

Annual Report 2010- 2011
Board of Radiation and Isotope Technology

Executive Summary

CH 4 Radiation Technologies & Applications

During 2010-2011 more than 53,000 consignments of various radio-isotope based products and round the clock radiation processing services were provided to customers across the length and breadth of the country as well as some located abroad bringing a **sales turnover of Rs.5500 lakhs**.

Healthcare

Two new products were introduced : a Kit for the preparation of ^{99m}Tc(III)-DMSA injection (TCK-33) for renal imaging and a single component kit for the preparation of ^{99m}Tc-MIBI injection (TCK-50A) for myocardial perfusion imaging. The contract work for labelling of monoclonal antibody (ch TNT 1/B) with ¹³¹I for M/s Peregrine Pharmaceuticals Inc., USA has been successfully completed. With this Phase II of clinical trials completed and another order is anticipated from M/s. Peregrine Pharmaceuticals.

More than 58,000 cold kits for formulation of ^{99m}Tc; 410 Ci of ⁹⁹Mo (TCM-2) for extraction of ^{99m}Tc at and approx. 15000 consignments of ready to use radiopharmaceuticals of ¹³¹I, ³²P, ⁵¹Cr and ¹⁵³Sm were supplied to various Nuclear Medicine Centers.

51 batches of Geltech generators were processed and supplied to nuclear medicine hospitals across India. 811 generators were supplied reflecting a **growth of about 48%** over previous year. A total number of 9058 radioimmunoassay (RIA) and immunoradiometric assay (IRMA) kits are produced and supplied to about 300 immunoassay laboratories throughout the country. BRIT has introduced **LH IRMA kit in the market**.

Column Generator Plant

Major components of ⁹⁹Mo-^{99m}Tc **Column Generator Plant** have arrived from Gamma Services, Leipzig, Germany & installation is completed. The plant will be commissioned shortly after training of the personnel.

Fission Molybdenum Production Facility

A new project "**Setting up of Medical use Mo-99 production (LEU fission based) facility**", under XI plan has been sanctioned for BRIT by Atomic Energy Commission. This is the single largest project worth **Rs. 128 crore** that has ever been approved for BRIT.

Nuclear & Biotechnological Tools

Labelled Compounds Programme supplied a wide variety of ¹⁴C, ³H and ³⁵S-labelled products, oligonucleotides (DNA primers) and ready-to-use non-radioactive (cold) kits used for labeling nucleic acid with ³²P-labelled nucleotides. Various types of Tritium Filled light Sources were prepared and supplied for defence applications. **An export order** received from **Germany** for radiolabelling of isosorbide with Carbon-14 was executed. Tritium labeling of herbal Arjun Sal and ¹⁴C labeling of Tulsi leaves were performed.

JONAKI had introduced an agarose gel based PCR detection kit for the detection of M. Tuberculosis last year. An improved multiplex PCR based M. Tuberculosis detection kit is developed. Work on real time PCR kit for EGFR mutants required for better cancer treatment based on the patented Real time PCR chemistry is in progress.

Radio-Analytical Laboratory analyzed about 3255 export commodities, 270 domestic water samples and 10 steel samples for identifying the possible contaminating trace-radionuclides. A Survey and Certification of one steel consignment was also undertaken.

Nuclear Medicine: Cancer diagnostic & treatment services

8 Teletherapy sources with 84 kCi (1400 RMM) of Co-60 activity were supplied for the treatment of cancer. Two Cs-137 applicator kits with 1366 mCi and 4 metres of Ir-192+Pt medical wires with 1658 mCi activity were supplied for brachytherapy. 37 pencils containing 3156 Ci of Cobalt-60 were loaded into 4 blood irradiators.

Radioisotope Sources

Sealed radiation sources for industrial irradiators comprising a total activity of 770 kCi were fabricated, processed and supplied. **More than 900 radiography sources were fabricated and supplied with 35 kCi Ir-192 activity.**

BRIT played a leading role in recovery of radiation sources after the mishap of Gammacell 220 at Mayapuri, New Delhi. BRIT team was involved in identification & segregation of sources, removal of stuck sources & their transportation to RLG for verification of total Co-60 activity.

Radiation Technology Equipment

IHDR source for '**KARKNIDON**' is approved by AERB with a C53312 classification. BRIT has supplied & installed GC-5000 to Institute of Nuclear Chemistry & Technology Warsaw, Poland as part of IAEA order of **US\$ 187,990** (Rs.85 L) and supplied 2 units of GC 5000 to ISRO, Bangalore and BARC Kalpakkam.. Two blood Irradiators have been supplied and installed at Prathama Blood Bank, Ahmedabad and Christian Medical College, Ludhiana. A new **Stainless Steel based ROLI 1 camera** is introduced. 70 radiography exposure devices were supplied by BRIT.

Gamma Radiation Processing Services (GRPS)

Radiation Processing Plant (RPP), Vashi and ISOMED has received accreditation from European Commission apart from this RPP, Vashi has also received ISO 22000: 2005 HACCP Based Food Management System certification. ISOMED has received certification from MHRA- Medicines & Healthcare Products Regulatory Agency, U K.

ISOMED sterilized about 5400 cubic metres medical products generating a revenue of Rs. 330 lakhs. Radiation Processing Plant at Vashi processed about 2000 MT of spices and allied products worth Rs. 131 lakhs and is expected to gross Rs. 190 lakhs by the end of March 2011.

Install & Operate Irradiator

Considerable progress has been made in the commissioning of Install & Operate Irradiator of capacity 400 kCi of Co-60 suitable for radiation processing of Frozen Marine Products.

New Radiation Processing Plants in Private Sector

BRIT has signed MoUs with i) Gujarat Agro Industries Corporation Ltd., Bavla ii) Aligned Industries, Haryana & ii) CCCL Pearl City Food Port SEZ Limited, Chennai iv) NIPRO India Corporation Pvt. Ltd., Pune for setting up of Radiation Processing Plants. The Radiation Processing Plant for M/s. Innova Agri Bio Park Ltd., Bangalore is commissioned with initial 100 kCi of C0-60 activity. BRIT also supplied 200 kCi radiation source to M/s. Jhunsons Chemicals (P) Ltd., Bhiwadi, Rajasthan.

