Radiation Safety Training Module: Diagnostic Radiology

Regulatory Requirements in Diagnostic Radiology Practice

Radiological Safety Division
Atomic Energy Regulatory Board

Content

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Expected questions to know after studying this lecture

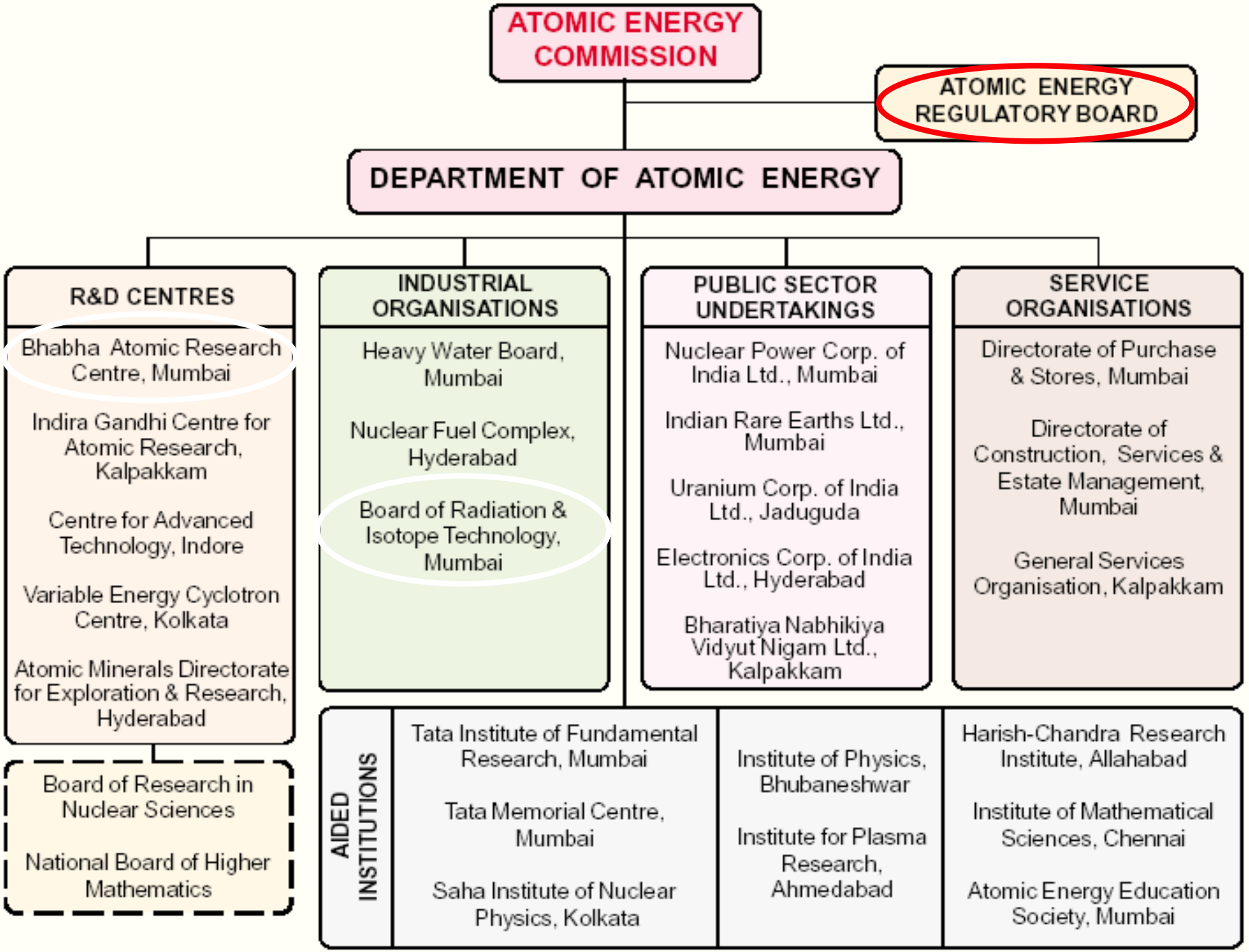
- Which Government Rule is applicable for radiation safety in the country?
- Who is the competent Authority for ensuring radiation safety in the country?
- What is the qualification of RSO in diagnostic radiology user's facility?
- What is the requirements for control room for CT & IR facilities?
- Understand the regulatory provisions for occupational radiation protection.

