Challenges in Safety Regulation of R&D activities for Advanced Technologies in DAE units

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Outline

- Introduction
- R&D in Advanced Technologies under Regulation
- Typical hazards associated with High Power & High Energy Advanced Technologies
- Legal Framework for Safety Regulation
- Nature of R&D projects and Challenges in Safety Regulation
- How AERB regulates?
- Way Forward..

Introduction ….1/2

Advanced Technologies

In the area of Advanced Technology, DAE has established capabilities in accelerators, laser systems, super computing, astronomy Robotics etc.

These technologies have many applications in the filed of medicine, industry and research.

BARC, IGCAR, VECC, RRCAT and other aided institutes like SINP, TIFR, IPR etc are engaged in the development and applications of these technologies

Introduction ….2/2

Before moving to Challenges in Safety Regulation of R&D activities for Advanced Technologies in DAE units , we would briefly discuss

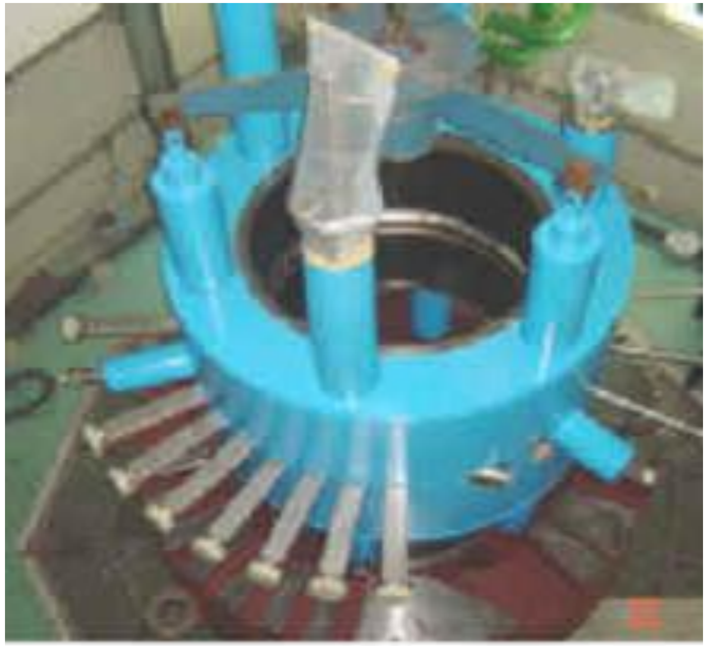
- Examples of R&D in Advanced technologies under Regulation and
- Typical hazards associated with them.

R&D in Advanced Technologies under Regulation- some examples

- High Energy Synchrotrons- ex. 2.5GeV INDUS-2 at RRCAT
- Acceleration of radioactive ions- ex: Radioactive Ion Beam facility at VECC
- Heavy Ion Acceleration at Superconducting Temperatures- ex: Super Conducting Cyclotron at VECC
- Liquid Metal Target interaction with high current proton beams eg. Medical Cyclotron at Kolkata
- High Power Lasers: e.g: Terawatt and Petwatt laser project at RRCAT

Hazards Associated with Advanced Technologies…1/9

- Cryogenic Safety



- Cold burns
- Materials become brittle
- Over-pressurisation
- Oxygen deficiency-asphyxiation

-Pressure relief devices, ventilation, PPEs

Hazards Associated with Advanced Technologies….2/9

- High Voltage Safety

(>1000V AC and 1500V DC)

- electric shocks

  Accidental contact with high voltage supplying sufficient energy may result in severe injury or death.
- Arcs --Fire
- blasts and fault current

- *Inbuilt features to prevent discharge and corona generation, insulation, earthing, interlocks, faraday cages, etc*

Hazards Associated with Advanced Technologies….3/9

- Magnetic Field

- The biological effects of strong magnetic fields are still not fully established. However, there are clear hazards of strong magnetic field on the impact on implanted medical devices, example pacemakers

- *- use of non-magnetic tools, cordoning and warning signs for magnetic fields greater than 0.5 mT, operated only by trained and qualified personnel.*

