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Canadian Society of Hospital Pharmacists
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Radiopharmacy: Guidelines for Healthcare Facility Pharmacies

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Radiopharmacy Guidelines: Guidelines for Healthcare Facility Pharmacies

PREFACE

This is the 1998 edition of the Canadian Society of Hospital Pharmacists Radiopharmacy: Guidelines for Healthcare Facility Pharmacies

These guidelines were approved under the title of Guidelines for the Practice of Radiopharmacy; the title was fine-tuned in 2009.

1. SCOPE

These Guidelines set forth basic requirements for the practice of Radiopharmacy in Canadian hospitals.

2. GLOSSARY OF TERMS, ABBREVIATIONS, AND SYMBOLS

The following definitions apply for terms used in these guidelines. They may have different meanings in other contexts.

Commercially available (product)	A product authorized for use in Canada by the Therapeutic Products Directorate of Health Canada, and marketed in Canada. Radiopharmaceuticals do not have DIN numbers.
Investigational drug	A medication approved by the Health Protection Branch for limited clinical use in Canada by approved investigators.
Levels of service	**Level 1** - all radiopharmaceuticals are purchased in their final form either in unit dose or multi-dose containers. **Level 2** - short-lived radiopharmaceuticals are prepared in house using radionuclide generators and commercially available radiopharmaceutical kits. Some radiopharmaceuticals are also purchased in their final dosage form. **Level 3** - radiopharmaceuticals may be manufactured from raw materials. Research and development may be performed. Includes radiolabelling of autologous blood cells using open containers in a laminar flow hood.
Radiopharmacy	The procurement, preparation, quality control and dispensing of radiopharmaceuticals for diagnostic or therapeutic use in patients referred to the nuclear medicine department of a hospital. It includes the provision of clinical services pertaining to the use of radiopharmaceuticals for nuclear medicine or other patient studies.
Radiopharmaceutical kits	Reagents which are used for the preparation of radiopharmaceuticals. Radioactive material must be added to prepare the final dosage form.
Radiopharmaceuticals	Radioactive drugs used in the diagnosis and treatment of disease.

3. PERSONNEL

3.1 General Principles

3.1.1

The radiopharmacist should be a pharmacist licensed with the provincial pharmaceutical licensing body.

3.2 Level 1 Service

3.2.1

The major function at this level of service is one of record keeping. Limited quality control is performed. This may be performed by staff of the Department of Nuclear Medicine, under the guidance of the pharmacy department.

3.3 Level 2 Service

3.3.1

This level of service may require a minimum of 0.5 to 1.0 full-time equivalent staff, depending on the scope of the service. The staff may include a qualified radiopharmacist or a nuclear medicine technologist certified by the provincial regulatory authority.

3.3.2

This service should be staffed by a qualified radiopharmacist. A qualified radiopharmacist should have completed one of the following:

a) a bachelor's degree in pharmacy followed by a nuclear pharmacy residency, or
b) a bachelor's degree in pharmacy followed by a postgraduate degree in nuclear pharmacy from a recognized university.

3.4 Level 3 Service

3.4.1

The number of staff required at this level of service is dependent upon the scope of the service but is a minimum of 2.0 full-time equivalents.

3.4.2

Pharmacists working in this pharmacy should be qualified radiopharmacists, preferably with an advanced degree, especially if significant research and development work is to be undertaken.

4. PREMISES

4.1 General Principles

4.1.1

General principles for the premises of a radiopharmacy fall under the Atomic Energy Control Board (AECB) regulations. Level 3 service may have additional requirements for the premises in order to meet Good Manufacturing Practice (GMP) regulations. All areas must be inspected by AECB prior to the granting of a license.

4.1.2

There shall be adequate, clean, well lighted laboratory space for the radiopharmacy.

4.1.3

The facilities should be in close proximity to the nuclear medicine department to encourage clinical radiopharmacy services.

4.1.4

Basic radiation safety equipment such as an area radiation monitor, lead glass table top shield and

syringe shields, lead containers and lead bricks shall be in place.

4.2 Level 1 Service

4.2.1

The premises for this level of service should include:

a) radioisotope calibrator and reference standards;
b) refrigerator and storage cabinets or shelves;
c) storage for record files; and
d) fume hoods where applicable.

4.3 Level 2 Service

4.3.1

The available space at this level of service should be divided into three distinct sections:

a) production;
b) quality control and dispensing; and
c) administration.

4.3.2

In addition to the equipment of the Level 1 service, the production area should be equipped with:

a) a fume hood and/or vertical laminar flow hood;
b) Molybdenum-99 shield assay system; and
c) a shielded water bath.

4.3.3

The quality control area should be equipped with:

a) basic chromatography system;
b) suitable equipment for the measurement of small amounts of radioactivity (i.e., gamma counter);
c) microscope and hemocytometer; and
d) centrifuge (if blood separation and/or labelling is performed).

4.3.4

The administrative area should be physically separate from any area of radioactivity and should be equipped with:

a) desk space; and
b) storage for record files.

4.4 Level 3 Service

4.4.1

The requirement for the premises of a Level 3 Radiopharmacy Service is determined by the institution. The current GMP Guidelines should be followed in the design and operation of the radiopharmacy facility and may include the following:

a) vertical laminar flow hood in a separate enclosed room;
b) pH meter and electrodes;
c) analytical balance;
d) centrifuge;
e) autoclave;
f) multichannel analyzer;
g) access to high performance liquid chromatography (HPLC) equipment; and
h) access to animal facilities and microbiology expertise if significant research is to be performed.

