

## Global Initiatives on Radiation Safety in Healthcare (Infrastructure)



Government of India

**AERB**

Atomic Energy Regulatory Board

**Dr. N. Ramamoorthy**

Chairman, SARCAR and Member, ACNRS  
AERB, Mumbai



Ex-Director, NAPC/IAEA, Vienna

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## Content Outline + Disclosure & Disclaimer

- Background information on radiation medicine (RM)
- Major wings of RM and respective safety aspects
- Global initiatives & support: IAEA, WHO, ... : guidance & documents, HRD, review/audit, ...
- RM practice-specific issues and challenges
- Human (Man) Factor & Machine Aspects
- Needs, Advocacy for Adoption & Sustenance



- Professional views & analytical perspectives →

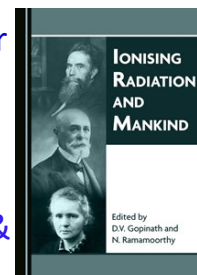
Coverage in broad context: global + India-specific → includes valuable inputs of RASD, AERB & Prof. Madan Rehani

- Views are not however attributable to AERB, IAEA

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## Preamble - Background

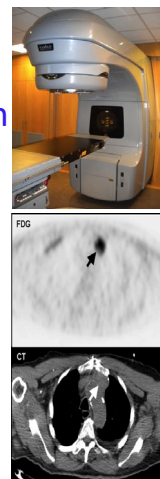
- Medical applications of radiation constitute the major segment of nuclear and radiation utilisation globally.
- Diagnostic & therapeutic procedures using ionising radiation are essential for patients with many diseases or dysfunction.
- UN bodies - WHO, IAEA, ILO - provide support to Member States (MS) for safe, effective deployment.
- Professional bodies at international & national level play similar/complementary roles, e.g. ICRP, IOMP, IARP, AMPI
- Roles of national regulatory bodies dealing with nuclear & radiation safety (e.g. NRC, ASN, AERB) are imperative.



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## Major Roles of Radiation in Medicine & Quantum/Volume of Global Use

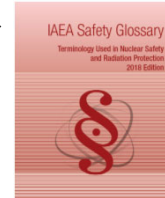
- Ionising radiation (from radiation sources) is used in 3 major branches of medicine → radiation medicine (**RM**)
- Radiation Oncology/Therapy (RO/RT) - cancer care: 8+ million treatment/year
- Nuclear Medicine (NM): 40+ million procedure/year
- *Diagnostic & Interventional Radiology (DR)*: 4.5+ billion/year
- few million persons - medical, paramedical, technical staff - engaged in delivering RM services to patients → large community of Radiation Professionals (RP)



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## Radiation Protection and Safety (RS) in RM

- Harnessing the benefit of radiation-based procedures in healthcare → involving use of sealed sources (in RT) & open sources (in NM)
- Involves radiation exposure, occupational and medical →
  - Workers (RP, trainees, other persons/staff, service team, ...)
  - Patients
  - Carers & Comforters
- Basis: Justification, Optimization, Dose Limits, ALARA - Management for Safety → Radiation Protection Programme (RPP)
- Safety Code: .....; Design of Radiation Sources, Equipment and Installation; Operational Safety; Handling Incidents/Emergency Situation; .....
- RSO/RPO: designated, empowered, effective functioning *-Human Factor*
- Licensees' & Employees' responsibilities (binding roles) *-Safety Culture*

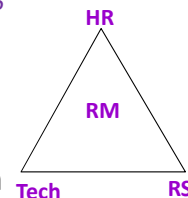


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## Addressing Radiation Safety in RM Practices (RT, NM focus)

### Man, Machine (Method, Management)

- 2 key domain aspects for the Man and Machine *-The National Commission for Allied and Healthcare Professions Act, 2021 (RP for RM)*
- qualification & eligibility for RP in RM *-Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022??*
- core competency in RM procedures *per se*; capability to manage associated radiation safety requirements
- qualification & approval of Machine in RM
- system technology per se; radiation safety features of the system
- **mostly governed by two distinct national entities, to work in unison**
- interface - synergy of QMS and compliance with safety requirements
- QA, dosimetry, calibration, SSDL use, RPP, PSR, RSO/RPO services, .....



