SOP RSC 4.1 Radiation Safety in Nuclear Medicine

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BACKGROUND

Nuclear medicine uses small amounts of radioactive materials (radiopharmaceuticals) to diagnose and treat disease:

- In diagnostic Nuclear Medicine, radiopharmaceuticals may be injected, inhaled, or swallowed. Radiation emitted from the patient is then detected in order to provide structural and functional information.
- In therapeutic Nuclear Medicine, radiopharmaceuticals may be administered orally, intravenously, or into a body cavity in order to treat disease, or to provide palliative pain relief.

Nature of the Hazard

Radionuclides commonly used for diagnostic studies in Nuclear Medicine are mostly gamma emitters with short half-lives (from hours to several days). A few beta emitting radionuclides are used for therapy, both systemic (administered orally or by injection) and intracavity (injection). Therapeutic radionuclides usually have longer half-lives, ranging from days to months. With all unsealed sources, there is a potential for both external and internal exposure. Sealed sources of long-lived radionuclides, primarily 57Co, 133Ba, 137Cs and 153Gd are used for testing instrumentation. These are primarily an external exposure risk.

External Exposure

Exposure to staff occurs mainly from radiopharmaceutical preparation, dose administration, and directly from subjects to whom a radiopharmaceutical has been administered. Exposure from most sources can be reduced by shielding. The principal source of external exposure to personnel is the subject. While providing nursing care or positioning the subject for imaging, reducing exposure depends mainly on working as quickly as possible.

Internal Exposure

Internal exposure of personnel is very unlikely in routine practice. However, it can occur as a result of contact with

- a spill of radioactivity arising from, for example:
- a leak during administration of a radiopharmaceutical;
- body fluids from the patient, especially urine, saliva, or vomitus; or
- a dropped or damaged source container.

Airborne activity may be released when a vial containing a 131I capsule is opened, or when 99mTc as Technegas is used for lung ventilation studies. Studies have shown that, in normal practice, inhaled 99mTc usually contributes less than a few percent of annual radiation exposure.

HUMAN CLINICAL

Area Designation in Nuclear Medicine

In Controlled Areas, University Personnel are required to follow specific procedures aimed at controlling exposure to radiation. There is usually restricted access marked by appropriate signage, and no eating or drinking is permitted in these areas.

Generally in the Nuclear Medicine, the Hotlab / Radiopharmacy, Therapy rooms, and injection and scanning areas will be designated as controlled areas.

Corridors adjoining rooms where activity is present are also usually designated controlled areas and should not provide public thoroughfare to other areas of the facility.

In Supervised Areas, working conditions are kept under review but special procedures to control exposure to radiation are not normally necessary.

Generally in the Nuclear Medicine facility, the waiting areas and patient toilet are designated as supervised areas.

Nuclear Medicine facilities must be registered under the RML as a “Premises on which radioactive substances are kept or used”, and are generally classified as “Medium Level” premises under the classification system.

Responsibilities

The Radiation Medical Practitioner (The Nuclear Medicine Specialist)

The Nuclear Medicine Specialist is responsible for the clinical management of the subject undergoing a diagnostic or therapeutic nuclear medicine procedure. This includes the decision to proceed with a Nuclear Medicine procedure based on the specialist’s knowledge of the potential risks and benefits of the procedure, taking into account the clinical information, and the sensitivity and specificity of the procedure

The Referrer

The referrer of the subject for a diagnostic or therapeutic procedure needs to be satisfied that the procedure is justified, being aware that the subject will receive a radiation exposure. The referral must state the clinical question that the diagnostic procedure should try to answer, or in the case of a therapeutic procedure, the medical condition for treatment. The referral should also alert the radiation medical practitioner when the referrer is aware that a female subject is pregnant or is lactating. The referral may be in hard copy or electronic form.

The Administering Person

Before any procedure is undertaken, the administering person needs to comply with the centre’s operating procedures regarding how to identify the patient. A series of protocols for specific clinical areas are available from the Australian Commission on Safety and Quality in Healthcare website.

The administering person needs to:

- be trained in intravenous injection and cannulation;

- use protective equipment designed to reduce radiation exposure (e.g. syringe shields, lead pots) and wear an approved personal radiation monitoring device when handling radioactive materials;
- ensure that only persons necessary to the procedure are present when performing administrations; and
- report any instance of accidental, abnormal, or unplanned exposure to the WHS/RSC, and where required also in accordance with RMP Section 19 - Radiation Incidents.

