IRRS Good Practices

Authorization
(Module 5)

Authorization of radiation sources facilities and activities

India – Follow-up Mission

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Good Practice

The integration of regulatory processes within e-LORA, an online platform used by all applicants, authorized parties and AERB, was noted as a good practice. E-LORA significantly improves the efficient management and process of information to be submitted by an applicant or authorized party in accordance with a graded approach. The logic hold-points set up in e-LORA contributes to efficiency and effectiveness of the regulatory processes and objectivity of its decisions. The system provides unique capabilities to assess electronic safety performance indicator (e-SPI) in order to measure the safety compliance of authorized party.

Observation

AERB developed a sophisticated, comprehensive and user-friendly online platform, e-LORA. e-LORA is key system for managing regulatory activities in relation to radiation sources. E-LORA is used by applicants for a consent, authorized parties, as well as AERB staff for authorization, review and assessment, inspection and enforcement. The platform incorporates logic-based on the legal hold-points in authorization process, it improves the application of an effective graded approach therefore a better use of the AERB's resources while improving the regulatory performance. The system largely prevents subjectivity in decision-making by individual staff members of the regulatory body. e-LORA also incorporates set of electronic safety performance indicator (e-SPI) in order to measure the safety compliance of authorized parties from all regulatory processes.

Bases

(1) GSR Part 1 (Rev. 1) Requirement 19 para. 4.16 states that “The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost-effective manner so as to build confidence.”

(2) GSR Part 1 (Rev. 1) Requirement 22 para. 4.26 states that “The regulatory process shall

be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based."

(3) GSR Part 1 (Rev. 1) Requirement 26 states that "Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."

IAEA Comments/Highlights

The authorization process is conducted through an online platform, e-LORA which is a sophisticated, comprehensive, and user-friendly electronic information system, operational since 2013. e-LORA guides applicants through the relevant authorization process, including for providing the required documentation in a specific format required by AERB. The applicants have to upload in e-LORA the demonstration of safety as prescribed in practice specific safety codes, safety standards, safety guidelines, safety guides, safety manuals and technical documents available on the AERB web site. Majority of data such as calibration date of an equipment are provided by an applicant in e-LORA. e-LORA establishes hold points for key steps of the process to obtain a consent to operate a facility or conduct an activity. e-LORA contains a pool of radiation professionals who have been approved by the AERB, including radiation safety officers and radiation workers who are a subject of personal dosimetry control, and also contains a list of approved equipment.

A consent can be issued only when all requirements are met. Whereas "licenses" or "authorizations" can only be issued only after AERB review & assessment. For "registration", applications are processed electronically through the e-LORA system with minimal human intervention by incorporating appropriate business logics. e-LORA enables that authorization and all core regulatory processes are fully integrated and documented. e-LORA has significantly improved the effectiveness and efficiency of the regulatory processes, including for consents, review & assessment, and inspection.