

Radiation Protection & Regulatory Control in Radiation Therapy



DR.P.K.DASH SHARMA

head.rsd@aerb.gov.in

HEAD

**RADIOLOGICAL SAFETY DIVISION
ATOMIC ENERGY REGULATORY BOARD
NIYAMAK BHAVAN, ANUSHAKTINAGAR
MUMBAI-400094**

What is in the presentation



- ❖ Radiotherapy facilities in India
- ❖ Basics of Radiation & its Protection
- ❖ Hazard Evaluation & Control
- ❖ Regulation of RT facilities in India



Radiotherapy Facilities in India

Teletherapy Facilities in India



Radiotherapy Centres Teletherapy Facilities

- Co-60 Units
- Linear Accelerators
- Gamma Knife
- Tomotherapy
- CyberKnife

: 500

: 729

: 159

: 534

: 6

: 22

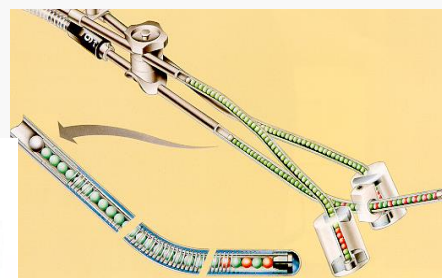
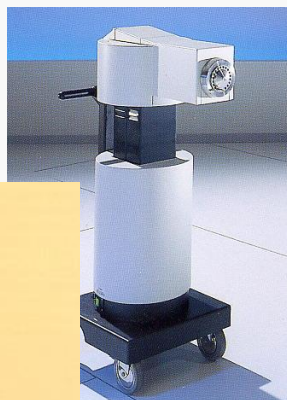
: 8



Brachytherapy Facilities in India

Brachytherapy Devices/Facilities

| | |
|--|-------|
| ○ Remote Afterloading Units (HDR/MDR/LDR) | : 387 |
| ○ Manual Afterloading kits (Cs-137) | : 318 |
| ○ Facilities using Sr-90, Ru-106 and I-125 | : 35 |
| ○ Intra Operative Radiotherapy (IORT) unit | : 57 |
| | : 01 |





Basics of Radiation & its Protection

Quantities & Units for Radiation Measurement

Exposure

Ionization produced in unit mass of air
Unit: C/Kg, Roentgen (R)



Absorbed Dose

Energy Deposited in unit mass of medium
Unit: Gray (Gy), Rad



Equivalent Dose

Effect of absorbed dose for radiation type
Unit: Sievert (Sv), Rem



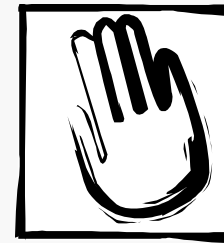
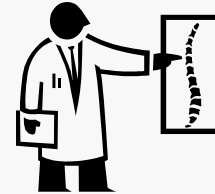
Effective Dose

Effect of equivalent dose in tissue
Unit: Sievert (Sv), Rem

System of Radiological Protection



- Justification of practice
- Optimization of protection
- Limitation of doses



Basis for the Dose Limit



- **To prevent deterministic effects**
- **To reduce the probability of stochastic risk at an acceptable level**

