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

It is mandatory for all indigenous manufacturers of medical diagnostic x-ray equipments and X-ray tubes to obtain a-priori **Licence for Commercial Production** from AERB as per Atomic Energy (Radiation Protection) Rules 2004 (Please refer Annexure-1 for detailed regulatory requirements)

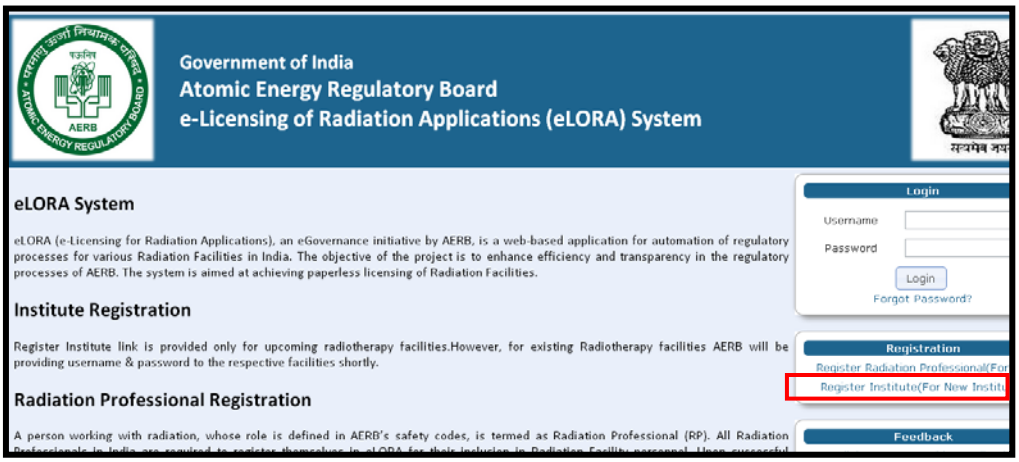
To facilitate online submission of applications for various regulatory consents, AERB has launched **Diagnostic Radiology Module** in its e-governance application e-LORA (e-**L**icensing **o**f **R**adiation **A**pplications) System (As on date the system is operational only for existing X-ray facilities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

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

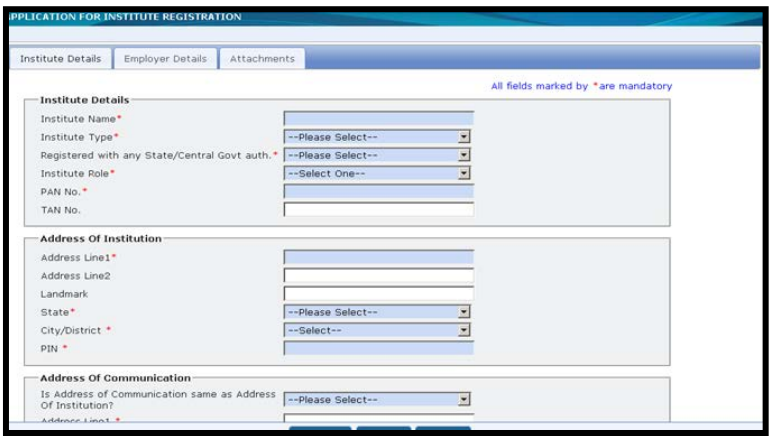
The guidelines for operating eLORA system are as follows:

Register Your Institute

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.

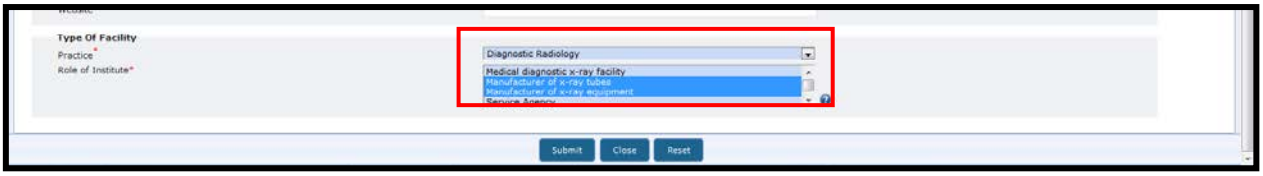


Important Note: Guideline to fill application form for Institute Registration is available on eLORA home page. It is advised to read the guideline and keep soft copy of required attachments ready before start filling of application form.

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 **Manufacturer of X-ray Tube** or **Manufacturer 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.

