

CHAPTER -02

SAFETY SURVEILLANCE OF RADIATION FACILITIES



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Radiation sources such as radioisotopes (⁶⁰Co, ¹³⁷Cs, ¹⁹²Ir, ⁷⁵Se, ²⁴¹Am, ^{99m}Tc, ⁸⁵Kr etc.) and radiation generating equipment (X-ray machines, accelerators etc.) are being used in multifarious applications in industry, medicine, agriculture and research for societal benefits. AERB regulates facilities using radiation sources in order to ensure radiation safety. These sources have radiation hazard potential ranging from very low to high. Proper design, handling and disposal methodologies are required for ensuring safe use of radiation sources, for the intended purpose.

2.0 Safety Review Mechanism of Radiation Facilities

As per the Atomic Energy (Radiation Protection) Rules, 2004, promulgated under the Atomic Energy Act, 1962, AERB reviews radiation safety in radiation facilities and issues regulatory consents in the form of Licence, Authorisation, Registration and Consent/Approvals based on the hazard potential. The regulatory requirements and safety review levels are applied following graded approach, before issuance of consent to operate the facility/equipment. The graded approach followed is depicted in Figure 2.1.

Type Approvals are issued to equipment conforming to the regulatory standards. No Objection Certificates (NOC) are issued to the suppliers to import either radiation generating equipment or equipment containing radioactive source, based on which the end-users apply for procurement permission. The performance tests / radiological assessments are witnessed by AERB for issuance of Type Approval. Only Type Approved equipment are licensed for operation by AERB.

AERB follows multi-tier review process for issuance of various consents to radiation facilities, based on the hazard potential involved. The safety review for radiation facilities' applications is carried out as per AERB Safety Guide on 'Consenting Process for Radiation Facilities' (AERB/RF/SG/G-3). AERB also issues shipment approval from radiological safety standpoint to facilitate safe transport of radioactive materials. The details of radiation facilities for various practices regulated by AERB are given in Table 2.1.

Practice	Total no. of Institutions	Modalities	Total no of Equipment/Sources
Radiotherapy	649	Proton Therapy Facility	2
		Telecobalt	174
		Gamma Knife	6
		Accelerator	736
		Tomotherapy	33
		Cyber knife	11

Table 2.1: Details of Radiation Facilities and Equipment/Sources as on 31st December 2023

Practice	Total no. of Institutions	Modalities	Total no of Equipment/Sources
Radiotherapy		HDR Brachytherapy Unit	401
		Intra Operative Radiation Therapy (IORT)	03
		Simulator and CT-Simulator	202
Nuclear Medicine	528	PET-CT	465
		PET-MR	5
		SPECT-CT	106
		SPECT/Gamma Camera	251
		Therapy Installations	166
		Radioimmunoassay (RIA)	64
Research/Academic Institutions using Sealed/Unsealed Sources	190	_	-
Diagnostic	73282	Radiography (Fixed)	39,494
Radiology		Radiography (Mobile)	38,025
		Radiography (Portable)	1,601
		Radiography and Fluoroscopy	2,427
		Interventional Radiology	3,895
		Computed Tomography	11,569
		Dental (Intra-oral, OPG, CBCT)	26,614
		Mammography	3,399
		C-Arm	28,941
		O-Arm	47
		Bone Densitometer	1,074
Industrial Radiography	768	Industrial Gamma Radiography Exposure Device	2,602
		Industrial X-ray Radiography Device	895
		Accelerators	20
Nucleonic Gauge	1278	Nucleonic Gauges Devices	9,178
Well Logging	55	Well Logging Sources	1,878
Radiation	47	GRAPF	31
Processing Facilities		IARPF	16

Practice	Total no. of Institutions	Modalities	Total no of Equipment/Sources
Gamma/X-	110	Gamma Irradiation Chamber (GIC)	123
Ray Irradiation Chamber		X-Ray Irradiation Chambers	10
Medical Cyclotron Facilities	22	Medical Cyclotron	22
Research Accelerator Facilities	11	Research Accelerator	11
Container Scanning Facilities	22	Radioisotope based Container Scanners	3
		Accelerator based Container Scanners	26

