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# Mid-term Evaluation

## QUALITY CONTROL OF HEALTH TECHNOLOGIES

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*U.S. Agency for  
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*Submitted by:*

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## 1. EXECUTIVE SUMMARY

### 1.1. Background

During March 28 - April 17, 1996, the Quality Control of Health Technologies (QCHT) Mid-term Evaluation Team, consisting of Dr. William E. Woodward (US - Team Leader), Dr. John Foulds (US), Dr. K.B. Sharma (India) and Dr. Prem K. Gupta (India), assessed the development of the National Institute of Biologicals (NIB) in New Delhi, India.

The project was signed in September, 1990. Under the Project, the United States Agency for International Development (USAID) is providing a \$13.3 million grant to the Government of India (GOI) in the form of technical assistance, training, and movable scientific equipment, currently scheduled through September, 1998. The Government of Japan (GOJ), through its Overseas Economic Cooperation Fund (OECF), will provide a \$50 million loan at 2.5% interest for buildings and fixed equipment, currently scheduled through February, 1999. The Government of India (GOI) is contributing land, staff salaries, and operational costs.

The Team met with the Director, NIB and her staff, and visited the interim facility and the permanent site. The Team had discussions with the Secretary of Health, Additional Secretary of Health, Drugs Controller India (DCI), and officials from USAID and the Japanese OECF. The Team also met with representatives from Vijay Rewal Associates and the Indian Hospital Services Consultancy Corporation (HSCC) and reviewed a number of documents related to the project.

### 1.2. Scope of Work

In this report the Evaluation Team has provided an overview of the development of NIB. The Team's scope of work was to:

1. Assess the progress of the project toward attainment of its objectives.
2. Identify and evaluate the problem areas and constraints which may inhibit such attainment.
3. Evaluate, to the degree feasible, the overall development impact of the project.

The leading concerns expressed during interviews, meetings, phone conversations, etc., have been with NIB as an autonomous institution and with the seemingly inordinate delays in all spheres, especially recruitment and staffing, training, commissioning of the interim facility, building of the science/animal block at the permanent facility at New Okhla Industrial Development Authority (NOIDA), and linkages. Each of these leading areas of concern was addressed by the Mid-term Evaluation Team.

### 1.3. NIB As An Autonomous Institution

The Secretary of Health noted that NIB was registered in 1992 as a self-governing autonomous organization under the Registration of Societies ACT XXI of 1860 and will be financed by the Ministry of Health. According to the Memorandum of Association, NIB is overseen by a General Body, which is to meet once a year to determine policy making, governance, and appellation. It is chaired by the Secretary of Health. A Governing Body, which is to meet at least twice a year, has the authority to constitute standing and *ad hoc* committees as may be considered necessary.

There is a Steering Committee, composed of representatives of DCI, U.S. Food and Drug Administration (FDA), NIB, U.S. National Institutes of Health (NIH), OECF, and USAID. There is also a Policy Committee composed of the donor agencies, Ministry of Health, OECF and USAID, with the Director, NIB as Member Secretary.

All committees have met only sporadically, with the last meeting in October, 1994. Therefore, many urgent matters have not been considered, resulting in substantial delays.

### 1.4. Recruitment and Staffing

NIB lacks scientific leadership. This is due to the absence of senior scientific staff. A minimum of a Deputy Director, Quality Control and three Grade I Scientists are required for the efficient operation of the interim facility. Efforts to fill these positions may be restricted by the limited availability of qualified applicants. Beyond these positions, the hiring of additional scientific staff for the interim facility should be dictated by the availability of laboratory space.

### 1.5. Training and Technical Assistance

NIB training and technical assistance needs are dictated by institutional priorities as defined by NIB and the DCI. A significant portion of training for NIB scientists is to be accomplished locally. Where necessary, training is also to be accomplished at overseas locations. Coordination is essential to the success of both local and overseas training, in order to assure the timely delivery of technical assistance and training to NIB. Constitution of a U.S. Technical Assistance Team, with a single point of contact, has been proposed to assist USAID with technical coordination. A similar function on the Indian side is needed to assure the availability and quality of local training. The composition of the Technical Assistance Team may limit the type and extent of training and technical assistance provided to NIB by FDA.

### 1.6. Interim Facility

The interim facility was to be ready in June, 1995, but has been delayed by 10 months. Some of the laboratories were handed over on April 10, 1996, and two testing laboratories, together with three-four support laboratories are planned to be equipped and functional by May 30, 1996.

The design of the interim facility was made by NIH and construction supervised by HSCC. NIH plans were altered [Indianized] by HSCC. Both the quality [reproducibility] of the tests performed and the safety of the laboratory personnel have been compromised as a result of design changes, substitution of some substandard materials, and poor workmanship.

Basic scientific work and statutory testing can be accomplished at the interim facility only if attention is paid to regular and scrupulous internal quality control. More advanced techniques cannot be carried out unless major renovations are made.

## **1.7. Permanent Facility**

Work has not yet begun on the laboratory and animal buildings at the NOIDA site. Once begun, construction will take an estimated three years. The start of construction of the permanent facility at NOIDA has been delayed for three reasons.

### **1.7.1. Design**

The Team found that both NIB (through HSCC) and NIH have contributed to delays in design of the science building. HSCC was awarded the contract to design the facility in April, 1991, but admitted in December, 1992, that it had no experience with sophisticated scientific buildings. In February, 1993, NIB requested that NIH provide the design. In March, 1993, USAID agreed to help do so but insisted that NIB first provide an Institutional Development Plan. With assistance from NIH, such a plan was prepared and accepted by the donors in October, 1993. The Participating Agencies Services Agreement was modified in November, 1993 to allow NIH to provide the design. NIH estimated 12-14 months for completion of design. In January, 1994, NIH solicited design bids from U.S. firms, and a contract was awarded in November, 1994. Bid documents at the 95% completion level, originally expected in August, 1995, were submitted to NIB for comment in November, 1995. Final bid documents were submitted to NIB in February, 1996.

### **1.7.2. Pre-qualification:**

In January, 1995, prequalification bids were invited from building contractors, utilizing criteria developed by HSCC. Of seven firms considered by HSCC to be qualified, only one was confirmed by OECF, using the same criteria. GOI rules require at least three bidders. The recently appointed Secretary of Health has indicated that he will examine the possibility of calling for a fresh round of bids to resolve the impasse.

### **1.7.3. Indianization:**

Widely divergent and incompatible views have been expressed about implementation of NIH design particularly with respect to use and equivalence of Indian materials in the construction of the science/animal block.

## **1.8. Linkages**

The NIB mandate calls for close coordination and effective linkage with DCI and State Drug Controllers. The team observed that DCI and NIB have not yet agreed on the items to be tested on priority in the initial phase at the interim facility.

## 1.9. Recommendations

The team found that there was a lack of both scientific and administrative leadership at NIB. Scientific leadership is lacking primarily due to the absence of ranking scientific personnel including the Deputy Director, Quality Control, and Grade I scientists. Administrative leadership is lacking primarily due to the absence of direction and decision-making from the Governing Body. The team has made a number of specific recommendations to improve NIB scientific and administrative leadership. Additional recommendations have been made to facilitate communication, decision-making, and training.

1. The General Body should meet annually to monitor the progress and provide direction for successful completion of the project.
2. The Governing Body should meet at least four times a year to make decisions on urgent matters.
3. Donor agencies should be invited as observers at meetings of the Governing Body.
4. A working group or progress monitoring cell should be created in the MOHFW to monitor the activities of NIB and to provide definitive agenda items for the Governing Body. The working group should meet once a month, at least until commissioning of the permanent facility.
5. The Director, NIB should exercise the full powers vested in the position and should call for regular meetings of the statutory bodies, the Steering and Policy Committees, and any other committees as may be formed to assist in completion of the project.
6. Appointment of the Deputy Director, Quality Control is key to the establishment of NIB as a high quality testing facility for biologics. Every effort should be made to fill this position. The Deputy Director, Administration, should also be filled immediately. Both positions are needed to:
  - ▶ Supervise and monitor the technical and administrative staff already in place,
  - ▶ Participate in future hiring decisions, and
  - ▶ Assume some of the duties currently discharged by the Director.
7. Recruitment and training should be phased with the development of the facilities.
  - ▶ Recruitment for Scientists Grade I and Grade II needed to complete the staffing of the interim facility should proceed according to the availability of laboratory facilities.
  - ▶ Training of additional scientific staff for both the interim facility and the permanent facility should begin only as laboratory space to exercise the skills acquired during their training becomes available.
8. The immediate hiring of an Executive Engineer is recommended to assist and provide advice to the Director, NIB and to provide a rapid response to day-to-day technical questions relating to construction.

9. Immediate action is required to constitute a Technical Assistance Team. The NIB, with the assistance of USAID and others as needed, should examine the value and implications of hiring a Technical Assistance Team inside or outside of FDA/CBER.
10. Preparation of a detailed plan describing the skills required of each scientific position and a structured plan for the training should be a priority. The Technical Assistance Team should assist NIB in the formulation of these specific training profiles and indicate, for each trainee, the type and extent of preliminary training to be undertaken locally prior to the overseas experience.
11. Formal training agreements between NIB and various Indian institutions are needed to define and assure the training experience.
12. A longer, intensive, more hands-on experience (minimum 6-12 months) for Grade III and Junior Scientists is recommended to assure that needed skills are obtained. Where specific skills are required by NIB scientists, hands-on training, not demonstration, is essential.
13. Standard Operating Procedures (SOP) for personnel, equipment, and maintenance, written by NIB staff for its laboratories, should be prepared soon after training is completed.
14. Because of deficiencies in construction of the interim facility, additional precautions will be needed to insure reliability and accuracy of tests.
15. The team strongly recommends that accreditation of the interim facility be obtained through a recognized international agency, e.g. WHO, but not until such time as the laboratories fully conform to predetermined criteria.
16. The provision of full utilities for the interim facility is essential and should be expedited.
17. The process to select a building contractor for the science/animal block should be started immediately.
18. The contractor should be fully responsible for selection of domestic or imported materials, equipment, and fittings.
19. HSCC should not have any role in the construction, supervision, or certification of the science/animal block.
20. There is need for DCI and NIB to undertake a detailed review of the Drugs and Cosmetics Act and Rules and to prepare a written plan of action regarding amendments to be made and notifications to be issued.
21. Persons to perform the function of Government Analyst and to address other regulatory matters need to be identified, trained, and provided with the requisite experience.
22. The protocols of tests and standards currently prescribed by DCI for biological products must be reviewed and updated.

## 2. QCHT MID-TERM EVALUATION

### 2.1. Economic, Political, and Social Context

India is the second largest country in the world, with a population projected to reach one billion during this decade. India has made remarkable advances in the health sector in the last fifty years. Average life expectancy has increased from 32 years in 1947 to 63 years, and infant mortality has decreased from 130/1000 in the early 1970's to 62/1000. Despite this progress, there are approximately 25 million births every year. Nearly one-third of children under age five suffer from mild to moderate malnutrition, and more than 1.5 million die each year from vaccine-preventable diseases.

India joined the Expanded Program of Immunization of the World Health Organization (WHO) in 1978, with coverage of six vaccine-preventable diseases currently reaching more than 85%. The burden of communicable disease remains high, however, with frequent childhood deaths due to pertussis, measles, and tetanus. Poliomyelitis accounts for 44% of lameness of Indian children (USAID project paper 1990).

To keep targets of Health for All by the Year 2000, the Government of India (GOI) has encouraged expansion of vaccine production in India. It recognizes that, in order to sustain a successful national immunization program, there is a need for substantially improved quality control capability.

### **3. SCOPE OF WORK**

The purpose of this mid-term evaluation is to:

1. Assess the progress of the Quality Control of Health Technologies (QCHT) project toward attainment of its objectives.
2. Identify and evaluate the problem areas or constraints which may inhibit such attainment.
3. Evaluate, to the degree feasible, the overall development impact of the project.

