2 WRHA Policy on Radiation Safety

Ionizing radiation is capable of producing biological effects that are detrimental to health. It is assumed that any radiation dose, no matter how small, could produce some effect. The purpose of a radiation safety program is to prevent unnecessary radiation exposures, and to control those that are necessary.

The WRHA is committed to high standards of ionizing radiation safety for patients, visitors, staff, trainees and students. To achieve these standards, it actively
supports the three following principles (broadly based on recommendations of the International Commission on Radiological Protection):

- No practice involving exposure to radiation shall be adopted unless it produces sufficient benefit to offset the radiation detriment it causes (justification);
- All exposures shall be kept as low as reasonably practicable (optimisation);
- The radiation exposure to individuals should be subject to dose limits or other control of risk to ensure that no person is exposed to unacceptable radiation risks (limitation).

Medical exposures of patients must be individually justified and optimized to ensure that the exposure should be of net benefit to the individual or society and that the radiation dose is the minimum required for the intended outcome or – in the case of a therapeutic intervention – carefully and appropriately planned.

Throughout this policy, the word ‘patient’ is to be taken also to include any other person undergoing a medical exposure for screening, medico-legal or research purposes.

This policy describes the principal means by which the WRHA seeks to ensure safe and effective use of ionizing radiation, in compliance with the relevant legislation. It covers all sites operated by the WRHA and all aspects of ionizing radiation use.

Particular stress is laid on ensuring that:

- Patients, staff and all other persons affected by the WRHA’s work are not unnecessarily exposed to ionizing radiation.
- Doses from necessary exposures are – except for planned exposures of patients receiving ionizing radiation therapy – kept as low as is reasonably practicable.
- Doses to target volumes for ionizing radiation therapy are carefully and appropriately planned to ensure that doses to non-target volumes and tissues are kept as low as reasonably practicable in relation to the intended radiotherapeutic purpose.

This policy document should be read in conjunction with the WRHA’s Risk and Health and Safety Policies.

2.3 Terms of Reference of the X-Ray Safety Committee

The operation of X-ray equipment in the hospitals of the WRHA is governed by Manitoba Regulation 341/88R. The equipment is licensed by registering it with Radiation Protection Department CCMB and it is subject to compliance evaluation according to national standards. The regulations and standards place responsibilities on the “owner” for the safe operation of the diagnostic x-ray facility.

The WRHA established the X-Ray Safety Committee in 2001 to oversee the
implementation of the X-Ray Safety Program in all of its facilities in accordance with the regulations and compliance standards.

a) Authority

The WRHA and its affiliated sites have bestowed authority on the XRSC, through the respective policies, to implement the X-Ray Safety Program and to develop the necessary procedures for x-ray safety.

b) Reporting

The XRSC reports to the Radiation Safety Council (RSC) on the progress and effectiveness of the X-Ray Safety Program. The RSC in turn reports to the Executive of the WRHA and of the individual hospitals through the Medical Director of the WRHA Diagnostic Imaging Program.

c) Officers

Chair: The Medical Director of the WRHA Diagnostic Imaging Program appoints the Chair of the XRSC. It is the responsibility of the Chair to conduct the affairs of the XRSC according to its Terms of Reference. The Chair is empowered to act on behalf of the XRSC. Any action taken by the Chair will be subject to ratification at the next meeting of the XRSC.

Vice Chair: The Vice Chair is appointed by the Chair and shall act as the designate of the Chair during the Chair’s absence.

Secretary: The secretary is elected from the membership and will serve for a two-year (renewable) term. Responsibilities of the secretary include: preparation and distribution of agenda; recording of the minutes of the XRSC and their distribution within 3 weeks of the meeting date; tracking of decisions and actions; maintaining XRSC correspondence and documentation; distributing minutes and documents of the XRSC to a named list established by the XRSC; maintaining a current list of members.

Quality Manager: The Diagnostic Imaging Quality Manager will serve as an officer of the Committee, providing direction in quality measurements and program development and encouraging the development of the safety program within the context of the broader quality perspective.

d) Membership, Quorum, Consensus, Voting, and Meeting Frequency

The Medical Director of the WRHA Diagnostic Imaging Program appoints the members of the XRSC. The membership shall be reviewed by the Medical Director on a five-year cycle. Members include staff and managers of the WRHA hospitals and
laboratories who have knowledge and stake in the efficient and safe implementation of the X-Ray Safety Program as well as external members who bring expertise to the Committee. A quorum shall consist of 50% plus one member of the voting members of the XRSC. The XRSC operates by consensus. In certain circumstances the Chair may put issues to a vote, in which event the decision shall be that of the majority of voting members present. The Chair shall cast the deciding vote in the case of a tie. The XRSC shall meet no less frequently than semi-annually and may meet at the call of the Chair for special meetings.

2.4 **Duties of the X-Ray Safety Committee**

1. Oversee the X-Ray Safety Program and x-ray safety matters on behalf of the executive of the WRHA, the Diagnostic Imaging Medical Directors and Managers of participating hospitals, and the WRHA Diagnostic Imaging program.

2. Advise Diagnostic Imaging Medical Directors and Managers on x-ray safety matters.

3. Review the design of proposed and the implementation of existing x-ray safety programs and procedures to ensure that x-ray exposures comply with regulatory limits and with the goal that they will be maintained as low as reasonably achievable (ALARA, see section 2.5).

4. Require and enable committee members to remain current with applicable regulatory requirements.

5. Evaluate the degree to which applicable regulations and licensing conditions are being fulfilled in WRHA facilities.

6. Develop and approve the XRSC policies and procedures.

7. Review the scope, content and delivery of the x-ray safety training programs and assess their adequacy for the respective work groups in relation to their work responsibilities and their potential exposure to x-rays.

8. Advise the Chair of the XRSC and appropriate directors/managers of any needs for additional resources to establish, maintain or improve the x-ray safety programs.

9. Receive reports (including summaries of occupational exposures) from all facilities of the WRHA. Act on the issues and concerns raised in these reports.

10. Review reports concerning any incidents or unusual occurrences that involve x-ray procedures; recommend measures or seek improvements to prevent recurrences.

11. Provide a forum for the discussion of items related to national and
international regulations and trends in x-ray safety and the specifics of the WRHA X-Ray Safety Program.

2.5 The ALARA Principle

Introduction

The WRHA Radiation Safety Program is committed to providing a safe environment for workers and members of the public with respect to all uses of ionizing radiation (x-rays) in the hospital environment – for diagnostic, therapeutic and research procedures.

As a general guide in developing and implementing a radiation safety program within the scope of its mandate, the XRSC endorses the principle that individual and collective staff doses and doses to members of the public are to be “as low as reasonably achievable” (ALARA).

A commitment to an ALARA radiation safety program means making every reasonable effort to maintain exposures as far below regulatory limits as is practical. These efforts take into account the economics of improvement related to the state of technology, benefits to public health and safety, and other socio-economic considerations.

The ALARA concept is based on three general criteria:

- **Justification**: the need to justify any action which involves radiation exposure on the basis that the expected benefits to society exceed the overall detriments;
- **Optimization**: the need to ensure that the benefits of such justifiable activities or practices is maximized for the minimum associated societal detriment, economic and social factors being taken into account; and
- **Dose and Risk Limitation**: the need to apply dose limits to ensure that individuals or groups of individuals do not exceed acceptable levels of risk.

Policy

1. Radiation doses received by workers within the workplace shall be kept below the statutory limit regardless of the practice.

2. The WRHA X-Ray Safety Committee shall maintain an on-going review of workplace facilities, operating procedures and personal radiation doses for the purpose of identifying those aspects of more significant contribution to total radiation dose and will evaluate changes to reduce radiation exposure consistent with the ALARA principle.

Procedure

1. Management control over work practices
Management is ultimately responsible to ensure that all aspects of safe work is being strictly adhered to and that the equipment and the facilities in which such equipment is installed and used meets all applicable radiation safety standards. This would include the following:

i. Ensuring all qualified users possess adequate qualifications for operating the equipment as required by any federal and provincial regulations and be certified according to a recognized standard.

ii. Ensure that all x-ray equipment, image processors, and auxiliary equipment is in good working order.

iii. Ensure that the equipment is used correctly.

iv. Establish safe operating procedures and ensure that all staff is adequately instructed in them.

v. Ensure that inexperienced operators operate the equipment only under the direct supervision of a licensed and experienced operator.

2. Personnel qualifications and training

It is the responsibility of the owner of each x-ray unit that all persons working with an x-ray source receive the appropriate training for the use of that x-ray source and possess the appropriate qualifications for operation of the equipment.

i. The training will consist of a general x-ray safety training session organized by the X-Ray Manager, and a work specific safety training session organized by the owner.

ii. For technologists, the Canadian Association of Medical Radiation Technologists (CAMRT) will be the standard.