Adult (>18 years) Occupational Dose Limits

Whole Body

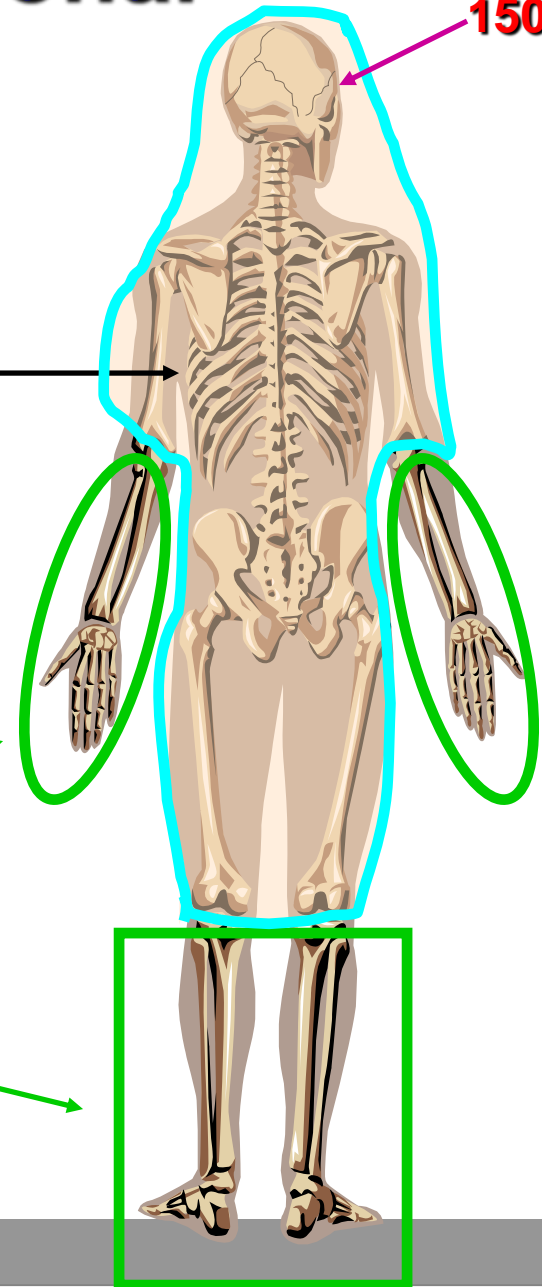
30 mSv maximum per year

20 mSv averaged over 5 years

Lens
150 mSv

Extremities

500 mSv per year

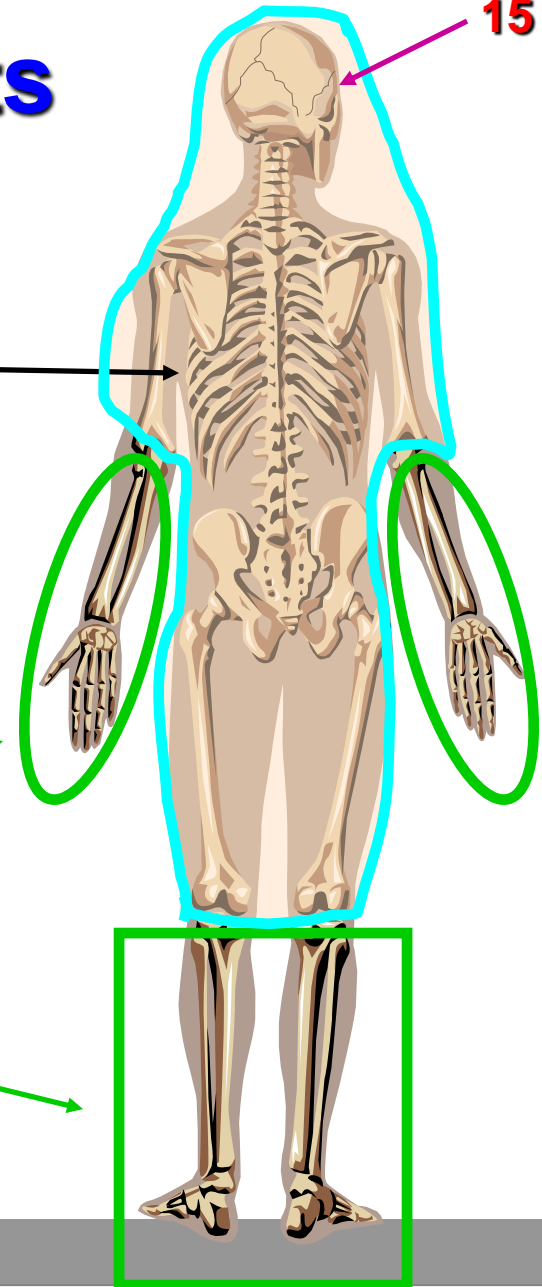


Public Dose Limits

Whole Body
1 mSv per year

Lens
15 mSv

Extremities
50 mSv per year

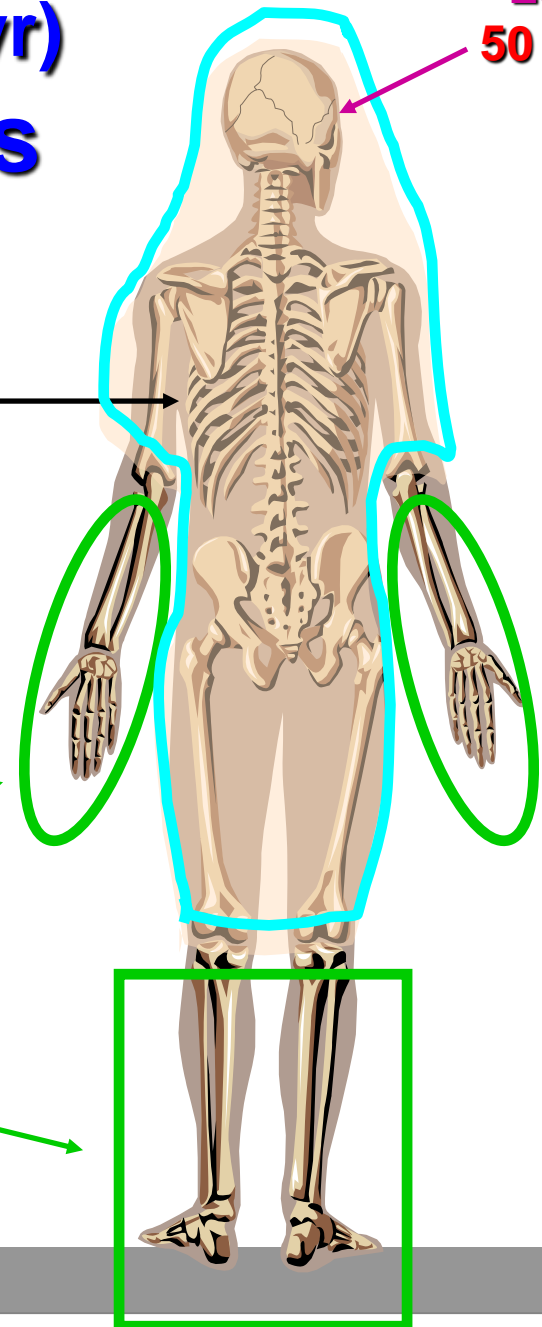


Apprentice/Trainee (16-18 yr) Occupational Dose Limits

Whole Body
6 mSv maximum per year

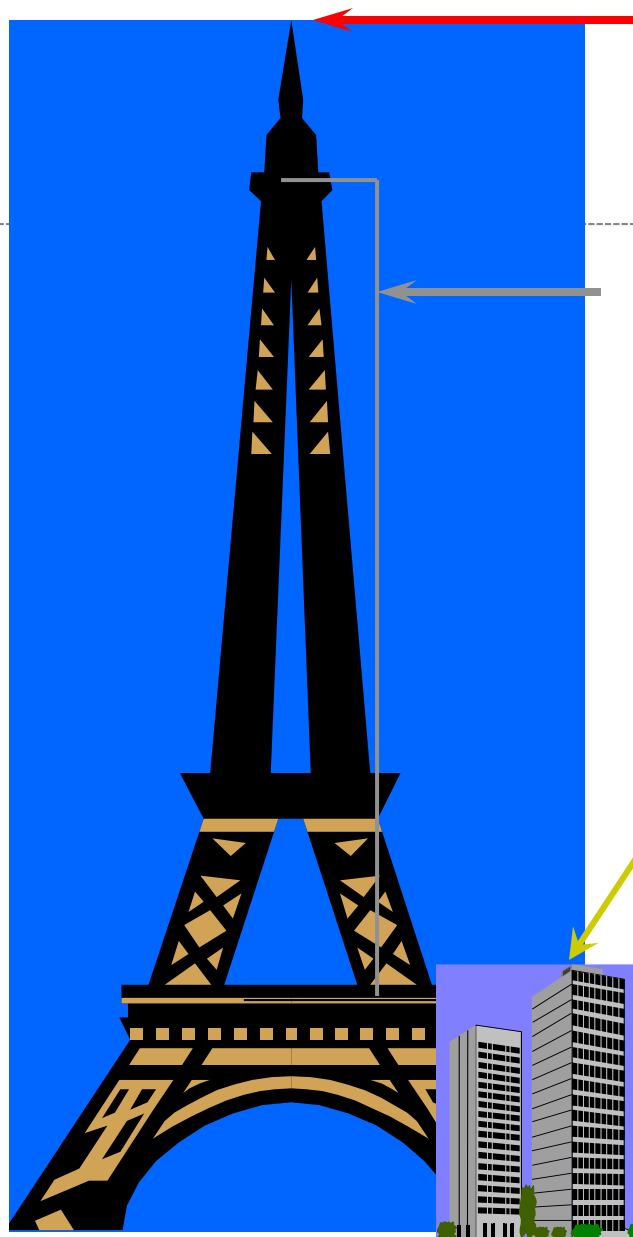
Extremities
150 mSv per year

Lens
50 mSv



Exposure to Radiation Dose

If a life threatening dose (50% probability) is illustrated by the height of the Eiffel tower (over 300 meters), the dose limit for occupational (radiation) workers corresponds to the height of a man (2 meters) and the limit for the public to the thickness of a brick (0.1 meters).



Life threatening dose

– more than 3000 mSv

**Radiation illness –
Passing
Symptoms**

**No symptoms,
temporary changes in
blood picture (A
Skyscraper)**

**No detectable
effects (A House)**

**Limit for the
Occupational
Worker (A Man)**

**Limit for the
public
(A Brick)**

Comparison of Risk

Accident type

Individual risk/year

Motor vehicle

1 in 4 000

Fires

1 in 25 000

Air travel

1 in 100 000

Electrocution

1 in 160 000

Lightning

1 in 2 000 000

Radiation Industry

1 in 5 000 000 000

Typical Average Annual Exposures

Practice

Average annual dose (mSv)

- **Industrial radiography** 0.9
- **Nucleonic gauges** 0.13
- **Gamma irradiators** not significant
- **Teletherapy** 0.55
- **Brachytherapy** 0.49
- **Nuclear medicine** 0.54
- **Diagnostic radiology** 0.49

Basic Safety Objective



- **Protection of occupational workers, patient, public and environment**
- **ALARA during normal operations**
- **Radiation exposure during normal operations within relevant dose limits**
- **Potential exposures and the magnitude of such exposures are kept ALARA**