## 4. PROJECT DESCRIPTION

The QCHT project is to create a National Institute of Biologicals (NIB) by means of a collaborative venture between three governments in order to fulfill India's need for a national testing and reference center. The United States Agency for International Development (USAID) has agreed to provide a \$13.3 million grant toward technical assistance, training and scientific equipment. The Government of Japan (GOJ) through its Overseas Economic Cooperation Fund (OECF) is providing a \$50 million loan with 2.5% interest for buildings and fixed equipment. The GOI is contributing land, staff salaries, and operational costs.

The agreement was signed in September, 1990, with USAID collaboration lasting to September, 1998, and GOJ collaboration to February, 1999.

The primary objective of the QCHT project is the development of NIB as a functioning national quality control institution for biological products in India, viz. bacterial and viral vaccines, blood products and immunodiagnostic kits.

The project will establish the NIB as an autonomous GOI organization responsible for:

1. Monitoring and certifying the quality of biologicals in collaboration with the Drugs Controller of India (DCI).
2. Validating and certifying other Indian testing laboratories for the DCI and the GOI.
3. Improving testing and manufacturing procedures throughout India.
4. Establishing, producing, maintaining and distributing national technical standards.
5. Providing training and technical support in quality control of biologicals to public and private manufacturers, testing laboratories and control organizations.
6. Establishing international linkages and serving as a data repository and source of information on quality control of biologicals.
7. As the NIB becomes fully functional, it will assist the GOI efforts to reduce child morbidity and mortality and to achieve Health for All by the Year 2000.

## 5. TEAM COMPOSITION

The team was selected and organized by Development Associates, Inc. under contract N<sup>o</sup>. 645000 from USAID.

|             |                              |
|-------------|------------------------------|
| Team Leader | Dr. William E. Woodward (US) |
| Members     | Dr. John Foulds (US)         |
|             | Dr. K.B. Sharma (India)      |
|             | Dr. Prem K. Gupta (India)    |

## **6. METHODS EMPLOYED**

Simply put, team evaluation consisted of interviews with project principals, re-interviews for further exploration and clarification, site visits, and review of pertinent documents. Remarkably mutual agreement followed upon extensive internal deliberations regarding findings, conclusions, and recommendations. The case study method was not employed.

## 7. MAJOR ISSUES ADDRESSED

### 7.1. NIB as an Autonomous Institution

#### 7.1.1. Findings

The USAID Project Paper of September 25, 1990 (QCHT 386-0514) reads (5.13, p.42) as:

"The NIB will be established as a self governing, autonomous organization under the Registration of Societies Act XXI of 1860".

The NIB was accordingly registered on January 27, 1992.

The Memorandum of Association lays down the aims, objectives, and functions in detail to realize these objectives. The rules and regulations describe the composition of the General Body which is the supreme policy making, governing and appellate body of the institute. The General Body has 17 members, with the Secretary of Health as Chairman, Secretary of Family Welfare as Vice Chairman, and Director, NIB as Member Secretary. An annual meeting of the General Body is required to be held every year to consider the annual report and accounts of the institute.

The Governing Body is composed of nine members, with the Secretary of Health as Chairman, Secretary of Family Welfare as Vice Chairman, and Director, NIB as Member Secretary. The Secretary of the Department of Biotechnology, Director General of Health Services (DGHS), Director General of the Indian Council of Medical Research, Joint Secretary (Health), Joint Secretary Financial Adviser (Finance), and DCI are the other members.

The Governing Body is required to meet twice a year and additional meetings can be held as the Chairman/Vice Chairman may decide. The Governing Body has the authority to constitute standing and ad hoc committees as may be considered necessary.

The team was informed that a meeting of the General Body of NIB has been held only once in 1992 and that the Governing Body has met three times (March 29, April 22, and October 17, 1994), since its constitution in 1992.

#### 7.1.2. Conclusions

NIB was originally planned to be completed in 1998, with its testing and quality control (QC) functions to begin earlier at an interim facility. More than five years have passed and the laboratories at the interim facility are yet to be commissioned. The permanent science and animal blocks at the New Okhla Industrial Development Authority (NOIDA) are still in the design and drawings stage. The project is overly delayed, and one of the reasons (amongst many) is that the meetings of the General Body and of the Governing Body have not taken place

as regularly as required. Decisions on urgent matters have been kept pending as the Governing Body has not met for more than 18 months.

According to its rules and regulations, the meeting of the Governing Body can be convened by the Member Secretary and, in the absence of the Chairman, can be chaired by the Vice Chairman or, in the absence of both, by any member chosen by the members present.

It is observed that the Director, NIB has the necessary executive and administrative powers per rules and regulations of the Memorandum of Association but has not exercised the full powers vested in the position for resolving urgent matters. The team believes that decisions on matters such as finalization of the pre-qualification (PQ) bid agreement for a contractor, Indianization of designs, recruitment of senior scientific staff, and commissioning of the interim facility should have been resolved by convening the Governing Body for prompt action.

### **7.1.3. Recommendations**

1. The General Body should meet annually to monitor the progress of various activities of NIB and provide overall direction for successful completion of the project.
2. The Governing Body should meet four times a year or more often, as and when necessary, at least until the permanent facility is commissioned.
3. Donor agencies should be invited to attend as observers at meetings of the Governing Board.
4. A working group should be created in the Ministry of Health and Family Welfare (MOHFW) to monitor the activities of NIB on a regular basis. This committee, consisting of the Additional Secretary of Health, Joint Secretary Financial Advisor, and representatives of donor agencies (USAID and OECF) should meet monthly on a fixed date to review the progress in each area. The issues raised in these meetings and problems, if any, should form the basis of the agenda to be discussed in the meetings of the Governing Body.
5. The Director, NIB should be vested with sufficient powers (if not already so) to resolve urgent matters, so that the time frame of the completion of NIB is not affected.

### **7.2. Functions and Powers of the Director, NIB**

According to the Memorandum of Association, the Director, NIB is responsible for the proper administration of the affairs and the funds of NIB under the direction and guidance of the Governing Body. The Director exercises general supervision and disciplinary control over the officers and staff of the institute and prescribes their duties and functions. The Director exercises general supervision over all the activities of the Institute.

In the capacity of Member Secretary, the Director, after obtaining prior approval of the Chairman/Vice Chairman, issues notice for the meeting of the General Body and Governing Body.

The Director complies forthwith with any direction issued by MOHFW and reports such matters to the Governing Body at the earliest possible opportunity thereafter.

**7.2.1. Findings**

In view of the fact that only three meetings of the Governing Body and one of the General Body have been held since the inception of NIB and none since October, 1994, most decisions regarding the development of NIB, including those relating to construction, have been taken without reporting to the Governing Body. Instead, the Director has referred matters to the Secretary of Health in the MOHFW. Thus it is observed that the Director does not seem to have taken full advantage of the autonomous status of NIB or to have taken the opportunity to exercise the full powers of the position to expedite urgent matters.

The Director also holds the rank of Additional DGHS, which has caused the perception that she has additional duties which may detract from her primary responsibility at NIB. The Director confirmed that now she is acting full-time, a fact confirmed by the Secretary of Health.

The Secretary of Health, who also chairs the Governing Body, indicated that the next meeting of the Governing Body would be held on May 8, 1996, to resolve all pending matters of construction of the laboratory/animal block.

**7.2.2. Conclusions**

Some decisions such as PQ, Indianization, and convening of the Governing Body have not been promptly made.

It is expected that the next meeting of the Governing Body will address all pending matters of construction, recruitment, and training.

**7.2.3. Recommendations**

1. The Director should pursue the development of NIB with the full powers provided in the original Memorandum of Association.
2. The Director should keep in close, frequent, and prompt contact with DCI and the donor agencies.

**7.3. Recruitment and Staffing**

**7.3.1. Overview**

Currently, the NIB staff totals approximately 58, including approximately 19 scientists and technicians. Ultimately, a scientific staff of 114 is planned. Briefly described, the duties of the NIB staff are to furnish services, information and recommendations to the DCI as previously outlined in NIB planning documents. These duties must be accomplished with the reliability, precision, and accuracy needed to assure the quality of the results and value of the

recommendations. In order to perform these duties with this degree of excellence, significant training of scientific and technical will be required.

### 7.3.2. Findings

#### *Background*

Until the commissioning of the permanent facilities at the NOIDA site, current plans call for the scientific staff, together with the NIB administration, to be housed in the interim facility located on Jhandewalan Extension in New Delhi. Six functioning laboratories and four support laboratories together with essential scientific staff (up to 30) are planned for this site. The commissioning of these laboratories, and presumably scientific staffing, will be phased. The first two laboratories, together with two-three support laboratories will be handed-over from the contractor, HSCC, to NIB in April, 1996.

#### *Scientific Leadership*

There is an absence of scientific leadership in NIB. Apparently, a decision has been made within NIB to focus hiring efforts on technicians and lower grade scientists (Scientist Grade III and Junior Scientist). Except for the Director, the NIB currently has no scientists above Grade II. Despite previous recommendations, no Deputy Directors have been appointed. A particular need has been identified for a Deputy Director, Quality Control. Three Grade I scientists are also needed to supervise the daily scientific activities of the anticipated six primary laboratories planned for the interim facility. All four of these positions are both authorized and planned. The Mid-term Evaluation Team was informed that, although efforts have been made to fill the position of Deputy Director, Quality Control, the NIB has found it difficult to identify qualified candidates.

### 7.3.3. Conclusions

The scientific program at NIB needs leadership. This deficiency is reflected, for example, in:

- ▶ The lack of Standard Operating Procedures prepared for Indian laboratories,
- ▶ The absence of formal training evaluations, and
- ▶ The inappropriate delivery of overseas training, planned for Laboratory Chiefs, but given to a Scientist Grade III and a Junior Scientist.

Recruitment efforts to fill scientific leadership positions at NIB should be an institutional priority. Appointment of the Deputy Director, Quality Control is critical for the scientific and technical success of the NIB. As this position may be difficult to fill, additional incentives should be considered. For example, the individual named to the position of Deputy Director, Quality Control would be expected to assume the position of Director.

Appointment of other senior staff should also remain a priority for NIB. Qualified persons should be available for the Scientist Grade I positions.

### 7.3.4. Recommendations

1. Appointment of Deputy Director, Quality Control is key to the establishment of NIB as a high quality testing facility for biologics. Every effort should be made to fill this position. The Deputy Director, Administration, should also be filled immediately. Both positions are needed to:

- ▶ Supervise and monitor the technical and administrative staff already in place,
  - ▶ Participate in future hiring decisions, and
  - ▶ Assume some of the duties currently discharged by the Director.
2. Recruitment and training should be phased with the development of the facilities.
- ▶ Recruitment for Scientists Grade I and Grade II needed to complete the staffing of the interim facility should proceed according to the availability of laboratory facilities.
  - ▶ Training of additional scientific staff for both the interim facility and the permanent facility should begin only as laboratory space to exercise the skills acquired during their training becomes available

3. The immediate hiring of an Executive Engineer is recommended. This post is already sanctioned. An Executive Engineer is needed to address a number of issues regarding maintenance of the interim facility, and to assist the Director in making rapid decisions regarding engineering issues affecting construction at the NOIDA site. The Engineering Committee, established to assist and provide advice to the Director, NIB, is unlikely to provide a rapid response to day-to-day questions.

## 7.4. Training and Technical Assistance

### 7.4.1. Overview

To achieve NIB institutional aims, the NIB staff must be highly qualified, thoroughly trained, and fully experienced. The timed delivery of training and technical assistance to NIB from USAID will depend, at least in part, upon recruitment which, in turn, will depend upon the availability of facilities, i.e. the planned phased operation of the interim (and perhaps the permanent) laboratories.

### 7.4.2. Findings

#### *Background*

At the Jhandewalan Extension site, operations will, at first, be limited by the availability of electric power. Plans for the first phase of operations at this site include two (or possibly three) testing laboratories (Blood Products and Diagnostic Kits), together with two-three support laboratories (autoclave, deep freeze, and media preparation). These laboratories are now

scheduled to be handed-over in April, 1996, after a delay of at least one year. The consequences of this delay include in-country training and overseas training delivered to NIB scientific staff before the laboratories could be occupied.

