CHAPTER 3 PROJECT EVALUATION AND RECOMMENDATIONS

3-1 Project Effect

(1) Expected Direct Benefits of the Project

As the result of the implementation of the Project, the following direct benefits are expected.

1) The Establishment of Domestic Production System for Measles Vaccine

WHO-GMP compliant measles vaccine production facilities will be constructed, making possible the domestic production of measles vaccine and providing stable supply of measles vaccine throughout the country.

2) Rise in Immunization Ratio of Measles Vaccine and Promotion of Routine Two-Dose Schedule

The planned stable production and supply of measles vaccine will raise the immunization ratio for measles vaccine and the routine two-dose schedule for measles vaccine will be promoted.

3) Reduction of Morbidity and Mortality from Measles

The reduction in number of infected patients and morbidity of measles will become possible through the increase in the immunization ratio and the social losses due to the disease will be reduced.

4) Transfer of Vaccine Production Technology

Through the implementation of the Project, vaccine production technology will be transferred to Viet Nam by human resources development as a result of Soft Component assistance from Japan.

(2) Expected Indirect Benefits of the Project

The measles vaccine production facilities by the Project are designed to be capable of expanding production capacity when the addition and expansion of the necessary equipment is carried out by self-funding of Viet Nam. This will allow the export of measles vaccine to neighboring countries and contribute to reduction of measles morbidity and mortality in the region.

(3) Establishing Targets Objectives

The evaluation of the Project will be based on monitoring the statistics for production volume of WHO-GMP compliant measles vaccine, the morbidity (numbers) of measles patients, mortality and introduction of routine two-dose schedule for measles vaccine.

The above direct and indirect benefits are summarized in the following table.

Table 3-1 Benefits of the Project

Present Condition and Problems	Measures under the Project	Benefits and improvements of by Project
Direct Benefits		
1. The continued stable and programmed supply of measles vaccine is in doubt, due to the total reliance on imported vaccine at present.	Measles vaccine production facilities in compliance with WHO –GMP will be constructed	The stable supply of necessary amounts of measles vaccine becomes possible throughout Viet Nam.
2. The supply of measles vaccine cannot meet the demand following the introduction of routine two-dose schedule for measles vaccine recommended by WHO*. (including fiscal reasons) *WHO recommends two-dose routine schedule for measles vaccine to compensate for primary immunization failure due to poorly developed cold chain and inherited maternal antibodies present at the initial immunization.	With the establishment of a domestic production organization for measles vaccine, the mass supply of relatively cheap measles vaccine according to demand becomes possible.	With the introduction of two-dose routine immunization schedule for measles vaccine nation-wide, the morbidity and mortality from measles will be reduced and it will eventually lead to reduction of the socio-economic costs of the disease.
Indirect Benefits		
The demand for measles vaccine is increasing in the South-East Asian region as a whole.	With the future expansion of measles production facilities and equipment, increased production capacity of measles vaccine is possible.	The supply of measles vaccine to surrounding countries will become possible, contributing to the reduction of morbidity and mortality from measles throughout the region.

3-2 Recommendations

It is important that project components to be undertaken under Vietnamese funding be carried out at the appropriate time during the course of the Project. The installation of infrastructure facilities, such as water supply and power supply must be completed as has been scheduled.
In addition, it is desirable that the following programs and institutions are strengthened and improved for the smooth and efficient implementation of the Project.

1) The Strengthening of the National Regulatory Authority (NRA)

The project facilities are to be constructed in compliance with WHO-GMP standards. The continued development of the Vietnamese NRA mainly under WHO assistance is necessary. The NRA is required to carry out complete monitoring of bio-medical products including production, distribution and surveillance of immunization adverse effects. For this purpose, it will be required to develop and strengthen the institutional capabilities of National Center for Control of Medico-Biological Products (CENCOBI), the NRA of Viet Nam, specifically for the 6 functions listed below now being developed with assistance of WHO.

- · A documented licensing system
- · Surveillance of vaccine performance
- · System of lot release
- · Use of laboratory facilities
- · Regular GMP inspections
- · Evaluation of clinical performance

The development of the NRA must be completed before the completion of the Project facilities.

2) Smooth Transfer of Technology and Education and Training

POLIOVAC already has experience in poliomyelitis vaccine production, but does not have any experience in production of measles vaccine and will require further training and education of its staff for the higher requirements in process control and quality control required for measles vaccine production. Presently, there are plans for further improvement of technical assistance with cooperation among Japan, Viet Nam and WHO.

Under the agreement for technology transfer of measles vaccine production process signed between Kitasato Institute, a measles vaccine producer in Japan, and POLIOVAC, the transfer of production process technology and the supply of seed virus (AIK-C strain) for the Project has been assured.

3) Establishment of Operational Organization

POLIOVAC is an independent public agency established to produce and supply poliomyelitis vaccine. POLIOVAC will undertake the operation of the project facilities to be established under the Project, but it will be completely independent from the poliomyelitis vaccine production facility. This will mean that not only the site is separate, but also all personnel at the facility will be assigned fulltime. Therefore, it will be necessary to secure the necessary personnel and budget required for the smooth and efficient operation, including the personnel required for the maintenance and management of the facilities and equipment. This will assure the improved and sustained operating conditions of the constructed facilities and procured equipment.

