REGULATORY GUIDE FOR APPLICATION FOR LICENSING OF MEDICAL USE OF SEALED / UNSEALED RADIOACTIVE MATERIAL

QUALITY ASSURANCE AND REGULATORY DIVISION
MINISTY OF HEALTH

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EXHIBITS

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE.

This regulatory guide is intended to assist applicants who are preparing an application for a license for the medical use of sealed / unsealed radioactive material and this guideline applies to any government or private health facility subject to obtain registration and operating license from the Quality Assurance and Regulation Division (QARD), Ministry of Health (MoH) to provide any medical service using unsealed radioactive material. QARD reserves the right to develop and amend the standards and guidelines for the service under chapter 3 of the "Health services Act" (29/2015).

Ministry of Health believes that an effective radiation safety program management is vital to safe operations that comply with International Atomic Energy Agency |regulatory requirements. To ensure adequate management involvement, a management representative must sign the submitted application acknowledging the management's commitment to and responsibility for the establishment of an effective radiation safety program to keep individual and collective doses as low as reasonably achievable (ALARA); and the provision of adequate resources (including space, equipment, personnel, time, and if needed, contractors) for the implementation of the radiation safety program to ensure that the general public and radiation workers are protected from radiation hazards.

1.2 APPLICABLE REGULATIONS.

- R1057-2019, "Regulation on dangerous chemicals", published in the Official Gazette, 2019.
- 29/2015, "Health Services Act", published in the Official Gazette, 2015
- 13/2015, "Health Professionals Act", published in the Official Gazette, 2015
- R-46/2014, "Medicine Regulation", published in the Official Gazette, 2014.
- R1059-2019, "Regulation on registration and licensing of health facilities

It is the responsibility of applicants to obtain copies of the regulations specified above and to read and abide by the provisions of these regulations that apply to the medical use of sealed /unsealed radioactive materials and associated radioactive sources.

2. FILING AN APPLICATION

Complete, "Application for Radioactive Material License for Medical Use of Sealed / Unsealed Radioactive Material". The application must include all information necessary to support its intended purpose. Completeness of submitted information will be determined by the reviewer before the application is docketed.
This license to operate does not restrict the facility to obtain any relevant license from other institutions / ministries applicable for the operation of the service
Registration / License to use radioactive material for medical use and / or calibration should be obtained from Maldives food and drug authority, Ministry of Health, Maldives
Registration / License to import radioactive material for medical use and / or calibration of medical equipment should be obtained from Ministry of Defence, Maldives

3. CONTENTS OF APPLICATION

This portion of the regulatory guide explains, item by item, the information requested in the form.

- New license, tick sub-item A.
- An amendment to an existing license, tick sub-item B.
- Renewal of an existing license, tick sub-item C.

ITEM 1. NAME AND MAILING ADDRESS OF APPLICANT.

List the applicant's legal name, mailing address, the name of the director or chairman of the institution, telephone number, and email address. The applicant may be a hospital, medical centre, medical clinics or a government institution. The name and signature of the individual who has the authority and responsibility over the radioactive material and the proposed use shall appear in the application, indicating his title or position in the institution.

ITEM 2. PERSON TO BE CONTACTED ABOUT THE APPLICATION.

Identify a contact person, usually the Radiation Safety Officer (RSO), who can answer questions about the application. The position or title, address, telephone number, and e-mail address of the contact person must be specified. The Quality Assurance & Regulation Division (QARD) must be notified if any of these information changes. Notification of these changes is for information purposes only and would not be considered an application for a license amendment unless the notification involves a change in the contact person who is also the RSO.

ITEM 3. LOCATION(S) OF USE.

Specify the location of use by the building number, department, street address, city/town. If the sealed / unsealed radioactive material is to be used at more than one location, provide the specific address of each location.

ITEM 4. RADIOACTIVE MATERIAL(S) AND PURPOSE(S) OF USE.

4.1 Unsealed Radioactive Material(s)

Using the table below as a guide, identify each radioactive material by indicating the radionuclide (e.g. I-131, Tc-99m), chemical and/or physical form, maximum amount to be possessed at any one time in megabecquerels (MBq). For unsealed radioactive materials, the maximum amount requested must be specified. The applicant should define the purpose of use by describing the applicable modality (e.g., any uptake, dilution, excretion, imaging or localization procedure). The use of unsealed radioactive material in therapy involves administering a radiopharmaceutical, either orally or intravenously, to treat or palliate a particular disease.

The following format may be used:

Radionuclide (Element-Mass Number)	Chemical/Physical Form	Max. Amount to be Possessed at Any One Time (MBq)	Purpose of Use
Tc-99m	Sodium Pertechnetate Solution	3700	For diagnostic imaging
I-131	Sodium Iodide Capsule	740	For thyroid therapy
I-125	Prepackaged Kits	7.4	Radioimmunoassay
F-18	Fluorodeoxyglucose	9250	PET imaging

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included (i.e., materials received awaiting use, materials in use or possessed, material classified as waste awaiting disposal or held for decay-in-storage).

A radiopharmaceutical that contains more than 150 Bq of molybdenum-99 per MBq of technetium-99m may not be administered to humans. The applicant who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical should measure the molybdenum-99 concentration in each eluate or extract.

Response from Applicant:

- Identify each radionuclide and include all information as described above.
- Attach MFDA-approval certificate or its equivalent for each radionuclide for its specific purpose of use.

4.2 Sealed Sources

Sealed sources such as those used for calibration, transmission and reference must be identified, including the manufacturer, distributor (foreign or local) and model/serial number. The maximum amount to be possessed at any one time in Becquerels (Bq) of each source must be indicated, as well as the purpose of use.

Sealed sources are required to be tested for leakage annually. The licensee shall keep a record of leak test results in units of Bq and retain the record for QARD inspection for 2 years after the leak test is performed or until the sealed sources are transferred or disposed. A model procedure for leak testing of sealed sources can be found in **Appendix L**.

Response from Applicant:

- Identify each sealed source and submit information as described above.

ITEM 5. RADIATION WORKERS AND THEIR TRAINING AND EXPERIENCE.

5.1 Radiation Safety Officer (RSO).

The regulation provides for the appointment of an RSO for the day-to-day oversight of the Radiation Safety Program. The RSO should ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the course of daily operation.

In order to fulfil the duties and responsibilities (found in **Appendix C**), the RSO must be on site to oversee licensed activities. An organization may employ a person to specifically fulfil the role or appoint an existing employee. The resources required to reasonably fulfil the responsibilities of an RSO will vary depending on the size and activities of the organization. The Assistant RSO will perform the duties and responsibilities of the RSO in his/her absence.

The individuals designated as RSO or ARSO must have successfully completed the applicable training and experience requirements within five (5) years before the date of application. A description of the relevant training and experiences of the RSO and ARSO must be made available to show that the proposed individuals are qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use.

Appendix F provides a list of broad topics related to radiation protection, safety assurance and quality assurance for professionals in nuclear medicine. The training should include subjects as applicable to the duties and responsibilities of the individual.

Response from Applicant:

- Specify the names of the proposed RSO and ARSO, their telephone/mobile numbers and email addresses;
- Submit the Delegation of Authority, as in **Appendix B**, duly signed by the designated RSO and ARSO;
- Fill out the attachment to the form number; **MOH-QA/F/23/136-0** as "**Attachment A**" "**MEDICAL USE TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION**"; and
- Attach proofs of compliance, i.e. copies of diploma, PRC license (as applicable), certificate/s of training, and proof of one (1) year relevant fulltime experience.

***Note**: It is important to notify QARD and obtain a license amendment prior to making changes in the designation of the RSO and ARSO responsible for the radiation safety program. If the RSO leaves the organization before an amendment is approved by the QARD, the ARSO shall be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the ministry regulations and specific license conditions.*

5.2 Authorized User(s).

The applicant should designate/appoint an individual to act as Authorized User (AU) who is qualified by training and experience. Authorized Users involved in medical use of unsealed radioactive material have the following special responsibilities:

(1) Examination of patients and medical records to determine if a radiation procedure is appropriate;
(2) Prescription of the radiation dose and route of administration.;
(3) Preparation of written directives;
(4) Actual use of, or direction of technologists or other paramedical personnel, in the use of radiopharmaceuticals;
(5) Interpretation of results of diagnostic nuclear medicine imaging or interpretation of results of Radioimmunoassay procedures only; and
(6) Evaluation of results of therapy using unsealed radioactive materials.

For in-vitro studies, the list of proposed AU(s) should include those individuals who will actually be responsible for the safe use of unsealed radioactive material for the requested use.

Authorized User(s) are required to have obtained a certification in radiation safety protection on top of the relevant academic qualification specific to the profession. A description of the relevant trainings and experience should be made available to demonstrate that the proposed AU is qualified by training and experience for the use(s) requested.

Response from Applicant:

- Submit the names of the proposed Authorized User(s), their telephone/mobile number and email address;
- Fill out the attachment to the **MOH-QA/F/23/136-0** as "**Attachment A" "MEDICAL USE TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION**"; and
- Attach proofs of compliance, i.e. copies of diploma, PRC license, certificate/s of training, and proof of two (2) years relevant fulltime experience.

5.3 Medical Physicist.

The roles and responsibilities of the medical physicist in nuclear medicine include dosimetry, image quality, optimization, research and teaching, radiation safety, quality assurance and equipment management. The medical physicist‟s knowledge of the complex techniques and equipment involved in modern diagnosis and treatment of disease are essential to the safe and effective application of nuclear medicine procedures.

Referring to IAEA Human Health Series No. 25 (IAEA, 2013) which establishes the following main responsibilities and functions of a clinically qualified medical physicist in nuclear medicine:

(1) Installation design, technical specification, acceptance, commissioning and maintenance of equipment, including the establishment of criteria for acceptable performance.
    - Be an essential part of the team for the shielding and installation design of new or modified facilities, ensuring that safety requirements are complied with;

- Leads the development of equipment specifications;
- Has responsibility for the acceptance and commissioning of equipment;
- Provides advice on equipment decommissioning.

(2) Radiation safety and protection of patients, staff and the general public.
- Develops the clinical radiation safety program for radiation protection of patients, staff and the public;
- Participates in the investigation of radiation incidents and accidents;
- Develops procedures for verifying the integrity, safe operation and use of nuclear medicine equipment and radioactive sources.

(3) Patient internal dosimetry.
- Performs activity measurements and calculation of dose received by different organs following the administration of radiopharmaceuticals in the various clinical procedures;
- Performs patient specific dose calculations, establishing tolerances.

(4) Optimization of the physical aspects of diagnostic procedures.
- Optimizes data acquisition processes and procedures to improve image quality while minimizing dose to patients;
- Assists nuclear medicine practitioners in evaluating examination efficacy and in image quality and perception studies.

(5) Quality management of the physical and technical aspects of nuclear medicine. Participates as a team member in designing and implementing a quality management program, being responsible for:
- Developing institutional policies and procedures for the continuous optimization of radiation use;
- Establishing and implementing a quality assurance program with appropriate elements for the handling and measurement of radioactive sources and regulatory compliance of imaging and dosimetry equipment;
- Performing risk assessment, identifying potential radiation exposures and developing action procedures for such events;
- Investigating unintended or accidental medical exposures.

(6) Collaboration with other clinical professionals.
- Provides consultation to nuclear medicine medical practitioners on special cases of diagnostic exploration or treatment and assist to establish the optimized approach of each case;
- Assists to introduce new clinical procedures, develop methods for their quality assurance and control, and supervise their implementation.

The medical physicist need not be employed full-time but the degree of his or her involvement is determined by the complexity of the procedures and associated risks. He/She may be assisted by properly trained individuals in obtaining data for performance monitoring. However, the medical physicist is still responsible for the interpretation and approval of all data, including the duly signed conclusion report.

Applicants/licensees must require the Medical Physicist to have successfully completed the applicable training and have met the experience requirements. A description of the relevant trainings and experience should be made available to demonstrate that the proposed Medical Physicist is qualified by training and experience for the use(s) requested.

Response from Applicant:

- Submit the name of the proposed Medical Physicist, his/her telephone/mobile number and email address;
- Fill out the attachment to the **MOH-QA/F/23/136-0** as "**Attachment A" "MEDICAL USE TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION**"; and
- Attach proofs of compliance, i.e. copies of diploma, transcript of records, certificate/s of training, and proof of one (1) year relevant fulltime experience and health professional license from the relevant professional body.

5.4 Nuclear Medicine Technologist(s).

The Nuclear Medicine Technologist / radiographer with radiation safety training, is directly involved with the preparation of radiopharmaceuticals under the supervision of the Authorized User. The Nuclear Medicine Technologist / radiographer should have obtained a certification in radiation safety protection on top of the relevant academic qualification specific to the profession. A description of the relevant trainings and experience should be made available to demonstrate that the proposed Nuclear Medicine Technologist is qualified by training and experience for the use(s) requested.

Response from Applicant:

- Submit the name(s) of the proposed Nuclear Medicine Technologist(s), his/her telephone number and email address;
- Fill out the attachment to the **MOH-QA/F/23/136-0** as "**Attachment A" "MEDICAL USE TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION**"; and
- Attach proofs of compliance i.e. copies of diploma, PRC license, certificate/s of training, and proof of six (6) months relevant fulltime experience. And health professional license from the relevant professional body.

ITEM 6. FACILITIES AND EQUIPMENT.

6.1 Facility Design and Safety Equipment.

Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep radiation exposures ALARA, and minimize the danger to life and property from the licensed activities. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, types of radioactive emissions, amount and form of radioactive materials possessed). Particular attention should be given to licensed activities using large quantities of radioactive materials; steps in preparing liquids, gases, and volatile radioactive materials; and the use of high-energy photon-emitters and high-energy beta-emitters.

In preparing the layout of the facility, the diagram must include the room(s) and adjacent areas where radiopharmaceuticals are received, prepared, used, administered, and stored (See **Figure 1** Sample Nuclear Medicine Facility Layout). A description of the additional safety equipment (e.g., fume hood, L-blocks, fixed area monitors, remote handling equipment), therefore, must also be provided. If the applicant has a radionuclide delivery line from a PET

radiopharmaceutical production area, a description of the room, location, and delivery line should be provided. For facilities that operate a small RIA laboratory for in-vitro studies, two dedicated rooms are required – one for counting and the other for the preparation and storage of radioactive materials. All information regarding an area or room should include a description of shielding requirements and dose calculations for adjacent areas and rooms, including those above and below the dedicated rooms.

Figure 1: Sample Nuclear Medicine Facility Layout

The applicant should provide areas to be used for radiopharmaceutical administration and patient isolation rooms (e.g. private room with private bath). If the radionuclide is administered in volatile liquid form, such as in radioactive iodine therapy, it is important to place the patient dosage in a closed environment (e.g., a fume hood). Also note that there are hazards associated with volatile iodine in solid (pill) form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

Performance testing of fume hood is required to be performed at least annually. The usual method used in performance evaluation is the measurement of face velocity. Face velocity is the average velocity of air moving perpendicular to the hood face, usually expressed in feet per minute (fpm) or meters per second (m/s). The ability of the fume hood to capture and contain hazardous fumes and vapours is often equated to its face velocity. The recommended average face velocity is **0.6 – 1 m/s** (125 - 200 fpm) and a minimum face velocity of **0.5 m/s** (100 fpm) to ensure that no radioactive material contaminant would escape. Air changes per hour is a measure of the number of times the air within an enclosed space is replaced. The Occupational Safety and Health Administration (OSHA) recommends **4 – 12 air changes/hour** indicating a normally adequate general ventilation if local exhaust systems such as fume hood are used as the primary method of control. A model procedure for fume hood performance testing can be found in **Appendix O**.

Response from Applicant:

- Submit an annotated diagram of the facility where unsealed radioactive materials are prepared, used, and stored. Drawing should be to scale, and the scale must be indicated in the diagram. Identify the room numbers and/or principal use of each room or area (e.g., in-vitro, hot lab, waiting area, examination area, imaging, post-administration room, quiet room, isolation room, fresh materials storage, radioactive waste storage, office, toilet, hallway, the location of direct transfer tubes from a PET radiopharmaceutical production facility). This should also indicate whether the room is controlled as defined in IAEA standards.
- Provide a description and assessment of the adequacy of shielding design, including information about the type, thickness, and density of any necessary shielding used (e.g., shielding of proposed isolation rooms, shielding for PET radionuclide direct transfer tubes); and
- Provide a description of the additional safety equipment.

