Radiation Hazard Evaluation and Control, Radiation Emergency Preparedness & Regulatory Requirements

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

What is in the presentation

- Radiotherapy facilities in India
- Hazard Evaluation & Control
- Emergency preparedness
- Regulatory System in India

Radiotherapy Facilities in India

Radiotherapy Centres	: 336
Teletherapy Facilities	: 499
○ Telecobalt Units	: 231
○ Linear Accelerators	: 253
○ Gamma Knife	: 8
○ Tomotherapy	: 3
○ CyberKnife	: 4
Brachytherapy Facilities	: 350
○ Remote Afterloading Units (HDR/MDR/LDR)	: 221
○ Manual Afterloading kits (Cs-137)	: 61
○ Manual Afterloding Interstitial Implants (Ir-192)	: 20
○ Brachy facilities using Sr-90, I-125, Ru-106	: 48

Medical Electron Accelerators

X-ray : 4 MV-18 MV

Electron: 4 MeV-20 MeV

Total units: 253

Tomotherapy

X-ray : 6 MV

Total units: 3

Cyberknife

X-ray : 6 MV

Total units: 4

Telecobalt unit

Co-60 : 8000 Ci – 15000 Ci

Total units: 231

Gamma-knife Unit

Co-60 : 200 sources

Total activity ~ 6000 Ci

Total units: 8

RAL Brachytherapy Unit

Ir-192 : Single 10 Ci

Co-60 : Single 2 Ci

Total units:221

Cs-137: Multiple sources
10-40 mCi each

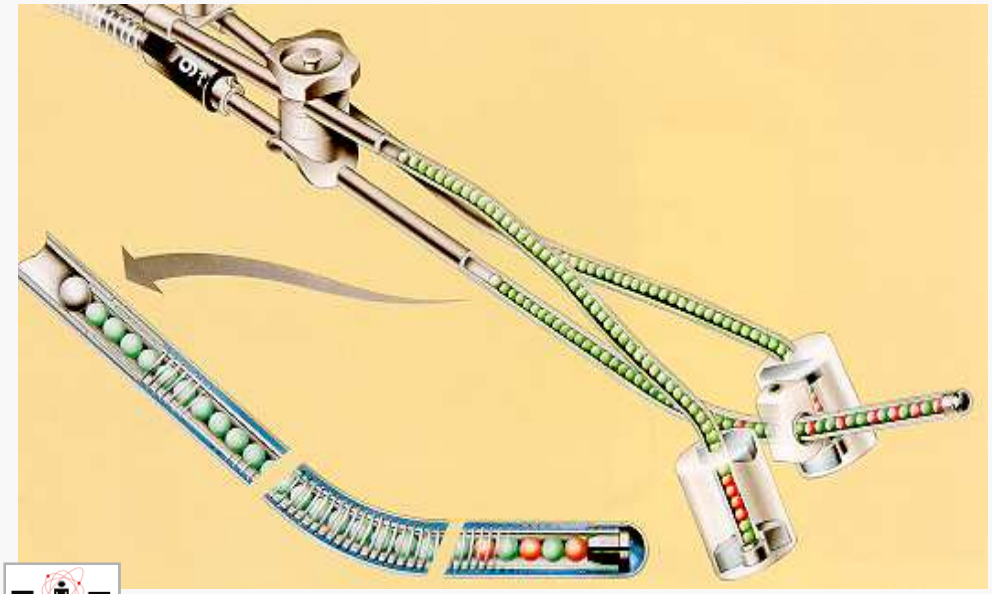
Ir-192 : Multiple sources
5-40 mCi each

MAL (LDR) Brachytherapy sources

Intracavitary application

Cs-137: Multiple sources
(10-40 mCi each)

Facilities: 61



Ocular therapy
I-125
Sr-90
Ru-106

Facilities: 48

Interstitial Implants

Ir-192: Multiple sources
(8 mCi – 40 mCi)

Facilities: 20

Intra-operative Brachytherapy Unit

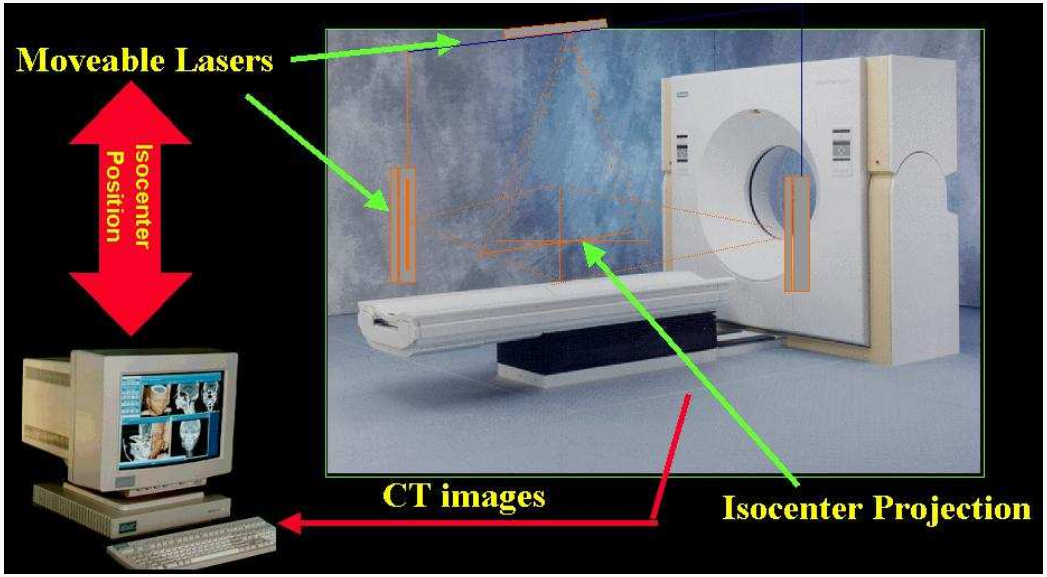
X-ray : 50 kV, 40 µA

Total units: 2

Simulator

X-ray : 125 kV

Total units: 150

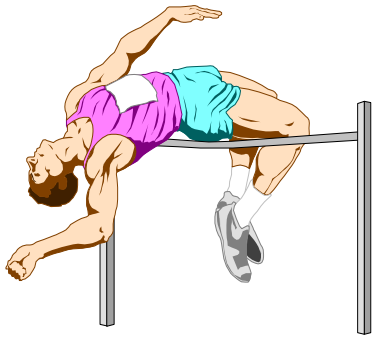


RADIAION PROTECTION

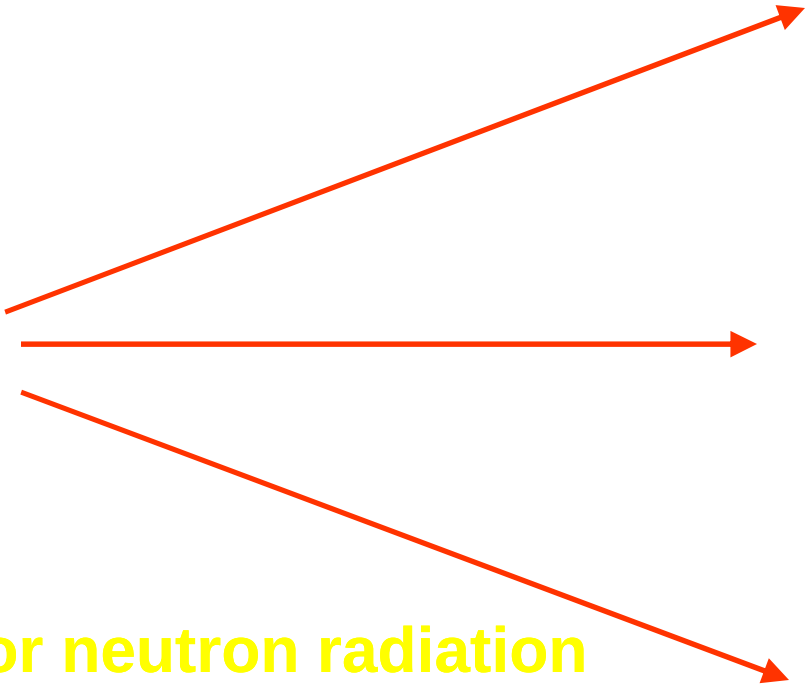
- **To prevent deterministic effects**
- **To reduce the probability of stochastic risk at an acceptable level**