5. ORDERING AND RECEIPT OF RADIO-PHARMACEUTICALS

5.1

Only radioactive materials listed in the department's Atomic Energy Control Board (AECB) Licence shall be ordered from suppliers.

5.2

On receipt, packages containing radiopharmaceuticals shall be wipe-tested for loose radioactive contamination.

5.3

Radiopharmaceuticals should be assayed for radioactivity upon receipt using a radioisotope dose calibrator.

5.4

Contaminated radioactive packages shall be reported to the supplier and/or the AECB.

5.5

Radiopharmaceuticals shall be stored under the conditions suggested by the manufacturer.

5.6

Records of receipt should be maintained for a period of at least five years.

6. QUALITY CONTROL

6.1 Level 1 Service

Quality control shall be limited to the assay of the radioactive dose prior to administration and dose calibrator quality control, since the products used in this level of service are prepared commercially.

6.2 Level 2 Service

6.2.1

The pharmacist or certified nuclear medicine technologist shall be responsible for the quality of the products, since the final chemical reaction producing the radiopharmaceutical occurs in-house.

6.2.2

Note: *The necessary quality control is outlined in the current Guidelines for Radiopharmaceutical Quality Assurance in Nuclear Medicine, Therapeutic Products Directorate of Health Canada and should include the following:*

a) radioactivity assay;
b) pH determination;
c) Molybdenum-99 and aluminum ion testing of Technetium-99m eluates;
d) radiochemical purity testing of radiopharmaceuticals;
e) clarity testing; and
f) particle sizing.

6.2.3

Radiolabelling of autologous blood cells using open containers must be done in a laminar flow hood using sterile plasticware and reagents and following a standard operating procedure. No more than one patient's blood will be radiolabelled at one time in the laminar flow hood to avoid cross-contamination.

6.2.4

Radiolabelling of autologous blood cells should only be carried out by a certified nuclear medicine technologist or a pharmacy technician working directly under the supervision of the radiopharmacist.

6.3 Level 3 Service

6.3.1

Quality control measures outlined in 6.2 shall be performed on the finished radioactive products.

6.3.2

Radiopharmaceuticals produced from raw materials shall be prepared in a biological containment cabinet or laminar air flow hood and according to current GMP Guidelines.

6.3.3

Quality control testing should include:

a) sterility testing on each individual batch of kits and retrospective sterility testing on randomly selected batches of final radiopharmaceutical products;
b) pyrogen testing on each individual batch of kits; and
c) additional testing according to current GMP standards for Schedule C drugs.

7. LABELLING

7.1

In addition to the labelling requirements outlined in the CSHP Standards of Practice, section 6.4.3 Medication Labelling, all radioactive materials prepared shall be labelled in keeping with the labelling requirements outlined in the Canadian Food and Drug Regulations and guidelines and shall include:

a) the total amount of radioactivity present;
b) the concentration;
c) the calibration times and date;
d) the specific activity;
e) the statement "CAUTION - RADIOACTIVE MATERIAL";
f) the expiry time;
g) licence number (if applicable); and
h) such additional labelling as required by Health Canada.

7.2

The design of the label shall be clear and legible, to minimize the possibility of medication incidents or discrepancies.

8. TRANSPORT OF RADIOACTIVE MATERIALS

8.1 Transportation within the Institution

8.1.1

All radioactive substances being delivered from a preparation area to an administration area shall be transported in a lead lined container.

8.2 Transportation outside the Institution

8.2.1

The shipping institution shall be responsible for ensuring that radioactive materials are transferred safely and in accordance with AECB and Transport Canada regulations.

Note: *The labelling and packaging of radioisotopes for transport in Canada is governed by the "Transport Packaging of Radioactive Materials Regulations" from the Atomic Energy Control Board. The transport of these items is controlled by the "Transportation of Dangerous Good Regulations" from Transport Canada. In addition, in order to distribute radiopharmaceuticals to an outside institution an Establishment license from Health Canada is required.*

9. INVESTIGATIONAL DRUGS

9.1

Investigational drugs shall be handled according to the CSHP Guidelines for the Use of Investi-gational Drugs in Hospitals.

9.2

The radiopharmacist should be responsible for preparation, quality control and radiopharmaceutical documentation.

9.3

Investigational radiopharmaceuticals shall be labelled as such and placed in a separate, designated area in the radiopharmacy.

9.4

Records shall be kept in accordance with the Therapeutic Products Directorate of Health Canada.

10. DRUG ADVERSE REACTION REPORTING

10.1

Suspected drug adverse reactions to radiopharmaceuticals should be reported to the Radio-pharmaceutical Division, Bureau of Biologics and Radiopharmaceuticals using the form “Appendix 1 - Drug Problem Reporting Program” outlined in Reference 1.

11. EDUCATION

11.1

The radiopharmacist shall participate in continuing education in nuclear pharmacy and should meet the continuing education requirements of the provincial licensing body.

11.2

The radiopharmacist should participate in the provision of education to other health care professional. Examples of such opportunities are:

a) in-service education for nuclear medicine technologists and students;
b) in-service education for other pharmacists, physicians, nurses, medical and pharmacy students, and residents; and
c) lecturing within the scientific community.

12. PATIENT-ORIENTED SERVICES

12.1

The radiopharmacist should participate in a clinical role. Examples of such opportunities are:

a) the provision of drug information related to radiopharmaceuticals;
b) monitoring for drug-radiopharmaceutical interactions and adverse reactions; and
c) liaison with nuclear medicine physicians regarding unexpected biodistribution of radiopharmaceuticals.

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