Continuing Education and Training

Members of staff carrying responsibility for clinical and practical aspects of patients’ radiation exposures are required to undertake continuing education and training. Where relevant, this is expected to include attention to new approaches with the potential to eliminate or lessen radiation exposures to patients, staff and other people – again with advice and support from the MPE. The WRHA will seek to promote and support both ‘Medical Exposures’ and general radiation safety training, linking this to its general program for staff development.

Training, Information, Communications, Audit and Incident Review
The WRHA is committed to achieve high standards for the training of all staff involved in ionizing radiation work. This is tackled both by training on site and by the use of external training provision. The WRHA recognises that a strong ongoing commitment is required to timely and effective on site training - including a clear focus on training for medical and other staff whose work relates to the radiation safety of patients and to compliance with the Regulations.

3. Control of occupational and public exposures

i. No radiological examination shall be performed unless the benefit to the individual examined is sufficient to warrant its use.

ii. Except for those persons who’s presence is essential, all persons must leave the room when irradiation is carried out.

iii. All entrance doors must be kept closed while a patient is in the room and an x-ray examination is in progress.

iv. Personnel must keep as far from the x-ray beam as practicable.

v. All personnel must take full advantage of available protective devices.

vi. Where there is need to support children or weak patients, holding devices should be used. If parents, escorts, or other personnel are called to assist, they must be provided with protective gloves and aprons. No person should regularly perform these duties.

vii. Each x-ray worker must wear a personal dosimeter (TLD/OSL) during work near an x-ray source, if they are likely to receive a radiation dose in excess of $1/20^{th}$ of the dose limit.

4. Engineering Controls

Engineering controls are physical barriers designated to keep the risks of using x-ray sources under control. To reduce the dose received by x-ray workers according to ALARA and under the permissible limits.

Structural or other shielding must be installed as is necessary:

i. Diaphragms, cones and adjustable collimators or other suitable devices must be provided and used as are necessary to limit the dimensions of the useful x-ray beam.

ii. Each port must 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 applicable.

iii. All unused ports must be secured in such a way as to prevent inadvertent opening.
5. Planning for incidents

It is the policy of the XRSC that all activities involving ionizing radiation or radiation emitting devices be conducted so as to keep hazards from radiation to a minimum.

i. X-ray supervisors will be responsible for the education and training requirements for x-ray safety, the potential x-ray hazards and associated control measures for all x-rays under the supervisor’s authority. The supervisor will be familiar with general operating procedures of x-rays under their control.

ii. Instruct all non radiation workers within the x-ray department, prior to employment to make them aware of the potential hazards of x-ray radiation, including genetic effects.

iii. Radiation Protection surveys of a facility are intended to demonstrate that the x-ray and auxiliary equipment function properly according to applicable standards. It is important that x-ray facilities be inspected at regular intervals.

iv. Should an equipment malfunction occur, or if the x-ray beam does not terminate, the equipment emergency shut off switch must be activated immediately and the malfunction reported to the x-ray supervisor.

3.0 REGULATION AND OPERATOR QUALIFICATIONS

3.1 Introduction

Diagnostic imaging is a multi-faceted procedure requiring a variety of operator skills and technologies. Qualified staff is essential, and staff must maintain their expertise through continuing education.

Regulation is a formal, documented process that is based on provincial and/or national legislation. It carries the force of law. Provinces are responsible for the regulation of the use of x-rays and ionizing radiation equipment that emit energies up to 10 MeV. In Manitoba regulation is provided through Manitoba Regulations 341/88R, the X-Ray Safety Regulation, pursuant to The Public Health Act. In addition to Manitoba Legislation, By-law 3-B of the College of Physicians and Surgeons of Manitoba contains specifications for the qualifications of technologists and radiologists and a specification of the role of Radiation Protection Services.

3.2 Review of Staff Competency
High standards in radiation work require up-to-date awareness of all factors contributing to good practice and proper performance. Staff members are expected therefore to follow a recognised Continuing Medical Education (CME) or Continuing Professional Development (CPD) program or to provide other clear evidence of keeping skills and knowledge up-to-date. Systems are in place for many members of the medical, nursing, radiographic and scientific staff to participate in established national CME or CPD programs but the WRHA will seek to extend the use of nationally recognised schemes to other staff groups. Staff members are also expected to maintain (and demonstrate evidence of) practical skills via the appraisal process, supervised practice, participation in local practical training sessions, involvement in audit and review and whatever other methods may be practicable within their discipline.

3.3 Communications

Regular meetings of the WRHA X-Ray Safety Committee and departmental visits by Radiation Protection staff are used to facilitate communication about radiation safety issues. The WRHA is developing feedback and analysis from Combined Incident Reporting and seeks to encourage regular departmental and service reviews of practice and developments.

3.4 Incident reporting

Incident reports, including those for ‘near-misses’, play a valuable role in checking and improving the efficacy of safety control measures. All staff members are therefore encouraged to discuss any incident situations with the relevant line manager and to contribute actively to the WRHA’s incident reporting program.

3.5 Audit of Procedures

The achievement and maintenance of standards is verified through a developing audit program aimed to include specific attention to the justification of ionizing radiation procedures and to the radiation doses from them. Clinical audit relevant to medical exposures is a legal requirement and the WRHA expects the relevant Clinical Heads of Service to play a key role in developing this.

3.6 Advice and Information

Members of staff working with ionizing radiation - or in areas where they may have concerns about the use of ionizing radiation - are encouraged to contact the Radiation Protection Department CCMB for an opportunity to seek advice or obtain information.

3.7 Risk Management

The proper management of radiation-related risks, linked to WRHA strategies and procedures for risk management as a whole, is seen as a very major, integral part of the WRHA’s policy for the safe use of ionizing radiation. All staff members working in radiation-using areas are expected to take a pro-active approach to the identification of
hazards, the assessment of risk, the control or elimination of specific risks and the implementation of plans for risk control or mitigation. Work on risk assessment – formally and informally – contributes to this but is not enough by itself. The key objective throughout has, when possible, to be able to eliminate risks and – when this is not possible – actively to manage and lessen risks. It is always important to try to lessen or eliminate risks (when possible) by changing procedures, equipment or the choice of the location for the procedure in question. Good training and good provision of information can play a very valuable role in facilitating such a risk reduction process. The WRHA fully recognises that risk management must be seen as a continuous process. The structured assessments of risk must be followed up with a demonstrably effective approach to lessening risk wherever this can be achieved.

3.8 Risk Assessment

The WRHA’s objective is to maintain up-to-date radiation and general risk assessment for each radiation area together with as many procedure-based risk assessments as may be appropriate. The WRHA expects line managers to play an active role in ensuring that these risk assessments are carried out and kept up to date in their areas of responsibility. They are requested to seek help as appropriate from relevant managerial staff, from the Radiation Protection Department and from other specialist advisers on different aspects of risk assessment. Detailed guidance for both radiation and general risk assessments is available from the Radiation Protection Department CCMB.

3.9 Radiation Safety of the Patient

The WRHA emphasizes its commitment to an active program of patient dose review and reduction for all ionizing radiation areas. For patient x-ray investigations, this will include as wide as practicable use of dose-area product readings or other dose indicators directly related to patient exposure. It will also include audited compliance with the use of Diagnostic Reference Levels (DRLs). Patient dose review and reduction is an important area of clinical governance; the WRHA therefore expects Clinical Heads of Service to play a lead role in supporting and developing the patient dose review and reduction program. The WRHA attaches high priority to the specific approach to patient radiation safety and on the justification of medical exposures. The WRHA expects managers and staff actively to involve the appointed MPEs in pursuing improvements in patient radiation safety and ionizing radiation utilization.

3.10 Procedure for the Correct Identification of Patients

It is the responsibility of the operator instigating the exposure of a patient to ionizing radiation to ensure the correct identity of that patient following the WRHA’s procedure.

3.11 Reducing the Probability and Magnitude of Accidental or Unintended Doses to Patients
It is, generally, the responsibility of the relevant service manager to try to ensure that no radiation exposures are ‘wasted’ because of faulty or inappropriately used equipment. This responsibility includes careful attention to equipment maintenance, quality assurance (including early fault reporting) and all relevant aspects of staff training. All operators should be aware at all times that they have a responsibility to try to avoid ‘wasted’ exposures. Levels of over-exposure requiring external reporting are subject to national review. Issues of possible ‘over-exposure’ should be reviewed initially - and urgently - with the Radiation Protection Department CCMB and the MPE.

3.12 Regulatory Statements

Manitoba Qualifications: “Who may use X-ray Equipment”

“5(1) No person shall use or prescribe the use of x-ray equipment for the irradiation of human subjects who is not authorized to do so by an Act of the Legislature

5(2) Notwithstanding subsection (1), a person who:

(a) is registered as a Radiological Technologist by the Canadian Association of Medical Radiation Technologists;

(b) is undergoing a course of instruction approved by the Minister (of health), or is a candidate for certification as a Radiological Technologist by the Canadian Association of Medical Radiation Technologists; or

(c) possesses training and experience commensurate with the radiological work he/she is called upon to do, and is authorized by the Minister to do that work, may, while under the supervision of a person authorized as set out in subsection (1), operate x-ray equipment for the irradiation of human subjects”.