Hazard Evaluation & Control

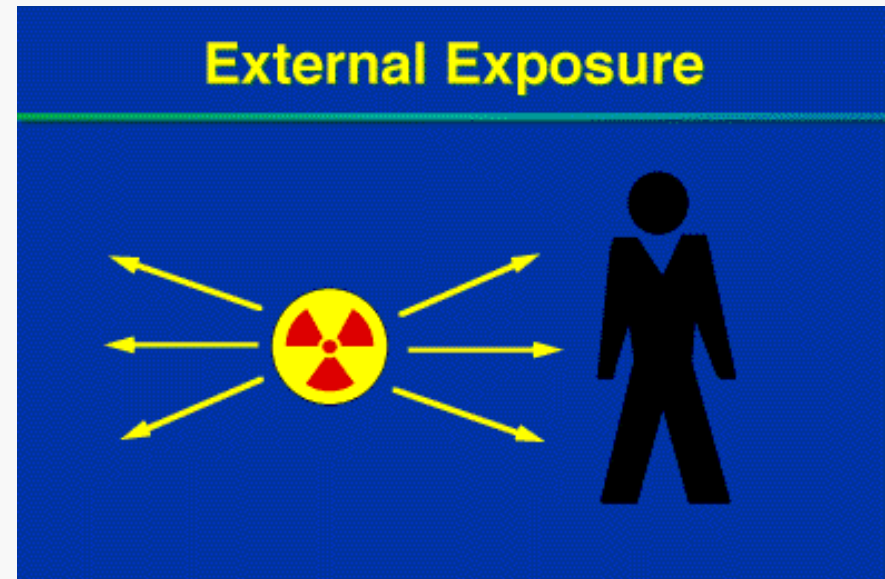
Basic Radiation Protection Techniques

- For External Hazards:

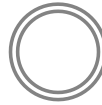
I. Time

II. Distance

III. Shielding

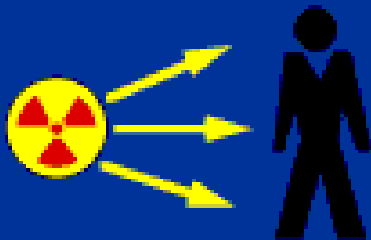


Reduce Time



Time Relationship

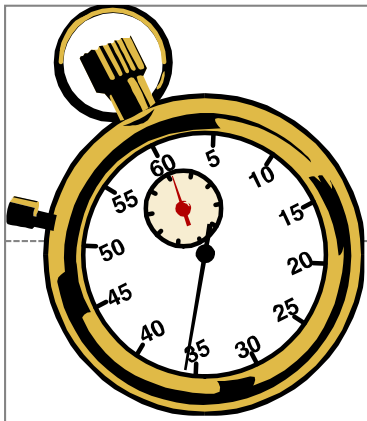
Exposure rate
= 1 mR/hr x Time = Total Exposure



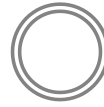
1 hour = 1 mR



2 hours = 2 mR

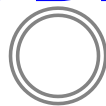


Time



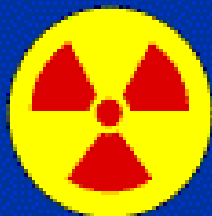
- ⌚ Less time = Less radiation exposure
- ⌚ Use Radioactive Material only when necessary
- ⌚ Dry runs (without radioactive material)
- ⌚ Shorten time when near Radioactive Material
- ⌚ Obtaining higher doses in order to get an experiment done quicker is NOT “reasonable”!