Hazards Associated with Advanced Technologies….4/9

- EMF and Radio frequency

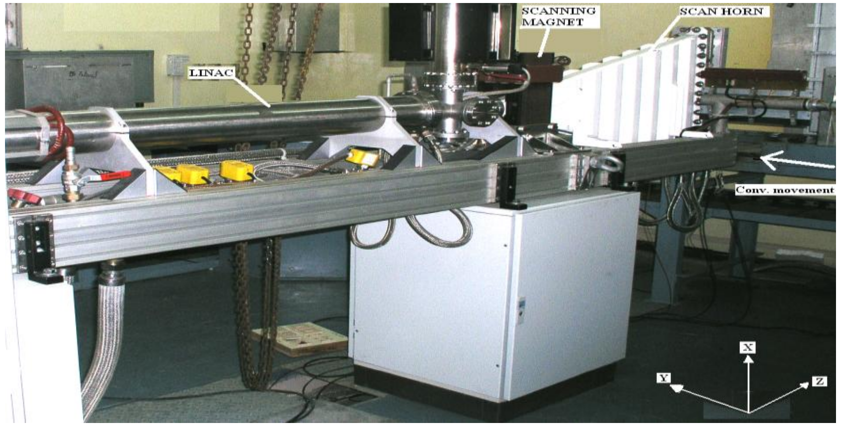
EMF radiation can be absorbed by body tissue and can give rise to temperature increases in exposed tissue, such as the lens of the eye.

Burns can occur when EMF induced current enters the body through contact between a small area of the body (such as finger) and an electrical conductor.

- *- access control, isolation, shielding and screening of equipment etc*

Hazards Associated with Advanced Technologies….5/9

- Exposure to Ozone

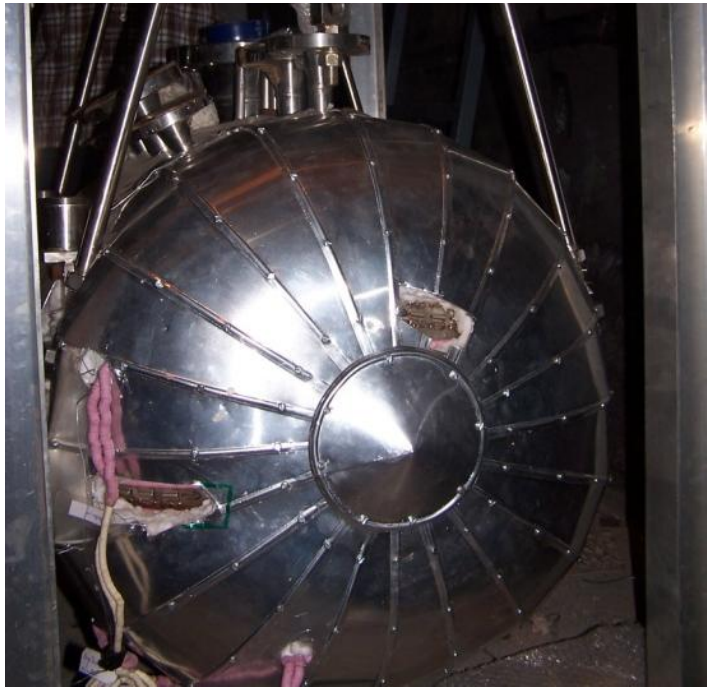


In electron accelerators, there is a possibility of ozone production. Ozone is known to be injurious to the respiratory tract. The permissible level of ozone is 0.1 ppm for light work.

- *- ventilation, time delay in interlocked doors, ozone monitoring etc*

Hazards Associated with Advanced Technologies….6/9

- Liquid Metal Handling

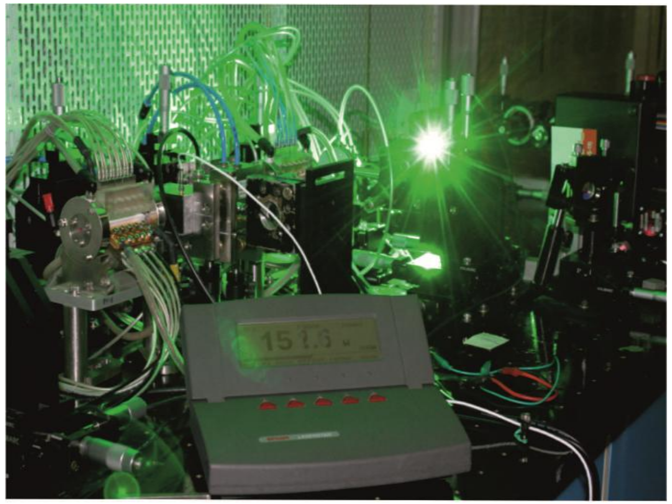


While Lead vapors pose the hazards of lead positioning, Lead Bismuth eutectic poses the hazard of exposure from polonium-210 and also because of its highly corrosive nature, may lead to corrosion fouling or corrosion embrittlement.

