



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 ■

**Terrestrial
Radiation from
rocks and soil**

Medical X
Rays

Fallout from
Weapon
Testing

Buried
RadioActive
Waste

Nuclear
Power Plants

Dental X Rays

Extra Cosmic Rays
from Air Travel

**Cosmic
Rays**

**Radon &
Daughters**

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





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



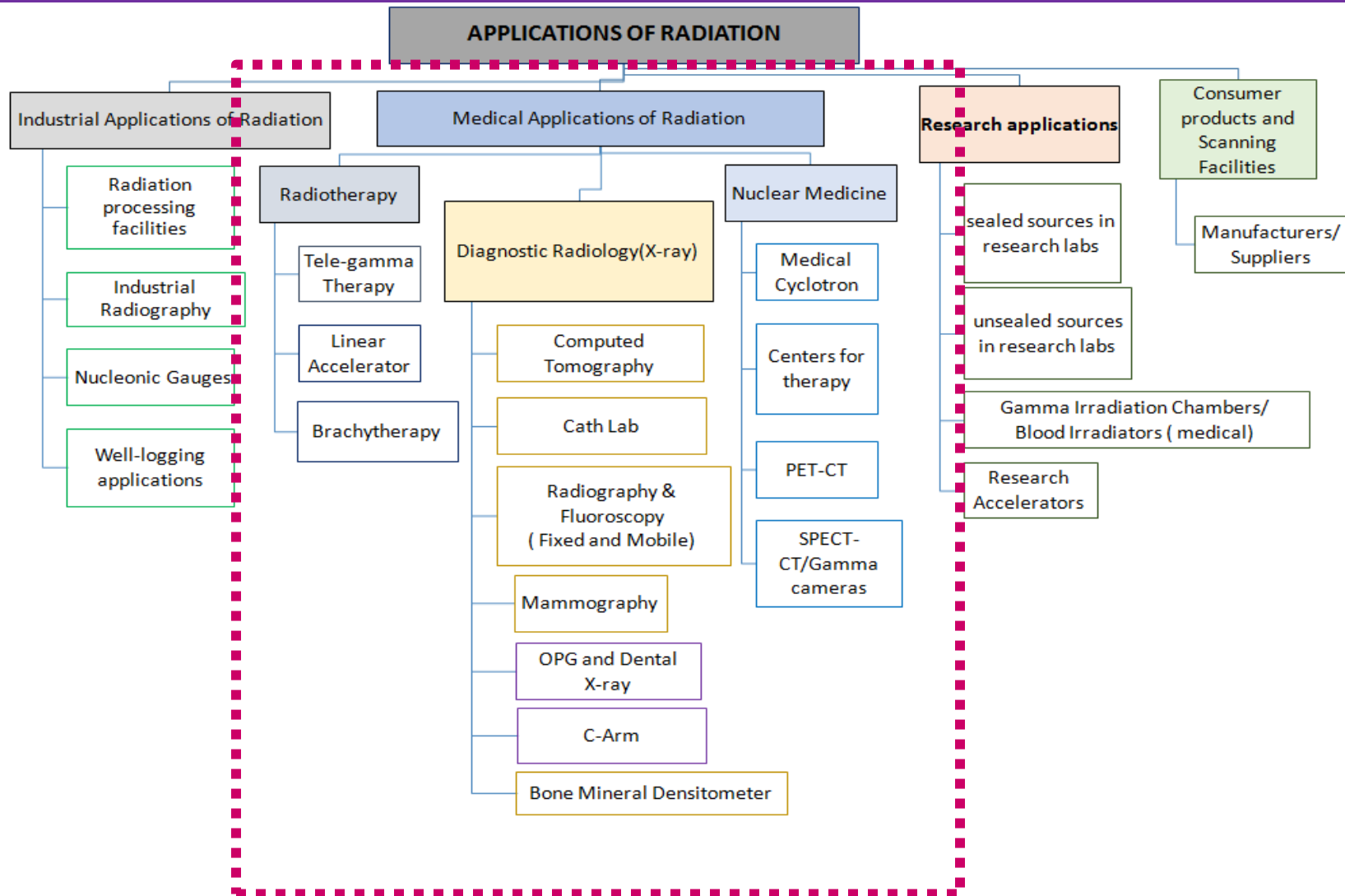
To Ensure that the “ *use of ionizing radiation and nuclear energy in India does not cause undue risk to the health of people and the environment.*”

