e-Licensing of Radiation Applications (eLORA) System



Guidelines

Radiotherapy Module

August 1, 2016

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Help Email id: <u>elora.rt@aerb.gov.in</u>

Important Updates

- In case of RapidArc or VMAT procurement, scan copy of separate request letter should be provided as an attachment while submitting application form for procurement of medical accelerator (See 8.2: Application for Procurement of (Equipment/Source), for more detail).
- Undertaking is required along with application for commissioning regarding construction of Radiotherapy facility. (See 8.7: Application for Commissioning, for more detail)
- Guidelines for preparation of Radiotherapy Site and Layout plan drawings available in HELP menu. Prepare radiotherapy site and layout plan drawings in accordance with the guidelines.

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 <u>www.aerb.gov.in</u> 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.

APPLICATION FOR INSTITUTE REGISTRATION	
Institute Details Employer Details Atta	ichments
Institute Details	All fields marked by *are mandatory
Institute Name*	
Institute Type*	Please Select
Registered with any State/Central Govt auth.*	Please Select
PAN No.	
TAN No.	
Address Of Institution	
Institute Name	
Address Linst*	
Su	ıbmit Close Reset

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'.

_				
1	Institute Details	Employer Details	Attachments	
	Institute Deta	ils		
. I	Institute Name*			ABC
	Institute Name* Institute Type*			ABC Joint Venture
	Institute Type*	any State/Central Gov	/t autn.*	

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

				_
In	stitute Details	Employer Details	Attachments	5
a	nd allowed file ty	ou to complete the For pes are:.doc,.docx,.xls e from http://www.7-	,.xlsx,.odt,.jpeg,	.jpg,.png,.zip,.p
	— Mandatory /	Attachments		
	Proof of ident	ity and date of birth*		Browse No
	Proof of empl	oyership [*] 🕜		Browse No
	Non-Mandat	ory/Context Based	Attachments	
	Upload photo	copy of PAN No Of ins	titute 🕜	Browse No
	Upload photo	copy of TAN No Of ins	titute 🕜	Browse No
		copy of Adhar Card o		Browse No
		py of registration wit	0	Browse No
		/Local Government A		
	Others (Such	as MoU/Partnership [Deed, etc.)	Attachment
				Browse No
	Add row	Delete row		

• **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.

Landmark		Please select the role	Minimize
State *			Minimize
City/District *		Manufacturer-Telecobalt	Radiation Facilit
PIN *		Manufacturer-Tomotherapy	Radiation Facilit
PIN		Radiation Facility-Check source	Radiation Facilit
Contact Details		Radiation Facility-CT simulator	Radiation Facilit
Phone(O)*		Radiation Facility-Cyber Knife	Suppliers-Check
Email(O) *		Radiation Facility-Gamma Knife	Suppliers-CT sir
Confirm Email(O) *	chytherapy	Radiation Facility-Intraoperative RT	Suppliers-Cyber
Fax		Radiation Facility-kV Imaging System	Suppliers-Gamn
Website	chytherapy	Radiation Facility-Manual Afterloading Brachytherapy	Suppliers-Intrac
		Radiation Facility-Medical Accelerator	Suppliers-kV Im
Type Of Facility	4		•
Practice*	Radiothera	т	
Role of Institute*	Radiation F	Facil x Radiation Facil x	
L			

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:
 - o Passport
 - \circ $\,$ 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 of 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 Id., Username and Password (Username and password of RP account) is sent to the registered email id of the radiation professional.



Important Note: 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.

3 Login to eLORA system

Login to the system using the "Username" and "Password" received no your registered email after approval Institute Registration application form. On first time login system will prompt to change the password.

	Login
Username	
Password	
	Login
F	orgot 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".

