Radiation Protection Authority

Zambia

SAFETY GUIDE

RPA SG 1

Licensing, Notification, Exemption and Exclusion

2015

NOTICE OF APPROVAL

The Radiation Protection Authority Board (RPAB), has on the (day/month/2015), approved the safety guide on Licensing, Notification, Exemption and Exclusion. This guide is approved for the purposes of providing practical guidance with respect to the Ionising Radiation Protection Act, No. 16 of 2005.

Dr. Esther Munalula Nkandu	Mr. Boster Dearson Siwila
….....	…..….....
CHAIRPERSON	EXECUTIVE DIRECTOR
Radiation Protection Authority Board	Radiation Protection Authority

FOREWORD

Over the last 50 years, the use of Ionising Radiation in Zambia has significantly increased. Institutions using Ionising Radiation include those in Health, Manufacturing, Mining, Agriculture, Research and Training sectors.

Notwithstanding its beneficial effects, human and environmental radiation exposure might cause harmful effects. To guarantee public, worker and environment radiation safety and security, there is need for all activities and practices involving the use of ionising radiation to be licensed in accordance with the legal requirements.

In 2005, the Zambian Government enacted the Ionising Radiation Protection Act to provide for the protection of the public, workers and the environment from the harmful effects arising from the use of devices or materials that produce ionising radiation. The Ionising Radiation Protection Act allowed for the establishment of the Radiation Protection Authority to spearhead the implementation of provisions of the Act. To fully implement the Act the Zambian Government has priotised strengthening national regulatory capacity. Strengthening national regulatory capacity includes among other equally important elements, the development and implementation of Safety Guides for Practices using ionizing radiation.

In view of the above, and the legal provisions on the use of ionising radiation, there is a great need to develop safety guides for the members of the public to build capacity and effectively comply with these practices so that protection against harmful effects of radiation can be attained. In fulfilment with the provisions of the Ionising Radiation Protection Act, No. 16 of 2005, this safety guide specifies the RPA scheme of Notification and Licensing of radioactive sources and devices. It describes the notification and licensing processes and the required information. It is my sincere hope that this guide will be a good basis for attaining sustainable radiation protection of the public, workers and the environment and compliance by Licensees with the provisions of the Law.

Hon Dr. Joseph Kasonde, MP

MINISTER OF HEALTH

LIST OF ACRONYMS

RPAB Radiation Protection Authority Board

RPA Radiation Protection Authority

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 General

1.1.1 The RPA is mandated to control the use of ionising radiation in Zambia. The need to control the use of radiation sources stems from their potential to cause harm to the public, workers, and the environment. Potential users of radiation sources are therefore required to notify the RPA of their intent to acquire a radiation source and thereafter seek to be licensed to possess and use the radioactive source.

1.1.2 Subject to exemption or exclusion, this guide applies to the following actions regarding radiation sources;

1.1.2.1 Possessing, processing and use,

1.1.2.2 Selling, disposing , leasing, or loaning,

1.1.2.3 Importation or exportation,

1.1.2.4 Transportation

1.1.2.5 Mining of radioactive ore,

1.1.2.6 Installation of radiation sources/devices (including whole body scanners)

1.1.2.7 Production and modification,

1.1.2.8 Use of ionising radiation in the manufacturing, assembling and distribution of consumer products , and

1.1.2.9 Any other activity relating to the use of ionising radiation.

1.2 Objectives

The objective of this safety guide is to outline the process used by RPA to examine notifications and license applications. It also provides the criteria for exempting and excluding sources and Practices from regulatory control.

2.0 NOTIFICATION

2.1 Any person who intends to carry out any of the actions specified in Section1.1.2 of this guide shall be required to provide justification for their intended actions. The justification shall form part of the notification by the applicant to the RPA. Notifications shall be filed with the RPA as stipulated in annex I of this guide.

3.0 RPA NOTIFICATION REVIEW PROCESS

2.2 The RPA review process is summarized in Figure 1.

2.3 The RPA shall notify the applicant of the outcome of the review within 30 days after receipt of the application.

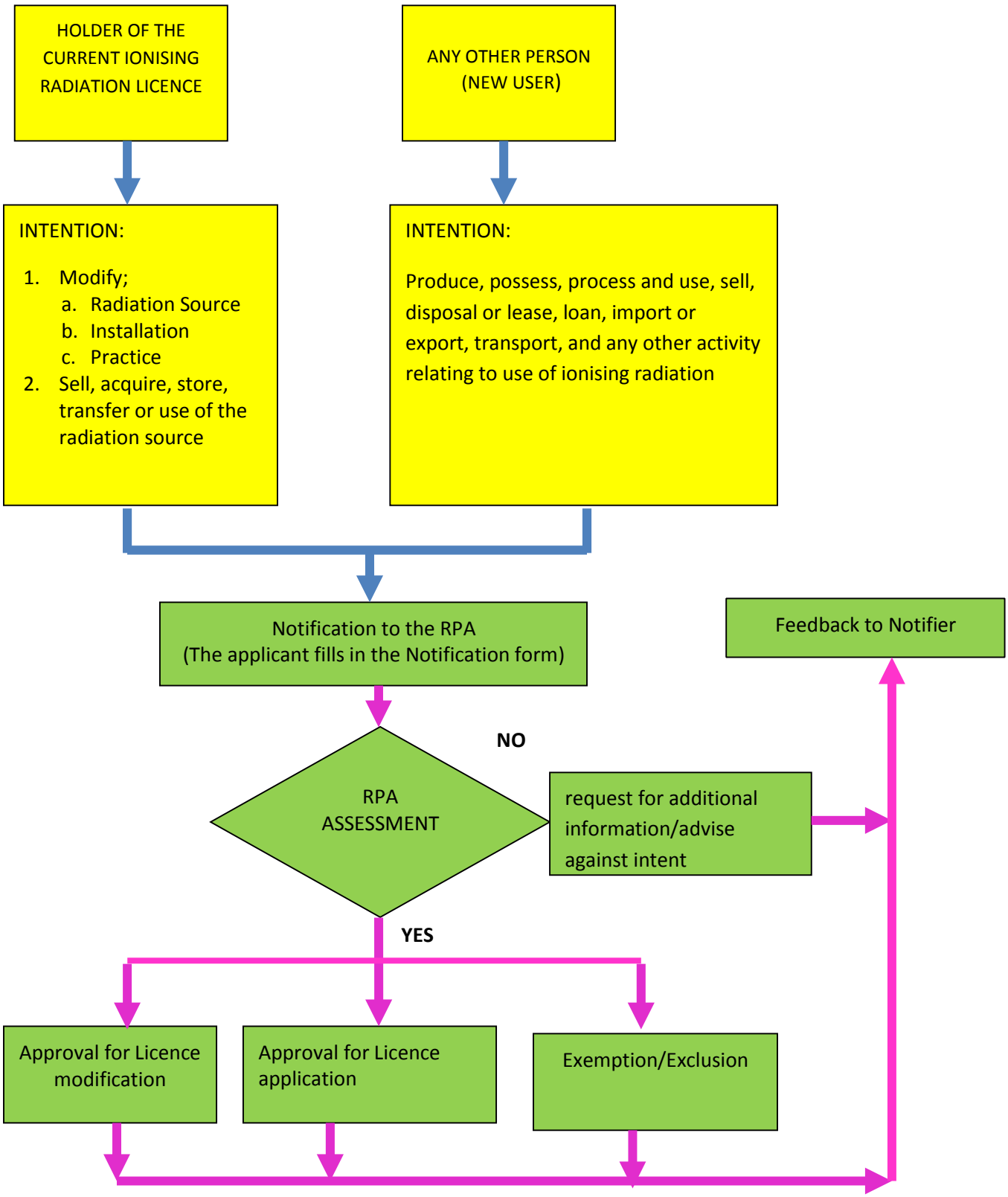
2.4 The outcome of the review process by the RPA shall either be;

2.4.1 approval for licensing,

2.4.2 exemption/exclusion,

2.4.3 request for modification /additional information from the application or 2.4.4 advise against intent

NOTIFICATION PROCESS



3.0 EXEMPTION

The RPA shall determine which categories of applicants shall be exempted from further scrutiny and review of their applications based on criteria set by the Authority. Applicants that meet the set exemption criteria shall be advised to proceed with the acquisition or use of the ionising radiation source.

To arrive at the exemption decision, the RPA will rely on the prescribed exemption schedule (Second Schedule Regulation 3) as provided for in the general regulations

5.0 EXCLUSION

Any exposure whose likelihood of occurrence is essentially not amenable to control shall be excluded from regulatory control. Such exposures could arise from naturally occurring radioactive materials, for example ^{40}K, cosmic radiation at the surface of the earth and unmodified concentrations of radionuclides.

6.0 LICENSING

6.1 Following the approval of notification, applicants may proceed to the licensing stage.

6.2 Any person applying for licensing shall submit to the RPA, the relevant information to make an assessment of the nature, magnitude and likelihood of the exposures attributed to the practice.

6.1 Licensing process

6.1.1 The applicant shall submit to the RPA a completed Licencing application form prescribed in Annex II of this guide.

6.1.2 The applicant shall be required to attach, where applicable, the following documents to the application form:

6.1.2.1 Personnel qualification/certification;

6.1.2.2 Structural and Design of shielding;

6.1.2.3 Equipment and maintenance plan;

6.1.2.4 Work procedures and instructions;

6.1.2.5 Transport Instruction; and

6.1.2.6 Radiation Protection Management Plan.

6.1.3 RPA may conduct a pre-licencing inspection in accordance with inspection procedures outlined in the Inspection Safety Guide. The result of the prelicensing inspection can be:

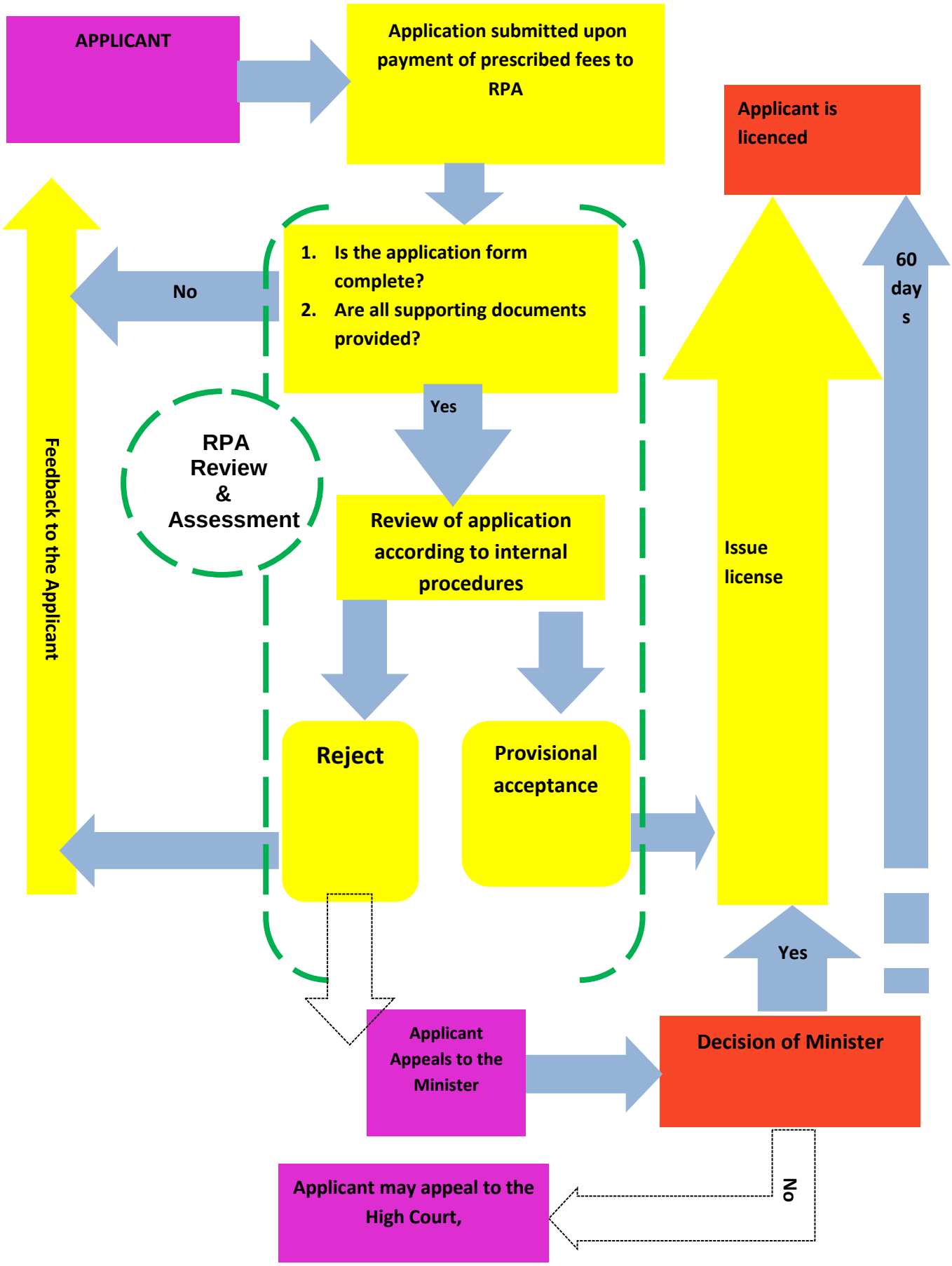
6.1.3.1 Licensing;

6.1.3.2 Request for additional information; and

6.1.3.3 Refusal.

6.1.4 Where additional information is required, a licence shall not be issued until the requested information fulfils the requirements for licensing.

LICENSING PROCESS



ANNEX

NOTIFICATION FORM

(To be completed in triplicate)

THE RADIATION PROTECTION AUTHORITY

NOTIFICATION FORM		
For official use only	Notification Number:	

Information Required (in BLOCK LETTERS)	
1. General Information of Applicant	
Name (s) of Applicant	
Nationality	
Identity card No.	
Passport No.	
Company Name	
2. Purpose of application *(include field of application and purpose(s) for which the radiation practices and sources are to be used)*	
3. Company / Organisation	
Name	
Physical Address	
Postal Address	
Fax:	
E-mail:	

Telephone (Office)	
Telephone (Home)	
Mobile	

4. Sources and Radiation generating equipment/ Irradiator Facility/ Accelerator (Electrical devices producing ionizing radiation)

Manufacturer	Model	Serial Number.	Maximum power (E.g. max. radiographic kVp, mA)	Use

5. For radioactive sources and apparatus containing radioactive substances

Radionuclide [e.g. Co - 60]	Activity [Bq] *(For sealed sources include the date at which the activity applies)*	Use	Form (*solid, gas, liquid, sealed, unsealed)*	If the source is enclosed in a device		
				Manufacturer	Model	Serial Number

Signature

Applicant's name

Date

FOR OFFICIAL USE ONLY

Received by:……..……

OFFICIAL STAMP

Officer

Date Received:……

ANNEX II: APPLICATION FORM FOR IONISING RADIATION LICENCE

FIRST SCHEDULE

(*Regulations* 4, 5(2), 6, 7, 8, 9, 10,11,12,13 and 14)

Form I

(Regulations 4)

(To be completed in triplicate)

THE RADIATION PROTECTION AUTHORITY

The Ionising Radiation Protection Act, 2005

(Act No. 16 of 2005)

The Ionising Radiation Protection (General) Regulations, 2011

APPLICATION FOR IONISING RADIATION LICENCE				
		Shaded field for official use only	Application No.	
			Licence Code	
Information required		*Information provided*		
1.	Name (s) of applicant			

2.	(a) Nationality		
	(b) Identity card		
	National Registration Card No.		
3.	Notification address		

	Fax:		
	Email:		
4.	Purpose of application		
5.	Name and qualifications of person responsible for radiation source (irradiator or radiography facility / radiation generating equipment / accelerator)		
6.	Contact details of person responsible for radiation source (irradiator or radiography facility/radiation generating/ equipment /accelerator radioactive material)		
7.	Licence previously held by the applicant under the Ionising Radiation Protection Act, 2005, or similar legislation outside Zambia*(attach certified copies)*	Licence No.	Location
8.	Licence currently held by the applicant in Zambia if any, under the Ionising Radiation Protection Act, 2005	Licence No.	Location

9.	Have you ever been convicted of an offence involving fraud or dishonesty or of any offence under the Ionising Radiation Protection Act, 2005, or any other law within or outside Zambia? If yes, specify details: ……..…… Nature of offence: ……...……. Date of conviction: ……..……. Sentence: …….	

10.	Have you ever applied for a licence under the Ionising Radiation Protection Act, 2005? If yes please give details below:					
	Licence applied for:	Activity	Location	Date of application	Status of application (Granted, rejected or pending)	
11.	Source and Irradiator Facility / Radiation generating equipment / Accelerator					
	Model / Type No.	Manufacturer	Supplier	Proposed date of commissioning	Class	

12.	Details of radioactive sources										
	Radionuclides	Number of sources				Total activity (Bq)		Source details		Storage Wet / dry	
		Per pencil	Per Module	Per rack	Total	Initial	At installation	Model No.	Designation		

DECLARATION

I ……. do solemnly declare as follows:

a) that the information provided in this Form is correct and true;
b) that I have never been debarred from practising my profession on the ground of professional misconduct;

c) that my name has never been removed from the Register kept in accordance with the laws of any country in which I have practiced my profession; and
d) no inquiry is pending which may result in the action referred to in paragraphs (b) and (c); and I make this solemn declaration conscientiously believing the same to be true to the best of my knowledge and belief.

_____
Signature

Declared ……..….this……..day of ……, 20…….. before me

.....
Commissioner of Oaths / Notary Public

_____ .....
Applicant's name Date

_____
Applicant's signature

FOR OFFICIAL USE ONLY

Received by:…….…….. RECEIPT No:……..……

Officer

Date

Received:……

Amount

OFFICIAL STAMP

Received:……..

Serial No. of application:……

ANNEX III: LICENSING GUIDANCE FOR APPLICANTS

I. DIAGNOSTIC RADIOLOGY

A. Note: The following numbers refer to the numbers on the application form

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of the X- ray equipment). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. In this case, the purpose for which the radiation sources are to be used is diagnostic radiology.
3. Enter the full name and address of the company or organization, the actual location(s) where the X- ray equipment will normally be used or stored.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e.. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. State the full name, qualifications, training, experience and contact details of the medical practitioner (s) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, diagnostic X-ray procedures. Attach the nominee's CV together with copies of supporting documentation. Include a description of the actions to be taken by the medical practitioner(s) to justify and optimise all procedures, and the actions to be taken in respect of pregnant or potentially pregnant patients.
7. Fill as appropriate; 8. Fill as appropriate; 9. Fill as appropriate;
10. Fill as appropriate;

11. Particulars of the radiation sources. State the manufacturer, model, serial number, purpose and location of the X- ray equipment together with the peak tube potential (kVp) and current (mA).

B. RADIATION PROTECTION PROGRAMME

*The operator must also submit a Radiation Protection Programme (**RPP)** addressing all aspects of radiation safety particularly the safety of the X- ray equipment and work practices. At a minimum, the **RPP** will include the following:*

a) Plan of the premises with a report from a QA verifying that the design and construction of the premises, and the siting of the X ray equipment, will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints/dose limits by appropriate scientific methods.

b) The qualifications, training and experience of medical practitioner(s), radiographers nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified medical practitioner(s) of those personnel who operate the X- ray equipment.

c) The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection:

- *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (irrespective of the reported dose).*
- *Provision of protective equipment for operators of X- ray equipment.*
- *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*

d) Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes:

- *Working rules for the X- ray procedures to be undertaken, e.g. the use of shielding, distance and time, patient protection, pregnant patients, children, use of grids, beam collimation, type and speed of image receptor, restrictions on the use of fluoroscopy (i.e. not to be used for routine patient positioning), etc.*
- *If research is performed that involves the exposure of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, 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.*

- *The policy for pre-employment radiography or radiography for insurance or administrative purposes.*

  Note: Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.
- *If the operator intends providing screening examinations (e.g. chest, mammography, bone density, etc.) provide the protocols to show that the specified examinations will be justified (i.e.. through the potential of the screening procedure for detecting disease as well as the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease).*

  ***Note:** Mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.*
- *The facility's QC programme for ensuring that the X ray equipment continues to comply with the prescribed design and performance standards and that film/image processing is optimized (e.g. darkroom light tight, properly safe lit, use of appropriate film image processors).*
- *The operator's protocols for determining patient radiation doses and ensuring compliance, where practicable, with guidelines values established by a recognized body or professional organization.*

e) *The arrangements to ensure safety of radiation sources: arrangements for regular safety audits including maintenance of the X-ray equipment inventory; reviewing safe working practices, warning signs, etc.*

f) *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*

g) *The legal person's plans for notifying the regulatory body of:*
   - *occupational or public radiation doses which exceed prescribed limits;*
   - *reportable incidents and accidents; and*
   - *any significant changes to the information previously provided to the regulatory body including:*

     □ a planned change of location for the operator's principal operations;
     and □ the receipt, transfer or other planned disposal of X ray equipment

II. DENTAL PRACTICES

A. Note: The following numbers refer to the numbers on the application form

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of the X- ray equipment). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.