6.2 Nuclear Medicine Imaging and Non-imaging Equipment.

Nuclear medicine depends significantly on the accurate and reproducible performance of the following clinical imaging and counting equipment, depending on the scope of the applicant's operation:

- Dose Calibrator and Other Equipment Used to Measure Dosages of Radiopharmaceuticals;
- Gamma camera;
- Single and Multi-probe Counting Systems for Gamma-Radiation Measurements – In vivo;
- Manual and Automatic Counting Systems for Gamma-Radiation Measurements – In vitro;
- Single Photon Emission Computed Tomography (SPECT);
- Positron Emission Tomography (PET); and
- Hybrid systems such as SPECT/CT; PET/CT.

A dosage measurement is required for applicants who prepare patient dosages. If the applicant performs direct measurements in accordance IAEA standards, the applicant is required to possess an instrument used to measure dosages (e. g., dose calibrator, well ionization chamber) which is calibrated in accordance with nationally recognized standards or the manufacturer's instructions. The procedure of calibrating a dose calibrator can be found in **Appendix S, Part B** which must be submitted as part of the Radiation Safety Program.

An appropriate quality assurance program is required in order to attain high standards of efficiency and reliability in the practice of nuclear medicine with the active participation of medical physicists, medical practitioners, nuclear medicine technologists, radio pharmacists and radiochemists, and in conjunction with other health professionals as appropriate. ISO defined quality assurance as "the assembly of all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. The term „quality control" is used in reference to the specific measures taken to ensure that one particular aspect of the procedure is satisfactory. A clear distinction between these terms should be made.

Each equipment must be in good condition and that the instructions and procedures concerning its use are appropriate. The acceptance of the equipment following its receipt and installation is a critical step towards the achievement of high quality and acceptable performance, and should be subject to careful testing. Acceptance testing is undertaken to ensure that the performance of the equipment meets the technical and performance specifications quoted by the manufacturer. This test should be carried out immediately after installation so that the supplier can be informed of any damage, deficiencies or flaws before the warranty has expired. At the time of acceptance testing, reference tests should be carried out, from the results of which the subsequent performance of the equipment may be assessed during routine testing. Performance testing should be carried out regularly, on a weekly, monthly, quarterly and annual basis, to ensure its optimum performance at all times and to determine the rate and extent of any deterioration in that performance with time. Finally, operational checks, carried out each day the instrument is used, should be put in force. Careful records of the results of all these tests should be kept and, if these reveal unsatisfactory performance, appropriate corrective action should follow. These quality control procedures do not, of course, obviate the need for the usual preventive maintenance procedures, which should still be carried out on a regular basis. The success of such a scheme depends above all on the understanding and acceptance of all concerned. It further requires a clear definition of responsibilities and adherence to test schedules, protocols and proper procedures for the follow-up of test results.

The quality assurance program of all nuclear imaging and non-imaging equipment must be included in the radiation safety program. A guide for the QA/QC of the proposed nuclear medicine equipment can be found in **Appendix J**.

Response from Applicant:

- Specify the type of equipment, manufacturer, model, serial number and the name of the supplier/distributor, and the name and license number of the service provider who will perform calibration.
- For newly-installed nuclear medicine equipment, submit the acceptance testing evaluation report of the proposed equipment, duly signed by a qualified medical physicist.
- For existing medicine equipment, submit the recent annual performance test of the equipment, duly signed by a qualified medical physicist.

6.3 Radiation Detection and Measuring Instruments.

Radiation survey meters are portable, battery-operated gas-filled ionization detectors or solid-state scintillation detectors used to detect and measure ambient radiation levels. As a minimum requirement, the applicant should possess survey meters for area monitoring sufficiently sensitive to measure from 1 uSv/h through 10 mSv/h and a contamination meter capable of measuring nanocurie or Becquerel amounts of activity per unit area (Bq/cm^2).

The following may be considered in selecting the proper instrument to be used in the facility:

(1) Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
(2) Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium

iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

(3) Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

(4) Typical survey instruments shown in the table below (except for items marked with an asterisk (*)), extracted from "The Health Physics & Radiological Health Handbook," Revised Edition, 1992, may be helpful in selecting instruments:

Portable Instruments Used For Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Range**	**Efficiency**
Exposure Rate Meters	Gamma	mR/h – R/h	Not applicable
Geiger-Mueller (GM)	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Gamma	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Range**	**Efficiency**
Gamma Well Counter	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Personnel who are handling or manipulating unsealed radioactive material with tongs or forceps or who are holding partially shielded containers of radioactive material with their hands should wear ring dosimeters. However, these dosimeters are not needed for personnel handling only the types of sources used for in vitro studies.

Calibration of radiation detection and measuring instruments must be performed by a licensed service provider or a licensee who is qualified to perform calibration in accordance to IAEA standards. **Appendix S, Part A** provides guidance on the calibration of radiation detection and measuring instruments.

Response from Applicant:

- Specify the type and quantity of each instrument, manufacturer, model, serial number, operating range (e.g. µSv/h, mSv/h, counts per minute, or counts per second, etc.) of the instrument, the date of last calibration, the name of the supplier/distributor, and the name and license number of the service provider that will perform calibration.

6.4 Personnel Monitoring Devices.

Personnel monitoring devices are instruments that measure radiation doses of an individual from gamma rays, neutron, alpha or beta particles. Individuals who are occupationally exposed are required to wear personnel monitoring devices such as direct reading pocket dosimeters or monitoring badges such as thermoluminescent dosimeter (TLD) or optically stimulated luminescence dosimeter (OSL). These devices must be worn in such a way that the part of the body likely to receive the greatest dose will be monitored. Licensed activities should not be performed if one of the required dosimeters is missing or inoperable. Each monitoring device must be assigned to, and worn only by one individual. It must also be protected from moisture, intense heat or light, and chemicals and must not be stored or placed in close proximity to radiation sources or radiation-emitting devices. If direct reading pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration.

All personal dosimeters must be processed and evaluated by a licensed service provider or a licensee who is qualified to perform dosimetry services as per IAEA standards and regulations. Records of radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body by the individual must be made available for QARD inspection.

A Personnel Motoring Program should be submitted as part of the Radiation Safety Program. A sample of which can be found in **Appendix E**.

Response from Applicant:

6.4.1 Passive Dosimeters

- Specify the type of personnel monitoring device (e.g., TLD, OSL), the number of units (quantity), the type of radiation detected (e.g., gamma, beta, neutron), the type of monitoring (e.g., whole body, extremities), frequency of change (e.g., every two months), and the names and addresses of the suppliers.

6.4.2 Direct Reading Dosimeters

- Specify the type of direct reading dosimeter (e.g., pocket dosimeter), the range, frequency of calibration, the date of last calibration, and the names and addresses of the suppliers;

ITEM 7. RADIATION SAFETY PROGRAM

Applicants must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation safety program during the licensing process. The appendices in this guide may be helpful in determining what information should be provided when applying for a license.

The table below presents all programs and procedures that are required to be included in your Radiation Safety Program. You may choose to adopt the model procedures or programs found in **Appendices A** to **V** of this Regulatory Guide or you may develop an equivalent procedure

or program for review by the QARD staff. Each procedure or program of the Radiation Safety Program must be customized to reflect the current practices or information of the facility.

Item	Title	Appendix
7.1	Organization, Duties and Responsibilities of Radiation Safety Committee	A
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7.6	Training Program	F
7.7	Procedure for Ordering, Receiving and Opening of Packages Containing Radioactive Materials	G
7.8	Procedure for Keeping Records of Radiopharmaceutical Use/ Dosages	H
7.9	Procedures for Developing, Maintaining, and Implementing Written Directives	I
7.10	QA/QC of the Proposed Nuclear Medicine Imaging and Non-imaging Equipment	J
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7.16	Radiation Safety During Radionuclide Therapy	P
7.17	Procedure for Hospital Care and Handling of Radioactive Patients, including Procedure for Release of Patients After Radionuclide Therapy	Q
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7.19	Procedure for Calibration of Instruments	S
7.20	Procedure for Radioactive Waste Disposal and Decay-in-Storage	T
7.21	Procedure for Safe Handling of Dead Persons that Contain Unsealed Radioactive Material	U
7.22	Emergency Plan	V

Response from Applicant:

- Submit a copy of each procedure/program stated above in the table. If you submit a copy of the model procedure or program, edit the content to identify key individuals, equipment by name or model, room numbers, or other specific information. Complete the application by marking the appropriate box for each procedure.

ITEM 8. CERTIFICATION

The application should be certified, signed and dated by an authorized representative of the institution, usually the Managing Director, Chief Executive Officer or Medical Director. Otherwise, a letter from such a person should be included affirming the signing authority of the representative who signed the application in his/her behalf. Unsigned applications will not be processed and will be returned to the applicant.

4. TERMINATION OF ACTIVITIES

Prior to informing QARD, a licensee who decides to terminate a license must determine whether residual radioactivity is present at the facility and whether the levels make the building or outdoor area suitable for release according to ministry requirements. A licensee's determination that a facility is not contaminated is subject to verification by ministry.

Response from Applicant:
The licensee is not required to submit a response to the ministry during the initial application. However, when the licensee decides to cease operations, any necessary decommissioning activities must be undertaken and information relevant to decommissioning must be submitted to QARD at least six (6) months before the start of decommissioning activities.

APPROVED:

(Sgd.) NAME OF DIRECTOR

Date:

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MOH-QA/F/23/136-0

Quality Assurance and Regulation Division
Ministry of Health
Male', Republic of Maldives

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

1. NAME AND COMPLETE ADDRESS OF APPLICANT.

Hospital/Institution _____
Address _____
Director/Chairman of the Institution _____
Telephone and Mobile Numbers _____
Fax Number _____
E-mail Address _____

2. PERSON TO BE CONTACTED ABOUT THIS APPLICATION.

Name _____
Position/Title _____
Address _____
Telephone and Mobile Numbers _____
Fax Number _____
E-mail Address _____

3. LOCATIONS OF USE.

Address Telephone _____
Number _____

4. RADIOACTIVE MATERIALS AND PURPOSE(S) OF USE.

4.1 Unsealed Radioactive Materials for Medical Use

Radionuclide (Element/Mass Number)	Chemical/Physical Form	Max. Amount to be Possessed at Any One Time (MBq)	Purpose of Use

4.2 Sealed Sources

Radionuclide (Element/Mass Number)	Manufacturer	Model/ Serial Number	Number of Units (Quantity)	Purpose of Use

5. RADIATION WORKERS AND THEIR TRAINING AND EXPERIENCE.

Worker	Name	Telephone Number	E-mail Address
Radiation Safety Officer (RSO)			
Assistant RSO			
Authorized Users (Physicians)			
Medical Physicist/s			
Nuclear Medicine Technologists			

6. FACILITIES AND EQUIPMENT.

6.1 Facility Design and Safety Equipment

	Attached	Remarks
Layout of the Facility	☐	_____
Shielding Design/Calculations	☐	_____
Additional Safety Equipment	☐	_____

6.2 Nuclear Medicine Imaging and Non-imaging Equipment

Type of Equipment	Manufacturer	Model	Serial Number	Supplier/ Distributor	Organization to Perform Calibration

	Attached	Remarks
Acceptance Testing Report of _____	☐	_____
Performance Testing Report of _____	☐	_____

6.3 Radiation Detection and Monitoring Instruments

Type/Quantity of Instrument	Model/ Serial Number	Sensitivity Range	Manufacturer /Distributor	Date of Last Calibration	Organization to Perform Calibration

6.4 Personnel Monitoring Devices

6.4.1 Passive Dosimeters

Type	Quantity	Type of Radiation Detected	Type of Monitoring	Frequency of Change	Name and Address of Supplier(s)

6.4.2 Direct Reading Dosimeters

Type	Quantity	Range	Frequency of Calibration	Date of Last Calibration	Name and Address of Supplier
Pocket Dosimeter					
Others					

7. RADIATION SAFETY PROGRAM.

Item	Appendix	Title	Procedure Attached	N/A	Remarks
7.1	A	Organization, Duties and Responsibilities of Radiation Safety Committee / Implementation of quality management system			
7.2	B	Designation of a Qualified RSO and ARSO	☐	☐	
7.3	C	Duties and Responsibilities of the RSO	☐	☐	
7.4	D	ALARA Program	☐	☐	
7.5	E	Personnel Monitoring Program	☐	☐	
7.6	F	Training Program	☐	☐	
7.7	G	Procedure for Ordering, Receiving and Opening of Packages Containing Radioactive Material	☐	☐	
7.8	H	Procedure for Keeping Records of Radiopharmaceutical Use/ Dosages	☐	☐	
7.9	I	Procedures for Developing, Maintaining, and Implementing Written Directives	☐	☐	
7.10	J	QA/QC of the Proposed Nuclear Medicine Imaging and Non-imaging Equipment	☐	☐	
7.11	K	Rules for Safe Use of Radiopharmaceuticals	☐	☐	
7.12	L	Procedure for Leak Testing of Sealed Sources	☐	☐	
7.13	M	Procedure for Radiation Area Monitoring	☐	☐	
7.14	N	Procedure for Minimization of Contamination and/or Spill	☐	☐	
7.15	O	Model Procedure for Monitoring, Calculating, and Controlling Airborne Concentrations, including Procedure for Performance Testing of Fume Hood	☐ ☐	☐ ☐	
7.16	P	Radiation Safety During Radionuclide Therapy			
7.17	Q	Procedure for Hospital Care and Handling of Radioactive Patients, including Procedure for Release of Patients After Radionuclide Therapy	☐ ☐	☐ ☐	
7.18	R	Radiation Safety Precautions and Instructions for Patients	☐	☐	
7.19	S	Procedure for Calibration of Instruments	☐	☐	

7.20	T	Procedure for Radioactive Waste Disposal and Decay-in-Storage	☐	☐	
7.21	U	Procedure for Safe Handling of Dead Persons that Contain Unsealed Radioactive Material	☐	☐	
7.22	V	Emergency Plan	☐	☐	

8. CERTIFICATION:

The applicant understands that all statements and representations made in this application are binding upon us. Further, the applicant and any official executing this certification on behalf of the applicant certify that this application is prepared in conformity with the applicable requirements and that all information contained herein is true and correct to the best of our knowledge and belief.

_____
Signature of Certifying Official

_____
Typed or Printed Name of Certifying Official

_____
Title/Position of Certifying Official

_____
Date

ATTACHMENT A

MEDICAL USE TRAINING AND EXPERIENCE AND SUPERVISOR ATTESTATION

Proposed Authorization:

☐ **Authorized User** ☐ **Medical Physicist**
☐ **Radiation Safety Officer** ☐ **Nuclear Medicine Technologist**

Name of Individual: _____

PRC License No. *(as applicable)*: _____Expiration Date: _____

1" x 1"
ID Photo

1. FORMAL TRAINING

Degree, Area of Study or Residency Program	Name of Program and Name of the Organization that Approved the Program (if applicable)	Location and Inclusive Dates

2. CLASSROOM AND LABORATORY TRAINING IN RADIATION SAFETY

Field of Training	Location of Training	Date of Training	Duration of Training (Hours)		
			Lecture	Laboratory	On-the-Job
a. Radiation Physics and Instrumentation					
b. Radiation Protection					
c. Mathematics pertaining to the Use and Measurement of Radioactivity					
d. Chemistry of Radioactive Material for Medical Use					
e. Radiation Biology					
f. Nuclear Regulations and Licensing					
g. Others					

3. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Radioactive Source/Device	Maximum Amount of Radioactive Source Handled	Where Experience Was Gained	Name of Supervising Individual(s)	Duration of Experience

4. SUPERVISING INDIVIDUAL – IDENTIFICATION AND ATTESTATION

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet the requirements, provide the following information of each)**:**

Name of Supervisor: _____

Address: _____ **Tel. No.:** _____

Supervisor is identified in Radioactive Material License Number _____ **as:**

☐ Authorized User ☐ Medical Physicist

☐ Radiation Safety Officer ☐ Nuclear Medicine Technologist

SUPERVISOR ATTESTATION

I attest that (Name of Individual) has satisfactorily completed _____ (year, months) of relevant fulltime experience required in IAEA standards, Section _____ Paragraph _____ , as documented in this form.

