e-Licensing of Radiation Applications (eLORA) System

Guidelines

Radiotherapy Module

April 24, 2023

Contents

Help Email id: elora.rt@aerb.gov.in

Important Updates:

The following Formats are available in the help menu of e-LORA for use by the radiotherapy facilities

(i) Format for preparation of emergency preparedness and response plan

(ii) Format of Decommissioning Plan for category-1 sources (for telecobalt/gamma knife sources)

(iii) Self-Assessment Checklist for compliance with regulatory requirements

eLORA Guidelines for Radiotherapy Module

eLORA module of Radiotherapy facilitate online submission of applications for regulatory consents (layout approval/ authorization for procurement/Licence/Registration/RSO approval, etc.) for **Radiotherapy Facilities.** All radiotherapy user Institutes are required to use eLORA system for obtaining requisite regulatory clearance from AERB.

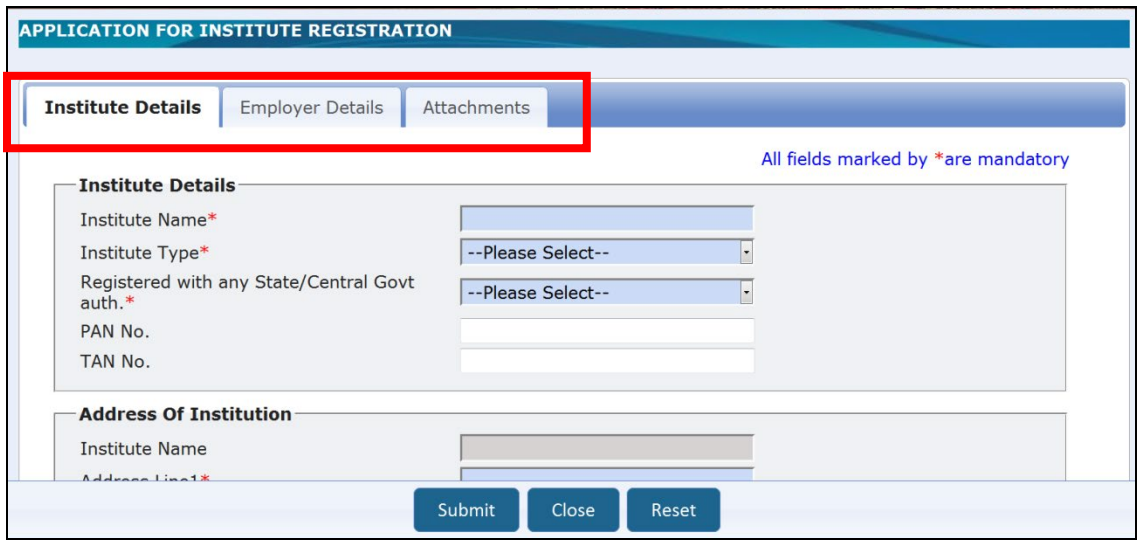
This document provides guidelines to use eLORA system for obtaining requisites regulatory consents from AERB for Radiotherapy facility.

Important Note: Guidelines for common functionalities of eLORA system are available in **Help** menu of eLORA. Users are also advised to refer these guidelines.

1 Register Institute

Visit home page of AERB website www.aerb.gov.in and click on the button **eLORA**. It will redirect you to eLORA system.

Click on **Register Institute** (see above figure) link available on eLORA home page. This will open application form for Institute Registration. Application form has three tabs.

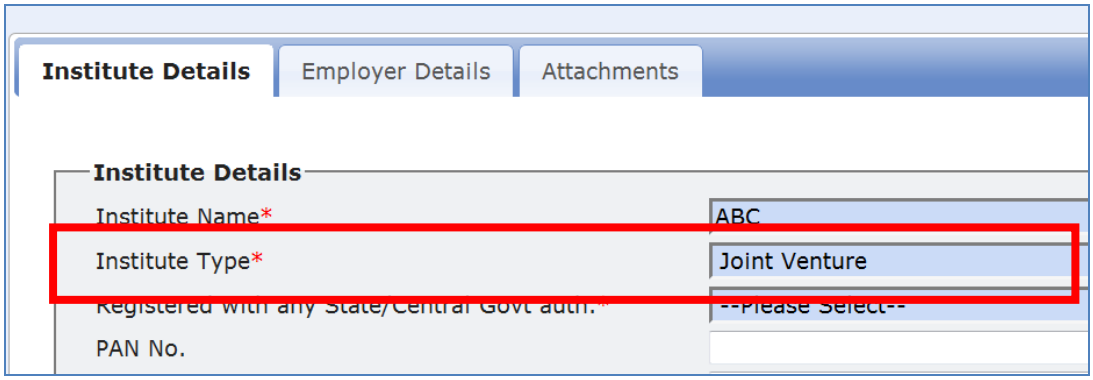


Important Note: Guidelines to fill application form for Institute Registration is available on eLORA home page. It is advised to read the guidelines and keep soft copy of required attachments ready before start filling of application form.

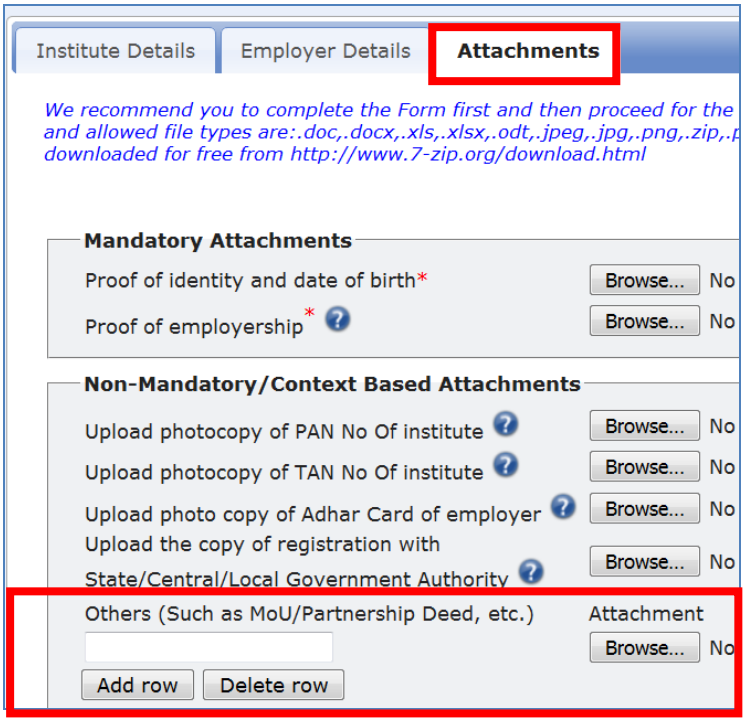
Fill the application form as per the guidelines. However, important points in each tab are mentioned below:

Tab Institute Details:

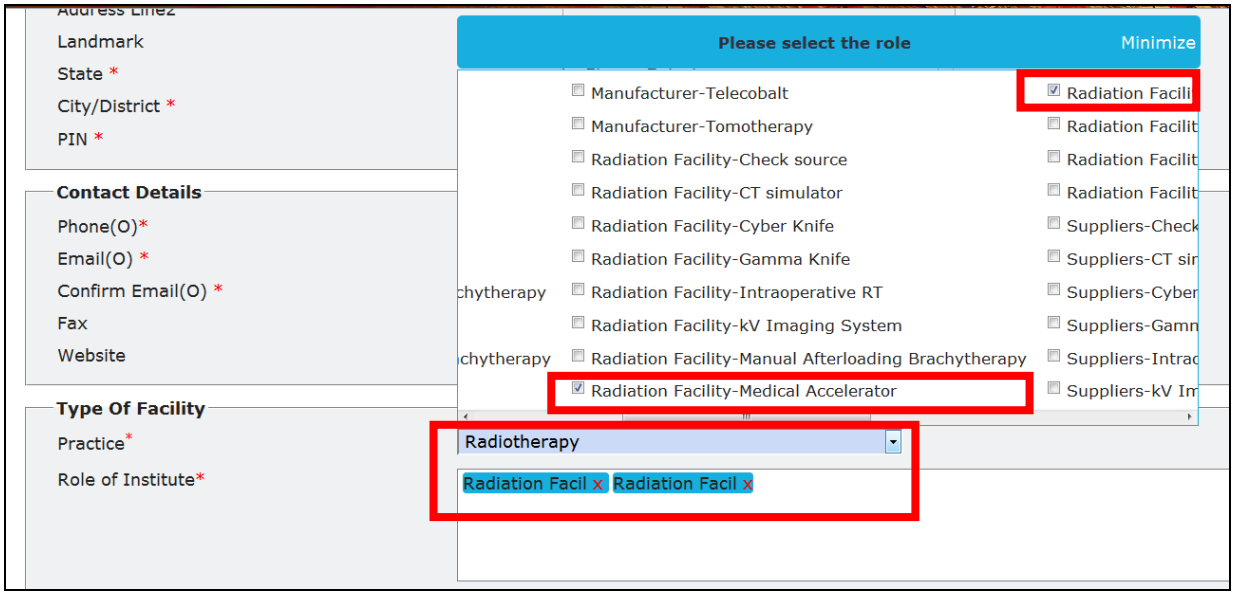
- **Type of Institute:** Select type of institute as either 'Central Government', 'State Government', Private' or 'Joint Venture'.



In case the institute type is 'Joint Venture', Please upload dully filled scan copy of undertaking as given in *Annexure B: Format of undertaking for 'Joint Venture' institute,* at the place given to upload 'Other' attachment in Tab: Attachments



- **Type of Facility**: In **Type of Facility** section, for the field **Practice** select **Radiotherapy** and for the field **Role of Institute** select the role by clicking check box as shown in the below screen. Multiple Check boxes can be chosen depending on the facilities proposed in your institution.



Tab 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 e-LORA account and for all future communications. (Make sure to provide correct email address).

Tab 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 Employership:** Example: (i) Appointment Letter of Employer, (ii) Board Resolution, (iii) Any Govt./PUC document substantiating proprietorship (iv) Partnership deed (notorised)
- Upload scan copy of any one of the document listed below (in the relevant position) for the proof of existence of institute (The institute name and address mentioned in the application form must match with any of the attached document):
  - PAN of Institute
  - TAN of Institute
  - 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 (Please note, this link will be active for a short period). You will also receive an acknowledgement mail with the copy of your application form (.pdf file) in your email (email address as provided in the application form).

Application for Institute Registration will be scrutinized by AERB. After the approval of institute registration by AERB, you will receive user ID and password in your registered email (email address of Employer, as provided in the application form).

Existing Radiotherapy User Institutes should not apply for Institute Registration

Important Note: Existing user institutions which have obtained license for operation through hard copy are preregistered by AERB and provided with user name and password. These institutions should not apply for Institute Registration through eLORA. Any such existing institution which has not received the user name and password may write to help email id elora.rt@aerb.gov.in

Adding Other Roles (viz. Diagnostic Radiology, Nuclear Medicine, etc) in account

Important Note: In case you wish to add more practice/roles to your institution (such as adding

diagnostic radiology and/or nuclear medicine facilities in a registered radiotherapy institution) the same can be done through the 'Update Institution' menu of eLORA.

2 Register Radiation Professional (RP)

It is essential for staff of Radiotherapy such as **Radiation Oncologist, Medical Physicist, Radiotherapy Technologist and Radiotherapy Safety Professional** to register themselves as Radiation Professional (RP) in eLORA. Only registered RP can be associated with an institution through his/her RP registration Id.

Application form for Radiation Professionals registration is available on eLORA home page. Once RP application is approved, person is registered in eLORA as RP and RP Registration number, username and Password (Username and password of RP account) are sent to the registered email id of the radiation professional.

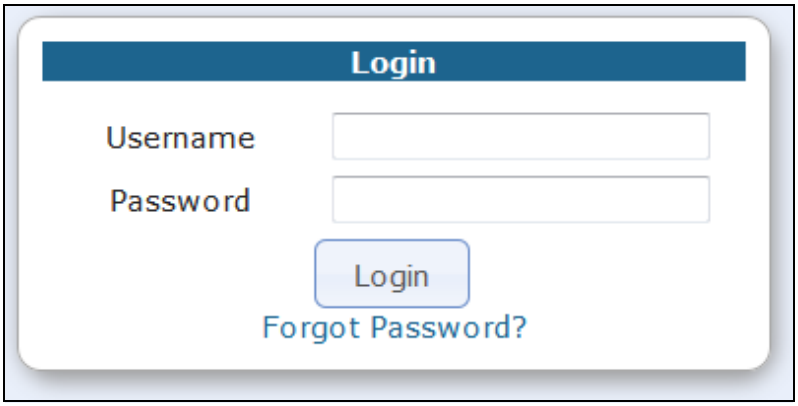
Important Note:

1)Guidelines to fill application form for RP registration is available on e-LORA home page. It is advised to read the guidelines and keep soft copy of required attachments ready before start filling application form.

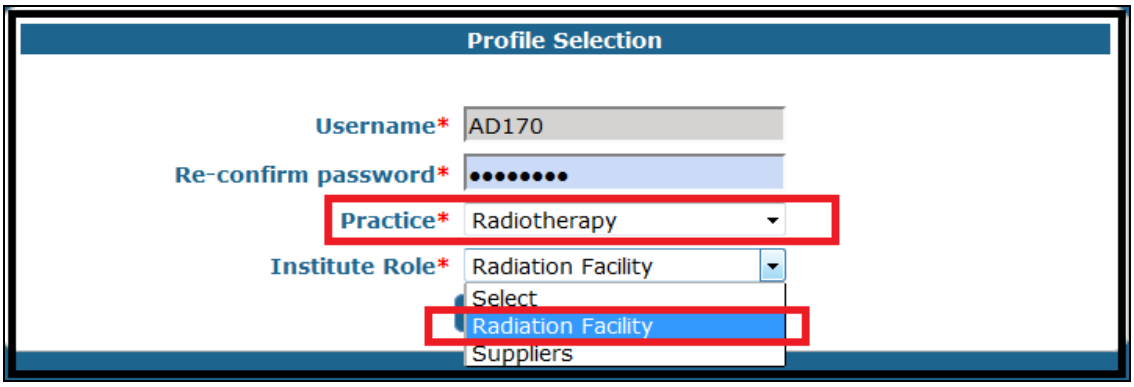
2) Radiation professional registration number (RP number) is unique for every radiation professional and therefore one radiation professional can have one RP number only. However, any radiation professional can apply for updation, if changing the professional role or practice.

3 Login to eLORA system

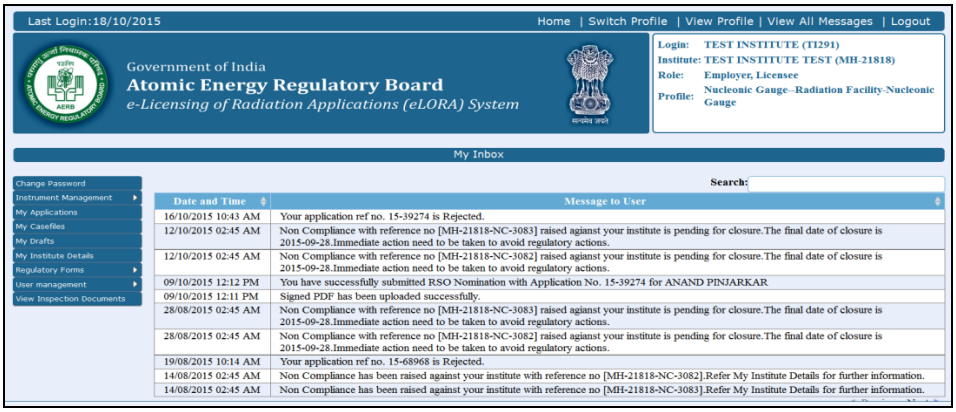
Login to the system using the "Username" and "Password" received on your registered email after approval of Institute Registration application form. On first time login, system will prompt to change the password.



In case, your Institute has multiple profiles, system will ask you to select the Practice and Institute Role. Please select Practice as “Radiotherapy” and Institute Role as “Radiation Facility”. (whether this screen is same?)



