Centre universitaire de santé McGill
McGill University Health Centre

McGill University Health Center

Radiation Safety Manual for Nuclear Substances, Radiation Devices and Diagnostic Radiology

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APPENDIX:

1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has recommended a philosophy of radiation protection based upon quantitative risk. The basic system was set forth in Recommendations of the ICRP, ICRP Publication 26, Publication 57, p. 9 and Publication 60:

"The primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure. In summary, the Commission recommends the adoption of a system of dose limitation based upon the following principles:

(a) Justification of the practice: no practice shall be adopted unless it results in a positive net benefit.

(b) Optimization of Protection: all exposures shall be kept As Low As Reasonably Achievable, economic and social factors being taken into account.

(c) Dose limits: the dose equivalents to the individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission."

Every rule and recommendation in this manual is set in accordance with these fundamental principles of radiation protection.

1.1 Purpose of the Manual

This manual constitutes a handbook of procedures for the safe handling and application of sources of ionizing radiation for Nuclear Substances and Radiation Devices (NSRD). At the MUHC, this includes the self-shielded irradiator (Group 2.3 license), diagnostic and therapeutic nuclear medicine (Group 2.4 licenses) and the consolidated uses of nuclear substances (Group 3.1 license). This manual also includes guidelines for the safe use of X-ray equipment used in diagnostic radiology.

The NSRD activities are regulated by the Canadian Nuclear Safety Commission (CNSC), and the X-Ray equipments are regulated by the *Loi sur la protection de la santé publique* of the Quebec government. The Class II nuclear facilities and prescribed equipment (radiation oncology) are not included in this manual, an activity that is managed and administered by the Department of Medical Physics at the MUHC where a Class II radiation Safety Manual is available.

The rules, recommendations and information included in this manual have been submitted to the Radiation Safety Committee as the basis of radiation safety for NSRD and X-Ray equipments at the McGill University Health Center. The overall intention of these rules and recommendations is as follows:

a) Protection of staff, patients and the general public from the hazards associated with the use of ionizing radiation sources of all kinds.

b) Compliance with federal, provincial and local laws, regulations and licensing requirements related to such sources.

1.2 ALARA Principle

The guiding principle throughout this manual is the ALARA Principle which demands that the doses received by workers and members of the public be kept As Low As Reasonably Achievable, social and economic factors taken into account (see CNSC Regulatory Guide G-129).

Adherence to the ALARA Principle is demonstrated by the following elements:

1) A demonstrated commitment from the management of the MUHC towards radiation safety (awarding of a budget for radiation safety, appointment of a RSO and a RSC and a continuing interest in their activities, delegation of a representative from the administration to the RSC, continuing interest and support for upgrading radiation safety, purchasing and renewal of equipment)

2) The provision of resources (see under 1), organization and support of training sessions, establishment of “action levels” (efforts are continuously made to further reduce radiation doses to employees and to the environment), proper documentation of all radiation safety related data and events

3) Regular operational reviews of dose records, frequency of incidents (contamination control), review and introduction of new technology for improved radiation protection.

Notes:

- Throughout this manual “shall” is used to designate features or actions that are essential, while “should” is used to designate features or actions that are recommended.
- This manual will be amended and supplemented from time to time in the light of changes in knowledge, equipment, organization or legal requirements.
- All quantities in this manual are in the Système International (SI) units.

2. Organization and Responsibilities

2.0 Organizational Management Structure

The organizational basis of radiation protection for NSRD and X-ray equipments at the McGill University Health Center is as follows:

a) A Radiation Safety Committee that reports to the Chief Operation Officer of the MUHC;

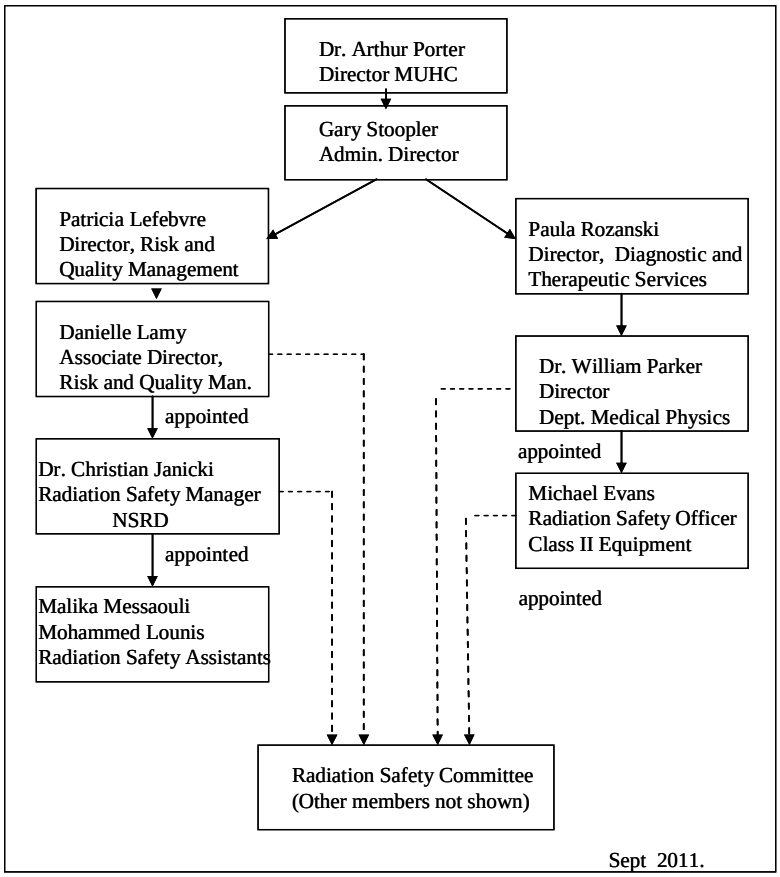
b) A Radiation Safety Manager and Officer (RSO) who reports to the Associate Director of Quality and Risk Management. The RSO is in charge of the Radiation Protection Service (RPS), a division of the Quality and Risk management Department at the MUHC;

c) Radiation Safety Assistants who work under the supervision of the Radiation Safety Manager;

d) Departmental Radiation Supervisors who, in co-operation with Heads of Departments and with the RPS, ensure compliance with the relevant radiation safety requirements within a defined geographical or departmental area;

e) Internal Permit holders (Consolidated uses of Nuclear Substances) are persons who are officially designated, for licensing and other purposes, as the individuals responsible for the procurement and use of specified radiation sources in laboratories; and

f) Individual radiation users who have the responsibility of using radiation sources in such a way that they do not endanger themselves or other people.



A diagram of the administration (Direction, RSO/NSRD and RSC) is illustrated here. This diagram also includes the RSO Class II administration for completeness.

2.1 Radiation Safety Committee (RSC)

2.1.1 Accountability

The Radiation safety Committee reports to the MUHC Chief Executive Officer of the MUHC.

2.1.2 Purposes

The responsibilities of the Radiation Safety Committee are as follows:

a) To provide overall co-ordination of the MUHC radiation safety program for all MUHC hospital sites and research institutes;
b) To ensure that the MUHC conforms to all applicable legislation and internal policies;
c) To review reports from committee members and/or representations from other individuals;
d) To provide a platform for the resolution of conflict on Radiation Safety issues;
e) To evaluate and respond to results of inspections and/or audits by the CNSC;
f) To promote adherence to good radiation safety and legal compliance to management and staff throughout the MUHC within the framework of ALARA (As Low As Reasonably Achievable);
g) To ensure adequate standards of radiation safety for staff, general public and all other individuals covered by MUHC licenses;
h) To rule on the suspension or approval of license activities when specifically requested to do so in writing;
i) To maintain written records of all meetings.

2.1.3 Composition of the RSC

The membership of the Committee should be as follows (total of 17 members):

- Chief Executive Officer Representative
- Manager* (Radiation Safety Officer): Radiation Protection
- Manager*: Nuclear Medicine
- Manager*: Radiation Oncology
- Manager*: Diagnostic Imaging
- Manager*: Medical Physics
- Manager*: Quality Assurance and Risk Assessment
- Manager*: Occupational Health and Safety
- Radiation Safety Officer Class II
- Researcher: Research Institutes
- Physicist: Nuclear Medicine
- Clinician Representative: Council of Physicians, Dentists and Pharmacists
- Clinician Representative: Nursing
- User Representative: Radioisotopes or Class II
- User Representative: Research Institutes

- MUHC-Montreal Children's Hospital – Radiation Safety Committee Rep.
- MUHC-Montreal Neurological Hospital – Radiation Safety Committee Rep.
  *Manager or their delegate may attend.

2.1.4 Structure and Membership

a) Chair
- Leads the RSC for a term of two years.
- Alternates between individuals in research and clinical activities
- May be appointed by the RSC from the existing members of the RSC in the event that the Vice-Chair is not able to assume the Chair.

b) Vice-Chair
- Appointed by the RSC from the existing members of the RSC for a term of two years. Substitutes for Chair at RSC meetings when necessary.
- Upon completion of a two year term the Vice-Chair assumes the Chair position.
- Alternates between individuals in research and clinical activities.

c) Secretary
- Appointed by the RSC from the existing members of the RSC for a term of two years. Renewable.
- Manager organizes RSC meetings including agendas and minutes.

d) Members
- Designated or appointed by departments for a two year term (renewable).

2.1.5 Meetings

Meetings are held at least four times per year. Exceptional meetings shall be arranged with the Chair or Vice-Chair. Quorum is 9 members including: a) either the Chair or the Vice-Chair and, b) either the Secretary or the Class II RSO and c) one Manager (not a delegate).

2.2 Radiation Safety Officer (RSO)

The RSO is the Manager of the RPS. The duties of the RSO shall include:

a) Assessment of the status of radiation safety measures undertaken in all rooms, wards and other locations where radiation sources (including patients containing radioactive sources) are housed and/or used;
b) Administration of all licenses (except class II) issued to the MUHC Research Institute by the CNSC by overseeing and coordinating all aspects of radiation protection within the institution;
c) Preparation, and revision from time to time, of a "Manual of Radiation Protection" which incorporates the rules, recommendations, instructions, data and other information required for the implementation of the Terms of Reference of the Committee;
d) Providing such services as may be required for radiation safety and for compliance with federal, provincial and local laws and recommendations, where these services cannot be provided internally by individual departments or laboratories. These services include:

- Instruction and training of employees in the safe handling of radiation sources;
- Verification of radiation monitoring equipment;
- Carrying out radiation surveys, including environmental surveys, personnel monitoring (additional to that provided by the national monitoring service), bioassays and surveys relating to particular equipment or procedures;
- Survey of the collection and disposal of radioactive waste;
- Planning for, and supervision of, emergency procedures and special decontamination operations;
- Maintenance of records relating to all aspects of radiation protection, including personnel exposure records, radiation survey records and licensing documents;
- Participation in the planning of new installations or procedures involving radiation sources;
- Co-operation with federal, provincial, and local authorities in all matters relating to radiation protection.

e) Reporting to the Radiation Safety Committee regularly and whenever any unusual or emergency situation arises or has recently been dealt with.

f) The RSO must notify the CNSC within 15 days of a change of RSO or applicant authority.

2.3 Radiation Safety Assistant

The Radiation Safety Assistant works under the supervision of the Radiation Safety Manager. The specific responsibilities of the Radiation Safety Assistant include but are not limited to:

a) Overseeing the intake and inspection of radioactive materials;

b) Overseeing the waste management program, which entails establishing and monitoring appropriate controls, pickup and disposal;

c) Overseeing, conducting and documenting radiation safety surveys and compliance audits, and personal badge monitoring system;

d) Presentation of radiation safety training programs including participating in education and safety programs for employees throughout the MUHC;

e) Serving as an advisor to responsible investigators, architects, physicians and administrative officers of affiliated institutions regarding appropriate design of facilities where radioactive material and/or x-ray producing equipment will be used.

f) Overseeing development of RPS management software and the RPS web site.

g) Ensuring compliance with applicable rules, regulations, and guidelines of regulatory agencies and investigation and analysis of incidents and badge exposures including documentation of appropriate corrective action recommendations.

h) Other technical and administrative responsibilities as directed by the Manager of the RPS.

2.4 Internal Permit Holder

An Internal Permit Holder (Consolidated uses of Nuclear Substances) is a person who is officially designated for licensing or other purposes, as the individual responsible for the procurement and use of specified radiation sources.

An Internal Permit Holder is normally Director of a department, division or laboratory and, as such, is ultimately responsible for supplying the facilities and supervision needed by his staff.

Frequently, the day-to-day responsibility for these matters is delegated to a Departmental Radiation Supervisor (e.g. Chief Technician). Whether the responsibility is exercised directly or is delegated, the list of duties in the field of radiation protection is as given in 2.5 below.

2.5 Departmental Radiation Supervisor (DRS) or Delegates

Departmental Radiation Supervisor or Delegate is a person who works full-time in a given area, laboratory or other circumscribed location, such that he is able to provide day-to-day supervision of the work of employees in matters of radiation safety. The DRS derives his authority from the Head of Department, Director of the Laboratory or other Permit holder as defined in 2.4. The DRS has to provide adequate facilities, equipment, supervision and instruction to enable radiation sources to be handled safely and in compliance with the requirements of this Manual. In particular, the DRS is responsible for:

a) Maintaining an up-to-date listing of rooms in which radiation sources are installed, stored, handled or applied.

b) Maintaining an inventory of radiation sources in the form of radiation-emitting equipment and/or radioactive sources, relative to each of his projects.

c) Ensuring that all persons handling radiation sources receive adequate instruction in the safety aspects of such handling. This implies, as a minimum, that the employee attends an approved Radiation Safety Training Course. Until the employee has completed such a course he must not be allowed to handle any radiation source except under supervision. The employee should also read the appropriate sections of this Safety Manual and other regulatory documents (including license conditions and information posters).

d) Allowing only authorized persons to enter areas that are specified as restricted for reasons of radiation safety.

e) Ensuring that personnel wear assigned radiation monitors throughout the working day and that such monitors are:

i) not left in close proximity to radiation sources when not being worn; and
ii) are handed in promptly at the end of each monitoring period.

f) Posting warning labels and signs as required by current laws and safety codes.

g) Establishing appropriate working procedures to ensure compliance with internal permit conditions, applicable laws and safety codes.

h) Ensuring that radioactive waste is disposed of, in strict accordance with Section 8 of this Manual.

i) Notifying the RPS when any female nuclear energy worker under his supervision, or any such worker about to come under his supervision, is known to be pregnant.

j) Supplying the RPS with all the information needed for licensing purposes and/or the issue of the internal permit and keeping this information up-to-date.

k) Ensuring that, when required, personnel make themselves available for bioassay procedures such as thyroid monitoring and that adequate records of the results of such procedures are maintained.

l) Monitoring the work area for radioactive contamination by the means of wipe tests at least weekly and recording the results in a logbook.

m) Ensuring that, once a year, a radiation protection survey is completed and a specific training session is held in the department with the cooperation of the RPS.

n) Report to the RPS all incidents involving radioisotopes.

2.6 Individual radiation users

a) Every individual who acquires, installs, stores, handles or applies radiation sources is responsible for working in such a way that he does not endanger either himself or his colleagues and that he complies with the procedures and rules laid down by this Departmental Radiation Supervisor and listed in the applicable sections of this Manual.

b) A radiation user is responsible for any radiation monitor (e.g. film badge or TLD monitor) assigned to him and must carry it on his person throughout the working day. He must not lend or assign his personal monitor to anyone else, nor leave the monitor outside working hours in such a location that it could be exposed to radiation.

c) A radiation user should observe and obey all notices and warnings and take all reasonable precautions for own safety and of safety of others. Also, he should promptly inform his/her supervisor of:

- Increase in risk
- Threat to security
- Failure to comply with act, regulations or license
- Any act of sabotage or theft of nuclear substance
- Unauthorized release of radioactive substance
-

d) A female nuclear energy worker is required to report the fact that she is pregnant to her Departmental Radiation Supervisor or to the Permit holder as early as possible. A review of her working environment, her tasks and her personnel dosimetry record will then be made by the RPS in order to ensure that the radiation dose to the foetus is kept at a minimum level.

e) A radiation user is assumed to have read and understood the relevant sections of this Manual and of the Safety Code applicable to his type of work and comply with procedures in a responsible and reasonable manner. To this end the worker may request a copy of this Manual and a copy of the relevant Safety Code (edited by the CNSC or Quebec Provincial authorities) for his personal use, if he so desires.

3. Licensing and Authorization

3.1 General Principles

3.1.1. The Canadian Nuclear Safety Commission (CNSC) licenses the possession and use of radiation sources in Canadian hospitals and research institutions. Licensed activities include the following categories:

a) Unsealed radioisotopes and radiopharmaceuticals used for diagnosis or therapy on human subjects, whether in a Department of Nuclear Medicine or elsewhere.

b) Unsealed radioisotopes used for investigations and research not involving human subjects (in-vitro or animal laboratory studies).

c) Unsealed radioisotopes used for investigations and research involving human subjects (human research studies such as positron emission tomography investigations on human volunteers).

d) Sealed radioisotopes used in therapy, including sources intended for implantation and sources housed in teletherapy (e.g. cobalt) units.

e) Sealed radioisotopes permanently housed in instruments and equipment. This category includes sealed isotopic sources provided for instrument calibration, for diagnostic purposes (e.g. bone mineralization scanners) and for neutron activation analysis.

f) particle accelerators that are capable of giving rise to high-energy ionizing particles, either as the useful product (e.g. a beam of high energy electrons) or as a by-product (e.g. stray neutrons). In practice this means that all medical accelerators (linear accelerators, betatrons, cyclotrons) are licensable.

g) Processing and shipping of radioisotopes produced by a particle accelerator (e.g., production and transfer, resp. sale, of 18F-FDG produced by a medical cyclotron).

3.1.2 The list in 4.1.1 excludes all radiographic and fluoroscopic equipment in the Diagnostic X-ray Department (at present under the jurisdiction of the “Laboratoire de Santé Publique du Québec). It is probable, but not certain, that x-ray machines will become licensable in the future under the Quebec Public Health Protection Act. In that event, this section of the manual will be revised.

3.2 MUHC Licenses for Nuclear Substances and Devices

3.2.1. There are four CNSC licenses for Nuclear Substances and Radiation Devices at the MUHC. These are:

1- Consolidated use of nuclear substances (Group 3.1)

2- Therapeutic Nuclear Medicine (Group 2.4)

3- Diagnostic Nuclear Medicine (Group 2.4)

4- Irradiation: self-shielded type (Group 2.3)

The licenses are valid for the period indicated on the Licenses (fixed by the CNSC) unless otherwise suspended, amended, revoked or replaced. Each license includes a list of conditions that shall be met by the licensee and subject to inspections or audits by the Commission on a periodic basis. Also, the licensee shall submit to the CNSC a written annual compliance report in a form acceptable to the Commission. Failure to comply with the all the regulations might result in the licenses being suspended or revoked by the Commission.

3.2.2. Copies of the MUHC licenses are accessible to all workers and include all the conditions that need to be met for compliance with the CNSC regulations. These conditions serve as a basis for the policies developed in this manual for the consolidated use of nuclear substances. This manual also includes policies that meet or exceed the conditions for all licenses listed above. Copies of the licenses are available from the RPS at the MUHC.

3.2.3. As part of the licensing conditions, some of the MUHC's obligations are:

a) to train workers to carry on the licensed activities in accordance with the Act, the regulations made under the Act and the license;

b) to take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security;

c) to take all reasonable precautions to control the release of radioactive nuclear substances within the sites of the licensed activities;

d) to notify the Commission of the person (name, position title) who is responsible for the management and control of the licensed activities, and notify the Commission of any changes in the above information within 15 days;

e) For any site where licensed activities (consolidated use of nuclear substances) are to be conducted for more than 90 days, notify the Commission in writing of the site within 7 days of starting to conduct the activities at the site. Also, notify the Commission in writing of the site within 7 days of the discontinuance of licensed activities at any site.

3.3 Use of radioactive sources on human volunteers

3.3.1. Administration of nuclear substances to human subjects is strictly prohibited under the Consolidated license as indicated in Condition 1 of the license (see Appendix 1).

3.3.2. Nuclear substances can only be administered to human subjects under the therapeutic or diagnostic nuclear medicine license, or it may require a special license from the CNSC if it involves healthy volunteers in an experimental protocol. Investigations of this nature fall under the jurisdiction of the MUHC's Ethics Committee, the role of the RPS being to advise on radiation dosimetry aspects of the proposal and licensing issues.

3.3.3. The guidelines published by the CNSC in the document *Guidelines for research on human subjects using radionuclides* (GMA-5), Dec 93, should be followed.

3.3.4. An applicant for a license for the use of radiation sources in human subjects has to satisfy the following conditions, as required by the CNSC:

a) he/she is a qualified and registered Nuclear Medicine specialist of the province of Quebec;

b) he/she is qualified and experienced in the handling of radioisotopes and radiation sources;

c) the quantities of radioisotopes to be purchased, stored and handled at any one time do not exceed the safe limits for the type of laboratory and facilities available;

d) the procedure (protocol) and administered radioactivity per subject (human volunteer) are approved by the Research Ethics Board (REB);

e) adequate instrumentation for measurement and monitoring of radiation is available.

3.3.5. The Manager of the RPS at the MUHC, in consultation with the applicant, will assure the complete and timely processing and/or renewal of any specific license application to be submitted to the CNSC.

3.4 Records, Reports and Licensing issues

3.4.1 The licensee must keep the following documentation related to the utilization of nuclear substance at the MUHC. Records to be kept are:

- List of all authorized users and their records of training
- List of all locations where nuclear substances are being used or stored
- The name, quantity, form and the location of any nuclear substance being used
- The manner in which it is used
- Name of each worker who uses or handles a nuclear substance
- List of all sealed sources or radiation devices (manufacturer, model, serial numbers)
- Records of any measurements and surveys done by the RPS staff (area monitoring, contamination monitoring)
- Any records of transfer, receipt, disposal or abandonment of nuclear substances
- The record of all inspections, measurements and tests done by the RPS
- The contamination monitoring records done by the laboratory workers
- Personal dose monitoring records (TLD results from NDS, thyroid monitoring)

With the exceptions below, all documents must be kept for a period ending 3 years after the expiry of the license. Contamination monitoring records must be kept for a period ending 1 year after the expiry of the license. Records of training for authorized users must be kept for a period ending 3 years after the termination of employment of the worker.

No documents shall be disposed unless the RSO has notified the CNSC of the date of disposal and of the nature of the records of at least 90 days before the date of disposal.

3.4.2 The RPS must maintain a list of all licenses issued by the CNSC related to the utilization of nuclear substances and radiation devices (NSRD)

3.4.3 The RPS is responsible for submitting annually an Annual Compliance Report as requested by the CNSC at a date fixed by the Commission (as indicated on the licenses).

3.4.4 The RPS is responsible for the administration of the CNSC licenses at the MUHC. This includes the any requests for amendments and renewal of licenses.

4. Regulatory Dose Limits

The Canadian Nuclear Safety Commission (CNSC), under the Radiation Protection Regulations (RPR SOR/2000-203), defines limits on the effective dose received by and committed to a person, and limits on the equivalent dose received by and committed to an organ or tissue.

4.1 Effective and Equivalent dose limits

4.1.1 Effective dose limits

The effective dose limits are given in the table below.

"Every licensee shall ensure that the effective dose received by and committed to a person described in column 1 of an item of the table to this subsection (below), during the period set out in column 2 of that item, does not exceed the effective dose set out in column 3 of that item". (RPR 13.1)

	Column 1	Column 2	Column 3
Item	Person	Period	Effective Dose (mSv)
1.	Nuclear energy worker, including a pregnant nuclear energy worker	(*a*) One-year dosimetry period	50
		(*b*) Five-year dosimetry period	100
2.	Pregnant nuclear energy worker	Balance of the pregnancy	4
3.	A person who is not a nuclear energy worker	One calendar year	1

4.1.2 Equivalent dose limits

The equivalent dose limits are given in the table below.

"Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection (below), or a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the effective dose set out in column 4 of that item." (RPR 14.1)

	Column 1	Column 2	Column 3	Column 4
Item	Organ or Tissue	Person	Period	Equivalent Dose (mSv)
1.	Lens of an eye	(*a*) Nuclear energy worker	One-year dosimetry period	150
		(*b*) Any other person	One calendar year	15
2.	Skin	(a) Nuclear energy worker	One-year dosimetry period	500
		(*b*) Any other person	One calendar year	50
3.	Hands and feet	(*a*) Nuclear energy worker	One-year dosimetry period	500
		(*b*) Any other person	One calendar year	50

Some of the definitions used in the tables above in the next section.

4.1.3 Definitions

Nuclear Energy Worker (NEW): A person who is required in the course of the person's business or occupation in connection with a nuclear facility, to perform duties in such circumstances that

there is a reasonable probability that the person may receive a dose of radiation that is greater than the prescribed limit for the general public.

One year dosimetry period: a period of one calendar year beginning on January 1 and every period of one calendar year thereafter.

Five year dosimetry period: a period of five calendar years beginning on January 1 and every period of five calendar years thereafter.

Balance of pregnancy: period of time from the moment the licensee is informed in writing of the pregnancy, until the end of pregnancy.

4.2 Nuclear energy workers

As defined in the Radiation Protection Regulations under the *Nuclear Safety and Control Act* (SOR/2000-203), a "Nuclear energy worker" means:

“a person who is required, in the course of the person’s business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in such circumstances that there are reasonable probability that the person may receive a dose of radiation that is greater then the prescribed limit for the general public.”

This refers to the maximum permissible dose for a member of the public of 1 mSv per year. Regulatory dose limits are discussed in details in section 3 of this manual. The RPS designates any person to be considered as a "Nuclear energy worker". These workers may include:

- Nuclear Medicine technologists and physicians
- Electronic technicians working in Nuclear Medicine
- Medical Physicists
- Isotope Laboratory workers
- The radiation safety officer and assistants

A person designated as a NEW at the MUHC must sign the Nuclear Energy Worker Designation form in Appendix 2.

At the MUHC, employees working in radioisotope laboratories are usually not classified as Nuclear energy workers, but the RPS reserves the right to change this classification if deemed necessary.

4.3 Pregnant Nuclear Energy Workers

4.3.1 Every nuclear energy worker who becomes aware that she is pregnant shall immediately inform the licensee in writing.

4.3.2 On being informed by a nuclear energy worker that she is pregnant, the licensee shall, in order to comply with the legal limits shown in the preceding table (4 mSv for the balance of the pregnancy), make any accommodation that will not occasion costs or business inconvenience constituting undue hardship to the licensee.

4.4 General Public

The dose limit for non-Nuclear Energy Workers and members of the public is 1mSv in one calendar year. As stressed in paragraph 1.2, the ALARA principle applies and every effort must be made to reduce the actual doses received by non-Nuclear Energy Workers to as low a level as possible. This applies to any situation in the hospital in which non-Nuclear Energy Workers or members of public, including patients, may be exposed to radiation from devices or substances regulated by the CNSC or to radioactive contamination, in circumstances such that the individual concerned derives no personal benefit from the exposure.

4.5 Action Levels

4.5.1. The doses listed in the tables above (section 4.1) are maximum permissible doses or MPD (also referred to as dose limits). They are in no sense "dose allotments" which can and should be used up. On the contrary, the guiding principle of all radiation work is: the dose should be as low as is reasonably achievable, economic and social factors being taken into account. This is called the "ALARA" principle and is central to all radiation safety.

4.5.2. In order to retain control over the radiation safety program, and in accordance with the CNSC Radiation Protection Regulations (sec. 6, SOR/2000-203), action levels are defined. “Action level” means a specific dose or other parameter that, if reached, may indicate a loss of control of part of licensee’s radiation protection program and triggers a requirement for specific action to be taken. Action levels are discussed in detail in the CNSC document G-228 *Developing and using Action Levels.*

4.5.3. Action levels for Nuclear Energy Workers at the MUHC:

Any Nuclear Energy Worker (NEW) whose annual dose exceeds *one-tenth of the yearly MPD* is subject to investigation by the RPS. This corresponds to an effective dose of 5 mSv over a one-year dosimetry period and is within the limits usually met by most Nuclear Medicine technologists. However, for some rare cases, this limit might be exceeded. Once this level has been reached for any NEW, and if there are no clear reasons to explain the unusual exposure report (e.g. unusual workload with nuclear medicine patients, emergency situations, …) the Manager of the RPS shall take the following actions:

- Conduct an investigation to establish the cause for reaching the action level
- Identify and take action to restore the effectiveness of the radiation safety program
- Notify the Commission within the period specified in the license if applicable

4.5.4. Action levels for laboratory workers (not Nuclear Energy Workers) at the MUHC:

For laboratory workers that are not declared NEW but that are monitored for radiation exposure with personal dosimeters (e.g. TLD's), the action level is set *one-half the yearly MPD.* This corresponds to an effective dose of 0.5 mSv over a one-year dosimetry period. For laboratory workers making extensive use of radionuclides and for which good laboratory practices and ALARA principle does not suffice to keep their effective dose below 1 mSv over a one-year period, the RPS will consider declaring them as NEW after examining every other alternatives.

4.5.5. The table below summarizes the action levels at the MUHC.

TYPE OF WORKER	ACTION LEVELS
Nuclear Energy Workers (NEW)	5 mSv (total body) 15 mSv (lens of an eye) 50 mSv (skin) 50 mSv (hand and feet)
Radioisotope workers (only if not declared NEW)	0.5 mSv (total body) 7.5 mSv (lens of an eye) 25 mSv (skin) 25 mSv (hand and feet)

4.5.6. Other Action levels include decontamination criteria, which are discussed in details in Chapter 6 of this manual. Any room, enclosure, device or work area where surface contamination criteria are reached or exceeded must be decontaminated immediately until the contamination level is reduced below the acceptable limits.

5. Radiation Monitoring

5.1 General Principles

Monitoring of dose and dose rates and measurement of contamination levels are essential components of any radiation protection program. Such monitoring includes:

- Area monitoring, i.e. measurement of radiation dose rate at various points in areas, rooms or enclosures where unsealed nuclear substances are used or stored;

- Technique monitoring, i.e. measurement of radiation dose rate received by specific individuals and/or at specific locations, during particular procedures involving radiation sources.

- Personnel monitoring, i.e. measurement of the total dose received by individual radiation users over a period of time.

- Bioassays to determine the level of radioisotopes ingested or inhaled by the user. These techniques are used when an incident occurs and incorporation of radioisotopes is suspected. Bioassays are also performed on a routine basis for users of volatile high toxicity isotopes such as I-125 and I-131 (Thyroid monitoring).

- Medical surveillance of users: pre-placement health assessment and special tests in case of overexposure.

- Leak testing of sealed sources;

- Contamination monitoring, i.e. measurement of contamination levels in all areas, rooms or enclosures where unsealed nuclear substances are used or stored.

Contamination monitoring will be discussed in detail in the next chapter.

5.2 Area and technique monitoring

5.2.1. The responsibility for these types of monitoring rests with the RPS. It is the RPS responsibility to carry out, either directly or by delegation, whatever surveys and measurements needed to ensure that room and equipment shielding are adequate to ensure a proper standard of radiation safety.

5.2.2 Permit holders, heads of department, departmental radiation supervisors and individual Nuclear Energy Workers have the duty to collaborate with the RPS in this task, and in particular, inform the RPS of any situation or procedure which warrants special investigation. In addition, permit holders and/or heads of department and departmental radiation supervisors have the responsibility of carrying out whatever recommendations are made as a result of such investigations.

5.2.3. No person shall use a radiation survey meter that has not been calibrated within the 12 months preceding its use. The requirements for gamma radiation survey meter calibration are described in the CNSC document CNSC *Regulatory Expectations for Calibration of Survey Meters*. All survey meters at the MUHC must be calibrated as per CNSC requirements.

5.2.4. All radiation readings performed during a radiation survey must be recorded. Information recorded should include the date and location of the measurement and the name, model and serial number of the measuring instrument.

5.2.5. Calibrated survey meters are available from the RPS at the MGH (room T9-100) or at the RVH (room H4.32). Calibrated survey meters are also available from the Nuclear Medicine department at the RVH (room. M2.11), the MGH (room D5.161) and the MCH (D-362-A).

5.3 Personnel monitoring

5.3.1 Nuclear Energy Workers are subject to routine, continuous monitoring of the radiation dose received from external sources by means of a Thermoluminescent Dosimeter (TLD) badge. TLDs are the official dosimeters for dose measurements of external radiation and must be worn by Nuclear Energy Workers.

5.3.2 TLD exposure monitoring is also performed on regular workers handling radioactive substances or devices as per CNSC regulations (e.g., workers handling more than 50MBq of P-32 need to wear an extremity TLD monitor) or if there is a real possibility of exposure to radioactivity either directly or indirectly.

5.3.3 The dosimeter service at the MUHC is provided by the National Dosimeter Service (NDS) of the Radiation Protection Bureau (RPB) of Health Canada, which is a service of the Federal Ministry of Health and Welfare. (The RPB is a provider of dosimetry services recognized by the CNSC).

5.3.4 Depending on the service requested by the various radiation users, TLDs are provided periodically by the RPB at intervals of ½ , 1 or 3 months. The distribution within the MUHC is

undertaken in each department or laboratory by the Departmental Radiation Supervisor or delegate.

5.3.5 At the end of a dosimetry period, the holders should be collected in each department or laboratory by the DRS or his delegate who:

a) removes the exposed TLD plaques;

b) examines each holder for possible damage;

c) inserts new plaques which have meanwhile been received from the NDS;

d) returns the exposed plaques to the NDS, with a list of the users;

e) distributes the holders containing the plaques to the individual workers;

f) enrolls pregnant workers on the special NDS semi-monthly monitoring program;

g) provides extremity badges to workers as needed.

5.3.6 The exposed TLD chips are measured by the NDS and a report of the radiation dose received by each worker is sent to the RPS. The RPS conducts a review of the report and any unusually high value (greater than the action levels set in section 4.4.5) is subject to investigation. The RPS retains the original of the report. For NEW (e.g. Nuclear Medicine technologists) and radiation workers (e.g. X-Ray technologists), the RPS sends a copy of the report to the departmental radiation supervisor who is responsible for displaying it on a departmental bulletin board (or otherwise conveying the results to the individuals concerned).

5.3.7 All radiation dose records, including measurements of external irradiation and estimated doses resulting from internal irradiation if applicable) are maintained at the radiation safety office and are available to the worker and his supervisor.

5.3.8 Responsibility of individual workers

The individual worker is responsible for:

a) taking good care of the monitor at all times;

b) wearing the monitor at all times during working hours. The monitor may be worn where the source is nearest, either at waist or at chest height. Where a lead apron or other

protective clothing is worn, the monitor should be carried under the apron since its job is to record the radiation reaching the body, not the radiation reaching the apron;

c) guarding the monitor as a personal monitor, issued to a named individual. In no circumstances may a monitor be loaned to another person or otherwise used to record doses received by more than one individual or used for any other purpose than personal monitoring;

d) taking care that the monitor does not accidently drop onto the floor or onto any place (e.g. a radiographic table) where it might accidently become exposed to a direct radiation beam;

e) taking care that the monitor is not accidently splashed or otherwise contaminated by a radioactive solution;

f) taking care that, outside working hours, the monitor is left in a safe place which is well away from any radiation source and from any source of intense heat including a radiator.

5.3.9 Additional information on the proper handling, wearing and storage of whole body and extremity dosimeters can be found in the CNSC INFO-0688 poster in Appendix 3.

5.3.10 Limitations of TLD monitoring

Personnel monitoring of the type described in the previous two sections is a satisfactory general indicator of whole-body dose due to external X or gamma-radiation. However, the system has some important limitations:

a) it does not record the additional dose received by the hands, limbs or face in some procedures; workers using large quantities of high energy beta emitters should therefore wear wrist or ring dosimeters to measure extremity doses,

b) it does not record exposure arising form internal ingestion of radioactive materials;

c) it does not record doses due to low energy beta rays such as those from tritium, carbon-14 and sulphur-35;

d) the 3-monthly cycle is too long for some individuals whose work carries a higher-than-average risk of exposure.

5.4 Thyroid Monitoring

5.4.1. Monitoring of internal radioactivity requires the setting up of special sensitive equipment for external counting of gamma radiation from radioisotopes deposited in the body. At present, only the measurement of radioiodine in the thyroid is carried out routinely by the RPS for users handling Iodine-125 radioisotopes.

5.4.2. The nuclear medicine department also performs thyroid monitoring for Nuclear Medicine technologists who manipulates Iodine-131 radioisotopes.

5.4.3. Every person shall undergo thyroid screening within five days who:

(a) uses in a 24-hour period a quantity of Iodine-125 or Iodine-131 exceeding;
(i) 2 MBq in an open room;
(ii) 200 MBq in a fume hood;
(iii) 20 000 MBq in a glove box;
(iv) any other quantity in other containment approved in writing by the Commission or a person authorized by the Commission; or

(b) is involved in a spill of greater than 2 MBq of Iodine-125 or Iodine-131;or
(c)on whom Iodine-125 or Iodine-131 external contamination is detected.

5.4.4. The RPS must be contacted as early as possible after use to make arrangements for thyroid monitoring. Failing repeatedly to report within five days for the mandatory screening (see conditions above) could result in the suspension or revocation of the Internal Permit to perform work with I-125 or I-131 (see Enforcement policy in section 6.14).

5.4.5. Screening for internal Iodine-125 and Iodine-131 is performed using a direct measurement of the thyroid with a thyroid uptake probe that can detect 1 kBq of I-125 or I-131. The RPS provides thyroid-monitoring service for laboratory workers. At the time of writing this manual, laboratory workers working under the Consolidated license manipulate only I-125. Nuclear Medicine technologists are occasionally exposed to I-131 volatiles, and for those workers, the monitoring is performed in the Nuclear Medicine department.

5.4.6. The RPS at the MUHC participates regularly to the Thyroid Intercomparison program from the Canadian National Calibration Reference Center for In-Vivo Monitoring and has demonstrated a Minimum Detectable Activity (MDA) for the counter and probe being used (LUDLUM 2200 + NaI gamma probe) of less than 100 Bq typically for I-125. Details about the MDA calculation for I-125 are presented in Appendix 4.

5.4.7. If thyroid screening detects more than 10 kBq of Iodine-125 or Iodine-131 in the thyroid, the RPS shall immediately make a preliminary report to the CNSC and have bioassay performed within 24h by a person licensed by the CNSC to provide internal dosimetry services.

5.5 Medical surveillance

The guidelines in this section are based on the document published by the CNSC in "Revised Guidelines for the Medical Surveillance of Nuclear energy workers", (GMA 8), May 93.

5.5.1 Pre-placement Health Assessment

Medical examinations for Nuclear energy workers need be no different than those for other workers performing similar tasks in the absence of radiation.
Every Nuclear energy worker should undergo a pre-placement medical assessment for the following purposes:

- to determine fitness for the "specific work" for which the worker is to be employed;
- to provide a baseline reference for use when considering subsequent changes which may be related to the worker's occupation or which may influence fitness for work;
- to provide data which may be useful for later epidemiological studies.

The medical conditions which a physician must look for are those which would impair the ability to wear protective clothing, the ability to hear alarms and to assess radiation hazards and the ability to work with specific tools and equipment.

5.5.2 Periodic Health Assessment
Occupational exposure to ionizing radiation below regulatory limits does not constitute a reason for performing periodic health assessments and termination of work health assessment.

5.5.3 Special assessments and tests may be warranted in cases of radiation overexposures exceeding regulatory limits. In these cases, the CNSC document"Guidelines for counselling after occupational overexposure to ionizing radiation" (GMA-6) will be followed.

5.6 Leak testing of sealed sources

5.6.1. The requirements for Leak testing are described in the CNSC document "*CNSC Regulatory Expectations for Leak Testing of Sealed Sources*". All leak tests at the MUHC must be done as per CNSC requirements.

5.6.2. Leak tests are performed on all sealed sources containing more than 50 MBq of radioactive material at the following frequencies.

i) For each sealed source continuously in storage - every 24 months;
ii) For each sealed source which is incorporated in a device - every 12 months;
iii) For a sealed source or shielding that is to be used after being stored for 12 or more consecutive months – immediately before using it;
iv) For any other sealed source over 50 MBq – every six months.

5.6.3. Leak testing is also arranged immediately following an incident that could have damaged a sealed source.

5.6.4. If leakage is detected in excess of 200 Bq, the sealed source or the radiation device shall be taken out of service and the RPS contacted immediately. The Manager of the RPS will take the necessary steps to control the spread of contamination and will immediately notify the CNSC.

6.0 Radiation Safety in Radioisotope Laboratories

6.1 General Principles

At the MUHC, unsealed nuclear substances are used and stored in many clinical or research laboratories. Users of radioisotopes in research and investigations not involving human subjects are not issued with individual licenses by the CNSC but are included in a consolidated MUHC license covering all applications of this kind.

6.2 Internal Permits for radioisotope laboratories

6.2.1. Internal Permits to work with nuclear substances in laboratories are issued by the RPS and delivered to Permit Holders who are responsible for the use of nuclear substances in their laboratories.

6.2.2. Each Permit Holder must hold a current Internal Permit issued by the RPS and valid for two (2) years. Each Internal Permit contains specified conditions of approval, compliance with which is mandatory. Failure to comply may result in the cancellation of the permit and may even jeopardize the MUHC consolidated license.

6.2.3. To apply for an Internal Permit, the form "Application for Radioisotope Internal Permit" should be obtained from the RPS, completed in full, and returned to the RPS (see Appendix 5). The Application is then reviewed by the RPS and conditions of approval are formulated if necessary.

6.2.4. A copy of the approved Internal Permit is sent to the applicant, usually within 2-3 weeks of the initial application, and another copy is retained by the RPS. The Permit holder shall forward to the RPS any changes in the information provided with the internal permit application, especially in the personnel using isotopes in his group.

6.3 Classification of laboratories and Posting

6.3.1 Any laboratory or area in which unsealed radioisotopes are stored, handled or used should be classified in accordance with CNSC Regulatory Document R-52 Rev 1 entitled "Design Guide for Basic and Intermediate Level Radioisotope Laboratories. This document details the facilities (including surface finishes, bench tops, fume hoods, air movement, floors, sinks and drains) required in laboratories designated as "basic" or "intermediate" level.

6.3.2 The classification of laboratories is determined by the Annual Limit of Intake (ALI) for specific isotopes manipulated. The ALI means "the activity, in Bq, of a radionuclide that will deliver an effective dose of 20 mSv during the 50-year period after the radionuclide is taken into the body of a person 18 years old or older or during the period beginning at intake and ending at the age of 70 after it is taken into the body of a person less than 18 years old." (RPR SOR/2000-203, 12.(1)). ALI values for isotopes used in laboratories are given in Appendix 8.

6.3.3. For radioisotope laboratory classification, condition 5 of the Consolidated license (see Appendix 1) indicates that:

The licensee shall classify each room, area or enclosure where more than one exemption quantity of an unsealed nuclear substances is used at a single time as:

(a) **basic-level** if the quantity does not exceed 5 ALI

(b) **intermediate-level** if the quantity does not exceed 50 ALI

(c) **high-level** if the quantity does not exceed 500 ALI; or

(d) **special purpose** if approved in writing by the Commission or a person authorized by the Commission

6.3.4. Except for the basic-level classification, the licensee shall not use unsealed nuclear substances in these rooms, areas or enclosures without written approval of the Commission or a person authorized by the Commission.

6.3.5. The responsible manager and/or permit holder must ensure that every point of access to an area, room or enclosure where there is more than 100 EQ of radioactive materials or where the radiation dose rate might exceed 25 μSv/h are labeled with a radiation warning sign that bears the trefoil symbol and the words "RAYONNEMENT-DANGER-RADIATION". Additional information on the warning sign could include the room number, usage and the CNSC classification of item 6.3.3. The RPS will identify the rooms that require the warning signs and will provide the posting material to the permit holder as necessary.

6.3.6. Based on the above classification, in laboratories falling into the basic-level category, the "Basic Level" poster (INFO-0728-1) shall be posted and kept posted in a readily visible area. For areas in the intermediate-level category, the "Intermediate Level" poster (INFO-0728-2) applies and for high-level areas, the "High Level" poster (INFO-0728-3).

6.3.7. A 24-h emergency contact (name and phone number) and the room identification number must be displayed clearly on the CNSC room classification posters.

6.3.8. In radioisotope laboratories, the CNSC poster *Spill Procedures* (INFO-0743 in Appendix 3) must be posted and kept posted in a readily visible area. The poster shall include the name and telephone numbers of the RSO and the person in charge of the laboratory (Permit Holder or DRS).

6.3.9. In radioisotope laboratories, the CNSC poster *Guidelines for Handling Packages Containing Nuclear Substances* (INFO-0744 in Appendix 3) must be posted and kept posted in a readily visible area.

6.3.10. In radioisotope laboratories, the current Internal Permit with the names of the Permit Holder and phone number, authorized users, room numbers, isotopes and authorized activities must be posted and kept posted in a readily visible area.

6.3.11. Any construction or modification of an existing laboratory must be submitted to the RPS for approval. For basic-level laboratories, the RPS will review the modifications according to the R-52 document entitled "Design Guide for Basic and Intermediate Level Radioisotope Laboratories" to ensure the modifications that are proposed are in agreement with the CNSC regulations and the conditions of the license.

6.3.12. Any construction or modification of Intermediate and High-level laboratories must, in addition to the condition above, be approved in writing by the CNSC.

6.3.13. A 24-hour emergency contact number must be posted in all storage rooms or areas. If more than 100 EQ of a nuclear substance is stored in a room, a radiation warning symbol with the wording RADIATION-DANGER-RAYONNEMENT must be posted at every point of access to the room or area.

6.3.14. A 24hour emergency contact number must be posted on or near all radiation devices (e.g. LSC). If the radiation device contains more than 100 EQ of a nuclear substance, a radiation warning symbol with the wording RADIATION-DANGER-RAYONNEMENT must be posted at every point of access to the room or area where the device is located.

6.3.15. No person shall post or keep posted a sign that indicates the presence of radiation or a nuclear substance (trefoil symbol) at a place where the radiation or nuclear substance is not present. For example, the trefoil symbol should not be posted on calculators, pipettes, rulers,

pencils or any other items used in the laboratories unless these items are contaminated with radioactivity and cannot be decontaminated immediately.

6.3.16. The trefoil symbol on any item must be defaced before this item is disposed into the regular garbage, radioactive waste container or any other waste containers (e.g. chemical, biohazard).

6.4 Project Approval for the use of more than 10, 000 EQ

6.4.1 For projects requiring the use of more than 10,000 EQ of a nuclear at a single time, a special authorization shall be obtained from the CNSC before starting any work.

6.4.2 The Manager of the RPS at the MUHC has been granted permission by the CNSC to approve projects where 10 mCi (370 MBq or 37000 EQ) of P-32 is being manipulated at a single time. Conditions for approval of any such projects are given in Appendix 6.

6.5 Purchases of Radioisotopes

6.5.1 All purchases of radioactive materials for Consolidated activities must be approved by the RPS prior to processing. The RPS maintains a record of all radioactive materials purchased at the MUHC.

6.5.2 The MUHC research laboratories and the Research Institute laboratories should submit their purchase requests to their respective purchasing department. The purchasing department shall not proceed with the order before approval by the RPS.