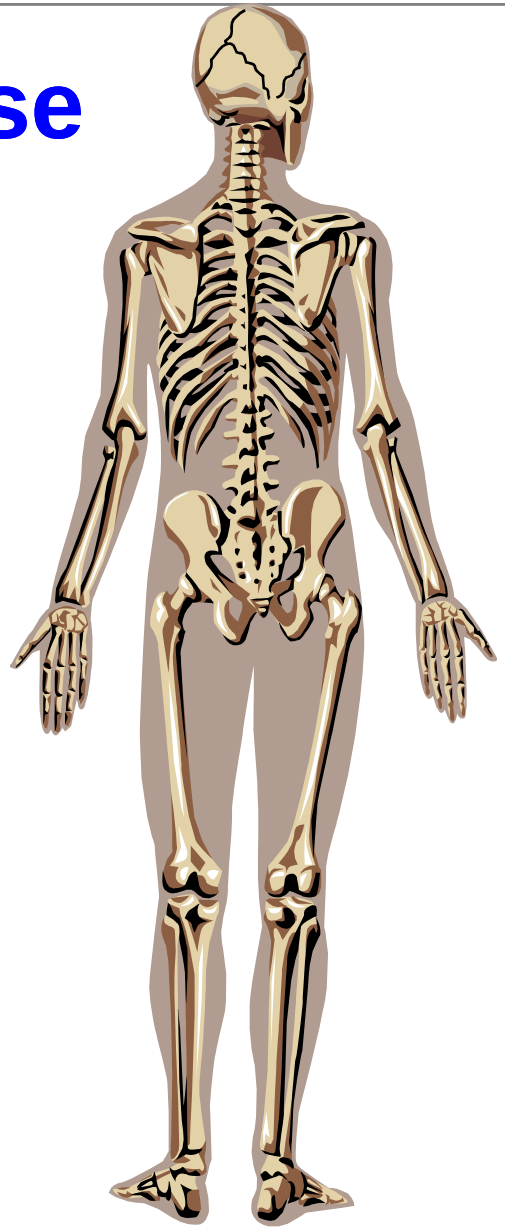
DOSE LIMITS

Part of the body	Occupational Exposure	Public Exposure
Whole body (Effective dose)	20 mSv/year averaged over 5 consecutive years; 30 mSv in any single year	1 mSv/y
Lens of eyes (Equivalent dose)	150 mSv in a year	15 mSv/y
Skin (Equivalent dose)	500 mSv in a year	50 mSv/y
Extremities Hands and Feet (Equivalent dose)	500 mSv in a year	-



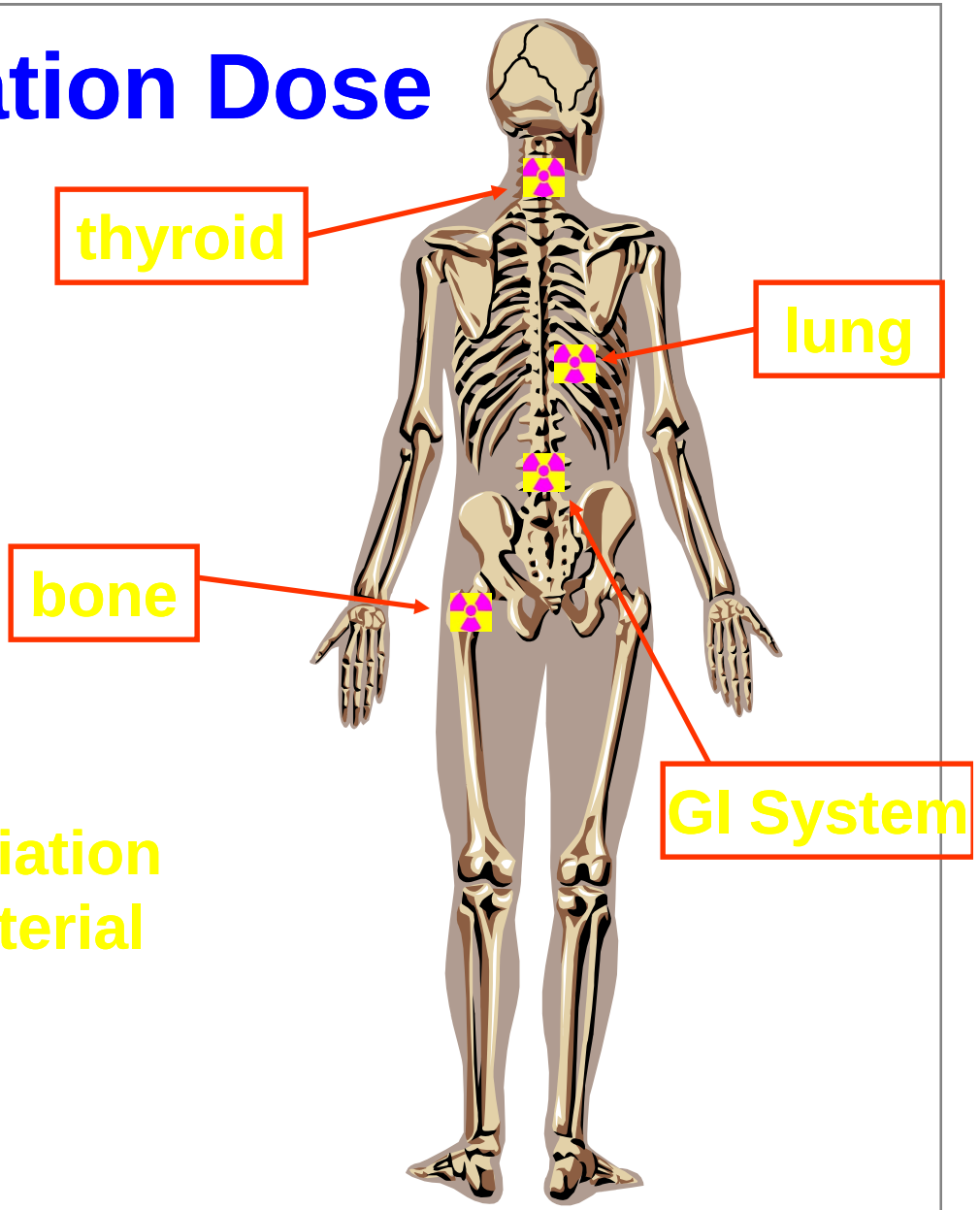
External Radiation Dose





Gamma, beta or neutron radiation emitted by radioactive material outside the body exposing the skin, lens of the eye, extremities & the whole body (i.e. internal organs)

Internal Radiation Dose



Alpha, beta or gamma radiation emitted by radioactive material inside the body exposing internal organs such as:

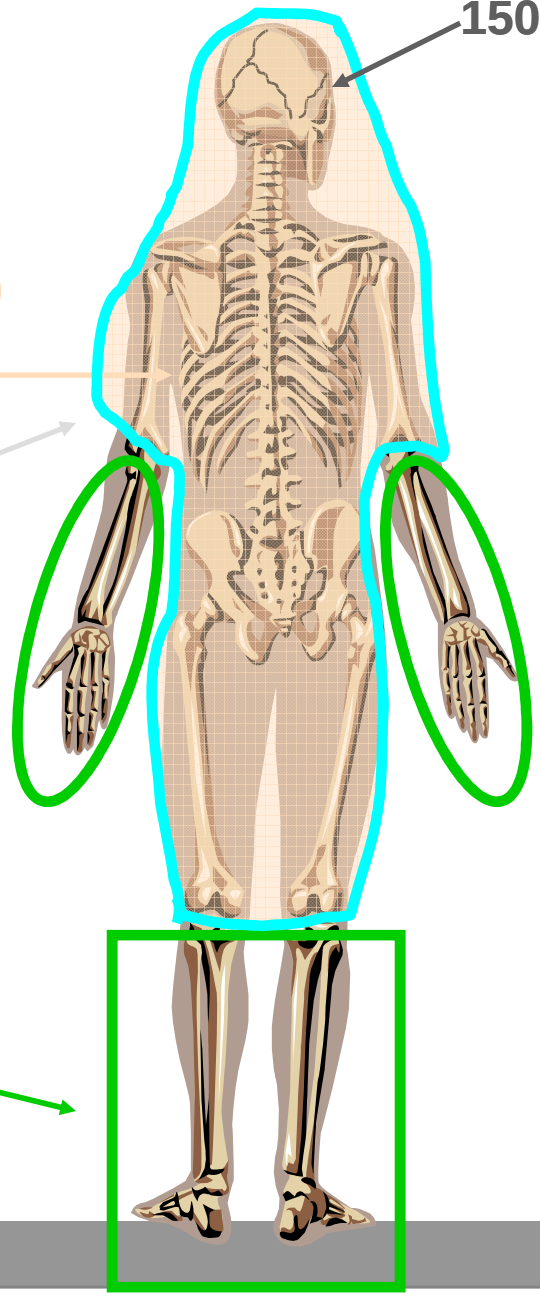
Adult Occupational Dose Limits

Lens
150 mSv

Whole Body (everything except extremities)
30 mSv maximum per year
20 mSv averaged over 5 years

