GUIDE NO. AERB/RF/SG/G-3 (Vol. 4 of 4)

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 4)

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/RF/SG/G-3 (Vol. 4 of 4)

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 4)

Atomic Energy Regulatory Board
Mumbai-400 094
India

March 2011

Price

Order for this guide should be addressed to:

Chief Administrative Officer
Atomic Energy Regulatory Board
Niyamak Bhavan
Mumbai-400 094
India

FOREWORD

Activities concerning establishment and utilisation of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act, 1962. In pursuance of the objective of ensuring safety of members of the public and occupational workers as well as protection of the environment, the atomic energy regulatory board (AERB) has been entrusted with the responsibility of laying down safety standards and enforcing rules and regulations for such activities. The Board, therefore, has undertaken a programme of developing safety standards, codes and related guides and manuals for the purpose. While some of these documents cover aspects such as siting, design, construction, operation, quality assurance and decommissioning of nuclear and radiation facilities, other documents cover regulatory aspects of these facilities.

Safety codes and standards are formulated on the basis of nationally and internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities. Safety codes establish the objectives and set requirements that shall be fulfilled to provide adequate assurance for safety. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. The documents are revised when necessary, in the light of experience and feedback from users as well as new developments in the field.

AERB issued a safety code on 'Regulation of Nuclear and Radiation Facilities' (AERB/SC/G) to spell out the requirements/obligations to be met by a nuclear or radiation facility for the issue of regulatory Consent at every stage. This safety guide apprises the details of the regulatory requirements for setting up the radiation facility. such as consenting process, the stages requiring consent, wherever applicable documents to be submitted and the nature and extent of review. The guide also gives information on methods of review and assessment adopted by AERB.

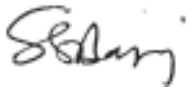
Consistent with the accepted practice, 'shall' and 'should' are used in the guide to distinguish between a firm requirement and a desirable option respectively. Appendices are an integral part of the document, whereas annexures, bibliography and list of participants are included to provide further information that might be helpful to the user. Approaches for implementation different to those set out in the guide may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public, and protection of the environment.

For aspects not covered in this guide, applicable national and international standards, codes and guides acceptable to AERB should be followed. Non-radiological aspects

such as industrial safety and environmental protection are not explicitly considered in this guide. Industrial safety shall be ensured by compliance with the applicable provisions of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996.

The guide has been prepared by AERB staff. It has been reviewed by experts and the Advisory Committee on Preparation of Code and Guides and on Governmental Organisation for Nuclear and Radiation Facilities (ACCGORN).

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft and helped in its finalisation. The list of experts, who have participated in this task, along with their affiliations, is included for information.



(S. S. Bajaj)
Chairman, AERB

DEFINITIONS

Acceptable Limits

Limits acceptable to the regulatory body for accident condition or potential exposure.

Accelerator

A device in which, charged particles are accelerated. Conventional X-ray tube is not considered as an accelerator.

Activity

The quantity 'A' for an amount of radionuclide in a given energy state at a given time, defined as:

$$A = dN/dt$$

where, 'dN' is the expectation value of the number of spontaneous nuclear transformations from the given energy state in a time interval 'dt'. The SI unit of activity is the reciprocal of second, (s^{-1}), termed the Becquerel (Bq).

Afterloading Applicator

A device applied to the patient into which radioactive sources are introduced either manually or by a remotely operated system.

Applicant

Any person who, applies to the competent authority for consent to undertake any of the actions for which the consent is required.

Approval

A type of consent issued by the regulatory body to a proposal.

Atomic Energy Regulatory Board (AERB)

A national authority designated by the Government of India having the legal authority for issuing regulatory consent for various activities related to the nuclear and radiation facility and to perform safety and regulatory functions, including their enforcement for the protection of site personnel, the public and the environment against undue radiation hazards.

Authorisation

A type of regulatory consent issued by the regulatory body for all sources, practices and uses involving radioactive materials and radiation generating equipment (see also 'Consent').

Becquerel

See 'Activity'

Betatron

An electron accelerator in which electrons are accelerated in an increasing magnetic field maintaining a stable orbit of electrons.

Commissioning

The process during which structures, systems and components of a nuclear and radiation facility, on being constructed, are made functional and verified to be in accordance with design specifications and to have met the performance criteria.

Competent Authority

Any official or authority appointed, approved or recognised by the Government of India for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

Computed Tomography

Reconstructive tomography in which image recording and processing are effected by a computing system.

Consent

It is a written permission issued to the 'consentee' by the regulatory body to perform specified activities related to nuclear and radiation facilities. The types of consents are 'licence', 'authorisation', 'registration', and 'approval' and will apply according to the category of the facility, the particular activity and radiation source involved.

Consentee

A person to whom consent is granted by the competent authority under the relevant Rules.

Construction

The process of manufacturing, testing and assembling the components of a nuclear or radiation facility, the erection of civil works and structures, the installation of components and equipment and the performance of associated tests.

Contamination

Presence of a radioactive substances in or on a material or in the human body or other place in excess of quantities specified by the competent authority.

Cyclotron

A device in which charged particles (other than electrons) travel in a succession of semicircular orbits of increasing radii under the influence of a constant magnetic field and are accelerated by traversing a number of times in an electric field produced by a high frequency generator.

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation, in

a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Decontamination

The removal or reduction of contamination by a physical or chemical means .

Disposal

The emplacement of a waste in a repository without the intention of retrieval or the approved direct discharge of waste into the environment with subsequent dispersion.

Dose

A measure of the radiation absorbed by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. The modifying terms are used when they are not necessary for defining the quantity of interest.

Dosimeter

A device, instrument or system, which can be used to measure or evaluate any quantity that can be related to the determination of either absorbed dose or equivalent dose.

Dosimetry

Measurements and/or calculations performed in connection with the determination of radiation dose and/or dose distributions in the irradiated volume.

Employer

Any person with recognised responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both a worker and employer).

Enclosed Installation

In case of industrial radiography any installation in which radiography operations are carried out in an enclosure which has walls providing adequate radiation protection to persons working outside the enclosure, and which prevents unauthorised entry of persons into the enclosure during radiography operations. Such installations may include open top installations also.

Ethical Review Committee

A committee of independent, qualified persons to advise on the conditions of exposure and the dose constraints to be observed for individuals exposed for biomedical research when there is no direct benefit to the exposed individual.

Fluoroscopy

The technique of imaging by using a fluorescent screen.

Handle

Manufacture, possess, store, use, transfer by sale or otherwise export, import, transport or dispose of.

Industrial Gamma Radiography Exposure Device (IGRED)

An assembly of components necessary to make radiographic exposures and which includes the source housing, mechanism for securing the source assembly, exposure mechanism, that includes source drive associated system, positioning devices and guide tubes.

Industrial radiography

Non-destructive testing of materials employing ionising radiation.

Ionisation

Formation of ions by the division of molecules or by the addition or removal of electrons from atoms or molecules.

Irradiation

Exposure to ionising radiation.

Irradiators

A facility that houses a particle accelerator, X-ray machine, or large radioactive sources for imparting high radiation doses to materials.

Licence

A type of regulatory consent, granted by the regulatory body for all sources, practices and uses for nuclear facilities involving the nuclear fuel cycle and also certain categories of radiation facilities. It also means authority given by the regulatory body to a person to operate the above said facilities.

Limit

The value of a parameter or attribute (which is variable) used in certain specific activities or circumstances that must not be exceeded.

Luminescence

Phenomenon in which certain substances, when excited, emit light of wavelength characteristic of the substance.

Microtron

A cyclic accelerator in which electrons are guided by a constant magnetic field in circular orbits of increasing radii, tangential to each other and accelerated at the beginning of each orbit, by traversing an electric field produced by a radio frequency generator.

Monitoring

The continuous or periodic measurement of parameters for determination , assessment in respect of structure, system or component in a facility or control of radiation.

Nuclear Medicine

The speciality that utilises radio-pharmaceuticals to investigate disorders of anatomy, physiology and patho-physiology, for diagnosis and/or treatment of diseases.

Package

The packaging with its radioactive contents as prescribed for transport.

Personnel Monitoring

Determination or estimation of the dose received by a person from external and internal radiation.

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 sources, so as to increase the exposure or the likelihood of exposure of people, or the number of people exposed.

Prescibed Limits

Limits established or accepted by the regulatory body.

Protective Barrier or Shielding (Radiation)

A barrier of appropriate thickness used to reduce radiation levels to specified values.

Protective Device

Device used for the purpose of radiological protection.

Quality Assurance

Planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service as per the design specifications.

Radiation

Gamma rays, X-rays or rays consisting of alpha particles, beta particles, neutrons, protons, and other nuclear, sub-atomic particles, but not sound or radio waves, or visible, infrared, ultraviolet light.

Radiation Facility

Any installation/equipment or a practice involving use of radiation-generating units or radioisotopes in the field of research, industry, medicine and agriculture.

Radioactive Waste

Material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen. It can be (a) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (b) exposure to which is not excluded from regulatory control .

Radioactive Waste Management Facility

Facility specifically designed to handle, treat, condition, temporarily store or permanently dispose of radioactive waste.

Radioactivity

The phenomenon whereby atoms undergo spontaneous random disintegration, usually accompanied by the emission of radiation.

Radiography (Medical)

Technique for obtaining, recording and optionally processing, directly or after transfer, information contained in an X-ray pattern at an image receptor area.

Radiography Source

A source sealed in one or more capsules, or an X-ray tube, or an electron accelerator or a neutron source used for industrial radiography.

Radiography Technician/Radiography Technologist/Radiographer

A worker, who performs radiography operations employing radiography sources and possesses a valid qualification, duly recognised by the competent authority for the specific purpose.

Radiological Safety Officer (or Radiation Safety Officer)

Any person who is so designated by the employer and who, in the opinion of the competent authority, is qualified to discharge the functions outlined in the Atomic Energy(Radiation Protection)Rules, 2004.

Radiotherapy/Radiation Therapy

Medical treatment by ionising radiation.

Registration

A type of regulatory consent issued by the regulatory body for all sources, practices and uses involving radioactive materials and radiation generating equipment.

Regulatory Body

See ‘Atomic Energy Regulatory Board’

Safety Assessment

Review of the aspects of design and operation of a source, which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

Safety Site-in-charge

A person who has the qualifications and training prescribed for Level 2 radiological safety officer and who is appointed by the 'consentee' as the person supervising industrial radiography operations at an authorised radiography site with approval of the competent authority.

Sealed Source

Radioactive source material that is (a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, as also under foreseeable mishaps.

Source

Any thing that causes radiation exposure, either by emitting ionising radiation or releasing radioactive substances or materials.

Source Changer

A device for transferring radiography sources from or to exposure device, and suitable for transport and storage of the source.

Source Housing

Shielding provided in any device containing a sealed source, in order to:

(i) define the useful beam; and

(ii) limit the radiation level outside of the useful beam to maximum permissible leakage levels, as specified by the competent authority.

Synchrotron

Particle accelerator in which charged particles travel in circular orbits of constant radius guided by an increasing magnetic field and accelerated by traversing a number of times an electric field produced by a high frequency generator in synchronism with the orbital motion.

Teletherapy

Treatment with external radiation beam(s) where the distance from source to skin is greater than 5 cm.

Tomography

Radiography of one or more sections/layers within an object.

Treatment Planning (Radiotherapy)

Planning of the techniques for radiation therapy, which may include treatment simulation and dosimetry.

Treatment Simulation

Methods by which the techniques and patient positioning for radiotherapy are simulated without delivering the therapy dose.

Type Approval

Approval, issued by the competent authority, based on evaluation of the device to ensure that it conforms to safety standards.

Type A package

A Package designed to withstand normal conditions of transport without loss or dispersal of its contents or loss of shielding integrity. The radioactive material may be transported in a Type A package, either in special form radioactive material or other form, with the provision that the activity shall not exceed the applicable limits prescribed in the relevant code on 'Transport of Radioactive Materials'.

Type B(U) package

A package designed to contain an activity in excess of A_1, if special form radioactive material, or in excess of A_2 if not special form radioactive material, that is designed to withstand normal and accidental conditions of transport specified in the relevant code on 'Transport of Radioactive Materials'.

Unusual Occurrence

Any occurrence which has the potential to impair or impairs the plant safety, radiological safety, industrial safety and/or environmental safety.

SPECIAL DEFINITIONS
(Specific for the Present Guide)

Consumer Product

A manufactured product or item containing radioactive substance, which is exempted from regulatory control.

Field Radiography

Radiography operations carried out on shop floors, erection sites or other such areas with provisions for adequate radiological safety for the radiography personnel and others including members of the public.

Person

Any individual, or a company, or association, or body of individuals, whether incorporated or not; or central government or a state government.

Worker

Any person who works, whether full-time, part-time or temporarily, for an employer and who has recognised rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker).

X-ray Equipment

Equipment consisting of combination of an X-ray generator, X-ray tube and associated equipment.

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ANNEXURE-36
(Refer section 3.11.2)

Form ID. AERB/RSD/CP- MANUF/AUTH

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR AUTHORISATION FOR PROCUREMENT AND USE OF THORIUM NITRATE FOR MANUFACTURE OF CONSUMER PRODUCT (GAS MANTLES)

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004) [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents*
(c)	*This form is intended to enable AERB to assess the suitability of the institution for procurement and use of radiation sources, (hereinafter referred to as 'source')*
(d)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(e)	*All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*
(f)	*Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the Institution:

Telephone No (O):
Fax No.
E-mail
Institution personnel monitoring service (PMS)number

A.2 Name, designation and address of the Head of the Institution[$] :

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Name and designation of the Radiological Safety Officer (RSO)* :

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail
RSO Approval reference no. :
Valid up to :

A.5 Address for correspondence with PIN code:

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*Applicant is the person in whose name Authorisation to handle the radiation generating equipment may be issued, under Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004], would have the responsibilities of **'licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution*

$ *The head of the institution is the person who would have the responsibilities of '**employer**' prescribed in AE(RP)R, 2004.*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of **'Radiological Safety Officer'** prescribed in AE(RP)R, 2004.*

PART B

DETAILS OF THE PROPOSED FACILITY

B.1 Purpose for the procurement of Thorium Nitrate:

B.2 Storage room for Thorium Nitrate

(i) Thorium nitrate is stored in an exclusive room: Yes/No

If yes; exclusive room is made of : Concrete/brick/steel/wooden material

(ii) Maximum amount of thorium proposed to be stored : ———————— /kg

B.3 Handling of Thorium Nitrate

(i) Whether any personnel protection measures adopted to avoid dust and inhalation of thorium powder during handling. : Yes/No

(ii) If yes; measures adopted to be listed : • Use of gas mask/cloth/ gloves/gum boots
• Any other measures

B.4 Handling area

(i) Condition of the floor : Smooth/rough/lined with glazed tiles

(ii) Drainage is connected to the main sewage.

(iii) If No, details of alternate measures to be mentioned : Yes/No

(iv) Number of exhaust fans installed : ————————————

(v) Number of exhaust fans in working condition : ————————————

(vi) Whether masks are used during the entire manufacturing process : Yes/No

B.5 Status of manpower/trained personnel

Name of employee	Gender	Age	Educational qualifications	Working experience	Type of work assigned

B.6 Documents to be attached with the Application:

(i) Lay-out plan of the production unit/factory indicating clearly the dimensions in scale (1:100) and the various operations carried out in the factory.

(ii) Proof from local state govt. authorities that the land/plot for installation of facility is in the name of the applicant.

(iii) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/ SG-1)-under preparation.

(iv) NOC from other statutory bodies including local municipality.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iv) the facility shall not be transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(v) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(vi) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as and when required by the competent authority will be duly carried out at my/our expense.

(vii) any female worker on informing me/us that she is pregnant, I/we will modify her working conditions, as necessary.

(viii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) duly qualified/experienced radiological safety officers/ operators, will be appointed if felt necessary in the opinion of the competent authority, before the commencement of the manufacturing facility.

(x) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xi) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place:

Date:

Signature:

Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-37
(Refer section 3.12.2)

Form ID. AERB/RSD/WL/PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NOC FOR IMPORT/CONSENT FOR PROCUREMENT OF SEALED RADIATION SOURCES FOR WELL LOGGING OPERATIONS

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004) [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected*
(d)	*All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*
(e)	*Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name the no objection certificate to import/ procure the source may be issued, under AE(RP)R, 2004, and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE DEVICE

B.1	Particulars of Radiation Source(s) :	
B.1.1	Purpose of the radiation source(s)	
B.1.2	Name of source(s)/neutron generators*	
B.1.3	Maximum activity Bq (Ci)	
B.1.3.1	Number of source(s)/neutron generators	
B.1.4	Serial number of each source/neutron generators	
B.1.5	Name and address of manufacturer of radiation source(s)/neutron generator(s): Telephone No. Fax No. Mobile No. E-mail	

B.1.6	Name and address of the supplier of radiation source(s)/neutron generator(s): Telephone No. Fax No. Mobile No. E-mail	
B.1.7	Sealed source classification no. (As per relevant national/ international standards)	
B. 1.8	*In case of portable neutron generator, give details of type approval from country of origin	
B.1.9	Whether a copy of the undertaking furnished by the supplier of the source to take back the disused/ cannot decayed source is attached ?	Yes/No [In the absence of such undertaking, authorisation be issued.]

B.2 Particulars of radiation sources already in the possession of the institution (attach additional sheets if necessary)

S. No.	**Description, make, model and S. No. of source/ Neutron generator**	**Activity of the source Bq (Ci)**	**Number of sources/ Neutron generators**	**Purpose/ Application of radiation source**	**Present location**	**Ref. No. and date of authorisation issued by AERB.**

B.3 Details of training and experience, if any, of your staff members in radiation safety aspects of nucleonic gauges (attach additional sheets if necessary)

Name/s	1 2
Designation	1 2

Academic qualifications	1 2
Training course on radiation safety aspects, if any	1 2
Year of passing	1 2
Experience (radiation sources used)	1 2
Whether the person undergone training on radiation safety aspects has obtained the radiological safety officer (RSO) approval from AERB	If yes, then furnish the following details : 1. Approval ref. No. : 2. Date of issuance : 3. Approval valid till:
	If No. The institution should nominate the person who has successfully completed the training course on 'Radiation Safety Aspects of Nucleonic Gauges' for RSO approval to AERB.

B.3.1 If there is no individual in your institution with the prescribed qualification, please furnish the following undertaking. (Please delete the following undertaking, if not applicable)

I hereby undertake to

(a) get one of our personnel trained on radiological safety aspects in nucleonic gauges before the procurement of the radiation sources, and

(b) obtain RSO approval from AERB, before taking up handling of radiation sources.

Signature of applicant

(Seal of institution)

B.4 Particulars related to the facility where the well logging source(s) are proposed to be handled

(a) Layout of the installation, if applicable

(b) Details of facilities for storage of radiation sources

(c) Details regarding the mode of transport from the storage room to the site(s) of use

B.5 Whether a radiation survey meter (RSM) is available in working condition: Yes / No

B.5.1 If 'Yes' (Please furnish the following particulars relating to RSMs)

Particulars	1	2	3
Make and type			
Model			
RSM S. No.			
Date of recent calibration			
Functional status			

B.5.2 If 'No', please furnish an undertaking as given below. (Please delete the following undertaking, if a monitoring instrument is available.)

I hereby undertake to procure a suitable radiation survey meter before the procurement of the radiation source for which this application is being made.

Signature of applicant

(Seal of institution)

B.6 Additional information, if any:

B.7 Documents to be attached with the application:

(i) Layout plan of the source storage facility indicating the occupancies in the immediate vicinity.

(ii) Copy of certificate for design approval of sealed source (including serial No.), classification and leak test certificates as per applicable national /international standard.

(iii) Copy of the letter awarding the contract for well logging operation from contract awarding party, in case of new contractor and new site.

(iv) Copy of the document of the institution registration with the local/ state/central government authorities, in case of new institution.

(v) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/ SG-1) and AERB safety guide on 'Security of Radioative Material during Transport' (AERB/NRF-TS/SG-10).

(vi) Copy of the undertaking furnished by the supplier of the source to take back the disused/decayed source.

(vii) Nomination of personnel in the standard format of application form for training in radiation safety aspects of nucleonic gauges (in case the personnel trained in radiation safety is not available)

(viii) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) no procurement shall be made prior to receipt of approval from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the well logging operations shall be commenced only after obtaining authorisation from the competent authority.

(vi) the radiation source(s) shall be stored and safeguarded so as to prevent unauthorised access, operation, removal and theft.

(vii) the handling of the radiation source would be done by authorized and/trained persons.

(viii) the details regarding radiation source(s) shall be furnished to the competent authority after receiving the radiation source(s).

(ix) the radiation source(s) shall be put into use only after obtaining registration from the competent authority.

(x) the radiation source(s) shall not be transferred/sold/ rented by me/us to another user without the prior permission from the competent authority.

(xi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the facility at any time.

(xii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(xiii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(xiv) the decayed/unused radiation sources shall be returned to the original supplier.

(xv) duly approved radiological safety officers will be appointed before the use of radiation source.

(xvi) the procedures approved by AERB regarding decommissioning and reuse of the site will be strictly complied with.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-38

(Refer section 3.12.3)

Form ID. AERB/RSD/WL/ACO

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR AUTHORISATION FOR COMMISSIONING/ OPERATION OF WELL LOGGING ACTIVITIES INVOLVING RADIATION SOURCES

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004) [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected*
(d)	*All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*
(e)	*Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name authorisation for use of the device may be issued, under AE(RP)R, 2004, would have the responsibilities of **'licensee/consentee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of **'employer'** prescribed in AE(RP)R, 2004.*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of **'Radiological Safety Officer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF WELL-LOGGING OPERATIONS

B.1 This application is for:

First time authorisation			
Renewal of authorisation	Ref No.:	Date:	Valid till:

B.2	Particulars of the well logging sources	
B.2.1	Purpose of the radiation source(s)	
B.2.2	Name of radiation source(s)/neutron generator	
B.2.3	In case of neutron generator, give details of type approval from country of origin	

B.2.4	Number of radiation sources/neutron generators	
B.2.5	Maximum activity Bq (Ci)	
B.2.6	Serial number of each source/generator	
B.2.7	Classification of the sealed source(s); if not submitted earlier: (as per relevant national/international standards)	
B.2.8	Name and address of manufacturer of radiation source/neutron generator Telephone No. Fax No. Mobile No. E-mail	
B.2.9	Name and address of the supplier of radiation source/neutron generator Telephone No. Fax No. Mobile No. E-mail	

B.3 Details of Radiological Safety Officer(s) (attach additional sheets if necessary)

Name	1 2
Designation	1 2
Year of passing the training course on radiation safety aspects of NG	1 2
RSO approval Ref. No. : Date of issue : Approval valid till:	1 2

B.4 Particulars of the radiation survey meters (RSM)

Particulars of RSM	1	2	3
Make and type			
Model			
RSM S. No.			
Date of recent calibration			
Functional status			

B.5 Availability of personnel monitoring services (PMS) : Yes/No

B.5.1 Institution PMS number:

B 5.2 No. of personnel availing PMS:

B.6 Additional information, if any:

B.7 Documents to be attached with the Application

(i) Report indicating the stray radiation levels at accessible locations around the source handling/storage facility.

(ii) Copy of certificate for design approval of sealed source (including serial No.), classification and leak test certificates as per applicable national /international standard in case not attached at the time of procurement.

(iii) Copy of Type Approval certificate for neutron generator from country of origin of design if applicable.

(iv) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/SG-1) and AERB safety guide on 'Security of Radioative Material during Transport' (AERB/NRF-TS/SG-10) in case not attached at the time of procurement.

(v) Emergency response plan and preparedness.

(vi) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for the purpose other than those specified in his form.

(iii) the radiation sources(s) shall be used only after obtaining Authorisation from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the radiation source(s) shall be stored, installed and safeguarded so as to prevent unauthorised operation, removal and theft.

(vi) the radiation source would be handled by authorized and trained persons.

(vii) the device shall not be transferred/sold/ rented by me/us to another user without the prior permission from the competent authority.

(viii) the log book pertaining to the radiation source(s) movements from permanent storage facility to different work sites shall be maintained.

(ix) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the facility at any time.

(x) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(xi) all recommendations made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(xii) the periodic status report of all sources in the possession of the institution shall be submitted to AERB.

(xiii) all the radiation survey meters/safety instruments will be maintained in functional condition all the time and will be calibrated periodically.

(xiv) servicing/maintenance and repair of the well logging tools containing radiation sources shall be carried out in the presence of radiological safety officer (RSO) and log-book in this respect would be maintained.

(xv) the decayed/unused radiation sources shall be returned to the original supplier.

(xvi) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xvii) any incident/accident such as fire, theft, damage, stuck of well logging tool inside the well etc., involving radiation source shall be promptly reported to AERB.

(xviii) an emergency response manual prescribing specific action plans to identified persons for specific emergency scenarios shall be prepared and periodically updated.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place:

Date:

Signature:

Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-39

(Refer section 3.13.1.2)

Form ID: AERB/RSD/MDX/SLA&PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR SITE AND LAYOUT PLAN APPROVAL AND PROCUREMENT OF DIAGNOSTIC X-RAY EQUIPMENT [RADIOGRAPHY/RADIOGRAPHY AND FLUROSCOPY (R&F)/ ORTHO- PAN-TOMOGRAPHY (OPG)/MAMMOGRAPHY/ BONE DENSITOMETER, ETC.]

