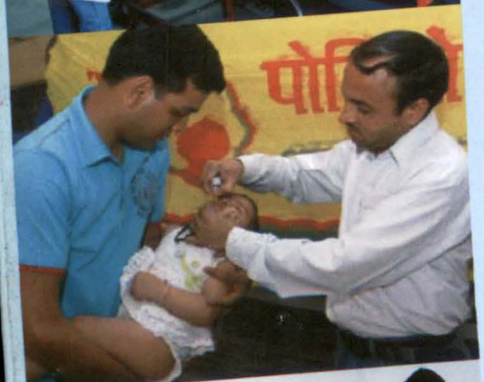

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Performance Audit of

National Institute of Biologicals (NIB)

(Ministry of Health and Family Welfare)

Report of the Comptroller and Auditor General of India

Union Government (Civil)
Autonomous Bodies
No. PA 30 of 2008-09
(Performance Audit)

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Comptroller and Auditor General
of India
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PREFACE

This Report of the Comptroller and Auditor General of India for the year ended March 2008, containing the results of the performance audit of National Institute of Biologicals, has been prepared for submission to the President under Article 151 of the Constitution.

The performance audit was conducted through test check of the records of National Institute of Biologicals pertaining to the period 2003-04 to 2007-08. Information from the Ministry of Health and Family Welfare and the office of the Drug Controller General of India was also sought, where required.

Chapter I : Executive Summary and Recommendations

1.1 Executive summary

Even after 16 years of its inception and expenditure of Rs. 256 crore, which was 95 *per cent* of the total project cost, the National Institute of Biologicals (NIB) could not fulfill its role of ensuring availability of safe and good quality biological products for consumption in India. NIB could not achieve its intended objectives of systematic examination of the quality of biologicals, development of national reference standards and human resource development in the field of biologicals. As a result, in spite of the establishment of a vast infrastructure, several batches of biological products continued to be released without independent quality assurance testing. In the case of imports, the country was compelled to rely essentially on claims of safety, potency and efficacy made by foreign manufacturers/ drug regulatory authorities of other countries.

NIB did not deploy Good Laboratory Practices compliant processes and procedures. Serious scientific lapses and malpractices were observed during audit. NIB was certifying blood products stating compliance with requirements of the pharmacopoeia without carrying out critical tests required under the pharmacopoeia. For example, it had certified many batches of immunoglobulin, a life-saving drug, without carrying out tests to ascertain whether the biological was actually immunoglobulin; whether it was safe for use and would not lead to abnormal toxicity and fever when administered and whether it would remain stable under given temperature conditions.

Owing to complaints regarding large scale irregularities in testing and reporting of results, the Ministry stopped the testing of biologicals by NIB in July, 2007 and forbade all subordinate offices of the Drug Controller General of India {DCG (I)}to send samples to NIB for testing. Despite this, some subordinate DCG(I) offices continued to send samples to NIB for batch release certification, rendering such testing irregular. Most of the samples received by NIB after July, 2007 were sent by one particular subordinate office of DCG(I) and belonged to one particular manufacturer/company.

One of the main reasons for under-performance of NIB, in addition to the above-mentioned lapses, was non-deployment of commensurate human and physical resources for timely achievement of intended objectives. This, coupled with undue delays in decision-making and lack of coordination and proper planning, led to delays in construction of infrastructure and inefficient management and utilization of available resources. Despite the completion of the main Laboratory Building and Animal House in February, 2006, only 75 persons were deployed in NIB as of October, 2008, against the assessed requirement of 363.

The procurement process followed by the institute did not ensure sufficient competition and was marred with irregularities. Equipment was procured without proper assessment of actual requirements and care to stagger purchases in tune with anticipated usage, leading to poor or no utilization of costly equipment. This resulted in wasteful deployment of funds in procurement and unfruitful expenditure on idle maintenance for long spells of time. About 88.5 *per cent* of the total fixed equipment installed in NIB was lying unutilized. The warranty periods of most of the fixed equipment had lapsed even before they were put to use.

Only one meeting of the General Body and three meetings of the Governing Body were held against 15 such meetings mandated under the Rules and Regulations of NIB during the five-year period reviewed by Audit. Deficient control and oversight over the performance of NIB deprived the Ministry of opportunities to address NIB's shortcomings and deficiencies in time.

1.2 Recommendations

- NIB should conduct all the crucial tests in accordance with the concerned pharmacopoeia so that the quality of biologicals is ensured before release in the market.
- Concerted efforts should be made for development of human resources in the field of biologicals and immunobiological products through proper training of scientific and technical personnel. Besides, efforts should be made for dissemination of knowledge through networking and linkages with national and international institutes.
- The Ministry and NIB should ensure deployment of sufficient scientific and technical manpower commensurate with the available infrastructure in NIB in a time-bound manner.
- NIB should systematize its procurement procedures and make proper assessment of the actual requirements of equipment before procurement. Besides, concerted efforts should be made to ensure proper utilization of the procured equipment.
- The internal controls within the institute and oversight by the Ministry should be strengthened.
- The Ministry should fix responsibility for the various lapses observed during audit, such as batch release certification by NIB without conducting the full complement of tests prescribed by the pharmacopoeia; sending of samples by subordinate offices of DCG (I) to NIB for quality control testing despite instructions of the Ministry to the contrary and purchase of a DNA sequencer, an expensive equipment, without any requirement by the institute.

Chapter II : Overview of National Institute of Biologicals

2.1 Introduction

The National Institute of Biologicals (NIB) was set up in January, 1992 to act as the national control laboratory for assuring the availability of high standard and good quality biological products[1] for consumption in India and for exports. It was set up as a society under the Societies Registration Act, 1860 for quality control of indigenously produced and imported biological products.

The cost of setting up the institute was estimated, in September 1987, at Rs. 19.55 crore, which was revised to Rs. 69.74 crore in September 1991, with a target of completion by the year 1998-99. The cost was again revised in February 2001 to Rs. 269.24 crore. As of 31 March 2008, Rs. 256 crore had been incurred on the establishment of the institute. The mandate of NIB is mentioned in Box-1.

Box-1 : Mandate of National Institute of Biologicals

- To undertake systematic examination of the quality of biologicals and immunobiological products, with a view to enable the release of indigenous and imported products after certification according to procedures prescribed under the Drugs and Cosmetics Act.
- To establish National Reference Standards and serve as a repository for reference standards and reagents for biologicals and immunobiologicals.
- To develop suitable networks/linkages with related institutions set up by the Central or State Governments or within Universities so as to effectively disseminate knowledge, develop manpower and act as a resource backup for long-term development of reference standards and quality control of biologicals/immunobiological products.
- To develop and establish pharmacopoeia* specifications appropriate for biologicals and immunobiologicals for use in India, in consultation with the Indian Pharmacopoeia Committee.
- To function as an accredited testing and reference laboratory for quality control of biological products available in the future and evaluate and advise on emerging technologies in these fields in terms of their specificity, sensitivity and replicability.
- To provide training to scientific and technical personnel in the procedures for development of standardization and quality control methods of biologicals.
- To develop technical guidelines/manuals on standards to be used by manufacturers and also for training scientific and technical manpower for standardization and quality control.
- To monitor ongoing research, establish linkages and exchange personnel with different institutions in India and abroad for the furtherance of its mandate.

* Guidelines specifying the requirements for production, quality control and sale of drugs/medicines.

[1] Vaccines, anti-sera, anti-toxins, blood products, immunodiagnostic kits etc,.

