e-Licensing of Radiation Applications (eLORA)

Guidelines

for

Medical Cyclotron Facility

Guidelines for Applying for Consents for Medical Cyclotron Facility through eLORA System

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General Guidelines

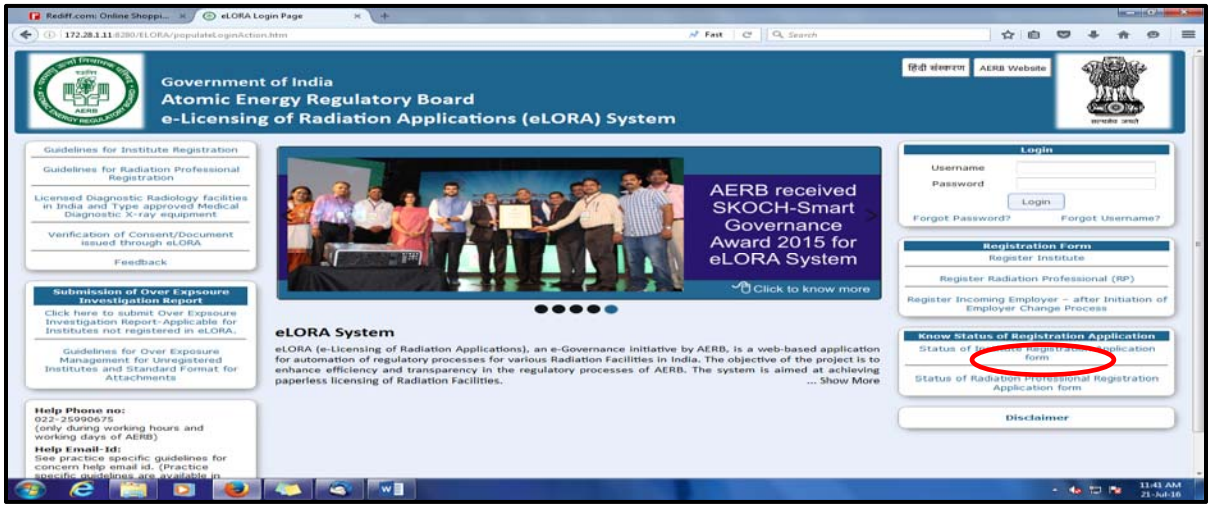
The practice of use of Medical Cyclotron Facilities in India is governed by the Atomic and Energy Act, 1962 and rules promulgated under the Act. In view of this, AERB issues regulatory consents at different regulatory stages for safe handling of the same and publishes codes and guides as per the act & relevant rules. To facilitate the mandate, AERB has launched e-LORA (e-**L**icensing **o**f **R**adiation **A**pplications), its e-governance application system to facilitate online submission of applications for regulatory consents and establish channel of communication with AERB for other regulatory requirements. All User Institutes having Medical Cyclotron Facility are required to use eLORA for obtaining relevant consents and approvals from AERB.

Note: Applications to be sent for relevant stages are described in Tabular form in Brief Description of the Regulatory Forms.

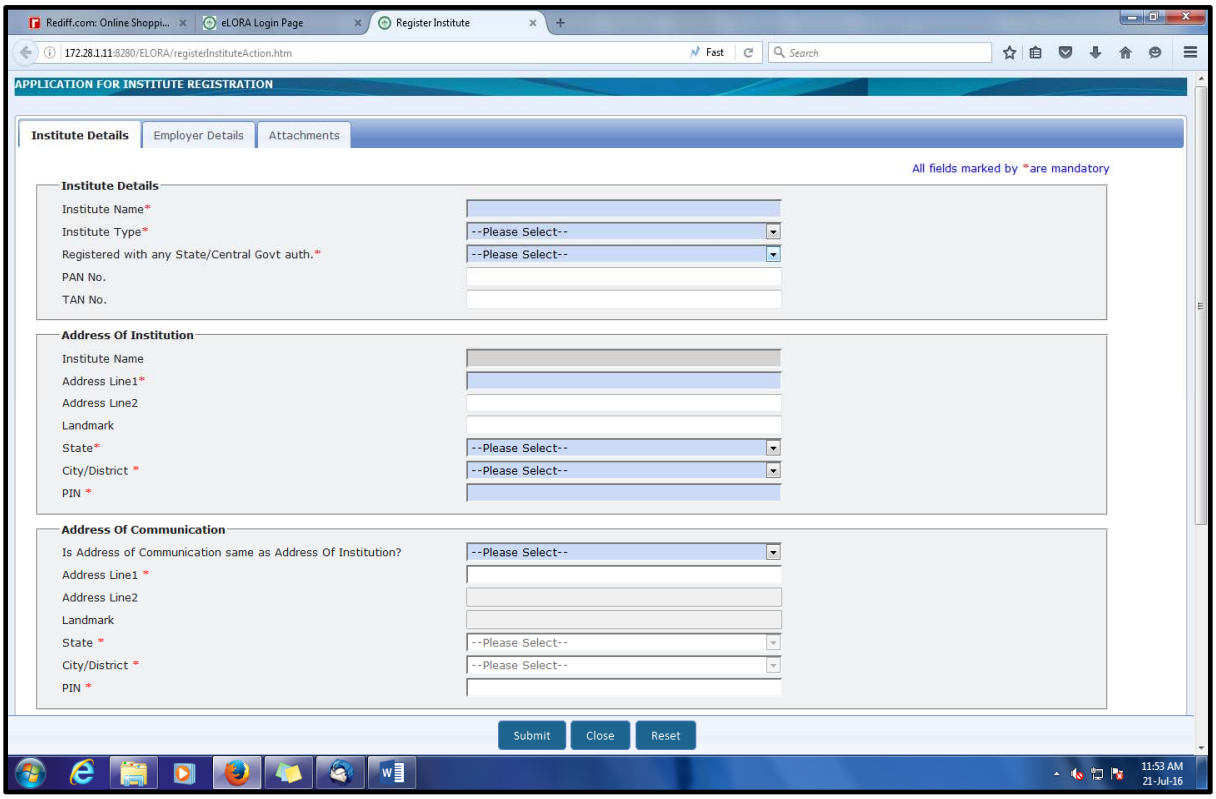
1. Register Your Institute

Note: Those who have already registered their institute through e-LORA for other practices, need not register again. The Medical Cyclotron facility can be updated in their Institute Profile. Guidelines for updation is available in e-LORA Home Page.

Visit our website www.aerb.gov.in. Click on **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 **Medical Cyclotron Facility** and for the **Role** select **Radiation Facility – Medical Cyclotron**

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:
  - o Passport
  - o PAN card issued by Income Tax Department
  - o Driving Licence issued by RTO
  - o Photo identity document/card having serial number and date of birth issued by Central/State Government or PSU
- ✓ **Proof of Employership:** Example: (i) Joining order as employer, (ii) Board Resolution, (iii) Any Govt./PUC document substantiating proprietorship (iv) Partnership deed (notarized) 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:**
  - o PAN of Institute
  - o TAN of Institute
  - o Registration with State/Central/Local Government Authority

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 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).

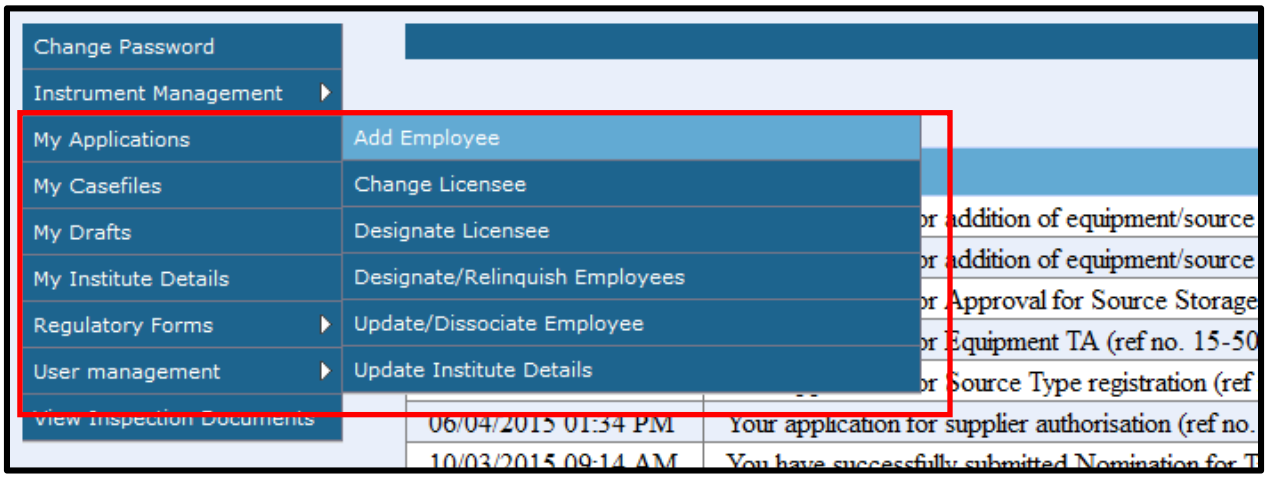
2. General Requisites

General details of the facility has to be recorded in the system by the following menus;

A. Declare Employees

Personnel with appropriate radiation safety training may be added as **Radiation Safety Professional** for **Medical Cyclotron Facility** as employee. **Radiation Safety Professional** having appropriate qualification may be nominated as RSO of the facility**.** Guidelines for the same is available in **Help Menu.**

For adding employees to your institution, please follow the path as;
Menu ⟶ **User Management** ⟶ **Add Employee** ⟶ Select required **Type of Employee** from drop down

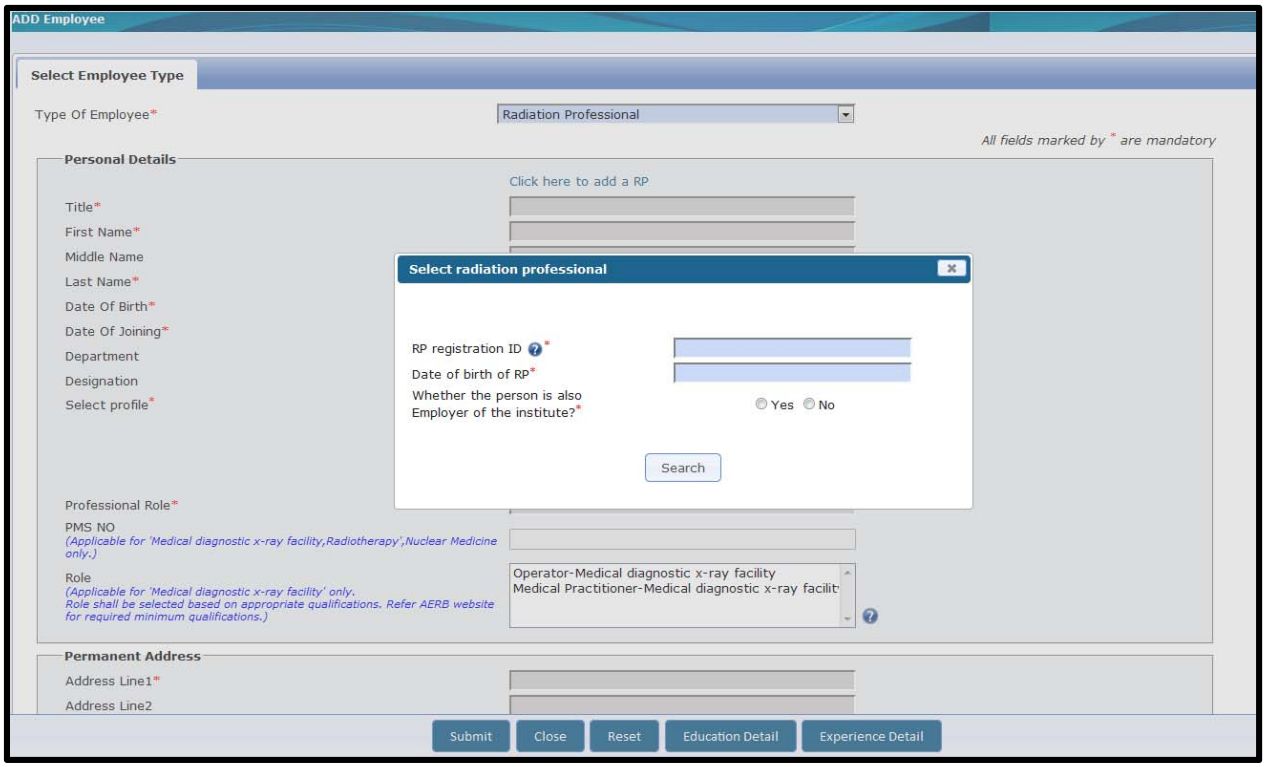


Three options are available in drop down for **Type of Employee** as follows**;**

- ✓ **Radiation Professional** (for **Radiation Safety Professional...**Note that these people can only be nominated as RSO)
- ✓ **Radiation Worker** (for supporting staffs eg **operators, pharmacist, helpers etc**)
- ✓ **Non Radiation Worker** (to add Licensee if he is not a radiation worker)