6.5.3. The activity of each type of radioisotope that can be purchased, stored and used by the individual Permit Holder or DRS is limited by the possession limit indicated on the internal permit and, for the institution as a whole, by the maximum quantities (possession limits) specified on the CNSC license.

6.5.4. Up-to-date individual inventories have to be maintained and posted close to the storage location by each Permit Holder with detailed data about each incoming shipment and its partial or total use in the laboratory and its disposal. The inventories have to be presented for inspection by the RPS, the CNSC or other competent authority. A copy of the recommended form of a radioisotope inventory is included in Appendix 5.

6.5.5 The RPS will only approve imports of nuclear substances and prescribed equipments that are authorized under the conditions of the CNSC consolidated license (see Appendix A). The total quantity of sealed and unsealed nuclear substances shall not exceed the limits set in Section IV of the consolidated license.

6.5.6 Condition 16 of the consolidated license (see Appendix A.) also limits the quantities of tritium, plutonium, thorium and uranium that can be purchased at the MUHC. The RPS will only approved purchases that are below the limits set in condition 16 of the consolidated license.

6.6 Receiving of radioactive packages

6.6.1 Radioactive packages are class 7 dangerous goods and are delivered to the MUHC according to the CNSC and the Transportation of Dangerous Goods regulations. The consignor (e.g. Fedex personnel) must trained and be able to produce a certificate of training in the Transport of Dangerous Goods (TDG, class 7) if asked by an inspector.

6.6.2. Transport by the consignor is completed when the package enters the building and arrive at the MUHC receiving area where it is unloaded and transferred to the MUHC personnel (consignee). A TDG certificate is not required to move or store temporarily the package inside the building.

6.6.2 Most class 7 packages delivered to laboratories are either excepted packages (no special marking) or Type A packages with Category I, II or III marking. Detailed information about the package labeling is given on the CNSC poster *Guidelines for Handling Packages Containing Nuclear Substances* (INFO-0744) in Appendix 3 of this manual.

6.6.3. Upon arrival at a loading dock of the MUHC, if the package is visibly damaged in any way, receiving personnel must contact immediately the laboratory personnel (indicated on the packing slip) or the radiation protection service (RPS) through MUHC Locating (ext.-53333) for assistance. Depending on the severity of the damage, the laboratory or RPS personnel will determine if the package should be accepted or returned to sender.

6.6.4 Excepted packages can be moved from the receiving area to the laboratory like any other ordinary packages. Type A, Category I packages (see INFO-0744, Appendix 3) can be moved also to the laboratories safely but preferably using a cart that will be pushed with arms extended (avoid unnecessary body contact). For Type A category II and III, receiving personnel should store the package in a safe area (locked area if unattended) and call the laboratory personnel or the RPS for further instruction. In most cases, category II and III packages will be picked-up directly by the laboratory personnel.

6.6.5 New packages containing radioactive material delivered to the laboratory must be examined by the Permit Holder or an authorized person following the guidelines set in CNSC document INFO-0744 "Guidelines for handling packages containing nuclear substances" (see Appendix 3).

6.6.6. Under no circumstances should it be possible for radioactive materials to be delivered and left unattended, without the knowledge of an authorized person.

6.7 Storage of Radioactive Material

6.7.1 After unpacking, all radioactive material must be kept in appropriately shielded containers that are marked with appropriate radiation warning signs and carry a label indicating the name of the radiolabel (e.g., 32P), its activity (e.g., 50MBq) and date of the assay (determination) of the activity (e.g., May 20th, 2003).

6.7.2 All containers must be stored in a safe area, compartment or facility, which must be lockable. Freezers located in hallways, if permitted by the Fire Marshal, that contain radioactive materials must be lockable and kept locked at all times. Only authorized/trained personnel should have access to the nuclear substances.

6.7.3 The storage area also has to be identified with the proper radiation warning sign (symbol in black or magenta on a yellow background and the words **"**RAYONNEMENT – DANGER – RADIATION**"** a) if more than 100 exemption quantities of a radioactive substance are stored in the area, or b) if there is a reasonable probability that a person in the area will be exposed to an effective dose rate greater than 25µSv/hr.

6.7.4 The storage location or facility must have sufficient shielding to reduce the radiation level to no more than 25µSv/hr in areas accessible to Nuclear Energy Workers only, and to a level not exceeding 2.5µSv/hr in areas accessible to other persons.

6.7.5 It is strictly forbidden to store or to consume any kind of food or beverage in an area where radioactive material is used or stored.

6.7.6 The storage facility must be of fireproof construction.

6.7.7 Gaseous radioactive materials should be kept in a fume-hood provided with adequate ventilation.

6.8 Handling of unsealed radioisotopes in laboratories

6.8.1 In any laboratory where both radioactive and non-radioactive work are carried out, a separate area must be set aside and clearly designated as the "radioactive area". (Do not use the official yellow and black, or yellow and magenta, radiation warning labels for outlining this area, rather use another type of warning label, e.g., a black radiation warning sign on white background).

6.8.2. The Permit Holder or DRS must ensure any container or device that contains a radioactive nuclear substance are labeled with:

- a radiation warning sign symbol (trefoil symbol in Appendix 3)
- the words “RAYONNEMENT-DANGER-RADIATION”;
- the name, quantity, date of measurement and form of the nuclear substance in the container or device;

This directive does not apply if in respect to a container or device

- that is used to hold a radioactive substance for current or immediate use and is under the continuous direct observation of the user;
- in which the quantity of radioactive nuclear substances is less or equal to the exemption quantity (EQ);

6.8.3 Smoking, eating, drinking and storage of food or drink are prohibited in any area used for storage, handling or use of radioactive material.

6.8.4 Pipetting of radioactive solutions must not be carried out by mouth.

6.8.5 Procedures involving radioactive materials should be carried out in trays or on benches lined with disposable absorbent material. Secondary containments should be used for all radioactive liquids.

6.8.6 Procedures that might produce airborne contamination should be carried out in a fume hood. In any case, some method of containment should be adopted.

6.8.7 Procedures involving dry radioactive powdered materials should be carried out in a glove box.

6.8.8 Laboratories must be kept locked when not in use.

6.8.9 When hand or clothing contamination is possible, protective gloves and clothing must be worn.

6.8.10 After handling unsealed radioactive materials and before leaving the laboratory the operator should monitor his/her hands for contamination.

6.8.11 Equipment, tools and utensils used for work with radioactive materials should not be used for other purposes and should be surveyed for contamination prior to removal from the laboratory.

6.9 Contamination Monitoring

6.9.1. Contamination monitoring must be done in all areas where unsealed nuclear substances with activities of more than 1 exemption quantity (1 EQ) are used.

6.9.2. Radioactive contamination should be measured directly or indirectly. Direct measurement means the use of portable radiation detection instruments to detect both fixed and removable contamination. Direct measurement may be used when background radiation levels are negligible compared to license criteria. Indirect measurement only detects removable contamination by means of wipe tests.

6.9.3. Monitoring for removable contamination should be done immediately following radioactive work or at least weekly. Surfaces that exceed the criteria stated in the license conditions must be decontaminated. Records of the monitoring and the decontamination results should be kept in a logbook and are subject to regular inspections by the RPS or the CNSC.

6.9.4 In laboratories where radioisotopes are manipulated regularly and frequently (at least once a week), contamination monitoring should be done at least weekly and the results recorded in the logbook. For laboratories that remain inactive for several weeks (as is often the case for small laboratories), contamination monitoring should be done shortly after each manipulation and the results recorded in the logbook. A statement such as “No nuclear substances used this week” should be filed in the logbook when appropriate, indicating that no contamination monitoring is necessary for that period.

6.9.5 Portable monitors, suitable for measuring contamination arising from the type of radionuclide stored or used in that laboratory must be available. Guidelines on instrument

selection and measurement methods for contamination monitoring (e.g. direct method using portable meter; indirect method using wipe tests) are detailed in Appendix 7. The RPS can assist in selecting the instrument that is suitable for each laboratory.

6.9.6 Before monitoring for contamination, portable instruments should be given operational checks as specified by the manufacturer (battery check, response check etc.) and the background radiation level should be measured.

6.9.7 Non portable instruments for counting wipes, such as liquid scintillation counters, well-crystal type gamma counters, should be routinely serviced according to the manufacturer's instructions. A copy of service information should be kept with the contamination monitoring records. A blank and a standard should be counted and recorded with each set of wipes.

6.9.8 The locations that are to be monitored should be numbered on a plan of the radioisotope work area or described on a detailed list. These locations should include working surfaces (benches, countertops, fume hoods, etc.), storage areas, and non-working surfaces (floors, instruments, refrigerator, sink, bench, etc.) as appropriate. Several random locations should also be monitored. Too rigid a set of locations may overlook problem areas.

6.9.9 Contamination monitoring records must be kept for 1 year after the expiry of the license and must include:

(a) date of measurement
(b) make an model of the instrument
(c) monitoring locations
(d) contamination monitoring results in Bq/cm2 (before and after decontamination)
(e) results of operational checks and background measurements for portable instruments.
(f) blank and standard measurement results for non-portable instruments.

6.9.10 The CNSC has grouped radionuclides into three classes – “Class A”, “Class B”, or “Class C”- on the basis of common radiological characteristics. A classification table for common radioisotopes is given in Appendix 8.

6.9.11 The contamination criteria set by the CNSC are as follows:

The non-fixed contamination in all areas, rooms or enclosures where unsealed nuclear substances are used or stored (controlled areas), averaged over an area not exceeding 100 cm^2, shall not exceed:

(i) 3 Bq/cm^2 for all Class A radionuclides;
(ii) 30 Bq/cm^2 for all Class B radionuclides;
(iii) 300 Bq/cm^2 for all Class C radionuclides.

The non-fixed contamination in all other areas (public areas), averaged over an area not exceeding 100 cm^2, shall not exceed:

(i) 0.3 Bq/cm^2 for all Class A radionuclides;
(ii) 3 Bq/cm^2 for all Class B radionuclides;
(iii) 30 Bq/cm^2 for all Class C radionuclides.

Surface contamination limits are given in Appendix 8 for common radioisotopes along with additional data.

6.9.12 For any contamination level above the legal limits defined in item 6.9.11, decontamination procedure shall be undertaken. However, these legal limits are by no means limits below which decontamination procedure should be stopped. On the contrary, efforts should be made to reduce the contamination to levels As Low as Reasonably Achievable (ALARA). While in principle there is no contamination level at which the ALARA concept should not be applied, the RPS considers that further decontamination effort is not normally required if the non-fixed contamination averaged over an area not exceeding 100 cm^2 does not exceed:

(i) 0.05 Bq/cm^2 for all Class A radionuclides;
(ii) 0.5 Bq/cm^2 for all Class B radionuclides;
(iii) 0.5 Bq/cm^2 for all Class C radionuclides.

6.10 Decommissioning of radioisotope laboratories

All items, rooms or equipment which have been used for work with unsealed radioactive materials must be properly decommissioned prior to their use in non radioactive circumstances or prior to their disposal in a non radioactive waste stream as appropriate.

6.10.1 Before any radioisotope facility is decommissioned, a radiation survey shall be performed and appropriate actions shall be taken to remove any areas of contamination where the count rate is above background. The form "Decommissioning Report" (see Appendix 9 for a copy of the form) has to be completed by the Permit Holder or DRS and sent to the RPS.

6.10.2 Items, equipment, fume hoods, enclosures or rooms used for unsealed radioactive material should be monitored for contamination using: a) Direct monitoring using a contamination meter or b) Indirect monitoring, using the wipe test method. Both contamination-monitoring methods are discussed in details in Appendix 7.

6.10.3 The non-fixed contamination, averaged over an area nor exceeding 100 cm2, shall not exceed the levels indicated in section 6 of this manual.

6.10.4 All nuclear substances and radiation devices must be transferred or disposed in accordance with the conditions of the license.

6.10.5 All radiation warning sign must be removed or defaced.

6.10.6 Once decommissioning is complete, the RPS will usually arrange for a final inspection to be conducted, and will arrange for notification of the permit holder that decommissioning is complete.

6.10.7 Note that CNSC approval is required for decommissioning where fixed contamination in an area remains. This would be as detected by the contamination monitoring instrument which is appropriate for detection of the radioisotope. The RPS will only approve the areas as decommissioned upon receipt of approval to do so from the CNSC.

6.10.8 Records of the monitoring results must be maintained on record for three years. Records should be maintained by the individual requesting the decommissioning and the RPS.

6.11 Using radioisotopes with animals

In laboratories where nuclear substances are administered to animals, the internal permit holder and radioisotope users should follow these guidelines in addition to all other procedures for the safe handling of radioisotopes in laboratories.

6.11.1. A request to amend an Internal Radioisotope Permit must be made to the RPS. Where appropriate, the animal center will be listed on the internal permit as a use room.

6.11.2. Animal caretakers personnel should be authorized by the RPS, or work directly under the supervision of authorized person.

6.11.3. Waste products from animals and cages that contains levels of radioactivity above background level must be kept for decay before disposal through the regular waste system. The RPS must be consulted prior to disposal of any radioactive waste through the municipal garbage system or municipal sewer to verify if the levels are below the limits set in Condition 19 of the Consolidated license (Appendix 1).

6.11.4. Whenever possible, radioactive animal carcasses and excreta must be stored in a freezer and kept for decay before being disposed through the normal route for biomedical or biohazard materials at the MUHC. The RPS will determine if the carcasses are radioactive or not by monitoring them with the appropriate instruments. If storage and decay is not possible, radioactive animal carcasses must be placed in a double plastic bag and frozen before disposal through the McGill Waste management center. A radioactive label must be tagged around the plastic bag indicating the internal permit number, isotope, estimated activity and date.

6.11.5. After cleaning the cages, contamination monitoring should be performed to ensure there is no contamination. If any contamination is found, the cage must be cleaned and tested again until there is no contamination present.

6.12. Inventory control and Disposal of Radioactive Waste

This section details the process by which radionuclides are inventoried and secured at the MUHC. It is essential to ensure the cost effective disposal of radioactive waste and also to meet regulatory and safety requirements that the amount of radioactivity present in the laboratory, the amounts used and the amounts transferred to radioactive waste are properly recorded and are accurate at all times.

6.12.1 All radioactive material in the radioisotope laboratory and in radioactive waste must be recorded using the McGill University electronic Radioisotope Tracking System (MyLAB). Details about the MyLAB system are given in Appendix 10. Comprehensive notes and visual slideshow on how to use the MyLAB for tracking and disposal of nuclear substances are available for download at http://www.mcgill.ca/eso/training/presentations/#1. When deemed necessary by the RPS (e.g. intermediate and high level laboratories), the running log form in Appendix 10 should also be filled and kept in a log book in the laboratory.

6.12.2. The inventory of each radioisotope (or multiple radioisotopes), by-products, and radioactive waste must be printed out and posted on the outside of the storage unit at least weekly so that it is easy to identify the radioactive products in the storage unit.

6.12.3. Waste generated from the use of radioactive material should be disposed of as radioactive waste via the McGill University Waste Management Program.

6.12.4. The Waste Management Program supplies laboratories with different types of containers. The user must properly complete identification tags, attached to each container, prior to pick up by the Waste Management Program technician. In addition, users are required to segregate radioactive waste in separate containers, according to three categories. They include:

- Liquid Scintillation Vials (LSV) are disposed in the 5 gallon (20 litre) steel pails and then the letters "LSV" are written on the container lid. There is no need to empty each liquid scintillation vial. It is recommended to place a plastic bag inside to line the pails and to attach the completed identification tag.

- Solid Waste is disposed in the 5 gallon (20 litre) steel pails or cardboard boxes or in smaller containers like 4 litre white plastic or 1 litre clear plastic containers. Only solid and dry materials should be placed in these containers and the completed identification tag must be attached.

- Liquid waste other than LSV must be emptied in 4 liter white plastic or 1 liter clear plastic containers and identified with the completed identification tag.

- Animal Carcasses must be put in a double plastic bag, tied and tagged with completed identification label. Carcasses must be frozen at the time of collection.

6.12.5. Radioactive waste is collected from laboratories at the MUHC as follows:

- At the RVH, radioactive waste is to be taken to H3.51 according to a schedule specified by the RPS;

- At the MGH, radioactive waste is collected by the technical support co-ordinator of the MUHC Research Institute as required;

- At the MCH, radioactive waste is collected by the RPS upon request.;

- At Place Toulon (MCH), radioactive waste is to be taken to the waste storage area according to a schedule specified by the RPS.

6.12.6. New, empty radioactive waste containers (1L and 4L plastic container, 20L metal pail or cardboard box) can be collected from the above locations at each site during waste collection dates.

6.12.7. The McGill Waste management System will only collect waste that are properly prepared prior to collection. Waste that are not in the specific containers indicated above, or waste that do not have an identification number, activity and date info will not be collected.

6.12.8 Lead waste may be recycled in a non-radioactive waste route once it has been monitored directly using an appropriate contamination monitor and once wipe tests have been taken and verified free of contamination. All radioactive warning labels must be removed.

6.12.9. Plastic pigs may be disposed of in the municipal garbage once they have been monitored directly using an appropriate contamination monitor and once wipe tests have been taken and verified free of contamination. All radioactive warning labels must be removed.

6.12.10. The MUHC is licensed only to dispose small quantities of radioactive waste across the entire institution to the municipal sewer or garbage routes. These limits are indicated in Condition 19 of the Consolidated license (Appendix 1). Additionally, MUHC must keep a detailed inventory of all unsealed nuclear substances disposed of to the sewer. For this reason any proposals to dispose of radioactive material to the municipal sewer or garbage must be referred to the RPS for prior approval.

6.12.11. Approval by the RPS must be obtained prior to the use of this disposal route, and inventory records must be maintained on all disposals and made available upon request.

6.12.12. All labels indicating the presence of radioactive material must be defaced prior to disposal in the municipal garbage.

6.13 Housekeeping and technical services

6.13.1. In rooms or enclosures where nuclear substances are used or stores, housekeeping personnel must:

- Always lock door when leaving the room;
- Never eat or drink in the room;
- Never touch a container or device labeled with the radiation warning sign;
- Never proceed with the cleaning of an intermediate or high-level laboratory without the supervision of an authorized user;

6.13.2. Technical staff that must proceed with the repair of ventilation system, construction work, plumbing, etc… must inform the RPS in order to have a contamination monitoring done before authorizing any work.

6.13.3. In case of an emergency (e.g. flooding, fire, …), work can be initiated without approval from the RPS. The RPS will monitor the room after the work is completed to verify the presence of any contamination.

6.14 Enforcement of the Radiation Protection Program in laboratories

6.14.1. It is the responsibilities of the Internal Permit Holder to ensure the radioisotope workers working under their supervision follow the procedures and working practices set forth in this manual to comply with the CNSC regulations and the conditions of the Consolidated license (Appendix 1).

6.14.2. The RPS can provide support on any issues related to the safe use and handling, transport or disposal of nuclear substances in the laboratories.

6.14.3. The RPS will inspect laboratories to verify compliance with the licensing conditions on a regular basis. High level laboratories should be inspected at least monthly, intermediate-level labs quarterly and basic labs annually. A monitoring checklist for internal compliance is provided in Appendix 11.

6.14.4. Offences will be categorized as minor or major. A major offence would result from violations that pose immediate risk or danger to safety, health, release to the environment of reportable quantities, doses of substantial amount to staff, or place the CNSC Consolidated Radioisotope License in jeopardy. Examples of a major offence include:

- contamination above license criteria;
- inadequate monitoring program;
- use or storage of food or drink in the laboratory;
- inadequate training of new staff;
- non-participation in required bioassay programs;
- inadequate and/or unsafe work and storage areas for radioisotopes; and
- inadequate and/or unsafe storage areas for radiation waste.

A minor offence would be an infraction that poses no immediate risk or threat to health, safety, the environment or the license. Examples of a minor offence would include:

- inadequate signage;
- inadequate posting (internal radioisotope permit, CNSC posters);
- inadequate inventory records;
- inappropriate use of warning labels; and
- inappropriate segregation and/or identification of radiation waste for disposal or decay.

6.14.5. Each major or minor infraction will be reported as a “strike” and additional strikes will be recorded if the problem has not been corrected. The policy is as follows:

- Strike 1: Infraction is observed and recorded by the RPS. The RPS will inform the Permit Holder by way of copy of inspection report or memorandum and sets a deadline for correcting the situation.

- Strike 2: Permit Holder has not replied within due date or the same infraction is observed during a follow up inspection. The RPS revises the deadlines and informs the Permit Holder that sanctions might follow if the situation is not corrected.

- Strike 3: The RPS will schedule a follow up inspection and to observe if the same infraction is still not corrected after the compliance deadline. If the same infraction is noted again, the RPS will notify the associate Dean and the Chair of the Radiation Safety Committee and will advise the Permit Holder of sanctions. Sanction options include suspension of purchasing privileges, suspension of Internal Permit or confiscation of radioactive materials by the RPS.

6.15 Packaging and Transport of Nuclear Substances

6.15.1 Any transfer of nuclear substance from the MUHC (consignor) to another licensee taking possession of the radioactive material (consignee) must be done in accordance with the Transport Canada Regulation on the Transport of Dangerous Goods (TDG) and the CNSC packaging and Transport of Nuclear Substances Regulations. A detailed procedure for the packaging and transport of Class 7 (radioactive) packages is described in Appendix 3A of the manual.

6.15.2 Anyone who transport or offers for transport a package containing a nuclear substance must be trained in the transport of dangerous goods (TDG class 7) and have a valid TDG certificate issued by his employer. It is strictly forbidden for anyone to transport or ship nuclear substance outside any building without TDG training and a valid TDG class 7 certificate.

6.15.3 Anyone worker who needs to package, transport or ship a nuclear substance outside their building must contact the radiation safety office for prior approval. The RPS will provide assistance for all issues related to the packaging and transport of the nuclear substance to a new consignee. Any transport papers must be signed by the RSP staff or a qualified person (with valid TDG class 7 certificate) before any package containing a nuclear substance is offered for transport outside the building.

7.0 Radiation Safety in Nuclear Medicine

7.1. General procedures in Nuclear Medicine

7.1.1. The administration of nuclear substances to humans at the MUHC is authorized under the Diagnostic Nuclear Medicine and the Therapeutic Nuclear Medicine CNSC licenses.

7.1.2. The Manager of Nuclear Medicine department at MGH, RVH and MCH and the manager of the Radiation Protection Service work together with respect to application for renewal of the diagnostic and therapeutic Nuclear Medicine Licenses and the submission of the annual report with respect to each license. The Manager of the Radiation Protection Service conducts the final submission of these documents to the CNSC.

7.1.3. It is the responsibility of the assistant-chief technologists to ensure that routine work conducted in the Nuclear Medicine department is performed in accordance with the procedures described in this manual.

7.1.4. Radiation exposures can occur in the nuclear medicine department during the handling of radiopharmaceuticals or through patient contact. All staff should minimize radiation exposure to unshielded radioactive materials as far as possible through the use of time, distance and shielding practices as described in the safe work procedures. Staff should also ensure that they wear the appropriate dosimetry at all times to record radiation exposures.

7.2 Classification of laboratories and Posting

7.2.1. All rooms where radioactive materials are stored, used or manipulated must be labeled with a radiation warning sign. The sign must be conspicuously placed allowing it to be immediately noticed by anyone entering the room or enclosure. The sign must bear the trefoil symbol, room number and usage and the CNSC classification.

7.2.2. A room is classified as “nuclear medicine” for the use of unsealed nuclear substances if the nuclear substance is prepared for or administered to a person. In these rooms, the “Nuclear Medicine” poster (INFO-0728-4/Rev.1) must be displayed (see Appendix 3).

7.2.3 The “hot lab” in nuclear medicine is classified as a “nuclear medicine” room in accordance with the definition given in item 7.2.2. The old classification as an "intermediate laboratory" is obsolete.

7.2.4. A 24-h emergency contact (name and phone number) and the room identification number must be displayed clearly on the CNSC room classification posters.

7.2.5. In radioisotope laboratories, the CNSC poster *Spill Procedures* (INFO-0743 in Appendix 3) must be posted and kept posted in a readily visible area. The poster shall include the name and telephone numbers of the RSO and the person in charge of Nuclear Medicine (manager or chief technician).

7.2.6. In the "hot lab" where radioactive packages are received and handled, the CNSC poster *Guidelines for Handling Packages Containing Nuclear Substances* (INFO-0744 in Appendix 3) must be posted and kept posted in a readily visible area.

7.2.7. Any construction or modification of an existing Nuclear Medicine must be submitted to the RPS for approval. The RPS will review the modifications following guidelines such as those given in CNSC document GD-52 "Guide for Nuclear Substances Laboratories and Nuclear Medicine Rooms" or use equivalent dose analysis to ensure the modifications that are proposed are in agreement with the CNSC regulations and the conditions of the license.

7.2.8. New nuclear medicine rooms or any changes to existing rooms must be approved by the CNSC.

7.3 Purchases, Reception and Storage of Nuclear Substances

7.3.1. The assistant-chief technologist or their delegate orders radioactive material from the manufacturer.

7.3.2. The nuclear medicine technologist records the date, time, name and activity information on the inventory sheet for each lot number as radiopharmaceuticals are administered to patients. The inventory records must always accurately reflect the nuclear substances in storage or use at any given time.

7.3.3. Unit doses are stored in their transport cases prior to use and are the container are returned to their transport cases following use. The case must be returned as an *excepted package*. The procedure is as follows:

1. Perform a visual inspection of the case.
2. Make sure that the case is empty. Remove all syringes and vials.
3. Complete an entry on your Shipping Log indicating date, case number, signature, contamination and radiation monitoring level.
4. Perform wipe test on the case, especially handles and latches. The result must be < 0.4 Bq/cm2.
5. Perform radiation monitoring on the case in contact with the dose rate meter. Radiation (dose) level may not exceed 0.5 mR/h or 5 uSv/h at any surface.
6. In case of non- compliance with the Exempted Packages conditions, leave and keep the case open in the nuclear medicine department until compliance can be achieved.
7. If the levels are below the limits, turn warning labels around so the "UN 2910" side is visible.
8. Leave the package in a safe and secure area.

7.3.4. Bulk radioisotope is also received with unit doses. The bulk Tc-99m is taken to the laboratory for the day. All unused bulk radioisotope and all unit doses are disposed of prior to return of the empty containers to the manufacturer.

7.3.5. Sealed sources for MGH, RVH and MCH nuclear medicine departments are ordered through and received by the assistant-chief technologist. The assistant-chief technologist maintains accurate inventory of sealed sources.

7.3.6 When there is no authorized individual is present in the room or the storage area that contains radioisotopes must be locked to prevent unauthorized access.

7.4 Handling of unsealed radioisotopes in Nuclear Medicine Rooms

7.4.1 Disposable gloves should be worn during the injection of radioactive material.

7.4.2 Syringes used for the injection of radioactive material must be shielded. This rule may be relaxed only in exceptional circumstances.

7.4.3 A lead apron shall be worn whenever possible during long manipulations or when high activity Tc-99 solutions are handled.

7.4.4 Distance between the technologist and the patient shall be maximized during imaging procedures.

7.4.5 Procedures involving a radioactive gas must be carried out in such a way, that no dispersal of the gas is possible into the immediate environment.

7.4.6 Radioactive substances shall be transported in a container that would prevent spillage. A cart shall always be used when material is transported in public areas.

7.4.7 Radioactive material in storage shall be shielded appropriately such that radiation levels shall not exceed 2.5 μSv per hour.

7.4.8 Used syringes or needles containing residues of radioactive material should be separated from other radioactive waste.

7.4.9 Waste shall be segregated according to the different half-lives. All waste shall be kept for 10 half-lives and checked with appropriate monitor prior to disposal.

7.4.10 Preparation and administration areas shall be surveyed every day.

7.4.11 All areas where radiopharmaceuticals are used or stored shall be surveyed for removable contamination every seven days and filed into a log book.

7.5 Thyroid Monitoring

7.5.1 Nuclear Medicine staff who manipulates Iodine-125 or Iodine-131 must follow the procedure for thyroid monitoring described in Section 5.5 of this manual.

7.5.2. The Nuclear Medicine department at the MUHC participates regularly to the Thyroid Intercomparison program from the Canadian National Calibration Reference Center for In-Vivo Monitoring and has demonstrated a Minimum Detectable Activity (MDA) for the counter and probe being used of less than 1 kBq for I-131 as required by the licensing conditions. Details about the MDA calculation for I-131 are presented in Appendix 4.

7.6 Contamination Monitoring and Leak tests

7.6.1. The Assistant-chief technologist is required to ensure that monitoring for radioactive contamination is conducted in the department.

7.6.2. Contamination monitoring in Nuclear Medicine is done according to the same guidelines as described in Section 6.9 of this manual.

7.6.3 The assistant-chief technologist arranges for routine leak tests of sealed sources in accordance the procedure *Leak Testing* in section 5.5 of this manual.

7.7 Decommissioning of Nuclear Medicine Rooms

7.7.1 Decommissioning of Nuclear Medicine rooms is the responsibility of the Nuclear medicine department. The RPS will approve the decommissioning after the decommissioning procedure is completed.

7.7.1 Items, equipment, fume hoods, enclosures or rooms used for unsealed radioactive material should be monitored for contamination using: a) Direct monitoring using a contamination meter or b) Indirect monitoring, using the wipe test method. Both contamination-monitoring methods are discussed in details in Appendix 7.

7.7.2 The non-fixed contamination, averaged over an area nor exceeding 100 cm2, shall not exceed the levels indicated in section 6 of this manual.

7.7.3 All nuclear substances and radiation devices must be transferred or disposed in accordance with the conditions of the license.

7.7.4 All radiation warning sign must be removed or defaced.

7.7.5 Once the decommissioning procedure is complete, the RPS will usually arrange for a final inspection to be conducted, and will notify the Nuclear Medicine manager when decommissioning is confirmed.

7.7.6 When a patient is administered radiopharmaceutical on a treadmill, the treadmill room should be temporarily posted with the radiation warning symbol. Also, the treadmill room should be decommissioned after the Nuclear Medicine procedure is completed.

7.7.7 CNSC approval is required for decommissioning where fixed contamination in an area remains. This would be as detected by the contamination monitoring instrument which is appropriate for detection of the radioisotope. The RPS will only approve the areas as decommissioned upon receipt of approval to do so from the CNSC.

7.7.7 Records of the monitoring results must be maintained on record for one year after the expiry of the license.

7.8 Inventory control and Disposal of Radioactive Waste

7.8.1 Nuclear medicine radioactive waste is segregated according to its half-life. Sharps are placed into hospital issued biohazard containers. A radioactive label is attached as well as a label indicating its contents.

7.8.2 Once the container is full, it is closed, dated, and decayed. Before disposal, the container is monitored using a contamination monitoring instrument. Radioactive labels are removed and the container is placed out for biohazard waste collection.

7.8.3 Labels are maintained in the waste removal inventory book with the date of disposal, the contamination monitor reading and the initials of the person who conducted the monitoring and authorized the waste for disposal.

7.8.4 Miscellaneous waste is collected in specially marked radioactive material waste containers. This is also monitored prior to disposal as previously described.

7.8.5 Waste can be disposed though the municipal garbage system when the reading using the contamination meter is comparable to the background radiation.

7.8.5 Sealed sources which are no longer in use will be transported and disposed of. This service is obtained through the RPS. The assistant-chief technologist will update the inventory to reflect the disposal of any sealed sources.

7.9 Therapeutic usage of Nuclear Substances

Iodine-131

Major uses of I-131 include the treatment of thyrotoxicosis (hyperthyroidism) and some types of thyroid cancer that absorb iodine. It is administered as a capsule but it can also be administered as an oral solution (depends on availability from pharmaceutical companies). In the form of capsule or oral solution, the I-131 is handled to the patient that ingests it himself (self administration). Iodine-131 is used also to treat neuroendocrine tumours in the form of MIBG (metaiodobenzylguanidine). I-131 MIBG is injected (slow intravenous injection) to the patient by a nuclear medicine technologist or physician following our standard handling procedures (section 7.4 of the RS manual).

The administration of I-131 is done in a treatment room that is temporarily classified as a nuclear medicine room using our classification procedure (section 7.2 of the RS manual). After the intervention is completed, the room is surveyed and declassified as described in section 7.7 of the RS manual.

7.9.1 Iodine-131 radiopharmaceuticals at therapeutic levels above 30 mCi can administered as an In-Patient therapy or as an Out-Patient therapy under the Therapeutic Nuclear Medicine License issued by the CNSC. The Out-Patient protocol for thyroid treatment described in Appendix 12b of the RSM was approved by the CNSC in October 2005 (CNSC Reference 1292557).

7.9.2 It is the responsibility of the nuclear medicine doctor to determine if the patient satisfies or not the conditions for Out-Patient therapy as described in Appendix 12b. The rest of this section applies only to In-Patient therapy.

7.9.3 For In-Patient therapy, the patient must remain in isolation until the amount of radioactivity has dropped below 30 mCi (usually in 48 to 72 hours). In-Patient isolation therapy rooms are available at both the RVH (Ross-5) and the MGH (18^{th} floor).

7.9.4 The I-131 therapy dose must be transported to the therapy room by the nuclear medicine technologist using a dedicated transportation cart and appropriate shielding.

7.9.5 All patients are given an information sheet on isolation guidelines during the treatment and radiation precautions following discharge. The RPS reviews this information with the patient. The patient instruction sheet is given in Appendix 12a.

7.9.6 The nuclear medicine staff or the RPS conducts periodic visits. The dose rate from the patient should be measured at 2 meter, at 1 meter using the dose rate meter. The measurements should be recorded on the form given in Appendix 12. If the remaining activity is greater than 30 mCi (+- 20%), inform the patient that he/she must remain in radioactive isolation and that you will be back next day to monitor him/her again.

7.9.7 The dose rate at the entrance door and adjacent rooms or corridors should also be monitored to ensure the dose rates does not exceed 2.5 μSv/h or that other patients do not receive a dose in excess of 500 μSv per hospital stay.

7.9.8 During the daily visit, the nuclear medicine staff or the RPS should segregate the radioactive waste for storing and decay. Waste can be disposed though the municipal garbage system when the reading using the contamination meter is comparable to the background radiation.

7.9.9 Bedding, towels and other linen used by the therapy patient shall not be released to the laundry if the dose rate exceeds 2.5 μSv/h.

7.9.10 The I-131 patient is released by the RPS. The patient must be released with sufficiently low residual activity (< 30 mCi) according to the CNSC regulations (specific living conditions taken into consideration). The following table is used to determine if less than 30 mCi is remaining in the patient (see also Appendix 12).

Location and Details		**Dose remaining**		**Approx. Radiation Level**	
		mCi	**MBq**	**mR/h**	**μSv/h**
@ 1m (NCRP37,1970)	***With* Restrictions**	30 mCi	1100MBq	**6.75**	**67.5**
@ 2m (GMA-4,1993)	***With* Restrictions**	29.7 mCi	1100MBq	**1.6**	**16**

7.9.11 If the remaining amount of radioactivity in the patient is less than 30 mCi, the patient may be released from isolation. The Nuclear Medicine Physician should be notified that, according to radiation protection, the patient can be released.

7.9.12 After the patient is released by the Nuclear Medicine Physician, the room should be decommissioned following the applicable guidelines described in section 7.7 of this manual.

Yttrium 90 (Theraspheres)

Y-90 is administered for the treatment of liver cancer (Theraspheres). The protocols and instructions to patients are detailed in Appendix 12c.

The Theraspheres are injected in the patient liver under fluoroscopy with the delivery catheter guided under fluoroscopy by an interventional radiologist. Once the catheter is in place, a nuclear medicine technologist or physician injects the Y90-Theraspheres as described in the protocol (Appendix 12c).

The intervention is done in a fluoroscopy suite that is temporarily classified as a nuclear medicine room using our classification procedure (section 7.2 of the RS manual). After the intervention is completed, the room is surveyed and declassified as described in section 7.7 of the RS manual.

Yttrium 90 (Zevalin)

Yttrium-90 Zevalin is given as an injection in the veins. The protocols and instructions to patients are detailed in Appendix 12c.

The dose is administered by a nuclear medicine technologist or physician following our standard handling procedures (section 7.4 of the RS manual). The injection is done in a treatment room that is temporarily classified as a nuclear medicine room using our classification procedure (section 7.2 of the RS manual). After the intervention is completed, the room is surveyed and declassified as described in section 7.7 of the RS manual.

P-32 for Polycythemia Vera

P32 as sodium phosphate for the treatment of polycythemia vera is given as an injection in the veins. The protocols and instructions to patients are detailed in Appendix 12c.

The dose is administered by a nuclear medicine technologist or physician following our standard handling procedures (section 7.4of the RS manual). The injection is done in a treatment room that is temporarily classified as a nuclear medicine room using our classification procedure (section 7.2 of the RS manual). After the intervention is completed, the room is surveyed and declassified as described in section 7.7 of the RS manual.

Ra-223 Chloride (Alpharadin) for treatment of bone metastases

Alpharadin (radium-223 chloride) is an experimental radiopharmaceutical under clinical evaluation to improve survival in patients with bone metastases from advanced cancer. The protocols and instructions to patients are detailed in Appendix 12c.

It is administered as an intravenous injection by a nuclear medicine technologist or physician following our standard handling procedures (section 7.4 of the RS manual). The injection is done in a treatment room that is temporarily classified as a nuclear medicine room using our classification procedure (section 7.2 of the RS manual). After the intervention is completed, the room is surveyed and declassified as described in section 7.7 of the RS manual.

7.10 Blood sample for I-131 patients

Under special circumstances, a blood sample may be required urgently for patients who have been administered I-131 for therapeutic reasons. According to regulations, there are no restrictions for taking a blood sample from the patient and to send it to the hospital central laboratory for analysis. As with any blood sample, universal precautions apply and this level of protection is sufficient for handling blood samples than contain small amounts of radioactive Iodine-131.

Assuming the patient was administered a maximum of 200 mCi of I-131, the MIRD Report No.5 (*MIRD Primer for Absorbed Dose Calculations*, Society of Nuclear Medicine, NY, 1991) indicates that the percentage of I-131 in the blood is reduced to 14.7% at 1h, 9.0% at 6h and down to only 1.6% at 24h after the administration. Bases on this data, it is estimated that a 5cc blood sample (assuming 5L total blood volume) will contain an activity of 1 MBq, 0.67 MBq and 0.12 MBq at 1h, 6h and 24h respectively. The exemption quantity for I-131 is 1 MBq. Therefore, any 5cc blood sample after 1h following the administration of 200 mCi of I-131 to the patient will be less or equal to the exemption quantity. The handling of the I-131 blood sample with such a small activity poses minimal risks and is not regulated.

The greatest risk involved with the taking of a blood sample from an I-131 patient is for the nurse who must be in close contact with the patient during the blood sampling itself. The dose rate at 50 cm from a patient who received a dosage of 200 mCi will be approximately 1.5 mSv/h (this is a worst case scenario since many patients get only 100 mCi or 150 mCi per treatment and activity will be reduced by about 50% after 24h). Because I-131 emits energetic gamma radiation (364 keV), using a diagnostic X-Ray lead apron is ineffective (less than 5% attenuation for 0.5 mm Pb apron). The only way to minimize personal exposure in the absence of adequate shielding is to minimize the time spent next to the patient.

Assuming the blood sampling will take about 2 minutes to complete, the nurse is likely to receive a maximum dose of 50 μSv during the procedure if done within the first 6h after the administration of 200 mCi of I-131 to the patient (we assume no I-131 clearance during that period). To put risks in perspective, this is equivalent to about 5 days of natural background exposure or flying from Montreal to Vancouver in an airplane. Nonetheless, nurses should be rotated in performing this task on a voluntary basis after being explained the risks involved.

In comparison, handling of the 5cc blood sample with less than 1 MBq results in an exposure rate of less than 0.2 μSv/h at 50cm distance which is barely discernible from the background radiation level and, as mentioned above, universal precautions are sufficient to protect the laboratory personnel who handle the blood sample.

7.11 Hemodyalisis for I-131 In-Patients

In the following is the safety procedure to be followed when hemodialysis is required on a patient treated with I-131 in order to ensure the safety of attending staff.

1. The manager of the Nuclear Medicine department should notify in advance the Radiation Protection Service (RPS) about I-131 patients who will require hemodialysis in order to allow preparation and training of the relevant personnel.

2. Whenever possible, dialysis should be conducted in the isolation room normally used for I-131 inpatient treatment. If not possible, the RPS will have to approve and classify the room for the I-131 patient who needs hemodialysis.

3. In consultation with the physicians involved, the I-131 treatment should be administered as soon as possible after the last hemodialysis of the patient, preferably on a Monday or Tuesday.

4. A whole body TLD should be worn by the staff attending to the hemodialysis patient unless informed otherwise by the RPS.

5. During the connection of the hemodialysis unit to the patient, the staff should minimize close contact with the patient and work efficiently to reduce time of radiation exposure.

6. As soon as the unit has been securely set up, the attending staff should move as far away as possible from the patient (avoid unnecessary close contact) in order to reduce their radiation exposure.

7. When the dialysis is complete, the unit should be disconnected taking the same precautions as described for connection of the unit.

8. The hemodialysis unit should be rinsed thoroughly in the patient's room until radioactivity levels has returned to background levels as assessed by the RPS.

9. Any waste material to be disposed should be monitored by the RPS prior to disposal. If necessary, some waste material (e.g. dialyzer) will be stored for decay until in can be disposed through the normal route. Biohazard waste materials that require radioactive decay should be put in doubled plastic bags or sealed containers to prevent any leakage.

10. Future hemodialysis should be conducted within the isolation room according to the same procedure until the patient is released from radiation safety controls by the RPS.

7.12 Ictal Brain SPECT in Epiletic patients at the MNH

7.12.1 Ictal Perfusion Brain SPECT is conducted on patients who are under observation in the Epilepsy Monitoring Unit (EMU) in the Montreal Neurological Hospital.

7.12.2 The Ceretec - Tc99m is prepared by the nuclear medicine technologist at the RVH on the morning of the procedure and the technologist places the dose in the appropriate lead container.

7.12.3 The dose is delivered to the nurse in the designated room by the nuclear medicine porter using the access tunnel to MNH and the appropriate leaded cart. The dose must be kept under direct supervision of the designated personnel until administration to the patient.

7.12.4 The nuclear medicine department collects the lead cart at the end of the day and returns it to the nuclear medicine department.

8. Radiation Safety for the Gammacell 3000 Irradiator

8.1 General Principles

8.1.1 The gammacell irradiator used at the Montreal Children's Hospital is operated under the CNSC Irradiation: self-shielded type (Group 2.3) license.

8.1.2 The Gammacell 3000 Irradiator is a self shielded type irradiator. It is composed of a high activity (Category II) Cs-137 radioactive source, the main biological shield, a movable rotor which houses the irradiation chamber and the control mechanisms. The radioactive source is installed in the source holder at the factory and is mechanically locked and welded in place in such a manner as to prevent any inadvertent or accidental removal.

8.1.3 According to the Gammacell 3000 Specifications Sheet by Best Theratronics, the average dose rate at 5 cm from the surface of the shield (front chamber, load position) will not exceed 2.5 μSv/h. This will be reduced to 0.07 μSv/h at 30 cm ($1/r^2$ law). According to the Laboratory manager – Transfusion Services at the MCH, the maximum workload for any worker using the irradiator is ~50h/y. Based on these figures, the RPS estimates that the effective dose received by any worker is less than 5 μSv/y at 30 cm over a one-year dosimetry period wich is ALARA.

8.2 Safety Procedures

8.1.1 The Laboratory Manager – Transfusion Services is responsible for ensuring that all staff and activities using the gammacell work in accordance with this procedure.

8.1.2. A list of authorised users of the gammacell is required to be maintained. The responsible manager must ensure that such a list is maintained and communicated to the Radiation Protection Service, and that all authorized users have:

- attended a radiation safety training session given by the Radiation Protection Service;
- been properly instructed in its safe use and in the contents of this procedure.

8.1.3. The key to access the room in which the gammacell is located must be kept in the designated storage location when the gammacell is not in use by an authorised user.

8.1.4. Whenever the gammacell is used, the user must record their usage in the computerised tracking system. Upon completion of use of the gammacell, the user must replace the key in the designated storage location.

8.1.5. When the gammacell is being used on a continuous basis, the key may be transferred from one user to another without returning to the storage location. The gammacell must not be left unattended at any time with the door unlocked.

8.1.6. Any requirements to modify the gammacell must be notified to the Manager of the Radiation Protection Service prior to the modification being made. The Manager of the Radiation Protection Service will only approve any such modifications in conjunction with approval from the CNSC as per license conditions. When in doubt as to whether a change to the gammacell is a modification, contact the Manager of the Radiation Protection Service for clarification.

8.1.7. Any plans to modify the location where the gammacell is stored (including displacing the machine, changing locks, and renovating the room) must be approved by the manager of the Radiation Protection Service prior to commencing work.

8.1.8. Any incident or malfunction involving the Gammacell Irradiator must be reported immediately to the Laboratory Manager-Transfusion Services who will contact the RPS if necessary in order that an appropriate response and follow up actions may be taken.

8.1.9. A leak test on the Cs-137 sealed source shall be done annually by a person or a company approved by the CNSC. The leak test report shall be kept by the Laboratory Manager – Transfusion Services, and a copy sent to the Radiation Protection Service.

8.1.10 The Laboratory Manager must contact the RSO for any purchasing, replacement, reception or transfer of the gammacell irradiator or source. The RSO will be responsible for any transport issues indicated above for which TDG training is mandatory.

9. Radiation Safety in Diagnostic Radiology

Background

Radiation emitting devices are regulated at the federal level by the Radiation Emitting Device (RED) Act (R.S. 1985, c. R-1) from the Canadian Department of Justice. The RED Act governs the sale, lease and import of certain radiation emitting devices used for medical and industrial purposes or by consumers. The Act sets safety performance standards for the sale, lease, import, labelling, packaging, and advertising of radiation emitting devices to ensure that workers and the public are not placed at risk. Any radiation emitting equipment acquired at the MUHC must comply with the RED act. The RED act does not regulate the usage and installation of equipment which fall under provincial governments jurisdictions.

Health Canada have issued safety codes for the usage and installation of radiation emitting equipments. Safety codes of interests for diagnostic radiology include:

- Safety Code 35. Radiation Protection in Radiology—Large Facilities (this document replaces Safety Code 20A).
- Safety Code 23. Guidelines for the Safe Use of Ultrasound: Part I - Medical and Paramedical Applications, 1989, 62 p.
- Safety Code 26. Guidelines on Exposure to Electromagnetic Fields from Magnetic Resonance Clinical Systems, 1987, 20 p.
- Safety Code 30. Radiation Protection in Dentistry, 1994, 86 p.
- Safety Code 31. Radiation Protection in Computed tomography Installations, 1994, 43 p.
- Safety Code 33. Radiation Protection in Mammography, 1995, 85 p.

Safety codes offer only specific guidance or guidelines for the radiologist, the physician, the operator and the medical or health physicist concerned with safety procedures, equipment performances and protection surveys. In Canada, usage and installation of X-Ray equipment and occupational exposure to X-rays fall under jurisdiction of provincials government. In Quebec, private radiology clinics are regulated by the Regulation respecting the application of the Public Health Protection Act entitled "*An Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, ambulance services and the disposal of human bodies*" (R.S.Q., c. L-0.2, s. 69). This Act was formerly entitled "*Public Health Protection Act*", title that was replaced in 2001.

