Diagnostic Radiology (DR) User Guidelines for regulatory applications submission in e-Licensing of Radiation Applications (e-LORA) system

Radiological Safety Division ATOMIC ENERGY REGULATORY BOARD, Mumbai September, 2021



The detailed steps are mentioned in subsequent pages in Table-A.

*For obtaining Registration of dental X-ray equipment, pl. refer e-LORA Dental Radiology Guidelines.

(Link location: https://10.55.55.11/images/PDF/dentalguidelines05082019.pdf)

Step	Purpose	Regulatory Form /	Page	
		Regulatory Process	Number	
Step-1	Register Institute in e-LORA System	Register Institute	4	<u>Click here</u>
Step-2	Obtain Procurement Permission	a. Procurement of new X-ray Equipment	5-6	<u>Click here</u>
		b. Procurement of Pre-owned X-ray Equipment	6-7	<u>Click here</u>
Step-3	Add instruments, 1	radiation workers and designate /	nominate F	RSO
	a. Add Operator and Medical Practitioner	a. Add Employee	7-10	<u>Click here</u>
	b. Declaration of Instruments(Radiation Protection Devices)	b. Add Instrument	10-11	<u>Click here</u>
	c. Radiological Safety Officer (RSO)	c. Nominate / Designate RSO (Separate RSO approval for CT and IR installation)	11-14	<u>Click here</u>
Step-4	Installation of x-ray equipment	a. For new X-ray equipment: Submission of installation report (including QA and Radiation Protection Survey) by the supplier from his e- LORA account	14-17	<u>Click here</u>
		b. For pre-owned X-ray equipment: Submission of Intimation of Receipt by the user from its account	17-18	<u>Click here</u>
Step-5	Obtaining Licence for operation	Licence for operation of New/Pre-owned X-ray Equipment	18-19	<u>Click here</u>
Other ro decon	egulatory processes such as imission of x-ray equipment	<i>modification of installation, r</i> <i>are listed in below <u>Table</u>-B.</i>	enewal of	licence, and

A. Steps for obtaining licence for operation of New/Pre-owned diagnostic X-ray equipment

Sr. No.	Process	Regulatory Form / Regulatory Process	Page Number	Reference
1	Obtaining Renewal of Licence	a. Renewal of Licence for operation (New/Pre-owned)	20	<u>Click here</u>
		b. Renewal of Licence for operation of Existing X-ray Equipment(declared X-ray equipment)	20-21	<u>Click here</u>
2	Obtaining Decommission Permission	a. Intimation of Decommissioning	21-22	<u>Click here</u>
		b. Confirmation of decommissioning by supplier	22	<u>Click here</u>
3	Modification of Installation, relocation and reposition of equipment from its original place	Change in Layout	22-23	<u>Click here</u>
4	QA test summary of periodic QA or QA test summary after layout change	QA Test Summary	23	<u>Click here</u>
5	Periodic Radiation Protection Survey Report	Radiation Survey Report	23-24	<u>Click here</u>
6	Non-compliance response	NC response screen	24	<u>Click here</u>
7	Safety Status Report of the Institute	Safety Status Report	25	Click here
8	Procurement of X-ray tube	Procurement of X-ray tube	25	Click here
9	Submission of receipt after receiving x-ray tubes	Intimation of receipt	26	<u>Click here</u>

B. Other Regulatory Approvals / Procedures applicable for Diagnostic X-ray Equipment

Adhoc Applications

Sr. No.	Process	Regulatory Form / Regulatory Process	Page Number	Reference
1	Remove duplicate or incorrect declared x-ray equipment	Adhoc Application	26-27	<u>Click here</u>
2	Recognition of X-ray Technologist course	Adhoc Application	27	Click here
3	Application for enforcement compliance report	Adhoc Application	27	<u>Click here</u>

Step-1: Register Institute in e-LORA System

- Visit AERB website **www.aerb.gov.in**.
- Click on the button e-LORA, which is available on website home page



- 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 below Guidelines for Institute Registration to proceed for registration in e-LORA. (https://elora.aerb.gov.in/ELORA/PDFs/Guidelines%20for%20Institute%20Registration.pdf)

Government of India of Atomic Energy Regulatory Board e-Licensing of Radiation Applications	Image: Second and Second	
In case of any difficulty/issue related to eLORA kind Unresolved matter may be escalated to Head, MAS for N and to Head, IAS (<u>rksingh@aerb.gov.in;</u> 022-25990417)	eLORA (e-Licensing of Radiation Applications) System	
RSD (trend rsd @aerb nov.in; 022-25990656)	An e-Govenance system for obtaining Regulatory Consents from AERB for following Radiation Facilities/Stakeholders: Diagnostic Radiology Radiotherapy Nuclear Medicine RIA (Radio Immuno Assay) Gamma Iradiation Chamber Industrial Radiography Nucleonic Gauge Well Logging Gamma Radiation Processing Facility IARPF (Industrial Accelerator and Radiation Processing Facility) Calibration Facility Consumer Product Medical Cyclotron Research and Sealed Source Research Directorate of Radiation Safety/Radiation Safety Agency Transport Package Manufacturers DAE (Department of Atomic Energy) Facilities-For Transport Approvals	
Licensed Diagnottic Radiology facilities in India and approved service agencies Statistics	eLORA System	
Always use employer e-mail l Application in e-LORA syste e-LORA applications.	D and mobile number while submitting Institute Registration mand save your user Id and password for submission of)n