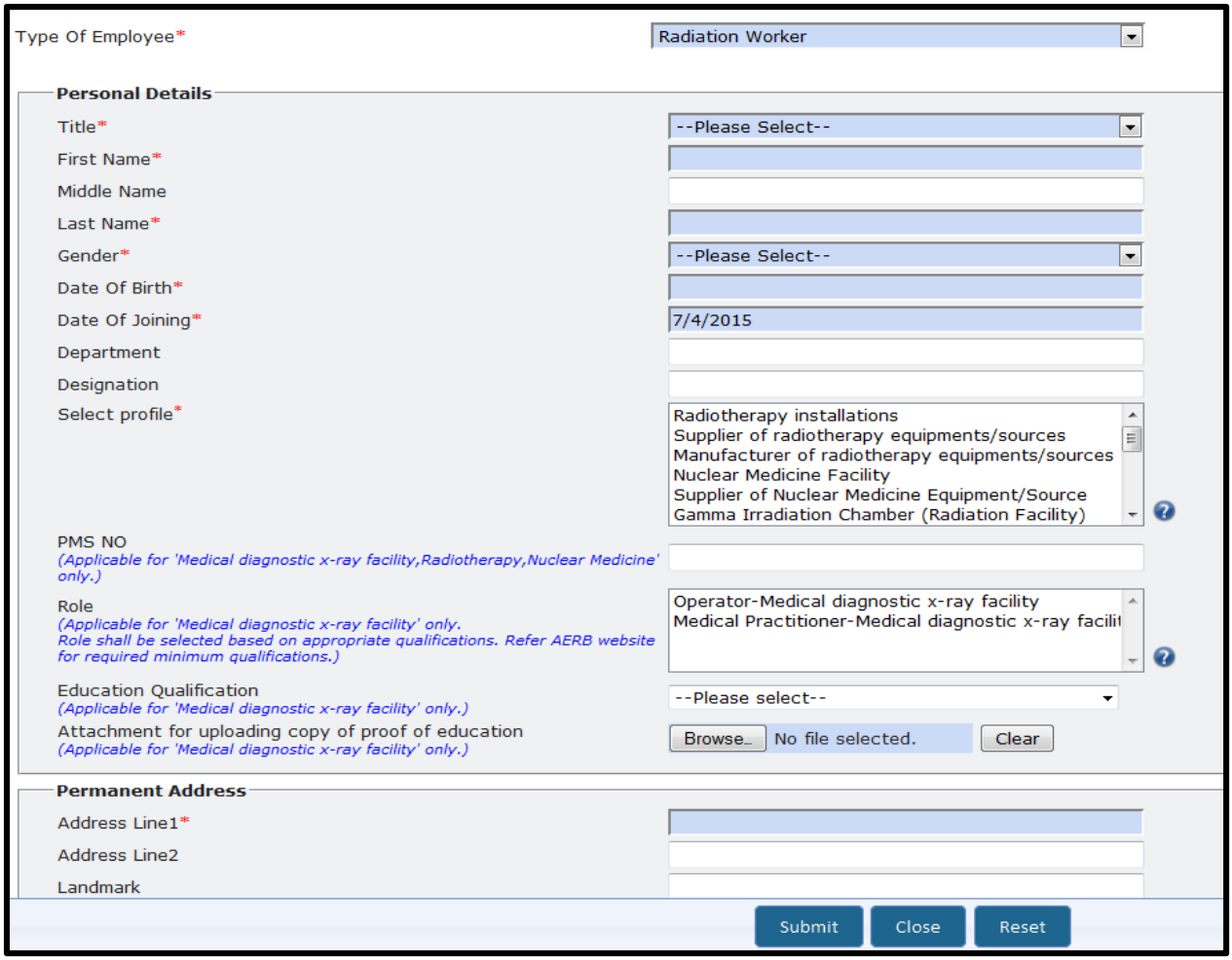
In the form for adding **Radiation Professional,**

- o A pop up will prompt you to provide **RP ID** and **DOB** of the personnel which will be available with the person. All other personal details will come automatically.
- o Provide Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department and Designation, Profile (i.e. 'Sealed Sources') and Professional Role (i.e. 'Radiation Safety Professional')
- o Provide Email (O)
- o Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**



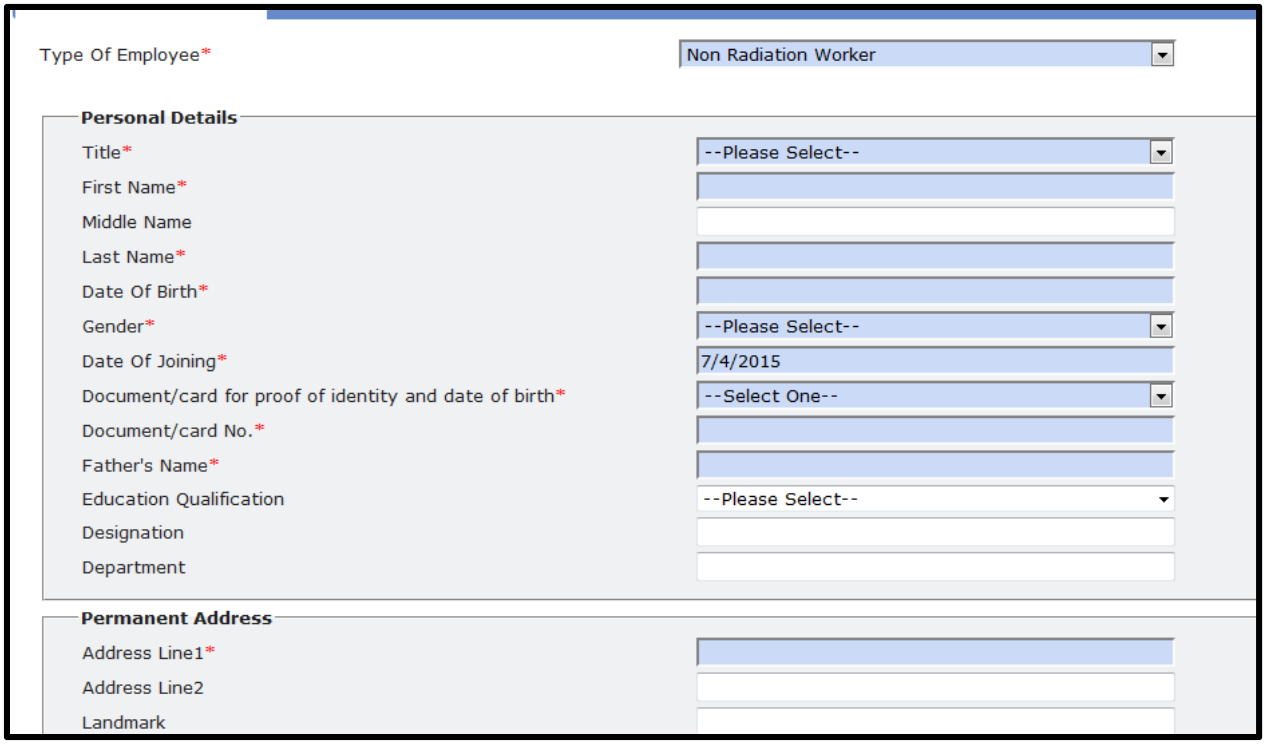
In the form for adding **Radiation Worker,**

- Provide required personal information of employee viz. Title, Name, Gender & 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 (i.e. 'Sealed Source').
- Provide address & contact details of employee
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**



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

- Provide required personal information of employee viz. Title, Name, Gender & Date of Birth, Father's Name, Educational qualification
- Provide required service information of employee viz. Date of Joining (of service in your institute), ID proof, Department, Designation
- Provide address & contact details of employee
- Browse and upload scan copy of joining /confirmation letter and proof of educational qualification of employee and click on **Submit**



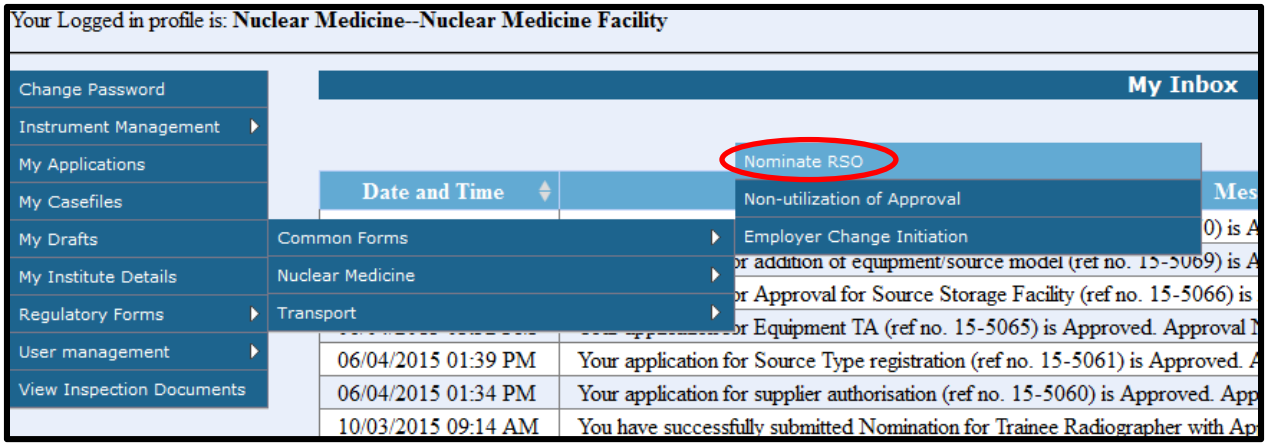
B. RSO Approval

A **Radiological Safety Officer** or **RSO** is mandatorily required for the facility. **Radiation Safety Professional** having appropriate qualification may be nominated as RSO of the facility**.**

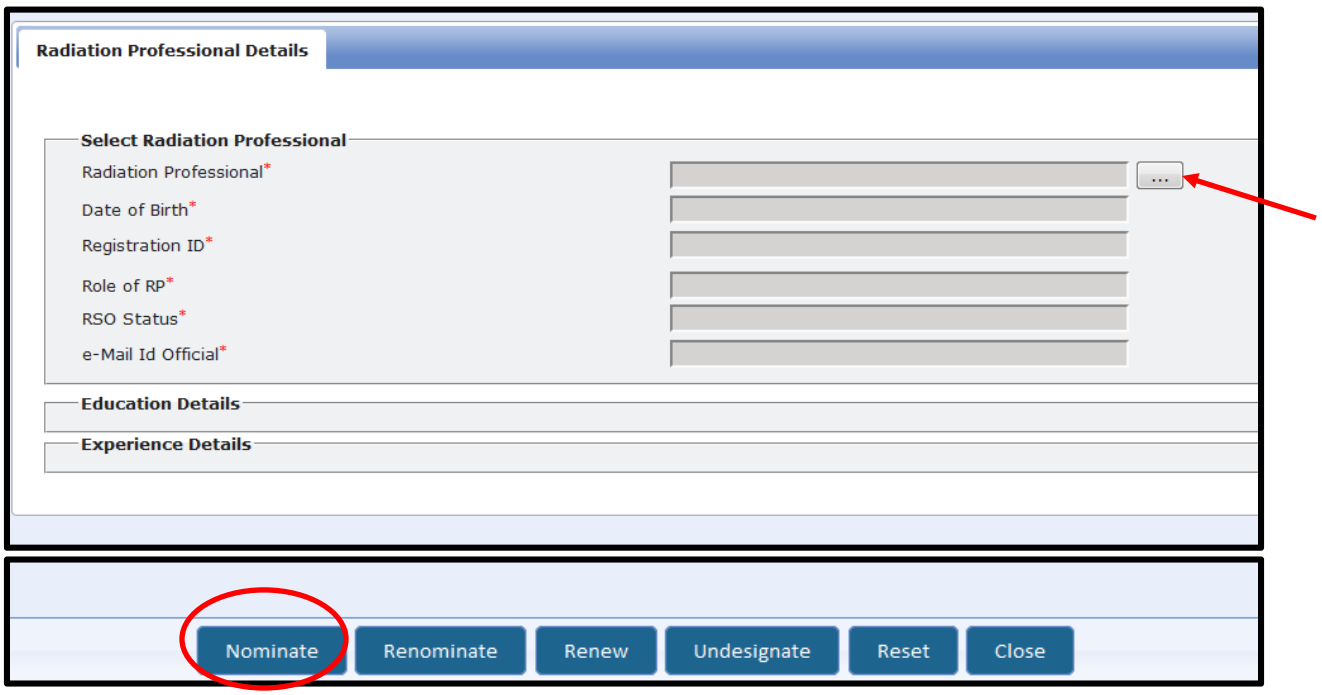
Guidelines for the same is available in **Help Menu.**

For adding RSO to the facility, please follow the path as;

Menu ⟶ **Regulatory Forms** ⟶ **Common Forms** ⟶ **Nominate RSO** as shown below;



You will be navigated to the following screen for nomination of RSO



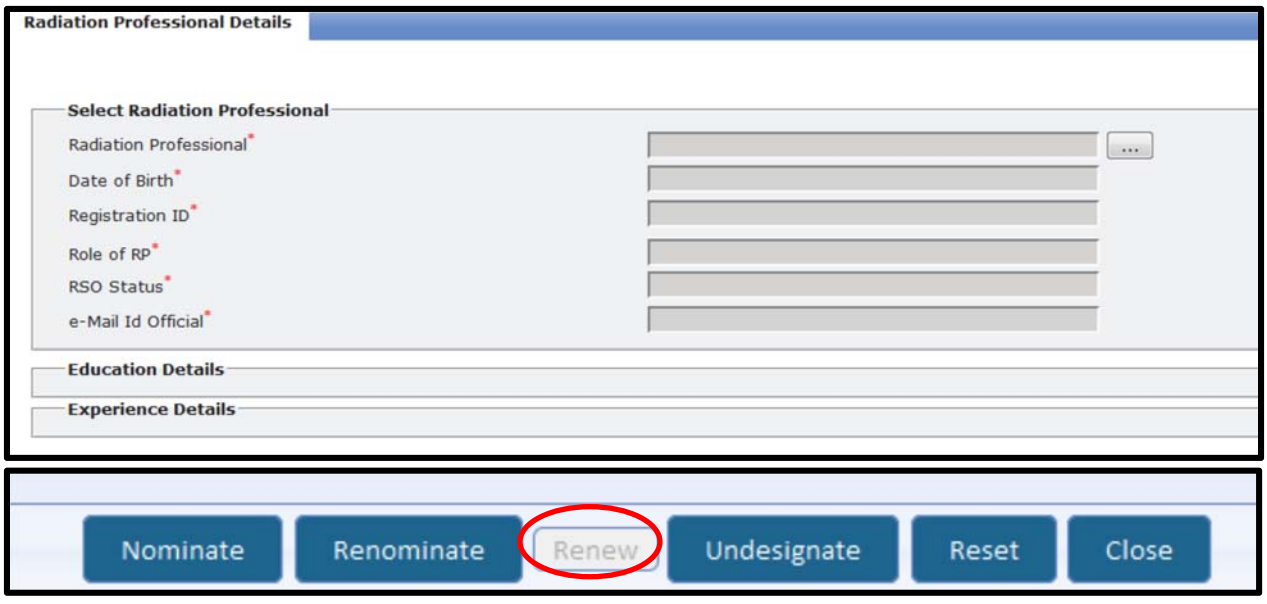
Nominate RSO (for first time approval in the institute):

"Nominate RSO" is applicable for nominating the employee for RSO of the institute for the first time. Select the employee from the List of Values (LOV) indicated in the right side of the Radiation professional label. The details of the selected employee will be populated in the rest of the fields. Choose the button "Nominate". Click on "Freeze". Now application form will be generated. You can download the form from the link provided in the message as follows,

Else you may choose “My Application” to download the same form. A scan copy in PDF format for the first page of the application after signed and affixed with the Institute Seal need to be uploaded and then select “Submit”. After successful approval of the RSO Nomination you (Employer and RSO) will receive a message in their email id as provided in eLORA. A copy of the approval letter will also be emailed to RSO’s email Id. Employer can view the approval copy in “My Application” and also choosing the infrastructure case file.