For public institution (hospitals), the Quebec Act (R.S.Q., c. L-0.2, s. 69) does not formally apply. However, institutions must adhere to the Organization and Management of Institutions Regulation (c. S-5, r.3.01) and the document "*An Act respecting health services and social services*" (R.S.Q., c. S-5, ss. 7, 18.1, 18.2, 70, 70.1, 71.3, 94, 102, 130 and 173 par. a, b, c, c.1, e,

f, i, j, j.1, k, l, q and r). Under this act, (Chap III, Div. II, item 11.) it is stated that *"An institution using appliances emitting radiation shall put into practice methods of controlling the use of appliances**, such as those** prescribed by the Regulation respecting the application of the Public Health Protection Act (c. P-35, r. 1)."* It is therefore the responsibility of the hospital administration to issue policies that are consistent with the *Public Health Protection Act*.

An excerpt from the Regulation respecting the application of the Public Health Protection Act for Diagnostic Radiology Laboratory is given in Appendix 14 of this manual. It contains all the applicable regulations for the maintenance and operation of the equipment and the safety procedures for staff working in a diagnostic radiology laboratory. It should be noted that the dose limits for workers and members of the public exposed to X-rays differ from the limits set by the CNSC for nuclear substances and devices. The Maximum Permissible Dose (MPD) Equivalents for exposure to X-rays in the Province of Quebec are given in Table 1-3 of Appendix 14.

New regulations in Quebec are being developed by our Health Ministry and will be based on the new Safety Code 35. The date when these new regulations will come into power has not yet been announced. However, letters from the Health Ministry was distributed to Hospital Institutions in Quebec asking these institutions to put into place X-Ray Safety Regulations as recommended by Heatlh Canada Code 35 (see letter in Appendix 14). Implementation of these new recommendations is a work in progress at the MUHC with some already in application (e.g. dose limits as set in section 4.1 of this manual).

9.1 General Principles

Most guidelines in this section are based on the Safety Code 20A (now replaced by Safety Code 35) prepared by the Radiation Protection Bureau of the Federal Ministry of Health and Welfare.

9.1.1 X-ray equipment must only be operated by properly trained individuals.

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

9.1.3 All personnel must take full advantage of the protective devices available.

9.1.4 Except for those persons whose presence is essential for the investigation, no person may be in the X-ray room when the exposure is carried out.

9.1.5 Personnel must at all times keep as far away from the useful beam as is practicable. Exposure of personnel to the useful beam must never be allowed unless the beam is adequately attenuated by the patient and by protective clothing or screens.

9.1.6 Operators should remain inside the control booth or behind protective screens when making an X-ray exposure. In cases where there are reasons that make this impractical, protective clothing must be worn.

9.1.7 When there is a 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 aprons and gloves, and be positioned so as to avoid the useful beam and to minimize exposure to scattered radiation. No one person should regularly perform these duties.

9.1.8 All entrance doors to an X-ray room, including patient cubicle and preparation room doors, should be kept closed while a patient is in the room.

9.1.9 An X-ray tube housing must not be held by hand during operation.

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

9.2 Guidelines for Operation of Radiographic Units

9.2.1 The X-ray exposure should, as a general rule, be controlled from the control panel located inside the control booth or behind a shielded wall. In the case of special techniques where the operator is required to control the exposure while at the side of the patient, appropriate protective clothing must be worn.
9.2.2 The operator must have a clear view of the patient during every exposure and be able to communicate with the patient and/or attendants without leaving the control booth.

9.2.3 Cassettes must never be held by hand during an exposure.

9.3 Guidelines for Operation of Fluoroscopic Units

9.3.1 All persons required to be in the room during a fluoroscopic procedure should wear protective aprons. Lead shields or curtains mounted on the fluoroscopic unit must not be considered a sufficient substitute for the wearing of protective clothing.

9.3.2 Protective gauntlets should be worn by the radiologist during every fluoroscopic examination. During fluoroscopy, palpation with the hand should be kept to a minimum.

9.3.3 During fluoroscopy and spotfilm operation associated with fluoroscopic operation where personnel are required to be at the side of the patient, appropriate protective clothing must be worn by these personnel.

9.3.4 All fluoroscopic examinations should be carried out as rapidly as possible and with minimum dose-rates and X-ray film sizes.

9.4 Guidelines for Operation of Mobile Units

9.4.1 Mobile units shall 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.

9.4.2 During operation, the primary beam should be directed away from the occupied area 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.

9.4.3 The operator must stand at least 3 meters from the X-ray tube and out of the direct beam.

9.4.4 The operator should wear a leaded apron when exposures are made.

9.5 Guidelines for Special Radiological Procedures

9.5.1 When performing special radiological procedures, the radiologist and other personnel in the vicinity of the patient can be subjected to appreciable scattered radiation from the patient when the X-ray beam is on. Therefore, the radiologist and other personnel should wear protective glasses and clothing and should remain as far away from the patient as practicable. The protective devices (e.g. shield panels, leaded drapes, extended collimator cones, etc.) provided with the X-ray equipment should be used whenever they do not interfere unduly with the diagnostic procedure. The smallest X-ray field consistent with the procedure should be used.

9.5.2 Angiography and catheterization procedures are both potentially sources of greatest exposure to personnel, since they require the presence of a considerable number of personnel close to the patient and involve fluoroscopy for extended periods of time and multiple

radiographic exposures. For such procedures all personnel must be aware of the radiation hazards involved and make every effort to adhere to the recommendations below:

a) Full use must be made of the protective devices provided with X-ray equipment (e.g. shielded panels, leaded drapes, bucky slot covers, etc.).

b) All personnel must wear protective clothing and personnel dosimeters. Protective glasses should also be worn.

c) All personnel who are not required to be immediately adjacent to the patient during the procedure must stand back as far as possible from the patient and, if at all possible, should stand behind a protective shield.

9.6 Guidelines for Dental X-ray Equipment

The dental practitioner or other personnel must not hold the film in place for the patient during the exposure. Wherever possible, the dental film should be fixed in position; otherwise it should be held by the patient.

The operator should stand behind a suitable barrier during each exposure. If it is necessary to remain in the room, then the operator should stand as far as possible from the patient and outside the path of the primary beam.

9.7 Safety guidelines for the portable CT (CereTom)

The CereTom (Neurologica) is a portable, small bore CT scanner designed primarily to scan the head and neck. The low power characteristics (low mA) for this small CT is a poor indicator of the radiation hazard. Workers must be informed about the true risk level in order not develop a false sense of security inspired by the lower mA. The risk level is discussed briefly in the following. Additional inquiry may be forwarded to the RSO.

9.7.1 Characteristics of the CT unit and radiation hazard

a) The CereTom geometry and filtration characteristics result in a lower tube current (mAs) for equivalent mAs and patient dose (CTDI) compared to a full size CT.

b) According to the manufacturer's specifications (ref. Neurologica, doc# 1-NL3000-110 rev 01), there is a ~12-15x factor on mAs for equivalent mAs on a large CT. For example, the patient

dose (CTDI) for the CereTom with standard settings (120 kV, 14 mAs/rot) equals that of a large CT with settings (120 kV, 170-210 mAs/rot).

c) The scattered radiation (assuming negligible leakage) in the CT room is roughly proportional to the X-ray dose (CTDI) to the head (major source of scattering). Therefore, the scattered radiation for the CereTom is comparable to that of a large CT
with ~20 μGy/scan @ 3 meters along the bed axis (z) for the standard settings in b).

d) The CereTom is mobile and used mainly in critical care units where public workers and other patients may be in close proximity. In order to minimize the scattered radiation level in the surrounding area, it is equipped with an "optional" radiation shielding upgrade (0.5 mm lead equiv.) at the front and back of the bore opening.

e) Along the gantry axis (x, y), the radiation level is reduced due to the shielding incorporated inside the gantry itself. The gantry is considered to provide one layer of protection to the workers for the scattered radiation from the patient's head..

9.7.2 Operational procedure

The safety procedures for the operation of the CereTom unit are as follows:

a) The optional radiation shielding upgrade (lead curtains) must be used at all times. According to the MUHC standards and ALARA principle, this is not an option.
(Note: Doubling the curtain layer from 0.5 mm to 1 mm lead equiv. is recommended and consistent with ALARA. Efforts should be made to contact the manufacturer in order to comply with this recommendation).

b) The lead curtains (front and back) should be in the "close" position as much as the patient's positioning/security/comfort permits in order to minimize the scattered radiation inside the room.

c) Every worker must be behind at least one protective layer. Therefore:

> i) The operator or medical staff monitoring (looking at) the patient during the scan must wear a lead apron (0.5 mm equiv.) and should stand at least 3 meters away from the patient's head. Protective (shielded) goggles are also highly recommended;
>
> ii) Other personal (public workers) not wearing a lead apron must be at least 4 meters away from the CT and must position themselves so that the lead curtains act as a barrier

between them and the patient's head (the worker must not see the patient's head from his position).

d) The above procedures ensure that workers will be exposed to less than 1 mSv/year for a workload of ~700 head scans/year or 2 scan/day on average.

e) These recommendations are subject to revision if any public worker is exposed to a larger workload.

10. Minimizing Dose to Patients in Diagnostic Radiology

The recommendations and procedures for the protection of the patient outlined in this section are directed toward the physician, the radiologist and the operator. They are intended to provide guidelines for elimination of unnecessary radiological procedures and for minimizing exposures to patients when radiological examinations are indicated.

10.1 Guidelines for the Prescription of Diagnostic X-Ray Examinations

The medical practitioner is in a unique position to reduce unnecessary radiation exposure to the patient by eliminating examinations which are not clinically justified. The Practitioner can achieve this by adhering, as mush as possible, to certain basic recommendations. These are as follows:

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

10.1.2 Routine or screening examinations, such as for pre-employment physical examinations, tuberculosis screening, mass mammography screening, etc., in which there is no prior clinical evaluation of patient, should not be prescribed.

10.1.3 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. The previous radiographs should be examined along with a clinical evaluation of the patient.

10.1.4 When a patient is transferred from one physician or hospital to another any relevant radiographs should accompany the patient and should be reviewed by the consulting physician.

10.1.5 When prescribing a radiological examination, the physician should specify precisely the clinical indications and information required.

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

10.1.7 In prescribing x-ray examinations of pregnant or possibly pregnant women, full consideration should be taken of the consequences of fetal exposure.

a) When radiography of the pelvic area or abdomen is required, the exposure must be kept to the absolute minimum necessary and full use must be made of gonad shielding and other protective shielding if the clinical objectives of the examination will not be compromised.

b) Radiography of the chest, extremities, etc., of a pregnant woman, for valid clinical reasons, should only be carried out using a well-collimated x-ray beam and with proper regard for shielding of the abdominal area. The dose to the region of the uterus in a female having a chest x-ray is usually less than 10 µGy.

10.1.8 If the radiograph contains the required information, repeat exposures should not be prescribed simply because a radiograph may not be of the "best" diagnostic quality.

10.1.9 Specialized studies should be undertaken only by, or in close collaboration with, a qualified radiologist.

10.1.10 Medical staff must not operate x-ray equipment, or be responsible for the use of such equipment, unless qualified to do so.

10.1.11 Radiographs must be monitored routinely to ensure that they satisfy diagnostic requirements with minimal patient exposure.

10.1.12 A patient's clinical records must include details of all x-ray examinations carried out.

10.2 Guidelines for Carrying Out X-Ray Examinations

The recommendations that follow are intended to provide guidance to the operator and radiologist in exercising their responsibility towards reduction of patient exposure.

10.2.1 General Recommendations

a) The operator must not perform any examination which has not been prescribed by the physician responsible for the patient.

b) The exposure of the patient must be kept to the lowest practicable value, consistent with clinical objectives and without loss of essential diagnostic information. To achieve this, techniques appropriate to the equipment available should be used.

c) Particular care, consistent with recommendations of Section 10.1.7, must be taken when radiological examinations of pregnant or potentially pregnant women are carried out.

d) The x-ray beam must be well collimated to restrict it as much as is practicable to the area of diagnostic interest.

e) The x-ray beam size must be limited to the size of the image receptor or smaller.

f) The x-ray beam should not be directed towards the gonads unless it is absolutely essential, in which case gonad shield should be used if possible.

g) Shielding should be used where appropriate and practicable to limit the exposure of body tissues. It is particularly important that special effort be made to protect the blood-forming organs, gonads and thyroids of children.

h) The target-to-skin distance should be as great as possible consistent with good radiographic technique.

i) For very young children, special devices should be employed to restrict movement.

j) Full details of the radiological procedures carried out should be noted on the patient's clinical records.

10.2.2 Recommendations for Radiographic Procedures

a) The edges of the x-ray beam should be seen on all x-ray films to ensure that no more than the desired area has been irradiated. The film size used should be as small as possible, consistent with the diagnostic objectives of the examination.

b) Screen-type film should not be used for non-screen techniques because it is less sensitive to direct x-radiation than non-screen film.

c) The fastest film or intensifying screen-film combination, consistent with diagnostically-acceptable results, should be used. When highest definition is not required a high-speed film-screen combination should be used. X-ray intensifying screens made from rare earth phosphors should be used where appropriate.

d) To ensure that patient exposure is kept to a minimum consistent with image quality, full advantage should be taken of a combination of techniques such as:

- use of an antiscatter grid between the patient and the image receptor.
- use of the optimum focus-to-film distance appropriate to the examination.
- use of the highest kilovoltage which produces films of good quality.
- use of automatic exposure control devices designed to keep all exposures to a minimum.

e) The radiographer should see the films after processing in order to verify that the techniques being used are producing diagnostic quality films and that the x-ray equipment is functioning correctly.

f) To avoid the necessity of retakes, it is particularly important before taking a long series of films that a single preliminary film of the series should be taken and processed to verify correctness of settings.

10.2.3 Recommendations for Fluoroscopic Procedures

a) 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.

b) Fluoroscopy must only be carried out by, or under immediate supervision of, a radiologist or physician properly trained in fluoroscopic procedures.

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

d) The exposure rate used in fluoroscopy should be as low as possible and must not exceed 5 roentgens per minute at the position where the central axis of the x-ray beam enters the patient.

e) The ambient light level in the fluoroscopic room should be set as low as possible.

f) Image intensification must be used in order to reduce patient exposure. Image intensifiers can significantly reduce both exposure rate and exposure 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.

g) Television monitoring should be used in conjunction with the image intensifier.

10.2.4 Recommendations for Special Procedures

a) Significant exposure to the patient's eyes can result from neurological radiography, such as carotid angiography. In projections where it does not interfere with the diagnostic information sought, an eye shield should be used.

b) During cardiac catheterization and angiography significant exposure of the patient's thyroid gland can occur. Appropriate shielding should be used whenever possible.

11. Radiation Safety in the Wards

Sources of ionizing radiation may be encountered in a hospital ward in the following circumstances:

a) A mobile X-ray unit may be used in a ward for diagnostic investigation of a patient.

b) An in-patient may undergo a diagnostic investigation with an unsealed radioisotope in the Department of Nuclear Medicine and be transported back to the ward.

c) An in-patient may undergo an investigation using radioisotopes in certain other locations in the hospital.

d) An in-patient may undergo treatment with an unsealed radioisotope.

e) An in-patient may undergo treatment with small sealed sources.

11.1 Use of mobile X-ray units in wards

The safety aspects of the use of mobile X-ray units have already been covered in Chapter 9, particular 9.4. It must be stressed that, when a radiographic examination is carried out in the ward, the operator must take every precaution to ensure that other patients and members of the staff are not irradiated by the unattenuated direct beam and are sufficiently far from the patient under investigation (at least 3 m) to reduce the scattered radiation to a low level. If necessary, portable screens or lead-rubber aprons arranged as screens, should be used to protect the other patients.

11.2 Patients undergoing diagnostic examination with unsealed radioisotopes

In general, patients who receive diagnostic doses of a radioisotope in the Nuclear Medicine department, do not present a serious radiation hazard. The isotopes involved have short half-lives and most of them are excreted rapidly by the body. The body fluids, especially urine, may contain appreciable amount of radionuclides. The usual precautions taken with these fluids are sufficient to prevent any contamination of the personnel. Frequent emptying of the bladder will lessen potential exposure to attending personnel as well as to the patient's gonads.
If a patient receives an injection of radioactive material in a ward or an intensive care unit, precautions have to be taken to prevent contamination of the area and the used syringe and lead shield should be returned to the Nuclear Medicine department.

11.3 In-patient undergoing treatment with unsealed radioisotopes

11.3.1 Iodine-131 is the isotope most commonly used for therapeutic purpose. The amounts of activity prescribed can vary, depending on the condition being treated, between 0.22 to 7.4 GBq. Occasionally P-32 is used for treatment, the activity being about 166 MBq.

11.3.2 In-patients being treated with unsealed radioisotopes must be housed in a single bedded room and the adjoining rooms should not be occupied on a full time basis.

11.3.3 Before the administration of a dose, the staff of Nuclear Medicine Department must ensure that the floor of the patient's bathroom and toilet are covered with absorbent material. Items in the room likely to be contaminated should also be covered (telephone, chair, arm-rests etc).

11.3.4 The patient should be instructed to flush the toilet several times after every use.

11.3.5 Visiting of patients undergoing treatment with unsealed sources should be restricted; in particular, visits by young and/or pregnant persons should be severely curtailed. Direct contact between visitors and the patient should be avoided and visitors should be instructed to remain as far as possible from the patient. The RPS will give more detailed instructions according to the individual patient and dose.

11.3.6 When surgery has to be performed on a patient who has recently received unsealed radioisotopes for therapeutic purposes, the RPS should be contacted in order to assess the degree of hazard arising from the activity remaining in the patient's body and advise the surgeon and operating room staff if any special precautions need to be taken.

11.3.7 After discharge of the patient, the RPS must monitor the room and its contents before freeing the room for further use.

11.3.8 Further instructions will be given to the ward staff by the RPS upon request.

11.3.9 If a patient should die soon after receiving unsealed radioisotopes for therapeutic purposes, the RPS must be notified. The RPS will notify the pathologist and all other staff concerned of the possible existence of a hazard and of the necessary precautionary procedures to be followed.

12. Radiation Accident, Emergency Procedures and Incident Reporting

12.1 General Principles

A radiation accident is any unplanned incident or occurrence that results or may result in exposure of human beings to either external or internal radiation. Such an incident can occur in one of two basic ways, the responses to which are different:

a) External exposure without contamination; usually but not invariably resulting from a failure or breakdown of a radiation generator, such as an X-ray unit or cobalt-60 therapy installation, or departure from a procedure designed to ensure safe working with such machines.

b) Contamination; by which is meant the spreading or dispersal of unsealed radioisotopes, which may lead to internal or external exposure or both.

For any emergency situations, the RPS can be contacted at the following numbers:

- Radiation Safety Manager and RSO: ext. 43666 (office) or 43862 (cell)
- Radiation Safety Assistant: ext. 36484 (cell)
- After normal working hours, "locating" at ext. 53333 will contact the RSO (24h on call service)

The MUHC safety measures for accidents involving radiation are given in Appendix 13.

Incident reporting also includes any of the following situations (Ref. General Nuclear Safety and Control Regulations, SOR/2000-202, May 2000, Section 29):

- Theft or loss of nuclear substances
- Unauthorized release of nuclear substances into the environment
- Attempted breach of security or sabotage
- System failure
- Serious illness, injury or death possibly incurred as a result of licensed activity

A worker who becomes aware of any situation listed above should immediately contact the RPS who may request a written report.

In situations where the RSO must submit a report to the CNSC, the report shall contain the following information:

(a) a description of the situation, the circumstances and the problem, if any, with the radiation device;

(b) the probable cause of the situation;

(c) the nuclear substance, and if applicable, the brand name, model number and serial number of the radiation device involved;

(d) the date, time and location where the situation occurred or, if unknown, the approximate date, time and location, and the date and time of becoming aware of the situation;

(e) the actions that the licensee has taken to re-establish normal operations;

(f) the actions that the licensee has taken or proposes to take to prevent a recurrence of the situation;

(g) if the situation involved an exposure device, the qualifications of the workers, including any trainee, who were involved;

(h) the effective dose and equivalent dose — as those terms are defined in subsection 1(1) of the Radiation Protection Regulations — received by any person as a result of the situation; and

(i) the effects on the environment, the health and safety of persons and the maintenance of security that have resulted or may result from the situation.

A full report will be submitted to the CNSC within 21 days of becoming aware of an incident.

12.2 Accidents involving only external exposure

Accidental exposure of the whole or part of the body to a direct radiation beam or unplanned proximity of high activity sources is unlikely but not impossible. Anybody who knows or suspects that he has been exposed to a direct radiation beam or unshielded source, must immediately report the fact with as much detail as possible to the RPS. The Manager of the RPS will:

a) Take immediate precautions to avoid the possibility of exposure to others (turn-off the beam, shield the source, cordon off the area, etc.)
b) Arrange for the exposed person to receive a medical examination, including full blood examination if needed.
c) Arrange for a cytogenetic examination if the exposure is likely to be above 200 mSv.
d) Investigate the accident with a view to assessing the dose received by the individual and the cause of the accident.
e) Collect the individual's TLDs' (if worn) and have them send to the Radiation Protection Bureau for dosimetry assessment.
f) Remove or re-shield the source of radiation, if necessary, with the help of provincial or federal radiation safety authorities.
g) Write a detailed report about the accident for submission to the MUHC, the RSC and pertinent authorities.

12.3 Contamination by nuclear substances

Even though every precaution is taken in order to avoid spills of nuclear substances, a large number of sources are handled under the Consolidated license activities and/or Nuclear Medicine, which increase the probability of an accidental spill. In such an event, care must be taken not to spread the contamination, and clean up procedures should proceed immediately. A spill procedure poster should be posted in every room where nuclear substances are being manipulated (INFO-0743, Appendix 3).

12.3.1 The procedure in case of a spill is as follows:

- Immediately inform persons in the area that a spill has occurred.
- Keep them away from the contaminated area.
- Cover the spill with absorbent material to prevent spread of contamination.
- Estimate the quantity of radioactive material involved in the spill.
- Follow the procedure for either Minor or Major spill below (12.3.2 or 12.3.3).

- Only qualified workers authorized to work with radioisotopes can proceed with the decontamination procedures.

12.3.2 Minor spills: typically less than 100 exemption quantities of a radioisotope, without contamination of personnel:

1. Wearing protective clothing and disposable gloves, clean up the spill using absorbent paper and place in plastic bags for disposal.
2. Wipe test or survey for contamination. Repeat decontamination if necessary until contamination monitoring results meet the license criteria.
3. Check hands, clothing and shoes for contamination.
4. Report the spill and cleanup to person in charge or the RSO if necessary.
5. Record spill details and contamination monitoring results. Adjust inventory and waste records.

12.3.3 Major spills involve more than 100 exemption quantities of a radioisotope, and/or contamination of personnel, or release of volatile material:

For Major spill, call 55555 Code Brown (Appendix 13). The RSO will be contacted and Security will assist in securing the area. Follow the major spill procedure described in the CNSC document INFO-0743 posted in the laboratories.

1. Clear the area. Limit movement of all personnel who may be contaminated until they are monitored.
2. Leave fume hood running in the laboratory (if applicable).
3. Close off and secure the spill area (post warning signs).
4. Notify the RSO or the person in charge immediately.
5. The RSO or person in charge will direct personnel decontamination and will decide about decay or cleanup operations.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and mild soap.
7. Follow the procedures for minor spill (if appropriate).
8. Record the names of all persons involved in the spill and details of contamination.
9. The RSO or person in charge will arrange for bioassay measurements if necessary.
10. Submit a written report to the RSO or person in charge.
11. The RSO must submit a report to the CNSC.

12.4 Contaminated patients who need medical attention

a) Isolate patient to protect the environment against the further spread of contaminating radioactive material. Usual surgical isolation technique should be applied.

b) Notify the RPS. The Manager of the RPS has the necessary instrument and knowledge to determine the amount and toxicity of the contamination and would also take care of the decontaminating procedures:

c) Unless very grave injuries make delays impossible, allow the radiation control personnel to decontaminate the patient and surrounding area.

d) If seriously injured, give emergency lifesaving assistance immediately.

e) handle contaminated patient and wound as one would a surgical procedure, i.e. use of gown, gloves, cap, mask, etc.

f) When external contamination is involved, save all clothing and bedding from ambulance, blood, urine, stool, vomitus, personal effects of the patient and your own surgical protective clothing, for the radiation control personnel to deal with. Disposable plastic bags should be used for this purpose, with tags attached to show date and content.

12.5 Fires involving radioactive material

a) The procedures to be followed in the event of a fire are well defined at the Hospital (code red), and they have to be carried out in all instances. The MUHC code red procedure is reproduced in Appendix 13

b) A 24-H emergency number (53333) is available to reach the RSO who will assist the fire unit as necessary. The Laboratory Manager should also be contacted immediately to assist with the location of any hazardous material inside the fire area.

c) The RSO and/or Laboratory Manager will provide to the best of their knowledge precise information to the fire-fighting units about the location of any radioactive material and about the extent of any radiation hazard.

d) Once the fire is dealt with, the RSO will monitor the whole area to verify that the dose rate is within acceptable and safe limits and to detect any contamination level.

e) Only after a careful radiation survey indicating that both the contamination level and the dose rate are below the acceptable limits will the area be allowed open to access.

13. Educations and Training of Personnel

The RPS main objective is to establish and maintain close contact with all those who work with or near radioisotopes and ionizing radiation at the MUHC. Information about new methods, eventual changes in procedures and re-evaluation of past activities means a constant need for training of the old and education of the new personnel. The training of the different groups at the MUHC is as follows:

13.1 Training of Laboratory Radioisotope Workers

13.1.1 Radiation safety training is mandatory to all workers before being an authorized user under the internal permit issued to handle nuclear substances. A Radiation Safety Training course is offered by the RPS to all new laboratory workers as required by the CNSC Nuclear Safety and Control Regulations. The training covers topics such as:

i) Regulations and Licensing;
ii) Basic Radiation Physics;
iii) Radiation and Risks;
iv) Detection Instruments;
v) Transport and Handling;
vi) Procedures for Working in Laboratories.

13.1.2. A training certificate is issued for those who have completed the training session. Workers are asked to sign a record of training where they certify to have understood *the regulations, obligations, radiation dose limits and levels that are associated with the designation as authorized users in radioisotope laboratories at the MUHC.*

13.1.3. Any person involved with the packaging and the transport of nuclear substances must also be trained in the Transport of Dangerous Goods (TDG, Class 7). The RPS offers a basic TDG training module and will issue a TDG certificate to the employee if the employer is satisfied hat the employee is adequately trained. The RPS may also refer the employee to an outside firm for advanced training if deemed necessary.

13.1.4. The TDG certificate is valid for a period of three years and must be renewed after that period by the employer in order for the employee to continue packaging and offering for transport radioactive packages. The employer may re-issue the TDG certificate if he considers that the employee is adequately trained (note that formal TDG retraining after 3 years is recommended but not mandatory).

13.1.5. The TDG certificate must be produced if asked by an inspector. The certificates must be kept for 3 years after the end of the employment or expiry of the license.

13.1.5 As part of the services being offered to the MUHC by the McGill University Waste Management Program, a 2h training session on how to use the McGill Radioisotope Tracking System (MyLAB) for tracking radioisotope usage, waste and disposal will be held at the MUHC when warranted.

13.1.6 Animal care workers who take care of animals injected with nuclear substances in radioisotope laboratories must be trained in radiation safety as described in section 13.1.1 of this manual.

13.2 Training of Gammacell 1000 Operators

13.2.1. A basic radiation safety course is offered by the RPS for the operators of the Gammacell 1000 Irradiator at the Montreal Children Hospital. The one-hour training covers topics such as: Regulations and Licensing; Basic Radiation Physics; Radiation and Risks.

13.2.2. The Laboratory Manager – Transfusion Services is responsible for the on-site training on how to operate the Gammacell 1000 Irradiator. The training includes: Instructions for irradiating blood products (automated method, manual method); Irradiation Indicator Tags; Quality Assurance and Radtag Product information; Irradiation Dose Rates 2% Yearly Time Adjustment;

13.2.3. A detailed Instruction Manual and Owner's guide for the Gammacell 1000 Irradiator is also available from the Laboratory Manager – Transfusion Services at the MCH for consultation.

13.3 Retraining

13.3.1 The RPS will offer Radiation Safety refresher courses to all employees who are referred by their employer or supervisor for retraining. As indicated in Section 2 of this manual (Organization and Responsibilities) it is the responsibility of the Permit Holder or the DRS to ensure that all persons handling radiation sources are adequately trained to work in their laboratories.

13.3.2 The RPS will offer to any employee the full Radiation Safety Training course for the purpose of retraining. Depending on the retraining requirements, the employee may choose to

participate only to some of the modules presented during the full day training session if authorized by his/her supervisor.

13.3.3 Refresher course or retraining is mandatory when there are changes in the regulations, the internal policy and procedures. The RSO will inform all authorized users of any such changes and set up special training sessions accordingly. This may take the form of formal training sessions (course), personal training during routine inspections or visit to the laboratories, or written communications and documentations. All retraining sessions will be recorded in the users' record of training.

13.3.4. A retraining or refresher course is also recommended for workers who have remained inactive for one year or more, or when there are important changes made to the laboratory procedures by the RPS. The RPS will send a general notice when such changes occur and will recommend training as deemed necessary.

13.4 Technologists in Nuclear Medicine and Diagnostic Radiology

They are qualified professionals who received academic and practical training and are practicing "Nuclear Energy Workers" or “Radiation Workers”. They are in constant communication with the RPS, may analyze or discuss any radiation issues or the exposure records together. Seminars are held when warranted or for special purposes (e.g. new regulations, treatment or equipment).

Nuclear medicine technologists also trained in TDG and are issued TDG certificates that are renewed every two or three years (air or ground transportation) as required by Transport Canada regulation.

13.5 Security and maintenance personnel

With the co-operation of those in charge of these departments, seminars are given at the most convenient time for all to attend. The main topics discussed are: possible accidents on the premises of the MUHC, radiation safety procedures in case of emergency and receiving, storage and disposal procedures at the MUHC.

Refresher training will be provided as deemed necessary if the MUHC working procedures or CNSC regulations change. Refresher training will also be given is declared necessary by the RSO.

13.6 Medical and nursing personnel in ICU, Emergency, OR, etc.

Lectures are held in these departments at the convenience of the personnel involved.

APPENDIX 1a:

MUHC Consolidated License

License is posted on all sites. Please contact the RSO office for details.

APPENDIX 1b:

MUHC Irradiator (self-shielded)

License is posted at the MCH (Gammacell room). Please contact the RSO office for details.

APPENDIX 1c:

MUHC Nuclear Medicine (Diagnostic)

License is posted at the RVH, MGH and MCH (nuc. med department). Please contact the RSO office for details.

APPENDIX 1d:

MUHC Nuclear Medicine (Therapeutic)

License is posted at the RVH, MGH and MCH (nuc. med department). Please contact the RSO office for details.

APPENDIX 2:

Nuclear Energy Worker Designation

McGill University Health Centre
Centre Universitaire de Santé McGill

NOTIFICATION OF NUCLEAR ENERGY WORKER STATUS

Name: _____ Sex: M / F

SIN: _____

Date of Birth: _____

Department and Site _____

In accordance with the *Nuclear Safety and Control Act* and *Regulations* of Canada, this is to inform you that you are a NUCLEAR ENERGY WORKER. A Nuclear Energy Worker as defined in the *Nuclear Safety and Control Act* means

"a person who is required, in the course of the person's business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in such circumstances that there are reasonable probability that the person may receive a dose of radiation that is greater then the prescribed limit for the general public."

As required by the *Radiation Protection Regulations* (RPR), I have been informed in writing of:

a) the risks associated with radiation to which I may be exposed in the course of my work, including the risk associated with exposure of an embryo and foetus to radiation;
b) the applicable dose limits prescribed in the RPR;
c) of my expected radiation dose levels;
d) for females, of my rights and obligations should I become pregnant

I understand the risks, my obligations, and the radiation dose limits and levels that are associated with being designated a NEW.

Signature of Worker: _____

Signature of Radiation Safety Officer: _____

Date: _____ (Y/M/D)

McGill University Health Centre
Centre Universitaire de Santé McGill

Notification du statut de travailleur du secteur nucléaire

Nom: _____ Sexe: M / F

NAS: _____

Date de naissance: _____

Département et Site _____

Conformément à la *Loi sur la sûreté et la réglementation nucléaires* et aux *Règlements* du Canada, la présente vous informe que vous êtes un TRAVAILLEUR DU SECTEUR NUCLÉAIRE. Selon la définition de la *Loi sur la sûreté et la réglementation nucléaires*, l'expression travailleur du secteur nucléaire s'entend d'une

"personne qui, dans le cadre de ses affaires ou occupations, doit effectuer des tâches avec une substance nucléaire ou dans une installation nucléaire dans des circonstances entraînant une probabilité raisonnable de recevoir une dose de rayonnement supérieure à la limite réglementée pour le grand public".

Conformément aux exigences du *Règlement sur la radioprotection* (RRP), j'ai été avisé par écrit :

a) des risques entraînés par le rayonnement auquel je peux être exposé durant le cours de mon travail, y compris les risques entraînés par l'exposition d'un embryon ou d'un fœtus;
b) des limites de doses applicables précisées dans le RRP;
c) des niveaux de dose de rayonnement auxquels je dois m'attendre;
d) (pour les femmes) de mes droits et de mes obligations si jamais je devenais enceinte.

Je connais les risques, mes obligations et les niveaux et les limits de dose de rayonnement associés à la désignation comme travailleur du secteur nucléaire.

Signature du travailleur: _____

Signature du responsable de la radioprotection: _____

Date: _____ (A/M/J)

Requirements of the Licensee

As a condition to the Radiation Protection Regulations (SOR/2000-203) the following provision of information must be given to all nuclear energy workers:

Pregnant Nuclear Energy Workers (RPR Section 11)

11.(1) Every nuclear energy worker who becomes aware that she is pregnant shall immediately inform the licensee in writing.

(2) On being informed by a nuclear energy worker that she is pregnant, the licensee shall, in order to comply with the legal limits shown in the preceding table (4 mSv for the balance of the pregnancy), make any accommodation that will not occasion costs or business inconvenience constituting undue hardship to the licensee.

Effective dose limits (RPR Section 13)

13.(1) Every licensee shall ensure that the effective dose received by and committed to a person described in column 1 of an item of the table to this subsection (below), during the period set out in column 2 of that item, does not exceed the effective dose set out in column 3 of that item".

	Column 1	Column 2	Column 3
Item	Person	Period	Effective Dose (mSv)
1.	Nuclear energy worker, including a pregnant nuclear energy worker	(*a*) One-year dosimetry period	50
		(*b*) Five-year dosimetry period	100
2.	Pregnant nuclear energy worker	Balance of the pregnancy	4
3.	A person who is not a nuclear energy worker	One calendar year	1

Equivalent dose limits (RPR Section 14)

14.(1) Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection (below), or a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the effective dose set out in column 4 of that item.

	Column 1	Column 2	Column 3	Column 4
Item	Organ or Tissue	Person	Period	Equivalent Dose (mSv)
1.	Lens of an eye	(*a*) Nuclear energy worker	One-year dosimetry period	150
		(*b*) Any other person	One calendar year	15
2.	Skin	(a) Nuclear energy worker	One-year dosimetry period	500
		(*b*) Any other person	One calendar year	50
3.	Hands and feet	(*a*) Nuclear energy worker	One-year dosimetry period	500
		(*b*) Any other person	One calendar year	50

Emergencies (RPR Section 15)

15.(1) During the control of an emergency and the consequent immediate and urgent remedial work, the effective dose and the equivalent dose may exceed the applicable dose limits prescribed by sections 13 and 14, but the effective dose shall not exceed 500 mSv and the equivalent dose received by the skin shall not exceed 5 000 mSv.

(2) Subsection (1) does not apply in respect of pregnant nuclear energy workers who have informed the licensee in accordance with subsection 11(1).

(3) The dose limits prescribed by sections 13 and 14 and subsection (1) may be exceeded by a person who acts voluntarily to save or protect human life.

Radiation Risks

The International Commission on Radiological Protection (ICRP) has published risk factors of cancer lethality by radiation, which is summarized in the following table:

Table 19-3.
ICRP Summary of Risks of Cancer Lethality by Radiation

	HIGH DOSE HIGH DOSE RATE	LOW DOSE LOW DOSE RATE
Working population	8×10^{-2} per Sv	4×10^{-2} per Sv
Whole population	10×10^{-2} per Sv	5×10^{-2} per Sv

(International Commission on Radiological Protection: Recommendations. Annals of the ICRP Publication 60. Oxford, Pergamon Press, 1990)

Assuming an effective dose of 5 mSv over a one-year dosimetry period for a NEW working in an hospital environment (e.g. Nuclear Medicine Technologist), this results in an Excess Relative Risk (ERR) of 0.005 Sv x 0.04/Sv = 0.00020, or 0.02% per one-year period of acquiring cancer. This should be compared to a lifetime probability of acquiring cancer of about 40% from all causes.[1]

[1]Statistics Canada, http://www.statcan.ca/english/Pgdb/health25a.htm

APPENDIX 3A – Transport of Dangerous Goods (Class 7)

Packaging and Transport of Class 7 (radioactive) Dangerous Goods

Introduction

Transport and Packaging of Class 7 (radioactive) Dangerous Goods must be done in compliance with the CNSC and Transport Canada's TDG regulations. This brief procedure is intended only as a refresher since any one who packages, offers for transport or transports Class 7 DG must be adequately trained to the employer's satisfaction and have a certificate of training issued by his employer or work in the presence of a trained person. The training must be up-to-date with the latest regulations involved and renewed every 24 months for air transport.

The following regulatory documents for the transport of DG are available online at the links indicated below (accessed November 27 2008). A trained person must be familiar will all items related to Class 7 material from the documents below before being authorized to offer Class 7 material for transport at the MUHC.

- *TDG Regulations consolidated to include SOR/2008-34 (Amendment 6)*
  http://www.tc.gc.ca/tdg/clear/part1.htm

- *Packaging and Transport of Nuclear Substances Regulations (SOR/2000-208)*
  http://laws.justice.gc.ca/en/n-28.3/sor-2000-208/154290.html

- *Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Amended) Safety Requirements, Safety Standards Series No. TS-R-1*
  http://www-ns.iaea.org/standards/documents/default.asp?sub=200
  (We will refer to this document as *IAEA TS-R-1*).

In the following, the instructions for identifying and packaging "Excepted", "Type A", and "Industrial" packages are given. These are the types of packages found most frequently at the MUHC for radioisotope laboratory and nuclear medicine. For Type B and C packages, special provisions will be taken in accordance with these same regulations when required.

The shipper's responsibilities are:

1 - Classifying and packaging the DG
2 - Marking and labeling the package
3 - Filling out documentation for shipping
4 - Verifying placarding

In the following, the procedures for filling out each step of the process are detailed. A complete IATA checklist to verify shipments at origin is given at the end of this document. Similar checklists are available from FEDEX.

1. Classifying and Packaging

Before allowing a carrier to take possession of a dangerous good for transport, the consignor must identify and determine the classification of the dangerous good in accordance with the TDG regulations. Identification and classification of Class 7 material is done using the *IAEA TS-R-1* document. If the package to be shipped was previously identified and classified by a previous consignor in accordance with the TDG regulation, the present consignor is allowed to use the classification determined by the previous consignor or by the manufacturer.

The classification of Class 7 material is based of two quantities A1 and A2 defined in the *IAEA TS-R-1* document for the different isotopes.

Below is a partial list for selected isotopes (a complete list can be found in *IAEA TS-R-1* document). A1 refers to special form material while A2 refers to normal form material.

Radionuclide	A1 (GBq)	A2 (GBq)
Americium-241	10,000	1
Carbon-14	40,000	3,000
Cadmium-109	30,000	2,000
Californium-252	50	3
Curium-244	20,000	2,000
Cobalt-57	10,000	10,000
Cobalt-60	400	400
Cesium-137	2,000	600
Iron-55	40,000	40,000
Iodine-125	20,000	3,000
Iodine-129	Unlimited	Unlimited
Iodine-131	3,000	700
Iridium-192	1,000	600
Lead-210	1,000	50
Nickel-63	40,000	30,000
Phosphorus-32	500	500
Radium-226	200	3
Strontium-90	300	300
Technetium-99	40,000	900
Tritium	40,000	40,000

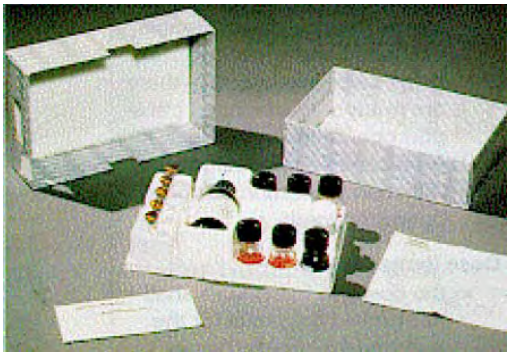
Table 1. List of radionuclide values for selected isotopes

The types of packaging for radioactive material will depend on the amount of material to be shipped (activity limit) as determined above. Most common types of packaging for MUHC radioisotope laboratories products will be either "Excepted packages", "Type A package" and "Industrial package" (for LSA-I material).

For any package, the non-fixed contamination on external surfaces of packages shall be kept as low as practicable and shall not exceed the following limits:

(a) For beta, gamma and low toxicity alpha emitters 4 Bq/cm2
(b) For all other alpha emitters 0.4 Bq/cm2

Excepted Packages



The activity limit for "Excepted package" is given in the table below:

Physical state of contents	Instrument or article		Materials
	Item limits[a]	*Package* limits[a]	*Package* limits[a]
Solids:			
special form	$10^{-2} A_1$	A_1	$10^{-3} A_1$
other forms	$10^{-2} A_2$	A_2	$10^{-3} A_2$
Liquids	$10^{-3} A_2$	$10^{-1} A_2$	$10^{-4} A_2$
Gases			
tritium	$2 \times 10^{-2} A_2$	$2 \times 10^{-1} A_2$	$2 \times 10^{-2} A_2$
special form	$10^{-3} A_1$	$10^{-2} A_1$	$10^{-3} A_1$
other forms	$10^{-3} A_2$	$10^{-2} A_2$	$10^{-3} A_2$

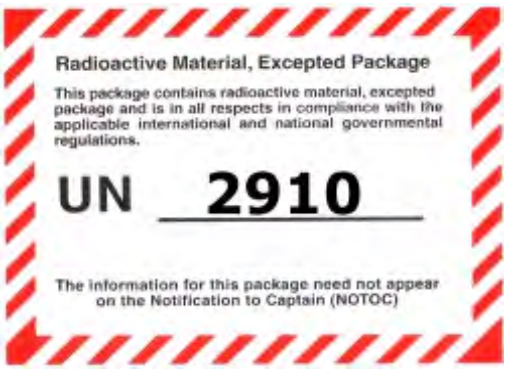
Table 2: Activity limits for excepted packages (*IAEA T-SR-1*, p.39)

Any package that meets the requirements from the table above can be shipped as an "Excepted Package". Another condition is that the dose rate must not exceed 5 microSv/h outside the package.

Excepted packages must be accompanied by a document which includes the shipping name and UN number of the material. If transporting by road, an excepted package of radioactive material must be marked on the outside of the package with the following:

1. The identification mark of the consignor or the consignee
2. The UN number of the radioactive material
3. The permissible gross mass of the package, if the mass is above 50kg.

Air carriers require that the UN number be marked a label entitled “Radioactive Material, Excepted Package" with the red hatching and additional info as illustrated below.



Sending excepted packages through Canada Post

Dangerous Goods, as defined by the Transportation of Dangerous Goods (Clear Language) Regulations (TDGR), are non-mailable matter, except, if permitted by the TDGR, the mailer of the dangerous goods offers them to Canada Post for transport, and if the Corporation is capable of handling them. Canada Post will not otherwise accept packages that contain dangerous goods or that display dangerous goods symbols.
(http://www.canadapost.ca/tools/PG/manual/PGnonmail-e.asp)

According to par 580 of the *IAEA T-SR-1*, an excepted package in which the activity of the radioactive contents does not exceed one tenth of the limits prescribed in Table 2 (above) may be accepted for international movement by post, subject in particular to the following additional requirements as prescribed by the Acts of the Universal Postal Union:

> (a) it shall be deposited with the postal service only by consignors authorized by the national authority;
> (b) it shall be dispatched by the quickest route, normally by air;
> (c) it shall be plainly and durably marked on the outside with the words “RADIOACTIVE MATERIAL — QUANTITIES PERMITTED FOR MOVEMENT BY POST”; these words shall be crossed out if the packaging is returned empty;
> (d) it shall carry on the outside the name and address of the consignor with the request that the consignment be returned in the case of non-delivery; and
> (e) the name and address of the consignor and the contents of the consignment shall be indicated on the internal packaging.

Type A packages

Type A packages shall not contain activities greater than the following:

(a) for special form radioactive material - A1; or
(b) for all other radioactive material - A2.

For mixtures of radionuclides, please refer to par 404 of the *IAEA T-SR-1* document.

Industrial Packages (LSA-I material)

The waste containers that are collected from the radioisotope laboratories are transferred to the McGill Waste Management center periodically as Industrial Packages, Type IP-1 (transported under excusive use). The wastes are classified *UN 2912, Radioactive Material, Low Specific Activity (LSA-I), non-fissile or fissile excepted*.

For the waste products, the following definition for LSA-I applies (*IAEA T-SR-1*, p.9):

> *Radioactive material in which the activity is distributed throughout and the estimate average specific activity does not exceed 30 times the values for activity concentration (for exempt material) specified in pars 401-406 (IAEA T-SR-1 document).*

For mixtures of radionuclides, the activity concentration for exempt material can be estimated using the formula in par. 404 of the *IAEA T-SR-1* document.

2. Marking and Labeling

Class 7 packages (other than excepted packages) require complete shipping description which includes:

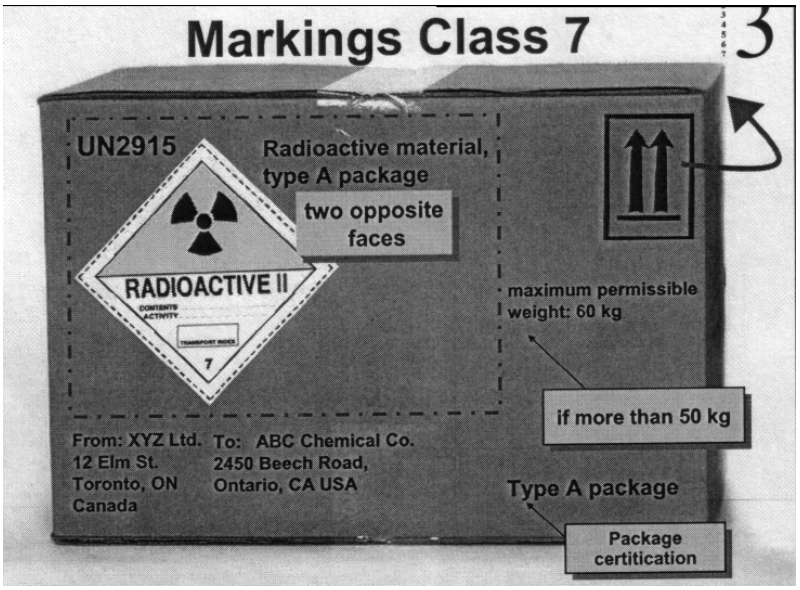
- Identification number (UN number)
- Shipping name
- Categories and Transport Index (TI)

The categories (I, II or III) and Transport Index are defined in CNSC document INFO-0744 in Appendix 3 of the RSM. Most frequently used UN numbers and shipping names are given in the table below (excerpt from Schedule 2 of the TDG regulation).

