Application No

REVIEW AND ASSESSMENT OF LICENCE APPLICATION
NUCLEAR MEDICINE

Diagnostic ☐ **Therapy** ☐

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF APPLICANT _____

PROCESSING OFFICER

ITEM	YES	NO	NOTES and ACTIONS
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	New applications - enter information into the database and record the application sequence number (and/or future licence number) on the application. Renewals - update the database as required.
Required details provided?	☐	☐	Has required information been provided including postal and physical address, RPO, source inventory, RPP, etc? If not, or if unclear, discuss with the assessment officer and, return the application for the additional information as directed. Mark record with bring-up date.
Legal person identified?	☐	☐	Name and position held has been stated? If not, discuss with the assessment officer.
Application signed by the legal person?	☐	☐	Application to be returned if unsigned. However, first discuss with the assessment officer as other matters may need to be raised with the applicant. Return the application for signature as directed. Mark record with bring-up date.
Correct fees paid?	☐	☐	Check that the correct fee has been paid. If not, first discuss with the assessment officer as other matters may need to be raised with the applicant. Send letter advising fee details. Mark record with bring-up date.
File and related papers prepared for assessment?	☐	☐	Create the licence file (retrieve previous file for renewal) and transfer with the application, related papers and the relevant review and assessment forms to the assessment officer
If all matters have been satisfactorily completed, the application is to be forwarded to the officer assigned to review this class of application. Applications held for further information must be followed up within 10 working days.			

COMMENTS (Record the details if the application is returned to the applicant for further information)	
Signature	**Date**

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Diagnostic ☐ **Therapy** ☐

FIRST APPLICATION ☐ **RENEWAL** ☐ **DATE RECEIVED** _____ / _____ / _____

NAME OF APPLICANT _____

ASSESSMENT OFFICER *(Tick relevant box or enter "n/a" if not applicable)*

ITEM	YES	NO	NOTES and ACTIONS
PERSONNEL RESOURCES AND TRAINING			
Nominated radiation protection officer satisfactory?	☐	☐	Confirm that the nominee has appropriate qualifications and experience for the position and has appropriate authority to undertake the required duties and responsibilities.
Nominated Qualified Expert satisfactory?	☐	☐	Confirm that the nominated QE has appropriate qualifications and experience. ***Note**: This person may also be the medical physicist.*
Responsible medical practitioner satisfactory?	☐	☐	Confirm that the nominated medical practitioner has appropriate qualifications and experience
Nominated medical physicist satisfactory?	☐	☐	The physicist is to be accredited in nuclear medicine by the appropriate professional body. Duties include performing or supervising the calibration of dose calibrators, imaging and counting equipment, supervising radiation safety during therapy administrations, etc. ***Note**: This person may also be the qualified expert.*
Nucleographers appropriately qualified?	☐	☐	Confirm that the nucleographers employed (or contracted by) the applicant have appropriate qualifications and will be supervised by an appropriately qualified medical practitioner. (If the applicant has combined CPECT/CT equipment, additional radiographic qualifications and/or training may be required.)
Other personnel appropriately trained and supervised?	☐	☐	Confirm that other personnel have appropriate radiation safety training and will be adequately supervised.
Nursing staff appropriately trained for in-vivo therapy procedures?	☐	☐	Where patients undergo therapy (and are in-patents) are nursing staff appropriately trained in radiation safety and emergency procedures?
FACILITIES, SOURCES AND EQUIPMENT, TRANSPORT			
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises, and the siting of the radiation sources (including patients to whom radioactive sources have been administered) and the use of operator protective barriers (where necessary) will ensure at least the minimum prescribed level of worker and public radiation safety.
Therapy Facilities Satisfactory?	☐	☐	• Confirm that the design, construction, ventilation, etc. of hospital rooms used for nursing therapy patients will ensure at least the minimum prescribed level of worker and public radiation safety. • For iodine therapy in particular, ensure that the facility

ITEM	YES	NO	NOTES and ACTIONS
			has waste storage tanks, etc to ensure that appropriate delay and decay takes place and that the effluent subsequently complies with the regulations.
Qualified Expert Report provided?	☐	☐	• A report is required to demonstrate that the premises are constructed to ensure compliance with the dose and dose rate limits prescribed by the regulations, that laboratories and rooms used for the preparation and administration of radionuclides and the nursing of patients meet the Regulatory Authority's requirements. • The report will also address all safety related matters including working rules for the safe handling of radioactive sources (sealed and unsealed), ventilation, warning signs, waste disposal, effluent concentration, survey meters, personal alarms and IEDs, storage, transport and disposal of radioactive sources, etc.
QE report satisfactory?	☐	☐	The report may need to be reviewed by an external expert if the Regulatory Authority does not have internal expertise.
Radioactive sources comply?	☐	☐	Are the radioactive sources and activities listed in the inventory approved by the Regulatory Authority for use in nuclear medicine (eg ^{99m}Tc, ^{99}Mo, ^{131}I, etc)?
X-ray equipment complies?	☐	☐	If the applicant has x-ray equipment (eg a combined SPECT/CT scanner) does the x-ray equipment comply with relevant design and performance standards?
Security of radioactive sources satisfactory?	☐	☐	Is access to radioactive sources, whether in storage or in use, adequately controlled to ensure a satisfactory level of security?
Leak Testing	☐	☐	Procedures for leak testing sealed radioactive sources (other than short half-life sources) satisfactory?
Imaging devices are subject to regular maintenance?	☐	☐	Is the imaging equipment subject to maintenance and calibration at intervals prescribed by the manufacturer?
Storage facility complies?	☐	☐	• Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, security, ventilation, external dose rate limits and potential public exposure? • Is it suitably labelled, including stating the means of contacting the licensee and/or RPO in case of emergency?
Survey meters and personal alarms, IEDs, etc. comply?	☐	☐	• Are the survey meters identified by the applicant suitable for the intended purposes? • Do they have a current satisfactory calibration for the radiation energies to be used, including test for fold back when subject to high radiation exposure rates? • Are there sufficient personal alarms and IEDs and are they subject to regular function checks?
Applicant has suitable, functioning dose calibrator?	☐	☐	• Is the dose calibrator suitable for the nuclides used? • Routinely used to measure all nuclides to be administered? • Calibrated at satisfactory intervals?

