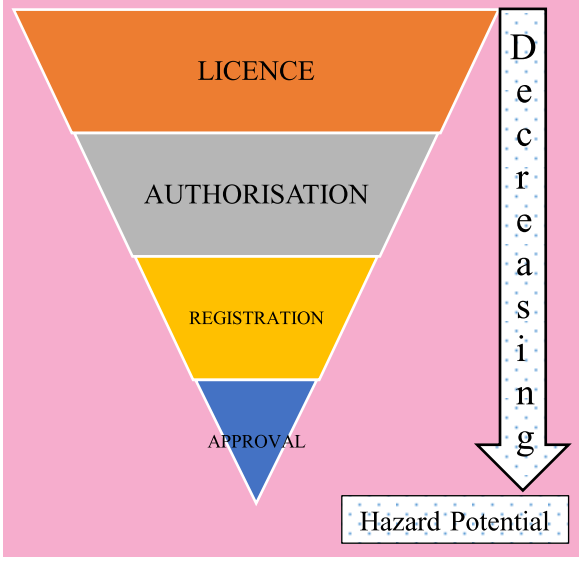
CHAPTER
2

SAFETY SURVEILLANCE OF RADIATION FACILITIES

Radiation sources such as radioisotopes (^{60}Co, ^{137}Cs, ^{192}Ir, ^{75}Se, ^{241}Am, ^{99m}Tc, ^{85}Kr 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 industry, medicine, agriculture and research institutions and AERB regulates these facilities/institutions. These sources have the radiation hazard potential ranging from very-low-to-high. Proper design, handling and disposal methodologies are required for ensuring safe and intended use of radiation sources.

The Graded approach in AERB Consenting Process based on Radiation Hazard Potential



2.1 SAFETY REVIEW MECHANISM OF RADIATION FACILITIES

As per the Atomic Energy (Radiation Protection) Rules, 2004 promulgated under the Atomic Energy Act, 1962, consents issued for handling the radiation sources are categorized as Licence, Authorisation, Registration and Consent/Approval categories, based on their hazard potential. Accordingly, the statutory requirements are graded and may require multiple stages of review to address the hazard, before issuance of consent to operate the facility/equipment. Approvals are also issued as an interim consent towards the respective Licences.

Type Approvals are issued to manufacturer / supplier for equipment conforming to the regulatory standards. No Objection Certificates (NOC) are issued to the suppliers to import either radiation generating equipment or radioactive source, based on which the end-users apply for procurement permission for prototype model on which type approval tests/radiological assessments are demonstrated for issuance of type approval or the respective consent for use.

AERB has a system of multi-tier review process 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 regulated in line with the international requirements specified by IAEA.

2.2 APPLICATIONS OF RADIATION SOURCES AND REGULATORY ACTIVITIES

A glimpse on various applications of radiation sources and status of licence/consent issued during the year to radiation facilities are detailed in following paragraphs.

2.2.1 Medical Applications of Radiation Sources

(i) Radiotherapy

Teletherapy

Teletherapy is a branch of radiotherapy in which tumour is treated by using ionising radiation keeping radiation source(s) at certain distance. The radioisotope like ^{60}Co and radiation generators such as Linear Accelerators (LINAC) are used. Sources and devices used in teletherapy are of high radiation hazard potential.

Proton Beam Therapy

It is a type of radiation therapy that uses a beam of protons having energies 70 to 230 MeV. Proton beam is specifically beneficial in treating paediatric cancers and deep-seated tumours more effectively than the conventional Gamma/ X-ray radiation therapy. First-of-a-kind Proton Beam Therapy facility in the country was licensed in December 2018.

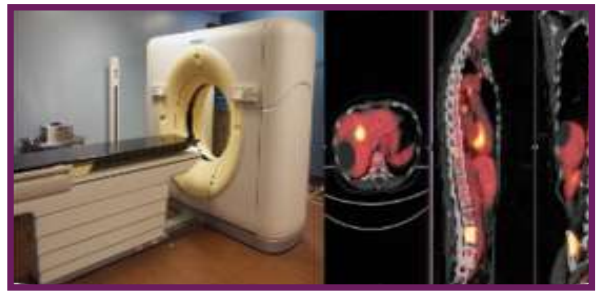
Proton Therapy equipment is of high radiation hazard potential.

