

BRIT-DAE Annual Report 2023-2024

Executive Summary

Board of Radiation & Isotope Technology (BRIT), the unit of DAE, is focussed on bringing the benefits of the use of radioisotope applications and radiation technology across industry, healthcare, research and agricultural sectors of the society. Harnessing the spin-offs from the mainstream programmes of DAE, such as R&D programmes at BARC and Nuclear Power plants for generating electricity by NPCIL, BRIT has independently created a separate visible area of contribution to the society.

National Technology Day, in India, is celebrated annually on May 11, with great enthusiasm. On May 11, 2023, India has celebrated its 25th anniversary. Prime Minister, Shri Narendra Modi, marked the occasion by laying the foundation stone and inaugurating multiple projects aimed at advancing the country's scientific and technological capabilities. Among the many projects dedicated to the nation, was, BRIT's Fission Molybdenum-99 Production Facility, located in BARC, Trombay, Mumbai. He underlined the significance of nuclear technology in India's progress and development.

A. Products

I. Healthcare

(a) Radiopharmaceuticals Production (RPhP), Vashi

Production & supply of medical radioisotopes and ready-to-use radiopharmaceuticals to nuclear medicine (NM) centres all over India, continued during the reported Year 2023-24.

Fission Moly Production Facility (FMPF): Radiopharmaceuticals Committee (RPC) approved for the production and supply of medical grade high specific activity Mo-99 from BRIT FMPF.

- 179 consignments of alumina column based Coltech (⁹⁹Mo/^{99m}Tc) Generators were produced and supplied to hospitals in India up to May 31 2023. 379 Gel generators were produced using low specific activity Mo-99 and supplied to nuclear medicine centers.
- Technetium-99m cold kits (19 Products; BRIT Code: TCK) for diagnostic imaging of diseases in various organs of the body were supplied to nuclear medicine centres in India.
- Radioimmunoassay (RIA) kits and Immunoradiometric Assay (IRMA) kits were supplied to pathology laboratories and nuclear medicine centres throughout the country for *in-vitro* diagnosis of thyroid disorders.
- Supply of Iodine-131 based products in the form of ¹³¹I-sodium iodide oral solution and capsules for the management of thyroid disorders was continued. Production and supply of I-131 labelled mIBG for diagnosis and therapy of Neuro Endocrine Tumors (NET) was also continued, during the reported period.
- ¹⁷⁷Lu products viz. ¹⁷⁷Lu-DOTA-TATE and ¹⁷⁷Lu-PSMA accounted for the major supply of ready to use injectable therapeutic products. 1300 consignments of these radiopharmaceuticals were supplied to nuclear medicine centers up to Dec. 2023. Around 70 patient doses of the injectable products for palliative care ¹⁷⁷Lu-EDTMP and ¹⁵³Sm-EDTMP were also produced and supplied on weekly basis to the hospitals.

- A new product ^{90}Y (Yttrium-90) labeled Glass Microspheres named “Bhabhasphere” for liver cancer therapy developed in BARC was commercialized from BRIT. The product was supplied to nuclear medicine centers along with an indigenously developed delivery system for patient end use.

(b) Quality Control Analysis & Quality Assurance of Radiopharmaceuticals (Allied Services to RPhP, Vashi)

- Around 411 batches of radiopharmaceutical samples (which includes TCK kits, ready-to-use radiopharmaceuticals injections and oral solution and capsules and ^{99}Mo - $^{99\text{m}}\text{Tc}$ COLTECH Generators, were routinely analysed and certified by QC during the reported period, Apr 2023-Dec 2023. Another, nearly 139 batches of products are expected to be analyzed upto March 2024.
- Regular Quality Assurance was performed before the batch release of all the radiopharmaceuticals which were supplied during the reported period. Batch release certificates were issued for a total of 300 batches of TCK cold kits, ready-to-use radiopharmaceuticals injections, oral radiopharmaceuticals. This also includes radiopharmaceuticals based on Lu-177, Ga-68 and ^{99}Mo - $^{99\text{m}}\text{Tc}$ COLTECH Generators.
- Quality Control services was provided for New Products that were produced at RPhP, Vashi, such as (a) Trial batches (3 Nos.) of FMP-generated ^{99}Mo (^{99}Mo - $^{99\text{m}}\text{Tc}$ COLTECH Generators); (b) ^{90}Y -Bhabhaspheres, were carried out, during the reported period.
- QC Laboratory received ISO 9001:2015 continuation certification after the third-party audit was conducted by AJA authorized agency.

