

IMPLEMENTATION OF RADIOACTIVE SOURCE SECURITY REGULATORY INFRASTRUCTURE IN ELECTRONIC LICENSING OF RADIATION APPLICATION (ELORA) - AN INDIAN PERSPECTIVE

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Abstract:

Ionizing radiation sources are used in multifarious applications in various fields such as medicine, industry agriculture, research, etc. Safety record of the sources used in these practices is generally good, however, if radiation sources are not handled safely and securely then it may give rise to potential exposure leading to unacceptable health hazards including death of exposed person. Regulation of facilities using ionizing radiation in India are carried out by Atomic Energy Regulatory Board (AERB). It is a statutory requirement, in accordance with the Atomic Energy (Radiation Protection) Rules, 2004 issued under Atomic Energy Act 1962, that all the radiation facilities need to obtain requisite License from AERB. The remarkable growth of Radiation Facilities in India has posed tremendous challenges for AERB to enforce safety regulation at all these facilities effectively and efficiently to ensure safety and security of radiation sources all the time. In order to meet the challenges, AERB took initiative for implementing state of art e-Governance system, eLORA (e-Licensing of Radiation Applications) for computerization of regulatory process associated with the use of ionizing radiation in India. This system provides platform for radiation facilities, associated stakeholders and AERB officials for application submission, review and process the regulatory applications pertaining to safety and security.

1. INTRODUCTION:

Activities concerning establishment and utilisation of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act, 1962 [1]. In India, radiation sources are being widely used for societal benefits in medical, industry, research, training and agriculture practices [2]. Over the years, safety parameters in handling of radioactive sources mainly operational safety and design safety are adequately addressed while dealing with radiation facilities in our country. It has been reported from all over the world that unsecured radioactive sources caused serious radiological accidents involving radiation injuries and fatalities [3-8]. There is a concern about safety and security of radioactive sources and hence the need of stringent regulatory control over the handling of the sources and their security [2, 9, 10]. Considering the present scenario, the threats from malevolent acts involving radioactive sources, it is clear that sources of certain magnitudes and types are more vulnerable to such acts than others. Therefore, it is necessary to adopt different security measures based on the potential hazard associated with the source and hence there is a need of stringent regulatory control to ensure security of radioactive sources. During the year 2011, Atomic Energy Regulatory Board (AERB), Govt. of India, published the safety guide i.e. Security of radioactive sources in radiation facility (AERB SAFETY GUIDE NO. AERB/RFRS/SG-1). This guide gives provisions necessary to safeguard radiation installations against theft of radioactive sources and other malevolent acts that may result in radiological consequences.

Further, the widespread use of ionising radiation has brought the necessity of voluminous transport of the radioactive material from one place to another. Transport of radioactive material in India is governed by the AERB safety code AERB/SC/TR-1 wherein ensuring safety requirements are stipulated [11]. However, realizing the fact that any breach in

security during the transport of radioactive material, could have safety consequences resulting in radiation exposure to workers and / or the public in excess of the dose limits, AERB has developed the technical basis to establish security levels for the safety of radioactive materials during transport and appropriate security measures commensurate with the potential radiological consequences that could result from malicious use of radioactive material [12]. These above published documents are the guiding materials for the radiation facilities while developing the security plans implemented at their facilities.

2.0 Computerization of Regulatory Process:

2.1 Overview

The safety review and enforcement of regulatory requirements at the facilities using ionising radiation in India are carried out by AERB. It is a statutory requirement to obtain requisite license from AERB to ensure safety and security while handling radiation sources [13]. The consenting process documents and documents on regulatory inspection are AERB/SG-G3 and AERB/SM-G3 respectively in addition to previously stated guides for implementation of security measures at radiation facilities. Due to accelerated growth of such facilities, AERB has been facing challenges in regulatory control of radiation facilities. In order to simplify the process to outreach large number of users and at the same time ensuring the implementation of safety regulation, AERB has undertaken several initiatives. One such major initiative taken by AERB is the implementation of eLORA, for computerization of regulatory processes associated with the use of ionising radiation in India. eLORA is a web-based Information and Communication Technology (I&CT) application establishing direct communication channel between AERB and its stakeholders for exchange of information and communication transaction for delivering its regulatory services as well as for achieving higher efficiency, reliability and transparency in dealings.