Brachytherapy

In brachytherapy, source is kept very near to the lesion. The radioisotopes 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.

(ii) Nuclear Medicine

Nuclear medicine facility uses very small amount of radioactive material in the form of radio-pharmaceuticals (eg. ^{99m}Tc, ^{131}I, ^{201}Tl and ^{18}F) for diagnosis and treatment. Imaging equipment such as PET-CT and SPECT are used in these practices. The facilities using radio-pharmaceuticals are of moderate-to-low radiation hazard.



(iii) Diagnostic Radiology (X-ray)

X-rays are used in medical facilities as an important diagnostic tool. Following practices use X-ray for various diagnostic examinations.

Interventional Radiology equipment (Cath-Lab)

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.

There are 2,150 Cath Lab. equipment

Computed Tomography (CT)

CT is a non-invasive medical examination that uses X-ray equipment to produce cross-sectonal images of the body. CT equipment pose moderate radiation hazard potential to both worker and patient

There are 5,363 CT equipment

Radiography and Fluroscopy

Radiography, Fluoroscopy, Dental X-ray, Mammography, Bone Mineral Densitometer equipment are used for diagnostic purpose. 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

There are about 79,941 such medical diagnostic X-ray equipment

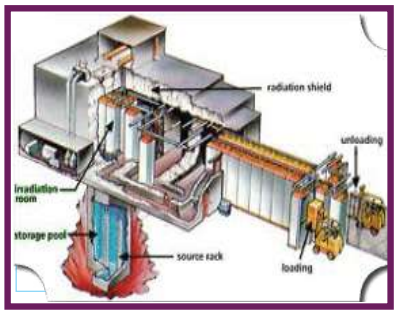
Following table provides the details of consents issued for Medical Radiation Facilities during the year 2020

Type of Consent / No. of Facilities / Equipment	Radiotherapy	Nuclear Medicine	X-ray
No. of Facilities	519	370	62,192
Equipment	752 (Teletherapy) +321(Brachytherapy)	–	87,432
Licence*	196	239	18,075+20 (Manufaturers)
Permission for Import/Procurement of Equipment	144	18	11,842
Permission for Procurement of Radioactive Sources	449	2,153	---
Type Approval/Renewal (Equipment)	07	01	359
Layout Approval	210	109	-

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

2.2.2 Industrial Applications of Radiation Sources

(i) Radiation Processing Facilities (RPF)



RPF includes Gamma Radiation Processing Facility (GRAPF)/ Gamma Irradiators and Electron Beam Accelerators. RPFs are used mainly for radiation processing of food (i.e. inhibiting sprouting, delay in ripening, microbial decontamination, insect disinfestation, shelf-life extension etc.), sterilisation of healthcare products. The activity range is about few PBq (e.g.10^{15} Bq) of ^{60}Co.

Industrial Accelerators Radiation Processing Facility (IARPF) operated in electron mode of energy range from 1.5 to 3 MeV are mainly used for cross linking of polymers in cable industries. One of the benefits of accelerators is that, unlike radioactive sources, it produces radiation only when they are energized.

The RPFs are of high radiation hazard potential.

(ii) Research Accelerators

Research Accelerators or Particle Accelerator Research Facilities (PARF) are generally installed in academic & research institutions and catering to the research needs of various fields of high energy physics, material science, radiation studies etc. Accelerators installed in our country operate in the energy range from a few hundreds of keV to GeV. The hazard associated with the facilities also diverse in nature and ranges from very high-to-moderate. 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).

Besides radiation hazard, other industrial hazards such as electrical, mechanical, Radio Frequency (RF), magnetic, cryogenic etc. are also present in an accelerator facility.

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

Gamma Irradiation Chamber is basically used for research and development and also in blood banks for irradiation of blood and blood components. Radioisotopes like ^{60}Co and ^{137}Cs are used in these applications. The activity ranges from few tens of TBq to few hundreds of TBq.

Now a days, X-ray based Irradiator are also used in blood banks and research application. X-ray energy range is from 160 to 300 keV.

They are of high-to-moderate radiation hazard potential.