ITEM	YES	NO	NOTES and ACTIONS
Transport of radioactive sources complies (where relevant)?	☐	☐	• Has the applicant made complying arrangements (where responsible) for the transport of radioactive sources? • Source containers secured, vehicles labelled, etc in compliance with IAEA Transport Regulations? • Procedures for monitoring incoming and outgoing packages satisfactory?
Waste disposal arrangements comply?	☐	☐	Has the applicant made suitable arrangements for the disposal of radioactive waste (gaseous, aerosols, liquids, solids) clearly identifying how this will be achieved?
JUSTIFICATION, OPTIMIZATION, RESEARCH			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of diagnostic and therapeutic procedures	☐	☐	• These matters are the responsibility of the designated medical practitioner. Guidelines on applicable activities to be administered should be available from the relevant professional body. • Protocols should describe the procedures required to perform the examination (or therapy) as well as working rules to properly identify patients and the radionuclide to be administered, and to ensure safety for the patient, staff and public. • Protocols should also explain procedures for investigations on pregnant or potentially pregnant patients, and children
Research procedures and protocols satisfactory?	☐	☐	If research is performed that involves the exposure of patients or volunteers, the applicant must show that they act on advice from an acceptable Ethical Review Committee and will comply with the provisions of the Helsinki Declaration and the guidelines prepared by the Council for International Organizations of Medical Sciences and the World Health Organization,
OCCUPATIONAL AND PUBLIC EXPOSURE			
Applicant's protocols ensure that occupational and public radiation doses will comply with the prescribed limits?	☐	☐	Does the applicant properly discriminate between occupationally exposed and non-occupationally exposed employees and the public who may be in the vicinity when radiation is used or where radioactive sources are stored?
Arrangements for Personal Radiation Monitoring comply?	☐	☐	• Has the applicant provided satisfactory information on the numbers and types of personal monitoring devices that will be used (film badges, TLD, OSL, personal alarms, etc? • Biological monitoring performed when necessary? • Has the applicant made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose? • Is the stated monitoring period (frequency) satisfactory?
Personal Monitoring Service Provider is approved?	☐	☐	Is the personal monitoring service provider approved by the Regulatory Authority

ITEM	YES	NO	NOTES and ACTIONS
WORKING RULES, RECORDS, EMERGENCY PROCEDURES, AUDITS,			
QA and Working Rules satisfactory?	☐	☐	Are the applicant's QA program and working rules satisfactory for the procedures to be undertaken by the applicant?
Working rules for therapy administration satisfactory?	☐	☐	• Does a medical physicist attend therapy administrations to ensure all safety procedures are satisfactory and that contamination risks are minimized? • Do protocols ensure compliance with the activity limits for the discharge of treated patients? • Are therapy out-patients given appropriate instructions on travel and other safety related matters? • Are procedures in place to deal with therapy patients who might die shortly after administration of the therapy (autopsy, embalming, cremation)?
Routine audit program satisfactory?	☐	☐	• The licensee audits the RPP at suitable intervals? • The licensee / RPO regularly (and without notice) audits radiation safety practices of its personnel?
Emergency, accident and incident plans satisfactory?	☐	☐	• The applicant's emergency procedures are appropriate? • Does the applicant have appropriate equipment to deal with emergencies (spills)? • Are the applicant's procedures for dealing with accidents and incidents appropriate? • Personnel appropriately trained with regard to dealing with emergencies and with the requirements for notifying accidents / incidents?
Records satisfactory?	☐	☐	Has the applicant made suitable arrangements for maintaining records (inventory, source movement register, occupational dose records, audits, etc)?
If a renewal, are there any outstanding items of non-compliance and/or is legal action being considered by the Regulatory Authority?	☐	☐	If yes, the application should be discussed with the assessor's supervisor to determine an appropriate course of action
If all matters have been satisfactorily completed, the application is to be forwarded to the assessor's supervisor and then to the officer authorised to sign the application			

COMMENTS		
	Signature	**Date**

ITEM	YES	NO	NOTES and ACTIONS

Supervisor			
Review an d Assessment Procedures Satisfactory?	☐	☐	Check that the Assessing Officer has completed all relevant sections, that the fee, authorization period, applicant's name, licensed location(s) and purpose(s) are correct and an authorization number and expiry date are stated.
Authorization can be approved?	☐	☐	Confirm that any attached conditions, restrictions or limitations imposed on the authorization are appropriate before the authorization is signed.
Inspection Personnel Informed?	☐	☐	Inspection personnel advised of the application for inclusion in the inspection program

COMMENTS		
	Signature	**Date**