2-2-4 Implementation Plan

2-2-4-1 Implementation Policy

(1) Project Implementation Organization

The Project will be implemented in accordance with Japan's Grant Aid Scheme after the decision by the Cabinet of the Government of Japan and conclusion of the Exchange of Notes (E/N) for the Project by and between the Governments of Japan and the Socialist Republic of Viet Nam.

The Vietnamese authority responsible for this Project will be MOH and the implementing agency will be Poliomyelitis Vaccine Research and Production Center (POLIOVAC). POLIOVAC will undertake the contracting of consulting services and construction and equipment procurement contracts as well as be responsible for the implementation of Vietnamese funded components of the Project. The organization for implementation of the Project is shown in the following diagram.

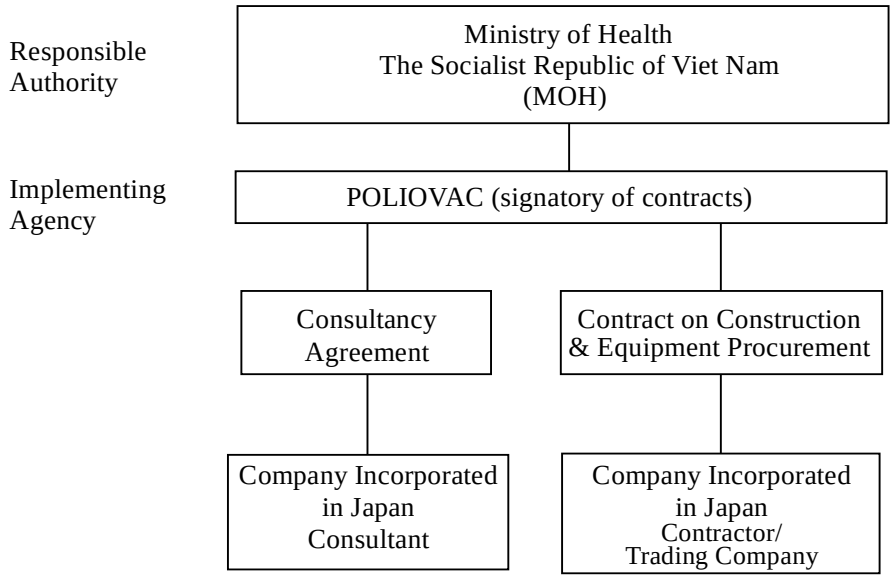
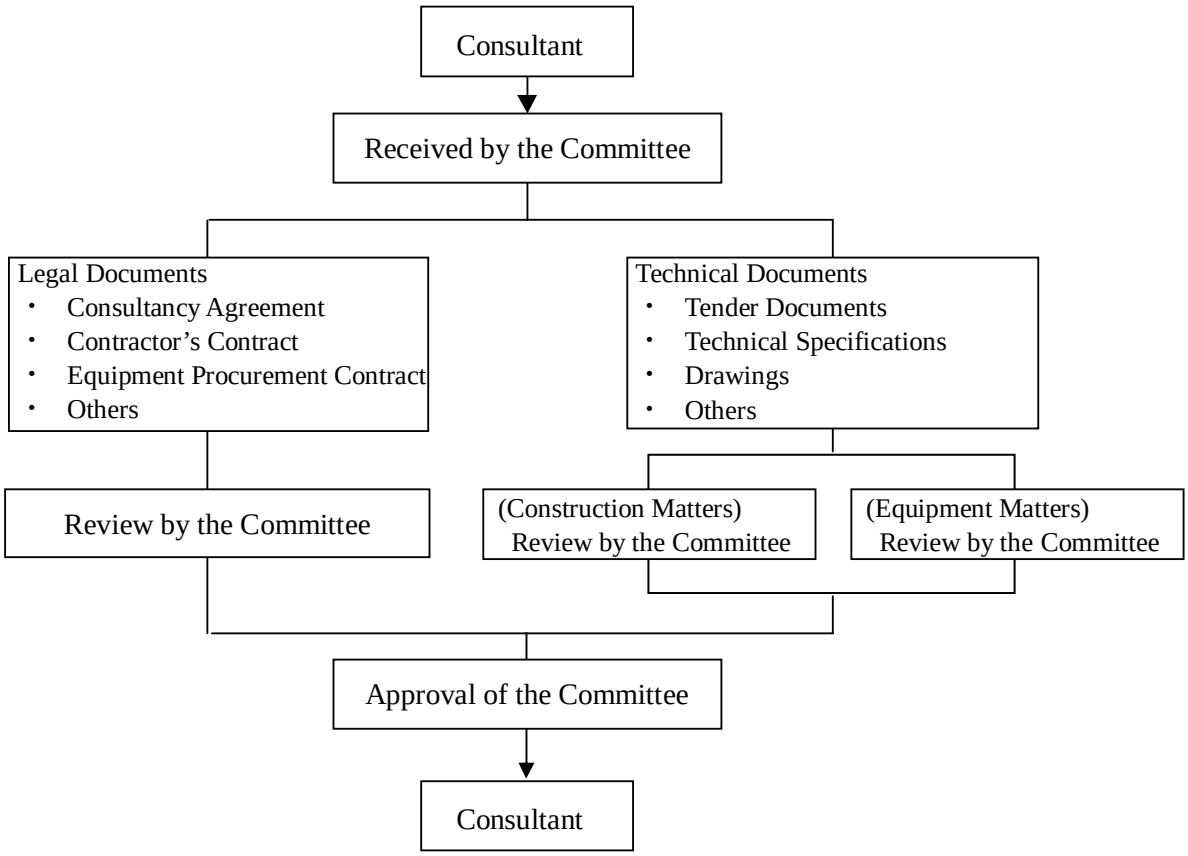


Figure 2-12 Organization of Project Implementation

The Project Promotion Committee will be established within POLIOVAC to promote the smooth implementation of the Project.

The inspection of the contents of tender documents, including detailed drawings and specifications, as well as the site inspections during building construction and equipment installation will be conducted by the Project Promotion Committee as the actual operation unit of POLIOVAC. POLIOVAC will provide final approval after receiving the report from the Committee.

The procedure is outlined in the following diagram.



Main Functions of Project Promotion Committee:

- Signing of Contracts and other necessary documents
- Promotion of the Project including tender procedures.
- Obtaining necessary approvals such as building approval and tax exemption.
- Allocation of personnel required for the implementation of the Project

Figure 2-13 Flow Chart for Project Implementation

Procedures for obtaining necessary building permits under the laws of Viet Nam are to be conducted by POLIOVAC.

(2) Consultant

After conclusion of E/N, POLIOVAC will enter a consultant services agreement with a Japanese consultant company regarding detail designs and supervision of the Project and obtain verification of the agreement from the Government of Japan. In order to implement the Project smoothly, it is important to conclude the consultant services agreement as quickly as possible after the conclusion of E/N. After conclusion of the agreement, the consultant will prepare the detailed design documents (tender documents)

based on this Basic Design Study Report in coordination with POLIOVAC and obtain confirmation of Vietnamese side for the detailed design documents following the procedure of approval as mentioned above. Based on the detailed design documents, the consultant will assist in implementation of the tender and conduct construction supervision.

(3) Selection of Contractor(s) for Construction and Equipment Procurement

Implementation works for the Project consist of construction of buildings and procurement of production equipment including installation and test running. The contractor(s) for building construction and equipment procurement are limited to qualified Japanese corporations and determined through open competitive tender with pre-qualification. Two methods can be considered for tendering of the Project. One is to deliver the Project in two separate contracts, namely building construction contract and equipment procurement and installation contract. The other is to make a single point contract with a consortium formed between two or more qualified Japanese corporations. The two methods of contracting will be closely examined and a decision to adopt either method will be based on an analysis of the comparative merits of the alternatives.

POLIOVAC will conclude the construction contract with the selected consortium or contractors and obtain verification(s) for each contract from the Japanese government. Subsequent to conclusion of the contract(s), the contractor(s) will expeditiously mobilize their personnel to start the project as stipulated in the contract.

(4) Employment of Local Consultants

As more than one building will be constructed simultaneously, local consultants will be employed to in addition to Japanese Site Engineer during supervision phase. The Production Building in the Project has a much higher proportion of building systems component with stringent cleanliness requirements compared to normal buildings, requiring the employment of local building systems engineers.

(5) Employment of Local Construction Technicians and Experts from Japan

The top local construction company in Viet Nam has approximately 18,000 personnel (including 5,000 on overseas projects), including 1,000 technical staff and has an annual construction volume of approximately 16.4 billion yen. There are 5 comparative companies in Hanoi and each has about 20 sub-contractors.

Some local construction companies have experience with Japanese corporation related construction and have knowledge of Japanese construction practices. When undertaking the construction of the Project facilities, the Japanese main contractor should place

experienced local construction technicians under the supervision of Japanese technical staff and carry out meticulous control and guidance on schedule, quality and safety procedures.