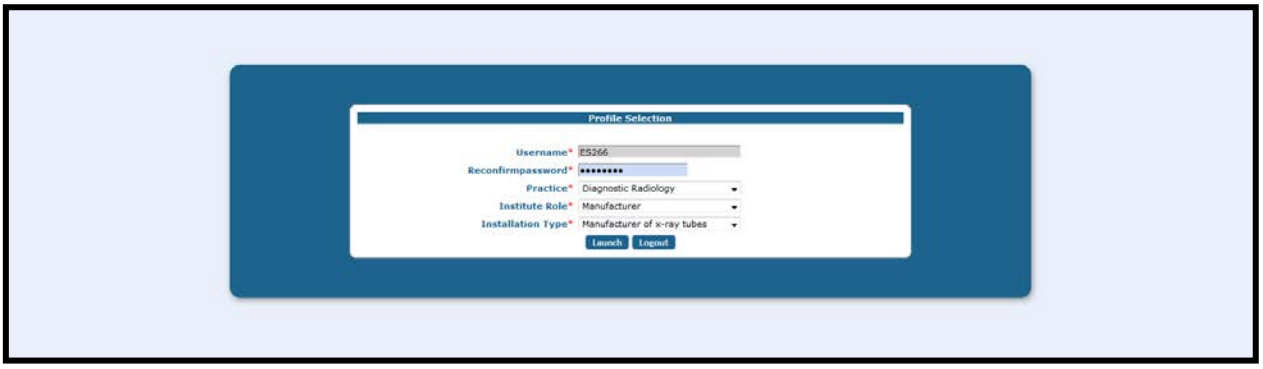
Important Note: Fields marked with * in the application form are mandatory. Application form will not be submitted if any mandatory field left blank.

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

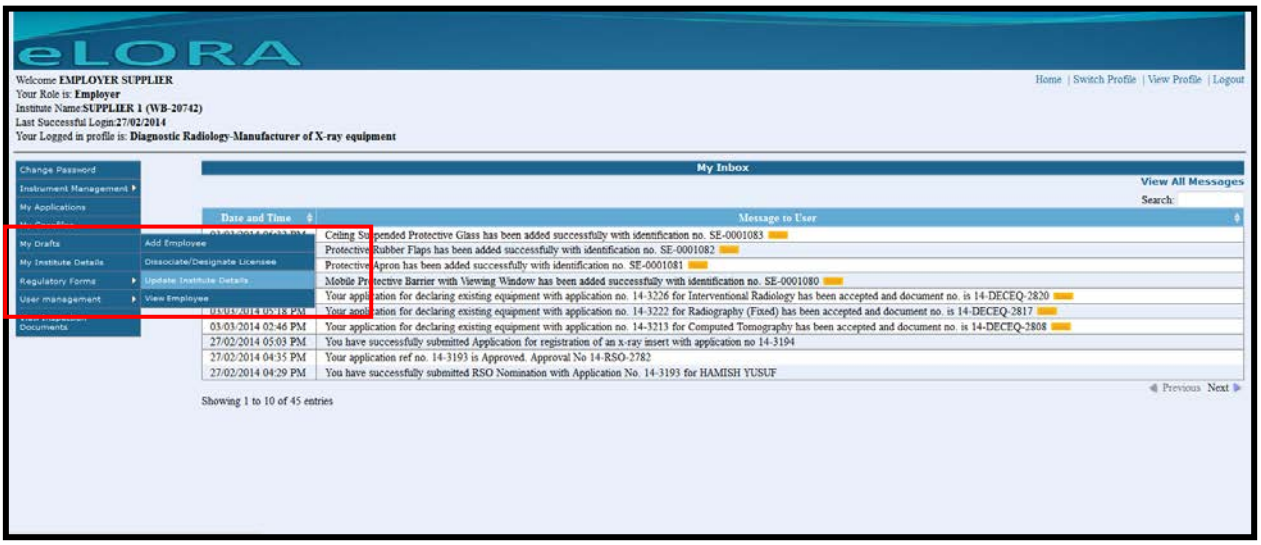
After acceptance of your application form, you will get USERNAME and PASSWORD of your eLORA account in your email. Visit to eLORA home page to login to the system.

In case you had applied for multiple institute roles (viz. **Manufacturer of X-ray Tube** as well as **Manufacturer of X-ray Equipment)**, you will see following screen for profile selection. Select your **Practice** as Diagnostic Radiology, **Institute Role** as Manufacturer 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 (viz. **Manufacturer of X-ray Equipment** can add additional role of **Manufacturer of X-ray Tube** and vice versa)
- 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 updations.