	Profile Selection	
Username* Re-confirm password*	AD170	
	Radiotherapy -	
	Select Radiation Facility	
	Suppliers	

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

Last Login:18/10/201	15		Home Switch Profile View Profile View All Messages Logout		
At		Regulatory Board tion Applications (eLORA) System	Karalita anti	Login: TEST INSTITUTE (T1291) Institute: TEST INSTITUTE TEST (MH-21818) Role: Employes, License Profile: Nucleonic Gauge-Radiation Facility-Nucleonic Gauge	
		My Inbox			
Change Password				Search:	
Instrument Management	Date and Time 👙		Message to Use		
My Applications	16/10/2015 10:43 AM	Your application ref no. 15-39274 is Rejected.			
My Casefiles My Drafts	12/10/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-308 2015-09-28.Immediate action need to be taken to avoid		itute is pending for closure. The final date of closure is	
My Institute Details	12/10/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-308 2015-09-28.Immediate action need to be taken to avoid		itute is pending for closure. The final date of closure is	
User management	09/10/2015 12:12 PM	You have successfully submitted RSO Nomination with	Application No. 15-3927	4 for ANAND PINJARKAR	
View Inspection Documents	09/10/2015 12:11 PM	Signed PDF has been uploaded successfully.			
	28/08/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-308 2015-09-28.Immediate action need to be taken to avoid		itute is pending for closure. The final date of closure is	
	28/08/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-308 2015-09-28.Immediate action need to be taken to avoid		itute is pending for closure. The final date of closure is	
	19/08/2015 10:14 AM	Your application ref no. 15-68968 is Rejected.			
	14/08/2015 02:45 AM	Non Compliance has been raised against your institute v	with reference no [MH-218	18-NC-3082].Refer My Institute Details for further information.	
	14/08/2015 02:45 AM	Non Compliance has been raised against your institute y	with reference no [MH-21]	18-NC-3083].Refer My Institute Details for further information.	

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

Change Password	Ad	dd Instrument		
Instrument Management		View Instrument		
My Applications		16/10/2015 10:43 AM	Your application ref no.	
My Casefiles		12/10/2015 02:45 AM	Non Compliance with re-	
My Drafts			2015-09-28.Immediate ad	
My Institute Details		12/10/2015 02:45 AM	Non Compliance with re-	
Regulatory Forms			2015-09-28.Immediate ad	
User management		09/10/2015 12:12 PM	You have successfully su	
View Inspection Documents		09/10/2015 12:11 PM	Signed PDF has been up	
		28/08/2015 02:45 AM	Non Compliance with re-	

Instruments are classified in to below four types:

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

APPLICATION INSTRUMENT REGISTRATION		
Type Of Instrument* Type Of Instrument Sub-type*	Please SelectPlease Select Measuring Tools Monitoring Tools QA Tools Safety Tools	All fields marked by * are mandatory
Su	ıbmit Close Reset	

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

Instrument Details		
		All fields marked by * are mandator
Type Of Instrument*	Measuring Tools	-
Type Of Instrument Gub type*	Thimble Chamber	
Availability *	Please Select	
Supplier *	Please Select	
Date of procurement *	Available Proposed	
Make *		
Model *		
Instrument Serial Number *		
Type of Detector*	Ion Chamber GM Counter Phosphor Solid State	

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

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

4.2 Manage Instrument Status

Use**Menu: Instrument Management →View Instrument** to manage status of Instrument

		My I
Change Password	Add Instrument	
Instrument Management 🔹 🕨	View Instrument	
My Applications	19/10/2015 03:02 PM	Survey meter has been
My Casefiles	16/10/2015 10:43 AM	Your application ref no
My Drafts	12/10/2015 02:45 AM	Non Compliance with
My Institute Details		closure. The final date
Regulatory Forms		actions.
User management	12/10/2015 02:45 AM	Non Compliance with
View Inspection Documents		closure.The final date

