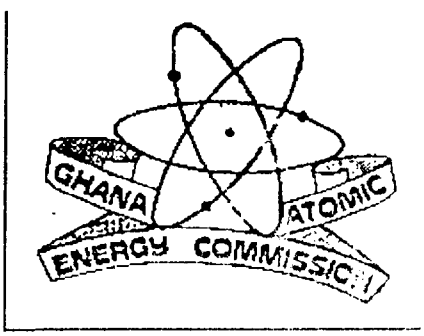
RADIATION PROTECTION BOARD

GHANA ATOMIC ENERGY COMMISSION



RADIATION PROTECTION AND SAFETY GUIDE

NO. GRPB-G2

NOTIFICATION AND AUTHORIZATION BY REGISTRATION OR LICENSING, EXEMPTION AND EXCLUSION

We regret that some of the pages in this report may not be up to the proper legibility standards, even though the best possible copy was used for scanning

RPB REPORT NO. GRPB-G2 (1995)

C. Schandorf, E. O. Darko, J. Yeboah, E. K. Osei, and S. D. Asiamah

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RADIATION PROTECTION AND SAFETY GUIDE

NO. GRPB-G2

Notification and Authorization

by

Registration or Licensing

Exemption and Exclusion

NOTICE OF APPROVAL

By virtue of section 11 of the Radiation Protection Instrument, LI 1559 of 1993 and with the consent of the Ghana Atomic Energy Commission, the Radiation Protection Board has on 12th July, 1995, approved the Radiation Protection and Safety guide on the Notification and Authorization by Registration or Licensing, Exemption and Exclusion.

This guide is approved for the purposes of providing practical guidance with respect to the Radiation Protection Instrument LI 1559.

This guide comes into effect on 1st November, 1995.

Signed:

? ? ?
PROF. F.K.A. ALLOTEY
CHAIRMAN
GHANA ATOMIC ENERGY COMMISSION

? ? ?
DR. L. TWUM-DANSO
CHAIRMAN
RADIATION PROTECTION BOARD

CONTENTS

FOREWORD

The Radiation Protection Board (RPB) was established in 1993 by the amendment of the Atomic Energy Act, Act 204 of 1963 by the Provisional National Defence Council Law, Law 308. The Primary Law was strengthened by the enactment of the Radiation Protection Instruments, LI 1559 in January 1993. The RPB is mandated to be the National Competent Authority in Ghana for licensing and inspection of sources and practices for the purposes of radiation safety.

This regulatory guide was developed to assist Registrant/Licensee to follow systematic procedures which will facilitate an effective implementation of the provisions of the radiation protection regulations.

Preparation of this guide was carried out with the assistance of International Atomic Energy Agency with the support of the Ghana Atomic Energy Commission.

PREFACE

In the framework of the IAEA Inter-regional Model Project on Radiation Protection for upgrading of regulatory capability for licensing and inspection, the need to prepare supporting documents such as codes of practice, guides and relevant document was recognized.

To fulfil these need IAEA recruited an expert to assist local staff of the Radiation Protection Board to prepare these documents. Based upon the review of the legislation in place and other document available the working group decided to develop the overall system of national regulation as follows:

Level 1	-	Ghana Atomic Energy Commission ACT, Act 204 of 1963 with Amendment: Atomic Energy Commission LAW, PNDC Law 308 of 1993.
Level 2	-	Ghana Radiation Protection INSTRUMENT, LI 1559 of 1993.
Level 3	-	Radiation Protection and Safety GUIDES, 1995 with current documents as follows :
GRPB-G1	-	Qualification and Certification of the Radiation Protection Personnel .
GRPB-G2	-	Notification and Authorization by Registration or Licensing. Exemption and Exclusions.
GRPB-G3	-	Dose Limits.
GRPB-G4	-	Inspection.

1.0 INTRODUCTION

1.1 General

The obligatory requirement for the notification of the Radiation Protection Board and application for authorization by registration or licensing are important elements of the national system for controlling radiation sources and practices which may be potentially harmful to people

The present document provides guidance for Notification and Authorization by Registration or Licensing.

1.2 Scope and Objective

In pursuance of the provision of the Radiation Protection Instrument, 1993, LI 1559, Part II- "Control and Use of Radiation Sources", the present Guide specifies the Radiation Protection Board (RPB) scheme of notification and authorization by registration or licensing.

Criteria for exempting and excluding sources and practices from regulatory control are highlighted.

1.3. Field of Application

1.3.1 The present Guide applies to Ghana.

1.3.2 Subject to exemption or exclusion the present Guide applies to the following actions concerning radiation sources, practices and facilities, shielded enclosures and nuclear installations included.

a) design, manufacture, production and modification
b) possessing or use
c) selling, disposing or leasing, loaning or dealing with,
d) import or export or
e) transport.

1.4 Responsibilities

a) Any person intending to carry out any action specified in paragraph 1.3.2 of this Guide bear the responsibility for NOTIFYING the RPB in writing of such intention.

b) To notify the RPB of any intended importation of the radiation source to Ghana, is the importer's responsibility (foreign companies included).

c) The HOLDER of a current authorization of the Radiation Protection Board (RPB), issued by registration or licensing bears the responsibility for NOTIFYING the RPB in writing of his intention:

i) to sell, acquire, store, install, transfer or use of the radiation source or
ii) of any change in the facility, shielded enclosures and nuclear facility which renders inaccurate the information supplied by him during licensing process.

d) The assessment of the NOTIFICATION documents is responsibility of the RPB.

e) Exemption and Exclusion as well as authorization by registration or licensing process is the responsibility of the Radiation Protection Board.

2.0 NOTIFICATION

a) Holder of current RPB licence or any person who intends to carry out any action specified in sections 1.3.2 and 1.4(c) shall notify the RPB of his/her intentions within a period of one month (see figure 1).

b) The applicant shall use the notification form attached.

