eLORA - Guidelines for Suppliers of Medical Diagnostic X-ray Equipments and X-ray tubes

It is mandatory for suppliers of medical diagnostic x-ray equipments and X-ray tubes to obtain Authorization from AERB as per Atomic Energy (Radiation Protection) Rules 2004 (Please refer Annexure-1 for detailed regulatory requirements)

To facilitate online submission of applications for various regulatory consents, AERB has launched **Diagnostic Radiology Module** in its e-governance application e-LORA (e-**L**icensing **o**f **R**adiation **A**pplications) System (As on date the system is operational for existing X-ray facilities, manufacturers of x-ray equipment/x-ray tubes, suppliers of x-ray equipment/ x-ray tubes and Service Agencies for medical diagnostic x-ray equipment). Guidelines for existing x-ray facilities and manufacturers are provided separately.

All medical diagnostic x-ray equipment and x-ray tube suppliers are required to communicate to AERB for Authorization and other regulatory consents through e-LORA.

The guidelines for operating eLORA system are as follows:

Register Your Institute

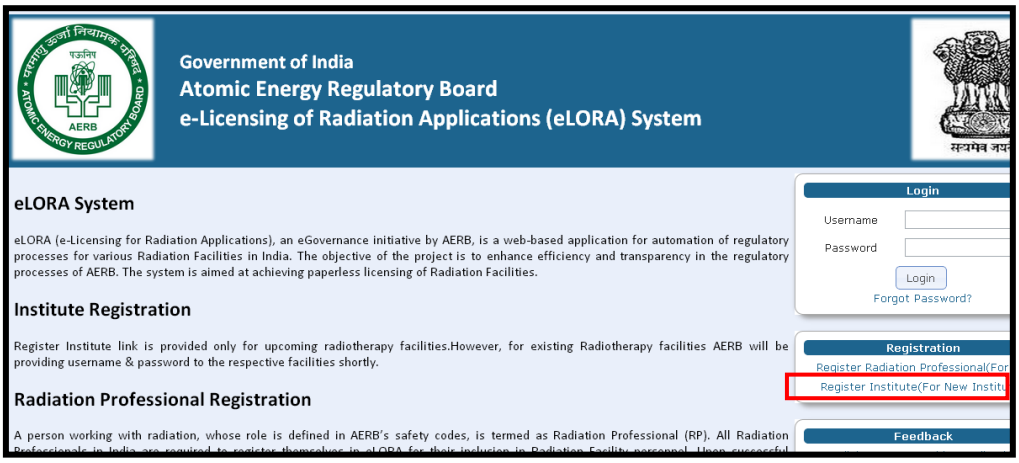
In case your institute is already registered with e-LORA for any other role, you can update your institute role as 'Supplier of x-ray equipment or X-ray tubes (or both)' by following as given:

Home page - Menu - User Management - Update Institute Details - Add required role

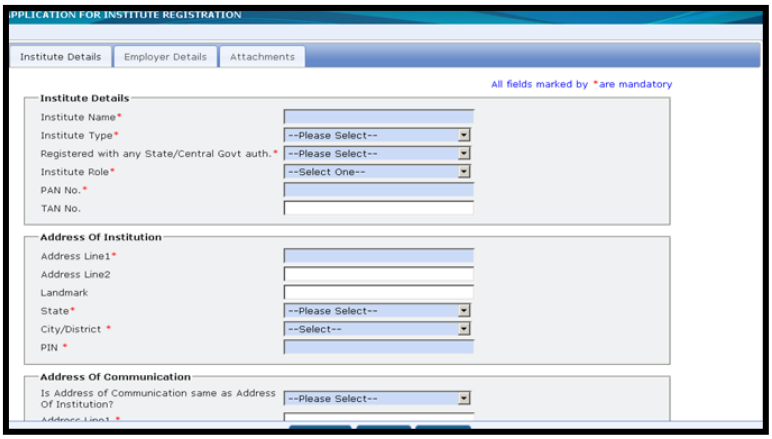
Then choosing required profile you can access the system.

If you are a new user,

Visit our website www.aerb.gov.in. Click on the button **eLORA,** which is available on website home page. It will redirect you to the following screen of **eLORA Home Page**.



Click on **Register Institute** (see above figure). This will open application form for Institute Registration.

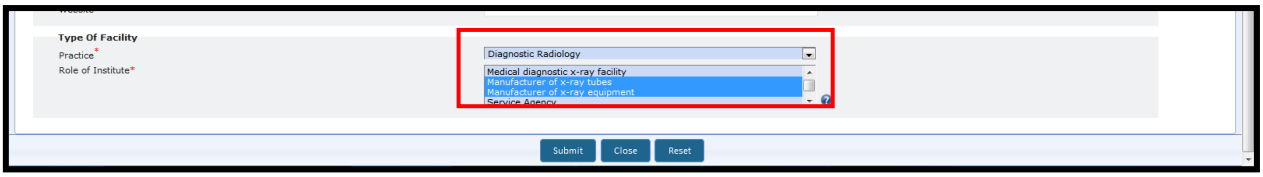


Important Note: Guidelines to fill application form for Institute Registration is available on eLORA home page. It is advised to read the guideline and keep soft copy of required attachments ready before start filling of application form.

Fill the application form as per the guideline. Important points in each tab are mentioned below:

Tab 1: Institute Details

In **Type of Facility** section, for the field **Practice** select **Diagnostic Radiology** and for the field **Role of Institute** click on **Supplier of X-ray Tubes** or **Suppliers of X-ray Equipment** (or both using Ctrl key – as applicable)



Tab 2: Employer Details

Name: Fill the complete name of employer as appearing in his/her document for **Proof of Identity/Date of Birth (DOB)** to be attached.