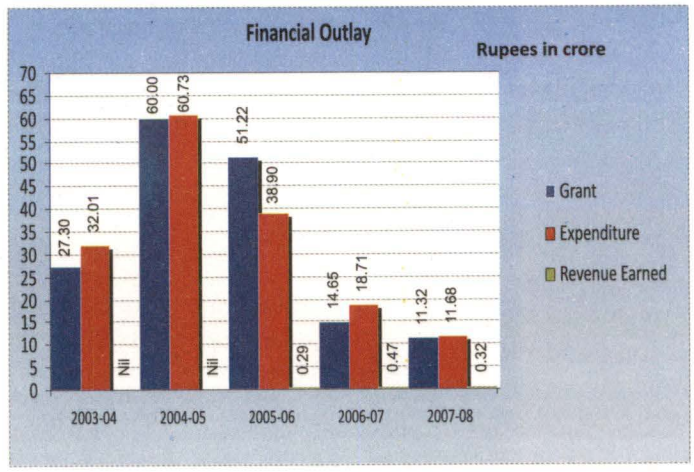
2.2 Organisational setup

The institute functions under the administrative control of the Ministry of Health and Family Welfare. Secretary (Health) is the ex-officio Chairman of the General Body and the Governing Body. The institute is headed by a Director, who is the chief executive and nodal officer of the project. The Director is assisted by five Deputy Directors looking after different departments *viz.* quality control and development; training and technical support; animal production and quarantine; environment and personnel safety and administration and finance.

2.3 Financial inputs and fund flow arrangements

Initially, the main sources of funds for the institute were grants from the Government of India (internal), a grant from USAID[2] and a loan from JBIC[3], Japan. The financial assistance from USAID and JBIC, Japan was available till September, 1998 and February1999, respectively.

(Chart – 1)



Thereafter, the project cost was being met by the Government of India through grants to the institute. The expenditure incurred and the revenue earned by way of testing of biologicals by NIB during the last five years were as given in Chart–1 above.

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[2] Rs. 8.32 crore from United States Agency for International Development

[3] Rs. 37.17 crore from Japan Bank for International Cooperation (erstwhile OECF-Overseas Economic Co-operation Fund).

Chapter III : Audit Approach

3.1 Audit objectives

Performance audit of NIB was conducted to verify that:

1. the institute fulfilled its role of systematic examination of the quality of indigenous and imported biologicals and immunobiological products and certified their quality; developed reference standards, quality control and testing procedures for them and finalized pharmacopoeia specifications appropriate for biological and immunobiological products;
2. it contributed to the development of human resources in the field of biological and immunobiological products through networking and linkages with national and international institutes for knowledge sharing and dissemination and conducted effective training programmes for scientific and technical personnel to address the assessed needs for training with optimum utilisation of its capacity;
3. the processes, procedures and resources deployed by the institute were commensurate with its mandate and were efficiently managed for timely achievement of the intended objectives;
4. the procurement process followed by the institute was transparent and ensured economy in purchases and the purchase of equipment and construction of the Laboratory and Animal House and other buildings were as per the specifications and requirements of the institute;
5. the internal controls within the institute and oversight by the Ministry were effective and addressed the shortcomings and deficiencies in time and the controls provided assurance against frauds, misuse and waste to ensure economic and efficient use of the inputs for the intended objectives.

3.2 Audit criteria and scope

The major audit criteria adopted for the performance audit of NIB were:

- the provisions of the Drugs and Cosmetics Act, 1940 and the rules framed thereunder,
- the mandate of NIB as enshrined in the Memorandum of Association (MOA) and the Expenditure Finance Committee (EFC) Memos (1991, 2000),
- adherence to good laboratory practices (GLP),
- adherence to drug specifications in the pharmacopoeia, and
- the provisions of the Standard Operating Procedure Manual (SOP) of NIB

The performance audit covered the examination of the records of NIB pertaining to the period 2003-04 to 2007-08. Information from the Ministry of Health and Family Welfare and the office of the Drug Controller General of India (DCGI) was also sought, where required.

3.3 Audit methodology

Audit methodology included test check of records, physical verification of utilisation of equipment and case studies. An entry conference was held with the Director, NIB in April, 2008 for discussing the audit objectives and the scope of audit. The exit conference was held with the Ministry in January 2009 for discussing the audit observations and recommendations. The Ministry accepted the audit findings and the recommendations and stated that remedial action had been initiated by effecting change in the Management of NIB in September, 2008 and that responsibility was being determined for the various lapses observed during audit.

3.4 Acknowledgement

We acknowledge the cooperation extended by the Ministry and the institute for facilitating the audit process and initiating remedial measures on audit findings.

Chapter IV : Audit Findings

Audit findings in this chapter have been presented under four broad categories *viz.*

a) Non-achievement of the primary objectives for which NIB was set up (Para 4.1)

b) Lapses in scientific activities (Para 4.2)

c) Lapses in purchases of equipment and their non/under-utilization (Para 4.3)

d) Lapses in administrative and internal control (Para 4.4)

4.1 Non-achievement of the primary objectives for which NIB was set up

Even after the lapse of 16 years since its inception and expenditure of Rs. 256 crore, which is 95 *per cent* of the total project cost, NIB has not been able to achieve the quality control objectives for which it was set up.

In spite of the establishment of the vast GLP compliant infrastructure of NIB, the quality assurance management of biologicals in the country continues to remain at the pre-1992 state. Several batches of indigenous products continue to be released either without independent quality assurance testing or on the strength of certification based on partial testing. Even today, for several imported biologicals, the country has to rely on claims of safety, potency and efficacy made by foreign manufacturers/drug regulatory authorities of other countries. The audit findings in this regard are as follows:

4.1.1 Quality control testing by NIB

One of the specific functions assigned to NIB was to undertake systematic examination of quality and enable the release of products after certification of all the biologicals manufactured indigenously and also those imported to the country.

As per EFC Memo, 2000, NIB was expected to carry out quality control testing of all the biologicals available in the market by the year 2003-04. It was, however, noticed that out of more than 116 biologicals available in the market, NIB was notified[4] by the Ministry as a Central Drug Laboratory[5]

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[4] In April, 2002

[5] A laboratory is declared as a CDL under the Drugs and Cosmetics Act, 1940 for carrying out quality control testing of specific types of drugs, biologicals etc. after following due process of inspection by expert/technical teams for ascertaining the adequacy of infrastructure, equipment, expertise, and also standardization of various tests.

(CDL) for carrying out quality control testing of only five biologicals[6] as it had not developed the requisite infrastructural facilities for testing of the remaining biologicals as of October 2008. Further, against the expected receipt of 30,000 samples *per annum* by the year 2004 as estimated in the EFC Memo, NIB received only 3733 samples for testing during the five-year period 2003-2007.

As per EFC Memo, 1991, NIB was intended to be established as an independent national level laboratory in order to separate the dual functions of production and national level quality control testing being discharged by the Central Research Institute, Kasauli in respect of mass produced biologicals such as vaccines and sera.

It was, however, noticed that except for limited testing of the Oral Polio Vaccine[7], NIB had not created facilities for carrying out quality control testing of vaccines and sera, which formed a major component of mass application biologicals, including vaccines against the six childhood diseases included under the Universal Immunization Programme. Consequently, NIB could not take over the work of national level quality control and testing of vaccines and sera from CRI, Kasauli. Incidentally, the Government had to close down the manufacturing unit of CRI, Kasauli in 2008 due to non-adherence to quality assurance measures provided under the Drugs and Cosmetics Act, 1940. This could perhaps have been avoided if NIB had taken up the work of quality assurance in time.