A. Steps for obtaining licence for operation of diagnostic X-ray Equipment

Step-2: Obtain Procurement Permission

a. Procurement of new X-ray Equipment

• After submitting the general details in e-LORA system, follow below path to open Procurement form for **new equipment**:

Regulatory Forms >>>Medical Diagnostic Radiology >>> Procurement of X-ray Equipment

AERB LOU	BOARD . TUPU	Govo Atc <i>e-Li</i>	ernment of Omic En censing of	f India ergy Re F Radiatio	gulatory Board		
					Procurement of X-ray Equipment		
n Key: Verify the Mol	oile n	umber and	l e-mail id of Empl	oyer & the second	Licence for Operation		
					Procurement of Pre-Owned Equipment		
					Change in Layout		
					Safety Status Report		
Change Password					QA Test Summary		
Change User ID					Radiation Survey Report		
Instrument Manageme	nt 🕨		In case of any di	fficulty/issue relate	Procurement of X-ray Tube		
My Applications		Common Fo	orms	۱.	Intimation of receipt		
My Casefiles		Incident Reporting		Þ	Intimation of Decommissioning		
My Institute Details		Medical Dia	agnostic Radiology	Þ	Existing X-ray Equipment Forms	Þ	
Regulatory Forms	Þ	Transport		Þ	Dental X-ray		
lype Approved Equipments			D 1 1 1				

• You will be required to provide the shielding details in the application form. For details, please refer 'Layout and shielding guidelines' available at AERB website (Link location: <u>https://10.55.55.11/images/PDF/layout_guidelines.pdf.)</u>

quipment Details	yout and Shielding Details Attachments			
				All fields marked by * are mandatory
ype of Equipment*		Select	~	
Nhether equipment to be u	used as vehicle mounted*	OYes ONo		
Expected workload*		Select	~	
Equipment Details				
Purpose of the Equipn	nent*	Select	~	
Approval required for	*	Select	~	
		I have read and agree to the Terms &	Conditions	

pment Details Layout and Shi	elding Details Attachmer	its					
Location of x-ray Installation							All fields marked by * are man
Room number*							
Floor*							
Wing							
Department*							
Layout Details							
Wall Identification	Distance from center c	exposure area (from of the couch) (m)	Mater	ial used for shielding	Occuj	pancy behind the wall	Thickness of the shielding material (c
Wall A*			[Select]	V	[Select]	V	
Wall B [*]			[Select]	Y	[Select]	¥.	
Wall C			[Select]	~	[Select]	V	
Wall D*			[Select]	V	[Select]	v	
Entrance Door [*]			Lead		[Select]	V	
Any other door			Lead		[Select]	Y	
Window, if any, if at the height m from outside finished floor of room	ess than 2 testing		[Select]	¥	[Select]	V	
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NOSTIC RADIOLOGY PROCUREN NOSTIC RADIOLOGY PROCUREN uipment Details Layout and Sh e recommend you to complete e dec, decc, vite, viter, viter, dec ther, viter, viter, viter, viter, dec ther Attachments, if any add row Delete row	IENT OF X-RAY EQUIPMENT ielding Details Attachme the Form first and th , png. zip, pdf Alternatively, you uipment installation(Please]	nts en proceed for the up might zip it and upload it. 3 Provise. No fil Attachment Brovise. No fil	pload for your Software for com le selected. ile selected. have read and	attachments. The may pressing files can be downloa	timum file size aded for free from h	allowed for each file ttp://www.7-tip.org/downloa Clear Clear	upload is 2 MB and allowed file ty d.html All fields marked by * are mandat

- Upload scan copy of duly signed and stamped layout plan.
- Read Terms and Condition of application prior to click Submit bottom.

When installation of X-ray equipment is complete in all aspects in your institute, contact your supplier to submit installation report from eLORA account. After acceptance of installation report by AERB, e-LORA system will allow you to submit application for Licence.

Submit Close Reset

b. Procurement of pre-owned X-ray equipment

• User is required to submit application form for "Procurement of pre-owned X-ray equipment" through eLORA account.

Kindly attach a documentary evidence in support of year of manufacturing of the x-ray equipment to be imported such as photographs of the x-ray equipment in which year of manufacturing is engraved along with serial no. of the equipment. Acceptable Criteria: Year of manufacturer for pre-owned diagnostic X-ray equipment to be imported is ten years for supplier authorized by OEM or seven years for service agency.

• You will be required to provide the shielding details in the application form. For details, please refer 'Layout and shielding guidelines' available at AERB website (*Link location: https://10.55.55.11/images/PDF/layout_guidelines.pdf.*)

AERB KOV RECULATO	Government of Atomic En e-Licensing of	f India e rgy Re f Radiatio	gulatory Board Adhoc Application Procurement of X-ray Equipment	`` ^ystem
		-	Licence for Operation	
			Procurement of Pre-Owned Equipment	
			Change in Layout	nbox
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Change Password			QA Test Summary	
Change User ID			Radiation Survey Report	
Instrument Management 🕨	In case of any d	ifficulty/issue relate	Procurement of X-ray Tube	elora.info
My Applications	Common Forms	Þ	Intimation of receipt	h@aerb.go
My Casefiles	Incident Reporting	•	Intimation of Decommissioning	
My Institute Details	Medical Diagnostic Radiology	► E	Existing X-ray Equipment Forms	•
Regulatory Forms 🛛 🕨	Transport	Þ	Dental X-ray	
Type Approved Equipments	Dete and Tim			
FAQ - Raise an Issue	Date and 1 im	e 🏺		

Step 3. Add instruments, radiation workers and designate / nominate RSO

Prior to apply for Licence; follow following steps:

a. Add Operator and Medical Practitioner:

Employee can be added in three tabs as follows:

•Radiation Worker (This is to add employee with role Operator and Medical Practitioner)

•Non Radiation Worker (This is to add Employer/ Licensee, who may not be a radiation worker)

•Radiation Professional (This is to add Radiation Professional who is to be nominated as RSO).