2. In this case, the purpose for which the radiation sources are to be used is dental radiology.
3. Enter the full name and address of the Company or organization, the actual location(s) where the X- ray equipment will normally be used or stored.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates. A dental practitioner may be nominated as the RPO.
5. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the registrant on radiation safety and perform regular audits of the registrant's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation. **Note**: The regulatory body may waive this requirement for basic intraoral installations where it is satisfied that potential occupational exposures are likely to be insignificant.
6. State the full name, qualifications, training, experience and contact details of the Dental Practitioner (or Medical Practitioner) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, the dental X-ray procedures. Attach the nominee's CV together with copies of supporting documentation. Include a description of the actions to be taken by the practitioner to justify and optimise examinations.
7. Fill in as appropriate; 8. Fill in as appropriate; 9. Fill in as appropriate;
10. Fill in as appropriate;
11. Particulars of the radiation sources. State the manufacturer, model, serial number, purpose and location of the X- ray equipment together with the peak tube potential (kVp) and current (mA). **Notes:**
    - Purposes include intraoral, panoramic and cephalometric radiography, etc.
    - The location may be a room number or room description. State the serial number on the X ray control panel.

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of the X- ray equipment and work practices. At a minimum, the RPP will include the following:

a) A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of the X -ray equipment, will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints dose limits by appropriate scientific methods.

***Note:** In general, for small, basic intraoral installations, the regulatory body will be satisfied if the dentist provides a plan (to scale) showing the location of the X- ray equipment, the exposure control and operator(s), the building materials and the use and occupancy of surrounding areas.*

b) *The qualifications, training and experience of Dental Practitioners, nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified Dental Practitioners of those personnel who operate the X- ray equipment.*

c) *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection: Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (irrespective of the reported dose).*

Note: *The regulatory body may exempt individual dental practices from routine monitoring of personnel where it is satisfied that potential occupational exposures are likely to be insignificant. Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes:*

d) *Working rules for the X- ray procedures to be undertaken. (e.g. the use of shielding, distance and time, patient protection, film holders, pregnant patients, children, beam collimation, type and speed of image receptor, etc.).*

e) *The facility's QC programme for ensuring that the X -ray equipment continues to comply with the prescribed design and performance standards and that film/image processing is optimized; arrangements for regular safety audits including maintenance of the X -ray equipment inventory; reviewing safe working practices, checking area dose rates, warning signs, etc.*

f) *The registrant's protocols for determining patient radiation doses and ensuring compliance, where practicable, with guidelines values established by a recognized body or professional organization.*

g) *If research is performed that involves the exposure of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, 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.*

h) *The policy for pre-employment radiography or radiography for insurance or administrative purposes.* ***Note:*** *Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide*

useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

i) *If the operator intends providing screening examinations (e.g. panoramic radiography, etc.) provide the protocols to show that the specified examinations will be justified (i.e. through the potential of the screening procedure for detecting disease as well as the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease).* ***Note****: The mass screening of population groups*

involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

j) The arrangements to ensure safety of sources: arrangements for regular safety audits including maintenance of the X- ray equipment inventory; reviewing safe working practices, warning signs, etc.

k) The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.

l) The registrant's plans for notifying the regulatory body of:

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents;*
- *any significant changes to the information previously provided to the regulatory body including:*
  - ✓*a planned change of location for the registrant's operations; and*
  - ✓*the receipt, transfer or other planned disposal of X- ray equipment.*

III. WELL LOGGING

A. Note: The following numbers refer to the numbers on the application form

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources in the practice of well logging). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. In this case, the purpose for which the radiation sources are to be used is well logging.
3. Enter the full name and address of company or organization the actual location(s) where radiation sources will normally be stored or used.
   - Field sites where authorized radiation sources are used for limited periods not need to be included on this application. However, any field site where logging operations may last more than 90 days must be identified. Where such sites arise after the licence is issued, the operator must give prior written notification of the details to the regulatory body.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's CV together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, and training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's curriculum vitae (CV) together with copies of supporting documentation.
6. Not applicable.
7. Fill as appropriate
8. Fill as appropriate
9. Fill as appropriate

10. Fill as appropriate
11. The operator must provide a full description of all radiation sources to be used. An inventory also must be provided for non-radioactive sources (e.g. electrically generated neutron sources, etc.).
    - List all non-exempt radionuclides to be used or stored (e.g.. ^{241}Am, ^{137}Cs, ^{131}I, etc.) together with the activity or, for short half-life material subject to regular replacement or dispersion during logging procedures, the maximum activity to be held at any one time. State all activities in SI units and, except for the short half-life material, the date at which the activity was determined.
    - Identify every source container or device that contains (or will contain) radioactive material by the manufacturer, model and serial number, including the type of logging tool in which the source is to be used. If depleted uranium is used for radiation shielding in any device state the mass (kg) in each.
    - For devices that generate ionizing radiation electrically, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA) and, in the case of neutron generators, the neutron flux and mean energy.

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) The qualifications, training and experience of in radiation protection of workers engaged in activities that involve or could involve occupational exposure. In addition to the well logger, the RPP also must address the initial and ongoing radiation safety training and supervision of logging assistants and show that the operator has, or will have, sufficient personnel to ensure that each assistant works under the immediate personal supervision of a qualified logger during all logging procedures.

b) A plan of the principal premises (i.e. where sources may be stored, maintained, calibrated, etc.) with a report from a qualified expert verifying that the design and construction of the premises will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.

c) The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.

- *Working rules for logging operations (e.g. the use of shielding, distance and time; the identification and marking of site boundaries; ensuring that before exposures no unauthorized persons are within controlled areas; supervision and control of site boundaries; the use of warning signs; the routine use of survey meter and personal*

alarms, including pre-operational checks; procedures for handling unsealed radiation sources).

- *Procedures for attempting recovery of radiation sources jammed in wells, including contamination-checking precautions in case a source is ruptured during the process, and the subsequent actions to be taken should this occur.*
- *If a radiation source jammed in a well is not recoverable, procedures for:*
    - ✓*securing the radiation source in the well (i.e. including the use of dyed concrete or other warning devices);*
    - ✓*capping the well and, where practicable, providing appropriate permanent identification at the well cap to minimize the risk of subsequent drilling through the source;*
    - ✓*reporting to the company drilling and/or holding the exploration or mining lease of the location of the jammed source (e.g. depth and geographical co-ordinates) to prevent further drilling that might intersect the location of the source; and*
    - ✓*informing the regulatory body (and other relevant government bodies such as the Ministry of Mines or Zambia Environmental Management Agency of the jammed source, its location and the actions taken.*
- *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The programme will also address biological monitoring for the use of unsealed radiation sources.*
- *The calibration and function checks of survey and contamination meters, including identifying the calibration service provider and calibration frequency. Details of the numbers of survey meters, personal alarms and detectors and the protocols for ensuring that each well logging team will be provided with appropriate and functioning survey meters for each radiation source they are using; evidence that working rules will require the use of survey meters after the use of a well logging tool to confirm sources are retrieved and returned to their shielded containers.*

d) The arrangements to ensure the safety of sources.

- *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate controls will be in place to prevent theft or accidental loss of radiation sources.*
- *The operator's procedures for safely transferring sources from storage containers to logging tools and vice versa, "spent" sources for new and the radiation monitoring procedures for incoming and outgoing packages.*
- *The arrangements for periodic equipment service, testing and maintenance of source containers, logging tools, etc. and for leak (wipe) tests of sealed sources in compliance with the manufacturers' recommendations.*

- *The facility's QA programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc.*

e) *The RPO's protocols for routine and unannounced audits of working practices at field sites; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give logging personnel authority to immediately cease operations when the prescribed safety\requirements cannot be met or radiation safety related equipment fails.*

f) *The arrangements for the management of radioactive waste, including the management of disused sources.*

g) *The procedures to ensure compliance with the transport regulations, including transport to and from field sites.*

h) *The procedures for dealing with different types of emergencies (i.e. for both sealed and unsealed radiation sources) including the range of safety equipment available.*

i) *The operator's plans for notifying the regulatory body of:*

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents, including jammed sources; and*
- *any significant changes to the information previously provided to the regulatory body including:*

  ✓ *a planned change of location for the operator's principal operations;*

  ✓ *a planned change in and / or storage arrangements for radiation sources; and* *the receipt, transfer or other planned disposal of radiation sources.*

IV. FIXED and/or PORTABLE NUCLEAR GAUGES

A. Note: The following numbers refer to the numbers on the application form.

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources in the practice with gauges, fixed and/or portable). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.

2. The purpose for which the radiation sources are to be used is to be stated (e.g. gauges for level detection, density measurement, in-stream analysis, road construction, etc.).

3. Enter the full name and address of *the company or organization,* the actual location(s) where radiation sources will normally be stored or used.

 Field sites where authorized radiation sources are used for limited periods need not be included on this application (i.e. other than stating that it is the operator's intention to use certain gauges at field sites according to demand). However, any field site where operations may last more than 90 days must be identified. Where such sites arise after

the authorization is issued, the operator must give prior written notification of the details to the regulatory body.

4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.

5. State the full name, qualifications, and training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

6. Not applicable.

7. Fill as appropriate 8. Fill as appropriate 9. Fill as appropriate

10. Fill as appropriate

11. The operator must provide a full description of all radiation sources to be used. An inventory also must be provided for non-radioactive sources (e.g. X ray gauges)
    - List all non-exempt radionuclides that will be used or stored (e.g. ^{60}Co, ^{137}Cs, etc.) together with the activity. State all activities in SI units together with the date at which the activity was determined.
    - Identify every gauge housing by the manufacturer, model, serial number and purpose (level, density, etc.). Survey meter check sources are to be included in this inventory unless otherwise exempted. If depleted uranium is used for radiation shielding in any device state the mass (kg) in each.
    - For X- ray gauges, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA). Identify which X ray tubes have beryllium windows and what permanent filtration is in place.

B. RADIATION PROTECTION POGRAMME

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) The qualifications, training and experience of workers engaged in activities that involve or could involve occupational exposure and both their initial and ongoing radiation safety training.

b) A plan of the premises (i.e. other than temporary field sites) with a report from a qualified expert verifying that the gauges will be installed (or used) in a manner that will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.

c) The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.

- *Working rules for persons who use portable gauges and for those who work near fixed gauges, who undertake work within bins or hoppers, etc. on which gauges are mounted, and for those responsible for changing windows on low energy in-stream gauges.*
- *Identifying the service provider, the type(s) of personal monitors to be used and the propose monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The use of personal monitors is not normally required for fixed gauges except during some installation and maintenance procedures.*
- *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*

d) The arrangements for safety of radiation sources.