### *Institutional Priorities*

Training needs are based on institutional testing priorities. Initial priorities for testing are established by NIB, in response to the needs of the DCI. Blood products and reagents, immunodiagnostic kits and vaccines (polio and measles) are biologicals designated as initial priorities by NIB. Except for polio and measles vaccines, these are all products for which no quality control testing facilities currently exist in India. These items are currently approved and released for use in India solely on the basis of examination of protocols provided by the manufacturer. The DCI has recently indicated that blood bags (not a biological) are also a priority.

### *Local (In-Country) Training*

Basic and specific training is deemed essential for nearly all NIB scientific staff. A detailed institutional training plan for NIB has been prepared by FDA/CBER. Recruitment and training time lines for 114 scientific NIB positions, have been prepared. In general, these plans call for approximately six months training at different Indian institutions. Some NIB scientists have already received this training.

To date, arrangements for local training have been made, informally, by Director, NIB, on an as-needed basis. No formal agreements with the various Indian institutions to assure provision and content of local training are in place or planned.

To date, training at local sites has been delivered to a total of 19 Grade III Scientists, Junior Scientists, and Laboratory Technicians. This training occurred during 1994 and 1995. Training was provided at one-three local sites including All India Institute of Medical Sciences (AIIMS), Postgraduate Institute of Medical Education and research (PGIMER), Indian Red Cross Society, and Central Research Institute (CRI) Kasauli. Depending upon the site, training lasted from 19-41 days. A portion of this training was delivered in the form of demonstrations. Some SOP's, based on this training have only recently been prepared. All SOP's prepared thus far are in draft form. None has been reviewed or approved.

### *Overseas Training*

Detailed profiles for overseas training at FDA/CBER for three NIB positions were prepared by FDA/CBER. Preparation of these profiles was based on the programmatic and managerial responsibilities defined for NIB scientists. The positions for which the profiles were prepared were chosen to reflect initial NIB testing priorities in these areas. Training profiles were prepared for:

- ▶ Chief, Blood and Blood Products Section,
- ▶ Chief, HIV/Hepatitis Test Kit Laboratory, and
- ▶ Chief, Blood Grouping Laboratory.

FDA/CBER noted that these training profiles were prepared without a clear understanding of the specific training needed to best serve NIB.

The profiles included:

- ▶ Programmatic and managerial responsibilities,
- ▶ Position description,
- ▶ Specific laboratory methods to be used,
- ▶ Suggestions for local training and other preparatory work, and
- ▶ Suggestions for proficiency testing and other follow-up activities.

It should be noted that these training profiles were prepared in 1994 without, for example, specific knowledge of the type(s) of HIV test kits approved by DCI for use in India. A variety of kits exist. Each requires different procedures, skills, and equipment to test.

On the basis of these profiles, two NIB scientists (Dr. R. Chhabra, Scientist Grade III and Mrs. A. Sircar, Junior Scientist) received overseas training. The scientists who were trained did not occupy the positions for which the training profiles were prepared. This was because no senior scientific staff had been hired.

#### *Evaluation of Training*

No training evaluations have been completed. No proficiency testing, at NIB, has been accomplished or planned. Dr. Ray will ask FDA/CBER to evaluate overseas training.

#### *Technical Assistance Coordination [Training]*

The need for the coordination of technical assistance has been noted previously in April, 1995 (Manclark), and the extensive duties and responsibilities associated with this function have been defined in the most recent PASA. Briefly, technical assistance provided thus far to NIB by USAID has consisted of:

- ▶ Assistance in project design (NIH lead),
- ▶ Assistance in training (FDA lead), and
- ▶ Description and purchase of movable equipment needed for the interim facility.

In this section of the Mid-term Evaluation report, technical assistance refers only to assistance provided for the training component. USAID assistance in construction design is addressed elsewhere (see sections of the report on [1] Interim Facility and [2] Permanent NOIDA Facility).

Coordination of technical assistance with the resources needed to accomplish this assistance is essential to the successful outcome of USAID's agreement with NIB. Yet, the specific nature and extent of the technical assistance required has not been defined, making planning difficult. Until approximately January, 1995, this function of defining and planning the nature of the technical assistance (training) was provided by a single person, located within FDA and serving part-time in India. Since then, no person or group has fulfilled this need.

Efforts to procure the services of a single person to serve full-time as coordinator of NIB training and assistance with resources within FDA have been unsuccessful. This was due, at least in part, to the extent of these duties and responsibilities, and to the need for significant time to be spent in India. FDA noted, in 1994, that technical coordination may best be accomplished by an FDA employee supported by a "number of technical experts within CBER." This concept has evolved. USAID and its PASA partner, the Office of International Health (OIH), agreed that the lead for technical assistance coordination would originate from a full-time position located within the OIH and funded by USAID. This plan also did not materialize.

A Technical Assistance Team, with a single contact point for USAID and NIB, was recently proposed to provide the needed coordination of overseas training and technical assistance. A similar Indian coordination team and single point of contact for local training was also proposed. These proposals from the "Strategic Plan for the Development of the Science Program..." arose from a meeting held on January 16, 1996, and attended by USAID consultants, NIB staff, Indian scientists chosen as expert advisors, the Assistant DCI, and others. The Evaluation Team was told that all parties "signed off line by line" on the strategic plan formulated at this meeting.

An essential component was the establishment of a Technical Assistance Team to provide the expertise and manpower for the several tasks previously attempted by the single technical coordinator. "A key element in the management proposal which will assist the collaborating parties in driving forward the project are quarterly meetings, [of the Technical Assistance Team or representative(s)]...." NIB, USAID, consultants, and experts all agreed in January that this plan needed to be implemented "within the next few weeks." To date, no plans have been made to constitute the Technical Assistance Team. After receiving the final report in mid-February, USAID decided to delay action until after the Mid-term Evaluation was completed. Despite a specific request, copies of the final "Strategic Plan," were not made available to the Evaluation Team prior to its arrival in New Delhi on March 28, 1996.

#### 7.4.3. *Conclusions*

##### *Local Training*

The required local (in-country) resources needed to provide Technical Assistance (training) must be defined and assured. Coordination of these activities and a single point of contact is needed.

Training may be of little or no value unless the skills acquired can be put to use. All, or nearly all, in-country and overseas training for NIB scientific staff is of questionable value because:

- ▶ Trained staff still have no bench space where the skills learned in 1994-95 can be applied,
- ▶ SOP's were written long after completion of training, and
- ▶ Evaluation of completed training has not been done.

Local training thus far delivered to NIB scientific staff does not meet requirements for excellence put forward in earlier NIB planning documents.

Limited domestic training, without formal agreements, can be easily arranged by the Director, NIB and promptly accomplished. Yet this training of existing NIB staff appears to have been

brief, erratic, and incomplete. Training for four-six weeks at various sites such as AIIMS, Red Cross, CRI Kasauli, and others provides exposure but does not provide sufficient hands-on experience.

### *Overseas Training*

The required overseas resources needed to provide Technical Assistance (training) must be defined and assured. Coordination of these activities and a single point of contact is needed.

Thus far, little overseas training has been provided to NIB scientists. The training that has occurred has been described by the scientists trained, the FDA, and NIB as fully successful, yet it failed to include critical follow-up activities such as evaluation and any scheme for proficiency testing.

### *Technical Assistance (Training) Coordination*

The technical assistance (training) that has already been provided to NIB under the terms of the PASA has been both substantial in amount and high in quality. Yet, additional help in this area is needed. The overall training plan as prepared in 1994 by FDA/CBER (Total Quality Training Program in Science and Technology, FDA/CBER 12/3/94 [Draft]) needs to be expanded. General and specific skills needed by NIB scientists should be identified and the training needed to achieve these skills defined. The sites where this training can be accomplished need to be identified. The end product of these efforts should be a set of position descriptions for NIB, each description containing a list of specific skills required to accomplish the NIB mission. As a pre-condition for undertaking this task, the NIB, together with the DCI, must provide the Technical Assistance Team with specific information on the biological and other products to be initially tested by NIB. This information should include packet inserts, where available. The Technical Assistance Team should also assist NIB with the preparation of agreements with local and overseas institutions to assure that necessary training, evaluations, and follow-up activities will be provided to NIB scientists.

The Technical Assistance Team, as formulated in "The Strategic Plan," appears to be an excellent solution to the inability of FDA/CBER, OIH, or USAID to hire a single person to fulfill this function.

The Mid-term Evaluation Team concluded that:

- ▶ A Technical Assistance Team would likely not use FDA/CBER as the lead institution for training assistance,
- ▶ High quality training for NIB scientists could be provided in most areas outside, as well as inside FDA/CBER,
- ▶ Insofar as some types of required training may not be available elsewhere, cooperation of FDA/CBER would be required.

How training and technical assistance may be enabled, or limited, by the use of a Technical Assistance Team should be examined by USAID, FDA/CBER and NIB. If the NIB and/or DCI requires that test results from NIB be *equivalent* to results obtained by FDA/CBER, the Technical Assistance Team should be formed within FDA/CBER. If the Technical Assistance Team is constituted outside of FDA, as suggested in the Strategic Plan, participation of FDA may be limited. US regulations limit access to FDA personnel, laboratories, and records by non-FDA employees.

Although the Technical Assistance team could provide NIB with *some* of the scientific leadership currently missing from the organization, it should not be viewed as a substitute for senior scientific staff, i.e. Deputy Director, Quality Control, and Grade I Scientists.

#### **7.4.4. Recommendations**

1. Immediate action is required to constitute a Technical Assistance Team. The NIB, with the assistance of USAID and others as needed, should examine the value and implications of hiring a Technical Assistance Team inside or outside of FDA/CBER.
2. Preparation of a detailed plan describing the skills required of each scientific position and a structured plan for the training should be a priority. The Technical Assistance Team should assist NIB in the formulation of these specific training profiles and indicate, for each trainee, the type and extent of preliminary training to be undertaken locally prior to the overseas experience.
3. Formal training agreements between NIB and various Indian Institutions are needed to assure an adequate training experience.
4. A longer, more intensive training (minimum 6-12 months) for Grade III and Junior Scientists is recommended to assure that needed skills are obtained. Where specific skills are required by NIB scientists, hands-on training, not demonstration, is essential.
5. SOPs, written by NIB staff for its laboratories and equipment, should be prepared soon after training is accomplished.

#### **7.4.5. Lessons learned**

In retrospect, the plans to provide technical assistance for training to NIB were set in motion too early in the development of the institution. If the clock for this portion of the PASA had begun approximately one year prior to the planned commissioning of the interim facility, sufficient assistance could, with planning, have been provided and the September, 1998 deadline would not today loom so large.

### **7.5. Interim Facility**

#### **7.5.1. Findings**

Discussions were first held in August, 1991 between NIB and counterparts on a Public Health Service team from the U.S., in order to identify an interim facility where testing could be

performed while the permanent facility was under construction. Visits were made to Jhandewalan to consider it as a potential site.

Discussions of the concept, program of requirements, cost estimates, and equipment needs continued in meetings in India and the U.S. in January, February, and October of 1992, culminating in a U.S. team visit in December to attend the third meeting of the Policy Committee. At this time, the National Institutes of Health (NIH) presented a layout for 10 laboratories, but consensus on the exact number and type of laboratories could not be reached.

In March, 1993, during an NIB visit to the U.S., Hospital Services Consultancy Corporation (HSCC) requested that NIH provide a conceptual layout. USAID agreed to access NIH services, after NIB wrote an Institutional Development Plan. In April, Dr. E. Seligman visited India to assist NIB in this regard. By October, the Institutional Development Plan was accepted by the donors.

Subsequently, the Evaluation Team was informed, NIH provided the design, and HSCC carried out the renovation.

During a tour of the interim facility, the Team noted multiple deficiencies and departures from NIH design specifications (see appendix Site Visits). These deficiencies pose a potential health hazard for personnel and may jeopardize QA/QC testing, due to microbial contamination resulting from inability to clean surfaces adequately.

In the 1995 NIB Project Summary, the interim facility was expected to be completed in June, 1995, with commissioning in September, 1995. Now, the Evaluation Team has been informed that the building will be handed over from the contractor to NIB this month. Dr. Ray indicates that HSCC is responsible for delays and alterations in NIH design.

