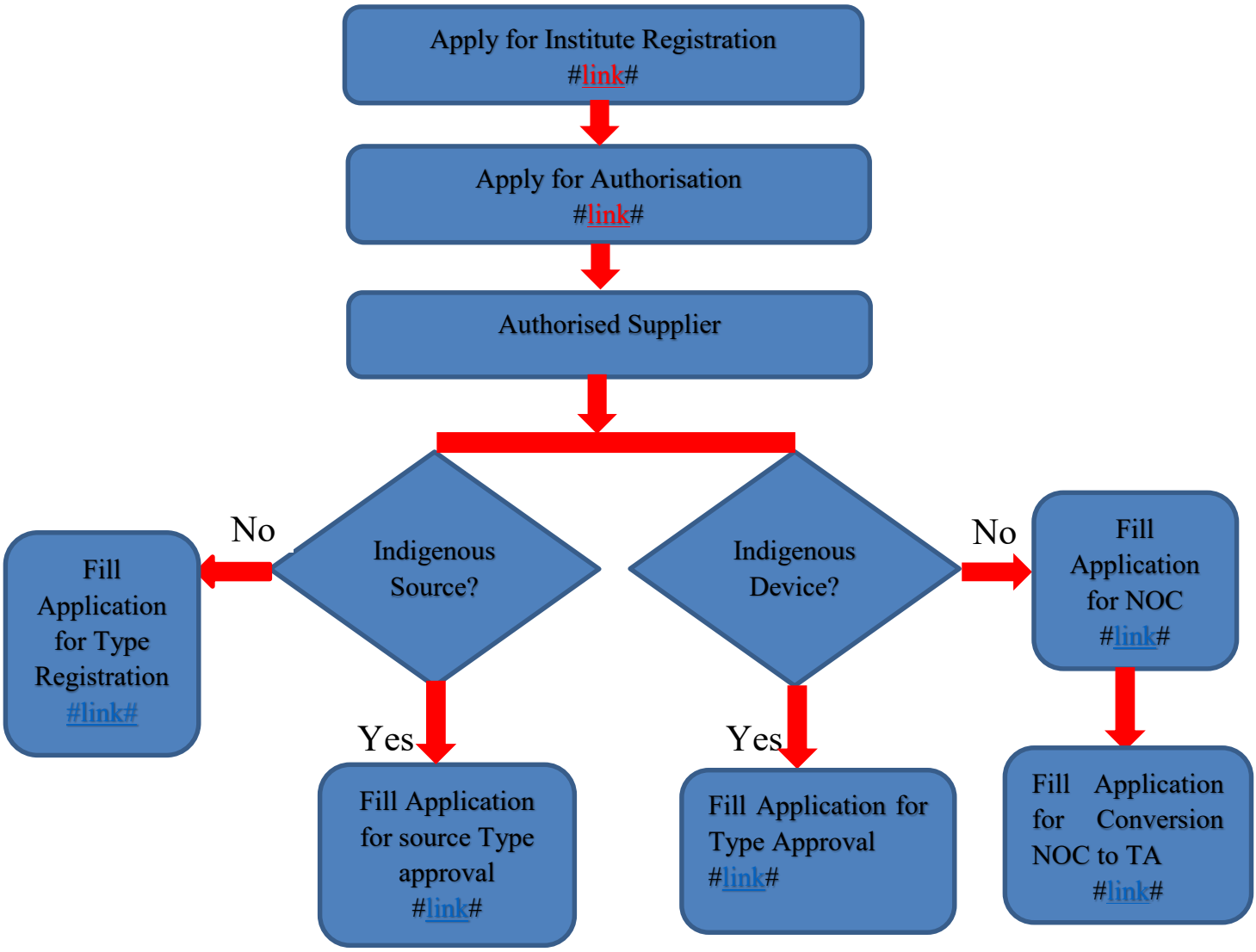
e-LORA Guidelines for Manufacturer /Supplier of Consumer Products and Container Scanners

February 2025

RADIATION APPLICATIONS SAFETY DIVISION AERB



*Note: If you involved in manufacturing the Consumer Product & Container Scanner, obtain Licence for manufacture of Consumer Product & Container Scanner device. Pl. refer the steps mentioned in Step 3**

Regulatory Processes in e-LORA for licensing process of manufacturer /supplier of Consumer Products and Container Scanners

This guidelines covers following equipment:

Radioactive Source based equipment • Ionisation Chamber Smoke Detector • Electron Capture Detector • Ion Mobility Spectrometer • Suspended Particulate Matter detector • Tritium based Devices • Any Other	Radiation Generator based equipment • X-ray Baggage Inspection System • X-ray Diffractometer • X-ray Fluorescence Device (Cabinet Type) • X-ray Fluorescence Device (Hand-held) • PCB Analyser • Food Scanner • Portable Scanner • Electron Beam Welding Machine • Any Other	Radiation Generator based Container Scanners Radioactive Source based Container Scanners

Regulatory Processes in e-LORA for licensing process of manufacturer /supplier of Consumer Products and Container Scanners

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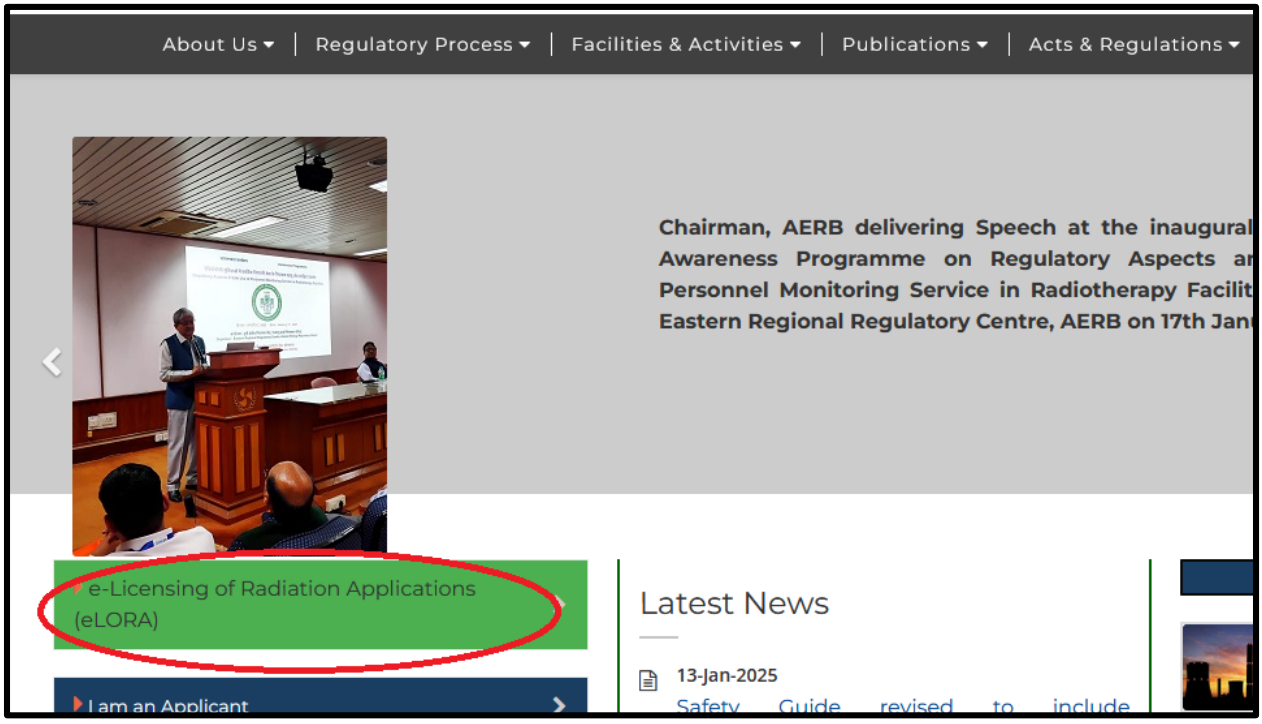
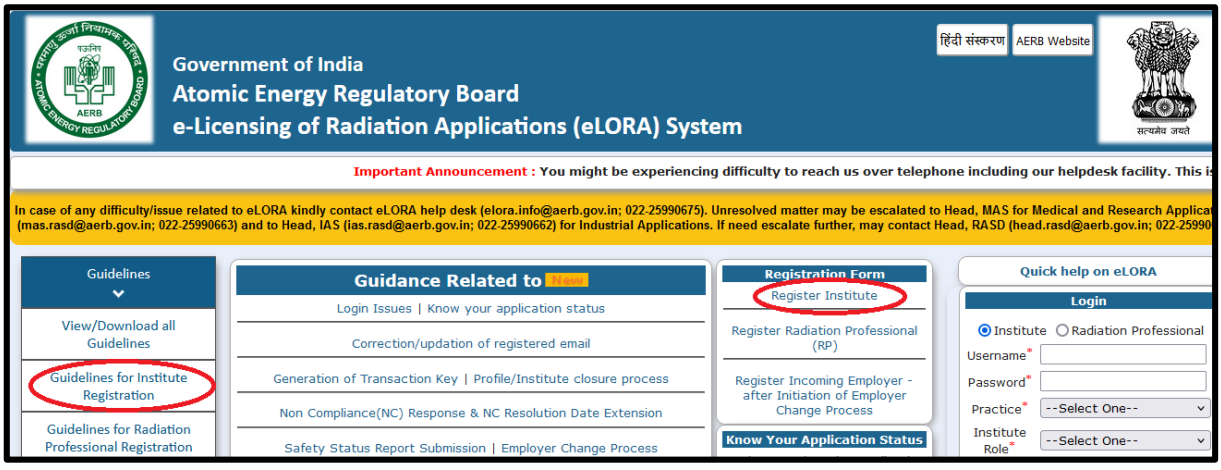
Section A: Regulatory process of Manufacturer and Supplier of CP&SF

Step-1: Register Your Institute



a. Visit AERB website www.aerb.gov.in.

b. Click on the button **e-LORA**. Click on "Go directly to e-LORA System" and "Click to proceed for e-LORA server". It will redirect you to below screen of **e-LORA home page.** Click on application form "Register Institute" to proceed for registration in e-LORA.



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.)

Step 2. Declaration of Safety Infrastructure

Prior to apply for Authorization of supplier complete the requisites as follows

- Add Employee: Declaration of qualified and trained personnel (Radiation Safety professional) in e-LORA system
- Add Instrument: Declaration of monitoring tools (radiation survey meter) as per regulatory requirement in e-LORA prior to apply for Authorisation.

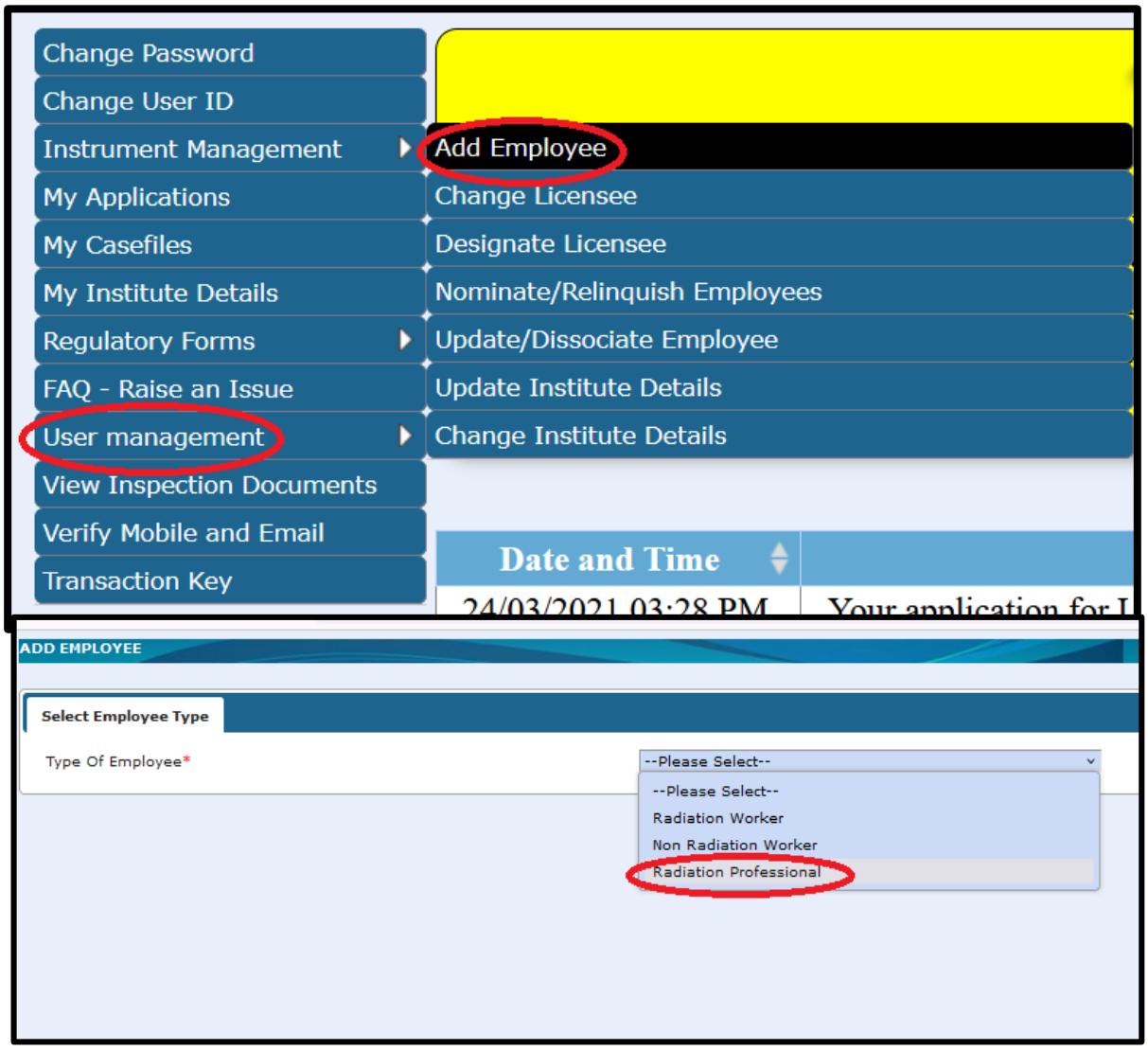
2a. Nominate Employee

For suppliers of all kinds of consumer products and container scanners equipment at least one person trained in radiation safety should be available. For adding such employee to your institution, please follow the path as:

User management>>>Add Employee>>> Select required Type of Employee from drop down

Please refer Annexure-1 for details of the eligibility criteria and relevant training courses.