- *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.*
- *The procedures for monitoring incoming and outgoing packages containing radioactive sources.*
- *The arrangements for periodic service, testing and maintenance of radioactive source containers and X-ray gauges.*
- *The procedures for routine leak tests of all radioactive gauges including the special requirements for low energy in-stream analysis gauges (e.g. counting the replaced window for contamination).*

e) The facility's QA programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc. Controls must be addressed for gauges that are temporarily removed from their installed (fixed) locations during plant maintenance.

f) The RPO's protocols for ensuring he is advised of planned work on plant or equipment on which gauges are mounted and the procedures in place to instruct workers and prevent unnecessary exposure.

g) The procedures to ensure compliance with the transport regulations, including transport to and from field sites.

h) The arrangements for the management of radioactive waste, including disused sources and information on the financial arrangements for such purposes.

i) The procedures for dealing with emergencies.

j) The arrangements for notifying the regulatory body of:

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents;*
- *and any significant changes to the information previously provided to the regulatory body including:*
    - ✓ *a planned change of location for the operator's operations;*

✓ *a planned change in and/or storage arrangements for radiation sources; and* *the receipt, transfer or other planned disposal of radiation sources.*

V. NUCLEAR MEDICINE

A. ***Note: The following numbers refer to the numbers on the application form.***

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of radiation sources in the practice of nuclear medicine). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. In this case, the purpose for which the radiation sources are to be used is nuclear medicine. However, the operator must also indicate if the purpose is diagnostic, therapeutic, or both, for each type of radionuclides.
3. Enter the full name and address of the Company or organization, the actual location(s) where radiation sources will normally be stored or used
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, and training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.

   Note*: This person may also be the medical physicist.*

   State the full name, qualifications, training, experience and contact details of the Medical Physicist who will be responsible for calibrating (or supervising the calibration) of the dose calibrator, imaging and counting equipment, and for supervising radiation safety during the administration of therapeutic radioactive substances. Attach the nominee's CV together with copies of supporting documentation. ***Note****: This person may also be the qualified expert.*
6. State the full name, qualifications, training, experience and contact details of the Medical Practitioner (MP) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during performance of, the nuclear medicine procedures. Attach the nominee's CV together with copies of supporting documentation.
7. Fill as appropriate; 8. Fill as appropriate; 9. Fill as appropriate;
10. Fill as appropriate;
11. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used. List all non-exempt radionuclides; including check and calibration sources, patient markers, etc. that will be used or stored (e.g. ^{99}Mo, ^{99m}Tc, ^{131}I, ^{57}Co, etc.) together with the activity or, for unsealed material, the maximum activity to be held. State all activities in SI units and, other than short half-life sealed sources, the date at which the activity was determined.

 For devices that generate ionizing radiation electrically (e.g. CT combined with SPECT), state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) *A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of the radiation sources (i.e. including waiting areas for patients to whom radioactive sources have been administered) will ensure worker and public safety. The plan and report must demonstrate compliance with the appropriate radiation dose constraints/dose limits by appropriate scientific methods.*

- *The plan also must address matters such as gas trapping procedures; ventilation (e.g. for gaseous radionuclides or aerosols); liquid waste disposal lines and dilution methods to ensure compliance with the regulations; disconnecting traps; bench, wall and other surface finishes for ready decontamination; room lighting, etc.*

b) *A safety assessment that:*

- *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
- *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and Assesses the quality and extent of the protection and safety provisions.*

c) *That states the probability and magnitude of potential exposures.*

d) *The qualifications, training and experience of medical practitioners, nucleographers nursing staff and others, including their initial and ongoing radiation safety training, and the supervision by appropriately qualified medical practitioners of personnel preparing and administering radiation to patients.*

e) *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*

- *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose). The programme will also address biological monitoring where this is relevant.*
- *The inventory of survey and contamination meters.*
- *The calibration of meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*

f) *The arrangements to ensure the safety of sources.*

- *The design and construction of storage facilities. It must show that appropriate control of sources will be in place to minimize the risk of fire, prevent theft or accidental loss of radiation sources.*
- *The operator's procedures for monitoring incoming and outgoing packages.*

g) *Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes.*

- *Working rules for the nuclear medicine procedures to be undertaken. (e.g. proper identification of patients and the doses to be administered, the use of shielding, distance and time; the use of warning signs, survey meters, personal alarms and dosimeters) including pre-operational checks; procedures for identifying and dealing with contamination, etc.*
- *The calibration and routine functions checks of dose calibrators.*
- *The facility's QA12 programme and arrangements for regular safety audits including maintenance and calibration of imaging and counting equipment, maintenance of the source inventory, source movement logbook, waste disposal, storage conditions, safe working practices, area dose rates, warning signs, etc.*
- *The operator's protocols for ensuring patient doses are minimized by ensuring that where practicable, the activity of radioactive substances administered to patients conforms to guideline values established by a recognized body or professional organization. Include a description of the actions to be taken by the practitioner to justify and optimize all procedures and in minimizing the radiation risk to pregnant or potentially pregnant patients and children.*
- *The operator's protocols for dealing with patients who are to undergo therapy with unsealed radioactive sources (i.e. administration of the radioactive source in a satisfactory environment; compliance with discharge limits; identification of treated patients; properly informing patients of the radiation safety precautions they must observe on discharge; actions to be taken in the untimely death of the patient (e.g. during autopsy, embalming, cremation) etc.).*

h) *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*

i) *The arrangements for the management of radioactive waste.*

j) *The arrangements to ensure compliance with the transport regulations.*

k) *The arrangements for dealing with different types of emergencies including the range of safety equipment available.*

l) *The arrangements for notifying the regulatory body of:*

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents; and*
- *any significant changes to the information previously provided to the regulatory body, including:*

i. a planned change of location for the operator's principal operations;
ii. a planned change in storage or disposal arrangements for radiation sources;
and iii. the receipt, transfer or other planned disposal of radiation sources

VI. INDUSTRIAL RADIOGRAPHY

A. Note: The following numbers refer to the numbers on the application form.

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of radiation sources in the practice of industrial radiography). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. In this case, the purpose for which the radiation sources are to be used is industrial radiography. Include any other purposes as may be relevant (e.g. the use of portable mineral analyzers, radioactive gauges, etc.).
3. Enter the full name and address of the company or organization, actual location(s) where radiation sources will normally be stored or used.
   - Field sites where licensed radiation sources are used for limited periods need not be included on this application (i.e. other than stating that it is the operator's intention to conduct radiography at field sites according to demand).
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, and training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. Not applicable.
7. Fill as appropriate; 8. Fill as appropriate; 9. Fill as appropriate;
10. Fill as appropriate;
11. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used.
    - List all non-exempt radionuclides that will be used or stored (e.g.. ^{192}Ir, ^{60}Co, ^{175}Se, ^{137}Cs, etc.) together with the activity or, for short half-life material subject to regular replacement, the maximum activity to be held. State all activities in SI units and, except for the short halflife material, the date at which the activity was determined.
    - Identify every source container or device that contains (or will contain) radioactive material by the manufacturer, model and serial number. Crawler control sources and survey meter check sources are to be included in this inventory. If depleted uranium is used for radiation shielding in these devices state the mass (kg) in each.
    - State the manufacturer's maximum activity rating for each source container and the length of the wind-out cable and source delivery tube.

- For X ray equipment, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA). Identify which X- ray tubes have beryllium windows and what permanent filtration will be used. State the length of the cables between the X- ray tube housing and the X- ray control panel.

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) The qualifications, training and experience in radiation protection of industrial radiographers. In addition to the industrial radiographers, the RPP also must address the initial and ongoing training and supervision of radiography assistants and show that the operator has, or will have, sufficient personnel to ensure that each assistant works under the immediate personal supervision of a Qualified Radiographer (QR) during all radiographic exposures.

b) A plan of the principal premises with a report from a qualified expert verifying that the design and construction of the premises will ensure worker and public safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints / dose limits by appropriate scientific methods.

c) A safety assessment that:
- *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
- *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable estimates the probabilities and the magnitudes of potential exposures; and assesses the quality and extent of the protection and safety provisions.*

d) The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.
- *Working rules for radiographic operations (e.g. the use of shielding, distance and time; the identification and marking of site boundaries; ensuring that before exposures no unauthorized persons are present; supervision and control of site boundaries; the use of warning signs; the routine use of survey meters, personal alarms and dosimeters) including pre-operational checks; the use of beam collimators, X -ray beam filtration and fast image receptors to minimize dose; the use of warning klaxons on crawler equipment in pipelines; etc.*
- *The radiation monitoring programme for occupationally exposed workers, identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be*

routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).

- *The inventory of survey meters existing in the enterprise.*
- *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency. Details of the numbers of survey meters, personal alarms and dosimeters and the procedures for ensuring that each radiography team will be provided with a functioning survey meter for each radiation source; evidence that working rules will require the use of survey meters after every exposure to confirm sources are shielded.*

e) *The arrangements to ensure the safety of sources.*

- *The design and construction of storage facilities, including those of a temporary nature at semi-permanent field sites. It must show that appropriate control of sources will be in place to minimize the risk of fire, prevent theft or accidental loss of radiation sources.*
- *The operator's procedures for ensuring that source containers and X -ray equipment comply on purchase, and continue to comply, with the prescribed design and performance standards (IEC, ISO, etc).*
- *The arrangements for safely transferring sources ("spent" for new).*
- *The radiation monitoring procedures for incoming and outgoing packages.*
- *The arrangements for periodic equipment service, testing and maintenance of source containers, wind-out cables, source delivery tubes, source-cable connectors, wipe tests of sealed sources (other than short half-life sources) and the S-bend of depleted uranium shielded containers, etc., in compliance with the manufacturers' recommendations. The maintenance of the source inventory and source movement logbook.*

f) *The facility's QA programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, warning signs, etc.*

g) *The RPO's protocols for routine and unannounced audits of working practices at field sites; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give radiography workers authority to immediately cease operations when the prescribed safety requirements cannot be met or should equipment fail.*

h) *The arrangements for the management of radioactive waste, including the management of spent sources, and information on the financial arrangements for such purposes.*

i) *The procedures to ensure compliance with the transport regulations, including transport to and from field sites.*

j) *The procedures for dealing with different types of emergencies including the range of safety equipment available (e.g. remote handling tongs, lead pots, bagged lead shot, bolt cutters, etc.).*

k) *The procedures for notifying the regulatory body of:*

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents; and*

- *any significant changes to the information previously provided to the regulatory body including:*
    - ✓ *a planned change of location for the operator's principal operations;*
    - ✓ *the addition of, or alterations to, structures that form a fixed radiographic enclosure;* *a planned change in and / or storage arrangements for radiation sources; and* *the receipt, transfer or other planned disposal of radiation sources.*

VII. IRRADIATORS

A. Note: The following numbers refer to the numbers on the application form.

1. Enter the legal name of the operator's business (i.e. the entity that has direct control over the use of the radiation sources). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
2. In this case, the primary purpose for which the radiation sources are to be used is irradiation.
3. Enter the full name and address of company or organisation the actual location(s) where radiation sources will normally be stored or used.
4. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
5. State the full name, qualifications, and training, experience and contact details of the person nominated to be the operator's qualified expert (i.e. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation.
6. Not applicable.
7. Fill as appropriate 8. Fill as appropriate 9. Fill as appropriate
10. Fill as appropriate
11. The operator must provide a full description of all radiation sources to be used. List all non-exempt radionuclides that will be used or stored (e.g.. 60Co) together with the activity. State all activities in SI units and the date at which the activity was determined. For devices that generate ionizing radiation electrically, state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA).