Obtaining Licence for Commercial Production

Prerequisite for Obtaining Licence

Prior to apply for Licence, complete the requisites as follows

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

A. Add Employee (minimum requirement)

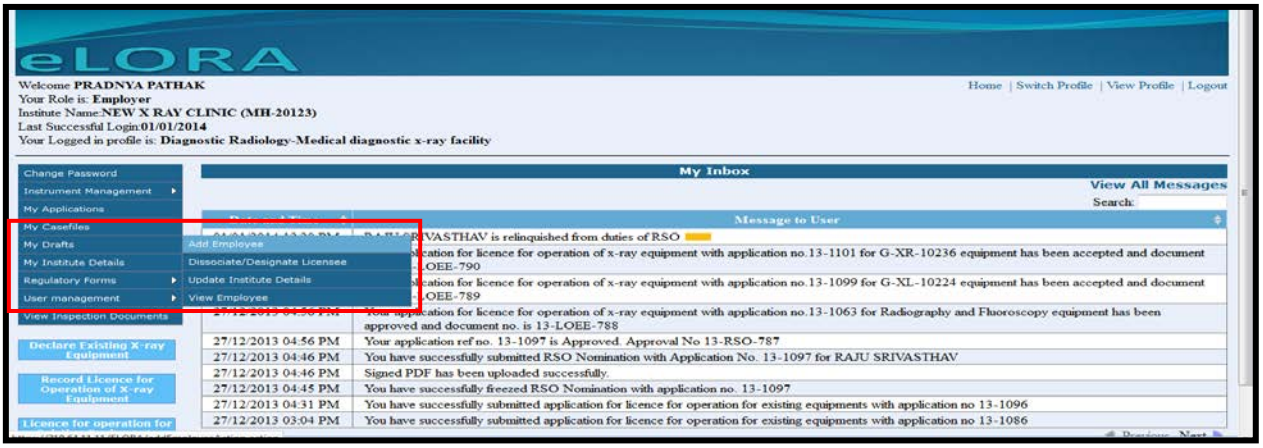
For Manufacturer of x-ray equipment and x-ray tubes, having at least one **service engineer** and **RSO** (Radiological Safety Officer) is mandatory for obtaining any Operating Licence.

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

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:

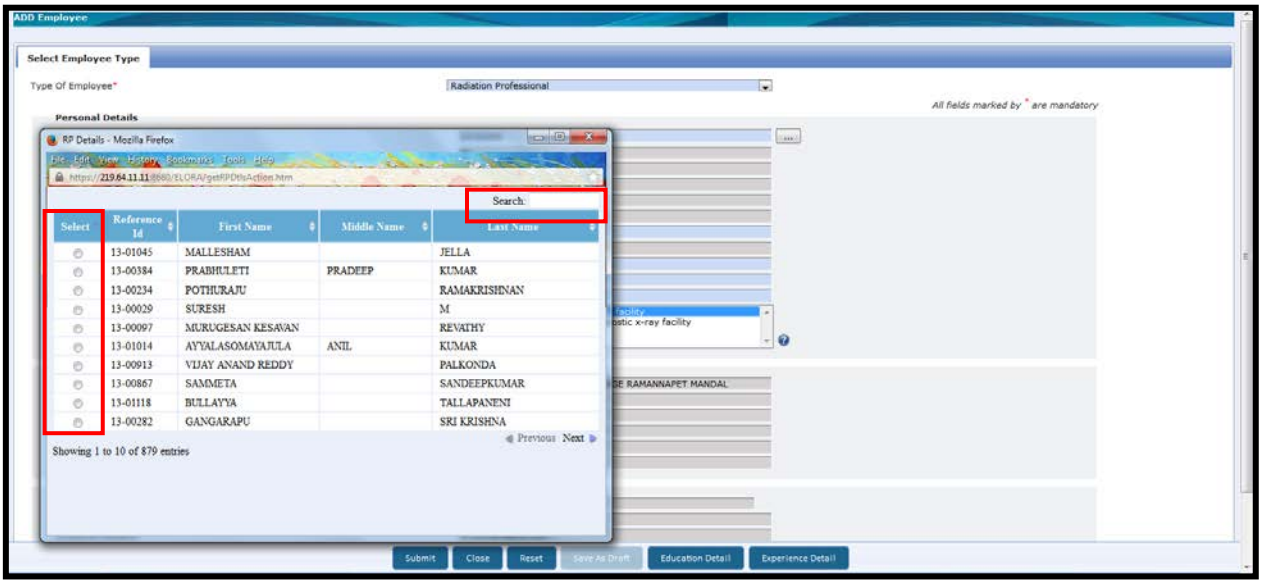
Menu → User management → Add Employee → Select required **Type of Employee** from drop down



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**.



