

e-Licensing of Radiation Applications (eLORA) System

Guidelines



Medical Diagnostic Radiology Module

July 14, 2016

Table of Content

Guidelines for Applying for Licence of Diagnostic Radiology X-ray Equipment through eLORA System

General Guidelines (Applicable for all types of equipments viz. existing as well as new)	4
1. Register Your Institute	4
2. Prerequisites for Licence	6
A. Declare Employees	6
B. Obtain RSO Approval	9
C. Add Instrument.....	11
D. Prepare Layout	12
E. Quality Assurance	13
Guidelines for Obtaining Licence for Existing X-ray Equipment.....	13
3. Declare Your X-ray Equipments.....	13
4. Record Licence Detail	14
5. Fill Application Form for Licence	15
6. Renewal of license.....	20
Guidelines for Obtaining Licence for New X-ray Equipment.....	20
7. Procurement of X-ray Equipment.....	20
8. Application for Licence	21
9. Guidelines for obtaining Licence for Pre-owned (Used/refurbished) X-ray Equipment	22
Guidelines for Other Processes	22
9. Change in Layout:	22
10. Safety Status Report	22
11. QA Test Summary	23
12. Radiation Survey Report.....	23
13. Procurement of X-ray Tube	23
14. Intimation of Receipt.....	23
15. Intimation of Decommissioning	23
Important Message	23
16. NO LICENSE FEE /PROCESSING FEE BY AERB.....	23
17. Deletion of duplicate or wrong declaration of X-ray equipment	24
18. Non-compliance.....	24
19. Authorised Service Agencies, AERB Type Approved X-ray equipment and AERB-Licensed X-ray facilities.....	24
20. Annexures:.....	25

Annexure - 1: Regulatory requirements in the use of X-ray equipment	25
Annexure – 2: List of Personnel Monitoring Service (PMS) Providers	27
Annexure - 3: Standard Layouts	28
a) Standard Layout of X-ray Installation	28
b) Standard Layout of CT Installation	29
c) Standard Layout of Interventional Radiology Installation.....	30
d) Standard Layout of Mammography Installation.....	31
Annexure - 4: Application Form for Removal of Duplicate or Wrong Declaration of Medical X-Ray Equipment in eLORA.....	32

Help Email id for Diagnostic Radiology Users

elora.dr@aerb.gov.in

General Guidelines (Applicable for all types of equipments viz. existing as well as new)

It is mandatory for all users of medical diagnostic x-ray equipments to obtain **Licence for Operation from AERB** as per Atomic Energy (Radiation Protection) Rules 2004.

To facilitate online submission of applications for regulatory consents and establish channel of communication with AERB for other regulatory requirements, AERB has launched **Diagnostic Radiology module** in its e-governance application e-LORA (e-Licensing of Radiation Applications) System. All diagnostic x-ray equipment user Institutes are required to use eLORA for obtaining operating Licence from AERB.

1. 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**.

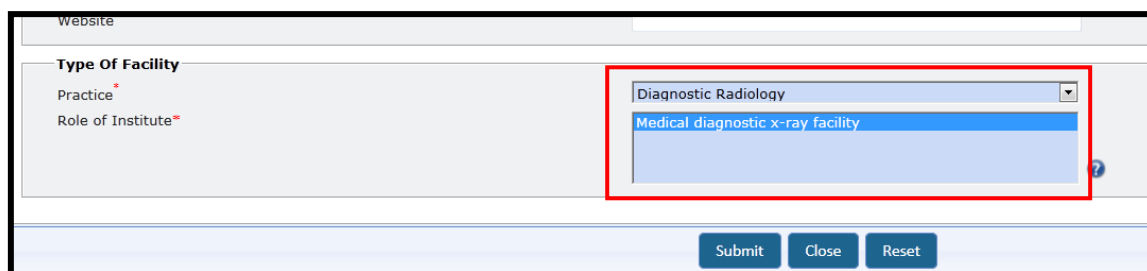
Click on **Register Institute**(see above figure). This will open application form for Institute Registration.

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

Fill the application form as per the guidelines. 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 **Medical Diagnostic X-ray Facility**



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): Acceptable documents are as follows:
 - Passport
 - PAN card issued by Income Tax Department
 - Driving Licence issued by RTO
 - Photo identity document/card having serial number and date of birth issued by Central/State Government or PSU
- ✓ **Proof of Employment:** Example: (i) Appointment Letter of Employer, (ii) Board Resolution, (iii) Any Govt./PUC document substantiating proprietorship (iv) Partnership deed (notorised) or (iv) Proprietor's self declaration on institute letter head affixed with institute seal
- ✓ **Upload scan copy of any one of the document (in the relevant position) for the proof of existence of institute:**
 - PAN of Institute
 - TAN of Institute
 - Registration with State/Central/Local Government Authority

Enter the Captch 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 short 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).

2. Prerequisites for Licence

Prior to apply for Licence; follow following steps:

A. Declare Employees

- For X-ray equipment/installation such as CT scan, Interventional Radiology, C-Arm/O-Arm and equipment with Fluoroscopy mode shall have adequate no. of Operator and **Medical Practitioner** for obtaining Operational Licence.
- For obtaining License for all other X-ray equipment availability of adequate no. of **Operator** is mandatory
- Operator & medical Practitioner shall be declared in eLORA through “**add employee**” menu.
- For CT and Interventional Radiology (IR) equipments, in addition to Operator and Medical Practitioner, **RSO (Radiological Safety Officer)** is mandatory for obtaining Operational Licence.
- Other than CT & IR equipment, if RSO is not available, “Registrant” may designate himself as RSO.

The minimum qualification requirement for employees in Diagnostic Radiology is as given below:

Role of Employee	Eligibility
Medical Practitioner	Related Medical Practitioners such as MD/MS/DNB/BDS/MDS/ equivalent associated with the use of X-ray equipment
Operator	Qualified X-ray technologist/Radiographers OR Medical Practitioner (as above)
RSO	<p>Any person having valid AERB RSO approval for your Institute.</p> <p>In case, no person is having valid AERB RSO approval for your Institute then any Medical Practitioner (as above) OR Qualified X-ray technologist (with three years experience in the field of CT/Interventional Radiology) can be nominated for RSO approval after registering as Radiation Professional (RP) in e-LORA.</p> <ul style="list-style-type: none"> • 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: ‘Radiation Safety Professional’.

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.

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

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

My Applications	Date and Time	Message to User
My CaseFiles	01/01/2014 12:00 PM	RAJESH K. RIVASTHAV is relinquished from duties of RSO
My Drafts	Add Employee	Application for licence for operation of x-ray equipment with application no.13-1101 for G LOEE-790
My Institute Details	Dissociate/Designate Licensee	Application for licence for operation of x-ray equipment with application no.13-1099 for G LOEE-789
Regulatory Forms	Update Institute Details	
User management	View Employee	
View Inspection Documents	27/12/2013 04:56 PM	Your application for licence for operation of x-ray equipment with application no.13-1063 for R approved and document no. is 13-LOEE-788

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

- **Radiation Worker** (this is to add employee with role **Operator** and **Medical Practitioner**)
- **Non Radiation Worker**(this is to add Licensee who may not be a radiation worker)
- **Radiation Professional**(this is to add **Radiation Professional** who is to be nominated as**RSO**)

You are required to add **Operator** and **Medical practitioner** in the type **Radiation Worker**.

The screenshot shows the 'ADD Employee' form. The 'Type Of Employee' dropdown is set to 'Radiation Worker'. The 'Role' dropdown is highlighted with a red box, showing options: 'Operator-Medical diagnostic x-ray facility' and 'Medical Practitioner-Medical diagnostic x-ray facility'. Other dropdowns include 'Well Logging (Radiation Facility)', 'Medical diagnostic x-ray facility', 'Supplier of x-ray equipments/x-ray tubes', 'Manufacturer of x-ray equipments/x-ray tubes', 'Medical Diagnostic-Service Agency', and 'Industrial Radiography (Radiation Facility)'. The 'Date Of Joining' is set to 25/9/2014. The 'PMS NO' field is empty. The 'Education Qualification' field is empty. The 'Attachment for uploading copy of proof of education' field is empty. The 'Submit', 'Close', 'Reset', and 'Save As Draft' buttons are visible at the bottom.

This is a close-up of the 'Role' dropdown menu. It shows two options: 'Operator-Medical diagnostic x-ray facility' and 'Medical Practitioner-Medical diagnostic x-ray facility'. Below the options is a '--Please select--' dropdown arrow.

This is a close-up of the 'Well Logging (Radiation Facility)' dropdown menu. It shows several options: 'Well Logging (Radiation Facility)', 'Medical diagnostic x-ray facility', 'Supplier of x-ray equipments/x-ray tubes', 'Manufacturer of x-ray equipments/x-ray tubes', 'Medical Diagnostic-Service Agency', and 'Industrial Radiography (Radiation Facility)'. The 'Medical diagnostic x-ray facility' option is highlighted in blue.

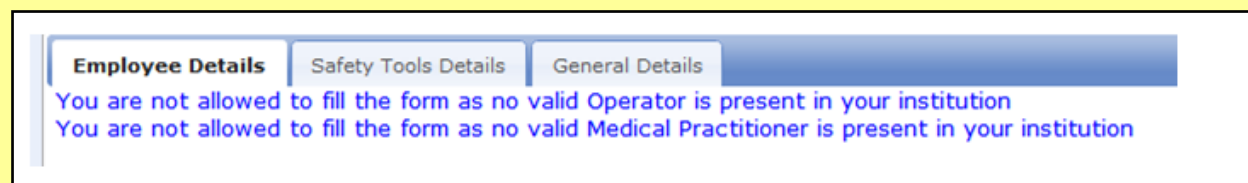
In the form for adding **Radiation Worker**,

- Provide required personal information of employee viz. Title, Name, Gender and Date of Birth
- Provide required service information of employee viz. Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department, Designation, **Profile (select 'Medical diagnostic x-ray facility')** , **Role (select any one or both using Ctrl key – as applicable) and Education Qualification (select value from drop down)**

- Provide address and contact detail of employee
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**

Repeat the above procedure to add your other **Operators** and **Medical practitioners**.

