

Annual Report 2005-2006

Board of Radiation & Isotope Technology

Executive Summary

Radiation Technologies & Applications

During 2005-2006, more than 43,000 consignments of various isotope products and 24 x 7 radiation processing services were provided to customers across the length and breadth of the country as well as some located abroad bringing in a sales turnover of Rs. 3300 lakhs.

Healthcare

48000 cold kits for formulation of ^{99m}Tc radiopharmaceuticals; 500 Ci of ^{99}Mo ; 450Ci of ^{131}I were supplied to nuclear medicine centers and cancer hospitals all over the country. A long-felt need of the medical community for an inexpensive alternative to bone palliation agents routinely imported is being fulfilled by the near completion of the development of Samarium ^{32}P Phosphate colloid injection. This is used for the treatment of the disease of joints and is currently being evaluated in multi-centred clinical trials. A new automated remote liquid dispensing system for dispensing radioactive consignments into vials was developed and deployed in the ^{99}Mo production plant. A new Clean Room Class 100 TCK production facility is near completion and will be commissioned in 2006. The clinical trial experiments of ^{14}C -urea capsules at KEM Hospital, Sion, Mumbai was successfully completed and approved by the Radiopharmaceutical committee (RPC) for regular production. Supply of Cs-137 Manual After-Loading Applicators was resumed for the benefit of cancer patients in the country, particularly, those suffering from the cancer of the cervix. Technology for the production of Hydrogel Burn & Injury dressings was transferred to Dr.Reddy's Laboratories, Hyderabad who are going to launch the product in a big way.

Nuclear & Biotechnological Tools

^{14}C - ammonium thiocyanate (500 mCi) and Tritiated Water (75 Ci) were supplied to ONGC for important Oil exploration efforts. High value orders for custom synthesis were executed on schedule to pharma majors. BRIT entered the burgeoning educational market by assembling a bouquet of kits for post-graduate students of molecular biology and biotechnology.

Radioisotope Sources

NDT centers in the country were the major beneficiaries as BRIT is the sole supplier of Ir-192 radiography sources in the country.

Sealed sources of total activity of about 504 kCi were fabricated, processed and supplied for various industrial applications. A 100 kCi ^{60}Co source pencils were exported to Vietnam and loaded into their VINAGAMMA irradiator.

Gamma Radiation Services

The ISOMED plant processed more than 14000 cubic meters of medical products generating a revenue of over Rs. 6.25 crores. The Radiation Processing Plant at Vashi processed about 1500 MT of spices and other allied products to reach a turnover of Rs. 1.5 crore by March 2006.

Radiation Processing Plants in Private Sector

Considerable progress has been achieved in the setting up of Radiation Processing Plants in Private Sector. Three new Gamma Irradiation Plants were completed in the period at Sonapat, Ambernath and Vadodara. Apart from supplying the ⁶⁰Co sources for the new plants, BRIT provides requisite technical guidance and facilitation services (from conception to commissioning stage) to enable the entrepreneurs to commission the plants in a time-bound manner. During this year four more private agencies have signed MOU with BRIT for setting up gamma irradiation plants in different parts of the country.

Customer Support Services Cell

As the nodal agency for sales and supply, marketing and customer relations, Co-ordination & logistics support were provided 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.

The transportation of about 43,000 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 RAPPCOF, Kota to Mumbai, Mumbai to Vadodara and Mumbai to Ambernath . Teletherapy sources from the hot cells in Trombay were supplied to various cancer hospitals in the country. New Gamma Chambers and Blood Irradiator units were supplied to various research centres and hospitals and a few of them were replenished with Co-60 sources.

Radioisotopes and allied products supplied by BRIT

Sr.No	Item	Actual between April-December, 2005	Expected to be achieved April,2005 – March, 2006
1	Consignments	31788	≈ 43,000
2	Activity	371 kilo curies	≈ 670 kilo curies
3	Sale Value	Rs. 2342 lakhs	Rs. 3300 lakhs

Test Facility for Type B(U) Packages

This facility for transport packages upto 10 ton capacity for 9m drop, punch and thermal tests has been set up at ARAI, Pune. Different units of DAE will find it useful for qualification of the packages for ensuring safety during transportation in the public domain.

ANNUAL REPORT 2005 - 2006

BOARD OF RADIATION AND ISOTOPE TECHNOLOGY

Descriptive Part

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 South Site, BARC ; 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 Regional Centres for Radiopharmaceuticals (RCR) located at Bangalore, Delhi and Kolkata and RIA Centre at Dibrugarh.