Col.1 UN number	Col.2 Shipping Name and Description	Col.3 Class	Col.4 Packing Group/ Category	Col.5 Special Provisions	Col.6 Explosive Limit and Limited Quantity Index	Col.7 ERAP Index	Col.8 Passenger Carrying Ship Index	Col.9 Passenger Carrying Road or Rail Index	Col.10 Marine Pollutant
UN2908	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - EMPTY PACKAGING	7		72	0				
UN2909	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - ARTICLES MANUFACTURED FROM DEPLETED URANIUM; RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - ARTICLES MANUFACTURED FROM NATURAL THORIUM; or RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - ARTICLES MANUFACTURED FROM NATURAL URANIUM	7		72	0				
UN2910	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL	7		72	0				
UN2911	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - ARTICLES; or RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - INSTRUMENTS	7		72	0				
UN2912	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-I) non-fissile or fissile excepted	7		74	0	100			
UN2913	RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I), non-fissile or fissile excepted; or RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-II), non-fissile or fissile excepted	7		74	0				
UN2915	RADIOACTIVE MATERIAL, TYPE A PACKAGE, non-special form, non-fissile or fissile excepted	7		74	0				
UN2916	RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, non-fissile or fissile excepted	7		74	0				
UN2917	RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, non-fissile or fissile excepted	7		74	0				
UN3321	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II), non-fissile or fissile excepted	7		74	0	100			
UN3322	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-III), non-fissile or fissile excepted	7		74	0	100			
UN3332	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, non-fissile or fissile excepted	7		74	0				
UN3333	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, FISSILE	7		74	0	0		Forbidden	

Table 3.: UN number and Shipping names for Class 7 radioactive Materials

An illustration of proper labeling for type A package is illustrated below:



All marks and labels on the package:

- must not be covered or obscured by any other item
- must not touch more than one face package
- must be displayed in size and orientation as designed

The radioactive I, II or III label (see above) must be filled out and include the isotope, activity and Transport Index value (if applicable).

Package must also be identified with UN number and proper shipping name on two opposite faces as illustrated above, the double arrows (on two opposite faces), complete address for the consignor and the consignee (from and to) and package certification.

3. Documentation

The shipper's main responsibility for documentation are to:

- produce a compliant document
- maintain a copy of document for 2 years
- provide copies to the carrier

For transportation, the shipper must provide the following documents:

- A declaration for dangerous good
- Any supporting documents
- An airway or way bill

The shipper's declaration must be in IATA format (see next page), be printed and completed in English, be completed manually or mechanically and be signed.

The following information must be included on a shipping document:

- the name and address of the place of business in Canada of the consignor;
- the date the shipping document
- the description of each of the dangerous goods, in the following order:
- the shipping name
- the primary class (class 7 for radioactive material)
- the UN number
- the quantity of dangerous goods (SI units)
- a “24-Hour" emergency number at which the consignor can be reached

In addition, for LSA-I material (UN 2912) in quantities of more than 100 Kg or Liters (ERAP Index=100), the shipping document must include the following information:

- the reference number of the emergency response assistance plan issued by Transport Canada preceded or followed by the letters “ERAP”
- the telephone number, including the area code, to call to have the emergency response assistance plan activated immediately.

For Type-A package, the person who packages the radioactive material shall keep a record of the following information:

- the technical specification of its design
- the type, quantity, form of the radioactive material it is designed to contain
- documents that demonstrates that the package meets the regulatory , including a written quality assurance program
- instructions for packaging, transport, receiving, maintenance and unpacking

SHIPPER'S DECLARATION FOR DANGEROUS GOODS
DÉCLARATION DE L'EXPÉDITEUR POUR MARCHANDISES DANGEREUSES

Shipper
Expéditeur

Air Waybill No.
No de L.T.A.

Page of Pages
Page de pages

Shipper's Reference Number *(optional)*
N° de référence de l'expéditeur *(facultatif)*

Consignee
Destinataire

Two completed and signed copies of this Declaration must be handed to the operator.
Deux copies de cette déclaration dûment remplies et signées doivent être remises à l'exploitant.

TRANSPORT DETAILS
RENSEIGNEMENTS SUR LE TRANSPORT

This shipment is within the limitations prescribed for: *(delete non-applicable)*
Cette expédition est dans les limites autorisées pour: *(biffer la mention inutile)*

PASSENGER AND CARGO AIRCRAFT / AERONEF PASSAGERS ET CARGO	CARGO AIRCRAFT ONLY / AERONEF CARGO SEULEMENT

Airport of Departure
Aéroport de départ

Airport of Destination:
Aéroport de destination:

WARNING
Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

AVERTISSEMENT
Le non-respect sur quelque point que ce soit de la Réglementation sur le transport des marchandises dangereuses peut constituer une infraction aux lois en vigueur, punissable par la loi. Cette déclaration ne peut en aucun cas être remplie et/ou signée par un groupeur, un transitaire ou une agence messagerie IATA.

Shipment type: *(delete non-applicable)* *Type d'envoi (biffer la mention incorrecte)*

NON-RADIOACTIVE / NON-RADIOACTIF	RADIOACTIVE / RADIOACTIF

NATURE AND QUANTITY OF DANGEROUS GOODS
NATURE ET QUANTITÉ DE MARCHANDISES DANGEREUSES

Dangerous Goods Identification / Identification des marchandises dangereuses					Quantity and type of packing / Quantité et type d'emballage	Packing Inst. / Instructions d'emballage	Authorization / Autorisation
Proper Shipping Name / Appellation réglementaire	Class or Division / Classe ou division	UN or ID No. / N°. UN ou ID.	Packing group / Groupe d'emballage	Subsidiary Risk / Risque subsidiaire			

Additional Handling Information
Renseignements complémentaires concernant la manutention

24 hr. Emergency Contact Tel. No.:
No de téléphone d'urgence (24 heures):

Shipment is made under the provisions of ICAO
L'envoi est effectué conformément aux dispositions de l'OCAI

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to appliable international and national governmental regulations.

Par la présente, je déclare que les renseignments relatifs à la description du contenu du chargement et à l'appellation réglementaire du produit expédié sont complets et exacts; et que le contenu est correctement classé, emballé, identifié, étiqueté/placardé et qu'il est conforme à tous égards aux règlements gouvernementals nationaux et internationaux en matière de transport.

Name/Title of Signatory
Nom/Titre du Signataire

Place and Date
Lieu et Date

Signature/
Signature
(See warning above)
(Voir-avertissement ci-dessus)

FM-USFL83B ICC Centre de Conformité Dorval, Québec - Mississauga, Ontario - Dartmouth, Nouvelle-Écosse Imprimé au Canada 07/01

Special provisions

(72 in col 5 of Schedule 2)

If the dangerous goods meet the definitions and criteria for inclusion in other classes in accordance with Part 2 (Classification) of the TDG regulation, the subsidiary class or classes must be shown on a shipping document along with the primary class for the dangerous goods.

(74 in col 5 of Schedule 2)

1. If these dangerous goods have a subsidiary class or classes, they must be assigned to Packing Group I, II or III, as appropriate, in accordance with the criteria in Part 2 of the TDG regulation (Classification) for the subsidiary class that takes precedence.

2. The description of the subsidiary class or classes of the dangerous goods and the labels and placards must be displayed on a means of containment in accordance with the requirements in Part 4 of the TDG regulation (Dangerous Goods Safety Marks).

3. The description of the subsidiary class or classes on a shipping document must be in accordance with Part 3 of the TDG regulation (Documentation).

4. Verifying Placarding

It is the responsibility of the shipper to verify the placards on the transporting vehicle. Placards are required on all 4 sides of the transport vehicle if DG meet one of the following:

- In bulk
- are class 7 category III
- are in quantities above 500 kg
- if an ERAP is required (UN2912, UN3321, UN3322)

For class 7 DG, the radioactive material placard is illustrated below:

5. Additional Information

For any packaging and transport issues that are not covered in this short document, please contact the MUHC Radiation Safety Office.

APPENDIX 3:

Posters and Radiation Warning Signs

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

INFO-0728-1

BASIC LEVEL
Use of Unsealed Nuclear Substances

This room has been classified as "basic level" for the use of unsealed nuclear substances in accordance with Canadian Nuclear Safety Commission guidelines. Below is a list of safe work practices to be followed when working in this room.

24-hour emergency contact (name and phone number)	Room identification

- Do not eat, drink, store food, or smoke in this room.
- In case of a spill or incident involving a nuclear substance, follow emergency procedures and notify the Radiation Safety Officer.
- Clearly identify work surfaces used for handling nuclear substances.
- Use protective clothing and equipment when working with nuclear substances.
- Check all packages containing nuclear substances for damage upon receipt.
- Store nuclear substances in a locked room or enclosure when not in use.

A room is classified as "basic level" for the use of unsealed nuclear substances when more than one exemption quantity is handled and where the largest quantity (in becquerels) of a substance handled by any worker does not exceed 5 times its corresponding annual limit of intake (in becquerels). Contact your Radiation Safety Officer for a list of annual limits of intake.

For more information, contact: Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, P.O. Box 1046, Station B, Ottawa, Ontario, K1P 5S9. Telephone: 1-888-229-2672. Facsimile: (613) 995-5086.

Canada

INTERMEDIATE LEVEL
Use of Unsealed Nuclear Substances

This room has been classified as "intermediate level" for the use of unsealed nuclear substances in accordance with Canadian Nuclear Safety Commission guidelines. Below is a list of safe work practices to be followed when working in this room.

24-hour emergency contact (name and phone number)	Room identification

- Do not eat, drink, store food, or smoke in this room.
- Wear appropriate dosimeter at all times.
- In case of a spill or incident involving a nuclear substance, follow emergency procedures and notify the Radiation Safety Officer.
- Clearly identify work surfaces used for handling nuclear substances.
- Use protective clothing and equipment when working with nuclear substances.
- After working with nuclear substances, monitor work area for contamination.
- Wash hands regularly and monitor them for contamination frequently.
- Check all packages containing nuclear substances for damage upon receipt.
- Store nuclear substances in a locked room or enclosure when not in use.

A room is classified as "intermediate level" for the use of unsealed nuclear substances where the largest quantity (in becquerels) of a substance handled by any worker does not exceed 50 times its corresponding annual limit of intake (in becquerels). Contact your Radiation Safety Officer for a list of annual limits of intake.

For more information, contact: Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, P.O. Box 1046, Station B, Ottawa, Ontario, K1P 5S9. Telephone: 1-888-229-2672. Facsimile: (613) 995-5086.

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

INFO-0728-3

HIGH LEVEL
Use of Unsealed Nuclear Substances

This room has been classified as "high level" for the use of unsealed nuclear substances in accordance with Canadian Nuclear Safety Commission guidelines. Below is a list of safe work practices to be followed when working in this room.

24-hour emergency contact (name and phone number)	Room identification

- Do not eat, drink, store food, or smoke in this room.
- Restrict access to authorized workers only.
- Wear appropriate dosimeter at all times.
- In case of a spill or incident involving a nuclear substance, follow emergency procedures and notify the Radiation Safety Officer.
- Work in a fumehood when required by the Radiation Safety Officer.
- Clearly identify work surfaces used for handling nuclear substances.
- Wear protective clothing and equipment at all times.
- After working with nuclear substances, monitor work area for contamination.
- Wash hands regularly and monitor them for contamination frequently.
- Check all packages containing nuclear substances for damage upon receipt.
- Store nuclear substances in a locked room or enclosure when not in use.

A room is classified as "high level" for the use of unsealed nuclear substances where the largest quantity (in becquerels) of a substance handled by any worker does not exceed 500 times its corresponding annual limit of intake (in becquerels). Contact your Radiation Safety Officer for a list of annual limits of intake.

For more information, contact: Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, P.O. Box 1046, Station B, Ottawa, Ontario, K1P 5S9. Telephone: 1-888-229-2672. Facsimile: (613) 995-5086.

Canada

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

INFO-0728-4/Rev. 1

NUCLEAR MEDICINE
Use of Unsealed Nuclear Substances

This room has been classified as a "nuclear medicine" room for the use of unsealed nuclear substances in accordance with Canadian Nuclear Safety Commission guidelines. Below is a list of safe work practices to be followed when working in this room.

24-hour emergency contact (name and phone number)	Room identification

- Do not eat, drink, store food, or smoke in this room.
- Wear appropriate dosimeter at all times.
- In case of a spill or incident involving a nuclear substance, follow emergency procedures and notify the Radiation Safety Officer.
- Work in a fumehood when required by the Radiation Safety Officer.
- Wear protective clothing and equipment at all times.
- Wash hands regularly and monitor them for contamination frequently.
- Perform thyroid screening or bioassay when required.
- Check all packages containing nuclear substances for damage upon receipt.
- Store nuclear substances in a locked room or enclosure when not in use.

A room is classified as "nuclear medicine" for the use of unsealed nuclear substances if the nuclear substance is prepared for or administered to a person.

For more information, contact: Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, P.O. Box 1046, Station B, Ottawa, Ontario, K1P 5S9. Telephone: 1-888-229-2672. Facsimile: (613) 995-5086.

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ISBN: 0-662-42107-8

Canada

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

INFO-0742

PROPER CARE AND USE OF PERSONAL DOSIMETERS

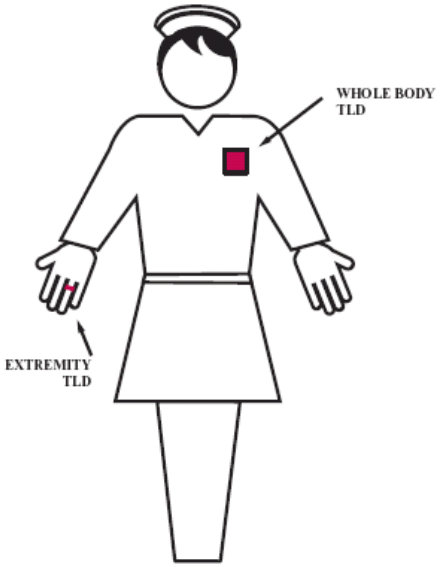
This poster describes the proper handling, wearing and storage of whole body and extremity dosimeters. These dosimeters are commonly referred to as Thermo Luminescent Dosimeters or TLDs. Your TLD measures the amount of radiation to which you are exposed. Here are some useful tips:

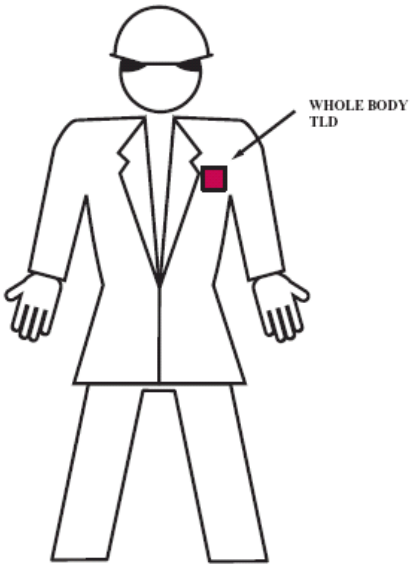
HANDLING

1. Do not expose the TLD to high temperature, water, direct sunlight or fluorescent light.
2. Change the plaques in a clean, dry area away from direct light and avoid direct skin contact.

WEARING

3. Clip your whole body TLD firmly to your clothing between your waist and neck.
4. If necessary, you may wear a second TLD on the area of your body most likely to receive the highest dose.
5. Extremity TLDs (rings) should be worn facing the source of radiation.
6. If you lose or damage your TLD you should stop working with radiation until you receive a replacement.





STORAGE

7. Store TLDs in a holder or rack when not in use.
8. TLDs are best stored in a low radiation background area away from direct light and heat.
9. It is good practice to keep extra TLDs as replacements for lost or damaged ones.

For more information, contact: Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, P.O. Box 1046, Station B, Ottawa, ON K1P 5S9. Telephone: 1-888-229-2672. Fax: (613) 995-5086.

Canada

SPILL PROCEDURES

Name and telephone number of the person responsible for enforcing safe work practices with nuclear substances in this work area:

Radiation Safety Officer	Telephone number

Person in charge	Telephone number

General Precautions

1. Inform persons in the area that a spill has occurred. Keep them away from the contaminated area.
2. Cover the spill with absorbent material to prevent the spread of contamination.

Minor Spills (Typically less than 100 exemption quantities of a nuclear substance)

1. Wearing protective clothing and disposable gloves, clean up the spill using absorbent paper and place it in a plastic bag for transfer to a labelled waste container.
2. Avoid spreading contamination. Work from the outside of the spill towards the centre.
3. Wipe test or survey for residual contamination as appropriate. Repeat decontamination, if necessary, until contamination monitoring results meet the Nuclear Substances and Radiation Devices licence criteria.
4. Check hands, clothing, and shoes for contamination.
5. Report the spill and cleanup to the person in charge and, if necessary, to the Radiation Safety Officer.
6. Record spill details and contamination monitoring results. Adjust inventory and waste records appropriately.

Major Spills (Major spills involve more than 100 exemption quantities, or contamination of personnel, or release of volatile material)

1. Clear the area. Persons not involved in the spill should leave the immediate area. Limit the movement of all personnel who may be contaminated until they are monitored.
2. If the spill occurs in a laboratory, leave the fume hood running to minimize the release of volatile nuclear substances to adjacent rooms and hallways.
3. Close off and secure the spill area to prevent entry. Post warning sign(s).
4. Notify the Radiation Safety Officer or person in charge immediately.
5. The Radiation Safety Officer or person in charge will direct personnel decontamination and will decide about decay or cleanup operations.
6. In general, decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and mild soap.
7. Follow the procedures for minor spills (if appropriate).
8. Record the names of all persons involved in the spill. Note the details of any personal contamination.
9. The Radiation Safety Officer or person in charge will arrange for any necessary bioassay measurements.
10. If required, submit a written report to the Radiation Safety Officer or person in charge.
11. The Radiation Safety Officer or person in charge must submit a report to the CNSC.

Major spill procedures should be implemented whenever minor spill procedures would be inadequate.

If an exposure may have occurred that is in excess of applicable radiation dose limits, the CNSC shall be contacted within 24 hours of the occurrence under Section 16 of the Radiation Protection Regulations

For more information, contact: Directorate of Nuclear Substance Regulation, Canadian Nuclear Safety Commission, P.O. Box 1046, Station B, Ottawa, ON K1P 5S9.
Telephone: 1-888-229-2672. Fax: (613) 995-5086.

GUIDELINES FOR HANDLING PACKAGES CONTAINING NUCLEAR SUBSTANCES

Identifying Packages Containing Nuclear Substances

The packaging and labeling of nuclear substances is governed by the Canadian Nuclear Safety Commission's *Packaging and Transport of Nuclear Substances (PTNS) Regulations.* Nuclear substances may be shipped in "Excepted Packages", "Type A" or "Type B" packages, "Industrial Packages I, II, III", and packages for "Fissile Material". The "radioactive" category labels also show radiation dose rates.

On Excepted Packages, no external labeling is required, and the safety mark "RADIOACTIVE" must be visible upon opening the package. The radiation level at any point on the external surface of the package must not exceed 5 µSv/h. All other packages must be categorized by radiation level and display the corresponding radiation warning labels as follows:

Category I-WHITE
Does not exceed 5 µSv/h at any location on the external surface of the package

Category II-YELLOW
Does not exceed 500 µSv/h at any location on the external surface of the package and the transport index does not exceed 1.

Category III-YELLOW
Does not exceed 2 mSv/h at any location on the external surface of the package and the transport index does not exceed 10.

The transport index is the maximum radiation level in microsieverts per hour at one metre from the external surface of the package, divided by 10.
Example: 1 µSv/h (0.1 mrem/h) at 1 m equals a TI = 0.1.

Upon receipt of a package containing nuclear substances, keep your distance. Examine the package for damage or leakage. If the package is damaged or leaking, contain and isolate it to minimize radiation exposure and contamination, and comply with Section 19 of the PTNS *Regulations*.

Opening Packages Containing Nuclear Substances

Radiation Safety Officer	Phone Number

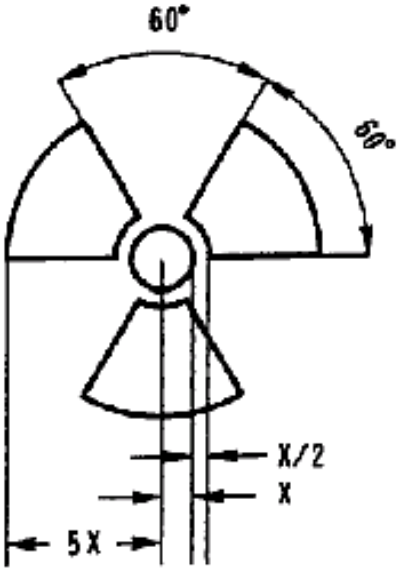
1. If an appropriate survey monitor is available, monitor the radiation fields around the package. Note any discrepancies.
2. Avoid unnecessary direct contact with unshielded containers.
3. Verify the nuclear substance, the quantity, and other details with the information on the packing slip and with the purchase order. Log the shipment details and any anomalies in the inventory record.
4. Report any anomalies (radiation levels in excess of the package labeling, incorrect transport index, contamination, leakage, short or wrong shipment) to the Radiation Safety Officer.

When opening packages containing unsealed nuclear substances, additional steps should be taken:

5. Wear protective clothing while handling the package.
6. If the material is volatile (unbound iodine, tritium, radioactive gases, etc.) or in a powder form, open the package in a fume hood.
7. Open the outer package and check for possible damage to the contents, broken seals, or discoloration of packing materials. If the contents appear to be damaged, isolate the package to prevent further contamination and notify the Radiation Safety Officer.
8. If no damage is evident, wipe test the inner package or primary container which holds the unsealed nuclear substance. If contamination is detected, monitor all packaging and, if appropriate, all locations in contact with the package, for contamination. Contain the contamination, decontaminate, and dispose in accordance with the conditions of the Nuclear Substances and Radiation Devices licence.

For more information, contact: Directorate of Nuclear Substance Regulation, Canadian Nuclear Safety Commission, P.O. Box 1046, Station B, Ottawa, ON K1P 5S9. Telephone: 1-888-229-2672. Fax: (613) 995-5086.

Radiation Warning Symbol



NOTE:
The three blades and the central disk of this symbol shall be:
(a) magenta and black
(b) located on a yellow background

NUCLEAR SAFETY AND CONTROL ACT: Radiation Protection Regulations, 31 May, 2000

Radiation Warning Sign for Laboratories

RAYONNEMENT-
DANGER-
RADIATION

24H Emergency contact: RSO through Locating 53333

Every point of access to an area, room or enclosure where there is more than 100 EQ of radioactive materials or where the radiation dose rate might exceed 25 μSv/h must be labeled with a radiation warning sign that bears the trefoil symbol and the words “RAYONNEMENT-DANGER-RADIATION”.

APPENDIX 4:

NCRC Thyroid Intercomparison Program

NCRC THYROID INTERCOMPARISON PROGRAM

The **N**ational **C**alibration **R**eference **C**entre for Bioassay and *In Vivo* Monitoring (NCRC) has specially designed neck phantoms that allow a facility to establish that the quality of their thyroid monitoring program, where necessary, meets the requirements of Regulatory Standard S-106. The phantoms, provided to participants in the NCRC's intercomparison program, can also be used to establish calibration factors.

The benefit of participation in the thyroid intercomparison program is two-fold. First, facilities can compare their results to other Canadian facilities and judge their performance based on the results. Second, and more important, the participation in the NCRC's intercomparison program allows the facility to show that their in-house calibrations are accurate and that their quality assurance program is performing as expected. The use of an outside independent standard gives any quality assurance program more credibility than it would otherwise have if all results were based on in-house data.

Each year, participants in the thyroid intercomparison program are mailed a kit that contains the following: a neck phantom modeled from a human neck made of material to closely approximate human tissue, inserts designed to mimic a real thyroid gland containing simulated ^{131}I, and/or ^{125}I, an overlay plate to allow for different thickness of tissue over the thyroid gland, instructions for the proper use of the phantom (including a training video), a report form, and a telephone "hot-line" number for assistance. The NCRC provides advice and assistance to participating facilities to solve problems identified through their participation in the thyroid intercomparison program and maintains a historical, confidential data base for efficient information retrieval and trend analysis.

The tests that can be performed with the neck-thyroid phantoms are:

- Accuracy of counting
- Determination of the **M**inimum **D**etectable **A**ctivity (MDA)
- Effect of overlaying tissue
- Precision of counting
-

Accuracy of Counting

The accuracy of counting B is obtained by evaluating the bias of the facility for any given phantom. The bias is given by the following expression:

$$B = \frac{A_i - A}{A} \times 100$$

Where:

B is the bias (expressed as a percent).

$\mathbf{A_i}$ is the observed value.

A is the true value.

The acceptable limit for bias, B(%), is that it should be greater than or equal to -25% and less than or equal to +50%. The activity in the test phantom must be greater than five times the MDA specified in Table 2 of Regulatory Standard S-106 for that nuclide. The actual activities of the inserts used and the bias results are sent to the participating facility in the form of a short report. The facility's contact person is telephoned, when necessary, to discuss remedial action that should be taken to improve the performance of their monitoring system.

Determination of the Minimum Detectable Activity

The Minimum Detectable Activity should be determined using an uncontaminated subject, and applying the following expression to the results.

$$MDA = \frac{4.65 \times \sqrt{BCKGND}}{E \times T} + \frac{3}{E \times T}$$

Where:

BCKND is the total number of counts in the region of interest for a given radionuclide.

E is the calibration factor used to convert the count rate to activity and includes geometry factors.

T is the count period, usually in seconds (assumed to be the same for sample and background).

Effect of Overlying Tissue

The facility can use the overlay plate to investigate the change in efficiency for their counting system. The change in counting efficiency will depend on detector type, detector size, counting geometry, and collimation.

Precision of Counting

Precision of counting is performed by counting the neck-thyroid phantom repeatedly. Between each count the phantom is removed and replaced in the counting position. The phantom is counted five times. Precision S is then estimated by the following expression:

$$S = \frac{100 \times \sqrt{\sum_{1}^{N} \frac{(A_i - M)}{(n-1)}}}{M}$$

Where:

S is the precision (expressed as a percent).

$\mathbf{A_i}$ is the observed value.

M is the mean of the data set.

N is the number of measurements (usually five).

The acceptable limit for precision, (S%), is that it should be less than or equal to 40%.

Ref.: http://www.hc-sc.gc.ca/hecs-sesc/ncrc/thyroid.htm

MUHC Intercomparison Program Results

In 2003, the MUHC participated in the NCRC Intercomparison Program for I-125 in-vivo thyroid monitoring. The detector used for the monitoring is a LUDLUM 2200 scaler with a NaI gamma probe located at 10cm from the source (thyroid).

The NCRC reports have indicated a counting efficiency for the I-125 thyroid phantoms without the overlay was 0.00783 cps/Bq. With the overlay plate, the counting efficiency was 0.00614 cps/Bq. Using the formula in the section above, with T=120 s and BKG ~ 600 counts typically for T=120 s, this correspond to MDA's of 0.082 kBq and 0.105 kBq respectively, thus satisfying the 1 kBq detection limit criterion set by the CNSC.

APENDIX 5:

McGill University Health Centre
Centre Universitaire de Santé McGill

Internal Permit Application for Acquisition and Use of Radioactive Materials

Identification:

1. Permit Holder — Address

Last name: **Office room number:**

First name: **Office phone number:**

Title: **Cell phone number:**

Department: **Pager number:**

Email:

2. Internal Radiation Safety Designate (or Departmental Radiation Supervisor)

This person should be able to provide day-to-day supervision of the work of employees in matters of radiation safety.

Last name: **Office room number:**

First name: **Office phone number:**

Title: **Cell phone number:**

Department: **Pager number:**

Email:

3. Radioisotope User Information

Please use one sheet per worker:

Personnel Information

Last name : _____ First name: _____

Permit number : _____ Title: _____

Radiation Safety Training (Location): _____ Date: _____

TDG class 7 Training (Location): _____ Date: _____

TLD Information (please circle)

Dosimeter type: 1) Whole Body 2) Ring / Wrist 3) Other: _____

Radioisotope Information

A) Radioisotope: _____ Maximum activity used: _____

Description of use:

_____

_____

_____

B) Radioisotope: _____ Maximum activity used: _____

Description of use:

_____

_____

_____

C) Radioisotope: _____ Maximum activity used: _____

Description of use:

_____

_____

_____

4. Personnel Not Working with Radioisotopes

Please use one sheet per worker:

Personnel Information

Last name : _____ First name: _____

Permit number: _____ Title: _____

TLD Information ***(if applicable)***

Dosimeter type: 1) _____

Laboratory Information

Reason for working in laboratory:

_____

_____

5. Radiation Exposure Monitoring

Do you use TLD (Thermoluminescent Dosimetry Radiation) badges? _____

If yes, please specify which dosimeter types and related group code (look on your Radiation Exposure Report from the Radiation Protection Bureau)

Type	Group Code	No. of Visitor Badges	Visitor Badges Issued to:
☐ Whole body dosimeter			
☐ Ring dosimeter			
☐ Wrist dosimeter			
☐ Other type of dosimeter Specify: _____			
☐ No dosimeter	NA	NA	NA

Note: According to our licence condition (2578-1), any person who handles more than 50 MBq of P-32, Sr-89, Y-90, Sm-157 or Rh-185 must wear a ring dosimeter.

6. Purchases and Possession limits

Please indicate the maximum activity per stock vial for any isotope. Also indicate the maximum quantity possessed at any given time.(use extra sheets as necessary). Indicate units clearly (ex. mCi, MBq, …)

Radioisotope (Ex. H-3, P-32, P-33, S-35,…)	**Maximum Activity per stock vial**	**Possession limit** **(max. activity per stock vial x number of vials)**
1		

7. Access to Radioisotopes

What arrangements are in place to prevent access to radioisotopes from unauthorised users?

_____

_____

_____

8. Liquid Scintillation Counter/Gamma Counter

List the gamma and beta counters you have access to. If the counter has an internal source (housed in equipment), please give source type, serial number, activity and date measured.

Type of Device	Company & Model	Serial Number	Internal Source	Source Serial Number	Source Activity	Date of Activity Measured	Room Number

9. Accessible Sealed Sources Inventory

List any other sealed sources that are not permanently housed in equipment.

Radio isotope	Serial Number	Activity	Date of Activity Measured	Use	Room Number

10. Laboratory Information (use extra sheets as necessary)

List all rooms and usage. Room description can be “Radioisotope Laboratory”, “Storage room” , “Counter room” or “Other”.

- For “Radioisotope Laboratory”, please indicate the maximum activity per stock vial than can be handled at any given time (should normally correspond to column 2 of item 6 (see above).
- For “Storage room”, indicate the maximum activity to be stored at any given time.
- For “Counter room” and “Others”, indicate the maximum activity entered at any given time in the room.

In case of doubt about the room description, please contact the RPS. A room is described as a “Laboratory” only if there is “manipulation” of open wet sources.

Room number: _____ Description:_____

	P32	P33	S35	I125	H3	C14	Other ____
Radioisotope Laboratory: max. activity (mCi)							
Storage room : max. activity (mCi)							
Counter room : max. activity (mCi)							
Other* room: max activity (mCi)							

*Note: If “Other”, please give details below about the room usage:

_____

_____

Room number: _____ Description:_____

	P32	P33	S35	I125	H3	C14	Other ____
Radioisotope Laboratory: max. activity (mCi)							
Storage room : max. activity (mCi)							
Counter room : max. activity (mCi)							
Other* room: max activity (mCi)							

*Note: If “Other”, please give details below about the room usage:

_____

_____

11. Storage Areas (only those located outside rooms mentioned in section 10)

Please indicate all storage areas (fridge or freezer) that are located in a hallway where radioisotopes may be stored. Indicate the room closest to the storage unit

Fridge/Freezer 1
Room number: _____

Fridge/Freezer 2
Room number: _____

Fridge/Freezer 3
Room number: _____

12. Animal Protocol

Do you work with or plan on using radioactive materials in animals.

Yes	No

If yes, please provide a copy of the animal protocol.

13. Survey Meter Inventory

Give a list of handheld meters available to your laboratory.

Type	Company & Model	Serial Number	Probe Model	Probe Serial Number	Date last Calibration	Room Number

14. Permit Holder Signature

I certify that the information entered in this form is valid.

Signature: _____

Date: _____

CURRENT INVENTORY FORM
(Source Vials)

Permit Holder: ____________________ Permit Number: ____________________

Room	**Isotope & Product**	**Activity** (uCi)	**Date Activity Measured**	**Initial Volume** (ul)	**Residual Volume** (ul)	**RTS Number**

APPENDIX 6:

Work requiring More Than 10,000 EQ

Work requiring the use of more than 10,000 exemption quantities (EQ)

Internal requests for the manipulation of nuclear substances of more than 10,000 exemption quantities (EQ) will be evaluated on a case-by-case basis and will require a written approval by the Radiation Safety Officer (RSO).

To obtain approval, the investigator will be required to submit a detailed step-by-step procedure for the radioisotope manipulation he wishes to undertake, indicating the name and title of the investigator, the type of isotope, form and amount of radioactivity being manipulated at each step during the experiment, and details about the waste handling. The experimental protocol should also include a short justification for manipulation of more than 10,000 EQ explaining why lower activities are not satisfactory for the success of the experiment.

The RSO will consider approval of the experimental protocol if the following criteria and conditions are met:

- Only experienced users can manipulate more than 10,000 EQ
- The primary user should be accompanied by another experienced user to assist in case of an accident or a spill.
- Appropriate dosimeters must be wear at all times during the manipulation (body and ring TLD's).
- Work should be conducted using ALARA principles approved by the RSO following a dry run or detailed on site interview (appropriate shielding, time involved for the manipulation, distance from the sources)
- Manipulations should be done under a fume hood if appropriate
- High Level Laboratory work practices (INFO-0728-3) should be applied strictly independent of the actual laboratory classification where the experiment is taking place.
- Warning signs indicating that a manipulation with more than 10,000 EQ is taking place should be posted near the access area and removed only upon completion of the experiment.
- Extra precautions should be taken in the preparation of the workplace to prevent the occurrence of a spill (double padding, source containment, removal of all unnecessary accessories).
- A dose rate meter should be placed near the workplace for real time monitoring if available.
- A contamination meter should be readily available at all times during the manipulation.
- Spill kit should be readily available in case of a spill.
- Emergency phone should be readily available in case of an accident or a spill.

In addition, the CNSC requires that:

- Any changes in laboratory classification to a higher level be approved by the CNSC
- Any such experiment be reported in the Annual Compliance Report
- CNSC must approve individually different types of experiments where the isotope and activity level being manipulated differ.

APPENDIX 7:

Contamination Monitoring

Approximate detection efficiencies for some common radionuclides and detectors

Radionuclide	LSC[1]	Pancake GM[2]	NaI(Tl) Meter[3]	NaI(Tl) Well[4]
H-3	20%	na[5]	na[5]	na[5]
C-14, S-35, P-33	50%	10%	na[5]	na[5]
Cr-51, Co-57, Tc-99m, I-125	30%	1%	50%	50%
P-32	100%	50%	na[5]	na[5]

LSC[1] : Liquid Scintillation Counter

PancakeGM[2] : Hand-held survey meter with pancake GM detector

NaI(Tl)[3] : Hand-held survey meter with well-type NaI(Tl) crystal

NaI(Tl)[4] : Multichannel analyzer with well-type NaI(Tl) crystal

na[5]: not applicable for this group of radionuclides

Ref.: http://www.stanford.edu/dept/EHS/prod/researchlab/radlaser/manual/radsafetymanual1.html

Contamination Monitoring using Wipe Tests and LSC

This table indicates the public area CNSC decontamination criteria (NC in CPM) for wipe tests measured in a Liquid Scintillation Counter (LSC). **The decontamination level NC is the net count rate of wipe tests (in CPM) below which a room can be opened to public.** However, it is good laboratory practice to continue decontamination procedure until the level is As Low As Reasonably Achievable (ALARA). The last column is a limit below which no additional decontamination efforts are normally required. Also indicated are the Exemption Quantities (EQ) below which a license is not required to possess, transfer or use radioisotopes (Exemption areas).

Isotope	EQ MBq	Class	LSC Nominal Efficiency (E)	Wipes Public Area Bq/cm2 (CL)	**Decontamination level in CPM* (NC)**	ALARA level of 0.5 Bq/cm2 in CPM**
C-14	10	C	0.5	30	**9000**	150
Ca-45	10	C	0.5	30	**9000**	150
Co-57	1	C	0.3	30	**5400**	90
Cr-51	10	C	0.3	30	**5400**	90
Fe-59	1	B	0.5	3	**900**	150
H-3	1000	C	0.2	30	**3600**	60
I-125	1	C	0.3	30	**5400**	90
P-32	0.1	C	1	30	**18000**	300
P-33	100	C	0.5	30	**9000**	150
Rb-86	0.1	B	1	3	**1800**	300
S-35	100	C	0.5	30	**9000**	150

*CNSC public area decontamination limit in CPM (net count rate) measured by Liquid Scintillation Counting (LSC) for various radioisotopes commonly used in laboratories.

The net count rate in CPM (background subtracted) that indicates decontamination level is reached is calculated using the following formula:

$$NC\ (CPM) = W_{eff} * E * CL * 60 * A\ ,$$

W_{eff} = Wipe efficiency (0.1 for wet wipes);
E = LSC nominal Efficiency for specific isotope;
CL = CNSC contamination level (Wipes Public Area) in Bq/cm2;
A = area wiped (100 cm2).

** ALARA limit below which no additional decontamination efforts are required (see MUHC Radiation Safety Manual/NSRD, items 6.9.11-6.9.12).

Direct Contamination Monitoring : Pancake Probe
Controlled Area

Isotope	EQ MBq	Class	Pancake Nominal Efficiency (E)	Wipes Controlled Area Bq/cm2 (CL)	**Decontamination level in CPM* (NC)**	Conversion factor Net CPM to Bq/cm2
C-14	10	C	0.03	300	**8100**	0.0370
F-18	1	A	0.1	3	**270**	0.0111
Na-22	1	A	0.1	3	**270**	0.0111
Ca-45	10	C	0.03	300	**8100**	0.0370
P-32	0.1	C	0.15	300	**40500**	0.0074
P-33	100	C	0.03	300	**8100**	0.0370
Co-58	1	B	0.03	30	**810**	0.0370
Ga-67	1	B	0.01	30	**270**	0.1111
Rb-86	0.1	B	0.15	30	**4050**	0.0074
S-35	100	C	0.03	300	**8100**	0.0370
Mo-99/Tc-99m	10	C	0.005	300	**1350**	0.2222
In-111	1	B	0.01	30	**270**	0.1111
I-123	10	C	0.005	300	**1350**	0.2222
I-131	1	B	0.11	30	**2970**	0.0101
Tl-201	1	B	0.02	30	**540**	0.0556

*Decontamination levels for radioisotope commonly used in laboratories in CPM (net counts) using an Pancake probe. The net counts (background subtracted) NC in CPM that indicates decontamination level is reached is calculated using the following formula :

NC (CPM) = E*CL*60*A

E = G-M Pancake measured Efficiency at 1 cm
CL = CNSC contamination level (Wipes Public Area) in Bq/cm2
A = area of Pancake (15 cm2)

LUDLUM 44-9 Specifications (4-pi):
C-14 : 5%
P-32 : 32%

Direct Contamination Monitoring : Pancake Probe
Public Area

Isotope	EQ MBq	Class	Pancake Nominal Efficiency (E)	Wipes Public Area Bq/cm2 (CL)	**Decontamination level in CPM* (NC)**	Conversion factor Net CPM to Bq/cm2
C-14	10	C	0.03	30	**810**	0.0370
F-18	1	A	0.1	0.3	**27**	0.0111
Na-22	1	A	0.1	0.3	**27**	0.0111
Ca-45	10	C	0.03	30	**810**	0.0370
P-32	0.1	C	0.15	30	**4050**	0.0074
P-33	100	C	0.03	30	**810**	0.0370
Co-58	1	B	0.03	3	**81**	0.0370
Ga-67	1	B	0.01	3	**27**	0.1111
Rb-86	0.1	B	0.15	3	**405**	0.0074
S-35	100	C	0.03	30	**810**	0.0370
Mo-99/Tc-99m	10	C	0.005	30	**135**	0.2222
In-111	1	B	0.01	3	**27**	0.1111
I-123	10	C	0.005	30	**135**	0.2222
I-131	1	B	0.11	3	**297**	0.0101
Tl-201	1	B	0.02	3	**54**	0.0556

*Decontamination levels for radioisotope commonly used in laboratories in CPM (net counts) using an Pancake probe. The net counts (background subtracted) NC in CPM that indicates decontamination level is reached is calculated using the following formula :

NC (CPM) = E*CL*60*A

E = G-M Pancake measured Efficiency at 1 cm
CL = CNSC contamination level (Wipes Public Area) in Bq/cm2
A = area of Pancake (15 cm2)

LUDLUM 44-9 Specifications (4-pi):
C-14 : 5%
P-32 : 32%

Direct Contamination Monitoring : NaI 44-3 Probe
Public Area

Isotope	EQ MBq	Class	Probe Nominal Efficiency (E)	Wipes Public Area Bq/cm2 (CL)	**Decontamination level in CPM* (NC)**	Conversion factor Net CPM to Bq/cm2
I-125	1	C	0.07	30	**630**	0.0476
Mo-99/Tc-99m	10	C	0.04	30	**360**	0.0833
In-111	1	B	0.04	3	**36**	0.0833

Direct Contamination Monitoring : NaI 44-3 Probe
Controlled Area

Isotope	EQ MBq	Class	Probe Nominal Efficiency (E)	Wipes Public Area Bq/cm2 (CL)	**Decontamination level in CPM* (NC)**	Conversion factor Net CPM to Bq/cm2
I-125	1	C	0.07	300	**6300**	0.0476
Mo-99/Tc-99m	10	C	0.04	300	**3600**	0.0833
In-111	1	B	0.04	30	**360**	0.0833

*Decontamination levels for radioisotope commonly used in laboratories in CPM (net counts) using an NaI probe. The net counts (background subtracted) NC in CPM that indicates decontamination level is reached is calculated using the following formula :

NC (CPM) = E*CL*60*A

E = NaI 44-3 measured Efficiency at 1 cm
CL = CNSC contamination level (Wipes Public Area) in Bq/cm2
A = area of NaI probe 44-3 (5 cm2)

LUDLUM 44-3 Specifications:
I-125 : 19% (4-pi)

McGill University Health Centre
Centre Universitaire de Santé McGill

CONTAMINATION CONTROL RECORD (DIRECT METHOD)

PERMIT HOLDER _____ PERMIT # _____

DEPARTMENT _____ ROOM # _____

ISOTOPES USED _____

Make and Model of Detector _____

Date: _____	BACKGROUND CPM _____

LOCATION	Net CPM	Bq/cm^2	After cleanup	COMMENTS
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Name (Print) : _____

Signature: _____

APPENDIX 8 :

Radionuclides data

Regulatory Quantities for Typical Radionuclides:

Exemption Quantities (EQ); Annual Limit of Intake (ALI); Laboratory Classification Limits (Basic, Intermediate, High); Surface Contamination Limits (Controlled, Public).

Radionuclide	EQ * in MBq *** 2008 revision (old value in parenthesis)**	ALI estimate (ingest) MBq/yr	Basic level MBq	Interm level MBq	High level MBq	Wipes Controlled area Bq/cm2	Wipes Public area Bq/cm2
Br-82	**1** (0.1)	37	185	1850	18500	30	3
C-14	**10** (100)	34	170	1700	17000	300	30
Co-57	**1** (0.1)	95	475	4750	47500	300	30
Co-58	**1** (0.1)	27	135	1350	13500	30	3
Co-60	0.1	6	30	300	3000	3	0.3
Cr-51	**10** (1)	530	2650	26500	265000	300	30
F-18	**1** (0.01)	400	2000	20000	200000	30	3
Fe-59	**1** (0.1)	10	50	500	5000	30	3
Ga-67	1	100	500	5000	50000	30	3
H-3	1000	1000	5000	50000	500000	300	30
I-123	10	95	475	4750	47500	300	30
I-125	1	1	5	50	500	300	30
I-131	**1** (0.01)	1	5	50	500	30	3
In-111	**1** (0.1)	70	350	3500	35000	30	3
Na-22	**1** (0.01)	6	30	300	3000	3	0.3
P-32	**0.1** (0.01)	8	40	400	4000	300	30
P-33	**100** (1)	80	400	4000	40000	300	30
Ra-226	0.01	0.07	0.35	3.5	35	3	0.3
S-35	100	26	130	1300	13000	300	30
Sb-124	**1** (0.01)	8	40	400	4000	3	0.3
Sr-85	**1** (0.1)	36	180	1800	18000	30	3
Tc-99m	10	900	4500	45000	450000	300	30
Tl-201	1	210	1050	10500	105000	300	30
Xe-133	**0.01** (100 GBq)					300	30

Note: More exhaustive list for EQ is given below

Classes of Nuclear Substances:

The following table organizes a number of common nuclear substances, including those for which surface contamination and waste disposal limits are typically incorporated into CNSC licenses, into three classes –"Class A", "Class B", or "Class C" – on the basis of common radiological characteristics.