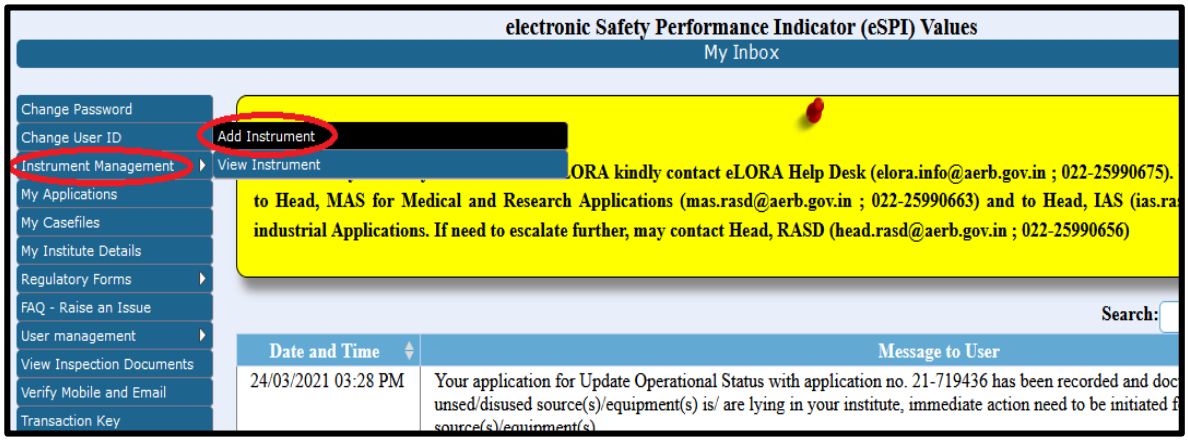
The trained persons are required to be added as Radiation Safety professional.

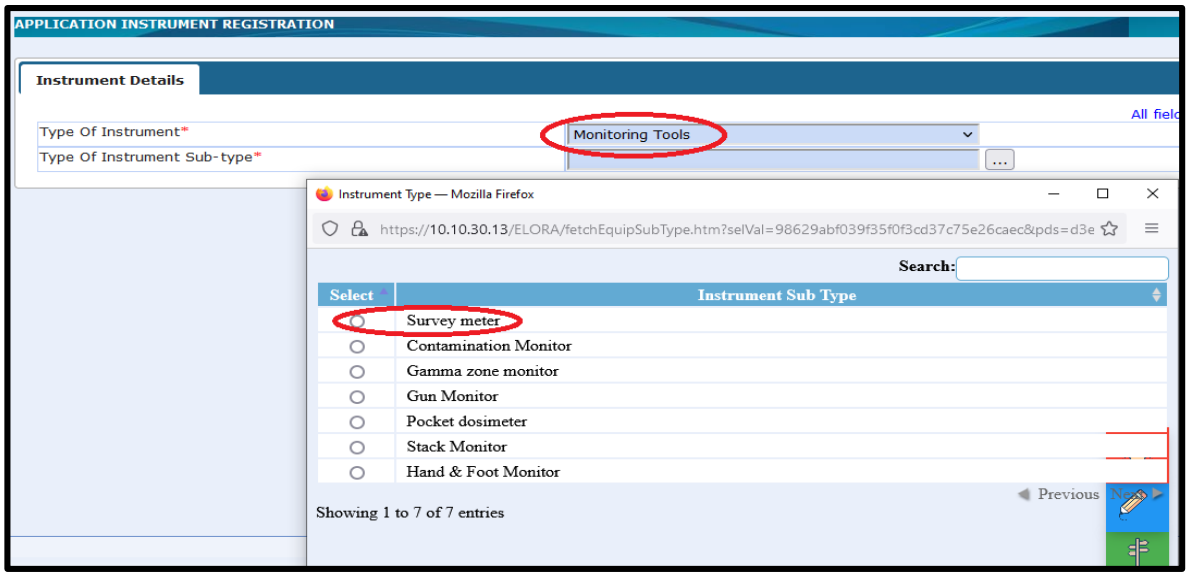


Nominate appropriate person fulfilling the qualifications as mentioned in Annexure-1 for radiation safety training to demonstrate the adequacy of radiation safety personnel. Once your nominate person successfully completed radiation safety training, advice him/her to update the profile a radiation safety professional. If the nominated personnel is involved in servicing /mentanaince of X-ray equipment (such as replacement of X-ray tube), then provide the TLD services for the personnel.

2b. Add Instrument

Supplier of consumer products and container scanners equipment should possess a suitable and calibrated radiation survey meter at the time of submitting supplier authorization. Hence please add the instrument in '***Safety Tool'*** option. *To declare instruments, follow the path as*:
Menu>>>Instrument Management>>>Add Instrument





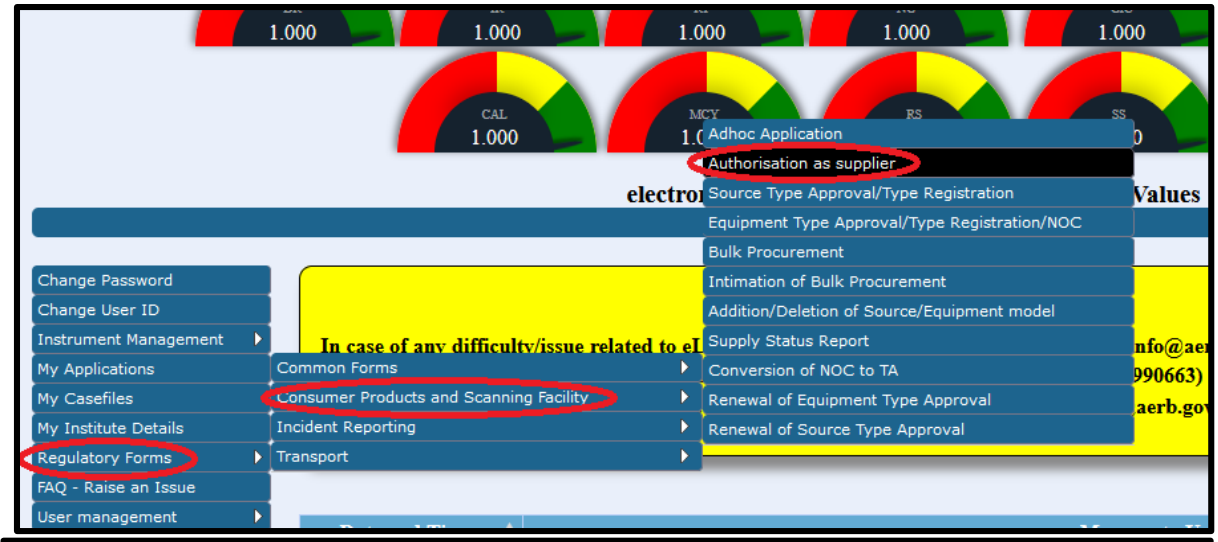
> ***Important Note:*** Procure *suitable survey radiation meter* for X-ray energy/radioactive source under reference and capable of measuring background radiation levels. Resolution of radiation survey metershall be at least 0.01µSv/h. *The survey meter should be calibrated.*

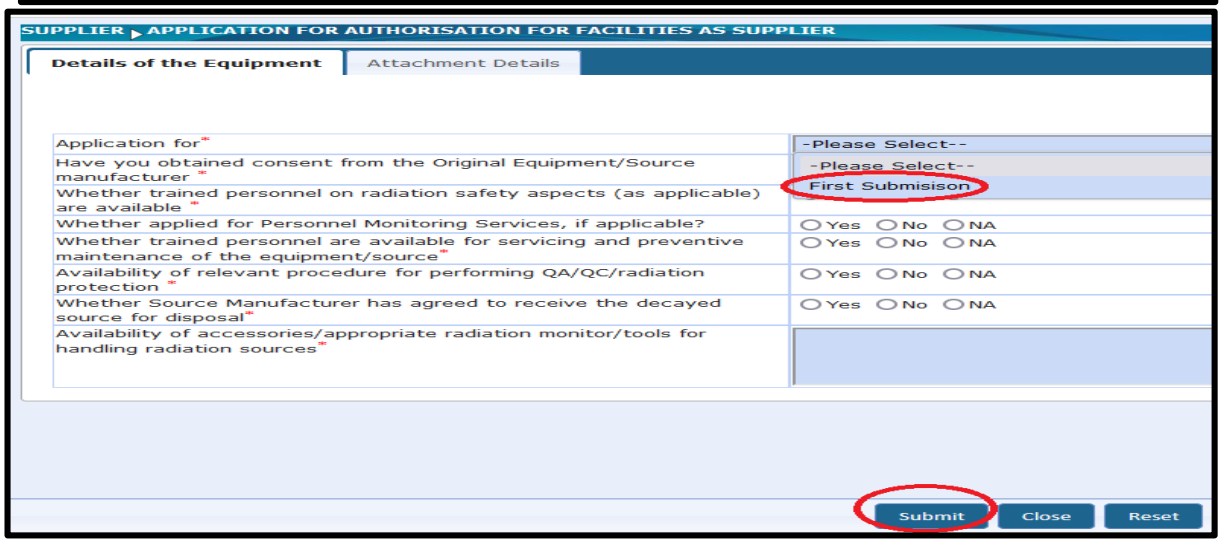
Select Monitoring tools from the field Type of Instrument. From the pop-up list, select Survey Meter. After filling all relevant information in the subsequent screen, submit for addition.

Step 3: Application for Authorisation as supplier

Suppliers should apply for authorization from AERB by submitting this form.
Regulatory Forms>Consumer Products and Scanning Facility >Authorisation of Supplier

> ***Important Note:*** *All other application forms will open-up for submission after this approval only. Following is the path for Supplier Authorization.*





Select the applicable fields such as "First Submission", and attach necessary documents such as

- Agreement letter from OEM authorizing the Indian Supplier for supplying the equipment in the country.
- Certificate of training from OEM to the person(s) of supplier, for servicing, maintenance and radiation safety aspects of the equipment.
- Calibration certificate of radiation survey meter.

After attaching above documents, press "Submit" button as mentioned above.

