RADIATION SAFETY IN MEDICAL APPLICATIONS

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An Overview…

- Regulatory Framework for Ionizing Radiation Sources
- Safety Requirements for Medical Applications
- Observations during Inspections
- Ensuring Patient Protection in Medical Exposures
- Challenges And Way Forward

Ionizing Radiation Is omnipresent..

Natural Sources of Radiation

Man-made Sources of Radiation

Extra Cosmic Rays from Air Travel

Cosmic Rays

Dental X Rays

Fallout from Weapon Testing

Nuclear Power Plants

Radon & Daughters

Medical X Rays

On an average, We all receive dose of ~3mSv/year due to natural radiation

Terrestrial Radiation from rocks and soil

Buried RadioActive Waste

Need to Regulate Radiation Sources

- There are obvious health benefits Vs well established risks from ionizing radiation

- Suitable control measures required to ensure that maximum benefits are derived with minimum radiological risk

Regulations are in place to avoid adverse health effects and ensure the safe use of radiation sources and equipment for patient as well as operators

ATOMIC ENERGY REGULATORY BOARD

The National Regulatory Authority

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***."

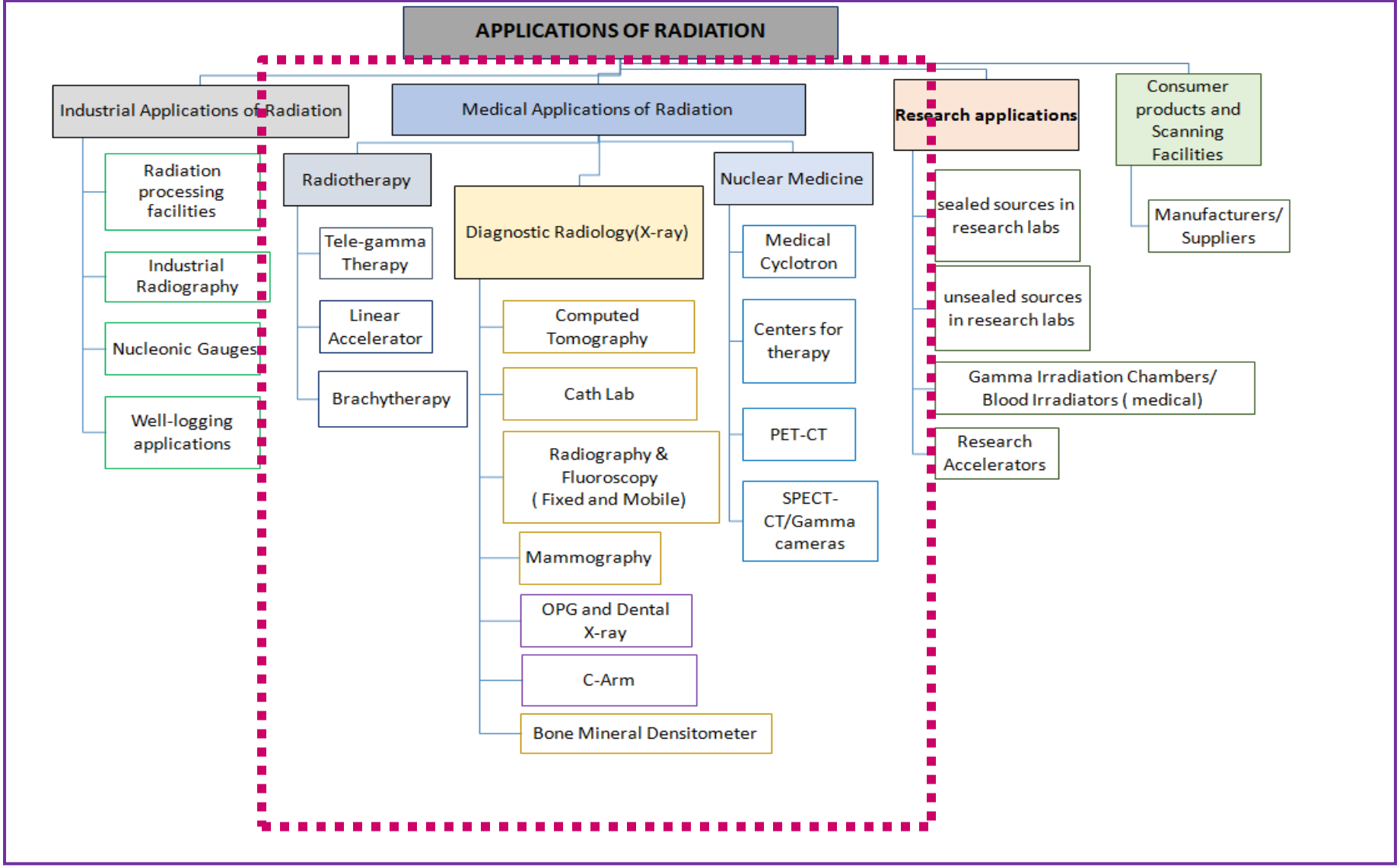
……Core Functions of AERB

- Development of regulatory safety documents

-Radiation Safety assessment for issuance of operational licence

- Regulatory Inspections

RADIATION FACILITIES



APPLICATION OF RADIATION IN MEDICINE

- Radiation in Medicine
  - Diagnostic
    - Diagnostic Radiology
    - Nuclear Medicine
  - Therapy
    - Radiotherapy
      - Teletherapy
      - Brachy Therapy
    - Nuclear Medicine

~67,000 Institutions and 92,000 X-ray equipment

389 Institutions and 616 NM equipment

529 Institutions and 1263 Radiotherapy Equipment

61 Institutions

CATEGORIES OF EXPOSURES

- Occupational exposures

  exposure of workers incurred as a result of their work with radiation sources (medical exposure and background radiation not included)

- Public exposures

  all exposures of the public other than occupational exposures and medical exposures of patients

- Medical exposures of patients

  incurred by patients as part of their own medical or dental diagnosis or treatment; volunteers helping in the support and comfort of patients; and biomedical research volunteers

DOSE DUE TO X-RAY EXPOSURES

- **ANNUAL GLOBAL X-RAY EXPOSURES**
  - Diagnostic X-ray Examinations : 3.1 billion
  - Dental X-ray Examinations : 0.5 billion
  - Collective effective dose : $4X10^6$ man-Sv
  - Effective dose per person : 0.62 mSv
  - Contribution due to CT scans : 43% of collective dose
  - Contribution due to IR procedures : 8 % (during last 10 years)

Diagnostic X-ray examinations in 1996 : 2.4 billion

Data Source: Unscear Report

SYSTEM OF REGULATORY CONTROL

Competent Authority – Chairman, AERB

Issued by Central Government

- Act

(Atomic Energy Act, 1962)

- Rules

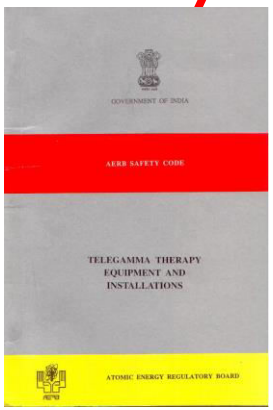
(Atomic Energy Radiation Protection) Rules, 2004)

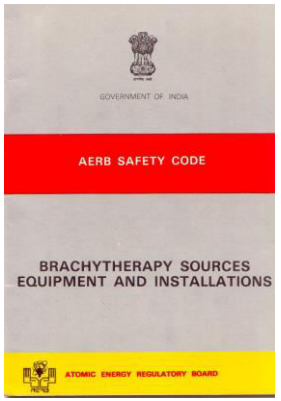
- Notifications

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

Published by AERB

- Safety Codes





- Safety Standards
  - Safety Guides
  - Safety Manuals

AERB SAFETY CODES ON MEDICAL APPLICATIONS

Radiotherapy	AERB safety code AERB/RF-SC/MED-1 (rev.1), 2011 on " Radiation sources, Equipments and Installations"
Nuclear Medicine	AERB safety code AERB/RF-SC/MED-2 (rev.2), 2011 on " Nuclear Medicine facilities"
Diagnostic Radiology	AERB safety code AERB/SC/MED-3 (rev.2), 2016 on "medical diagnostic x-ray equipment and installation"