.....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

Therapy

Diagnostic Radiology



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

Nuclear Medicine



389 Institutions and
616 NM equipment

Radiotherapy

Teletherapy



529 Institutions and 1263 Radiotherapy
Equipment

Brachy Therapy



Nuclear Medicine



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 : 4×10^6 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

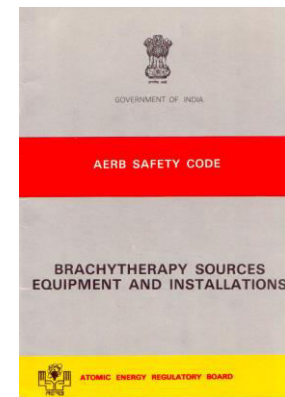
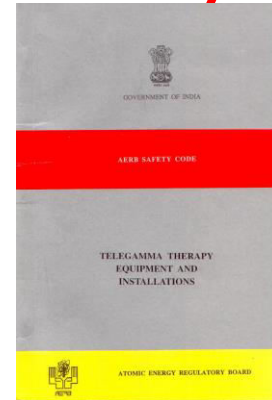
(Atomic Energy Radiation Protection) Rules, 2004)

❖ 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

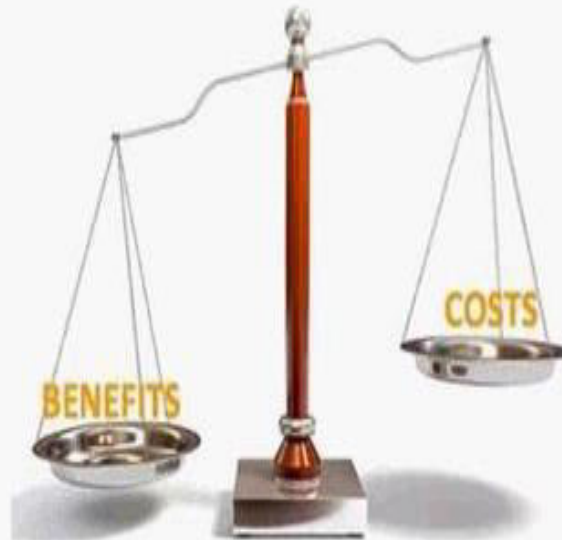
AERB safety code AERB/SC/MED-3 (rev.2), 2016 on “medical diagnostic x-ray equipment and installation”

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)



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



Lesson 1

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)



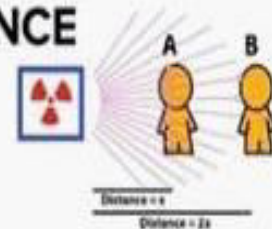
TEAM WORK



TIME



DISTANCE



SHIELDING



Quality



OPTIMIZATION OF DOSES

Dose vs. Noise

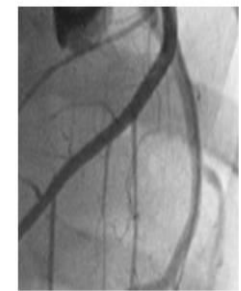
- ▶ All Justified medical exposures should ensure that the doses are such that
 - ❑ Maximum information is obtained through minimum possible doses to the patient i.e, **Acceptable quality images with minimum patient dose**
 - ❑ Dose to the operators/occupational workers is As Low as Reasonably Achievable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



2 μ R per frame



15 μ R per frame



24 μ R per frame

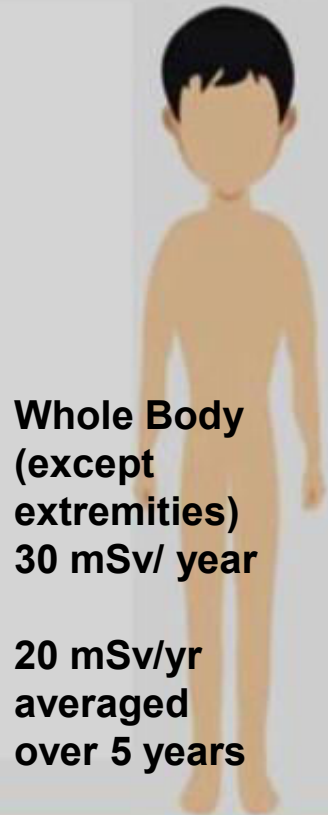
Crisp Images = increased dose to patients ..