Policy

It is the policy of the X-Ray Safety Committee that the Medical Director should verify and confirm that staff are meeting the regulatory qualifications described in the Manitoba X-Ray Safety Regulation.

Procedure

The list of persons so qualified is to be made available to the Chief Inspector, X-Ray Safety, on request.

4.0 X-RAY SAFETY POLICIES

4.1 X-ray Shielding

Background: Shielding of x-ray facilities for the protection of staff and members of the public is one of the primary prevention activities.

Policy

It is the policy of the XRSC that x-ray facilities must be shielded to the extent
necessary to reduce the unnecessary exposure of staff and members of the public to levels considered to meet the ALARA condition.

**Procedure**

1. Shielding **must** be provided such that the calculated radiation doses shall be less than 1 mSv/annum for persons occupationally exposed and members of the public.

2. The ALARA concept will be achieved in shielding calculations by the conservative application of occupancy factors.

3. Shielding specifications will be provided in written form by Radiation Protection Department CCMB based on the workload and surroundings of each x-ray suite.

4. When a new facility is being designed or an existing facility is being renovated, a representative of the owner **must** contact Radiation Protection Department CCMB and provide the following information:
   - Identity of the person responsible for the project;
   - A workable copy of the floor plan, to scale; indicating the following:
     - compass direction;
     - location of the x-ray table;
     - location of any upright film holder;
     - existing wall, floor and ceiling construction;
     - location of operator shield;
     - nature (public or occupational) of the occupancy and use of areas adjacent to the room;
     - the anticipated weekly workload – how many and of what kind of procedures (final specification of workload will be in mA-min per week);
     - the operating parameters (kVp, mA, time) of each procedure;
     - the direction of the primary beam;
     - a contact list – those persons who **should** receive a copy of the written barrier specifications.

4.2 **New X-ray Equipment Compliance Policy**

- All new, used and refurbished medical x-ray equipment, and accessories, purchased or leased in Canada **must** conform to the requirements of the Radiation Emitting Devices (RED) Act and Regulations, and the Food and Drugs Act’s Medical Devices Regulations for diagnostic x-ray equipment.

- It is the responsibility of the manufacturer or distributor to ensure that the equipment conforms to the requirements of the regulation.

- All diagnostic x-ray equipment **must** meet provincial or territorial requirements established for such equipment. The Canadian Standards
Association and Manitoba Hydro utility should be consulted for further information.

- The purchase of medical imaging equipment is one of the most significant expenditures of an imaging facility. It is therefore essential to ensure that the desired design and level of performance are being obtained in a cost-effective manner.

- Acceptance testing must be performed prior to any clinical use of the equipment. Acceptance testing is a process to verify compliance with the performance specifications of the x-ray equipment as written in the purchase contract.

- It must also verify that the equipment performance meets the manufacturer’s specifications and complies with federal and provincial or territorial regulations. It is recommended that acceptance testing be performed by a medical physicist, or other individuals with in-depth knowledge of the particular type of x-ray equipment and the relevant regulations. This individual must be independent of the manufacturer.

- Acceptance testing of a medical x-ray system includes several major steps. They are:
  1. The verification that delivered components or systems correspond to what was ordered;
  2. The verification of the system mechanical integrity and stability, including safety mechanisms, automatic patient release, power drives, interlocks;
  3. The verification of electrical installation, including electrical safety, power line fluctuation;
  4. The verification of x-ray performance; and
  5. The verification of imaging or diagnostic performance.

- The results from the acceptance testing should be used to set baseline values and limits on operational performance of the x-ray equipment. These baseline values and limits are essential to the Quality Assurance Program.

- A radiation protection survey of a facility is intended to demonstrate that the x-ray and auxiliary equipment function properly and according to applicable standards, that the equipment is installed and used in a way which provides maximum radiation safety for operators and others.

- Safety measures such as protective equipment and shielding are also examined to ensure that they are present and provide the required protection. It is important, therefore, that x-ray facilities are inspected at regular intervals.

4.3 Personal Dosimetry
Background

Dosimeters are used in Manitoba healthcare facilities to measure staff exposure to ionizing radiation produced by x-ray machines and radioactive material.

Environmental and Personal Monitoring

Personal monitors are supplied to members of staff working with ionizing radiation. Where appropriate, job descriptions should for specific posts specify the need to wear a personal monitoring device. Environmental monitoring checks are carried out from time to time – and, in particular, after any significant structural or procedural changes - in Diagnostic Radiology areas as a means of checking the adequacy of shielding and other control measures.

Who Needs Dosimeters?

Section 11 of the Manitoba X-Ray Safety Regulation (341/88 R) prescribes that:
“The owner of the x-ray equipment must ensure that personal dosimeters are worn by all x-ray workers while on duty.”

where

“X-ray worker means any person whose occupation requires him or her to use or operate an x-ray machine or regularly to enter an x-ray area where the x-ray machine is in use and actually obtains or might obtain radiation doses in excess of 1 mSv per year.

Presently, specific occupational classifications and job assignments that are issued with dosimeters include:
- X-ray technologists
- CT technologists
- Cardiology technologists
- Radiologists
- Radiology Residents
- Radiology students
- “Angio” Nurses
- “CT” Nurses
- Orthopedics Staff
- Urology Staff
- “Communication Therapists” and Speech Language Pathologists
- Porters, Health Care Aides etc – those who may hold patients during x-ray procedures

Note: not all of classifications will be issued with dosimeters. Only those staff that have a potential to receive a radiation dose greater than 1 mSv per year.

Policy
It is the policy of the XRSC that workers who are required by Regulation and those who have the potential to receive occupational doses in excess of the dose to a member of the general public **must** be provided with personal dosimeters.

**Procedure**

General Guidelines for Issue and Use of Dosimeters

1. When an individual is provided with a personnel-monitoring device, the individual is instructed to only wear the device assigned to him/her. Each personnel monitoring device is assigned to and worn by only one individual.

2. The normal wearing period for an NDS TLD/OSL badge is three months. At the end of each three month period, a new set of plaques will be issued by NDS. Badges **should** be worn on the chest or abdomen (i.e. anywhere between the collar and belt). If wearing a lead apron or other protective clothing, the badge **must** be worn inside the apron. You are interested in the dose to your body, not the dose to the apron.

3. At each facility, a supervisory/management staff member shall authorize the initial issue of a dosimeter to an individual. At least annually, this staff member **should** review the list of dosimeter users to ensure that dosimeters are still required in their work activities. Person reviewing quarterly exposure records **shall** indicate that they have done the review by dating and signing the exposure report. Dosimetry records contain personal information and should not be posted for everyone to see.

4. Persons who do not operate x-ray machines but who may attend activities in an x-ray area (for observation or training purposes, or to assist with specific aspects of procedures) do not generally require dosimeters, but may be issued with dosimeters at the discretion of the supervisory/management staff member. The frequency of participation in such activities, and the nature of the participation, **should** be considered in deciding on dosimeter issue. When necessary, such persons **should** also be instructed in the use of appropriate protective equipment (like a lead apron) and in other measures (such as "stepping away" when an x-ray machine is operated).

5. The nature of the potential radiation exposure **should** be considered in deciding to issue a dosimeter. The usual dosimeter, worn on the trunk of the body, is the National Dosimetry Service “badge” type that contains two TLD/OSL “chips.” If exposure of the extremities, particularly hands and fingers, is possible, a “finger ring” is required. Unusual potential exposure situations (for example, irradiation of a localized body part like the head of an x-ray worker) must be discussed with a radiation protection specialist, who **should** assist in developing a suitable monitoring practice.

6. An issued dosimeter **shall** be worn when the person, to whom the dosimeter has been issued, is in an x-ray area. Wearing of the dosimeter at all times while at the work site is also encouraged. Facility supervisory/management
staff should perform periodic checks to ensure that issued dosimeters are worn in x-ray areas. Further instructions for the proper use and care of dosimeters may be provided to users by facility management or by Radiation Protection Services at CancerCare Manitoba.

7. To minimize the possibility of extra charges for late return or lost dosimeters at dosimeter change time, supervisory/management staff member should establish a procedure that will facilitate the dosimeter change process. Suggestions include the use of central dosimeter storage racks and an advance e-mail notice of an impending dosimeter change.

8. Dosimetry service administrators may receive notice of (or consult) advisory documents issued by authorities (like Health Canada) and offering information on dosimeter use. Questions or concerns about such information must be discussed with Radiation Protection Services at CancerCare Manitoba.

9. The supervisory/management staff member who is responsible for the dosimetry system must examine the quarterly dose records for unusual trends in doses or for elevated doses and initiate action to address unusual doses.

10. Should a dose be observed that is above the limit, an investigation must be initiated and information must be provided to Radiation Protection Department CCMB. An investigation will be conducted as to the circumstances surrounding any high or abnormal dose readings.