☐ *He/She has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for the medical use of unsealed radioactive material.*

☐ *He/She has achieved a level of competency sufficient to function independently as a/n (Proposed authorization) for the medical use of unsealed radioactive material for (Diagnostic/therapeutic) purposes.*

_____

Name and Signature of Supervisor

Date: _____

I CERTIFY THAT THE INFORMATION GIVEN ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

_____

Name and Signature of Proposed Individual

Date: _____

Endorsed by the Radiation Safety Committee:

_____

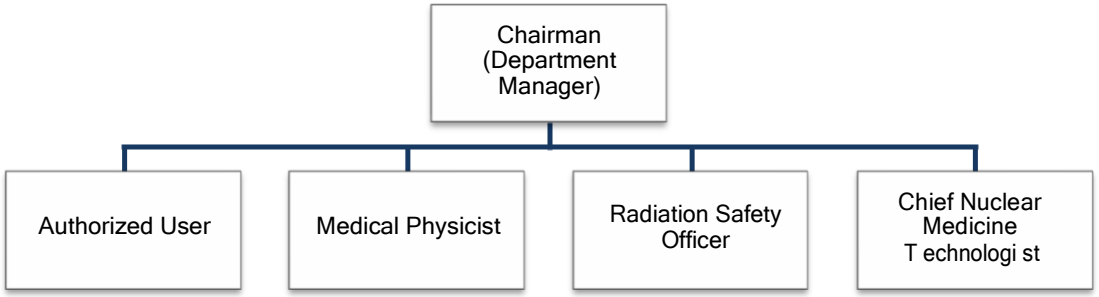
Name and Signature of Chairman of RSC

Date: _____

APPENDIX A

ORGANIZATION, DUTIES AND RESPONSIBILITIES OF RADIATION SAFETY COMMITTEE

Organizational Structure:



Mandate. The Committee shall:

(1) Ensure that radioactive material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;
(2) Ensures that radioactive material is used in compliance with XXXXX regulations and the radioactive material license;
(3) Ensure that the use of radioactive material is consistent with the ALARA philosophy and program;
(4) Establish a table of investigational levels for individual occupational radiation exposures; and
(5) Identify program problems and solutions.

Duties and Responsibilities. The Committee shall:

(1) Be familiar with all pertinent regulations, the license application, the license, and amendments;
(2) Review the training and experience of the proposed authorized users, the authorized technologist, Radiation Safety Officer (RSO), Assistant RSO, and the medical physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
(3) Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all request for authorization to use radioactive material within the institution;
(4) Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users and workers, and special monitoring procedures;
(5) Review semi-annually the RSO"s summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
(6) Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used are appropriately instructed, (e.g., nursing, security, and housekeeping).
(7) Review at least annually the RSO"s summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO,

results of inspections, written safety procedures, and the adequacy of the management control system;

(8) Recommend remedial action to correct any deficiencies identified in the radiation safety program;

(9) Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

(10) Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

(1) The Committee shall meet as often as necessary to conduct its business but not less than twice in each calendar year.

(2) Membership must include at least one authorized user for each type of use authorized by the license, the RSO and/or medical physicist, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping and other departments. (Adjunct members should abstain from voting on radiation safety technical questions such as Items 2 through 5 in the “Duties and Responsibilities” section above).

(3) To establish a quorum, one-half of the Committee‟s membership, including the RSO and the management representative, must be present.

Implementation of quality management system

Annual internal audit using the IAEA quality management system in nuclear medicine should be performed. A summary of findings / radar plot should be submitted together with the application.

APPENDIX B

DESIGNATION OF A QUALIFIED RSO AND ARSO

SAMPLE DELEGATION OF AUTHORITY FOR THE RADIATION SAFETY OFFICER

Memo To: _____, Radiation Safety Officer

From: _____, Department Manager

Subject: **RSO Delegation of Authority**

You, (*Complete name of the RSO*), have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Safety Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of unsealed radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Philippine Nuclear Research Institute at any time. It is estimated that you will spend _____hours per week conducting radiation protection activities.

_____ _____

Signature of Department Manager Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

CC: Affected department heads

APPENDIX C

DUTIES AND RESPONSIBILITIES OF THE RSO

The Radiation Safety Officer shall:

(1) Investigate, document and report to XXXXX overexposures, accidents, spills, losses, and thefts; unauthorized orders, receipts, uses, transfers, and disposals; and other deviations from the approved radiation safety practice and implement corrective actions, as necessary;
(2) Establish and implement written policy and procedures for:
   a) Authorizing the purchase of radiopharmaceuticals;
   b) Receiving and opening packages of radiopharmaceuticals;
   c) Storing radiopharmaceuticals;
   d) Keeping an inventory record of radioactive material;
   e) Using radiopharmaceuticals safely and ensuring that all radiation workers are properly trained;
   f) Taking emergency action in the event of an accident involving radioactive material;
   g) Ensuring the use of personnel monitoring devices as required;
   h) Performing or arranging for leak tests on all radioactive sources;
   i) Performing periodic radiation surveys;
   j) Performing operational checks of survey instruments and other safety equipment;
   k) Disposing of radioactive waste and disused radioactive sources;
   l) Transport of radioactive material or radioactive waste;
   m) Training personnel;
   n) Decommissioning of the facility; and
   o) Keeping a copy of all records and reports required by the regulations, a copy of these regulations, a copy of each licensing request, license and license amendments, and the written policy and procedures required by the regulations.
(3) Interface with regulatory inspectors and provide access to required records for inspection;
(4) Conduct briefings to management once each year on the program of use of unsealed radioactive materials;
(5) Establish investigational levels for personnel exposure, that, when exceeded, will initiate an investigation by the RSO of the cause of the exposure;
(6) Establish higher personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RSO of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;
(7) Conduct review of radiation safety program and ensure that the results of audits, identification of deficiencies and recommendations for change are documented, maintained and provided to management for review. He shall ensure that prompt action is taken to correct deficiencies; and
(8) Assist the Radiation Safety Committee (RSC) in the performance of its duties.

APPENDIX D

MODEL ALARA PROGRAM

1. Management Commitment

a. We, the management of this (*Medical facility, hospital, etc.*) , are committed to the program describe herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if, necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as low as reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this will involve exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)

a. Review of Proposed Radiation Workers and Types of Use
   1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of radioactive materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
   2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA.
   3) The RSC will ensure that the users and workers justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority
   (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program).
   1) The RSC will delegate authority to the RSO to enforce the ALARA concept.
   2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the meeting.

c. Review of ALARA Program
   1) The RSC will encourage all users and workers to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the Investigational Level I Table 1 is exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when trigger levels are exceeded (see Item 6 below for the discussion of trigger levels).*
3) The RSC will evaluate the institution‟s overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety officer (RSO)

a. Annual and Semi-annual Review
   1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
   2) Semi-annual review of occupational exposures. The RSO will review every six months the external radiation doses of authorized users and workers to determine that their doses are ALARA and will prepare a summary report for the RSC.
   3) Semi-annual review of records of radiation surveys. The RSO will review radiation surveys in supervised and controlled areas to determine that dose rates and amounts of contamination were ALARA levels during the previous period and will prepare a summary report for the RSC.

b. Educational Responsibilities for ALARA Program
   1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

   2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures
   Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

   1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
   2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices
   The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses
   1) The Authorized User will consult with the RSO and/or RSC during the planning stage before using the radioactive materials for new uses.
   2) The Authorized User will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User‟s Responsibility to Supervised Individuals
   1) The Authorized User will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
   2) The Authorized User will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions
b. Workers will be instructed in resources available if they feel ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or RSO. The investigational levels that we have adopted are listed in **Table D-1**. These levels apply to the exposure of individual workers. The RSO will review and record results of personnel monitoring at least every six (6) months.

In cases where a worker‟s or group of workers‟ doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

Table D-1. Investigational Levels

	Investigational Levels* (mSv)
1. Total Effective Dose Equivalent	1
2. Lens of the Eye	1
3. Extremities (hands and feet) or to the skin	25

*The investigational levels in this program are not new dose limits but, serve as a check points above which the results are considered sufficiently important to justify investigations. It is based on the recommended monitoring dose equivalent to 3/10 of the annual dose limit for the exposed worker.

7. **Signature of Certifying Official** *

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____
Signature

_____
Name

_____
Title

* The person who is authorized to make comments for the administration of the institution (e.g., hospital administrator)

APPENDIX E

PERSONNEL MONITORING PROGRAM

PROGRAM

(1) The Radiation Safety Officer (RSO) will review, sign and date all exposure reports at least every six months to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a thermoluminescent dosimeter (TLD), or optically stimulated luminescent dosimeter (OSL).

(2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a TLD or OSL whole body monitor that will be processed by a XXXXX service provider or a XXXXX licensee who is qualified to perform dosimetry processor.

(3) All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a TLD or OSL extremity monitor that will be processed by a contract service on a bi-monthly basis.

(4) All individuals who are occupationally exposed to radiation in excess of 5 mSv in a year, such as nurses caring for radiopharmaceutical therapy patients, or entering a high or very high radiation area will be issued a whole body monitor when caring for such patients.

(5) Individuals who are exposed to radiation on an occasional basis are not normally issued exposure monitors. Examples of these individuals are: security personnel who receive or deliver packages; secretarial personnel who work in the nuclear medicine clinic but do not work with patients; and nurses who occasionally care for patients who have received diagnostic dosages.

(6) All personal dosimeters will be processed and evaluated by a dosimetry provider holding a XXXXX license.

RECORDS

(1) For each individual who is likely to receive in a year an occupational dose requiring monitoring, the facility will determine the occupational radiation dose received during the current year and attempt to obtain the records of lifetime cumulative occupational radiation dose.

(2) We will prepare for employee requiring personnel monitoring a report of the radiation exposure data for each affected individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body by the individual. This report will include data and results obtained as required.

(3) Upon the request of the employee, a written report of his/her exposure to radiation at this facility will be given after termination of employment. This report will be furnished to the former employee within 30 days of termination of the employee or within 30 days after the exposure of the individual has been determined by the facility, whichever is later. This report will cover every two months in which case the employee‟s working activities involved the exposure to sources of radiation and shall include dates and location of work under the license in which the worker participated. Records will be maintained for 2 years that indicate these reports were furnished to each employee.

APPENDIX F

MODEL TRAINING PROGRAM FOR RADIATION PROTECTION

Personnel need to be instructed in radiation protection before assuming their duties with, or in the vicinity of, radioactive materials. Refresher training should be conducted every five (5) years or whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material used.

Table F-1 provides lists of broad topics related to radiation protection, safety assurance and quality assurance for professionals in nuclear medicine such as Authorized Users, medical physicists, RSOs, technologists, nurses and maintenance staff. The degree of detail needed for each of these professionals will necessarily differ. Curricula for training should be developed in consultation with the appropriate professional bodies.

The training should include the following subjects, as applicable to the duties and responsibilities of the individual.

Table F-1. Training Program for Radiation Protection.

Module	Contents
1. Radiation Physics	
1.1. Atomic structure	Basic atomic structure
1.2. Interactions of electrons with matter	Bremsstrahlung production Characteristic X ray production Primary and secondary ionization Elastic scattering of electrons
1.3. Interactions of photons with matter	Types of interaction Photoelectric effect Compton scattering Photon attenuation Half-value thickness Beam attenuation and half-value thickness
1.4. Interaction of neutrons with matter	Relevance to cyclotrons producing 8F, 13N, etc.
1.5. Radiation quantities and units	Electronic structure: Quantities and units Exposure and exposure rate Absorbed dose and kerma Mean absorbed dose in a tissue Equivalent dose *H* Effective dose Tissue weighting factors
1.6. Radiation detectors and dosimeters	Basic principles in detection of ionizing radiation (gas filled detectors, scintillation detectors and semiconductor detectors) Personnel dosimetry systems, for example thermoluminescence dosimetry types of monitoring instrument Operating principles and limitations Workplace monitoring
2. Biological Effects of Ionizing Radiation	
2.1. Biological effects of ionizing radiation	Basic concepts in radiobiology Deterministic and stochastic effects Radiosensitivity Factors affecting radiosensitivity Dose-effect response curve
2.2. Epidemiological studies and risk assessment	Whole body response: acute radiation syndrome (bone marrow syndrome, gastrointestinal syndrome and central nervous syndrome) Effects of antenatal exposure Delayed effects of radiation Risks, weighting factors and types of epidemiological study (e.g. retrospective or prospective)

	Confounding factors and definition of risk Risk perception, risk estimates and risk models Historical overview of exposed populations(in the medical field) The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)
3. International Framework and Regulatory Requirements	
3.1. Principles of radiation protection	The ICRP Concept and aims of radiation protection Framework of radiation protection System of radiation protection: Justification, Optimization Dose limitation
3.2. The IBSS	Preamble and principal requirements Detailed requirements; occupational, medical and public exposures, potential exposures, emergency exposure situations and chronic exposure
3.3. Regulatory control	Establishment of a regulatory body System of notification, licensing, inspection and enforcement Guidance for implementation of the IBSS in nuclear medicine
4. Safety of Sources and Design of Facilities	
4.1. Introduction	Principles of safety of sources
4.2. Sources	The concepts of defense-in-depth and categorization of hazards Relevant international safety standards Examples of the unsealed and sealed sources used in therapeutic and diagnostic nuclear medicine
4.3. Building requirements	Room design, ventilation, plumbing, washing, toilets, shielding and safe storage of unsealed sources Fume hoods Special requirements in radionuclide therapy wards
4.4. Safety equipment	Shielding of sources and shielding calculations
5. Occupational Protection	
5.1. Responsibilities and conditions of service	Responsibilities of licensees, employers and workers Special compensatory arrangements, pregnant workers and conditions for young persons
5.2. Classification of areas	Definitions of controlled and supervised areas Examples of classification of the different rooms in a nuclear medicine department
5.3. Sources of exposure	External and internal exposures Radioactive patients Typical dose rates from patients and
5.4. Personal protective equipment in nuclear medicine Safe handling of sources	sources Time, distance and shielding Correct design and use of shields for vials and syringes Tools for remote handling of sources Contamination and decontamination Special requirements in the care of hospitalized patients undergoing radionuclide therapy
5.5. Individual and workplace monitoring	Methods of individual monitoring Instruments for workplace monitoring Monitoring procedures Decommissioning of therapy wards
5.6. Local rules and supervision	Definitions of the procedures and applications that need to be converted into local rules An example of local rules
5.7. Health surveillance	Design of a health surveillance program for radiation workers
5.8. Records	Type and contents of records to be kept for workers ILO code of practice regarding records to be kept
6. Medical Exposures	
6.1. Responsibilities	Definition of the responsibilities of the referring physician, the nuclear medicine specialist, the medical physicist and the nuclear medicine technologist in accordance with the XXXXX regulations, the IBSS and other IAEA publications
6.2. Justification and optimization	The principle of justification and optimization applied to exposure of the patient and biomedical research
6.3. Guidance level of activity	Presentation and discussion of reference levels of activity Investigation of accidental exposures
6.4. Medical records	Requirements for medical records to be kept
7. Protection during Diagnostic Procedures	
7.1. Activity meters and calibration of sources	Principles of operation Operational considerations and quality control Traceability

