# Guidelines for establishment of Radiotherapy Centre

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Government of India

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- Need of regulation
- Regulatory Framework
- Status of Radiotherapy facilities in India
- Regulatory Process  for Radiation Facilities
- e-Licensing of Radiation Applications (e-LORA)
- Regulatory Inspection
- Conclusion

# Need of Regulation

Why regulation?

- As ionizing radiation is hazardous in nature, a suitable control measures must be in place to ensure minimum radiation exposure so that maximum benefits are derived with minimum radiological risk i.e. use of ionising radiation does not cause undue risk to the health of people and the environment.

# Responsible organization for enforcing the rules & regulation?

# Atomic Energy Regulatory Board(AERB)

- AERB established in 1983 under the Atomic Energy Act, 1962

- Regulatory and safety functions envisaged under sections 16, 17 and 23 of the Atomic Energy Act

  - **Control of Radioactive Substances**
  - **Radiation Safety in Nuclear and Radiation facilities**
  - **Industrial Safety in Department of Atomic Energy**

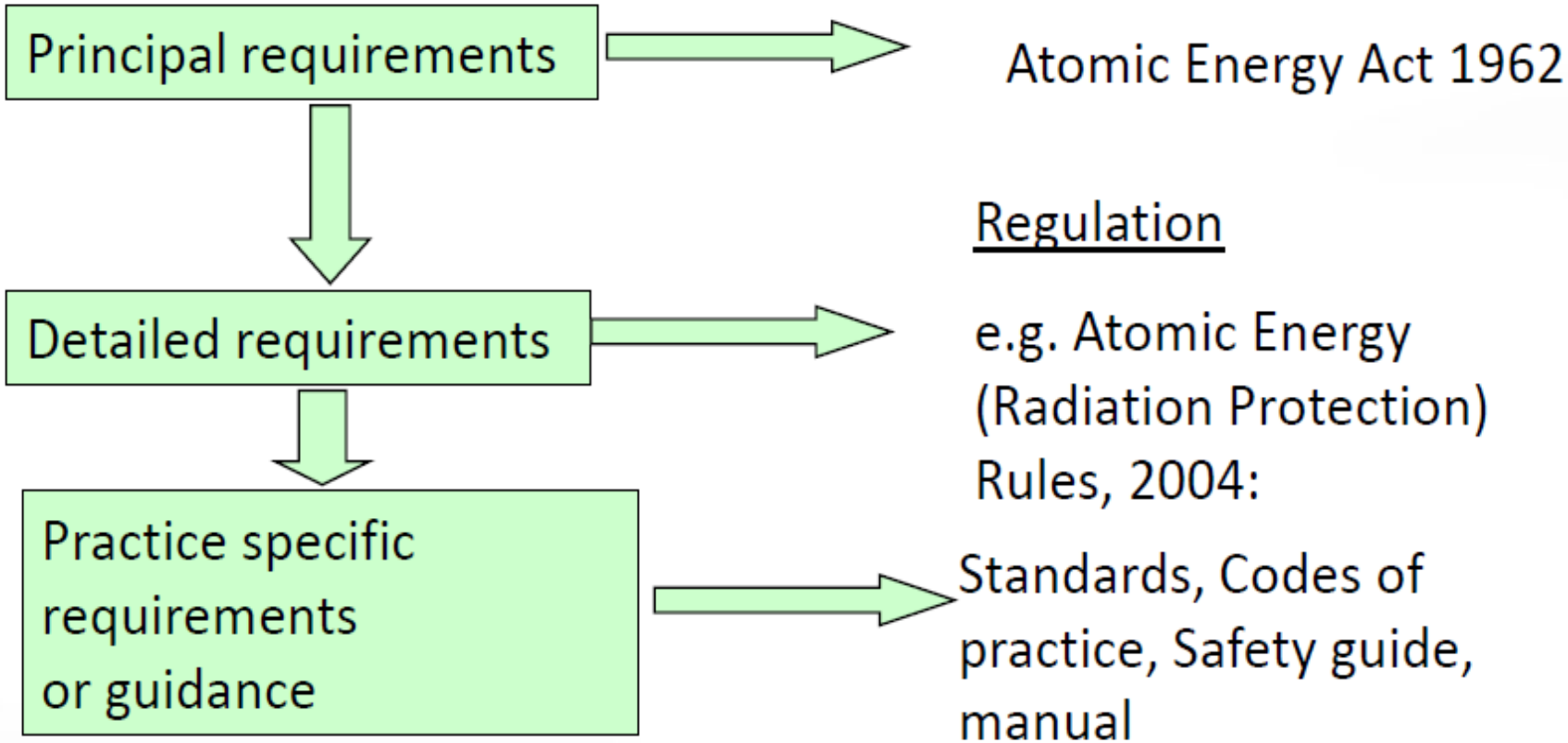
    **(DAE) installations**

# Mission of AERB


To ensure that the use of ionizing radiation and nuclear energy in India does not cause undue risk to the health of people and the environment.