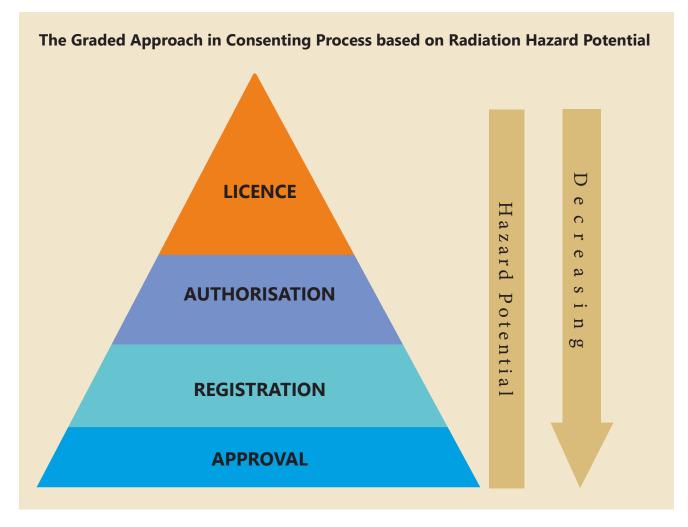


Figure 2.1 Graded Approach in Consenting Process

2.1 Applications of Radiation Sources and Regulatory Activities

An overview of various applications of radiation sources and details of license/consents issued during the year 2023 to radiation facilities are elaborated in the following paragraphs

2.2 Medical Applications of Radiation Sources

2.2.1 Radiation Therapy

(i) Teletherapy

Teletherapy is a branch of radiation therapy, which deals primarily with treatment of cancer,



using ionising radiation, where in the radiation source(s) are kept at a certain distance from the patient. ⁶⁰Co radioisotope emitting gamma rays or radiation generators such as Linear Accelerators (LINAC) emitting X-ray or electron beams are mainly used for the treatment. Sources and devices used in teletherapy are of high radiation hazard potential.

An indigenously developed Medical Accelerator Model "SIDDHARTH-II ICONIC PLUS", was tested for its safety performance and based on its satisfactory performance, Type Approval was issued by AERB for the equipment to the Indian manufacturer.

(ii) Proton Beam Therapy

It is a type of teletherapy using proton beams having energies in the range of 70 MeV to 230 MeV. Proton beams are specifically beneficial in treating paediatric cancers and deep-seated tumours more effectively than the conventional Gamma/X-ray based radiation therapy. Proton Therapy is a cutting-edge treatment modality which offers unique benefits in treating cancer with high precision and minimal impact on healthy tissues.



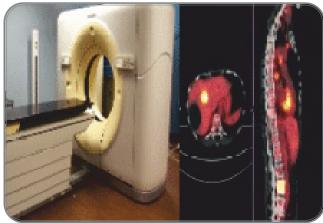
AERB issued licence for operation from radiological safety view point to Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Mumbai; for the operation of Gantry Treatment Room-3 (GTR-3) of Proton Therapy facility model Proteus Plus, after satisfactory safety review and prelicensing inspection. This is the first Proton Therapy Facility in India established in a Government set-up.

(iii) Brachytherapy

In brachytherapy, radiation source is kept very near to or inside the lesion. The radioisotopes used are typically ¹⁹²Ir, ¹³⁷Cs, ⁹⁰Sr, ¹⁰⁶Ru, ¹²⁵I and ⁶⁰Co with activity range from few MBq to GBq. They are of moderate radiation hazard potential as compared to teletherapy.

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2.2.2 Nuclear Medicine

Nuclear medicine imaging has special importance as it can detect the molecular level activity within the body which helps in identification of disease



in its early stage and the metastasis growth in cancer. For diagnosis purpose, the gamma rays



emitted from the radio isotopes such as ^{99m}Tc, ¹⁸F, ²⁰¹Tl, ⁶⁷Ga, ⁶⁸Ga are detected by special detection devices (e.g. Gamma Camera, SPECT, PET) and images are reconstructed using computer algorithms. For therapeutic purpose, beta emitting radioisotopes such as ¹³¹I, ¹⁷⁷Lu, ¹⁵³Sm, ⁹⁰Y, ³²P, ¹⁸⁸Re are used which deliver localised radiation dose once radio-pharmaceutical accumulates at the area of interest. The facilities using radiopharmaceuticals are of moderate to low radiation hazard potential.