(iv) Medical Cyclotron

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

(v) Industrial Radiography (IR)

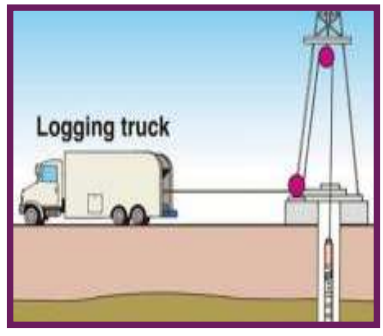
Radiography using Industrial Radiography Exposure Device (IRED), is one of the important non-destructive (NDT) methods used for study / evaluation of weld joints, castings etc. Radioisotopes like ^{192}Ir, ^{60}Co, ^{75}Se, and different energies of X-rays are used in the field of industrial radiography. The activity range is from few hundreds of GBq to few TBq. The X-ray energy range is from few hundreds of keV to few MeV. IREDs are of high-to-moderate radiation hazard potential.

(vi) Nucleonic Gauges (NG)

Nucleonic Gauges also known as Ionising 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 for nucleonic gauges comprise of gamma sources (e.g. ^{60}Co, ^{137}Cs, ^{241}Am etc.), beta sources (e.g. ^{85}Kr, ^{90}Sr, ^{147}Pm, ^{204}Tl) and neutron sources (^{241}Am-Be and ^{252}Cf). The activity range is from MBq to GBq. X-ray based gauges of energy in the range of 30 to 160 keV are also used in industries for coating thickness measurement. IRGDs are of moderate-to-low radiation hazard potential.

(vii) Well Logging (WL)

Radioactive sources are used in well logging application for exploration of oil, coal and geophysical logging etc. The sources used are mainly ^{137}Cs for density measurement, ^{241}Am-Be and neutron generators (Deuterium-Tritium generators) for exploration of hydrocarbon. The activity range is from kBq to GBq. They are of moderate-to-low radiation hazard potential.
Some calibration sources such as as ^{60}Co, ^{226}Ra, ^{232}Th of MBq activity are also used in well logging.



Following table provides the details of consents issued for Industrial Radiation Facilities during the year.

Type of Consent / No. of Facilities / Equipment/ Devices	RPF	Research Accelerators	Medical Cyclotron	GIC	IR	NG $	WL
No. of Facilities	23 (GRAPF) & 13 (IARPF)	10	21	114	660	1150	53
Equipment/ Devices	22 (Accelerators)	10	21	129	3119	8115	1746 (Sources)
Licence*	07	03	05	21	164	119	05
Type Approval/Renewal (Equipment)	---	---	---	08	07	35	---
Type Approval/Renewal Sources	---	---	---	---	19	22	09
Permission for Import/Procurement of Equipment	08	---	---	---	298	365	---
Permission for Procurement of Radioactive Sources	23	---	---	---	1444	107	132
Approval (Layout/ Commissioning/ Source Storage Facility)	08	---	---	---	528	---	05

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

$Nucleonic gauge institute registration and migration of equipment in e- LORA is in progress.

2.2.3 Consumer Products and Research Applications

(i) 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. The products containing radioactivity above the exempt limits have to be assessed for safety and are required to be type approved by AERB.

(ii) Container Scanner Facility

Container scanners are used at various ports (land/sea) for inspection of material inside cargo/container without opening them. These scanners are either accelerators or ^{60}Co based. They are high-to-moderate radiation hazard potential.

(iii) X-ray Baggage Scanner

Scanning facilities are used for detection of contrabands and explosives. Scanning facilities are mainly X-ray based equipment of energy 160 keV and of extremely low radiation hazard potential. Design (Type) approval is carried out by AERB. Only the manufacturers /suppliers of equipment are regulated.

(iv) Facilities using Sealed and Unsealed 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. Unsealed sources are also used in various academic and research institutions such as agriculture research, veterinary science, tracer studies. The activity range is from kBq to GBq. They are of moderate-to-low radiation hazard potential.