**Chairman,** Atomic Energy Regulatory Board is the Competent Authority to enforce the rules & regulations framed under the Atomic Energy Act, 1962 for radiation safety in the country.

# Structure of the legal framework




AERB has issued more than 160 regulatory documents for Nuclear and radiation facility

# Organisational Structure (AERB)

| Board | Secretariat |
| --- | --- |
| • Chairman : Chairman AERB<br>• Ex-officio Member : Chairman SARCOP<br>• External Members : 4 (experts from outside Dept. of Atomic Energy)<br>• Secretary: AERB Official | **8 technical Directorates /Divisions**<br>**1 Safety Research Institute**<br>**Three Regional Centres**<br>➢ **Southern (Chennai),**<br>➢ **Eastern (Kolkata) &**<br>➢ **Northern (New Delhi)** |

# Functions of AERB

- Development of Safety Documents
- Safety Review and Issue of License/Authorisation to Nuclear and Radiation Facilities
- Verify compliance with the stipulated requirements by the nuclear and radiation facilities
- Regulatory Inspections
- Safety Research
- Licensing of Key Operating Personnel
- Review of Emergency Preparedness
- Public Information

# Regulated Installations

## Nuclear and Fuel Cycle Facilities

- Nuclear Power Plants and Research Reactors
- Uranium Mines and Mills
- Beach Sand Minerals
- Fuel Fabrication Plants
- Reprocessing Plants
- Waste Management Facilities
- R&D Facilities

## Radiation Facilities/Activities

- Medical Applications of Ionisation Radiation
- Industrial Radiography
- Nucleonic Control System / Nucleonic Gauges
- Radiation Processing Facilities
- Accelerators and Cyclotron Facilities
- Radioactive Sources in R&D
- Transport of Radioactive Material

# Regulated Radiation Facilities

Medicine

Industry

Research

Agriculture

| | |
|---|---|
| Radiotherapy Installations | -465 |
| Industrial Radiography Installations | - 549 |
| Gamma Radiation Processing Facilities | - 21 |
| Gamma Irradiation Chambers | - 114 |
| Medical cyclotrons | - 18 |
| Nuclear Medicine Centers | - 301 |
| Medical X-ray | - 42481 |
| Institutions using Nucleonic Control System/Nucleonic gauges | - 482 |
| Manufacturer of consumer products & Scanning Facilities | -23 |

# Radiotherapy facilities in India

## Radiotherapy Centers : 465

### Teletherapy Facilities

- Telecobalt Units : 206
- Linear Accelerators : 446
- Gamma Knife : 7
- Tomotherapy : 12
- Cyberknife : 6

### Brachytherapy Facilities

- Remote Afterloading Units (HDR/MDR/LDR) : 300
- Ocular brachytherapy : 05
- IORT : 03