	Record keeping of administered
7.2. Monitoring instruments	activity Principles of operation
	Operational considerations and quality
7.3. In vivo and in vitro probes	control Principles of operation
and counters	Operational considerations and quality control
7.4. Equipment for morphological	Scanners, gamma cameras, SPECT, PET and
and functional studies	coincidence systems: principles of operation
	Operational considerations and quality control
7.5. Clinical dosimetry	Methods of calculating doses absorbed by patients
	Internal dosimetry: Medical Internal Radiation Dose (MIRD)
	and ICRP concepts on internal dosimetry
8. Protection during Therapeutic Procedures	
8.1. Radionuclide therapy	Operational considerations, calibration, clinical dosimetry
	and quality control
	Instructions to patients concerning spread of contamination
	Minimization of exposure to family members
	Conception after therapy
	Requirements for discharge
9. Radioactive Waste	
9.1. Basic requirements	The general principles for the safety of waste as stated in
	the IBSS and related publications issued by the IAEA
9.2. Types and quantities	Types of waste generated in hospitals Methods of collection
	and segregation Storage for decay, facilities for interim
9.3. Storage	storage Identification of the different procedures for final
9.4. Disposal	disposal of waste (sewage systems, open air, landfills and
	transport to a national plant for radioactive waste)
10. Quality Assurance Program	
10.1. Definition	Definition of the concept of quality assurance and its application to
	radiation protection and safety in nuclear medicine
10.2. Organization	Responsibilities and duties
10.3. Administrative routines	Requests, scheduling, patient identification and information,
	and diagnostic reports
	Ordering and receipt of radioactive
	material Records
	Local rules
	Procedure manuals
10.4. Purchase of instruments	General rules for purchase of instruments (purchase
	specifications, bid analysis, warranty, vendor selection
	and acceptance testing)
10.5. Maintenance	The need for preventive maintenance and corrective
	actions Organization
10.6. Education and training	The different professionals needed in a nuclear
	medicine department and their formal education
	Program for continuing education
11. Potential Exposure and Emergency Preparedness	
11.1. Potential exposure	The basic principles of safety assessments in order to identify
	the potential exposures in the handling and use of unsealed
	sources for diagnosis and therapy
11.2. Accident prevention	Examples of accidents and incidents
	Discussion of the actions that should be taken
	Lessons learned
12. Protection of the General Public	
12.1. Dose limits	Dose limits for the general public
12.2. Design considerations	Safe storage and prevention of spread of contamination
12.3. Radioactive patients	Release of patients from hospital
	Visiting restrictions
	Restricted contact with children and pregnant women
12.4. Special problems	Handling of radioactive cadavers
12.5. Transportation	Information about the international rules on safe transport
	Principles of internal transportation

APPENDIX G

PROCEDURE FOR ORDERING, RECEIVING AND OPENING OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

A. Ordering

(1) The Radiation Safety Committee, through the Radiation Safety Officer (RSO) or a designee will authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting Authorized User and that possession limits are not exceeded.
(2) The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

- Records that identify the reference number of the written directive prepared by the AU, radionuclide, physical and/or chemical form, activity purchased, date ordered, mode of order and the supplier;
- The above records will be checked to confirm that the material received was ordered through proper channels.

B. Receiving

(1) For deliveries during normal working hours, the RSO will tell the carriers to deliver radioactive packages directly to a specific area.
(2) For deliveries during off-duty hours, the RSO will tell the security personnel or other designated persons to accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

Sample Memorandum

Memo to: Chief of Security
From: Radiation Safety Officer
Subject: Receipt of Packages Containing Radioactive Material

The security guard on duty should accept delivery of packages containing radioactive material outside of normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room . Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have questions concerning this memorandum, please call our hospital Radiation Safety Officer, at _____ .

	Name	Home Telephone
Radiation Safety Officer	_____	_____
Chief of Nuclear Medicine	_____	_____
Chief Nuclear Medicine Technologist	_____	_____

See **Exhibit 1** for a sample form of ORDERING AND RECEIVING RADIOACTIVE MATERIAL.

C. Opening

During normal working hours, packages containing radioactive materials will be monitored as soon as practicable after receipt (not to exceed 3 hours). Packages received after normal working hours will be monitored within 3 hours from the beginning of the next working day.

Model Procedure

(1) Put on gloves to prevent hand contamination.
(2) Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and immediately notify the RSO (or the designee of the RSO if the RSO is not present).
(3) Monitor the external surfaces of the package for radioactive contamination.
(4) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
(5) Remove the packing slip.
(6) Open the outer package, following any instructions that may be provided by the supplier.
(7) Open the inner package and verify that the contents agree with the packing slip.
(8) Check the integrity of the final source container. Notify the RSO (or the RSO‟s designee) of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
(9) If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. Note: a dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.
(10) Check the ordering form to ensure that the material received is the material that was ordered.
(11) Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
(12) Make a record of the receipt.

EXHIBIT 1

WD	ORDERING						RECEIVING							
Ref. No	Radionuclide	Chemical Form	Activity Purchased	Supplier	Date Ordered/ Mode of Order	Signature of RSO	Date Received	P.O. No.	Packing Slip No.	Activity at Receipt	Condition of Package	Package Dose Rate		Signature of Recipient
												Surface	at 1 m	

Instrument Used for Survey: _____ Calibration Date: _____

APPENDIX H

PROCEDURE FOR KEEPING RECORDS OF RADIOPHARMACEUTICAL USE/DOSAGES

Records of Unit Dosage Use

For each unit dosage received from a supplier, make a record of the:

(1) Radionuclide;
(2) Generic name or its abbreviation or trade name;
(3) Date of receipt;
(4) Supplier;
(5) Lot number or control number, if assigned;
(6) Activity in megabequerels or kilobequerels as recorded on the unit dosage or packing slip and its associated time;
(7) Date of administration or disposal;
(8) If administered,
    a) Prescribed dosage (unless already recorded in clinical procedure manual),
    b) Measured activity in megabequerels or kilobequerels and date and time of measurement,
    c) Patient name and identification number if one has been assigned;
(9) If discarded, the date and method of disposal; and
(10) Initials of the individual who made the record.

See **Exhibit 2** for a sample Unit Dosage Receipt and Use Log Form.

Records of Multidose Vial Use

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

(1) Radionuclide;
(2) Generic name or its abbreviation or trade name;
(3) Date of receipt or preparation;
(4) Date and time of initial assay and amount in both megabequerels and cubic centimeters (cc) or milliliters (ml);
(5) Supplier or kit manufacturer;
(6) If administered,
    a) Prescribed dosage (unless already recorded in clinical procedure manual),
    b) Date and time dosage was drawn and measured,
    c) Calculated volume that is needed for the prescribed dosage,
    d) Measured activity in megabequerels or kilobequerels,
    e) Patient name and identification number if one has been assigned;
(7) If discarded, the method of disposal and date; and
(8) Initials of the individual who made the record.

See **Exhibit 3** for a sample Multidose Vial Preparation and Use Log Form.

EXHIBIT 2

UNIT DOSAGE RECEIPT AND USE LOG FOR_____AS_____

Date Received	Supplier	Lot No.	Dosage (MBq)	Label Time	Date dispensed	Time	Measured (MBq)	Patient	ID#	INITIAL

EXHIBIT 3

MULTIDOSE VIAL PREPARATION AND USE LOG FOR _____AS_____

Date Prepared	Time	Generator Received	Kit Source	Kit Lot	mCi/cc	cc	Measured (MBq)	Patient	ID#	INITIAL

APPENDIX I

PROCEDURES FOR DEVELOPING, MAINTAINING AND IMPLEMENTING WRITTEN DIRECTIVES (WD)

(1) An Authorized User (AU) must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients‟ charts.

(2) Prior to administering a dose or dosage, the patient‟s or human research subject‟s identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient‟s ID bracelet, hospital ID card, driver‟s license, or other government-issued card. Asking or calling the patient‟s name does not constitute positive patient identity verification.

(3) The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, or using clearly marked storage locations.

See **Exhibit 4** for a sample written directive.

EXHIBIT 4

SAMPLE WRITTEN DIRECTIVE

Patient Name: _____ **Patient No**.: _____ **Date**: _____
Date of Birth: _____ **Diagnosis**: _____

Patient Identification
_____Patient name _____Spelling of Name _____ID Card
_____Birth date _____Wristband _____Other_____

Pregnancy/Breastfeeding Status
Negative pregnancy confirmed by: _____PG Test _____LMP ____N/A
Breastfeeding: _____Yes _____No ____N/A

Desired Procedure
☐ I-131 for Whole Body Scan
☐ I-131 for Hyperthyroidism
☐ I-131 for Thyroid Cancer
☐ Sr-89 for Palliation of Osseous Mets
☐ P-32 for Polycythemia Vera

☐ Draw Blood? TSH
Tiroglobulina B-Hcg
☐ Pregnancy excluded by _____
☐ Patient Requires Dialysis? (If yes, notify RSO)
☐ Patient Breastfeeding? (If yes, notify RSO)
☐ Other _____

☐ Anyone in the household pregnant? (Give extra instruction)

Radiopharmaceutical (Circle One)

^{89}Sr Chloride ^{153}Sm Samarium Sodium ^{32}P ^{131}I Sodium Iodide

Prescribed Dose: _____ **Route**: _____

Authorized User Signature: _____ **Date**: _____

Administered Dose: _____ **By**: _____ **Date**: _____

APPENDIX J

QA/QC OF NUCLEAR MEDICINE IMAGING AND NON-IMAGING EQUIPMENT

Quality Control of Dose Calibrator

Table J-1 lists the quality control tests for a dose calibrator, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used.

Table J-1. Tests for periodic quality control of dose calibrators.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing				Purpose of the Test
			Weekly	Quarterly	Semi-Annually	Annually	
Physical inspection	x						To inspect a radionuclide calibrator for general condition.
Precision and Accuracy Test	x	x				x	To test the precision and accuracy of a radionuclide calibrator in activity measurements in standard geometry at selected gamma radiation energies.
Linearity and Activity Response	x	x		x			To test the linearity of the activity response of a radionuclide calibrator over the range of activities for which it is to be used.
Test of Background Response	x	x	x				To test the background response of a radionuclide calibrator under conditions in which any increase in response is most readily observable.
Operational Checks							
Check of reproducibility							To check the day-to-day reproducibility of performance of a radionuclide calibrator in measurements on commonly used radionuclides.
Check of background response							To check the background response of a radionuclide calibrator under the operational conditions appropriate to a particular radionuclide.

Quality Control of Gamma Camera

Table J-2 lists the quality control tests for a gamma camera, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used.

Table J-2. Tests for periodic quality control of a gamma camera.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing			Purpose of the Test
			Weekly	Quarterly	Semi-annuall	
Physical Inspection	x					To inspect the camera, control console and data storage, and display devices for shipping damage and production and design flaws.
Preset and Manual Pulse Height Analyzer (PHA) Window Settings		x			x	To test that the preset PHA facilities for clinical imaging with particular radionuclides in a gamma camera correspond to the manual settings.
Intrinsic Flood-field Uniformity	x	x		x		To test the intrinsic response of a gamma camera to a spatially uniform flux of incident gamma radiation over the field-of-view.
Flood-field Uniformity over available PHA Window Widths		x			x	To test the intrinsic flood-field response of a gamma camera throughout the range of available PHA window widths.
Flood-field Uniformity at Energies other than 140 keV (^{99m}Tc) or 392 keV (^{113m}In)		x			x	To test the intrinsic flood-field response of a gamma camera for all other appropriate photon energies.
System Flood-field		x			x	To test the system flood-field response of a gamma

Uniformity						camera with al multi-hole collimators used.
Intrinsic Spatial Resolution	x	x			x	To test the intrinsic spatial resolution of a gamma camera in terms of the full width at half-maximum (FWHM) of its line-spread function.
System Spatial Resolution	x					To test the system spatial resolution of a gamma camera in terms of the full width at half-maximum, FWHM, of its line-spread function.
Intrinsic Count-rate Performance (Alternative I)	x	x			x	To test the intrinsic count-rate performance of a gamma camera in terms of its response to an increasing flux of incident gamma radiation.
Intrinsic Count-rate Performance (Alternative II)	x	x			x	To test the intrinsic count-rate performance of a gamma camera in terms of the count rate corresponding to a 20% count loss (Two-source method).
Maximum Count-rate	x	x			x	To test the maximum count rate of a gamma camera. This test is to be performed only in conjunction with the Test of Intrinsic Count-rate Performance, Alternative II.
System Count-rate Performance		x		x		To test the system count-rate performance of a gamma camera in terms of the count rate corresponding to a 20% count loss with the sources placed in a scattering medium (Two-source method).
System Plane Sensitivity	x					To test the response of the gamma camera to a radionuclide source of known activity.
Detector Head Shielding Leakage	x					To test that the detector head of a gamma camera responds only to radiation incident upon the crystal after transmission through the collimator.
Spatial Resolution and Spatial Linearity		x	x			To test the spatial resolution and spatial linearity of a gamma camera on a weekly basis.
Test of Total Performance		x	x			To test all components of a gamma camera, including the display device and digital image processor under simulated clinical conditions.
Multiple-window Spatial Registration	x	x			x	To test that the X and Y gains of each PHA are adjusted so that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously in an additive or subtractive mode.
Operational Checks						
Collimator and Detector Head Mountings	To check the collimator and detector head mountings in a gamma camera.					
Energy Calibration of PHA	To centre the clinically-used PHA window of a gamma camera on the photopeak.					
Flood-field Uniformity and Sensitivity	To check the flood-field uniformity and, coincidentally, the sensitivity of a gamma camera.					
Background Count-rate	To check the background count rate of a gamma camera under the conditions for routine clinical imaging with a particular radionuclide.					
Check of Oscilloscope	To check the size and shape of the flashes on the display device with hard copy of a gamma camera.					
Check of Film Handling and Processing	To check the adequacy of the film handling and processing for a gamma camera.					

Quality Control of SPECT Systems

Table J-3 lists the quality control tests for Single Photon Emission Computed Tomography (SPECT) systems, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used.

Table J-3. Tests for periodic quality control of SPECT systems.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing			Purpose of the Test
			Weekly	Quarterly	Semi-annually	
Mechanical inspection of the SPECT system	x				x	To check the mechanical performance of the system and its ability to rotate the scintillation camera in manner suitable for SPECT.
Test to determine the absolute size of a pixel	x			x		To determine the absolute pixel size in the matrix used for tomographic reconstruction.
Test of the center of rotation offset and alignment of Y axis to axis rotation		x	x			To test the centre of rotation offset, alignment of the camera Y axis and head tilt with respect to the axis of rotation.
Test of tomographic	x	x	x			To test the tomographic uniformity of a rotating

uniformity of the system						scintillation camera SPECT system and to check the body contour outlining procedure.
Test of tomographic resolution in air	x	x		x		To measure the tomographic resolution of the system in air, and to ensure that the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction.
Test of tomographic resolution with scatter	x	x		x		To check the tomographic resolution of the system in clinical conditions, that is, with a radius of rotation which is realistic, and with scatter present. To give an indication of the resolution which is likely to be achieved clinically.
Test for slice thickness at centre of slice	x				x	To test the thickness of a tomographic slice at the centre of the field of view. To ensure that the resolution along the tomographic Z axis is within acceptable limits.
Test of variations of sensitivity and uniformity with rotation of the system	x	x			x	To determine the variations in system sensitivity as a function of angular position of the detector.
Test of Total Performance	x	x	x			To check that the system is performing adequately in conditions similar to those used in clinical practice. To estimate the contrast of objects of known size.
Operational Checks						
Check of routine function and center of rotation offset	To ascertain proper function of a SPECT system and to ensure that the centre of rotation offset is minimal.					

Quality Control of PET Camera

For *quality control* of a Positron Emission Tomography (PET) system in use, tests that are primarily recommended are those from the manufacturer, using radiation sources recommended by the manufacturer, and at least the tests and suggested frequencies for the repetition of reference tests in routine testing shown in **Table J-4**. The operational checks should be carried out each day the instrument is used.