4.4 X-ray Protective Clothing

Policy

It is the policy to provide protective aprons, gauntlets and thyroid shields, and protective eyewear, where necessary, to WRHA staff and for the use of caregivers who may be present in facilities in accordance with the established standard.

Procedure

The standard for the inspection and issue of lead aprons, gauntlets and thyroid shields in WRHA facilities is included in this procedure.

1. The standard for the thickness of lead protective aprons and gauntlets used to shield x-ray workers shall be ideally 0.5 mm lead equivalence but not less than 0.35 mm lead equivalent thickness.

2. Protective lead garments must be inspected annually.

3. Newly purchased lead garments must be examined soon after delivery and prior to being implemented in the department for first use.
4. The inspection procedure may be performed manually to confirm that the shielding material has not slumped or to check for obvious holes or tears.

5. The standard for inspection and acceptance of protective lead clothing is as follows:

   **MANITOBA RADIATION PROTECTION STANDARD**

   **Lead Aprons, Gloves, Gonadal and Thyroid Shielding Integrity Check**

   **TEST FREQUENCY** - Initially and annually thereafter
   **STANDARD** - No breaks in protective garments

   **ACTION:** Assign responsibility for the lead shielding integrity test – both the initial acceptance test and the annual testing procedure. Examine the integrity of the personal shielding garments to ensure optimal protection to staff and patients when positioned properly.

   The annual integrity test for protective garments is a good opportunity to remind staff of the necessity of using personnel shielding on themselves and patients.

1. It is a requirement to present the results of the annual protective garment test to Radiation Protection Services at the time of the annual compliance survey.

2. Facilities may choose the manner in which they assign the responsibility for these tests.

3. Do not assume that brand new aprons, gloves, etc. are free of defects. Visual examination is not sufficient to ensure integrity of shielding. New aprons, gloves, etc. should be examined under x-ray soon after arrival (acceptance test) and returned to the supplier if defects are found.

4. Lead aprons should be properly hung on designated hangers. They must not be folded. Cracks in the lead lining can develop at the fold, reducing the useful life of the apron.

5. A numerical inventory numbering procedure is recommended. The nature of the numbering system is left to individual facilities.

6. Protective devices must be checked annually for defects, such as holes, cracks, or tears. This check can be done by visually inspecting or feeling the protective devices or may also be done by x-raying these items. A record will be kept of this check. An example of the information that should be included in a typical garment inspection is included in the Table 1 below. If a defect is found at the time of the annual check or on any other occasion, notify the supervisor and remove the device from service until it can be repaired or replaced. Protective devices should be radiographed and the images reviewed for defects in the devices.
Table 1. Sample of Protective Devices Survey (Lead Aprons, Gloves, Thyroid Shields, Gonadal Shields)

<table>
<thead>
<tr>
<th>Id# Of Shield</th>
<th>List Defects(Tears, Holes, Etc)</th>
<th>Initial Of Person</th>
<th>Date Of Test</th>
</tr>
</thead>
</table>

PROCEDURE: PERSONAL LEAD SHIELDING INTEGRITY TEST

Equipment required: Personnel shielding devices
Quality Control Log - Annual Protective Garment Tests

A. If an image intensified fluoroscopy unit is available

1. Lead aprons **must** meet the specification of 0.5 mm lead equivalency.
2. Identify the inventory number assigned to the device.
3. Lay out the item to be checked on the table.
4. Examine the entire item using fluoroscopy.
5. The primary standard is described as the “I would wear this myself” test.
6. Look for radiation leakage that indicates breaks in the lead lining.
7. Aprons are to be rejected if the diameter of the sum of defects exceeds 670mm², equivalent to a single effect with a diameter of 29 mm. However, the apron or collar should be rejected if a single defect in the vicinity of the thyroid or of the reproductive organs exceeds the equivalence of a 5 mm diameter circle.
8. Stitching holes at rear of wrap-around may be acceptable if the observer judges them to be small and not distended.
9. A few small pinholes may be acceptable if they pass the observer’s criteria of: “I would wear this myself”. A pinhole itself does not pose a risk, the question to be asked is ‘how many pinholes’ and ‘is there is a chance that a pinhole or a cluster of pinholes will become a tear’.
10. Protective garments constructed from synthetic materials may have a mottled look. They **must** meet the “I would wear this myself” test – otherwise reject at time of delivery.
11. Record the garment identification number, observer’s name, date and test results on Quality Control Log - Annual Tests; provide a copy to Radiation Protection Services during the annual compliance test, otherwise retain the record for 2 years.
12. Rejected lead aprons **should** be so marked with the date of rejection. Lead is a hazardous substance and lead aprons **must** be disposed of in an environmentally responsible manner – contact the facility’s environmental officer for instructions.

B. If an image intensified fluoroscopy unit is not available

1. Lead aprons **must** meet the specification of 0.5 mm lead equivalency.
2. Identify the inventory number assigned to the device.
3. Closely inspect each item for breaks, cracks, creases and irregularities. Run your hands over the surface of the item pressing firmly. You may feel damage that you cannot readily see.
4. Take a radiograph of suspect areas.
5. Process the film and look for radiation leakage that indicates breaks in the lead lining.
6. Apply the criteria given in Part A, along with the “I would wear this myself” test.
7. Record the garment identification number, observer’s name, date and test results on Quality Control Log - Annual Tests, provide a copy to Radiation Protection Services during the annual compliance test, otherwise retain the record for 2 years.
8. Rejected lead aprons should be so marked with the date of rejection. Lead is a hazardous substance and lead aprons must be disposed of in an environmentally responsible manner – contact the facility’s environmental officer for instructions.

CORRECTIVE ACTION: Any item displaying breaks in the lead lining should be replaced. Refer to the instructions above with respect to disposal of rejected lead garments. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

Table 2. This table is provided as the basis for evaluating the effectiveness of x-ray clothing protection during x-ray procedures. The table provides the percentage of the incident x-ray beam that is transmitted through a lead apron of thickness 0.5 mm for various applied x-ray tube voltages.

<table>
<thead>
<tr>
<th>kVp</th>
<th>Percentage Transmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>0.09 %</td>
</tr>
<tr>
<td>60</td>
<td>11 %</td>
</tr>
<tr>
<td>80</td>
<td>19 %</td>
</tr>
<tr>
<td>100</td>
<td>24 %</td>
</tr>
<tr>
<td>125</td>
<td>27 %</td>
</tr>
<tr>
<td>150</td>
<td>28 %</td>
</tr>
</tbody>
</table>

4.5 Management of Pregnant X-ray Workers

Policy

The limit of radiation dose to the abdomen of a pregnant x-ray worker is 4 mSv. Work assignments are to be adjusted, if necessary, to ensure that this limit is not reached.

Once the pregnancy of a X-ray worker has been declared, the supervisor must confirm the dose this employee has received in the past year of her work. The most recent working conditions should be such that additional dose to the fetus will not likely exceed 1 mGy during the remainder of the pregnancy. The responsibilities lie with both the worker and the employee.
Procedure

1. An X-ray worker shall declare her pregnancy to her supervisor at an early stage.

2. The worker is to be informed of the potential risks, local policies, and the recommended dose limits.

3. The supervisor must examine the most recent dose record and assess the dose incurred during the pregnant employee’s work over the previous year. If this dose is 1 mSv or less, no change in assigned working duties is required to address the radiation risk.

4. If the dose is greater than 1 mSv, following procedure the supervisor and the pregnant employee will work together to limit the radiation exposure to the unborn child using the following methods:
   
   i. Reduce the time spent in the radiation area, if possible, by working out a schedule to modify the duties during the time of pregnancy or to an area in the department where there is less scattered radiation.
   
   ii. Stand in a shielded area during all radiographs; keep an extra distance (greater than 3 m) from the radiation source whenever possible.
   
   iii. The pregnant radiation worker continues to faithfully wear her personal dosimeter on her abdomen.
   
   iv. The exposure record at the end of each wearing period is to be examined and further action taken if required on the basis of the dose accumulated.

4.6 Gonadal Shielding

Policy

Shielding of the gonads of all patients is to be provided except in cases when the shielding interferes with the prescribed diagnostic procedure.

Procedure

1. Unless prevented by the prescribed procedure, shielding of the gonads of all patients is to be provided, regardless of their age or child-bearing capacity.

2. Specific area gonadal shielding, that is gonadal shielding that covers and is slightly larger than the region of the gonads, is used when the gonads will lie within the primary x-ray field, or within close proximity (about 5
centimeters), despite proper collimation of the x-ray beam.

3. Specific area gonadal shielding is not to be used as a substitute for careful patient positioning, proper beam limitation, correct technique factors and proper film processing.

4. Specific area ovarian shielding is used on female patients after having determined that she is not pregnant.

4.7 Holding of Patients

Policy

No single person should be identified to regularly hold a patient during an x-ray examination.

Procedure

1. Holding devices are the preferred method of support where there is a need to support children or weak patients.

2. Escorts or others called to assist in the event that holding devices are impractical must be provided with protective aprons and gloves (0.5 mm lead equivalent) and be positioned so as to avoid the direct beam.