### Radiotherapy Simulator (Standard) : 147

As on September, 2018

# How the Radiation Safety is ensured?

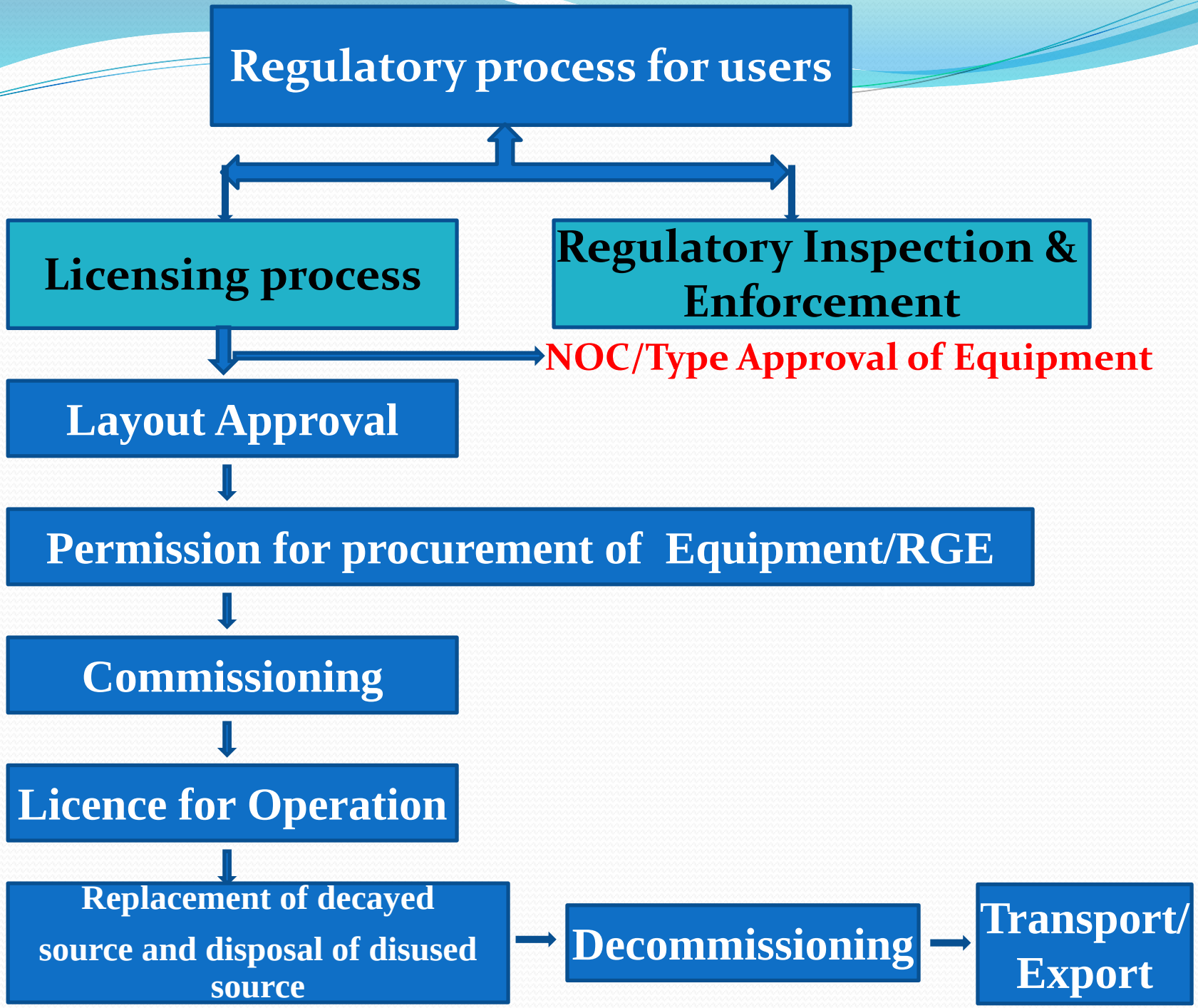
# Radiation Safety is ensured

- **Built-in Safety**
  - Room planning from radiation safety stand point
  - Equipment to meet desired standards & specification (Type approval/NOC for the equipment)
- **Operational Safety**
  - Licensing requirement
    - Qualified staff
    - PMS
    - Measuring & Monitoring instruments
  - Periodic maintenance & QA of the equipment
  - Source inventory and periodic radiation survey
  - Annual status report on safety
  - Periodic Regulatory Inspection
  - Formulating procedures for emergency situation
  - Reporting off-normal situations to AERB promptly
  - Servicing and maintenance of the equipment by the AERB authorized agency