Date of Birth: Fill the DOB as appearing in the proof of identity/DOB to be attached

Document/card for proof of identity and date of birth (of employer): Select one from the drop down. (Soft copy of this is a mandatory attachment).

Document/Card No. (of Proof of Identity/DOB): Must match with the proof of identity/DOB attached

E-mail (O): Will be used to send USERNAME and PASSWORD of your eLORA account and for all future communications. (Make sure to provide correct email address).

Tab 3: Attachments

Upload of following attachments are mandatory:

- ✓ **Proof of Identity and Date of Birth** (of employer): as mentioned (via selecting from the drop down) in the application form. (The options available are, PAN card/Passport/ Driving License/Government Id)
- ✓ **Proof of Employership**
  Upload document substantiating employership of the institute.
  Example: Appointment Letter, Board Resolution, Any Govt./PUC document substantiating proprietorship, Partnership deed (notorised), Or Proprietor's self declaration on institute letter head affixed with institute seal (only for Diagnostic Radiology Institutes)

Enter the Captcha and submit the application form.

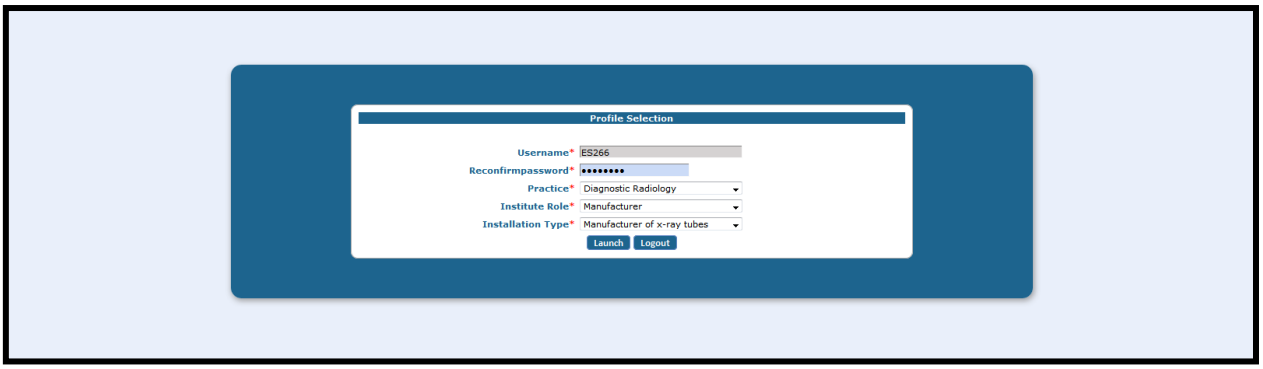
Important Note: Fields marked with * in the application form are mandatory. Application form will not be submitted if any mandatory field left blank.

You will get acknowledgement message upon successful submission of application form. The copy of submitted application (.pdf file) can be downloaded for which link will be provided (pl. note, this link will be active for a shot period). You will also receive an acknowledge mail with the copy of your application form (.pdf file) in your email (email address as provided in the application form).

Login to Your Account

After acceptance of your application form, you will get USERNAME and PASSWORD of your eLORA account in your email. Visit to eLORA home page to login to the system.

In case you had applied for multiple institute roles (viz. Supplier of x-ray equipment, **Manufacturer of X-ray Tube**, **Manufacturer of X-ray Equipment)**, you will see following screen for profile selection. Select your **Practice** as Diagnostic Radiology, **Institute Role** as Supplier and **Installation Type** as applicable.



You can always update your Institute detail as well as **Institute Role** as follows:

Menu → User management → Update Institute Details

In the form for **Update Institute Details**, you can update following:

- Institute's address of communication
- Institute's contact details
- Add more role to the institute
- Employer's contact detail

Once you have done required changes, click on 'Update' button. You will get confirmation message after successful update.

Important Note: All the email communications are sent on employer's email, enter correct email and check for updates.

Obtaining Authorization for supply of medical diagnostic x-ray equipment

Prerequisite for Obtaining Authorization

Prior to apply for Authorization complete the requisites as follows

- **Add Employee:** Declaration of qualified and trained personnel (Service engineers) in e-LORA
- **RSO approval:** In case you have radiation test facility, Obtain RSO (Radiological Safety Officer) approval through e-LORA.
- **Add Instrument:** Declaration of measuring, monitoring, QA and safety tools as per regulatory requirement in e-LORA
- **Preparation of Layout (if available):** Prepare layout of radiation testing facility as per regulatory requirement for submission in e-LORA in the application for Authorization. (Please refer Annexure II for detailed guidelines)

A. Add Employee (minimum requirement)

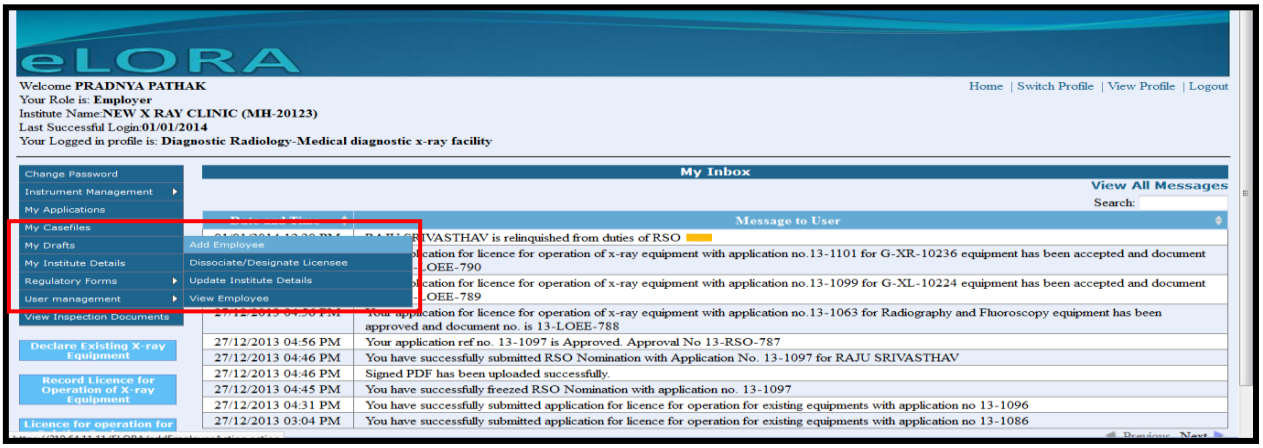
For supplier of x-ray equipment, having at least one **service engineer** and **RSO** (Radiological Safety Officer)if applicable is mandatory.