AIM

The Mission of AERB is to ensure the use of ionizing radiation and nuclear energy in India does not cause undue risk to the health of people and the environment.”

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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Tata Institute of Fundamental Research, Mumbai
Tata Memorial Centre, Mumbai
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Institute of Physics, Bhubaneshwar
Institute for Plasma Research, Ahmedabad
Harish-Chandra Research Institute, Allahabad
Institute of Mathematical Sciences, Chennai
Atomic Energy Education Society, Mumbai

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

REGULATORY FRAMEWORK…

- AERB was constituted in 1983 for carrying out the regulatory and safety functions envisaged in the Atomic Energy Act, 1962.

- Main Functions of AERB
  - Safety assessment for granting licence
  - Regulatory Inspections
  - Development of regulatory safety documents

SAFETY CODE:

Safety codes for each application/practice are identified on the basis of national and international practices.

- The requirements covered in Safety Code are mandatory in nature.
- Safety codes spell out requirements to be compiled by the licensee at all stages of activities of nuclear/radiation facilities.
- Safety assessment is based on satisfactory fulfilment of such requirements by the licensee for granting licence by AERB.

AERB Safety Code No. AERB/RF-MED/SC-3 (Rev. 2)

It contains seven sections and two appendices:

Sections:

1. Introduction
2. Design Requirement for X-ray Equipment
3. Regulatory Requirements for Manufacturers of X-ray Equipment and X-ray Tubes
4. Regulatory Requirements for Suppliers of X-ray Equipment and X-ray Tubes
5. Regulatory Requirements in Use of X-ray Equipment
6. Responsibilities of Employer, Licensee, RSO and Radiation Worker
7. Requirements for Occupational Radiation Protection

Appendices:

Appendix-I Design Specifications for X-ray Equipment

Appendix-II Design Specifications for Radiation Protection Devices

Objective:

This Safety Code is intended to govern radiation safety in design, manufacture, installation, operation and decommissioning of diagnostic x-ray equipment for medical diagnostic purposes in order to:

i. ensure that radiation workers and members of public are not exposed to radiation in excess of dose limits;
ii. reduce radiation exposures below these limits to levels ALARA and
iii. ensure that radiation exposures to patients are optimized.

Scope:

i. The Code stipulates radiological safety requirements for manufacturers, suppliers and users of medical diagnostic x-ray equipment.
ii. This Code does not address the conventional safety and fire safety requirements of medical diagnostic x-ray equipment.
iii. Safety Code also covers roles & responsibilities of personnel involved in handling of x-ray equipment.

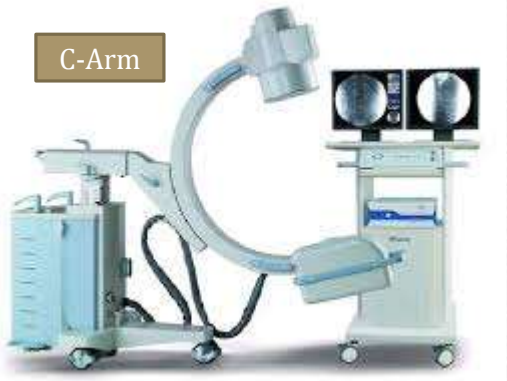
AERB Safety Code No. AERB/RF/SC/MED-2 (Rev. 2)….

- The following x-ray equipment are covered in this Code:
  - Radiography (Fixed, Mobile, Portable)
  - Interventional Radiology, C-Arm
  - Computed Tomography
  - Dental radiography [Dental (intra-oral), OPG, Dental CBCT]
  - Mammography
  - Bone Mineral Densitometer
  - Any of the above x-ray equipment mounted on vehicles
- Requirements for PET-CT/SPECT-CT & CT Simulator shall be met in conjunction with Safety Code on Nuclear Medicine Practice & Radiotherapy Practices respectively.