Important Note: You will not be able to fill application form for Licence (and will get following error message) unless you declare **Operator** and **Medical Practitioner** of your Institute.



In case your institute is not having valid RSO, you need to obtain RSO approval from AERB. For a person required to be nominated as RSO, you need to add him/her in the type **Radiation Professional (RP)**. While adding RP, system will ask RP registration ID and Date of birth of RP. (Obtain these details from the Radiation Professional)

In the form for adding **Radiation Professional**,

- Enter **Registration ID** and Date of birth of RP—personal detail of RP will come automatically.
- In case RP is Employer of Institute, select 'Yes' for 'Whether the person is also Employer of the Institute?'
- Provide Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department and Designation, Profile (i.e. 'Medical diagnostic x-ray facility') and Role (i.e. 'Operator', Medical Practitioner' or both)
- Provide Email (O)
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**

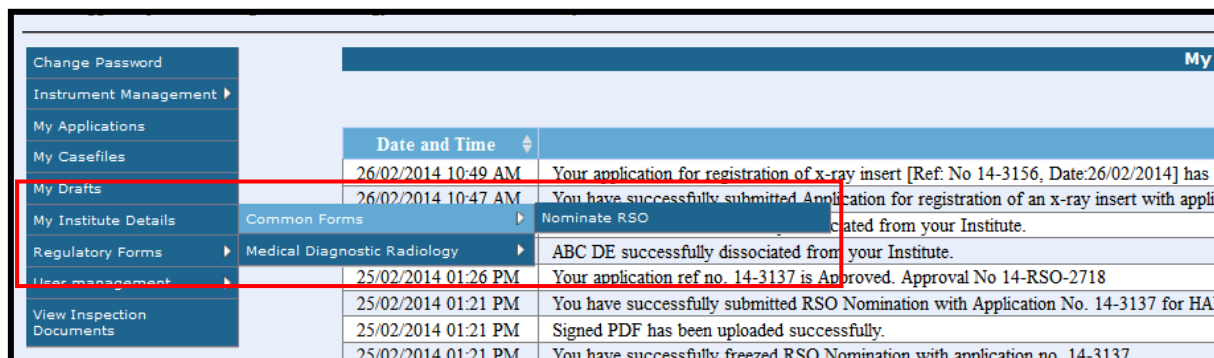
Important Note: Radiation Professional can subsequently be nominated for the approval of Radiological Safety Officer (RSO). Process of RSO nomination explained in Sr. No.:B

B. Obtain RSO Approval

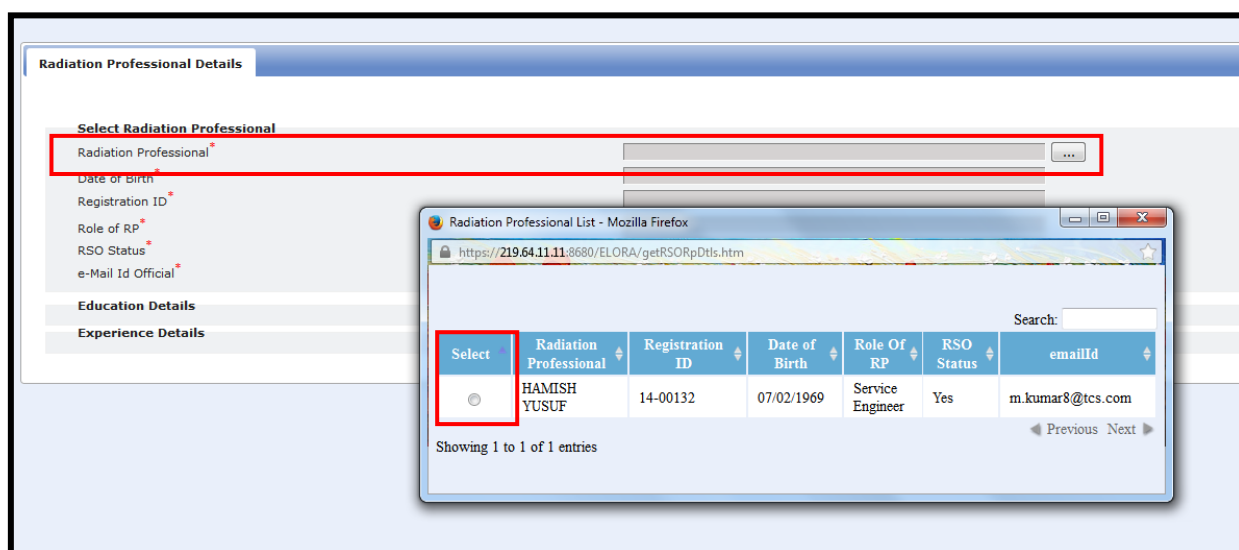
In case you do not have valid RSO for your CT and Interventional Radiology facility, obtain RSO approval.

For CT and Interventional Radiology facilities, RSO approval is mandatory. For nominating your employee for RSO approval, follow the path as:

Menu → Regulatory Forms → Common Forms



Select the name of employee in **Radiation Professional**



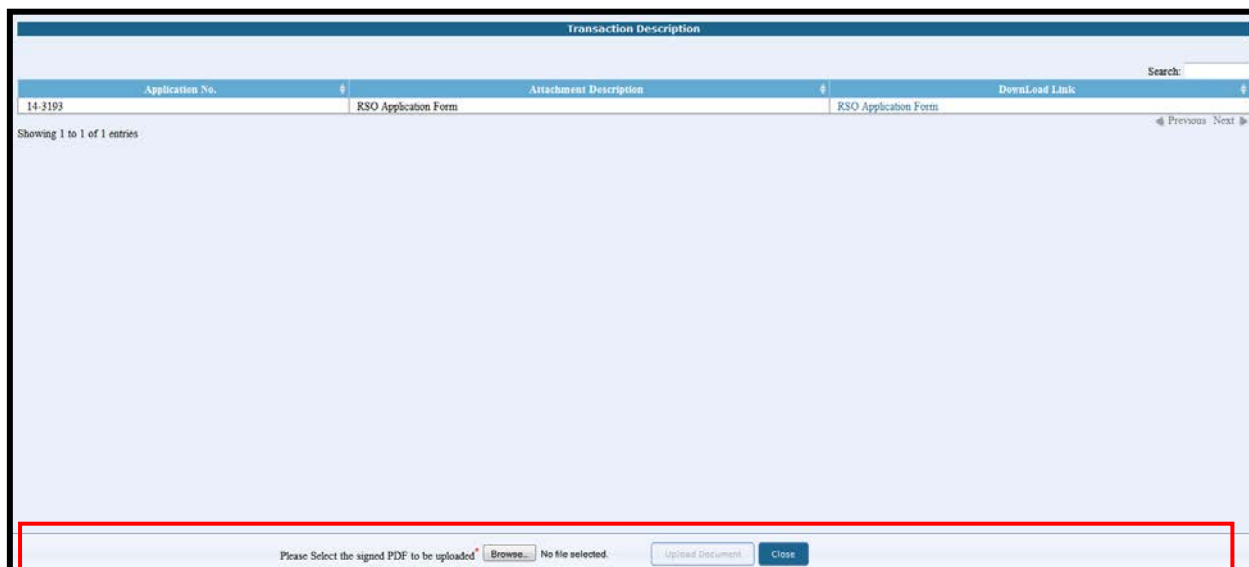
Fill the asked information and click on **Freeze**. This will freeze your application form and show your application number. **Please note, Freeze does not mean submission of application form to AERB.**

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

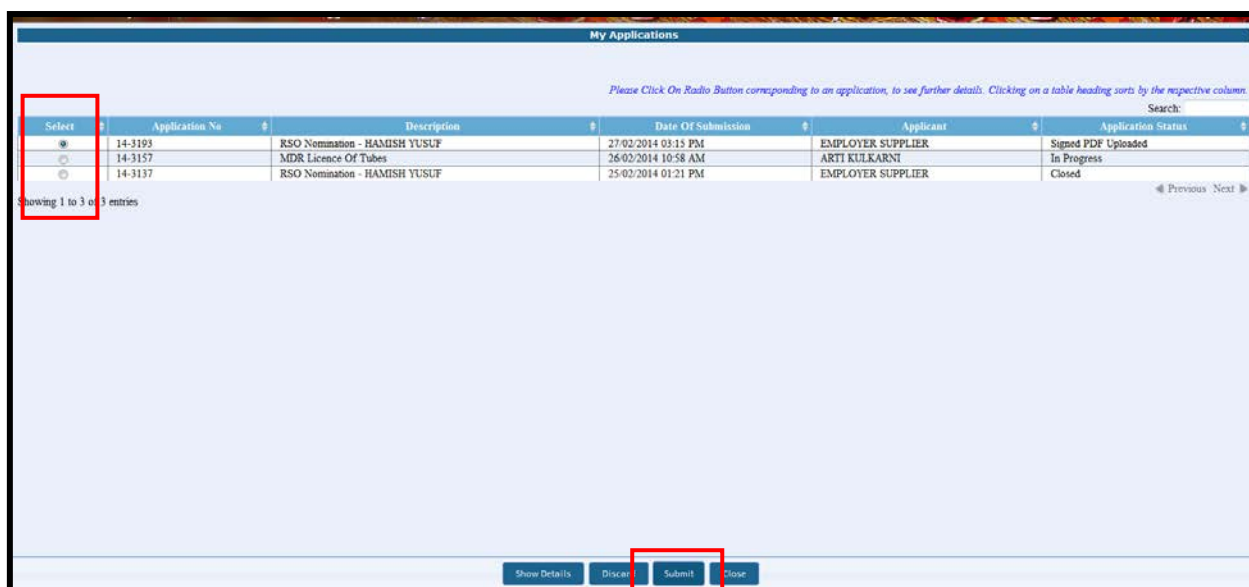
Menu → My applications



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 signature of two persons required.