Increase Distance



Distance Effect

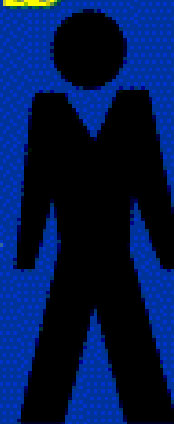
Inverse Square Law



12,000 mR/hr
at 1 cm from
source

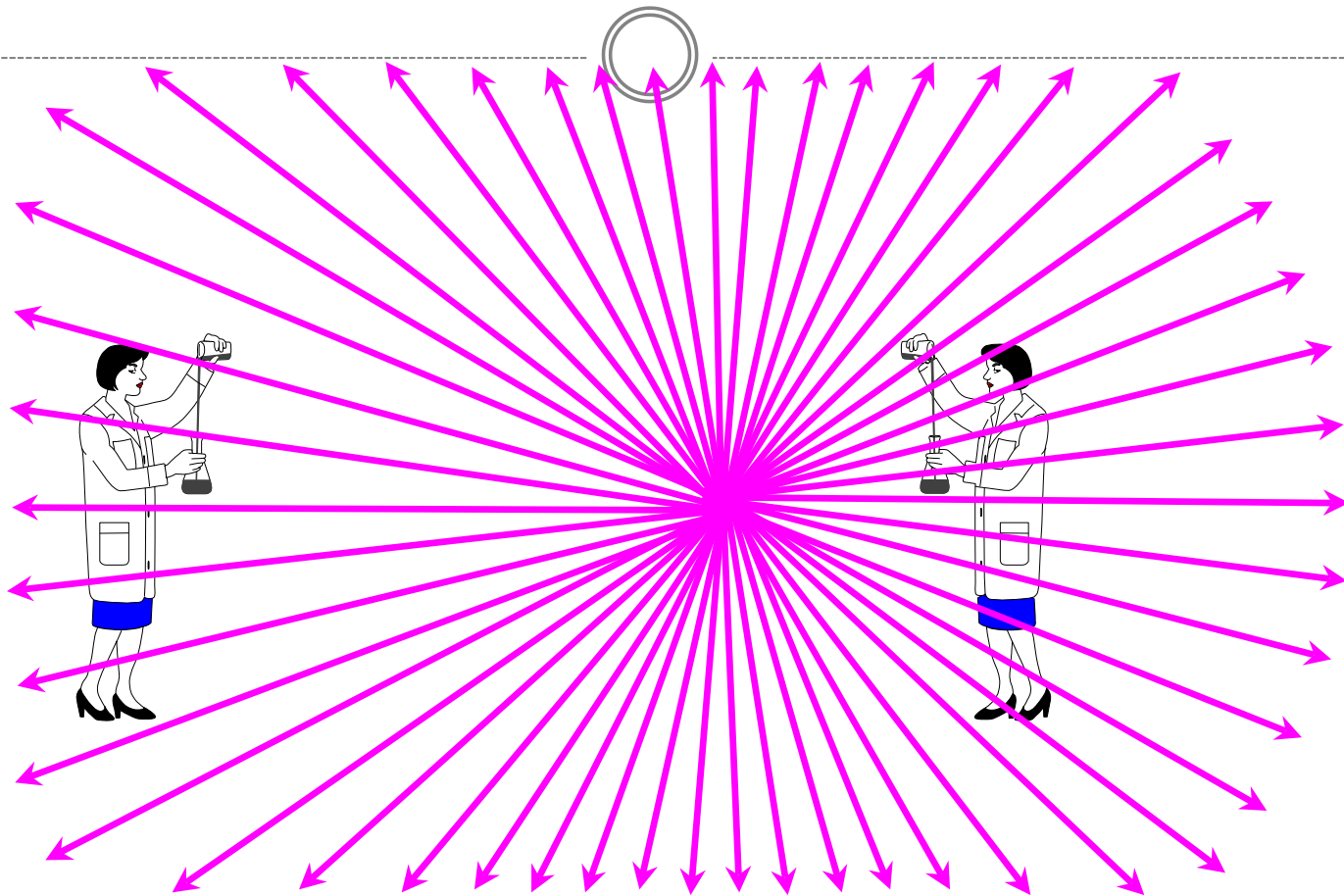


$d = 50 \text{ cm}$

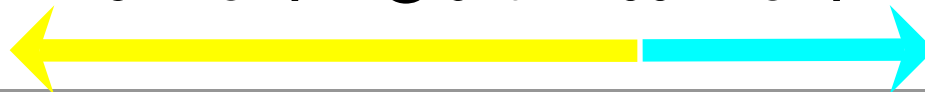


4.8 mR/hr

Effect of Distance on Dose Rate

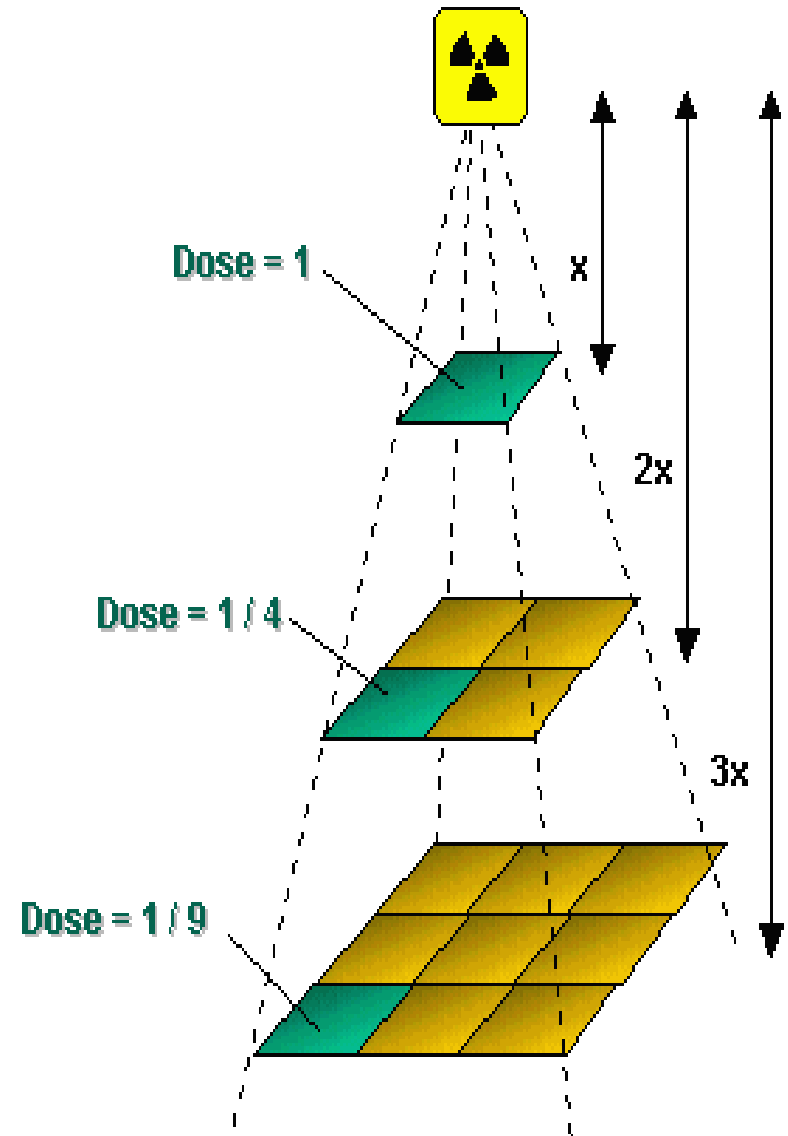


25 mrem/hr @ 6 ft 100 mrem/hr @ 3 ft

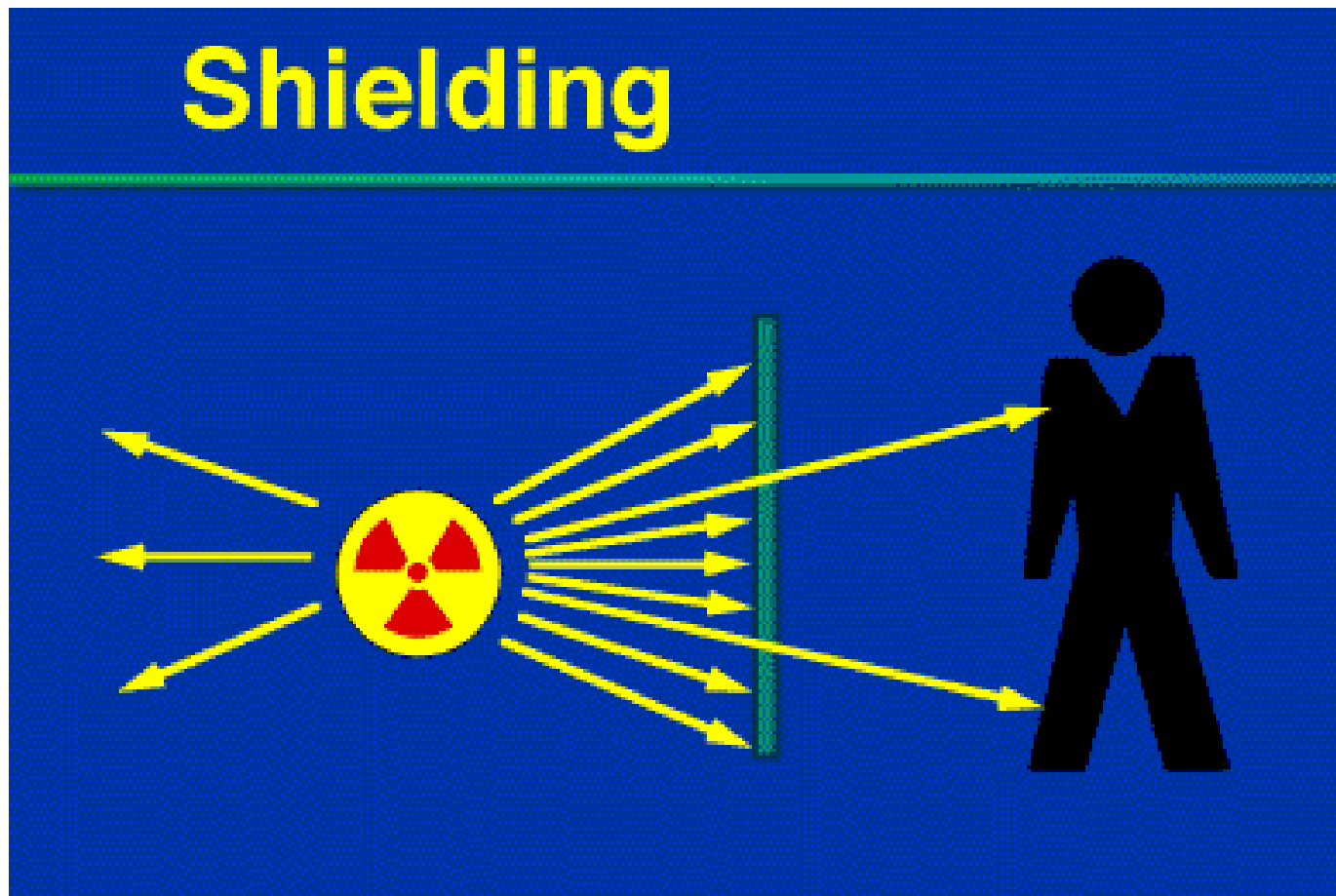
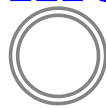


Distance

- Effective & Easy
- Inverse Square Law
 - Doubling distance from source, decreases dose by factor of four
 - Tripling it decreases dose nine-fold
- More Distance = Less Radiation Exposure
- Tongs, Tweezers, Pipettes, Pliers