Equipment's used in Diagnostic Radiology Facilities

Radiography (fixed)

Computed tomography



C-Arm

Dental (intra-oral)

Interventional Radiology

Mammography

Dental (OPG)

BMD

PRE-REQUISITES FOR OBTAINING LICENCE FOR OPERATION OF X-RAY EQUIPMENT

- X-ray Room Layout and Shielding Requirements
- Staffing Requirements
- Radiological Safety Officer (RSO)
- Radiation Protection Devices
- Personnel Monitoring Service
- Quality Assurance (QA) Requirements

REGULATORY REQUIREMENTS IN THE USE OF X-RAY EQUIPMENT

Procurement of X-ray Equipment: The employer of X-ray facility shall procure NOC validated/ Type Approved X-ray equipment from authorized supplier(s) and after obtaining procurement permission from the Competent Authority.

Operation of X-ray Equipment: **No diagnostic X-ray equipment shall be operated for patient diagnosis unless Licence for operation is obtained from the Competent Authority.**

Requirements for Room Layout of X-ray Equipment

- The room housing an X-ray equipment shall have an appropriate area to facilitate easy movement of staff and proper patient positioning.
- Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray equipment so that radiation exposures received by workers and the members of the public are kept to the minimum and shall not exceed their respective dose limits.
- The control console of computed tomography equipment shall be installed in a separate room located outside but adjoining to computed tomography room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient.
- Interventional Radiology equipment room shall have an adjoining control room with appropriate facilities for shielding, direct viewing and oral communication facilities between the operator and the patient.

Requirements for Room Layout of X-ray Equipment …

- In case of room housing radiography equipment, chest stand shall be located in X-ray room such that no significant stray radiation reaches at control console/entrance door/ areas of full time occupancy such that the dose limits to radiation worker and members of public are not exceeded.
- **Mobile X-ray equipment, when used as fixed X-ray equipment, shall comply with all the requirements of those of fixed X-ray installation.**
- Movement of mobile X-ray equipment shall be restricted within the institution for which it is registered.
- A permanent radiation warning symbol and instructions for pregnant/likely to be pregnant women shall be posted on the entrance door of the X-ray installation, illustrating that the equipment emits X-radiation when energized.
- X-ray equipment installed in a mobile vehicle, shall be provided with an appropriate shielding enclosure to ensure adequate built-in protection for persons likely to be present in and around the vehicle. Shielding shall be provided around the equipment from all the sides up to height of 2 m from external ground surface.

Staffing Requirements

- X-ray installations shall have a radiologist/related medical practitioner/ X-ray technologist with adequate knowledge of radiation protection, to operate the X-ray equipment.

- All installations having X-ray equipment with fluoroscopy facility, computed tomography and all establishments performing special procedures, shall have the services of a qualified radiologist or related medical practitioner, with adequate knowledge of radiation protection for interpretation and reporting.

Radiological Safety Officer (RSO)

- X-ray department shall have a RSO approved by the Competent Authority.
- The RSO may either be the employer himself/herself or an employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his X-ray installation(s).
- The minimum qualification and training shall be as prescribed by the Competent Authority.

Qualification of RSO

Licence category DR facilities (CT and IR)

(a) Radiologist/Related Medical Practitioner , Or

X-ray Technologist passed from a recognized institution with three years working experience in the field of CT/IR facility.

Or

Institutions, where radiotherapy or nuclear medicine facility is available, AERB approved Radiological Safety Officer can be designated as RSO of DR facility subject to submission of undertaking by that RSO for ensuring radiation safety in DR facilities, and

(b) An approval from competent authority

Registration category DR facilities-

Appropriate Registrant shall be assigned the responsibilities of RSO subject to furnishing "Undertaking" that he/she is familiar with the regulatory requirements and radiation protection aspects of medical X-ray installation.

Radiation Protection Accessories

- Appropriate radiation protection devices such as barrier, apron, goggles, and thyroid shields shall be used during operation of X-ray equipment. These devices shall be verified periodically for their shielding adequacy.

- Mobile Protective Barrier (MPB)- 1.5 mm Lead Eqv
- Lead Aprons - 0.25 mm Lead Eqv
- Rubber hanging Flaps (In IR)-0.5 mm Lead Eqv
- Hand Gloves -0.25 mm Lead Eqv
- Lead Glass window- 2 mm Lead Eqv

QUALITY ASSURANCE (QA)REQUIREMENTS:

QA programs are designed to ensure that the radiology equipment can yield the desired diagnostic information.