Skin of the Whole Body
500 mSv per year

Extremities
500 mSv per year

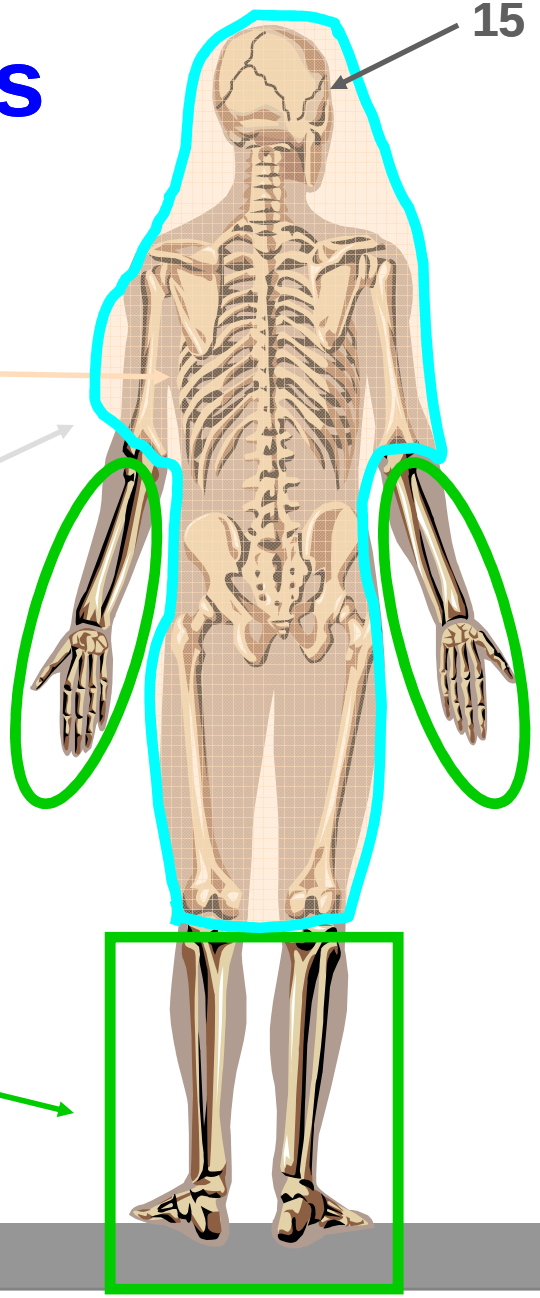


Public Dose Limits

Whole Body (everything except extremities)
1 mSv per year

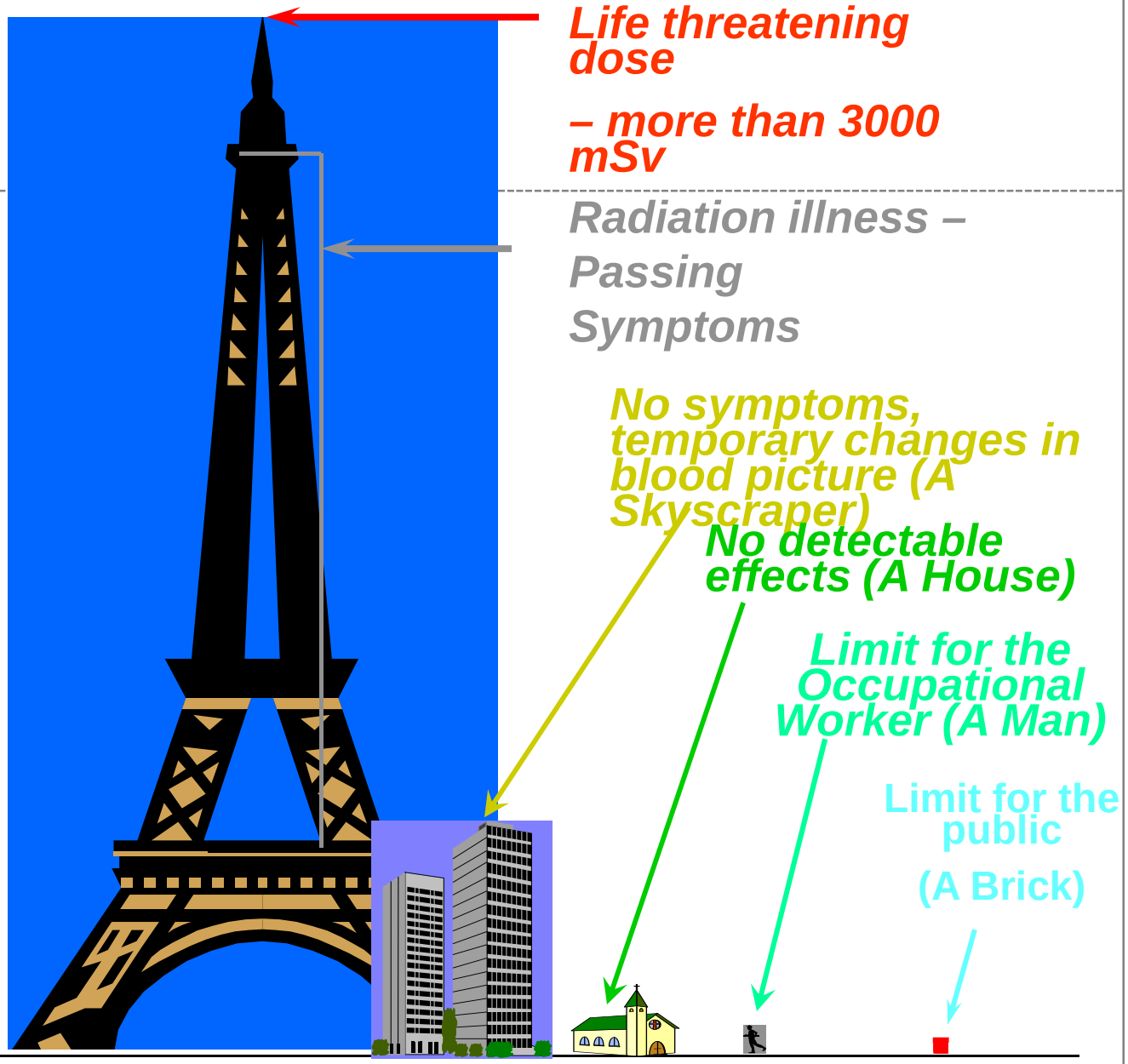
Skin of the Whole Body
50 mSv per year

Extremities
50 mSv per year



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).



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

Average annual exposures

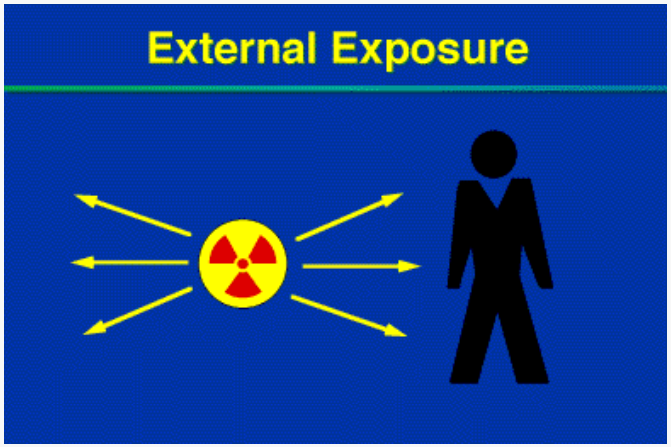
Practice	Average annual dose (mSv)
Industrial radiography	0.9
Nucleonic gauges	0.13
Gamma irradiators	not significant
Teletherapy	0.55
Brachytherapy	0.49
Nuclear medicine	0.54
Diagnostic radiology	0.49

Basic Safety Objective

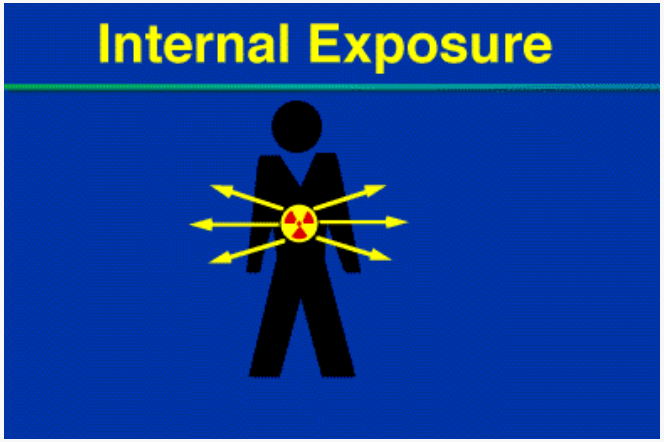
- Protection of occupational workers, patient, public and environment
- ALARA during normal operations
- Radiation exposure during normal operations with in relevant dose limits
- Potential exposures and the magnitude of such exposures are kept ALARA