Use Shielding



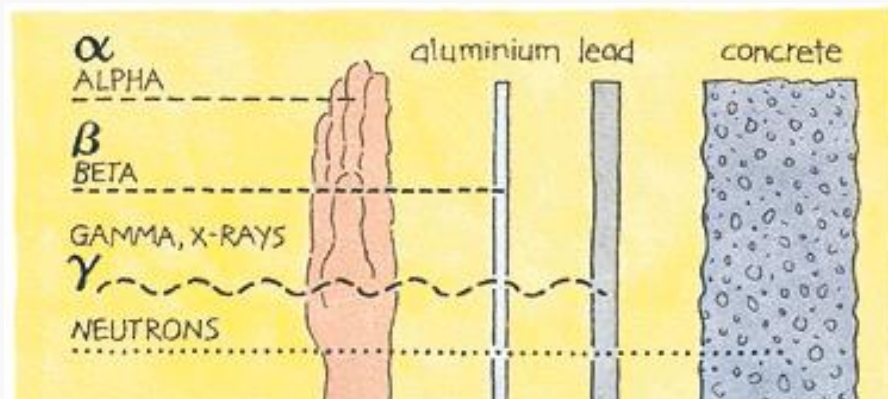
Shielding

- Alpha Emitters (^{238}U , ^{230}Th , ^{241}Am , ^{222}Rn)

- Paper

- Low Energy Beta Emitters (^3H , ^{14}C , ^{35}S , ^{33}P)

- Paper



- Medium / High Energy Beta Emitters (^{32}P)

- Plastic

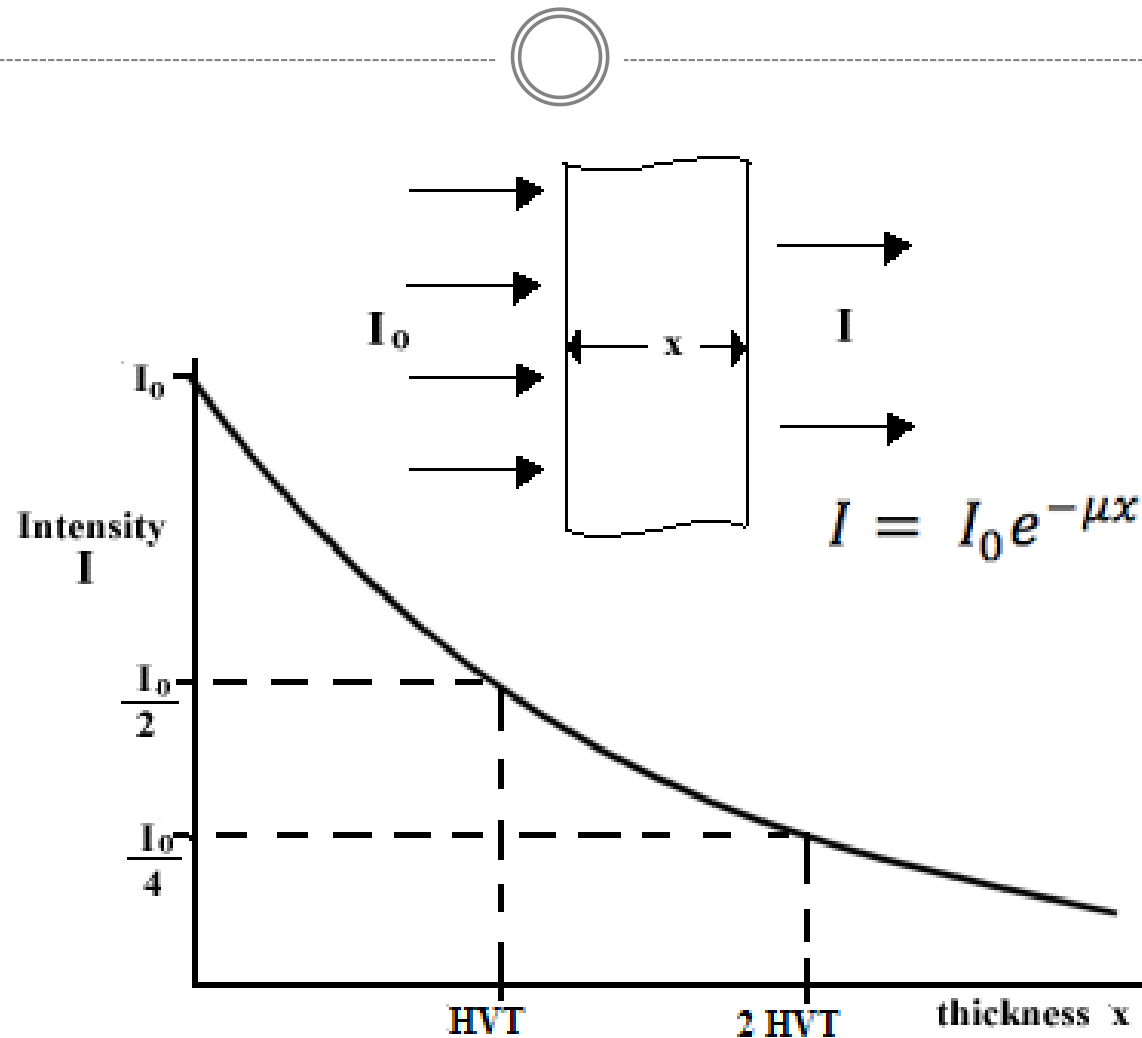
- X-ray & γ -ray Emitters (^{60}Co , ^{137}Cs , ^{192}I , ^{125}I)

- Lead, concrete, steel, etc.

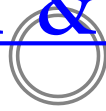
- Neutron Sources (Accelerators, Reactors, Am/Be)

- Water, plastic, paraffin, etc.

Shielding of X-ray/ γ -ray



Half value & Tenth value thickness (HVT & TVT)



HVT- It is that thickness of the shielding material which will reduce the radiation intensity to half of the original intensity

TVT- It is that thickness of the shielding material which will reduce the radiation intensity to one tenth of the original intensity

$$\text{TVT} = 3.3 \times \text{HVT}$$

Reduction Factor

1 HVT of a shielding material provide a reduction factor of 2

2 HVT produces a reduction factor of 2×2 or $2^2 = 4$

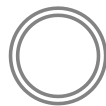
The reduction factor offered by **n number of HVT** of shielding material is 2^n

1 TVT of a shielding material provide a reduction factor of 10

2 TVT produces a reduction factor of 10×10 or $10^2 = 100$

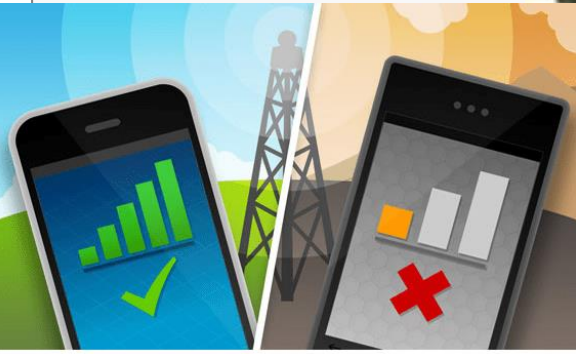
The reduction factor offered by **n number of TVT** of shielding material is 10^n