Please use individual email ID for every Radiation Worker/Radiation Safety Professional in place of using common email ID of the institution.

 You are required to add Operator and Medical practitioner in Radiation Worker. For adding employees to your institution, please follow the path as: User management>>>Add Employee>>> Select required Type of Employee from drop down



Designation	
Select profile	Radiation facility - Cooled Sources
	Medical diagnostic x-ray facility
	Supplier of x-ray equipments/x-ray tubes
	Medical Diagnostic-Service Agency
	Industrial Radiography (Radiation Facility)
PMS NO *	
(Applicable for 'Medical diagnostic x-ray facility,Radiotherapy,Nuclear Medici	ine' xxxxxxxCxxxxx
oniy.)	
Role	Medical Dractitioner-Medical diagnostic x-ray facility
(<i>Appncable for 'Medical diagnostic x-ray facility' only.</i> Role shall be selected based on appropriate qualifications. Refer AERB webs	site
for required minimum qualifications.)	v 😨
Education Qualification	
(Appressive for "reasear diagnostic x-ray facility" only.)	Please select
Attachment for uploading copy of proof of education (Applicable for 'Medical diagnostic x-ray facility' only.)	Y Day Tackarda sista Cayraa
	x-kay rechnologists Course
Permanent Address	MBB2
Address Line1*	MD
Address Line2	MS
Landmark	BDS
State*	MDS
City/District *	DNB
PIN*	MCh
	Diploma (After MBBS)
email(0)*	DM
Phone(O)*	
Attachment for uploading copy of Joining/Confirmation*	Browse No file selected. Clear
Attachment for uploading copy of proof of identity *	Browse No file selected. Clear

While adding Radiation Worker in e-LORA, provide the following details;

- > Provide required personal information of employee viz. Title, Name, Gender and Date of Birth
- Provide required service information of employee viz. Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department, Designation,
- Profile (select 'Medical diagnostic x-ray facility'),
- Role (select any one or both using Ctrl key as applicable) and Education Qualification (select value from drop down)
- Provide address and contact detail of employee
- Browse and upload scan copy of educational qualification, joining /confirmation letter of employee and
- click on Submit

Repeat the above procedure to add your other Operators and Medical practitioners.

The minimum qualification requirement for personnel in diagnostic x-ray installation is mentioned in <u>Annexure-1</u>.

You will not be able to fill application form for Licence (and will get following error message) unless you declare operator and medical practitioner of your institute. For CT and Cath lab facility please add one of your employee as Radiation Professional for nominating him as RSO.

The guideline for radiation professional registration is available in the link;

https://10.55.55.13/ELORA/PDFs/GUIDELINES%20FOR%20SUBMISSION%20OF%20RADI ATION%20PROFESSIONAL%20FORM%20_09Nov2016.pdf.

Government of India Atomic Energy Reg e-Licensing of Rad	ulatory Board iation Applications (eLOR/	A) System	हिंदी संस्करण AERB Website
In case of any difficulty Unresolved matter may b and to Head, IAS (<u>rksingt</u> RSD (<u>head.rsd@aerb.gov</u>	/issue related to eLORA e escalated to Head, MAS f @aerb.gov.in; 022-259904 .in; 022-25990656)	kindly contact eLORA Help Desk (elora.info@aerb.g for Medical and Research Applications (gsahani@aerb. 17) for industrial Applications. If need to escalate furth	tov.in; 022-25990675). gov.in; 022-25990663) her, may contact Head,
Guidelines	Know Your Application Status	Frequent Queries	
~	Institute Registration Application	RP/Institute registration status Reason for non-acceptance	Login
Guidelines for Institute Registration	Radiation Professional Registration Application	Correction in e-mail id and mobile no. Login issues Profile/role issues Practice issues	Institute ORadiation Professional ORSO
Guidelines for Radiation Professional Registration	Verification of Consent/Document	Check application status Correct submitted data	Username*
Licensed Diagnostic Radiology facilities in India and approved service agencies	issued through eLORA	Institute Registration Step by step help Raise an issue to AERB	Password* Practice*Select One v
Type approved equipment list	eLORA Application Processing	Registration of RP Training Courses Feedback	Institute RoleSelect One V
Feedback	Statistics	Authorised QA/Service/Supplier for DR	Installation Type
Personnel monitoring of Radiation workers in Radiation Facilities	4	TA equipment List of survey meter/dosimeter suppliers	Login
Unregistered Institute Excessive Exposure Investigation Report Submission	radiation installations & application sub	For regulatory support you may contact Help Desk No. 022-25990675 during working days between 10:00 AM - 05:00 PM New	Forgot / not received my password Forgot / not received my User Id
<u> </u>	Click here for details		Forgot/Wrong email id & mobile no
Processing time for issuance of Regulatory Consents			

b. Declaration of Instruments (Radiation Protection Devices)

- Diagnostic X-ray facility must have certain types of safety tools (radiation safety devices). The list is given in the below table and the same must be declared in e-LORA. Hence, please add the instrument in '*Safety Tool*' option.
- To declare instruments, follow the path as: Menu>>>Instrument Management>>>Add Instrument

Change Passwo		o maromeni						
Instrument Mai	nagement 🕨 Vie	w nstrument						
My Applications			1.771					
My Casefiles		26/	Date and 11m 02/2014 10:40	ie ≑ AM Vou	annlication t	or registrati	on of x-ray ins	ert [Ref: No 1
ou will no	t be able to	fill applicat	ion form f	for Licenc	e (and wi	l get foll	owing erro	r message
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• Add following Instruments as applicable to each type of equipment.