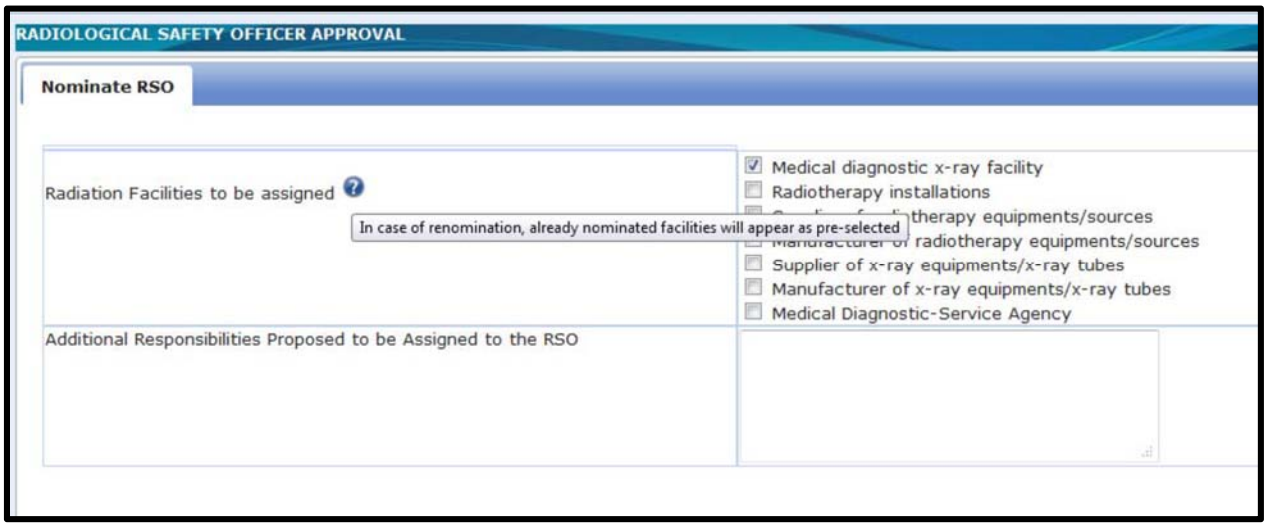
RSO renewal (renewal on expiry of RSO approval)

Renewal of RSO can be initiated by employer of the facility. From the employee list, only employee can be selected whose RSO status is “Yes”.



RSO Renomination (to add or remove roles of the RSO)

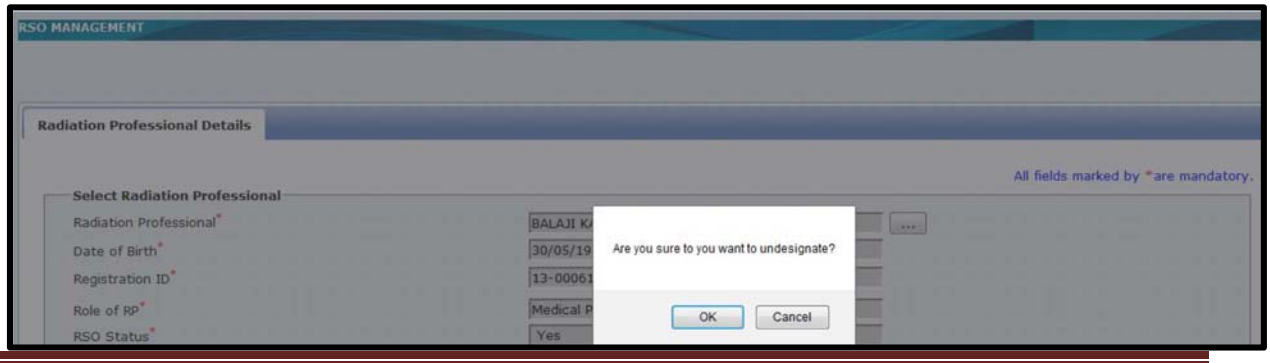
Only approved RSOs of the institution can be renominated for addition/removal of roles of the institute. Renomination button will be deactivated for the employee whose RSO status is “Yes” before one month of RSO approval validity.



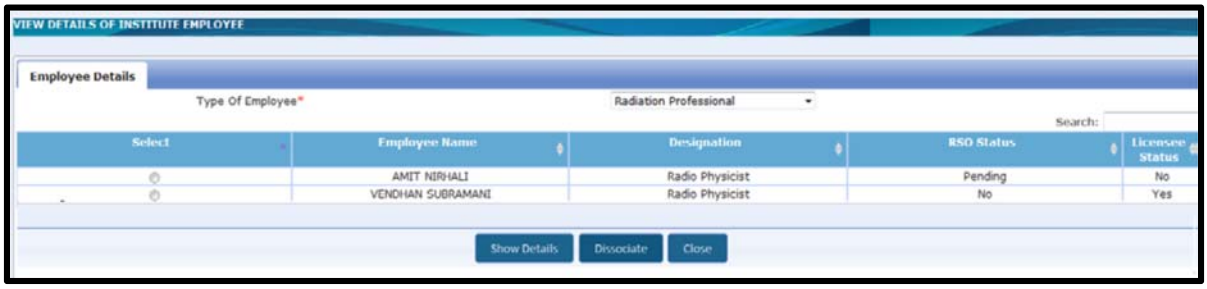
Click on “Freeze”. Now application form will be generated. You can download the form from the link provided there. Else you may choose “My Application” to download the same form. A scan copy in PDF format for the first page of the application after signed and affixed with the Institute Seal need to be uploaded and then select “Submit”. Status of the application can be viewed from “My Application” and also choosing the infrastructure case file.

RSO Undesignate (to remove the RSO roles completely)**:**

In case, employer wants to withdraw the role of RSO from an approved RSO, the same can be initiated through “Undesignate” option. Only approved RSOs can be undesignated and he/she will no longer be RSO of the institute. However, he/she will continue to be employee of the institute.



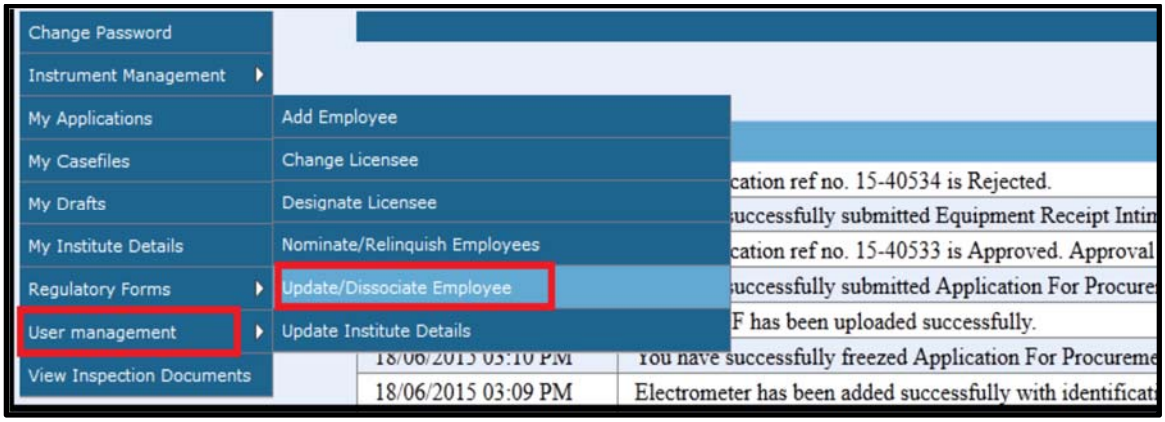
In the “View employee list”, the status of RSO will be indicated as “No”. In case the RSO is leaving the Institute, the employer has to “Undesignate” the RSO and then “Dissociate” him/her. A relinquishing letter for the RSO dissociation will be available in RSO approval file and the status of the RSO file will be “close”.



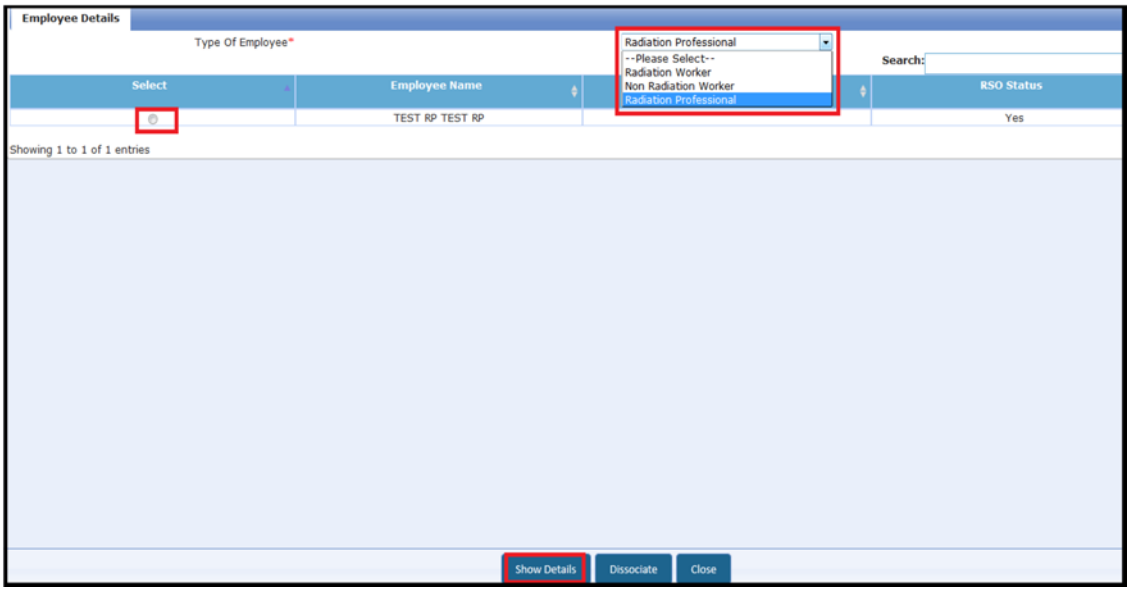
C. Update/Dissociate Employee

Employer can update/dissociate employee from his/her institution. Employer can update employee details such as PMS No., Designation, Department and e-mail (O). Employer can also dissociate employee. Follow the path:

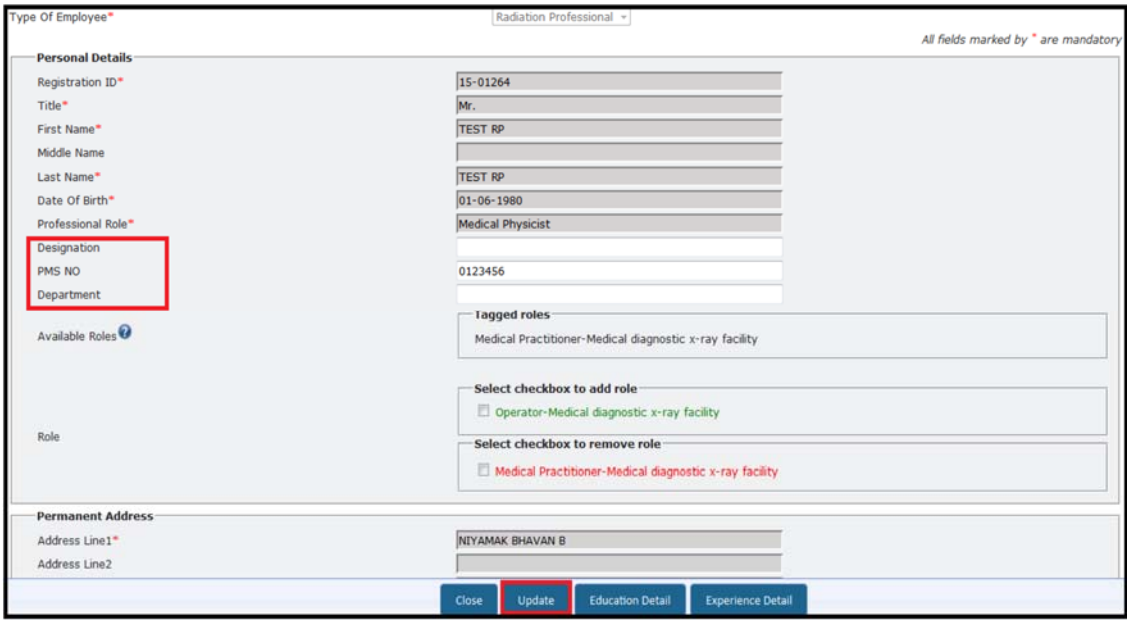
Menu ⟶ User Management ⟶ Update/Dissociate Employee



