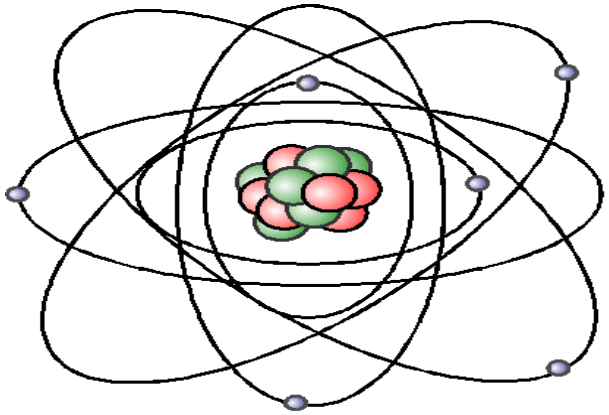
ISO 9001:2008
Organisation



सत्यमेव जयते

Regulatory Aspects and Radiation Protection in Medicine

Outline

- Introduction
- Applications of radiation sources in Medicine
- Radiation protection
- Regulatory framework
- Conclusions

Application of Radiation in Medicine

- Radiation in Medicine
  - Diagnostic
    - Diagnostic Radiology
      - 
      - >50, 000 equipment
    - Nuclear Medicine
      - 
      - 143facilities
  - Therapy
    - Radiotherapy
      - Teletherapy
        - 
        - 836 equipment in
      - Brachytherapy
        - 
        - 352 facilities
    - Nuclear Medicine
      - 
      - 51 centers (includes diagnostics)

Radiotherapy

- An estimated 5.1 million courses of radiotherapy treatment were administered annually between 1997 and 2007.

  UNSCEAR 2008 Report

- Every year, 1 million new cancer cases are detected in India of which 40,000 cancer cases occur in children.

  TMH,Mumbai Report

- Over the last three decades, at least 3000 patients have been affected by radiotherapy incidents and accidents.

- These accidents do not affect patients directly (e.g. harm and death), but might also undermine the public's confidence in the treatment.

- Preventable medical errors overall also cost countries billions of dollars each year.

  IAEA

Diagnostic Radiology

- An estimated 3.6 billion (3.1 medical and 0.5 dental) x-ray examinations were undertaken annually in the world between 1997 and 2007.
- Total annual collective effective dose to the global population (6,446 millions) from diagnostic medical exposures was estimated to be 4000 $x10^3$ manSv .
- Annual per caput effective dose is 0.62 mSv.
- CT scanning accounts 43% of the total collective effective dose due to diagnostic medical radiology.

UNSCEAR 2008 Report

Nuclear Medicine

- Nuclear medicine includes all uses of unsealed radioactive sources for diagnostic and therapeutic purposes.

- An estimated 33 million diagnostic nuclear medicine examinations performed annually worldwide.

- Annual collective effective dose to the world population due to diagnostic nuclear medicine examinations is estimated to be 202 $x10^3$ manSv.

- For diagnostic nuclear medicine, the main contribution to the collective effective dose arise from Tc-99m bone scans, Tl-201 cardiovascular studies and iodine thyroid scans.

UNSCEAR 2008 Report

Global Increase in Diagnostic X-ray Examinations

(Ref.UNSCEAR 2008 Report : Diagnostic X-ray examinations)

Year	Annual Number of Exams (MM)	Annual Frequency per 1,000 population	Annual *per capita* Dose (mSv)
1998	1,380	280	0.35
1993	1,600	300	0.3
2000	1,960	330	0.4
2008	3,143	488	0.62

Increasing dose ..because of..few reasons !

1. Shorter scanning times and thinner slices requires higher tube current to maintain good image quality

2. For cardiac CT, excessive tissue overlap (low pitch) is aften required to reduce motion artifacts-translates to higher patient dose

3. Image quality higher than necessary

4. Unjustified examinations (reported cases > 30%)

5. Not using the features for dose reduction that the machine provides

Global Annual Collective Effective Dose

- World Population 6,446 million
- Annual collective effective dose (manSv)

Medical- 4000 $x10^3$ manSv

Dental- 11 $x10^3$ manSv

Nuclear Medicine- 202 $x10^3$ manSv

Total- 4200 $x10^3$ manSv

- Annual per caput effective dose to the global population due to all sources of ionization is 3.1 mSv.