Quality control techniques used to test the components of the radiological system and verify that the equipment is operating satisfactorily

The end user shall ensure that periodic QA (once in two years) of X-ray equipment is carried out by agencies authorized by the regulatory body.

PERSONNEL MONITORING SERVICE

Personnel monitoring services shall be provided to all the radiation workers handling diagnostic X-ray equipment.

PMS DETAILS

Sr. No.	Name of Accredited Laboratory	States Covered	Telephone
1	M/s. Avanttec Lab. Private Limited,31,Kamraj Street, Srinivasa Nagar, Padi, Chennai, Tamil Nadu, Pin-600050	Andhra Pradesh, Tamil Nadu, karnataka, Kerala, Puducherry (Southern Region)	044-26345288,044-26630553/54/56
2	M/s. Renentech Lab. Private Limited,C-106, Synthofine Industrial Estate, Off Aarey Road, Goregaon(E),Mumbai,Pin-490063,	Maharashtra, Gujarat, Rajasthan, Goa (Western Region)	022-40037476
3	M/s. Ultratech Lab. Private limited,Cloth Market, G.E. Road, kumhari, Bhilai, Durg, Chhattisgarh, Pin- 490042	All other states in the Central, Northern and North Eastern parts of the country	788-3295166, 09981212431
4	Defence Laboratory, Jodhpur	All Defence institutions of the country	

SERVICING : The end user shall ensure that servicing of the X-ray equipment is carried out by agencies authorized by the regulatory body.

PERIODIC SAFETY REPORTS: The utility shall submit periodic safety reports in the format and frequency specified by the regulatory body.

RENEWAL OF LICENCE: The Licence accorded by the Competent Authority shall be renewed before its expiry.

DECOMMISSIONING OF X-RAY EQUIPMENT: Decommissioning of the X-ray equipment shall be carried out by authorized agencies with prior intimation to the Competent Authority.

Responsibilities of Radiology Personnel

- **Responsibilities of individuals**

Employer

Licensee

RSO

Radiation worker

→ As per AE (RP) R-2004

- The ultimate responsibility of ensuring radiation safety in medical x-ray installation shall rest with the employer.

Responsibilities of Radiology Personnel

Responsibilities of Employer

- Ultimate Responsibility- rest with employer. He is the custodian of x-ray equipment in his possession.
- Prohibition of employment below a certain age
- Dose records- Obtain dose records of worker from his former employer, where applicable.
- Designate RSO.
- Facilitate Licensee, RSO and other worker(s) to carry out their functions effectively.
- Implementation of AE(RP)R,2004 at radiation installation.
- Health surveillance of classified workers and radiation surveillance of all radiation workers
- Provide dose records on termination of the service of radiation worker.
- **Inform the Competent Authority if the licensee and/or the Radiological Safety Officer leaves the employment.**
- **Comply with the terms and conditions of Licence.**

Responsibilities of Radiology Personnel

Responsibilities of Licensee

- Written Procedure- for controlling exposure of radiation workers, members of the public and patients, wherever applicable.
- **Periodic Training - radiation workers for performing their intended task.**
- Maintain dose records
- Investigate excessive exposure cases with consultation of RSO
- Arrange QA Tests
- Pregnant Worker- Advise the employer for modifications in working condition of a pregnant radiation worker.
- Ensure that the workers are familiarized with content of the relevant surveillance procedures, safety documents issued by the Competent Authority.
- **Inform the Competent Authority when he/she leaves the employment.**
- **Comply with the terms and conditions of Licence.**

Responsibilities of Radiology Personnel

Responsibilities of RSO-

The Radiological Safety Officer shall be responsible for advising and assisting the employer and licensee on safety aspects aimed at ensuring that the provisions of AE(RP)R,2004 are complied with.