Further, instead of conducting systematic examination of quality, NIB was resorting to batch release certification based on partial testing only. In many cases, NIB released certificates for use of drugs by the public, invoking the names of the concerned pharmacopoeia without conducting many of the crucial tests prescribed by it to prove the identity, potency, efficacy and safety of the products under test. (This point is dealt with in detail in Para 4.2.1 of this report).

Owing to complaints regarding irregularities in testing and reporting of results by NIB, the Ministry stopped the testing of biologicals by NIB in July, 2007. NIB, however, continued to receive samples from some subordinate offices of DCG (I) and issued test reports even after July, 2007, despite instructions of the Ministry to the contrary.

Thus, instead of becoming an instrument for preventing distribution of substandard products in the country, issue of certificates by NIB without proper testing entailed a risk of NIB becoming a conduit for distribution of sub-standard products.

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[6] Oral Polio Vaccine, HIV diagnostic kits, Hepatitis B Surface Antigen Kits, Hepatitis C Kits and Blood Grouping Reagents

[7] NIB carried out only potency testing of OPV during 1997-2005. The same was discontinued from March 2005.

Reasons for such underperformance by NIB are explained in the succeeding paragraphs. They are, broadly, non-deployment of commensurate manpower despite completion of infrastructure, delay in construction of laboratory infrastructure, mismanagement by the institute and lack of oversight by the Ministry.

The Ministry stated (February 2009) that the institute had not been able to function at the level envisaged for it because of managerial lapses. With the change in Management in September 2008, corrective action had been initiated and responsibility was being determined for the lapses observed during audit.

4.1.2 Development of national reference standards

Developing national reference standards and serving as a repository for reference standards and reagents was one of the major objectives of NIB. A reference standard for a biological is the benchmark against which the test results of its samples are compared to assess whether they are of standard quality. Manufacturers were expected to draw national reference standards from NIB for bringing uniformity in testing procedures and for better comparability in results obtained at their end and at the Central Drug Laboratories (CDL).

Despite having a well-equipped Reference Standard Laboratory (completed in January 2007) possessing sophisticated equipment including a freeze drier costing Rs. 6.52 crore, NIB confirmed (October 2008) that so far it had not done anything in this critical area and was yet to draw up any specific plans to start this important activity.

The Ministry, while accepting the audit observation, stated (February, 2009) that steps were being taken to start work on preparation of reference standards for insulin, albumin and sera panels for testing HIV, HBV and HCV kits. As regards the freeze drier, it was stated that the equipment would now be utilised for the development of reference materials by the Indian Pharmacopoeia Commission and NIB so as to optimally utilise its large capacity.

Recommendation

- *NIB should conduct all the crucial tests in accordance with the concerned pharmacopoeia so that the quality of biologicals is ensured before release in the market.*

4.1.3 NIB's role as a premier national institute for dissemination of knowledge

In its capacity as a specialized national centre for quality assurance, NIB, in order to disseminate knowledge to sister institutions in pursuit of its goal to upgrade the quality management of biologicals in the country, was supposed to develop technical guidelines/manuals on the standards to be used by

manufacturers and also for training scientific and technical manpower. However, NIB had not issued any such guidelines /manuals so far.

Quality assurance of biologicals is a dynamic area where new technologies and procedures evolve constantly and an institution like NIB should have regularly monitored ongoing research, established linkages and exchanged personnel with different institutions in India and abroad for the furtherance of its mandate, thereby facilitating absorption of new developments from the international arena. Being a specialized nodal institution, NIB was expected to disseminate new developments to other institutions in the country, involved in the manufacture and quality control of biologicals. So far it had neither evaluated and advised on any of the emerging technologies nor set up any mechanism for monitoring international research.

As per its objectives, the institute had to assess from time to time, the availability of qualified manpower to meet the needs of quality control and manufacturing of biologicals/immunobiologicals so as to advise the government on appropriate measures and the scope of upgradation of existing facilities within the country. It was observed that the institute had not initiated any action to achieve this mandate.

4.1.4 Development of human resources

NIB was mandated to provide training to scientific and technical personnel of related institutions including manufacturing units in the procedures for development of standardization and quality control methods. The institute organized only nine training programmes for 185 scientific and technical officers from the States during the last five years. Further, no training had been imparted by NIB during 2007-08. During the five years under review, NIB did not organize any training programme for Indian manufacturers, as required under its mandate. This was despite the availability of a vast training infrastructure costing Rs. 4.55 crore in addition to its scientific infrastructure.

The Ministry, while accepting the deficiencies in the field of development of human resources and dissemination of knowledge, stated (February 2009) that steps were now being initiated by the institute in these crucial areas. The Ministry stated that 50 laboratory technicians had been trained by NIB in January 2009 and a total of 240 laboratory technicians would be trained by March 2009.

Recommendation

- *Concerted efforts should be made for development of human resources in the field of biologicals and immunobiological products through proper training of scientific and technical personnel. Besides, efforts should be made for dissemination of knowledge through networking and linkages with national and international institutes.*

4.2 Lapses in scientific activities

Audit observed lapses in testing and reporting of test results by NIB. Biological products were certified for use by the public without conducting adequate tests as required under the pharmacopoeia. Test reports were inordinately delayed, with the result that many of them were issued just a few days before the expiry dates of the batches. These included test reports for HIV diagnostic kits also. Good laboratory practices (GLP) were violated because major elements of the quality management system required under Indian standards/GLP were not in place or were far from complete. The audit findings in this regard are as follows:

4.2.1 Batch release certification of blood products without testing critical parameters prescribed by pharmacopoeia

The Indian Pharmacopoeia sets out the national requirements of quality of biologicals/drugs by way of several specific parameters for strict compliance by both manufacturers and quality control laboratories.

For all the 18 blood product samples[8], test reports of which were examined by Audit, NIB had issued batch release certificates stating that the products complied with the requirements of the pharmacopoeia, without carrying out tests on many parameters prescribed by it. These products were certified for release in the market for use by the Indian public without even carrying out the prescribed critical tests of identity, purity, safety and stability. This lapse in the working of NIB can be illustrated by taking the examples of testing of Human Albumin solutions and Human Immunoglobulin.

The Indian Pharmacopoeia 2007 had specified tests to be carried out to establish 19 parameters before terming a batch/lot of Human Albumin as 'of standard quality'/ 'not of standard quality'. However, it may be seen from Table-1 that NIB, instead of conducting the full complement of tests mandated by the Indian Pharmacopoeia, had carried out tests for only 8-10 out of the 19 parameters prescribed by it.

[8] Albumin, immunoglobulin, Coagulation factor VIII, Coagulation factor X, Plasma Pools etc,.