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004..*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division, (RSD) AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(e) *Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No. (O):
Fax No.
E-mail

A.2 Name, designation and address of the Head of the institution[$]

Telephone No. (O): (R)
Fax No.

Mobile No.
E-mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name the relevant consent may be issued, under AE(RP)R, 2004, and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE PROPOSED FACILITY

B.1 Purpose of the facility:

B.2 Whether the layout approval is for: New/modified facility

B.3 Address of the proposed X-ray installation:

B.4 Details of the X-ray unit to be installed:

(i) Proposed date of installation:

(ii) Type of X-ray unit: Radiography/ R&F/OPG /mammography/bone densitometer

(iii) Model name :

(iv) Make:

(v) NOC/Type Approval No.:

(vi) Maximum operating potential:

(vii) Maximum operating current:

B.5 Name and address of the supplier:

B.6 Name and address of the manufacturer:

B.7 Details of existing X-ray units in the facility

(a) Date and year of installation:

(b) Whether the equipment has been registered: (Yes / No)
(If No, please attach application for layout approval/ registration, as appropriate)

B.8 Documents to be attached with the Application:

(i) Copy of the NOC/Type Approval certificate for the unit, as applicable.

(ii) In case of NOC, an undertaking from the supplier that they shall not supply the unit to any other institution till the unit is type approved by AERB.

(iii) Two duly signed and stamped copies of the layout plan (scale 1:50) indicating the location of the X-ray unit, mobile protective barrier, control panel/control room, chest stand, windows, doors with appropriate lead lining, wall thickness, dimensions and material of the walls are enclosed.

(iv) Two duly signed and stamped copies of the floor plan (scale 1:100) indicating the location of the X-ray rooms, waiting area etc. are enclosed.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) site and layout activities shall be taken only after receipt of approval from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the facility shall not be transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) the facility shall be put into operation only after obtaining registration from the competent authority.

(ix) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(x) duly qualified and trained manpower (including Radiological Safety Officer, shall be appointed before the commencement of operation of the facility.

(xi) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/ we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

(To be filled by the manufacturer/supplier)

Our company will supply a unit, which is having a valid NOC/type-approval certificate from AERB. After installation of the said unit, its performance/acceptance test will be

demonstrated to the AERB and/or user’s representative as the case may be.

Place:	Signature of the Service Engineer
Date:	Name:
	Designation:
	Company:

(Seal of the company)

ANNEXURE-40

(Refer section 3.13.1.3)

Form ID: AERB/RSD/MDX/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR REGISTRATION OF DIAGNOSTIC X-RAY EQUIPMENT [RADIOGRAPHY/RADIOGRAPHY AND FLUROSCOPY (R&F)/ORTHO-PAN-TOMOGRAPHY (OPG)/MAMMOGRAPHY/ sBONE DENSITOMETER, ETC.]

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *This form is intended to enable AERB to assess the suitability of the institution for commissioning and operation of radiation generating equipment (hereinafter referred to as 'source')*

(c) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(d) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(e) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(f) *Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No. (O):
Fax No.
E-mail
Institution personnel monitoring number

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.

A.5 Name and designation of the Radiological Safety Officer (RSO)* :

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail
RSO Approval reference No.:
Valid up to

[#] *Applicant is the person in whose name Registration for use of the equipment may be issued, under AE(RP)R, 2004, would have the responsibilities of* ***'licensee'*** *prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '****employer'*** *prescribed in AE(RP)R, 2004.*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of 'Radiological Safety Officer' prescribed in AE(RP)R, 2004.*

PART B

DETAILS OF THE EQUIPMENT

B.1 Type of Equipment

(i) Radiography (fixed)

(ii) Radiography (mobile)

(iii) Radiography and Fluroscopy combined: (conventional/with image intensifier tube)

(iv) Dental

(v) Mammography

(vi) C-arm

(vii) Bone densitometer

(viii) Others (specify)

B.2 Details of equipment:

(i) Manufacturer of the equipment:

(ii) Supplier of the equipment:

(iii) Model name:

(iv) AERB Type Approval No.:

(v) Maximum rated operating potential (kV):

(vi) Maximum rated current (mA):

(vii) Date of installation:

B.3 Workload

Type of examination and projections	**No. of patients/day**	**mA**	**kV**
Chest			
Abdomen			
Extremities			
Skull			
Any other examination (spinal etc.)			
Special procedures			

B.4 Availability of radiation measuring and monitoring instruments and radiation protection accessories

(a) Mobile protective barrier Yes/No

(b) Lead apron Yes/No

(c) Personnel monitoring badges (TLD) Yes/No

(d) Quality assurance kit: Yes/No

(e) X-ray installation plan approval status: Yes/No

(f) Red light, X-ray caution symbol and warning placards: Yes/No

B.5 Staff details

Name	Designation	Academic/ Professional qualifications	Experience in the field	Personnel monitoring (PMS) No.	Full-time/ Part-time

B.6 Documents to be attached with the Application:

(i) Test report containing quality assurance checks as per **Appendix-8C-II** or **Appendix-8C-III** (as appropriate).

(ii) Copy of layout approval certificate along with approved plan.

(iii) Proof from local state govt. authorities that the land/plot for installation of facility is in the name of the applicant.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the equipment shall be put into operation only after obtaining Registration certificate from the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) all provisions of AERB Safety Code on 'Medical Diagnostic X-ray Equipment and Installations', [AERB/SC/MED-2 (Rev. 1)] or the revised version thereof currently in force shall be complied with.

(vi) the equipment shall be stored, installed and safeguarded so as to prevent unauthorised access, operation, removal and theft.

(vii) The installation/maintenance of the equipment would be done by authorised and trained persons.

(viii) the equipment shall not be transferred/sold/ rented by me/us to another user without the prior permission from the competent authority.

(ix) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the equipment at any time.

(x) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(xi) all recommendations made from time to time by the competent authority in respect of radiation safety measures will be duly implemented.

(xii) all the radiation survey meters/safety instruments will be maintained and regularly sent for calibration.

(xiii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation

(Seal of the institution)

(To be filled by the manufacturer/supplier)

Our company has supplied a _____ unit, which is a type-approved unit. I have installed the said unit, and demonstrated its performance/acceptance test to the user's representative. I hereby undertake that the unit satisfy all the test results as per our company's protocol and are at par with the test results carried out during type-approval of the said unit.

Place: Signature of the Service Engineer

Date: Name :

Designation:

Company:

(Seal of the company)

ANNEXURE-41

(Refer section 3.15.2)

Form ID. AERB/RSD/NG/PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NOC FOR IMPORT/CONSENT FOR PROCUREMENT OF IONISING RADIATION GAUGING DEVICES (IRGDs)/NUCLEONIC GAUGES (NGs) CONTAINING RADIOACTIVE SOURCES

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*
(b)	*This form is intended to enable AERB to assess the suitability of the institution for procurement and use of radiation sources, which includes radiation generating equipment (hereinafter referred to as 'source')*
(c)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents*
(d)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(e)	*All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*
(f)	*Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name the No Objection Certificate (NOC) to import/procure the source may be issued, under AE(RP)R, 2004, and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE DEVICE

B.1	Particulars of new IRGD/NG	
B.1.1	Purpose of the IRGD/NG	
B.1.2	Unit model and serial number	
B.1.3	Name of source(s)	
B.1.4	Maximum activity Bq (Ci)	
B.1.5	Number of IRGD/nucleonic gauges	
B.1.6	Name and address of manufacturer of IRGD/nucleonic gauge(s): Telephone No. Fax No. Mobile No. E-mail	

B.1.7	Reference of AERB Type Approval certificate for the IRGD/ nucleonic gauge(s) :	
B.1.8	Name and address of the supplier of sealed source(s): Telephone No. Fax No. Mobile No. E-mail	
B.1.9	Sealed source classification no.: (as per relevant national/international standards)	
B.1.9.1	Whether a copy of the undertaking furnished by the supplier of the source to take back the disused/decayed source is attached:	Yes/No
B.1.9.2	If the source will be used as a replacement source in the existing gauge	Yes/No
B.1.9.3	If yes, whether permission for disposal has been obtained from AERB	Yes/No
B.1.9.4	If yes, reference number of AERB permission for disposal	
B.1.10	Name and address of the local vendor agency, if any: Telephone No. (O): Fax No. Mobile No. E-mail	

B.2 Particulars of nucleonic devices already in the possession of the institution (attach additional sheets if necessary)

S. No.	Description, make model No. and s. No. of nucleonic devices	Activity of the source Bq (Ci)	Number of IRGD/ NG	Purpose/ Application of nucleonic devices and its status	Installation location	Ref No. and date of authorisation issued by AERB

B.3 Details of training and experience, if any, of your staff members in radiation safety aspects of nucleonic gauge. (attach additional sheets if necessary)

B.3.1 For trained personnel

Name(s)	
Designation	
Academic qualifications	
Training course on radiation safety aspects of NG, if any	
Year of passing	
Experience (Nucleonic device/ radiation sources used)	
Whether the person who has undergone training on radiation safety aspects has obtained the radiological safety officer (RSO) approval from AERB	If yes, then furnish the following details: (i) Approval ref. No. : (ii) Date of issue : (iii) Approval valid till:
	If No. The institution should nominate the person who has successfully completed the training course on 'Radiation Safety Aspects of Nucleonic Gauges' for RSO approval to AERB.

B.3.2 For untrained personnel

If there is no individual in your institution who has undergone the required training to qualify for RSO, please furnish the following undertaking. *(Please delete the following undertaking, if not applicable).*

I hereby undertake to

(a) get one of our personnel trained on radiation safety aspects of nucleonic gauges before the procurement of the IRGD/NG radiation sources, and

(b) obtain RSO approval from AERB, before taking up handling of IRGD/NG radiation sources.

Signature of applicant

(Seal of institution)

B.4 Particular related to the facility where the nucleonic device proposed to be handled

(a) Layout of the installation

(b) Details of facilities for storage of nucleonic devices before installation after use of decayed souces.

(c) The height at which the nucleonic gauge shall be installed, in the case of fixed nucleonic devices.

(d) Details regarding the storage room and the mode of transport from the storage room to the site(s) of use, in the case of portable nucleonic devices.

B.5 Whether a radiation survey meter (RSM) is available in working condition: Yes/No

B.5.1 If 'Yes' *(Please furnish the following particulars relating to RSM)*

Particulars of Monitor	**1**	**2**	**3**
Type of monitor			
Make			
Model			
S. No.			
Date of recent calibration			
Functional status			

B.5.2 If 'No', please furnish an undertaking as given below.

(Please delete the following undertaking, if a monitoring instrument is available.)

I hereby undertake to procure a suitable radiation survey meter before the procurement of the IRGD/NG/radiation source for which this application is being made.

Signature of applicant

(Seal of institution)

B.6 Additional information, if any.

B.7 Documents to be attached with the Application:

(i) Sketch of the installation indicating the exact location of the IRGD/ nucleonic gauge including the occupancies in the immediate vicinity and layout of storage room in case of portable nucleonic devices.

(ii) Copy of certificate for design approval of sealed source (including serial No), classification and leak test certificates as per applicable national/international standard.

(iii) Copy of AERB Type Approval certificate for the IRGD/nucleonic gauge(s).

(iv) Copy of document of the institution registration with the local/ state/ central government authorities.

(v) Nomination of personnel in the standard format of application form for training in radiation safety aspects of nucleonic gauges (in case the personnel trained in radiation safety are not available).

(vi) Security Plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/ SG-1).

(vii) A copy of the undertaking furnished by the supplier of the source to take back the disused/decayed source.

(viii) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified under item of this form.

(iii) the import/procurement of the device shall be done only after receipt of NOC/Consent from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the device shall be stored, installed and safeguarded so as to prevent unauthorised operation, removal and theft.

(vi) the installation/maintenance of the unit containing radiation source would be done by qualified/trained persons.

(vii) the device shall be put into operation only after obtaining Registration certificate from the competent authority.

(viii) the device shall not be transferred/sold/ rented by me/us to another user without the prior permission from the competent authority.

(ix) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the device at any time.

(x) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(xi) all recommendations made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(xii) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xiii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of institution:

Designation:

(Seal of the institution)

ANNEXURE-42
(Refer section 3.15.2)

Form ID. AERB/RSD/NG/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR REGISTRATION OF IONISING RADIATION GAUGING DEVICES (IRGDs)/NUCLEONIC GAUGE(S) (NGs) CONTAINING RADIOACTIVE SOURCES

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.

(c) Incomplete applications and those without all relevant documents are liable to be rejected.

(d) All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in

(e) Attach extra sheets wherever required.

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No. (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name Registration for use of the device may be issued, under AE(RP)R, 2004, would have the responsibilities of* ***'licensee/consentee'*** *prescribed in AE(RP)R, 2004 and should be a full time employee of the institution*

[$] *The head of the institution is the person who would have the responsibilities of '****employer'*** *prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE IRGD/NUCLEONIC GAUGING DEVICE(S)

B.1 This application is for:

First time Registration			
Renewal of Registration	Ref No.:	Date:	Valid till:

B.2	Particulars of IRGD/NG	
B.2.1	Purpose of the nucleonic device	
B.2.2	Unit make, model and serial number(s)	
B.2.3	Name of source(s)	
B.2.4	Maximum activity Bq (Ci)	
B.2.4.1	Quantity of source(s) and device(s):	
B.2.4.2	S. No(s). of the sources	
B.2.4.3	Classification of the sealed source(s) if not submitted earlier : (as per relevant national/ international standards)	

B.2.4.4	Classification of the IRGD/NG, if not submitted earlier: (as per relevant national/international standards)	
B.2.4.5	Name and address of the supplier of source(s) : Telephone No. Fax No. Mobile No. E-mail	
B.2.5	Name and address of the local vendor agency if any: Telephone No. (O): Fax No. Mobile No. E-mail	

B.3 Details of Radiological Safety Officer(s): (attach additional sheets if necessary)

Name(s)	
Designation	
Year of passing of radiation safety training course	
Approval ref. No. : Date of issue : Approval valid till:	

B.4 Particulars of the radiation monitoring and measuring instruments:

Particulars of monitor	**1**	**2**	**3**
Type of monitor			
Make			
Model			
S. No.			
Date of recent calibration			
Functional status			

B.5 Availability of personnel monitoring services (PMS), (as applicable):

B.5.1 No. of personnel availing PMS:

B.5.2 Institution PMS number:

B.6 Additional Information, if any:

B.7 Documents to be attached with the Application

(i) Layout of installation of IGRD/NG and storage room, if any.

(ii) Installation report by manufacturer/supplier, indicating the stray radiation levels at accessible locations around the IRGD/nucleonic gauge with source on and off condition.

(iii) Copy of certificate for design approval of sealed source (including serial No), classification and leak test certificates as per applicable national /international standard, in case not attached at the time of procurement.

(iv) Security Plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/SG-1 (under preparation) and AERB safety guide on 'Security of Radioactive Material during Transport' (AERB/NRF-TS/SG-10) in case not attached at the time of procurement

(v) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified under item of this form.

(iii) the device shall be put into operation only after obtaining Registration from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the device shall be stored, installed and safeguarded so as to prevent unauthorised operation, removal and theft.

(vi) the device containing radiation source would be installed/maintained by qualified/trained persons.

(vii) the device shall not be transferred/sold/rented by me/us to another user without the prior permission from the competent authority.

(viii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the device at any time.

(ix) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(x) all recommendations made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(xi) the periodic safety status report of all devices in the possession of the institution shall be submitted to AERB.

(xii) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xiii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source and/or IRGD/NG shall be promptly reported to AERB.

(xiv) an emergency response manual prescribing specific action plans to identified persons for specific emergency scenarios shall be prepared and periodically updated.

(xv) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-43a

(Refer section 3.16.2.2)

Form ID: AERB/RSD/RL/L&CA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR LAYOUT PLAN AND CONSTRUCTION APPROVAL FOR RESEARCH LABORATORIES HANDLING RADIOISOTOPES

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(e) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
Mobile No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

[#] *Applicant is the person in whose name the consent to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of '**licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE FACILITY

B.1 Purpose of the facility

B.2 Type of location of the proposed facility:
(Non residential building/part of research unit/educational institution)

B.3 Details of the studies in which radioisotopes are used:

B.4 List of radioactive sources with activity proposed to be handled:

B.5 Documents to be attached with the application:

(i) Proof from local state govt. authorities that the land/plot for installation of facility is in the name of the applicant.

(ii) Location drawing of facility indicating the floor and peripheral occupancies.

(iii) Layout plan of the facility (with dimensions on B3 size paper, i.e. 353 X 500mm^2) clearly indicating different rooms, location of doors, windows and exhaust if any, location of work table, sink, fumehood, radioactive source and waste storage (should be submitted in duplicate), and thickness and material of the walls, floors and ceiling of the facility.

(iv) Any other supporting documents.

PART C

UNDERTAKING

I/ we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified under item of this form.

(iii) layout and construction activities shall be carried out only on obtaining approval from the competent authority;

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the facility shall not be transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical protection measures will be duly implemented.

(ix) duly qualified/experienced radiological safety officer(s)/operator(s), will be appointed before the commencement of operation of the facility.

(x) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xi) AERB will be informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-43b

(Refer section 3.16.2.2)

Form ID: AERB/RSD/RL/PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR PROCUREMENT OF RADIOISOTOPES FOR RESEARCH LABORATORIES HANDLING RADIOISOTOPES

(a) *This application would be considered by the competent authority for issuance of permission for procurement of radioisotopes for the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *All the forms pertaining this facility can be downloaded from the website www.aerb.gov.in*

(e) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Institution personnel monitoring No:
Fax No.
Mobile No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O) (R)
Fax No.
Mobile No.
E-mail

A.4 Layout approval of the facility: (Give AERB reference no.)

A.5 Name and designation of the Radiological Safety Officer (RSO)*:

Telephone No. (O) (R):
RSO certificate approval reference No:
Validity:

[#] *Applicant is the person in whose name the consent to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of* ***'licensee'*** *prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '****employer'*** *prescribed in AE(RP)R, 2004*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of 'Radiological Safety Officer' prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF RADIOACTIVE SOURCES

B.1 Purpose for procurement:

B.2 Details of radioisotopes

S. No.	Radioiso-tope	Radio-chemical	Specific purpose	Maximum activity proposed to be procured from BRIT** with periodicity	Maximum activity proposed to be imported with periodicity

** Please specify the name of the BRIT unit from where radiochemicals will be procured

B.2 Name, qualification and experience of personnel

S. No.	Name of the user	Academic qualification	Radiological safety training details	Personnel monitoring service No.	Authorisation reference No.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my/our knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the sources shall be procured only after obtaining approval from the competent authority.

(iv) the sources shall be used only after obtaining Authorisation for commissioning and operation of the facility from the competent authority.

(v) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(vi) the sources shall be handled by authorised and trained persons.

(vii) the sources shall not be transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(viii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the facility at any time.

(ix) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by AERB will be duly carried out at my/our expense.

(x) the periodic status report of radiation safety of the facility shall be submitted to AERB.

(xi) all the radiation survey meters/safety instruments will be maintained in functional condition all the time and will be calibrated periodically.

(xii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(xiii) duly qualified/experienced radiological safety officer(s)/operator(s) shall be appointed prior to the procurement of the sources.

(xiv) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xv) the decayed/unused radiation sources shall be disposed safely as per procedures approved by AERB.

(xvi) AERB will be informed about the absence of any qualified manpower immediately.

(xvii) any incident/accident such as fire, theft, damage etc., involving radioactive sources shall be promptly reported to AERB.

(xviii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of the Head of institution:

(Seal of the institution)

ANNEXURE-44
(Refer section 3.16.2)

Form ID: AERB/RSD/RL/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR REGISTRATION OF RESEARCH LABORATORIES HANDLING RADIOISOTOPES (COMMISSIONING AND OPERATION)

(a) *This application would be considered by the competent authority for issuance of relevant consent for the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with necessary documents*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected*

(d) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(e) *Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
Mobile No.
E-mail

A.2 Name and address of the Head of the institutions[$]:

Telephone No. (O) (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O) (R):
Fax No.
Mobile No.
E-mail

A.4 Name and designation of the Radiological Safety Officer (RSO)*:

Telephone No. (O) (R):
RSO certificate approval reference No
Validity:

[#] *Applicant is the person in whose name the authorisation (licence) to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of **'licensee'** prescribed in Atomic Energy (Radiation Protection)Rules, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of **'employer'** prescribed in Atomic Energy (Radiation Protection)Rules, 2004*

***** *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of **'Radiological Safety Officer'** prescribed in Atomic Energy (Radiation Protection)Rules, 2004.*

PART B

PARTICULARS OF THE FACILITY

B.1 This application is for

First regulatory licence			
Renewal	Ref No.	Date:	Valid till:

B.2 Details of proposed radioactive sources to be used

S. No.	Radioisotope	Radiochemical	Maximum proposed activity to be procured from BRIT per week	Maximum proposed activity to be imported per week

B.3 List of sealed source(s) if any (to be used for calibration) used in the facility with the radionuclide, activity, date of procurement, purpose and supplier/ manufacturer details.

B.4 Equipments details

B.4.1 Counting equipment

Name of the equipment	Make and model	Date of installation	Working (Yes/No)

B.4.2 Monitoring and Measuring Instruments

Name of the instrument	Make, model and serial No.	Measurement range	Working status	Date of last calibration

B.5 Handling and General Facilities

Fume hoods (F.H.)	No. of functioning F.H. available:	Used for:
L-benches	No. of L-benches	Used for:
Lead bricks/lead pots for shielding		
Drainage system		
Radioactive waste storage facility	Solid waste: Liquid waste:	

B.6 Name, qualification and experience of personnel

S. No.	Name of personnel	Academic qualification	Type of training/ Experience	When and where trained	Duration of training	Personnel monitoring service No., if applicable

B.7 Procedures for disposal of radioactive waste

Radioisotope	Nature of waste generated		Method of disposal		Activity disposed MBq/week	
	Solid	Liquid	Solid	Liquid	Solid	Liquid

B.8 Documents to be attached with the Application:

(i) Copy of layout plan approval of the research laboratory issued by AERB/BARC

(ii) Copy of RSO approval certificate.

(iii) Personnel monitoring services details

(iv) Copy of appointment and acceptance letters for the radiation workers

(v) Security Plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/SG-1) (under preparation).

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my/our knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iv) the facility shall be operated and maintained by authorized and trained persons.

(v) the facility shall be put into operation only after obtaining Registration certificate from the competent authority.

(vi) the facility shall not be transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(viii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(ix) the periodic status report of all devices in the possession of the institution shall be submitted to AERB.

(x) all the radiation survey meters/safety instruments will be maintained in functional condition all the time and will be calibrated periodically.

(xi) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(xii) duly qualified/experienced radiological safety officer(s)/operator(s), will be appointed before the commencement of operation of the facility.

(xiii) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xiv) the decayed/unused radiation sources shall be returned to the original supplier.

(xv) AERB shall be informed about the absence of any qualified manpower immediately.

(xvi) any incident/accident such as fire, theft, damage etc., involving radioactive sources shall be promptly reported to AERB.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

(Seal of the institution)

ANNEXURE-45

(Refer section 3.16.3)

Form ID: AERB/RSD/Biomed/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FORMAT FOR OBTAINING REGISTRATION FOR BIOMEDICAL RESEARCH STUDIES ON HUMANS

(a)	*This application would be considered by the competent authority for issuance of relevant consent for the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with necessary documents*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected*
(d)	*All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*
(e)	*Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.4 Name and designation of the Radiological Safety Officer (RSO)*:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail
RSO approval reference No. :
Valid up to

[#] *Applicant is the person in whose name the authorisation (licence) to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of **'licensee'** prescribed in Atomic Energy (Radiation Protection) Rules, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of **'employer'** prescribed in Atomic Energy (Radiation Protection) Rules, 2004*

***** *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of **'Radiological Safety Officer'** prescribed in Atomic Energy (Radiation Protection) Rules, 2004.*

PART B

DETAILS OF THE STUDIES

B.1 Purpose for undertaking the biomedical studies on human volunteers :

B.2 Justification for the use of radioisotope :

B.3 Radioisotope, its form and activity to be used for individual volunteer :

B.4 Projected dose to be received by individual volunteer during the entire study :

B.5 Duration of the study :

B.6 Number of human volunteers involved :

B.7 Age group of the human volunteers:

B.8 Mode and number of administrations of radioisotope per volunteer:

B.9 Whether volunteer informed of risks of administration of radioisotope and consent obtained.

