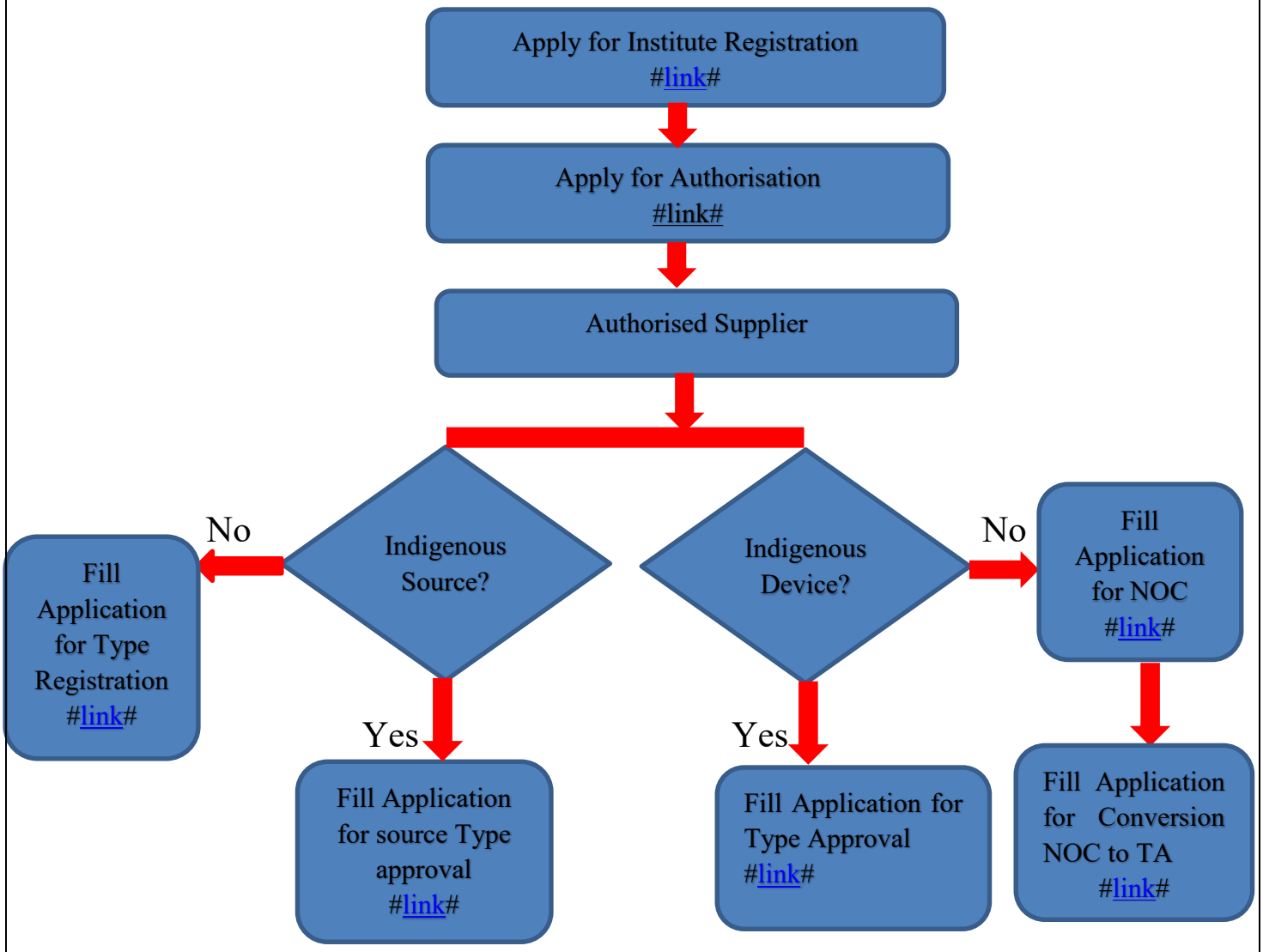
e-LORA Guidelines for Supplier of Nucleonic Gauge Devices/Sources

Radiation Applications Safety Division
AERB, Mumbai
May, 2024


Apply for Institute Registration
#link#
Apply for Authorisation
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Authorised Supplier
Indigenous Source?
No
Fill Application for Type Registration
#link#
Yes
Fill Application for source Type approval
#link#
Indigenous Device?
No
Fill Application for NOC
#link#
Yes
Fill Application for Type Approval
#link#
Fill Application for Conversion NOC to TA
#link#

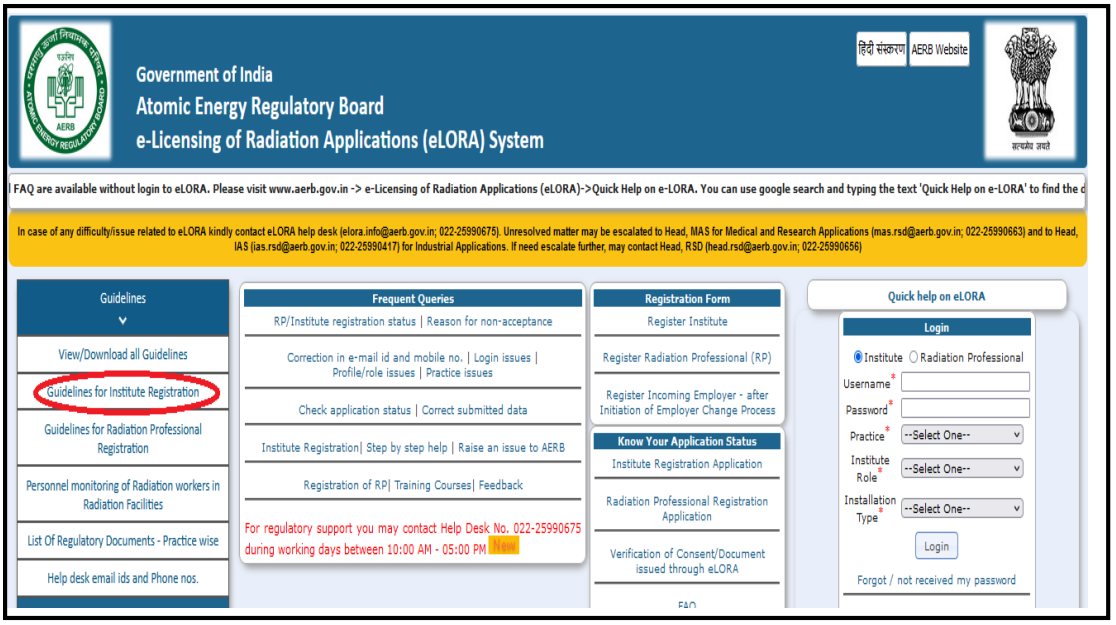
Regulatory Processes in e-LORA for Supplier of Nucleonic Gauge (NG) Source/Equipment

Steps	Purpose	Regulatory Form/Regulatory Processes	Page	Reference
Section A: Authorisation of Supplier for NG device				
Step 1	Registration of Institute in to eLORA System	Register Institute	3	Click here
Step 2	Declaration of Safety Infrastructure			
2a	Declare Trained man power	Nominate Employee	3-4	Click here
2b	Declaration of Radiation Monitoring and emergency handling tools details	Add Instrument	4-5	Click here
2c	Obtaining RSO approval	Nominate RSO	5-6	Click here
Step 3	Obtaining authorization for supplier of NG device	Authorisation as supplier	6-7	Click here
Section B: Applications for Type Registration/Type Approval (New/Renewal) NG Source				
Step 1	Obtaining Source Type Approval/Type Registration	Source Type Approval/Type Registration	7-8	Click here
Step 2	Obtaining renewal of Source Type Approval	Renewal of Source Type Approval	9-10	Click here
Section C: Applications for NOC/Type Approval (TA)/Renewal of TA of NG device				
Step 1	Obtaining Equipment Type Approval/Type Registration/NOC	Equipment Type Approval/NOC	10-11	Click here
Step 2	Obtaining TA conversion	Conversion of NOC to TA	11-12	Click here
Step 3	Obtaining renewal of Equipment Type Approval	Renewal of equipment Type Approval	12	Click here
Section C: Other Processes				
1	For Addition/Deletion of Source/Equipment	Addition/Deletion of Source/Equipment model	13	Click here
2	Non-compliance response	NC response screen	14	Click here
3	Supply report	Supply Status Report	15	Click here
6	Unusual incident reporting	a. Incident Information Report b. Incident Update Report c. Incident Investigation Report	16-17	Click here Click here Click here
7	Frequently Asked Question (FAQ)		18-23	Click here
****Note: Guideline on Regulatory Processes in e-LORA for Transport is available in "Help" menu of your e-LORA account**				

Section A: Authorisation of Supplier for NG device

Step-1: Register Your Institute

Visit our website www.aerb.gov.in. Click on the button **e-LORA,** which is available on website home page. Then click on "Go directly to e-LORA System" and "Click to proceed for e-LORA server". It will redirect you to the following screen of **e-LORA home page** and then click on application form "Register Institute" to proceed for registration in e-LORA.



Step 2. Declaration of Safety Infrastructure

Prior to apply for Authorization complete the requisites as follows

- Add Employee: Declaration of qualified and trained personnel (Radiation professional) in e-LORA
- RSO approval: Obtain RSO (Radiological Safety Officer) approval through e-LORA.
- Add Instrument: Declaration of monitoring tools as per regulatory requirement in e-LORA prior to apply for Authorisation.

