eLORA - Guidelines for Service Agency of Medical Diagnostic X-ray Equipments

The agencies associated with installation, commissioning, servicing, Quality Assurance, decommissioning and sale of pre-owned (*used/refurbished*) diagnostic x-ray equipment are termed as service agencies.

The service agencies can undertake one or more of the following activities after obtaining Authorization from the regulatory body.

a) Sale of pre-owned x-ray equipment
b) Servicing of x-ray equipment
c) Providing Quality Assurance services

It is mandatory for Service Agencies of medical diagnostic x-ray equipments 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, manufacturers and suppliers are provided separately.

Service Agencies of medical diagnostic x-ray equipment 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

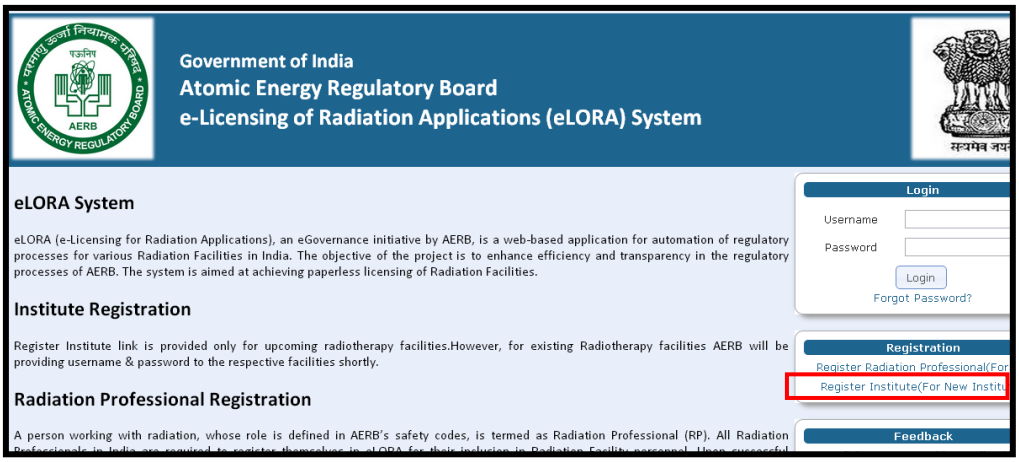
In case your institute is already registered with e-LORA for any other role, you can update your institute role as 'Service Agency' by following way:

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

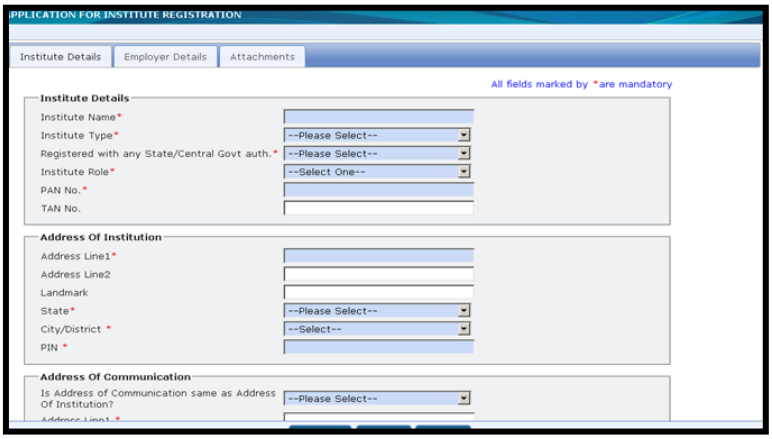
Then choosing required profile you can access the system.

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.

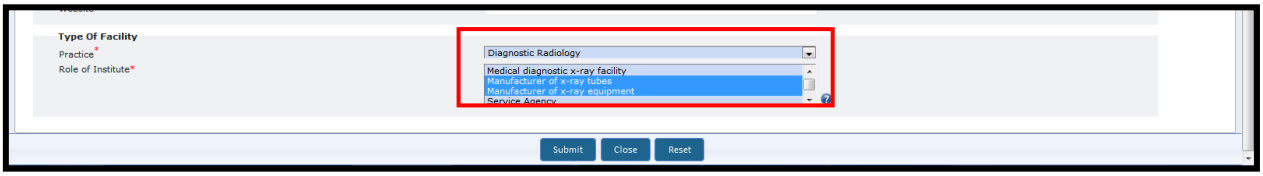


Important Note: Guidelines to fill application form for Institute Registration is available on eLORA home page. It is advised to read the guideline and keep soft copy of required attachments ready before start filling of application form.

