2-2 Current Status of the Immunization Program in Indonesia

2-2-1 Expanded Program on Immunization and Status of Its Implementation

(1) Status of Implementation

With respect to the Expanded Program on Immunization (EPI) marked as one of the objectives to be achieved by WHO between 1970 and 1990, the recommendations of the group formed largely by US AID and UNICEF stated that greater efforts should be made to provide preventive inoculation for the entire population of Indonesia for the six major communicable diseases. These six major communicable diseases are pertussis, diphtheria, tetanus, tuberculosis, polio and measles. Preventive inoculation for these six diseases is currently implemented by the doctors, nurses and medical personnel dispatched from the health centers to the POSYANDU, which are the smallest autonomous health units in the organization of the health administration. It is necessary to have effective preventive inoculation with respect to all children of one year of age or less but if inoculation is done at too early an age, the natural inoculation passed on from the mother will become ineffective. For this reason, WHO has set the standards in table 2-22 as the appropriate timing for inoculation and in Indonesia this is being carried out accordingly.

As can be seen from Fig. 2-12, there have been great increases made in REPELITA IV for preventive inoculation (1984/1989). It can also be seen from Table 2-23, that at the end of the current fiscal year (March, 1989) preventive inoculation for the six major communicable diseases had been performed for 65% of newborns (children between the ages of 3 and 11 months).

Moreover, the objective for 1990 to have an inoculation ratio of 80% has been formally set for the REPELITA V, and this is seen as an objective that can be achieved.

Table 2-21 Schedule of Immunization (EPI)

Age	Vaccination					
	BCG	DTP	Polio	Measles	DT	TT
3 - 4 month	BCG	DTP-1	Polio-1	-	-	-
4 - 5 month	-	DTP-2	Polio-2	-	-	-
5 - 6 month	-	DTP-3	Polio-3	-	-	-
9 - 11 month	-	-	-	Measles	-	-
6 - 7 year	-	-	-	-	DT (1 or 2x)	
11 - 13 year	-	-	-	-	-	TT (1 or 2x)
Pregnant woman	-	-	-	-	-	TT-2x

Remarks: - BCG: Bacillus Calmette Cuerin Vaccine
- DTP: Diphtheria-Tetanus-Pertussis vaccine
- Polio: Poliomyelitis vaccine
- DT: diphtheria-Tetanus-vaccine
- TT: Tetanus-vaccine

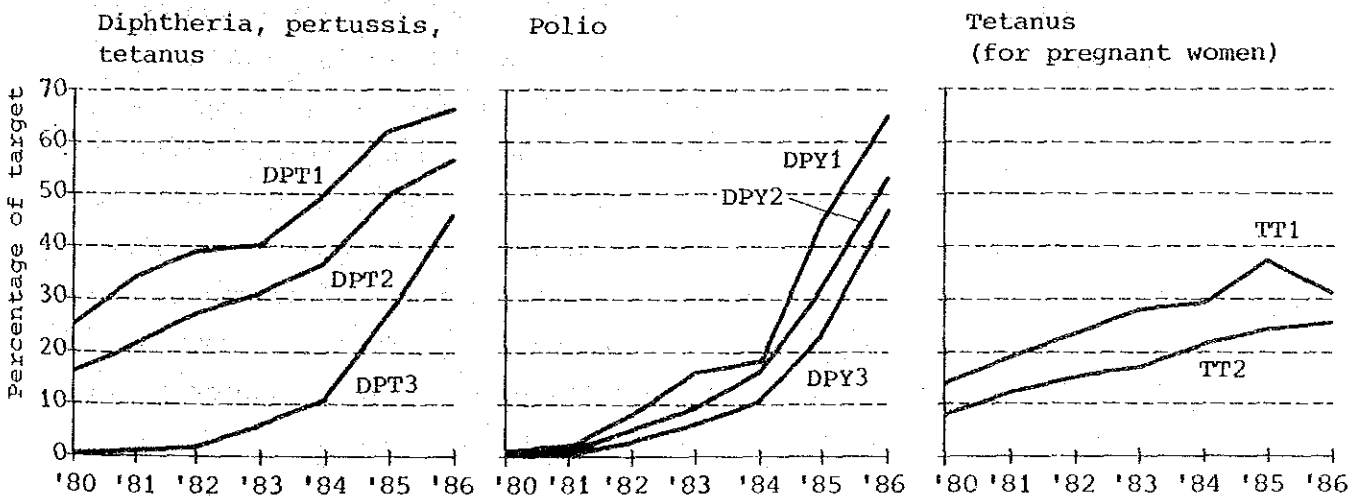

Fig. 2-12 Immunization Coverage of Multiple-Dose Vaccines, by Individual Dose 1980 - 1986

Table 2-22

Fiscal 1986/1987: Object number of persons: 5,168,536

BCG	DPT 1	DPT 2	DPT 3	OPV 1	OPV 2	OPV 3	MS
66.1%	66.0%	56.2%	46.5%	64.1%	52.7%	44.2%	45.2%

Fiscal 1987/1988: Object number of persons: 4,963,438

BCG	DPT 1	DPT 2	DPT 3	OPV 1	OPV 2	OPV 3	MS
76.7%	77.7%	68.6%	63.5%	78.0%	69.3%	64.6%	56.8%

Fiscal 1988/1989: Object number of persons: 5,070,379

BCG	DPT 1	DPT 2	DPT 3	OPV 1	OPV 2	OPV 3	MS
30.9%	31.5%	26.6%	24.6%	32.0%	27.2%	25.5%	22.3%

Because the program for 1988/1989 is currently underway, the percentage comparison with the previous year is rather low.

Table 2-23 shows the plan for 1989 onwards, along with the amounts of the related budget and implementation results for EPI from 1984 onwards. This table indicates the number of newborn babies and pregnant women who were inoculated with the polio vaccine (Each person vaccinated 3 times) and the number of pregnant women inoculated with the tetanus vaccine (Each person vaccinated twice). The amount of the budget is indicated separately from the amount for the national development budget (APBN) and the amount of loans. According to this, 1987 showed no great progress and it can be seen that most of the funding came from loans. However the inoculation ratio for newborn babies grew approximately 50% with respect to the 65% achieved for the previous year.

Fig. 2-13 and 2-14 show the number of patients admitted to hospital versus the mortality of patients for measles and polio respectively over the period form 1979 to 1984. This data was collated from about 300 hospitals in Indonesia. Also indicated is the vaccination coverage for measles and polio over the period from 1984 to 1987.

In the case of polio, the total number of patients started to decline when the vaccination coverage increased, particularly when the vaccination coverage was more than 50%. When this coverage reaches the 90% level, the number of patients is expected to drop to practically nil, as polio would have been eradicated altogether.

The situation for measles is not as clear-cut as that for polio. In the fig. 2-13, 'CAMPAK' refers to both measles and rubella in the Indonesian language. Therefore, the total number of patients may also include those of rubella, as well as those of measles. In general, the number of patients for measles also shows a tendency to decline with the increase of vaccination coverage.

It must be noted that while the death rate of polio patients in the 300 hospitals surveyed was actually nil, that for measles is high in comparison. The reason for this is that the measles patients were admitted to hospital when their illness had already reached an advanced stage, as a result of which many of them eventually died through other complications such as pneumonia etc.

It is difficult to generalise on the situation for measles and polio for the whole country. These statistics, however, is a fairly representative reflection of the patient numbers in relation to vaccination coverage, with regard to measles and polio.

Table 2-23 EPI Implementation Performance and Related Budget Items

Repelita	Years	Target		Achievement		National Budget (1,000,000 Rp)	Loan (1,000,000 Rp)
		babies	Pregnant women	Polio 3	TT2 I. II.		
No. IV 5-year plan	1984	5,657,285	6,223,014	648,754 11.5%	1,279,084 20.6%	4,043.7	5,212.7
	1985	5,143,559	5,657,909	1,241,079 24.1%	1,397,794 22.5%	7,041.8	2,217.9
	1986	5,168,536	5,685,390	2,283,369 44.2%	1,447,598 23.1%	4,976.7	4,929.7
	1987	4,963,438	5,459,782	3,204,234 64.6%	1,632,611 27.2%	1,074.9	12,392.7
	Up to second quarter 1988	5,070,379	5,577,417	1,291,911 25.5%	685,853 12.3%	9,828.5	2,158.8
No.V 5-year plan	1989	5,178,006	5,695,806			5,800	
	1990	5,283,917	5,812,342			6,200	
	1991	5,211,462	5,732,608			7,400	
	1992	5,307,343	5,838,078			8,100	
	1993	5,402,189	5,942,4408			8,700	

Polio 3: Complete immunization for babies
TT2 I.II.: Complete immunization for pregnant women

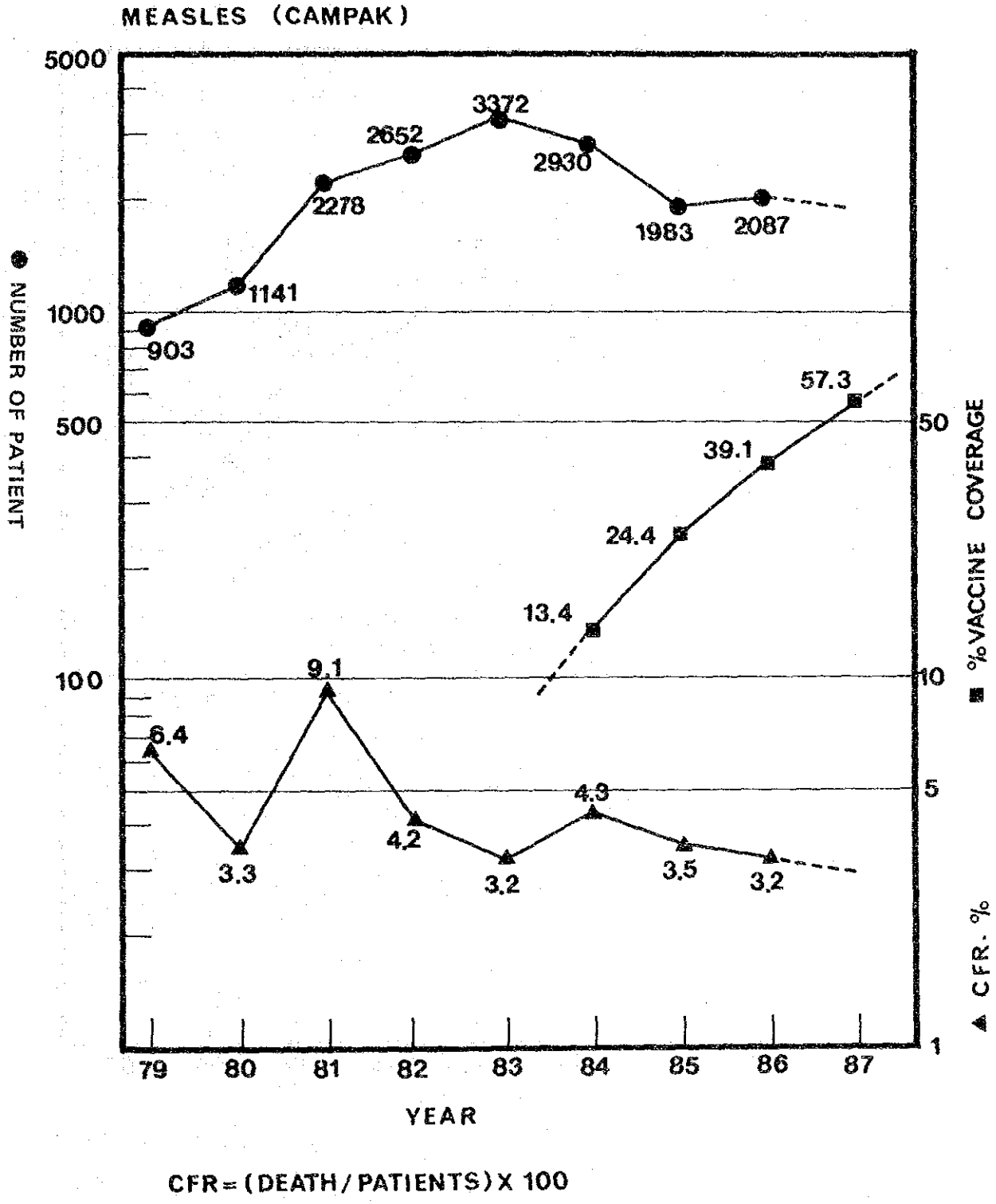

Fig. 2-13 Measles Vaccine Coverage and No. of Patients

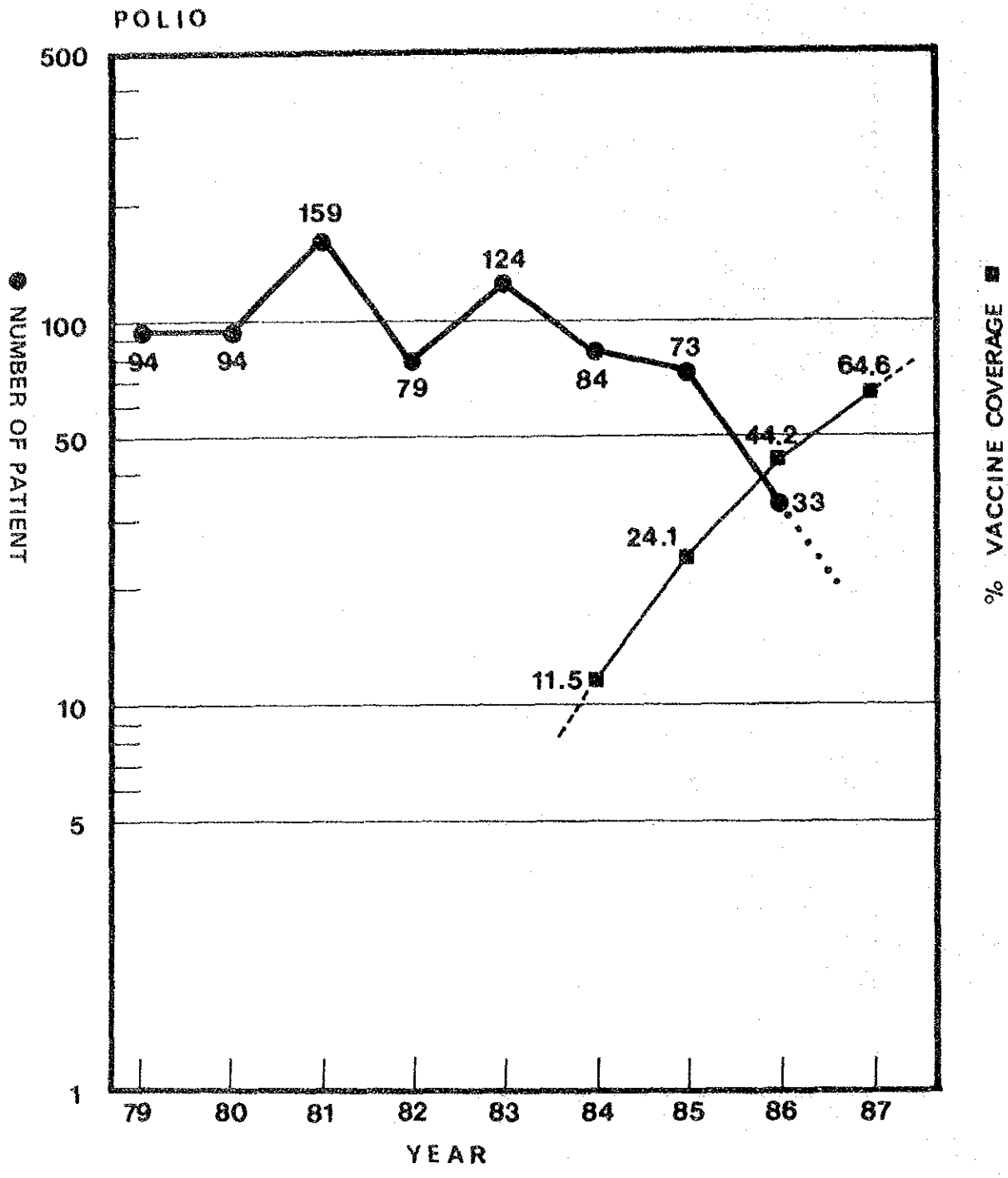

Fig. 2-14 Polio Vaccine Coverage and No. of Patients

(2) Cold Chain

Virus vaccines of weak toxicity have active viruses, as their name implies. This degree of activity is called the potency identity and the production, shipping and dosing (inoculation) or vaccines must be done at the specified low temperatures (+4°C to -20°C, etc.) so that this potency identity does not drop. For this reason, there must be a system maintained for each stage shown on the following transportation flow diagram. This system is a cold chain and this cold chain is an important factor in EPI. As shown in Fig. 2-15, vaccines are first transported to the PUSKESMAS (HC) by air, land or sea in refrigerated containers and then placed in ice-filled polystyrene cooler boxes and transported to the POSYANDU. Table 2-24 shows the contents of the cold chain facilities (5,413 health centers for 301 provinces) for each of the 27 provinces in Indonesia. According to this, the cold chain is practically complete at the state and provincial levels. UNICEF has provided each of the vaccine carriers from the provinces with one small-scale kerosene refrigerator (costing about US$700). Also, the transportation from the health centers to the POSYANDU has been considerably improved since the provision of two compact ice-boxes for each POSYANDU. However, in addition to these ice-boxes being too small for the total amount of vaccines, there is also the problem of incomplete recovery. These problems with the cold chain, particularly at the end of the chain, are a major reason for the inefficacy of the vaccines.

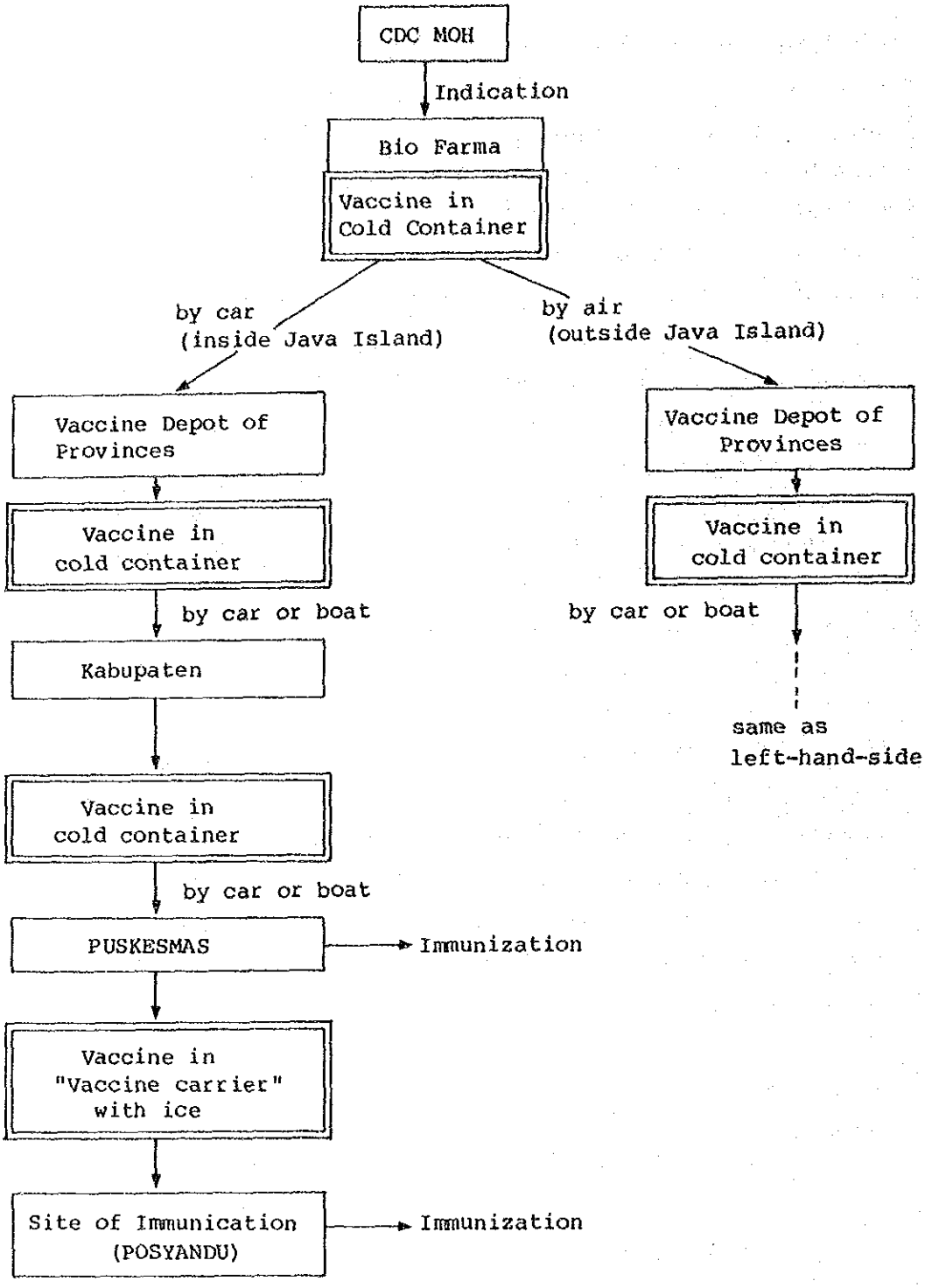

Fig. 2-15 Flow Chart of Vaccine Distribution System

Table 2-24 Cold Chain Facilities for Each Province

Province: 27 Regency: 301 Health Center: 5,413

No.	PROVINCE	VACCINE DEPOT OF PROVINCE			REGENCY		HEALTH CENTER		REMARKS
		COLD ROOM	FREEZER	MODIFIED REFRIGE.	REFRIGE.	FREEZER	REFRIGE.	FREEZER	
1.	MUSA TENGGARA BARAT	1	3	4	29	16	137	-	
2.	SUMATRA UTARA	1	5	1	25	20	264	-	
3.	SUMATRA BARAT	-	2	7	28	14	278	-	
4.	RIAU	1	2	5	15	7	145	-	
5.	JAMBI	-	4	3	8	7	90	-	
6.	SUMATRA SELATAN	1	3	1	11	10	250	-	
7.	BENGROLO	-	2	4	8	5	121	-	
8.	LAMPUNG	1	4	8	8	4	102	-	
9.	D.K.I. JAKARTA	-	4	3	15	7	268	-	
10.	JAWA BARAT	1/1	8	3	130	24	760	-	
11.	JAWA TENGAH	1/1	6	-	72	35	577	-	
12.	D.I. YOGYAKARTA	-	1	12	11	5	108	-	
13.	JAWA TIMUR	1/1	7	-	48	37	1104	-	
14.	KALIMANTAN BARAT	-	4	3	7	7	112	-	
15.	KALIMANTAN TENGAH	-	4	7	23	11	126	-	
16.	KALIMANTAN SELATAN	-	3	4	22	11	149	-	
17.	KALIMANTAN TIMUR	-	1	8	12	7	85	-	
18.	SULAWESI OTARA	-	3	9	24	7	121	-	
19.	SULAWESI TENGAH	-	4	9	8	4	93	-	
20.	SULAWEST SELATAN	1	4	-	23	25	155	-	
21.	SULAWESI TENGGARA	-	4	6	12	4	69	-	
22.	BALI	1	4	2	24	8	76	-	
23.	MUSA TENGGARA BARAT	-	2	7	12	6	108	-	
24.	NUSA TENGGARA TIMUR	-	3	8	25	12	67	-	
25.	MULURU	-	1	3	10	5	82	-	
26.	IRIAN JAYA	-	2	2	26	9	103	-	
27.	TIMOR TIMUR	-	1	10	26	-	40	-	
		8/3	91	129	662	307	5522		70% kerosene 30% electrical
		(-2 ~ -8°C)	(0 ~ -12°C)	refrigerators					

2-2-2 Indonesian Vaccine Production and Imports

All of the vaccines produced in Indonesia are produced by Bio Farma and the four vaccines relating to EPI are Pertussis, BCG, tetanus and diphtheria. The vaccines for measles and polio are either imported in bulk (i.e. before filling) and stabilizers added to them and the vaccines filled, or the products are imported in their final form. In 1986/1987, the fall in the price of oil caused difficulties for the Indonesian government and a request was made to UNICEF and USAID for the supply of vaccines that were then in short supply. Part of the deficiency was made up for by a loan from the World Bank. In 1987/1988, the total amount of bacteriological vaccines produced in Indonesia, other than measles and polio vaccines, was from Bio Farma. In the same year, the measles vaccines required in Indonesia was imported with the assistance of World Bank loans, while the polio vaccines was donated by the International Rotary Club. In 1988/1989, the total amount of bacteriological vaccines was produced by Bio Farma through the President's Special Budget (INPRES) while imports of the measles vaccine were covered by the INPRES budget and the additional (ABT) budget. Continuing on from the year before, assistance from the International Rotary Club was received for the supply of the polio vaccines.