Basic Radiation Protection Techniques

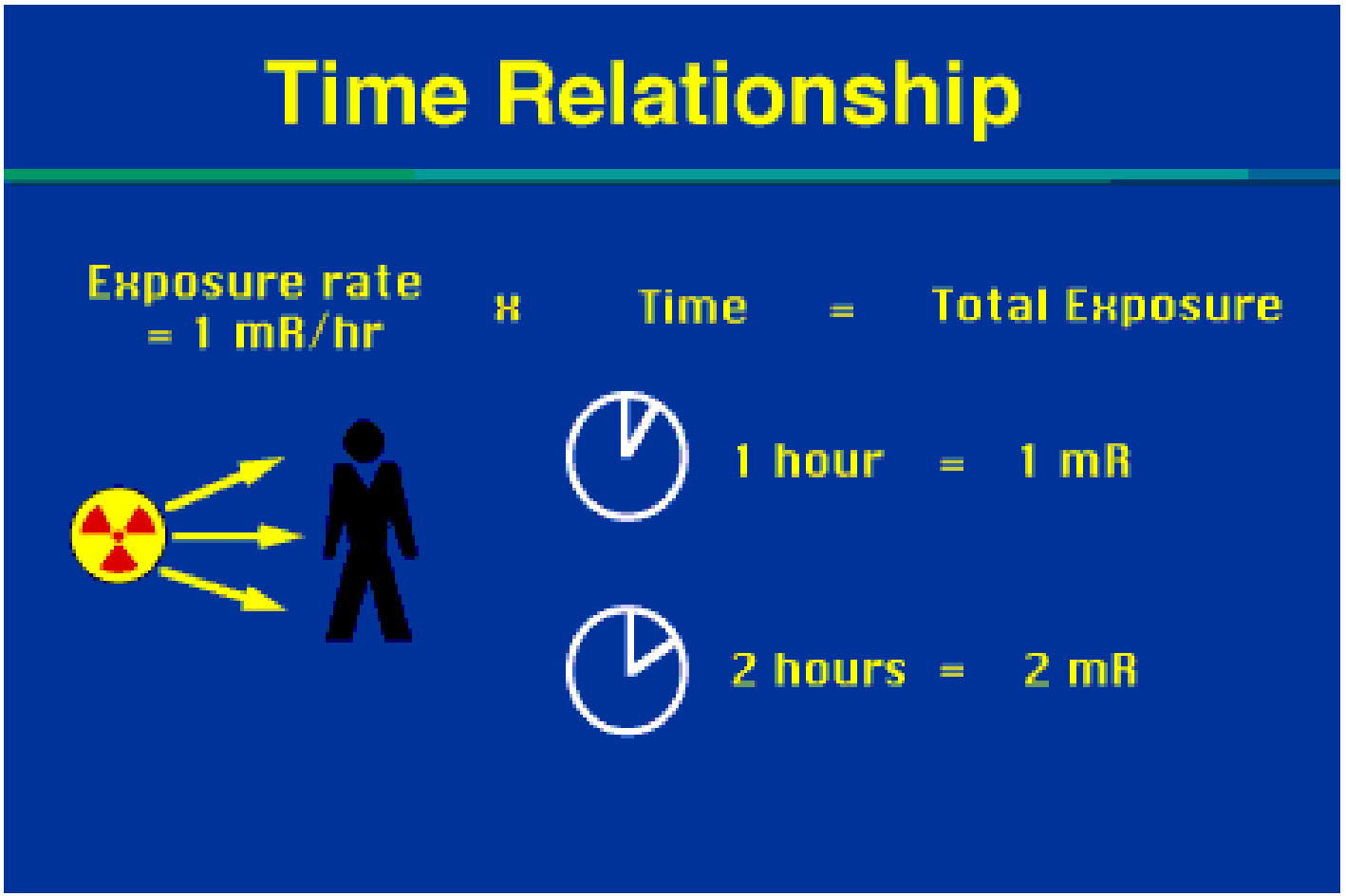
- For External Hazards:
  - I. Time
  - II. Distance
  - III. Shielding

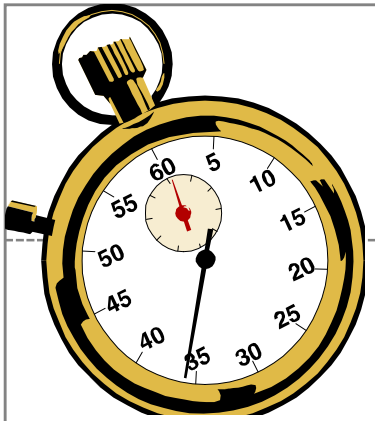


- For Internal Hazards:
  - I. Contamination control



Reduce Time

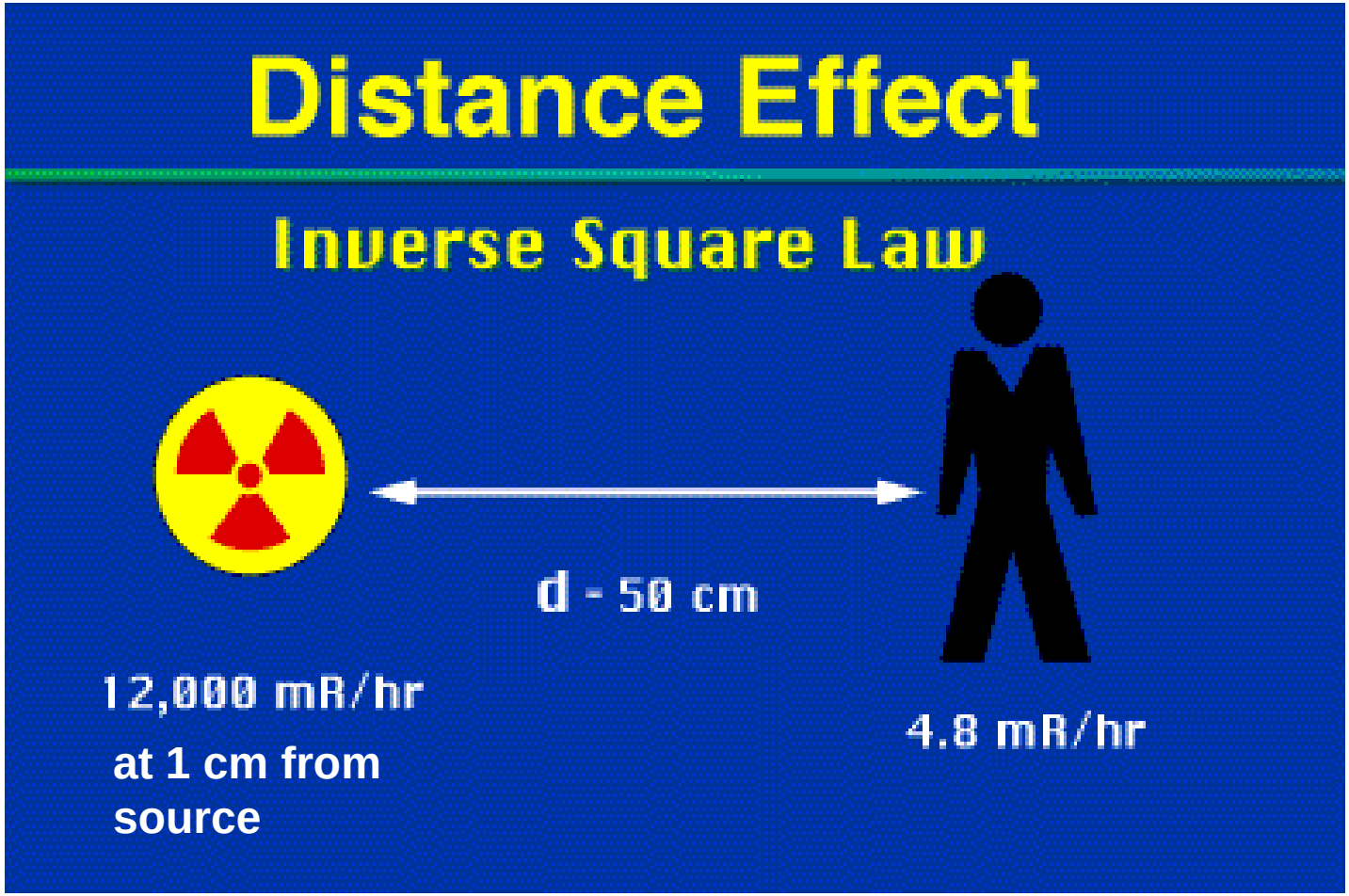

Time Relationship
Exposure rate
= 1 mR/hr
x
Time
=
Total Exposure
1 hour
=
1 mR
2 hours
=
2 mR