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) The qualifications, training and experience in workers engaged in activities that involve or could involve occupational exposure, including their initial and ongoing radiation safety training.

b) *A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises will ensure at least the minimum prescribed level of worker and public radiation safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.*

c) *A safety assessment that:*
   - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
   - *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and assesses the quality and extent of the protection and safety provisions.*

d) *The occupational radiation protection programme, including arrangements for the monitoring or workers and the workplace, the classification of areas, the provision and maintenance of personal protective equipment, and equipment for radiation detection.*
   - *Working rules for safe operation of the irradiator; ensuring before exposures that no persons are present in the irradiation room; supervision and control of all access points; the use of warning signs; the routine use of survey meters, personal alarms including pre-operational checks; water contamination, etc.*
   - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).*
   - *The inventory of survey meters.*
   - *The calibration of survey meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*

e) *The arrangements to ensure safety of sources.*
   - *The design and construction of the facility, including a description of the safety system e.g.*
     interlocks. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.
   - *The arrangements for safely transferring sources (i.e. "spent" for new) The radiation monitoring procedures for incoming and outgoing packages.*
   - *The calibration and function checks of other instruments required for safe operation of the irradiator (e.g. water levels, water contamination, etc..*
   - *The arrangements for periodic service, testing and maintenance of the irradiator, particularly of the safety features and related instrumentation.*
   - *The operator's QA programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, storage conditions, safe working practices, area dose rates, area dose rate monitors and alarms, other safety instrumentation, warning signs, etc.*

f) The RPO's protocols for routine and unannounced audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance; working rules that give the irradiator's operators authority to immediately cease operations when the prescribed safety requirements cannot be met or essential equipment fails.

g) The arrangements to ensure compliance with the transport regulations.

h) The arrangements for dealing with radioactive waste, including the management of disused sources and information on the financial arrangements for such purposes.

i) The procedures for dealing with different types of emergencies including the range of safety equipment available.

j) The arrangements for notifying the regulatory body of:

- *occupational or public radiation doses which exceed prescribed limits;*
- *reportable incidents and accidents; and*
- *any significant changes to the information previously provided to the regulatory body including:*
  - ✓ *a planned change of location for the operator's operations;*
  - ✓ *a planned change in and / or storage arrangements for radiation sources; and □ the receipt, transfer or other planned disposal of radiation sources.*

VIII. RADIOTHERAPY

A. Note: The following numbers refer to the numbers on the application form

12. Enter the legal name of the operator's business (i.e. the entity that has direct control over the possession and use of the radiation sources in the practice of radiotherapy). An individual may be designated as the operator only if the individual is acting in a private capacity. State the full mailing address to where correspondence (e.g. such as future renewal notices) should be sent.
13. In this case, the purpose for which the radiation sources are to be used is radiotherapy.
14. Enter the full name and address of the company or organization, the actual location(s) where the radiation sources will normally be stored or used.
15. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's Radiation Protection Officer (RPO). Attach the nominee's curriculum vitae (CV) together with copies of relevant qualification and training certificates.
16. State the full name, qualifications, training, experience and contact details of the person nominated to be the operator's qualified expert (i.e.. the person who will advise the operator on radiation safety and perform regular audits of the operator's radiation protection programme). Attach the nominee's CV together with copies of supporting documentation. **Note**: This person may also be the Medical Physicist.

    State the full name, qualifications, training, experience and contact details of the Medical Physicist who will be responsible for calibrating the radiation sources and supervising radiation safety during

LDR, HDR and interstitial X ray radiation beams; brachytherapy, performing the patient's treatment planning, etc. Attach the nominee's CV together with copies of supporting documentation. **Note**: This person may also be the Qualified Expert.

17. State the full name, qualifications, training, experience and contact details of the medical practitioner (s) who will be responsible for ensuring overall patient protection and safety in the prescription of, and during the performance of, therapeutic procedures. Attach the nominee's CV together with copies of supporting documentation..
18. Fill as appropriate; 19. Fill as appropriate; 20. Fill as appropriate;
21. Fill as appropriate;
22. Particulars of the radiation sources. The operator must provide a full description of all radiation sources to be used.
    - List all non-exempt radionuclides, including calibration and check sources, to be used or stored together with the activity (e.g. ^{60}Co, ^{192}Ir, ^{137}Cs, etc.). State all activities in SI units and the date at which the activity was determined. For short half-life nuclides subject to regular replacement (e.g. ^{192}Ir) state the maximum activity that will be on the premises at any one time. Include the date when the radiation output (or for brachytherapy sources, the activity) of each was last determined.
    - For equipment that generates ionizing radiation electrically (e.g. superficial and deep X-ray therapy, linear accelerators, interstitial X ray therapy, etc.), state the manufacturer, model and serial number together with the peak tube potential (kVp) and current (mA). Include the date when each was last fully calibrated.

B. Radiation Protection Programme

The operator must also submit a Radiation Protection Programme (RPP) addressing all aspects of radiation\ safety particularly the safety of radiation sources, work practices, the transport of radioactive sources and emergency procedures. At a minimum, the RPP will include the following:

a) A plan of the premises with a report from a qualified expert verifying that the design and construction of the premises, and the siting of radiation sources (i.e. including patients undergoing brachytherapy), will ensure worker and public safety. The plan and report must demonstrate compliance with the prescribed radiation dose constraints/dose limits by appropriate scientific methods.

b) The qualifications, training and experience of medical practitioners, radiation therapists, nursing staff and others including their initial and ongoing radiation safety training and the supervision by appropriately qualified medical practitioners of other personnel.

c) A safety assessment that:
    - *identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment:*
    - *determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and assesses the quality and extent of the protection and safety provisions.*

d) *The occupational radiation protection programme, including arrangements for the monitoring of workers and the workplace, the classification of areas, local rules and procedures, the maintenance and provision of personal protective equipment, and equipment for radiation detection.*
    - *Identifying the service provider, the type(s) of personal monitors to be used and the proposed monitoring frequency; the maintenance of dose records and how personnel will be routinely advised of, and have access to, their dose records (i.e. irrespective of the reported dose).*
    - *The inventory of survey meters and dose rate meters.*
    - *The calibration of meters (i.e. and routine function checks) including the name of the calibration service provider and calibration frequency.*

e) *The arrangements to ensure the safety of sources.*
    - *The design and construction of storage facilities. It must show that appropriate control of sources will be in place to minimize the risk of fire and to prevent theft or accidental loss of radiation sources.*
    - *The operator's procedures for monitoring incoming and outgoing packages. Maintenance of the source inventory and source movement logbook.*

f) *Information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes.*
    - *Working rules for the therapy procedures to be undertaken (e.g. ensuring proper identification of patients, the use of shielding, distance and time; the use of warning signs, survey meters, personal\ alarms and dosimeters) including pre-operational checks: radiation beam calibrations, patient's treatment planning, etc.*
    - *If research is performed that involves the treatment of patients or volunteers, explain how the operator, acting on advice from an Ethical Review Committee, 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.*
    - *The manufacturer and model of radiation measuring instruments used to calibrate the radiation output of therapy radiation sources, the name of the organization that calibrates these instruments and the date of the last calibration. Calibrations must be traceable to a recognized standard.*
    - *The facility's QA13 programme and arrangements for regular safety audits including maintenance of the source inventory, source movement logbook, waste disposal, source security and storage conditions, safe working practices, area dose rates, area dose rate monitors, warning signs, etc.*
    - *The operator's protocols for ensuring patient treatment regimes are in conformity with guidelines established by a recognized authority (e.g. the regulatory body) or professional organization. Include a description of the actions to be taken by the practitioner to justify and optimise all procedures.*

g) *The operator's protocols for training nursing staff and properly informing patients who are to undergo brachytherapy with permanent or semi-permanent implanted sources or with afterloaders.*

h) *The RPO's protocols for routine audits of working practices; evidence that the RPO has authority to stop activities if they are considered unsafe or not in compliance.*

i) *The arrangements for the management of radioactive waste.*

j) *The arrangements to ensure compliance with the transport regulations where this is appropriate.*

k) *The operator's plans for dealing with different types of emergencies including the range of safety equipment available. Emergencies will include, for example, a ^{60}Co teletherapy source jammed in the "ON" position, failure of an afterloader source retrieval mechanism, etc.*

l) *The operator's plans for notifying the regulatory body of:*

- *occupational or public radiation doses which exceed prescribed limits;*
- *patient radiation doses which exceed prescribed treatment doses;*
- *reportable incidents and accidents; and*
- *any significant changes to the information previously provided to the regulatory body including:*
  - ✓ *a planned change of location for the operator's principal operations;*
  - ✓ *a planned change in storage or disposal arrangements for radiation sources; and □ the receipt, transfer or other planned disposal of radiation sources.*

ANNEX IV: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF

RADIO-NUCLIDES (ROUNDED)*

Nuclide	Activity concentration (*Bq*/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^6	1×10^9	Fe-52	1×10^1	1×10^6
Be-7	1×10^3	1×10^7	Fe-55	1×10^4	1×10^6
C-14	1×10^4	1×10^7	Fe-59	1×10^1	1×10^6
0-15	1×10^2	1×10^9	Co-55	1×10^1	1×10^6
F-18	1×10^1	1×10^6	Co-56	1×10^1	1×10^5
Na-22	1×10^1	1×10^6	Co-57	1×10^2	1×10^6
Na-24	1×10^1	1×10^5	Co-58	1×10^1	1×10^6
S1- 31	1×10^3	1×10^6	Co-58m	1×10^4	1×10^7
P-32	1×10^3	1×10^5	Co-60	$1 \times 10'$	1×10^5
				1×10	1×10
				1×10	1×10

					1 X 10
					1 X 10
P-33	1 x 10^5	1 X 10^8	Co-60m	1 x 10^3	1 X 10^6
S-35	1 x 10^5	1 X 10^8	Co-61	1 x 10^2	1 X 10^6
C1-36	1 x 10^4	1 X 10^6	Co-62m	1 x 10^1	1 x 10^5
C1-38	1 x 10^1	1 x 10^5	N1-59	^{4}	^{8}
Ar-37	1 x 10^6	1 X 10^8	N1-63	^{5}	^{8}
Ar-41	1 x 10^2	1 X 10^9	N1-65	1 x 10^1	6
K-40	1 x 10^2	1 X 10^6	Cu-64	1 x 10^2	6
K-42	1 x 10^2	1 X 10^6	Zn-65	1 x 10^1	1 X 10^6
K-43	1 x 10^1	1 X 10^6	Zn-69	1 x 10^4	1 X 10^6
Ca-45	1 x 10^4	1 X 10^7	Zn-69m	1 x 10^2	1 X 10^6
Ca-47	1 x 10^1	1 X 10^6	Ga-72	1 x 10^1	1 x 10^5
Sc-46	1 x 10^1	1 X 10^6	Ge- 71	1 x 10^4	1 X 10^8
Sc-47	1 x 10^2	1 X 10^6	As-73	1 x 10^3	1 X 10^7
Sc-48	1 x 10^1	1 x 10^5	As-74	1 x 10^1	1 X 10^6
V-48	1 x 10^1	1 x 10^5	As-76	1 x 10^2	1 x 10^5
Cr-51	1 x 10^3	1 X 10^7	As-77	1 x 10^3	1 X 10^6
				1 x 10	1 X 10
				1 x 10	1 X 10