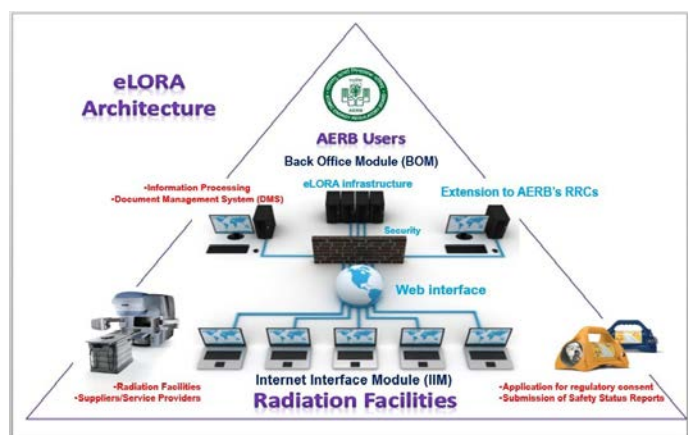
The eLORA system is designed to automate the comprehensive business processes of regulatory affairs for radiological application regulations targeted to large number of facilities involved in use of ionising radiation as well as radiation workers working with them.

2.2 Pre-Era of Computerization

The external stakeholders used to approach AERB for various purposes such as applications for obtaining permissions, safety status reports, compliance report for inspection findings, etc. All such information were submitted to AERB through manually filled forms along with necessary supporting documents as prescribed in consenting process documents. Managing such records, source inventory and processing of routine case papers were imposing huge difficulties. In the same time, utility also faces several difficulties such as update on application status, various transition lags, clear understanding on the regulatory requirements, promptly aware about any changes in regulation etc.

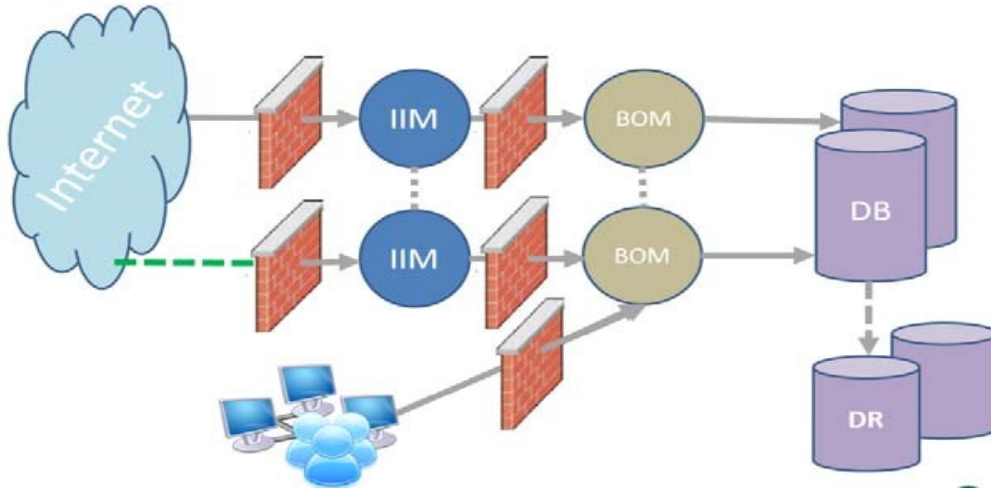
2.3 Key Note on eLORA System

Being a web-based I&CT application it establishes a medium for exchanging information among AERB and its stakeholders through Internet Interface Module (IIM) and Back Office Module (BOM). The business process developed in eLORA system is as per stipulated requirements of the RPR 2004 [13] and regulatory documents developed by AERB (viz. Regulatory Codes, Manuals and Standards). Various modules have been designed, developed and implemented for external stakeholders such as



(Figure 1: Architecture of eLORA System)

Radiation Facilities, Supplier, Manufacturer, Disposal Agencies etc. and internal stakeholders such as AERB officials operating from head office located at Mumbai and other regional offices located at different parts of the country.