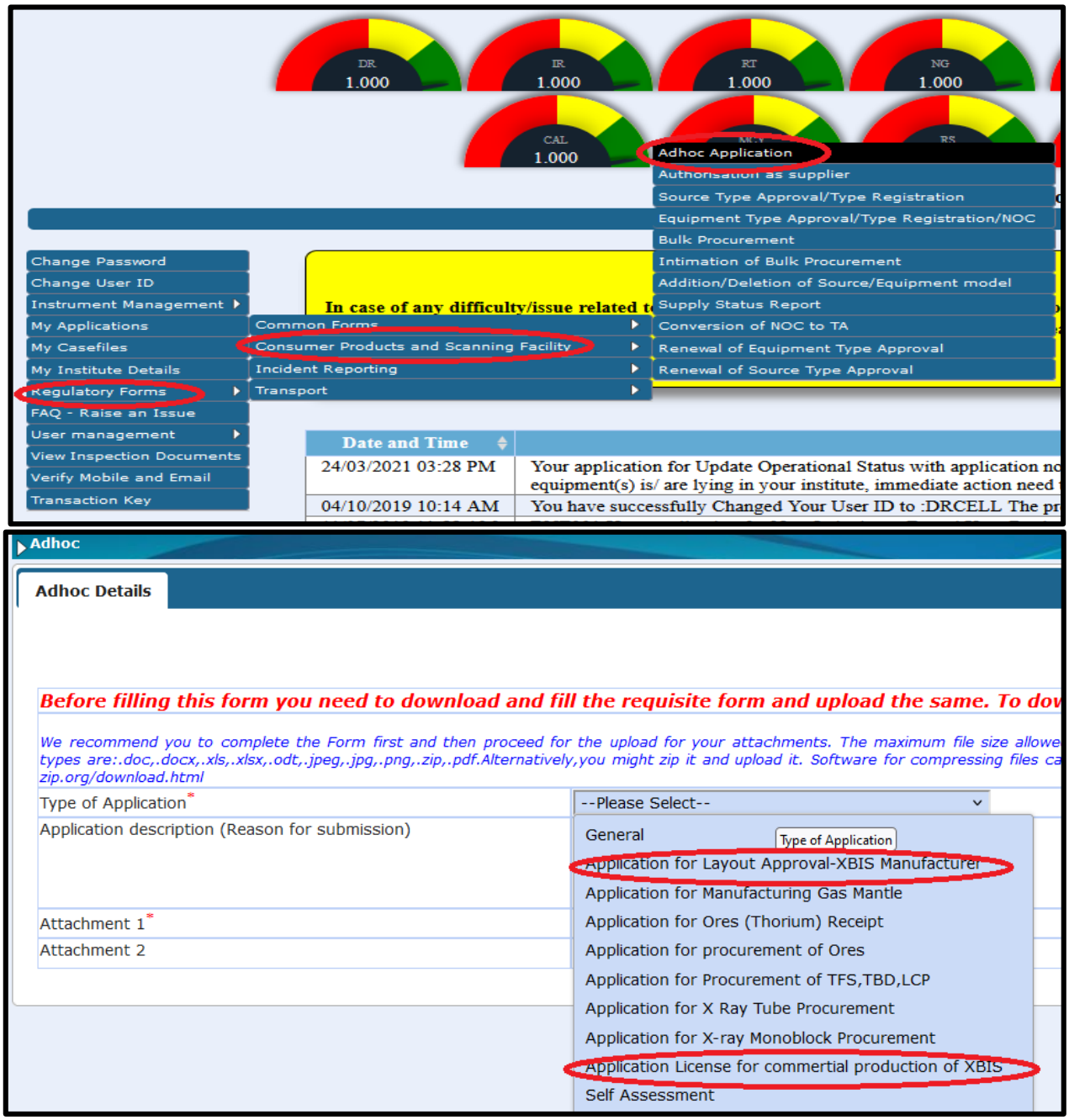
Important Note: After getting approval you can download your issued certificate by using following path: My Application>>Select Application No.>>Show Details>>Approval letter

Step 3*: Licensing for radiation testing facility in CP&SF

If your institution is involved in manufacturing of Consumer products and container scanner, you are required to obtain approval of following:

i. Layout approval
ii. RSO Approval
iii. Application of Licence for radiation testing facility

i. Layout approval: Submit Layout approval application via adhoc application by following path: **Regulatory Forms>Consumer Products and Scanning Facility>Adhoc Application**



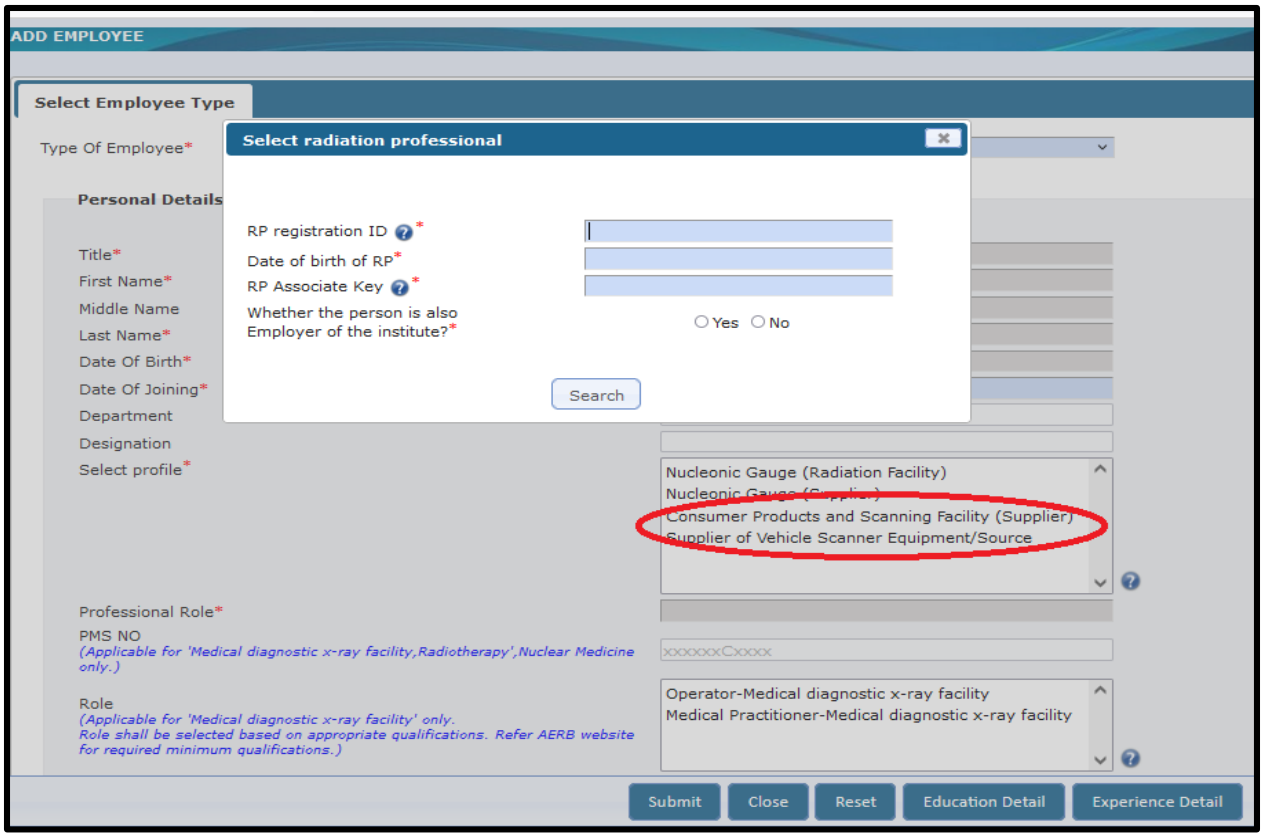
A dedicated radiation testing facility shall be constructed, located away from other working areas not related to radiation testing. The shielding and space requirements for the testing facility shall be such that the dose limits for radiation workers and members of public, as prescribed by the Competent Authority are met with and the exposures are maintained ALARA. The facility shall be equipped with required protective devices. A warning placard shall be displayed outside the testing facility. For Layout Approval attach necessary documents such as

- Prepare a sketch of layout of test facility to the scale 1:50 mentioning all the details such as area, wall thickness, shielding material (wall material), position of doors, windows, equipment, control console, protective barriers etc.
- Prepare a sketch of floor layout of test facility to the scale 1:100 mentioning the areas

around the test facility and details of occupancy. The copies of both the layouts shall be submitted to AERB along with application in e-LORA

ii. Radiological Safety Officer (RSO): For obtaining RSO approval follow the path as;

- ***Step-a:*** For a person required to be nominated as RSO, you need to add him/her in the type **Radiation Professional (RP).** While adding RP, system will ask RP registration ID and Date of birth of RP. (Obtain these details from Radiation Professional).

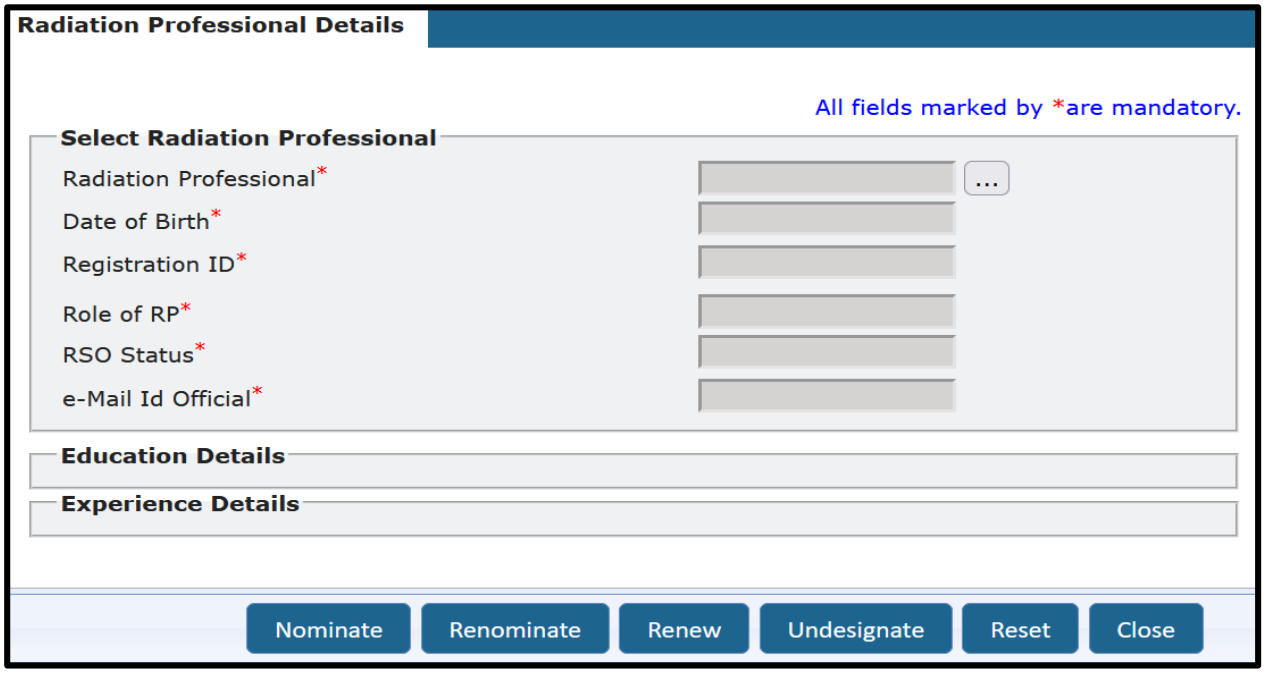


The 'RSO eligibility certificate' of the proposed RSO should be available in his/her Radiation Professional (RP) profile in eLORA. If not, please update the 'RSO eligibility certificate' using the "Radiation Professional Updation" option in eLORA prior to submitting the RSO application form. Fill the form by following path**; Menu>> Regulatory Forms>> Common Forms>>Nominate RSO Instructions:**

1. **Nominate:** To Nominate any RP for the first time.
2. **Re-Nominate:** An existing RSO can be renominated for addition/removal of radiation facilities Till 1 month to RSO approval validity. i.e. Button will be disable for one month before Expiry date
3. **Renew:** An existing RSO can be Renewed before one month of RSO approval validity date. i.e.Renew button will be enable for One Month Before expiry.
4. **Undesignate:** An existing RSO can be removed from his role.

5. ***Example on Re-Nominate, Renew:*** *If RSO application valid till '2021-09-16', then users can Re-Nominate RSO till '2021-08-16' after that Renew option will be enable to Renew RSO. So users can Apply for Renewal of RSO till '2021-09-16'.*

> ***Important Note*** **:** Employer will be able to Nominate/Re-nominate/Renew for Person A, only if Person A has completed course for the selected practice in eLORA eLearning Portal.



Radiation professional can subsequently be nominated for the approval of RSO. The process of RSO is as follows;

- ***Step -b:*** **First generate the transaction key by using tab "Transaction key"**

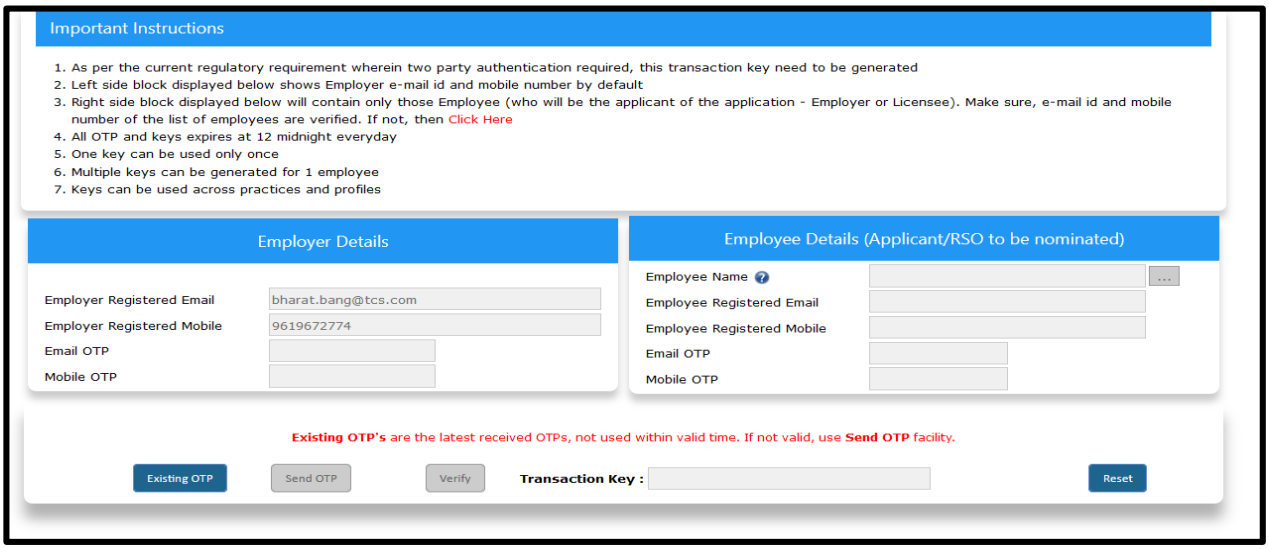
Before generating the transaction key, verify whether email id and Mobile number of an employee in eLORA. The process of verification is as follows;

- First log in to the employer profile (Institute Log in),
- Click on "My Institute Details",
- Click on "Contact Details".