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 Stat
۲	Measuring Tools	Thimble Chamber	SE-0000056	Standard Imaging	0.057cc	Available
0	Measuring Tools	Thimble Chamber	SE-0000032	IBA	cc13	Available
0	Measuring Tools	Thimble Chamber	SE-0000034	IBA	CC13	Available
0	Measuring Tools	Thimble Chamber	SE-0000035	IBA	FC65G	Available
0	Measuring Tools	Thimble Chamber	SE-0000036	IBA	FC65G	Available
0	Measuring Tools	Thimble Chamber	SE-0000037	IBA	FC65G	Available
0	Measuring Tools	Thimble Chamber	SE-0000038	NE	0.6CC	Available
D	Measuring Tools	Thimble Chamber	SE-0000039	PTW	Unidos	Available
D	Measuring Tools	Thimble Chamber	SE-0000040	PTW	Pin Point	Available
D	Measuring Tools	Thimble Chamber	SE-0000041	Standard Imaging	Exradin A19	Available

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	ТОМО
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**

Change Password			
Instrument Management			
My Applications	A	d Employee	
My Casefiles	С	ange Licensee	ne/well type ion
My Drafts	D	signate Licensee	r absolute dosim
My Institute Details	D	signate/Relinquish Employees	source storage h
Regulatory Forms) U	date/Dissociate Employee	hantom has been
User management	• U	date Institute Details	er has been adde
	_	2//02/2013 03.24 FIVI	runnoie Chamber has been
View Inspection Documents		25/02/2015 04:42 PM	Your Application has been a

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** 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).

Select radiation professional		×
RP registration ID ?* Date of birth of RP* Whether the person is also Employer of the institute?*	© Yes ◎ No	
	Search	

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 **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

Change Password			Nominate RSO	
Instrument Management	Date and Time 🔶		Non-utilization of Approval	
My Applications	10/10/2015 03:02 PM	Survey meter has been	Employer Change Initiation 15	
My Casefiles	Common Forms	►.	NC Response Screen	
My Drafts	Incident Reporting		Exposure Investigation Report	
My Institute Details	Nucleonic Gauge	Þ	of closure is 2015-09-28.Immediate action need to b	
Regulatory Forms	Transport	Þ		
User management	12/10/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-3082] raised agianst y		
View Inspection Documents		closure. The final date of closure is 2015-09-28. Immediate action need		
		actions.		

On clicking 'Nominate RSO' the following form will appear

RSO MANAGEMENT			
Radiation Professional Details			
Select Radiation Professional Radiation Professional [*] Date of Birth [*]			ed by *are mandatory.
Registration ID* Role of RP* RSO Status*			here to get the list of nployees
e-Mail Id Official [®] Education Details			
Experience Details			
	Nominate Renominate Renew Undesig	gnate Reset Close	

6.1 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:

adiation Facilities to be assigned	 Radiotherapy installations Supplier of radiotherapy equipments/sources Nuclear Medicine Facility Supplier of Nuclear Medicine Equipment/Source Manufacturer of Nuclear Medicine Source Nucleonic Gauge (Radiation Facility) Nucleonic Gauge (Supplier) Nucleonic Gauge (Manufacturer) Well Logging (Radiation Facility) Medical diagnostic x-ray facility Supplier of x-ray equipments/x-ray tubes Manufacturer of x-ray equipments/x-ray tubes Medical Diagnostic-Service Agency Industrial Radiography (Radiation Facility)

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).

6.2 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".

Radiation Professional Details	
Select Radiation Professional	
Radiation Professional [*]	
Date of Birth [*]	
Registration ID [*]	
Role of RP*	
RSO Status [*]	
e-Mail Id Official [*]	"Renew" button will be enabled for the employee whose
Education Details	RSO status is "Yes" before one month of RSO approval
Experience Details	validity date.
Nominate Re	enominate Renew Undesignate Reset Close

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 \rightarrow Upload Signed PDF \rightarrow Submit. (Please refer 'General Guidelines to use eLORA System', available in eLORA Help menu).

6.3 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.

Nominate RSO	
Radiation Facilities to be assigned $oldsymbol{0}$	Industrial Radiography (Radiation Facility) Radiotherapy installations Nuclear Medicine Facility Gamma Irradiation Chamber (Radiation Facility) Kuelear Used (Radiation Facility) Wel Logging (Radiation Facility) Wel Logging (Radiation Facility) Industrial Radiography (Supplier)
Additional Responsibilities Proposed to be Assigned to the RSO	
	Freeze Back

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).