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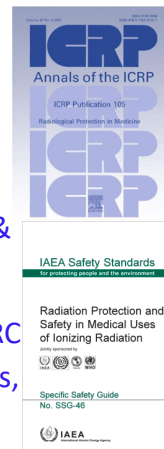
## Managing Radiation Protection & Exposure in RM

- multi-pronged approach to address & ensure safety and
- unfailing commitment of management - licensee, employer, organization -
  - to workers - i.e. controlling occupational radiation exposure to remain below prescribed dose limits - and
  - to patients - i.e. ensuring efficacy without compromising safety
- Radiation Safety Culture in RM encompassing all stakeholders and every action essential to improve the protection & safety of:
  - patients - stipulations involve medical councils or similar body, health ministry, radiation safety regulator (*medical decision finally*)
  - workers exposed to radiation - includes regulatory oversight + licensees ensuring radiation safety aspects of the facilities - *i.e. infrastructure, QMS, RPP* - and practices - *i.e. O&M, SOP, E&T (fit-for-the-job)*
- self-evaluation; inter-comparison exercise; LSC; peer review (& audit) of status of adherence to safety & quality; .....

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## Global support aiding Radiation Safety in RM

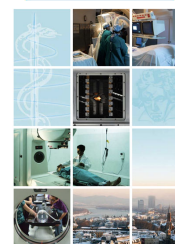
- IAEA & WHO joint roles + associated initiatives → backbone of global support to radiation-based healthcare services
- Professional bodies: expertise based; national entities, others
- National authorities derive much strength from such tools, mechanisms
- e.g. adopting, fostering: standards, DRL (DR, NM), good practices, xxx
- Valuable guidance available in documents compiled by experts
  - international level - e.g. ICRP 105 - Radiation Protection in Medicine; IAEA & WHO - SSG-46, STI/PUB/1775 - Radiation Protection and Safety in Medical Uses of Ionizing Radiation
  - national authority, e.g. Australia-ARPANSA, France-ASN, India-AERB, US-NRC
- Advocacy of Radiation Safety Culture in RM - to encompass all the practices, facilities, stakeholders
- Review/Audit of RM practices by external experts; e.g. IAEA schemes - QUATRO, QUANUM, ...



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## Radiation Protection of Patients of IAEA & other ones

- <https://www.iaea.org/resources/rpop> - RPOP for Health Professionals, Patients & Public (*Credit: Dr Madan Rehani*)
- highly popular as the leading resource for practitioners, patients and public on the safe, effective use of radiation in medicine.
- focus on: medical exposure, esp. to patients & means to minimise + avoiding unnecessary exposures
- xxxx (largest number of hits!)
- Bonn Call for Action seeks to foster coordinated work to address issue in radiation protection in medicine; issued at 2012 Intl. Conf. Bonn, Germany; strengthened in follow-up Conf. Vienna, 2017 (<https://www.who.int/publications/m/item/bonn-call-for-action>)
- <https://www.massgeneral.org/imaging/approach/professional-services/global-outreach-radiation-protection> (*Dr Madan Rehani*)

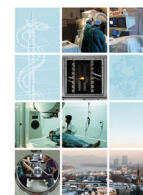


BONN CALL FOR ACTION  
10 Actions to Improve Radiation Protection  
in Medicine in the Next Decade

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## Bonn call for Action: 10 Actions to Improve Radiation Protection in Medicine in the Next Decade

- Enhance the implementation of the principle of justification
- Enhance the implementation of the principle of optimization of protection and safety
- Strengthen manufacturers' role in contributing to the overall safety regime
- Strengthen radiation protection education and training of health professionals
- Shape and promote a strategic research agenda for radiation protection in medicine
- Increase availability of improved global information on medical exposures and occupational exposures in medicine
- Improve prevention of medical radiation incidents and accidents
- Strengthen radiation safety culture in health care
- Foster an improved radiation benefit-risk-dialogue
- Strengthen the implementation of safety requirements globally



BONN CALL FOR ACTION  
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## RM: Typical Issues & Challenges - Global & National

- **RT & NM**

- qualified staff - availability, education & training (E&T); RSO; approval for equipment, system; QA; calibration; continual technology advances; .....