Principles of Radiation Protection -1

Assure the right test is done on the right patient for the right reason

Justification

The patient shouldn't receive dose without a potential benefit

Patient outcome

Dose to patient and personnel

Justification of medical exposures:

Level 1 deals with use of radiation in medicine in general

(In practice this is accepted as doing more good than harm, and its justification is taken for granted)

Level 2 deals with specified procedures with a specified objective

(The aim at this level is to judge whether the procedure will improve diagnosis or provide necessary information about those exposed)

Level 3 deals with the application of the procedure to an individual

(The particular application should be judged to do more good than harm for the individual patient)

Current issues and actions in radiation protection of patients Ola Holmberg et al.; *European Journal of Radiology* 2010 76, 15-19

Example of Level 2 Justification

Figure 11: The American College of Radiology's Appropriateness Criteria® guidance for right lower quadrant pain in children

Variant 4: Fever, leukocytosis, possible appendicitis, atypical presentation in children (less than 14 years of age)

Radiological Procedure	Rating	Comments	RRL*
US abdomen RLQ	8	With graded compression	○
CT abdomen and pelvis with contrast	7	May be useful following negative or equivocal US. Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
X-ray abdomen	6	May be useful in excluding free air or obstruction.	☢☢
US pelvis	5		○
CT abdomen and pelvis without contrast	5	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
MRI abdomen and pelvis without and with contrast	5	See statement regarding contrast in text under "Anticipated Exceptions".	○
CT abdomen and pelvis without and with contrast	4	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
MRI abdomen and pelvis without contrast	4		○
X-ray contrast enema	3		☢☢☢☢
Tc-99m WBC scan abdomen and pelvis	2		☢☢☢☢

Rating scale: 1,2,3 Usually not appropriate; 4;5;6 May be appropriate; 7,8,9 Usually appropriate

* Relative Radiation Level

Source: ACR (2015); reproduced with kind permission of the American College of Radiologists.

Principles of Radiation Protection -2

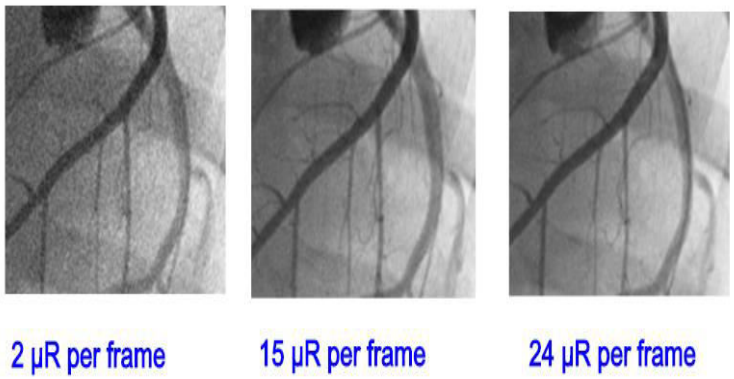
Optimization

The medical team is responsible to ensure the radiological procedure provides quality images, adequate for diagnosis and treatment, while keeping the radiation dose As Low As Reasonably Achievable (ALARA)

OPTIMIZATION OF DOSES

- All Justified medical exposures should ensure that the doses are such that
  - Maximum information is obtained through minimum possible doses to the patient i.e, Acceptable quality images with minimum patient dose
  - Dose to the operators/occupational workers is As Low as Reasonably Achievable (ALARA)

Dose vs. Noise

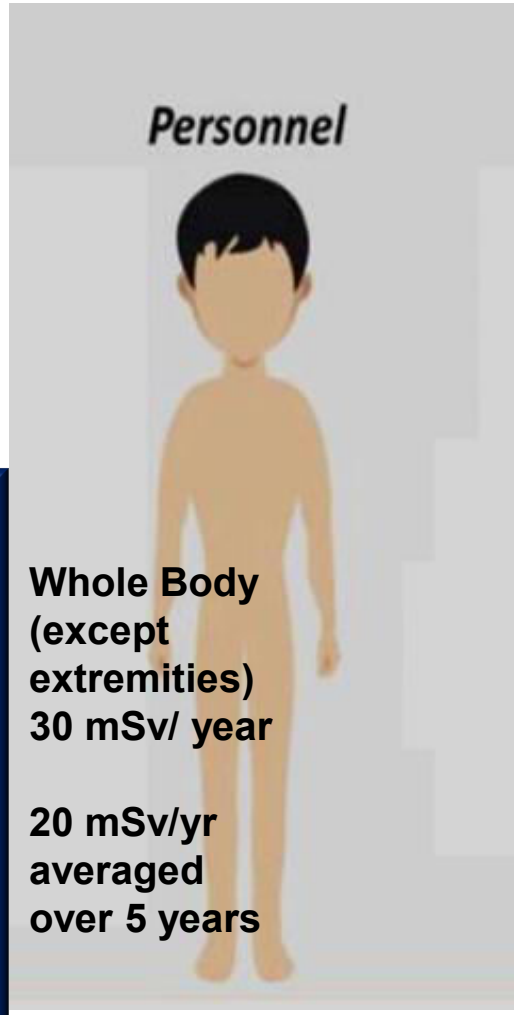


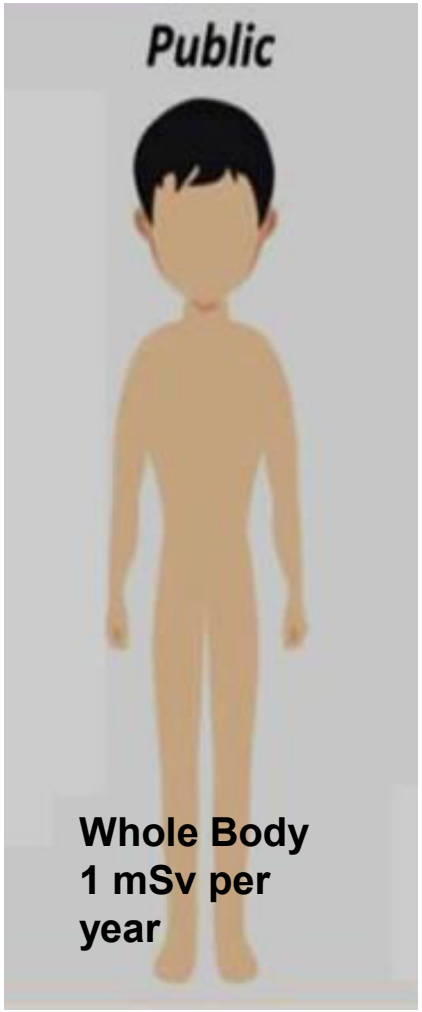
Crisp Images = increased dose to patients ..