- Natural background radiation represents 2.4 mSv (79%) and diagnostic x-ray examinations represents 0.66 mSv (20%) of the average annual per caput dose to the global population.

UNSCEAR 2008 Report

Principles of Radiation Protection

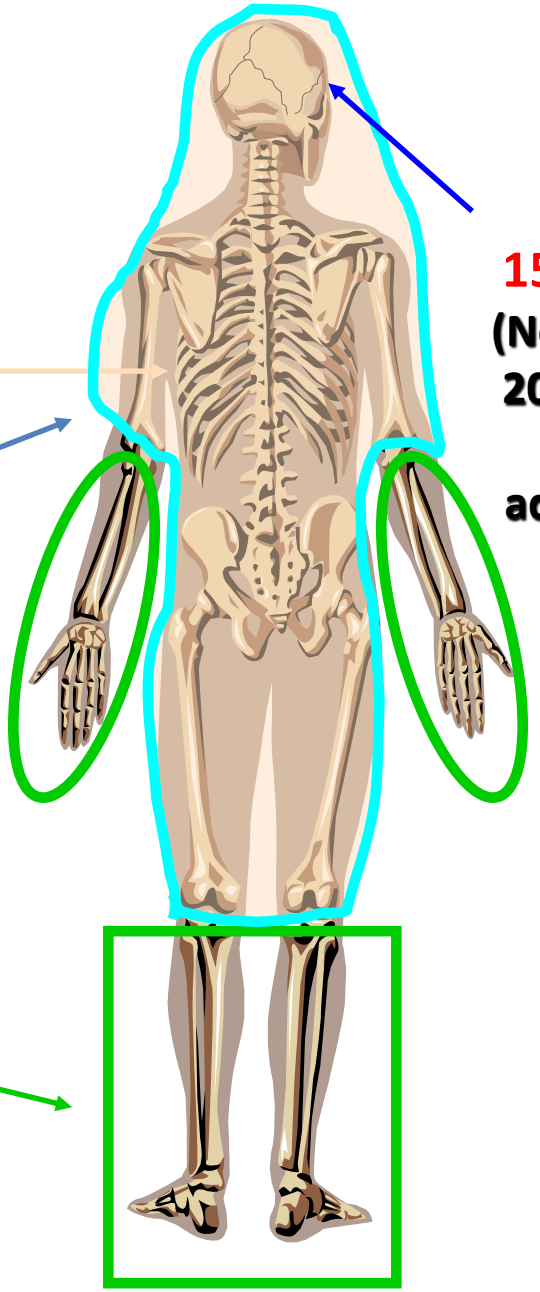
- Justification- whether benefit of use of radiation outweighs the risk
- Optimisation- If exposure justified, then keep it as low as reasonably achievable (ALARA)
- Dose Limits- exposures should be within the prescribed dose limits

Adult Occupational Dose Limits

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



Lens
150 mSv
(New limit 20 mSv/y to be adopted)

- In case of a *WOMAN worker of* Reproductive age , once *PREGNANCY* has been established, the Conceptus shall be protected by applying Supplementary Equivalent Dose Limit to the Surface of the Women's Abdomen (Lower Trunk) of *1 mSv for the remainder of the pregnancy*.

- *Dose constraints for comforters and visitors of patients:*

  5 mSv for adults and 1 mSv for children.