Settle for acceptable quality images

Principles of Radiation Protection -3

DOSE LIMITS PRESCRIBED BY AERB

Personnel



Whole Body
(except
extremities)
30 mSv/ year

20 mSv/yr
averaged
over 5 years

Public



Whole Body
1 mSv per
year

Patients



**NO
LIMITS !**

Local DRLs to
be established
for optimizing
the dose to
patients.



RADIATION DOSE MONITORING – PERSONNEL MONITORING

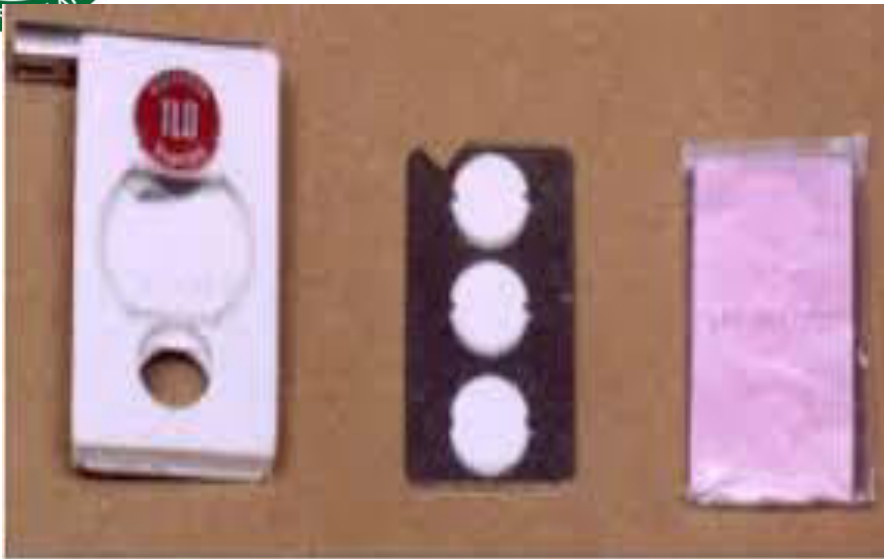


Exposure to any worker in excess of 10 mSv during a monitoring period (3 months in case of medical applications) needs to be investigated by the institution and report sent to AERB for review