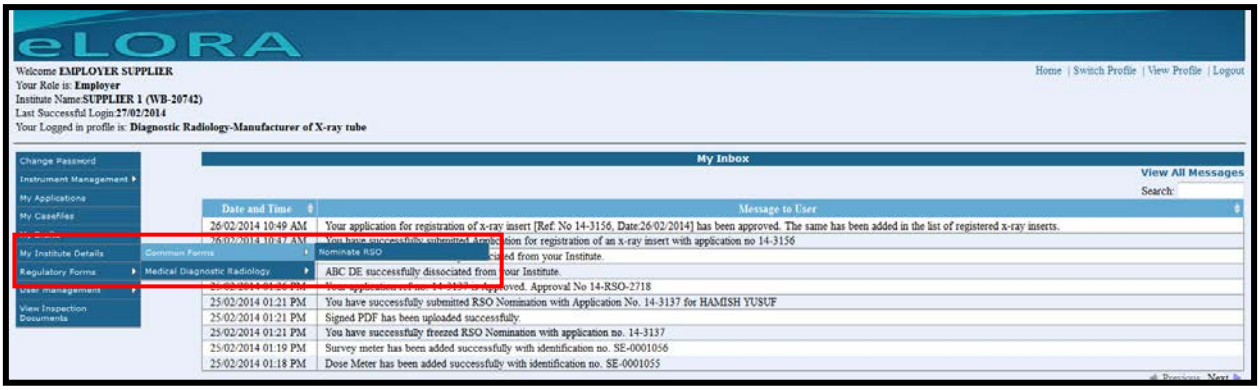
Fill required details and upload scan copy of Joining/Confirmation letter and click on **Submit.**

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

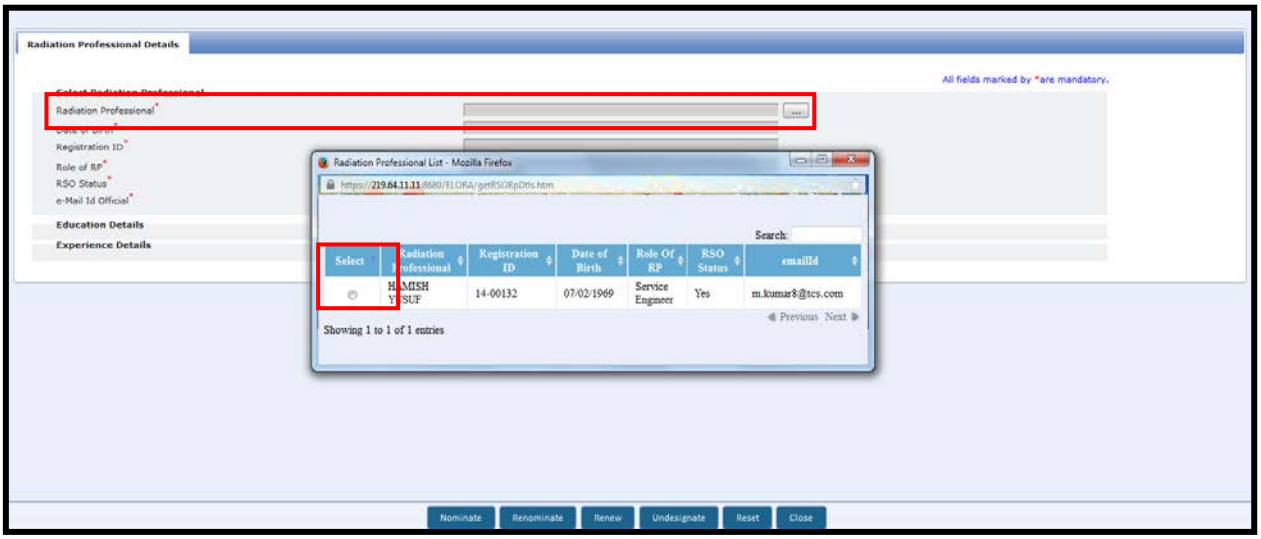
B. Obtain RSO Approval

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

Menu → Regulatory Forms → Common Forms



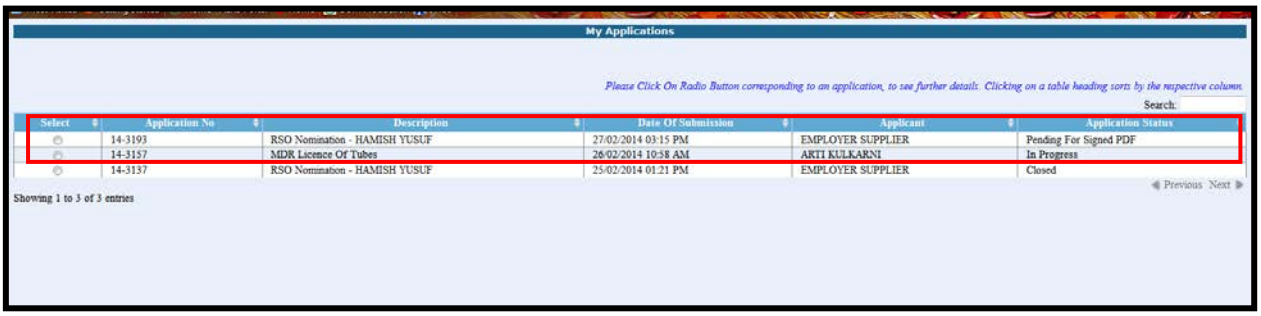
Select the **Radiation Professional** as Service Engineer of your institute, to be nominated as RSO.