4) Equipment Management Organization

Venders of procured equipment will provide technical guidance in addition to submitting maintenance and inspection manuals, operation manuals and circuitry diagrams, et cetera. The efficient implementation of maintenance and management of the equipment will require the efficient use of these manuals. It also desirable that mid to long term budget projections be prepared based on a spare parts procurement plan and equipment replacement plan. These plans are prepared from a thorough grasp of the dates of the receipt of materials and equipment, frequency of use, repair records, all of which should be then compiled in a record book for each piece of equipment.

5) Preparation of Annual Report

It preferable that annual reports be prepared after completion of the Project facilities, describing the operational status of the facilities and equipment. It will be possible to use these reports to grasp the operational status of the facilities and equipment and to utilize the reports as reference material for improvement of operations.

Appendix 1 Member List of Basic Design Survey Teams

Basic Design Survey 1

Mr. Kazumi JIGAMI	Team Leader	Director, Second Grant Aid Management Division, Grant Aid Management Dept., JICA
Mr. Koji OKAMOTO	Communicable Disease Control	Director of International Cooperation, International Affairs Division, Ministry of Health, Labor and Welfare
Mr. Hisashi NOGUCHI	Grant Aid	Assistant Director, Grant Aid Division Ministry of Foreign Affairs
Dr. Tomio LEE	Measles Vaccine Production Technology	Deputy Director, Research Center for Control Biologicals, Kitasato Institute
Mr. Tomonao HAMADA	Chief Consultant /Architectural Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kanichi KUWANA	Architectural Design	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazuo TOZAKI	Vaccine Production Process Control	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Tamotsu NOZAKI	Operation & Administration	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Shuzo ISHIKAWA	Building Systems Design	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Yoichi SUGIURA	Equipment Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazunori SHIMIZU	Construction Planning /Cost Survey	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazunori KATO	Translator	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Ms. Akiko Kamei	Assistant Architectural Design	The Consortium of Nihon Sekkei, Inc. and JGC Corporation

Basic Design Survey 2

Mr. Hisashi NOGUCHI	Team Leader	Assistant Director, Grant Aid Division Ministry of Foreign Affairs
Dr. Takeshi SATO	Vaccine Quality Control	Department of Virology Ⅲ, National Institute of Infectious Diseases
Dr. Tomio LEE	Measles Vaccine Production Technology	Deputy Director, Research Center for Control Biologicals, Kitasato Institute
Ms. Saeda MAKIMOTO	Project Management	Staff, Second Grant Aid Division, Grant Aid Management Dept., JICA
Mr. Tomonao HAMADA	Chief Consultant	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kanichi KUWANA	Architectural Design/ Architectural Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazuo TOZAKI	Vaccine Production Process Control	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Shuzo ISHIKAWA	Building Systems Design	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazunori KATO	Translator	The Consortium of Nihon Sekkei, Inc. and JGC Corporation

Draft Basic Design Explanation Survey

Mr. Hisashi NOGUCHI	Team Leader	Assistant Director, Grant Aid Division Ministry of Foreign Affairs
Dr. Tomio LEE	Measles Vaccine Production Technology	Deputy Director, Research Center for Control Biologicals, Kitasato Institute
Dr. Yoshitake TANAKA	Technological Assistance Planning	Deputy Director, Research Center for Production Process Biologicals
Mr. Hisakazu HIRAOKA	Project Management	Staff, Second Grant Aid Division, Grant Aid Management Dept., JICA
Mr. Tomonao HAMADA	Chief Consultant	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kanichi KUWANA	Architectural Design	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazuo TOZAKI	Vaccine Production Process Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Shuzo ISHIKAWA	Building Systems	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Tamotsu NOZAKI	Consultant Operation & Project Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kazunori KATO	Interpreter	The Consortium of Nihon Sekkei, Inc. and JGC Corporation
Mr. Kaori SHIMIZU	Assistant Vaccine Production Process Planning	The Consortium of Nihon Sekkei, Inc. and JGC Corporation

