



Department of Health

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LICENSING REQUIREMENTS FOR NEW NUCLEAR MEDICINE PRACTICES

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Proposed Authority Holder:	
Applicant (practice or branch):	
☎:	Fax:
Email:	
Premises address	
General site info:	
Street:	
Building:	
Section:	
Suburb: Postal code:.....	

1. General

1. Authority

Yes	No	Has the proposed authority holder already applied for an authority on form RN787?	
Yes	No	Does the applicant have other existing authorities?	
A	B	C	Does the application include type A, B or C laboratories?
Yes	No	Have a Radiation Protection Officer (RPO) and Acting Radiation Protection Officer (ARPO) been appointed?	
Yes	No	Have a Medical Physicist (MP) and Acting Medical Physicist (AMP) been appointed?	
Yes	No	Are contractual agreements, including duties, of the RRP, ARPO, MP and AMP in place?	
Yes	No	Are copies of the qualifications of staff available?	
Yes	No	Has a Radiation Protection Management Plan been included in the Application?	

2. Facilities

2.1 Air conditioning and ventilation

Yes	No	Are the room ventilation and air conditioning of such a nature to prevent recirculation of exhausted air from rooms where radionuclides are used, and which could under accident conditions become contaminated, into inactive areas or into the central air conditioning system of the hospital/building?
Yes	No	Is the hot laboratory classified as a Type B laboratory?
Yes	No	If Yes, are radioactive materials in a volatile form introduced into the facility?
Yes	No	Is a fume hood provided?
Yes	No	Is the extraction fan able to ventilate the hot laboratory with a ventilation rate of at least 12 air changes per hour?
Yes	No	Is the hot laboratory classified as a Type C laboratory?

2.2 Sinks

Yes	No	Are two basins provided in the hot laboratory?
Yes	No	Is the wash basin allocated for liquid waste disposal clearly marked as such?
Yes	No	Does the sink for liquid waste disposal have a resilient non-permeable surface, e.g. polypropylene, PVC or stainless steel?
Yes	No	Is a separate (non-active) hand wash basin, fitted with an elbow-operated tap, provided near the exit of the laboratory?

2.3 Sealing of areas

Yes	No	Are all joints on working surfaces and all corners sealed?
Yes	No	Are all joints around wash basins in the laboratory, as well as in the gamma camera room, sealed?

2.4 Surfaces

Yes	No	Are the walls, floor and work surfaces of impermeable material and easy to clean?
Yes	No	Are all the floors, walls and work surfaces smooth and non-absorbent to facilitate cleaning and decontamination?
Yes	No	Does the material have good thermal and chemical resistance to substances which are normally used in the laboratory?
Yes	No	Are the walls covered with non-absorbent paint?
Yes	No	Are the ceilings similarly surfaced?
Yes	No	Is the floor covering "non-slip" and (after welding if necessary) in one continuous sheet?
Yes	No	Is the junction of floors, walls and work surfaces rounded off in order to facilitate cleaning?
Yes	No	Where joints are unavoidable, are they placed where the risk of spills and splashes is small, and are they filled with a sealing compound?
Yes	No	Are working surfaces covered with disposable material (e.g. Bench-cote)?

2.5 Hot laboratory

Yes	No	Is the hot laboratory area at least 4 m ² ?
Yes	No	Is the door of the hot laboratory lockable from the inside?

2.6 Toilets

Yes	No	Are separate toilet facilities available for public, patients and staff?
Yes	No	Are radiation signs posted on toilet facilities used by patients?
Yes	No	Will radiation monitoring be done in facilities used by patients?

2.7 Protective clothing

Yes	No	Will laboratory coats be worn when working with unsealed radioactive nuclides?
Yes	No	When not handling radionuclides, will protective clothing be removed so that the spread of contamination is prevented?
Yes	No	Has a suitable hook been mounted near the exit of the hot laboratory for hanging up coats after use?
Yes	No	Is an area near the exit of the laboratory demarcated to provide space for changing coats, shoes, gloves, etc?
Yes	No	Is equipment for hand & foot monitoring available?
Yes	No	Will hand & foot monitoring be recorded when staff exit the hot area?