Type Registration was issued for new SPECT nuclear medicine imaging equipment installed at AIIMS, Delhi, based on satisfactory demonstration of quality assurance tests.

2.2.3 Diagnostic Radiology (X-ray)

X-rays are used in medical facilities as an important diagnostic tool. A wide variety of X-ray equipment are used for various diagnostic examinations.

The details of Medical Radiation Facilities/ Equipment and Consents issued for various medical facilities during the year 2023 are given in Table 2.2.

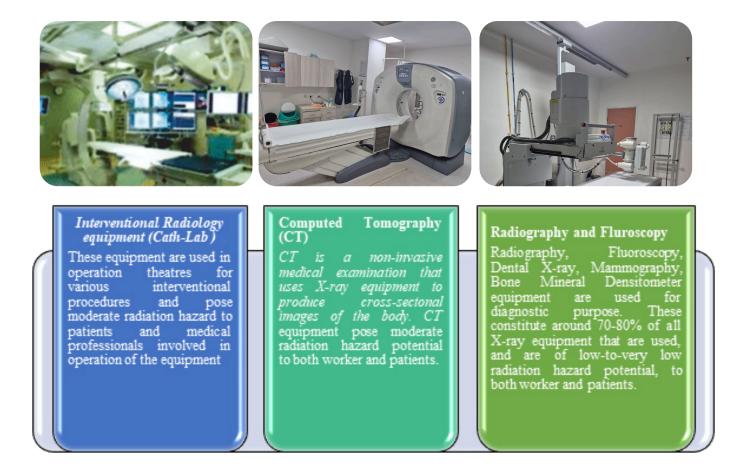


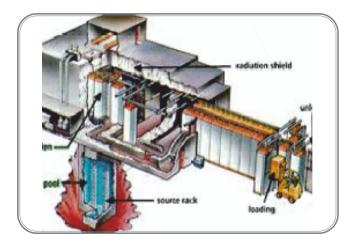
Table 2.2: Details of Consents/Renewals issued for Medical Radiation Facilities in the Year 2023

Type of Consent	Radiation Therapy	Nuclear Medicine	X-ray
Licence*	317	356	23,136
Permission for Import/Procurement of Equipment from Radiation Safety Stand Point	748	99	13,575
Permission for Procurement of Radioactive Sources	-	2,870	-
Type Approval/Renewal /Type Registration (Equipment) from Radiation Safety Stand Point	30	1	379
Layout Approval	401	206	-

*Licence includes Licence / Authorisation / Registration for various radiation facilities

2.3 Industrial Applications of Radiation Sources

2.3.1 Radiation Processing Facilities (RPF)



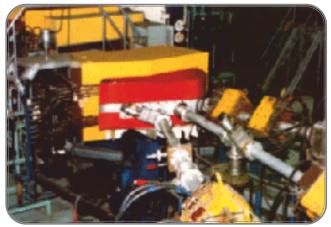
Radiation Processing Facilities (RPF) include Gamma Radiation Processing Facility (GRAPF)/ Gamma Irradiators and Industrial Accelerators Radiation Processing Facility (IARPF). GRAPFs are mainly used for radiation processing of food (viz. inhibiting sprouting, delay in ripening, microbial decontamination, insect disinfestation, shelf-life extension etc.) and sterilisation of healthcare products. 60Co is used as a radiation source with activity of about few PBq. IARPF are mainly used for cross-linking of polymers in cable industries and are operated in electron beam mode with energy ranging from 1.5 MeV to 3 MeV. Such accelerators, unlike radioactive sources, produce radiation only when energized. The RPFs are of high radiation hazard potential.



AERB issued Approval for technology demonstration of first of its kind 'Low Temperature Gamma Irradiator' installed at BRIT, Vashi (having 100 kCi ⁶⁰Co source). This is a Category-I, self-contained, dry storage irradiator to irradiate food, marine and medical products.