HVT & TVT Values



| Radio-isotope | Concrete (cm) | | Steel (cm) | | Lead (cm) | | Depleted Uranium (cm) | |
|-------------------------------------|---------------|------|------------|-----|-----------|-----|-----------------------|-----|
| | HVT | TVT | HVT | TVT | HVT | TVT | HVT | TVT |
| ^{192}Ir | 4.6 | 14 | 1.25 | 4.0 | 0.48 | 1.6 | 0.31 | 1.0 |
| ^{137}Cs | 4.8 | 15.7 | 1.5 | 5.2 | 0.7 | 2.2 | 0.4 | 1.3 |
| ^{60}Co | 6.6 | 21.8 | 2.0 | 6.6 | 1.2 | 4.0 | 0.7 | 2.2 |

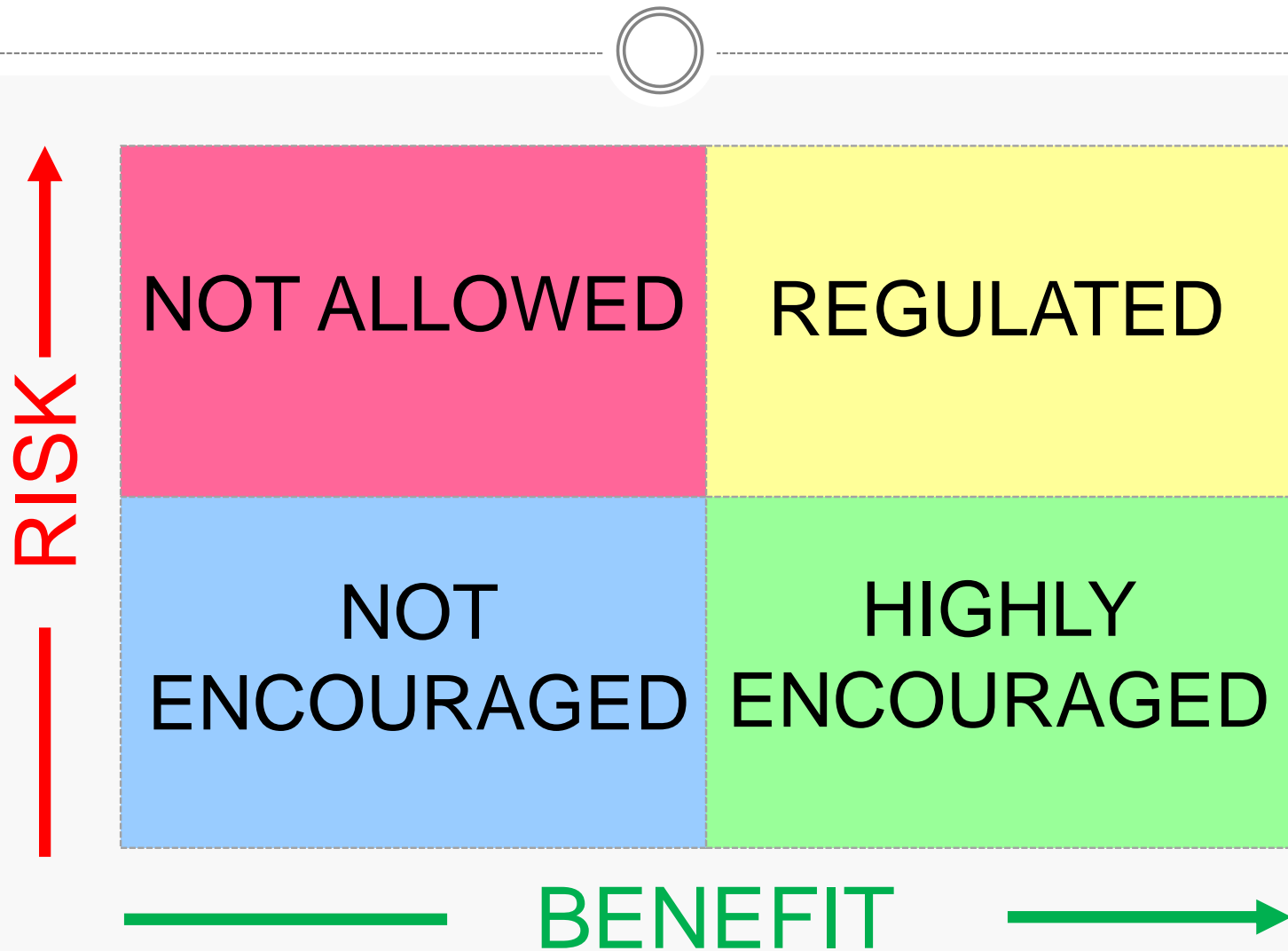
Radiation Monitoring Instruments





Regulation of Radiotherapy Facilities in India

Why Regulation ?



What is Regulation ?



- ❖ **Regulation** refers to “controlling human or societal behavior by **rules** or **restrictions**”
- ❖ **Costs** for some and **benefits** for others
- ❖ Efficient where the total benefits to some people exceed the total costs to others
- ❖ Regulatory agencies deal in regulation or rulemaking and enforcing rules and regulations for the **benefit of the public at large**

System of Regulatory Control

Issued by Central Government

❁ Act

(Atomic Energy Act, 1962)

❁ Rules

(Atomic Energy Radiation Protection) Rules, 2004)

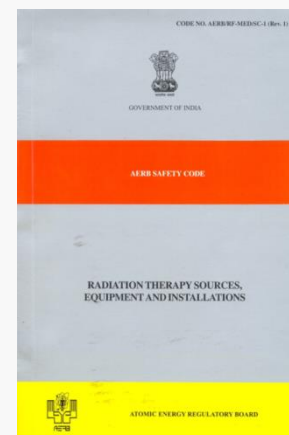
❁ Notifications

(Radiation Surveillance Procedures for Medical Applications of Radiation, 1989)

Published by AERB

❁ Safety Code

AERB/RF-MED/SC-1 (Rev.1)