Table J-4. Tests for periodic quality control of PET systems.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing			Purpose of the Test
			Monthly	Quarterly	Annually	
Physical inspection	x					To check the total system for shipping damage (e.g. gantry, console, computer, display devices) and production and design flaws
Spatial Resolution	x	x				To measure the tomographic spatial resolution of the system in air and to ensure that spatial resolution is not degraded by either the tomographic acquisition or the reconstruction process.
Sensitivity	x	x				To determine the rate of detected true coincidence events per unit of radioactivity concentration for a standard source configuration, for example, a cylindrical phantom of given dimensions.
Scatter fraction, count losses and random measurement	x	x				To measure the relative system sensitivity to scattered radiation. To measure the effects of system dead-time and the generation of randoms events at several levels of source activity.
Energy Resolution	x	x				To assess proper photomultiplier calibration and to ensure that the efficiency of light collection is within the specifications.
Image Quality and accuracy of attenuation and scatter correction	x	x			x	To determine the hot and cold spot image quality of the standardized image quality phantom. To assess the accuracy of the absolute quantification of radioactivity concentration in the uniform volume of interest inside the phantom.
Uniformity of reconstructed image	x	x		x		To describe the ability to measure the same activity independent of location within the imaging field of view.
PET Normalization	x	x	x			To acquire crystal efficiency data for use in

						correcting acquired sinograms for detector non-uniformities.
2-D – 3-D Radioactivity concentration calibration	x	x	x			To acquire scanner efficiency data for use in correcting acquired sinograms for detector non-uniformities.
Operational Checks						
Coincidence timing resolution for TOF PET	x	x				To determine the capability of the system to estimate the difference in time of arrival of the two coincidence photons, and hence obtain information about the likely location of the annihilation along the Line of Response (LOR).
PET detector stability test		x				To assess the constancy of the detector performance and to allow early detection of any sudden change, for example, failure of a detector module.
Test of PET scan in clinical mode		x				To check the overall operation of the system in patient scan mode.

Quality Control of Single and Multi-probe Counting Systems for Gamma-Radiation Measurements – In Vivo

Table J-5 lists the quality control tests for a non-imaging gamma ray detecting probe, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used.

Table J-5. Tests for periodic quality control of Single and Multi-probe Counting Systems – In Vivo.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing			Purpose of the Test
			Weekly	Quarterly	Semi-Annuall	
Physical inspection	x					To inspect a counting system for gamma-radiation measurements in vivo for general condition.
Function of Scaler timer/ Ratemeter	x	x	x			To test the function of a scaler-timer and/or ratemeter in a counting system for gamma-radiation measurements in vivo.
Energy Calibration	x	x	x			To effect, and subsequently to test, the energy calibration of a counting system for gamma-radiation measurements in vivo.
Energy Resolution (% FWHM)	x	x			x	To test the energy resolution of a counting system for gamma-radiation measurements in vivo in terms of its "percentage full width at half-maximum" (% FWHM) for gamma radiation.
Sensitivity	x	x	x			To test the sensitivity of a counting system for gamma -radiation measurements in vivo by measurements on a certified gamma-radiation source.
Counting Precision (X_2 test)	x	x		x		To test the counting precision of a counting system for gamma-ray measurements in vivo.
Linearity of Energy Response	x	x			x	To test the linearity of the settings of the pulse-height analyzer base (threshold) control of a counting system for gamma-radiation measurements in vivo with respect to radiation energy.
Integral Background Count Rate	x	x	x			To test the background count rate of a counting system for gamma-radiation measurements in vivo under conditions in which any increase in count rate is most readily observable.
Linearity of Activity Response	x	x			x	To test the linearity of the count rate of a counting system for gamma-radiation measurements in vivo with respect to the activity of the radioactive material in the field of view.
Preset Analyzer Facilities	x	x			x	To test the preset pulse-height analyzer facilities for routine measurements on particular radionuclides in a counting system for gamma-radiation measurements in vivo.
Linearity of Response of Recorder	x	x			x	To test the linearity of response of a strip-chart recorder in a counting system for gamma-radiation measurements in vivo.

Chart Drive of Recorder	x	x			x	To test the chart drive of a strip-chart recorder in a counting system for gamma-radiation measurements in vivo with respect to exactness and uniformity of chart speed.
Operational Checks						
Check of Collimator and Probe Mountings	To check the collimator and probe mountings in a counting system for gamma-radiation measurements in vivo.					
Check of Recorder Function	To check the function of a strip-chart recorder in a counting system for gamma-radiation measurements in vivo.					
Check of Analyzer Peak Setting	To check that the "peak" setting of the pulse-height analyzer of a counting system for gamma-radiation measurements in vivo is appropriate for routine measurements on a particular radionuclide.					
Check of Probe Sensitivity	To equalize the sensitivities of the individual probes of a multi-probe counting system for gamma-radiation measurements in vivo on a particular radionuclide.					
Check of Background Count Rate	To check the background count rate of a counting system for gamma-radiation measurements in vivo under the conditions for routine measurements on a particular radionuclide.					

Quality Control of Manual and Automatic Counting Systems for Gamma-Radiation Measurements – In Vitro

Table J-6 lists the quality control tests for a single-sample or multi-sample gamma counter, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used.

Table J-6. Tests for periodic quality control of manual and automatic counting systems for gamma-radiation measurements- in vitro.

Test	Acceptance Test	Reference Test	Frequency in Routine Testing			Purpose of the Test
			Weekly	Quarterly	Semi-Annually	
Physical inspection	x					To inspect a counting system for gamma-radiation measurements in vitro for general condition.
Function of Scaler-timer/Ratemeter	x	x	x			To test the function of a scaler-timer and/or ratemeter in a counting system for gamma-radiation measurements in vitro.
Energy Calibration	x	x	x			To effect, and subsequently to test, the energy calibration of a counting system for gamma-radiation measurements in vitro.
Energy Resolution (% FWHM)	x	x			x	To test the energy resolution of a counting system for gamma-radiation measurements in vitro in terms of its "percentage full width at half-maximum" (% FWHM) for gamma radiation.
Sensitivity	x	x	x			To test the sensitivity of a counting system for gamma -radiation measurements in vitro by measurements on a certified gamma-radiation source.
Counting Precision (X_2 test)	x	x		x		To test the counting precision of a counting system for gamma-ray measurements in vivo.
Linearity of Energy Response	x	x			x	To test the linearity of the settings of the pulse-height analyzer base (threshold) control of a counting system for gamma-radiation measurements in vitro with respect to radiation energy.
Integral Background Count Rate	x	x	x			To test the background count rate of a counting system for gamma-radiation measurements in vitro under conditions in which any increase in count rate is most readily observable.
Linearity of Activity Response	x	x			x	To test the linearity of the count rate of a counting system for gamma-radiation measurements in vitro with respect to the activity of the measured sample.
Preset Analyzer Facilities	x	x			x	To test the preset pulse-height analyzer facilities for routine measurements on particular radionuclides in a counting system for gamma-radiation measurements in vitro.
Operational Checks						
Check of Analyzer Peak Setting	To check that the "peak" setting of the pulse-height analyzer of a counting system for gamma-radiation measurements in vitro is appropriate for routine measurements on a particular radionuclide.					
Check of Background Count Rate	To check the background count rate of a counting system for gamma-radiation measurements in vitro under the conditions for routine measurements on a particular radionuclide.					

EXHIBIT 5

GAMMA CAMERA QUALITY CONTROL

Instrument _____ Date _____ Time _____
Collimator _____ Orientation Setting _____

RADIONUCLIDE _____(identify)

Liquid Phantom _____ Sheet Source _____ Point source _____ (check one)
Activity _____ MBq Gamma Energy _____ keV

INSTRUMENT SETTINGS

Auto Peak _____ Manual Peak _____ (check one)
Photopeak setting (gain, "centerline" or preset) _____ Window _____ %
If multiple PHAs, please identify 1 _____ 2 _____ 3 _____
Dot focus check on CRT (if accessible) YES _____ N/A _____ (please check)
Display format: transparency _____ polaroid _____ analog _____ digital _____
(check if applicable)

IMAGE PARAMETERS

	Field Uniformity Test	Spatial Resolution Test
Phantom Used	N/A	
CRT Intensity		
Preset Count	x 10^3	x 10^3
Time (Seconds)		
Background count	c/s	

EVALUATION

Calculate photopeak consistency _____ % change (applicable only for manual settings)
Calculate sensitivity from field uniform acquisition data _____ c/s/MBq

Background Acceptable	Yes or No
Does image appear symmetrical on flood?	
Does image appear uniform on flood?	
If not, is uniformity clinically acceptable?	
Smallest pattern resolved? _____ cm. Is pattern distorted?	
If so, is distortion localized?	

Other comments (any noticeable items needing attention)

_____
Medical Physicist

APPENDIX K

RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

(1) Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
(2) Wear disposable gloves at all times while handling radioactive materials.
(3) Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.
(4) Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).
(5) Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
(6) Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
(7) Wear extremity dosimeters, if required, when handling radioactive material.
(8) Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
(9) Never pipette by mouth.
(10) Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
(11) Survey with a radiation detection survey meter all areas of licensed material use (which now includes use of accelerator-produced radioactive materials or discrete sources of radium-226), including the generator storage, kit preparation, and injection areas, daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily (except when administering therapy dosages in patients‟ rooms when patients are confined).
(12) Store radioactive solutions in shielded containers that are clearly labeled.
(13) Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled.
(14) Syringes and unit dosages must be labeled. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). To avoid mistaking patient dosages, label the syringe with the type of study and the patient‟s name.
(15) For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it.
(16) Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an AU.
(17) When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
(18) Check the patient‟s name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a WD, the patient‟s identity must be verified and the administration must be in accordance with the WD.
(19) Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
(20) Secure all licensed material, including accelerator-produced radioactive materials and discrete sources of radium-226, when not under the constant surveillance and immediate control of an individual authorized under the XXXXX license (or such individual‟s designee).

APPENDIX L

MODEL PROCEDURE FOR LEAK TESTING OF SEALED SOURCES

Facilities and Equipment

(1) To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
(2) Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
(3) Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting or alpha-emitting sources (e.g., Sr-90).
(4) Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μCi) of radioactivity. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

Model Procedure for Performing Leak Testing

(1) For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
(2) Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
(3) Number each wipe to correlate identifying information for each source.
(4) Wear gloves.
(5) Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.

Model Procedure for Leak Test Analysis

(1) Measure the background count rate and record.
(2) Check the instrument"s counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard.
(3) If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) should be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + [4.65(bkg / t)]^{1/2}}{Eff}$$

where: MDA = minimum detectable activity in disintegrations per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
Eff = detector efficiency in counts per disintegration

For example:
where: bkg = 200 cpm
Eff = 10%, or 0.1
t = 2 minutes

$$MDA = \frac{3 + [4.65(200 cpm / 2 \text{ min})]^{1/2}}{0.1} = 495 dpm$$

(4) Calculate efficiency of the instrument.

For example,

$$Eff = \frac{cpm_{std} - cpm_{bkg}}{A}$$

where: Eff = efficiency,
A = Activity,
cpm = counts per minute,
std = standard, and
bkg = background.

(5) Analyze each wipe sample to determine net count rate.

(6) For each sample, calculate the activity in Bq and record.

(7) The activity on the wipe (or absorber) sample is given by:

$$A = \frac{cpm_{sample} - cpm_{bkg}}{Eff}$$

(8) Leak test records will be retained in accordance with IAEA standards or standard license condition for 2 years. Licensees should include the following in records:
- The model number and serial number (if assigned) of each source tested;
- The identity of each source radionuclide and its estimated activity;
- The measured activity of each test sample expressed in Bq;
- A description of the method used to measure each test sample;
- The date of the test; and
- The name of the individual who performed the test.

(9) If the wipe test reveals 185 Bq (0.005μCi) or greater:
- Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired.
- File a report within 5 days of the leak test

APPENDIX M

MODEL PROCEDURE FOR RADIATION AREA MONITORING

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys

(1) Perform radiation level surveys with a survey meter sufficiently sensitive to detect 1 uSv/hr per hour in the following areas, at the frequency specified:
- **At the end of each working day:** all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration).
- **Weekly:** all radionuclide use, storage, and waste storage areas.
- **Monthly:** all laboratory areas where only small quantities of gamma-emitting radioactive material are used (≤ 10 MBq at a time).

(2) If trigger levels listed below are exceeded, follow internal procedures for responding and investigating what caused the trigger level to be tripped. Examples of trigger levels for controlled and supervised areas are presented in **Table M-1**.

Table M-1: Ambient Dose Rate Trigger Levels

Area Surveyed	Trigger Level
Supervised	0.5 uSv/hr
Controlled	10 uSv/hr

Contamination Surveys

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

(1) Contamination surveys are performed in areas where unsealed forms of materials are used:
- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate contamination of users and workers and the immediate work area, at the end of the day, when licensed material is used;
- In supervised areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly; and
- In areas adjacent to controlled areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

(2) Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in **Tables M-2** for controlled areas and public or supervised areas. Removable contamination survey samples should be measured in a low-background areas. The following areas and frequencies should be followed:
- **Weekly:** radiopharmaceutical elution, preparation, assay, administration areas, and radionuclide storage and radionuclide waste storage areas.

- **Monthly:** all laboratory areas where only small quantities of photon-emitting radioactive material are used (≤ 10 MBq).

(3) A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.
(4) The area should be decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
(5) If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger level to be tripped. Examples of action levels for controlled areas are presented in **Table M-2**. Contamination found in supervised areas and on personal clothing will be immediately decontaminated to background levels.

Table M-2: Allowable Non-fixed (Removable) Contamination in Controlled and Public Areas

Nuclide	Allowable Removable Contamination	
	Controlled Area (Bq/cm^2)	Public Area (Bq/cm^2)
Long-lived alpha emitters	3	0.3
Long-lived beta or gamma emitters	30	3
*Short-lived beta or gamma emitters	300	30

* Include most of the commonly used radionuclides, e. g. H-3, C-14, P-32, P-33, I-125

Contents of Survey Records

1. A diagram of the area surveyed;
2. A list of items and equipment surveyed;
3. Specific locations on the survey diagram where wipe tests were taken;
4. Ambient radiation levels in mSv/hr (or µSv/hr);
5. Contamination levels Bq/cm^2 ($cpm/300\ cm^2$);
6. Make and model number of instruments used;
7. Background radiation levels in mSv/hr (or µSv/hr);
8. Actions taken in the case of excessive dose rates or contamination and follow-up survey information; and
9. Name and signature of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor‟s signature.

See **Exhibit 6** for a sample form for contamination monitoring in a nuclear medicine facility.

EXHIBIT 6

CONTAMINATION MONITORING IN A NUCLEAR MEDICINE FACILITY

Area Survey:

Date /time of survey	Location/area surveyed /or code number as per floor plan	Contamination meter reading, cps, cpm	Performed by/signature	Remarks *

Trigger level: _____cps, cpm

*If contamination meter reading is above the trigger level, conduct swipe test, as appropriate and use the Form below:

Instrument used for the survey: _____

Model No. _____ Serial No._____

Date of calibration : _____

Calibration efficiency: _____

Swipe test analysis:

Date	Location/area swiped or code number as per floor plan	Instrument used for analysis/efficiency	Contamination level , Bq/300 square cm.	Performed by/ signature	Remarks/Corrective Actions Done **

1. Perform decontamination of areas
2. Perform post contamination survey done/document results
3. Return to normal use

Reviewed by:

_____

Radiation Safety Officer

APPENDIX N

PROCEDURE FOR MINIMIZATION OF CONTAMINATION AND/OR SPILL

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a bag labeled “caution radioactive material” for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper labeled “CAUTION RADIOACTIVE MATERIAL,” but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

Major Spill or Minor Spill

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spreading contamination, types of surfaces contaminated, and the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be to restrict access pending decay to background levels.

Use **Table N-1** as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented.

Table N-1. Relative hazards of common radionuclides.

Radionuclide	Activity (MBq)	Radionuclide	Activity (MBq)
P-32	37	Tc-99m	3700
Cr-51	3700	In-111	370
Co-57	370	I-123	370
Co-58	370	I-125	37
Fe-59	37	I-131	37
Co-60	37	Sm-153	370
Ga-67	370	Yb-169	370
Se-75	37	Hg-197	370
Sr-85	370	Au-198	370
Sr-89	37	Tl-201	3700

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these Mbq amounts are considered major, below are considered minor. Spills involving GBq quantities of PET radionuclides should initially be considered major spills; either downgrade to a minor spill after decay or restrict access pending complete decay.

Spill/Contamination Kit

Assemble a spill/contamination kit that may contain the following items:

- Disposable gloves and housekeeping gloves,
- Disposable lab coats,
- Disposable head coverings,
- Disposable shoe covers,
- Roll of absorbent paper with plastic backing,
- Masking tape,
- Plastic trash bags with twist ties,
- “Radioactive Material” labeling tape,
- Marking pen,
- Pre-strung “Radioactive Material” labeling tags,
- Contamination wipes,
- Instructions for “Emergency Procedures,”
- Clipboard with copy of Radioactive Spill Report Form,
- Pencil, and
- Appropriate survey instruments, including batteries.

