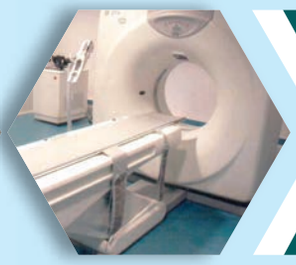



Chapter 2
SAFETY SURVEILLANCE OF RADIATION FACILITIES

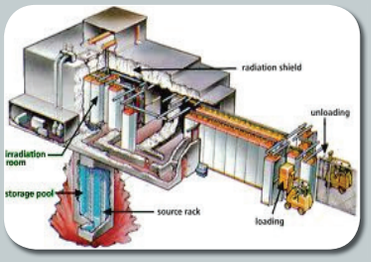
2.1 APPLICATIONS OF RADIATION SOURCES IN MEDICAL, INDUSTRY AND RESEARCH

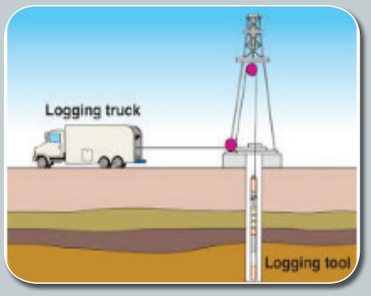
Radiation sources such as radioisotopes (^{192}Ir, ^{60}Co, ^{137}Cs, ^{170}Tm, ^{75}Se, ^{241}Am, ^{99m}Tc etc.) and radiation generating equipment (X-ray machines, accelerators etc.) are being used in multifarious and ingenious ways to achieve overall societal health and prosperity. The radiation sources have a wide range of applications in the industries, medicine, agriculture and research institutions and AERB regulates these facilities/institutions. These sources have the radiation hazard potential ranging from high to very low. Proper design, handling and disposal methodologies are required for ensuring safe and intended use of radiation sources. Regulation of these sources is in accordance with the radiation hazard potential involved and the extent of use in the public domain.

A glimpse on the various applications of these sources and their licensing status is as given below.

	Description	No. of Facilities / Equipment Licensed as on December 31, 2017
MEDICAL APPLICATIONS OF RADIATION SOURCES		
Teletherapy 	In teletherapy (branch of Radiotherapy) tumour is treated using ionising radiation keeping radiation source(s) at certain distance. The radioisotopes like ^{60}Co and radiation generators such as Linear Accelerators are used. They are of high radiation hazard potential.	*448 facilities with 648 teletherapy units*
Brachytherapy 	In brachytherapy (branch of radiotherapy in which the source is kept very near to the lesion) the isotopes used are ^{192}Ir, ^{137}Cs, ^{90}Sr, ^{106}Ru, ^{125}I and ^{60}Co with activity range from few MBq to GBq. They are of moderate radiation hazard potential as compared to teletherapy.	*283 Remote After Loading and 51 Manual After Loading equipment*

	Description	No. of Facilities / Equipment Licensed as on December 31, 2017
Cath Lab  **Computed Tomography**  **Radiography and Fluroscopy** 	X-rays are used in medicine as an important diagnostic tool. Diagnostic Radiology using X-rays are: • ***Interventional Radiology equipment (Cath-Lab and C-Arm)*:** These equipment are used in operation theatres for various interventional procedures and pose moderate radiation hazard to patients and medical professionals involved in operation of the equipment. The C-Arm equipment is of low to moderate hazard potential. • ***Computed Tomography (CT):*** These equipment are of moderate radiation hazard potential to both worker and patient. • ***General purpose Radiography and Fluoroscopy equipment and Dental equipment:*** These constitute around 70-80% of all X-ray equipment that are used, and are of low to very low radiation hazard potential, to both worker and patients. • ***Mammography, Bone Mineral Densitometer*:** These equipment are of very low radiation hazard potential.	• *1,360 Cath Lab equipment* • *3,179 CT equipment* • *41,988 other medical X-ray equipment*
Nuclear Medicine Facilities 	In Nuclear Medicine, radio-pharmaceuticals, such as ^{99m}Tc, ^{131}I, ^{201}Tl and ^{18}F are used for diagnosis and treatment. ^{18}F radiopharmaceuticals are routinely used in PET-CT facilities, while ^{131}I is used for diagnosis and treatment of thyroid cancers. The facilities using radio pharmaceuticals are of moderate-low radiation hazard.	*272 facilities. (PET-CT, SPECT and Gamma Camera)*