2a. Nominate Employee

For supplier of NG equipment, at least one Radiation safety professional and RSO (Radiological Safety Officer) should be avilable.For adding employees to your institution, please follow the path as:

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

(Qualification required for radiation safety professional is provided in Table-1 below)

Once a Radiation safety professional gets registered as RP, his/her name will be included in eLORA in the list of RPs (which will be available for selection to the institution for Add Employee). For

adding employees to your institution, follow the path as:

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

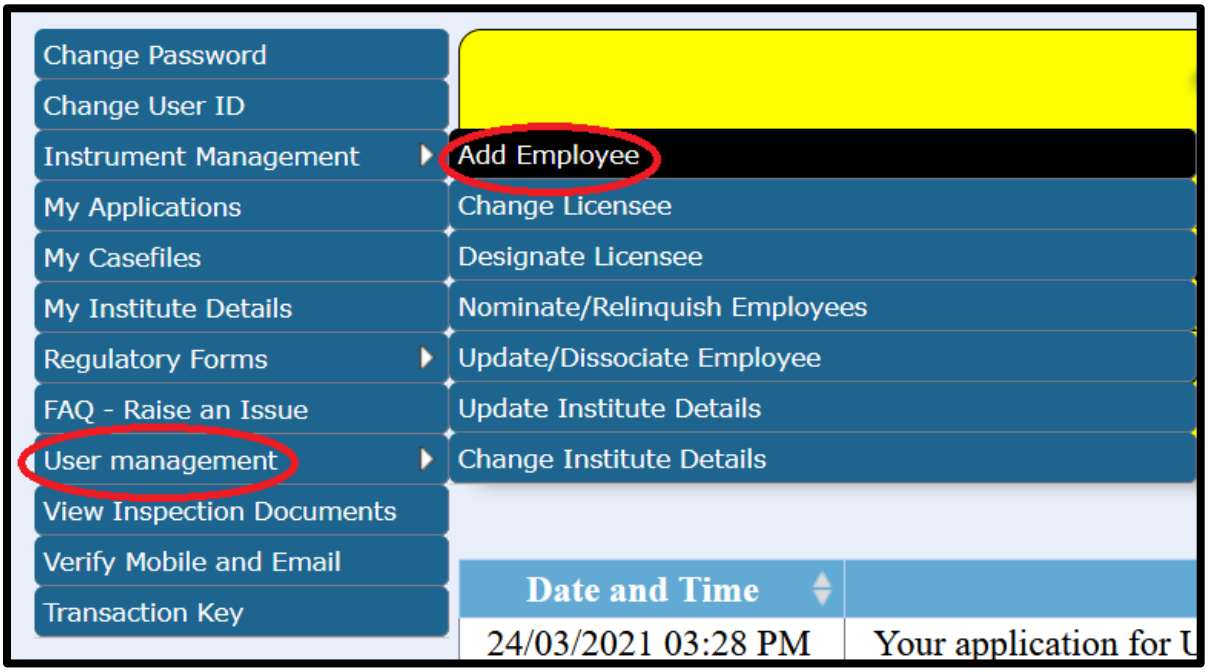


Table-1

Role	Basic Qualification	Professional Qualification
Radiation Safety Professional	• Diploma/Degree in Engineering • B.Sc. • B.E. • B. Tech	➢ Training Course on Radiation Safety Aspects of Nucleonic Gauges ➢ Training Course on Safety Aspects in the Erection & Maintenance of Nucleonic Gauges ➢ Training Course on Radiography Testing Level-1 (RT-1) ➢ Training Course on Radiography Testing Level-2 (RT-2) ➢ Training Course on Industrial Radiography and Safety Aspects (IRG-1) ➢ Certification by BARC as Site -In- Charge ➢ Post M.Sc. Diploma in Radiological Physics (Dip. R. P.)

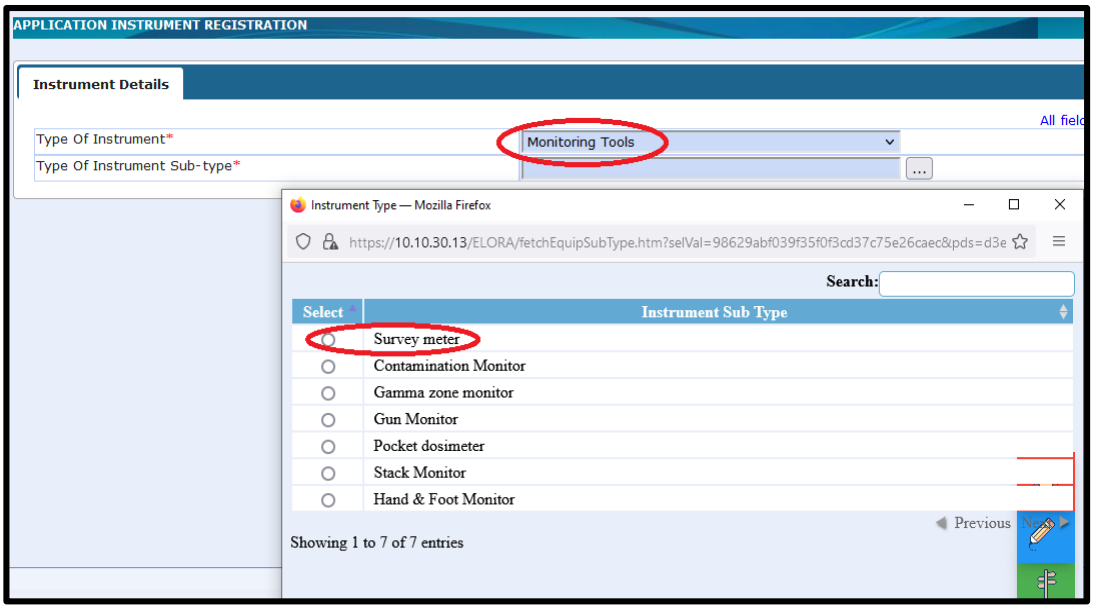
2b. Add Instrument

Supplier must have certain types of safety tools and the same must be declared in eLORA. Hence please add the instrument in '***Safety Tool'*** option.

Emergency handling tools like source storage container needs to be declared in e-LORA.

To declare instruments, follow the path as:

Menu>>>Instrument Management>>>Add Instrument



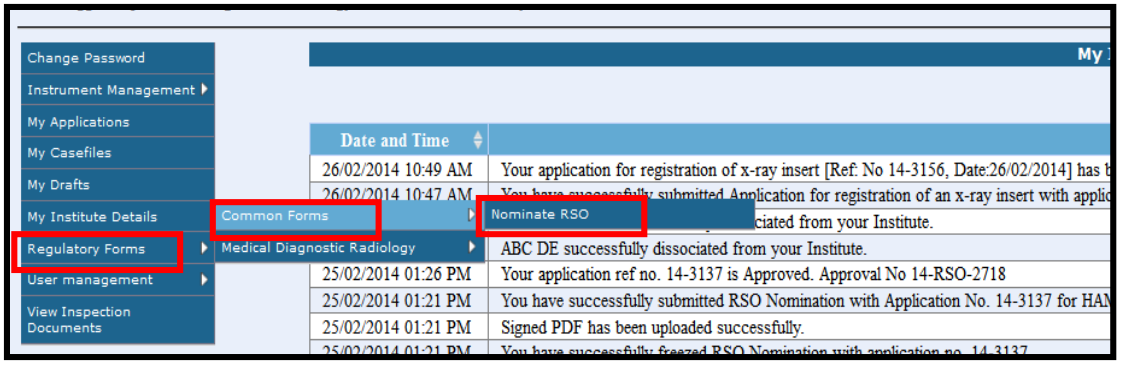
Add appropriate radiation survey instrument in the instrument management (suitable for the X-ray energy under reference and shall measure background radiation levels- resolution shall be at least 0.01µSv/h). Please mention only those applicable monitoring instruments i.e, survey meter, which is having a valid calibration certificate from accredited laboratory.

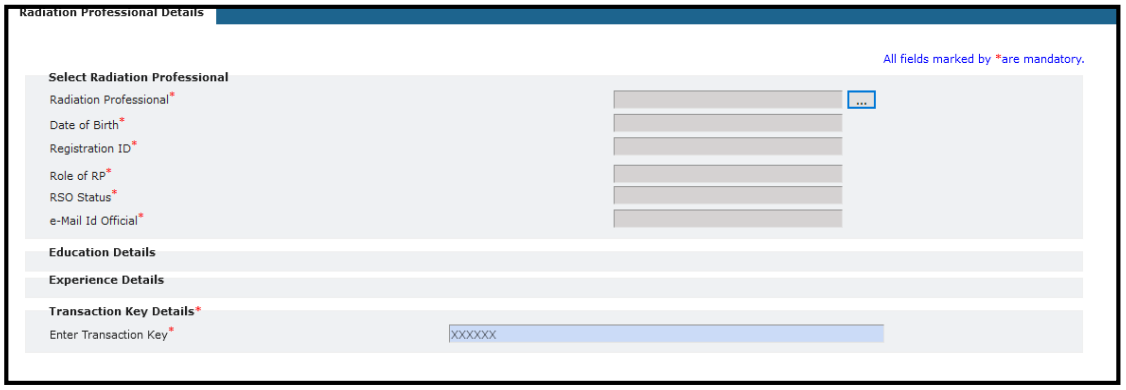
2c. Obtain RSO Approval

For nominating your employee for RSO approval if you are in possession of radioactive sources, follow the path as:

Path-a: For a person required to be nominated as RSO, you need to add him/her in the type **Radiation Professional (RP).** The detailed guideline for RSO approval is available in help menu. For submitting the application, an OTP based transaction key needs to be provided by the applicant. The Procedure for Transaction Key Generation for RSO application submission.pdf is available in help menu of your e-LORA account. You can access the RSO application by following path

Regulatory Forms>> Common Forms>>Nominate RSO





For submission of RSO nomination application form, fill the generated the transaction key and then nominate. Your RSO nomination form will be reviewed by AERB and after acceptance; you will get its notification in your e-LORA account. Further detailed guideline is available in https://www.aerb.gov.in/images/PDF/RSO-eLORA-guidelines.pdf.