- **Update Employee Details**
  After clicking on Update/Dissociate Employees, the following screen will appear;



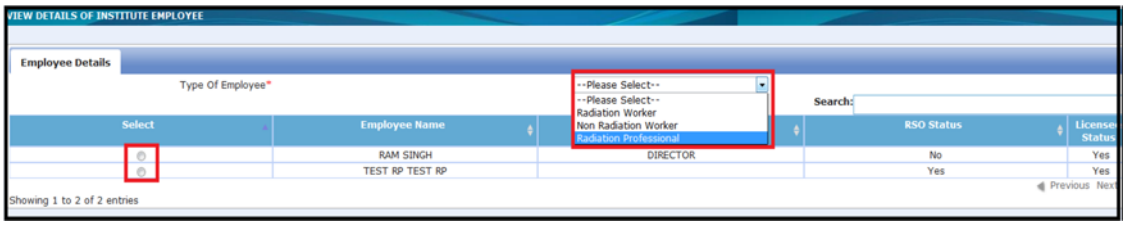
Employer need to select Type of employee as shown above and then select employee detail(s) and click on show details as shown above, the following screen will appear:



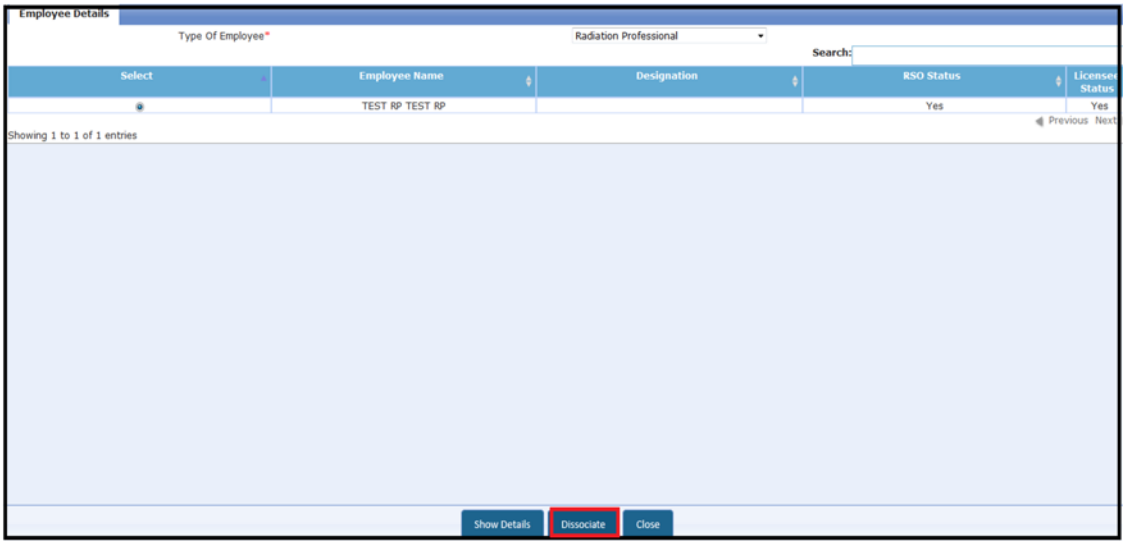
Employer can update employee details such as PMS No., designation, department, E-mail (O), Roles, etc. The details will be updated and can be viewed in 'My Institute Details'.

- **Dissociate Employee**

  After clicking on update/dissociate employee, the following screen will appear:



Employer need to select Type of employee as shown above and then select employee detail(s) and click on dissociate as shown below. Then employee will be dissociated from the institution.



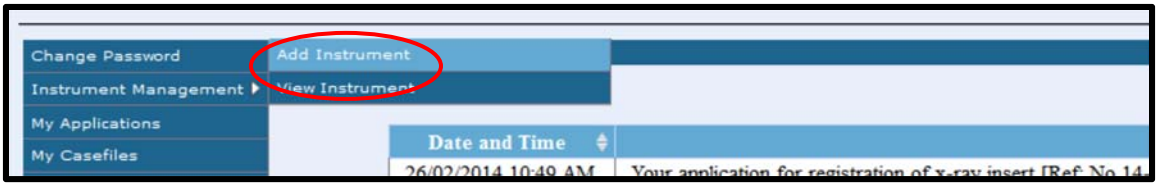
D. Declaration of Instrument

Measuring (viz. Secondary Standard Dosimeter), Monitoring (Viz. Survey meter), QA and Safety Tools can be declared one time in your eLORA account through Instrument Management menu. The status of instruments (viz. proposed/available, update in calibration date, etc) can also be managed through this menu.

- **Add Instrument**

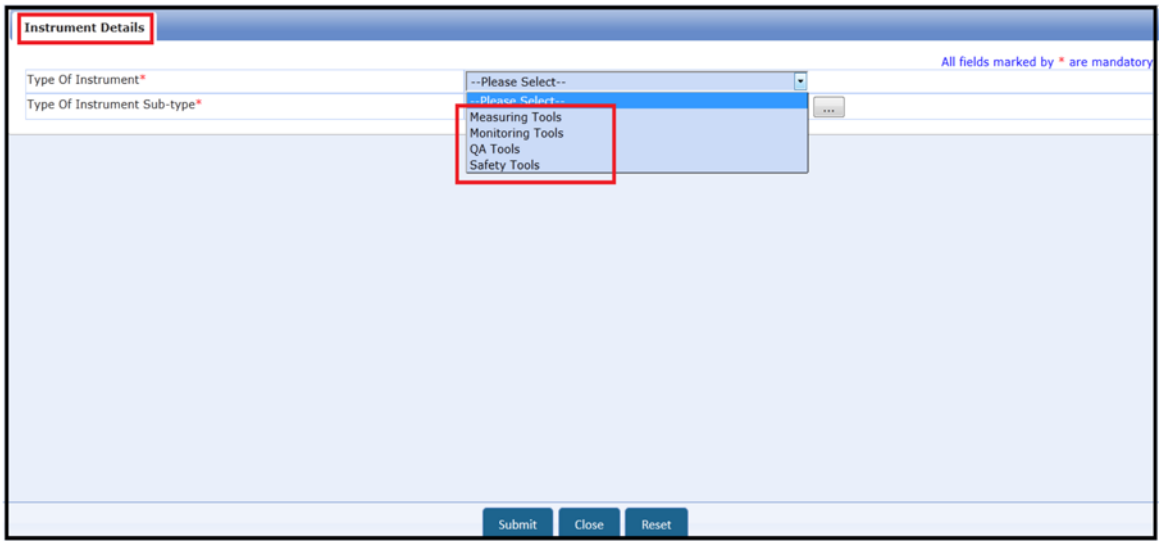
  Medical Cyclotron facilities may require instruments e.g. survey meter, contamination monitor, area monitors etc for day to day functioning of the facility. The instruments need to be declared in e-LORA. To declare the same follow the path as:

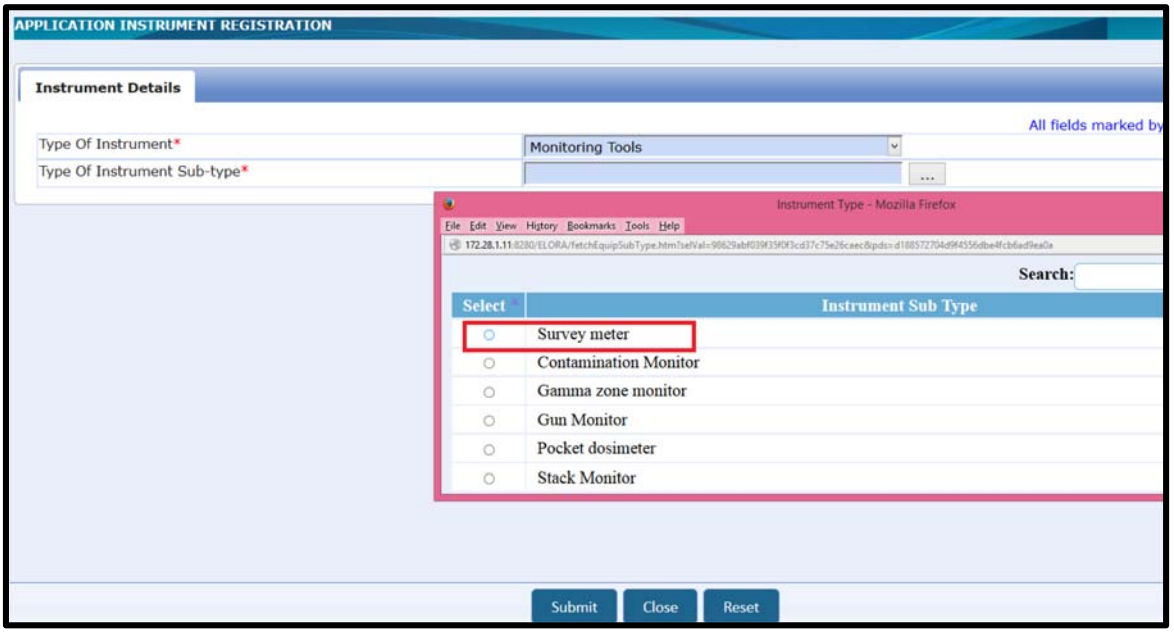
  Menu ⟶ Instrument Management ⟶ Add Instrument/View Instrument



Following options are available in Drop Down for Type of Instrument,

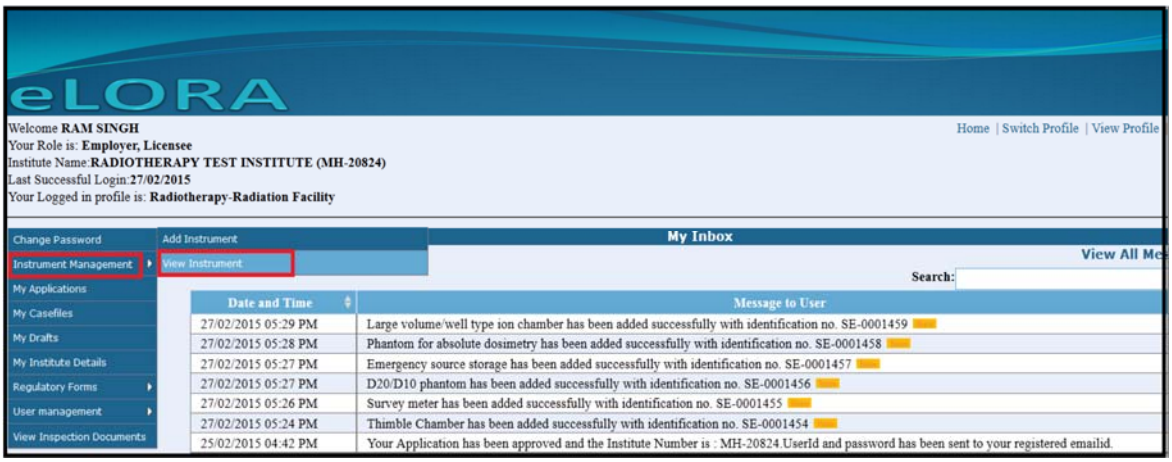
- Measuring Tools (Dose Calibrator etc)
- Monitoring Tools (Survey Meter, Area Monitor etc)
- QA Tools (Phantoms & other accessories)
- Safety Tools (Safety accessories like Fume Hood, Tongs, Glove Box, Hot Cells etc)



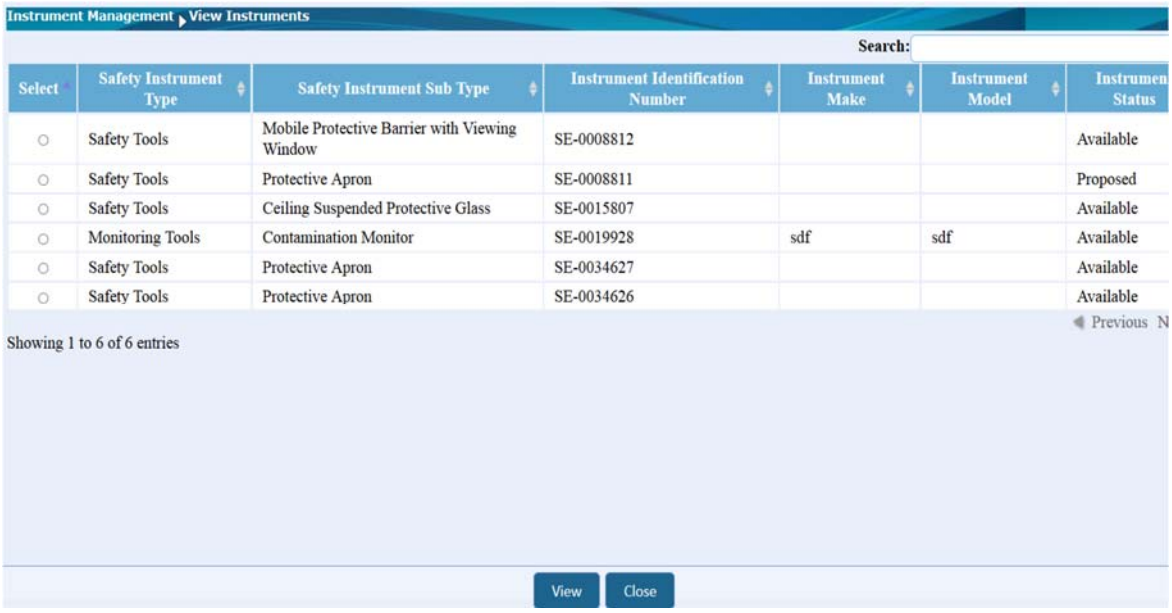


All the instruments has to be declared separately to the system which will store all the details. The LOV for Type of Instrument Sub-type will list out all the relevant instruments as per the selection in the previous field.