- Maintain QA and radiation survey records
- Verify the performance of radiation safety systems, protective devices such as lead aprons, and other safety systems such as structural shielding in the radiation installation if any.
- Advise the employer and licensee regarding

- necessary steps that ensure the dose of radiation workers are well within the dose limits prescribed by the Competent Authority;
- **modifications in working condition of a pregnant worker;**
- **assist the employer and licensee in instructing the workers on hazards of radiation; suitable safety measures and work practices aimed at optimizing exposures and**
- **inform the Competent Authority when he leaves the employment.**

Responsibilities of Radiology Personnel

Responsibilities of Worker-

- Provide employer information about his previous occupation including radiation work, if any.
- Undergo training provided by the supplier, towards appropriate exposure parameters and dose reduction protocols.
- **Use appropriate exposure parameters for adults and pediatric x-ray examinations.**
- Use protective devices during operation of x-ray equipment.
- **Use personnel monitoring devices appropriately and monitor dose received.**
- Inform the Radiological Safety Officer and the Licensee of any accident or potentially hazardous situation that may come to his notice.
- **Female workers shall, on becoming aware of her pregnancy, notify the employer, licensee and Radiological Safety Officer in order that her working conditions may be modified, if necessary.**

Responsibility of Student/Trainee

- Medical students/trainees shall not operate x-ray equipment except under direct supervision of authorized operating personnel.
- The effective dose in any calendar year shall not exceed 6 mSv.

Requirements for Occupation Radiation Protection

The operator shall

- avoid routine holding of patients without using protective aprons;
- ensure holding of children or infirm patients for x-ray examination shall be done by a person wearing lead aprons;
- always wear protective apron while operating mobile/portable x-ray equipment;
- use design provided protective ceiling suspended screens and table curtains/flaps and
- use personnel monitoring services (TLD badges) as per the guidelines issued by accredited labs and regulatory body

Additional Requirements in fluoroscopy:
Interventional procedures constitute higher radiation exposure to the physicians and allied medical professionals, as the procedures are lengthy, complex and carried out at close proximity to radiation field.

Therefore all personnel associated with the use of the interventional radiology/ C-Arm/fluoroscopy equipment shall:

(i) use design provided protective ceiling suspended screens and table curtains/flaps

(ii) position the imaging system as close to the patient surface, as possible.

(iii) in oblique orientation, position themselves opposite to the X-ray tube.

Responsibilities of Medical Practitioner

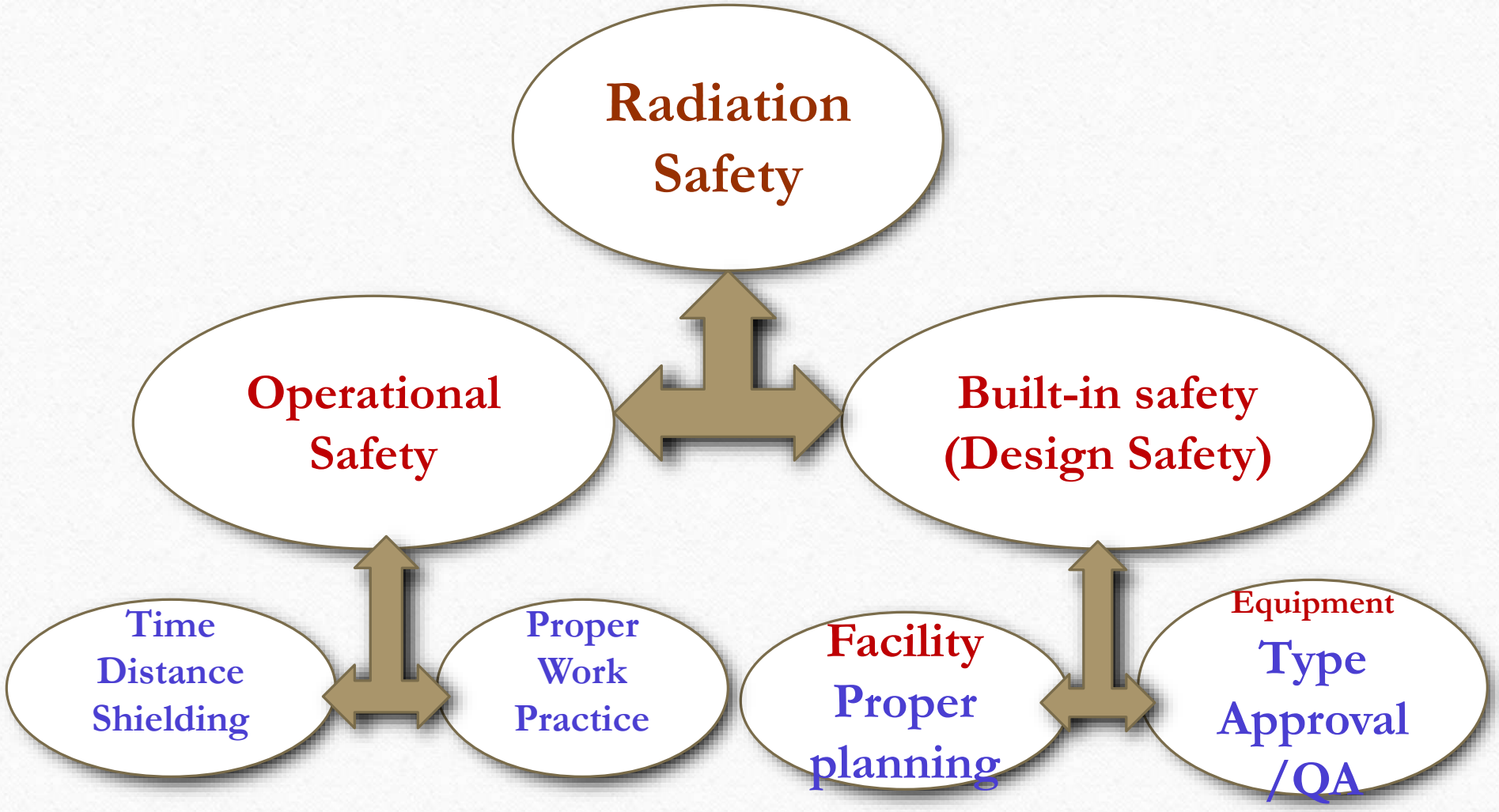
The medical practitioner shall undertake an X-ray examination on the basis of medical requirement. The medical practitioner shall:

- be satisfied that the necessary clinical information is not available from radiological examinations already done or from any other medical tests or investigations.
- be conscious of the patient dose and for any given examination shall attempt to be in line with international reference levels or those recommended by the regulatory body.
- evaluate medical procedures continuously for possible reduction of doses, especially for pediatric procedures.
- customize the exposure protocols as per his expectation for optimum image quality for new installations.

Offences and Penalties

Any person who contravenes the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, elaborated in this safety code, or any other terms or conditions of the Licence/Registration/Certification granted to him/her by the Competent Authority, is punishable under sections 24, 25 and 26 of the Atomic Energy Act, 1962.

The punishment may include suspension of licence, fine, imprisonment, or both, depending on the severity of the offence.

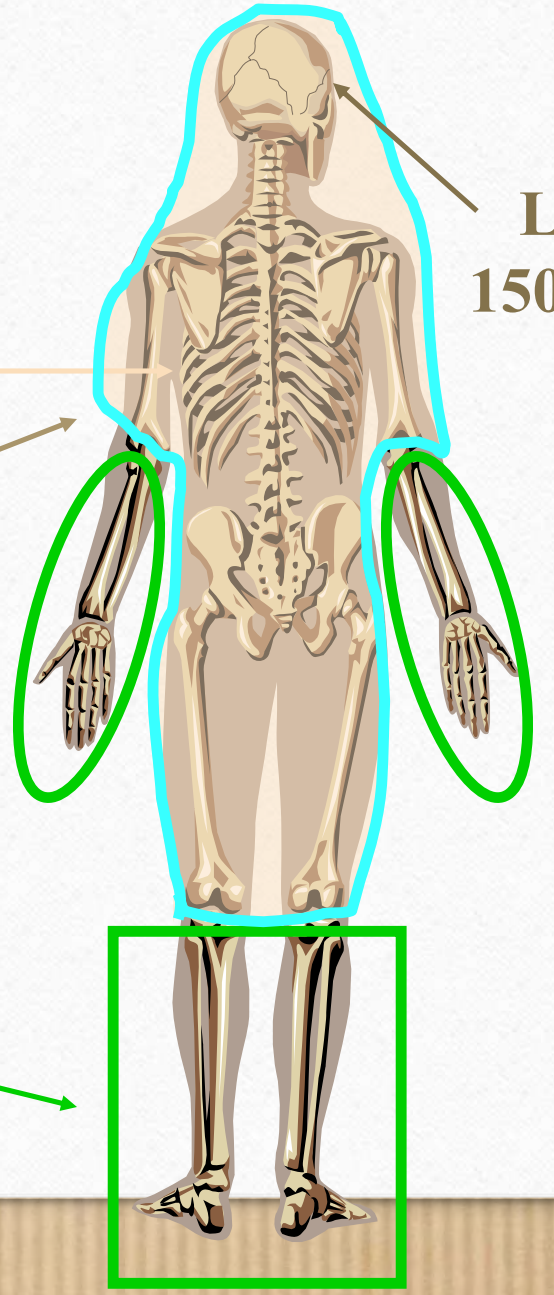

Radiation Safety
Operational Safety
Built-in safety (Design Safety)
Time
Distance
Shielding
Proper
Work
Practice
Facility
Proper
planning
Equipment
Type
Approval
/QA

DOSE LIMITS FOR WORKER

