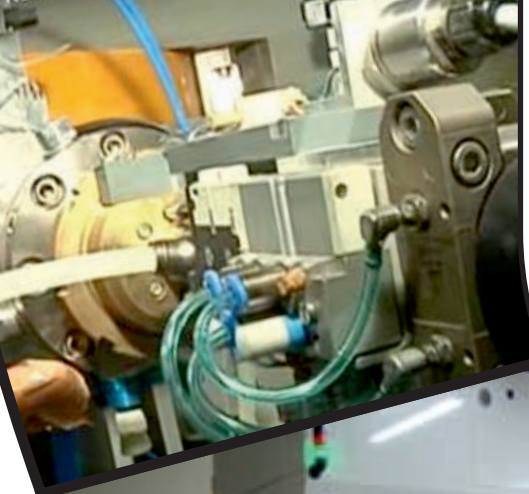

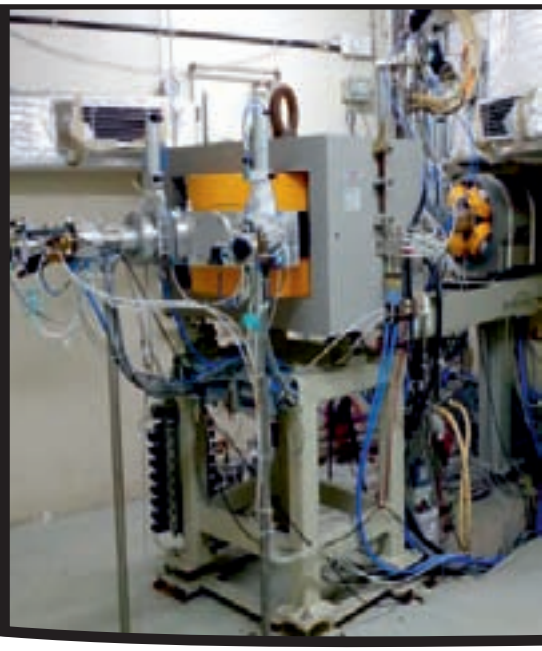

सत्यमेव जयते

GOVERNMENT OF INDIA

ANNUAL REPORT
2018-2019

राष्ट्र की सेवा में परमाणु

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BRIT

ATOMS IN THE SERVICE OF THE NATION

BOARD OF RADIATION & ISOTOPE TECHNOLOGY (BRIT)

DEPARTMENT OF ATOMIC ENERGY

BOARD OF RADIATION & ISOTOPE TECHNOLOGY

DEPARTMENT OF ATOMIC ENERGY

GOVERNMENT OF INDIA

BRIT

ANNUAL REPORT 2018-2019

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CHAPTER 1

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.

A. Products

I. Healthcare Products

(a) Radiopharmaceuticals Production (RphP), Vashi

- Regular production and supply of new ready-to- use radiopharmaceutical injections based on Ga-68 (PSMA-11 and DOTA-TATE) (PET radiopharmaceuticals), useful for the diagnosis of prostate cancer and neuroendocrine tumors (NET) has been started during the reported period of 2018-19. These supplies were possible after the facility for imported ^{68}Ge-^{68}Ga Generator was installed and validated for regular use at BRIT.

- More than 617 Ci of I-131 products in ~23000 consignments have been supplied to various hospitals in the form of capsules and solution for both, diagnosis and treatment of thyroid disorders including the treatment of thyroid cancer. This data also includes I-131 radiolabelled mIBG which is being used for diagnosis and therapy of Neuro Endocrine Tumors (NET).

- New therapeutic product based on I-131 radiolabelling, ^{131}I-Lipiodal injection for the treatment of Liver Cancer, was produced by RPhD, BARC and supplied by BRIT in the reported period.

- Nearly 47 Ci in 490 consignments of theraputic products, other than I-131 based radioactive products, such as ^{153}Sm, ^{177}Lu and ^{32}P for bone pain palliation, were supplied to nuclear medicine hospitals upto March 2019.

- Regular production and supply of new therapeutic radiopharmaceutical, ^{177}Lu-DOTA-TATE injection for the treatment of sstr-positive neuroendocrine tumors (NET), has been continued for treating NET successfully.

- 2107 consignments containing approximately 515 Ci of ^{99}Mo in the form of Sodium Molybdate solution for Coltech Generators, Geltech Generators and Solvent Extraction Generator for obtaining Technetium-99m at hospital end, have been supplied to various hospitals in India in the Financial year 2018-19.

- More than 15600 consignments of Technetium-99m cold kits (19 Products; BRIT Code: TCK) for imaging various organs have been supplied to nuclear medicine centres in India. Production and regular supply of new products, ^{99m}Tc-cold kit for the preparation of ^{99m}Tc-Macro Aggregated Albumin (MAA) injection, useful for lung perfusion imaging and ^{99m}Tc-Ubiquicidine (Tc-UBI), used for infection imaging, which started last year, continued, during the reported time.

- Production of 'Kit for the preparation of ^{99m}Tc-HYNIC-TATE injection', useful for imaging neuroendocrine tumors, started as a part of technology transfer from RPhD, BARC.

- Various Tc-99 cold kits were exported to Molecular Supplies SpA, Santiago, Chile. These include kits for the preparation of ^{99m}Tc-Radiopharmaceuticals, such as kits for preparation of ECD injection, EC injection, HSA-Nanocolloid for sentinal node imaging, and Q-Tech kits.

- A total of 1278 consignments of Radioimmunoassay (RIA) and Immunoradiometric Assay (IRMA) kits were supplied to various pathology laboratories and nuclear medicine centres throughout the country for *in-vitro* diagnosis of thyroid disorders.

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

- Around 600 batches of radiopharmaceutical samples (which includes TCK kits, ready-to-use radiopharmaceuticals injections and oral solution and capsules) and 48 batches of ^{99}Mo-^{99m}Tc COLTECH Generators were routinely analysed and certified by QC during this period.

- 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 482 batches of TCK cold kits, ready-to-use radiopharmaceuticals injections, oral radiopharmaceuticals. This also includes recently launched radiopharmaceuticals based on Lu-177, Ga-68 and ^{99}Mo-^{99m}Tc COLTECH Generators.

(c) Labelled Compounds (LC)

- This Section of BRIT continued the synthesis and supply of a variety of ^{14}C, ^{3}H and ^{35}S-labelled products and various types of Tritium-filled self luminous sources (TFS). It is also involved in the production and supply of C-14 Urea Capsules. The 'Urea Breath Test' using these capsules is useful in the diagnosis of the infections caused by microorganisms named, Helicobacter pylori, a spiral bacterium, which may be responsible for gastritis, gastric ulcer, and peptic ulcer disease. During the Year 2018-19, more than 14100 TFS sources of various sizes, shapes and tritium content were supplied to defence establishments and used for illumination of various types of gadgets and instruments. Supply of 150 Ci of Tritiated water was supplied to M/s ONGC.

- Based on MoU between BRIT and Heavy Water Board, deuterated NMR solvents were dispensed and supplied to various customers. All the solvents supplied had >99.8% Deuterium abundance.

(d) Medical Cyclotron Facility (MCF)

- 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, [18F]-FLT, and [F-18]-FET, which are produced in smaller scales. So far ~300 Ci of [F-18] FDG in 476 consignments have been supplied to various hospitals in Mumbai for PET imaging upto March 2019. More than 15000 patients are benefitted with PET investigations in the reported year 2018-19.

(e) RCR's of BRIT

- Production of Fluorine-18 isotope for the preparation of Fluorodeoxyglucose (FDG) was carried out successfully using Medical Cyclotron, CYCLONE-30, at Radiopharmaceutical Facility of Regional Centre (Kolkata) of BRIT, located at Variable Energy Cyclotron Centre (VECC), Kolkata.

II. Engineering Products

(a) Sealed Radiation Sources

- Twenty teletherapy sources (CTS) of ^{60}Co containing activity in the range of 153 and 232 RMM were supplied to different cancer hospitals in India and abroad during 2018-19.
- **Co-60 teletherapy source of 1MCi was exported to REVISS Services (UK) Ltd. in July 2018. This is the biggest export order executed in the history of BRIT.**
- **Three CTS sources were exported to Sri Lanka and one source exported to IMO, International Health Systems Ltd., Nigeria.**
- Co-60 source with total activity of 55,560 Ci in forty two source pencils were loaded in four units of Gamma Chamber 5000 (GC-5000).
- Seventy two W-91 Irradiator sources of industrial grade & 163 BC-188 Irradiator sources with 3842 kCi activity in 16 consignments were supplied to 14 radiation processing plants within the country during the year 2018-19.
- A total of 646 consignments (with total activity of 24,597 Ci) of ^{192}Ir & ^{60}Co Radiography sources were supplied to NDT user's during the year 2018-19.
- 750 consignments of Co-60 Custom Made Reference (CMR) sources with total activity of 1.38 Ci were supplied to various users upto March 2019.
- Dose mapping of Gamma Chamber - 5000 unit was done with Cs-137 source.

(b) Radiation Equipments

- 47 numbers of Radiography Cameras, ROLI-2 model, were supplied to various NDT users within India and services were provided for 500 numbers of BRIT and imported radiography cameras.
- Four Blood Irradiators – 2000 (BI-2000) units with 15 kCi of Cs-137 source in 24 pencils were supplied to hospitals in India during the year. Replenishment of source to ACTREC was made.
- Gamma Chamber–5000 units with 27,959 Ci have been supplied to IIT, Roorkee, India, and another one was exported to Vietnam for research purposes during 2018-19. The services was provided by BRIT for 10 units of GC-5000. Also, services for decommissioning of five units was given to users.

B. Services Provided by BRIT

I. Consultancy and MoU for Radiation Processing Plant

- BRIT signed NINE 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 2018-19.

II. Gamma Radiation Processing Services (GRPS)

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

- 2664 Cubic meters of medical supplies have been sterilized using gamma radiation processing at ISOMED, BRIT during 2018-19.

(b) Radiation Processing Plant (RPP), Vashi

- Radiation Processing Plant extended their services to irradiate about 4340 MT of spices and allied products during the reported time period.
- Radiation Processing Plant Facility at Vashi was certified for ISO 9001:2015 (Upgraded from 9001:2008 to 9001:2015). Surveillance audits for ISO 22000:2005 (Food Safety Management Systems) and ISO 9001:2008 were also carried out by the certifying agency and found in full compliance with standard's requirement.
- Plant commissioning dosimetry AMC of 'Dry Sludge Gamma Irradiator' was completed.
- Plant commissioning dosimetry for Class III and Class VI products of M/s Electromagnetic Industries was also completed during the reported period.
- Dose rate certification was provided to four blood irradiators and two gamma chambers which were supplied to various cancer hospitals and research universities respectively.
- Production & supply of ~2 Lakhs Ceric-Cerous Sulphate Dosimeters were done for various gamma irradiators in the country and abroad for the measurement of absorbed dose.

III. Radiation Physics Services

- ❖ Source loading pattern was designed for replenishment of Co-60 activity for ten Gamma Radiation Processing Irradiators provided by BRIT under MoU's.
- ❖ Shielding evaluations were done for the upgradation of the gamma processing plant belonging to M/s Agrosurg Irradiators (India) Pvt. Ltd. at Vasai, Maharahtra.
- ❖ Theoretical dose evaluations were carried out for the new Radiation Processing Plant belonging to M/s Electromagnetic Industries, Vadodra, Gujarat.
- ❖ Radiological Surveillience was provided to various facilities of BRIT such as, Radiation Processing Plant (RPP) and Decayed Source Removal Facility (DSRF). Regular inspection for safety systems, contamination checks & personnel monitoring are done followed by sending the Safety Status Reports to AERB by the Radiation Physics Group.
- ❖ Probabilistic Safety Assessment for RAPPCOF expansion was carried out during the reported period.

IV. Calibration Services for Portable Radiation Monitoring Instruments

❖ BRIT is providing calibration services for gamma radiation survey instruments. A total of 190 survey meters, dosimeters and portable area monitors are calibrated upto March 2019

V. Isotope Application Services (IAS)

- Isotope Application Services was provided for Gamma Column Scanning for seven different petroleum industries. Gamma scanning of Process columns and Identification of leaky heat exchangers using radiotracer techniques to trouble shoot different kinds of problems at various industries such as IOCL Mathura Refinery, BPCL, Kochi Refinery, thereby saving crores of rupees for the country.

- Radiotracer study was performed by BRIT for safe disposal of fly ash at NTPC, Talcher, during 2018-19.

VI. Radioanalytical Laboratory (RAL) Services:

- During the Calendar year 2018-19, Radioanalytical Laboratory (RAL) has carried out more than 6844 tests on export/domestic commodities and 910 tests on water samples for gross alpha, gross beta, ^{226}Ra, ^{228}Ra and total uranium content.

- Radioanalytical Laboratory offered services for the measurement and certification for the food items for humans & animal consumption for man-made (artificial) radioactivity, naturally occurring radioisotopes in environmental samples, such as coal, flyash, soil, rock phosphate, phosphor gypsum etc., Total uranium in water samples by assay using fluorimeter, Co-60 contamination levels in steel samples and surface radiation dose of steel consignments at factory premises and warehouses.

C. 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 about 2000 user institutions in the healthcare, industrial, research and agricultural sectors.

CHAPTER 2

DESCRIPTION

BRIT has achived highest Turnover so far, Rs. 134.43 Crores in 2018-19

The application of radioisotopes in healthcare, industry, agriculture and research is one of the most wide-spread peaceful uses of the nuclear sciences, next to nuclear power production. Realizing the importance of the use of the radioisotopes for societal benefits and national development, the Department of Atomic Energy has, over the years, built up adequate infrastructure facilities for the production and applications of radioisotopes which is in the form of Board of Radiation & Isotope Technology (BRIT). BRIT has completed its three decades this year on 01, March, 2019. It continues its endeavour towards providing its best services to mankind through meeting the demands of the users, be it in the fields of nuclear medicine, healthcare or towards advanced technologies such as engineering and radiation technology equipments for medical as well as industrial uses, radiation processing services, isotope applications or radioanalytical services.

A. Products

I. Healthcare Products

BRIT continued the supply of healthcare products and its services useful for in-vivo and in-vitro investigations apart from the products from labelled compounds and radiochemicals for varied research purposes and production and supply of tritium filled sources (TFS) useful for defence establishments.

(a) Radiopharmaceuticals Production (RPhP)

Radiopharmaceuticals are meant for in-vivo use, mainly for diagnostic and therapeutic purposes. Since they are meant for in-vivo use as pharmaceutical grade products, compliance to good manufacturing practices (GMP) is mandatory. In-vitro Radioimmunoassay (RIA) and Immunoradiometric Assay (IRMA) Kits and C-14 Urea capsules are used mainly for diagnostic use. Positron Emitting Tomography (PET) is a powerful imaging agent through which quantitative information on the distribution of positron-emitter labelled radiopharmaceuticals (PET radiopharmaceuticals) in the body can be realized. ^{18}F-FDG is currently the most widely PET radiopharmaceutical in clinical oncology in addition to its clinical applications in cardiology and neurology. The application of PET in clinical oncology is increasing since many molecular targets relevant to cancer can be labelled with positron emitter radiopharmaceuticals and also these products needs to be produced in strict GMP compliance.

- Regular, uninterrupted, production and supply of radiopharmaceuticals, all over India, was continued. However, efforts were made towards expanding the production capacity by introducing some new products based on ^{99m}Tc, ^{177}Lu, ^{68}Ga and ^{188}Re radiopharmaceuticals

- ^{131}I as Na^{131}I is one of the most important isotopes which is mainly used for diagnosis and therapy of various thyroid disorders, including thyroid cancers. Approximately 632 Ci of Na^{131}I and over 23000 consignments were processed, formulated and supplied to various nuclear medicine hospitals all over India in the form of solution and capsules. This also includes I-131 labelled mIBG, which is supplied as sterile injections and is used for the diagnosis and treatment of Neuro Endocrine Tumors (NET).

- Pneumatic based, remote foot operating ATOMLAB 400 Dose Calibrator is installed inside the fume hood and in between the transport box of both, ^{131}I-NaI Solutions (IOM-1) plant in the main Production Laboratory. This set-up would help increase the integrity of Quality Assurance as well as decrease the MAN REM dose.

- BRIT continues to supply I-131 labelled therapeutic product, I-131-Lipiodol, used for the treatment of Hepatocellular Carcinima [the most common type of Liver Cancer (single patient dose is 75mCi of I-131)] which was launched last year in collaboration with RPhD, BARC.

- During the reported period, another milestone of 12th Plan Project, "Advanced Facilities for Radiopharmaceuticals Production (AFRP)", ~740 GBq (20Ci) capacity GMP compliant ^{131}I-mIBG Production Facility (Procured from ITD, Dresden, Germany) has been installed and cold commissioning is awaited. Trial cold runs for pharmaceutical validation are presently being undertaken.

- Amongst the other therapeutic products supplied by BRIT, such as P-32 [Samarium Phosphate Colloidal Injection] for radiation synovectomy, Sm-153-EDTMP injection for bone pain palliation, ready-to-use ^{177}Lu-EDTMP injection for bone pain due to the spread of cancer in bones, a new therapeutic radiopharmaceutical, namely, Lu-177-DOTA-TATE which was launched last year for treatment of metastatic (somatostatin receptor positive) neuroendocrine tumors (NET) has gained a lot of importance. ~47 Ci in 494 consignments were supplied to nuclear medicine centres all over India during the reported year 2018-19.

- BRIT has introduced two ready-to-use diagnostic radiopharmaceuticals based on peptide labelling with Gallium-68 (Ga-68) isotope for imaging cancers of different origin. Supply has started for ^{68}Ga-Prostate Specific Membrane Antigen (PSMA) for diagnosis of Prostate Cancer and ^{68}Ga-DOTA-TATE for the diagnosis of neuroendocrine tumours (NET). These radiopharmaceuticals were supplied to the nuclear medicine centres in and around Mumbai only (short half-life of Ga-68 radionuclide, which is only 68 minutes) after the installation of ^{68}Ge-^{68}Ga Generator at BRIT.

^{68}Ga-Radiopharmaceuticals synthesis module along with ^{68}Ge-^{68}Ga generator

^{68}Ga-PSMA scan carried out with BRIT product

- During the year 2018-19, more than 16500 Nos. of cold kits for formulation of ^{99m}Tc radiopharmaceuticals (19 products; BRIT Code-TCK) in nearly 16000 consignments were formulated, lyophilized, QC tested and supplied to various nuclear medicine hospitals all over India.

- Nearly 525 Ci of ^{99}Mo, in 2150 generators in form of Sodium Molybdate solution, for solvent extraction generator, Coltech generators and Geltech generators is supplied to the Nuclear Medicine Centres in India.

- More than 2,50,000 In-vivo diagnostic investigations are estimated to have been carried out this year with varied diagnostic radiopharmaceuticals, the major one being, ^{99m}Tc based cold kits and ^{99}Mo-^{99m}Tc generator systems and around 17000 therapeutic applications are estimated to have carried out during the reported year using BRIT therapeutic radiopharmaceuticals including Na^{131}I for treating hyperthyroidism and thyroid cancer therapy.

- 'Facility for the production of cold kits for the preparation of Tc-99m Radiopharmaceuticals' was awarded the certificate for the compliance to WHO cGMP requirements by M/s URS Certification Ltd (a member of URS Holdings Group, U.K.) (Recertified as per Current Standards).

- Various Technetium-99m Cold Kits for the preparation of Technetium-99m radiopharmaceutical injections were exported to Chile, South America.

- A total number of about 1381 radioimmunoassay (RIA) and immunoradiometric assay (IRMA) kits to serve about 1,25,250 in-vitro investigations, were supplied to various hospitals, research centres and immunoassay laboratories throughout India.

- Radioimmunoassay (RIA) and Immunoradiometric Assay (IRMA) Kits manufacture, supply and R&D accreditated for compliance to ISO 9001:2015 and ISO 13485:2016 by UKAS (United Kingdom Accreditation Services) during the reported period.

(b) The Medical Cyclotron Facility (MCF)

The Medical Cyclotron Facility (MCF), Parel continues the production and supply of Positron Emission Tomography (PET) radiopharmaceuticals, mainly ^{18}F-FDG and ^{18}F-Sodium Fluoride and to a lesser extent ^{18}F-Flurothymidine (FLT) and newly launched [F-18]-Fluro Ethyl–L-Tyrosine (FET).

➢ Regular and uninterrupted supply of about 476 consignments of PET radiopharmaceuticals such as ^{18}F- FDG, ^{18}F-NaF, ^{18}F-FLT, and ^{18}F-FET to various hospitals in and around Mumbai accounting for nearly 303 Ci of radioactivity during the year 2018-19. More than 15000 patients benefitted with PET investigations in the reported year.

(c) Quality Control Testing and Quality Assurance of Radiopharmaceuticals (Allied Services to RPhP)

Quality Control group is responsible for the analyses of various ready-to-use radiopharmaceuticals, radiochemicals, TCK cold kits, certifying the product and the timely release of QC reports. During the year 2018-19, following are the QC reports:

- Routine sample analyses: More than 500 batches of radiopharmaceutical samples and 48 ^{99}Mo-^{99m}Tc COLTECH Generators were routinely analysed and certified by QC during this period 2018-19. These samples are tested for their performance in physico-chemical analyses, sterility tests, bacterial endotoxin tests and animal biodistribution studies (wherever necessary).

- Routine maintenance and documentation activities such as microbiological environment testing of clean rooms and production facilities during production were carried out on routine basis. QC testing equipments such as Radio TLC scanners, HPLC, Spectrophotometers, micropipettes, Biological Safety Cabinets etc were also routinely calibrated and maintained in the laboratory.

- Refurbishment of Quality Control Laboratory and GMP Certification: Refurbishment work was taken up by Technology Development (TD) Group. The work is completed. Quality Control Laboratory was audited by third party auditor for GMP compliance. Based on the audit report of TCK Production and Quality Control, GMP Certification was renewed for TCK Production Facility.

- RPC approval for Quality Control testing method for implementation in routine QC: HPLC and Paper Chromatography methods were standardized for determination of Radiochemical Purity (RCP) of ^{68}Ga-PSMA-11. Regulatory approval has been obtained from Radiopharmaceutical Committee (RPC) for implementation in routine QC.

- Method Development/Modifications: a) Standardization of HPLC method for the determination of RCP (QC-Physicochemical analysis) of ^{99m}Tc-EC and ^{99m}Tc-GHA. The results would be put up for the approval by RPC committee. (b) Standardization of QC methods of analyses of trial batches of ^{68}Ga-PSMA and ^{68}Ga-DOTA-TATE, the results were submitted to RPC for its approval followed by routine production & supply of these products since August 2018. (c) Standardization of Quality Control testing methods for trial batches of ^{177}Lu-PSMA was carried out and the data is submitted for RPC Clearance. (d) A Class III Biosafety Cabinet was procured from internal sources in BARC for its use in regular Sterility Testing of injectable radiopharmaceuticals, while the validation of this cabinet was completed during the reported period.

  Quality Assurance (QA): Production and Quality Control Testing processes were routinely monitored and documented by QA Section and appropriate QA certification for a total of 384 batches of radiopharmaceuticals were released from April 2018 to March 2019. Batch Manufacturing Production Records (BMPR) for TCK cold kits (12 products) were modified and improvised as per the GMP guidelines. Preparation of QA documents for new products, such as ^{68}Ga-DOTA-TATE and ^{68}Ga-PSMA, ^{99}Mo-^{99m}Tc Coltech Generator and new TCK cold kit [^{99m}Tc-Macroaggregated Albumin (^{99m}Tc-MAA)] were introduced. Batch Manufacturing Records, Quality Control analyses data records, Certificate of Analysis and Batch Release Certificate were prepared during the reported period.

(d) Labelled Compounds (LC)

Labelled Compounds Programme of BRIT is involved in the synthesis & supply of a variety of ^{14}C, ^{3}H and ^{35}S-labelled products and various types of Tritium-Filled Self-Luminous sources.

- During 2018-19, Labelled Compounds Programme has supplied 21000 Tritium Filled Self-luminous (TFS) sources of various sizes and shapes to defence establishments and used for illumination of various types of gadgets and instruments.

- Work related to design and fabrication of Tritium trapping system was completed and is successfully being implemented for the production of TFS sources during the reported year.

- Custom synthesis of variety of labelled compounds along with ^{35}S-labelled amino acids, having very high specific radioactivity and radiochemical purity, are also supplied. Labelled Compounds Laboratory also continued the production and supply of ^{14}C-Urea Capsules which is used for diagnosis of Helicobacter Pylori infection which causes stomach ulcers.

- Based on the MoU signed between BRIT and Heavy Water Board, deuterated NMR solvents were dispensed and supplied to various customers. All the solvents that were supplied had >98% Deuterium abundance.

- Supply of 150Ci of Tritiated water was supplied to M/s ONGC.

II. Engineering Products

The various engineering products offered by BRIT included the supply of more than 4128 kCi of radioactivity in various forms and for varied uses.

(a) Sealed Radiation Sources:

➢ Co-60 Teletherapy Sources (CTS) for Cancer Hospitals: Twenty ^{60}Co-teletherapy sources with total activity of about 224 kCi in the range of 154 and 232 RMM were supplied to various cancer hospitals in India.

➢ Out of these, three numbers of Co-60 teletherapy sources with the strength of 214 RMM, 209 RMM and 210 RMM were exported to Sri Lanka through M/s Teambest Theratronics Asia Pvt. Ltd. Another Co-60 teletherapy source (177 RMM) was exported to IMO International Health Systems Ltd. (IIHS), Nigeria. Yet another 10 Nos. of sources are fabricated and ready for supply. Twenty decayed sources were unloaded from the teletherapy units and stored for fabrication of irradiator source. These sources were fabricated at RAPPCOF, Kota using Co-60 produced indigenously in nuclear power reactors.

➢ Industrial Irradiator Sources: Seventy two irradiator sources with total activity of around 4000 kCi were supplied in sixteen consignments to various processing plants within the country. The irradiators to which these sources are supplied are namely, (a) AVPP, Ambernath – 219990 Ci; (b) ALIGNED Industries, Bhiwandi – 124999 Ci; (c) OGFL, Kolkata – 124995 Ci (d) PINNACLE, Ahmadabad – 99963 Ci; (e) AMC, Ahmadabad – 149985 Ci; (f) REVISS, UK – 998900 Ci; (g) NIPRO, Pune – 299998 Ci, (h) MICROTROL, Bangalore – 247981 Ci; (i) SARC, Delhi – 199368 Ci; (j) RPP, Vashi – 200000 Ci; (k) EMI, Vadodra – 299999 Ci; (l) GAMMA AGRO, Hyderabad – 249993 Ci; (m) UML, Vadodra – 299816 Ci and (n) AGROSURG, Vasai – 154393 Ci. A total of 360 kCi of irradiator sources are supplied to the following: (a) INNOVA, Bangalore – 160 kCi; (b) MSAMB, Vashi – 100 kCi and (c) PINNACLE, Ahmadabad – 100 kCi.

➢ **One single supply of Co-60 Irradiator source (1000kCi) was exported to REVISS SERVICES Ltd. (UK).**

➢ ^{192}Ir and ^{60}Co Radiography sources: A total of 646 consignments of Ir-192 & Co-60 radiography sources with total activity 24597.5 Ci were supplied from April 2018 to March 2019.

➢ Custom Made Sources (CMR) and Reference Sources: 824 consignments (27 Nos.) with total activity of 1.38 Ci of Custom Made Sources (CMR) of Co-60 were supplied up to March 2019.

- Ir-192 Pt wire for Brachytherapy: One consignment containing 0.8345 Ci of Ir-192 was supplied to the cancer hospital for its use in brachytherapy was supplied during the reported period.

- A contract is to be signed with LANL, USA for provision of technical support on repatriation of decayed radioactive sources in India back to USA. The sources from five institutes are to be collected, removed from the devices and repatriated to USA. The contract is already forwarded to DAE for their approval.

(b) Radiography and other Radiation Equipment Devices

- Radiography Camera: Production and supply of 47 new indigenous radiography camera, model ROLI-2, and servicing and inspection of 388 numbers of BRIT manufactured as well as imported ROLI cameras, were the highlights during the reported period.

- Gamma Chamber 5000: Three units of GC-5000 were loaded with Co-60 source and transported to different institutions in India.

- Out of these, one Gamma Chamber – 5000 unit was exported to NEAD-Technology Application and Development Company Ltd. VIETNAM.

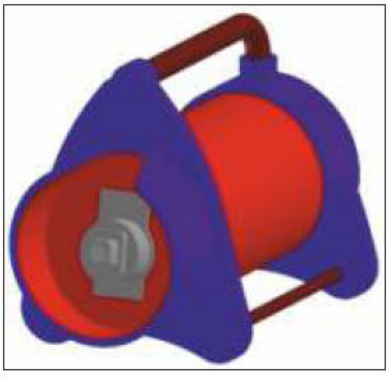
- Blood Irradiator: Four Blood Irradiators-2000 units with Cs-137 source (9116 Ci) have been supplied to hospitals in India during April 2018 to March 2019.

(c) Engineering Design Development

- Co-60 based Radiography Camera using Tungsten & Depleted Uranium shielding has been tested and approval for Type B (U) Package has been obtained from AERB.

- Radiography Camera device is designed for source strength of 120 Ci of Ir-192. It uses depleted uranium as shielding material.

- BLC-200 transportation cask is developed for the transportation of 200 kCi of Cobalt-60 Irradiator source. This cask has been approved by AERB as Type B (U) package.



B. Services

I. Consultancy and MoU for Radiation Processing Plants

- MOU was signed with M/s ZarimsDrynamics LLP, Ahemdabadfor setting up a Gamma Radiation Processing Plant for disinfestation, shelf life extension of food products and sterilization applications of healthcare products near Kheda, Gujarat.

- MOU signed with M/s Solas Industries, Noida for setting up a Gamma Radiation Processing Plant for disinfestation, shelf life extension of food products and sterilization applications of healthcare products at Mathura (Uttar Predesh).

- MOU signed with M/s Microtrol Sterilization Services Pvt. Ltd., Mumbai for setting up a Gamma Radiation Processing Plant for disinfestation, shelf life extension of food products and sterilization applications of healthcare products at Rewari(Haryana).

- MOU signed with M/s HiMedia Laboratories Pvt. Ltd., Mumbai for setting up a Gamma Radiation Processing Plant for disinfestation, shelf life extension of food products and sterilization applications of healthcare products at Ambernath (E), Maharashtra.

- MOU signed with M/s AV Gamma Tech LLP, Mumbai & M/s Gamma Agro Medical Processing, Hyderabadfor setting up a Gamma Radiation Processing Plant for disinfestation, shelf life extension of food products and sterilization applications of healthcare products nearAmbernath, Thane&near Aerospace Park, Bangalore.

II. Gamma Radiation Processing Services (GRPS)

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

- ISOMED facility, engaged in contract gamma radiation processing services for terminal sterilization of the medical products has processed 2664 Cubic mtrs of products.

(b) Radiation Processing Plant, Vashi (RPP, Vashi) and Dosimetry

- Radiation Processing Plant, Vashi has provided gamma radiation processing services for Spices, Ayurvedic raw material, healthcare products and pet feed etc. to 285 customers from all over the country. Source strength of the plant was increased up to 700 kCi so as to increase the throughput of the plant. Eight new customers for Spice, Ayurvedic raw material and pet feed were registered with the facility during last nine months. New products such as coconut water powder, liver extract powder, watermelon powder and tobacco were also successfully irradiated to achieve microbial decontamination.

- During the current financial year, 4749.56 MT of spices and other products were processed against the annual target of 4500 MT.

- ISO 9001:2015 Certification & source replenishment of Radiation Processing Plant, Vashi (BRIT): ISO 9001:2015 (Upgraded from 9001:2008) Certification for Quality Management System was received for Radiation Processing Plant, Vashi (BRIT) for providing Gamma Radiation Processing Services for Hygienization of spices, ayurvedic raw materials, pet feed and packaging materials.
  Source replenishment of 200 kCi of Co-60 was carried out for Radiation Processing Plant, Vashi (BRIT) to increase the throughput in September, 2018.

- As a support for R&D activities, following materials/equipments were irradiated at various doses to study the effect of radiation so as to develop radiation resistant materials:

  1. 22KW motor from MAPS.
  2. Air filter regulator from M/s Placka Instrumentation.
  3. Heat shrinkable sleeves from M/s Poshya & Co.
  4. Silicon resin bonded woven glass cloth laminated sheets from M/s Karad Motors Pvt. Ltd.
  5. Pressure transmitters from M/s Indexel Engineering and M/s Baldota Controls.
  6. PTFE Dumbels and Fluoro elastomers from M/s L&T and M/s Industrial Spares Manufacturing Co.
  7. Motor insulation materials from M/s Hydrodyne.
  8. Cables from M/s Apar Industries.

(c) Activities at Dosimetry Group of RPP include the following:

- Additional revenue was obtained from GRPS related products and services which include the production & supply of 2.0 Lakh Ceric-Cerous Sulphate dosimeters for various gamma irradiators in the country and around 1500 Nos. of Ceric-Cerous Sulphate dosimeters were made and exported to Atomic Energy Regulatory Board, Sri Lanka, for absorbed dose measurements.
- Radiation Processing Plant recommissioning dosimetry was carried out in eight plants in the country for low, medium and high dose application. Dosimetry for mango irradiation was carried out at M/s

Innova Agri Bio Park, Bengaluru, M/s IFC, Vashi, for approval of the facility by USFDA – APHIS for quarantine purpose.

- Plant commissioning dosimetry for Dry Sludge Gamma Irradiator at AMC, dosimetry for medical products sterilization plant at M/s Pinnacle Therapeutics Pvt. Ltd., Ahmedabad and plant commissioning dosimetry for Class VI and Class III products of M/s EMI were provided by BRIT.

- Dose rate certification were provided for 10 Nos. of blood irradiators supplied to various cancer hospitals and four Nos. of Gamma Chambers that were supplied to research universities in the reported period.

III. Isotope Application Services

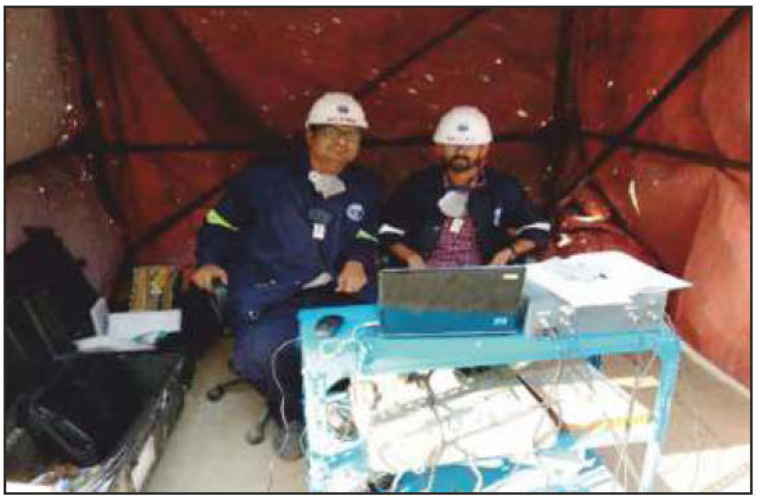
Isotope Application Services (IAS) Section of Marketing & Services (M&S) Division of BRIT offered its valuable, timely and elegant services and solutions to various industries across the nation.

(a) Gamma scanning:

1) IOCL Mathura Refinery

a) FCCU Reactor Section: lower spent catalyst powder output from reactor to the regenerator was observed in fluidized catalytic cracker unit. Coke deposition or lumps formation was suspected in the packing present in the annular region of the reactor. To identify the location of the problem, four cordial scan lines were identified and around 10 m of the section was scanned by 80 mCi Co-60 source. The radiation data was recorded by scintillation detector and plotted as elevation versus count rate. Good flow of powder flow was observed in one half of the reactor section whereas in another half, intermittent flow was observed with few lumps present.

b) Debutanizer column: off specification products were obtained from the debutanizer column of FCCU unit. The column height was around 35m and diameter around 2.5m. two scan lines were identified for two pass trays of the column. The attenuation profile obtained indicates that the trays were mechanically intact. Flooding and high vapor density was observed at some locations of the column.



c) Amine regeneration column: very high sulphur content was observed in the lean amine generated from amine regeneration column. Due to highly corrosive environment in the column, mechanical damage was suspected inside of the column. The column height and diameter were 25m and 2m respectively. Scanning of the column concluded that all the trays in the column are intact with liquid up to the weir height and appropriate clear vapor space. Uneven liquid distribution over the chimney tray was observed.

2) BPCL Kochi Refinery

In vacuum column of Kochi refinery, high MCR, Asphaltenes and metals content in VGO was observed. It was suspected that wash oil bed#5 is not functioning properly. Probable causes may be maldistribution, coking, bed packing damage etc. hence BRIT was requested to carry out gamma scanning to ascertain the cause of malfunction.
Four cordial and two diagonal scanlines were identified for the gamma scanning of wash oil bed to identify the cause of malfunctioning. 150 mCi of Co-60 was used to scan the wash oil bed of vacuum column. Gamm scanning results showed improper functioning of liquid distributor above the bed. Uneven liquid distribution was observed over the bed;however, bed was mechanically intact.

(b) Radiotracer study to identify the leaky heat exchanger

- In DHDT unit of BPCL Kochi refinery, sulphur content in the diesel product was very high (around 800 ppm). It was suspected that any of the feed preheating heat exchangers may be leaking due to which final diesel product was contaminated with sulphur. Online identification of the leaky heat exchanger was carried out by injecting organic Mo-99 as radiotracer in shell side inlet (high pressure) and leakage was detected by placing leakage detectors on the tube side outlet (low pressure). Out of the eight exchangers in the series, two heat exchangers (102-F & 102-H) were found leaky. During shutdown of the unit, the above said heat exchangers were taken offline and it was verified that gasket heat exchangers got ruptured. This study helped BPCL to reduce their shut downtime time and hence save the valuable revenue.

(c) Radiotracer study for fly ash disposal at NTPC, Talcher

- Thermal power plants generate several tons of fly ash every day. Safe disposal of fly ash is a major issue as it contains many toxic chemical constituents which may pollute the environment. One of the modern methods of fly ash disposal is to judiciously dump its slurry in a nearby abandoned open cast mine void. To understand the leaching behaviour of heavy metals to surrounding surface and ground water of the near by area of mine void, radiotracer study was carried out as recommended by MoEF. The neutron irradiated fly ash was used as radiotracer. Zn-65 present in the fly ash was isotope of interest as its half life is 245 days and it is having high gamma energy. Automatic can cutter was

Operating the automatic can cutter & Injection of irradiated fly ash to the slurry tank

developed to cut the cold pressed aluminium can containing the radiotracer. The radiotracer was injected to the mine void through the slurry pipe line. After injection, spread of the radiotracer was tracked through under water detection system. The background samples were collected from the mine void and near by strategically located bore wells and hand pumps. The samples will be collected in regular intervals from these locations up to two years. Analysis of the samples will be carried out by RAL,BRIT.

(d) Troubleshooting FCCU catalyst losses by radiotracer study

- In the fluidized catalytic cracking unit of BPCL, Mumbai Refinery & MRPL, Mangalore Refinery, heavy catalyst loss was observed which was leading high financial losses & environmental pollution. To understand the function of air distributor, flow dynamics of catalyst powder & analyse any mechanical damages to the cyclones inside of the regenerator and reactor of the FCCU unit, radiotracer study was conducted using scandium glass as a radiotracer. The tracer was injected to the system by specially fabricated injection system and path of the tracer was recorded by placing scintillation detectors at various strategic locations. The data was recorded through multi input data acquisition system. The cause of the malfunction was identified.

Injection arrangements at PFCCU Unit,MRPL

IV. Radiation Physics Services Group

- During the reported period, Radiation Physics Group was involved in designing the source loading pattern for replenishment of Co-60 activity in the following eleven Gamma Radiation Processing Plants:

  - SARC, Delhi
  - NIPRO, Satara
  - MICROTROL, Bengaluru
  - AIIPL, Vasai
  - RPP, Vashi
  - EMI, Vadodra
  - GAMPPL, Hyderabad
  - UML, Vadodra
  - MSAMB, Vashi
  - INNOVA, Bengaluru
  - GAMPPL, Hyderabad – second loading during the reported period

- The Gamma Radiation Processing Plant of M/s Agrosurg Irradiators (India) Pvt. Ltd. was designed for 1.0 Mega Curie of Cobalt-60 radioactive source and was used for the radiation processing of food commodities and sterilization of medical products. M/s. Agrosurg wanted to upgrade the plant to 1.5 Mega Curie to meet their irradiation requirements. Adequate shielding thickness were evaluated and recommended for all protective barriers of the plant are as per AERB SAFETY STANDARD No. AERB/RF-IRRD/SS-6 (Rev-1) for land based stationary Gamma Irradiators. New shield design was also provided to M/s. Agrosurg Irradiators (India) Pvt. Ltd..

- For the commissioning of the newly set up Gamma Radiation Processing Plant of M/s Electro Magnetic Industries, Vadodra, theoretical dose evaluations were carried out in the product material before the first source loading.

- Probabilistic Safety Assessment (PSA) for RAPPCOF expansion: As part of the PSA study for RAPPCOF, first initiating events have been identified. The safety measures present in the facility against the initiative events are taken into consideration. Scenario modelling is done using Event Tree Analysis and Fault Tree Analysis. Event trees and Fault trees are developed that relates the potential accident sequences and response of the relative safety measures to the undesirable consequence of the event.

- Radoplogical surveillance to the Radiation Processing Plant and Decayed Source Removal Facility (DSRF) was provided, which included inspection of safety systems, area monitoring and personnel monitoring and the safety report thus made was forwarded to AERB.

V. Calibration Services for Portable Radiation Monitoring Instruments

- BRIT is providing calibration services for gamma radiation survey instruments. So far 525 Portable Radiation Monitoring Instruments such as survey meters, portable area monitors etc. have been calibrated till March 2019.

- The laboratory is approved by AERB in accordance with the Rule-29 of Atomic Energy Regulatory Board (AERB) Radiation Protection Rules, 2004.

VI. Radioanalytical Laboratory Services

Radioanalytical Laboratory (RAL) carried out the assay for the following measurement and certification services:

- Man-made (artificial) radioactivity levels in large number of food items for human & animal consumption
- Naturally occurring radioactive materials (NORMs) in environmental samples such as coal, fly ash, soil rock phosphate, gypsum etc
- Co-60 contamination in steel.
- Survey & certification for surface radiation dose of steel consignments at factory premises and warehouses.
- Gross alpha, gross beta and other specific radioisotopes such as ^{226}Ra & ^{228}Ra in water samples
- Total Uranium in water samples by assay using Fluorimeter.

During the year 2018-19, Radioanalytical Services at Vashi Complex carried out more than 5520 tests on export/domestic commodities and 1374 tests on water samples (gross alpha, gross beta ^{226}Ra & ^{228}Ra).
The laboratory is accreditated by NABL for testing many of the parameters and empanelled by BIS for the testing of gross alpha and gross beta in water samples.

VII. Services extended by RCR's, BRIT, and RPh-QC Section, Vashi Complex

IRegional centres at Delhi, Dibrugarh & Kolkata, Hyderabad (also k/as Jonaki), Bengaluru, and Kota continued the services of ready-to-use-radiopharmaceuticals to surrounding nuclear medicine hospitals, preparation & supply of labelled compounds, radioanalytical certifications and processing of Co-60 sources for their various uses in Engineering Programme of BRIT respectively. Around 3,000 consignments of in-vivo and in-vitro kits were supplied to RCR's for providing extended services to nearby hospitals, research centres, or institutions at and surrounding these cities.

RCR, Kolkata & Dibrugarh :

- Sale of cold kits for radiopharmaceuticals from the retail outlet at RC, Kolkata: During the year 2018-19, approximately 270 Nos. of Technetium cold kits for formulation of ^{99m}Tc-radiopharmaceuticals were supplied to various Nuclear Medicine Hospitals in Kolkata

- Fluorine-18 isotope was successfully produced for the first time using CYCLONE-30 in Medical Cyclotron Project (MCP), Kolkata during the reported period 2018-19.

- Fluorodeoxyglucose (FDG) synthesis was also carried out at RCR, Kolkata, and also FDG synthesis module was indigenously developed at RCR, Kolkata located at Variable Energy Cyclotron Centre (VECC).

- Services at RC, Dibrugarh: Regional centre BRIT, Dibrugarh located at Assam Medical College & Hospital is rendering RIA and IRMA diagnostic services for the benefit of patients of the entire North-Eastern region. The Radiopharmaceutical products produced and supplied by BRIT, Vashi complex are extensively used by the RC, Dibrugarh for the diagnosis & investigation of various diseases. More than 7000 patients of the region avail the services from this centre.

F-18 target and its associated systems/modules

CYCLONE-30, Cyclotron Machine at Medical Cyclotron Project (MCP) at VECC

RCR, Bengaluru :

- Regional Centre, BRIT, Bengaluru supplied ~85 Ci of ready-to-use ^{99m}Tc-pertechnatate to nuclear medicine hospitals and 820 TCK cold kits were sold through retail outlet and door delivery for the preparation of ^{99m}Tc-radiopharmaceuticals to nearby nuclear medicine centres.

- Gamma irradiation unit, BI-2000 is decommissioned and sent to BRIT, Vashi Complex for loading of new Cs-137 source.

- Radioanalytical Laboratory analyzed and certified 186 samples for the measurement of residual radioactivity in various commodities such as food items for human & animal consumption, medicine and miscellaneous items.

RCR, Delhi :

- Regional Centre for Radiopharmaceuticals, Delhi continued the supply of clinical grade, ready to use diagnostic ^{99m}Tc-radiopharmaceuticals injections in compliance with GMP and RPC, ready-to-use radioactive therapeutic injections of ^{131}I-mIBG, ^{177}Lu, ^{153}Sm, COLTECH/GELTECH Generators and TCM-2 (^{99}Mo Generator kit for Solvent Extraction), for nuclear medicine centres in Delhi and NCR regions. During the period, 2018-19, Regional Centre, Delhi has been involved in production & supply of ~22.7 Ci of clinical grade, ready-to-use Tc-99m radiopharmaceuticals injections.

- RCR, Delhi has obtained NOC from AERB for the procurement of ^{68}Ge/^{68}Ga generator from abroad. The procurement of hot cell, labelling module and automatic dose dispenser for setting up of ^{68}Ge/^{68}Ga generator facility at Regional Centre, Delhi is in progress.

RCR, Hyderabad (Jonaki) :

- During the period, Regional Centre of BRIT, Hyderabad (Jonaki) obtained NOC from AERB to procure Sodium Molybdate solution (185GBq/week) & ^{68}Ge-^{68}Ga Generator (1.85GBq/Six months) to initiate the supply of Tc-99m and Ga-68 radiopharmaceuticals to local Nuclear Medicine Centres. It received exemption from authorization for safe disposal/transfer of radioactive waste for Jonaki, BRIT, and transport permission from AERB to start the production & supply of ready-to-use $^{99m}TcO_4^-$ (pertechnatate). RCR, Hyderabad, has also set up Sterility testing (ST) and Bacterial Endotoxin Testing (BET) laboratories where physicochemical tests, ST and BET tests were all performed for batches of $^{99m}TcO_4^-$ (pertechnatate) using Autosolex before their supply.

- Also, it continued the synthesis and supply ^{32}P labelled nucleotides (436 consignments – 287.5mCi) and a few molecular biology reagents such as Taq DNA Polymerase (~7.7 Lac Units), PCR master mix and enzymes, for research in frontier areas of Molecular Biology, Biotechnology, Biomedical and Drug Discovery research of the country. It marketed ^{35}S-labelled amino acids products and TCK cold kits (972 Nos.), produced at BRIT, Vashi Complex.

RCR, Kota (RAPPCOF)

- RAPPCOF facility continued the tasks related with the supply of Co-60 for various uses, right from receiving the adjuster rods from various Indian PHWR power reactors (a by-product of neutron regulation), processing of the activity, fabrication of sealed sources, to supply of Co-60 sources (irradiator sources & teletherapy sources), are all carried out.

- At RAPPKOFF, Kota, total activity of Co-60 which was processed during the year was about 4214 kCi during the financial year 2018-19, which is a milestone in the history of BRIT.

- RAPPCOF successfully fabricated Co-60 Teletherapy Source with highest RMM possible as of now, i.e. 242 RMM, indigenously.

- After obtaining special arrangement approval from AERB, RAPPCOF was successful for transportation of eight adjuster/absorber rods in four consignments from KAPS, Gujarat to RAPPCOF during the reported period.

Quality Control Analysis Services from Vashi Complex for Outside Agencies

- **Testing Services:** a) Drug Control General (India) (DCGI) entrusted the responsibility of quality testing of ^{99}Mo-^{99m}Tc Generators imported in India by various vendors as well as imported TCK cold kits. During the reported period, one batch of Tc cold kit for the preparation of Tc-99m-labelled Tetrafosmin (Myoview) was analyzed for outside agency (GE Healthcare), whereby certificate of analysis was provided to them after evaluating the performance for all the QC parameters, including animal biodistribution studies for the evaluation of physiological distribution of ^{99m}Tc-Tetrafosmin injection.

C. 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 about 2000 user institutions in the healthcare, industrial, research and agricultural sectors.

Twenty new customers were registered for supply of radiopharmaceuticals during the year 2018-19. 125-150 No. of A1 forms are processed every week for ordering radiopharmaceuticals and till date 125 standing order forms have been registered for supply of Radiopharmaceuticals. Domestic requirement of Irradiator source and Teletherapy source were also met as per the order received. Applications for various permissions and approvals are also being processed through eLORA portal to meet the regulatory compliance.

Export orders of four teletherapy sources, one low dose Irradiator (GC-5000), one Irradiator source consignment of 1000kCi, two dosimeter consignments and radiopharmaceutical cold kits were also processed and supplied bringing foreign exchange revenue.

In an effort to improvise on sales support, feedback was collected during various conferences and seminars which have been consolidated and analyzed. During the year 2018-19, the Marketing staff participated in five exhibitions. The staff also participated in the National union of Journalist along with participants from various DAE units and held BRIT stall for them at Kaiga Power Station, NPCIL, Kaiga.

D. HRD and Activities related to Official Language Implementation at BRIT

HRD activities of BRIT: Apart from the services towards the commercialization of radioisotope activities in healthcare, industries and radiation processing, BRITians are also involved in human resource development programmes. These comprises of taking part in not only imparting training to post graduate students and research scholars from different colleges and universities in all sectors of BRIT programme, but also they are active in participating in various workshops and conferences. They are also active in pursuing various research projects pertaining towards their products or towards developing new designs and products which are useful for the society.

Activities related to the Official Language Implementation at BRIT:

- BRIT, along with its scientific activities, has continuously encouraged the use of Official Language in its official correspondence by complying with the directions issued jointly by Department of Official Language and Department of Atomic Energy (DAE). The quarterly meetings of Official Language Implementation Committee (OLIC) are organized regularly, during which the OLIC members positively discuss the various activities with regard to implementation and propagation of official language and also monitor its progress.

- Apart from the routine work, BRIT has organized Hindi Workshops and Hindi Competitions under the auspices of Joint Official Language Implementation Committee and also conferred the prizes to the winners of the competitions on the eve of Hindi Diwas in Joint Ceremony.

- The officers/employees were nominated in the workshops organized under the aegis of Joint Official Language Implementation Committee. Similarly, BRIT officers/employees have been also nominated in technical/scientific seminars organized by Heavy Water Board, Atomic Energy Regulatory Board and BRIT officers presented lectures in Hindi on the scientific topics in the seminars held.

- Additional competitions, such as Quiz, Dictation & Essay writing and Noting/Drafting and Extempore Speech, under the auspices of Official Language Implementation Committee in Vashi Complex premises during the period 2018-2019 and its Prize distribution ceremony is proposed to be organized.

- Senior officers of BRIT had attended a discussion on Parliamentary questionnaire with regard to Official Language organized on March 26, 2019.

- Dominant/effective measures for the propagation among the BRIT staff taken by OLIC are as follows during the reported period: (a) To make the officials aware of Hindi books, a brief description or any other information related to the Hindi books purchased for BRIT library is being displayed all around the year on the screen situated in the administration building of BRIT. (b) Apart from the Hindi noting sentences etc. are also being displayed

- Overall along with other successful activities of BRIT, the implementation and propagation activities of Official Language are effectively progressing day by day.

Plan Projects

A. Project: DAE Medical Cyclotron Project: Radiopharmaceutical Facility.

- **Progress:** Production of F-18 using CYCLONE-30 Medical Cyclotron at BRIT, VECC, was initiated. Fluorodeoxyglucose (FDG) target was installed followed by the preparation of ^{18}F-FDG. Procurement of bio-quality control equipments like PTS (portable endotoxin testing system), incubator for sterility testing, sterility reagents (media), and Bacterial Endotoxin test (BET) reagents etc. has been completed. Installation of different instrumentation modules such as Syringe drive module, Helium manifold, Target manifold module and Liquid distribution cabinet (input/output), supplied by M/s IBA, were completed. The liquid target assembly was installed on the corresponding target stations provided inside the FDG target vault. Two targets were assembled, installed and successfully tested for any leakage or any vacuum problems. Mechanical support for both, the targets were designed and fabricated indigenously. Electric cables were routed to the control room where the control PLC is installed. Teflon tubing connections required for the F-18 targets operation were completed and tested. Cold run was carried out to test different operations and the consistency of the system before the hot trials, or in other words, with F-18. Thus, FDG synthesis was successfully completed for the first time at RCR, BRIT.

B. Setting up of Fission based ^{99}Mo Production Facility.

- **Progress:** External civil construction is completed & occupied. Internal civil modification is ongoing and only 50% completed so as to accommodate M/s. INVAP design layout of the processing equipment.
  More than 80% of the equipments required in the plant and machinery has been received and their installations are in progress.

C. Advanced Facilities for Radiopharmaceuticals Production

- Civil construction of first floor over RPL extension building is completed in all respects is completed and occupied by staff.

External and Internal view of Fission Molybdenum Project (FMP) building

- ~740 GBq (20Ci) capacity GMP compliant, I-131 mIBG production facility (procured from Dresdon, Germany), has been installed and cold commissioning is completed.
- New lyophilizer (LYOMAX), is procured and installed.

D. Project : Technology Development for Radiation Technology Equipment

- Civil construction for setting up of manufacturing facility for I-125 seeds as brachytherapy sources, which would be useful for the treatment and management of Prostate Cancer, is completed. Tender for the procurement of plant on 'turnkey' basis has been raised.

- Transportation cask, BLC-200, for Co-60 has been developed and the design is approved by AERB.

BRIT Website:

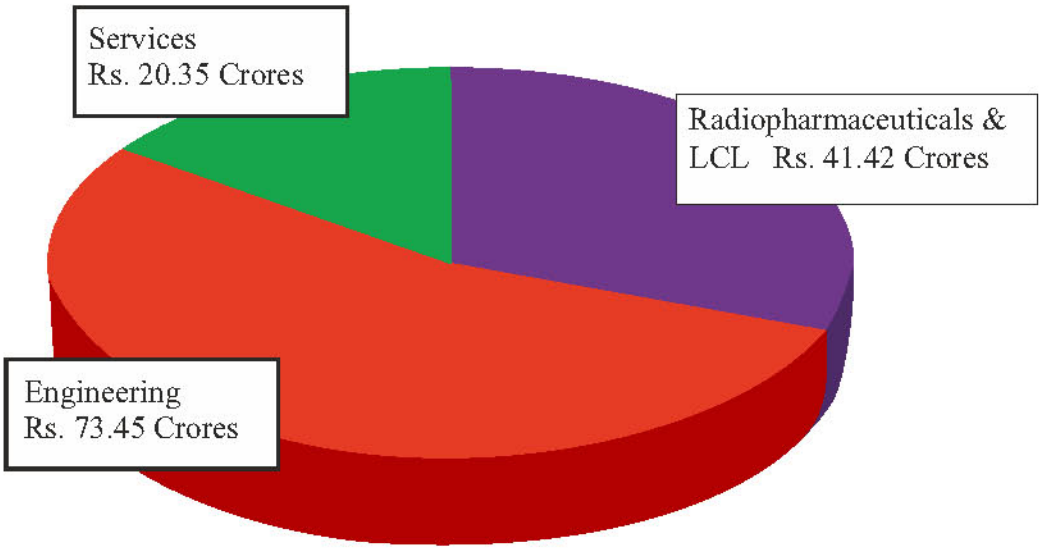
BRIT website provided regular updates on various programs and activities related to developments in BRIT. Customer oriented reports were uploaded on website almost on daily basis enhancing co-ordination and communication with the customers.

Also, Marketing & Services programme of BRIT has undertaken project to revamp its current website located at < www.britatom.gov.in > along with building an online sales management system (SMS); online quality management system (QMS) and an online radioisotope inventory management system (RIMS). The modules are proposed to be implemented in phase-wise manner.

Sales Turnover in 2018-19

Appropriate Services and Sales of Radioisotopes & Allied Products Supplied by BRIT during 2018-19

S.No.	Item	Sales turnover from April 2018-March 2019
1.	Consignments	63, 807
2.	Activity	~ 4133 kCi
3.	Total Sale/Target Sale	Rs. 134.43 Crores/ Rs. 110 Crores



CHAPTER 3

Research & Development

A. Development Work by Design & Development Section of Engineering Division:

(i) Type B(U) approval of package design for BLC-200 obtained from AERB

AERB granted type B(U) certificate to BLC-200. The radioactive source transportation cask is designed to carry 200 kCi of Co^{60}. The cask dimensions are 942 mm dia. X 1386 mm height. The gross weight of cask is 4.85 Te. It uses lead and tungsten are used as shielding material and SS304L as structural material. An outer enclosure has been provided to keep accessible temperature within permissible limit. The cask is basically an upgraded version of the existing BLC-125 cask. The source capacity of BLC-125 is 125 kCi Co^{60}. The increased source capacity of BLC-200 required enhancement in radiation shielding and it uses a hybrid shielding of lead and tungsten. Upcoming irradiation facilities in private sector are higher capacity and supply order of irradiator sources of more than 125 kCi Co^{60} are often received. To reduce number of transportation of such casks, higher capacity casks are desirable.

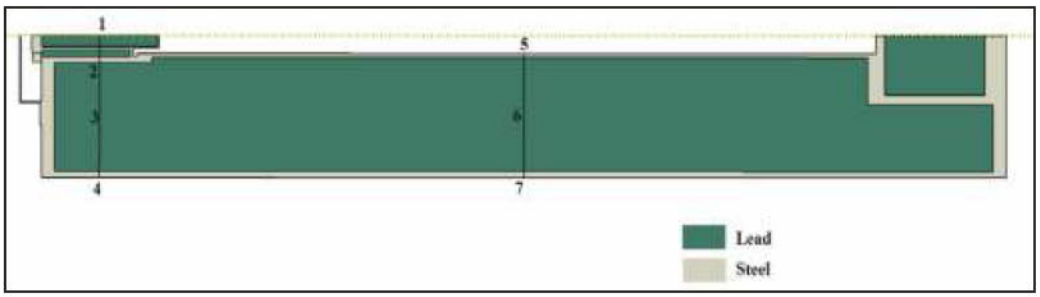
Fig. (a) BLC-200 radioactive source transportation cask and (b) without outer enclosure

Although the changes made in design are not expected to give different results in structural analysis w.r.t BLC-125, the surface temperature during normal conditions and melting of lead during fire test are expected to increase due to additional heat load of 75 kCi of ^{60}Co source. The package was analyzed extensively for shielding, mechanical and thermal test using FE numerical simulations to show its conformance to the regulatory requirements

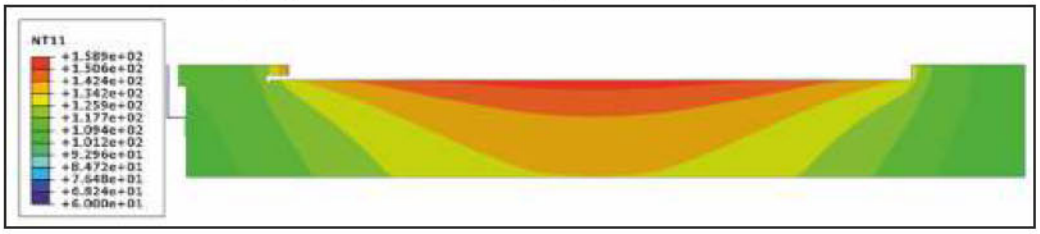
(ii) Thermal simulation of absorber rod transportation cask

The absorber rod transportation container is used to remove and transport cobalt absorber rods from NPPs to RAPPCOF, Kota. The container is designed as a type B(U) package having a source capacity of 300kCi of Co^{60}. The shielding material used in the cask is lead encased in steel shells. In order to re-qualify the package as type B(U) package mandated by AERB finite element thermal simulation of the package in axi-symmetric configuration was done. The package was evaluated for normal conditions

followed by fire test and finally concluded with post-fire analysis. The axi-symmetric model of the cask is shown in fig.



(a) Fig. Axi-symmetric model of cask used in simulation



(b) Fig. Normal condition temperature distribution in cask w/o solar flux

The normal condition temperature contours of package (excluding pipe cage and saddle support) without solar insolation is shown in fig. it can be seen that the maximum inner shell temperature of package is 159°C. As shown in fig. at the end of 30 minutes fire-test 52.4% lead melting was observed whereas the result of post-fire analysis is shown in fig. The maximum lead melting observed in package was 76% at 25 minutes into postfire. The temperature history plots for upto 1 hr into post-fire at various nodes along thickness of cask is shown in fig. .

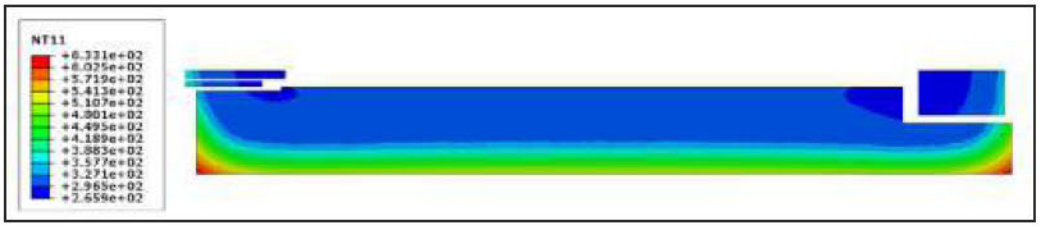


Fig. Temperature contour in lead portion of cask after 30 min fire test (52.4% lead melting)

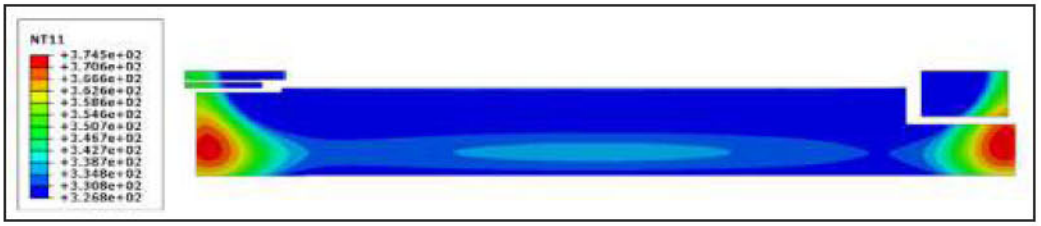


Fig. Temperature contour in lead at 25 min into postfire(max lead melting 76%)

It is seen that the package has an unacceptable 76% lead melting during thermal test. In order to reduce lead melting to acceptable range various design modifications to the package such as addition of fins and over-pack were simulated using FE and a comparative study was done to arrive at an optimised solution.

It was seen that with 18 nos. of 25 mm long fins and an over-pack having cut-outs the lead melting is reduced to 19.6% and the normal condition accessible temperature of the package is 78°C both of

which are within permissible range of transport regulations and this result is inferred as the optimised solution of the problem.

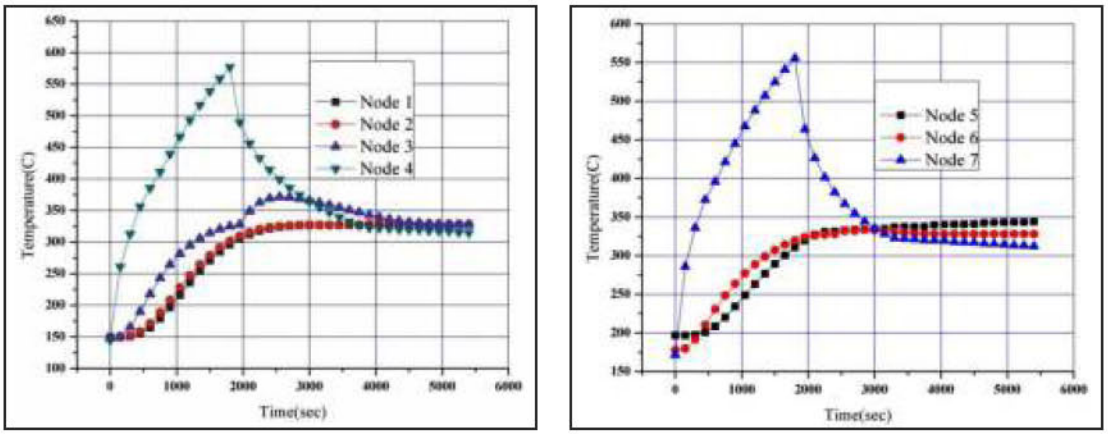


Fig. Temperature transients at various nodes in the cask (Nodes 1-4 & 5-7)

(iii) Thermal analysis of Rotex-I (Radiography Exposure Device)

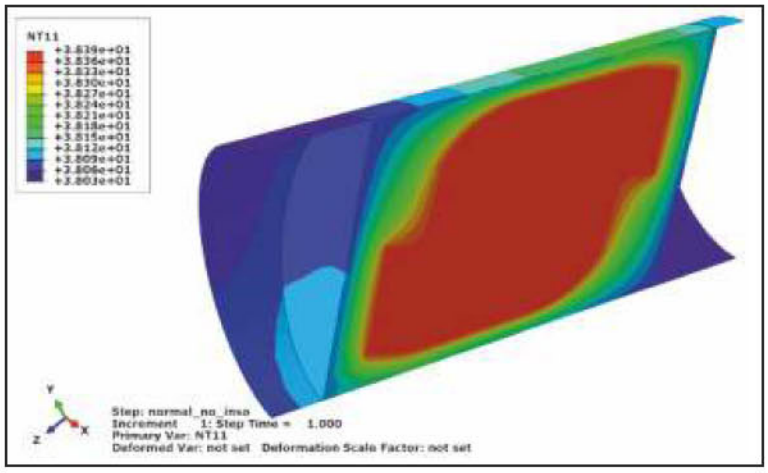


Fig. Temperature contour without solar insolation (sectional view)

The Rotex-I is a portable radiography camera having a source capacity of 65 Ci Ir-192. The total weight of package is approx. 28 kg. The shielding material used in package is tungsten alloy resulting in compact design. The empty space between outer shell and tungsten shield is filled with polyurethane foam (PUF) layer to protect the camera during impact and fire incidents. The outer jacket of camera is made from HDPE for impact, abrasion resistance and superior aesthetics. The package was evaluated for normal and accident conditions of transport to satisfy the requirements of a Type B(U) package.

The temperature contour of package without solar flux is shown in fig. the maximum temperature is 38.4°C. The sectional view of 3D model of IGRED used for analysis and location of nodal points used for plotting the temperature history is shown in fig.

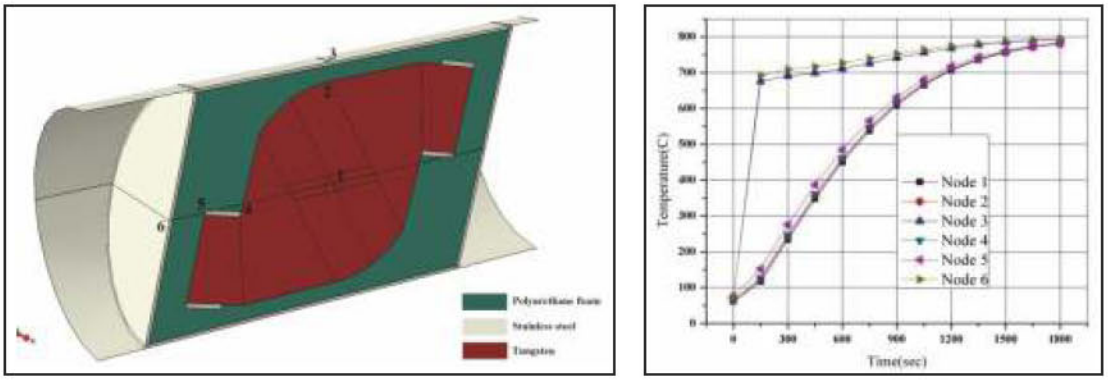


Fig. Temperature history of various nodes of IGRED during fire test analysis

The temperature history at various nodes during fire test is shown in fig. .As polyurethane foam (PUF) is neglected during fire test analysis the results of fire test are expected to be highly conservative since PUF acts as insulating protective medium against fire.

B. Development work done by Radiation Physics Group Section

Thermoluminescence Dosimetry: Thermoluminescence (TL) dosimetry makes use of the thermoluminescent properties of certain materials. These materials store the energy of incident ionizing radiation and release it again as light when heated. The emitted amount of light is largely proportional to the irradiated dose. A preliminary study was carried out using Nucleonix make TL Research Reader to make use ofvarious TL materials such as calcium sulphate, lithium fluoride, lithium borate etc. for dosimetry. The dose range studied was of 100 – 1000 Gy.The neutral density filters with optical densities 0.15, 0.30, 0.40 and 0.60 were used with calcium sulphate discs for measuring the transmission (Fig.1). A typical TL glow curve is shown in Fig.2 for lithium fluoride powder irradiated for a dose of 1000Gy of ^{60}Co-gamma rays.

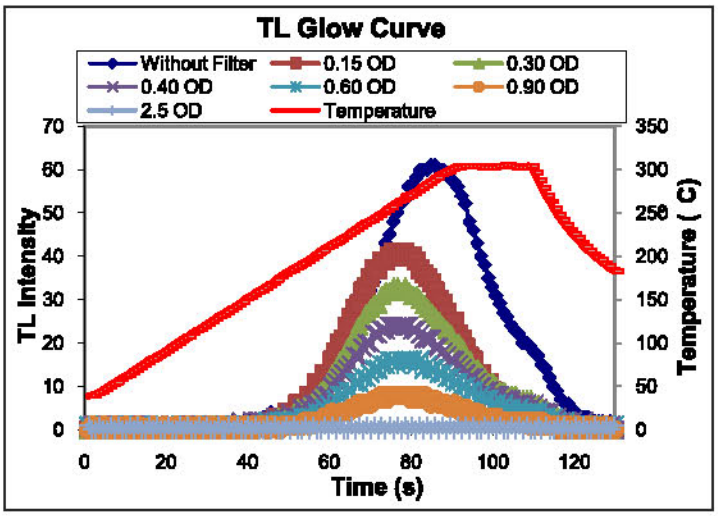


Fig.1: Transmission through various neutral density filters

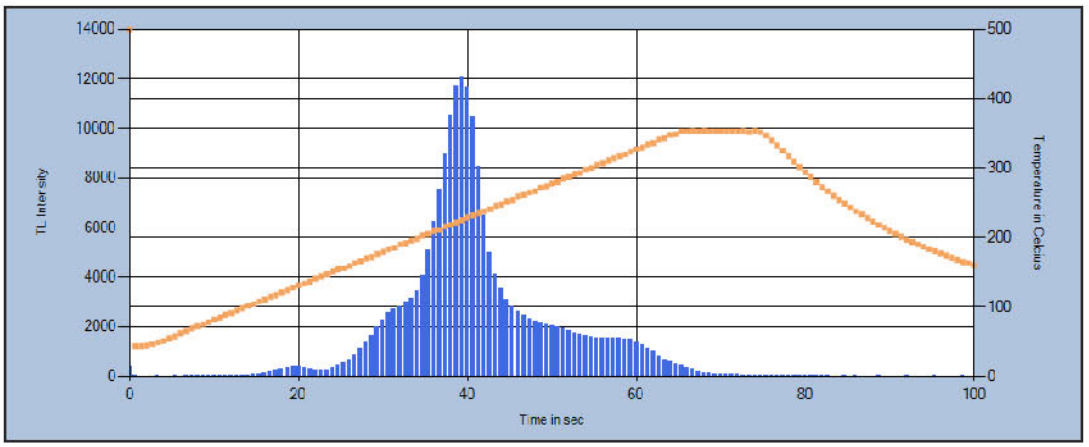


Fig. 2: TL glow curve for lithium fluoride exposed to 1000Gy of ^{60}Co-gamma rays

C. Development work done by Microbiology Section of Radiation Processing Plant (RPP), Vashi Complex

(i) Development of shelf stable herbal mouthwash formulations by exploitation of radiation preservation technology

Dental caries & periodontal diseases are the most common infectious diseases. Commercial mouthwash although effective against oral pathogens contains many chemicals which are harmful to mucous membranes and are toxic when swallowed/inhaled. Herbal Mouthwashes are in high

demand, having very less side effects, however they have very short shelf life. The current research work is an attempt to develop a herbal mouthwash formulation which is shelf stable and having no harmful chemicals by exploitation of radiation preservation technology. Number of formulations was tried with combination of different spices & herbs. Some of the formulations got spoiled within a week due to bacterial growth leading to offensive smell whereas other formulations showed a fungal contamination within 3-5 days posing lot more difficulties in preparation of the final mouthwash. All the raw spices & herbs used for formulation of mouthwash when analysed for microbial quality showed a maximum aerobic plate count of 1.05 x 106 CFU/g and total yeast & mould count of more than 2.0 x 10^3 CFU/g. Radiation preservation technology is a well known most effective technique used for preservation of spices & herbs. The native bacterial species from the spoiled mouthwash was isolated & studied for its radiation sensitivity. The D10 value of the bacterial isolate was found to be 1.08 kGy, the 12D concept was applied to sterilise the raw ingredients such as spices & herbs used in the formulation of herbal mouthwash. Considering the D10 value of spoilage bacterial isolate 12D dose of about 13 kGy was found to be sufficient to sterilize the raw ingredients. Thus a dose of 10-15 kGy was tried to prepare the fruitful formulations. The fungal species commonly observed in the spoiled mouthwash were Aspergillus & Penicillium spp. which are very much sensitive to gamma radiation. The aqueous extracts of raw ingredients such as clove powder, cinnamom powder, neem, guava & basil leaf powder, and pomegranate peels powder were assessed for their antimicrobial activities by agar well diffusion method. The aqueous extract to the extent of 1-2% of clove, pomegranate peel & guava leaf powders showed good antimicrobial activity against all the bacterial species tested such as *S. aureus, B. Subtilis, P. Aerguginosa, E. Coli, B. Pumilus and lactic acid bacteria.* Thus the herbal mouthwash formulation were prepared as 1 & 2% concentration in sterile distilled water as aqueous extract by using irradiated ingredients treated with radiation doses of 5, 10, & 15 kGy and compared with aqueous mouthwash formulation prepared from non-irradiated ingredient such as Guava leaf, pomegranate peel & clove powder for antimicrobial activity and shelf life. The shelf life studies showed spoilage of aqueous mouthwash prepared from non-irradiated ingredients due to fungal growth and bacterial spoilage in case of mouthwash prepared from irradiated ingredients treated with 5 kGy radiation dose. However the mouthwash prepared from irradiated ingredients treated with 10-15 kGy radiation dose showed no bacterial or fungal growth over a period of 4 months studies. No significant difference was observed in antimicrobial activity of mouthwash prepared from irradiated ingredients as compared to non-irradiated showing antimicrobial effect against all bacterial species studied such as S. aureus, B. Subtilis, P. Aerguginosa, E. Coli, B. Pumilus and lactic acid bacteria. The herbal mouthwash formulation thus prepared also showed a better antimicrobial activity when compared with two widely used commercial mouthwashes available in the local market. The sensory evaluation of the herbal mouthwash prepared from irradiated ingredients treated with radiation dose of 15 kGy showed a good overall acceptability of 6-7 points on 9 point hedonic scale by a panel of five members. Thus the herbal mouthwash formulation prepared from 1-2 % (10-20 mg/ml) irradiated ingredients such as guava leaf, pomegranate peel & clove powder treated with radiation dose of 10-15 kGy has a good shelf life, better antimicrobial activity, and good acceptability and is without any harmful chemicals. Such mouthwash will be cost effective as compared to commercial mouthwash.

(ii) Assessment of antimicrobial effect of Copper-T to incorporate suitable neutralizing agents during bio-burden determination while establishment of radiation sterilization dose for Copper-T

Copper being well known for its antimicrobial activity, the procedure for bio-burden determination for establishing radiation sterilization dose of IUCD, Copper-T needs to be modified. USP and guidelines of standard ISO 11737-1 recommends incorporation of neutralizing agent or application of correction factor while bio-burden determination for such products. The present study is an attempt to assess the antimicrobial effect of copper in Copper-T and incorporation of chelating agents such as EDTA (Ethylene di-amine tetra acetic acid) & citric acid as neutralizers to reduce the inhibitory effect of copper. The maximum inhibitory effect to the extent of 45% with recovery of 55% was observed when recovery efficiency was studied with Copper-T by inoculation of S. aureus for exposure time of 2 minute in phosphate buffered saline. The incorporation of 0.01% EDTA or citric acid in the diluents while bio-burden determination showed significant reduction in inhibitory effect to 0.21 – 11.5 %. Thus it s recommended to modify the procedure for determination of bio-burden of Copper-T with incorporation of 0.01% EDTA or citric acid as neutralizers in the diluents. Also the exposure/shaking time of the product in the diluents should be restricted to 2 minutes as prolonged exposure may add to the inhibitory effect of copper as observed in the experiments carried out with B. subtilis to the extent of 59.9 % for 10 minutes of exposure/shaking. Alternatively it is recommended to apply an additional correction factor corresponding to the inhibitory effect of copper in case neutralizing agents are not available. In the present studies the minimum recovery efficiency observed was 55% with S. aureus, hence an additional correction factor of 1.81 (100/55) is suggested while calculating overall average bio-burden if avoiding any neutralizing agents during bio-burden determination. The case studies for bio-burden determination of copper-T from different manufacturers were done and a remarkable difference of about 10-11 % in the calculation of verification dose was observed when applied an additional correction factor.

D. Development work by Radiopharmaceuticals Production Programme (RPhP), Vashi Complex

(i) Preparation and evaluation of'NANOTECH ^{99}Mo/ ^{99m}Tc column generator based on mesoporous alumina

Mo-99/Tc-99m Column Generators based high adsorption capacity mesoporous alumina(MPA) for molybdenum and use of (n,γ) Mo-99 is an attractive development for column based Mo-99/Tc-99m generators. The high adsorption capacity of mesoporous alumina material (size 50-100# and molybdenum adsorption capacity 100-130mgMo/g of MPA) and the process for preparing such generators were transferred to BRIT by RPhD, BARC for preparing generator on commercial scale and ultimate use at hospital end.

In order to use MPA for preparing large number of generator on commercial scale in BRIT, a lead shielded (2 inch) plant facility for preparing 'NANOTECH Mo-99/Tc-99m Generator' based on mesoporous alumina (MPA) containing ~3.5g MPA has been set up at RPhP/BRIT. Initially few' NANOTECH Mo-99/Tc-99m column Generators' were prepared in collaboration with RPhD, BARC, following the protocol provided by them and using (n,γ) Mo-99 activity upto ~100mCi on each generator. All operations such as transfer of Mo-99 solution, dilution of Mo-99 solution, pH adjustment loading of Mo-99 solution, washing of MPA column containing loaded with Mo-99 etc.

were carried out remotely using different process gadgets installed in the facility. The duration of processing for two generators was ~ 2hrs. Initial studies on the preparation and evaluation of the generators produced in this facility show that the generator capacity was ~100mCi (on first day of use with 3.5g MPA powder), adsorption capacity of MPA was 126mgMo/g MPA, % Tc-99m elution efficiency was in the range 65-76% and Mo-99 break through was in the range of 0.006 - 0.06% (with 2g of Al_2O_3 bed for each elution processes).Performance of the generator was evaluated in terms ease of operation of the generator, % Tc-99m yield, smooth of elution,Mo-99 break-through, pH of Tc-99m eluate etc. and found to be satisfactory. Smooth functioning of the facility was demonstrated. In order to prepare higher capacity nanotech generator (Mo-99 activity ~300mCi) with higher quantity of MPA powder (6-7gMPApowder per column) few bigger size glass columns were made available and accordingly generator shielding also have been modified. Performance of the generator were evaluated in terms ease of operation of the generator, Tc-99m yield (66-81%) in 20 ml of 0.9% NaCl eluent solution, Mo-99 break-through were more than 0.1% with 2gm alumina purification column. Mo-99 break-through should be always less than 0.1% in addition to other acceptable quality features of Tc-99m eluate. Further improvement in the performance of the generator and standardization in quality of the MPA powder are underway.

(ii) Initiation in the development of ^{177}Lu-PSMA-617 for the treatment of metastatic castration resistant prostate cancer

^{177}Lu-PSMA-617 is a proven therapeutic radiopharmaceutical for the treatment of metastatic castration-resistant prostate cancer. Recently PSMA-617 raw material has been indigenously synthesized by BOD, BARC and a suitable cost-effective radioactive formulation has been developed for patient end use. PSMA-617 was synthesized on peptide synthesizer following conventional Fmoc-solid phase peptide synthesis. The peptide was then radiolabeled with ^{177}Lu to yield the desired radiopharmaceutical. Briefly, ^{177}Lu-PSMA-617 is synthesized by reaction of ^{177}Lu (Sp. act. >15 Ci/mg; 200 mCi) with PSMA-617 peptide (2.0-2.5 equivalents) in sodium acetate buffer (0.1 M). This is then diluted with sodium acetate (0.1 M, pH 4) buffer containing 2% sodium ascorbate and sterilized by membrane filtration and dispensed as single patient dose (200 mCi). Clinical evaluation in diseased cancer patients is beingunderway at TMH, Mumbai to evaluate the therapeutic effectiveness of the product. Therapeutic doses of clinical grade ready-to-use ^{177}Lu-PSMA-617 for prostate cancer therapy are submitted to Radiopharmaceuticals committee and are awaiting approval for its launch as a regular BRIT product.

(iii) Standardization of protocols for production and supply of ready to use ^{68}Ga radiopharmaceuticals

Availability of ^{68}Ga, a positron emitter, through a long lived ^{68}Ge-^{68}Ga generator system has facilitated the growth of PET technology and will be the mainstay of diagnostic nuclear medicine in near future. Though the radionuclide is short lived ($t_{1/2}$ ~ 68 min), there is a commercial interest to explore the feasibility of production and supply of its labeled radiopharmaceuticals via a centralized radiopharmacy, similar to ^{18}F-labeled radiopharmaceuticals. In this view, ^{68}Ga-DOTA-TATE and ^{68}Ga-PSMA labeling protocols were standardized and logistics evaluated for its regular production and supply using a 50 mCi ^{68}Ge-^{68}Ga generator. ^{68}Ge-^{68}Ga generator (50 mCi) alongwith semi-automated shielded synthesis module was obtained from ITG, Germany. Total six batches of ^{68}Ga-labeled RPhs viz. ^{68}Ga-DOTA-TATE and ^{68}Ga-PSMA were prepared as per the approved RPC monograph. The

production was optimized with respect to time for different stages of production starting from elution of ^{68}Ga activity to labeling with peptide ligands, purification, sterilization, quality control analyses and final packing of ^{68}Ga-labeled radiopharmaceuticals.The total production time for both labeled radiopharmaceuticals post ^{68}Ga elution was around 0.5 h. The activity observed in the labeled radiopharmaceutical post sterilization was around 70% of the generator activity. The radiochemical purity (RCP) observed upto 4 h was > 95% as per RPC monograph. The total production period including radiolabeling and quality control analyses (RCP/BET) for all the batches were complete within 1h post 68Ga elution. Only one or two patient doses (3-5mCi) of ^{68}Ga labeled radiopharmaceuticals (DOTA-TATE/PSMA) can be produced from a 50 mCi generator for consumption within 3 h post-production upto a period of six months.

E. Development work by Quality Control & Quality Assuarance Section of Radiopharmaceuticals Production Programme (RPhP), Vashi Complex

(i) Biological Quality Control of ^{64}Cu-radiopharmaceuticals

^{64}Cu-radiopharmaceuticals are rapidly emerging as potential diagnostic and therapeutic tools in oncology for targeting neuroendocrine tumours, prostate and hypoxic tumors. $^{64}CuCl_2$ is a unique radiopharmaceutical with physiological properties that are compatible with its use as a theranostic agent. Trial batches (06 nos.) of this product, produced for RPC clearance, were received from RPhD, BARC, Sterility Testing & Bacterial Endotoxin Testing were carried out and reports submitted to BARC.

(ii) Shelf-life extension studies of Plate Count Agar

Plate Count Agar is regularly used for Environmental Control testing during production and quality control testing of all injectable radiopharmaceutical products. Shelf-life extension studies of in-house prepared Plate Count Agar was carried out by verifying the Sterility and carrying out Growth Promotion Tests using microbial cultures as specified in the Indian Pharmacopeia (IP 2018). Organisms which were used for these experiments included *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923 and *Bacillus subtilis* ATCC 6633. As a result of this work, the shelf-life of this medium has been extended to eight weeks instead of the prevailing four week period.

(iii) Automation of vacuum-pump based model for Sterility Testing (ST)

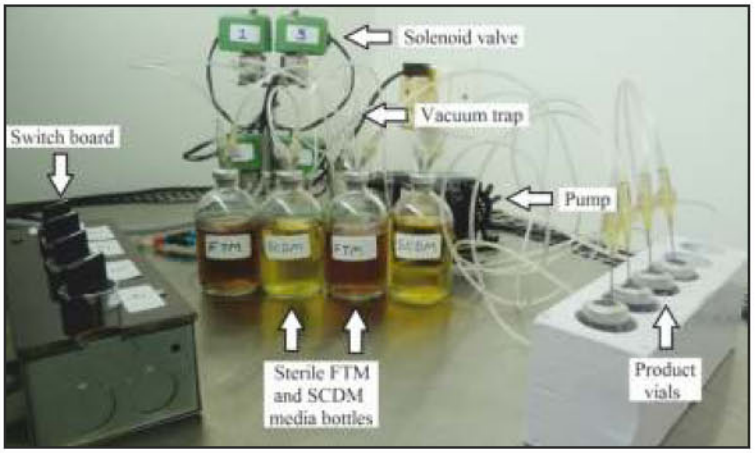


Fig. 1: Vacuum manifold apparatus for Sterility Testing of injectable radiopharmaceuticals

Conventional method for ST involves manual transfer of test samples into sterile growth media under aseptic conditions. This method is time-consuming, requires skilled persons and results in considerable radiation exposure to the analyst. A simple vacuum-based manifold system was designed in house, validated and tested in routine use to circumvent these problems. This consisted of four silicone tubings connected to a

vacuum pump and attached to sterile needles which were introduced into sterile media bottles. A sterile assembly containing a spinal needle connected to a sterile needle via silicone tubing was used. The spinal needles were introduced into the sample vials such that their tip touched the base of the vials. Individual vacuum control for each of the four sets was done using solenoid valves placed between the media bottles and the vacuum trap (Figure 1). Switching on the vacuum and respective solenoid valve ensured withdrawal of the entire sample volume into the media vial. The whole assembly was set up inside a Biosafety Cabinet (Class III). The inoculated media were incubated at 30-35°C and 20-25°C respectively for 14 days and examined visually. Sterile saline was used to inoculate the media in the same manner and used as controls. The radiopharmaceuticals tested by this method included: ^{153}Sm-EDTMP, ^{131}I-mIBG and $Na^{99m}TcO_4$ eluates from ^{90}Mo-^{99m}Tc generators [04 batches each, RAC ~20mCi/mL (740MBq/mL) per vial]. All the injectable radiopharmaceutical products tested passed the ST as indicated by absence of microbial growth on completion of the 14 days incubation period. This method can result in a significant reduction in the radiation dose and provides a feasible alternative to the conventional method.

(iv) Green Analytical Chemistry

The aim of this work was to standardize an eco-friendly, alternative green analytical procedure for assessing Radiochemical Purity (RCP) of $Na^{99m}TcO_4$ using Double Distilled Water (DDW) as the mobile phase (MP).

$Na^{99m}TcO_4$ was eluted from a ^{99}Mo/^{99m}Tc Column (alumina) generator (BRIT). Paper chromatography of $Na^{99m}TcO_4$ was done in duplicate by ascending chromatography using strips of Whatman No.3 (3x23cm). Determination of Reduced Hydrolysed ^{99m}Tc (RHT) (impurity) in these eluates (06 batches) was done in the same manner by adding 10% $SnCl_2$ in 0.1N HCl to the eluates and heating for 10 minutes at 100°C. The chromatography strips were scanned in a radioTLC scanner and the RCP data was computed.

RCP determination using DDW is very convenient to use in hospital radiopharmacies as DDW is inexpensive and easily available. The procedure standardized by us provides an opportunity for utilizing the Green Analytical Chemistry techniques in the field of QC, besides offering significant ecological and economical merits.

The %RCP of $Na^{99m}TcO_4$ & RHT (Table 1) using the alternative procedure (DDW) is in good agreement

Table 1: % RCP values of $Na^{99m}TcO_4$ and RHT in four different solvent systems

Batch No.	% RCP							
	85% Methanol		MEK		Saline		DDW	
	RHT	$Na^{99m}TcO_4$	RHT	$Na^{99m}TcO_4$	RHT	$Na^{99m}TcO_4$	RHT	$Na^{99m}TcO_4$
1	0.08	99.22	0.12	96.52	0.32	98.80	**0.16**	**98.35**
2	0.08	99.34	0.05	98.33	0.07	99.68	**0.09**	**99.44**
3	0.12	99.26	0.14	98.62	0.14	99.34	**0.27**	**98.83**
4	0.22	99.23	0.22	98.17	0.48	98.78	**0.15**	**99.36**
5	0.02	99.29	0.12	98.94	0.23	99.05	**0.15**	**99.25**
6	0.03	99.37	0.025	98.96	0.12	99.48	**0.16**	**99.31**

with the other three standard chromatography procedures. Hence, this method can be used as an alternative method, as it is compatible with routine nuclear medicine practices and can be easily adopted in hospital radiopharmacies.

(v) Standardization of alternate methods for Quality Control of ^{177}Lu-radiopharmaceuticals

RCP of ^{177}Lu-radiopharmaceuticals is conventionally carried out by paper chromatography method but this method is time consuming. Hence, alternative methods using HPLC for ^{177}Lu-DOTA-TATE and cation exchange chromatography for ^{177}Lu-EDTMP were standardized. The existing HPLC method for RCP estimation of ^{177}Lu-DOTA-TATE was further refined by standardizing the gradient elution programme resulting in a further saving of ~7 minutes whereas the cation exchange chromatography method for ^{177}Lu-EDTMP resulted in a substantial saving of at least 45 minutes as compared to the paper chromatography method.

(vi) Developmental work for advances in use of radiopharmaceuticals as infection imaging agents

Shelf-life extension study of ^{99m}Tc-Ubiquicidin (UBI 29-41) kit was carried out with an aim to reduce the frequency of production of this product. ^{99m}Tc-UBI kit samples were studied on the date of expiry as well as after one month post-expiry and were found to be sterile, endotoxin-free and physico-chemically compliant with all the defined RPC parameters. Hence the ^{99m}Tc-UBI kits are stable up to seven months shelf-life. ^{99m}Tc-UBI kits have in earlier studies practically been found to be stable for longer periods than the designated shelf-life of six months but further work is required on six consecutive batches of the kit for longer storage periods in order to obtain RPC approval.

As an adjunct to this work, shelf-life extension studies for in-house produced as well as imported ^{99}Mo-^{99m}Tc column generators were also carried out to assess the integrity of the various kinds of filters incorporated in them. Physico-chemical tests were also carried out so as to verify the validity of the separation technique, post-expiry of the generator. Samples eluted from all the batches of in-house ^{99}Mo-^{99m}Tc column generators on production and expiry dates and those eluted up to 12-months post-expiry passed all QC criteria (ST, BET and physic-chemical parameters) as per the RPC monograph. Further studies on these were not possible as they had been dismantled by this period. Samples eluted from imported generators were available and found to be sterile post-expiry up to as long as 21 months but failed in BET. This may be a result of slow release of lipo-polysaccharides from non-viable bacteria that may have been present during the shelf-life of the generators when they had been in daily use. ^{99}Mo-^{99m}Tc column generators cannot be assigned an indefinite shelf-life, based on the constraints of radioactivity present in the raw material (^{99}Mo) loaded during production but this data will be of value for production of high-radioactivity (≥1 Ci) ^{99}Mo-^{99m}Tc generators having a potential shelf-life greater than the currently stipulated 10 day period.

F. Development Work by Regional Centre for Radiopharmaceuticals (RCR, BRIT), Kolkata

1. Progress in DAE Medical Cyclotron Project: Radiopharmaceutical facility

1.1. FDG Target Installation

There has been a remarkable progress in the installation of liquid target and its associated systems for the production of FDG. F-18 was successfully produced for the first time using cyclone-30 in Medical Cyclotron Project (MCP), Kolkatta. The following are the various activities carried out.

Literature survey was done to carry out the installation of the F-18 target and its associated systems indigenously. Equipments, modules, components, and spares were identified from several consignment boxes supplied by IBA and sorted all the components of relevant systems as per the available documents provided by IBA. The liquid target assembly was installed on the corresponding target stations provided inside the FDG target vault. Two targets were assembled, installed and successfully tested for any leakage or any vacuum problems. Mechanical support for both the targets were designed and fabricated indigenously. Installation of different Instrumentation modules:

a. Syringe Drive Module.
b. Hellium manifold.
c. Target manifold module.
d. Liquid Distribution Cabinet (Input/ Output).

Installation of PET PLC on the control room rack was completed. Electrical field wiring was carried out for connection of different field input and output devices. Electrical cables were routed to the control room where the control PLC is installed. Teflon tubing connections required for the transportation of liquid were completed. All the hydraulic and pneumatic connections required for the F-18 targets operation were completed and tested. Some of the missing components required during the installation were fabricated in house. Cold run was carried out to test different operations and the consistency of the system as the whole before the hot trials. F-18 was successfully produced for the first time using cyclone-30, MCP, Kolkatta. FDG synthesis successfully completed for the first time at BRIT (RC, Kolkata) Lab. For FDG synthesis a module was indigenously developed at BRIT (RC, Kolkata) Lab.

1.1.1. Description of F-18 production facilities at MCP:

The different subsystems which are associated with the F-18 target assembly are described below.

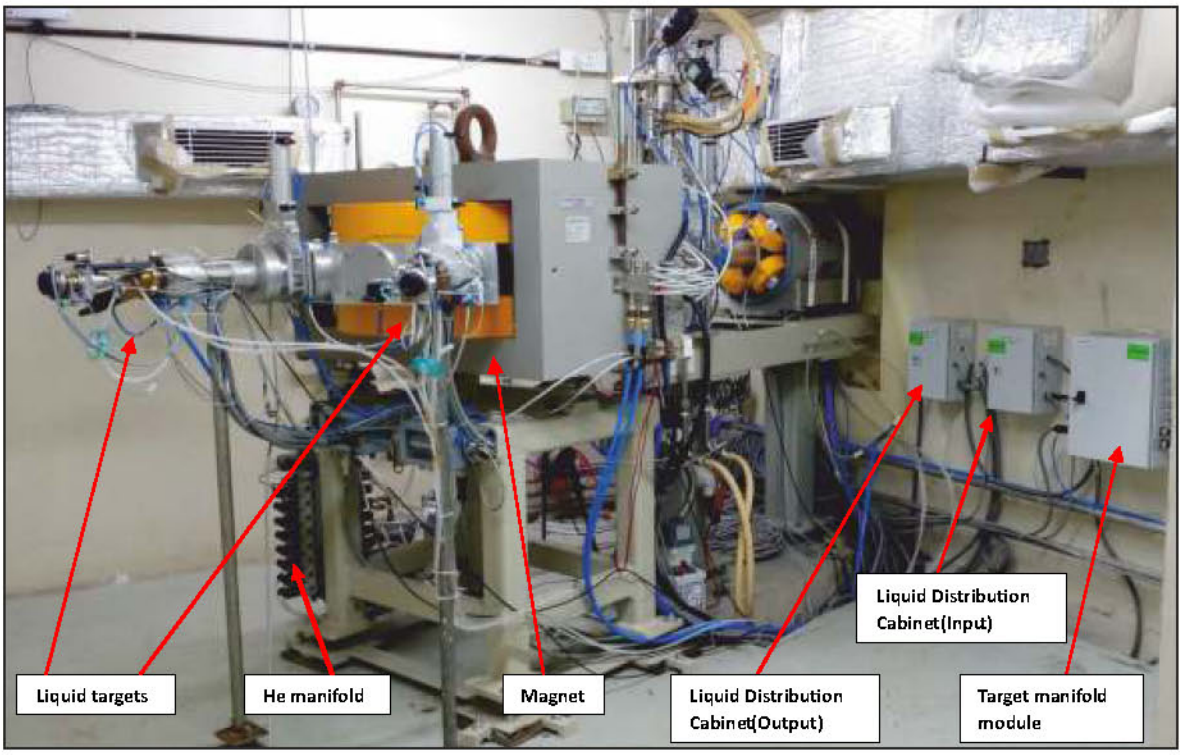


Fig. 1: F-18 target and its associated systems/modules

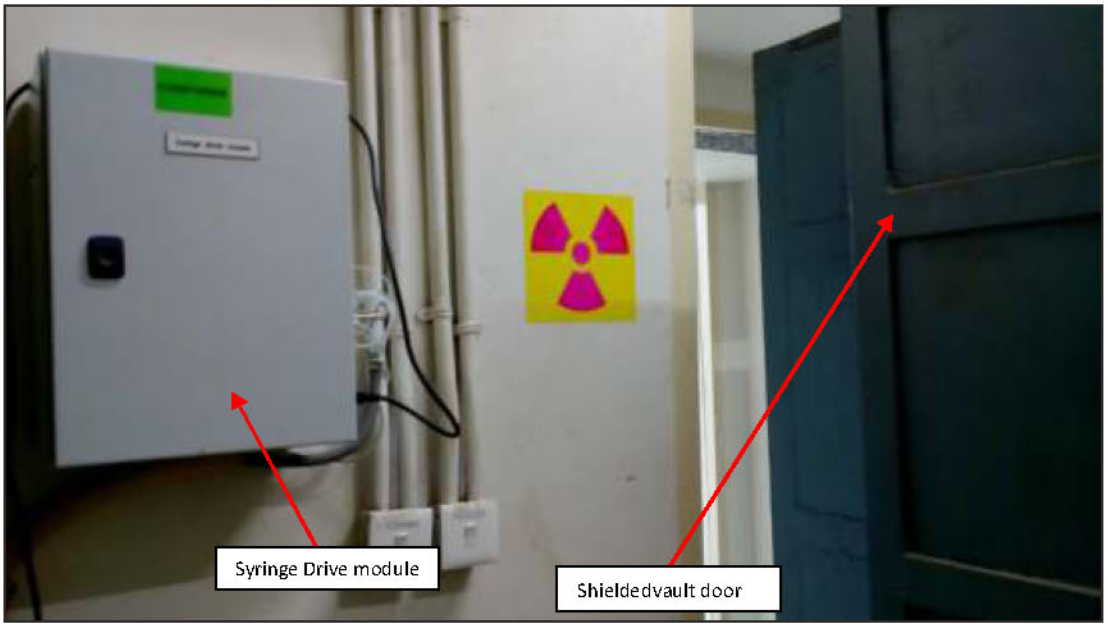


Fig. 2: Syringe Drive module

Each modules will have specific functions associated with it. All the operations are controlled by the master control PLC from the control room.

Syringe Drive Module

- This system has two functions
  1. Supply of O-18 water to the target.
  2. Supply of helium for F-18 transport.
- Supply of O-18 will be done by a syringe actuator operated by a stepper motor. Stepper motor rotation is converted to the linear motion of the syringe actuator over the complete stroke. A drive will operate the stepper motor.
- The module is interfaced with the main control through industrial ethernet. All the operations would be controlled from the main control unit in the control room.
- This system is placed outside the FDG vault room so that the working personnal can safely load O-18 water without any exposure to radiation as shown in Fig. 2.
- Hellium supply pressure could also be adjusted from the same module.

Helium manifold

- The function of this module is to supply helium to the target for cooling the havar foil which is always exposed to the beam during irradiation.
- Havar foil is a cobalt base alloy widely used in cyclotron targetry as it has the property of very high strength at high temperatures.
- The supply for Hellium for all the five targets(two is installed presently) is provided from this manifold. He gas is supplied to the manifold through He inlet valve.
- The different operating parameters like He manifold pressure, flow are constantly monitored by the PET PLC from the control room.
- All the field inputs/outputs are terminated to the electrical box. The electrical box is interfaced to the PET PLC through the 24-pin burndy connector and a shielded flexible 24 core, 0.5mm2 cable will connect the module to the PLC.

Target manifold module

- The function of this module is to selectively transfer the O-18 water to different targets.
- This module have multiple position solenoid valves used for the selection of different liquid targets.
- This module will also give signals to operate the rheodyne valve to load/unload/close the selected liquid target. The excessive liquid coming out from the liquid target during filling will get collected in the overflow vial placed inside the module.
- Hellium supply to different targets is also given through the same module.
- The module is interfaced to the PET PLC through the 24-pin burndy connector and Unshielded flexible 24 core, 0.5mm2 cable will connect the module to the PLC.

Liquid Distribution Cabinet (Input/Output)

- The function of this module is to selectively transfer the O-18 water to different targets.
- This module have multiple position solenoid valves used for the selection of different liquid targets.
- This module will also give signals to operate the rheodyne valve to load/unload/close the selected liquid target. The excessive liquid coming out from the liquid target during filling will get collected in the overflow vial placed inside the module.
- Hellium supply to different targets is also given through the same module.
- The module is interfaced to the PET PLC through the 24-pin burndy connector and Unshielded flexible 24 core, 0.5mm2 cable will connect the module to the PLC.

Liquid Distribution Cabinet (Input/Output)

- This module will receive the irradiated liquid from different targets and distribute it to various hot cells.
- It can support a maximum of up to eight liquid target stations and eight hot cell modules.
- The module is interfaced to the PET PLC through the 12-pin burndy connector. Unshielded flexible 12 core, 0.5mm2 cable will connect the module to the PLC.

Magnet

- Each beam lines can be diverted to multiple target positions by deflecting the beam to different

Fig.3: PET liquid target assembly mounted on the PET beam line

stations.

- This magnet is used to divert the beam line into several target stations.
- There are five different target stations available out of which two liquid target assemblies are installed at present.

1.1.2. Production of ^{18}F and preparation of ^{18}F-FDG using Cyclone-30 Medical Cyclotron at BRIT, VECC

PET liquid target system was mounted to one of the PET target irradiation ports (5 numbers) in the PET vault (Fig. 3 and Fig. 4).

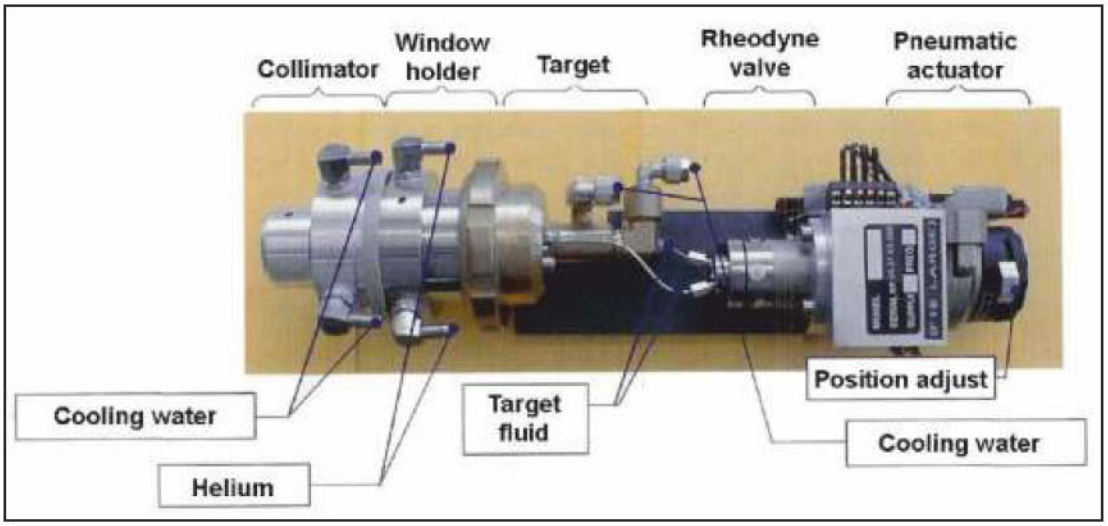


Fig. 4: F-18 water [18O] H2O target

Target cavity volume is 2.4 ml. After loading 2.0 ml O-18 water through syringe, if no overflow took place, 2.0 ml of O-18 water is ensured to fill in target cavity.

1.1.2.1. [F-18] FDG Production Steps :

Step 1: Loaded 2.4 ml of $[^{18}O]H_2O$ into the target system using a syringe before putting ON the beam.

Step 2: Beam current and energy of the cyclotron was set to 5 μA, 18 MeV, proton beam and the irradiation was started.

Step 3: The sample was irradiated for about 30 min continuously and about 50 mCi ^{18}F activity

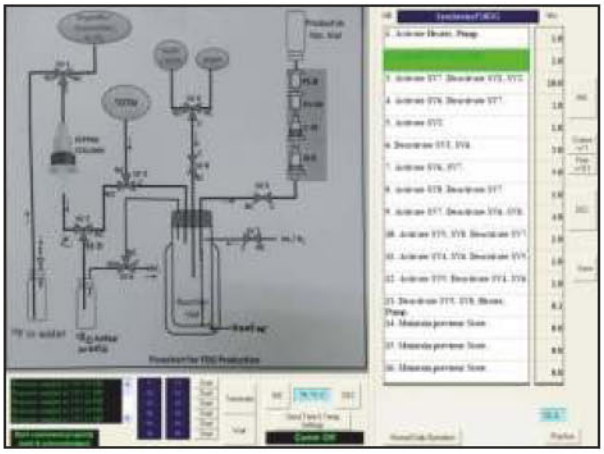


Fig. 5: Chemical Process for synthesis of [^{18}F] FDG *Fig. 6. Chemical synthesis module [^{18}F] FDG*

was produced.

Step 4: Transfered the produced ^{18}F activity in a closed vial (10 ml volume) kept inside the LP30 transportation flask (AERB approved container which is being routinely used for transporting ^{18}F-FDG activity upto 250mCi at RMC, BARC/ BRIT) by remotely operating the solenoid valve through PLC placed at control room. The LP30 was placed inside TPPL-1 bucket.

Step 5: The activity collected was transported from MCP site, Chakgaria to RC, Kolkata, BRIT Lab, VECC, Salt Lake for further chemistry synthesis.

Step 6: The chemistry for preparation of FDG was carried out inside the Fumehood using remotely operated computer controlled automated module (Fig. 5 & Fig. 6).

1.1.2.2. Quality control of ^{18}F & $^{18}FFDG$

The Radiochemical purity of the ^{18}F-FDG has been found to be 99.9% by using TLC method. The Rf was found to be 0.45 as per standard reported value. The radionuclidic purity and half life of ^{18}F have been determined by using HPGe detector and were found to be 99.99% and 108.3 min, respectively.

1.2. Solid target system

To integrate the Solid target with medical cyclotron Cyclone-30 necessary steps were taken as follows

- Drawing studied thoroughly and different components/equipments searched from several packing boxes of IBA.
- A solid target irradiation assembly has been fixed with beam line 2.1, after cleaning thoroughly and the old pneumatic tubings and electrical wiring have been replaced (Fig. 7).
- Missing components of Rabbit Transfer line/solid target has been listed and procurement has been initiated for the same.
- Ga-67/Tl-201 synthesis module integrated as per IBA manuals and tested by taking several cold runs using the integrated software.

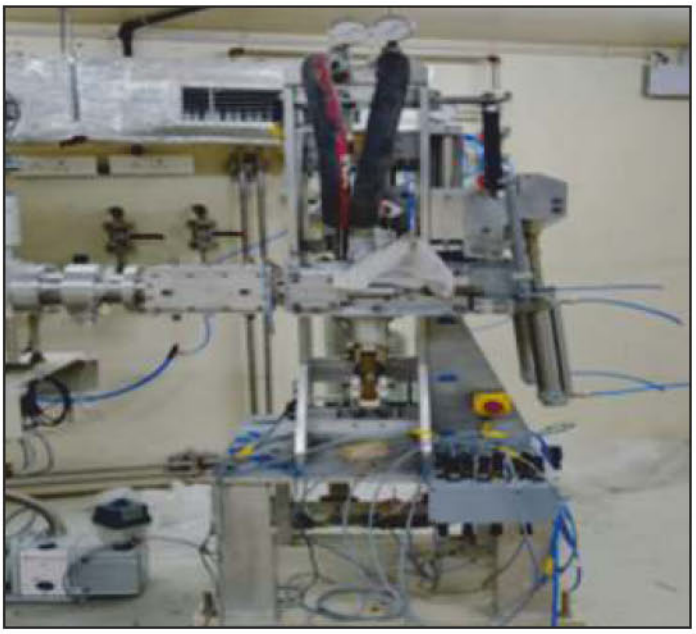


Fig. 7: Solid target assembly

Fig. 8: Cu base plate for solid target

- Base copper plate for the preparation of solid target by electropling method has been fabricated in VECC workshop (10 numbers) (Fig. 8).
- The Zn-target electroplating system for production of ^{67}Ga is made operational.

1.3. Bio-quality control lab equipment

- Procurement of heating block and BET reagents has been done for pyrogenicity testing of radiopharmaceuticals by gel-clot method.
- Sterility reagents (SCD and FTM) for sterility test have been procured.
- Incubator for sterility testing has been procured through indent received at the site and installation will be held on 9th and 10th January, 2019.
- PTS instrument for pyrogenicity testing of ^{18}F-FDG has been procured through indent received

Fig. 9: PTS instrument

at the site and installation will be held on January, 2019 (Fig.9).

- Laminar flow benches (2 numbers) have been procured through indent and received.

1.3. Other activities:

- SPECT Trench: Solid target transfer line shielding with lead has been finalised with VECC authorities. Work order has been placed.
- Requirements of Utilities/services (As per COMECER) for the installation of hot cells (By COMECER) are checked at site and verified as per drawing .
- All the service lines (Compressed air, N_2 and He) are checked room wise and finalised.
- Lab furniture (kitchen cabinets, Racks and Wash basin) requirement/location and number room wise finalised, drawing for the same prepared. PO has been awarded.
- Procured Fume hoods were received at the site and kept in secured place with utmost care.
- Inlet and outlet supply of wash basin and drain lines from the cleanroom and other lab areas with the low level liquid waste room have been identified. Numbers and types of pass through requirement for the clean room and other areas are finalised along with the necessary civil work requirement. Work is under progress.
- Representatives of M/S COMECER visited MCP site and VECC site for pre-auditing their supplied materials.
- Missing/damaged components of hot cell and accessories are listed and procurement has been done through indenting procedure.
- Clean room panels/electrical wiring/ventilation duct/utilities lines were dismantled temporarily for the installation of the hot cell.
- MS Platform to install low level liquid waste receiving tanks fabricated and installed.
- Detailed layout/instrumentation/piping/automation required for the management of the high level liquid waste finalised and work order is under process.

- Detailed layout/instrumentation/automation required for the management of the solid waste has been finalised and the work order will be placed soon.

2. Progress in VECC Cyclotron Experiments

2.1. Production of In-111 from ^{nat}Ag target through internal Irradiation using VEC Cyclotron for, bio-evaluation study at RMC, BARC, BRIT, Mumbai

Hemispherical Ag metal fixed on Cu base by brazing method (Fig. 10) has been used as a target. The target was irradiated internally with a 32 MeV, 40μA alpha particle beam for 24 h in a specially designed water cooled target assembly. The irradiated Ag target (Fig. 11) was cooled sufficiently to decay the short lived In isotopes before doing chemistry. The intensity of the

Fig. 10. Silver Target before irradiation

Fig. 11. Silver Target after irradiation

beam failing on the target during the irradiation was recorded with a current integrator and digitizer.

Radiochemical separation of ^{111}In from irradiated Ag has been carried out by indigenously developed sephadex based column chromatography method as reported in 2017-18 annual report. The thick target yield of ^{111}In estimated from the irradiated target was found to be about 7.5 MBq/ Ah at EOB. The recovery yield of ^{111}In was 90% with radiochemical purity of ^{111}In was >99% (as determined by TLC) and the radionuclidic purity of In-111 was >99.99%. Radiolabelling of ^{111}In with DTPA, 8-hydroxy quinolone (oxine) and DTPA-octreotide were carried out and radiochemical purities of labeled compounds were estimated as follows:

^{111}In-DTPA

100μCi $^{111}InCl_3$ was mixed with 40μg DTPA solution(1mg/ml) & pH 7 was maintained with 0.5M $NaHCO_3$ and incubated for 10 mins at room temperature with occasional stirring.
Q. C. TLC – 10% NH_4- acetate : Methanol (1:1);^{111}In-DTPA- S.F (100%) & P. S.=0%

^{111}In-oxine

100μCi $^{111}InCl_3$ was added to a solution containing 50μg Oxine, 100μg polysorbate 80 and 6mg HEPES buffer in 0.75%NaCl & pH of resulting solution was 7 and incubated for 30 min at room temperature with occasional stirring.
Q. C. TLC – 10% NH_4- acetate : Methanol (1:1); ^{111}In-Oxine- S.F (100%) & P. S.=0%

^{111}In-DTPA-octreotide

200μCi $^{111}InCl_3$ was mixed with 3.5μg/ml FeCl3 solution and then added to a solution containing 4.9mg trisodium citrate, 2mg gentisic acid, 10 mg inositol, 0.4mg citric acid and

20µg pentreotide(1mg/ml) & pH of resulting solution was 3-4 and incubated for 30 mins at room temperature with occasional stirring.
Q. C. TLC – 0.1 N Na-citrate at pH-5; ^{111}In-DTPA-octreotide- P. S. (100%) & S. F.=0%
About 75mCi [^{111}In]$InCl_3$ solution in dilute acid solution has been sent to RMC,BARC, BRIT for finding out the efficacy of radiolabelled ^{111}In-Pentetretide towards clinical use by performing various physicochemical and biological quality control studies. Also various in-vitro and in-vivo studies were performed to prove its pharmacological behavior.

Preclinical studies through biodistribution, cell binding assay and scintigraphic imaging ascertains the potential of the in-house developed ^{111}In-pentreotide as a diagnostic radiopharmaceutical.

3. IAEA Coordination Research Project (CRP) Work

3.1. A compact and portable ^{99}Mo-^{99m}Tc generator based on solvent-extraction, mimic to the conventional A compact solvent extraction based ^{99}Mo/^{99m}Tc generator for hospital radiopharmacy

^{99}Mo-^{99m}Tc alumina column generator is much-needed commodity for use in hospital radiopharmacy setup. The present study includes the development of a portable, simple and low cost ^{99}Mo-^{99m}Tc-generator based on MEK solvent extraction technique to obtain a very high concentration of no-carrier added (nca) ^{99m}Tc solution, where low specific activity ^{99}Mo source is obtained through ^{98}Mo(n, γ)^{99}Mo reaction in a research reactor. The unit is intended for operation under the conditions of medical radiological laboratories. Technical trials showed that the mean time of preparation of sodium [^{99m}Tc] pertechnetate radiopharmaceutical did not exceed 15 min. The quality and yield of ^{99m}Tc-pertechnetate is upto the mark for formulation of radiopharmaceuticals. We have designed, developed and fabricated a portable prototype ^{99}Mo-^{99m}Tc generator (Fig. 12) based on solvent extraction technique utilizing (n, γ) ^{99}Mo in sodium chloride solution for usage in hospital radiopharmacy. The size and shape of the newly developed ^{99}Mo-^{99m}Tc of 500 mCi batch size mimics to the commercially available alumina column based ^{99}Mo-^{99m}Tc generator. In the present work, the size of the present generator has been drastically reduced with a significant modification in its shape as compared to the previously reported ^{99}Mo-^{99m}Tc generator. Moreover the operation of the present ^{99}Mo/^{99m}Tc generator has become more user-friendly as compared to the reported ^{99}Mo-^{99m}Tc generator. The chromatographic purification columns (alumina) and all the vessels/vials required in the present MEK solvent extraction technique are replaceable and disposable; they are arranged in the respective positions by pricking on the inlet needles directly before preparation of radiopharmaceutical grade [^{99m}Tc]Tc -pertechnetate. The time required to complete the whole process was 15 min. The average yield of separation of ^{99m}Tc was about 90% (n=10) and ^{99}Mo breakthrough in ^{99m}Tc-pertechnetate was estimated to be< 0.0002% (n=10). The pertechnetate in saline obtained in high radioactive concentration (80 mCi/mL) was clear having pH 6–7. The final Na^{99m}TcO4 has the Mo and Al content of< 10 ppm and MEK content of < 0.1% v/v, with RC Purity> 99% and RN Purity > 99.9%. The RC Purity of ^{99m}Tc -MDP, ^{99m}Tc – DTPA and 99mTc-MIBI was > 95% (n=6).

The newly developed ^{99}Mo-^{99m}Tc generator based on MEK solvent extraction in absence of

NaOH can provide the highly concentrated and purified ^{99m}Tc-pertechnetate using indigenously produced LSA ^{99}Mo from research reactor and finds its application for hospital radiopharmacy. This method could also be employed in separation of pharmaceutical grade ^{99m}Tc from any LSA ^{99}Mo source produced in linear accelerator and also applicable in separation of ^{99m}Tc produced in cyclotron. The newly developed, portable ^{99}Mo/^{99m}Tc generator based on MEK solvent extraction method provides purified ^{99m}Tc-pertechnetate in

Fig. 12: Portable ^{99}Mo-^{99m}Tc Generator (500 mCi).

high radioactive concentration in shorter time as compared to the other solvent extraction generators which could be used in hospital radiopharmacy.

3.2. Simulation Study on Purification of Spent ^{100}Mo and ^{99m}Tc from Nb, Zr, Y and Ru Traces

Molybdenum-99 production and direct ^{99m}Tc production can be achieved through $^{100/nat}$Mo(γ, n) reaction, using high-power electron linear accelerator (LINAC) and ^{100}Mo(p,2n) reaction in medical cyclotron, respectively, where various non-isotopic impurities like Nb,Y, Zr, Ru and various isotopic impurities are also co-produced. While recycling expensive spent ^{100}Mo, it is mandatory to remove both elemental and non-isotopic impurities from the recovered ^{100}Mo, since, the ^{100}Mo target will be unsuitable for further use in production of ^{99m}Tc or ^{99}Mo. We report here a novel, indigenous sephadex column method for removal of Nb, Zr and Y isotopes from Mo and a versatile MEK solvent extraction method for removal of Nb, Zr, Y, Ru and Mo isotopes from ^{99m}Tc.

The ^{99}Mo activity produced in the Dhruva reactor of BARC,was obtained from BARC/BRIT, Mumbai, India.The radiotracers of ^{97}Ru /^{95}Tc,^{91m,92m}Nb and ^{89}/^{88}Zr /^{88}Y were produced from Mo, Y target foils by irradiation with alpha and proton beam, respectively, in VECC Cyclotron, Kolkata, India. An aliquot of the samples before and after separations were taken and counted in a HPGe detector coupled with a MCanalyzer.

Simulation study to remove radioisotopes of Nb, Y & Zr from Mo: A solution of inactive Mo (madein NH3 solution) was doped with trace quantities of radioactive isotopes (pre-load solution). 20mL of the test solution in 6% NH3 solution, was loaded on a pre-conditioned sephadex G-25 column (2mL) and the column was washed with 5mL 6% NH3 solution [Fig13].

Simulation Study to remove radioisotopes of Mo, Nb, Y, Zr & Ru from ^{99m}Tc: An inactive Mo solution (10 mL) in NaOH/KOH/NH_4OH doped with trace quantities of radioactive isotopes of ^{99}Mo/^{99m}Tc, Nb, Y, Zr and Ru were taken in a 25mL centrifuge tube and neutralized to pH-7. Five milliliter methyl ethyl ketone (MEK) solvent was added to this solution and mixed thoroughly

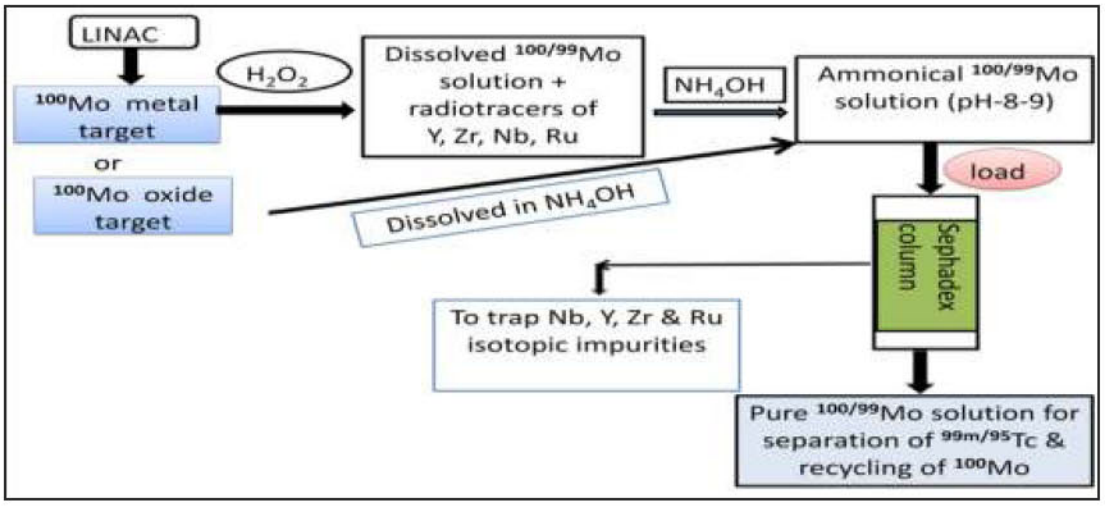


Fig. 13: Schematic diagram of sephadex based purification of ^{100}Mo from Nb,Y, Zr and Ru

for 1min. ^{99m}Tc extracted in MEK was passed through a pre-conditioned alumina column (1g) [Fig 14].

Simulation experiments were carried out to eliminate Nb, Y, Zr and Ru radioisotopes using a small sephadex column and MEK solvent extraction methods to mimic the actual experimental condition while using irradiated ^{100}Mo.There was a complete adsorption of non-isotopic impurities on the column (99.99%; n=3) based on size-exclusion principle. The recovery yield

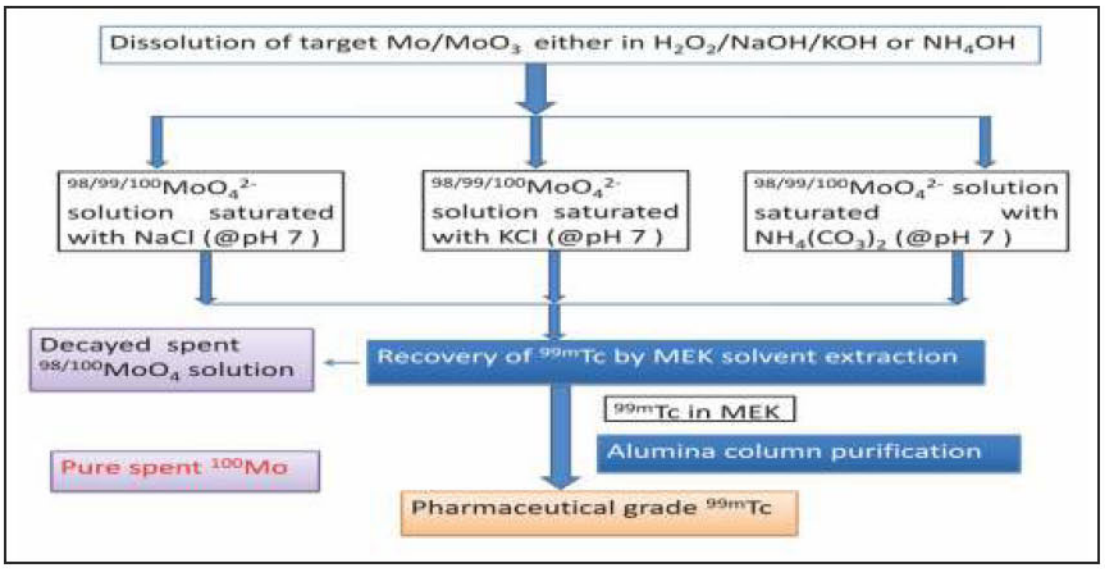


Fig 14: Schematic representation of MEK Solvent Extraction Method of pure 99mTc using MEK

of ^{99}Mo (99.98%) and ^{99m}Tc (98%) was almost quantitative (n=3). The extraction efficiency of pure ^{99m}Tc- from various Mo solution was 97% (n=3). The RN Purity of ^{99m}Tc using solvent extraction method was 99.99% (n=3).

It can be concluded that the simulation studies reveal that the newly developed sephadex G-25 column chromatography technique is very effective for removal of non-isotopic impurities from irradiated ^{100}Mo solution. Therefore, in case of direct production of ^{99m}Tc in cyclotron, the recovery of ^{99m}Tc by MEK solvent extraction method from the irradiated ^{100}Mo, the spent ^{100}Mo may be purified by sephadex column chromatography technique. In LINAC, purification of ^{99}Mo from non-isotopic impurities by sephadex method followed by the recovery of ^{99m}Tc by MEK solvent extraction may be adopted. A combination of sephadex G-25 purification and recovery by MEK solvent extraction methods may offer good separation of non-isotopic impurities and can produce pure spent ^{100}Mo for biomedical applications.

CHAPTER 4

Human Resource Development

Training Imparted/Lectures given / attended Workshops and/or Seminars/Conferences

1. Smt. Chanda Arjun, QC, RPL, was awarded the PhD degree (Applied Biology) by the University of Mumbai in April, 2018. The title of her thesis was "Development of Novel Radiolabelled Agents for the Diagnosis of Microbial Infections". This work was completed under the guidance of Dr. (Smt.) Meera Venkatesh, Ex-Head, RPhD, BARC and Ex-Director, Division of Physical and Chemical Sciences, Department of Nuclear Sciences and Applications, International Atomic Energy Agency (IAEA). It has resulted in the development of a new radiopharmaceutical which has been launched by BRIT as a regular product in the form of a kit for preparation of ^{99m}Tc-Ubiquicidine.

2. Dr (Smt) Jain Reji George was involved in coordinating the visit of 18th batch of Nuclear Fuel Complex Training School Officers, 2018-19, during their visit at BRIT on 16th March, 2019 and gave a briefing on 'BRIT Activities'. Dr (Smt) Jain Reji George was also involved in imparting a lecture on "Brachytherapy Sources" to 57th batch of Diploma in Radiation Protection Trainees course (organized by RPAD, BARC) during January 30th 2019.

3. Two weeks Practical Training and lectures were conducted for a batch of trainees of "Certification Course for Operators of Radiation Processing Facilities". This was also coordinated by. Lectures cum demonstration were given by Scientific Officers from Radiation Physics Group, Calibration Services, Electron Beam Services and Radiation Processing Plant, Vashi Complex. Lecture on 'Overview of Radiation Processing Facilities' to Operator trainees. Design aspects of Gamma Irradiators Management of Radiation Processing Plants, Radiation Safety and Dosimetry' were delivered by the Officers of Radiation Processing Plant, namely, Shri Ranjit Singh, Shri Atul Tyagi, Shri Rahul Kharat and Kum. Kalpana Khedkar respectively. Shri S.B. Kamble of Calibration Services Group was involved in delivering a lecture cum demonstration about' Calibration of Survey Meters & Pocket Dosimeters'.

4. Dr. Tarveen Karir delivered a Guest lecture on Overall BRIT Activities' for 18th Batch of Training School Officers at Nuclear Fuel Complex, Hyderabad, during November 2018.

5. Best Oral Paper Presentation award was given to Shri Dheeraj Kumar for the Scientific work, "Design, Characterization and Evaluation of ^{99m}Tc-Labelled Functionalized Gold Nanoparticles for Imaging FR Positive Cancers" at 4th International Conference on Application of Radiotracers and Energetic Beams in Sciences (ARCEBS 2018), Kolkata, India.

6. Dr. (Smt.) Tarveen Karir, Dr. S.K. Sarkar, Dr (Smt) Chanda Arjun, Shri Vishwas Murhekar and Smt. Priya Gunjal attended Hindi Vaigyanik Sangoshthi' organized jointly by Navi Mumbai Narkas (TOLIC) and BARC (OL) which was held on 20th February 2019 at Multi Purpose Hall, Anushaktinagar, Mumbai.

7. Under the banner of Swatchhata Pakhwada – 2019, Swatchhata Action Plan Committee was formed with Shri Piyush Srivastava as the Convener, Shri M. Bose as Member-Secretary, Shri Manoj Jagasia, and Smt. Vidya Swaminathan as members of the committee. First meeting took place on 9th January 2019 at BRIT Board Room, where the invitees were Shri. A.C. Dey, Shri Amir Shrivastava, Shri Ranjit Singh, Dr. (Smt.) Tarveen Karir, Shri Chetan Kothalkar, Dr. Vivek Dabade, Shri G. Chatterjee and Shri Shankar S. Following which appropriate actions were taken.

8. Shri Krishnamohan Repaka delivered two lectures on Radioactive Tracers in Biology & amp; Drug Development' for Training School Officers batch at Mumbai.

9. Shri. A.C. Dey, Shri N. Jayachandran, Shri Pravin Kumar, Dr. Yojana Singh, Dr. Tarveen Karir, Smt. Neetu Kurra, Shri K.V. Sethuraman, Shri Praveen Koli and Smt. Priya Gunjal attended a talk presented on the Official Language Parliamentary Questionnaire and a talk was organized by HWB on 26th March 2019 at ATI, Anushaktinagar, Mumbai.

Publications in Peer Reviewed Journals

1. **A Compact Solvent Extraction based ^{99}Mo/^{99m}Tc Generator for Hospital Radiopharmacy.**

   Sankha Chattopadhyay, Sujata Das, Luna Barua, Asit K. Pal, Umesh Kumar, Madhusmita, Md. Nayer Alam, Arup K. Hudait, Sharmila Banerjee

   Applied Radiation & Isotopes 143 (2019) 41-46. DOI: 10.1016/j.apradiso.2018.10.017.

2. **Gallium-68 Labeled Ubiquicidine Derived Octapeptide as a potential Infection Imaging Agent.**

   Jyotsna Bhatt, Archana Mukherjee, Ajit Shinto, Kamaleshwaran Koramadai Karuppusamy, Aruna Korde, Mukesh Kumar, Haladhar Dev Sarma, Krishnamohan Repaka, Ashutosh Dash

   Nucl. Med. And Biol 62-63 (2018) 47-53.

3. **Synthesis and Biodistribution Studies of ^{99m}Tc labelled Fatty acid Derivatives prepared via "Click Approach" for Potential Use in Cardiac Imaging.**

   Soumen Das, Anupam Mathur, Navin Sakhare, Madhava B. Mallia, Haladhar Dev Sarma, Satbir Singh Sachdev, Ashutosh Dash

   J. Labelled Compds. & Radiopharm. 61 (2018) 1048-1057. DOI: 10.1002/jlcr.3681.

4. **Use of ESI-MS for Semi-Quantitative Estimation of Inactive Precursor in No-Carrier Added (nca) ^{131}I-meta Iodo Benzyl Guanidine Radiopharmaceutical Preparation.**

   Anupam Mathur, Soumen Das, Navin Sakhare, S.S. Sachdev

   Jour. of Pharmaceutical & Biomed. Analysis165 (2019) 261-267. DOI: 10.1016/j.jpba.2018.12.016.

5. **Synthesis and Evaluation of ^{99m}Tc-Analogues of [123/131I] mIBG prepared via 99mTc [Tc(CO)3(H2O)3]+ Synthon for Targeting Norepinephrine Transporter.**

   Soumen Das, Navin Sakhare, Anupam Mathur, Madhava B. Mallia, Shubhangi Mirapurkar, M. Sheela, H. D. Sarma, S. S. Sachdev, Ashutosh Dash

   Nucl. Med. & Biol 68-69 (2019) 49-57. DOI: 10.1016/j.nucmedbio.2019.01.001.

6. ***In-vitro* Enzymatic Technique for Biological Quality Control of 99mTc-ECD.**

   Soumen Das, Anupam Mathur, Preethi Nair, R. Vanaja, S.S. Sachdev

   Jour. Radioanal. & Nucl. Chem. 318 (2018) 1287-1295.

Abstract Publication

1. **Synthesis and Evaluation of a Novel ^{99m}Tc Labelled Folic Acid Derivative for Targeting Folate Receptor Positive Cancer.**

   Soumen Das, Navin Sakhare, Anupam Mathur, Shubhangi Mirapurkar, M. Sheela, S. S. Sachdev

   Book of Abstracts of Applications of Radiotracers and Energetic Beams (ARCEBS 2018) Vol. 5, pp-129-130.

2. **Design, Characterization and Evaluation of ^{99m}Tc-Labelled Gold Nanoparticles for Imaging FR Positive Cancers.**

   Dheeraj Kumar, Navin Sakhare, Pooja Kale, Soumen Das, Anupam Mathur, Shubhangi Mirapurkar, Sheela M., S.S. Sachdev

   Book of Abstracts of Applications of Radiotracers and Energetic Beams (ARCEBS 2018) Vol. 5, pp-133-134.

3. **Evaluation of ^{99m}Tc-Methoxy-Isobutyl-Isonitrile Formulation Prepared by Microwave Assisted Radiolabelling Procedure.**

   Krishna Mohan Repaka, Anupam Mathur, V.V. Murhekar and D. Padmanabhan

   IJNM 33 (2018) pp-S88.

4. **Targeting efficiency of ^{99m}Tc-Labelled Polymeric Nanoparticles.**

   Swapna Nair, Alka Mukne, R. Krishna Mohan and Aruna Korde

   IJNM 33 (2018) pp-S88.

5. **Validation of an *in-vivo* Technique for Quality Assessment of ^{99m}Tc-HSA Nanocolloid Kit and its Shelf-life Extension.**

   Krishna Mohan Repaka, Suresh Subramanian, Usha Pandey, Aruna Korde

   IJNM 33 (2018) pp-S96.

6. **Production and Supply of ready-to-use Ga-68 Radiopharmaceuticals: BRIT Experience.**

   Soumen Das, Dheeraj Kumar, Anupam Mathur, Kiran Mehra, P.C. Vrinda, S. Mirapurkar, Chanda Arjun, Barakha K., Ravi S., S. S. Sachdev

   IJNM 33/5 (2018) pp-S1.

7. **Bacterial Endotoxin Test, An Alternative Method for Pyrogen Test for Technetium-^{99m} Cold Kits.**

   Geetha Rajagopalan, Seema Syed

   IJNM 33/5 (2018) Pv52.

8. **Radiolabelling and in-vitro Evaluation of Ga-68 MAA Formulated using BRIT TCK-56 Cold Kit.**

   Ashok Chandak, Sutupa Rakshit, Archana Ghodke, R. Vanaja, H.H. Shimpi

   IJNM 33 (2018) PP-S102.

9. **Radiochemical Studies and Preclinical Evaluation of ^{111}In-Pemetetrotide using Indigenously Produced $^{111}InCl_3$ via $^{109}Ag(\alpha,2n)$ Nuclear Reaction.**

   A. Chakraborty, A. Mitra, S. Lad, T. Upadhyay, M. Tawate, S. Satamkar, R. Bhoite, S.S. Das, L. Barua, S. Chattopadhyay, S. Banerjee

   Book of Abstracts of International Conference of Applications of Radiotracers and Energetic Beams (ARCEBS 2018) pp-175-176.

10. **A New Sephadex based Separation of ^{43}Sc from Alpha Irradiated $^{nat}CaCO_3$ Target.**

    Sujata Saha Das, Sankha Chattopadhyay, Luna Barua,, Md. Nayer Alam, Madhusmita, Asit K. Pal, Umesh Kumar, Arup K. Hudait Sharmila Banerjee

    Book of Abstracts of International Conference of Applications of Radiotracers and Energetic Beams (ARCEBS 2018) pp-179-180.

11. **Simulation Study on Purification of Spent Mo-100 and Tc-99m from Nb, Zr, Y and Ru Tracers.**

    Sankha Chattopadhyay, Sujata Saha Das, Madhusmita, Md. Nayer Alam, Sharmila Banerjee

    Book of Abstracts of International Conference of Applications of Radiotracers and Energetic Beams (ARCEBS 2018) pp-181-182.

12. **Mitigation of Emergency Situations in Radiation Processing Plant: 2 Decades of Experience.**

    Jain Regi George and B.K. Pathak

    Book of Abstracts of International Conference on Radiation Emergency and Management (ICONRADEM 2019) RUHS Journal of Health Sciences, Vol. 4 (2019) pp-S-31.

13. **Emergency handling of a Radiography Camera.**

    Rahul Kharat and Jain Regi George

    Book of Abstracts of International Conference on Radiation Emergency and Management (ICONRADEM 2019) RUHS Journal of Health Sciences, Vol. 4 (2019) pp-S-31.

14. **Bioavailability of Major Elements and ^{40}K in Vegetables.**

    Jyoti, Aditi C. Patra, J.S. Dubey, V.L. Thakur, Jain Reji George

    Proceedings of 20th National Symposium on Environment (NSE-20) (2018) pp-81-82.

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