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E-Licensing of Radiation Applications (eLORA) in Armed Forces Hospitals: 'Nuts and Bolts'

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ABSTRACT

As per current statutory requirement, licence for operation of all medical radiation facilities (diagnostic radiology/radiotherapy/nuclear medicine) in India has to be obtained using the e-Licensing of Radiation Applications (acronym as 'eLORA') platform which is a web-based application on Atomic Energy Regulatory Board (AERB) website. This article is envisaged as a procedural guide for all medical administrators and radiologists in service institutions processing eLORA. Specific focus has been placed on practical methods to deal with inherent procedural hurdles unique to armed forces institutions, based on first-hand experience gained in successful eLORA processing at a tertiary care hospital.

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Introduction

It is mandatory that all medical radiation facilities (diagnostic radiology/radiotherapy/nuclear medicine) in India be registered with Atomic Energy Regulatory Board (AERB)¹ and armed forces medical units are no exception. As per AERB announcement dated 10 September 2014,² licence for operation of all such facilities has to be obtained compulsorily and exclusively using the e-Licensing of Radiation Applications ('eLORA') platform. eLORA is a comprehensive web-based application created by AERB for standardising and automating the regulatory process involved at their website.

However, as a first time user during our journey to becoming a fully AERB certified diagnostic radiology facility

in a service hospital, we experienced numerous speed breakers on this e-way, which we dealt with sequentially. This article is a step-by-step guide for all armed forces hospitals/institutions processing eLORA, with special emphasis on sharing our experiences in tackling the procedural hurdles unique to service institutes at each step. We have highlighted these as 'Nuts and Bolts' (NB) in each section.

The issue in perspective

The four broad sequential steps involved in eLORA registration are:

A. Preliminary preparation.

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- B. Registration of the institute with AERB.
- C. Registration of radiation professional (RP).
- D. Application for licence.
- A. Preliminary preparation

As in any well-planned activity, the first steps will set the direction and pace to the further course. The vital components to be paid attention to at the beginning of this journey are summarised in the following listed nine steps. Early attention to completion of these will save a lot of time and effort later.

- 1) **Arrange a computer** with Internet access and attached scanner.
- 2) **Download the 'User guide to registration'** from www.aerb.gov.in.³
- 3) **Identify employer** – Commanding Officer (CO) unit/ Senior Medical Officer unit can be nominated as head of institution or employer.
- 4) **Identify RP**: Any Medical officer or radiographer having diploma in medical imaging (with 3 years experience in the field of CT/Interventional Radiology) or a person having valid radiological safety officer approval from AERB can qualify as RP.
- 5) **Identify radiation workers (RW)**: Besides radiographers, all personnel working with radiation applications, such as Cardiologists, Urologists, Neurosurgeons, Orthopaedicians, Gastroenterologists and their respective assistants will qualify as RW. For every radiographic equipment, at least one Operator and one Medical Practitioner are mandatory for obtaining Operational Licence. For Computerised Tomography (CT) and Interventional Radiology (IR) equipments, in addition to Operator and Medical Practitioner, having a Radiological Safety Officer (RSO) is mandatory.

NB: In case of shortage of eligible RW (as in smaller units), any Medical Officer can be defined a role of both medical practitioner and operator.

- 6) **Personnel document aggregation**: Mandatory scanned documents for all personnel as in paras 3–5 above include age proof, identity proof, education proof, proof of employership (posting certificate), photograph and email id. In addition, for all RP and RW, the personal monitoring service no., also known as thermoluminescent dosimeter (TLD badge) no. is also required.

NB:

- a. Posting certificate should be signed by administrative officer clearly stating designation and date of joining the unit.
- b. Only radiographers in possession of diplomas in medical imaging (as issued from Medical Training Centre, Indian Air Force, Bangalore/School Of Medical Assistants, Indian Naval Hospital Ship Ashwini, Mumbai/Armed Forces Medical College, Pune or equivalent) are eligible. As on date, in-service X-ray assistant Class I/II/III are not recognised by eLORA.
- c. Since we have a constantly changing manpower in armed forces, every RW coming on posting to the unit has to apply for a TLD badge on arrival.
- d. Ensure the size of each document upload to be less than 2 MB.

- 7) **Equipment-related document aggregation**: All valid quality assurance (QA) reports and licences of equipment and AERB-approved room layout plans available at the department should be scanned.

- 8) **Actions to update incomplete equipment-related documentations**: If any equipment does not have the requisite QA report, fresh QA report for the same needs to be obtained after due inspection by an agency certified by AERB for this purpose. Once obtained, a QA report is valid for 2 years. Similarly, if any premises housing radiation appliances does not have approved layout plans, these should first be prepared as per guidelines and model layout plans available on AERB website.