The Project facilities include a measles vaccine production building, which requires an extremely high level of quality control for many components. Therefore, it is necessary to have highly experienced Japanese experts in those fields to provide technological guidance and construction supervision. Especially in specialized fields such as clean rooms, the implementation plans shall provide for the dispatching of qualified experts from Japan.

The employment of normal construction workers present no problems.

2-2-4-2 Implementation Conditions

(1) Temporary Works

Field offices for Contractors, Subcontractors and Consultant will be built temporarily in the project site along with material storage and fabrication areas.

As for concrete, ready mixed concrete will be brought in by mixing trucks from concrete plants located in the outskirts of Hanoi. It will take about 30 minutes for concrete transportation and there will be no need to have a temporary concrete batch plant on the site.

Japanese and Vietnamese contractors and their personnel will be working simultaneously on site. In order to prevent accidents and theft of materials and construction equipment, temporary works for in-site roads and storage areas will be worked out in detail between the respective parties before commencing construction.

(2) Procurement of Construction Materials

Major construction materials like concrete, steel bars, concreting forms, bricks etc. are all procurable in Hanoi. Finishing materials such as stone products, ceramic tiles, woodworks, sheet glass, paints are all locally produced. However there are quality problems for some products such as plate glass, paints and manufacturing technique of woodworks. In many cases in Hanoi, aluminum window frames are cut and framed on site and then installed using imported aluminum bars. This is the cause of failure in water and air tightness compared with factory finished products and is a major potential cause of water leakage in buildings. These finishing materials which have potential quality problems, including aluminum window frames, will be procured from third countries. Almost all major items of electrical and mechanical building systems, except for wires and pipes, are imported from Singapore, Thailand, Hong Kong and Japan.

The finishing material for the clean rooms and specialty items in mechanical and electrical systems are not produced locally and these items will be procured in Singapore, Thailand or Japan.

(3) Method of Construction

The Project buildings are all made of reinforced concrete frame structure with brick masonry walls. In order to get the critical performance of cleanliness of air, partitions for clean rooms will be finished with dry construction panel construction.

Roofs are made of flat concrete slabs with thermal insulation and water proofing.

(4) Special Interior Works (Interior Finish of Clean Rooms)

Finishing works for clean rooms are designed so as to realize the stipulated grades of air cleanliness and comply with the WHO-GMP codes along with production equipment and air conditioning system.

2-2-4-3 Scope of Works

(1) Division of Responsibilities

The division and scope of works for both countries are shown in the following table.

Table 2-15 Scope of Works

Scope of works under Japanese responsibility	Scope of works under Vietnamese responsibility
1. Architectural and Structural Works (including fixed furnishings) - Production Building - Animal Laboratory 2. Electrical Works - Production Building - Animal Laboratory - Mechanical Building 3. Air-conditioning, Sanitary and Plumbing Works - Production Building - Animal Laboratory - Mechanical Building 4. Medical Gas Works - Production Building 5. External Works for Production Building & Animal Laboratory - Concrete slabs surrounding building - Drainage works upto first diversion box 6. Production Equipment necessary for Measles vaccine production.	1. Landfill and grading of the site 2. Construction of the following buildings including Architectural, Electrical and Mechanical Works - Administration Buildings - Parking Garage - Canteen - Security Guard House 3. Architectural and Structural Works of Mechanical Building 4. Site Works - Fences and gates - Landscaping - All in-site roads and pavements 5. Lead-in Works and connection of utilities - Lead-in and connection of incoming utilities, electrical power, telephone line and city water - Drainage connection after sewage tank. Drainage works after first diversion box. 6. Furniture and Fixtures for Production Building, Mechanical Building and Animal Laboratory - Curtains and Blinds (curtain rails and boxes provided by Japanese side) - General office furniture 7. All other necessary furniture and equipment 8. Wells, water tanks extinguishing fires 9. Incinerator 10. Others - Relocation of existing furniture and equipment

It is most important to coordinate and adjust the progress of all respective trades – architectural, electrical/mechanical works and equipment installation works. All contractors should be well versed in the requirements of the specialized production facilities and adjust their works accordingly. Also there are works under Vietnamese responsibility, for which good coordination and monitoring of progress of both sides are required with the Japanese contractor. The site is still under preparation. It has been confirmed with the Vietnamese authorities that public utilities such as city water, telephone and electrical power are to be completed in the time for the completion of the Project facilities. However, meticulous discussions with relevant parties will be required to insure the completion of Project related infrastructure as scheduled and that test running and adjustment activities are not effected.

2-2-4-4 Construction Supervision

(1) Construction Supervision Plan

A Japanese consultant firm will conclude the Agreement for Consultants Services with POLIOVAC and the said consultant will prepare the tender documents for construction and equipment procurement. After assisting in tendering of the Project, upon the award of construction and equipment procurement contract(s), the consultant will commence the construction supervision services. The purpose of supervision services executed by the consultant is to oversee the construction and the procurement and installation of equipment to ensure quality and construction progress is consistent with the contents of contract documents. To secure this, the consultant as a supervisor will issue guidance, advice and coordination to the contractor(s) regarding quality of works and progress of construction schedule. The consultant services includes the following items:

1) Assistance in tendering of construction and equipment procurement contract(s).

This item includes the preparation of tender documents necessary to select the contractor(s) for construction and equipment procurement and also the issuance of Tender Notice, acceptance of tender applications, pre-qualification of applicants, holding of explanatory meeting for tendering, distributes tender documents and accepts and evaluates tenders. Furthermore, the consultant will lend guidance and assistance for the contract signing procedure between the successful tenderer and POLIOVAC.

2) Issuing guidance, advice and coordination to contractor(s)

The consultant will examine the construction schedule, construction plans, procurement plan of construction materials and procurement & installation plans for equipment submitted by the contractor and issue guidance, advice and provide coordination.

3) Inspection and approval of working drawings and shopdrawings prepared by contractor(s), subcontractors and suppliers.

The consultant will inspect the work drawings, shop drawings and other construction documents and provide approval along with any necessary guidance.

4) Confirmation and approval for construction materials and production equipment

The consultant will inspect the proposed construction materials and equipment for conformity with the contract documents and issue approval of their use and procurement.

5) Inspections of works.

The consultant will conduct factory inspections of construction materials and procured equipment, attend construction tests and conduct tests to measure quality and performance compliance as necessary.

6) Progress report of construction and installation.

The consultant will ascertain the status of construction schedule and site conditions and report on the construction progress to concerned agencies of both countries.

7) Confirmation and verification of trial run results and final inspection upon completion.

The consultant will conduct completion inspections for buildings, ancillary systems and equipment procurement and conduct trial runs of the equipment to confirm that the completed facilities meet the performances stipulated in the contract documents and submit a completion inspection report to POLIOVAC.

8) Construction Supervision Organization

The consultant will assign one resident engineer to perform the activities described above. In addition, the consultant will send experts in relevant fields to the site, as necessary, following the progress of the construction works. The experts will conduct discussions, inspections, guidance and coordination necessary for project implementation. Furthermore, the consultant will assign experts in Japan to establish a back up system. Finally the consultant will report to the concerned agencies of the Government of Japan concerning relevant matters on the progress of the Project, payment procedures, completion and handing over and other matters.

A draft Supervision Organization is shown in the following figure.

