Application No

REVIEW AND ASSESSMENT OF LICENCE APPLICATION
RADIOTHERAPY

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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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 radiotherapy physics by the appropriate professional body. ***Note**: This person may also be the qualified expert.*
Radiation Therapists appropriately qualified?	☐	☐	Confirm that the radiation therapists employed (or contracted by) the applicant have appropriate qualifications and will be supervised by an appropriately qualified medical practitioner.
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 brachytherapy and afterloading techniques?	☐	☐	Where patients undergo brachytherapy with implanted sources (and are in-patents) or are treated by afterloader techniques, are nursing staff appropriately trained in radiation safety and emergency procedures?
FACILITIES, SOURCES, EQUIPMENT, TRANSPORT			
Premises satisfactory?	☐	☐	Confirm that the design and construction of the premises, and the siting of the radiation sources (including those within patients), will ensure at least the minimum prescribed level of worker and public radiation safety.
Qualified Expert Report provided?			• A report is required to demonstrate that the premises are constructed to ensure compliance with the dose and

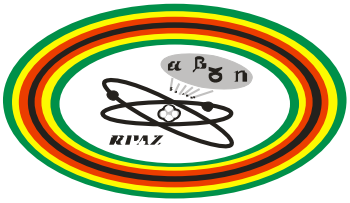
☐ ☐

ITEM	YES	NO	NOTES and ACTIONS
			dose rate limits prescribed by the regulations. • The report will also address all safety related matters including the working rules for the safe operation of the radiation sources, interlocks, warning signs, fixed area alarms, survey meters, personal alarms and IEDs, storage, transport and disposal of radioactive sources, operational security 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 radiotherapy (eg ^{192}Ir, ^{60}Co, ^{137}Cs)?
Therapy devices and x-ray equipment comply?	☐	☐	Do the radiation devices (x-ray equipment, linear accelerators, teletherapy and brachytherapy equipment) comply with specified design and performance standards? eg ISO, IEC
Security of radioactive sources satisfactory?	☐	☐	• Is access to radioactive sources whether in use, storage or installed in radiation devices adequately controlled to ensure a satisfactory level of security? • Are devices physically secured to prevent operation (eg key required to operate), tampering, interference, removal or maintenance by unauthorized persons?
Leak Testing	☐	☐	Procedures for leak testing sealed radioactive sources (other than short half-life sources) satisfactory?
Radioactive source replacement equipment?	☐	☐	• Applicant has appropriate equipment to safely exchange new and spent sources? • Are the source transfer procedures satisfactory?
Radiation devices are subject to regular maintenance?	☐	☐	• Are the radiation devices subject to maintenance at intervals prescribed by the manufacturer? • Is service undertaken by authorized personnel?
Storage facility complies?	☐	☐	• Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, security, 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?
Transport of radioactive sources complies (where relevant)?	☐	☐	• Has the applicant (when responsible) made complying arrangements 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?
Radiation source disposal arrangements	☐	☐	Has the applicant made suitable arrangements for the disposal of spent radioactive sources and unwanted x-ray

ITEM	YES	NO	NOTES and ACTIONS
satisfactory?			equipment, clearly identifying how this will be achieved?
JUSTIFICATION, OPTIMIZATION, RESEARCH, CALIBRATIONS			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of, therapeutic procedures	☐	☐	• These matters are the responsibility of the designated medical practitioner. Guidelines on applicable treatment regimes should be available from the relevant professional body. • Protocols should describe the procedures required to achieve the desired clinical outcome as well as working rules to properly identify patients and to ensure safety for the patient, staff and public.
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,
Does the applicant possess a suitable radiation measuring instrument for calibrating the radiation output of the radiation sources?	☐	☐	The make and model should be described, together with details of its calibration schedule, identification of the calibrating organization and confirmation that the calibration is traceable to a recognized standard.
Have all radiation devices been calibrated in compliance with the Regulatory Authority's requirements?	☐	☐	The applicant should provide details of the last full calibration for each device. For brachytherapy sources, the date the activity (dose rate) was last re-calculated should be stated.
Are protocols for daily, weekly, monthly performance and safety checks of radiation devices satisfactory?	☐	☐	Routine output reproducibility and related safety checks will usually be performed by the medical physicist and/or radiation therapists under the supervision of the medical physicist. These checks do not replace full calibration procedures.
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? • 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 each type of therapy to be undertaken by the applicant?
Brachytherapy (LDR, HDR, permanent implants, interstitial x-ray therapy) procedures satisfactory?	☐	☐	• Permanent implants - does the medical physicist attend treatments to ensure all sealed sources are accounted for and that safe working procedures are observed? • Afterloaders (LDR) – does the medical physicist supervise the device's initial set-up, the commencement of treatment and confirm source retrieval at the end of the treatment? • HDR and interstitial x-ray therapy – is the medical physicist present throughout the procedure to supervise radiation safety procedures?
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 plans satisfactory?	☐	☐	• The applicant's emergency procedures are appropriate? • Does the applicant have appropriate emergency equipment?. • Personnel appropriately trained in these procedures?
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**



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SUPERVISOR

ITEM	YES	NO	NOTES and ACTIONS
Review and 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**