  - You can check the verification status of the email and mobile number of the employer from the list appears.

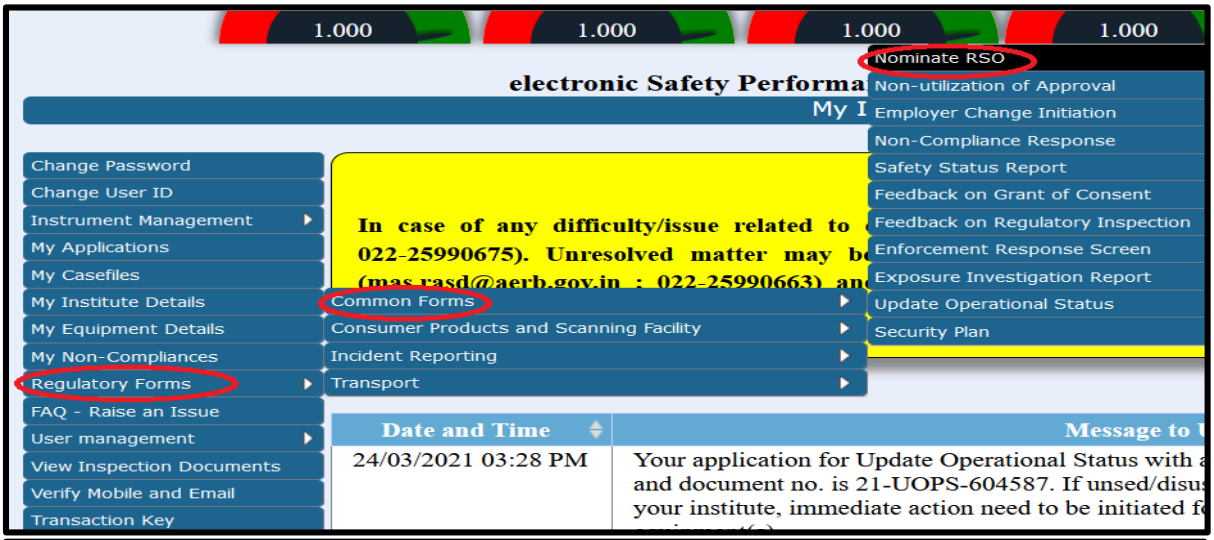
  - If status of verification is "no", then corresponding employee has to Log in to the system (RP log in for RSO).

  - Fill complete PMS No in the field PMS No in the format XXXXCXXXX that is first 4 digits institute number and last 4 digits personnel number as written on TLD badge.



Important Note: Only name of employee, whose email id and mobile number are verified, will appear in the employee list for transaction key generation. For RSO, email id and mobile number has to be verified after log in to his/her Radiation Professional (RP) Profile (Using RP user id and password).

- ***Path-c:*** Fill the form by following path; Menu>> Regulatory Forms>> Common Forms>>Nominate RSO



iii. Application of Licence for radiation testing facility

Fill this form to obtain Licence for radiation testing facility to manufacture X-ray Baggage Inspection System (XBIS) or any other radiation generating based consumer products. (Same form is also applicable for renewal of licence). Documents required to be attached with this form:

i) Radiation protection manual of the facility
ii) Ownership document/rented property agreement of the site
iii) Drawing (scale 1:50) of the test facility
iv) Drawing (scale 1:100) of the floor layout of test facility

Section B: Type Registration/Type Approval (New/Renewal)

List of equipments which requires Type Approval

- X-ray Inspection System
- Food Scanners
- X-ray Diffractometer
- X-ray Fluorescence Device (Cabinet Type)
- X-ray Fluorescence Device (Hand Held)
- PCB Analyzers
- Portable Scanner
- Vehicle Scanner (X ray based)
- Vehicle Scanner (Isotope based)

List of equipments which requires Type Registration

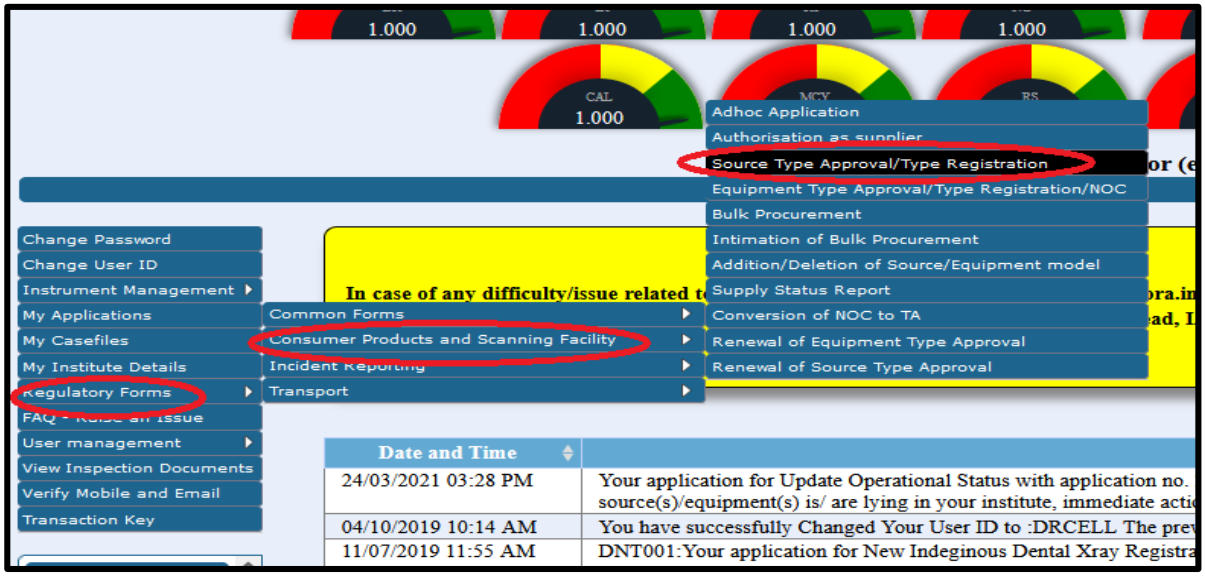
- Ionisation Chamber Smoke Detector
- Electron Capture Detector
- Ion mobility spectrometer
- Suspended Particulate Matter detector
- Tritium Based Devices

Step 1: Source Type Approval/Type Registration:

If your institution is dealing with radioactive sources used in consumer products and container scanner, follow the step of "Source Type Approval/Type Registration. For radioactive sources manufactured in India, apply for Source type approval. For imported radioactive sources, apply for source type registration. The option type-registration should be used in case of sources using consumer products and scanning facilities.

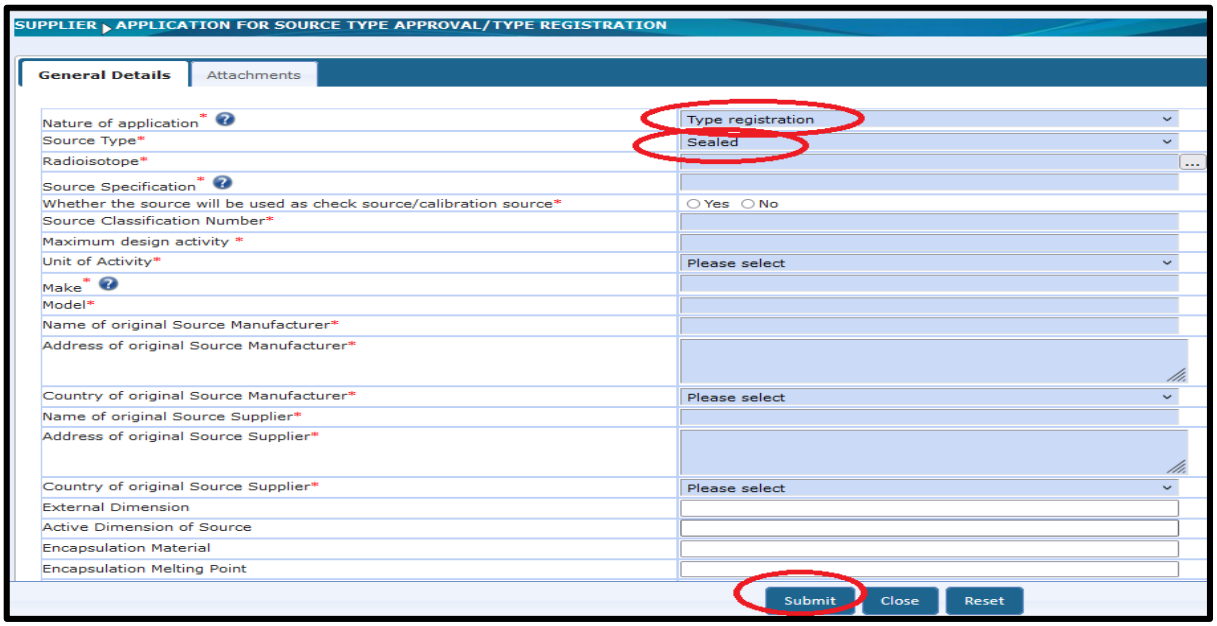
Following is the path:

Regulatory Forms>Consumer Products and Scanning Facility>Source Type Approval/Type Registration



After clicking on the form, following screen will appear. Choose nature of application as "Type registration" and filled the applicable details and submit.
It is required to submit the appropriate source type as "Sealed" in the application form. During complete submission of this form, please attach following documents:

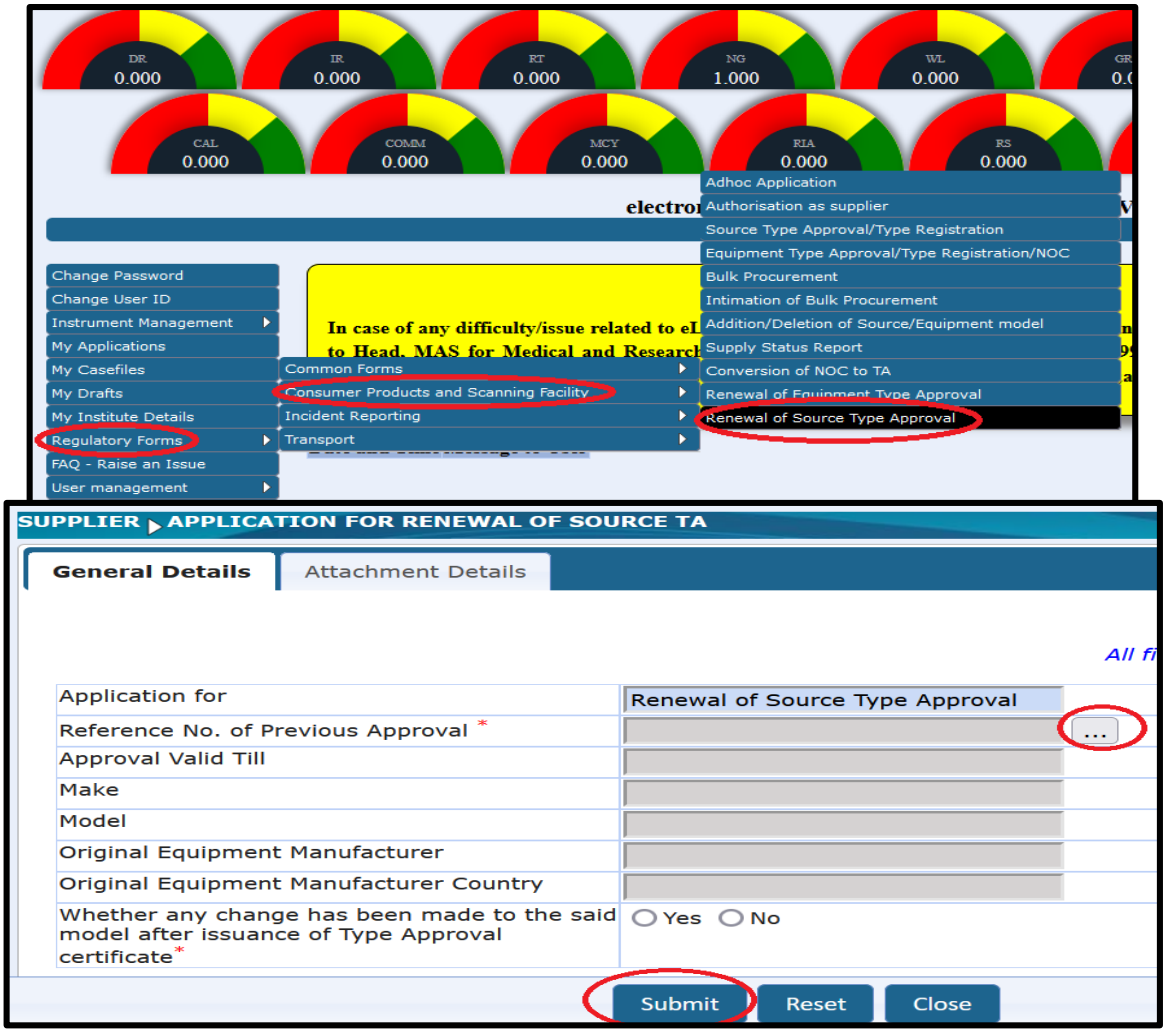
- Documents on Source Classification Number
- Sealed Source Compliance Standard certificate
- Specify the Standards (national / international) to which the source complies
- Performance verification test certificate/test report certified by accredited laboratory / approved agency
- Documents mentioning details of the source such as Maximum design activity, External Dimension, Active Dimension of Source, Encapsulation Material, Encapsulation Melting Point, Dose Rate(at a reference distance), Physical Form of source, Chemical form of source, Maximum Stray radiation level at 10 cm, leak test certificate/report, Accident Condition (Fire Temperature, Duration),
- Approval Certificate of the CP&SF source from the competent authority of country of origin, if any