Schedule of Basic Design Survey 1

No.	Title		Team Leader	Communicable Disease Control	Grant Aid	Measles Vaccine Production Technology	Chief Consultant/ Architectural Planning	Architectural Design	Vaccine Production Process Control	Operations, Administration	Building Systems Design	Equipment Planing	Construction Plan, Cost Survey	Translator
	Date	Name	Kazumi Jigami	Koji Okamoto	Hisashi Nogami	Tomio Lee	Tomonao Hamada	Kanichi Kuwana	Kazuo Tozaki	Tamotsu Nozaki	Shuzo Ishikawa	Yoichi Dsugiura	Kazunori Shimizu	Kazunori Kato
1	March, 12	Tue					Lv. Tokyo for Jakarta		Lv. Tokyo for Jakarta		Lv. Tokyo for Jakarta			
2	March, 13	Wed					Lv. Jarkarta for Bandung, survey of Bio Farma		Lv. Jarkarta for Bandung, survey of Bio Farma		Lv. Jarkarta for Bandung, survey of Bio Farma			
3	March, 14	Thu					Survey of Bio Farma, Lv. Bandung for Jarkarta		Survey of Bio Farma, Lv. Bandung for Jarkarta		Survey of Bio Farma, Lv. Bandung for Jarkarta			
4	March, 15	Fri					Team Meeting, Collating Information		Team Meeting, Collating Information		Team Meeting, Collating Information			
5	March, 16	Sat					Lv. Jarkarta for Bangkok		Lv. Jarkarta for Bangkok		Lv. Jarkarta for Bangkok			
6	March, 17	Sun					Lv. Bangkok for Hanoi	Lv. Tokyo for Haoi (via Hong Kong)	Lv. Bangkok for Hanoi		Lv. Bangkok for Hanoi			
7	March, 18	Mon					Courtesey call on Embassy of Japan, NIHE, POLIOVAC			Lv. Tokyo for Haoi (via Hong Kong)	Courtesey call on Embassy of Japan, NIHE, POLIOVAC	Lv. Tokyo for Haoi (via Hong Kong)		Lv. Tokyo for Haoi (via Hong Kong)
8	March, 19	Tue					Discussions with POLIOVAC, surveys							Discussions with POLIOVAC, various surveys
9	March, 20	Wed				Lv. Tokyo for Haoi (via Hong Kong)	Discussions with POLIOVAC, surveys						Lv. Tokyo for Haoi (via Hong Kong)	
10	March, 21	Thu				Lv. Hanoi for Nha Trang, survey of IVAC		Discussions with POLIOVAC, surveys	Lv. Hanoi for Nha Trang, survey of IVAC	Discussions with POLIOVAC, surveys	Lv. Hanoi for Nha Trang, survey of IVAC	Discussions with POLIOVAC, surveys		Lv. Hanoi for Nha Trang, survey of IVAC
11	March, 22	Fri				Survey of IVAC		Discussions with POLIOVAC, surveys	Survey of IVAC	Discussions with POLIOVAC, surveys	Survey of IVAC	Discussions with POLIOVAC, surveys	Procurment Surveys	Survey of IVAC
12	March, 23	Sat				Leave Nha Trang for Hanoi		Discussions with POLIOVAC, surveys	Leave Nha Trang for Hanoi	Discussions with POLIOVAC, surveys	Leave Nha Trang for Hanoi	Discussions with POLIOVAC, surveys	Procurment Surveys	Leave Nha Trang for Hanoi
13	March, 24	Sun	Leave Narita for Hanoi (via Hong Kong)			Internal Team Meeting, collation of Information								
14	March, 25	Mon	Courtesey Call to JICA Viet Nam Office, Embassy of Japan, MOH, MPI and WHO					Discussions with POLIOVAC, various surveys	Courtesey Call to JICA Viet Nam Office, Embassy of Japan, MOH and MPI	Discussions with POLIOVAC, surveys	Infrastructure Surveys	Discussions with POLIOVAC, surveys	Procurment Surveys	Coutesey calls to JICA Viet Nam Office, Embassy of Japan, MOH and MPI
15	March, 26	Tue	Discussions with POLIOVAC and WHO							Discussions with POLIOVAC, surveys			Procurment Surveys	Discussions with POLIOVAC and WHO
16	March, 27	Wed	Discussions with POLIOVAC										Procurment Surveys	Discussions with POLIOVAC, surveys
17	March, 28	Thu	Prepration of Darft Minutes of Discussions, Discussions with CENCOBI										Procurment Surveys	Preparation of Draft Minutes, Discussions with CENCOBI
18	March, 29	Fri	Discussions with POLIOVAC, Leave Hanoi for Danang	Discussions with POLIOVAC on Minutes	Discussions with POLIOVAC, Lv. Hanoi for Danang	Discussions with POLIOVAC, various surveys							Procurment Surveys	Discussions on Minutes with POLIOVAC, surveys
19	March, 30	Sat	Survey of Hue Hospital	Leave Hanoi for Tokyo (via Hong Kong)	Survey of Hue Hospital	Discussions with POLIOVAC, various surveys		Contracting of natural conditions survey	Discussions with POLIOVAC, surveys				Contracting of natural conditions survey	Discussions with POLIOVAC, surveys
20	March, 31	Sun	Survey of Danang Hospital, Lv. Danang for Hanoi		Survey of Danang Hospital, Lv. Danang for Hanoi	Team Discussions, Collating Information								
21	April, 1	Mon	Report to JICA Office, Embassy of Japan, Signing of Minutes of Discussions		Report to JICA Viet Nam Office, Embassy of Japan, Signing of Minutes of Discussions			continued studies	Report to JICA Viet Nam Office, Embassy of Japan, Signing of Minutes of Discussions	continued studies				Report to JICA Viet Nam Office, Embassy of Japan, Signing of Minutes
22	April, 2	Tue	Leave Hanoi for Tokyo (via Hong Kong)		Leave Hanoi for Tokyo (via Hong Kong)		continued studies							
23	April, 3	Wed					continued studies					Leave Hanoi for Tokyo (via Hong Kong)	continued studies	
24	April, 4	Thu					Signing of Technical Notes, Visit JICA office and Embassy of Japan						Signing of Technical Notes, Visit JICA office and Embassy of Japan	
25	April, 5	Fri					Leave Hanoi for Tokyo (via Hong Kong)						Leave Hanoi for Tokyo (via Hong Kong)	