Isotope Application Services

The IAS group carried out leak detection studies using Br-82 in heat exchangers at three sections of M/s RIL, Patalaganaga. Mo-99 was used to identify leakage in underground pipeline of M/s RIL, Jamnagar, M/s Indian Oil Corporation Ltd., Sewree Terminal, Mumbai and M/s HPCL, Mumbai. Furnace blockage was detected at HPCL, Mahul. Gamma scanning was done for 3 columns at HPCL Visakhapatnam; in 31 T1 process column; in Fluidized Catalytic Cracking Unit (FCCU) at HPCL, Mumbai and on two vacuum gas oil hydro treater reactors of DTA refinery of RIL, Patalganga.

Customer Support

Customer Support Programme continued its services to vast array of customers and made it convenient to customers to interact with the officials of BRIT and regulatory authorities. 53,000 consignments of radioisotopes and allied products were transported safely to different destinations in the country besides movement of kilocurie amounts of radioactive sources from RAPPCOF, Kota to Mumbai, Mumbai to Vadodara, Delhi, Vasai and Ambarnath; and teletherapy sources from Mumbai to various cancer hospitals and Gamma Chamber and Blood Irradiator units to various research centres and hospitals.

Radioisotopes and allied products supplied by BRIT

| Sr.No | Item | Actual between April-December, 2010 | Expected to be achieved April,2010 – March, 2011 |
|-------|--------------|-------------------------------------|--|
| 1 | Consignments | 42000 | ≈ 53000 |
| 2 | Activity | 850 kilo curies | ≈ 1200 kilo curies |
| 3 | Sale Value | Rs. 4397 lakhs | Rs. 5500 lakhs |

The website continued providing regular updates on Airway Bill Numbers, status of radiography cameras and other important messages. BRIT Website is updated almost on a daily basis. Proposal for making BRIT website GIGW compliant is being finalized with NICS.

Annual Report 2010- 2011
Board of Radiation and Isotope Technology

Descriptive Part

CH 4 Radiation Technologies & Applications

Board of Radiation & Isotope Technology (BRIT) continued its mandate towards progress by regular production and supply of a vast array of high quality radioisotope products which include sealed radiation sources of activity ranging from few microcuries to millions of curies mainly for medical and industrial use; radiation technology equipment such as gamma radiography camera, gamma chamber units, Blood irradiators; radiopharmaceuticals, immunoassay kits, radiochemicals, labeled compounds, labeled biomolecules, ^{99m}Tc generators, 'cold' kits, oligo nucleotides, self-luminous compounds, etc. As a service provider, BRIT also operates plants for radiation sterilization of medical products (ISOMED) at Trombay; Radiation Processing Plant at BRIT Vashi Complex for radiation processing of spices and allied products, and runs Co-60 handling facility (RAPPCOF) at RAPS, Kota, JONAKI Laboratory at Hyderabad and has other Regional Centres located at Bangalore, Delhi, Kolkata and Dibrugarh. BRIT runs a Radio-analytical Laboratory at Vashi for detection of radioactivity in products for the benefit of various exporters and importers.

The various activities carried out by BRIT related to the production and supply of radioisotopes and allied products and radiation technology equipment for use in Healthcare, Industry, Agriculture and Research during the period of this report are as follows:

4.5 Healthcare

4.5.1. Radiopharmaceuticals

More than 58,000 cold kits for formulation of ^{99m}Tc radiopharmaceuticals (code-TCK: 11 Products) were supplied to various Nuclear Medicine Centers. 410 Ci of ^{99}Mo (TCM-2) was supplied for extraction of ^{99m}Tc at hospitals. In addition to this, various accessories of ^{99m}Tc solvent extraction generator systems and other products were supplied. Nearly 15000 Consignments of ready to use radiopharmaceuticals of ^{131}I , ^{32}P , ^{51}Cr and ^{153}Sm were supplied to various Nuclear Medicine Centers. Majority of these contained ^{131}I radiopharmaceuticals, which amounted to about 450 Ci ; over 14000 consignments. The production and supply of ^{32}P as sodium orthophosphate was majorly due to unavailability of quality radioisotope ^{32}P . The supply of following injectable products ^{153}Sm -EDTMP and ^{131}I MIBG has increased to various nuclear medicine centers in India.

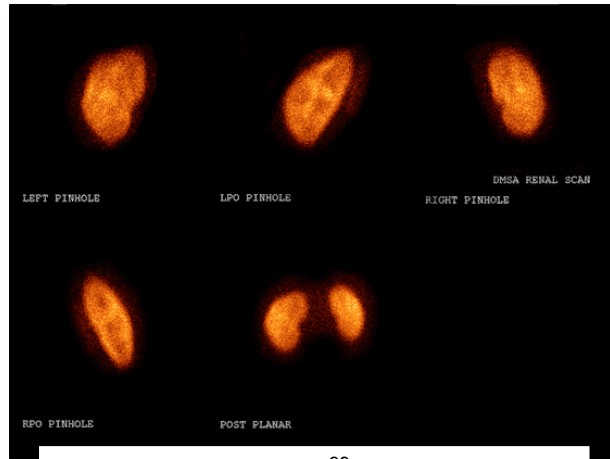


The ongoing contract work, of monoclonal antibody (ch TNT 1/B) labelling with ^{131}I , for M/s Peregrine Pharmaceuticals Inc., USA, has continued in the year 2010. The phase II of clinical trials has been completed. Another order is expected from M/s.Peregrine Pharmaceuticals to enable them to go ahead with Phase III trials.

The production of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ Column generator using high specific activity ^{99}Mo was a part of XI plan project. The fabrication of facility and inspection at the works of supplier German Company is complete. The erection and installation of hot cells and in-cell equipments, at RPL, BRIT has also completed and commissioning is at advanced stages.

A new project “**Setting up of Medical use Mo99 production (LEU fission based) facility**”, under XI plan has been sanctioned by Atomic Energy Commission. This is the single largest project worth Rs. 125 crore that has ever been approved for BRIT. The work towards the design and procurement aspects has been initiated.