On clicking on ‘launch’ button, the following screen will be displayed

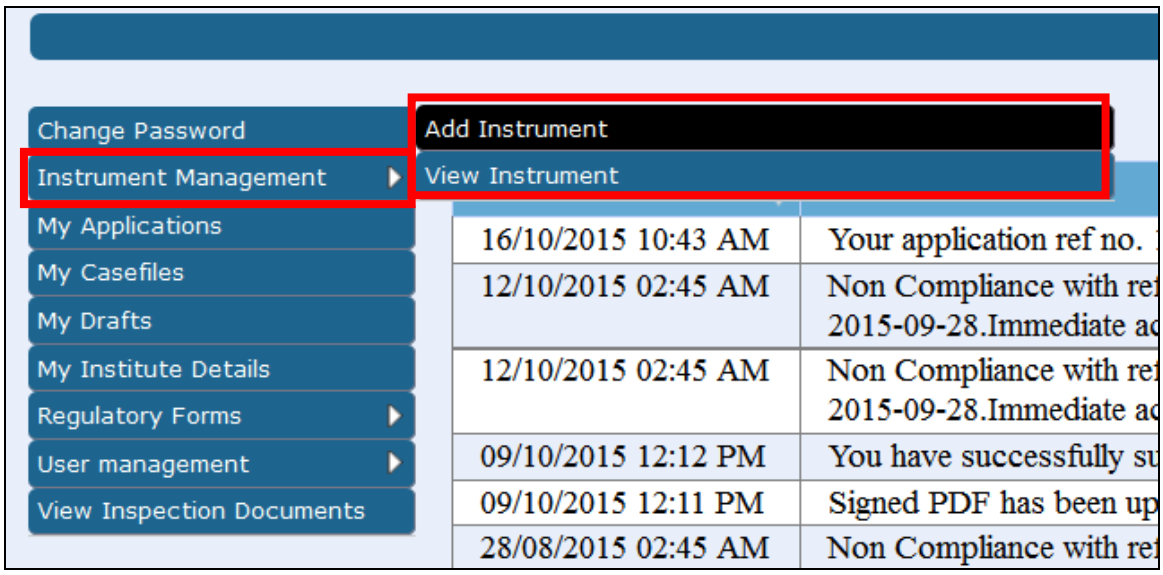


4 Declaration of Instrument

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.

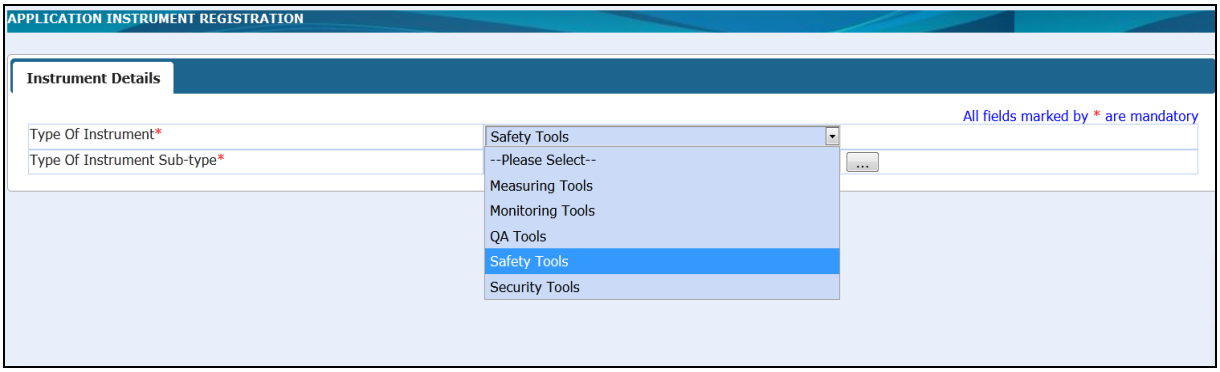
4.1 Add Instrument

Use **Menu: Instrument Management → Add Instrument** to add instruments

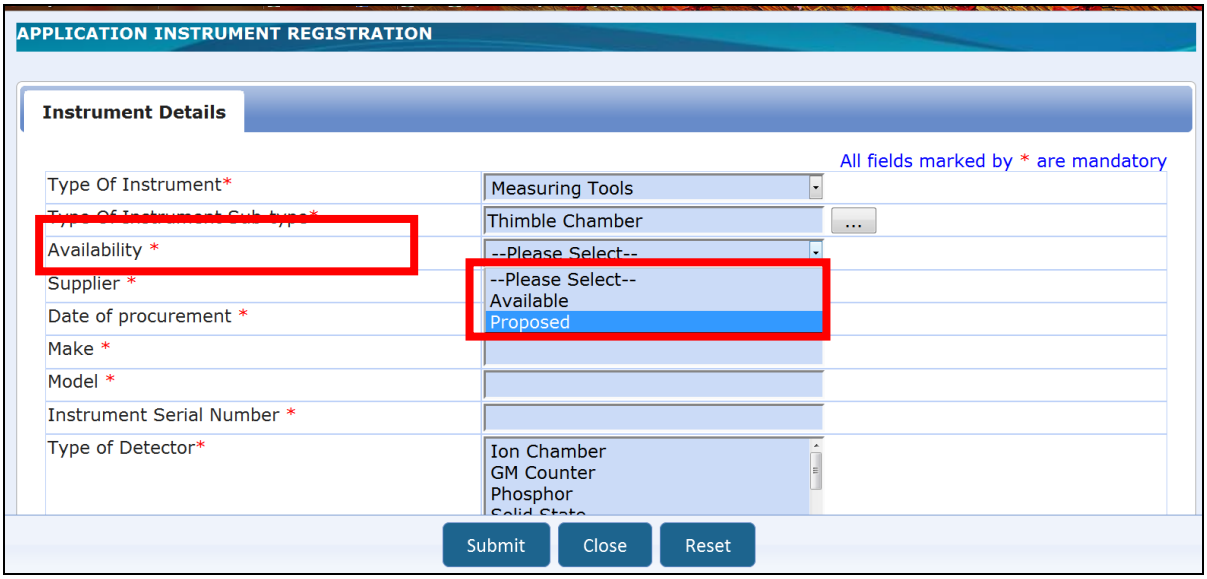


Instruments are classified in to below four types:

- Measuring instruments
- Monitoring instruments
- QA tools
- Safety tools
- Security tools



While adding instrument, it is important to mention availability of instrument i.e. either “Proposed” or “Available”.



Detail of instrument required to be declared for each type of installation is given in Annexure A: List of Requisite Instruments

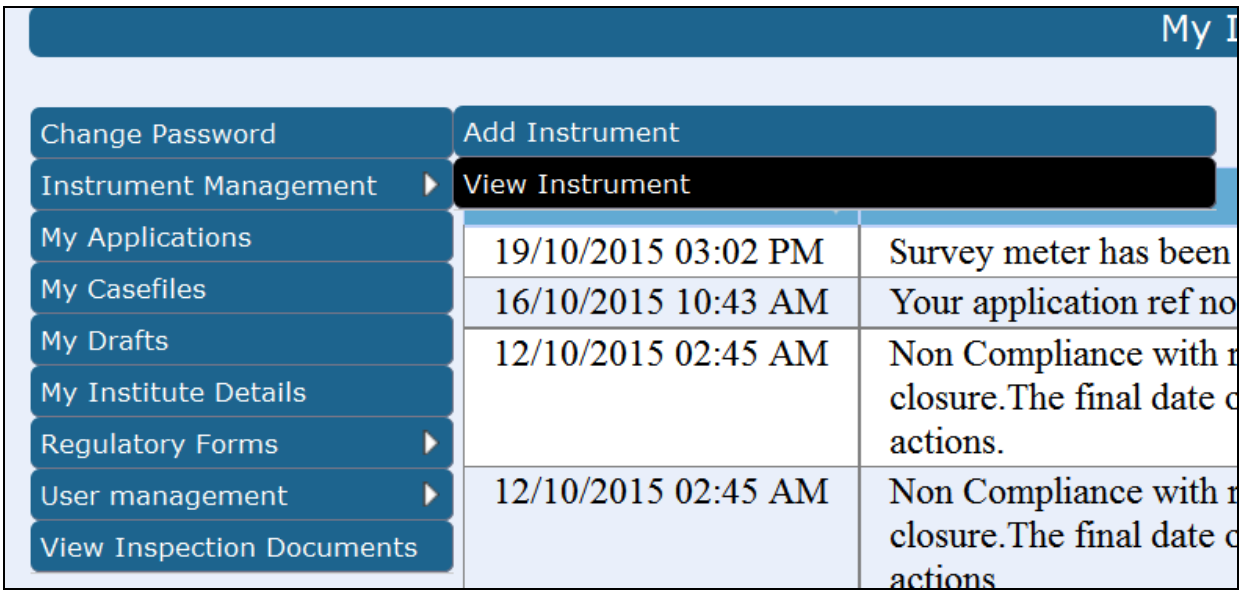
Important Note:

1)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 declared in eLORA.

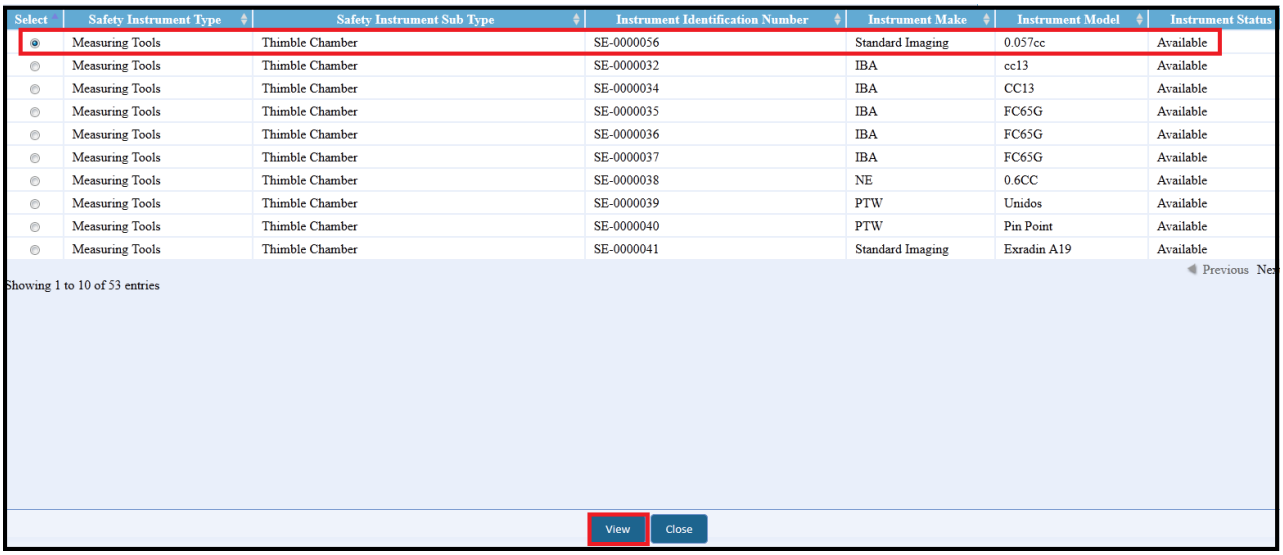
2) Please mention only those applicable measuring/monitoring instruments i.e, thimble chamber, parallel plate chamber, survey meter, well type chamber and electrometer which are having a valid calibration certificate from accredited laboratory. Any other additional instruments or cross calibrated instruments (e.g. used in relative dosimetry) in the institution need not be entered in e-LORA. Please refer AERB circular in this regard available in e-LORA main page.

4.2 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.



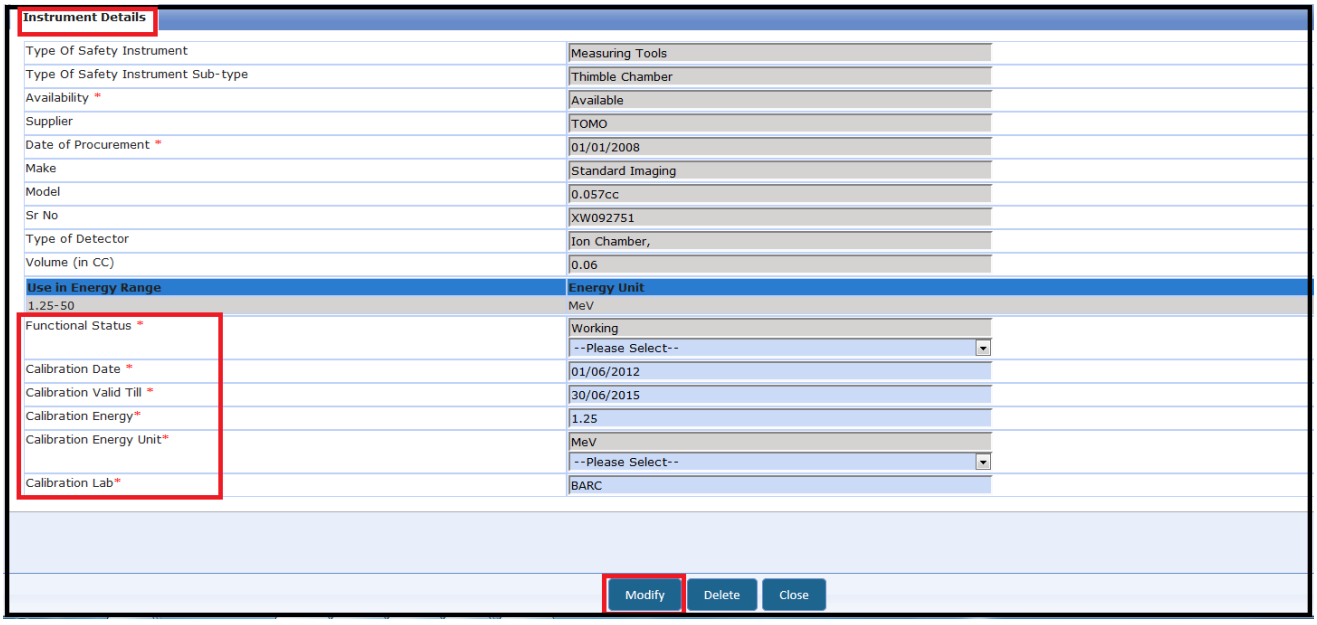
Select	Safety Instrument Type	Safety Instrument Sub Type	Instrument Identification Number	Instrument Make	Instrument Model	Instrument Status
◉	Measuring Tools	Thimble Chamber	SE-0000056	Standard Imaging	0.057cc	Available
○	Measuring Tools	Thimble Chamber	SE-0000032	IBA	cc13	Available
○	Measuring Tools	Thimble Chamber	SE-0000034	IBA	CC13	Available
○	Measuring Tools	Thimble Chamber	SE-0000035	IBA	FC65G	Available
○	Measuring Tools	Thimble Chamber	SE-0000036	IBA	FC65G	Available
○	Measuring Tools	Thimble Chamber	SE-0000037	IBA	FC65G	Available
○	Measuring Tools	Thimble Chamber	SE-0000038	NE	0.6CC	Available
○	Measuring Tools	Thimble Chamber	SE-0000039	PTW	Unidos	Available
○	Measuring Tools	Thimble Chamber	SE-0000040	PTW	Pin Point	Available
○	Measuring Tools	Thimble Chamber	SE-0000041	Standard Imaging	Exradin A19	Available

Previous Ne

Showing 1 to 10 of 53 entries

View Close

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.