The Nuclear Medicine Technologist

The nuclear medicine technologist is responsible for performing nuclear medicine procedures as prescribed by the referring doctor, and verified by the nuclear medicine specialist:

This will include one or more of the following duties:

- perform imaging and *in vitro* protocols to ensure optimal data acquisition and analysis;
- prepare, dispense, and administer radiopharmaceuticals; and/or
- perform quality assurance procedures for radiopharmaceuticals, instrumentation, and image quality.

The nuclear medicine technologist's role may include the responsibilities of the administering person and the person preparing radiopharmaceuticals.

The Person Responsible for Radiopharmaceuticals

The person responsible for radiopharmaceuticals needs to develop systems for the:

- procurement of radionuclides/radiopharmaceuticals;
- storage and waste management of radionuclides/radiopharmaceuticals;
- in-house reconstitution of radiopharmaceuticals;
- development of safe procedures and practices for the preparation and manipulation of radiopharmaceuticals, in consultation with relevant staff and the RSC; and
- implementation of a quality assurance program for radiopharmaceuticals.

The radiopharmacist / radiochemist plays, in addition to the above duties, a central role in the:

- in-house manufacture of radiopharmaceuticals;
- implementation of a comprehensive quality assurance program for radiopharmaceuticals; and
- provision of advice on the safe and efficacious use of radiopharmaceuticals.

The Nuclear Medicine Physicist

A Nuclear Medicine Physicist is required to be available for consultation regarding optimisation of medical exposures, including clinical dosimetry and quality assurance, and to give advice on matters relating to radiation protection.

The nuclear medicine physicist works closely with the nuclear medicine specialist and technologists in the optimisation of clinical studies – through image acquisition, analysis, display optimisation, and ongoing oversight of the quality control of equipment.

In addition, a medical physicist is required to provide Human Research Ethics Committees with a radiation dose estimation and risk assessment for any research studies that involve the research

participants receiving an exposure from ionising radiation, in accordance with the requirements of ARPANSA's Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005).

The Radiation Safety Committee

The RSC will oversee and provide advice on radiation safety within the Nuclear Medicine Department.

PROCEDURE

General Procedural Considerations

- Gloves must be worn whenever handling unsealed radioactive sources.
- Eating and drinking in Controlled Areas is strictly prohibited, and neither food nor drink may be stored in a refrigerator used for storing radioactive materials.
- Any cut or break in the skin should be covered with a waterproof dressing before a person enters an area where unsealed radioactive materials are handled.
- Radioactive materials should be received, handled, and stored at the specifically designated controlled location. Vessels containing radioactive materials should be labelled with the radionuclide name, chemical form, activity, and date and time of calibration, and should be properly shielded while in use and in storage.
- All containers used for radioactive materials are to be clearly labelled with the radionuclide, form, activity, time, date, and when appropriate, a note as to the sterility/ expiry time or otherwise.
- All such containers are to be adequately sealed and shielded at all times. Except for very small activities, containers are not to be handled directly and if possible, long handled tongs or syringe shields should be used.
- Equipment provided specifically for the safe handling of unsealed radioactive materials should always be used and should not be removed from the work area. Pipettes should never be operated by mouth. Recapping of syringe needles, if absolutely necessary, should be performed using a suitable recapping device.
- Shielding should always be considered for any radioactive source. The prior risk assessment should identify the shielding that is required and what type and form it should take. Appropriate shielding may be obtained using a variety of materials such as tungsten, lead, lead glass, aluminium, or Perspex, depending on the characteristics of the radionuclide to be shielded.
- Lead syringe holders should be used to transport syringes containing radioactive materials. Syringe shields should be provided for ready use during radiopharmaceutical preparation and administration whenever practicable. It should be noted that any additional time spent in manipulating the syringe when adjusting the activity to be administered to a patient can result in additional dose to the hands of the administering person.
- All work surfaces where unsealed radioactive substances will be used must be covered with absorbent paper such as "Benchcote".
- All staff handling radioactivity are to be familiar with contamination and decontamination procedures.

- Personal radiation monitors are to be worn by designated staff at all times when working in the DRA. Designated staff include all nuclear medicine technologists, physicians, physicists, radiochemists, nursing staff, and other relevant university personnel.
- Finger radiation monitors are to be worn on the index finger of the technologist's hand used for injecting, when any radioactivity or radioactive subjects are being handled.
- Packaging, containers, lead pots etc. which no longer contain radioactive material, and which are to be disposed of MUST have any radiation warning labels removed or covered before disposal. Empty containers, lead pots, and packaging MUST be removed from the working area and disposed of as appropriate.
- A long-sleeved gown must be worn when administering Technegas to a subject.
- During imaging in the scanning rooms, the staff should remain behind the lead glass shielded console areas as much as possible.