The details of this vaccine supply and budgetary provisions are indicated in Table 2-25. According to this table, a total of 8,218,350 doses (10 doses per vial) of the measles vaccine and 20,000,000 doses (20 doses per vial) of the polio vaccine was acquired and this amount was sufficient for the immunization of all infants (approximately 5 million). In 1989/1990, the plan is for bacteriological vaccines and polio vaccines to be obtained as for the previous years, and for the import of measles vaccine to be covered by the Overseas Economic Cooperation Fund (OECF) loan. The purchase of imported vaccines is undertaken by the respective countries who would first indicate the amount required to UNICEF, which then determines the suppliers by international bidding. In the case of Indonesia, the EPI Implementation Plan proposed by CDC is used as the basis for the ordering and receiving work for which Bio Farma is in charge. The imports are conducted on a quarterly basis but there are delays in the delivery because of circumstances of the supply manufacturers, as well as delays at customs and other problems which often cause obstacles to the immunization programs.

Table 2-25 "INPRES" and Additional Budget (ABT) 1988/1989

No.	Vaccine	Unit	Central "INPRES"	Local "INPRES"	Additional Budget (ABT)	Total
1	BCG Vaccine in Rupiah's	Ampoule	56,340	508,071	491,640	1,056,051
	(@ Rp. 1.070)		60,283,800	543,635,970	526,054,800	1,129,974,570
2	DPT Vaccine in Rupiah's	Vial	148,844	1,341,353	415,700	1,905,897
	(@ Rp. 750)		111,633,000	1,006,014,750	311,775,000	1,429,422,750
3	TT Vaccine in Rupiah's	Vial	161,397	1,449,143	314,500	1,925,040
	(@ Rp. 610)		98,452,170	883,977,230	191,845,000	1,174,274,400
4	DT Vaccine in Rupiah's	Vial	18,972	170,061	41,600	230,633
	(@ Rp. 3.175)		60,236,100	539,943,675	132,080,000	732,259,775
5	Measles Vaccine in	Vial	250,421	145,366	426,048	821,835
	Rupiah's (@ Rp. 3.475)		870,212,975	505,146,850	1,480,516,800	2,855,876,625
6	Meningitis in Rupiah's	Ampoule	0	0	5,000	5,000
	(@ Rp. 3.000)		0	0	15,000,000	15,000,000
	Total in Rupiah's		1,200,818,045	3,478,718,475	2,657,271,600	7,336,808,120
	Polio Vaccine (Donation from International Rotary Club) in Rupiah's	Vial	1,000,000			1,654,057,377
					Total in Rupiah's:	8,990,865,497

Note: Vaccine cost without government tax.

2-2-3 Outline and Current Status of Perum Bio Farma

Bio Farma is the state-owned enterprise directly responsible for this present project. It is a public corporation affiliated with Perushaan Umum (Perum) and is directly controlled by the Ministry of Health. Perum is a public corporation and is one of three types of public corporations established in accordance with Chapter 33 of the Indonesian Constitution. These three types of public corporations are 1) Perjan (Perusahaan Jawatan), 2) Perum (Perusahaan Umum) and 3) persero (Perusahaan Perseraan) and their individual functions are described below.

1) Perjan handles services to the population.
2) perum handles welfare services to the population and obtain a profit in addition to recovering costs.
3) Persero seeks profits as corporations in their various fields, and in so doing, stimulate the development of industry for private corporations and cooperative unions, etc.

Bio Farma, which is the organization for the implementation of this project, is a corporation of the type 2, and its corporate management aims to exhibit autonomy as much as possible while not disadvantaging the private sector at the same time. The management aims to attain the following objectives:-

1) To contribute to the development of the society and economy of the country and to obtain income for the state through its economic activities.
2) To carry out corporate production activities and to produce a reasonable profit.
3) To produce good-quality goods and services for which there is a public demand and to obtain a profit for the state.
4) To have corporate activities that cannot be provided by public corporations or cooperative unions.
5) To use its knowledge and experience gained, in order to plan for guidance in assisting the activities of the public corporations or cooperative unions.
6) To promote the economic support and development of the state.

The current status of Bio Farma is described below.

(1) Outline

Company name:	Perum Bio Farma (Commonly known as the Pasteur Institute, even though there is no relationship with the French institution of the same name)
Address:	Jl, Pasteur 28, Bandung 40161, INDONESIA
Total area of site:	93,200 m^2
Total area of building:	26,566 m^2
Content of main business activities:	Production of serums and vaccines, and the performance of diagnostic research
Number of employees:	435 (in 1988)
Working hours:	7:15am to 15:30pm (Monday to Friday) 5-day week
History:	1890 Established within the Welteurenden Hospital of Jakarta, for the production of natural smallpox vaccine
	1895 The production of the rabies vaccine was introduced, and the institute was renamed the Pasteur Institute.
	1913 Institute designated by the government for the production of vaccines and serums
	1920 Institute moved to its present site in Bandung.
	1923 In addition to the production of vaccines and serums, diagnostic research was also started.
	1955 Name changed to P.N. Pasteur
	1961 Name changed to P.N. Bio Farma
	1978 Name changed to Perum Bio Farma
	1986 Production of blood transfusion products started

(2) Content of Business Activities

1) Vaccine Production

Bio Farma is the only facility in Indonesia where vaccines and serums for human use are produced. They are produced up to the amounts necessary to cover the 27 provinces of Indonesia.

The vaccines that are produced are for rabies, cholera, intestinal typhoid, pertussis, BCG, tetanus and diphtheria.

Polio and measles vaccines are not produced and so there is a complete dependence upon imported finished products. The production of natural smallpox vaccines has a long history but there has been no production since the 1980 WHO declaration of the eradication of smallpox.

2) Blood Serum Production

The four types of blood serum for tetanus, diphtheria, snakebite and rabies, are currently being produced at Bio Farma.

3) Public Health Laboratory Examination

In addition to the production of vaccines and serums, public health examinations, clinical testing and examinations have also been an important function since 1923. These functions are provided as support for doctors who are commencing practice, and approximately 42,000 examinations have been conducted each year (on average) between 1981 and 1985. The examination and testing sections are as follows:-.

Diagnostic laboratories

1. Bacteriology Laboratory
2. Serology Laboratory
3. Clinical Biochemistry Laboratory
4. Mycology Laboratory
5. Virus Laboratory
6. Cell Culture Laboratory

(3) Organization of Bio Farma

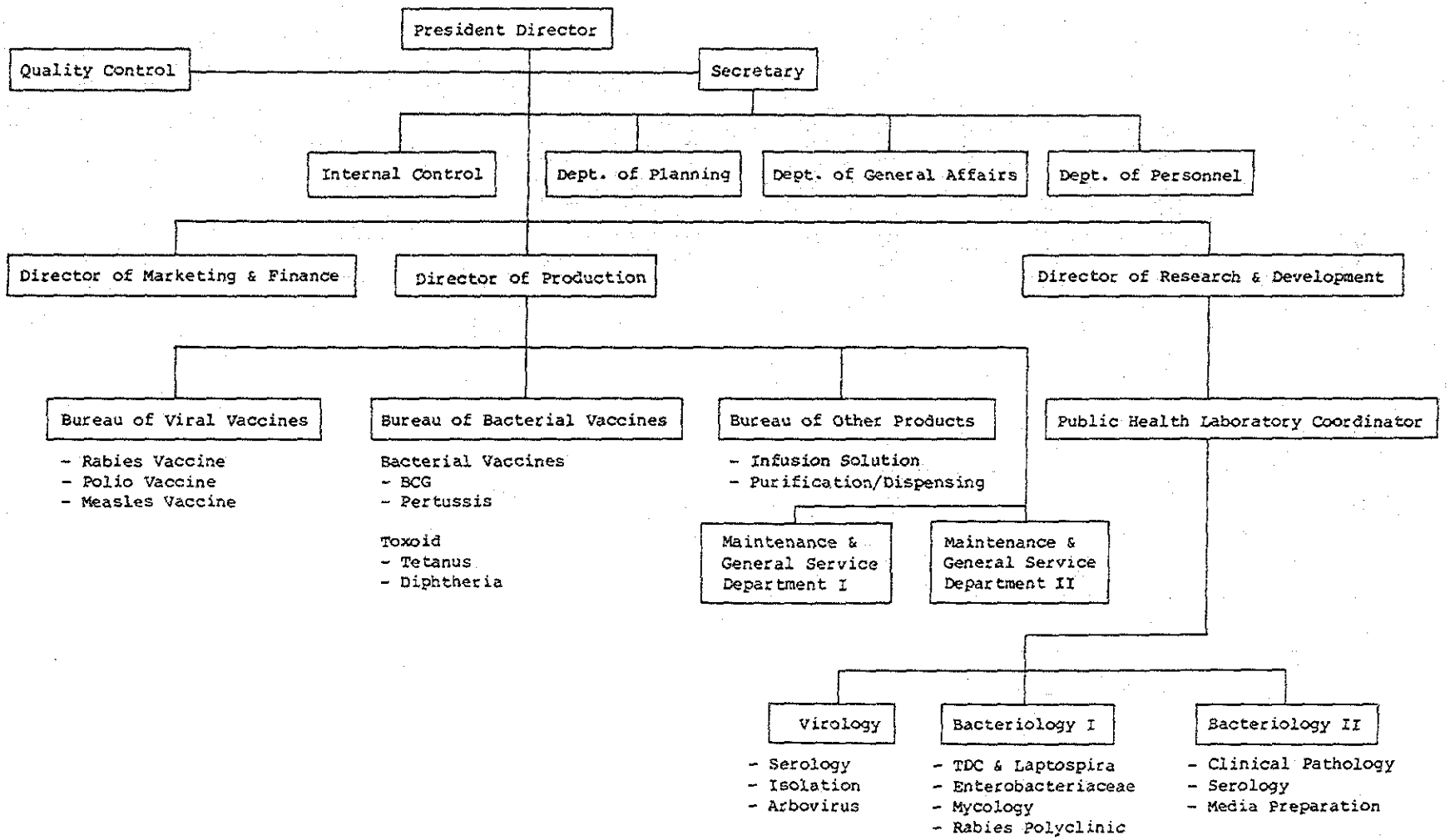

Fig. 2-16 Organization Chart of Perum Bio Farma

(4) Staff Configuration

The configuration of the staff for the entire facility is shown below.

Staff

(1)	Sr. Scientist	19	Persons
(2)	Scientist	25	Persons
(3)	Sr. Technician	48	Persons
(4)	Technician	35	Persons
(5)	Attendant	114	Persons
(6)	Other Clerk	40	Persons
	Store Keeper	8	Persons
	Electrician	4	Persons
	Plumber	3	Persons
	Mechanic	17	Persons
	Security	22	Persons
	Sweeper	10	Persons
	Driver	7	Persons
	Others	83	Persons
	TOTAL	435	Persons

(5) Site Location in Bio Farma

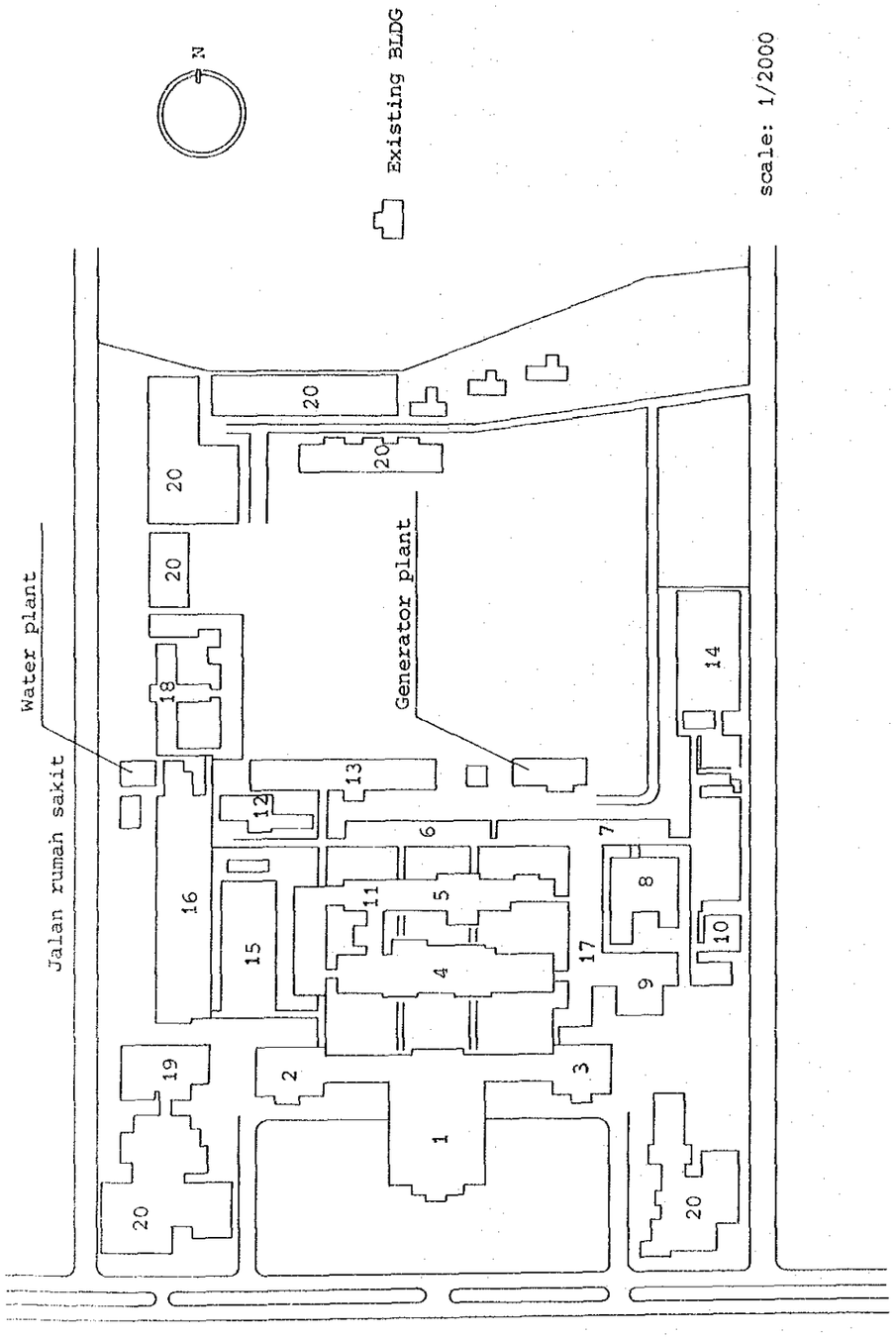

Fig. 2-17

Building location in Bio Farma

1) Administrative building
2) Rabies Vaccine Production Department
3) Finance department
4) Bacterial Vaccine Production and Quality Control Department
5) Chemical and Purification Department
6) Diphtheria Vaccine Production
7) Serum Department
8) BCG Vaccine Department
9) Shipping Department
10) Tetanus Vaccine Department
11) Virology Department
12) Media Preparation Department
13) In vivo (animal) Quality Control Department
14) Infusion Solution Production Department
15) School for Laboratory Technician
16) Central Store and Workshop
17) Filling and Packaging Department
18) Public Health Laboratory and Rabies Treatment Clinic
19) Garage
20) Accommodation for Bio Farma Staff

(6) Main Equipment at the Various Facilities.

No.	Building	Name of dept.	Major equipment	Quantity
1	2	Rabies Vacc. Production Dept.	- Freezedrying Machine Usifroid SMB-B	3
			- Automatic Sealing Machine Kumabe ES-100	1
			- Autoclave	1
			- Cold Room	1
			- Deep Freezer	2
2	4	- Bacterial Vacc. Production (Pertussis)	- Fermenter (Novo Paljas NW - 300 - 70 L)	8
			- Laminar Air Flow	4
			- Incubator Room	1
			- Cold Room	1
		- Quality Control I Dept.	- Laminar Air Flow	4
			- Incubator Room	1
			- Freeze Drying Machine	1
3	6	Diphtheria Vacc. Dept.	- Fermenter NBS IF - 250 New Brunswick	1
			- Fermenter Novo Paljas NW - 300 - 70 L	3
			- Fermenter Magno Paljas NW - 300 - 350 L	1
			- Meta Press	1
			- Laminar Air Flow	1
			- Medium Preparation Vessels GN. 500 EW	1
			- Neo Ultron	1 set of cartridge
			- Transport Vessels	
			. 200 L	35
			. 75 L	2
			- Cold Room 5.8 m x 3 m x 2.5 m	1
			- Incubator Room 4 m x 3.5 m x 2.5 m	1
4	11	Viral Vacc. Production Dept.	- Freezer - 20°C	3
			- 65°C	1
			- Laminar Air Flow (Vertical)	1
			- Autoclave Double Ended	1
			- Dry Oven	2
5	8	BCG Vacc. Dept.	- Freeze Drying Machine	
			. Virtis 5 RC - 8000	1
			. Virtis 5 RC - 4500	1
			- Automatic Sealing Machine ES - 100 (Kumabe)	2
			- Cold Room 60 M^3	1
			40 M^3	1

No.	Building	Name of dept.	Major equipment	Quantity
			- Laminar Air Flow	
			. Horizontal flow	4
			. Vertical flow	1
			- Autoclave Double Ended	1
			- Autoclave One Ended	2
			- Incubator Room	1
			- Small Incubator	5
			- Dry Oven	1
6	10	Tetanus Vacc. Production Dept.	- Fermenter - 1000 Shinko Pfandler	1
			- Medium Preparation Vessels 100 L	2
			- Animal Ultra Filtration Unit	2
			- Cold Room 2.4 m x 2.0 m x 2.8 m	1
			- Incubator Room 6 m x 6 m x 2.8 m	1
			- Transport Vessel	
			. 360 L	4
			. 200 L	39
			. 150 L	10
7	5	Purification Dept.	- Water Distillation Plan	
			. 50 L/Hr	1
			. 100 L/Hr	1
			. 200 L/Hr	1
			- Amicon Ultra Filtration DC - 30	2 units
			- Cold Room 5.8 m 3 m x 2.5 m	1
			- Refrigerated Centrifuge 6 x 1000 ml	1
8	7	Serum Dept.	- Amicon Ultra Filtration DC - 30	1
			- Cold Room $\pm$38 M^3	1
			- Filter Press	2 units
9	17	Dispensing & Packing	- Washing Machine	
			. 6000 vial/Hr	1
			. 2500 vial/Hr	1
			- Dry Sterilizer (oven)	
			. double ended	2
			. double front door	1
			- Autoclave Double Ended	1
			- Filling Machine	
			. for ampoules	1
			. for vials	2
			- Laminar Air Flow (vertical)	4
			- Labeling Machine	
			. 7500 unit/Hr	1
			. 9000 unit/Hr	1
			- Cold Room	
			. 5.5 m x 3.6 m x 2.5 m	1
			. 9.6 m x 5.2 m x 2.6 m	1

The above facilities comprise mainly machines for the production of biological materials and are thought to be a suitable array.

(7) Financial Situation

The financial situation of the corporate activity is shown in Table 2-26 for the years from 1980 to 1986. The total accumulated dividend over this period is 11,944,158,000RP and it shows a tendency to increase yearly.

The corporation is a public corporation and its primary aim is not the pursuit of profit. However these figures show the strict self-management that is imposed to overcome the obstacles that tend to plague public corporations, and the sound financial situation is deemed to be the result of corporate efforts.

Moreover, there is also the contribution from the sales of infusion solution products, the production of which commenced in fiscal 1986. Nevertheless, the setting of the product selling price of the requires the approval of the government and so the price had to be set in accordance with the expenses incurred in the production.

1) Income

a) Total Income

The total income of Bio Farma including the laboratory examination income and the rabies diagnosis and examination income is shown below.

Fiscal Year	Amount
1983	2,767,456,440 RP.
1984	3,069,485,035 RP.
1985	5,792,685,624 RP.
1986	4,128,171,301 RP.
1987	3,692,591,441 RP.
1988 (estimate)	6,026,688,597 RP.
1989 (planned)	8,836,836,000 RP.

Table 2-26 Statistical Summary from 1980 Until 1986

No.	Financial (acounts in Rp 000's)	1980	1981	1982	1983	1984	1985	1986
1	Total sales on main product (Serum and vaccine)	1,286,278	2,034,929	2,187,459	2,734,629	3,031,102	5,728,691	4,054,554
2	Total cost of goods sold and operating expenses	1,330,335	2,031,861	2,185,587	2,653,500	2,749,077	5,082,774	4,099,588
3	Income before income taxes	71,332	202,258	188,041	297,497	535,756	805,739	351,671
4	Expenditure on R&D Program	8,001	13,105	25,033	30,064	26,820	24,329	20,094
5	Current assets	830,199	1,191,540	2,061,034	2,185,797	2,788,838	5,817,010	6,909,691
6	Fixed assets	5,490,579	5,662,475	7,075,055	7,500,498	8,832,710	10,326,739	9,857,767
7	Allowances for depreciation	514,288	744,603	1,011,048	1,372,510	1,682,420	1,950,150	2,451,749
8	Current liabilities	265,960	526,202	515,578	523,942	1,045,287	1,567,074	1,702,300
9	Long term liabilities	-	-	-	-	-	1,638,000	3,121,000
10	Accumulated funds	5,510,531	5,583,218	7,609,463	7,789,842	8,893,840	10,988,525	11,944,158

No.	Staff	1980	1981	1982	1983	1984	1985	1986
1	Total payroll full-time staff	218,441	286,701	293,886	332,650	439,353	442,422	843,277
2	General welfare (health, recreation, insurance, etc.)	241,736	252,413	354,913	401,447	321,225	508,681	352,893
3	Full-time staff strength	337	349	356	366	387	408	419
4	Revenue per employee	648	831	825	909	1,135	1,084	2,012

No.	Product statistics (Expressed in thousands)	1980	1981	1982	1983	1984	1985	1986
1	Vaccine	6,361	9,652	7,496	12,811	13,237	25,394	21,830
2	Serum	1,080	933	1,124	1,110	1,435	1,047	957
3	Others	2,340	1,308	970	786	2,068	2,501	13,102

b) Main Product Sales

Bio Farma is the only specialised facility in Indonesia for the production of biological agents. The sales figures for vaccine antigens and the other main products for each fiscal year from 1985 to 1987 are as follows:-

Fiscal 1985	Fiscal 1986	Fiscal 1987
5,729,129,849 RP	4,054,553,927 RP	3,638,294,135 RP

c) Supplementary Income

Bio Farma has the rabies diagnosis and clinical laboratories as auxiliary facilities and also has the personnel for the analysis and clinical diagnosis in other areas (rabies and bacteriological clinical examinations) that the medical staff cannot handle.

The income from these activities is as follows:-

Source of Income	Fiscal 1985	Fiscal 1986	Fiscal 1987
(Laboratories)	55,671,650 RP	55,853,900 RP	46,328,175 RP
(Rabies)	8,322,875 RP	17,763,473 RP	7,969,131 RP
TOTAL	63,994,525 RP	73,617,373 RP	54,297,306 RP

The ratio of this supplementary income to the sales of the vaccines and other biological products is as follows:-

1.12 %	1.82 %	1.37 %

d) Other Income

Miscellaneous income is derived from the handling and sales of biological products of large pharmaceutical producers, as well as from the sales of small animals for testing, etc.

	Fiscal 1985	Fiscal 1986	Fiscal 1987
Breakdown:	147,552,500 RP	340,757,431 RP	471,509,139 RP
Handling and sales agency:	8,006,393 RP	7,248,007 RP	6,861,248 RP
Interest:	16,891,453 RP	75,178,119 RP	78,280,421 RP
Animal sales:	34,762,189 RP	32,333,570 RP	34,415,804 RP
Other product sales:	41,318,509 RP	6,177,609 RP	75,305,296 RP
Miscellaneous income:	46,573,954 RP	219,820,124 RP	276,646,368 RP

2) Expenditure

The costs incurred in obtaining this income and the proportion with respect to the income is shown in the following table.