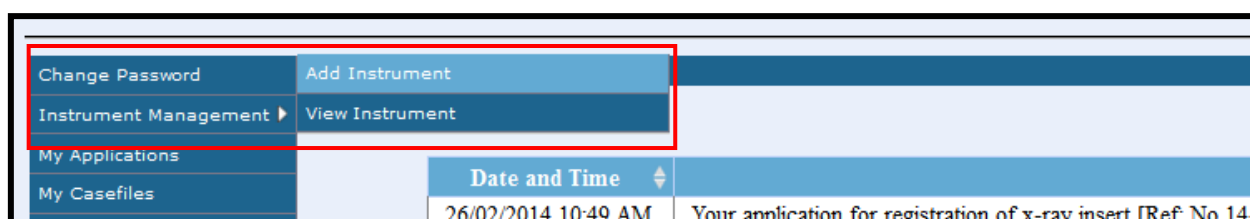
Your RSO nomination form will be reviewed by AERB and after acceptance; you will get its notification in your eLORA account.

C. Add Instrument

Diagnostic X-ray facility 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 (not applicable for you)
- Monitoring Tool (not applicable for you)
- QA Tool (not applicable for you)
- **Safety Tool**

Add following Instruments as applicable to each type of equipment:

Table 1: List of Instruments Required

Type of Equipment	Instruments to be added	
	Type of Instrument	Instrument Sub Type
Interventional Radiology	Safety Tool	<ul style="list-style-type: none"> • Protective Apron (minimum 3) • Protective Rubber Flaps • Ceiling suspended protective glass
Computed Tomography	Safety Tool	<ul style="list-style-type: none"> • Protective Apron
Radiography & Fluoroscopy	Safety Tool	<ul style="list-style-type: none"> • Mobile Protective Barrier with lead equivalent Viewing Window • Protective Apron • Protective Rubber Flaps
Radiography(fixed)	Safety Tool	<ul style="list-style-type: none"> • Mobile Protective Barrier with lead equivalent Viewing Window • Protective Apron

Mammography OPG CBCT	Safety Tool	<ul style="list-style-type: none"> Mobile Protective Barrier with lead equivalent Viewing Window
Radiography (Mobile) Radiography (Portable) C-arm/O-Arm Dental (Intra-oral) Dental (Hand –held)	Safety Tool	<ul style="list-style-type: none"> Protective Apron

Provide the required information while adding equipment.

Important Note: You will not be able to fill application form for Licence (and will get following error message) unless you declare required **Instrument(s)**.

D. Prepare Layout

Prepare a sketch of layout (1:50 scale) of each x-ray room (**not applicable for Radiography (mobile), C-Arm, O-Arm, Dental (Intra-oral) and Dental (Hand –held) X-ray equipment**) providing all the details about wall dimensions, wall thickness, wall/shielding material, distances of all walls/shielding from x-ray equipment, relative positions of x-ray equipment, couch, control console/control room, protective barrier, door(s), window(s), occupancy around the x-ray room etc. For the preparation layout details, **guidelines** and **model layout plans** are available on AERB website (http://www.aerb.gov.in/AERBPortal/pages/English/X-Ray/X-Ray_jsp.action) as well as enclosed here as Annexure - 3: Standard Layouts.

You are required to preserve the duly signed and stamped copy of x-ray room with details of shielding at your institution and same will be verified during AERB inspection.

There is no requirement to prepare a new layout plan in case you already have AERB approved layout plan. The same can be used as a record for layout.

If your x-ray room is as per model layout or has AERB approved layout, you need not to submit all details in the application form for License.

In case your x-ray room does not follow standard requirements,

- You will be required to provide the details in the prescribed format in the application form for operating Licence, as well as
- You will have to get radiation survey done from supplier of equipment or authorized agencies as per prescribed format as given in application form for operating Licence.

Important Note: While submitting Operational Licence application form for CT and Interventional Radiology equipment, you will be asked to upload scan copy of duly signed and stamped layout plan.

E. Quality Assurance

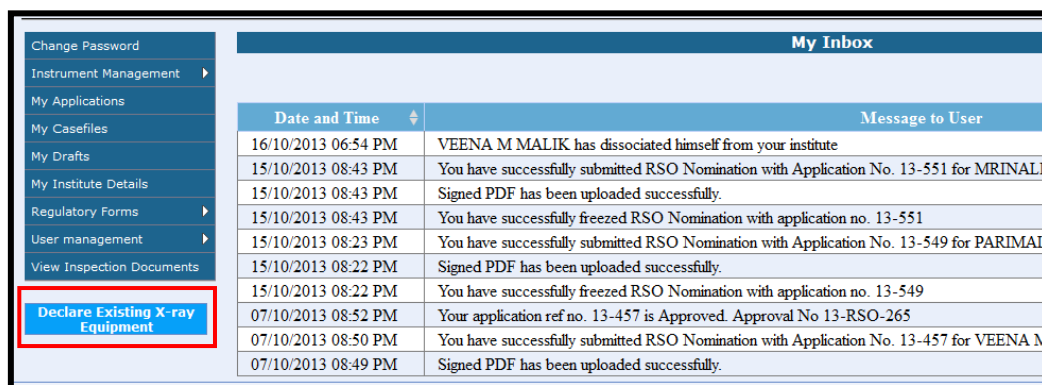
Prior to apply for license for operation of existing x-ray equipment; carry out its Quality Assurance (QA) tests as per AERB prescribed format. Quality Assurance shall be carried out only by AERB Authorised agencies. The Quality Assurance (QA) formats are available on AERB website (http://www.aerb.gov.in/AERBPortal/pages/English/X-Ray/XRAYmanform_jsp.action).

Important Note: While submitting Operational Licence application form for CT and Interventional Radiology equipment, you will be asked to upload scan copy of duly signed and stamped QA.

Guidelines for Obtaining Licence for Existing X-ray Equipment

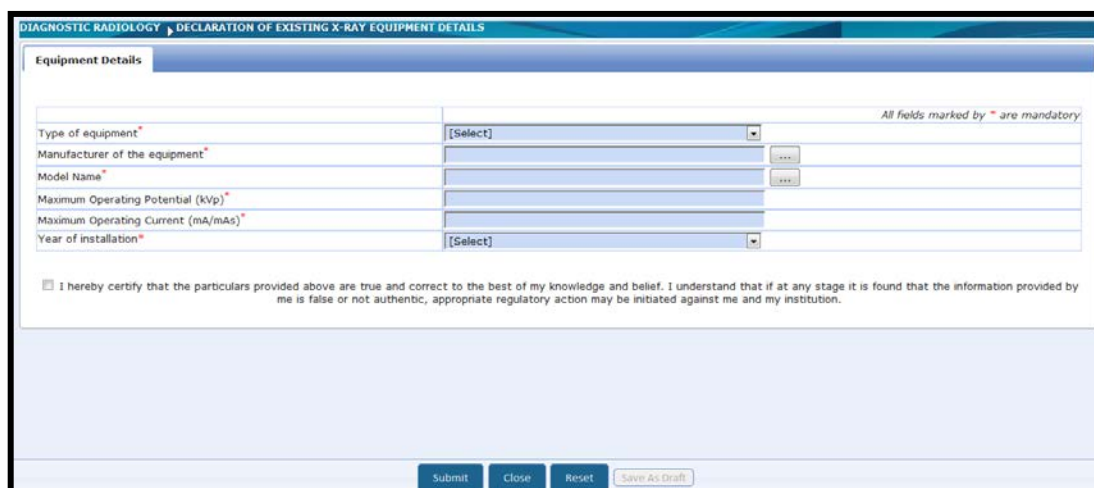
3. Declare Your X-ray Equipments

After login, you will see following screen with various **Menu** on left hand side. You will have to declare your all X-ray equipments one-by-one. Click on **Declare Existing X-ray Equipment** to declare your existing x-ray equipment.



Date and Time	Message to User
16/10/2013 06:54 PM	VEENA M MALIK has dissociated himself from your institute
15/10/2013 08:43 PM	You have successfully submitted RSO Nomination with Application No. 13-551 for MRINALI
15/10/2013 08:43 PM	Signed PDF has been uploaded successfully.
15/10/2013 08:43 PM	You have successfully frozen RSO Nomination with application no. 13-551
15/10/2013 08:23 PM	You have successfully submitted RSO Nomination with Application No. 13-549 for PARIMAL
15/10/2013 08:22 PM	Signed PDF has been uploaded successfully.
15/10/2013 08:22 PM	You have successfully frozen RSO Nomination with application no. 13-549
07/10/2013 08:52 PM	Your application ref no. 13-457 is Approved. Approval No 13-RSO-265
07/10/2013 08:50 PM	You have successfully submitted RSO Nomination with Application No. 13-457 for VEENA M
07/10/2013 08:49 PM	Signed PDF has been uploaded successfully.

Provide the detail as asked in the form and click on **Submit**.



DIAGNOSTIC RADIOLOGY - DECLARATION OF EXISTING X-RAY EQUIPMENT DETAILS

Equipment Details

All fields marked by * are mandatory

Type of equipment* [Select]

Manufacturer of the equipment* [Text Field]

Model Name* [Text Field]

Maximum Operating Potential (kVp)* [Text Field]

Maximum Operating Current (mA/mAs)* [Text Field]

Year of installation* [Select]

I hereby certify that the particulars provided above are true and correct to the best of my knowledge and belief. I understand that if at any stage it is found that the information provided by me is false or not authentic, appropriate regulatory action may be initiated against me and my institution.

Submit Close Reset Save As Draft

After successful submission, an acknowledgement message with equipment id will be displayed.

Your application has been submitted successfully and the application number is 13-771

Click the given link to view the submitted application form [Application_Form.pdf](#)
 Your X-ray equipment details are recorded in eLORA and the equipment id is G-XR-10152.
 Acknowledgment of the same has been sent to your registered email address.