6.4 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.

SO MANAGEMENT		
Radiation Professional Details		_
		All fields marked by *are mandatory.
Select Radiation Professional Radiation Professional		
Date of Birth	BALAJI K/ 30/05/19 Are you sure to you want to undesignate?	
Registration ID*	30/05/19 Are you sure to you want to undesignate?	
		Use "Undesignate" option
Role of RP*	Medical P OK Cancel	
RSO Status [*]	Yes	to revoke RSO.
	Nominate Renominate Renew Undesignate Reset	0056
	Renerative Renerative Reserve	ologe and a second seco

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".



7 Steps involved in obtaining various regulatory clearances

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

	шистъј побинитот ј	Doura			
e-Licensing of Radiation Applications (eLORA) System		Application For Site and Layout Approval			
			Application For	Procurement (Source/Equipment)
	Equipment Receipt Intimation				
	Source Receipt	Intimation			
		My Inbox	Application For	Source Superv	ision Authorization
			Source Transfer Report		
Change Password			Application For Commissioning		
Instrument Management 💦 🕨	Date and Time 🔶		Survey Report		
My Applications	22/01/2016 05·32 PM	Your Application no	Application For	Licence	
My Casefiles	Common Forms	•	Renewal Of Lice	ence	T
My Drafts Incident Reporting		•	QA/QC Report		
My Institute Details Radio Therapy Practice		Þ	Application For	Decommission	ing and Disposal
Regulatory Forms	ransport	►.	Intimation For I	Decommissioni	ng l.
User management 🔹 🕨	Your application ref	no. 15-93255 is	s Rejected.		

Change Password				
Instrument Management		Date and Time	¢	
My Applications		16/10/2015 10:43 AM		Your application ref no. 15-39274 is Rejected.
My Casefiles	Com	mon Forms		pliance with reference no [MH-21818-NC-3083]
My Drafts	Incid	ent Reporting		-28 Immediate action need to be taken to avoid reg
, My Institute Details	Radi	o Therapy Practice		Transport of Registered Source
Regulatory Forms	Tran	sport		Transport of Unregistered Source
User management	2	09/10/2015 12:12 PM		You have Intimation of Export/Transport/Disposal
View Inspection Documents		09/10/2015 12:11 PM		Signed PDF has been uproaded successfully.
		20/00/2015 02:45 434		New Compliance with reference on DATE 01010 NC 20021.

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

7.1 Regulatory processes for Telecobalt and Gamma Knife installation

Step 1. 0		time Licence		
Step 1. 0	Obtaining site and lawout approval			
	Obtaining site and layout approval	Application for Site and Layout Approval		
Step 2. 0	Obtaining RSO approval	Nominate RSO		
Step 3. 0	Obtaining procurement permission	Application for Procurement (Equipment/Source)		
	of equipment (equipment without source)			
	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)		
Step 5. In	intimating receipt of equipment	Equipment Receipt Intimation		
	Obtaining authorization to	Source Supervision Authorization		
	supervise source transfer operation			
S	Intimating receipt of radioactive source	Source Receipt Intimation		
	For providing detail of source cransfer operation	Source Transfer Report		
	Obtaining commissioning approval of equipment (i.e. prior permission	Application for Commissioning		
	for switching ON beam)			
	Submission of radiation survey	Survey Report		
	evels measured around the nstallation			
	Obtaining licence for operation of equipment	Application for Licence		
		wal of Licence		
Step 1. R	Renewal of existing Licence	Renewal of Licence		
	-	rement of Source		
	Obtaining procurement permission of radioactive source	Application for Procurement (Equipment/Source)		
	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization		
	Intimating receipt of radioactive source	Source Receipt Intimation		
	For providing detail of source transfer operation	Source Transfer Report		
	For resumption of operation after	Form is not yet developed in eLORA.		
S	source replacement	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			
	Obtaining consent for decommissioning	Application for Decommissioning and Disposal		
Step 2. 0	Obtaining authorization to supervise source transfer operation	Source Supervision Authorization		
Step 3. 0	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