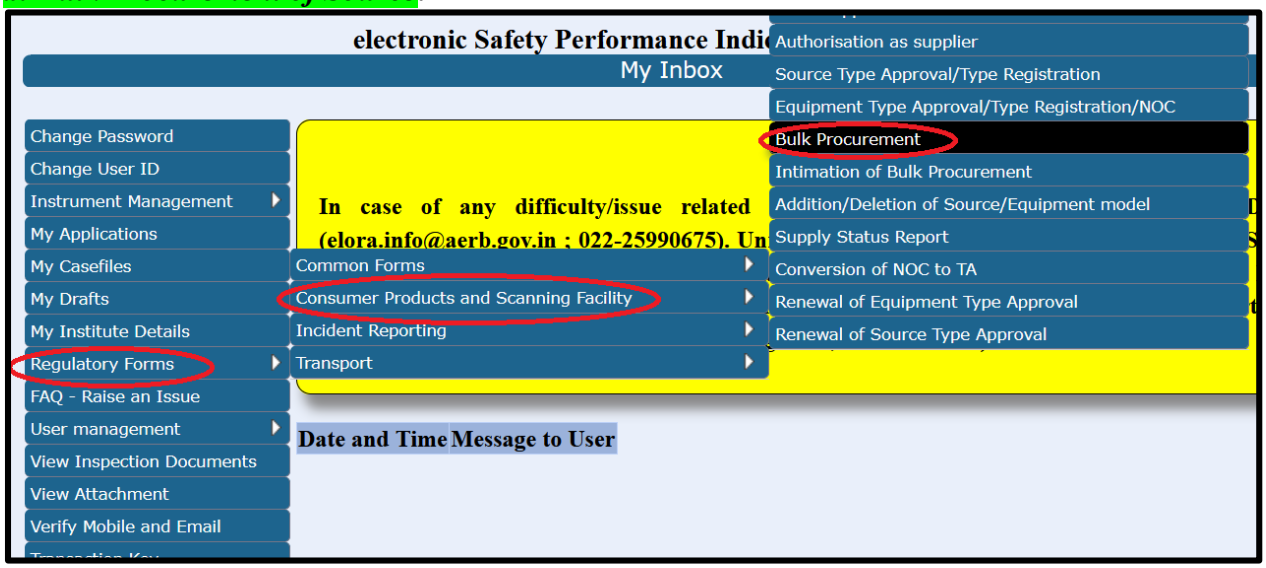
Important Note: *Type Approval (design approval) is applicable for the indigenous sources(s) i.e. manufactured in India.*

Step 2: Renewal of Source Type Approval:

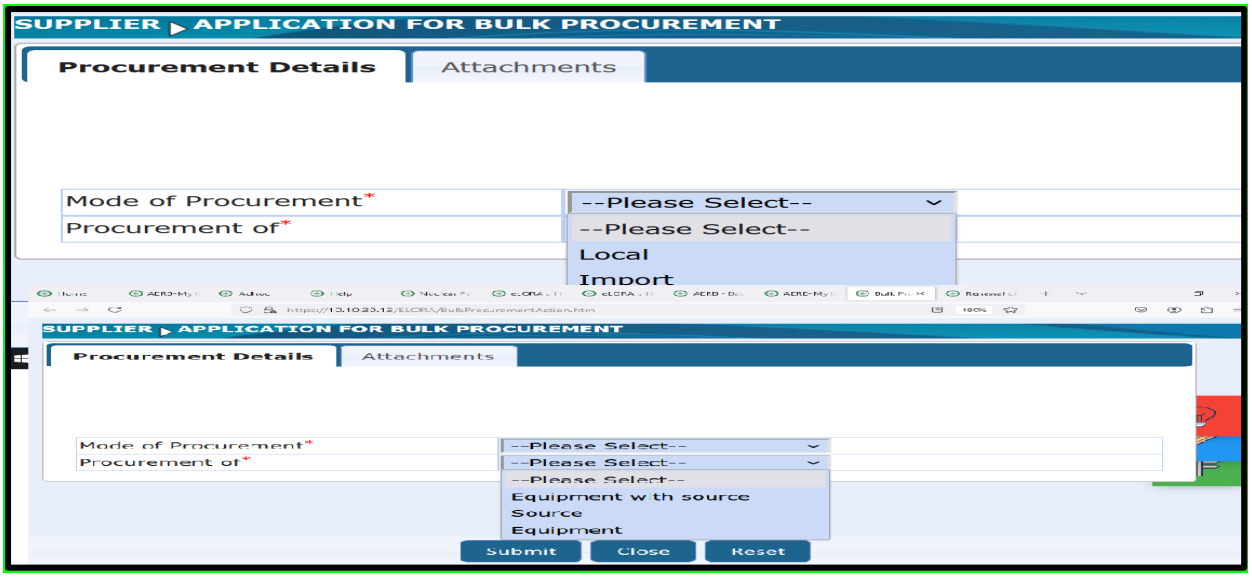
To renew the source type approval, follow the path: Regulatory Forms>Consumer Products and Scanning Facility>Renewal of Source Type Approval



***a: Bulk Procurement of Source*:**

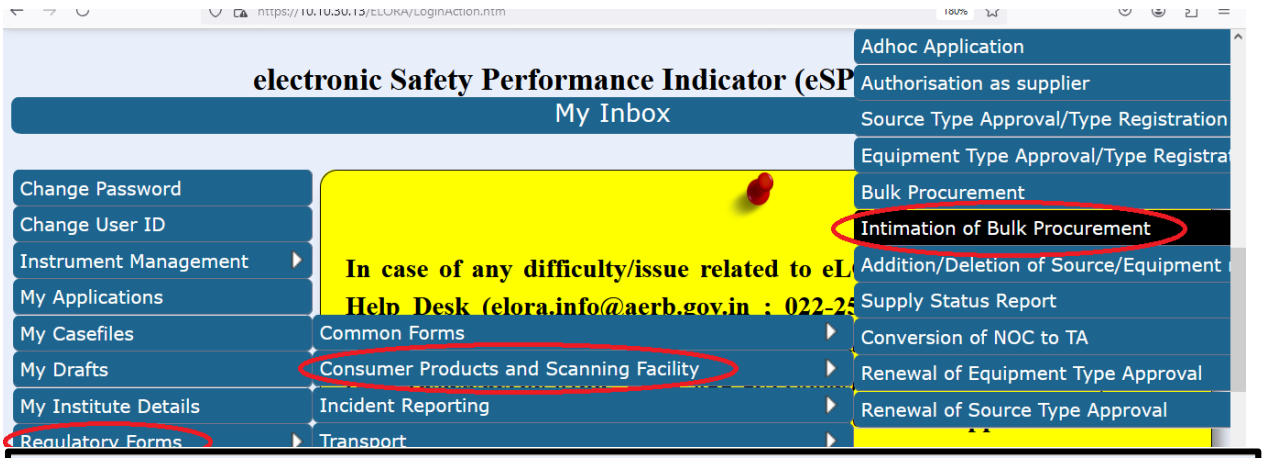


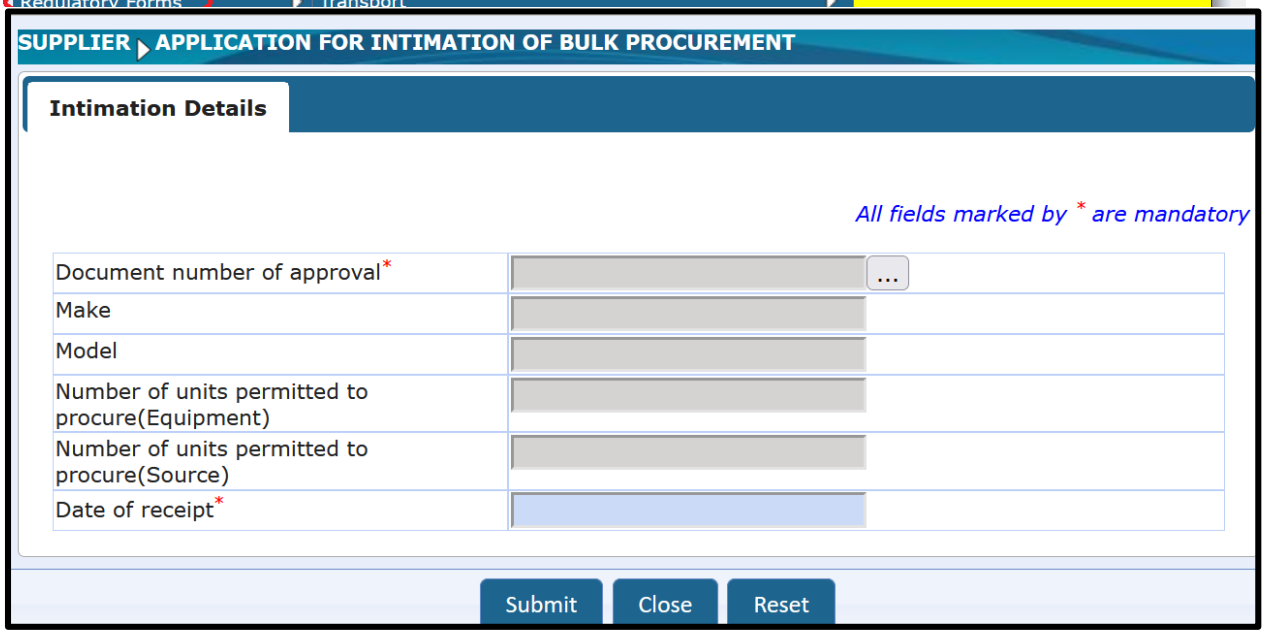
Select mode “Import”, if the source is imported. It is the first the source to be type registered, then you can apply for bulk procurement of the source by selecting the import option. Select mode “local” for indigenous sources Local sources which are type approved, can be applied for bulk procurement.



From the dropdown you need to select the source details and then submit.