CLASS	RADIONUCLIDE				
CLASS A	All alpha emitters and their daughter isotopes			Ag-110m	Ar-41
	C-11	Co-56	Co-60	F-18	Ga-68
	Ga-72	I-124	La-140	Mn-56	N-13
	Na-22	Na-24	Nb-98	O-15	Sb-124
	Ta-182	V-48	Y-86	Zn-65	
CLASS B	As-74	Au-198	Ba-133	Br-82	Co-58
	Cu-64	Fe-59	Ga-67	Gd-153	Hg-194
	Hg-203	I-131	In-111	In-113m	In-114m
	Ir-192	K-42	Kr-79	Kr-81m	Nb-95
	Pa-233	Rb-84	Rb-86	Ru-103	Sc-46
	Se-75	Sm-153	Sn-123	Sr-85	Sr-90
	Xe-127				
CLASS C	Au-195m	C-14	Ca-45	Cd-109	Ce-141
	Ce-144	Cl-36	Co-57	Cr-51	Fe-55
	Ge-68	H-3	I-123	I-125	In-114
	Kr-85	Lu-177	Ni-63	P-32	P-33
	Re-186	Re-188	S-35	Sn-113	Sr-89
	Tc-99	Tc-99m	Tl-201	V-49	W-188
	Xe-133	Y-86	Y-90	Yb-169	

EXEMPTION QUANTITIES (Exhaustive List)

Ref: Nuclear Substances and Radiation Devices Regulations (SOR/2000-207) current to August 13th, 2008

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Actinium 227	1×10^{-1}	1×10^{3}
Actinium 228	1×10^{1}	1×10^{6}
Americium 241	1×10^{0}	1×10^{4}
Americium 242	1×10^{3}	1×10^{6}
Americium 242m[a]	1×10^{0}	1×10^{4}
Americium 243[a]	1×10^{0}	1×10^{3}
Antimony 122	1×10^{2}	1×10^{4}
Antimony 124	1×10^{1}	1×10^{6}
Antimony 125	1×10^{2}	1×10^{6}
Argon 37	1×10^{6}	1×10^{8}
Argon 41	1×10^{2}	1×10^{9}
Arsenic 73	1×10^{3}	1×10^{7}
Arsenic 74	1×10^{1}	1×10^{6}
Arsenic 76	1×10^{2}	1×10^{5}
Arsenic 77	1×10^{3}	1×10^{6}
Astatine 211	1×10^{3}	1×10^{7}
Barium 131	1×10^{2}	1×10^{6}
Barium 133	1×10^{2}	1×10^{6}
Barium 140[a]	1×10^{1}	1×10^{5}
Berkelium 249	1×10^{3}	1×10^{6}
Beryllium 7	1×10^{3}	1×10^{7}
Bismuth 206	1×10^{1}	1×10^{5}
Bismuth 207	1×10^{1}	1×10^{6}
Bismuth 210	1×10^{3}	1×10^{6}
Bismuth 212[a]	1×10^{1}	1×10^{5}
Bromine 82	1×10^{1}	1×10^{6}
Cadmium 107	1×10^{3}	1×10^{7}
Cadmium 109	1×10^{4}	1×10^{6}
Cadmium 113m	1×10^{3}	1×10^{6}
Cadmium 115	1×10^{2}	1×10^{6}
Cadmium 115m	1×10^{3}	1×10^{6}
Calcium 45	1×10^{4}	1×10^{7}
Calcium 47	1×10^{1}	1×10^{6}
Californium 246	1×10^{3}	1×10^{6}
Californium 248	1×10^{1}	1×10^{4}
Californium 249	1×10^{0}	1×10^{3}
Californium 250	1×10^{1}	1×10^{4}
Californium 251	1×10^{0}	1×10^{3}
Californium 252	1×10^{1}	1×10^{4}
Californium 253	1×10^{2}	1×10^{5}
Californium 254	1×10^{0}	1×10^{3}
Carbon 11	1×10^{1}	1×10^{6}
Carbon 14	1×10^{4}	1×10^{7}
Cerium 139	1×10^{2}	1×10^{6}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Cerium 141	1×10^{2}	1×10^{7}
Cerium 143	1×10^{2}	1×10^{6}
Cerium 144[a]	1×10^{2}	1×10^{5}
Cesium 129	1×10^{2}	1×10^{5}
Cesium 131	1×10^{3}	1×10^{6}
Cesium 132	1×10^{1}	1×10^{5}
Cesium 134	1×10^{1}	1×10^{4}
Cesium 134m	1×10^{3}	1×10^{5}
Cesium 135	1×10^{4}	1×10^{7}
Cesium 136	1×10^{1}	1×10^{5}
Cesium 137[a]	1×10^{1}	1×10^{4}
Cesium 138	1×10^{1}	1×10^{4}
Chlorine 36	1×10^{4}	1×10^{6}
Chlorine 38	1×10^{1}	1×10^{5}
Chromium 49	1×10^{1}	1×10^{6}
Chromium 51	1×10^{3}	1×10^{7}
Cobalt 55	1×10^{1}	1×10^{6}
Cobalt 56	1×10^{1}	1×10^{5}
Cobalt 57	1×10^{2}	1×10^{6}
Cobalt 58	1×10^{1}	1×10^{6}
Cobalt 58m	1×10^{4}	1×10^{7}
Cobalt 60	1×10^{1}	1×10^{5}
Cobalt 60m	1×10^{3}	1×10^{6}
Cobalt 61	1×10^{2}	1×10^{6}
Cobalt 62m	1×10^{1}	1×10^{5}
Copper 60	1×10^{1}	1×10^{5}
Copper 64	1×10^{2}	1×10^{6}
Copper 67	1×10^{2}	1×10^{6}
Curium 242	1×10^{2}	1×10^{5}
Curium 243	1×10^{0}	1×10^{4}
Curium 244	1×10^{1}	1×10^{4}
Curium 245	1×10^{0}	1×10^{3}
Curium 246	1×10^{0}	1×10^{3}
Curium 247	1×10^{0}	1×10^{4}
Curium 248	1×10^{0}	1×10^{3}
Dysprosium 159	1×10^{3}	1×10^{7}
Dysprosium 165	1×10^{3}	1×10^{6}
Dysprosium 166	1×10^{3}	1×10^{6}
Einsteinium 253	1×10^{2}	1×10^{5}
Einsteinium 254	1×10^{1}	1×10^{4}
Einsteinium 254m	1×10^{2}	1×10^{6}
Erbium 169	1×10^{4}	1×10^{7}
Erbium 171	1×10^{2}	1×10^{6}
Europium 152	1×10^{1}	1×10^{6}
Europium 152m	1×10^{2}	1×10^{6}
Europium 154	1×10^{1}	1×10^{6}
Europium 155	1×10^{2}	1×10^{7}
Fermium 254	1×10^{4}	1×10^{7}
Fermium 255	1×10^{3}	1×10^{6}
Fluorine 18	1×10^{1}	1×10^{6}
Gadolinium 153	1×10^{2}	1×10^{7}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Gadolinium 159	1×10^{3}	1×10^{6}
Gallium 67	1×10^{2}	1×10^{6}
Gallium 72	1×10^{1}	1×10^{5}
Germanium 68	1×10^{1}	1×10^{5}
Germanium 71	1×10^{4}	1×10^{8}
Gold 195	1×10^{2}	1×10^{7}
Gold 198	1×10^{2}	1×10^{6}
Gold 199	1×10^{2}	1×10^{6}
Hafnium 181	1×10^{1}	1×10^{6}
Holmium 166	1×10^{3}	1×10^{5}
Hydrogen 3	1×10^{6}	1×10^{9}
Indium 111	1×10^{2}	1×10^{6}
Indium 113m	1×10^{2}	1×10^{6}
Indium 114m	1×10^{2}	1×10^{6}
Indium 115	1×10^{3}	1×10^{5}
Indium 115m	1×10^{2}	1×10^{6}
Iodine 123	1×10^{2}	1×10^{7}
Iodine 125	1×10^{3}	1×10^{6}
Iodine 126	1×10^{2}	1×10^{6}
Iodine 129	1×10^{2}	1×10^{5}
Iodine 130	1×10^{1}	1×10^{6}
Iodine 131	1×10^{2}	1×10^{6}
Iodine 132	1×10^{1}	1×10^{5}
Iodine 133	1×10^{1}	1×10^{6}
Iodine 134	1×10^{1}	1×10^{5}
Iodine 135	1×10^{1}	1×10^{6}
Iridium 190	1×10^{1}	1×10^{6}
Iridium 192	1×10^{1}	1×10^{4}
Iridium 194	1×10^{2}	1×10^{5}
Iron 52	1×10^{1}	1×10^{6}
Iron 55	1×10^{4}	1×10^{6}
Iron 59	1×10^{1}	1×10^{6}
Krypton 74	1×10^{2}	1×10^{9}
Krypton 76	1×10^{2}	1×10^{9}
Krypton 77	1×10^{2}	1×10^{9}
Krypton 79	1×10^{3}	1×10^{5}
Krypton 81	1×10^{4}	1×10^{7}
Krypton 83m	1×10^{5}	1×10^{12}
Krypton 85	1×10^{5}	1×10^{4}
Krypton 85m	1×10^{3}	1×10^{10}
Krypton 87	1×10^{2}	1×10^{9}
Krypton 88	1×10^{2}	1×10^{9}
Lanthanum 140	1×10^{1}	1×10^{5}
Lead 203	1×10^{2}	1×10^{6}
Lead 210[a]	1×10^{1}	1×10^{4}
Lead 212[a]	1×10^{1}	1×10^{5}
Lutetium 177	1×10^{3}	1×10^{7}
Manganese 51	1×10^{1}	1×10^{5}
Manganese 52	1×10^{1}	1×10^{5}
Manganese 52m	1×10^{1}	1×10^{5}
Manganese 53	1×10^{4}	1×10^{9}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Manganese 54	1×10^{1}	1×10^{6}
Manganese 56	1×10^{1}	1×10^{5}
Mercury 197	1×10^{2}	1×10^{7}
Mercury 197m	1×10^{2}	1×10^{6}
Mercury 203	1×10^{2}	1×10^{5}
Molybdenum 90	1×10^{1}	1×10^{6}
Molybdenum 93	1×10^{3}	1×10^{8}
Molybdenum 99	1×10^{2}	1×10^{6}
Molybdenum 101	1×10^{1}	1×10^{6}
Neodymium 147	1×10^{2}	1×10^{6}
Neodymium 149	1×10^{2}	1×10^{6}
Neptunium 237[a]	1×10^{0}	1×10^{3}
Neptunium 239	1×10^{2}	1×10^{7}
Neptunium 240	1×10^{1}	1×10^{6}
Nickel 59	1×10^{4}	1×10^{8}
Nickel 63	1×10^{5}	1×10^{8}
Nickel 65	1×10^{1}	1×10^{6}
Niobium 93m	1×10^{4}	1×10^{7}
Niobium 94	1×10^{1}	1×10^{6}
Niobium 95	1×10^{1}	1×10^{6}
Niobium 97	1×10^{1}	1×10^{6}
Niobium 98	1×10^{1}	1×10^{5}
Nitrogen 13	1×10^{2}	1×10^{9}
Osmium 185	1×10^{1}	1×10^{6}
Osmium 191	1×10^{2}	1×10^{7}
Osmium 191m	1×10^{3}	1×10^{7}
Osmium 193	1×10^{2}	1×10^{6}
Oxygen 15	1×10^{2}	1×10^{9}
Palladium 103	1×10^{3}	1×10^{8}
Palladium 109	1×10^{3}	1×10^{6}
Phosphorous 32	1×10^{3}	1×10^{5}
Phosphorous 33	1×10^{5}	1×10^{8}
Platinum 191	1×10^{2}	1×10^{6}
Platinum 193m	1×10^{3}	1×10^{7}
Platinum 197	1×10^{3}	1×10^{6}
Platinum 197m	1×10^{2}	1×10^{6}
Plutonium 234	1×10^{2}	1×10^{7}
Plutonium 235	1×10^{2}	1×10^{7}
Plutonium 236	1×10^{1}	1×10^{4}
Plutonium 237	1×10^{3}	1×10^{7}
Plutonium 238	1×10^{0}	1×10^{4}
Plutonium 239	1×10^{0}	1×10^{4}
Plutonium 240	1×10^{0}	1×10^{3}
Plutonium 241	1×10^{2}	1×10^{5}
Plutonium 242	1×10^{0}	1×10^{4}
Plutonium 243	1×10^{3}	1×10^{7}
Plutonium 244	1×10^{0}	1×10^{4}
Polonium 203	1×10^{1}	1×10^{6}
Polonium 205	1×10^{1}	1×10^{6}
Polonium 207	1×10^{1}	1×10^{6}
Polonium 210	1×10^{1}	1×10^{4}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Potassium 40	1×10^{2}	1×10^{6}
Potassium 42	1×10^{2}	1×10^{6}
Potassium 43	1×10^{1}	1×10^{6}
Praseodymium 142	1×10^{2}	1×10^{5}
Praseodymium 143	1×10^{4}	1×10^{6}
Promethium 147	1×10^{4}	1×10^{7}
Promethium 149	1×10^{3}	1×10^{6}
Protactinium 230	1×10^{1}	1×10^{6}
Protactinium 231	1×10^{0}	1×10^{3}
Protactinium 233	1×10^{2}	1×10^{7}
Radium 223[a]	1×10^{2}	1×10^{5}
Radium 224[a]	1×10^{1}	1×10^{5}
Radium 225	1×10^{2}	1×10^{5}
Radium 226[a]	1×10^{1}	1×10^{4}
Radium 227	1×10^{2}	1×10^{6}
Radium 228[a]	1×10^{1}	1×10^{5}
Radon 220[a]	1×10^{4}	1×10^{7}
Radon 222[a]	1×10^{1}	1×10^{8}
Rhenium 186	1×10^{3}	1×10^{6}
Rhenium 187	1×10^{6}	1×10^{9}
Rhenium 188	1×10^{2}	1×10^{5}
Rhodium 103m	1×10^{4}	1×10^{8}
Rhodium 105	1×10^{2}	1×10^{7}
Rubidium 86	1×10^{2}	1×10^{5}
Ruthenium 97	1×10^{2}	1×10^{7}
Ruthenium 103	1×10^{2}	1×10^{6}
Ruthenium 105	1×10^{1}	1×10^{6}
Ruthenium 106[a]	1×10^{2}	1×10^{5}
Samarium 151	1×10^{4}	1×10^{8}
Samarium 153	1×10^{2}	1×10^{6}
Scandium 46	1×10^{1}	1×10^{6}
Scandium 47	1×10^{2}	1×10^{6}
Scandium 48	1×10^{1}	1×10^{5}
Selenium 75	1×10^{2}	1×10^{6}
Selenium 79	1×10^{4}	1×10^{7}
Silicon 31	1×10^{3}	1×10^{6}
Silver 105	1×10^{2}	1×10^{6}
Silver 110m	1×10^{1}	1×10^{6}
Silver 111	1×10^{3}	1×10^{6}
Sodium 22	1×10^{1}	1×10^{6}
Sodium 24	1×10^{1}	1×10^{5}
Strontium 85	1×10^{2}	1×10^{6}
Strontium 85m	1×10^{2}	1×10^{7}
Strontium 87m	1×10^{2}	1×10^{6}
Strontium 89	1×10^{3}	1×10^{6}
Strontium 90[a]	1×10^{2}	1×10^{4}
Strontium 91	1×10^{1}	1×10^{5}
Strontium 92	1×10^{1}	1×10^{6}
Sulphur 35	1×10^{5}	1×10^{8}
Tantalum 182	1×10^{1}	1×10^{4}
Technetium 96	1×10^{1}	1×10^{6}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Technetium 96m	1×10^{3}	1×10^{7}
Technetium 97	1×10^{3}	1×10^{8}
Technetium 97m	1×10^{3}	1×10^{7}
Technetium 99	1×10^{4}	1×10^{7}
Technetium 99m	1×10^{2}	1×10^{7}
Tellurium 123m	1×10^{2}	1×10^{7}
Tellurium 125m	1×10^{3}	1×10^{7}
Tellurium 127	1×10^{3}	1×10^{6}
Tellurium 127m	1×10^{3}	1×10^{7}
Tellurium 129	1×10^{2}	1×10^{6}
Tellurium 129m	1×10^{3}	1×10^{6}
Tellurium 131	1×10^{2}	1×10^{5}
Tellurium 131m	1×10^{1}	1×10^{6}
Tellurium 132	1×10^{2}	1×10^{7}
Tellurium 133	1×10^{1}	1×10^{5}
Tellurium 133m	1×10^{1}	1×10^{5}
Tellurium 134	1×10^{1}	1×10^{6}
Terbium 160	1×10^{1}	1×10^{6}
Thallium 200	1×10^{1}	1×10^{6}
Thallium 201	1×10^{2}	1×10^{6}
Thallium 202	1×10^{2}	1×10^{6}
Thallium 204	1×10^{4}	1×10^{4}
Thorium 226[a]	1×10^{3}	1×10^{7}
Thorium 227	1×10^{1}	1×10^{4}
Thorium 228[a]	1×10^{0}	1×10^{4}
Thorium 229[a]	1×10^{0}	1×10^{3}
Thorium 230	1×10^{0}	1×10^{4}
Thorium 231	1×10^{3}	1×10^{7}
Thorium 232	1×10^{1}	1×10^{4}
Thorium 234[a]	1×10^{3}	1×10^{5}
Thorium natural[a]	1×10^{0}	1×10^{3}
Thulium 170	1×10^{3}	1×10^{6}
Thulium 171	1×10^{4}	1×10^{8}
Tin 113	1×10^{3}	1×10^{7}
Tin 125	1×10^{2}	1×10^{5}
Tungsten 181	1×10^{3}	1×10^{7}
Tungsten 185	1×10^{4}	1×10^{7}
Tungsten 187	1×10^{2}	1×10^{6}
Uranium 230[a]	1×10^{1}	1×10^{5}
Uranium 231	1×10^{2}	1×10^{7}
Uranium 232[a]	1×10^{0}	1×10^{3}
Uranium 233	1×10^{1}	1×10^{4}
Uranium 234	1×10^{1}	1×10^{4}
Uranium 235[a]	1×10^{1}	1×10^{4}
Uranium 236	1×10^{1}	1×10^{4}
Uranium 237	1×10^{2}	1×10^{6}
Uranium 238[a]	1×10^{1}	1×10^{4}
Uranium 239	1×10^{2}	1×10^{6}
Uranium 240	1×10^{3}	1×10^{7}
Uranium 240[a]	1×10^{1}	1×10^{6}
Uranium natural[a]	1×10^{0}	1×10^{3}

Column 1 Radioactive Nuclear Substance	Column 2 Activity Concentration (Bq/g)	Column 3 Activity (Bq)
Vanadium 48	1×10^{1}	1×10^{5}
Xenon 123	1×10^{2}	1×10^{9}
Xenon 129m	1×10^{3}	1×10^{4}
Xenon 131m	1×10^{4}	1×10^{4}
Xenon 133	1×10^{3}	1×10^{4}
Xenon 135	1×10^{3}	1×10^{10}
Ytterbium 169	1×10^{2}	1×10^{7}
Ytterbium 175	1×10^{3}	1×10^{7}
Yttrium 90	1×10^{3}	1×10^{5}
Yttrium 91	1×10^{3}	1×10^{6}
Yttrium 91m	1×10^{2}	1×10^{6}
Yttrium 92	1×10^{2}	1×10^{5}
Yttrium 93	1×10^{2}	1×10^{5}
Zinc 65	1×10^{1}	1×10^{6}
Zinc 69	1×10^{4}	1×10^{6}
Zinc 69m	1×10^{2}	1×10^{6}
Zirconium 93[a]	1×10^{3}	1×10^{7}
Zirconium 95	1×10^{1}	1×10^{6}
Zirconium 97[a]	1×10^{1}	1×10^{5}

PHYSICAL CHARACTERISTICS and ANNUAL LIMITS of INTAKE for COMMONLY USED RADIONUCLIDES

Radio-nuclide	Half-Life	Major Radiation Energies[a, b or c] MeV (% abundance)		Specific gamma-ray Constant		Shielding Data			Annual Limit or Intake (Bq)			
		Beta	Gamma	R h^{-1} mCi^{-1} at 1 cm_{ab}	mGy h^{-1} Mbq at 1 cm	Half-Value Layer in Pb $(mm)_{a,c}$	Tenth-Value Layer in Pb $(mm)_d$	Maximum Range of Beta Particles in Water $(mm)_d$	Based on 50mSv Dose Limit, ICRP-30		Based on 20 mSv Dose Limit, ICRP-61	
									Ingestion	Inhalation[e]	Ingestion	Inhalation[e]
^{3}H	12.3 y	0.018(100)						0.007	3×10^{9}	3×10^{9}	1×10^{9}	1×10^{9}
^{11}C	20.3 m	β+ 0.97(100)	0.511(200)	5.91	1.6	4			2×10^{10}	2×10^{10}	6×10^{9}	6×10^{9}
^{14}C	5730 y	0.16(100)						0.3	9×10^{7}	9×10^{7}	4×10^{7}	4×10^{7}
^{13}N	10.0 m	β+ 1.20(100)	0.511(200)	5.91	1.6	4			not listed	not listed	not listed	not listed
^{15}O	2.0 m	β+ .74(100)	0.511(200)	5.91	1.6	4			not listed	not listed	not listed	not listed
^{18}F	1.8 h	β+ 0.65(97)	0.511(194)	5.73	1.5	4			2×10^{9}	3×10^{9}	4×10^{8}	9×10^{8}
^{22}Na	2.6 y	β+ $0.546(90)_d$	$1.275(100)_d$	12	3.2	10	37	$(2.0)_d$	2×10^{7}	2×10^{7}	1×10^{7}	7×10^{6}
^{24}Na	15.0 h	1.4(100)	1.369(100)	18.4	4.96	15	59	6.4	1×10^{8}	2×10^{8}	5×10^{7}	6×10^{7}
^{32}P	14.3 d	1.7(100)						8.2	2×10^{7}	1×10^{7}	8×10^{6}	5×10^{6}
^{33}P	25.4 d	0.249(100)						0.7	3×10^{8}	1×10^{8}	8×10^{7}	3×10^{7}
^{35}S	88.0 d	0.17(100)						0.33	4×10^{8}	8×10^{7}	7×10^{7}	3×10^{7}
^{36}Cl	301000 y	0.709(98)						2.8	6×10^{7}	9×10^{6}	2×10^{7}	3×10^{6}
^{45}Ca	165 d	0.25(100)						0.7	6×10^{7}	3×10^{7}	1×10^{7}	1×10^{7}
^{47}Ca	4.56 d	0.67(82) 1.98(18)	0.490(5) 0.815(5) 1.308(74)	5.7	1.541			9.7	3×10^{7}	3×10^{7}	1×10^{7}	1×10^{7}
^{51}Cr	27.8 d		0.320(9)	0.164	0.04	2	7		1×10^{9}	7×10^{8}	4×10^{8}	2×10^{8}

Radio-nuclide	Half-Life	Major Radiation Energies[a, b or c] MeV (% abundance)		Specific gamma-ray Constant		Shielding Data			Annual Limit or Intake (Bq)			
		Beta	Gamma	$R\ h^{-1}\ mCi^{-1}$ at 1 cm[ab]	$mGy\ h^{-1}$ Mbq at 1 cm	Half-Value Layer in Pb (mm)[a,c]	Tenth-Value Layer in Pb (mm)[d]	Maximum Range of Beta Particles in Water (mm)[d]	Based on 50mSv Dose Limit, ICRP-30		Based on 20 mSv Dose Limit, ICRP-61	
									Ingestion	Inhalation[e]	Ingestion	Inhalation[e]
^{55}Fe	2.7 7		0.0059(23)						3×10^8	7×10^7	1×10^8	6×10^7
^{59}Fe		0.27(46) 0.46(53) 1.56(0.3)	0.19(2.4) 1.1(43)	6.19	1.7	11	44		3×10^7	1×10^7	1×10^7	5×10^6
^{67}Ga	78 h	0.09(15)	0.93(40) 0.185(24) 0.296(22) 0.388(7)	0.95	0.26	0.7			3×10^8	4×10^8	8×10^7	1×10^8
^{68}Ga	1.13 h	β+ 1.90(87)	0.511(176)	5.37	1.45	4			6×10^8	2×10^9	2×10^8	5×10^6
^{57}Co	267 d		0.014(9) 0.122(87)	0.93	0.25	0.3	~0.7		2×10^8	2×10^7	6×10^7	8×10^6
^{60}Co	5.26 y	0.31(99+)	0.173(100)	13.2	3.568	12	40		7×10^6	1×10^6	3×10^6	4×10^5
^{63}Ni	100.1 y	0.066	-	-	-	-			3×10^8	6×10^7	1×10^8	1×10^7
^{64}Cu	12.9 h	0.057(39) β+0.64(19)	0.511(38)	1.16	0.31	4			4×10^8	8×10^8	2×10^8	3×10^8
^{65}Zn	245 d	1.1 0.33(2)	1.150(49)	2.7	0.73	10	42		1×10^7	1×10^7	5×10^6	4×10^6
^{75}Se	120 d	0.08-0.25 e	0.121(16) 0.136(57) 0.265(60) 0.280(25) 0.401(13)	2	0.541	2	5.1		2×10^7	2×10^7	5×10^6	4×10^6

Radio-nuclide	Half-Life	Major Radiation Energies[a, b or c] MeV (% abundance)		Specific gamma-ray Constant		Shielding Data			Annual Limit or Intake (Bq)			
		Beta	Gamma	R h^{-1} mCi^{-1} at 1 cm_{ab}	mGy h^{-1} Mbq at 1 cm	Half-Value Layer in Pb (mm) [a,c]	Tenth-Value Layer in Pb $(mm)_d$	Maximum Range of Beta Particles in Water $(mm)_d$	Based on 50mSv Dose Limit, ICRP-30		Based on 20 mSv Dose Limit, ICRP-61	
									Ingestion	Inhalation[e]	Ingestion	Inhalation[e]
^{85}Sr	64 d	0.5(1)	0.514(100)	3	0.811	4	16		9×10^7	6×10^7	1×10^7	4×10^7
^{89}Sr	50.5 d	1.463(100)	-	-	-			6.8_d	2×10^7	5×10^6	6×10^6	2×10^6
^{90}Sr	28 y	0.66(100) ^{90}Y 2.3(100)	-	-	-			11	1×10^6	1×10^5	6×10^5	6×10^4
^{90}Y	64.0 h	2.274(100)	-	-	-	-	-	11	2×10^7	2×10^7	5×10^6	7×10^6
^{99}Mo	66.7 h	1.23(82) 0.45(17)	0.181(7) 0.740(14) 0.778(5)				20	5.6	4×10^7	5×10^7	2×10^7	1×10^7
^{99m}Tc	6.04 h	0.12	0.141(90)	0.7	0.189	0.3	0.9		3×10^9	6×10^9	1×10^9	2×10^9
^{111}In	2.8 d		0.173(89) 0.247(94)				2.5		2×10^8	2×10^8	5×10^7	9×10^7
^{113m}In	1.67 h		0.393(55)	1.8	0.49		9.5		2×10^9	5×10^9	2×10^9	9×10^8
^{123}I	13.0 h	0.13(tr)	0.159(97)				1.2		1×10^8	2×10^8	9×10^7	2×10^8
^{125}I	60.2 d	0.03(tr)	0.036	~0.7			0.06		1×10^6	2×10^6	1×10^6	2×10^6
^{129}I	1.57×10^7 y	0.15(100)	0.04(7.5) 0.030-0.035 (69)				0.07		2×10^5	3×10^5	9×10^7	2×10^8
^{131}I	8.05 d	0.61(90)	0.08(2.6) 0.284(5) 0.364(82) 0.635 (6.5)	2.23	0.6	3	11	2.3	1×10^6	2×10^6	8×10^5	1×10^6

Radio-nuclide	Half-Life	Major Radiation Energies[a, b or c] MeV (% abundance)		Specific gamma-ray Constant		Shielding Data			Annual Limit or Intake (Bq)			
		Beta	Gamma	$R\ h^{-1}\ mCi^{-1}$ at 1 cm_{ab}	$mGy\ h^{-1}$ Mbq at 1 cm	Half-Value Layer in Pb $(mm)_{a,c}$	Tenth-Value Layer in Pb $(mm)_d$	Maximum Range of Beta Particles in Water $(mm)_d$	Based on 50mSv Dose Limit, ICRP-30		Based on 20 mSv Dose Limit, ICRP-61	
									Ingestion	Inhalation[e]	Ingestion	Inhalation[e]
^{133}Ba	10.5 y		0.056(2) 0.079(29) 0.274(1) 0.302(26) 0.358(70) 0.381(10)	2.12	0.57				6×10^7	3×10^7	1×10^6	2×10^6
^{133}Xe	5.3 d	0.35(100)	0.08(35) Cs x-rays	0.1	0.027		≤0.70	1	-	4×10^6	-	not listed
^{141}Ce									6×10^7	2×10^7	2×10^7	8×10^6
^{137}Cs	30 y	0.51(95) 1.18(7)	0.662(84)	6.5	21	0.6			4×10^6	6×10^5	1×10^5	2×10^6
^{153}Sm	1.9 d	0.64 0.71 0.81	0.103(28)						6×10^7	1×10^8	2×10^7	3×10^7
^{169}Yb	31.8 d		0.063(45) 0.110(18) 0.177(22) 0.197(35) 0.131(11) 0.308(10)						7×10^7	3×10^7	2×10^7	9×10^6
^{186}Re	3.7 d	0.93(23) 1.07(73)	0.137(10) 0.122(1)				59		7×10^7	6×10^7	2×10^7	2×10^7
^{188}Re	17 h	2.116	0.155(27)						6×10^7	1×10^8	2×10^7	3×10^7
^{188}W	69.4 d	0.349							1×10^7	5×10^7	5×10^5	2×10^7

Radio-nuclide	Half-Life	Major Radiation Energies[a, b or c] MeV (% abundance)		Specific gamma-ray Constant		Shielding Data			Annual Limit or Intake (Bq)			
		Beta	Gamma	$R\ h^{-1}$ mCi^{-1} at 1 cm_{ab}	$mGy\ h^{-1}$ Mbq at 1 cm	Half-Value Layer in Pb (mm) $_{a,c}$	Tenth-Value Layer in Pb $(mm)_d$	Maximum Range of Beta Particles in Water $(mm)_d$	Based on 50mSv Dose Limit, ICRP-30		Based on 20 mSv Dose Limit, ICRP-61	
									Ingestion	Inhalation$_e$	Ingestion	Inhalation$_e$
^{192}Ir	74.2 d								4×10^7	8×10^6	1×10^7	3×10^6
^{198}Au	2.7 d	0.97(99)	0.412(96)	2.34	0.632	0.3			5×10^7	6×10^7	1×10^7	2×10^7
^{203}Hg	47 d	0.214(100)	0.279(82)	1.33	0.359				9×10^7	4×10^7	1×10^7	1×10^7
^{201}Ti	73 h		0.135(2.6) 0.167(10) x-rays 0.068 - 0.08(95)	0.44		0.2	≤ 0.9		6×10^8	6×10^8	3×10^8	4×10^8

a Padikal TN & Fivozinsky SP, Medical Physics Data Book, National Bureau of Standards (1982)

b ICRP Publication 25 The Handling, Storage, Use and Disposal of Unsealed Radionuclides in Hospitals and Medical Research Establishments (1971)

c Gordon K, Shields R and Komarov EI; Manual on Radiation Protection in Hospitals and General Practice: Volume 4 Unsealed Sources, jointly sponsored by IAEA / ILO / WHO / PAHO / CEC (in press)

d Institute of Physical Sciences in Medicine Report 63, Radiation Protection in Nuclear Medicine and Pathology (1991)

e To describe the clearance of inhaled radioactive materials from the lung, materials are classified as D, W or Y which refer to their retention in the pulmonary region. This classification applies to a range of half-times for D of less than 10 days, for W from 10 to 100 days and for Y greater than 100 days. In the interest of simplicity when creating the above table, the most restrictive inhalation ALI was selected. The same strategy was applied for different values of ingestion ALIs in ICRP 61.
Note that besides applying a lower annual dose limit, ICRP-61 uses a new system of tissue weighting factors. Please refer back to the original ICRP publications (see f and g below) for more detailed information.

f ICRP Publication 30 Limits for Intakes of Radionuclides by Workers Part 1 (1979), Part 2 (1980) and Part 3 (1981)

g ICRP Publication 61 Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations (1991)

APPENDIX 9:

Decommissioning Report

DECOMMISSIONING REPORT

Permit Holder: _____ Internal Permit: _____ Room #:_____

Part A: To be completed by the Permit Holder

1) Confirm that all radioactive materials have been properly disposed of. This includes source vials, by-products and waste (liquid, solid, and LSV). YES NO

2) Please identify **all** areas and equipment used for radioactive work in this lab. A written list and a map are required. Please attach the documents to this form. YES NO

3) Were any drains used for radioactive work (e.g. disposal)? YES NO

4) Were any fume hoods used? YES NO

5) Confirm that all items/areas which may have been used for radioactive work have been:
   a) direct monitored (specify instrument and probe): _____ YES NO
   b) wipe tested. (Please attach results to this form) YES NO

6) Confirm that all radiation warning labels have been removed from work areas and equipment. Do not remove door sign, lab classification posters and permit. YES NO

I certify that the information entered in this form is valid.

Signature: _____ Title: _____ Date:_____

Part B: To be completed by the Radiation Protection Service

1) Checked survey results. YES NO

2) Removal of warning signs verified. YES NO

3) Comments:

_____

_____

_____

4) Door signs, lab classification posters and permit removed. YES NO

5) Permit removed from RPS database. Date removed: _____ YES NO

Signature: _____ Title: _____ Date: _____

APPENDIX 9:

Inspection and Decommissioning Report

DECOMMISSIONING REPORT

Permit Holder: _____ Internal Permit: _____ Room #:_____

Part A: To be completed by the Permit Holder

1) Confirm that all radioactive materials have been properly disposed of. This includes source vials, by-products and waste (liquid, solid, and LSV). YES NO

2) Please identify **all** areas and equipment used for radioactive work in this lab. A written list and a map are required. Please attach the documents to this form. YES NO

3) Were any drains used for radioactive work (e.g. disposal)? YES NO

4) Were any fume hoods used? YES NO

5) Confirm that all items/areas which may have been used for radioactive work have been:
   a) direct monitored (specify instrument and probe): _____ YES NO
   b) wipe tested. (Please attach results to this form) YES NO

6) Confirm that all radiation warning labels have been removed from work areas and equipment. Do not remove door sign, lab classification posters and permit. YES NO

I certify that the information entered in this form is valid.

Signature: _____ Title: _____ Date:_____

Part B: To be completed by the Radiation Protection Service

1) Checked survey results. YES NO

2) Removal of warning signs verified. YES NO

3) Comments:

_____

_____

_____

4) Door signs, lab classification posters and permit removed. YES NO

5) Permit removed from RPS database. Date removed: _____ YES NO

Signature: _____ Title: _____ Date: _____

Centre universitaire de santé McGill
McGill University Health Centre

Site : _____ Room: _____ Classification: _____

MUHC Nuclear Medicine Rooms Inspection Form	Yes	No	N/A
1- Signs and Labels			
CNSC Posters displayed (Room classification, Spill, Pkg. Handling)?			
24-h Emergency contact info displayed?			
Radiation Warning Signs on doors for rooms with more than 100 EQ?			
2- Control of radioisotopes			
Are radioisotopes properly secured from non-authorized users?			
Are inventory records available/accurate?			
3- Contamination Monitoring			
Is contamination monitoring done every 7 days or after each use?			
Locations monitored identified on a map?			
Records in good order?			
Is decontamination being conducted when required?			
Is follow-up contamination being recorded?			
4- Handling Practices			
Is there evidence for food, drink, smoking?			
Are lab coats and gloves being worn?			
Are work areas covered with absorbent pads?			
Are staff wearing dosimeters as required?			
Is shielding being used when required?			
Is work conducted in fume-hood when required?			
5-Intrumentation			
Are correct instruments provided?			
Are instruments functioning and in good condition?			
Have survey meters been calibrated during the past 12 months?			

Radiation Survey (to be measured by RSO during visit):
Max. dose rate at storage area (μSv/h): _____
Max. dose rate in occupied areas around storage (μSv/h): _____

Contamination level below CNSC limits for Isotopes in use (Y/N): _____
(Attach results from contamination survey)

Comments: _____

_____

_____

(Continue on reverse if necessary)

Date : _____ RSO signature : _____

Centre universitaire de santé McGill
McGill University Health Centre

Permit Number: _____ Permit Holder: _____

Room: _____ Classification: _____

MUHC Laboratories Inspection Form	Yes	No	N/A
1- Signs and Labels			
CNSC Posters displayed (Room classification, Spill, Pkg. Handling)?			
24-h Emergency contact info displayed?			
Radiation Warning Signs on doors for rooms with more than 100 EQ?			
2- Internal Permit Information			
Internal Permit displayed?			
Internal Permit current/accurate?			
3- Control of radioisotopes			
Are radioisotopes properly secured from non-authorized users?			
Are inventory records available/accurate?			
4- Contamination Monitoring			
Is contamination monitoring done every 7 days or after each use?			
Locations monitored identified on a map?			
Records in good order?			
Is decontamination being conducted when required?			
Is follow-up contamination being recorded?			
5- Handling Practices			
Is there evidence for food, drink, smoking?			
Are lab coats and gloves being worn?			
Are work areas covered with absorbent pads?			
Are staff wearing extremity dosimeters when required (> 50 MBq P-32)?			
Is shielding being used when required?			
Is work conducted in fume-hood when required?			
6-Intrumentation			
Are correct instruments provided?			
Are instruments functioning and in good condition?			
Have survey meters been calibrated during the past 12 months?			

Radiation Survey:
Make/Model/SN of survey meter used: _____
Max. dose rate at storage area (μSv/h): _____
Contamination level below CNSC limits for Isotopes in use (Y/N): _____

Comments: _____

_____

_____

Date : _____ RSO signature : _____

APPENDIX 10:

McGill Radioisotope Tracking System (MyLAB)

How to track the Use of a Radioisotope in the McGill Radioisotope Tracking System

1. Log on the McGill MyLAB site at:
   https://mylab.mcgill.ca/EHSAWeb/EHSAWebISAPI.dll/EXEC

2. Enter your User ID and Password (contact the RSO for creating a new account).

3. Upon receipt of a new vial, create a new vial record. Enter a unique identification number for the vial, e.g. the PO number, as well as the relevant data such as reference date, isotope, etc. **Each** vial, including those already in storage, must be entered into the computer.

4. Create radioactive waste containers electronically that will be used for the disposal of radioactive waste. The computer will generate a waste container number. Mark this number on the designated waste container before using. Separate containers must be provided for:

   - Solid radioactive waste (one isotope per container)
   - Liquid radioactive waste (one isotope per container)
   - Liquid scintillation vials
   - Empty stock vials

   With the exception of liquid scintillation vials, radioactive waste containers cannot be shared between permit holders at this time.

5. As the vial is used, record the amount of activity removed from the vial using the "vial use reports".

6. When radioactive material is not disposed of immediately, record the use as by-product.

7. Whenever a new product (by-product or secondary product) is made from an original vial, this new product must be labelled with the radioisotope, date, activity and name of the individual responsible for the item using the label shown below.

8. Remove or deface all markings prior to disposal in the radioactive waste container.

9. When more than one radioisotope is required to be disposed of at one time, e.g. for dual labelling experiments where it is not possible to segregate isotopes, then each radioisotope should be entered into the inventory program separately and two radioactive waste containers created electronically. The number of each of the

generated waste containers and the isotope and activity for each isotope should be written on the one waste container that is actually used to dispose of the combined radioisotope waste.

10. Tracking of LSV waste is not required on the computer unless a large percentage (e.g. more than 1%) of the activity of the vial has been disposed of in LSV. In this case, select LSV as the disposal container. Normally a total activity of the LSV container is adequate for labelling of the LSV container.

11. All radioisotope tracking forms (both electronic and paper form) should be completed with the user's first initial and full last name; a user's initials or nickname are not considered adequate identification by the Canadian Nuclear Safety Commission.

12. An online training video on how to use the tracking software MyLAB is available at: http://knowledgebase.mcgill.ca/display/2/articleDirect/index.asp?aid=9640&r=0.2002985

RADIOISOTOPE RUNNING LOG FORM

Radioisotope & Product: _____ Date of Measured Activity: _____ Volume: _____

Activity: _____ Vial ID: _____ Date of Reception: _____

Date	User	Activity Removed (uCi)	Volume Removed (ul)	Activity Remaining (uCi)	By Product ID *	By Product RTS Code	Solid Waste (uCi)	Liquid Waste (uCi)	Date of Disposal

Disposed by: _____ Date of disposal of vial: _____ Activity disposed: _____

APPENDIX 11:

Laboratory Inspection Sheet

Centre universitaire de santé McGill
McGill University Health Centre

Permit Number: _____ Permit Holder: _____

MUHC Laboratories Inspection Form	Yes	No	N/A
1- Signs and Labels			
CNSC Posters displayed (Room classification, Spill, Pkg. Handling) ?			
24-h Emergency contact info displayed?			
Radiation Warning Signs on all doors?			
Radiation Warning Signs on storage areas?			
Work Areas Labeled?			
2- Internal Permit Information			
Internal Permit displayed?			
Internal Permit current/accurate?			
3- Control of radioisotopes			
Are radioisotopes properly secured from non-authorized users?			
Are inventory records available/accurate?			
Was there any unauthorized transfer of radioisotopes?			
4- Contamination Monitoring			
Is contamination monitoring performed/documented every 7 days?			
Locations identified on a wipe test map?			
Records in good order?			
Is decontamination being conducted when required?			
Is follow-up contamination being recorded?			
5- Handling Practices			
Is there evidence for food, drink, smoking?			
Are lab coats and gloves being worn?			
Are work areas covered with absorbent pads?			
Are staff wearing TLDs when required?			
Is shielding being used when required?			
Is work conducted in fume-hood when required?			
6-Intrumentation			
Are correct instruments provided?			
Are instruments functioning and in good condition?			
Have survey meters been calibrated during the past 12 months?			

Radiation Survey Reading at storage area (µSv/h): _____

Comments: _____

_____

Date : _____ RSO signature : _____

Site : Montreal Children Hospital
Room : CB-8B
Device: MDS Nordion Gammacell 1000

Gammacell Inspection Form	Yes	No	N/A
1- Signs and Labels			
Radiation warning sign posted on door?			
24-h Emergency contact info displayed?			
2- CNSC Permit Information			
CNSC Permit displayed in room?			
CNSC Permit current/accurate?			
3- Security			
Is the Gammacell accessible only to authorized users?			
Security lock in good condition?			
Motion detector operational?			
Double bias door switch operational?			
Security system connected to 24H security desk?			
4- Leak test			
Annual leak test indicated source not leaking?			
Last Leak test done during the past 12 months (date: _____) ?			
5-Intrumentation			
Survey meter available (model: _____; serial: _____) ?			
Survey meter in good condition?			
Have survey meters been calibrated during the past 12 months?			

Radiation Survey (done by RSO):

Make/Model/SN of survey meter used: _____
Dose rate at 1 meter from the Gammacell (μSv/h): _____
Dose rate at 5 cm from the Gammacell sample chamber (μSv/h): _____

Comments: _____

_____

_____

Date : _____ RSO signature : _____

Centre universitaire de santé McGill
McGill University Health Centre

Site : _____ Room: _____ Classification: _____

MUHC Nuclear Medicine Rooms Inspection Form	Yes	No	N/A
1- Signs and Labels			
CNSC Posters displayed (Room classification, Spill, Pkg. Handling)?			
24-h Emergency contact info displayed?			
Radiation Warning Signs on doors for rooms with more than 100 EQ?			
2- Control of radioisotopes			
Are radioisotopes properly secured from non-authorized users?			
Are inventory records available/accurate?			
3- Contamination Monitoring			
Is contamination monitoring done every 7 days or after each use?			
Locations monitored identified on a map?			
Records in good order?			
Is decontamination being conducted when required?			
Is follow-up contamination being recorded?			
4- Handling Practices			
Is there evidence for food, drink, smoking?			
Are lab coats and gloves being worn?			
Are work areas covered with absorbent pads?			
Are staff wearing dosimeters as required?			
Is shielding being used when required?			
Is work conducted in fume-hood when required?			
5-Intrumentation			
Are correct instruments provided?			
Are instruments functioning and in good condition?			
Have survey meters been calibrated during the past 12 months?			

Radiation Survey (to be measured by RSO during visit):
Max. dose rate at storage area (μSv/h): _____
Max. dose rate in occupied areas around storage (μSv/h): _____

Contamination level below CNSC limits for Isotopes in use (Y/N): _____
(Attach results from contamination survey)

Comments: _____

_____

_____

(Continue on reverse if necessary)

Date : _____ RSO signature : _____

APPENDIX 12a:

I-131 Treatment
(In-Patients)

Information to patient regarding Iodine-131 treatment

1. Introduction

You will receive a treatment using radioactive iodine (Iodine-131). For this, you will have to be admitted to the hospital for a few days because of the amount of activity that you will receive. During this period, you will be restricted to a private room with very short visits from friends or relatives. Consequently, you may wish to bring reading material, games and rent a T.V.

When you will go back home, you will still have to take certain precautions regarding sleeping arrangement, cleaning your clothes, etc., for a few days.

2. About Iodine-131

The Iodine-131 that you will receive for your therapy is radioactive. After you administered the Iodine-131, gradually some of it will go into your body fluids to be eliminate via urine, faeces, perspiration, saliva, etc. The elimination rate will depend on many factors; it varies from one individual to another. Nevertheless, all the iodine-131 will gradually disappear.

While this exposure to radiation is necessary for you, you will become an additional source of radiation for the people around you. It is therefore necessary to limit the exposure of your visitors. In order to achieve that, they can visit you only for a short period each day and remain far enough from you during visits.

3. Your Treatment

Before your treatment, a physician or a resident M.D. from the floor, will see you for admission purposes.

Then, people from Radiation Safety Service and Nuclear Medicine Department will come to explain the different restrictions related to this type of treatment.

Later, the physician and people from Radiation Safety Service and Nuclear Medicine Department will come to your room for the treatment to administer the I-131. As we told you previously, there are usually minimal side effects.

4. Restrictions related to isolation

You must not go out of your room unless there is an exceptional circumstance. However, you can open your door.

Nothing (including meal tray and waste***) can go out of your room***. Everything has to be checked and cleared by the people from Radiation Safety Service or Nuclear Medicine Department.

Flush the toilet 2 to 3 times after you go there and thoroughly wash your hands. ***Males should sit down when they go to the toilet*** to avoid splashing.

5. **Visitors**

Visitor should not come, the first day, after the treatment. The day after, visitors can come into your room for a short time and after that they can come for a longer time each day after. However, ***pregnant women and children should not visit during your hospitalisation***.

Visitors must ***keep their distance***, ***avoid touching you***. They must ***not use your bathroom***. They must ***not drink or eat into your room***.

6. **Discharge**

People from the Radiation Safety Service or Nuclear Medicine Department will visit to take some external measurement regarding level of radioactive dose rate from your body. These measurements will help us to evaluate when it will be appropriate to discharge you (usually one or two days after the treatment).

7. **Upon the treatment**

For the ***next 8 days*** after discharge:

- ***spend as little time as possible close to young children and pregnant women***;
- ***Use separate*** clothes, linen, towels, utensils, etc. and **wash them separately** from those of the rest of your family;
- ***Sleep alone*** (as much as possible)
- ***Use good hygiene habits***. Wash your hands thoroughly after you go to the washroom. Flush the toilet 2-3 times after each use.

Specifically for ***women***, it is recommended that they:

- wait ***1 year before getting pregnant*** to ensure that no other treatment is necessary
- wait ***2 months before breastfeeding***

Specifically for ***men***, it is recommended that they:

- wait ***2 months before child conceptions***
- ***sit down to urinate*** for two weeks

McGill University Health Centre
Centre Universitaire de Santé McGill

Information aux patients concernant les traitements à l'Iode-131

1. Introduction

Vous allez subir une thérapie à l'iode radioactif I-131. Ce traitement consiste simplement en l'administration d'un composé d'Iode-131. Cependant, en raison de l'activité administrée, nous devons vous admettre à l'hôpital pour quelques jours dans une chambre privée où, sous certaines conditions, vous ne serez autorisé à recevoir des visiteurs que pour de courtes périodes. Conséquemment, nous vous suggérons d'apporter des livres, des jeux et de louer un téléviseur.

De plus, lorsque vous retournerez à la maison, vous aurez aussi à prendre, pour quelques jours encore, des dispositions particulières tel que dormir séparément, laver vos vêtements séparément, etc.