Table 1

Sl. No.	IP Requirements	Lot Nos 4B40000123-127 (6 Lots) NIB Ref BP/544	Lot Nos 4B40000117-122 (6 Lots) NIB Ref. BP/531	Lot No 4B40000201 NIB Ref.BP/625	Lot Nos 4B40000276-292 (16 Lots) NIB Ref BP/678	Lot No 4B40000210 NIB Ref. BP/629
1.	Clarity	Done	Done	Done	Done	Done
2.	Colour	Done	Done	Done	Done	Done
3.	pH	Done	Done	Not Done	Done	Not Done
4.	Total Protein	Done	Done	Done	Done	Done
5.	Identity by Immunodiffusion	Done	Done	Done	Done	Done
6.	Identity by Electrophoresis	Not Done	Not Done	Not Done	Not Done	Not Done
7.	Denatured protein	Not Done	Not Done	Not Done	Not Done	Not Done
8.	Alkaline Phosphatase	Not Done	Not Done	Not Done	Not Done	Not Done
9.	Stability	Not Done	Not Done	Not Done	Not Done	Not Done
10.	Pyrogenicity	Not Done	Not Done	Not Done	Not Done	Not Done
11.	Abnormal Toxicity	Not Done	Not Done	Not Done	Done	Not Done
12.	Haem Content	Done	Done	Done	Done	Done
13.	Sterility	Not Done	Done	Not Done	Not Done	Not Done
14.	Potassium	Not Done	Not Done	Not Done	Not Done	Not Done
15.	Aluminium	Not Done	Not Done	Not Done	Not Done	Not Done
16.	Sodium	Not Done	Not Done	Not Done	Not Done	Not Done
17.	HCV Ab	Done	Done	Done	Done	Done
18.	HIV Ab	Done	Done	Done	Done	Done
19.	HBsAg	Done	Done	Done	Done	Done

In these cases, NIB resorted to batch/lot release certification without conducting crucial tests for sterility, pyrogenicity, protein purity, integrity and stability.

Similarly, samples of Human Immunoglobulin, a life-saving drug, were certified as meeting the requirements of the pharmacopoeia without even establishing whether the biological put to test actually contained immunoglobulin (test of identification), whether it was safe for use and would not lead to abnormal toxicity and fever when administered (tests of sterility, abnormal toxicity and pyrogenicity), and whether it would remain stable under given temperature conditions (test of stability). Such action on the part of NIB could prove to be a potential health hazard for unsuspecting end users.

Audit also observed that the number of parameters tested by NIB before batch release certification varied substantially from batch to batch.

Despite repeated requests, NIB and the Ministry did not furnish information pertaining to any special authorization extended to NIB for carrying out quality control testing of blood products as it had not been notified as a CDL for carrying out testing of such products.

Certain discrepancies in batch release certification of products of Chinese origin, which were found during audit, are mentioned in the case study given below:

Case Study: Discrepancies in batch release certification for products based on Chinese pharmacopoeia

NIB was testing biological products of Chinese origin and issuing batch release certificates certifying compliance with the requirements of the Chinese Pharmacopoeia.

Despite repeated requests by Audit, NIB did not produce a copy of the pharmacopoeia for reference and informed orally that it did not possess one. It is noteworthy that NIB had undertaken to test these samples and had issued batch release certification certifying compliance with the pharmacopoeia, even when it was not in a position to ascertain the actual requirements in the absence of a copy of the concerned pharmacopoeia.

Further, during test check of seven cases, it was noticed that the Chinese firms had not disclosed their manufacturing licence numbers, a mandatory requirement under GLP and NIB's Standard Operating Procedure (SOP). The manufacturing licence number for a product given by a regulatory body was the most important element to ascertain the credentials of a manufacturer and the quality of the product in question as manufacturing licences were to be granted based on rigorous inspection and verification. In fact, as per the same, NIB was not expected to entertain samples from any unknown/new manufacturer until and unless complete dossiers of the manufacturer, quality control, field trial/ approvals in the country of origin including manufacturing licence etc., were made available by it. In the first instance, NIB should not have accepted samples when the manufacturing licence numbers were not disclosed. After having done that, NIB decided to depend heavily on the claims of quality made by the manufacturers without conducting the full complement of tests and without ascertaining the requirements of the concerned pharmacopoeia, before issuing batch release certification.

Scrutiny of records disclosed that NIB had arbitrarily chosen to test the products for far fewer parameters than would be required by any pharmacopoeia. Tests to assure the identity, safety, potency and stability of the products were not conducted in the seven cases test-checked in audit.

Such practices by NIB were violative of the responsibility of a quality assurance laboratory, which was expected to act as a watchdog to assure the quality of biologicals in the country and were also against the spirit of the Drugs and Cosmetics Act.

The Ministry, while accepting the audit findings, stated (February 2009) that responsibility was being determined for issuing of test reports by NIB without carrying out the prescribed tests before batch release of blood products. The Ministry stated that the then Director of the institute had been suspended in January 2009 on the basis of findings of the committees appointed by it for examining the working of NIB. Disciplinary proceedings were being initiated against the then Director and other persons found responsible for the alleged irregularities.

The Ministry added that the tests prescribed under the pharmacopoeia for blood products were being standardized and assured that the full complement of tests would be conducted before batch release certification by NIB. Updated versions of the European, American and Chinese Pharmacopoeia had also been procured by the institute.

4.2.2 Incomplete testing of biologicals under Rules 40 and 41 of the Drugs and Cosmetic Rules, 1945

As per Rules 40 and 41 of the Drugs and Cosmetics Rules, 1945, quality control testing of samples of imported drugs was to be done only by laboratories appointed by the Central Government as Central Drug Laboratories (CDL) for the purpose.

A sample check of files disclosed that NIB, which had not been appointed as a CDL for the purpose, was carrying out quality control testing of drugs such as hormones, enzymes and blood products under the above mentioned Rules, rendering such testing illegal.

It was also noticed that NIB was certifying only infection reactivity[9] of such samples sent to it by Customs authorities under the extant rules. This could not provide assurance regarding the standard quality of the samples as complete testing of the samples as per the concerned pharmacopoeia was required. Issue of certificates of analysis, only on the basis of infection testing, without conducting any tests to prove the safety, identity and potency of a drug did not serve the purpose of quality assurance.

The Ministry stated (February 2009) that the reasons for testing of samples without authorization and non-compliance of test protocols were being investigated and responsibility would accordingly be fixed on persons found guilty of the same. They stated that the tests, as given in the Indian Pharmacopoeia, had now been standardized, and included tests to prove the safety, identity and potency of the products.

4.2.3 Acceptance and testing of samples by NIB despite stoppage by the Government

As stated earlier in para No. 4.1.1, owing to complaints regarding large scale irregularities in testing and reporting of results, the Ministry stopped the testing of biologicals by NIB in July, 2007 and forbade all subordinate offices of the Drug Controller General of India {DCG (I)}to send samples to NIB for testing.

Despite this, some of the subordinate DCG (I) offices continued to send samples to NIB, which tested and issued batch release certificates for such samples for public use.

Audit scrutiny disclosed that out of the total of 220 samples accepted irregularly by NIB during September 2007 and August 2008, 190 (86 *per cent*) were sent by CDSCO[10], West Zone. Ninety four *per cent* of these samples sent by CDSCO, West Zone were from a particular manufacturer.

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[9] To show that products, particularly blood products do not carry the risk of transmitting infections of Hepatitis B, Hepatitis C & HIV.

[10] Central Drugs Standard Control Organisation

The Ministry accepted the audit findings. In response to the audit recommendation of determining responsibility for sending samples to NIB, the Ministry stated (February 2009) that the matter was being investigated by CDSCO to make the responsible persons accountable.

Though the Ministry had assured that it would take action for these lapses, it is felt that it needs to strengthen its oversight mechanism so as to ensure compliance of its own instructions by the institute and the drug regulatory system.

4.2.4 Issue of test reports of biologicals very close to their dates of expiry

The date of expiry (DOE) of a drug or a diagnostic kit is a very important rider, which is arrived at after extensive studies/trials to see how long the efficacy and safety of the product is assured. The Drugs and Cosmetics Rules, 1945 prohibit the sale of date expired substances.