2.3.2 Research Accelerators

Research Accelerators or Particle Accelerator Research Facilities (PARF) are generally installed in academic & research institutions and cater to the research needs of various fields of high energy physics, material science, radiation studies



etc. Research Accelerators operate in the energy range from a few hundreds of keV to GeV. The hazard associated with the facilities is also diverse in nature and ranges from moderate to high. The radiation hazard potential of an accelerator mainly depends on the type of ion(s) accelerated, type of accelerator and beam parameters (e.g. energy & current, target system).

2.3.3 Medical Cyclotron

Short-lived radioisotopes that are used in nuclear medicine for PET scans are generally produced in medical cyclotron facilities. In India, cyclotrons are primarily utilised for the production of ¹⁸F labelled radio-pharmaceuticals. The hazard



potential associated with medical cyclotron facilities ranges from moderate to high.

2.3.4 Gamma /X-ray Irradiation Chamber (GIC/XIC)

Gamma Irradiation Chambers are basically used for research and development purposes and also in blood banks for irradiation of blood and blood components. Radioisotopes like ⁶⁰Co and ¹³⁷Cs are normally used in these applications. The activity ranges from few tens of TBq to few hundreds of TBq. X-ray based Irradiation Chambers with



X-ray energy ranging from 160 keV to 300 keV are also being used in blood banks and research applications. These equipment are of moderate to high hazard potential.

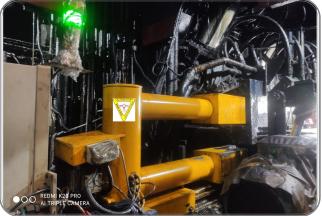
2.3.5 Industrial Radiography (IR)

Radiography using Industrial Radiography Exposure Device (IRED), is one of the important Non-Destructive Testing (NDT) methods used for study / evaluation of weld joints, castings etc. Radioisotopes like ¹⁹²Ir, ⁶⁰Co, ⁷⁵Se and different energies of X-rays are used in the field of industrial radiography. The activity of radioisotopes range from few hundreds of GBq to few TBq whereas in case of X-ray based devices, the low energy X-ray ranges from 50 kV-450 kV and high energy X-ray ranges from 4MV-15MV. IREDs are of moderateto-high radiation hazard potential.



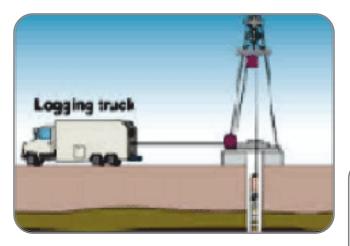
2.3.6 Nucleonic Gauges (NG)

Nucleonic Gauges also known as lonizing Radiation Gauging Devices (IRGD) are used for online measurement/monitoring of quality control parameters such as thickness, level,



density, coating thickness, composition of material, elemental analysis etc. Sources used in nucleonic gauges depends on the application for which the gauges are intended and comprise of gamma sources (e.g. ⁶⁰Co, ¹³⁷Cs, ²⁴¹Am etc.), beta sources (e.g. ⁸⁵Kr, ⁹⁰Sr, ¹⁴⁷Pm, ²⁰⁴Tl) and neutron sources (²⁴¹Am-Be and ²⁵²Cf). The activity ranges from MBq to GBq. In addition, X-ray based gauges of energy in the range of 30 keV to 160 keV are also used in industries for coating thickness measurement. IRGDs are of low-to-moderate radiation hazard potential.

2.3.7 Well Logging (WL)



Radioactive sources are used in Well Logging applications for exploration of oil, coal and geophysical logging etc. The sources used are mainly gamma sources such as ¹³⁷Cs for density measurement and neutron sources such as ²⁴¹Am-Be and Deuterium-Tritium generators (neutron generators) for exploration of hydrocarbons. The activity ranges from kBq to GBq. They are of lowto-moderate radiation hazard potential.

2.3.8 License for Operation of Radiopharmaceutical Facility

Based on safety review, License for operation was issued to Radiopharmaceutical facility, Vijaywada for manufacturing and supplying ¹³¹I labelled



radiopharmaceuticals to AERB authorised nuclear medicine centres.