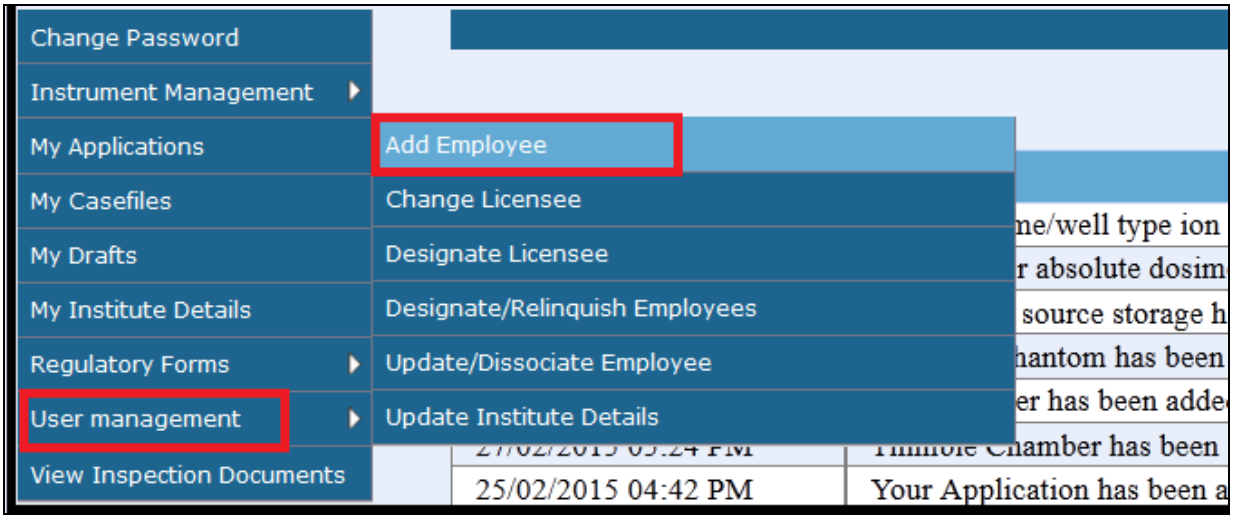
Instrument Details

Type Of Safety Instrument	Measuring Tools
Type Of Safety Instrument Sub-type	Thimble Chamber
Availability *	Available
Supplier	TOMO
Date of Procurement *	01/01/2008
Make	Standard Imaging
Model	0.057cc
Sr No	XW092751
Type of Detector	Ion Chamber,
Volume (in CC)	0.06
Use in Energy Range	**Energy Unit**
1.25-50	MeV
Functional Status *	Working
	--Please Select--
Calibration Date *	01/06/2012
Calibration Valid Till *	30/06/2015
Calibration Energy*	1.25
Calibration Energy Unit*	MeV
	--Please Select--
Calibration Lab*	BARC

Modify Delete Close

5 Declaration of Staff

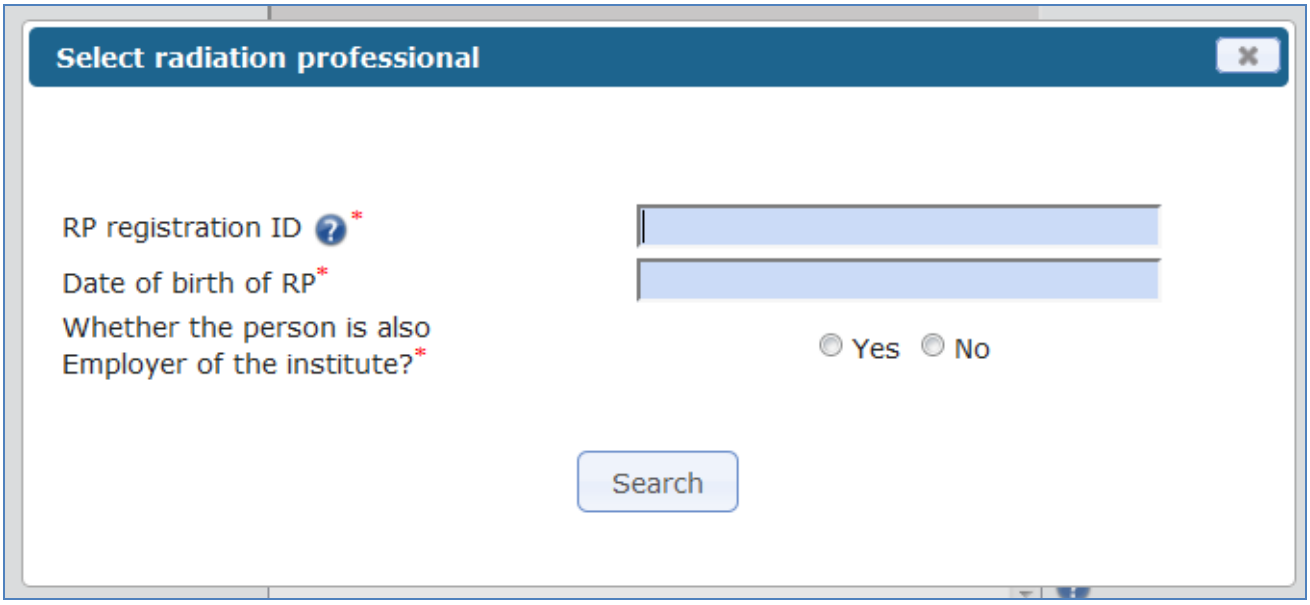
Radiotherapy staff can be added in eLORA account through **Menu: User Management → Add Employee**



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

- **Radiation Worker** (this is to add non-RP radiation workers viz. ward boy, nurse, etc working in radiation area of radiotherapy department. PMS must be provided to such staff as detail of PMS is mandatory for declaring Radiation Worker)
- **Non Radiation Worker** (this is to add employee to be nominated as Licensee who is not a radiation worker)
- **Radiation Professional** (this is to add **Radiation Professionals (RP)** of Radiotherapy viz. Radiation Oncologist, Medical Physicist, Radiotherapy Technologist and Radiotherapy Safety Professional)

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,**

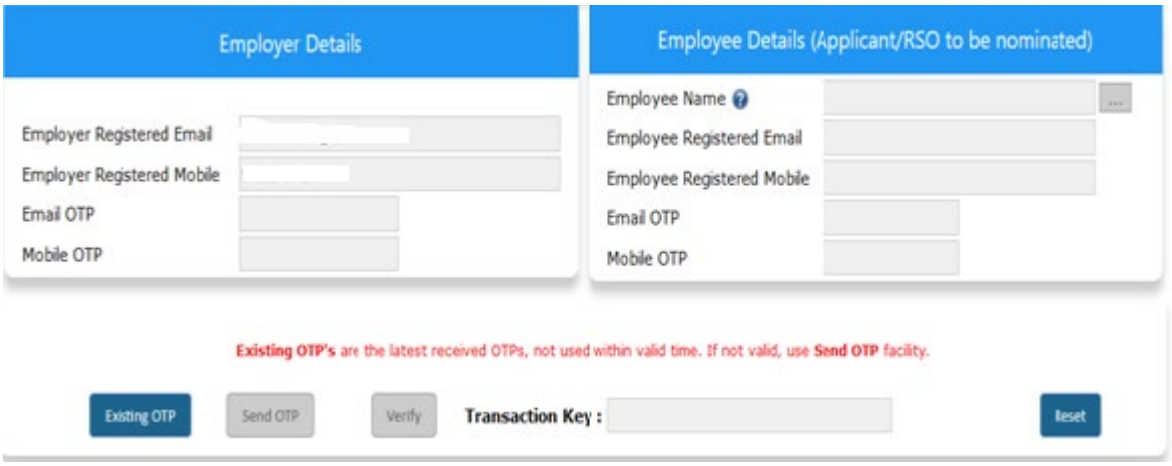
- Enter **Registration ID** and Date of birth of RP –personal detail of RP will come automatically.

- 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, Provide Email (O)
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**

To upload "Attachment for uploading copy of Joining/Confirmation*",you can attach a Scanned copy of the Joining/confirmation letter of the added staff or a letter signed by the appropriate authority of the facility mentioning the Name and Designation of all existing staff members working in the Radiotherapy Department.

6 Transaction key

As per the current regulatory requirement wherein two party authentication required for submission of certain types of applications by using transaction key. Below is the transaction key screen shot:



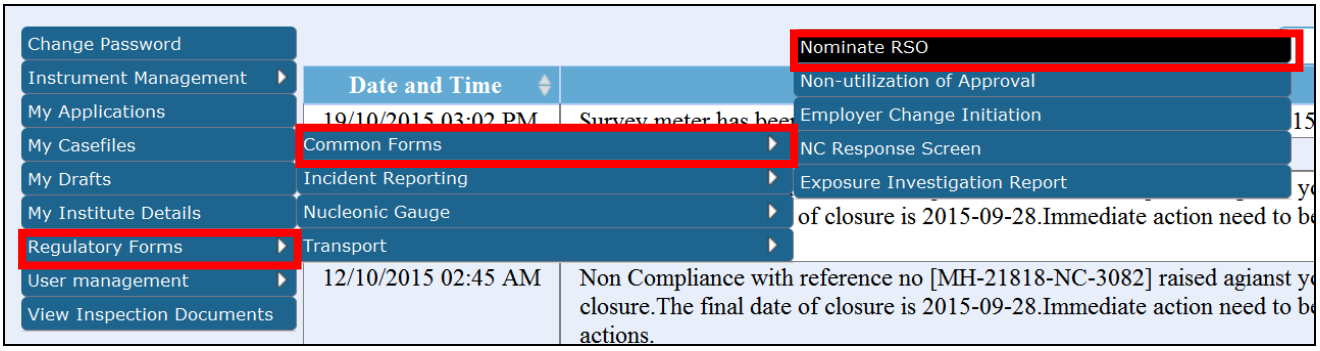
The transaction key generation option is available in employer login. Left side block displayed above shows Employer e-mail id and mobile number by default. Right side block displayed in the transaction key screen will contain only that Employee who will be the applicant (Employer or Licensee) of the application or the person whose name is to be nominated as RSO.

Prior to generation of transaction key, you need to verify e-mail id and mobile number of the employees. The email ID and mobile of employer & licensee can be verified using the respective log-in. The mobile number & email of the person to be nominated as RSO can be verified using the person's Radiation Professional (RP) registration login. The email ID and mobile are verified using the One Time Password (OTP). You need to follow all the procedure mentioned in e-LORA for generating the transaction key.

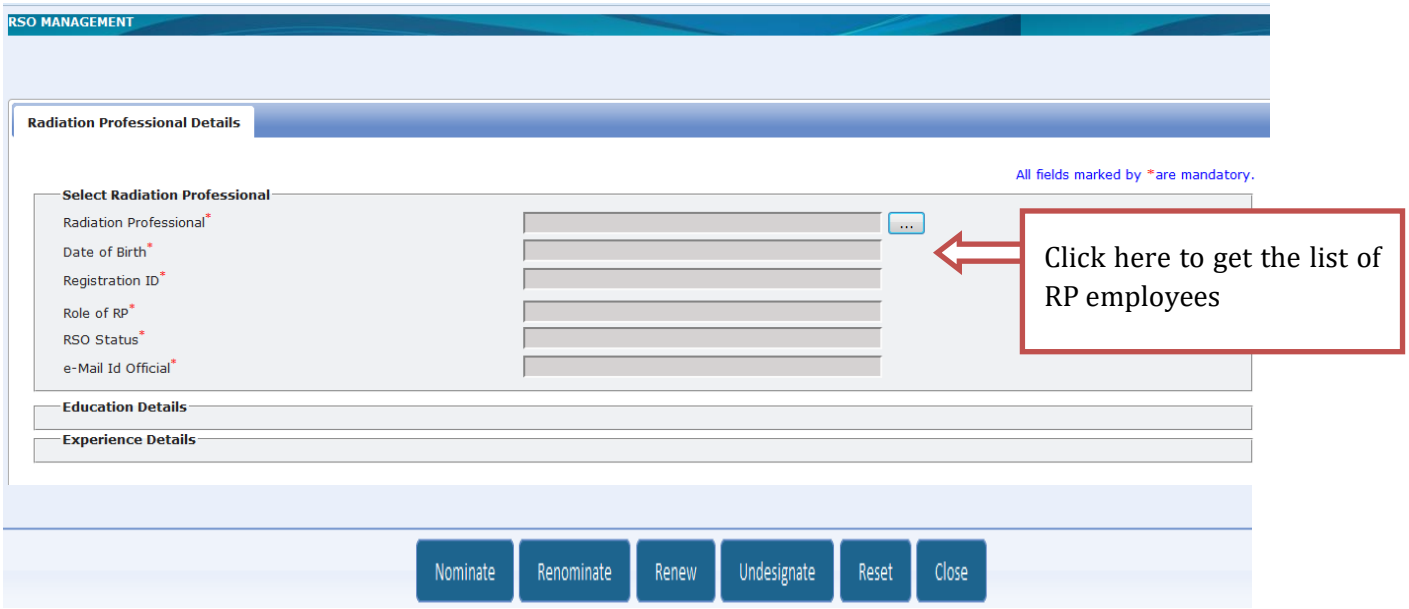
7 Obtaining RSO approval

Radiological Safety Officer (RSO) approval process can be initiated by Employer.

Use **Menu: Regulatory form → Common Forms → Nominate RSO** to access RSO nomination form

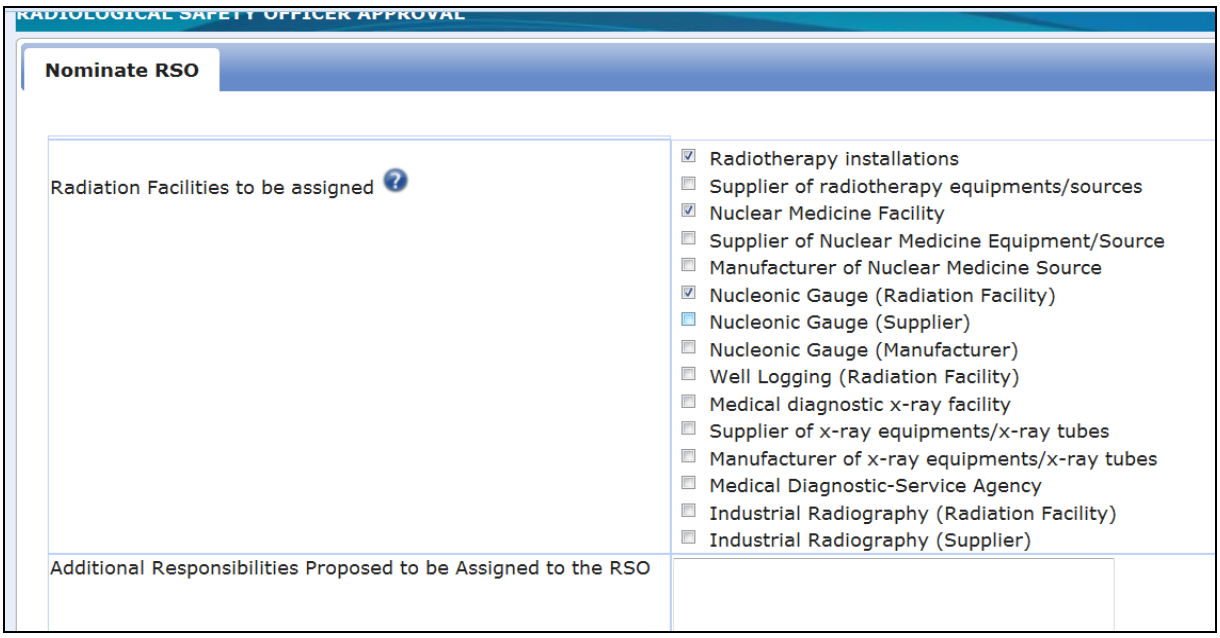


On clicking 'Nominate RSO' the following form will appear



7.1 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 Radiation Professional to be nominated for RSO. The details of the selected RP employee will be populated automatically in the rest of the fields. Click on the button "Nominate". The following screen will appear:

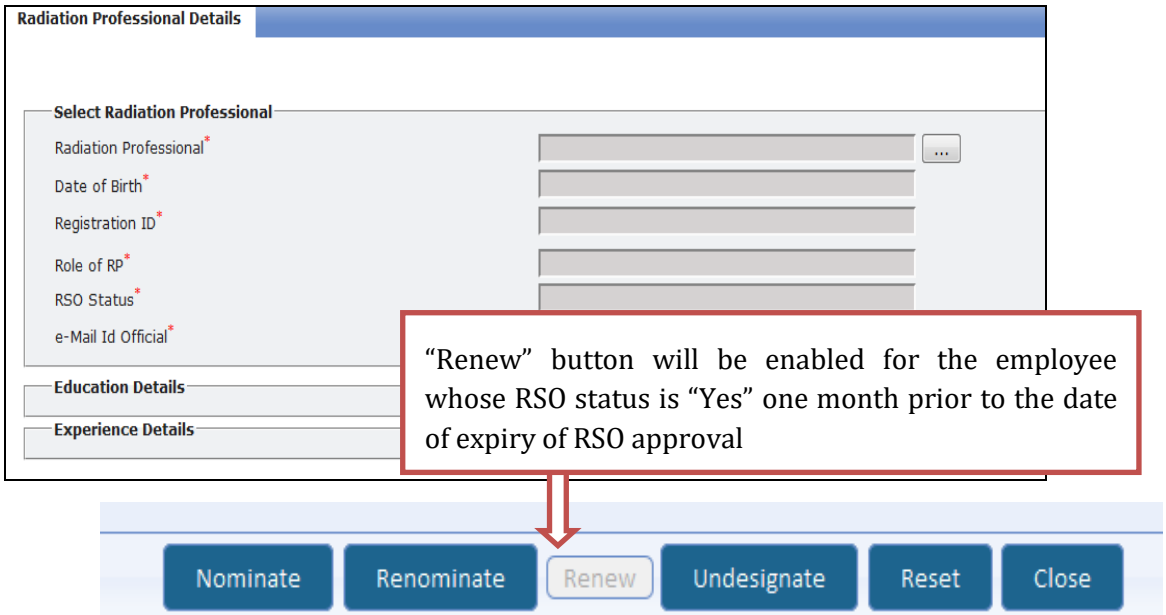


Select the appropriate radiation facilities for which the candidate is to be nominated (as shown above).