Fiscal Year	Amount	Percentage
1983	2,215,236,371 RP.	81.25 %
1984	2,198,764,262 RP.	72.54 %
1985	4,190,254,013 RP.	73.15 %
1986	3,402,501,027 RP.	83.92 %
1987	3,248,551,254 RP.	89.29 %
1988 (estimate)	4,475,641,841 RP.	75.00 %
1989 (planned)	6,361,330,000 RP.	72.00 %

Of this, the figures for up to fiscal 1987 are the figures as shown in the government accounts (As of November 23, 1988; Biro Pengawasan Intern.).

The following table shows the ratio that each of the items of expenditure (with the exception of miscellaneous expenses) have with respect to the total expenditure.

		1985	1986	1987
	Expenses	5,095,459,296 RP	4,662,769,050 RP	4,701,519,467 RP
1)	Direct expenses (research, production, machines, etc.)	47.45 %	38.73 %	36.32 %
2)	Personnel expenses	20.23 %	25.65 %	26.92 %
3)	Welfare	1.52 %	1.89 %	2.08 %
4)	Facility maintenance (including building maintenance)	3.59 %	2.17 %	2.39 %
5)	Machine installation (electricity, oil costs, etc.)	11.65 %	15.17 %	16.62 %
6)	Vehicle and transportation expenses (for vehicle maintenance)	0.46 %	0.41 %	0.42 %
7)	Purchase and raising of horses for serum collection	0.12 %	0.10 %	0.06 %
8)	Sales expenses	9.82 %	7.94 %	7.19 %
9)	Office expenses	0.79 %	0.76 %	0.88 %
10)	Other expenses (transportation, communication)	4.37 %	7.18 %	7.12 %
	Total	100 %	100 %	100 %

The expenses for each of the above items over the past three years was compared to the total and percentages produced and also compared with the figures for the 1985 settlement of accounts. The results showed that although there was a reduction in the total sales for 1986 and 1987, there was an increase in the proportion of personnel expenses. Moreover, the amount of subsidies from the government had tended to increase yearly up to 1986 but stopped in 1987.

From this, it can be seen that although the corporation is a public corporation, it cannot rely upon government subsidies and has therefore been requested to achieve self-autonomy through its own efforts.

3) Regarding the Profit Margins

Nevertheless, the facility is an important national facility, where the EPI plan is being thoroughly implemented and this, coupled with the experience as a producer of biological agents, is slowly producing the desired results. The first half results for fiscal 1988 and onwards show that the profit ratio which had fallen to 1.08% had recovered to 6%, with that for fiscal 1989 estimated at 10%.

Fiscal Year	Profit ratio on total sales	Gross profit ratio (less tax)
1985	11.28 %	7.09 %
1986	5.68 %	2.28 %
1987	3.44 %	1.08 %
1988	15.00 % (estimate)	6.00 % (estimate)
1989	19.00 % (planned)	10.00 % (planned)

4) Vaccine Salling Prices

The factory shipping prices of the representative types of vaccines produced by Bio Farma are shown in the following list which compares their prices to the UNICEF Essential Drugs Price List.

	Bio Farma Factory Shipment Price		UNICEF Price
BCG	20 ds	1,035.00 RP	1.10 (1,914,00 RP)
DT	5 ml	730,00 RP	0.68 (1,183,20 RP)
TT	5 ml	590,00 RP	0.50 (870,00 RP)
DPT	5 ml	730,00 RP	0.85 (1,479,00 RP)
TT	5 ml	590,00 RP	0.50 (870,00 RP)
DPT	5 ml	730,00 RP	0.85 (1,479,00 RP)
* Polio	10 ds	1,380,00 RP	0.95 (1,653,00 RP)
* Measles	10 ds	3,065,00 RP	1.50 (2,610,00 RP)

(US$1.00 = 1,740RP as of February 1, 1989)

The above vaccines are used as the main vaccines to combat communicable diseases in Indonesia.

The asterisk indicates the factory shipment prices for those products where the full amount is imported, stored, and then shipped upon CDC request.

Table 2-27 Financial Data of Bio Farma (1983 - 1987)

(Unit: 1,000 RP)

No.	Item	1983	1984	1985	1986	1987
1	GROSS SALES ON MAIN PRODUCT OF SERUM AND VACCINE TO:					
	- Government	1,592,070	1,735,259	4,666,553	2,939,596	2,281,764
	- Private	1,142,560	1,295,843	1,062,577	1,114,958	1,356,530
	Total Gross Sales on Main Product	2,734,630	3,031,102	5,729,130	4,054,554	3,638,294
	Sales Return	8,170		439		
	Net Sales	2,726,460	3,031,102	5,728,691	4,054,554	3,638,294
2	PUBLIC HEALTH LABORATORY:					
	- Laboratory	34,658	31,062	55,672	55,854	46,328
	- Rabies Policlinic	6,338	7,321	8,323	17,763	7,969
	Total	40,997	38,383	63,995	73,618	54,297
3	TOTAL NET SALES	2,767,456	3,069,485	5,792,686	4,128,171	3,692,591
4	COST:					
	- Cost of Goods Sold	2,215,237	2,198,764	4,190,254	3,402,501	3,248,551
	- % Cost of Goods Sold	81.25%	72.54%	73.15%	83.92%	83.29%
5	GROSS PROFIT ON SALES	552,219	870,721	1,602,432	725,670	444,040
6	OPERATING EXPENSES:					
	- Selling Expense	212,258	341,208	614,236	374,314	351,340
	- General & Administration Exp.	226,008	209,104	278,284	322,767	365,008
	Total Operating Expenses	428,265	550,312	892,519	697,087	716,348
7	NET PROFIT FROM OPERATIONS	113,954	320,408	709,912	28,583	(272,308)
8	NON OPERATING INCOME:					
	- Pharmaceutical Wholesaler	3,089	5,677	8,003	7,248	6,861
	- Interest	13,245	11,298	16,891	75,178	78,280
	- Animal Births	24,953	24,839	34,762	32,334	34,416
	- Other Sales	4,081	116,061	41,319	6,178	75,305
	- Other Income	195,358	75,509	46,573	219,820	276,646
	Total Non Operating Income	240,726	233,383	147,553	340,757	471,509
9	OTHER LOSSES:					
	- Damaged goods, etc.	48,448	10,795	44,212	10,859	7,178
	- Dead Animals	8,734	7,241	7,512	6,810	8,504
	Total Other Losses	57,183	18,036	51,725	17,669	15,682
10	NET INCOME BEFORE TAXES	297,497	535,756	805,739	351,672	183,519
11	TAXES	779,249	190,432	278,347	121,198	56,232
12	NET INCOME AFTER TAXES	218,247	345,324	527,391	230,473	125,287
13	CAPITAL:					
	- Total Assets	8,313,786	9,556,171	14,193,598	16,767,458	16,493,430
	- General, Expansion, etc.	(102,500)	(105,094)	(195,658)	(351,065)	(411,547)
		(160,047)	(150,761)	(2,628,727)	(998,145)	718,314
	Total	8,051,234	9,300,315	11,369,214	15,418,248	16,800,137
	Assets of Govern. Funds in construction	248,947	1,423,322	2,736,552	3,337,307	3,880,480
	Total	7,802,291	7,876,993	8,632,661	12,080,941	12,319,717
14	LONG TERM LIABILITY	--	--	1,638,000	3,121,000	3,874,286
15	GOVERNMENT FUNDS	686,000	1,701,072	3,509,669	4,243,677	4,249,677
16	RATIO:					
	a. Liquidity Ratio: Current Ratio = Current Assets / Current Liabilities	557.42%	326.92%	462.79%	507.31%	1064.19%
	b. Solvability Ratio = Working Capital / Total Assets	65.55%	18.79%	31.68%	31.77%	60.58%
	c. Activity Ratio = Net Sales / Total Assets	1.6 kali	1.7 kali	1.8 kali	0.8 kali	0.8 kali
	d. % Gross profit on Sales = Gross profit / Net Sales	18.75%	27.46%	26.85%	17.58%	12.20%
	e. % Net Income before taxes = Net Income before taxes / Net Sales	10.91%	9.30%	11.28%	5.68%	3.44%
	f. Rot	3.81%	6.14%	7.09%	2.28%	1.08%

2-2-4 Current Status of International Cooperation with Respect to Perum Bio Farma

The subsidies with respect to each of the different vaccines are as shown in the previous section and the current status of international cooperation with respect to Bio Farma, which produces the main vaccines for inoculation, is as follows:-

Table 2-28 Foreign Aid from 1976

1) Japanese Government 1976	¥	20,400,773
2) UNICEF 1978 - 1983	US$	270,417,92
3) Government of the Netherlands 1978	HLF	10,502,25
4) Colombo Plan (Australia) 1981 - 1985	Austr. $	972,373,99
5) US AID 1982 Equipment & training	US$	1,622,000,00

2-2-5 Content and Progress of the Request

The WHO Expanded Program on Immunization, commenced in 1976 and inoculation activities are being carried out in Indonesia, particularly in the fourth 5 year plan (1985 to 1989). Raising the level of public health was targeted as a major objective and there was a large increase in the spread of immunization practises. Related to this expanded program was the request by the Indonesian Government to the Japanese Government for technical cooperation concerning the production of vaccines to counter measles and polio. The content of this request was for large amounts of measles and polio vaccines in order to implement a systemized inoculation program with respect to the 170 million population of Indonesia. The government has planned for the low-cost manufacture of the complete amount from raw materials, and to export the surplus. Because of this, it was necessary for experts to be dispatched to Indonesia for the vaccine production and quality control, and for trainees to be sent to Japan as the technical cooperation component, as well as to have the necessary equipment supplied.

On July 3, 1984, the two governments reached agreement on the dispatch of a Japanese study team with respect to this project and the Japanese Government entrusted this work to the Japan International Cooperation Agency (JICA). JICA sent a contact mission headed by Dr. Isao Yoshioka, Executive Director, Japan Polio Research Institute (JPRI) to Indonesia as the "REPUBLIC OF INDONESIA MEASLES & POLIO VACCINE PRODUCTION FACILITY CONSTRUCTION PLAN BASIC DESIGN SURVEY TEAM" from April 8 to April 15, 1986. This survey team recommended that the building that would serve as the facility for the manufacture of the polio and measles vaccines should be provided by the Indonesian side (Bio Farma) and that the Japanese side be responsible for the acceptance of trainees, the dispatch of production experts to Indonesia, and the provision of equipment.

During the period from June 1 to June 14, 1986, JICA dispatched the "Indonesia-Thailand-Philippines Communicable Disease Countermeasure Cooperation Survey Team", headed by Dr. Konosuke Fukai, Chairman, Board of Directors, Research Foundation for Microbial Diseases of Osaka University (BIKEN), and this team was in Indonesia from June 1 to June 4.

Thereafter on August 4, 1987, the Government of Indonesia made a formal request whereby in addition to the above mentioned technical cooperation, there should also be a 2,000 m^2 building for the manufacture of the measles vaccine and for the quality control facilities, a 250 m^2 animal house, a 2,000 m^2 building for the manufacture of the polio vaccine and for the quality control facilities and a 450 m^2 animal house, each to be provided as separate buildings.

With respect to this request, JICA again dispatched the preliminary survey team for "Fundamental Technology Transfer Relating to Polio and Measles Vaccines" headed by Dr. Fukai from February 29, to March 9, 1988. The survey team confirmed that the facility should also be included under Grant Aid, in addition to technical cooperation.

In order to have more detailed discussions with Bio Farma, JICA again dispatched the same survey team from August 25 to September 4, 1988. In the discussions, Bio Farma stressed the following points:-

1. The final objective is the production of 7,500,000 doses of measles vaccine and 20,000,000 doses of polio vaccine.
2. The management of monkeys for the production of the polio vaccines and the SPF eggs for the production of the measles vaccine should be undertaken by Bio Farma itself. Because of this, the scale of the animal sheds should be larger than that described in the request of August, 1987.
3. Bio Farma would like all of the facilities to be completed in as short a period as possible.
4. In consideration of the WHO inspections, the facility should be able to pass the international standards such as the GMP standards set by the FDA of the USA.

In addition, a building area of 9,000 m^2 was proposed. This building would comprise the area for the manufacture of the polio and measles vaccines (3,270 m^2), the quality control section (1,400 m^2), the animal houses (2,200 m^2) and the machine room (1,680 m^2).

A list of the equipment required for the facility was also submitted by Bio Farma.

During the period from December 1 to 20, 1988, JICA dispatched the "REPUBLIC of INDONESIA MEASLES & POLIO VACCINE PRODUCTION FACILITY BUILDING CONSTRUCTION BASIC DESIGN SURVEY TEAM" headed by Dr. Fukai to Indonesia and agreement was reached based on the following points:-

1) Facilities to be constructed as Grant Aid assistance
   a) Animal houses for raising SPF chickens and other animals
   b) Bulk manufacturing building
   c) Facilities for the quality control of the final products and also for the quality control of the manufacturing processes
   d) Facilities for the filling, freeze-drying and packaging processes

2) Technical Cooperation
   a) Fundamental technology transfer for the production of polio and measles vaccines
   b) Dispatch of experts from Japan
   c) Training in Japan for the Indonesian counterparts
   d) Provision of machinery and equipment

3) Responsibility of the Government of Indonesia
   a) Provision of the site, cleared of existing buildings, and with site leveling work complete
   b) Connection of the facility to the existing infrastructure and utilities
   c) Securing the budget necessary for the suitable use of the facility and equipment provided by the Grant Aid, and for the maintenance.
   d) Prompt unloading, loading, customs clearance and tax-free handling for the imported goods necessary for the construction of the facility
   e) Non-imposition of value-added taxes (VAT), or the bearing of such.

CHAPTER 3 CONTENT OF THE PROJECT

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3-1 Objectives of the Project

The immunization program for babies and infants, as well as mothers and women of childbearing age is given the highest priority in Indonesia's REPELITA V. The timely supply of adequate vaccines are essential for executing this program.

However, Indonesia depends on imports for the measles and polio vaccines, which are live attenuated vaccines of low toxicity. As a result of this dependence on imports, timely and effective immunization cannot be guaranteed.

It is pointless to provide vaccines for people if they do not get them at the right time. The loss of lives due to the unavailability of vaccines will bring about immeasurable negative effects not only to the nation's society and economy, but also to individuals and their families.

The Republic of Indonesia has therefore planned for the domestic production of vaccines by utilizing Bio Farma's technology of bacterial vaccine production and their experience in facilities management. Accordingly, the Indonesian Government has requested Grant Aid for facilities and equipment and technical cooperation from the Japanese Government.

In this request, the facilities, which would also include important machinery and equipment for the transfer of technology, are to be constructed in Bio Farma. These facilities would be capable of producing the measles and polio vaccines which are needed by the Republic of Indonesia.

The objectives of this project therefore are to contribute to the improvement of public health and hugiene, and to transfer advanced technology, including cell culture, in order to raise the standard of vaccine production in Indonesia.

3-2 Study on Content of Requests

The content of various requests, which were made prior to the basic design survey in December 1988, was described in chapter 2-2-5. The content of individual requests will be studied here in consideration of the provision of a measles and polio vaccine plant in Indonesia.

(1) Production of Measles and Polio Vaccines by Cell Culture

In response to WHO's EPI promotion, the Republic of Indonesia aims to raise the immunization rate of all babies to 85% by the end of the REPELITA V, and finally to 100%. The annual number of newborn babies has been about 5 million for the past several years. The requested yearly production of vaccines is 7.5 million doses (10 doses/vial) for measles and 20 million doses for polio. (Polio vaccine is administered 3 times to each person.) These production quantities are considered appropriate in view of the wastage at the time of vaccination, the wastage during the cold chain and the natural increase of newborn babies.

The team examined the past records, the facilities currently available, their usage and the standard of research and engineering staff of Bio Farma. Bio Farma is to be the direct executor of this project and it is also the only producer of vaccines in Indonesia. It is considered that Bio Farma is sufficiently capable of independent production by means of adequate technology transfer, although they have no experience of producing low toxicity vaccines by the cell culture method.

(2) Facilities to be Constructed

The final request regarding the facilities to be constructed is given below.

Production facilities	3,720 m^2
Animal houses	2,200 m^2
Quality control facilities	1,400 m^2
Machine room, work shop etc.	1,680 m^2
Total Area	9,000 m^2

The sizes and types of rooms requested for production facilities were generally appropriate. However, the area can be reduced without affecting the general functioning of the facility because the measles and polio facilities could share a washing room and a packing or labeling room etc., and some existing facilities of Bio.Farma can be used as a warehouse for final products etc.

It is considered acceptable that the size of the facilities for test animals in the animal houses can also be reduced. The peripheral corridors here, which are designed for maintaining cleanliness and for visitors, are not necessarily essential. As for the quality control facilities, the types and the sizes of pathological laboratories are generally appropriate, although some necessary rooms are missing in cell laboratories in the clean area. The peripheral corridors here, like those of the animal houses, are seen to be unnecessary.

(3) Equipment

Indonesia submitted a list of the equipment they required at the time of the preliminary survey of "Fundamental Technology Transfer Project for Production of Live Attenuated Measles and Poliomyelitis Vaccines" in September, 1988. Their request is considered to be generally appropriate. However, a sufficient study should be made in relation to the time of installation, the production setup, the timing of supply and the technical cooperation.

(4) GMP Standards and This Project

The Republic of Indonesia has requested that the production facility must meet GMP Standards which are recognised by WHO. This request is considered appropriate because WHO will not supply the Sabin strain of polio vaccine unless the production facilities meet the standards. It will be fatal to the present project. Since GMP Standards cover not only the facilities and equipment, but also the quality control and research personnels' quality and skill, it will be important to train research personnel under technical cooperation etc.

3-3 Outline of the Project

3-3-1 Organizations Involved in Execution of Project

The main organizations involved in this project are the Ministry of Health and Perum Bio Farma, as stated in the separate minutes (Minutes of Discussion on the Project for Construction of Production Facilities of Live Attenuated Measles and Poliomyelitis Vaccines in the Republic of Indonesia, December 9, 1988).

(1) General Manager, who will assume overall responsibilities

Secretary General of the Ministry of Health

(2) Operation Manager, who will be responsible for management and administration

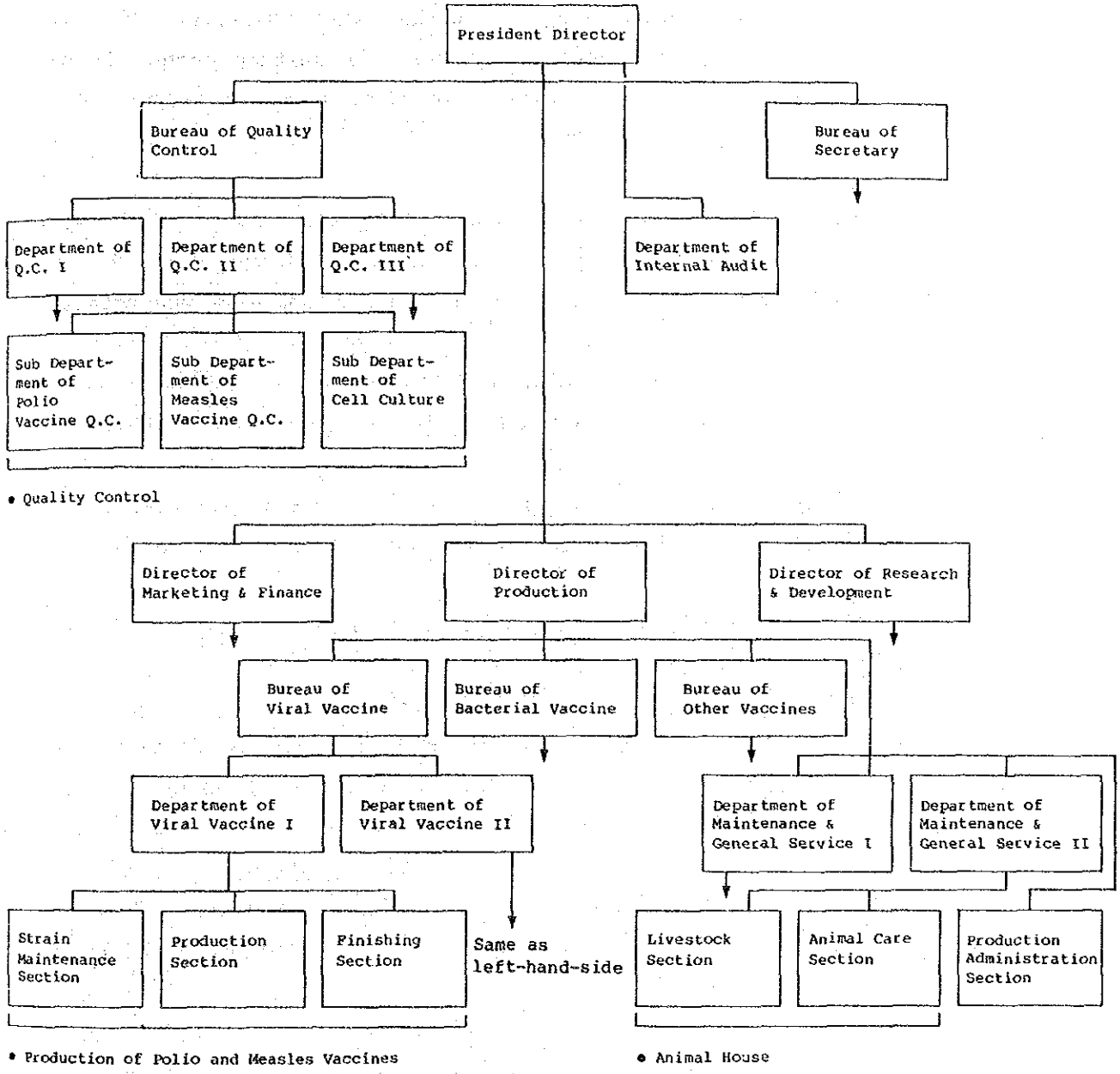
Drs. Soesilo, Director General of Food & Drug Control

(3) Person responsible for project implementation and for the operation, maintenance and management of facilities after completion

Drs. Darodjatun, President Director of Perum Bio Farma

Figure 3-1 shows the various departments of Bio Farma which are involved with this project.

Fig. 3-1 Organization Chart of Perum Bio Farma



3-3-2 Project Management Planning

This project concerns the construction of facilities for the fundamental transfer of technology regarding the production of live attenuated measles and polio vaccines by the cell culture method in Bio Farma, which is the only bio medicine producer in the Republic of Indonesia.

The project aims to become the basis for executing the EPI Plan proposed by WHO and to promote the effectiveness of immunization by the timely supply of vaccines for infectious diseases in adequate quantities.

The facilities, with Japan's technical cooperation are to have enough capacity for producing the following quantities of vaccines per year:-

Polio	20,000,000 doses (each person to be vaccinated 3 times)
Measles	7,500,000 doses (each person to be vaccinated once)

The required area of the facilities is already available in the grounds of Bio Farma.

The Japanese Government plans to start technical cooperation from fiscal year 1990/1991 to transfer the skills of the cell culture method in parallel with the construction of the facilities.

BIKEN (The Research Foundation for Microbial Diseases of Osaka University) and WHO are to supply Sabin stocks of measles vaccine and polio vaccines respectively.

The project consists of the following plans to meet annual demands:-

1) Breeding SPF hens which will provide fertilized eggs for producing the measles virus culture medium, breeding monkeys for producing the polio virus culture medium, and breeding test animals for quality control

2) Quality control in the process of live attenuated vaccine production and inspection for quality assurance of final products

3) Producing live vaccines in bulk under strict biological management

4) Adequate management of filling, freeze-drying, packing, storage lines etc.

Eighty seven men chosen from Bio Farma's current employees are to be assigned to this work. Under Japan's technical cooperation, technical training is to be given to Indonesian staff in Japan and Japanese experts are to be dispatched to Indonesia for technology transfer.