3. Persons who periodically hold a patient (e.g. a family member or personal care giver) will not require the assignment of a dosimeter.

4. Porters, nurses or non-radiology residents, for example, who occasionally hold patients or the x-ray film, during an x-ray procedure when a holding device is impractical, may be assigned a personal dosimeter if the supervisor deems this to be prudent.

4.8 Who May Be Present in the X-ray Room during a Procedure

Policy

Only those persons whose presence is essential for the successful completion of the x-ray procedure may be present in the room during the procedure.

Procedure

1. For diagnostic imaging, the X-ray technologist will determine who must be present in the room during the x-ray procedure in order to successfully complete the procedure. The guidelines of Policy 4.7 are to be followed when a person must be present during the x-ray procedure.

2. No person will permit or arrange for the intentional irradiation of a human being except for the purpose of medical diagnosis or treatment.
3. Only individuals required for the medical procedure, for training, or for equipment maintenance will be permitted in the radiographic, fluoroscopic or computed tomography rooms during an exposure.

4. Individuals who are present in the radiographic, fluoroscopic, or computed tomography room during any exposure must wear protective aprons of at least 0.5 mm lead equivalent during every exposure.

5. Individuals whose hands may be in the primary beam will be required to wear protective gloves of at least 0.5 mm lead equivalent.

6. No person will be permitted to operate an x-ray producing machine unless he/she understands and uses radiation safety procedures necessary to keep radiation exposure as low as reasonably achievable.

4.9 X-ray Safety Incident Policy

Any Radiation Users or X-Ray Workers who know or suspect that they or anyone else, have been involved in any abnormal situation, shall immediately report the fact, with as much detail as possible, to the X-ray Supervisor or Manager.

- An incident/occurrence form must be completed and submitted to the Radiation Protection Department at the earliest opportunity and not later than 48 hours following the event. An in-depth comprehensive investigation and further report may be required following the direction of the Radiation Protection Department.

4.10 Radiation Warning Signs

Radiation warning signs must be posted on all entrance doors of each radiographic room. The x-ray control panel must bear a permanent and conspicuous sign warning that hazardous x-radiation is emitted when the equipment is in operation and prohibiting unauthorized use.

The x-radiation warning sign is a sign that:
- Has a yellow background and black text;
- Is clearly visible and identifiable from a distance of 1 meter;
- Has no outer dimensions less than 2 centimeters;
- Bears the words “CAUTION X-RAYS” and “ATTENTION RAYONS X”;
- Is designed in accordance with the following diagrams:
4.11 CT Organ Shielding

Organ (breast, thyroid, gonads) shielding should be available at all CT sites. Their use should follow the following guidelines:

- Use of organ shields is advised when the organs lie within or in close proximity to the x-ray beam.
- Use of organ shields does not compromise the operation of other dose saving features of the CT scanner, such as tube current modulation, leading to a net increase in patient radiation risk.
- Use of organ shields does not compromise clinical objectives as determined by the interpreting radiologist

4.12 Medical X-ray Exposures Other Than Intended.

Background

An overdose is of primary concern. The owner of the equipment must take all reasonably practicable steps to prevent failure of radiation equipment where such failure could result in exposure of patients to ionizing radiation greater than intended. The employer must also implement steps to limit the consequence of such failure.

When an owner suspects, or is informed, that an incident may have occurred in which a patient was exposed to ionizing radiation to an extent much greater than intended, an immediate investigation must be carried out. Unless the investigation shows beyond reasonable doubt that no such incident has occurred, the owner must immediately notify the Radiation Protection Department of CancerCare Manitoba. This notification should not be delayed pending further investigation. The owner is then required to make or arrange for a detailed investigation of the circumstances of the exposure, and an assessment of the dose received. This may be done in conjunction
with the Radiation Protection Department or Medical Physics Experts of the Imaging Physics Department of CancerCare.

**Guidelines for notification of incidents involving medical radiation equipment used for medical X-ray exposure**

The intended exposure for each examination was assumed to be the reference dose as recommended by Health Canada in Safety Code 35 – Diagnostic Reference Levels.

Advice on what is meant by “much greater than intended” is given in the table below.

Table Guidelines for notification

<table>
<thead>
<tr>
<th>Examination</th>
<th>Guideline multiplying factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium enemas, IVUs, angiography and other such procedures involving fluoroscopy (including digital radiography and computerized tomography)</td>
<td>3</td>
</tr>
<tr>
<td>Lumbar spine, abdomen, pelvis, mammography and all other examinations not referred to elsewhere in this table</td>
<td>10</td>
</tr>
<tr>
<td>Extremities, skull, chest, dental examinations and other simple examinations such as elbow, knee and shoulder</td>
<td>20</td>
</tr>
</tbody>
</table>

**Procedure for Reporting "Much Greater Than Intended" Exposures**

The primary safety concern arises when the patient exposure is greater than that intended. However, it may be difficult to ascertain the degree of patient exposure. The purpose of the reporting protocol is thus to record as much relevant information as possible immediately after the occurrence in order to enable the most accurate possible estimation of the resulting patient dose. The responsibility of the technologist on duty will thus be to record, as accurately as possible, relevant information about exposure, by following the applicable Critical Incident or Occurrence Reporting Policies. The degree of patient exposure will be determined subsequently by qualified personnel, and any necessary steps taken to ensure patient safety.

In order to assess the potential exposure, the report should include the following:

a) information describing the intended procedure,

b) any available information about the state of the equipment and;

c) a description of the incident as observed by the technologist, supplemented by any relevant observations from the patient (if appropriate) or other staff present.

Specifically, the following information should be recorded by the technologist:

1. Intended Procedure, including
   a. exam type and corresponding protocol selected at the operator’s console,
   b. exposure technique, including as appropriate depending on the modality
      i. kVp,
ii. tube current,
iii. exposure time,
iv. alternatively to (c) and (d), exposure time – current product,
v. focus to skin distance,
vi. focus to image receptor distance,
vii. modality-specific technique factors, such as CT slice thickness, etc.,
viii. DAP Readings
ix. an account of what happened by the person operating the equipment
c. projected exposure or dose value provided at the operator’s console for the specified exam and technique (e.g. dose-area product, patient entrance exposure, entrance skin dose, computed tomography dose index, dose-length product, etc.) and
d. commentary describing any modification or adjustment made by the technologist to the programmed technique factors for a given protocol.

2. If the exposure was a result of an equipment failure, include the state of equipment at Time of Failure, including
   a. any available values displayed by the equipment at the time of failure for technique factors listed above in section 1(b),
   b. any available dosimetric information available at the time of failure, such as dose-area product or other values listed in section 1(c) and
   c. commentary describing any observations from the technologist regarding the validity of the values observed in 2(a) and 2(b).

3. Description of the Incident, including
   a. patient name and identification number, age, gender, height and weight, to enable patient dose calculation and follow-up contact as required. It may be more convenient to obtain patient data from the patient record at a later time.
   b. a brief description of the circumstances and chronology of the failure event,
   c. any relevant observations from the technologist, patient or other staff regarding unusual equipment behavior and,
   d. any relevant observations from the technologist or other staff regarding recent problems or service of the equipment in question and
   e. information about the condition and location of any images produced during the procedure. If hard copy images are available, they should be labeled and set aside for collection and analysis. Soft copy images should be stored locally or sent to PACS, with a brief description of the image(s) and their location.

5.0 GUIDANCE FOR THE REDUCTION OF STAFF EXPOSURES

5.1 Introduction

The objective of a safety program is not to provide absolute protection from any level of radiation exposure, no matter how small. It is, however, directed towards
reducing exposures to staff and members of the public to a level that carries low risk. This series of guidelines is provided as protection for occupational health care workers. These safe-working practices are to be combined with specific policies of the WRHA and personal good sense in order to achieve radiation exposures that are ALARA.

5.2 Guidelines for Minimizing Radiation Exposure to Personnel – General Diagnostic Imaging

1. An x-ray room must not be used for more than one radiological investigation simultaneously.

2. Only those persons whose presence is essential for the imaging and well-being of the patient are to be in the room during x-ray exposure.

3. Holding devices are to be used where practical to support children or weak patients. Patients, escorts or persons other than regular x-ray staff should be called upon to hold a patient if a holding device proves impractical.

4. Where health care workers must be present during the use of x-rays, a lead apron must be worn.

5. The x-ray exposure should be controlled from a location within the shielded control booth.

6. Shielding aprons are to have a lead equivalency of 0.5 mm lead.

7. The irradiation of workers by the direct beam should not be permitted unless the beam is attenuated by the patient or by a protective device (e.g. a shielding screen). When using mobile x-ray equipment the technologist should be positioned such that the beam is directed away from them.

8. Personnel must, at all times, keep as far away from the x-ray beam as practicable. Radiation exposure of personnel by the x-ray beam must never be allowed unless the beam is adequately attenuated by the patient and by protective screens or protective clothing.