The latest estimate for fully equipping the first two laboratories (blood products and immunodiagnostic kits) is May 30, 1996. It is not clear, however, that even these two laboratories will be able to function fully without increased electrical power. Mr. Bhatia, NIB Administrative Officer, indicated that Delhi Electricity Supply Undertaking (DESU) has agreed to supply 550 KW to the facility in three-four months.

### **7.5.2.        *Conclusions***

There have been substantial delays in renovating the interim facility and making it operational. Alterations in construction design, materials, and fittings pose a potential health hazard and threat to reliability of test results. Delays, poor construction work, and alterations in design have been attributed to HSCC.

Despite these deficiencies, the Team believes that high quality QA/QC testing can be accomplished at this site, as long as enhanced attention to quality and monitoring is maintained and until the permanent facility is made available.

The Team does not believe that certain specialized testing, such as polymerase chain reaction, can be conducted reliably in the interim facility, without major improvements.

### 7.5.3. Recommendations

1. Additional precautions are needed to insure reliability, precision, and accuracy of tests conducted in the interim facility, beyond the precautions normally required for this type of laboratory (such as routine internal and external quality control, Good Laboratory Practices, etc.).
2. Additional internal quality control procedures to rigorously monitor staff, procedures, and laboratory should be undertaken.
3. Present institutional plans call for accreditation of these facilities approximately six months after testing begins. The team strongly recommends that accreditation not be sought until such time as the laboratories at the interim facility *fully* conform to predetermined criteria. Accreditation should be obtained through the auspices of a recognized international agency such as WHO.
4. The provision of full utilities is essential and should be expedited.
5. As future laboratories in the interim facility come on line, NIB procurement is urged to have all movable equipment on site well before scheduled occupancy.

## 7.6. Permanent NOIDA Facility

### 7.6.1. Findings

Nineteen acres were purchased from NOIDA by the GOI in April, 1992 for the construction of a permanent NIB facility to consist of a science/animal block, administration building, library, auditorium, residential facilities, cafeteria, and various support buildings.

A summary of the progress of construction is presented below. For further details, consult the Appendices on Chronology of Events and on Site Visits.

#### *Design*

HSCC was awarded the contract to design the facility in April, 1991, but later admitted that it had no experience with sophisticated scientific buildings. In December, 1992, it requested that NIH prepare designs instead. In December, 1993, funds were added to the original Participating Agencies Service Agreement (PASA) to enable NIH to prepare designs for the complex. At the time of the addition of funds, NIH estimated 12-14 months to complete the designs. Work on the design began prior to the signing of a contract with the architecture and engineering firm of Zimmer Gunsul Frasca in November, 1994. Bid documents at the 95% design level, incorporating all comments from NIB and HSCC, were submitted to NIB via USAID only in February, 1996, 26 months after the modified PASA.

#### *Prequalification*

In January, 1995, using criteria developed by HSCC, pre-qualification (PQ) bids for construction were invited. Of 17 responding companies, HSCC felt that seven qualified. However, using the

same criteria, OECF concluded in April, 1995 that only one bidder qualified, a matter unacceptable according to GOI regulations and one yet to be resolved. The recently appointed Secretary of Health has indicated to the Evaluation Team, however, that he will examine the possibility of calling for a fresh round of bids. The simultaneous inclusion in the bids of both technical and financial components will obviate the need for a repeat of the separate PQ process.

### *Indianization*

Concern about adaptation of NIH design and use of equivalent Indian materials and equipment, a process dubbed "Indianization," was expressed as early as May, 1994. However, the issue has yet to be resolved since various parties have widely divergent views on the subject. In summary, HSCC believes that several thousand items are involved and that decisions regarding each would require a great deal of time and substantial charges to the project. Vijay Rewal Associates, the Indian design subcontractor for NIH, states that only a few (perhaps 25-50) items are involved, with rapid resolution possible. USAID takes a middle position. HSCC and Vijay Rewal Associates have each expressed strong opinions that it should be the sole construction project manager.

### **7.6.2. Conclusions**

Considerable delays have been experienced in completion of the NOIDA facility, especially the science/animal block, and deadlines have been subjected to repeated postponement.

There is no simple explanation or single entity responsible for the delays encountered. Supervisory councils (General Body, Governing Body, Steering and Policy Committees) have not met since October, 1994. Decisions, capable of being made by the NIB Director with the powers vested in the position, have instead been referred up the chain of command of MOHFW and not to the Governing Body. NIB Deputy Directors have not been recruited and have thus not been available to relieve some of the pressure on the Director. Selection of HSCC, with self-admitted lack of experience in this arena, delayed the eventual selection of NIH to provide building plans. NIH designs were submitted late and at the 95% level, when earlier, less complete versions would have sufficed for PQ bidding purposes. Alterations in NIH design for the interim facility and substandard workmanship by HSCC have directed attention away from the permanent facility. HSCC-provided criteria for PQ have not been strictly followed by HSCC, leaving donor agencies perplexed. Responses to communications have not been made in a timely fashion and sometimes have not been made at all.

The result has been that only four buildings (administration, cafeteria, guest house, and hostel) are currently under construction, with a completion date estimated in 8-12 months.

Ground for the heart of the complex, the science and animal buildings, has yet to be broken. All parties seem to agree that construction of these elements will require about 45 months (nine months for selection of a contractor, 36 months for construction), with an additional six months needed to develop full operational capability. This would place completion of the scientific portion circa July, 2000, even if all impasses were resolved today.

Donor agencies are becoming increasingly concerned about the timely completion of construction. While all have expressed a strong desire for its successful outcome, they are more and more aware of approaching deadlines and, consequently, the possible need to terminate the project prematurely.

Adaptation of NIH design and use of equivalent Indian materials and equipment is a process that has been dubbed "Indianization." Indianization issues need to be resolved as quickly as possible, without compromising the standards of the scientific/animal buildings.

If HSCC is selected as the sole construction manager, to include its final approval of whether design specifications have been met, NIH will most likely insist upon release from any liability for deviations from its design.

As a result of their admission of lack of experience and their poor performance with the interim facility, the Team concludes that HSCC is not qualified to build or to supervise the building of the science/animal block, or to certify its adherence to design specifications.

### **7.6.3. Recommendations**

1. The Governing Body needs to take overall supervision of the project to hand and should meet with the regularity and frequency necessary to expedite matters.
2. The MOHFW should appoint a working group that meets on a monthly basis, establishes definite milestones, and ensures that goals for construction are being met.
3. The Team agrees with the intention of the Secretary of Health to initiate a fresh round of bids, incorporating both technical and financial aspects, as long as this can be accomplished rapidly.
4. A single construction manager should be selected to avoid the conflicts that have risen between HSCC and Vijay Rewal Associates and appear insoluble.
5. HSCC should not have any role in the construction, supervision, or certification of the science/animal block.
6. The contractor should be fully responsible for selection of materials and equipment, whether domestic or imported.

## **7.7. Linkages with DCI and Regulatory Functions**

### **7.7.1. Findings**

The Constitution of India mentions health in the concurrent list, which means both Central Government and State Governments can legislate and enforce laws on health matters.

The Drugs and Cosmetics Act 1970 and the Drugs and Cosmetics Rules 1945 regulate the import, manufacture and sale of drugs (including biologicals) and cosmetics.

These are Central regulations, but State Governments are empowered to enforce them within their states. The Central Drug Standard Control Organization, headed by DCI, is responsible for the quality of imported drugs, approval of new drugs, provision of standards (Indian Pharmacopoeia, National Formulary), amendment of laws, and directions to states to ensure uniform enforcement throughout the country. State Governments are responsible for licensing the manufacture and sale of drugs within their states.

Although testing facilities in India can be considered reasonable for chemical and instrumental analysis, the testing capacity and quality control of biological products are woefully inadequate. For these, the DCI has no testing laboratory of its own and has to depend on others, primarily the one in CRI, Kasauli. It acts as the National Control Laboratory and tests samples of vaccines, toxoids, sera, immunologicals, sutures, etc. forwarded by Drug Inspectors and Port Offices at the time of importation.

Drug control organizations at the central and state levels are clearly understaffed, especially so in handling the review, licensing, indigenous production, monitoring, and inspection of manufacturers of biologicals.

It is this background that led to the concept of establishing the NIB, whose primary purpose is to develop the institutional capacity of the GOI to monitor effectively the quality of biologicals, both imported and locally produced. The NIB project is to set up a biological laboratory with trained scientific and professional staff of the highest caliber. It will serve as the National Control Laboratory and provide reliable test data, reference standards, regulatory procedures and standards, and improved testing/manufacturing methods to assist DCI in its regulatory function as the National Control Authority.

The Drugs and Cosmetics Rules, amended in 1992, provide that the license to manufacture whole human blood or blood products, large volume parenterals, sera, and vaccines will be issued by the License Approving Authority of the Central Government. The control of the manufacture and testing of biological products has thus been shifted from the states to the Central Government.

### **7.7.2. Conclusions**

The basic functions and mandate of NIB require a close interaction, effective linkage, and continuous coordination with DCI and state Drug Controllers.

It is planned that NIB, initially at the interim facility and later at its permanent NOIDA site, will perform the six essential functions of the National Control Laboratory, in accordance with the WHO guidelines for National Control Authorities as outlined in the document "The Strategic Plan for the Development of the Science Program of NIB" by George Siber and others.

After discussion with the Director, NIB and a limited telephone conference call with DCI, the team is concerned that there does not appear to be sufficient coordination of information and formal written strategic link between the two.

For example, it was the contention of DCI that, as initial priorities, he would like NIB to provide testing facilities for diagnostic reagents, diagnostic kits, blood bags and other biologicals for

which no testing facilities currently exist in the country and which are released for sale on the basis of manufacturers' protocols only. It is the understanding of the Team, however, that the interim facility will evaluate HIV and HBV test kits (but not diagnostic reagents), blood products and blood grouping reagents (but not blood bags), polio and measles vaccine (but not other biologicals).

DCI stated that he is waiting for NIB to inform him when the facilities are ready so that he can issue the desired amendment for notifying NIB under the provisions of the Drugs and Cosmetics Act.

These observations indicate that there is need for closer coordination between NIB and DCI to fulfill the desired mandate.

NIB is required to provide DCI with scientific expertise in testing, production, inspection, review, and advice on all matters pertaining to biologicals. At present DCI does not have sufficient staff strength and Drug Inspectors are not adequately trained to inspect private manufacturers, either existing or new. If this linkage is to be provided by NIB, it is essential that the DCI identify the areas in which NIB scientists and his own officers are to be trained for performing regulatory functions. It is desirable that an officer of DCI and a scientist from NIB should be identified as early as possible so that the desired training for each can be planned. The qualifications of Government Analyst, responsible for signing test reports, are specified in the Drugs and Cosmetics Rules. It would be desirable to identify now one or more NIB scientists so that he may be trained to fulfill the qualifications for certification as Government Analyst.

The team observed that no effort seems to have been made to prepare a formal plan of action for linking NIB with the regulatory authority (DCI). It will require an in-depth examination of Drugs and Cosmetics Act and Rules to determine the extent of amendments, additions, and deletions that are required to make NIB (the National Control Laboratory) an integral part of DCI (the National Control Authority).

If the functions of clinical evaluation, licensing, lot testing, lot release, inspections, and post-marketing surveillance are to be performed by the NIB, it is obvious that appropriate rules must be framed to provide a legal basis. It is also necessary to review all standards for biologicals as laid down in Schedule F of the Drugs and Cosmetics Act and those in the Indian Pharmacopoeia. The testing procedures and specifications should be brought on par with the FDA Code of Federal Regulations and WHO standards.

### **7.7.3.        *Recommendations***

1.        There should be closer coordination between DCI and NIB. There should be full agreement on items to be tested on priority and the testing expertise required.
2.        For performing regulatory functions, officers from DCI and NIB should be identified and trained in all required procedures, laws and regulations. The person to be notified as Government Analyst should be identified, hired, and trained for the purpose and should have the requisite experience.

3. DCI and NIB should prepare a detailed plan of action from the legal and administrative point of view, including any necessary amendments and notifications.