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 **Service Agency**



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.

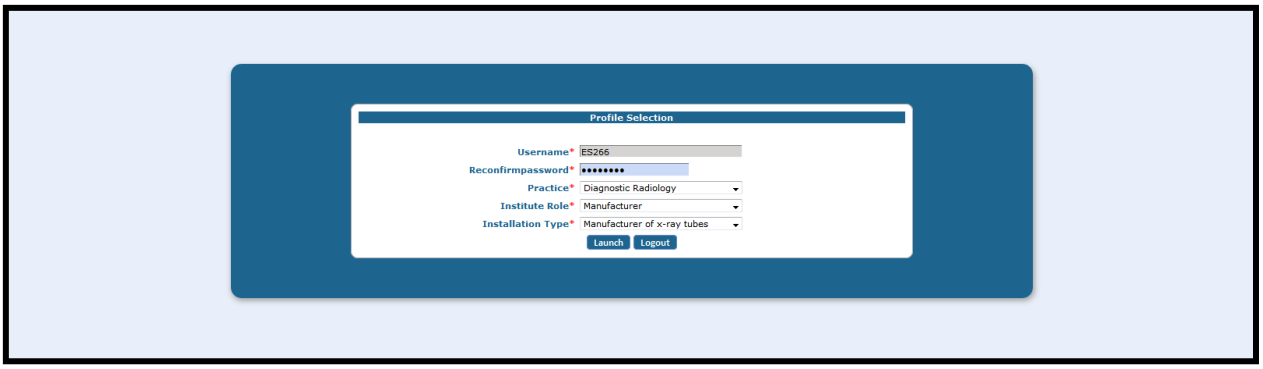
Important Note: Fields marked with * in the application form are mandatory. Application form will not be submitted if any mandatory field left blank.

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 Service Agency 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)

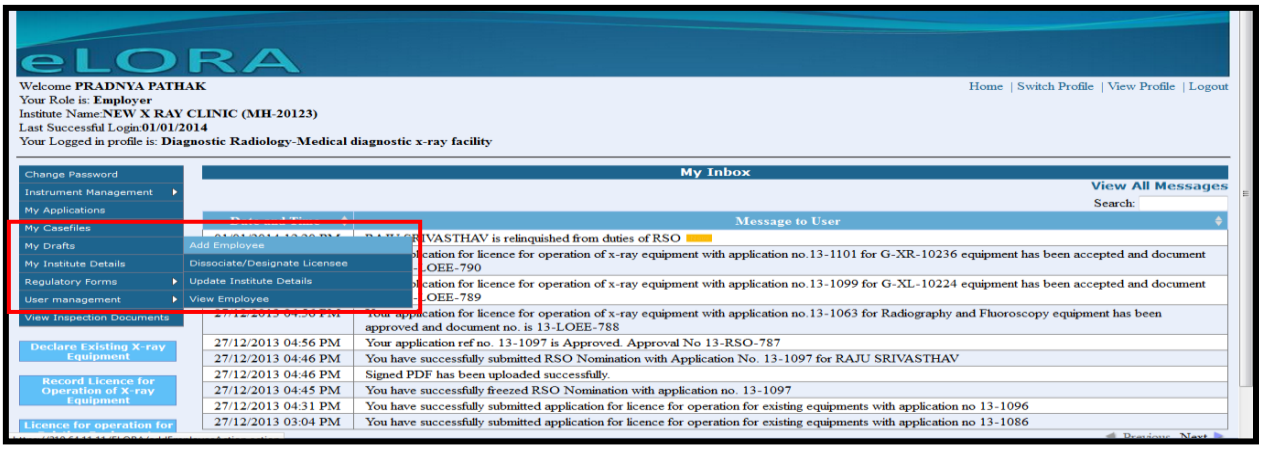
For Service Agency of x-ray equipment, having at least one **service engineer** and **RSO** (Radiological Safety Officer)if applicable is mandatory.