- **Manage Instrument Status**
  Use **Menu** → **Instrument Management** → **View Instrument** to manage status of Instrument



After clicking on **View Instrument** the following screen will appears. You can view details of all instruments or update details of particular instrument or delete any particular Instrument from your Institute account. Select the instrument and click on **View** as shown below.

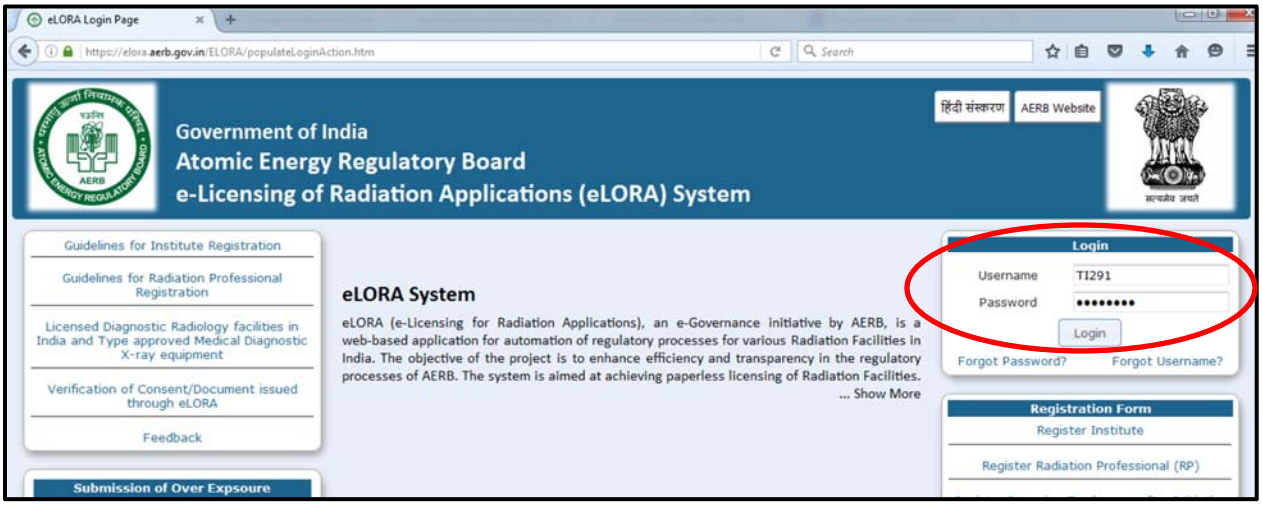


After clicking on “view’ the following screen will appear. Through this Employer of the Institute can modify status of the instruments (viz. Functional status, Calibration date, Calibration valid till date, Calibration energy and calibration lab detail). The selected equipment can also be deleted by clicking on ‘Delete’ button.

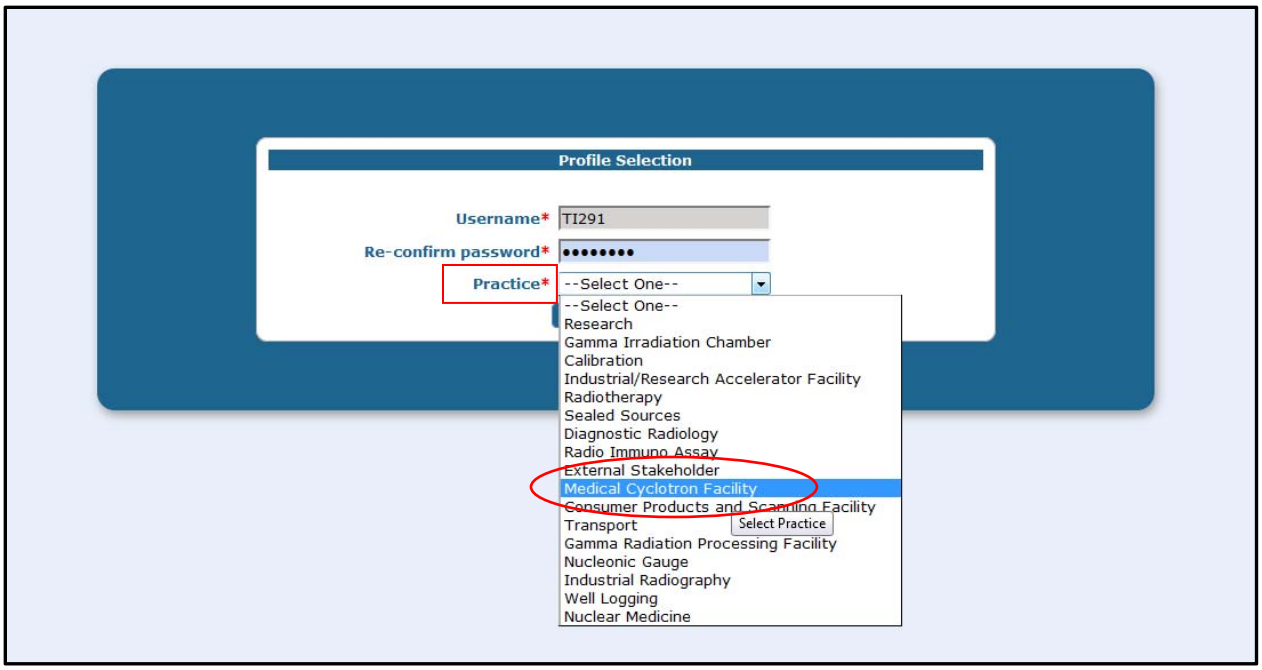
Important Note: Regulatory clearances will not be issued till all requisite Measuring instruments, Monitoring instruments, QA tools and Safety tools for particular type of facility are successfully recorded in eLORA.

Application for various AERB Consents through eLORA

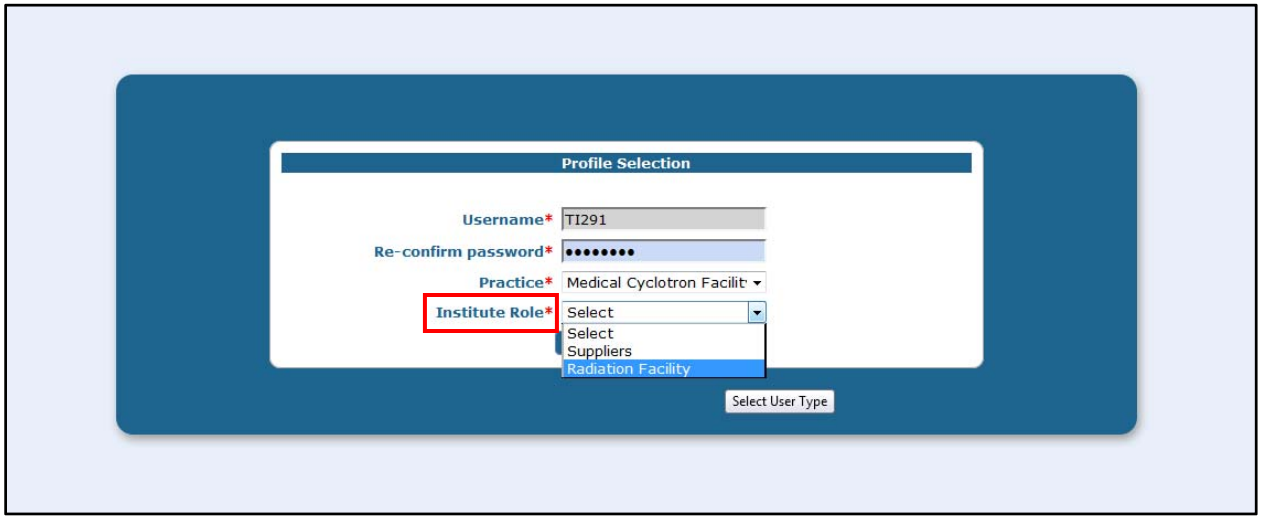
This user guide brief about the online submission process of the regulatory application forms for obtaining various clearances for operating the Medical Cyclotron Facility. To start transacting with eLORA, you must have a user credential i,e user id and password. This credential will be issued to you after your institute registration application is approved in eLORA. The process for Institute Registration has already been detailed in this guidelines. The user id and password issued through eLORA will be posted in your e-mail id provided in the application form. Use this login credential to access the menus available for this practice.

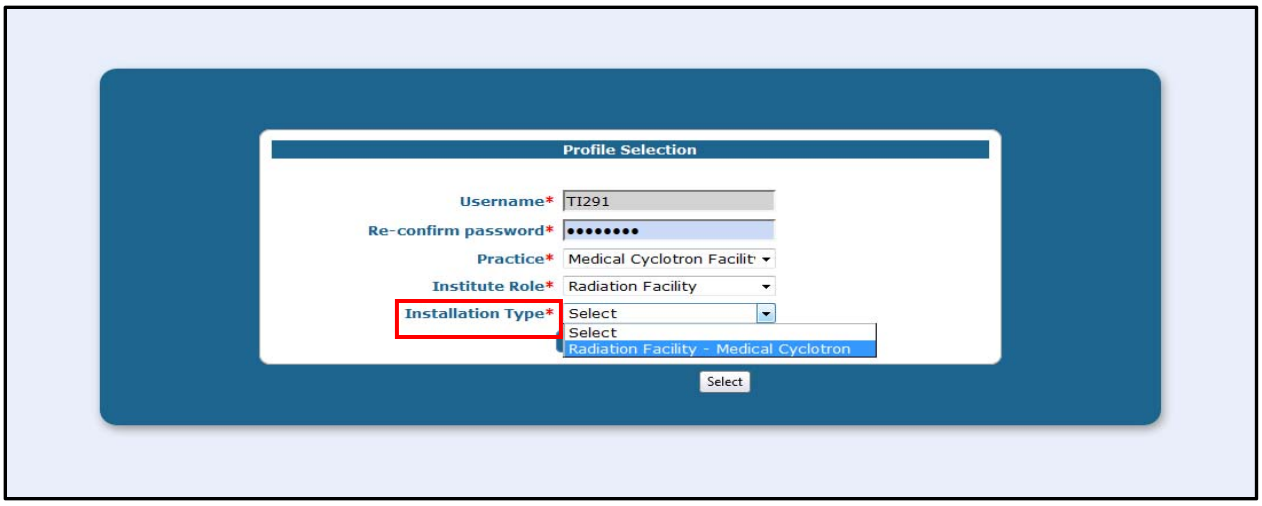


Click on “Login” the following screen appears.

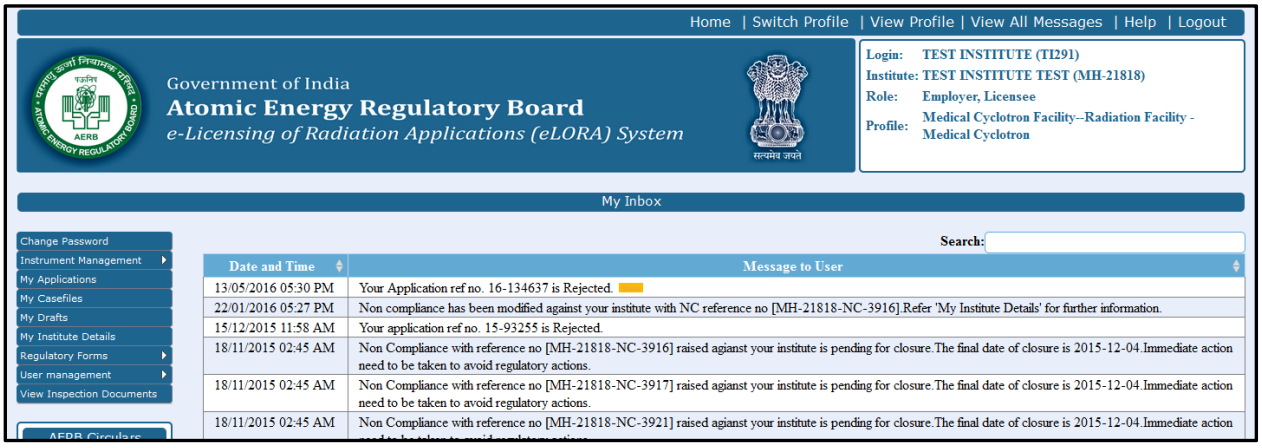


Reconfirm your password and select your practice, role and installation type. You can select only one item at a time. In case, you would like visit other profile, use “switch profile” option available in your logged in page.

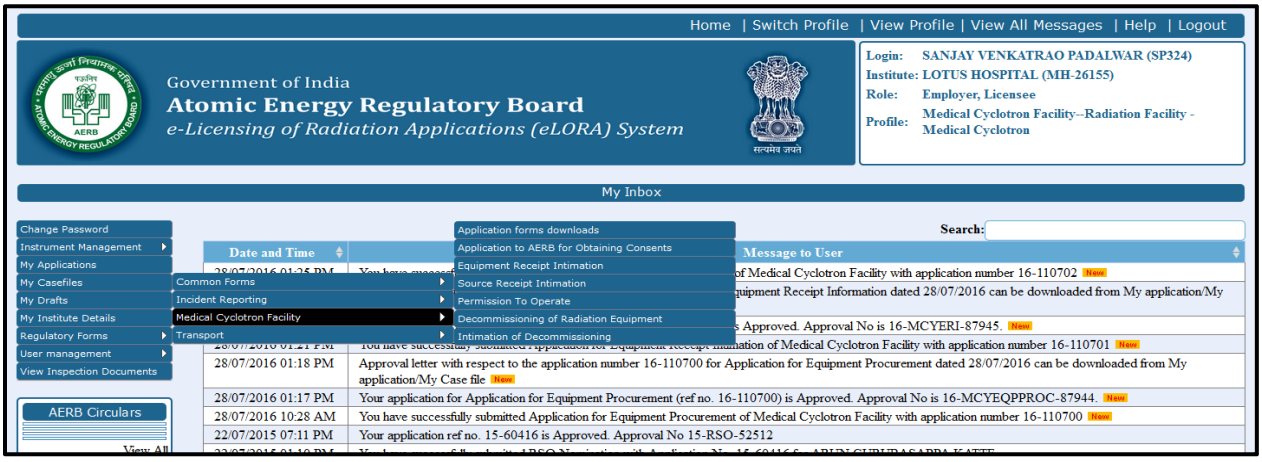




Click on **Launch**. The following screen will appear.