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

instanation					
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			
	Renewa	al of Licence			
Step 1.	Renewal of existing Licence H	Renewal of Licence			
	Decom	missioning			
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			

7.3 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 measured around the installation	Survey Report		
Step 11.	Obtaining licence for operation of equipment	Application for Licence		
	Renewa	al of Licence		
Step 1.	Renewal of existing Licence R	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-procure	ement 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		

7.4 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 Receipt Intimation			
	source				
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			

7.5 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 R	Renewal of Licence	
Decommissioning			
Step 1.	Obtaining consent for decommissioning	Application for Decommissioning and Disposal	
Step 2.	Intimating decommissioning of equipment	Intimation for Decommissioning	

7.6 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			

7.7 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		
	Renew	val 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		

7.8 Regulatory processes for Check Source

Steps	Purpose	Regulatory Form Name				
	First ti	me 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				
	Renewa	al of Licence				
Step 1.	Renewal of existing Licence H	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	Intimation of Export/Transport/Disposal
	source	

8 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.

8.1 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.

8.2 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 \rightarrow Radiotherapy Practice \rightarrow Application for Procurement (source/ equipment)

- Pre-requisite for equipment procurement:
 - Site and layout approval
 - o 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)
 - $\circ \quad \text{RSO approval} \quad$
 - 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'.

Important Note: Accessories used in Linear Accelerator (viz. IMRT, VMAT, RapidArc, MLC, etc.) should be selected in procurement for form equipment. **In case of RapidArc or VMAT procurement, scan**

copy of separate request letter should be provided as an attachment while submitting application form for procurement of medical accelerator.

8.3 Equipment Receipt Intimation

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

Menu: Regulatory Form \rightarrow Radiotherapy Practice \rightarrow 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.

8.4 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.

8.5 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 \rightarrow Radiotherapy Practice \rightarrow Application for source supervision authorization

- Pre-requisite for source supervision authorisation:
 - Availability of Medical Physicist
 - o 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.

8.6 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

8.7 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).

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

Important Note

Only after obtaining Commissioning Approval from AERB, user shall energize the equipment to carry out radiation survey.

8.8 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:
 - o 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.

Employee Details Survey Report Details Attachments	
We recommend you to complete the Form first and then proceed for the upload for your attachmer might zip it and upload it. Software for compressing files can be downloaded for free from http://ww	Medical Accelerator Excel Opening PurMedAccExcelatia Browse No file selected.
	Freeze Close Reset

8.9 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

In the 'Attachment' tab of Application for Licence form, template for 'QA Specification Sheet' in excel file is available for download. This excel 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.

8.10 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 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
 - $\circ \quad \text{Submission of periodic safety status report}$

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.**

Equipment Type [*]	Please Select	-	
-----------------------------	---------------	---	--

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→



	Radiation Fa	cility		
lick on the below links to view			Search:	
	S.No.	Description	File Download	🔶 Last Updated On
ontent of particular profile	1	Detail of tests which does not meet the prescribed tolerance limits for QA/QC (for RT-Licence Renewal QA/QC attachment, as applicable)	QAQC_RTRenewal_v1.pdf	2016/03/28
Common	2	Format for providing radiation survey data- Tomotherapy facility	PSRTomotherapy_V1.xlsx	2016/03/28
common	3	Format for providing radiation survey data- Cyber Knife facility	PSRCyber Knife_V1.xlsx	2016/03/28
Radiation Facility	4	Format for providing radiation survey data- Manual Brachytherapy facility	PSRManual Brachytherapy_V1.xlsx	2016/03/28
	5	Format for providing radiation survey data- Simulator facility	PsrSimExcel_V1.xlsx	2016/03/28
Supplier	6	Format for providing radiation survey data- CT Simulator facility	PsrCTSimExcel_V1.xlsx	2016/03/28
	7	Format for providing radiation survey data-Medical Linear Accelerator facility	PsrMedAccExcel_V1.xlsx	2016/03/28
	8	Format for providing radiation survey data- HDR Brachytherapy facility	PsrRalExcel_V1.xlsx	2016/03/28
	9	Format for providing radiation survey data-Telecobalt facility	PSRTelecobalt_V1.xlsx	2016/03/28
	10	User Manual for Radiotherapy Consenting Process	eloraRTGuidelines_R1.pdf	2016/02/26

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".