(1) Operation Plan

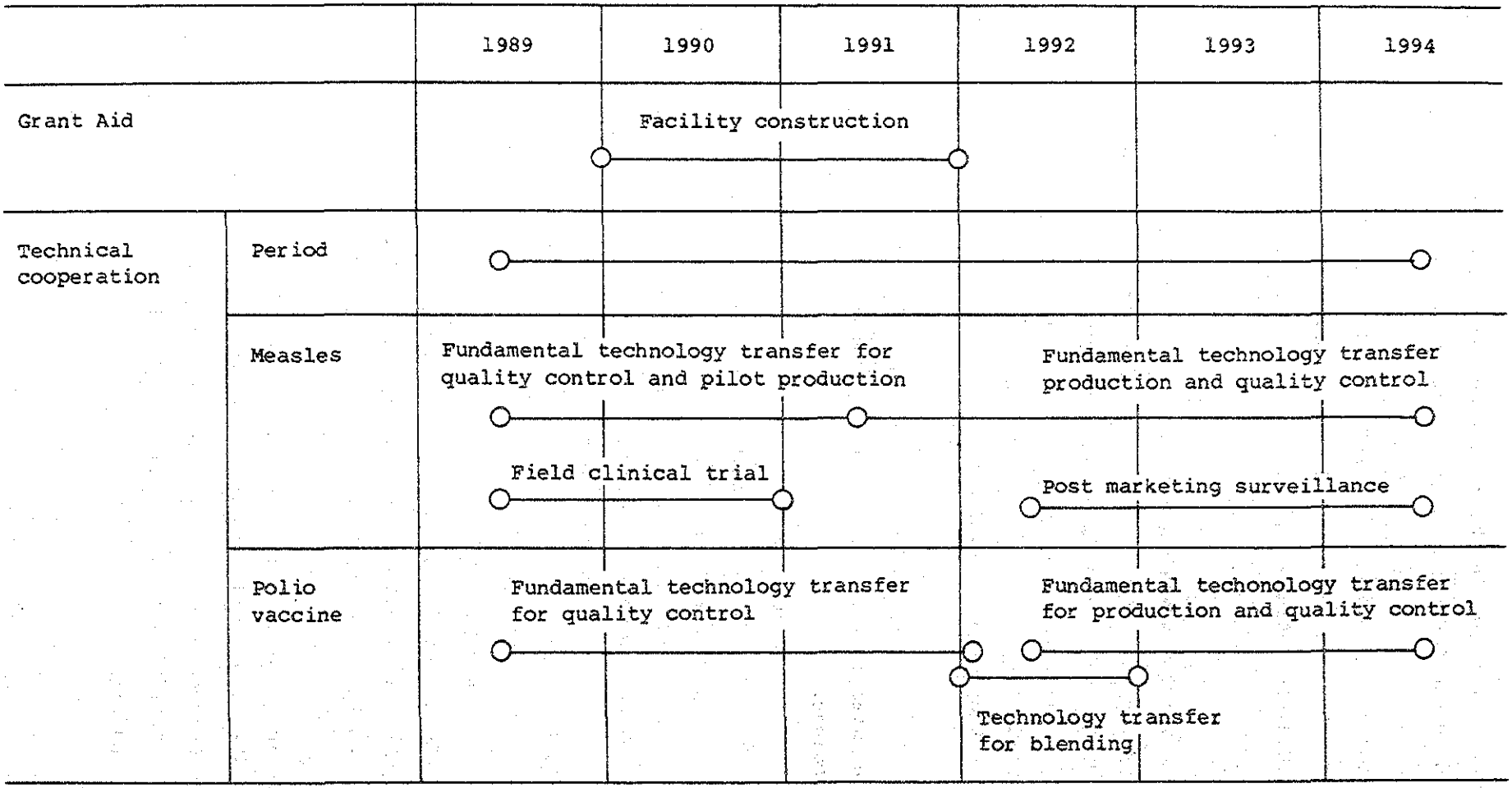
The policy of this project is fundamental technology transfer for the simultaneous and integrated production of measles and polio vaccines.

However, it is not recommended to start the production from the beginning because Bio Farma does not have sufficient specialized medical and scientific technology, and has no experience in operating equipment and machines utilizing the bio-clean technology. It is adequate to follow the schedule shown in Table 3-1. The schedule is briefly described below.

1) The supply of vaccines required for EPI project cannot be interrupted. Therefore, Indonesia is to depend on a gift from the International Rotary Club for polio vaccines and on imports for measles vaccines.

2) The construction work of the vaccine production facilities will be completed in 1991 through Grant Aid from the Japanese Government. The measles vaccine production and quality control facilities will be able to divide, fill and pack bulk vaccine supplies.

Table 3-1 Project Schedule



3) Indonesia is to acquire the knowhow of vaccine production under the technical cooperation to be started in fiscal year 1989/1990. The rsearch personnel who are dispatched overseas are to return at the completion of the production facilities. They are to receive training under the guidance of the experts dispatched from Japan. At the same time, they are to transfer the technology to newly appointed full-time research personnel and technicians.

4) During stage 3) above, Bio Farma is to import bulks of measles and polio vaccines and to acquire skills from the test production consisting of mixing, dividing and packing processes. At the same time, the research personnel are to receive training in integrated test production beginning with the breeding of SPF hens and roosters, collection of fertilized eggs, breeding of monkeys and collection of kidney cells.

(It should be possible to obtain Sabin strain of Polio virus for executing this training plan.)

5) At the earliest, full-scale production can be expected to start in 1995, after the above steps have been taken. By that time, Indonesia will not have to depend on imported vaccines. The need to improve the cold chain system should be stressed to CDC.

(2) Staffing Plan

The anticipated number of personnel when the Bio Farma facility enters full-scale production is 87, and the expected number of persons for each section is indicated in the table 3-2. Many of the personnel will be experienced personnel currently employed at Bio Farma.

Engineers are to be given sufficient training at BIKEN and JPRI in Japan to acquire the technology. At the same time, Japanese experts are to be dispatched to Bio Farma to raise the standards of the production technology at the new facilities.

Table 3-2 Staffing Arrangement

Appointment	No. of staff
Production Section	42
Measles	10
Polio	15
Media	3
Joint facilities (washing, packaging, etc.)	14
Quality Control Section	25
Cell culture (including washing)	15
Pathology, immunology inspection	10
Animal House	16
Test animals	4
House for chickens for measles	4
House for monkeys for polio	4
Joint facilities (washing)	4
Other facilities (office, etc.)	4
TOTAL	87

(3) Production Costs

If the production of 7,500,000 doses of measles vaccine and 20,000,000 doses of polio vaccine is commenced according to this plan, the anticipated production costs are as shown in the table 3-3.

Table 3-3 Production Cost

	Item	Measles (1,000 Rp)	Polio (1,000 Rp)	Notes
A)	Personnel expenses	126,150	126,150	for 87 persons
B)	Consumables	86,300	86,300	HEPA filters, vessels, uniforms, others
C)	Maintenance & management	117,750	117,750	telephone, gas, special gases, cleaning, building repairs, building facility and machine repair
D)	Energy	264,000	264,000	oil for generator and boiler
E)	Materials used in manufacture	1,362,305	1,389,140	animals and their feed, pharmaceuticals, blood serum and other production components, vials, seals, stoppers
TOTAL		1,956,505	1,983,340	

Concerning E) cost of materials for production, the estimates were made by choosing the raw materials which are currently used for producing measles and polio vaccines in Japan (converted to 7.5 million doses and 20 million doses respectively) and by calculating their prices using Bio Farma's unit prices.
The cost per dose was calculated on the basis of the above figures and the following result was obtained:-

Table 3-4

Measles	Polio
261 Rp/dose	125 Rp/dose

Ordinarily, the depreciations of facility construction cost and material expenses are added to the unit price of a product. However, they were not considered in the above estimate because the present project is supported by Japan's gratuitous fund assistance.

The following table shows the prices of the two vaccines which Bio Farma imported in fiscal year 1988. The following figures include CIF, labeling, pooling and other expenses.

Table 3-5

Measles	Polio
230 Rp/dose	125 Rp/dose

Therefore, there appears to be no large difference between the production costs and the import prices.

3-3-3 Conditions of Project Site

(1) Location

The location of the present project site is near the center of Bandung. Approximately 1 km to the north of Bandung National Railroad Station. The project site is within the grounds of Bio Farma.

Bio Farma was moved to the present location from Jakarta in 1920. The site is about 250 m (east-west) x 400 m (north-south), forming almost a rectangle. Its area is about 90,000 m^2.

The site faces JL. Pasteur in the south, the hospital street and the national polyclinic hospital in the west, a 2 m wide vacant lot for infrastructure and houses in the east, and houses in the north.

JL. Pasteur is a road with a central divider and is beautifully lined with palm trees. A local agency of the Ministry of Health as well as the Geology Research Institute are located on the south side of JL. Pasteur.

The ground of Bio Farma forms a gentle rising slope from south to north. The level difference between north and south is about 7 m. The front garden facing JL. Pasteur has a well-cared for lawn, and gigantic trees which are about 60 years old. The main building has white walls of the Dutch colonial style and a tiled roof.

There are more than 60 buildings, including employees' lodging houses. The production and research facilities are connected by corridors. There is a turfed square with big trees and tennis courts at the north end of the site.

The site of this project is located in the north east corner. At present, there is a 6.5 m wide road used by oil tanker lorries etc. coming from JL. Cipaganti. A PLN sub-station (national power company) and a guardhouse are located on both sides of the entrance driveway. There is a canteen, a musholla, an animal house as well as the remaining foundations of former facilities. These foundations must be removed for the execution of this project.

According to the soil investigation report of the building extension work for the Geology Research Institute located to the south of Bio Farma, an extremely weak soil with an N value below 5 exists from the ground level to a depth of 9 m - 10 m. The soil from the ground level to a depth of about 6 m consists of silty clay. A mat foundation is difficult because differential settlement would occur easily. Even a 2-story building will need piles down to the 10 m - 11 m deep supporting ground. In fact, the building for which the soil investigation was conducted was eventually supported by concrete piles because it had three storys. Piles were also used for the 2-story building which was recently constructed for the adjacent hospital.

The geological survey of this site was conducted by a cone penetration test at 10 locations and a standard penetration test at 4 locations.

According to the survey data, an extremely soft silty clay stratum having a cone resistance value of 2 - 8 kg/cm^2 exists from the ground level to a depth of 7 m. A hard stratum exceeding 200 kg/m^2 appears only after a depth of 8.8 m.

A dense gravel stratum appears below the level of 11.4 m. A stratum with N value over 50, which can be the supporting ground for the pile foundations, appears at 12 - 16 m.

The water level in the bore holes was at 4.0 - 5.0 m.

(2) Natural Conditions

Bandung is located approximately 120 km to the south east of Jakarta, the capital of Indonesia. Although it is in the tropical zone, it has a mild climate throughout the year because its altitude is 800 m AMSL.

According to the latest meteorological data, the annual mean temperature is 22.9°C (1984 - 1988), the average daily maximum temperatures is 28.1°C (1952 - 1985), the average daily minimum

temperatures is 18.4°C (1952 - 1988), the maximum temperature recorded is 33.7°C (Nov. 9, 1972) and the minimum temperature recorded is 12.2°C (Apr. 8, 1986). The climate is comfortable, and heating and air-conditioning is not required.

The humidity is also at a comfortable level. The daily mean humidity is 80%, the maximum humidity is 100% and the minimum humidity is 33% over the past 5 years.

Concerning rainfall, Bandung does not have clearly distinguished dry and rainy seasons as in Jakarta. It rains throughout the year. The annual rainfall is about 2,000 mm. The largest daily rainfall recorded is 119 mm (Feb. 18, 1959) and the largest hourly rainfall recorded is 69.4 mm (Mar. 3, 1980).

No floods have been recorded in the past at the site of this project. There should therefore be no need to worry about the possibility of floods.

The main wind directions are west (30 - 40%) and east (20 - 30%). The mean wind velocity is about 2 m/sec. and the maximum is about 9 m/sec. The wind conditions can be said to be generally mild.

Indonesia is located in a volcanic zone, and damages by volcanoes and earthquakes have been reported. An earthquake of 5 GAL was recorded in 1979 and damages by a volcano in 1969.

(3) Infrastructure

1) Water Supply

There are five wells in the grounds of Bio Farma. They are used as the water source for all the facilities in Bio Farma. At present, three of the five wells can be used. The other two are out of order and are not being used.

Well water is showered, filtered and stored in a receiving tank (capacity 300 m^2). Then, it is lifted to an elevated water

tank (capacity 25 m^3) and supplied to the facilities by the gravity method. The water supply capacity of the wells is said to be sufficient for the existing facilities.

Bandung has a complete water service system. A main water pipe (350mmø) is located below ground level on the east side of Bio Farma. However, wells are used at Bio Farma.

According to the available data, the well-water contains a large amount of iron and manganese, and has a high degree of hardness.

2) Drainage and Sewerage System

Sewage and general waste water:
A main drain pipe is located below ground level on the east side of Bio Farma. Part of the sewage and general waste-water are discharged directly to this main pipe. However, the waste-water of the present project cannot be discharged to this main pipe in view of its diameter (about 200 mm) and the depth (GL-60 to -70 cm). The main drain pipe is connected to the main sewer which runs to the city's waste-water treatment plant.

The waste-water from the existing infusion solution production facility is treated in a septic tank and discharged by ground penetration.

Chemical waste-water:
The waste-water in chemicals is neutralized in a neutralization tank and discharged to the main drain pipe together with the sewage and general waste-water.

Rainwater:
Rainwater is discharged into the open drains which are located around the facilities.

3) Gas

Both city gas and LPG are used at Bio Farma. City gas is used for production and quality control, while LPG is used for igniting boilers.

4) Refuse Disposal

Paper, cloth, wooden refuse and garbage are temporarily stored in the ground and disposed. The dead bodies of animals are burned in the two incinerators on the site.

5) Steam

There are presently three steam boilers in Bio Farma. They supply medium-pressure steam to the facilities. The boilers are generally sufficient for the existing facilities, and they seem to have enough surplus capacity. At present, one of them is out of order and the other two are used alternately.

Diesel oil is used as fuel. Fuel is supplied from an outdoor oil tank. This oil tank supplies fuel to the generator also and its capacity is 40,000 liters. Fuel is supplied by a large tanker-lorry twice a week. The fuel supply seems to be stable.

6) Electricity

Bio Farma uses both commercial power from PLN (national power company) and power from the generators located on the site.

However, commercial power is used only for lighting because of problems concerning its reliability and quality. Its voltage and capacity are 3ø4W, 380/220 V, 198 kVA. In other words, the power used for production is supplied entirely from the generators. Its principal specifications are described below.

a. Generator rating	3 ø 4 W, 220/127 V, 50 Hz, 1,000 RPM

b.	Capacity and number	500 kW x 2, 300 kW x 2 Total 1,600 kW
c.	Operating method	- The two 500 kW generators can be operated in parallel. - The 300 kW generators cannot be operated in parallel.
d.	Maximum existing power consumption	About 700 kW
e.	Fuel	Diesel light oil
f.	Main tank capacity	20,000 liter x 2 tanks (also used as boilers)

Therefore, reliable and high-quality power from the normal service generators should be used for this project.

7) Telephone

Bio Farma has a PABX. The facilities are connected by extensions. The system is briefly described below.

a.	Type and number of line wires	Overhead, 3 lines
b.	Number of existing extensions (Maximum extension capacity of PABX)	50 lines (50 lines)
c.	Exchange method	Attendant console
d.	Location of PABX	Existing administration office

3-4 Scope of Technical Cooperation

The technical cooperation for this project is described in Memorandum of Discussion on the Fundamental Technology Transfer Project for Production of Live Attenuated Measles and Poliomyelitis Vaccines (Sep. 3, 1988). It is summarized below.

1) Bio Farma has requested the technology transfer of measles and polio vaccines to be started at the same time. However, the phasing of their project execution may be different due to the differences in the two vaccine technologies.

2) Technologies will be transfered in phases as itemized below.

   1. Transfer of fundamental technologies, including the methods of culturing, producing, managing and inspecting substrate cells for measles and polio vaccines and other testing methods

   2. Test/pilot production of measles vaccine

   3. Test/pilot production of polio vaccine (including production from imported bulk)

   4. Full-scale production of measles vaccine

   5. Full-scale production of polio vaccine

   6. Establishment of integrated production system of both vaccines

3) The period of the project will be 5 years.

4) The project leaders and senior members of Bio Farma will visit facilities of participating organizations in Japan before the commencement of the project.

5) Bio Farma will send three counterparts to Japan every year to receive training.
The list of the candidate trainees in the fiscal years of 1988/89 and 1989/90 has been submitted.

6) The list of the equipment to be used for the present project is included in the Appendices of this Report.

7) CAM-70 is to be used as measles vaccine stock because it has been successfully used in Japan and South American countries since 1970. Small-scale comparative field studies between the currently-used measles vaccine in Indonesia and CAM-70 vaccine will be conducted to validate the adoption of the CAM-70 strain.

8) When the pilot products of measles and polio vaccines become available, small-scale field studies will be conducted to confirm their safety and viability.

9) WHO's standards will be applied to both the measles and polio vaccines.

10) An application to WHO for the production of Oral Polio Vaccine (OPV) (Sabin) stocks of polio vaccine at Bio Farma will be made prior to the basic production of vaccines.

CHAPTER 4 BASIC DESIGN

CHAPTER 4 BASIC DESIGN

4-1 Basic Design Policy

The following items constitute the basic design policy after considering the contents and requirements outlined in Chapters 2 and 3.

(1) Building and Facilities

1) Provision of Functions

The facility is for the production of measles and polio vaccines. These vaccines are different from other vaccines in that the antiserum bacteria must be kept alive from the start to the end of the production process, and therefore sterilization and disinfection must not be carried out at all for any of the processes. This is to say that the facilities require that production and quality control (GMP) be performed so that an extremely high level of cleanliness, which does not permit the entry of other types of bacteria, is maintained. This GMP is set to international standards and if an inspection according to WHO standards is not passed, the attenuated polio virus Sabin strain that distributes the antiserum for polio in particular, will not be supplied. Because of this, the most important factor of the basic policy is that the facilities satisfy the GMP standards.

2) Facility Scale

The scale of the facility is set at that which can bring about the transfer of basic technologies for the production of measles and polio vaccines. However, the facility must be of a size that is able to produce 7.5 million doses of measles vaccines and 20 million doses of polio vaccines per year. Because of this, the facility must also provide for the quality control of the vaccines produced, as well as for animal houses for the supply of the necessary materials for vaccine production.

3) Reducing the Construction and Operation Costs

Since the facility requires a high level of cleanliness, the internal finishes of the building and the air conditioning facilities will account for almost double the proportion of the

construction costs than they would normally, and so the production and related facilities must have their costs reduced to the minimum, and existing facilities used wherever possible. These items include the storerooms for the final products, the boilers, generators and other energy supply facilities. The structural plan will be rational, and the facility and equipment plan will be designed to allow for further reductions in the energy consumption.

4) Design Suitable for the Environment

The facility is to have a high degree of livability suitable for the climatic conditions of Bandung where the site is located. Moreover, the design should also ensure that there is no disharmony with each of the Bio Farma facilities that is already on the site.

5) Basic Policy for the System Planning

The system planning will have priorities given to function and minimization of running costs. The selection of systems and equipment should ensure easy maintenance and high reliability with respect to the local climatic conditions.

6) Basic Policy for the Selection of Equipment

The equipment should be selected with priority given to function rather than to automation and precedence should be given to equipment which utilizes local labor. The equipment should also have high durability, good operatability and high reliability.

4-2 Setting the Design Conditions

The basic design should be planned so as to incorporate the various design conditions determined on the basis of the previously described basic design policy.

The design conditions are the functional conditions that the facility has to satisfy; the legal conditions that it must satisfy as a building; natural conditions such as weather and topography; the infrastructure conditions; operation and management conditions; conditions imposed by local customs, manners and religion; and the various technical and budgetary conditions relating to the building. Amongst these conditions are some that are contradictory, and it will be important to set the conditions appropriately. The following conditions are considered to be relevant for this project:-

(1) Functional Conditions

- To have the measles vaccine and polio vaccine production facilities completely separated.
- To preferably have the receiving of feed for the test animal and the transportation out of waste substances performed from the first (ground) story.
- To have the quality control area separated from the production area.
- To have zoning in accordance with the level of cleanliness required for each of the production processes.

(2) Legal Conditions

- To satisfy the laws relating to buildings, electricity, water supply and drainage, and the environment, as well as the building laws of Indonesia.
- To satisfy the standards for fire prevention and other fire regulations of Indonesia.
- To go through the relevant Indonesian organizations for all applications and approvals relating to the building.

(3) Natural Conditions

- Site location: 7°S, 107.5°E; Altitude: 760m (above sea level)
- To consider the low sun penetration from the east and west, and the high sun penetration from the north.
- Annual average temperature: 22.9°C; Maximum daily average temperature: 28.1°C; Minimum daily average temperature: 18.4°C; Maximum recorded daily temperature: 33.7°C; Minimum recorded daily temperature: 12.2°C
- Annual rainfall: 2,000mm; Maximum recorded daily rainfall: 119mm; Maximum recorded hourly rainfall: 69.4mm
- The soil has a soft silty clay to a depth of 7 meters, and the stratum that can support pile footings occur at a depth of 13-17 meters.

(4) Infrastructure Conditions

- All of the power is to be supplied by generators on the site.
- The existing telephone exchange should be replaced with the most up-to-date system to ensure sufficient capacity.
- Water is to be supplied from wells.
- Drainage is to be discharged to the sewers after treatment.
- Gas is to be provided by city gas.

(5) Operation and Management Conditions

- Operation and management of the measles vaccine production, the polio vaccine production, the quality control and the animal facilities is to be provided by expert staff at the respective facilities.
- Work pertaining to the management as a company is to be undertaken by the existing facility.
- The existing canteen, the energy-related rooms (generator rooms and boiler room), and the existing storerooms are to be used as part of the present project.

(6) Local Customs, Manners and Religious Conditions

- Indonesian-style toilets are to be used (with water faucets in the toilet cubicles)
- The work efficiency of the Muslim construction laborers will drop when they observe fasting during the fasting season.

(7) Construction and Technical Conditions

- There are few clean room technicians and so the guidance of Japanese technicians is essential.
- The equipment and materials for the clean rooms (wall boards, flooring materials, sanitary corners, seal materials, epoxy paint, air handling units, HEPA filters and lighting fixtures for clean room etc.) will practically all be imported products.
- The delivery of construction materials and equipment will require an approach from the eastern road (JL CIPAGANTI).

(8) Budgetary Restrictions

- Local materials and local methods are to be used to reduce the initial cost for as long as this does not affect the functional requirements beyond the acceptable range.
- In order to raise the operating efficiency, the plan is to use systems that will lessen running costs.

4-3 Basic Planning for Facilities

4-3-1 Setting the Facility Scale

The scale of the facility for the production of live vaccines, for which there are very few precedents, was determined by experts from BIKEN and JPRI who reviewed those facilities currently in operation in Japan. The conclusion of their study and the opinions of the on-site experts were used as a reference to determine the sizes of the necessary rooms. BIKEN and JPRI received the WHO inspection in November, 1988 and in 1979 respectively, and have been designated as having satisfied the GMP standards. However, since almost 10 years have passed since JPRI was inspected and because the standards have changed slightly since then, these changes have been incorporated into the sizes of the rooms and the layout, etc. However, when compared with facilities currently in operation, both facilities have practically no differences as far as the room types and sizes are concerned.

At BIKEN, the average annual production of measles vaccine is 1.5 million to 2 million doses and at JPRI that for polio vaccine is about 3.5 million to 4 million doses. Because of this, both facilities have an average operating ratio of 1 to 2 times a week. Since the operating ratio of the Bio Farma facility is to be 4 to 5 times per week, it has been determined that the facility will be able to manufacture the necessary 7.5 million doses of measles vaccine and 20 million doses of polio vaccine. In other words, it will be possible to produce the necessary amounts of vaccines only if both facilities are of the same level as BIKEN and JPRI, and if both facilities are in full operation throughout the year. The size of the proposed facility is considered to be the smallest practicable size for such a facility.

Furthermore, in order to make the scale economical, there are to be shared facilities for the measles and polio sections for as far as is possible, and as explained in chapter 3-2-2, the area of the new facility to be constructed will be further reduced by using existing buildings for the storage of the final products and the manufacturing equipment, by placing the meeting room, rest area and the kitchen zone in existing buildings, and by also using the existing boiler and machine rooms.