Role of Employee	Eligibility
Service Engineer	Degree/ Diploma in Electrical /Electronic /Biomedical /Mechanical engineering or in an associated discipline/Basic degree in Science with Physics as one of the subject from a recognized University/Institution, and Certification of successful completion of training course on "Radiation Safety and Quality Assurance in Diagnostic Radiology" conducted by authorized agencies. Service engineer is required to register himself/herself as **Radiation Professional** (RP) in e-LORA. Prior to adding in any institution. • Complete guideline and application form for RP registration is available in e-LORA home page. A person need to submit RP registration form for **Practice:** 'Diagnostic Radiology' and **Professional Role:** 'Service Engineer'
RSO	Any qualified and trained Service Engineer can be designated as RSO

Once a Service Engineer gets registered as RP, his/her name will be included in eLORA in the list of RPs (which will be available for selection to the institution for Add Employee).

For adding employees to your institution, follow the path as:

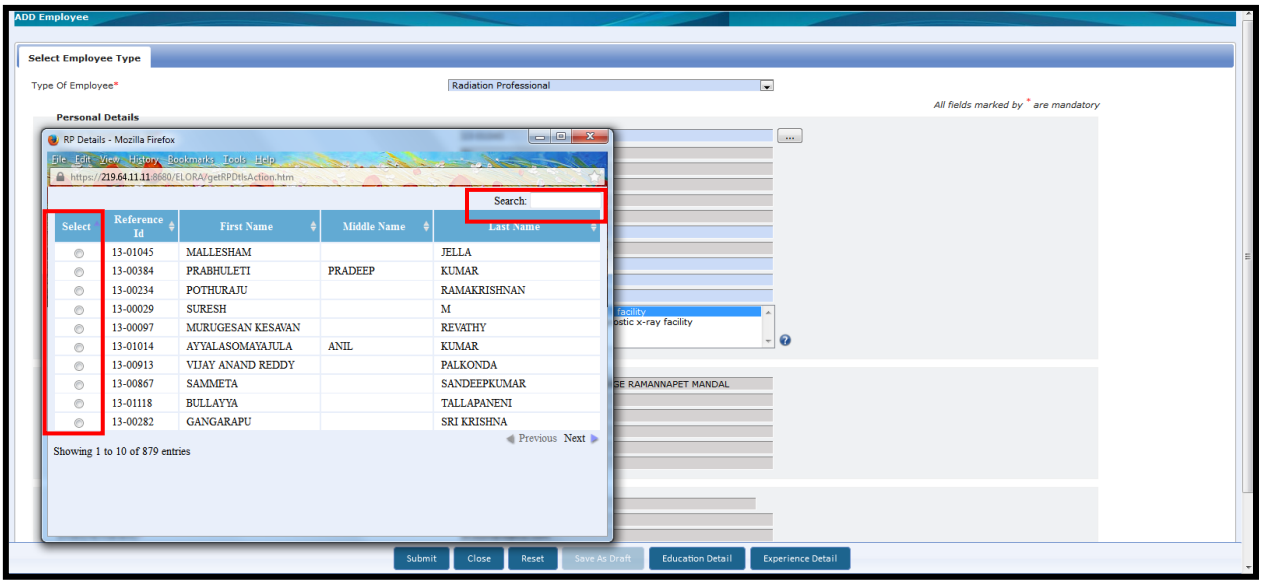
Menu → User management → Add Employee → Select required **Type of Employee** from drop down



In drop down for **Type of Employee**, three options available as follows:

- Radiation Worker
- Non Radiation Worker
- **Radiation Professional**

For Manufacturer, you are required to add **Service Engineer** in the type **Radiation Professional**. Click on **Select Registration ID** and find out name of RP (using **Search**) and **Select**.



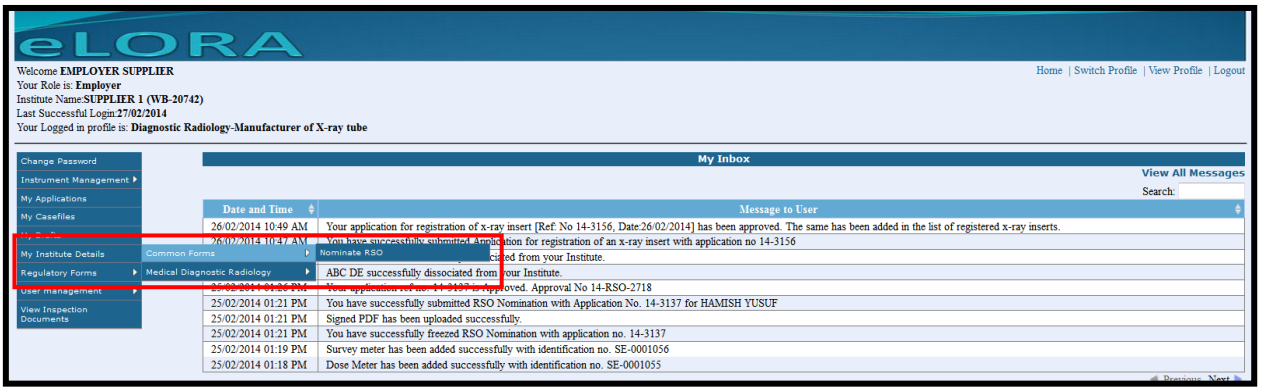
Fill required details and upload scan copy of Joining/Confirmation letter and click on **Submit.**