- *Diagnostic Reference levels / Guidance Levels*

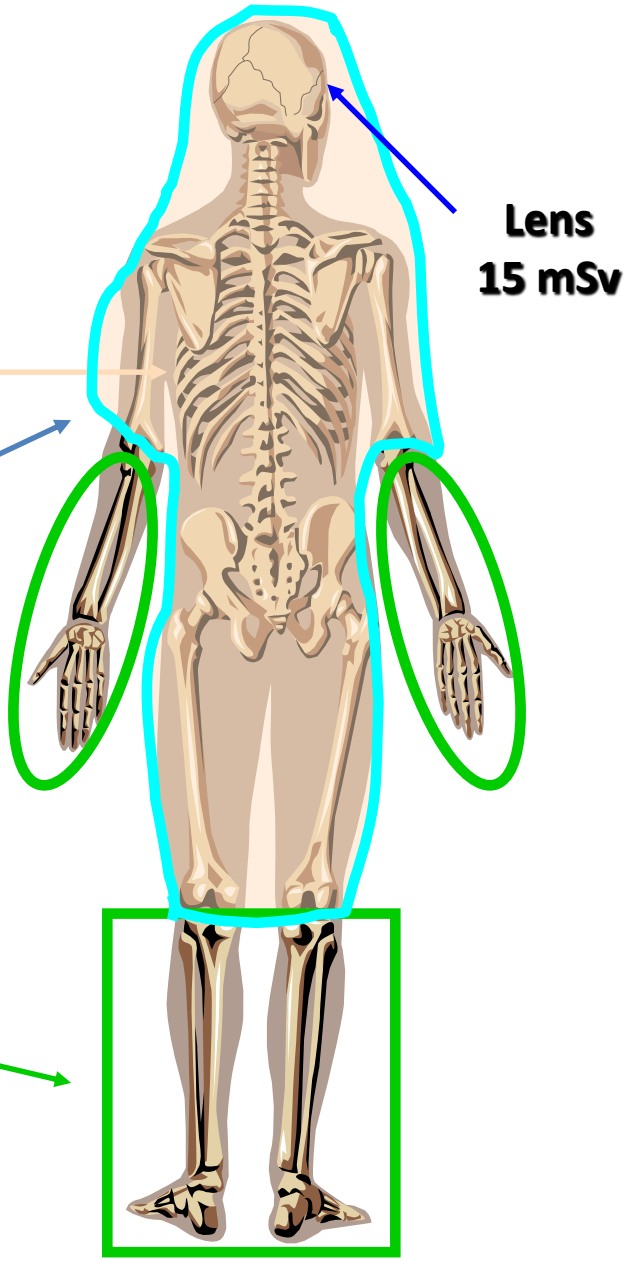
  (Radiography, Fluoroscopy, CT & Cardiology procedures, Nuclear Medicine)

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



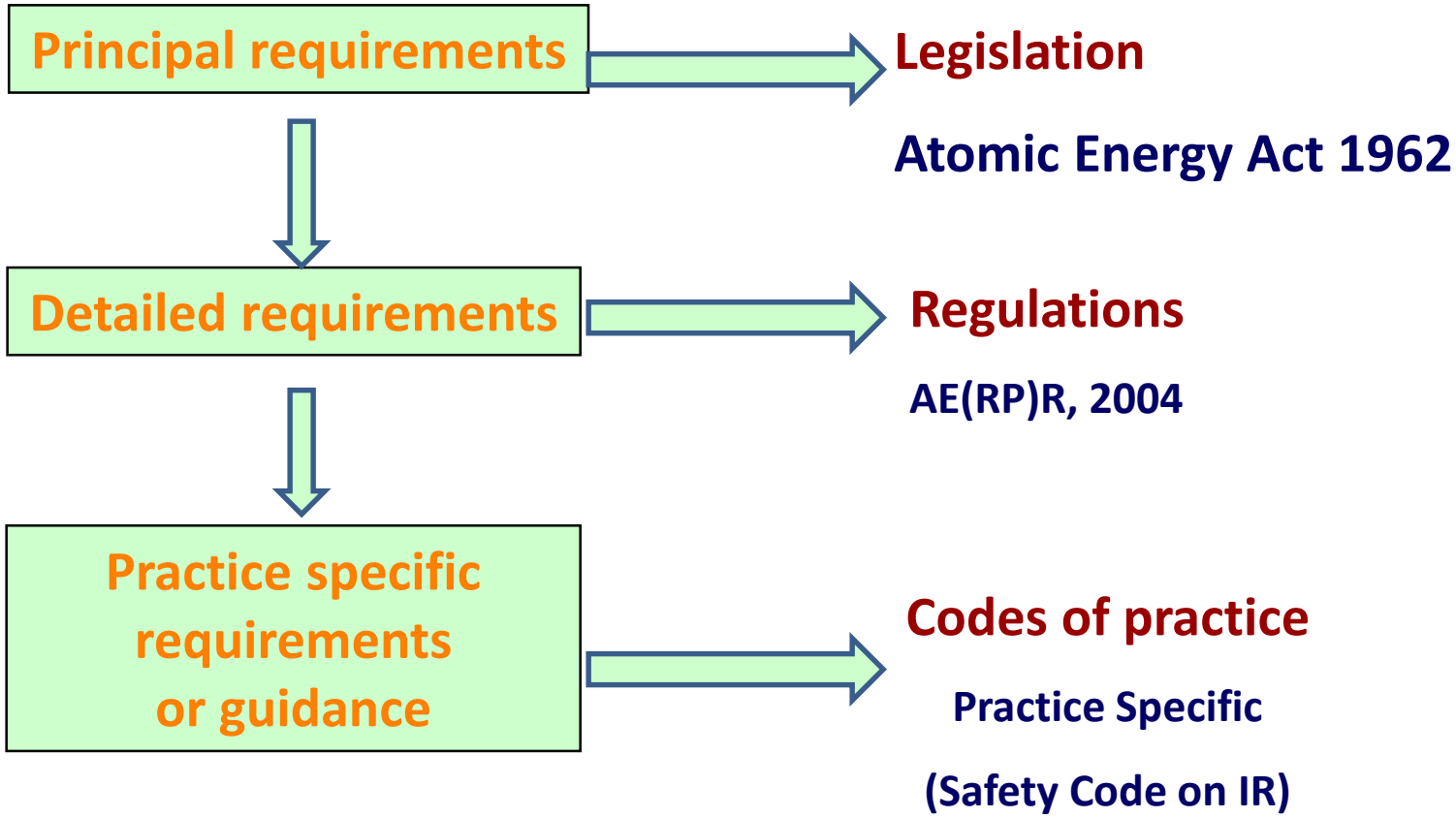
Average annual occupational exposures in various practices using radiation sources (2012)