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

Healthcare

Radiopharmaceuticals

5250 consignments of ready to use radiopharmaceuticals of Iodine-131, Phosphorous-32, Chromium-51 and Samarium-153 were supplied to various Nuclear Medicine centers. Majority of these contained Iodine-131 radiopharmaceuticals, which amounted to about 450 Ci. 2526 consignments; 500 Ci of Mo-99 (TCM-2) was supplied for extraction of Tc-99m at hospitals. In addition to this various accessories of Tc-99m-Solvent extraction generator system and other products were supplied. About 48000 Cold Kits for formulation of Tc-99m radiopharmaceuticals (Code-TCK; 11 products) were supplied to various Nuclear Medicine centers.

A very important product useful in treatment of disease of joints has been developed namely Samarium ³²P Phosphate colloid- injection and is currently being evaluated in multi-centred clinical trials.

During this year there has been no major cancellations or disruptions in the scheduled supply of radiopharmaceuticals even during the week of heavy monsoon in July-2005.

A new automated remote liquid dispensing system, for dispensing radioactive consignments into vials has been developed and commissioned in Mo-99 (TCM-2)

production plant. Till now more than 2000 consignments have been supplied to users , which were processed using this automated system and the performance has been found to be error free. A new Clean Room class 100, TCK production facility is near completion and will be commissioned in 2006.

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

Facility for handling of radioactive raw material - ⁹⁹Mo transport container and transfer of ⁹⁹Mo inside shielded processing cell has been completed, sliding door in connecting tunnel rectified, desired vacuum achieved, the facility has been utilized continuously during cold trials. Difficulties that cropped up in initial test trials have been tackled successfully. Redesigning and fabrication of certain process vessels as per requirement have been completed. Extensive cold trials conducted & data collected and analyzed. Compliance w.r.t. radioactivity handling has been achieved (regarding total facility). Safety analysis report submitted, subsequently clearance for low activity ~74 GBq (~ 2 Ci) handling has been obtained from AERB. Design improvements were incorporated in Gel generators for ease of assembly /dismantling/ reuse. 25 pieces have been modified to cater to initial requirements. System integration, testing and evaluation of all the in cell equipments of the processing plants are in progress and nearing completion. Low-level radioactive runs are to be commenced after implementing certain regulatory requirement suggested by AERB which will be completed in a month or so.

Nuclear Medicine : Diagnostic & Treatment Service

Nearly 9250 kits of RIA and IRMA were supplied during the year to 300 immunoassay laboratories throughout the country.

Free T₄ kits (based on coated tubes) and HCG IRMA kits (based on magnetizable particles) have been cleared by RPC and will be launched in the market shortly.

The Regional Radiopharmaceutical centres located at Bangalore and Delhi processed ready-to-use ^{99m}Tc radiopharmaceuticals for use in the host medical centres apart from supplying the products to other hospitals in the region. RCR, Bangalore carried out 3750 investigations and supplied 5500 mCi of ready to use formulations. 3150 blood bags were irradiated. The Bangalore centre also organized 3 workshops on Radioimmuno Assay techniques and demonstrated the efficacy of the low dose Irradiator for deployment in mutation research at the University of Agricultural Sciences.

RCR, Delhi produced 60000 mCi of ready-to-use ^{99m}Tc radiopharmaceuticals. The center also completed the IAEA research project “ Standardization & Quality Control of in-house formulation of ^{99m}Tc DMSA in tumor imaging and assessment of tumor biology”.

Apart from carrying out R & D work related to PET radiopharmaceuticals, the Radiopharmaceutical Lab of BRIT at VECC, Kolkata is actively involved in the setting up of the radiopharmaceutical production facility of the DAE Medical Cyclotron project. The RIA centre of Dibrugarh continued to provide RIA and IRMA diagnostic investigations to the poor and needy patients in the region.

Nuclear & Biotechnological Tools

Labelled Compounds

Labelled Compounds Laboratory (LCL) group continued the synthesis and supply of a variety of ^{14}C -, ^3H - and ^{35}S -labelled products of high quality and specific activity in addition to the assembling/preparation and supply of ready-to-use non-radioactive (cold) kits and oligonucleotides to users in various research institutions/universities who are involved in diverse investigations in the fields of biology, agriculture, medicine and chemistry as per orders received. The group also completed the production and supply of tritium-filled self-luminous sources and tritium-titanium suspension as per orders received.

The major achievements during the year are as follows:

The clinical trial experiments of ^{14}C -urea capsules at KEM Hospital, Sion, Mumbai was successfully completed and the approval of RPC for its regular production and supply was received.

^{14}C -ammonium thiocyanate (500 mCi) and tritiated water (75 Curie) were synthesized and supplied as per order.