Schedule of Basic Design Survey 2

No.	Title		Team Leader	Vaccine Quality Control	Measles Vaccine Production Technology	Project Management	Chief Consultant/ Architectural Planning	Architectural Design	Vaccine Production Process Control	Building Systems Design	Translator
	Date	Name	Hisashi Noguchi	Takeshi Sato	Tomio Lee	Saeda Makimoto	Tomonao Hamada	Kanichi Kuwana	Kazuo Tozaki	Shuzo Ishikawa	Kazunori Kato
1	May, 22	Wed		Leave Tokyo for Hanoi (via Hong Kong)							
2	May, 23	Thu		Courtesey Call on Embassy of japan, JICA Viet Nam Office, MOH and WHO							
3	May, 24	Fri		Discussions with MOH and POLIOVAC							
4	May, 25	Sat		Internal Team Meeting, Datqa Analysis							
5	May, 26	Sun		Internal Team Meeting, Datqa Analysis							
6	May, 27	Mon		Discussions with WHO concerning facilities Planning, Equipment Plans and Discussions with CENCOBI							
7	May, 28	Tue	Leave Tokyo for Hanoi (via Hong Kong)	Conduct Workshop in coraboration with WHO							
8	May, 29	Wed	Explain contents of facilities and Equipment plans to POLIOVAC, Preparation of Draft Minutes of Discussions								
9	May, 30	Thu	Signing of Minutes of Discussions, Report to Embassy of Japan, and JICA Viet Nam Office			Signing of Minutes of Discussions, Report to Embassy of Japan, and JICA Viet Nam Office, Lv. Hanoi for Tokyo (via Hong Kong)	Signing of Minutes of Discussions, Report to Embassy of Japan, and JICA Viet Nam Office				
10	May, 31	Fri	Discussions with Embassy of Japan	Lv. Hanoi for Tokyo (via Hong Kong)			Lv. Hanoi for Tokyo (via Hong Kong)				
11	June, 1	Sat	Document Filing								
12	June, 2	Sun	Leave Hanoi								

Schedule of Draft Basic Design Explanation

No.	Title		Team Leader	Measles Vaccine Production Technology	Technological Assistance Planning	Project Management	Chief Consultant/ Architectural Planning	Architectural Design	Vaccine Production Process Control	Operations / Administration	Translator
	date	Name	Hisashi Noguchi	Tomio Lee	Yoshitake Tanaka	Hisakazu Hiraoka	Tomonao Hamada	Kanichi Kuwana	Kazuo Tozaki	Tamotsu Nozaki	Kazunori Kato
1	August, 26	Mon	Leave Tokyo for Hanoi (via Hong Kong), discussions with JICA Viet Nam Office				leave Tokyo for Hanoi (via Hong Kong)				
2	August, 27	Tue	Courtesey call to Embassy of Japan and MOH, discussion with POLIOVAC				Internal Team Meeting, discussions with POLIOVAC				
3	August, 28	Wed	Discussions with POLIOVAC (explanation of Draft Basic Design)								
4	August, 29	Thu	Discussions with POLIOVAC (Draft Minutes of Discussions, contents of technical assistance)								
5	August, 30	Fri	Signing Of M/D at MOH, Rreport to Japanese side in Hanoi	Signing Of M/D at MOH, discussions with water company, power company and suppliers of Vials, etc.		Signing Of M/D at MOH, Rreport to Japanese side in Hanoi	Signing Of M/D at MOH, discussions with water company, power company and suppliers of Vials, etc.				
6	August, 31	Sat	Leave Hanoi for Tokyo (via Hong Kong)	Discussions on technical assistance		Leave Hanoi for Tokyo (via Hong Kong)	Discussions with POLIOVAC				
7	Sept.,1	Sun		Leave Hanoi for Tokyo (via Hong Kong)			Data Analysis			Data Analysis	
8	Sept.,2	Mon					Discussions with POLIOVAC (Technical Notes), document filing			Discussions with POLIOVAC (Technical Notes), document filing	
9	Sept.,3	Tue					Discussions with fire department, survey of dry ice suppliers, survey of city water, sampling of well water and signing of Technical Notes, report to JICA Viet Nam Office			Discussions with fire department, survey of dry ice suppliers, survey of city water, sampling of well water and signing of Technical Notes, report to JICA Viet Nam Office	
10	Sept.,4	Wed					Leave Hanoi for Tokyo (via Hong Kong)			Leave Hanoi for Tokyo (via Hong Kong)	

Appendix 3 List of Parties Concerned in the Recipient Country

1. Viet Nam Parties		
1-1	Ministry of Planning and Investment (MPI)	
	Engineer Tran Kim Nguyen	Senior Expert, Dept. of Labor and Social - Culture Affairs
	Mr. Ho Minh Chien	Deputy Director, Dept. of Labor and Social - Culture Affairs
	Mr. Nguyen Xuan Tien	Department of International Economic Relation
1-2	Ministry of Health (MOH)	
	Professor Do Nguyen Phuong	Minister of Health
	Dr. Trinh Quan Huan	Deputy Director of Preventive Medicine Department
	Dr. Truong Viet Dung	Deputy Director of Planning Department
	Mrs. Le Thu Ha	Deputy Director of International Cooperation Dept.
	Mrs. Giang Huong	International Cooperation Department
	Mr. Nguven Quang An	Deputy Director of Finance Department
	Mrs. Tran Thi Giang Huong	International Cooperation Department
	Dr. N D Duy	Equipment Department
	Dr. Tran Trong Hai	International Cooperation Department
	Mr. Duong Van Tinh	Director of Medical Equipment & Civil Construction Dept.
	Dr. Ho Quang Minh	Vice Director of International Cooperation Dept.
	Mr. Nguyen Xuan Tien	International Cooperation Department
	Mr. Nguyen Huy Lieu	Director of Planning Department
	Mrs. Tran Thi Ha	Planning Department
1-3	National Institute of Hygiene & Epidemiology (NIHE)	
	Professor Hoang Thuy Long	Director of NIHE
	Associate Professor Do Si Hien	Director of EPI
	Professor Dang Duc Trach	President of General Assoc. of Medicine and Pharmacy
	Dr. Hoang Minh Tuyet	Director of Animal Breeding House
	Professor Nguyen Thu Van	Director of Vaccine and Biological Products Co. No 1
1-4	Poliomyelitis Vaccine Research and Production Center (POLIOVAC)	
	Professor Nguyen Van Man	Director of POLIOVAC
	Dr. Nguyen Thi Quy	Deputy Director of POLIOVAC
	Dr. Nguyen Dang Hien	Head of Cell Culture and Bulk Vaccine Preparation Department
	Mr. Tran Van Du	Chief Accountant, Finance Department
	Mrs. Nguyen Thanh Thuy	Head of Planning and Material Department
	Mrs. Nguyen Thi Hai Thanh	Planning and Material Department
	Dr. Hoang Thu Hien	Cell Culture and Bulk Vaccine Preparation Dept.
	Mrs. Nguyen Thuy Huong	Medium Preparation Department
	Mr. Le Hoang Nam	Engineer, Administration Department
	Mrs. Dang Bich Lien	Finance Department
	Mrs.Thinh	Medium Preparation Department
	Mrs.Dung	Quality Control
	Mrs.Thu	Quality Control
	Hoang Quane Huy	Quality Control
	Duong Thi Nga	Chief of Quality Assurance Department
	Nguyen Nu Anh Thu	Researcher of Quality Assurance Department
	Doan Van Luu	Researcher of Production Department