B.10 Whether pre-clinical studies on animals were carried out:

B.11 Reference of layout plan approval of the radioisotope: laboratory wherein the study will be undertaken

B.12 Details of staff involved in the studies:

Name	Academic qualifications and designation	Type of experience or training	When and where the radiation sources were used

B.13 Any additional relevant information

B.14 Documents to be submitted along with the Application:

(i) Report on the biomedical studies using radioisotopes giving the purpose and procedure to be undertaken for the studies

(ii) Approval of the Ethical Review Committee of the institution

(iii) Proof of pre-clinical studies on animals

(iv) Consent for participating in the research from individual volunteers

(v) Clearance from relevant statutory bodies (eg. Drug Controller of India)

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.;

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) studies shall be carried out only after obtaining approval from the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) followed Helsinki declaration

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the study at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) any unusual occurrences shall be reported to the competent authority.

(x) duly qualified and experienced personnel, will be appointed before the commencement of the study.

(xi) results of the study for which the application is sought will be submitted.

(xii) AERB will be informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

(Seal of the institution)

Signature:

Name of Head of the institution:

Designation

(Seal of the Head of the institution)

ANNEXURE-46
(Refer section 3.17.2)

Form ID: AERB/RSD/RIA/LA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar
Mumbai-400094.

APPLICATION FOR LAYOUT PLAN APPROVAL FOR RIA/IMMUNO RADIOMETRIC ASSAY (IRMA) LABORATORY

(a) *This application would be considered by the competent authority for issuance of relevant consent for the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with necessary documents*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected*

(d) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(e) *Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the Applicant[#]:

Telephone No. (O): (R):
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name relevant consents may be issued, under AE(RP)R, 2004, would have the responsibilities of '**licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004*

PART B

PARTICULARS OF THE PROPOSED FACILITY

B.1 Location of the proposed facility (commercial/residential):

B.2 Brief description of the facility:

B.2.1 Make and model of the proposed counting device(s):

B.2.2 Type of radioactive sources to be handled:

B.2.3 Thickness and material of the walls, floors, ceiling of the facility:

B.2.4 Floor in which facility is situated

(i) Number of rooms:

(ii) Location of doors, windows and exhaust, if any:

(iii) Location of work table, sink, radioactive source and waste storage.

B.3 Documents to be submitted along with the Application:

(i) Proof from local state govt. authorities that the land/plot for installation of facility is in the name of the applicant.

(ii) NOC from other local bodies with regard to permission for installation.

(iii) Layout plan of the facility drawn to scale 1:50 indicating the occupancy all around the facility and number of rooms, location of doors, windows and exhaust if any, location of work table, sink,

radioactive source and waste storage (should be submitted in duplicate.)

(iv) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified under item of this form.

(iii) the RIA/IRMA laboratory will not be set up until Approval is received from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the facility shall not be transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical protection measures will be duly implemented.

(ix) duly qualified and experienced radiological safety officer(s)/ operator(s), will be appointed before the commencement of operation of the facility.

(x) AERB will be informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby accept that appropriate regulatory

actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place:

Date:

Signature:

Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the institution)

ANNEXURE-47
(Refer section 3.17.3)

Form ID: AERB/RSD/RIA-IRMA/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR REGISTRATION OF RADIOIMMUNO ASSAY (RIA)/IMMUNO RADIOMETRIC ASSAY FACILITY (IRMA) (COMMISSIONING AND OPERATION)

(a)	*This application would be considered by the competent authority for issuance of relevant consents of the facility, under the Atomic Energy (Radiation Protection)Rules, 2004).*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with necessary documents*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected*
(d)	*All the forms pertaining to RIA laboratories using open radioisotopes can be downloaded from the website: www.aerb.gov.in*
(e)	*Attach extra sheets wherever required*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Name and designation of the Head of the Department in which the RIA kits would be used

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name the authorisation (licence) to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of **'licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution*

[$] *The head of the institution is the person who would have the responsibilities of **'employer'** prescribed in AE(RP)R, 2004*

PART B

PARTICULARS OF THE FACILITY

B.1 This application is for

First regulatory Licence			
Renewal	Ref No.	Date:	Valid till:

B.2 Name of the certified person to handle the kits:

B.3 Particulars of RIA kits for which this application is made

S. No.	Radiosotope	Specification	Number of kits per year

B.4 Equipment details

B.4.1 Counting equipment

Name of the equipment	Make and model	Date of installation	Working (Yes/No)

B.4.2 Monitoring and measuring instruments (survey instruments)

Name of the instrument	Make, model and serial No.	Measurement range	Working status	Date of last calibration

B.5 Additional information:

B.5.1 Are the floor areas of the rooms covered with special material linoleum/ PVC ?

B.5.2 Are the walls coated with strippable paint/ non-porous washable paint?

B.5.3 The work benches covered by: stainless steel/laminated top/any other material

B.5.4 Radiation protection accessories: (e.g. lead bricks, storage safe etc.)

B.5.5 Radioisotope laboratory accessories: (e.g. stainless steel trays/sinks, foot operated waste bins, micropipette, forceps, long tongs etc.)

B.5.6 Proposed procedure for disposal of radioactive waste: (e.g. solid, liquid)

B.6 Documents to be attached along with the Application:

(i) Copy of approval of layout plan of the RIA/IRMA facility issued by BARC/AERB

(ii) Copy of certificate of qualified person as per B.2

(iii) Any other document as required.

(iv) Copy of appointment and acceptance letters for the radiation workers

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the facility shall not be commissioned/operated until the Registration is obtained from the cmpetent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the facility shall not be transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect this installation at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) duly qualified and experienced personnel, will be appointed before the commencement of operation of the facility.

(x) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xi) AERB will be kept informed about the absence of any qualified manpower (as given in B.2) immediately.

(xii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

(Seal of the institution)

ANNEXURE-48

(Refer section 3.17.3)

Form ID: AERB/RSD/RIA/PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR PROCUREMENT OF RADIO-ISOTOPES FOR RADIOIMMUNO ASSAY (RIA)/IMMUNO RADIOMETRIC ASSAY FACILITY (IRMA)

(*a*) *This application would be considered by the competent authority for issuance of permission for procurement of radioactive material for the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *This form is intended to enable AERB to assess the suitability of the institution for procurement and use of radiation sources, (hereinafter referred to as 'source')*

(c) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(d) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(e) *All the forms pertaining to this facility can be downloaded from the website www.aerb.gov.in*

(f) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]:

Telephone No. (O): (R)

Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Name and designation of the Head of the Department in which the RIA kits would be used

A.5 Layout approval of the facility: (Give AERB reference no.)

[#] *Applicant is the person in whose name the authorisation (licence) to handle the source may be issued, under AE(RP)R, 2004, would have the responsibilities of '**licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF RADIOACTIVE SOURCES

B.1 Purpose for procurement:

B.2 Details of radioisotopes

S. No.	Radiosotope	Specification	Number of kits per year

B.3 Name of the certified person to handle the kits

B.4 Particulars of RIA kits for which this application is made

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my/our knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the sources shall be used only after obtaining Authorisation for commissioning and operation of the facility from the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the sources shall be handled by authorized and trained persons.

(vi) the sources shall not be transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the facility at any time.

(viii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by AERB will be duly carried out at my/our expense.

(ix) the periodic status report of radiation safety of the facility shall be submitted to AERB.

(x) all the radiation survey meters/safety instruments will be maintained in functional condition all the time and will be calibrated periodically.

(xi) all recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(xii) duly qualified/experienced radiological safety officer(s)/operator(s), shall be appointed prior to the procurement of the sources.

(xiii) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xiv) the decayed/unused radiation sources shall be disposed safely as per procedures approved by AERB.

(xv) inform AERB about the absence of any qualified manpower immediately.

(xvi) any incident/accident such as fire, theft, damage etc., involving radioactive sources shall be promptly reported to AERB.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby accept that appropriate regulatory

actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place:

Date:

Signature:

Name of the applicant:

Designation:

Signature:

Name of the Head of institution:

(Seal of the institution)

ANNEXURE-49

Government of India
Atomic Energy Regulatory Board

FORM-V

APPLICATION FOR AUTHORISATION TO DISPOSE OF RADIOACTIVE WASTES/DECAYED/UNUSED SOURCES (BY SMALL INSTALLATIONS)

[Under G.S.R.-125 Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987-Rule 15(1)]

PART A
(To be filled in by all institutions)

Particulars of the institution

1.	Name, designation and official address of the applicant (with Tel. Numbers, FAX No. and e-mail address during and after office hours)		:
2.	Name and address of Head of the institution		:
3.	Address of agency to whom the radioactive waste or decayed/ unused sources are sent for disposal (if applicable)		:
4.	Ref. No. and date of most recent Authorisation/NOC of BARC to use radioactive source(s)		:
5.	(a)	Name of the radiological safety officer (RSO) of the institution	:
	(b)	Qualification, training and experience of the RSO	:
6.	Number of staff members in the Institution experienced in radioactive waste disposal		:

PART B

To be filled in by institutions disposing sealed sources used in Industrial Applications, Nucleonic Gauges and Logging Devices

1. Source(s) from radiography camera(s) to be disposed annually in the next three years:

Details of Camera		Radionuclide	Number of source replacements per year	Maximum activity of the decayed source(s) to be sent for disposal	Remarks
Make and model S. No	Make and model	S. No.			

2. Source(s) from nucleonic gauge(s)/logging device(s) to be disposed :

Make and model of gauge/ Logging device	Purpose and type of gauge/Device	Total number of gauges/ Devices of each model and type	Radio-nuclide present in the source	Activity of individual decayed source(s) to be sent for disposal	Remarks

3. Any other source(s) to be disposed in the next three years : (e.g. reference sources, irradiators, gamma chambers). Please specify details of the source(s) and the equipment. (Attach additional sheet(s) if required).

PART C

(To be filled in by hospitals and research institutions disposing sealed sources)

1. Source(s) from brachytherapy equipment to be disposed in the next three years :

S. No.	Make and model of the equipment	Description of decayed source(s) and the radionu-clide present	No. and activity (with date) of each source	Total activity of sources to be sent for disposal in a year	Proposed date(s) of disposal	Remarks

2. Source(s) from teletherapy unit(s) to be disposed in the next three years :

Make and model of the unit	Details of the decayed source(s) and the radionuclide present	Name and address of the original supplier of the source	Present activity of the source (with date)	Proposed date of disposal (month and year)	Remarks*

* In case of teletherapy source head with depleted Uranium, the total weight of uranium to be disposed should be stated.

3. Any other source(s) to be disposed in the next three years : (e.g. reference sources, irradiators, gamma chambers). Please specify details of the source(s) and the equipment. (Attach additional sheet(s) if required).

PART D

(To be filled in by institutions disposing unsealed sources)

1. Brief description of the nature of work to be carried out with radioisotopes:

2. Proposed activity of each radioisotope to be procured in a year and the duration of the above programme:

3. Details of radioactive waste (RAW) proposed to be disposed annually in the next three years:

Waste particulars		Waste from		
		Solid	Liquid	Gaseous
(i)	Description of unsealed RAW :			
	(a) General contents of the waste			
	(b) Chemical characteristics			
(ii)	Nature of conditioning* of waste (if any) :			
(iii)	Annual volume of conditioned waste (m^3/y) :			

(iv) Radionuclides present in the waste :

(v) Total activity, per year, of each radionuclide present in the waste (MBq/y) :

(vi) Mode of disposal of waste (for local disposal) :

(vii) Location of disposal (for local disposal) :

(viii) Remarks (if any) :

---

* Elaborate, e.g. dilution, delay for decay, incineration, compaction, fixation and solidification.

PART E

(To be filled in by all institutions)

1. Facilities and procedures for waste management operations :

	Facilities for each waste form		
Procedures	**Solid**	**Liquid**	**Gaseous**
(a) Collection :			
(b) Transfer :			
(c) Interim storage :			
(d) Disposal :			
(e) Monitoring and surveillance for radioactivity. :			

2. Please enclose a sketch of the site, indicating the location(s) of RAW disposal and the radioisotope laboratory/installation. Specify the nature of environment, including the nature of occupancies, upto a radius of 200 meters around the burial pit(s), the incinerator and the discharge point(s) for liquid/gaseous effluents (as applicable).
(Please provide a brief description of the design and capacity of the incinerator, if it is to be used).

3. Any other relevant information

4. Undertaking

We hereby certify that

(i) all the statements made above are correct to the best of our knowledge and belief.

(ii) the radioactive waste will not be disposed of except as specified in this application.

(iii) radioactive waste will not be moved from the authorised site without prior approval of the competent authority.

(iv) any change in personnel, equipment and working conditions from that given in this application will be made only with the approval of the competent authority.

(v) full facility will be accorded to any authorised representative of the competent authority to inspect the installation where the radioactive waste is handled.

(vi) radiation monitoring and surveillance will be provided to ensure adequate protection for workers and the public.

(vii) radioactive waste will not be sold, rented or transferred to any other institution, without prior approval of the competent authority.

(viii) all stipulations, that may be made from time to time by the competent authority under Radiation Protection Rules, 1971 and Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, will be duly implemented.

Place : Signature:

Date : Name of the applicant:

Signature :

Name (Head of the institution):

Seal of the institution

To be mailed to :- The Chairman, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400 094.

ANNEXURE-50

Form no. AERB/RSD/TR/TRF

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar
Mumbai-400094.

APPLICATION FOR AUTHORISATION TO TRANSFER RADIOACTIVE MATERIAL TO THE SUPPLIER/AUTHORISED WASTE MANAGEMENT AGENCY

(a)	*This application would be considered by the competent authority for issuance of authorisation for transfer of radioactive material, under the Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987.*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*All the forms pertaining to transport of radioactive material can be downloaded from the website: www.aerb.gov.in*
(e)	*Packages should be dispatched only after obtaining authorisation for transport of radioactive material.*
(f)	*Attach extra sheets wherever required .*

PART A

GENERAL PARTICULARS

A.1 Name and address of the Institution:

Telephone No. (O):
Institution personnel monitoring No:
Fax No.
E-mail

A.2 Name and address of the Head of the Institution[$] :

Telephone No. (O): (R)
Fax No.

Mobile No.
E-mail

A.3 Name of the Consigner

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A. 4 Name and designation of the radiological safety officer (RSO)* :

Telephone No. (O) (M):
Fax No.
E-mail
RSO approval reference No. :
Valid up to:

A.5 Address for correspondence with PIN code:

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*Applicant is the person in whose name Authorisation to to transfer the radioactive material may be issued, under Atomic Energy (Radiation Protection) Rules, 2004), [AE(RP)R, 2004], would have the responsibilities of '**licensee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

$ *The head of the institution is the person who would have the responsibilities of '**employer**' prescribed in AE(RP)R, 2004.*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of '**Radiological Safety Officer'** prescribed in AE(RP)R, 2004.*

PART B

DETAILS OF THE PROPOSED TRANSFER

1. Is the Institution permitted by BARC/AERB for handling: radioactive material ? Give reference, if any.

2. Date of procurement of radioactive material and activity of the material on that date :

3. Name and address of the supplier of the radioactive material :

4. Reasons for disposal of the material :

5. Name and address of the Agency where the waste material is to be disposed off (BARC/BRIT/Original supplier abroad) :

6. Description of the radioactive material :

   (a) Name(s)

   (b) No. of sources :

   (c) Activity of each source as on date : —— Bq/Ci/mCi

   (d) Physical form(s) solid/liquid/gas/ powder/contaminated object:

   (e) Chemical form(s) :

   (f) Principal radionuclide(s) contained in the material :

   (g) Nature of application : Teletherapy/brachytherapy/industrial radiography /nucleonic gauges/others

   (h) Volume of radioactive material(s) in cm^3 : (Please attach additional sheet, if necessary)

7. (a) Details of source housing/container showing the position of the source with diagram/sketch and procedure for retrieval of the source :

   (b) Details of the package in which radioactive material is proposed to be transported. :

8. Total number of packages and the number of source(s) in each package :

9. Gross weight of each package :

10. Maximum radiation level at external surface of the package : ———— mrem/h

11. Maximum radiation at 1 m from external surface of the package : ———— mrem/h

12. Proposed mode of transport : Road/rail/air/sea

13. If it is type B package, package identification No. :

    Serial No. :

14. Details of facilities for handling the package :

15	Whether material is proposed to be transported in the original package supplied by the supplier (If yes, whether the packaging is in good condition)	:	Yes/No
16.	How the package is proposed to be immobilised in the vehicle during transport (applicable for packages of gross weight exceeding 30 kg)	:	
17.	Whether empty container, after removal of source is required (applicable only for sources disposed off at BARC/BRIT)	:	
18.	Any other information	:	
19.	Document to be attached with the Application	:	

(i) Details of source housing/container showing the position of the source with diagram/sketch along with procedure for retrieval of the source.

(ii) Details of the package in which radioactive material is proposed to be transported along with blue print or sketch showing all the dimensions including shielding details

(iii) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Material during Transport' (AERB/NRF-TS/SG-10)

PART C

UNDERTAKING

I/we hereby certify that

(i) the external surface of the package is free from non-fixed (transferable) contamination.

(ii) the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packed, marked and labeled, and are in all respects in proper condition for transport, according to the transport regulations currently in force.

(iii) all the statements made above are correct to the best of my knowledge and belief.

(iv) no activity will be carried out for purposes other than those specified in this form.

(v) all applicable provisions of the Atomic Energy (Radiation Protection) Rules, 2004 and Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987 shall be strictly complied with.

(vi) the radioactive source shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect during transfer/ transport at any time.

(viii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(ix) all stipulations/recommendations made by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(x) any incident/accident such as fire, theft, damage etc., involving radioactive material during transport shall be promptly reported to AERB.

(xi) All other necessary approvals from the concerned state/central government shall be obtained before the commencement of transfer/ transport of the radioactive material.

(xii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution in accordance with the applicable Rules.

Place:	Signature:
Date	Name of the applicant:
	Designation:
Place:	Signature of Radiation Safety Officer/ Site-in-charge
Date	Name:
	Designation

(Seal of the institution)

ANNEXURE-51

(Refer section 3.18.2)

Form ID: AERB/RSD/TR/SA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR APPROVAL OF SPECIAL ARRANGEMENT FOR TRANSPORT OF RADIOACTIVE MATERIAL

(a) *This form shall be duly filled in by the consignor who proposes to transport the radioactive material under special arrangement and submitted to the Director/Head, Radiological Safety Division, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400 094.*

(b) *No para should be left blank. If not applicable, write NA.*

(c) *Words and expressions used in this form shall have the same meaning assigned to them as in the Atomic Energy Regulatory Board Safety Code on 'Transport of Radioactive Material'(AERB/SC/TR-1).*

(d) *Incomplete applications and those without all relevant documents are liable to be rejected*

(e) *All the forms pertaining to shipment approval under special arrangement can be downloaded from the website www.aerb.gov.in*

(f) *Attach extra sheets wherever required.*

1.	Name and address of the consignor	:
2.	Name and address of the consignee	:
3.	Whether the consignee is authorised to receive the consignment by AERB If, Yes, Ref. No.	: Yes/No :
4.	Whether the storage facility for the consignment is approved	: Yes/No

	If Yes, give details of the approval of the facility	:
5.	Whether the consignee is prepared to accept the consignment	: Yes/No
6.	Name of the carrier	:
7.	Probable date (s) of the shipment	:
8.	Mode of transport	: Road/rail/sea/air
9.	Details of the consignment • Identity of radioactive materiel : • Activity of the material in Bq (Ci) : • Physical state : • Chemical state : • Mass and volume of fissile material (if applicable) : • Percent enrichment (if applicable) : • Fissile material composition (if applicable) :	
10.	Packaging details • Number of packages per shipment : • Dimensions of the package (s) : • Gross mass of the package (s) : • Shielding material : • Shielding thickness (on all sides) (Please provide a cut-away sketch of the dimensions 21 cmx30 cm, showing the components of the packaging, construction materials and closures) :	

	• Maximum radiation level on the surface of the package	:	
	• Maximum radiation level at 1 m from the outer surface of the package (TI)	:	
	• Contamination on the outer surface of the package	:	
	• Heat flux on the outer surface of the package	:	Watt/cm^2
	• Surface temperature of the package		
	• Are there any valves attached to the package for intermittent venting	:	Yes/No
	If Yes, No. of such valves	:	
	• Maximum normal operating pressure for the containment system of the package	:	
11.	(a) Whether the packages have been subjected to all the relevant performance tests	:	Yes/No
	If Yes, what was the response of the package	:	
	(b) Whether the package has been subjected to only few of the required performance tests	:	Yes/No
	If Yes, identify the names of the performance tests	:	
	What was the response of the package	:	
	(c) Whether the design of the package wassubmitted to AERB for approval	:	Yes/No
	If Yes, whether it was approved	:	Yes/No
	If Yes, indicate identification no. of the package	:	
	If No, what was the reason for not approving ?	:	

	(d) What steps have been taken to get the package approved	:	
12.	Reasons for special arrangements	:	Design not approved/leakage radiation levels higher/validity of the design approval expired/.....
13.	Proposed compensatory measures to maintain overall level of safety	:	(a) Shipment under exclusive use (b) Provision of escort in a separate vehicle (c) Provision of health physicist escort (d) Provision of portable fire fighting and emergency handling equipment for the shipment (e) Provision of personnel monitoring of transport workers such as driver, cargo handler etc. (f) Provision of communication system such as mobile cell phone, VHF commination facility (g) Any other provision
14.	State whether the approval is required for a single shipment or multiple shipments during a specified period	:	
15.	State whether emergency instructions (including TREMCARD) have been prepared for the shipment	:	Yes/No

16.	Provisions for quality assurance program		
	(a) Date of manufacture of the package	:	
	(b) No. of times used for transport	:	
	- with source	:	
	- without source	:	
	(c) Whether any incident happened during transport causing significant damage to the package	:	Yes/No
	If Yes, how the damage was repaired	:	
	(d) Maintenance of the package		
	- whether NDE is used	:	Yes/No
	If Yes, what type of NDE	:	
	- whether NDE results are satisfactory	:	Yes/No
	- if No, steps taken towards corrective measures	:	
	Frequency of conducting NDE	:	
	(e) Steps to prevent rusting and corrosion of the package	:	

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the accept regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place:	Signature of the applicant:
Date:	Name:
	Designation:

(Seal)

ANNEXURE-52
(Refer section 3.18.1)

Form ID: AERB/RSD/TR/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR PACKAGE DESIGN APPROVAL FOR TRANSPORT OF RADIOACTIVE MATERIAL

(a) *This form shall be duly filled in by the designer/consignor who proposes to deploy the packaging for transport of radioactive materials and submitted to the Director/Head, Radiological Safety Division, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400 094.*

(b) *It should be ensured that the necessary submissions such as the Safety Analysis Report (SAR) and a cut-away sketch of 21 cm x 30 cm showing make-up of the packaging are attached along with the application.*

(c) *The SAR shall contain details of analyses / tests to demonstrate compliance with the regulatory design requirements.*

(d) *No para should be left blank. If not applicable, write NA.*

(e) *Words and expressions used in this form shall have the same meaning as assigned to them in the Atomic Energy Regulatory Board Safety Code on 'Transport of Radioactive Material'(AERB/ SC/TR-1).*

(f) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(g) *All the forms pertaining to package design approval can be downloaded from the website www.aerb.gov.in*

(h) *Attach extra sheets wherever required*

PART 1: GENERAL INFORMATION

1.1	Name, address, telephone and Fax number and e-mail ID of the Applicant	:	
1.2	Type of design approval required	:	
1.3	Design approval required	:	First approval/renewal

PART 2 : DETAILS OF RADIOACTIVE CONTENTS

2.1	Identity of radioactive material and its maximum strength in TBq	:	
2.2	Whether it is a mixture of radionuclides, if yes the fraction of activity concentration of each radionuclide	:	
2.3	Physical form	:	
2.4	Chemical form	:	
2.5	Special Form	:	Yes/No
2.6	If Yes, certification details, (if obtained already, attach copy of certificate and special form test reports)	:	
2.7	Mass and volume of contents	:	
2.8	Mass and volume of fissile material (if applicable)	:	
2.9	Fissile material composition with percent enrichment (if applicable)	:	
2.10	Any other dangerous property	:	

PART 3 : PACKAGING DETAILS

3.1	Packaging model name	:	
3.2	Whether approved earlier	:	Yes/No
3.3	Competent authority identification mark if previously allocated	:	
3.4	Date of expiry of the certificate issued by the competent authority, (if applicable)	:	
3.5	The gross mass of the package	:	
3.6	External dimensions of the packaging (Relevant detailed drawings of the containment system and also tie-down should be attached.)	:	
3.7	Whether there is any protruding feature on the external surface of the packaging	:	Yes/No

3.8	Whether behaviour of radioactive material rial under varying conditions of temperature and pressure have been taken into account	:	Yes/No
3.9	Whether the packaging is provided with facilities for enabling safe handling	:	Yes/No
3.10	Whether the materials of the packaging and components of structures are physically and chemically compatible with each other and with the package contents, taking into account their behaviour under irradiation	:	Yes/No
3.11	Whether the packaging material can withstand temperature range of - 40° C to + 70° C	:	Yes/No
3.12	Whether a cut-away sketch of dimensions 21 cm x 30 cm has been provided showing make-up ofthe package	:	Yes/No
3.13	Whether specifications of packaging construction materials have been attached	:	Yes/No
3.14	Whether the outer layer of the packaging is designed to prevent the collection and retention of water	:	Yes/No
3.15	Whether the external surface of the packaging is so designed as to facilitate easy and swift decontamination	:	Yes/No
3.16	In case lifting attachments are included in the design of the packaging, whether such attachments are capable of supporting the weight of the packaging without imposing stresses on the structure of the package, in excess of the yield stresses of the relevant parts of the said structure (snatch lifting taken into consideration)	:	Yes/No/Not applicable
3.17	Whether the lifting attachments on the outer surface of the packaging, which are to be used to lift the package, are removable during transport	:	Yes/No/Not applicable