High value custom-synthesis of ^{14}C -labelled compound for a pharmaceutical firm was successfully completed and the product supplied in time.

The procedure and protocol for assembling of 7 molecular biology teaching kits were standardized and they are being launched as new products in the market for the benefit of post-graduate students in the molecular biology/biotechnology stream.

R&D activities were carried out as before for (i) adapting new methods (ii) increasing yield (iii) enhancing quality (iv) standardizing preparative procedures for new labelled products being taken up on custom-synthesis basis.

Sodium lauryl - ^{14}C sulphate, acetyl- ^{14}C - coenzyme-A, chloramphenicol diacetyl- ^{14}C and ^{14}C -PNP also were custom-synthesized for the first time for supply to users.

This year, BRIT received a few enquiries for the custom-synthesis of specific ^3H - and ^{14}C -labelled products, mainly from the pharmaceutical houses and we are in the process of completing the formalities for the synthesis and supply of these products, after receiving confirmed orders.

A three day workshop on 'The Uses of Radioisotopes in Biology' was organized & conducted by BRIT in Dolphin Institute of Biomedical & Natural Sciences at Dehradun in Uttaranchal, during Nov 25-27, 2005. A one day workshop on 'Applications of Radioisotope Tracers in Oil Field Investigations' was jointly organized by BRIT & ONGC at 6th April 2005.



Inauguration of Workshop on 'Applications of Radioisotope Tracers in Oil Field Investigations' organized by BRIT & ONGC.

10 scientific papers based on the R&D work carried out on the radiosynthesis of compounds labeled with ^{14}C or ^3H were accepted for publication in international journals/presentation in symposia.

The sales value (revenue) for the year crossed a record Rs. 1 crore for the first time in the history of LCL which augurs well for planning ahead as far as the performance and progress of the group is concerned.

JONAKI Laboratory at CCMB Campus, Hyderabad

JONAKI laboratory at Hyderabad supplied more than 1850 consignments of 1100 mCi of P-32 and 40 mCi of P-33 labelled nucleotides to 35 research institutes. Also, 3 enzymes which are not commercially available and which are required for production of P-32 and P-33 labeled nucleotides were standardized and prepared for in-house use.



JONAKI, Hyderabad

Quality Control Programme

Quality control testing and analysis was carried out on all ready to use radiopharmaceuticals, generator based products, RIA/IRMA kits, inactive raw materials and active raw materials. Up-gradation of the facilities was constantly done by installation of the latest state-of-the-art equipment wherever possible and also by preparing up-to-date monographs for all products being tested.

Nuclear Medicine: Cancer diagnostic & treatment services

Six teletherapy sources had already been sold upto December 2005 and it is expected that eight sources of total activity of 75.6 KCi will be supplied to Cancer Hospitals in India fetching a sale value of Rs. 1.98 Crore by March 2006. 42 meters of ^{192}Ir -Pt wire is expected to be prepared and supplied to various hospitals and medical research centres for the treatment of cancer. 3 nos of ^{137}Cs manual after-loading brachytherapy kits were supplied.

Technology Transfer of Hydrogel Burn & Injury Dressings

Technology for production of Hydrogel based Burn & Injury Dressings which is developed by BARC has been transferred to Dr. Reddy's Laboratories, Hyderabad for large scale implementation of it for the benefit of the society. An agreement for this was signed on April 19, 2005. This technology has earlier been transferred to another party in Vadodara.



Signing of Technology Transfer Agreement between Dr. Reddy's Lab and BRIT for Hydrogel based Burn & Injury Dressings

Industrial Applications:

Radioisotope Sources.

During the year 2005-2006, sealed radiation sources of total activity of about 504 kCi were fabricated, processed and supplied for use in various types of industrial applications. An export order for supply 100kCi ^{60}Co source to Vietnam for radiation processing applications was executed during this year. More than 730 nos of ^{192}Ir radiography sources of about 29 kCi total activity were fabricated and supplied for use in NDT. About 120 nos of custom made ^{60}Co , ^{137}Cs , ^{170}Tm and ^{46}Sc sources were fabricated and supplied for use in radiography, nucleonic gauges and other industrial applications during the year. 592 kCi ^{60}Co was transported from RAPP COF, Kota upto December 2005 and another 500 kCi is expected to be transported by March 2006.