Whether valid AERB licence for operation (Licence/Registration) is available for this equipment
 Yes No

You will receive a system generated mail in your registered email id with acknowledgement letter as an attachment. Acknowledgement letter can also be downloaded from menu **My Applications**.

Repeat the same procedure to declare your all X-ray equipment.

4. Record Licence Detail

In case the declared X-ray equipment of your Institute is having valid license (issued by AERB) for operation, select 'Yes' in the below screen. Form for recording license details will be opened.

Your application has been submitted successfully and the application number is 13-771

Click the given link to view the submitted application form [Application_Form.pdf](#)
 Your X-ray equipment details are recorded in eLORA and the equipment id is G-XR-10152.
 Acknowledgment of the same has been sent to your registered email address.

Whether valid AERB licence for operation (Licence/Registration) is available for this equipment
 Yes No

Otherwise, the form for recording license detail can be accessed by clicking on menu **Record Licence for Operation of X-ray Equipment** (as shown below)

<ul style="list-style-type: none"> Change Password Instrument Management ▶ My Applications My Casefiles My Drafts My Institute Details Regulatory Forms ▶ User management ▶ View Inspection Documents Declare Existing X-ray Equipment Record Licence for Operation of X-ray Equipment 	My Inbox																						
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Date and Time</th> <th style="text-align: left;">Message to</th> </tr> </thead> <tbody> <tr> <td>14/11/2013 02:56 PM</td> <td>Your application ref no. 13-759 is Rejected.</td> </tr> <tr> <td>14/11/2013 02:50 PM</td> <td>You have successfully submitted Application for Record Licence for Operation of</td> </tr> <tr> <td>14/11/2013 02:44 PM</td> <td>Your application ref no. 13-749 is Rejected.</td> </tr> <tr> <td>14/11/2013 02:20 PM</td> <td>Your application for recording licence of x-ray Equipment with application no. 13-13-RLXE-547</td> </tr> <tr> <td>14/11/2013 12:21 PM</td> <td>You have successfully submitted Application for Record Licence for Operation of</td> </tr> <tr> <td>12/11/2013 06:29 PM</td> <td>You have successfully submitted Application for Record Licence for Operation of</td> </tr> <tr> <td>12/11/2013 06:24 PM</td> <td>Your application for declaring existing equipment with application no. 13-748 for 13-DECEQ-540</td> </tr> <tr> <td>11/11/2013 05:12 PM</td> <td>Your application ref no. 13-731 is Rejected.</td> </tr> <tr> <td>11/11/2013 05:08 PM</td> <td>You have successfully submitted Application for Record Licence for Operation of</td> </tr> <tr> <td>11/11/2013 05:06 PM</td> <td>Your application for declaring existing equipment with application no. 13-730 for 13-DECEQ-515</td> </tr> </tbody> </table> <p style="text-align: center;">Showing 1 to 10 of 35 entries</p>		Date and Time	Message to	14/11/2013 02:56 PM	Your application ref no. 13-759 is Rejected.	14/11/2013 02:50 PM	You have successfully submitted Application for Record Licence for Operation of	14/11/2013 02:44 PM	Your application ref no. 13-749 is Rejected.	14/11/2013 02:20 PM	Your application for recording licence of x-ray Equipment with application no. 13-13-RLXE-547	14/11/2013 12:21 PM	You have successfully submitted Application for Record Licence for Operation of	12/11/2013 06:29 PM	You have successfully submitted Application for Record Licence for Operation of	12/11/2013 06:24 PM	Your application for declaring existing equipment with application no. 13-748 for 13-DECEQ-540	11/11/2013 05:12 PM	Your application ref no. 13-731 is Rejected.	11/11/2013 05:08 PM	You have successfully submitted Application for Record Licence for Operation of	11/11/2013 05:06 PM	Your application for declaring existing equipment with application no. 13-730 for 13-DECEQ-515
Date and Time	Message to																						
14/11/2013 02:56 PM	Your application ref no. 13-759 is Rejected.																						
14/11/2013 02:50 PM	You have successfully submitted Application for Record Licence for Operation of																						
14/11/2013 02:44 PM	Your application ref no. 13-749 is Rejected.																						
14/11/2013 02:20 PM	Your application for recording licence of x-ray Equipment with application no. 13-13-RLXE-547																						
14/11/2013 12:21 PM	You have successfully submitted Application for Record Licence for Operation of																						
12/11/2013 06:29 PM	You have successfully submitted Application for Record Licence for Operation of																						
12/11/2013 06:24 PM	Your application for declaring existing equipment with application no. 13-748 for 13-DECEQ-540																						
11/11/2013 05:12 PM	Your application ref no. 13-731 is Rejected.																						
11/11/2013 05:08 PM	You have successfully submitted Application for Record Licence for Operation of																						
11/11/2013 05:06 PM	Your application for declaring existing equipment with application no. 13-730 for 13-DECEQ-515																						

This will open form as shown below:

DIAGNOSTIC RADIOLOGY RECORD LICENCE FOR OPERATION OF X-RAY EQUIPMENT

Licence Details

All fields marked by * are mandatory.

Equipment Id*

Manufacturer*

Model*

Reference number of licence for operation*

Issuance date*

Expiry date*

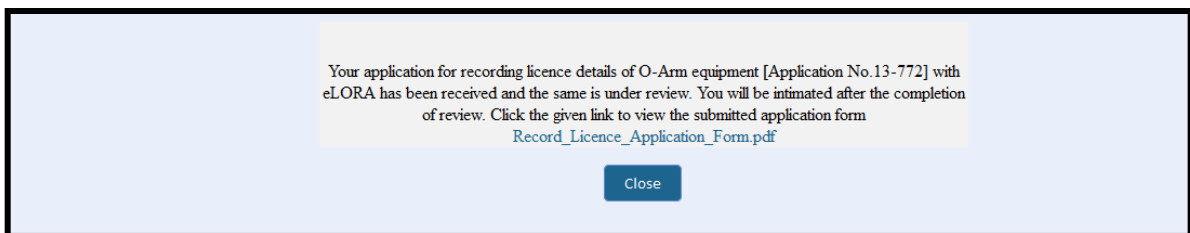
Upload copy of licence for operation* No file selected.

I hereby certify that the particulars provided above are true and correct to the best of my knowledge and belief. I understand that if at any stage it is found that the information provided by me is false or not authentic, appropriate regulatory action may be initiated against me and my institution.

Provide following required details and submit the form:

- **Equipment Id:** To be selected from provided List (all your declared equipments will appear here)
- **Reference number of licence for operation:** as appearing on AERB licence/registration
- **Issuance date:** as appearing on AERB licence/registration
- **Expiry date:** as appearing on AERB licence/registration
- **Upload copy of Licence for operation:** Browse and upload scanned copy of AERB licence/registration

After successful submission, following message will be displayed. The submitted application form (pdf file) can be downloaded from the link provided therein.



Your Licence record detail will be verified by AERB. After acceptance of your submitted detail, you will receive a system generated message in your registered email address with an acknowledgement letter as an attachment. An acknowledgement letter can also be downloaded from menu **My Applications**.

5. Fill Application Form for Licence

The application form for license is available in menu.

Menu → Licence for Operation of Existing Equipments

Important Note: You won't be able to fill the application form if required prerequisites are not completed.

My Drafts	03/03/2014 05:31 PM	Protective Rubber Flaps has been added successfully with identification no. SE-0001082
My Institute Details	03/03/2014 05:30 PM	Protective Apron has been added successfully with identification no. SE-0001081
Regulatory Forms	03/03/2014 05:30 PM	Mobile Protective Barrier with Viewing Window has been added successfully with identification no. SE-0001080
User management	03/03/2014 05:28 PM	Your application for declaring existing equipment with application no. 14-3226 for Interventional Radiology has been added successfully with identification no. SE-0001079
View Inspection Documents	03/03/2014 05:18 PM	Your application for declaring existing equipment with application no. 14-3222 for Radiography has been added successfully with identification no. SE-0001078
Declare Existing X-ray Equipment	03/03/2014 02:46 PM	Your application for declaring existing equipment with application no. 14-3213 for Computed Tomography has been added successfully with identification no. SE-0001077
Record Licence for Operation of X-ray Equipment	27/02/2014 05:03 PM	You have successfully submitted Application for registration of an x-ray insert with application no. 14-3193
Licence for operation for Existing Equipments	27/02/2014 04:35 PM	Your application ref no. 14-3193 is Approved. Approval No 14-RSO-2782
	27/02/2014 04:29 PM	You have successfully submitted RSO Nomination with Application No. 14-3193 for HAN

Showing 1 to 10 of 45 entries

A form will be opened as shown below:

Name	Date of Birth	Designation	Qualification	Experience (in years)	PMS No.
HAMISH YUSUF	07/02/1969	INCHARGE TESTING	B. Sc	0.08	12356