APPENDIX O

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIRBORNE CONCENTRATIONS, INCLUDING PROCEDURE FOR PERFORMANCE TESTING OF FUMEHOOD

Preface

It is assumed that the facility where radioactive gas will be used is under a dedicated air handling system. This means that the air coming into the controlled area empties directly to the outside and not into a return system. It is further understood that some nuclear medicine departments will be built into an existing facility that does not have exhaust capability. In those cases this limitation should be brought to the attention of the XXXXX and that the use of aerosols instead of gases should be considered.

Model Procedure for Calculating Worker Dose from Concentrations of Radioactive Gases in Work Areas (Controlled Area)

(1) Collect the following data:

a) Estimated number of studies per week;
b) Activity to be administered per study;
c) Estimated activity lost to the work areas per study (you may assume 20% loss);
d) Measured airflow supplied by each vent in the imaging room;
e) Measured air flow exhaust by each vent in the imaging room, (e.g., a fume hood); and
f) Maximum permissible air concentrations in controlled and supervised areas are listed in **Table O-1**.

Table O-1: Maximum Permissible Air Concentrations

Radionuclide	Controlled Area	Supervised Area
Xe-133	0.37 Bq/ml	0.011 Bq/ml
Tc-99m	1.48 Bq/ml	0.037 Bq/ml

(2) The following calculations must be made:

a) The sum of all measured exhaust rates and the sum of all measured supply rates. For negative pressure, the exhaust rate must be larger than the supply rate, in milliliters.
b) The estimated average concentration in controlled areas:
    i. The total activity released to the controlled area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable permissible value for a controlled area.
    ii. If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)
c) The Derived Air Concentration (DAC) Values is defined as the concentration of radionuclide such as the exposure for 1 year (2000 hours) would result in either a committed dose equivalent 50 mSv or a committed dose equivalent of 500 mSv to any organ or tissue, with no consideration of the contribution of external dose.

Model Procedure for Calculating Airborne Effluent Concentration

(1) Divide the total activity released to an uncontrolled area (activity used each week that is released in exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable modified derived air concentration value for an uncontrolled area.
(2) If this is not the case, plan for a fewer studies and do the calculation again. Alternatively, collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration of the boundary of the controlled area may be considered.

Sample Problem:
A nuclear medicine lab plans to use 370 MBq Xe-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance?

Maximum activity lost per week:

$$A = \frac{370\ MBq}{pt} \times \frac{10\ pt}{wk} \times \frac{10^6\ Bq}{1MBq \times 0.20}$$

$$A = \frac{7.4 \times 10^8\ Bq}{wk} \times \frac{1}{0.37 \frac{Bq}{mL}}$$

$$A = 2.0 \times 10^9\ \frac{mL}{wk}$$

The required ventilation rate is

$$\frac{2.0 \times 10^9\ \frac{mL}{wk}}{\frac{hr}{40\,wk}} \div \frac{1.0 \times 10^6\ \frac{mL}{hr}}{\frac{m^3}{hr}} = 50\ \frac{m^3}{hr}$$

The answer shows that, in order to meet the requirements, the imaging room (CONTROLLED AREA) must have a ventilation rate of at least 50 cubic meter per hour with no return of the contaminated air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. **Consider every alternative in order to maintain the air concentration of Xe-133 as low as reasonably achievable.**

Guidance for Monitoring or Checking Trap Effluent

Charcoal traps can significantly reduce air concentration. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

(1) If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer‟s instructions and keep a record of the checks.
(2) If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble

gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of a date, background cpm, and bag cpm.

(3) The RSO will establish a trigger level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.

(4) Follow the trap manufacturer"s instructions for replacing the trap.

Spilled Gas Clearance Time:

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described below should be done to determine for how long a room should be cleared in case of gas spill. This clearance time should be posted in the room.

Guidance for Calculating Spilled Gas Clearance Time

(1) Collect the following data:
   a) **A**, the highest activity of gas in a single container, in MBq;
   b) Measure airflow supply from each vent in the room in milliliters per minute;
   c) **Q**, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal exhaust or a specially installed gas exhaust system;
   d) **C**, the maximum permissible air concentration in controlled and supervised areas as in **Table O-1**; and
   e) **V**, the volume of the room in milliliters.

(2) For each room make the following calculations:
   a) The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
   b) The evacuation time

$$t = \frac{-V}{Q} \times \ln\left(\left|\frac{C \times V}{A}\right|\right)$$

Model Procedure for Performance Testing of Fume Hood

GENERAL TEST CONDITIONS

The following must be observed:

(1) Any room ventilating systems shall be in operation during these tests.

(2) Any standard procedures for the laboratory shall be observed during these tests (e.g. limitations on the number of hoods in operation at one time, etc.)

(3) The sash or sashes shall be located in the design position or positions.

(4) If the hood has an auxiliary supply, the supply shall be in operation during the tests. If the supply is capable of convenient adjustment by laboratory personnel, the adjustments shall be as specified.

(5) General activity in the laboratory shall be maintained in as normal a state as possible.

(6) The tests shall be conducted with normal hood apparatus in place and in operation.

FLOW VISUALIZATION TEST

Purpose:

The purpose of the flow visualization test is to visualize the hood's ability to contain vapors and render an observation of hood performance as it is typically used. The test includes both a small local challenge and a gross challenge to the hood.

Equipment:

(1) Controllable source of visible smoke (e.g. titanium tetrachloride or another source of persistent, neutral buoyancy aerosols that can be discharged under the control of the person conducting the test).
(2) Watch or other timer.
(3) Notebook for recording observations.

Procedure:

A. Local Visualization Challenge

In the following tests, it is expected that all smoke shall be carried to the back of the hood and exhausted. Any movement of smoke towards the face of the hood is defined as negative airflow, and any lack of movement is defined as dead air space.

Note: *If there is visible smoke flow out of the front of the hood during any of these tests, the hood fails the test and shall be taken out of service.*

Perform the following challenges. In all cases, airflow patterns and time for hood clearance should be recorded.

a) Bottom Air Bypass Air Foil - run smoke under the air foil. Smoke should be exhausted smoothly and not be entrained in the vortex at the top of the hood.
b) Walls and Floor - discharge a stream of smoke along both walls and the floor of the hood in a line parallel to the hood face and 15 cm behind the face of the hood and along the top of the face opening.
c) Back of Hood - discharge smoke in a 20 cm diameter circle on the back of the hood.
d) Top of Hood - discharge smoke at top of hood and observe airflow patterns and time for hood clearance.
e) Equipment in Hood - discharge smoke around any equipment in hood.

B. Large Volume Visualization Challenge

In the following test, a release of smoke from the hood that is steady and visible is an indication of failure and the hood shall be taken out of service.

a) A large volume of smoke shall be released inside the hood and observations of containment shall be made from the side of the hood face, as well as time for hood clearance.
b) The smoke shall be released from the center of the sash opening on the work surface, 15 cm inside the rear edge of the sash.
c) The smoke should not have an unacceptably high directional component to it that would affect hood performance (e.g. a jet of high velocity smoke), nor should the smoke source be designed/used in a manner that disrupts hood performance.

FACE VELOCITY MEASUREMENTS

Purpose:

The purpose of this test is to quantitatively measure air velocity at the hood face.

Equipment:

1) Anemometer or velometer, either mechanical or electrical, that has been recently calibrated. It shall be capable of measuring in the range of 0.25 m/s to 2.0 m/s (50 to 400 fpm) with an accuracy of 5% of the reading.
2) Notebook for recording observations.

Procedure:

The minimum acceptable velocity for each hood face cell shall be 0.5 m/s (100 fpm). If any cell fails to meet this requirement, the hood fails the test and shall be taken out of service.

a) Divide the hood opening into a grid of equally spaced imaginary cells (about 30 cm x 30 cm).

b) Air velocity measurements shall be taken with a properly calibrated anemometer fixed at the center of each cell, with the anemometer held in the plane of, and parallel to, the hood sash (if the airflow is not perpendicular to the plane of the sash opening, the anemometer should be held perpendicular to the airflow, even if this causes it to not be parallel with the sash opening). Care should be taken to stand to the side during measurement so as to affect the airflow as little as possible.
c) Velocity measurements shall be integrated over a period of at least five (5) seconds. If the anemometer takes only instantaneous readings, at least four (4) readings shall be taken at each point.
d) Calculate the average of the velocity measurements, noting the minimum and maximum measurements as well.
e) Compare measured face velocities with manufacturer specifications.

Performance testing of fume hood adapted from the ANSI/ASHRAE "Method of Testing Performance of Laboratory Fume Hoods" standard (ANSI/ASHRAE 110-1995).

EXHIBIT 7

FUME HOOD PERFORMANCE TESTING REPORT

Name and Location of Facility: _____ Date: _____

_____

_____

Radioactive Material and Activity: _____

DATA AND RESULTS

a. Description of Fume Hood:

1. Fume Hood Dimensions

Item	Dimension per submitted documents	Actual Measurements
Length (L)		
Width (W)		
Height (H)		
Volume (V)		

2. Room Dimensions

Item	Dimension per submitted documents	Actual Measurements
Length (L)		
Width (W)		
Height (H)		
Volume (V)		

3. Blower/Motor Specifications

Item		

4. Face Velocity

Item	1	2	3	4	Ave
Fully-opened (m/s)					
Area (sq. m)					
Half-opened (m/s)					
Area (sq. m)					

b. Observations and Analysis of Flow Visualization Test

1. Local Visualization Challenge

2. Large Volume Visualization Challenge

c. Radiation Monitoring Results (include drawings and locations of where monitoring is conducted)

1. Before Opening the Vials
   - 1.1 Door
   - 1.2 One meter from the fume hood
   - 1.3 Filter box

	Closed (blower off)	Closed (blower on)
Prefilter		
Hepa		
Charcoal		

   - 1.4 Filter box

	Open (blower off)	Open (blower on)
Prefilter		
Hepa		
Charcoal		

2. After Opening the Vials
   - 2.1Door
   - 2.2Fume hood
   - 2.3Filter box

	Vial closed (blower off)	Vial open (blower on)
Prefilter		
Hepa		
Charcoal		

d. Contamination Monitoring Results (include drawings and locations where monitoring is conducted)

e. Air Sampling Results
1. Air sampling 1 _____
2. Air sampling 2 _____
3. Air sampling 3 _____
4. Air sampling 4 _____

f. Calculations for Room Air Changes
Ave. face velocity =_____
Area of sash opening =_____
Volume of Room =_____
Room Air Change (h^{-1}) =_____

g. Evaluation
h. Recommendation

Performed by: Approved by:

_____ _____

_____

_____

Date: Date:

_____ _____

APPENDIX P

RADIATION SAFETY DURING RADIONUCLIDE THERAPY

Procedures for Administering Therapeutic Radiopharmaceuticals

(1) The Authorized User will personally review the patient‟s case to assure that the therapeutic procedure is appropriate.
(2) The Authorized User will prepare a written directive for each therapy procedure.
(3) The Authorized User will use radioactive material or direct technologists in using radioactive material. At facilities authorized for physician training, the Authorized User will use radioactive material or direct physicians in training in using radioactive material, with the approval of the Radiation Safety Committee.
(4) The Authorized User will regularly review the progress of the patient receiving therapy and modify the originally prescribed dose if needed.
(5) Check each patient‟s name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
(6) Each therapeutic radiopharmaceutical dosage will be assayed in the dose calibrator before it is administered to a patient. Do not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent, except for prescribed dosages of less than 370 kBq. (When measuring the dosage the radioactivity that adheres to the syringe wall or remains in the needle need not be considered.)
(7) Each therapeutic radiopharmaceutical dose will be assayed within 30 minutes before it is administered to a patient.

Safety Procedures for Use of Therapeutic Radiopharmaceuticals Requiring Hospitalization

(1) The patient's room is as far away from the nursing station and heavily trafficked hallways as is consistent with good medical care. It is a non-carpeted private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released.
(2) Room preparation
   a) Use leak-proof absorbent paper to cover large surfaces that are likely to be contaminated, such as the bed, chairs, and the floor around the toilet. Small items, such as the telephone, door knobs, nurse call cord, bed remote control, and television control may be covered with absorbent paper or plastic bags.
   b) Prepare separate containers for linen, disposable waste, and non-disposable contaminated items. Place a single large re-sealable plastic bag in each container, or supply several small plastic bags.
   c) Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use by nursing, nuclear medicine, and radiation safety personnel.
   d) Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine is collected, prepare collection containers.
      - Urine collection containers are unbreakable and closable.
      - When no assay or volumetric determination is required and urine is decayed in storage, add an absorbent such as vermiculite to each container.
      - Place containers in a box or deep tray lined with a plastic bag and absorbent paper or vermiculite, to avoid room contamination in the case of a spill.
      - Supply a few half-value layers of shielding for each container. (One half-value layer of iodine-131 is approximately 3 mm of lead.)
      - Supply a wide-mouth anti-splash funnel.
(3) Order disposable table service (i.e. paper or plastic plates, cups, and utensils) for the duration of the patient's stay.
(4) Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
(5) Supply the nurses with TLDs, OSLs or pocket ionization chambers.

(6) Ensure that nurses have received current radiation safety training, and the facility training program. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
(7) Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
(8) Post the room with a "Caution - Radioactive Materials" or “Danger, Radioactive Materials” sign.
(9) Only individuals needed for medical, safety, or training purposes will be present during the administration.
(10) After administering the dosage, measure the dose rate in mSv/hr at bedside, at 1 meter from bedside, at the likely point for the “visitors' safe line," and in the surrounding hallways and rooms.
(11) Mark the “visitors' safe line” on the floor. Determine where the safe line should be based on the survey measurements.
(12) Record survey results and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form.
(13) For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker‟s name, amount of I-131 activity in a thyroid phantom in Becquerel and associated counts per minute (cpm), the counts per minute from the worker‟s thyroid, the calculated thyroid burden, and date.
(14) As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area. Materials and items removed from the patient‟s or human research subject‟s room will be monitored to determine any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or these materials and items will be handled as radioactive waste.
(15) Do not release any patient until it has been established by either a medical physicist of the RSO that the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 3 mSv.
Measure dose rates with a radiation survey meter at a distance of 1 meter from the umbilicus while the patient is standing, or if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
(16) Provide the patient with written radiation safety instructions. These instructions will include steps the patient may take to lessen radiation exposure to family members or others in contact with the patient.

Note: See **Exhibit 8** sample form “Nursing Instructions for Patients Treated with I-131, P-32 or Au-198.

Releasing a Room for Unrestricted Use

(1) Remove all absorbent paper, and place it in the appropriate radioactive waste container.
(2) Transfer all containers to a decay-in-storage or decontamination area.
(3) Use a radiation detection survey meter to check for room contamination.
(4) Conduct wipe tests for removable contamination in the patient‟s room and private sanitary facilities.
(5) Clean contaminated areas until removable contamination is at background levels when surveyed with a G-M survey meter, or less than 200 dpm/100 cm^2.
(6) Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Note: See **Exhibit 9** for Radiation Safety Checklist for Iodine Therapy over 555 MBq (15 mCi).

EXHIBIT

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131, PHOSPHORUS-32, OR GOLD-198

Patient Name: _____ Patient Number: _____
Attending Physician: _____ Tel: _____ Mobile: _____
Patient Room Number: _____
Dose: _____ MBq of _____ As _____ Was Administered On ___ :_____ AM/PM
Signature: _____ Date ---------- _____

RADIATION DOSE RATES

UNRESTRICTED AREAS: Door ___-mSv/hr; room ___-mSv/hr; room ___ -mSv/hr
Patient Supine in bed or _____

Date	Time	Radiation Dose Rate (mSv/hr)			
		Bedside	1 m from bed	"Visitor's Line"	Door

INSTRUCTIONS

VISITOR RESTRICTIONS:
☐ No visitors.
☐ No visitors under 18 or pregnant.
☐ ___minutes each day maximum for each visitor.
☐ Visitors must stay behind line on floor at all times.