Batch release certification by a quality assurance laboratory enables a manufacturer to release a product for sale/use. Thus, it is expected that the manufacturer would submit a product well in time to the testing laboratory so that there is enough time left before the DOE. Further, it is reasonably expected from a testing laboratory that it would

- accept only those samples submitted to it with sufficient length of time before the DOE, and
- undertake testing of products only when sufficient length of time is left before the DOE. Once samples are accepted for testing, test reports/batch release certification should be issued within a reasonable time limit.

Good Laboratory Practices and NIB's own SOP also require examination of the DOE before a sample is received. NIB, however, had not laid down any cut off days for expiry to decide whether a sample was to be accepted or rejected on account of its DOE.

In disregard of the standard procedures, NIB resorted to testing and issue of test reports/batch release certification on many samples even when only two to eight days were left before the DOE. An indicative list of some of these samples is given in Table-2. The National Aids Control Organisation (NACO) guidelines, provided to Audit by NIB, prescribe that samples may be submitted/ received for testing when at least 12 months of their life is left. It was found that most samples of test kits received by NIB had less than 12 months of remaining life. There were several instances where NIB had delayed the testing/despatch of reports, thereby allowing the dates of expiry to be crossed. The six cases presented in Table-2 were with NIB for periods ranging between five to six and a half months and were on the verge of crossing the DOE when the test reports were issued. It is also evident from Table-2 that three batches of diagnostic kits meant to diagnose HCV and HIV viruses were certified as being of standard quality only two to 56 days before

their DOE. Such cases entailed a serious risk of unfair/unethical trade practices and jeopardizing of the health of unsuspecting end users.

Table - 2

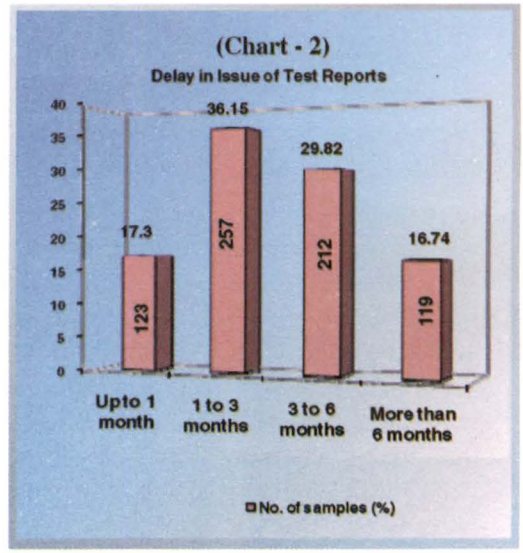
Biological particulars	*Date of receipt*	*Date of expiry*	*Result*	*Date of issue of report*	Number of days left before DOE
Lot. No.F0766, BIO ELISA HCV 4.0	29-09-06	16-02-07	**Standard Quality**	14-02-07	**2**
Lot No. 25160703, AIDS HEPASCAN-HCV Combo ELISA test kit,	10-01-07	June 2007	Not Standard Quality	22-06-07	**8**
Lot No. 25160704, AIDS HEPASCAN-HCV Combo ELISA test kit	10-01-07	June 2007	**Standard Quality**	22-06-07	**8**
Lot No. 25160705, AIDS HEPASCAN-HCV Combo ELISA test kit	10-01-07	June 2007	Not Standard Quality	22-06-07	**8**
Lot No. 25160702, AIDS HEPASCAN-HCV Combo ELISA test kit	10-01-07	June 2007	Not Standard Quality	22-06-07	**8**
Lot No. 6060701 AIDS-Hepascan HIV HCV Combo Spot test	10-01-07	June 2007	**Standard Quality**	04-05-07	**56**

In response to the audit recommendation of fixing a timeframe by the NIB for receipt, testing and issue of test reports vis-à-vis the DOE of batches of biological products, the Ministry stated (February 2009) that the said timeframe had been fixed and the SOPs had been revised accordingly.

4.2.5 Delay in testing and issue of test reports

A time limit of 45 days from the dates of receipt of samples was fixed by NIB for issuing test reports of samples.

Scrutiny of 873 samples received from January 2007 to August 2008 disclosed that test reports were issued in time for only 91 samples (10 *per cent*). Test reports in respect of 711 samples (81 *per cent*) were delayed with 46 *per cent* of test reports being despatched after delays of more than three months. The remaining 71 samples (eight *per cent*) received during January 2007 to August 2008 were pending as of August, 2008. The extent of delay in issue of the reports was as given in Chart-2.



The Ministry, while accepting the audit observation, stated (February 2009) that steps were being taken for placing all types of equipment under annual maintenance contract and the requirements of consumables for the tests had

been worked out so that delays would not occur due to breakdown of equipment or non-availability of consumables. The Ministry assured that the turnaround time for the tests would be regularly monitored as per the SOP.

4.2.6 Good Manufacturing and Laboratory Practices not followed

At the time of project appraisal, the EFC had recognized that despite adequate legal provisions for Good Manufacturing Practices (GMP) and GLP for quality control management, enforcement of these provisions was significantly deterred by inadequate and antiquated testing facilities; use of outdated methodologies; minimal existing capacity to collect and analyse data relating to the quality of biological products and limited capacity to train quality control personnel.

NIB had been set up to remove these deterrents, set optimum standards in quality assurance and thereby facilitate enforcement of GMP and GLP for biologicals in the country. The infrastructure at NIB was designed to follow the best international practices in quality control. However, despite the availability of an extensive GLP compliant infrastructure, NIB not only failed to establish and maintain its own standards under GLP but also failed to assist sister institutions in imbibing higher standards of GLP. It may be noted that the Government of India was compelled to close down three major vaccine manufacturing units[11] in the country and to stop testing of samples of biologicals at NIB, all on account of poor GMP/GLP. Poor standards of GMP/GLP, thus, had led to a major setback for the biological industry in the country.

4.3 Lapses in equipment purchase and their non/under-utilization

The procurement process followed by the institute did not ensure sufficient competition and was marred by irregularities, pointing towards the risk of vested interests. Purchases were made without proper assessment of actual requirements. Care was not taken to stagger purchases in tune with the anticipated usage, leading to poor or no utilization of expensive equipment. This resulted in wasteful deployment of funds in procurement and unfruitful expenditure on maintenance for long spells of time as detailed in the succeeding paragraphs.

4.3.1 Purchase of DNA sequencer without requirement

The NIB management purchased a DNA Sequencer in June, 2006 for Rs. 1.02 crore, without any requirement for the same. It purchased this equipment despite expert opinion to the contrary and without any provision for its purchase in the EFC memo, 2000.

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[11] (i) Central Research Institute, Kasauli in Himachal Pradesh, (ii) Pasteur Institute of India, Coonor in Tamil Nadu and (iii) BCG Vaccine Laboratory, Chennai in Tamil Nadu.

A DNA Sequencer is a sophisticated modern equipment, which is employed to analyze the structural sequence and related details of genetic material of human beings, microbes or plants at sub-molecular levels. Hence, it is generally found only in laboratories involved in molecular biology research. Scrutiny of records at NIB and the literature pertaining to various tests prescribed by the pharmacopoeia and those undertaken by NIB on a limited number of types of biological, disclosed that there was no requirement, whatsoever, at NIB for a DNA Sequencer. In reply to the audit observation, NIB stated (September 2008) that it had been procured for genetic characterization of viruses like, HIV, HbsAg and HCV. However, it could not produce any records to substantiate its application in routine sample testing nor for any genetic analysis. Purchase of this equipment raised a doubt for the following two reasons also:

The equipment was originally indented by the Blood Product Laboratory but was installed at the Reference Standard Laboratory. The reasons for installing the DNA Sequencer in the Reference Standard Laboratory were not furnished by the institute. After installation in September 2006, it had never been put to use as the laboratory itself was non-functional.