9. Deliberate irradiation of an individual for training purposes or equipment evaluation must never occur.

10. All personnel must take advantage of available protective devices.

11. All workers who are likely to receive a radiation dose in excess of 1 mSv per annum require personal dosimeters.

12. A female X-ray worker shall immediately notify her employer upon knowledge that she is pregnant, in order that appropriate steps may be taken to ensure that her work duties during the remainder of the pregnancy are compatible with the recommended dose limits as stated in Table 3. Depending on the type of facility and on the type of work being performed by
the employee, it may not be necessary to remove a pregnant staff member from their duties of operating the X-ray equipment.

13. Where there is a need to support weak patients or to support or comfort children, holding devices should be used. If parents, escorts or other personnel are called to assist, they must be provided with protective aprons and gloves, and be positioned so as to avoid the x-ray beam. No person should regularly perform these duties.

14. When a protective apron is worn, the personal dosimeter must be worn under the apron. If extremities are likely to be exposed to significantly higher doses, additional dosimeters should be worn at those locations on the body.

15. Doors to the x-ray room are to be closed while a patient is being imaged.

16. X-ray machines which are energized and ready to produce radiation must not be left unattended.

17. X-ray equipment must be operated only by individuals who are properly trained for the equipment and the procedures being performed.

18. X-ray workers of new equipment are to receive adequate training in the equipment prior to imaging of patients.

Table 3. (updated to reflect forthcoming legislation)

<table>
<thead>
<tr>
<th>Applicable Body Organ or Tissue</th>
<th>Radiation Workers (mSv)</th>
<th>Members of the Public (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Skin</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>Hands</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>All other organs</td>
<td>500</td>
<td>50</td>
</tr>
</tbody>
</table>

5.3 Guidelines for Minimizing Radiation Exposure to Personnel – Fluoroscopically Guided Procedures

Note: All guidelines as indicated under section “Guidelines for Minimizing Radiation Exposure to Personnel – General Diagnostic Imaging” will apply for Fluoroscopically Guided Procedures with the following additional guidelines:

1. All persons, with the possible exception of the patient, required to be in the room during a fluoroscopic procedure shall wear protective aprons. Lead shields or curtains mounted on the fluoroscopic unit are not a sufficient substitute for the wearing of protective clothing.

2. Protective gauntlets should be worn by the radiologist during palpation in every fluoroscopic examination. During fluoroscopy, palpation with the hand should be kept to a minimum.
3. During fluoroscopy and spot film operation associated with the fluoroscopic operation, where personnel are required to be at the side of the patient, appropriate protective clothing must be worn by these personnel.

4. Eye protection must be made available to all X-ray workers who have the potential to exceed the 20mSv dose limit to the eyes. Currently, the individuals that have the potential to receive appreciable eye doses are the primary operator and their first assistant in the high dose procedures of interventional radiology, cardiology and neuroradiology. Consult Medical Physics, CCMB for guidance in purchasing suitable eye protection.

5. All radioscopic examinations should be carried out as rapidly as possible using minimum dose rates and x-ray field size.

6. Direct-viewing radioscopy must not be carried out. Image intensified fluoroscopy must be used.

5.4 Guidelines for Minimizing Radiation Exposure to Personnel – Mobile Procedures

Some of the suggested guidelines contained in Safety Code 35 include the following:

1. Mobile units must be used only if the condition of the patient is such as to make it inadvisable for the examination to be carried out with a stationary unit in the main X-ray department.

2. During operation, the x-ray beam should be directed away from occupied areas if at all possible, and every effort must be made to ensure that this beam does not irradiate any other persons in the vicinity of the patient.

3. A protective apron must be assigned to each mobile x-ray unit. The operator must stand at least 3 meters from the x-ray tube and out of the direct beam.

4. The operator must be shielded when irradiations are made.

5. In a capacitor discharge unit, after an x-ray irradiation has been made, there is a residual charge left in the capacitors. The residual charge can give rise to a “dark current” and result in x-ray emission even though the irradiation switch is not activated. Therefore, the residual charge must be fully discharged before the unit is left unattended.

6. Request the public, other health professionals, physicians, and other patients to leave the immediate area prior to exposure

7. Announce, in a loud voice that you intend to make an exposure and permit sufficient time for others to leave. Always inform these persons that you will be finished in a moment, request for them to remain nearby, and inform them
promptly when you are finished.

8. Never place your hands, head or any other body part in the primary x-ray beam.

6.0 GUIDANCE FOR THE CONTROL OF PATIENT EXPOSURES

6.1 Guidelines for Minimizing Radiation Exposure to Patients – General Diagnostic Imaging

The risk to the individual patient from a single radiographic examination is very low. However, the risk to a population is increased by increasing the frequency of radiographic examinations and by increasing the number of persons undergoing such examinations. For this reason, it is important to reduce the number of radiographs taken, the number of persons examined radiographically, and the doses associated with the examinations.

To accomplish this reduction, it is essential that patients be subjected to only necessary radiological examinations and, when a radiological examination is required, it is essential that patients be protected from excessive irradiation during the examination.

This can be done by adhering, as much as possible, to certain basic recommendations. These recommendations are presented below:

1. The prescription of an x-ray examination of a patient must be based on clinical evaluation of the patient and should be for the purpose of obtaining diagnostic information.

2. X-ray examinations must not be performed if there has been no prior clinical examination of the patient.

3. No radiological screening should be performed unless for the procedure, it has been proven that the benefit to the individual examined or the population as a whole is sufficient enough to warrant its use.

4. It should be determined whether there have been any previous x-ray examinations which would make further examination unnecessary, or allow for the ordering of an abbreviated examination. Relevant previous radiographs or reports should be examined along with a clinical evaluation of the patient.

5. When a patient is transferred from one physician or hospital to another any relevant radiographs or reports should accompany the patient and should be reviewed by the consulting physician.
6. When prescribing a radiological examination, the physician should specify precisely the clinical indications and information required.

7. The number of radiographic views, required in an examination, should be kept to the minimum practicable, consistent with the clinical objectives of the examination.

8. The referring clinician should establish pregnancy status prior to referral and should complete and sign the relevant fields on the Request for Consultation for Diagnostic Imaging Exam form.

Before performing x-ray examinations on females of child bearing age (11-55 years), the patient must be asked whether there is any chance that they may be pregnant. Care must be taken to protect the fetus from radiation when the x-ray examination is not avoidable. Radiological examinations of the pelvic area in women of childbearing age should be undertaken in the ten-day period following the onset of menstruation, since the risk of pregnancy is very small during this period. To ensure enquires with regard to pregnancy are asked in a consistent way, all enquiries regarding pregnancy should be made in as sensitive a manner as possible, especially when the patient is young and/or accompanied by a parent or guardian.

The technologist or radiologist responsible for establishing pregnancy status prior to exposure should complete the relevant field in the Radiological Information System (RIS).

9. If a radiograph contains the required information, repeat procedures should not be prescribed simply because the radiograph may not be of the “best” diagnostic quality.

6.2 Guidelines for Minimizing Radiation Exposure to Patients – Pediatric Imaging

Note: All guidelines as indicated under section “Guidelines for Minimizing Radiation Exposure to Patients – General Diagnostic Imaging” will apply for Pediatric Imaging with the following additional guidelines:

The risk of cancer from radiological exams accumulates over a lifetime; each exam contributes to lifetime radiation exposure. Children have longer life expectancy and, thus, more time to manifest radiation-related cancer. Because there is a reported increase in the use of radiological examinations in children, careful adherence to any ICRP guidance is important. More than adults, children are susceptible to low levels of radiation because they possess many rapidly dividing cells. In rapidly dividing cells, the repair of mutations is less efficient than in resting cells. When radiation causes DNA mutations in a rapidly dividing cell, the cell cannot sufficiently repair the damaged DNA and continue to divide; therefore, the DNA remains in disrepair.
1. Positioning errors accounted for approximately 1/5th of repeat radiological examinations. Positioning can also account for unnecessary radiation exposure to sensitive organs. For example, when making a radiograph of the hand, the patient's gonads may be exposed to excessive radiation due to improper positioning. Simply turning the patient away from the table can eliminate any exposure to the gonads.

2. The use of a posteroanterior (PA) projection or an AP projection can affect radiation dose. For example, a PA projection should be used for a scoliosis series of young female patients because their breast tissue is extremely sensitive to the development of radiation-induced breast cancer. When the examination is performed using a PA projection, the breast tissue receives the exit dose of radiation as opposed to the entrance dose. This can reduce the mean glandular dose to the breast tissue by as much as 98%. On the other hand, a premature neonate in an isolate may be restricted to an AP projection. In this case, the patient receives a greater radiation dose.

3. Because radiation exposure is directly proportional to the time of exposure (total exposure = exposure rate x time), exposure time should be kept as short as possible to minimize patient exposure and to reduce the chance of patient movement.