After successful submission of form as per the standard procedure of eLORA (Please refer 'General Guidelines to use eLORA System', available in eLORA Help menu), the form will be scrutinized by AERB. After approval of the RSO Nomination, Employer and approved RSO will receive intimation email. A copy of the approval letter will also be emailed to RSO's email Id (O).

7.2 RSO renewal (renewal on expiry of RSO approval)

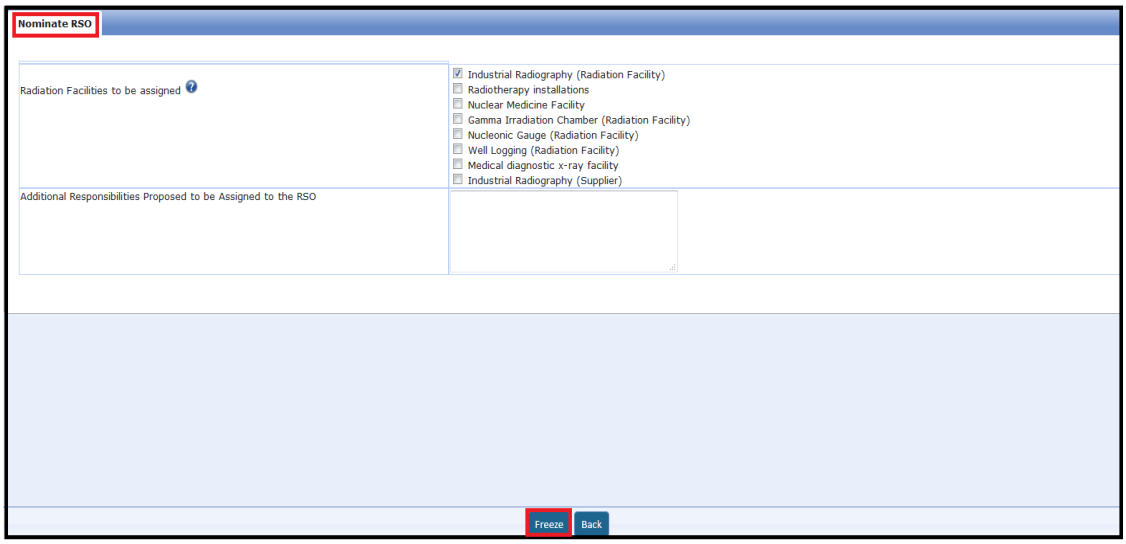
Renewal of RSO can be initiated by employer of the facility. From the employee list, only such employee can be selected whose RSO status is "Yes".



On clicking on 'renew' button, the application form is generated which needs to be freezed and submitted as per the standard procedure of eLORA i.e. Freeze → Upload Signed PDF → Submit. (Please refer 'General Guidelines to use eLORA System', available in eLORA Help menu).

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

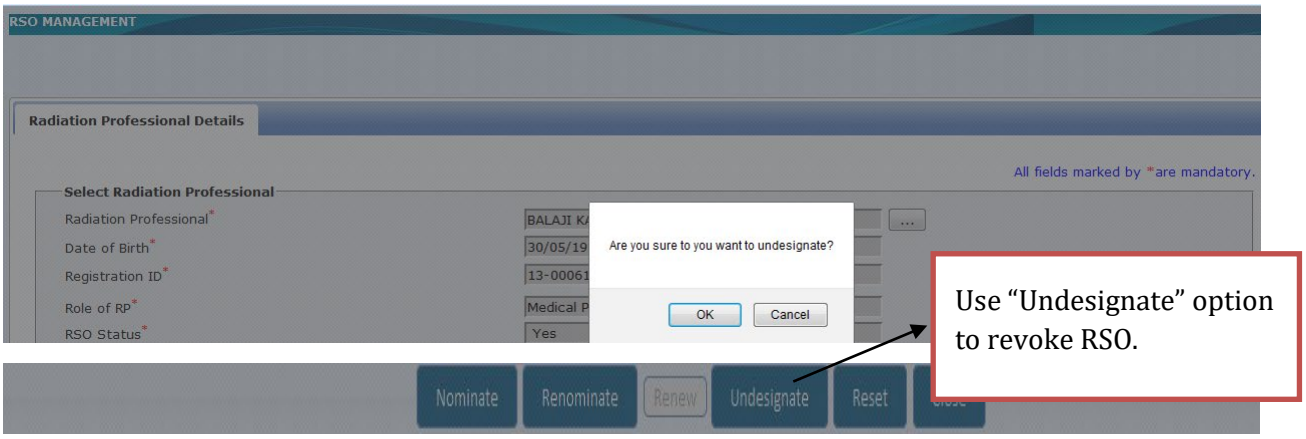
Only approved RSOs of the institution can be renominated for addition/removal of radiation facilities for which the RSO will be responsible. Renomination button will be deactivated for the employee whose RSO status is "Yes" one month before expiry of RSO approval validity.



Click on 'freeze' button and submit the form as per standard procedure of eLORA (Please refer 'General Guidelines to use eLORA System', available in eLORA Help menu).

7.4 RSO Undesignate (to remove 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.



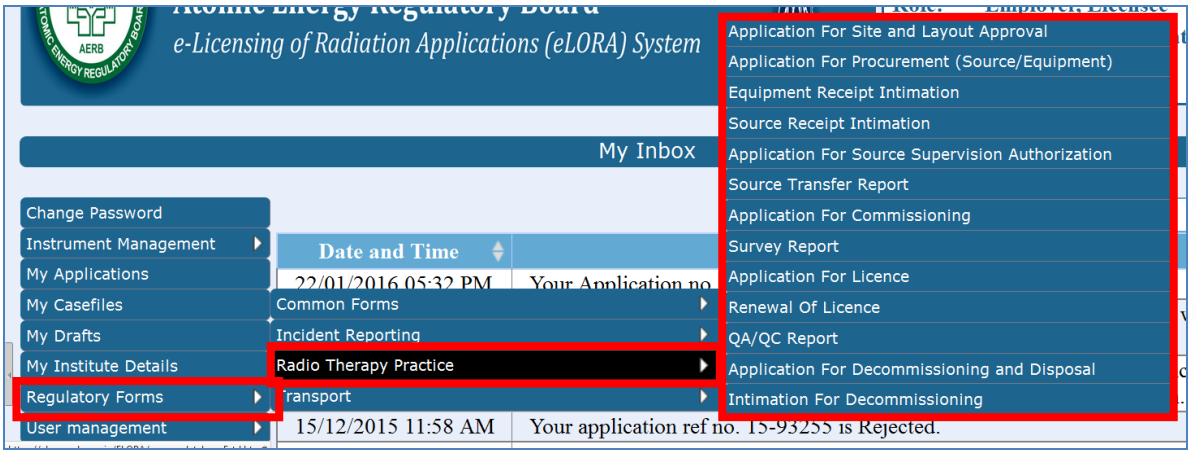
In the "View employee list", the status of RSO will be indicated as "No".

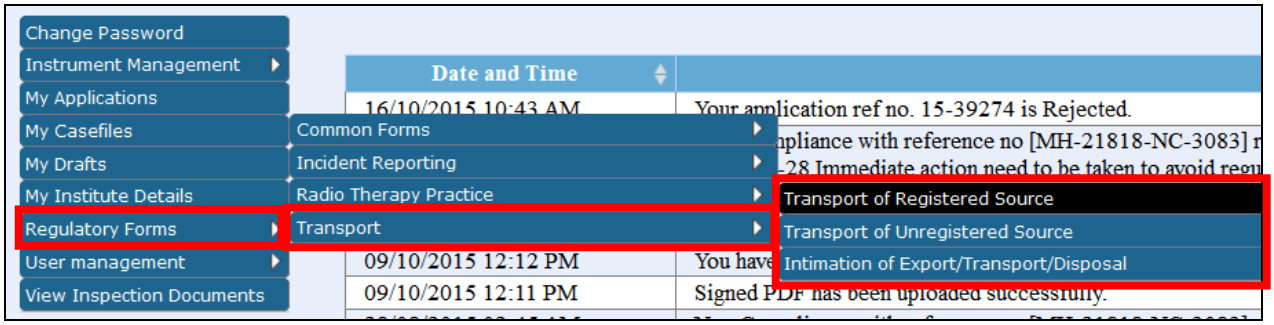
Relinquishing RSO from Institute
Important Note: In case the RSO is leaving the Institute, the employer has to "Undesignate" the

RSO first 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”.

8 Steps involved in obtaining various regulatory clearances

Forms pertaining to regulatory consenting process of Radiotherapy are available in **Menu: Regulatory Forms → Radiotherapy** and **Menu: Regulatory Forms → Transport.**





List of processes applicable to each type of installation is given below:

8.1 Regulatory processes for Telecobalt and Gamma Knife installation

Steps	Purpose	Regulatory Form Name
First time Licence		

Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of equipment (equipment without source)	Application for Procurement (Equipment/Source)
Step 4.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 5.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 6.	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization
Step 7.	Intimating receipt of radioactive source	Source Receipt Intimation
Step 8.	For providing detail of source transfer operation	Source Transfer Report
Step 9.	Obtaining commissioning approval of equipment (i.e. prior permission for switching ON beam)	Application for Commissioning
Step 10.	Submission of radiation survey levels measured around the installation	Survey Report
Step 11.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Re-procurement of Source		
Step 1.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 2.	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization
Step 3.	Intimating receipt of radioactive source	Source Receipt Intimation
Step 4.	For providing detail of source transfer operation	Source Transfer Report
Step 5.	For resumption of operation after source replacement	Form is not yet developed in eLORA. Please submit paper application: AERB/RSD/RT/COM and AERB/RSD/RT/UT-COM along with radiation survey and QA report. The above forms in PDF are available on AERB website.
Decommissioning and Disposal		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization
Step 3.	Obtaining transport permission of disused radioactive source	Transport of Registered Source
Step 4.	For providing detail of source transfer operation	Source Transfer Report
Step 5.	Intimating disposal of radioactive source	Intimation of Export/Transport/Disposal
Step 6.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.2 Regulatory processes for Linear Accelerator including Tomotherapy and Cyber Knife installation

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of equipment	Application for Procurement (Equipment/Source)
Step 4.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 5.	Obtaining commissioning approval of equipment (i.e. prior permission for switching ON beam)	Application for Commissioning
Step 6.	Submission of radiation survey levels measured around the installation	Survey Report
Step 7.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Decommissioning		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Obtaining transport permission of Depleted Uranium (DU), if applicable	Transport of Un-registered Source
Step 3.	Intimating disposal of Depleted Uranium (DU), if applicable	Intimation of Export/Transport/Disposal
Step 4.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.3 Regulatory processes for Remote After Loading Brachytherapy installation (HDR/LDR/PDR/MDR)

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of equipment (equipment without source)	Application for Procurement (Equipment/Source)
Step 4.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 5.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 6.	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization
Step 7.	Intimating receipt of radioactive source	Source Receipt Intimation
Step 8.	For providing detail of source transfer operation	Source Transfer Report
Step 9.	Obtaining commissioning approval of equipment	Application for Commissioning
Step 10.	Submission of radiation survey levels	Survey Report

	measured around the installation	
Step 11.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Disposal of Disused Radioactive Source		
Step 2.	Obtaining transport permission of disused radioactive source	Transport of Registered Source
Step 3.	Intimating disposal of radioactive source	Intimation of Export/Transport/Disposal
Re-procurement of Source		
Step 1.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 2.	Intimating receipt of radioactive source	Source Receipt Intimation
Decommissioning and Disposal		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Obtaining transport permission of disused radioactive source	Transport of Registered Source
Step 3.	Intimating disposal of radioactive source	Intimation of Export/Transport/Disposal
Step 4.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.4 Regulatory processes for Manual After loading Brachytherapy installation

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 4.	Intimating receipt of radioactive source	Source Receipt Intimation
Step 5.	Submission of radiation survey levels measured around the installation	Survey Report
Step 6.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Re-procurement of Source		
Step 1.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 2.	Intimating receipt of radioactive source	Source Receipt Intimation
Disposal		
Step 1.	Obtaining consent for disposal	Application for Decommissioning and Disposal
Step 2.	Obtaining transport permission of disused radioactive source	Transport of Registered Source

Step 3.	Intimating disposal of radioactive source	Intimation of Export/Transport/Disposal

Important Note: Guidelines for deployment of radioactive seed sources for ocular brachytherapy Available in "Help Menu" of eLORA account. Users are also advised to refer these guidelines.

8.5 Regulatory processes for Simulator and CT Simulator installation

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of equipment	Application for Procurement (Equipment/Source)
Step 4.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 5.	Obtaining commissioning approval of equipment (i.e. approval for beam ON)	Application for Commissioning
Step 6.	Submission of radiation survey levels measured around the installation	Survey Report
Step 7.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Decommissioning		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.6 Regulatory processes for kV Imaging system

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining RSO approval	Nominate RSO
Step 2.	Obtaining procurement permission of equipment	Application for Procurement (Equipment/Source)
Step 3.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 4.	Obtaining commissioning approval of equipment (i.e. prior permission for switching ON beam)	Application for Commissioning
Step 5.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Decommissioning		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.7 Regulatory processes for IORT installation

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining site and layout approval	Application for Site and Layout Approval
Step 2.	Obtaining RSO approval	Nominate RSO
Step 3.	Obtaining procurement permission of equipment	Application for Procurement (Equipment/Source)
Step 4.	Intimating receipt of equipment	Equipment Receipt Intimation
Step 5.	Obtaining commissioning approval of equipment (i.e. prior permission for switching ON beam)	Application for Commissioning
Step 6.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Decommissioning		
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal
Step 2.	Intimating decommissioning of equipment	Intimation for Decommissioning

8.8 Regulatory processes for Check Source

Steps	Purpose	Regulatory Form Name
First time Licence		
Step 1.	Obtaining RSO approval	Nominate RSO
Step 2.	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)
Step 3.	Intimating receipt of radioactive source	Source Receipt Intimation
Step 4.	Obtaining licence for operation of equipment	Application for Licence
Renewal of Licence		
Step 1.	Renewal of existing Licence	Renewal of Licence
Disposal		
Step 1.	Obtaining consent for disposal	Application for Decommissioning and Disposal
Step 2.	Obtaining transport permission of disused radioactive source	Transport of Registered Source
Step 3.	Intimating disposal of radioactive source	Intimation of Export/Transport/Disposal

9 Detail of Regulatory Forms

In order to obtain requisite regulatory clearance from AERB, user need to fill and submit application form in eLORA. Detail of Radiation Professionals employees (viz. their availability, PMS no. etc.)and Instruments (viz. availability, date of calibration) shown in certain application forms must be verified by user before submission of application form. In case update is required in employee and instrument details, user should update the details before submission of application form. All statements made in the application form are considered correct and best of the knowledge and belief of applicant.

9.1 Application for Site and Layout Approval

Submit this form for obtaining site and layout approval. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Application for site and layout approval

- Pre-requisite for site and layout:
  - Institute Registered in eLORA

Important Note: Guidelines for preparation of Radiotherapy Site and Layout plan drawings available in HELP menu of eLORA. Prepare the plan drawings in accordance with the guidelines.

9.2 Application for Procurement of (Equipment/Source)

Submit this form for obtaining procurement permission for equipment and source. Equipment permission must be obtained first before applying for source procurement permission.

Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Application for Procurement (source/ equipment)

- Pre-requisite for equipment procurement:
  - Site and layout approval
  - RSO approval
  - Requisite Instruments (as applicable to give type of installation – see Annexure for detail) must be recorded as 'Proposed' (if not procured so far) or 'Available' (if procured) in 'Instrument Management'.
- Pre-requisite for source procurement:
  - Equipment procurement permission (in case of Telecobalt, Gamma Knife and RAL Brachytherapy source)
  - RSO approval
  - Requisite Instruments (as applicable to give type of installation – see Annexure for detail) must be recorded as 'Proposed' (if not procured so far) or 'Available' (if procured) in 'Instrument Management'.
  - Security plan for category-1 & 2 sources should be submitted in eLORA as separately (see box below for submission)

While submitting application form for source procurement, decommissioning plan (In case of the Telecobalt/GammaKnife unit) for safe management of Co-60 source(s) at the end of useful life, shall be submitted along with application. The format of decommissioning plan is available in the "Help Menu" of e-LORA account.

Important Note:1) Accessories used in Linear Accelerator (viz. IMRT, VMAT, RapidArc, MLC, etc.) should be selected in procurement form of the equipment.

2) Application for Security plan, format of which is available in the "Help Menu" of e-LORA account, shall be submitted (Applicable for Telecobalt, GammaKnife and HDR brachytherapy unit). To access this form **Regulatory Form → Common forms→Application for Security plan**

9.3 Equipment Receipt Intimation

Submit this form after receipt of equipment. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→Equipment Receipt Intimation

- Pre-requisite for equipment receipt intimation:
  - Procurement permission for equipment

Important Note: This form captures details of equipment received against procurement permission. In this step user can selected the energies of equipment which has been received by them. For linear accelerators, energies selected in this stage will be available for further regulatory processes like commissioning, survey and license. Hence, submit this form after verification with the procurement permission, to avoid any mismatch of details during later regulatory stages.

9.4 Source Receipt Intimation

Submit this form after receipt of radioactive source. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→Source Receipt Intimation

- Pre-requisite for source receipt intimation:
  - Procurement permission for source

Important Note: This form captures details of radioactive source received against procurement permission. In this step user can mention activity of radioactive source which has been received by them. The data provided in this stage will be carry forwarded for further regulatory processes like commissioning, survey, license, etc. Hence, submit this form after verification with the procurement permission, to avoid any mismatch of details during later regulatory stages.

9.5 Source Supervision Authorization

This form is applicable for each source loading/unloading in Telecobalt and Gamma Knife equipment and first time source loading in RAL Brachytherapy equipment. The user institute needs to submit this application 15 days before the tentative date of source transfer. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Application for source supervision authorization

- Pre-requisite for source supervision authorisation:
  - Availability of Medical Physicist
  - Equipment Receipt Intimation

Important Note: In cases, Medical Physicist of the user institution never involved in source transfer operation, the user institute can seek assistance of Medical Physicist (who has experience in source transfer operation) from any other institute during source transfer operation. In such case, it is mandatory to submit as an attachment, the letter of consent of the assisting Medical Physicist endorsed by his/her employer.

9.6 Source Transfer Report

This form is applicable for each source loading/unloading in Telecobalt and Gamma Knife equipment and first time source loading in RAL Brachytherapy equipment. Submit this form to provide detail of source transfer operation viz. date of source loading, detail of service engineer, detail of persons involved and dose recorded in their pocket dosimeter. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Source Transfer Report

- Pre-requisite for source transfer report:
  - Equipment Receipt Intimation
  - Source Receipt Intimation
  - Source Supervision Authorisation

9.7 Application for Commissioning

Submit this form for obtaining commissioning approval. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Application for Commissioning

- Pre-requisite for Commissioning Approval:
  - RSO Approval
  - Availability of adequate no. of Radiation Oncologist, Medical Physicist and Radiotherapy Technologist
  - Availability of requisite Instruments with valid calibration (as applicable to give type of installation – for detail see: Annexure A: List of Requisite Instruments).
  - Emergency preparedness and response plan (see box below for submission)

  While submitting application form for commissioning, scan copy of an undertaking regarding construction of Radiotherapy facility shall be submitted along with application. The format of undertaking is provided inAnnexure D: Undertaking to be submitted along with application for commissioning.

Important Note
1) Only after obtaining Commissioning Approval from AERB, user shall energize the equipment to carry out radiation survey. 1)Emergency preparedness and response plan, format of which is available in the "Help Menu" of e-LORA account, shall be submitted through "Adhoc application" separately in e-LORA.To access this form **Regulatory Form →Radiotherapy Practice→Adhoc application**

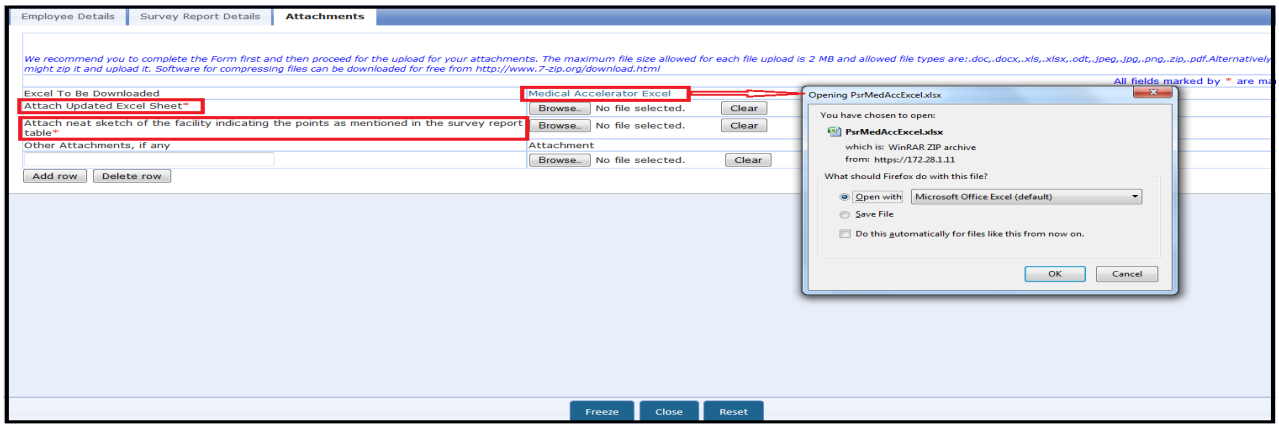
9.8 Survey Report

Submit this form to provide radiation survey report of installation. Follow below path to access this form:

Menu: Regulatory Form→ Radiotherapy Practice→ Survey report

- Pre-requisite for survey report:
  - RSO Approval
  - Commissioning Approval

In the 'Attachment' tab of Survey report form, template for survey report in excel file is available for download. User need to download and save this excel file. This excel file needs to filled up with the requisite measured data and then uploaded through the same tab. It is advised to download this excel file prior to conduct radiation survey. A neat sketch of the facility (showing the points of measurement and occupancy around the installation) also needs to uploaded in **Other Attachment** section. Upload scan copy of Neutron Survey meter calibration certificate in **Other Attachment** section, in case of neutron survey.



9.9 Application for Licence

Submit this application for obtaining Licence. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→Application for License

- Pre-requisite for Licence:
  - RSO Approval
  - Availability of adequate no. of Radiation Oncologist, Medical Physicist and Radiotherapy Technologist
  - Availability of requisite Instruments with valid calibration (as applicable for given type of installation – see Annexure A: List of Requisite Instruments).
  - Compliance to QA standards
  - Emergency preparedness and response plan
  - Security plan for category-1 & 2 sources
  - Decommissioning plan for safe management of disused Co-60 source(s) (In case of the Telecobalt/GammaKnife unit)

In the 'Attachment' tab of Application for Licence form, template for 'QA Specification Sheet' in excel file is available for download. Thisexcel sheet needs to filled up with the requisite measured data and then uploaded through the same tab. It is advised to download this excel file in advance.

9.10 Renewal of Licence

Each licence has validity of 5 years. Licence shall be renewed before its expiry. The Renewal of Licence form is enable for submission 59 days before the date of expiry of Licence.

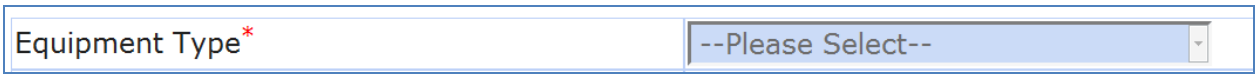
Follow the below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→Renewal of Licence

- Pre-requisite for Licence renewal:
  - RSO Approval
  - Availability of adequate no. of Radiation Oncologist, Medical Physicist and Radiotherapy Technologist
  - Availability of requisite Instruments with valid calibration (as applicable for given type of installation – see Annexure A: List of Requisite Instruments).
  - Compliance to QA requirements

- Compliance to Radiation protection survey
- Submission of periodic safety status report
- Submission of Emergency preparedness and response plan and security plan

Verify the detail of employees and instruments before submission of this form. In case, employee detail and instrument detail is not up to date, update these details. Select 'Equipment Type' from drop down. **Logged-in user can see only those equipment/sources for which he/she is Licensee.**



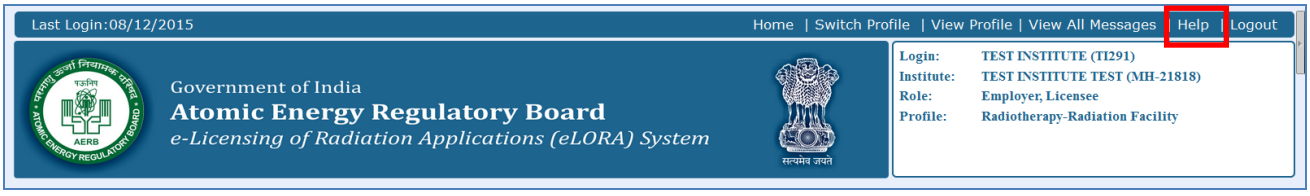
A. Provide compliance status on QA/QC report and radiation protection survey:

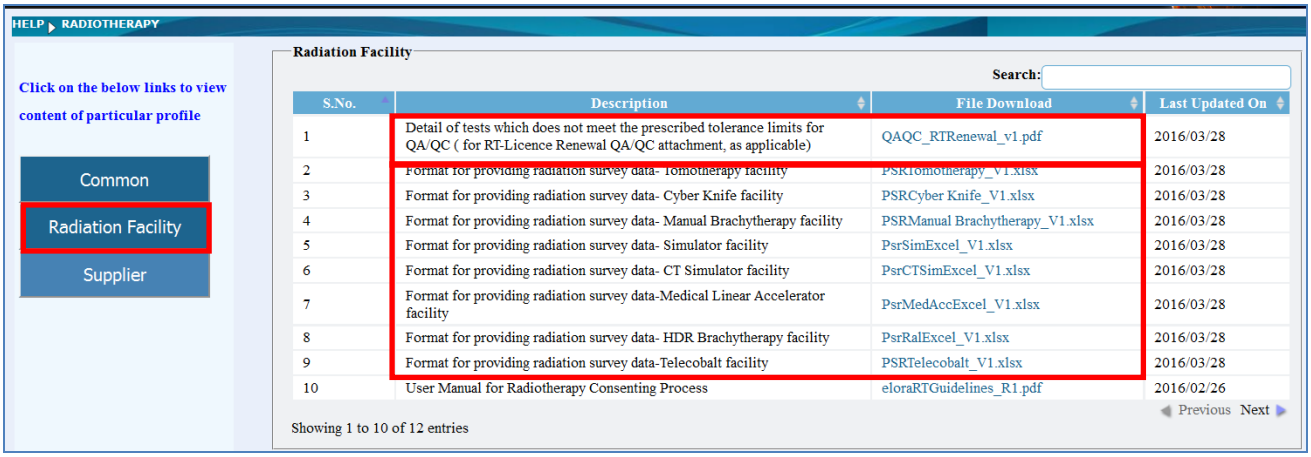
QA/QC report*	QA/QC has been carried out for the equipment/source /installation selected above and the result found satisfactory/within acceptable tolerance limit. QA/QC has been carried out for the equipment/source /installation selected above and the result found not satisfactory/ not within acceptable tolerance limit.
Radiation protection survey*	Radiation protection survey has been carried out for the equipment/source/installation selected above and the result found satisfactory/within acceptable tolerance limit. Radiation protection survey has been carried out for the equipment/source/installation selected above and the result found not satisfactory/ not within acceptable tolerance limit.

Select the compliance status of QA/QC and Radiation protection survey

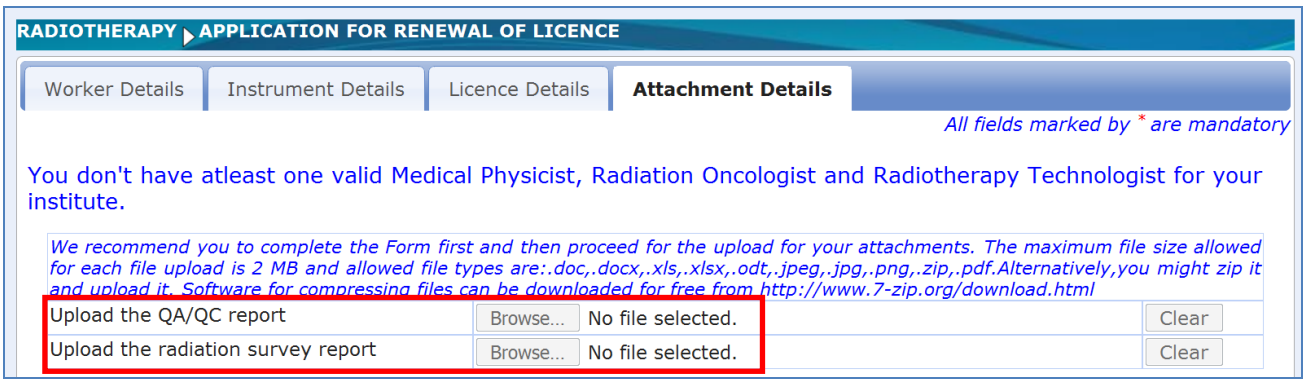
1. In case, QA/QC result found **not satisfactory or not within acceptable tolerance limit**, provide **detail of tests which does not meet the prescribed tolerance limits for QA/QC**(in a format provided in Help Menu) as an attachment of application form.
2. In case, Radiation protection survey found **not satisfactory or not within acceptable tolerance limit**, provide **radiation survey data** (in a format provided in Help Menu) as an attachment of application form.

Format to provide **detail of tests which does not meet the prescribed tolerance limits for QA/QC**and **radiation survey data** are available in Help menu→

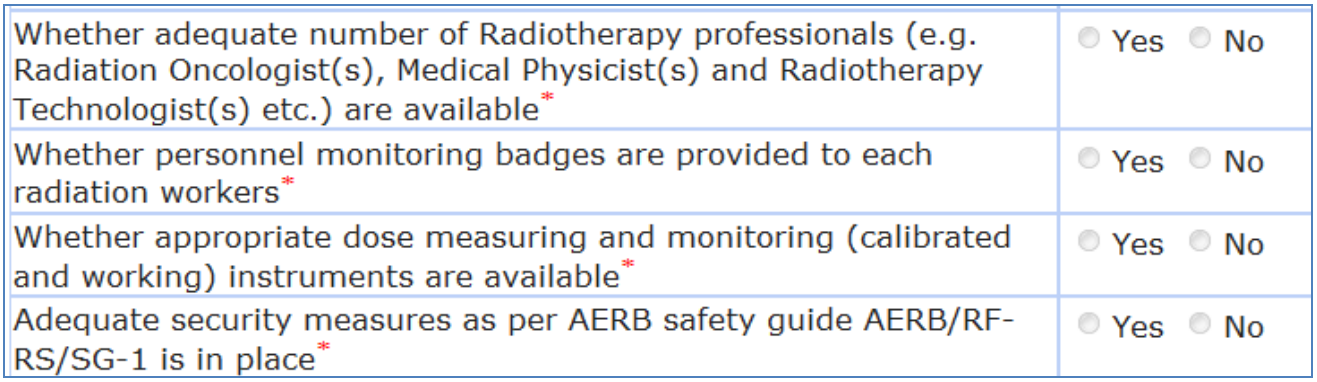




Upload scan copy QA/QC report in option for "Upload the QA/QC report" and radiation survey data (in Excel file) in option for "Upload the radiation survey report" respectively in Tab: "Attachment Details".