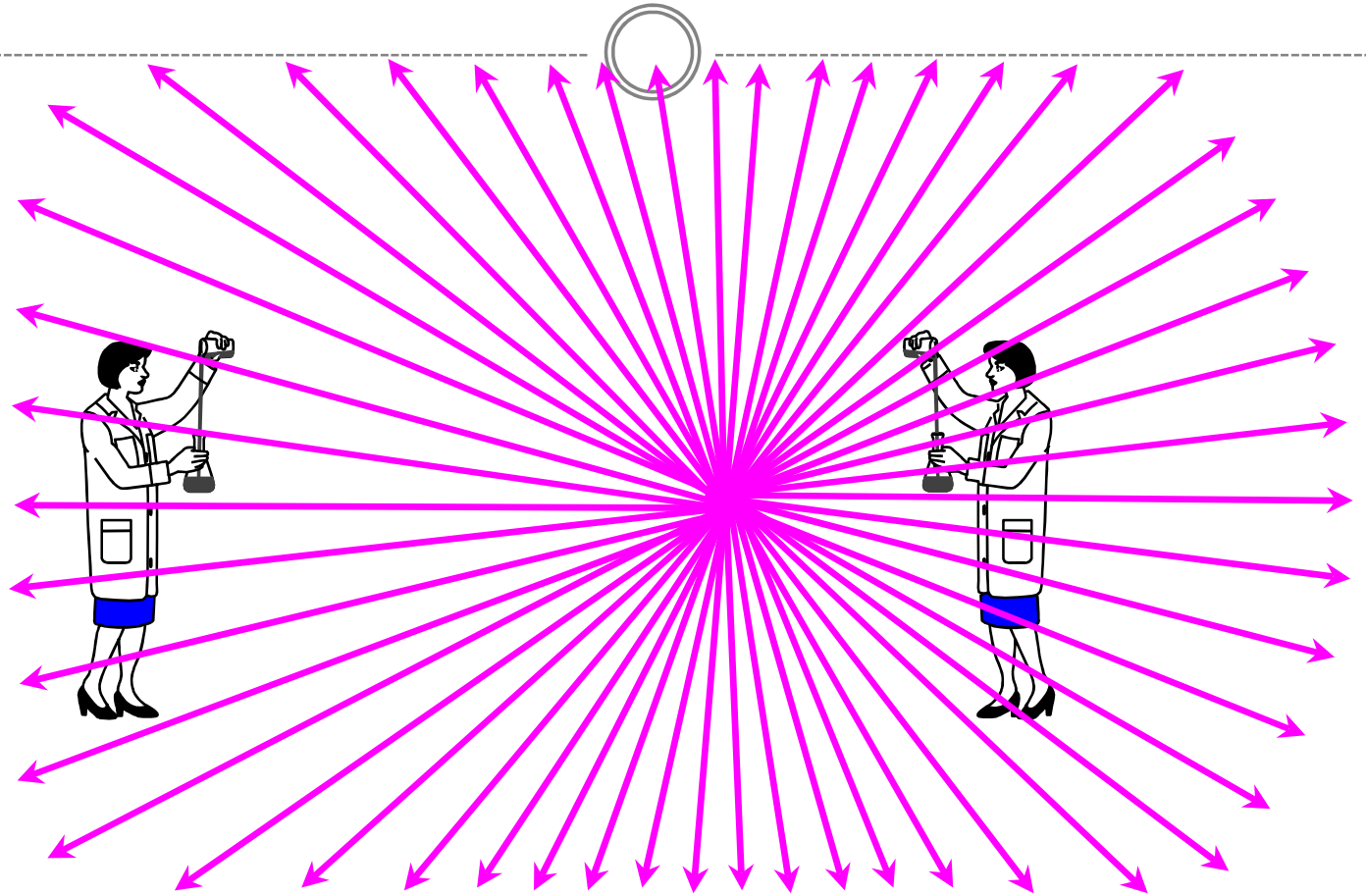
Time

- Less time = Less radiation exposure
- Use Radioactive Material only when necessary
- Dry runs (without radioactive material)
  - Identify portions of the experiment that can be altered in order to decrease exposure times
- Shorten time when near Radioactive Material
- Obtaining higher doses in order to get an experiment done quicker is NOT “reasonable”!

Increase Distance



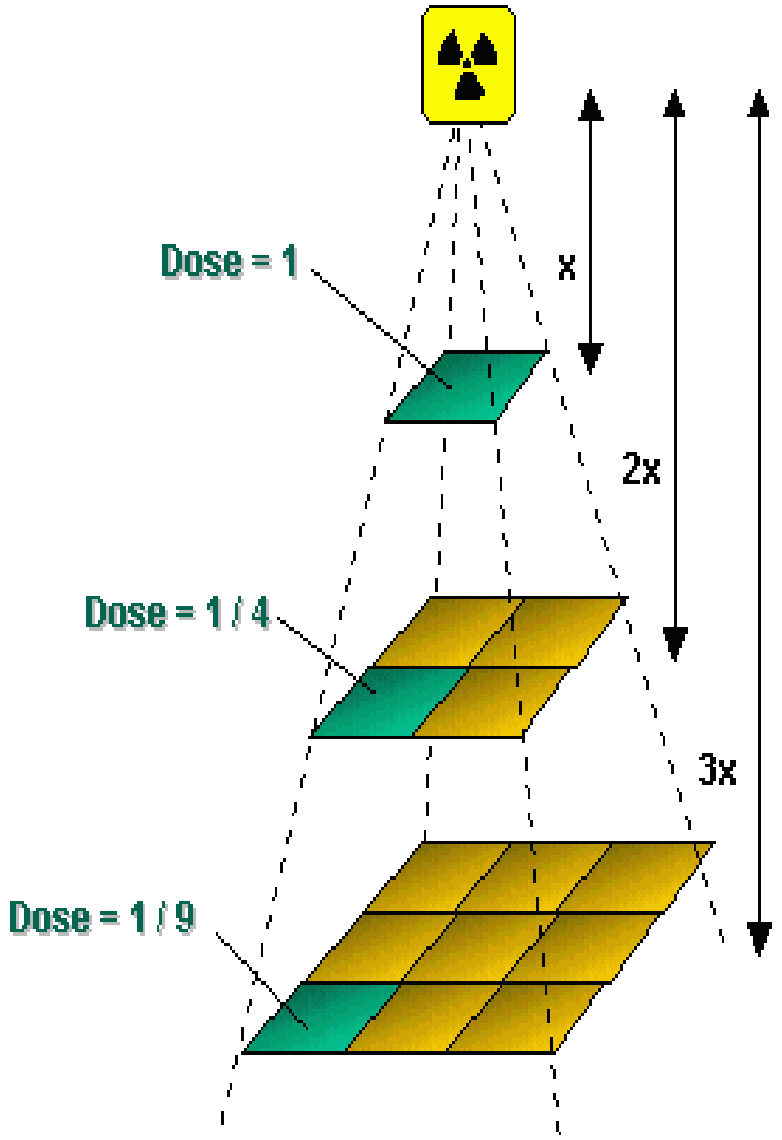
Effect of Distance on Dose Rate



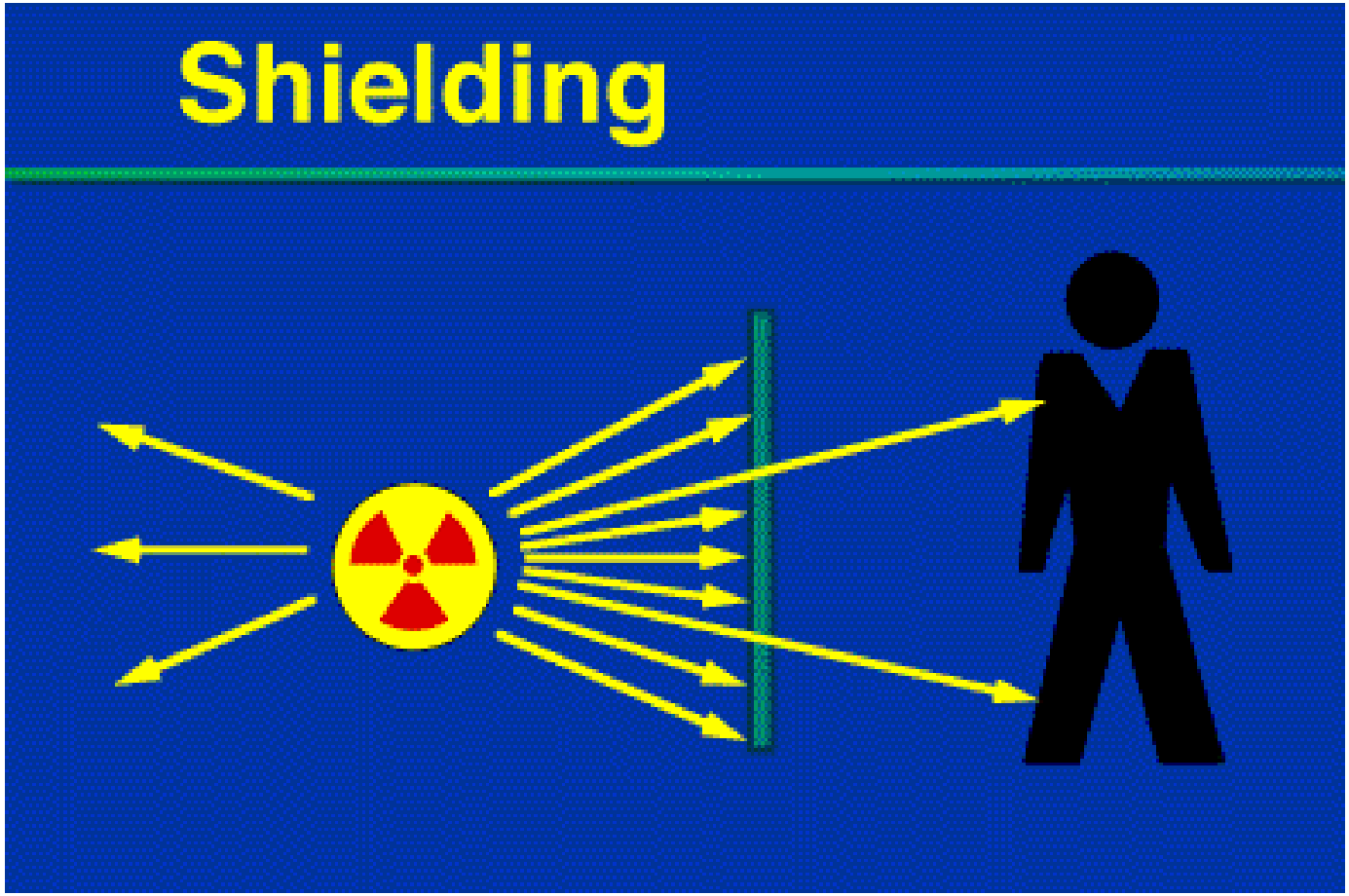
25 mrem/hr @ 6 ft **100 mrem/hr @ 3 ft**