- **DR**

- ~~huge number of diverse facilities~~ *-The National Commission for Allied and Healthcare Professions Act, 2021 → RP for RM*

*-Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022??*

### HR-related aspects

- availability v/s attrition; career prospects related; location-based; keeping pace with tech advances - CME, CAPE?; greener pasture attraction; .....

### Vendor support aspects

- certified equipment/system; AMC/PMC; spares; obsolescence; QA; training; (remote) tech support; commercial competition; mergers; ...

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## Radiotherapy (RT)

- 50-70% of all cancer patients need radiation treatment at some stage
- Time-tested use of radiation - radioisotope sources  $^{60}\text{Co}$ ,  $^{192}\text{Ir}$  & machine-generated radiation (electrons, protons, ...) both in use → EBRT, BT
- The latter has distinctly superior advantages → continual advances of technology & systems - e.g. Linac - MLC, IGRT, IMRT, Cyber-knife, Hadron
- Use of RI sources ('telecobalt' units) declined & reducing, except for Brachytherapy - required to treat certain cancers, e.g. cervical cancer
- Dosimetry management is a crucial requisite for safe, efficacious treatment

*Treatment involves multiple sittings for receiving fractionated dose following imaging + treatment planning; specific/key roles of Radiation Oncologist (RO), Medical Physicist (MP), RT Technologist*

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## Nuclear Medicine (NM) Practice - Indian Scene

- ~560 NM centres in India; RSO for every centre
- 677 RSOs are working in NM centres (1.2 RSO/centre)
- 72 candidates are annually qualifying for RSO-NM
- 35 new NM centres/year licensed (average over 10 years)



[AERB/RF-MED/SC-2 \(Rev. 2\)](#)

[NM Facilities](#)

### Challenges

- Qualified Staff - Radiation Professional (RP) - Availability, Sustainability
- QA of NM imaging equipment
- Rapid technological advances & complexity in NM imaging systems
- Radioactive waste management for NM therapy procedures
- Calibration related
- Radiopharmacy operations-related; large amounts of open sources



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## Select DR Facilities & RSO Status: Indian Scene

- RSO approval issued only for DR facilities with Computed Tomography (CT) and Interventional Radiology (Int.R) equipment
- e-LORA records →
- 11048 institutes have CT and Int.R equipment
- ~24790 radiation safety professional (RP) registered; eligible for RSO
- *Sheer huge volumes of such DR pose regulatory and safety challenges!*
- *Self-control, Self-regulation, Discipline essential for safe DR services!?*

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## *Patient-related issues of Radiation Safety in RM*

- Diverse status of health (+ literacy) of patients requiring RM →
- Radiation Safety dependent on certain degree of 'patient abilities' →
- Impact on: image quality; treatment planning; therapy efficacy; radioactive waste (in NM); report to referral physician;..... →
- Safety Requirements & Stipulations to reckon with the above →
- e.g. repetition of procedure & additional exposure - not uncommon  
→ not only medical exposure to patients, but also occupational exposure to workers
- Fostering the use of: guidance, good practices, lessons learnt, sharing (reporting) experience, ... → Role of global/professional bodies

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## *Needs, Advocacy for Adoption and Sustenance*

- Focus on fostering holistic approach to safety (& security) in RM - Leveraging international advisory, guidance, good practices, .....
- Nurturing Safety Culture and harnessing synergies of safety & quality in RM services
- Management commitment + Responsible conduct by every member in the RM team
- Human Resources - competency & availability, consistent with tech. advances in RM
- National responsibility in setting laws, norms, policy, .... and in inter-authority coordination + facilitating effective regulatory enforcement

*Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022??*

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## The Bottom Line!

- Radiation applications in healthcare are far too important to be left to the impact of any vulnerability, vagary, gap in safety compliance.
- Overarching duty of global/national RM community should be to sustainably ensure safety of facilities & practices, and in turn of patients, occupational workers & associated persons.

*'Discretion is the better part of valour.'* - WS

'Prevention is better than ~~cure~~ mitigation!' - NR

**Thank you**

Q & A - Discussion  
nramasta@gmail.com