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



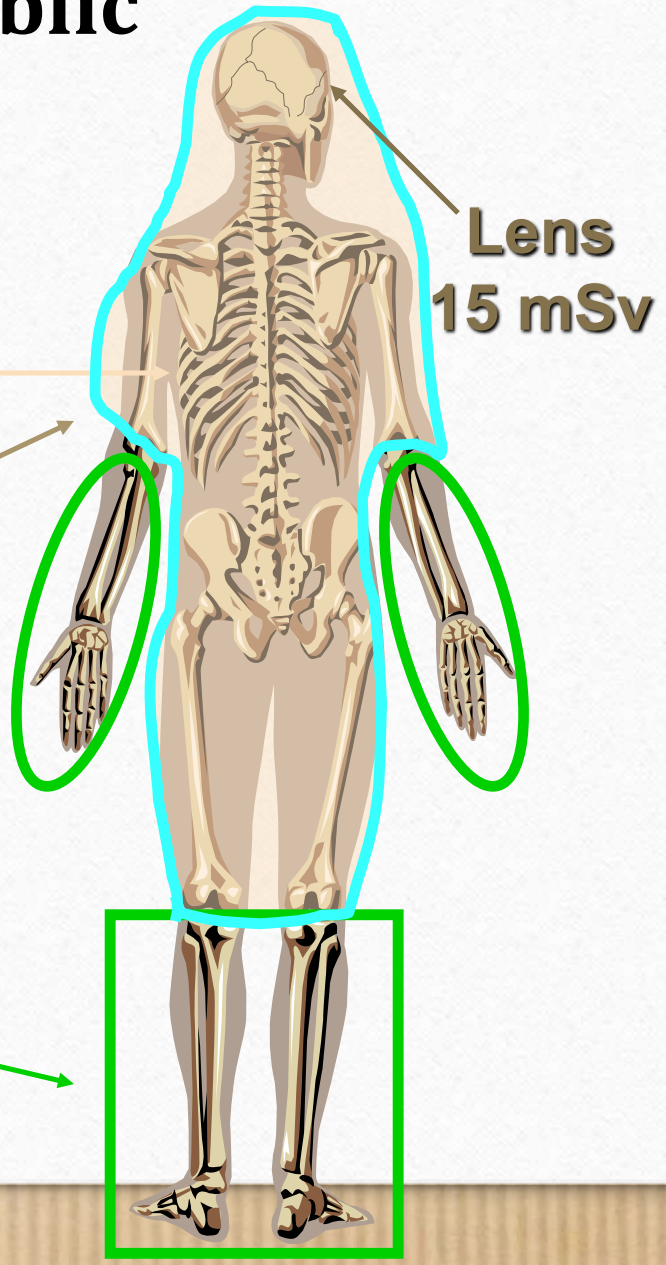
Lens
150 mSv

Dose Limits for Members of Public

Whole Body (everything except extremities)
1 mSv per year

Skin of the Whole Body
50 mSv per year

Extremities
50 mSv per year



Radiation Safety

Radiation safety of workers in handling of RGE is ensured by:

- Periodic QA and radiation survey around installation
- Selection of AERB type approved equipment
- Use of Personnel Monitoring Services
- Use of radiation protective devices
- Making good use of time-distance-shielding (TDS) principle
- Timely detection & prompt rectification of malfunctioning of RGE
- Maintenance of Records (QA, servicing & maintenance of equipment etc.)
- Decommissioning of installation by trained personnel/authorised service agencies with permission of AERB

Radiation safety of patient is ensured by:

- Limiting the total "beam–on" time
- Avoiding oblique lateral projections
- Collimation to limited beam size
- Selecting low dose rate protocol
- Use of exposure protocols for patient examinations including paediatric patients
- use of DLP in CT and DAP values for IR procedures and
- record- keeping of patient's doses for CT and IR procedures.