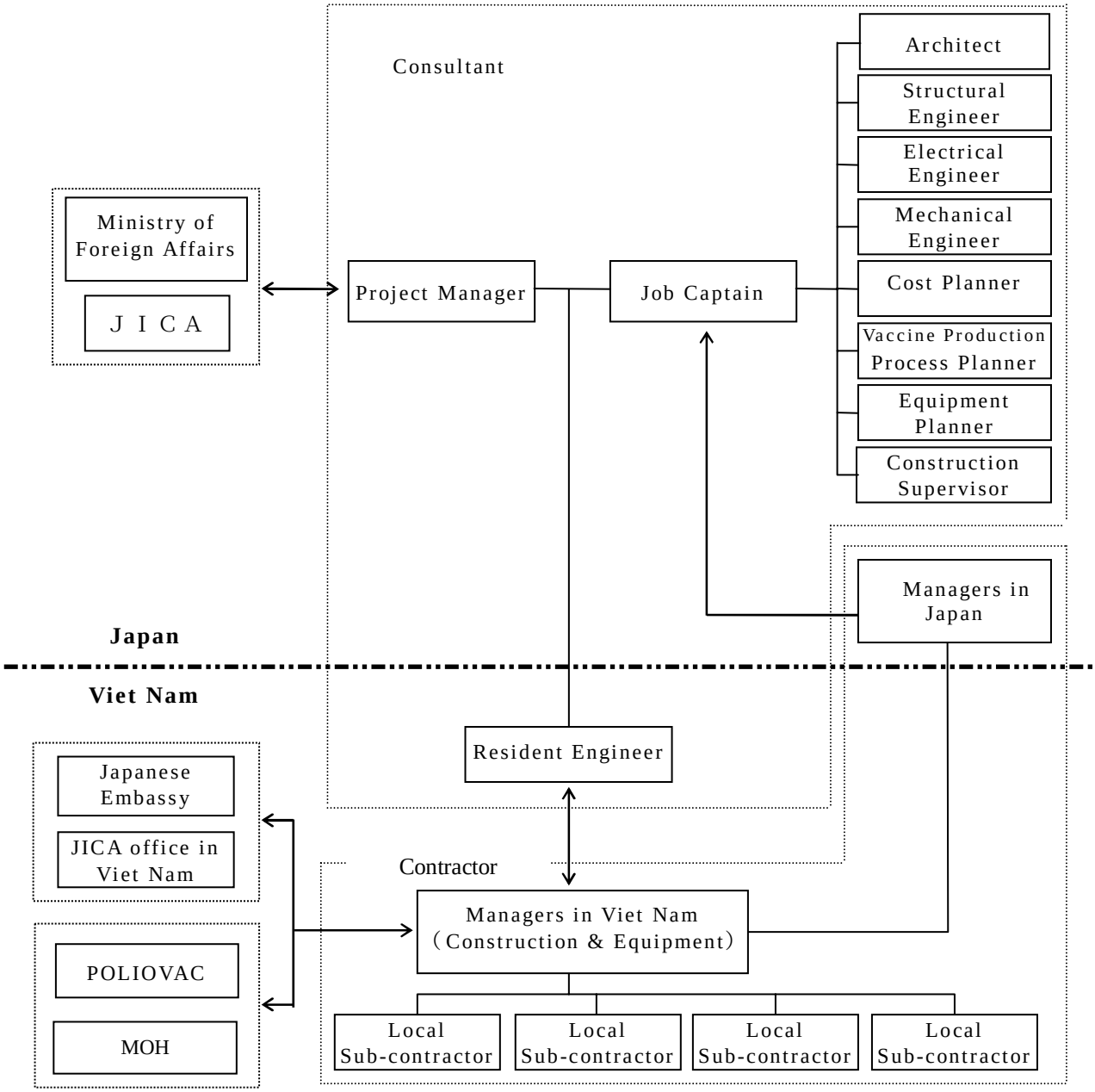


Figure 2-14 Construction Supervision Organization

2-2-4-5 Quality Control Plan

(1) Materials

1) Cement

Ordinary Portland cement will be used.

2) Aggregate

・Fine Aggregate

Crushed stones or sand will be used as fine aggregate. When using sea sand, the chloride ion content must be below the standard set in JASS 5.

・Coarse Aggregate

River gravel or crushed stones will be used as coarse aggregate. The maximum size of coarse aggregate will be 20mm.

・Admixture

Standard AE water-reducing agent or equivalent will be used.

・Water

Water from city water mains or equivalent will be used. Recycled water will not be used in general.

(2) Mix Proportion Plan

・The required quality is for the strength of the structural concrete after 28 days to be equal to or above design standard strength. To achieve the required quality, the ratio of components will be determined by trial mixings, with reference to the following.

① Water Content

② AE water-reducing agent will be used when appropriate to ensure a good workability with water content of 185kg/m^3 or less.

③ Cement Content

The cement content should be a minimum of 270kg/m^3 and a maximum water/cement ratio of 65%, with the water/cement ratio as small as possible.

④ Air Content

Air content of 4.5% will be the standard.

⑤ Chloride Content

The chloride content, measured as the chloride ion content, should be 0.3kg/m^3 or less, taking into account the volume of chemical admixture.

・ Establishment of Mix Proportion Strength

In principle, the mix proportion strength will be set following JASS 5. The mix proportion strength is expressed as the compressive strength of normally cured samples after 28 days. The larger of the values calculated from the equations given below is regarded as the mix proportion strength of the sample.

$$F = Fc + T + 1.73\,\sigma$$

$$F = 0.85\,(Fc + T) + 3\,\sigma$$

where

F: Mix proportion strength of concrete (N/mm^2)

Fc: Standard design strength of concrete (N/mm^2)

σ: Standard deviation of strength of concrete used (N/mm^2)

T: Correction factor for estimated average temperature for the 28 day period following concrete placement (N/mm^2)

(3) Receipt of Concrete at the Site

When using ready-mixed concrete from a factory, it must be confirmed that the following points are conformed to.

1) The factory must have permanently-stationed engineers who have a thorough knowledge of concrete techniques.
2) The factory must be located close enough for it to take less than 120 minutes from the start of mixing till completion of casting when the temperature is below 25℃, or less than 90 minutes when the temperature is above 25℃.
3) The product must be of the quality required in the Project documents.

(4) Quality Control for Concrete

1) System of Quality Control for concrete work

Quality control for concrete will conform to the procedures shown in the table below.

Table 2-16 Quality Control for Concrete Works

Process	Test Item	Control Items	Record Method
Supervision of concrete placement	Quality of fresh concrete	Slump test, Flow test, Air content, Concrete temperature, Chloride content	Concrete Casting Control Table
Supervision of sample curing	Ambient temperature	Average temperature	Temperature Control Table
	Temperature of curing water	Average water temperature	Temperature Control Table
Control of strength	Confirmation of strength at removal of formwork	Equal to or greater than required strength obtained from calculation	Strength Control Table
	Judgement of strength of structural concrete	Equal to or greater than required strength obtained from calculation	Strength Control Table

2) Test for Quality Control of Fresh Concrete

Pre-casting inspection and confirmation will be carried out for the items given in the table below.

Table 2-17 Quality Control Tests for Fresh Concrete

Test Item	Test Method	Timing / Frequency	Criterion of Judgement
Slump Value	JIS A 1101 equivalent	Each batch	Tolerance of ±2.5cm
Slump Flow Value	JASS 5 T-503 equivalent		Tolerance of ±7.5cm
Air Content	JIS A 1128 equivalent		Tolerance of ±1.5 %
Temperature of concrete	Measurement by thermometer		35℃ or below
Segregation	Visual Inspection		No segregation visible
Chloride Content	JASS 5 T-502 equivalent	First batch each Day	Chloride ion content of 0.3kg/m^3 or less

3) Control of Concrete Strength

Sampling methods and methods of curing used to test the strength of concrete are summarized in the table below.

Table 2-18 Control of Concrete Strength

Purpose of Test		Confirmation of Strength of Structural Concrete	Confirmation of Strength at Removal of Formwork
Sampling	Sampling Method	JASS 5 T603 Equivalent, Samples Taken on Site	JASS 5 T603 Equivalent, Samples Taken on Site
	Frequency of Test	Every casting day and every 100m^3 cast	Every casting day Normally twice a day, three samples each time
	Number of samples	Three each time	Three each time
	Form of sample	15cm Cylinder	15cm Cylinder
Curing of Samples	Method of curing	On site curing in water	In sealed condition on site
	Place of curing	On Site	On Site
Strength Test	Place of Test	At an official institution or on Site	At an official institution or on Site
	Witness to test	Consultant Supervisor	Consultant Supervisor

- Judgement and Confirmation of Concrete Strength

a) Judgement Standard for strength of structural concrete

$\overline{X_{28}} \geqq F_C + 3$ (N/mm^2)

b) Judgement Standard for strength at removal of formwork.

$\overline{X} \geqq F_N$ (N/mm^2)

where, $\overline{X_{28}}$: average crush strength of three samples at 28 days (N/mm^2)

$\overline{X}$: average crush strength of three sealed-cured samples (N/mm^2)

F_C: design strength of concrete

F_N: required strength for formwork removal according to JASS 5

2-2-4-6 Procurement Plan

(1) Procurement of Construction Materials

The Project facilities are for the production of measles vaccine. In order to meet the objective of the facilities, special consideration is given to sustain the performance of special equipment and materials and ease of maintenance, operations and cleaning. Durable materials and equipment are chosen based on the above criteria. The policy for procurement is summarized below.

1) Local Procurement

In order to allow ease of repairs, maintenance and cleaning after completion of the facilities, locally available materials are selected as much as possible. Confirmation is made of the quality and availability of sufficient volume on the local market for the selected items. Imported items freely available on the local market (items not requiring import procedures), are considered to be local materials and equipment.

2) Imported Procurement

Materials and equipment not available on the local market, items for which locally available products do not have the required quality and items with insufficient stability in supply are to be procured and imported from Japan or third countries. In this case, the contractor must maintain close contact with POLIOVAC concerning the relevant procedures for tax exemption and ensure their smooth implementation.

When the combined cost of procurement and transportation costs from Japan or a third country is less than for a comparable product available in Viet Nam, the item will also be procured by importation.