2. À propos de l'Iode-131

L'Iode-131 que vous allez recevoir lors de votre thérapie est radioactive. Après son ingestion, une partie de l'Iode-131 ira graduellement se mêler à vos fluides corporels pour être éliminé via l'urine, les selles, la transpiration, la salive, etc. Le taux d'élimination dépend de plusieurs facteurs et conséquemment varie d'un individu à l'autre. Cependant tout l'Iode-131 disparaîtra graduellement de votre corps.

Bien qu'il soit nécessaire pour vous d'être exposés à ce type de rayonnement, en raison de l'Iode-131 présent dans votre corps, vous allez devenir une source de rayonnement supplémentaire pour votre entourage. Pour limiter leur exposition, vos visiteurs ne seront donc autorisés qu'à vous visiter pour de courtes périodes chaque jour et devront rester à une bonne distance de vous.

3. Votre traitement

Avant votre traitement, un médecin ou un médecin résidant vous rencontrera pour l'examen d'admission.

Ensuite, des gens du service de radioprotection ou de médecine nucléaire viendront vous expliquer les différentes restrictions reliées à ce type de traitement.

Plus tard, le médecin (avec quelqu'un du service de médecine nucléaire ou du service de radioprotection) viendra vous donner votre traitement. Comme il a été mentionné précédemment, le traitement consiste en l'administration d'Iode-131. Les effets secondaires sont minimaux.

4. Restrictions reliées à l'isolation

Vous ne devez pas sortir de votre chambre à moins de circonstances exceptionnelles. Cependant la porte peut demeurer ouverte, à votre convenance.
Rien ne doit sortir de votre chambre sans avoir été préalablement vérifié par le service de radioprotection ou le département de médecine nucléaire. Cela inclut les déchets, les plateaux-repas. Quelqu'un de médecine nucléaire ou radioprotection viendra vous voir chaque jour.

Lorsque vous irez à la toilette, vous devrez rincer la cuvette deux à trois fois et bien vous laver les mains. De plus, les ***hommes doivent s'asseoir pour uriner***.

5. Visiteurs

Vous ne devriez pas recevoir de visiteur le jour de la thérapie. A partir du lendemain, des visiteurs pourront venir, pour une courte période le premier jour, puis des périodes de plus en plus longue, jour après jour, tel qu'indiqué sur la porte de votre chambre. Cependant, ***les femmes enceintes et les enfants ne sont pas autorisés à vous visiter***.

Les visiteurs doivent ***demeurer à une bonne distance*** de vous et ***éviter de vous toucher***. Ils ne ***doivent pas utiliser votre salle de toilette***. Ils ne ***doivent pas manger ou boire*** dans votre chambre.

6. **Congé de l'hôpital**

Pendant votre séjour à l'hôpital, quelqu'un du service de médecine nucléaire ou du service de radioprotection vous visitera tous les jours. Il prendra des mesures externes du débit de dose de rayonnement provenant de l'Iode-131, dans votre corps. Ces mesures nous aideront à déterminer le moment adéquat pour vous donner votre congé (de un à trois jours après le traitement habituellement).

7. **Lors du retour à la maison**

Pour les ***8 prochains jours***:

- ***Réduisez*** autant que possible ***le contact et le temps passé à proximité des enfants et les femmes enceintes***;
- **Utilisez vos propres** serviettes, vêtements, ustensiles, etc. et **lavez-les séparément** du reste de la famille
- ***Dormez seul*** (autant que possible)
- ***Appliquez de bonnes mesures d'hygiène***. Lavez-vous soigneusement les mains après être allé à la toilette. Tirez la chasse d'eau 2-3 fois après chaque utilisation.

En ce qui concerne les ***femmes***, vous devez:

- Attendre ***1 an avant de devenir enceinte*** au cas ou un second traitement serait nécessaire ;
- Attendre ***2 mois avant d'allaiter au sein***

En ce qui concerne les ***hommes***, vous devez:

- Attendre ***2 mois avant de concevoir un enfant*** ;
- ***Vous asseoir pour uriner*** et ce pendant 2 semaines.

McGill University Health Centre
Centre Universitaire de Santé McGill

Hôpital:_____

Traitement I-131

Nom
Name: _____

Patient ID#:
_____

Numéro de chambre
Room number: _____

Conditions de vie du patient/Patient living
_____

Date de traitement
Date of treatment: _____

Activité administrée
Activity administered : _____

Nombre de capsules
Number of capsules: _____

Heure de l'administration
Time of administration : _____

REMINDER:

1 mR/h ~ 10 μSv/h

LOCATION	Exposure level in uSv/hr or mR/hr Mesures d'exposition en uSv/hr ou mR/h						
	Date						
	Heure/ Time						
Cou (niveau thyroïde) Neck(thyroid level)							
Épaule (niveau thyroïde) Shoulder (thyroid level)							
1 mètre / 1 metre							
2 mètres / 2 metres							
Entrée de la chambre Entrance of room							
Chambre voisine (mur adjacent) Next room (adjacent wall)							
Thorax patient voisin (lit) Next patient chest (bed)							
BDF normal Normal BKG							
Dose Rate Meter Used **Débitmètre Utilisé**							

	Dose résiduelle **Residual Dose**	**Niveau Approximatif de radiation** **Approximate Radiation Level**
À 1 mètre /At 1 metre (NCRP 37, 1970)	8 mCi (296 MBq)	18 uSv/hr / 1.8 mR/hr
	30 mCi (1110 MBq)	67.5 uSv/h / 6.75 mR/hr
À 2 mètres / At 2 metres (GMA-4, 1993)	8.11 mCi (300 MBq)	4uSv/hr / 0.4 mR/hr
	29.7 mCi (1100 MBq)	16 uSv/hr / 1.6 mRhr

Decontamination and Decommissioning of I-131 Therapy Patient's Room

POLICY

The purpose of decommissioning is to locate and clean any areas of contamination and render the room open to other patients according to CNSC regulations.

PROCEDURE

1. The person who conducts the decommissioning must be trained in radiation safety or work directly under the supervision of a trained person.

2. The following equipment and supplies are required for decommissioning of therapy rooms:

    - Contamination meter
    - Absorbent pads
    - Garbage bags
    - Gloves and shoe covers
    - Decontamination solution
    - I-131 Treatment Room Survey sheet

3. Before entering the room, put on a lab coat, gloves and shoe covers.

4. Monitor linen using the dose rate meter. Linens may be released to laundry if the contact dose rate does not exceed 2.5 μSv/h. Linen not released to the laundry must be kept for decay until the release criterion is met.

5. Remove all absorbent pads, plastic covers and other waste material. Using a contamination meter, segregate items between radioactive and non-radioactive waste and put in separate plastic bags outside the room. Label the radioactive waste with a tag and specify the date and number of CPM detected at the surface of the bag using the contamination meter.

6. Using a contamination meter calibrated for I-131, verify that the contamination levels on all surfaces are below the CNSC limits for I-131 (30 Bq/cm^2 if the room is a controlled area; 3 Bq/cm^2 if the room is opened to public). The calibration factor for the contamination meter (number of counts in CPS or CPM) corresponding to the lower contamination criterion (3 Bq/cm^2) should be documented on the survey sheet.

7. For any surface where contamination is detected above the background level, clean thoroughly using the decontamination solution and measure the contamination level again after the cleaning is completed. Repeat the procedure until no statistically significant decrease in the total (*fixed + loose*) contamination level is detected. Record the final contamination level reading on the *I-131 Treatment Room Survey Sheet.*

8. If the contamination level is at the background level (undetectable), the room can be reopened to public immediately (no *fixed* or *loose* contamination).

9. If the contamination level is above the legal limits (averaged over a 100 cm^2 surface) after the final

cleaning, the room should be closed and left for decay until the legal limit levels are reached (30 Bq/cm^2 if the room is a controlled area; 3 Bq/cm^2 if the room is opened to public).

10. The licensee shall ensure that prior to the release of the patient treatment room, the dose rate of non-removable (fixed) contamination (usually found inside the plumbing under the bathroom sink)does not exceed 2.5 microSv/h measured from any surface in the patient bathroom. For a bathroom with a typical occupancy factor of 1/20 (NCRP 147), this ensures that a patient will not receive a dose in excess of 50 microSv after 15 days or more of hospitalization.

11. The final room clearance must be approved by the RPS. Following room clearance approval, all warning signs must be removed from the door and the head nurse should be informed that the room is clear to be reopened.

I-131 Treatment Room Survey Sheet

Site/Room: _____ Patient's name: _____

Location	Contamination & Survey Meter Readings		
	Contamination meter [CPM]	**Survey meter [μSv/h]**	**Comments**
1. ***Background***			
2. Sink			
3. Sink Faucets			
4. Floor in front of sink			
5. Bathtub faucets			
6. Floor in front of bathtub			
7. Bathtub			
8. Floor in front of toilet			
9. Toilet bowl (exterior)			
10. Toilet seat			
11. Shower curtain			
12. Floor in front of bathroom			
13. Patient's chair			
14. Floor in front of patient chair			
15. Visitor's Chair			
16. Window ledge near chair			
17. Food Table			
18. Remote control for TV			
19. Night table			
20. Pillow			
21. Mattress			
22. Floor in front of bed			
23. Doorknobs of bathroom door			
Contamination meter used (model, serial):			
Survey meter used (model, serial) :			
Comments:			

Conversion Bq versus CPS for public and controlled areas:
Note: Pancake probe nominal efficiency = 15 % for I-131 (beta radiation)

Public area : 450 cpm over BKG = 3 Bq/cm^2
Controlled area : 4 500 cpm over BKG = 30 Bq/cm^2

The treatment room has been decommissioned and can be reopened for general patient use.

Signature: _____ Date:_____

APPENDIX 12b:

I-131 Thyroid Treatment
(Out-Patients)

Outpatient I-131 Thyroid treatment

1.1. Iodine-131 radiopharmaceuticals at therapeutic levels above 1100 MBq (30 mCi) can be administered to patients on an outpatient basis in situations where:

i) a patient meet the criteria for outpatient therapy;

ii) patients have been informed of the radiation safety consideration;

iii) patient consents to the treatment mode and agrees to follow the radiation precautions as instructed;

iv) it is agreed by the Radiation Safety Officer (RSO), Nuclear Medicine Physician or designate that radiation exposure will not exceed 5 mSv to the caregiver and 1 mSv for members of the public (including family).

1.2. The criteria for outpatient therapy are indicated in Form A, and must be filled by the Nuclear Medicine physician or designate. The questionnaire determines if the patient can minimize exposure (direct and indirect) to the caregiver, family members and the public based on the ALARA principle. A mandatory item in Form A (item 10.) is the dose assessment result from Form B that must indicate a maximum dose of 5 mSv to caregiver and 1 mSv to pubic.

1.3 Form B is a dose assessment for caregivers and public members that must be filled and signed by the Radiation Safety Officer or designate.

The calculations are based on the US document NUREG-1556-rev.1, Vol.9, App.U, Eq.B-5.[1] However, we use a gamma constant for I-131 of = 7.65e-5 mSv/MBq @ 1m from ref. [2] which is ~30% greater than that of Ref.[1] (this yields to a higher dose estimate and a better safety criteria). The "I-131 dose calculator" (see Appendix) calculates the dose during travel and the dose at home separately using the same formula. Since the travel is assumed to take place during the first 8h, the occupancy factor after the first 8h E2(travel) is set to 0.

[1] : http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf
[2]: Handbook of Health Physics, 3rd Ed., B. Shlein, L.A. Slabak, B.K. Birky, W&W Ed., pp. 6-11, 1998.

1.4. Sample of dose calculations are given in Appendix for 2 scenarios.

- Example 1 assumes that the caregiver travels home for 2h (E1-travel=0.25; E2-travel=0) and sits at 1 meter distance from the patient inside the vehicle. At home, it assumes a 2h occupancy for the first 8h (E1-home = 0.25) and 6h/day afterward (E2-home = 0.25) also at 1 m distance. For an initial dosage Q0 <= 200 mCi administered to the patient, Example 1 indicates that the dose to the caregiver is less than 5 mSv (4.95 mSv).

- Example 2 assumes that a member of the public travels home for 1h (E1-travel=0.125; E2-travel=0) and sits at 1 meter distance from the patient inside the vehicle. At home, it assumes a 1h occupancy for the first 8h (E1-home = 0.125) and 3h/day afterward (E2-home = 0.125) at 2 m distance. For an initial dosage Q0 <= 200 mCi administered to the patient, Example 2 indicates that the dose to the public is less than 1 mSv (0.95 mSv).

1.5 In situations where the typical conditions of Example 1 and 2 are met (travel time, occupancy factors, distances), the simplified Form B can be used instead of the detailed form B to assess the maximum dose to the caregiver and the public.

1.6 Written instructions in Form C must be given to the patient before being released from the hospital. The patient should confirm that the instructions are well understood and commit to following them thoroughly.

1.7 In situations where the patient does not qualify for an outpatient treatment, the patient will be treated as an inpatient and confined to a room. The inpatient I-131 treatment protocol then applies.

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FORM A:
I-131 Therapy: Evaluation of Patient's Living Conditions

Patient Information:

ID:_____ Date:_____ Male____ Female____

Person Interviewed:

Patient ____ Spouse ____ Guardian ____ Other ___

Comments: _____

General Contact Information	YES	NO
1. Will someone be driving home with the patient from the hospital? If yes, indicate the travel time ____ (h) and distance from passenger ____ (m)		
2. After the patient arrives at home, will he be able to stay there for at least 3 days?		
3. Is there a bathroom that can be used exclusively by the patient for the first 3 days?		
4. Will the patient be able to sleep alone in a private room for the first 7 days?		
5. Can the patient minimize contact with children (< 12 y) and pregnant woman for the first 7 days?		
6. Can the patient keep the occupancy factor to less than 6h/day and a minimum distance of 1 m for caregivers for the first 7 days? If not, indicate time spent ____ (h/day) and distance from caregiver ___ (m)		
7. Can the patient keep the occupancy factor to less than 3h/day and a minimum distance of 2m for other persons for the first 7 days? If not, indicate time spent ___ (h/day) and distance from other person ___ (m)		
8. Is the patient continent?		
9. Is the patient capable of self-care?		
10. The dose estimates from Form B indicate a maximum dose of 5 mSv to caregiver and 1 mSv to member of the public.		

_____

_____

Based on the information collected and the dose assessment results, I am satisfied that the patient meets the criteria for outpatient therapy.

Nuclear Medicine Physician or designate : _____

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FORM B:
I-131 Therapy External Dose Assessment (Detailed)

A) Patient Information:

ID:_____ Date:_____ Male____ Female____

Dosage administered **Q0** = _____ mCi

B) Dose estimate to: Caregiver ____ ; Other person ____

C) Exposure during Travel home:

1. Will the person in B) travel home with the patient? Yes:___ ; No ___

2. If yes, what is the travel time in hours: _____
   (divide by 8 to obtain occupancy factor E1-travel)

3. Minimum distance between patient and caregiver or other persons in B) inside the vehicle: **D(m)** = _____

Use Q0 in A), travel time (h) and D (m) in the "dose calculator" to estimate the cumulative dose during travel home. Since the travel time is less than 8h, the occupancy factor E2 (after 8 h) is set to 0. Indicate the result in the box below:

D(travel) = _____ mSv

D) Exposure during Home stay:

4. What is the minimal distance between patient and the person in B) (default is 1 m for caregiver, 2 m for others): **D(m) = _____**

5. How many hours spent with the patient during the first 8h : _____
   (divide by 8 to obtain occupancy factor E1-home)

6. How many hours a day spent with the patient after the first 8h : _____
   (divide by 24 to obtain occupancy factor E2-home)

Use Q0 in A), occupation time for first 8 h and after first 8h and D (in 4., 5. and 6.) in the "dose calculator" to estimate the cumulative dose during the home stay. Indicate the result in the box below:

D(Home) = _____ mSv

E) Total Exposure

The total exposure D(Total) is the sum D(Travel) + D(Home) from the boxes above.

D(Total) = _____ mSv

F) Final dose assessment for conditional release of patient

The value D(Total) must be less than 5 mSv for caregivers and less than 1 mSv for others.

Is the radiation exposure condition for outpatient therapy satisfied ?

Yes _____ ; No _____

RSO or designate : _____

FORM B: I-131 Therapy External Dose Assessment (Simplified)

A) Patient Information:

ID:_____ Date:_____ Male____ Female____

B) Dosage to patient

1. Is the administered dosage less than or equal to 200 mCi :

Yes ___; No ____;

C) Radiation Exposure for the caregiver

2. Is the travel time between the hospital and the patient's home less than 2h for the caregiver (answer Yes if not applicable)?

Yes ___; No ____;

3. Can the occupancy factor be maintained to less than 2h for the caregiver for the first 8h at home?

Yes ____; No ____;

4. Can the occupancy factor be maintained to less than 6h/day for the caregiver after the first 8h at home?

Yes ____; No ____;

5. Can the minimal distance between the patient and the caregiver be maintained to 1 m during the first 7 days?

Yes ___; No ____;

<u>If answered Yes to Q.1 to 5., the total exposure to the caregiver is less than 5 mSv</u>.

D) Radiation Exposure Conditions at home for other persons

6. Is the travel time between the hospital and the patient's home less than 1h for the person traveling with the patient (answer Yes if not applicable)?

Yes ___; No ____;

7. Can the occupancy factor be maintained to less than 1h during the first 8h at home for other persons?

Yes ____; No ____;

8. Can the occupancy factor be maintained to less than 3h/day after the first 8h at home for other persons?

Yes ____; No ____;

9. Can the minimal distance between the patient and other persons be maintained to 2 m during the first 7 days?

Yes ___; No ____;

<u>If answered Yes to Q1 and to Q.6 to 9., the total exposure to a member of the public is less than 1 mSv</u>.

E) Final dose assessment for conditional release of patient

The value D(Total) must be less than 5 mSv for caregivers and less than 1 mSv for others.

Is the radiation exposure condition for outpatient therapy satisfied ?

Yes _____ ; No _____

RSO or designate : _____

Form C)

Instructions to patients suitable for I-131 outpatient therapy

1. When traveling home after treatment, preferably travel alone; if not, maintain as large a distance as possible between yourself and the driver.
2. If you feel nauseated, take Gravol (50 mg orally) up to 6 hours if needed for up to 2 days (consult physician).
3. To minimize exposure to others, keep distance to a maximum and exposure time to a minimum.
4. For the 72 hours (3 days) from the time you take the iodine 131 therapy pills, try to spend:
    - a maximum of 6hours per day at 1 m from caregiver;
    - a maximum of 3 hours per day at 2 m from other people;
5. Stay at your home for 3 days.
6. Drink plenty of liquids starting 90 minutes after dose administration for 3 days.
7. Reserve a bathroom for your personal use only for 3 days.
8. Take at least 1 shower or bath per day; wash hands frequently for 3 days.
9. Launder your clothes, bedclothes, towels, etc., separately for 3 days.
10. Stay away from work for 3 days.
11. Do not travel on public transit for 3 days.
12. For the next 3 days, use good hygiene habits. Wash your hands thoroughly after each toilet use. Males should sit when urinating, to avoid splashing. Flush the toilet twice after each use.
13. Thoroughly clean your bathroom prior to allowing anyone else to use your bathroom, on the fourth day following treatment.
14. Try to keep the time you spend in close contact (< 1 m) with others to a minimum (e.g., sleep alone) for 7 days.
15. Minimize time spent with pregnant women and children under 12 years for 7 days.
16. Wait before starting a pregnancy for 12 months (male or female).
17. For any medical emergencies, contact your referring physician or Nuclear Medicine.
18. In case of an important spill of body fluids (full emptying of bladder, vomiting, excessive bleeding) in the first 3 days after treatment, the care giver should use universal precautions to clean up:
    - Avoid direct contact with skin (use protective clothing and disposable gloves and shoe covers if available);
    - Clean up the spill using absorbent paper and place it in a plastic bag or flush in toilet;
    - Avoid spreading the contamination. Work from outside of the spill toward the center;
    - Wash hands thoroughly when cleanup is completed;
    - Wash clothing separately – use 2 wash and rinse cycle;

- Contact the Nuclear Medicine department or Radioprotection if non caregivers were contaminated during the spill and to determine if a follow up (thyroid screening) is necessary.

19. For radiation safety emergencies (between 8am-5pm), contact Radioprotection at (514) 934-1934 x43866 (Christian Janicki), x36484 (Malika Messaouli), or x44922 (Mohamed Lounis). Outside regular hours, contact RSO through MUHC locating at (514) 934-1934 x 53333.

Instructions pour les patients admissibles pour la thérapie à l'Iode-131 en externe

1. En voyageant à la maison après le traitement, voyagez de préférence seul; sinon, maintenez une distance aussi grande que possible entre vous et le chauffeur.

2. Si vous avez la nausée, prendre du Gravol (50 mg oralement) aux 6 heures si le besoin est pendant 2 jours (consultez le médecin).

3. Pour minimiser l'exposition à d'autres, gardez la distance à un maximum et le temps d'exposition à un minimum.

4. Pendant les premières 72 heures (3 jours) à partir du temps ou vous prenez le comprimé d'iode 131, essayez de passer:

   - un maximum de 6 heures par jour à 1 m du préposé aux soins (caregiver);

   - un maximum de 3 heures par jour à 2 m d'autres gens;

5. Restez à la maison pendant les 3 premiers jours.

6. Buvez beaucoup de liquides commençant 90 minutes après l'administration de la dose pendant les 3 premiers jours.

7. Réserver une salle de bains pour votre utilisation personnelle exclusivement pendant les 3 premiers jours.

8. Prendre au moins 1 douche ou bain par jour; lavez-vous les mains souvent pendant les 3 premiers jours.

9. Laver vos vêtements, literie, serviettes, etc., séparément pendant les 3 premiers jours.

10. Absentez-vous du travail pendant les 3 premiers jours.

11. Ne pas voyager par les transports en communs pendant les 3 premiers jours.

12. Pour les 3 prochains jours, utilisez de bonnes habitudes d'hygiène. Lavez bien vos mains après chaque utilisation de la toilette. Les hommes devraient s'asseoir en urinant pour éviter de faire des éclaboussures. Tirez la chasse d'eau deux fois après chaque utilisation.

13. Nettoyez bien votre salle de bains avant de permettre son utilisation à une autre personne le quatrième jour après le traitement.

14. Essayer de garder le temps que vous passez en contact proche (<1 m) avec d'autres à un minimum (par ex., dormez seuls) pendant les 7 premiers jours.

15. Minimiser le temps passé avec les femmes enceintes et les enfants moins de 12 ans pendant les 7 premiers jours.

16. Attendre 12 mois avant de provoquer ou d'amorcer une grossesse (homme ou femme).

17. Pour toute urgence médicale, contactez votre médecin ou la médecine nucléaire.

18. En cas d'un déversement accidentel important de liquides corporels (vidange complète de la vessie, vomissement, saignement excessif) durant les 3 premiers jours après le traitement, le préposé aux soins devrait utiliser des précautions universelles pour nettoyer:

    - Éviter le contact direct avec la peau (utilisez des vêtements protecteurs et des gants jetables et des couvres chaussures jetables);

    - Nettoyez le déversement accidentel en utilisant du papier absorbant et le placer dans un sac de plastique ou le jeter dans les toilettes;

    - Éviter d'étendre la contamination. Travailler de l'extérieur du déversement accidentel vers le centre;

    - Bien se laver les mains quand le nettoyage est terminé;

    - Laver les vêtements séparément – utiliser 2 cycles de lavage et de rinçage;

    - Contacter le département de Médecine Nucléaire ou de Radioprotection si des gens autre que le préposé aux soins ont été contaminés pendant le déversement accidentel afin de déterminer si un suivi (essaie thyroïdien) est nécessaire.

19. Pour les cas d'urgence de radioprotection (entre 8am-5pm), contactez Radioprotection (à 514) 934-1934 x43866 (Christian Janicki), x36484 (Malika Messaouli), ou x44922 (Mohamed Lounis). Les heures régulières extérieures, contactez le RSO du MUHC via Location au (514) 934-1934 x 53333.

Appendix A: Example of dose calculation using the "I-131 Therapy External Dose Calculator"

I-131 Therapy External Dose Calculator

Dose Model based on NUREG-1556-rev.1, Vol.9, 2005.*		Author: C. Janicki, RSO, MUHC, 2005.
Patient ID: _____		**Date: _____**
Comments: Dose to Caregiver travelling with patient		
Isotope :	I-131	
Half-life Tp:	8.02	days
Exposure rate constant Γ1**:	7.65E-05	mSv h-1 per MBq @ 1m
Input Parameters:		
Patient dosage Q0:	200	mCi
Travel time (hospital to home)	2	hours
Distance from patient in vehicle	1	meters
Time spent during first 8h (home)	2	hours
Time spent after first 8h (home)	6	hours/day
Distance from patient (home)	1	meters
Model Parameters (NUREG-1556):		
Assumed thyroid uptake F1	0.95	
Assumed thyroid uptake F2	0.05	
T1-eff	0.32	extrathyroidal half-life (days)
T2-eff	7.3	thyroidal half-life (days)
Occupancy factor E1 (travel)	0.25	
Occupancy factor E1 (home):	0.25	
Occupancy factor E2 (home):	0.25	
Results:		
Cumulated dose (Travel):	0.88 mSv	
Cumulated dose (home):	4.07 mSv	
Total dose (Travel + home)	**4.95 mSv**	

Note: Total dose must be < 5 mSv to caregivers, < 1 mSv to others.

*: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf

**: Handbook of Health Physics, 3rd Ed., B. Shlein, L.A. Slabak, B.K. Birky, W&W Ed., pp. 6-11, 1998.

Example 1: In this example, we assume a dosage Q0 = 200 mCi to the patient. We calculate the dose received by the caregiver for a 2h travel time (E1-travel = 0.25) at 1m distance from the patient in the vehicle. We also calculate the cumulated dose at home assuming 2h occupancy during the first 8h (E1-home = 0.25) and 6 hours/day (E2-home = 0.25) at 1 meter distance from the patient. Under these conditions, the maximum dose to the caregiver is 4.95 mSv from both contributions.

I-131 Therapy External Dose Calculator

Dose Model based on NUREG-1556-rev.1, Vol.9, 2005.*	Author: C. Janicki, RSO, MUHC, 2005.

Patient ID: _____ **Date:** _____

Comments: Dose to public members travelling and staying home with the patient

Isotope :	I-131	
Half-life Tp:	8.02	days
Exposure rate constant Γ1**:	7.65E-05	mSv h-1 per MBq @ 1m
Input Parameters:		
Patient dosage Q0:	200	mCi
Travel time (hospital to home)	1	hours
Distance from patient in vehicle	1	meters
Time spent during first 8h (home)	1	hours
Time spent after first 8h (home)	3	hours/day
Distance from patient (home)	2	meters
Model Parameters (NUREG-1556):		
Assumed thyroid uptake F1	0.95	
Assumed thyroid uptake F2	0.05	
T1-eff	0.32	extrathyroidal half-life (days)
T2-eff	7.3	thyroidal half-life (days)
Occupancy factor E1 (travel)	0.125	
Occupancy factor E1 (home):	0.125	
Occupancy factor E2 (home):	0.125	
Results:		
Cumulated dose (Travel):	0.44 mSv	
Cumulated dose (home):	0.51 mSv	
Total dose (Travel + home)	**0.95 mSv**	

Note: Total dose must be < 5 mSv to caregivers, < 1 mSv to others.

*: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf

**: Handbook of Health Physics, 3rd Ed., B. Shlein, L.A. Slabak, B.K. Birky, W&W Ed., pp. 6-11, 1998.

Example 2: In this example, we assume a dosage Q0 = 200 mCi to the patient. We calculate the dose received by the vehicle occupant (or driver) for a 1h travel time (E1-travel = 0.125) at 1m distance from the patient. We also calculate the cumulated dose at home assuming a 1h occupancy during the first 8h (E1-home = 0.125) and 3 hours/day (E2-home = 0.125) at 2 meters distance from the patient. Under these conditions, the maximum dose to a member of the public is 0.95 mSv coming from both contributions.

APPENDIX 12c:

P-32, Y-90 and Ra-223 protocols

P-32 Treatment of Polycythemia Vera

P-32 Treatment of Polycythemia Vera in Nuclear Medicine (General Information)

INDICATIONS: Therapy for thrombocytosis/ polycythemia vera.

EXAM TIME: 60 minutes for dose administration (if pregnancy test is needed it may take an additional one–two hours)

PATIENT PREPARATION:

Results of a recent CBC and platelet counts should be available.
The patient should not be involved in any protocols involving the administration of chemotherapeutic agents.

Before administering the therapeutic dose: inject 1 mCi Tc-99m pertechnetate IV, count the injection site and the contralateral arm with a gamma probe for 1 minute each to determine if the line is widely patent.
The patient will receive verbal and written information before signing the consent form.

RADIOPHARMACEUTICAL: P-32 sodium phosphate 2.3 mCi/m2 of body surface area not to exceed 5 mCi (185 MBq)

ROUTE OF ADMINISTRATION: IV in 250 ml sterile normal saline over 30 minutes via 18-20 gauge angiocath.

REFERENCES:
1) Chaudhuri TK. Role of P-32 in polycythemia vera and leukemia. In Therapy in Nuclear Medicine, RP Spencer, ed, Grune & Stratton, New York, 1978, pp 223-235.

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^{32}P phosphate treatment for Polycythaemia vera

Administration

The radiopharmaceutical is administered by a slow intravenous injection by one of the nuclear medicine physicians of the MUHC.

The catheter in place has to be tested to make sure that there is no chance of infiltration of the injection.

The activity generally used is either 74–111 MBq/m2 body surface (2–3 mCi/m2) with a maximum upper activity limit of 185 MBq (5 mCi).

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Traitement au ^{32}P phosphate pour polycythaemia vera

Instructions aux patients

- Il est recommandé d'éviter une grossesse pour au moins 4 mois suivant le traitement.
- Il y a excrétion dans l'urine pour **2 jours** après le traitement. Le patient doit respecter des règles d'hygiène strictes pour éviter de contaminer ceux qui utilisent la même toilette. Pour 2 jours vous devez faire partir la chasse d'eau 2 fois après chaque utilisation.

^{32}P phosphate treatment for polycythaemia vera

Instructions to patients

- Following treatment, patients should avoid pregnancy for at least 4 months.

- Excretion in urine is of particular concern during the first **2 days** post administration. Patients should be advised to observe rigorous hygiene in order to avoid contaminating others using the same toilet facility. For those 2 days flush the toilet twice after each use.

Pour information vous pouvez rejoindre le : (514) 934-1934 poste 34102
For information you can reach us at: (514) 934-1934 Ext: 34102

Y-90 Therasphere™

TheraSphere Treatment

This section describes the procedures to be performed on the day of treatment and patient after-care guidelines for patients in the TheraSphere treatment arm. In brief, patients will have laboratory blood work on the day of TheraSphere treatment, an arterial catheter will be placed and angiographic evaluation performed to guide catheter placement.
The day of randomization is Day 0 in the trial calendar for the purpose of calculating target dates for follow-up visits and the primary endpoint for the trial.

1 : Catheter Placement

The goals of percutaneous catheter placement for use in TheraSphere administration are to limit the distribution of TheraSphere to the target lobe, to confirm patient safety to receive TheraSphere treatment; and to deliver TheraSphere as specified in the treatment plan.
On the day of treatment, the patient will have a catheter placed percutaneously via the femoral or brachial artery under imaging guidance. The interventional radiologist performs this procedure. The patency of the catheter is maintained by an infusion of normal saline and a coagulation inhibitor (per institutional protocols) administered via a continuous infusion pump.

The catheter is accessed by a 3-way stopcock. Proper catheter positioning in the selected location in the hepatic artery will be verified by angiography before TheraSphere administration.

2 :Administration of TheraSphere

The TheraSphere administration procedure is described in the TheraSphere Package Insert (See Appendix 1).
Any technical problems or complications related to the delivery of TheraSphere treatment to the patient must be documented in the medical record. The details of any event and its impact on the planned treatment should be clearly described.

3 :Immediate Post-Treatment Care

Following TheraSphere treatment, the patient should remain under observation consistent with institutional standard of care guidelines for aftercare in procedures involving femoral or brachial artery catheterization.
Prior to discharge, patients should be instructed regarding after-care and provided with a 24-hour telephone number that they may use to contact the Site Investigator if they develop a problem or have questions about their treatment.
Any concomitant medication or therapy deemed necessary, including gastric prophylaxis, to provide adequate supportive care to the patient in the post-treatment period may be administered according to institutional standards of clinical care (see also best supportive care, above).

Package Insert

TheraSphere® Yttrium-90 Glass Microspheres

Description

TheraSphere consists of insoluble glass microspheres where yttrium-90 is an integral constituent of the glass [1]. The mean sphere diameter ranges from 20 to 30 µm. Each milligram contains between 22,000 and 73,000 microspheres. TheraSphere is supplied in 0.6 mL of sterile, pyrogen-free water contained in a 0.3 mL vee-bottom vial secured within a clear acrylic vial shield. TheraSphere is available in six dose sizes: 3 GBq (81 mCi), 5 GBq (135 mCi), 7 GBq (189 mCi), 10 GBq (270 mCi), 15 GBq (405 mCi) and 20 GBq (540 mCi).

A preassembled single use TheraSphere Administration Set and a TheraSphere Needle Guide Set are provided with each dose. A 20 cc syringe with a visible pressure reading capable to at least 30 psig and with two modes of operation (turning and pushing) should be used with the Administration Set. The TheraSphere Administration Accessory Kit is supplied to new user sites. The kit includes reusable items (i.e. shielding acrylic box, support stand, handling tools, and two RAD-60R radiation dosimeters).

Physical Characteristics

Yttrium-90, a pure beta emitter, decays to stable zirconium-90 with a physical half-life of 64.2 hours (2.67 days). The average energy of the beta emissions from yttrium-90 is 0.9367 MeV. To correct for the physical decay of yttrium-90, the fractions that remain at selected intervals from the time of calibration are shown in Table 1.

Table 1
Yttrium-90 Physical Decay Table
(half-life 64.2 hours)

Day 1 Hour	Fraction Remaining	Day 2 Hour	Fraction Remaining	Day 3 Hour	Fraction Remaining
-4	1.044	20	0.806	44	0.622
-2	1.022	22	0.789	46	0.609
0*	1.000	24	0.772	48	0.596
2	0.979	26	0.755	50	0.583
4	0.958	28	0.739	52	0.570
6	0.931	30	0.723	54	0.558
8	0.917	32	0.708	56	0.546

* Calibration Time

Clinical Pharmacology

Following embolization of the yttrium-90 glass microspheres in tumourous liver tissue, the beta radiation emitted provides a therapeutic effect [2-6]. The microspheres are delivered into the liver tumour through a catheter placed into the hepatic artery which supplies blood to the tumour. The microspheres, being unable to pass though the vasculature of the liver due to arteriolar capillary blockade, are trapped in the tumour and exert a local radiotherapeutic effect with some concurrent damage to surrounding liver tissue [7-14].

Indication

TheraSphere may be used in the treatment of hepatic neoplasia in patients who have appropriately positioned arterial catheters.

Contraindications

The use of TheraSphere is contraindicated in patients who demonstrate the potential for shunting of the radioactive microspheres to the lungs or gastrointestinal tract.

In some persons a fraction of the hepatic arterial blood supply bypasses the capillary bed and flows directly to the venous system. This may be associated with pathologic abnormalities of the liver. For such persons a certain fraction, F, of spheres injected into the hepatic artery will not be embolized in the liver but will flow to the heart and subsequently to the lungs. As the product of the bypass fraction, F, and the injected activity, A, increases, the potential for delivering a damaging dose of radiation to the lungs increases. Consequently, it is essential that F be measured before use of this product. This can be done by injecting a tracer dose of technetium-99m macroaggregated albumin (Tc-99m MAA) and observing with an Anger camera. The observed radiation from the lung field, divided by the total radiation observed by the camera is a direct measure of F. The product of F by A is then the activity which will go to the lungs [23]. Medical judgement is required to determine whether A-V shunting for a particular patient is so large as to contraindicate this therapy. Based on experience with other ionizing radiations and preclinical studies with TheraSphere, an upper limit of F x A of 370 MBq (10 mCi) is recommended with medical judgement required above that level.

Patients with definite flow of Tc-99m MAA to the stomach and duodenum are not candidates for treatment with TheraSphere. It is suggested that balloon catheterization techniques be employed to occlude the gastroduodenal artery and thus prevent the refluxing of microspheres into the gastric mucosa.

The use of TheraSphere is contraindicated in pregnancy.

Warnings

Radioactive products should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Adequate shielding and precautions for handling radioactive material must be maintained.

Since adequate studies have not been performed in animals to determine whether this product affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus, this product should not be administered to pregnant or nursing women unless it is considered that the benefits to be gained outweigh the potential hazards.

Ideally, the use of this product in women of childbearing capability should be performed during the first

few (approximately 10) days following the onset of menses.

Precautions

As in the use of any radioactive material, care should be taken to ensure minimum radiation exposure to the patient extraneous to the therapeutic objective and to ensure minimum radiation exposure to workers and others in contact with the patient.

Dose rate to personnel should be monitored during administration. Any spills or leaks must be cleaned up immediately and the area monitored for contamination at the end of the procedure.

The TheraSphere dose vial is supplied secured within a clear acrylic vial shield to limit radiation exposure to personnel. The dose rate at the vial shield surface is still high enough to require caution including the use of tongs and a lead shielded container when possible. The dose vial should always be stored in a shielded location away from personnel.

Adverse Reactions

Based on clinical and preclinical animal experience with TheraSphere and other yttrium-90 microspheres, certain adverse reactions have been identified [4-6, 15, 16, 17, 18]. The introduction of microspheres into the vasculature of the stomach, duodenum or other organs of the gastrointestinal tract can cause chronic pain, ulceration and bleeding. Microsphere shunting to the lungs can cause edema and fibrosis which may not be reversible. Extrahepatic shunting may be identified through the injection of Tc-99m MAA into the hepatic artery [19, 20]. Shunting to the gastrointestinal tract may be avoided by the use of balloon catherization or other angiographic techniques to block such flow [21]. The use of this product leads to irradiation of both tumorous and normal liver tissue. As a result, patients with diseases which compromise the functioning of the non-tumorus liver tissue or with very small lesions scattered throughout the liver may be at greater risk of liver function impairment. In some cases, transient fever has been reported following the administration of TheraSphere [4].

Dosage and Administration

Preliminary Patient Evaluation

Prior to the administration of TheraSphere, the patient should undergo hepatic arterial catheterization using balloon catheterization or other appropriate angiographic techniques to prevent extrahepatic shunting [21]. Following the placement of the hepatic catheter, 75 to 150 MBq (2 mCi to 4 mCi) of Tc-99m MAA is administered into the hepatic artery to determine the extent of A-V shunting to the lungs. If such flow is present and cannot be corrected using established angiographic techniques, the patient is disqualified from treatment. When the possibility of extrahepatic shunting has been evaluated and the patient deemed acceptable for treatment, TheraSphere may be administered.

Calculation of Dose

The recommended dose range to the liver is 80 Gy to 150 Gy (8,000 to 15,000 rad). The amount of radioactivity required to deliver the desired dose to the liver may be calculated using the following formula:

$$\text{Activity Required (GBq)} = \frac{[\text{Desired Dose (Gy)}][\text{Liver Mass (kg)}]}{50}$$

The liver volume and corresponding liver mass may be determined using CT or ultrasound scans.

Delivery of the desired activity is accomplished by first calculating the activity to be injected using the equation above and then using the Yttrium-90 Physical Decay Table (Table 1) to determine the appropriate time of injection.

Administration will be accomplished within the product's shelf life. At some point during this period, one of the six dose sizes will allow a patient with liver mass between 0.9 kg and 7.0 kg to be administered sufficient yttrium-90 activity to deliver up to 150 Gy (15,0000 rad).

Patient Catheterization

The following general guidelines are provided to facilitate the selection of the appropriate catheter for the administration of TheraSphere:

- A catheter with an internal diameter of ≥0.5 mm (0.020 inch) is required to deliver TheraSphere to the liver. Excessive resistance to flow in the administration system due to a smaller catheter diameter may cause microspheres to be retained in the blue stopcock of the TheraSphere Administration Set and in the catheter.

- Since the delivery of TheraSphere is dependent on blood flow through the hepatic vasculature distal to the catheter tip, it is important that the catheter does not occlude the vessel in which it is placed to effect delivery of TheraSphere.

- Maintain a syringe pressure of 10 – 15 psig for the duration of each flush (one flush is 20 cc as indicated on the barrel of the syringe). Flushing should be continued until optimal delivery of TheraSphere is achieved. A minimum flush of 60 cc is recommended. Radiation monitoring of the TheraSphere Administration Set and the catheter must be used to establish when optimal delivery has been achieved. Infusion pressure should not exceed 30 psig on any flush.

TheraSphere Administration Set and TheraSphere Administration Accessory Kit

The TheraSphere Administration Set (Table 2, Diagram 1 & 3) consists of one inlet set, one outlet set, one empty vial and a TheraSphere Needle Guide Set composed of two interlocking units: a positioning needle guide and a priming needle guide. The inlet set and outlet set are made up of preassembled sterile, apyrogenic components. The Needle Guide Set is sterilized. A 20 cc syringe with visible pressure reading, capable to at least 30 psig, with two modes of operation (turning and pushing) and a standard luer lock fitting, should be used with the TheraSphere Administration Set.

The TheraSphere Administration Accessory Kit (Table 3, Diagram 2) contains reusable accessories including an acrylic box (base and cover), stainless steel stand, two RAD-60R radiation dosimeters and handling tools including tweezers and a stopcock extension handle. The TheraSphere Administration Accessory Kit ensures optimal layout of the TheraSphere Administration Set and TheraSphere dose vial to facilitate monitoring of the infusion process and provides beta radiation shielding.

The inlet set is used to transfer fluid from the fluid source (1) to the TheraSphere dose vial. The fluid line (3), inlet line (6) and syringe (5) are joined together via a either a red stopcock or a blue stopcock marked with a red button ('red stopcock') (4). The red stopcock is used to switch between the fluid line and inlet line, so that fluid may be drawn into the syringe, then flushed through the inlet line and into the TheraSphere dose vial.

The piercing pin (2) at one end of the fluid line is used to connect the inlet set to the fluid source (1). The inlet needle (7) at the opposite end of the inlet line is used to connect the inlet set to the TheraSphere dose vial (8). The inlet needle is equipped with a check-valve to prevent microspheres from flowing back

into the inlet line. As a result, the inlet set will be free from radioactivity during a normal procedure.

The outlet set is used to connect the TheraSphere dose vial to the patient catheter. It consists of an outlet line (12) and a vent line (14) joined together via a blue stopcock (13). The patient catheter is connected to the free port on the blue stopcock. The blue stopcock is used to switch between the vent line and catheter, so that the lines are properly primed before TheraSphere is administered. The outlet needle (11) at one end of the outlet line is inserted into the TheraSphere dose vial. The filter vent assembly at the end of the vent line is used to connect the outlet set to the empty vial (15). The empty vial is used to safely collect fluid and any microspheres that may flush through during system priming. The filter vent assembly prevents pressure build-up in the empty vial and blocks any microspheres from escaping. The outlet set, including the empty vial, may contain radioactivity at the end of the administration procedure. For added safety, a lead pot (16) is used to hold the empty vial during the procedure.

Throughout the administration procedure, the TheraSphere dose vial (8) remains sealed within the clear acrylic vial shield (10) in which it was supplied. The removable plug at the top of the acrylic vial shield provides access to the septum of the TheraSphere dose vial. A Needle Guide Set composed of a positioning needle guide (18) and priming needle guide (17) are provided as part of the TheraSphere Administration Set to properly position the needles during the priming and administration procedure.

The TheraSphere Administration Accessory Kit is provided to position the TheraSphere Administration Set components for optimal infusion of TheraSphere. The blue stopcock is positioned on the support arm (23) which, when fully extended, sits over the patient to provide a gravity feed into the inlet luer fitting on the infusion catheter. The support arm is mounted on a two section acrylic box (20 & 25), which provides proper positioning of the TheraSphere dose vial relative to the blue stopcock. The box also provides a stable positioning for the empty vent vial (15) and its lead pot (16), as well as the TheraSphere dose vial. The empty vial is placed in the lead pot to provide additional shielding from radiation in the event that a significant quantity of TheraSphere is inadvertently flushed into the empty vial. The acrylic box also provides beta radiation shielding during the infusion process.

The acrylic box is mounted onto a stainless steel stand (24) which should be placed on a sturdy cart or table that is positioned beside the patient, close to the infusion catheter inlet luer fitting.

The stainless steel stand incorporates several features. The hook (31) suspends the fluid source. The stopcock holder (28) positions the red stopcock and the syringe holder (30) for the syringe. This holder stabilizes the syringe to facilitate a more consistent infusion pressure while pressing on the syringe handle. The holder has been designed to accommodate a Merit Monarch series syringe.

Use of a syringe with visible pressure reading, capable to at least 30 psig, with two modes of operation (turning and pushing) and standard luer lock fitting, allows the user to control the rate of fluid flow during the infusion process by providing a pressure readout. With the plunger in the ‘turning’ position, the user may employ a turning motion to the plunger. This position allows for controlled release of fluid to minimize the potential for inadvertently flushing microspheres into the vent line and empty vial. With the plunger in the ‘pushing’ position, the user may employ a pushing motion. This position is used when infusing the TheraSphere dose.

The TheraSphere Administration Accessory Kit also contains two Rad-60R radiation dosimeters (19 & 21). These dosimeters are set to read dose rate, and are placed at two locations on the acrylic box. The first is placed behind the TheraSphere dose vial. The ratio of the reading taken on the TheraSphere dose vial prior to administration to the reading taken when the infusion is complete provides a measurement of the residual radioactivity left in the TheraSphere dose vial. The second dosimeter is placed on the support arm, near the blue stopcock. In this position, it provides an indication of the quantity of TheraSphere remaining in the inlet luer fitting to the catheter and blue stopcock.

In order to minimize the potential of a high radiation hand dose, two remote handling tools, a stopcock extension handle (26) and tweezers (27) have been provided as part of the TheraSphere Administration Accessory Kit. The stopcock extension handle allows the user to operate the blue stopcock in a safe manner. The tweezers allow safe insertion of the needles into the septum and adjustment of the needles after the priming step is complete.

Administration Instructions

The entire contents of the TheraSphere dose vial are administered to the patient.

The directions for administration should be followed to ensure accurate delivery of the calculated dose. Approximately 96% of the radioactivity in the TheraSphere dose vial will be delivered to the patient using the recommended technique.

Preparation of TheraSphere Dose Vial (Table 4, Diagram 2 & 3)

1. The acrylic box cover base (25) is placed on the stainless steel stand (24). The radiation dosimeters are turned 'ON', set to 'dose rate - mR/h', and then secured in the respective dosimeter holders located on the acrylic box. One radiation dosimeter is clipped to the bracket behind the TheraSphere dose vial and the other is clipped inside the bracket on the support arm.

2. The tamper-evident seal is removed from the top of the acrylic vial shield (10) exposing the acrylic plug. The acrylic plug is removed by inverting the vial shield while adhering to appropriate radiation safety procedures. Alternately, the plug is removed by placing surgical tape onto the plug and lifting upward.