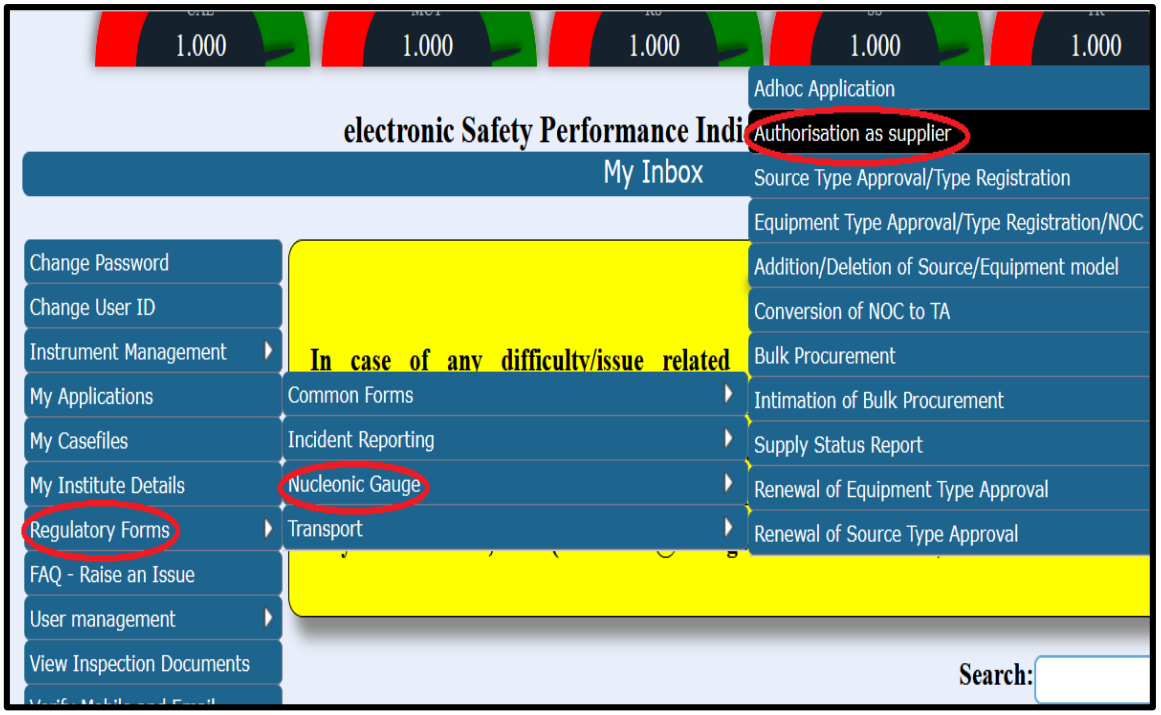
Note:

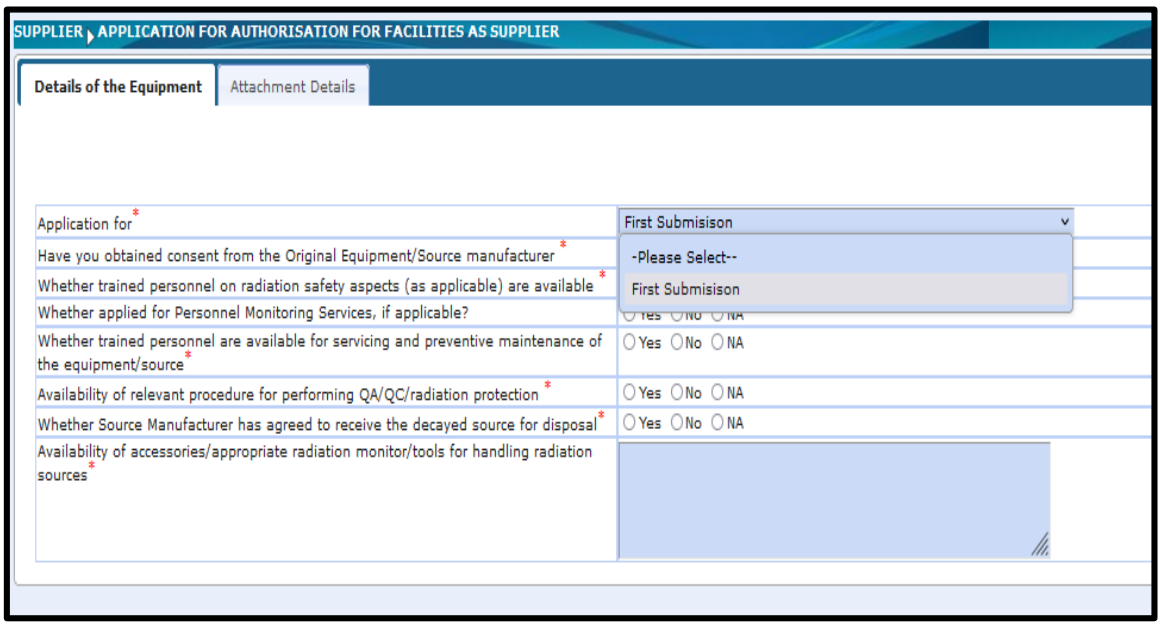
For Suppliers, radiation workers (such as service engineers who are working close to the source) are to be provided with personnel monitoring badges and their radiation dose records should be maintained as specified in AE(RP)R, 2004.

Step 3: Application for Authorisation as supplier

Following is the path for Supplier Authorization.

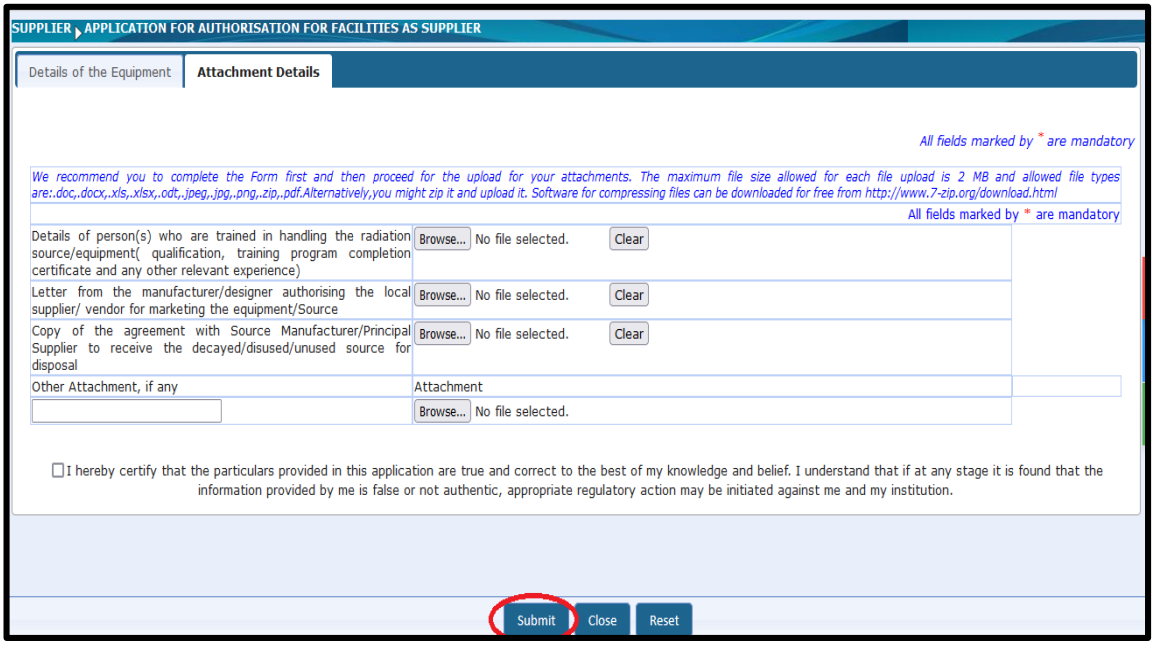
Regulatory Forms>Nucleonic gauge>Authorisation of Supplier





Select the applicable fields such as “First Submission”, and attached the necessary documents such as

- letter from the manufacturer/designer authorizing the local supplier/vendor for marketing the equipment/source,
- copy of agreement with source manufacturer/principal supplier to receive the decayed /disused/unused source for disposal



After completing the filling of the form, you wish to submit application form.

Section B: Applications for Type Registration/Type Approval (New/Renewal) NG Source

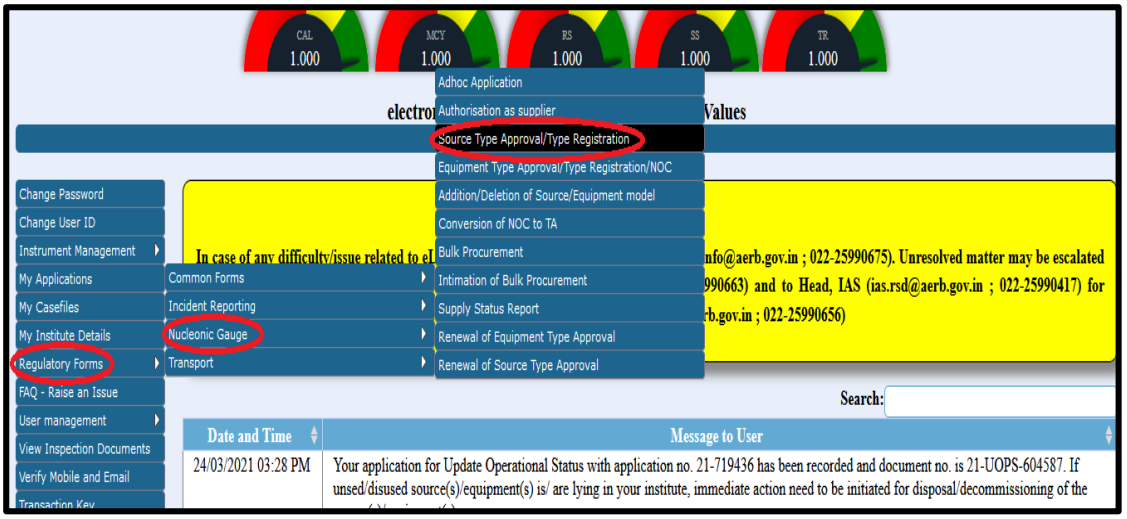
Note:

1. Indian Manufacture should obtain source type approval

2. For imported sources, the Indian supplier should obtain source Type Registration

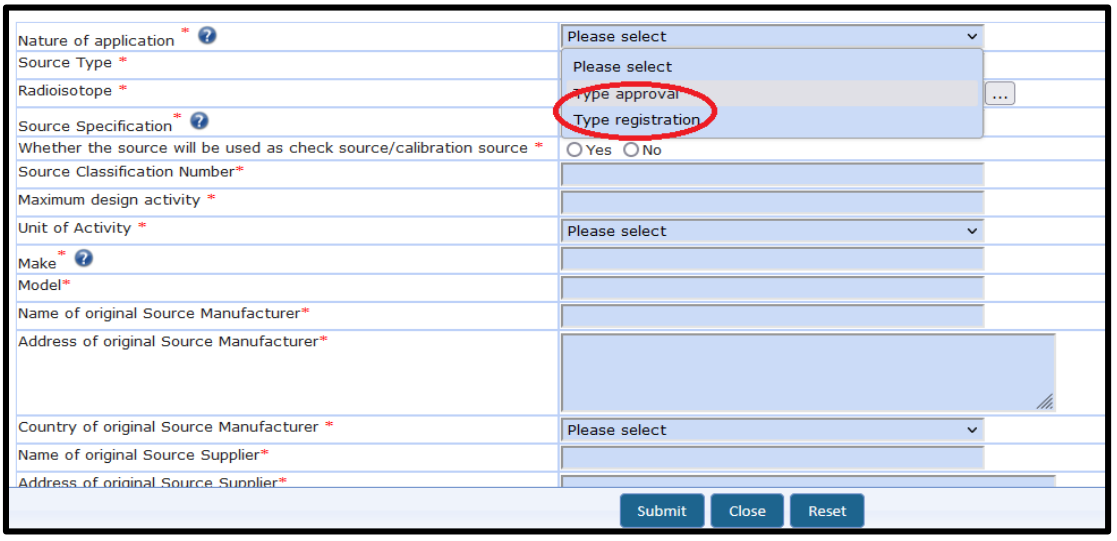
Step 1: Source Type Approval/Type Registration:

After supplier authorization, you are required to register the radiation sources through Type Registration process. Following is the path:



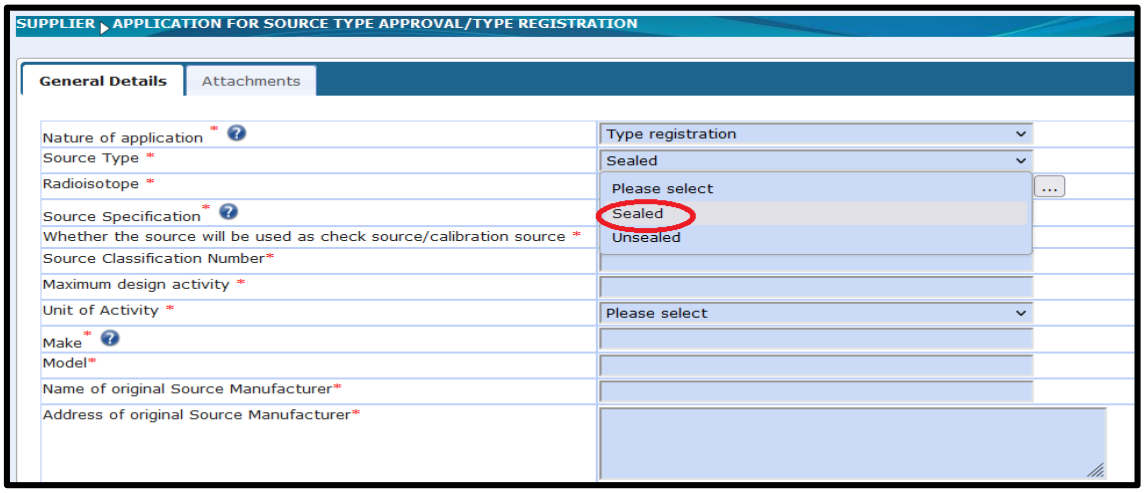
Regulatory Forms>Nucleonic gauge>Source Type Approval/Type Registration

After clicking on the form, following screen will appear. Choose nature of application as "Type registration" and filled the applicable details and submit.



Note:

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



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 (ANSI/ISO etc.) 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 5 cm, leak test certificate/report, Accident Condition (Fire Temperature, Duration),
- Approval Certificate of the NG source from the competent authority of country of origin, if any

Step 2: Renewal of Source Type Approval

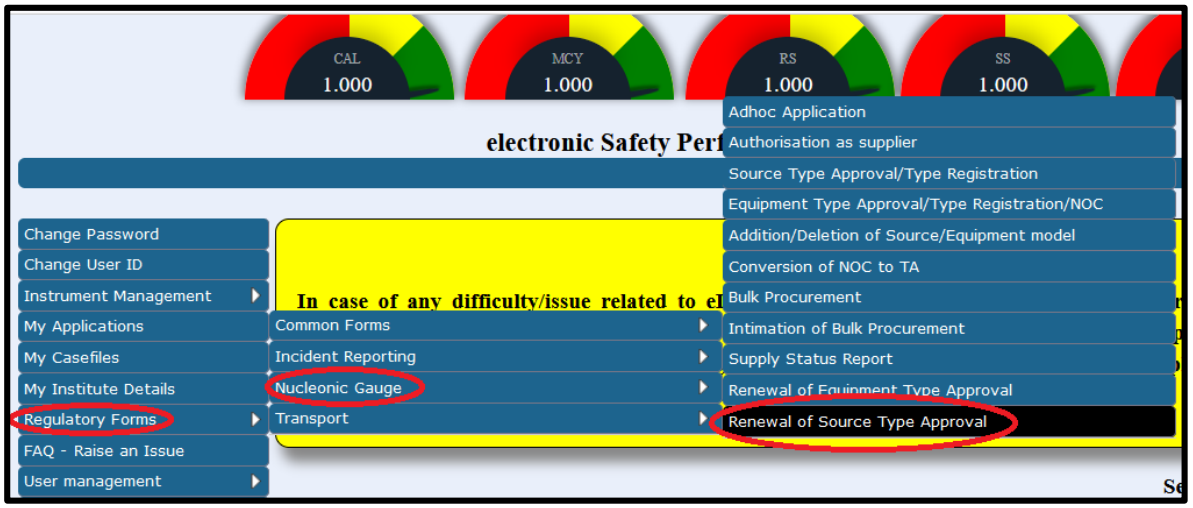
Note:

Renewal of Source Type Approval (design approval) is applicable for the indigeneous sources(s) i.e. manufactured in India.

Fill and submit this form to obtain renewal of type approval of equipment. Application of the renewal should be submitted well in advance prior to the date of expiry. Within30 days of expiry of

your approval, you can fill the form

Regulatory Forms >> Nucleonic Gauge >> Renewal of Source Type Approval



Section C: Applications for NOC/Type Approval (TA)/Renewal of TA of NG device

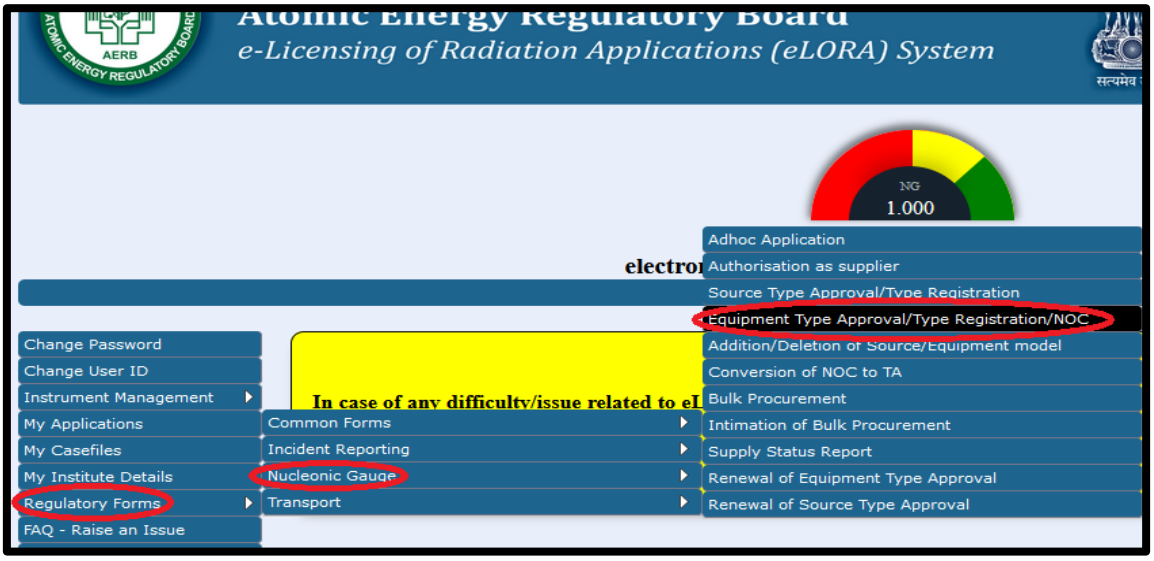
Note:

Prior to applying for NOC/ Type approval of the new NG device with source, supplier should ensure that get the Type Approval/Type Registration for Source is approved in e-LORA (to enable the source to be tagged to the new NG device).

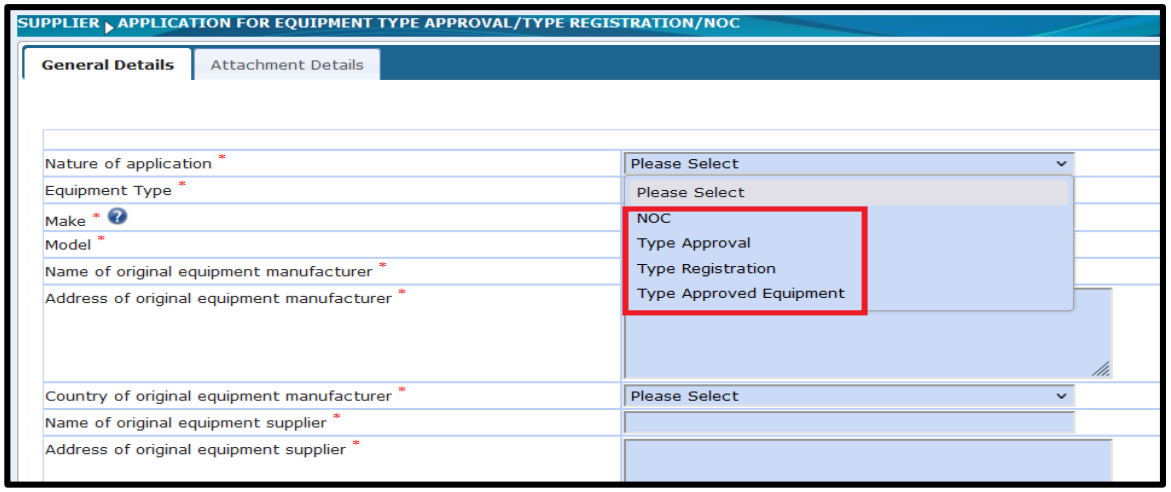
Step 1: Equipment Type Approval/ NOC:

To facilitate the end user to select the NG model in import/procurement application, all the manufacturers/suppliers are required to obtain the type approval of the NG device through following path:

Regulatory Forms>Nucleonic gauge> Equipment Type Approval/Type Registration/NOC



Step-A: NOC (No Objection Certificate, applicable only for imported NG device): 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 equipments not manufactured in India.