3) Inland Transportation

Items to procured from Japan or third countries are to be shipped by sea to Haiphong Port. From the port the items will be shipped overland in commercial trucks. Although the project site is not located within the Hanoi City limits, heavy trucks over 3.5 tons are banned from entering Hanoi City area from 6:00 in the morning to 22:00 at night, requiring detour of trucks around Hanoi during daytime.

Some materials and equipment have risk of reduced performance when exposed to shocks, humidity or high temperatures. These items will require special protective packaging to withstand transportation.

4) Procurement Plan

The allocation of procurement from local sources, third countries and Japan for main items are summarized in Table 2-19 below. Most main materials for electrical and mechanical building systems will be imported from Japan or third countries, with only minor exceptions.

Table 2- 19 Summary of Procurement of Major Construction Materials

Building Works

Work Item	Material	Local	Third Country	Japan	Notes
Reinforced Concrete Works	Portland Cement	○			Procured locally
	Fine Aggregate	○			Procured locally
	Coarse Aggregate	○			Procured locally
	Deformed Steel Bars	○	○		Material compliant with BS or JIS will be selected
	Formwork	○			Imported material
Structural Steel Work	Structural Steel	○	○	○	Material compliant with BS or JIS will be selected
Masonry	Bricks	○			Procured locally
	Concrete Blocks	○			Procured locally
Waterproofing Works	Asphalt Waterproofing	○	○	○	Imported material with local contractor responsibility
	Waterproof Coating		○	○	Imported material with local contractor responsibility
Plastering Works	Cement Mortar	○	○		Cement material is imported
Tile Works	Porcelain Tile	○	○		
	Ceramic Tile	○	○		
Stone Works	Stone	○	○		
	Terrazzo	○	○		
Wood Works	Wood	○	○		
	Laminated Wood	○	○		
	Plywood	○	○		
Metal Works	Light Weight Steel Ceiling Hangers		○		
	Expansion Joints		○		
	Decorative Metal Works and Handrails	○	○	○	
	Roof Drains		○	○	
	Curtain Rails	○	○		
Wooden Doors	Doors and Frames	○	○		
Metal Doors and Windows	Aluminum Windows		○		
	Steel Doors		○		
	Stainless Steel Doors		○		
	Door & Window Hardware		○		
Glass Works	Plate Glass	○	○		
	Glass Blocks	○	○		
Painting Works	Exterior Paints	○	○		
	Interior Paints	○	○		
Interior Finish Works	Gypsum Board	○	○		
	Acoustic Ceiling Panels	○	○		
	Rock Wool	○	○		
	Hardboard	○	○		

Work Item	Material	Local	Third Country	Japan	Notes
Miscellaneous Works	Sinks		○		
	Hanging Cabinets		○		
	Signage	○	○	○	
Exterior Works	Pavement (Asphalt)	○			
	Interlocking Blocks	○			
	Curb Blocks	○			
	Flag Poles		○		
	Gratings		○		

Mechanical and Electrical System Works

Work Item	Material	Local	Third Country	Japan	Notes
Mechanical System Works	Air Cooled Chiller			○	No locally manufactured products available
	Steam Boiler		○		
	Air Conditioner		○		
	Ventilation Fans		○		
	Exhaust & Intake Grates		○		
	Filters		○		
	Ducting Materials		○		
	Pumps		○		
	Septic Tanks			○	No locally manufactured products available
	Sanitary Fixtures		○		
	Steel Piping		○		
	PVC Piping		○		
	Insulation Materials		○		
	Fire Extinguishers		○		
	Automatic Control Equipment			○	
Electrical System Works	Transformers		○		
	Generators		○		
	Distribution Boards		○		
	Electrical Piping		○		
	Electrical Boxes		○		
	Electrical Wiring		○		
	Cables		○	○	Fire-resistant cabling will be procured from Japan
	Lighting Fixtures		○	○	Clean Room lights, Sterilizing lights will be procured in Japan
	Conduits		○		
	Telephone Handsets		○		
	Paging Systems			○	No locally manufactured products available
	Automatic Fire Alarm Systems		○		
	Interphone Systems			○	No locally manufactured products available
	Battery Clocks			○	No locally manufactured products available
	Lightning Conductors		○		
Elevator Systems	Elevators	○	○		

(2) Production Equipment Procurement

The present maintenance conditions of production equipment (procured mainly under Japanese assistance) at POLIOVAC are generally acceptable. However, the equipment to be procured by the Project requires routine maintenance to sustain their specified quality and stable product supply. Routine maintenance and parts replacement requires technical staff with expert knowledge. It is preferable that POLIOVAC can employ the requisite personnel on its own, but in case this proves infeasible, it will be necessary to choose from manufacturers (including manufacturers agents) who have the requisite engineers stationed in Viet Nam.

If the procurement of imported items is restricted to Japan, fair competitive tendering (less than three eligible manufacturers, et cetera) cannot be assured for some items. In such cases or when local or Japanese manufacturers cannot provide after care support, due to lack of agents with qualified personnel, the items will be procured from third countries.

The following Table 2-20 summarizes the procurement plan main equipment components.

Table 2-20 Summary of Equipment Procurement

Name of Equipment	Local	Japan	Third Country	Notes
Water Supply Unit, Rubber stopper washer, Filling Machine, Freeze dryer		○		
Vial washing machine, Dry sterilizing/cooling tunnel, Capping machine, Tray loading Machine, Labeling machine			○	Local & Japanese manufacturers lack agents making after care support difficult
Autoclave A , B			○	Competitive tendering cannot be assured
Laminar flow unit, CO2 incubator, Rotator for microtiter plate, pH meter, Safety cabinet, Dry oven		○		
Incubator, Centrifuge, Endotoxin analyzer, Autoclave for Lab, Thermo-hygrometer, Moisture content apparatus		○		
Vacuum drying oven, Integrity test machine, Dryer, ELISA reader, Refrigerator (4℃), Freezer (-30℃), Deep Freezer (-70℃)		○		
Bio guard clean bench, Cell counter (manual), Microscope, Fluorescent type microscope, Inverted microscope, Water bath A, Hand washer		○		
Electric Dispenser, Compressor, Pump tubing, Vacuum pump, Osmometer, Stirrer, Stand, Icemaker		○		
Test tube mixer, Ultrasonic washer, Descicator, Electric balance, Table for electric balance, Draft chambers, Pipet washer		○		
Weight for calibration, Plate washer	○			
Pooling tank, Egg incubator, Incubator for egg stock, Hot plate, Formalin perfusion system (dispersion), Formalin perfusion system (decomposition)		○		
Magnetic stirrer, Hand alcohol spray, Particle counter (for Air), Particle counter (for water for injection), Manual mixing device		○		
Laundry Machine, Drying Machine, Conductivity meter, Air velocity meter, Constant temperature device immersion, Disinfection tank, Sealer, Portable pump		○		
Filtration device, Pressure tank, Air sampler, Recorder		○		

2-2-4-7 Implementation Schedule

The implementation schedule of the Project after the conclusion of E/N is indicated in the following sheet. Major activities consist of consultant's detail design, tender assistance services, construction works executed by contractor and consultant's supervision services.

(1) Detail Design Stage

POLIOVAC and a Japanese consultant will enter into a consultancy agreement for the detail design (including preparation of tender documents) of the Project, which will be verified by the Government of Japan. After verification, the consultant will develop the tender documents based on this Basic Design Report following discussions with POLIOVAC and obtain POLIOVAC's approval of the tender documents.

The duration of the detail design stage is estimated to be 8months.

(2) Tendering Stage

The period necessary to complete tender is estimated to be 4 months.

(3) Construction works and consultant's supervision services

POLIOVAC will conclude a construction contract(s) with a Japanese contractor(s)for the Project, which will be verified by the Government of Japan. Subsequent to the conclusion of the construction contract(s) and the verification by the Government of Japan, the contractor(s) will commence the construction works. Simultaneously, the consultant will begin their supervision services of construction works.