4. NIB should prepare complete protocols of tests for the currently produced and imported biologicals as well as those which are likely to be introduced. The standards prescribed in the Indian Pharmacopoeia and Schedule F of the Drugs and Cosmetics Rules should be reviewed and updated with the latest standards available from the World Health Organization (WHO) and the British and U.S. Pharmacopoeias. This will enable DCI to exercise control over the quality of all biological products, now and in the future.

## 8. GENERAL TEAM FINDINGS AND CONCLUSIONS

The Evaluation Team is greatly encouraged by discussions with the newly appointed Secretary of Health and Additional Secretary of Health and believes that prospects for the successful outcome of the project are improved. The Team's opinion is that the original mission of the NIB continues to be entirely relevant in the eyes of the MOHFW, OECF, and USAID.

If anything, the parties involved believe that the mission to establish NIB as the National Control Laboratory is even more urgent than before:

1. To assist the national effort in child survival by insuring immunization with safe and effective products.
2. To address the emergence of new diseases, e.g. AIDS, and the ability to diagnose appropriately with accurate testing methods.
3. To evaluate new products that are constantly being introduced into India without proper screening.

The Team believes that by no later than the USAID deadline in September, 1998, the following accomplishments, at a minimum, should have been made:

1. The interim facility should be fully operational, accredited, and passing reliable test results to the DCI.
2. Construction of the permanent science/animal block should have been well under way for at least one year and should be at least one-third completed.
3. Coordinated technical assistance should have been established and should have been arranged so as to provide appropriately trained scientists at all levels, in phase with the opening of new laboratories.

To reach these goals by the target date of September, 1998, NIB should establish milestones with specific dates for completion, in concert with, and agreeable to, the donor agencies. Examples of milestones to be set include:

1. The selection of a contractor for the science/animal block.
2. The selection of a single project manager for the science/animal block.
3. Resolution of all Indianization issues.

4. Commissioning of the interim facility for full operation.
5. Formal coordination with DCI so as to establish effective linkage.
6. Recruitment of senior scientific personnel, including a Deputy Director of Quality Control and of Administration.

Milestones with specific dates for completion should also be set by USAID. Examples of milestones to be set include:

1. Establishment of a technical coordination team.
2. Appropriately phased technical assistance and training.
3. Resolution with NIH of all Indianization issues.

The Team believes that milestones need to be sufficiently detailed so as to allow their regular monitoring on a frequent, e.g. monthly, basis. We do not think, however, that an Evaluation Team is the appropriate mechanism for setting the specific dates for milestones to be reached.

The Team believes that the goals outlined above are entirely possible. It notes that, during the last week, two significant steps have already been taken: 1) the convening of the Governing Body on May 8, 1996, and 2) the intention to solicit a second expert engineering opinion on Indianization issues before the meeting of the Governing Body.

The Team recommends that, as long as specific milestones are set and adhered to, USAID extend the project past the September, 1998 deadline. Since the remaining time for the project has been severely curtailed by previous delays, the Team further recommends that a second interim evaluation be undertaken in approximately one year.

If measurable milestones are not met, the Team believes that options available to USAID are as follows:

1. The milestone may be reset. However, this action must be based on:
  - a. The specific milestone not met and its relative importance to others.
  - b. The reasons for not meeting the milestone.
  - c. The possibility for correcting the conditions leading to the missed milestone.
2. USAID may consider otherwise how to structure assistance to NIB. For example, if delays in the construction of the permanent facility continue, USAID may determine how best to provide assistance (training and equipment) within the sole context of the interim facility. It should be noted, however, that the amount and quality of testing that can ever be accomplished at the interim facility are limited. The interim facility will never be able to replace the intended function of the permanent facility nor serve as an adequate national substitute.

3. USAID may consider that the project has drifted so far from its original goals that support should be withdrawn.

In this report, the Evaluation Team has provided an overview of progress in the development of NIB. In so doing, it has addressed a variety of issues, including autonomy, the full-time nature of the NIB director, staff and recruitment, training, construction of the interim and permanent facilities, funding, and linkages.

The Team has attempted to include some historical background and chronology of events leading up to the current situation in all of these areas. Based on these findings, conclusions have been drawn and a series of recommendations have been made as specifically as was felt possible.

The overarching concern throughout has been for the fate of the overall project. For whatever reasons, progress to date has been lamentable. There have been innumerable delays at almost every stage. Deadlines have had to be postponed repeatedly. Requests for further information, assistance or approval, and the subsequent answers to these requests, have been delayed and/or misinterpreted. Parties have been excluded from the deliberations of other parties.

The effect has all too often been misunderstanding, thinly veiled recriminations and friction. The result is that a project, with the potential for substantial good to the people of India, is in imminent danger of expiring from its own intramural weight.

If all parties continue to believe that the project is worthy of pursuit (and they appear to do so), it is mandatory that there be an immediate sea change in overall philosophy and attitudes. This will require that relatively petty differences be set aside by all concerned.

The Governing Body must govern; it cannot do so if it never meets. The same holds true for the General Body, the Steering and Policy Committees. The Director, NIB must direct. She must delegate to reliable senior deputies, who are recruited now and whose positions are not filled by junior staff who "grow into the job". She should not be burdened by daily minutiae and, instead, should avail herself of the full powers already vested in the position in order to direct the broad scope of progress. The consultants must consult and not be surprised when some of their advice is not taken or is altered to fit local conditions. Donor agencies should rightfully expect the appropriate use of their donations and that contract deadlines be met; they should be included at least as observers in the various deliberative bodies.

Above all, there must be immediate action based on broad vision and leadership, vested in a single entity to which all parties agree.

**9. APPENDIX I: ABBREVIATIONS AND ACRONYMS**

|        |  |
|--------|--|
| AIIMS  | All India Institute of Medical Sciences                        |
| CBER   | Center for Biologicals Evaluation and Research (US)            |
| CRI    | Central Research Institute (India)                             |
| DCI    | Drugs Controller of India                                      |
| DGHS   | Director General of Health Services (India)                    |
| FDA    | Food and Drug Administration (US)                              |
| GOI    | Government of India  |
| GOJ    | Government of Japan  |
| HBV    | Hepatitis B virus  |
| HIV    | Human immunodeficiency virus                                   |
| HSCC   | Hospital Services Consultancy Corporation (India)              |
| MOHFW  | Ministry of Health & Family Welfare (India)                    |
| NIB    | National Institute of Biologicals (India)                      |
| NIH    | National Institutes of Health (US)                             |
| NOIDA  | New Okhla Industrial Development Authority (India)             |
| OECF   | Overseas Economic Cooperation Fund (Japan)                     |
| OIH    | Office of International Health (US)                            |
| PASA   | Participating Agencies Service Agreement (US)                  |
| PGIMER | Postgraduate Institute of Medical Education & Research (India) |
| PQ     | Pre-qualification  |
| QA/QC  | Quality assurance/quality control                              |
| QCHT   | Quality Control of Health Technologies                         |
| SOP    | Standard operating procedure                                   |
| USAID  | United States Agency for International Development             |
| WHO    | World Health Organization                                      |
| ZGF    | Zimmer Gunsul Frasca (US)                                      |

## 10. APPENDIX II: DOCUMENTS REVIEWED

### Source Documents [In chronologic order of publication]

1. Project Paper. Quality Control of Health Technologies (No. 386-0514). U.S. Agency for International Development, New Delhi, India. September, 1990.
2. Articles of Agreement between NIB and HSCC. February 27, 1991.
3. Memorandum of Association, National Institute of Biologicals. Certificate of Registration Act XXI of 1860. January 27, 1992.
4. Institutional Development Plan. National Institute of Biologicals. 1993.
5. Ira Ray, Director, NIB and G. K. Majumdar, Chairman & Managing Director, HSCC. National Institute of Biologicals. Project Summary and Master Plan Formulation. June, 1993.
6. Vaccine Supply in India, Final Report. CVI Task Force Team. Regional Office for South-east Asia, World Health Organization. July 22, 1993.
7. Minutes of Discussions on Quality Control of Health Technologies Project (ID-P74) between The Overseas Economic Cooperation Fund and National Institute of Biologicals. New Delhi. December 20, 1993.
8. Draft (Conceptual) Training Plan. Total Quality Training Program in Science and Technology. National Institute of Biologicals. U.S. FDA (CBER). December, 1993.
9. Preliminary Comments from FDA regarding Dr. Ray's Proposal for Technical Assistance, and Draft Training Profiles. NIB Project, India. June, 1994.
10. Health Laboratory Services in Support of Primary Health Care in Developing Countries, WHO, New Delhi. 1994 .
11. Annual Report. Ministry of Health and Family Welfare, Government of India. 1994-95.
12. Dr. (Mrs.) Ira Ray, Director, NIB, R. Sen Gupta, Consultant, NIB. Testing of Biologicals in India, Present Status. National Institute of Biologicals, Ministry of Health & Family Welfare, Government of India. March, 1995.

13. Manclark, Charles R., Ph.D. Review of Technical Assistance Requirements and Arrangements for the National Institute of Biologicals, India. For the United States Agency for International Development, New Delhi, India. April, 1995.
14. Proposed NIB Facilities at NOIDA. Environmental Impact Assessment. Final Report. ENC Consulting Engineers, New Delhi. July, 1995.
15. Information Systems Plan for the National Institute of Biologicals. Professional Services Organization, HCL Hewlett-Packard Limited, A-10/11, Sector III, NOIDA, Uttar Pradesh. Version 2.0. November 15, 1995.
16. Dr. (Mrs.) Ira Ray, Director, NIB. Project Summary. National Institute of Biologicals. Ministry of Health & Family Welfare. Government of India. 1995.
- 17-24. Quarterly Reports of Activities under PASA No. 386-0514-P-HI-2292-00 Biomedical Research Support Project. Office of International and Refugee Health, Office of Public Health and Science, Department of Health & Human Services, USA.
25. Annual Report 1995. The Overseas Economic Cooperation Fund, Japan.
26. The Strategic Plan for the Development of the Science Program of the National Institute of Biologicals, India. Training, Consultation, and Management Resources (TCMR), Dover, Delaware, USA, and William Joiner Foundation, Inc., Boston, Massachusetts, USA. February 16, 1996. [DRAFT]

#### **Other Documents**

1. Copies of three PASA's (original and two modifications).
2. The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetic Rules, 1945. The Indian Drug Manufacturers' Association.
3. S. Lamba, Joint Secretary. The Gazette of India: Extraordinary (Part II-Section 3i) Notification, (Specifying Blood and Blood Products, Intravenous Fluids, Sera and Vaccines).
4. Trip report to NOIDA, CBER/FDA. October 27, 1992.
5. NIB Master Plan for NOIDA, HSCC. (date 1993?).
6. Draft. Total Quality Training Program in Science and Technology. U.S. FDA (CBER). December, 1993.

**Various CBER/FDA documents, reports, etc:**

1. Plan to provide assistance in design and implementation of the science and training programs.
2. Summary Meeting Minutes of FDA/CBER. March 11, 1993.
3. Agenda and supporting materials for February 2, 1994 meeting at NIH including:
  - i. Summary of notable events (progress/impediments) since February, 1993.
  - ii. Minutes of February 5, 1993 FDA/CBER briefing.
  - iii. Scope Of Work for CBER.
  - iv. Projected impact of PASA on CBER.
  - v. April, 1994 agenda/itinerary.
  - vi. CBER memorandum, February 5, 1995.
4. Trip report. Sushil Nagpaul (NIH). January 21-February 16, 1996.