	Description	No. of Facilities / Equipment Licensed as on December 31, 2017
Medical Cyclotron 	Radio-isotopes that are used in Nuclear Medicine are generally produced in Medical Cyclotron facilities. Cyclotrons are utilised for the production of ^{18}F labelled radiopharmaceuticals. The medical cyclotron facilities are of moderate to high radiation hazard potential.	*18 facilities*
INDUSTRIAL APPLICATIONS OF RADIATION SOURCES		
RPF  	**R**adiation **P**rocessing **F**acilities **(RPF)** including Gamma Irradiators and Electron Beam Accelerators are used mainly for radiation processing of food, sterilisation of healthcare products and crosslinking of polymers in cable industries. Radiation processing of food items includes inhibiting sprouting, delay in ripening, microbial decontamination, insect disinfestation, shelf-life extension etc. The activity range is about few PBq (10^{15}). They are of high radiation hazard potential.	*19 Gamma Irradiators* *8 Accelerator Facilities*
IRED 	Industrial radiography using Industrial Radiography Exposure Device (IRED), is one of the important non-destructive (NDT) methods used for study / evaluation of weld joints, castings etc. Radioisotopes like ^{192}Ir, ^{60}Co, ^{170}Tm, ^{75}Se and different energies of X-rays are used in the field of industrial radiography. The activity range is from few TBq to few tens of TBq. The X-ray energy range is from few hundreds of keV to few MeV. They are of high to moderate radiation hazard potential.	*554 facilities with 2,701 equipment*

	Description	No. of Facilities / Equipment Licensed as on December 31, 2017
GIC 	**G**amma **I**rradiation **C**hamber (GIC) is basically used for research and development and also in blood banks for irradiation of blood and its components. Usually ^{60}Co and ^{137}Cs radioisotope are used in this application. The activity ranges from few tens of TBq to few hundreds of TBq. They are of high to moderate radiation hazard potential. Irradiator based on X-ray generator are also used in blood banks.	*102 facilities with 118 devices*
Nucleonic Gauges 	Nucleonic Gauges also known as Ionising Radiation Gauging Devices (IRGD) are used for monitoring and measuring of physical parameters such as thickness, level, density, coating thickness, elemental analysis etc. Sources used for nucleonic gauges are gamma sources such as ^{60}Co, ^{137}Cs, ^{241}Am etc., beta sources such as ^{85}Kr, ^{90}Sr, ^{147}Pm, ^{204}Tl and neutron sources such as ^{241}Am-Be and ^{252}Cf. The activity range is from MBq to GBq. They are of low radiation hazard potential.	*1,920 facilities*
Well Logging 	Radioactive sources are used in well logging application for exploration of oil, coal, geophysical logging etc. The sources used are mainly ^{137}Cs, ^{241}Am-Be, some calibration sources such as ^{60}Co, ^{226}Ra, ^{232}Th etc. and neutron generators (e.g. Deuterium-Tritium (DT)). The activity range is from kBq to GBq. They are of moderate to low radiation hazard potential.	*63 facilities*

APPLICATIONS OF RADIATION SOURCES IN RESEARCH AND CONSUMER PRODUCTS

	Description	No. of Facilities / Equipment Licensed as on December 31, 2017
Consumer Goods Manufacturing Facilities  	Consumer products such as smoke detectors, thorium gas mantles and starters, gaseous tritium luminescence devices use exempt quantity of radioactive sources. They are of very low hazard potential. However, regulatory control exists on the manufacturing facilities of these devices.	*15 facilities*
Facilities using Sealed Sources 	Though sealed radioactive sources are used in various industrial and medical applications, but here sealed source means those used in education, research and calibration purposes. The activity range is from kBq to GBq. They are of low to moderate radiation hazard potential.	*259 facilities*
Facilities using Unsealed Sources 	Unsealed sources are used in various research and academic institutions such as agriculture, veterinary science, tracer studies etc. They are of low radiation hazard potential.	*213 facilities*

2.2 SAFETY REVIEW MECHANISM OF RADIATION FACILITIES

2.2.1 Issuance of Consents

Consenting process involves the issuance of consent, in the form of Licence, Authorisation or Registration (in the order of decreasing hazard potential), to operate the equipment/ facility. Type Approvals are issued to manufacturer/ supplier for equipment conforming to the regulatory standards. Approvals are also issued as an interim consent towards the respective Licences. No Objection Certificates (NOC) are issued to the stakeholders to import either equipment or radioactive source, after which the stakeholders need to obtain either a Type Approval or the respective consent for use. AERB has a system of multi-tier review process (i.e. review by AERB and its Safety Committees)

for various consents depending on the hazard potential involved. The process of issuance of various consents is as per AERB Safety Guide on 'Consenting Process for Radiation Facilities' (AERB/RF/SG/G-3).