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

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:

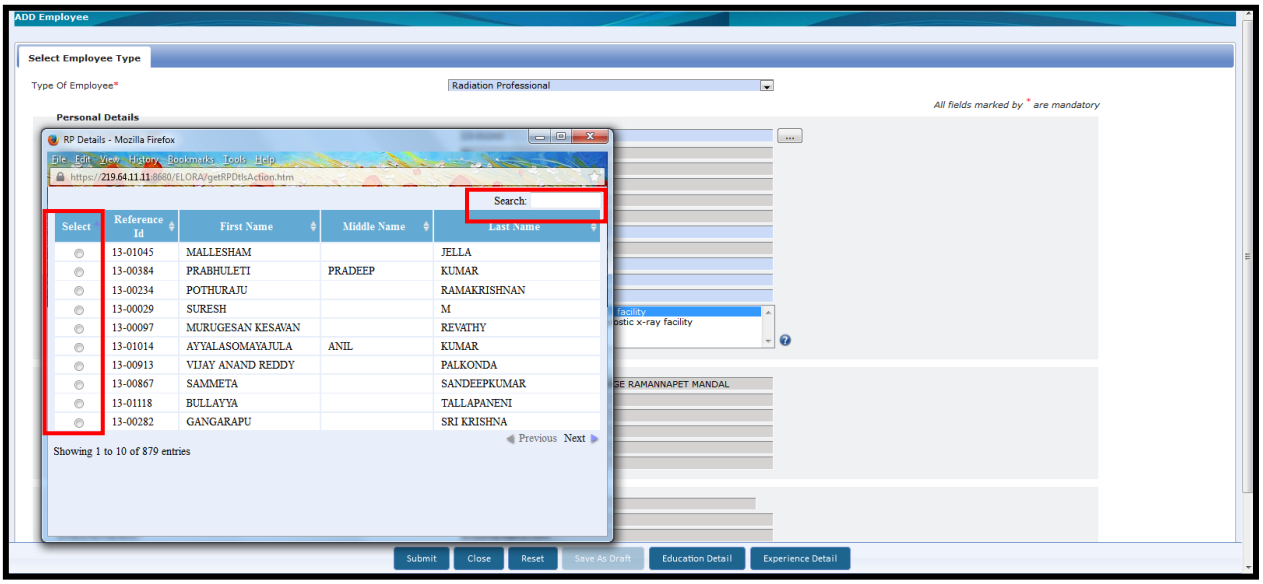
Menu → User management → Add Employee → Select required **Type of Employee** from drop down



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**.



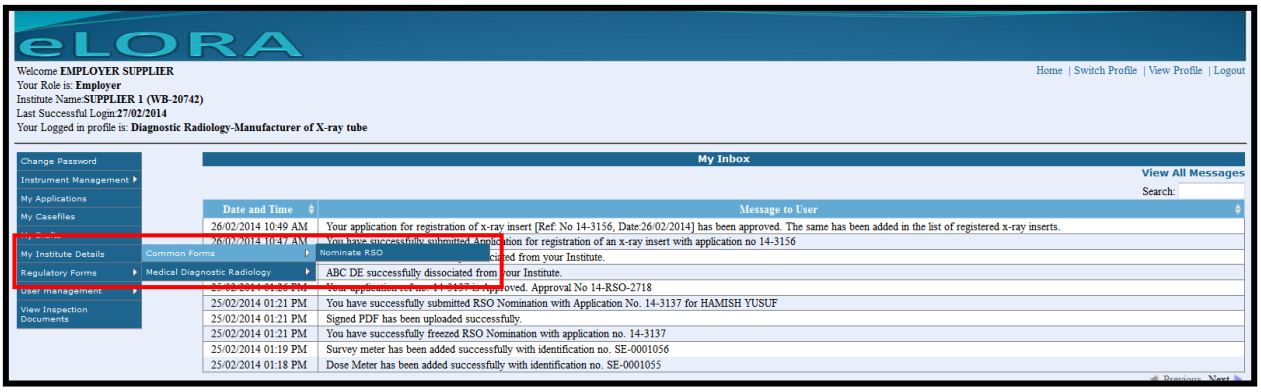
Fill required details and upload scan copy of Joining/Confirmation letter and click on **Submit.**