- Dump tank, confinement, ventilation, etc

Hazards Associated with Advanced Technologies….7/9

- Laser Safety



The most common risk from laser is damage to the eyes. Other common laser concerns include skin damage, electrical hazards from high-energy power sources, Chemical exposure, fire/explosion hazards, and exposure to cryogenic materials. Many lasers emit invisible ultraviolet or infrared radiation.

- Access control, use of safety goggles etc

Hazards Associated with Advanced Technologies….8/9

- Conventional hazards

- Fire hazards- flammable substances, electrical cables
- Mechanical hazards -guarding of rotating parts, lifting machineries
- chemical hazards- storage of gas cylinders, release of toxic vapours
- Noise, Illumination, etc

Hazards Associated with Advanced Technologies….9/9

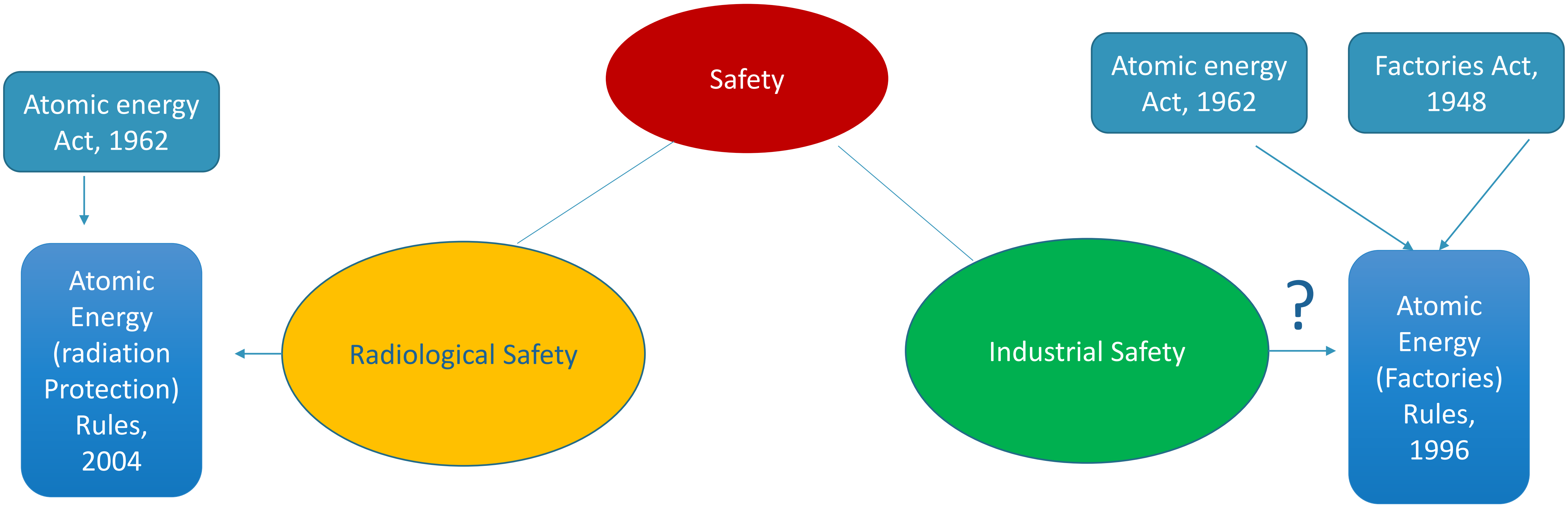
- Exposure to Ionising radiation

Prompt radiation- Bremsstrahlung X-rays, photo neutrons, low energy X-rays

Residual radiation- due to induced activity (components, cooling water)

- *Time & occupancy limitation, shielding, Search and Scram system, access control, safety interlocks, Audio-visual warning systems, etc*

Legal Framework for Safety Regulation



Factories Act definitions..1/2

- ‘Factories’ means: any premises or precincts thereof –

  (i) whereon 10 or more workers are working, or were working, on any day of the preceding 12 months, and in any part of which a **manufacturing process** is being carried on with the aid of power, or is ordinarily so carried on; or

  (ii) whereon twenty or more workers are working, or working on any day of the preceding 12 months and in any part of which a **manufacturing process** is being carried on without the aid of power ,or is ordinarily so carried on,

but does not include (i) a mine subject to the operation of the Mines Act 1952, or (ii) a mobile unit belonging to the armed forces of the Union of India, (iii) a railway running shed, or (iv) a hotel , (v) a restaurant, (vi) eating place., (vii) poly house or (viii) Green house engaged in the activity of floriculture or pomology or high value crops.