# Responsibilities assigned as per RPR-2004

- Employer
- Licensee
- RSO
- Radiation worker

# How the Radiation Facilities are regulated?

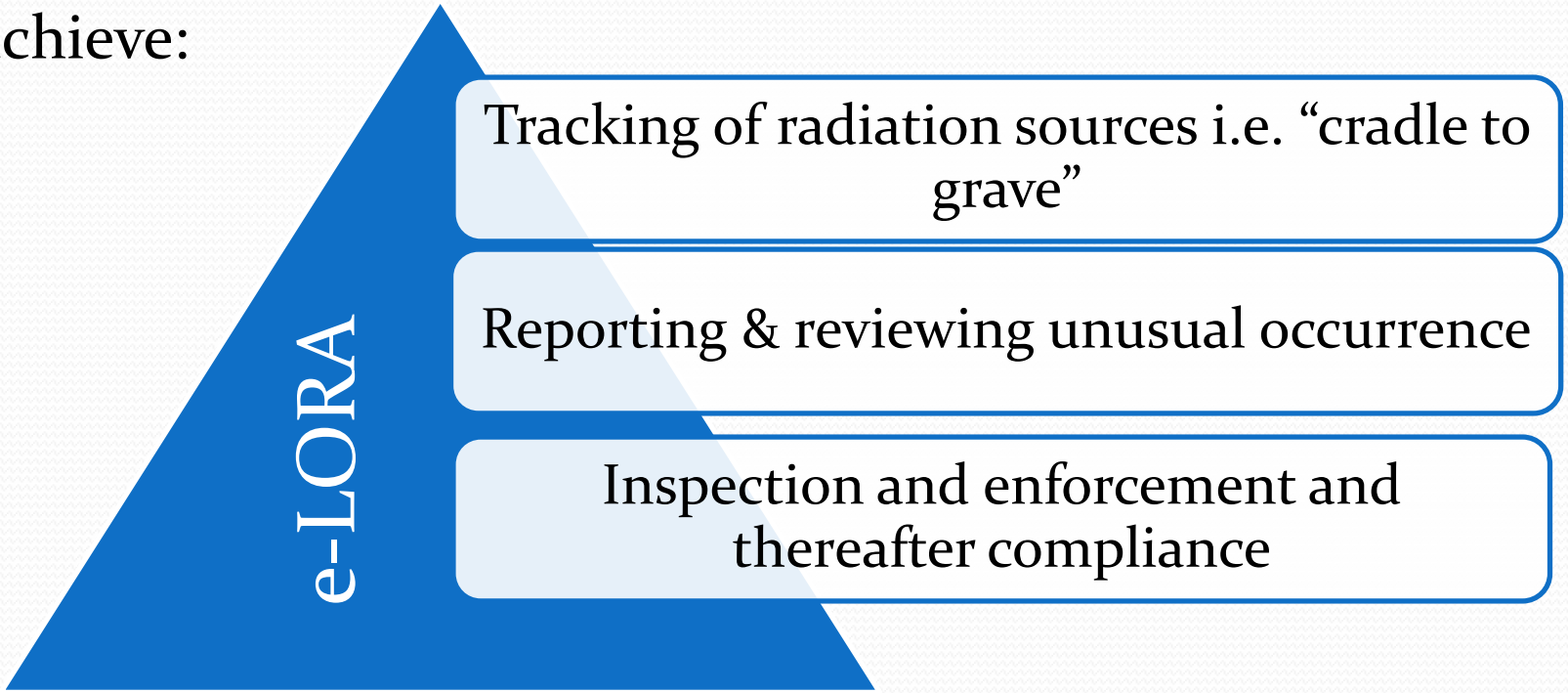

Regulatory process for users
Licensing process
Regulatory Inspection & Enforcement
NOC/Type Approval of Equipment
Layout Approval
Permission for procurement of Equipment/RGE
Commissioning
Licence for Operation
Replacement of decayed source and disposal of disused source
Decommissioning
Transport/ Export

# AERB e-Governance Project
# (e-LORA) [e-Licensing Of Radiation Applications]

*e-LORA is launched for achieving more efficiency, reliability and transparency in regulation.*

- **Feature of e-LORA**

  Apart from online consenting/licensing, e-LORA is used to achieve:



# e-LORA

- For obtaining requisite regulatory clearance, user need to submit relevant application through AERB's e-Governance application - eLORA (e-Licensing of Radiation Applications) System

- To access eLORA system, employer need to register his/her institute for obtaining login credentials (user Id & Password).

- **Institute Registration**


File Edit View History Bookmarks Tools Help
Today's Meeting Room - S...
eLORA Login Page
https://elora.aerb.gov.in/ELORA/populateLoginAction.htm
Search
Government of India
Atomic Energy Regulatory Board
e-Licensing of Radiation Applications (eLORA) System
हिंदी संस्करण
AERB Website
सत्यमेव जयते
Guidelines for Institute Registration
Guidelines for Radiation Professional Registration
Licensed Diagnostic Radiology facilities in India and Type approved Medical Diagnostic X-ray equipment
Verification of Consent/Document issued through eLORA
Feedback
Submission of Over Expsoure Investigation Report
Click here to submit Over Expsoure Investigation Report-Applicable for Institutes not registered in eLORA.
Guidelines for Over Exposure Management for Unregistered Institutes and Standard Format for Attachments
Help to operate eLORA System
Help desk email ids and Phone nos.
It is mandatory for all users/owners of Medical Diagnostic X-ray equipment to obtain Licence/Registration from AERB for Operation of the equipment as per Atomic Energy (Radiation Protection) Rules 2004.
Obtain AERB Licence/Registration for Medical Diagnostic X-ray equipment through eLORA
Click to know more
eLORA System
eLORA (e-Licensing of Radiation Applications), an e-Governance initiative by AERB, is a web-based application for automation of regulatory processes for various Radiation Facilities in India. The objective of the project is to enhance efficiency and transparency in the regulatory processes of AERB. The system is aimed at achieving paperless licensing of Radiation Facilities.
... Show More
Login
Username
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Forgot Password?
Forgot Username?
Registration Form
Register Institute
Register Radiation Professional (RP)
Register Incoming Employer – after Initiation of Employer Change Process
Know Status of Registration Application
Status of Institute Registration Application form
Status of Radiation Professional Registration Application form
Disclaimer
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# Regulatory stages in e-LORA system

- Institute Registration
- Site and Layout Approval
- RSO approval
- Permission for procurement of Equipment
- Permission for procurement of radioactive source(s)
- ERI/SRI
- SSA (For equipment housing radioactive sources such as telecobalt & RAL brachytherapy unit)
- Source transfer report
- Commissioning permission (after updating Staff, PMS,M & M instruments, QA tool etc.)
- Radiation survey
- Licence for operation (attaching QA details)
- Consent for decommissioning

Note: All the Radiation Professionals must obtain RP registration No. through eLORA

# Institute Registration

- Guidelines for institute registration is provided on e-LORA (AERB website www.aerb.gov.in and click on 'eLORA'.)

- Institute registration application along with following documents;
  - Employer's proof of Identity and Date of Birth
  - Address proof (registered documentary evidence from govt. or local authority ) for the Institution
  - Document substantiating employership of the institute.

    *Example: (i) Appointment Letter, (ii) Board Resolution, etc.*

Hospital name and address mentioned in the application should be of actual radiotherapy site address

# Radiation Professional Registration

Guidelines for Radiation professional registration is provided on e-LORA (AERB website www.aerb.gov.in and click on 'eLORA'.)

