

Chapter 4 – Audit findings from specific projects

This Chapter highlights some of the significant audit findings from specific projects, such as delays in establishment of infrastructure required for the projects, injudicious procurements, inadequate planning, incomplete activities, inadequate co-ordination, etc.

4.1 Unproductive expenditure in executing a project without requisite infrastructure

CDRI took up (October 2003) a network project titled 'Animal models and animal substitute technologies' with a sanctioned cost of ₹33.43 crore. One of the objectives of the project was development of internationally acceptable models to study human genes/diseases. Development of new drugs involved mandatory pharmacology and toxicology studies, which have to be done on internationally acceptable models and guidelines. For this, Good Laboratory Practices²¹ (GLP) accreditation of its laboratories was a necessary condition.

The project was completed (March 2007) after incurring an expenditure of ₹30.56 crore. Audit observed that though 41 technologies were developed under the project, none could



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be submitted to international agencies as the tests were carried out in facilities of CDRI that did not have GLP accreditation. Although CDRI had planned (May 2003) to set up a world class drug institute (duly GLP accredited) through another network project during 2004 to 2008, but the project on development of animal models and animal substitute technologies was already

completed before the said institute could be developed. The new drug research institute was still under development (July 2012).

Thus, injudicious decision to take up the project without having required GLP accredited facilities rendered expenditure of ₹30.56 crore unproductive from international acceptance perspective.

²¹ Many international regulatory agencies require GLP accreditation from international agencies such as Organisation of Economic Co-operation and Development, France. Good Laboratory Practices include factors such as proper recording of data, proper maintenance of equipment, proper sample collection and preservation, purity of reagents, proper laboratory safety and analytical quality control.

CSIR stated (July 2012) that effective use of these models for the ongoing drug development programme of CSIR would enable development of new drugs. The reply needs to be viewed in the context that for getting international acceptance, the models would need to be re-developed in GLP accredited laboratory.

4.2 Unfruitful expenditure due to non-utilisation of equipment

CRRRI undertook (August 2003) a project titled ‘New and improved road technologies’ at a sanctioned cost of ₹23.92 crore. The project had four²² activities further sub divided into 12 components. Audit observed that equipment procured at cost of ₹14.05 crore remained unutilised, as discussed below:

4.2.1 Under the activity on road materials and construction techniques, CRRRI was to establish Accelerated Pavement Testing Facility²³ (APTF). CRRRI had initially proposed (2002) to establish stationery type APTF, but a High Power Expert Committee recommended (October 2004) procurement of Mobile type APTF instead of stationary type, for its advantages.



Accelerated Pavement Test Facility

CRRRI placed (February 2007) purchase order for equipment at a cost of ₹13.37 crore. The equipment was delivered in January 2010 and commissioned in April 2010. In the meantime the project was declared as completed (January 2010). Audit observed that APTF was not deployed on site for testing of pavements even as of July 2012.

Thus APTF procured at a cost of ₹13.37 crore could not be established till closure of the project and even beyond, thereby rendering expenditure of ₹13.37 crore as unfruitful for the project.

CSIR accepted the delay and stated (July 2012) that delay was on account of deployment of teams for pre-shipment factory acceptance test and training, re-tendering in selection of transporter and creation of infrastructural facilities.

²² (i) Road materials and construction techniques; (ii) Highway system planning and management; (iii) Environment and Transport management and (iv) Indigenous development of instrumentation for road transport.

²³ APTF is a facility to evaluate performance of a pavement in reduced time duration. Desired specifications could be tested within three to six months as compared to 10 to 20 years in normal conditions.

4.2.2 CRRRI installed (August 2006) Advanced Parking Lot Management System (APMS) costing ₹67.90 lakh at NDMC²⁴ parking lot in Palika Bazar, New Delhi. Audit observed that APMS was installed without receiving any formal request from NDMC or any formal agreement with NDMC.

NDMC subsequently requested (March 2009) CRRRI to allow it to retain APMS at said parking lot free of cost. As CSIR procedure did not allow the transfer of system free of cost, CRRRI did not agree with the request of NDMC and removed the system from the Palika Bazar parking lot. The equipment was taken out but could not be used further and was eventually rendered unserviceable.

Thus, injudicious decision to install APMS at NDMC parking lot without obtaining its consent in advance resulted in wasteful expenditure of ₹67.90 lakh.

CSIR stated (July 2012) that concerted efforts were made by CRRRI to sign MoU with NDMC but the same could not be achieved.

4.3 Poor planning of project leading to incomplete activity

CSIR took up (April 2004) the network project titled 'Discovery, development and commercialisation of new bio-actives and traditional preparations' at a cost of ₹39.60 crore. One of the main objectives of the project was to develop single molecules as drugs and take them to IND²⁵ state for diseases of interest to India and international community. Major components in this regard were collection of single molecules, *in vitro*²⁶ and *in vivo*²⁷ tests, fractionation, optimisation and regulatory pharmacology and toxicology investigations. In order to carry out these studies, CSIR planned to create test facilities such as automated microscopic facilities, super critical extraction facilities, molecular modelling workstations, automated fractionation facilities, *in vitro* and *in vivo* screening facilities, etc. under the same project during 2004-05 to 2006-07 at an estimated cost of ₹23.60 crore.