Factories Act definitions..2/2

‘ Manufacturing process’ means any process for -

- making, altering, repairing, ornamenting, finishing, packing, oiling, washing, cleaning, breaking up, demolishing or otherwise treating or adopting any article or substance with a view to its use, sale, transport, delivery or disposal; or
- pumping oil, water, sewage, or any other substance; or
- generating, transforming or transmitting power; or
- composing types for printing, printing by letter press, lithography, photogravure or other similar process or book-binding ;or
- constructing, reconstructing, repairing, refitting, finishing or breaking up ships or vessels;or
- preserving or storing any article in cold storage;

Therefore, R&D units cannot be considered as ‘factories’ and Factories Act provisions cannot be directly applied

Nature of R&D projects and Challenges in Safety Regulation…1/4

FLEXIBILITY AND CREATIVITY

- R& D programme to yield fruitful results warrants maximum flexibility and unhindered creativity.
- During R&D stage much of the information required for drawing up the regulatory requirements may not be available
- Regulators require that all the hazards are adequately addressed, submission of various information
- The researcher undertaking the R&D activity may not be aware at that stage. These information will emerge upon only during/after undertaking the research.
- Hence, there is a conflicting requirement and the regulatory demands can be seen to constrain the researcher's 'freedom' and 'creativity.

Nature of R&D projects and Challenges in Safety Regulation…2/4

RELAXATION AND TRADE-OFFS

- In R&D and pilot plants, lot of exemptions are allowed by the Regulator owing to direct involvement of experts who have the complete knowledge and understanding of systems and their safety significance.
- The engineering scale/production scale of operation needs stringent regulation and operational discipline as this activity will be carried out by personnel other than the R&D experts.
- The biggest challenge in such cases of **transition from R&D mode to production mode** is not only to retrofit the plant as per industrial standard but also the inculcation of regulatory discipline.
- The operators need to understand and appreciate the requirements of detailed submissions and stage-wise reviews conducted by the regulatory body during this transition

Nature of R&D projects and Challenges in Safety Regulation….3/4

DEVIATION FROM ESTABLISHED PROCEDURES

- the regulation of first of a kind of such activities is a challenge due to limited safety / regulatory experience.
- while established procedures may be available to begin an R&D project, deviation from these procedures may occur often as a legitimate component of the conduct of R&D.
- Entirely new procedures are often developed through a process of trial and error.
- The creative and uncertain nature of R&D makes the knowledge and expertise of individual researchers essential to the quality of the work and the results.
- It also makes documenting the progress of R&D essential, because the described path will serve as a guide for others to follow, reproduce and will serve as a clear record of problems faced and their solutions.

Nature of R&D projects and Challenges in Safety Regulation…4/4

R&D SCALE TO COMMERCIAL SCALE OPERATION

- At times, requirement of laboratory scale R&D facilities / pilot plants to operate beyond their original intended use, pose further challenge to regulator

- It demands comprehensive safety review with fresh inputs, since certain regulatory requirements were relaxed for R&D and pilot scale facilities which were expected to operate in a limited scale of time or throughput.

How AERB regulates?....1/7

- Specifies requirements in form of Codes, Guidelines etc
- Reviews and Assesses the hazards
- Issues licences
- Monitors and enforces Compliances

- Unique features:
  - *Not by the letter of the rule but by spirit of the rule*
  - *Judgment based on scientific understanding*
  - *Prime responsibility for safety lies with the owner*

Added advantage is matured, qualified operators

How AERB regulates? ….2/7

- Specifying limits

	ICRP recommended limits	AERB prescribed limits
Occupational Worker		
5 years	100 mSv (annual average 20mSv)	100mSv (annual average 20mSv)
One year	50 mSv	30mSv
Life time	1000mSv	1000mSv
Public		
One year	1mSv	1mSv