Distance

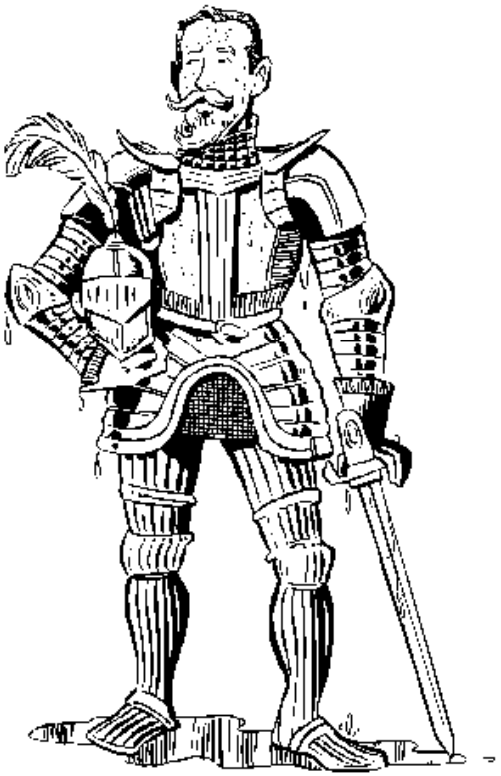
- Effective & Easy
- Inverse Square Law
  - Doubling distance from source, decreases dose by factor of four
  - Tripling it decreases dose nine-fold
- More Distance = Less Radiation Exposure
- Tongs, Tweezers, Pipettes, Pliers



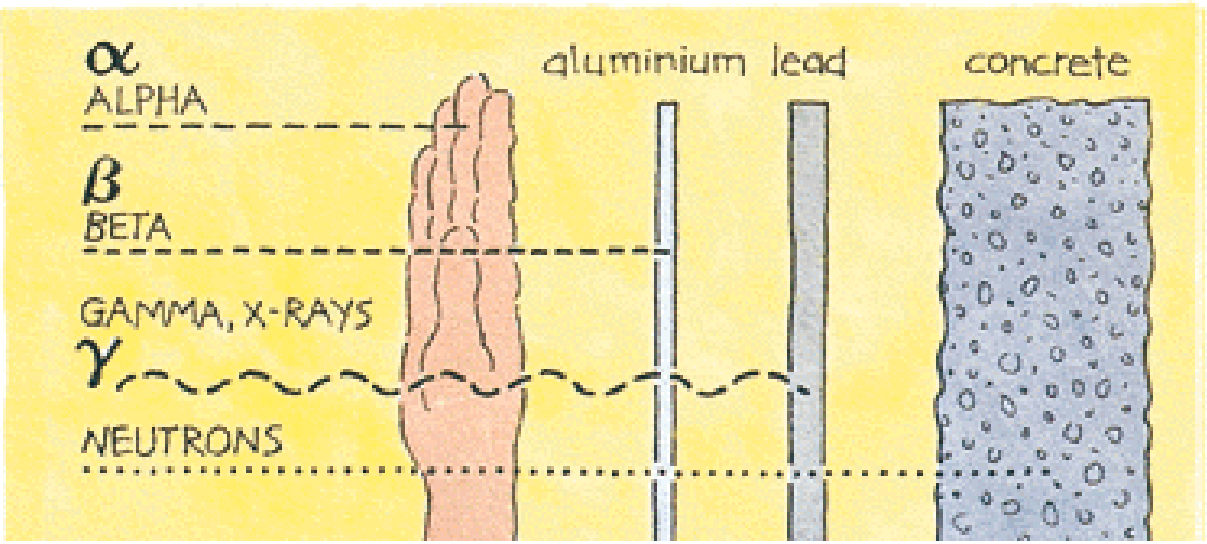
Use Shielding



Shielding

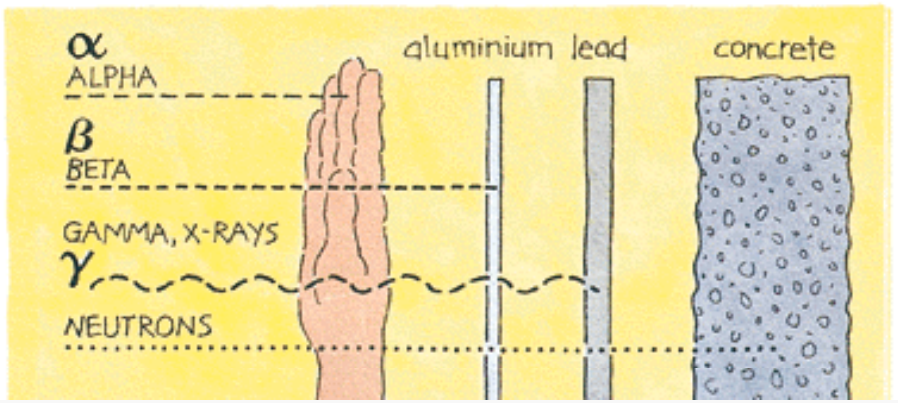


- Materials “absorb” radiation
- Proper shielding = Less Radiation Exposure



Shielding

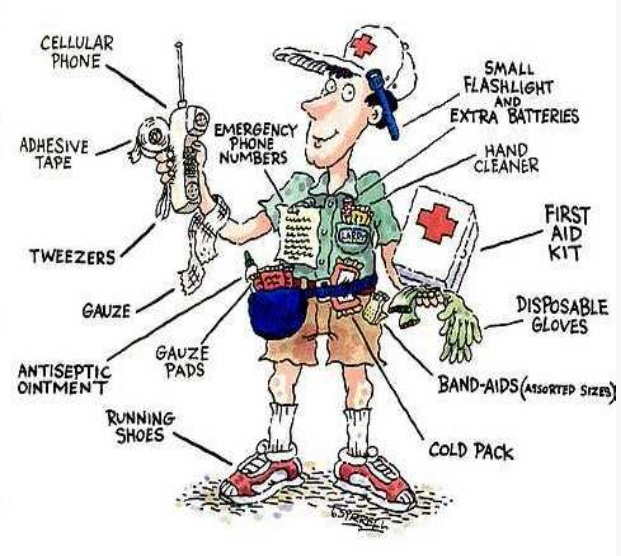
- Alpha Emitters (^{238}U, ^{230}Th, ^{241}Am, ^{222}Rn)
  - Paper
- Low Energy Beta Emitters (^{3}H, ^{14}C, ^{35}S, ^{33}P)
  - Paper



- 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.

Emergency Preparedness

- Availability of Devices and Survey Meter for handling emergency and display of procedure to be followed
  - In control room of telecobalt/RAL Brachytherapy unit
  - In source handling area of manual brachytherapy
- Emergency situations include
  - failure of source movement mechanism of telegamma and remote after-loading brachytherapy equipment
  - loss of source in manual brachytherapy



Preparation of Emergency Action 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.

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

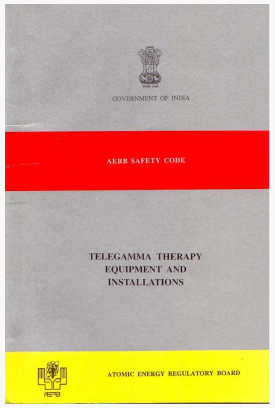
(Atomic Energy Radiation Protection) Rules, 2004)