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

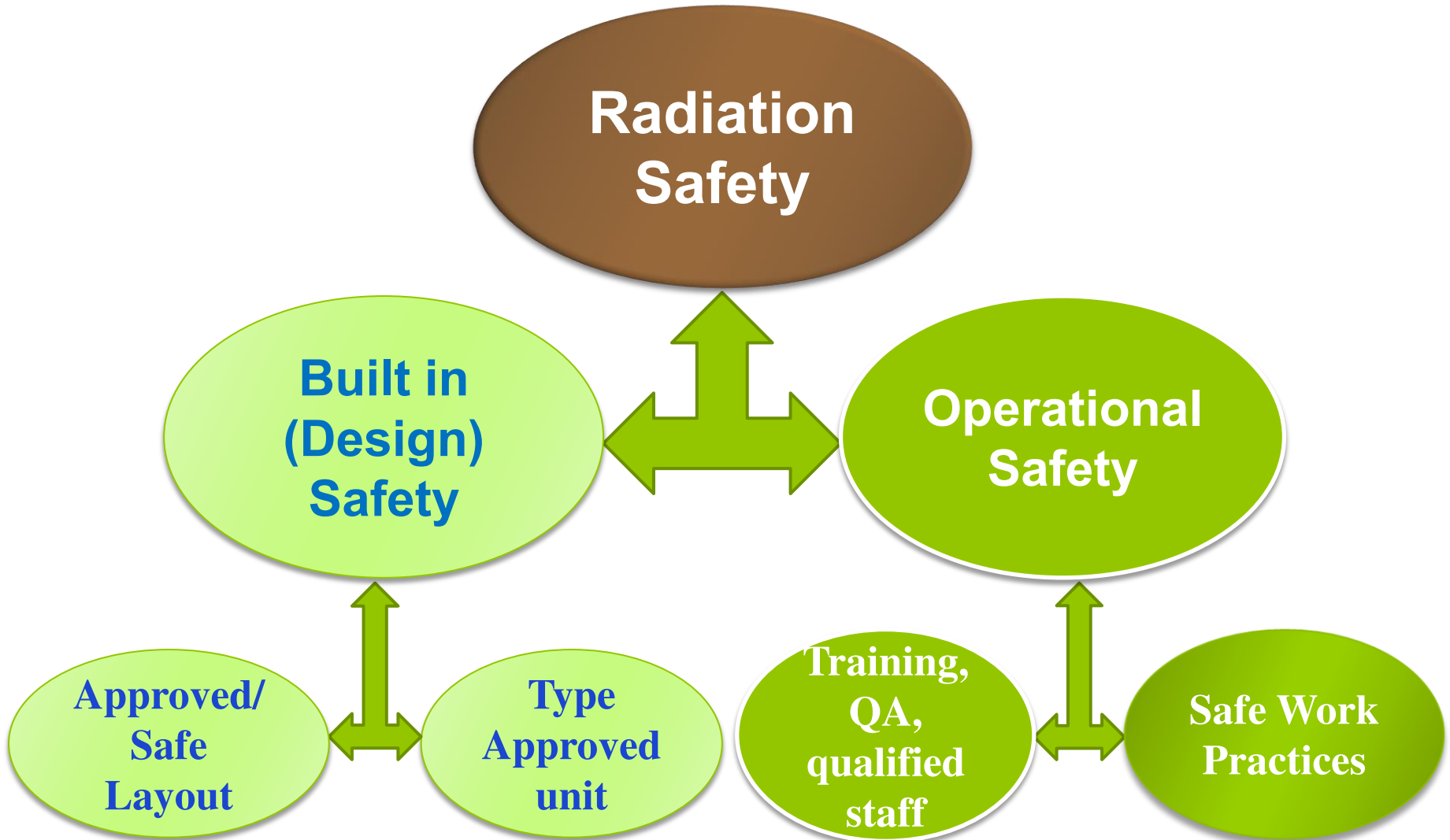
Consenting Process

(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 approved equipment

- ✓ BIS standards IS 7620
- ✓ IS 13450 (part 2/sec 43) – x-ray equipment for
- ✓ IS 13450 (part 2/sec 44 – Computed Tomography
- ✓ IS 13450 (part 2/sec 45)/ IEC60601-2-45:2001
- ✓ IEC 60601-2-63 (Part2-63) Dental (extra-oral) equipment
- ✓ IEC 60601-2-65 (Part2-65) Dental (intra--oral) equipment
- ✓ **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)**