Table 4-1 shows a comparison of the standard room sizes related to production as indicated in the WHO "Manual for the Design, Equipping and Staffing of Facilities for the Production and Quality Control of Bacterial Vaccines," and the sizes of the rooms for this project. The WHO standards are for the production of 1.5 million doses of vaccine for the bacteriological diseases of diphtheria, pertussis and tetanus, and are not specifically for production by cell culture as will be the case for this facility. Nevertheless, it is thought that there are many parts of the standards that are applicable. Moreover, the process of increasing the number of manufacturing cycles without altering the basic units has already been described as sufficient to produce the necessary amounts.

Table 4-1 Comparison of Areas

WHO standards		This project	
Room name	Area sq.m	Room name	Area sq.m
Materials storage	25	Storerooms (for measles, polio)	27
Records storeroom	25	Office areas (with record store, 1 room each for polio, measles)	22x2
Changing rooms (6 persons)	25	Changing rooms (42 persons)	45x2
Seed culture preparation room	25	Cell culture room	25 26
Incubation room	25	Virus inoculation room	49
Harvest room	50	Harvest room (polio)	39
Blending room	25	Blending room (polio)	70 (measles)
Filling area	75	Filling + ancillary spaces	75 (polio)
Packaging and labeling	50	Packaging, labeling room (shared for measles, polio)	36

According to this table, it can be seen that the main rooms of the production facility are close to the standard sizes.

For the animal houses, the room sizes are determined by the number of animal cages and the work spaces required. For example, the monkey houses are as shown below. The corridor in the middle is the minimum dimension for a person to pass through beyond the reach of the monkeys with their arms extended.

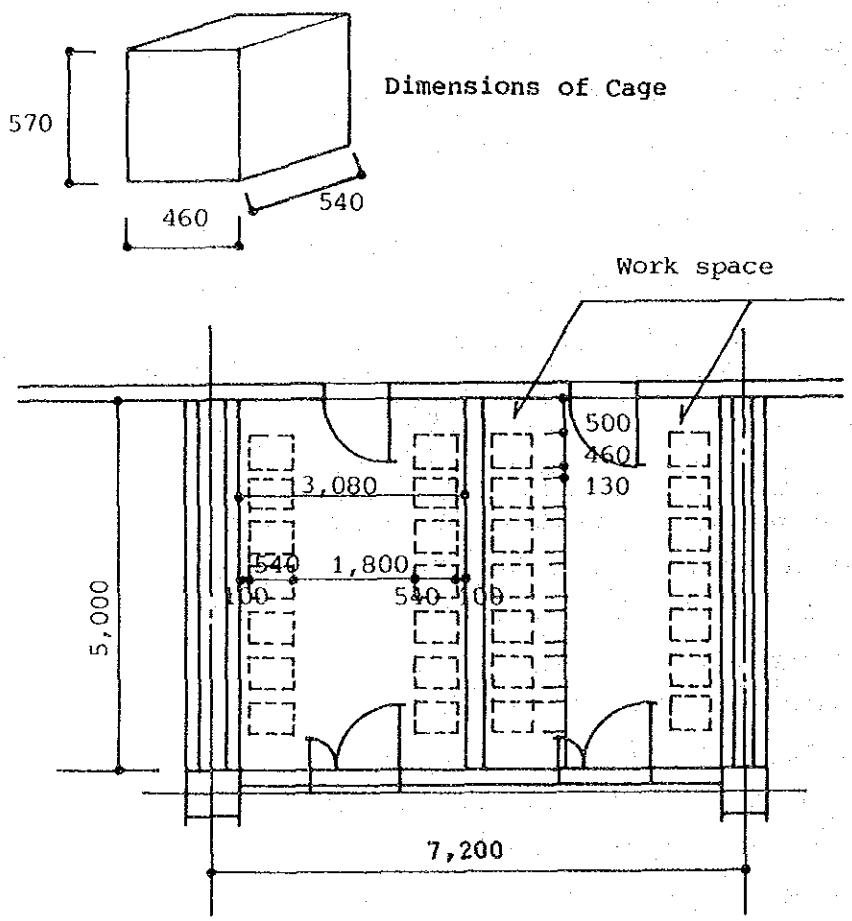


Fig. 4-1 Cage Layout for Cynomolgus Monkeys

The SPF chicken houses have enough space for 20 isolators, with one rooster and four chickens per isolator.

For quality control, the quality control tests indicated in the appendices must be performed. Also, the clean areas are designed to take up less space by having various rooms (such as the cold store, the cell culture rooms and the clean testing rooms) used for both polio and

measles. Practically all of the pathological testing laboratories can be used in common, and the space required for them does not differ greatly from that of facilities currently in operation. When the production facility is in full operation, it will also be possible to have the quality control facility in full operation. As a result of a study into all of these matters the sizes of the various facilities are as indicated in Table 4-2.

Table 4-2 Floor Area Requirements

Section	Usage			Floor Area
Production Section	Measles	cell culture, virus culture, incubator, pooling, cap sealing, filling, preparation	812	
	Polio	cell culture, virus culture, prep. of cell culture, blending, filling, incubator	964	
	Media	media preparation, media filtration, cold for media, freezer	169	2,859
	Joint usage	washing, pure water prep., packaging, storage	408	
	Other	record room, lockers, toilets, corridor, stair	506	
Quality Control Section	Measles	observation, virus titration, cell culture	95	
	Polio	control cell, observation, neutralization, marker test	188	
	Joint usage	sterility test, cell culture test, cold room, washing	603	1,553
	Testing	pathological testing room, immunological testing room	289	
	Other	office, rest room, locker	378	
Animal Section	Measles	SPF chicken breeding, seed chicken breeding, incubator	286	
	Polio	cynomolgus monkey, green monkey, feed preparation	573	1,759
	Joint usage	washing, house for test animal, feed preparation	641	
	Other	locker, corridor, rest, entrance	259	
Other	Mechanical	air conditioning equipment room, plumbing equipment room		958
TOTAL FLOOR AREA				7,129

4-3-2 Block Plan

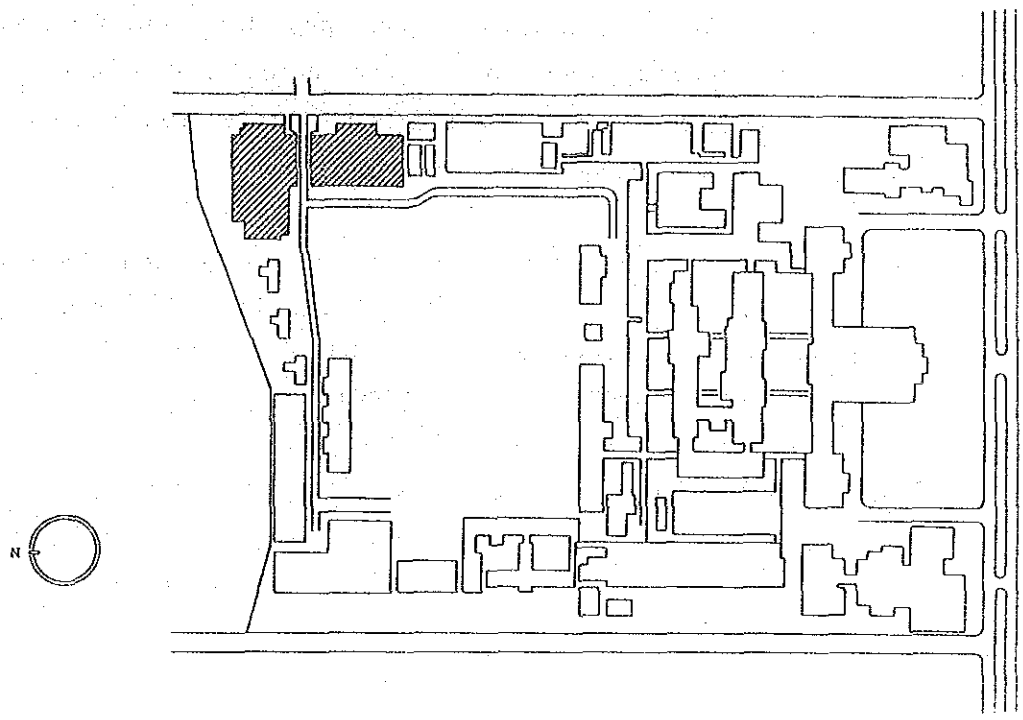


Fig. 4-2 Site Plan of Bio Farma

The following are the points that have been considered in the planning of the site layout:-

(a) Consideration of the relationship with the existing Bio Farma facilities.
(b) Consideration of the direction of the prevailing winds, so that animal odors do not affect nearby residents.
(c) Utilization of the natural slope of the site.
(d) Rational building layout for optimum services and electrical routes.

In consideration of all of these points, the axis of the building will be set north-south as shown in the plan above. In this way, the existing road and the PLN (power receiving room) are not affected and optimum use will be made of the prevailing winds.

Moreover, by setting the building axis north-south, the rainwater and the water discharged from the laboratories can flow naturally down to the processing facility.

The layout has the animal sections on the north side facing the road, for management purposes since there will be considerable traffic of pedestrians and goods, while the management and inspection sections will be located on the south side because of the relationship with the existing Bio Farma facilities. Moreover, the second story will house the production section in order to raise the operating ratio.

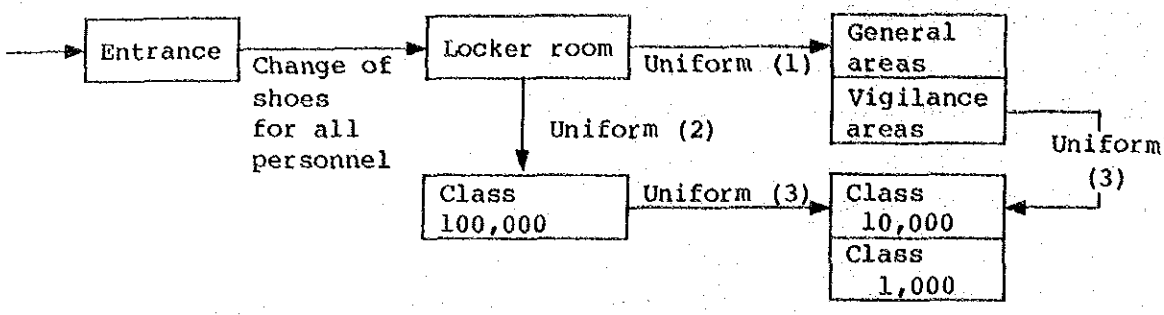
The machine room and other facilities such as the pumps and the water processing facilities will be in a separate building located between the main building and the existing buildings.

4-3-3 Architectural Planning

(1) Floor Plan

1) GMP Standards and Clean Rooms

Because of the specific functions of each room of this facility, the levels of cleanliness are divided into the six classes of 100, 1,000, 10,000, 100,000, a vigilance area (of 300,000) and a general area (for cooling and ventilation only). When entering zones with a level of cleanliness of 100,000 or higher, the GMP standards stipulate that the work clothes must be changed in accordance with that level of cleanliness. Moreover, for the movement of goods between zones, different levels of cleanliness must be ensured by using pass boxes or pass rooms. Because of this, it becomes extremely difficult to perform work unless rooms between which there is to be frequent movement of people and goods do not have the same level of cleanliness. Increasing the level of cleanliness entails spending more money initially on not only the finishing materials of the room, but also for the number of air changes that the air conditioning equipment has to perform, the use of special lighting fixtures and their running cost, etc. In this plan, the levels of cleanliness will be classified so as not to exert an adverse influence upon the work being performed, and class 100 will use downward laminar flow only, with the area for class 10,000 kept to the minimum. The basic plan for changing clothes within the facility is shown in the diagram on the next page.



Uniform (1) .... Changing hats, coats, trousers

Uniform (2) .... Changing hats, coats, trousers and shoes (for dustproof costs; for Class 100,000)

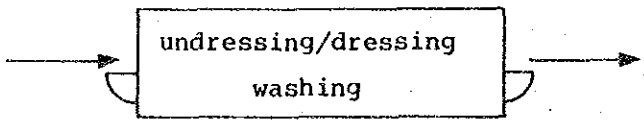
Uniform (3) .... Hats, coat, trousers (or one-piece dresses), Shoes, masks, socks (all dustproof, for Class 1,000, 10,000)

Fig. 4-3 Uniform Changing Sequence for Clean Rooms

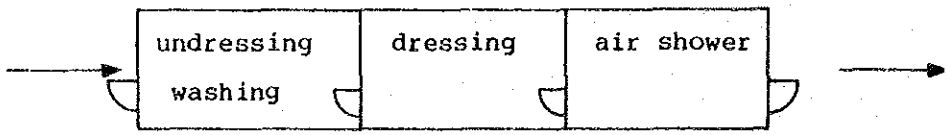
Accordingly, it will require two changes of clothes in order to enter rooms having a level of cleanliness of class 10,000 or 1,000. The reason why all rooms are to have air conditioning is that there is the fear of the entry of insects, small animals and dust that would contaminate the clean rooms. This is the reason why all personnel have to change their outer shoes.

The changes of clothing required in order to enter clean rooms with levels of cleanliness of class 100,000 or higher is shown in the diagram below.

a. When entering class 100,000



b. When entering class 10,000 or 1,000



2) Manufacturing Process and Floor Plan

Figs 4-4, 4-5, 4-6 and 4-7 are flow charts and plans indicating the process for the production of the measles and polio vaccines. As seen in the flow charts, the difference between the processes for the production of the measles vaccine and the polio vaccine is that when the incubators and other equipment used for production are returned to the washing room, it is satisfactory to perform disinfection for only the equipment from the virus culture section for measles whereas in the case of polio, it is necessary that everything be returned for sterilization. This is because of the fear that the equipment used could have been contaminated during any of the processes.

Moreover, the annual amount of measles vaccine to be produced is 7.5 million doses but in the case of polio vaccine, it is necessary to produce about 20 million doses which is about three times the amount of measles vaccine. Because of this, each of the processes for the measles vaccine (cell culture, virus culture, filling, freeze drying) are to use exclusive autoclaves, dry ovens, and pass boxes so that the production equipment can be passed into the clean rooms. However, in the case of the polio vaccine, the same equipment will be used in order to reduce the number of expensive autoclaves required.

Contaminated equipment will pass through the dirty corridor and then be sterilized in a single autoclave, before it is returned to the washing room. Strictly speaking this is not a desirable method since there is the danger of cross contamination but it solves the problem of shifting the timing of the production process (so that cell treatment is done on Monday, and virus treatment on Tuesday, etc.). Basically the classification of clean rooms is as follows:-

Fig. 4-4 Measles Vaccine Production Process Diagram

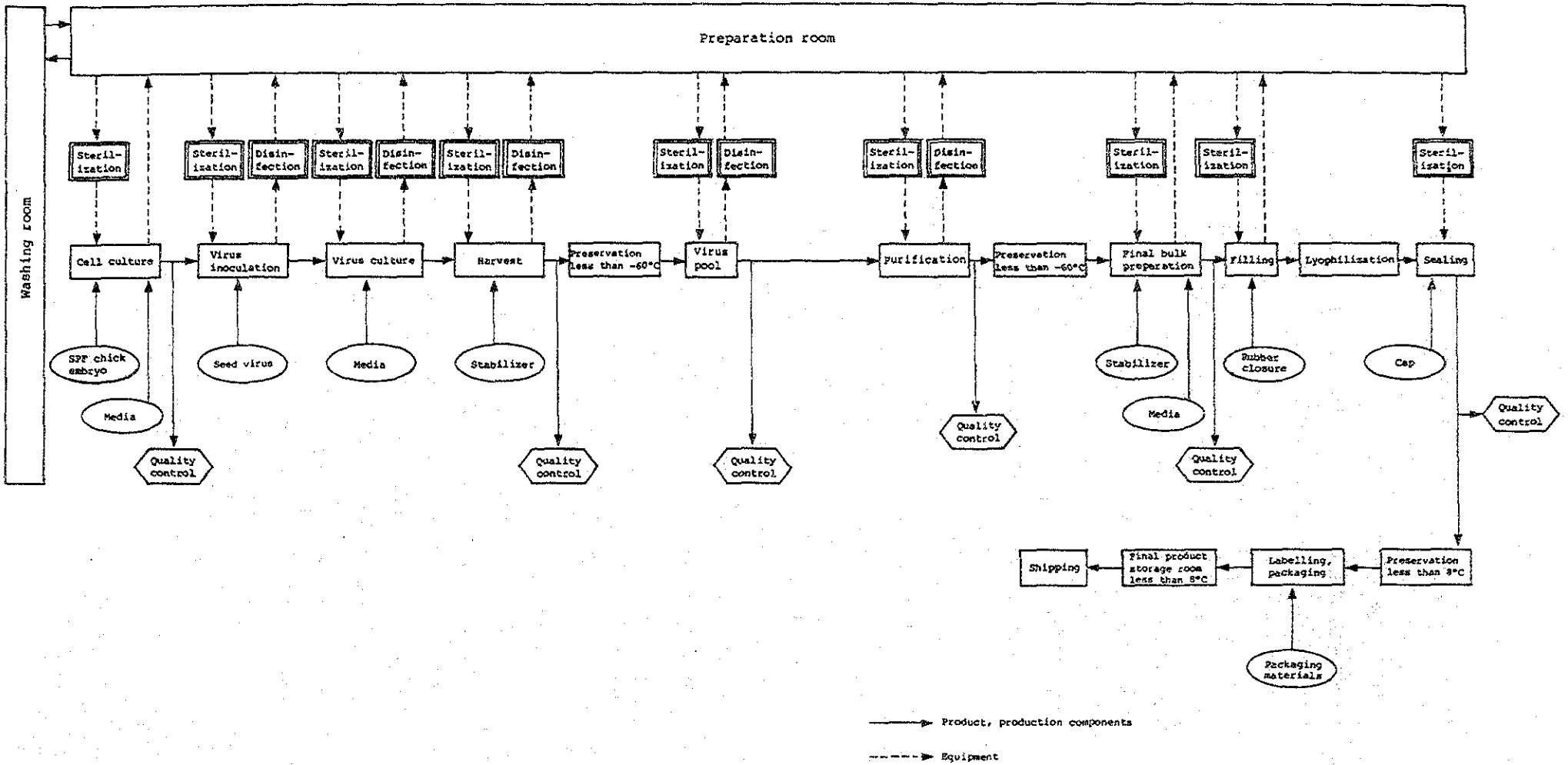
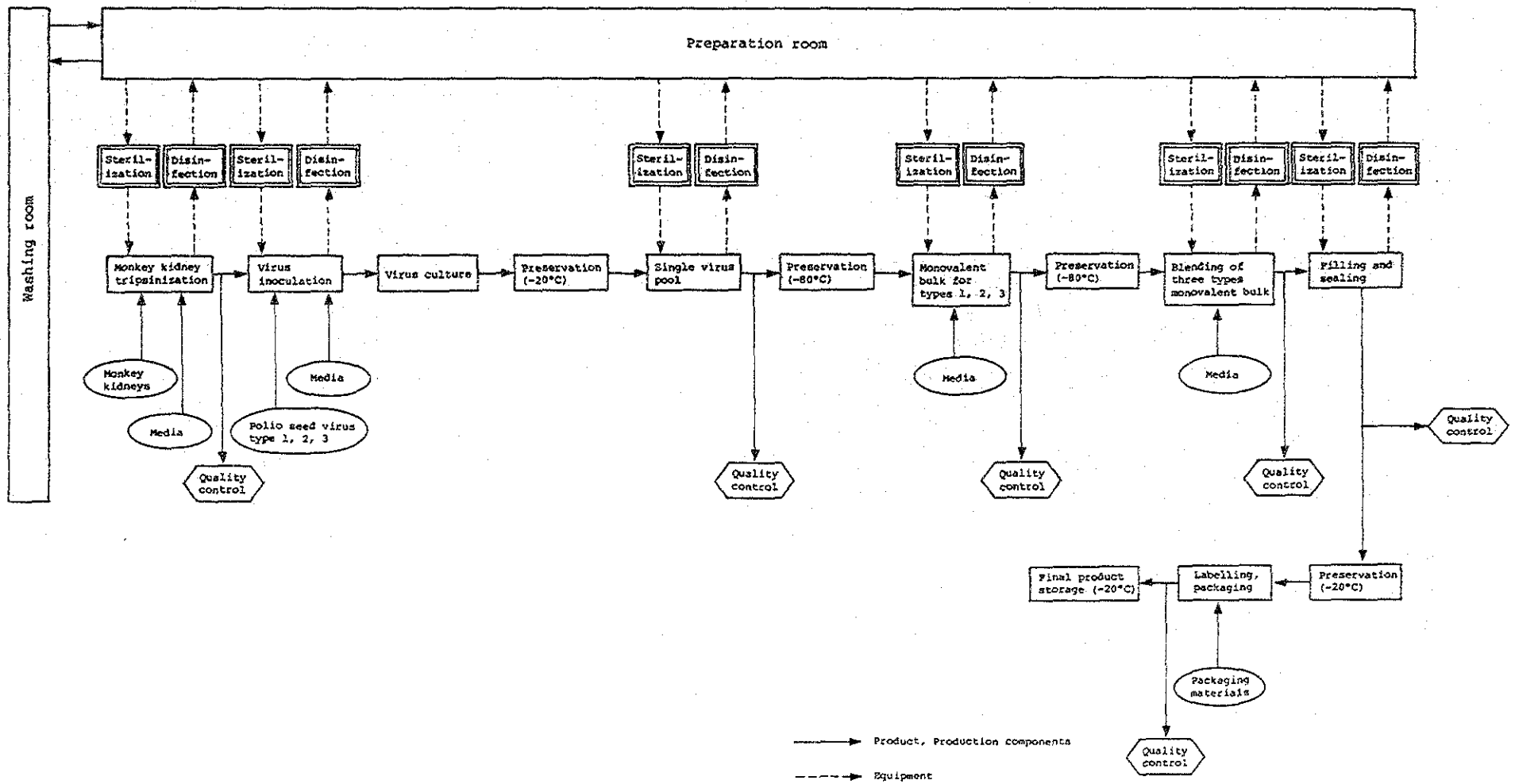
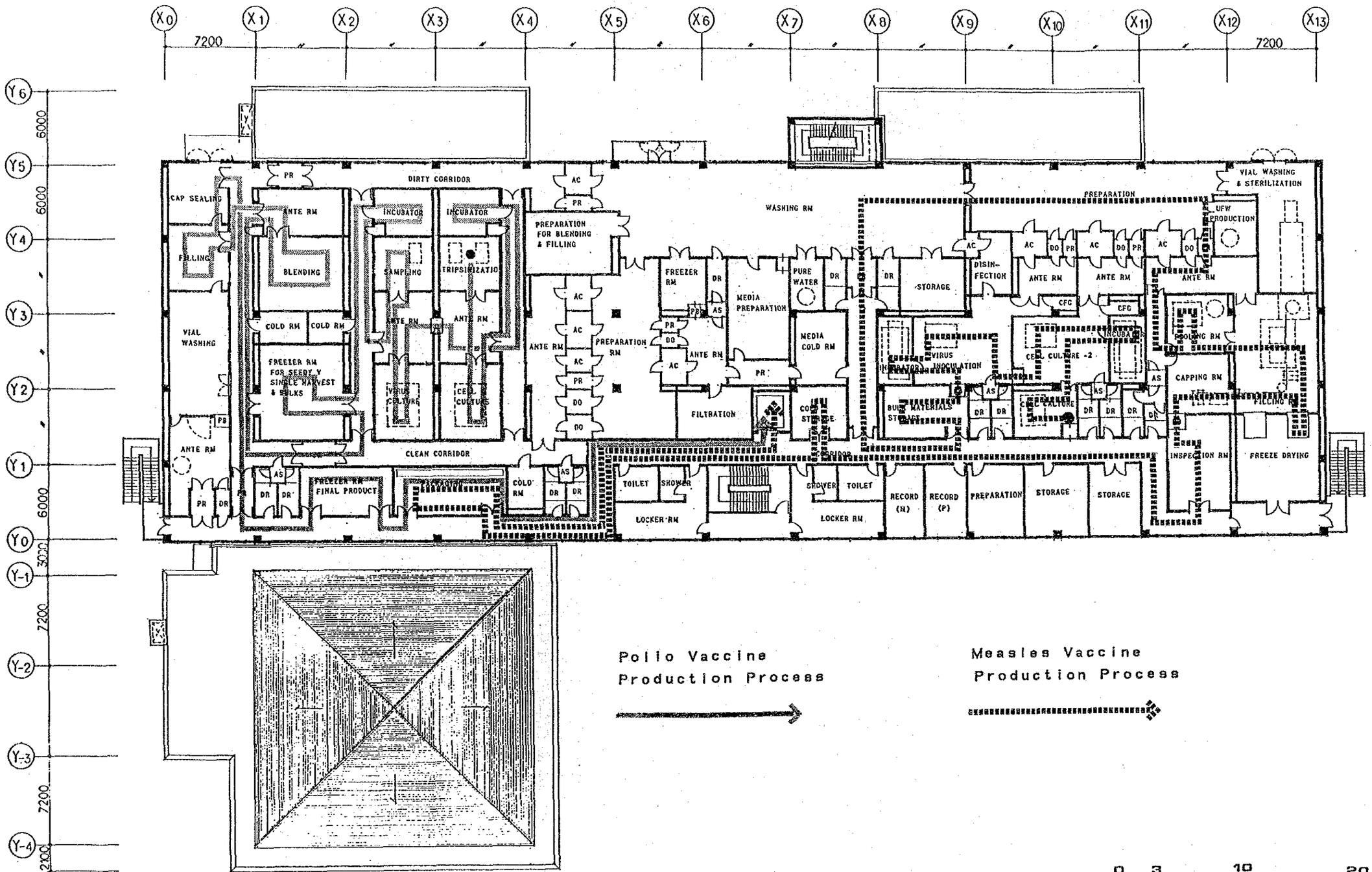