For procedures specifically relating to Preparation and Dispensing of Radiopharmaceuticals, see Part 4.5 below.

Facilities Required

The radiopharmacy facility should be located, designed, constructed, and maintained to suit the operations to be carried out. The layout and design should be such as to minimise the risk of errors and to permit effective cleaning and maintenance, the avoidance of cross contamination, the build-up of dust or dirt, and any other influences that may adversely affect the quality of radiopharmaceuticals. Additionally, the facility needs to be designed to give proper radiation and contamination protection to personnel.

Construction features of a laboratory area should include:

- Floors: smooth, continuous, non-absorbent, washable, no penetrations. eg. Welded sheet vinyl coved up the walls
- Walls: Shielded, free of dust collecting ledges and pipework. eg. concrete, masonry, plasterboard with lead lining, high gloss paint, sheet vinyl, laminate
- Bench Tops: Resistant to chemicals, hard wearing, strong supports, lipped & coved. eg. High grade laminate on water resistant board, polymer resins, stainless steel.
- Plumbing: Draining direct to main sewer, traps for monitoring. eg. Shower, toilets for patient, shower, toilets, handbasin, eyewash for staff; sink, cleaners sluice, pan steriliser.
- Air handling: controlled temperature and humidity, exhaust ventilation for waste store, I-131.
- Usually, there should be a shielded store for waste.
- AS/NZ 2982. Laboratory Design and Construction

Equipment Required

Radiopharmacies, laboratories, and other work areas where unsealed radioactive substances are handled should be provided with radiation protection equipment kept specifically for this purpose. This equipment may include:

- lead barriers (fixed or mobile) with lead glass windows for work with photon emitters;
- Perspex barriers for work with beta emitters;

- syringe shields;
- shielded containers;
- drip trays to contain any spillage;
- tongs or forceps to maximise the distance of the worker from the source;
- radiation and contamination monitoring equipment;
- dose calibrators;
- fume cupboards;
- biohazard cabinets;
- shielded transport containers; and
- equipment and materials to deal with spills.

Personal Protective Equipment

Protective clothing is to be used in work areas where there is a likelihood of contamination, both to protect the body or clothing of the worker, and to help prevent contamination to other areas. The clothing should be monitored and removed before leaving designated areas, e.g. when visiting the staff room.

The clothing may include:

- laboratory coats or protective gowns;
- waterproof gloves; and
- face masks where there is a risk of airborne droplets.

Overshoes are not routinely required but may be needed in radiopharmacies handling greater than 200 GBq of technetium-99m and should be included in the decontamination kit, to be worn when cleaning up a major spill.

The following uses of personal protective equipment are suggested:

Gloves	Unpacking radionuclide packages Administering diagnostic injections Handling closed waste containers Administering I-131 capsules Preparing low activity samples for counting
Gloves, gown	Milking Mo-99 generator Preparing radiopharmaceuticals Dispensing injections Nursing sweaty or incontinent subjects Changing contaminated bedding Administering lung ventilation radiopharmaceuticals Preparing Tc-99m sources for gamma camera QC
Gloves, gown, plastic apron	Emptying bed pans, bottles, catheter bags, changing contaminated bedding
Gloves, gown, eye protection	Giving therapy injections or oral liquids, eg Sr-89, Y-90, I-131, (I-131 MIBG, or I-131 iodide) Labelling blood cells

Double gloves gown overshoes	Cleaning up spills

In certain circumstances, staff may need to wear a protective lead apron. This may be necessary if staff need to be in close contact with subjects containing greater than 800 MBq of 99mTc, such as during myocardial perfusion studies or gated cardiac blood pool studies. Protective aprons should preferably have a thickness of 0.5mm lead equivalence. Preferred designs are those comprising a separate vest and skirt that wrap around fully. Open back designs are not recommended. All protective clothing should be examined under fluoroscopy at least annually to confirm the integrity of the protection.

Lead aprons provide little or no protection for higher energy photons and should not be used for radionuclides such as gallium-67 or iodine-131 or for positron emitters.

Staff leaving designated areas should remove protective clothing, wash their hands, and monitor their hands, clothing, and body as appropriate.

Mobile shielding barriers may be required for therapeutic nuclear medicine procedures using gamma-emitting radionuclides.