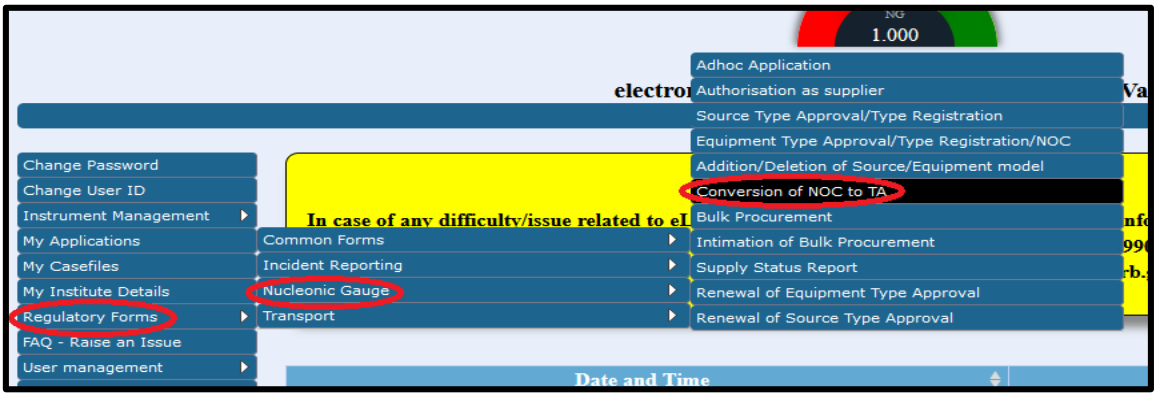
Certificates based on ISO, ANSI, other national standards for country of origin should be provided in support of application to obtain 'NOC' or Type Approval of NG Equipment (Associated Equipment/Radiation Generating Equipment). Further submit technical reference table for evaluation of NOC/ Type Approval Application of Nucleonic Gauge (NG) equipment as per the Annexure-1.

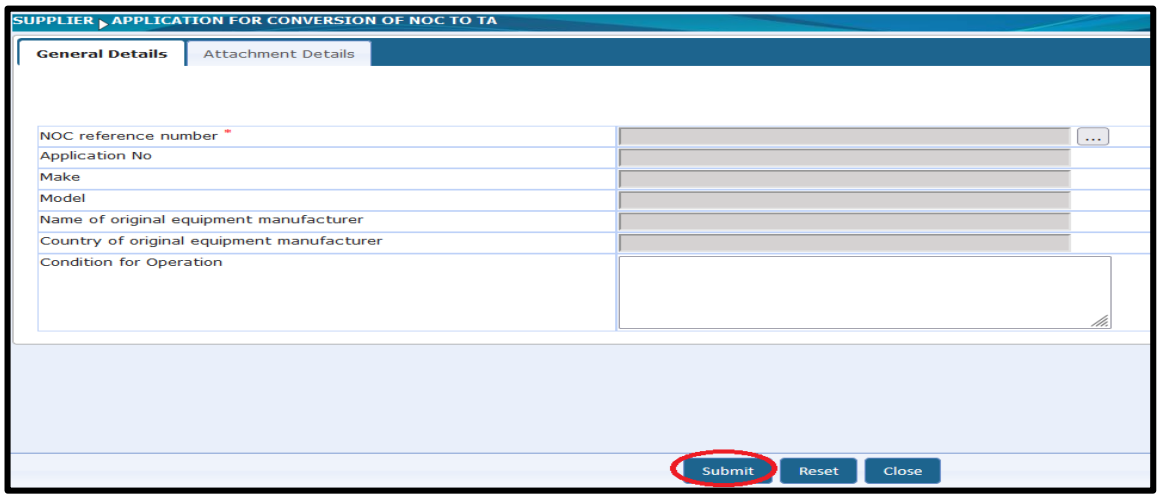
After obtaining the NOC, Type Approval for the equipment model (as approved in NOC) need to be applied using the form "Conversion from NOC to TA"

Step-B: 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 >> Nucleonic Gauge >> Conversion of NOC to TA





Select the NOC reference number from dropdown.

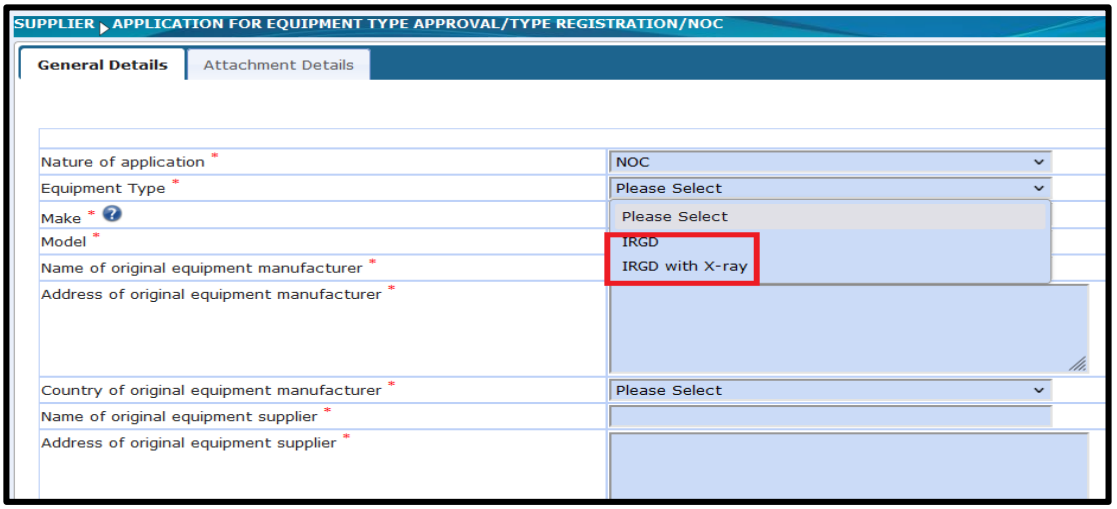
During complete submission of this form, please attach following documents:

- Type approval test report in the AERB format (Available in Help).
- Installation report
- Customer Acceptance Report
- Comparison sheet in AERB format, if similar model is already.

1) Latest MoU with the OEM regarding receipt of disused sources 2) Availability of transport container in case of emergency 3) List of institutions wherein devices have been supplied 4) Report on unusual incident, of any, with the device 5) Letter from OEM with regards to change in design, if any, in the approved model.

Type Approval: This form is applicable for the equipment's manufactured in India. NOC form is not applicable for the equipment's manufactured in India.

After selecting the nature of application, appropriately select the type of equipment IRGD or IRGD with X-ray based on your NG device.



If selected as IRGD then during complete submission of this form, please attach following documents:

- Design drawing of the Gauge (source housing/ holder)
- Performance Test Results as per AERB Standard AERB/SS-2 or equivalent International Standard (certificate on compliance with National / International Standards, issued by Competent Authorityfrom country of origin should be submitted)
- Certification of Type of Package (Type-A registration Cert. / Type B approval cert., as Applicable)
- Source Removal / retrieval Procedure
- Product technical catalogue
- Quality Assurance (QA) Manual of the IRGD
- List of countries where such IRGDs have been supplied by the manufacturer
- Manual for installation / servicing / maintenance / disposal / emergency
- OEM (Original Equipment Manufacturer) authorization certificate issued to Supplier of the IRGD model (if supplier is other than OEM)
- OEM (Original Equipment Manufacturer) undertaking issued to the supplier for take-back of the disused sources for disposal.

If selected as IRGD with X-ray then during complete submission of this form, please attach following documents:

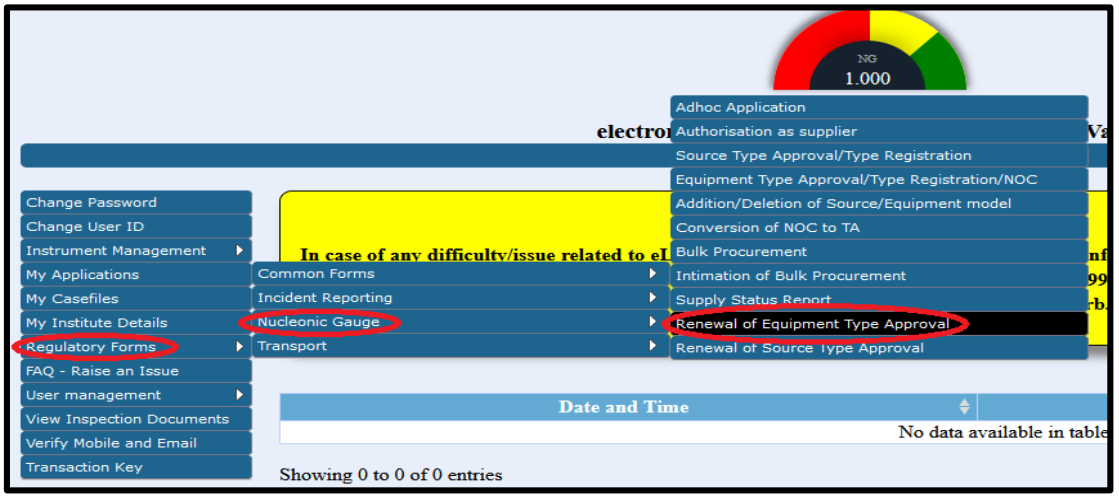
- Certificate of conformity for the device including X-ray tube, generator and monoblock - English version of CE / FDA Certificate or equivalent, preferably issued by notified/certified body.
- Design certification from Competent Authority of country of origin with respect to radiological safety, as applicable.