Click on Regulatory Forms to access the applicable form menu.

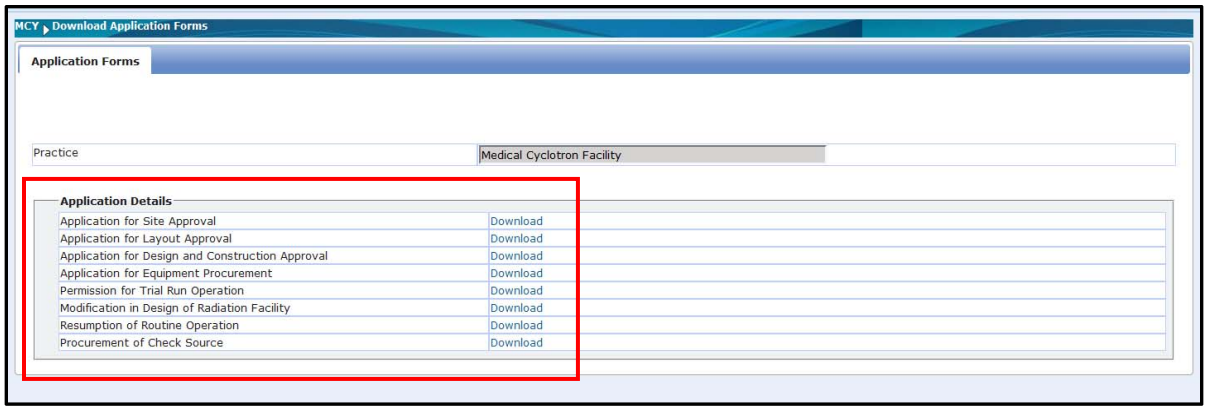


1. Application forms downloads

All relevant forms for application for different clearances for Medical Cyclotron Facility are available under this. You may access the same by the following path:

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Application forms downloads

Download the requisite application form. Completely fill the application form, scan/soft copy with appropriate signature and save the file. Make sure that the file is in PDF format and the size is not exceeding the 4MB upload limit.



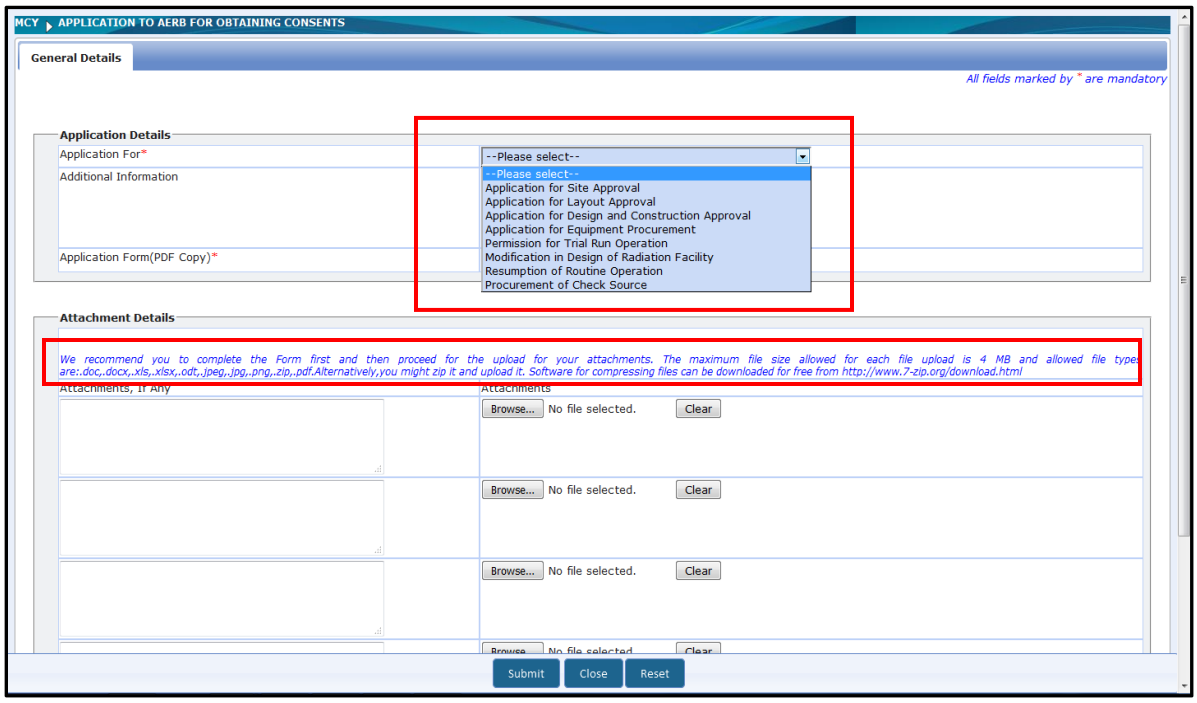
2. Application to AERB for Obtaining Consents

Application for any clearances pertaining to the facility should be processed through this step. To access the applications, please follow the path below:

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Application to AERB for Obtaining Consents

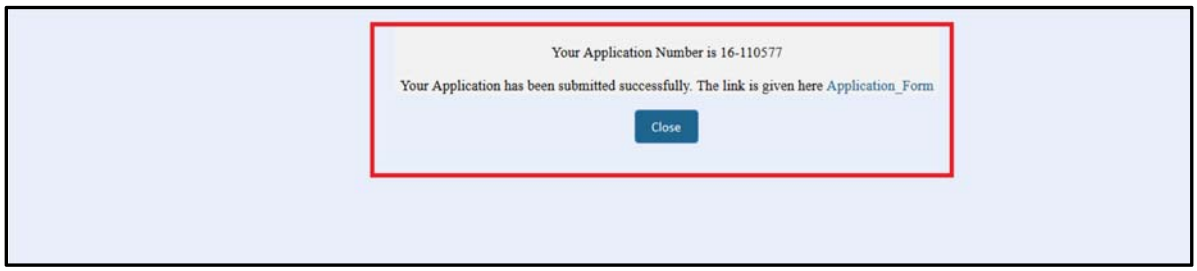
Choose the appropriate application for what you want AERB clearance. Upload copy of the appropriate form for that stage as downloaded earlier. Ensure that the application should be duly filled in and signed in all respects and it belongs to that stage only.

You may provide Additional Information in the designated area.

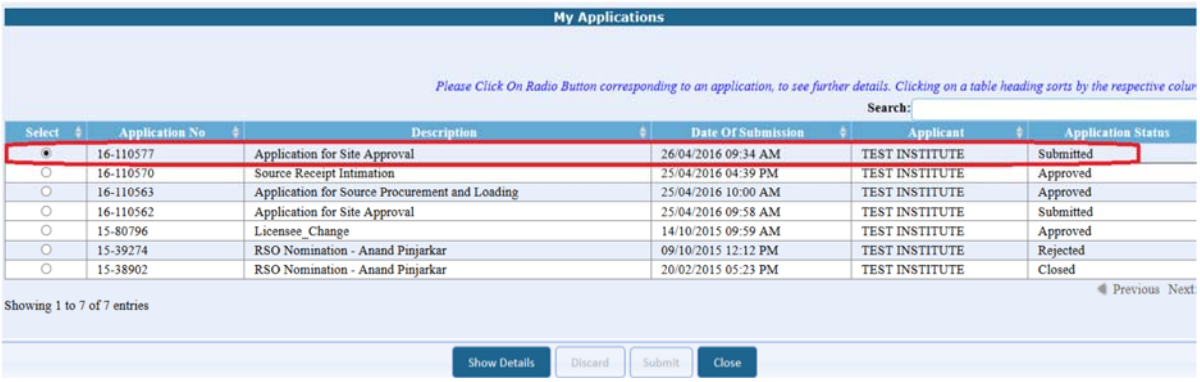


Required attachments are listed in Application Forms for that stage. Name the attachments and upload them as required. Click on **Submit** to send the form to AERB.

On successful submission, the following screen will appear. You can download your submitted application form this link or from the menu “My Application”.



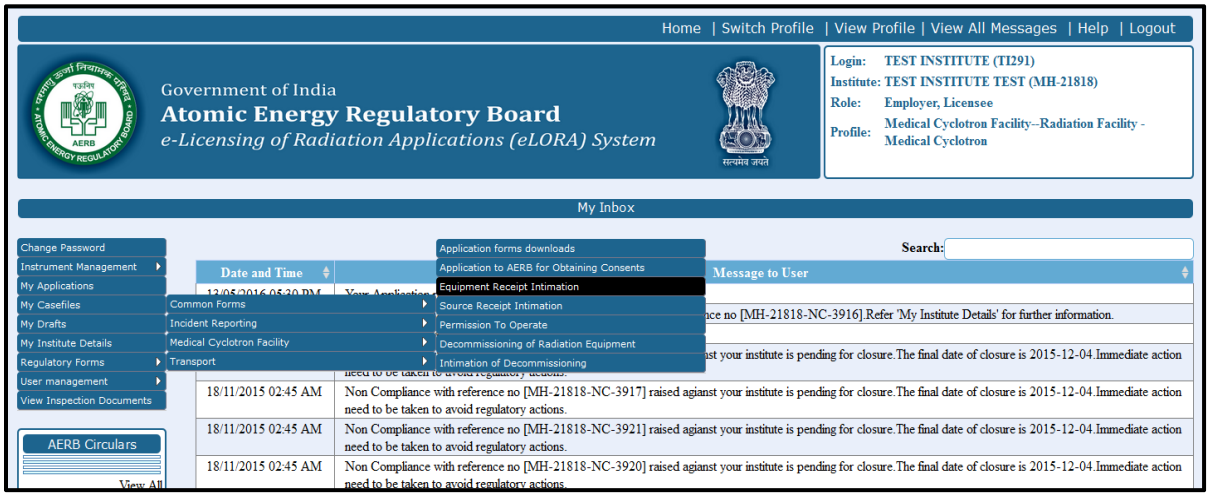
In My Application menu you can view the submitted details at any time and the status of the application will be tracked from this menu such as Submitted, In Progress, Approved or Rejected.



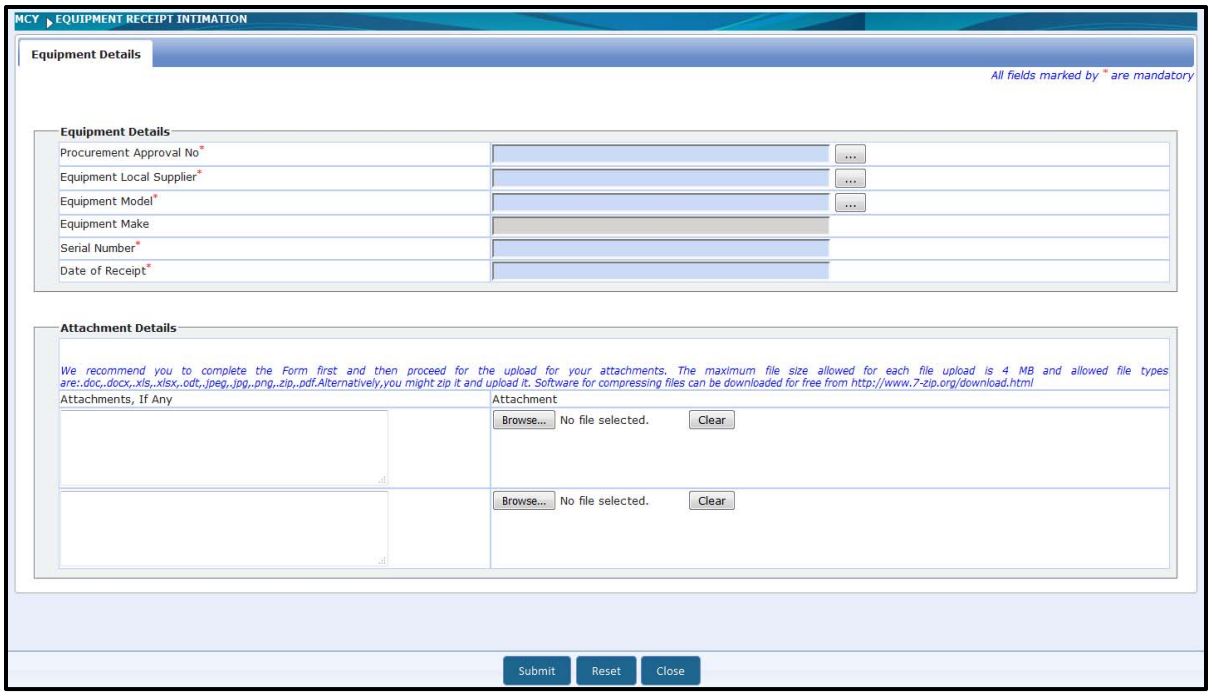
3. Equipment Receipt Intimation

After due approval of equipment procurement obtained from the regulatory body via the aforementioned procedure and further receipt of the Medical Cyclotron at the facility, you are required to submit the Equipment Receipt Intimation as mentioned below:

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Equipment Receipt Intimation



The following screen will appear;



Fill up the page as mentioned below and submit;