Settle for acceptable quality images

Principles of Radiation Protection -3

DOSE LIMITS PRESCRIBED BY AERB





IAEA RPoP

RADIATION DOSE MONITORING – PERSONNEL MONITORING

Exposure to any worker in excess of 10 mSv during a monitoring period (3 months in case of medical applications) needs to be investigated by the institution and report sent to AERB for review

RADIATION DOSE MONITORING – PERSONNEL MONITORING

!!!True representation of radiation doses received is possible only if TLD is used and stored as per instructions

- To answer some questions:

  - **Is there an excess risk to occupational workers in a radiation facility ….**

NO .. ***If dose is within prescribed limits***

Radiation Safety Procedures
Regulation of Radiation Sources

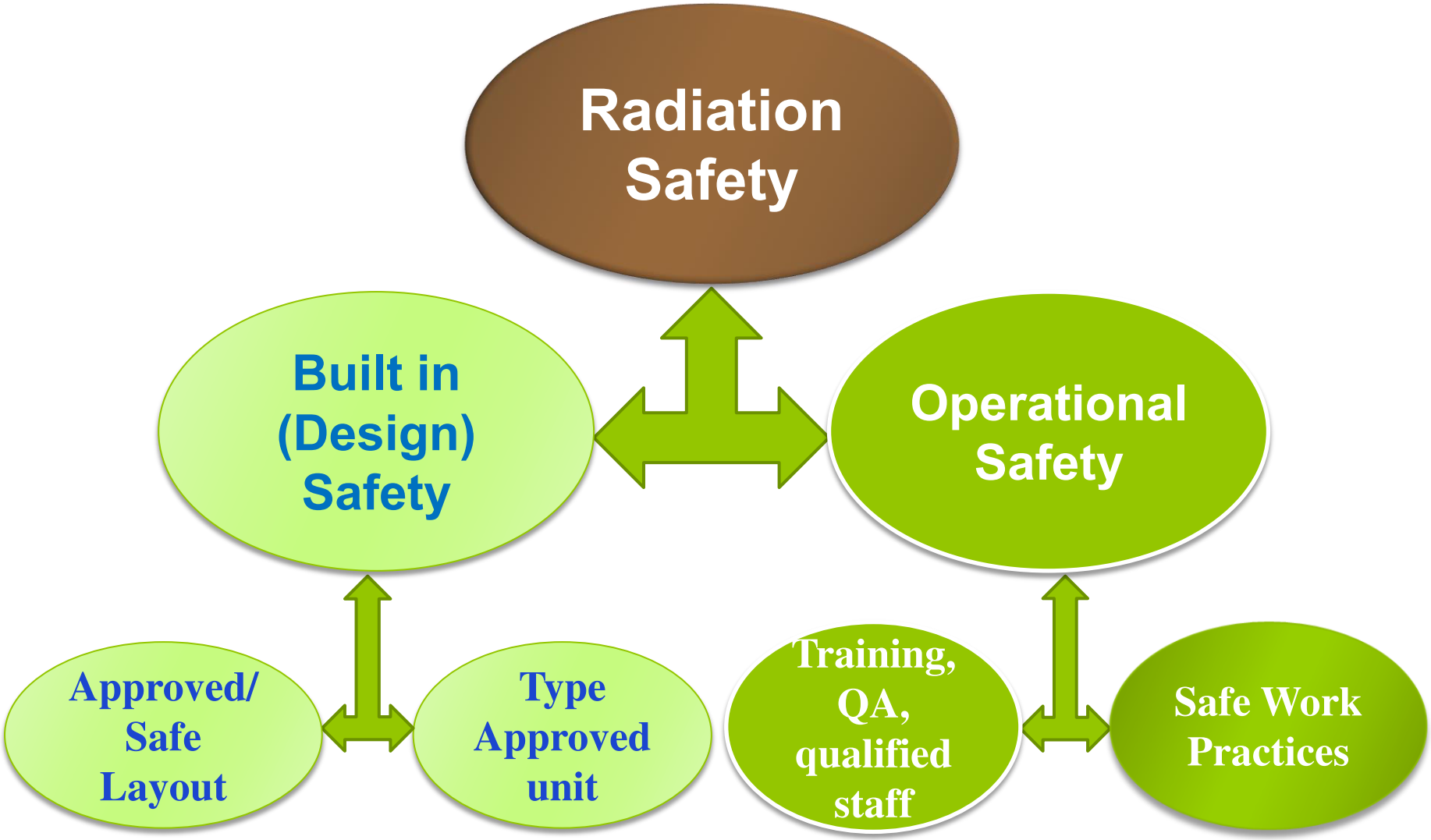
Consenting Process

(*License for design & construction, commissioning, Operation, decommissioning & disposal issued under AE(RP)R, 2004*)

Regulatory Inspection and Enforcement

(***Compliance verification***)

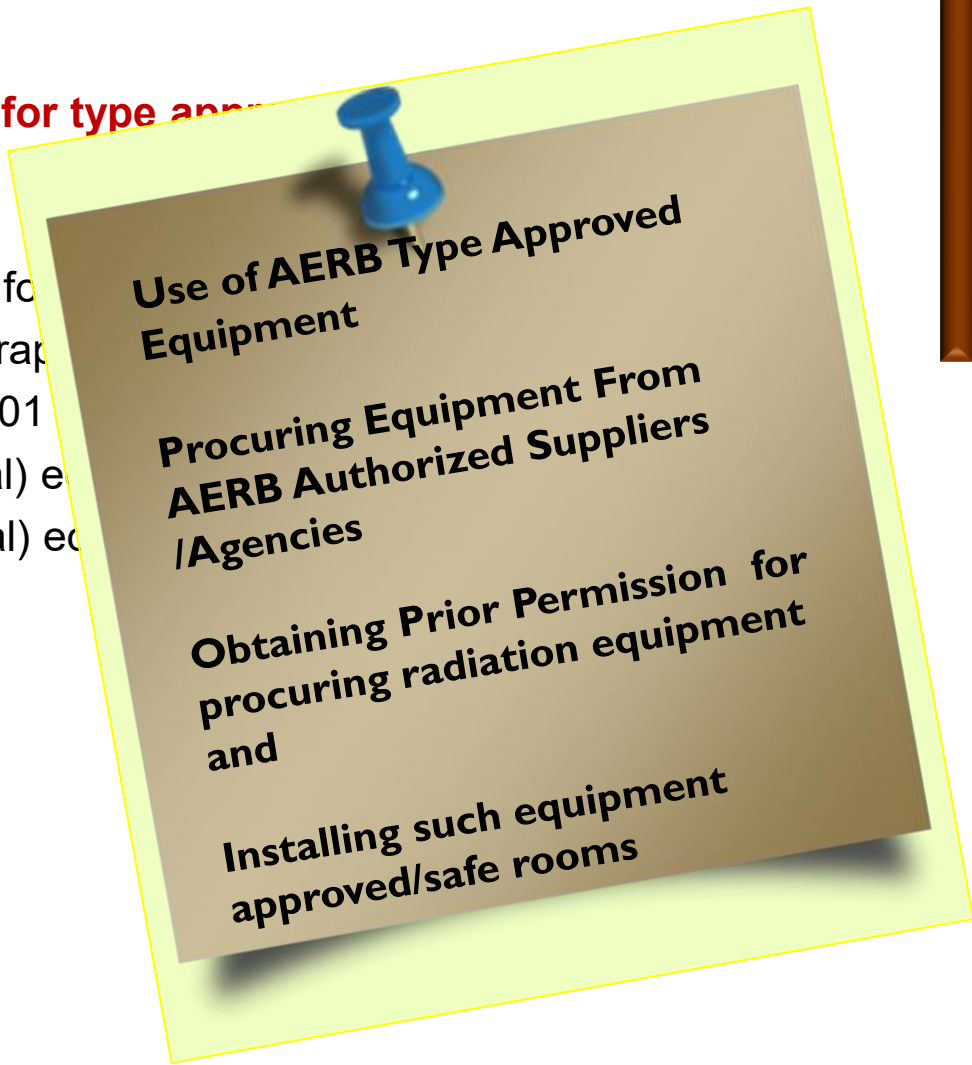
ENSURING RADIATION SAFETY- how?