Use of AERB Type Approved Equipment

Procuring Equipment From AERB Authorized Suppliers /Agencies

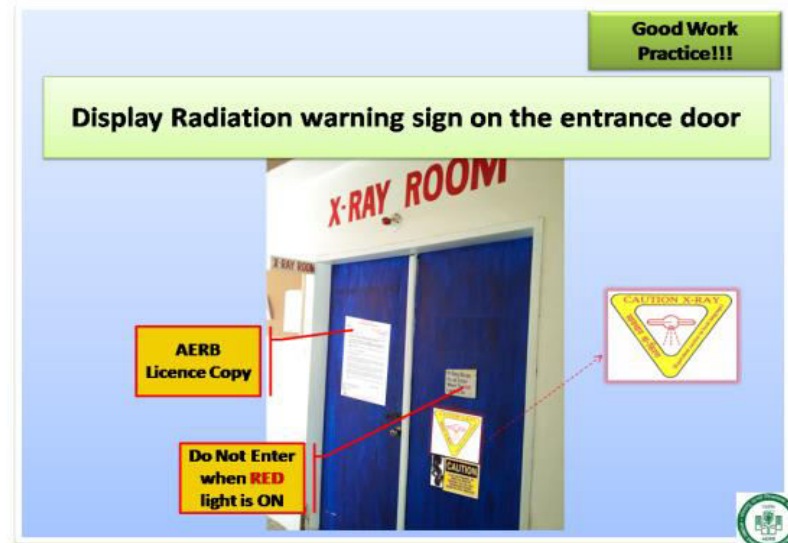
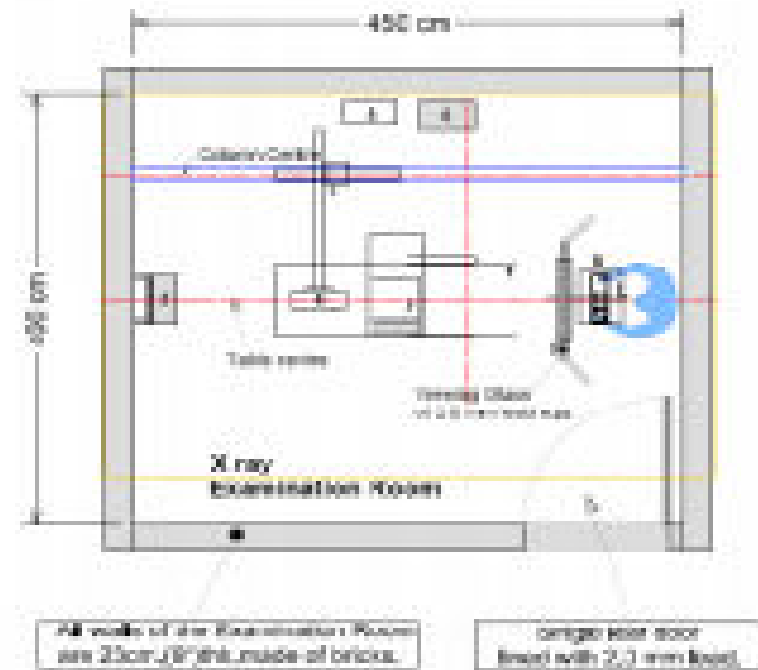
Obtaining Prior Permission for procuring radiation equipment and

Installing such equipment approved/safe rooms

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

Guidelines

▼

Unregistered Institute Excessive Exposure Investigation Report Submission

▼

Processing time for issuance of Regulatory Consents

▼

Help to operate eLORA System

▼


Know Your Application Status

Institute Registration Application

Radiation Professional Registration Application

Verification of Consent/Document issued through eLORA

eLORA Application Processing Statistics



To know more about number of

Click here for details

Frequent Queries

RP/Institute registration status | Reason for non-acceptance

Correction in e-mail id and mobile no. | Login issues | Profile/role issues | Practice issues

Check application status | Correct submitted data

Institute Registration | Step by step help | Raise an issue to AERB

Registration of RP | Training Courses | Feedback

Authorised QA/Service/Supplier for DR

TA equipment | List of survey meter/dosimeter suppliers

For regulatory support you may contact Help Desk No. 022-25990675 during working days between 10:00 AM - 05:00 PM **Now**

Login

☒ Institute ☐ Radiation Professional ☐ RSO

Username ^{*}

Password ^{*}

Practice ^{*} --Select One--

Institute Role ^{*} --Select One--

Installation Type ^{*} --Select One--

Login

Forgot / not received my password

Forgot / not received my User Id

Forgot/Wrong email id & mobile no

Registration Form


Register Institute

Register Radiation Professional (RP)