Summary/Learning Outcome

- The goal of safe work practice is to eliminate inappropriate utilization of radiological imaging procedures.
- Built-in safety (design safety) and operational safety of medical diagnostic x-ray equipment shall comply the national safety regulation.
- **The prime responsibility for ensuring safety of X-ray installations rests with the user institution.**
- **Increased awareness among health professionals will improve radiation safety standards in healthcare.**

Expected Questions:

Q.1 Which Government Rule is applicable for radiation safety in the country?

Ans. Atomic Energy (Radiation Protection) Rules, 2004

Q.2 Who is the competent Authority for ensuring radiation safety in the country?

Ans. Chairman, AERB

Q.3 What is the qualification of RSO in licence category X-ray user's facility?

Ans. a) Radiologist/Related Medical Practitioner

Or X-ray Technologist passed from a recognized institution with three years working experience in the field of CT/IR facility.

Or

Institutions, where radiotherapy or nuclear medicine facility is available, AERB approved Radiological Safety Officer can be designated as RSO of DR facility subject to submission of undertaking by that RSO for ensuring radiation safety in DR facilities, and

b) An approval from competent authority

Expected Questions:

Q.4 What is the requirements for control room for CT facilities?

Ans. The control console of computed tomography equipment shall be installed in a separate room located outside but adjoining to computed tomography room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient.

Q.5 Write five responsibilities of Employer.

Ans. 1. He is the custodian of x-ray equipment in his possession.

2. Prohibition of employment below a certain age

3. Dose records- Obtain dose records of worker from his former employer, where applicable

4. Designate RSO

5. Facilitate Licensee, RSO and other worker(s) to carry out their functions effectively.

Expected Questions:

Q.6 Write four responsibilities of Radiation worker.

Ans. 1. Providing employer information about his previous occupation including radiation work, if any

2. Use protective devices during operation of x-ray equipment.

4. Use personnel monitoring devices appropriately and monitor dose received

5. Female workers shall, on becoming aware of her pregnancy, notify the employer, licensee and Radiological Safety Officer in order that her working conditions may be modified, if necessary.

Expected Questions:

Q.7 What is the average annual whole body dose limit for radiation worker?

Ans. 20 mSv

Q.8 Pl. specify the lead equivalence of lead aprons.

Ans. 0.25 mm

Q.9 Pl. specify the lead equivalence of mobile protective barrier & viewing window.

Ans. 1.5 mm

Q.10 Pl. specify the lead equivalence of ceiling suspended/couch hanging screen/flaps:

Ans. 0.5 mm lead eq.

Expected Questions:

Q.11 Where should I wear the TLD badge

a) Above the lead apron

b) Back side of lead apron

c) Below the lead apron

d) Not to use TLD badge

Ans. c

Q.12 Who should hold the patient whenever it is required during radiological procedures?

a) Operator (X-ray technologist)

b) Pregnant women

c) Staff helper

d) Patient relative with lead Apron

Ans. d

Q.13 Where should I keep my TLD badge after radiation work

(a) Inside X-ray room (b) Outside X-ray room in radiation free zone

Ans. (b)

References and sources for additional information:

1. ATOMIC ENERGY ACT, 1962

2. ATOMIC ENERGY (RADIATION PROTECTION) RULES, 2004

3. AERB SAFETY CODE NO. AERB/RF-MED/SC-3 (Rev. 2), RADIATION SAFETY IN MANUFACTURE, SUPPLY AND USE OF MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

List of presentations in the training Module

Basics of Diagnostic X-ray Equipment
Biological effects of Radiations
Medical X-ray imaging techniques
Planning of Diagnostic X-ray facilities
Quality Assurance of X-ray equipment
Quality Assurance of Computed Tomography equipment
Radiation Protection in Diagnostic Radiology Practice
Causes, prevention and investigation of excessive exposures in diagnostic radiology
Regulatory Requirements for Diagnostic Radiology Practice

THANK YOU