## 11. APPENDIX III: TEAM NOTES

### 11.1. Meetings and Phone Calls: Summary Table

| Date           | Time      | Location  |
|----------------|-----------|---|
| March 28, 1996 | 0930-1300 | USAID   |
| March 29, 1996 | 1150-1430 | NIB Interim Facility, Jhandewalan                   |
| March 30, 1996 | 1030-1730 | NOIDA Permanent Site                                |
| April 2, 1996  | 1000-1250 | Mr. C.K. Gaur, OECF                                 |
| April 2, 1996  | 1500-1715 | Vijay Rewal Associates                              |
| April 3, 1996  | 1105-1250 | Dr. Ira Ray   |
| April 4, 1996  | 1010-1100 | Mr. P.P. Chauhan, Secretary of Health, GOI          |
| April 4, 1996  | 1530-1605 | Ms. Linda Morse, Mission Director, USAID            |
| April 5, 1996  | 1900-1930 | Phone call: Dr. Ken Bart, OIH                       |
| April 5, 1996  | 1940-2030 | Phone call: Dr. Elaine Esber, FDA/CBER              |
| April 9, 1996  | 1150-1430 | NIB Interim Facility, Jhandewalan                   |
| April 9, 1996  | 1630-1645 | Phone call: Dr. P. Dasgupta, DCI                    |
| April 10, 1996 | 1630-1730 | Ms. S. Chandra, Additional Secretary of Health, GOI |

### 11.2. Team Notes: Meetings and Phone Calls

#### 11.2.1. *March 28, 1996 0930-1300 USAID*

Mr. Desaix Myers, Mr. John Rogosch, Ms. Rekha Masilamani, Dr. K. Sudhakar

#### *Purpose*

Initial meeting to provide the evaluation team with background information on the project, from the USAID perspective.

*Issues briefly discussed:*

1. NIB autonomy under an act of parliament versus under MOHFW requires different linkages.
2. Does Dr. Ray have DGHS responsibilities or is she full-time at NIB?
3. There is a ministry management committee (Governing Body) but it does not supervise?
4. USAID project implementation committee meets on an ad hoc basis, and reviews progress twice yearly.
5. Misapprehension on the part of some that NIB is to have a regulatory component.
6. USAID is asking evaluation team to identify critical areas, obstacles, and delays and to refine plans and priorities.
7. There is reluctance on the part of USAID to extend the project past its deadline in September, 1998, unless significant solutions to obstacles can be effected in the near future. In any event, an extension would be limited to two years maximum.

**11.2.2. March 29, 1996 1150-1430 NIB Interim Facility, Jhandewalan Extension**

Present: Dr. Sokhey and other staff

*Tour of Laboratories:*

The renovation of laboratories is essentially complete, we were told. The required power upgrade is not far away. Until this occurs, only one-to laboratories will be equipped and operational: 1) Blood Products, and 2) Kits (i.e. HIV and HBV testing).

Even after the laboratories are turned over from the contractor (HSCC) and properly equipped, they will remain substandard. Several deficiencies were noted that may pose a health hazard to workers and may jeopardize QC/QA testing:

- ▶ Ceilings warped with taped joints, and limited water damage visible.
- ▶ Baseboards elevated about 10 mm above the floor and without concave moldings.
- ▶ Laboratory bench tops are not chemically resistant.
- ▶ Polyvinyl chloride flooring is subject to wear and gouging.
- ▶ Paint peeling from walls and ceiling in some places.
- ▶ Cabinet space over bench tops is limited, and cabinets are of inferior quality.
- ▶ Roof drain, near main electrical panels, is stopped. Potential exposure of rooftop electrical panels to rainwater.
- ▶ Electrical cord for freezer is lying on the floor across the entrance to the room.

These deficiencies pose a future health hazard to personnel and may jeopardize QA/QC testing, due to microbial contamination resulting from inability to clean surfaces adequately.

Additional renovation tasks to be completed include:

- ▶ Laminar flow hood to be connected.
- ▶ Finish painting and taping of ceilings.
- ▶ Pass-through autoclave is not on site.

#### *Discussion with NIB Interim Facility Staff*

Dr. Reba Chhabra and Ms. Ajanta Sircar, the two scientists who have been trained at FDA/CBER in the testing of HIV and HBV kits, reported on their overseas training. Although the training was apparently successful, some problems were noted:

- ▶ Standard serum panel:

Training was to include the establishment of a standard serum panel. This failed. Testing of 50 serum aliquots, testing HIV<sup>+</sup> in Delhi, showed 37 (74%) were HIV<sup>-</sup> at FDA. Eleven (16%) of 70 HBV samples tested positive in Delhi, also were negative at FDA. No explanation for these discrepancies was offered. The Team expressed concern that substantial waste of donor blood may result from such testing inaccuracies and that donors may be informed of an incorrect HIV status.

- ▶ Standard operating procedure (SOP):

Indian SOPs, based on FDA SOPs, should have been prepared immediately upon return from abroad. These are apparently available only in draft form (information from Director, NIB).

- ▶ Local training in India:

Training completed at Indian sites (AIIMS, etc.) did not appear to be based on specific job descriptions. Each trainee should have obtained, in addition to basic skills needed for QA/QC testing, specific skills needed to evaluate the products that are available for use in India. For example, there are currently several different HIV test kits available, each requiring different skills and equipment. However, no list of such products was made available; therefore, training must have been limited.

- ▶ Evaluation of training:

As yet, there has been no evaluation of domestic and foreign training of NIB scientists. Combined with the absence of SOPs, the lack of available facilities in which to utilize the skills learned, and the limited supervision that can be provided in the absence of the Deputy Director, QC and Grade I scientists, the lack of evaluation does not augur well for the success for the training already accomplished.

- ▶ Coordination of staffing and facilities development:

The need for phased coordination of equipment procurement, staffing, and operational laboratories was discussed. The Team was informed that the facility should be handed over from

the contractor on April 1, 1996. The estimated time for fully equipping the first two laboratories is May 30, 1996. It is not clear, however, that even these two laboratories will be able to function fully without increased power. As future laboratories in the interim facility come on line, NIB procurement is urged to have all movable equipment on site well before scheduled occupancy.

### *Conclusions*

Despite these deficiencies, the team felt that, with appropriate precautions, high quality QC/QA testing could be accomplished at this site. Additional precautions are needed to insure reliability, precision, and accuracy of tests conducted, beyond the precautions normally required for this type of laboratory (such as routine internal and external quality control, Good Laboratory Practices, etc.). Additional precautions especially include a higher frequency of internal quality control procedures to *continuously* monitor staff, procedures, and laboratory. Strict internal audits of performance will be required on at least a daily basis. External quality assessment, where identical samples are tested by the interim facility and a reference laboratory, will only need to be increased where internal QC/audit has identified problems. Special care will be required to maintain a clean, safe environment in the face of problems created by deficiencies noted above. This should include air sampling and monitoring of environmental contamination.

Present institutional plans call for accreditation of these facilities approximately six months after testing begins. The team strongly recommends that accreditation not be sought until such time as the laboratories at the interim facility *fully* conform to predetermined criteria. Accreditation should be obtained from a recognized international agency such as WHO.

### **11.2.3. March 30, 1996 1030-1730 NOIDA Site**

Present: Team, Dr. Sudahakar, Mr. Prasada, Chairman, and Mr. Sarup of HSCC, and others.

### *Background and Observations*

The 19 acres site is located on of Plot No. A-32, Institutional Area, National Highway No. 24, NOIDA, Phase II, Uttar Pradesh. The team visited each of four construction projects underway at the site (administration building, guest house, hostel, and cafeteria) and noted the status of each. The hostel has progressed the furthest. The guest house is also nearing the point where finish work can be started. The cafeteria and administration buildings are expected to be completed by November-December, 1996. All four buildings are expected to be available for use by March, 1997.

### *Topics and Discussions*

#### ▶ Indianization:

Building designs of laboratory and animal house. HSCC stated that the design specifications are for American materials and fittings. They believe that most of these items (numbering several thousand) are available in India. They expect NIH to identify all such items for which Indian equivalents are available before pre-bid documents are prepared. Mr. Prasada stated that the

work to identify and give Indian specifications for all the items is voluminous and cannot be done by HSCC unless additional money is provided.

- ▶ HSCC and NIH working together:

Mr. Sarup explained that per the existing agreement, NIH is responsible for certifying the quality of construction in accordance with the design specifications contained in the USAID contract with NIH. HSCC, being the construction manager, will have to deal with the contractors and make payments for the work done after certification by NIH. HSCC thinks that this arrangement is likely to create problems and will not work smoothly. They are of the opinion that it would be much better if both the certification and payment functions are handled by them.

#### *Pre-qualification (PQ) of construction companies:*

Bids were invited in January, 1995 by sending letters to the embassies and by advertising in newspapers. Seventeen bids were received. HSCC (NIB) short-listed seven firms fulfilling the following criteria and sent them to OECF for approval.

- ▶ The company should have built at least two scientific buildings, i.e. comparable laboratories.
- ▶ The company's annual turnover should be at least Rs. 40 crore.

OECF examined the bids and found that only one of the seven firms qualified according to the same criteria. NIB believes that GOI rules do not permit a single pre-qualified firm to be asked to bid further for construction. The matter rests with NIB for further action to resolve this issue.

#### **11.2.4. April 2, 1996 1000-1250 OECF**

Present: Team, Dr. Sudahakar, and Mr. C.K. Gaur, Senior Project Officer

Mr. Gaur indicated that OECF is one mechanism by which the GOJ expends yen credit in various countries, without regard to the sector of involvement. GOJ has provided under the Fifth Medium-Term Target for ODA (1993-1997) \$70-75 billion. It has been active in India for the past 17 years, where current expenditures in power projects account for 49% of its total. NIB represents its first venture into the health sector in India.

The loan to the GOI for the capital expenditures of NIB was signed on January 23, 1991, with closing scheduled on February 5, 1999. Terms are 30 years at 2.5%, with a 10-year grace period for paying interest only. As of March 1, 1996, only ¥157 million (2%) of ¥7,964 million has been disbursed. Although additional expenses may have been incurred, these bills have not been received by OECF.

OECF hopes for the project have been extremely disappointed by delays, especially since ready solutions are not apparent. Mr. Gaur inquired as to what are the obstructing issues, if they soluble, and by whom.

He noted, as an example, the delays encountered in the PQ process for a contractor, in which OECF found only one of seven companies to have fulfilled the HSCC criteria. Having requested further information from NIB on the other bidders in order to consider some compromise but having received no reply, OECF notified NIB on September 8, 1995 that Mitsui was the only qualified bidder. In a subsequent meeting on December 1, 1995, Mr. Chaudhary, Additional Secretary of Health at the time, agreed with the OECF decision re Mitsui and indicated that he would consult with HSCC and others regarding a single bidder. To date, no further information has been provided to OECF on this subject.

He felt that the three most important issues to be resolved are:

- ▶ True autonomy for NIB
- ▶ A full-time Director, NIB
- ▶ Better coordination between various agencies and HSCC

He noted that OECF will not compromise on international standards for the permanent science and animal buildings at NOIDA.

He wondered whether the interim facility will be functional in the near future, since there is no scientific work to do and since adequate electrical power will not be available for one year.

The next high level meeting on the Japanese side will occur in May, 1996 in Tokyo, at which time serious questions will be asked by senior OECF personnel who are unhappy with progress to date.

Finally, he noted that the Ministry of Finance, GOI has already prematurely terminated two OECF non-health projects in the past for non-performance.

In a later meeting on April 8, 1996 with Mr. Gaur and Mr. Suzuki, Senior Representative, Mr. Suzuki confirmed the comments above. He reiterated the OECF position that a single bid is acceptable, since further negotiations with the bidder are always possible. He also noted that OECF believes strongly that it is accountable to the Japanese taxpayer for the quality of its projects, as measured against economic terms, efficiency, and non-discrimination.

#### ***11.2.5. April 2, 1996 1500-1715 Vijay Rewal Associates***

Present: Mr. Vijay Rewal, Mr. Naresh Arora, Civil Engineer, Mr. Shafat Ahmed, Construction Manager, Mr. Saurav Banerjee, Architect

Mr. Rewal indicated that currently HSCC is handling the "quantity" of the project, i.e. supervision of the actual construction of NOIDA, while Rewal is handling the "quality", i.e. approval of whether design specifications have been met by the contractor. Only if the latter approval is given can HSCC make payment to the contractor.

He has found it difficult to work effectively with HSCC under the present arrangements, claiming to have been constantly "badgered" by HSCC. In general, he was reluctant to work with government agencies.

With regard to delays in the project, he indicated that he was able to secure the building permit from NOIDA authorities soon after securing the contract, in spite of previous prolonged delays.