2.3.9 Type B(U) Design Approval for Industrial Radiography Device Model ROTEX-1

Based on satisfactory safety review, AERB issued Type B(U) design approval to an indigenously developed remote operated Industrial Radiography Device (Model ROTEX-1) of BRIT.



The device contains ¹⁹²Ir source of 2.4 TBq (65 Ci) capacity with tungsten shield.

2.4 Consumer Products, Scanning and Research Applications

2.4.1 Consumer Goods Manufacturing Facilities

Consumer products such as smoke detectors,



thorium gas mantles and starters, gaseous tritium luminescence devices use miniscule amounts (i.e exempt quantity) of radioactive sources. They are of very low hazard potential. However, AERB exercises regulatory control on the manufacturing facilities of these devices. Those products containing radioactivity above the exempt limits have to be assessed for safety and are required to be type approved by AERB.

2.4.4 Facilities using Sealed and Unsealed Sources

Various sealed and unsealed sources are used in education, research and calibration purposes in academic and research institutions. Unsealed sources are also used in agriculture research, veterinary science, tracer studies, etc. The activity ranges from kBq to GBq. They are of low-tomoderate radiation hazard potential.

2.4.2 Container Scanner Facility

Container scanners are used at various ports (land/sea) for inspection of material inside cargo/ container without opening them. These systems are based on either Linear Accelerators (photon energy in the range of 6 to 9 MV) or ⁶⁰Co isotope (activity of the order of 1 Ci). They contain moderate-to-high radiation hazard potential.

Licenses for operation of accelerator based Drive Container Scanner were issued to M/s Gangavaram Port Ltd., Vizag and M/s Syama Prasad Mookerjee Port, Kolkata.

2.4.3 X-ray Baggage Scanner

Scanning facilities are used for detection of contrabands and explosives. Scanning facilities are mainly X-ray based equipment of energy around 160 kV and of extremely low radiation hazard potential. Design (Type) Approval of the equipment is carried out by AERB from radiation stand point of view.



The details of Industrial Radiation Facilities/ equipment and consents/renewals issued for various industrial facilities during the year 2023 are given in Table 2.3.



Table 2.3: Details of Consents issued for Industrial Radiation Facilities during the year 2023

Type of Consent	RPF	Research Accelerators	Medical Cyclotron	GIC	IR	NG	WL
Licence*	22	00	2	36	218	305	8
Type Approval / Renewal Equipment	ŀ	÷	Ţ	12	30	43	-
Type Approval / Renewal Sources	-	Ţ	-	0	-	25	3
Permission for Import/ Procurement of Equipment From Radiation Stand Point	10 (IAPRF)	-	-	-	334	602	÷
Permission for Procurement of Radioactive Sources	20	-	-	15	1,688	126	216
Approval (Layout/ Commissioning/ Source Storage Facility/D&C)	10	-	1	22	388	-	8

*Licence includes Licence / Authorisation / Registration for various radiation facilities

The details of Consumer Products and Scanning Facilities / equipment and consents issued for

various consumer products and scanning facilities during the year 2023 are given in Table 2.4.

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Type of Consent	Consumer Goods Manufacturing Facilities	Container/ Baggage Scanner	Research Facilities (Sealed and Unsealed Sources)
Licence*	-	1,151	72
Permission for Procurement of Radioactive Sources/ Equipment From Radiation Stand Point	-	1,601	274
Type Approval (Source & Equipment) From Radiation Stand Point	-	330	-

Table 2.4: Details of Consents/Renewals issued for Consumer Productsand Scanning Facilities for the Year 2023

*Licence includes Licence / Authorisation / Registration for various radiation facilities

2.5 Approval of Radiological Safety Officers

While the built-in safety of the equipment and institution's operational preparedness towards operational safety are ensured by adhering to requirements specified by AERB in various regulatory safety documents, Radiological Safety Officer (RSO) carries out the implementation of radiation safety. The RSOs act as extended arms of AERB at every radiation facility and also play pivotal role between the facility and the regulatory body. The number of RSO approvals/ renewals issued for different practices during the year are as given in Table 2.5.