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

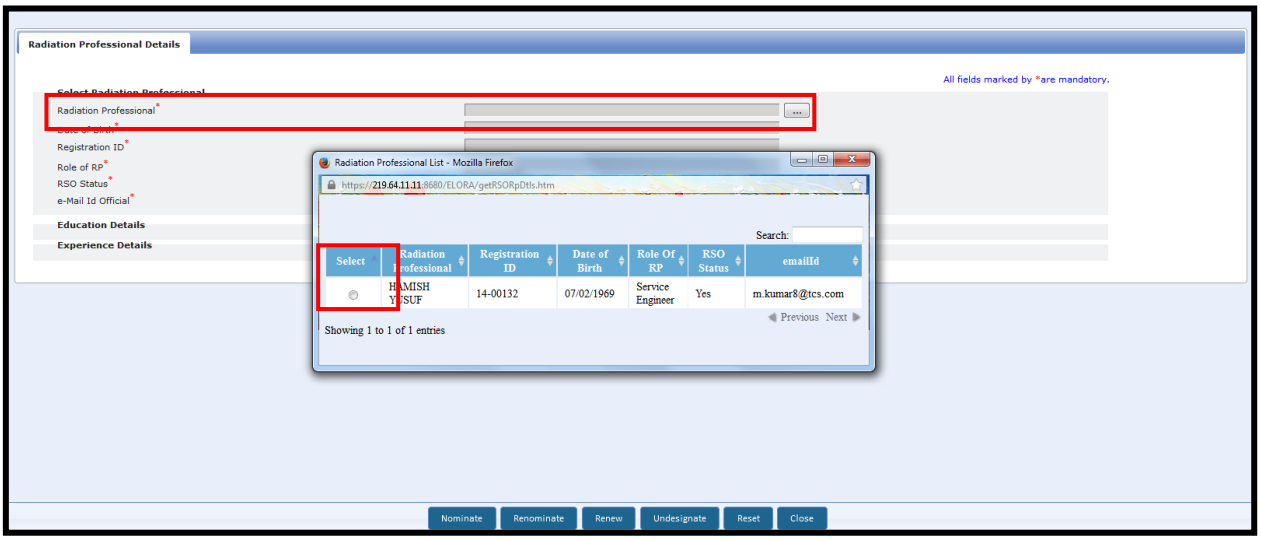
B. Obtain RSO Approval

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

Menu → Regulatory Forms → Common Forms



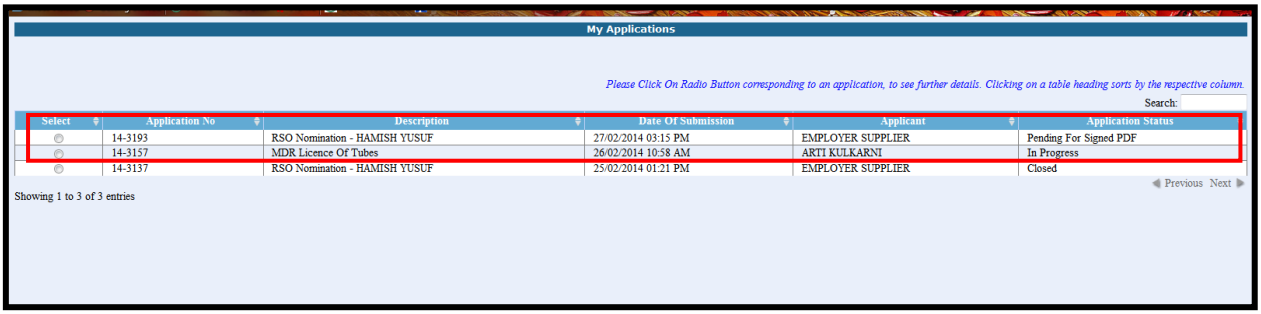
Select the **Radiation Professional** as Service Engineer of your institute, to be nominated as RSO.