Important Note: Service Engineer can subsequently be nominated for the approval of Radiological Safety Officer (RSO). Process of RSO nomination explained below: Obtain RSO Approval

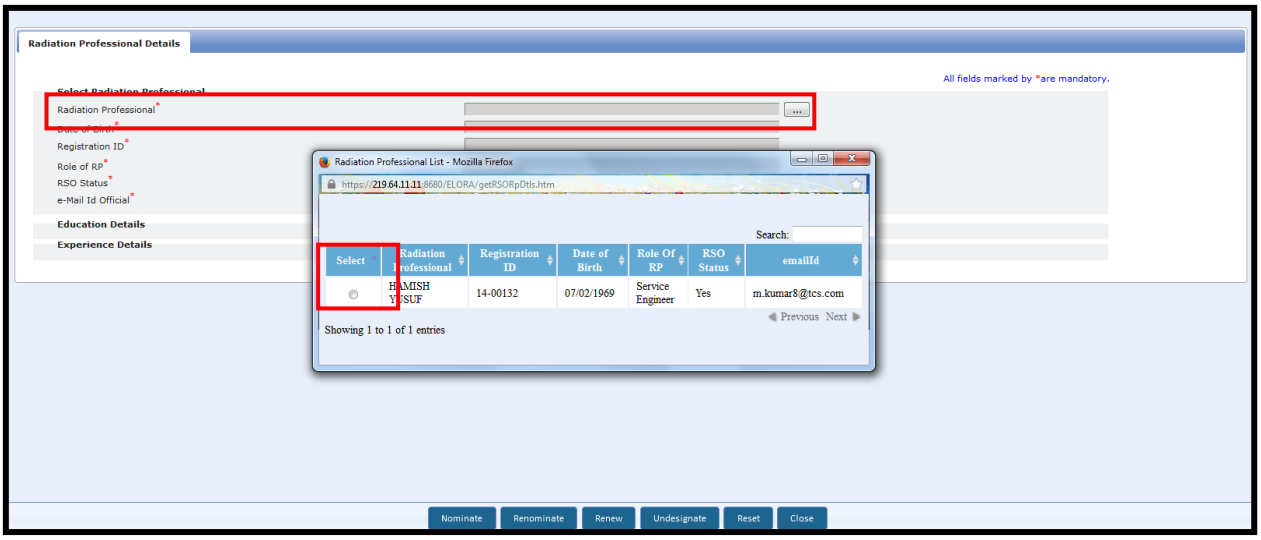
B. Obtain RSO Approval

For nominating Service Engineer for RSO, follow the path as:

Menu → Regulatory Forms → Common Forms



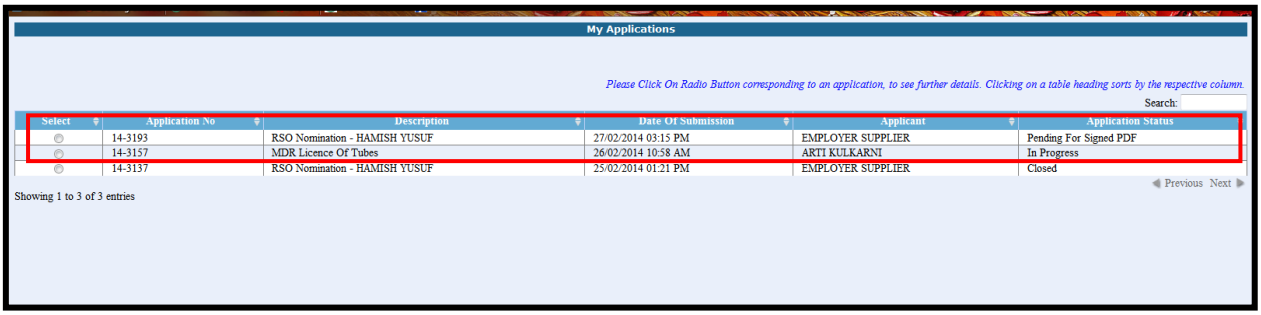
Select the **Radiation Professional** as Service Engineer of your institute, to be nominated as RSO.



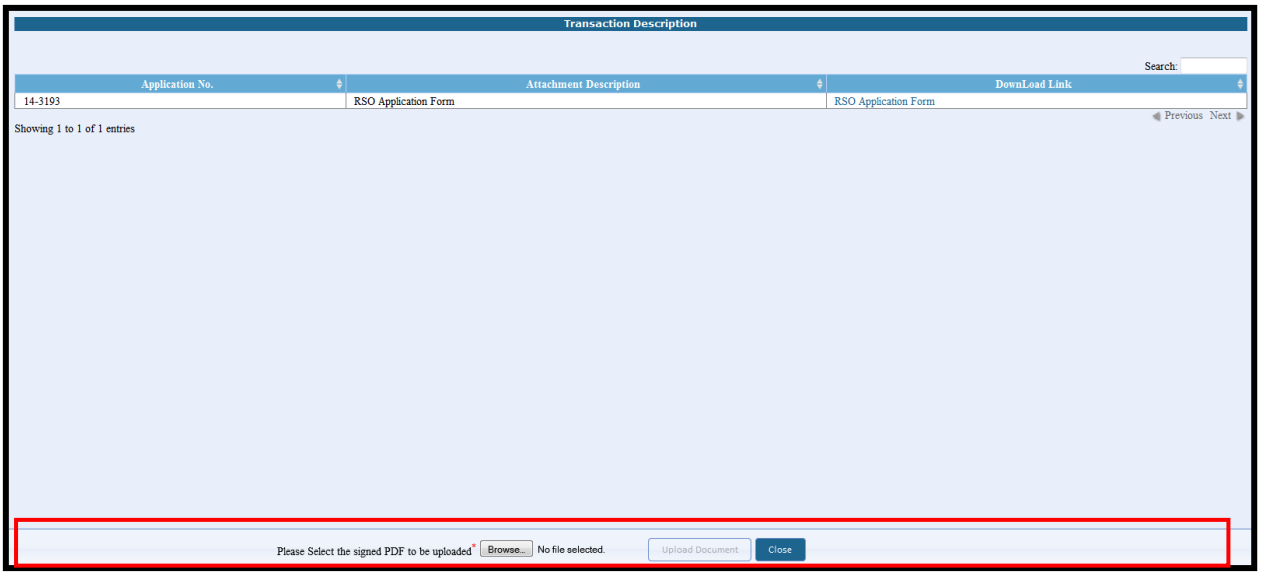
Fill the required details and click on **Freeze.** This will freeze your application form and show your application number. **Please note, Freeze does not mean submission of application form to AERB.**