Type of Practice	Number	Type of Practice	Number
Radiation Therapy	432	Medical Cyclotron	15
Nuclear Medicine	400	Industrial Radiography	506
Diagnostic X-ray Facilities	3444	Nucleonic Gauges	460
Research Centres	104	Well Logging	32
Radiation Processing Facilities	59	Consumer Product Manufacturer & Scanner Facilities	79
Gamma Irradiation Chamber	58		

Table 2.5: Approval of Radiological Safety Officers in Radiation Facilities for the Year 2023

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2.6 R&D Units and other Facilities in Construction and Operation

AERB also exercises regulatory oversight on certain R&D and other facilities of the Department of Atomic Energy (DAE). These include Variable

Energy Cyclotron Centre (VECC), Raja Ramanna Centre for Advanced Technology (RRCAT), Indira Gandhi Centre for Research (IGCAR) and Board of Radiation & Isotope Technology (BRIT). The status of R&D units and other facilities is presented in Table 2.6 below.

Table 2.6: Status of R&D Units and Other DAE Facilities

Type of Facility	Name	Functional Status	Scope of the Facility	Validity of Current Licence
	Facilities oper	ated by VECC, K	olkata, West Bengal	
Particle Accelerator	Room Temperature Cyclotron (K-130)	In operation	Heavy Ion Acceleration	September 1, 2027
Research Facility (PARF)	Super Conducting Cyclotron (K-500)	Commissioning	Heavy Ion Acceleration	-
	Medical Cyclotron Project	Stage-2 Commissioning	Cyclotron Machine along with 3 Beam Lines for Production of Radio- Pharmaceuticals and 2 Beamlines for Research Purpose	January 13, 2024
	Facilities operate	ed by RRCAT, Inc	dore, Madhya Pradesh	
LASER	150 TW Ti: Sapphire Laser System	In operation	90 TW (for regular) and 150 TW (trial) (25 femto-second)	June 30, 2026
IARPF	Agricultural Radiation Processing Facility (ARPF)	In operation	Electron Acceleration, 2 x (10 MeV, 5 kW) Technology Demonstration for Food Irradiation	January 11, 2029
	INDUS-1	In operation	450 MeV, 100 mA Electron Storage Ring	March 31, 2026
	INDUS-2	In operation	2.5 GeV, 200 mA Synchrotron Radiation Source (SRS)	March 31, 2026

Type of Facility	Name	Functional Status	Scope of the Facility	Validity of Current Licence
LASER	1 PW Laser System	Commissioning and Trail Run	1 PW (femto second)	March 15, 2024
Superconducting RF Cavity (SCRF)	Horizontal Test Stand for SCRF	Operation and Testing of SCRF Cavities	Testing of SCRF Cavities at 650 MHz	September 12, 2027
Superconducting RF Cavity (SCRF)	Vertical Test Stand of SCRF	Operation and Testing of SCRF	Testing of Single Cell or Multi Cell SCRF Cavities	January 19, 2028
	Facilities operat	ted by IGCAR, Ka	alpakkam, Tamil Nadu	
Accelerator	1.7 MV Tandetron Accelerator	In operation	Heavy Ion Acceleration	August 31, 2026
	150 kV Accelerator	In operation	Heavy Ion Acceleration	August 31, 2026
	Fa	cilities operated	by BRIT	
Board of Radiation and Isotope Technology	BRIT, Navi Mumbai	In operation	Production of Radio- Isotopes used in Radiation Facilities, Radio- Pharmaceutical mainly for Nuclear Medicine Application, Radiation Processing etc.	January 31, 2029
	BRIT-RAPPCOF, Kota	In operation	Production of Radio- isotopes mainly for Radiation Processing Plants	January 31, 2029

2.6.1 RRCAT Facilities

Raja Rammana Centre for Advanced Technology (RRCAT) is engaged in R&D in front line research areas of Lasers, Particle Accelerators and related technologies.