Major points to be noticed (specific to registration as Radiation Oncologist):

- Applicant name mentioned in the application should exactly match with at least one of the supporting document
- Proof of identity and Date of Birth
- Basic qualification (MBBS) and Professional qualification passing certificate from university to be enclosed.

# Regulatory stages for Linear Accelerator installation in eLORA

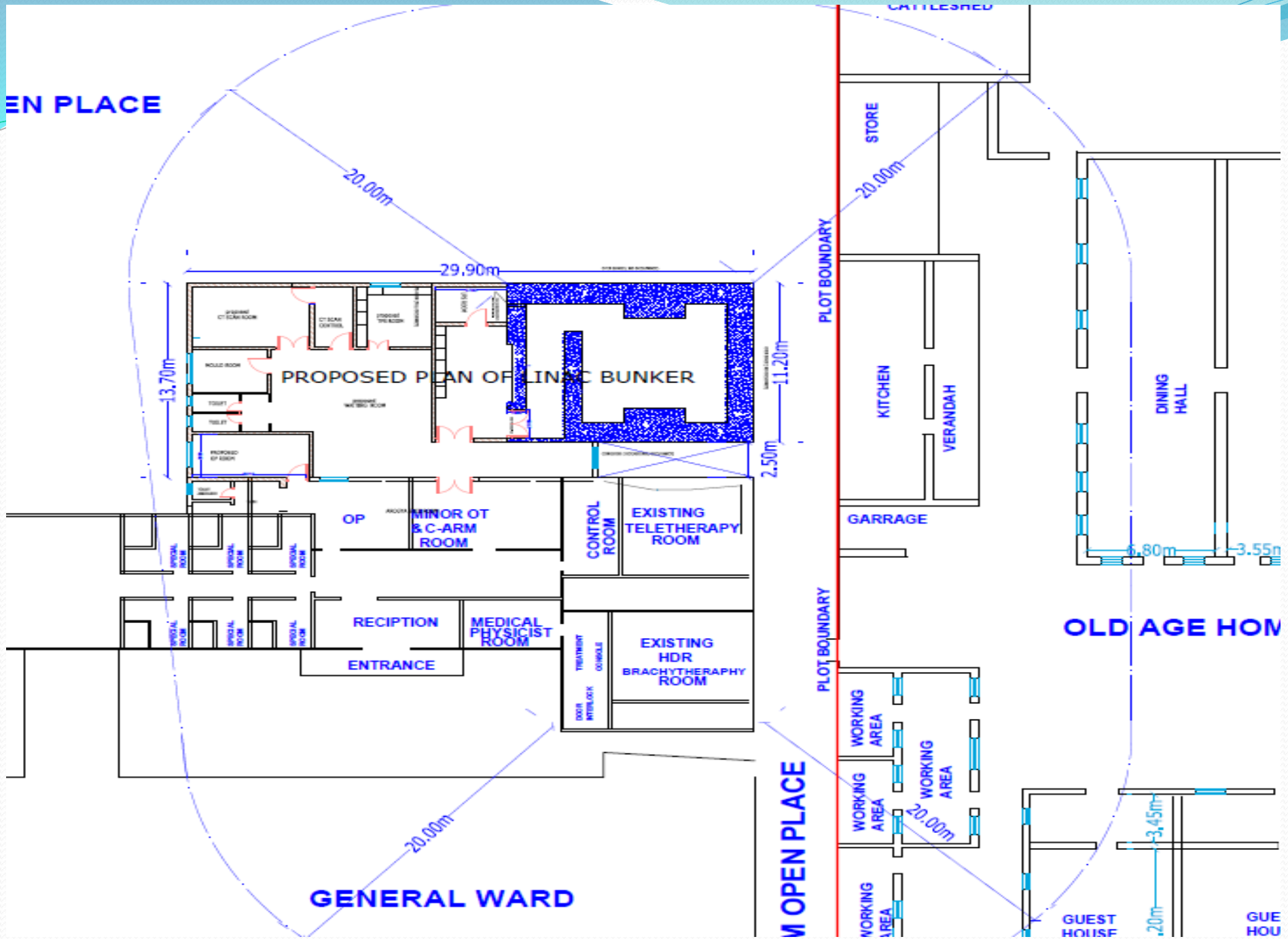
| Steps | Purpose | Regulatory Form Name |
|---|---|---|
| **First time Licence** | | |
| Step 1. | Obtaining site and layout approval | Application for Site and Layout Approval |
| Step 2. | Obtaining RSO approval | Nominate RSO |
| Step 3. | Obtaining procurement permission of equipment | Application for Procurement (Equipment/Source) |
| Step 4. | Intimating receipt of equipment | Equipment Receipt Intimation |
| Step 5. | Obtaining commissioning approval of equipment (i.e. prior permission for switching ON beam) | Application for Commissioning |
| Step 6. | Submission of radiation survey levels measured around the installation | Survey Report |
| Step 7. | Obtaining licence for operation of equipment | Application for Licence |
| **Decommissioning** | | |
| Step 1. | Obtaining consent for decommissioning | Application for Decommissioning and Disposal |
| Step 2. | Obtaining transport permission of Depleted Uranium (DU), if applicable | Transport of Un-registered Source |
| Step 3. | Intimating decommissioning of equipment | Intimation for Decommissioning |
| Step 4. | Intimating disposal of Depleted Uranium (DU), if applicable | Intimation of Export/Transport/Disposal |

# Site and Layout Approval

Site and layout application along with drawings of site plan on ground floor, main layout and cross-sections along breadth, length and through maze.