DESIGN SAFETY OF EQUIPMENT

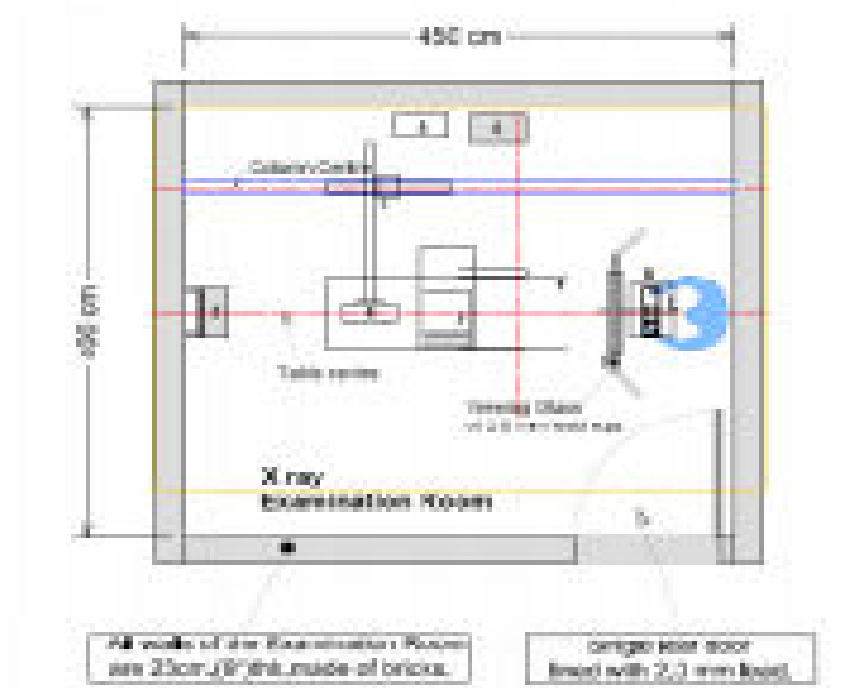
Standards used in performance Evaluation for type appr
equipment

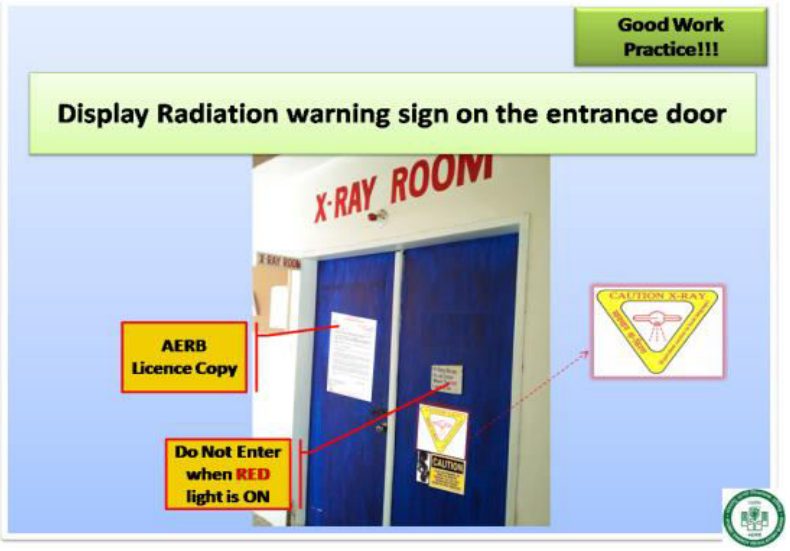
- ✓ BIS standards IS 7620
- ✓ IS 13450 (part 2/sec 43) – x-ray equipment fo
- ✓ IS 13450 (part 2/sec 44 – Computed Tomograp
- ✓ IS 13450 (part 2/sec 45)/ IEC60601-2-45:2001
- ✓ IEC 60601-2-63 (Part2-63) Dental (extra-oral) e
- ✓ IEC 60601-2-65 (Part2-65) Dental (intra--oral) ec
- ✓ **AERB/SC/MED-3 (Rev-2)**
- ✓ IEC 60601-2-1 Medical Accelerators
- ✓ IEC 60601-2-11 Telegamma Equipment
- ✓ **AERB/RF-SC/Med-1 (Rev 01)**



Design Safety: Installation

- Shielding Adequacy
- Placement of Chest X-ray Stand
- Placement of Control Console
- Availability of lead lined doors
- Mobile protective barrier
- Viewing window (CT and IR) with adequate shielding
- Ceiling suspended lead glass (IR)





Detailed guidelines for layout and shielding requirements are available on www.aerb.gov.in

PRE-REQUISITES FOR OBTAINING LICENCE FOR OPERATION

- Adequacy of shielding of the installation
- Type approved equipment
- Qualified Personnel, Radiological Safety Officer
- Radiation Protection Devices
- Personnel Monitoring Service
- Quality Assurance (QA) Requirements
- Satisfactory Performance for intended use (Image quality, stability of operating parameters etc)