(c) Medical Cyclotron Facility (MCF) at Parel, Mumbai

- The Medical Cyclotron Facility (MCF) of BRIT continued the synthesis and supply of Positron Emitting Tomography (PET) radiotracers, the maximum being [F-18]-FDG. Other PET radiopharmaceuticals include [F-18]-NaF, and [F-18]-FET, which are produced in smaller scales. So far ~173 Ci of [F-18] FDG have been supplied to various hospitals in Mumbai for PET imaging. More than 15000 patients are benefitted with PET investigations upto December 2023.

(d) Medical Cyclotron Facility at RCR, BRIT, Kolkata

- Routine production of various Cyclotron-produced radiopharmaceuticals like, [^{18}F] FDG, were carried out and were supplied to various Nuclear Medicine (NM) Centres in Kolkata.
- Regular Quality Assurance (QA) was performed before the batch release of all the radiopharmaceuticals which were supplied. The Quality Control (QC) for [^{18}F] FDG (83 batches) were routinely analyzed and certified.
- Services towards the supply of TCK Cold kits to various NM Centres in and around Kolkata, were also part of the activities performed by RC, Kolkata.
- Apart from these, RC, Kolkata, is also involved in product oriented Research & Development (R&D) work, which involves (i) Preparation and Radiochemical Separation of ^{68}Ge from irradiated Ga-Ni alloy target in 30 MeV Cyclotron; (ii) Production and Radiochemical Separation of ^{64}Cu from enriched ^{68}Zn target in 30 MeV Cyclotron; (iii) Indigenous development of no-carrier added (nca)- ^{203}Pb radioisotope from low cost natural thallium target using 30 MeV Cyclotron; (iv) Target

preparation, radiochemical separation and sample preparation for Indium-111 RIB using 30 MeV Cyclotron; (v) First time production method standardization of no-carrier-added (nca) Na[¹²³I]I in India, using 30 MeV Cyclotron.

(e) Labelled Compounds (LC)

This Section of BRIT continued the supply of the following labelled Compounds to its users:

- **185 consignments of ¹⁴C & ³H labelled compounds**, were synthesized & supplied during the reported period
- Supply of **10152 numbers of tritium filled light sources (TFS)** were made to defense establishments (April 2023 - December 2023).
- Setting up of Tritium handling facility in CIRUS building, BARC is completed and Cold as well as Hot trials were conducted during the reported period.
- Supply of **76 consignments of deuterated solvents** were made to various users.

Engineering

BRIT continued the tasks related with the safe supply of Cobalt-60 sealed sources such as Cancer treatment Cobalt-60 Teletherapy Sources & Multi-Purpose Gamma irradiator sources. Other Engineering products includes the production and supply of radiography cameras, Blood irradiators and Gamma Chambers.