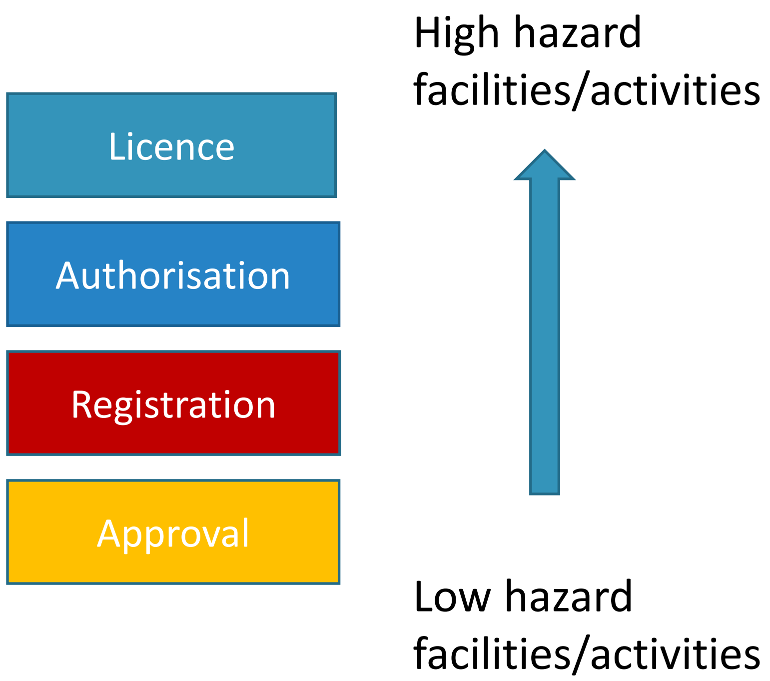
How AERB regulates? ….3/7

Safety Codes and Standards

- Codes (mandatory)
- Standards (mandatory)
- Guidelines (mandatory)
- Guides
- Manuals

How AERB regulates?....4/7

Issuance of Consents: Graded Approach



Exemption- do not warrant regulatory control- normally inherent safe practices such as Cathode Ray Tube in Televisions, activity concentration below exempt levels

Exclusion – not amenable to control ex; cosmic rays, K-40

How AERB regulates?....5/7

Safety Review process

Extent of review commensurate with the hazard involved.

As per established codes and guides

Multi tier review Process

- Fair, just and reasonable
- Independent
- Non-Subjective
- Comprehensive
- Broad based

Safety Review Committees: experts from AERB, DAE units, I
MoEF, Academic Institutions etc.

Participation of stake holders

How AERB regulates?....6/7

From cradle to grave

Siting

↓

Construction

↓

Commissioning

↓

Operation

↓

Decommissioning

How AERB regulates?....7/7

Inspection

- AERB staff can inspect any premise, radiation installation or conveyance
  - At any date and time (announced) or unannounced
  - During any licensing stage

- Inspector may
  - Check compliance with the licensing conditions
  - make tests and measurements necessary for assessing radiation safety;
  - investigate unusual incidents or accidents, if any
  - review and verify implementation of corrective actions and
  - inspect radioactive consignments in any conveyance carrying radioactive material and inspect any package containing radioactive material.

REGULATORY APPROACH ADOPTED FOR R&D FACILITIES…1/2

- In view of the peculiar and unique challenges associated with research and developmental activities, a cautious approach is adopted which requires a lot of R&D inputs and expertise for safety review.
- Safety assessment of such facilities is done in a pragmatic manner by ensuring the compliance of safety requirements while not being overly restrictive.
- The R&D activities have to be performed in a manner which provides assurance that safety requirements are adequately addressed.
- AERB has adopted an approach of participatory regulation, where the inputs of stakeholders are taken in its regulatory processes pertaining to Safety Review, Document Development and Operating Experience Feedback.

REGULATORY APPROACH ADOPTED FOR R&D FACILITIES…2/2

- The entire R&D programme is conducted under an overarching safety envelope, without infringing the creativity and freedom of the researcher.