B. Provide compliance status on Radiotherapy staff, PMS, measuring and monitoring tools and security measures:



Submit the application form as per the standard procedure of eLORA i.e. Freeze → Upload Signed PDF → Submit.

9.11 Application for Decommissioning and Disposal

Submit this application for obtaining approval for decommissioning and disposal. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice → Application for Decommissioning and Disposal

- Pre-requisite for decommissioning and disposal approval:
    - Acceptance letter from the supplier to carryout decommissioning operation (not applicable for MAL sources)
    - Copy of the concurrence letter from disposal agency for accepting the disused radioactive source.

Important Note: In case of decommissioning of Telecobalt and Gamma Knife equipment, apply for source supervision authorization after obtaining decommissioning approval from AERB. In case of imported sources, the decayed source should be exported back to the country of origin

9.12 Transport of Registered Source

Submit this form for obtaining for obtaining transport permission to transport the radioactive source to disposal agency/export to country of origin. Follow below path to access this form:

Menu: Regulatory Form →Transport→Transport of Registered Source

- Pre-requisite for transport permission
    - Approval for disposal

Important Note: In case of imported sources, the decayed source should be exported back to the country of origin

9.13 Intimation for Decommissioning

Submit this form for intimating decommissioning of installation. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice →Intimation for Decommissioning

- Pre-requisite for intimation for decommissioning
    - Approval for decommissioning

While submitting application for intimation, confirmation of dismantling& decommissioning of the equipment by the involved agency shall be enclosed along with application.

9.14 Intimation of Export/Transport/Disposal

Submit this form for intimating export/transport/disposal of radioactive source. Follow below path to access this form:

Menu: Regulatory Form →Transport→Intimation of Export/Transport/Disposal

- Pre-requisite for intimation
    - Approval for transport

While submitting application for intimation, confirmation of receipt of source by disposal agency shall be enclosed along with application.

10 Re-approval of site and layout plan

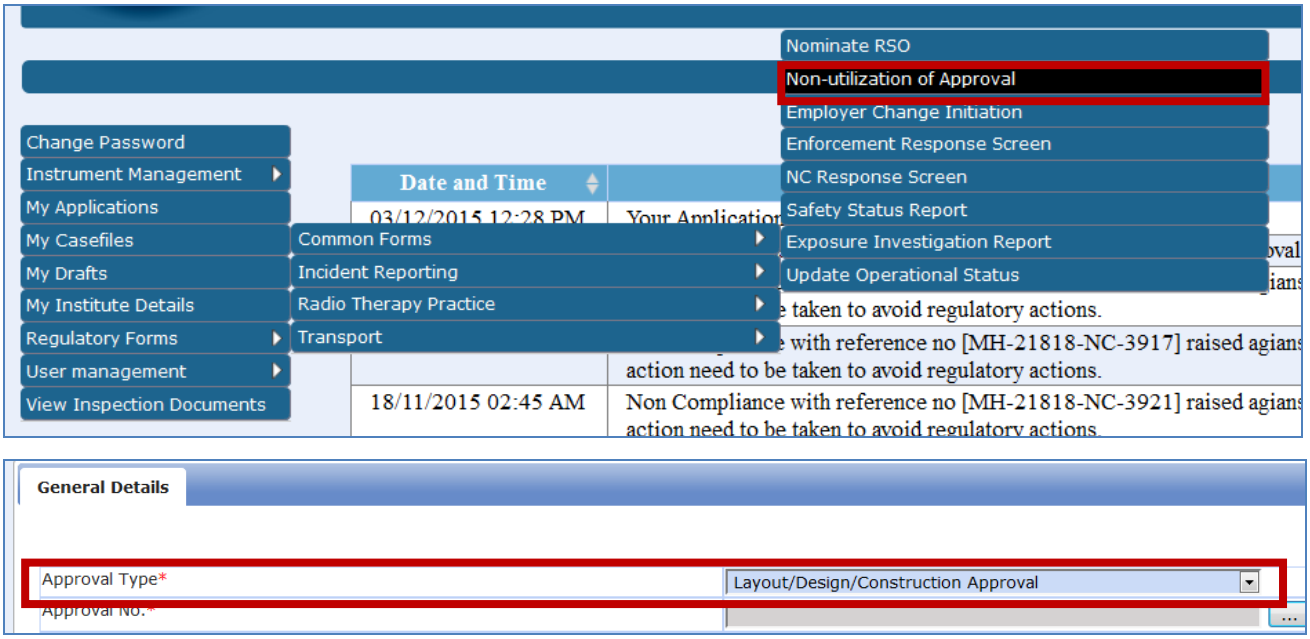
If there is change in Make, Model or any other specification of equipment/installation for which layout plan approval is being already obtained through eLORA, you can obtain re-approval for the same. Please follow the procedure as mentioned below for re-approval of site and layout.

10.1 Submit Non-utilization of Approval form

Submit Non-utilization of already approved site and layout approval using 'Non-utilization of Approval' form. Follow below path to access this form:

Menu: Regulatory Form →Common Forms → Non-utilization of Approval

Select Approval Type as 'Layout/Design/construction Approval' and 'Approval No.' form list of values.



10.2 Submit application for Site and Layout

After obtaining approval to 'Non-utilization of Approval' for the existing site and layout approval, submit fresh application form for site and layout again with for revised Make and Model / other specifications of equipment/installation. Follow below path to access this form:

Menu: Regulatory Form → Radiotherapy Practice→ Application for site and layout approval

Fill the required detail in application form. **If there is no change in the drawings then do not upload the plan again.** Submit undertaking, as per the format given in *Annexure C: Format of undertaking for re-approval of site and layout plan.*

11 Submission of Safety Status Report

It is mandatory for all Radiation Facilities to submit Safety Status Report (SSR) to AERB periodically. For the user's convenience SSR can be submitted anytime during the year in e-LORA. It is advisable to submit the Safety Status Report at a frequency of once in six months by the radiotherapy facility but must be submitted once in a year.

The steps to be followed for Safety Status Report Submission through eLORA are given below:

Step 1. Update Operational Status of sources and equipment (Menu: Regulatory Form → Common Forms → Update Operational Status)

Step 2. Verify and update (if required) Staff Details, Measuring and Monitoring Equipment etc.

Step 3. Download excel sheet from Top Menu: Help→Radiation Facility (Radiotherapy-SSR-~~2015~~.xlsx) and fill it.

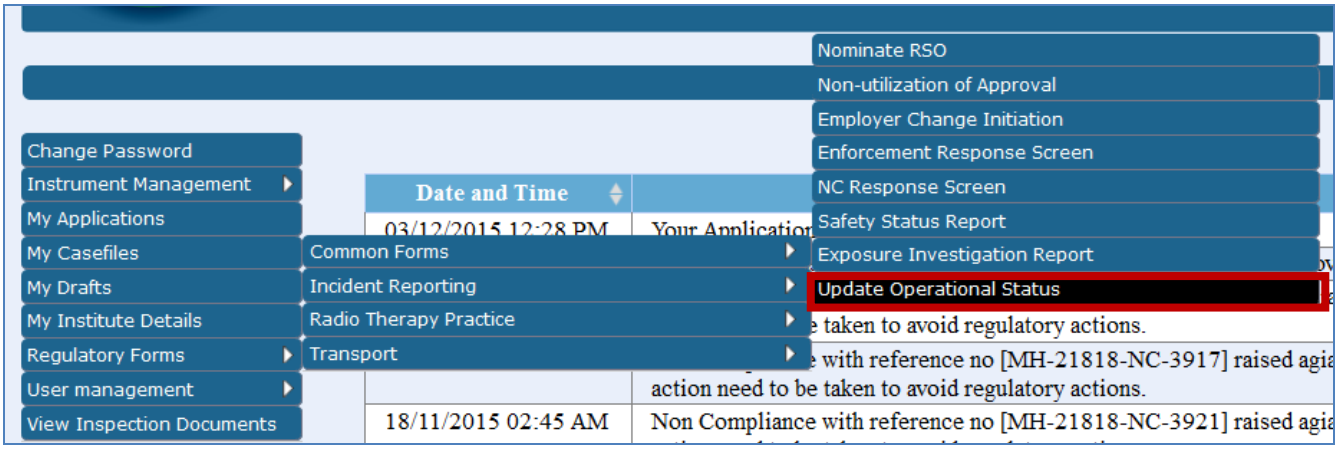
Step 4. If any additional information need to be provided please prepare make ready the file for additional attachment

Step 5. Access Safety Status Report form (Menu: Regulatory Form → Common Forms→ Safety Status Report) and submit.

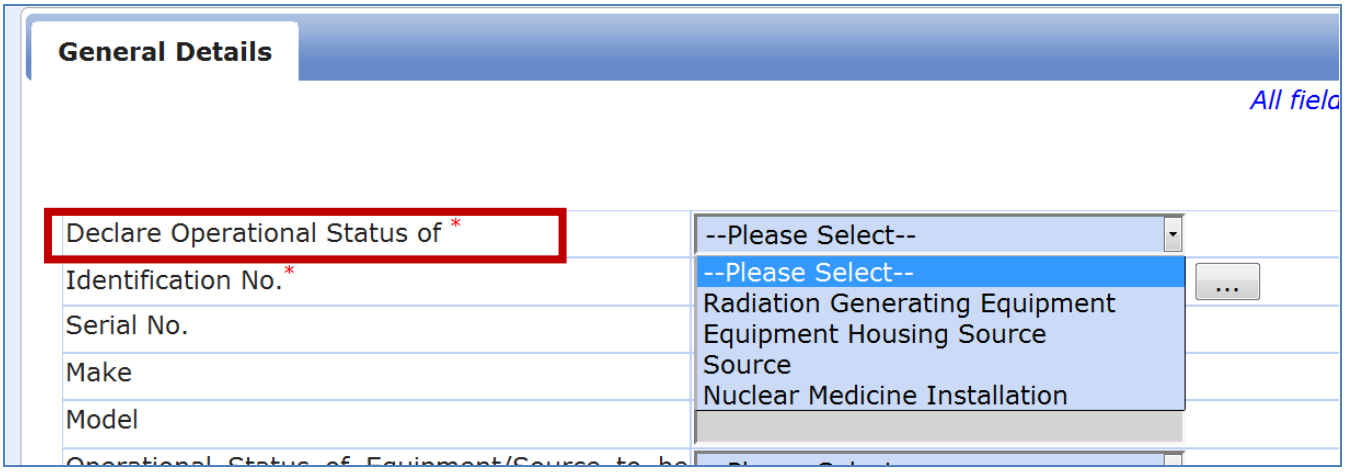
11.1 Update Operational Status of Sources and Equipment

Follow below path to access form to update operational status of each radioactive sources and equipment:

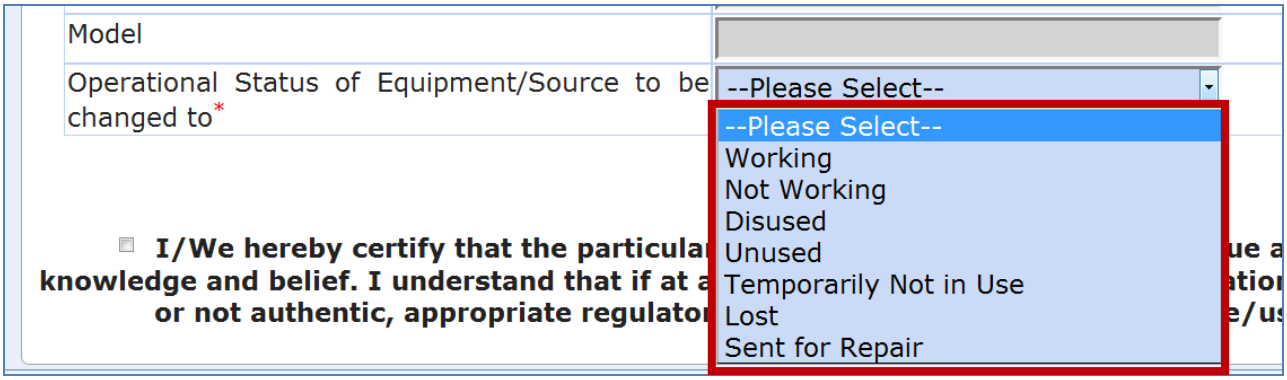
Menu: Regulatory Form → Common Forms → Update Operational Status



Select 'Radiation Generating Equipment' for Linear Accelerator, Simulator, etc., 'Equipment Housing Source' for Telecobalt, HDR, etc. and 'Source' for radioactive source. Then select 'Identification No.' from the list of values. Serial No., Make and Model will be displayed automatically after selection of 'Identification No'.



Select operational status as of Equipment or Source.



The description to use for operational status is given below:

Operational Status	Applicable to	Description
Working	Equipment and Radioactive Sources	If equipment/radioactive source is being used
Not Working	Equipment	If equipment is not working/not being used
Disused	Radioactive Sources	If radioactive source is not being used
Unused	Radioactive Sources	If radioactive source has never been used
Temporarily Not in Use	Equipment and Radioactive Sources	If equipment/source is not being used but intended to be used in near future
Lost	Equipment and Radioactive Sources	If equipment/radioactive source is lost
Sent for Repair	Not applicable for Radiotherapy equipment	-

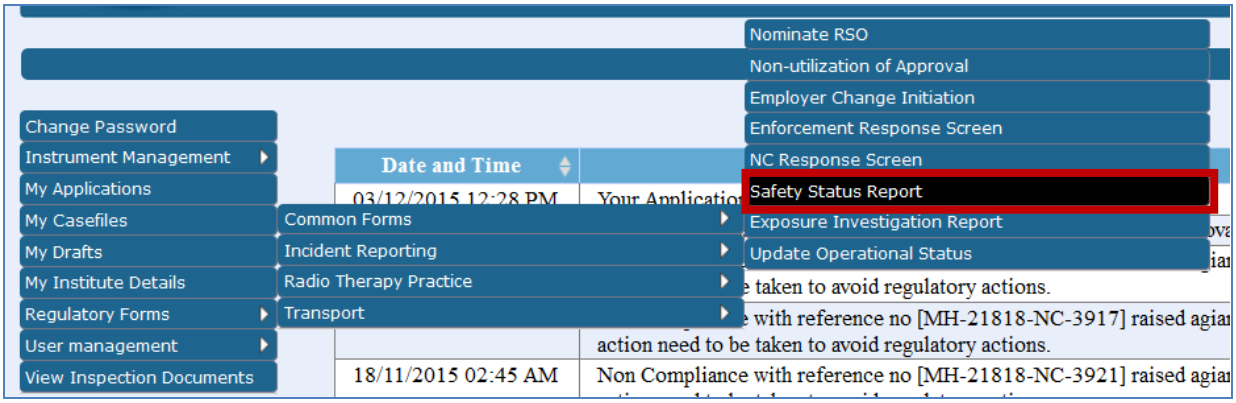
Follow the above procedure to update operational status of each radioactive source, equipment (i.e. radiation generating equipment or equipment housing radioactive source(s)) one-by-one.