NB:

- a. In case the radiographic equipment had been installed within the last 2 years, QA report should be available with the equipment; if not, the equipment supplier should be contacted to provide the same.
- b. As per the authors' knowledge, AFMSD Pune is in correspondence with AERB for obtaining permission to issue QA reports. Till such time, this service should be outsourced from AERB-authorised private agencies, with the expenditure borne out of office contingency grant or equivalent public fund.
- c. AERB-approved layout plan would be provided by vendor in case of a turnkey installation.
- d. Layout plans are not applicable for mobile radiographic units, C-Arm, O-Arm, Dental (intra-oral), Dental (hand-held) and BMD equipments.
- e. If the available premises do not meet the stringent specifications laid down as per AERB, local commanders are to ensure the modifications of premises through MES resources or otherwise. Special attention has to be given to lead lining of doors.
- f. On completion of modifications of premises, a radiation survey in the prescribed format has to be carried out either by equipment manufacturer or AERB-authorised agencies.
- 9) **Details of safety instruments**: Diagnostic radiographic facility must have certain types of safety tools like Mobile Protective Barrier Protective Apron and Rubber Flaps. Note down the quantity, functional status, dimensions in mm (length/height, breadth) and lead equivalence in mm. Dimensions are not required for lead aprons.

NB: QA should be regularly carried out for these safety tools.

- B. Registration of institute

- 1) Log in to www.aerb.gov.in/elora.
- 2) Click 'Register Institute' ⇒ fill the application form (Fig. 1).
- 3) In tab 'Institute Details', the following will be required.

NB:

- a. Proof of registration with Central govt.: A numbered certificate from the Registrar/Adjutant hospital stating the Government Of India authority under which the unit was established (as mentioned in unit policy page). This number will have to be mentioned during registration.

Fig. 1 – Application for institute registration shows the tabs institute details, employer details and attachments.

b. Unit PAN/TAN number: TAN number is available with the unit accounts section.

- 4) Select 'Diagnostic Radiology' as the type of facility from drop down list and 'Medical diagnostic X-ray facility' as the role of institute from the sublist that appears.

End point: On submission of completed application form, the employer will receive the login details required for further registration process.

NB: The hospitals already registered for radiotherapy and/or nuclear medicine facilities only need to add diagnostic radiology in their existing profile and can bypass steps 1–4 above.

C. Registration of RP

Simply following the steps as illustrated below will enable a smooth registration process of RPs:

eLORA home page ⇒ 'Register RP' ⇒ 'Personal details'. At this stage, carefully select practice as Diagnostic Radiology and professional role as Radiation Safety Professional (Fig. 2). Complete educational details of each RP and upload necessary attachments.

NB: A newly posted individual with RSO certification in previous unit will have to be registered afresh as RP from present unit for him to be nominated as RSO of the unit.

End point: Upon acceptance of application, a RP id will be issued.

D. Application for licence

- 1) Login to your eLORA account using the employers' allotted username and password.
- 2) **Declare equipment:** Click on tab 'Declare existing X-ray equipment'. Each equipment will have to be individually declared. During this process, maximum KvP and maximum mAs are to be entered as per equipment manual.

NB: The manufacturer and model name should be selected from the pre-existing list provided, and if not in the list, it should be carefully typed. Once submitted,

it cannot be changed as there is currently no provision for deleting wrong entries.

End point: After submission of details for each equipment note down the unique equipment id.

- 3) **Add RW** – eLORA account home page ⇒ Add employee.

Provide required information of all RWs, and in case of shortage of RW, roles of both practitioner and operator can be assigned to any medical officer using Ctrl key (ref para 5 of preliminary preparation).

- 4) **Add RP** – eLORA account home page ⇒ Add employee RP ⇒ Select Registration ID and find out name of RP.

NB: Add as many RPs as feasible for ease in change of RSO in case of transfer of existing RSO.

- 5) **Nominate RSO** – From amongst the RP, an RSO has to be nominated as follows:

- i) Menu ⇒ regulatory forms ⇒ common forms nominate RSO (Fig. 3).

- ii) Select the name of employee in RP.

- iii) At this stage, it is crucial to 'Freeze' the completed form and note the generated application number.

- iv) Download and print a portable document format (PDF) of the saved application from 'My Applications' on eLORA account home page. Upload the scanned first page in PDF format, duly stamped and signed by CO hospital and nominated RSO. Application status will now change to signed PDF uploaded.

- v) Complete submission of application form (application Status will change to Submitted).

- vi) On acceptance of nomination, notification will be received in eLORA account.

- 6) **Add instrument** – Instrument Management' ⇒ Add Instrument.

- i. Select type of instrument as Safety tool.

- ii. Select requisite type of safety tool and add details.