2.8 Disposal of radioactive waste

Yes	No	Will radioactive waste be stored until it has decayed to acceptable levels?
Yes	No	Before disposal, will the radiation levels of the waste be measured to ascertain that the radioactive material has decayed to background levels?
Yes	No	Are sufficient refuse bins provided to allow for appropriate segregation of solid waste?
Yes	No	Do the bins have foot-operated lids?
Yes	No	Are the bins lined with removable plastic bags to facilitate the removal of waste without contamination?
Yes	No	Are all receptacles for radioactive waste clearly identified (e.g. as "low-level radioactive waste", "non-active waste", etc.)?
Yes	No	Are all active waste bins marked with radiation warning signs?

2.9 Radiation storage facilities

Yes	No	Is a source inventory for sealed sources, including source calibrations certificates, available?
Yes	No	Is the maximum radiation level outside the storage facility within prescribed levels?
Yes	No	Is the security of the storage facility adequate?
Yes	No	Is an area for decay of low-level waste available?
Yes	No	Will the management of low-level waste disposal be adequately managed and recorded?

2.8 Isolation rooms

Yes	No	Will therapeutic doses (I-131 / I-125) be administered to patients?
Yes	No	Are isolation rooms available?
Yes	No	Do the isolation rooms comply with requirements?

3. Radiation protection

3.1 Area surveillance, radiation levels and contamination

Yes	No	Has area surveillance been performed by a medical physicist?
Yes	No	Are areas demarcated according to radiation exposure levels?
Yes	No	State the maximum exposure rate measured at the position next to the ⁹⁹ Mo generator that corresponds to the position of the radiographer $\mu\text{Sv/h}$
Yes	No	Will areas where isotopes are used be monitored on a daily basis?
Yes	No	Will records be kept of the results of routine monitoring of the workplace?

3.2 Radiation warning signs

Yes	No	Are radiation warning signs displayed appropriately on all entrance doors to rooms where radioactive material is handled, i.e. all entrances to counting rooms, administration rooms, the hot laboratory etc.?
Yes	No	Do the abovementioned doors display the name and telephone number of the RPO and ARPO as required?
Yes	No	Is a sign indicating the type of facility, e.g. Type B laboratory displayed at the entrance to the hot laboratory?
Yes	No	Is a radiation warning sign affixed to the waste receptacles?
Yes	No	Is a radiation warning sign affixed to the waste bin?
Yes	No	Is a radiation warning sign affixed to all containers for radioactive waste?
Yes	No	Is a radiation warning sign displayed on radiation storage facilities?

4. Equipment

4.1 Radiation monitoring equipment

Yes	No	Is appropriate radiation monitoring & surveillance equipment available?
Yes	No	Is the abovementioned equipment calibrated, and are the results recorded?

4.2 Isotope calibrator

Yes	No	Is at least one dose calibrator available?
Yes	No	Does the range of isotopes on the calibrator adequately cover the isotopes that will be used in the facility?
Yes	No	Is a suitable check source, e.g. an 8-10 MBq Cs-137 source, permanently available on site for this purpose?
Yes	No	Will quality control be performed daily on the isotope calibrator?
Yes	No	Will a record book be kept and updated?
Yes	No	Will independent calibration checks be done, and by whom?
		What imaging equipment will be used?

4.3 Imaging and other diagnostic equipment

Yes	No	Has the medical physicist done acceptance tests on imaging and other diagnostic equipment?
Yes	No	Are QA procedures, frequencies, responsibilities clearly defined and recorded?
Yes	No	Will record books be kept and updated?
Yes	No	Will the MP oversee QA procedures, maintenance records and equipment failures?

4.4 Emergency equipment

Are the following items of emergency equipment provided and readily available?