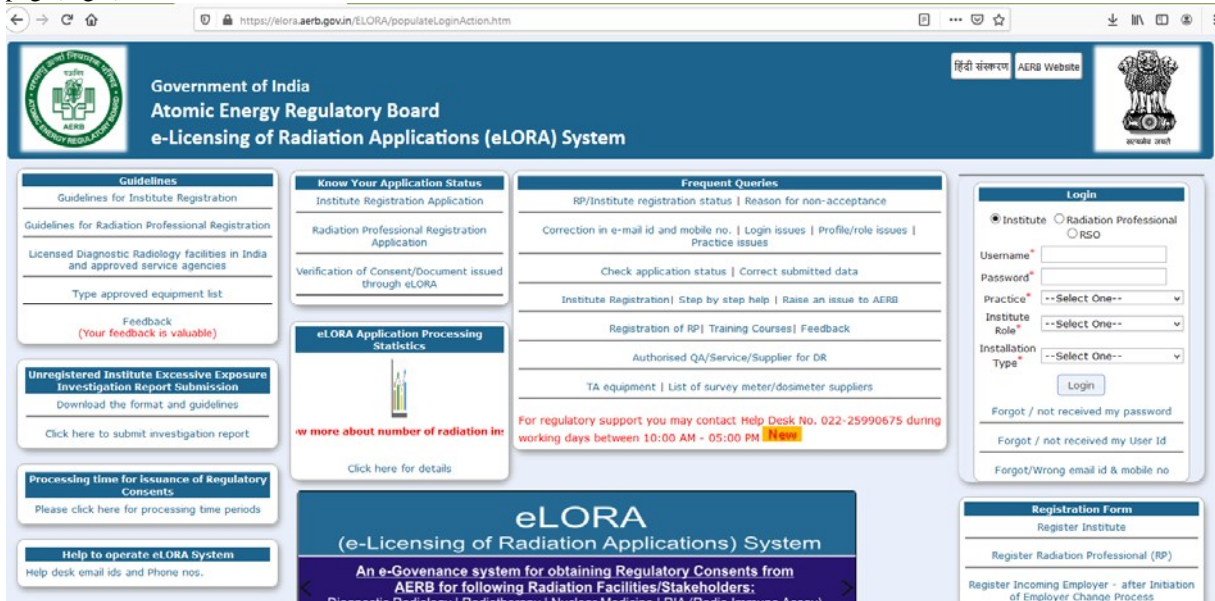


(Figure 2. eLORA security layer: DB : Database, DR: Disaster Recovery)

Presently eLORA security infrastructure (fig.1, fig.2) is designed using a multi-tier architecture, where the actual data resides in the last layer, protecting direct access to it by the users. Further, the data is being accessed using role based authentication to ensure the access on need-to-know basis. Internally, the system is hosted in a different LAN segment than AERB’s corporate LAN and connectivity to it is provided under strict control. eLORA IIM can be accessed by the licensees only using a Secured Socket Layer (SSL) connection. The internal AERB (BOM) users have been provided with Secured Socket Layer – Virtual Private Network (SSL-VPN) tokens for accessing eLORA from outside the AERB LAN. eLORA is hosted on a set of high availability clusters of servers. All the other components of eLORA infrastructure are having redundancy to ensure the availability of the infrastructure. There is a Disaster Recovery Center (DRC) for eLORA. The IIM and email servers of AERB are loaded with global digital certificates to prevent spoofing.

2.3.1 Internet Interface Module (IIM)

This module aims at facilitating external stakeholders. The primary objective of this module is to enable external stakeholders for online submission of various regulatory forms for obtaining regulatory clearances/licenses by providing desired information as per the regulatory requirement. It supports dissemination of information regarding regulatory process, operational features of eLORA, guidelines, and notifications to external stakeholders through the eLORA home page (Fig.3).



(Figure 3. eLORA Home Page)

2.3.2 eLORA Home Page

The eLORA web application has been hosted under www.aerb.gov.in. The eLORA home page (Fig. 3) provides various information towards use of the eLORA system, login screens, guidelines, and ready reference data on radiation facility, regulatory consent verification facility, search function for Diagnostic Radiology facilities etc.

2.3.3 Institute Registration

Introduction of each end-user starts with registration process in eLORA wherein various supporting documents for facility and its owner are submitted along with application form. After review of these details at AERB end, the system generate unique login credential. End user access the system using these login credential.

2.3.4 Radiation Professionals Registration

Based on the qualifications stipulated in various codes applicable for radiation practices, a terminology has been defined in eLORA as “Radiation Professional”. They need to do independent registration in eLORA system by submitting the desired details. After review of these details at AERB end, the system generate unique login credentials. These professionals are later eligible to be nominated for Radiation Safety Officer (RSO) at radiation facilities.

