Radiation Protection and Regulations in Nuclear Medicine in India

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Topics covered in presentation

- Atomic Energy Regulatory Board
- National Regulatory Framework for radiation facilities
- Regulatory control for nuclear medicine facilities
- Regulatory issues in focus
- Conclusion
The National Regulatory Authority for radiation protection

AERB constituted in 1983.

The *mission* of the Board is to ensure that the use of ionizing radiation and nuclear energy in India does not cause undue risk to health and the environment.

*Chairman, AERB* is the Competent Authority for all the matters related to radiation protection.
“Licence in accordance with Atomic Energy (Radiation Protection) Rules, 2004 from AERB is mandatory requirement for the procurement and use of radiation sources in India”.
Regional Regulatory Centers (RRC) of AERB

AERB Headquarter
Mumbai

Northern Regional Regulatory Centre
Delhi

Eastern Regional Regulatory Centre
Kolkata

Southern Regional Regulatory Centre
Kalpakkam
System of Regulatory Control

Issued by Central Government
- Act
  [Atomic Energy Act, 1962]
- Rules
  [Atomic Energy (Radiation Protection) Rules, 2004]
- Notifications

Published by AERB
- Safety Codes
- Safety Standards
- Safety Guides
- Safety Manuals
Regulatory Framework – Nuclear Medicine

- Atomic Energy Act, 1962
- Atomic Energy (Radiation Protection) Rules, 2004
- AERB Safety Guide for Radioisotope Handling Facilities,
AERB Safety Codes on Medical Applications


Nuclear Medicine: AERB safety code AERB/RF-SC/MED-2 (rev.2), 2011 on “Nuclear Medicine facilities”

Diagnostic Radiology: AERB safety code AERB/SC/MED-3 (rev.2), 2016 on “Medical diagnostic x-ray equipment and installation”
Number of nuclear medicine facilities (NMF) in India

- NMFs ~ 245 operating NMFs
  - ~ 70 NMFs having facilities approved for undertaking high dose therapy procedures

- Imaging Equipment details
  - SPECT ~ 70
  - SPECT CT ~ 160
  - PET CT ~ 170
Number of nuclear medicine facilities (NMF) in India

- **Medical cyclotrons**
  - Operational - 18
  - Under design review - 2

- **Facilities for Commercial production of radio pharmaceuticals**
  - BRIT
  - One facility in private sector

- **Suppliers of radiopharmaceuticals and generators**
  - ~ 18 facilities
Radiation Safety Manpower availability in Nuclear Medicine

- Nuclear Medicine Technologists – 12 Centres recognized for conducting NMT Courses (graduate, post graduate level degree/diploma programmes)
- Nuclear Medicine Physicians - DRM/MD (NM), DNB(NM)
- Radiological Safety Officer for Diagnostic & LDTF procedures – NMT or NMP can become
- Radiological Safety Officer for HDTF - RSO (M) or NMT/NMP RSO with HDTF field training
Regulation for Nuclear Medicine Facility

New Radiation Facility
   Application for Plan Approval
     Review
       Plan Approval
         RSO Approval
           Authorisation under AE(RPR), 2004
             NOC / Authorization for Radioisotopes

- Guidelines for Setting up of Laboratory
- Application forms (www.aerb.gov.in)
- Legal status
- Site plan
- Layout plan / Elevation plan
- Shielding adequacy
- Availability of qualified and trained man power
- Availability of radiation protection instruments
- Radiation surveillance
- Handling tools, PMS for staff
Monitorning of Nuclear Medicine Facility

Radiation Facility

Submission of Annual Status Report

Review

NOC / Authorization for Radioisotopes

Decommissioning

- Availability of qualified staff, radiation monitoring instruments
- Procurement of radioisotopes as per authorized quantity
- Management of radioactive waste
- Radiation surveillance
- Unusual occurrences
Objectives of e-LORA

- Online registration of Institutes and radiation professionals
- Electronic submission of applications for regulatory clearances
- Online tracking of submitted applications
- e-Approvals
Use of newer therapeutic radiopharmaceuticals

- Clearance from the Hospital Ethics Committee
- Radiological safety aspects – handling, management of waste/decayed radionuclide generator
- Patient management
- Data on radiological safety aspects from other countries on usage of the desired radioisotope(s)/radionuclide generator
Updates on regulatory requirements pertaining to NM practice

Proposed changes:

- Assessment of all Radiation Professionals (RP) prior to RP registration in eLORA (preferably an online assessment)
- RP registration to have a validity, renewal also based on assessment
- Number of Nuclear Medicine Technologist (NMT) to be based on the number of imaging equipment
- Harmonization of radiological safety syllabus for clinical programs – radiological safety syllabus to be included in courses for MD/DNB
Regulatory issues in focus...

- Diagnostic reference levels for radiopharmaceuticals used in NM procedures – country specific
- Patient specific dosimetry in use of newer therapeutic radiopharmaceuticals
- Estimation of radiation dose to the critical organ of the patients undergoing Diagnostic and Therapeutic procedures
- Misadministrations – intimation to AERB, NMP to draw procedures to deal with such events – in light of patient safety through medical exposure
- Security of radioactive material – recent cases of loss of consignments of radioactive material
- Management of decayed sealed sources eg. decayed Ge-68 sources for QA in PETCT
Regulatory issues in focus...

- Categorization of nuclear medicine facilities
- Radioactive waste disposal from high dose therapy facilities – necessity of delay tanks, liquid radioactive effluent assessment procedures
- Assessment of dose to lens of eyes in case of nuclear medicine staff in light of the revised recommendations of the IAEA
Conclusion

▶ Optimisation of patient exposure during any radiological medical procedures is very essential and can be achieved by joint efforts of radiological medical practitioner and the supporting staff.

▶ For any nuclear medicine procedure, the primary and paramount focus should remain on the accurate, timely, and safe diagnosis of illness and disease.

▶ Compliance with regulations and increased familiarity with the implications of these regulations will assure both practitioners and patients of adequate and effective radiation safety practices.

▶ Overall occupational doses in medical applications of radiation are found to be much below the prescribed annual effective dose limits. However, number of excessive exposure incidents to workers in the monitoring period are being reported in medical practices such as diagnostic radiology and nuclear medicine. This needs to be minimized/prevented.

▶ Awareness about radiation hazards and adherence with medical ethic would play crucial role in ensuring optimised and adequate radiation protection.
Thank you

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