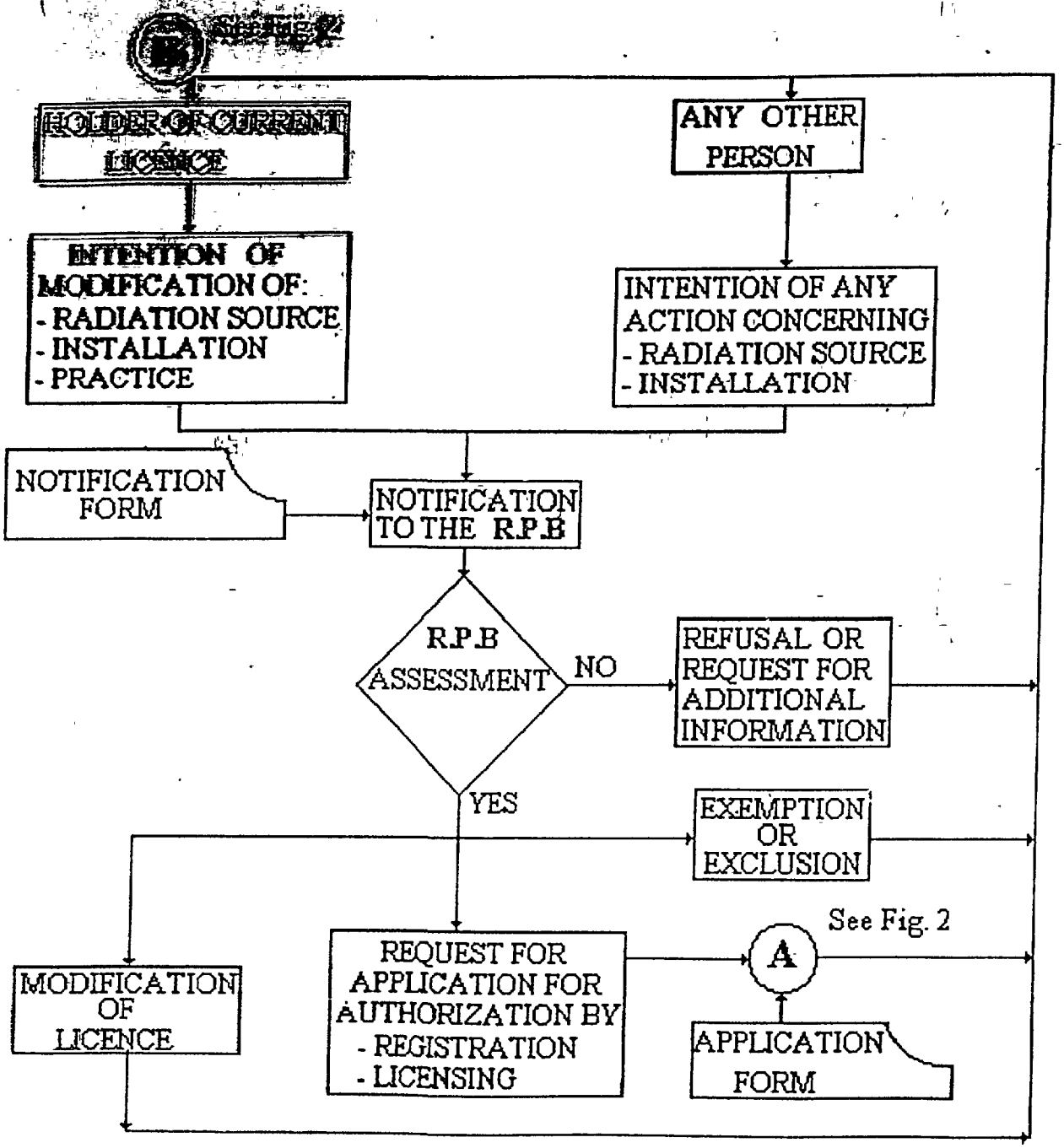
c) The RPB within one month shall proceed with the assessment of the notification documentation.

d) The result of the assessment by the RPB should be

i) Exemption or Exclusion
ii) Request for application for athorization by registration or licencing
iii) Modification of the authorization conditions and limits
iv) Request for additional information or
v) Refusal

e) Notification for consumer products is required only with respect to manufacturing, assembling and distributing.

Fig. 1: NOTIFICATION FLOW-CHART



3.0 EXEMPTION

3.1 Exemption Criteria

a) Practices and sources within practices may be exempted from the requirements of the Guides, including registration or licensing, if the RPB is satisfied that the sources meet the exemption criteria or the exemption levels in the Annex or other exemption levels specified by the RPB on the basis of these exemption criteria. Exemption should not be granted to permit practices that would otherwise not be justified.

b) A practice or a source within a practice may be exempted without further consideration provided that the following criteria are met in all feasible situations:

   i) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year, and

   ii) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option.

3.2 Exempted Sources and Exemption Levels

a) Under the criteria in paragraphs 3.1,b i,ii, the following sources within practices are for registration and licensing exempted without further consideration from the requirements of the Guide.

   i) radioactive substances for which either the total activity ot a given nuclide present on the premises at any one time or the activity concentration used in the practice does not exceed the exemption levels given in Annex of this Guide, and

   ii) radiation generators, of a type approved by the RPB and any electronic tube, such as a cathode ray tubes for the display of visual images, provided that:

      - they do not cause in normal operating conditions an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv.h^{-1} at a distance of 0.1 m from any accessible surface of the apparatus; or
      - the maximum energy of the radiation produced is no greater than 5 keV.

b) Conditional exemptions may be granted subject to conditions specified by the RPB such as conditions relating to the physical or chemical form and to the use or disposal of the radioactive materials. In particular, such an exemption may be granted for an apparatus containing radioactive substances not otherwise exempted provided that:

i) it is of a type approved by the RPB;

ii) the radioactive substances are in the form of sealed sources that effectively prevent any contact with radioactive substances or their leakage except that this should not prevent exemption of small quantities of unsealed sources such as those used for radioimmunoassay;

iii) in normal operating conditions it does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 $\mu Sv.h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; and

iv) necessary conditions for disposal have been specified by the RPB.

c) Radioactive substances from an authorized practice or source whose release to the environment has been authorized, are exempted from any new requirements of notification, or licensing unless otherwise specified by the RPB.

3.3 Clearance

Sources, including substances, materials and objects, within notified or authorized practices may be released from the requirements of the Guide subject to complying with clearance levels approved by the RPB. Such clearance levels shall take account of the exemption criteria specified in Section 3.1 and shall not be higher than the exemption levels specified in Section 3.2 unless otherwise approved by the RPB.

4.0 EXCLUSION

Any exposure whose magnitude or likelihood is essentially unamendable to control through the requirements of the Guides is considered to be excluded from the Guides.

Examples are exposures from ^{40}K in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials.

5.0 AUTHORIZATION BY REGISTRATION/LICENSING

5.1 General

a) The requirements concerning application documentation are commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures;

b) Any person applying for an authorization shall:

i) submit to the RPB, the relevant information and to make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for radiation protection and safety of the radioactive source (installation), regarding both workers and the public.

ii) refrain from carrying out any of the actions described in Section 1.3.2 (LI 1559 Part II Section 5,6 and 7) for practices of the Guide until the registration or license, as appropriate has been granted.

c) If the potential for the exposure is greater than the level specified in the Guide GRPB-G3 "Dose Limits" then a SAFETY ASSESSMENT and Q A programme shall be developed and submitted to the RPB as a part of the application;

d) The application scheme for authorization by registration or by licencing is similar (see fig.2). But the requirements concerning the safety documentation are more stringent for authorization by licencing than by registration.