1. Viet Nam Parties		
1-5	National Center for Control of Medico-Biological Products (CENCOBI)	
	Dr.Nguyen Dinh Bang	Director of CENCOBI
	Dr. Hoang Thi Lien	Deputy Director of CENCOBI
	Dr. Hoang Thi Hong	Quality Assurance Department
1-6	National Institute of Vaccines and Biological Substances (IVAC)	
	Associate Professor Le Van Hiep	Director
	Dr. Le Van Be	Vice Director
	Mr. Nguyen Van Binh	Chief of Immunoglobulin Preparation Dept.
1-7	Hanoi City Fire Department	
	Mr. Le Cong Thang	
	Mr. Pham Ngoc Hung	
1-8	Hanoi Power Company (HPC)	
	Mr. Tri Xuan Nguyen	Vice Chief of Technical Dept.
	Mr. Tran Duc Hung	Vice Director of Business Dept.
1-9	Hanoi Post Office	(Telephone Company)
	Mr. Duong Thanh Binh	Development Dept.
1-10	Hanoi Water Busines Company	
	Mr.Bui Van Mat	Director
1-11	Hanoi City Chief Architect’s Office	
	Mr. Dao Ngoi Ngeeieui	
	Mr. Luu Hoat	
1-12	Government Pricing Committee	
	Engineer Vu An Khang	Deputy Director of Department
	Engineer Nguyen Thi Vinh Long	Economic Expert
1-13	Rural Development & Construction Company Number 1	
	Mr. Nguyen Cong Khai	Engineer-Director

2. Japanese Parties in Viet Nam		
2-1.	Embassy of Japan in Viet Nam	
	His Excellency, Ryuichirou Yamasaki	Ambassador of Japan
	Mr. Kenji Miyagawa	First Secretary
2-2.	Japan International Cooperation Agency, Viet Nam Office	
	Mr. Morimasa Kanamaru	Resident Representative
	Mr. Masato Togawa	Senior Deputy Resident Representative
	Mr. Kouzou Watanabe	Deputy Resident Representative
	Ms. Yuki Hayashi	Deputy Resident Representative
	Mr. Kazuyuki Kobayashi	Senior Project Formulation Officer
3. Others		
3-1	PT BIO FARMA , Indonesia	
	Drs. Marzuki Abdullla	President Director
	Drs. Maman Hidayat	Planning and Development Director
	Drs. Isa Mansyur	Production Director
	Dr. Erman Boedisetianto	Head of Vial Vaccine Production
	Drs. Dori Ugiyadi	Head of Measles Vaccine
	Drs. Juliman	Head of Supporting Facilities
3-2.	World Health Organization (WHO)	
	Mrs. Pascal Brudon	WHO Representative in Viet Nam
	Dr. Chris Tunon	Officer in Charge, WHO
	Mr. Angus Pringle	Inter-country EPI Technical Officer, Vietnam
	Dr. Yoshikuni Sato	Medical Officer, EPI, WPRO
	Dr. Rihhe Schutz	EPI Officer , WHO
	Dr. Norman Ackland	Short Term Consultant
	Mr. Lahovari Belgharbi	NRA

Appendix 4. Minutes of Discussions

4-1 Minutes of Discussions (Basic Design Survey I)

ATTACHMENT

1.Objective of the Project

The Objective of the Project is to produce measles vaccine locally in accordance with implementation of national measles control program through construction of the measles vaccine production facility.

2.Project site

The site of the Project is Thanh Tri Commune, Thanh Tri District, Hanoi City as shown in ANNEX - 1.

3.Responsible and Implementing Agency

3-1.The Responsible Agency is the Ministry of Health (MOH).

3-2.The Implementing Agency is the Poliomyelitis Vaccine Research and Production Center (POLIOVAC).

4.Construction of the facilities of the Project.

4-1. After discussions with the Team, the Vietnamese side requested to the Japanese side the construction of the following facilities and the supply of relevant equipment.

- Production facilities
  - -Bulk production zone, Final production zone
  - -Pharmaceutical water plant
- Quality control facilities
- Animal testing laboratory facilities
- Building services facilities (Electrical and Mechanical systems)
- Waste water treatment plant
- Incinerator

4-2. The Vietnamese side committed to complete the following.