Following Licenses were issued for various facilities of RRCAT:

- Licence (renewal) for Operation of Vertical Test Stand (VTS) of RRCAT, Indore and testing of Superconducting RF cavities (SCRF) was issued on January 20, 2023.
- Amendment of Licence for Operation of Agricultural Radiation Processing Facility (ARPF) of RRCAT was issued on July 10, 2023.
- AERB extended Licence for Operation of Indus-1 Accelerator facility in September, 2023.

- Consent for Commissioning and Trial Run operation of Linac Test Stand Facility in IMA Building of RRCAT, Indore was issued on September 21, 2023.
- Consent for Commissioning and Trial Run Operation of 1 PW Laser System at RRCAT, Indore was issued on September 21, 2023.
- Permission for Trial Run of TWINDUS-LINAC-4 at IMA Building, RRCAT, Indore was issued on October 27, 2023.

2.7 Unusual Occurrences/ Enforcement Actions

2.7.1 Enforcement action was taken against an Industrial Radiography institution located in Delhi for making false claim regarding availability of Radiological Safety Officer. The licence was suspended for a period of six months.

2.7.2 Licence for operation issued to an Industrial Radiography institute located in Mathura,UP was suspended for a period of six months for operating industrial radiography equipment without licence and without Personnel Monitoring Services (PMS) for the radiation workers. The approval issued to the RSO was also withdrawn.

2.7.3 Licence for Operation of an Industrial Radiography facility located in Trichy, was suspended for six months for engaging untrained personnel, use of enclosure without valid consent and high radiation levels outside the radiography enclosure. The approval issued to the RSO was also withdrawn on failure of discharging the responsibilities.

2.7.4 Licence for operation of an Industrial Radiography facility located in Ahmednagar was suspended for a period of six months for falsely declaring RSOs in e-LORA system.

2.7.5 Registrations of two RSOs of Industrial Radiography institutes were withdrawn from e-LORA system on failure of discharging their responsibilities.

2.8 Management of Disused Radioactive Sources

The radiation sources are either procured from Indian supplier or imported from other countries. All the radioactive sources must be safely managed when they reach the end of their useful life or if they are not in use for intended purpose. As per the terms and conditions of the Licence, these disused sources need to be sent back to the original manufacturer/supplier for its safe management.

557 approvals were issued for export (towards repatriation) of radioactive sources to the country of origin, and 333 approvals were issued for returning the sources to the Indian supplier, for their safe management during the year 2023.

Moreover, there were 23 ⁶⁰Co Category-1 disused sources in telecobalt units, of which 9 were decommissioned, 5 were restarted and the remaining 9 are under regular follow-up for decommissioning. In 2023, 2 units have been decommissioned and one has restarted.

Similarly, there are 24 ⁶⁰Co Category-1 disused sources used in GICs and GRAPFs, of which 14 are decommissioned in 2023, and 10 are under decommissioning.

AERB is in communication with the concerned institutions regarding safety status and followup actions for decommissioning of the disused sources. Frequent inspections are conducted for facilities possessing disused Category-1 sources.

2.9 Safety Committees for Radiation Facilities

AERB has constituted several safety committees for safety review based on hazard potential of RFs. The safety committees review the radiation safety aspects of RFs using radioactive sources / radiation generating equipment. The committees also recommend issuance of Licence for Operation or issuance of Type Approval, based on safety review and assessment. The committees consist of experts from the industry, medical and academic institutions apart from the experts from BARC, BRIT and AERB. Number of meetings conducted by various committees for safety review of RFs and transport of radioactive material during the year is given in Table 2.7.

Table 2.7: Meetings of Safety Review Committees of Radiation Facilities for the Year 2023

Name of Committee	Number of Meeting
Safety Review Committee for Applications of Radiation (SARCAR)	03
Safety Review Committee for Radiation Processing Plants (SRC-RPP)	02
Committee on Safe Transport of Radioactive Material (COSTRAM)	03
Safety Committee for Hadron Therapy Facilities (SCHTF)	01
Accelerator and Laser Safety Committee (ALSC)	03
Committee for Review of Exposure Cases in Nuclear Fuel Cycle and Radiation Facilities (CRENRAF)	04