Yes	No	appropriate emergency equipment and procedures
Yes	No	protective clothing, including overshoes
Yes	No	decontamination materials, including absorbent material for wiping up spills
Yes	No	warning notices and fencing off material (adhesive tape and labels)
Yes	No	tools, cans and plastic bags for handling, temporary storage and disposal of contaminated articles
Yes	No	portable monitoring instruments

4.5 Other

Yes	No	Will Spect-CT be done in the facility?
Yes	No	Will PET-CT be done in the facility?

5. **Procedures**

5.1 Plastic gloves and paper towels

Yes	No	Are plastic gloves and paper towels available in the laboratory and placed so that they are easily accessible when needed?
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5.2 Before leaving the radioisotope facility, will workers:

Yes	No	Remove gloves in a manner which prevents contact between the potentially contaminated outer surface and the skin?
Yes	No	Remove protective clothing?
Yes	No	Wash hands thoroughly?
Yes	No	Monitor hands, clothing and shoes?

5.3 Dedicated fridge/microwave oven/stove

N/A

Yes	No	Will dedicated appliances e.g. fridge/microwave oven/stove inside the hot laboratory be used for radioactive material?
		Is the staff aware that the abovementioned appliances may not be used for general purposes?
Yes	No	Is a notice to that effect displayed on each of the appliances?
Yes	No	Do all rooms where unsealed radioactive material is handled or stored display a notice prohibiting eating, drinking, smoking, applying cosmetics, pipetting by mouth of any liquid containing radioactive material, or storage of any personal objects?
Yes	No	Will the same radiographer perform duties in the hot-lab and on imaging equipment?
		If yes, how will contamination of imaging equipment be prevented and monitored?

6. Radiation Protection Management

6.1 Health register & personnel monitoring

Yes	No	Have medical examinations pertaining to the registration of all the radiation workers already been arranged?
Yes	No	Has a Health Register been opened for each registered radiation worker?
Yes	No	Will all personnel working with radionuclides wear personal dosimeters (TLD badges)?
		Will personnel handling radionuclides wear finger TLD badges, where applicable?
Yes	No	Will radiation workers have access to their personal dose register?
Yes	No	Are electronic personal dosimeters (EPDs) available, where applicable?

6.2 Record-keeping

Yes	No	Will records of all patients receiving radionuclides, including doses administered, be available?
Yes	No	Will records of radionuclides delivered to the facility be available, dose deviation and suppliers?
Yes	No	Will a stock record of unsealed sources be kept and updated?
Yes	No	Will a record of waste disposal be kept and updated?
Yes	No	Will a record of incidents be kept and updated?
Yes	No	Will a record of the annual leak test(s) of calibration source(s) be kept?
Yes	No	Have internal rules been compiled pertaining to the specific circumstances in this undertaking which might create a radiation hazard to the health or safety of persons attached to work with radioactive material, e.g. all aspects of receiving, handling, dispensing, storing, preparation and calibration of radioactive material; disposal of radioactive waste; emergency procedures to be followed in cases of emergencies or accidents; procedures to be followed in case of loss or theft; safe transport of radionuclides; procedures for dealing with spills; responsibilities of the radiation protection officers and medical physicists; radiation warning signs, stock records, leak tests, etc? If Yes, please attach a copy.
Yes	No	Are standard operating procedures (SOPs) available for all procedures involving radionuclides?
Yes	No	Are SOPs available for all QA procedures?
Yes	No	Are procedural arrangements available for all foreseen incidents and contamination events?
		How often will internal rules and SOPs be reviewed?

6.2 Re-locations and removal/disposal of obsolete/redundant equipment

Yes	No	Are arrangements for relocation and/or closure of the facility available?
Yes	No	Are arrangements for removal/disposal of obsolete/redundant radioactive sources and/or equipment containing radionuclides available?

On behalf of (Name of Institution/Authority Holder),

I, (RPO, please print), and

I, (Medical Physicist, please print),

hereby declare that the information supplied in this document has been verified and/or measured and is to the best of my knowledge true and correct.

Signature: Date:
RPO

Signature: Date:
Medical Physicist