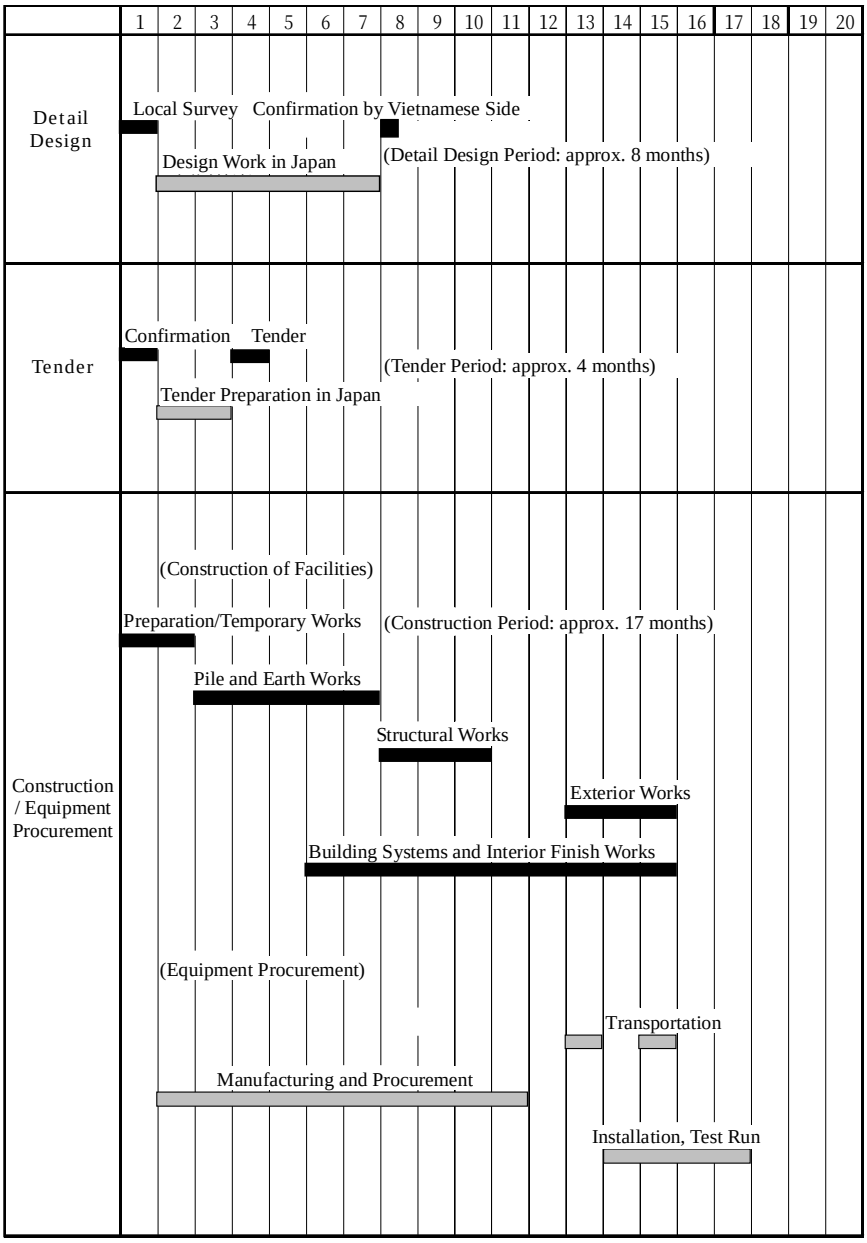
The duration of the construction period is estimated to be 17 months.

The Project will be implemented with funding from Japanese Government bonds due to its contents and scope. The Project will be implemented from fiscal year 2002 (detail design only), fiscal years 2003through 2005 (tendering and construction). The contents of the construction contracts are summarized below.

Table 2-21 Construction Items

Facility Construction	Production Building Reinforced concrete, two story structure, Floor area: 3,116m^2(1st fl. 1,591 m^2, 2nd fl. 1,525 m^2) Final product Production Zone: Final bulk composition, Vial filling, freeze drying, capping, visual inspection, packaging, labeling, delivery Bulk Production Zone: SPF eggs receiving, incubation, cell culture, virus culture, medium culture Quality Control Zone: Aseptic testing, cell testing, chemical testing Animal Laboratory Reinforced concrete, two story structure, Floor area: 358m^2(1st fl. 292 m^2, 2nd fl. Machine room 66 m^2) Animal Testing Zone: Animal Testing rooms, washing rooms Mechanical Building (architecture and structure are to be funded by Vietnamese side) Reinforced concrete, single story structure, Floor area: 484m^2 Equipment for mechanical rooms (boilers, chillers, pumps), transformer room, generator room
Equipment Procurement	Equipment necessary for operation of the above facilities (water supply unit, rubber stopper washing, sterilization machines, vial filling machine, capping machine, autoclaves, others)

Table 2-22 Implementation Schedule



2-3 Obligations of Recipient Country

(1) Major Undertakings

The major obligations of the Vietnamese side for this Project include the following items.

1) Exemption of all taxes relating to the Project
2) The approvals and permissions needed for the building and construction work to be implemented under this Project.
3) Issuance of a Bank Arrangement (B/A) and Authorization of Payment (A/P), and the payment of commissions for the same.
4) Guarantees of prompt unloading at the port of landing, custom/duty free handling, clearing and prompt transportation within Viet Nam.
5) Assistance to Japanese nationals entering and staying in Viet Nam for the purpose of fulfilling their duties in the provision of equipment and materials and implementation of the Project in accordance with the verified contracts.
6) Exemption from customs/duties and other taxes for Japanese nationals entering and staying in Viet Nam for the purpose of fulfilling their duties in the provision of equipment and materials and implementation of the Project in accordance with the verified contracts.
7) Budgetary measures for the efficient operation and management of the facilities constructed and the equipment procured under the Grant Aid scheme.
8) The demolition of existing structures on the proposed site, and preparation of the site.
9) Installation of lead-in electrical power supply lines, water supply pipes, waste water pipes and telephone lines to the receiving points in the proposed construction site.
10) The purchase and installation of general furniture.
11) Other necessary costs incurred in the implementation the Project except those borne under the Grant Aid scheme.

Vietnamese side is obligated to construct the following facilities in concert with the main facilities. The construction schedule is shown below.

Table 2-23 Construction Schedule of Ancillary Facilities (Vietnamese Funding)

Ancillary Facilities		1st Year									
		1	2	3	4	5	6	7	8	9	10
Guard House Fl Area: 9m^2 Single story	Construction: 1.2 m.										
Administration B. Fl Area: 554m^2 Two story	Construction: 10.0 m.										
Canteen Fl Area: 70m^2 Single story	Construction: 5.0 m.										
Parking Garage Fl Area: 84m^2 Single story	Construction: 2.5 m.										
Bicycle Parking Fl Area: 104m^2 Single story	Construction: 3.0 m.										

(2) Cost Estimate for the Scope of Vietnamese Works

1) Capital Investment of Vietnamese Side

The Project will be completed as a whole with the input from Vietnamese side for the items mentioned previously. The cost of the items are estimated from information obtained during the Basic Design Study and are summarized in the table below:

Table 2-24 Capital Investment of Vietnamese Side (Total)

		Total Construction Cost (US$)
Hard Components (facility construction & equipment procurement)	(1)Security guard house, Administration building, Canteen, Parking garage, Mechanical building structure	585,000
	(2)Site works	88,300
	(3)Wells, Incinerator	40,000
	(4)Equipment	188,300
Sub-total		901,600
Soft Components	(5)Technology transfer & training	1,000,000
Total		1,901,600

Conditions of estimation

1) Date of estimation: October 2002
2) Exchange rate: 1 US$ = 124.25 Japanese Yen
   I VND = 0.0079 Japanese Yen
3) Construction period: Same as described in Clause 2-2-4-8 Project Implementation

2-4 Project Operation Plan

(1) Personnel Plan

1) Personnel Organization

WHO-GMP has staffing requirements summarized below.

1. The heads of production and quality control should be independent of each other.
2. All production processes must be conducted under the supervision of clearly designated responsible personnel.
3. All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training.

Under the above considerations, personnel organization planning was carried out. The results are summarized in Table 2-16. The new organization will have 63 total staff, of which 43 will be transferred from POLIOVAC and 20 newly hired.

Table 2-25 Staffing List for the Project Facilities

Name of departments	Manager	Chief Engineer	Workers	Total	Personnel Costs (US$)	
					Unit rate	Total
(1) General Manager	*1			1	4,800	4,800
(2) Medium Adjustment/Washing	*1	*2	*4	7	3,600	25,1200
(3) Production Zone	*1			1	4,800	4,800
1) Bulk Production		*3	*4+2	9	3,600	32,400
2) Final product						
- Vial filling & Freeze-drying		*3	*2+2	7	3,600	25,200
- Labeling & Packing		*1	*3+2	6	3,600	21,600
(3) Quality Control	*1			1	4,800	4,800
1) Microbiological test		*2	*1+2	5	3,600	18,000
2) Animal test		*1	*2	3	3,600	10,800
3) Chemical test		*1	*2	3	3,600	10,800
4) GMP & Validation		*1	+3	4	3,600	14,400
5) Animal Breeding		*1	*1	2	3,600	7,200
(4) Administration						
1) Management		*1	+2	3	2,400	7,200
2) Accounting		*1	+1	2	2,400	4,800
3) Production Plan & Procurement		*1	+1	2	2,400	4,800
4) Maintenance (Building/Equipment)	*1	*1	+2	4	3,600	14,400
5) Security		+1	+2	3	1,200	3,600
Total	5	20	19 (+19)	63		214,800

Note: * indicates transfer from POLIOVAC, + indicates newly hired staff (Source: POLIOVAC 2002 March)

As summarized above, the total personnel costs are estimated to be US$214,800 annually.