For submission of RSO nomination application form, follow the path as:

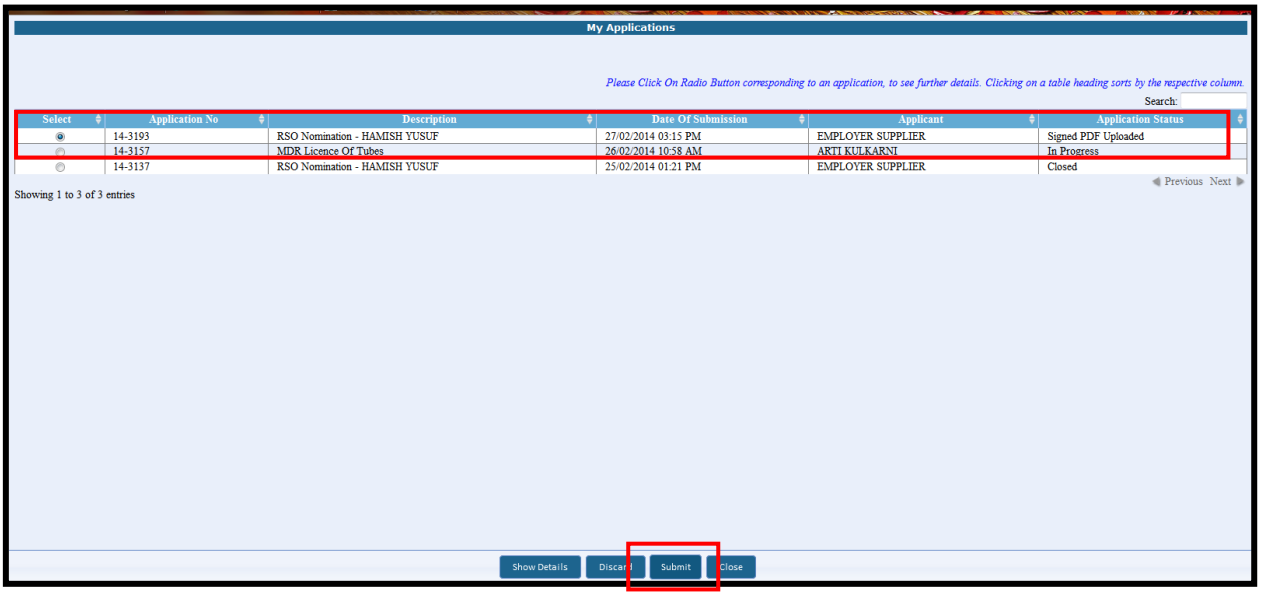
Menu → My applications



Select required **Application No.** (Application Status is shown as **Pending For Signed PDF**). Click on **Show Details** and download PDF of your application form from **Download Link**. Take a print of first page, Employer and Nominated RSO shall duly sign the first page (their names will appear in the form, sign above the respective names) and affix institute seal on it. Scan this page (in .pdf format), **Browse** and upload this scan copy.



After uploading of scan file, **Application Status** will change to **Signed PDF Uploaded**



Select the **Application No** and click on **Submit** to complete submission of application form (**Application Status** will change to **Submitted)**.

Important Note: The above mentioned procedure of submission of application is applicable for other regulatory forms where signatures of two persons are required.

Your RSO nomination form will be reviewed by AERB and after acceptance; you will get its notification in your eLORA account.

C. Designate/Relinquish Service Engineer:

By this process, after successful designation service engineer will get a login id and password, using which he/she can submit the following user related regulatory forms against your institution.

Installation Report
QA report summary
Radiation Survey Report
Confirmation of Decommissioning

For designating employee as 'Service Engineer' follow the path as:

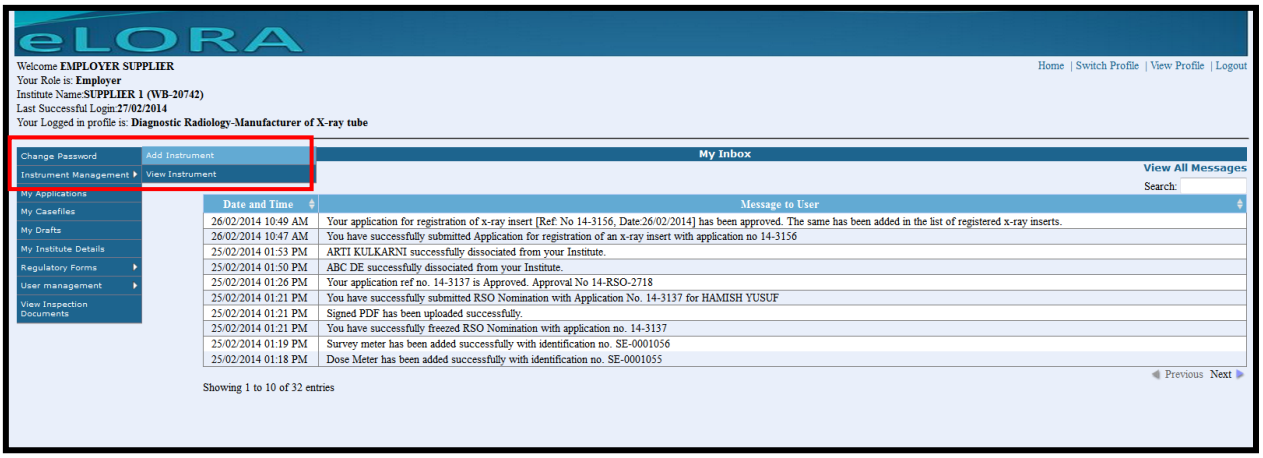
Menu → User Management → Designate employee

D. Add Instrument

Manufacturer must have certain types of instruments (list is given in Table 1: List of Instruments Required) and the same must be declared in eLORA.

To declare instruments, follow the path as:

Menu → Instrument Management → Add Instrument



In drop down for **Type of Instrument**, four options available as follows:

- Measuring Tool
- Monitoring Tool
- QA Tool
- Safety Tool

Add following Instruments as applicable to each type of equipment proposed to manufacture:

Table 1: List of Instruments Required for Manufacturer of X-ray Equipment

Applicable for Suppliers of X-ray Equipment		
Type of Equipment	Instruments to be added	
	Type of Instrument	Instrument Sub Type
Radiography Radiography & Fluoroscopy Interventional Radiology	Measuring Tools	• kVp Meter • Dose Meter • Timer

C-arm/O-arm Computed Tomography Mammography Dental (intra-oral, OPG.CBCT)		
All types of x-ray equipment	Monitoring Tools	• Survey Meter
Radiography Radiography & Fluoroscopy Interventional Radiology C-arm/O-arm Dental (intra-oral, OPG.CBCT)	QA Tools	• Radiation and Optical Field Alignment Test Tool • Beam Alignment Test Tool • Focal Spot Test Tool • Low Contrast Resolution Test Tool • High Contrast Resolution Test Tool
Computed Tomography	QA Tools	• CT Imaging Phantom • CTDI (Head) Phantom • CTDI (Body) Phantom
Mammography	QA Tools	• Mammography Imaging Phantom
Radiography Radiography & Fluoroscopy Interventional Radiology C-arm/O-arm Computed Tomography Mammography Dental (intra-oral, OPG.CBCT)	Safety Tool	• Protective Apron • Protective Barrier with Viewing Window

E. Preparation of radiation testing facility layout: (detailed guidelines are given in Annexure-2)

Prepare a sketch of layout of radiation testing facility to the scale 1:50 mentioning all the details such as Area, wall thickness, shielding material (wall material), position of doors, windows, equipment, control console, protective barriers etc.

Prepare a sketch of floor layout of radiation testing facility to the scale 1:100 mentioning the areas around the test facility and details of occupancy around.

Scan and preserve duly signed and stamped copies of both the layouts.

Important Note: While submitting application form for Operating Licence, you will be asked to upload duly signed and stamped copies of both the layouts.

Fill Required Regulatory Forms

Follow the path to access Regulatory forms for getting various regulatory clearances:

Menu →Regulatory Forms →Medical Diagnostic Radiology

1. **Authorization for supply of medical diagnostic x-ray equipment:** Fill and submit this form to obtain Authorization. (Same form is also applicable for renewal of Authorization)

   Documents required to be attached with this form:
   i) OEM authorization/s for all the models proposed for supply
   ii) Ownership document/rented property agreement of the site

iii) Drawing (scale 1:50) of the test facility

2. **Modification of Authorization:** Fill and submit this form for addition/deletion of x-ray equipment model authorised to supply.
   Documents required to be attached with this form:
   i) OEM authorization for the model proposed for supply.

3. **Registration of X-ray Tube Insert:** Supplier need to register all models of X-ray tube inserts which are to be imported/procured. Fill and submit this form to register X-ray tube insert.

   Documents required to be attached with this form:
   i) Copy of certification(s) of compliance to standards
   ii) Technical catalogue of x-ray tube insert

4. **Registration of X-ray Tube:** Supplier needs to register all models of X-ray tube which are to be imported/procured. Fill and submit this form to register X-ray tube.

   Documents required to be attached with this form:
   i) Copy of certification(s) of compliance to standards
   ii) Technical catalogue of x-ray tube

5. **Procurement of X-ray Tube:** Fill and submit this form to obtain permission to procure X-ray tube (permission of bulk procurement is permitted)

6. **Procurement of X-ray equipment:** Fill and submit this form to obtain permission to procure X-ray equipment (permission of bulk procurement is permitted)

7. **Intimation of Receipt:** Fill and submit this form to intimate AERB about the receipt of x-ray equipment/X-ray tube insert/x-ray tube if imported.

8. **Type Approval of X-ray Equipment**: This form is not applicable for X-ray tube suppliers. In case x-ray equipment to be supplied is imported (foreign make) supplier is required to obtain the Type Approval. Fill this form to obtain type approval of diagnostic x-ray equipment. In this application form, a template (in Excel format) is provided to fill certain technical specification of the equipment. The duly filled in Excel file is required to be uploaded during submission of application form. It is advised to visit this form first and download the template.