Tab: Equipment Details

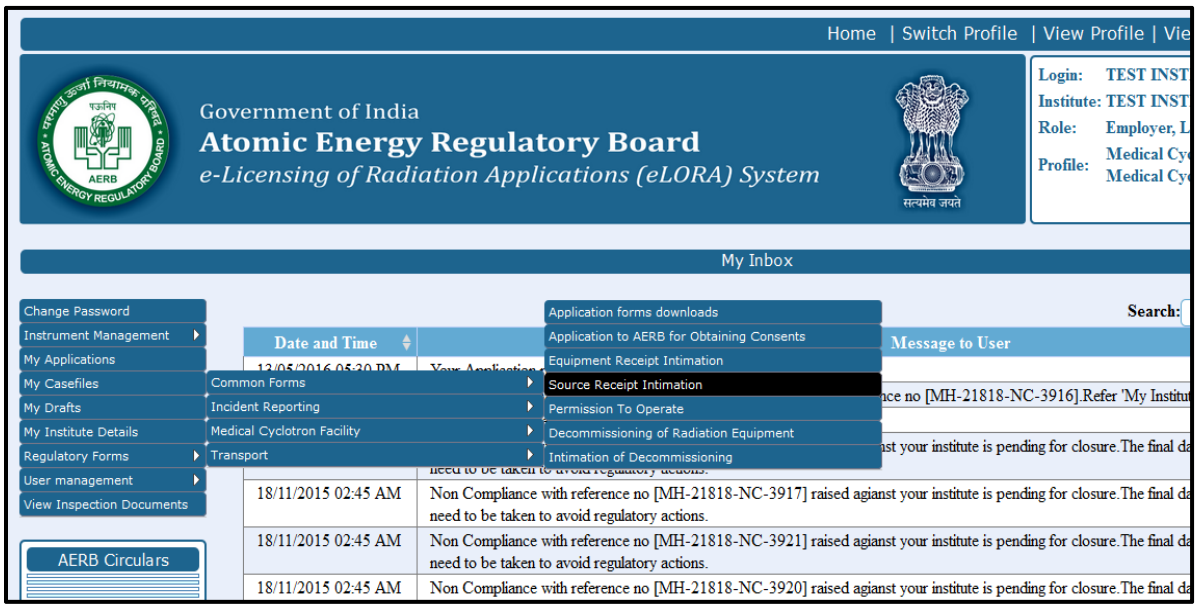
- **Procurement Approval No:** Choose appropriate **Procurement Approval No** from the list intended for the received medical cyclotron.
- **Equipment Local Supplier:** Choose appropriate **Supplier** of the equipment from the list.
- **Equipment Model:** Choose appropriate **Model** of the Cyclotron from the list.
- **Equipment Make:** Will be automatically populated based on previous selection.
- **Serial No:** Enter serial no of the equipment.
- **Date of Receipt:** Enter date of receipt of the cyclotron.

Requisite **Attachments** like Technical Specification, User Manual of the Cyclotron and any conformity certificate from National or International bodies should be attached with proper naming.

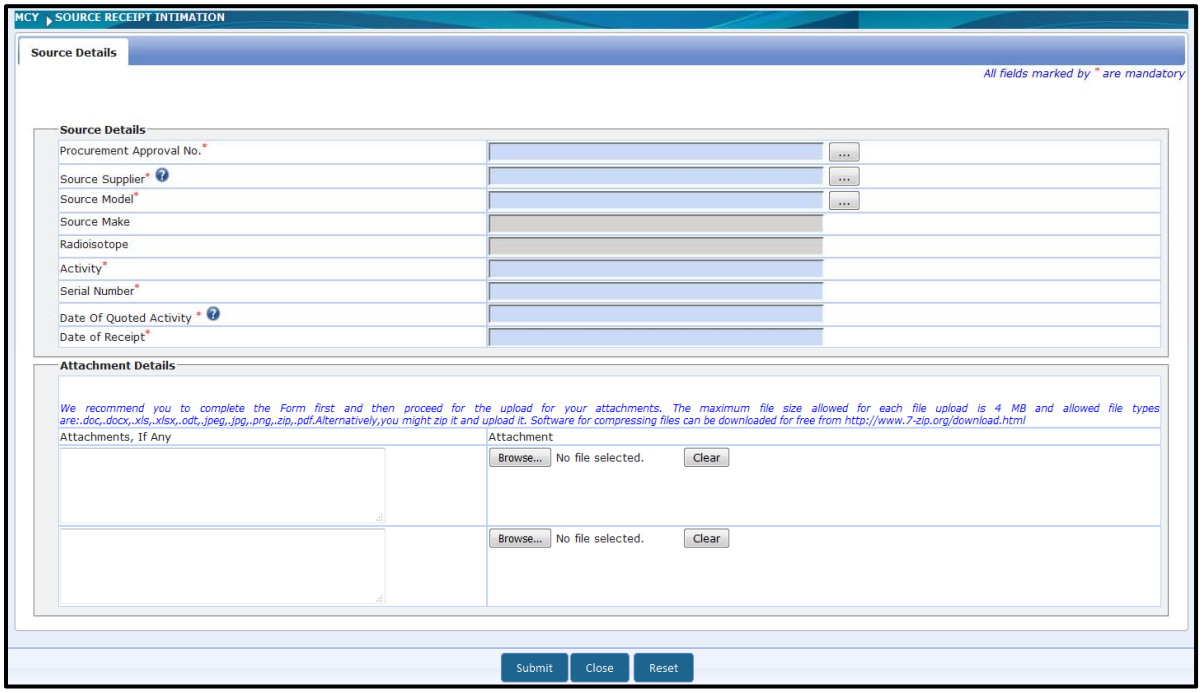
4. Source Receipt Intimation:

Similarly, after due approval of procurement of check source obtained from the regulatory body via the aforementioned procedure and further receipt of the same, you are required to submit the Source Receipt Intimation as mentioned below:

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Source Receipt Intimation



The following screen will appear;



Fill up the page as mentioned below and submit;

Tab: Source Details

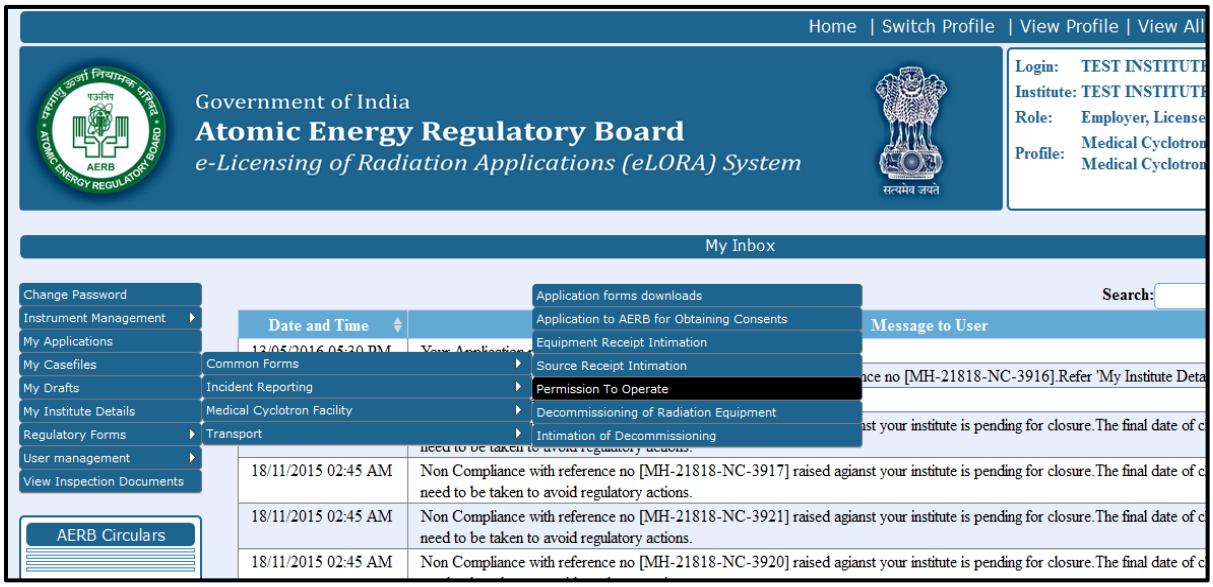
- **Procurement Approval No:** Choose appropriate **Procurement Approval No** from the list.
- **Source Supplier:** Choose **Supplier** of the source from the list.
- **Source Model:** Choose **Model** of the Source from the list.
- **Source Make/ Radioisotope:** Will be automatically populated based on previous selection.
- **Activity:** Enter activity of the source in specific unit.
- **Serial No:** Enter serial no of the source.
- **Date of Quoted Activity:** Enter quoted date of the activity entered previously.
- **Date of Receipt:** Enter date of receipt of the Source.

Requisite **Attachments,** if any, should be attached with proper naming.

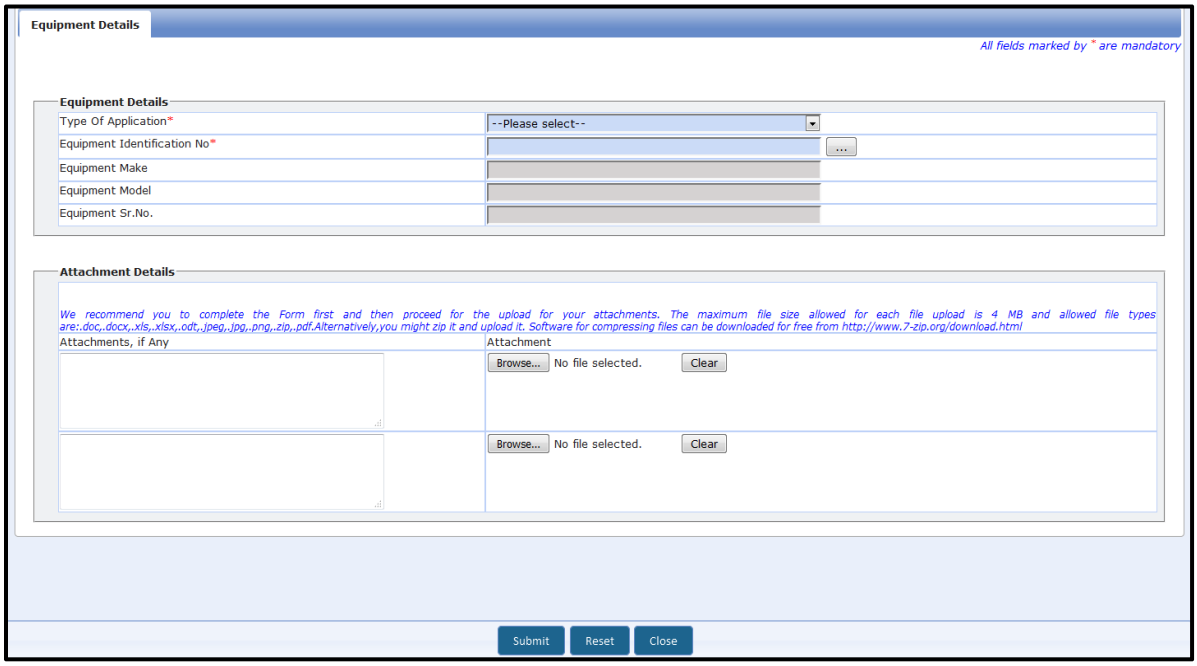
5. Permission to Operate

After successful **Trial Run** of the installed Medical Cyclotron Facility, the user requires License for daily operation of the equipment. The application may be done by following the path below;

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Permission to Operate



The following screen will appear;



Fill up the page as mentioned below and submit;

Tab: Equipment Details

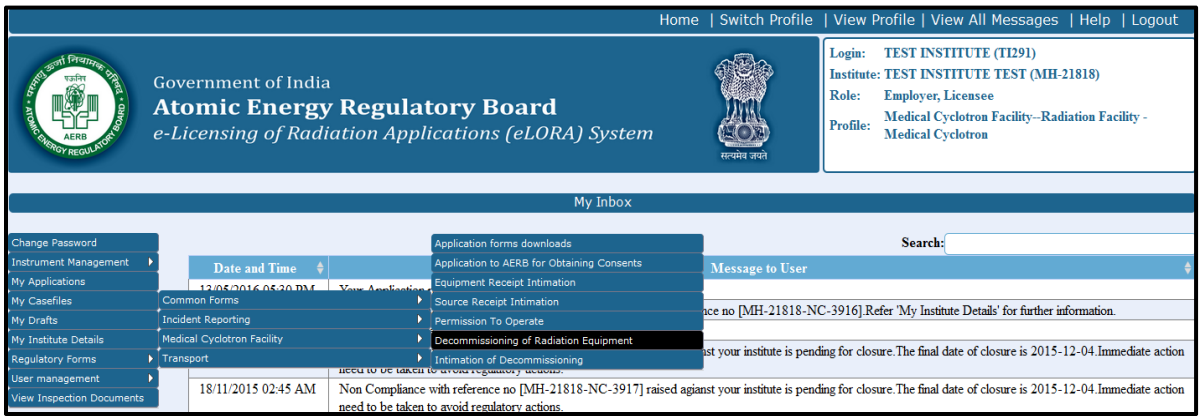
- **Type of Application:** Select **New**, if you are applying for License for the first time. Select **Renewal**, if you want to renew your already approved License.
- **Approval No:** Applicable for **Renewal** only. Select Approval No of the License from the list for which you require renewal.
- **Equipment Identification No:** Choose appropriate Medical Cyclotron. The list will populate the Medical Cyclotron for which you have received Equipment Receipt Intimation approval. For Renewal, the field will be auto populated.
- **Equipment Make:** Will be automatically populated based on previous selection.
- **Equipment Model:** Will be automatically populated based on previous selection.
- **Equipment Serial No:** Will be automatically populated based on previous selection.

Requisite **Attachments,** if any, should be attached with proper naming. For **New** License, mandatorily attach **Final Safety Analysis Report (FSAR)** as per the specified format.