The transportation of radioactive material (including that of nuclear material from nuclear facilities) is governed by regulations specified by AERB in Safety Code for the 'Safe Transport of Radioactive Materials' and is in line with the international requirements specified by IAEA for safe transport of radioactive material.

The number of licences and other consents issued during the year are as follows:

Consent	Practice	Equipment/ Facility/Activity	Number Issued
Licence	Radiotherapy	Linear Accelerator and Tele-cobalt	67
	Nuclear Medicine	Medical Cyclotron Facility	10
		PET-CT and SPECT-CT	55
	Diagnostic X-ray	Interventional Radiology	427
		Computed Tomography	913
		Manufacturing facilities of diagnostic X-ray equipment	11
	Radiation Processing Facilities (RPF)		13
	Industrial Radiography		140
	Research Accelerators		2
Authorisation	Radiotherapy	HDR Brachytherapy	31
	Gamma Irradiation Chamber (GIC)		19
	Well Logging		2
	Nuclear Medicine Facilities		67
	Diagnostic X-ray Facilities	Suppliers	18
		Service Agencies	21
Registration	Diagnostic X-ray		12,593
	Ionising Radiation Gauging Devices (IRGD)/ Nucleonic Gauges		73
	Facilities using radio-isotopes for research	Unsealed sources	68
		Sealed sources	33
	Consumer Products Manufacturing Facilities		24
	Type A package		20
Type Approval/ Renewal	Radiotherapy		23
	Interventional Radiology		18
	Computed Tomography		12

Consent	Practice	Equipment/ Facility/Activity	Number Issued
Type Approval/ Renewal	Diagnostic Radiology		118
	Industrial Radiography Exposure Device (IRED)		12
	Ionising Radiation Gauging Devices/Nucleonic Gauges		62
	Well Logging Source		47
	Consumer Products and Scanning Facility		57
NOCs Issued for Import of Equipment	Medical Linear Accelerator		64
	Tele-cobalt		12
	Radiotherapy Simulator		12
	PET-CT/SPECT-CT		29
	RAL Brachytherapy Unit		35
	Diagnostic Radiology		66
	Computed Tomography		6
	Interventional Radiology		7
	Industrial Electron Beam Accelerator		1
	Industrial Radiography Exposure Devices (IRED)		260
	Ionising Radiation Gauging Devices/Nucleonic Gauges		400
	Scanning Facilities		52

Permission for Procurement of Radioactive Sources	Practice	Indigenous	Imported
	Industrial Radiography	1038	362
	Well logging	-	175
	Nucleonic Gauges	80	
	GIC	13	-
	Thorium Nitrate	-	3
	Consumer Products	-	535
	Tele-cobalt source	40	4
	HDR Brachytherapy	-	386
	MAL Brachytherapy	6	7
	Nuclear Medicine		2,734
	Radio Immuno Assay (RIA)		34
	Radioisotopes used in Research Facilities		167

Consent	Equipment/ Facility/Activity	Number Issued
Disposal of Radioactive Sources (permission for transportation of radioactive material for safe disposal)	Exported to the original supplier	1,521
	Disposal in Authorised waste management facility within the Country	824
	Disposal of Contaminated Material	02
Transport of Radioactive material	Renewal of certificate of approval of design for special form radioactive material	160

Intermediate Approvals leading to issuance of Licence:

	Consent	Equipment / Facility	Number Issued
Other Approvals	Site	Medical Cyclotron	3
		Gamma Radiation Processing Facility	5
		Industrial Accelerator Radiation Processing Facility	5
	Layout plan	Radiotherapy	306
		Nuclear Medicine Centres	120
		Medical Cyclotron	1
		Research Centres	56
		Sources Storage Pit (well logging)	9
		Source Storage Facility (Industrial Radiography)	273
		Industrial Radiography Enclosure	175
		Gamma Irradiation Chamber	12
		Scanning Facilities	12
		RIA	5
	Design and Construction	Research Accelerator	1
		Radiation Processing Facility	4
	Commissioning	Medical Linear Accelerator (Radiotherapy)	53
		Tele-cobalt	8
		RAL Brachytherapy Facilities (HDR)	28
		Radiotherapy Simulator	8