RADIOTHERAPY	APPLICATION FOR REI	NEWAL OF LICENC	CE			
Worker Details	Instrument Details	Licence Details	Attachment	Details		
					All fields marked by	* are mandatory
institute. We recommend y for each file uplo and upload it. So	rou to complete the Forn ad is 2 MB and allowed 1 ftware for compressing f	n first and then proc file types are:.doc,.c	ceed for the uploa docx,.xls,.xlsx,.od	d for your t,.jpeg,.jp	d Radiotherapy Technolog attachments. The maximum fil g,.png,.zip,.pdf.Alternatively,yo w.7-zip.org/download.html	e size allowed
Upload the QA/Q	2C report	Browse N	o file selected.			Clear
Upload the radia	tion survey report	Browse N	o file selected.			Clear

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

Whether adequate number of Radiotherapy professionals (e.g. Radiation Oncologist(s), Medical Physicist(s) and Radiotherapy Technologist(s) etc.) are available [*]	© Yes ◎ No
Whether personnel monitoring badges are provided to each radiation workers [*]	Yes No
Whether appropriate dose measuring and monitoring (calibrated and working) instruments are available [*]	Yes No
Adequate security measures as per AERB safety guide AERB/RF- RS/SG-1 is in place [*]	Yes No

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

8.11 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 \rightarrow Radiotherapy Practice \rightarrow 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.

8.12 Transport of Registered Source

Submit this form for obtaining for obtaining transport permission to transport the radioactive source to disposal agency. Follow below path to access this form:

Menu: Regulatory Form → Transport → Transport of Registered Source

- Pre-requisite for transport permission
 - Approval for disposal

8.13 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

8.14 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

9 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.

9.1 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 \rightarrow Common Forms \rightarrow Non-utilization of Approval

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

Instrument Management Date and Time + NC Response Screen My Applications 03/12/2015 12-28 PM Your Application My Casefiles Common Forms Exposure Investigation Report My Drafts Incident Reporting Update Operational Status My Institute Details Radio Therapy Practice taken to avoid regulatory actions. Regulatory Forms Transport with reference no [MH-21818-NC-3917] raised ag User management action need to be taken to avoid regulatory actions.					Nominate RSO	
Change Password Enforcement Response Screen Instrument Management Date and Time NC Response Screen My Applications 03/12/2015 12:28 PM Your Application My Casefiles Common Forms Exposure Investigation Report My Drafts Incident Reporting Update Operational Status My Institute Details Radio Therapy Practice e taken to avoid regulatory actions. Regulatory Forms Transport with reference no [MH-21818-NC-3917] raised ag User management action need to be taken to avoid regulatory actions.					Non-utilization of Approval	
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My Applications O3/12/2015 12:28 PM Your Application Safety Status Report My Casefiles Common Forms Exposure Investigation Report My Drafts Incident Reporting Update Operational Status My Institute Details Radio Therapy Practice taken to avoid regulatory actions. Regulatory Forms Transport with reference no [MH-21818-NC-3917] raised ag User management action need to be taken to avoid regulatory actions.	Change Password				Enforcement Response Screen	
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Regulatory Forms Transport with reference no [MH-21818-NC-3917] raised ag User management action need to be taken to avoid regulatory actions.	My Drafts	Incide	nt Reporting	•	Update Operational Status	iar
User management	My Institute Details	Radio	Therapy Practice	►	e taken to avoid regulatory actions.	
	Regulatory Forms			Þ	with reference no [MH-21818-NC-3917] raised	agiar
18/11/2015 02:45 AM Non Compliance with reference on [MH 21818 NC 2021] reject as	User management action need to be taken to avoid regulatory actions.				-	
view inspection bocuments 18/11/2013 02.43 Aivi Non Compliance with reference no [NH-21818-NC-3921] faised ag	View Inspection Documents		18/11/2015 02:45 AM	· ·	e with reference no [MH-21818-NC-3921] raised e taken to avoid regulatory actions.	agiar

9.2 Submit application for Site and Layout

Approval Type³

pproval No.