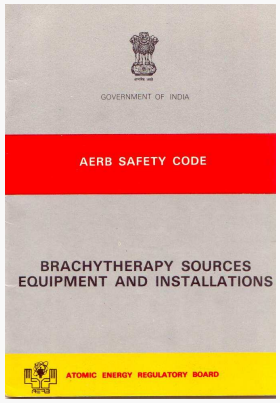
- Notifications

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

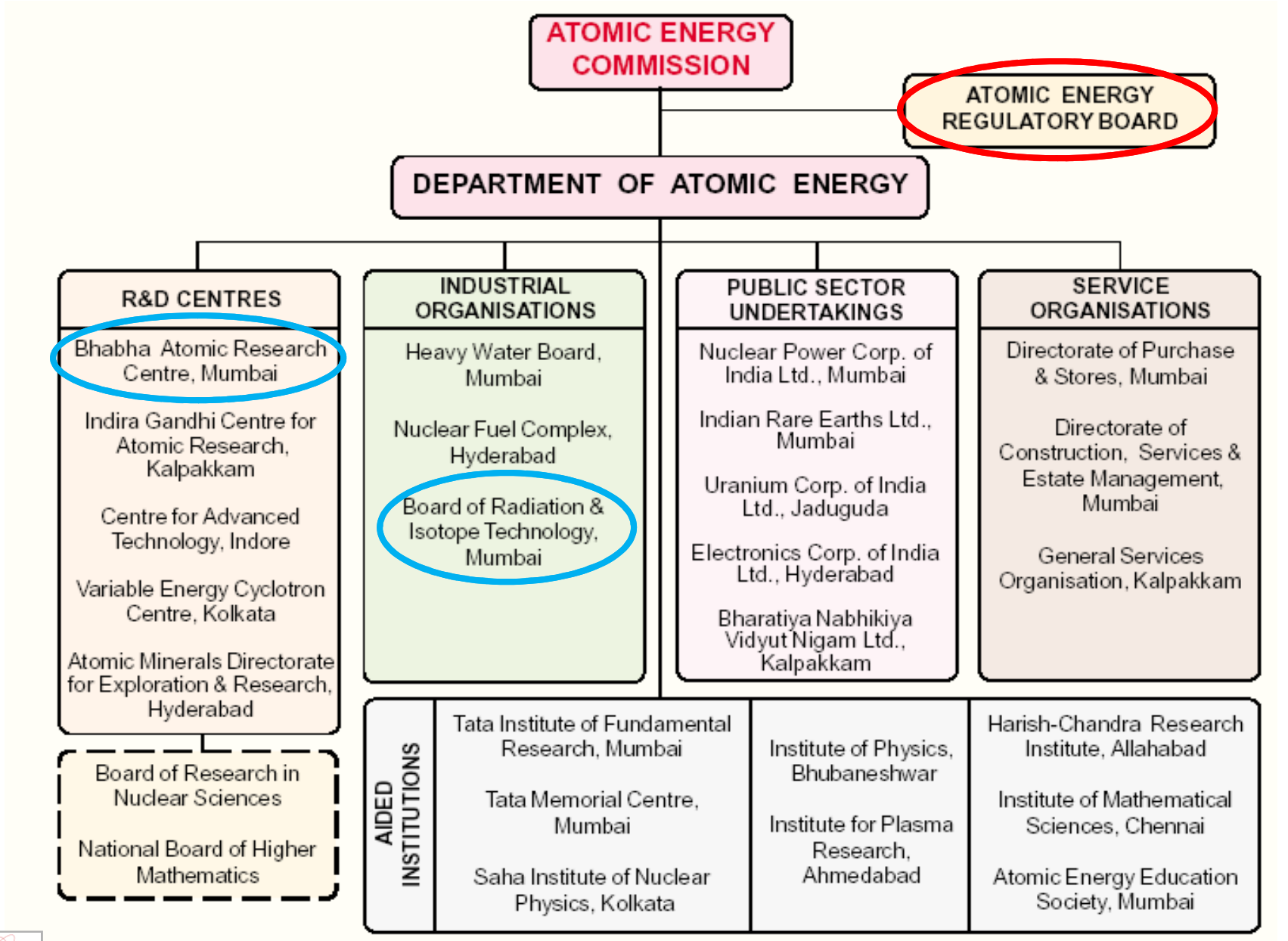
Published by AERB

- Safety Codes





- Safety Standards
- Safety Guides
- Safety Manuals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ATOMIC ENERGY REGULATORY BOARD
DEPARTMENT OF ATOMIC ENERGY
R&D CENTRES
Bhabha Atomic Research Centre, Mumbai
Indira Gandhi Centre for Atomic Research, Kalpakkam
Centre for Advanced Technology, Indore
Variable Energy Cyclotron Centre, Kolkata
Atomic Minerals Directorate for Exploration & Research, Hyderabad
Board of Research in Nuclear Sciences
National Board of Higher Mathematics
INDUSTRIAL ORGANISATIONS
Heavy Water Board, Mumbai
Nuclear Fuel Complex, Hyderabad
Board of Radiation & Isotope Technology, Mumbai
PUBLIC SECTOR UNDERTAKINGS
Nuclear Power Corp. of India Ltd., Mumbai
Indian Rare Earths Ltd., Mumbai
Uranium Corp. of India Ltd., Jaduguda
Electronics Corp. of India Ltd., Hyderabad
Bharatiya Nabhikiya Vidyut Nigam Ltd., Kalpakkam
SERVICE ORGANISATIONS
Directorate of Purchase & Stores, Mumbai
Directorate of Construction, Services & Estate Management, Mumbai
General Services Organisation, Kalpakkam
AIDED INSTITUTIONS
Tata Institute of Fundamental Research, Mumbai
Tata Memorial Centre, Mumbai
Saha Institute of Nuclear Physics, Kolkata
Institute of Physics, Bhubaneshwar
Institute for Plasma Research, Ahmedabad
Harish-Chandra Research Institute, Allahabad
Institute of Mathematical Sciences, Chennai
Atomic Energy Education Society, Mumbai

Radiation Safety

Total Radiation Safety is achieved by

Built-in Safety

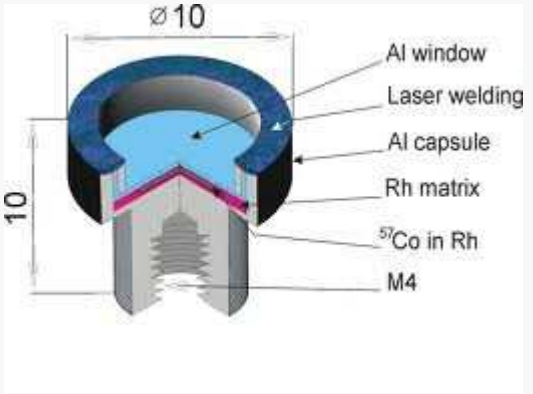
combined with

Operational Safety

Built-in Radiation Safety

- Sealed Source – Classification

  (safety of worker and public)



- Equipment – Type-approval

  Electrical, Mechanical, Radiological

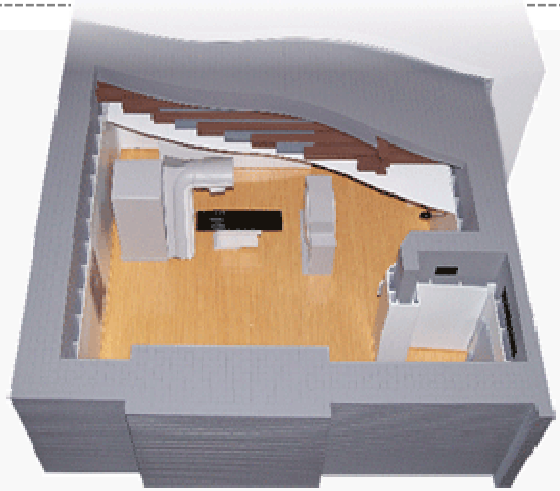
  (safety of rad. worker and patient)

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
- Preventive maintenance of equipment
- Interaction with regulatory body
- Emergency planning and preparedness

Operational Safety

- Qualified and certified persons

  (Radiation Oncologist, Medical Physicist, Radiation Therapy Technologist)

- Personnel monitoring

Operational Safety

- Work place monitoring

(Gamma Zone Monitor)

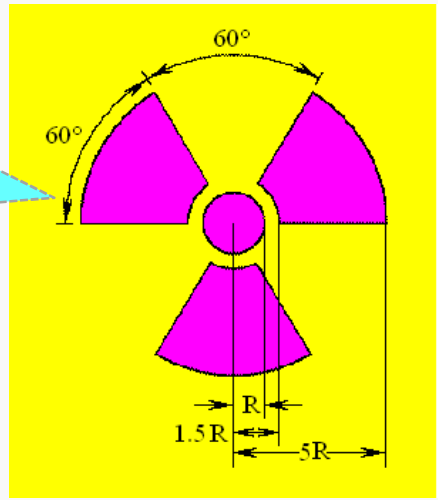
(Switches, Interlocks, Indicators)

- Preventive maintenance

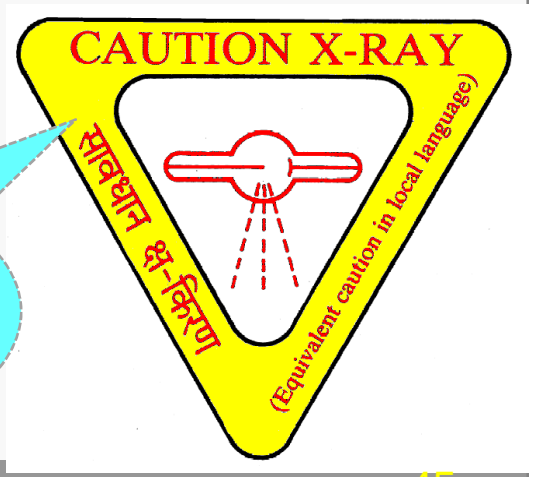
Radiation Symbol

- 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

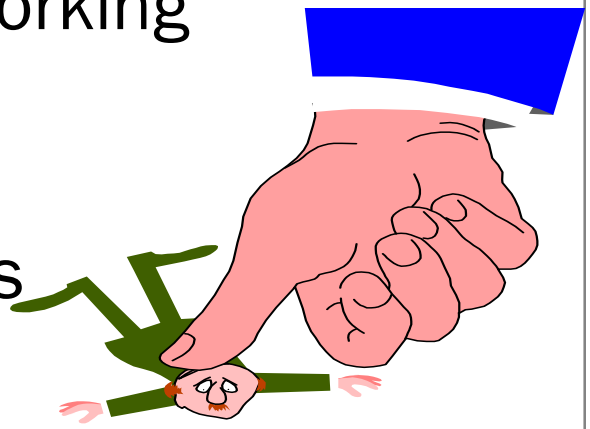


For Linac/Simulator facility



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



Clearance of the unit by AERB

- Prior to procurement, verify whether the unit is
  - Type Approved by AERB
  - If no, NOC from AERB
- Demand for the copy of the certificate issued by AERB from supplier
- No unit shall be purchased if the supplier has not obtained '**Type Approval**' **or** '**NOC**'

GOVERNMENT OF INDIA
परमाणु ऊर्जा नियामक परिषद
ATOMIC ENERGY REGULATORY BOARD

अध्यक्ष
CHAIRMAN

नियामक भवन, अणुशक्ति नगर, मुंबई-400094.
Niyamak Bhavan, Anushakti Nagar, Mumbai-400094

BY COURIER

AERB/445/TAC/TC/RSD/RT/KT-901/2009/ November 19, 2009

Type Approval Certificate for Telegamma Therapy Unit Model Bhabhatron-II-AW Manufactured by M/s. Panacea Medical Technologies (P) Ltd., Bangalore