Mn-51	1×10^{1}	1×10^{5}	Se-75	1×10^{2}	1×10^{6}
Mn-52	1×10^{1}	1×10^{5}	Br-82	1×10^{1}	1×10^{6}
Mn-52m	1×10^{1}	1×10^{5}	Kr-74	1×10^{2}	1×10^{9}
Mn-53	1×10^{4}	1×10^{9}	Kr-76	1×10^{2}	1×10^{9}
Mn-54	1×10^{1}	1×10^{6}	Kr-77	1×10^{2}	1×10^{9}
Mn-56	1×10^{1}	1×10^{5}	Kr-79	1×10^{3}	1×10^{5}
Kr-81	1×10^{4}	1×10^{7}	Tc-97	1×10^{3}	1×10^{8}
Kr-83m	1×10^{5}	1×10^{12}	Tc-97m	1×10^{3}	1×10^{7}
Kr-85	1×10^{5}	1×10^{4}	Tc-99	1×10^{4}	1×10^{7}
Kr-85m	1×10^{3}	1×10^{10}	Tc-99m	1×10^{2}	1×10^{7}
Kr-87	1×10^{2}	1×10^{9}	Ru-97	1×10^{2}	1×10^{7}
Kr-88	1×10^{2}	1×10^{9}	Ru-103	2	6
Rb-86	1×10^{2}	1×10^{5}	Ru-105	1	6
Sr-85	1×10^{2}	1×10^{6}	Ru-1068	1×10^{2}	1×10^{5}
Sr-85m	1×10^{2}	1×10^{7}	Rh-103m	1×10^{4}	1×10^{8}
Sr-87m	1×10^{2}	1×10^{6}	Rh-105	1×10^{2}	1×10^{7}
Sr-89	1×10^{3}	1×10^{6}	Pd-103	1×10^{3}	1×10^{8}
Sr-908	1×10^{2}	1×10^{4}	Pd-109	1×10^{3}	1×10^{6}
Sr-91	1×10^{1}	1×10^{5}	Ag-105	1×10^{2}	1×10^{6}
Sr-92	1×10^{1}	1×10^{6}	Ag-llOm	1×10^{1}	1 X
		1 X 10		1 x 10	1 X 10
		1 X 10		1 x 10	1 X 10

					1 X 10
					1 X 10
					10^6
Y-90	1×10^3	1×10^5	Ag-1ll	1×10^3	$\frac{1}{10^6}$ X
Y-91	1×10^3	$1 X 10^6$	Cd-109	1×10^4	$\frac{1}{10^6}$ X
Y -91 m	$1 X 10^2$	$1 X 10^6$	Cd-1 15	1×10^2	$\frac{1}{10^6}$ X
Y-92	1×10^2	1×10^5	Cd-115m	1×10^3	$\frac{1}{10^6}$ X
Y-93	1×10^2	1×10^5	1n-1ll	$1 X 10^2$	$\frac{1}{10^6}$ X
Zr-938	1×10^3	$1 X 10^7$	1n-113m	1×10^2	$\frac{1}{10^6}$ X
Zr-95	1×10^1	$1 X 10^6$	1n-114m	$1 X 10^2$	$\frac{1}{10^6}$ X
Zr-978	$1 X 10^1$	1×10^5	1n-115m	1×10^2	$\frac{1}{10^6}$ X
Nb-93m	1×10^4	$1 X 10^7$	Sn-l13	$1 X 10^3$	$\frac{1}{10^7}$ X
Nb-94	1×10^1	$1 X 10^6$	Sn-125	$1 X 10^2$	1×10^5
Nb-95	1×10^1	$1 X 10^6$	Sb-122	1×10^2	$\frac{1}{10^4}$ X
Nb-97	1×10^1	$1 X 10^6$	Sb-124	1×10^1	$\frac{1}{10^6}$ X
Nb-98	1×10^1	1×10^5	Sb-125	1×10^2	$\frac{1}{10^6}$ X
Mo-90	1×10^1	$1 X 10^6$	Te-123m	$1 X 10^2$	$\frac{1}{10^7}$ X
Mo-93	1×10^3	$1 X 10^8$	Te-125m	1×10^3	$\frac{1}{10^7}$ X
Mo-99	1×10^2	$1 X 10^6$	Te-127	$1 X 10^3$	$\frac{1}{10^6}$ X
				1 x 10	1 X 10
				1 x 10	1 X 10

Mo-101	1×10^{1}	6	Te-127m	3	7
Tc-96	1×10^{1}	6	Te-129	2	6

	1 X 10	1 x 10	1 X 10
	1 X 10	1 x 10	1 X 10

					1 X 10
					1 X 10
Tc-96m	1 x 10^3	1 X 10^7	Te-129m	1 x 10^3	6
Te-13 1	1 x 10^2	1 x 10^5	Ce-143	1 x 10^2	6
Te-13lm	1 x 10^1	1 X 10^6	Ce-l44a	1 x 10^2	1 x 10^5
Te-132	1 x 10^2	1 X 10^7	Pr-142	1 x 10,^{2}	1 x 10^S
Te-133	1 x 10^1	1 x 10^5	Pr-143	1 x 10^4	1 X 10^6
Te-133m	1 x 10^1	1 x 10^5	Nd-147	1 x 10^2	1 X 10^6
Te-134	1 x 10^1	1 X 10^6	Nd-149	1 x 10^2	1 X 10^6
1-123	1 x 10^2	1 X 10^7	Pm-147	1 x 10^4	1 X 10^7
1-125	1 x 10^3	1 X 10^6	Pm-149	1 x 10^3	1 X 10^6
1-126	1 x 10^2	1 X 10^6	Sm-1S1	1 x 10^4	1 X 10^8
1-129	1 x 10^2	1 x 1O^S	Sm-1S3	1 x 10^2	1 X 10^6
1-130	1 x 10^1	1 X 10^6	Eu-152	1 x 10^1	1 X 10^6
1-131	1 x 10^2	1 X 10^6	Eu-152m	1 x 10^2	1 X 10^6
1-132	1 x 10^1	1 x 1O^S	Eu-154	1 x 10^1	1 X 10^6
1-133	1 x 10^1	1 X 10^6	Eu-155	1 x 10^2	1 X 10^7
1-134	1 x 10^1	1 x 1O^S	Gd-153	1 x 10^2	1 X 10^7
1-135	1 x 10^1	1 X 10^6	Gd-159	1 x 10^3	1 X 10^6
		1 X 10		1 x 10	1 X 10
		1 X 10		1 x 10	1 X 10

					1 X 10
					1 X 10
Xe-13lm	1 x 10^4	1 X 10^4	Tb-160	1 x 10^1	1 X 10^6
Xe-133	1 x 10^3	1 X 10^4	Dy-165	1 x 10^3	1 X 10^6
Xe-135	1 x 10^3	1 X 10^{10}	Dy-l66	1 x 10^3	1 X 10^6
Cs-129	1 x 10^2	1 x $1O^S$	Ho-l66	1 x 10^3	1 x $1O^S$
Cs-13 1	1 x 10^3	1 X 10^6	Er-169	1 x 10^4	1 X 10^7
Cs-132	1 x 10^1	1 x $1O^S$	Er-171	1 x 10^2	1 X 10^6
Cs-134m	1 x 10^3	1 x 10^S	Tm-170	1 x 10^3	1 X 10^6
Cs-134	1 x 10^1	4	Tm-171	4	8
Cs-135	1 x 10^4	7	Yb-175	3	7
Cs-136	1 x 10^1	1 x 10^S	Lu-l77	1 x 10^3	7
Cs-137a	1 x 10^1	1 X 10^4	Hf-181	1 x 10^1	6
Cs-138	1 x 10^1	1 X 10^4	Ta-182	1 x 10^1	1 X 10^4
Ba-13 1	1 x 10^2	1 x 10^6	W-181	1 x 10^3	1 X 10^7
Ba-140a	1 x 10^1	1 x $1O^S$	W-185	1 x 10^4	1 X 10^7
La-140	1 x 10^1	1 x 10^S	W-187	1 x 10^2	1 X 10^6
Ce-139	1 x 10^2	1 X 10^6	Re-186	1 x 10^3	1 X 10^6
Ce-141	1 x 10^2	1 X 10^7	Re-188	1 x 10^2	1 X $1O^S$
Os-185	1 x 10^1	1 X 10^6	Rn- 222 a	1 X 10^1	1 X 10^8
		1 X 10			
		1 X 10			

					1 X 10
					1 X 10
Os-191	1 X 10^2	1 X 10^7	Ra-223a	1 X 10^2	1 X 10^5
Os-191m	1 X 10^3	1 X 10^7	Ra-224 a	1 X 10^1	1 X 10^5
Os-193	1 X 10^2	1 X 10^6	Ra-225	1 X 10^2	1 X 10^5
1r-l90	1 X 10^1	1 X 10^6	Ra-226 a	1 X 10^1	1 X 10^4
1r-192	1 X 10^1	1 X .10^4	Ra-227	1 X 10^2	1 X 10^6
1r-194	1 X 10^2	1 X 10^5	Ra-228a	1 X 10^1	1 X 10^5
Pt-191	1 X 10^2	1 X 10^6	Ac-228	1 X 10^1	1 X 10^6
Pt-193m	1 X 10^3	1 X 10^7	Th-226a	1 X 10^3	1 X 10^7
Pt -197	1 X 10^3	1 X 10^6	Th-227	1 X 10^1	1 X 10^4
Pt-197m	1 X 10^2	1 X 10^6	Th-228a	1 X 10°	1 X 10^4
Au-198	1 X 10^2	1 X 10^6	Th-229a	1 X 10°	1 X 10^3
Au-l99	1 X 10^2	1 X 10^6	Th-230	1 X 10°	1 X 104
Hg-197	1 X 10^2	1 X 10^7	Th-231	1 X 10^3	1 X 10^7
Hg-197m	1 X 10^2	1 X 10^6	Th-nat	1 X 10°	1 X 10^3
Hg-203	1 X 10^2	1 X 10^5	(1ncl. Th-232)		
Tl-200	1 X 10^1	6	Th-234 a	1 X 10^3	1 X 10^5
T1-201	1 X 10^2	6	Pa-230	1 X 10^1	1 X 10^6
Tl-202	1 X 10^2	1 X 10^6	Pa-231	1 X 10°	3
T1-204	1 X 10^4	1 X 10^4	Pa-233	1 X 10^2	7
Pb-203	1 X 10^2	1 X 10^6	U-230a	1 X 10^1	1 X 10^5