Gamma Radiation Processing Services (GRPS)

Radiation Sterilization Plant for Medical Products (ISOMED)

ISOMED continued to offer prompt and efficient gamma sterilization services to large numbers of customers spread all over the country. About 14000 cubic meters of different types of products were sterilized during the year. The plant availability factor and plant utilization factors were maintained well above 85% and 80% percent respectively through meticulous planning of operation and regular servicing/maintenance schedule of the facility by a team of experienced and dedicated staff members. The revenue generated for the current year is over Rs. 6.25 crores.

Radiation stability testing of materials and equipments was carried out at ISOMED for various DAE units such as NPCIL, BARC, ECIL etc. to assess their suitability for use in various nuclear installations.

Ceric-cerous sulphate dosimeters for routine dosimetry and dose mapping studies and biological indicators using *Bacillus pumilus* spores for microbiological monitoring were produced at ISOMED. These products were also supplied to other irradiation facilities in the country. ISOMED provided the manpower training to those organizations who are in the process of setting up new radiation processing facilities in the country.

Local Safety Committee meetings were held periodically to discuss, review and improve the radiation and operational safety status of the plant.

Expert services for plant commissioning dosimetry were extended by BRIT to M/s A V Processors, Ambarnath and M/S. Universal Medicap, Vadodara during the commissioning of their new gamma irradiation plants.



ISOMED

Radiation Processing Plant, Vashi (RPP, Vashi)

The plant continued offering its radiation processing services to all its customers from all over the country. Approximately 1500 MT of spices and allied products were processed during April to November 2005 earning a revenue of Rs. 8.5 lakhs. It is expected to earn a total revenue of Rs, 1.5 crore during revenue year 2005-2006.



Radiation Processing Plant, Vashi

Radiation Processing Plants in Private Sector

Considerable progress has been achieved in the setting up of Radiation Processing Plants in Private Sector. Three new Gamma Irradiation Plants were commissioned in the period at Sonapat, Ambernath and Vadodara. Apart from supplying the ^{60}Co sources for the new plants, BRIT provided requisite technical guidance and facilitation services (from conception to commissioning stage) which enabled them to commission the plants in a time bound manner. During this year four more private agencies have signed MOU with BRIT for setting up gamma irradiation plants in different parts of the country.



A.V. Processors Ltd., Ambernath Plant Dedication Ceremony.



Inauguration of M/s Universal Medicap Ltd's Radiation Processing Plant at Vadodara

Accelerators

All the components like chains, tracks, carts etc., of Toweyor conveyor meant for the 10 MeV Electron Beam Accelerator facility at Khargar, Navi Mumbai have been received at site. Installation of the conveyor is in progress.

Radiation Technology Equipment

Gamma Chamber GC 5000:

During the current year, the production and testing of three new GC 5000 units each loaded with about 12,000 curies of ^{60}Co source has been undertaken for installation and commissioning at the Food Technology Division of BARC; Agricultural University, Trichur and The Central Glass & Ceramic Research Institute, Kolkata.



GAMMA CHAMBER 5000

Radiography Camera ROLI-1

25 New ROLI cameras were supplied during the period resulting in sale value of Rs. 36 lakhs. 275 ROLI-1 cameras were serviced during this period.

Blood Irradiator

The programme of production & supply of Blood Irradiator BI 2000 has been pursued further. During the year, 4 nos of new Blood Irradiator units were fabricated, source loaded and tested for installation and commissioning in hospitals and research institutions.



BLOOD IRRADIATOR

Install & Operate Irradiator

This new design of batch type captive radiation processing plant can be integrated into the production line and would prove to be very much useful for small agencies for the radiation processing of products such as marine frozen, chicken, mutton etc. The tender order is placed on M/S. Danver Hydromatics and the manufacturing of components is to start immediately. Tender has also been floated.

Source Housing of large container gamma scanning

Tender for the fabrication of source housing of large container gamma scanning was floated and is being manufactured at M/S. Friends Industry.

Source Changer for Camera

A multi-position Source Changer has been designed to facilitate radiography source loading at places other than Trombay. Two prototypes have been fabricated.

Development of Category III irradiator

An irradiator of Category III is under development. In this, the source pencils are to be arranged in a two-tier rectangular frame. The maximum source strength as well as the

4.14.2.Engineering Support Services Unit (ESSU)

Engineering Support Services Unit (ESSU) provided the vital infrastructural and utility services to BRIT and BARC facilities at Vashi Complex. Provision of uninterrupted electrical power, air conditioning and ventilation services on continuous basis to the radioactive laboratories, civil and public health services and communication services in Vashi complex are the major challenges faced. Quality service provided by the ESSU have enabled the production units to meet the production and supply schedules as planned.