Two new products a) Kit for the preparation of $^{99m}\text{Tc(III)-DMSA}$ injection (Code: TCK-33), for renal imaging, and b) Single component Kit for the preparation of $^{99m}\text{Tc-MIBI}$ injection (code:TCK-50A), for myocardial perfusion imaging, for which Radiopharmaceutical Committee (RPC) had granted approvals for regular production and supply for trial clinical use at Radiation Medicine Centre, BARC, have been introduced in the list of regular products, after successful use at RMC .



Renal Scan using of $^{99m}\text{Tc(III)-DMSA}$,

^{99m}Tc Column Generator Production Facility (TcGPF)

Regular production and supply of ‘**Geltech**’ generator had started since Nov 2006 and weekly supply had started since April 2009. During the period, Jan-Dec 2010, 51 batches of Geltech generators were processed and supplied to the nuclear medicine hospitals across India.

Numbers of generator supplied were 811 which is about 48% growth in comparison to the previous year. Significant achievement in this period was that all the batches were prepared using indigenously produced (n, γ) ^{99}Mo and supplied to the users contain larger quantity (9-10g gel powder / generator) Zr ^{99}Mo gel powder .

Column Generator Plant

Major components have arrived from Germany & installation is in progress of $^{99}\text{Mo}-^{99m}\text{Tc}$ Column Generator Plant. The Plant will be commissioned shortly after training of personnel.

4.5.2 Nuclear Medicine : Diagnostic & Treatment Service

A total number of about 10,000 radioimmunoassay (RIA) and immunoradiometric assay (IRMA) kits are produced and supplied to about 300 immunoassay laboratories throughout the country.

The work on development of IRMA kit for human thyroid stimulating hormone (TSH) based on magnetizable particles was completed. The user-friendly kit formulation makes use of in-house produced magnetizable cellulose particles along with ready-to-use serum based standards to cover physiological and diagnostically useful range. Supporting documents for the regulatory approval for regular production and supply of kits will be submitted to Radiopharmaceutical Committee (RPC) during this year.

The work on the modification of RIA kit for human insulin to measure the relative concentrations of insulin in rat serum was completed. More than 700 samples were analyzed for various academic institutions using this kit during this year.

Immunoassay Development Group from RIA programme received the GROUP ACHIEVEMENT AWARD 2009 of DAE for its group activity titled "A Novel Method for Preparation of Magnetizable Cellulose Particles and its Application in the Development and Production of RIA and IRMA kits for Diagnosis".

Regional Center, BRIT, Delhi carried out production and supply of around 90,000 mCi of various ready-to-use Tc-99m Radiopharmaceuticals injections (Tc-99m Pertechnetate, MDP, DTPA, GHA, DMSA (V), Mebrofenin and S-Colloid Injections) in compliance with GMP and RPC for Diagnostic Nuclear Medicine Studies in 21 hospitals in Delhi and NCR region. The value of supplied Tc-99m Radiopharmaceuticals is estimated as Rs. 28.50 lakhs.

Research and Development studies were further carried out to eliminate initial difficulties in Prototype column based alternate Tc-99m Generator based on utilization of SPE method developed by us which is compatible with indigenous reactor produced low/medium specific activity Mo-99 molybdate. Development and evaluation of prototype Tc-99m generator is in progress.

Retail outlet for supply of cold kits for preparation of various Tc-99m Radiopharmaceuticals was utilized by Nuclear Medicine hospitals in Delhi. Around 800 kits valued as Rs. 17 lakhs were supplied.

RCR, Bangalore carried out 4500 RIA investigations and supplied 76,400 mCi of ready-to-use ^{99m}Tc formulations. 675 consignments meant for customers in Bangalore region were collected by the RCR Bangalore on behalf of customers in the region. 765 TCK cold kits were sold through retail outlet. Dr. V. Bhupal, Head RCR, Bangalore delivered six invited talks under various programmes of Government of Karnataka to popularize the beneficial aspects of nuclear medicine and diagnostic services. The audience comprised college lecturers and high school students.

At the Regional Centre, Kolkata, significant progress has been made in the DAE Medical Cyclotron Project.

A versatile, user-friendly PC controlled and automated ⁹⁹Mo/^{99m}Tc generator using Alumina column and MEK is developed. It is a generator based on the technique of separation of ^{99m}Tc from indigenously produced low specific activity ⁹⁹Mo. This generator can be expected to provide the much needed relief from the recent severe shortage of fission ⁹⁹Mo for medical use. The quality control of pertechnetate and its efficacy in labeling some of the Technetium cold kits were checked. Automation has been done with the help of VECC and generator has been demonstrated.

Electrodeposition of Zinc and Cobalt were done using square wave pulse electroplating. Pulse electrodeposition of zinc was carried out in citrate and hydroxide baths. Deposition quality and grain size were found to be better in the hydroxide bath for which the deposition parameters were optimized. Similarly pulse electrodeposition of Cobalt was

carried out in sulphate bath and the parameters were optimized. Excellent deposit quality was obtained under the optimized conditions.

^{67}Ga and ^{69}Ge have been produced from Zn target by irradiating with alpha beam in the VECC room temperature cyclotron. Separation of Ga and Ge from bulk quantity of Zn is done by anion exchange column chromatography. Irradiated target was dissolved in 1M HCl was loaded on the column - Zn was held in the column when eluted with 70 ml 30% methanol in 1M HCl when Ga and Ge are expected to be eluted. Zn was eluted out from the column with 60 ml 0.1M HCl. Retention of Zn in the column and its subsequent elution from the column was ~100%.

Production of ^{61}Cu from natural Ni and Co target and Cobalt targets was carried out with 40 MeV alpha beam. Target is dissolved in HNO_3 and reconstituted in 6N HCl containing 3% ascorbic acid and loaded on an anion exchanger column. ^{61}Cu was eluted with 25 ml 2N HCl containing 1 ml H_2O_2 . Recovery of ^{61}Cu was more than 88% with more than 99% radionuclidic purity. The same process was repeated with Co targets and ^{61}Cu was eluted with 10 ml 2N HCl containing 1ml H_2O_2 . Recovery of ^{61}Cu was 90-100% with more than 99% radionuclidic purity in this case.