He felt that there had been unneeded delay since the PQ bid could have been made at the 70% design stage, rather than the 95% stage, without any compromises.

He said that the issue of Indianization is not an overriding problem and felt that there are only a few (25-50) items in question.

He was bothered by the fact that he has not been formally involved in the pre-qualification process to select a contractor.

He felt that his company has the requisite experience to serve as the sole design and project manager for the permanent NOIDA facility since he has already done so for the National Institute of Immunology and the International Center for Genetics. The former was constructed in 17 months. Each of these projects involved the importation of considerable numbers of items, with no delay in construction.

However, he indicated that, if his company is selected as the sole construction manager, he absolutely refuses to work with the Special and General conditions of the present contract, which gives unfair advantage to the builder vis a vis money, in his opinion. He has previously expressed this position to NIH.

**11.2.6. April 3, 1996 1105-1250 Dr. Ira Ray, Director, NIB**

Present: Dr. Prem Gupta, Dr. K.B. Sharma, Dr. John Foulds, Dr. K. Sudhakar

Issues discussed and comments:

**a. Autonomy:**

NIB is registered as a society under the Registration of Societies Act XXI of 1860 and is autonomous. An Act of Parliament is not necessary. Institutions such as AIIMS and PGIMER are autonomous as a result of an Act of Parliament; institutions such as the National Institute of Family Welfare and National Institute of Mental health and Neurological Sciences (NIMHANS) are, like NIB, autonomous as a result of registration.

Also discussed were NIB pay scales which are believed to be on a par with AIIMS and NIMHANS, the possibility of recruiting from the open market, and the use of the NIB Governing Body.

**b. Dr. Ray as full time Director, NIB:**

In response to a direct question, Dr. Ray responded "I am full time." She added that her position as Additional DGHS is "only for the grade."

**c. HSCC competence:**

The team questioned the competence of HSCC to manage construction of the laboratory and animal facilities at NOIDA, based on:

- ▶ Deficiencies at the interim facility
- ▶ Delays at the interim facility
- ▶ HSCC's self-acknowledged lack of expertise to design laboratory and animal facilities

**d. Future delays:**

Dr. Ray acknowledged deficiencies at the interim facility and asked if the team did not think that HSCC had "learned some lessons." The team responded that the importance of the NIB and the complexity of design dictated that no chances should be taken. The team suggested that NIB replace HSCC with, for example, NIH. This would also avoid impending conflict (as described by Mr. Sarup, HSCC) at the NOIDA site where NIH supervises quality and HSCC supervises NIH. Dr. Ray noted that she must use HSCC. The money must go from GOI (MOHFW) to NIB and then to HSCC. She will: 1) call both parties to a meeting of the Governing Body to attempt to resolve differences, 2) appoint an Engineering Committee to advise NIB about Indianization and other issues, and 3) consider the team suggestion that HSCC be hired in name only. In this instance, HSCC would subcontract total management of the science buildings at the NOIDA site to, for example, NIH.

**e. Deputy Directors, Quality Control and Administration:**

Dr. Ray noted that the Deputy Director, QC, equivalent to a dean, is a difficult position to fill. One round of advertisements did not uncover a qualified candidate. Dr. Ray would like to fill this position from NIB ranks, i.e. Grade I Scientist, as NIB matures as an institution. She believes this will provide an incentive for Grade I Scientists.

**f. Delays in construction of laboratory and animal facilities:**

Dr. Ray blamed delays on the donor agencies, primarily USAID (NIH). She said that the decision to hire NIH was made in December, 1992, and NIH estimated that drawings would be ready in 12-14 months. These drawings instead arrived just last month.

**g. Pre-qualification:**

Dr. Ray acknowledged delays from September, 1995. She indicated that she did not have the power to make an executive decision. Any decision had to await the appointment of a Secretary of Health, a position then vacant. The Additional Secretary could not make the decision. She felt that the decision would be made soon.

**h. Electric power at Interim Facility**

The team indicated that only very limited activities could be supported at the interim facility without upgrade of power to 450-550KW. Dr. Ray indicated that progress was imminent.

**i. Training:**

Dr. Ray believes that FDA is probably not moving away from support of NIB, as evidenced by its responsiveness to a plague outbreak. She indicated that she has an excellent personal relationship with Dr. Elaine Esber. NIB wants someone outside of NIB to:

- ▶ Identify sorts of training (domestic and foreign) needed,
- ▶ Identify overseas sites for training,
- ▶ Arrange for overseas training, and
- ▶ Arrange for evaluation of both domestic and foreign training.

**j. Construction delays and future support from donor agencies:**

Dr. Ray felt that OECF will likely continue support beyond the current deadline and that USAID ought to continue since it was responsible for the previous delays. The team expressed concerns to Dr. Ray about future donor support. The team believes that only with a well defined NIB institutional and construction plan, together with measurable milestones to assure donor agencies of adherence, would support from USAID and OECF continue beyond their deadlines in September, 1998 and February, 1999, respectively.

**11.2.7. April 4, 1996 1010-1100 Mr. P.P. Chauhan, Secretary of Health**

Ms. Rekha Masilamani introduced the members of the Evaluation Team to the Secretary and briefly described the objectives of the Team regarding the NIB.

Dr. Woodward apprised the Secretary about the visits of the Team to the interim facility and the NOIDA site, as well as discussions with Dr. Ira Ray, HSCC, OECF, and present staff of NIB at the interim facility. The Team wanted to know about the autonomous status of NIB, whether the NIB director was working full-time or was sharing duties as Additional DGHS.

It was also explained to the Secretary that only 2 years and 5 months remained in the USAID project and 2 years, 10 months in the OECF project.

At NOIDA, the administration, cafeteria, guest house, and hostel buildings are proceeding satisfactorily and are likely to be functional in about one year's time.

However, a major hurdle has been the building of the permanent laboratory and animal facilities at NOIDA without which the future recruitment and training of the full complement of scientific staff cannot proceed. Delays have been due primarily to lack of agreement on Indianization of fittings and materials as insisted upon by HSCC, and to difficulties in the pre-qualification process which, according to OECF, has identified only a single eligible contractor (Mitsui). The Director, NIB has referred the latter issue to the GOI for resolution, but has received no reply as yet.

Though renovation of the interim facility is complete, it has not been handed over to NIB. Doubts have been expressed about it becoming fully functional in the near future for want of full

electricity supply. At present, 53 KW is available, but 550 KW is needed. Even with full electricity, all laboratory activities could not be performed due to lack of space.

It was felt, however, that the Deputy Director, QC should be recruited without further delay.

Responding to the presentation of the Team, the Secretary explained that NIB is an autonomous institution by virtue of its being registered under the Societies Act of 1860. It is being administered by the Governing Body, of which the Secretary is the Chairman.

He was sure that Dr. Ira Ray is devoting full-time as Director, NIB as of now. He stated that the OECF funds are not a grant, in which case there would have been no problem with a single eligible PQ bidder. Instead, since the funds are a loan, a minimum of three PQ bidders will be required, per GOI rules. Regarding Indianization, he felt that as far as possible Indian parts conforming to NIH criteria be used, but, if not possible, he would have no objection to imported parts being used.

He also stated that since NIB was being financed by MOHFW, many hurdles could be crossed by active intervention of the Chairman of the Governing Body in his capacity as Secretary of Health. He provided the example of construction of Apollo Hospital in record time, during which he had been Chairman of its Governing Body and Chief Secretary, NCT Delhi.

As he has recently become Secretary, he would reactivate the meetings of the NIB Governing Body, so that all constraints remaining in construction, recruitment, and other matters could be resolved expeditiously. He was hopeful of the next meeting in about three to four weeks, soon after the elections are over. If need be, NIH engineers could be invited to attend this meeting or an Indian engineer could go to the USA to resolve any differences in construction matters.

The members of the Team thanked the Secretary for his consideration. They requested one debriefing meeting with him on April 15 or 16, to which he agreed.

**11.2.8. April 4, 1996 1530-1605 Ms. Linda Morse, Mission Director, USAID**

Ms. Morse was given a brief update on the findings of the Evaluation Team to date.

She reiterated the desire of USAID for the successful completion of the project but indicated reluctance to extend the deadline past eight years, unless substantial resolution of obstacles can be promptly made and definite milestones established. She felt that the Team needs to address the issue of the many delays already encountered.

She noted that there is considerable pressure emanating from Washington to reduce budgets in general, making a possible extension of the project more problematic. A potential source of rupees is the US-India fund, but this would entail considerable effort to secure approval from multiple agencies.

**11.2.9. April 5, 1996 1900-1930 Phone call: Dr. Ken Bart, OIH**

Present: John Foulds

*Issues discussed and comments:*

OIH was called in an attempt to speak to Linda Vogel. Linda is on vacation until April 15th. In her absence, Ken Bart was available.

Provision of required technical assistance to NIB requires a lot of FDA time. FDA has a lot of work otherwise and is not an anxious partner in this. Rather, FDA wants to see NIB succeed because of the spirit.

Important questions for the Team to answer: What does GOI want NIB to be? If NIB is to be an international testing facility, then no contractor can provide what FDA brings to the table. What are the conditions "precedent" to FDA participation?

He strongly suggested that the Team speak with Linda Vogel (OIH) before debriefing.

**11.2.10. April 5, 1996 1940-2030 Phone call: Dr. Elaine Esber, FDA/CBER**

Present: John Foulds

*Issues discussed and comments:*

Elaine has just received a copy of the Strategic Plan (George Siber) sent by USAID to Dr. Zoon. The copy contains only every other page, so she will not be able to comment.

She indicated that FDA would have no problem with the possibility of USAID hiring an outside contractor to coordinate technical assistance to NIB. But the outcome will be radically different.

Where the coordinator is located depends on the outcome that NIB wants -whether its standards would be the *same* as FDA, or whether it only wants training.

As of now, FDA is acting on the assumption that NIB will become an equal partner, similar to agreements among US, Canada, and UK in which tests performed at one site are deemed equivalent to tests performed at another. Does NIB want to be able to say that the results obtained in New Delhi are the same as what FDA would get?

If NIB wants an equivalent relationship, then FDA must participate and the coordinator must be an FDA employee, because access to FDA records, laboratories, and personnel is restricted to FDA employees.

If NIB only wants training, without FDA equivalence, then FDA would have no problem with an outside coordinator. FDA would help provide technical assistance to NIB but would not be able to share records and test results. For example, if a company wished to introduce a new

biological product simultaneously in India and the US, NIB would be denied access to FDA test results or even the fact that the product was being evaluated.

*11.2.11. April 9, 1996 1150-1430 NIB Interim Facility, Jhandewalan Extension*

Present: John Foulds, Dr. Sokhey and other NIB staff

*Tour of laboratories*

Due to a number of problems, the laboratories have not yet been handed over from HSCC to NIB.

Although some movable equipment has been installed (e.g. plate reader), most of the problems noted during the Team visit on March 29, 1996 remain.

Additional problems with construction and alteration of design were discussed:

- a. In the autoclave room, equipment for water purification (Millipore) has been put in place and will soon be functional. However, there is only one electric outlet to serve this equipment and two temporary autoclaves.
- b. Marked evidence of water leakage and the odor of mildew were noted in several locations.
- c. A BL/2 cabinet has been installed without an appropriately sited electric outlet. Closest power point is located across the room on countertop.
- d. Overhead lighting was not operational in two-three rooms.
- e. The tape joining portions of the ceiling has already failed.
- f. Stools are poorly designed for use in laboratories.
- g. Screws attaching portions of countertops are not countersunk.

These details are listed to substantiate the Team's belief that HSCC has performed poorly on this project.

*Additional Topics*

The draft SOPs were discussed with Dr. Sokhey and others. The SOPs should have been prepared, under the supervision of senior NIB scientific staff, immediately following in-country and overseas training.

The question of electric power was again discussed. An upgrade of power at this site should not be expected for six months, or more. Still, Dr. Sokhey anticipates that sufficient power is

available to operate two testing laboratories (including window air conditioning) and three support laboratories.

**11.2.12. April 9, 1996 1630-1645 Telephone conference with Dr. P. Dasgupta, DCI**

Present - Team members and Dr. Sudhakar.