- AERB's approach encompasses elements of various regulatory approaches like
  - prescriptive regulation,
  - outcome based regulation
  - risk-informed and hazard informed regulation
  - process based regulation
  - self-assessment based regulation and
  - knowledge / experience based regulation in varying degree and extent depending on the specific issues

Way Forward…1/4

- All work performed as a part of the R&D plan should follow sound engineering and scientific principles
- During the commissioning of the equipment, the calibration and performance requirements of tests, measurement and diagnostic equipment should be defined to a level of detail to ensure that R&D goals are achieved.
- In the operation, the researcher should ensure that the systems and sub-systems of the experimental equipment are functioning as intended.
- The management should assess the performance of the R&D plan to a level of detail that ensures that accepted practices are being employed and that objectives are being met.

Way Forward…2/4

- The goals of self-assessment should be to
  - identify problem
  - correct them
  - determine their root cause, and
  - subsequently prevent problems that could hinder the achievement of objectives specified in the R&D plan.

- Independent assessment of the R&D plan should be conducted to evaluate progress toward achieving the defined performance objectives.

Way Forward….3/4

- There are many decisions and adjustments that must be made during early development and design stages. These are however often too early or too specialised or localised to come under formal safety assessment scrutiny. Nevertheless, if there is not a particularly **positive and active safety culture**, safety may at times be viewed as someone else's responsibility, or something that can be fixed later on.

- **Management commitment** to safety, resource allocation, adherence to policy and strategy for safety, safety auditing, risk assessment and training and involvement in safety activities, are some of the key factors which are collectively responsible for inculcating a strong safety climate in an organisation

Way Forward…4/4

For every radiation related activity, there needs to be

- Justification – benefit should outweigh the risk
- Optimisation- to keep exposure as low as reasonably achievabale
- Dose limitation- to keep the exposure below the prescribed dose limits

To sum up…

Safety in DAE units have been an integral part and built on the professionalism within the scientific community and decades of hard-work, dedication in evolving best safe operating practices. To sum up,

- R&D programme warrants maximum flexibility and unhindered creativity. Regulatory demands can be seen to constrain researchers freedom and creativity
- Biggest challenge is transition from R&D mode to production mode and regulation of First of a kind R&D activities
- Direct involvement of researchers who have complete knowledge and understanding of system. They play a play a key role in safety administration
- Participatory regulation –a cautious and pragmatic regulatory approach without being overtly restrictive

The way forward has always been the directive issued by Dr. Homi Jehangir Bhabha, which reads

'"Radioactive material and sources of radiation should be handled in Atomic Energy Establishment, in a manner, which not only ensures that no harm can come to workers in the Establishment or anyone else, but also in an exemplary manner so as to set a standard which other organization in the country may be asked to emulate".

- H.J. Bhabha; Directive issued 27 Feb, 1960

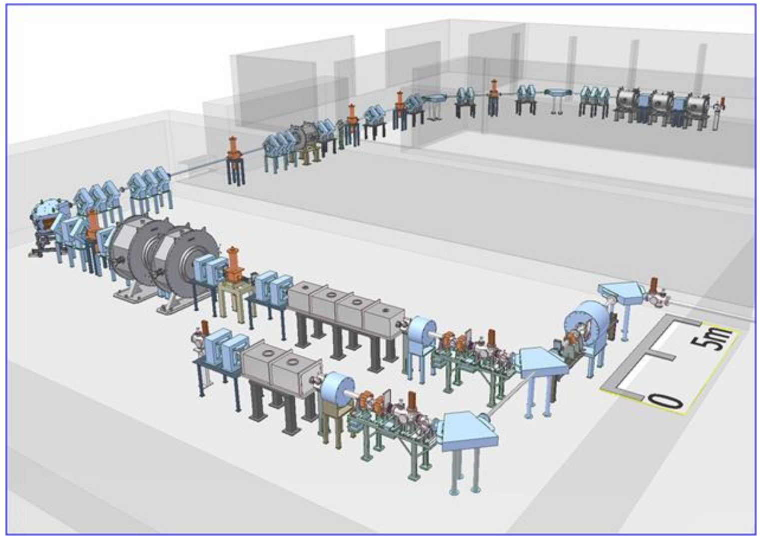
R&D in Advanced Technologies under Regulation- some examples…..1/5

- High Energy Synchrotrons- ex. 2.5GeV INDUS-2 at RRCAT

Electrons are accelerated to 2.5GeV using RF source and confined in a circular orbit using bending magnets. The intense low energy synchrotron radiation emitted during bending of the electrons is trapped through beamlines for carrying out R&D experiments.