2.3.5 Instrument Management

Regulatory compliances in radiation facilities prescribe availability of adequate number of functional and calibrated radiation measuring instrument, radiation monitoring instrument and availability of adequate number of security devices for ensuring the desired safety and security at radiation facilities. eLORA system facilitates the stakeholders for efficient management of these instruments/devices. This process starts with the registration of instruments/devices in eLORA, where in all applicable details are provided by the stakeholders. The first time registration of the instruments and further modification/updates functionalities are available in these modules. The stakeholders are getting notified for the non-compliances arises due to non-availability of above mentioned safety and security instruments as per the radiation installation available with them.

2.3.6 Employee Management

As per the stipulations of ‘RPR-2004’ [13], applicable ‘Safety Codes’ of the practices under regulatory control, safety code on ‘Security of Radioactive Materials’ and ‘Security Of Radioactive Material During Transport’ the role and responsibility of various employee such as Employer, Licensee, Radiation Safety Officer, radiation workers, security staff members are well defined. eLORA provides the platform to manage the staff members working in a radiation facility through various processes such as association of the employee, dissociation of the employee, designate licensee, nominate RSO, nominate site-in-charge etc. At the same time, it also monitors the non-availability of designated staff members to report it as a non-compliance.

2.3.7 Application Form Submission

Application forms for various practices are designed under Regulatory Practices such as Radiotherapy, Nuclear Medicine, Diagnostic Radiology, Research, Sealed Source, Radio Immuno Assay, Industrial Radiography, Nucleonic Gauge, Well Logging, Gamma Irradiation Chamber, Gamma Radiation Processing Facility, Industrial Accelerator Processing Facility, Transport, etc. The registered end user can login to eLORA as per his role such as Employer, Licensee, RSO, etc. to fill the application forms and submit it through eLORA. The printable version of the application form are getting generated through the system after submission of the application form. These forms are in accordance with AERB/SG/G3.

The regulatory consenting application forms for various clearances are interlocked among the subsequent consenting stages such as siting, design, commissioning, decommissioning etc. and integrated to aforesaid compartments with emphasize on the tracking of radiation sources starting from the procurement to its safe disposal i.e. cradle to grave. One of the module completely designed for submission of the security plan through eLORA system and integrated along with the above consenting application forms. System creates interlocks in case of non-availability of qualified security plan while submitting the applications for source procurement, commissioning and operational licence with a decision making provision at regulators end. As eLORA is a fully integrated system, provision for submission and review of security plan for medical/industrial practices and during transport are in one place which assist in quick review and decision making process. Non-submission and non-availability of qualified security plan will attract regulatory non-compliance and enforcement actions.

2.3.8 Supporting Modules

Various supporting modules are designed in eLORA to facilitate core regulatory activities such as licensing, regulatory inspection and enforcement etc. These modules include Unusual Incidence Reporting, Radiation Exposure Management, Transport and Movement related approvals for radioactive material, Regulatory Inspection Module, Noncompliance tracking and its closure etc.

2.3.9 Security Plan Submission Module

The module consists of categorization of sources, and detailed security plan submission mechanism, reports associated with the security plan, security devices/instrument management features.

2.3.9.1 CATEGORIZATION OF SOURCES:

A dangerous source is defined as a source whose activity is high enough to deliver a radiation dose which would result in severe deterministic effects in the exposed individual [14]. As previously stated that eLORA system manages the sources from cradle to grave, the creation of master radioisotopes was carried out from our end. The radioactive sources of various make and model of the isotopes as per the master list is created by registered manufacturer and/or supplier of the sources through submission of applicable regulatory application forms along with supporting documents. After the approval at BOM, the source is available for the end users to apply for procurement permission. Each procured source has been identified with unique number and it is maintained to its full life cycle. Every day system calculates the current activity of the source and using the “D” value it gives the source categorization at the time of initial procurement and the current categorization.

2.3.9.2 SECURITY PLAN

Part of the requirement for security plan submission are taken care by institute registration process wherein credentials of the user institute as desired from the security view point are reviewed considering the hazard associated with the radiation facility. Secondly, the employee management module and instrument management module plays important role towards the security measures required for the radiation facilities as stipulated in AERB safety guide on ‘security of radioactive sources’ AERB/RF-RS/SG-1. The site and layout application submission process and its approval for the radiation facilities suffice the requirement for description of the environment, building and/or facility where the source is used or stored by providing clear layout / diagram of the radiation facility and security systems installed or proposed to be installed in the radiation facility with proper indication in the layout drawings. The layout also includes immediate surroundings around the radiation facility, location of the building or facility relative to areas accessible to the public by asking for clear sketch of the whole premises and surroundings where radiation facility is located with proper indication of different buildings / facilities / roads/ security cabin / reception/ entry or exit / roads etc. The sketch should also include and indicate areas accessible to the public around the radiation facility.