The DCI was unable to meet with the Team during its three-week stay. In a telephone conference, the Team discussed with him matters regarding effective linkage with NIB and the need for coordination in areas of priority testing and training of personnel.

DCI stated that:

- a. He would like the testing of the following items to be started by NIB on a priority basis: blood bags, immunodiagnostic reagents, and such other biological products which are being used in the country but for which no testing facilities exist currently.
- b. He would initiate action for notifying NIB as the statutory National Control Laboratory as soon as he receives official information from NIB that they are ready to do so.
- c. He would get the NIB facilities accredited by Indian and/or overseas experts before notifying (designating) NIB as the National Control Laboratory.
- d. He is a member of several committees of NIB but commented that he acted "in no capacity as adviser to NIB."
- e. He did not require the test results of NIB to be equivalent to FDA results at this time. He viewed that equivalency could be achieved in a phased manner over the years.

**11.2.13. April 10, 1996 1630-1730 Ms. Shailaja Chandra, Additional Secretary of Health**

The Team provided an overview of its scope of work and the findings of the mid-term evaluation to date. Ms. Chandra, who has recently been appointed to her position, had already familiarized herself with a number of the troublesome issues, such as Indianization and PQ. She was also entirely aware that no meetings of the Governing Body and other committees had been held since October, 1994.

She informed the Team that a meeting of the Governing Body has already been scheduled for May 8, 1996, at which time she felt that most of these and other issues will be discussed and action taken. She was of the opinion that most of them were readily amenable to rapid solution, although she could not be completely assured of this in advance of the meeting. She also agreed that the nature of the project was important to India and that forceful leadership was entirely appropriate to see it through to completion.

## 12. APPENDIX IV: CHRONOLOGY OF EVENTS

- Apr 1-12, 1991 NIB team visit to U.S. by Mr. Mishra, Dr. Ira Ray, Mr. John Dumm, and Dr. K. Sudhakar to meet FDA, NIH, and USAID/W officials, to initiate NIB project discussion, and to visit FDA laboratories and manufacturing units.
- Apr, 1991 NIB-HSCC agreement. HSCC appointed as a consulting agency for various NIB activities and is responsible for the design of NIB laboratory and animal facilities.
- Aug 8-16, 1991 Public Health Service team visit to India by Dr. Ed Seligman (FDA), Dr. E. Esber (FDA), and Dr. Merfyn Williams for NIB implementation, workshops, Steering Committee meeting, initial discussion on interim facility, and visits to Jhandewalan as a potential site for the interim facility.
- Jan-Feb, 1992 NIB team visit to U.S. by Dr. Ray, Mr. Majumdar, and Dr. K. Sudhakar for consultation with FDA and NIH staff, discussion on the priorities of the interim facility, and design of a brief for layouts.
- Feb 21-Mar 19, 1992 Visit to India by Dr. M. Williams and Mr. Sushil Nagpaul to discuss Program of Requirements for the interim facility, including different options for the number of laboratories (3, 6, and 10), cost estimates, and equipment needs. Visit to Madras to see Indian production units of BCG Kings' Institute.
- Apr, 1992 Land for permanent NOIDA facility procured.
- Aug, 1992 Prior to this date, USAID support for the project came from funds of the Biomedical Research Support (BRS) Project.
- Oct 9-19, 1992 Visit to India by Dr. M. Williams and Mr. S. Nagpaul to provide a preliminary draft on interim facility laboratories, a science program at NOIDA (space allocation) QCHT paper, equipment needs/list, draft on recruitment guidelines, and personnel needs at interim facility (88 scientists or less).
- Oct, 1992 PASA signed with OIH/PHS.

- Dec, 1992 Visit to India by Dr. M. Williams, Dr. E. Esber, Ms. L. Vogel, Mr. J. Pallas, and Mr. S. Nagpaul to attend meeting of the Policy Committee. FDA presented a 10-laboratory layout, but consensus could not be reached on the exact laboratories required for interim facility. Issue of animal facilities at Jhandewalan worked out. Dr. Williams met with BIBCOL, UNICEF, DCI. Dr. Esber met with DCI and UNICEF.
- Dec, 1992 HSCC expressed inability to design the sophisticated facilities and requested NIH to do so.
- Feb, 1993 NIB requested USAID to arrange design assistance from NIH.
- Mar 5-16, 1993 Visit to U.S. by NIB team. Three architecture and engineering candidate firms selected. NOIDA master plan reviewed. HSCC requested NIH for conceptual layouts of interim facility. Discussion of recruitment of junior scientists, NIB priorities, etc.
- Mar, 1993 USAID agreed to access NIH services, provided NIB prepares an Institutional Development Plan.
- Apr 19, 1993 Mr. M. Williams, project coordinator, reassigned. USAID requested OIH/FDA to get a project coordinator.
- Apr 17-29, 1993 Visit to India by Dr. E. Seligman to assist NIB in the preparation of an Institutional Development Plan. Timelines for recruitment and training developed for each division of NIB. Programs for interim facility and administrative building discussed.
- Jul 16, 1993 Dr. Esber discussed the Institutional Development Plan.
- Jul-Aug, 1993 Visit to India by NIH staff.
- Oct, 1993 NIB prepared an Institutional Development Plan, which is accepted by the donors.
- Oct 1, 1993 Dr. Peter Patriarca assigned as parttime project coordinator.
- Nov, 1993 USAID added funds to the PASA with OIH in order to acquire NIH design services.
- Dec 5-16, 1993 Visit to India by Dr. P. Patriarca, Dr. E. Seligman, and Mr. S. Nagpaul to assist NIB in the OECF review. Equipment list reviewed in light of HSCC information. Draft conceptual training plan, prepared by Patriarca, reviewed.
- Jan, 1994 NIH invited bids from U.S. architecture and engineering firms for the NIB design work and the review of the bids initiated.

Feb-Mar, 1994      Communications between FDA and NIB regarding training profiles and agenda for Steering Committee meeting.

Apr 6-11, 1994      Visit to U.S. by NIB team (Dr. Ray, Mr. Chaudhuri, Mr. Prasada, Dr. K. Sudhakar) for second meeting of Steering Committee. Provided terms of reference for committees, discussed Dr. Ray's note on needs of technical assistance from FDA, FDA inputs in design of laboratory and animal blocks, initial training plans for interim facility scientists, and blood/bloodproducts as the initial aim.

May, 1994          NIH developed the Program of Requirements for the NIB laboratory and animal blocks. FDA responded to NIB on technical assistance.

Jul, 1994          NIB requested Dr. Patriarca's assistance in identifying specific NIB tasks.

Aug 16-20, 1994      Visit to India by U.S. NIH team and architecture and engineering firm to begin the pre-design process, six months later than originally scheduled. Provided elements of scope of work of consultants in biologics, blood products, equipment systems. Discussed profiles for training with Dr. Ray. FDA coordinator still not full-time.

Sep, 1994          NIB initiated a study on testing of biologicals in India and shared scope of work with FDA consultants.

Oct, 1994          Visit to U.S. by Ms. R. Masilamani to discuss NIB needs for and problems related to technical assistance, role of CBER, and FDA coordinator issue.

Nov, 1994          Visit to Amsterdam by Dr. Ray to attend Children's Vaccine Initiative meetings and to meet Dr. E. Esber.

Nov, 1994          Contract awarded to ZGP, the U.S. architecture and engineering firm. Net delay was six months. All work proceeded without a contract in place as pre-design activities.

Dec, 1994          Draft of scope of work for review of technical assistance arrangements prepared.

Jan, 1995          HSCC advertised the pre-qualification (PQ) notification in embassies and newspapers. Search began for consultants to conduct a review of technical assistance arrangements. Visit to U.S. by NIB team to finalize 25% design of laboratory facilities. Visit by Dr. Ray to various U.S. institutions.

Feb, 1995          25% design developed and approved by the Indian and FDA subcommittees. FDA coordinator absent at these meetings.

Mar, 1995          Preparations began to train two NIB staff scientists in U.S.

Apr, 1995 HSCC short-listed seven construction companies out of 17. Using the criteria fixed by HSCC for PQ, OECF concluded that only one firm (Mitsui Corporation) qualified.

May, 1995 Visit to U.S. by two NIB staff scientists for training.

Jun, 1995 OECF and HSCC negotiations on PQ process. Visit to U.S. by Dr. Ray for review of 50% design. Preliminary recommendations of Dr. Manclark consultancy submitted. Discussions with Ms. Linda Vogel on modifications to PASA.

Jul, 1995 PASA modified to enable OIH to hire project coordinator.

Aug, 1995 More information on short-listed firms requested by OECF.

Aug, 1995 70% design submission in Delhi. NIB request for Indianization of the design. NIH agreed to modify the specifications and incorporate Indian standards wherever possible. At no stage did HSCC review the design but, on NIB's pressure, had only cursory review. HSCC expected to work on the draft General and Special conditions for the bid documents. The draft did not include any changes to construction of the laboratory building.

Sep, 1995 NIB asks MOHFW to make a decision on PQ.

Oct, 1995 Vijay Rewal Associates submits the application for NOIDA approval (permit set drawings).

Nov, 1995 Attempts to hire Dr. M. Williams as project coordinator failed.

Dec, 1995 Mr. Chaudhary, Additional Secretary, at a coordination committee meeting noted delay and assured action as soon as possible after consultations within MOHFW.

Dec, 1995 95% design submission.

Jan 16, 1996 Indian Expert Scientist Advisors (IESA) meeting of 20 persons (scientists - six, NIB - six, consultants - four, donors - three, DCI - one).

Feb, 1996 NIH team visit to India to discuss the 95% design.

Feb, 1996 NIH submits bid documents at 95% level to NIB via USAID. Documents incorporate all comments received from NIB and HSCC. Bid documents were originally expected in August, 1995, but the Indianization issue contributed to the delay.

Feb, 1996 NOIDA approval for construction of laboratory and animal buildings obtained by Vijay Rewal Associates.

|               |  |
|---------------|--|
| Feb 16, 1996  | Report of CBER team consultancy submitted to USAID.  |
| Mar, 1996     | PQ issue still unresolved. MOHFW planning to re-advertize and request fresh applications for PQ. |
| Mar-Apr, 1996 | Midterm Evaluation   |

## 13. APPENDIX V: COMMITTEES

### 13.1. General Body

Composed of 17 members, with Secretary of Health as Chairman, Secretary of Family Welfare as Vice Chairman, and Director, NIB as Member Secretary.

#### *Meetings*

One meeting, in 1992, none since.

#### 13.1.1. *Governing Body*

Composed of nine members, with Secretary of Health as Chairman, Secretary of Family Welfare as Vice Chairman, Director, NIB as Member Secretary, Secretary of Biotechnology, DGHS, Director General of Indian Council of Medical Research, Joint Secretary of Health, Joint Secretary Financial Adviser (MOF), and DCI.

#### *Meetings*

Mar 29, Apr 22, and Oct 17, 1994

#### 13.1.2. *Steering Committee*

Composed of representatives from DCI, FDA, NIB, NIH, OECF, USAID.

#### *Meetings*

Aug 12, 1991 and Apr 4-7, 1994

#### 13.1.3. *Policy Committee*

Composed of donor agencies (MOHFW, OECF, USAID, with Director, NIB as Member Secretary).

#### *Meetings*

1. Jun 18, 1991 Discussion of issues related to land acquisition, the Memorandum of Association, etc.

2. Aug 24, 1992 EFC Memo clearance, purchase of land and interim facility, etc.
3. Dec 3, 1992 Master plan development, design of laboratory facilities (possibility of NIH involvement), role of interim facility, etc.
4. Jan 4, 1993 Approval of reallocation of project funds to access NIH design assistance.
5. Oct 6, 1993 Discussion of staffing issues especially senior members, HSCC staffing, procurement packages and methods, etc.
6. Mar, 1994 Farewell for Mr. R.L. Mishra on his super-annuation.
7. Oct 28, 1994 Discussion of schedule for NOIDA site development (meeting adjourned due to unexpected assignment for Secretary of Health from the Prime Minister's office).