The project was completed (March 2008) after incurring expenditure of ₹32.77 crore. Audit observed that though CSIR developed five single molecules for conditions of dementia, hypertension, psychosis, cancer and immunostimulatory disease, none could be translated to IND stage as essential studies on the single molecules could not be completed due to lack of above specialised facilities or expertise.

²⁴ New Delhi Municipal Corporation

²⁵ IND refers to Investigational New Drug, which is a new drug that is used in a clinical investigation. IND program is the means by which approval for clinical trials on the drug is obtained before it is cleared for marketing application.

²⁶ Related to processes taking place outside a living organism e.g. in a test tube

²⁷ Related to processes taking place within the living organism

The decision to include development of single molecules for IND stage in the network project when specialised facilities for conducting the studies were still under development reflected deficient planning.

CSIR stated (July 2012) that desired facilities were created and the molecules were under different stages of investigations. The reply of CSIR indicated that work was not completed as of July 2012, i.e. after more than four years of completion of the project.

4.4 Failure to take ethical clearance for studies on human subjects

In case of projects that require tests on human subjects, Government rules²⁸ stipulate that clinical trials on a new drug shall be initiated only after approvals have been obtained from the Ethics Committee.

CCMB undertook an activity under the project titled 'Asthma and Allergic Disorders Mitigation Mission' to carry out determination of the genetic basis of asthma and study of genetic interactions between causative agents and concerned genes with a view to adopting predictive measures and develop predictive medicines related to asthmatic and allergic disorders. The activity required collection of bronchoalveolar lavage fluid from patients.

Audit observed from the project proposal that CCMB did not take clearance from Ethics Committee prior to taking up the activity, which was in contravention of Government rules.

While carrying out studies, CCMB faced problems due to ethical considerations. The main objective of adopting predictive measures and development of predictive medicines for asthma and allergic disorders was not achieved, as functional validation of genes could not be completed, rendering expenditure of ₹2.21 crore incurred on the activity as unfruitful.

CSIR stated (July 2012) that CCMB faced problems with collection of bronchoalveolar lavage fluid from patients which could not be anticipated while formulating the project proposal. The reply of CSIR needs to be viewed in the context that genetic studies and development of medicines was a planned objective of the activity.

4.5 Incomplete activities under projects

Audit observed that status of completion of activities reported in the consolidated project completion reports of two projects was incorrect. In another project, objective of an activity was not achieved, reportedly due to deficient manpower, which was a fact already known to the laboratory. The cases are discussed below:

²⁸ Para 2 (1) of Drugs and Cosmetics (II Amendment) Rules 1945, which made (January 2005) approval from Ethics Committee mandatory in clinical trials on human subjects.

4.5.1 NAL undertook (February 2005) a project titled ‘Developing and sustaining high science and technology for national aerospace programme’ at a sanctioned cost of ₹80.70



crore. The objective of the project was to undertake planned research and technology development for national aerospace sector. The project work was divided into 48 activities, of which five²⁹ activities were implemented in networking mode along with four³⁰ participating laboratories. Audit reviewed all five activities that were executed in network mode. Though

consolidated project completion report declared that only one networked activity viz. development of cockpit display systems had not been completed, audit observed that two more activities in addition to the above also remained incomplete. The cases are discussed below:

Incomplete activities under project on ‘Developing and sustaining high science and technology for national aerospace programme’

Development of rolling element bearing standards for aerospace application

NAL and CMERI jointly undertook above activity at an estimated cost of ₹61 lakh with objective of developing reliable methodology to measure quality of rolling element bearings in terms of fatigue and wear life. CMERI received (August 2007) funds of ₹30 lakh for procurement of equipment. Due to late release of funds, CMERI requested CSIR to carry forward the funds up to September 2008. CSIR however did not respond to the request of CMERI. The project activity was closed (March 2008) and CMERI surrendered the amount of ₹30 lakh (March 2008). The Activity Completion Report stated that majority of the work experimentation could not be done as CMERI was unable to manufacture and integrate the test rig owing to late release of funds.

CSIR stated (July 2012) that the testimonials of the project required consideration before arriving at any conclusion on non-achievement of objectives. The reply of CSIR was interim and completion report of the activity clearly mentioned that the objective had not been achieved.

Process technology optimisation for aerospace application

NAL undertook (March 2005) above activity on design, synthesis and characterisation of light weight high performance alloys and composites for development of various aerospace components jointly with AMPRI at sanctioned cost of ₹2.01 crore. The project was completed (March 2008) after incurring an expenditure of ₹1.38 crore. Audit observed that die design, development and performance evaluation of components was not completed.