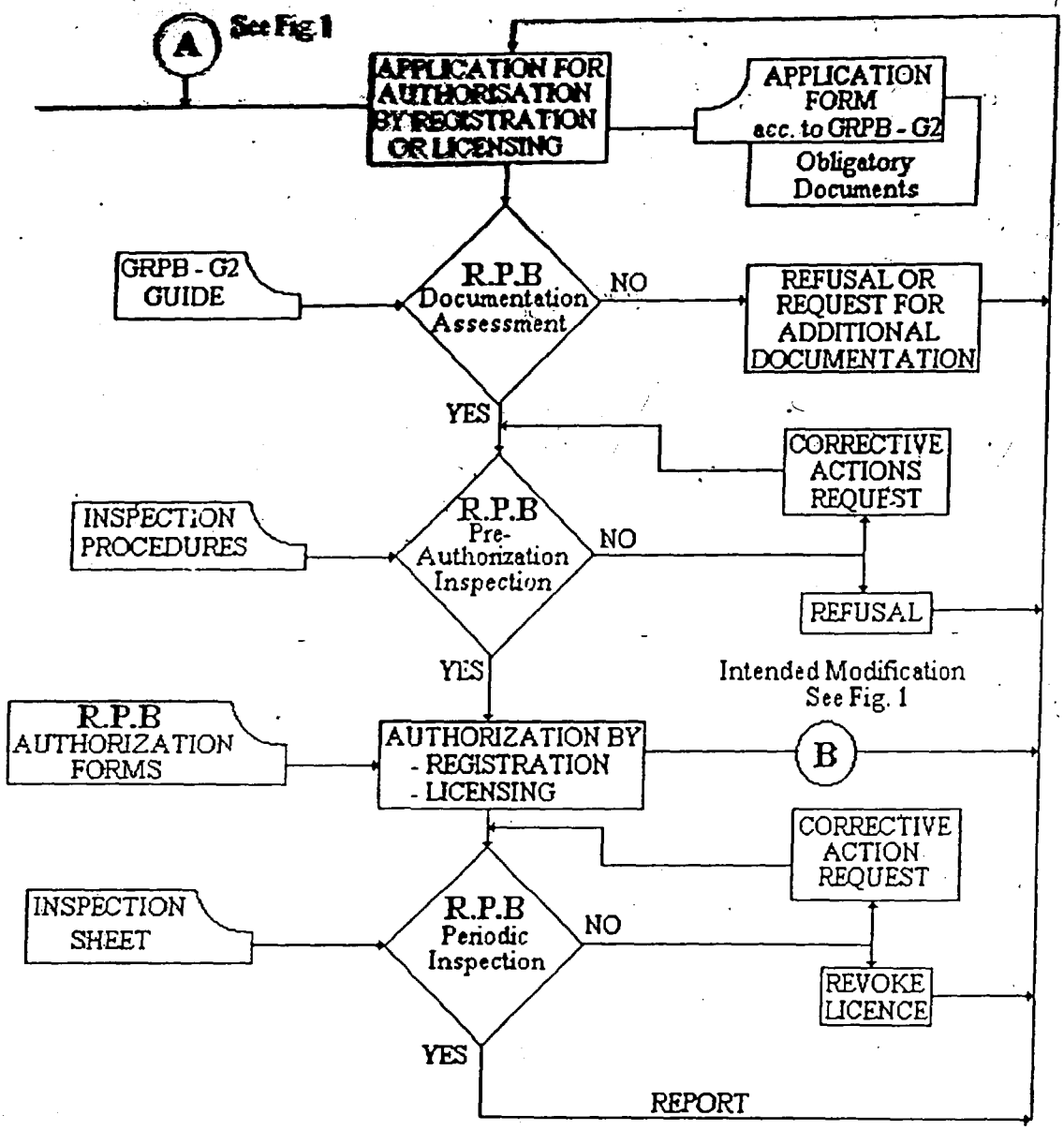
5.2 Authorization Scheme

a) The applicant applies to the RPB for authorization by Registration/Licensing using the form attached (see Annex 3)

b) The list of documents which should be attached to the application form is specified in the form attached. The most important of them are:

- Personnel qualification/certification
- Design of shielding (if any)
- Equipment and maintenance
- Work procedures and instructions
- Transport Instruction (if applicable)
- Emergency planning

Fig. 2 REGISTRATION OR LICENSING FLOW CHART



- Q A programme (for licensing only)
- Safety Analysis Report (if applicable)

c) The RPB proceeds with the assessment of the documentation and the results of which can be:

i) Refusal;
ii) Request for additional documentation;
iii) Acceptance of the application documentation and proposition of pre-authorization inspection.

d) The pre-authorization inspections are conducted by the RPB in accordance with inspection procedures developed by the Board. The result of the pre-authorization inspection can be:

i) Refusal;
ii) Request for corrective actions;
iii) Authorization by registration/licensing.

e) The Authorization by registration shall not be issued until all eventual corrective actions have been complied with and confirmed by successive pre-authorization inspection.

f) The authorization by Licensing can take the form of:

i) Provisional (conditional or temporary)
ii) Limited authorization
iii) Full authorization

g) The RPB will conduct periodic inspections at the facility to ensure that the conditions and terms as stated in the authorization and in the SAR (where applicable) are complied with. (see GRPB-G4 Guide)

h) The inspection conducted by the RPB can be:

i) Planned i.e. prearranged inspection with licensee or registrant.
ii) Adhoc i.e. such inspections can be conducted without prearrangement with the licensee or registrant.
iii) At the request of the licensee or registrant.

i) The holder of a licence shall carry out a comprehensive system of planned and documented internal quality audit to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

j) The results of the periodic inspection can be:

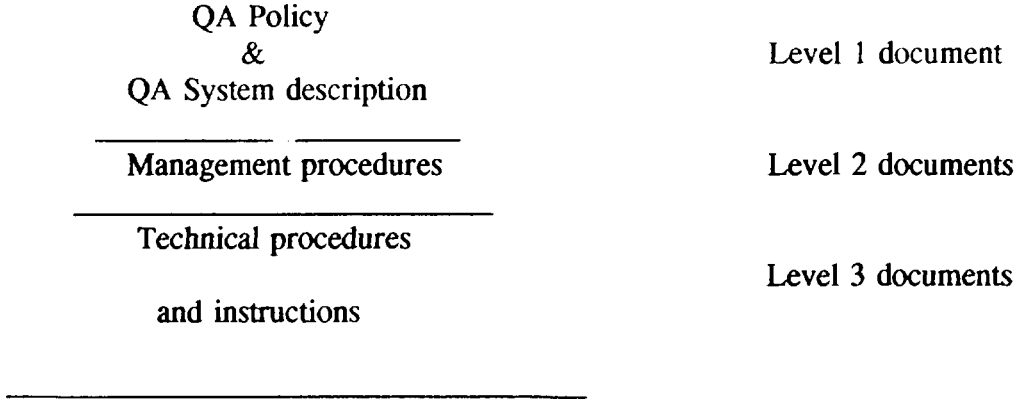
i) revoke of licence.
ii) request for corrective actions
iii) no remarks

6.0 QUALITY ASSURANCE

a) The system of authorization by registration and by licencing is expected to be a subject of a quality assurance programme developed by the Radiation Protection Board. The objective of the Q A programme is to provide:

i) adequate level of confidence that the requirements of this Guide are respected;
ii) quality control mechanisms and assessing the overall effectiveness of radiation protection and safety measures.

b) The structure of the QA Programme is as follows:



DEFINITIONS

The following definitions apply for the purpose of this guide:

NOTIFICATION

A document submitted to the RPB 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 Radiation Protection Instrument LI 1559, Part II, Sections 5, 6 and 7.(paragraphs 1.3.2 and 1.4(c) of this Guide)

AUTHORIZATION

A permission granted in a document by the RPB to a legal person who has submitted an application to carry out a practice or any other action described in the paragraph 1.3.2 of this Guide. The AUTHORIZATION can take the form of a REGISTRATION or a LICENCE

REGISTRATION

A 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 RPB. 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.

LICENCE

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

EXEMPTION

Full or conditional permission to carry out some practice or use sources within a practice without obligation to comply with the requirements of authorization.

EXCLUDED

Not subject to the requirements of the guide.

PRACTICE

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing exposure of people or number of people exposed.