Register Incoming Employer - after Initiation of Employer Change Process

Disclaimer

CAUTION X-RAY



सावधानता से चलिए

Equivalent caution in local language

Ways to achieve Radiation Safety in Diagnostic Radiology Facility

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



OPERATIONAL SAFETY – RADIATION WORKERS

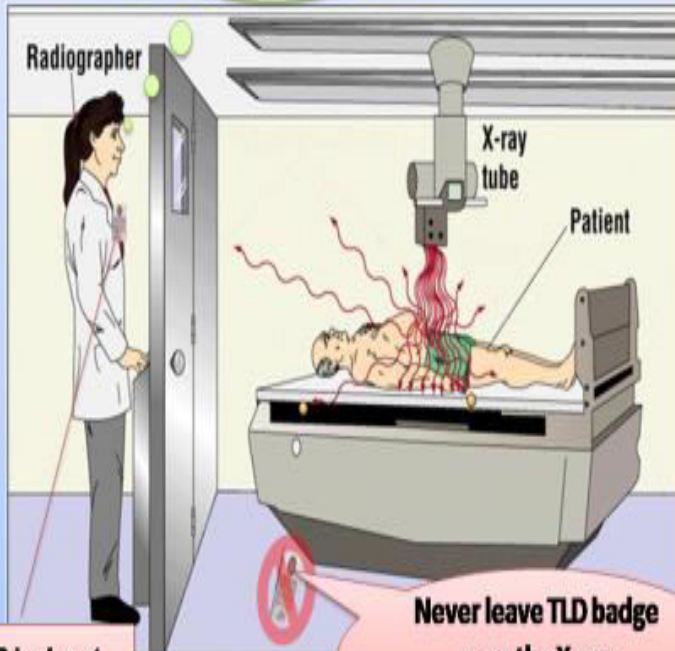
- Handling of equipment by qualified and certified persons
- Work Place Monitoring – Radiation Survey
- Use of Personnel Monitoring Services (PMS)
- Use of Radiation Protective Accessories
- Periodic Quality Assurance Testing of equipment
- Periodic Servicing and Maintenance
- **Following Safe Work Practice**



Safe Work Practice-Operational Guidelines

Radiation Safety in Radiography

Always work behind a protective barrier (min. 1.5 mm lead)



Wear TLD badge at the chest level

Never leave TLD badge near the X-ray equipment



Radiation Safety in Mobile X-ray

Operate the mobile X-ray machine from a distance using control cable extension, Use Lead Apron