4. Shielding should always be used provided that it does not interfere with the area of interest. Specific areas of shielding are as follows:

   *Gonads:* Germ cells may have no dose threshold at which radiation produces mutations. Although a small gonadal dose may have no harmful effect on the patient or progeny, small doses as a whole will affect the genetic pool. In addition, girls are born with all the eggs they will ever have, and every x-ray examination exposes those eggs to damaging radiation. Thus, gonadal shielding is required for both boys and girls in pediatric imaging. Whenever the gonads lie within 5 cm of the collimation line and do not interfere with the anatomy of interest, gonadal shielding with at least a 0.5 mm lead equivalence should be used. Shielding will reduce the gonadal dose by as much as 90%. Additional shielding can be achieved by positioning the gonadal region as far from the radiation beam as possible.

   *Eyes:* In tomography of the head, the eyes can receive large doses of radiation. The use of a PA projection rather than an AP projection can reduce the exposure 20 to 30-fold. For other examinations, lead goggles or glasses prevent exposure of the lens of the eye.

   *Thyroid:* Because visualization of the airway is important in chest radiographs, shielding the thyroid is not practical. However, it may be of some value in dental radiography.

   *Breasts:* Breast shielding should be used because pediatric breast tissue is considered more sensitive to the induction of cancer than bone marrow.
Breasts can be shielded in the lateral projection; whereas the AP projection does not afford shielding opportunities in examinations such as a scoliosis series.

5. Collimation reduces the amount of scattered radiation; more importantly, collimation reduces the irradiated volume, thus limiting the patient's effective dose. In pediatric radiography, it is not enough to collimate to the size of the film. The radiological technologist must collimate to the anatomical area of interest.

6.3 Guidelines for Minimizing Radiation Exposure to Patients – Fluoroscopically Guided Procedures

Note: All guidelines as indicated under section “Guidelines for Minimizing Radiation Exposure to Patients – General Diagnostic Imaging” will apply for Fluoroscopically Guided Procedures with the following additional guidelines:

1. In view of the relatively high exposure that results from fluoroscopy, such procedures should only be carried out when an equivalent result cannot be obtained from radiography. Fluoroscopy must not be used as a substitute for radiography.

2. Fluoroscopy must only be carried out by a radiologist or physician properly trained in radioscopic procedures, or by a technologist which has been properly trained in fluoroscopic procedures and under immediate supervision of physician or radiologist.

3. All fluoroscopic procedures should be carried out as rapidly as possible with the smallest practical x-ray field sizes.

4. Image intensification must be used in order to reduce patient exposure. Image intensifiers can significantly reduce both irradiation rate and irradiation time. However, the operator must monitor the x-ray tube current and voltage on equipment with automatic brightness control, since both can rise to high values without the knowledge of the operator, particularly if the gain of the intensifier is decreased.

5. Mobile fluoroscopic equipment should only be used for examinations where it is impractical to transfer patients to a permanent fluoroscopic installation.

6. Cinefluorography produces the highest patient doses in diagnostic radiology because the x-ray tube voltage and current used are generally higher than those used in fluoroscopy. Therefore, this technique should not be used unless significant medical benefit is expected.

6.4 Guidelines for Minimizing Radiation Exposure to Patients – Mobile X-ray Procedures in multiple bed suites (e.g. ICU)

Note: All guidelines as indicated under section “Guidelines for Minimizing Radiation
Exposure to Patients – General Diagnostic Imaging will apply for Mobile X-ray Procedures in the multiple bed suites (OR, ICU) with the following additional guidelines:

1. Provide gonadal shielding for the patient.
2. Carry enough protective aprons to ensure that the patient has one for added shielding.
3. Label and handle each cassette carefully to avoid repeats.

6.5 Average Manitoba Entrance Doses for X-ray Imaging Procedures

Table 4. Year-2008, average “exposure” for 400 speed system speed for conventional film x-ray procedures to compare with CR

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Phantom Thickness cm.</th>
<th>Average Entrance Exposure mGy*</th>
<th>Standard Deviation +/- (mGy)</th>
<th>% Coeff of Variation</th>
<th># Facilities with Exp &gt; Ave + 1 S.D.*</th>
<th>Ave Film Optical Density of Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP Abdomen</td>
<td>18</td>
<td>1.40</td>
<td>.436</td>
<td>31%</td>
<td>10/62</td>
<td>1.6</td>
</tr>
<tr>
<td>PA Chest</td>
<td>10</td>
<td>.096</td>
<td>.023</td>
<td>24%</td>
<td>9/60</td>
<td>1.7</td>
</tr>
<tr>
<td>C-Spine</td>
<td>13</td>
<td>.420</td>
<td>.144</td>
<td>34%</td>
<td>11/99</td>
<td>1.5</td>
</tr>
<tr>
<td>Lat. Skull</td>
<td>15</td>
<td>.571</td>
<td>.172</td>
<td>30%</td>
<td>8/59</td>
<td>1.2</td>
</tr>
<tr>
<td>L-Spine</td>
<td>23</td>
<td>2.83</td>
<td>.827</td>
<td>29%</td>
<td>14/97</td>
<td>1.3</td>
</tr>
<tr>
<td>T-Spine</td>
<td>18</td>
<td>1.25</td>
<td>.431</td>
<td>34%</td>
<td>14/93</td>
<td>1.5</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>18</td>
<td>15.7 mGy/min</td>
<td>+/-6.96 mGy/min</td>
<td>N/A</td>
<td>4/22</td>
<td>N/A</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>23</td>
<td>30.5 mGy/min</td>
<td>+/-14.79 mGy/min</td>
<td>N/A</td>
<td>5/22</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Note: The data are provided in the unit in which the ion chamber meter is calibrated. Modern SI usage would record these data as entrance air kerma in milligray. 100 mR = 0.87 mGy in air.

Note: The following data is defined as the number of actual measurements is out of the total number of measurements. For example: AP Abdomen totaled 10 measurements with exposures greater than the average by at least 1 standard deviation out of a total of 62 measurements.

Table 5. Year-2008, average “exposure” for Computed Radiography in WRHA facilities

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Phantom Thickness cm.</th>
<th>Average Entrance Exposure mGy*</th>
<th>Standard Deviation +/- (mGy)</th>
<th>% Coeff of Variation</th>
<th># Facilities with Exp &gt; Ave + 1 S.D.*</th>
<th>Ave Film Optical Density of Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP Abdomen</td>
<td>18</td>
<td>1.66</td>
<td>.606</td>
<td>37%</td>
<td>12/63</td>
<td>Na</td>
</tr>
<tr>
<td>PA Chest</td>
<td>10</td>
<td>.145</td>
<td>.048</td>
<td>33%</td>
<td>10/60</td>
<td>Na</td>
</tr>
<tr>
<td>C-Spine</td>
<td>13</td>
<td>.529</td>
<td>.189</td>
<td>36%</td>
<td>12/63</td>
<td>Na</td>
</tr>
<tr>
<td>Lat. Skull</td>
<td>15</td>
<td>.746</td>
<td>.284</td>
<td>38%</td>
<td>12/62</td>
<td>Na</td>
</tr>
<tr>
<td>L-Spine</td>
<td>23</td>
<td>3.72</td>
<td>1.06</td>
<td>28%</td>
<td>12/62</td>
<td>Na</td>
</tr>
<tr>
<td>T-Spine</td>
<td>18</td>
<td>1.32</td>
<td>.43</td>
<td>33%</td>
<td>10/62</td>
<td>Na</td>
</tr>
</tbody>
</table>
Note: The data are provided in the unit in which the ion chamber meter is calibrated. Modern SI usage would record these data as entrance air kerma in milligray. 100 mR = 0.87 mGy in air.

Note: The following data is defined as the number of actual measurements is out of the total number of measurements. For example: AP Abdomen totaled 12 measurements with exposures greater than the average by at least 1 standard deviation out of a total of 63 measurements.

7.0 QUALITY ASSURANCE PROGRAM

Quality Assurance is a plan that involves continuous monitoring to ensure consistent film processing, regular testing to detect equipment malfunction, regularly scheduled equipment maintenance, and an ongoing assessment of variables that could affect image quality and diagnosis. The implementation of a Quality Assurance program need not be complicated. It may consist in establishing Quality Control procedures for the equipment along with an administrative methodology to ensure that monitoring, evaluation and corrective actions are properly performed. The quality assurance program includes many facets, including quality control, as well as preventive maintenance and calibration of equipment, and is recommended for all diagnostic radiological facilities.

Quality Control is an integral part of quality assurance. It is a series of distinct technical procedures and tests that ensure the production of a satisfactory product, e.g., high-quality diagnostic images. These tests will enable the facility to recognize when parameters are out of limits. Out of limits parameters result in poor quality images and can increase the radiation exposure to patients.

Simply performing the quality control tests will not result in any useful information if the data is not evaluated. Whenever quality control test results exceed established operating parameters, corrective action is required immediately.