11.2 Safety Status Report Form

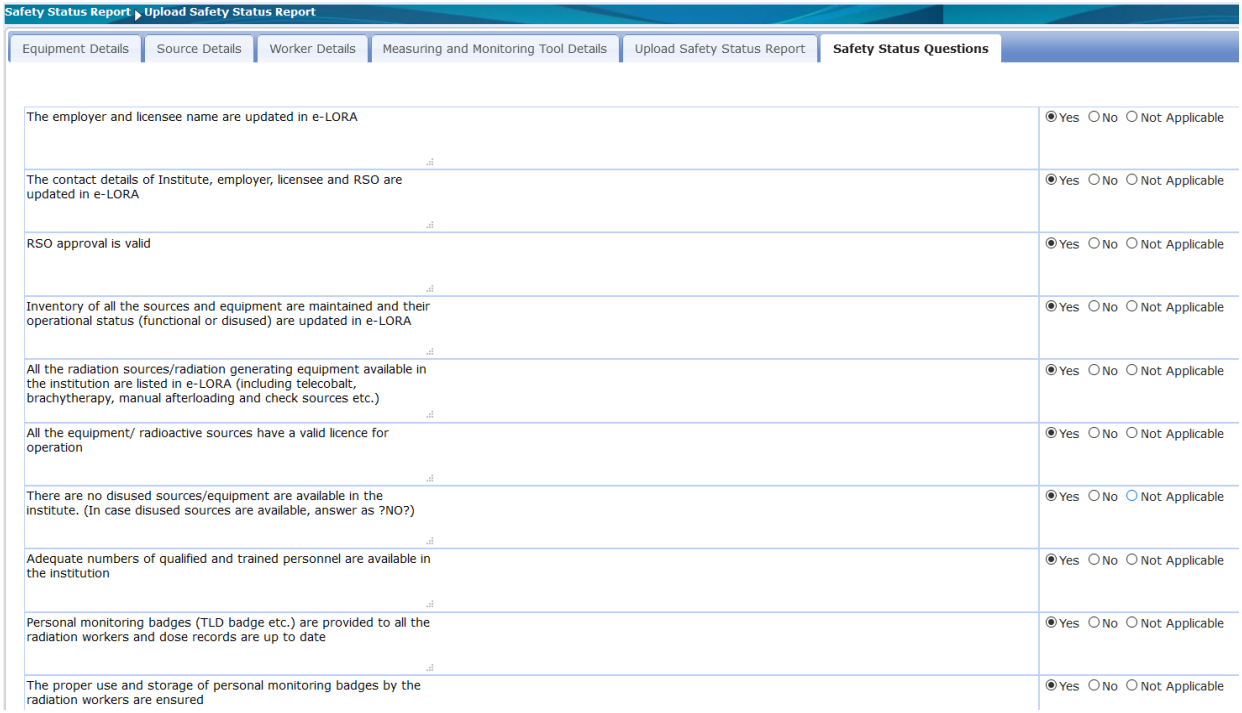
Before submission of safety status report, verify and update (if required) Staff details and Measuring and Monitoring Equipment details. Please refer General Guidelines to use eLORA System (available in eLORA Help menu) to update these details.

Follow the below path to access form for Safety Status Report:

Menu: Regulatory Form → Common Forms → Safety Status Report



The details of equipment, source, worker, measuring & monitoring instruments are displayed in first few tabs. Fill the information as asked in tab: 'safety status questions'.



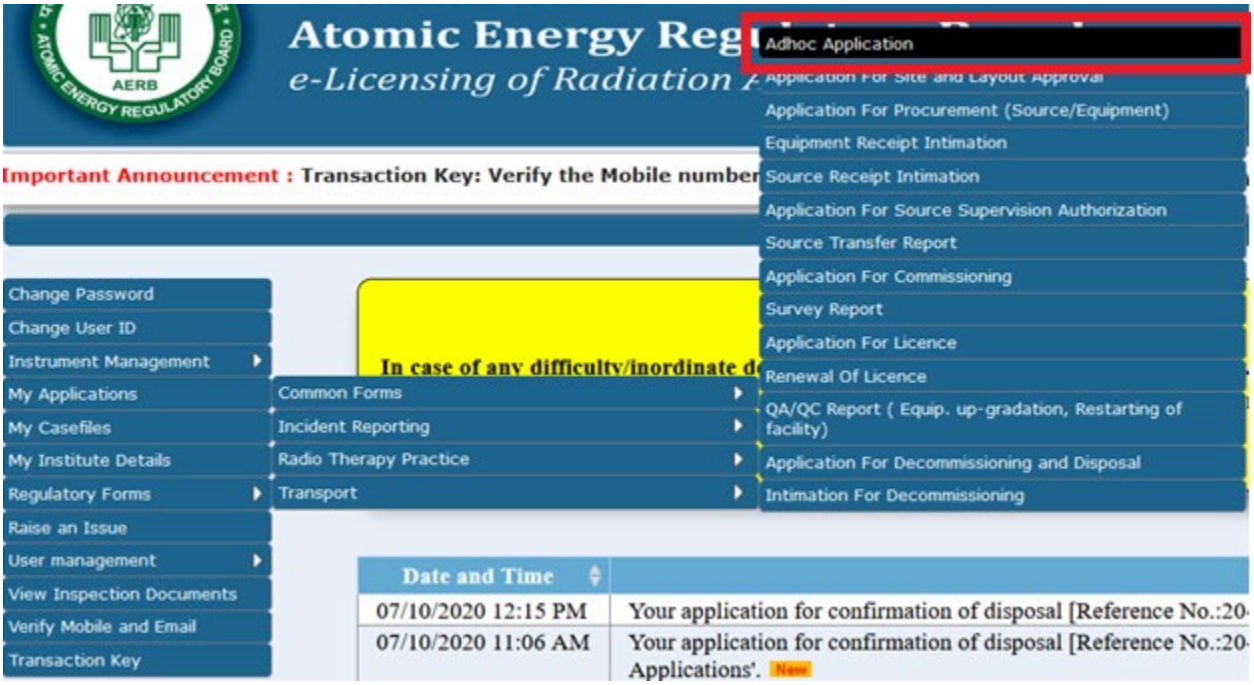
Press 'Submit' for submission of safety status report.

12 Submission of Adhoc application

Adhoc application is to submit such application for which regulatory process does not exist in e-LORA such as medical physics course recognition, radiotherapy technologist course recognition, emergency preparedness plan, resumption of operation of telecobalt after source replacement etc.

Follow below path to access this form:

Menu: Regulatory Form →Radiotherapy practice → Adhoc application


Atomic Energy Reg
e-Licensing of Radiation
Important Announcement : Transaction Key: Verify the Mobile numbe
Change Password
Change User ID
Instrument Management
My Applications
My Casefiles
My Institute Details
Regulatory Forms
Raise an Issue
User management
View Inspection Documents
Verify Mobile and Email
Transaction Key
In case of any difficulty/inordinate d
Common Forms
Incident Reporting
Radio Therapy Practice
Transport
Adhoc Application
Application For Site and Layout Approval
Application For Procurement (Source/Equipment)
Equipment Receipt Intimation
Source Receipt Intimation
Application For Source Supervision Authorization
Source Transfer Report
Application For Commissioning
Survey Report
Application For Licence
Renewal Of Licence
QA/QC Report (Equip. up-gradation, Restarting of facility)
Application For Decommissioning and Disposal
Intimation For Decommissioning
Date and Time
07/10/2020 12:15 PM
Your application for confirmation of disposal [Reference No.:20
07/10/2020 11:06 AM
Your application for confirmation of disposal [Reference No.:20
Applications'.
New

=0=0=0=0=0=

13 Annexure A: List of Requisite Instruments

This gives list of measuring, monitoring, QA and safety tools required to be declared in **Menu: Instrument Management → Add Instrument**

13.1 For Linear Accelerator including Tomotherapy and Cyber Knife

List of Instruments Required to be declared in 'Instrument Management'	
Installation Type: Linear Accelerator including Tomotherapy and Cyber Knife	
Type of Instrument	Instrument Sub Type
Measuring Tools	• Thimble Chamber • Parallel Plate Chamber**(applicable for electron beam)** • Electrometer
Monitoring Tools	• Survey meter**(Ion chamber based)**
QA Tools	• Thermometer • Barometer • RFA Phantom • D20/D10 phantom • Phantom for absolute dosimetry • Phantom for relative dosimetry **(Solid phantom for electron beam) – While declaring this instrument, Please write 'for electron beam' suffix to Model name. Viz. Model XYZ – for electron beam** • Phantom for any specific QA**(for special techniques like 3DCRT/IMRT/IGRT /VMAT/SRS/SRT)** • Therapy verification film**(In absence of EPID)** • QA gadgets**(for special techniques like 3DCRT/IMRT/IGRT /VMAT/SRS/SRT)**
Safety Tools	• Mechanical front pointer(s)

13.2 For Telecobalt and Gamma Knife

List of Instruments Required to be declared in 'Instrument Management'	
Installation Type: Telecobalt and Gamma Knife	
Type of Instrument	Instrument Sub Type
Measuring Tools	• Thimble Chamber • Electrometer
Monitoring Tools	• Survey meter • Gamma zone monitor
QA Tools	• Thermometer • Barometer • Phantom for absolute dosimetry • Therapy verification film • Isodose charts
Safety Tools	• Mechanical front pointer(s) • T-Rod

13.3 For Remote After Loading Brachytherapy (HDR/LDR/PDR/MDR)

List of Instruments Required to be declared in 'Instrument Management'	
Installation Type: Remote After Loading Brachytherapy	
Type of Instrument	Instrument Sub Type
Measuring Tools	• Large volume/well type ion chamber/Dose Calibrator • Thimble Chamber**(as applicable)** • Electrometer
Monitoring Tools	• Survey meter • Gamma zone monitor
QA Tools	• Thermometer • Barometer • Phantom for any specific QA**(if applicable)**
Safety Tools	• Emergency source storage

13.4 For Simulator, CT Simulator, kV Imaging system and IORT system

List of Instruments Required to be declared in 'Instrument Management'	
Installation Type: Simulator, CT Simulator, kV Imaging system and IORT system	
Type of Instrument	Instrument Sub Type
Monitoring Tools	• Survey meter**(Ion Chamber based)**

13.5 For Check Sources/Ophthalmic applicator sources

List of Instruments Required to be declared in 'Instrument Management'	
Check Sources/Ophthalmic applicator sources	
Type of Instrument	Instrument Sub Type
Monitoring Tools	• Survey meter

14 Annexure B: Format of undertaking for 'Joint Venture' institute

Please submit undertaking in below format in Institute Registration application form if Institute to be registered is 'Joint Venture' institute.

Radiotherapy facilities under Lease Agreement/ Joint Venture

This lease / jointventure* agreement is made between Mr. …… age…. years an adult, Indian Inhabitant residing at address ……., hereinafter called and referred to as the "*First party"*.

AND

Mr. …… age …….. years an adult, Indian Inhabitant, residing at address …… hereinafter called and referred to as the "*Second party"*.

Whereas the *first party* is the Lawful Owner of land/premises at…… and the *second party* has approached the *first party* to install and/or operate the radiotherapy facility at the above premises.

The first party & Second party undertake as the following:

1. Mr. …… *First party/Second party**, is designated as the Employer of the Radiotherapy Facility and shall discharge the responsibilities of employer as per Atomic Energy (Radiation Protection) Rules-2004. The employer will designate (*himself/herself or his/her own employee*)* as the licensee, who shall discharge the responsibility of licensee as per Atomic Energy (Radiation Protection) Rules-2004.

2. We hereby undertake that in the event of any dispute or non-extension of lease, the radiotherapy equipment will be decommissioned and all the radioactive sources will be disposed off safely as per the procedures stipulated by the competent authority.

3#. First party undertakes to give a period of at least six months to *second partyto* facilitate the decommissioning/disposal of radiotherapy facility.

4#. In case the *second party* fails to complete the decommissioning/disposal within the time period provided by first party, then responsibility of the decommissioning/disposal will lie with the *first party*i.e.owner of land.

First party	*Second party*
Signature	Signature
Name:	Name:
Designation:	Designation:
Affiliation:	Affiliation:
Date	

**Please strike out whichever is not applicable.*

#*clause 3 & 4 are required incase First Partyis not the employer.*

15 Annexure C: Format of undertaking for re-approval of site and layout plan

This undertaking is for layout plan(s) which was already approved through eLORA but needs re-approval due to any of the reasons mentioned below in undertaking format. Since module for amendment of layout plan is not yet developed in eLORA, therefore as an interim arrangement, institute needs to furnish an undertaking in the below format while submitting application for re-approval through eLORA.

Format of undertaking to be submitted while applying for re-approval of layout plan after submitting non-utilization of earlier approved plan

1. **Details of earlier plan approval:**
   a) Case file No.:
   b) Document No.:
   c) Date of approval:
2. **Re-approval is required due to following reasons:**

a) In case of change in make and model:

Make and model as per earlier approval:_____

Proposed make and model now:_____

b) In case of change in the beam energy:

Beam energy(ies) as per earlier approval:_____

Proposed beam energy(ies) now:_____

c) Any other reason, kindly specify:_____

3. **Due to above changes (tick wherever is applicable):**

a) There is no need to change the plan/drawings already approved, so the plan is not being uploaded again. **(Refer note III)** ☐

b) Since there is requirement of changing the plan/drawings, the modified plan is being uploaded herewith. **(Refer Note IV)** ☐

Name & signature of applicant: **Name & signature of Head of the Institution:**

Name and seal of institution

NOTE: Instructions to be followed wherever re-approval of layout plan is required.

I. Fill up the non-utilization form to close the earlier approved plan.
II. Submit a fresh application for site and layout through eLORA.
III. If there is no change in the drawings then instead of uploading already approved drawings, upload this format in all the attachments. Do not upload the drawings in this case. In case drawings are attached, though not required, the application is liable for rejection.

IV. If there is change in the drawings then kindly upload the modified drawings while applying for re-approval and also upload this format through other attachment tab.

16 Annexure D: Undertaking to be submitted along with application for commissioning

Undertaking regarding construction of radiotherapy facility

(To be submitted along with commissioning application in eLORA)

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eLORA Institution Number:

Institution Name and Place:

We hereby undertake that, we have compared the approved layout plan issued by AERB Vide Application No.: _____document No.: _____dated_____ with the constructed Radiotherapy facility and found that all the walls, doors, partitions, nature of occupancy all around the installation, construction materials and density etc. are same as approved by AERB.

We are fully aware that construction of bunker and/or modification in the approved layout plan without prior approval of AERB is a violation of Atomic Energy (Radiation Protection) Rules, 2004 and therefore, the license for operation issued by AERB liable to be revoked in case any deviation found in future.

Name & signature of RSO

Name & signature of Head of the Institution

Date:

Seal of the institution

==========

Undertaking from the Installation Engineer

Prior to installation of the radiotherapy equipment, I have verified that the design of the radiotherapy facility and nature of occupancy all around the installation are in accordance with the above mentioned layout plan approved by AERB.

Name & Signature of the Installation Engineer (Representative of supplier)

eLORA RP. No.:

Company:

Date:

17 Annexure E: Format for "Proof of Employership" for Institute Registration/Employer Change applications in eLORA

While processing of applications pertaining to "Institute registration or Employer Change" in eLORA, it has been noticed that in some of the cases, employee of the institute declares himself/herself as an employer without properly issued certificate as a proof of employership.

In this regard, as employer is the custodian of the radiation sources as per Atomic Energy Radiation Protection Rules-2004 promulgated under Atomic Energy act, 1962**,** the owner of the institute should be declared as employer along with supporting documents in support of his/her claim in such application in eLORA. However, in case, due to some unavoidable circumstances, owner of the institute wishes to designate one of its employees as an employer of the institute, who will discharge the role & responsibilities as stipulated in Atomic Energy (Radiation Protection) Rules-2004 promulgated under Atomic Energy Act,1962 then certificate for employership of the designated employer shall be issued by the owner(s) of the institution in thefollowing format for the saidpurpose:

(To be printed on the institution letterhead)

Ref. No.: Dated:

I/We,Dr./Shri/Ms._____, Owner(s) of the _____ (name of the institution, City) hereby designate Dr./Shri/Ms._____ (designated employer) to discharge role &responsibilities as stipulated in Atomic Energy (Radiation Protection) Rules-2004 promulgated under Atomic Energy Act, 1962.

I, Dr./Shri/Ms._____(designated employer) undertake to discharge the role &responsibilities of the employer as stipulated in Atomic Energy (Radiation Protection) Rules-2004 promulgated under Atomic Energy Act,1962 for the _____(name of the institution, City). I am fully aware about the role & responsibilities of the employer as per the above said Rules& Act.

In the event of Dr./Shri/Ms._____(designated employer) leaves the institution, the undersigned owner(s) will become the employer for discharging the role & responsibilities as stipulated in Atomic Energy (Radiation Protection) Rules-2004 promulgated under Atomic Energy Act, 1962.

Owner(s) of the institution:	Designated Employer
Designation:	Designation:
Institution:	Institution:
Address:	Address:
Place:	Place:
Date:	Date:

Seal of the institution

18 Annexure F: Frequently Asked Questions (FAQs)

18.1 Institute Registration related questions

Q. Our Institute is functioning under Central/State Government; whose detail should we furnish for Employer?

Ans: Employer of an Institute is Head of Institute/Department who is responsible for execution of duties of Employer as stipulated in Atomic Energy (Radiation Protection) Rules, 2004. Furnish detail of your Head of Institute/ Department in Employer detail.