SOURCE

Any irradiating device or radioactive material

EXPOSURE PATHWAYS

The routes by which radioactive material can reach or irradiate humans

REFERENCES

[1] Ghana Atomic Energy Commission ACT, Act 204 of 1963 with Amendment: Atomic Energy Commission LAW, Law 308 of 1993.

[2] Ghana Radiation Protection INSTRUMENT, LI 1559 1993. Arrangement of Regulation.

[3] International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, April 1994.

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11.	Asamoah D. (Miss)	Secretary

ANNEX 1

EXEMPTION LEVELS:

Exempt Activity Concentrations and Exempt Activities of Radionuclides

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
H-3	1.00e+06	1.00e+09
Be-7	1.00e+03	1.00e+07
C-14	1.00e+04	1.00e+07
O-15	1.00e+02	1.00e+09
F-18	1.00e+01	1.00e+06
Na-22	1.00e+01	1.00e+06
Na-24	1.00e+01	1.00e+05
*Si-31	1.00e+03	1.00e+06
P-32	1.00e+03	1.00e+05
*P33	1.00e+05	1.00e+08
S-35	1.00e+05	1.00e+08
Cl-36	1.00e+04	1.00e+06
*Cl-38	1.00e+01	1.00e+05
Ar-37	1.00e+06	1.00e+13
Ar-41	1.00e+02	1.00e+09
*K-40	1.00e+02	1.00e+06
K-42	1.00e+02	1.00e+06
*K-43	1.00e+01	1.00e+06
Ca-45	1.00e+04	1.00e+07
Ca-47	1.00e+01	1.00e+06
Sc-46	1.00e+01	1.00e+06
*Sc-47	1.00e+02	1.00e+06
*Sc-48	1.00e+01	1.00e+05
*V-48	1.00e+01	1.00e+05
Cr-51	1.00e+03	1.00e+07
Fe-52	1.00e+01	1.00e+06
Fe-55	1.00e+04	1.00e+06
Fe-59	1.00e+01	1.00e+06
*Mn-51	1.00e+01	1.00e+05
*Mn-52	1.00e+01	1.00e+05
*Mn-52m	1.00e+01	1.00e+05
Mn-53	1.00e+04	1.00e+09

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
Mn-54	1.00e+01	1.00e+06
Mn-56	1.00e+01	1.00e+05
*Co-55	1.00e+01	1.00e+06
Co-56	1.00e+01	1.00e+05
Co-57	1.00e+02	1.00e+06
C0-58	1.00e+01	1.00e+06
*Co-58m	1.00e+04	1.00e+07
Co-60	1.00e+01	1.00e+05
*Co-60m	1.00e+03	1.00e+06
*C0-61	1.00e+02	1.00e+06
*Co-62m	1.00e+01	1.00e+05
*Ni-59	1.00e+04	1.00e+08
Ni-63	1.00e+05	1.00e+08
*Ni-65	1.00e+01	1.00e+06
Cu-64	1.00e+02	1.00e+06
Zn-65	1.00e+01	1.00e+06
*Zn-69	1.00e+04	1.00e+06
Zn-69m	1.00e+02	1.00e+06
*Ge-71	1.00e+04	1.00e+08
Ga-72	1.00e+01	1.00e+05
*As-73	1.00e+03	1.00e+07
As-74	1.00e+01	1.00e+06
*As-76	1.00e+02	1.00e+05
*As-77	1.00e+03	1.00e+06
Se-75	1.00e+02	1.00e+06
Br-82	1.00e+01	1.00e+06
*Kr-74	1.00e+02	1.00e+09
*Kr-76	1.00e+02	1.00e+09
*Kr-77	1.00e+02	1.00e+09
*Kr-79	1.00e+03	1.00e+10
*Kr-81	1.00e+04	1.00e+11
Kr-83m	1.00e+05	1.00e+12
Kr-85	1.00e+05	1.00e+11

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*Kr-85m	1.00e+03	1.00e+10
*Kr-87	1.00e+02	1.00e+09
*Kr-88	1.00e+02	1.00e+09
Sr-85	1.00e+02	1.00e+06
Sr-85m	1.00e+02	1.00e+07
Sr-87m	1.00e+02	1.00e+06
Sr-89	1.00e+03	1.00e+06
Sr-90+	1.00e+02	1.00e+04
*Sr-91	1.00e+01	1.00e+05
*Sr-92	1.00e+01	1.00e+06
Y-90	1.00e+03	1.00e+05
*Y-91	1.00e+03	1.00e+06
*Y-91m	1.00e+02	1.00e+06
*Y-92	1.00e+02	1.00e+05
*Y-93	1.00e+02	1.00e+05
Rb-86	1.00e+02	1.00e+05
*Zr-93+	1.00e+03	1.00e+07
Zr-95	1.00e+01	1.00e+06
*Zr-97+	1.00e+01	1.00e+05
*Nb-93m	1.00e+04	1.00e+07
*Nb-94	1.00e+01	1.00e+06
Nb-95	1.00e+01	1.00e+06
*Nb-97	1.00e+01	1.00e+06
*Nb-98	1.00e+01	1.00e+05
*Tc-96	1.00e+01	1.00e+06
*Tc-96m	1.00e+03	1.00e+07
*Tc-97	1.00e+03	1.00e+08
*Tc-97	1.00e+03	1.00e+07
*Tc-99	1.00e+04	1.00e+07
Tc-99m	1.00e+02	1.00e+07
*Mo-90	1.00e+01	1.00e+06
Mo-93	1.00e+03	1.00e+08
*Mo-99	1.00e+02	1.00e+06

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*Mo-101	1.00e+01	1.00e+06
*Ru-97	1.00e+02	1.00e+07
Ru-103	1.00e+02	1.00e+06
*Ru-105	1.00e+01	1.00e+06
Ru-106+	1.00e+02	1.00e+05
*Rh-103m	1.00e+04	1.00e+08
*Rh-105	1.00e+02	1.00e+07
*Pd-103	1.00e+03	1.00e+08
*Pd-109	1.00e+03	1.00e+06
Cd-109	1.00e+04	1.00e+06
*Cd-115	1.00e+02	1.00e+06
*Cd-115m	1.00e+03	1.00e+06
*Ag-105	1.00e+02	1.00e+06
Ag-110m	1.00e+01	1.00e+06
Ag-111	1.00e+03	1.00e+06
In-111	1.00e+02	1.00e+06
In-113m	1.00e+02	1.00e+06
*In-114m	1.00e+02	1.00e+06
*In-115m	1.00e+02	1.00e+06
*Sn-113	1.00e+03	1.00e+07
*Sn-125	1.00e+02	1.00e+05
Sb-122	1.00e+02	1.00e+04
Sb-124	1.00e+01	1.00e+06
Sb-125	1.00e+02	1.00e+06
I-123	1.00e+02	1.00e+07
I-125	1.00e+03	1.00e+06
*I-126	1.00e+02	1.00e+06
*I-129	1.00e+02	1.00e+05
*I-130	1.00e+01	1.00e+06
I-131	1.00e+02	1.00e+06
I-132	1.00e+01	1.00e+05
*I-133	1.00e+01	1.00e+06
*I-134	1.00e+01	1.00e+05

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*I-135	1.00e+01	1.00e+06
*Cs-129	1.00e+02	1.00e+05
Cs-131	1.00e+03	1.00e+06
*Cs-132	1.00e+01	1.00e+05
*Cs-134m	1.00e+03	1.00e+05
Cs-134	1.00e+01	1.00e+04
*Cs-135	1.00e+04	1.00e+07
*Cs-136	1.00e+01	1.00e+05
Cs-137+	1.00e+01	1.00e+04
*Cs-138	1.00e+01	1.00e+04
*Te-123m	1.00e+02	1.00e+07
*Te-125m	1.00e+03	1.00e+07
*Te-127	1.00e+03	1.00e+06
*Te-127m	1.00e+03	1.00e+07
*Te-129	1.00e+02	1.00e+06
*Te-129m	1.00e+03	1.00e+06
Te-131	1.00e+02	1.00e+05
*Te-131m	1.00e+01	1.00e+06
Te-132	1.00e+02	1.00e+07
*Te-133	1.00e+01	1.00e+05
*Te-133m	1.00e+01	1.00e+05
*Te-134	1.00e+01	1.00e+06
*Xe-131m	1.00e+04	1.00e+11
Xe-133	1.00e+03	1.00e+10
*Xe-135	1.00e+03	1.00e+10
Ce-139	1.00e+02	1.00e+06
Ce-141	1.00e+02	1.00e+07
*Ce-143	1.00e+02	1.00e+06
Ce-144+	1.00e+02	1.00e+05
*Ba-131+	1.00e+02	1.00e+06
Ba-140+	1.00e+01	1.00e+05
La-140	1.00e+01	1.00e+05
*Pr-142	1.00e+02	1.00e+05

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
Pr-143	1.00e+04	1.00e+06
Pm-147	1.00e+04	1.00e+07
*Pm-149	1.00e+03	1.00e+06
*Nd-147	1.00e+02	1.00e+06
*Nd-149	1.00e+02	1.00e+06
Sm-151	1.00e+04	1.00e+08
*Sm-153	1.00e+02	1.00e+06
Eu-152	1.00e+01	1.00e+06
*Eu-152m	1.00e+02	1.00e+06
Eu-154	1.00e+01	1.00e+06
Eu-155	1.00e+02	1.00e+07
*Gd-153	1.00e+03	1.00e+07
*Gd-159	1.00e+03	1.00e+06
*Tb-160	1.00e+01	1.00e+06
*Dy-165	1.00e+02	1.00e+06
*Dy-166	1.00e+03	1.00e+06
*Ho-166	1.00e+03	1.00e+05
Er-169	1.00e+04	1.00e+07
*Er-171	1.00e+02	1.00e+06
Tm-170	1.00e+03	1.00e+06
*Tm-171	1.00e+04	1.00e+08
*Yb-175	1.00e+03	1.00e+07
*Lu-177	1.00e+03	1.00e+07
Ta-182	1.00e+01	1.00e+04
*Hf-181	1.00e+01	1.00e+06
*W-181	1.00e+03	1.00e+07
W-185	1.00e+04	1.00e+07
*W-187	1.00e+02	1.00e+06
Re-186	1.00e+03	1.00e+06
*Re-188	1.00e+02	1.00e+05
*Os-185	1.00e+01	1.00e+06
*Os-191	1.00e+02	1.00e+07
*Os-191m	1.00e+03	1.00e+07

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*Os-193	1.00e+02	1.00e+06
*Ir-190	1.00e+01	1.00e+06
Ir-192	1.00e+01	1.00e+04
*Ir-194	1.00e+02	1.00e+05
*Pt-191	1.00e+02	1.00e+06
*Pt-193m	1.00e+03	1.00e+07
*Pt-197	1.00e+03	1.00e+06
*Pt-197m	1.00e+02	1.00e+06
Hg-197	1.00e+02	1.00e+07
*Hg-197m	1.00e+02	1.00e+06
Hg-203	1.00e+02	1.00e+05
Au-198	1.00e+02	1.00e+06
*Su-199	1.00e+02	1.00e+06
*Ti-200	1.00e+01	1.00e+06
Ti-201	1.00e 02	1.00e+06
*Ti-202	1.00e+02	1.00e+06
Ti-204	.00e+04	1.00e+04
Bi-206	1.00e+01	1.00e+05
*Bi-207	1.00e+01	1.00e+06
*Bi-210	1.00e+03	1.00e+06
*Bi-212+	1.00e+01	1.00e+05
*Pb-203	1.00e+02	1.00e+06
Pb-210+	1.00e+01	1.00e+04
*Po-221+	1.00e+01	1.00e+05
*Po-203	1.00e+01	1.00e+06
*Po-205	1.00e+01	1.00e+06
*Po-207	1.00e+01	1.00e+06
Po-210	1.00e+01	1.00e+04
*At-211	1.00e+03	1.00e+07
*Rn-220+	1.00e+04	1.00e+07
Rn-222+	1.00e+01	1.00e+08
*Ra-223+	1.00e+02	1.00e+05
*Ra-224+	1.00e+01	1.00e+05

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*Ra-225	1.00e+02	1.00e+05
Ra-226+	1.00e+01	1.00e+04
*Ra-227	1.00e+02	1.00e+06
*Ra-228+	1.00e+01	1.00e+05
*Th-226+	1.00e+03	1.00e+07
*Th-227	1.00e+01	1.00e+04
Th-228+	1.00e+00	1.00e+04
*Th-229+	1.00e+00	1.00e+03
Th-230	1.00e+00	1.00e+04
*Th-23	1.00e+03	1.00e+07
Th-NAT (incl. Th-232)	1.00e+00	1.00e+03
*Th-234+	1.00e+03	1.00e+05
*Ac-227+	1.00e+01	1.00e+02
*Ac-228	1.00e+01	1.00e+06
*Pa-230	1.00e+01	1.00e+06
*Pa-231	1.00e+00	1.00e+03
*Pa-233	1.00e+02	1.00e+07
*U-230+	1.00e+01	1.00e+05
*U-231	1.00e+02	1.00e+07
*U-232+	1.00e+00	1.00e+03
*U-233	1.00e+01	1.00e+04
U-234	1.00e+01	1.00e+04
*U-235+	1.00e+01	1.00e+04
*U-236	1.00e+01	1.00e+04
*U-237	1.00e+02	1.00e+06
U-238+	1.00e+01	1.00e+04
U-nat	1.00e+00	1.00e+03
*U-239	1.00e+02	1.00e+06
*U-240	1.00e+03	1.00e+07
*U-240+	1.00e+01	1.00e+06
*Np-237+	1.00e+00	1.00e+03
*Np-239	1.00e+02	1.00e+07
*Np-240	1.00e+01	1.00e+06

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*Pu-234	1.00e+02	1.00e+07
*Pu-235	1.00e+02	1.00e+07
*Pu-236	1.00e+01	1.00e+04
*Pu-237	1.00e+03	1.00e+07
Pu-238	1.00e+00	1.00e+04
Pu-239	1.00e+00	1.00e+04
*Pu-240	1.00e+00	1.00e+03
*Pu-241	1.00e+02	1.00e+05
*Pu-242	1.00e+00	1.00e+04
*Pu-243	1.00e+03	1.00e+07
*Pu-244	1.00e+00	1.00e+04
Am-241	1.00e+00	1.00e+04
*Am-242	1.00e+03	1.00e+06
*Am-242m+	1.00e+00	1.00e+04
*Am-243+	1.00e+00	1.00e+03
*Cm-242	1.00e+02	1.00e+05
*Cm-243	1.00e+00	1.00e+04
Cm-244	1.00e+01	1.00e+04
*Cm-245	1.00e+00	1.00e+03
*Cm-246	1.00e+00	1.00e+03
*Cm-247	1.00e+00	1.00e+04
*Cm-248	1.00e+00	1.00e+03
Bk-249	1.00e+03	1.00e+06
*Cf-246	1.00e+03	1.00e+06
*Cf-248	1.00e+01	1.00e+04
*Cf-249	1.00e+00	1.00e+03
*Cf-250	1.00e+01	1.00e+04
*Cf-251	1.00e+00	1.00e+03
Cf-252	1.00e+01	1.00e+04
*Cf-253	1.00e+02	1.00e+05
*Cf-254	1.00e+00	1.00e+03
*Es-253	1.00e+02	1.00e+05
*Es-254	1.00e+01	1.00e+04

NUCLIDE	ACTIVITY CONCENTRATION Bq/g	ACTIVITY Bq
*ES-254m	1.00e+02	1.00e+06
*Fm-254	1.00e+04	1.00e+07
*Fm-255	1.00e+03	1.00e+06

(*) The potential use of these radionuclides is unknown.
(+) Refers to progeny as follows:

Parent Nuclide	Progeny included in secular equilibrium
Sr-90+	Y-90
Zr-93+	Nb-93m
Zr-97+	Nb-97
Ru-106+	Rh-106
Cs-137+	Ba-137m
Ce-134+	La-134
Ce-144+	Pr-144
Ba-140+	La-140
Bi-212+	Tl-208(35), Po-212(64)
Pb-210+	Bi-210,Po-210
Pb-212+	Bi-212, Tl-208(36), Po-212(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, Tl-207
Ra-224+	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(36), Po-212(64)
Ra-226+	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228+	Ac-228
Th-226+	Ra-222, Rn-218, Po-214
Th-228+	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208(36), Po-212(64)
Th-229+	Ra-225,Ac-225,Fr-221,At-217,Bi-213,Po-213,Pb-209
Th-NAT	Ra-228,Ac-228,Th-228,Rn-220,Po-216,Pb-212,Bi-212,Tl-208(36),Po 212(64)
Th-234+	Pa-234m
Ac-237+	Th-227, Ra-223, Rn-219, Po-215, Pb-211, Bi-211, Tl-207
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(36),Po-212(64)
U-235+	Th-231
U-238+	Th-234, Pa-234m
U-NAT	Th-234,Pa-2324m,U-234,Th-230,Ra-226,Rn-222,Po-218,Pb-214,Bi-214,Po-214,Pb-210,Bi-210,Po-210
U-240+	Np-240m
Np237+	Pa-233
Am-242m+	Am-242
Am-243+	Np-239

RPB Form G2-1 ANNEX 2

NOTIFICATION FORM
RADIATION PROTECTION BOARD
GHANA ATOMIC ENERGY COMMISSION
P. O. BOX 80, LEGON, GHANA

INSTITUTION: .....

ADDRESS: .....

FAX NO: ..... TELEX: .....

CONTACT PERSON: .....

SOURCE CHARACTERISTICS:	QUANTITY
X-RAY: ..... KV: ..... mA: ..... MOBILE/FIXED:	.....
GAMMA RAY: ..... TYPE: ..... Bq(Ci):	.....
CONTAINER/APPARATUS/TYPE:	.....
OTHERS:	.....

TYPE OF INTENDED PRACTICE OR MODIFICATION: .....

.....

DURATION OF PRACTICE: .....

LOCATION OF SOURCE/PRACTICE: .....

IRRADIATION FACILITY (SHIELDING): .....

SOURCE STORAGE: .....

RADIATION PROTECTION MEANS: .....

PERSONAL MONITORING: .....

AREA MONITORING: .....

PERSONNEL QUALIFICATION: .....

REMARKS: .....

.....

LICENCE/REGISTRATION NO: ..... SIGNATURE: .....

OFFICIAL STAMP:

DATE: ..... NAME: .....

TITLE: .....

REPUBLIC OF GHANA

REF: RPB Form 1B

Radiation Protection Board
Ghana Atomic Energy Commission
P. O. Box 80, Legon, Accra
Ghana

Date: .....

RADIATION PROTECTION INSTRUMENT, LI 1559, 1993

(PART III SUB-SECTION 9)

Application for Authorization for the use of Radiation emitting Device

1. Name of Applicant .....
   Telephone No. .....
   Address .....
   .....
   .....

2. Name and Address of owner where the device will be used, stored or installed .....
   .....
   .....

3. Name and Address of the responsible Radiation Safety Officer
   .....
   .....
   .....

4. List the names of authorized users

NAME	TITLE
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....

Part "A" X-RAY EQUIPMENT

(Use a separate form for each x-ray equipment)

5. Identification

Name of manufacture: .....

Model: .....

Control Console Type: .....

Serial No.: .....

Tube Head Type: .....

Serial No.: .....

Tube Insert Type: .....

Serial No. .....

6. Type of Installation

a) Fixed/mobile

b) Combine/Radiography/Fluoroscopic/photofluorographic/cine fluorography/dental

c) Others

7. Rectification

Specify: .....

Single phase: self/half wave/full wave

Three phase : six pulse/twelve pulse

Constant potential

Capacitory energy storage

8. For combined Radiographic/Fluorographic Equipment

Indicate the flowing:

Bucky Radiography/Serial Radiography/Tomography/Fluoresent screen/image intensifier with spot camera for 70mm/100mm of optical viewer or television/cine camera for 16mm/35mm continuous operation/pulse operation.

(specify) max

Frame speed: .....

Frames/sec.: .....

9. Total Rating

(a) For capacitor discharged equipment

Peak tube Voltage .....

Max quality charge .....

Coulombs or Condenser capacitance .....μF

(b) For pulsed Equipment

Peak tube Voltage .....Kvp

No. of x-ray pulses .....

(c) For other Equipment

Peak tube voltage .....Kvp

Max. tube current .....mA

Max. exposure time .....sec.

Max. mAs .....mAs

10. Filtration

Inherent Filtration .....mmAl

Added Filtration .....mmAl

11. Timer

(a) Built in monitoring system/filter safety switch .....

(b) Automatic exposure control - phototimer ionisation type .....

12. Tube insert

Stationary anode/Rotating anode .....

air cooled/oil cooled/grid controlled/non grid controlled

Fine focus .....

Broad focus .....

Heat storage capacity .....

Cooling rate .....

13. Stabilisation

Main voltage stabilisation/voltage stabilisation/tube current stabilisation.

Specify % Fluctuation in output .....

14. Collimation

Cones/single - leaf/multi - leaf/applicators/light beam

15. Directions in which exposure can be made

One direction/two directions/multi-directions

(specify the orientations in the layout of the facility)

16. Describe use of the authorized device(s)

.....

.....

.....

.....

.....

17. Describe Radiation Monitoring Equipment to be used

TYPE	MANUFACTURER	MODE #	TYPE OF RADIATION DETECTED	SENSITIVITY

18. Calibration of Instruments listed in Item 17

Calibrated by A service Company .....

Regulatory Body (RPB) .....

Frequency Quarterly .....

Yearly .....

19. Personnel Monitoring Service

Type	Supplier	Frequency of Exchange

20. Attachments

Provide a description of each individual's educational background and experience with radiation.

Provide a resume of emergency plan and procedures to deal with any foreseeable accident/incident.

A layout of the facility specifying the orientations in which exposures will be made.

Any other information relevant to the prompt processing of this application.

21. Certification

The applicant and any other official executing this certification on behalf of the named applicant, certify that all information provided therein, including any attached hereto, is true and correct to the best of his/her knowledge and belief.

Warning - LI 1559 of 1993, Part III section 15 makes it a crimi al offence to make a wilfu! false statements(s) or representation(s) to the Radiation Protection Board or ar.y authorised Radiation Protectio1 Officer(s).

.....	.....	....
Certifying Officer	Name of Ce ifying Officer	Title

Date: .....

RADIATION PROTECTION BOARD
GHANA ATOMIC ENERGY COMMISSION

RPB FORM 1A
LI 1559 PART 111, Sub-Section 9

APPLICATION FOR AUTHORIZATION BY REGISTRATION OF RADIOACTIVE MATERIAL

1. Type of Application: ☐ New Authorization ☐ Amendment to Authorization No: ☐ Renewal of Authorization

2. Applicant's Name (Institution, Firm, Person etc)

3. Name and title of Person to be contacted regarding this Application

4. Applicant's Mailing Address

5. Telephone:
Telex No.:
Fax No. :

6. Name(s) of those who will use or directly supervise the use of the radioactive material

Full Name	Title

7. Radiation Safety Officer(s)

8. Types of Radioactive Material	Chemical/Physical Form	Name of Manufacturer and Model Number	Maximum activity of source to be possessed at any one time

9. Describe use of Radioactive Material

10. Storage of Sealed/Unsealed Sources

Container and or Device in which each source will be stored or used	Name of Manufacturer	Model Number

11. Radiation Monitoring Equipment

Type	Name of Manufacturer	Model Number	Number Available	Type of Radiation Detected	Sensitivity Range

12. Calibration of Instruments Listed in Item 11:

☐ Calibrated by a Service Company
Name and Address; Frequency

☐ Quarterly

☐ Yearly

☐ Calibrated by Regulatory Body
Name and Address; Frequency

☐ Quarterly

☐ Yearly

13. Personnel Monitoring Service

Type	Supplier (Company)	Frequency of Exchange
☐ Film badges		☐ Monthly
☐ TLD		☐ Quarterly
☐ Other(s):_____		☐ Others:
_____		_____

14. Facility and Equipment: (Attach Drawing and descriptions where applicable)

☐ Laboratory Facilities

☐ Storage facilities, Containers, Special Shielding

☐ Remote Handling Tools or Equipment

☐ Respiratory Protective Equipment

15. Waste Disposal:

☐ Name of Waste disposal service to be employed

☐ If the spent isotope will be returned for disposal under an agreement with the supplier, state so and supply a copy of the agreement.

16. Attachments:

☐ Provide a description of each individual's educational background and working experience with radiation.

☐ Provide a resume of emergency plan and procedures to deal with any foreseeable incident/accident.

☐ Technical specification of the soruce and leakage test programme.

☐ Any other information relevant to prompt processing of this application.

17. Certification:

The applicant and any official executing this certification on behalf of the named applicant, certify that all information provided therein, including any attachment hereto, is true and correct to the best of his/her knowledge and belief.

Warning - LI 1559 of 1993, Part 111 Section 15 makes it a criminal offence to make a wilfully false statement or representation to the Radiation Protection Board or authorized Radiation Protection Officer(s).

.....	.....	.....
Certifying Officer (Signature)	Name of Certifying Officer	Title

Date: .....

RADIATION PROTECTION BOARD
GHANA ATOMIC ENERGY COMMISSION

APPLICATION FOR AUTHORIZATION AND SAFETY ASSESSMENT OF RADIOTHERAPY FACILITIES IN GHANA

TYPE OF AUTHORIZATION

- New Application
- Amendment to existing authorization number .....
- Renewal of Authorization number .....

PURPOSE OF APPLICATION

..... Construction (Complete Sections I through III)
..... Import/Purchase (Complete Sections I and II)
..... Use/Begin operation (Complete Section I through V)
..... You may refer to previous submissions by date and application or authorization number(s) .....

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

SECTION I
GENERAL INFORMATION

1. a. Name and Address of organization.
   b. List mailing address if different from above:
   c. Address of premises where, or from where, the work is to be carried on if different than 1a:

2. Name of the authorized representative (e.g., President) of the legal person (registrant or licensee) responsible for the sources: .....
   Telephone number ..... Facsimile ..... E-mail .....

3. Subsidiary responsible persons:

   Name of Radiation Oncologist:
   Name of Qualified Expert in Radiotherapy Physics:
   Name of Radiation Safety Officer(s): .....

Telephone number ..... Facsimile ..... E-mail .....
Details of experience/training/qualifications:

4. Proposed date of installation and/or commissioning of facilities and equipment: .....

SECTION I
GENERAL INFORMATION

1. Indicate to which IEC and ISO standards does the equipment and sources used for medical exposure conform.

2. For external beam therapy specify the following:

   a. The type of unit (accelerator, Co-60, or Cs-137) .....
   b. Name and address of the manufacturer:
      .....
      .....
      .....
   c. Name of the unit:
   d. Model:
   e. Type of the unit Stationary/Rotating
   f. Type of Gantry Stationary/Rotary
   g. Freedom of movement of the treatment table (cm):
      .....
      .....
   h. Types of source carrier or shutter:
      (exposure mechanism)
   i. Year and country of manufacture:
   j. Maximum capacity in source strength of the equipment:
   k. Activity of source/output Gy/min at isocenter.

3. For External Beam Therapy, describe the features that will be available, including:

   a. External Beam Therapy Electrical Indicator/Interlocks (treatment room door, head lock, off shield, hand control, treatment mode - Fixed/Arc/Skip/Rotation, treatment angle, source drawer or shutter, emergency stop buttons to interrupt the irradiation, head collision switch, fixed area radiation monitor).
   b. External Beam Source Head Displays (Beam "OFF" indicator, beam "ON" indicator, head lock indicator, collimator rotation indicator, off shield indicator, light field displays).

      i) performance specifications and operating and maintenance instructions,

including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;

ii) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;

c. Teletherapy Control Console Displays (beam "OFF" indicator, beam "ON" indicator, head lock indicator, off shield indicator, arm position indicator, door position indicator).

d. Teletherapy Control Console Functions (Power switch, reset switch, beam "ON" switch, beam "OFF" switch, timer switch with treatment & elapsed time displays, treatment mode selection switch - Fixed/Arc/Skip/Rotation, selection switch for clockwise & anti-clockwise rotation).

4. For brachytherapy, specify:

a. Type(s) of brachytherapy (manual, remote, low or high dose rate): .....
b. Name and Address of manufacturer/supplier of the equipment
.....
.....
.....
c. Model Nos.: .....
d. Number of Channels (remote after loading equipment) .....
e. Maximum source capacity of remote devices: .....
f. Details of radionuclides used:

Radionuclide	Physical dimension & shape of the source	Model no. and designation of the source	Total activity; per cm in case of wires or ribbons	No. of sources; total strength in case of wires or ribbons
Cobalt-60				
Caesium-137				
Iridium-192				
Any other (Specify)				

5. For remotely loaded brachytherapy sources, describe the equipment features including:

   a. Door to treatment room electrically interlocked with source movement mechanism; and
   b. Fixed area radiation monitor.

6. For manual brachytherapy, describe source handling devices that will be available including:

   a. Source storage and transport container;
   b. Source handling devices and accessories (Such as tongs, lead containers, etc.); and
   c. Radiation Protection barrier during manual source loading in patient.

7. Identify who will be authorized to perform service and maintenance on the equipment and their authorization number (3).

SECTION III
FACILITIES

Approval should be obtained from the Regulatory Authority before starting construction of the treatment rooms.

1. Provide a detailed location of the facility.

2. Describe factors such as the layout of the facility and its immediate surroundings, including:

   a. building materials;
   b. alarms;
   c. shielding; and
   d. engineering controls (mechanical interlocks, warning safety devices, emergency stop buttons inside/outside enclosure, prevention of unauthorized personnel entering area, and means of escape or communication from within enclosure).

3. Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawing any penetrations or openings in the shielding materials such as conduits or ventilation ducts.

4. Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the treatment room(s) which could be occupied. For these calculations, assume any radiation beam is oriented in the position that would result in the highest directional exposures. Include a statement of all assumptions used in the calculations.

SECTION IV
PROGRAMME FOR USE

1. ORGANIZATIONAL STRUCTURE

a. Describe your organization and management control systems including assignment of responsibilities related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the RSO, authority of the RSO to stop unsafe operations, personnel training, and maintenance of records.

b. Identify the authorized users, radiation physicist, and radiation safety officer by name and include their training, qualifications and experience. (Note: the authorized user, radiation physicist, and/or radiation safety officer may be the same individual).

c. Confirm that training will include: explanation of written procedures, use of equipment (radiation source and instrumentation), meanings of warning signals, and a method to confirm adequacy of training (Testing or demonstrations).

2. RADIATION MONITORING AND CLASSIFICATION OF AREAS

a. Describe your programme for monitoring the workplace (BSS, I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.

b. Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21-I.25).

c. Described personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36).

Denote type: Film
TLD
DRD
Other: .....

3. LOCAL RULES AND SUPERVISION

a. Describe your local rules and procedures regarding: investigation or authorized levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I-26.I.27).

b. Provide copies of your operating and safety procedures including: area access control, entry procedures, source inventory and lead testing, etc.

c. Describe your training programme to ensure all appropriate personnel are adequately trained in the operating procedures (BSS, I.27).

d. Describe your policies regarding notification by female workers of pregnancy and the instructions you will provide to female workers (BSS, I.16-I.17 and I.27).

e. Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41-I.43).

4. QUALITY ASSURANCE

a. Describe your programme to periodically review procedures, maintain procedures current and available, and your procedure modification process.
b. Describe your programme for optimizing occupational and public exposures to levels as low as reasonably achievable.

5. TRANSPORTATION OF RADIOACTIVE MATERIAL

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Series 6). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents and details of shipments preparation.

6. EMERGENCY PROCEDURES

Provide your emergency procedures to address potential emergencies such as potential damage to the source, loss of source shielding, or stuck sources, and misadministration to patients. If other emergencies are envisaged, please provide additional appropriate emergency procedures.

7. TRANSFER OR DISPOSAL OF RADIOACTIVE SOURCES

Describe arrangements for transfer or disposal of spent radioactive sources.

8. SYSTEM OF RECORDS (BSS, I.44, II.31), including:

a. Disposal of spent sources.
b. Personnel exposure
   - current records
   - prior work history
c. Area surveys
   - dose or dose rate
   - contamination
d. Instrument tests and calibrations.
e. Tests for radioactive sealed source leakage.
f. Inventory of sources and accountability.
g. Audits and reviews of radiation safety programme.
h. Incident and accident investigation reports.
i. Maintenance and repair work.

j. Facility modifications.
k. Training provided.
l. Evidence of health surveillance of workers.
m. Transportation.

9. AUTHORIZED SIGNATURE

....

Signature of authorized representative of the legal person Date

.....

Title

Notes:

1. *The Regulatory Authority may require additional information to fully consider this application prior to issuing an authorization.*

2. *In the event that all the above information is not available at the time of application, the Regulatory Authority may issue an authorization limiting the applicant to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorizing use of the radiation sources.*

3. *Medical exposure may be under the jurisdiction of a regulatory authority other than the regulatory authority responsible for occupational and public exposure. However, the authorized user should address the items in Section IV for referral to the appropriate authority.*

SECTION IV
MEDICAL EXPOSURE

1. RESPONSIBILITIES FOR MEDICAL EXPOSURE

a. Describe your arrangements to assure that patient treatment will only be prescribed by medical practitioners.
b. Describe your arrangements to assure that calibration, dosimetry and quality assurance requirements for therapy are conducted by or under the supervision of a qualified expert in radiotherapy physics.
c. Describe criteria and arrangements to ensure an adequate number of trained medical and paramedical personnel to discharge assigned tasks.

2. JUSTIFICATION OF MEDICAL EXPOSURES

a. Describe your arrangements to ensure that the therapeutic benefits will be weighted against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

b. Confirm that exposure of humans for medical research will always be in accordance with the Helsinki Declaration and will follow the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organizations.

c. Confirm that each exposure of humans for medical research is subject to the advice of an Ethical Review Committee or other similar institutional body.

3. OPTIMIZATION OF PATIENT PROTECTION

Describe your arrangements to ensure that with regard to equipment consisting of radiation generators and that containing sealed sources for medical exposures:

a. whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards;

b. performance specifications and operating and maintenance instruction, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;

c. where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles, in a major world language acceptable to the user.

4. CALIBRATION

a. Describe your systems to ensure the calibration of sources used for medical is exposure traceable to a Standards Dosimetry Laboratory.

b. Describe radiotherapy equipment calibration in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions (IAEA Technical Report Series No. 277).

c. describe procedures for calibration of sealed sources as of a reference date, for activity or at a specific distance in terms of reference air kerma in air or absorbed dose rate in a specific medium.

d. describe your programme of calibration to be carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals.

5. CLINICAL DOSIMETRY

Describe your arrangements to ensure that:

a. in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses;
b. for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;
c. in brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient;
d. in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and
e. in all radiotherapeutic treatments, the absorbed doses to relevant organs.

6. QUALITY ASSURANCE FOR MEDICAL EXPOSURE

Describe your quality assurance programme (BSS II.22) which should include:

a. Verification of the appropriate physical and clinical factors used in treatment including measurements of physical parameters at the time of commissioning and periodically thereafter;
b. Written records of relevant procedures and results;
c. Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment;
d. Verification of patient identity; and
e. Regular and independent quality audit reviews.

7. INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURE

Describe the procedures to promptly investigate any of the following incidents:

a. any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue secondary effects;
b. any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
c. any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

and, with respect to any investigation, to:

a. calculate or estimate the doses received and their distribution within the patient;
b. indicate the corrective measures required to prevent recurrence of such an incident;
c. implement all the corrective measures that are under their own responsibility;
d. submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
e. inform the patient and his or her doctor about the incident.

8. DOSE CONSTRAINTS TO COMFORTERS AND VISITORS TO PATIENTS

Describe your procedures to ensure that the dose of any comforter or visitor of patients be unlikely to exceed 5mSv during the patient's treatment.