(2) Maintenance and Management Plan

1) Facilities

In order to ensure smooth conduction of maintenance and management of the Project facilities, especially the Production Building and Animal Laboratory, the maintenance of the interior clean environment by the air conditioning system is essential. It is necessary to maintain positive pressure differentials between clean rooms in the facilities and surrounding areas and to also provide a filtering system for supply air that is capable of removing fine particles. These filters will become clogged through use and require periodical cleaning and replacement.

The above maintenance activity is also important in complying with WHO-GMP. POLIOVAC personnel are well aware of the necessity of maintenance and are planning training activities to develop the technical competence of the maintenance personnel.

2) Equipment

Some of the equipment are very complicated, such as the freeze drying machine. These machines differ from those used in poliomyelitis vaccine production. POLIOVAC is planning training activities to enhance the technical competence of the maintenance personnel for the above new machines.

One present POLIOVAC personnel, who will become the responsible personnel for technical management and guidance, will be selected to undertake training in Japan at the Kitasato Institute. Another POLIOVAC personnel, who become the responsible personnel for production, will receive training in Viet Nam. Two personnel to be newly hired will receive training in Viet Nam to become the personnel responsible for general maintenance and management, for a total maintenance and management organization composed of 4 staff.

Further training of technical personnel in a similar manner will be required on a continuous basis in the future.

(3) Operation and Maintenance Costs

1) Estimated costs for maintenance and management

The Project facilities will undergo technology transfer for 2 years after completion, which is defined as the bulk production period. In the bulk production period, bulk (the material for commencing vaccine production during initial phase) will be

imported and 0.5 million doses of measles vaccine is planned to be produced. After the bulk production period, it is planned to eliminate the dependence on imported bulk by producing the bulk within the project facilities. With the fully achieved technology transfer, the Project facilities will eventually attain the full production of 7.5 million doses of measles vaccine annually (full production period).

The maintenance and management costs for the bulk production period and full production period have estimated as shown in Table 2-27. The costs for the bulk production period have been estimated to be half the full production period figures.

Table 2-26 Operation & Maintenance Costs

Unit: VND (Vietnamese Don)

Item	Annual Costs for Bulk Production Period	Annual Costs for Full Production Period	Note
① Electricity	1,386,000,000	2,772,000,000	
② Telephone	65,472,000	130,944,000	
③ Medical Gas	3,000,000	6,000,000	
④ Water Supply	47,250,000	94,500,000	
⑤ Propane Gas	28,980,000	57,960,000	
⑥ Fuel for Generator	26,794,800	53,589,600	
⑦ Fuel for Boilers	930,375,000	1,860,750,000	
⑧ Filter Change	768,500,000	1,537,000,000	
⑨ Building Maintenance	533,520,000	1,067,040,000	
⑩ Equipment Maintenance	409,525,000	819,050,000	
Total	4,199,416,800	8,398,833,600	
(US$)	279,961	559,922	US$1 = 15,000VND

① Electricity ·····2,772,000,000 VND/year

According to the supply regulations of Hanoi Power Corporations (HPC), the following charge is applicable to the facilities.

Fixed base charge: 0 VND/kW・month (No base price applicable)

Unit price for use: 770 VND/kWh

The annual cost is estimated as follows:

300,000 kWh/month×12 months×770 VND/kWh = 2,772,000,000 VND/year

② Telephone ·····130,944,000 VND/year

Telephone cost is estimated on the assumption of following monthly use.

Intracity calls	264,000 VND/month	× 12 months =	3,168,000 VND/year
Long distance calls	3,960,000 VND/month	× 12 months =	47,520,000 VND/year
International calls	6,688,000 VND/month	× 12 months =	80,256,000 VND/year
		Subtotal	130,944,000 VND/year

③ Medical Gas ·····6,000,000 VND/year

Only medical gas to be used in the Project is nitrogen gas for freeze-dryer machine. The annual use is estimated to be approximately 12 Nm^3. The unit cost for nitrogen gas is 500,000 VND/ Nm^3 and the annual cost can be calculated as below.

Annual cost for nitrogen gas 12 Nm^3×500,000 VND/ Nm^3 = 6,000,000 VND/year.

④ Water Supply·····94,500,000 VND/year

The daily amount of water consumption is estimated at 90 m^3/day. The water cost is calculated on the basis of currently applicable water charges.

Monthly water consumption 90 m^3/day × 25 days/month = 2,250 m^3/month

Water charges 3,500 VND/m^3 × 2,250 m^3/month = 7,875,000 VND/month

Annual water cost 7,875,000 VND/month ×12 months/year = 94,500,000 VND/year

⑤ Propane Gas ·····57,960,000 VND/year

Propane gas is used mainly for laboratory tests. Daily consumption is assumed to be 600 kg/month. Current price of propane gas is around 7,000 VND/kg and the total costs are estimated as follows.

Monthly propane gas cost

690 kg/month × 7,000 VND/kg = 4,830,000 VND/month

Annual propane gas cost

4,830,000 VND/month × 12 months/year = 57,960,000 VND/year

⑥ Fuel for Generators·····59,544,000 VND/year

Estimated frequency and duration of power failure is once in a month and 6 hours per one failure. Adding the required periodical test run, the cost is calculated with current diesel oil price at 4,135 VND/liter.

Annual consumption 14,400 ℓ/year × 4,135 VND/ℓ = 59,544,000 VND/year

⑦ Fuel for Boilers·····1,860,750,000 VND/year

Boilers are used as heat source for equipment (autoclaves, production water supply) and reheating of air-conditioning system. Fuel consumption per hour is

approximately 300 liters/h and running time is assumed to be 5 hours per day. Therefore, estimated daily consumption is 1,500 liters. Diesel oil price is 4,135 VND/liter.

Monthly consumption 1,500 ℓ/day × 25 days/month = 37,500 ℓ/month
Fuel cost per month 4,135 VND/ℓ × 37,500 ℓ/month = 155,062,500 VND/month
Therefore, annual fuel costs are
155,062,500 VND/month × 12 months/year =1,860,750,000 VND/year

⑧ Filter Change Cost ·····approximately 1,537,000,000 VND/year

HEPA and mid-performance filters are provided for air conditioning systems in Production Building and Animal Laboratory. Activated carbon filters for deodorizing are provided for Exhaust System in Animal Laboratory. The cost is estimated on the assumption that HEPA filters are to be replaced once every other year (once a year for Animal Laboratory) and mid-performance filters and deodorant filters twice a year.

Animal Laboratory

HEPA filter A: 14 Nos.×1times/year×7,500,000 VND/ No. = 105,000,000VND/Year
HEPA filter B: 17 Nos.×1times/year×11,200,000 VND/ No. = 190,400,000VND/Year
Mid-performance filter: 10 Nos.×2 times/year×2,700,000 VND/ No. = 54,000,000VND/Year
Deodorant filter: 8 Nos.×2 times/year×11,000,000 VND/ No. = 88,000,000VND/Year
Total 525,400,000VND/Year

Production Buiding

HEPA filter B: 121 Nos.×0.5times/year×11,200,000 VND/ No. = 677,600,000VND/Year
HEPA filter C: 13 Nos.×0.5times/year×14,000,000 VND/ No. = 91,000,000VND/Year
Mid-performance filter: 45Nos.×2 times/year×2,700,000 VND/ No.= 243,000,000VND/Year
Total 1,011,600,000VND/Year
Total annual cost for filter replacement 1,537,000,000VND/Year

⑨ Building Maintenance Cost·····1,067,040,000 VND/year

One of the design objectives for the Project is to achieve low cost maintenance by selecting durable and easily maintained materials for interiors and exteriors of the buildings. The following maintenance cost is estimated from adjusted Japanese statistical data, 273,600 VND/month/m3×12 months×3,900m^2 per year including repair works for interior and exterior finishing, asphalt waterproofing of buildings and spare parts costs for electrical/plumbing/air-conditioning maintenance.

⑩ Annual Maintenance Cost for Major Items of Production Equipment

Annual maintenance cost for major items of equipment is summarized in the following table.

Table 2-27 Annual Maintenance Cost of Major Equipment Items

Items of equipment	Quantity	Maintenance cost per unit/year (VND)	Annual maintenance cost for each equipment category (VND)	Remarks
Autoclave	5	19,045,000	95,225,000	Door gaskets, Diaphragm valve, HEPA filters, Record paper,
Freeze-dryer	1	192,400,000	192,400,000	Gaskets, HEPA filters, Record paper, Vacuum pump oil, Nitrogen gas
Water purification system for production	1	198,860,000	198,860,000	Filters, RO membrane, Ion exchange resinous polymer, Record paper
Laminar flow unit	6	19,300,000	115,800,000	HEPA filters, Curtains, etc.
Clean bench	6	2,250,000	13,500,000	HEPA filters, etc.
Safety cabinet	2	1,430,000	2,860,000	HEPA filters, etc.
Complete Vial Line	1	200,405,000	200,405,000	Filters, Gaskets, Needles, etc.
		Total	819,050,000	

2) Operational Cost of Measles Vaccine Production

The production cost of measles vaccine is estimated as shown in Table 2-29. The production cost of measles vaccine during bulk production period is estimated to be approximately 0.89million US$ annually, US$ 1.88 million for the first year of the full production period and US$ 1.52 million for following years.