Following table provides the details of consents issued for Consumer Products Facilities and Research Applications during the year 2020

Type of Consent / No. of Facilities/ (Equipment)	Consumer Goods Manufacturing Facilities	Container / Baggage Scanner	Research Facilities (Sealed and Unsealed Sources)
	28	22 (31)	311 and 188
Licence*	05	07	85
Permission for Procurement of Radioactive Sources	04	---	262
Type Approval (Equipment)	97	01	---

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

2.2.4 Management of Disused Radioactive Sources

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

During this year, 662 approvals were issued for export of radioactive sources to country of origin, and 80 approvals for returning the sources to Indian supplier or authorised radioactive waste management site(s) in India for safe management.

2.2.5 Safety Committees for Radiation Facilities

The safety committees review the radiation safety aspects of medical, industrial and research radiation facilities which use 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 in the field from the industry, medicine and academic institutions apart from the experts from BARC, BRIT and AERB.

Number of meetings conducted by various committees for safety review of radiation facilities and transport of radioactive material during the year is as given in Table 2.1.

Table 2.1: Meetings of Safety Review Committees of Radiation Facilities

Name of Committee	Number of Meetings
Safety Review Committee for Applications of Radiation (SARCAR)	02
Safety Review Committee for Radiation Processing Plants (SRC-RPP)	01
Committee on Safe Transport of Radioactive Material (COSTRAM)	01
Safety Committee for Hadron Therapy Facilities (SCHTF)	02
Accelerator and Laser Safety Committee (ALSC)	01
Committee for Investigation and Review of Exposure in Nuclear Fuel Cycle and Radiation Facilities (CIRENURA)	04
Total	**11**

2.2.6 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 in various regulatory safety documents, the implementation of radiation safety is carried out by AERB approved Radiological Safety Officers (RSO). The RSOs are thus not only acting as extended arms of AERB at every radiation facility, but they are also the pivotal interface between the radiation facility and the regulatory body.

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The number of RSO approvals/renewals issued for different practices during the year are as given in Table 2.2.

Table 2.2: Approval of Radiological Safety Officers in Radiation Facilities

Type of Practice	Number	Type of Practice	Number
Radiotherapy	264	RPF /Gamma Chamber/ Medical Cyclotron	93
Nuclear Medicine	195	Industrial Radiography	300
Diagnostic X-ray	2,032	Nucleonic Gauges & Well Logging	306
Research Centres	40	Consumer Product Manufacturer & Scanner Facilities	26

2.2.7 Other Regulatory Activities

(i) Approval of Classification Designation of ^{106}Ru Eye Plaque

^{106}Ru eye plaque for brachytherapy treatment of eye cancers was indigenously developed by BARC. Based on requirements the design was modified as Eye Plaque-Round (A) and Eye Plaque Notch (N) type). Accordingly, application for approval of Classification Designation of radioactive sources was submitted to AERB. Based on design safety review and on witnessing the testing of classification of ^{106}Ru eye plaque source models (Eye Plaque-Round (A) and Notch (N) type), AERB issued approval of Classification Designation to ^{106}Ru eye plaque.

^{106}Ru Eye Plaque for Brachytherapy Treatment

(ii) Licence for Operation of Proton Therapy Facilities in India

Licence for operation for the fixed gantry treatment room of Proton Therapy facility of Apollo Hospitals, Chennai was granted on October 15, 2020. With the issuance of this licence, all three treatment rooms of the above facility have now been licensed from radiation safety standpoint. Apart from this, NOC for supply of Single Gantry Proton Therapy Accelerator of model Proteus One was issued to supplier (M/s IBA Particle Therapy India Pvt. Ltd., Chennai) on October 19, 2020 for supply of accelerator to AERB authorised institution.

(iii) Development of QA Test Protocol for Specialised Radiotherapy Equipment

A Task Group (TG) consisting of members from AERB, BARC and experts from radiotherapy institutions was constituted for formulation of Standard Acceptance Test/ QA protocols for specialized radiotherapy equipment such as Gamma Knife, Cyber Knife, Tomotherapy and Intra Operative Radiotherapy. The draft of Acceptance / QA Test Protocol developed by TG was circulated amongst stakeholders in the relevant practice and comments/suggestions of stakeholders were incorporated appropriately. The Acceptance / QA test protocol is now finalized and implemented.