AMPRI stated (January 2012) that due to some practical difficulties, materials development took a long time during project implementation leaving no scope to conceive and develop suitable component. CSIR did not offer comments on the issue (November 2013).

²⁹ (i) Development of rolling element bearing standards for aerospace applications; (ii) Process technology optimisation for aerospace application; (iii) Development of wind tunnel models using time compression technologies; (iv) Development of cockpit display systems and (v) Multi instrument monitoring to improve prediction- GPS

³⁰ CMERI, AMPRI, CSIO and NPL

4.5.2 With a view to exploring secondary raw material and energy resources and development of innovative construction technologies for sustainable development of building sector, CBRI undertook a project titled ‘Developing New Building Construction Materials’ along with 11³¹ participating laboratories at a sanctioned cost of ₹23 crore. The project was completed (March 2007) with expenditure of ₹19.34 crore.

Work under the project was divided into 36 activities. Audit observed that though consolidated project completion report stated that all activities were successfully completed, five activities actually remained incomplete, as discussed below:

Incomplete activities under project ‘Developing New Building Construction Materials’

<p>Bulk utilisation of industrial solid wastes for production of aggregates and cement clinker</p> <p>The above activity was taken up jointly by CBRI and IMMT. The activity involved evaluation of raw materials like fly ash, pond ash, bottom ash and mill reject coal of thermal plant and process optimisation on five kg scale followed by up scaling to 50 kg scale and commissioning of pilot facility of 100 kg per batch. Audit observed that the activity could not be completed as quantity of samples produced by IMMT was only 35kg which was not sufficient.</p>
<p>Development of corrosion resistant coating system for reinforcing steel rebar</p> <p>The activity was carried out by CECRI. It involved development of corrosion resistant coating system for protection of steel reinforcement bars embedded in concrete structures and its evaluation through short term and long term field exposure tests. CECRI stated in its activity completion report that the objective of long term field exposure tests for assessing the durability of coating could not be completed due to unforeseen delay in standardisation and selection of effective coating system.</p>
<p>Wood substitutes from agro industrial wastes with polymeric binder</p> <p>The activity was taken up by NEIST with an objective to develop a technology for making building construction material from polymeric and agro-industrial wastes as a substitute for timber. It was seen from the activity report that process technology for developing wood substitutes was developed at laboratory scale, but pilot scale trials were not done due to non-availability of machines required for making bigger samples.</p>
<p>Cement/Polymer based building boards from bagasse</p> <p>The activity was undertaken by CBRI with objectives of developing building boards using bagasse and developing door shutter from these building boards. It was seen from the activity report that the objective of development of door shutter was not achieved as the activity was foreclosed.</p>
<p>Development of high performance smart concrete</p> <p>The activity was undertaken by CRRI with objectives of developing an alternate for silica fume and development of high performance smart concrete. Activity completion report of CRRI stated that the latter objective was not achieved due to time and manpower constraints.</p>

³¹ CGCRI, CIMFR, CECRI, CRRI, IICT, NML, AMPRI, IMMT, IIIM, NIIST and SERC

Thus the consolidated project completion reports showed inaccurate account of the status of completion of activities in above projects.

CSIR did not comment on the above issue (November 2013).

4.5.3 CEERI undertook (January 2004) a project titled 'Developing capabilities for micro electromechanical systems³² and sensors' at a sanctioned cost of ₹31.71 crore. The project had six³³ activities. Under an activity, CEERI and AMPRI were to develop micro pump, valves, cells and micro channels of different kinds and to integrate them to realise a micro total analysis system on a chip.

It was seen from the project completion report that objective of this activity was not achieved as AMPRI was unable to develop micro pump, micro valves, reservoirs, mixing and PCR channels, reportedly due to death (August 2003) of the activity leader.

Audit, however, noticed that this fact was known to AMPRI much before the project actually commenced (January 2004).

CSIR stated (July 2012) that systems which were not developed by AMPRI, were not required as the analysis of fluids using electrophoresis was successfully done. The reply of CSIR was not acceptable because stated objective of the activity was to realise a micro total analysis system which was not achieved.

Recommendation 8:

CSIR may ensure that resources required for a particular project are planned in advance and optimally utilised so as to avoid adverse impact on outcome of project.

³² Micro-electromechanical Systems (MEMS) consist of micro-components, which experience force due to physical, chemical or biological phenomena and produce electrical stimuli in response to the respective changes caused in their mechanical characteristics. This whole sequence is utilised in making a miniaturised sensor. Miniature sensors and actuators are emerging very fast because of their ever increasing applications in diverse fields.

³³ Development of Polymer Composite Gas Sensor, Ion Sensitive FET Sensor, MEMS Technologies, μ -heater Embedded Gas Sensor, μ -cantilever Beam Array, μ -TAS