***b: Intimation of Bulk Procurement of Source*:**

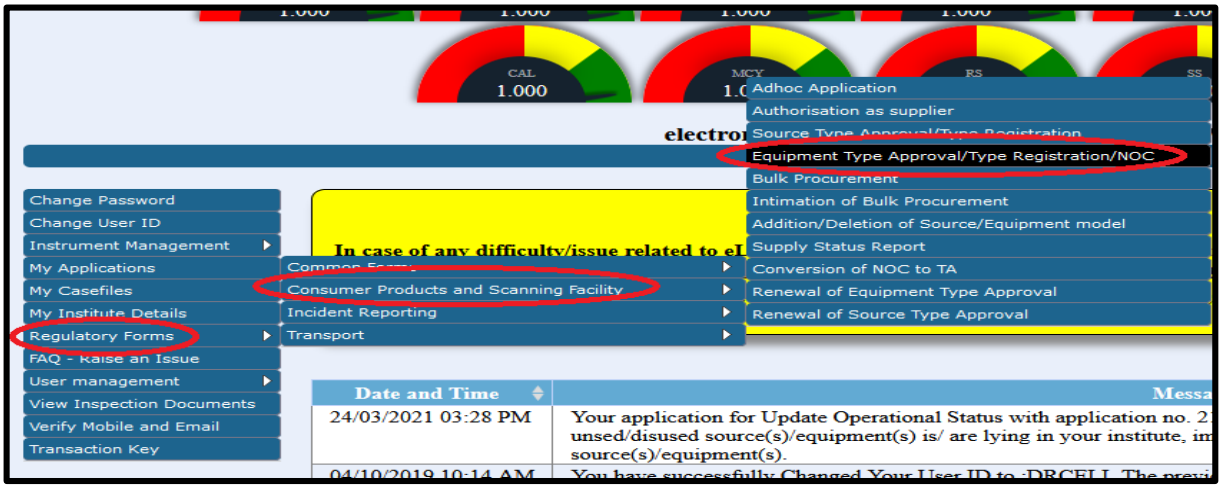




Section C: Applications for NOC/Type Approval (TA)/Renewal of TA of CP&SF

For list of documents to be submitted with the different type of application provided in Annexure-2

Step 1: Equipment Type Approval/ NOC:

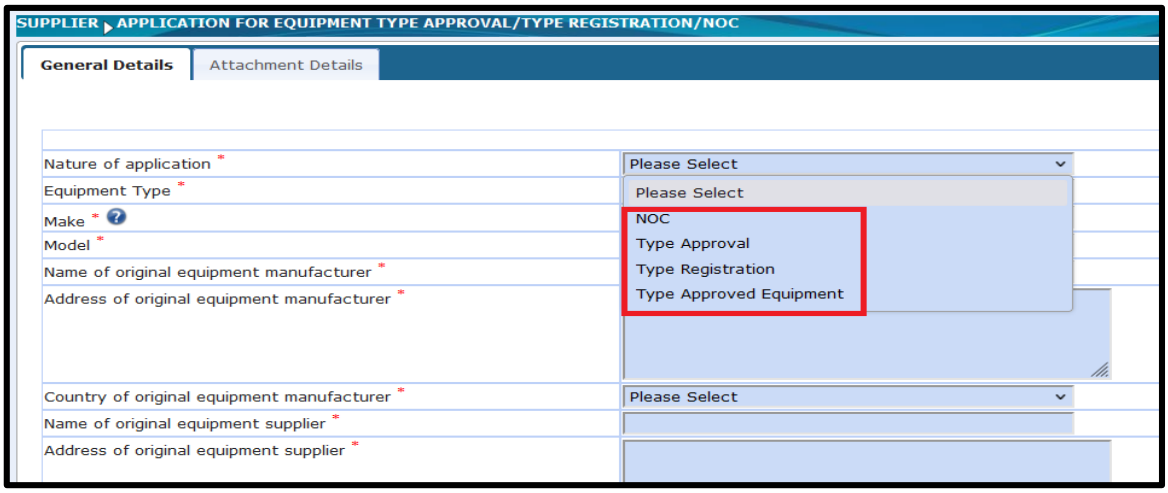


For foreign make equipment, all the suppliers are required to obtain the type approval through following path: **Regulatory Forms>Consumer Products and Scanning Facility> Equipment Type Approval/Type Registration/NOC**

(Note: Without a valid TA, end user cannot select the equipment in e-LORA)

Step-1: NOC (No Objection Certificate, applicable only for imported CP&SF equipment):

Obtain NOC after clicking the form, the below screen will appear, where you need to select the nature of application "NOC" appropriately. This form is applicable for the imported equipment (foreign make).



After complete filling of the form following documents to be attached:

1. National/International Standards to which the equipment conforms (Certificate of conformity for the device including X-ray tube, generator and monoblock - English version of CE / FDA Certificate or equivalent, preferably issued by notified/certified body)
2. Product technical details (Technical catalogue and manual of equipment as a whole)
3. Operation Manual
4. Radiation Leakage Test Report
5. OEM Authorisation for supply of Equipment
6. Technical reference table for evaluation of NOC/ Type Approval Application of self shielded X-

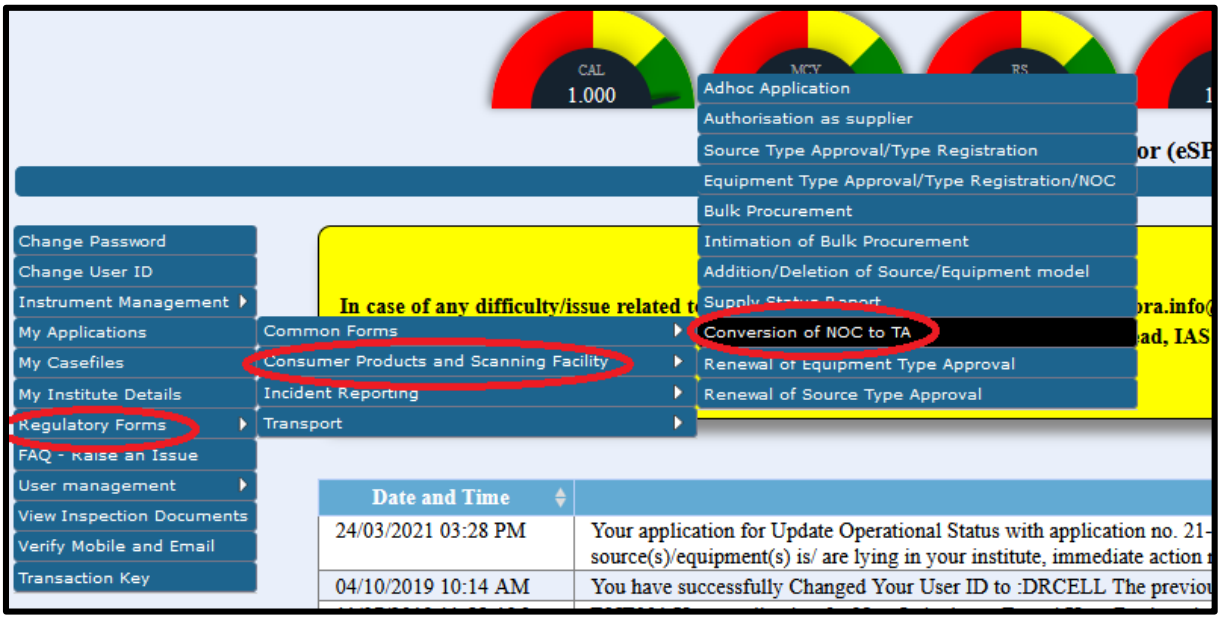
ray based equipment as per the Annexure-3.

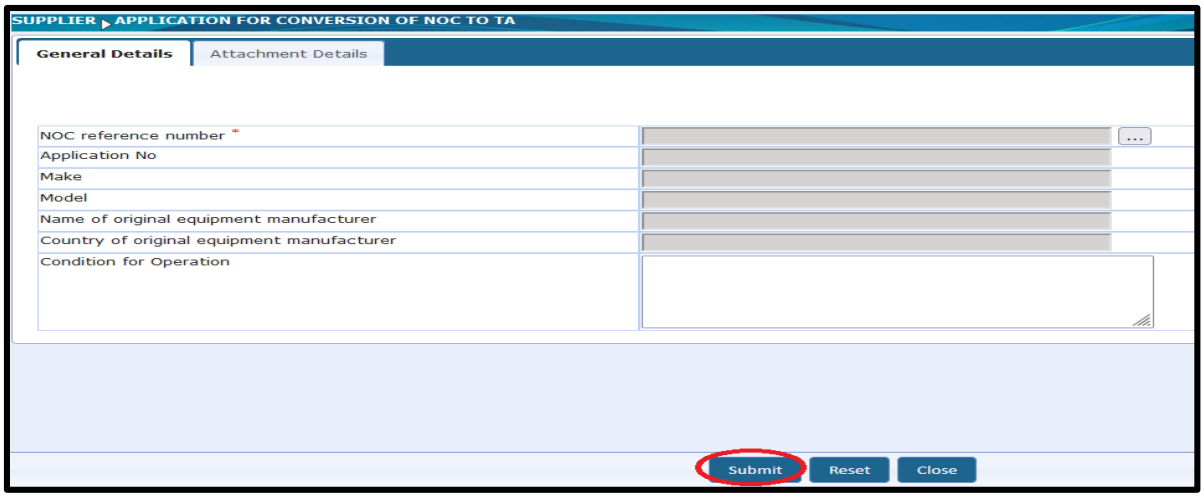
> ***Important Note:*** *After obtaining NOC, Type Approval for the equipment model (as approved in NOC) need to be applied using the form "Conversion from NOC to TA"*

Step-2: Conversion of NOC to TA:

Indian Supplier is required to apply for conversion of NOC to TA after obtaining NOC. Follow the path:

Regulatory Forms >> Consumer Products and Scanning Facility >> Conversion of NOC to TA





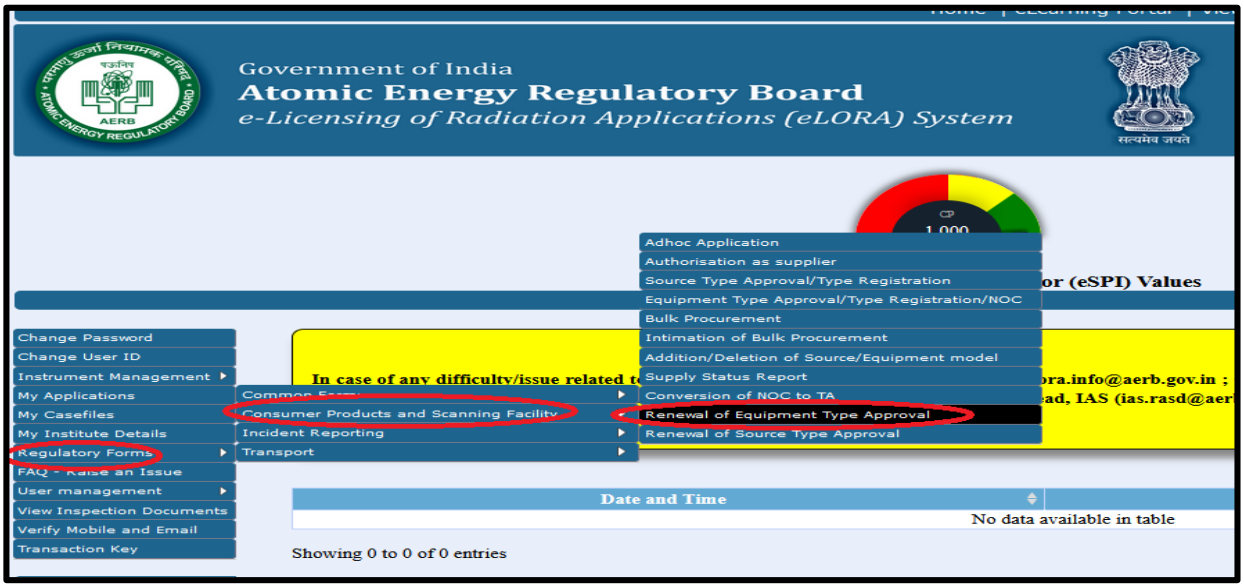
Select the NOC reference number from dropdown.

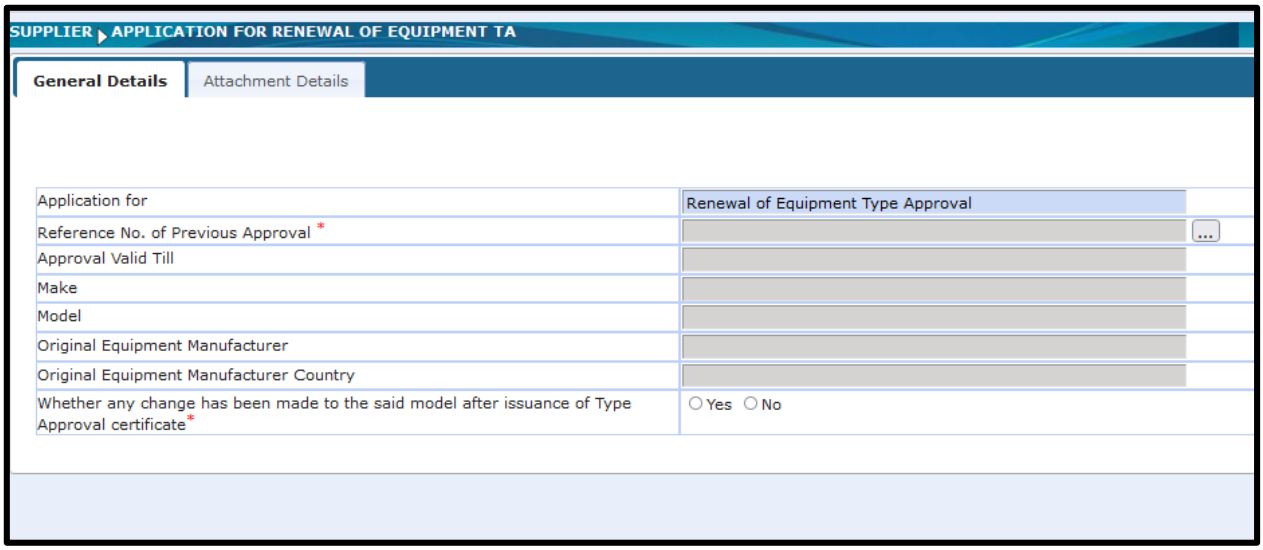
During complete submission of this form, please attach the Type approval test report in the AERB format (Available in e-LORA Help menu).