Always use the TLD at the chest level, inside lead apron

Extendable Control Cable





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

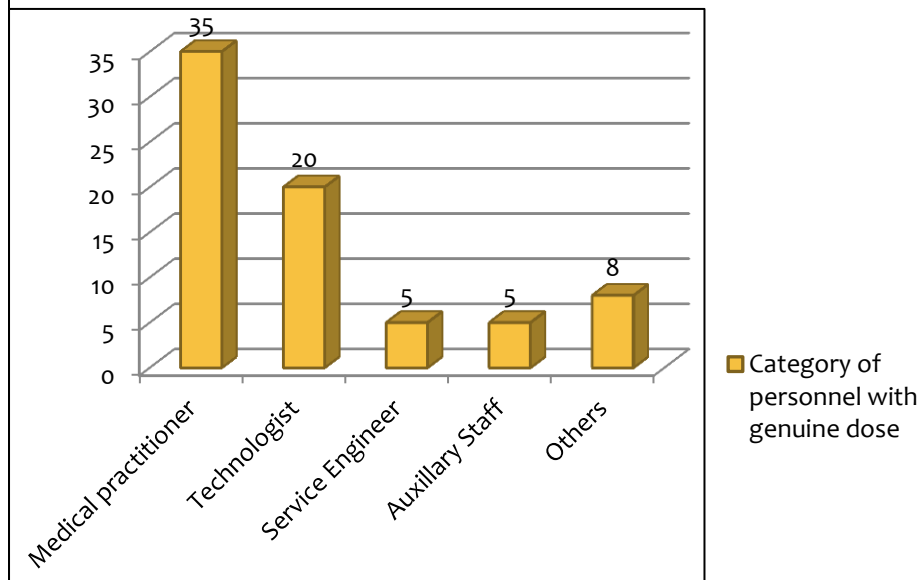
Use of equipment in unshielded rooms





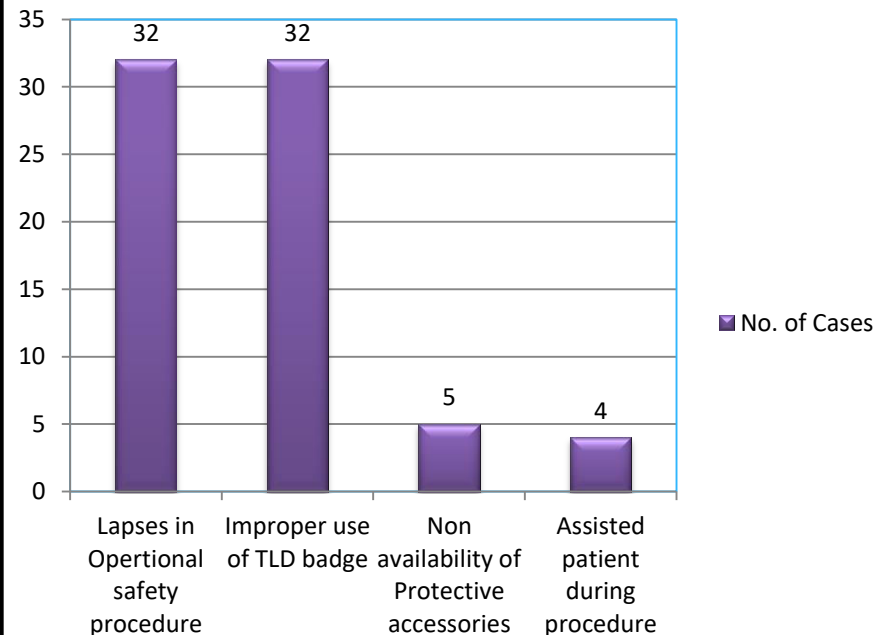
Exposures above IL (in a 5 year period) to Cathlab Personnel

Category of personnel with dose > IL



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

Causes





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 (flourosocopy)
- 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?

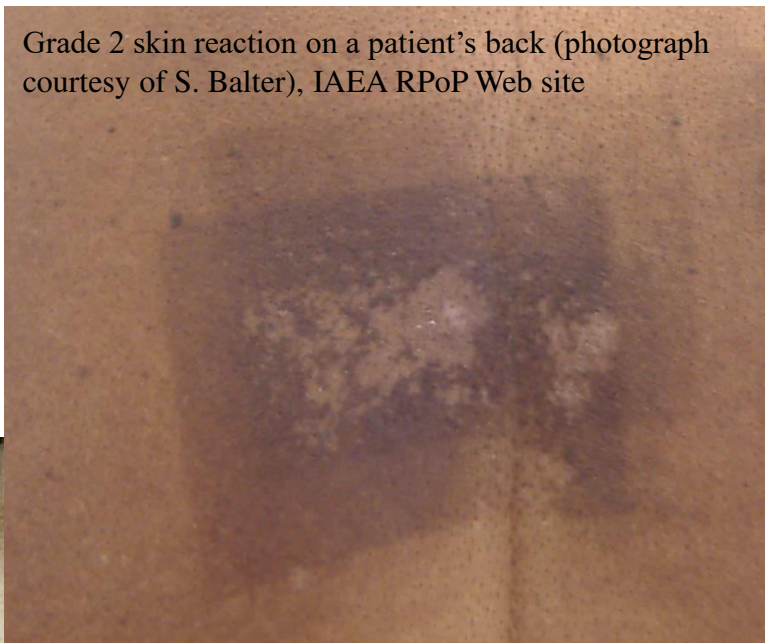
Restriction on motion appropriate?

Technical setting is appropriate?



Reported Injuries due to IR procedures

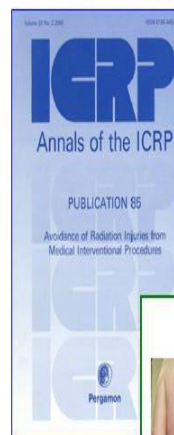
Grade 2 skin reaction on a patient's back (photograph courtesy of S. Balter), IAEA RPoP Web site