(iv) Self-assessment of Regulatory Compliances by Radiotherapy Facilities

As regulatory inspections were constrained due to the COVID-19 pandemic, a simplified safety status report (SSR) format based on self-assessment of regulatory compliances was prepared and circulated to all the radiotherapy facilities for submission. The reports submitted by the institutions were reviewed for assessment of safety status and verification of regulatory compliance.

(v) Assessment and Resolution of Excessive Exposure Cases for Radiation Facilities

Radiation dose to workers in excess of regulatory constraint of 10 mSv in a specified monitoring period is reported to AERB by Personnel Monitoring Service (PMS) providers, which is communicated further to respective user institution of radiation facility for investigation. Such investigation reports are reviewed by AERB for not only assigning the dose to the worker but also to initiate regulatory actions to prevent such recurrences. For resolution of such reported cases, each reported exposure case is investigated by AERB and the investigation report has to undergo through multi-tire review process in AERB. At present, excessive exposure cases from radiation facilities are dealt by In- House Review Group (IHRG), Committee for Investigation and Review of Exposure in Nuclear Fuel Cycle and Radiation Facilities (CIRENURA) and Safety Review Committee for Applications of Radiation (SARCAR).

During the year 2020, 637 excessive exposure cases were reported from radiation facilities among which 558* (87%) cases were investigated and resolved by In- House Review Group (IHRG) (by applying established criteria for resolution of these cases) and with due concurrence through CIRENURA and SARCAR. Analysis of the investigated cases shows that around 88% of the reported cases are from Diagnostic Radiology (DR) practice alone and out of the reported cases from DR practice, about 95% cases are found to be non-genuine, where the persons were not actually exposed to the reported radiations. Such non-genuine exposure cases are mainly due to storage of TLD badge inside the X-ray installation, use of bare TLD card, wearing the TLD badge over lead apron (which normally reduced the exposure level by around 90%).

Decision of each investigated excessive exposure case is intimated to the utility with appropriate guidelines for further prevention of non-genuine exposure and reports of resolved exposure cases are sent to the PMS Laboratories and NODRS, BARC for maintenance of individual dose records.

AERB also initiated several steps including spreading awareness to the workers about proper use of TLD badges and safe work practice.

2.3 UNUSUAL OCCURRENCES AND ENFORCEMENT ACTIONS

(i) Unauthorised Operation of Manufacturing Facility for X-ray based Equipment

AERB issued show-cause notice to one of the manufacturer of X-ray based equipment (XRF used to check purity of gold) on September 22, 2020 for violating the regulatory requirements specified in Atomic Energy (Radiation Protection) Rules, 2004. The manufacturer had not obtained Type approval (design certification) of the equipment, and also Licence for commercial production of equipment from AERB.

AERB directed the institution to suspend the manufacturing and supply of radiation generating equipment till the issue is resolved. Thereafter, a surprise inspection was also carried out wherein it was found that the institution is in non-operating state. The institution has now approached AERB and committed to obtain all the requisite clearances.

(ii) Un-availability of RSO in Radiotherapy Facility for long duration

AERB conducted surprise regulatory inspection of radiotherapy facility at Ghaziabad, UP. During inspection it was noted that RSO of the facility was on long leave since past several months. A show-cause notice was issued to the institute to explain the non-intimation of long absence of RSO and institute was directed to stop radiotherapy treatment. Subsequently, RSO resumed the duties in the institute. Based on satisfactory response to show-cause by institution, AERB issued permission for resumption of radiotherapy treatment along with a warning to ensure compliance with regulatory requirements.

(iii) Unsafe Industrial Radiography Work

Industrial radiography work on a pipe line at Meerut-Saharanpur road was being carried out by a radiography institution on September 27, 2019, without following radiation-safety precautions. The same was noticed by AERB officials while they were on their official tour. For indulging in such unsafe industrial radiography operations, enforcement actions were initiated on February 06, 2020 by suspending the institution's licence for radiography operations for a period of one year. The approval of Radiological Safety Officer and Radiographer responsible for the unsafe operations has also been withdrawn for a period of one year with requirement of re-certification after one year in case they wish to continue in the profession.