R&D in Advanced Technologies under Regulation- some examples…..2/5

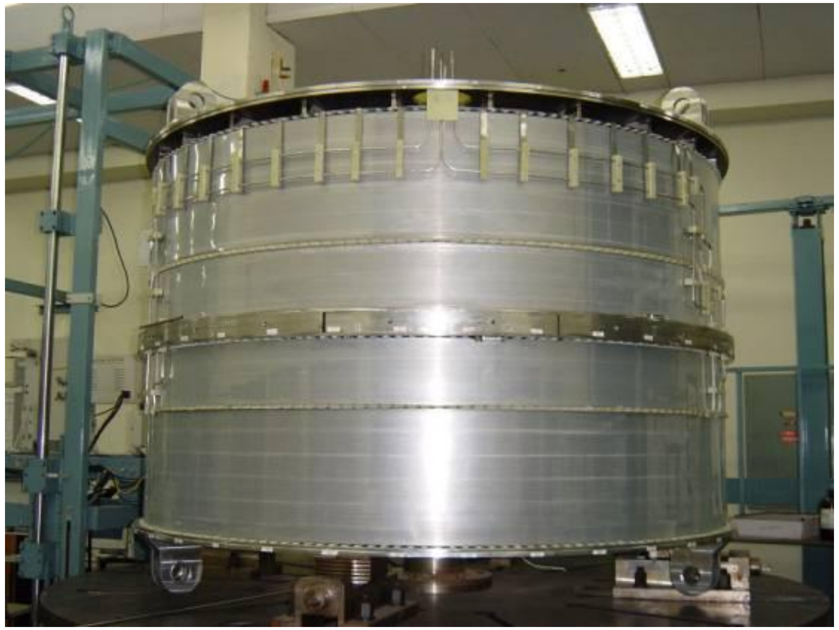
- Acceleration of radioactive ions- ex: Radioactive Ion Beam facility at VECC



Radionuclides are produced inside a thick target using proton and alpha particle beams from existing room temperature cyclotron at VECC. The radionuclides diffusing out from the thick target will be ionized in the integrated target-ion-source and then it will be subsequently accelerated using series of LINAC to the desired final energy of about 4 MeV/u .

R&D in Advanced Technologies under Regulation- some examples…..3/5

- Heavy Ion Acceleration at Superconducting Temperatures- ex: Super Conducting Cyclotron at VECC



One of the major component of this cyclotron is the super conducting magnet coil which produces very high magnetic field required for rotating high energy charge particles. The magnet coil of the Superconducting Cyclotron is immersed in liquid Helium (4.2K) in a specially built stainless steel Cryostat.

R&D in Advanced Technologies under Regulation- some examples…..4/5

- Liquid Metal Target interaction with high current proton beams eg. Medical Cyclotron at Kolkata

DAE has taken up a comprehensive R&D programme to develop Accelerator Driven Subcritical reactors. One of the key components that have to be developed is the very high intensity neutron spallation target. These targets will be based on heavy density liquid metals like Lead-Bismuth-Eutectic (LBE) alloy. Many issues are required to be studied, which include thermal-hydraulics, corrosion, radiation damage, radiotoxic etc.

R&D in Advanced Technologies under Regulation- some examples…..5/5

- High Power Lasers: e.g: Terawatt and Petwatt laser project at RRCAT

150 TW Ti- Sapphire Laser: 150 TW Ti- Sapphire Laser is under operation at RRCAT. At ultra-high intensities using ultra short (femto second) laser pulses, the laser intensity can go more than 10^{18} W/cm2.

1 PW Ti- Sapphire Laser: 1 PW Ti- Sapphire Laser (25 J energy, 25 fs pulse duration, and 1 Hz repetition rate) is under construction for ultra-high intensity experiments. The interaction studies will be carried out at 10^{20} W/cm2.

How to treat 'R&D' Facilities

Office Order by Dr. A. Kakodkar, then Director, BARC (September 3, 1997)

" BARC being an R&D Unit, these rules (Atomic Energy (factories) Rules, 1996) are not strictly applicable to the Centre. However, this Centre has always observed its own discipline in ensuring that rules and procedures related to all aspects of Health and Safety requirements are followed in all our activities including industrial type of operations. It is proposed to strengthen this activity further so that excellent record of the Centre in respect to industrial hygiene and safety is not only maintained but further improved."