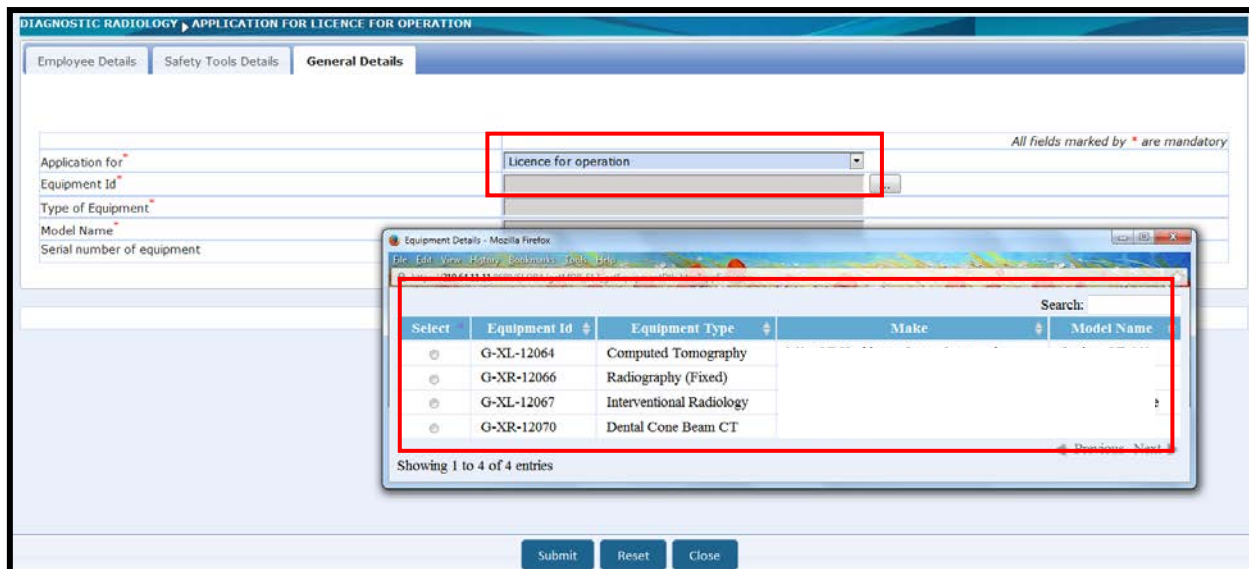
Showing 1 to 1 of 1 entries
Proceed to fill the form if the details is up to date. If details are correct move to next Tab else update the Worker Details

I have read and agree to the Terms & Conditions.

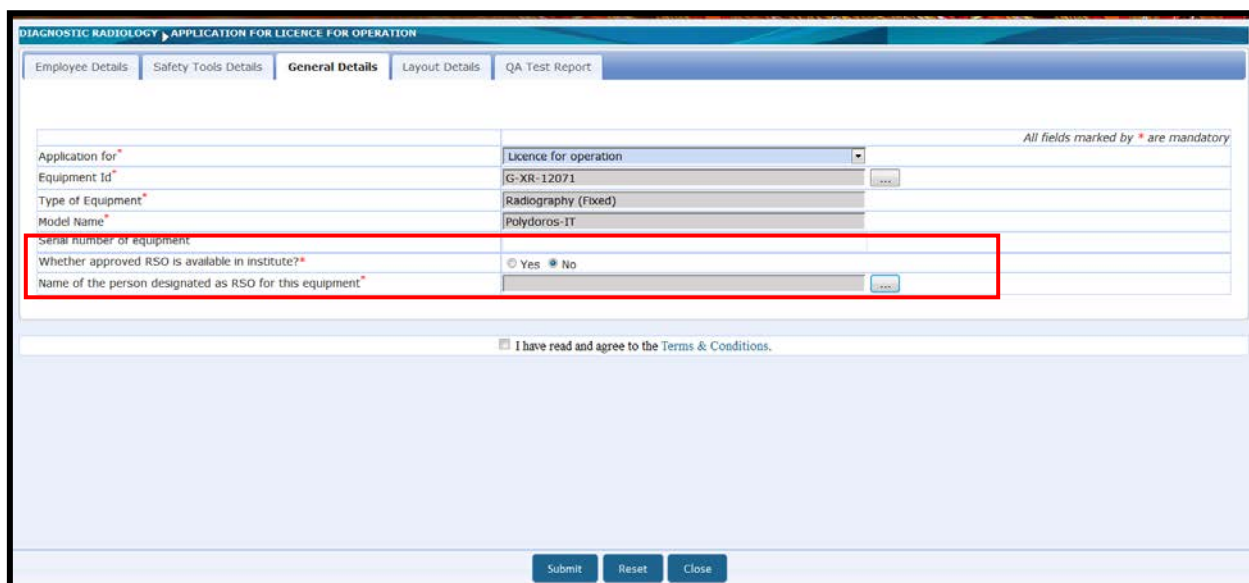
Submit Reset Close

Form initially will have three tabs:

- Employee Detail:** This will show the list of employees added as **Radiation Professional**. (Employees added as Radiation Worker and Non Radiation Worker will not be show).
- Safety Tools Detail:** This will show the list of Instruments added.
- General Detail:** In the field **Application for**, select **Licence for Operation** for first time application. In future, select **Renewal of Licence for Operation** for submission of form for renewal of existing Licence. Then click on **Equipment Id**, it will show list of equipments declared by you. Select Equipment for which you wish to submit application form.



Provide **Serial Number of Equipment** if available.



In case you have approved RSO (RSO approval received on paper), select **Yes** and provide required detail and upload scan copy of RSO approval letter.

In case you do not have approved RSO, then select **No** and select one of your employee in the field **Name of the person designated as RSO for this equipment**(this will not be applicable for CT and Interventional Radiology equipment).

Important Note: Obtain prior approval of RSO for CT and Interventional Radiology equipment if you do not have valid RSO.

After selection of equipment, two more tabs will be displayed (viz. **Layout Detail** and **QA Test Report**)

- Layout Detail:** If installation layout of your equipment is as per AERB model layout, then select **Yes**

Important Note: While submitting Operational Licence application form for CT and Interventional Radiology equipment, you will be asked to upload scan copy of duly signed and stamped layout plan.

If X-ray equipment installation layout is not as per AERB model layout, then select **No**.

Wall identification	Distance from exposure area (from center of the couch) (m)	Material used for shielding	Occupancy behind the wall	Thickness of the shielding material (cm)
Wall A*		[Select]	[Select]	
Wall B*		[Select]	[Select]	
Wall C*		[Select]	[Select]	
Wall D*		[Select]	[Select]	
Entrance door*		Lead	[Select]	
Any other door		Lead	[Select]	
Window, if any, if at the height less than 2 m from outside finished floor of testing room		[Select]	[Select]	

Radiation Survey Report Details

Equipment Settings

Applied voltage* [] kV

Applied current* [] mA

Exposure time* [] Sec

Workload* [] mAs/week

Survey Details

Date of survey* []

Whether radiation survey meter used for the survey has valid calibration certificate* Yes

Maximum Radiation Levels at:

-Near control console (Operators position)* [] mS/hr

-Outside patient entrance door(s)* [] mS/hr

-Behind chest stand wall [] mS/hr

-Behind windows (if any) [] mS/hr

-Patient waiting area* [] mS/hr

- Provide the detail as per your room layout plan (as explained above in section D: Prepare Layout)
- upload copy of room layout plan(in case of CT and Interventional Radiology)

For Radiation Survey Report: Get radiation survey done from supplier of equipment or authorized agencies as per prescribed format and provide the details in the application form (as applicable):

The exposure parameters to be selected for while carrying out survey are given in the table:

Type of Equipment	Applied Voltage # (kV)	Applied Current (mA)	*Exposure time (Sec)	Workload (mA-min/Week)
Interventional Radiology	80-100	50 – 100	1.0 -2.0	5000
Radiography & Fluoroscopy Radiography(fixed)	80-100	50 – 100	1.0 -2.0	500
OPG CBCT	60-100	8-20	1.0 -2.0	300
Computed Tomography	110-140	50 - 100	1.0 – 2.0	25000
Mammography	30-35	100-200	1.0 – 2.0	300

* Exposure time should not be less than 1 Sec

Provide the values of maximum radiation level (in mR/hr) at following places:

- Near control console (operators position)
- Outside patient entrance door
- Behind chest stand wall
- Behind window (if any)
- Patient waiting area

5. **QA Test Report:** Refer QA test report of x-ray equipment and provide required test results. Attach the copy of QA test report in the prescribed format (applicable for CT and Interventional Radiology equipment).

The screenshot shows a web-based QA Test Report form. The form is titled "Quality Assurance Test Report" and includes the following fields:

- Date of QA test: 14/03/2013
- Accuracy of Operating Potential: Applied potential (50.00, 70.00) and Measured potential (52.00, 72.00)
- Reproducibility of radiation output (CoV): 0.01
- Half Value Thickness (HVT): Applied Voltage (kVp) (<=70) and Measured Half Value Thickness (HVT) (2.00)
- Maximum radiation leakage level from x-ray tube housing (mGy in one hour at 1m): 1.00
- Image Quality (as per equipment and phantom specifications): Acceptable

At the bottom of the form, there is a checkbox labeled "I have read and agree to the Terms & Conditions." which is checked. Below the checkbox are buttons for "Submit", "Reset", and "Close".

For submission of your application form, read and select the terms and condition and click for **Submit**. After successful submission you will receive the acknowledgement in your inbox and registered email. Repeat the same procedure for submission of Licence application form for your other equipments.

6. Renewal of license

The application form for renewal of license is available in **Menu: Regulatory Forms> Medical Diagnostic Radiology> Licence for Operation of X-ray equipment> equipment details tab**

The screenshot shows a web browser window with the URL https://elora.aerb.gov.in/ELORA/MDR_LicenceOfOperation_prePopulate.htm. The page title is "DIAGNOSTIC RADIOLOGY > LICENCE FOR OPERATION OF X-RAY EQUIPMENT". The form has three tabs: "Employee Details", "Safety Tools Details", and "Equipment Details". The "Equipment Details" tab is active. The form contains the following fields and sections:

- Application for:** A dropdown menu with "Renewal of Licence for operation" selected.
- AERB License Number:** A text input field with a search icon.
- Equipment Id:** A text input field.
- Maintenance of Records:** A section with three questions, each with "Yes" and "No" radio buttons:
 - Whether dose records of radiation workers are maintained*
 - Whether servicing/maintenance records are maintained*
 - Whether quality assurance and radiation protection survey records are maintained*
- Agreement:** A checkbox labeled "I have read and agree to the Terms & Conditions."
- Buttons:** "Submit", "Close", and "Reset" buttons at the bottom.