Step-C: Renewal of equipment Type Approval

Fill and submit this form to obtain renewal of type approval of equipment within 30 days of expiry of

type approval, you can fill the form
Regulatory Forms >> Consumer Products and Scanning Facility >> Renewal of Equipment Type Approval





During complete submission of this form, please attach following documents:

- Certificate from the Original Equipment Manufacturer regarding incident/accident occurred anywhere in the world while using the above model
- Submit supply details of the applied model (as per the format available in help menu.)
- Any other- operational feedback for container scanner (as per the format)

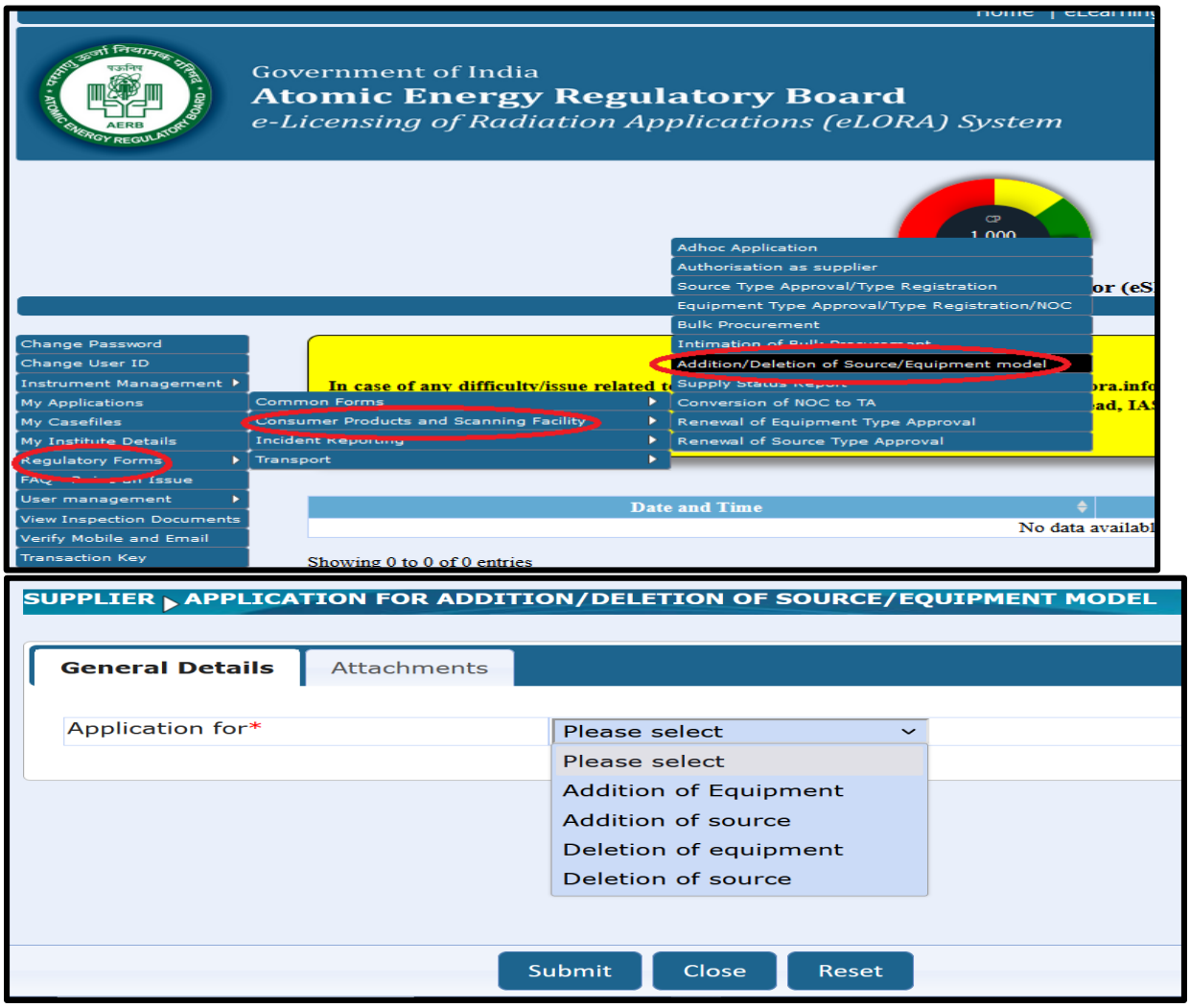
Section D: Other Processes

1. Addition/Deletion of Source/Equipment model

Kindly note that each source model/equipment model need to be register by only one supplier. If one supplier has registered the particular source model, then the other supplier importing the same source model/equipment model need not register it again, but he has to simply add the source in their account through **Addition/deletion of** Source/Equipment model.
Similarly, once one equipment is type approved then same model need not be registered again. Other

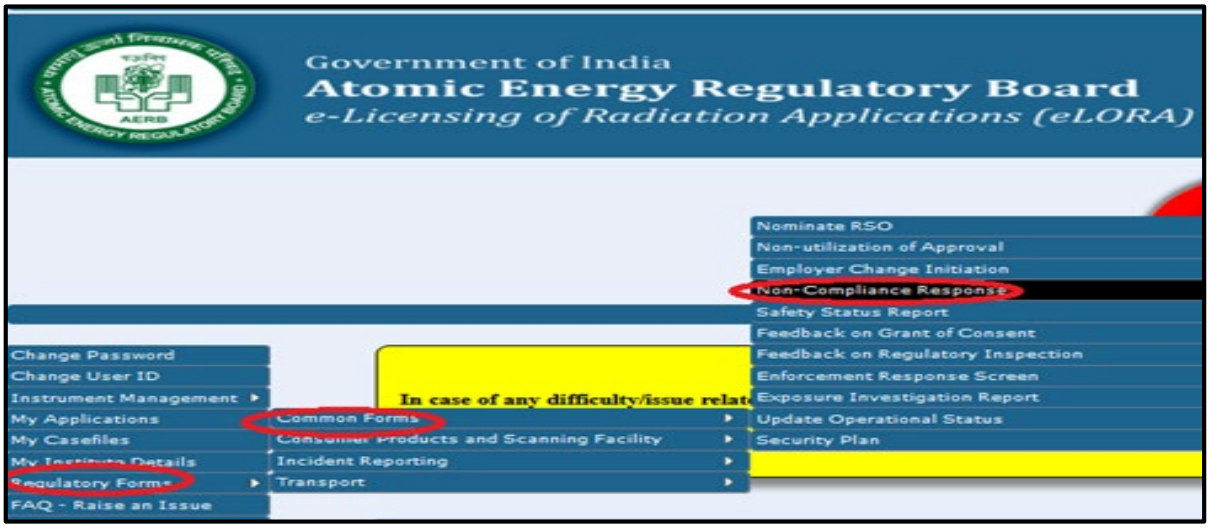
supplier can add in their e-LORA profile by following path;

Menu: Regulatory Forms >> Consumer Products and Scanning Facility >> Addition/Deletion of Source/Equipment model



No separate Approval letter is issued, but the name of the new supplier will be shown to the end user during procurement application.

2. NC response screen

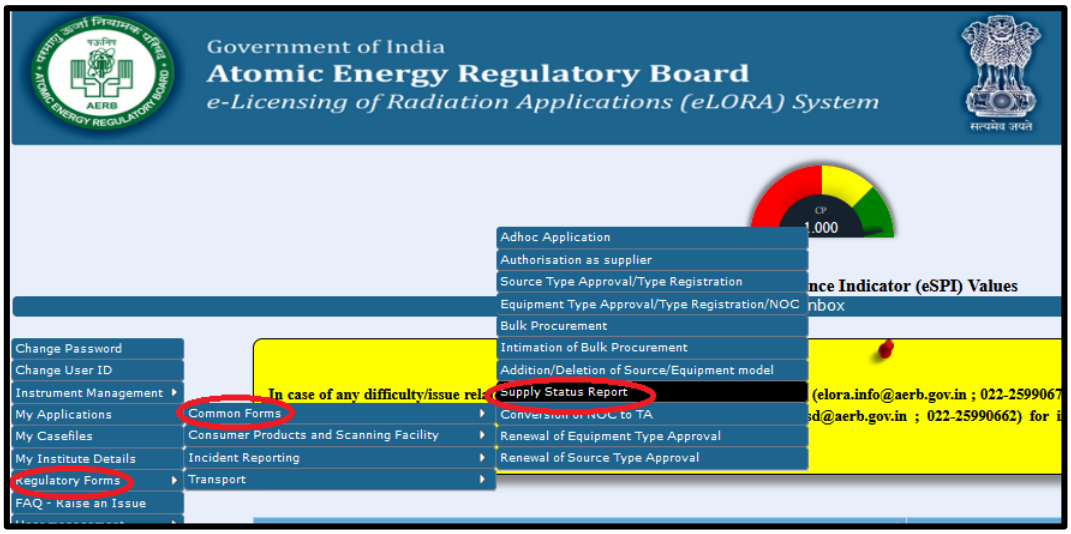


For response to the non-compliances raised through regulatory inspection, follow the path: **Regulatory Forms>> Common Forms>>Non-Complaince Response**.
You need to attach the documentary evidences against the compliance status.

3: Supply Status Report

Carry out an audit once in **annually** and submit to the Competent Authority in the safety status report. Use this form to submit safety status of your Institute. Follow following path to access this form:

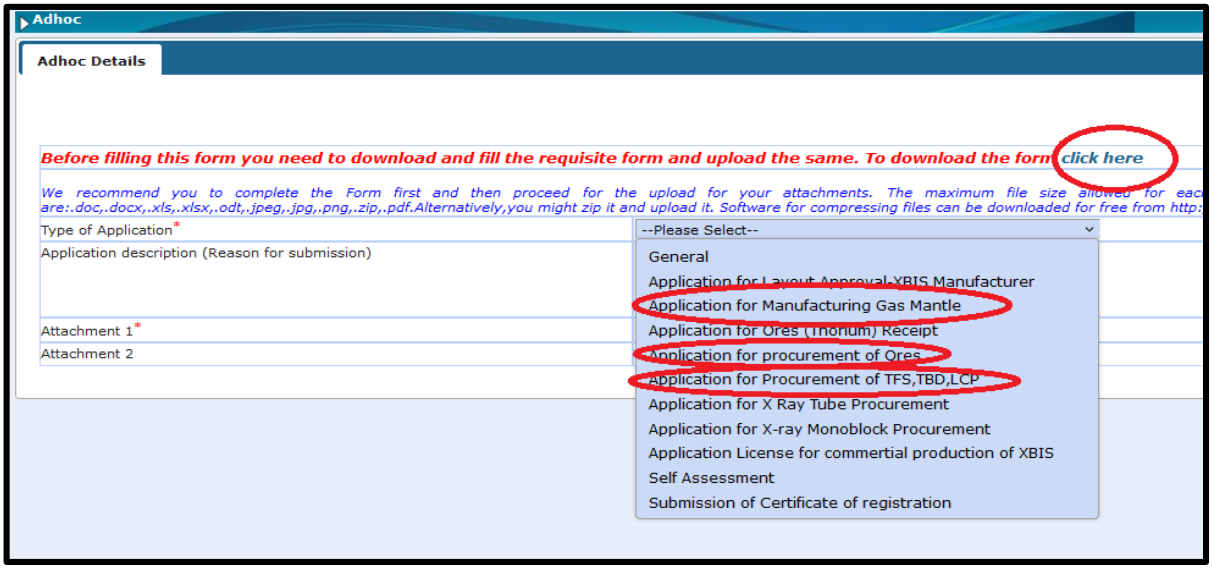
Regulatory Forms >> Common Forms >> Safety Status Report



4. Adhoc Application

a. Bulk Procurement of X-ray tube(s)

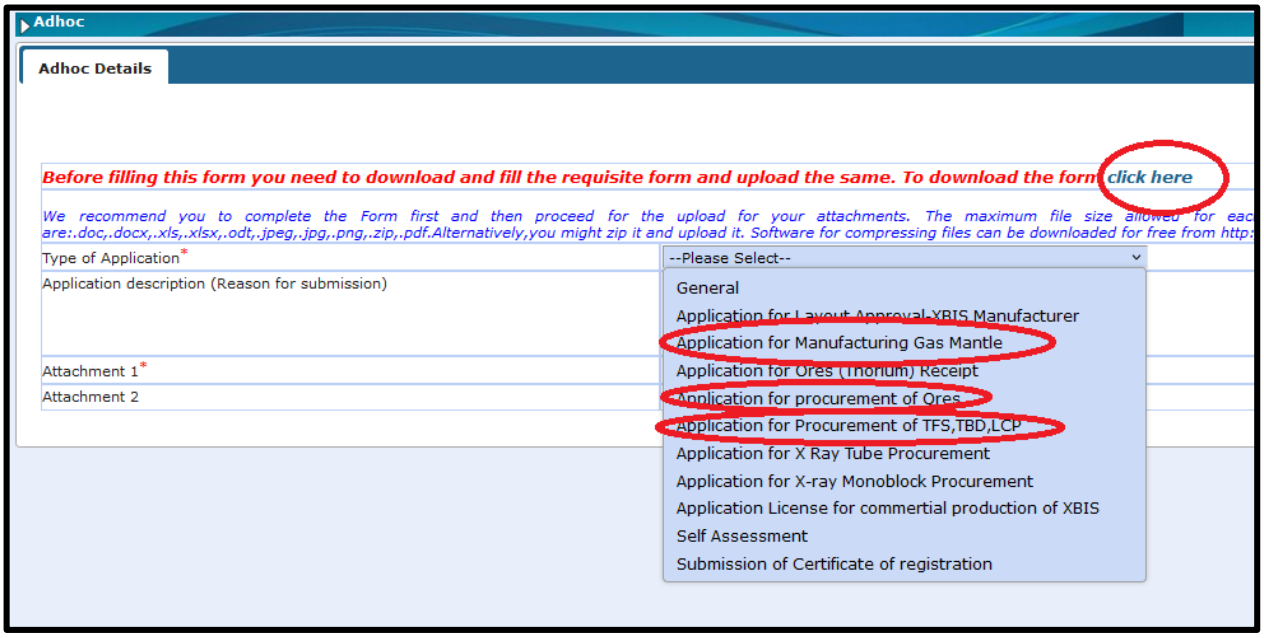
You are required to apply through, **Regulatory Forms>> CP&SF >> Adhoc application**
Submit the completely filled application (Format available in help menu) and necessary documents as mentioned.
You are hereby advised to make use of the '*Application for Bulk procurement of X-ray Tubes'* (based on the numbers as per your annual requirements) for above purposes. Also, it may be noted that the X-ray tubes procured through bulk procurement may be supplied to authorized end-users (i.e. licensed equipment) for repair/replacement, and for such activity end-users need not again obtain separate permission.