- Allotment of 8,500 m² of land in Thanh Tri District for the Project.
- Supply of more than 2 billion VND for leveling the new site and construction of fence and gate in the year 2001 and 2002.
- Construction of the following work
  - -Administration building
  - -Parking garage

-In-site road
-Canteen
-Security guard house
-Landscaping of the site

5.Japan's Grant Aid Scheme

5-1. The Vietnamese side understands the Japan's Grant Aid Scheme explained by the Team, as described in Annex-2.

5-2. The Vietnamese side will take the necessary measures, as described in Annex-3, for smooth implementation of the Project, as a condition for the Japanese Grant Aid to be implemented.

6.Schedule of the Study

6-1. The consultants will proceed with further studies in Viet Nam until April 5, 2002.

6-2. JICA will dispatch a mission to Viet Nam in order to discuss the issues of GMP and National Regulatory Authority in detail around June 2002.

6-3. JICA will prepare the draft report in English and dispatch a mission to Viet Nam in order to explain its contents around September 2002.

6-4. In case the contents of the report are accepted in principle by the Government of Viet Nam, JICA will complete the final report and send it to the Government of Viet Nam by February 2003.

7.Other relevant issues

7-1. Both sides reconfirmed all the contents of the Minutes of Discussions of the Preparatory Study signed on 21 June, 2001.

7-2. The Vietnamese side expressed that the manufacturing process of measles vaccine shall be met with the WHO-GMP standard.

7-3. The Japanese side was informed that the Ministry of Health of Viet Nam decides to appoint the National Center for Quality Control of Medical Biologicals (CENCOBI) as the sole institution responsible for carrying out the functions of a National Regulatory Authority (NRA) for vaccines and biological products in Viet Nam. Both sides understood that strengthening of the NRA with technical assistance from the World Health Organization (WHO) is necessary for measles vaccine production to meet WHO-GMP standards. The Vietnamese sides expressed that the NRA shall receive WHO assessment and achieve the qualification of the six critical functions by the end of the year 2005.

7-4.The Vietnamese side requested the following technology transfer, including training in Japan, Viet Nam and other countries as needed. Both sides understood that technical input from Viet Nam, Japan and WHO will be necessary for the following;

-Measles vaccine production

-Measles vaccine quality control

-GMP

-Validation

-Maintenance of the facilities and equipment

The Vietnamese side also expressed that they wish technical cooperation from Kitasato Institute to develop local measles vaccine production including the;

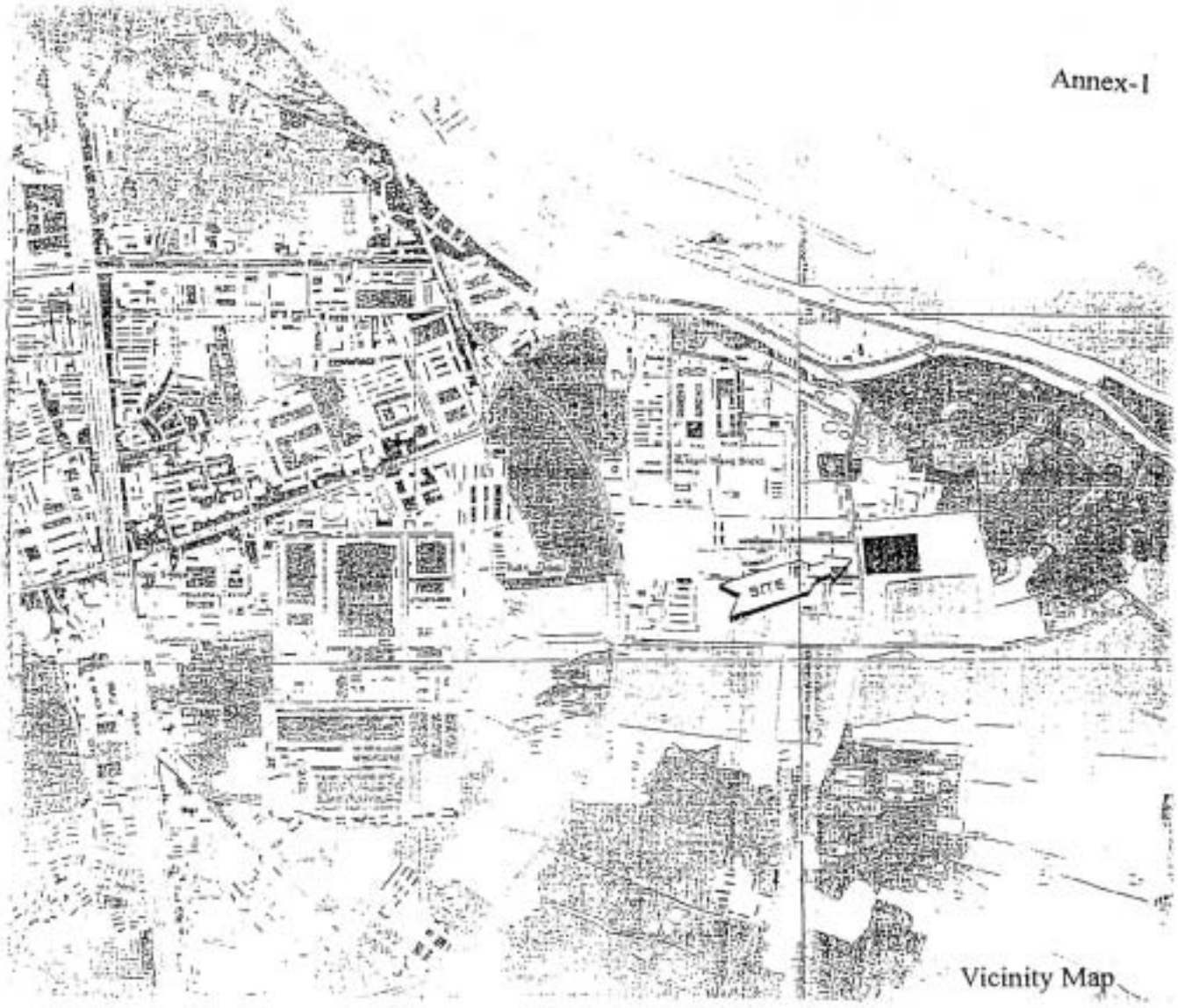
-Supply of bulk vaccine for the first 2 years after completion of the facilities

-Supply of master and working seed viruses (AIK-C).