Procedures for the Preparation and Dispensing of Radiopharmaceuticals

The following rules should be observed when preparing or dispensing radiopharmaceuticals:

- Eating, drinking, smoking, or the application of cosmetics are prohibited.
- All preparation and dispensing of radiopharmaceuticals must be carried out behind suitable lead or lead-glass shielding.
- Disposable gloves should be worn at all times, and preferably so should laboratory coats or gowns. Safety glasses must be used if the work is of a hazardous nature to the eyes. Gloves should be changed at regular intervals in order to minimise the spread of contamination.
- Personal dosimeters are to be worn at all times when handling radioactive materials or working in areas where they are handled or stored.
- Packaging and containers for radioactive material must be observed for contamination on opening.
- The receipt of all radioactive material must be recorded in the Radionuclide Register.
- The work area should be prepared and set up by covering surfaces with plastic-backed absorbent material (such as Benchcote) and laying out needles, syringes, shields, forceps, diluents, gloves, and other necessary items.
- Radioactive materials should be kept in closed, sealed vials within shielding containers.
- For reconstituted vials, a radiopharmaceutical record sheet should be maintained. It should include the batch numbers, manufacturer, date received, expiration time/date, the name of the person preparing the radiopharmaceutical, and any quality assurance tests performed. Identifying labels with a dated batch number should be affixed to radiopharmaceutical vials and shielding containers prior to the preparation of patient doses. These should identify the radiopharmaceutical, the total radioactivity, the volume, and the time and date of calibration.

- Each individual patient/subject dose which is prepared must be recorded in the register and the staff member preparing the dose must be recorded electronically or by signature.
- All working surfaces should be covered with absorbent paper that has an impermeable plastic coating – plastic side facing the bench-top.
- Small spills that present no radiological hazard to persons should be cleaned up as soon as possible. Major spills may require evacuation of the area before clean-up is undertaken, and need to be reported immediately to the RSC. See RMP Section 19.
- Mouth pipetting of any radioactive substance is TOTALLY PROHIBITED.
- Interruptions to the preparation or dispensing of radiopharmaceuticals should be avoided.
- In order to demonstrate confinement of radioactivity, a suitable electronic radiation detector should always be available when radioactive materials are handled.
- Hands, shoes, and clothing should be monitored for contamination in a low-background area, allowing sufficient time for instrument response, before leaving the radiopharmaceutical laboratory.
- A radiation survey for contamination and sources must be done at the end of the working day in the radiopharmacy dispensing bay and Hot Lab, paying particular attention to the waste bins. A complete radiation contamination survey MUST be done weekly, with all results documented.

Special Procedures for Therapy Administration

If there is ever any need to for therapy administration, then reference and compliance with ARPANSA RPS 14 and sub sections is mandatory. WHS and the RSC must be consulted at all times for this.

Pregnant or Breastfeeding Staff

If an occupationally exposed member of the nuclear medicine staff is pregnant, then the foetus should be afforded the same level of protection as a member of the public. This may be achieved by controlling the exposure of the employee such that the dose received by the foetus is less than the public effective dose limit of 1 mSv for the remainder of the pregnancy. For external irradiation from technetium-99m or iodine-131, a dose of 1.3 mSv to the surface of the maternal abdomen has been shown to give rise to a dose of 1 mSv to the foetus. For higher energy photons, such as those from positron emitters, the dose to the foetus may be similar to the dose at the surface of the abdomen.

The likely dose to the foetus of a pregnant employee from each work activity should be assessed. This will usually require an examination of the employee's personal monitoring records, and an assessment of the likelihood of incidents leading to either external or internal exposure of the foetus. If the foetus could receive more than 1 mSv over the declared term of the pregnancy, a change in work practice should be discussed and agreed to with the employee. It would be prudent to provide an occupationally exposed pregnant staff member with an electronic personal dose monitor.

Pregnant women, or those intending a pregnancy or breast-feeding, should not work with large amounts of radioiodine.

If a member of staff is breast-feeding she should not take part in procedures or work in areas where there is a significant risk of bodily contamination, e.g. cleaning up a large spill of radioactivity. An assessment should be undertaken of the potential radiation dose to the infant resulting from a chance inhalation by the mother of radioactive gases or aerosols arising from her work and appropriate procedures put in place to restrict this dose if necessary.

Emergency Procedures in Nuclear Medicine

Accident Decontamination Procedures

There are three major causes of contamination by a radioactive material:

- Spillage from a source container;
- Leakage during an injection procedure; and/or
- From patient excretion such as urine, faeces, sweat, saliva, and vomitus.

Spills of radioactive material should not be regarded as an unavoidable hazard in the day-to-day operation of the department. Any spill carries some degree of risk and acceptance of minor spills may lead to a casual approach to major spills. Accidents involving radioactive material must be reported to the Radiation Safety Committee of the University. In cases where personal injury is also involved, even if this is minor, e.g. a scratch on the skin where radioactive material may enter the person's body, an Incident Report Form must also be filled out.