3. When the acrylic plug has been removed, the septum of the TheraSphere dose vial (8) is swabbed with disinfectant, using a handling tool such as tweezers. The positioning needle guide (18) and the priming needle guide (17) are placed in the acrylic vial shield opening as illustrated in Diagram 3, using a remote handling device such as tweezers. The two needle guides will position the inlet and outlet needles during the priming and infusion of TheraSphere in addition to providing radiation shielding. The acrylic vial shield in the shipping lead pot is placed into the appropriate bottom ring of the acrylic box base (25). The support arm is extended fully at this point if it is not already in that position. After a stabilization period of approximately one-minute, the initial readings of the radiation dosimeters are taken and documented.

Assembly of Dose Vial Inlet Set (Table 4, Diagrams 1 & 2)

NOTE: Leakage of fluid may occur if the fittings are not tightly secured.

4. The fluid line (3) is connected to the fluid source (1) by inserting the white piercing pin (2) into the fluid source. The hook (31) provided with the TheraSphere Administration Accessory Kit may be used to suspend the fluid source.

5. The syringe (5) is connected to the free port on the red stopcock (4). Note that the red stopcock may actually be a blue stopcock with a red button. The red stopcock is placed into the stopcock holder (28) on the side of the stainless steel stand (Diagram 2).

6. The red stopcock is turned to open the fluid line (i.e. tab pointing to inlet line).

7. When applicable, the syringe pressure display is turned 'ON' and is set to read in psig following the instructions provided with the syringe. The syringe is filled from the fluid source. Air is

expelled by pushing on the syringe plunger while the syringe outlet is pointing upwards until all of the air is displaced into the fluid source (1). The syringe is filled with approximately 20 cc of fluid. The syringe can then be placed into the syringe holder (30) located on the side of the stainless steel stand (Diagram 2).

NOTE: The syringe is intended to be used in the turning mode during priming steps (Step 18) to control the fluid flow and to minimize turbulence in the system. During all other operations, the syringe is operated in the push-pull mode as opposed to the rotating mode. Refer to the operating instructions provided with the syringe for more information.

8. The syringe can be secured into the syringe holder (30) with the clevis pin (29). Mounting the syringe in this fashion facilitates application of sufficient force on the syringe handle during infusion.

9. The red stopcock is turned to the inlet line (i.e. tab pointing to fluid line). Ensure that the inlet needle fitting is tight. Remove the cover from the inlet needle (7). Prime the inlet line.

10. Using tweezers (27), the inlet needle (7) is carefully inserted through the priming (17) and positioning (18) needle guides and through the TheraSphere dose vial septum. The needle is pushed downwards until the needle hub touches the needle guide.

Assembly of Outlet Set (Tables 4 & 5, Diagrams 1 & 2)

11. The flip-off seal is removed from the empty vial (15).

12. The filter vent assembly on the end of the vent line (14) is inserted through the septum of the empty vial (15).

13. The empty vial (15) is placed in the lead pot (16), then placed into the appropriate location in the acrylic box (25).

14. Ensure that the outlet needle fitting is tight. Using tweezers (27), the outlet needle (11) at the opposite end of the outlet line (12) is carefully inserted through the priming needle guide (17) and the positioning needle guide (18) into the TheraSphere dose vial septum and pushed down until the needle hub touches the needle guide. The priming needle guide positions the needle just below the septum at the appropriate height for priming the TheraSphere dose vial.

15. The acrylic box cover (20) is placed on the box to provide additional beta radiation shielding.

System Priming

16. The blue stopcock is placed into the stopcock holder (22) on the support arm (23). This position ensures optimal transfer of microspheres through the outlet line and catheter. The blue stopcock is turned to the vent line (i.e. tab pointing to catheter).

17. The red stopcock is turned to the inlet line (i.e. tab pointing to fluid line).

18. Using the turning mode of operation for the syringe, fluid from the syringe is slowly injected through the inlet line, into the TheraSphere dose vial until fluid is just visible above the outlet needle (11). A low flow is achieved by slowly turning the syringe handle clockwise with the threads engaged. Allow at least 30 seconds to ensure the microspheres are settled to the bottom of the TheraSphere dose vial. Continue priming the outlet and vent lines until the air is expelled from the system and fluid has just entered the blue stopcock. Using a sterile instrument, the

priming needle guide is removed by tipping it back out of the way, pushing horizontally near the top edge of the guide. The needles are then pushed into the TheraSphere dose vial until they touch the positioning needle guide. It may be necessary to temporarily remove the top of the acrylic box for part of steps 18 and 19.

19. The catheter is connected to the outlet luer fitting of the blue stopcock, taking care to ensure that the fitting is tight.

TheraSphere Administration

20. The blue stopcock is opened to the catheter (i.e. tab to the vent line).

21. After verifying that both stopcocks are correctly positioned, the administration of TheraSphere may proceed. The fluid in the syringe is expelled continuously (using the push mode of operation for the syringe) to carry the microspheres out of the TheraSphere dose vial, through the outlet line, and into the catheter. The flow rate required for efficient transport of the microspheres has been found to vary according to catheter characteristics. Maintaining the recommended pressure range will facilitate control of the flow rate. Refer to the "Patient Catheterization" section for administration guidance.

22. The red stopcock is switched to the fluid line and the syringe is refilled from the fluid source.

23. The red stopcock is turned back to the inlet line and flush fluid is administered as in step 21. Steps 21 and 22 are repeated until the optimal delivery of TheraSphere is attained. Additional flushing is required if the readings observed during radiation monitoring indicate that the microspheres have not been adequately transferred to the patient.

    NOTE: When the TheraSphere dose vial is empty, the dosimeter (19) at the TheraSphere dose vial should have a reading that is less than or equal to 1% of the initial reading to confirm transfer of microspheres. The dosimeter (21) near the blue stopcock may indicate that microspheres have been caught in the fittings of the blue stopcock or catheter. In general, the dosimeter near the blue stopcock should show an increased reading during TheraSphere administration, returning to a reading that is approximately two times the initial reading after line flushing. This dosimeter may also detect a radiation field emanating from the patient. A beta specific radiation survey instrument should be used to monitor the outlet line (including the exposed catheter) and fittings for trapped microspheres. As the microspheres move through the TheraSphere Administration Set, they may become caught in the catheter inlet luer fitting. If this occurs, additional flushing and gentle tapping may be used to dislodge the microspheres.

Disassembly

24. The blue stopcock is opened to the vent line (i.e. tab pointed to catheter).

25. The catheter is withdrawn from the patient. A high radiation field may be present near the catheter and the outlet line fittings. Appropriate radiation protection measures must be taken.

26. The TheraSphere dose vial and the TheraSphere Administration Set (including the catheter but excluding the syringe and the fluid source) should be stored for decay or disposed of as radioactive waste. Care should be taken to maintain connections and system integrity to avoid potential radioactive contamination.

27. Appropriate radiation protection measures must be employed to remove draping materials. The room, equipment and personnel must be monitored for any potential radioactive contamination.

Radiation Dosimetry

The yttrium-90 in TheraSphere is a constituent of an insoluble matrix thereby limiting irradiation to the immediate vicinity of the microspheres. The average range of the radiation in tissue is 2.5 mm. One GBq (27 mCi) of yttrium-90 per kg of tissue gives an initial radiation dose of 13 Gy (1,297 rad) per day. The mean life of yttrium-90 is 3.85 days; thus, the radiation dose delivered by yttrium-90 over complete radioactive decay starting at an activity level of 1 GBq (27 mCi) per kg is 50 Gy (5,000 rad).

How Supplied

TheraSphere is available in six dose sizes: 3 GBq (81 mCi), 5 GBq (135 mCi), 7 GBq (189 mCi), 10 GBq (270 mCi), 15 GBq (405 mCi) and 20 GBq (540 mCi). The dose is supplied in 0.6 mL of sterile, pyrogen-free water in a vee-bottom vial sealed within a clear acrylic vial shield.

Each TheraSphere dose vial is supplied with all the components required for administration, exclusive of items used in catheterization and the syringe. A preassembled single use Administration Set and a Needle Guide Set are provided with each dose. A syringe with visible pressure reading, capable to at least 30 psig, with two modes of operation (turning and pushing), and a standard luer lock fitting, should be used with the TheraSphere Administration Set. Each new user site is provided with a TheraSphere Administration Accessory Kit containing reusable components. The kit includes a two-part acrylic box, support stand, handling tools and two RAD-60R radiation dosimeters.

Handling and Storage

Each TheraSphere dose vial contains one of six available dose sizes of yttrium-90, a high-energy beta emitter. Even with low-density materials such as the acrylic vial shield, the attenuation of beta particles gives rise to Brehmsstrahlung radiation which requires lead shielding. Users should avoid exposure by leaving the vial in the acrylic product container, and by leaving the acrylic container in the lead shield as much as possible. The use of additional shielding is recommended. Finger-ring dosimeters should be worn in the orientation most likely to record the highest exposure to the fingers.

The TheraSphere dose vial should not be removed from its acrylic vial shield. It should be stored in the lead pot and acrylic shield in which it is packaged. The TheraSphere dose vial, TheraSphere Administration Set, TheraSphere Needle Guide Set and TheraSphere Administration Accessory Kit should be stored at room temperature. The requirements of the applicable regulatory agency for safe handling and storage of radioactive materials should be consulted and must be followed.

Distribution

TheraSphere is manufactured and distributed by MDS Nordion:

MDS Nordion
447 March Road
Ottawa, ON
Canada K2K 1X8
www.therasphere.com

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Table 2
TheraSphere Administration Set Configuration

Drawing Number	Item
1	Fluid Source or Flush Fluid (Supplied by Physician)
2	Piercing Pin
3	Fluid Line
4	Red Stopcock
5	Syringe with visible pressure reading, capable to at least 30 psig, two modes of operation, and a standard luer lock fitting (Merit Monarch™ 30 illustrated). (not part of TheraSphere Administration Set; supplied by physician)
6	Inlet Line
7	Inlet Needle (with Check Valve)
8	TheraSphere Dose Vial
9	Lead Pot (Dose Vial)
10	Acrylic Vial Shield
11	Outlet Needle
12	Outlet Line
13	Blue Stopcock
14	Vent Line
15	Empty Vial
16	Lead Pot
17	Needle Guide Set: Priming Needle Guide
18	Needle Guide Set: Positioning Needle Guide

Note: Inlet set is comprised of numbers 1-7. Outlet set is comprised of numbers 11-14.

Table 3
TheraSphere Administration Accessory Kit

Drawing Number	Item
19	Dosimeter RAD-60R
20	Acrylic Box: Cover
21	Dosimeter RAD-60R
22	Stopcock Holder (Blue Stopcock)
23	Support Arm
24	Stainless Steel Stand
25	Acrylic Box: Base
26	Stopcock Extension Handle
27	Tweezers
28	Stopcock Holder (Red Stopcock)
29	Clevis Pin
30	Syringe Holder
31	Hook

Diagram 1
TheraSphere Administration Set)

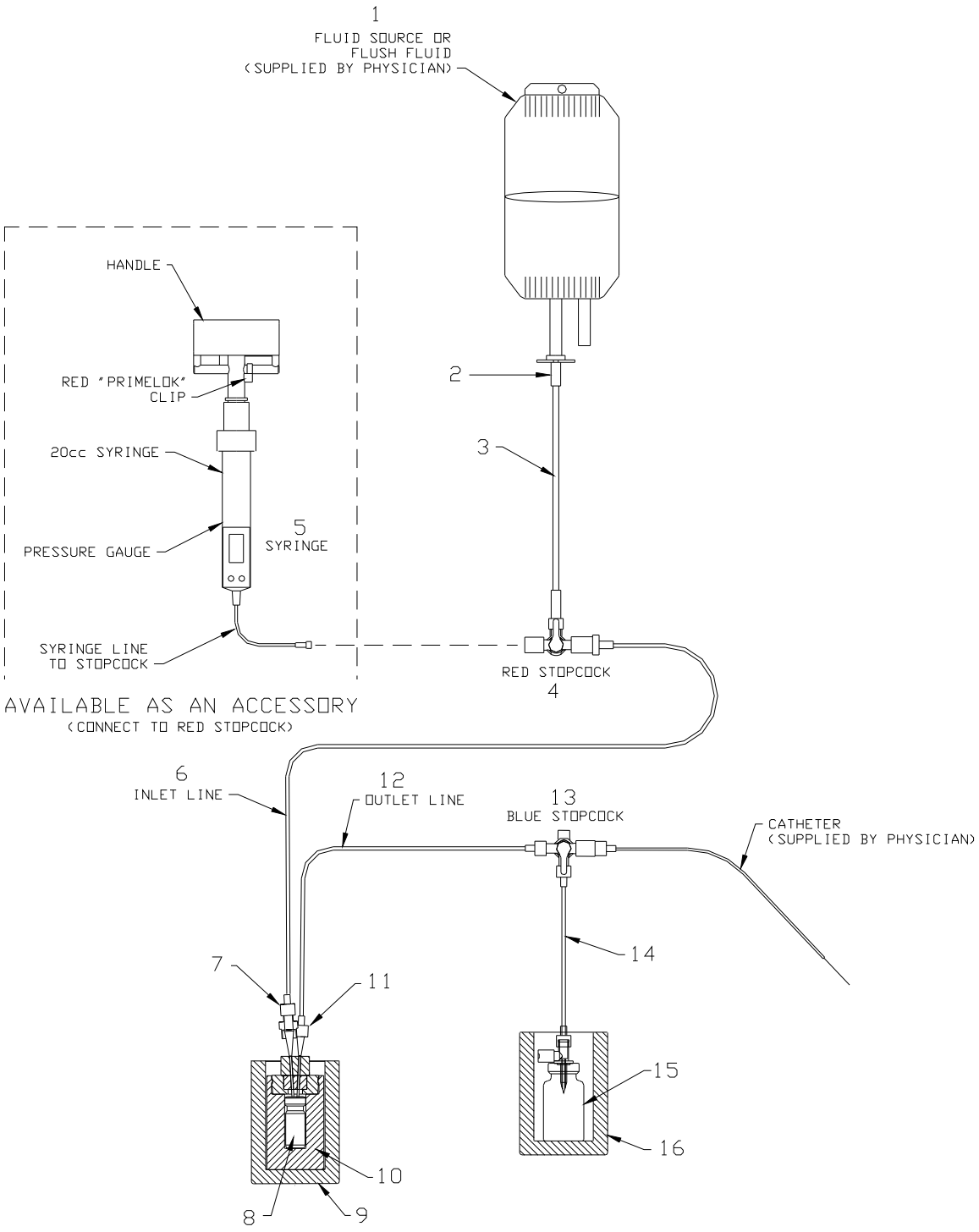


Diagram 2
TheraSphere Administration Accessory Kit
(shown assembled with the TheraSphere Administration Set)

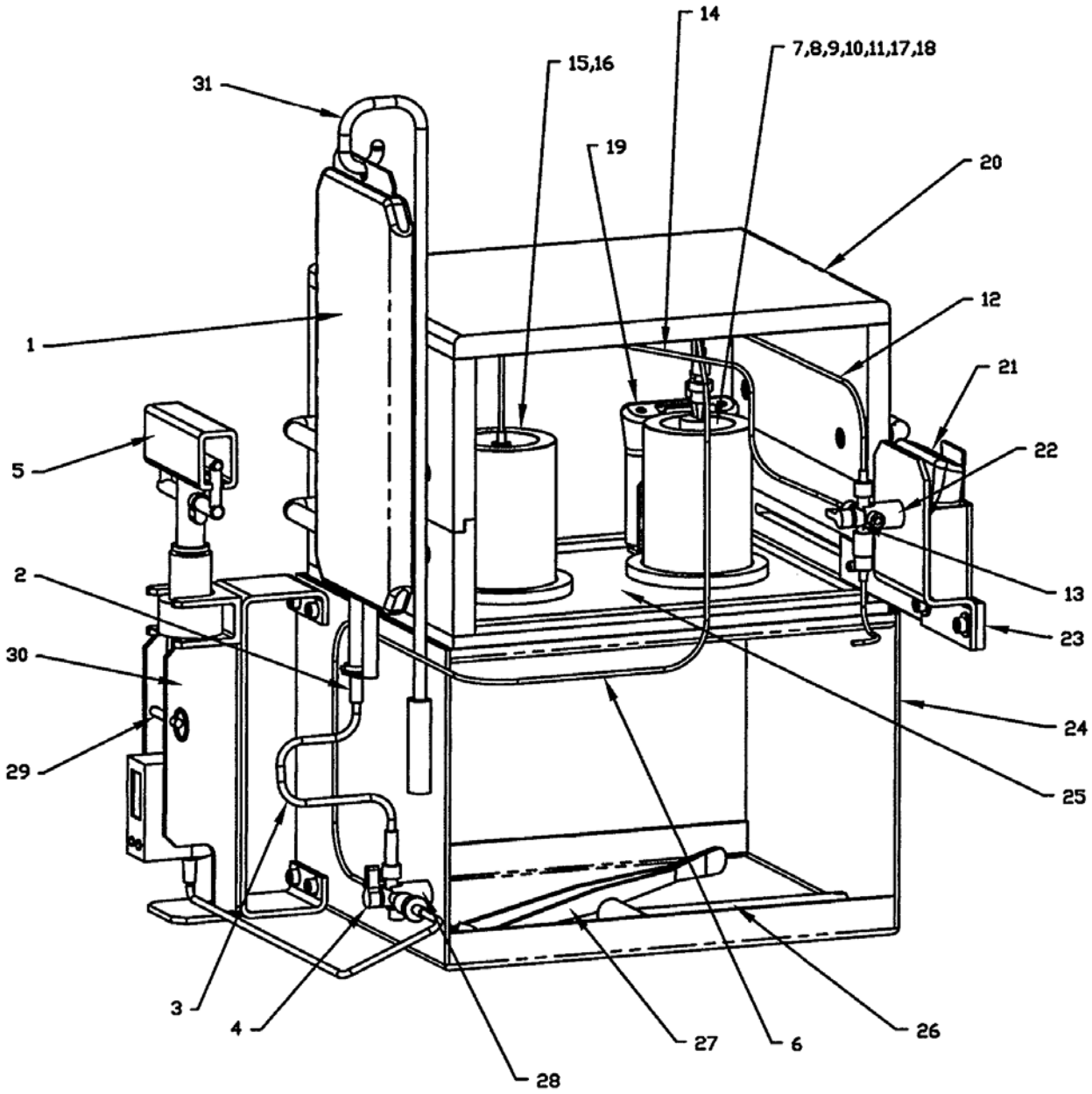
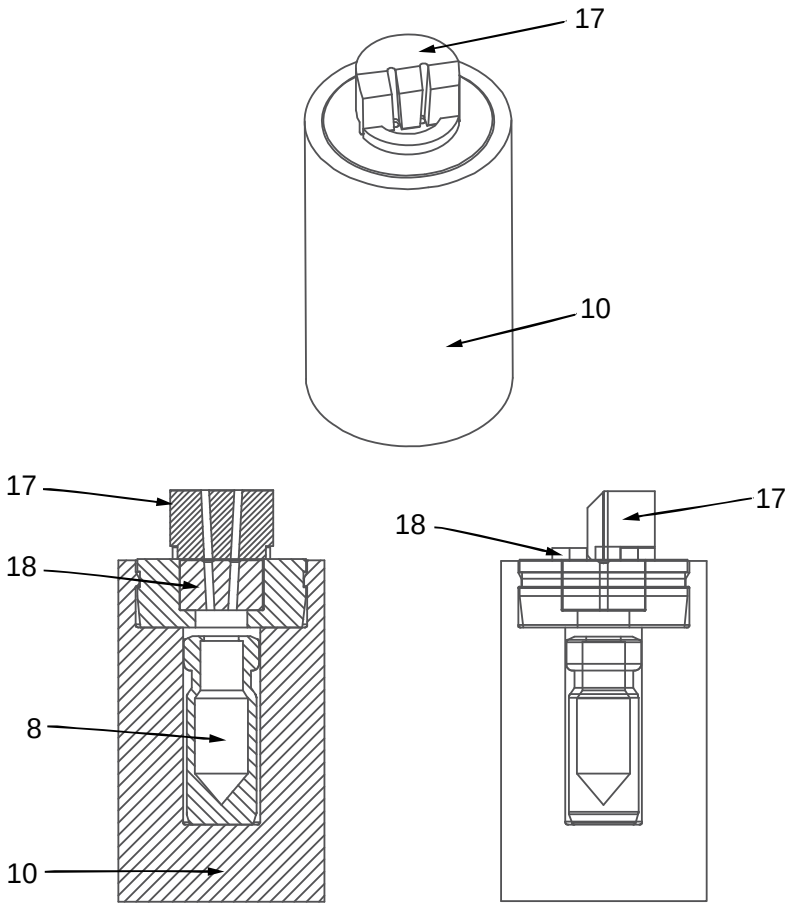


Diagram 3
Positioning Needle Guide and Priming Needle Guide Cross Sectional Views



TheraSphere Checklist

Patient Name _____ ***Number*** _____

Date of Treatment _____

TheraSphere Lot Number _____ ***Labeled Quantity (GBq)*** _____

Catheter Information:
(Place catheter sticker in the space provided below)

1. *Materials Required for TheraSphere Administration:*

- ☐ Signed Written Directive Form (patient prescription for TheraSphere)

- ☐ Ionization Survey Meter
- ☐ GM Contamination Meter
- ☐ Spill Kit
- ☐ Drape for floor – apply under cart in angiography suite

- ☐ Place a sterile drape on the cart.
- ☐ Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***
☐ Hemostat	☐ TheraSphere Acrylic Box → remove top shield and fully extend stainless steel arm.
☐ Scissors	☐ Bag hook → install on acrylic box.
☐ Steri-strips	☐ Saline Bag → hang on hook.
☐ Towels	☐ Electronic dosimeter (RADOS RAD 60R or equivalent) → turn on, set to **mR/h**, clip to bracket on acrylic box.
☐ Gauze	☐ 2L Nalgene waste container with Beta Shield → remove lids.
☐ Administration Set → open and remove from the sterile blister pack. (includes 20 mL syringe, 20 mL vial)	☐ TheraSphere Dose Vial (in lead pot) → Gently rock the lead pot back and forth to wet any microspheres on the vial septum. Place lead pot inside acrylic box holder.
	☐ Alcohol Swabs

TheraSphere Checklist

2. *Administration Set Priming*

- ❑ Insert the non-vented white piercing spike (CLEAR CAP) into the saline bag.
- ❑ Insert the white vented spike (BLUE CAP) into the empty 20mL vial and place the empty 20 mL vial in holder on the acrylic box and push the relief valve tube into gripper clip 'A'.
- ❑ Remove the (RED RUBBER) shield cap from the Needle Injector Assembly and place the Needle Injector Assembly on a sterile towel.
- ❑ Turn syringe plunger fully clockwise to ensure it is unlocked.
- ❑ Slowly fill and discharge the syringe to remove air from the Administration Set tubing and syringe. Continue priming until there are no bubbles in the lines and there are continuous streams of saline flowing out of both needle holes in the Needle Injector Assembly. Fill the syringe when priming is complete.

3. *Dose Vial Preparation*

- ❑ Remove the lead pot lid and place it upside down on a non-sterile surface.
- ❑ Use a hemostat to remove the purple seal from the top of the dose vial acrylic shield. Discard the seal in the Nalgene waste container.
- ❑ Use a Steri-strip to remove the acrylic shield plug. Discard the plug and Steri-strip in the Nalgene waste container.
- ❑ Use an alcohol swab and a hemostat to disinfect the dose vial septum. Discard the swab in the Nalgene waste container.

4. *Final Assembly*

- ❑ Close the pinch clamp on outlet tubing near label 'E'.
- ❑ Hold the Needle Injector Assembly and place inlet line through slot 'B' in the acrylic box, and outlet line through slot 'D'.
- ❑ Insert the Needle Injector Assembly into the acrylic dose vial shield. Press on the GREEN cap to lock in place. **You will hear or feel a click or snap.**
- ❑ Loop tubing around the side and slide connection firmly into slot 'C'.
- ❑ Push the YELLOW tabs all the way down, locking the needles into the dose vial. **You will hear or feel a click or snap at the bottom of travel.**
- ❑ Place the top shield on the acrylic box with the sloped shield towards the catheter. Ensure tubing is not pinched or kinked.
- ❑ Record the dosimeter initial reading:

Dose Vial (mR/h)

- ❑ Measure and record the initial radiation field for the patient, using an ionization survey meter.

_____

- ❑ Move the cart close to patient. Lower the bed to lowest position.

TheraSphere Checklist

- ❑ Place a sterile towel under the extension arm holder 'E'.
- ❑ Place a sterile towel across the gap between the acrylic box and the patient.
- ❑ Interventional Radiologist (IR) flushes catheter to ensure flow. Inspect the visible portion of the catheter for kinks or damage. Replace the catheter if it is damaged or does not have satisfactory flow.
- ❑ Disconnect the outlet line labeled 'E' from the priming line at holder 'C'. Firmly connect the outlet line 'E' to the catheter.

ATTENTION: DO NOT USE A CATHETER EXTENSION OR EXTRA FITTINGS. REPLACE A CATHETER WHICH IS TOO SHORT.

- ❑ Place the catheter connection into the slotted holder 'E' at end of extended arm. Outlet line 'E' will be above the holder, and the catheter hanging vertically below.
- ❑ IR to verify catheter position.
- ❑ **Release the pinch clamp from the outlet line.**

5. *TheraSphere Administration*

ATTENTION: BETA RADIATION FIELDS CAN BE VERY HIGH DURING MICROSPHERE TRANSFER. STAND BEHIND BETA SHIELDING OR MAINTAIN DISTANCE.

- ❑ Record starting time of the administration: _____
- ❑ Infuse TheraSphere Y-90 glass microspheres using steady pressure on the syringe plunger. Infuse continuously until syringe is empty (20 mL).

  NOTE: If the pressure applied to the syringe is over 30 psi, excess fluid will drip into the vented empty vial. If this occurs, reduce the pressure being applied on syringe until no flow is seen going into the vented vial.

- ❑ Observe the outlet line and catheter for proper operation. If a problem is observed, inform team and take corrective action.
- ❑ Re-fill syringe for subsequent flushes by pulling back the syringe plunger.
- ❑ Minimum 3 flushes are recommended. Continue flushes until desired dosimeter reading is achieved.

- ❑ Record the number of flushes completed: _____
- ❑ Record the time treatment was completed: _____
- ❑ Record the dosimeter final reading:

Dose Vial (mR/h)

- ❑ Measure and record the final radiation field for the patient using an ionization survey meter.

_____

TheraSphere Checklist

6. *Disassembly*

- ☐ Cut the inlet line at indicated position.
- ☐ Remove the acrylic box top shield and side shield.
- ☐ Lift the catheter connection out of the extended holder 'E'.
  Do not disconnect the catheter from the outlet line.
- ☐ IR to pull the catheter tip inside the guide catheter, then remove both together from the patient. Use gauze or a small towel to handle the catheters and control the tip.
- ☐ Place contaminated waste into the Nalgene waste container (in its beta shield):
  - catheters and attached tubing and towels/gauze
  - dose vial with attached Needle Injector Assembly (lift lead pot and dump out dose vial)
  - contaminated items - gauze, towels and IR's outer gloves.
- ☐ Use a GM contamination meter to check IR's hands for contamination.
- ☐ Survey all staff leaving the room with the GM contamination meter.

7. *Cleanup and Waste Disposal*

- ☐ Use GM contamination meter to check for contamination on the cart, lead pot, equipment, and the areas under the catheter connection and cart.

  NOTE: Radiation from fluoroscopy, the patient, and the waste container will affect the ability to detect and measure contamination.

- ☐ Decontaminate or dispose of items (tubing, lead pot, etc.) as appropriate.
- ☐ Seal the cap of the Nalgene waste container and place the lid on the beta shield. Remove for measurements to determine % delivery and for disposal.
- ☐ (As required) Clean the TheraSphere acrylic box with mild soap, water and a clean soft cloth. In case of blood contamination, alcohol wipes may be used minimally (alcohol may degrade the acrylic adhesive after extended time). Do not use cleaner wipes, ammonia (do not use Windex) or abrasives to clean the acrylic parts of the Accessory Kit.
- ☐ Place top and side shields back on acrylic box. Retract the extension arm and remove the bag hook. Turn off the dosimeter. Store the kit.

Notes and Comments:

Centre universitaire de santé McGill
McGill University Health Centre

Date_____

To: Mr(s). _____ RVH #_____

Address:_____
_____
_____

From : Dr. Robert Lisbona, Director, Medical Imaging (MUHC)
Dr. David Valenti, Radiologist

Re: Agreement Concerning Therasphere Treatment at the MUHC

Dear Mrs. _____,

Your treating physician has referred you to the Departments of Radiology and Nuclear Medicine to offer you to be treated with a new therapeutic modality with which we are very familiar, as some of the research work to prove its efficacy has been and still is carried out at this institution. The clinical results are such that it is not anymore considered to be an experimental approach, and therefore is not covered anymore, in a case like yours, by research funding. We wish to inform you about the procedure so that you can give a well-informed consent to the clinical procedure, and also to make you aware of the interim financial constraints that exist and have you explicitly agree to the proposed administrative procedure.

What is Therasphere treatment?

Therasphere treatment is used in the treatment of liver cancer. It is used for cancers that have started in the liver, and also for cancers that have spread to the liver. For cancers that start elsewhere, for example in the intestines, and spread to the liver, it is usually given after several treatments with chemotherapy. For cancers starting in the liver it may be the first treatment for the disease.
The treatment works by injecting very small radio-active beads into the blood vessels that feed the tumours. The type of radiation is very localized, so it does very little damage to normal surrounding tissues, but can cause significant damage to the cancer cells.
In Canada Therasphere is approved for the treatment of liver cancer.

What steps are involved? How is it given?

In order to undergo the treatment it is necessary to first complete some other tests to determine whether it can be done safely and to calculate the dose. The safety test

involves an angiogram and a shunt study. The angiogram is a test where a small tube is placed in the blood vessel feeding the liver and a map is made of all vessels in and around the liver. Sometimes a blood vessel needs to be blocked with a small device called a coil, in order to be sure that the treatment goes only to the liver and not to other organs. The shunt study is to determine whether the treatment dose will stay in the liver or travel through the liver to the lung. If too much dose goes to the lung then the treatment may be cancelled, because the lung would be at risk of radiation damage.

Is it covered by Medicare?

Most of the costs of this procedure are covered by the hospital. This includes all the tests, angiograms, and CT scans. The only item the hospital cannot pay at this time is the medication itself. The MUHC has not yet been able to secure funding from the government for this medication, which would make it available to all patients covered by Medicare. Rather than not offer the treatment at all, we have created a mechanism whereby the patient has the option to pay for the medication only. This is a much more attractive option than travelling to another country where the patient would have to pay for the medication and all the other costs associated with it. In the US a typical treatment would be between $80,000 and $150,000. The medication in Canada has a retail price of $15,000 per treatment and most patients need 2 treatments.

The only way the MUHC can offer patients this treatment at this time is for the patient to pay for the medication. Some insurance companies may reimburse all or part of the fee.

To proceed with the treatment the hospital will need payment prior to the treatment being provided.

I hereby confirm that I have read the above and agree with the conditions listed.

NAME OF PATIENT: _____

PATIENT SIGNATURE: _____

DATE: _____

NAME OF WITNESS: _____

SIGNATURE OF WITNESS: _____

DATE: _____

Montréal, le

À : Patient

De : Dr Robert Lisbona, directeur, Imagerie médicale (CUSM)
Dr David Valenti, radiologiste

Objet: Consentement éclairé relatif au traitement TheraSphere au CUSM

Madame, Mademoiselle, Monsieur,

Votre médecin traitant vous a dirigé vers notre Département de radiologie et de médecine nucléaire pour fins thérapeutiques. En effet, nous pouvons vous offrir un traitement innovateur, dont les mécanismes d'actions et les modalités d'administration nous sont très connus et très familiers, compte tenu des travaux de recherche que nous avons menés et que nous poursuivons dans notre établissement quant à l'efficacité de ce traitement. Or, les résultats cliniques obtenus sont tels, que ce traitement n'est plus considéré comme approche expérimentale et n'est donc plus couvert, dans un cas comme le vôtre, par le financement de la recherche. Par contre, nous tenons à vous apporter de plus amples informations sur cette intervention thérapeutique afin que vous puissiez y consentir ou y refuser, et cela, de façon libre et éclairée. Nous tenons également à vous mettre au courant des restrictions financières accessoires qui existent afin que vous nous donniez, également et explicitement, votre accord relativement à la procédure administrative proposée.

En quoi consiste le traitement TheraSphere?

TheraSphere est un traitement innovateur contre le cancer du foie. En fait, il est utilisé pour les cancers hépatiques primitifs –c'est-à-dire qui ont commencé dans le foie--- et pour les cancers qui se sont disséminés (propagés) au foie. Par contre, pour les cancers qui ont commencé ailleurs (par exemple dans les cas de cancer colorectal), mais qui se sont propagés au foie (métastases hépatiques), TheraSphere est généralement administré après plusieurs traitements de chimiothérapie. Par contre, il peut être, dans les cas de cancers primitifs du foie, le premier traitement contre cette maladie.
Cette méthode ou traitement consiste en de minuscules particules de verre ou sphères microscopiques radioactives qui sont injectées au moyen d'un cathéter dans les vaisseaux sanguins qui nourrissent la tumeur. Ce type de rayonnement étant très localisé, fait très peu de dommages. En effet, ces rayonnements détruisent uniquement la tumeur en épargnant majoritairement les tissus sains du foie.

Au Canada, TheraShpere a été homologué (approuvé) comme traitement du cancer du foie.

Comment se déroule le traitement?

Avant de commencer le traitement, il vous sera demandé de passer différents examens qui sont essentiels, d'une part, pour déterminer si le traitement est le plus adapté à votre situation et s'il peut être fait sans risque et essentiels, d'autre part, au calcul de la dose. Ces tests impliquent notamment une angiographie par cathéter et une étude de la vascularisation artérielle de la tumeur. L'angiographie consiste à introduire un cathéter (petit tube mou) et à le positionner dans un vaisseau sanguin qui nourrit le foie. On procède ensuite à une cartographie de tous les vaisseaux intra-hépatiques et des vaisseaux entourant le foie. Il

arrive parfois que l'on doive obstruer un vaisseau sanguin à l'aide d'un serpentin ou *coil* ou d'un gel moussant afin de s'assurer que les microsphères vont au foie uniquement et qu'elles ne dérivent pas vers d'autres organes. Par ailleurs, l'étude de la dérivation (shunt) vise à déterminer si la dose thérapeutique reste dans le foie ou si elle migre vers les poumons. Le cas échéant, si la dérivation des microsphères dépasse la dose recommandée, le traitement pourrait être annulé. En effet, une telle dose pourrait endommager les poumons par radiolésion ou lésion par irradiation.

L'assurance maladie couvre-t-elle le coût total du traitement ?

L'Hôpital assume la majorité des coûts, y compris les frais liés aux examens, angiographies et tomodensitométries. Par contre, elle ne paie pas, à l'heure actuelle, le coût du médicament lui-même. En effet, le CUSM n'a pas encore réussi à en obtenir le financement par le gouvernement, ce qui permettrait d'offrir ce médicament à tout patient couvert par un régime public d'assurance maladie. Aussi, plutôt que de ne pas offrir le traitement, nous avons contourné le problème en offrant au patient la possibilité de payer pour les médicaments uniquement. Une telle alternative est beaucoup plus attrayante et agréable que de voyager dans un autre pays, où le patient aurait à payer et pour le médicament et pour tous les autres coûts associés.

Sur le marché américain, le prix pour un traitement classique est de l'ordre de 80 000 $ à 150 000$, tandis qu'au Canada, le prix de vente du médicament lui-même s'élève à 14 000$ par traitement.

À l'heure actuelle, le CUSM ne peut offrir ce traitement que si le patient accepte d'assumer le coût du médicament. Il existe cependant certaines compagnies d'assurances qui acceptent d'en rembourser le prix, soit en totalité, soit en partie. Pour entreprendre ce traitement, vous devez avoir acquitté la facture de l'Hôpital ci-jointe quant au coût du médicament TheraSphere.

Je confirme, par la présente, avoir lu ce qui précède et être d'accord avec les conditions énumérées.

NOM DU PATIENT : _____

SIGNATURE DU PATIENT : _____

DATE :_____

NOM DU TÉMOIN : _____

DATE :_____

Therasphere^{TM}

Radiation safety precautions

Radiation safety is a natural concern for many patients being discharged from the hospital following TheraSphere treatment; however, no special safety precautions are required. It has been established that patients leaving the hospital are not at risk to those around them; the radiation field outside their body is sufficiently low to be deemed not a radiation safety issue. As a precaution, many hospitals have general instructions as suggested guidelines. You will be provided with further information on these precautions when you leave the hospital.

If you anticipate traveling across international borders, the security screening equipment may detect low radiation levels as a result of your TheraSphere treatment. Your physician can provide you with a letter explaining the circumstances and it is available upon request.

Please note: Although TheraSphere radioactivity continues to diminish over time, TheraSphere will remain permanently implanted in the liver tissue. Special liver tissue handling may be required at the time of surgery or if cremation is considered.

Discharge Instructions

On the day of discharge, limit your activities:

• No physical exercise or heavy lifting (greater than 4.5 kilos/10 pounds) for the next 3 days.
• Do not drive for 24 hours after the procedure.
• You may resume all other daily activities 24 hours after the test.
• You should drink at least 6 glasses of water (250 mL/8 oz) over the next 24 hours. Water helps to clear the dye used during the pre-planning angiogram.

Therasphere^{TM}

Précautions de radioprotection

La radioprotection est une préoccupation naturelle pour de nombreux patients quittant l'hôpital à l'issue d'un traitement par TheraSphere. Aucune précaution particulière n'est cependant nécessaire. Il a été établi que les personnes quittant l'hôpital ne constituent pas un risque pour leur entourage. Le champ de rayonnement qui les entoure est inférieur aux niveaux considérés comme dangereux.

Si vous prévoyez de voyager et de franchir les frontières, les équipements de sécurité pourraient détecter de faibles taux de rayonnement dus à votre traitement par TheraSphere. Une lettre expliquant la situation a été fournie à votre médecin. Elle vous sera remise sur demande.

Remarque : bien que le taux de radioactivité de TheraSphere continue de diminuer au fil du temps, TheraSphere restera définitivement implanté dans le tissu hépatique. Un traitement particulier peut être nécessaire en cas d'intervention chirurgicale ou après le décès.

Instructions concernant votre sortie de l'hôpital

Le jour de votre sortie, vous devez limiter vos activités.

• Ne pratiquez aucun exercice physique et ne soulevez pas de charges lourdes (plus de 4,5 kg) pendant les 3 premiers jours.
• Vous ne devez pas conduire pendant les 24 heures qui suivent l'intervention.
• Vous pouvez reprendre toutes vos autres activités quotidiennes 24 heures après l'examen.

Y-90 ZEVALIN

Centre universitaire de santé McGill
McGill University Health Centre

Recommended handling and administration of ^{90}Y-ibritumomab tiuxetan

1. Patients will be treated with a 14.8 MBq/kg (0.4 mCi/kg) dose of yttrium-[90].

2. A 0.22 micron filter is required for the administration of the drug. **NB: Record dose administered on worksheet.**

3. **Vials should be stored with proper shielding at 2 - 8°C.** Do not freeze or store at room temperature. The drug is a protein -- HANDLE GENTLY AND AVOID FOAMING. The avoidance of foaming during product handling, preparation and administration is important, as foaming may lead to the denaturing of the product proteins.

   NOTE: Do not use evacuated glass containers which require vented administration sets because this causes foaming as air bubbles pass through the solution.

4. All transfer procedures require strict adherence to aseptic techniques, preferably in a laminar flow hood.

5. ^{90}Y- ibritumomab tiuxetan may be directly infused by stopping the flow from the IV bag and injecting the radiolabeled antibody directly into the infusion port. A 0.22 micron filter must be on line between the syringe and the infusion port.

6. The administration of the radiolabeled drug will be accomplished by one of the nuclear medicine physician from the MUHC. Injection by 10 minute slow IV push. **CAUTION: DO NOT ADMINISTER AS AN INTRAVENOUS BOLUS. Flush the line with at least 10 ml of normal saline after radiolabeled product has been infused.**

7. IV pumps may be used with the ^{90}Y- ibritumomab tiuxetan infusion. Do not infuse concomitantly with another IV solution or IV medications.

8. If a delay in administration occurs after the ^{90}Y- ibritumomab tiuxetan is prepared, the radiolabeled product must be kept refrigerated after preparation at 2 - 8°C and may be used for up to eight and 12 hours, respectively. If not used soon after the calibration time, the actual dose activity will have decayed and therefore requires recalculation.

McGill University Health Centre
Centre Universitaire de Santé McGill

Fact Sheet & Radiation Safety Guidelines for Y-90 Zevalin

1. Y-90 Zevalin is a murine monoclonal antibody that is linked by a chelator to the beta emitter Y-90.

2. The administered dose of Zevalin for the treatment of Non-Hodgkin's lymphoma is 0.3 to 0.4 mCi/Kg, with a maximum of 32 mCi.

3. Y-90 is a pure beta emitter with a maximum energy of 2.3 MeV and a half-life of 64.1h.

4. In vivo (soft tissues), the mean effective path length of Y-90 beta radiation is 5 mm (100-200 cell diameters). Thus, the beta radiation of Y-90 cannot penetrate outside the patient's body.

5. The bremsstrahlung (X-ray emission from the beta particles stopped in tissues) is the only source of external exposure to other persons after Y-90 Zevalin has been administered.

6. Calculations and measurements have shown that radiation dose to workers and patient's family members during Zevalin therapy are very low.

7. The exposure rate due to the bremsstrahlung for Y-90 in a 70 Kg patient is approximately 0.005 μSv/mCi-h at 1 m. For a maximum dosage of 32 mCi, the dose rate from the patient will be 0.15 μSv/mCi-h at 1 m, which is below the natural background radiation level.

8. Urinary excretion is the main route of biologic elimination of Y-90 Zevalin with 7.3 +- 3.2% of the administered dose excreted through the urinary system over a 7-d period. The excreted fraction of a maximum dose of 32 mCi is about 3 mCi, which is in the range of tens of microcuries per void of urine.

9. The effective half-life of Y-90 Zevalin in the blood stream is 30h.

Instructions for Workers:

Y-90 Zevalin is administered on an outpatient basis. Medical personal should take universal precautions (wearing gloves and a laboratory coat or disposable gown) when handling the patient's body fluids. This is sufficient to prevent contamination of personal. Radiation exposure is minimal (comparable to background radiation level) and no other safety precautions are necessary.

Patient Release Instructions:

- For 3 days after treatment, the patient should take precautions to avoid his body fluids to come in contact with other persons.

- For 1 week after treatment, use condoms for sexual relations.

- For 1 year after treatment:
Avoid pregnancy
Mothers should discontinue breast-feeding infants and use formula instead of breast milk

Ref.:
A.M. Zimmer, *Seminars in Nuclear Medicine*, Vol XXXIV, No. 1 Suppl 1 (January), 2004:pp 14-19.
X. Zhu, *Seminars in Nuclear Medicine*, Vol XXXIV, No. 1 Suppl 1 (January), 2004:pp 20-23.

McGill University Health Centre
Centre Universitaire de Santé McGill

Radiation Safety Guidelines for patients receiving Y-90 Zevalin

- **For 3 days after treatment, the patient should take precautions in order to avoid the possibility that body fluids might come in contact with others persons. These include:**
    - **Flushing the toilet twice after each use**
    - **Males should sit to urinate**
    - **Wash your hands thoroughly after each and every use of the toilet**
- **For 1 week after treatment, use condoms for sexual relations.**
- **For 1 year after treatment:**
    - **Avoid pregnancy**
    - **Mothers should discontinue breast-feeding infants and use formula instead of breast milk**

Directives de radioprotection pour les patients recevant le Y-90 Zevalin

- Pendant 3 jours suivant le traitement, le patient doit prendre des précautions pour éviter la possibilité que les fluides corporels puissent entrer en contact avec d'autres personnes. Il s'agit notamment de:

-Tirer la chasse deux fois ou après chaque utilisation
- Pour les hommes, s'asseoir pour uriner
-Lavez-vous soigneusement les mains après chaque utilisation des toilettes

- Pendant 1 semaine après le traitement, utiliser des préservatifs pour des relations sexuelles.

- Pendant 1 an après le traitement:
-Eviter une grossesse ou
-Si vous êtes mère, arrêter l'allaitement des nourrissons et utiliser le lait maternisé à la place de l'allaitement

Ra-223 Alpharadin

Alpharadin™ Intravenous Injection (radium-223 chloride)

The administration of Alpharadin is similar to any other ready-to-use radiopharmaceutical, except that external radiation doses are considerably lower than other radiopharmaceuticals.

As for all radiopharmaceuticals, handling should be performed in a safety bench or fume cupboard. Personnel should wear gloves and eye protection during preparation, syringe filling and administration. In case of contact with skin or eyes, the affected area should be rinsed immediately with plenty of water.

Although the patient dose is calculated by volume using the certified activity stated on the vial, the radioactivity in the vial is controlled in a dose calibrator before dispensing. The calculated volume of Alpharadin is drawn into a syringe by the radiopharmacist and the radioactivity in the vial is controlled again in a dose calibrator after dispensing.

During preparation and administration, the following guidelines apply:

• As for all radiopharmaceuticals, Alpharadin should be handled by individuals who are qualified by training and experience in the safe handling of radionuclides. The hospital facilities must be licensed by the relevant national authorities for the specific radionuclide

• The vials are supplied within a lead container and should be stored in the container in a secure facility at temperatures ≤ 25°C. If stored in a refrigerator, they should be left to stand at room temperature for one hour before use

• The person preparing the syringe should wear gloves and eye protection during syringe filling to prevent contamination of skin and eyes

• The persons administering Alpharadin to the patient should also wear medical gloves

• The area beneath the administration site should be protected with a bench liner sheet

• The person authorised to administer the drug inserts the intravenous cannula for injection. Intravenous access should be secured by flushing with saline prior to injection of study drug in order to minimize the risk of extravasal administration. The syringe containing the study drug is fitted directly to a two/three way adapter

• Alpharadin is administered as a slow intravenous injection (from 2 to 5 minutes)

• After the administration of study drug, the cannula should be flushed with saline to ensure that all study drug has been administered to the patient

• After administration, the equipment used to prepare and administer the drug is treated as short-lived radioactive waste and is disposed in accordance with hospital procedures

GUIDELINES FOR PATIENTS
PARTICIPATING IN THE RADIUM-223 (ALPHARADIN™) STUDY

You should be given a card which informs people that you have been injected with a radioactive medicine, always carry this card with you.

There are no restrictions regarding contact with other people after receiving the study drug.

During the first week after each study drug injection there may be some radioactivity in your blood, urine and stools, and you should take the following precautions:

- Use medical gloves when wiping up blood, urine, stools or vomit, or when handling stained clothes.

- A normal toilet should be used in preference to a urinal. The sitting position should be used instead of the standing position. Flush the toilet twice after use.

- Wipe up any spilled urine or stool with a tissue and flush it away.

- If you are sick, wipe up spilled vomit with a tissue and flush it away.

- Ensure that you always thoroughly wash your hands after using the toilet or after wiping up spilled fluids.