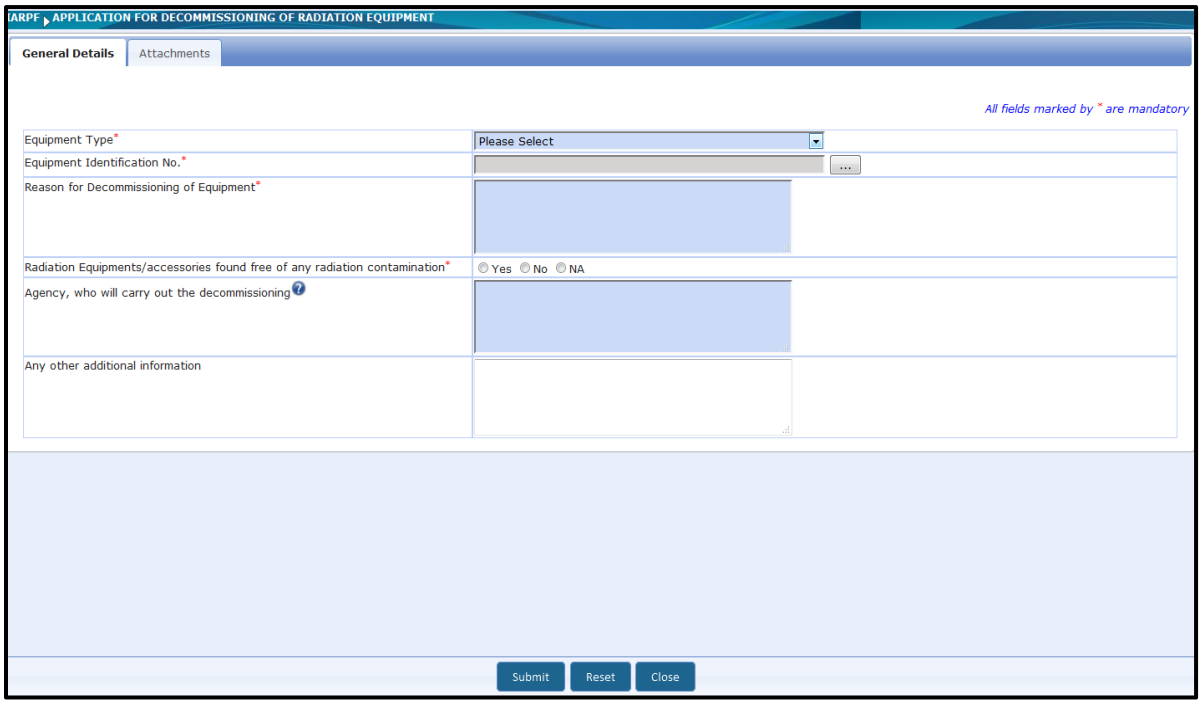
6. Decommissioning of Radiation Equipment

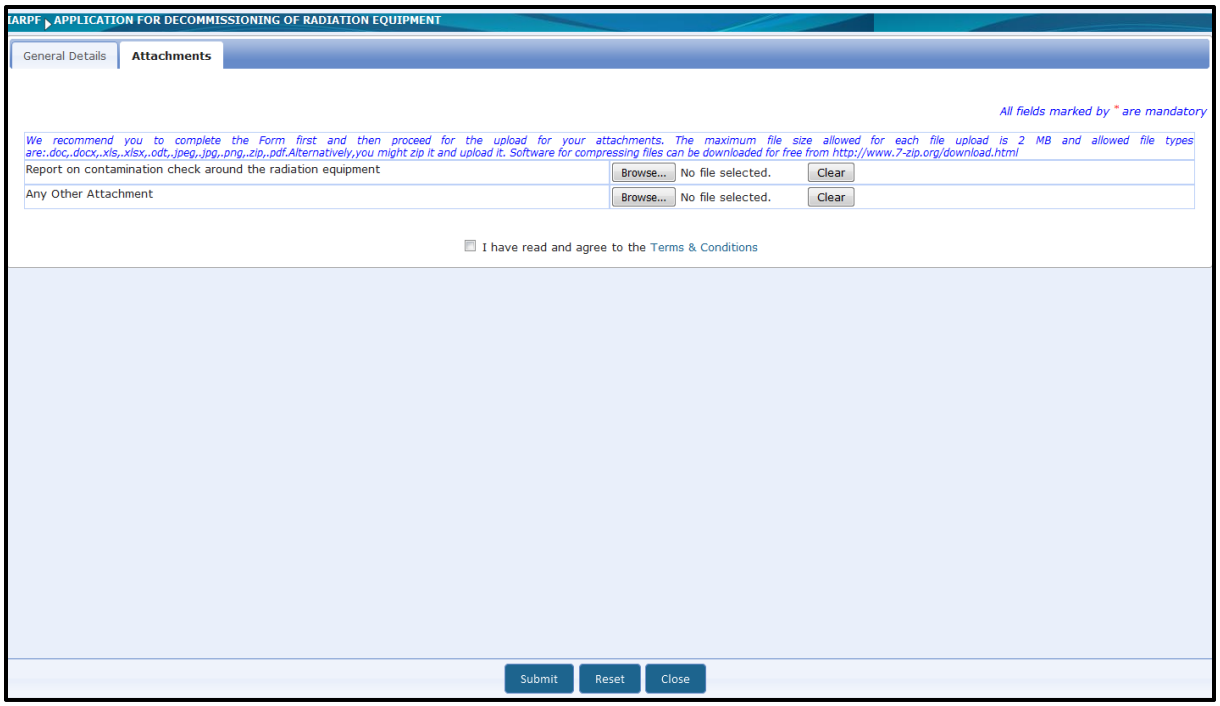
After useful life of the equipment, the facility may opt for decommissioning the equipment for which permission has to be sought from AERB. The Application for the same may be submitted by following the path as follows;

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Decommissioning of Radiation Equipment



Screen shown below will follow;





Fill up the page as mentioned below and submit;

Tab: General Details

- **Equipment Type:** Select **Medical Cyclotron**.
- **Equipment Identification No:** Choose appropriate Medical Cyclotron. The list will populate the Medical Cyclotron for which you have received Equipment Receipt Intimation approval.
- **Reason for Decommissioning of Equipment:** Text Field. Write the reason for decommissioning.
- **Radiation Equipments/accessories found free of any radiation contamination:** Select between **Yes**, **No** and **NA**.
- **Agency, who will carry out the decommissioning:** Provide Name, Address, City & State of the agency involved in decommissioning.
- **Any other additional information:** Provide any information you want to share with AERB for the application.

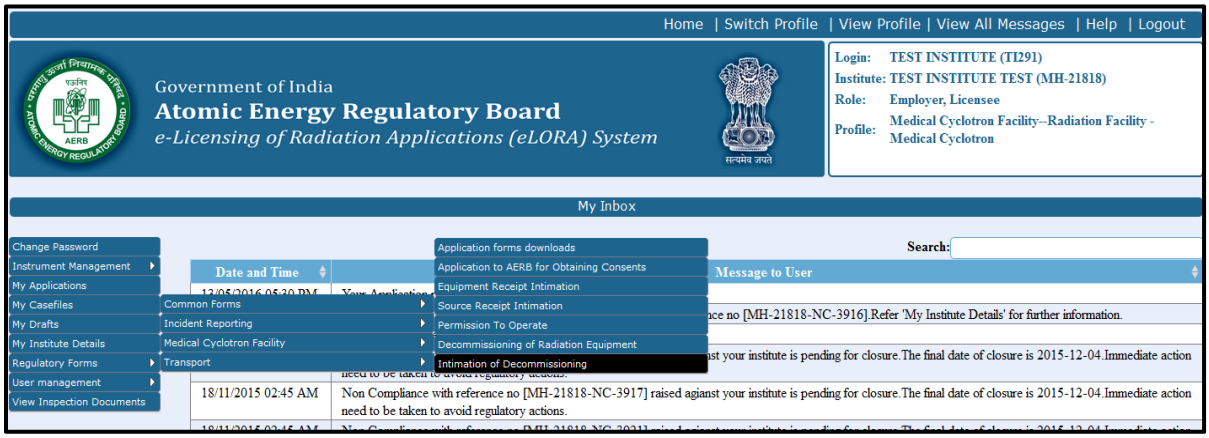
Tab: Attachments

- Attach **Report on Contamination check around the equipment.**
- Attach Consent letter from the agency involved in decommissioning in **Any other attachment.**

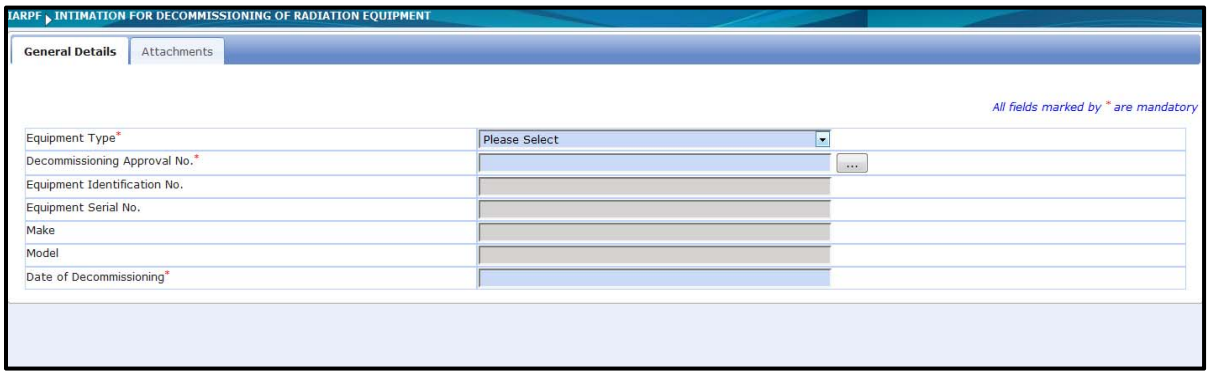
7. Intimation of Decommissioning

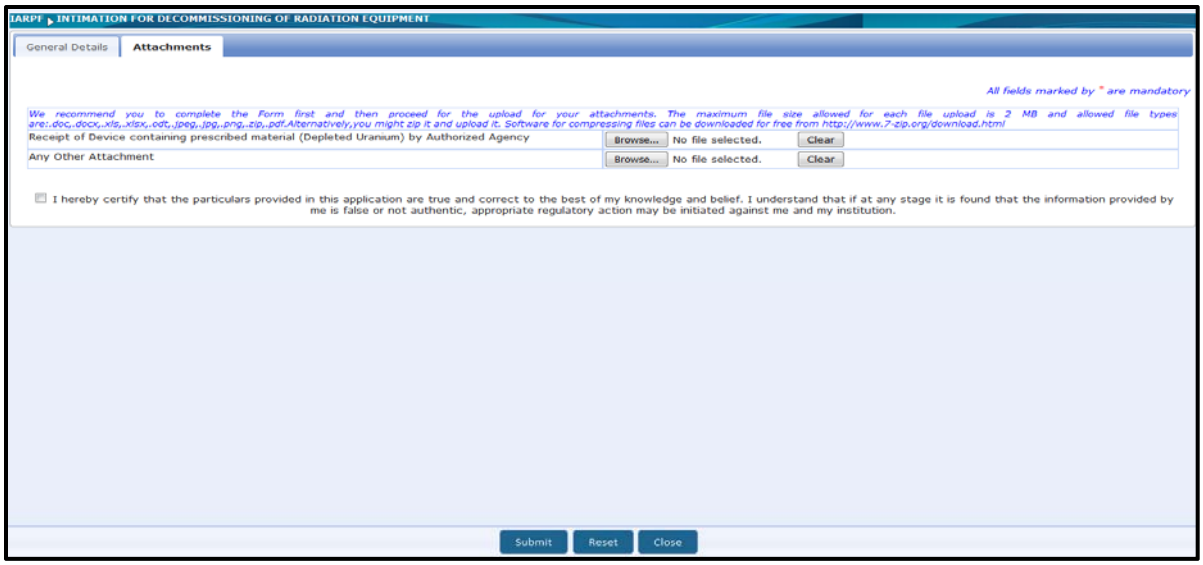
Intimation of Decommissioning of the Equipment can be submitted by following the path as follows;

Menu: Regulatory Forms ⟶ Medical Cyclotron Facility ⟶ Intimation of Decommissioning



Following screens will follow;





Fill up the page as mentioned below and submit;

Tab: General Details

- **Equipment Type:** Select **Medical Cyclotron**.
- **Decommissioning Approval No:** Choose appropriate Approval No from the list.
- **Equipment Identification No:** Will be automatically populated based on previous selection.
- **Equipment Serial No:** Will be automatically populated based on previous selection.
- **Make:** Will be automatically populated based on previous selection.
- **Model:** Will be automatically populated based on previous selection.
- **Date of Decommissioning:** Provide the date of completion of decommissioning.

Tab: Attachments

- Attach Decommissioning Report including Radiation Survey and Contamination check of the facility in **Any other attachment.**

8. Brief Description of the Regulatory Forms

Sr. No.	Stage / Application	Description
1.	Application for Site Approval	Applicable when applying for new facility
2.	Application for Layout Approval	Not Applicable
3.	Application for Design and Construction Approval	Applicable when applying for new facility after Site Approval

4.	Application for Equipment Procurement	Applicable for Procurement of Medical Cyclotron
5.	Permission for Trial Run Operation	Applicable after approval of Equipment Receipt Intimation and installation
6.	Modification in Design of Medical Cyclotron Facility	Applicable when there is a proposed change in design of the facility
7.	Resumption of Routine Operation	Applicable after the design modification approval.
8.	Procurement of Check Source	Applicable when the check source will be procured

9. Common Forms

The following applications may also be submitted through eLORA by following the path;
Menu: Regulatory Forms ⟶ Common Forms

1. Nominate RSO
2. Non-utilization of Approval
3. Employer change initiation
4. NC Response Screen
5. Safety Status Report
6. Feedback on Grant of Consent
7. Feedback on Regulatory Inspection
8. Enforcement Response Screen
9. Exposure Investigation Report
10. Update Operational Status
11. Security Plan

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