	Consent	Equipment / Facility	Number Issued
Other Approvals	Commissioning	Medical Cyclotron	4
		Industrial Radiography Enclosure	115
		Well Logging Source Storage Facility	63
	Decommissioning	Tele-cobalt units	15
		Remote After Loading (RAL) brachytherapy unit	1
		Gamma Irradiation Chamber (GIC)	2
		Nuclear Medicine	15
		Simulator	10
	Source Movement	Well logging	748
		Industrial Radiography Exposure Devices	2,239
		IRGD/Nucleonic Gauges	26
	Source replacement/ replenishment	Gamma Radiation Processing Facility	8

2.2.2 Safety Committees for Radiation Facilities

The safety committees review the radiation safety aspects of medical, industrial and research institutions which use radioactive sources/ radiation generating equipment.

The committees also recommend issuance of licence for operation or issuance of Type Approval, based on their review. The committees consist of experts in the field from the industry, medicine and academic institutions apart from the experts from Bhabha Atomic Research Centre (BARC), Board of Radiation & Isotope Technology (BRIT) and AERB.

Name of Committee	Abbreviations	Number of Meetings
Safety Review Committee for Applications of Radiation	SARCAR	3
Accelerator and Laser Safety Committee	ALSC	2
Safety Review Committee for Radiation Processing Plants	SRC-RPP	2
Committee on Safe Transport of Radioactive Material	COSTRAM	5
Committee for Recognition of Calibration Laboratories for Radiation Monitoring Instruments	CRCL	1

Name of Committee	Abbreviations	Number of Meetings
Committee to Review functioning and Accreditation of Environmental Survey Laboratories (ESL) at NPPs and other Radio Analytical Laboratories (RAL)	CORFAL	1
Committee for Accreditation of Personnel Monitoring Laboratories	CAPML	–
Committee for Investigation and Review of Exposure in Nuclear Fuel Cycle and Radiation Facilities	CIRENURA	3

2.2.3 Approval of Radiological Safety Officers

While the built-in safety of the equipment and institution's operational preparedness towards safety are ensured by adhering to requirements specified by AERB, the implementation of radiation safety is carried out by the AERB approved Radiological Safety Officers (RSO). The RSOs are thus not only acting as extended arms of the regulatory body at every radiation facility, but are also the pivotal interface between the radiation facility and the regulatory body.

The number of RSOs approved for different practices during the year are as given in following table:

2.3 UNUSUAL OCCURRENCES AND ENFORCEMENT ACTIONS

(i) Violations of Regulatory Requirements by Radiotherapy Facility

AERB carried out special regulatory inspection during June 2-3, 2017 for investigation of complaints received against a Radiotherapy Centre, alleging violations pertaining to radiation safety norms in the institute. During the inspection, AERB team observed several non-compliances, major ones being providing false calibration date for well type chamber in e-LORA system, non-provision of TLD badges to students, performing brachytherapy treatment without verifying the position of applicators by appropriate imaging system and shortcomings in carrying out the Quality Assurance tests of radiotherapy equipment.

Based on these findings, a show-cause notice was issued against the institution on June 27, 2017. Institute admitted certain lapses in its response to show-cause. The representatives of the institution were invited to present their case before the AERB safety committee. While admitting the lapses, the representatives assured of implementation of corrective measures to address all the non-compliances. AERB observed that person entrusted with the dual responsibilities as licencee and RSO in the institution had failed to discharge his duties and did not have the requisite administrative authority

Type of Practice	Number	Type of Practice	Number
Radiotherapy	404	Radiation Processing Facilities	19
Nuclear Medicine	134	Industrial Radiography	266
CT and Cath-lab Centres	1622	Ionising Radiation Gauging Devices	165
Research Centres	63	Well Logging	16
Gamma Irradiation Chamber	40		

for ensuring overall effective implementation and management.

Enforcement Actions:

(a) Institution was directed to transfer the responsibility of Licencee to Employer or a suitable radiation professional of Radiotherapy Department, with adequate empowerment to discharge the overall responsibilities of Licencee in an effective manner.

(b) Suspension of RSO approval for a period of three months.