1. **M/s. Panacea Medical Technologies Pvt. Ltd., Bangalore** is hereby informed that the Atomic Energy Regulatory Board (AERB) approves the **Telegamma Therapy Unit Model Bhabhatron-II-AW** manufactured by **M/s. Panacea Medical Technologies (P) Ltd., Bangalore** for sale, installation and use in India.
2. The **maximum strength** of **^{60}Co source** loaded in the **Bhabhatron-II-AW head** shall not exceed **555 TBq**.
3. This approval is valid till **November 30, 2012**
4. This type approval becomes invalid if any change is made in the approved Telegamma Therapy Unit model Bhabhatron-II-AW.
5. The Telegamma Therapy Unit model Bhabhatron-II-AW shall be supplied only to person authorised by Radiological Safety Division, AERB, Mumbai and installed only at authorised premise. A copy of this certificate shall be provided to the user to enable them to obtain authorisation for procurement of the said unit, from AERB.
6. M/s. Panacea Medical Technologies Pvt. Ltd., Bangalore shall be responsible for installation, commissioning, servicing and maintenance, supply of spares, source transfer, decommissioning/dismantling and disposal of the radioactive source and radioactive material from the source head of the telegamma therapy unit model Bhabhatron-II-AW.
7. M/s. Panacea Medical Technologies Pvt. Ltd., Bangalore shall keep AERB informed about the sale, installation, commissioning, decommissioning and performance status of the Telegamma Therapy Unit model Bhabhatron-II-AW. Such information shall be in the form of reports to AERB in the months of January and July every year.
8. The sale of the unit after the expiry of the type approval is conditional upon revalidation of the type approval.

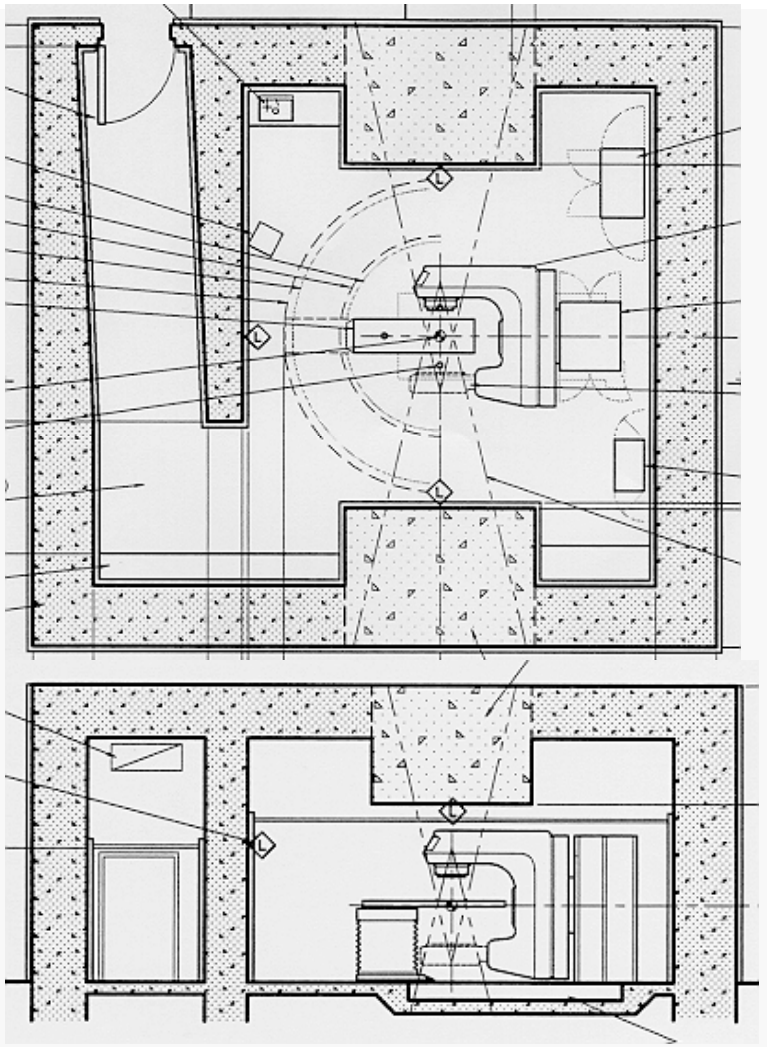
Competent Authority

M/s.Panacea Medical Technologies Pvt. Ltd.
(Kind Attn.:Shri G.V.Subrahmanyam, Director)
Plot No. 7A/1, Kadugodi Industrial Area
White Field
Bangalore – 560 067
Karnataka

दूरभाष/TELEPHONE : (022) 2556 2343 (सार्वजनिक)
फैक्स/Fax : (022) 2556 2344 / 2556 5717 ई-मेल/E-MAIL : sksharma@aerb.gov.in

Approval of Room Layout Plan

- Submission to AERB for design approval
- **Not to construct without obtaining approval**
- No modification to be carried out without concurrence of AERB



Appointment of Staff

- Appoint adequate number of qualified staff as stipulated in AERB safety code
  - Radiation Oncologists – min. one per unit
  - Medical Physicists – min. one per unit
  - Radiological Safety Officer – (nominate Medical Physicist, if eligible, to perform additional responsibility)
  - Radiotherapy Technologists – min. two per unit

Appointment of Staff

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  - Radiation Oncologists – min. one per unit
  - Medical Physicists – min. one per unit
  - Radiological Safety Officer – (nominate Medical Physicist, if eligible, to perform additional responsibility)
  - Radiotherapy Technologists – min. two per unit

Procurement of Equipments

- Personnel Monitoring Badges from the agency recognised by AERB for all the radiation workers

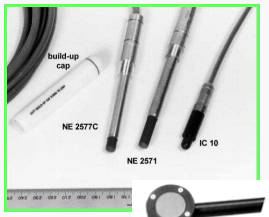
- Pocket dosimeters for the radiation workers may also be procured

Procurement of Equipments (contd…)

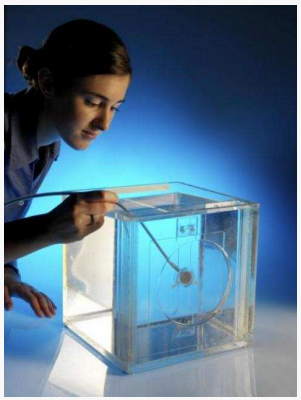
- Appropriate Monitoring equipment (survev meter. contamination monitor, gamma zone monitor[auto/manual] etc.)



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

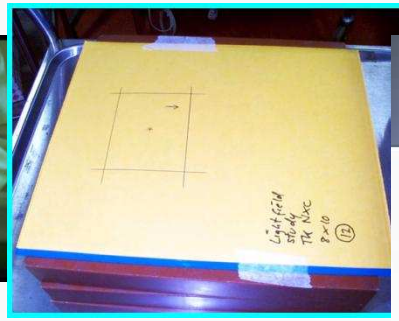


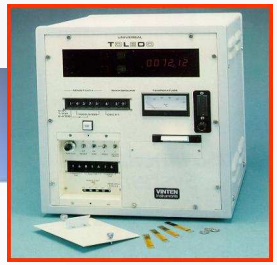





Procurement of other associated equipments

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





Authorisation to procure Radiation Sources

- Obtain authorisation from RSD, AERB for **procurement of sources**
  - Issued based on availability of
    - adequate no. of qualified manpower
    - personnel monitoring badges for staff
    - approved and constructed room for source
    - radiation monitoring equipments
    - dosimetric equipments
    - minimum required QA tools

Receipt of Sources and Installation

- Intimate regarding the receipt of the source
- Install the unit
- Source transfer, in case of telecobalt unit, to be supervised by authorised Medical Physicist

Acceptance test & Commissioning

- Acceptance tests to be carried out including survey
- Permission to be obtained from AERB for using the unit for the patient treatment
- **The unit shall not be used for the patient treatment without obtaining the permission**

Licences for operation

Radiotherapy is the only practice, in which all category of licences to be issued as per RPR-2004

- Licence – Operation of Telegamma & Accelerators
- Authorisation – Operation of Brachytherapy
- Registration – Operation of Therapy Simulator

- Consent – Approval for
  - siting, design, construction
  - commissioning
  - decommissioning
  - sealed sources, radiation generating equipment
  - Equipment containing radioactive sources
  - package design for transport
  - shipment approval for radioactive consignments

Periodic Performance/ Status Report

- Performance tests of the unit, integrity check of the sources, Survey of the installations to be carried out periodically
- Maintenance of records, to be produced during inspection
- Submission of annual safety status report by the end of each calendar year
- Reporting incidents or accidents within 24 hrs.

Decommissioning/Disposal of sources

- Decommissioning of the unit and disposal of sources with due approval
  - Disposal of radioactive materials
  - Segregation and disposal of Depleted Uranium and Contamination part
  - Verification to ensure no radioactivity in the equipment
  - Deform the equipment before handing over to scrap dealer so that it can not be reassembled
- Transport of sources as per the transport regulation for radioactive material

Availability of forms and procedures

- All regulatory forms and procedures are available at our website

www.aerb.gov.in

- Various other regulatory documents are also available in this website

THANK YOU

Any container bearing this symbol probably houses a radioactive material