- 7) **Fill application form** – click on licence for operation of existing equipment and fill the form (Fig. 4).

- i. Employee details and safety tool details will be available as per paras 3–6 above.

Fig. 2 – Application for registration of radiation professional shows the tabs personal details, educational details and attachments.

Date	Time	Description
05/09/2015	05:49 PM	Your application for declaring existing equipment with application no. 15-72796 for Radiography (Fixed) has been accepted and document no. is 15-DECEQ-59871
15/04/2015	07:41 PM	Your application for Application for Operational Safety Report with application no. 15-45948 has been approved and approval no. is 15-DR_OSRPT-38367
15/04/2015	07:39 PM	Your application for Application for Patient Examination Report with application no. 15-45947 has been approved and approval no. is 15-DR_PERPT-38366
19/12/2014	12:20 PM	Your application for licence for operation of x-ray equipment with application no.14-29422 for Computed Tomography equipment has been approved and document no. is 14-LOEE-25900
12/12/2014	10:21 PM	Your application for licence for operation of x-ray equipment with application no.14-28738 for Radiography (Fixed) equipment has been approved and document no. is 14-LOEE-25025
09/12/2014	03:30 PM	You have successfully submitted application for licence for operation for x-ray equipment with application no 14-29422

Fig. 3 – Nomination of RSO shows the path to be followed for nominating RSO.

- ii. General details: Select 'Licence for Operation' for first time application and 'Renewal of Licence for Operation' for renewal of existing Licence. Select the equipment and select yes for approved RSO.
- iii. Layout details: Upload scanned copies of AERB-approved layout plans for CT and IR equipment. If layout is not approved, fill in the requisite details vide para 8 (e, f) of preliminary preparation.
- iv. QA test report: Fill in requisite details from test report (Fig. 5).

NB:

- a) Half value thickness (HVT) is Aluminium (Al) thickness added in mm that is closest to 50% transmission. This can be calculated from graph/table labelled 'Total filtration' provided in the report. A value of 2.5 mm or lower will not be accepted by the system.

- b) Accuracy of operating potential can be determined from a table in report labelled 'Accelerating voltage' or 'Measurement of operating potential'.
- c) Maximum radiation leakage level from X-ray housing tube should be mentioned in milligray (mGy) in 1 h and not in milliroentgen (mR). The conversion factor of 1 mGy = 100 mR can be used if report mentions the value only in mR.
- d) Ensure completing steps 3-6 before step 7 to avoid system error.

- 8) Repeat the above steps separately for all those equipment without a licence.

NB: If an equipment has an existing valid licence, declare the equipment as in para 2 and record the licence as follows:

- a) Click 'Record Licence for operation of X-ray equipment'.
- b) Selected the equipment id from provided list.

DIAGNOSTIC RADIOLOGY APPLICATION FOR LICENCE FOR OPERATION

Employee Details Safety Tools Details **General Details** Layout Details QA Test Report

Application for* Licence for operation

Equipment Id* G-XR-21676

Type of Equipment* Radiography (Fixed)

Model Name* MARS40 AERB/12/1401

Serial number of equipment

All fields marked by * are mandatory

☐ I have read and agree to the Terms & Conditions.

Submit Reset Close

https://elora.aerb.gov.in/ELORA/getMDR_E12_prePopulate.htm#tabs-3

Fig. 4 – Application for licence for operation shows the form with multiple self-explanatory tabs.

Quality Assurance Test Report

Accuracy of Operating Potential

Applied potential* Measured potential*

Reproducibility of radiation output (CoV)*

Half Value Thickness (HVT)*

Applied Voltage (kVp)* Measured Half Value Thickness (HVT)*

Maximum radiation leakage level from x-ray tube housing (mGy in one hour at 1m)*

Image Quality (as per equipment and phantom specifications)*

☐ I have read and agree to the Terms & Conditions.

Submit Reset Close

Fig. 5 – Quality assurance test report shows the various parameters of QA report required to be provided.

- c) Enter reference number, issuance date and expiry date as appearing on AERB licence and upload a copy of same.
- 9) After submission, the status of all the applications can be checked from 'My applications' tab after logging in.
- 10) It usually takes 1-2 weeks time for an online licence to be issued if all the documents are correct.

envisage that as more and more units embark on this journey, further 'NB' would emerge in times to come, to add on to the existing framework we have provided.

Conflicts of interest

The authors have none to declare.

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Conclusion

As on date, many of our medical units have not commenced their process for eLORA registration due to varied reasons. This article will come handy as a trouble shooting ready reckoner to assist unit commanders, medical administrators and radiologists in the process of commencing/completing mission eLORA. It has been our endeavour to make this article contemporary, comprehensive and oriented towards armed forces medical units, based on the successful experience of eLORA certification at our tertiary care centre. Nonetheless, we