Q. Our Institute is functioning under Central/State Government; we do not have Govt. Registration No./PAN/TAN, what should we upload in Institute Registration form?

Ans: Upload scan copy of certificate (issued by your Head of Institute on letter head affixed with Institute seal) mentioning Government status of your Institute. Do not forget to give Certificate No., as the same (certificate no.) will be required to be mentioned in Institute Registration form.

Q. What is format for "proof of employership" while applying for institute registration in e-LORA.

Ans: For format of "proof of employership", kindly refer Annexure E of Radiotherapy guidelines.

18.2 Forgot User ID and Forgot Password

Q. I have forgotten my user ID and password, how to obtain new user ID and password?

Ans. Visit eLORA home page and click on 'Forgot user ID?'. Provide the detail and click on **Submit** after entering Captcha. You will receive new user ID on your registered email address as well as on registered mobile no. via SMS. (This process is applicable for Institute as well as Radiation Professional accounts).

Once user ID received using above process then click on 'Forgot user ID and Password?' on eLORA home page. Provide your 'Username' and 'Registered Email Id' and click on **Submit** after entering Captcha. You will receive new password on your registered email address as well as on registered mobile no. via SMS. (This process is applicable for Institute as well as Radiation Professional accounts).

18.3 Radiation Professional

Q. Employer of institute is Radiation Professional/Radiation Worker, how to declare Employer as Radiation Professional/Radiation Worker employee of institute?

Ans. Follow the below path **Menu: User Management --> Add Employee -->** Select **'Employee Type'**, either **'Radiation Worker'** or **'Radiation Professional'** (if approved as RP). While adding employee, system will ask "whether the person is employer?", Select **'Yes'** and proceed ahead to fill the other details asked in the form.

Q. What is acceptable proof for professional qualification during RP registration?

Ans. 1) Professional qualification passing certificate from university need to be enclosed. However, in case of RP registration for medical physicist and radiotherapy technologist, if course conducting institute name is not mentioned on the passing certificate from university then you need to enclose passing mark sheet of all the years.

Q. Why my application for RP registration rejected due to name mismatch?

Ans. Applicant name mentioned in the RP application should be consistent with name mentioned on the enclosed documents/certificates. At least one of the documentary evidence should match with the name mentioned in the application form

Q. I want to update my experience, additional qualification such as Ph.D in my RP registration account.

Ans. When there is no change in existing Practice and existing Professional Role then you are requested not to submit application of RP update for adding experience or additional qualification.

Q. Whether internship is mandatory for all the candidates to be eligible to be eligible to work as medical physicist?

Ans: Candidates who passed M.Sc.(Medical Physics) or Dip.R.P./Dip.M.P. ,as applicable, in year 2013 onwards must have internship of minimum 12 months in a recognised well-equipped radiation therapy department (kindly refer guidelines for medical physics internship available on AERB website). However, candidates passed above courses prior to 2013 are not required to have an internship certificate to be eligible to work as medical physicist.

Q. Whether RSO (Medical) eligibility certificate obtained from RP&AD, BARC is mandatory for all the candidates to be eligible to become RSO in Medical facilities?

Ans:

a) Candidates who passed Diploma in Radiological Physics from RP&AD BARC in year 2013 onwards must have RSO (Medical) eligibility certificate issued by Head, RP&AD, BARC, Mumbai to be able to work as RSO in Medical facilities, (with due approval from AERB). However, Candidates passed Diploma in Radiological Physics from RP&AD BARC prior to 2013 are not required RSO (Medical) eligibility certificate (since prior to 2013, their RSO eligibility was being evaluated during the final Dip.R.P Examinations).

b) All Candidates passing M.Sc. Medical Physics/Radiation physics/Radiological Physics courses **irrespective of year of passing** must have RSO (Medical) eligibility certificate issued by Head, RP&AD,BARC, Mumbai, to be eligible to work as RSO in Medical facilities.(again subject to approval from the AERB)

Q. I am radiotherapy technologist. Though my qualification was not in line with as prescribed in the revised Radiotherapy safety code, I have successfully completed safety certification course from RP&AD, BARC as a part of one time regularization program conducted by AERB. I have already registered as radiation professional in e-LORA. Whether I am eligible to work as radiotherapy technologist in the country

Ans: Any candidate who have registered in e-LORA as a radiotherapy technologist are eligible to work as radiotherapy technologist in the country. It may be noted that the RP registration of AERB is approved subject to the candidate fulfilling the radiation safety competency requirements.

Q. I am a radiation professional (Radiation oncologist, medical Physicist and Radiotherapy technologist) and registered in e-LORA and received RP number. Whether I can consider that I am eligible to work as radiation professional in the country.

Ans: AERB registration as Radiation professional is based on the candidate fulfilling the radiation safety competency requirements for the particular practice/role. Any candidate who has registered in e-LORA as a radiation professional is eligible to work in the country for the specified role, from a radiation safety perspective.

Q. I am a radiation professional (Radiation oncologist, medical Physicist and Radiotherapy technologist). Whether I can have more than one radiation professional registration number.

Ans: Radiation professional registration number (RP number) is unique for every radiation professional and therefore one radiation professional can have one RP number only. However, any radiation professional can apply for updation, if changing the professional role or practice.

18.4 Site and Layout Approval Related Question

Q. Make and Model of equipment (e.g. Linear Accelerator, HDR, Telecobalt, CT Simulator, etc) is being asked in site and layout application form but we have not decided make and model of equipment so far for purchase, how to obtain layout approval?

Ans. You can apply for any similar equipment (for e.g. LA with same highest photon energy) so that design requirement will not vary. At a later date, the site and layout approval can be regularised for actual equipment you wish to purchase. Please see Re-approval of site and layout planfor more detail.

Q. Option of Linear Accelerator, Simulator, Manual After Loading Brachytherapy, etc (various types of equipment/facilities) is not available in the drop down of 'Layout form submitted for' option in site and layout application form.

Ans: The options to select type of equipment in site and layout application form as well as application forms related to various equipment types are visible based on your institute's profile (viz. Radiotherapy) and role (viz. Linear Accelerator-Radiation Facility, etc). Please update your institute's role to see various types equipment in drop down list and other application forms relevant to the role. Use below path to update institute's role:

Menu: User Management --> Update institute details--> tab 'Institute detail', select additional role by ticking check boxes and click on 'Update'

Q. I want to submit site and layout application. What are the guidelines for preparation of radiotherapy site and layout drawings.

Ans. Guidelines for preparation of radiotherapy site and layout drawings are available on AERB website. Please follow these links in AERB website www.aerb.gov.in. Radiation Facilities->Medical Applications of Radiation->Radiotherapy->Guidelines for preparation of site and layout drawings

Q. My site and layout plan is approved by AERB. Now I want to carry out some modification in the site plan but modifications are in associated facilities in which are awayfrom the approved Radiotherapy bunker. Whether I should submit modified site and layout plan to AERB for approval.

Ans. Separate permission for the proposed modification in the AERB approved layout plan is required only if the changes are proposed in or adjacent to the bunker/control console (the room/facilities which share a common wall with bunker). Further, proposed modification above the roof needs prior approval.

18.5 RSO related questions

Q. My RSO application got rejected for incorrect entry of PMS/TLD no., how to correct PMS/TLD no.?

Ans: Login through Employer's account, use following path **Menu: 'User Management' --> 'Update/Dissociate Employee' -->** Select Employee from **'Employee Details'** --> click on **'Show Details'** --> Update your PMS No. --> click on **'Update'**

(You can also update your Email address and Designation in the above Update Screen)

18.6 Handling error message

Q. I'm getting message 'Sorry, someone is already logged in this browser. Two person cannot log in the same browser', what should I do?

Ans. This may happen when eLORA system is directly closed without logout. In such case, Please restart your internet browser and access eLORA system.

Q. Error "Contact System Administrator" displayed while applying for any application such as export NOC, procurement etc.

Ans: A new functionality i.e. ticket management system has been deployed in eLORA. Using this functionality, user can raise issues pertaining to regulatory process. A new menu "raise an issue" is placed at left panel menu bar in your account. Kindly submit your issue using this menu in e-LORA along with screen shot of the error message/or any supporting attachments. You will receive the communication regarding resolution of the issue through eLORA.

Q.Where can I find the contact details of Officials who could be contacted in case of any queries in Radiotherapy

Ans Contact details of eLORA Help desk is provided AERB website under the tab Contact ->Help desk for radiation facilities. Contact details of key officials for each type of practice are also available by clicking the tab "Contact List for Radiation Facilities"

18.7 Changing details

Q. How to change email address of Institute Employer?

Ans. After login, follow the menu **'User Management --> Update Institute Detail'** select tab **'Employer Detail'** and change **'Email (O)'** as required and click on **'Update'** button. You will receive all future correspondences on this updated email address.

Q. My RSO application got rejected for incorrect entry of PMS/TLD no., how to correct PMS/TLD no.?

Ans: Login through Employer's account, use following path **Menu: 'User Management' --> 'Update/Dissociate Employee' -->** Select Employee from **'Employee Details'** --> click on **'Show Details'** --> Update your PMS No. --> click on **'Update'**

(You can also update your Email address and Designation in the above Update Screen)

Q. How to change Employer?

Ans: Please see General Guidelines to use eLORA System (available in eLORA Help menu) for step-by-step process for changing Employer detail.

18.8 How to check status of application

Q. We have submitted application form through my eLORA account, I want to know its status?

Ans. The status of all application form can be seen through your account. After login, follow the Menu: **'My Applications'**. You will see status in **'Application Status'** for a given Application No.

Please note, only short informative messages are displayed in 'Inbox' (after login) about the processing status of applications, use **'My Applications'** to see the details of approval/rejection of application.

18.9 Instrument related

Q. Whether all the instruments available in the institute are required to be updated in the institute details in e-LORA?

Ans:

a) List of measuring, monitoring, QA and safety tools which are required to be declared in Instrument Management in the institute details in e-LORA is provided in e-LORA RT Guidelines (please refer Annexure-A of e-LORA RT Guidelines available in the eLORA help menu)

b) The minimum required instruments with valid calibration should be available in the institution and updated in eLORA. Out of all the measuring and monitoring instrument, it is acceptable if only one instruments of each type i.e. thimble chamber, parallel plate chamber, electrometer, well type chamber and survey meter (as applicable) which are calibrated by AERB recognized laboratory (Kindly refer

AERB website for the list of recognized laboratory) are updated in Instrument Management in the institute details in e-LORA. Other redundant (extra) instruments if any, that are cross calibrated by the institution need not be updated in eLORA.

Q. I have Non-compliances (NC) and the final date of resolution is over but I need some time for the resolution of these NCs? My e-LORA account is also blocked. How I can extend the period of NCs?

Ans: In order to extend NC period, pls provide filled-in NC extension forms (scan copy through mail), format of which is available in the help menu of your e-LORA account.

Q. Several non-compliances (NCs) are pending in my institute, however, these NCs are not available in NC response screen for submission of response.

Ans: Please note that there are two type of NCs in e-LORA.

(i)One is system generated NCs such as license renewal, instruments calibration date, RSO renewal etc. Once renewal taken in e-LORA or calibration date of instruments updated in e-LORA then these non-compliances automatically closed from your e-LORA account. Please note that such NCs are not available in 'NC respond screen' to submit the response.

(ii) Another type is manual generated NCs such as NCs generated after inspection or based on safety status report etc. After compliance, institute need to submit the application through 'NC respond screen' and after approval of the same, NC will be closed in the system.

18.10 Licence renewal related questions

For RENEWAL one must select "Renewal of Licence" and not "Application for Licence"

Q. I'm not able to see equipment/source in Licence renewal form?

Ans. Please check the name of Licensee of equipment/source in Menu (as shown below): My Institute Details→ Tab 'Equipment' /Tab 'Radiation Sources'. Please login through the Licensee account of respective equipment/source. **Only current Licensee can submit application for renewal of Licence**.

Q. I'm not able to see Telegamma Therapy equipment or Remote After Loading Brachytherapy (HDR/LDR/PDR/MDR) equipment in Licence renewal form?

Ans. At present, Telegamma Therapy equipment orRemote After Loading Brachytherapy (HDR/LDR/PDR/MDR) equipment will not be available for renewal of Licence if no radioactive source associated with the equipment having status "received"/"Licensed". (Please check detail of associated radioactive source in Menu: My Institute Details→Tab 'Radiation Sources'). In case the status of all the

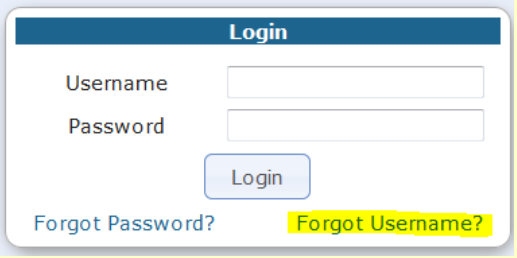
radioactive sources associated with the equipment is “disposed”/“to be disposed”, the equipment will not be available for renewal of Licence. However, application for renewal of licence can be submitted after approval of Source Receipt Intimation of new source.

Q. Licensee of equipment/source shown in eLORA is no more available in the institute?

Ans. It is required to change Licensee in the eLORA whenever Licensee dissociates from the institute or relinquishes the responsibility of Licensee. Employer (through Employer login) can change the Licensee and nominate any employee of the institute as a Licensee for any particular equipment/source. Please refer 'Process for Change Licensee' given in ‘General Guidelines to use eLORA System’ (available in Help menu) for detailed procedure. **New Licensee through his/her login can apply for renewal of Licence.**

Q. Licensee has forgotten eLORA account ‘Username’/’Password’, how to obtain it?

Ans. Use ‘Forgot Username’ or ‘Forgot Password’ option available on eLORA home page as desired to obtain Username or Password.



Q. Do I need to submit ‘QA/QC report’ as an attachment of Licence Renewal application form?

Ans. QA/QC report is not required to be submitted if QA/QC results are satisfactory and within acceptable tolerance limit.

However, in case, QA/QC result found **not satisfactory or not within acceptable tolerance limit**, provide **detail of tests which does not meet the prescribed tolerance limits for QA/QC** (in a format provided in Help Menu) as an attachment of application form.

Q. Do I need to submit ‘Radiation Protection survey report’ as an attachment of Licence Renewal application form?

Ans. Radiation protection survey report is not required to be submitted if survey report results are satisfactory and within acceptable tolerance limit.

However, in case, Radiation protection survey found **not satisfactory or not within acceptable tolerance limit**, provide radiation survey data (in a format provided in Help Menu) as an attachment of application form.

Note: There is no need to conduct survey for neutron in case of high energy Medical Accelerator for this purpose.

Q. I have obtained procurement permission for accelerator. But while applying for procurement of kV imaging system, accelerator model is not appearing.

Ans. Pls follow the steps/path mentioned below:

Step 1. User management -> Update institute detail -> Select radiotherapy practice- Add the role of institute as kV imaging system

Step 2. User management -> Designate Licensee -> Select person to whom the procurement permission or Licence is issued -> Designate Licensee -> Select kV imaging system-> Designate

Step 3. Regulatory forms -> Radiotherapy practice ->Application for procurement (source/equipment) -

> Generator -> kV Imaging ->To be procured accelerator or already procured accelerator.

18.11 Decommissioning and Disposal Regularization

Q. I have already obtained decommissioning/disposal permission from AERB on paper (not through eLORA) for decommissioning/disposal of equipment/radioactive source. Equipment/radioactive source is being decommissioned/disposed based on the paper approval. However, the decommissioned equipment/disposed source is still shown in my institute account with status 'Licensed'.

Ans: You need to regularise decommissioning/disposal in eLORA. Please refer guidelines for steps involved for decommissioning/disposal of various types of equipment/sources. For an attachment in the application form for decommissioning/disposal, please upload scan copy of AERB approval obtained on the paper. For intimation of decommissioning/disposal form, upload scan copy of disposal agency confirmation/airway bill (as applicable). After acceptance of intimation form, the status of equipment and radioactive source will change to "Decommissioned" and "Disposed" respectively.

18.12 Help email address

In case of any further difficulty, you can write to our help email address elora.rt@aerb.gov.in

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