3.18	Whether any other features on the outer surface of the cask which are not designed for lifting are inoperable for lifting during transport	:	Yes/No/Not applicable
3.19	Whether the tie down attachments on the package are so designed that under both normal and accident conditions of transport, the forces in these attachments will not impair the ability of the package to meet the requirements of the regulations	:	Yes/No/Not applicable
3.20	Whether neutron absorbers have been provided, where applicable, if fissile material is transported	:	Yes/No/Not applicable
3.21a	Specification/code followed for quality assurance programme in manufacture of packaging	:	Yes/No
3.21b	Whether maintenance programme for packaging is prepared	:	Yes/No
3.22	Whether a feature such as seal is incorporated on the exterior of the package as proof against tamper.	:	Yes/No
3.23	Mode of transport	:	Road/rail/air/water

PART 4 : CONTAINMENT SYSTEM

4.1	Whether the containment system has adequate leak-tightness	:	Yes/No
4.2	Whether the material of the containment system is likely to be degraded by the contents ?	:	Yes/No
4.3	Whether the containment system is capable of retaining its radioactive contents under the reduction of ambient pressure to 60 kPa	:	Yes/No
4.4	Whether pressure relief valves are provided in the packaging	:	Yes/No

4.5	Whether the radioactive contents could escape through valves other than pressure relief valves and, if yes,	:	Yes/No/Not applicable
	Whether such valves are protected against unauthorised operation and provided with an enclosure to retain leakage	:	Yes/No/Not applicable
4.6	Whether radiolytic decomposition of the liquids or other vulnerable materials and the generation of gas by chemical reaction and radiolysis have been taken into account in the construction of the containment system	:	Yes/No/Not applicable
4.7	Whether the fastening device of the enclosure is designed in such a way as to prevent unintentional opening and opening by a pressure which may arise within the package	:	Yes/No/Not applicable
4.8	In case the containment system forms a separate unit of the packaging, whether it is capable of being securely closed by a positive fastening device which is independent of any other part of the packaging	:	Yes/No/Not applicable
4.9	Whether the package meets the additional requirements for packages transported by air	:	Yes/No/Not applicable

PART 5 : RADIATION SHIELDING IN THE PACAGING

5.1	Shielding material and thickness	:	
5.2	Estimated maximum radiation level on external surface of the package for designed activity of the radioactive content	:	mSv/h
5.3	Estimated maximum radiation level at 1 m from the external surface of the package for designed activity of the radioactive content	:	mSv/h
5.4	Transport index (TI) (estimated)	:	

PART 6 : PACKAGE ANALYSES AND TESTS

6.1	Whether the package will be able to withstand effects of any acceleration, vibration or vibration resonance which may arise under routine conditions of transport without any deterioration in the closing devices on the various receptacles or in the integrity of the package as a whole, e.g. nuts, bolts, and other securing devices becoming loose or being released unintentionally, even after repeated use.	:	Yes/No
6.2	Whether evaluation has been done to demonstrate design of the packaging under normal and accident conditions of transport as per the regulatory requirements	:	Yes/No
6.3	Maximum temperature at any accessible surface of package in presence/absence of insulation	:	
6.4	Maximum surface heat flux (W/m^2)	:	
6.5	The expected absolute maximum normal operating pressure(MNOP) of the containment system	:	
6.6	Whether details of actual tests on prototype/scale model have been provided	:	Yes/No/Not applicable
6.7	If calculation/analytical methods have been used for demonstrating compliance with test requirements, please state whether the analysis is based on computer codes validated by experiments	:	Yes/No/Not applicable

PART 7 : INFORMATION REQUIRED ONLY FOR PACKAGES OF FISSILE MATERIAL

7.1	Whether at least two water barriers are found effective under accident conditions	:	Yes/No/Not applicable

7.2	Maximum number of package that remain subcritical under normal conditions of transport	:
7.3	Maximum number of packages that remain subcritical under accident conditions of transport specified for fissile material	:
7.4	Criticality safety index (CSI)	:

PART 8 : ANY OTHER RELEVANT INFORMATION

PART 9 : ENCLOSURES

(i) Safety analysis report

(ii) QA programme

(iii) ……

(iv) …….

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iii) any additional information as required by the competent authority in connection with the design approval will be provided promptly.

(iv) any stipulations/recommendations made from time to time by the competent authority about the package design will be duly implemented.

(v) any incident/accident such as fire, theft, damage etc., involving the package design approved by competent authority shall be promptly reported to AERB.

(vi) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the accept regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place:	Signature of the applicant:
Date:	Name:
	Designation:

(Seal)

ANNEXURE-53

(Refer section 3.18.1)

Form ID: AERB/RSD/SS/ NOC-TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)*/ TYPE APPROVAL OF SEALED SOURCE

(a)	*This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*For all the forms pertaining to this practice, AE(RP)R, 2004 and other information in this regard, refer to website: www.aerb.gov.in*
(e)	*Separate application should be submitted for each model of sealed source.*
(f)	*Attach extra sheets wherever required and strike off which is not applicable.*

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant/manufacturer[#]

Telephone No. (O): (R)
Fax No.
E-mail

A.2 Name and address of the local supplier[#]

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

[#] *Applicant/Manufacturer is the person in whose name the 'Type Approval' for the sealed source may be issued, under AE(RP)R, 2004.*

PART B

PART B1 : PARTICULARS OF THE SEALED SOURCE

B1.1 Radionuclide : .....

B1.2 Other radionuclides present (nature and quantity): .....

B1.3 Target element in case of neutron source : .....

B1.4 Chemical and physical form : .....

B1.5 Mass (g)/volume (mm^3) : .....

B1.6 Maximum activity (GBq/Ci) : .....

B1.7 Material(s) of construction : .....

B1.8 External dimensions (mm) : .....

B1.9 Active dimensions (mm) : .....

B1.10 Thickness of wall/covering/cladding (mm): .....

B1.11 Method of sealing : .....

B1.12 Number of encapsulation(s) : .....

B1.13 Freedom from surface contamination : .....

B1.13.1 Test method (specify) : .....

B1.13.2 Result(s) : .....

B1.14 Manufacturer's identification mark : .....

B1.15 Tests for source classification

Number of random samples for testing: : .....

(The para numbers below given in parentheses refer to relevant sections in AERB safety standard titled 'Testing and Classification of Sealed Radioactive Sources' [AERB/SS-3(Rev. 1)]

S. No.	Test	Classification number
1	Temperature (3.4.2)	
2	Pressure (3.4.3)	
3	Impact (3.4.4)	
4	Vibration (3.4.5)	
5	Puncture (3.4.6)	
6	Bend (6.2.1)	
7	Impact (6.3.2.1)	
8	Percussion (6.3.2.2)	
9	Bending (6.3.3.3)	
10	Heat (6.3.2.4)	
11	Enhanced thermal (6.4.1.1)	
12	Impact (6.4.1.2)	

B1.16 Source classification : .....

B1.17 Results of leak test : .....

B1.17.1 Radioactive method(s) (specify) : .....

B1.17.2 Non-radioactive method(s) (specify) : .....

B1.18 Anticipated useful life of the sealed source: ..... years

B1.19 Intended use of sealed source : .....

B1.20 Details of person(s) who are trained in handling the radiation source(s) :

S. No.	Name of person	Designation	Academic qualification	Radiation source handling experience	Details of training on radiation safety, If any	PMS No.

B1.21 Documents to be attached with the Application:

(i) Sketch/drawing showing details of radioactive source and its encapsulation.

(ii) Quality assurance (QA) manual for design and manufacturing of sealed radioactive sources.

(iii) Procedures to demonstrate that the manufactured sources are identical to the prototype.

(iv) Classification and leak test certificates (including Serial No.) as per applicable national /international standard

(v) Copy of design approval certificate for the sealed source issued by manufacturer/country of origin of design in case of imported sources.

(vi) Test report describing the method and the evaluation of results.

(vii) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/SG-1) and AERB safety guide on 'Security of Radioative Material during Transport' (AERB/NRF-TS/SG-10).

(viii) Any other document.

PART B2 : RENEWAL OF TYPE APPROVAL OF SEALED SOURCES (TO BE FILLED IN ALONG WITH PART B1)

B2.1 Nos. of sealed sources supplied so far in the country (with S. Nos.)

B2.2 Name and address of the institutions where these sealed sources are being supplied

B2.3 Any modification to the present design or changes in components/materials of construction/QA procedures incorporated in the approved model. If so, give details.

B2.4 Occurrence of incidents, if any and causes/remedial measures.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the source shall be imported/supplied only after obtaining a NOC/ type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the source shall not be transported/ transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) shall provide to the user along with the source (i) technical specifications; (ii) operating, servicing and maintenance manuals; (iii) Type approval certificate.

(x) shall provide to the user with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xi) duly qualified/experienced persons will be appointed for demonstration of type testing of the source.

(xii) the rules regarding decommissioning/disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xiii) shall provide technical assistance to the user in case of decommissioning/dismantling of equipment/device and arrange for disposal of the decayed source and any other contaminated material of the equipment.

shall take back the faulty device/equipment involving source housing and other safety related systems/components at our own expenses for disposal/repair.

(xiv) shall assist the user in case of any emergency related with radioactive source.

(xv) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xvi) AERB will be informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-54

(Refer section 3.18.1)

Form ID: AERB/RSD/TT/NOC-TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC) FOR IMPORT/TYPE APPROVAL OF TELEGAMMA THERAPY EQUIPMENT*

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*All the forms pertaining to this equipment can be downloaded from the website www.aerb.gov.in*
(e)	*Attach extra sheets wherever required.*
(f)	*Separate Application forms should be submitted for each model of Telegamma therapy equipment.*
(g)	*This Application format can also be used for Gamma Knife System (GKS).*

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (Local Supplier)[#] :

Telephone No.: (O): (R)
Fax No.:
Mobile No.:
E-mail:

A.2 Name and address of the manufacturer

Telephone No.: (O):
Fax No. :
Mobile No.:
E-mail :

A.3 Name of the representative of the applicant to be contacted regarding the application

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

---

* *This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.*

Applicant (local supplier) is the person in whose name the 'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.

PART B

DETAILS OF EQUIPMENT

B.1 Name of the equipment

B.2 Type of equipment

(a) Rotating

(b) Stationary

B.3 This application is for:

Type Approval/NOC			
*Renewal of Aype Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.13 needs to be furnished.

B.4 Location where the unit is to be type tested for type approval

B.5 Details of equipment specification

(a) Name of the unit:

(b) Make, model and type:

(c) Year and country of manufacturer:

(d) Type of Gantry : Stationary/rotary gantry wall mounted gantry/ceiling mounted gantry

(e) Freedom of movement of the treatment table (longitudinal/ transverse/vertical/rotational):

(f) Source movement mechanism for exposure (e.g. pneumatic, etc):

(g) Details on safety interlocks, display and measurement of irradiation time, and the backup systems provided.

(h) Additional facilities provided with the telegamma unit:

B.6 Details of source head and radioactive source

(a) Specification of the radiation head (Attach detailed drawing of source head and material(s) used for shielding)

(b) Dimensions and activity of the radioactivity source used

(c) Radioactive source used (Co-60/Cs-137) :

(d) Classification of sealed source to be used :

(e) Maximum rated capacity (source strength) : _____ TBq and of the telegamma unit _____ RMM

B.7 Built-in safety features/operation:
(Furnish all procedures to prevent any radiologically unsafe malfunction of the equipment)

B.7.1 Details of automatic source withdrawal provision in the event of power failure or at the termination of pre-set time or any other type of failure of the system

B.7.2 Details of manual beam 'OFF' provision in the event of failure of automatic provisions (Please attach detailed description and relevant drawings)

B.7.3 Details of backup system for set and elapsed time display:

B.8 Details of beam limiting devices and accessories

(i) Maximum field size at SSD/SAD :

(ii) SSD/SAD

(iii) Wedge filters available (details of wedge angle, thickness, isodose chart available etc.)

(iv) Beam applicators (provide details)

(v) Spare parts made available :

B.9 Specify the design specification of the following parameters[£] :

S. No	Parameters	Tolerance limit [&]	Designed value	Remarks
1.	Orthogonality of Jaws			
2.	Parallelism of Jaws			
3.	Symmetry of Jaws			
4.	Optical and Collimator axes coincidence			
5.	Accuracy of isocentre			
6.	Accuracy of table top vertical motion			
7.	Accuracy of table top lateral motion			
8.	Accuracy of table top longitudinal motion			
9.	Shift in optical field due to rotational motion from minimum to maximum position			
10.	Shift in optical field due to vertical motion from -90^0 to 90^0 position			
11.	Accuracy of optical field Size			
12.	Accuracy of optical distance indicator			
13.	Accuracy of mechanical front pointer			
14.	Optical field overlap 0^0 to 180^0			
15.	Optical field overlap 90^0 to 270^0			
16.	Optical and radiation field congruence			
17.	Shutter timer error			
18.	Penumbra for photon beam			
19.	Cross-wire centering vs. collimator rotation			

20.	Coincidence between optical beam and radiation beam axes			
21.	Coincidence between radiation and mechanical isocentre			
22.	Gantry rotation speed (0.1 to 1 RPM)			
23.	Accuracy of angular scale of gantry			
24.	Wedge position reproducibility			
25.	Tray position reproducibility			
26.	Table top sag			
27.	Leakage radiation level (μSv/h) at 5 cm from any accessible location on the surface of the source housing averaged over 10 square cm area with source OFF position for maximum source strength of the unit head			
28.	Leakage radiation level (μSv/hr) at 1m from the source averaged over 100 square cm area with source OFF position for maximum source strength of the unit head			
29.	*Maximum leakage radiation through beam limiting devices (secondary collimators)			
30.	*Leakage radiation in the patient plane$ measured with source ON position		Maximum:	
			Average:	
31.	**Maximum leakage of radiation of unit head in other than patient plane measured at 1 m from the radiation source with source ON position			
32.	Maximum leakage radiation of unit head during source transition from beam OFF to the beam ON			

32. (Contd.)	condition and vice versa measured at 1 m outside the maximum cross-section of the radiation beam at 1 m from the radiation source with radiation source in the worst case position			

£ Applicable clauses of the table B.9 shall be filled in for GammaKnife Unit.

& as per the relavant standards

* Percentage leakage radiation of maximum absorbed dose for 10 cm x 10 cm radiation field size measured on central beam axis at NTD

** Percentage leakage radiation of maximum absorbed dose for 10 cm x 10 cm radiation field size measured on central beam axis at 1 m

$ Circular plane of radius 2 m centered on radiation beam axis at NTD.

B.10 Source transfer, servicing and certification

(i) Can the source transfer be done at the hospital : Yes/No

(ii) Whether the source head is approved for transport of the source in the head : Yes/No

(iii) Whether a Approved Type B(U) transport container will be made available locally : Yes/No

(iv) Whether the source used for the unit is available in India : Yes/No

(v) Details of person(s) who are trained in handling the radiation source/equipment :

Name(s) and designation(s) of qualified and trained engineers available in India for servicing, maintenance and to attend the emergency situations

S. No.	Name of person with designation	Academic qualification	Radiation source/ Equip-ment handling experience	Details of training on radiation safety, if any	Personnel monitoring service No.

(vi) Anticipated useful life of the unit

(vii) Is this unit type approved by competent authority of the country of manufacture : Yes/No

(if Yes, please furnish the certificate from the competent authority)

(viii) Any other information you may like to furnish

B.11 Specify the Standards to which the equipment comply : Bureau of Indian Standards/ IEC/any other standards (specify)

B.12 Documents to be attached with the Application:

(i) Design drawings of the source housing (shielding and material composition of the unit), beam status indicators, interlock, along with the functional description of safety related control systems, back up power supplies and retrieval of dose delivery parameters.

(ii) QA Manual for design and manufacture.

(iii) Manual for operation, servicing, maintenance, disposal and emergency procedures.

(iv) Copy of certificate of approval from country of origin.

(v) Copy of classification certificate of sealed source to be used in the telegamma equipment

(vi) In case of imported equipment, relevant national/International Standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language)

(vii) Detailed test report with description of each test, the sequence in which the tests are carried out and evaluation of test results.

(viii) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the equipment.

(ix) Copy of the Type Approval [B(U)] Certificate for Source Head in case the source head is used as a source transport container

(x) Copy of the Type Approval [B(U)] certificate for source transport container.

(xi) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the equipment.

(xii) List of countries to which such devices were earlier sold.

(xiii) Any other relevant document(s).

B.13 In case of Renewal of Type Approval, then the following additional information/documents is to be submitted

(a) Nos. of equipment supplied so far in India as well as in other countries (with serial numbers)

(b) The name, address and contact details of the institutions in India, where the units installed.

(c) Details of servicing and preventive maintenance of these equipment carried out

(d) Any modification to the present design or changes in components/ materials of construction/QA procedures incorporated in the approved model. If so, give details.

(e) A certificate from the principal company that no reported incident/ accident occurred anywhere in the world while using the above model. In case any reported incident/accident of the same model, the details need to be submitted regarding remedial measures undertaken by the company.

(f) Provide operational experience feedback (OEF) with respect to performance of equipment supplied in India so far. (Attach details on the following)

  (i) Availability of minimum safety accessories/spares and provide list

  (ii) Common failures observed in the equipment supplied

  (iii) Generic deficiencies/operational problems reported by the users

  (iv) Occurrence of incidents, if any and causes/remedial measures.

(g) Whether the operational experience feedback (OEF) has been obtained from user of the equipment. Provide copies of feedback from duly signed by the users in India regarding performance of the unit.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit shall be imported/ supplied only after obtaining a NOC/ Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority;

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our unit any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations that may be made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) shall carry out installation, commissioning, servicing and maintenance, of the equipment supplied by me/us.

(x) shall provide to the user along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; iii) Type approval certificate

(xi) shall provide to the user with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xiii) shall provide the training to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xv) shall provide technical assistance to the user in case of decommissioning/dismantling of equipment and arrange for disposal of the decayed source and any other contaminated material of the equipment.

(xvi) shall take back the faulty equipment involving source housing and other safety related systems/components at our own expenses for disposal/repair.

(xvii) shall assist the user in case of any emergency related with radioactive source.

(xviii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-55

(Refer section 3.18.1)

Form ID: AERB/RSD/MLA/NOC-TA

Niyamak Bhavan
Anushktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC) FOR IMPORT/TYPE APPROVAL OF MEDICAL LINEAR ACCELERATOR (MLA)

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *All the forms pertaining to this equipment can be downloaded from the website www.aerb.gov.in*

(e) *Separate application forms need to be submitted for each model of Medical Linear Accelerator.*

(f) *Attach extra sheets wherever required.*

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (Local Supplier)[#] :

Telephone No.: (O): (R)
Fax No. :
Mobile No. :
E-mail:

A.2 Name and address of the manufacturer

Telephone No.: (O):
Fax No. :
Mobile No.:
E-mail:

A.3 Name of the representative of the applicant to be contacted regarding the application

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

[#] *Applicant (local supplier) is the person in whose name the'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.*

PART B

DETAILS OF THE EQUIPMENT

B.1 Purpose for which the equipment will be used :

B.2 Type of equipment (Choose as applicable)

(a) Portable
(b) Mobile
(c) Stationary

B.3 This application is for:

Type Approval/NOC			
[£]Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

[£] For renewal of Type Approval certificate, additional information, as given in B.11 needs to be furnished.

B.4 Location where the unit is to be type tested for type approval

B 5 Details of equipment specification

(a) Make and model of the unit :
(b) S. No. of the unit :

(c)	Year and country of manufacture	:	
(d)	Type of beam : (electron/photon/any other):		
(e)	Maximum current in (μA/mA)	:	
(f)	Maximum particle fluence rate at 1 meter in (cm^{-2} s^{-1})	:	
(g)	Photon beam energies available	:	MV
(h)	Electron beam energies available	:	meV
(i)	Output of the photon beam under reference condition	:	
(j)	Output of the electron beam under reference condition	:	
(k)	Available dose rate(s) in water for photon beam under reference conditions	:	
(l)	Available dose rate(s) in water for electron beam under reference conditions	:	
(m)	Therapy mode(s) (Fixed/Rotational/ Arc/Skip)	:	
(n)	Field sizes available at isocenter	:	
(o)	Over travel distance for asymmetrical field size	:	
(p)	Gantry rotation range	:	
(q)	Gantry rotation speed	:	
(r)	Collimator rotation range	:	
(s)	Couch rotation range patient support assembly	:	
(t)	Distance between bottom of collimator surface and isocenter	:	
(u)	Isocenter height from finishing floor	:	
(v)	Details of MLC or mMLC, if available	:	
(w)	Special technique available in the unit like SRS/SRT/IMRT/IGRT etc.	:	
(x)	Anticipated working life of the unit	:	
(y)	Maximum absorbed dose rate in water at one metre from the source for 10 x 10 square cm field size for various beam energies (cGy/min)	:	
(z)	Any other information	:	

B.6 Details of person(s) who are trained in handling the radiation source/ equipment:
Name(s) and designation(s) of qualified and trained engineers available in India for servicing, maintenance and to attend the emergency situations

S. No.	Name of person	Designation	Academic qualifications	Radiation source/ Equipment handling experience	Details of training on radiation safety, if any	Personnel monitoring service No.

B.7. Specify the design specification of the following parameters:

S. No	Parameters	Tolerance limit &	Designed value	Remarks
1.	Orthogonality of adjacent jaws			
2.	Parallelism of opposite jaws			
3.	Symmetry of opposite jaws			
4.	Optical and collimator axes coincidence			
5.	Shift in isocentre due to collimator, couch and gantry rotation			
6.	Optical field size accuracy			
7.	Accuracy of optical distance indicator			
8.	Accuracy of mechanical front pointer			
9.	Optical and radiation field congruence			
10.	Accuracy of isocenter			
11.	Coincidence between radiation and mechanical isocentre			
12.	Reproducibility of MLC leaf-positions			
13.	Optical field overlap due to collimator rotation (0^0 to 180^0 and 90^0 to 270^0)			

14.	Cross-wire centering vs. collimator rotation			
15.	Gantry rotation speed (0.1 to 1 RPM)			
16.	Accuracy of angular scale of gantry			
17.	Wedge position reproducibility			
18.	Tray position reproducibility			
19.	Positional accuracy of electron applicator			
20.	Table top sag			
21.	Accuracy of table top vertical motion			
22.	Accuracy of table top lateral motion			
23.	Accuracy of table top longitudinal motion			
24.	Quality index for photon beam(s)			
25.	Depth of maximum absorbed dose to water (d max) for 10 cm x 10 cm field size under reference condition			
26.	Percentage depth dose values (PDD) for different photon beam energy (ies) at 10 cm depth for 10 cm x 10 cm field size.			
27.	Beam flatness for photon beam energies			
28.	Beam flatness for electron beam energies			
29.	Symmetry of the radiation field for photon beam energies			
30.	Symmetry of the radiation field for electron beam energies			
31.	Dose linearity for photon beam energies			

32.	Dose linearity for electron beam energies			
33.	Penumbra for photon beam			
34.	Penumbra for electron beam			
35.	Wedge factor for various wedges			
36.	Tray factor			
37.	Couch transmission factor			
38.	Termination of irradiation by the dose monitoring system			
39.	X-ray contamination of electron beam			
40.	*Photon leakage radiation through beam limiting devices (secondary collimator) at normal treating distance (NTD)		Maximum :	
			Average:	
41.	*Photon leakage radiation through MLCs		Maximum *(when either pair of jaws is replaced with MLCs):*	
			Average *(when either pair of jaws is replaced with MLCs):*	
			Maximum *(if MLCs are used as tertiary jaws):*	
42.	*Photon leakage radiation in the patient plane[#]		Maximum:	
			Average :	
43.	*Neutron leakage radiation in the patient plane		Maximum:	
			Average :	

44.	*Maximum percentage leakage radiation at 1 m from the path of electrons between electron gun and the target or electron window, and the reference axis (in other than patient plane)		For photon:	
			For neutron:	
45.	When the electron energy exceeds 10 MeV, ambient dose equivalent due to induced activity accumulated over a period of 5 min starting 10 s after the final termination of irradiation at the end of 4 h series of irradiation of 4 Gy with maximum specified absorbed dose rate, separated by off periods of 10 min (alternatively ambient dose equivalent rate can be specified within 3 minutes of the final termination of irradiation)		at 5 cm from the surface of the enclosure:	
			at 1 m from the surface of the enclosure:	

& as per the relevant standards

* Percentage leakage radiation of maximum absorbed dose for 10 cm x 10 cm radiation field size measured on central beam axis at NTD.

Circular plane of radius 2 m centered on radiation beam axis at NTD.