Further, NIB purchased the equipment without ensuring sufficient competition as required under the financial rules. The purchase order was awarded after receiving only two bids and the presence of only one technically approved bidder.

In response to the audit recommendation of determining responsibility for the purchase of the DNA sequencer, the Ministry stated that action had been initiated against the persons responsible for this purchase.

4.3.2 Imprudent purchase of generator sets

Three diesel generator (DG) sets of 2.5 MW capacity were purchased by NIB in the year 1998 at a cost of Rs. 10.71 crore. Two generator sets were to be used for providing power backup while the third was to be used as standby in the case of failure of one of the two generator sets. The need for one additional standby generator vis-à-vis the criticality of activities discharged by NIB was not furnished by NIB.

It was disclosed that these three generator sets were purchased by NIB when there was no immediate need for the same. The process of construction of the Laboratory and Animal House had not yet started in the year 1998. As a result, none of the three DG sets were utilized for power backup for almost nine years up till September, 2007. An amount of Rs. 72.33 lakh spent on their maintenance during this period was, thus, rendered unfruitful. Even after September, 2007, the backup power requirement of NIB never exceeded the capacity of one DG set.

Further, these sets having become obsolete, NIB had to purchase one more generator costing Rs. 66.12 lakh with quick start technology for immediate

back up of critical functions during the seven to 10 minutes time taken by the generator sets to start.

4.3.3 Lack of competition in purchases

NIB purchased two types of equipment[12] costing Rs. 22.20 lakh on the basis of a single bid, despite the fact that they were not proprietary items. Further, three[13] more types of equipment costing Rs. 75.93 lakh were purchased on the basis of only one technically approved bid, without ensuring sufficient competition as required under the financial rules. Further, NIB went ahead with the purchase of the equipment during April to September, 2006, despite an objection from its Quality Control Officer on the ground of lack of competition.

The Ministry stated (February 2009) that responsibility was being fixed for the irregularities in the purchase of various costly equipment and that necessary disciplinary action in this regard would be taken as per the extant rules and procedures.

4.3.4 Machinery and equipment lying unutilized

The institute had machinery and equipment worth Rs. 57.04 crore as of March 2008. It had not maintained any item-wise list of such assets nor had it conducted physical verification of the same as required under the financial rules. In the absence of a proper account and a physical verification report, the actual availability of assets and whether they were in working condition could not be verified.

4.3.4.1 Fixed equipment lying unutilized and non-functional

The audit team, along with three representatives of the institute, sample-checked fixed equipment in the Laboratory and Animal House, which had been installed during September, 2006 to January 2007. It was found that 19 types of equipment worth Rs. 26.87 crore were lying unused (**Annex-I**).

The idle equipment accounted for 88.5 *per cent* of the total cost of fixed equipment installed in NIB.

It was not known whether these equipment were in working condition as they had never been put to use after their taking over by NIB. It was noted that the warranty periods of most of the equipment had also expired. Arrangements, if any, made for maintenance of these to keep them in working condition, were not furnished to Audit by NIB.

[12] Auto analyzer and Osmometer
[13] HPLC-I, HPLC-II and Geldoc

Had the institute staggered the purchase on the basis of availability of manpower and actual immediate needs as per the work plans, blockage of the funds and the lapse of warranty without utilization could have been avoided.

Further, it was disclosed that the main Laboratory and Animal House building had been taken over by NIB despite the fact that some of the fixed equipment such as Bio-safety cabinets and Laminar Flow Work stations costing Rs. 1.64 crore were not commissioned. Besides, major defects had been noticed by NIB in some other fixed equipment, during their warranty periods. Many types of essential equipment like cold rooms and incubator rooms were also lying unutilised because of defects. The contract had sufficient defect liability protection but NIB failed to get these defects rectified from the contractor or any other agency at their risk and cost, by invoking the contract provisions.

The Ministry, while accepting the managerial lapses in optimal utilisation of the equipment, stated (February 2009) that some of the equipment were purchased as part of the original planning and package which did not find immediate use in the institute and, thus, were lying idle. The Ministry assured that a plan to utilise the equipment was being prepared so that these could be put to use.

4.3.4.2 Movable equipment lying unutilized

Test-check of records relating to procurement of movable equipment disclosed that seven types of equipment valuing Rs. 2.50 crore, procured by the institute between January 2006 and May 2006, were lying unused since their procurement/ installation as detailed in **Annex-II**.

Four of these, costing Rs. 2.02 crore were purchased without immediate requirement at the time of purchase as they were purchased for laboratories that were neither functional nor under standardization for taking up work in the near future.

Four out of the above seven types of equipment had been installed as of March 2006. Warranties of three had elapsed in January 2009 and that of the fourth would lapse by September, 2009.

It was not known whether these equipment were in working condition. Arrangements, if any, made for their maintenance to keep them in working condition were not furnished by NIB.

The Ministry stated (February 2009) that all the equipment being used in the functional laboratories had now been placed under maintenance contracts. Four out of the seven types of equipment that were lying idle as mentioned in **Annex-II** would be put to use in the blood products and recombinant laboratories on resumption of quality control testing by them.

Recommendation

- *NIB should systematize its procurement procedures and make proper assessments of the actual requirements of equipment before procurement. Besides, concerted efforts should be made to ensure the proper utilization of the procured equipment.*

4.4 Lapses in administrative and internal control

The under-performance of NIB was also attributable to lapses in administrative and internal control such as lack of involvement of the higher Management and oversight by the Ministry; lack of quality oversight; non-segregation of duties; non-deployment of commensurate manpower resources; undue delays in decision-making and lack of coordination and proper planning; delays in construction of infrastructure and inefficient management and utilization of available resources, as explained below.

4.4.1 Lack of oversight by the Ministry

The General Body[14] of NIB, chaired by Secretary (Health), is the supreme policy making governing and appellate body of the institute. As per the rules and regulations of NIB, the annual general meetings of the General Body are to be held once in a year to consider and approve the programme of work for the ensuing year. It was found that only one General Body meeting had been held during the last five years. The last General Body meeting was held as far back as in July, 2003.

The Governing Body, also chaired by the Secretary (Health)[15], is responsible for pursuing and carrying out the objectives of the institute and has full powers to manage, administer and control its affairs and funds. As per the rules and regulations of NIB, the Governing Body should meet at least twice a year. However, only three Governing Body meetings were held during the last five years, showing lack of involvement by the higher Management in the affairs of the institute.

The Ministry admitted that it had not prescribed any periodic reports to monitor the performance of NIB. The fact that NIB continued to issue test reports on samples received from subordinate offices of DCG(I) for testing

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[14] Members of the General Body include Secretary (Health), Secretary (Family Welfare), DGHS; Secretary, Department of Biotechnology, DG (ICMR), Additional Secretary (Health); Joint Secretary and Financial Advisor, M/o Health and Family Welfare; two Joint Secretaries, M/o Health and Family Welfare, Drug Controller (India); Directors of two public sector undertakings producing vaccines/ biologicals, Directors of two private sector units producing vaccines/biologicals, Health Secretaries from two States and Director, NIB (Member Secretary).

[15] Members of the Governing Body include Secretary (Health), Secretary (Family Welfare), DGHS; Secretary, Department of Biotechnology; DG (ICMR); Additional Secretary (Health); Joint Secretary and Financial Advisor, M/o Health and Family Welfare; Drug Controller (India) and Director, NIB (Member Secretary).

despite instructions of the Ministry to the contrary depicted lack of effective oversight by the Ministry in the functioning of NIB.