Type of Equipment		Instruments to be
Type of Equipment		added
	Type of	Instrument Sub Type
	Instrument	
Interventional	Safety Tool	• Protective Apron (Minimum 3)
Radiology		Protective Rubber Flaps
		Ceiling suspended protective glass
Computed Tomography	Safety Tool	Protective Apron
Radiography and	Safety Tool	• Mobile Protective Barrier with lead equivalent
Fluoroscopy	-	Viewing Window
		Protective Apron
		Protective Rubber Flaps
Radiography(fixed)	Safety Tool	Mobile Protective Barrier with lead equivalent
		Viewing Window
		Protective Apron
Mammograpy	Safety Tool	Mobile Protective Barrier with lead equivalent
Dental (OPG)		Viewing Window
Dental (CBCT)		
Radiography	Safety Tool	Protective Apron
(Mobile)		
Radiography		
(Portable)		
C-arm/		
O- Arm		
Dental (Intra-oral)		
Dental(Handheld)		

<u>c. Radiological Safety Officer (RSO)</u>

For obtaining RSO approval follow the path as:

- <u>*Path-a:*</u> For a person required to be nominated as RSO, you need to add him/her in the type **Radiation Professional (RP).** While adding RP, system will ask RP registration ID and Date of birth of RP. (Obtain these details from Radiation Professional).
- For RSO Nomination: Select name of the "RSO Designate" from the employee List

Email ids of both employer and Radiation Professional should be different. Use separate (unique) email id and mobile no. for each employee. For Radiation professional, please use personnel email id and mobile no. for verification in eLORA.

In the form for adding 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	

- 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. e.g.: 000297C0198),
- Department and Designation,
- Profile (i.e. 'Medical diagnostic x-ray facility') and Role (i.e. 'Operator', Medical Practitioner' or both)
- Provide Email (O)
- Browse and upload scan copy of joining /confirmation letter of employee and
- click on Submit

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

<u>Path-b:</u> First generate the transaction key by using tab "Transaction key"

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

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

 Lett side block displayed number of the list of emplo 4. All OTP and keys expires a 5. One key can be used only 6. Multiple keys can be gener 7. Keys can be used across p 	elow show's employer e-mail id and mobile number by pelow will contain only those Employee (who will be th yees are verified. If not, then Click Here t 12 midnight everyday once ated for 1 employee ractices and profiles	gerauit le applicant of the application - Employ	ver or Licensee). Make sure, e-mail id and mobile
	Employer Details	Employee Details	s (Applicant/RSO to be nominated)
mployer Registered Email mployer Registered Mobile mail OTP 10bile OTP	bharat.bang@tcs.com 9619672774	Employee Name 🕡 Employee Registered Email Employee Registered Mobile Email OTP Mobile OTP	
Existing OTP	Existing OTP's are the latest received OTPs, not Send OTP Verify Transaction	used within valid time. If not valid, use Sin Key :	end OTP facility. Reset

- You can check the verification status of the email and mobile number of the employer from the list appears.
- If status of verification is "no", then corresponding employee has to Log in to the system (RP log in for RSO).

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

• <u>Path-c:</u> Fill the form by following path; Menu>> Regulatory Forms>> Common Forms>>Nominate RSO

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Change Password						Myl
Instrument Manageme	ent 🕨					
My Applications						
My Casefiles			Date	and Time 🍦		
Mu Durfte			26/02/2	014 10:49 AM	Your application for	registration of x-ray insert [Ref: No 14-3156, Date:26/02/2014] has b
My Drafts			2.6/02/2	014 10 [.] 47 AM	Von have successful	y submitted Application for registration of an x-ray insert with applic
My Institute Details		Common For	ms	D	Nominate RSO	ciated from your Institute.
Regulatory Forms	₽	Medical Diag	nostic Rad	iology 🕨 🕨	ABC DE successfull	y dissociated from your Institute.
User management	•		25/02/2	014 01:26 PM	Your application ref	no. 14-3137 is Approved. Approval No 14-RSO-2718
View Inspection			25/02/2	014 01:21 PM	You have successful	ly submitted RSO Nomination with Application No. 14-3137 for HAN
Documents			25/02/2	014 01:21 PM	Signed PDF has been	n uploaded successfully.
			25/02/20	014 01·21 PM	Vou have successful	ly freezed RSO Nomination with application no. 14-3137

		All fields marked by *are manda
Select Radiation Professional		An Heldo Harred by Gromanda
Radiation Professional*		· · · · · · · · · · · · · · · · · · ·
Date of Birth*		
Registration ID*		
Role of RP*		
RSO Status*		
e-Mail Id Official*		
Education Details		
Experience Details		
Transaction Key Details*		
Enter Transaction Key*	XXXXXX	

• 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.