Fig. 4-5 Polio Vaccine Production Process Diagram





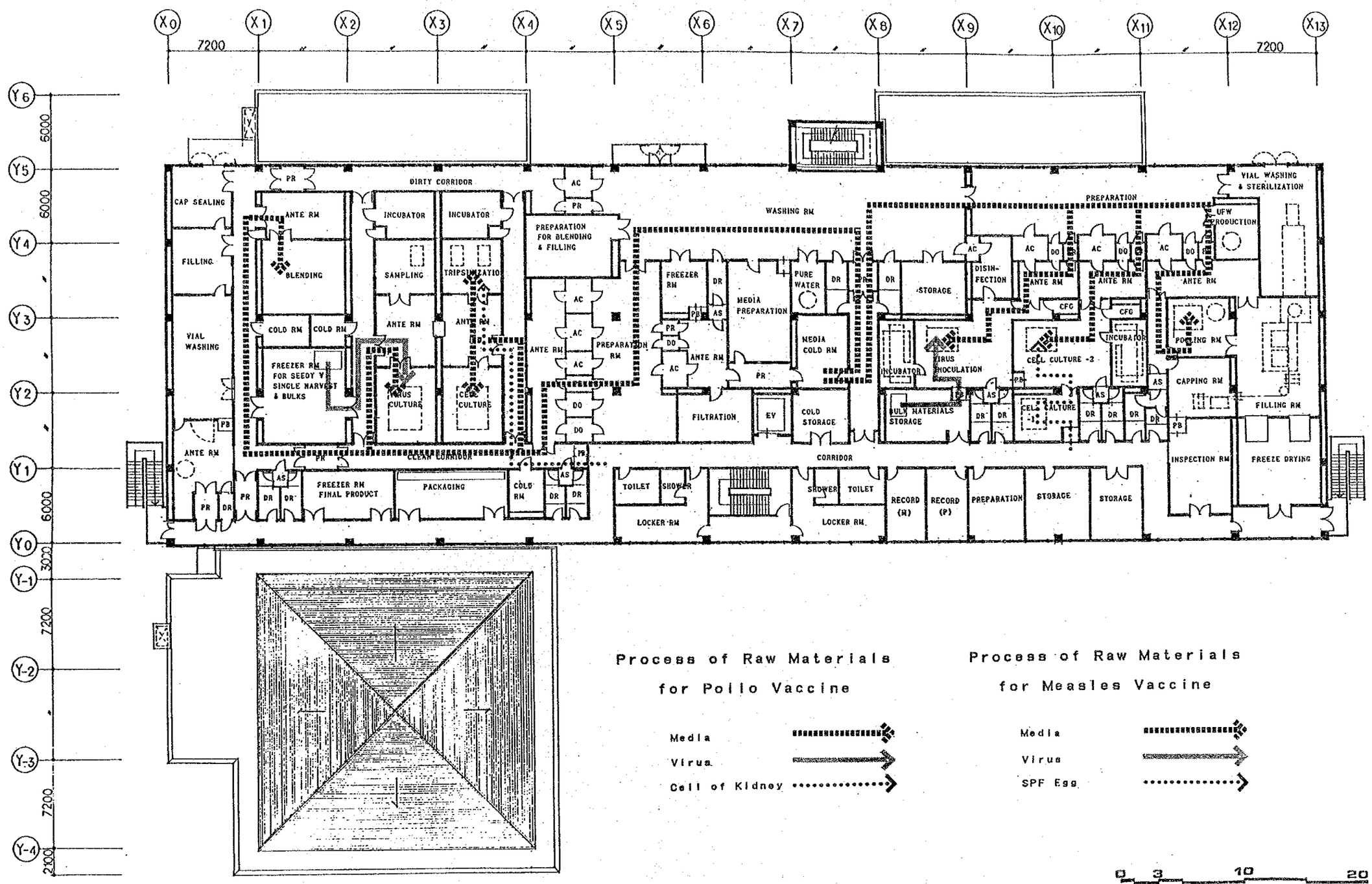
Polio Vaccine Production Process

Measles Vaccine Production Process

Fig. 4-6 Production Process Plan

0 3 10 20
1 5 15

SECOND STORY PLAN



Process of Raw Materials for Polio Vaccine

Media
Virus
Cell of Kidney

Process of Raw Materials for Measles Vaccine

Media
Virus
SPF Egg

Fig. 4-7 Process of Raw Materials Plan

0 3 10 20
1 5 15

SECOND STORY PLAN

Class 100	under laminar flow
Class 1,000	pooling room, capping room, filling room and ante room for measles
Class 10,000	rooms which have laminar flow and other rooms, including corridors, which are connected to those rooms with laminar flow
Class 100,000	other clean rooms
Vigilance area (class 300,000)	other rooms except locker room and staircases

The floor plan considers all these aspects of the manufacturing process and has the associated rooms for the production of the measles and the polio vaccines separated by the washing room and the media room that are to be used jointly.

Moreover, since the production of the measles vaccine involves machines that create a great deal of vibration, it is arranged not above the animal houses but above the quality control sections.

3) Quality Control (QC)

This is an important facility for certifying the safety and effectiveness of the products, and the GMP standards contain stipulations for the provision of a quality control section and for that being organized separately from the production section. The facility is to be divided into clean room areas for the sterilization laboratory and the cell culture laboratory, and into general areas for the pathological laboratory and the immunological laboratory and others. The clean room areas contain the laboratories for the measles and polio sections, as well as the laboratories, cold store, and the incubators for joint usage. The level of cleanliness is to be 10,000 for the sterilization laboratory only, and 100,000 for the remainder.

4) Animal Houses

These facilities consist of two sections. One section contains the chickens and the monkeys which supply the sterile cells that form the base for the measles and polio vaccines. The other section contains the monkeys, rabbits, mice and guinea pigs to be used in testing. The greatest fear here is that of cross contamination between the animals and so each section will be separated, and the workers will be required to change clothes when passing from section to section. Workers entering the animal facilities from the clean corridor will go back through a door to the dirty corridor, leave their contaminated clothes in the locker room, change into their regular work clothes and re-enter the building from the general area once again.

5) Structural Layout

The module for this facility was set at 1.2 meters, with 5 times this length (i.e. 6 meters) being used in the short direction, and 6 times this length (i.e. 7.2 meters) being used for the longitudinal direction.

The 7.2 x 6.0m span divisions are close to the values that are considered to be an economical span ratio in the case of reinforced concrete construction. The production sections on the second story have an unregulated layout consisting of both small and large rooms. There is therefore a large amount of potential flexibility with respect to future changes. The second story is the top floor and so heavy items cannot be brought in. Because of this, the spans in the short direction were made 12-6-12 meters with the 12-meter parts having steel or prestressed concrete frameworks to support a roof made of local tiles. The central 6-meter span is for the machine room which can utilize the additional space under the roof.

(2) Sectional Design

1) Setting the Level of the First Story

The site for this project declines by a maximum of 2 meters from south to north. The level of the first (ground) story is at about the middle of this slope across the site in the east-west direction, and was set from the level of the existing service road, to be approximately 0.45 meters (AP = 764^{M}.280). Moreover, the proposed pipework would be below the floor in a trench, whose invert level is 1FL-2.0 meters. Because of this, the bottom of the cut is 0.7 meters from the current ground level at the northern end, and 2.340 meters from the current ground level at the southern end.

2) Floor and Ceiling Heights

Since more than half of the facility is to have clean rooms, a high ceiling would mean that a larger volume of air would have to to be purified, therefore resulting in increased expenses. However, a sufficiently high ceiling (as high as 3 meters) is required so that the required laminar flow can be produced. The ceiling height in facilities of this type is normally in the range of 2.7 to 3.0 meters and after taking this into consideration, the ceiling height was finally set at 2.7 meters. The floor-to-floor height was set at 5.1 meters because of the 1.6 meters depth required for the ducting for the clean rooms, and 0.8 meters minimum depth required for the beams. Compared to the first story, the second story has more rooms that require a high level of cleanliness and so the duct space becomes greater than that for the first story. But at both ends of the 12-meter spans, there is still sufficient space where the roof slopes down and so the floor-to-floor height for the central 6-meter span (with the machine room above it) was set at 5.1 meters.

(3) Finishes Schedule

In selecting the internal and external finishes the following points were considered:-

a. Basic Concept

The finishing materials were selected on the basis of the following points according to the guidelines of the GMP standards for clean rooms:-

(1) Anti-friction surfaces that do not flake or peel
(2) Difficult for dust to adhere to
(3) Do not produce problems with static electricity
(4) Excellent thermoconductivity and thermal characteristics
(5) Resistant to moisture penetration
(6) Difficult for cracks or holes to appear
(7) Vibration resistant
(8) Easy processing for joints with other materials
(9) Can be formed into any shape
(10) Can be produced in sanitary (white or off white) colors
(11) Easily replaceable

Local materials are to be used as much as possible for all other finishes so as to reduce the cost, to improve the workability and to facilitate maintenance.

The following internal and external finishes are to be used on the basis of this approach:-

b. External Finishes Schedule

Roof: local tiles for pitched roofs, asphalt and waterproof paint for the flat roofs (machine room portion)
External walls: sprayed textured coating trowelled over mortar on brickwall, sprayed textured coating trowelled over mortar on concrete walls
Building fittings: aluminum windows (double glazing in the clean rooms), steel door, aluminum louvers (with insect screens)

c. Internal Finishes Schedule (See Table 4-3)

Table 4-3 Internal Finishes Schedule

level of clean-liness	Room name	Floor	baseboards	Wall	Ceiling
100 | 1,000	Cell culture, cell culture preparation, ante rooms Virus culture, virus culture preparation, ante rooms	Epoxy resin coating (Mortar trowelled base)	Epoxy resin coating (Aluminum backing base)	Ceramic board	Ceramic board
10,000	Media filtration, blending room, others			Silicon joint	Silicon joint
100,000	Washing, preparation (rooms for washing)	↑ (Water-proof asphalt)	↑	Epoxy resin coating (taperboard base)	Epoxy resin coating (taperboard base)
	Animal houses	↑	↑	↑ (mortar base)	↑
Vigilance area (300,000)	Packaging, bulk materials store, inspection, corridors	PVC tiles	Aluminium	Paint (taperboard base or brick and mortar trowelled base)	Paint (taperboard base)
Air conditioning only	Offices, lockers, pathological examination rooms, general corridors	PVC tiles	PVC	Paint (plasterboard base or brick and mortar trowelled base)	Mineral acoustic tile
	Washing rooms (QC and animal houses), toilets	Mosaic tiles (waterproof asphalt for 2nd storey toilets)	Ceramic tile	Ceramic tile (brick and mortar trowelled base)	Mineral acoustic tile

(4) Structural Planning

1) Frame Planning

The structure was simplified as far as possible to a two-story building with a building coverage of approximately 94m x 30m, and a one-story building with a building coverage of approximately 27m x 24m, linked by an expansion joint. Both buildings are of reinforced concrete construction in a rigidly connected frame. However, the pitched roofs are of steel frame or pre-stressed concrete construction.

The two-story building has a 6.0 x 7.2m span for the first story portion and 12.0 x 7.2m and 6.0 x 7.2m spans for the two-story portion. This is to withstand the weight of the vaccine production equipment on the second story, and to ensure a greater degree of flexibility. This building is a long building 94m in length and so a rigid foundation beam is placed beneath the first story and efforts should be made to prevent subsidence occurring as a result of the piling work.

2) Foundation Planning

The gravel layer having a minimum N-value of 50 which appears at GL-13m to -17m is the layer that will serve as the support for the pile foundations. The piles are to be 400mm square or 450mm diameter piles of pre-stressed concrete and are to be driven. The vibration and noise caused by the pile driving is thought to be within acceptable limits since the location where the piles are to be driven is at least five meters from existing buildings.

In the course of conducting the pile driving work, test piles are to be driven for approximately 3 to 5% of all the piles in order to determine their lengths, and loading tests are to be carried out for two or three piles so as to confirm their strength.

3) Seismic Planning

In accordance with Indonesian regulations, the base shear coefficient for the building is to be Cd = 0.15. This was determined from the fact that the building will be in ZONE 3, the soil is SOFT SOIL, the importance coefficient is I = 1.5 and the structural characteristics coefficient is K = 1.

4) Materials Planning

The concrete is to be ready-mixed concrete produced on-site. The strength is to be FC210 or FC240. The steel reinforcements are to be those that conform to Indonesian Industrial Standards (SII).

(5) Building Services Planning

1) Electrical System Planning

a) Generator System

The existing generator system will be upgraded in order to ensure the electrical power required for this project. Specifically, this means that of the existing four generators, the No.1 generator and the No.3 generator will be replaced with 500kW to 600kW generators. In addition to these, the No.2 generator (500kW) and the No.4 generator (500kW) will be given new control panels. If this is done, synchronizing operation will be possible for all four generators and the efficient operation of the generator system will be ensured.

The power generation rating will be 3-phase, 4-wire, 380/220V, 50Hz, 1500 RPM.

b) Main and Submain System, and Motor Control System

These will also be upgraded along with the power distribution panel in the existing sub-station. In order to improve the reliability and the ease of maintenance, the main power lines will be duplicated and installed under the ground from the existing power plant to the new facility.

The distribution voltage will be 3-phase 380V for the motor, and single-phase 220V for the lighting and general-purpose receptacles. If necessary, single-phase 100V power will also be provided.

c) Lighting and Receptacle System

The illumination will conform to Japan Industrial Standards (JIS). The fluorescent light will be the most commonly used because of its high efficiency. The clean rooms will have special lighting fixtures in accordance with the grade of cleanliness required.

The receptacles will be positioned and have the specifications determined after a detailed study into the types of power, the capacities required, and the methods of connection, etc. Outdoor lights will be provided for the grounds as a security measure.

d) Lightning Protection and Earthing System

The facility is in a region where there is much lightning activity and so the building is to be provided with a rooftop lightning conductor system. Earthing will have to be provided for the production equipment and the analysis equipment etc. according to necessity.

e) Telephone System

The existing telephone exchange will be replaced because of its age and insufficient capacity. A new electronic type exchange having sufficient capacity will be installed. Terminal boards will be provided within the facility and conduits and wirings will be provided to rooms where telephone sets are to be installed.

f) PA System

Speakers will be installed in the corridors and other suitable places to facilitate Public Address (PA) announcements and emergency messages. The microphone and amplifier are to be installed in the administration office.

g) Interphone System

Interphones will be installed in places where equipment maintenance and communication are necessary such as between each of the machine rooms and the administration office, and between the front and the rear side of autoclaves.

h) Battery Clocks

Battery clocks of a suitable design will be provided for the administration office and the rest areas, etc.

i) Security System

An unauthorised entry detection system will be provided to prevent virus cross contamination and to maintain the cleanliness of the clean rooms for the safety of the vaccine production.

j) Automatic Fire-Alarm System

An automatic fire alarm and detection system will be provided to detect fire at the earliest stage automatically. A gas leakage detection system will also be provided in places where combustible gases are handled. The "Fire Prevention Code of Indonesia" will be applied as the installation criteria.

2) Plumbing System

a) Water Supply System

Water source: The wells on the Bio Farma site will be used as the water source. The amount of water used by the facility is estimated to be 200 m^3 per day. If the water supply capacity of the wells is insufficient, then it will be necessary for the number of wells to be increased. This will be the responsibility of the Indonesian Government.

Water quality: According to data obtained from Bio Farma, the water from the wells has a high degree of hardness and a high content of iron and manganese. Therefore, water treatment will be necessary.

Water supply flow: As indicated in Fig. 4-8, the water from the Bio Farma wells is first stored in a receiving tank (prior to processing) and then passed through a softener, through devices to remove the iron and manganese, and stored. It is then piped by lift pump to an elevated water tank and supplied by gravity to where it is required. The water is also treated with chlorine to remove harmful bacteria.

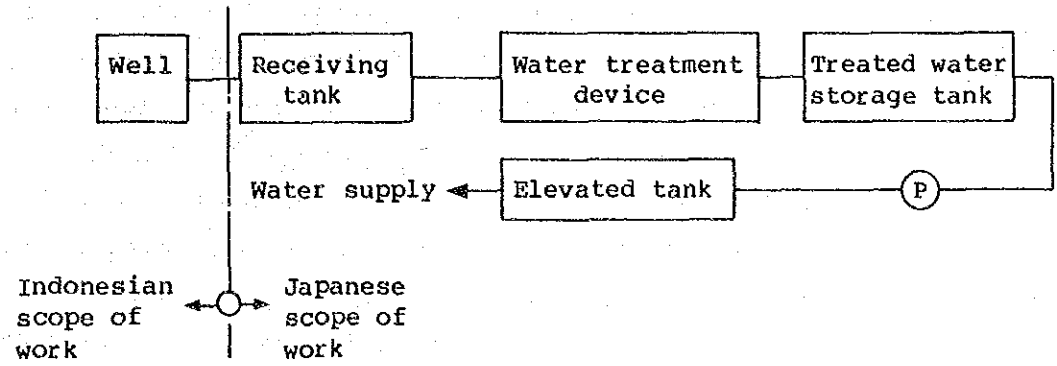


Fig. 4-8 Water Supply Flow

b) Hot Water Supply System

Hot water from a central storage tank heated by steam will be supplied to the measles and polio vaccine production sections, the quality control sections, the washing rooms for the animal houses and other areas that require hot water in large amounts.

c) Sanitary Fixture System

Western-style toilets, Indonesian-style toilets and Indonesian-style urinals will be installed in accordance with local customs. The types of fixtures selected will be those that can be easily replaced locally, should there be any damage or breakage after the completion of the facility.

d) Drainage System

Sewerage and general waste-water: Sewerage and general waste-water from the washbasins and showers, etc. will be discharged, after treatment by the sewage treatment plant.

Production and laboratory waste-water: waste-water that contains chemicals and which is produced in the production and laboratory processes will be processed in a waste-water processing tank and then discharged to the sewage treatment plant with the sewerage and general waste-water.

Animal waste-water: Waste-water including animal hair and faeces from the animal house will be processed in a waste-water processing tank and then discharged to the sewage treatment plant, together with the sewerage and general waste-water.

Rainwater: Rainwater from the roof and the site will be channeled to the existing open drain on the Bio Farma site.

Figure 4-9 shows the flow system for the drainage water.

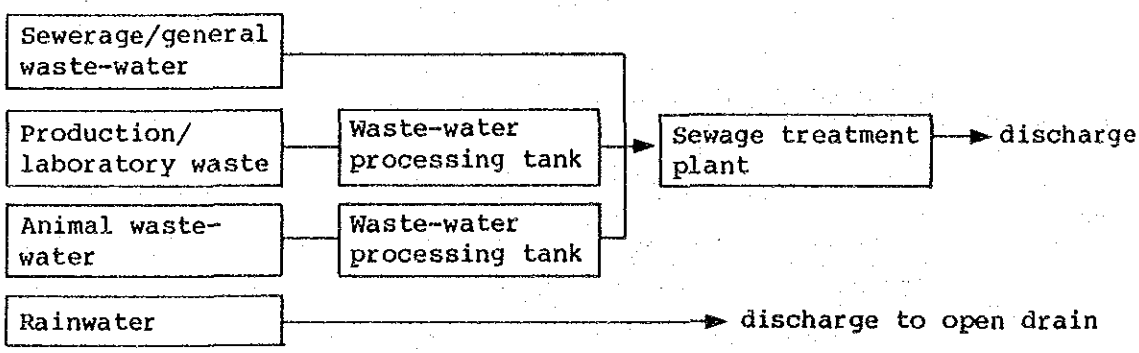


Figure 4-9 Waste-Water Flow

e) Gas System

Only a small amount of gas is used for the production of the vaccines and for quality control and other processes, and so city gas will be used because it is safer.

f) Fire Fighting System

In principle, a fire fighting system will be provided to comply with the Indonesian laws and regulations. The following systems will be provided throughout the building:-

- Sprinklers
- Indoor hydrants
- Outdoor hydrants
- Fire extinguishers

g) Sewage Treatment System

Sewage and general waste-water: Sewage and general waste-water will be treated by the biological method and sterilized.

Production/laboratory waste: waste-water that includes acids, alkalis and other chemicals will undergo neutralization processing, and monitoring will be carried out to confirm the degree of neutralization before it is discharged.

Animal waste-water: prior to its discharge, waste-water that includes animal faeces and hair will have the hair removed before the waste-water undergoes sedimentation and is disinfected.

3) Air Conditioning System

a) Basic Policy for the Air Conditioning System

This facility is a "biological agent production facility" as defined by WHO and it is a precondition that the air conditioning systems be in accordance with the GMP standards contained in the WHO guidelines. The following are the important points in these GMP standards:-

- Clarification of clean zones and dirty zones
- Prevention of cross contamination
- Ensuring the required levels of cleanliness

This facility is to be operated by Bio Farma and the operation, management and maintenance require that the local conditions and situations be adequately dealt with in the respective planning. With this in mind, the basic policy to be observed in the air conditioning system is as described below.

- Ensuring that the system is in agreement with the GMP standards
- Simplifying the system and planning to facilitate the operation and management
- Backing up the system to increase its reliability
- Systemization to reduce the running costs
- Flexible planning in consideration of easier maintenance and future renewal

b) Heat Source System (See Fig. 4-10)

Heat source: This facility requires steam for sterilization (in the autoclaves, etc.), for the production of distilled water, for the supply of hot water, and for the air conditioning (to dehumidify the air). In addition to the existing boiler at Bio Farma, an additional medium-pressure boiler of 3 tons/h capacity will be installed and operated so as to back up the existing boiler. The fuel will be the same diesel fuel as the existing boiler.

Cooling source: Two chiller units will be provided as the cooling sources mainly for the air conditioning in the clean rooms. The conditions for site maintenance and management were considered and the air-cooled reciprocating type of chiller unit was selected because of the ease of operation, maintenance and management.