Synthesis, labeling and evaluation of HYNIC- Tyr3Octreotide (HYNIC-TOC) was carried out at RCR Kolkata. Tyr3Octreotide was synthesized at IICB, Jadavpur, Kolkata following standard Fmoc solid phase synthesis on O-t-butyl-threoninol-2-chlorotrityl resin in a semi-automated peptide synthesizer. It was purified by HPLC and characterized by mass spectroscopy. The purity of purified Tyr3Octreotide was compared with commercially available Tyr3Octreotide. The crude product was purified by HPLC and characterized by MS, radiolabelling of HYNIC-Tyr3Octreotide (HYNIC-TOC) and Biodistribution studies. Radiolabelling of HYNIC-Tyr3Octreotide (HYNIC-TOC) with $^{99\text{m}}\text{Tc}$ was performed using a reducing agent $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$. The radiochemical purity and quality control were determined by ITLC. The radiolabelling efficiency of the $^{99\text{m}}\text{Tc}$ -HYNIC-TOC in the preparation was more than 98%. In the biodistribution study, a high uptake of $^{99\text{m}}\text{Tc}$ - HYNIC-TOC in kidney than any other organs was found. The blood clearance was rapid with rapid excretion through kidneys and relatively low uptake in liver.

Regional Center, Dibrugarh provided RIA & IRMA diagnostic services for the patients of the entire North-Eastern region. More than 10,000 patients of the region avail the services from this center. Apart from medical colleges, patients also come from the nearby tea garden hospitals, civil hospitals etc.

4.3.2 Nuclear & Biotechnological Tools

4.3.2.1 Labelled Compounds

Labelled Compounds Programme of BRIT is involved in the preparation and supply of a variety of ^{14}C , ^3H and ^{35}S -labelled products, oligonucleotides (DNA primers) and ready-to-use non-radioactive (cold) kits used for labeling nucleic acid with ^{32}P -labelled nucleotides. All these products are powerful and versatile tools and are used as radiotracers in diverse investigations in the fields of biology, agriculture, medicine and chemistry.

Carbon-14 and tritium labelled compounds, in addition to biological applications find extensive uses in drug discovery.

At labelled compounds laboratory, tritium filled light sources of various types are also regularly prepared and supplied for defence applications. These sources are used for the illumination of various types of military gadgets and instruments.

Custom-synthesis of a few radiolabelled compounds was also carried out to meet the specific requirements from researchers.

In addition to the above, development work for the preparation of selected deuterated NMR solvents having deuterium abundance >99% was also carried out.

Details of the products supplied during the year 2010 -11 are given below.

| Sl.No. | Product Category | Total No. of consignments* |
|--------|-------------------------------|----------------------------|
| 1. | ¹⁴ C-products | 15 |
| 2. | ³ H-products | 27 |
| 3. | ³⁵ S-products | 47 |
| 4. | Kits | 04 (53 nos) |
| 5. | Oligonucleotides | 14 (160 nos) |
| 6. | Custom synthesis/TLS | 01 |
| 7. | TFS &TTS (Tritium Sources) | 21 (8668 nos) |
| 8. | ¹⁴ C-urea capsules | 02 (75 nos) |
| 9. | Taq DNA Polymerase | 04 (34500 U) |

* figures upto 15th December 2010

Highlights

1. Custom synthesis of one ¹⁴C-radiolabelled compound to meet the export order from Germany. ³H-labelled compounds such as Juglone-T(G), Vitamin D3 (T(G) and MK 886 were also custom synthesized successfully.
2. Tritium labeling of Arjun Sal, a herbal product for Haffkine Institute, Mumbai.
3. Carbon-14 labelling of Tulsi leaves using carbon-14 urea.
4. Method standardization for the preparation a few selected deuterated solvents having deuterium abundance > 99%.

4.3.2.2 JONAKI Laboratory at CCMB Campus, Hyderabad

JONAKI, the Labelled Biomolecules Laboratory of BRIT at CCMB campus is primarily involved in the production of ³²P labeled nucleotides required for molecular biology, biotechnology, biomedical and drug discovery research. It also markets ³⁵S labelled amino acids produced at labelled compounds laboratory at BRIT, Mumbai. Further, this laboratory produces and supplies many nucleic acid purification kits, polymerase chain reaction kits and Taq DNA polymerase. This laboratory meets the requirements of about 100 research institutes and universities and many industrial research centers. In addition, this laboratory provides services to the Nuclear Medicine Centers around

Andhra Pradesh by locally providing nuclear imaging cold kits produced at the radiopharmaceuticals laboratory of BRIT at Mumbai. A turnover of Rs. 1.38 crore has been achieved till November 2009 and a turnover of Rs. 1.5 crore is expected this year.

JONAKI has entered the field of molecular diagnostics last year by introducing an agarose gel based PCR detection kit for the detection of M. Tuberculosis in collaboration with LNMS, RMC, BARC. An improved multiplex PCR based M. Tuberculosis detection kit has been developed and it is in the process of introduction. Real time PCR kit for detection M Tuberculosis and detection of EGFR mutants required for better cancer treatment based on the patented Real time PCR chemistry developed at Jonaki laboratory is in progress.

4.3.2.3 Radio-Analytical Laboratory, Vashi Complex, Navi Mumbai

Radio-Analytical Laboratory is engaged in the measurement and certification of man-made residual radioactivity in various commodities such as food samples, animal feed supplements, steel samples, water samples and other miscellaneous items. Generally, the level of ^{137}Cs radioactivity is certified in food samples, whereas ^{60}Co contamination level is checked in steel samples. Water samples are routinely analyzed for gross alpha/gross beta radioactivity, ^{226}Ra and ^{228}Ra content. During this year, considerable number of water samples were received for the assay of uranium content .

In addition to the analysis of representative steel sample in our laboratory, the service of survey and certification of steel consignments at factory site has also been initiated.

During April - December 2010, RAL has analyzed about 3500 export commodities, 300 domestic water samples and 10 steel samples. Survey and certification of one steel consignment was also carried out. Total revenue generated up to December 2010 has touched Rs. 1 crore mark.