NURSING RESTRICTIONS:
☐ Patient is restricted to room.
☐ No nurse who is pregnant may render care.
☐ ___minutes each day per nurse in the room.

PATIENT CARE:
☐ Wear disposable gloves. Wash your hands after caring for patient.
☐ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in room
☐ Collect urine in containers provided. Discard feces in toilet.
☐ Discard urine and feces in toilet. Flash 3 times.
☐ Housekeeping personnel are not permitted in the room.
☐ Only RSO may release room to admitting office.
☐ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
☐ _____
☐ _____

In case of emergency, or if you have question, call:
RSO: _____ Work: _____ Home: _____ Mobile: _____
MD: _____ Work: _____ Home: _____ Mobile: _____

EXHIBIT

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 555 MBq

Patient: _____ Room: _____Date: _____

PREPARATION

- ☐ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
- ☐ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- ☐ Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.
- ☐ Prepare urine collection containers if urine will be collected.
- ☐ Stock room with disposable gloves, absorbent paper, and “radioactive waste".
- ☐ Mark a visitors' "safe line" on the floor.
- ☐ Order disposable table service.
- ☐ Notify housekeeping not to clean the room until further notice.
- ☐ Brief the nursing staff on radiation safety measures. Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedure.
- ☐ Administer the dosage.
- ☐ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line", and surrounding hallways and rooms.
- ☐ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

- ☐ Measure the thyroid burden of all personnel who were present for the administration. Pick up waste for decay-in-storage or decontamination.
- ☐ Release the patient.
- ☐ Decontaminate and survey the room. Remove the "Radioactive Materials" sign. Call the Housekeeping Office to clean the room.

APPENDIX Q

MODEL PROCEDURE FOR HOSPITAL CARE AND HANDLING OF RADIOACTIVE PATIENTS INCLUDING PROCEDURE FOR RELEASE OF PATIENTS AFTER RADIONUCLIDE THERAPY

Guidelines for Nursing Personnel Working with I-131 Therapy Patients

Any patient receiving major therapies may be admitted to the hospital as determined by patient-specific dose calculations. If calculations demonstrate the potential total effective dose equivalent to any individual would be greater than 3 mSv, the patient shall remain hospitalized. Radiation exposure and contamination are both concerns when working with I-131 patients. The following guidelines should be observed when working with I-131 patients:

- ☐ Always wear your personnel monitoring dosimeter when attending the patient. Wear the badge between your waist and collar and make sure that the badge worn is the one issued in your name for the current monitoring period. Do not share badges with other workers.
  When you are not working, store your badge in a controlled area away from all radiation sources.
- ☐ Provide all necessary care, but:
  - try to minimize time spent with patient
  - work no closer to patient than necessary
  - wear disposable gloves, gowns, and booties when attending patient.

- ☐ Carefully note instructions posted with the "**CAUTION: RADIATION AREA**" sign (Figure Q.1) and any radiation safety instructions written in the patient"s chart.

☐ As primary contact for matters of the patient"s care, be prepared to answer questions from other nurses, physicians, technical staff members, and visitors. Note the following:

Other hospital staff members are allowed in patient room if stay times and other safety instructions are observed. (Exception: Personnel who do not routinely work with radiation therapy patients may not be required to wear a personnel monitoring device. Visitors may be permitted if they observe the visitor instructions posted at the room entrance.)

Housekeeping and Dietary staff are not permitted in I-131 patient rooms. I-131 patients are to be provided with isolation food trays. Note: Housekeeping may accompany Radiation Safety personnel into patient room during clean-up process under unusual circumstances.

☐ Do not remove room items without clearance from Radiation Safety Officer.

☐ The RSO will survey the patient daily and will notify the physician when activity contained in patient is below release criteria.

☐ Notify the RSO (see posted emergency numbers) if there is a spill of patient urine, the patient vomits or if there is a medical emergency (including patient death).

Model Procedure for Release of Patients After Radionuclide Therapy

The new criteria authorize patient release according to a dose-based limit (3 mSv to the maximally exposed individual) rather than the traditional dose rate limit (0.025 mSv/h) or the activity-based limit (555 MBq) at 1 meter. In most cases, the maximally exposed individual will be a close family member.

The following guidance may be used in calculating the dose at the time of release. The most common criterion considered is the administered dose of the radionuclide. This is the activity of the radionuclide actually given to the patient at the onset of therapy. As the radionuclide decays inside the body, the activity decreases. A significant value that maybe estimated from the administered activity is the retained activity. This generally pertains to the activity of the radionuclide at a certain time of measurement after administration, usually at the release date of the patient given by

$$= \qquad \frac{}{0 \quad 0}$$

(Equation Q.1)

Where :

Q – Retained activity at release in MBq

Q_o – Administered activity in MBq

D – Dose rate at release in mSv/hr

D_o – Dose rate after uptake in mSv/hr

Given that initial activities after release from hospital could be estimated, the equation for accumulated dose at a time t, of an individual can be calculated based on the equation given by the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, “Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides”.

$$( ) = \frac{34.6 \; _0 \; (1 - \; ^{-0.693/})}{}$$

(Equation Q.2)

Where :

D(t) – Accumulated dose for the time period, t

34.6 – Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ – Specific gamma ray constant of a point source

Q_o – Initial activity of the point source at the time of release (this is the retained activity Q in Equation S.1)

T_p – Physical half-life of the radionuclide

E – Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient

r – Distance from the point source to the point of interest

t– Exposure time in days

This Appendix uses the Equation Q.2 in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, (1-e -0.693t/Tp) is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation Q.2 is modified to account for the uptake and retention of the radionuclide by the patient.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation Q.2), at a distance of 1 meter. The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior, suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

This equation calculates the dose from external exposure to gamma radiation. It does not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose. In addition, these calculations use only the physical half-life of the radionuclide, not the effective half-life, which assumes that the body retains the radionuclide until it is fully decayed and that none is cleared through biologic processes. This assumption therefore is likely to overestimate the dose an individual may receive if exposed to a patient treated with therapeutic radionuclide. The licensee may use a patient-specific dose calculation provided that the determination of the dose at release is well-documented for XXXXX inspection.

Physical Data for Iodine-131

Gamma –ray Constant: 2.2 R-cm^2/mCi-hr at 100 cm

Half-life: Physical $T_{1/2}$: 8.04 days

Biological $T_{1/2}$: 120 – 138 days (unbound iodine)

Effective $T_{1/2}$: 7.6 days (unbound iodine)

Example 1: A patient received 5550 MBq of iodine-131 for the treatment of thyroid remnants and metastases. The dose rate at 1 m from the patient was measured to be 0.32 mSv/hr. After 24 hours, the dose rate at 1 m was measured to be 0.1 mSv/h. This dose rate further reduced to 0.04 mSv/h after 48 hours (2 days) of hospitalization. Calculate the maximum likely dose to an individual exposed to a patient if the patient is released after 2 days. The patient received instructions to maintain a prudent distance from others for at least 2 days, sleep alone in a room, and have sole use of a bathroom.

Solution: Using the Equation S.1, we can calculate the retained activity at the end of 2 days.

$$Q = 5550 \text{ MBq} \left(\frac{0.32 \text{ mSv/h}}{0.04 \text{ mSv/h}}\right)$$

$$Q = 693.75 \text{ MBq}$$

The dose to total decay (t = ∞) is calculated based on the physical half-life using Equation S.2. (This calculation illustrates the use of physical half-life and does not account for biological elimination.) Because the effective half-life of Iodine-131 is more than 1 day, the occupancy factor of 0. 25 at 1 meter may be used.

$$(\infty) = \frac{34.6\,(5.95 \times 10^{-5}\ \text{mSv} \cdot \text{m}^2)\,(693.75 \text{ MBq})(8.04 \text{ d})}{(1 \text{ m})^2} \quad (0.25)$$

$$(\infty) = 2.87 \text{ mSv}$$

Since $(\infty) < 3$ mSv, the patient can be released pursuant to IAEA standards. Instructions shall be given to the patient on maintaining doses to others as low as is reasonably achievable. In addition, a record of the calculation must be maintained, consisting of the equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose.

APPENDIX R

RADIATION SAFETY PRECAUTIONS AND INSTRUCTIONS FOR PATIENTS RECEIVING I-131 THERAPY

You have been given a radioactive drug, Iodine-131, for treatment of hyperthyroidism.

Immediately after treatment and for the next _____days at home, follow these instructions:

- ☐ Do not eat or drink for the next 2 hours.
- ☐ After the first 2 hours, drink plenty of water to keep yourself well hydrated for the next 2 days.
- ☐ If you vomit within the first 3 hours of your therapy, avoid touching the vomit with your hands; instead use paper towels or plastic bag to pick up the vomit and flush it down the toilet. Notify us by phone immediately.
- ☐ After treatment, go home directly without stopping at any public places (this may include work) and avoid long trips (longer than 4 hours) in the car or in other forms of transportation where contact with others is unavoidable. If you are driving home with someone after the treatment, make sure you sit apart at the farthest corners of the vehicle.
- ☐ Avoid close contact with others (maintain a distance of at least 2 meters at all times) and limit your time spent close to others to less than half an hour.
- ☐ Avoid close contact with children (less than 18 years old) and pregnant women for the entire week after the treatment to avoid ill-effects of radiation on children and babies.
- ☐ Avoid preparing food for others (use gloves if this is necessary).
- ☐ Do not share food, drink or eating utensils with others; use separate or disposable eating utensils and wash them separately.
- ☐ Make sure you urinate frequently (every hour) especially for the first 12 hours to avoid radiation to accumulate in your bladder.
- ☐ Sit while urinating and flush the toilet twice with the lid down after each use. If possible use a separate bathroom.
- ☐ Change clothes daily (more often if you are sweating) and keep these clothes away from others and wash them separately.
- ☐ Take daily showers and shampoo your hair well. Use separate towel and if you share bathroom with others, keep the towel in your room after use.
- ☐ Sleep alone in a separate bed and room (if possible).
- ☐ Avoid hugging and mouth-to-mouth kissing.
- ☐ No sexual intercourse for 1 week. After that, use contraceptives to avoid pregnancy for 6 months to 1 year after the treatment (as treatment may result in birth defects or loss of pregnancy).
- ☐ Breastfeeding is absolutely prohibited – radioactive iodine can be passed to your child in breast milk.
- ☐ If hospitalized within 7 days, call _____.

Additional Instruction:

_____

_____

_____

I _____ have carefully read and understood the above instructions for radiation safety and will follow these instructions for ____days until _____.

Signature: _____ *Date:* _____

APPENDIX S

PROCEDURE FOR CALIBRATION OF INSTRUMENTS

Calibration of Radiation Survey Meters

Radiation Survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing").

(1) The source must be approximately a point source.

(2) Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

(3) A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

(4) The source should be of sufficient strength to give an exposure rate of about 0.3 mSv/hr (30mR/hr) at 100 cm. Minimum activities of typical sources are 3.145 GBq (85 mCi) of Cs-137 or 0.78 GBq (21 mCi) of Co-60.

(5) The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

(6) A record must be made of each survey meter calibration.

(7) A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

(8) Three kinds of scales are frequently used on survey meters:
   a) Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
   b) Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on each one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.
   c) Meters that have automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

(9) Readings above 10mSv/hr (1000 mR/hr) need not be calibrated. However, such sales should be checked for operation and approximately correct response.

(10) At the time of calibration, the apparent exposure rate from a built-in or owner-supplier check source must be determined and recorded.

(11) The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
   a) The owner or user of the instrument;
   b) A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

c) The description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
d) For each calibration point, the calculated exposure rate, the indicated exposure rate, the deducted correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
e) The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
f) The angle between the radio flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons travel either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specific surface of the instrument);
g) For detectors with removable shielding, an indicator of whether the shielding was in place or removed during the calibration procedure;
h) The apparent exposure rate from the check source; and
i) The name of the person who performed the calibration and the date on which the calibration was performed.

(12) The following information will be attached to the instrument as a calibration sticker or tag:

a) The source that was used to calibrate the instrument;
b) The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
c) For each scale or decade, one of the following as appropriate;
   - The average correction factor,
   - A graph of graphs from which the correction factor for each scale or decade may be deducted, or
   - An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
d) The angle between the radiation flux and the detector during the calibration; and
e) The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report May be used on the calibration sticker.

Calibration of Dose Calibrator

1. Test for the following at the indicated frequency. Repair, replace, or correct mathematically if the dose calibrator falls outside the stated tolerances.
   - Constancy at least once each day prior to assay of patient dosages, during an assigned shift for facilities operating continuously, or after re-location of the dose calibrator. Repair or replace if outside ± 10 percent.
   - Accuracy at installation and at least every 12 months thereafter. Repair or replace if outside ± 10 percent.
   - Linearity at installation and at least every three months thereafter. Repair, replace or correct mathematically if outside ± 10 percent.
   - Geometry dependence at installation. Repair, replace or correct mathematically if outside ± 10 percent.
2. After repair or adjustment of the dose calibrator, repeat the above tests as appropriate.
3. Any of the above dose calibrator tests other than daily constancy tests may be performed by an individual licensed by the XXXXX. Nationally recognized standards or the manufacturer"s instructions may be used to calibrate instrumentation. The standards or instructions used must be available for inspection by the department.

Constancy Test Procedures

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, or Co-57 using a reproducible geometry each day before using the calibrator. Use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
3. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of a suspected malfunction of the calibrator. These action levels will be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

Accuracy Test Procedures

Accuracy means that, for a given calibrated reference source, the indicated activity (in mCi or Bq) value is equal to the activity value determined by the Secondary Standards Dosimetry laboratory (SSDL) or by the supplier who has compared that source to a source that was calibrated by the SSDL. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) will be used. One source will have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it will be at least 10 µCi (3.7×10^5 Bq); other sources will be at least 50 µCi (1.85×10^6 Bq). Use at least one reference source with an activity in the range of activities normally assayed.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
2. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for other calibrated reference sources.
4. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

Linearity Test Procedures

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of that calibrator. This test will be done using a vial or syringe of Tc-99m or F-18 whose initial activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy dose, whichever is largest. The test shall continue until the activity contained in the vial or syringe is smaller than the smallest activity assayed, but greater than 10 µCi (3.7×10^5 Bq).

Decay Method

1. Assay the Tc-99m or F-18, syringe or vial in the dose calibrator, and subtract background to obtain the net activity in mCi (or in Bq). Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.
2. If starting at 8:00 a.m., repeat the assay at 2:00 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity normally assayed. For dose calibrators with a range switch, select the range normally used for the measurement.

3. Convert the time and date information recorded for each assay to hours elapsed since the first assay.
4. On a sheet of semi-log graph paper, label the logarithmic vertical axis in mCi (or in Bq) and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
5. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A(observed) - A(line)}{A(line)} = deviation$$

6. If the worst deviation is more than ± 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
7. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Shield Methods

For initial calibration or reinstallation of the dose calibrator the decay method will be used to determine linearity and to establish calibration factors for shield methods.

☐ A nationally recognized standard or the manufacturer‟s linearity test kit and instructions will be used for doing linearity tests of the dose calibrator. These standards or instructions must be available for review by the department for inspection. Submission of standards or manufacturer‟s instructions to the XXXXX is not required.

☐ We will use a set of "sleeves" of various thicknesses‟ to test for linearity other than the manufacturer‟s test kit. The sleeves will be calibrated using the following procedure:

Calibration of the sleeves:

(1) Begin the linearity test as described in the above decay method. After making the first assay, the sleeves will be calibrated as follows. Steps (b) – (d) below must be completed within six minutes.
(2) Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.
(3) Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.
(4) Continue for all sleeves.
(5) Complete the decay method linearity test steps (b) – (g) above.
(6) From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve one in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step (b).
(7) Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step (c).
(8) Continue for all sleeves.
(9) The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

Calibration of the dose calibrator:

(1) Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the new activity in mCi (or in Bq). Record the net activity.
(2) Steps (c) – (e) below must be completed within six minutes.