Guidelines for Obtaining Licence for New X-ray Equipment

7. Procurement of X-ray Equipment

After fulfilling the general requirements, follow following path to open Procurement form for new equipment:

Regulatory Forms → Medical Diagnostic Radiology → Procurement of X-ray Equipment

The screenshot shows the user interface of the AERB web portal. The user is logged in as "Diagnostic Radiology--Medical diagnostic". The "Regulatory Forms" menu is expanded, showing "Medical Diagnostic Radiology" and "Procurement of X-ray Equipment" highlighted. The "Procurement of X-ray Equipment" menu item is circled in red. Below the menu, a table shows a list of recent actions with columns for "Date and Time" and "Message".

Date and Time	Message
19/09/2014 11:42 AM	M
19/09/2014 11:41 AM	M
12/09/2014 11:11 AM	Signed PDF has been uploaded successfully
12/09/2014 11:10 AM	You have successfully freed RSO Nomina
05/09/2014 12:04 PM	SURESH TAMILARASU successfully dis
04/09/2014 04:20 PM	Your application ref no. 14-4083 is Approv

Fill the information asked in the form and upload mandatory attachments. Your application will be reviewed by AERB. After approval/rejection, you will get notification in your eLORA account. You can view your complete application along with AERB letter in 'My Applications'.

Important Note: After supply of equipment, your supplier has to submit installation report on behalf of your institute. After acceptance of installation report by AERB, you need to submit application for Licence. (You will get notification of installation report acceptance in your eLORA account as well as in your email).

8. Application for Licence

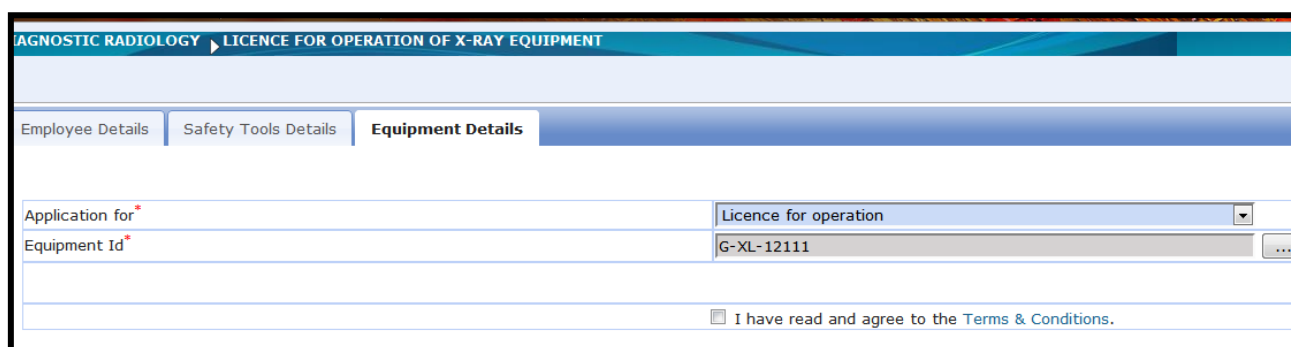
After approval of installation report of your X-ray equipment by AERB, fill the application form for Licence. Licence form has to be submitted within 6 months from the date of acceptance of installation report. In case Licence form is not submitted within 6 month, you have to submit fresh QA report before applying for Licence.

Ensure that required Employee and Instrument details are provided in your account. Follow following path to access Licence form:

Regulatory Forms → Medical Diagnostic Radiology → Licence for Operation



Select the equipment id, agree terms and conditions and press submit button for submission of your application form.



9. Guidelines for obtaining Licence for Pre-owned (Used/refurbished) X-ray Equipment

- User is required to submit application form for “Procurement of pre-owned X-ray equipment” through eLORA account.
- After installation & commissioning of X-ray equipment, user will submit “Intimation of Receipt” through eLORA.
- Supplier/ Service Agency shall provide installation report & QA report to user (Required for submission for License through eLORA)
- User is required to apply for License for operation of pre-owned X-ray equipment through eLORA.

Guidelines for Other Processes

9. Change in Layout:

In case of change in layout (due to Layout modification of installation, relocation and reposition of equipment from its original place), you need to fill form for Change in Layout. Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Change in Layout

The screenshot shows the eLORA user interface for a user named 'Advanced Centre for Treatment, Research & Education'. The user is logged in as 'Diagnostic Radiology--Medical diagnostic'. The interface includes a sidebar with navigation options like 'Change Password', 'Instrument Management', 'My Applications', 'My Casefiles', 'My Drafts', 'My Institute Details', 'Regulatory Forms', 'Type Approved Equipments', 'User management', and 'View Inspection Documents'. The 'Regulatory Forms' menu is expanded to show 'Medical Diagnostic Radiology', which is further expanded to show 'Change in Layout'. A red box highlights the 'Change in Layout' option in the menu. Other options in the menu include 'Procurement of X-ray Equipment', 'Licence for Operation', 'Safety Status Report', 'QA Test Summary', 'Radiation Survey Report', 'Procurement of X-ray Tube', 'Intimation of receipt', and 'Intimation of Decommissioning'. The main content area shows a table with columns for 'Date and Time' and 'Message', with several entries related to equipment management and safety reports.

Pl. note, in this form you will have to provide detail of shielding around X-ray equipment as asked in Licence form. Fill the detail as required in the form and submit.

10. Safety Status Report

Use this form to submit safety annual safety status of your Institute. Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Safety Status Report (Patient Examination Report /Operation Safety Report)

11. QA Test Summary

Use this form to submit QA test summary of periodic QA or QA done after layout change. Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → QA Test Summary

12. Radiation Survey Report

In case of change in layout, you need to submit radiation survey around the installation. The same form is also be used to submit Periodic RSR (RSR – Radiation Survey Report). Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Radiation Survey Report

13. Procurement of X-ray Tube

This form is used to apply for procurement of X-ray tube (in case of replacement of old/damaged x-ray tube). Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Procurement of X-ray Tube

14. Intimation of Receipt

After receipt of new X-ray tube, you need to intimate its receipt through Intimation of Receipt form. Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Intimation of Receipt

15. Intimation of Decommissioning

In order to intimate decommissioning of your X-ray equipment, use this form. Follow following path to access this form:

Regulatory Forms → Medical Diagnostic Radiology → Intimation of Decommissioning

Important Message

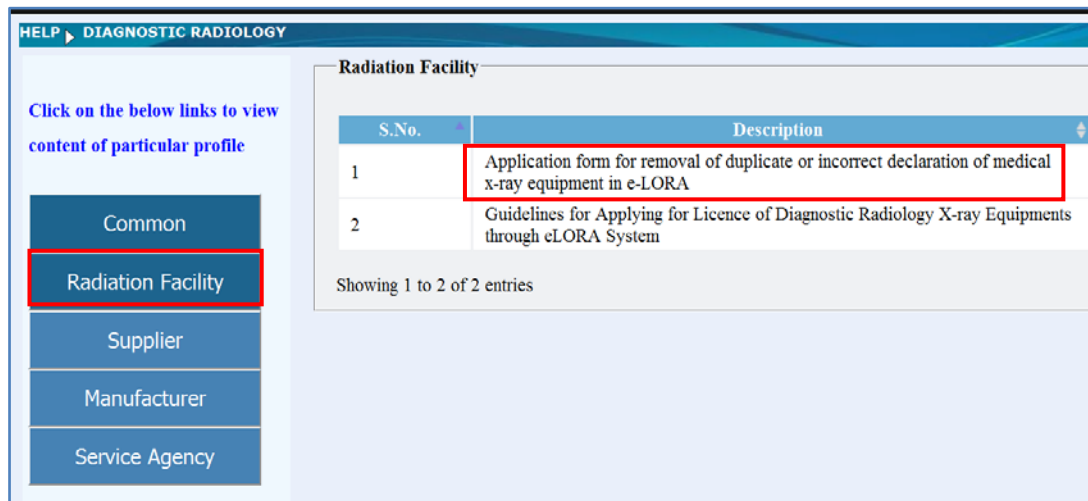
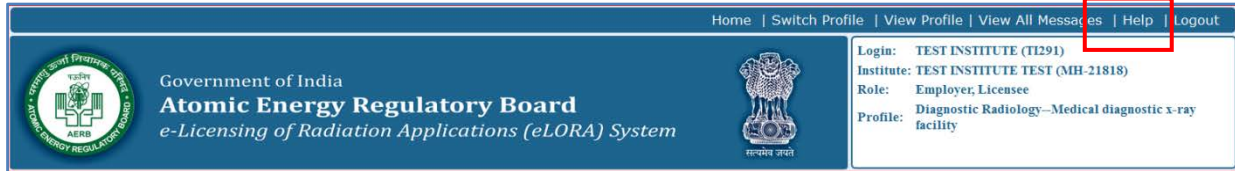
16. NO LICENSE FEE /PROCESSING FEE BY AERB

It may please be noted that at present AERB does not charge any fee for issuance of regulatory consents including license or registration. However, It has been brought to the notice that some of the suppliers/agencies, while providing services/assistance to the users of Diagnostic X-ray facility for getting their X-ray equipment licensed or registered by AERB, are demanding money to be paid to AERB. In case anybody demands for payment to be made to AERB or any of its officials, kindly provide all the details to:

The Vigilance Officer
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar
Mumbai – 400094
Telefax: 022-25576255
E-mail: lrbishnoi@aerb.gov.in

17. Deletion of duplicate or wrong declaration of X-ray equipment

For deletion of duplicate or wrong declaration of X-ray equipment in the eLORA, you are required to submit completely filled & duly signed application form as given in annexure-3 which is also available in "Help" menu of eLORA



S.No.	Description
1	Application form for removal of duplicate or incorrect declaration of medical x-ray equipment in e-LORA
2	Guidelines for Applying for Licence of Diagnostic Radiology X-ray Equipments through eLORA System

18. Non-compliance

In case, Non-compliance (NC) is raised against the institute, Employer needs to take immediate action to resolve it. If more time is required for resolution of NC, same may be intimated to AERB with necessary justification.