Table 2-28 Net Production Cost of Measles Vaccine in the New Facility

(Unit: US$)

		Bulk 1	Bulk 2	Full Production (First Year*)	Full Production (Subsequent Years*)
	Production Volume (million doses)	0.50	0.50	7.50	7.50
	Items				
(1) Material Costs		197,515	197,515	411,075	411,075
	Chemicals, medium materials (for Production)	16,940	16,940	242,000	242,000
	Chemicals, medium materials (for QC)	700	700	10,000	10,000
	SPF Eggs (imported from USA)	0	0	18,000	18,000
	Vial, stoppers, aluminum caps (for freeze-dried vaccine)	4,489	4,489	64,125	64,125
	Vial, stoppers, aluminum caps (for solvents)	4,279	4,279	61,125	61,125
	Packing Materials	1,108	1,108	15,825	15,825
	Bulk suspension	170,000	170,000	0	0
(2) Fuels, Electricity, Water, etc.		163,870	163,870	327,740	327,740
	Fuels	65,271	65,271	130,541	130,541
	Electricity / Telephone	95,491	95,491	190,982	190,982
	Water supply	3,109	3,109	6,217	6,217
(3) Personnel Costs		214,800	214,800	214,800	214,800
	Managers (5 persons)	21,600	21,600	21,600	21,600
	Chief engineers (20 persons)	66,000	66,000	66,000	66,000
	Common Staff (38 persons)	127,200	127,200	127,200	127,200
(4) Maintenance Costs	(for Building System / Equipment)	126,742	126,742	153,684	153,684
	Cleaning / Security	29,600	29,600	29,600	29,600
	Building maintenance	70,200	70,200	70,200	70,200
	Equipment maintenance (including pure water system)	26,942	26,942	53,884	53,884
(5) Miscellaneous		37,354	37,354	61,471	61,471
	Consumables (Reagents, HEPA Filter, Garments, etc.)	2,339	2,339	33,421	33,421
	Outsourcing fee (Consultants, validation, documentation, etc.)	35,000	35,000	28,000	28,000
	Animals for QC tests	15	15	50	50
(6) Wastages	[(1), (2) and (5)] x 33%	79,748	79,748	280,100	264,094
	Sub Total 1 : Total (1)～(6)	820,030	820,030	1,448,870	1,432,864
(7) Depreciation	Budgeted by Viet Nam Government	36,064	36,064	36,064	36,064
	US$901,600, 25 years installment.				
	Sub Total 2 : Total (1)～(7)	856,094	856,094	1,484,934	1,468,928
(8) Running Royalties	[Net Production Cost ＋ Profit] x 3%	29,535	29,535	51,230	50,678
	* Profit =(Net Production Cost ((1)～(7)) x 15%)				
(9) Seed Virus		0	0	340,000	0
	Production Cost : Total (1)-(8)	885,629	885,629	1876,164	1,519,606
	Unit Cost (Net) / dose	1.771	1.771	0.250	0.203

[Assumed Selling Price to Government]					
Assumed Profit	Net Production Cost x 15%	128,414	128,414	222,740	220,339
Assumed Sales	Net Production Cost + Assumed Profit	1,014,043	1,014,043	2,098,904	1,739,946
Assumed Price/dose	Assumed Sales/number of doses (US$)	2.285	2.285	0.310	0.261

This estimation is made on the following assumptions.

① Annual Production Volume of Measles Vaccine based on Technology Assistance Plan of Kitasato Institute

The production is planned for using imported Bulk for the initial two years and then proceeding to full production with bulk produced in the Project facilities in full production period.

Table 2-29 Annual Vaccine Production Volume by Year

	First year with imported Bulk	Second year with imported Bulk	First Year of Full Production and later
Production Volume	0.5 million doses	0.5 million doses	7.50 million doses

② Cost of Materials and Miscellaneous Materials for Vaccine Production

During the initial two year bulk production period, bulk suspension will be purchased from Kitasato Institute, at a cost of approximately US$ 0.34 per dose will be required. Approximately US$ 0.41 million will be required for the purchase of chemicals, culture medium, SPF eggs, vials and other miscellaneous materials in the first year of full production of 7.5 million doses.

③ Cost of Fuels and Utilities, and Maintenance

The operation cost for fuel, electricity and water supply are calculated as approximately 330,000 US dollars for the full production period.

④ Personnel Cost

The annual personnel cost is estimated at about 210,000 US dollars annually, based on planned personnel organization of POLIOVAC.

⑤ Royalties

The initial royalty charges of approximately US$ 0.34 million for seed measles virus (AIK-C strain) is included in the costs for initial year of full production.

⑥ Analysis of Net Production Costs

Other expenditures such as consumables, depreciation costs, and other miscellaneous costs should be included in expenditure. With such items included, annual net production cost is calculated as shown below.

Table 2-30 Estimation of Net Production Costs of Measles Vaccine

	First year	Second year	First year full production from SPF eggs	Full production subsequent years from SPF eggs
	Production with imported Bulk	Production with imported Bulk		
Net Production Cost / dose / year	US$1.771 (J¥212.52)		US$0.250 (J¥30)*	US$0.203 (J¥24.36)

Notes: The exchange rate is calculated at 1 US$ = J¥120
*: Seed virus charge (J¥40,000,000 /7.5million doses = J¥5.33/ dose (US$0.0444) is added.

Currently MOH of Viet Nam is importing measles vaccine products from foreign countries at the price around US$0.167 (J¥20) per dose. In the initial year of full production, the royalty charges for seed virus amounting about US$0.04 (J¥5) per dose is added to the net production cost and the resulting per dose cost is higher than for imported vaccine. However, WHO considers that the present price for measles vaccine has dropped too low and that the prices will rise in the near future. Furthermore, vaccine producers in developed countries are moving away from measles vaccine market with its depressed prices to the production of higher value added vaccines. Therefore, there are many reasons for measles vaccine price to rise in the future while no reasons for a reduction in price are present.

Based on the above reasoning, the costs per unit for the second year of full production is considered to compare favorably with the international market prices.

2-5 Other Relevant Issues

2-5-1 "Soft Component" Plan

(1) Contents of Technology Transfer

As results of Basic Design Studies, the Viet Nam has requested technological assistance for the following five fields.

i. Production technology regarding measles vaccine production.
ii. Quality control technology regarding measles vaccine production.
iii. GMP Technology.
iv. Technical knowledge to execute Validations.
v. Maintenance and management technology for building systems and production equipment.

Vietnamese side strongly requested the implementation of items iv and v as the "Soft Component" for the Project under the Grant Aid scheme.

(2) Relevant issues for the introduction of "Soft Components" scheme

The objectives of the Project are to construct the set of buildings and equipment for vaccine production capable of satisfying the total demand for measles vaccine and dramatically improving the supply structure of measles vaccine in Viet Nam, with POLIOVAC as the implementation agency. However, the current organization and personnel organization of POLIOVAC, the proposed operator for the completed facilities of the Project, require some development to meet the requirements. Especially, the staff organization needs considerable assistance with respect to the specialist education and training in the operation of the sophisticated equipment to be provided by the Project. It is evident that it is currently impossible to expect efficient operation, maintenance and administration of the facilities after completion. Furthermore, at present the staff also lack the necessary experience to build and procure the facilities and production equipment and conduct the quality control required of vaccine manufacturers, including Drawing Review (DR), Installation Qualification (IQ), Operational Qualification (OQ), Process Qualification (PQ) and the day to day quality control necessary for WHO-GMP certification.