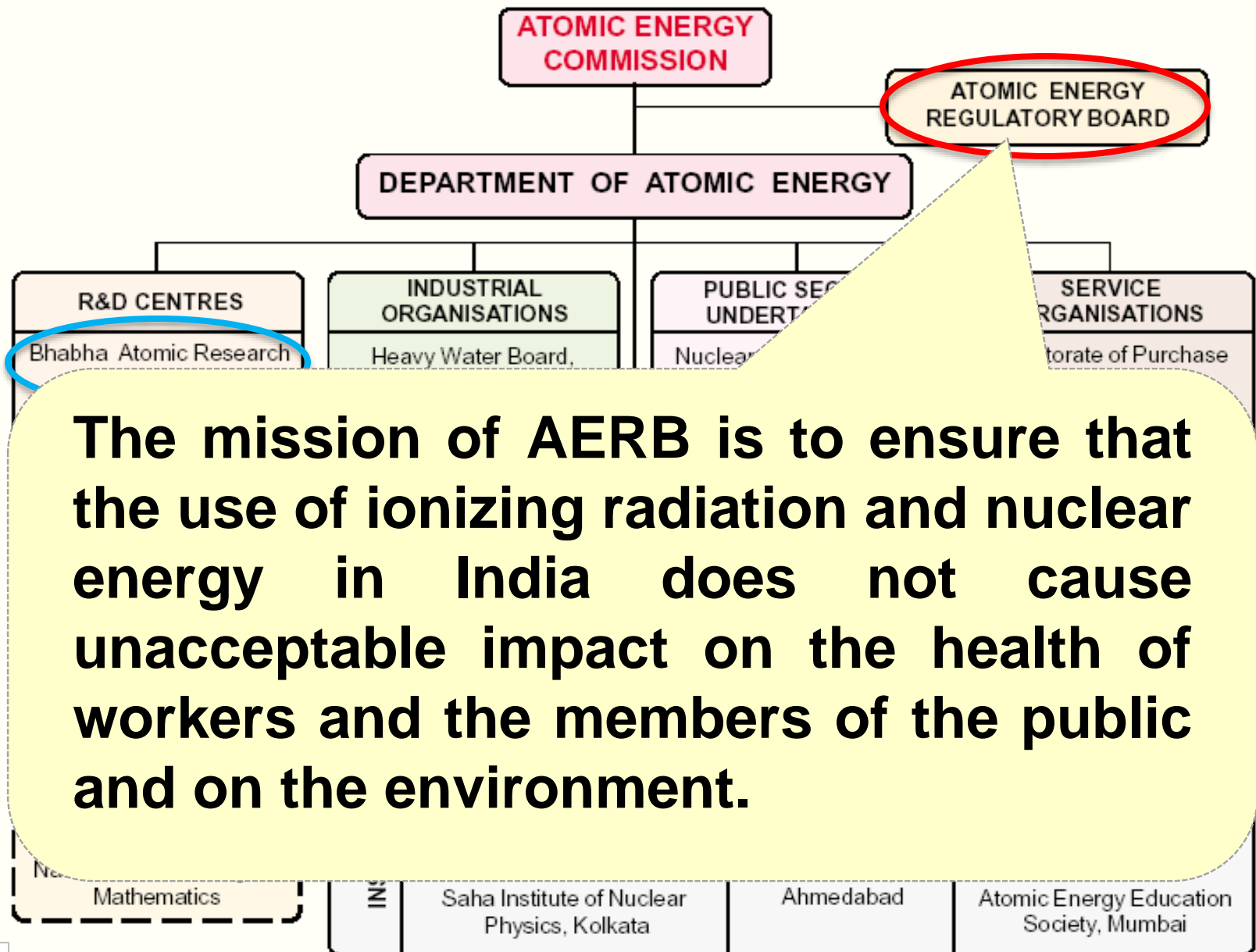


❁ Safety Standards

❁ Safety Guides

❁ Safety Manuals





Responsibility of Safety ?



Though AERB oversee Safety in use of Radiation Sources in the country,

the Prime Responsibility of ensuring Radiation Safety in the facility lies with the Licensee

Radiation Safety

37

Total Radiation Safety is achieved by

Built-in Safety

combined with

Operational Safety

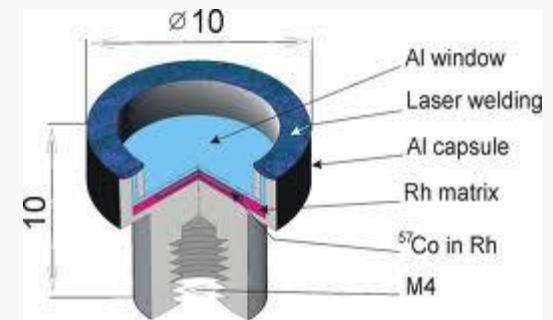


Built-in Radiation Safety



❖ Sealed Source – Classification

(safety of worker and public)



❖ Equipment – Type-approval

Electrical, Mechanical,
Radiological

(safety of rad. worker and patient)



Built-in Radiation Safety



- **Installation – Plan Approval**

Thick concrete walls, maze

(safety of rad. worker, public and patients' relatives)



- **Transport Package – Package approval**

(safety of worker, public)



Operational Safety



Components of operational safety

- ◉ Qualified and certified persons
- ◉ Work place monitoring
- ◉ Personnel monitoring
- ◉ Safe and secure storage place
- ◉ Desirable equipment for safety, dosimetry, QA
- ◉ Preventive Maintenance
- ◉ Interaction with regulatory body
- ◉ Emergency planning and preparedness

Operational Safety- Manpower, PMS

- ❖ Adequate No. of Qualified and certified persons

(Radiation Oncologist, Medical Physicist, Radiation Therapy Technologist)



- ❖ Personnel monitoring
(TLD for all radiation worker)



Operational Safety – Monitoring, Maintenance

◉ Work place monitoring



(Gamma Zone Monitor)



(Switches, Interlocks, Indicators)

◉ Preventive maintenance

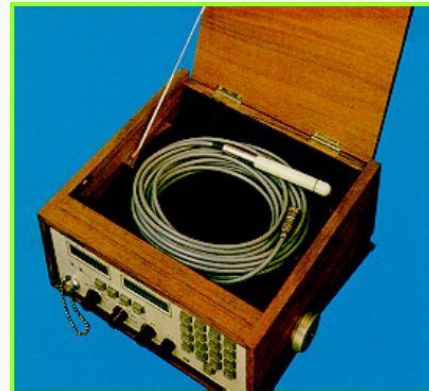
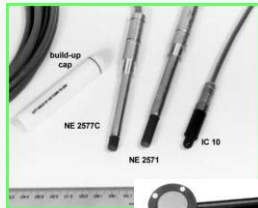


Operational Safety – Survey, Dosimetry

- Appropriate Monitoring equipment (survey meter, contamination monitor, gamma zone monitor_[auto/manual] etc.)



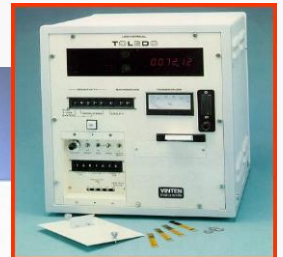
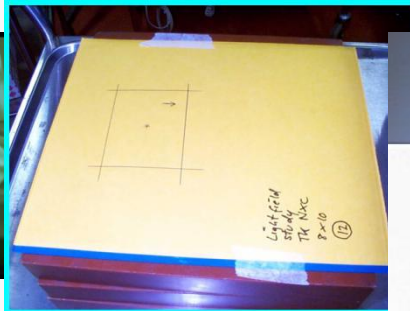
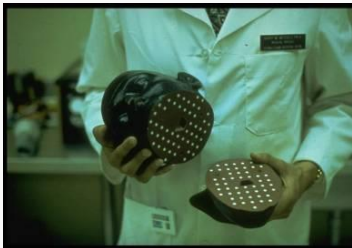
- Appropriate Measuring equipment (RFA, SSD with thimble /parallel plate/well type chamber etc.)



Operational Safety – QA & others



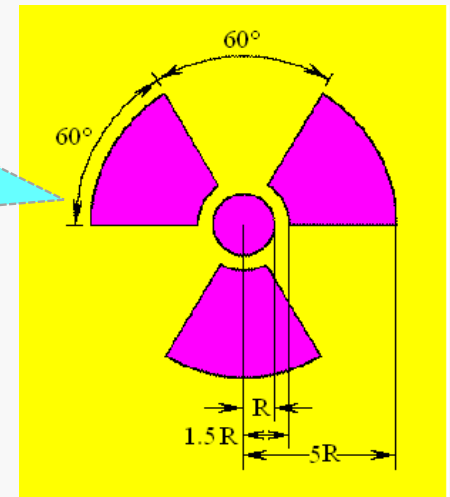
- ❖ *TPS*
- ❖ *Simulator*
- ❖ *CT-Simulator*
- ❖ *Beam modifiers*
- ❖ *Moulds*
- ❖ *QA test tools*