- Wash any linen or clothes that become stained with urine, blood or stools separately from other clothes and rinse them thoroughly.

- If you are sexually active, the use of a condom is recommended during intercourse for the first week after each study drug injection because there may be some radioactivity in the body fluids (but most in blood, urine and stools).

- If sampling of blood, urine or stools are necessary during the first week following a study drug injection, please inform the personnel that you have been treated with radioactive radium-223.

- If you need medical care such as an operation or hospital admission during the first week following injection, please inform the personnel that you have been treated with radioactive radium-223 using the contact information given below.

Principal Investigator
- <Name, phone number>

Study nurse
<name, phone number>.

INFORMATION TO FAMILY AND FRIENDS OF THE PATIENTS PARTICIPATING IN THE CLINICAL STUDY WITH RADIUM-223 (ALPHARADIN™)

Aim of the Treatment

Your close relative is participating in this study investigating the clinical effects, safety and benefit, of Alpharadin on the bone metastases from his prostate cancer. It is a controlled study, which means that he will receive best supportive care plus Alpharadin or best supportive care plus saline (control). Neither he nor his doctor will know which treatment group he has been assigned to until the end of the study.

The study drug is a radiopharmaceutical, which means it contains a radioactive ingredient (radium-223). It is designed to target areas where the cancer is attacking the bone. An injection will be given every four weeks with a total of six injections (via a vein into the blood).

Previous studies with the drug have shown that there is a possibility of constipation, transient diarrhoea, or transient nausea and vomiting; if it occurs this is usually of short duration. In addition, it is possible that your relative may have a temporary increase in bone pain a few days after the injection. He will be closely monitored throughout the study to check his safety and well-being.

Precautions after receiving Alpharadin

Your relative has been given a leaflet explaining the additional hygiene precautions to be taken during the first week following each study drug injection (enclosed). Please read this leaflet and discuss it with him. There is no restriction regarding contact with your relative after the administration of the study drug. He can return home the same day he receives the treatment, and there is no need to change the way that you interact with him.

The major part of the radiation from Alpharadin has such a very short range that it will not pass through the body of your relative. A tiny fraction of the radiation will escape his body, but will not cause any damage to him or the people in his vicinity. Even if you are pregnant, there is no need to take special precautions regarding contact with your relative after his treatment. No extraordinary precautions are required for your relative during contact with children.

Please note that if the patient is your husband/partner, then the use of a condom is recommended during intercourse for the first week after each study drug injection, because there may be some radioactivity in the body fluids (mostly in blood, urine and stools).

For the same reason, for the first week following the study drug injection, medical gloves should be worn if you have to wash your relative's clothes that have become stained with blood, urine or stools. These clothes should be washed separately and rinsed thoroughly.

In a situation where your relative needs to have a blood test, the hospital staff should be informed that the patient is participating in this clinical trial with a radioactive drug. Your relative will be given an information card to carry at all times, giving the names and phone numbers of the research medical doctor/nurse.

If you have any questions or concerns, please contact the research medical doctor/nurse.

APPENDIX 13:

Emergency Measures

RADIATION

Ionizing radiation cannot be detected by the senses. Trained personnel with appropriate detection instruments are required to evaluate potential exposures, and assist in decontamination procedure (if required)

RADIOACTIVE SPILL:
Follow the Procedure for **Code Brown**
Rescue the employees / **Isolate** the room. (See Note 1)
Try to control the spill if it can be done in a secure manner. (See Note 2)

MALFUNCTION OF A RADIATION EMITTING DEVICE:
Cut power to the device and **evacuate** the room. (See Note 3)
Prevent access to the room and post a notice on the door preventing entrance.
Call 55555 to advise the Radiation Safety Officer.

INJURY WITH POSSIBILITY OF RADIOACTIVE CONTAMINATION:
1- Treat serious physical traumas. (See Note 4)
2- Decontaminate the patient as soon as possible after his condition has been stabilized.
3- Advise the Radiation Safety Officer (Through locating if needed).

LOSS OR THEFT OF RADIOACTIVE MATERIAL:
1- Report the incident to the Radiation Safety Officer.
The lost or theft of greater than 1 exemption quantity (EQ) of radioactive material must be reported to the Canadian Nuclear Safety Commission (CNSC) within 24 hours (or as soon as possible).

DISCOVERY OF A RADIOACTIVE MATERIAL OR PACKAGE:
1- Call Security and the Radiation Safety Officer.

Additional informations:

1 Only the personnel with the appropriate training may inspect and clean radioactive material.

2 If it can be done in a secure manner.
Mesures to be taken for contaminated personnel:
- Remove clothing and shoes.
- Flush the skin with lukewarm water and mild soap.

3 The Canadian Nuclear Safety Commission (CNSC) will be advised by the Radiation Safety Officer within 24 hours following the incident. A written report will be supplied to the CNSC as well as to the Hospital Occupational Health and Safety Department.

4 There are three main categories of radiation sources.

- Sealed or encapsulated.
Designed and periodically evaluated to ensure their integrity, should remain intact for most accident conditions. May pose a significant external exposure hazard, but only under extreme accident conditions.

- Unsealed.
Solid (powder), liquid or gaseous state. Much lower activities than those above, but more easily dispersed into the environment than are seal sources. Contamination by, and ingestion or inhalation of, unsealed sources must therefore be considered in accidents involving unsealed sources.

- Machine Produces Radiation.
The equipment is not radioactive, it requires electricity to produce radiation, and does not render anything radioactive (most equipments). Radiation emergencies involving this equipment usually involves a limited number of individuals.

5 **Accidents involving sealed radioisotopes.**
In radiotherapy with external beams, the machine may fail to switch off at the end of the required irradiation period or (in the case of cobalt unit) the cobalt source may fail to return to the OFF position. These situations are recognizable either by the status indicated by the machine or by the continued operation of the visual scatter radiation monitor when the technician enters the room. The procedure in this situation is:
- The technician presses the "Emergency OFF" button to shut the machine down completely. However, if a cobalt source is stuck on the "ON" button, it will remain so even after emergency shut down.
- The patient must be removed from the beam, and from the room, as quickly as possible. The technician must take care not to expose himself to the direct beam during this operation.
- The room is closed and barred.
- The Radiation Safety Officer and the physicist on duty in the Department of Radiation Oncology must be informed as soon as possible.
- It is the physicist's responsibility to apply Emergency procedures.
- The Radiation Safety Officer investigates and records the incident, and reports to the Radiation Safety Committee.

- Non sealed sources are located in Nuclear Medicine (D5) in clnical labs and in research. Sealed hight activity sources are located in radiotherapy and medical imaging.

Reference notes.

Note 1 **Rescue the employees / Isolate the area:**
- Remove the victim from the radiation area.
- Provide first aid.
- If needed, control the fire according to the appropriate procedure.
- Prevent access to the room.

If the spill occurs in a laboratory, leave the fume hood running to minimize the release of volatile radioactive materials to adjacent rooms and hallways.

Note 2 **Try to control the spill**:
- Wear disposable gloves and a lab coat, or disposable coveralls.
- Establish a protection line around the contaminated area.
- Cover the spill with a small blanket, a small cushion or any absorbant tissue, from the outside of the spill toward the center.
- For powder material: cover with a wet blanket.
- Place the spill and the absorbing material in a plastic bag for transfer to radioactive waste container.
- Limit the departure of any involved employee until they are examined.
- Adjust inventory and waste records appropriately.

Note 3 **Evacuation.**
Keep a safe distance of 10 meters from the equipment.

Note 4 **Patient Care**
Treating personnel must observe all elementary precautions and treatment principles stated in the Atomic Energy Commission Board Group of Medical Advisors document "GMA-3 - Guidelines on Hospital Emergency Plans for the Management of Minor Radiation Accidents".

Code brown:
Internal spill or release of hazardous materials

Call 55555
Department responsible: Occupational Health and Safety (OH&S)
Definition

Code brown is used to alert MUHC personnel of an internal hazardous spill of chemical and pharmaceutical products, radioisotopes and biohazardous materials, as well as gas leak

In the event of a chemical spill, the individual(s) who caused the spill or the first individual who noticed the spill or leak is responsible for prompt and proper communication with other occupants, his/her immediate supervisor, and locating

2. General Instruction

When you call 55555 for every emergency situation, make sure that you can provide as much information as possible for instance building, room number, exact location of the spill, name of the product spilled or leak and any other description of the situation which may help to asses the risk. If possible try keep the Material Safety Data Sheet handy for emergency personnel

In case of spill of hazardous materials, MUHC personnel may assess the situation based on inherent toxicity of the materials, availability of personal protection equipment, training, ventilation and other relevant factors. The employees then may initiate cleaning the spill if they are certain that there will be no risk of exposure or injury. Otherwise, the employees are strongly advised to wait for Occupational Health and Safety.

An overexposure or a personal contamination only is not defined as a code Brown emergency. Please contact the Department of Occupational Health and Safety. In case of serious personal exposure seek medical attention by calling code medical 2-3.

Procedure 1

Pull fire alarm and Call 55555 Code brown or if necessary code red or code blue
Remove all occupants out of the danger to your best of capability and inform your immediate supervisor
Do not touch the spilled materials. Evacuate the area
Provide as much information as possible to locating such as room number, name of the spilled product, amount, exact location of spill
Do not engage in any clean up
Remain available if possible
If you are exposed, get fresh air, remove contaminated clothing, seek medical attention
Do not reenter area until instructed to do so by OH&S
Fill up an accident/incident report have it signed by your manager and sent it to OH&S

Procedure 2

Call 55555 code brown
Do not hide it, advise all occupants and your supervisor
get the Material Safety Data Sheet and leave the spill or leak area to a safe area, but remain available if possible**
Provide as much information as possible to locating such as room number, spilled area, name of product amount spilled etc
Do not ask housekeepers to clean up the spill
Wait for security agent and OH&S on Call, do not engage in any clean up
Get fresh air remove contaminated clothing, flush your eyes and skin if necessary
Do not enter to spill area until OH&S confirms that decontamination is complete and normal activity can resume
Fill up an accident/incident report have it signed by your manager and send it to OH&S

** If you think that your body or your clothing is contaminated with radioisotopes, please follow the procedure for radioisotope spills at the end of this document

4. Spill of Radioisotopes (Code Brown)

Scenario 1:
There is an actual or immediate potential for a fire or explosion in an area where radioactive materials are present.

What to do: Follow Procedure #1

Scenario 2:
Radioactive material has been spilled on the floor and/or on the counter

What to do:

Spills are classified as Minor (less than 100 exemption quantities) or Major (100 exemption quantities or more). Many laboratory workers manipulate only very small quantities of radioisotopes that are below one exemption quantity (1 EQ). In this situation, the procedures for Minor spill should be followed at all times. Decontamination procedures for Minor and Major spills are as follows:

- Immediately inform persons in the area that a spill has occurred.
- Keep them away from the contaminated area.
- Cover the spill with absorbent material to prevent spread of contamination.
- Estimate the quantity of radioactive material involved in the spill.
- Follow the procedure for either **Minor** or **Major** spill below.
- Only qualified workers authorized to work with radioisotopes can proceed with the decontamination procedures.

Minor spill (Minor spill typically involve less than 100 Exemption Quantities)
Routine procedure should be followed for clean up. **There is no need to call code brown**.
Qualified workers authorized to work with radioisotopes should be able to proceed with the decontamination procedures without any further assistance. Decontamination procedures are described in the CNSC document INFO-0743 posted in the laboratories (see also item 12.3.1 and Appendix 2 of the MUHC Radiation Safety Manual/NSRD).

1. Wearing protective clothing and disposable gloves, clean up the spill using absorbent paper and place in plastic bags for disposal.
2. Wipe test or survey for contamination. Repeat decontamination if necessary until contamination monitoring results meet the licence criteria.
3. Check hands, clothing and shoes for contamination.
4. Report the spill and cleanup to person in charge or the RSO if necessary.
5. Record spill details and contamination monitoring results. Adjust inventory and waste records.

Major Spill (Major spills involve more than 100 Exemption Quantities, or contamination of personnel, or release of volatile material)

Note: If the spill is well contained over a working area (e.g. workbench or fume hood) and can be cleaned up easily, it is not necessary to initiate a code brown. However, if the spill has spread over a large area (e.g. floor, hallways, ...) and poses a risk to workers or members of the public, initiate a Code Brown (call 55555). The RSO will be contacted via the 24-H on call emergency number (53333) and security will be called in immediately to help and secure the area.

Always follow the major spill procedure described in the CNSC document INFO-0743 posted in the laboratories.

1. Clear the area. Limit movement of all personnel who may be contaminated until they are monitored.
2. Leave fume hood running in the laboratory (if applicable).
3. Close off and secure the spill area (post warning signs).
4. Notify the RSO or the person in charge immediately.
5. The RSO or person in charge will direct personnel decontamination and will decide about decay or cleanup operations.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and mild soap (do not use abrasive techniques like scratching).
7. Follow the procedures for minor spill (if appropriate).

8. Record the names of all persons involved in the spill and details of contamination.
9. The RSO or person in charge will arrange for bioassay measurements if necessary.
10. Submit a written report to the RSO or person in charge.
11. The RSO must submit a report to the CNSC.

Major spill procedures should be implemented whenever Minor spill procedures would be inadequate for spills of more than 1 EQ.

Notice: An overexposure or personal contamination only is not defined as a code brown emergency. In this case, contact the radiation protection service 24h emergency personnel via locating (53333) immediately.
* remove contaminated clothing
* rinse contaminated area with lukewarm water and soap
* do not use abrasive techniques like scratching
* close eyes, nose and mouth if rinsing face.

Code red - Fire

Anyone discovering a fire, or witnessing an explosion, has the responsability and authority to take whatever measures necessary to protect lives and property. This responsability is transferred to a superior or Fire Marshall upon arrival at the scene.

1 Upon discovery of a fire or smoke:

Pull the fire alarm and advise your colleagues. (See the fire alarm and advise your colleagues. (See Note 2)
Remove all persons from the danger area. Do not enter danger zone alone. (See Note 1
Close all doors and windows. (See Note 3)
Fight the fire with available equipment. (See Note 3)
Call 55555. If there is no answer, call (9) 9-1-1 directly.

2 Upon the announcement of a code red in another area than yours:

1- Return to your working area.
2- Do not call the Switchboard or Security
3- Do not use elevators.
4- Listen to voice announcements.
5- Prepare to evacuate and wait for voice directions.
6- Clear fire exits, close doors and windows.
7- Secure offices, stores, valuables, etc.
8- Turn off electrical and gas appliances, but not lights.
9- Be ready to assist affected areas, if directed.
10- Return patient charts to the Nursing station.
11- On a Care Unit, visitors are asked to evacuate immediately.

Additional information:

1 **Oxygen.**
DO NOT TURN OFF the main oxygen supply valves located in the corridors unless instructed by the Nurse in Charge or the Nursing Resource Manager.

2 **Assistance.**
If the fire is in a patient's room, pull the alarm bell in the bathroom, to obtain assistance from other employees.

3 **Lighting.**
Turn the lights on in the room to allow the emergency teams to move around easily in the affected area.

4 **Oxygen and Survival Equipment.** (respirators, anaesthesia equipment, oxygen masks, etc.)
The Fire Brigade (Red Team) will do their best to provide all necessary services, however, it could be necessary to close certain installations such as oxygen and medical gas, etc. without notice. Consequently, life equipment support operators (doctors, nurses, respiratory technicians, etc) should, at all times, remain on alert as soon as the fire alarms are activated.

5 **Radiation**
If radioactive material is present, the response team must be equipped with a Self Contained Breathing Apparatus.

6 **Move in the smoke**.
If you have to move in the smoke, crawl on the floor. The safest breathing area is located no more than 18 inches above the floor.

7 **Operating Rooms**.
When a code red is transmitted:
- Advise the Chief Surgeon and the Chief Anaesthetist of the fire location.
- No new surgery should be started.
- Evaluate the current state of each undergoing surgery.
- Prepare all personnel to ensure the operation of essential equipment in the event of an electrical power shutdown.

8 **Parking**
Ensure that all vehicules parked around the various buildings of the complex will not hinder fire fighting or resue operations. Vehicules should be towed away if needed.

- **Self Contained Breathing Apparatus**
  The hospital has six Self Contained Breathing Apparatus' situated in the following areas:
  - Two respirators in the 1st basement, near the Pine elevators, next to Room Cs1 109;
  - Two respirators on the 6th floor, near the guard desk, facing Room E6 107.5;
  - Two respirators on the main floor, Livingston Hall, Room Ls1 404.
- **Fire Fighting Equipment**
  The is a cart containing special emergency equipment on the 6th floor Cedar near the guard desk and on the 1st basement near Pine elevators. It includes:
  - two complete firemen suits (jackets, helmets, boots, gloves);
  - spare hoses;
  - spare compressed air tanks for Self Contained Breathing Apparatus;
  - spot light;
  - fire blanket.
- **Emergency Tool Box**.
  Emergency tool boxes are situated on every floor in the stairwell. Es.3 on Pine, near the elevators, Es.7 Cedar, and Es.10 near the elevators in Livingston Hall.
  The boxes contain: a) one pick hell fire axe; b) one crowbar; c) one nylon rope.
- **Portable alarm - Combustible Gas and Oxygen**.
  The combustible gas sensor designated to measure combustible gas or vapour and oxygen in the air and is located at the guard desk, Room D6 108.
  This apparatus is explosion proof and can be used in any type of environment.
  This apparatus is to be used BEFORE entering an area where there is a danger in order to determine the level of danger and the type of personal protective equipment to be used during the intervention.
- **Portable Smoke Gas Ejector.**
  The portable smoke and gas ejector is used whenever smoke, gas or vapors need to be ejected outside the building or when fresh air is required.
  It is equipped with a 20 foot length of 18 inch diameter flexible hose.
  This equipment is explosion proof and can be used in any type of environment.
  This equipment is located on the fire cart in the room facing E6 107.5.

- **Fire Alarm System.**
  Fire Alarm Panels are located in the following area:
  - Pine Avenue entrance for Wings A, B, C.
  - Guard Desk (D6) for Wings D, E, F, G, J and S;
  - L6 for Wings L and R;
  All alarms are transmitted and printed to the folowing areas:
  - Locating (Switchboard Area) (Cs1 228);
  - Guard Desk (D6).
  *** Alarms for Wings F, G, J and S are received only at the Guard Desk.
  *** The main panel controlling the fire alarm system is situated at Locating (Switchboard Area) (Cs1 228).
  The red fire phones situated at various locations on all floors are to be used only for emergencies. These telephones automatically ring at Locating (Switchboard area).
  The activation of a fire alarm will, besides signal the alarm:
  - automatically close the fire doors in the affected area;
  - automatically unlock emergency exits in the affected area.
- **Fire hoses**
  Fire hoses are located throughout the complex, except for wings: F, G, J, K and S.
- **Alarm Bells.**
  The activation of a manual alarm sends a signal to the central surveillance area, and in some cases, will activate the alarm bells. The combined action of the manual alarm with a fire detector or the action of two detectors, or two manual stations will, however, always cause the alarm bells to ring.
- **Pressurisation**
  Some staircases will become pressurized with the sounding of the alarm. Compressed air will be fed from the top to the ground floor and doors, which will automatically open, must not be forced closed.

  Some elevator shafts may also become pressurized. The elevators will descend to the ground floor, the doors will open and the elevators will shut down until an attendant can operate them manually.
- **Building Services**
  - Ensure that the ventilating system is shut down when required.
  - Check booster pump for water pressure to fire water supply.
  - Standby in the boiler room for special instructions as required by the Fire Prevention Department to shut down main gas lines, medical gases, exhaust system or to activate the emergency power generators.

Reference notes:

Note 1 **Remove people from danger.**
If the attempt to extinguish the small fire fails or if the size of the fire is such that the life of the occupants is in immediate danger or if smoke could create a problem, an immediate evacuation is to be made.

- Evacuate the room(s).
- Check bathrooms, cupboards and under beds to make sure no one is hiding or lying unconscious.
- Shut off and remove oxygen cylinders from the area.

Note 2 **Activate the alarm.**
Pull or have someone else pull a manual fire alarm located near the closest stairwell.

People from the Neuro will skip step 3 (Call 555) and go directly to step 4.

Note 3 **Contain the fire.**
- Close doors and windows. Do not lock the doors.
- Assure that fire doors leading to stairwells and corridors are closed..

- Turn off all electrical equipment, except lights. If it is life support equipment (respirator, IV pump, cardiac monitor, dialysis equipment, etc), check if the equipment is battery powered. If not, manual support should be provided whenever possible.
- Fight the fire with available equipment.

Fight the fire.
If the fire is minor and controllable, try to extinguish it. 5555 must still be advised even if it has been extinguished.

Unless it is completely safe, do not return to the scene of the fire after having evacuated. After evacuation, only the Fire Marshall can authorize the personnel to return to evacuated areas.

Fire Fighting Equipment.
Do not use the fire equipment and hoses without knowing how.

Extinguishers.
Extinguishers are installed throughout the complex. Everyone should familiarize with the exact location of the extinguishers and how to use them before an emergency situation occurs. The appropriate extinguisher must be used according to the type of fire.
Class A = Inflammable solids (wood, paper, fabric, etc.);
Class B = Inflammables liquids (fuel, oil, solvents, paint, etc.);
Class C = Electrical equipment or installations.

APPENDIX 14:

Public Health Protection Act (Quebec)
Diagnostic Radiology Laboratory

Excerpt from:

Regulation respecting the application of the Public Health Protection Act

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

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

DIVISION II
DIAGNOSTIC RADIOLOGY LABORATORY

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

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

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

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

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

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

§ 1. Equipment

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

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

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

(b) identification of the image recording devices;

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

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

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

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

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

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

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

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

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

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

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

151. An x-ray machine installed after 28 May 1979 must be equipped with devices permitting a reduction in exposure time to 1/60 of a second.

152. An x-ray tube used for diagnosis must be set and adjusted inside the tubehead housing or shielded structure, which latter must isolate such x-ray tube so that, for maximum potential, radiation leakage does not exceed 0,1 % of primary radiation at the same distance from the focus.

153. In radiology, except in the case prescribed in section 154, an x-ray machine must be equipped in such a manner that the focus-skin distance cannot be less than 30 centimetres.

154. In dental radiology, except where a machine for intra-oral usage is employed, an x-ray machine must be equipped in such a manner that the focus-skin distance cannot be less than 18 centimetres.

155. A dental radiography machine must be equipped with a device which does not allow the primary radiation beam to exceed a diameter of 7 centimetres at the extremity of the localization cone.

156. An x-ray machine to be used at voltages higher than 70 kilovolts must be equipped with a filter set in the machine to ensure total aluminium-equivalent filtration of at least 2,5 millimetres.

An x-ray machine to be used at voltages lower than 50 kilovolts must be equipped with a filter set in the machine to ensure total aluminium-equivalent filtration of at least 0,5 millimetres.

An x-ray machine to be used at voltages higher than 50 kilovolts but lower than 70 kilovolts must be equipped with a filter set in the machine to ensure a total aluminium-equivalent filtration of at least 1,5 millimetres.

An x-ray machine to be used at any voltage and not equipped with a filter set in must be equipped in such a way as to disallow exposure unless it ensures filtration equivalent to that provided for in the preceding paragraphs.

157. The attenuation of x-rays by the surface of the examination table must not be more than the equivalent of 1 millimetre of aluminium measured at 100 kilovolts (peak voltage) where the tube is above the table.

158. In fluoroscopy, when the operator of an x-ray machine is stationed directly behind the detector, the primary x-ray beam must be located within the surface area of the fluoroscopic screen while leaving an unexposed margin of at least 6 millimetres.

159. A photofluorographic x-ray machine must be equipped in such a manner that the surface of the primary radiation beam cannot exceed 36 centimetres by 43 centimetres at the plane of the shielding whatever the focus-skin distance.

160. A fluoroscopic machine installed subsequent to 28 May 1979 must be equipped with a light intensity control.

161. The primary radiation employed in fluoroscopy must be attenuated by a screen with a lead-equivalent of at least 1,5 millimetres in the case of x-ray machines operating at a maximum potential of 100 kilovolts. For each additional kilovolt, a 0,01 millimetre lead-equivalent is added.

Exposure must be interrupted automatically when the screen is removed from the useful beam.

162. A fluoroscopic machine installed subsequent to 28 May 1979 must be equipped with a shielding equivalent to 0,25 millimetre of lead allowing the covering of the opening of the Bucky during the examination.

163. A radiology machine must be equipped with a spring-type exposure switch or with a switch requiring continuous pressure.

164. Except in fluoroscopy, the exposure switch of an x-ray machine shall be so arranged that the operator may not make exposures outside the control station.

165. The control desk of the radiography machine must be equipped with a device indicating when x-rays are produced at the time of exposure.

166. A fluoroscopic machine must be equipped with a timing device to alert the operator, by an audible signal, that a maximum 5-minute exposure time has elapsed.

167. A fluoroscopic machine must be equipped with a current, voltage and time exposure indicator so arranged that the operator may supervise such variations during the examination.

168. A radiology machine must permit at least 90 kilovoltage except in mammography and in dental radiography.

169. Except in dental radiography, an x-ray machine must be equipped with a device capable of limiting the field to the dimensions of the image receptor.

170. A laboratory must be equipped with a stationary x-ray machine after 28 May 1979. In a laboratory where there already is a mobile x-ray machine, the latter must be set in and the room where it is used must be shielded in accordance with Subdivision 6.

§ 2. Staff

171. A holder of a permit is responsible for the quality of all work carried out within a diagnostic radiology laboratory, for the application of Chapter VIII, and

(a) he must ensure that every person who operates an x-ray machine is either a member in good standing of a professional corporation whose members are empowered by law to use x-rays on an animate being and, when the law requires, that the said member holds a permit issued in accordance with sections 186 and 187 of the Professional Code (R.S.Q., c. C-26), namely, a student who carries out a professional training period for the purpose of obtaining a permit to practise issued under one of those acts governing professionals;

(b) he is responsible for preparing and keeping up-to-date a manual of methodology describing the different techniques employed in examinations and shall see that it is accessible to the staff at all times;

(c) he must take into account the qualifications and training of each employee when he ensures the distribution of tasks;

(d) he must keep up-to-date and keep at the laboratory the files contemplated in sections 115, 145, 148, 173 as well as the register contemplated in section 179.

172. A holder of a general diagnostic radiology laboratory permit must ensure that a physician holding a specialist's certificate in diagnostic radiology issued by the Corporation professionnelle des médecins du Québec ensures the supervision of such laboratory during its operating hours.

The holder of a specific diagnostic radiology laboratory permit must ensure that a member of a professional corporation whose Act authorizes him to use x-rays on animate beings and, when such Act requires, who holds a permit issued in accordance with sections 186 and 187 of the Professional Code (R.S.Q., c. C-26), ensures the supervision of such laboratory during its operating hours.

173. An up-to-date file must be maintained for each of the staff members and must include:

(a) a medical certificate at the time of hiring, and thereafter yearly, certifying that the person is qualified to work in a radiology laboratory;

(b) the results of the medical examinations contemplated in sections 174, 175, 176 and 185;

(c) reports of x-ray dose equivalents to which they, individually, have been exposed;

(d) a duplicate of every diploma or certificate of studies pertinent to their work and documents certifying that they have fulfilled the requirements contemplated in paragraph a of section 171;

(e) where applicable, the forms contemplated in sections 181 and 189.

174. The permit holder must ensure that every staff member directly assigned to work under x-rays has undergone a medical examination when hired including:

(a) an anamnesis directed towards the risks to which the employee may be exposed and relating to:

(i) the possible existence of hereditary diseases or defects;

(ii) possible blood count abnormalities; and

(iii) an estimate of occupationally derived x-ray dose equivalents received previously. If, for a given period of the professional life of a person, previously directly assigned to work under x-rays, the accumulated dose equivalent is not known with certainty, it shall be considered equal to the maximum permissible dose prescribed in Schedule 8 corresponding to such period;

(b) a physical examination; and

(c) a full blood count including red blood cell, white blood cell and platelet counts and a differential blood count.

175. The holder of a permit must ensure that every staff member directly assigned to work under x-rays has, each year, undergone the medical examination contemplated in section 174.

176. The holder of a permit must ensure that at the end of the first and second month of employment, every person directly assigned to work under x-rays and every person contemplated in section 184 has undergone the examinations contemplated in paragraph c of section 174.

§ 3. Operation

177. Before an x-ray machine is put in operation, the operator must ensure that the persons present in the examination room, except those persons undergoing the examination, are protected in accordance with section 186 and that the shielded doors of the examination room are closed.

178. The operator of an x-ray machine who x-rays a person must identify both that person and the radiological plates that have been taken.

The radiological plates must be identified in a permanent manner for as long as the file is conserved.

179. A daily register indicating the number of each type of examination undertaken by 24-hour period must be maintained.

§ 4. Protection of staff

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

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

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

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

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

185. When a staff member receives x-ray dose equivalents in excess of those prescribed in Schedule 8, he must be advised thereof immediately and, if the dose is personal, the holder of the permit must ensure that he again undergoes the medical examination contemplated in section 174.

186. The staff carrying out a radiological examination must protect themselves from radiation by remaining in a control booth or behind a screen and by wearing protective clothing contemplated in the second paragraph.

Protective clothing must be available and conform to the following specifications,

(a) the protective aprons employed in dental radiology must bring about an attenuation of the beam equivalent to that brought about by 0,25 millimetres of lead;

(b) protective aprons other than those provided for in subparagraph a must bring about an attenuation of the beam equivalent to that brought about by 0,5 or 0,25 millimetres of lead according to the needs;

(c) the gloves must provide protection equivalent to that provided by 0,5 millimetres of lead.

187. The lead-equivalent thickness of the material utilized must be clearly indicated on each article of clothing.

188. Immobilization accessories must be available in a diagnostic radiology laboratory.

When it is impossible to immobilize a patient with such accessories, the person immobilizing him must protect himself by standing away from the primary beam of radiation and by wearing the protective clothing contemplated in section 186.

189. At the time of hiring, the holder of the permit must see to it that the staff member signs the form prescribed in Schedule 10 informing her of the limits of exposure to x-rays during pregnancy.

190. When the holder of a permit is advised that a staff member is pregnant, he must ensure that she is not exposed to radiation dose equivalents in excess of the dose prescribed in Schedule 8 for pregnant women.

191. A pregnant staff member may continue to carry out her duties provided a weekly control of the doses received is carried out.

192. In dental radiography, the x-ray machine operator must not himself hold the film at the time of radiation exposure. Such film must be held in position by a device designed for that purpose or by the person undergoing the examination.

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

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

Except in dental radiography, the operator of an x-ray machine must ensure that the cone of the radiation beam protects the epiphyses of children and the gonads of persons of an age of reproductive capacity.

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

§ 6. Shielding

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

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

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

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

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

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

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

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

MAXIMUM PERMISSIBLE DOSE (MPD) EQUIVALENTS FOR X-RAY EXPOSURE :

Table 1

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

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

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

3) members of the public.

Organ or tissue	Maximum permissible dose (MPD) equivalents in rems
	Per year
Whole body, gonads, red bone marrow, lens of eye	0,5
Bone, skin	3
Thyroid	
a) persons under 16 years of age	1,5
b) persons 16 years of age and over	3
Any tissue of the hands, forearms, feet and ankles	7,5
Other single organs or tissues	1,5

Table 2

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

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

Table 3

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

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

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

Note : 1 rem = 10 mSv

Santé et Services sociaux Québec

CIRCULAIRE

Expéditeur

Le directeur général des Services de santé et médecine universitaire

Date

2009-07-02

Destinataires (*)

Les directrices et directeurs généraux des établissements de santé et de services sociaux et les présidentes-directrices et présidents-directeurs généraux des agences de la santé et des services sociaux

Sujet

Mécanisme de radioprotection en imagerie médicale clinique en radiologie utilisant les rayons X dans les établissements

PRÉAMBULE Les établissements ont la responsabilité d'offrir des services de radiologie de qualité et de sécurité et, pour sa part, le ministre de la Santé et des Services sociaux a la responsabilité de s'assurer de l'accès aux services d'imagerie et du respect des normes de qualité et de sécurité notamment en matière de radioprotection. De nouvelles mesures de radioprotection s'imposent notamment parce que les équipements, les procédures, et le type d'examens de radiologie diagnostiques ont considérablement changé ces dernières années et que le volume d'examens croît de façon exponentielle.

REMARQUES Cette circulaire ne s'applique pas au Conseil Cri de la santé et des services sociaux de la Baie-James.

Les titulaires de permis de laboratoires d'imagerie médicale (LIM) et les titulaires de permis de radiologie diagnostique (LRD) tel que défini par la Loi sur les laboratoires médicaux, la conservation des organes, des tissus, des gamètes et des embryons et la disposition des cadavres (L.R.Q., chapitre L-0.2), ainsi que les directeurs médicaux des LIM recevront une directive semblable à celle des établissements de santé sur les nouvelles normes de radioprotection.

Lorsque l'expression LIM est utilisée, elle réfère au laboratoire d'imagerie médicale tel que créé par le projet de loi 95 (2008, chapitre 28) et modifié par le projet de loi 34 (2009, chapitre 29) « Loi modifiant diverses dispositions législatives concernant les centres médicaux spécialisés et les laboratoires d'imagerie médicale générale ».

(*) Cette circulaire s'adresse également, en adaptant les destinataires, au Centre régional de santé et de services sociaux de la Baie-James et à la Régie régionale de la santé et des services sociaux du Nunavik.

Site Internet : www.msss.gouv.qc.ca/documentation
« Normes et Pratiques de gestion »

Direction(s) ou service(s) ressource(s)	Numéro(s) de téléphone	Numéro de dossier
Direction de l'organisation des services médicaux et technologiques	418 266-6946	2009-033

Document(s) annexé(s)	Volume	Chapitre	Sujet	Document
	01	02	40	12

OBJET La présente circulaire vise à informer les établissements des nouvelles dispositions concernant la radioprotection dans les laboratoires d'imagerie médicale au Québec. Ainsi, le ministère de la Santé et des Services sociaux (MSSS) informe les établissements du réseau de l'adoption par le Québec des normes récentes de Santé Canada sur la radioprotection en radiologie et de la désignation d'un centre d'excellence en radioprotection chargé de la coordination d'un groupe d'experts en calibration des équipements de radiologie.

MODALITÉS Les établissements devront appliquer d'ici le 1er avril 2010, les recommandations contenues dans le document de Santé Canada intitulé : Radioprotection en radiologie - Grands établissements, Procédures de sécurité pour l'installation, l'utilisation et le contrôle des appareils à rayons X dans les grands établissements radiologiques médicaux. Code de sécurité 35 : prioriser le programme d'assurance qualité.

Ce code de sécurité a été produit en 2008 par Santé Canada. Les établissements utilisaient d'autres critères et processus de radioprotection mais l'adoption de nouvelles normes favorisera une meilleure protection du public et une harmonisation des pratiques.

Les établissements doivent mettre en place un système qui porte sur la protection de toutes personnes susceptibles d'être exposées aux rayons émis par les appareils radiologiques utilisés dans un établissement opérant un laboratoire d'imagerie médicale en radiologie.

Les établissements devront s'assurer avant de conclure une entente de services avec un établissement ou un LIM que celui-ci applique rigoureusement le Code de sécurité 35.

Les établissements doivent s'assurer que les paramètres d'utilisation des équipements de radiologie sont optimaux. Le groupe d'experts en calibration supportera les établissements dans l'atteinte de cet objectif.

SUIVI La direction ressource est disponible pour tout renseignement additionnel.

Le directeur général,

Original signé par

Michel A. BUREAU

Ministère de la Santé
et des Services
sociaux
Québec

Direction générale des services de santé et médecine universitaire
Bureau du directeur général

COURRIER ÉLECTRONIQUE

Québec, le 20 avril 2010

Les présidentes-directrices et les présidents-directeurs généraux des agences de la santé et des services sociaux
Les directrices et les directeurs généraux des établissements de santé et de services sociaux

Madame,
Monsieur,

Par la présente, je désire apporter une réponse aux inquiétudes actuelles concernant le Code de sécurité 35 et son application au Québec.

Le plan d'action ministériel, relatif à la réduction de l'exposition aux rayonnements ionisants, comporte neuf actions à prendre. Une d'entre elles porte sur les nouvelles dispositions à mettre en place pour améliorer la radioprotection et se lit comme suit :

> « Adoption de la norme de radioprotection de Santé Canada publiée en 2008 (Document intitulé : *Radioprotection en radiologie – Grands établissements – Procédures de sécurité pour l'installation, l'utilisation et le contrôle des appareils à rayons X dans les grands établissements radiologiques médicaux Code de sécurité 35*) et obligation pour les établissements ayant un service de radiologie comportant un ou plusieurs tomodensitomètres, de s'y conformer au plus tard le 1er avril 2010. »

Dans ce plan d'action, le ministère de la Santé et des Services sociaux (MSSS) désigne le Centre hospitalier universitaire de Sherbrooke comme responsable de la mise en place et du maintien d'un centre d'expertise clinique en radioprotection (CECR).

L'action portant sur le Code de sécurité 35 a soulevé plusieurs réactions et inquiétudes, dont la difficulté d'appliquer intégralement ce code dans sa forme actuelle, ainsi que le court échéancier de mise en œuvre.

... 2

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Le MSSS est conscient des impacts qu'apporte la mise en application d'un tel code. Afin de venir en aide aux établissements du réseau de la santé, le CECR a reçu comme premier mandat de réviser le Code de sécurité 35, de voir à son degré d'application et de formuler des recommandations, d'établir un échéancier de mise en œuvre et de soutenir les établissements qui y travaillent. L'accent est mis sur les services de radiologie qui utilisent la tomodensitométrie.

Pour ce faire, le CECR met en place un comité d'experts dont le rôle est de se pencher sur le contenu du Code de sécurité 35, de l'adapter à l'environnement québécois et de planifier une adoption progressive du code.

Pour obtenir plus d'informations, vous pouvez communiquer avec le Centre d'expertise clinique en radioprotection :

- par téléphone aux numéros suivants : 1 819 348-3842 pour la région de Sherbrooke ou 1 877 348-3842 pour l'extérieur de la région.
- par courrier électronique à l'adresse suivante : cecr.chus@ssss.gouv.qc.ca.

Je vous prie d'agréer, Madame, Monsieur, l'expression de mes sentiments les meilleurs.

Le directeur général,

Michel Bureau

Michel A. Bureau, M.D., FRCPC

APPENDIX 15:

Glossary and Units

GLOSSARY OF TERMS

ABSORBED DOSE:
The energy imparted by ionizing radiation per unit mass of irradiated material.

ACTIVITY:
The rate of decay (disintegrations/time) of a given amount of radioactive material.

ALARA:
An acronym for As Low As Reasonably Achievable. The principal that radiation doses should be kept as low as reasonably achievable taking into account economic and social factors.

ALPHA PARTICLE (α):
A strongly ionizing particle emitted from the nucleus during radioactive decay which is equivalent to a helium nucleus (2 protons and 2 neutrons).

ANNIHILATION RADIATION:
The two 511 keV photons produced when a positron combines with an electron resulting in the annihilation of the two particles.

ANNUAL LIMIT ON INTAKE (ALI):
The activity, in Bq, of a radionuclide that will deliver an effective dose of 20 mSv during the 50-year period after the radionuclide is taken into the body of a person 18 years old or older or during the period beginning at intake and ending at the age of 70 after it is taken into the body of a person less than 18 years old

BACKGROUND RADIATION:
Ionizing radiation arising from sources other than the one directly under consideration. Background radiation due to cosmic rays and the natural radioactivity of materials in the earth and building materials is always present.

BECQUEREL (Bq):
The SI unit of activity equal to one disintegration per second. (1 Bq = 2.7E-11 CI).

BETA PARTICLE (β):
A charged particle emitted from the nucleus of an atom, having a mass equal to that of the electron, and a single positive or negative charge.

BIOLOGICAL HALF-LIFE:
The time required for the body to eliminate by biological processes one-half of the amount of a substance which has entered it.

BREMSSTRAHLUNG:
X-rays produced by the deceleration of charged particles passing through matter.

CONTAMINATION:
The deposition of radioactive material in any place where it is not desired, particularly in any place where its presence may be harmful.

CURIE (CI):
The unit of activity equal to 3.7×10^{10} disintegrations per second.

DOSE:
A general term denoting the quantity of radiation or energy absorbed in a specified mass. The unit is the Gy (= 1 J/Kg).

EFFECTIVE DOSE:
Quantity obtained by multiplying the equivalent dose to various tissues and organs by the risk weighting factor appropriate to each, and summing the products. The unit of effective dose is sievert (Sv).

EFFECTIVE HALF-LIFE:
Time required for a radioactive nuclide in the body to be diminished fifty percent as a result of the combined action of radioactive decay and biological elimination.

EQUIVALENT DOSE:
Product of absorbed dose and factors that take into account the biological effects of the particular type of radiation. For x-rays the modifying factor is equal to 1, therefore an absorbed dose of 1 Gy results in a dose-equivalent of 1 Sv.

EXEMPTION QUANTITY (EQ):
Quantity of a nuclear substance or activity of a source below which a person may carry on activities (possess, transfer, import, export, ..) without a licence.

EXPOSURE:
A measure of the ionizations produced in air by x-ray or gamma radiation. The roentgen (R) is the traditional unit of measurement for exposure, the charge produced in air by gamma or x-rays. The SI unit of exposure is coulombs per kilogram (C/kg) of air.
(1 C/kg = 3876 R ; 1 R = 2.58E-4 C/kg)

FILM BADGE:
A packet of photographic film in a holder used for the approximate measurement of radiation dose.

GAMMA:
Electromagnetic radiation (photon) of nuclear origin.

GEIGER-MUELLER (G-M) COUNTER:
A radiation detection and measurement instrument.

GRAY (Gy):
The SI unit of absorbed dose equal to 1 Joule/kilogram.

HALF VALUE LAYER:
The thickness of any specified material necessary to reduce the intensity of an x-ray or gamma ray beam to one-half its original value.

ION:
Atomic particle, atom, or chemical radical bearing an electrical charge, either negative or positive.

IONIZATION:
The process by which a neutral atom or molecule acquires either a positive or a negative charge.

IONIZATION CHAMBER:
A radiation detection and measurement instrument.

IONIZING RADIATION:
Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, by interaction with matter.

ISOTOPES:
Nuclides having the same number of protons in the nuclei, and hence having the same atomic number, but differing in the number of neutrons, and therefore in mass number. Almost identical chemical properties exist among isotopes of a particular element.

LABELED COMPOUND:
A compound consisting, in part, of radioactive nuclides for the purpose of following the compound or its fragments through physical, chemical, or biological processes.

NUCLIDE:
An of atom characterized by its mass number, atomic number, and energy state of its nucleus.

OCCUPANCY FACTOR:
Estimated fraction depending on the proportion of the irradiated time that an area is occupied, averaged over a year.

POSITRON:
A particle having a mass equal to that of an electron and a charge equal to that of an electron, but positive.

RAD:
The unit of absorbed dose equal to 100 erg/gram (or 0.01 Joule/kilogram).

RADIATION:
Energy propagated through space or a material medium.

RADIOACTIVE DECAY:
Disintegration of the nucleus of an unstable nuclide by the spontaneous emission of charged particles, neutrons, and/or photons.

RADIOACTIVE HALF-LIFE:
The time required for a radioactive substance to lose fifty percent of its activity by decay.

RADIOACTIVITY:
The property of certain nuclides of spontaneously disintegrating and emitting radiation.

RADIONUCLIDE:
An unstable (radioactive) nuclide.

RADIOTOXICITY:
The potential of a radioactive material to cause damage to living tissue by radiation after introduction into the body.

REM:
The unit of dose equivalent equal to the absorbed dose in rad multiplied by any necessary modifying factors.

ROENTGEN (R):
The unit of radiation exposure in air equal to 2.58E-4 coulombs/kilogram.

SCINTILLATION COUNTER:
A radiation detection and measurement instrument in which light flashes produced in a scintillator by ionizing radiation are converted into electrical pulses by a photomultiplier tube.

SEALED SOURCE
"A radioactive nuclear substance in a sealed capsule or in a cover to which the substance is bonded, where the capsule or cover is strong enough to prevent contact with or the dispersion of the substance under the conditions for which the capsule or cover is designed." *Nuclear Substances and Radiation Devices Regulations (SOR/2000-207)*

SHALLOW-DOSE EQUIVALENT:
The dose equivalent at a tissue depth of 0.007 cm from external exposure of the skin or an extremity.

SIEVERT (Sv):
The SI unit of dose equivalent equal to 1 Joule/kilogram.

SPECIFIC ACTIVITY:
Total activity of a given radionuclide per unit mass or volume.

SYSTEME INTERNATIONAL (SI):
A system of units adopted by the 11th General Conference on Weights and Measurements in 1960 and used in most countries of the world.

THERMOLUMINESCENT DOSIMETER (TLD):
A dosimeter made of a crystalline material which is capable of both storing energy from absorption of ionizing radiation and releasing this energy in the form of visible light when heated. The amount of light released can be used as a measure of absorbed dose.

WEIGHTING FACTOR:
The proportion of the risk of stochastic effects for an organ or tissue when the whole body is irradiated uniformly.

X-RAY:
Electromagnetic radiation (photon) of non-nuclear origin having a wavelength shorter than that of visible light.

Measurement Units Conversion Table

Système International (SI) Units *1 Bq = 1 disintegration/second

The rad (rad) is replaced by the gray (Gy)

1 kilorad (krad)	=	10 grays (Gy)
1 rad (rad)	=	10 milligrays (mGy)
1 millirad (mrad)	=	10 micrograys (μGy)
1 microrad (μrad)	=	10 nanograys (nGy)

The gray (Gy) replaces the rad (rad)

1 gray (Gy)	=	100 rad (rad)
1 milligray (mGy)	=	100 millirad (mrad)
1 microgray (μGy)	=	100 microrad (μrad)
1 nanogray (nGy)	=	100 nanorad (nrad)

The rem (rem) is replaced by the sievert (Sv)

1 kilorem (krem)	=	10 sieverts (Sv)
1 rem (rem)	=	10 millisieverts (mSv)
1 millirem (mrem)	=	10 microsieverts (μSv)
1 microrem (μrem)	=	10 nanosieverts (nSv)

The sievert (Sv) replaces the rem (rem)

1 sievert (Sv)	=	100 rem (rem)
1 millisievert (mSv)	=	100 millirem (mrem)
1 microsievert (μSv)	=	100 microrem (μrem)
1 nanosievert (nSv)	=	100 nanorem (nrem)

The curie (Ci) is replaced by the becquerel (Bq)*

1 kilocurie (kCi)	=	37 terabecquerels (TBq)
1 curie (Ci)	=	37 gigabecquerels (GBq)
1 millicurie (mCi)	=	37 megabecquerels (MBq)
1 microcurie (μCi)	=	37 kilobecquerels (kBq)
1 nanocurie (nCi)	=	37 becquerels (Bq)

The becquerel (Bq)* replaces the curie (Ci)

1 terabecquerel (TBq)	=	27 curies (Ci)
1 gigabecquerel (GBq)	=	27 millicuries (mCi)
1 megabecquerel (MBq)	=	27 microcuries (μCi)
1 kilobecquerel (kBq)	=	27 nanocuries (nCi)
1 becquerel (Bq)	=	27 picocuries (pCi)