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:

Layout/Design/Construction Approval

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 reapproval of site and layout plan.*

10 Submission of Safety Status Report

It is mandatory for all Radiation Facilities to submit Safety Status Report to AERB periodically. The frequency of submission of Safety Status Report for Radiotherapy Facility is one year. Therefore, all the Radiotherapy Facilities shall submit the Safety Status Report by the end of calendar year but not later than 31st January of the next year, i.e. the report for the year 2015 must be submitted by 31st January 2016.

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.

10.1 Update Operational Status of Sources and Equipment

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

		Nominate RSO
		Non-utilization of Approval
		Employer Change Initiation
Change Password		Enforcement Response Screen
Instrument Management	🕨 🛛 Date and Time 👙	NC Response Screen
My Applications	03/12/2015 12:28 PM	Your Application Safety Status Report
My Casefiles	Common Forms	Exposure Investigation Report
My Drafts	Incident Reporting	Update Operational Status
My Institute Details	Radio Therapy Practice	taken to avoid regulatory actions.
Regulatory Forms	▶ Transport	with reference no [MH-21818-NC-3917] raised agi
User management		action need to be taken to avoid regulatory actions.
View Inspection Documents	18/11/2015 02:45 AM	Non Compliance with reference no [MH-21818-NC-3921] raised agi

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'.

General Details	
	All fie
Declare Operational Status of *	Please Select
Identification No.*	Please Select
Serial No.	Radiation Generating Equipment
Make	Source
Model	Nuclear Medicine Installation
Operational Status of Equipment/Sour	

Select operational status as of Equipment or Source.

	Model		
	Operational Status of Equipment/Source to be		
	changed to [*]	Please Select	
		Working	
		Not Working	
		Disused	
	I/We hereby certify that the particula	Unused	ue a
k	nowledge and belief. I understand that if at a	Temporarily Not in Use	atior
	or not authentic, appropriate regulato	Lost	e/us
		Sent for Repair	

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.

10.2 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. You will need also to provide safety report in excel file. To download template for this excel file, use 'Help' menu given at the top.



Select 'Radiation Facility' and click on 'Radiotherapy-SSR-2015.xlsx' to download the excel file.

ick on the below links to view			Search:	
ntent of particular profile	S.No.	Description	🝦 🛛 File Download 🔶	Last Updated On
	1	Circular: Security plan submission for Telecobalt and Gamma Knife facilities	Circular-RF-TG-2015.pdf	2015/12/07
Common	2	For providing the details required for Radiotherapy Safety Status Report	Radiotherapy- SSR-2015.xlsx	2015/12/03

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

Menu: Regulatory Form \rightarrow Common Forms \rightarrow Safety Status Report

				Nominate RSO
				Non-utilization of Approval
				Employer Change Initiation
Change Password				Enforcement Response Screen
Instrument Management 🛛 🕨		Date and Time 🔶		NC Response Screen
My Applications		03/12/2015 12:28 PM	Your Application	Safety Status Report
My Casefiles	Comn	ion Forms	•	Exposure Investigation Report
My Drafts	Incide	ent Reporting	•	Update Operational Status
My Institute Details	Radio	adio Therapy Practice 🔹 🕨		taken to avoid regulatory actions.
Regulatory Forms	Trans	port	•	with reference no [MH-21818-NC-3917] raised agia
User management 🛛 🕨 🕨			action need to b	e taken to avoid regulatory actions.
View Inspection Documents		18/11/2015 02:45 AM	_ <u> </u>	e with reference no [MH-21818-NC-3921] raised agia