Step-4: Installation of X-ray equipment

a. For new X-ray equipment: submission of installation report by the supplier from his e-LORA account

- Users should obtain the procurement permission.
- Prior to supply of x-ray equipment, Supplier should ensure that the end user has obtained **Procurement Permission** from AERB.
- After Installation of X-ray equipment carry out the QA and Radiation protection Survey around the X-ray installation.

<u>Quality Assurance and radiation protection survey:</u> Prior to apply for license for operation of x-ray equipment, arrange Quality Assurance (QA) from authorized suppliers/ accredited service agencies as per AERB prescribed formats. The Quality Assurance (QA) formats are available on AERB website:

Radiography / Radiography & Fluoroscopy /C-Arm / Interventional Radiology https://10.55.55.11/images/PDF/DiagnosticRadiology/1-FORMAT-FOR-

QUALITY-ASSURANCE-TEST-FOR-DIAGNOSTIC-X-RAY-EQUIPMENT.pdf

Computed Tomography

https://10.55.55.11/images/PDF/DiagnosticRadiology/2-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-COMPUTED-TOMOGRAPHY-EQUIPMENT.pdf

Mammography

https://10.55.55.11/images/PDF/DiagnosticRadiology/3-FORMAT-FOR-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-MAMMOGRAPHY-EQUIPMENT.pdf **<u>Radiation Protection Survey:</u>** Radiation protection survey needs to be carried out from authorized supplier of equipment or approved service agency as per prescribed format and provide the details in the application form (as applicable).

Keep the water phantom on the table (In place of water phantom plastic bucket with 30 cm height water in it can be used) to simulate the patient. The primary beam has to be directed to the water phantom by opening collimator setting to the maximum and measure the radiation level at different locations of interest by using calibrated Ionisation Chamber/Semiconductor based survey meter.

The typical exposure parameters (column 2, 3 and 4) to be selected for carrying out survey and the typical workload for each type of facility are mentioned in the table;

Type of Equipment	Applied Voltage (kV)	Applied Current (mA)	*Exposure time (Sec)	Typical Workload (mA-min/Week)
	()			
Interventional	70-80	8-10 (fluoro mode)	1.0 -2.0	5000
Radiology				
Radiography (fixed)	~70	~50	1.0 -2.0	500
Radiography &	~70	3-10	1 0-2 0	500
Fluoroscopy	70	0 10	1.0 2.0	500
(Use fluoro mode)				
OPG	60-80	10-12	1.0 -2.0	300
CBCT				
Computed	100-120	40-50	1.0 - 2.0	25000
Tomography				
Mammography	30-35	~50	1.0 - 2.0	300

* Exposure time should not be less than 1 Sec

Provide the values of maximum radiation level (in mR/hr), measured by radiation survey meter at following places:

Place of Interest	Maximum radiation level (in mR/hr)
Near control console (operators position)	
Outside patient entrance door	
Behind chest stand wall	
Behind window (if any)	
Patient waiting area	

• Supplier should submit installation report after installing the x-ray equipment

 To submit the installation report. Supplier need to fill the form for Installation report from his e-LORA account and follow the path; Regulatory forms -> Medical Diagnostic radiology -> Installation Report.

				Registration of X-ray tube
				Type approval
				Procurement of x-ray equipment
Change Pass	word			Procurement of x-ray tubes
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My Casefiles		Incident Reporting)	Radiation Survey Report
My Institute [Details	Medical Diagnostic Radiology	•	Confirmation of decommissioning
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After filling all the tabs then click **on submit**.

b. For pre-owned X-ray equipment: Submission of Intimation of Receipt by the user from its account

- Users should obtain the procurement permission
- After installation & commissioning of X-ray equipment, user should submit "Intimation of Receipt" through eLORA.
- (Please approach to Supplier/ Service Agency to obtain installation report, QA report and radiation protection survey as referred above it is one of the conditions mentioned in authorization/approval of supplier/service agency. Also check whether QA report and survey report and installation report is as per AERB guidelines).

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Step-5: Obtaining Licence for Operation

- After checking approval/submission status of installation report (for new) and intimation of receipt (for pre-owned) of X-ray equipment in e-LORA system, fill the application form for Licence.
- Ensure that required Employee(s) and Instrument details are provided in your account.
- Follow below path to access Licence form: Regulatory Forms >> Medical Diagnostic Radiology >>Licence for Operation

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mployee Details	Safety Tools Details	Equipment Details			
Application for*				Licence for operation of new x-ray equipments	
Equipment Id [*]					
Supplier/Service Ag	gency responsible for QA*	i.			
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			M	I have read and agree to the Terms & Conditions.	
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- Select the equipment ID, agree terms and conditions and
- Press submit button for submission of your application form.
- After submission you can get the application status by using "My Application" tab which is available in your e-LORA account.
- After getting approval you can **download your issued** Licence/Registration certificate by using following path My Application>>Select Application No.>>Show Details>>Approval letter attachment

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B. Other Regulatory Approvals / Procedures applicable for Diagnostic X-ray Equipment

1: Obtaining Renewal of Licence

a. Renewal of Licence for operation (New/Pre-owned)

The application form for Renewal of License is available in Menu:

Regulatory Forms> Medical Diagnostic Radiology> Licence for Operation > equipment details tab>>select renewal.