					1 X 10
					1 X 10
Pb-2lOa	1 X 10^{1}	1 X 10^{4}	U-231	1 X 10^{2}	1 X 10^{7}
Pb-212a	1 X 10^{1}	1 X 10^{5}	U-232a	1 X 10°	1 X 10^{3}
BI-206	1 X 10^{1}	1 X 10^{5}	U-233	1 X 10^{1}	1 X 10^{4}
BI-207	1 X 10^{1}	1 X 10^{6}	U-234	1 X 10^{1}	1 X 10^{4}
BI-21O	1 X 10^{3}	1 X 10^{6}	U-235a	1 X 10^{1}	1 X 10^{4}
BI-212a	1 X 10^{1}	1 X 10^{5}	U-236	1 X 10^{1}	1 X 10^{4}
Po- 203	1 X 10^{1}	1 X 10^{6}	U-237	1 X 10^{2}	1 X 10^{6}
Po- 205	1 X 10^{1}	1 X 10^{6}	U-238a	1 X 10^{1}	1 X 10^{4}
Po- 207	1 X 10^{1}	1 X 10^{6}	U-nat	1 X 10°	1 X 10^{3}
Po-21O	1 X 10^{1}	1 X 10^{4}	U-239	1 X 10^{2}	1 X 10^{6}
At-21 1	1 X 10^{3}	1 X 10^{7}	U-240	1 X 10^{3}	1 X 10^{7}
Rn-220a	1 X 10^{4}	1 X 10^{7}	U-240a	1 X 10^{1}	1 X 10^{6}
Np-2373	1 x 10^{0}	1 X 10^{3}	Cm-244	1 x 10^{1}	1 X 10^{4}
Np-239	1 X. 10^{2}	1 X 10^{7}	Cm-245	1 x 10^{0}	1 X 10^{3}
Np-240	1 x 10^{1}	1 X 10^{6}	Cm-246	1 x 10^{0}	1 X 10^{3}
Pu-234	1 x 10^{2}	1 X 10^{7}	Cm-247	1 x 10^{0}	1 X 10^{4}
Pu-235	1 x 10^{2}	1 X 10^{7}	Cm-248	1 x 10^{0}	1 X
		1 X 10			
		1 X 10			

					1 X 10
					1 X 10
					10^3
Pu-236	1 x 10^1	1 X 10^4	Bk-249	1 x 10^3	1 X 10^6
Pu-237	1 x 103	1 X 10^7	Cf-246	1 x 10^3	1 X 10^6
Pu-238	1 x 10^0	1 X 10^4	Cf-248	1 x 10^1	1 X 10^4
Pu-239	1 x 10^0	1 X 10^4	Cf-249	1 x 10^0	1 X 10^3
Pu-240	1 x 10^0	1 X 10^3	Cf-250	1 x 10^1	1 X 10^4
Pu-241	1 x 10^2	1 x 10^5	Cf-251	1 x 10^0	1 X 10^3

1 X 10

Pu-242	1×10^{0}	1×10^{4}	Cf-252	1×10^{1}	4
Pu-243	1×10^{3}	1×10^{7}	Cf-253	1×10^{2}	1×10^{5}
Pu-244	1×10^{0}	1×10^{4}	Cf-254	1×10^{0}	1×10^{3}
Am-241	1×10^{0}	1×10^{4}	Es-253	1×10^{2}	1×10^{5}
Am-242	1×10^{3}	1×10^{6}	Es-254	1×10^{1}	1×10^{4}
Am-242m3	1×10^{0}	1×10^{4}	Es-254m	1×10^{2}	1×10^{6}
Am-2433	1×10^{0}	1×10^{3}	Fm-254	1×10^{4}	1×10^{7}
Cm-242	1×10^{2}	1×10^{5}	Fm-255	1×10^{3}	1×10^{6}
Cm-243	1×10^{0}	1×10^{4}			

[a]Parent nuclides and their progeny included in secular equilibrium are listed 1n the following:

Sr-90 Y-90
Zr-93 Nb-93m
Zr-97 Nb-97
Ru-l06 Rh-106
Cs-137 Ba-137m
Ce-134 La-134
Ce-l44 Pr-l44
Ba-140 La-l40
Bi-212 Ti-208 (0.36), Po-212 (0.64)
Pb- 210 Bi-21O, Po-210
Pb-212 Bi-212, T1-208 (0.36), Po-212 (0.64)
Rn-220 Po-216
Rn-222 Po-218, Pb-214, Bi-214, Po-214
Ra-223 Rn-219, Po-215. Pb-211. Bi-211, T1-207
Ra-224 Rn-220, Po-216, Pb-212, Bi-212, T1-208 (0.36), Po-212 (0.64)
Ra-226 Rn-222, Po-218, Pb-214, Bi-214, Po-214. Pb-21O, Bi-21O, Po-21O
Ra-228 Ac-228
Th-226 Ra-222, Rn-218, Po-214
Th-228 Ra-224, Rn-220, Po-216. Pb-212, Bi-212, T1-208 (0.36), Po-212 (0.64)

Th-229 Ra-22.5, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, T1208, (0.36), Po212 (0.64)
Th-234 Pa-234m
U-230 Th-226, Ra-222, Rn-218, Po-214
U-232 Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235 Th-231,
U-238 Th-234, Pa-234m,
U-nat Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-21O, Bi-21O, Po-210
U-240 Np-24Om
Np-237 Pa-233
Am-242m Am-242
Am-243 Np-239

*****The guidance exemption levels set forth in Table 1-1 of the Third Schedule are subject to the following considerations:

a) They have been derived using a conservative model based on

i) the criteria of para. (1-3) and ii) a series of limiting (bounding) use and disposal scenarios. The values of activity concentration and total activity represent the lowest values calculated in any scenario for a moderate quantity of material. (See COMMISSION OF THE EUROPEAN

COMMUNITIES, Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) below Which Reporting is Not Required in the European Directive, Radiation Protection 65, Doc. XI-028/93, CEC, Brussels (1993).

b) The application of exemption to natural radionuclide, where these are not excluded, is limited to the incorporation of naturally occurring radionuclide into consumer products or their use as a radioactive source (e.g. Ra-226, Po-210) or for their elemental properties (e.g. thorium, uranium).

c) In the case of more than one radionuclide, the appropriate sum of the ratios of the activity or activity concentration of each radionuclide and the corresponding exempt activity or activity concentration shall be taken into account

d) Unless the exposure is excluded, exemption for bulk amounts of materials with activity concentrations lower than the guidance exemption levels of Table 1-1r. May nevertheless require further consideration by the Regulatory Authority.

DEFINITIONS

Clearance

The removal of *regulatory control* by the *regulatory body* from *radioactive material* or *radioactive* objects within notified or authorized *practices*.

Θ Removal of *control* in this context refers to *control* applied for *radiation protection* purposes.

Excluded

Not subject to the requirements of the guide.

Exemption

The determination by the RPA that a *source* or *practice* need not be subject to some or all aspects of *regulatory control* on the basis that the *exposure* and the *potential exposure* due to the *source* or *practice* are too small to warrant the application of those aspects or that this is the optimum option for *protection* irrespective of the actual level of the *doses* or *risks*.

Licence

An authorization granted by the RPA on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.

Notification

A document submitted to the RPA by a holder of the current licence or by any other person, to notify an intention to carry out a practice or any other action described in statutory instrument No. 98 of 2011, and its amendment No. 19 of 2011 PART IV- Ionising Radiation Licence.

Quality Assurnace

The function of a *management system* that provides confidence that specified *requirements* will be fulfilled.

Θ Planned and systematic actions are necessary to provide adequate confidence that an item, *process* or service will satisfy given *requirements* for quality; for example, those specified in the *licence*. This statement is slightly modified from that in ISO 921:1997 (Nuclear Energy: Vocabulary) to say 'an item, *process* or service' instead of 'a product or service' and to add the example. A more general definition of *quality assurance* and definitions of related terms can be found in ISO 8402:1994.

Radiation source

A Radiation Source is any radioactive substance or electrical device that produces ionising radiation when energized. It includes sources that the owner or the person in possession has reasons to believe are, or should be exempt from regulatory control. The Regulatory Body will rule on the exemption status of any particular source and inform the holder accordingly.

a) Source

Any irradiating device or radioactive material.

b) Exposure pathways

The routes by which radioactive material can reach or irradiate humans.

Registration

Form of authorization for practices of low or moderate risks whereby the person responsible for the practice has an appropriate, prepared and submitted a safety assessment of the facilities and equipment of the RPA. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitation applied to the practice should be less severe than for Licensing.

material can reach or irradiate humans.

ANNEX:CHECKLISTS

RPA SG 1

CHECKLIST FOR SAFETY GUIDE 1

LICENCING, NOTIFICATION, EXEMPTION AND EXCLUSION

Application No……..

First Application ☐ *Renewal* ☐

Date;……..

Name of Operator:……

Practice involved:…… Code:……..

RECEIVING RADIATION SAFETY OFFICER

ITEM	***YES***	***NO***	***NOTES and ACTION***
DATABASE ENTRY, PRELIMINARY DATA CHECK, FILE CREATION			
Database entry completed?	☐	☐	***New applications*** *- enter information into the RAIS database and record the application sequence number on the application.* ***Renewals*** *- update the database as required.*
Required details provided?	☐	☐	*Has required information been provided including postal and physical address, RPO, X ray equipment inventory, RPP, etc?* *If not, or if unclear, return the application for the additional information. Mark record with bring-up date.*
Operator			*Name and position held by the operator has been stated? If not, contact the applicant for*

identified?			*additional information.*
Application signed by the operator?	☐	☐	*Application to be returned if unsigned. However, first discuss with the Assessment team, as other matters may need to be raised with the operator. Return the application for signature as directed. Mark record with bring-up date.*
File and related papers prepared for assessment?	☐	☐	*Create the authorization 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 operator for further information)*			
Signature…….. Date……			

ASSESSMENT TEAM

ITEM	***YES***	***NO***	***NOTES and ACTION***
PERSONNEL RESOURCES AND TRAINING			
Nominated	☐	☐	*Confirm that the nominated Radiation*

Radiation Protection Officer satisfactory?			*Protection Officer 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 Qualified Expert has appropriate qualifications and experience*
Responsible Medical Practitioner satisfactory?	☐	☐	*Confirm that the nominated Medical Practitioner has appropriate qualifications and experience.*
Radiographers appropriately qualified?	☐	☐	*Confirm that the radiographers employed (or contracted by) the operator 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 training and will be adequately supervised. State personnel and level of training*