(ii) Unauthorised Loaning and Operation of Industrial Radiography Device

During an unannounced regulatory inspection, on December 26, 2016 it was observed that personnel belonging to an Ahmedabad based radiography agency were operating an Industrial Gamma Radiography Exposure Device (IGRED) belonging to a Delhi based radiography agency. During investigation it was found that the device was taken on loan basis. For loaning of the device no prior permission was obtained from AERB.

AERB has taken following enforcement actions on May 09, 2017 against the agency who loaned the device.

Enforcement action was also taken against the facility which had taken the IGRED on loan basis. (This is the same facility as referred in point (iii) below)

Enforcement Actions:

- Suspension of licence to operate radiography devices for a period of one year.
- Suspension of RSO approval to carry out industrial radiography work for a period of one year.

(iii) Detachment of the Source assembly of Industrial Radiography Device

Incident of detachment of the source assembly from driving unit due to breakage of driving unit ball tip was reported by a radiography agency based in Mumbai. However on investigation, it was revealed that the above radiography device does not belong to the agency that operated the device and in turn was loaned by another radiography agency based in Kolkata. Though the incident happened on July 06, 2017, the Employer/ Licencee of the radiography agency did not report the same to AERB within the specified time period.

Enforcement Action:

Suspension of the licence of radiography agency who loaned the radiography device for a period of one year with effect from October 30, 2017.

Follow-up of Radiation Incident Reported in Year 2016

- **Radiation Injury to the Untrained Person in Industrial Radiography**

Radiation injury on the right hand fingers of an untrained and unmonitored person, who had been engaged for radiography work by a radiography agency at Ahmedabad was reported to AERB on December 22, 2016. The source pigtail with radioactive source (30 Ci of ^{192}Ir) got decoupled from the driving cable and remained in the guide tube during operation of IGRED. The said person continued the radiography job without knowing that the source was in exposed condition, since he was not provided with a radiation survey meter. Later he found that the pigtail was in the guide tube. Without knowing the repercussions, he lifted the source by bare hand and put the source back into the IGRED, which resulted the radiation injury.

The person was neither a trainee nor had undergone any radiation safety program and was not provided personal monitoring device (TLD badge) and radiation survey meter for handling radiography device. AERB issued show-cause notice on December 30, 2016 to which institute submitted response on January 31, 2017 and same was discussed in AERB Apex committee. Subsequently, AERB took following enforcement actions against the institution on May 09, 2017.

Enforcement Action:

- Revoke the Licence of radiography facility, who engaged the untrained person on radiography work.
- Suspension of approval of RSO and Certified Radiographer of radiography institution to carry out industrial radiography work for a period of one year.

INITIATIVE ON PATIENT DOSE MONITORING

Project Report on Patient Dose Recording and Monitoring:

AERB discussed a proposal on patient dose monitoring from Tata Memorial Hospital (TMH), Mumbai on November 08, 2016 in a meeting held at AERB with representative of TMH and representatives of manufacturers/suppliers of computed tomography (CT) and interventional radiology (IR) equipment. The objective of the meeting was to develop a mechanism for linking of patient doses in CT and IR procedures with patient identification number to track his/her radiation dose(s). This tracking of radiation dose would be helpful for alerting the medical practitioner(s) on medical dose history of the patient for taking informed judgment on the medical exposure or repeated radiological procedures. Analysis of patient doses would also be helpful for establishing national level 'Reference Criteria' on the appropriate use of radiological examinations.

A pilot project for recording and monitoring of radiation doses of patients undergoing medical diagnostic procedure as well as IR procedure were deployed at TMH. TMH used Aadhaar no. of patient, wherever possible, as unique identity number for tagging radiation dose record of each individual patient. A meeting was held on April 11, 2017 at TMH, Mumbai with representatives of TMH, All India Institute of Medical Sciences (AIIMS), Delhi and AERB for discussion on collecting and monitoring of accumulated dose to the patients undergoing diagnostic radiology procedure. AIIMS representatives mentioned that patient dose recording and monitoring system is already deployed in the Department of Neuroimaging and Interventional Neuroradiology of AIIMS, Delhi. On May 29, 2017 AERB requested AIIMS to run a similar pilot project on radiation dose recording and monitoring system for the patients undergoing diagnostic radiology as well as IR procedures at AIIMS.

The inputs received from this project would be helpful for devising a roadmap for implementation of radiation dose recording and monitoring system at national level.