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.**

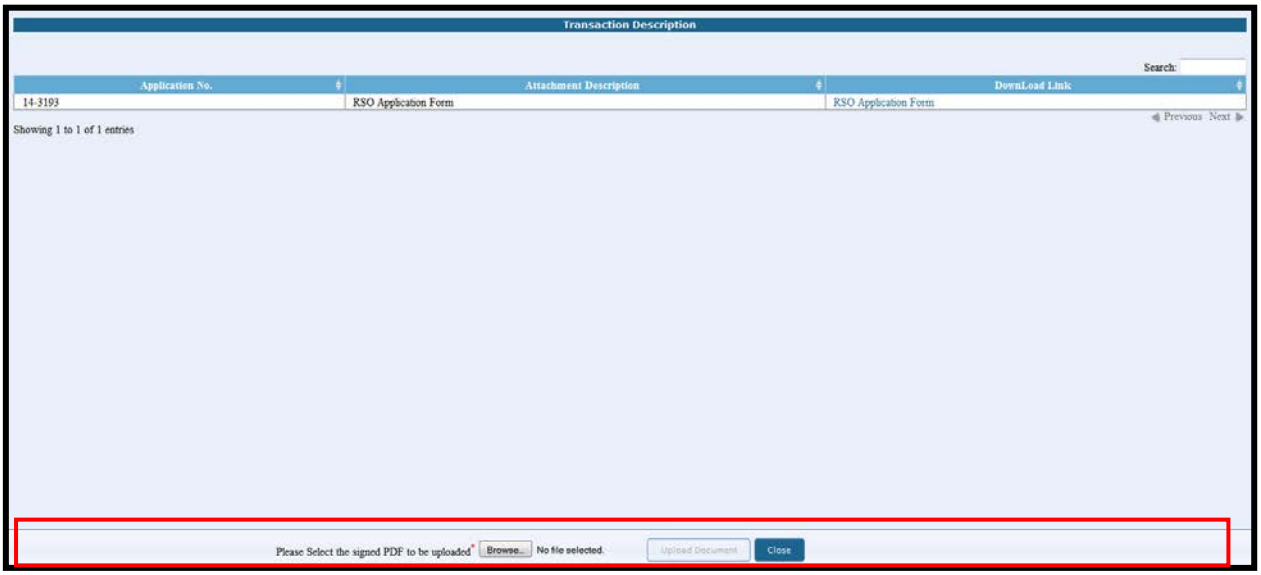
For submission of RSO nomination application form, follow the path as:

Menu → My applications

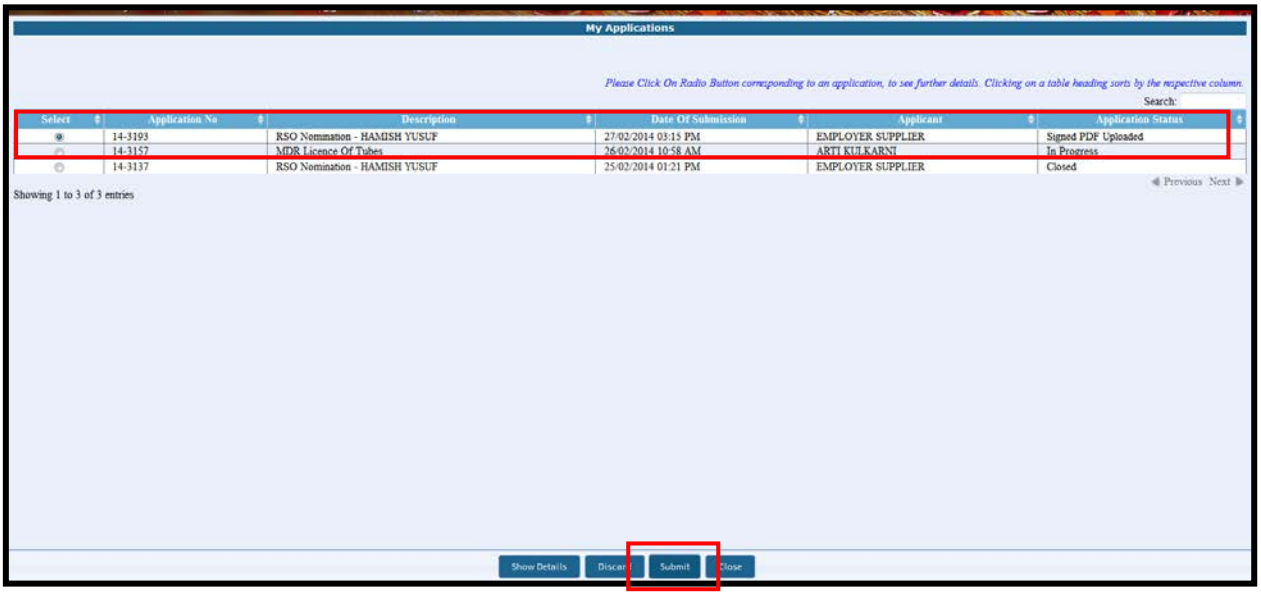


Select required **Application No.** (Application Status is shown as **Pending For Signed PDF**). Click on **Show Details** and download PDF of your application form from **Download Link**. Take a print of first page, Employer and Nominated RSO shall duly sign the first page (their names will appear in

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.

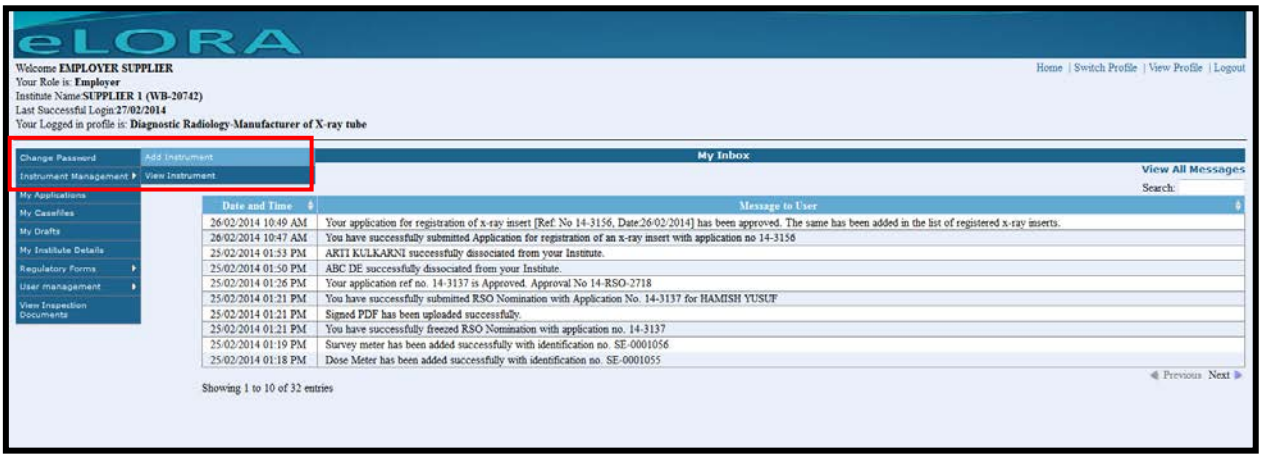
Your RSO nomination form will be reviewed by AERB and after acceptance; you will get its notification in your eLORA account.

C. 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 Manufacturer of X-ray Equipment		
Type of Equipment	Instruments to be added	
	Type of Instrument	Instrument Sub Type
Radiography Radiography & Fluoroscopy Interventional Radiology C-arm/O-arm Computed Tomography Mammography Dental (intra-oral, OPG.CBCT)	Measuring Tools	• kVp Meter • Dose Meter • Timer
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

Table 2: List of Instruments Required for Manufacturers of X-ray Tube

Applicable for Manufacturer of X-ray Tube		
Type of Equipment	Instruments to be added	
	Type of Instrument	Instrument Sub Type
For all types of X-ray tubes	Monitoring Tool	• Survey Meter
	Safety Tool	• Protective Apron • Protective Barrier with Viewing Window

D. 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. **Licence for Commercial Production:** Fill this form to obtain Licence for commercial production diagnostic X-ray equipments. (Same form is also applicable for renewal of licence)

   Documents required to be attached with this form:

   i) Radiation protection manual of the facility
   ii) Ownership document/rented property agreement of the site

iii) Drawing (scale 1:50) of the test facility
iv) Drawing (scale 1:100) of the floor layout of test facility

2. **Registration of X-ray Tube Insert:** Every manufacturer need to register each X-ray insert of all models which are to be imported/procured/manufactured. Fill this form register to X-ray 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

3. **Registration of X-ray Tube:** Every manufacturer need to register each X-ray tube of all models which are to be imported/procured/manufactured. Fill this form register to 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

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

5. **Intimation of Receipt:** Fill this form to intimate AERB about the receipt of X-ray insert/tube.