(iv) Misuse of Radiation Professional Registration for Nucleonic Gauge Facilities

While reviewing the application for regulatory consent by AERB, it was noticed that Radiation Professional (RP) Certificate of two personnel were repeatedly being used by multiple Nucleonic Gauge (NG) institutions to fulfil the regulatory requirement for obtaining procurement permission of nucleonic gauges from particular NG supplier. These two radiation professionals were associated with one of the supplier of nucleonic gauges earlier. As a result of these regulatory violations, regulatory actions were initiated by issuing warning letters to the eight NG institutes, which have designated these radiation professionals as RSO for obtaining procurement permission of NGs supplied by the supplier (as referred above) and for not having a RSO thereafter, notifying their negligence about compliance with regulatory requirements. Warning letter was issued to the concerned supplier also for committing improper work practices in supply of NGs. For misuse of RP certificates, the concerned personnel have been recommended to re-appear in the NG Course for re-certification prior to continue their services as radiation safety professional in nucleonic gauge practice.

(v) Unusual Incident at Industrial Radiography Facility

An unusual incident involving detachment of ^{60}Co source (A~1.21 TBq / 32.7 Ci) from Sentinel 680B radiography device was reported on May 19, 2020 by one of the Industrial Radiography institution. Incident was safely handled by the institution and submitted report to AERB. While handling the incident, the RSO of the Institute received a whole body dose of 14.55 mSv. As per the investigation report submitted by the supplier of the equipment, the incident happened due to inadequate lubrication, lack of maintenance and severe environmental conditions leading directly to excessive and unusual wear on the source assembly. To avoid similar incident in future, equipment supplier suggested for frequent maintenance of equipment with special attention to the drive cable. The source was disposed of after retrieval.

2.4 INITIATIVES TOWARDS MAXIMUM GOVERNANCE, MINIMUM GOVERNMENT

(i) Formation of dedicated Section for Technical Support

Radiological Safety Division (RSD) is involved primarily in consenting process of Radiation Facilities (RF) handling radiation sources in Medical, Industrial and Research practices. Due to the voluminous routine activities, the technical matter arising out of the routine activities and other issues could not be not be prioritized and a need was felt to create a Technical Services Section (TSS) dedicated to address these.

This section was formed with a mandate to provide technical support for all RSD related activities which includes development of new regulation/procedures for Radiation Facilities based on inputs from all the stakeholders, coordinating with various Divisions/Directorates of AERB and providing inputs as necessary for various purposes, monitoring e-LORA issues and suggest

modifications.

Following are the major accomplishments after its formation:

(a) Being the nodal section for the Integrated Regulatory Review System (IRRS) related activities, TSS played key role in the execution of the action points identified as a result of self-assessment.

(b) Expedited review of regulatory documents under development for RFs.

(c) Prepared roadmap for seamless transfer of Quality Assurance Agencies in Diagnostic Radiology to NABL for accreditation.

(e) Joint meeting with Indian Institute of Packaging (IIP) to establish seamless regulation w.r.t. the approval of packages for transport of radioactive material.

(ii) Guidance Document on Personnel Monitoring in Radiation Facilities

Utilising its regulatory insight garnered over several regulatory inspections and reviews carried out during consenting processes, including feedback from utilities and Radiological Safety Officers of radiation facilities, the AERB prepared a guidance document entitled 'Personnel Monitoring of Radiation Workers in Radiation Facilities'. This document consists of practice wise suggestions for appropriate personnel monitoring in radiation facilities, taking into account the operational safety aspects, hazard potential and work profile of the workers involved in the practice. It is expected to help the RSO to advise the Licensees on provision of personnel monitoring and maintenance of their dose records. The guidance document has been circulated to all the stakeholders and also made available on the eLORA home page on AERB website for guidance of utilities/stakeholders.

(iii) Booklet on Radiation Safety in Hindi

Subsequent to release of AERB Booklet on 'Radiation Safety in Diagnostic Radiology' in English in 2019, the booklet was translated and re-released in Hindi for extensive understanding by concerned people. This booklet provides ready reference material to owners of X-ray facilities, radiation workers such as medical practitioners and X-ray technologists and other associated workers; on basic information related to use of diagnostic X-ray equipment and radiation safety.

डायग्नोस्टिक रेडियोलॉजी में विकिरण संरक्षा सबंधी पुस्तिका