The deficient control and oversight over the performance of NIB deprived the Ministry of opportunities to address NIB's shortcomings and deficiencies in time.

The Ministry, rather than giving a reply with substantive facts, stated (February 2009) that the performance of NIB was reviewed through the meetings of the Governing Body, Standing Finance Committee and other meetings held in the Ministry from time to time.

4.4.2 Lack of quality assurance oversight

For an effective quality management system, GLP and the standards prescribed by the Bureau of Indian Standards, require the formulation of a Quality Manual along with quality policies and SOPs for various scientific activities. It was disclosed that a Quality Manual was issued by NIB only in June, 2007. Most of the documents pertaining to its quality control policy and SOPs for various scientific activities were also developed in 2007 or later. NIB, in its role as a quality assurance laboratory, had, therefore, been engaged in testing and certification of biological when major elements of the quality management system as mandated were not in place or were far from complete. Despite these deficiencies, Ministry had notified NIB as a CDL for some products as early as in 2002.

An independent Quality Manager who had defined responsibilities and authority for ensuring that the management system related to quality was being implemented and followed at all times and who would be having direct access to the highest level of Management, was also not appointed by NIB, in contravention of GLP. Also, as per GLP, NIB was expected to set up and maintain an internal quality audit system manned by qualified auditors, under which periodic checks were to be instituted to ensure the efficacy of each scientific/technical activity and to focus on the need for improvements. NIB had not instituted any such internal audit system.

As per GLP, a Management Review was to be conducted at least once in a year to assess whether the quality system was functioning effectively and whether the laboratories' quality policy and objectives were being implemented as prescribed. The quality manual of NIB stipulated that such reviews should be held by the Director, heads of departments, persons in-charge of laboratories, the Quality Manager and the Technical Manager. Observations and decisions of the Management Review were to be documented and implemented for improving the systems. No such review had been conducted by NIB during the last five years.

Proficiency testing[16] had been prescribed by GLP as an important parameter to check the reliability of quality assurance laboratories. Except for the Blood Group Reagent Laboratory and the Infection Diagnostic Laboratory, no other laboratories had undergone any such proficiency testing.

Training and retraining of NIB personnel of all levels involved in quality assurance programmes, in order to ensure the required skill levels and also to keep them abreast of newer developments/ improvements, were crucial requirements under GLP. NIB did not furnish any reply to Audit regarding the details of training programmes planned and conducted by it during the period 2003-2008, and the number of personnel who underwent such training. In the absence of a reply, assurance on whether this requirement of GLP was being followed by NIB could not be derived.

The Ministry stated (February 2009) that the institute was taking initiatives to remove the deficiencies pointed out by Audit. The Quality Manual had been revised and the SOPs had been redrafted, keeping in view WHO guidelines and the Indian Pharmacopoeia requirements. As regards the nodal Quality Control Manager, the Ministry stated that steps were being taken to expeditiously fill up the vacant post of Deputy Director (Quality Control). As regards the Management Reviews, the Ministry assured that they would be carried out annually. As regards proficiency testing, the Ministry stated that the SOP for proficiency testing had now been drafted and the first round of proficiency testing would be carried out by March 2009.

4.4.3 Lack of segregation of duties

The Central Receipt, Despatch and Archives unit of NIB is responsible for receipt of biological samples and their onward transmission to the concerned laboratories for testing. It was disclosed during audit that the personnel responsible for receipt of the samples were also assigned the responsibilities relating to their testing.

It was noticed that the Ministry, at the time of project appraisal by the EFC in 2000, had committed that only coded samples would be sent to the laboratories for evaluation to obviate any bias or unfair practice. The samples could be decoded in compliance of GLP provisions, only after the testing was completed and the results had been filed. However, it was noticed that NIB had never undertaken any coding/decoding of samples till date.

Thus, the practice of involving the same set of persons both for receipt and testing without coding/decoding indicated not only weak internal controls in the organization but was also fraught with the risk of favouritism in issuing test reports by NIB.

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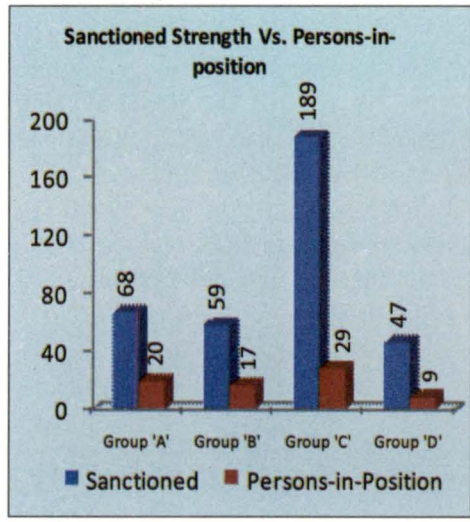
[16] National/international agencies conduct proficiency test programmes of laboratories by giving coded samples to them for testing after which the results are compared with the master results to judge the proficiency of those laboratories.

After this was pointed out, NIB bifurcated the sample receipt and testing functions in October, 2008.

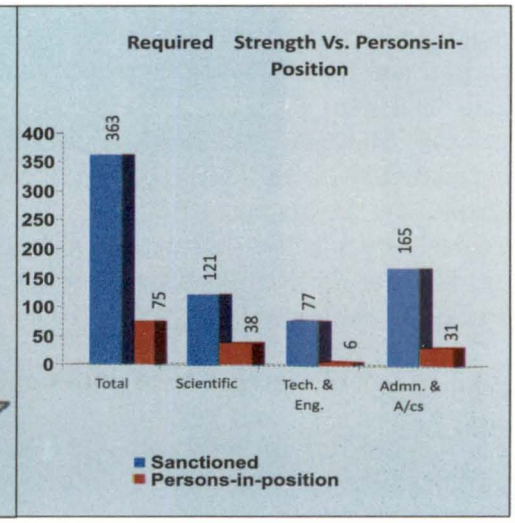
4.4.4 Non-deployment of commensurate manpower despite completion of Laboratory and Animal House

Despite the completion of the Laboratory and Animal House of NIB in February, 2006 at a cost of Rs. 118.06 crore, only 75 personnel were deployed there as of October, 2008 against the requirement of 363[17] persons. The shortfall in three categories of manpower *viz.* scientific; technical and engineering as well as administration and accounts was as given in Charts 3 and 4.

(Chart - 3)



(Chart - 4)



Only 38 scientific (31.4 *per cent*) and six technical (7.79 *per cent*) personnel were deployed in NIB against the assessed requirement of 121 and 77, respectively. The large infrastructure of NIB was lying unutilized in the absence of requisite manpower.

It was disclosed during audit that despite repeated requests/proposals from the institute, the Ministry did not sanction commensurate manpower that was essential for commissioning the rest of the laboratories of NIB.

In spite of getting approval of the Ministry of Finance for creation of 27 posts in May, 2007, the Ministry did not sanction appointments in NIB for 11 months after that date. The reason stated by the Ministry for not sanctioning manpower to NIB even after obtaining concurrence from the Ministry of Finance was delay in sorting out the long pending demand of the existing employees for career progression.

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[17] as per EFC Memo, 2000.

Delay in deployment of manpower was also observed at the level of NIB. Though the Ministry had directed NIB in April, 2008 to submit a plan of action including constitution of selection committees/ Departmental Promotion Committees for filling up of these posts for the approval of the Chairman of the Governing Body, the same had not been submitted by NIB as of December, 2008 despite the lapse of more than six months.