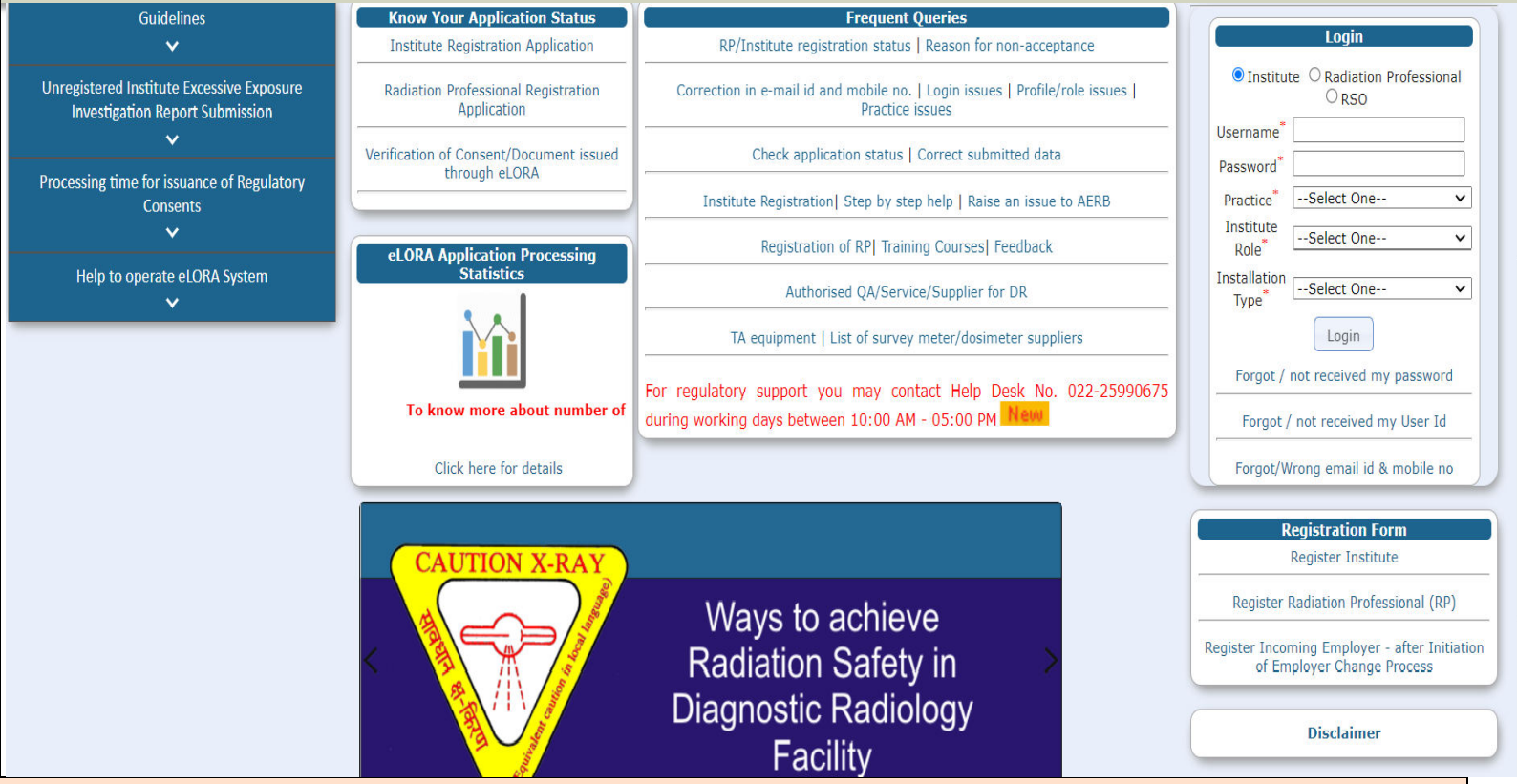
REGULATORY COMPLIANCE THROUGH e-LORA

(e-Licensing of Radiation Applications)-The e-Governance system of AERB

It is a statutory requirement for the owners/users to obtain Licence for operation from Atomic Energy Regulatory Board as per Atomic Energy (Radiation Protection) Rules -2004 prior to handling of radiation sources. Online system 'e-LORA' for licensing of radiation facilities provides transparent and effective means for obtaining regulatory clearances from AERB

Features of eLORA…

- **Web-based online system→ easily accessible**
- **Many of the process are automated→ instantaneous approval**
- **Free of cost**

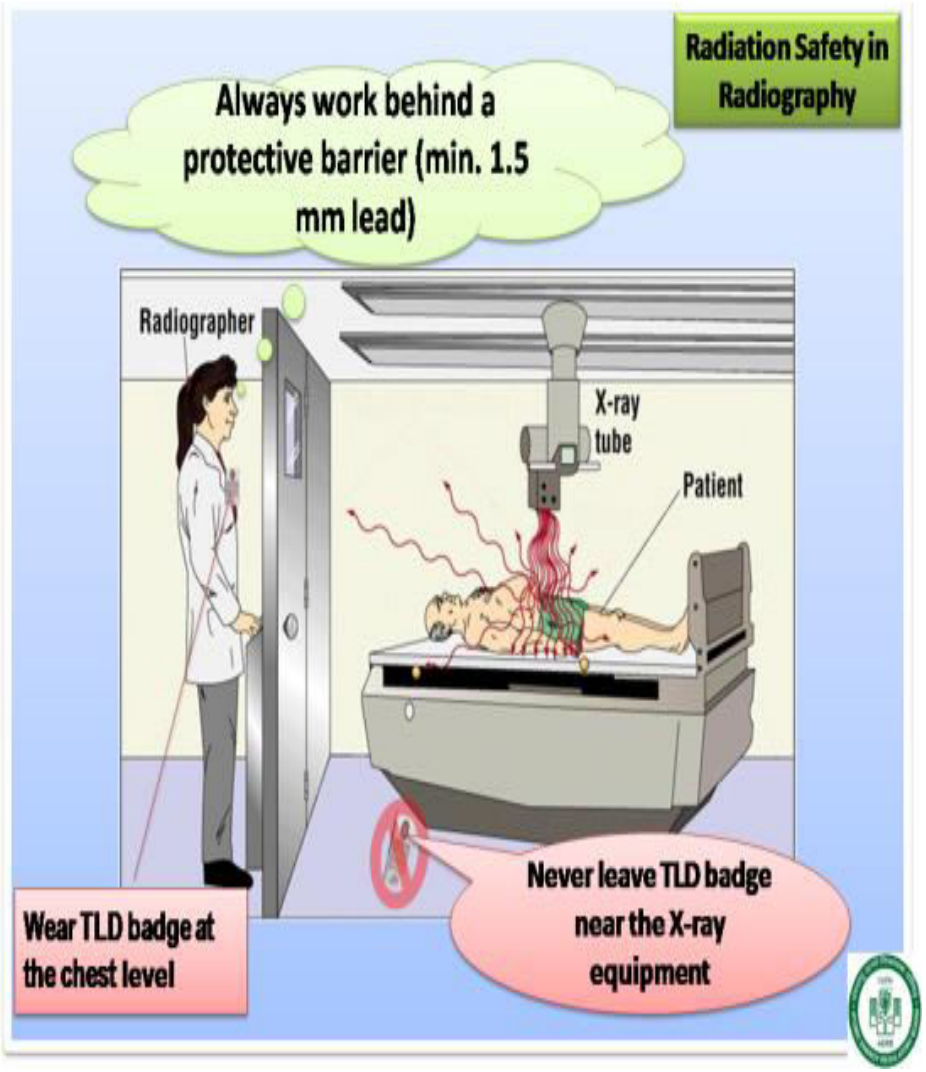


For more information, guidelines and documents visit www.aerb.gov.in

OPERATIONAL SAFETY – RADIATION WORKERS

- Handling of equipment by qualified and certified persons
- Work Place Monitoring – Radiation Survey
- Use of Personnel Monitoring Services (PMS)
- Use of Radiation Protective Accessories
- Periodic Quality Assurance Testing of equipment
- Periodic Servicing and Maintenance
- **Following Safe Work Practice**

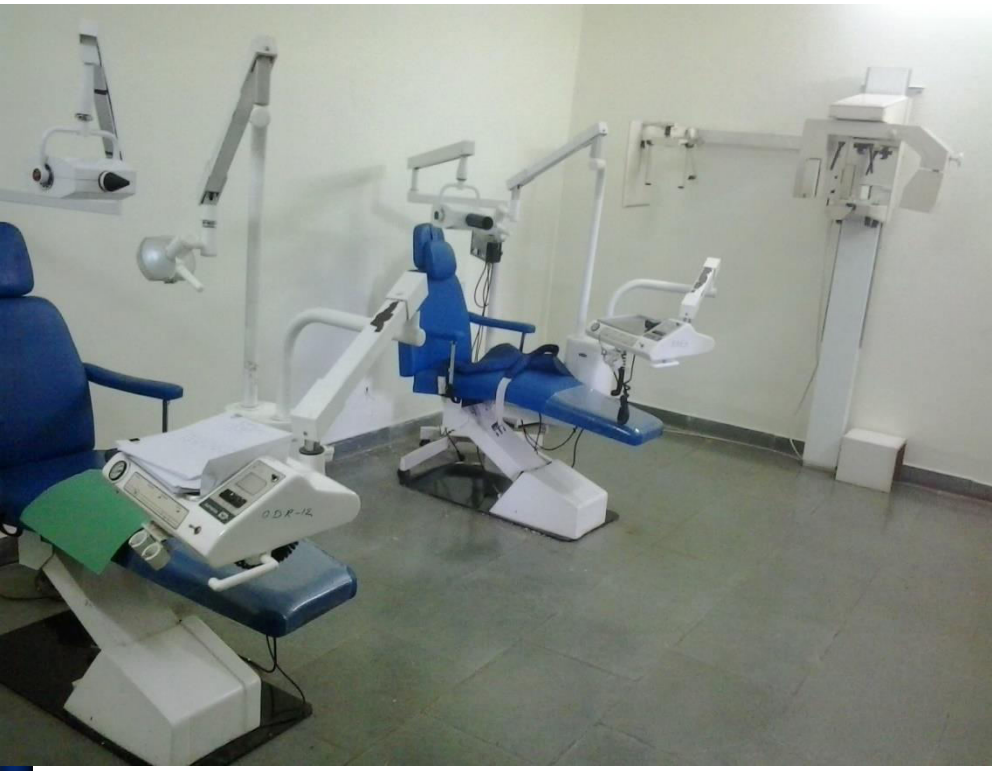
Safe Work Practice-Operational Guidelines