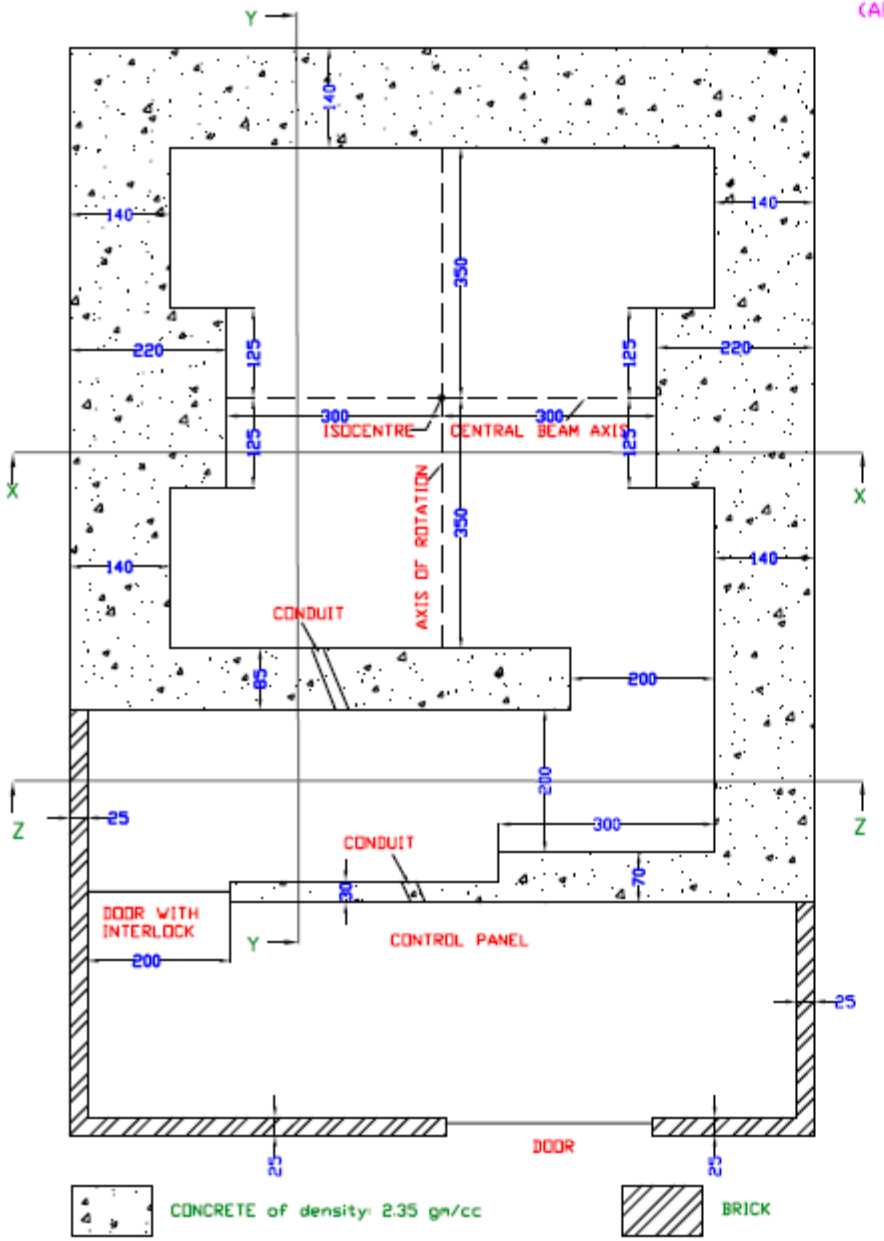
Major points to be consider while preparing for radiotherapy layout drawings:

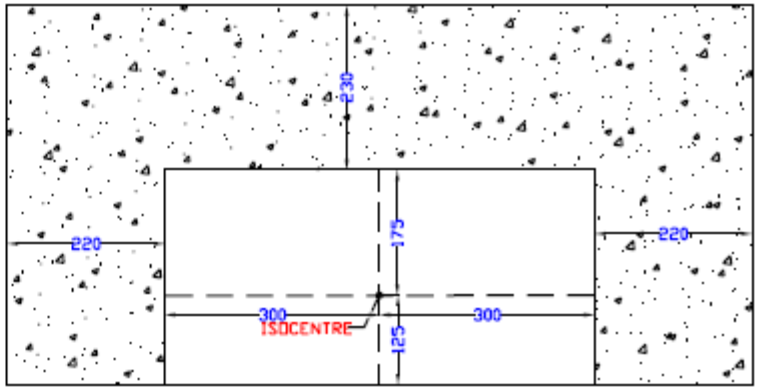
- The location of the radiotherapy installation should be so chosen that it is away from unconnected facilities and is close to the related facilities such as Simulator Room, Mould Room etc.
- Specify nature and type of occupancy around the radiotherapy room
- In case of multiple installations (e.g. two medical accelerator installations, etc.), show the proposed individual installation completely and other adjoining installation(s) partially.
- Legend for each type of material (brick, concrete etc.) and its density should be provided
- Primary barrier width on either side of central beam axis - in case of Teletherapy installation.
- Source position and bed position - in case of Brachytherapy installation


EN PLACE
20.00m
29.90m
13.70m
PROPOSED PLAN OF LINAC BUNKER
11.20m
2.50m
OP
MINOR OT & C-ARM ROOM
CONTROL ROOM
EXISTING TELETHERAPY ROOM
RECIPTION
MEDICAL PHYSICIST ROOM
ENTRANCE
EXISTING HDR BRACHYTHERAPY ROOM
TREATMENT
DOOR INTERLOCK
CCTV/CUE
PLOT BOUNDARY
STORE
KITCHEN
VERANDAH
GARRAGE
DINING HALL
6.80m
3.55m
OLD AGE HOM
WORKING AREA
WORKING AREA
WORKING AREA
20.00m
20.00m
20.00m
GENERAL WARD
M OPEN PLACE
3.45m
GUEST HOUSE
GUE HOU

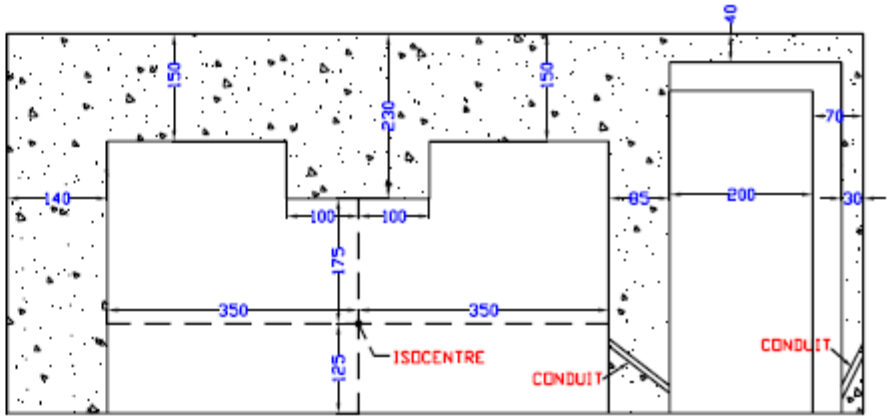
# TYPICAL LAYOUT OF 15MV MEDICAL LINEAR ACCELERATOR

(AREA: 6mx7m)

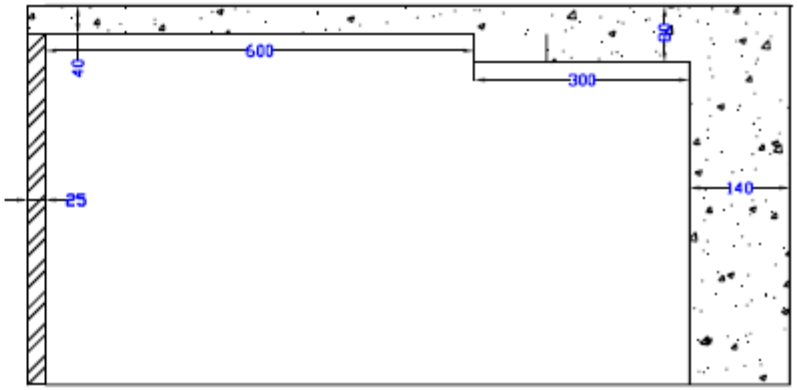



SECTION X-X




SECTION Y-Y




SECTION Z-Z

NOT TO SCALE : All dimensions are in Centimeter

# Site and Layout Approval contd..

- Control console should be placed adjacent to the entry to treatment room door i.e. interlocked door, so that the interlocked door is under direct supervision from the control console and there is no barrier (not even glass partition) in between the interlocked door and control console.
- Drawings should be in conjunction with each other
- Owner's plot boundary to be indicated in the site plan
- All facilities at the vicinity of 20 m from the external walls of radiotherapy room should be shown in the site layout plan.
- If radiotherapy room is to be constructed in the basement and natural earth is to be used as a shielding material, declaration regarding THICKNESS of the Earth and it's LEVEL to be maintained forever in owner's property should be clearly mentioned.
- Name of institute and address of institute ('Permanent Address' of institute as seen in eLORA account) should be mentioned on all the drawing.