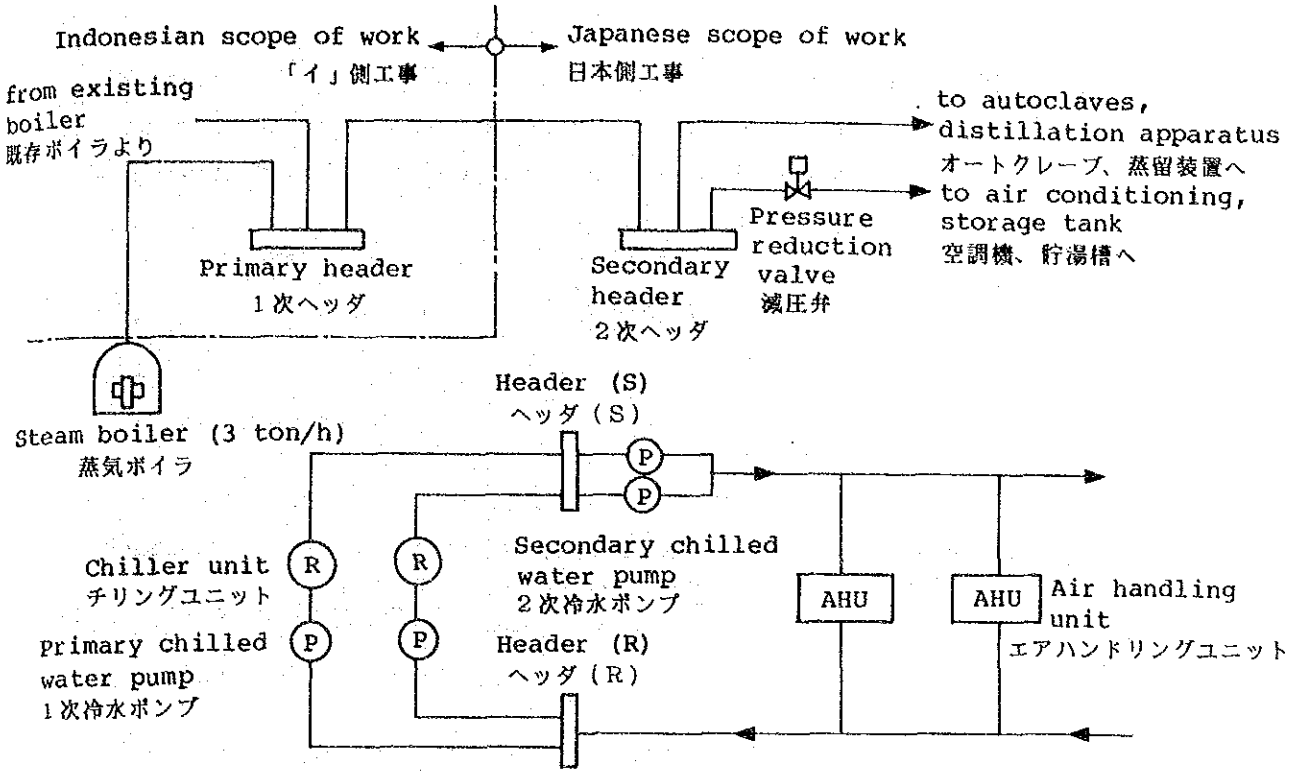


Fig 4-10 Heat Source System Diagram

c) Air Conditioning Method

The temperature and humidity conditions, the cleanliness level, the uses and the air conditioning hours for each of the rooms were considered in the choice of the following air conditioning methods:-

Table 4-4 Air Conditioning System

Air conditioning method	Room	Main features
Air handling	Clean rooms, animal houses	-In principle, 24-hour operation -High level of cleanliness obtained -Temperature/humidity control
Air cooled package (Central)	General air conditioning room	-In principle, operation for specific times -Temperature control
Air cooled package (Individual)	Individual rooms	-Operation only when room is occupied -Temperature control

d) Air Conditioning System Design Criteria

a: The air conditioning criteria for the rooms that are to be air conditioned are listed in Table 4-5.

Table 4-5 Air Conditioning System Design Criteria

Room	Temp. (°C)	R.H. (%)	Cleanliness level (NASA Std.)	Notes
Clean room (Cl.100)	24±2	60±10	100	Laminar flow, clean booths
Clean room (Cl.1,000)	24±2	60±10	(1,000)	
Clean room (Cl.10,000)	24±2	60±10	10,000	
Clean room (Cl.100,000)	24±2	60±10	100,000	
Vigilance Area (cl. 300,000)	24±2	60±10	300,000	
Animal houses (rabbits, mice, guinea pigs)	22±2	55±10	---	All fresh air
Animal houses (monkeys)	25-30	60±10	---	All fresh air
Animal houses (chickens)	24±2	55±10	---	All fresh air HEPA filter
Animal houses (chickens in isolators)	24±2	55±10	---	All fresh air HEPA filter
General rooms	25±2	free	---	

b: The conditions of the external air taken for the calculations for the cooling load are as follows:-

Temperature: 31°C, Relative humidity: 80%

e) Air Conditioning for the Clean Rooms

The cleanliness level of the clean rooms is greatly affected by the performance of the filters, the number of air changes and the air flow, as well as the pressure inside the room. The object cleanliness level (objective values) for the rooms are shown in the table.

At this facility, the cleanliness level of the clean rooms is to be achieved by giving the plan the following specifications:-

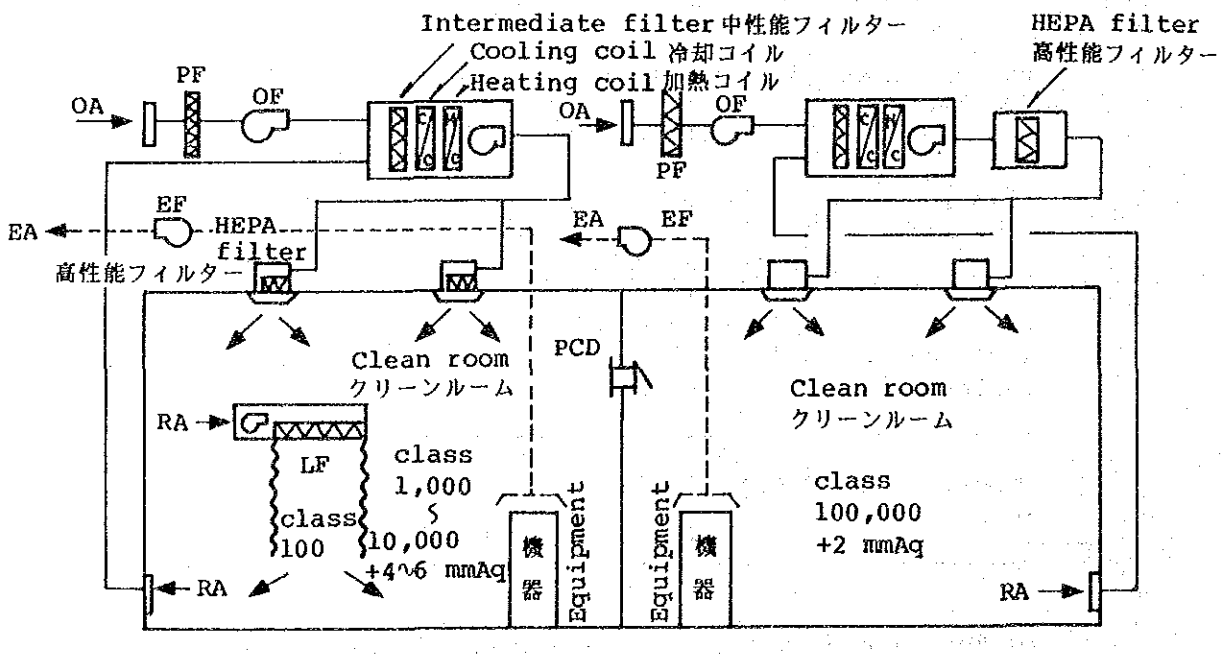
Filter: Combination of prefilters + intermediate filters + HEPA filters

Number of air changes: 40-20 times per hour (Class 1,000 to 100,000 in the NASA standards)

Type of air flow: turbulent method (laminar flow for class 100)

Room pressure: In principle, about 2mmAq difference between classes

The system of the air conditioning for the clean room is shown in the figure below.



OA: Outdoor air RA: Return air EF: Exhaust fan EA: Exhaust air
LF: Laminar flow PCD: Pressure control damper PF: Pre-filter

Figure 4-11 Clean Room Air Conditioning System

f) Air Conditioning for the Animal Houses

The features of the air conditioning for the animal houses are listed below.

- These are facilities where the quarantine, feeding, breeding and testing of animals are carried out and so the air conditioning is to be operated 24 hours a day.
- There are strong odors of animal feed and faeces (and so the full use of fresh air is desirable).
- Depending on the type of animal, controlled temperatures and humidities are required.
- Noise and vibration must be considered in the planning and layout of the facility.
- The chickens must have SPF (Specific Pathogen Free) conditions.
- A backup mechanism is to be incorporated into the system.

The air conditioning for the animal houses has a high running cost because of these reasons and this would effect the management of the facility. An air conditioning system that can maintain the desired level of environmental conditions in the animal houses and also reduce the running costs is desirable.

As can be seen in the figure on the next page, all of the air for the air conditioning of the animal houses is taken from outdoors, and all the air is discharged. In order to prevent the discharge of bacteria along with this air, the air is taken to the roof where it is processed through HEPA filters before being discharged.

The SPF chickens are largely bred indoors and so it is difficult to control the outbreak of disease. The isolator method will therefore be adopted and the air both inside and outside the isolators will be air conditioned using fresh air in a separate system. A backup system will be provided.

The air conditioning system for the animal houses is shown in Fig. 4-12.

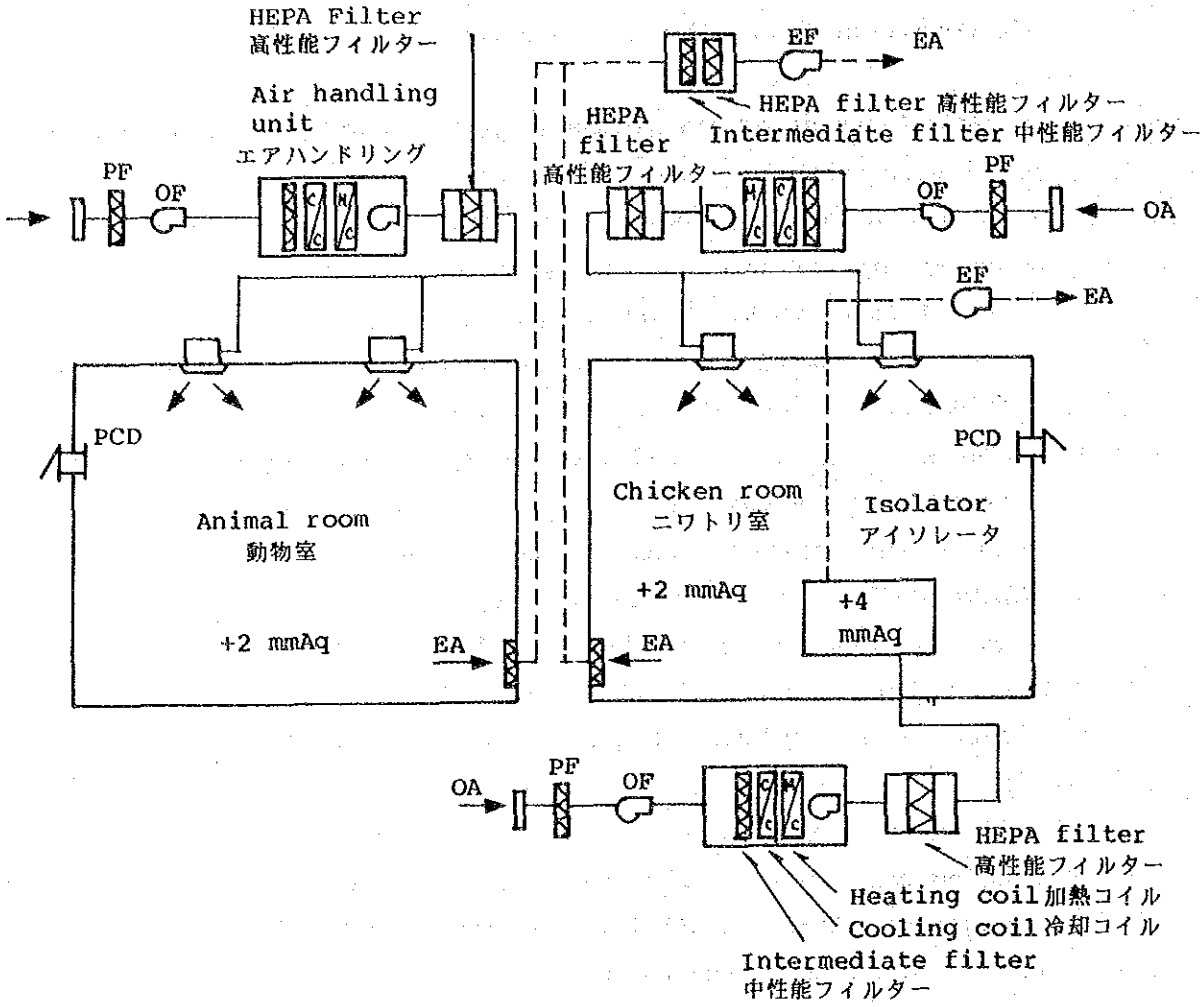


Figure 4-12 Air Conditioning System for Animal Houses

(6) Construction Material Planning

1) Criteria for Choice of Construction Materials

One of the objectives of the Japanese Government's Grant Aid is to contribute to the development of the receiving country through the utilization of local construction materials. This condition was also indicated in the Indonesian Government's request for technical cooperation. Therefore, in this project, local materials will be used so far as they comply with the design and operational specifications.

The production and quality control of vaccines would require a very high level of technology and therefore a heavy cost will be incurred in the procurement of the essential equipment and building technology. This will be a substantial but necessary

burden to be borne by the Indonesian Government. The use of local construction materials would help to keep down the total project cost since the prices of these materials are lower and the construction period will also be shortened as a result of using local materials.

2) Availability of Construction Materials in Indonesia

A study has shown that most of the construction materials specified in this project are presently available in Indonesia. The principal construction materials are listed in Table 4-6.

3) Construction Materials for Clean Rooms

For the construction of the clean rooms, special boards (ceramic boards etc.), aluminium baseboards, vinyl sheets, epoxy paints etc. would be required, in order to ensure the high level of cleanliness that is specified. All these materials must be imported from Japan. Also to be imported from Japan will be the clean room equipment, lighting apparatus, air-conditioning equipment, high performance filters etc. The materials and equipment for the clean rooms are listed in Table 4-7.

Table 4-6 List of Principal Materials

Building Works	Materials	Use of Indonesian products	Use of imported products	Reason for using imported products
Ground work	precast concrete work	o		
Reinforced concrete work	Cement	o		
	Reinforcing bar	o		
Formwork	Mold form	o		
Steel work	Section steel	o (small)	o (large)	Not available in Indonesia
Concrete block Brick work	Concrete block			
	Brick			
Water-proofing work	Asphalt water-proofing		o	Not available in Indonesia
	Paint film water-proofing		o	"
	Sealing material		o	"
Stone work	Marble	o		
	Terazzo	o		
Tile work	Semi-porcelain tile	o		
	Porcelain tile	o		
Wood work	Lumber	o		
	Laminated lumber	o		
	Plywood	o		
Roof work	Roofing tile	o		
Metal work	Light steel frame base		o	Not available in Indonesia
Plaster work	Cement mortar	o		
	Field terazzo	o		
Fitting work	Aluminium fittings	o (general)	o (special)	Not available in Indonesia
	Steel fittings	o (general)	o (special)	"
	Wooden fittings	o		
Glass work	Ordinary sheet glass	o		

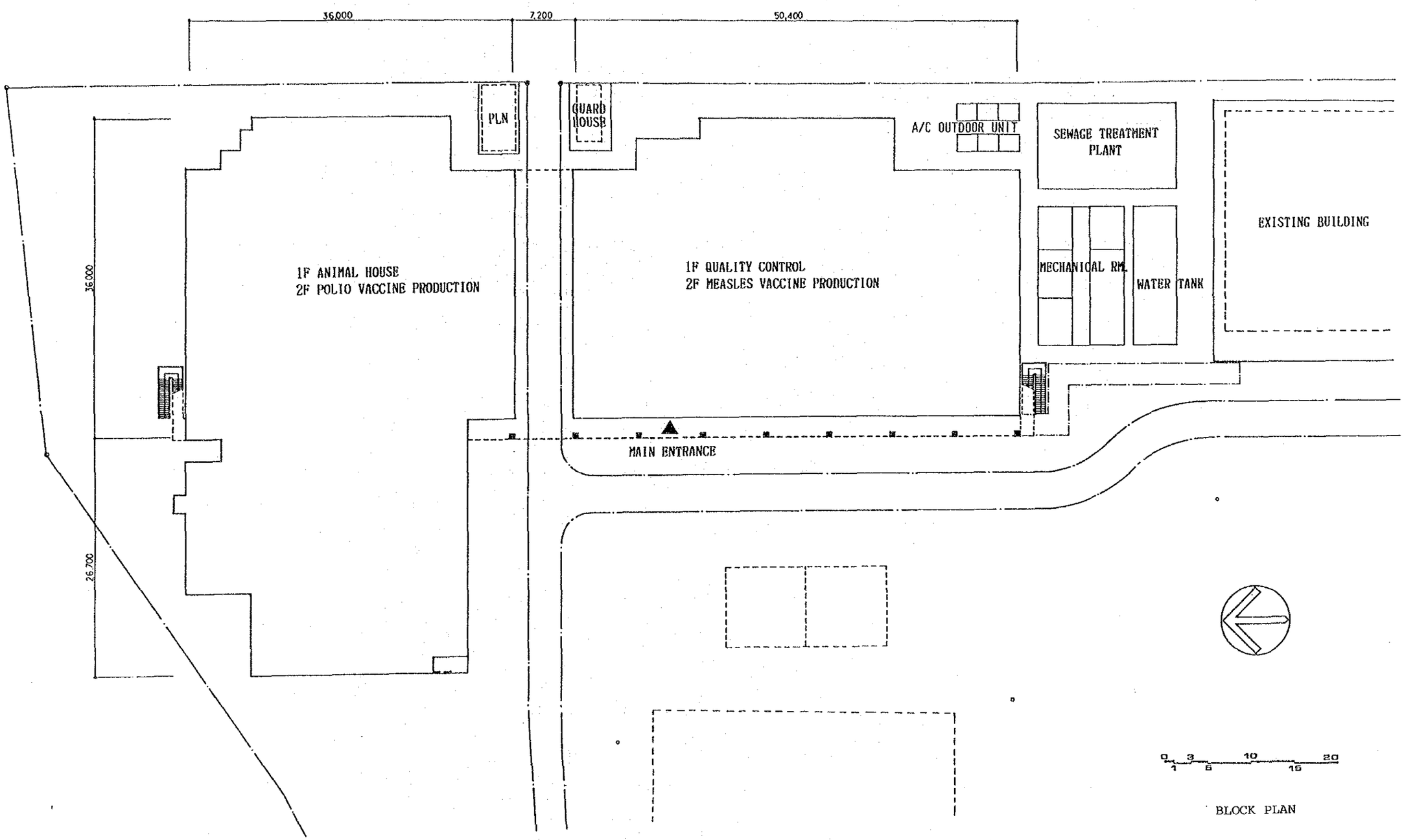
Building Works	Materials	Use of Indonesian products	Use of imported products	Reason for using imported products
Painting work	Interior paint	o		
	Exterior paint	o		
Interior work	Gypsum board		o	Not available in Indonesia
	Sound-absorbing rockwool board		o	"
	Plastic tile		o	"
	Glass wool		o	"
	Form polystyrene		o	"
Miscellaneous work	Sink	o		
Exterior work	Paving material	o		
	Drain chute	o		
	Planting	o		
Electrical equipment work	Electrical & wiring apparatus	o		
	Lighting apparatus	o (general)	o (special)	Not available in Indonesia
	Boards	o		
	Generator & dry transformer		o	"
Machine equipment work	Freezer		o	Not available in Indonesia
	Boiler		o	"
	Air-handling conditioner	o (general)	o (special)	"
	Package air conditioner	o		
	Air blower & exhauster	o (general)	o (special)	Not available in Indonesia
	Diffuser, blower	o (general)	o (special)	"
	Kitchen equipment	o		
	Sanitary equipment	o		
	Water treatment machine		o	Not available in Indonesia
	Ducting material	o		

Building Works	Materials	Use of Indonesian products	Use of imported products	Reason for using imported products
	Piping material	o (general)	o (special)	Not available in Indonesia
	Insulating material		o	"
	Automatic control machinery		o	"
Elevator equipment	Elevator, dumbwaiter		o	Not available in Indonesia

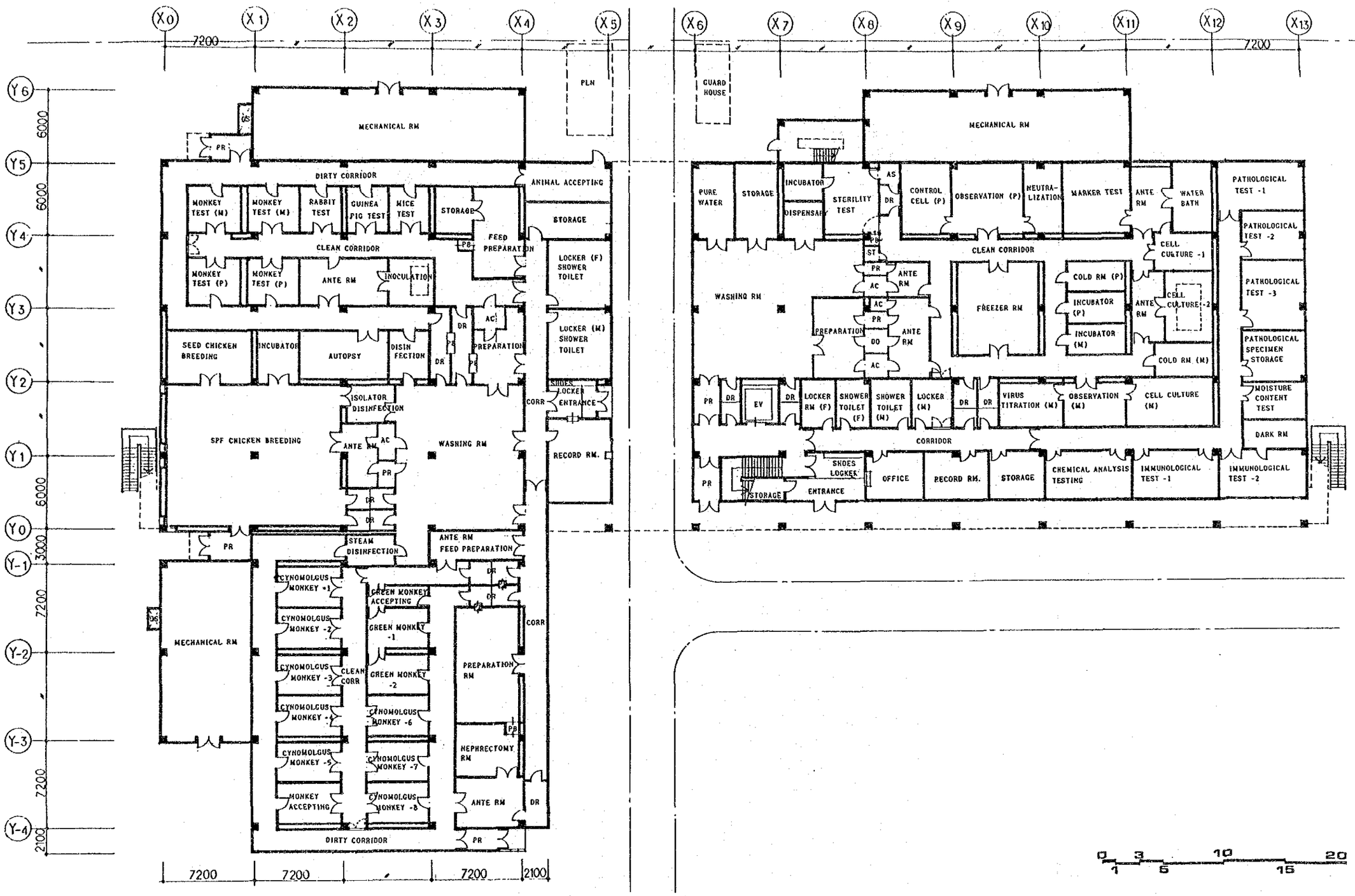
Table 4-7 List of Construction Materials for Clean Room

Building Works	Materials	Use of Indonesian products	Use of imported products	Reason for using imported products
Interior work	Ceramic board		o	Not available in Indonesia
	Epoxy resin board (tapered board base)		o	"
	Epoxy paint		o	"
	Aluminum baseboard		o	"
	Long vinyl sheet		o	"
	Silicon sealing material		o	"
Electrical equipment work	Lighting apparatus		o	Not available in Indonesia
Machine equipment work	Air-handling air conditioner		o	Not available in Indonesia
	Air blower & exhauster		o	"
	Diffuser, blower		o	"
	High-performance filter		o	"
	Micro differential pressure damper		o	"