B.8 Built-in safety features/operation :
(Furnish all procedures to prevent any malfunction of the equipment)

B.8.1 Details of the all the mechanical and electrical interlocks

B.8.2 Details of automatic irradiation OFF provision in the event of termination of pre-set monitor unit or any other type of failure of the monitor chamber or timer

B 8.3 Details of backup system for set and elapsed treatment parameters display :

B.9 Specify the Standards to which the Accelerator comply : Bureau of Indian/IEC/any other standards (specify)

B.10 Documents to be submitted along with the Application

(i) Drawing of the treatment head showing the radiation shielding and materials of construction (scale 1:2) with beam status indicators,

interlock, along with the functional description of safety related control systems, back up power supplies and retrieval of dose delivery parameters

(ii) Drawings along with the functional description of safety related control systems and devices

(iii) National standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language)

(iv) Test report on the performance of the accelerator demonstrating the compliance with the national/international standards (e.g. IEC 60601-1-1, IEC 60601-2-1)

(v) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for medical use

(vi) Report on the performance of accelerator of the same type used in India during the past 5 years

(vii) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the equipment

(viii) Relevant documents on built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment

(ix) Installation manual, operation/servicing manual

(x) Any other information you may like to furnish.

B.11 In case of renewal of Type Approval, then the following additional information/documents is to be submitted

(a) Nos. of equipment supplied so far in India as well as in other countries (with serial numbers)

(b) The name, address and contact details of the institutions in India, where the units installed.

(c) Details of servicing and preventive maintenance of these equipment carried out.

(d) Any modification to the present design or changes in components/ materials of construction/ QA procedures incorporated in the approved model. If so, give details.

(e) A certificate from the principal company that no reported incident/ accident occurred anywhere in the world while using the above model. In case any reported incident/accident of the same model, the details need to be submitted regarding remedial measures undertaken by the company.

(f) Provide operational experience feedback (OEF) with respect to performance of equipment supplied in India so far. (Attach details on the following)

(i) Availability of minimum safety accessories/spares and provide list

(ii) Common failures observed in the equipment supplied

(iii) Generic deficiencies/operational problems reported by the users

(iv) Occurrence of incidents, if any and causes/remedial measures.

(g) Whether the operational experience feedback (OEF) has been obtained from user of the equipment. Provide copies of feedback from duly signed by the users in India regarding performance of the unit.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) shall supply the unit only after obtaining a NOC/Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our unit at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations that may be made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) shall carry out installation, commissioning, servicing and maintenance, of the equipment supplied by me/us.

(x) shall provide to the user along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; (iii) Type approval certificate

(xi) shall provide to the user with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xiii) shall provide the training to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xv) shall provide technical assistant to the user in case of decommissioning/dismantling of equipment and arrange for disposal of the decayed source and any other contaminated material of the equipment.

(xvi) shall take back the faulty equipment involving source housing and other safety related systems/components at our own expenses for disposal/repair.

(xvii) shall assist the user in case of any emergency related with radioactive source.

(xviii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-56

(Refer section 3.18.1)

Form ID: AERB/RSD/BT-RAL/NOC-TA

Niyamak Bhavan
Anushktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC) FOR IMPORT/TYPE APPROVAL OF REMOTE AFTERLOADING (RAL) BRACHYTHERAPY EQUIPMENT

(a) *This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected*

(d) *All the forms pertaining to this equipment can be downloaded from the website www.aerb.gov.in*

(e) *Separate Application forms are to submitted for each model of RAL Brachytherapy equipment*

(f) *Attach extra sheets wherever required.*

* This application is for the purpose of importing the equipment to obtain Type approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type approval. This application form would be reviewed for considering Type approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (Local Supplier)[#] :

Telephone No.: (O): (R)
Fax No. :
Mobile No. :
E-mail :

A.2 Name and address of the manufacturer

Telephone No.: (O): (R)
Fax No. :
Mobile No. :
E-mail :

A.3 Name of the representative of the applicant to be contacted regarding the application

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

[#] *Applicant (local supplier) is the person in whose name the 'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.*

PART B

DETAILS OF THE EQUIPMENT

B.1 Purpose for which the equipment will be used :

B.2 Type of equipment (choose as applicable)

(a) Portable
(b) Mobile
(c) Stationary

B.3 This application is for:

Type Approval/NOC			
[£]Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

[£] For renewal of Type Approval certificate, additional information, as given in B.15 needs to be furnished.

B.4 Location where the unit is to be type tested for Type approval

B .5 Details of equipment specification

(a) Name of the unit:

(b) Make, model and type:

(c) Year and country of manufacturer

(d) Number of channels :

(e) Maximum capacity of the source container of the unit:

(f) Anticipated working life of RAL

B.6 Details of radioisotope(s) used in the RAL unit

Radioisotope	**Physical dimensions and shape of the source**	**Source classification** and its model number**	**Total activity or activity/ cm in case of wires/ ribbons**	**Number of sources or total length in case of wire and ribbon sources**
Co-60 Cs-137 Ir-192 Any other (specify)				

** As per national/international standards, give details.

B.7 Built-in safety features/operation:
(Furnish all procedures to prevent any radiologically unsafe malfunction of the equipment)

B.8 Specify the national/international standards to which the RAL comply:

B.9 Details of person(s) who are trained in handling the radiation source/ equipment :

Name(s) and designation(s) of qualified and trained engineers available in India for servicing, maintenance and to attend the emergency situations

S. No.	**Name of person and designation**	**Academic qualifi-cations**	**Radiation source/ equipment handling experience**	**Details of training on radiation safety, if any**	**Personnel monitoring service No.**

B.10 Name and address of the source supplier

B.11 Specify the design specification of the following parameters:

S. No	Parameters	Tolerance Limit [&]	Designed value	Remarks
1.	Source safe display for 'OFF' and 'ON' conditions are provided			
2.	Useful parameters display in control console are provided			
3.	Coincidence between dummy and active source positions			
4.	Accuracy of source position within the applicator			
5.	Reproducibility of source position			
6.	Timer error			
7.	Timer linearity			
8.	End error			
9.	Maximum dose equivalent rate (μSv/h) due to leakage radiation at distance of 5 cm from any accessible location of the source housing (surface of the machine for maximum rated source capacity of the unit)			
10.	Maximum dose equivalent rate (μSv/h) due to leakage radiation at distance of 1 m from any accessible location of the source housing (surface of the machine) for maximum rated source capacity of the unit			

[&] as per the standard

B.12 Built-in safety features/operation :
(Furnish all procedures to prevent any malfunction of the equipment leading to radiation safety)

B.12.1 Details of automatic source withdrawal provision in the event of power failure or at the termination of pre-set time or any other type of failure of the system

B.12.2 Details of manual beam "OFF" provision in the event of failure of automatic provisions
(Please attach detailed description and relevant drawings)

B.12.3 Details of backup system for set and elapsed time display
(Please attach detailed description and relevant drawing)

B.13 Specify the Standards to which the equipment comply : Bureau of Indian Standards/ IEC/any other standard (specify)

B.14 Documents to be submitted along with the Application:

(i) Drawing of the source housing of the Remote Controlled Afterloading Brachytherapy unit showing the shielding and materials of construction (scale 1:2), beam status indicators, interlock, along with the functional description of safety related control systems, back up power supplies and retrieval of dose delivery parameters.

(ii) Drawing along with the functional description of the safety related control systems and devices.

(iii) National standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language).

(iv) Performance report demonstrating compliance with the naational standard or IEC standard.

(v) Certificate from the competent authority of the country of design/ manufacture to the effect that the equipment is approved for medical use.

(vi) Test report and certificate of compliance of the equipment/source transport container as approved package for safe transport of radioactive material.

(vii) Test report and certificate from the source manufacturer showing classification designation of the sealed source.

(viii) Performance report on equipment of the same type used in India during the past 5 years.

(ix) Detailed description and relevant drawings indicating automatic source withdrawal provision in the event of power failure or at the termination of pre-set exposure or any other type of failure of the system.

(x) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the equipment.

(xi) Quality Assurance programme in the manufacture of equipment showing evidence for documentation, materials of construction, control, internal and external audit and quality conformance verification.

(xii) Copy of the Type approval certificate for source transport container.

(xiii) List of countries to which such devices were earlier sold.

(xiv) Any other information you may like to furnish.

B.15 In case of Renewal of Type approval, then the following additional information/documents is to be submitted.

(a) Nos. of equipment supplied so far in India as well as in other countries (with serial numbers).

(b) The name, address and contact details of the institutions in India, where the units installed.

(c) Details of servicing and preventive maintenance of these equipment carried out.

(d) Any modification to the present design or changes in components/ materials of construction/QA procedures incorporated in the approved model. If so, give details.

(e) A certificate from the principal company that no reported incident/ accident occurred anywhere in the world while using the above model. In case any reported incident/accident of the same model, the details need to be submitted regarding remedial measures undertaken by the company.

(f) Provide operational experience feedback (OEF) with respect to performance of equipment supplied in India so far. (Attach details on the following)

(i) Availability of minimum safety accessories/spares and provide list.

(ii) Common failures observed in the equipment supplied.

(iii) Generic deficiencies/operational problems reported by the users.

(iv) Occurrence of incidents, if any and causes/remedial measures.

(g) Whether the operational experience feedback (OEF) has been obtained from the user of the equipment. Provide copies of feedback form duly signed by the users in India regarding performance of the unit.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) shall import/supply the unit only after obtaining NOC/Type approval from the competent authority and only to users authorised by the competent authority

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our unit any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations that may be made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) shall carry out installation, commissioning, servicing and maintenance, of the equipment supplied by me/us.

(x) shall provide to the user along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; iii) Type approval certificate.

(xi) shall provide to the user with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xiii) shall provide the training to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xv) shall provide technical assistant to the user in case of decommissioning/dismantling of equipment and arrange for disposal of the decayed source and any other contaminated material of the equipment.

(xvi) shall take back the faulty equipment involving source housing and other safety related systems/components at our own expenses for disposal/repair.

(xvii) shall assist the user in case of any emergency related with radioactive source.

(xviii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-57

(Refer section 3.18.1)

Form ID. AERB/RSD/ MDX/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)* FOR IMPORT/TYPE APPROVAL OF DIAGNOSTIC X-RAY EQUIPMENT/RADIOTHERAPY SIMULATOR

[RADIOGRAPHY/RADIOGRAPHY AND FLUOROSCOPY (R&F)/DENTAL/ ORTHO-PAN-TOMOGRAPHY (OPG)/MAMMOGRAPHY/BONE DENSITOMETER/ MEDICAL X-RAY TUBE AND TUBE HEAD]

(a)	*The duly filled-in form (to be submitted in duplicate) should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(b)	*This application would be considered by AERB for issuance of other relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004,[AE(RP)R, 2004].*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*For all the forms pertaining to this Type approval, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*
(e)	*Separate application should be submitted for each Model of Medical X-ray equipment.*
(f)	*Attach extra sheets wherever required.*

* This application is for the purpose of importing the equipment to obtain Type approval. Subsequent to grant of NOC by AERB, it is required to submit separate application form for Type approval. To obtain Type approval, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (local supplier)[#]

Telephone No. (O): (R)
Fax No.
E-mail

A.2 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

[#] *Applicant is the person in whose name the 'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.*

PART B

PARTICULARS OF THE X-RAY EQUIPMENT

B. 1 Details of the equipment

B.1.1 Model and type of equipment :

(a) Generator:
(b) Tube:
(c) Table(s):
(d) Receptor/detector

B.1.2 Type of unit :

(a) Fixed radiography (conventional/digital)
(b) Radiography (mobile)
(c) Combined radiography and fluoroscopy (conventional/IIT/digital)

(d) Orthopan-tomography (OPG)
(e) Mammography
(f) Dental
(g) Bone densitometer
(h) Medical X-ray tube/tube head
(i) Others (specify)

B.1.3 This application is for

Type Approval/NOC			
Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

B.1.4 Number of equipment to be manufactured/ supplied per annum :

B.1.5 Anticipated useful life of the equipment :

B.1.6 Location with address where the equipment will be: demonstrated for type approval

B.1.7 Specifications of equipment:

(a) Maximum rating of the unit (Give individual ratings for all modes available)

(i) Operating potential (kV) :

(ii) Operating current (mA) :

(iii) Exposure time (in seconds) :

(b) Number of tubes :

(c) Details of generator:

(i) Name of the manufacturer and country :

(ii) Nominal voltage : ..... kV

(iii) Type of rectification : Half/full wave/other (specify)

(iv) Input power requirement : (Phase, voltage and frequency) :

(v) Generator output capacity : …….. kW

(d) Details of the X-ray tube

(i) Name of the manufacturer and country :

(ii) Tube voltage : ..... kV

(iii)	Tube current	:	..... mA
(iv)	Nominal continuous current	:	..... mA
(v)	Type of anode	:	Stationary/rotating
(vi)	Anode material	:	
(vii)	Anode heat capacity	:	..... HU
(viii)	Method of cooling of anode	:	
(ix)	Target material used and target angle:		
(x)	Number of focal spots	:	One/two
(xi)	Focal spots size	:	(Small:.....mm x ....mm) (Large:.....mm x.....mm) (Accuracy ..... mm)
(xii)	Whether position of focal spot marked on tube housing	:	Yes / No

(e) X-ray tube housing:

(i)	Shielding material and thickness (specify type of material and its lead equivalence)	:	
(ii)	Leakage radiation from the tube housing or maximum number of radiographs in one hour *	:	….µGy in one hour
	(*measured air kerma at maximum rating and measured values to be averaged over an area of 100 cm^2 at a distance of one metre from the target)		

(f) Beam limiting device

(i)	Type of beam limiting device(s) used	:	Light beam diaphragm/ cone/collimator/any special arrangements
(ii)	Leakage radiation through beam limiting devices *	:	..... µGy in one hour
(iii)	Light field and radiation field congruence (attach a radiograph)	:	within .....mm
(iv)	Dimensions of cones provided (Dental)	:	

(g) Filtration provided

(i) Inherent filtration (in mm of Al)

(ii) Added filtration (in mm of Al)

(iii) Total filtration (in mm of Al)

(iv) Specify if any material other than Al is used (in mm)

(h) Details of radiation output :

(i) X-ray beam output in mGy/mA at 80 kV for 20 x 20 cm^2 field at one metre : ..... µGy/mA

(ii) Exposure rate at table top for fluoroscopy for .... kV ..... mA (specify target to table top distance) : ..... µGy/min

(i) Details of fluoroscopy machines

(i) Minimum target to table top distance provided : .....cm

(ii) Lead glass backing of fluorescent screen (lead equivalence in mm) :

(iii) Specify the margin left all around the screen for maximum field size at minimum Target to table top distance :

(iv) Shutter movement mechanism :

(v) Type of 'ON'-'OFF' switch provided : Continuous/dead man type

(vi) Lead rubber flaps : Size Lead equivalence

(i) Below the screen : ..... X ..... cm^2 ..... mm

(ii) Sides of the screen : ..... X..... cm^2 ..... mm

(vii) Automatic exposure termination device: Yes/No

(viii) Maximum continuous exposure time and corresponding operating potential :

(ix) Material used for table top and aluminium equivalence of table top :

(x) Details of field limiting diaphragm :

(j) Details of image intensifier TV (IITV)

(i) Make and model :

(ii) Screen size :

(iii) High contrast resolution :

(iv) Low contrast resolution :

(v) Provision for reading kV, mA and pulse repetition rate :

(k) Details of digital detector

(i) Size/dimensions of the detector provided : .....cm X .....cm

(ii) Size of individual detector element : .....cm X .....cm

(iii) Type of detector and material : scintillator photodiode/ others (specify)

(iv) High contrast resolution :

(v) Low contrast resolution :

(l) Additional facilities for special examination : DSA/pulsed fluoro/cine radiography/others if any

B.1.10 Specify the national/ international standards :

B.1.11 Any other relevant information you may like to furnish

B 2 Renewal of Type approval

B.2.1 Any modification to the present design or changes in components

B 2.2 Provide operational experience feedback (OEF) with respect to performance of X-ray units supplied so far. (Attach details on the following)

(a) Common failures observed in the equipment supplied

(b) Generic deficiencies/operational problems reported by the users

(c) Occurrence of incidents, if any and causes/remedial measures

(d) Provide copies of feedback from the user institution.

B.3 Documents to be attached with the Application:

(i) Product technical catalogue

(ii) QA manual covering design and manufacturing aspects

(iii) Tube catalogue covering cooling curves for anode

(iv) Detector/image intensifier tube catalogue

(v) Copy of IEC certificate (in case of NOC) along with certificates from the laboratory where tests were carried out, with signatures of persons witnessing the test

(vi) Copy of BIS certificate (in case of local manufacturers)

(vii) Test report containing quality assurance checks as per **Appendix 8C-II** or **Appendix 8C-III** (as appropriate)

(viii) Manual for installation, operation, servicing, maintenance, dismantling, decommissioning

(ix) Letter from the manufacturer/designer authorising the Applicant (local supplier/vendor) for marketing the unit

(x) Special instructions to user on radiation safety in installation and use of X-ray equipment.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iv) the unit shall not be transported/transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(v) quarterly report will be provided giving information related to user (name, address and contact details); details of the X-ray units (number of X-ray units, model name, address and date of installation.)

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations that may be made from time to time by the competent authority in respect of radiation safety measures will be duly implemented.

(ix) the unit will be supplied only after obtaining a Type approval from the competent authority and only to users authorised by the competent authority.

(x) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(xi) the user shall be provided along with the equipment (i) Type approval certificate (ii) technical specifications; and (iii) operating, servicing and maintenance manuals.

(xii) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xiii) duly qualified/experienced persons will be appointed for demonstration of type testing of the device/equipment.

(xiv) the training shall be provided to the user on servicing/maintenance of the equipment.

(xv) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment.

(xvi) the faulty equipment involving safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xvii) any incident/accident such as fire, theft, damage etc., involving radiation generating equipment shall be promptly reported to AERB.

(xviii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules**.**

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-57a

(Refer section 3.18.1)

Form ID. AERB/RSD/ SIM/NOC-TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC) FOR IMPORT*/TYPE APPROVAL OF RADIOTHERAPY SIMULATOR

(a)	*The duly filled-in form (to be submitted in duplicate) should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(b)	*This application would be considered by AERB for issuance of other relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004].*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*For all the forms pertaining to this Type Approval, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*
(e)	*Separate application should be submitted for each Model of Radiotherapy Simulator equipment.*
(f)	*Attach extra sheets wherever required.*

***** This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, it is required to submit separate application form for Type Approval. To obtain Type Approval, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (local supplier)[#]

Telephone No. (O): (R)
Fax No.
E-mail

A.2 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

Applicant is the person in whose name the'Type Approval' for the radiation generating equipment may be issued under AE(RP)R, 2004.

PART B

PARTICULARS OF RADIOTHERAPY SIMULATOR

B.1 Details of the equipment

B.1.1 Model and type of equipment :

(a) Generator :

(b) Tube :

(c) Table(s) :

(d) Receptor/detector :

B.1.2 This application is for

Type Approval/NOC			
*Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.4 needs to be furnished.

B.1.3 Anticipated useful life of the equipment :

B.1.4 Location with address where the equipment will be demonstrated for type approval :

B.1.5 Specifications of equipment :

(a)	Maximum rating of the unit			
	(i)	Operating potential (kV)	:	
	(ii)	Operating current (mA)	:	
	(iii)	Exposure time (in seconds)	:	
(b)	Number of tubes		:	
(c)	Details of generator		:	
	(i)	Name of the manufacturer and country	:	
	(ii)	Nominal voltage	:	.....kV
	(iii)	Type of rectification	:	Half/Full wave/other (specify)
	(iv)	Input power requirement (Phase, voltage and frequency)	:	
	(v)	Generator output capacity	:	…….. kW
(d)	Details of the X-ray tube			
	(i)	Name of the manufacturer and country	:	
	(ii)	Normal tube voltage	:	..... kV
	(iii)	Normal tube current	:	..... mA
	(iv)	Nominal continuous current	:	..... mA
	(v)	Type of anode	:	Stationary/rotating
	(vi)	Anode material	:	
	(vii)	Anode heat capacity	:	..... HU
	(viii)	Method of cooling of anode	:	
	(ix)	Target material used and target angle	:	
	(x)	Number of focal spots	:	One/two
	(xi)	Focal spots size	:	(Small: .....mm x ....mm) (Large: .....mm x.....mm) (Accuracy ..... mm)
	(xii)	Whether position of focal spot marked on tube housing	:	Yes/No

(e) X-ray tube housing:

(i)	Shielding material and thickness: (specify type of material and its lead equivalence)		
(ii)	Leakage radiation from the tube housing* (*measured air kerma at maximum rating and measured values to be averaged over an area of 100 cm^2 at a distance of one metre from the target)	:	..... μGy in one hour

(f) Beam limiting device

(i)	Type of beam limiting device(s) used	:	Light beam diaphragm/ collimator/any special arrangements
(ii)	Leakage radiation through beam limiting devices* (*under condition specified in item (e)(ii) above)	:	..... μGy in one hour
(iii)	Light field and radiation field congruence (attach a radiograph)	:	within ..... mm

(g) Filtration provided

(i)	Inherent filtration (in mm of Al)	
(ii)	Added filtration (in mm of Al)	
(iii)	Total filtration (in mm of Al)	
(iv)	Specify if any material other than Al is used (in mm)	

(h) Details of image intensifier TV (IITV)

(i)	Make and model	:
(ii)	Screen size	:
(iii)	High contrast resolution	:
(iv)	Low contrast resolution	:
(v)	Provision for reading kV, mA and pulse repetition rate	:

(i) Details of digital detector

(i) Size/dimensions of the detector provided : ..... cm X ..... cm

(ii) Size of individual detector element : .....cm X ..... cm

(iii) Type of detector and material : Scintillator/photodiode/ other (specify)

(iv) High contrast resolution :

(v) Low contrast resolution :

(j) Additional facilities for special examination, if any :

B.1.6 Specify the national/ international standards to which unit complies :

B.1.7 Any other relevant information you may like to furnish

B.2 Specify the design specifications of the following parameters:

General Information:

(i) SAD (Source to axis distance), provide the details of range of SAD if available

(ii) Maximum field size at SAD :

S. No	Parameters	Tolerance limit &	Designed value	Remarks
1.	Hand control box, displays and safety interlocks provided and working satisfactorily			
2.	Coincidence between light field and X-ray field			
3.	Coincidence of X-ray cross wire projections at 90 and 270 degree			
4.	Optical beam and collimator axis coincidence			
5.	Shift of optical field due to vertical motion of couch			
6.	Shift in isocentre due to collimator, couch and gantry rotation			

S. No	Parameters	Tolerance Limit [&]	Designed value	Remarks
7.	Accuracy of ODI (70 - 150 cm)			
8.	Optical field size accuracy			
9.	Parallelism of delineators			
10.	Orthogonality of delineators			
11.	Symmetry of delineators			
12.	Coincidence of X-ray cross wire projections at 90^0 and 270^0			
13.	Optical field overlap0^0 & 180^0 and 90^0 and 270^0			
14.	Gantry angular scale verification			
15.	Table top material and its Al equivalence			
16.	Accuracy of kVp			
17.	Accuracy of timer			
18.	Linearity of mA station			
19.	Linearity of timer			
20.	Output consistency			
21.	Focal spot size			
22.	Total filtration (mm of Al) of the X-ray tube			
23.	Radiation leakage level at 1 meter from the tube for maximum rating in µGyh/hour			
24.	Image resolution (lp/mm)			

[&] as per the relevant standards

B.3 In case of renewal of Type Approval, then the following additional information/documents are to be submitted

(a) Nos. of equipment supplied so far in India as well as in other countries (with serial numbers).

(b) The name, address and contact details of the institutions in India, where the units installed.

(c) Details of servicing and preventive maintenance of these equipment carried out

(d) Any modification to the present design or changes in components/ materials of construction/QA procedures incorporated in the approved model. If so, give details.

(e) A certificate from the principal company that no reported incident/ accident occurred anywhere in the world while using the above model. In case any reported incident/accident of the same model, the details need to be submitted regarding remedial measures undertaken by the company.

(f) Provide operational experience feedback (OEF) with respect to performance of equipment supplied in India so far. (Attach details on the following)

(i) Availability of minimum safety accessories/spares and provide list

(ii) Common failures observed in the equipment supplied

(iii) Generic deficiencies/operational problems reported by the users

(iv) Occurrence of incidents, if any and causes/remedial measures.

(g) Whether the operational experience feedback (OEF) has been obtained from user of the equipment. Provide copies of feedback form duly signed by the users in India regarding performance of the unit.

B.4 Documents to be attached with the Application:

(a) Product technical catalogue

(b) QA manual covering design and manufacturing aspects

(c) Tube catalogue covering cooling curves for anode

(d) Detector/image intensifier tube catalogue

(e) Copy of IEC certificate (in case of NOC) along with certificates from the laboratory where tests were carried out, with signatures of persons witnessing the test

(f) Manual for installation, operation, servicing, maintenance, dismantling, decommissioning .