Quality Control Program

Quality control is provided for the production and supply of various radiopharmaceuticals and cold kits and covers analysis of ready to use radiopharmaceuticals, TCK cold kits, $^{99\text{m}}\text{Tc}$ Gel-Generator eluates, Non-radioactive raw materials and Radioactive raw materials. Physico-chemical and Biological tests are carried out as per requirements. Appearance, pH, radioactive concentration, radionuclide identification, radionuclidic purity and radiochemical Purity, sterility, bacterial endotoxin & bio-distribution studies are performed.

Quality Control Support was provided to several batches of radiopharmaceutical products and the raw material that were analyzed and certified by QCP.

The use of $^{99\text{m}}\text{Tc}$ for Mucoadhesion studies was demonstrated in collaboration with Bombay College of Pharmacy. Synthesis, characterization, radioiodination and biodistribution of a thermo-responsive polymer for localized radiotherapy in mice with tumor was completed. $^{99\text{m}}\text{Tc}$ -Ciprofloxacin bacterial uptake assay was standardized. Filter for $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ Gel generator were validated for sterility and pyrogens. Immunization of rabbits for raising antisera for vitamin D was done. Radiation detector for HPLC is installed and tested. Hospital Radiopharmacy Course for DRM and DMRT trainees was conducted. Standardization of Bacterial Endotoxin; An alternate method

for RCP determination of ^{99m}Tc -pertechnetate; EB Sterilization of vacuum vials and Bacterial culture media; QC Analysis of ^{99m}Tc eluate from Solkol generator and HPLC analysis of ^{131}I -mIBG and ^{99m}Tc -Ciprofloxacin are in progress.

^{99m}Tc -Pertechnetate was supplied to ACTREC for calibration of imported FLEX (PET/SPECT/CT trimodality scanner) imaging system. QCP was given the best oral presentation award at 42nd Annual Conference of SNM. A lecture and practical demonstration were given at the workshop organized by Indian Women Scientist Association (IWSA) at Navi Mumbai for School children.

Quality Assurance

The quality control analysis of TCK cold kits and IOM - 80 were documented. Calibration of Radiation counters, QC and TCK balances were done in collaboration with respective groups. Specific QC reports forms were designed and inducted for use in QC of TCK kits.

4.5.3. Nuclear Medicine: Cancer diagnostic & treatment services

8 Teletherapy sources with 84 kCi (1400 RMM) of Co-60 activity were supplied to various hospitals for the treatment of cancer. Two numbers of Cs-137 applicator kits with 1366 mCi were supplied to hospitals for brachytherapy. 4 metres of Ir-192+Pt medical wires with 1658 mCi activity were supplied for brachytherapy 4 blood irradiators were loaded with total 37 Cobalt-60 pencils of the activity 3156 Ci.

Industrial Applications

4.7.1. Radioisotope Sources.

48 numbers of Industrial irradiator pencils with 770 kCi of Cobalt-60 activity were fabricated and loaded in 4 irradiators.

| | |
|--------------------|-----------|
| AIPL, Vasai | : 300 kCi |
| AVPPL, Ambarnath | : 100 kCi |
| UML, Vadodara | : 200 kCi |
| Jhunsons Chemicals | : 170 kCi |

Two consignments of 100 kCi for Vietnam with 11 pencils and 20 kCi with 2 pencils are being exported.

| | |
|--------------------|-------------|
| Vinagamma, Vietnam | : 100412 Ci |
| Jakarta, Indonesia | : 20009 Ci. |

900 Ir-192 Radiography Sources of activity ranging from 20 Ci to 70 Ci with a total activity of 35 kCi were fabricated and despatched to various users. 13 Co-60 Radiography Sources with 640 Ci of activity ranging from 20 Ci to 100 Ci were fabricated and despatched to various users. One Thulium170 Radiography source was fabricated and supplied to M/s Larsen & Toubro Ltd., with 13 Ci activity.

Following Custom made Radiation Sources for Nucleonic Gauges and uses were made :

Co-60 : 27 sources with activity of 4765 mCi
Cs-137 : 15 sources with 806 mCi
Sc-46 : One consignment with 8 Ci of activity

One Gamma Chamber 1200 was loaded with 4750 Ci activity in 10 pencils. BRIT played a leading role in recovery of radiation sources after the mishap of Gammacell 220 at Mayapuri, New Delhi. The team was involved in identification & segregation of sources, removal of stuck sources & their transportation to RLG for verification of total Co-60 activity. Sources from PANBIT, BARC were removed and transported to HIRUP hotcells and PANBIT was dismantled. Two empty lead containers were supplied to Emergency response team for the commonwealth games.

4.7.2. Gamma Radiation Processing Services (GRPS)

4.7.2.1. Radiation Sterilization Plant for Medical Products (ISOMED)

The facility continued to operate, in confirmation with all the requisite regulatory requirements with an average Plant Load Availability Factor above 99% and average Plant Utilization Factor of 90% thus providing customer friendly quality gamma sterilization services to large numbers of customers spread all over the country. Total 5415 cubic meters of Healthcare products were processed from April 2010 to November 2010 generating revenue of Rs. 221 lakhs. By March 2010, the facility is expected to yield total revenue to the tune of Rs. 331 lakhs.

The novel access monitoring cum control system for the personnel cell door has been successfully implemented at the facility which has been appreciated at various national / international forums.

Advanced automation features in the existing Ceric-Cerous Potentiometer Dose measurement are being introduced so as to reduce the potential likelihood of manual error of omission / commission.

The facility acquired European Union (EU) GMP compliance certification from medicine and healthcare regulatory agency (MHRA) UK which is a substantial value addition to the exporters of medical devices to UK; accredited with ISO 9001:2008 Quality Management System and ISO 22000: 2005 – Food Safety Management System; accreditation as a certified foreign device manufacturer from Government of Japan; approval from EU for Radiation processing of Food Products meant for export to European union in March 2010.

Regular audits in respect of Supplier Quality Management system, and Quality Management System Surveillance pertaining to various customers of the facility were also conducted.