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.**

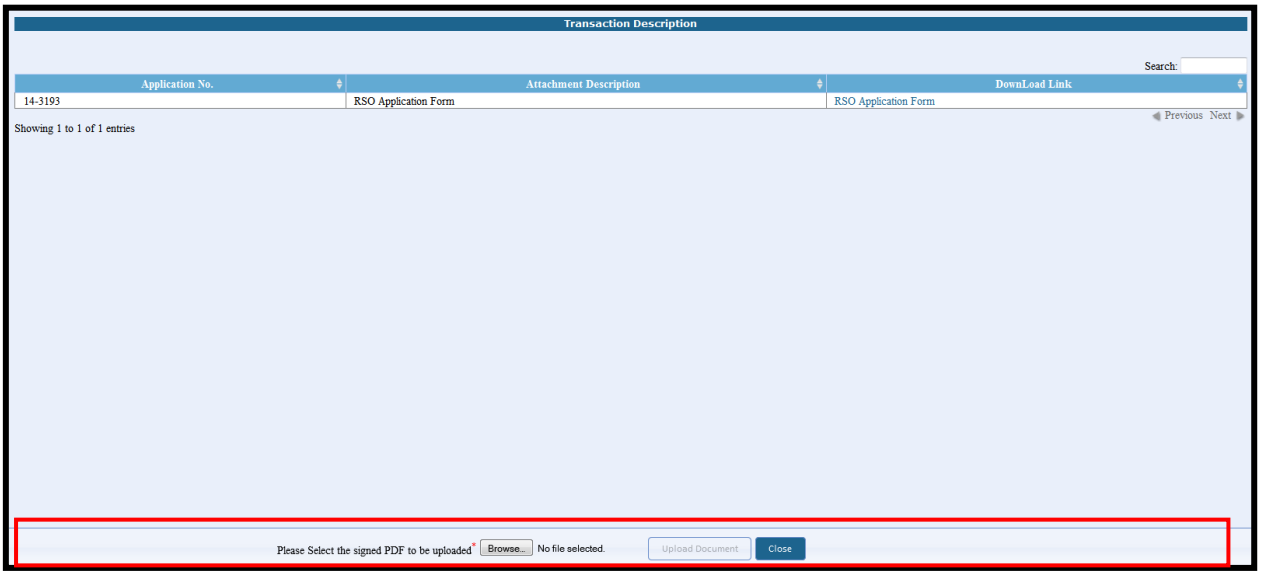
For submission of RSO nomination application form, follow the path as:

Menu → My applications

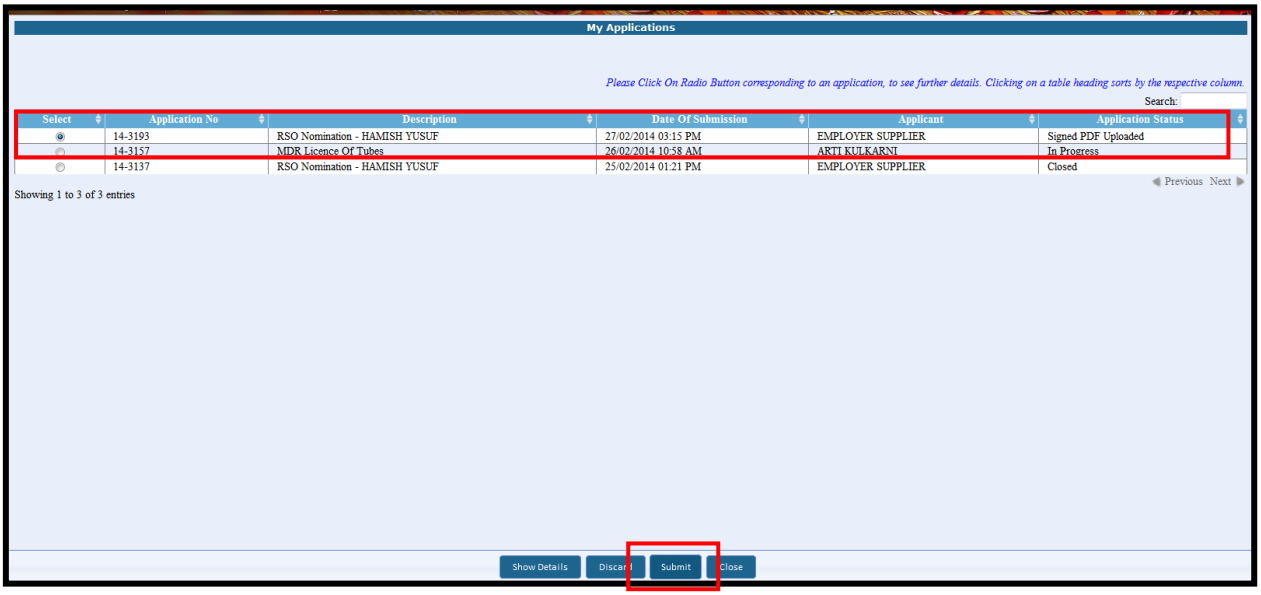


Select required **Application No.** (Application Status is shown as **Pending For Signed PDF**). Click on **Show Details** and download PDF of your application form from **Download Link**. Take a print of first page, Employer and Nominated RSO shall duly sign the first page (their names will appear in

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:

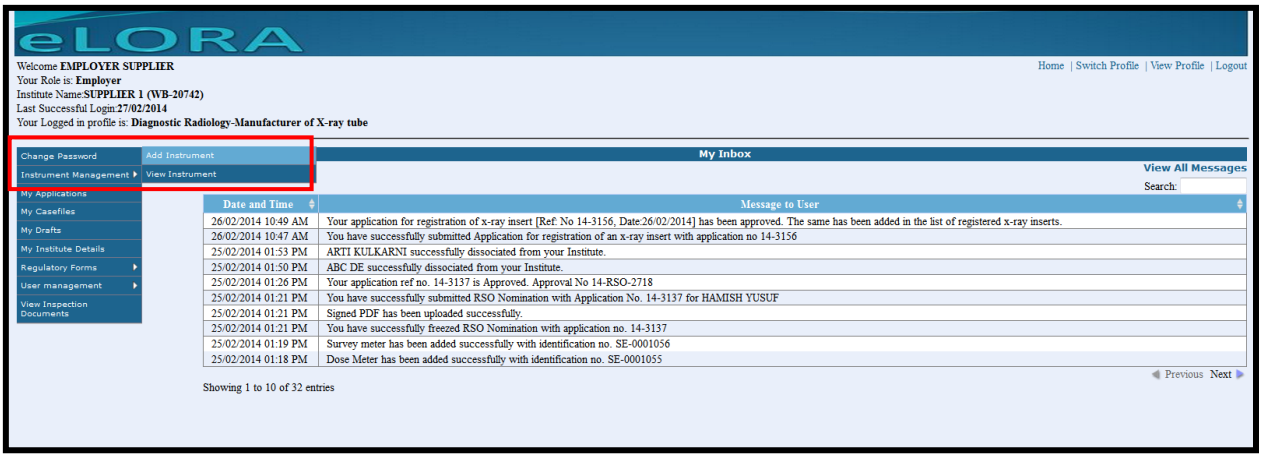
Menu → User Management → Designate employee

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 Service Agencys 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 Service Agency 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 OEM Authorization whose x-ray equipment would be proposed to refurbish.

   Documents required to be attached with this form:
   i) OEM authorization for the model proposed for supply.

3. **Registration of X-ray Tube Insert:** Service Agency 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:** Service Agency 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. **Intimation of Receipt:** Fill and submit this form to intimate AERB about the receipt of X-ray tube insert/x-ray tube if imported.

7. **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 Service Agency.

8. **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.

9. **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.

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

11. **Termination of Services:** Fill this form to intimate about termination of your services as Service Agency.

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Annexure-1

REQUIREMENTS FOR SERVICE AGENCIES

The agencies associated with installation, commissioning, servicing, Quality Assurance, decommissioning and sale of pre-owned (*used/refurbished*) diagnostic x-ray equipment are termed as service agencies.

The service agencies can undertake one or more of the following activities with appropriate recognition from the regulatory body.

d) Sale of pre-owned x-ray equipment
e) Servicing of x-ray equipment
f) Providing Quality Assurance services

The owner of the agency is identified as Employer as per AE (RP) R, 2004. Employer is considered as the 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 as Service Agency

a) **Radiation testing facility**: In case the service agency seeks recognition for 'Sale of pre-owned x-ray equipment' and also for refurbishment of x-ray equipment (if required), 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. A warning placard shall be displayed outside the testing facility.

b) **Staff requirements**: Service agencies 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.