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Application for [*] AERB License Number [*] Equipment Id [*] Supplier/Service Agency responsible fo	or QA ⁺	Renewal of Licence for op	eration
Maintenance of Records Whether dose records of radiatio Whether servicing/maintenance r Whether quality assurance and r	n workers are maintained [®] ecords are maintained [®] adiation protection survey record	S are maintained*	
		☐ I have read and agree t	o the Terms & Conditions.

<u>b. Renewal of Licence for operation of Existing X-ray Equipment (declared X-ray equipment in eLORA)</u>

For Renewal of Existing Equipment, follow the below path;

Regulatory Forms> Medical Diagnostic Radiology> Licence for Operation of X-ray equipment> General details tab>>select application for renewal of licence for operation

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2: Obtaining Decommission permission

a: Intimation of Decommissioning

- For decommissioning of x-ray equipment, first contact agency to whom you are availing services for decommissioning
- Follow the path:

Regulatory forms -> Medical Diagnostic radiology -> Intimation of Decommissioning.

e the Applicant (who	Gran · CHNOR	Government of Inc Atomic Energ e-Licensing of Ra	lia gy Re diation	Adhoc Application Procurement of X-ray Equipment Licence for Operation Procurement of Pre-Owned Equipment	`_)
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My Casefiles		Incident Reporting	Þ	Intimation of Decommissioning	
My Institute Details		Medical Diagnostic Radiology	Þ	Existing X-ray Equipment Forms	•
					_

b: Confirmation of decommissioning

- Contact supplier/service agency for submission of 'confirmation of decommissioning' in e-LORA.
- After submission of confirmation of decommissioning by the supplier/service agency e-LORA account, the status of equipment will change to "Decommissioned".

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Change User ID				Intimation of receipt
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My Applications	Common Fo	rms	•	Quality Assurance Test Report Summary
My Casefiles	Incident Re	porting	۱.	Radiation Survey Report
My Institute Details	Medical Dia	gnostic Radiology	•	Confirmation of decommissioning
Regulatory Forms	Transport		•	Termination of services as supplier
Type Approved Equipments				

3. Modification of Installation, relocation and reposition of equipment from its original place:

In case of change in layout (due to Layout modification of installation, relocation and reposition of equipment from its original place), Submit application form for Change in Layout.

• Follow below path to access this form:

Regulatory Forms >> Medical Diagnostic Radiology>> Change in Layout

THE REPORT OF TH	Gove Atc e-Li	ernment of mic En censing of	India e rgy Re <i>Radiatio</i>	gulatory	Board
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My Casefiles	Incident Re	porting	Þ	Intimation of Decomm	issioning
My Institute Details	Medical Dia	agnostic Radiology	•	Existing X-ray Equipm	nent Forms 🔹 🕨
Regulatory Forms 🛛 🕨	Transport		•	Dental X-ray	
Type Approved Equipments				*	

• Pl. note, in this form you will have to provide detail of shielding around

X-ray equipment as asked in Licence form.

• Fill the detail as required in the form and Submit.

4. QA Test Summary of periodic QA or QA test summary after layout change

Use below path to submit QA test summary of periodic QA or QA done after layout change. Path to access application form :

Regulatory Forms >> Medical Diagnostic Radiology >>QA Test Summary

AFRB AT	e-Licensing of R	adiatio	
HERGY REGULATOT			Procurement of X-ray Equipment
er & e-mail id.			Procurement of Pre-Owned Equipment
			Change in Layout
			Safety Status Report
hange Dassword		_	OA Test Summary
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GNOSTIC RADIOLOGY NOUA	LITY ASSURANCE TEST REPORT SUMMARY		
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QA test conducted by*		Periodic	QA
		1 million of 6	Change

- In case of change in layout, you are required to submit radiation survey around the installation.
- The same form is also be used to submit Periodic RSR (RSR Radiation Survey Report).
- Follow the path to access this form: Regulatory Forms >> Medical Diagnostic Radiology >> Radiation Survey Report

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Change Password				QA Test Summary	
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My Applications	Common F	orms	•	Intimation of receipt	J.
My Casefiles	Incident R	eporting	•	Intimation of Decommissioning	
My Institute Details	Medical Di	agnostic Radiology	•	Existing X-ray Equipment Forms	
Regulatory Forms	Transport		•	Dental X-ray	
Type Approved Equipments					_

6. Non-compliance Response

- To check active Non-compliances details in your institute follow the path: My Institute details>>Non-Compliance Details
- For submission of response to the non-compliances raised through **regulatory inspection**, follow the path: Regulatory Forms>> Common Forms>>Non-Complaince Response.
- You are required to attach the documentary evidences against the compliance status.

	Govern Atom	ment of India I ic Energy Re	Nominate RSO
CONTRACT ALERBATOR	e-Licer	ising of Radiatio	Non-utilization of Approval
CY REGOD			Employer Change Initiation
was 8 the second party who will be the Applicant (who is asing to take (Non-Compliance Response
byer & the second party w	no will be the A	pplicant (who is going to take	Procurement-supply status
			Safety Status Report
			Feedback on Grant of Consent
Change Password			Feedback on Regulatory Inspection
Change User ID			Enforcement Response Screen
Instrument Management 🕨	Ind	case of any difficulty/issue relat	Exposure Investigation Report
My Applications	Common Forms	•	Update Operational Status
My Casefiles	Incident Reportir	ig 🕨 🕨	Security Plan
My Institute Details	Medical Diagnost	tic Radiology 🔹 🕨	
Regulatory Forms 🔹 🕨	Transport	•	
Type Approved			

- In case, Non-compliance (NC) is raised against the institute, Employer needs to take immediate action to resolve it.
- If more time is required for resolution of NC, same may be intimated to AERB with necessary justification in NC extension form, which can be downloaded from "Help" menu of e-LORA system.
- For closing NCs related to Renewal of Licence and Renewal of RSO Approval, kindly apply Renewal of Licence and Renew RSO Approval for their closure.