Radiation practice	No. of persons monitored	Annual average dose (mSv)
Industrial radiography	7253	0.58
Radiation therapy	9270	0.29
Nuclear Medicine	1989	0.49
Diagnostic Radiology	50868	0.38
Research	4139	0.10

Why regulatory control over radiation facilities is necessary?

- To ensure that radiological risk from radiation facilities *(e.g. radiotherapy, nuclear medicine, medical x-ray room, industrial radiography, radiation processing plants, nucleonic control systems etc.)* is prevented and/or minimized .
- To ensure that radiation sources/equipment are safely handled, stored, transported and disposed off.
- To ensure that the prescribed dose limits are not exceeded to occupational workers and the public.
- To ensure that radiation sources do not become orphan /vulnerable.

Structure of Legal Framework



Atomic Energy (Radiation Protection) Rules, 2004 (AE(RP)R, 2004)

- Published in August 25, 2004 as GSR 303
- Main basis of Regulatory Framework for Radiation Protection in India
- Issued under following Sections of Atomic Energy Act, 1962

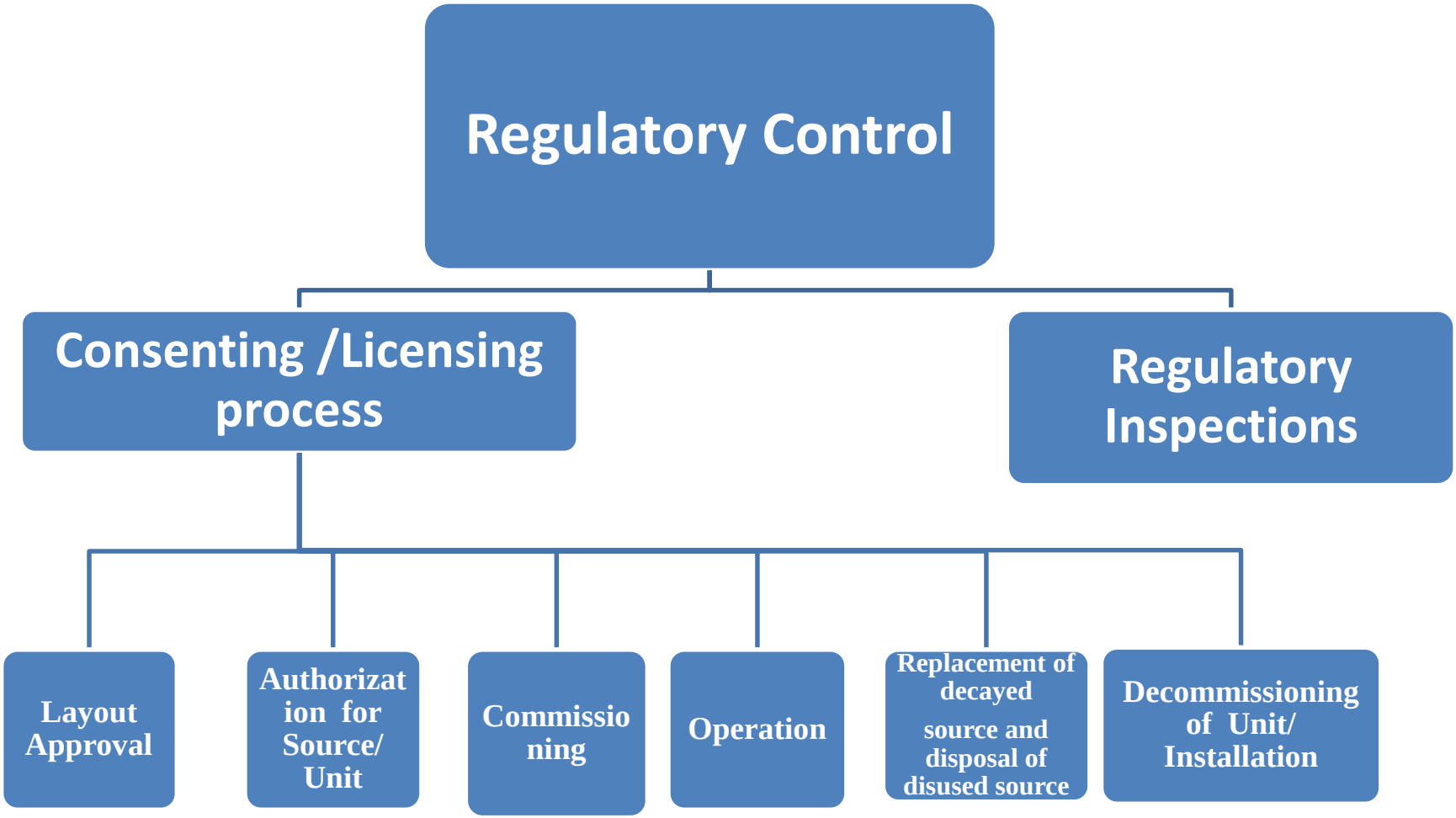
  -- Section 30
  -- Section 14
  -- Section 16
  -- Section 17

Objective

- Establishment of statutory requirements for the control of practices adopted and interventions applied with respect to radiation sources and extend to whole of India.
- Issuance of licence from the Competent Authority.
- The terms and conditions of licence ensure the compliance with requirements laid down in the safety standards and safety codes issued under AE(RP)R, 2004.

Atomic Energy Regulatory Board (AERB) – *the National Regulatory Authority*

- AERB constituted in 1983.
- *Chairman, AERB* is the Competent Authority for radiation protection in India to enforce AE(RP)R-2004.
- 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.


Regulatory Control
Consenting /Licensing process
Regulatory Inspections
Layout Approval