The owner of an x-ray facility has the responsibility of establishing a Quality Assurance program which should examine some or all of the following practices of the facility:

1. Information Quality - to ensure all diagnostic information produced provide for accurate clinical assessment.

2. Clinical Efficiency - to ensure all steps leading to accurate diagnosis and intervention are taken and the information is made available in a timely fashion to the patient’s physicians or primary medical professionals.

3. Patient Dose - to ensure that the x-ray examination is performed with the lowest possible radiation dose to the patient consistent with clinical imaging requirements.
For further information or assistance on setting up a Quality Assurance program, the following may be contacted:

Radiation Protection Department  
Division of Medical Physics CancerCare Manitoba  
675 McDermot Avenue  
Winnipeg, MB  
R3E 0V9

Imaging Physics Department  
Division of Medical Physics CancerCare Manitoba  
675 McDermot Ave  
Winnipeg, MB  
R3E 0V9

1-204-787-4145  
1-204-775-1684 Fax

7.1 Processors and Solutions QC

Each facility should establish a written organizational flow chart detailing the duties and responsibilities of each person involved in the processor quality assurance program. Facilities doing mammography must follow the protocol as required for accreditation purposes.

1. Preventive maintenance on both the processor and chemicals should be performed initially and at least every 2 months or according to manufacturers' specifications and more frequently if needed.

2. Photographic materials should be stored at temperatures less than 24°C (75°F), preferably in the range of 15°C to 21°C (60°F to 70°F). Open packages of photographic film should be stored in an area with humidity ranging between 40% and 60%.

3. Photographic materials should not be stored in areas where they can be exposed to direct sunlight, chemical fumes or radiation.

4. Processor chemistry should not be used after the expiration date.

5. The emulsion batch of film that will expire first should be used first. Film should not be allowed to remain in the film bin past the expiration date. New shipments of film should be checked and should not be accepted from the vendor unless they can be used before the expiration date.

6. If expired film is used to clean the processor, the box will be clearly marked “NOT FOR PATIENTS.”

7.2 Preventative Maintenance and Repair Program; Who may Service
**Diagnostic X-ray Equipment**

Preventive maintenance and repair work on radiographic equipment may be performed only by appropriately trained individuals using appropriate test equipment and repair methods. These staff may be from original equipment manufacturers, third party service companies or a hospital. Service personnel **must** carry appropriate acts and omissions insurance coverage. Any individual conducting service **must** provide written documentation of the work performed that at a minimum includes a brief description of the work/tests performed and the parts replaced.

**8.0 Radiation Protection X-ray Compliance Surveys**

A radiation protection survey of a facility is intended to demonstrate that the x-ray and auxiliary equipment function properly and according to applicable standards, that the equipment is installed appropriately. Safety measures such as protective equipment and shielding are also examined to ensure that they are present and provide the required protection. It is important, therefore, that x-ray facilities are inspected at regular intervals.

(a) General Procedures

Routine operation of any new installation or an installation which has undergone modifications **should** be deferred until a complete survey has been made by a qualified expert. The owner of the facility (or another delegated staff member such as the Radiation Protection Safety Officer) **must** contact the appropriate regulatory agency to ascertain inspection and acceptance testing procedures in that jurisdiction. Some jurisdictions may require that the facility be declared in compliance with applicable governmental regulations prior to operations. For new facilities or modifications to existing facilities, the applicable regulatory authority should be contacted at the planning stage.

In an existing facility, a survey **must** be carried out after any changes that may affect protection of the operator or others. This includes alteration of protective barriers, equipment modification, changes in operating procedures, or increased workloads. Surveys **should** be carried out at regularly scheduled intervals to detect problems due to equipment failure or any long-term trends toward a decrease in the level of radiation safety.

Radiation protection surveys must include testing of the x-ray and auxiliary equipment and the facility. When testing equipment, quality control tests listed in subsection C-3 of Health Canada Safety Code 35, which are applicable, **should** be performed. Testing of the facility includes a review of operating procedures, verification of the adequacy of existing shielding and also a review of the facility quality assurance program to ensure it exists and is maintained. The survey **should** also perform an investigation of any unusually high exposures from previous personal dosimetry reports.

The results of such surveys, including conclusions drawn by a qualified expert such as a medical physicist, **must** be submitted to the owner or responsible user in a written report. All such reports **must** be retained by the owner or responsible user.
(b) Survey Report

The survey report must present, in a clear systematic way, details and results of the measurements carried out, as well as the conclusions drawn and recommendations made by the surveyor. Any unusual findings about the equipment itself, the facility or operating procedures, which could affect the safety of operators or other persons in the vicinity of the x-ray facility must be clearly identified.

The survey report should include the following:

1. Identification of the x-ray equipment (i.e. the name of the manufacturer, model designation and serial number of the generator control, x-ray tube assembly, x-ray table, etc. as applicable) and the date, or at least approximate date manufactured.

2. The method of support of the x-ray tube assembly (i.e. floor-to-ceiling tube stand, ceiling suspended over table tube, etc.).

3. Observations of the operational conditions (both electrical and mechanical) of the x-ray equipment at the time of the survey.

4. The actual or estimated total workload of the facility, as well as the workload apportioned into various x-ray beam directions and procedures used, etc.

5. Results of radiation measurements carried out both inside and outside the controlled area under “typical” operating conditions. The locations at which the measurements are made.

6. An assessment of the condition of patient restraint, protective aprons, gloves, mobile protective barriers and other protective devices.

7. An estimate of potential exposures to personnel and general public in or around the facility.

8. An evaluation of the x-ray performance and the imaging or diagnostic performance (this may include performing applicable quality control tests from subsection C-3 of Health Canada Safety Code 35).

9. An assessment of radiological techniques from the point of view of radiation safety and an assessment of the Diagnostic Reference Levels for the facility. Attention must be drawn to any practices which are or could be detrimental to the patient or to personnel working in the facility. Recommendations of improved or safer techniques should be made in such cases.

10. A summary of typical loading factors used and a measurement of the total filtration in the x-ray beam.
11. Results of investigations of any unusually high exposures from previous personnel dosimetry reports and recommendations on whether other persons should be included in the personnel dosimetry service.

12. Recommendations regarding the need for a follow-up survey.

8.1 **Newly Purchased Medical X-ray Equipment**

All new, used, and refurbished medical x-ray equipment, and accessories for such equipment, which is sold, imported or distributed in Canada, **must** conform to the requirements of the Radiation Emitting Devices Act and the Food and Drugs Act and their promulgated regulations. These are the Radiation Emitting Devices Regulations and the Medical Devices Regulations. The Radiation Emitting Devices Regulations specify standards of construction and performance of equipment, with respect to radiation safety. The Medical Devices Regulations encompass all other safety considerations and the question of efficacy for all medical x-ray equipment sold in Canada. It is the responsibility of the manufacturer or distributor to ensure that the equipment conforms to the requirements of these regulations. In addition, x-ray equipment **must** meet any applicable requirements under provincial or territorial jurisdictions for such equipment. Part XII of the Radiation Emitting Devices Regulations addressing medical x-ray equipment, in effect at the time of publication of Health Canada Safety Code 35, is reproduced in Appendix VI. These regulations may be amended from time to time, to keep up-to-date with changing technology in the field. Information on the applicability and currency of the Radiation Emitting Devices Regulations may be obtained by contacting the Consumer & Clinical Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1.

8.2 **Existing Medical X-ray Equipment**

Whenever possible, existing medical x-ray equipment **must** be upgraded to incorporate as many as possible of the safety and performance features required of new medical x-ray equipment. It should be noted that it is a requirement of the Radiation Emitting Devices Regulations that replacements for any component or subassembly of an x-ray machine, for which a construction or performance standard has been specified in the Regulations, applicable to the class of x-ray equipment, **must** comply with the standards in effect at the time of replacement.

8.3 **Retrofitting with CR and DR systems**

When purchasing a CR system for a new or existing x-ray system or an after market DR detector to be installed on an existing system, both CR and DR systems **must** meet requirements of the Radiation Emitting Devices Act and the Medical Devices Regulations. Furthermore, the x-ray system including the CR or DR systems **must** meet the requirements of Part XII of the Radiation Emitting Devices Regulations reproduced in Health Canada Safety Code 35 Appendix VI. For radiography, it is recommended that the detector pitch be equal or better than 200 micrometres, and the system radiation sensitivity should be greater than an equivalent 200 speed film screen system for equivalent diagnostic images.
9.0 REFERENCES AND BIBLIOGRAPHY

New Jersey Department of Environmental
Bureau of Radiological Health
P.O. Box 415
Trenton NJ 08625
http://www.state.nj.us/dep/rpp/download/qaman.pdf

Safety Code 35: Safety Procedures for Installation, Use and Control of X-Ray Equipment in Large Medical Radiological Facilities
Consumer and Clinical Radiation Protection Bureau
Health Canada
775 Brookfield Road, PL 6301A
Ottawa, ON K1A 1C1

Manitoba X-Ray Safety Regulation 341/88R and successor regulations


Radiation Emitting Devices Regulation, C.R.C., c. 1370, s. 3, Part XII Diagnostic X-ray Equipment.