IX Plan Projects of BRIT

1. Augmentation of Cobalt handling Facility at RAPPCOF (ACHF) , Kota

This project envisages to recover upto 2.5 Megacuries of Cobalt-60 per year and to fabricate sealed sources of 1 MCi per year for use in Irradiation Plants.

The summary of the important activities which were carried out during the year 2005 – 2006 include :

Electrification and ventilation jobs which are expected to be completed by January 2006. Execution of EOT and In cell cranes has been completed. Load Testing of cranes will be conducted by end January. Installation of shielding windows, MSMS lead packing etc., is envisaged to be completed shortly.

2. Design, Development of Radiation Equipment and Test Facility (DDRE&TF)

This project was given financial sanction in July 99 with project outlay of Rs. 850 lakhs. This project has two parts. First part is Design and Development of Radiation Technology Equipment (Blood Irradiator and Depleted Uranium Cameras) & 2nd part is Design and construction of a 10 Ton capacity Test Facility for Type B(U) radioisotope Package testing.

The first part of the project has been completed except fabrication of 5nos. of BI-2000 units which is expected to be completed by Mar.2006. Already 13 nos of BI-2000 have been supplied to various institutions in the country out of 25 nos. which have been fabricated.

The second part is Design and Construction of the 10 Ton capacity Test Facility. In this connection BRIT entered into an MoU on 6th Feb, 2004 with M/s ARAI for construction, operation & maintenance of Test Facility after getting approval from DAE. Design and construction of a 10 Ton capacity Test Facility for Type B (U) package at ARAI, Pune is completed and commissioned in Dec.2005. This was inaugurated by Chairman DAE in ARAI, Pune on 4th Jan. 2006.



Inauguration of Test Facility for Type B (U) package at ARAI, Pune

X Plan Projects of BRIT

1. Integrated Facility for Radiation Technology (IFRT)

The objective of this project is to set up a Hot Cell (max 300 kCi of Co-60) and its associated facilities for handling radioactive sealed sources* for Radiation Technology Equipment and Irradiators. Project outlay is Rs 910 lakhs and the expected date of completion is March, 2007.

The progress of the project is as follows :

- Design of Hot cell and its associated systems along with plan layout have been Completed
- Site clearance from AERB is obtained.
- Site development work is in progress including Investigation of Geo Technical parameters.
- Order placed for major components such as Radiation Shielding Window, MSM, Steel shielded door etc
- Fabrication & supply of all service sleeves including External Transfer Drawer have been completed
- Revised DBRs for civil construction as per new IAEA Tecdoc- 1347 is prepared & submitted to AERB committee & discussion for their approval is in progress.
- Architectural and civil engineering drawings completed and ready for tendering subject to AERB approval for civil construction.
- There is proposal to upgrade the scope of the project i.e operation of the Hot cell to carryout fabrication of Sealed sources also which is presently limited to only handling of sealed sources as envisaged in the project report to meet future requirements. A review of additional work/cost to meet this is in progress.

2. Revamping & Augmentation of Infrastructural Facilities (RAIF)

The objective of the project is to enhance infrastructural support for production facilities at Vashi Complex including construction of some additional area both for medical as well as engineering products. During the year 2005-2006 a new pharmaceutical standard clean room facility is completed and the revalidation process is in progress. Procurement of 1250 kVA, 22/10, 33 kV transformer has been completed. Civil construction of QA/QC laboratory, administrative building, conference hall and the RPL extension is in progress. Automation of remote radioactive dispensing has been carried out. Fabrication order for install & operate irradiator has been placed. Various safety equipments have been procured under this project.



Clean Room Facility at RPL

3. DAE Medical Cyclotron at Kolkata – Processing Facility for Cyclotron produced Radioisotopes and Radiopharmaceuticals

BRIT is entrusted with the following responsibilities in the DAE Medical Cyclotron Project

Setting up of Radiopharmaceutical processing laboratory including hot cell facility.

Procurement, installation and commissioning of requisite laboratory accessories, instruments, hot cell and laboratory equipment, provision of manpower for laboratory, arranging for AERB and other regulatory approvals etc.

Regular production & supply of cyclotron based radiopharmaceutical products after commissioning of the Medical Cyclotron.

The following activities were carried out with respect to the project during the period of this report :

1. Proposal for the sanction of additional manpower has been submitted to DAE. Plans for deployment of staff from the existing staff of BRIT is being made.
2. Visits to installations/ factories of potential bidders have been completed.

3. Technical evaluation of the offers received from the bidders has been completed and recommendation for purchase has been submitted to the steering committee for this project.
4. Price negotiation with vendor has been completed
5. Order for the cyclotron and the associated radiochemistry systems is expected to be placed in the next two months.