19. Authorised Service Agencies, AERB Type Approved X-ray equipment and AERB-Licensed X-ray facilities

List of AERB Authorised Service Agencies on:

<http://www.aerb.gov.in/AERBPortal/pages/English/X-Ray/X-Ray.jsp>

List of AERB Type Approved X-ray equipment and AERB-Licensed X-ray facilities is available on:

<https://elora.aerb.gov.in/ELORA/prePopulateGraphData.htm>

=O=O=O=O=O=

20. Annexures:

Annexure - 1: Regulatory requirements in the use of X-ray equipment

General Requirements

The 'Employer' and 'Licensee' of the organization as defined in Atomic Energy (Radiation Protection) Rules, 2004, shall fulfill the responsibilities prescribed in the AERB safety code on radiation safety in manufacture, supply and use Of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)].

Procurement of X-ray Equipment

The employer shall procure NOC validated/ Type Approved X-ray equipment from authorized suppliers and after obtaining procurement permission from the Competent Authority.

Operation of X-ray Equipment

No diagnostic X-ray equipment shall be operated for patient diagnosis unless Licence for operation is obtained from the Competent Authority.

Pre-requisites for obtaining Licence for Operation of X-ray Equipment

X-ray Room Layout and Shielding Requirement

The room housing X-ray equipment shall have an appropriate area to facilitate easy movement of staff and proper patient positioning. Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray equipment so that radiation exposures received by workers and the members of the public are kept to the minimum and shall not exceed the respective limits for annual effective doses as per directives issued by the Competent Authority. Appropriate overlap of shielding materials shall be provided at the joints or discontinuities.

The control console of computed tomography equipment shall be installed in a separate room located outside but adjoining to computed tomography room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient. The gantry and couch shall be placed such that it enables the operator to have the complete view of the patient from the control room viewing window.

Interventional Radiology equipment room shall have an adjoining control room with appropriate facilities for shielding, direct viewing and oral communication. In case of room housing radiography equipment, chest stand shall be located in X-ray room such that no significant stray radiation reaches at control console/entrance door/ areas of full time occupancy such that the dose limits to radiation worker and members of public are not exceeded.

Mobile X-ray equipment, when used as fixed X-ray equipment, shall comply with all the requirements of those of fixed X-ray installation. Movement of mobile X-ray equipment shall be restricted within the institution for which it is registered.

A permanent radiation warning symbol and instructions for pregnant/likely to be pregnant women shall be pasted on the entrance door of the X-ray installation, illustrating that the equipment emits x-radiation.

Vehicle Mounted X-ray Equipment:

X-ray equipment installed in a mobile van or vehicle, shall be provided with an appropriate shielding enclosure to ensure adequate built-in protection for persons likely to be present in and around the vehicle. Shielding shall be provided around the equipment from all the sides up to height of 2m from external ground surface. Radiation warning symbol shall be displayed on all sides of the vehicle.

Staffing Requirements

X-ray installations shall have a radiologist/related medical practitioner/ X-ray technologist with adequate knowledge of radiation protection, to operate the X-ray equipment. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as prescribed in AERB safety code on radiation safety in manufacture, supply and use Of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)]. The minimum qualification and training shall be as prescribed by the Competent Authority. All installations having X-ray equipment with fluoroscopy facility, computed tomography and all establishments performing special procedures, shall have the services of a qualified radiologist or related medical practitioner, with adequate knowledge of radiation protection for interpretation and reporting.

Radiological Safety Officer (RSO)

X-ray department shall have a RSO approved by the Competent Authority. The RSO may either be the employer himself/herself or an employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his X-ray installation. The minimum qualification and training shall be as prescribed by the Competent Authority.

Radiation Protection Devices

Appropriate radiation protection devices such as barrier, apron, goggles, and thyroid shields shall be used during operation of X-ray equipment. These devices shall be verified periodically for their shielding adequacy. The requirements for radiation protection devices are as specified in Appendix-II.

Personnel Monitoring Service

Personnel monitoring services shall be provided to all the radiation workers.

Quality Assurance (QA) Requirements

The end user shall ensure that periodic QA of the equipment is carried out by AERB authorized agencies. Periodic Quality Assurance shall be carried out at least once in two years and also after any repairs having radiation safety implications.

Servicing

The end user shall ensure that servicing of the X-ray equipment is carried out by agencies authorized by the regulatory body.

Periodic Safety Reports

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

Renewal of Licence

The Licence accorded by the Competent Authority shall be renewed before its expiry.

Decommissioning of X-ray Equipment

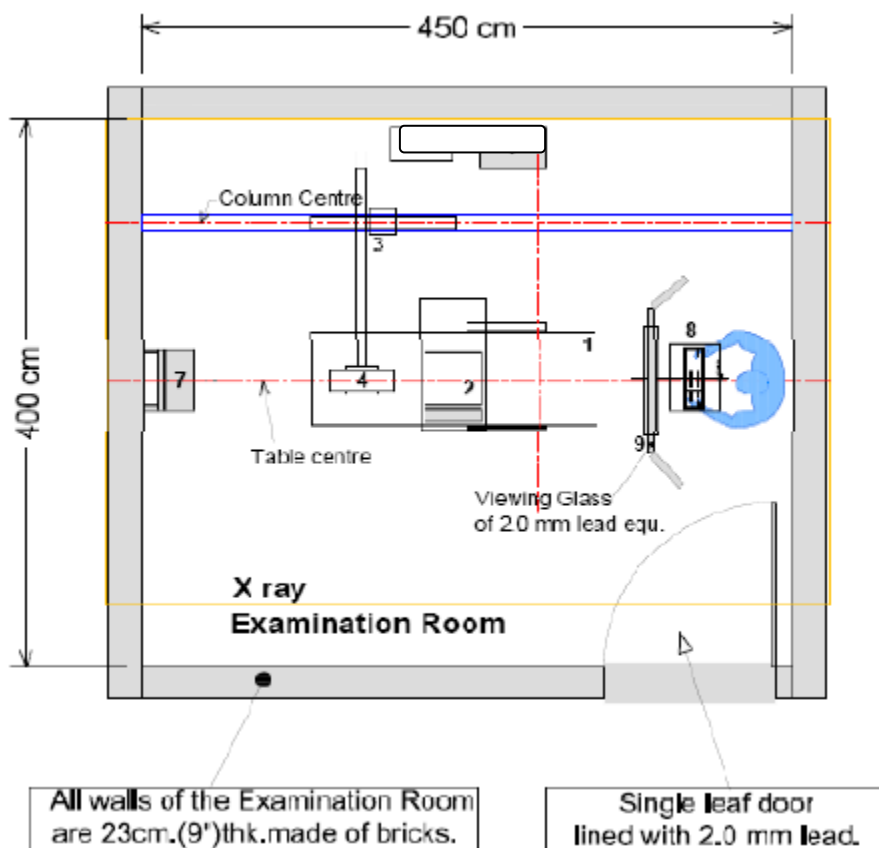
Decommissioning of the X-ray equipment shall be carried out by authorized agencies with prior intimation to the Competent Authority.

Annexure – 2: List of Personnel Monitoring Service (PMS) Providers

The following Accredited Laboratories provide TLD services in the respective states as mentioned below:

Sr. No.	State	Name of Accredited Laboratory
1.	Andhra Pradesh, Telangana, Tamil Nadu, Karnataka, Kerala, Puducherry, Andaman and Nicobar and Lakshdeep (Southern Region)	Avanttec Lab. Private Limited Plot No.17, Arignar Anna Industrial Estate, Mettukuppam, Vanagaram, Chennai Pin- 600095 Tel.: 044-23862025 Email-tldlab@avanttec.net
2.	Maharashtra, Gujarat, Rajasthan, Goa, Dadra and Nagar Haveli and Diu (Western Region)	Renentech Lab. Private Limited C-106, Synthofine Industrial Estate, Off Aarey Road, Goregaon (E), Mumbai, Maharashtra Pin- 490063 Tel.:022-40037476
3.	All other states in the Central, Northern and North Eastern parts of the country	Ultratech Lab. Private limited Cloth Market, G.E. Road, kumhari, Bhilai, Durg, Chhattisgarh Pin- 490042 Tel.: 0788-3295166, 09981212431
4.	All Defense institutions of country	Defense Laboratory, Jodhpur

a) Standard Layout of X-ray Installation



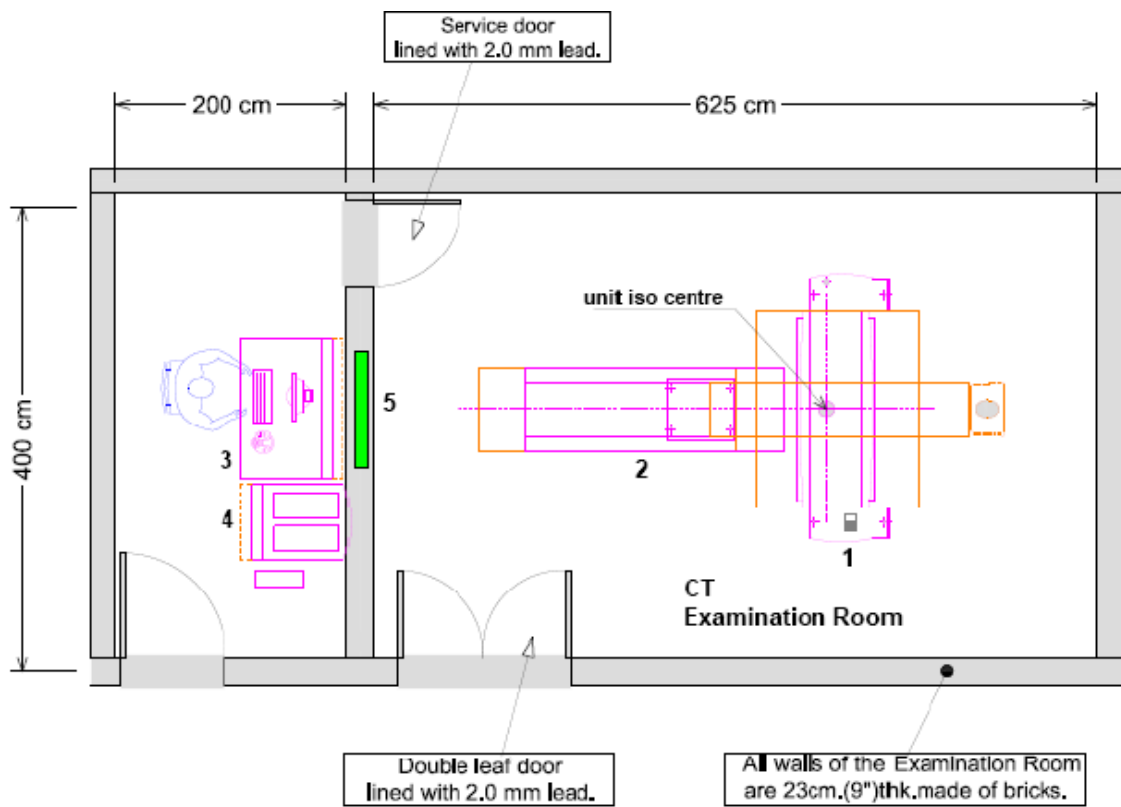
Legend:

- 1. Examination Table
- 2. Spot Film Device
- 3. Column Stand
- 4. X-ray Tube Head
- 7. Chest Stand
- 8. Control Unit
- 9. Mobile Protective Barrier with lead glass viewing window of 1.7 mm lead equivalence

Name of Institute:	
Complete Address of Institute:	
Make of X-ray Equipment:	
Model of X-ray Equipment:	
Signature of Head of Institute:	

[Seal of Institute]

b) Standard Layout of CT Installation



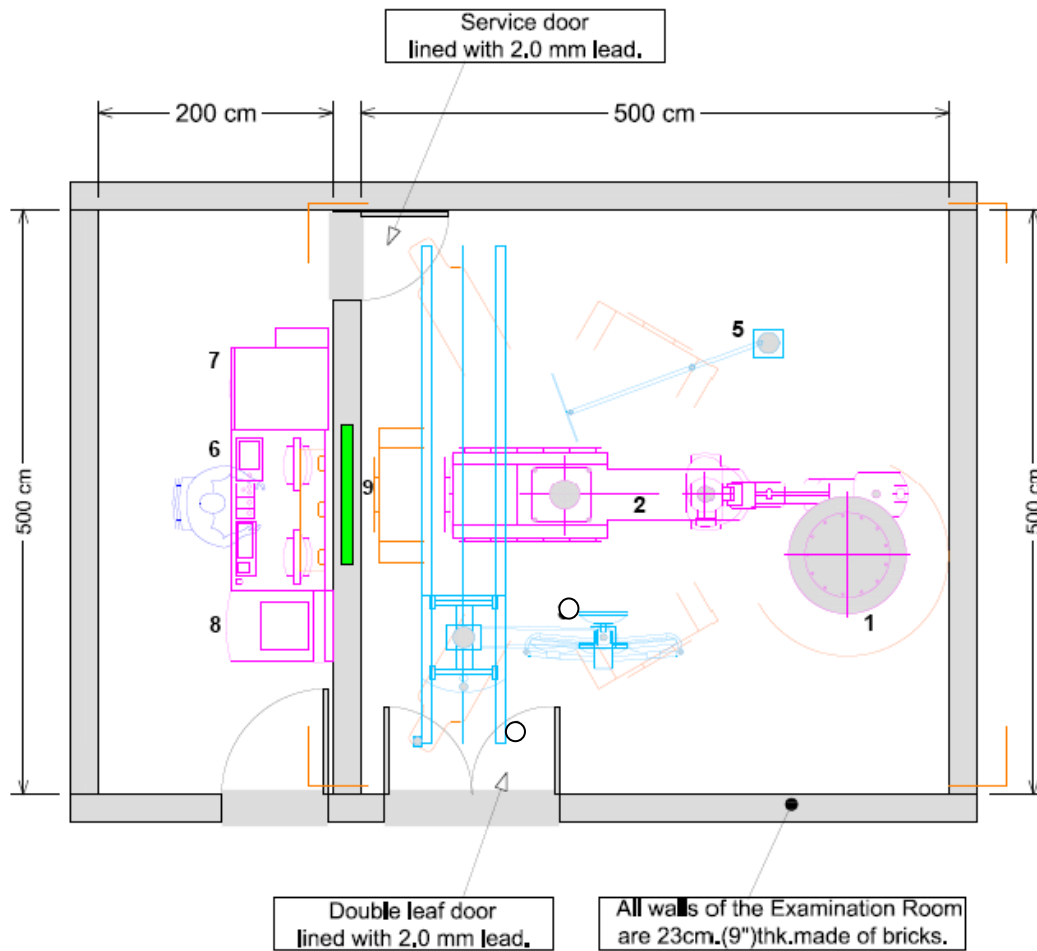
Legend:

- 1. CT Gantry
- 2. Examination Table
- 3, 4. Control Unit
- 5. Viewing glass window of 100cm x 80cm of 2.0 mm lead equivalence

Name of Institute:	
Complete Address of Institute:	
Make of X-ray Equipment:	
Model of X-ray Equipment:	
Signature of Head of Institute:	

[Seal of Institute]

c) Standard Layout of Interventional Radiology Installation



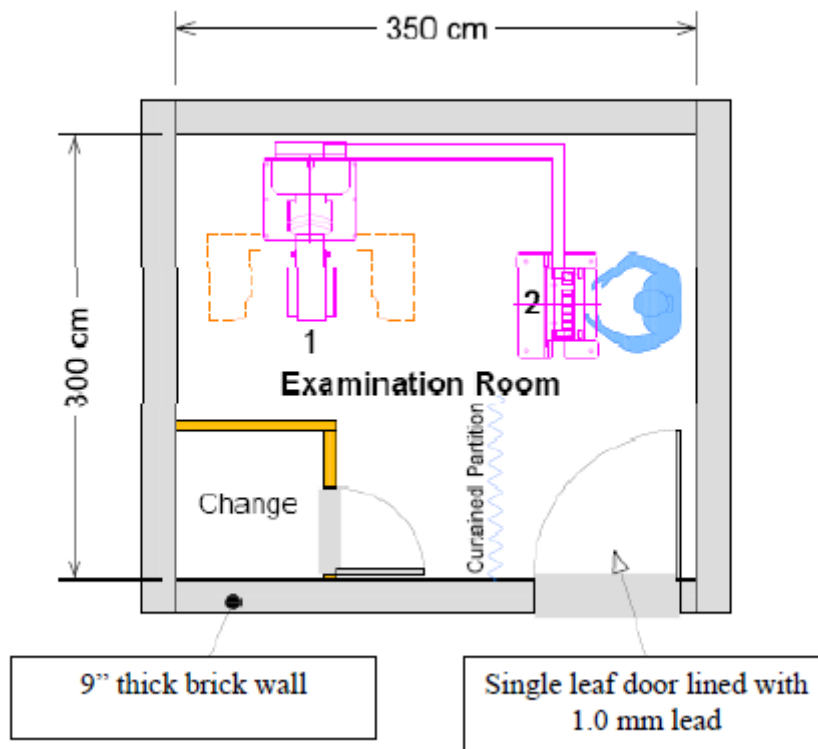
Legend:

- 1. C-arm
- 2. Examination Table
- 5. Fixed Radiation Shield
- 6,7,8. Control Unit
- 9. Viewing glass window of 120cm x 100cm of 2.0 mm lead equivalence

Name of Institute:	
Complete Address of Institute:	
Make of X-ray Equipment:	
Model of X-ray Equipment:	
Signature of Head of Institute:	

[Seal of Institute]

d) Standard Layout of Mammography Installation



Legend:

1. Mammography Equipment
2. Control Unit with protective barrier of 1.5 mm lead equivalence

Name of Institute:	
Complete Address of Institute:	
Make of X-ray Equipment:	
Model of X-ray Equipment:	
Signature of Head of Institute:	

[Seal of Institute]

Annexure - 4: Application Form for Removal of Duplicate or Wrong Declaration of Medical X-Ray Equipment in eLORA



GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD
NIYAMAK BHAVAN, ANUSHAKTINAGAR, MUMBAI – 400 094



AERB/RSD/DRG-eLORA

APPLICATION FORM FOR REMOVAL OF DUPLICATE OR INCORRECT DECLARATION OF MEDICAL X-RAY EQUIPMENT IN e-LORA

(Completely filled & duly signed application form in **hard copy** needs to be submitted in case the institution has incorrectly declared/made duplicate entries of medical diagnostic x-ray equipment in e-LORA. Please send the filled in form to the Head, Radiological Safety Division, Atomic Energy Regulatory Board (AERB), Niyamak Bhavan-B, Anushaktinagar, Mumbai-400094)

PART- A (General Information)

1. Institute Registration No issued by AERB:
2. Name of the Institute:
3. Address:
4. City:
5. Pin code:
6. State:
7. Name of the Licensee:
8. Name of the Employer:

PART-B (Equipment Details)

Sr No	Type of Equipment	Name of Manufacturer	Model Name	Equipment ID in e-LORA	Status of equipment in eLORA (declared/applied for license /license recorded/license obtained)
1					
2					
3					

Specify reason for removal of the above X-ray equipment(s) in eLORA (with documentary proof):

.....
.....
.....
.....
.....
.....

UNDERTAKING:

I hereby certify that the particulars provided in this application are true and correct to the best of my knowledge and belief. I understand that if at any stage it is found that the information provided by me is false or not authentic, appropriate regulatory action may be initiated against me and my institution.

Date:

Signature of the Licensee:

Signature of the Head of Institution (Employer)

Name: Name:

Designation:

Designation:

SEAL

FOR AERB OFFICE USE

Verified by:

Approved by:

Date:

Entry removed on..... by.....

Signature