The following procedure should be followed on discovery of a contamination problem:

(i) All persons involved in the incident are to vacate the immediate vicinity but are not to move freely around the department, as this involves a danger of spreading contamination.

(ii) Notify IMMEDIATELY, the University Radiation Safety Committee (or the medical physicist) and the senior technologist for the area.

(iii) If the contamination is due to a container spill of liquid and the hands are protected with gloves, right the container, and ensure that it is adequately shielded. If the problem is due to a leaky syringe or other container, place suspect item in a labelled plastic bag and remove it to the Waste Room.

(iv) Seal off the area involved and in particular ensure that personnel do not walk on any possible contaminated floor area. Discard any clothing which is contaminated and place it in a labelled plastic bag and store in Waste Room. If there is any radioactive material on the skin, flush thoroughly with water.

Decontamination of Personnel

- Wash with soap and water, scrubbing lightly with a soft nail brush, avoiding spreading contamination to the eyes and mouth. If the hair is contaminated, it will be necessary for the individual to shower in order to remove this contamination.
- Monitor with an appropriate radiation monitor until the count rate is less than 1000 cps or the dose rate is less than 10 µSv/hr. with the detector at a point close to (but not touching) the contaminated region of skin.
- Eyes which are contaminated should be washed using the dedicated eyewash station. The mouth should be rinsed with water.

- Contaminated wounds should be washed under fast running water and bleeding encouraged. Finally, apply a gentle antiseptic and a first aid dressing.

Decontamination of Work Environment or Equipment

The following should be performed by the University RSC, the Chief technologist, or a Senior technologist:

- Define the area of contamination using an appropriate survey meter and, if appropriate, mark hot spots with a felt tipped pen. Be aware that this pen may become contaminated and must be dealt with accordingly.
- Permit no person to resume work in the area until a survey is made and decontamination procedures have been satisfactorily carried out.
- Decontamination of any contaminated area cannot be performed by a fixed set of rules, but must have regard for the radioisotope form and type of contamination. The decontamination trolley stored in the Hot Lab should be used. The following general information applies in most cases:
    i. In cases of spillage during patient injection or drawing up of a dose, a suitably clad (gown, gloves, overshoes) person shall soak up any obvious liquid contamination with blue incontinence sheets or absorbent paper, placing them into a labelled plastic bag for storage. Once this step has been performed, decontamination of contaminated surfaces can take place.
    ii. Swabs or similar absorbent material soaked in decontamination fluid shall be used to swab and scrub small contaminated areas until a minimum decontamination effect is attained. This will in most cases mean that the surface dose rate at the area in question can be reduced to something less than 10 µSv per hour.
    iii. Where items of equipment have been contaminated it may be preferable to store such items until the activity has been reduced to a safe level.
    iv. Relatively low activity spills of 99mTc (count rate less than 1000 cps) may be handled by technologists in this manner. Areas that have been decontaminated and where the dose rate is still at a high level should be avoided until the activity has reached a safe level.
    v. Floor surfaces that cannot be completely decontaminated, or where it is uncertain if further activity is present, should be covered with a plastic sheet until the activity has decreased to a satisfactory level. The covering must be marked with brief details such as radionuclide, dose rate, and date.

Further advice on Decontamination principles and Decontamination Kits can be found in Radiation Incidents - (See RMP Section 19).

Miscellaneous Exposure from Radioactive subjects

On occasions when a subject who has already been administered a diagnostic radiopharmaceutical is then required to undergo another medical procedure, a radioactive patient presents a source of radiation exposure to other staff. Therefore, as a general rule, it may be prudent to consider performing other procedures before the administration of the radiopharmaceutical.

However, the risk to staff is extremely small, and in practice there are very few requirements for special scheduling of procedures for subjects who have been administered diagnostic radiopharmaceuticals. It is important to note that the prior administration of a radiopharmaceutical to a subject is not of itself a contraindication to performing X-ray, ultrasound, or other procedures. A decision about what precautions should be adopted (if any) depends upon an assessment of the amount of radiation exposure to others from the subject as a result of the nuclear medicine procedure. The decision to proceed with the other test should be based primarily on clinical need. Social and economic factors should also be taken into account when balanced with:

- medical implications of delayed diagnosis;
- the cost for accommodation incurred by lengthening stays; and
- the inconvenience for subjects who must return for the test.

Special scheduling requirements would very rarely be justified.

With sonography, due to the potential for extended periods of close contact, there is further advice in NSW Health Policy Directive – Limiting Staff Exposure to Ionising Radiation.

REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
Dec 2014	Version 1	William Bartolo, Bartolo Safety Management Service
May 2016	Version 2	William Bartolo, Bartolo Safety Management Service
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