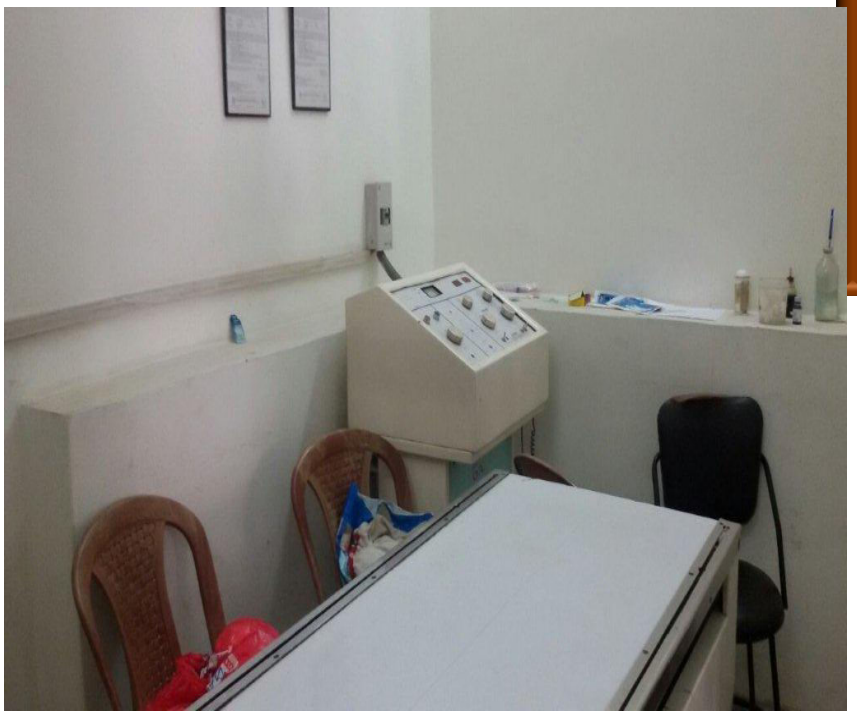
Cathlab equipment

- ✓Use ceiling suspended screens, lateral shields and table curtains.
- ✓They provide more than 90% protection from scattered radiation in fluoroscopy

Unsafe Practices Observed During Inspections



Unsafe Design of equipment and Operation of multiple X-ray units in a single rooms



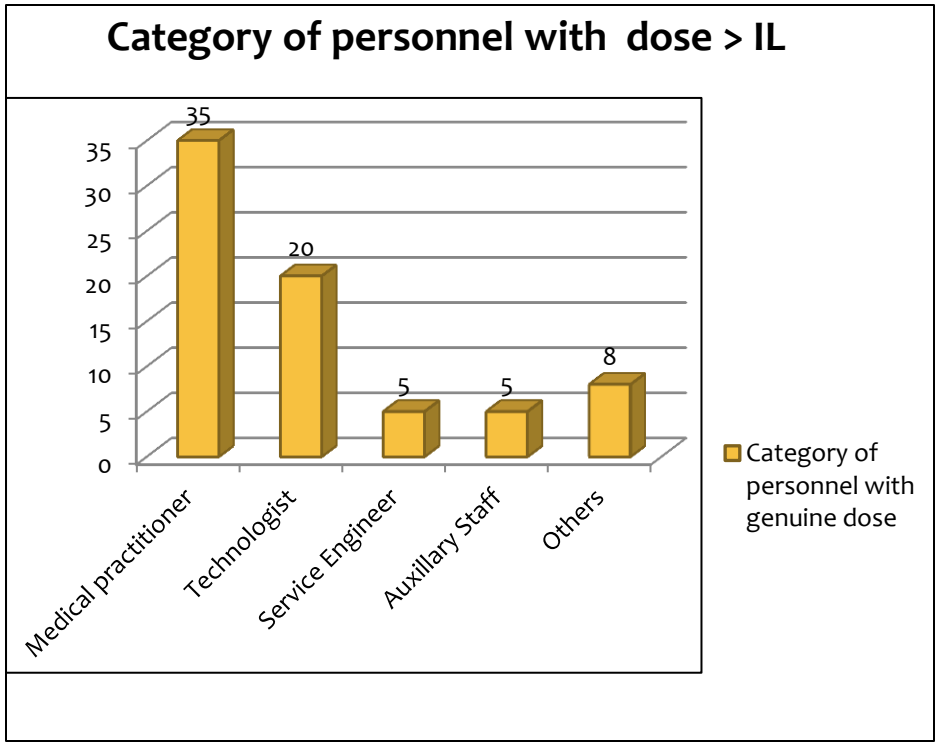
Use of X-ray unit without protective accessories

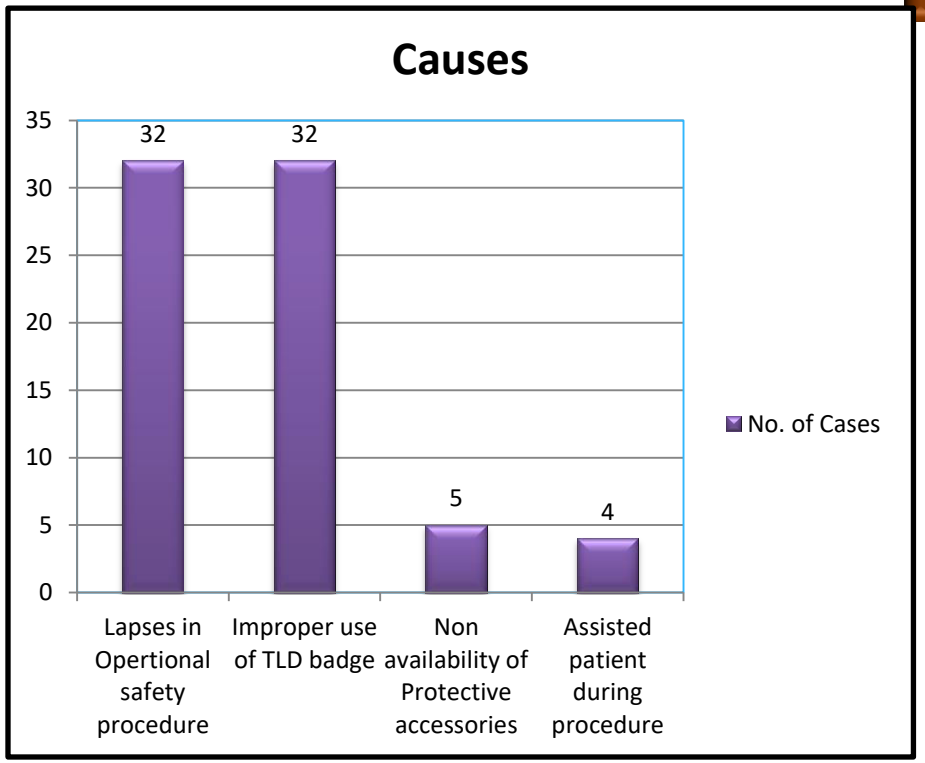
Unsafe Practices Observed During Inspections

Unsafe Refurbishment of equipment

Use of equipment in unshielded roooms

Exposures above IL (in a 5 year period) to Cathlab Personnel





IL= Investigation Level of > 10 mSv in a monitoring period

Excessive Exposures to Radiographers - HOW??