ITEM	***YES***	***NO***	***NOTES and ACTION***
FACILITIES, SOURCES AND EQUIPMENT			
(a)Layout of the facility			
Premises satisfactory?	☐	☐	*Confirm that the design and construction of the premises, the siting of the X ray equipment and the provision of operator protective barriers, etc. will ensure at least the minimum prescribed level of worker and public radiation safety.*
Shielding adequate?			
(b) Equipment			
Equipment or source complies?	☐ ☐	☐ ☐	*Are all details regarding equipment (manufacturer, model,, serial no. etc.) provided?* *Does the X ray equipment comply with relevant design and performance standards*

	☐ ☐	☐ ☐	*(e.g. IEC)?* *Will the equipment be used for X ray examinations appropriate to its designed purpose?* *Are the radioactive sources and activities listed in the inventory approved by the regulatory body for use in industrial radiography (e.g. ^{192}Ir, ^{60}Co, ^{175}Se, ^{137}Cs control sources) and does the encapsulation comply with standards (e.g. ISO)?*
**Radioactive source replacement equipment?*	☐ ☐	☐ ☐	*Does the operator have appropriate equipment to safely exchange new and spent sources?* *Are the source transfer procedures satisfactory?*
**Darkroom, film / image processing equipment satisfactory?*	☐	☐	*Is the darkroom light proof and are safelights appropriate? Will the operator be using appropriate and satisfactory film/image equipment and processing equipment*
X ray equipment and source containers comply?	☐ ☐	☐ ☐	*Are the source containers and X ray equipment of a type approved by the regulatory body for industrial radiography?* *Do they comply with specified design and performance standards (e.g. IEC)?*
Permanent exposure facility complies?	☐ ☐ ☐	☐ ☐ ☐	*Does the operator plan to perform radiography in a permanent exposure facility?* *Does the facility satisfy the requirements of the regulations?* *Does the construction of an enclosed radiography facility complies with dose constraints and dose limits prescribed by the regulations (i.e. under the worst practicable conditions).*

(c) Safety assessment			
Safety assessment provided?	☐ ☐	☐ ☐	*A safety assessment is in place that:* *(a) identifies the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;* *(b) determines the expected magnitudes of normal exposures and, to the extent reasonable and practicable, estimates the probabilities and the magnitudes of potential exposures; and (c) assesses the quality and extent of the protection and safety provisions.* *"The safety assessment may need to be reviewed by an external expert if the regulatory body does not have internal expertise"*
Leak Testing	☐	☐	*Procedures for leak testing of sealed radioactive sources (other than short half-life sources) satisfactory?*
Storage facility complies?	☐ ☐	☐ ☐	*Is the store for radioactive sources suitably constructed in compliance with the regulations, including minimizing fire risks, control, ventilation, external dose rate limits and potential public exposure?* *Is it suitably labelled, including stating the means of contacting the operator and / or RPO in case of emergency?*
Operator has appropriate safety equipment for routine radiography operations?	☐	☐	*Does the operator have sufficient warning signs, ropes (i.e.* *for barriers), beam collimators, etc.*
(d) Safety Systems			

X ray equipment subject to regular maintenance?	☐ ☐	☐ ☐	*Is the X ray equipment subject to maintenance at intervals prescribed by the manufacturer?* *Is service of x ray equipment undertaken by authorized personnel?*
Access to X ray equipment?	☐	☐	*Are appropriate measures in place to control access to and prevent use of the X ray equipment by unauthorized persons?* ***Note:*** *e.g. restricting the use of fluoroscopic equipment to appropriately trained Medical Practitioners?*

ITEM	***YES***	***NO***	***NOTES and ACTION***
OCCUPATIONAL AND PUBLIC RADIATION PROTECTION			
Occupational protection programme complies?	☐ ☐ ☐	☐ ☐ ☐	*Are local rules satisfactory?* *Is classification of areas appropriate?* *Does the operator apply appropriate limits to workers exposed as part of their work and to workers whose exposure is not directly related to their work?*
Protective aprons, gloves and other protective devices satisfactory?	☐ ☐	☐ ☐	*Is sufficient personal protective equipment (e.g. lead protective aprons) provided;* *And does it comply with the relevant standard (e.g. IEC)?*
Arrangements for *Personal Radiation* *Monitoring comply?*	☐ ☐ ☐	☐ ☐ ☐	*Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (film badges, TLD, etc)?* *Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose?* *Is the stated monitoring period (frequency) satisfactory?*

Is Personal Monitoring Service Provider approved?	☐	☐	*Is the personal monitoring service provider approved by the regulatory body*
Occupational and public protection programme complies?	☐ ☐	☐ ☐	*Do operator's protocols ensure that occupational and public radiation protection is optimized, work areas are appropriately classified, and doses will comply with the prescribed limits?* *Do protocols ensure dose rates at boundaries around radiography operations comply with prescribed limits?*
Working rules satisfactory?	☐ ☐ ☐	☐ ☐ ☐	*Are the operator's working rules satisfactory?* *Do the rules require work to cease if the user's survey meter fails or in the event of any safety related failure of a radiation source or a breach of a site boundary?* *Do the rules require users to verify with a survey meter that radioactive sources have been safely returned to the source container after each and every exposure?*
Occupational and public protection programme complies?	☐ ☐ ☐	☐ ☐ ☐	*Do operator's protocols ensure that occupational and public radiation protection is optimized;* *Work areas are appropriately classified;* *And doses will comply with the prescribed limits?*
QA and working rules satisfactory?	☐ ☐	☐ ☐	*Are the operator's QA programme and working rules satisfactory?* *Do the rules require users to verify that radioactive sources have been safely returned to their shielded condition before entering the irradiation room?*
Survey meters and personal	☐	☐	*Are the survey meters identified by the operator suitable for the intended purpose?*

alarms, etc. comply?	☐ ☐ ☐	☐ ☐ ☐	*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 sufficient complying survey meters available?* *Are there sufficient personal alarms and are they subject to regular function checks?*
Arrangements for *Personal Radiation* *Monitoring comply?*	☐ ☐ ☐	☐ ☐ ☐	*Has the operator provided satisfactory information on the numbers and types of personal monitoring devices that will be used (e.g. film badges, TLD, OSL, personal alarms, etc.)?* *Has the operator made suitable arrangement for keeping personnel regularly and routinely informed of their recorded occupational radiation dose?* *Is the stated monitoring period (i.e. frequency) satisfactory?*
Personal Monitoring Service provider is approved?	☐	☐	*Is the personal monitoring service provider approved by the regulatory body?*

ITEM	***YES***	***NO***	***NOTES and ACTION***
WASTE MANAGEMENT			
Disposal of unwanted X ray equipment?	☐	☐	*Does the operator have procedures in place to ensure that unwanted X ray equipment is transferred only to an appropriate authorized user unless otherwise approved by the regulatory body?*
Waste disposal arrangements comply?	☐	☐	*Has the operator made suitable arrangements for the disposal of radioactive waste (e.g. gaseous, aerosols, liquids, solids) clearly identifying how this will be achieved?*

ITEM	YES	NO	NOTES and ACTION
TRANSPORT PLAN			
Transport of radioactive sources complies (where relevant)?	☐ ☐ ☐	☐ ☐ ☐	*Has the operator made complying arrangements (where responsible) for the transport of radioactive sources?* *Are Source containers secured, vehicles labelled, etc. in compliance with IAEA Transport Regulations?* *Are procedures for monitoring incoming and outgoing packages satisfactory?*

ITEM	YES	NO	NOTES and ACTION
EMERGENCY PREPAREDNESS AND RESPONSE			
Accident/incident plans satisfactory?	☐ ☐	☐ ☐	*Are the operator's procedures for dealing with accidents and incidents appropriate?* *Are workers appropriately trained with regard to the requirements for notifying accidents/incidents?*
Emergency, accident and incident plans satisfactory?	☐ ☐ ☐	☐ ☐ ☐	*Are the operator's emergency procedures appropriate?* *Does the operator have appropriate equipment to deal with emergencies (e.g. spills)?* *Are the operator's procedures for dealing with accidents and incidents appropriate?* *Is the personnel appropriately trained with regard to dealing with emergencies and with the requirements for notifying accidents / incidents?*

ITEM	YES	NO	NOTES and ACTION
RECORDS AND AUDITS			

Records satisfactory?	☐	☐	*Has the operator made suitable arrangements for maintaining records (e.g. inventory, occupational dose records, audits, etc.)?*
Routine audit programme satisfactory?	☐ ☐	☐ ☐	*Does the operator propose to audit the RPP at suitable intervals?* *Does the operator/RPO regularly (and without notice) audits radiation safety practices of its personnel?*
If a renewal, are there any outstanding items of non-compliance and/or is a legal action being considered by the regulatory body?	☐	☐	*If yes, the application should be discussed with the assessor's Supervisor to determine an appropriate course of action*

B. MEDICAL PRACTICES

ITEM	***YES***	***NO***	***NOTES and ACTION***
RADIOLOGICAL PROTECTION OF PATIENTS			
Are there appropriate protocols for ensuring overall patient protection and safety in the prescription of, and during the performance of diagnostic procedures	☐ ☐	☐ ☐	*"These matters are the responsibility of the designated Medical Practitioner"* *Are protocols describing the procedures required to perform the examination as well as working rules to properly identify patients and to ensure safety for the patient, staff and public in place?* *Are protocols explaining procedures for pregnant or potentially pregnant patients and for examinations of children In place?* *Does the operator possess patient protective devices and enforce their use where these will not interfere with the examination?*
Is QA	☐	☐	*Is the operator's QA programme (including*

programme satisfactory?			*image receptors, film/image processors, repeat analysis, etc.) satisfactory?*
Has the operator to determine typical patient doses for comparison to guidance levels?	☐	☐	*Is the operator's Qualified Expert to determine typical patient doses for comparison to guidance levels published by an appropriate professional organization or prescribed by the regulatory body in place?*
Research procedures and protocols satisfactory?	☐	☐	*If research is performed that involves the exposure of patients or volunteers, the operator 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.*
Screening protocols satisfactory?	☐	☐	***Note:*** *Mass screening of population groups involving medical exposure is not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.* *If the operator intends providing screening examinations (e.g. chest, mammography, bone density, etc.) is there evidence that account has been taken to justify the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease?*
Pre-employment, legal or administrative radiography policy satisfactory?	☐	☐	***Note:*** *Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by*

			those requesting it in consultation with relevant professional bodies.

AFTER EVALUATION

ITEM	***YES***	***NO***	***NOTES and ACTION***
ISSUANCE OF QUOTATION, FEE PAYEMENT AND LICENCE			
Applicant informed of decision?	☐	☐	*Contact the applicant for additional information or collection of quotation.*
Quotation Issued?	☐	☐	*Has the correct fees been quoted? Has the applicant collected the quotation?*
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 operator. Send letter advising fee details.* *Mark record with bring-up date.*
Has the licence template been made and signed?	☐ ☐	☐ ☐	*Has the correct licence template be made?* *Ensure that the cover letter has been made to be attached to the licences. A copy of the cover letter should be kept in the licensing file.* *Has it been signed by the Executive.Director and the Board Chairperson.*