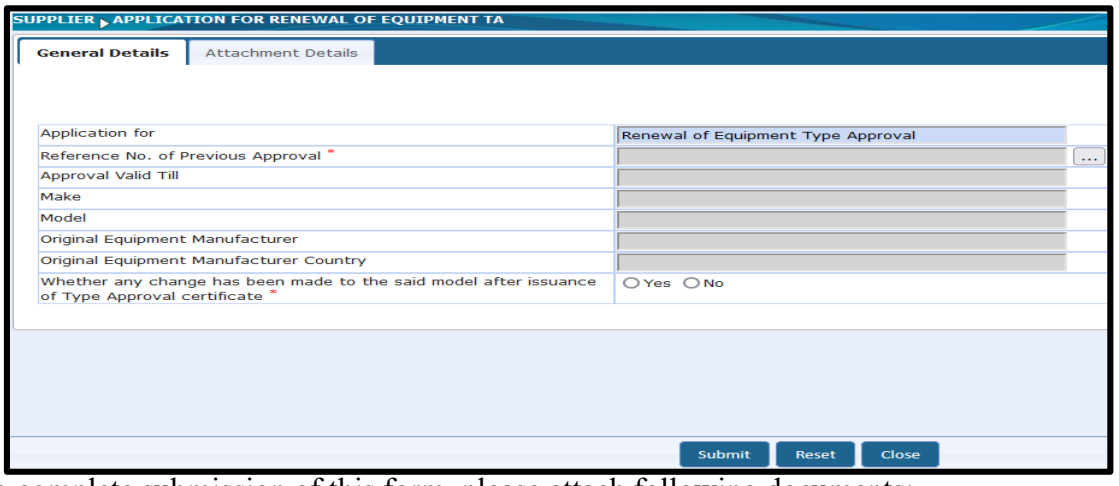
- Technical details of X-ray tube and generator system[maximum operating potential (kV), maximum operating current (mA), generator capacity (watt), focal spot size, type of cooling system, type of High Voltage generator etc.
- Technical catalogue and operation manual of X-ray tube/equipment as a whole
- Test report for measurement of radiation leakage at 5 cm from the outer accessible surface of the cabinet at maximum kV and corresponding maximum mA.
- Following details are required to be furnished regarding system i. Beam status (ON/OFF) on control console ii. Key control operation and password protection operation. iii. Emergency stop switch iv Door and other

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 your approval, you can fill the form

Regulatory Forms >> Nucleonic Gauge >> Renewal of Equipment Type Approval





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

- Certification from manufacturer about non-alteration of design of the IRGD model
- Submit supply details of IRGD (e.g. Equipment model, user address details, contact details,

source name, installation date etc.)

- Certification regarding reported accident / incidents, if any, while using the IRGD
- User's feedback about performance of the IRGD

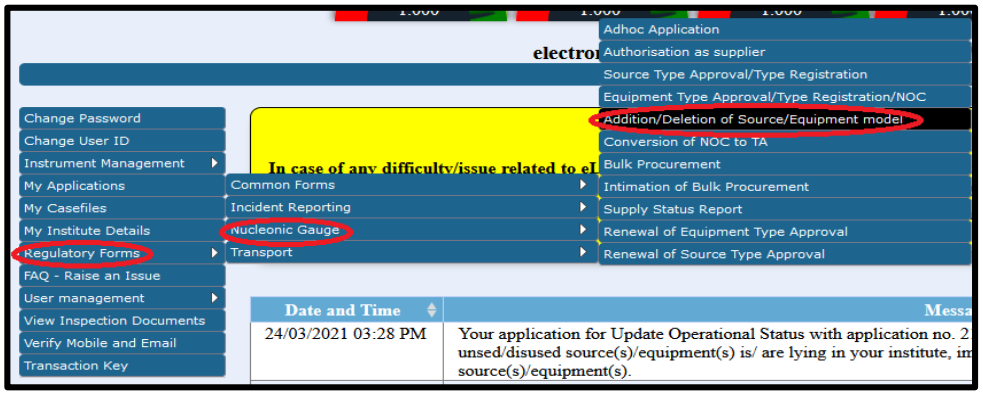
Section C: Other Processes

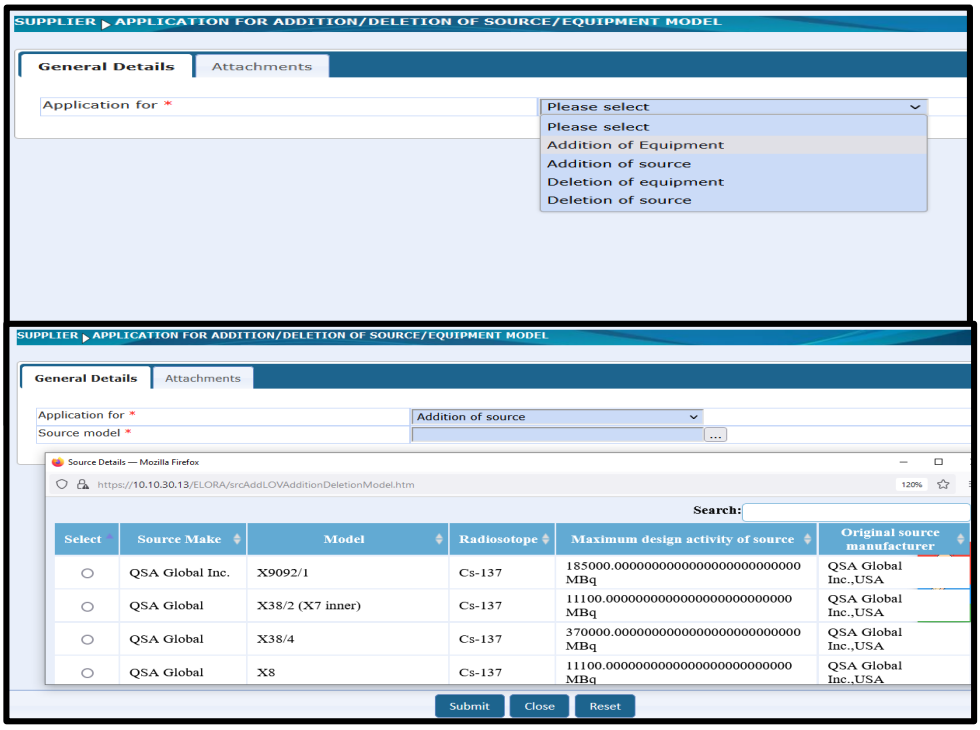
1. Addition/Deletion of Source/Equipment model

Kindly note that each source 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 model need not register it again, but he has to simply add the source in their account through **Addition/deletion of** Source/Equipment model.

The application form for Addition/deletion of Source/Equipment model is available in

Menu: Regulatory Forms >> Nucleonic Gauge >> Addition/Deletion of Source/Equipment model



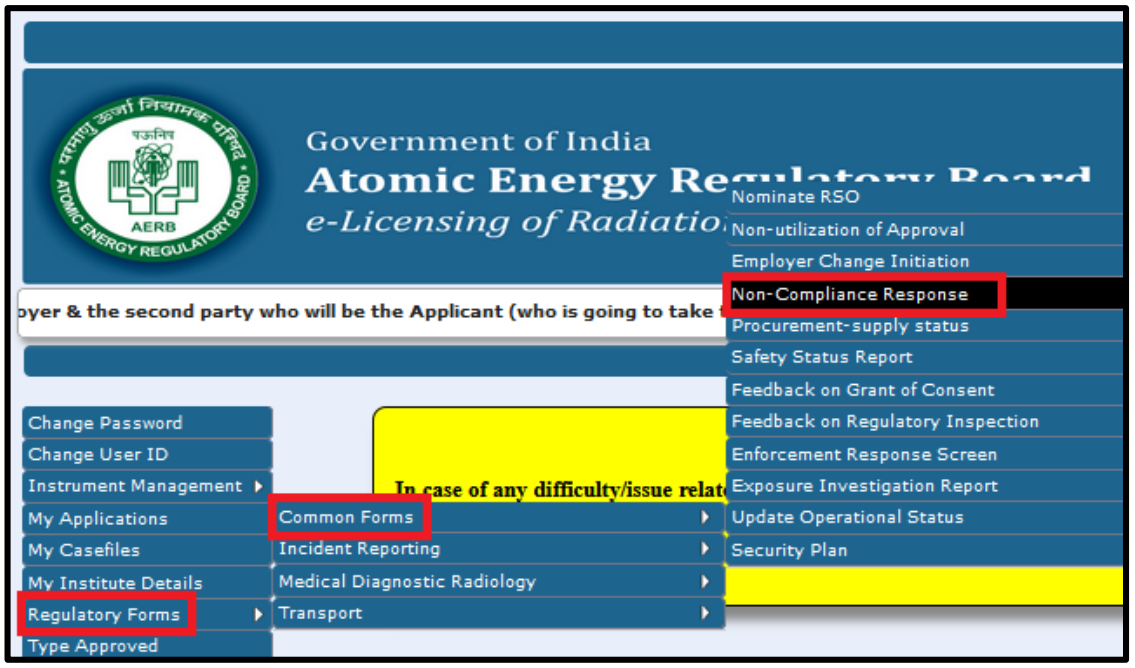


No separate Approval letter is issued, but the name of the new supplier will be shown to the end user during procurement application

2. NC response screen

For response to the non-compliances raised through regulatory inspection, follow the path: **Regulatory Forms>> Common Forms>>Non-Complaince Response**.

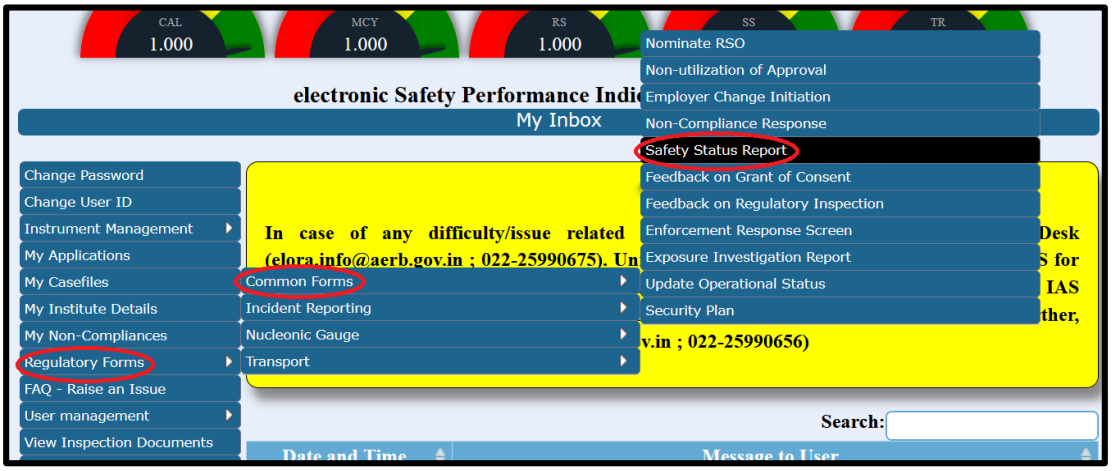
You need to attach the documentary evidences against the compliance status.