Once site and layout plan approved by AERB, RT installation shall be constructed as per AERB approved layout plan

# Procurement permission

- Permission shall be obtained from AERB to procure any radiation source/equipment. Equipment may be either based on NOC or TA
- Required staff- RSO shall be available, No other staff required
- Requisite M&M instrument- Proposed/available

# Commissioning permission

Permission shall be obtained from AERB to commission radiation source/equipment- i.e. permission for beam ON

- Requisite Qualified staff
  - Minimum required Radiation Oncologist, Medical Physicist, Radiotherapy Technologist, Radiological Safety Officer shall be available
- Personnel Monitoring Services (PMS)
  - All Radiation workers must be provided with Personnel Monitoring Badges (TLD badge)
- Requisite M&M instrument-available
- QA tools, Safety tools- available

After commissioning approval- Radiation survey data of all around the installation need to be submitted

# License for operation

Permission shall be obtained from AERB prior to operation

- Performance test report of the radiotherapy equipment must be carried out as per prescribed QA documents of AERB & Acceptance test Criteria

# Replacement of decayed source

- Performance of the unit is satisfactory
- Authorization is to obtained from AERB for procurement of fresh source
- Replacement of the source is done by trained and certified engineer under supervision of RSO (Authorized for Source Transfer Supervision by AERB)
- Report on source transfer is to be sent to AERB
- Performance tests is carried out and approval obtained from AERB for restarting treatment

# Disposal of disused sources

- Unused sources in public domain are potential risk
- Must be sent back to the original supplier of the source/authorised waste disposal agency for safe disposal
- No source is transported without approval of AERB
- Regulatory requirements are to be complied during transport (such as labeling, marking, documentation and emergency response)

# Decommissioning of Radiotherapy equipment

Consent for decommissioning/disposal of radiotherapy equipment/sources shall be submitted to AERB along with following document:

- Acceptance from supplier to carry out decommissioning of radiotherapy equipment. It should be carried out by the trained and certified service engineer and authorized agency
- Concurrence from disposal agency for acceptance of disused source (for equipment containing radioactive source e.g. telecobalt)

After decommissioning consent,

- Source supervision authorisation for supervision of source transfer operation in radiotherapy equipment (for Telecobalt unit) shall be obtained from AERB
-

# Regulatory Inspection(RI) of Radiation Facilities

- **Objective:**

"To ensure that the activities performed by the Consentee during all stages of consenting process are in compliance with the laid down safety requirements stipulated in Regulatory and Statutory documents".

# Regulatory Inspection

AERB has published following documents for Regulatory Inspection and initiating enforcement actions:

- AERB Safety Guide entitled “Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities” (AERB/SG/G-4)
- Safety Manual entitled “Regulatory Inspection And Enforcement in Radiation Facilities”- AERB Safety Manual No. AERB/RF/SM/G-3

# Type of Inspections

- Announced/Planned inspection
- Unannounced/Surprise inspection
- Special inspections

Number of regulatory inspection carried out last year was around 700 radiation facility.

Who has the right or the obligation to conduct RI?

-----***Authorized Persons By the Competent Authority***

Non compliances are brought to the notice of the institution and they shall comply with the requirements

# Frequency of regulatory inspections

- Potential for significant exposure, categorisation of sources
- Non-submission of periodic safety status report
- Possessing disused sources
- Reported unusual occurrences
- Past experience on regulatory compliance with safety requirements

# Challenges faced in Control of Radiation Sources

- Lack of commitment from the management to ensure safe use of radiation sources
- Lack of safety culture
- Lack of awareness regarding their duties and responsibilities under AE(RP)R, 2004 by the employer/licensee/RSO
- Lack of effective radiation protection infrastructure
- Financial constraints in disposal of disused source by employer
- Insufficient training of personnel in the safe handling of radiation sources
- Non-existence of comprehensive quality audit program
- Non-reporting of radiation incidences
- Higher patient load per machine

# Conclusion

- There exists an effective regulatory framework for governing control over radiation sources/equipment used in medicine
- High standard of radiation safety is ensured through inherent built-in safety features incorporated in the design (Type Approval) & operational and administrative controls at the installation
- Joint efforts by all the stakeholders (AERB, Supplier/Manufacturer and end user) are required for obtaining maximum benefits of radiation while minimizing the risks
- It must be ensure that institute has all the requisite approvals from AERB prior to undertake the installation/decommissioning/transport etc. for meeting safety objective
- The prime onus of ensuring the overall radiation safety, security and safe handling of sources rests with the employer/licensee and its personnel.
- Expeditious review of applications and transparency is assured by AERB
- After deployment of eLORA, almost all the stakeholders can make their offices paperless(electronic storage of documents)

# Conclusion contd..

Radiation Safety Culture is within every radiation worker's own responsibility, NOT IMPOSED or DO it Because some one wants.


THNAK YOU FOR
YOUR ATTENTION
NIYAMAK BHAVAN-B