(3) Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
(4) Remove sleeve one and put it in sleeve two. Record the sleeve number and indicated activity.
(5) Continue for all sleeves.
(6) On a sheet of semi-log graph paper, label the logarithmic vertical axis in mCi (or in Bq), and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
(7) Plot the data using the equivalent decay time associated with each sleeve.
(8) Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A(observed) - A(line)}{A(line)} = deviation$$

(9) If the worst deviation is more than ± 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow a conversion from activity indicated by the dose calibrator to "true activity."
(10) Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Geometry Test Procedures

Geometry dependence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. When using generators and radiopharmaceutical kits, you will also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cm^3 plastic syringes and that radiopharmaceutical kits are made in 30-cm^3glass vials. If volumes of syringes and vials differ from above, then the procedures will be changed so that syringes and vials are tested throughout the range of volumes commonly used.

(1) In a small beaker or vial, mix 2 cm^3 of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline or tap water.
(2) Draw 0.5 cm^3 of the Tc-99m solution into the syringe and assay it. Document the volume, mCi and record instrument setting.
(3) Remove the syringe from the calibrator, draw an additional 0.5 cm^3 of non-radioactive saline or tap water, and assay again. Record the volume and mCi indicated.
(4) Repeat the process until a 2.0-cm^3 volume has been assayed.
(5) Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. The data will be graphed with horizontal 10 percent error lines drawn above and below the chosen "standard volume."
(6) If any correction factors are greater than 1.10 or less than 0.90, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
(7) To test the geometry dependence for a 30-cm^3 glass vial, draw 1.0 cm^3 of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and mCi indicated.
(8) Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cm^3 of nonradioactive saline or tap water, and assay again. Record the volume and mCi indicated.
(9) Repeat the process until a 19.0-cm^3 volume has been assayed. The entire process must be completed within 10 minutes.

(10) Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed and draw horizontal 10 percent error lines above and below the chosen "standard volume."

(11) If any correction factors are greater than 1.10 or less than 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Calibration Records

1. Constancy check records shall include:
   (b) The model and serial number of the dose calibrator;
   (c) The identity and decay corrected activity of the radionuclide contained in the check
   (d) source;
   (e) The date of the check;
   (f) The activity measured;
   (g) The percent error;
   (h) The instrument settings; and
   (i) The initials of the individual who performed the check.
2. Accuracy test records shall include:
   (a) The model and serial number of the dose calibrator;
   (b) The model and serial number of each source used and the identity of the radionuclide
   (c) contained in the source and its activity;
   (d) The date of the test;
   (e) The results of the test;
   (f) The instrument settings; and
   (g) The name of the individual performing this test.
3. Linearity test records shall include:
   b. The model and serial number of the dose calibrator;
   c. The calculated activities;
   d. The measured activities;
   e. The date of the test; and
   f. The name of the individual performing this test.
4. Geometry dependence test records shall include:
   (a) The model and serial number of the dose calibrator;
   (b) The configuration of source measured;
   (c) The activity measured and the instrument setting for each volume measured;
   (d) The date of the test; and
   (e) The name of the individual performing this test.

Note: See **Exhibits 10 - 12** for some forms on calibration of dose calibrator.

EXHIBIT 78

DOSE CALIBRATOR ACCURACY WORKSHEET

Facility Name: _____ Test Date: ____/____/____

Instrument Name: _____ Model Number: _____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Source	Calculated Current Activity	Measured Activity #1	Measured Activity #2	Measured Activity #3	Background
Co-57	Bq	Bq	Bq	Bq	Bq
Ba-133	Bq	Bq	Bq	Bq	Bq
Cs-137	Bq	Bq	Bq	Bq	Bq

Accuracy Performed by: _____

EXHIBIT 79

DOSE CALIBRATOR LINEARITY WORKSHEET

Facility Name: _____ Test Date: ____/____/____ @_____

Instrument Name: _____ Model Number: _____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Delay	Measurement Date	Actual Time	Measured Activity	Background
0.0 Hours	____/____/____	:	Bq	Bq
6.0 Hours	____/____/____	:	Bq	Bq
24.0 Hours	____/____/____	:	Bq	Bq
30.0 Hours	____/____/____	:	Bq	Bq
48.0 Hours	____/____/____	:	Bq	Bq
54.0 Hours	____/____/____	:	Bq	Bq
72.0 Hours	____/____/____	:	Bq	Bq
78.0 Hours	____/____/____	:	Bq	Bq

Note: Reading should be taken at the lowest possible range setting and converted to Bq units.

Linearity Performed by: _____

EXHIBIT 80

DOSE CALIBRATOR GEOMETRY WORKSHEET

Facility Name: _____ Test Date: ____/____/____

Instrument Information

Instrument Name: _____ Model Number: _____

Manufacturer: _____ Serial Number: _____

Last Linearity Date: _____ Instrument ID: _____

Enter Test Data Below

Volume	Actual Time	Activity
1 ml	:	Bq
2 ml	:	Bq
3 ml	:	Bq
5 ml	:	Bq
10 ml	:	Bq
20 ml	:	Bq

Dose calibrator geometry must be performed at installation and after repair / relocation of the calibrator according to facility license conditions.

Geometry Performed by: _____

APPENDIX T

MODEL PROCEDURE FOR RADIOACTIVE WASTE DISPOSAL AND DECAY-IN-STORAGE

This model provides acceptable procedures for waste disposal. Note that some short half-life radionuclide products (e.g., Tc-99m/Mo-99 generator columns) contain long half-life contaminants that may preclude disposal by decay-in-storage.

Model Procedure for Decay-In-Storage

Section 34 describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.
- Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:
    1. Use a survey instrument that is appropriate for the type and energy of the radiation being measured.
    2. Check the radiation detection survey meter for proper operation and current calibration status.
    3. Monitor in a low-level radiation (<0.5 μSv/hr) area away from all sources of radioactive material, if possible.
    4. Remove any shielding from around the container or generator column.
    5. Monitor, at contact, all surfaces of each individual container.
    6. Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as accordance to IAEA regulatory standards
    7. Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive waste material recipient.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators may be returned to the manufacturer in accordance IAEA regulatory standards. Perform the following actions when returning generators:

- Assemble the package in accordance with the manufacturer‟s instructions,
- Perform the dose-rate and removable-contamination measurements,
- Label the package and complete the shipping papers in accordance with the manufacturer‟s instructions, and

Retain records of receipts and transfers in accordance with IAEA regulatory standards.

APPENDIX U

MODEL PROCEDURE FOR SAFE HANDLING OF DEAD PERSONS THAT CONTAIN UNSEALED RADIOACTIVE MATERIAL (Administered with Therapeutic Dose of I-131)

The precautions to be taken in handling radioactive cadavers depend on the nature and quantity of the radionuclide still remaining and on the type of handling intended (e.g. autopsy or embalming prior to burial).

1. Storage

Storage of the cadaver in an adequately refrigerated compartment is necessary until the dose rate at one meter from it is less than 0.025 mSv/hr. The storage area must be labeled restricted area.

2. Post-mortem Examinations

When post-mortem examinations are performed at places other than treatment centers, no special precautions are necessary provided that the activities remaining in the cadaver do not exceed 555 MBq of I-131. Where the pathologist needs to carry out the post-mortem procedures before the activity has decayed to below the above values, the RSO should be consulted so that the radiation levels likely to be encountered are identified and the hazards involved are assessed. Every effort shall be made to adopt procedures which minimize contamination, and any contamination should be removed immediately after the post mortem examination has been completed.

3. Embalming

The embalming of radioactive cadavers constitutes an undesirable hazard and should be avoided if possible. If the body is not autopsied and embalming is done simply by injection method, the contamination risk to the embalmer is small. All embalmers should wear disposable gloves, protective clothing and face protectors. Embalmers should be supervised by the RSO to observe proper radiation protection measures. Embalming should not normally be carried out if the residual activity in the cadaver exceeds 555 MBq of I-131, but if there are special reasons for doing so, the embalmer should be advised by the RSO of the hospital as to what precautions should be taken. All cadavers in this category shall have a label attached, identifying the radionuclide and its activity at the time of death.

4. Autopsy

Autopsy is inadvisable if the amount of radioactivity in the cadaver is greater than 555 MBq of I-131. The autopsy of highly radioactive cadavers should be invariably restricted to the absolute minimum. It is essential that the staff should wear disposable gloves, and supplementary measures for radiation protection and decontamination should be provided in consultation with the RSO.

5. Cremation

No special precautions are necessary for the cremation of cadavers containing not more than 555 MBq of I-131. Cadavers containing levels in excess of these values should be stored until these limits are reached. The RSO should be consulted before the cadaver is released for cremation.

6. Burial

The amount of incorporated radioactivity allowed at the time of burial depends on the regional and environmental conditions such as climate, distance to cemetery, type of transport, and availability of low-temperature refrigerators.

Precautions to be taken may be classified according to three levels of activity remaining at the time of burial.

(1) Residual activity up to 555 MBq of Iodine-131.

There is no need for personal dose control either of the staff or of the relatives of the deceased and no need for supervision by the RSO. It is unnecessary to mark the cadaver, the coffin, or the clothes or to undertake a contamination test.

(2) Residual activity of 555 - 1110 MBq of Iodine-131.
There is no need for personal dose control of the staff or of the relatives of the deceased. Preparations for burial and any contact between relatives and the cadaver should be controlled by the RSO. The body should be marked with the radiation symbol but no need to label the coffin. All objects, clothes, etc. that might have been in contact with the deceased must be monitored for contamination.

(3) Residual activity of 1.11-11.11 GBq of Iodine-131.
Public viewing must be discouraged at all cost. If necessary relatives must be prevented from coming into contact with the body, and people must not be allowed to linger in the presence of the coffin. The hospital staff, the coroner, the persons washing and preparing the corpse for burial, the staff of the undertaker, and the transportation and cemetery staff must be instructed by the RSO and monitored for their personal dose rate by means of pocket dosimeters. While there is no need to mark the coffin, all objects, clothes, etc. must be monitored for contamination. It is expedient to wrap the cadaver in plastic foil immediately after death has occurred, and it should never be handled unless with disposable protective gloves.

Emergency Procedures in Case a Patient Dies

(1) The nurse or hospital staff on duty must immediately notify the attending physician and the RSO of the death of a radioactive patient.
(2) If the Physician finds that there is still significant residual activity in the cadaver, he must attach a tag with a label indicating that the body contains radioactivity and the estimated activity.
(3) The attending physician must ensure that appropriate instructions and information are given to the relatives of the dead patient.
(4) The RSO shall only allow post-mortem examination or any related activities on the cadaver if the measured exposure dose rate at one meter from the body is less than 0.025 mSv/hr.
(5) The RSO must set the working time limits and provide the proper radiation protection accessories if it is necessary to attend to the body immediately.
(6) If the body is stored and it is necessary for the workers to be near the storage area, then the RSO must set the working time limits and the distance from the area.

Information that should be immediately available

(7) Date and time the patient died.
(8) Radioactive substance remaining in the body of the cadaver (type of radionuclide and activity).
(9) Amount of the radionuclide that was initially administered to determine the residual activity at the time of death.
(10) Radiation dose measurements at different distances from the cadaver.

APPENDIX V

EMERGENCY PLAN

On the basis of events identified by the safety assessment, the licensee shall prepare emergency procedures. The procedures should be clear, concise and unambiguous and shall be posted visibly in places where their need is anticipated.

An emergency plan shall, as a minimum, list/describe the following:

(1) Predictable incidents and accidents, and measures to deal with them;
(2) The persons responsible for taking actions, with full contact details;
(3) The responsibilities of individual personnel in emergency procedures (for example, authorized users, medical physicists and nuclear medicine technologists);
(4) Equipment and tools necessary to carry out the emergency procedures;
(5) Training and periodic rehearsals;
(6) Recording and reporting systems;
(7) Immediate measures to avoid unnecessary radiation doses to patients, staff and the public;
(8) Measures to prevent access of persons to the affected area;
(9) Measures to prevent spread of contamination.

Emergency kits should be kept readily available for use in an emergency.
These may include the following:

(1) Protective clothing, for example overshoes and gloves;
(2) Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
(3) Decontamination materials for persons;
(4) Warning notices;
(5) Portable monitoring equipment;
(6) Bags for waste, tape, labels and pencils.

Types of Emergency Situations

Lost sources

It is critical for this type of event that an up-to-date inventory exists so that it can be determined immediately which source(s) is/are missing, what its type and activity are, when and where it was last known to be, and who last took possession of it. A proactive attitude is important for the case that sources are ordered and not received at the expected time. Making a check for the arrival of a source at the expected receipt time should be part of the procedures. The actions to be part of the contingency plans include:

(1) Obtain assistance from the RSO.
(2) Conduct a local search.
(3) Check and ensure security and control of other sources.
(4) Check all possibilities in the hospital.
(5) If still not found, call the company and inform them of the failure so that they can trace the shipment and find out where the radioactive material is.
(6) If not found, report the loss of the material according to the rules given by the XXXXX.

Damage to Tc-99m generators

Generators contain a relatively large amount of radioactivity. In the event of a 99mTc generator being damaged, the measures to be taken are:

(1) Evacuate the area immediately.
(2) Inform the RSO, who should confirm the spillage and supervise the decontamination and monitoring procedures.
(3) Record the event and make a report according to the rules given by the XXXXX.

Spillage of small amounts of radioactivity
After such a spillage the following actions should be taken:

(1) Use protective clothing and disposable gloves.
(2) Quickly blot the spill with an absorbent pad to keep it from spreading.
(3) Remove the pad from the spill.
(4) Wipe with a towel from the edge of the contaminated area towards the center.
(5) Dry the area and perform a wipe test.
(6) Continue the cycle of cleaning and wipe testing until the wipe sample indicates that the spill has been cleaned.
(7) Use a plastic bag to hold contaminated items. Suitable bags shall be available as well as damp paper towels.

Spillage of large amounts of radioactivity
After such a spillage the following actions should be taken:

(1) The RSO should immediately be informed and directly supervise the clean-up.
(2) Throw absorbent pads over the spill to prevent further spread of contamination.
(3) All people not involved in the spill should leave the area immediately.
(4) Monitor all people involved in the spill for contamination when leaving the room.
(5) If clothing is contaminated, remove and place it in a plastic bag labeled „RADIOACTIVE".
(6) If contamination of skin occurs, wash the area immediately.
(7) If contamination of an eye occurs, flush with large quantities of water.

Medical emergencies involving radioactive patients
This is particularly important for therapy patients containing large amounts of radioactivity. Medical personnel should proceed with emergency care (for example, when a patient has suffered a stroke), while taking precautions against spread of contamination and minimizing external exposure. The staff should avoid direct contact with the patient's mouth, and all members of the emergency team should wear impermeable protective gloves. Medical staffs are to be informed and trained on how to deal with radioactive patients. Rehearsals of the procedures should be held periodically.

Need for urgent patient attention, including surgery
Radiation protection considerations should not prevent or delay life saving operations in the event that surgery on a patient is required. The following precautions should be observed:

(1) Notify the operating room staff.
(2) Modify operating procedures under the supervision of the RSO to minimize exposure and spread of contamination.
(3) Protective equipment may be used as long as efficiency and speed are not affected.
(4) Rotation of personnel may be necessary if the surgical procedure is lengthy.
(5) The RPO should monitor all individuals involved.
(6) Measure doses to members of staff.

Fires
The normal hospital drill should be observed, with the safe evacuation of patients, visitors and staff being the most important consideration. When the fire brigade attends, they should be informed of the presence of radioactive material. No one is allowed to re-enter the building until it has been checked for contamination.

Emergency Preparedness and Response

(1) Preparation of a list of predictable incidents and accidents as well as measures to deal with them;
(2) Designation of persons responsible for taking actions, with complete relevant contact information, including telephone numbers;

(3) Responsibilities of individuals (for example, the nuclear medicine specialist, the qualified expert in nuclear medicine physics and nuclear medicine technologists) in an emergency defined in procedures;
(4) Set of concise instructions posted in a visible area;
(5) Availability of or quick access to persons responsible for carrying out emergency response actions;
(6) Availability of equipment and tools necessary to carry out the procedures;
(7) Training and periodic rehearsals carried out;
(8) Recording and reporting systems in place;
(9) Immediate measures taken to avoid unnecessary radiation doses to patients, staff and the public;
(10) Measures taken to prevent access of persons to the affected area during the time that the sources are exposed and before normal conditions are restored.

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