   After review AERB will issue NOC to import the x-ray equipment for obtaining Type Approval. Subsequently supplier or proposed end user is required to apply for procurement permission for this model of x-ray equipment. Once equipment is imported, supplier is required to demonstrate its performance to AERB representative after submission of 'Intimation for Type Approval'.

   Documents required to be attached with this form:
   i) Technical catalogue of the equipment

ii) OEM authorization
iii) Manual for quality assurance
iv)Manual for installation, operation, servicing, maintenance, dismantling and decommissioning
vi)Special instructions to user on radiation safety in installation and use of x-ray equipment
vii) Certification(s) of compliance to standards

9. **Installation Report:** Fill and submit this form against procurement permission for x-ray facility after installation and commissioning of x-ray equipment. X-ray equipment user can apply for Licence only after receipt of installation report by supplier.

10. **QA test report summary:** Fill and submit this form against intimation of 'Change in layout/Repositioning/Relocation of x-ray equipment' to intimate AERB about the completion of activity. QA report summary also can be submitted prior to Renewal of Licence for Operation of x-ray equipment.

11. **Radiation Survey Report:** Fill and submit this form against intimation of 'Change in layout/Repositioning/Relocation of x-ray equipment' to intimate AERB about the completion of activity.

12. **Confirmation of Decommissioning:** Fill and submit this form against 'Intimation of decommissioning of x-ray equipment' to intimate AERB about the completion of activity.

13. **Termination of Services:** Fill this form to intimate about termination of your services as supplier.

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Annexure-1

REQUIREMENTS FOR SUPPLIERS OF X-RAY EQUIPMENT AND X-RAY TUBES

The supplier shall obtain the requisite recognition to supply x-ray equipment and x-ray tubes. In case the supplier intends to market equipment of foreign make, he shall obtain NOC for import, for the prototype, from the competent authority and demonstrate it for Type Approval, prior to marketing in the country.

As per AE (RP) R, 2004, Head of the institute is identified as Employer and Licencee under AE (RP)R by default. Employer may designate any of his employees as Licensee under AE (RP) R. The employer and Licencee shall fulfill the responsibilities as specified in this Code.

I) Pre- requisites for obtaining Authorization for supply of X-Ray Equipment

a) **OEM Authorisation:** Supplier shall obtain an OEM authorisation, for all models(equipment and tubes) proposed to be supplied.

b) **Radiation testing facility for demonstration of Type Approval**: A testing facility, if available, shall be located away from other working areas not related to radiation testing. The shielding and space requirements to the testing facility shall be such that the dose limits for radiation workers and public, as prescribed by competent authority are met with. The facility shall be equipped with required protective accessories. A warning placard shall be displayed outside the testing facility.

c) **Staff requirements**: Suppliers shall employ qualified and trained personnel for radiation testing, QA, and servicing of diagnostic x-ray equipment. The minimum qualification and training shall be as prescribed by regulatory body.

d) **Radiological Safety Officer (RSO):** In case supplier has radiation testing facility, shall have Radiological Safety Officer (RSO) approved by the competent authority. The minimum qualification and training shall be as prescribed by regulatory body.

II) Conditions of Supplier Authorization

a) The AERB recognition will be valid for the duration and models for which OEM authorisation exists.

b) The supplier shall adhere to requirements prescribed in this code

c) For procurement/import of x-ray tube(s), the supplier shall obtain procurement permission from the competent authority.

d) The supplier shall adhere to any other conditions stipulated by competent authority from time to time.

f) The supplier shall supply to the customer (utility) only AERB Type approved models and

- on installation of the x-ray equipment, shall carry out acceptance testing/quality assurance as part of commissioning of x-ray equipment;
- shall provide servicing and maintenance during the useful life-time of diagnostic x-ray equipment;
- shall ensure that the customer has the requisite radiation protection devices such as protective barrier, protective apron, couch hanging lead equivalent rubber flaps, as applicable. In case of computed tomography equipment, the supplier shall provide the required phantoms for performance checks.
- shall submit after every installation, an installation report to the regulatory body in the specified format.
- shall check for layout and shielding adequacy at the customer site.
- shall carry out dismantling/ decommissioning of equipment at customer end and inform AERB on further action.

g) Any other conditions stipulated by competent authority from time to time.

III) Type Approval/ No Objection Certificate (NOC)

The Type Approval of the x-ray equipment shall be obtained by the Authorised suppliers:

a) Prior to marketing the x-ray equipment the supplier of imported equipment, shall obtain a Type Approval Certificate from the competent authority, on demonstration of performance of the prototype of x-ray equipment.

b) Import of prototype of x-ray equipment, meant for Type Approval, shall be carried out by the recognized supplier only after obtaining NOC for import for Type Approval, from the competent authority.

c) Type Approval/NOC will be issued only if the equipment satisfies the safety specifications of this Code and the standards in force.

d) Once x-ray equipment is Type approved, routine Import of the type approved models shall be carried out only after obtaining procurement permission, for each consignment, from the competent authority.

Type Approval becomes invalid if any change is made in the design of the Type approved model.

IV) Periodic Safety Reports: The Licensee shall submit periodic safety status reports in the format and frequency specified by the regulatory body.

V) Renewal of Authorization: The Authorization accorded by the competent authority shall be renewed before expiry.

VI) Termination of Services: AERB shall be intimated in case the supplier decides to cease functioning as a supplier.

Annexure-2

Guidelines for design of radiation testing facility

Introduction:

It is a pre-requisite for obtaining Licence for commercial production of x-ray equipment and x-ray tubes, that a dedicated radiation testing facility shall be available, The shielding and space requirements to the testing facility shall be such that the dose limits for radiation workers and public, as prescribed by competent authority are met with. The facility shall be equipped with required protective accessories.

The adequacy of shielding depends on the material and thickness used for this purpose. Different materials can be used for shielding. However, brick or concrete are considered the most common materials, as they are easily available, economical, and have good structural strength.