7. Safety Status Report

- Use this form to submit safety annual safety status of your Institute.
- Follow following path to access this form:

Regulatory Forms >>Common forms>>Safety Status Report

	र्षि प्रजी नियामक मुद्र	Covernment of India	Nominate RSO
	e mæm 🍋		Non-utilization of Annroval
L		Atomic Energy Re	Employer Change Initiation
L	AERB SE	e-Licensing of Radiatio	¹ Non-Compliance Response
L	CARGY REGULA		Procurement-supply status
L		e	Safety Status Report
L		•	Feedback on Grant of Consent
L	Change Password		Feedback on Regulatory Inspection
L	Change Liser ID		Enforcement Response Screen
L	Instrument Management	In one of our differents/income subst	Exposure Investigation Report
L	My Applications	Common Forms	Undate Operational Status
L	My Applications	Incident Paparting	
L	My Casenies	Medical Disposetia Badialany	Security Plan
I.	My Institute Details		
ľ	Regulatory Forms	Transport	
L	Type Approved		

8. Procurement of X-ray Tube

- This form is used to apply for procurement of x-ray tube (in case of replacement of old/damaged x-ray tube).
- Follow following path to access this form:

Regulatory Forms \rightarrow Medical Diagnostic Radiology \rightarrow Procurement of X-ray Tube



9. Submission of receipt after receiving X-ray tubesIntimation of Receipt

- After receipt of new X-ray tube, pl. submit its receipt through Intimation of Receipt form.
- Follow following path to access this form: Regulatory Forms →Medical Diagnostic Radiology→ Intimation of Receipt

		Home eL
Soft Frence Constant	Government of India Atomic Energy Regu <i>e-Licensing of Radiation A</i>	latory Board
TGY REGULA		Procurement of X-ray Equipment
a) from the right side so	seen. In the right side screen, the list will n	Licence for Operation
e) from the right side sci	een. In the right side screen, the list win p	Procurement of Pre-Owned Equipment
		Change in Layout
		Safety Status Report
Change Password		QA Test Summary
Change User ID		Radiation Survey Report
Instrument Management 🕨	In case of any difficulty/issue related	t Procurement of X-ray Tube
My Applications	Common Forms	Intimation of receipt
My Casefiles	Incident Reporting	Intimation of Decommissioning
My Institute Details	Medical Diagnostic Radiology	Existing X-ray Equipment Forms
Regulatory Forms	Transport	Dental X-ray
Type Approved Equipments		

Adhoc Application:

1. Remove duplicate or incorrect declared x-ray equipment

- For Removal of duplicate or incorrect entry, follow the path: Regulatory Forms>> Medical Diagnostic Radiology>>Adhoc application.
- Attach an application form 'Removal of duplicate or incorrect declaration of medical x-ray equipment,' which can be downloaded from "Help" Menu of e-LORA system.



dhoc Details	
efore filling this form you need to download and fill the re	equisite form and upload the same. To download the form click here
e recommend you to complete the Form first and then p re:.doc,.docx,.xls,.xlsx,.odt,.jpeg,.jpg,.png,.zip,.pdf.Alternatively,you migh	proceed for the upload for your attachments. The maximum file size allowed f It zip it and upload it. Software for compression files can be downloaded for free from http://www.7
ype of Application [*]	Application for removal of incorrect declaration X-ray Equipment 🗔
pplication description (Reason for submission)	maximum 500 characters allowed
	in the second
ttachment 1 [#]	Browse No file selected. Clear

11. Recognition of X-ray technologist course:

- Submit the completely filled the application for Medical Imaging Technologist course, which is available in AERB website; <u>https://10.55.55.11/images/PDF/DiagnosticRadiology/Application-form-for-Recognition-of-</u> X-ray-technologists-courses.pdf.
- Submit the filled application forms with necessary documents through the path;

Regulatory Forms>> Medical Diagnostic Radiology>>Adhoc application

Adhoc Details	
Before filling this form you need to download and fill the requisite for We recommend you to complete the Form first and then proceed for are:.docdocxxlsxlsxodtjpeqjpqpnqzippdf.Alternatively.you might zip it and upl	m and upload the same. To download the form click l the upload for your attachments. The maximum file si oad it. Software for compression files can be downloaded for free fro
Type of Application [*]	Application for Course Recognition (X-ray-Technologist)
Application description (Reason for submission)	maximum 500 characters allowed
	a de la companya de l
Attachment 1 [*]	 Browse No file selected. Clear

12. Enforcement compliance report:

• For submission of compliance with respect to enforce inspection action viz. Seal/ Warning of Seal of x-ray equipment of your institute, inspection compliance along with documentary evidence based on Inspection recommendations are required to be submitted through the following path:

Regulatory Forms>> Medical Diagnostic Radiology>>Adhoc application

Before filling this form you need to download and fill the	requisite form and upload the same. To download the form clic
Ve recommend you to complete the Form first and then re:.docdocx,.xls,xs,.odt,.jpeg,.jpg,.png,.zip,.pdf.Alternatively,you mig	proceed for the upload for your attachments. The maximum file ght zip it and upload it. Software for compressing files can be downloaded for free
ype of Application	Application for enforcement compliance report
Application description (Reason for submission)	maximum 500 characters allowed
Application description (Reason for submission) Attachment 1 [*]	maximum 500 characters allowed .:: Browse No file selected.