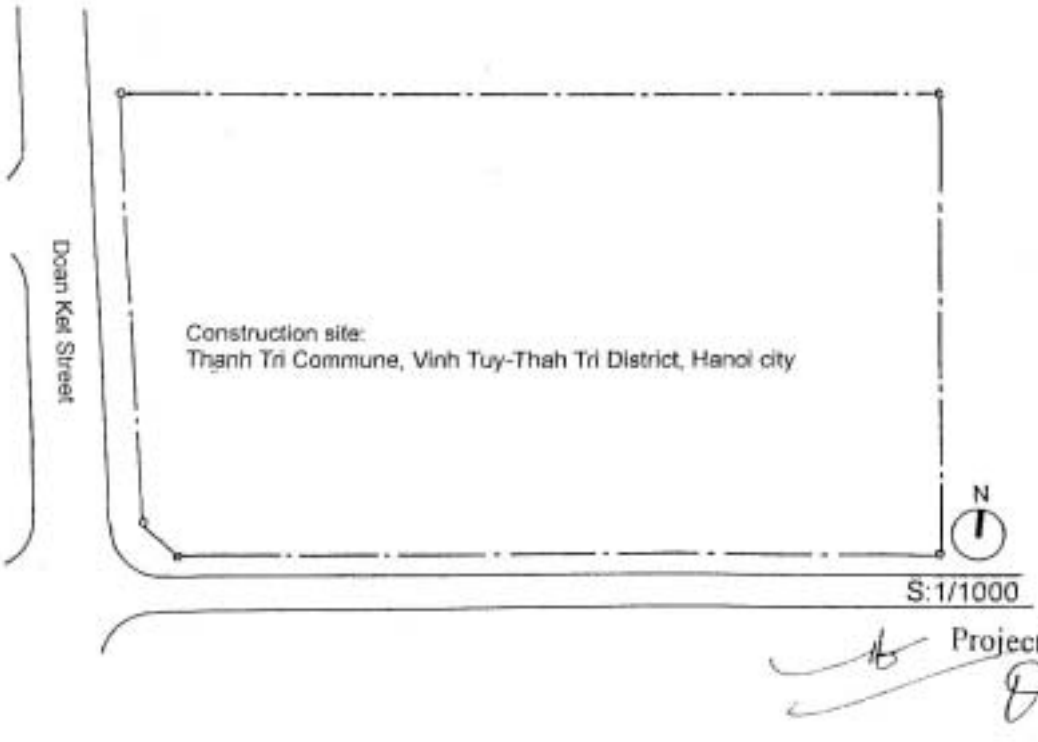
7-5.The Vietnamese side confirmed that the Ministry of Health of Viet Nam will be responsible for the operational costs and the allocation of the necessary personnel once the facilities enter into production.

7-6.The Vietnamese side will secure the official appraisal and approval required for the implementation of the Project by the Government of Viet Nam by October 2002.

Annex-I



Vicinity Map



Project Site

Japan's Grant Aid Program

1. Japan's Grant Aid Procedures

(1) The Japan's Grant Aid Program is executed by the following procedures.
Application (request made by a recipient country)
Study (Basic Design Study conducted by JICA)
Appraisal & Approval (appraisal by the Government of Japan and approval by the Cabinet of Japan)
Determination of Implementation (Exchange of Notes between both Governments)
Implementation (implementation of the Project)

(2) Firstly, an application or a request for a Grant Aid project submitted by the recipient country is examined by the Government of Japan (the Ministry of Foreign Affairs) to determine whether or not it is eligible for Japan's Grant Aid. If the request is deemed appropriate, the Government of Japan assigns JICA to conduct a study on the request.

Secondly, JICA conducts the study (Basic Design Study), using (a) Japanese consulting firm(s).

Thirdly, the Government of Japan appraises the project to see whether or not it is suitable for Japan's Grant Aid Program, based on the Basic Design Study Report prepared by JICA and the results are then submitted to the cabinet for approval.

Fourth, the project approved by the cabinet becomes official with the Exchange of Notes signed by the Government of Japan and the recipient country.

Finally, for the implementation of the Project, JICA assists the recipient country in preparing contracts and so on.

2. Contents of the Study

(1) Contents of the Study

The purpose of the Basic Design Study conducted by JICA on a requested project is to provide a basic document necessary for appraisal of the project by the Japanese Government. The contents of the Study are as follows:

a) confirmation of the background, objectives, benefits of the project and also institutional capacity of agencies concerned of the recipient country necessary for project implementation,

b) evaluation of the appropriateness of the project for the Grant Aid Scheme from a technical, social and economical point of view,

c) confirmation of items agreed on by the both parties concerning a basic concept of the project,
d) preparation of a basic design of the project,
e) estimation of cost of the project.

The contents of the original request are not necessarily approved in their initial form as the contents of the Grant Aid project. The Basic Design of the project is confirmed considering the guidelines of Japan's Grant Aid Scheme.