6. **NOC to Import X-ray Equipment**: This form is applicable for X-ray Equipment Manufacture. Fill this form to obtain permission to import X-ray equipment, which manufacturer is intended to use for research.
   Documents required to be attached with this form:
   i) Technical specifications of equipments
   ii) Technical catalogue of the equipment
   iii) Manual for quality assurance
   iv) Certification(s) of compliance to standards

7. **Type Approval of X-ray Equipment**: This form is not applicable for X-ray tube Manufacture. Fill this form to obtain type approval of diagnostic x-ray equipment manufactured. 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 while submission of application form. It is advised to visit this form first and download the template . (Same form is also applicable for renewal of Type Approval)
   Documents required to be attached with this form:
   i) Technical specifications of equipments
   ii) Technical catalogue of the equipment
   iii) Manual for quality assurance
   iv) TA test report
   v) 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

8. **Consent for Decommissioning:** Fill this form to obtain decommissioning permission from AERB.

9. **Confirmation of Decommissioning:** Fill this form to intimate AERB after decommissioning of facility.

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Annexure-1

Regulatory Requirements for Manufacturers of X-Ray Equipment and X-Ray Tubes

It is statutory requirement for the indigenous manufacturer of medical diagnostic x-ray equipment and x-ray tubes to obtain a-priori Licence for commercial production from the competent authority as per Atomic Energy (Radiation Protection) Rules 2004.

The manufacturer shall obtain import permission for x-ray tubes and x-ray tube inserts. He shall maintain data of testing of x-ray tubes and equipment.

Indigenous manufacturer of x-ray equipment shall also obtain Type Approval certificate from the competent authority for the prototype of every model of x-ray equipment before manufacturing on commercial scale.

Pre-requisites to obtain Licence for commercial production of X-Ray Equipment and X-ray Tubes

a) **Radiation testing facility:** A dedicated testing facility shall be available, 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. (please see layout guidelines for details)

b) **Quality Assurance test tools:** All the prescribed quality assurance test tools shall be available for testing. Any such test tool used to perform checks needs to have a calibration traceable to an acceptable national or international standard.

c) **Staff requirements:** Manufacturers shall have qualified and trained service engineers for radiation testing and Quality Assurance of diagnostic x-ray equipment. The minimum qualifications for service engineers shall be as prescribed by the competent authority from time to time.

d) **Radiological Safety Officer (RSO):** Every manufacturer shall have a Radiological Safety Officer (RSO) having qualifications as prescribed and approved by the competent authority from time to time.

Minimum Qualifications and Experience required for personnel is as follows:

a) **Service Engineer:**

1. 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

2. Certification of successful completion of training course on “Radiation Safety and Quality Assurance in Diagnostic Radiology” conducted by authorized agencies.

b) **Radiological Safety Officer(RSO)**

1. 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

2. Certification of successful completion of training course on "Radiation Safety and Quality Assurance in Diagnostic Radiology" conducted by authorized agencies, and

3. A certification from the competent authority

Renewal of License: The Licence shall be renewed before expiry in the format specified by the regulatory body.

Decommissioning of the facility: The licensee shall obtain the requisite consent for decommissioning of the facility. All authorized supplier shall be intimated six months in advance prior to actual decommissioning.

Terms and Conditions of Licence for Commercial Production of X-ray equipment and x-ray tubes:

1. No activity shall be carried out by your institute for purposes other than those specified in this Licence.

2. The radiation testing of the x-ray equipment and/or x-ray tubes shall be carried out in the location as per approved layout.

3. The regulatory **responsibilities of the employer, licensee and RSO** as laid down in the Atomic Energy (Radiation Protection) Rules, 2004 or the latest revision of AERB Safety Code (AERB/SC/Med-2) shall be adhered to.

4. Availability of qualified and trained personnel and personnel monitoring service to radiation workers shall be ensured all the time.

5. All models of x-ray tube and x-ray tube insert to be imported/indigenously manufactured shall be registered with AERB through eLORA.

6. For import/procurement of x-ray tube(s)/x-ray tube inserts, the manufacturer shall obtain NOC for import/permission for procurement from the competent authority.