4.7.2.2 Radiation Processing Plant, Vashi (RPP, Vashi)

Radiation Processing Plant, Vashi is providing gamma radiation processing services for spices, ayurvedic raw material and pet feed etc. to more than 135 customers from all over the country.

During the current financial year, about 1884.5 MT of spices and other products were processed till November 2010 which is 17.7% increase in quantity over the corresponding period last year (1601 MT). Revenue generation till November 2010 is about 131 lakhs which is about 33% more than the revenue generated in corresponding period last year (98.5 lakhs). The year the plant is expected to process around 2800 MT spices and allied products yielding revenue of about 190 lakhs. Since its inception, this facility has processed about 15,900 tonnes of products realizing revenue of about Rs. 833 lakhs.

Source replenishment is planned to enhance source strength from 350 kCi to 500kCi to cope up with the increased demand for radiation processing.

The facility was certified with ISO-9001:2000 (Quality Management Systems) during 2009 and in the current year Facility received ISO-22000:2005 (Food Safety Management Systems) certification. The facility was also included in the list of EU Approved irradiators.

4.7.2.3 New Radiation Processing Plants in Private Sector



The radiation processing plant M/s Innova Agri Bio Park Ltd., Bangalore is commissioned and loaded with 100 kCi of Co-60.

MoU for setting up of Radiation Processing Plant has been signed with M/s CCCL Pearl City Food Port SEZ Ltd., Chennai, M/s NIPRO INDIA Pvt. Ltd., Pune and M/s Aligned Industries, Haryana.



MoU Signed with CCCL Pearl City Food Port SEZ Ltd.

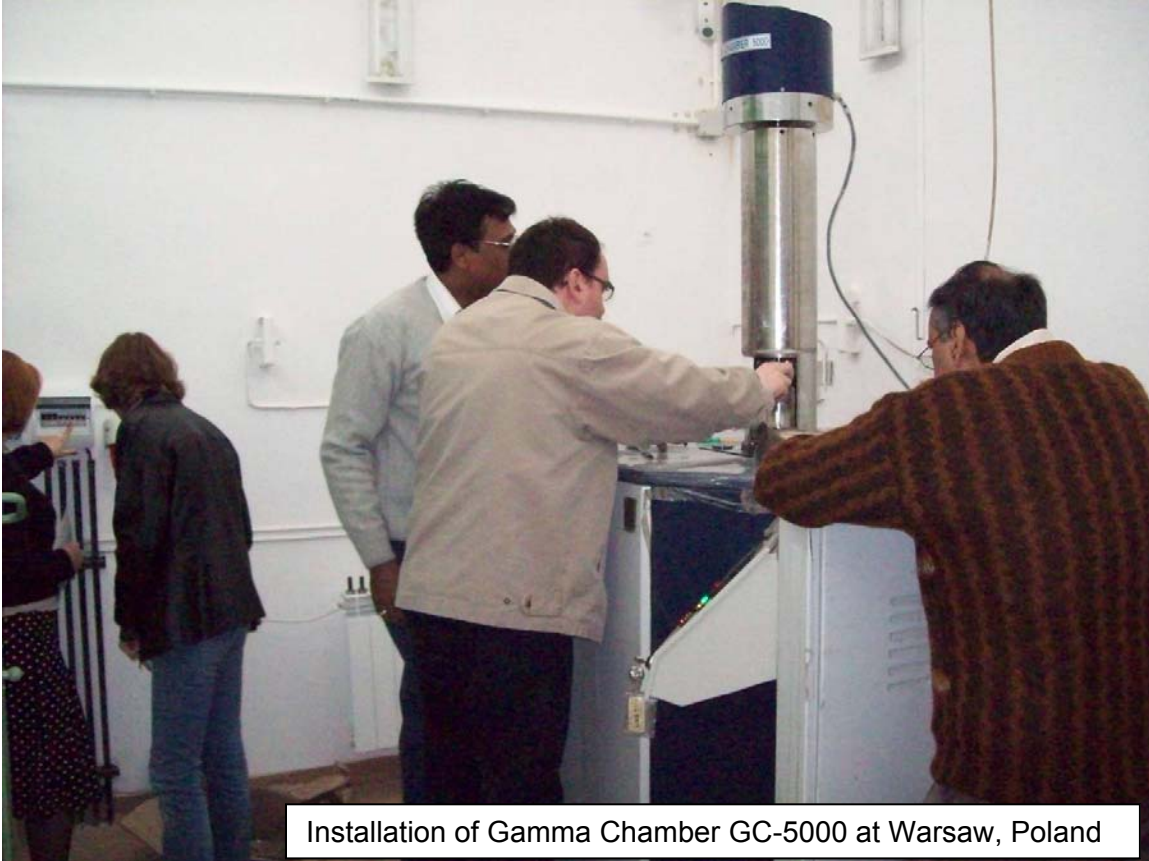
4.7.2.5 EB Processing

An amount of Rs.20 lakhs was earned through ILU-6 EB commercial processing services which included processing of around 1 lakh pieces of automobile polymer adaptors, diamond irradiation. Parameter optimization of EB process for imparting required degree of cross linking of polymer blend insulation sheets was completed. A material handling system comprising of a pay-off and take-up equipment has been designed and fabricated which is under installation at the facility. The local chiller unit has been modified and put in use for its increased cooling efficiency of the accelerator equipment and it is working satisfactorily.

4.7.3. Radiation Technology Equipment

4.7.3.1. Gamma Chamber GC 5000

During the current financial year Gamma Chamber GC 5000 has been supplied to ISRO, Bangalore and BARC Kalpakkam. Few more Gamma Chambers are expected to be supplied to following organizations by March 2011. The GC-5000 supplied to the Institute of Nuclear Chemistry & Technology Warsaw, Poland, was installed as a part of IAEA order of **US\$ 187,990** (Rs.85 L).



Installation of Gamma Chamber GC-5000 at Warsaw, Poland

1. Mangalore University , Mangalore
2. RSD, BARC, Trombay, Mumbai
3. ACD, BARC, Trombay, Mumbai – to be installed at Barampur
4. IAEA order for Romania
5. Inter University Accelerator Centre (IUAC), New Delhi

4.7.3.2. Radiography Camera ROLI-1 & III

BRIT supplied 41 radiography exposure devices up December 2010. It is expected to sell another 30 more cameras by March 2011.