- Non-Type approved/substandard equipment and accessories (Built in safety)
- Misuse of TLD badges (improper use and/or improper storage)
- Refurbishment of the equipment (At User level)
- Wrong work practices & procedures
- No proper maintenance of the equipment
- Periodic Quality Assurance (QA) tests are not performed
- Untrained manpower & excessive workload (flouroscopy)
- Sub Standard Accessories
- Non availability / no use of radiation protection devices such as MPB and lead aprons
- Holding of patients during x-ray examination

Annual average exposures for occupational workers in India

Practice	No. of persons Monitored	Average dose per monitored person (mSv/year)
Diagnostic Radiology	125767	0.22
Radiotherapy	15266	0.13
Nuclear Medicine	2622	0.48
Allowable limits : 20 mSv/year		

(AERB Annual Report 2019)

NEED FOR PATIENT PROTECTION

- Patient is irradiated by the direct beam
- Medical personnel is irradiated by the scatter radiation (which is only 0.1% of direct beam)
- Patients may undergo repeated radiation procedures
- A patient may receive in one procedure a dose equivalent to dose the staff may receive in one (or several) years

- No regulatory limits for exposures to patients
- AERB's design specifications and availability of trained personnel can ensure that equipment can deliver correct exposure to patients
- Optimizing the patient doses - responsibility of physician and technologists involved in referring, conducting, and reporting the findings..!!

"SMART" - TECHNIQUE

Shielding is appropriate?

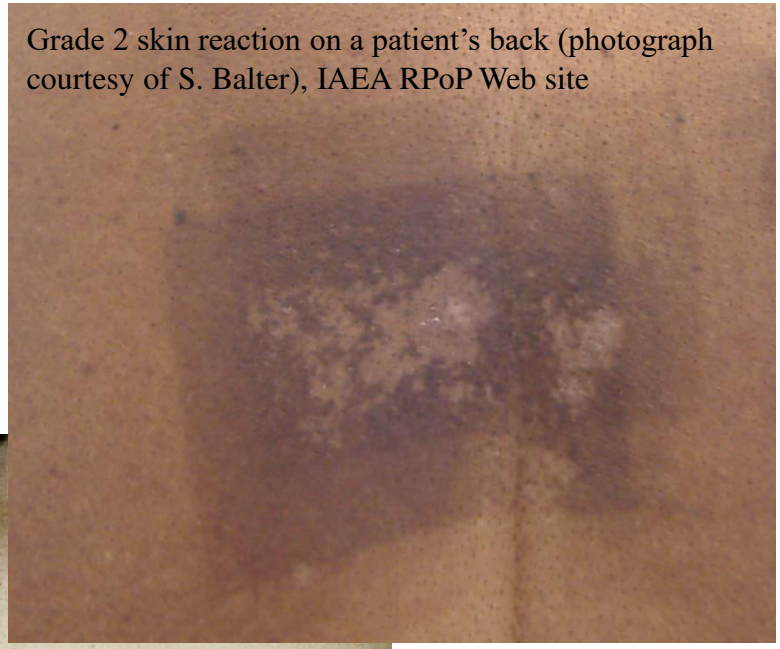
Marking of the film, ID etc. are appropriate?

Area collimation is appropriate?

Restriction on motion appropriate?

Technical setting is appropriate?

Reported Injuries due to IR procedures

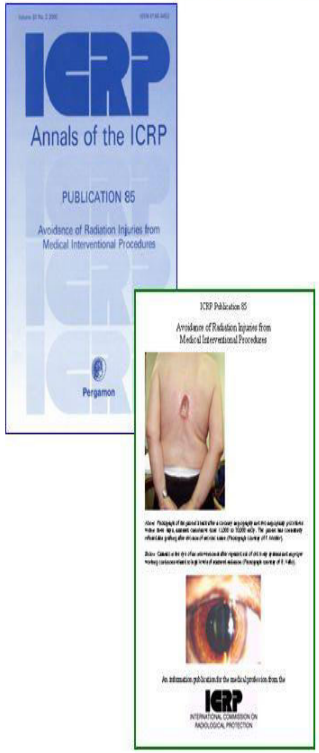


Grade 2 skin reaction on a patient's back (photograph courtesy of S. Balter), IAEA RPoP Web site

Grade 4 skin reaction on a patient's back (photo IAEA RPoP

First Case repor te d 199 ?

ICRP Report 85 (2001): Avoidance of Radiation Injuries from Interventional Procedures



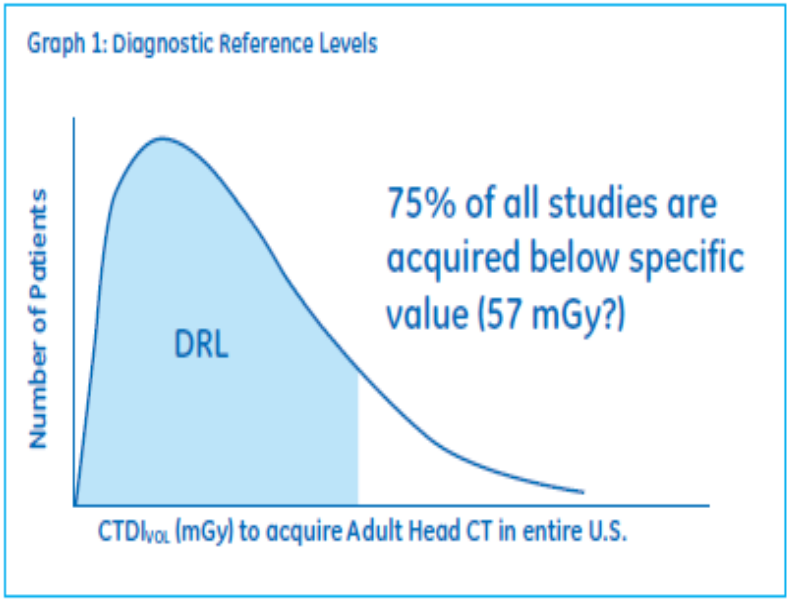
ICRP recommend:

- Warn patient of risk, if maximum skin dose exceeds 3 Gy
- Identify patients who have repeated interventions where the dose exceeds 1 Gy and warn them of risk

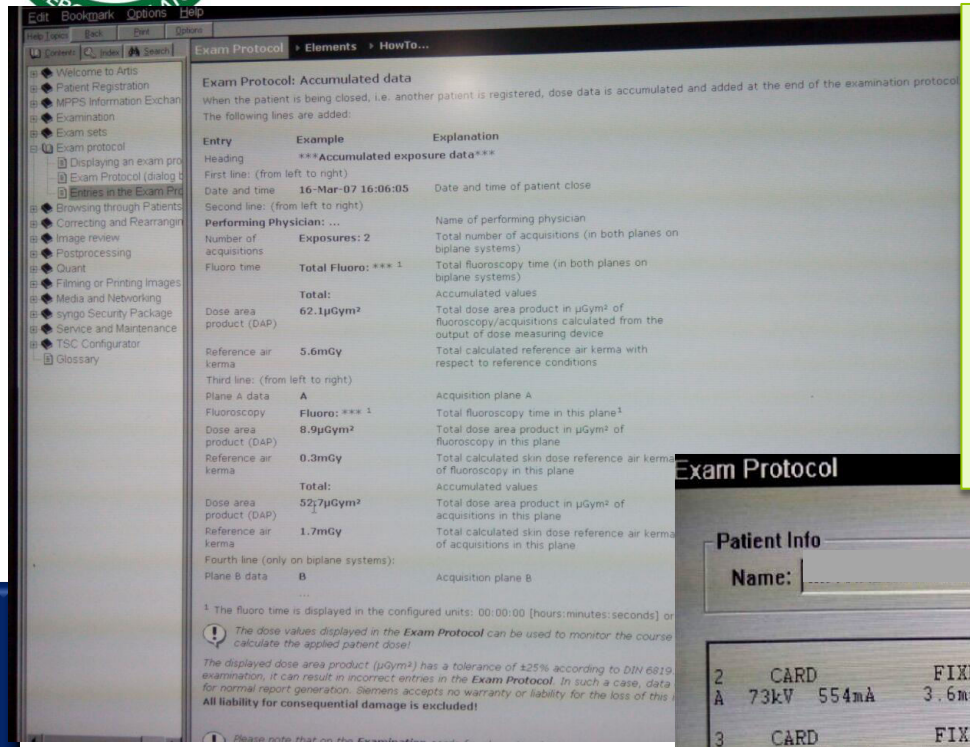
Is my patient is receiving more dose??