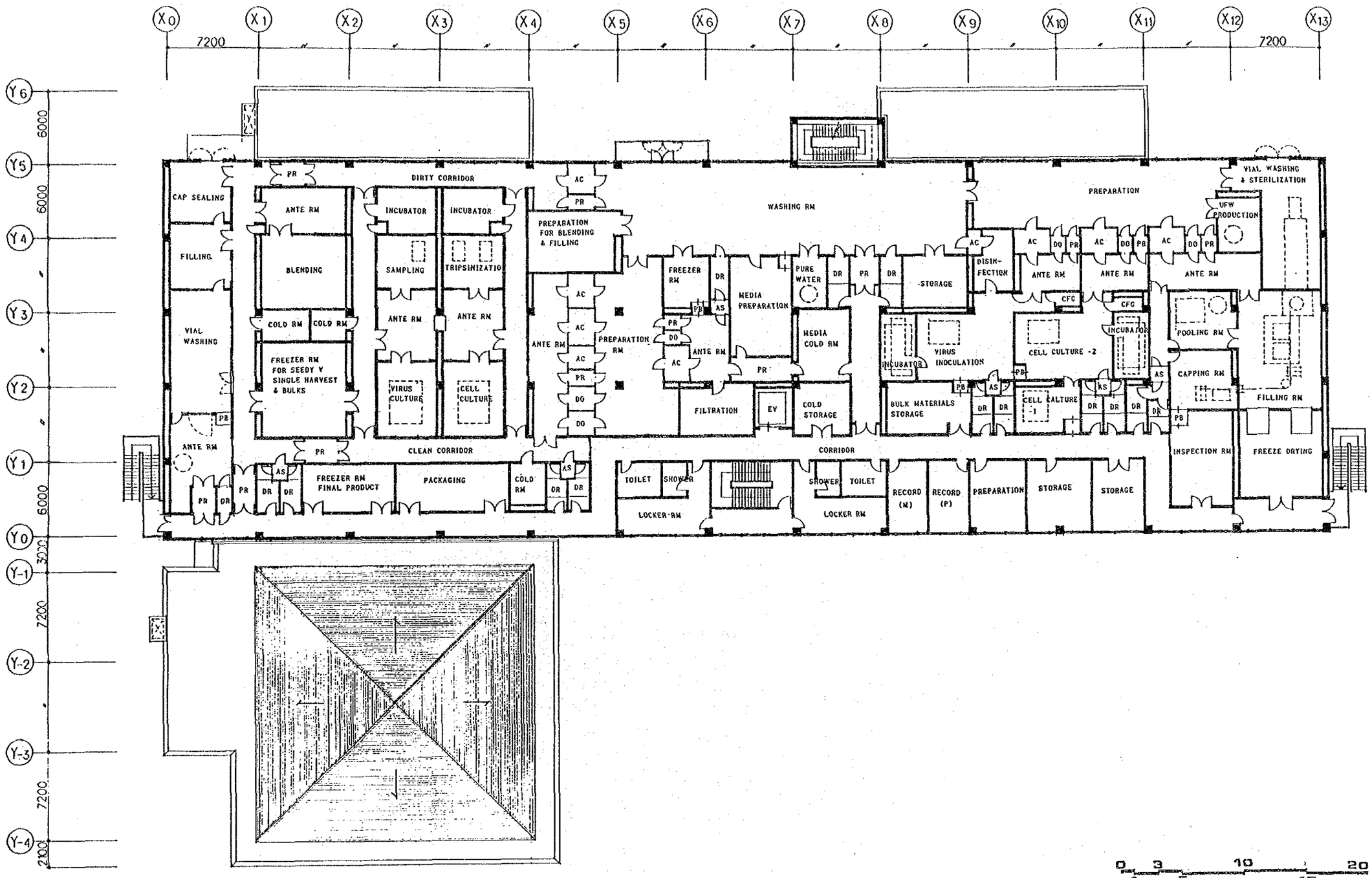
4-3-4 Basic Design Drawing



BLOCK PLAN

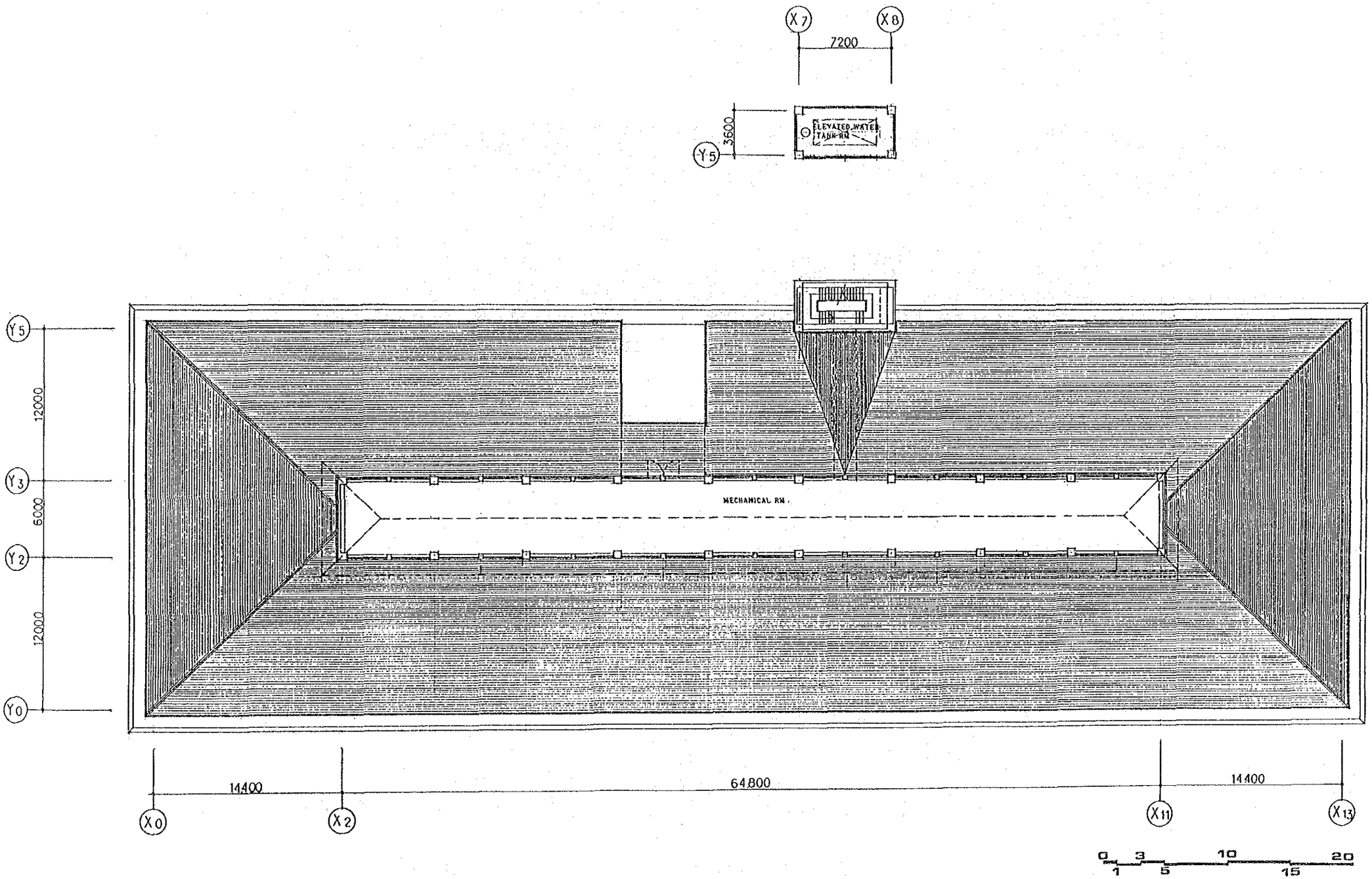


FIRST STORY PLAN

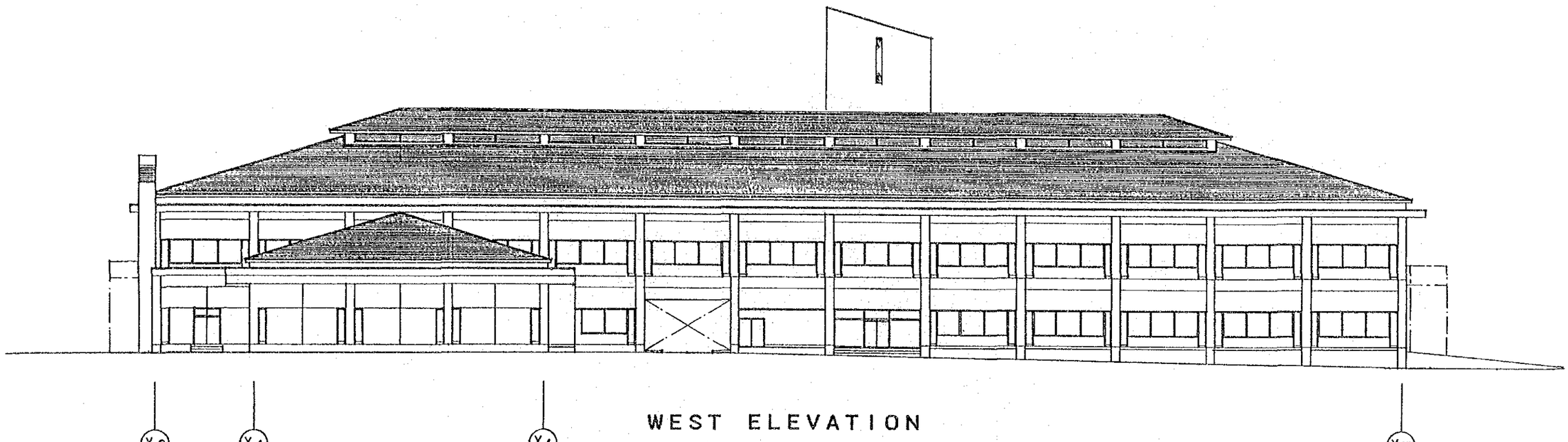


0 3 10 20
1 6 15

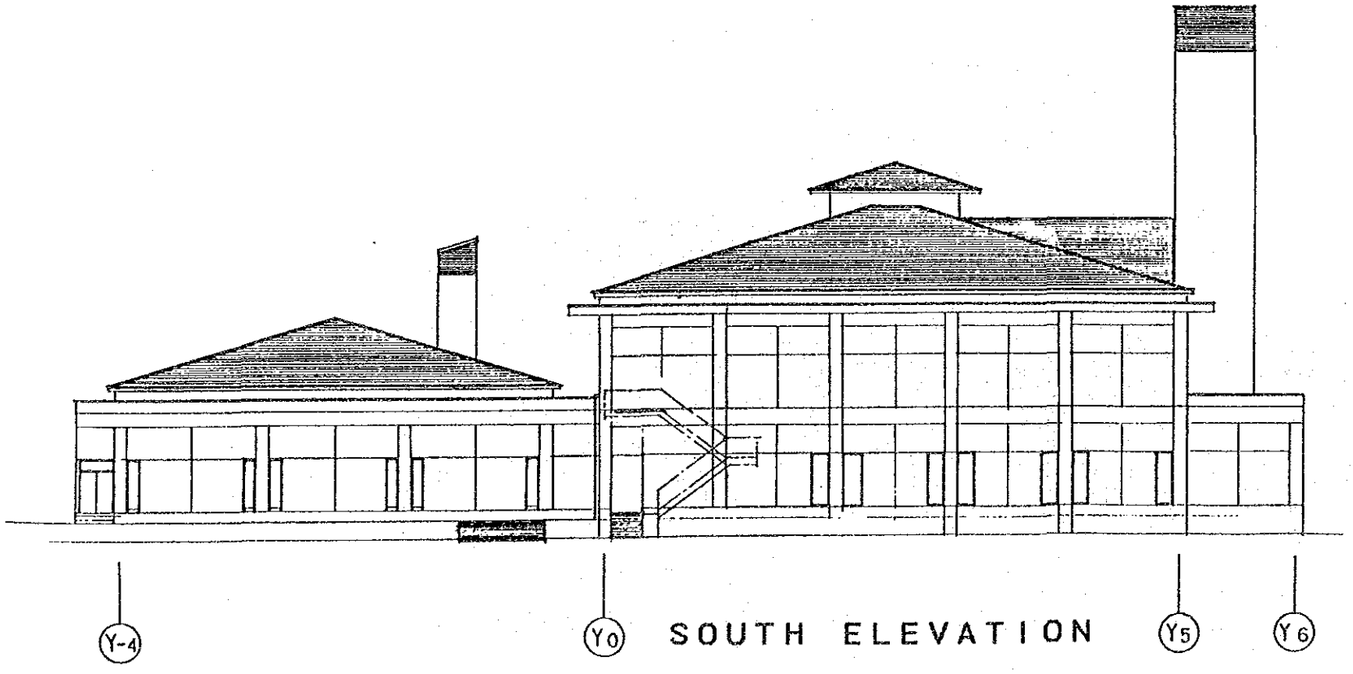
SECOND STORY PLAN



ROOF STORY PLAN

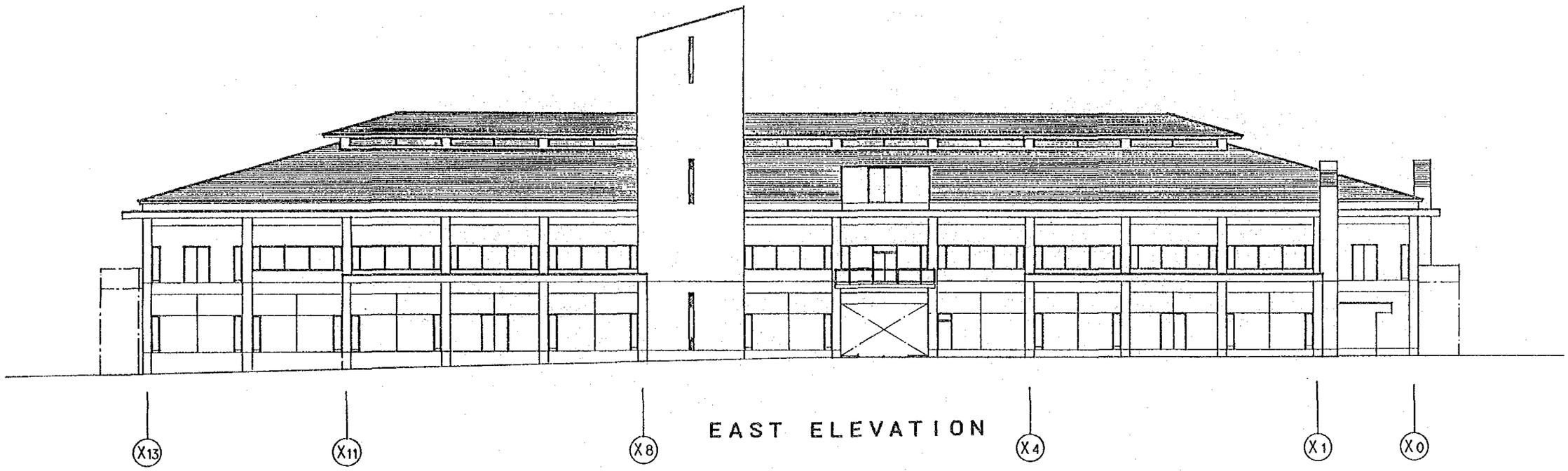


WEST ELEVATION

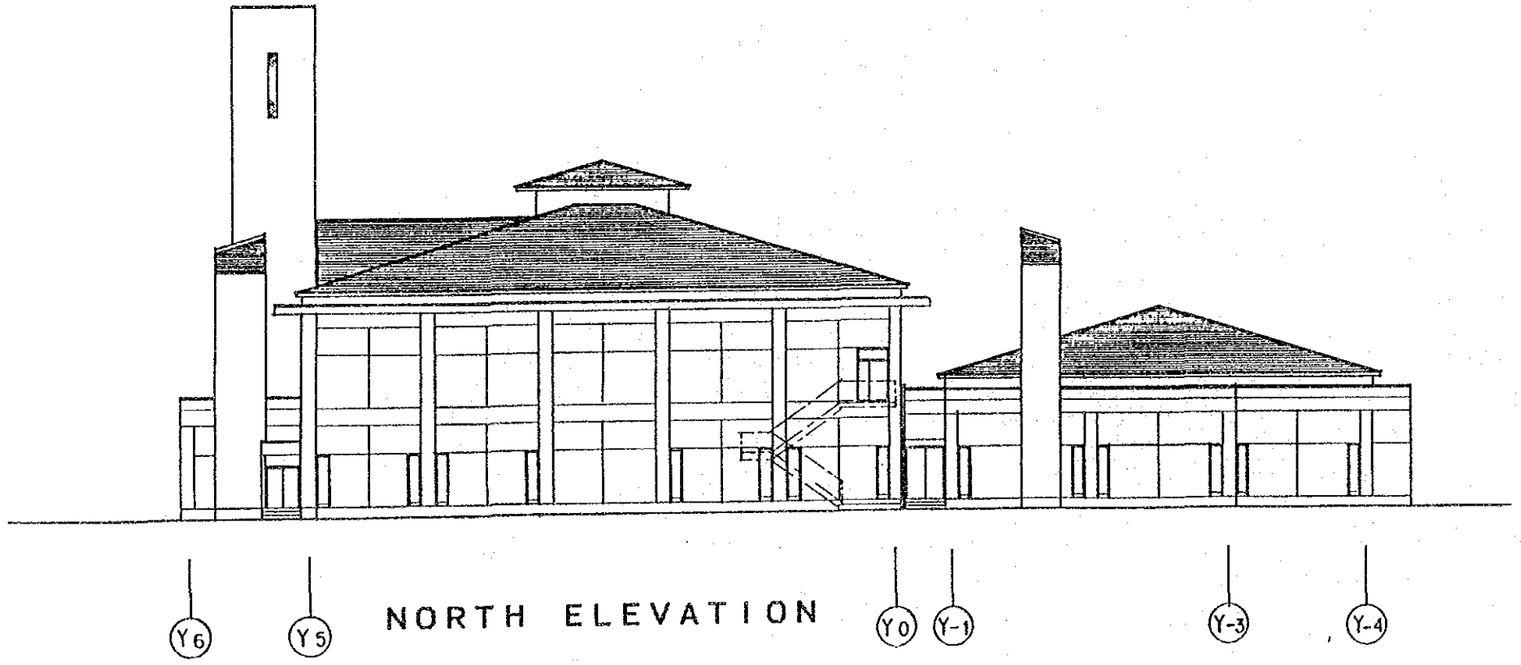


SOUTH ELEVATION

0 3 10 20
1 5 15

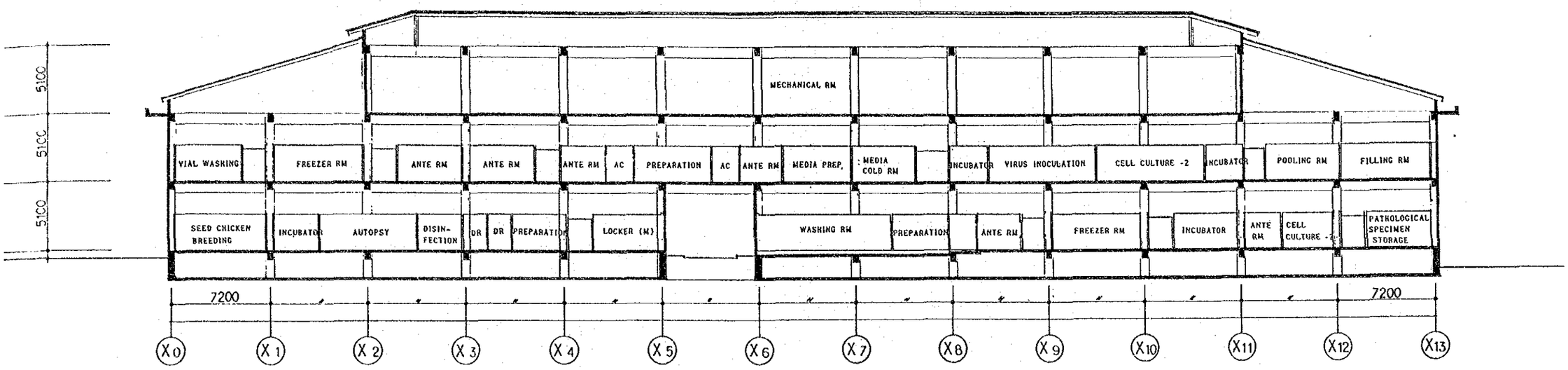


EAST ELEVATION

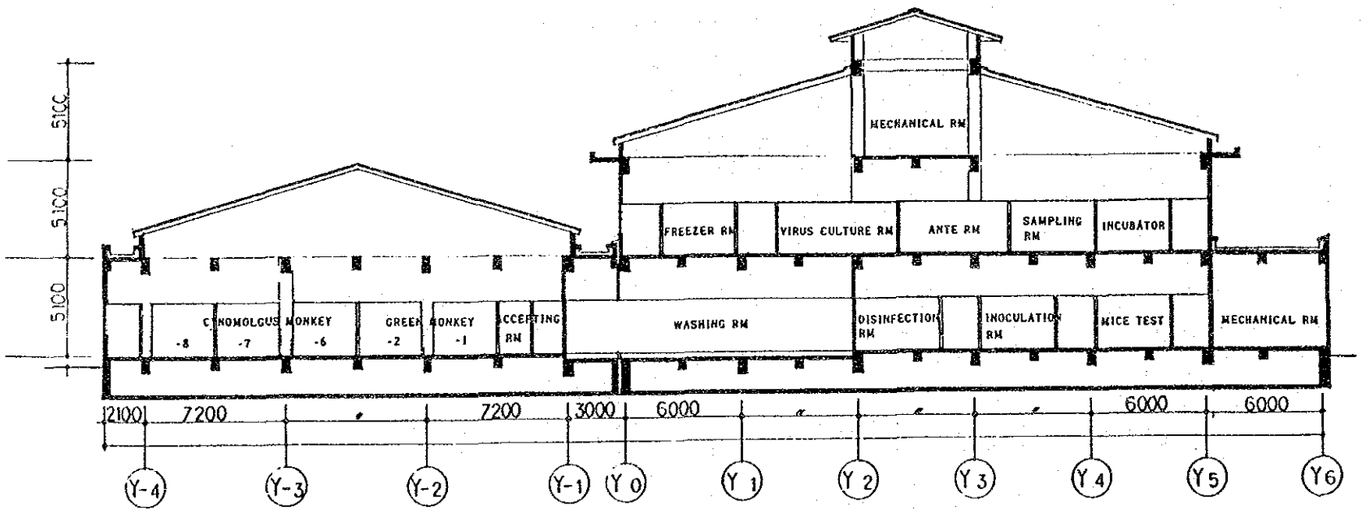


NORTH ELEVATION

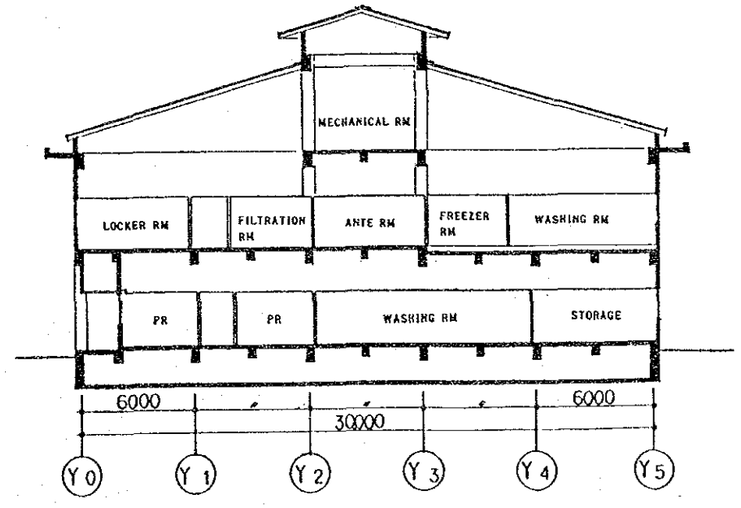
0 1 3 5 10 15 20



EAST–WEST SECTION



SOUTH–NORTH SECTION–1



SOUTH–NORTH SECTION–2

0 3 10 20
1 5 15