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

Conditions of Authorization

The service agency shall be responsible for ensuring compliance with terms and conditions of Authorization and Type Approval issued by competent authority. The service agency hereinafter called the "employer" and "Licencee" shall fulfil all requirements as prescribed in this code.

Specifically the service agency involved in one or more of the activities mentioned above shall ensure that

a) Only Type approved models shall be re-sold. (for agencies involved in the sale of equipment)

b) Report on installation of x-ray equipment shall be submitted to regulatory body in the prescribed format.

d) Ensure availability of protective accessories (such as MPB, lead apron, lead goggles, etc) at the x-ray installation/equipment.

f) Every equipment re-sold, shall be labelled as PRE-OWNED before installation.

g) Service Agency shall provide the following documents to new utility at the time of supply.

- Installation report, Acceptance test report and radiation survey report of x-ray equipment/installation.
- Technical catalogues, service, QA and Design manuals of the equipment.
- Submission of exposure protocols for patient examinations
- Providing training on operational aspects and radiation safety to the users.

h) In case of service to utility involving decommissioning/ dismantling of x-ray equipment, intimation shall be submitted to regulatory body in the prescribed format.

IV) Periodic Safety Reports:

The Licensee shall submit periodic safety status reports in the format and frequency specified by the regulatory body.

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

VI) Termination of Services: AERB shall be intimated in case the service agency decide to cease functioning.

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:

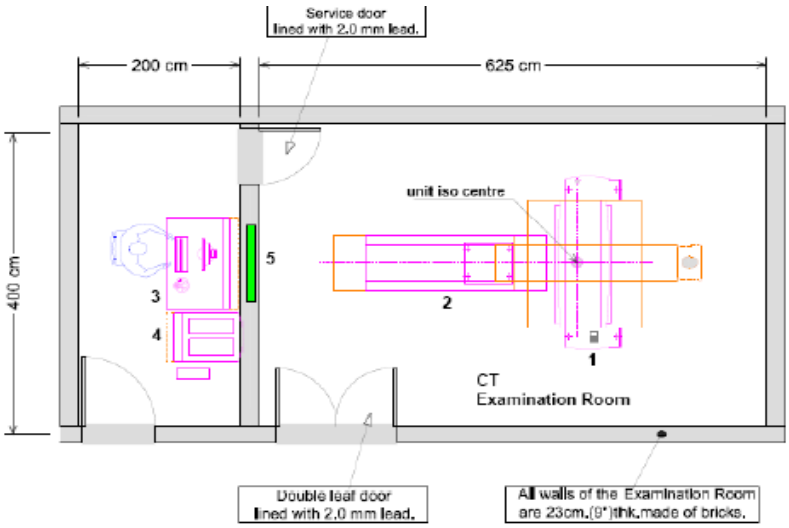
- Decide a suitable room/bay for testing of X-ray equipment located as far away as feasible from other working areas not related to radiation testing and area of high occupancy and general traffic.
- Ensure that the thickness of the wall(s) of the testing room(s) should not be less than 23 cm thick brick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



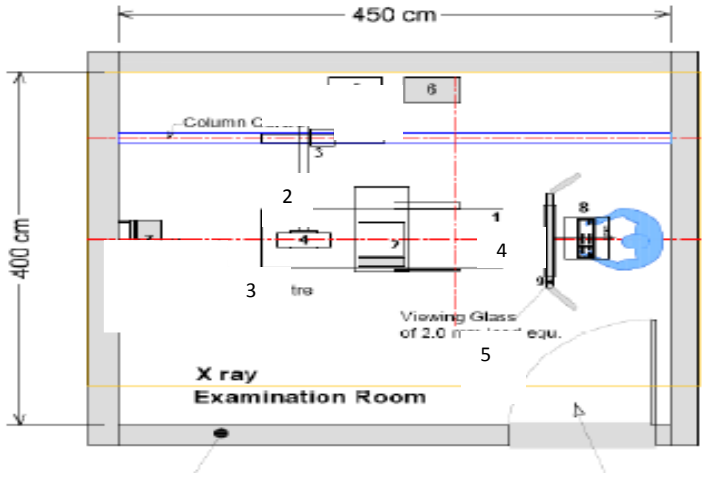
Legend:

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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