While lead is a suitable shielding option for energies encountered in diagnostic x-rays, it is a weak structural material with tendency to lose uniformity and needs periodic radiation survey to ensure its continued adequacy. Also, Lead poses a serious environmental hazard and the use of it is being discouraged the world over. Recently, many new materials are being used/ developed as potential shielding materials, as an alternate to Lead. AERB would like to promote use of these materials, on demonstration of shielding adequacy.

Regulatory recommendations to set up testing facility at manufacturing premises:

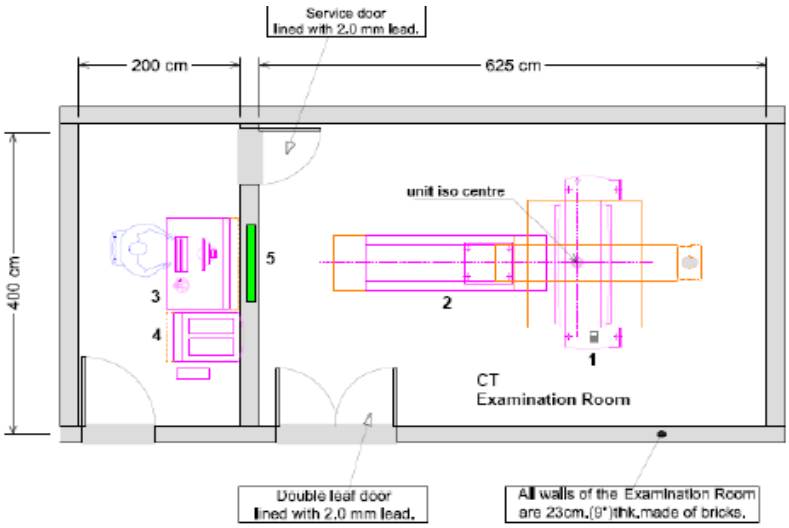
- Decide a suitable room/bay for testing of X-ray equipment located as far away as feasible from other working areas not related to radiation testing and area of high occupancy and general traffic.
- Ensure that the thickness of the wall(s) of the testing room(s) should not be less than 23 cm thick brick or equivalent.
- Testing room should have preferably only one entrance door having shielding equivalent of 2 mm of Lead and window if present should be at above height of 2 m from the outside finished floor level of testing facility.
- Area of the X-ray equipment testing room should be at least 18 m^2 for testing of general purpose radiography / Fluoroscopy / C-Arm/ Mammography /BMD/ OPG/Dental & CBCT equipment.
- Area of the CT scan & Interventional Radiology (IR) equipment testing room should be at least 25 m^2.
- In case of CT & IR equipment, separate control room should be available adjacent to testing room with proper lead glass viewing window of adequate size.
- X-ray equipment, control console, protective barrier etc. should be appropriately placed in the testing room so as to avoid primary beam facing control console or entrance door.

- Appropriate warning sign, and placards shall be displayed outside the testing facility

General information:

- Testing room layout or bay shall be constructed as per AERB recommendations only.
- Testing of x-ray equipment shall be carried out by trained & authorised personnel.
- Personnel monitoring badges (TLD) shall be provided to all the radiation workers.
- All types of radiation protection devices shall be provided to radiation workers.
- After constructing the testing facility, radiation protection survey should carry out to ensure the shielding adequacy of the testing room / bay.
- If the radiation assessment survey shows deficiencies, additional shielding or modification in the testing facility are required.
- **Prepare a sketch of layout of test facility to the scale 1:50 mentioning all the details such as Area, wall thickness, shielding material (wall material), position of doors, windows, equipment, control console, protective barriers etc.**
- **Prepare a sketch of floor layout of test facility to the scale 1:100 mentioning the areas around the test facility and details of occupancy.**
- **Duly signed and stamped copies of both the layouts shall be submitted to AERB along with application for Licence for commercial production.**

Testing room model layout for CT or Cath Lab equipment*:



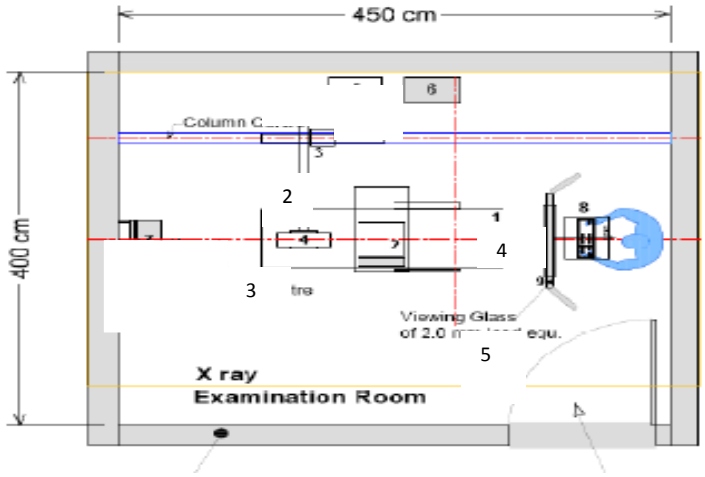
Legend:

1. CT gantry
2. Examination Table
3. Control Unit
4. Electronics
5. 2 mm lead equivalence viewing glass window

All dimensions are in cm scale 1:50

***Note:** Same type of room layout plan can be used for testing of Cath Lab equipment.

Testing room model layout for general X-ray radiography equipment *:



Legend:

1. Examination table
2. Column stand
3. X-ray tube head
4. Control Unit
5. Protective barrier with Lead glass viewing window of 1.7 mm lead equivalence

All dimensions are in cm scale 1:50

***Note:** Same room layout plan can be used for testing of Radiography/Radiography & Fluoroscopy, C-Arm, Mammography, BMD, Dental, OPG/CBCT etc equipment.

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