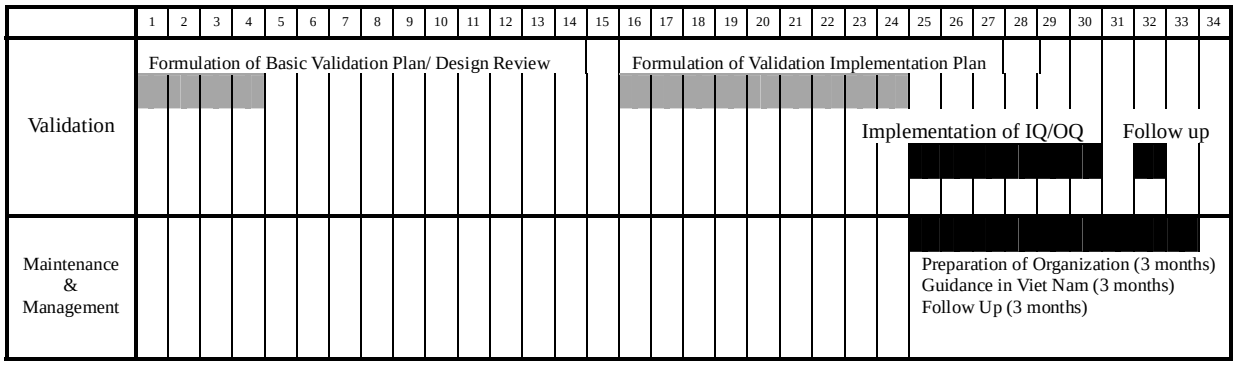
From this it is evident that the Ministry of Health and POLIOVAC will need to first employ capable and technically qualified staff required for each field concurrently with the progress of the Project. Together with the existing staff, they must be provided with

systematic education and training. In Soft Component will have the objective of providing technical assistance to POLIOVAC by receiving Viet Nam staff in Japan for training and education and also to send Japanese experts to Viet Nam to organize the maintenance system and provide assistance for validation procedures. POLIOVAC is basically responsible for the implementation of validation, but parts of the validation procedures will be carried out in partnership with the process licensor, consultant, contractor(s) and venders. Furthermore, advisory services concerning data organization and documentation will be provided by the Consultants.

(3) Implementation "Soft Component"

The Japanese side will dispatch specialist engineers in each field to Viet Nam on a periodical basis, in line with the progress of the Project to conduct training and education of the Vietnamese staff and managers. The following Soft Component implementation schedule was formulated to train and educate the operational staff to be fully capable in time for the trial runs for equipment and building systems. In order to provide more effective assistance, monitoring of the operations after completion will be conducted and appropriate advice to MOH and POLIOVAC will be provided accordingly.

Table 2-31 Soft Component Implementation Schedule



The contents of "Soft Component" are summarized below.

i. Technical Support for Improving Validation Techniques

The consultant will grasp the total process of validation and commence with assistance to POLIOVAC in the organization and required functions of the validation committee. The consultant will also advise each staff so they will understand their roles and responsibilities, while monitoring the progress of the entire process.

At an early stage of the detail design, the consultant will assist POLIOVAC in establishing the validation master plan (Basic Validation Plan), which will become the

reference for the whole process. In detail, the two POLIOVAC staff responsible for the validation process (Production Process Manager, and Quality Control Manager) will be receive training in Japan, where the consultant will provide assistance in the preparation of the Basic Validation Plan, in cooperation with the production process owner. Following this, concurrently with the progress of the Project, the protocols (The Implementation Plan for Validation), will be established in the same manner as above and the same two POLIOVAC staff will receive further training in Japan, where they will be assisted by the consultant in the preparations of the documents. Finally, when the actual validation process is commenced on site by POLIOVAC, the process owner and the consultant will send appropriate engineers to Viet Nam, who will provide assistance in validation to POLIOVAC as needed. Furthermore, appropriate assistance required for preparation and translation of validation documents will also be provided.

ii. Improvement of Maintenance & Management Technique

It will be necessary for POLIOVAC to prepare an organization framework during the construction stage of the Project, in order for the timely training and education of maintenance and management staff for the facilities and equipment. After qualified staff have been appointed to their future positions appropriate training and education through “Soft Component” services will be provided. This will assure that the same person will receive instructions for documentation, experience in the operation of the facilities and equipment along with mastering of technique.

Also, training and education of workers for the production zones will also be carried out to ensure proper use and enhanced operational capabilities of the facilities and equipment.

(4) Contents and Extent of Soft Component Activities

Table 2-32 Contents and Extent of Soft Component Activities

Procedure	Assistance Activities	Output
Validation Process	1) Advice on establishment of Validation Committee of POLIOVAC 2) Seminars and guidance to staff for furthering their understanding of the validation process 3) Assistance for DR 4) Assistance for IQ 5) Assistance for OQ 6) General assistance in preparation of various Plans and other documents 7) Receiving of POLIOVAC staff in Japan	- Organization Chart of Validation Committee - Seminar reference materials (Basics of Validation, etc.) - Validation Master Plan - Standard Procedures for Measurement and Testing of Equipment - Validation Implementation Plan - Translation of SOP documents - Various data (GMP documents)
Maintenance of Facilities and Production Equipment	1) Advice on organization, staff and improvement of capabilities 2) Introduction of Maintenance Guidelines 3) Advice on improvement of efficiency 4) Training activities of maintenance 5) Advice on system for appropriate management of inventory 6) Advice on establishing purchase procedures for spare parts. 7) Advice on systematic documentation procedures 8) Assistance in translation of technical manuals, etc. into Vietnamese.	- Equipment Maintenance Register - Equipment Repair Record Book - Repair Request Form - Facilities and equipment management system using personnel computers - Parts management system using personnel computers - Guidelines for periodical maintenance - Budget for Annual Maintenance - Long Term Maintenance Plan - Preparation of other manuals

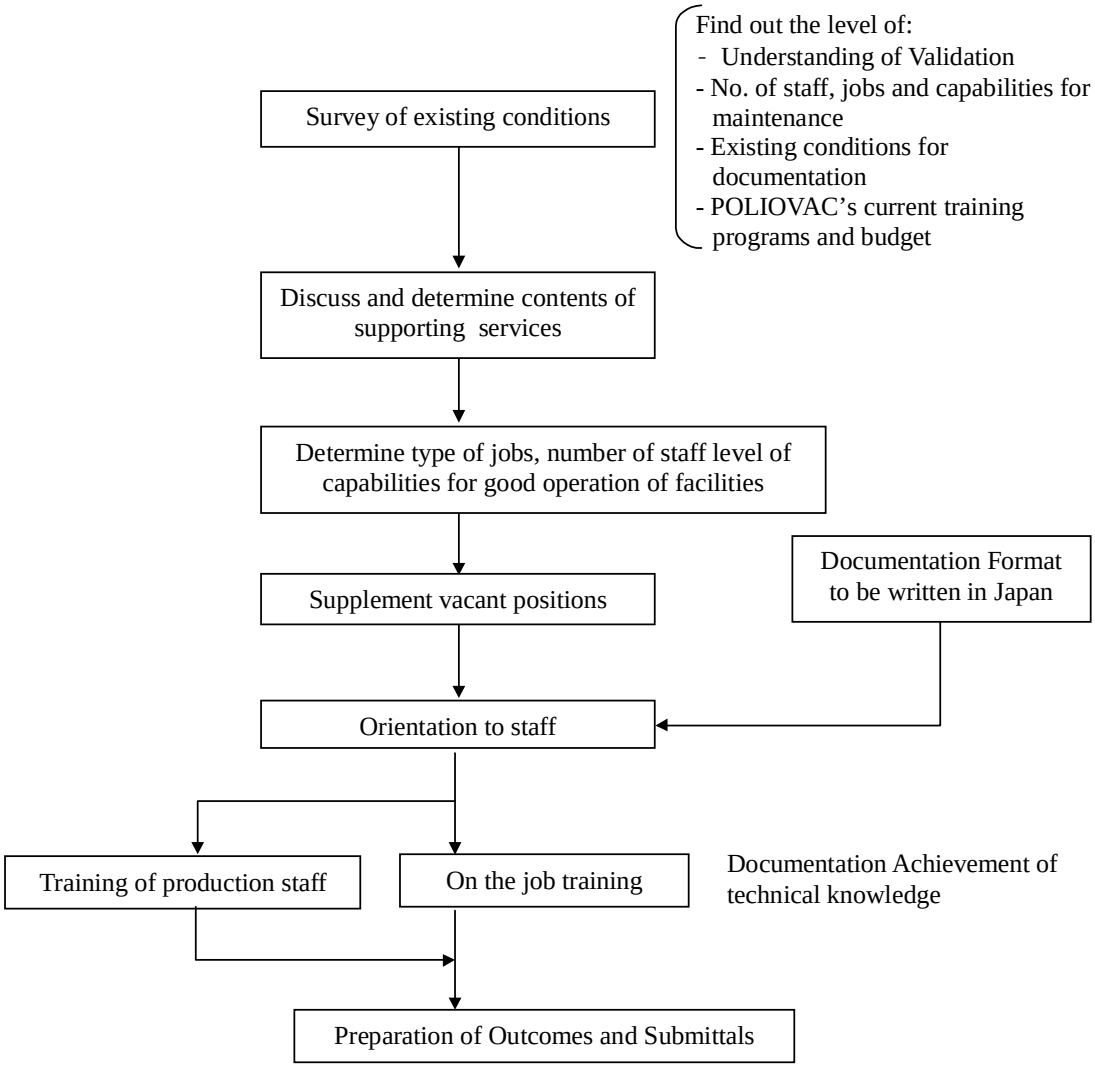


Figure 2-15 Flow Chart for Implementation of Soft Component