7. Prior to commercial production of every model of x-ray equipment the manufacturer shall obtain Type Approval from the competent authority, on demonstration of performance of the prototype of x-ray equipment. (Not applicable for x-ray tube manufacturers)

8. Shall abide by the Quality Control procedure in manufacturing and ensure quality of x-ray tubes and the type approved model/s is maintained.

9. Manufacturer shall ensure that before supply, their supplier(s) (if any) obtain AERB Authorization.

10. The **periodic safety status report** in the prescribed format and frequency shall be submitted to AERB.

11. In case there is change in information specified in this licence after its issuance, such as change of Employer, Licensee, name of institution it shall be ensured by licensee that the necessary **amendment** to this effect to the licence is obtained from the Competent Authority.

12. The Licence shall be renewed before expiry.

13. Facilities shall be accorded to any authorized inspector of the competent authority to inspect the facility at any time. Records on manufacturing/supply/Quality Assurance Tests /Type Approvals shall be made available.

14. If part or complete activity of manufacturing is outsourced by the OEM, to any agency, it shall be the responsibility of the OEM to ensure that all the quality protocols in the manufacturing are duly complied with. The outsourced agency shall also be subjected to inspection by the regulatory body as applicable to OEM.

15. Any incident involving radiation exposure to person shall be intimated to AERB immediately.

16. For closure of manufacturing facility, the licensee shall obtain the requisite consent for decommissioning of the facility. All authorized suppliers shall be intimated in advance prior to actual decommissioning.

17. This license may be suspended, modified or withdrawn as specified in the Atomic Energy (Radiation Protection) Rules, 2004, in the event of contravention of the provisions of the above Act / Rules / Codes or terms and conditions of the Licence. Where deemed appropriate, AERB may also initiate penal action against the Employer/licensee in such an event.

Annexure-2

Guidelines for design of radiation testing facilities for x-ray equipment at manufacturing premises

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:

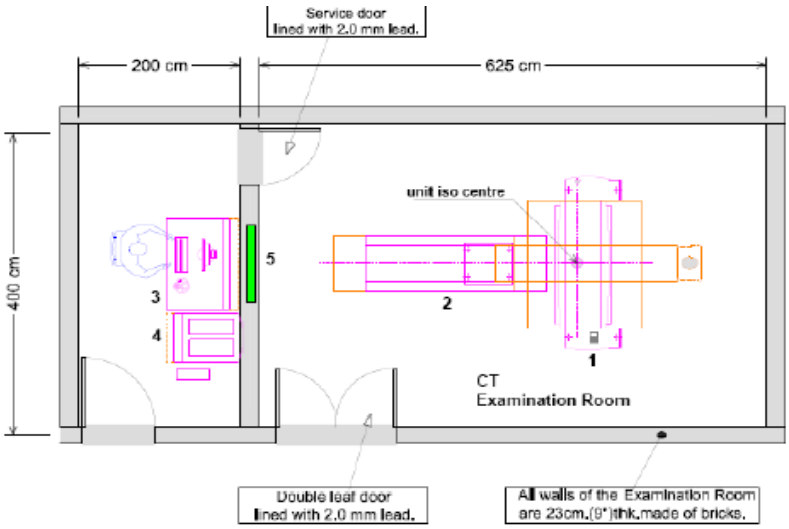
- Decide a suitable room/bay for testing of X-ray equipment located as far away as feasible from other working areas not related to radiation testing and area of high occupancy and general traffic.
- Ensure that the thickness of the wall(s) of the testing room(s) should not be less than 23 cm thick brick 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*:



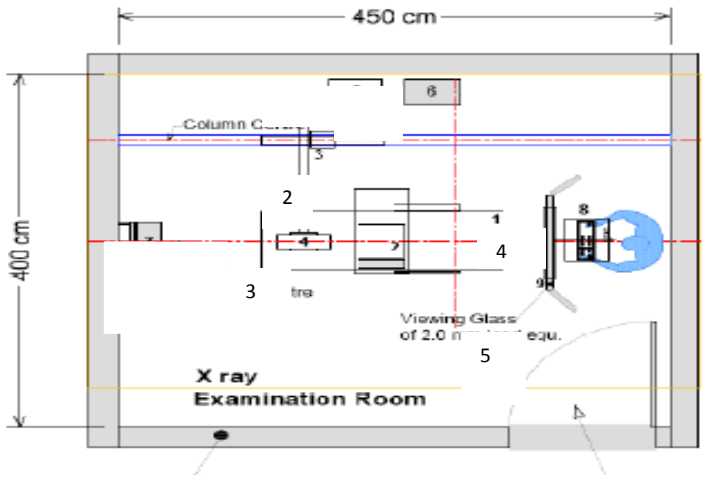
Legend:

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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