(a) Sealed Radiation Sources

- Nine ⁶⁰Co-teletherapy sources (CTS) with total activity of about 80 kCi in the range of 193 and 214 RMM were supplied to various cancer hospitals in India.
- **Co-60 Irradiator sources were exported to Sotera (MDS Nordion), Canada (1000 kCi) during the reported period.**
- **64 nos. of W-91 irradiator sources & 252 nos. of BC-188 Irradiator sources** with total activity of **around 4053 kCi were fabricated and 3544 kCi were supplied to various processing plants within the country and abroad.** The irradiators to which these sources are supplied are namely, (a) Akshargamma, Ambarnath – 530 kCi; (b) Gamma Agro, Hyderabad – 190 kCi; (c) NORDION, Canada – 1000 kCi (d) Lion Foods, Gujarat – 300 kCi; (e) Ansell Steriles, Coimbatore – 300 kCi, (f) SOLAS, Mathura – 200 kCi; (g) MICROTROL, Haryana – 400 kCi; (h) Hi-Media, Ambarnath – 500 kCi; (i) SARC, Delhi-124 kCi
Another 2500 kCi is expected to be supplied by March 2024.
- 527 nos. of sources with total activity 21463 Ci of Ir-192 and 6 nos. of Co-60 radiography sources with total activity 307 Ci and 40 nos of CMR sources with total activity 3526 mCi were supplied to various users.
Another 250 nos of Ir-192 source with 6000 Ci is expected to be supplied by March 2024.

(b) Industrial Radiography Devices & Radiation Equipment's

- **Industrial Radiography Devices:** A total of 51 numbers of indigenous industrial radiography devices, which includes ROLI series, and recently launched COCAM-120 radiography device, were supplied to various NDT users within India, upto December 2023. Another 4-5 Nos. of these devices are expected to be supplied by March 2024. Decayed source removal, inspection & servicing of 667 Nos. of radiography devices were done upto December 2023 and ~133 Nos. of devices are expected to be inspected upto March 31, 2024.
- **Four Blood Irradiators-2000 units** with Co-60 source have been supplied to hospitals in India during April 2023 to December 2023 and supply of 02 units of BI-2000 is expected to be supplied upto March 2024.
- **Gamma Chamber 5000: One unit of GC-5000** with Co-60 source was supplied during April 2023 to December 2023, and supply of **Two Units of GC-5000 is expected upto March 2023**. A total of Seven old Units of gamma chambers were decommissioned during the reported period.

B. Services Provided by BRIT

I. Consultancy and MoU for Radiation Processing Plant

- **BRIT signed Two MoU's for setting up Gamma Radiation Processing Plants (GRPF) at various places within the country for disinfestations, shelf-life extension of food products and sterilization applications of healthcare products during the reported year 2023-24.** These are namely M/s Honourable Balasaheb Thackeray Haridra Research & Training Center, for setting up plant at Hingoli in Maharashtra, and, M/s Poly Medicure Ltd., for setting up the plant at Palwal, Haryana.
- Apart from these MoU's, Gamma radiation processing plant of M/s Deptt. of Agricultural Marketing and Agri Business (DAMAB), Tamilnadu, and M/s Lion Foods Pvt. Ltd., Gujarat, were **commissioned** during the reported period.

II. Gamma Radiation Processing Services (GRPS)

(a) Radiation Sterilization Plant for Medical Products (ISOMED)

Gamma Radiation Processing Plant at ISOMED, BRIT, is being revamped and is under renovation. Completely renovated facility building, thus ensuring full compliance to cGMP licensing requirements as per the latest provisions of Drug and Cosmetics Act - 1940 of the Government of India, is under construction. The project safety system upgradation and refurbishment of the ISOMED facility has accomplished ~ 97% of the physical progress till December 2023.

ISOMED continued to offer commercial Gamma Radiation Processing services in GIC-5000 to the vendors of NPCIL, under equipment qualification programme.

(b) Radiation Processing Plant (RPP), Vashi

- Radiation Processing Plant, Vashi provided gamma radiation processing services for Spices and allied products to various exporters from all over the country. Twenty Five new customers were registered during the current year. Main products processed were spices (whole & ground both), pet feed, ayurvedic raw materials & healthcare products. Industrial samples like

switch, induction motor, cable etc were received from NPCIL vendors & exposed with desired doses of gamma radiation as per qualification test criterion.

- During the current financial year, 2023-24, 2252 MT of spices, Ayurvedic raw material, healthcare products and other products were processed.
- Surveillance audits for ISO 9001:2015, 22000:2018 and ISO 13485:2016 were got carried out by certifying agency and found in full compliance with the Standard's requirement.

(c) **Plant Dosimetry & Microbiology – RPP Services from Vashi**

- Dosimetry services during the **commissioning of One Radiation Processing Plants** (private vendors) for sterilization of medical products, were completed during the reported period. **Recommissioning dosimetry was carried out for Four radiation processing plants.** Plant recommissioning dosimetry for two radiation processing plants are expected to be completed by March 2024.
- Dose rate certification was provided to **Two blood irradiators** (BI-2000) and **One Gamma Chamber-5000**, during the reported period. Dose rate certifications to be provided for two Laboratory Irradiators is planned for the next quarter, i.e. upto March 2024.
- Production and supply of 1.6 Lakhs Ceric-Cerous sulphate dosimeters was made available for various gamma irradiators in the country, to measure the absorbed doses during April 2023 to December 2023. Another **1 Lakh Nos. of these dosimeters** and export of these dosimeters to Sri Lanka are expected to be supplied from Jan 2024 to March 2024.
- Dose mapping studies for Product box optimization for Cryo-irradiator is completed.
- Production & supply of 1800 biological indicators to different customers of RPP. 48 lots of tissue grafts received for testing from Biocover laboratories, Tissue Bank, TMC & Novo Tissue bank tested for sterility & bio-burden tests. Also, two lots of spices, chilli powder was tested for microbiological analysis.

III. Radiation Physics Services

- Feasibility study of using non-uniform BC-188 pencils filled with lower and higher activity inner slugs ^{60}Co in industrial gamma irradiators.
- Theoretical study into the potential utilization of radioactive cesium waste canisters for gamma radiation processing purposes.
- Shielding assessment of Ge-68 target plate transportation cask, IFRT Extension hot cell, GS120 cask, and preliminary shielding calculations for transporting F-18 radioisotope.
- Source Loading configurations were designed for 10 Gamma Irradiators.
- Dose rate evaluations based on Monte Carlo simulations for blood irradiators and its validation.
- Radiological Safety of check sources stored with Radiation Physics Group.

IV. Calibration Services for Portable Radiation Monitoring Instruments

BRIT is providing calibration services for gamma radiation monitoring instruments. A total of 112-Nos. of radiation monitoring instruments such as survey meters, dosimeters and portable area monitors are calibrated during the period, from Apr-2023 to Dec-2023. By Mar-2024, 40-more instruments are

expected for calibration. So far, total of **1477** instruments of various type/make are calibrated in the laboratory. Further, due to useful test results obtained by Space Application Centre (SAC)/ISRO, during first round of tests, the Agreement for testing Radiation Sensors, with BRIT, is renewed by SAC. These sensors are to be used in satellite payloads and future manned missions of ISRO. During this period 5-test cycles are completed. Each test cycle lasts ~1.5 working day and involves dose rate of the order of 6-R/h, which is accurately calibrated and traceable to BARC. The data collected during testing of sensors at BRIT facility, has helped SAC/ISRO to fine tune the electronic calibration of these sensors. More number of such tests are planned in near future.



Fig. 1: Test Set up for Radiation sensor by SAC/ISRO, at BRIT Calibration Laboratory

V. Isotope Application Services (IAS)

During the Year 2023-24, following Isotope Application Services were provided by BRIT

➤ Gamma Scanning of Process Columns & Vessels

- TCPP Inlet Separator (02), TPP Glycol Contactor (02) & HP Relief Scrubber, ONGC Offshore, Mathura Tapti Field
- CDU Column (15-C-102), CPCL, Manali Refinery
- EF Condenser (EE-4005A/B), ROG Reboiler (912-EE-2707), Water Seal Drum (952-VV-102), HMEL, Bathinda Refinery
- Condenser (V-104), Petronet LNG, Dahej Plant

➤ Identification of Leaky Heat Exchangers

- DHDT Unit, IOCL, Paradip Refinery
- HCU-DHT Unit, BPCL, Bina Refinery
- DHDT Unit, IOCL, Digboi Refinery

➤ Leakage Detection in Mumbai-Manmad Underground-Underwater Pipeline, BPCL, Mumbai

➤ **Leakage Detection in Esterification Loop, RIL, HMD, Hazira**

➤ **Radiometry Services**

- Na-I solution and capsule production Hot Cell, GRIL, Vijayawada
- I-131 Dispensing Hot Cells, Samruddhi Health Equipment's Pvt. Ltd. Talaja

VI. Radioanalytical Laboratory (RAL) Services

Nearly, 135.5 mCi of ³²P labelled nucleotides, 787 nos. of TCK Cold kits, Ready-to-use Sodium pertechnetate and nonradioactive molecular biology reagents and kits were supplied, on customer demand, was supplied from Regional Centre, BRIT, Hyderabad. Development of a new product 'Magnetic cellulose (MagCell) bead based genomic DNA extraction kit (MAGCK-01/02)' was taken up and completed.

C. Radiation Technology - Design & Development

- Successful commissioning and inauguration of Cryo-Irradiator with 95 kCi of Co-60 for irradiating marine products.
- Design approval is obtained for Mobile Food Irradiator (MFI), which is a category-II, panoramic, dry storage, batch type gamma irradiator, designed to irradiate low and medium dose food products like fresh fruits and vegetables, cereals, pulses etc. The work contract for the construction of Mobile Food Irradiator is in the advance stage.
- Fabrication of first commercial operational prototype COCAM-A radiography device with lower strength (2 Ci Co-60) for effective marketing is completed.
- Designed the Package for Transportation of Molybdenum-99 (MTP-1200) to carry 44.4 TBq (1200 Ci) of Mo-99 radioisotope is completed. Based on the Safety assessment report (SAR), AERB has accorded the Type B(U) transport package approval to the MTP-1200 package.
- Construction of Integrated Facility for Industrial Radiography (IFIR) Devices: An integrated facility is conceptualized for the complete operations being carried out related to the industrial radiography device at BRIT-Vashi.

D. Customer Support:

As the nodal agency for sales and supply, marketing and customer relations, co-ordination & logistics support cell continued to provide regular and uninterrupted supply of radioisotopes & allied products, radiation technology equipments to more than 3000 user institutions in the healthcare, industrial, research and agricultural sectors.

- More than 13000 radiopharmaceutical orders with a total revenue of 43.37 Cr were processed during 2023-24 period. The revenue from sales of Radiopharmaceutical products has been steady during the period
- Y-90 based Glass microspheres (Product code YM-40) was launched during FY 2023-24 and has been given wide publicity.
- "BRIT at doorstep" initiative continued efficiently, spreading the product supply to more regions in the country. Door delivery of BRIT products has been well accepted and appreciated by BRIT customer base across the nation. The door delivery of products has tremendously increased the customer satisfaction, especially the pick-up support of spent generators.

- Two export orders for Co-60 source (1300 kCi) with a total foreign revenue of USD 51,13,600 were carried out. One more major export order (625 kCi) of Co-60 for USD 2562960 is ready for dispatch and is scheduled in March 2024.
- For radiopharmaceutical products, 25 new customers were registered on the eportal during the period April, 2023-Feb, 2024. For. non-medical products, 37 new customers in offline mode and 97 new customers in online mode were added during 01.04.2022 to 04.03.2023 (total 159 new customers)

E. Right to Information (RTI)

A total of 71 RTIs were received by BRIT during the reported Financial Year 2023-24. These were effectively dealt and disposed off by the Administration Section of BRIT.