Authorization for Source/ Unit
Commissioning
Operation
Replacement of decayed source and disposal of disused source
Decommissioning of Unit/ Installation

Licence in accordance with AE(RP)R, 2004 from AERB is mandatory requirement for the procurement and use of radiation sources in India.

Emergency Response Plans and Preparedness

- Rule – 33 of Atomic Energy (Radiation Protection) Rules, 2004

- Objective :

  “To mitigate radiological consequences of accidents and prevent / minimise the normal & potential exposures to workers, members of the public & the environment”

Security of radiation sources

… International concern !!!!

Why??

- Its hazardous material
- It can be used for anti-social activities by adversaries
- May be used with explosives for making RDDs
- Its explosion may lead to severe social, economical, political Impact
- Waste disposal issues after explosions
- Radiation fear in society

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

- Online registration of Institutions and radiation professionals
- Electronic submission of applications for regulatory clearances
- Online tracking of submitted applications
- e-Approvals

Conclusions

- The applications of ionising radiation for human welfare are well established and are indispensable.

- It must be realized that radiation can be hazardous if not handled judiciously.

- The effective regulatory framework for governing control over radiation sources has been well established in the country.

- The high standard of safety in multifarious applications of radiation can be achieved through the inherent built-in safety features incorporated in the design and operational and administrative controls.

- The prime responsibility for ensuring safety and security of radiation sources rests with the operating organisation.

- *For more information , you may visit AERB website at,*

"www.aerb.gov.in"

Thank You!!