- Same procedure by different operators, different equipment may lead to different patient doses.

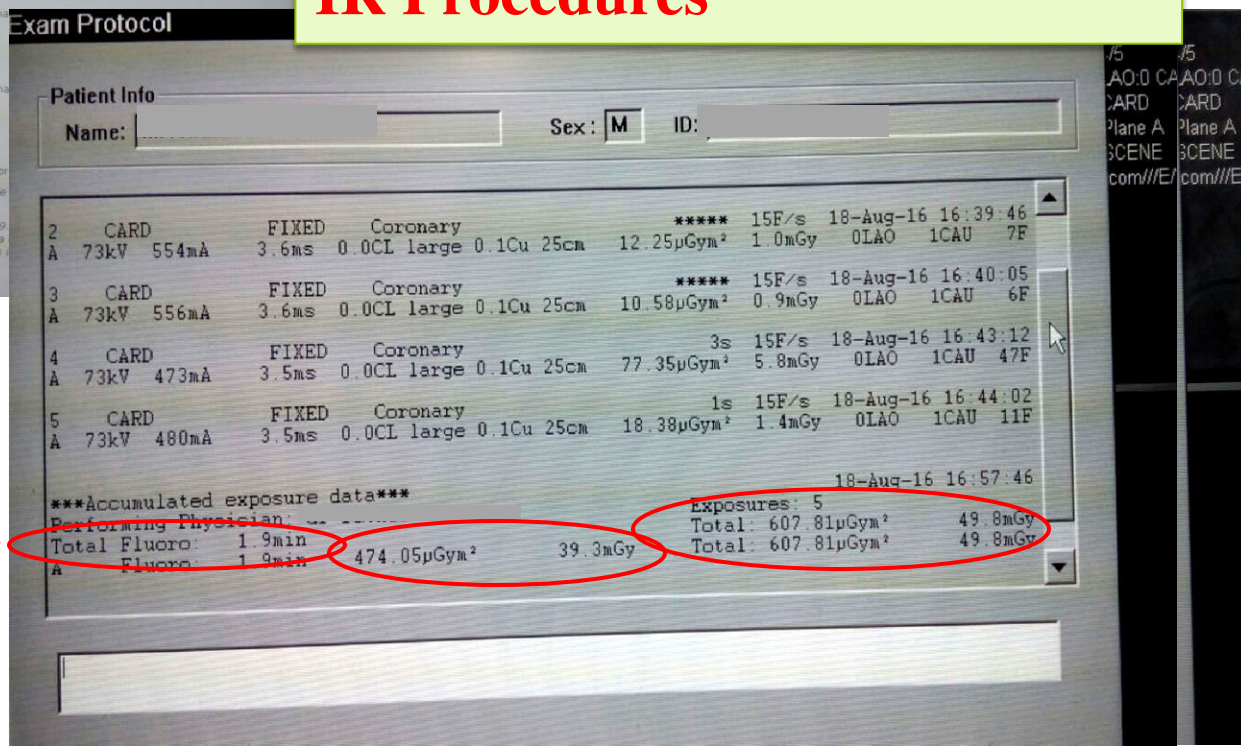
- **Diagnostic Reference Levels** Guide the medical practitioner (DRLs) on optimum doses achievable in routine diagnostic procedures



Patient Dose Record in IR system

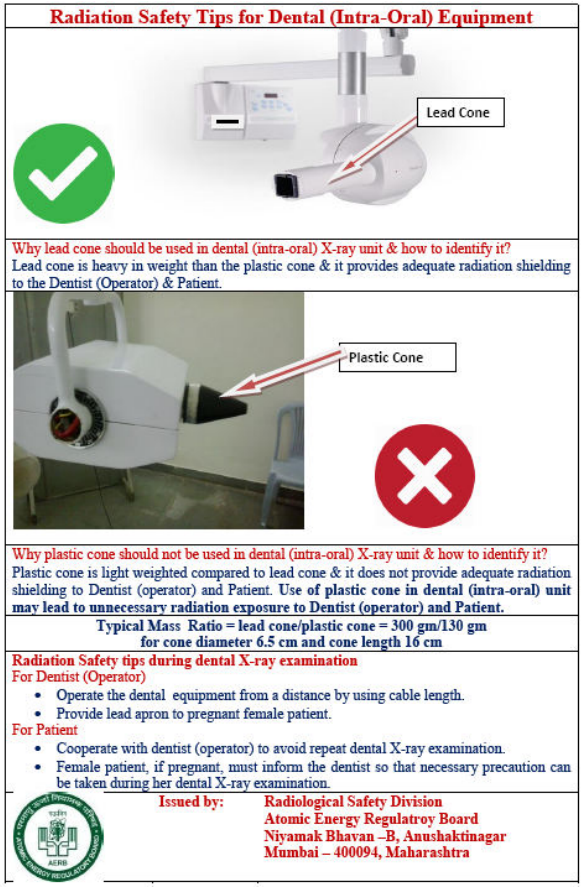


IDENTIFY THE DOSE AND TIME DISPLAYS ON THE MONITOR. **Maintain a Record of the Patient Doses in IR Procedures**



Real-time DAP values and dose are displayed on monitor

Initiatives of AERB



Safety Posters

Interactions with professional associations

Atomic energy team seals X-ray units in city hosps

Crackdown on MYH, Several Pvt Hospitals

TIMES NEWS NETWORK

Indore: A team of the Atomic Energy Regulatory Board (AERB) on Thursday found MY Hospital violating norms set to operate various kinds of X-ray equipment, thereby exposing patients and staffers to radiation hazard. In a surprise drive, the team from Mumbai sealed one X-ray unit in the facility and issued notices stating that seven other units would be shut down if the hospital management fails to secure an AERB license within the next 30 days.

"Apart from the license, the team checked availability of trained operators, room space, thermoluminescent dosimeter (TLD) badges, lead apron, lead lined door and width of X-ray unit's wall -- which should be at least nine inches," AERB scientific officer BK Singh told TOI.

The team took an undertaking from MYH authorities that all windows of the X-ray units which were found open during the inspection will be closed down permanently to stop spread of radiation in the surroundings.

Dharmendra Khatke

An AERB team member sealing X-ray unit at MY Hospital

"Non-compliance can be hazardous for patients & staffers. It increases possibility of cancer, cataract and hair-fall

Arti Kulkarni, AERB

▶Continued on P 4

Special Inspections & Enforcement Actions

Challenges and Way Forward

- Enhancement of radiation safety awareness among users' of X-ray equipment
- Establishment of Diagnostic Reference Levels to optimize medical exposures
- Provision of Referral Guidelines to the referring medical practitioners to take informed decisions
- Ensuring Operational safety training commensurate with advancement in technology
- Use of Patient dose recording and monitoring system in hospitals, especially for high dose imaging systems.
- Strengthen reporting of abnormal doses or radiation injuries
- Standardize professional training programs for radiation workers

CONCLUSION

- Effective regulatory framework exists for governing control over radiation sources/equipment used in medicine
- Radiation safety is ensured through inherent built-in safety features in the design (verified through Type Approval) & operational controls
- Availability of DRLs and Referral Guidelines will further improve optimization of patient doses
- Involvement by all the stakeholders (AERB, Professional Associations, Health Authorities, Supplier/Manufacturer and end user) required for strengthening radiation protection

Prime Responsibility for Safety lies with the Employer/Licensee of the Institution at all times

THANK YOU...

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