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

First Case reported 1993

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



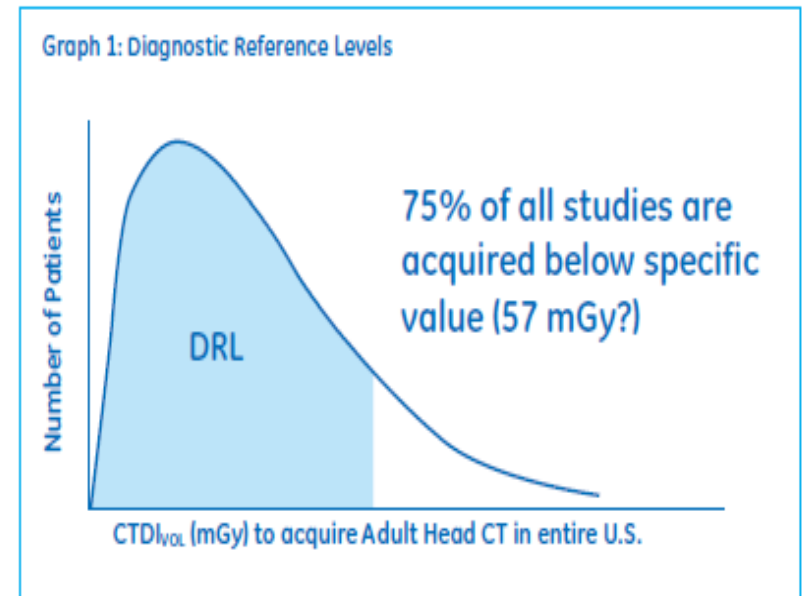
ICRP recommend:

- ❖ 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





**Real-time DAP values
and dose are displayed
on monitor**

Exam Protocol

IR Techniques

Patient Info

Name:

Sex:

ID:

2	CARD	FIXED	Coronary	*****	15F/s	18-Aug-16 16:39:46		
A	73kV 554mA	3.6ms	0.0CL large 0.1Cu 25cm	12.25 μ Gym ²	1.0mGy	OLAO 1CAU 7F		
3	CARD	FIXED	Coronary	*****	15F/s	18-Aug-16 16:40:05		
A	73kV 556mA	3.6ms	0.0CL large 0.1Cu 25cm	10.58 μ Gym ²	0.9mGy	OLAO 1CAU 6F		
4	CARD	FIXED	Coronary	3s	15F/s	18-Aug-16 16:43:12		
A	73kV 473mA	3.5ms	0.0CL large 0.1Cu 25cm	77.35 μ Gym ²	5.8mGy	OLAO 1CAU 47F		
5	CARD	FIXED	Coronary	1s	15F/s	18-Aug-16 16:44:02		
A	73kV 480mA	3.5ms	0.0CL large 0.1Cu 25cm	18.38 μ Gym ²	1.4mGy	OLAO 1CAU 11F		

Accumulated exposure data

Performing Physician:

Total Fluoro: 1.9min

A Fluoro: 1.9min

474.05 μ Gym²

39.3mGy

Exposures: 5

Total: 607.81 μ Gym²

Total: 607.81 μ Gym²

49.8mGy

49.8mGy



Initiatives of AERB

Radiation Safety Tips for Dental (Intra-Oral) Equipment

Why lead cone should be used in dental (intra-oral) X-ray unit & how to identify it?
Lead cone is heavy in weight than the plastic cone & it provides adequate radiation shielding to the Dentist (Operator) & Patient.

Why plastic cone should not be used in dental (intra-oral) X-ray unit & how to identify it?
Plastic cone is light weighted compared to lead cone & it does not provide adequate radiation shielding to Dentist (operator) and Patient. Use of plastic cone in dental (intra-oral) unit may lead to unnecessary radiation exposure to Dentist (operator) and Patient.

Typical Mass Ratio = lead cone/plastic cone = 300 gm/130 gm
for cone diameter 6.5 cm and cone length 16 cm

Radiation Safety tips during dental X-ray examination

For Dentist (Operator)

- Operate the dental equipment from a distance by using cable length.
- Provide lead apron to pregnant female patient.

For Patient

- Cooperate with dentist (operator) to avoid repeat dental X-ray examination.
- Female patient, if pregnant, must inform the dentist so that necessary precaution can be taken during her dental X-ray examination.

Issued by: Radiological Safety Division
Atomic Energy Regulatory Board
Niyamak Bhavan -B, Anushaktinagar
Mumbai - 400094, Maharashtra



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 team member sealing X-ray unit at MY Hospital

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

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

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.

► 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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www.aerb.gov.in