Important Note: *Procurement permission for X-ray tube will be issued only to the supplier of the equipment*

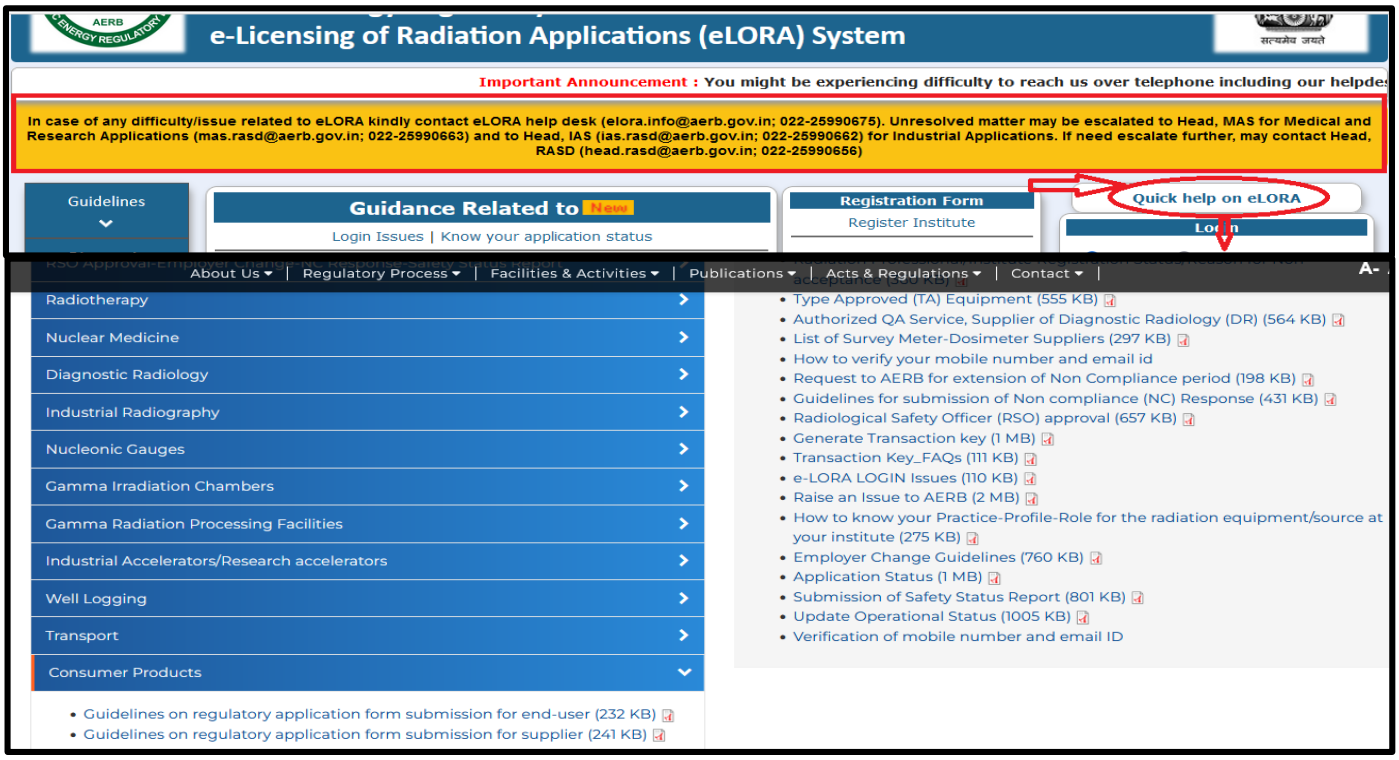
b. Authorisation for Manufacturing Gas Mantle:

You are required to apply through, Regulatory Forms>> CP&SF >> Adhoc application
Submit the completely filled application



More Information:

I. **For more details click on "Quick help on eLORA"**



II. **In case, issue persist, pl. submit the problem through 'Raise an issue' option of e-LORA system**

III. **You contact us at following Help Desk Number**

Help Desk No. and Email id

022-25990675 & elora.info@aerb.gov.in

Important Message

NO LICENSE FEE /PROCESSING FEE BY AERB

It may please be noted that at present AERB does not charge any fee for issuance of regulatory consents including License or Registration. In case anybody demands for payment to be made to AERB or any of its officials, kindly provide all the details to:

The Vigilance Officer,
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar,
Tel: 022-25990611
Email: vigilance@aerb.gov.in

Annexure-1

Annexure-1: Details of Radiation Safety Certification Courses

Sr. No.	Practice	Minimum Eligibility Criteria	Training Course in which candidates will be inducted
1	Manufacturer/Supplier/Radiation Facilities of Container/Vehicle Scanners	Basic degree in Science or equivalent from a recognized University/Institution Or Diploma in Engineering from a recognized University/Institution	RSO Certification for Scanning Facilities **(Seven working days)**
2	Manufacturers/ Suppliers of X-ray Inspection Equipment such as • X-ray Baggage Inspection System, • X-ray Diffractometer (XRD), • X-ray Fluorescence (XRF) Device, (Cabinet /Hand-held) • X-ray based PCB Analyser, • X-ray based Food Scanner, and • Portable X-ray Scanner etc.		Radiation Safety and Quality Assurance of Diagnostic X-ray Equipment with special lecturers on radiation safety and regulatory requirements of X-ray Inspection Equipment **(Five working days)**
3	Manufacturers/Suppliers of analytical equipment incorporated with radioactive source(s) such as • Smoke detectors, • Tritium based devices, • Electron Capture Detector, • Ion Mobility Spectrometer, & (Chemical/Explosive/Narcotic Detectors) • Radioactive source based XRF etc.		RSO Certification for Nucleonic Gauges and Well logging Applications with special lecturers on radiation safety and regulatory requirements of radioactive source based analytical equipment. **(Five working days)**
4	Manufacturers of Gas Mantles & Fluorescent Lamp Starters	10+2 science or equivalent examination passed from a recognized Board/ University	RSO Certification for Gas Mantles & Fluorescent Lamp Starters Manufacturing Facility **(Five working days)**

- Complete syllabi of above courses are available at AERB website at following link: (https://www.aerb.gov.in/images/PDF/Complete_amended_syllabi_document.pdf)
- The courses are conducted by Radiological Physics and Advisory Division (RP&AD, Bhabha Atomic Research Centre (BARC), CT&CRS Building, Anushaktinagar, Mumbai-400094

• For further information related to courses (Sr. Nos. 1,3 &4), **please contact**: Dr. T. Palani Selvam Head, Computational Radiation Physics & Quality Assurance Section, RP&AD,BARC **Phone (Off):** 022-69298653 **e-mail:** pselvam@barc.gov.in	• For further information related to course (Sr. No. 2), **please contact**: Dr. Sunil Dutt Sharma Head, Medical Physics Section, RP&AD,BARC **Phone (Off):** 022-69298713 **e-mail:** sdsharma@barc.gov.in

Annexure -2

Documents to be submitted along with NOC, NOC-Type Approval & Type Approval applications

- Practice: Consumer Products
- Type of Equipment: **X-ray Inspection System** [X-ray Baggage Inspection System, X-ray Diffractometer, X-ray Fluorescence Device (cabinet /hand-held), PCB Analyser, Food Scanner, Portable Scanner etc.]
- Institute Role: Suppliers
- Installation Type: Supplier-CP Facility

Sr. No.	NOC (Imported Equipment)	NOC to Type Approval	Type Approval (Indian Manufacturer)	Renewal of Type Approval
1.	Product Technical Details	Type Approval Test Report of X-ray Inspection Equipment (As per format)	Product Technical Details	Supply Report (As per format)
2.	Operation Manual		Operation Manual	Certificate from the Original Equipment Manufacturer regarding incident/accident occurred anywhere in the world while using the above model
3.	Radiation Leakage Test Report		National/International Standards to which the equipment conforms	
4.	OEM Authorisation for Supply of Equipment		Type Approval Test Report of X-ray Inspection Equipment (As per format)	
5.	National/International Standards to which the equipment conforms		Summary Sheet and Technical Specifications Comparison Sheet for X-ray Inspection Equipment (As per format)	
6.	Summary Sheet and Technical Specifications Comparison Sheet for X-ray Inspection Equipment (As per format)			

- Practice: Consumer Products
- Institute Role: Suppliers
- Installation Type: Supplier- **Vehicle Scanner**

Sr. No.	NOC (Imported Equipment)	NOC to Type Approval	Type Approval (Indian Manufacturer)	Renewal of Type Approval
1.	Product Technical Details	Type Approval Test Report	Product Technical Details	Supply Report (As per format)
2.	Operation Manual		Operation Manual	Certificate from the Original Equipment Manufacturer regarding incident/accident occurred anywhere in the world while using the above model
3.	Radiation Leakage Test Report		National/International Standards to which the equipment conforms	Operational Feedback (As per format)
4.	OEM Authorisation for Supply of Equipment		Type Approval Test Report	
5.	National/International Standards to which the equipment conforms			

Annexure-3

Technical Reference Table for evaluation of NOC/ Type Approval Application of X-ray based Self-shielded Equipment

[Application may be liable for rejection if this sheet is not attached]

Sr. No.	Attribute/ Parameter(s)	Specification	Attach document and specify the page no. for reference with relevant portion highlighted	Remarks, if any
1.	Maximum operating voltage (kV) of the Equipment			
2.	Maximum operating current (mA) of the Equipment			
3.	Maximum Generator Power of Equipment (kW)			
4.	Number of X-ray tubes in the equipment			
5.	Model Name of X-ray tube(s)			
6.	Maximum Tube Potential (kV) of the mentioned X-ray tube (Pl. write both values if two tubes are used)			
7.	Maximum Tube Current (mA) of X-ray tube (Pl. write both values if two tubes are used in the equipment)			
8.	Maximum Power of X-ray Tube (kW)			
9.	CE /IEC certificate or country of origin certificate or equivalent **mentioning model name** of applied equipment			
10.	Radiation leakage at 10 cm from any accessible surface of the equipment **Permissible limit: 1 µSv/hr.**			
11.	For Portable Scanner: Value of dose per scan at 30 m distance in front of portable scanner without placing any object and imager **Permissible limit: 5 µSv/ scan**			
12.	Type of detector			
13.	Size of detector			
14.	Number of detectors			
15.	Type of shielding material			

16.	Thickness of shielding material			
17.	**Whether operating modes are only selectable by the operator (pre-set kV and mA) or any kV and mA can be set/selected by the operator			For more details please check Note:2
18.	Availability of other safety features in the unit			
	a. details of safety interlocks			
	b. details of emergency stops			
	c. details of X-ray warning indicators			
	d. details of X-ray caution symbol			
	e. details of key controlled operation			
19.	Any Special features available in the unit/any other details			

Note:

1. Kindly furnish the above information/technical data with the application for Equipment NOC/ Type Approval. Wherever it is not applicable ***'NA'*** may please be mentioned. ***Mention specification instead of mentioning refer the attached document(s) or manual(s).** CE/equivalent certificate and test reports need to be signed. All the attachments with regard to e-LORA application are not mandatory and kindly do not submit the same document multiple times.
2. If the operating parameters can be changed by the operator, then please mention, in the application, the highest kV and mA that can be set by the operator. If the operator cannot change the operating parameters, then please mention the maximum preset operating kV and maximum preset operating mA in the application.
3. **If NOC or Type Approval is already obtained with similar model, please attach Technical Specifications Comparison Sheet available in Help menu of eLORA system.**

Date: Signature:
Place: Name of Licensee: