सत्यमेव जयते

GOVERNMENT OF INDIA

BRIT

Board of Radiation & Isotope Technology

ANNUAL REPORT

2016-2017

DEPARTMENT OF ATOMIC ENERGY


Green city clean city,
My dream city.
हम सब का एक ही नारा,
साफ सुथरा हो देश हमारा.

BOARD OF RADIATION & ISOTOPE TECHNOLOGY

DEPARTMENT OF ATOMIC ENERGY
GOVERNMENT OF INDIA

BRIT

ANNUAL REPORT 2016-2017

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CHAPTER - 1

EXECUTIVE SUMMARY

IF EVERYONE IS
MOVING FORWARD
TOGETHER,
THEN SUCCESS TAKES
CARE OF ITSELF.

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

- 632 Ci of I-131 products in ~28000 consignments have been supplied to various hospitals in the form of capsules and solution for both, diagnostic and therapeutic purposes for thyroid disorders and treating thyroid cancer.
- 33.57Ci of other theraputic products such as ^{153}Sm, ^{177}Lu and ^{32}P for bone pain palliation were supplied to nuclear medicine hospitals during the year 2016-17.
- **New ready-to-use radiopharmaceutical product, ^{177}Lu-DOTATATE injection' developed, successfully tested at RMC, BARC on patients. RPC clearance is awaited for the product to launch it in market. The product is used for the treatment of patients with metastatic neuroendocrine tumors (NETs).**
- 1765 consignments containing 623Ci of ^{99}Mo for Technetium-99m Column Generators to obtain ^{99m}Tc at hospital end, have been supplied to various hospitals in India during the annual year 2016-17.
- Nearly 44Ci of ^{99}Mo, in the form of Sodium Molybdate solution, in 243 consignments were supplied to nuclear medicine centres for solvent extraction of ^{99m}Tc at the hospital end.
- A total of 17985 consignments of Technetium-99m cold kits for imaging various organs have been supplied to nuclear medicine centres in India. Recertification and accreditation for 'cGMP-Pharma Products' by United Registrar of Systems was Completed for the production of '^{99m}Tc-Radiopharmaceutical cold Kits' during the reported period.
- **New product, ^{99m}Tc-cold kit developed by BRIT for preparation of ^{99m}Tc-Macro Aggregated Albumin (MAA) injection, useful for lung perfusion imaging, has been approved by Radiopharmaceutical Committee (RPC), DAE.**
- **Radiopharmaceutical Committee (RPC) approval is also obtained for extension of shelf-life (expiry date) of Technetium-99m cold kits, DTPA, Phytate & MIBI injections, from existing 6 months to one year and extension of expiry date for ^{99m}Tc-Sulphur Colloid cold kit from existing 100 days to six months.**
- A total number of about 2613 radioimmunoassay (RIA) and Immunoradiometric Assay (IRMA) kits to serve about 4 Lakh in-vitro investigations, were supplied to various hospitals, research centres and immunoassay laboratories throughout India during 2016-17.

- New in-cell roof hanging and remote operated, decapping tool, for use od radioactive liquid vials, developed and installed in production plants.
- Facility with in-cell gadgets and synthesis module developed in an existing lead shielded production plant for the regular production of ^{177}Lu-DOTATATE injection.

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

- Around 353 radiopharmaceutical samples and 36 ^{99}Mo-^{99m}Tc COLTECH Generators were routinely analysed and certified by QC during the annual period 2016-17.
- **RPC approval obtained for the following quality control procedures: (a) Alternate BET method for TCK cold kits analyses; (b) QC methods for new products to be launched by BRIT, such as, ^{177}Lu-DOTATATE; ^{99m}Tc-MAA cold kits and ^{99m}Tc-UBI.**
- GMP compliance achieved for batch manufacturing records of 12 TCK products.

(c) Labelled Compounds (LC)

- Labelled compounds Programme 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).
- Since April 2016, more than 33500 TFS sources of various sizes and shapes were supplied to defence establishments.
- Based on MoU between BRIT and Heavy Water Board, deuterated NMR solvents were dispensed and supplied to various customers.

(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, [18F]-FMISO and [F-18]-FET, which are produced in smaller scales.
- **[F-18]-Fluro Ethyl–L-Tyrosine ([18F]-FET) was cleared by Radiopharmaceutical Committee (RPC) for regular supply. This will be used for biopsy guidance and treatment planning of cerebral gliomas.**
- So far 377 Ci of F-18 radiotracer, mainly [F-18]-FDG, have been supplied to various hospitals in Mumbai for PET imaging during the annual period of 2016-17.

II. Engineering Products

(a) Sealed Radiation Sources

- Twenty three consignments with a total activity of 237960 Ci of teletherapy sources (CTS) of ^{60}Co containing activity in the range of 164 and 226 RMM were supplied to different cancer hospitals in India and abroad during the annual year of 2016-17.
- 69 Nos. of sealed sources containing Cs-137 with a total activity of 16474 Ci were loaded into 6 units of Blood Irradiator 2000.

- Eighty eight Irradiator sources of industrial grade in eight consignments with total activity of 16, 38, 976 Ci (1639 kCi) were supplied to nearly eight radiation processing plants within the country. Another 675 kCi of activity is planned to be sent to three processing plants within India and one to Sri Lanka.
- A total of 1133 numbers (with total activity of 52, 695Ci) of ^{192}Ir & nine numbers of ^{60}Co Radiography sources were supplied to NDT user's upto March 2017.
- One consignment each of Sc-46 and Cs-137 custom made reference sources (CMR) of 6.9 Ci and 970 mCi respectively were also supplied upto December 2016. Another fifteen Cs-137 CMR sources with 6500 mCi is supplied upto March 2017.
- Three numbers of Co-60 CMR with total activity of 427 mCi were supplied upto December 2016 while another five sources with 500mCi is supplied upto March 2017.
- Licence for operation of Integrated Facility for Radiation Technology (IFRT) obtained from AERB and for the first time sealed sources were fabricated and handled at IFRT, Vashi.

(b) Radiation Equipments

- 100 Radiography Cameras, ROLI-2 model were supplied to various NDT users within India and services were provided for 658 numbers of BRIT and imported radiography cameras.
- Three Blood Irradiators – 2000 (BI-2000) units with Cs-137 source were supplied to hospitals in India.
- Three Gamma Chambers – 5000 units have been supplied to universities and institutions for research purposes.

B. Services

1. Consultancy and MoU for Radiation Processing Plant

- BRIT signed five MoU's for setting up Gamma Radiation Processing Plants for disinfestations, shelf-life extension of food products and sterilization applications of healthcare products, each with M/s Suzaina Foods Pvt. Ltd. at Kundh, Chikli District, Navsari, Gujarat, M/s KGS Agrotech Pvt. Ltd. at Saiwad, Jaipur, Rajasthan, M/s. Gaur Chemtech, Rohini, Delhi, M/s. Pinnacle Therapeutics Pvt. Ltd., Vadodra, Gujarat and M/s Jamnadas Industries, Dahod (Gujarat) at Indore, Madhya Pradesh.

2. Gamma Radiation Processing Services (GRPS)

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

- 7169 Cubic meters of medical supplies have been sterilized using gamma radiation processing at ISOMED, BRIT from April 2016 to March 2017.

(b) Radiation Processing Plant (RPP), Vashi

- About 5170.79 Ton of spices and other products like herbal raw material, pet feed, colour powder etc. were processed during the reported time period.

- **NABL accreditation for calibration of dosimetry laboratory of RPP, Vashi, was continued after the initial surveillance audit during this period.**

- **Radiation Processing Plant, Vashi, obtained ISO-13485:2016 for quality management system for healthcare products.**

- Dose rate certification was provided to eight blood irradiators and four gamma chambers which were supplied to various cancer hospitals and research universities respectively.

3. Radiation Physics Services

- **Source loading pattern was designed for replenishment of Co-60 activity for various Gamma Radiation Processing Irradiators provided by BRIT under MoU's.**

- Carried out a study for using Cs-137 as source in Panoramic Gamma Irradiators for processing food commodoties.

- Radiological Survellience was provided to various facilities of BRIT such as, Radiation Processing Plant (RPP), Decayed Source Removal Facility (DSRF) and Integrated Facility for Radiation Technology (IFRT). 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.

4. Calibration Services for Portable Radiation Monitoring Instruments

- BRIT is providing calibration services for gamma radiation survey instruments. So far 280 Numbers of Portable Radiation Monitoring Instruments have been calibrated.

5. Isotope Application Services (IAS)

- Isotope Application Services was provided for Fly ash disposal studies for Bhushan steel Ltd., Odisha, Gamma scanning of Process columns and Identification of leaky heat exchanger in a Series using radiotracer techniques to trouble shoot different kinds of problems at various industries such as BPCL, HPCL, IOCL etc. thereby saving crores of rupees for the country.

- Shield integrity confirmation using radiometry technique was also provided for AREVA, U.S., a project by Larson & Toubro. Radiometry studies of shielding casks of BLC-125 flasks for IS, SS&L, BRIT and exposure device for calibration of portable radiation equipments was undertaken during the reported period.

- **A new method has been developed to extract Mo-99 was in the organic phase (20% D2EHPA in kerosene), which can be dissolved in diesel to carry out leak detection studies in diesel carrying components of crude oil refineries. Extraction of ^{99}Mo in aqueous solution was carried out with more than 80% recovery in organic phase. This procedure was developed first time by RPL in collaboration with IAS group and helped in faster service to the industries, removing the dependency on BARC for organic radiotracer supply.**

6. Radioanalytical Laboratory (RAL) Services

- Radioanalytical Laboratory carried out more than 6362 tests on export/domestic commodities for gross alpha, gross beta, ^{226}Ra, ^{228}Ra and total uranium content and 940 tests on water samples.

- NABL accreditation was received for the Radio Analytical Laboratory (RAL), Vashi during the reported time.

- Radioanalytical Laboratory has started surveying and certifying surface radiation dose of steel consignments at factory premises and warehouses. Total of three steel surveys were conducted for certification of surface radiation dose.

7. Services by RCR's and Quality Control Analysis of Radiopharmaceuticals FOR Outside Agencies

- Regional Centres at Delhi, Bengaluru, Hyderabad (Jonaki), Dibrugarh & Kolkata, continued the supplies of ready-to-use-radiopharmaceuticals to surrounding nuclear medicine hospitals, . Around 3800 consignments of *in-vivo* and *in-vitro* kits were formulated, and provided appropriate services to the nearby hospitals at these cities.

- Quality Control testing services were provided for kit effocacy and safety performance of cold kit for 99mTc labelled Myoview for M/s GE Healthcare which was onrequest from DCGI and appropriate certificates of analyses were released.

8. Customer Support

Inroduced online payment facility at BRIT website, www.britatom.gov.in, through State Bank of India's payment portal "State Bank Collect".

CHAPTER - 2

DESCRIPTIVE PART

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). After completing its silver jubilee (March, 2014), 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, tritium filled sources (TFS) for defence establishments and radioanalytical services. The combined revenue from the sales and services of healthcare products for the year 2016-17 amounted to Rs. 36.06 Crores.

(a) Radiopharmaceuticals Production (RPhP), Vashi Complex and Medical

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. The Medical Cyclotron Facility (MCF), Parel continues the production and supply of Positron Emission Tomography (PET) radiopharmaceuticals, mainly ^{18}F-FDG and to a lesser extent, ^{18}F-Sodium Fluoride to meet the requirements of several hospitals in Mumbai. ^{18}F-Flurothymidine (FLT), ^{18}F-Fluoromisoisonidazole (FMISO) and ^{18}F-Fluoro Ethyl-L-Tyrosinamide (FET) is also produced, but the requirements for these are limited.

- Regular, uninterrupted, production and supply of radiopharmaceuticals, all over India, was continued. However, due to limited availability of I-131 radioisotope from BARC for prolonged periods during the year 2016, the production and supply of I-131 labelled radiopharmaceuticals were less compared to previous year.

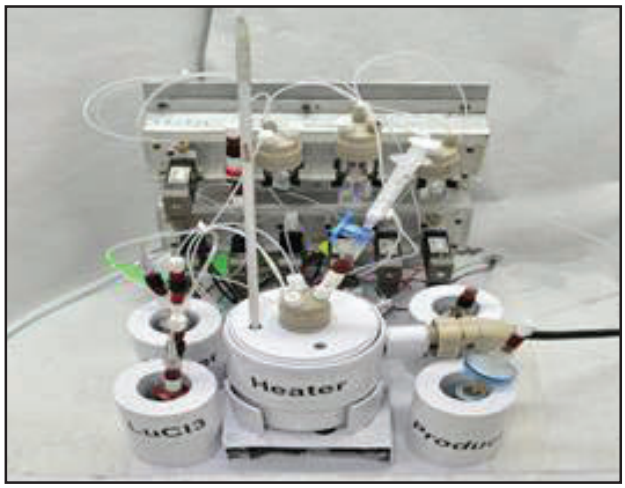
- Radiopharmaceuticals Programme, BRIT, has developed new products and production processes, thus enabling the capabilities towards increasing the production capacity and quality of products which has enabled BRIT to enhance the production frequency, production volume and regularize the production of new products that were introduced during previous years.

- Approximately 631Ci of Na^{131}I and over 27500 consignments were processed, formulated and supplied to various nuclear medicine hospitals all over India in the form of oral solution and capsules.

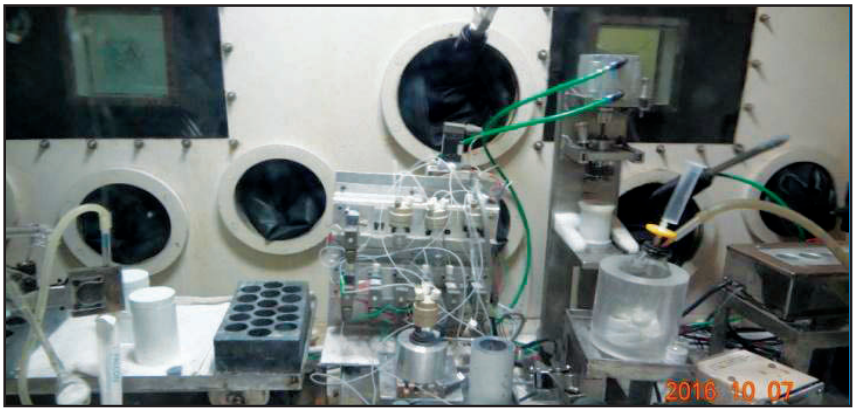
- The total revenue from the sale of only I-131 products (both, diagnostic and therapeutic) amounted to be **Rs. 10 Crores**. These are mainly used for diagnosis and therapy of thyroid disorders and for the treatment of thyroid cancer. The other I-131 product is ^{131}I-meta Iodo Benzyl Guanidine (^{131}I-mIBG) in the form of ready-to-use injection, which is used for the diagnosis and treatment of Neuro Endocrine Tumors (NET) in case of Pheochromocytoma and Neuroblastoma.

- **New Ready-to-use radiopharmaceutical product, '^{177}Lu-DOTATATE injection' was developed, successfully tested on patients at RMC, Parel during the reported period. This is now awaiting the approval from Radiopharmaceutical Committee (RPC), DAE.** This product would be an ideal choice for the treatment of Neuro Endocrine Tumors (NET).

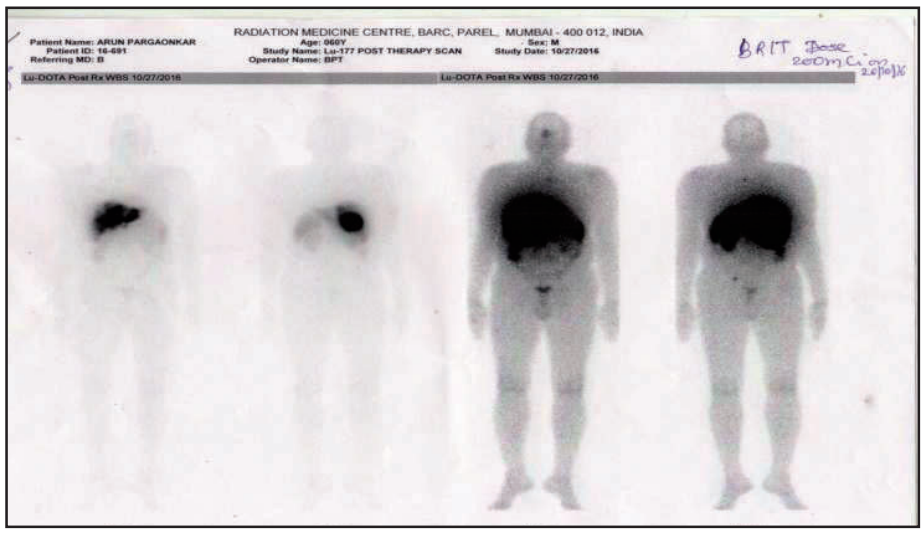
- **Facility with in-cell gadgets and synthesis module developed, in an existing lead shielded production plant, for regular production of "^{177}-Lu-DOTATATE Injection".**



^{177}Lu-DOTATATE Automated Synthesis module



Internal layout of Lead shielded hot cell for manufacturing Therapeutic doses of ^{177}Lu-DOTA-TATE



Clinical study (18 h Post Therapy scan) with BRIT ^{177}Lu-DOTA-TATE
Performed at RMC, BARC

- As regular production, about 339 consignments containing nearly 33.57 Ci of ready-to-use radiopharmaceuticals of ^{32}P, ^{153}Sm in the sterile injectable form and ^{177}Lu as radiochemical were supplied to various nuclear medicine hospitals all over India. ^{32}P, ^{153}Sm-EDTMP and ^{177}Lu-EDTMP Injections are used for bone pain palliation and BRIT could earn a revenue of **Rs. 2.9 Crores**.

- **New in-cell roof hanging and remote operated, de-capping tool, for radioactive liquid vials was developed and installed in production plants.**

- **Total number of therapeutic treatments based on supplies is estimated to be more than 30000 patients. This includes therapeutic doses of Na^{131}I for the treatment of thyroid cancer and hyperthyroidism.**

- During the year 2016-17, more than 80000 ^{99m}Tc-cold kits (TCK) in 18000 consignments for formulation of ^{99m}Tc radiopharmaceuticals (15 Products; BRIT Code-TCK) was processed, lyophilized and supplied to various nuclear medicine hospitals all over India, whereby the annual sales of ^{99m}Tc cold kits amounted to be **Rs. 5.79 Crores**.

- **New product, '^{99m}Tc-cold kit for the preparation of ^{99m}Tc-Macro Aggregated Albumin (MAA) injection' was developed by BRIT during the reported period. This will be useful for lung perfusion imaging and has been approved by Radiopharmaceutical Committee (RPC), DAE. Currently this product is being imported by the hospitals.**

- **RPC Committee has approved the extension of shelf-life (expiry date) of TCK cold kit preparation of ^{99m}Tc-Sulphur Colloid injection (Code – TCK-5) from existing 100 days to six months and TCK cold kits of ^{99m}Tc-DTPA, ^{99m}Tc-Phytate & ^{99m}Tc-MIBI from existing 6 months to 1 year.**

- Re-certification and accreditation for cGMP-Good Manufacturing Practices-Pharma Products' (in accordance with WHO requirements) by United Registrar of Systems Certification of Manufacturing Facility for "Kits for the Preparation of Technetium Cold Kits (TCK)" was completed.

- Nearly 44Ci of ^{99}Mo, in form of Sodium Molybdate solution, for solvent extraction generator, has been supplied. Approximately 623Ci of ^{99}Mo in the form of Sodium Molybdate was processed and supplied in form of ^{99}Mo-^{99m}Tc Gel Generators and alumina column generator (COLTECH).

Sale of ^{99}Mo in the form of Sodium Molbdate and ^{99}Mo-^{99}mTc Generators resulted in the revenue collection of **Rs. 5.96 Crores**.

- **More than 2,30,165 *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.**

- A total of about 2613 radioimmunoassay (RIA) and immunoradiometric assays (IRMA) kits to serve ~4 Lakh *in-vitro* investigations were supplied to various hospitals, research centres and immunoassay laboratories throughout India. The revenue collected from the sale of RIA & IRMA kits for the year 2016-17 is about **Rs. 74.3 Lakhs**.

(b) Medical Cyclotron Facility (MCF), Parel

- **The Medical Cyclotron Facility** (MCF), Parel, located in the basement of Tata Memorial Annexe Building, continued supplying about 475 consignments of PET radiopharmaceuticals (used for diagnosis) such as ^{18}F- FDG, ^{18}F-FLT, ^{18}F-NaF and ^{18}F- FMISO to various hospitals in and around Mumbai accounting for nearly 377 Ci of radioactivity and generating the revenue of **Rs. 5.91 Crores** during the year 2016-17. **Approx. 15000 patients benefitted with PET investigations in the reported year.**

- **^{18}F-Fluoro ethyl-L- tyrosine (^{18}F-FET) was cleared by Radiopharmaceutical Committee (RPC) for regular supply. ^{18}F-FET PET is superior to ^{18}F-FDG for biopsy guidance and treatment planning of cerebral gliomas. The uptake of ^{18}F-FDG is associated with prognosis, but the predictive value is limited and a histological evaluation of tumor tissue remains necessary. Therefore, amino acids like ^{18}F-FET are the preferred PET tracers for the clinical management of cerebral gliomas.**

- Regular maintenance of radiofrequency system, secondary chiller, ion source, Helium cooling system and vacuum system was carried out. Major maintenace of the cyclotron was scheduled during first week of April 2016. Breakdown maintenance of ion source, primary chiller, heat exchanger, water manifold and motor interlock fault was carried out followed by annual inspection of the facility by ULSC-PA on December 01, 2016. Periodic safety report (PSR) was also presented to ULSC-PA and OPSRC for renewing the licence upto December 31, 2020.

(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 2016, following are the QC reports:

- **Routine sample analyses**: Around 600 radiopharmaceutical products and raw materials were analyzed and certified for specified quality compatibility during the reported period. These samples are tested for their performance in physico-chemical analyses, sterility, tests, bacterial endotoxin tests and animal biodistribution studies as per standardized and approved quality control procedires of individual product. Additionally, several Tc-99m based cold kits were evaluated for stability beyond the assigned shelf life.

- **QC Analysis for products under development:** QC protocols were established for the analysis of

new products being developed. Several batches were analyzed for various purity parameters including biodistribution studies for obtaining regulatory clearance from DAE-Radiopharmaceutical Committee (RPC) such as kit for Macro Albumin Aggregates (MAA) for lung perfusion studies, Autosolex generator, Ready-to-use injectable radiopharmaceutical ^{177}Lu-DOTATE for the treatment of tumors expressing somatostatin receptors such as Neuroendocrine Tumors (NET).

- **Method Development:** (a) New method of Bacterial Endotoxin Testing (BET) of TCK-cold kits was standardized and DAE-RPC Clearance is obtained for this method of testing BET as an alternative method for currently followed pyrogen testing.

(b) Kit for Tc-99m Ubiquicidine (29-41) injection suitable for infection imaging (developed by QC in collaboration with RPHD, BARC) was standardized; RPC cleared and is launched in February 2017. (c) HPLC method for the analysis of ^{99m}Tc-TRODAT has been standardized using PRP column and DMGA buffer as a part of validation of Indian Pharmacopeia method.

Quality Assurance (QA): Production and Quality Control Testing processes are routinely monitored and documented by QA Section and appropriate QA certification for a total of 241 batches of radiopharmaceuticals were released from April 2016 to December 2016. Another 80 batches are expected to be produced in next three months. Batch Manufacturing Production Records (BMPR)

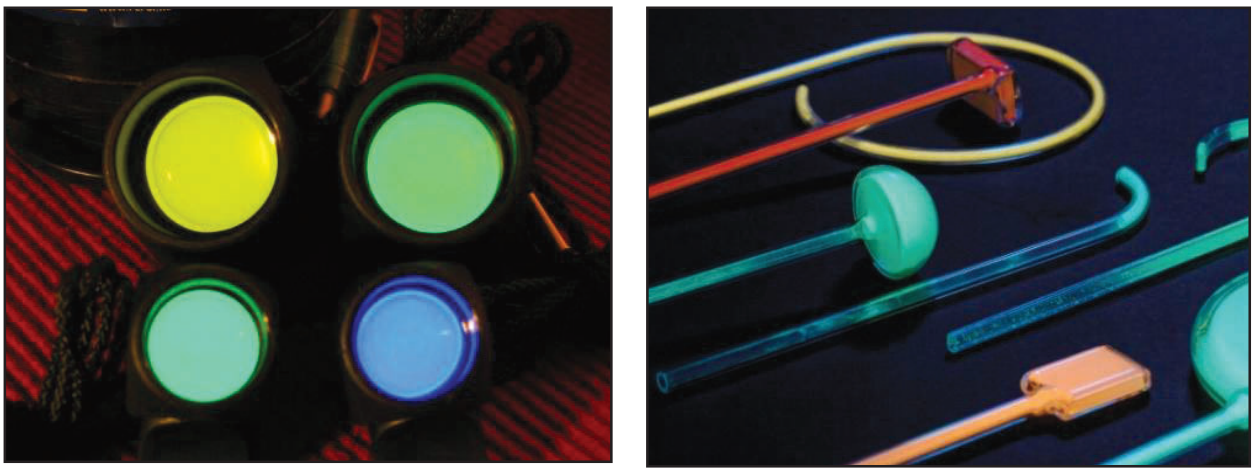
for TCK cold kits (12 products) were modified and improvised as per the GMP guidelines.

ST and BET Laboratory in Radiopharmaceutical Laboratory Programme

(d) Labelled Compounds (LC)

During 2016-17, Labelled Compounds Programme of BRIT continued the supply of more than 26000 sources of Tritium Filled Self-luminous sources of various sizes and shapes for defence establishments along with the custom synthesis & supply of a variety of ^{14}C, ^{3}H and ^{35}S-labelled products.

Based on the MoU signed between BRIT and Heavy Water Board, deuterated NMR solvents were dispensed and supplied to various customers.



TFS sources of various sizes & shapes

II. Engineering Products

The various engineering products offered by BRIT included the supply of more than 1748 kCi of radioactivity in various forms and for varied uses. The combined revenue for the engineering products and radiation processing services is estimated close to **Rs. 57.34 Crores**.

(a) Sealed Radiation Sources:

- **Co-60 Teletherapy Sources (CTS) for Cancer Hospitals: Nine** ^{60}Co-teletherapy sources with total activity of about 118 kCi in the range of 164 and 226 RMM were supplied to various cancer hospitals in India. Out of the nine CTS sources, one source is exported to Tanzania and another source is kept ready for export to Kenya. 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: Eighty eight** irradiator sources with total activity of around 1438.17 kCi were supplied in eight consignments to various processing plants within the country. The irradiators to which these sources are supplied are namely, (a) AVPP, Ambernath – 199976 Ci; (b) AIIPL, Vasai – 199998 Ci; (c) Aligned Industry, Bhiwandi – 99998 Ci (d) RPP, Vashi – 213220 Ci; (e) UML, Vadodra – 199990 Ci; (f) GAICL, Ahmedabad – 199990 Ci; (g) MICROTROL, Bengaluru – 199998 Ci and (h) GAMPPL, Hyderabad – 124999 Ci.

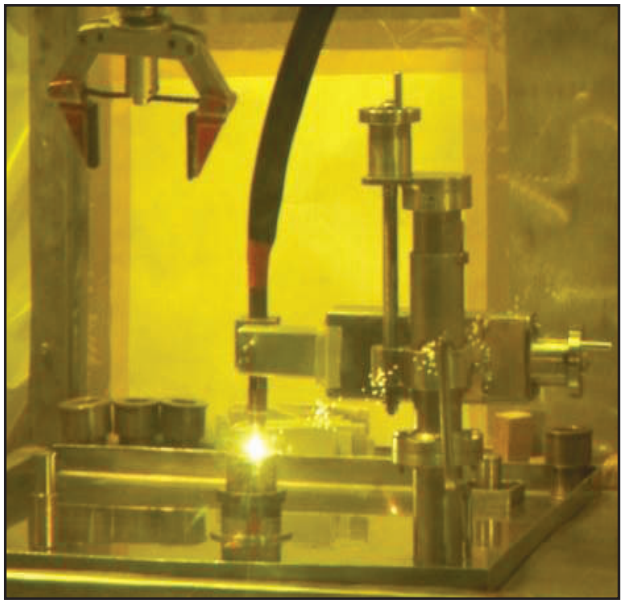
- A total of 675 kCi of irradiator sources are planned to supply upto 31st March, 2017. These are: MSAMB, Vashi – 350kCi; Aligned Industry, Bhiwandi – 100kCi and Sri Lanka – 125kCi and OGFL, Kolkata – 100kCi.

- **^{192}Ir and ^{60}Co Radiography sources**: Nearly 789 radiography consignments of Ir-192 and Co-60 with total activity of approx. 37.5 kCi were supplied to various radiography customers in the country. It is planned to supply four hundred more radiography sources up to March 2017.

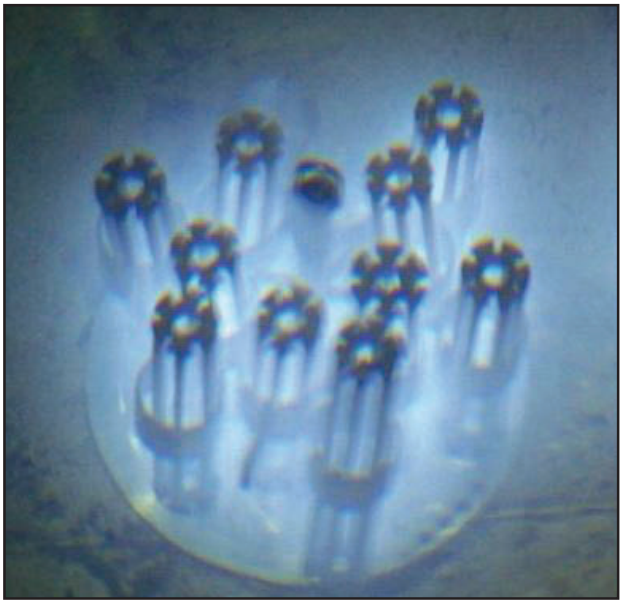
- **Custom Made Sources (CMR) and Reference Sources:** Custom Made Sources of **Co-60, Cs-137 and Sc-46** were supplied on request, for Nucleonic Gauges and other calibration uses in 690 consignments upto December 2016. A total of 6.33 Ci of radioactivity was supplied for reference and custom made sources**.** Three custom made ^{60}Co radiation sources with total activity of 427 mCi were supplied till December 2016. It is planned to supply another five more Co-60 sources with an activity of 500 mCi up to March 2017. One Cs-137 CMR source with a total activity 970 mCi

was supplied and it is planned to supply 15 custom made ^{137}Cs radiation sources with 6.5 Ci activity up to 31st March 2017. One CMR source of Sc-46 with 6.9 Ci was supplied upto December 2016.

- 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.
- At RAPPKOFF, Kota, total activity of Co-60 which was processed during the year was about 63.52PBq (1717 KCi). Safe handling, transportation of adjuster rods from various reactors were transported to RAPPKOFF, Kota for processing of Cobalt-60 and subsequently transported for fabrication of sources at Mumbai and the necessary documentation of the records were performed.
- ^{60}Co Teletherapy sources (CTS) are prepared using indigenous pellets recovered after cutting 09 pellet capsules. This is the first time; we have successfully fabricated more than 200 RAM CTS using indigenous ^{60}Co pellets. Machine and procedure for cutting of pellet capsules, recovery of pellets and filling of pellets in inner CTS containers is developed at RAPPCOF, Kota and duly endorsed by various regulatory committees of AERB.



Sealed source fabrication using tig Welding inside hot cell



Cobalt sub-assemblies in storage pool

(b) Radiography and other Radiation Equipment Devices

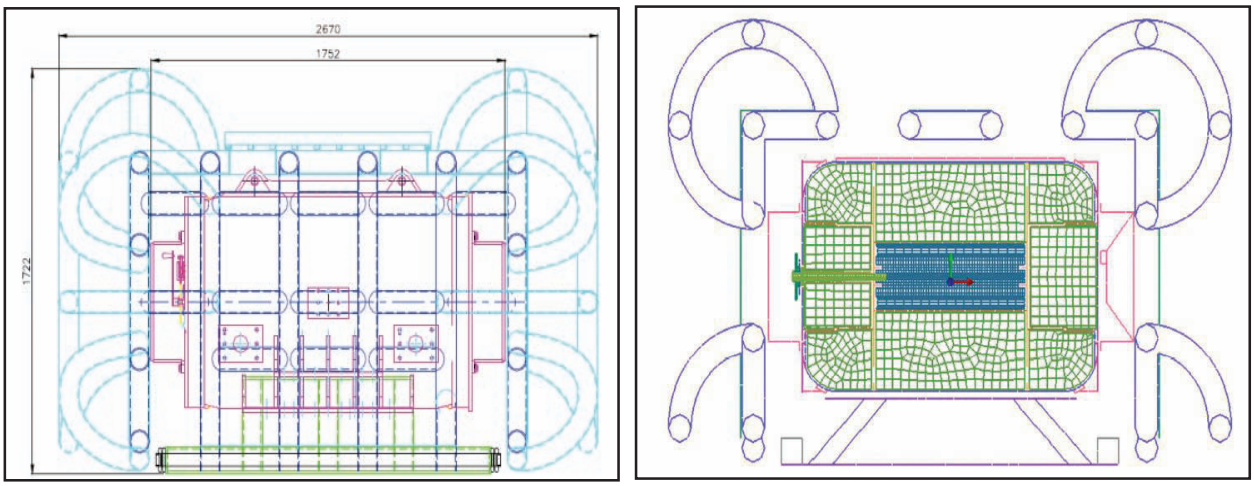
Radiography Camera: Production and supply of 100 new indigenous radiography camera model ROLI-2 and servicing and inspection of 658 numbers of BRIT manufactured as well as imported ROLI cameras were the highlights during the reported period.

Gamma Chamber 5000: One unit of GC-5000 was loaded with ~14000Ci of ^{60}Co and transported to Crop Research Unit, Research Directorate Bidhan Chandra Krishi Viswavidyalaya, Mohanpur, Kolkata, upto December 2016.

Blood Irradiator: Two Blood Irradiators-2000 units with Cs-137 source have been supplied to hospitals in India. 69 numbers of sealed sources of Cs-137 with a total activity of 16474 Ci were loaded into 6 units of Blood Irradiator 2000.

(c) Engineering Design Development

- **ISOMED Cask Package:** ISOMED cask package was fabricated for 300 kCi Co-60 source transportation and loading/unloading in ISOMED and other similar facilities. The package contains a shielded cask with loading/unloading arrangement, a source magazine and a shock absorber to protect cask from stipulated accidents during transport.



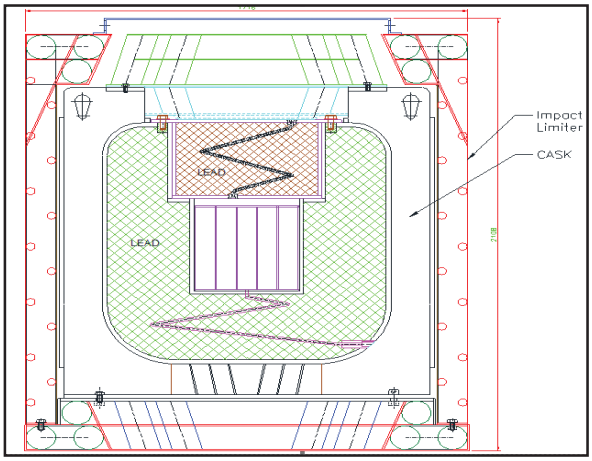
(a) *(b)*

ISOMED Cask Package (a) assembly (b) sectional view of meshed model

- **Decayed Source recovery using Mobile Hot Cell:** Decayed source recovery operations were carried out using BRIT's dismentlable Mobile Hot Cell. Nine such operations were carried out to recover disused source pencils containing Co-60 sources form GC-900 irradiators.

Mobile Hot cell at BRIT/BARC Vashi Complex

- **BLC-800 Cask:** A transport package named BLC-800 for absorber rod sub assembly coming out from 700MWe PHWRs under design. The Co-60 in these subassemblies will be used to fabricate sealed radiation sources for irradiator applications. One set of impact and thermal analysis is completed for this package. The package will be used to transport these subassemblies from reactor area to RAPPCOF water-pool for storage and further processing.



BLC-800 Cask Package under development

4) Co-60 based radiography camera developed having capacity 120 Ci. Testing of camera is completed and is under review for AERB approval

5) AERB approval is obtained for Multi Position Source Changer which is designed and fabricated in-house and which can have 11 radiography sources at a time. This has been tested for Type B (U) package at Pune

B. Services

I. Consultancy and MoU for Radiation Processing Plants

- MoU was signed with Bhamji Food Irradiators Pvt. Ltd. for a setting up of Gamma Radiation Processing Plant for disinfestations, shelf-life extension of food products and sterilization applications of healthcare products at Kundh, Chikli Taluka, Navsari District, Gujarat.

- MoU was signed with M/s KGS Agrotech Pvt. Ltd. for a setting up of Radiation Processing Plant for disinfestations of food products and sterilization of healthcare products at Saiwad, Shahpura Tehsil, Jaipur, Rajasthan.
- MoU was signed with M/s Gaur Chemtech, for a setting up of Radiation Processing Plant at Rohini, Delhi for radiation processing of food and medical products.

➢ Consultancy was obtained for commissioning Radiation Processing Plant for processing food and medical products by M/s Pinnacle Therapeutics Pvt. Ltd. at Vadodra, Gujarat.

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 7169 Cubic mtrs of products and BRIT could earn **Rs. 3.01 Crores** during the annual period of 2016-17.

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

- Radiation Processing Plant, Vashi has provided gamma radiation processing services for 5171 Tons of Spices, Ayurvedic raw material, healthcare products and pet feed etc. to ~300 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. Eighteen new customers for Spice, Ayurvedic raw material and pet feed were registered with the facility during last 12 months. The total revenue generated from RPP services during the year was **Rs. 5.21 Crores.**

- During the current financial year, 2016-17, 51.71 MT of spices and other products were processed.

- Survellience audits for ISO-22000:2005 (Food Safety Management Systems) and ISO 9001:2008 were carried out by NABL accreditation of dosimetry laboratory at RPP, Vashi Complex and was found to be in full compliance.

- Additional revenue was obtained from GRPS related products and services were towards the supply of 1.7 Lakhs of ceric-cerous dosimeters to various gamma irradiators in the country for absorbed dose measurement generating **~ Rs. 45.55 Lakhs** revenue.

- 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:

(i) Gamma irradiation of Stator coils from M/s Crompton Greaves Ltd. for 150 kGy to develop radiation resistant stator winding for motors.

(ii) Gamma irradiation of various sizes of valves and cable samples from various suppliers of NPCIL was carried out for radiation test qualification.

Spices for gamma irradiation

QA activities at RPP include the following:

- Export of 2500 Nos. of Ceric-Cerous dosimeters to Atomic Energy Regulatory Board, Srilanka. One Lakh Ceric-Cerous dosimeters were supplied to various private irradiators for low, medium and high absorbed dose measurement in radiation processed medical and food products.

- Radiation Processing Plant recommissioning dosimetry was carried out in seven 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, Bangalore for approval of the facility by USFDA – APHIS for quarantine purpose.

  Dose rate certification of eight Blood Irradiators based on Cesium-137 supplied to various cancer hospitals and four gamma chambers supplied to research universities was carried out.

III. Isotope Application Services

Isotope Application Services (IAS) Section of Marketing & Services Division of BRIT offered its valuable, timely and elegant services and solutions to various industries across the nation. The total revenue generated by IAS during the year 2016-17 is **Rs. 1.21 Crores**.

(a) Fly ash disposal studies for Bhushan steel Ltd., Odisha:

After querying the coal from mine, void is created. Torrential rains fill the mine void with water.

In coal fired thermal power stations huge quantity of fly ash is generated. Ministry of Environment and Forest, Government of India, permitted M/s. Bhushan Steel Limited to dispose off the fly ash generated from their power plants into Jagannath coal mine void at Talcher in Dhenknal district of Odisha. This would provide information of its impact on the surrounding environment which should be within the

stipulated limits. Radiotracer study was carried out at to understand and analyze leaching characteristics of fly-ash into the groundwater in surrounding areas. Flyash labeled with Sc-46 was used as radiotracer.

- A batch of about 3 tons of fly ash mixed with water in agitator was labelled at site with about 5 Ci of scandium in chloride form. The labelled fly ash slurry was dumped in to the water in the mine void.
- The radiotracer plume movement in the stagnant mine pit water was monitored. Groundwater samples from the strategically placed bore wells and piezometers were analyzed at RAL, BRIT to study the appearance of radiotracer.

- It was found that there was no radiotracer leaching into the groundwater till four months after injection. The groundwater sampling is continued on a monthly basis. The report on the study was sent to the Ministry of Environment and Forest (MoEF) by BSL for obtaining approval to continue safe disposal of fly ash into the mine void pit.

(b) Gamma scanning of Process columns:

- In the refinery Bharat Petroleum Corporation Limited Mumbai, temperature difference was observed over the Heavy Vacuum Gas Oil packed bed in the Vacuum Distillation column of 10 meters diameter, which was affecting the product quality. To identify the cause, Gamma scanning was done with the help of auto column scanner. Collimated 200 mCi of Co-60 source on one side of the column and collimated BGO detector on the other side were simultaneously manoeuvred to get 6 scan-lines.

- Interpretation of the data showed that in the upper half of the bed liquid distribution was not uniform. This helped BPCL in saving the shutdown time by carrying out maintenance of the liquid distributor above the bed.

- In the petroleum refineries, water mixed with hydrocarbon in drainage system is called as sour water from which hydrocarbon is recovered in the sour water stripping unit. In the stripping unit coarse separation of water is carried out in a drum and hydrocarbons are stripped off in an adjoining column. In HPCL, Mumbai, the product quality from the Sour Water Stripper unit was not as expected. To understand the cause, gamma scanning of the SWS column and the preceding surge drum was done. The gamma scanning showed that the separation baffle in the surge drum was damaged and several trays in the SWS were partially damaged. In some sections of the column heavy flooding was observed.

(c) Leak detection study of PET plant, RIL, Dahej, Gujarat

- In continuous polymerization plants of M/s. Reliance Industries Ltd. Dahej, Gujarat, CP-1 and CP-2, ingress of process side fluid was observed in to the heat transfer fluid which posed a danger of clogging in the pipelines and has affected the heat transfer performance. Radiotracer study was done by using Tc-99m in organic phase which was extracted on site by using solvent extraction process.

- The leak was pin pointed and was confirmed visually during shutdown of the plant. Corrective actions were taken by plant engineers. After successful completion, RIL has now requested BRIT to carry out one more study in the same plant to ascertain that there is no additional leak.

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 nine Gamma Radiation Processing Plants:

AVPPL, Ambernath: added 200 kCi in 10 source pencils to 785 kCi.

AIIPL, Vasai: added 200 kCi in 10 source pencils to 792 kCi.

ALIGNED Industries, Gurgaon: added 100 kCi in 6 source pencils to 169 kCi.

RPP, Vashi Complex: added 215 kCi in 10 source pencils to 488 kCi.

UML, Vadodra: added 200kCi in 10 source pencils to 608 kCi.

MICROTROL, Bengaluru: added 200kCi in 6 source pencils to 235 kCi.

Gujarat Agro (GAICL): added 200 kCi in 10 source pencils to 726 kCi.

GAMPL, Hyderabad: added 125 kCi in 6 source pencils to 150 kCi.

MSAMB, Vashi: added 350 kCi in 14 source pencils to 76 kCi.

- A study was conducted for using Cs-137 as source in Panaromic Gamma Irradiators for processing food commodities. Apart from these, the group is involved in regular Radiological Surveillance to the facilities of BRIT, Vashi, and submitting the Safety Status Reports to AERB every quarter. Under this, Regular inspection of safety systems, survey for radiation area monitoring and personnel monitoring at Radiation Processing Plant (RPP), Decayed Source Removal Facility (DSRF) and contamination checks at Integrated Facility for Radiation Technology (IFRT) are made on regular basis.

V. Calibration Services for Portable Radiation Monitoring Instruments

- BRIT is providing calibration services for gamma radiation survey instruments. So far 280 Numbers of Portable Radiation Monitoring Instruments have been calibrated.

- 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) is carrying out the assay of man-made radioactivity in large number of food items, especially those meant for export. Generally, Cs-137 content is measured for certification on man-made radioactivity levels. In addition to the above, Radioanalytical Laboratory carries out the measurement & certification of engaged in the measurement and certification of residual radioactivity content in water samples, uranium content in water samples, naturally occurring radioactive materials (NORMs) in environmental samples such as coal, fly ash, soil rock phosphate, gypsum etc. and Co-60 contamination in steel. Large numbers of environmental samples such as soil, coal, flyash etc. were analyzed during the year for the presence of ^{238}U, ^{232}Th, ^{226}Ra and ^{40}K content. Another activity taken up by Radioanalytical Laboratory is the survey & certification of surface radiation dose of steel consignments at factory premises and warehouses.

- **Radioanalytical Laboratory (Vashi Complex) received [IS:17025 (2005)] NABL accreditation in the field of Radiological Testing during September 2016.**

- During the year 2016-17, RAL, Vashi alone has carried out more than 6332 tests on export/domestic commodities and 940 tests on water samples (gross alpha, gross beta, ^{226}Ra & ^{228}Ra). Total of three steel surveys were conducted for certification of surface radiation dose. The revenue generated by RAL, Vashi, alone is **Rs. 1.68 Crores**. Radioanalytical Laboratory Services both, at Vashi Complex and RCR, Bengaluru, together performed **approximately 6435 analyses of food and water samples for the presence of radioactivity**.

VII. Radiopharmaceuticals Services by RCR's, BRIT and Quality Control Section at Vashi Complex

Regional centres at Delhi, Bengaluru, Jonaki, Hyderabad, Dibrugarh & Kolkata, continued the services of ready-to-use-radiopharmaceuticals to surrounding nuclear medicine hospitals, labelled compounds and radioanalytical certifications. 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 these cities.

RCR, Kolkata & Dibrugarh

- **Sale of cold kits for radiopharmaceuticals from the retail outlet at RC, Kolkata:** More than 300 Nos. of Technetium cold kits for formulation of ^{99m}Tc-radiopharmaceuticals were sold this year 2016-17 by RC, Kolkata, to nuclear medicine centres at Kolkata.

- **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.

RCR, Bengaluru

- Regional Centre, BRIT, Bengaluru supplied ~70 mCi of ready-to-use ^{99m}Tc-pertechnatate to nuclear medicine hospitals and 1081 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 services were provided for 1932 blood bags to Kidwai hospital. Also, radioanalytical services for the measurement and certification of residual radioactivity in various commodities such as food items for human & animal consumption, medicine, steel and other miscellaneous items were provided.

- Radioanalytical Laboratory analyzed and certified 92 samples for the measurement of residual radioactivity in various commodities such as food items for human & animal consumption, medicine etc

RCR, Delhi:

- Regional Centre for Radiopharmaceuticals, Delhi continued to supply clinical grade ready to use ^{99m}Tc-radiopharmaceuticals in compliance with GMP and RPC for diagnostic nuclear medicine centres in Delhi and NCR regions.

RCR, Hyderabad (Jonaki):

- During the period, Regional Centre of BRIT, Hyderabad (Jonaki) supplied ready-to-use $^{99m}TcO_4^-$ (Pertechnatate) and ^{99m}Tc-Radiopharmaceuticals through their retail outlet to the nuclear medicine centres of Andhra Pradesh. Also, it continued to supply ^{32}P labelled nucleotides and a few molecular biology kits and enzymes, for research in frontier areas of Molecular Biology, Biotechnology, Biomedical and Drug Discovery research of the country. It markets ^{35}S-labelled amino acids products produced at BRIT, Vashi Complex.

Quality Control Analysis Services from Vashi Complex for Outside Agencies

- Two batches of Tc cold kits for the preparation of Tc-99m-labelled Myoview were analyzed for outside agencies (GE Healthcare) whereby certificates of analyses were provided to them after evaluating the performance for all the QC parameters.

VIII. Customer Support

- As the nodal agency for sales and supply, marketing and customer relations, Co-ordination & logistics support cell continued to provide the regular and uninterrupted supply of radioisotopes & allied products, radiation technology equipments to about 2000 user institutions in the healthcare, industrial, research and agricultural sectors.
- Many new BRIT customers were registered for supply of radiopharmaceuticals during the year 2016.
- Feedback forms were collected during the conferences and seminars which were consolidated and analyzed for providing better support.
- Online payment system was introduced through 'State Bank Collect' for the convenience of the customer support.
- Export orders of two C0-60 nucleonic gauge sources, two teletherapy sources and dosimeters were also processed and supplied appropriately bringing foreign exchange revenue.
- In an effort to provide better service, the Customer Support at BRIT started supplying radiopharmaceuticals through Jet Airways in addition to Air India. This has helped in solving logistics problems faced during transportation to places like Chandigarh and Srinagar also.
- Around 140 standing orders for Radiopharmaceuticals were processed. Order processing of Lu-177, Irradiator source and Teletherapy sources were all streamlined so as to provide better service to the customer base.
- Applications for various permissions and approvals are also being processed through eLORA portal to meet the regulatory compliance. eLORA (e-licensing of Radiation Applications), an e-governance initiative by AERB, is a web-based application of automation of regulatory processes for various Radiation Facilities in India. Process of listing BRIT products in the eLORA portal is being taken up as per the AERB guidelines.

IX. Scientific Events, HRD & Development activities, activities related to Official Language Implementation at BRIT and other miscellaneous activities

- A **training course** on **'Radiotracer related techniques for diagnostic laboratory'** was conducted during 20th April – 30th April, 2016 at Radiopharmaceutical Programme of Board of Radiation &

Isotope Technology and was attended by doctors, pharmacists and research scholars. Nine students from varied fields underwent a thorough training in the use of radiotracers such as ^{99m}Tc, ^{125}I, ^{131}I and ^{14}C for diagnostic laboratory. A test was conducted at the end of the 10 working days and issued them the said certificates.

- Famililiarization courses were conducted for students of DRM/DMRIT of HBNI and Nuclear Medicine Technologists of INHS, Aswini Hospital, Mumbai at Radiopharmaceuticals Programme, Vashi Complex.

- Seminar on 'Radiation Protection and Safety Measures' was conducted at BRIT, Vashi Complex for all the staff of Radiopharmaceutical Laboratory and Labelled Compounds Laboratory who are responsible for handling radioactivity. This initiative was taken up as a part of refreasher activity.

- Accreditation programme for the officers of RPhP, QCP and Technology Development Group as 'Operators' was done by the selected committee as per AERB guidelines.

- **HRD and Development activities of BRIT:** Apart from the services towards the commercialization of radioisotope activities in healthcare, industries and radiation processing, BRITians are also involved in continuous research & development activities along with 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. These are highlighted in the next two chapters.

- **Activities related to the Official Language Implementation at BRIT:** In addition to the scientific activities, BRIT has always encouraged the use of Official Language in official activities by making an attempt to comply the directions issued by Department of Official Language in official works. BRIT has been organizing Workshops, Hindi Day, World Hindi Day, Various Competitions, Official Language Talks, etc. Under the Official Language Talk, along with the knowledge-oriented talk by the Scientific Officer of BRIT, Prize Distribution Ceremony is organized on the eve of Hindi Day for the Officers/Employees of BRIT under the aegis of Official Language Implementation Committee. Recently, on the eve of World Hindi Day, Dr. Mohaseen Khan, HOD, Hindi Department, J.S.M. College, Alibagh gave a presentation on "Hindi Bhasha-Devanagari Lipi : Vaishvik Paridrushya". In continuation, Shri Chandan Rai, Renowned Gazal Singer and Lyricist presented his poems. Both the presentations have been appreciated by the audiences. Quarterly meetings of Official Language Implementation (OLIC) are conducted regularly and to monitor the progress of Hindi with view of the 'Quarterly Progress Report'.

Some Glimpses of Rajbhasha Section for Annual year 2016-17

- BRIT continuously encourages the use of Rajbhasha in official activities by complying with the directions issued by Department of Official Language.

- Quarterly meetings of Official Language Implementation Committee are organized regularly, in which a positive attitude is adapted through discussion for the monitoring of each quarterly progress.

- BRIT organized Hindi Workshops, Hindi Day, World Hindi Day programmes and Various Hindi Competitions, Rajbhasha Talks, etc.

Hindi Day Celebrations

Saraswati Prayer being recited & Lecture by Chief Guest Dr. Vijaya Lad during the function

Guest R.C. Mallik being welcomed

Certificate being received by Smt. Sapkal

Chief Executive, BRIT Shri G. Ganesh being welcomed

Message of Chairman-AEC by Smt. Priya Gunjal

Audiences enjoying the programme organized on the eve of Hindi Day Celebrations

Rajbhasha Vaarta

- A Rajbhasha Vaarta in Hindi by Shri Amit Shrivastava, Facility In-Charge, ISOMED on 26.08.2016 and another Rajbhasha Vaarta by Shri A.C. Dey on " HDR Brachytherapy Equipment Develop of 'Karknidon' " on 09.02.2017 in REPF Hall were delivered. Both were based on Scientific topics.

A Rajbhasha Vaarta being delivered by Shri Amit Shrivastava & by Shri A.C. Dey

BRIT Officials attending the Rajbhasha Vaarta lectures

Hindi Competitions

- Dictation, Essay Writing, Noting/Drafting Competitions were organized on the eve of Hindi Day under the auspices of Official Language Implementation Committee from 28 / 09 / 2016 to 30 / 09 / 2016.


BRIT Officials participating in Essay Writing & Noting/Drafting Hindi Competitions

- A Quiz competition was held at REPF Lecture Hall of BRIT on 26.08.2016 for all the staff members of BRIT and the winners of Quiz competition were given away the prizes by Chief Executive of BRIT.


Shri Sudhir Singh conducting the Quiz Competition


Chief Executive Shri G. Ganesh giving the prizes to the winners of Hindi Quiz Competition

Hindi Competition Prize Distribution Ceremony

Chief Executive Shri G. Ganesh giving away the prizes to the winners

Smt. Priya Gunjal conducting the Hindi Programme

Vote of thanks by Dr. Pankaj Mehta

World Hindi Celebrations

- World Hindi Day Celebrations were conducted on 13/01/2017, in which Dr. Mohseen Khan, Head of Department, J.S.M. College, Alibagh delivered a talk on “Hindi Bhasha-Devanagri Lipi : Vaishvik Paridrushya” and Shri Chandan Rai, Renowned Ghazal Writer and Lyricist recited Ghazals. Both the programmes have been immensely applauded by the audiences.

Kavi Shri Chandan Rai being welcomed by Dr. Pankaj Mehta

Shri A.C. Dey addressing the gathering on World Hindi Day

Plan Projects

(a) Project: DAE Medical Cyclotron Project: Radiopharmaceutical Facility at VECC, Kolkata.

Progress: Civil construction and related major work for the Medical Cyclotron Facility is in advanced stage of completion. Work on HVAC, electrical work, LCW system etc. are completed. The cyclotron will be moved to medical cyclotron vault soon. Installation and commissioning will be started after physical inspection from the vendor's side. Installation of 'Clean-room Panel' with Flashed floor for the different room is completed. Installation of 'air-shower' is also completed. Validation work for the clean room is to be followed after installation of terminal.

(b) Project: Indigenous HDR Brachytherapy Equipment (IHDR)

Progress: Equipment development and fabrication work is completed and 10 units are ready for supply. Radiation qualification is done by RPAD, BARC and the equipment is found to be satisfactory for all the required conditions. The machine/equipment is currently undergoing IEC qualification test for its compliance. Radioactive Ir-192 source is developed for the equipment. Treatment Planning Software (TRS) is under development.

(c) Project: Setting up of Fission based ^{99}Mo Production Facility.

Progress: The production process of fission based ^{99}Mo is a sophisticated technology. It is similar to a small scale "back end nuclear fuel cycle" of a nuclear power plant, involving handling of large scale of activity, having scores of long/short lived isotopes and all kind of radioactivity namely alfa, beta and gamma. With the completion of this plant of BRIT, DAE will be able to meet long standing requirement of health care sector, by producing most crucial isotope ^{99}Mo (n, f). Indigenous production of ^{99}Mo will bring about stability in the current uncertain market and bring down the cost of ^{99}Mo-^{99m}Tc generator considerably. It will also facilitate the growth of nuclear medicine in India and finally, larger section of the patients would be benefitted due to availability of high-tech diagnostic procedures at affordable rate.

This project consists of setting up of a State-of-the Art GMP compliant facility capable of producing 300Ci (6 day pre-calibrated) /week ^{99}Mo, utilizing LEU targets. The scope includes commissioning of set of modern hot cells equipped with manipulators, in cell equipments, radiation surveillance instrumentation and data logging system, special AC & ventilation system, waste management equipments, civil construction of building and setting up of world class quality control labs, modern security system, construction of new building at approved site in ISOMED Complex, BRIT near South Gate BARC, etc.

After the site clearance by AERB, the design documents for the building have been submitted to AERB. As per requirements of security and safety authorities, the work of construction of new RCC boundary wall for the complex, new security watch tower is over and installation of new security and surveillance equipment is ongoing. The work on civil construction of laboratory building is nearing completion. The work on installation of facilities for waste management, electrical supply, water supply etc. is progressing.

The procurement of the production plant shall be on turnkey basis. During the year, the procurement vide Purchase order in favour of M/s INVAP, Argentina for design, fabrication, supply, installation and commissioning of facility, was operationalized. Major work on the construction of Facility and Plant Building is completed. Work on under floor embedment for Hot Cells is also completed. Work on building interior partitions and structures are in progress. M/s INVAP has submitted documents for Critical Design Review (CDR). CDR is being done by a committee, constituted by Director, BARC, consisting of members from both, BRIT and BARC.

Fission Molybdenum Project Site

Low level Liquid waste treatment Facility
Development as on Dec 2016

Under floor embedment installation for Hot Cells and Hot Cell area concrete pouring

(d) Project: Advanced Facilities for Radiopharmaceuticals Production

The project scope comprises of building Advanced Radiopharmaceutical Manufacturing and testing facility for new generation Radiopharmaceuticals with radioisotopes using ^{90}Y, ^{177}Lu, ^{89}Sr, ^{131}I, ^{32}P, ^{153}Sm. etc . Also the present production capacity of radiopharmaceuticals and services from RPL, Navi Mumbai and Jonaki Hyderabad would be enhanced under this project.

New Pharmaceuticals Services Facility area is commissioned and is in operation during the reported period. Old facility area is decommissioned. Hot cells in the Main Production Laboratory is refurbished and refitted with the new hot cells for production of new Ready-to-use Radiopharmaceutical product, ^{177}Lu-DOTATATE injection.

Work is in progress for the construction of new sitting place for the staff and the laboratory area above RPL extension building. The work is expected to be completed by April 2017. The project envisages asset built up for overall improvement of technical capabilities of BRIT to meet the advanced needs of Nuclear Medicine. The project scope comprises of building Advanced Radiopharmaceutical Manufacturing and testing facility for new generation Radiopharmaceuticals with radioisotopes using ^{90}Y, ^{177}Lu, ^{89}Sr, ^{131}I, ^{32}P, ^{153}Sm. etc . Also the present production capacity of radiopharmaceuticals and services from RPL, Navi Mumbai and Jonaki Hyderabad will be enhanced under this project.

Highlights of achievement in 2016 are as below

Construction, Electrical and HVAC work for new laboratory space at first floor over RPL extension building, is in progress (70% completed).

Construction on first floor over RPL extension building (outside view and inside view)

New exhaust system for the fume hoods in synthesis laboratory on the ground floor of RPL extension building completed and commissioned. This has capacity for future extension to laboratory areas on first floor.

New exhaust system for the fume hoods in synthesis laboratory

Refurbishing and augmentation of microbiology test laboratory for biological testing of radiopharmaceutical products is, commissioned with advanced features and is in regular use.

Refurbished microbiology lab with interlocking double door system'

- Facility with in cell gadgets and synthesis module developed, in an existing lead shielded production plant, for regular production of "^{177}Lu-DOTATE injection".

- New in cell roof hanging and remote operated Vial capping and de-capping tools, for radioactive liquid vials, developed and installed in production plants.

Pneumatic vial capping and de-capping tools, in ^{131}I capsule plant

(e) Project: Technology Development for Radiation Technology Equipment

The civil construction for the I-125 seeds plant Facility is in advanced stage of completion at BRIT Vashi Complex. Tender has been floated for the supply of I-125 seeds manufacturing plant which is on 'Turn-key' basis.

I-125 Seeds Plant Construction Site

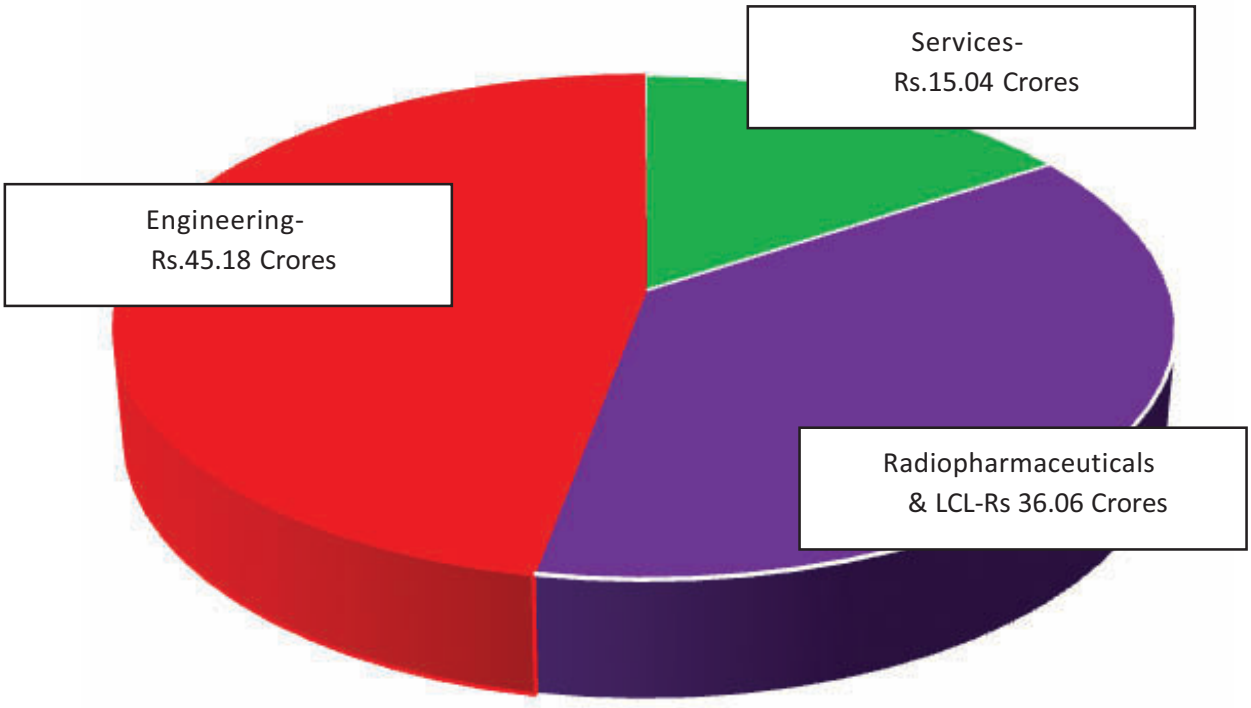
BRIT Website

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.

SALES TURNOVER IN 2016-17

Appropriate Services and Sales of Radioisotopes & Allied Products Supplied by BRIT during 2016-17

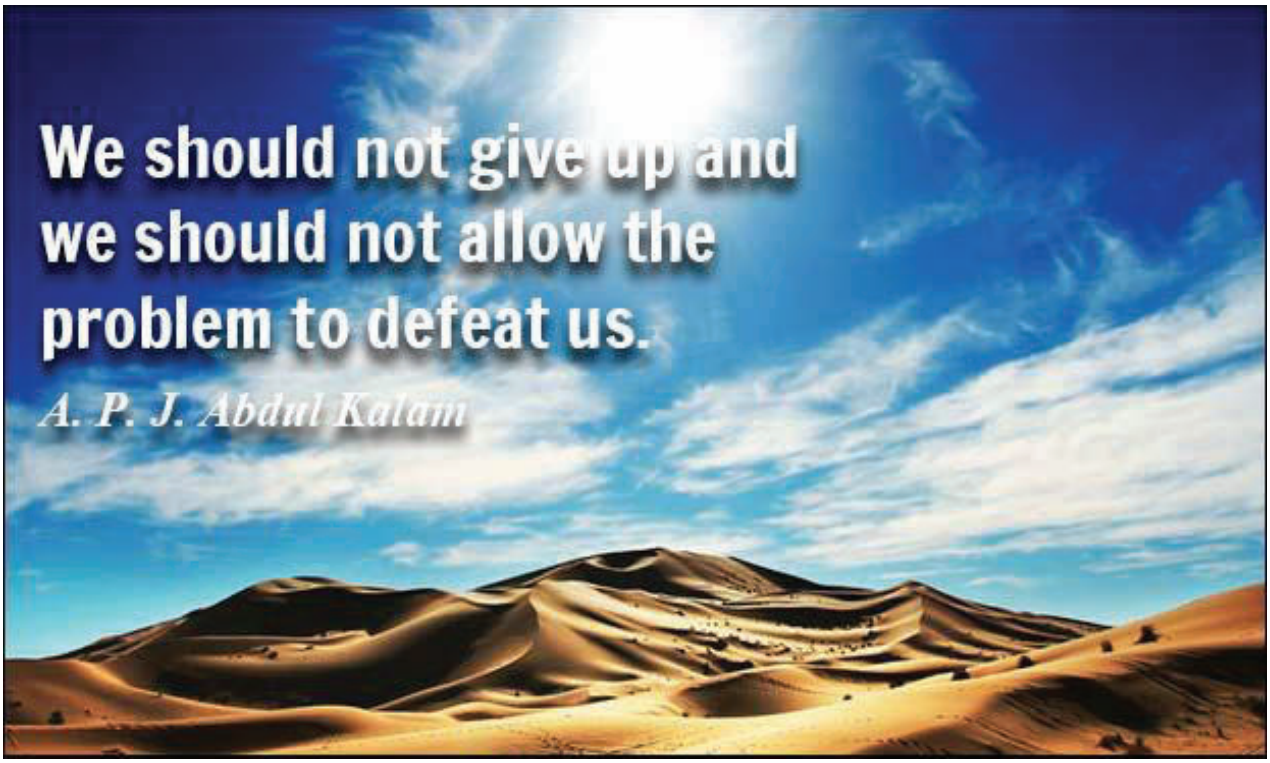
S.No.	Item	Sales turnover from April 2016-March 2017
1.	Consignments	94, 883
2.	Activity	~ 2006 kCi
3.	Total Sale/Target Sale	Rs. 95.96 Crores/Rs. 100 Crores



CHAPTER 3

RESEARCH & DEVELOPMENT ACTIVITIES AT BRIT

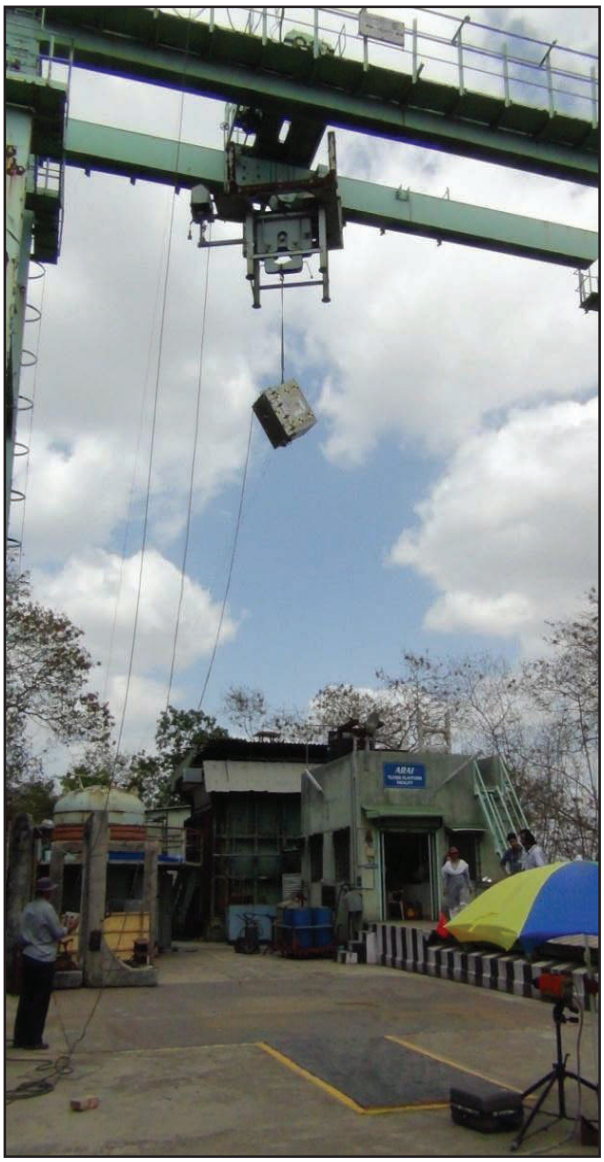

R&D
Research and Development
investigative activities that an
new products or procedures in
innovations and improvement
Market research is one of the


We should not give up and
we should not allow the
problem to defeat us.
A. P. J. Abdul Kalam

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

(i) COCAM-120 under 9m drop, 1m punch and Fire test

Cobalt based radiography exposure device is designed for a source strength of 120 Ci of Co-60 which will be used for non-destructive testing. The device can be used to find defects in weld in the thickness range from 40 mm to 200 mm in steel. The device is made primarily of a combination of shielding material such as lead, tungsten and DU to make it compact and economical. Zircaloy-2 tube in form of S-shaped is used for smooth movement of pigtail and to avoid radiation streaming. COCAM-120 is designed to meet the requirements of Type B (U) package as per the guidelinesof AERB and IAEA. The package was subjected to 9m drop test on unyielding target, 1m drop test on a punch followed by 800^{0}C thermal test for 30 minutes at the testing facility of Automotive Research Association of India (ARAI), Pune. Figures below show the actual drop, punch and fire test of COCAM-120.

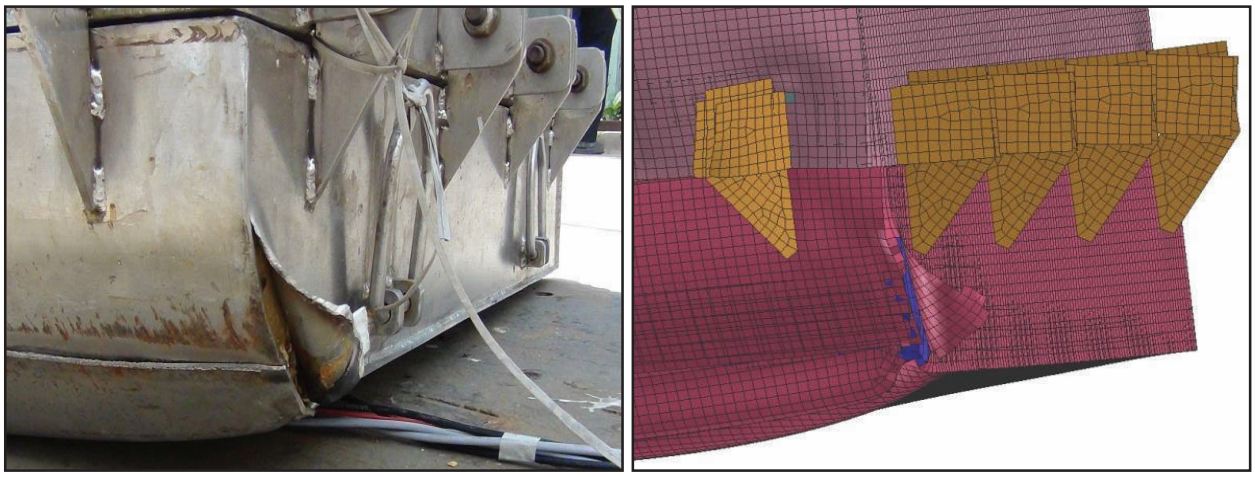


COCAM-120 device under 9m drop test on unyielding target

Deformation of COCAM-120 after 9m drop test

COCAM-120 device after 800^{o}C fire test

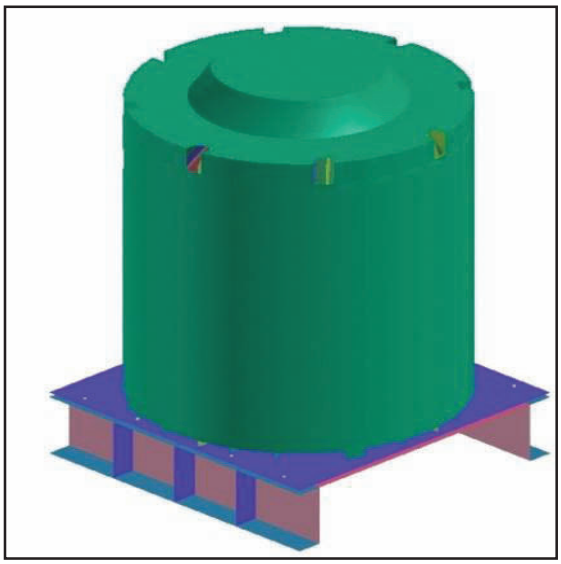
Numerical situation were also carried out to ascertain its structural and shielding integrity. This is the second time after source changer that PUF is being used in the over packs which act as a shock absorber and fire retardant. Figures below show the tearing of plate at corner by actual drop test and finite element analysis.



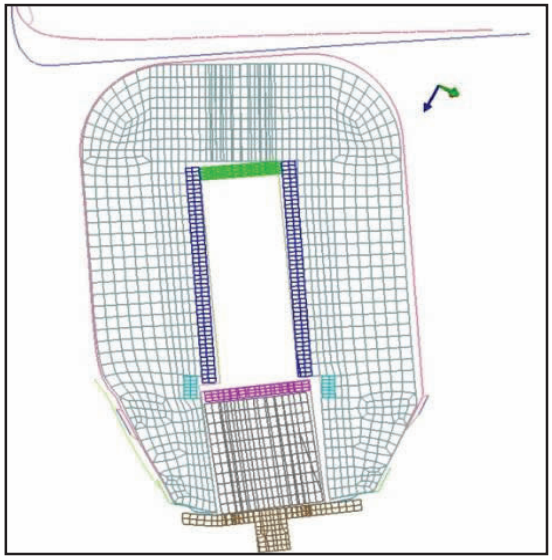
Experimental and numerical result showing tearing of steel outer enclosure at the corner

(ii) Numerical simulation of BLC-200 transportation Cask under 9m drop and thermal test.

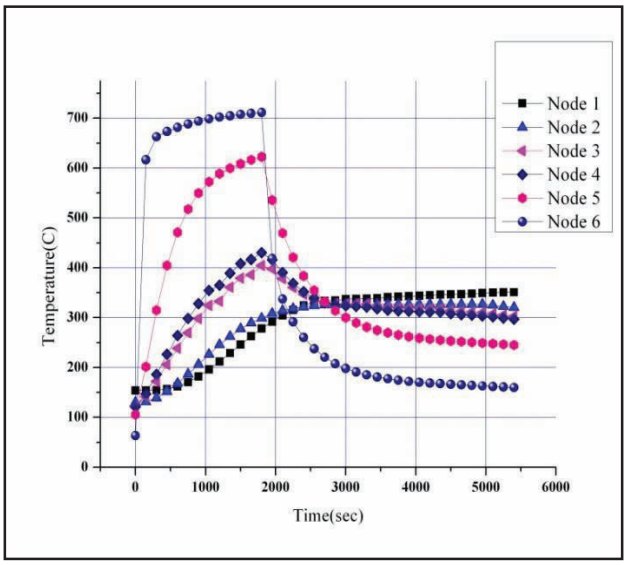
BLC-200 which is an upgraded version of BLC-125 has been designed to carry 200 kCi of Co-60. Tungsten in form of an annular cylinder with 22mm thick has been provided adjacent to inner shell to keep the radiation level within permissible limit due to the increased capacity of radioactivity while maintaining its outer dimensions same as BLC 125. The cask was been designed to meet the requirement of Type B(U) package.The performance of the cask under 9m drop test was carried by numerical simulation using explicit finite element solver PAM Crash for different orientations such as end drop, side drop, inverted end drop and corner drop.The stress intensity of the critical components such as outer shell, inner shell, plug shell and tungsten cylinder are found to be within the safe limit and meet the ASME criteria. It was found that the cask maintains its structural and shielding integrity under 9 meter drop test. The FEM model and final deformation under 9m drop is shown in figures below. Thermal analysis of the cask was carried out using finite element method. It was found that the maximum temperature on the surface of the cask was 59.4°C. During fire test and post fire analysis 56% lead melting was observed.



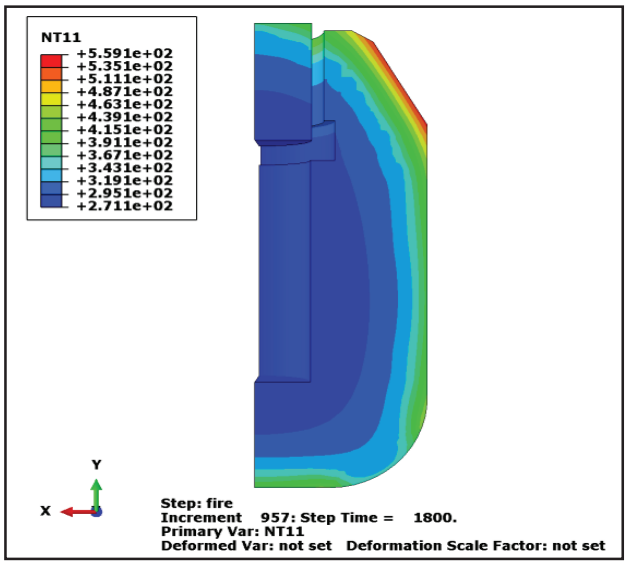
Model of BLC-200 Cask



Final deformation of cask under 9m corner drop



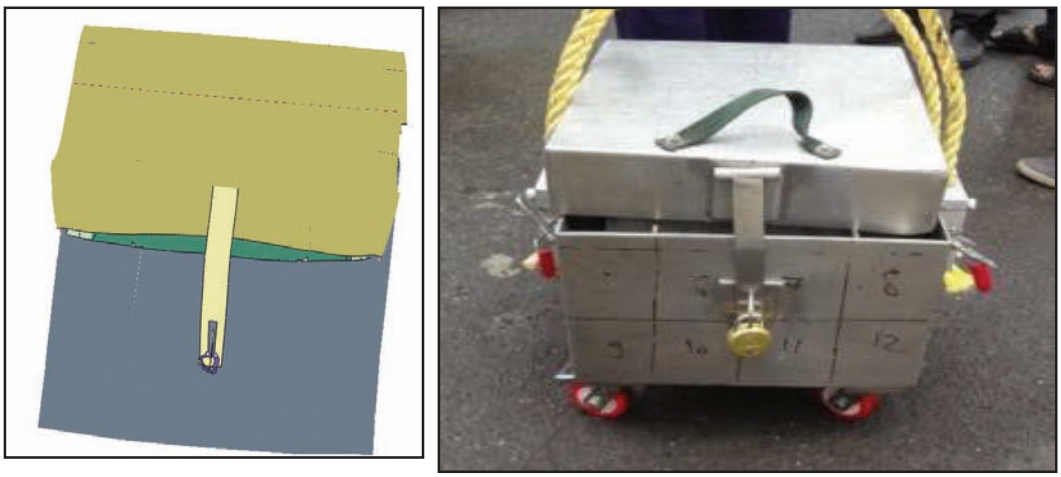
Temperature profile of BLC-200 Cask



Temperature countour under 800 °C fire test

(iii) Numerical simulation and Experimental test of I-131 Package under 9m drop test

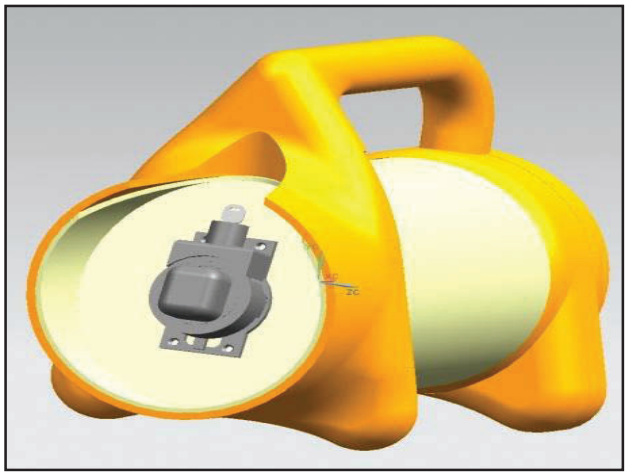
Iodine-131 cask was designed for safe transportation of the radioactive Iodine-131 source. The Iodine-131 cask consists of outer enclosure made of stainless steel, stiffeners, lead sheets, EP, and three lead pots. Analysis was carried out to find out the worst damaging orientation of Iodine-131 cask under 9m drop test. Three potentially most damaging orientations (viz. side drop, vertical drop, inverted edge corner drop were simulated. Maximum deformation was observed in the 9m invertededge cornerdrop and was the worst damaging orientation. Based on the numerical result, the package was dropped from 9m. Figure below shows the final deformation of the package after the inverted edge corner drop.



Numerical and experimental result showing deformation of I-131 transportation cask after inverted edge corner drop

(iv) Remotely Operated Tungsten based Exposure device (ROTEX-I)

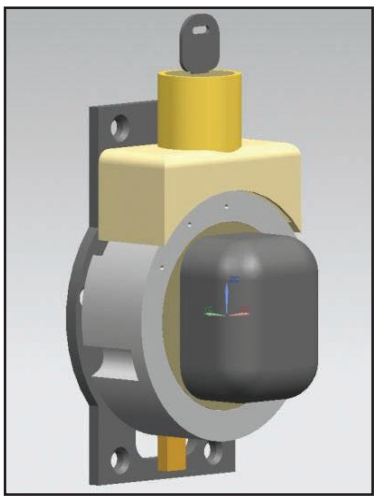
Roli II, which is currently being used for NDT, is designed for 65 Ci of Ir-192. The weight is approximately 38 Kg whereas the imported devices are 22 - 23 Kg. Hence, there was a need to develop radiography devices which are light in weight and compact. Remotely Operated Tungsten based Exposure device (ROTEX-I) has been designed completely with tungsten. The S – shaped bend path has been provided in the tungsten block so that additional tube is not required. The tungsten block is put inside a stainless steel shell of diameter 160 mm and fixed with gussets. The empty space in between is filled with polyurethane foam (PUF) to act as a shock absorber under impact loading. The device is mounted in a High Density Polyethylene (HDPE) structure .The weight of such a device is less than 25 Kg.



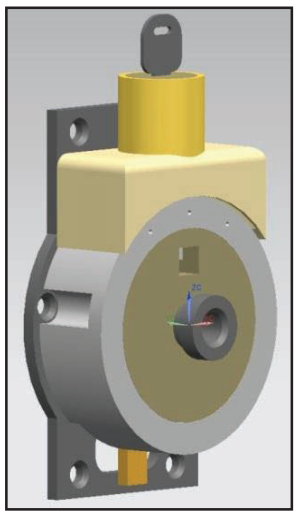
Isometric View of ROTEX-I

(v) Interlock Mechanism for Radiography devices

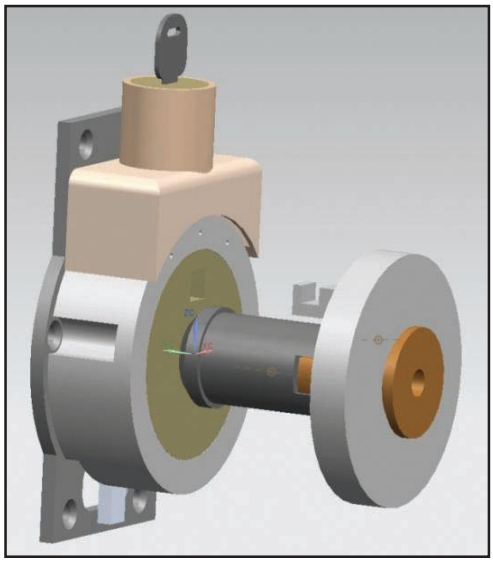
Compact, light weight interlock mechanism has been designed based on ISO 3999 with additional safety and security features. The new interlock has been designed as a four stage interlocking mechanism to avoid any chance of unintended exposure.While maintaining the existing safety features of the current interlocking mechanism, some additional security features were also incorporated in the new interlock to enhance level of safety and security. The interlock cannot be removed or unscrewed from the device in safe lock position as screws connecting interlock to the device remains inaccessible. A person with access key can only be able to operate or remove it for any intended use.



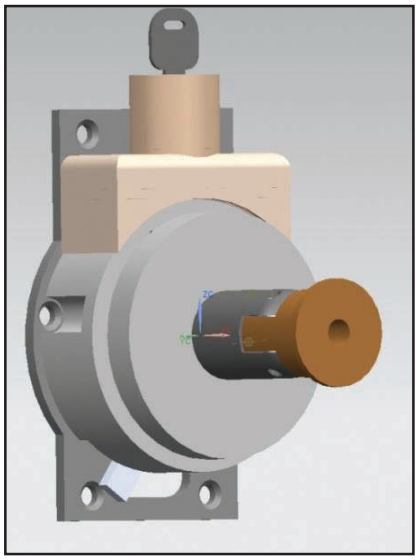
Model view of New Interlocking Mechanism in safe lock position



Interlock Mechanism in unlock position with safety-plug removed from the interlock



Interlocking Mechanism with attached claw assembly(remote control) to provide

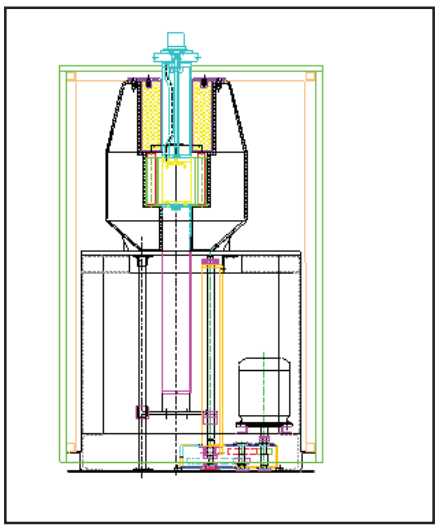


remote access of the exposure device
Interlocking mechanism in exposure condition allowing source assembly to driven out for exposure

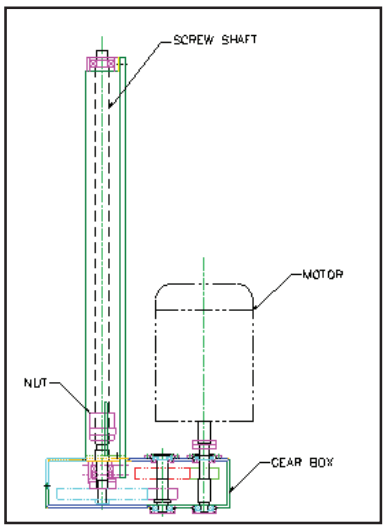
An additional safety plug has been introduced which ensures source assembly cannot be driven out of device by any means in the safe lock position. This plug can't be removed unless interlock gets unlocked with the help of key. These added security features prohibits any un-authorized meddling of the exposure device with mala-fide intentions. With all these added features new interlocking mechanism weighs just ***500gms*** against the 1.1kg weighted current interlock.

(vi) Design of drawer movement mechanism for Low Dose Irradiator

Current Low dose Irradiators such as Blood Irradiators and Gamma Chambers use pulley mechanism for drawer (product chamber) movement. This makes the driving system bulky and complex. The new design is a simple mechanism designed using screw shaft and nut. Screw shaft will get rotated using motor and gear system and nut will run along the screw shaft, this nut will be coupled with drawer (product chamber) to give the desired motion. The advantages of such a system are proper balance, high accuracy of movement, ease of installation and less maintenance.



General Assembly of new drawer movement mechanism



Screw Shaft Details

B. Development work by MIG Section of Enggineering Division, Vashi

(i) Development of prototype Area Gamma Monitor

One such instrument is being developed in BRIT, **The Area Gamma Monitor**, which is very well known instrument for measuring dose rate in the vicinity. It denotes Radiation dose rate in terms of either mR/hr or µSv/hr. The instrument uses a very rugged and well known Geiger-Muller tube (GM Tube). Apart from that High Voltage DC source for biasing the GM tube. Pulse shaper and counter circuit. Microcontroller based readout and alarm generation. Optional modules such as RS-485 serial communication and 4-20mA industrial current loop are available. We know that GM tube is gaseous ionization detector used to detect nuclear radiation by using Townsend Avalanche effect. The tube contains a gas mixture at low pressure of about 0.1 atm. The chamber contains two electrodes as shown in Figure 1.

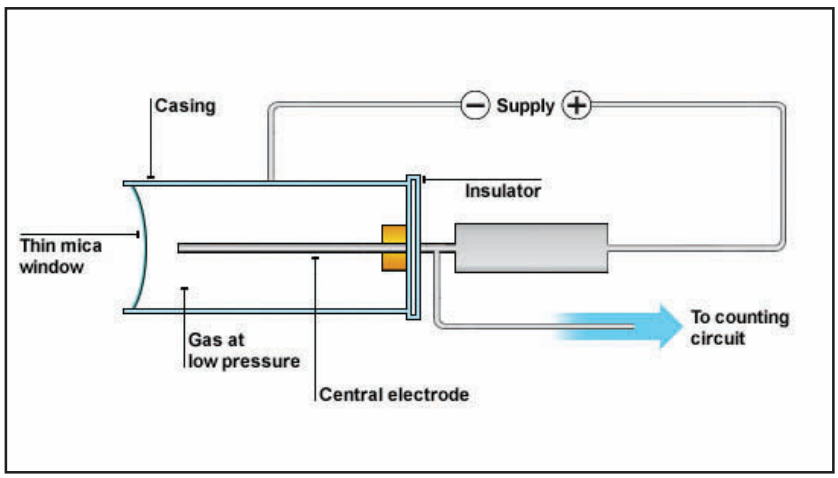


Figure 1.

The walls of the tube are either metal or have their inside surface coated with a conductor to form the cathode, while the anode is a wire in the center of the chamber.

When ionizing radiation strikes the tube, some molecules of the gas are ionized, either directly by the incident radiation or indirectly by means of secondary electrons produced in the walls of the tube. This creates positively charged ions and electrons, known as ion pairs, in the fill gas. The strong electric

field created by the tube's electrodes accelerates the positive ions towards the cathode and the electrons towards the anode. Close to the anode in the "avalanche region" the electrons gain sufficient energy to ionize additional gas molecules and create a large number of electron avalanches which spread along the anode and effectively throughout the avalanche region. This is the "gas multiplication" effect which gives the tube its key characteristic of being able to produce a significant output pulse from a single ionizing event.

This short, intense pulse of current can be measured as a count event in the form of a voltage pulse developed across an external electrical resistor. This can be in the order of volts, thus making further electronic processing simple.

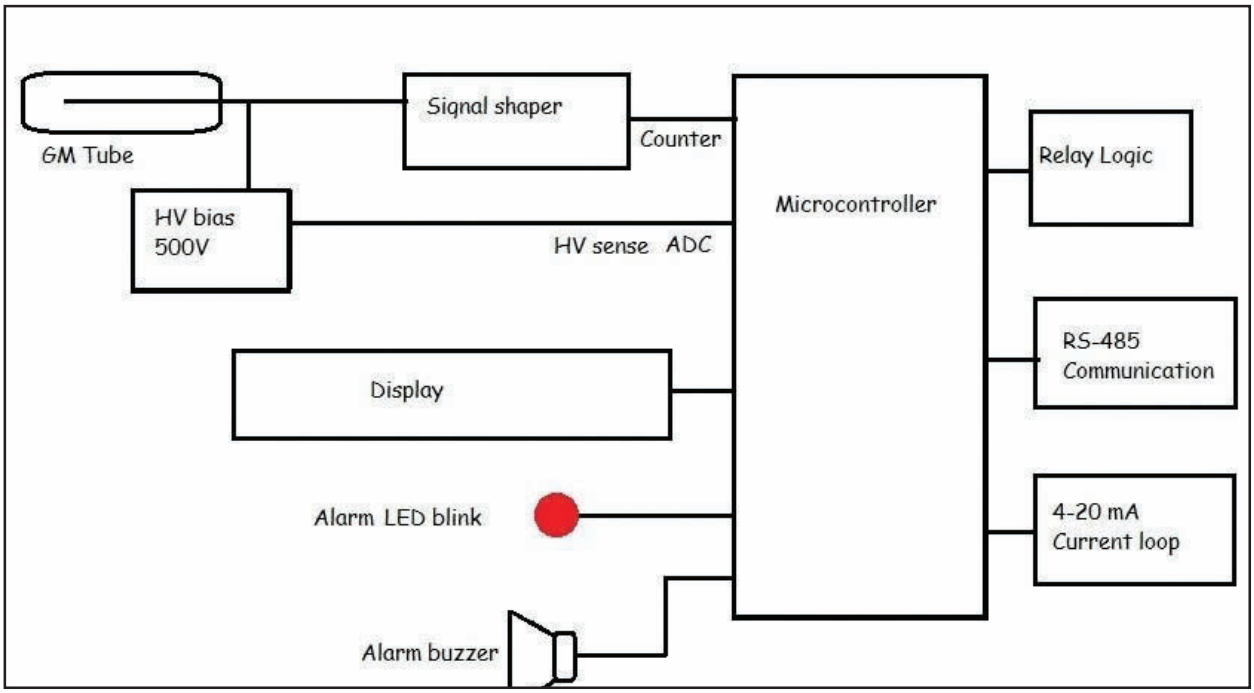


Fig. 2 Block Diagram of the unit under fabrication

The GM Tube used is LND7121 that works from a range of 450V to 600V HVDC. The HVDC circuit has been constructed using a boost converter that converts 12V DC to 500V DC and is a clean DC Voltage. When radiation is incident on GM tube and inside the pulse output can be seen in Figure 3. The pulses are processed and converted into Logic level compatible pulses using pulse shaper circuit as in Figure 4, so that it can be read by Microcontroller based Counter assembly as CPM or CPS, as well as dead time compensation for GM tube is done. The Microcontroller contains calibration data that converts the respective counts in terms of mR/hr or µSv/hr. There is preset Alarm radiation threshold in the system, and if the incident radiation crosses this limit the Logic relay is activated for safety interlocking as well as the Alarm LED starts to blink and Alarm buzzer starts to sound. The entire data can be seen on Instrument local display that consists of a very high contrast OLED display screen as seen in Figure 7. Further plan is to develop 4-20mA current loop module for the instrument which is very useful for gathering instrument parameter value to a centralized PLC based system with Analog Input modules which would help to gather all the Plant Radiation data on to a single system and display on SCADA. Further development may also include RS-485 based serial communication module that is essential for Industrial digital serial communication.

The present status of the development can be seen as the Printed circuit board development in Figure 5.

The board assembly has been done as shown in Figure 6. Many iterations in design has been done to make HVDC power supply efficient for very high dose rate, proper component placement modifications has been done in order to reduce interference noise of DC to DC boost module.

Use of OLED display in place LCD display has been done in order to provide very high contrast display for easy readability from all angles and at a given minimum distance. (Figure 7).

The Calibration graph has been plotted between CPS and Dose rate is found to be almost linear for a range of 0-100mR/hr. (Figure 8).

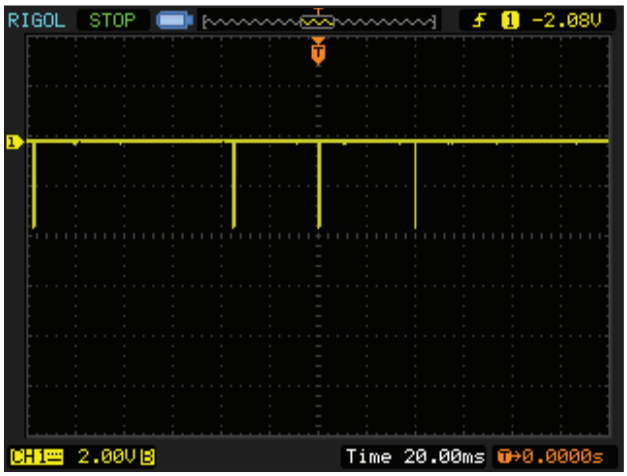


Fig. 3.The oscilloscope readout of GM tube pulses

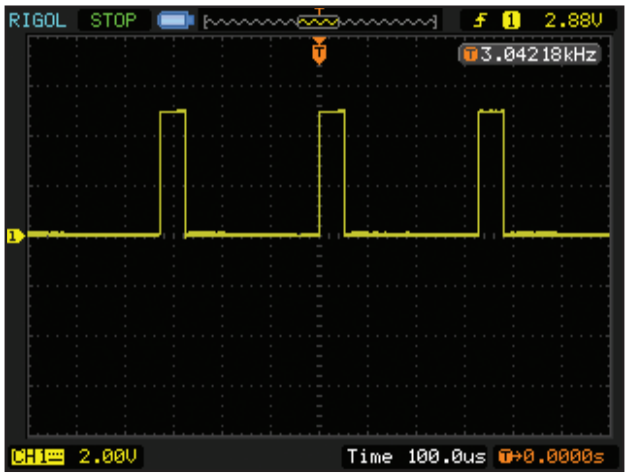


Fig. 4. The output of Signal shaper

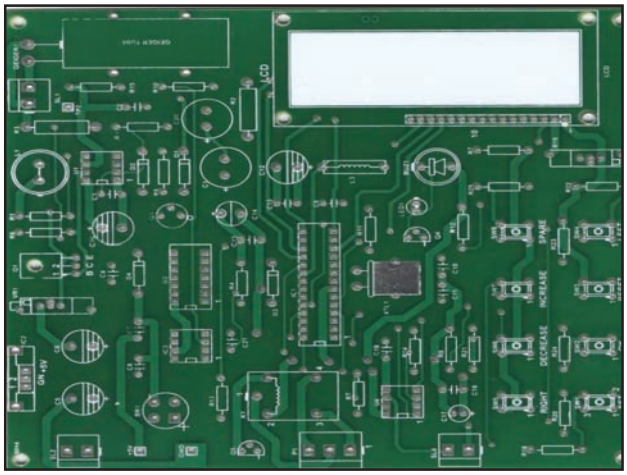


Fig. 5. Prototype Printed circuit board

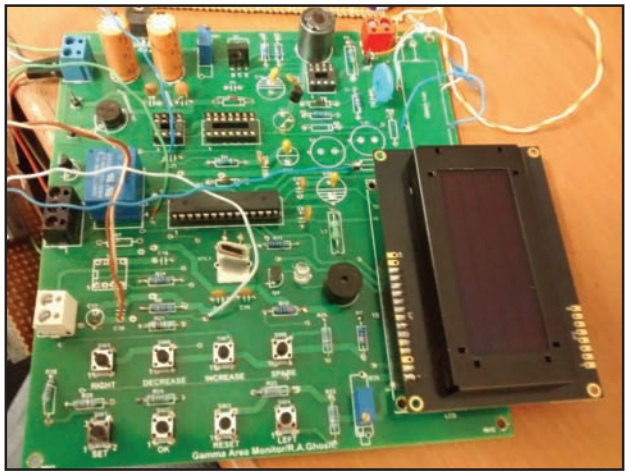


Fig. 6. Prototype assembled circuit board

Fig. 7. Instrument readout screen

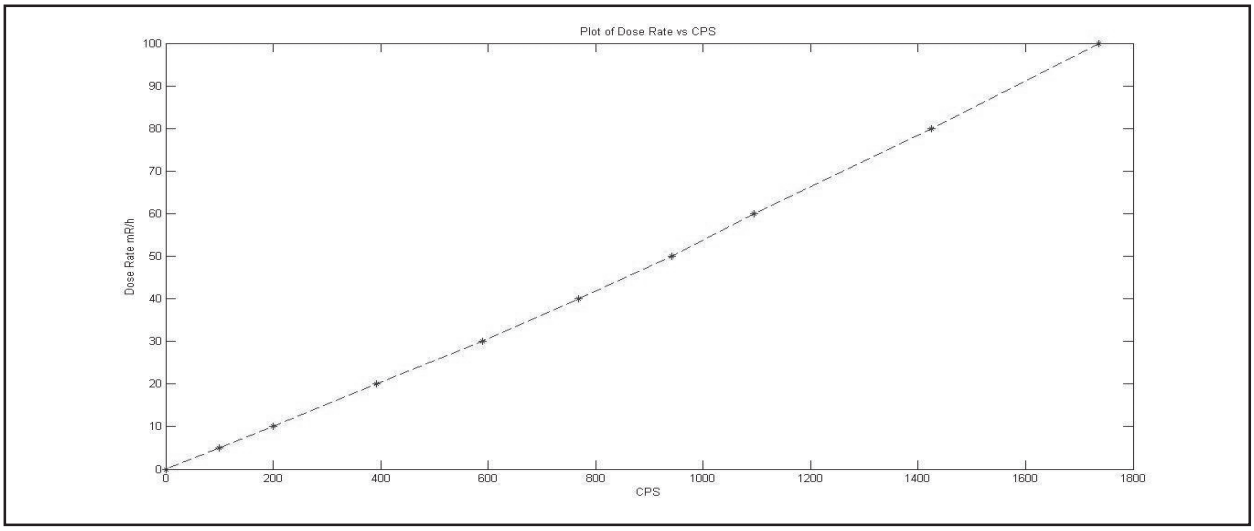


Fig. 8. The plot of Dose rate vs CPS (Calibration performed in BRIT Calibration lab)

The Calibration was done for a range of 0mR/hr to 100mR/hr and after that instrument prototype was found to be accurate within 10% of Actual reading which is acceptable.

Additional features include:

Push button based Alarm Threshold radiation limit set in mR/hr.

RS-485 Device address setting via push button.

Relay logic and LED/Buzzer based Alarm system found to be working successfully.

It can be seen that our first prototype has been successful and is providing basic functionality of an Area Gamma Monitor for Radiation safety.

Further Development work is in progress.

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

(i) Elimination of fungal contamination from Indian laddu by exploring radiation preservation technology

Indian traditional food product - laddus such as *besan* and *boondi* laddus being of the origin of cereal base products are often amenable to fungal contamination. A number of fungal problems have been reported in laddus which are commonly distributed as *prasad* in various temples as well as prepared by commercial manufacturers of the laddus. Vacuum packaging of ladddus has emerged as solution to this issue by which shelf life of laddus can be extended. However, vacuum sealing is not a microbicidal process and hence the microbes that are already present in the food product may survive and spoil the food. Therefore, along with vacuum packaging another method that has a microbicidal action needs to be discovered.

A survey of microbiological quality of besan and boondi laddu from localities in Navi Mumbai and Kalyan region showed microbial contamination as high as 3.5×10^3CFU/gm of total aerobic plate count and 5.7×10^2 CFU/gm of total yeast and mold count(with exception of 1 sample where count obtained was 1.9×10^3 CFU/gm). No coliform count was detected in any of the samples under studies of the survey. Few fungal species were isolated from the laddu samples and studied for radiation sensitivity

in terms of their D10 values (radiation dose required for 90% killing). The observed D10 value of the fungal isolates was found to be in the range of 0.33 to 0.70 kGy. Considering the high sensitivity of fungus to radiation and observed contamination level of about 10^2 CFU/gm in the laddu, a mixed population of isolated fungal spores more than 10^3 CFU/10gm was inoculated in one of the laddu samples such as besan laddu. The laddus were then exposed to the radiation doses of 1kGy and 3kGy. The irradiated laddu when analyzed showed a significant reduction in fungal count at 3kGy of radiation dose. Also ~1Log reduction in fungal count was observed at 1kGy of radiation dose. The sensory evaluation of the laddu irradiated to radiation dose of 1, 1.5, 2 and 3 kGy was carried out by 8-14 panel members. No significant changes in sensory attributes were observed in laddu irradiated to radiation dose of 1kGy. However a drastic change in flavor and taste was observed in the laddu irradiated to radiation dose of 3kGy. The overall acceptability of the laddu was found to be 7.6, 6.9, 6.4, and 6.5 for the laddu irradiated to the radiation dose of 1, 1.5, 2 and 3 kGy respectively on 9 point hedonic scale, showing good acceptability at radiation dose of 1kGy.

Thus the study concludes that although radiation dose of 3kGy helps in elimination of fungal contamination in laddus, a drastic change in sensory attributes of the product was observed. The radiation doses needs to be restricted to the dose of 1kGy where good acceptability of the product was observed, however there is no significant reduction in fungal contamination. Thus other alternative techniques such as vacuum packaging in combination with low doses of radiation may be helpful in elimination of fungal contamination in laddus.

(ii) Hygenization of green chutney by exploring radiation preservation technology

Green chutneys is commonly served with chat items and snacks in India. However a survey on microbiological quality of green chutney from different localities of Navi Mumbai & Kalyan region showed a heavy microbial contamination as high as 4.5×10^8 CFU/g of total aerobic plate count, 6.0×10^3 CFU/g of total yeast & mold count and 3.5×10^4 CFU/g of total coliform count. Pathogenic organisms such as salmonella spp. and staphylococcus spp. were also detected in some of the green chutney samples. Raw ingredients used in the preparation of green chutney was also evaluated for microbial quality to find out the sources of contamination, a high microbial counts were observed as high as 9.3×10^6 CFU/g of total aerobic plate count, 3.8×10^4 CFU/g of total yeast & mold count and 2.9×10^5 CFU/g of total coli form count in the raw ingredients. To reduce such high level of microbial contamination the raw ingredients such as mint leaves, green chilli, coriander leaves, turmeric powder & garlic were exposed to gamma radiation to the radiation doses of 1, 3 & 5 kGy in gamma chamber 4000 at BRIT, Vashi, Navi Mumbai. The green chutney was prepared using these irradiated ingredients. Boiled & cooled water was used in the preparations to avoid contamination from water. The green chutney thus prepared when evaluated for microbiological quality a significant reduction in the microbial count to the level of $10^2 – 10^3$ CFU/g at 3 & 5 kGy of radiation doses was observed. The shelf life studies of the chutney at room temperature were carried out. It was observed that there was no significant increase in the microbial count in the chutney prepared form irradiated ingredients to the radiation dose of 3 & 5 kGy even after 7-8 days of storage at room temperature. Also no pathogenic organisms such as salmonella & staphylococcus spp. was detected in any of the green chutney prepared from irradiated ingredients. However the chutney prepared from unirradiated ingredients showed a significant increase in the count exceeding 10^7 CFU/g of total aerobic plate count with presence of pathogenic organisms such as salmonella & staphylococcus spp. after 3 days of storage at room temperature. The sensory evaluation of the chutney prepared from irradiated raw ingredients with radiation dose of 3 & 5 kGy was carried out by 7-8 panel members and the overall acceptability of the product was found to be 7.3 & 8.4 for 3 & 5 kGy radiation doses on 9 point hedonic scale. Thus the studies concludes that radiation dose of 3-5 kGy is sufficient for hygenization of green chutney which may also help to enhance its shelf life.

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

(a) Regular production and supply of lyophilized kit for the preparation of Tc-Macro Aggregated Albumin (MAA) for lung perfusion imaging

Lung perfusion imaging study is an important investigation in various pulmonary diseases. Human Serum Albumin (HSA) macroaggregated particles are especially useful in biomedical applications because of their advantage of being metabolized easily and being non-antigenic to humans.Tc-99m- labeled Human Serum Albumin Macro Aggregates (MAA) have been used extensively as routine diagnostic nuclear medical imaging procedures for diagnosis of lung perfusion. Presently ^{99m}Tc-MAA is being imported and used in India. The need to have an indigenous kit for technetium labeled radiopharmaceuticals for lung imaging was expressed by physicians for a long time and hence Radiopharmaceuticals Programme, Board of Radiation and Isotope Technology (BRIT) has undertaken this work on preparation and analysis of kit for ^{99m}Tc –MAA.. Six consecutive batches of freeze dried kits were prepared and evaluated at RPhP, BRIT. The performance of all the six consecutive batches showed satisfactory results.

Kit for the preparation of ^{99m}Tc-MAA (Code-TCK-56) is being approved by Radiopharmaceutical committee (RPC), BRIT in the month of December 2016. Regular supply started from January 2017, till date around 120 vials are supplied to different nuclear medicine centers all over India.

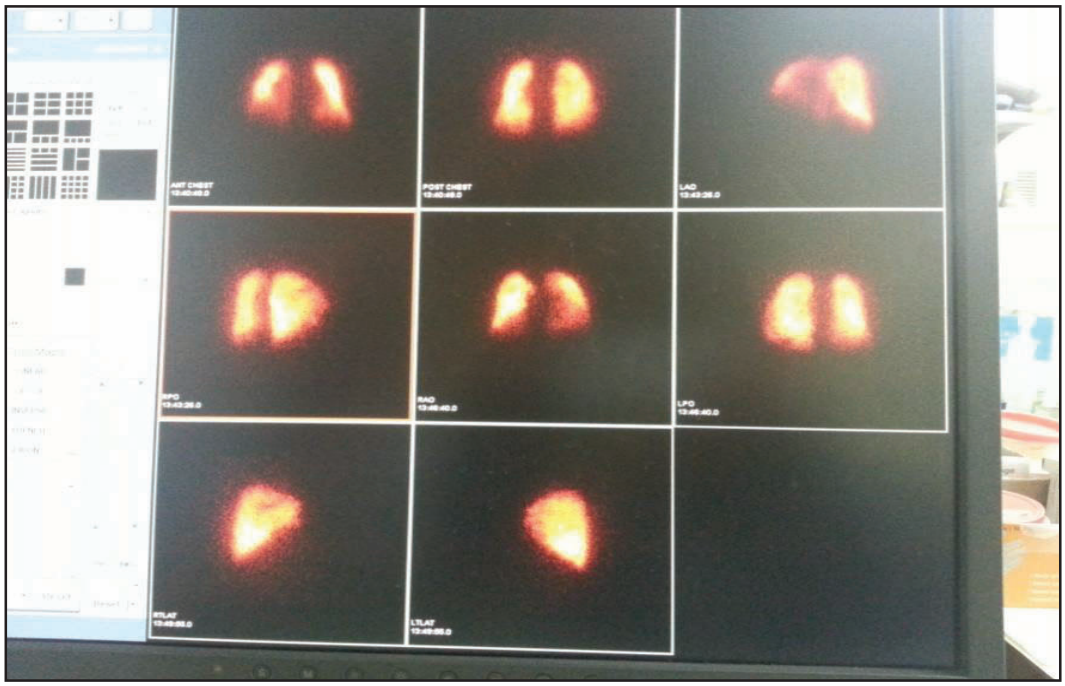


Fig. Lung Image using ^{99m}Tc – Macroaggregated albumin (MAA)

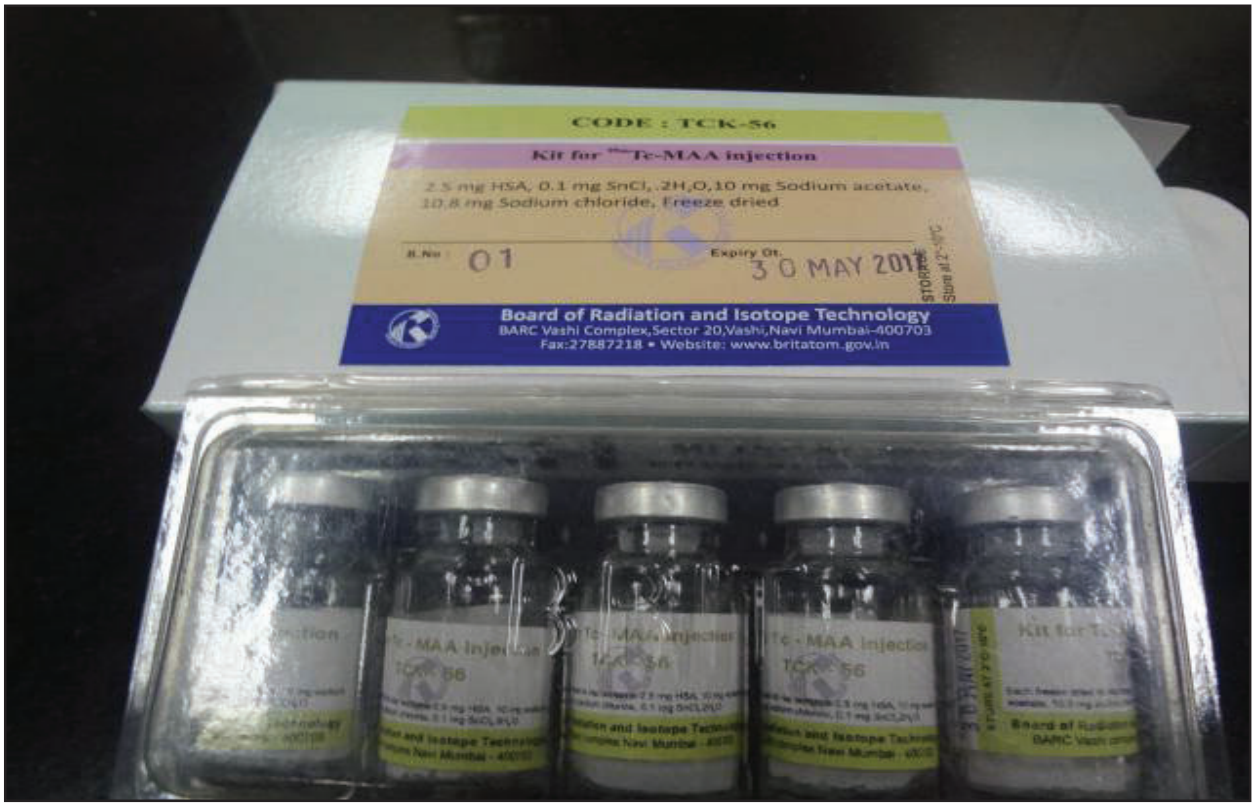


Fig:TCK Cold Kit for labelling with Tc-99m (TCK-56) being supplied from BRIT

(b) Extension of shelf life of cold kits for the preparation of ^{99m}Tc radiopharmaceuticals

Cold kits constitute important inactive ingredients in lyophilized powder form required for the preparation of ^{99m}Tc radiopharmaceuticals at the hospital end. These inactive chemicals are present in millimolar concentrations and their integrity over time determines the shelf-life of the cold kit. Most of the BRIT kits launched early presented reduced shelf-life. Hence, with an aim to extend the shelf life, studies were undertaken to evaluate the performance of the kits for the preparation of ^{99m}Tc-Sulphur colloid, for liver imaging, ^{99m}Tc-DTPA, ^{99m}Tc-GHA for renal studies and the kit for the preparation of ^{99m}Tc-Mebrofenin for hepatobiliary imaging.

100 vials each from six consecutive batches were used for these studies. Physicochemical tests for respective kit formulations were studied every 15 days/ one month for the kits after the current expiry date of 100 days and six months (whichever applicable) upto a period of 6 months upto 13 months and 25 months respectively. Bio-distribution studies were done at 6, 13 and 25 months respectively after production.

The results showed that all the aforementioned kits comply with the specification for the kit as per RPC monograph/Indian Pharmacopeia-2014 and approval for extension of the shelf-life from six months to a year for ^{99m}Tc-Sulphur colloid, 1 year for ^{99m}Tc- Mebrofenin and 2 years for^{99m}Tc-DTPA, ^{99m}Tc-GHA was granted by Radiopharmaceutical Committee.

(c) ^{177}Lu-DOTA-TATE development for Neuroendocrine tumor therapy

^{177}Lu labeled DOTA-TATE is a therapeutic radiopharmaceutical that is in evaluation worldwide for the treatment of Neuroendocorine tumors. Currently this product is manufactured in house at the hospital end and used clinically. The aim of the present work was to indigenously prepare a ready to use formulation and supply to different Nuclear Medicine centres. In this respect, different batches of

^{177}Lu-DOTA-TATE were synthesized to optimize the reaction conditions and determine its shelf-life for routine product supply. The labeling reaction of DOTA-TATE with ^{177}Lu was optimized with different ligand/metal ratios (0.75-3), purification using sep-pak (C18 columns) and stability of the product at different radioactive concentrations (15-30 mCi/mL) containing different concentrations of radioprotectant (gentisic acid/ ascorbic acid) under different storage conditions. Hence, the optimized protocol involved heating the ^{177}Lu radiochemical (1 eq) with DOTA-TATE (2-3 eq) (dissolved in solution containing sodium acetate -13.2 mg/mL and gentisic acid- 10 mg/mL) for 45 min under boiling water conditions. Thereafter the reaction mixture was allowed to cool and loaded on sep-Pak cartridge with pure product being eluted in ethanol (1 mL). The purified product was then diluted with gentisic acid solution (10 mg/mL)/ ammonium acetate (0.2 M) to bring the final radioactive concentration of the product to 20 mCi/mL. The purified product was stable for a period of 1 week at -70°C as characterized by HPLC. All the parameters have been standardized and six batches of product have been prepared and tested in NET patients at RMC which showed expected distribution in suffering patients. A proposal for its approval for regular production and supply has been put in RPC and is awaiting clearance.

(d) New approach for preparing ^{99m}Tc analogue of ^{131}I-mIBG

In continuation with our previous aim of preparing a ^{99m}Tc analogue of ^{131}I-mIBG, a new ^{99m}Tc synthetic strategy was attempted with the aim to achieve superior target specificity than the previously evaluated ^{99m}Tc analogue (^{99m}Tc-4+1 approach). The new synthetic scheme involved preparing ^{131}I-mIBG analogue via $^{99m}Tc(CO)_3$ approach. The rationale for selecting this core was its size which will contribute little to the overall molecular mass of the final labeled complex. Hence, the work involved synthesis of suitable precursor, radiolabeling via $^{99m}Tc(CO)_3$ core and bio-evaluation in SK-N-SH neuroblastoma cells. The synthesis work involved introducing an iminodiacetate tridentate chelate to xylylenediamine in a three step synthetic procedure. Briefly, xylylenediamine was treated with N,N'-di-Boc-S-methyl isothiourea in THF to convert the single amine group to guanidine moiety. This was then treated with *t*-butyl bromoacetate in presence of triethylamine in DMF under refluxing condition overnight to obtain the di-substituted guanidine intermediate which was treated with TFA to yield the final product *N*-(3-(guanidinomethyl)benzyl)iminodiacetic acid. The latter compound was then radiolabeled with freshly prepared $[^{99m}Tc(CO)_3]^+$ synthon (synthesized from carbonyl kit) under boiling water condition to yield the desired negatively charged complex. The formation of the final complex was confirmed through radio-HPLC. The complex was found to be hydrophilic and serum stable. The biological efficacy of the synthesized complex in SK-N-SH neuroblastoma cell line revealed reduced uptake in the cells in comparison to nca-^{125}I-mIBG and uptake was found to be completely non-specific as desmethylimipramine, which is a known inhibitor of uptake-1 pathway, could not completely inhibit the tracer uptake. Hence, the present ^{99m}Tc design revealed sub-optimal behaviour for neuroendocrine tumor imaging.

(e) Development of *in-vitro* tests for evaluation of ^{99m}Tc-ECD biological behavior *in- vivo*

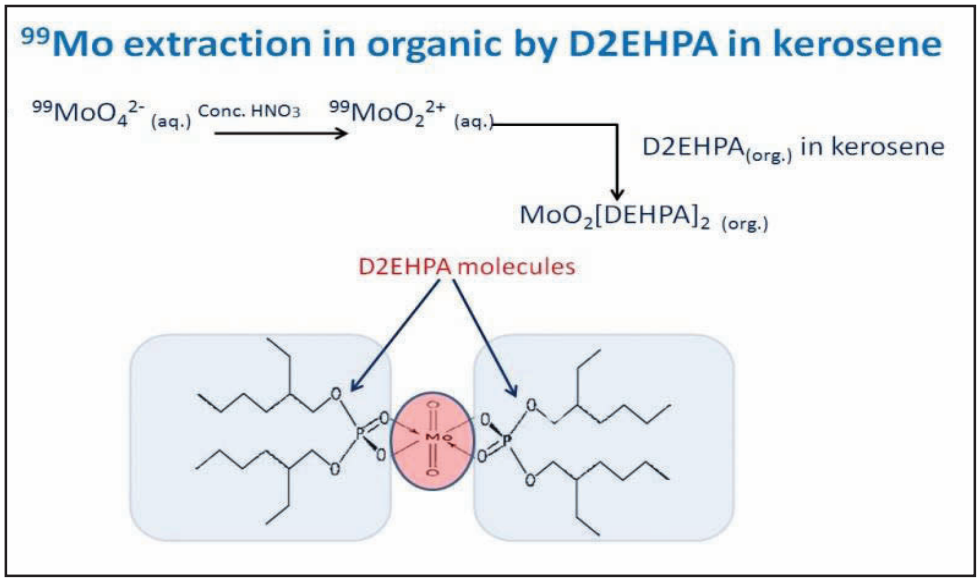
ECD kit is a regular product of BRIT which is labelled with ^{99m}Tc to produce ^{99m}Tc-ECD, a diester complex, used for brain perfusion imaging. Currently there are no biological quality control tests to evaluate the *in-vivo* performance of kit. This is because this complex undergoes enzymatic hydrolysis only inside the brain of primates and gets trapped providing useful clinical information. Non-primates do not show any such biological behaviour as esterase enzyme is lacking in their brain. Thus, the aim of the present work was to develop an in vitro method which could substitute the primate testing, as the latter species are not available for biological evaluation of radiopharmaceuticals. In this respect, an *in vitro* enzymatic reaction method was developed, which involved incubating the ^{99m}Tc-ECD complex with pig liver esterase enzyme at 37β^0C and monitoring the reaction progress. Different concentrations of the enzyme

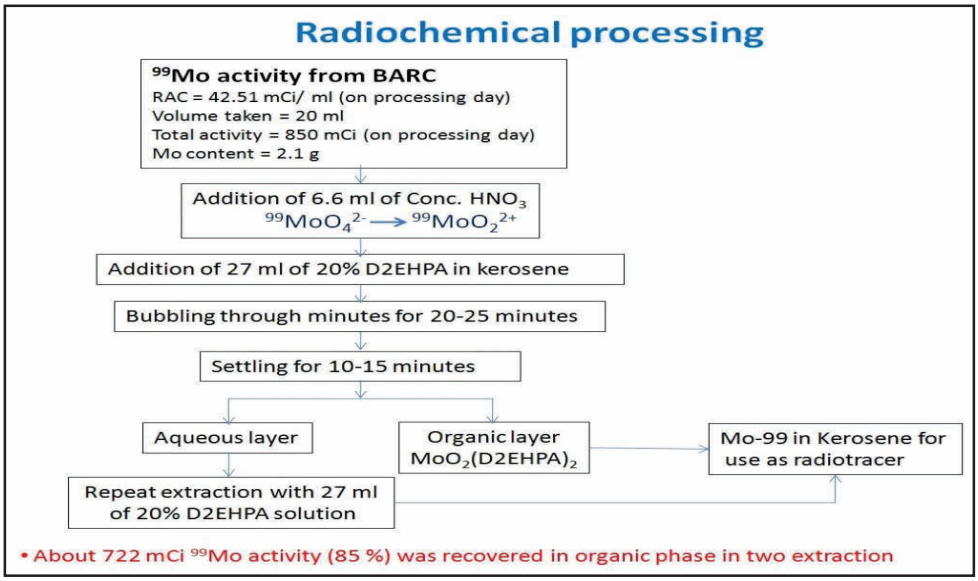
were added to the ^{99m}Tc-ECD complex and incubated for different time periods and the hydrolysis pattern was studied. The kinetics of the reaction was studied using radio-HPLC. HPLC characterization confirmed mono-ester hydrolysis where an additional peak was observed exactly midway between the peaks of ^{99m}Tc-diester and ^{99m}Tc-diacid complexes. Another observation found was that simultaneous diester hydrolysis kinetics was poor as increased concentrations of enzyme incubated even for 1 day could not produce ^{99m}Tc-diacid product in appreciable yield. The latter information is observed to be true with the clinical behaviour of ^{99m}Tc-ECD complex *in-vivo* where it is known that mono-ester of the complex is formed in the brain too. This particular in vitro method developed shows promising results and will now be used for evaluation of different batches of ECD kit production and a RPC proposal for its inclusion in QC monograph will be put up soon.

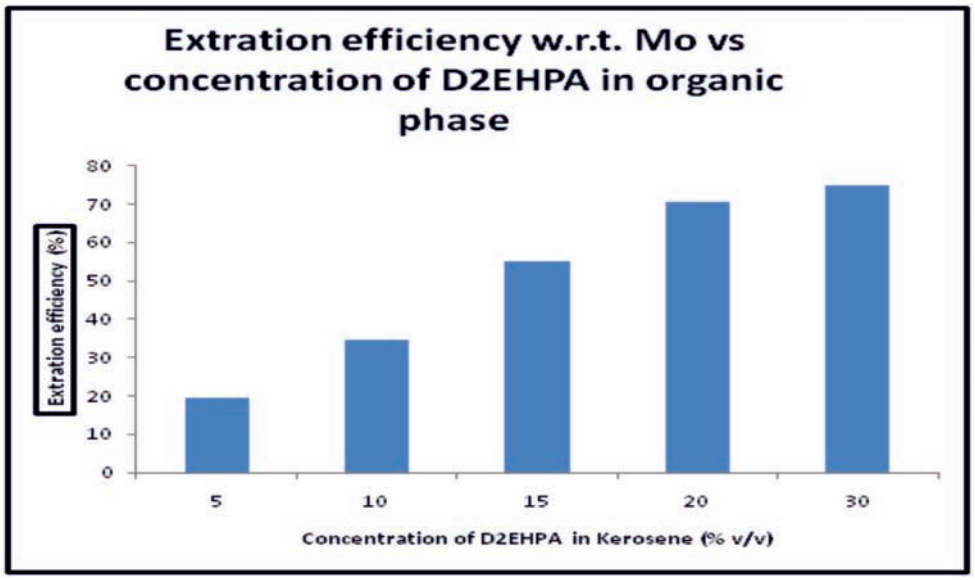
(f) New method for extraction of ^{99}Mo in kerosene for use as a radiotracer in Oil Refineries

Owing to stringent pollution control norms diesel produced in petroleum refineries should contain very minor quantity of sulphur. Therefore in petroleum refineries hydrotreating is carried out in order to remove the sulphur from diesel to make it to EURO-V specifications sulphur (<50ppm). Timely detection of any leak present in stream of the unit is required for good quality diesel product.

Usually, radiotracer used for leak detection in such case is Br-82 as dibromobiphenyl dissolved in diesel. In this present study a novel method has been developed for leak detection in diesel stream employing ^{99}Mo as tracer by converting them in required chemical form suitable for mixing with diesel. The (n,γ)^{99}Mo activity in aqueous from obtained from BARC/ RLG was preconditioned with HNO_3 to get the desired speciation of molybdenum (MoO_2^{2+}). After that, ^{99}Mo activity present in the aqueous phase was efficiently extracted to the kerosene organic phase containing **Bis (2-ethylhexyl) phosphoric acid** (D2EHPA) as extractant. Kerosene, containing (n,γ)^{99}Mo activity was then tested in diesel carrying stream of three oil refineries for leak detection studies and yielded in successful leak detection.







Sr. No.	^{99}Mo Activity (in kerosene) suplied	Volume of ^{99}Mo activity supplied (ml)	Remark
1	500 mCi	50	Bongegaon Refinery
2	100 & 200 mCi	50	Haldia Refinery
3	2X250 mCi	50	Bhatinda refinery

Table-1: Different refineries where (n,γ)^{99}Mo in kerosene was utilized for leak detection

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

(a) Freeze Dried formulation (TCK-57) for the Preparation of ^{99m}Tc-Ubiquicidine (^{99m}Tc-UBI) for Infection Imaging)

Ubiquicidine (UBI) is an antimicrobial peptide. The freeze dried kit formulation of UBI fragment (29-41) suitable for the preparation of ^{99m}Tc labelled UBI (29-41) injection was developed by QCP, BRIT, in

collaboration with RPhD, BARC. The methods were standardized for radiochemical testing and biological evaluation studies were carried out in infection induced animals. After obtaining approval from — (Radiopharmaceutical Committee) (RPC), clinical evaluation was carried out in collaboration with clinicians at Kovai Medical Centre and Hospital Limited (KMCH), Coimbatore, where it was proved about the efficacy of this kit in assessing musculo-skeletal infections with a specific emphasis on prosthesis evaluation. UBI (29-41) kits (Code: TCK-57) was launched in January 2017. To date, BRIT has commercially supplied ~30 kits to the users all over the country. This is the first kit which is indegenously available in India for the application in Infection Imaging.

b) Development of high-performance liquid chromatography method for quality Control analysis of ^{131}I-sodium iodide solution using cationic modification of C-18 reverse phase column

Radioiodines ($^{131}I^-$, $^{124}I^-$, and $^{125}I^-$) are integral part of radiopharmaceuticals. Iodate ($IO_3^{"}$) is a radiochemical impurity which can be present in radioactive sodium iodide (NaI) solution. Radiochemical purity (RCP) of ^{131}I NaI (specified limit>95%) is performed by paper chromatography using 70% Methanol as a mobile phase. Instrument-based methods such as high-performance liquid chromatography (HPLC) are preferred over conventional methods due to their resolution, reproducibility, and accuracy. HPLC method for analysis of ^{131}I-sodium iodide solution was hence standardized using cationic modification of C-18 reverse phase column to separate I^- from $IO_3^{"}$ for determination of RCP of ^{131}I NaI solution. Concentration of modifier and polarity of mobile phase were optimized. Cold standards were added to ^{131}I NaI solution as carriers. The results of RCP were compared with that obtained by standard method.

Substantial difference in retention time was observed with I^- at 12.19 (±0.19, n = 6) min. and $IO_3^{"}$ at 3.94 (±0.1, n = 6) min. This difference was favourably exploited for determination of RCP of $^{131}I^-$ sodium Iodide solution.RCP (98.71%) obtained with HPLC procedure was found to correlate with that obtained by standard method. The developed method can be applied for regular quality control analysis for determination of RCP of ^{131}I-NaI.

c) Radium chloride ($^{223}RaCl_2$) as a potential radiochemical for bone pain palliation

Radium chloride ($^{223}RaCl_2$) produced in Radiochemistry Division, BARC, was evaluated by way of bio-distribution studies as a potential therapeutic radiopharmaceutical for treating metastatic cancers in bone. The pharmacokinetic behaviour – specifically its uptake and retention in the bone, and clearance from non-target organs was studied in laboratory animals by bio-distribution studies carried out at different time points after intravenous injection of $^{223}RaCl_2$. The results obtained were encouraging and comparable to the previously reported results (United States Patent: Larsen et al, No. US 6,635,234 B1: Dated Oct 31, 2003.) Further work is planned for preparation and evaluation of patient dose.

(d) Development of Tumor specific radioligands

Urokinase Plasminogen Activator receptors (μPAR) are overexpressed in many tumor types. Peptide ligand specifically binding to μPAR with high affinity is identified. Suitable modification of peptide is carried out in order to facilitate radiolabelling with ^{99m}Tc. Radiolabelling and radiochemical evaluation methods were standardized. Studies are underway for biological evaluation of radiolabelled peptide.

(e) Bio-safety lab-II Facility development

A new facility was developed and a certificate from IBSC, BARC was also obtained for handling infectious organisms (up to Type 2) in animals to facilitate evaluation of infectious agents

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

(a) Production and radiochemical separation of a potential immuno-PET imaging agent ^{89}Zr from proton irradiated ^{nat}Y target

^{89}Zr is an interesting immuno-PET imaging agent due to its favorable physical characteristics of 78.4 h half-life and relatively low positron energy of 0.9 MeV. The production of ^{89}Zr from ^{nat}Y foil has been carried out with 12 Mev as well as 18 MeV proton beam from VEC cyclotron through ^{89}Y(p, n)^{89}Zr reaction. Radiochemical separation of ^{89}Zr from irradiated Y target matrix has been achieved by different separation methodologies like anion-exchange chromatography, cation-exchange chromatography and size exclusion chromatography (Sephadex G-25 resin). A novel and simple method based on size exclusion chromatography (Sephadex G-25) for radiochemical separation of ^{89}Zr with no harmful substances has been explored (Fig.1). The experimental yield of ^{89}Zr from natural yttrium target was found to be 27 MBq/ìAh using 12 MeV proton. The yttrium content in the separated ^{89}Zr has been monitored by ^{88}Y radioisotope. The radionuclidic purity of the separated ^{89}Zr in all separation methods is about 99.9% (n=5) as determined by HPGe spectroscopy. The advantage of using Sephadex G-25 resin is that ^{89}Zr is obtained in small volume of 0.1 M HCl with high radioactive concentration (RAC) and thus can be directly used for various labeling purposes. Moreover, the beauty of the Sephadex column separation is that a very small column (1ml bed volume) can selectively retain no-carrier added ^{89}Zr from the bulk Y-target and requires less separation time (20 minutes) in comparison to the time required (90 minute) for anion exchange resin column/2 M HCl separation. Finally, ^{89}Zr has been labeled with oxine to check the chemical as well as radiochemical purity of ^{89}Zr. It was found that the labeling yield of ^{89}Zr with oxine was 93 ± 5.4% (n=3).

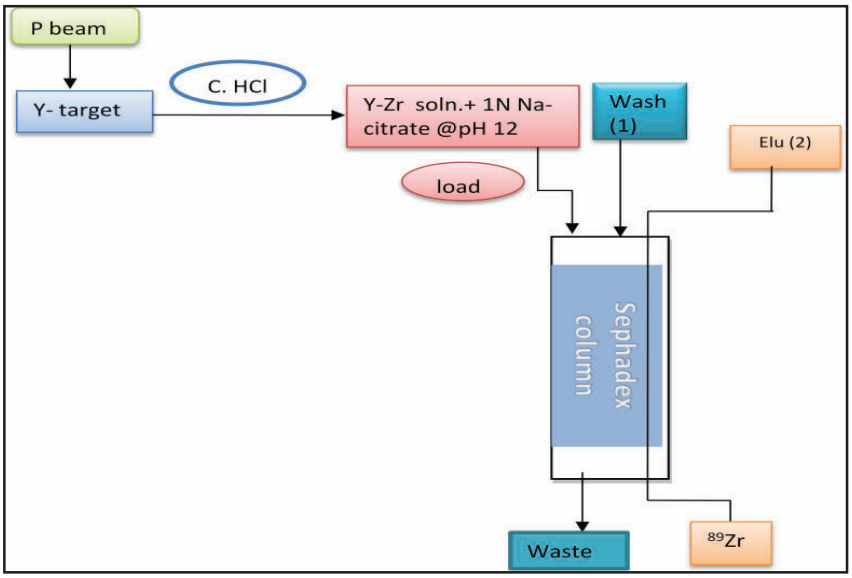


Fig.1. Radiochemical separation of ^{89}Zr from irradiated Y target using Sephadex G25 Column

It can be concluded the separation of ^{89}Zr from Y-target by sephadex methodology is the new, innovative method; most suitable for further direct radiolabelling.

(b) ^{68}Ge-^{68}Ga generator :

- **Targetry for production of ^{68}Ge for preparation of ^{68}Ge-^{68}Ga generator**

The ^{68}Ga radioisotope is an excellent source in clinical PET application due to its ease of availability from ^{68}Ge/ ^{68}Ga generator having a shelf life of 1 year. The parent radionuclide ^{68}Ge can be produced in a cyclotron through ^{69}Ga(p, 2n)^{68}Ge reaction. Since melting point of Ga metal is very low (m. pt. 29°C),

a special type of target holder has been designed and fabricated with the help of mechanical engineering department, VECC. A 25 ìm thick Nb cover foil has been used to secure the Ga target in the Nb metal groove of the target holder. In addition, in front of this target holder a 50ìm thick Havar-foil will be placed to seal the main vacuum of the cyclotron. Since liquid Ga reacts with Nb above 400^{0}C, the target has front side water cooling arrangement in addition to the back side water cooling. Considering 18 Mev beam enrgy and 10 µA beam current and around 1.5 cm^2 target area, front side water cooling of flow rate 6 LPM at 8 Kg/cm^2 pressure and back side cooling of flow rate 2 LPM at 3 Kg/cm^2 pressure the target assembly has been designed.

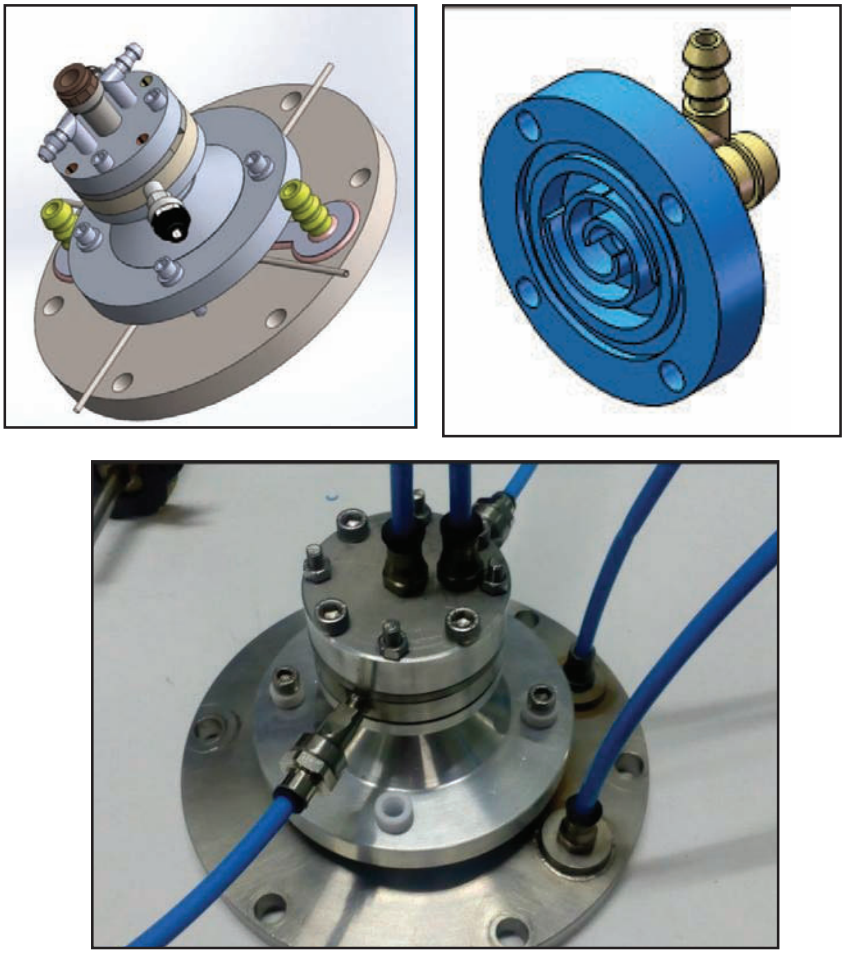


Fig. 2. Target assemblies for production of ^{68}Ge from ^{nat}Ga target

- **A new methodology for preparation of pure ^{68}Ga acetate precursor for formulation of radiopharmaceuticals**

The primary ^{68}Ga eluate was post purified by using a small cation exchange resin (Dowex-50) column chromatography. Gallium-68 retained on the cation exchange resin column was eluted with dilute sodium hydroxide solution. The final purified ^{68}Ga has been reconstituted in sodium acetate buffer for labeling of various compounds. In this paper, the results on the physicochemical studies of ^{68}Ga obtained after the purification have been reported. The breakthrough of ^{68}Ge before and after purification of ^{68}Ga eluate was 0.014% and 0.00027%, respectively. The average recovery yield of ^{68}Ga after purification was 84% ± 8.6% (SD, n = 335).

The results of physicochemical studies confirmed that the ^{68}Ga-acetate obtained is suitable for labelling of radiopharmaceuticals.

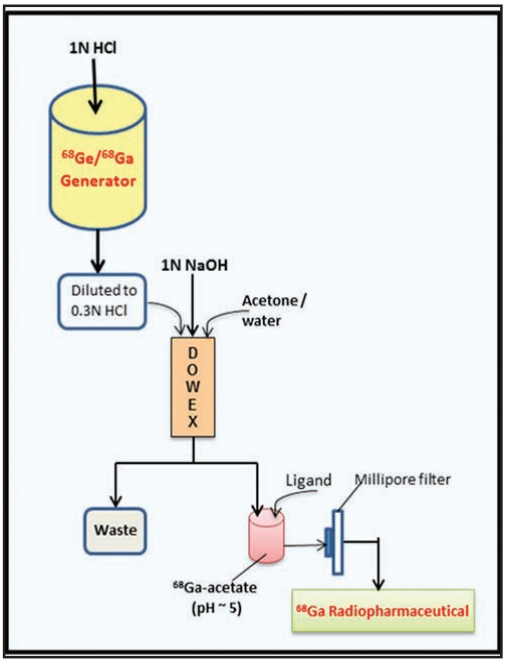


Fig.3. Flow diagram for formulation of ^{68}Ga-Radiopharmaceuticals from ^{68}Ga-acetate

- **Automated Module For ^{68}Ga Purification & Radiolabelling:**

The above mentioned process has been automated with the help of solenoid valves, pump and temperature controlled heater. A 16-bit microcontroller based embedded system has been designed to automate the entire process.

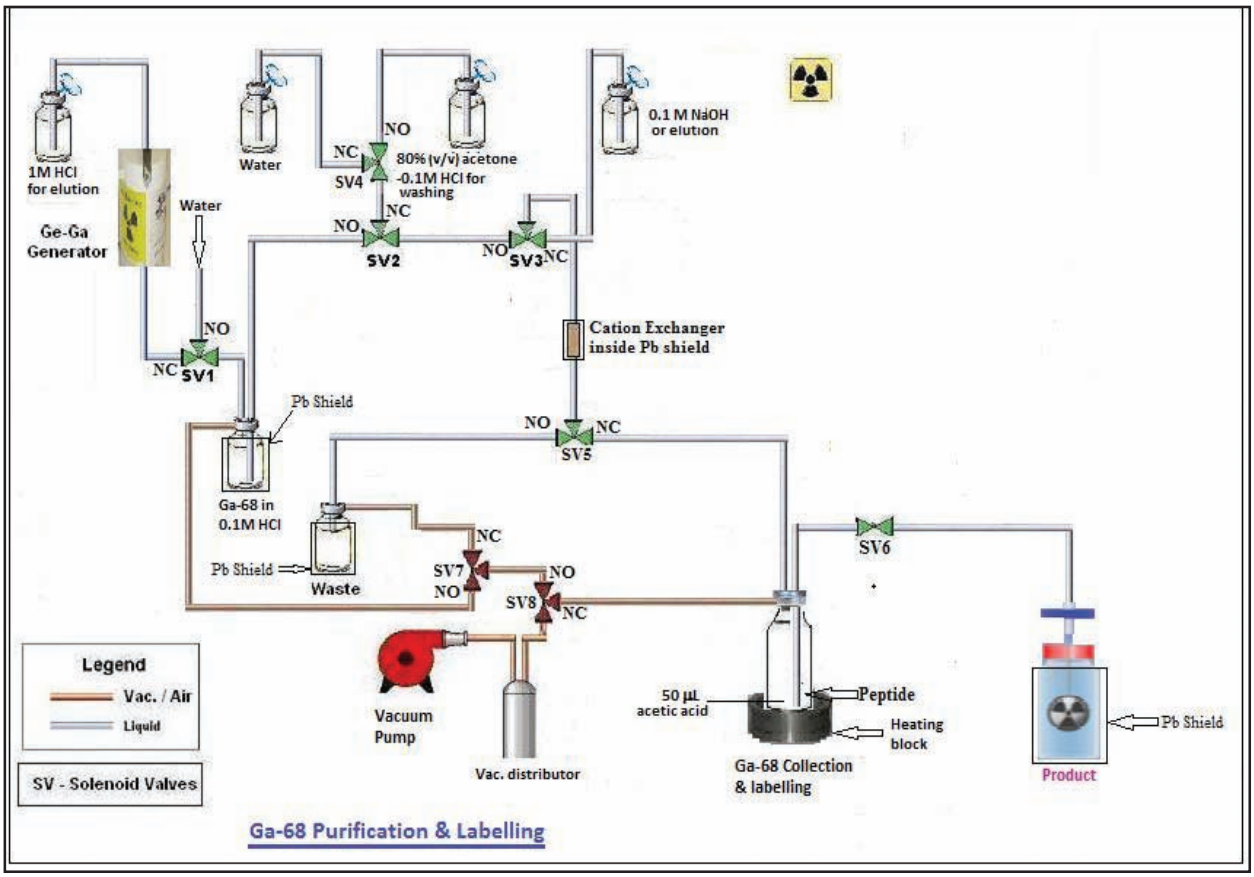


Fig. 4. Flow diagram of automated module for ^{68}Ga purification & radiolabelling

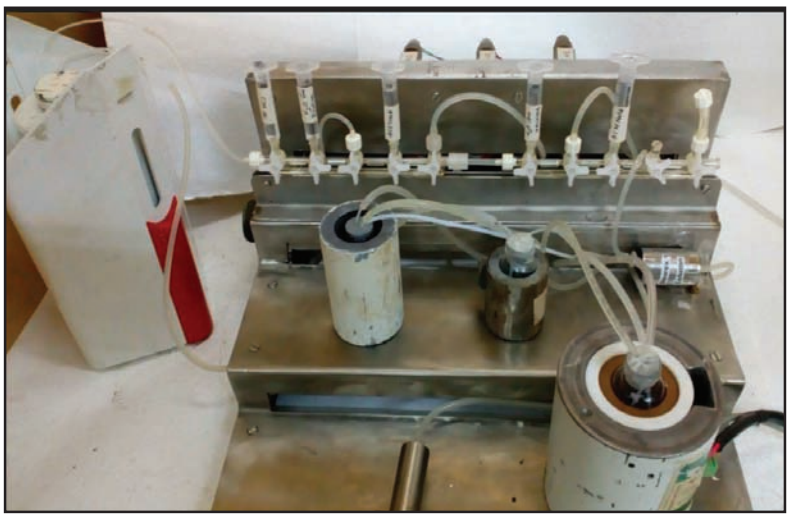


Fig. 5. Automated module for ^{68}Ga purification & radiolabelling

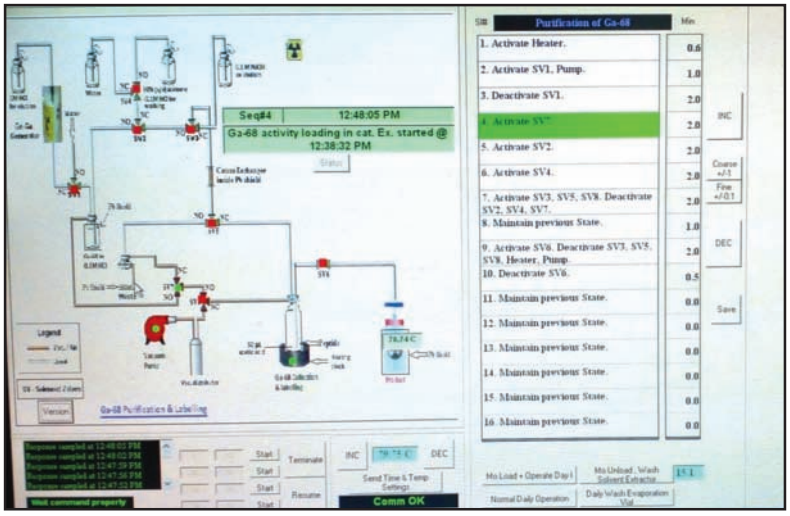


Fig.6. GUI for Automated ^{68}Ga Purification & Labelling

(c) Preparation of ^{99}Mo/^{99m}Tc generator based on cross-linked chitosan polymer using low-specific activity (n,ã)^{99}Mo

The cross-linked chitosan polymer (CCM) is an emerging non-toxic, highly radiation stable, bio-degradable adsorbent matrix. The CCM matrix has very high adsorption for Mo and thus can be utilized to prepare ^{99}Mo/^{99m}Tc generator using low-specific activity (n, ã) ^{99}Mo in sodium molybdate form. The precursors for this CCM synthesis are Chitosan and glutaraldehyde and characterization of CCM has been carried out with X-ray diffraction method, scanning electron microscopy, FT-IR spectroscopy.. Adsorption of ^{99}Mo using low specific activity $Na_2[^{99}Mo]MoO_4$ (upto 250mCi) on CCM (both oxidized and non-oxidized) has been studied. The schematic diagram of the ^{99}Mo/^{99m}Tc generator preparation based on CCM polymer is shown in Fig. The column was evaluated with respect to the elution efficiency of ^{99m}Tc with saline, ^{99}Mo breakthrough from the generator with and without using alumina guard column. It has been found that the adsorption efficiency on oxidized and non-oxidized CCM polymer was almost same, around 50 – 60 % of the loaded activity (~500-600 mg Mo/g CCM matrix). The elution efficiency of ^{99m}Tc from ^{99}Mo/^{99m}Tc generator based on the CCM polymer oxidized and non-oxidized form has been found more than 75% and about 40%, respectively. The ^{99}Mo breakthrough of the primary CCM column without alumina guard column was found to be little above the ^{99}Mo

breakthrough limit (< 0.1% of ^{99}Mo in ^{99m}Tc activity) having an average value of 0.09 ±0.7 (n=6), however, ^{99}Mo breakthrough in the ^{99m}Tc fraction with alumina guard column (0.5g) was found to be 0.002 ± 0.003 (n=9) much lower than Mo breakthrough limit. The Al and Mo content in the eluted ^{99m}Tc was found to be less than standard value (10µg/ml). The R C Purity of the different labeled compounds prepared from in-house kits was found to be >95%.

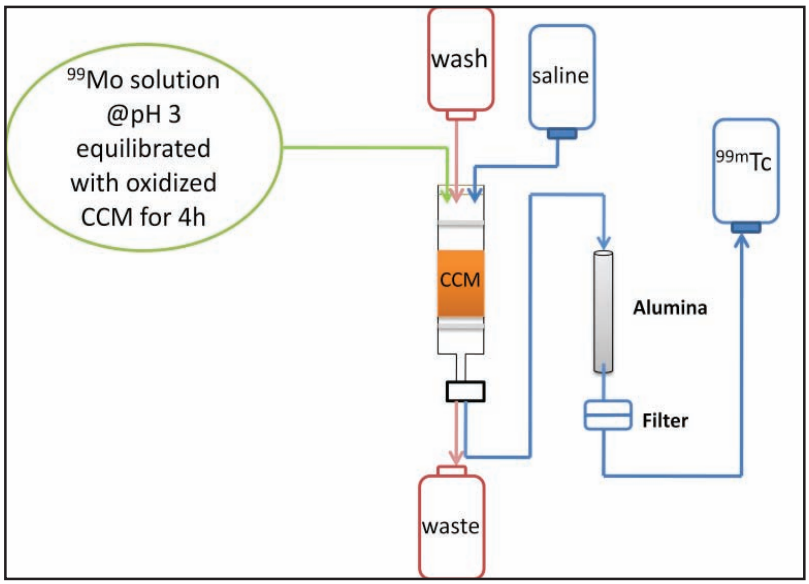


Fig.7. Schemetic diagram for the preparation of ^{99}Mo-^{99m}Tc generator based on CCM

The quality of pertechnetate solution obtained from this generator system was found to meet all the requirements of ^{99m}Tc pertechnetate injection as specified in various pharmacopeia.

The preparation of this CCM matrix is very simple. Preparation of ^{99}Mo/^{99m}Tc generator with oxidized CCM matrix is cost effective and time saving process. Thus, the CCM based ^{99}Mo/^{99m}Tc generator using low-specific activity (n, ã) ^{99}Mo as [^{99}Mo]Na_2MoO_4 may be prepared for clinical use.

(d) Production of ^{43}Sc, a promising PET imaging isotope from $^{nat}CaCO_3$

^{43}Sc (β^+ = 88.1%, $T_{½}$ = 3.9 h) shows suitable nuclear properties, such as a high positron branching ratio and suitable half-life, which are similar to those of other commonly used radionuclides including ^{68}Ga (β^+ 88.9%, $T_{1/2}$ = 68 min), ^{64}Cu (β^+ = 17.6%, $T_{1/2}$ =13 h), ^{89}Zr (β^+ 22.7%, $T_{1/2}$ = 3.3 d), or ^{124}I (β^+ 22.7%, $T_{1/2}$ = 4.2 d), and is, thus, useful for long-term PET imaging studies. ^{43}Sc has been produced in VEC cyclotron by alpha irradiation of a natural calcium target via ^{40}Ca(α,p) and ^{40}Ca(α,n) channels. The $^{nat}CaCO_3$ pellet target was placed in a aluminium target holder (Fig. 1) and a 100 µm Cu foil was placed in front of the target to degrade the beam energy from 40 MeV to 30.4 MeV. Thus, the $^{nat}CaCO_3$ target was irradiated externally with 30 MeV α- beam of about 0.8 µA current for 2.75 h. The irradiated target was dissolved in iron-free 1 M HCl. ^{43}Sc has been selectively separated from the bulk calcium target dissolved solution by co-precipitation with 50 µg Fe(III) at pH 9.0 using ammonium hydroxide solution. The final purification of ^{43}Sc from iron was carried out with anion exchanger Dowex-1× 8 (Fig. 2)and Fe content in the final ^{43}Sc solution was estimated by using di-pyridyl test. Finally, ^{43}Sc was labelled with DOTA (25 µg) using standard protocol to check the chemical purity of the separated ^{43}Sc. The experimental yield of ^{43}Sc was 70 MBq/iAh at end of bombardment (EOB). The final yield of ^{43}Sc after chemical separation was 80%. The radionuclidic purity of ^{43}Sc is 99.5% at the end of bombardment. The Fe content in the purified ^{43}Sc samples were less than 5 ppm. The radiochemical purity of ^{43}Sc-DOTA was 98% (n=3) confirmed by ITLC method.

Fig.8. Calcium carbonate target on Al target holder

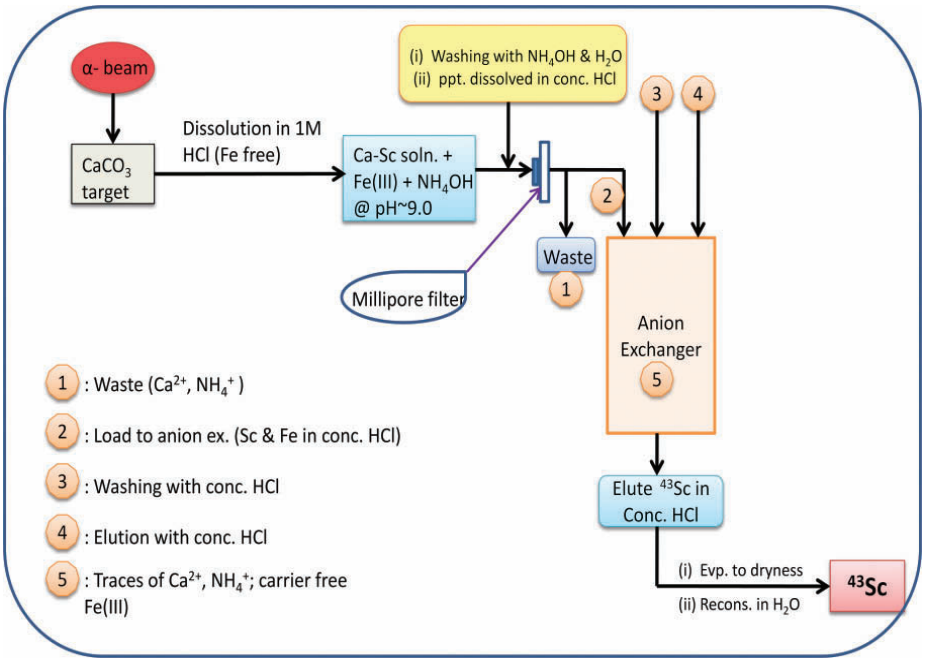


Fig.9. Schematic diagram of radiochemical separation of ^{43}Sc from proton irradiated $^{nat}CaCO_3$ target

The production of ^{43}Sc in (α,n) and (α,p) nuclear reactions on a natural $CaCO_3$ target was successfully performed, and extrapolation of the results obtained creates the opportunity to produce sufficient activity levels of ^{43}Sc for medical applications.

(e) Production of In-111 from ^{nat}Ag target through internal Irradiation in VEC Cyclotron for RIB

^{111}In has been produced in VEC cyclotron by internal irradiation of specially designed electroplated hemispherical silver target for Radioactive Ion Beam Group, VECC, with the aim to study the structural and electronic properties of TiO_2(110) single crystal after incorporation of metal impurity. ^{111}Cd atoms will be inserted in to a crystalline TiO_2 target by radioactive ^{111}In ions beam implantation. ^{111}In converted to ^{111}Cd after radioactive decay. The emitted two cascade gamma rays (171 keV and 245 keV) are used to study the change of Electric Field Gradient by Perturbed Angular Correlation (PAC) Spectroscopy. 5 keV, ^{111}In ion beams has been produced using a Electronic Cyclotron Resonance ion source attached to a low energy ion beam system at VECC RIB facilities. The silver target (~200 ìm thick) was irradiated with 32

MeV, 40 ìA alpha particle beam for 24 h. The radiochemical separation of ^{111}In from silver target was achieved by solvent extraction with di-isopropyl ether (DIPE) and the schematic diagram of the radiochemical separation of as shown in Fig.11. The thick target yield of ^{111}In was found to be about 7.0 MBq/ìAh at the end of bombardment (EOB). Radionuclidic purity of the final product obtained was > 99% at 48 h after EOB. The radiochemical purity was > 95% .

Fig.10. Handling of the irradiated target : Removal of Irradiated Ag target from Dee [A], Ag target after irradiation [B], Remote dismantling of the irradiated target [C]

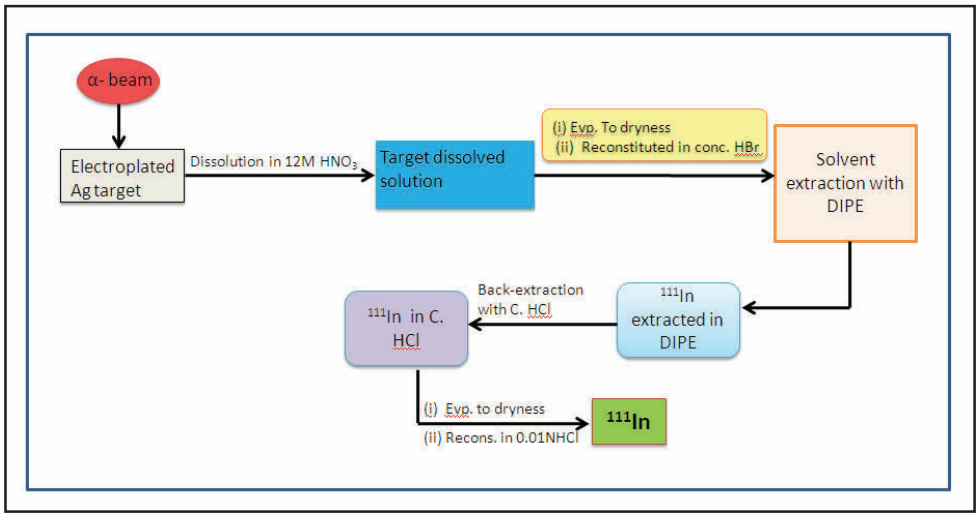


Fig.11. Schematic diagram of the separation of ^{111}In from alpha irradiated ^{nat}Ag target

F. Development work carried out at Labelled Compounds, BRIT, Vashi Complex

(a) Preparation and supply of carbon-14 Planchet Source

For the first time, Labelled Laboratory has prepared and supplied one carbon-14 planchet source to Radiological Physics & Advisory Division, BARC for use with the Automatic Air Activity Sampler (AAAS) device being developed by them. The device is meant for determination of mass concentration on the basis of beta attenuation of sampled aerosol load. The planchet source is prepared by uniformly mixing suitable carbon-14 labelled compound with epoxy-polymer ingredients and depositing on stainless steel planchet. Once the polymerization process is completed, a thin layer of the polymer having thickness less than 2 mm is formed on the inner surface of the planchet. The Thickness of the polymer material is maintained to the minimum possible level so that the self attenuation of the carbon-14 beta rays by the polymer is minimized.

G. Development work carried out at Medical Cyclotron Facility (MCF), BRIT,

(a) Development of a prototype automated module for synthesis of ^{177}Lu- DOTA Peptides

Development of a prototype automated module for synthesis of ^{177}Lu- DOTA Peptides using a Microcontroller and Human Machine Interface (HMI) Software was done during the reported time. The prototype automated system for the routine production of ^{177}Lu-DOTA Peptides is based on ATMega8-8 bit AVR Microcontroller with 8k Bytes In-System Programmable Flash Memory. The controller takes commands and provides feedback to the HMI software that communicates to the hardware controller board through the USB port. The control signal then drives the solid state relays (SSRs) that control the hardware (solenoid valves, heaters etc.) as per the time list created to carry out the steps required for the synthesis. The hardware is mounted on an aluminium frame with the reaction vial and reagent vials connected through various valves by suitable inert and radiation resistant tubing.

(b) Resolving false-positive bacterial endotoxin test results obtained with some radiopharmaceuticals and cold kits due to the presence of cations, colloidal particles or fatty acids

AIM: We have reported that certain ^{99m}Tc-radiopharmaceuticals (Tc-RPs) can give a false-negative BET due to the Ca^{++} in the lysate of the LAL reagent being trapped by the Tc-RPs (*JNMT,2014,42,278-282*). We now report instances where certain radiopharmaceuticals can give false-positive results due to the presence of cations, colloidal particles or fatty acids and how this effect can be overcome.

MATERIALS: (a) Reagents: 9.6mM Ca^{++} and Mg^{++} free pH 7.1 PBS, LAL reagents (Sensitivity: 0.03EU/ml) used for BET including LAL-reagent water (LRW), Control Standard Endotoxin, Portable BET Test System (PTS) cartridges (Sensitivity:5-0.05EU/ml).(b) Radiopharmaceuticals studied: ^{99m}Tc-TRODAT, ^{99m}Tc-GHA, ^{99m}Tc-HSA-nanocolloid, ^{99m}Tc-Sulfur-colloid and their cold kits. ^{99m}Tc-carbonyl-DTPA-Rituximab, ^{99m}Tc-carbonyl-DTPA-Bevacizumab, ^{177}Lu-DTPA-Nimotuzumab, ^{177}Lu-DOTA-Nimotuzumab and their bi-functional chelated monoclonal antibody (BFCMA) cold kits, and ^{131}I-Lipiodol.

METHODS: BET assays were performed for the RPs and cold kits using LRW or PBS as dilution agent by both gel-clot method (GCM) and kinetic chromogenic method (KCM) at various Maximum Valid Dilution (MVD) (400, 200,100 and 50) taking care of maximum injection volume and endotoxin limits (EL: 6 EU/ml- RPs, 1 EU/mg - BFCA-MoAb).

RESULTS: ^{99m}Tc-TRODAT, ^{99m}Tc-GHA and their cold kits, ^{177}Lu-BFCA-MoAb and its cold kit exhibited false-positive result (enhanced-BET) by GCM when using LRW as diluting agent, but this was resolved using PBS instead. Enhanced-BET in ^{99m}Tc-HSA-nanocolloid, ^{99m}Tc-Sulfur-colloid and their cold kits were resolved by filtering with 0.22µm PES membrane filter before testing. Enhanced-BET in ^{131}I-Lipidol, by GCM, was avoided by vigorous vortexing at 1:400 MVD in LRW. KCM did not exhibit any difference in BET values (Recovery Positive Product Control < 200%) on using either LRW or PBS. KCM could not be performed on colloid-RPs or their cold kits.

CONCLUSIONS: Radiolabeled compounds and cold kits with high cation concentration can cause unusual aggregation resulting in a pseudo-coagulation reaction due to disruption of ionic bonds between divalent cations and PO_4^- moiety of lipo-polysaccharide (LPS). Hence, PBS prevents this in GCM assay.

We were successful in overcoming the enhanced-BET seen in GCM-BET assays for the above mentioned radiopharmaceuticals and cold kits having interfering cationic salt concentrations, using PBS for dilution. Enhanced-BET observed with RPs having fatty acids and colloids was successfully taken care of after increasing the dilution and filtering the product respectively before the assay.

Enhanced-BET was not observed with KCM as the assay is based on absorbance of released chromophore. However, KCM is not recommended to replace GCM for pharmaceuticals (including RPs) where interference in the latter method is observed.

(c) Bacterial Endotoxin and Sterility Testing of Active Pharmacological Ingredients and Reagents used in the production of different Fluorine-18, Gallium-68 and Lutetium-177 labeled Radiopharmaceuticals

AIM: The aim of the present study was to validate biological quality control tests, viz., bacterial endotoxin test (BET) and sterility test of the active radiopharmaceutical ingredients (API) viz., precursors, reagents and solvents used in the radio-synthesis of different [F-18], [Ga-68] and [Lu-177] labeled radiopharmaceuticals. The validation is a requisite as per the CGRP guidelines.

MATERIALS: Acetonitrile, Acetone, DMSO, Ethanol, $TBAHCO_3$ (75mM), CH_3COONa (0.2M), CH_3COONH_4 (0.1M), NaCl (10%), NaH_2PO_4 (1M), HCl (1N/0.1N), NaOH (0.33N), Ethanolic-water (50-8%), HCl (0.02N)/acetone(98%), Mannose-triflate, ethylene-di-tosylate, L-Tyrosine, Ni(II)-FBPB-Tyrosine-OTs, 4-nitro-benzaldehyde, Anhydro-DMTr-Thymidine, Lysate(ë:0.125/0.03EU/ml), Tris-base/HCl (0.25/0.5/0.1N). Cultures of *s.aureus, p.aeruginosa, b.subtilis, c.albicans* were obtained from Microbiologics Inc, Minnesota, USA.

METHODS: The endotoxin limit (EL) for API's was fixed at 1EU/mg(precursor), 5EU/ml(reagents) and 2EU/ml(solvents) based on concentration, volume used and alteration limit. BET assays were performed by gel-clot method using two sensitivities of lysate. MVD was calculated considering the sensitivity of lysate, EL, concentration and volume of API's used for radiosynthesis. Sterility testing was validated by

direct inoculation(DI) method using FTM and SCD media. Positive controls for *s.aureus, p.aeruginosa, b.subtilis, c.albicans* were set up at bacterial concentration <100CFU (serial dilution- spread plate method) and corresponding negative controls were set up with and without APIs.

RESULTS: In BET, HCl, NaOH, CH_3COONa, CH_3COONH_4, HCl/acetone exhibited inhibition due to extreme pH. However, inhibition could be resolved by neutralizing with sterile and endotoxin negative (<0.25EU/ml) Tris-base/HCl at first dilution. BET assay of organic solvents did not demonstrate any inhibition, since the test volume is 1.0/1.5ml (typical volume used in radiosynthesis). However, with the increase in test volume of organic phase, MVD was decreased resulting in inhibition in the assay, which was reversed by short evaporation step at corresponding boiling point. NaCl, NaH_2PO_4, $TBAHCO_3$ and ethanolic-water (8 - 50%) did not show interferences.

In sterility testing, luxuriant growth was observed for positive control culture in the presence of 1ml of any of acetonitrile, acetone, ethanol or DMSO following incubation for 24 hour (*s.aureus, p.aeruginosa*) and 72 hours (*b.subtilis, c.albicans*). Growth of all these microorganisms were partially inhibited (<100 CFU) in HCl(1N) and $TBAHCO_3$(75mM). However, good growth were observed on neutralization with sterile and endotoxin negative Tris-buffer (0.5N) and addition of polysorbate-80(0.05%) respectively. Mannose-Triflate and other reagents exhibited no inhibition with all the above strains. No growth was seen in all APIs without the addition of above microorganisms (negative controls).

CONCLUSIONS: Standardizing of sterility and BET for various APIs used in radiopharmaceuticals' production was carried out using suitable methods that are validated.

(d) Automated Synthesis of Pharmaceutical Grade [^{18}F] FLT using 5'-O-(Benzoyl)-2,3'-anhydrothymidine Precursor

Automated production of pharmaceutical grade [^{18}F] FLT with solid phase extraction (SPE) purification using 5'-O-(Benzoyl)-2, 3'anhydrothymidine precursor (Benzoyl) poses a major challenge. The present study is focused on an automated one-pot, two-step radiochemical synthesis of pharmaceutical grade [^{18}F] FLT using Benzoyl. The optimization of SPE purification using a combination of SepPak® cartridges while maintaining radiochemical purity (RCP), chemical purity (CP) and residual solvent levels (RSL) within the specified limits has been the significant achievement. The current method yields clinical grade [^{18}F] FLT, suitable for inclusion as a generic drug product in Indian Pharmacopeia.

[^{18}F]$^-$ trapped on an anion exchanger, eluted with 75mM tetrabutyl ammonium bicarbonate. Benzoyl in DMSO was heated to 170°C for 15 min. After base hydrolysis (0.25N NaOH, 65°C, 15 min), reaction mixture passed through SepPak® cartridges (using neutral alumina oxide (Alox-N)'!cation exchanger'!anion exchanger'! Alox-N'!C18) followed by aqueous ethanol wash. Finally, [^{18}F] FLT eluted with 5% aqueous ethanol, while pH and isotonicity were maintained using NaCl and NaH_2PO_4. RCP and CP checked by HPLC using C18-RP column (300 mm L x 4 mm od, 5 µm). Flow rate maintained at 1mL/min in Water/Ethanol 93/7 at isocratic mode. Silica-gel TLC performed using Acetonitrile/Water 95/5 and Ethylacetate/Heptane 2/1. RSL detected by gas chromatography.

Using $FX_{F\text{-}N}$ module, a fully automated synthesis of [^{18}F]FLT with only SepPak® purification using Benzoyl precursor with total synthesis time of 55±5 min is achieved. RCP and CP of the [^{18}F]FLT were >98% and >97% (<1.2µg/ml in terms of concentration) respectively, as evaluated by HPLC and TLC. The amount of acetone, acetonitrile and DMSO were <100ppm, whereas ethanol levels in the final product were 3900ppm. Retention time of [^{18}F] FLT is 10.5 minutes, confirmed with reference standard [^{19}F] FLT. [^{18}F] FLT obtained as a clear and colorless product having pH~6.5 with R_f 0.85 and 0.20 in two different mobile phases. Decay un-corrected radiochemical yield was 3% (n=14).

The synthesis of pharmaceutical grade [^{18}F]FLT by nucleophilic fluorination of benzoyl in a fully automated process and subsequent purification via-use of a combination of different SepPak® cartridges were achieved. Impurities levels in [^{18}F]FLT produced by this method were within specified limits defined by Cancer Imaging Programme, NIH, USA for considering the product as generic drug.

(e) Process for Making Sterile Evacuated Clear Colorless Glass Vials – Used in Radiopharmaceuticals Production

Objective: Producing sterile, pyrogen free, evacuated clear colorless glass vials plays critical role in the production of generator based radiopharmaceuticals (RPs) and dispensing PET RPs in closed lead shielded automated dispenser. In this study we have developed a process for making sterile, pyrogen free ready to use USP typeI glass vials without any gamma ray (γ), electron beam (EB) or ethylene oxide (EO) sterilization after evacuation in freeze dryer.

Materials: USP typeI glass vials, ã irradiated bromobutyl rubber closures, Hot air oven, depyrogenated forceps, Lyophilizer, Class 100 cleanroom facility, FTM & SCD , Lysate, and bromothymol blue(BTB).

Methods: Vials washed, rinsed (metal free water), dried, wrapped (25µm Al foil) and depyrogenated (250°C 1hr). Aseptically inside clean room rubber closure were placed on vials opening with depyrogenated forceps. Vials loaded in lyophilizer with shelf and ice condenser temperature preset at -10°C and -55°C respectively. Pressure brought down by maintaining vacuum between 0.05-0.08 mbar for 45 minutes, simultaneously the shelf temperature increased to +10°C to extracted vapour from vacuum. These are then autosealed under vacuum and aerated using PTFE filter. Vacuumed vials are crimped and tested for vacuum integrity by glow discharge method. In accordance with USP/IP, 10% of batch size was tested for sterility, apyrogenecity (Gel-clot) and acidity/alkalinity (BTB titration).

Results: All the 12,500 evacuated vials produced by our in-house developed method complies sterility and BTB titration test, while endotoxin limit is <0.06 EU/ml without any γ, EB or EO sterilization. Produced vials internal vacuum <1mbar with 5-6% rejections.

Conclusions: We could successfully use these in-housed produced sterile, pyrogen free, evacuated clear colorless glass vials for automated dispensing and elution of radiopharmaceuticals at our facility.

H. Development work carried out at Electron Beam Processing Services, BRIT

An Industrial type 5MeV, 15kW ILU-EB Accelerator Facility is operated regularly for R&D applications and commercial irradiation. We are highlighting here some recent activities, which will give the flavor of our line of activities. Recently, we have done some commercial irradiation as below.

Trial irradiations of medical products from ISOMED and private companies werew performed. Irradiation for R&D for Vegetables (**Figure: 1, Mint, Spinach & Coriander sample),** Fish, Shrimps and Meat (**Figure:2)** for shelf life extension. Irradiation of Polymer blends, nano composites and oil-water separator for R&D. EB Treatment of domestic wastewater at semi-Pilot Scale was also demonstrated. Enhanced bio-degradation of Industrial wastewater and Degradation of pharmaceutical effluent was observed.

We have performed dosimetry for ILU-EB Accelerator, which includes Quality assurance and Quality control for the facility and the products has been routinely carried out using different dosimeter systems. X rays have been generated from the electron beam for using it as an alternative to the use of EB or gamma for radiation processing applications. Dosimetry studies were carried out for ISOMED medical products for diverting some of the products for EB irradiation for its sterilisation and dosimetry intercomparison for other EB facilities in India.

Side by side our section is involved in forefront research and development. Our group in materials science and technology is working on development of super absorbent for oil/water separation and polymer blends, composites and nano composites. We have developed recently a unique cheap, biodegradable and efficient oil-water separator which can separate immiscible as well as emulsified oil-water mixture (**Figure: 3).** This material can be used for several times. In addition, this group (materials science) has also developed a high temperature and radiation resistant polymer blends and composites for cable applications (**Figure:4).**

Besides, the material science our section is involved in microbiology research. The research is going on shelf-life enhancement of meat/fish product/Indian fermented food, *Idli* (Food Safety & Security) and sterilization of Pharmaceutical products.

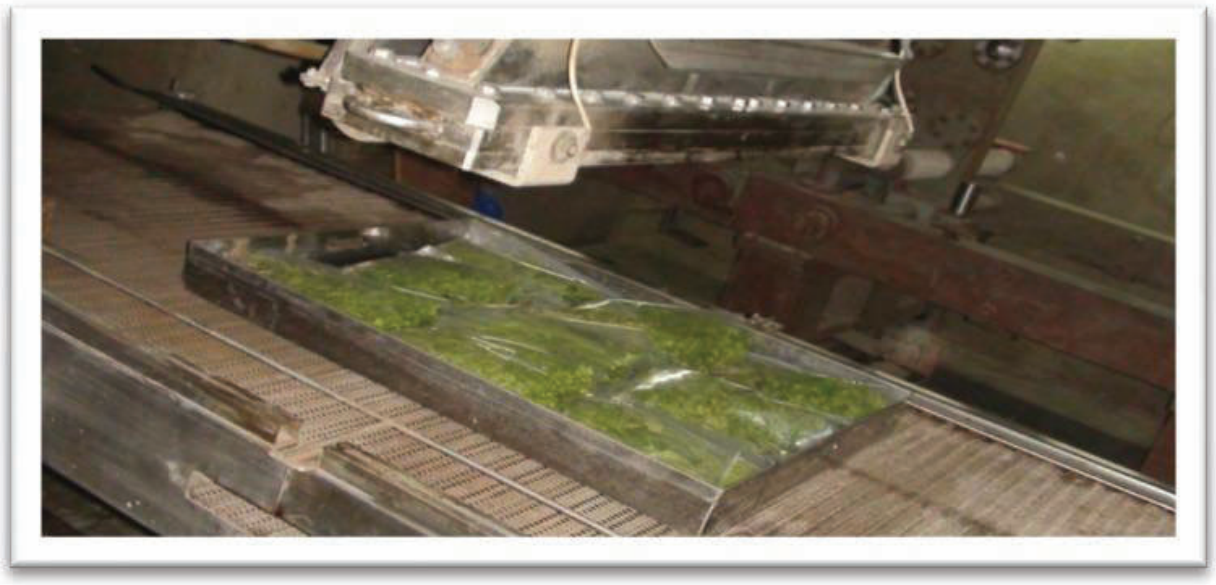


Figure: 1. Mint, Spinach & Coriander sample

Figure: 2. Meat sample

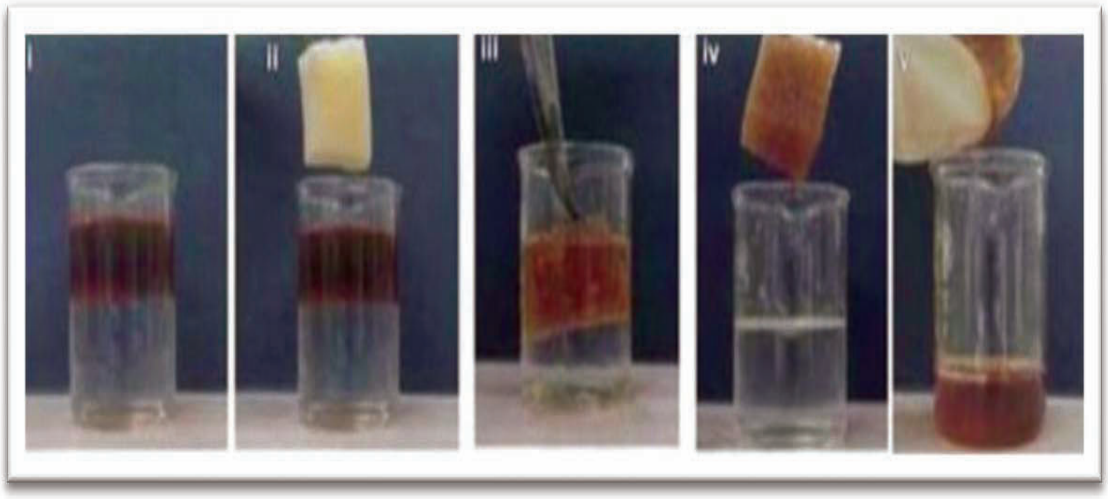
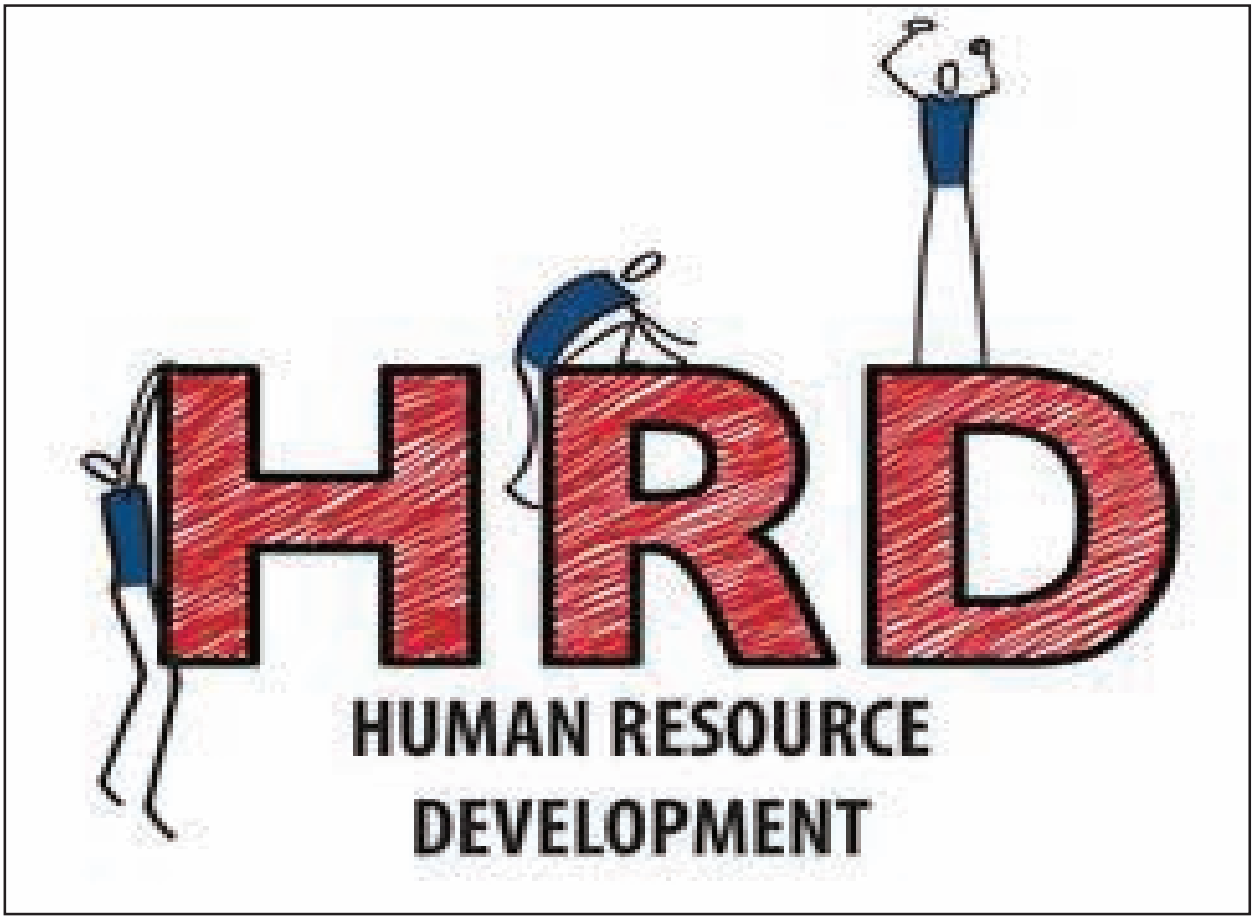


Figure: 3. Oil/water separation

Figure: 4. High temperature and radiation resistant material

CHAPTER - 4

HUMAN RESOURCES DEVELOPMENT ACTIVITIES OF BRIT



Successful people are always looking for **opportunities** to help others. Unsuccessful people are asking, **What's in it for me?**

Training Imparted / Lectures Given / Workshops and / or Seminars Attended

1. Oral Presentation about '**BRIT's roadmap for next years in Radiopharmaceutical production**' was given by Dr. Anupam Mathur & Shri G. Ganesh at Indian College of Nuclear Medicine, (Sponsored by SAMEER-2016) during SNM(I) conference at Ahmedabad.

2. Dr. K. M. Mathew was involved in imparting the orientation programme on —Tritium Handling to the participants of Radiation Safety Officer Course organized by RPAD, BARC for Defence Personnel.

3. Two-weeks in-plant training was conducted for a batch of trainees of Certification course for Operators of Radiation Processing Facilities' at Radiation Processing Plant (RPP), Vashi Complex.

4. One-week workshop on —Sterility and Bacterial Endotoxin Testing (BET)' was conducted at BRIT, Vashi Complex and RMC, Parel, for BRIT employees from Regional Centres at Delhi, Kolkata, Bengaluru and Hyderabad. Shri V.V. Murhekar coordinated the workshop along with Head, RMC, Dr. M.G.R. Rajan. Dr. Sangeeta Joshi and Smt. Chanda Arjun served as a faculty who delivered relevant lectures and Smt. Barkha Karkhanis conducted practicals along with RMC staff.

5. Dr. Geetha Rajagopalan delivered a lecture on —Production and Quality Control of Radiopharmaceuticals' and coordinated educational tour program of Nuclear Medicine Technologist Trainees from INHS, Asvini.

6. A total of four BRNS projects were reviewed by Shri V.V. Murhekar and Smt. Chanda Arjun during the reported period.

7. Three officers from Radiopharmaceutical Laboratory are certified as —Internal Auditors for ISO 9001:2015.

8. Two Officers from Radiopharmaceutical Laboratory successfully completed the course on training on —Dangerous Goods Regulations Category-3 organized by Mumbai International Airport Pvt. Ltd.

9. Dr. Vivek Yelgaonkar delivered an oral presentation on "Flow dynamics study of catalyst powder in CCU for troubleshooting" at the "Iternational Conference on Applications of Radiation Science and Technology (ICARST-2017)". The conference was held at the International Atomic Energy Agency Headquarters in Vienna, Austria, from 24 to 28 April 2017.

10. Dr. Sankha Chattopadhyay attended and presented "Solvent Extraction Based System for Automatically Separating ^{99m}Tc Radionuclide From Low-Medium Specific Activity ^{99}Mo" at the Technical Meeting on "New Ways of Producing Tc-99m and Tc-99m Generators" held at IAEA Headquarters, Vienna, Austria.

Publications in Journals

1. **Performance of BLC-200 cask under 9m Drop Test.**
   Saquib, D.K. Sahoo, P. Srivastava, A.K. Kohli, G. Ganesh
   Procedia Engineering 173 (2017) 455-462.

2. **Performance of monolithic plate and layered plates under blast load.**
   D.K. Sahoo, Anirben Guha, Asim Tewari, R.K. Singh
   Procedia Engineering 173 (2017) 1909-1917.

3. **Numerical simulation and experimental drop testing of COCAM – 120 – An industrial radiography device.**
   D.K. Sahoo, J.V. Mane, P. Srivastava, A.K. Kohli, G. Ganesh
   Procedia Engineering 173 (2017) 1918-1925.

4. **Performance of gamma chamber under blast loading.**
   D.K. Sahoo, P. Dewan, P. Srivastava, A.K. Kohli, I.P.S. Sandhu, Rajesh Kumari, D.R. Saroha, Anirben Guha, Asim Tewari, R.K. Singh
   Annals of Nuclear Energy 105 (2017) 240-248.

5. **Impact stress reduction by shell splitting in cask for transporting radioactive material.**
   Kuldeep Sharma, Anirben Guha, Dnyanesh n. Pawaskar, R.K. Singh
   Annals of Nuclear Energy 79 (2015) 111-124.

6. **Study on urea breath test: a tool for Helicobacter pylori infection.**
   R.V. Kolekar, Anita Gadgil, S.P.D. Bhade, Priyanka Reddy, Prashant Bhandarkar, N. Roy, S.P. Patil, Rajvir Singh
   Radiation Protection and Environment 39/3 (2016) 146-148.

7. **Separation of Mo from Nb, Zr and Y: Applicability in the purification of the recovered enriched ^{100}Mo used in the direct production of ^{99m}Tc in cyclotrons.**
   M.K. Das, S.S Das, M.A. Nayer, S. Chattopadhyay, L. Barua, S, Dutta
   Journal of Radioanal. and Nucl. Chem. 311/1 (2017) 643-647.

8. **Production and separation of ^{99m}Tc from cyclotron irradiated $^{100/nat}$Mo targets: a new automated module for separation of ^{99m}Tc from Molybdenum targets.**
   M.K. Das, S. Chattopadhyay, S.S Das, L. Barua, M.A. Nayer, U. Kumar
   Journal of Radioanal. & Nucl. Chem. 310/1 (2016) 423-432.

9. **Paclitaxel-loaded solid lipid nanoparticles modified with Tyr-3-Octreotide for enhanced anti-angiogenic and anti-glioma therapy.**
   I.Banerjee, K.De, D. Mukherjee, G. Dey, S. Chattopadhyay, M. Mukherjee
   Acta Biomaterialia 38 (2016) 69-81.

10. **A simple method for preparation of pure ^{68}Ga-Acetate precursor for formulation of radiopharmaceuticals: Physicochemical characteristics of the ^{68}Ga eluate of the SnO_2 based ^{68}Ge/^{68}Ga column generator.**
    S. Chattopadhyay, M. Alam, M. Smita, U. Kumar, S.S. Das, L. Barua
    Radioanal. & Nucl. Chem. 60/1 (2016) 62-68.

11. **Fabrication of surfactant-free quercetin-loaded PLGA nanoparticles: evaluation of hepatoprotective efficacy by nuclear scintigraphy.**
    S. Ganguly, R.H. Gaonkar, S. Sinha, A. Gupta, D. Chattopadhyay, S.S. Sachdev, M.C. Debnath
    Journal of Nanoparticle Res. 18 (2016) 196.

12. **Radiochemical studies, pre-clinical investigation and preliminary clinical evaluation of ^{170}Tm-EDTMP prepared using in-house, freeze-dried EDTMP kit.**
Tapas Das, Ajit Shinto, Koramadai K. Kamaleshwaran, Haladhar D. Sarma, Sahiralam Khan Mohammed, Arpit Mitra, Sangita Lad, M.G.R. Rajan, Sharmila Banerjee
App. Rad. & Isotop. 122 (2017) 7-13.

13. **Studies on batch formulation of a kit for the preparation of the ^{99m}Tc-Ubiquicidine (29-41): an infection imaging agent.**
Chanda Arjun, Archana Mukherjee, Jyotsna Bhatt, Pradip Chaudhari, Krishna Mohan Repaka, Meera Venkatesh, Grace Samuel
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14. **^{68}Ga-labeled Ciprofloxacin conjugates as radiotracers for targetting bacterial infection.**
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Chem. Biol. Drug Des. 87/5 (2016) 680-686.

15. **^{68}Ga labeled fatty acids for cardiac metabolic imaging: Influence of different bifunctional chelators..**
Jain A, Mathur A, Pandey U, Sarma HD, Dash A.
Bioorg. Med. Chem. Lett. 26 (2016) 5785-5791.

16. **Synthesis and evaluation of a ^{68}Ga labeled folic acid derivative for targeting folate receptors.**
Jain A, Mathur A, Pandey U, Bhatt J, Mukherjee A, Ram R, Sarma H.D, Dash A.
Appl. Radiat. Isot. 116 (2016) 77-84.

17. **Synthesis and evaluation of a novel ^{99m}TcN(PNP) Complex with Metronidazole Isocyanide ligand as a marker for Tumor Hypoxia.**
Vats, K., Mallia, M.B., Mathur, A., Sarma, H.D., Banerjee, S.
Journal of Radioanal. & Nucl. Chem. 308 (2016) 363-369.

18. **Synthesis and characterization of a novel ^{99m}Tc analogue of ^{131}I-mIBG showing affinity for nor-epinephrine transport positive tumors.**
Sakhare, N., Das, S., Mathur, A., Mirapurkar, S.M., Paradkar, S., Sarma, H.D., Sachdev, S.S.
RSC Advance 6 (2016) 64902-64910.

19. **Clinical utility of ^{99m}Tc-Ubiquicidin (29–41) as an adjunct to bone scan in differentiating infected versus non-infected loosening of prosthesis before revision surgery.**
Ajit Shinto, Archana Mukherjee, Kamaleshwaran Koramadai Karuppusamy, Jephy Joseph, Jyotsna Bhatt, Aruna Korde, Indira Upadhya, Chanda Arjun, Grace Samuel, Ashutosh Dash.
Nucl. Med. Commun. 38/4 (2017) 285-290.

Abstract Publication

1. **Development of an indigenous kit for the preparation of ^{99m}Tc-Macroaggregated Albumin for lung perfusion imaging.**
   Archana S. Ghodke, R. Krishnamohan, Jyothi Sharma, Sangeeta H. Joshi, R. Vanaja, S.S. Sachdev
   Abstract Published in IJNM 31 (2016) S41.

2. **Development of high performance liquid chromatography (HPLC) method for quality control analysis of ^{131}I-Sodium Iodide solution using cationic modification of C-18 reverse phase column.**
   V.V. Murhekar, P.B. Dodke, D. Padmanabhan, Aruna Korde, M.G.R. Rajan
   Abstract Published in IJNM 31 (2016) S36; P20.

3. **Clinical utility of ^{99m}Tc-UBI (29-41) in assessing musculoskeletal infection with a specific emphasis on prosthesis evaluation.**
   Mukherjee A., Shinto A., Kamaleshwaran K.K., Jephy J., Bhatt J., Korde A., Arjun C., Upadhyaya I., Dash A.
   Abstract Published in IJNM 31 (2016) S22-23.

4. **Operational and clinical evaluation of ^{99}Mo/^{99m}Tc-TCM-Autosolex generator at hospital radiopharmacy centre.**
   Mitra A., Chandak A., Lad S., Upadhye T., Banerjee S., Chattopadhyay S., Rajan M.G.R.
   Abstract Published in IJNM 31 (2016) S36.

5. **Design and evaluation of a novel ^{99m}Tc analogue of ^{131}I-mIBG synthesized via ^{99m}Tc(CO_3) core for Neuroendocrine Tumor Imaging.**
   Soumen Das, Navin Sakhare, Anupam Mathur, Shubhangi Mirapurkar, Madhava Mallia, S.S. Sachdev
   Abstract Published in IJNM 31 (2016) S32-S33.

6. **Comparison of the cytotoxic effects of m-[^{131}I] Iodo Benzyl Guanidine on the Human Neuroblastoma cell lines SK-N-SH and IMR-32.**
   Shubhangi Mirapurkar, Sheela Murlidharan, Navin Sakhare, Anupam Mathur, Joseph N.C., S.S. Sachdev
   Abstract Published in IJNM 31 (2016) S6.

7. **Ensuring cGMP compliance in production and quality control of various diagnostic radiopharmaceuticals – used in cancer treatment and management.**
   Mitra A., Lad S., Yuvaraj N., Kulkarni S., Rajan M.G.R.
   Absract Published in Eur. J. Cancer 54 (2016) Suppl 1:S34.

8. **Resolving false-positive bacterial endotoxin test results obtained with some radiopharmaceuticals and cold kits due to the presence of cations, colloidal particles or fatty acids.**
   Mitra A., Lad S., Kulkarni S., Rajan M.G.R.
   Absract Published in Eur. J. Cancer 54 (2016) Suppl 1:S34.

9. **Automated Synthesis of Pharmaceutical Grade [^{18}F] FLT using 5'-O-(Benzoyl) -2-3'-anhydrothymidine Precursor.**
   Arpit Mitra, Chinagandham Rajesh, Sangita Lad, Trupti Upadhye, Sharmila Banerjee, Ramakrishna Rajan
   Abstract Published in J. Label. Comp. Radioparm. 60 (Suppl.1) (2016) S616.

10. **Convenient method for labelling of noradrenalin with tritium isotope.**
    Deepak B. Kalgutkar, Ranajit Kumar Sahu, N. Jayachandran, Harish Chander
    Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings F-2 (2017) pp 472-473.

11. **A convenient one-pot synthesis of [Carboxyl-C-14]-Glycophosphate.**
    S.P. Patil, Ranajit Kumar Sahu, Sudarshan G. Chemate, N. Jayachandran, Harish Chander
    Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings F-3 (2017) pp 474-475.

12. **Development of a high-yield, low pressure [O-18] water target of Niobium, for routine F-18 production in a Medical Cyclotron.**
B.K. Sharma, S.P. Rivastava, R.K. Gupta, V. Bhardwaj, A. Gopalkrishnan, Yuva Raj Nitin, K. Kushwaha, Kamaldeep, M.G.R. Rajan, S. Banerjee
Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings, F-24 (2017) pp 516-517.

13. **Production of Cu-67 at electron Linacs – Development of Photonuclear Technology.**
A.Gopalkrishnan, S.V. Suryanarayana, T.S. Dixit, K. Thakur, B.K. Nayak, H. Naik, A. Deshpande, R.Krishnan, P. Maletha, Kamaldeep, S. Banerjee, A. Saxena
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14. **Evaluating Impurities Profile in One-pot Two-step Seppak [F-18] FLT Synthesis.**
Mitra, C. Rajesh, S. Lad, T. Upadye, S. Banerjee, M.G.R. Rajan
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15. **Theoretical estimation of Cu-64 production via $^{64}Ni(p,n)^{64}Cu$ and radiation field in a prototype solid target irradiation system**
K. Kushwaha, C. Sunil, K. Bijju, Sharmila Banerjee, A. Dash
Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings, F-23 (2017) pp 514-515.

16. **Synthesis of [F-18] Fluoropropyl-S-Tyrosine (FPT) via Ni (II) complex of Chiral Schiff's base with tyrosine precursor.**
Lakshminarayanan, N., M.G.R. Rajan, Sharmila Banerjee
Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings, F-17 (2017) pp 502-503.

17. **Production and radiochemical separation of a separation of a potential imaging agent ^{89}Zr from proton irradiated ^{nat}Y target.**
Sujata Saha Das, Sankha Chattopadhyay, Luna Barua, Md. Nayer Alam, Madhusmita Umesh Kumar
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18. **Preparation of $^{99}Mo/^{99m}Tc$ generator based on cross-linked chitosan polymer using low-specific activity (n,?) ^{99}Mo.**
Sankha Chattopadhyay, Sujata Saha Das, Md. Nayer Alam, Madhusmita Umesh Kumar
Abstract Published in the 13th DAE-BRNS Nuclear and Radiochemistry Symposium Proceedings, F-12 (2017) pp 492-493.

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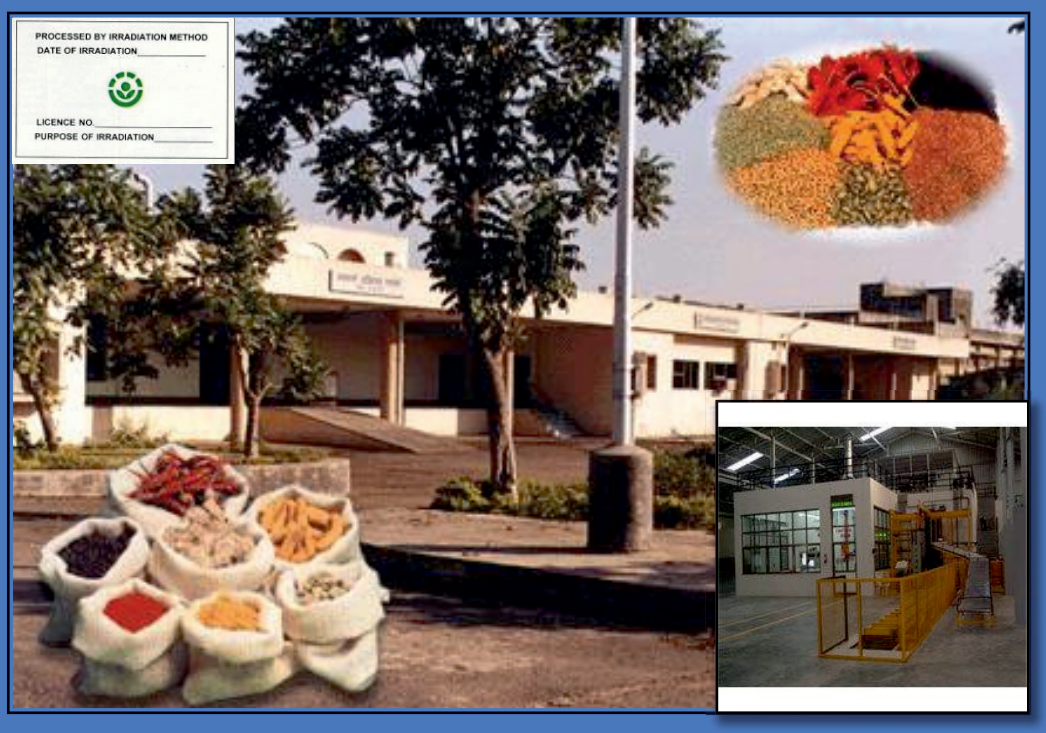

Spice Plant at BRIT Vashi Complex

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