344 ROLI cameras were serviced up to 10 December 2010 and another 128 cameras will be serviced before March 2011. 787 decayed sources were removed between April December 2010. Another 240 sources will be disposed off by March 2011. 657 imported cameras were inspected by December 2010. By March 2011 another 250 imported cameras will be inspected. A new SS based ROLI 1 camera is being introduced shortly.

4.7.3.3. Blood Irradiator

The production and supply of Blood Irradiator BI 2000 has been pursued further. Two Blood Irradiators has been supplied and installed at

- Prathama Blood bank, Ahmedabad
- Christian Medical College, Ludhiana

Orders have been received from:

- TMC, Kolkata
- CMC, Vellore
- NEHU Shillong

4.7.3.4 Install & Operate Irradiator

The civil work for the irradiator is completed. EOT crane has been installed. The fabrication of components is completed and installation is in progress.



Install and Operate Irradiator being installed.

4.7.3.5. QA of Sealed Sources, Radiometry Scanning and Irradiation Services

ROLI 1 cameras were tested at the REPF workshop and the Radiological lab of BARC. Density measurements were carried out on cobalt-59 pellets and slugs and also chemical analysis and XRF analysis were carried out for the acceptance of the material for irradiation.

All the sealed sources were subjected to the various quality control checks before release.

4.7.3.6. Isotope Application Services

IAS group has successfully carried out leak detection studies in heat exchangers at three sections RIL, Patalaganaga using Br-82. Radiotracer studies using Mo-99 was carried out to identify leakage in underground pipeline of M/s Reliance Industries Limited (RIL), Jamnagar, M/s Indian Oil Corporation Ltd., Sewree Terminal, Mumbai and M/s Hindustan Petroleum Corporation Limited (HPCL), Mumbai. Furnace blockage was detected at HPCL, Mahu. Gamma scanning was done for 3 columns at HPCL Visakhapatnam. Gamma scanning was carried out in 31T1 process column and in Fluidized Catalytic Cracking Unit (FCCU) at Hindustan Petroleum Corporation Ltd., Mumbai. Gamma scanning was also carried out on two vacuum gas oil hydro treater reactors of DTA refinery of Reliance Industries Ltd., Patalganga

4.14. Supporting Services

4.14.1. Customer Support

As the nodal agency for sales co-ordination & logistics, Customer Support Programme continued to provide support for the regular and uninterrupted supply of radioisotopes & allied products and radiation technology equipment to about 2000 user institutions in the healthcare, industrial, research and agricultural sector.

During the year 2010-11, Customer Relationship Cell (CRC) continued serving customers and made it more convenient to customers to interact with the officials of BRIT and regulatory authorities in matters relating to procurement and use of radioisotope products and equipment. The retail outlet for supply of cold kits set up for the benefit of nuclear medicine user institutions in and around Mumbai continued serving customers bringing in a revenue of approximately Rs. 16 lakhs.

The transportation of about 53,000 consignments of radioisotope and allied products, majority of them by air was carried out in a safe manner. Major transportation activities carried out during the year includes movement of kilocurie amounts of radioactive sources from RAPP COF, Kota to Mumbai, Mumbai to Vadodara, Delhi, Vasai and Ambarnath; and teletherapy sources from Mumbai to various cancer hospitals in the country and Gamma Chamber and Blood Irradiator units to various research centres and hospitals.

BRIT website provided information on the products, services and various activities of BRIT. The website continued to provide prompt information on the airway bill numbers for the despatched products and a regular update on the status of radiography cameras besides the important customer oriented messages. Website is updated on a daily basis and includes ordering forms for the customers besides information on scientific aspects. Proposal for making BRIT website GIGW compliant is being finalized with NICSI.

Radioisotopes and allied products supplied by BRIT

| Sr.No | Item | Actual between April-December, 2010 | Expected to be achieved April,2010 – March, 2011 |
|-------|--------------|-------------------------------------|--|
| 1 | Consignments | 42000 | ≈ 53000 |
| 2 | Activity | 850 kilo curies | ≈ 1200 kilo curies |
| 3 | Sale Value | Rs. 4397 lakhs | Rs. 5500 lakhs |

4.14.2. Engineering Services

Engineering services provided the vital infrastructure and utility services to BRIT and BARC facilities at Vashi Complex, Project House at Deonar and ISOMED at Trombay.

Efficient operation & Maintenance of the two 22 KV substations at Vashi complex led to achieve a unity power factor that saved Rs.15 to Rs.20 Lakhs by way of incentive from MSECDL. Services are also provided for maintenance of electrical equipments like window A/cs, lighting fixtures and Telephone exchange. A centralized workshop caters support for minor fabrication and repair requirements. The workshop is equipped with two EOT cranes for the heavy duty material handling. Civil, Cosmetic & Horticultural maintenance and pest control system support is also provided by engineering services.

Status of the Plan Projects

X Plan Projects

BRIT has taken up several projects for execution under the plan project scheme. All these projects have been aimed to enhance its capacity for the development of new products, improvement in quality and also development of infrastructural facilities. Under the X Plan, in the three major projects, progress has been made as given below:

1. Integrated Facility for Radiation Technology (IFRT)
2. Revamping and Augmentation of Infrastructural Facility (RAIF)
3. DAE Medical Cyclotron at Kolkata

1. Project: Integrated Facility for Radiation Technology (IFRT)

Objective of the project is to set up a Hot Cell at BRIT Vashi Complex for handling, storage and fabrication of sealed sources up 300 kCi of Co-60. The financial outlay of the project is Rs. 1805 lakh.

This project is in advance stage of execution as civil construction for administrative building, water pool, Radiometry room and Hot Cell has been completed. Project is expected to be completed as per schedule.

2. Project: Revamping & Augmentation of Infrastructural Facilities (RAIF)

The project is proposed for Revamping and Augmentation of Infrastructural Facilities of BRIT at Vashi to enhance infrastructural support for production facility. The major activities of the project is to procure instruments and equipment for revamping and augmenting production, quality and safety of operations and personnel. Financial outlay of the project is Rs. 1592 lakhs and completion date is March 2010.