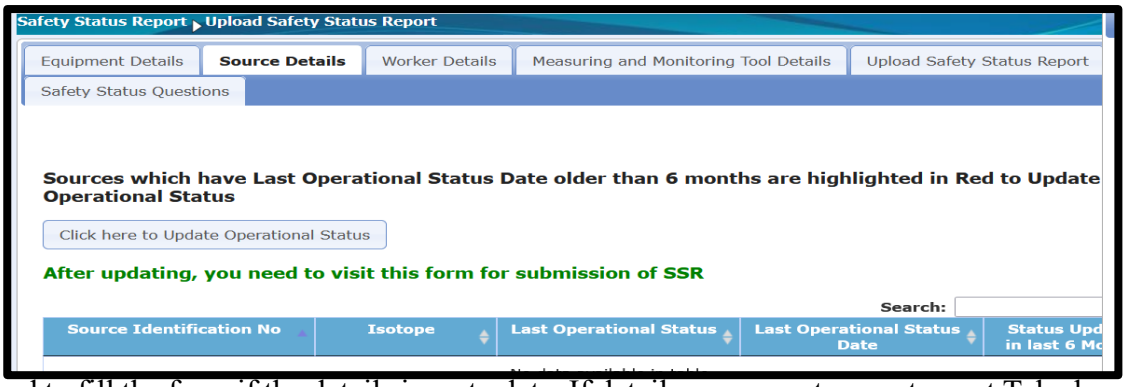


3: Supply Status Report

Carry out an audit once in **six months** of radioactive sources and of their locations, 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





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

Note:

> ***The new template of Supply Status Report is already shared with all the suppliers. The same is also available in eLORA HELP Menu.***

6. Unusual incident reporting

The Competent Authority should be notified immediately of an unusual occurrence involving the IRGD/source such as:

- Loss of a Gauge or failure to account for it
- functional impairment of a shutter or source control mechanism;
- occurrence of any extreme natural event, (e.g. fire, flood, earthquake or similar
- event);
- a gauge being damaged/ suspected of being damaged; and
- the results of radiation monitoring being in excess of the prescribed limits.

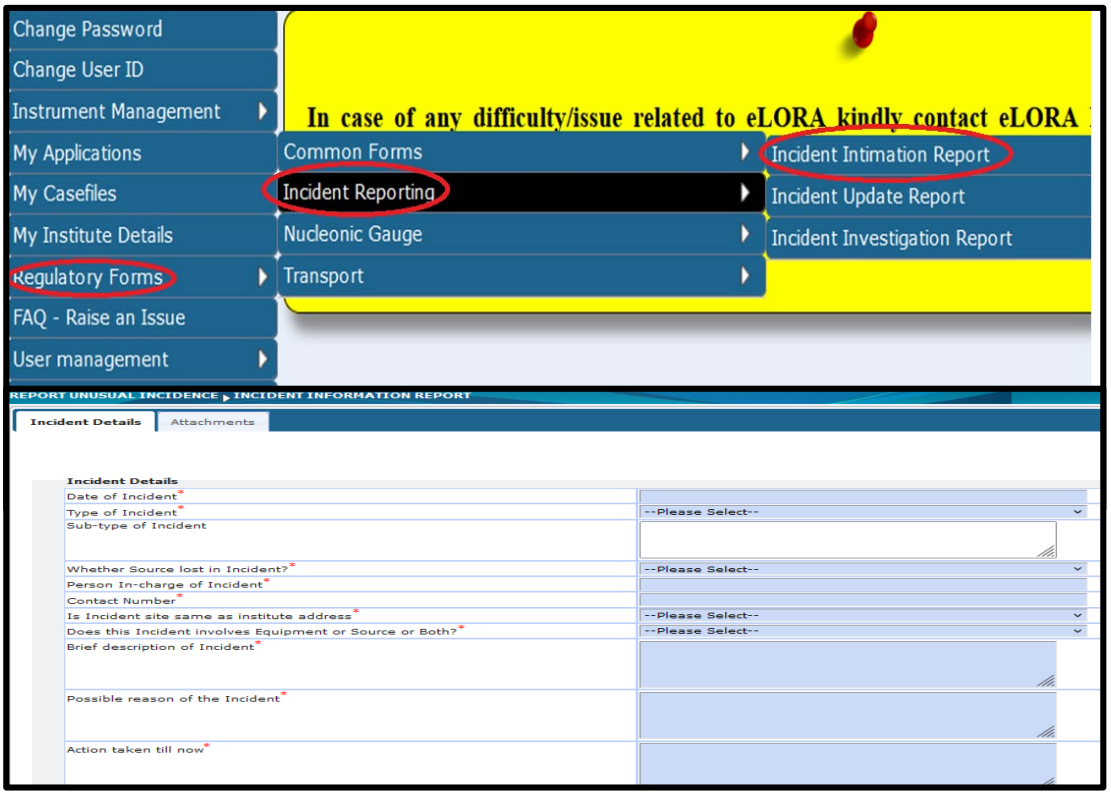
Specific emergency handling procedure should be established and the same should be implemented while handling any kind of unusual incident involving radiation source.

6a. Incident Information Report:

Any unusual incident reported with NG source or NG equipment in your facility, you need to intimate to AERB within 24 hrs through the form Incident Intimation Report.

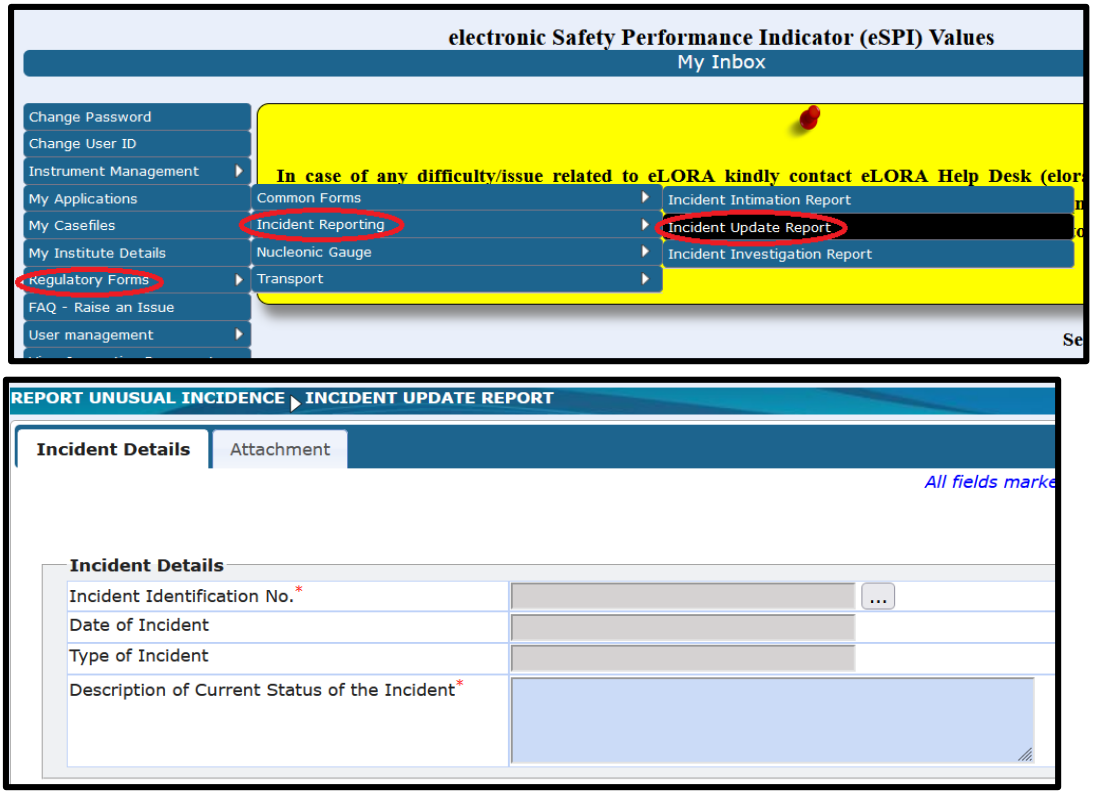
Follow following path to access this form:

Regulatory Forms >> Incident Reporting >>Incident Intimation Report



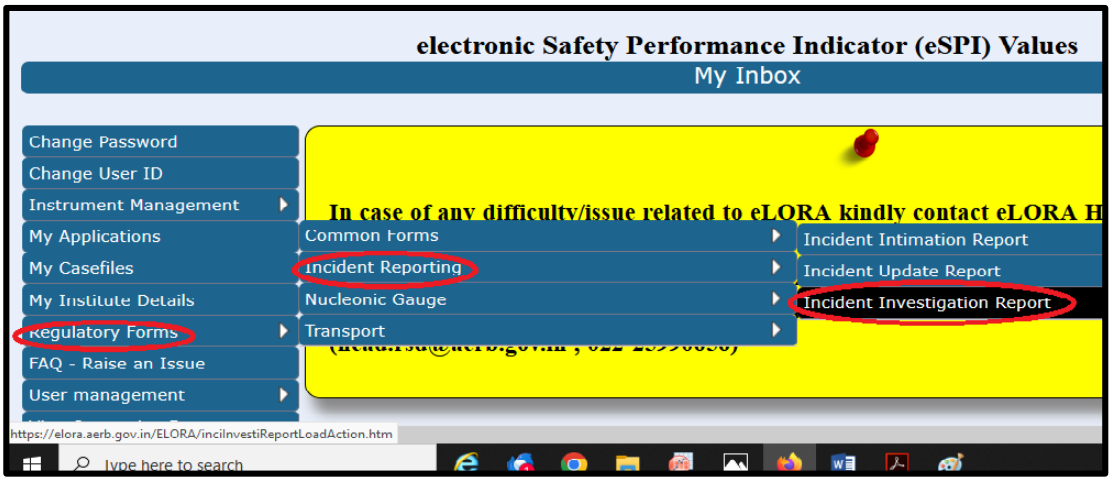
6b. Incident Update Report

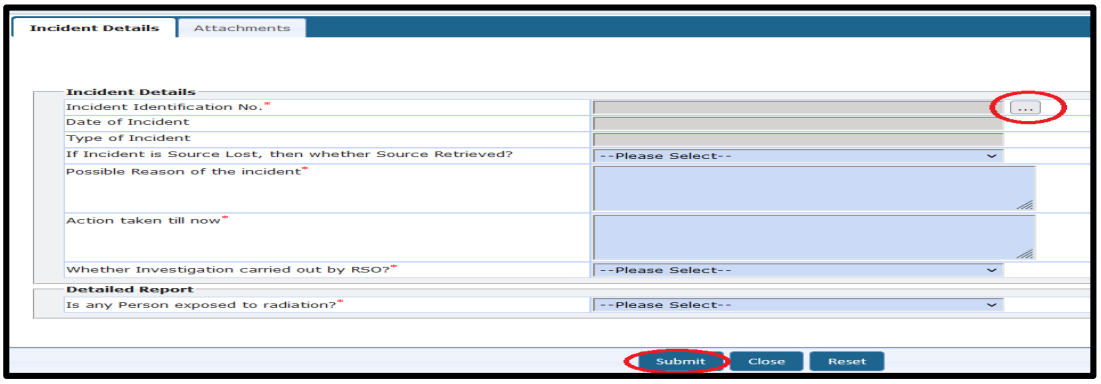
You need to submit the incident update report for the particular incident related to the NG source.



6c. Incident Investigation Report

Following any unusual occurrence involving the IRGD/source: the gauge, if any functional impairment has occurred, is not used until the function of the shutter or source control mechanism is thoroughly tested and restored to normal condition.





Annexure-1

Technical reference table for evaluation of NOC/ Type Approval Application of Nucleonic Gauge (NG) equipment [Application may be liable for rejection if this sheet is not attached]

Type of Installation:	Fixed installation ☐ Portable gauge ☐ Any other, specify____
Type of Gauge	Gamma gauge ☐ Beta gauge ☐ Neutron gauge ☐ X-ray tube gauge ☐ (tick applicable one).
Purpose/use:	

Model Name	**Name of manufacturer & Country**

Sr. No.	**Parameter(s)**	**Specification***	**Attach document and specify the page no. for reference with relevant portion highlighted**
1.	Name of the radio-isotope contained in NG equipment		
2.	Shielding materials for housing of NG equipment		
3.	Number of radioactive source(s) in the NG equipment		
4.	Maximum design capacity (activity) for the equipment		
5.	Specify the Standards to which the equipment complies		
6.	Classification designation of the NG model as per the respective standard to which it complies		
7.	Performance verification test certificate/test report certified by accredited laboratory		
8.	External Radiation Level: (µSv/h) Maximum Stray radiation level at 5 cm Maximum Stray radiation level at 100 cm		
	Normal Use Condition: High temperature Low temperature		
	Accident Condition: Fire Temperature Duration		
9.	Environmental condition of use and storage for which the NG equipment is designed to operate (e.g. temperature, vibration, humidity, corrosion etc.)		
10.	Type of package for NG and its certificate		
11.	Certificate from the competent authority of country of origin (for intended purpose)		
12.	In case of X-ray based equipment specify following:		
	Maximum tube potential (kV):		
	Maximum tube current (mA):		
	Radiation output at 10 cm :(specify kV and mA)		
	Stray radiation level (ON)		
	Max. temperature the device is designed to operate		
13.	Any Special features available in the unit/any other details		

Note: 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)**.

Date: Signature of the Licensee:

Place: Name: Designation:

7. Frequently Asked Question (FAQ)

Question	**Answer**
1. I am unable to register nucleonic gauge in e-LORA. How do I do it?	If you already have nucleonic gauge in your institution and you want to register them in e-LORA then you are required to send the details of the nucleonic gauges to us for migration to e-LORA in the standard template available in the Help Menu. The migration of the same will be done from AERB's end. You may also consult with your NG supplier for the guidance. Standard template for NG data migration is available in the 'Help Menu' of institute e-LORA account.
2. We want to move the radioactive source. When we apply for the permission of movement of sources in regulatory forms link of e-LORA, it shows the message? you do not have a valid license to operate	If you have not applied for Licence for operation of the facility, you are not authorized to use the source. You are required to obtain Licence for operation of the facility first. Then the system will allow you to submit the application. The regulatory process for obtaining 'Licence for operation' may be referred from the e-LORA user guidelines available in the Help menu.
3. We want to buy a nucleonic gauge. When we apply for procurement of the source in regulatory forms link of e-LORA, it shows the message? You do not have a valid license to operate the source".	If you have not applied for Licence for operation of the facility, you are not allowed to buy another source. You are required to obtain Licence for operation of the facility first. Then the system will allow you to submit the application. The regulatory process for obtaining 'Licence for operation' may be referred from the e-LORA user guidelines available in the Help menu.
4. We have procured the nucleonic gauge for our company at one site/location/district and now we want to transfer this gauge permanently to our company's another unit at different site/location/district	Please note that if your company has different units at different site/location/district, these units have to be registered as separate institutes. For permanent transfer of the nucleonic gauge from one unit to another you cannot apply for movement permission of it though the units are under the same company. In this case the unit which is currently possessing the nucleonic gauge has to apply for 'Consent for Release' of the NG. Once accepted/approved the particular NG will be available for selection by the other

	institution. Now the unit where the NG is to be transferred have to apply for procurement of the NG by selecting the resale option for the type of procurement.
5. We have approved radiation safety officer for our company and the tenure of RSO approval is expired now. How to apply for the renewal of approval of radiation safety officer, although we have tried	It appears that you have not obtained the RSO approval through e-LORA. You are required obtain the RSO approval through e-LORA. For this you need to register yourself as radiation professional in e-LORA and add yourself/RP in your institution employee list. Please see General Guidelines to use e-LORA System available in the Help Menu.
6. How can I get RSO certification after passing the safety training course in Nucleonic Gauge?	First you have to obtain Radiation Professional (RP) No. in e-LORA after passing the NG training course, which you have to obtain one time. The RP no. you have to share with your present employer for nominating you as RSO by the employer
7. How do I submit safety status report (SSR)	Follow the below path in eLORA: Regulatory forms>>Common forms>> Safety status report. A pop-up message will come, you may directly click on the link 'Click HERE' to download the format for SSR by selecting Radiation Facility profile
8. We have procured the nucleonic gauge and installed it. While submitting the installation report the procurement approval no. is not available (the message "No data is available" appears). Please guide	You are required to submit Source Receipt Intimation for Procurement Approval and then data will be available for Installation report
9. What is the frequency for submission of periodic safety status report through e-LORA	Once in 6 months and submission is only through e-LORA

10. We want to dispose our unused/disused radioactive source. But when we apply for decommissioning of radiation equipment we are not finding any Equipment and source linked to the same. Please guide	You are required to select for Transport of Registered Source for obtaining permission for export/transport/disposal of disused radioactive source. If the supplier is from abroad, you have to select export and if the original supplier is from India (for indigenous NG) Transport of radioactive source option is to be selected. After the export permission is obtained and export being done you need to go for Intimation of Export/Transport/Disposal, submit this form for intimating export/transport/disposal of radioactive source. Later on decommissioning of the equipment to be done as per the e-LORA process
11. We want to dispose our unused radioactive sources, but these radioactive sources are not registered/available in e-LORA. How do we proceed	For disposal of the disused sources which are not registered/not being migrated in e-LORA, you are required to select the option for Transport of unregistered source (available in Regulatory Forms ---Transport).
12. Our employer is retiring/transferred to another unit, we want to change the present employer with a new employer in e-LORA. Please guide how to change the employer	For employer change you need to submit the change of employer application, the outgoing employer (employer already registered with e-LORA) has to initiate generation of request-id for employer change by following the path: Regulatory Forms >>Common Forms >>Employer Change Initiation. Please see General Guidelines to use e-LORA System for step-by-step process for changing Employer detail
13. How to change email address of Institute Employer	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
14. Our institute name has been changed due to merger of the companies, we want to update the present name in e-LORA. Kindly guide	Any change in the institution details (viz. change in institute name, address etc.) cannot be done from the user's end, such provision is not given to the users. If any such changes need to be updated in e-LORA you are required to send the proof/legal document for the change in name of the institute or address whichever applicable to AERB along with the covering letter for necessary action.

15. In case of emergency such as loss of source or NG device or any unusual incident, involving IRGD/NG device or source, whom do I suppose to contact in AERB	Any unusual incident involving radiation source(s) should be informed to Head, Radiological Safety Division, Atomic Energy Regulatory Board, Mumbai within 24 hrs. The communication details are given below: Ph: 022-25990656; Fax: 022-25990650 Email: head.rsd@aerb.gov.in
16. NC was raised for the calibration of the instrument. We have calibrated the instrument, but the attachment (New calibration Certificate) is not getting uploaded	Your NC is system generated, if you have re calibrated the instrument you can update the calibration status (date of calibration and the date of expiry of the calibration) in the instrument management menu. Once it is updated NC will go by itself after 24 hrs
17. Which Type of radiation survey-meter (RSM) I should procure and how to add it in the e-LORA	Your RSM should be suitable for detecting and measuring the type of radiation (gamma / beta /alpha/ neutron / x-ray), which your institution is using for the intended purpose. For procurement of the suitable RSM, you may contact your Nucleonic Gauge supplier. There is 'ADD INSTRUMENT' provision in e-LORA for adding RSM in e-LORA
18. Can I obtain Licence for Operation for a Non-Type Approved Equipment	No. Only Type Approved Equipment can obtain Licence for Operation.

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