(g) Letter from the manufacturer/designer authorising the Applicant (local supplier/vendor) for marketing the unit.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iv) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(v) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vi) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(vii) all stipulations/recommendations that may be made from time to time by the competent authority in respect of radiation safety measures will be duly implemented.

(viii) the unit will be supplied only after obtaining a Type Approval from the competent authority and only to users authorised by the competent authority.

(ix) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(x) the user shall be provided along with the equipment (i) copy of Type Approval certificate (ii) technical specifications; and (iii) operating, servicing and maintenance manuals.

(xi) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the device/equipment.

(xiii) the training shall be provided to the user on servicing/maintenance of the equipment.

(xiv) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment.

(xv) the faulty equipment involving safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xvi) any incident/accident such as fire, theft, damage etc., involving radiation generating equipment shall be promptly reported to AERB.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules**.**

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-58
(Refer section 3.18.1)

Form ID:AERB/RSD/BIS/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR TYPE APPROVAL OF BAGGAGE INSPECTION X-RAY SYSTEM (BIS)

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004].*

(b) The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.

(c) Incomplete applications and those without all relevant documents are liable to be rejected.

(d) For all the forms pertaining to this equipment, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in

(e) Separate application should be submitted for each model of BIS.

(f) Attach extra sheets wherever required.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (Local Supplier)[#] :

Telephone No.: (O): (R)

Fax No. :
Mobile No. :
E-mail :

A.2 Name and address of the manufacturer

Telephone No.: (O):
Fax No. :
Mobile No. :
E-mail :

A.3 Name of the representative of the applicant to be contacted regarding the application

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

Applicant (local supplier) is the person in whose name the'Type Approval' for the radiation generating equipment may be issued under AE(RP)R, 2004.

PART B

DETAILS OF THE SYSTEM

B. 1 Details of the product:

(a) Name of the model of the unit

(b) Serial number of the Unit

(c) Name of the manufacturer

(d) Year and country of the manufacture of the equipment

(e) Type of unit : Cargo screening/Parcel viewing/Personal baggage checking/Any other:

B.2 Details of X-ray tube

(a) Name of manufacturer :

(b) Type/model- S. No. :

(c) Nominal maximum voltage:

(d) Nominal continuous current rating in mA:

(e) Type of anode:

(f) Stationary/rotating

(g) Anode heat capacity

(h) Method of cooling the anode

(i) Target material used and target angle

(j) Number of focal spots and focal spot size : One/two……mm x …….mm

(k) Inherent filtration provided in mm and material used :

B.3 Details of X-ray generator

(a) Nominal voltage

(b) Type of rectification (Half wave/Full wave/Multiples)

(c) Main power requirements

(d) Beam divergence……degrees

(e) Direction of X-rays facing up/facing side

B.4 Details of X-ray tube housing and beam limiting devices:

(a) Material of X-ray tube housing (shielding) and thickness. If the material used is other than lead, specify its lead equivalence.

(b) Type of beam limiting device/ devices used (collimator/any other)

Beam slit size (width) : ……..cm

(c) Filtration provided

(i) inherent/permanent filtration as to what is the number

(ii) added filtration

(iii) total (in mm of Al):

B.5 X-ray beam output : ……..µGy/mAs at ..…kV

B.6 Details of the cabinet of the baggage inspection X-ray system

(a) Cabinet size

(b) Tunnel size

(c) Conveyor length

(d) Conveyor speed

(e) Resolution

(f) Lead rubber flaps

(g) Size: ……..x…….cm^2

(h) Lead equivalence: ……mm

(i) Controls

(j) Safety interlocks

(k) Safety lock and key for the power supply

(l) X-ray beam 'ON' indicator lights

(m) Warning signs

B.7 Specify the national/international standards : Bureau of Indian Standards/ Any other (specify)

B.8 Any other relevant information you may like to furnish

B.9 Documents to be attached with the Application:

(a) Cooling curves

(b) Cross sectional drawing of the tube housing and tunnel indicating lead thickness in two perpendicular planes covering the detector

(c) Quality assurance manual for design and manufacture

(d) Manual for installation, operation, servicing, maintenance

(e) Copy of certificate of approval of the product for public use from the competent authority of the country of origin.

(f) In case of imported BIS, relevant national/international standards to which the product conforms (copy of the standard or its authentic English translation if the standard is in any other language.)

(g) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the BIS.

(h) Any other relevant documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit shall be supplied only after obtaining a Type Approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vi) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(vii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety measures will be duly implemented.

(viii) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(ix) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; and (iii) a copy of Type Approval certificate.

(x) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xi) the training shall be provided to the user on servicing/maintenance of the equipment.

(xii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-59

(Refer section 3.18.1)

Form ID. AERB/RSD/IGRED&X-RAY/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)* FOR IMPORT/CONSENT FOR TYPE APPROVAL OF INDUSTRIAL GAMMA RADIOGRAPHY EXPOSURE DEVICE (IGRED)/ SOURCE CHANGER/INDUSTRIAL X-RAY MACHINE

(a)	*This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*For all the forms pertaining to this practice, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*
(e)	*Separate application should be submitted for each model of Industrial Gamma Radiography Exposure Device and Source Changer/Industrial X-ray Machine.*
(f)	*Attach extra sheets wherever required and strike off which is not applicable.*

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the Applicant/Local Supplier #

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.2 Name and address of the local supplier:

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence of the applicant with PIN code:

Applicant/local supplier is the person in whose name the 'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.

PART B

PARTICULARS OF THE EQUIPMENT
(Fill as Applicable)

PART B.1 : PARTICULARS OF IGRED AND SOURCE CHANGER

B.1.1 Name and model of IGRED:

B.1.2 This application is for

Type Approval			
*Renewal of Type Approval	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.3 needs to be furnished.

B.1.3 Exposure device

B.1.3.1 Name and model:

B.1.3.2 Class of exposure device : Portable/Mobile/Fixed

B.1.3.3 Gross weight : ..... kg

B.1.3.4 Overall external dimensions (provide detailed drawing of the device) : ..... mm x ..... mm x ..... mm

B.1.3.5 Maximum source capacity : ..... GBq of ..... (specify the radionuclide)

B.1.3.6 Exposure mechanism :

B.1.4 Source housing

B.1.4.1 Material of shielding and its weight (If depleted uranium is used, specify its specific activity in Bq/Kg) :

B.1.4.2 Maximum thickness and minimum thickness : ……..... mm, maximum
: ..... mm, minimum

B.1.4.3 Source location from external reference points (specify) : ..... cm

B.1.4.4 Leakage radiation levels measured at maximum source capacity

(a) at 5 cm from source housing averaged over an area of 10 cm^2 : …..... mSv/h

(b) at 100 cm from source housing averaged over an area of 100 cm^2 : ..... mSv/h

B.1.5 Safety features

B.1.5.1 Locks (describe briefly the types of safety locks provided, locking mechanism etc.)

B.1.5.2 Can the source assembly be pushed/ pulled out of the equipment without operating the driving mechanism : Yes/No

B.1.5.3 Collimators (specify the type of collimator such as panoramic/straight beam/diaphragms, their radial angles, material of construction etc.) : .....

B.1.5.4 Any other safety device

B.1.6 Radioactive source assembly

B.1.6.1 Name and address of the manufacturer

B.1.6.2 Name and address of supplier

B.1.6.3 External dimensions : ..... mm x ..... mm x ..... mm

B.1.6.4 Gross weight : ..... g

B.1.6.5 Materials of construction (specify the materials of source capsule, source holder and provide a separate drawing giving the dimensions of various components of the source assembly)

(a) Source capsule :

(b) Source holder :

B.1.6.6 Classification number (attach a copy of the certificate) : C/E.....

B.1.6.7 Type of coupling provided between the source assembly and driving mechanism : .....

B.1.7 Source drive system

B.1.7.1 Model/type

B.1.7.2 Gross weight : kg .....

B.1.7.3 Overall external dimensions :

B.1.7.4 Source guide tube assembly

(a) Material : .....

(b) Diameter : ..... mm

(c) Length : ..... cm

B.1.7.5 Source drive cable

(a) Material : .....

(b) Diameter : ..... mm

(c) Length : ..... cm

B.1.7.6 End fittings (specify material, dimensions of end fittings to source guide tube and drive cable)

(a) Material : .....

(b) Diameter : ..... mm

(c) Length : ..... cm

B.1.7.7 Maximum distance between exposure device and control unit : ..... metre

B.1.7.8 Maximum distance between exposure device and source in extreme exposure positions when guide tube is connected : ..... metre

B.1.7.9 Operational mechanism of remote control : (describe briefly about any special lock, source position indicator, mechanical counter etc. provided in the cranking unit)

B.1.7.10 (a) Is the guide tube flexible or rigid ? : Flexible / rigid

(b) Material and dimension of the of guide tube : .....

B.1.7.11 Type of mounting provided for cranking unit : ..... (stand type/spool type/pistol grip type/any other)

B.1.8 Quality Assurance

For first approval, please furnish quality assurance procedures for entire manufacturing as well as procedures for servicing and maintenance

B.1.9 Details of person(s) trained in handling IGRED:

S. No.	Name	Designation	Academic qualifications	Gamma ray job experience	Details of training on radiation safety, if any	PMS No.

B.1.10 Specify the national/international standards to which the equipment conforms

B.1.11 Documents to be attached with the Application:

(a) Design drawings of the radiation source assembly, source housing, (shielding and material composition of the unit), beam status indicators, interlocks

(b) QA manual for design and manufacture

(c) Manual for operation, servicing, maintenance, disposal and emergency procedures

(d) Copy of certificate of type/design approval issued by competent authority of country of origin of design

(e) In case of imported equipment, provide the certificate of compliance with ISO/3999, (latest version) or AERB/RF-IR/SS-1 (Rev. 1) or other national standards of country of origin of design

(f) Copy of authenticated English version of the national/international standards to which the equipment conforms

(g) Copy of certificate for device as transport package issued by the competent authority of country of origin of design

(h) Detailed test report with description of each test, and the sequence in which the tests are carried out and evaluation of test results

(i) Certificates from the laboratory, if applicable, where tests were carried out, along with signatures of persons witnessing the test and authenticated photographs as evidence to the method adopted for carrying out the performance verification test

(j) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the unit

(k) Source retrieval/removal procedures

(l) List of countries to which such devices were earlier sold.

(m) Security plan for the facility as per 'AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' AERB/RF-RS/SG-1

(n) A copy of certificate for classification of sealed sources.

(o) Any other relevant document(s)

PART B. 2 PARTICULARS OF INDUSTRIAL X-RAY MACHINE

B.2.0 This application is for

Type Approval			
*Renewal of Type Approval	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.3 needs to be furnished.

B.2.1 Details of industrial X-ray machine :

B.2.1.1 Make :

B.2.1.2 Model/type :

B.2.1.3 Type of the X-ray unit :(directional/panoramic)(Fixed/mobile/portable)

B.2.1.4 Type of application of X-ray unit : (radiography/real time radiography/ digital radiography/tomography)

B.2.1.5	Maximum rating of the X-ray unit			
	(a)	Tube potential (kV)		
	(b)	Tube current (mA)		
	(c)	Exposure time (min.)		
	(d)	Cable length in accordance with tube potential		
B.2.1.6	Type of cooling of tube head, if any		:	Oil/water/air/others
B.2.1.7	Year and country of manufacture		:	
B.2.2	Details of X-ray tube		:	
B.2.2.1	Name of the manufacturer		:	
B.2.2.2	Type of X-ray tube		:	(metal ceramic tube/glass envelope)
B.2.2.3	Model No.		:	
B.2.2.4	Nominal peak voltage of the X-ray tube		:	
B.2.2.5	Nominal continuous current rating of the X-ray tube (in mA)		:	
B.2.2.6	Focal spot (s)			
	(a)	No. of focal spots	:	
	(b)	Focal spot size (s)	:	
	(c)	Specify the standard it conforms	:	NEMA/IEC/EN/others
B.2.2.7	Beam cone angle/direction		:	
B.2.2.8	Filtration (mm of Al)		:	
	(i)	Inherent	:	
	(ii)	Added	:	
	(iii)	Total	:	
B.2.3	Details of voltage generator		:	
B.2.3.1	Nominal voltage		:	
B.2.3.2	Type of rectification		:	Full wave/half wave/constant potential/high frequency

B.2.3.3	Mains power requirements	:	Single phase/Three phase
B.2.3.4	Type of cooling/insulation of generator : Oil/SF_6	:	
B.2.4	Details of X-ray tubing	:	
B.2.4.1	Material of X-ray tube housing (shielding) and thickness given. If the material used is other then lead then please specify its lead equivalence	:	
B.2.4.2	Leakage radiation from the tube housing (measured at maximum rating and measured values to be averaged over an area of 100 sq. cm. at 1 m from the target).	:	
B.2.5	Details of radiation output and leakage level	:	
B.2.5.1	Maximum beam output of the X-ray machine at its maximum rating in R/mA.min (X-ray out put in R/mA.min at 1 m for different kV should be furnished)	:	
B.2.5.2	Maximum head leakage level of the X-ray machine	:	
B.2.6	Details of imaging systems (for real time/digital radiography systems)	:	
B.2.6.1	Make and model of image intensifier tube (IIT)/CCD	:	
B.2.6.2	Name of the manufacturer	:	
B.2.6.3	Input and output phosphor of IIT	:	
B.2.6.4	Type of imaging systems	:	Imaging plate/Flat panel/CCD
B.2.6.5	Imaging area and magnification factor	:	
B.2.6.6	Name of the manufacturer of viewing systems	:	

B.2.6.7 Name of the manufacturer of recording systems :

B.2.6.8 Resolution achieved (Line pair/mm) :

B.2.6.9 Contrast achieved (Visible hole and wire mesh line) :

B.2.7 Details of type testing :

B.2.7.1 Place where the unit is tested for type approval :

B.2.7.2 Details of type testing facilities available with manufacturer/applicant

B.2.7.3 Quality assurance programme during manufacturing

B.2.8 Details of person(s) trained in handling the industrial X-ray machines:

S. No.	Name	Designation	Academic qualifications	X-ray job experience	Details of training on radiation safety, if any	PMS No.

B.2.9 Other relevant information :

B.2.9.1 Specify the national/international standard : ISO/EN/IEC/BIS/others

B.2.9.2 Standards to which equipment conform :

B.2.10 Whether the equipment complies with the relevant requirements of AERB Safety Code on 'Industrial Radiography' (AERB/SC/IR-1) : Yes/No (Documentary evidence to be provided)

B.2.11 Documents to be attached with the Application :

(a) Design drawings of the X-ray tube housing (shielding and material composition of the unit), beam status indicators, interlocks and control circuits

(b) QA manual for design and manufacture

(c) Manual for operation, servicing, maintenance, and emergency procedures

(d) Copy of certificate of type/design approval issued by competent authority of country of origin of design

(e) In case of imported equipment, relevant national/international standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language)

(f) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the unit

(g) Invoice copy of procured QA kits / tools in respect of radiation safety

(h) List of countries to which such devices were earlier sold

(i) Any other relevant documents.

PART B.3 RENEWAL OF TYPE APPROVAL OF IGERD/SOURCE CHANGER/X-RAY MACHINE

B.3.1 No. of equipment supplied so far in the country (with S. Nos.)

B.3.2 Name and address of the institutions where these equipment are being used

B.3.3 Any change in the radioactive material or its quantity in the approved model

B.3.4 Details of servicing and preventive maintenance of these equipments are carried out

B.3.5 Any modification to the present design or changes in components/materials of construction/QA procedures incorporated in the approved model.
If so, give details.

B.3.6 Provide operational experience feedback (OEF) with respect to performance of equipment supplied so far. (Attach details on the following)

(a) Availability of minimum safety accessories/spares and provide list

(b) Common failures observed in the equipment supplied.

(c) Generic deficiencies/operational problems reported by the users

(d) Occurrence of incidents, if any and causes/remedial measures.

B.3.7 Whether the operational experience feedback (OEF) has been obtained from user of the equipment (Provide copies of feedback from the user institution.)

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit will be supplied only after obtaining a Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(x) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; and (iii) a copy of Type Approval certificate.

(xi) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xiii) the training shall be provided to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xv) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment and disposal of the decayed source and any other contaminated material of the equipment be arranged.

(xvi) the faulty equipment involving source housing and other safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xvii) the user shall be assisted in case of any emergency related with radioactive source.

(xviii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-60
(Refer section 3.18.1)

Form ID: AERB/RSD/IRGD-NG/NOC-TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)* FOR IMPORT/TYPE APPROVAL OF IONISING RADIATION GAUGING DEVICES (IRGDs)/NUCLEONIC GAUGES (NGs)

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*

(b) The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.

(c) Incomplete applications and those without all relevant documents are liable to be rejected.

(d) For all the forms pertaining to this equipment, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in

(e) Separate application should be submitted for each model of IRGD/NG.

(f) Attach extra sheets wherever required.

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the Applicant/Local supplier#

Telephone No. (O): (R)
Fax No.

Mobile
E-mail

A.2 Name and address of the local supplier:

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Name of Radiological Safety officer (RSO[$])

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail
RSO approval ref. No.
Valid up to:

A.6 Address for correspondence of the applicant with PIN code:

[#] *Applicant/local supplier is the person in whose name the NOC/Type Approval' for the IRGD/NG may be issued, under Atomic Energy(Radiation Protection)Rules, 2004.*

[$] *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of 'Radiological Safety Officer' prescribed in Atomic Energy (Radiation Protection) Rules, 2004.*

PART B

PARTICULARS OF THE IRGD/NUCLEONIC DEVICE

B.1 This application is for:

Type Approval/NOC			
*For renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in PART C needs to be furnished.

B.2 Details of the IRGD/gauging device

B.2.1 Model and type designation :

B.2.2 Description of the nature of the device : Level gauge/Density gauge/ Moisture gauge/Thickness gauge/any other ———— (specify)

B.2.3 Description of the type of the device : Portable/fixed/dolly mounted/ any other ———— (specify)

B.2.4 Principle of operation of the device : Radiation transmission/radiation backscatter/ ——— (specify)

B.2.5 The purpose for which the device is likely to be installed :

B.2.6 Number of devices to be manufactured/ supplied/per annum :

B.2.7 Anticipated useful life of the gauging device :

B.2.8.1 Place where the device will be demonstrated for type approval :

B.2.8.2 Details of test facilities available at the site :

B.2.9 What is the height at which the device is likely to be installed : Ground level/ : at a height of 9 m or less/ at a height of more than 9 m

B.2.10 Source holder (detailed drawing and design description) :

B. 2.11 Source location from external reference points :

B.2.12 Source housing (detailed drawing and design description) :

B.2.13	Radiation shielding material (maximum and minimum thickness in mm and IS designation of the material)	:	
B.2.14	What is the frequency of operation of the shutter of the device (operations/year)	:	————
B.2.15	Gross weight of the device	:	
B.2.16	What is the source housing classification (as per the national/international standards)	:	
B.3	Radiation source		
B.3.1	Radioactive material	:	
B.3.2	Chemical and physical form of radionuclide	:	
B.3.3	Maximum source rating	:	.....Bq (.....Ci) of..... (radionuclide)
B.3.4	Number of sources in the device (specify radionuclide and maximum activity of each source)	:	
B.3.5	Overall dimensions of the source	:	
B.3.6	Active dimensions of the source	:	
B.3.7	Material and thickness of encapsulation or protective covering	:	
B.3.8	Sealed source classification (Please attach the source certification)	:	C/E……
B.3.9	Source retrieval/removal procedures and availability of accessories/tools for retrieval/removal		
B.3.10	X-ray tube source (if applicable)	:	
	(a) Maximum tube voltage	:	.....kV
	(b) Maximum tube current	:	..... mA
	(c) Radiation output at 10 cm (specify kV and mA)	:	

B.3.11	Source access control (sketch or drawing to describe the physical protection of the source and description of control)	:	
B.4	Useful beam controls		
B.4.1	Type of useful beam control (moving shutter/moving source in case of radionuclide device and electrical controls in case of X-ray tube device)	:	
B.4.2	What is the frequency of operation in case of moving shutter	:	———————— operations/year
B.4.3	Useful beam control mechanism	:	
	(a) pneumatic		
	(b) electrical		
	(c) mechanical		
	(d) electromechanical		
B.4.4	Description of useful beam control mechanism with detailed drawings showing material and thickness of the shutter or useful beam absorber/ shield	:	
B.4.5	Dimensions of the measuring gap	:	
B.4.6	Size and shape of the useful beam	:	
B.4.7	Automatic source 'OFF' mechanism for radionuclide device	:	
B.4.8	Description of beam 'ON/OFF' mechanism for X-ray source	:	
B.4.9	Useful beam status indicators (visual/other)	:	
B.4.10	Location of status indicators	:	
B.4.11	Distance from the device up to which the status indication is observable in clear day light	:	
B.4.12	Markings and labels affixed on the gauging device	:	

B.4.13 Maximum number of operational cycles for which the device is designed :

B.4.14 Anticipated useful life of the gauging device :

B.5 Results of Type tests

B.5.1 Maximum stray radiation level in µSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.2 Normal use condition-temperature test

High temperature :

Low temperature :

B.5.2.1 Was the gauge in operational condition after the test : Yes/No

B.5.2.2 Maximum stray radiation level in µSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.3 Accident condition
Fire (specify temperature)

B.5.3.1 Did the source remain captive after the test : Yes/No

B.5.3.2 Maximum stray radiation level in µSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.4 Accident condition drop test − 9 m :

B.5.4.1 Did the source remain captive after the test : Yes/No

B.5.4.2 Maximum stray radiation level in μSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.5 Endurance test : Yes/No

(specify the number of trials) : ———— cycles

B.5.5.1 Maximum stray radiation level in μSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.6 Vibration test : Yes/No

Specify the frequency : ———— Hz

B.5.6.1 Maximum stray radiation level in μSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.7 Impact test (applicable only to portable gauges) : Applicable/Not applicable

B.5.7.1 Horizontal shock test : Yes/No

B.5.7.1.1 Maximum stray radiation level in μSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.7.2 Vertical shock test : Yes/No

B.5.7.2.1 Maximum stray radiation level in μSv/h at the specified distances from the external surfaces of the device :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.5.8 Any other test :

B.5.9 Gauge classification designation :

B.6 Tests for Transport Package

(a) Water spray test : Yes/No

(b) Free drop test : Yes/No

(c) Penetration test : Yes/No

(d) Stacking test : Yes/No

(e) Captivity of the source in the package : Yes/No

(f) Maximum stray radiation level at the specified surface of the package in which the device would be transported :

Radiation level-position	at 5 cm from the surface	at 100 cm from the center of the source
ON		
OFF		

B.7 Quality assurance programme
(Please furnish a copy of the quality assurance manual giving details of QA organisation, material control, document control, internal and external audit etc.)

B.8 Description of packaging for transport:
(Furnish information on the design of the packages and tests carried out for compliance with AERB Safety Code for 'Transport of Radioactive Materials', (AERB/SC/TR-1)

B.9 Radiation safety requirements in installation and use

(a) Nature and description of interlocks:

(b) Nature and description of auxiliary shielding:

(c) Recommended procedures for in-service maintenance and repairs

(d) Organisation responsible for servicing and maintenance

(e) Recommendations on decommissioning, dismantling and disposal of gauging devices

(f) Recommended procedures for removal and disposal of radiation source

(g) Organisation responsible for decommissioning, dismantling and disposal of radiation source

B.10 Emergency provisions

B.10.1 Provision in case of the device getting stuck in the 'ON' position

B.10.2 Provision for physical security of the : source from tampering, theft or unauthorised use

B.10.3 Other safety provisions to protect the device from

(a) chemical corrosion

(b) ingress of water, mud, dust

(c) protection from fire and flood :

B.11 Standards to which the gauging device conforms to AERB/SS-2 (Rev. 1) or any other (if the device is designed and built in accordance with a standard, please furnish a copy of the standard or its authentic English translation if the standard is in any other language.)

B.12 Details of person(s) who are trained in handling the IRGD/nucleonic devices:

S. No.	Name of person	Designation	Academic qualifications	RIGD handling experience	Details of training on radiation safety, if any	PMS No.

B.13 Documents to be attached with the Application:

(a) Design drawings of the radiation source holder, source housing (shielding and material composition of the unit), useful beam controls, useful beam status indicators, interlocks and control circuits.

(b) QA manual for design and manufacture of the device/source.

(c) Manual for installation, operation, servicing, maintenance, dismantling, decommissioning and disposal and emergency procedures

(d) Copy of certificate of type/design approval issued by competent authority of country of origin of design

(e) Special instructions to user on radiation safety in installation and use of gauging devices

(f) Copy of the standard to which device complies with [if other than AERB/SS-2 (Rev. 1)]

(g) Detailed test report with description of each test, the sequence in which the tests are carried out and evaluation of test results

(h) Certificates from the accredited laboratory where tests were carried out, along with signatures of persons witnessing the test and authenticated photographs as evidence to method adopted for carrying out the performance verification test

(i) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the unit.

(j) Source retrieval/removal procedures and list of accessories/tools available for retrieval/removal

(k) National/international standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language).

(l) List of countries to which such devices were earlier sold.

(m) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' AERB/RF-RS/SG-1

(n) Undertaking from the original supplier of the source for accepting disused/decayed/damaged source for disposal

(o) Any other information you may like to furnish

PART C

RENEWAL OF TYPE APPROVAL OF IRGD/NG
(TO BE FILLED IN ALONG WITH PART B.1)

C.1.1 Nos. of devices supplied so far in the country (with S. Nos.)

C.1.2 Name and address of the institutions where these devices are being used

C.1.3 Any change in the radioactive material or its quantity in the approved model

C.1.4 Details of servicing and preventive maintenance of these devices carried out

C.1.5 Any modification to the present design or changes in components/materials of construction/QA programme incorporated in the approved model.
If so, give details.

C.1.6 Provide operational experience feedback (OEF) with respect to performance of devices supplied so far. (Attach details on the following)

(a) Availability of minimum safety accessories/spares and provide list

(b) Common failures observed in the devices supplied

(c) Generic deficiencies/operational problems reported by the users

(d) Occurrence of incidents, if any and causes/remedial measures.

C.1.7 Whether the operational experience feedback (OEF) has been obtained from user of the device (Provide copies of feedback from the user institution.)

PART D

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit shall be imported/supplied only after obtaining a NOC/Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) the unit will be supplied only after obtaining a Type Approval from the competent authority and only to users authorised by the competent authority.

(x) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(xi) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; and (iii) a copy of Type Approval certificate.

(xii) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xiii) duly qualified/experienced persons will be appointed for demonstration of type testing of the device/equipment.

(xiv) the training shall be provided to the user on servicing/maintenance of the equipment.

(xv) the procedures described by AERB regarding decommissioning, disposal of contaminated/decayed sources and reuse of the unit will be strictly complied with.

(xvi) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment and disposal of the decayed source and any other contaminated material of the equipment be arranged.

(xvii) the faulty equipment involving source housing and other safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xviii) the user shall be assisted in case of any emergency related with radioactive source.

(xix) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xx) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-61

(Refer section 3.18.1)

Form ID: AERB/RSD/CP/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR TYPE APPROVAL OFCONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*

(b) The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.

(c) Incomplete applications and those without all relevant documents are liable to be rejected.

(d) For all the forms pertaining to this equipment, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in

(f) Attach extra sheets wherever required.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (Local Supplier)[#] :

Telephone No.: (O): (R)
Fax No. :
Mobile No.:
E-mail:

A.2 Name and address of the manufacturer

Telephone No.: (O):
Fax No. :
Mobile No.:
E-mail:

A.3 Name of the representative of the applicant to be contacted regarding the application

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

Applicant (local supplier) is the person in whose name the 'Type Approval' for design and manufacture of consumer product containing radioactive material may be issued, under AE(RP)R, 2004.

PART B

PARTICULARS OF THE CONSUMER PRODUCT

B.1 Details of the product:

(a) Name, model

(b) Description of the product :

(c) Intended use :

(d) Expected useful life :

(e) Identification, concentration and total activity of the radionuclide(s) used in product.

(f) Chemical and physical form of the radionuclides to be applied to or incorporated in the product.

(g) Radiation level on the accessible external surface of the product and the method of measurement.

(h) Function served by the radionuclide(s).

(i) Justification for choice of radionuclide, particularly in relation to other radionuclides of lower radiotoxicity or more appropriate half-life that could be used.

(j) Justification for the use of the radioactive substance in the product making comparison with any non-radioactive alternatives.

B.2 Documents to be attached with the Application:

(a) Detailed drawings of the design of product, particularly as related to the containment and shielding of the radionuclide under normal and adverse conditions of use and disposal.

(b) Details of manufacturing process along with flow chart.

(c) Quality assurance programme addressing design, manufacture and quality control tests to be applied to radiation source, other components and finished products.

(d) Assessment report addressing the following:

  (i) total activity of radioactive material(s) expected to be distributed in the consumer products annually

  (ii) importance of the market

  (iii) future avenues of distribution.

(e) Instructions for use, installation and maintenance.

(f) Copy of certificate of approval of the product for public use from the competent authority of the country of origin.

(g) In case of imported consumer product, relevant national/international standards to which the product conforms (copy of the standard or its authentic English translation if the standard is in any other language).

(h) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the consumer product.

(i) Assessment of possible consequences of misuse, damage or failure.

(j) Description and results of tests for demonstrating radiological integrity of the product in normal use, misuse and accidental damage.

(k) Details of information (in advertising material, technical brochures, maintenance instructions, guarantee certificates, etc.) on the radionuclide(s) incorporated and the total amount of activity in the product.

(l) Information on how it is intended to label the product (e.g. name of product, date of manufacture and product identification number, radionuclide(s) identification and activity and radiation warning symbol)

(m) Any other relevant documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the product shall be supplied only after obtaining a Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vi) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(vii) all stipulations/recommendations made from time to time by the cmpetent authority in respect of radiation safety measures will be duly implemented.

(viii) the rules regarding disposal of disused consumer products containing radioactive sources will be strictly complied with.

(ix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-62
(Refer section 3.18.1)

Form No: AERB/RSD/MCY/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE FOR IMPORT/TYPE APPROVAL OF MEDICAL CYCLOTRON

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *For all the forms pertaining to this practice, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*

(e) *Separate application should be submitted for each model of medical cyclotron.*

(f) *Attach extra sheets wherever required and strike off which is not applicable.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant#

Telephone No. (O): (R)
Fax No.
E-mail

A.2 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

Applicant is the person in whose name the ' Type Approval' for the radiation generating equipment may be issued, under Atomic Energy (Radiation Protection) Rules, 2004.

PART B

PARTICULARS OF THE EQUIPMENT

B.1 Purpose for which the equipment will be used:

(a) Production of radioisotopes (list radioisotopes):

(b) Any other (specify) :

B.2 Type of equipment

(a) Self shielded :

(b) Non- self shielded :

(c) Any other (specify) :

B.3 This application is for:

Type Approval/NOC			
**Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

** For renewal of Type Approval certificate, additional information, as given in B.9 needs to be furnished.

B.4 Location where the unit is to be type tested for Type approval

B.5 Details of equipment specification

(a) Name of the unit:

(b) Make, model and type:

(c) Year and country of manufacturer:

(d) Anticipated working life of the cyclotron:

(e) Beam details

(i) Particle accelerated:

(ii) Target Material:

(iii) No. of target ports:

(iv) Maximum energy in (MeV):

(v) Maximum current in (μA/mA):

(i) Single beam:

(ii) Dual beam:

(f) Leakage radiation level for neutrons and gamma rays at one metre from the target when beam is 'ON' for maximum energy and maximum current.

(g) Isodose profiles around the cyclotron

(h) Details of housing including self-shielding material, its thickness and density.

(i) TVT for the shielding materials for neutrons and gamma radiation.

B.6 Built-in safety features/operation :
(Furnish all features to prevent any radiologically unsafe malfunction of the equipment)

B.7 Specify the national/international standards to which the cyclotron comply:

B.8 Documents to be attached with the Application:

(a) Relevant documents such as installation manual, operation/servicing manual and quality assurance (QA) aspects

(b) Drawing showing the radiation shielding and material composition of the unit (scale 1:2).

(c) Drawings along with the functional description of safety related control systems and devices. (Electrical/mechanical/fire/chemical/ toxic gases etc.)

(d) In case of imported equipment, relevant national/international standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language.)

(e) Test report on the performance of the cyclotron demonstrating the compliance with the applicable standard.

(f) Copy of certificate of approval from country of origin that the equipment is approved for production of radioisotopes for medical use.

(g) Any other information you may like to furnish.

B.9 Renewal of Type Approval of medical cyclotron

B.9.1 No. of equipment supplied so far in the country (with S. Nos.)

B.9.2 Name and address of the institutions where these equipment are being used

B.9.3 Details of servicing and preventive maintenance of these equipment carried out

B.9.4 Any modification to the present design or changes in components/materials of construction/QA procedures incorporated in the approved model.
If so, give details.

B.9.5 Provide operational experience feedback (OEF) with respect to performance of equipment supplied so far. (Attach details on the following)

(a) Availability of minimum safety accessories/spares and provide list

(b) Common failures observed in the equipment supplied.

(c) Generic deficiencies/operational problems reported by the users.

(d) Occurrence of incidents, if any and causes/remedial measures.

B.9.6 Whether the operational experience feedback (OEF) has been obtained from user of the equipment (Provide copies of feedback from the user institution.)

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the equipment will be supplied only after obtaining NOC/Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(viii) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(ix) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; and (iii) Type approval certificate

(x) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xi) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xii) the training shall be provided to the user on servicing/maintenance of the equipment.

(xiii) the rules regarding decommissioning, disposal/reuse of contaminated equipment will be strictly complied with.

(xiv) technical assistance to the user in case of decommissioning/ dismantling of equipment shall be provided and disposal of any contaminated material of the equipment be arranged.

(xv) the user shall be assisted in case of any emergency related with radioactive source.

(xvi) any incident/accident such as fire, theft, damage etc.,involving ionising radiation source shall be promptly reported to AERB.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-63

(Refer section 3.18.1)

Form ID. AERB/RSD/IND-ACC/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)* FOR IMPORT/CONSENT FOR TYPE APPROVAL OF INDUSTRIAL ACCELERATOR FACILITY

(a)	*This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*
(b)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(c)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(d)	*For all the forms pertaining to this practice, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*
(e)	*Separate application should be submitted for each model of industrial accelerator.*
(f)	*Attach extra sheets wherever required and strike off which is not applicable.*
*	This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the Applicant[#]

Telephone No. (O): (R)

Fax No.
Mobile No.
E-mail

A.2 Name and address of the local supplier:

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence of the applicant with PIN code:

[#] *Applicant/local supplier is the person in whose name the 'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.*

PART B

PART B.1 FOR FIRST TYPE APPROVAL OF ACCLERATOR

B.1 Particulars of the equipment

B.1.1 Purpose for which the equipment will be used: (choose as applicable)

(a) Radiography: Open field/Enclosed installation

(b) Radiation processing

(c) Others (Please specify)

B.1.2 Type of equipment (choose as applicable)

(a) Portable

(b) Mobile

(c) Stationary

B.1.3 This application is for:

Type Approval/NOC			
*Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.2 needs to be furnished.

B.1.4 Location where the unit is to be type tested for Type Approval

B.1.5 Details of equipment specification

B.1.5.1 Name of the unit:

B.1.5.2 Make, model and type:

B.1.5.3 Year and country of manufacturer:

B.1.5.4 Anticipated working life of the accelerator:

B.1.5.5 Beam details

(i) Type of beam :

(ii) Maximum energy in (MeV) :

(iii) Maximum current in (ì A/mA) :

B.1.5.6 Maximum beam dimension/shape :

B.1.5.7 Maximum particle fluence rate at 1 meter in ($cm^{-2} s^{-1}$)

B.1.5.8 Maximum energy, of the beam when unit is operated at full rated capacity:

B.1.5.9 Stray radiation levels when unit is operated at full rated capacity at distance of one metre from the source head (in mGy/h):

B.1.6 Built-in safety features/operation :
(Furnish all procedures to prevent any radiologically unsafe malfunction of the equipment)

B.1.7 Details of person(s) who are trained in handling the radiation source/ equipment:

S. No.	**Name of person**	**Designation**	**Academic qualifications**	**Radiation Source/ equipment handling experience**	**Details of training on radiation safety, if any**	**PMS No.**

B.1.8 Specify the national/international standards to which the accelerator comply:

B.1.9 Whether the equipment complies with the relevant requirements of AERB Safety Code on 'Industrial Radiography' (AERB/SC/IR-1) and guidelines issued by competent authority : Yes/No
(Documentary evidence to be provided)

B.1.10 Documents to be attached with the Application:

(a) Design drawings of the source housing (shielding and material composition of the unit), beam status indicators, interlocks, along with the functional description of safety related control systems and devices.

(b) QA manual for design and manufacture

(c) Manual for operation, servicing, maintenance, disposal and emergency procedures.

(d) Copy of certificate of approval from country of origin

(e) In case of imported equipment, relevant national/international standards to which the equipment conforms (copy of the standard or its authentic English translation if the standard is in any other language.)

(f) Detailed test report with description of each test, the sequence in which the tests are carried out and evaluation of test results.

(g) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the equipment

(h) List of countries to which such devices were earlier supplied/ installed.

(i) Any other relevant document(s).

PART B 2

RENEWAL OF TYPE APPROVAL OF INDUSTRIAL ACCELERATOR (Fill as Applicable)

B.2.1 Nos. of equipment supplied so far in the country (with S. Nos.)

B.2.2 Name and address of the institutions where these equipment are being used

B 2.3 Details of servicing and preventive maintenance of these equipment carried out

B.2.4 Any modification to the present design or changes in components/materials of construction/QA program procedures incorporated in the approved model. If so, give details.

B.2.5 Provide operational experience feedback (OEF) with respect to performance of equipment supplied so far. (Attach details on the following)

(a) Availability of minimum safety accessories/spares and provide list

(b) Common failures observed in the equipment supplied.

(c) Generic deficiencies/operational problems reported by the users

(d) Occurrence of incidents, if any and causes/remedial measures.

B.2.6 Whether the operational experience feedback (OEF) has been obtained from user of the equipment (Provide copies of feedback from the user institution.)

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form

(iii) the equipment will be supplied only after obtaining Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(viii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(x) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals; and (iii) a copy of Type Approval certificate

(xi) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the equipment.

(xiii) the training shall be provided to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal/reuse of contaminated equipment will be strictly complied with.

(xv) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment and disposal of any contaminated material of the equipment be arranged.

(xvi) the user shall be assisted in case of any emergency related with radioactive source.

(xvii) any incident/accident such as fire, theft, damage etc. involving ionising radiation source shall be promptly reported to AERB.

(xviii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-64

(Refer section 3.18.1)

Form ID: AERB/RSD/GIC/NOC-TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)* FOR IMPORT/TYPE APPROVAL OF GAMMA IRRADIATION CHAMBER (GIC)

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004].*

(b) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *For all the forms pertaining to this equipment, AE(RP)R, 2004 and other information in this regard, refer to the website: www.aerb.gov.in*

(e) *Separate application should be submitted for each model of GIC.*

(f) *Attach extra sheets wherever required.*

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. This application form would be reviewed for considering Type Approval. However, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the Applicant/Local supplier[#]

Telephone No. (O): (R)
Fax No.
Mobile
E-mail

A.2 Name and address of the local supplier:

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Name of radiological safety officer (RSO*), if any

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail
RSO approval Ref. No.
Valid up to:

A.6 Address for correspondence of the applicant with PIN code:

Applicant/local supplier is the person in whose name the 'NOC/Type Approval' for the GIC may be issued, under Atomic Energy(Radiation Protection)Rules, 2004.

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of 'Radiological Safety Officer' prescribed in Atomic Energy (Radiation Protection) Rules, 2004.*

PART B

PART B.1 PARTICULARS OF THE DEVICE

B.1 This application is for:

Type Approval/NOC			
*Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of type approval certificate, additional information, as given in B.2 needs to be furnished.

B.2 Details of GIC

B.2.1 Model and type designation :

B.2.2 Description of the nature of GIC : Gamma chamber/Gamma cell/ Blood irradiator

B.2.3 The purpose of the GIC :

B.2.4 Number of devices to be manufactured/ supplied/per annum :

B.2.5 Anticipated useful life of the GIC :

B.2.6 Place where the GIC will be demonstrated for type approval :

B.2.7 Gross weight of the GIC

B.2.8 Source location from external reference points :

B.2.9 National/international standards to which the GIC conforms to :

B.3 Particulars of radiation source and shielding

B.3.1 Name of radioisotope:

B.3.2 Chemical and physical form of radioisotope :

B.3.4 Maximum source strength : ..... Bq (.....Ci)

B.3.5 Number of sources in the device maximum activity of each source :

B.3.6 Overall dimensions of the source and geometry in GIC :

B.3.7 Active dimensions of the source :

B.3.8 Material and thickness of encapsulation or protective covering :

B.3.9 Sealed source classification number :

B.3.10 Radiation shielding material (maximum and minimum thickness in mm and IS designation of the material) :

B.4 Particulars of the control panel indicators

B 4.1 Device ON/OFF status indicators (visual/other) :

B.4.2 Location of status indicators :

B.4.3 Distance from the device up to which the status indication is observable :

B.4.4 Markings and labels affixed on the GIC :

B.5 Maximum stray radiation level in μSv/h (mR/h) at the specified distances from the external surfaces of the GIC:

Radiation level-position	**at 5 cm from the surface**	**at 100 cm from the source**
ON		
OFF		

B.6 Description of packaging for transport:

Whether GIC is approved as a transport package (In case yes, a copy of transport package certificate to be attached) : Yes/No

B.7 Radiation safety requirements

B.7.1 Standard operating procedures for GIC : Available/Not available

B.7.2 Nature and description of interlocks :

B.7.3 Recommended procedures for in-service maintenance and repairs : Available/Not available

B.7.4 Organisation responsible for servicing and maintenance :

B.7.5 Recommendations on decommissioning, dismantling and disposal of GIC : Available/Not available

B.7.6 Recommended procedures for removal and disposal of radiation source : Available/Not available

B.7.7 Organisation responsible for decommissioning, dismantling and disposal of radiation source :

B.8 Emergency provisions

B.8.1 Provision in case of the sample chamber getting stuck during irradiation.

B.8.2 Provision for physical security of source from tampering, theft or unauthorised use.

B.9 Documents to be attached with the Application

(a) Design drawing and description of the radiation source holder, source housing, useful beam controls, useful beam status indicators, interlocks, and control circuits.

(b) Source retrieval/removal procedures and list of accessories/tools available for retrieval/removal

(c) Source access control (sketch or drawing to describe the physical protection of the source and description of control)

(d) Undertaking from the supplier of the source for disposal

(e) Description details for safety systems, interlocks control systems, etc.

(f) Description of packaging for transport along with a copy of transport package certificate issued by competent authority of the country of origin of GIC

(g) Quality assurance manual during manufacturing of GIC

(h) National/international standard to which GIC complies with (copy of the standard or its authentic English translation if the standard is in any other language)

(i) Installation and operation manual giving procedures to be followed during emergency situations.

(j) Certificate from the competent authority of the country of design/ manufacture to the effect that the gamma chamber is approved for use.

(k) Sealed source classification certificate issued by source manufacturer

(l) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the unit

(m) Performance report on the GIC of same type used in India or anywhere else for the past five years.

PART B.2 RENEWAL OF TYPE APPROVAL OF GIC (FILL AS APPLICABLE)

B.3.1 Nos. of devices supplied so far in the country (with S. Nos.)

B.3.2 Name and address of the institutions where these devices are being used

B.3.3 Any change in the radioactive material or its quantity in the approved model

B.3.4 Details of servicing and preventive maintenance of these devices are carried out

B.3.5 Any modification to the present design or changes in components/materials of construction/QA procedures incorporated in the approved model. If so, give details.

B.3.6 Provide operational experience feedback (OEF) with respect to performance of devices supplied so far.
(Attach details on the following)

(a) Availability of minimum safety accessories/spares and provide list

(b) Common failures observed in the devices supplied

(c) Generic deficiencies/operational problems reported by the users

(d) Occurrence of incidents, if any and causes/remedial measures.

B.3.7 Whether the operational experience feedback (OEF) has been obtained from user of the device (Provide copies of feedback from the user institution)

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit shall be imported/supplied only after obtaining a NOC/Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/transferred/sold/rented by me/us to another user without the prior permission of the competent authority.

(vi) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(vii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as

required by the competent authority will be duly carried out at my/ our expense.

(viii) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(ix) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(x) the user shall be provided along with the equipment (i) technical specifications; (ii) operating, servicing and maintenance manuals, (iii) a copy of Type Approval certificate.

(xi) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xii) duly qualified/experienced persons will be appointed for demonstration of type testing of the device/equipment.

(xiii) the training shall be provided to the user on servicing/maintenance of the equipment.

(xiv) the rules regarding decommissioning, disposal of contaminated/ decayed sources and reuse of the unit will be strictly complied with.

(xv) technical assistance shall be provided to the user in case of decommissioning/dismantling of equipment and disposal of any contaminated material of the equipment be arranged.

(xvi) the faulty equipment involving source housing and other safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xvii) the user shall be assisted in case of any emergency related with radioactive source.

(xviii) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xix) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the

regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place:	Signature:
Date:	Name of applicant:
	Designation:

(Seal of the institution)

ANNEXURE-65

(Refer section 3.18.1)

Form ID. AERB/RSD/ MDX-CT-CATH/TA

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR NO OBJECTION CERTIFICATE (NOC)*/TYPE APPROVAL OF MEDICAL DIAGNOSTIC X-RAY EQUIPMENT [COMPUTED TOMOGRAPHY (CT)/INTERVENTIONAL RADIOLOGY (CATH LAB)]

(a) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004]*

(b) The duly filled-in form should be sent to The Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents

(c) Incomplete applications and those without all relevant documents are liable to be rejected

(d) For all the forms pertaining to this equipment, AE(RP)R, 2004 and other information in this regard, refer to our website: www.aerb.gov.in

(e) Separate application should be submitted for each model of X-Ray equipment

(f) Attach extra sheets wherever required

* This application is for the purpose of importing the equipment to obtain Type Approval. Subsequent to grant of NOC by AERB, *it is required* to submit separate application form for Type Approval. To obtain Type Approval, other documents as required by AERB should be submitted.

PART A

GENERAL PARTICULARS

A.1 Name and address of the applicant (local supplier)#

Telephone No. (O): (R)
Fax No.
E-mail

A.2 Name and address of the manufacturer

Telephone No. (O):
Fax No.
Mobile No.
E-mail

A.3 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Address for correspondence of the applicant with PIN code:

Applicant is the person in whose name the'Type Approval' for the radiation generating equipment may be issued, under AE(RP)R, 2004.

PART B

PARTICULARS OF THE EQUIPMENT

B.1 Details of the equipment

B.1.1 Model and type of equipment :

(a) Generator:

(b) Tube:

B.1.2 Type of unit :

(i) Computed tomography

(ii) Interventional radiology

B.1.3 This application is for

Type Aproval/NOC			
*Renewal of Type Approval/NOC	Ref No.:	Date:	Valid till:

* For renewal of Type Approval certificate, additional information, as given in B.2 needs to be furnished.

B.1.4 Number of equipment to be manufactured/supplied per annum :

B.1.5 Anticipated useful life of the equipment :

B.1.6 Location with address where the equipment will be demonstrated for type approval :

B.1.7 Specifications of equipment:

(a)	Maximum rating of the unit		:	(Give individual ratings for all modes available)
	(i)	Operating potential (kV)	:	
	(ii)	Operating current (mA)	:	
	(iii)	Exposure time (in seconds)	:	
(b)	Number of tubes		:	
(c)	Details of generator		:	
	(i)	Name of the manufacturer and country	:	
	(ii)	Nominal voltage	:	.....kV
	(iii)	Type of rectification	:	Half/full wave/others (specify)
	(iv)	Input power requirement (Phase, voltage and frequency)	:	
	(v)	Generator output capacity	:	…….. kW
(d)	Details of the X-ray tube			
	(i)	Name of the manufacturer and country	:	
	(ii)	Tube voltage	:	.....kV
	(iii)	Tube current	:	..... mA
	(iv)	Nominal continuous current	:	..... mA
	(v)	Type of anode	:	Stationary/rotating
	(vi)	Anode material	:	
	(vii)	Anode heat capacity	:	..... HU
	(viii)	Method of cooling of anode	:	
	(ix)	Target material used and target angle	:	
	(x)	Number of focal spots	:	One/two
	(xi)	Focal spots size	:	(Small : .....mm x ....mm) (Large : .....mm x.....mm) (Accuracy ..... mm)

	(xii)	Whether position of focal spot marked on tube housing	:	Yes/No
(e)	X-ray tube housing:			
	(i)	Shielding material and thickness (specify type of material and its lead equivalence)	:	
	(ii)	Leakage radiation from the tube housing (measured air kerma at maximum rating and measured values to be averaged over an area of 100 cm^2 at a distance of one metre from the target) for maximum number of radiographs in one hour)	:	..... μGy in one hour
(f)	Beam limiting device			
	(i)	Type of beam limiting device(s) used	:	Light beam diaphragm/ collimator/any special arrangements
	(ii)	Leakage radiation through beam limiting devices under condition specified in item (e) (ii) above	:	..... μGy in one hour
(g)	Filtration provided			
	(i)	Inherent filtration (in mm of Al)		
	(ii)	Added filtration (in mm of Al)		
	(iii)	Total Filtration (in mm of Al)		
	(iv)	Specify if any material other than Al is used (in mm)		
	(v)	Dose area product meter provided	:	Yes/no

(h)	Details of radiation output (applicable for Cath-lab)		:	
	(i)	X-ray beam output in µGy/mAs at 80 kV for 20 x 20 cm^2 field at one metre	:	..... µGy/mAs
	(ii)	Exposure rate at table top for fluoroscopy for .... kV..... mA (specify target to table top distance)	:	..... µGy/min
	(iii)	Shutter movement mechanism:		
	(iv)	Type of 'On'-'Off' switch provided Continuous/dead man type	:	
	(v)	Lead rubber flaps provided	:	Yes/No
	(vi)	Lead equivalence (mm)	:	
	(vii)	Automatic exposure termination device	:	Yes/No
	(viii)	Maximum continuous exposure time and corresponding operating potential	:	
	(ix)	Material used for table top and aluminium equivalence of table top	:	
(i)	Details of image intensifier TV (IITV) (applicable for Cath-lab)			
	(i)	Make and model		
	(ii)	Screen size	:	
	(iii)	High contrast resolution	:	
	(iv)	Low contrast resolution	:	
	(v)	Provision for reading kV, mA and pulse repetition rate	:	
	(vi)	Dose area product (DAP) display available	:	Yes/No
(j)	Details of digital detector			
	(i)	Size/dimensions of the detector provided	:	.....cm X .....cm

(ii) Size of individual detector element : .....cm X .....cm

(iii) Type of detector and material: scintillator/photo-diode/others (specify)

(iv) High contrast resolution :

(v) Low contrast resolution :

(k) Additional facilities for special examination :DSA/pulsed fluoro/cine radiography/others if any (applicable for Cath-lab)

B.1.8 Details of computed tomography unit

(i) No. of slices per rotation :

(ii) Slice thickness : (min) .....mm to (max) .....mm

(iii) Scan time per rotation (full rotation): (min).....seconds to (max) .....seconds

(iv) Type of detectors : scintillator/photodiode/ others (specify)

(v) Weighted computed tomography dose index ($CTDI_W$ in mGy/100 mA) :

(i) 16 cm (Head phantom) :

(ii) 32 cm (Body phantom) :

B.1.9 Specify the national/ international standards :

B.1.10 Any other relevant information you may like to furnish

B.2 Renewal of Type Approval (Fill as applicable)

B.2.1 Any modification to the present design or changes in components

B.2.2 Provide operational experience feedback (OEF) with respect to performance of X-ray units supplied so far. (Attach details on the following)

(a) Common failures observed in the equipment supplied

(b) Generic deficiencies/operational problems reported by the users

(c) Occurrence of incidents, if any and causes/remedial measures.

B.2.3 Whether the operational experience feedback (OEF) has been obtained from user of the X-ray units (Provide copies of feedback from the user institution)

B.3 Documents to be attached with the Application:

(a) Product technical catalogue

(b) QA manual covering design and manufacturing aspects.

(c) Tube catalogue covering cooling curves for anode.

(d) Detector/image intensifier tube catalogue

(e) Copy of IEC certificate (in case of NOC) along with certificates from the laboratory where tests were carried out, with signatures of persons witnessing the test.

(f) Copy of BIS certificate (in case of local manufacturers)

(g) Test report containing quality assurance checks as per Appendix-8C-I and Appendix 8C-II as appropriate.

(h) Manual for installation, operation, servicing, maintenance, dismantling, decommissioning .

(i) Letter from the manufacturer/designer authorising the local supplier/ vendor for marketing the unit

(j) Special instructions to user on radiation safety in installation and use of X-ray equipment.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified in this form.

(iii) the unit will be supplied only after obtaining a Type approval from the competent authority and only to users authorised by the competent authority.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the unit shall not be transported/ transferred/sold/ rented by me/us to another user without the prior permission of the competent authority.

(vi) the list of installations will be provided quarterly with detailed addresses of the users and the units installed.

(vii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect our facility at any time.

(viii) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(ix) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety measures will be duly implemented.

(x) installation, commissioning, servicing and maintenance of the equipment supplied by me/us shall be carried out.

(xi) the user shall be provided along with the equipment (i) Type Approval certificate (ii) technical specifications; and (iii) operating, servicing and maintenance manuals.

(xii) the user shall be provided with detailed procedures for quality assurance tests and checks to be carried out with specified frequency to verify correct performance of the device/equipment.

(xiii) duly qualified/experienced persons will be appointed for demonstration of type testing of the device/equipment.

(xiv) the training shall be provided to the user on servicing/maintenance of the equipment.

(xv) technical assistance shall be provided to the user in case of decommissioning/ dismantling of equipment.

(xvi) the faulty equipment involving safety related systems/components shall be taken back at our own expenses for disposal/repair.

(xvii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of applicant:

Designation:

(Seal of the institution)

ANNEXURE-66
(Refer section 3.16.1)

Form ID. AERB/RSD/SS/PROC

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400 094.

APPLICATION FOR CONSENT FOR PROCUREMENT OF SEALED RADIOACTIVE SOURCES FOR RESEARCH/ CALIBRATION PURPOSES

(a)	*This application would be considered by the competent authority for issuance of relevant consents, under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004].*
(b)	*This form is intended to enable AERB to assess the suitability of the institution for procurement and use of radiation sources, which includes radiation generating equipment (hereinafter referred to as 'source')*
(c)	*The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*
(d)	*Incomplete applications and those without all relevant documents are liable to be rejected.*
(e)	*All the forms pertaining to this facility can be downloaded from the website: www.aerb.gov.in*
(f)	*Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution with pin code

Telephone No. (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No. (O): (R)

Fax No.
Mobile No.
E-mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.4 Representative of the applicant to be contacted regarding the application:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Address for correspondence with PIN code:

[#] *Applicant is the person in whose name the no objection certificate to import/ procure the source may be issued, under AE(RP)R, 2004, and should be a full time employee of the institution.*

[$] *The Head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF THE SEALED SOURCE

B.1 Particulars of sealed source (SS)

B.1.1	Purpose of the SS	
B.1.2	Model and serial number	
B.1.3	Name of source(s)	
B.1.4	Number of sources	
B.1.5	Maximum activity Bq (Ci)	
B.1.6	Physical and chemical form	
B.1.7	Name and address of manufacturer of SS : Telephone No. Fax No. Mobile No. E-mail	

B.1.8	Reference of AERB Type Approval certificate for the SS, if any :	
B.1.9	Name and address of the supplier/ vendor agency of sealed source(s) : Telephone No. Fax No. Mobile No. E-mail	
B.1.10	Sealed source classification no. : (as per relevant national/international standards)	
B.1.11	Whether a copy of the undertaking furnished by the supplier of the source to take back the disused/decayed source is attached :	Yes/No

B.2 Partiulars of sealed sources already in the possession of the institution (Attach additional sheets if necessary)

S. No.	Description, make, model and S. No. of SS	Activity of the source Bq (Ci)	Number of SS	Purpose/ Application SS and its status	Installation for handling	Ref. No and Date of authorisa-tion issued by AERB

B.3 Brief note on the objective of study/studies for which radioisotope(s) is/are required

B.4 Details of person(s) who are involved in handling the radiation source(s):

S. No.	Name of person	Designation	Academic qualifi-cations	Radiation source handling experience	Details of training on radiation safety, if any	PMS No.

B.5 Details of training and experience, if any, of your staff members in 'Radiation Safety Aspects in Research Applications of Ionising Radiation' (Attach additional sheets if necessary)

B.5.1 For trained personnel

Name(s)	
Designation	
Academic qualifications	
Training course on radiation safety aspects in research applications of ionising radiation, recognized by AERB	
Year of passing	
Experience (Handling of sealed sources)	
Whether the person who has undergone training on radiation safety aspects has obtained the Radiological Safety Officer (RSO) approval from AERB	If yes, then furnish the following details : (i) Approval Ref. No. : (ii) Date of issuance : (iii) Approval valid till:
	If No, the institution should nominate the person who has successfully completed the training course on 'Radiation Safety Aspects in Research Application of Ionizing Radiation' for RSO approval to AERB.

B.5.2 For untrained personnel

If there is no individual in your institution who has undergone the required training to qualify for RSO, please furnish the following undertaking. *(Please delete the following undertaking, if not applicable)*

I hereby undertake to

(a) get one of our personnel trained on 'Radiation Safety Aspects in Research Application of Ionizing Radiation' before the procurement of the sealed sources, and

(b) obtain RSO approval from AERB, before taking up handling of sealed sources.

Signature of applicant

(Seal of institution)

B.6 Whether a radiation survey meter (RSM) is available in working condition: Yes/No

B.6.1 If 'Yes' *(Please furnish the following particulars relating to RSM)*

Particulars of monitor	**1**	**2**	**3**
Type of monitor			
Make			
Model			
S. No.			
Date of recent calibration			
Functional status			

B.6.2 If 'No', please furnish an undertaking as given below.
(Please delete the following undertaking, if a monitoring instrument is available.)

I hereby undertake to procure a suitable radiation survey meter before the procurement of the sealed sources for which this application is being made.

Signature of applicant

(Seal of institution)

B.7 Details of the transport facility available form the storage room to the site(s) of use in case of filed operations.

Type of transport container	**Mode of transport**	**Destination**

B.8 Additional Information, if any.

B.9 Documents to be attached with the Application**:**

(a) Sketch of the laboratory/storage room indicating the exact location of the source including the occupancies in the immediate vicinity (i*n case of sealed source for research purpose)*

(b) Copy of certificate of Approval of sealed source (including serial No), classification and leak test certificates as per applicable national/ international standard

(c) Copy of AERB Type Approval certificate for the selaed source, if any.

(d) Copy of document of the institution registration with the local/state/ central Government authorities, as applicable.

(e) Two copies of duly signed and stamped document on layout plan (scale 1:100) of storage and calibration room indicating the following *(in case for SS used in calibration of radiation monitors)*:

  (i) Size of the room

  (ii) Thickness of the walls and shielding material details

  (iii) Location of entrance door, position of windows (if any) along with height from ground level

  (iv) Pit size (as applicable)

  (v) Occupancy in the immediate vicinity of the installation room

(f) Nomination of personnel in the standard format of application form for training in radiation safety aspects in research application of ionising radiation (*in case the personnel trained in radiation safety are not available)*

(g) Security plan for the facility as per AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/ SG-1) and AERB safety guide on 'Security during Transport of Radioactive Material' (AERB/NRF-TS/SG-10)

(h) A copy of the undertaking furnished by the supplier of the source to take back the disused/decayed source

(i) Any other supporting documents

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for purposes other than those specified under item of this form.

(iii) the import/procurement of the sources shall be done only after receipt of NOC/Consent from AERB.

(iv) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(v) the sources shall be stored, installed and safeguarded so as to prevent unauthorised operation, removal and theft.

(vi) the sources shall be put into operation only after obtaining registration certificate from the competent authority.

(vii) the sources shall not be transferred/sold/ rented by me/us to another user without the prior permission from the competent authority.

(viii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the device at any time.

(ix) radiation surveillance of the installation and health surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(x) all recommendations that may be made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(xi) the procedures approved by AERB regarding decommissioning/ dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(xii) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place: Signature:

Date: Name of the applicant:

Designation:

Signature:

Name of Head of institution:

Designation:

(Seal of the Head of the institution)

ANNEXURE-67
(Refer section 3.16.1)

Form ID: AERB/RSD/SS/REG

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR REGISTRATION OF SEALED RADIATION SOURCES USED IN RESEARCH, CALIBRATION OF RADIATION MONITORS AND OTHER APPLICATIONS

(a) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(b) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R, 2004].*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *For all the forms pertaining to this facility, AE(RP)R, 2004 and other information in this regard, refer to website: www.aerb.gov.in*

(e) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution with pin code:

Telephone No. (O):
Fax No.
E-mail :

A2. Name and address of the department where sealed radiation sources are used

A.3 Name and designation of the Head of the institution[$]

Telephone No. (O): (R)
Fax No.

Mobile No.
E-mail

A.4 Name and designation of the applicant[#]:

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5 Name of the Radiological Safety Officer(s) (RSO*):

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.5.1 Approval reference No.

A5.2 Approval valid till:

[#] *Applicant is the person in whose name Registration for use of the device may be issued, under AE(RP)R-2004, would have the responsibilities of '**licensee/consentee'** prescribed in AE(RP)R, 2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE(RP)R, 2004.*

* *RSO is the person who is so designated by employer and approved by competent authority and have the responsibilities of '**Radiological Safety Officer'.***

PART B

PARTICULARS OF THE DEVICE

B.1 Particulars of the sealed radiation source/s: (Attach extra sheet if required)

B.1.1	Name and address of the manufacturer/ original supplier of sealed radiation source/s: Telephone No. Fax No. E-mail	

B.1.2	Name and address of the local supplier/ vendor agency of sealed source/s, if any: Telephone No. (O): Fax No. Mobile No. E-mail			
B.1.3	Details of radioisotope/s			
Name	**Quantity and activity**	**Purpose/Application**	**S. No provided by supplier**	**Ref. No. of the authorisation/NOC issued by AERB**
B.1.3.1	Sealed source classification number (as per relevant national/ international standards)			

B.3 Particulars of the radiation survey meter (RSM) available in working condition

Particulars of RSM	**1**	**2**	**3**
Make			
Model			
RSM Sr. No.			
Date of recent calibration			
Functional status			

B.4 Availability of personnel monitoring services (PMS) : Yes/No

B.4.1 Institution PMS number, if allotted:

B.4.2 No. of personnel availing PMS:

B.5 Additional information, if any:

B.6 Documents to be attached with the Application:

(a) Stray radiation levels at accessible locations around the sealed radiation sources in used condition.

(b) Sealed source classification certificate(s) and leak test certificate from the supplier of the source

(c) Layout of the laboratory (A blue print of the laboratory wherein the radiotracer study is conducted indicating clearly the nature of occupancies in the immediate vicinity should be forwarded with this application)

(d) Facilities available for the storage of the source in the laboratory when not in use, upon receipt, storage of waste.

(e) Copy of the authorisation/NOC issued by AERB for the procurement of sealed sources

(f) Emergency response plans and preparedness

(g) Any other supporting documents.

PART C

UNDERTAKING

I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) no activity will be carried out for the purpose other than those specified in this form.

(iii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iv) the source/device housing shall be stored, installed and safeguarded so as to prevent unauthorised operation, removal and theft.

(v) the radiation source would be used/maintained by authorized and trained persons.

(vi) the radiation source shall be used only after obtaining registration certificate from the competent authority.

(vii) the source shall not be transferred/sold/rented by me/us to another user without the prior permission from the competent authority.

(viii) full facility will be accorded by me/us to any authorised representatives of the competent authority to inspect the device at any time.

(ix) all stipulations/recommendations made from time to time by the competent authority in respect of radiation safety measures and physical security measures will be duly implemented.

(x) the periodic status report of all sources in the possession of the institution shall be submitted to AERB.

(xi) all the radiation survey meters /safety instruments will be maintained in functional condition all the time and will be calibrated periodically.

(xii) the decayed/unused radiation sources shall be returned to the original supplier.

(xiii) the procedures approved by AERB regarding decommissioning/ dismantling and reuse will be strictly complied with disposal of sealed sources.

(xiv) any incident/accident such as fire, theft, damage etc., involving ionising radiation source shall be promptly reported to AERB.

(xv) an emergency response manual prescribing specific action plans to identified persons for specific emergency scenarios shall be prepared and periodically updated.

(xvi) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or not authentic, then I/we hereby undertake to comply with the regulatory action(s) enforced against me/us and our institution, in accordance with the applicable Rules.

Place:

Date:

Signature:

Name of the applicant:

Designation:

Signature:

Name of Head of the institution:

Designation:

(Seal of the Head of the institution)

ANNEXURE-68
(Refer section 3.18.3)

Form No. AERB/RSD/RSO/APP

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan,
Anushaktinagar,
Mumbai-400094.

APPLICATION FOR APPROVAL OF RADIOLOGICAL SAFETY OFFICER (RSO)

(a) *The duly filled-in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(b) *This application would be considered by the AERB for issuance of relevant consents under the Atomic Energy (Radiation Protection) Rules, 2004, [AE(RP)R, 2004]*

(c) *Incomplete applications and those without all relevant documents are liable to be rejected.*

(d) *For all the forms pertaining to this facility, AE(RP)R, 2004 and other information in this regard, refer to our website: www.aerb.gov.in*

(e) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the Institution

Telephone No. (O):
Fax No.
E-mail

A.2 Name and address of the Head of the institution[$]

Telephone No. (O): (R)
Fax No.
Mobile No.
E-mail

A.3 Address for correspondence of the applicant with PIN code:

$ *The head of the institution is the person who would have the responsibilities of* ***'employer'*** *prescribed in AE(RP)R, 2004.*

PART B

PARTICULARS OF NOMINATED RSO

B.1 Details of the nominated RSO

B.1.1 Name in full

B.1.2 Present designation

B.1.3 Office address

Telephone No.
Fax No.
Mobile No.
E-mail

PLEASE AFFIX A RECENT PASSPORT SIZE PHOTOGRAPH

B.1.4 Permanent residential address

Telephone No.
Fax No.
Mobile No.
E-mail

B.1.5 Present residential address

Telephone No.
Fax No.
Mobile No.
E-mail

B.2 This application is for

RSO Approval			
Renewal of RSO Approval	Ref No.:	Date:	Valid till:

B.3 Academic qualifications and training courses in radiation safety

Qualifications	**S.No.**	**University/ Examining body**	**Degree/ Diploma Certificate**	**Year of passing**	**Subject(s) of study**
*Academic					
Training courses in radiation safety					

* For RSO Level-III, the academic qualification shall be given starting from graduation onwards.

B.4 Experience in radiation work

S. No.	Year(s) of work	Name of institution and address	Radiation equipment/ sources handled	Maximum activity handled	Personal monitoring badge No.
1					
2					

B.5 Radiation facilities for which the RSO shall be responsible (tick appropriate box/boxes)

(a) Irradiator ☐
(b) Industrial Radiography ☐
(c) Gamma Irradiation Chamber ☐
(d) Nucleonic Gauges ☐
(e) Oil Well Logging ☐
(f) Research Accelerator ☐
(g) Radiation Therapy ☐
(h) Nuclear Medicine ☐
(i) Dianostic Radiology ☐
(j) Medical Cyclotraw ☐
(k) Univercity/Academic Research ☐
(l) Medical Research ☐
(m) Industrial/Agricultural Research ☐
(n) Calibration Laboratories ☐
(o) Any other (please specify) _____

B.6 Additional responsibilities proposed to be assigned to the RSO:

B.7 Documents to be attached with the Application

(a) Copy of eligibility certificate for nomination of RSO of the candidate

(b) Copies of academic qualifications starting from graduation

PART C

UNDERTAKING

C.1 I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iii) I undertake to abide by the conditions stipulated by the competent authority from time to time and follow guidelines in discharging the duties and responsibilities as RSO.

(iv) I further undertake to inform the Atomic Energy Regulatory Board immediately in case I am relieved of my services as RSO and return the certificate of RSO to AERB.

(v) AERB will be informed about any changes in the information furnished above

In case, it is found, at any stage, that the information provided by me/us is false and/ or not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place:

Date: Signature of Nominated RSO

C.2 I/we hereby certify that

(i) all the statements made above are correct to the best of my knowledge and belief.

(ii) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(iii) all necessary facilities will be provided to the RSO to discharge his duties and functions effectively.

(iv) Atomic Energy Regulatory Board will be immediately informed in case the RSO is relieved of his duties and his original certificate would be returned.

Place:

Date: Signature of the Head of the institution

Seal of the institution

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LIST OF PARTICIPANTS

DRAFT DOCUMENT PREPARED BY (1994-2006)

Late Dr. I.S. Sundara Rao	:	AERB (Former)
Shri K.D. Pushpangadan	:	AERB (Former)
Shri T.N. Krishnmurthi	:	AERB (Former)

DRAFT DOCUMENT FULLY REVISED (2008-2009)

WORKING GROUP

Dates of meeting:	August 21, 25, 26,	2008
	September 8, 9, 15, 25, 30,	2008
	October 1,	2008
	November 6, 7,	2008
	December 1, 2, 3, 4, 5, 8, 11, 12, 29,	2008
	January 13, 27,	2009
	February 3, 4, 5, 11, 12, 13, 17, 18,	2009
	March 2, 3,	2009
	April 11, 12, 13,	2009
	May 7, 8, 13, 14, 15, 18, 19, 21, 22,	2009

Shri S.T. Swamy (Convenor)	:	AERB
Dr. R.M. Nehru	:	AERB
Shri A.U. Sonawane	:	AERB
Shri R. Kannan	:	AERB
Shri R.P. Gupta	:	AERB
Dr. P.K. Dash Sharma	:	AERB
Shri R.K. Singh	:	AERB
Shri Suneet K.	:	AERB
Smt. Bharati I.	:	AERB
Smt. Anuradha V. (Member-Secretary)	:	AERB

LIST OF PARTICIPANTS

ACKNOWLEDGEMENTS (2008-2010)

(for contributions in revision of document)

Shri S.A. Hussain	:	AERB
Shri V.K. Shirva	:	AERB (Retd.)
Smt B. Nagalakshmi (Retd)	:	AERB (Retd.)
Dr. P.K. Tandon	:	AERB
Shri V.S. Iyer	:	AERB
Shri Brijesh K. Singh	:	AERB
Shri Dinesh M. Rane	:	AERB
Shri Ghanshyam Sahani	:	AERB
Shri Pravin Patil	:	AERB
Shri Soumen Sinha	:	AERB
Shri M.Senthil Kumar	:	AERB
Smt. Manisha Inamdar	:	AERB
Shri Nidhip M. Chodankar	:	AERB
Shri Amit Sen	:	AERB
Kum. Arti Kulkarni	:	AERB
Shri Neeraj Dixit	:	AERB
Shri R.K. Chaturvedi	:	AERB
Shri Bibek Mishra	:	AERB

CONSISTENCY CHECK (APRIL - JULY 2010)

Shri K. Srivasista	:	AERB

ADVISORY COMMITTEE ON PREPARATION OF CODES, GUIDES AND MANUALS ON GOVERNMENTAL ORGANISATION FOR NUCLEAR AND RADIATION FACILITIES (ACCGORN)

Dates of meeting:	January 23, 1998	February 10, 1998
	June 17, 1999	July 12, 1999
	October 5 & 6, 2000	October 17, 2000
	April 1, 2005	August 4, 2006
	September 25 & 26, 2006	October 5, 2006
	November 24, 2007	July 4, 2008
	August 7 & 8, 2008	November 28, 2008

Chairman, Members and Invitees of ACCGORN:

Late Dr. S.S. Ramaswamy, Chairman (till January 2003)	:	Director General, Factory Advice Director General, Factory Advice Service and Labour Institute (FASLI) (Former)
Shri G.R. Srinivasan, Chairman (Since February 2003)	:	Vice Chairman, AERB (Former)
Shri G.V. Nadkarny	:	NPCIL (Former)
Shri A.K. Asrani	:	AERB (Former)
Shri T.N. Krishnamurthi	:	AERB (Former)
Late Dr. I.S. Sundara Rao	:	AERB (Former)
Shri N.K. Jhamb	:	AERB (Former)
Dr. K.S. Parthasarthy	:	AERB (Former)
Shri P.K. Ghosh	:	AERB (Former)
Shri G.K. De	:	AERB (Former)
Shri Deepak De	:	AERB (Former)
Shri P. Hajra	:	AERB (Former)
Shri R. Venkataraman	:	AERB (Former)

ADVISORY COMMITTEE ON PREPARATION OF CODES, GUIDES AND MANUALS ON GOVERNMENTAL ORGANISATION FOR NUCLEAR AND RADIATION FACILITIES (ACCGORN) (Contd.)

Chairman, Members and Invitees of ACCGORN (Contd.):

Shri S.P. Agarwal	:	AERB (Former)
Shri S.K. Chande	:	AERB
Dr. S.K. Gupta	:	AERB
Dr. P.C. Basu	:	AERB
Shri R.I. Gujrathi	:	AERB
Dr. Ompal Singh	:	AERB
Shri R. Bhattacharya	:	AERB
Shri Y.K. Shah (Member Secretary)	:	AERB
Shri S.T. Swamy (Permanent Invitee)	:	AERB
Smt. V. Anuradha (Permanent Invitee)	:	AERB

PROVISIONAL LIST OF CODES, GUIDES AND MANUALS FOR REGULATION OF NUCLEAR AND RADIATION FACILITIES

Safety Series No.	Titles
AERB/SC/G	Regulation of Nuclear and Radiation Facilities
AERB/NPP&RR/ SG/G-1	Consenting Process for Nuclear Power Plants and Research Reactors
AERB/NF/SG/G-2	Consenting Process for Nuclear Fuel Cycle Facilities and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SG/G-3	Consenting Process for Radiation Facilities
AERB/SG/G-4	Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities
AERB/SG/G-5	Role of AERB with respect to Emergency Response and Preparedness at Nuclear and Radiation Facilities
AERB/SG/G-6	Codes, Standards and Guides to be Prepared by the AERB for Nuclear and Radiation Facilities
AERB/SG/G-7	Regulatory Consents for Nuclear and Radiation Facilities: Contents and Formats
AERB/SG/G-8	Criteria for Regulation of Health and Safety of Nuclear Power Plant Personnel, the Public and the Environment
AERB/NPP&RR/ SM/G-1	Regulatory Inspection and Enforcement in Nuclear Power Plants and Research Reactors
AERB/NF/SM/G-2	Regulatory Inspection and Enforcement in Nuclear Fuel Cycle and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement in Radiation Facilities

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