<u>Annexure-1</u>

- 1. The Qualification and Experiences for Personnel in medical X-ray installations are available at AERB website. (<u>https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/Qualification-Requirements-for-personnel-in-Medical-X-ray-Installation.pdf</u>)
- 2. For registering personnel of medical X-ray installation in e-LORA system, kindly refer below table

Role	Qualifications and Experience
Medical Practitioner	 Medical Practitioner having qualification such as MD/MS/DNB /DM/M.Ch./Post MBBS Diploma or equivalent in Radiology/Cardiology/Orthopedics/Neurology/Urology/ Gastroenterology/ Radiotherapy/ Nuclear Medicine or equivalent or BDS/MDS degree. For veterinary medicine facility, medical practitioner having qualification B.V.Sc. & AH/ M.V.Sc. & AH or equivalent
	obtained by the medical practitioner from Abroad.
Operator *	X-ray technologist passed Radiographer's/X-ray Technologist's course from a recognized Institution/Board/University or Medical Practitioner
Radiological Safety	A. RSO for medical X-ray installation (CT/IR installation)
Officer (RSO)	Medical practitioner having qualification mentioned above
	Or X-ray technologist passed Radiographer's/ X-ray Technologist's course from a recognized Institution/Board/University with three years working experience in the field of Computed Tomography (CT) / Interventional Radiology (IR). Or
	Medical Physicist having qualified certificate of RSO level-III (RSO-Medical)
	Nuclear Medicine Technologist / Nuclear Medicine Physician having qualifying certificate of RSO Level-II (RSO-Nuclear Medicine)
	B. RSO for medical X-ray installation (other than CT/IR installation) Employer/Licensee shall designate appropriate person as RSO subject to furnishing "Undertaking" that he/she is familiar with the regulatory requirements and radiation protection aspects of medical x-ray installation by mentioning his/her name in Registration Application Form submitted to AERB.

*Note:-

In certain installations such as Interventional Radiology/Computed Tomography/Fluoroscopy equipment, it is not practicable for a Medical Practitioner to operate the equipment, while also performing the procedure. It is advisable that such institute should ensure that a qualified X-ray technologist is available for operating such equipment in addition to the Medical practitioner.

More Information:

- I. Pl. refer Frequently asked Questions of Diagnostic Radiology Practice available in 'Help' menu of e-LORA system
- II. In case, issue persist, pl. submit the problem through 'Raise an issue' option of e-LORA system
- III. Please click quick help on e-LORA: https://10.55.55.11/index.php/english/quick-help-on-e-lora
- IV. You contact us at following Help Desk Number

Help Desk No. and Email id for Diagnostic Radiology Users

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

Important Message

NO LICENSE FEE /PROCESSING FEE BY AERB

It may please be noted that at present AERB does not charge any fee for issuance of regulatory consents including License or Registration. However, It has been brought to the notice that some of the suppliers/agencies, while providing services/assistance to the users of Diagnostic X-ray facility for getting their X-ray equipment licensed or registered by AERB, are demanding money to be paid to AERB. In case anybody demands for payment to be made to AERB or any of its officials, kindly provide all the details to:

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

References:

I.	AERB Safety Code 'Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-Ray Equipment' (No. AERB/RF-MED/SC-3 (Rev. 2), 2016)
	https://10.55.55.11/images/PDF/DiagnosticRadiology/Safety-Code-for-Diagnostic-
II.	<u>Radiology.pdf</u> Diagnostic radiology AERB Web Page
	https://10.55.55.11/english/regulatory-facilities/radiation-facilities/application-in- medicine/diagnostic-radiology
III.	Qualification Requirements for personnel in Medical X-ray Installation <u>https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/Qualification-Requirements-for-personnel-in-Medical-X-ray-Installation.pdf</u>
IV.	Layout and shielding guidelines: https://10.55.55.11/images/PDF/layout guidelines.pdf
V.	TLD badges https://www.aerb.gov.in/images/PDF/tldpage.pdf
VI.	Format for warning placards to be pasted outside x-ray installations
	https://www.aerb.gov.in/images/PDF/placard.pdf
VII.	List of licensed X-ray Facilities
	https://10.55.55.13/ELORA/prePopulateGraphData.htm
VIII.	List of type approved x-ray equipment
	https://10.55.55.13/ELORA/prePopulateGraphDataTypeApproved.htm
IX.	List of approved service agencies
	https://10.55.55.13/ELORA/prePopulateGraphData.htm
Х.	Quick Help on e-LORA
	https://10.55.55.11/index.php/english/quick-help-on-e-lora
XI.	Booklet on 'Radiation Safety in Diagnostic Radiology- Information for X-ray Technologist'
	https://www.aerb.gov.in/images/PDF/drsafetybook.pdf
VII	Desident on Dediction Sofaty in Discussion Dedicloses? in Undi

XII. Booklet on 'Radiation Safety in Diagnostic Radiology' in Hindi https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/29_06_2020_hindi_safet y_booklet.pdf

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