Final project components are subject to approval by the Government of Japan and therefore may differ from an original request. Implementing the project, the Government of Japan requests the recipient country to take necessary measures involved which are itemized on Exchange of Notes.

(2) Selection of Consultants

For smooth implementation of the study, JICA uses (a) registered consulting firm(s). JICA selects (a) firm(s) based on the proposals submitted by the interested firms. The firm(s) selected carry (ies) out a Basic Design Study and write(s) a report, based upon terms of reference set by JICA.

The consulting firm(s) used for the study is (are) recommended by JICA to a recipient country after Exchange of Notes, in order to maintain technical consistency and also to avoid any undue delay in implementation should the selection process be repeated.

3. Japan's Grant Aid Scheme

(1) What is Grant Aid?

The Grant Aid Program provides a recipient country with non reimbursable funds to procure the equipment and services (engineering services and transportation of the products, etc.) for economic and social development of the country under principles in accordance with relevant laws and regulations of Japan. The Grant Aid is not supplied through the donation of materials or such.

(2) Exchange of Notes (E/N)

Both Governments concerned extend Japan's Grant Aid in accordance with the Exchange of Notes in which the objectives of the Project, period of execution, conditions and amount of the Grant Aid etc., are confirmed.

(3) "The period of the Grant Aid" means one Japanese fiscal year that the Cabinet approves the Project for. Within the fiscal year, all procedure such as Exchange of Notes, concluding a contract with (a) consulting firm(s) and (a) contractor(s) and a final payment to them must be completed.

(4) Under the Grant, in principle, products and services of origins of Japan or the recipient country are to be purchased.

When the two Governments deem it necessary, the Grant may be used for the purchase of products or services of a third country.

However the prime contractors, namely, consulting, contractor and procurement firms, are limited to "Japanese nationals". (The term "Japanese nationals" means persons of Japanese nationality or Japanese corporations controlled by persons of Japanese nationality.)

(5) Necessity of the "Verification"

The Government of the recipient country or its designated authority will conclude contracts denominated in Japanese yen with Japanese nationals. The Government of Japan shall verify those contracts. The "Verification" is deemed necessary to secure accountability to Japanese taxpayers.

(6) Undertakings Required to the Government of the Recipient Country

In the implementation of the Grant Aid project, the recipient country is required to undertake such necessary measures as the following:

a) to secure land necessary for the sites of the project prior to the installation work in case the project is providing equipment,

b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities in and around the sites,

c) to secure buildings prior to the installation work in case the project is providing equipment,

d) to ensure all the expenses and prompt execution for unloading, customs clearance at the port of disembarkation and internal transportation of the products purchased under the Grant Aid,

e) to exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which will be imposed in the recipient country with respect to the supply of the products and services under the Verified Contracts,

f) to accord Japanese nationals whose services may be required in connection with the supply of the products and services under the Verified Contracts, such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work.

(7) Proper Use

The recipient country is required to maintain and use the equipment purchased under the Grant Aid properly and effectively and to assign staff necessary for the operation and maintenance as well as to bear all expenses other than those covered by the Grant Aid.

(8) Re-export

The products purchased under the Grant Aid shall not be re-exported from the recipient country.

(9) Banking Arrangement (B/A)

a) The Government of the recipient country or its designated authority shall open an account in the name of the Government of the recipient country in a bank in Japan. The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by Government of the recipient country or its designated authority under the Verified Contracts.

b) The payments will be made when payment requests are presented by the bank to the Government of Japan under an Authorization to Pay issued by the Government of the recipient country or its designated authority.

Annex-3

Major Undertakings to be taken by Each Government

NO	Items	To be covered by Grant Aid	To be covered by Recipient side
1	To secure land		●
2	To clear, level and reclaim the site when needed		●
3	To construct gates and fences in and around the site		●
4	To construct the parking lot		●
5	To construct roads		
	1) Within the site		●
	2) Outside the site		●
6	To construct the building	●	
7	To provide facilities for the distribution of electricity, water supply, drainage and other incidental facilities		
	1)Electricity		
	a.The distributing line to the site		●
	b.The drop wiring and internal wiring within the site	●	
	c.The main circuit breaker and transformer	●	
	2)Water Supply		
	a.The city water distribution main to the site		●
	b.The supply system within the site (receiving and/or elevated tanks)	●	
	3)Drainage		
	a.The city drainage main (for storm, sewer and others) to the site		●
	b.The drainage system (for toilet sewer, ordinary waste, storm drainage and others) within the site	●	
	4)Gas Supply		
	a.The city gas main to the site		●
	b.The gas supply system within the site	●	
	5)Telephone System		
	a.The telephone trunk line to the main distribution frame / panel (MDF) of the building		●
	b.The MDF and the extension after the frame / panel	●	
	6)Furniture and Equipment		
	a.General furniture		●
	b.Project equipment	●	
8	To bear the following commissions to a bank of Japan for the banking services based upon the B/A		
	1) Advising commission of A/P		●
	2) Payment commission		●
9	To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country		
	1) Marine(Air) transportation of the products from Japan to the recipient country	●	
	2) Tax exemption and customs clearance of the products at the port of disembarkation		●
	3) Internal transportation from the port of disembarkation to the project site	●	

10	To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contract such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work		●
11	To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contract		●
12	To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant Aid		●
13	To bear all the expenses, other than those to be borne by the Grant Aid, necessary for construction of the facilities as well as for the transportation and installation of the equipment		●