Security measures available/implemented or to be implemented by the radiation facility are described mainly considering the followings along with the application in the form of security plan.

- a) Perceived Threats to the radiation facility
- b) Objectives of Security Plan
- c) Technical Measures to be used for detection, delay, response and security management
- d) Administrative Measures such as;
 - i. Roles & responsibilities of management, staff and others to be specified in the plan
 - ii. Routine and non-routine operations, including accounting for the source(s)
 - iii. Maintenance & testing of equipment / physical protection systems (PPS) and Methods to ensure continued functionality of the security systems
 - iv. Determination of the trustworthiness of personnel
 - v. Application of information security
 - vi. Methods for access authorization / access control
 - vii. Security related aspects of the emergency plans, including event reporting
 - viii. Training / awareness on security
 - ix. Key control procedure
 - x. Periodic updating of the security plan to ensure its continued effectiveness
 - xi. Procedure for reporting security related events
 - xii. Periodic evaluation of security systems for their functional performance

This module supports various upload provisions catering the need for first submission and subsequent resubmissions/ad-hoc submissions owing to the modification/change in facility layout/design/occupancy, change in functional status of the radiation sources, augmentation of new radiation sources, change in security scenario, increased threat perception etc. Additionally, provision has been made for submission of Police Verification Certificates of key personnel for Category 1 radiation facilities. Provision has also been designed keeping in view to extend the System for other coordinating government authorities involved in implementing the security measures at radiation facilities.

To facilitate stakeholders for submission of security plan a detailed checklist is provided to ensure that the plan is as per the prescribed security guide of AERB. Security plan is institution-centric irrespective of various practices available at the institute. Accordingly, interdependence across the practices, sharing of resources, and credit from safety systems are part of this Module in eLORA. During the plan submission process, stakeholders need to declare/provide the operational status of the existing radiation sources/institute, police verification details and all relevant attachments such as complete security plan describing each component, PVC copy, layout of the facility indicating security architectures etc.

2.4 Back Office Module (BOM)

Back Office Module in eLORA designed for AERB personnel to carry out core regulatory activities. This module supports Internal Stakeholders (i.e. AERB officials at main office as well as in regional offices), in application processing and associated activities which includes information processing and document management. Managing complex processes such as tracking the movement of radiation sources, maintaining observations of inspections and managing non-compliances of each facility, record management of radiation sources etc. have become well-organized with the help of eLORA.

2.4.1 Security Plan Application Processing

AERB officials, identified for this purpose receive the complete submissions. The review process depends on the categorization of the source(s). For the facilities possessing Category 1 & 2 source(s), security plans are reviewed through multi-tier review system adopted by AERB and for Category 3, 4 & 5 facilities, security plan are reviewed within the Division. The entire process is assisted through eLORA with various features such as view legacy documents, case files, history of the institution, review check list etc. The review comments are recorded and appropriately transmitted through eLORA to the end users regarding the shortcomings/acceptance of the submitted plan. For new facilities, security plan acceptance is the pre-requisite prior to issuance of licence for handling the radioactive sources.

2.4.2 Reports and Files

eLORA supports generation of various reports through a reporting tool configured in the system. BOM users can generate predefined reports consisting of several information/data recorded from the end users. Report customization feature, report presentation & analysis feature are added options in this module. Various data elements captured for the Security Plan submitted by the facilities are configured for the report generation for analysis and management decisions.

3. Conclusion

Various mechanisms were adopted by AERB for implementation of security measures at radiation facilities with respect to the provisions stipulated in the applicable code [2,11]. eLORA, a comprehensive regulatory system for effectively handling the applications of ionising radiation, provides a unique platform facilitating security plan submission process. Several challenges were faced during design and development of the system while implementing automation in business process of radiological application regulations, management of huge data of radiation worker and integration of same platform for licensing, regulatory inspection and non-compliance management, etc. Integrated features, starting from registering an institute, radiation workers safety/security instruments/devices to licensing, inspection, etc. has made the security plan submission and review process easy. Additionally, source categorization feature in eLORA helps in implementation of graded approach in various regulatory functions. All of our radiation facilities using radioactive sources are harnessing the benefit of eLORA system.

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