Integrated Facility for Radiation Technology (IFRT)



Civil construction for install and operate irradiator is completed and clean room facility has been commissioned. Apart from this procurement of equipment is in progress and Automated Column Scanning system has been procured and also orders for mobile Hot Cell is fabrication and it is being installed. Fabrication of installed and operate irradiator is completed and installation is in progress is in progress

3. Project:: DAE Medical Cyclotron Project: Pharmaceuticals Facility

A medical cyclotron facility is being installed at VECC, DAE, and Kolkata for the production of PET and SPECT radioisotopes to be used for diagnostic and therapeutic purposes. Major equipment including hot cells has been procured. Isotope for establishing procedure for production is being procured.

XI Plan Projects

Apart from the X Plan project here are 5 more projects which are proposed for execution under XI Plan. These projects are aimed towards development of new products, improvement in quality of existing products and improvement in manufacturing processes. One number project "Production facility of medical grade Fission Moly has been added and has been approved.

Brief description of the XI plan projects is given below:

1. Project : Integrator Irradiator Development Project

Estimated Cost: Rs.300 lakhs

Objectives

To upgrade safety and security features in the RPP, Vashi and ISOMED facilities and to set up an Irradiator Training Facility for training of personnel for operation of irradiator.

Progress: Following work has been carried out:

- Access control system installed at Vashi.
- System for vehicle tracking system has been installed
- Early fire warning system for ISOMED is procured
- Aerosol generator has been designed and fabricated
- Pamcrash software for safety evaluation of cask has been procured.

2. Project: Production Facility for $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ Column Generators of High Specific Activity Mo-99.

Estimated Cost: Rs. 750 lakhs.

Objectives.

Setting up of a new automated facility for production of Mo-99 Tc-99m Column Generators using high specific activity Mo-99.

Progress: Automated facility for Mo-99 Tc-99m column generators has been supplied and it is being commissioned.

3. Project: Construction of State-of-the-Art Immunoassay Facility

Estimated Cost: Rs. 205 lakhs.

Objectives.

- a. Development of building up of infrastructure for coated tube technology and state of the art Laboratory with GMP/GLP compliance with a special focus on contract manufacturing.
- b. Development and building up of infrastructure for immunoassay based on non-isotopic labels.
- c. Development of diagnostic kits for infectious diseases.

Progress: Procurement of following equipments needed for development of isotopic/non-isotopic assays has been completed.

- Spectrophotometer
- Dehumidifier
- Multi-well RIA counter
- Laboratory has been refurbished partly

- BT reader
- RO water system
- T3 antibody

4. Project: Construction of State-of-the-Art GLP and GMP

Estimated Cost: Rs. 340 lakhs.

Objectives.

Upgradation of the laboratory for GLP and GMP compliance by following:

- Removal of the existing corroded 20 years old fume hoods, cut and disposal through WMD.
- Installation of new fume hoods
- Wear resistant laboratory flooring of Laboratory.
- Furnish the lab and facelift office for aesthetic look.
- Introduce the state of the art synthesis facility, enhance the analytical evaluation, quality control of the
- labeled compounds. Introduction of microwave synthesis and introduction of instrumental analysis.
- Augmentation of oligo-nucleotides synthesis facility.
- Setting up of state of the art lab for C-14 urea capsule production and
- Setting up of low background counting lab food analysis.

Progress: Following work has been carried out

- Decontamination of working tables and fume hoods in two laboratories is completed
- Order placed for procurement of stainless steel fumehoods (12 Nos), new working tables, flooring, paneling etc.
- HPLC instrument is procured
- UV spectrophotometer and Portable liquid scintillation is procured.
- Refurbishment of Lab is in progress.

5. Project: Indigenous HDR Brachytherapy Equipment (IHDR)

Estimated cost: Rs. 800 lakhs

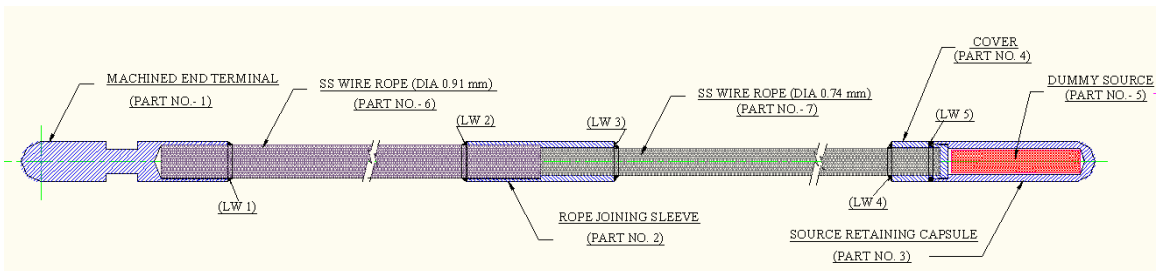
Objectives:

- Establishing the complete process and facilities for fabrication of Ir-192 HDR
- sources for regular production.
- Development of indigenous, remote operated high dose rate (HDR) brachytherapy equipment including necessary treatment.



Progress: Type approval for the HDR source for machine “Karknidon” was obtained from AERB. The classification designation was C53312.

HDR source assembly, which has four miniature stainless steel micro-machined components viz.; machine end terminal, rope joining sleeve, source retaining capsule and cover & two stainless steel wire ropes (dia 0.91 and 0.74 mm). Maximum size of the assembly is Ø1.1 mm and length of 2.1 meters and there are five laser welded joints between SS wire ropes and miniature components.



6. Project : Setting up of facility for production of medical grade Fission Molybdenum.

A new project “Setting up of Medical use Mo-99 production (LEU fission based) facility”, under XI plan has been sanctioned for BRIT by Atomic Energy Commission. This is the single largest project worth **Rs. 128 crore** that has ever been approved for BRIT. Project is scheduled to be completed by 2014. This will enable BRIT to supply fully indigenous column generators to various diagnostic centres and hospitals in the country.