The Ministry stated (February 2009) that steps were being taken to expeditiously fill up the newly allotted posts and for promotion of scientists stagnating in their posts for want of any scheme for promotion. They also stated that the DPC meetings had been held and that the selection committees were being constituted.

Recommendation

- *The Ministry and NIB should ensure deployment of sufficient scientific and technical manpower commensurate with the available infrastructure in NIB in a time-bound manner.*

4.4.5 Delay in construction of laboratory infrastructure and consequent cost overrun

Out of 34 laboratories planned to be functional in NIB by the year 2003-04, only four[18] laboratories were functioning as of October, 2008. Another three[19] laboratories were in the process of standardization. The remaining 27 laboratories were still to be commissioned.

The main Laboratory Building and Animal House, which was to be completed by March, 2003 was completed after a delay of about three years in February, 2006. The reasons for delay in the project were identified as lack of a project team, absence of a monitoring mechanism and system deficiencies.

Further, as a result of delays, the institute had to pay a penalty of Rs. 4.89 crore to New Okhla Industrial Development Authority (NOIDA) as it could not construct the requisite 30 *per cent* of the built up area till April, 1997, as required under the lease deed.

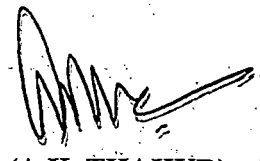
Recommendations

- *The internal controls within the institute and oversight by the Ministry should be strengthened.*
- *The Ministry should fix responsibility for the various lapses observed during audit, such as batch release certification by NIB without conducting the full complement of tests prescribed by the*

[18] (i) Blood Grouping Reagent Laboratory; (ii) Immuno Diagnostic Kit Laboratory (iii) Blood Product and (iv) Antibody Laboratory

[19] (i) Enzyme and Hormone Laboratory (ii) Bacterial Vaccine Laboratory and (iii) Re-combinant Product Laboratory.

pharmacopoeia; sending of samples by subordinate offices of DCG (I) to NIB for quality control testing despite instructions of the Ministry to the contrary and purchase of a DNA sequencer, an expensive equipment, without any requirement by the institute.



(A.K. THAKUR)
Director General of Audit
Central Revenues

New Delhi
Dated: 22 May 2009

Countersigned

(VINOD RAI)
Comptroller and Auditor General of India

New Delhi
Dated: 16 June 2009

ANNEXURES and GLOSSARY

Annex-I

(Refers to Paragraph 4.3.4.1)

Fixed equipment lying unutilized

Sl. No.	Name of the equipment	Quantity	Date of purchase/taking over	Cost *(Rupees in lakh)*
1.	Canopy Hood	3	Between September 2006 and January 2007	15.83
2.	Bench top chemical fume hood	16	-do-	45.08
3.	Biological Safety Cabinet 19530 mm	24	-do-	45.88
4.	Biological Safety Cabinet 15300 mm	16	-do-	35.83
5.	Biological Safety Cabinet 8100 mm	11	-do-	26.45
6.	Biological Safety Cabinet 900 mm	2	-do-	6.01
7.	Gravity Steam Sterilizer 510x510x965mm	7	-do-	502.04
8.	Gravity Steam Sterilizer 610x920x1220mm	6	-do-	612.78
9.	Vacuum Steam Sterilizer 670x1574x1929mm	1	-do-	134.17
10.	Glass washer	2	-do-	99.20
11.	Glassware dryer	2	-do-	31.72
12.	Cage and rack washer	2	-do-	199.68
13.	Tunnel washer	1	-do-	106.95
14.	Bedding dispenser	1	-do-	24.32
15.	Bottle filter item	1	-do-	10.69
16.	Down Draft Necropsy Table	2	-do-	22.86
17.	Under counter glass washer	8	-do-	65.98
18.	Freeze dryer	1	-do-	651.64
19.	Laminar flow work station	4	-do-	49.43
			Total	**2686.54**

Annex-II

(Refers to Paragraph 4.3.4.2)

Movable equipment lying unutilised

Sl. No.	Name of the equipment	Date of purchase/ installation	Cost (*Rupees in lakh*)	Present status
1.	Auto analyser	24-01-06	18.31	Not commissioned
2.	High Pressure Liquid Chromatography (HPCL) –I	30-03-06	63.73	Installed but not in use
3.	High Pressure Liquid Chromatography (HPCL)–II			
4.	FTIR Spectrophotometer	29-03-06	13.95	Installed but not in use
5.	Thermo gravity analyser	30-03-06	12.44	Not installed
6.	Fluorescence Activated Cell Sorter (FACS)	30-03-06	137.89	Installed but not in use
7.	Geldoc	05-05-06	4.07	Not commissioned
		Total	**250.39**	

Glossary of terms

Term	Definition
Biologicals	Vaccines, cultures and other preparations made from living organisms and their products, intended for use in diagnosing, immunizing, or treating.
DNA sequencer	An instrument used to automate the DNA sequencing process.
Efficacy	In a healthcare context, the capacity for beneficial change (or therapeutic effect) of a given intervention e.g. a medicine or a medical device.
Enzymes	Biomolecules that catalyze (i.e., increase the rates of) chemical reactions. Almost all enzymes are proteins.
Good Laboratory Practices (GLP)	A set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals (only preclinical studies), agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, detergents etc,. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can, therefore, be relied upon when making risk/safety assessments.
Good Manufacturing Practices (GMP)	Guidelines ensuring the quality and purity of products that are intended for use in pharmaceutical applications, and controls ensuring that methods and facilities used for production, processing, packaging, and storage result in drugs with consistent and sufficient quality and purity.
Hormones	Chemicals released by cells that affect cells in other parts of the body. Only a small amount of hormones is required to alter cell metabolism. Essentially a chemical messenger that transports a signal from one cell to another.
Immunobiologicals	An antigenic or antibody-containing preparation derived from animals or human donors and used for immunization and immune therapy.
Immunoglobulin	A protein produced by plasma cells and lymphocytes and characteristic of these types of cells. Immunoglobulin plays an essential role in the body's immune system.

Term	Definition
Microbes	A general or non-specific term for any micro-organism such as bacteria, fungi (molds), algae, or protozoa.
National Regulatory Authority (NRA)	The regulatory institution responsible for issuing licenses, controlling prices, resolving disputes, etc.
Pharmacopoeia	An authoritative book containing a list of medicinal drugs along with their uses, preparation and dosages.
Potency	The amount of drug (usually expressed in milligrams) needed to produce an effect, such as relief of pain or reduction of blood pressure.
Proficiency testing	The use of inter-laboratory comparison for determining the performance of individual laboratories for specific tests.
Protein	Compounds composed of carbon, hydrogen, oxygen, and nitrogen, which are arranged as strands of amino-acids. They play an essential role in the cellular maintenance, growth, and functioning of body organs.
Reagents	Substance used to produce a chemical reaction to detect measure, produce, etc., other substances.
Reference Standards	A benchmark against which the test result of a sample is compared to assess whether it is of standard quality.
Sera	The clear liquid part of the blood that remains after blood cells and clotting proteins have been removed.
Standard Operating Procedures (SOP)	A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Every good quality system is based on its standard operating procedures.
Sterility	The absence of viable contaminating microorganisms; aseptic state, asepsis.
Test of identification	A test performed to establish absolute proof of identity.
Test of Pyrogenicity	Involves measurement of the rise in body temperature following the intravenous injection of a sterile solution of the substance under examination.
Vaccines	A biological preparation, which is used to establish or improve immunity to a particular disease.

PRICE: INLAND : **Rs 65.00**
FOREIGN: US$ 5
(Including postage/air mail)