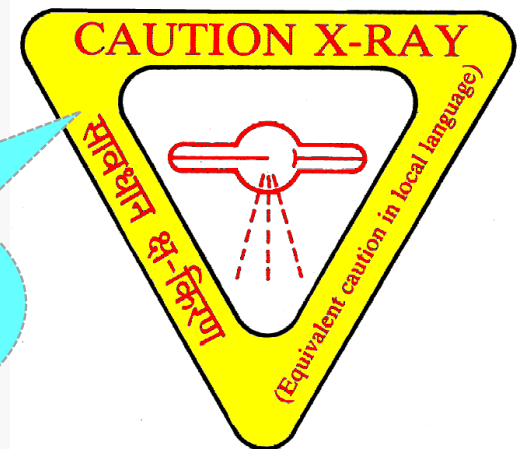
Radiation Symbol

- Radiation symbol to be posted at
 - Entrance of treatment room
 - Entrance of the controlled and supervised areas
- A legend in Hindi, English and Local language indicating radiation hazard

For
Telegamma/
Brachytherapy
facility



For
Linac/Simulator
or facility



Control measures adopted in India

- **Pre-licensing stage**

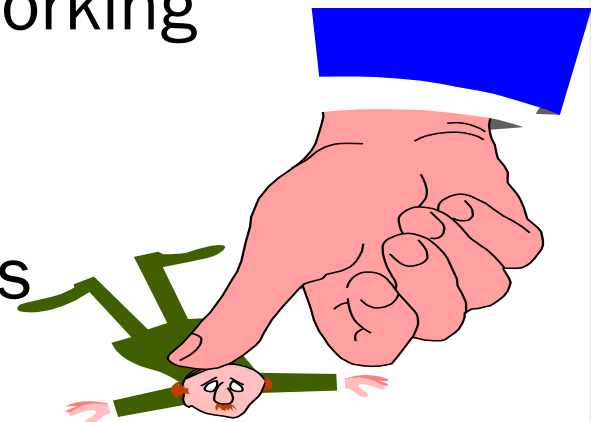
- Design Approval of Room layout
- Approval for procurement of source
- Commissioning approval
- Licence for operation

- **During the useful life**

- Information for any change in working condition
- Radiation safety report
- Reporting incidents or accidents

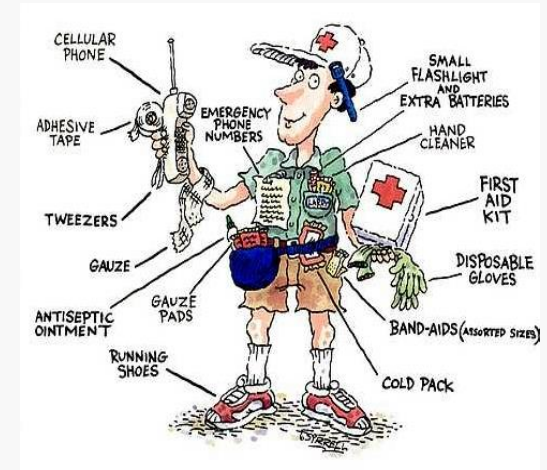
- **Post use**

- Approval for Decommissioning/Disposal



Preparation of Emergency Preparedness Plan

- Foreseeable emergencies, include
 - Radioactive source failing to return to the safe shielding position
 - Dislodge/loss/theft of radioactive source during use, storage, transport, loss of shielding
 - Natural calamities such as fire, flood, or earthquake
 - Death of patient, with sources *in situ*
 - Selection of wrong treatment mode
 - Selection of wrong beam modifiers and wrong dose delivery.



Emergency Handling and Reporting



- Display of Emergency Procedures
- Ensure that all workers are familiar with the emergency action plan
- Release of dead body containing sources, after removal and monitoring by RSO
- Report to licensee/employer immediately and to the competent authority within 24 hours
- Lodge written complaint with police in case of loss or theft of radioactive sources, if not traced within 24 hours.

Reporting of emergency/unusual occurrences/accidental medical exposures


- Investigation report on emergency to be submitted to AERB which includes
 - (i) any **equipment failure, accident, mishap, miscalculation** or other **unusual occurrence** with the potential for causing a patient dose significantly different from that intended, and
 - (ii) any therapeutic treatment delivered to either the **wrong patient**, or the **wrong tissue**, or using **wrong source**, or with a **dose or dose fractionation** differing substantially from the value prescribed by the radiation oncologist, or that may lead to undue acute secondary effects.

Security Plan in case of Radioactive Sources

- Security Plan is required to be prepared for radioactive sources
- Security plan for Telecobalt and Gamma Knife units need to be registered with local law enforcement agency




e-Licensing of Radiation Applications (eLORA)



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 C

CAUTION X-RAY

Ways to achieve


Login

Username


Password

Login

Home | Switch Profile | View Profile | View All Messages | Help | Logout



Government of India
Atomic Energy Regulatory Board
e-Licensing of Radiation Applications (eLORA) System



सत्यमेव जयते

Login: TEST INSTITUTE (TI291)

Institute: TEST INSTITUTE TEST (MH-21818)

Role: Employer, Licensee

Profile: Radiotherapy-Radiation Facility

Submission of

Click here to sub Report-Applicabl

Guidelines for (Unregistered Ins

Help Phone no: 022-25990675 (only during workin AERB)

Help Email-Id: See practice speci email id. (Practice 'Help' menu after lc

Change Password

Instrument Management

My Applications

My Casefiles

My Drafts

My Institute Details

Regulatory Forms

User management

View Inspection Documents

AERB Circulars

Submission of security plan for Telecobalt and Gamma Knife facilities

View All

My Inbox

Search:

| Date and Time | Message to User |
|---------------------|---|
| 30/05/2016 03:06 PM | You have successfully submitted the application for Change licensee with application no :16-138481 and application is accepted. |
| 13/05/2016 05:30 PM | Your Application ref no. 16-134637 is Rejected. |
| 22/01/2016 05:32 PM | Your Application no. 16-104840 has been discarded successfully . |
| 22/01/2016 05:32 PM | You have successfully freezed Application For Site and Layout Approval with application no. 16-104840 for Accelerator,Precise Digital |
| 22/01/2016 05:27 PM | Non compliance has been modified against your institute with NC reference no [MH-21818-NC-3916].Refer 'My Institute Details' for further information. |
| 15/12/2015 11:58 AM | Your application ref no. 15-93255 is Rejected. |
| 10/12/2015 02:01 PM | Your Application no. 15-92092 has been discarded successfully . |
| 10/12/2015 01:56 PM | You have successfully freezed Application For Site and Layout Approval with application no. 15-92092 for Accelerator,Precise Digital |
| 03/12/2015 12:28 PM | Your Application no. 15-90391 has been discarded successfully . |
| 03/12/2015 12:27 PM | You have successfully freezed Application For Site and Layout Approval with application no. 15-90391 for Accelerator,Vital Beam with FFF |

Showing 1 to 10 of 57 entries

◀ Previous Next ▶



Stages in eLORA for Radiotherapy



- ◉ Institute Registration
- ◉ Obtaining Layout Plan Approval
- ◉ Radiation Professional Registration(RO/MP/RTT)/their tagging/availability of Personnel Monitoring Badges
- ◉ Declaring availability of survey, dosimetry and QA equipment
- ◉ Obtaining RSO Approval
- ◉ Obtaining Equipment Procurement Permission/Intimation of Receipt
- ◉ Obtaining Source Procurement Permission/Intimation of Receipt
- ◉ Obtaining Commissioning Approval
- ◉ Submission of Survey Report and its clearance
- ◉ Obtaining License for operation
- ◉ Submission of periodic Safety Status Report
- ◉ Obtaining permission for Disposal/Decommissioning

THANK YOU

Any container bearing
this symbol probably
houses a radioactive
material