The details of staff and measuring and monitoring instruments are displayed in first two tabs. Fill the information as asked in tab: 'Upload Safety Status Report' and upload duly filled excel file in the upload option for 'Safety Status Report'.

fety Status Repor	t Vpload Safety Status Report			
Worker Details	Measuring and Monitoring Tool Details	Upload Safety S	status Report	
types are:.doc,.d http://www.7-zip. Whether trained is/are adequate a Whether function	bu to complete the Form first and then proc ocx,.xls,.xlsx,.odt,.jpeg,.jpg,.png,.zip,.pdf.A org/download.html /certified staff member(s) declared in und available in your institute? ^{**} onal radiation measuring tool(s), mo s) and safety tool(s) are available as dec	eLORA Ores onitoring Yes	ght [°] zip it and uploa No	
eLORA? Whether all the Radioactive source(s), equipment(s) and installation(s) are safe and secured from radiation safety		s) and ⊚ Yes ⊚	No	
standpoint?*	re sale and secured norm radiation	Salecy		
Whether Operational Status of Radioactive source(s), equipment(s) and installation(s) declared in eLORA is/are updated?*				
From Date [*]				
To Date [*]				
Safety Status Re	port*	Browse	No file selected.	Clear
Any Other Attach	ment	Browse	No file selected.	Clear

Accept the undertaking by ticking on check box and press 'Submit' for submission of safety status report.

=0=0=0=0=0=

11 Annexure A: List of Requisite Instruments

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

11.1 TOT Enitedi Accelerat	tor including romotherapy and Cyber Kine
List of Instru	uments 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 DODT (UNDAT) (ODT)
	3DCRT/IMRT/IGRT /VMAT/SRS/SRT)
Safety Tools	 Mechanical front pointer(s)

11.1 For Linear Accelerator including Tomotherapy and Cyber Knife

11.2 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	

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	

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

11.4 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)		

11.5 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		

12 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.

The undertaking should include the followings:		

We, (*names and addresses of beneficiaries*), declare that we have made a joint venture to start radiotherapy facility at (*place address*). (*Elaborate on the proposed joint venture....*)

The land/premise, where the radiotherapy facility will be erected belongs to (*name of authorised person of land/premise* (*one of the beneficiaries*)) and thereby, he/she will be the employer and shall discharge the responsibilities of employer as per Atomic Energy (Radiation Protection) Rules-2004. The employer will designate either himself/herself or nominate his/her own employee as the licensee, who shall discharge the responsibility of licensee as per Atomic Energy (Radiation Protection) Rules-2004.

Further, we undertake that in the event of any dispute, the equipment would be decommissioned and the sources would be disposed off safely as per the procedures approved by the competent authority.

(Authorised person of land/premise)

(Other beneficiary)

Cirrature	Cignature
Signature	Signature
Name of Authorised	Name of Authorised
person of land/premise:	representative of other beneficiary:
Designation:	Affiliation:
Name of the hospital:	
Address:	Address:
Date:	Date:

13 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 reapproval 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

<u>NOTE</u>: 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.

14 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)
eLORA Institution Number:
Institution Name and Place:
We hereby undertake that, we have compared the approved layout plan issued by AERB Vide Application 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
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:

15 Annexure E: Frequently Asked Questions (FAQs)

15.1 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.

15.2 Forgot Password

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

Ans. Visit eLORA home page and click on <u>'Forgot Password?</u>'. Provide your 'Username' and 'Registered Email Id' and click on **Submit** after entering Captcha. <u>You will receive new password on your</u> <u>registered email address as well as on registered mobile no. via SMS</u>. (This process is applicable for Institute as well as Radiation Professional accounts).

15.3 If Employer is 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.

15.4 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 plan for 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'

15.5 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)

15.6 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.

15.7 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-bystep process for changing Employer detail.

15.8 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.

15.9 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 or Remote 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. Login Login Forgot Password? Forgot Username?

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.

15.10 Decommissioning and Disposal Regulatisation

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 this Manual 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.

15.11Help email address

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

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