Chapter 2. Contents of the Project

CHAPTER 2. CONTENT OF THE PROJECT

2-1 Basic Concept of the Project

Japan's cooperation to Kenya for prevention of infectious diseases began with a grant aid programme of 1979 for the construction of the headquarters' facilities of KEMRI, which put together hitherto scattered functions, and implementation of a project-type technical cooperation "The Research and Control of Infectious Diseases Project in Kenya." Thereafter, Japan has extended project-type technical cooperation four times. Specifically, the cooperation was aimed at prevention of hepatitis and diarrhoea. The fourth project-type technical cooperation (1996 to 2001) included basic researches of AIDS, acute respiratory tract infections, and HB, in addition to the prevention of hepatitis and diarrhoea. As a result, KEMRI has successfully developed a blood screening kit suited to the conditions of Kenya. Japan extended technical transfer to the entire manufacturing process of the blood screening kit and technical extension to the laboratory technicians. Further, KEMRI has held third country training courses, "Seminar for Blood Screening", since 1999 for its neighbouring countries with the project-type technical cooperation of Japan. This may be taken to indicate that KEMRI is developing to be not merely a medical research institute of Kenya but to be a core medical research institute in East Africa. Since May 2001, the fifth project-type technical cooperation, "Project for Control of Infectious and Parasitic Diseases," has started, expected to last for five years. The fifth project-type technical cooperation continues cooperation on countermeasures for HIV/AIDS and HBV/HB from the viewpoint of blood safety, and is also extending cooperation on parasite control as part of the Okinawa Infectious Diseases Initiative.

The infectious diseases and parasitic diseases are still regarded as major diseases in Kenya.

Among all infectious diseases, AIDS is the most noticeable in Kenya, reportedly, with more than 2.5 million people harbouring HIV, with more than 520 people dying of AIDS every day, and with more than 200 thousand people contracting HIV every year. To say nothing of the disease's serious effects upon Kenya's economic development, the disease is considered to affect the very survival of the country. Under such a circumstance, in its 8th National development Plan (1997 to 2001) the government of Kenya attaches particular importance to prevention of HIV infection, showing particular concern to the adverse effects of AIDS on healthcare and medical service, on Kenya's socioeconomic activities and the problem of increasing AIDS orphans. In addition, the president himself has named spread of AIDS as a national emergency and has stressed the need to establish a system for testing and surveillance, and to do everything to stop further infection. The government, in response to the president's

remark, has established the National AIDS Control Council (NACC), reporting directly to the president, with the objective of reducing the HIV infection rate, now estimated at 13 to 14 percent, to 10 percent by 2004.

Regarding HB, the blood banks attached to the eight province-run hospitals of Kenya conducted blood tests from 1991 to 2000 on 153,029 voluntary blood donors by the blood screening kit developed by KEMRI. The result was that 3.6 percent (or 5,487) of blood samples tested positive to HB antigen. This indicates that 5,487 potential infections of HBV by blood transfusion were successfully forestalled during the same period.

Among these, as control for infectious diseases, securing of safe blood by means of blood screening is one of essential measures for prevention of HIV and HBV infection through such routes as blood transfusion or mother-to-baby infection. Kenya (KEMRI) has already succeeded in manufacturing, of its own, blood screening kits on a laboratory scale, supported by Japan's project-type technical cooperation. Hereafter, steady and stable production of these quality-assured blood screening kits is required so that these blood screening kits may be extensively used as necessary.

This project aims to install in the premises of KEMRI a facility to manufacture the blood screening kit which should be able to provide Kenya's own blood screening kits, cheaper than imported commercial products and better suited to the actual conditions of Kenya. Consequently, they may be effectively used in as many hospitals and blood banks in Kenya as possible.

Regarding parasitic diseases, the malaria, soilborne parasitic diseases, schistosomiasis, filariasis are still serious diseases in Kenya. Of these parasitic diseases, the malaria is regarded by the government as a particularly serious issue, because of it accounting for one-third of outpatients of medical institutes in Kenya. Under such a circumstance the government of Kenya has established the Division of Malaria Control in the MOH with a view to reducing parasitic diseases. The objective is to reduce both the infection rate and mortality rate of malaria of 1999 by 30 percent by 2004.

Japan proposed to the Birmingham Summit to establish centres for human resource development and networks in Asia and Africa for intensifying international movements for controlling parasitic diseases. KEMRI has been named as one of the centres in Africa.

Similarly, as control for infectious and parasitic diseases, research in these fields and development of researchers have been promoted at KEMRI, also by Japan's project-type technical cooperation. Hereafter, it is necessary to make the achievements of the research available to all levels of concerned people, in Kenya as well as in neighbouring countries, such as policy makers, engineers, medical technicians, students, by training and other means.

This project, within such movements, intends to install training facilities to intensify international movements for controlling parasitic diseases, and to conduct training courses (including third-country training courses) for Kenya and neighbouring countries.

The purpose of this project is to install facilities for controlling infectious diseases and parasites in the premises of KEMRI in Nairobi while maintaining collaboration with the project-type technical cooperation to achieve the above-mentioned objectives. This project is expected to contribute to strengthening of the infectious and parasitic diseases control in Kenya and neighbouring countries. The Requested Japanese Assistance is to construct the following facilities and to procure equipment necessary of their operation.

Table 2-1 Outline of the Grant Aid Project

Name of facility (by building)	Component	Total floor area, (m^2)	Remarks
Production Unit	Blood screening kit production division for AIDS (PA kit)	1,737	Manufacturing capacity: 250,000 tests/year
	Blood screening kit production division for HB (HEPCELL kit)		Manufacturing capacity: 400,000 tests/year
Animal House	Animal breeding division	262	Rabbits, guinea pigs
Training Unit	Lecture division	2,083	3 lecture rooms each accommodating 16 persons, and others
	Laboratory division		2 laboratory rooms each accommodating 16 technicians, and others
	Data processing, management and operation division		1 data processing room accommodating 16 persons, and others
Total		4,082	

2-2 Basic Design of the Requested Japanese Assistance

2-2-1 Design Policy

(1) Basic Policy

1) The basic design is closely connected with the action plan (including third-country training courses), expert dispatch plan and implementation plan of the ongoing Japan's project-type technical cooperation project for KEMRI, "Project for Control of Infectious and Parasitic Diseases".

2) The process of developing the basic design gives due consideration to the total master plan of KEMRI (the planned construction of facilities, equipment procurement, etc.).

3) The process of developing the basic design considers the managing capacity of KEMRI (the number of professional staff members, its technological level, its financial ability, procurement of spareparts and consumables, etc.) so that the basic design may secure KEMRI's autonomous technical and financial development.

4) The hardware aspect of the basic design, or that portion of the basic design which concerns the production unit of the blood screening kit, will be based upon Japan's GMP voluntary standards. Japan's GMP voluntary standards have been prepared based upon the GMP of WHO, and are applicable in Japan to the design of production units and others for "In Vitro Diagnostic Medical Device (IVD)".

5) Since it is difficult to extend Japan's technology transfer to the management (covering method of manufacturing, quality control, maintenance and management of facility and equipment) of the blood screening kit production unit within the framework of the grant aid programme, the technology transfer is not included in the Grant Aid project. Nevertheless, the technology transfer to the management of the blood screening kit production unit is considered indispensable to smooth implementation of this project. Accordingly, it is strongly desired that the necessary technology transfer be done under Japan's technical cooperation.

6) The facilities planned to be built by the Grant Aid project will be managed by KEMRI, a Kenyan governmental organisation. It is assumed that the facilities, including the management, organisation will not be privatised in the foreseeable future.

7) The basic design fully considers environmental conservation relative to the planned facilities and surroundings.

(2) Policy for Blood Screening Kit Production System

1) Market Forecast for the Blood Screening Kit

The following is adopted for the market forecast for the blood screening kit in Kenya.

Table 2-2 Market Forecast of the HIV Blood Screening Kit

	Number of tests
Blood transfusion	170,000
VCT	1,800,000
Diagnosis	500,000
Total	2,470,000

- The demand for VCT exists mainly in the district hospital level.

Table 2-3 Market Forecast of the HBV Blood Screening Kit

	Number of tests
Blood transfusion	170,000
Diagnosis	170,000
Maternity health checkup	1,000,000
Total	1,340,000

- The maternity health checkup is assumed to cover 1 million pregnant cases out of about 2 million births a year.
- Although the official request for this project indicates forecast export to the neighbouring third countries, the export is excluded from the forecast for the time being, because of a number of uncertainties about export, such as these countries' national policies or budgets.

The development of forecast demand will take into consideration the following study report, the results of studies at NPHLS and Kenyatta National Hospital.

Table 2-4 Study Report

Test kit market	HIV (number of tests)	HBV (number of tests)
Blood transfusion	170,000	170,000
VCT (including maternity health checkup)	1,800,000	1,000,000 (including maternity health checkup)
Diagnosis	530,000	

Source: The Study on Blood Transfusion System in Kenya (JICA, MOH), January 2002.

Table 2-5 Information from NPHLS and Kenyatta National Hospital

Test kit market	HIV (number of tests)	HBV (number of tests)
Blood transfusion	200,000	200,000
VCT (including maternity health checkup)	2,000,000	N/A
Diagnosis	500,000	170,000

Source: Information obtained from NPHLS and Kenyatta National Hospital

2) Planned Production Number of the Blood Screening Kits

The number of blood screening kits to be produced by KEMRI (HIV blood screening kit called PA kit and HBV blood screening kit called HEPCELL kit) will be determined based on the forecast blood screening kit market for Kenya, using the following premises. The KEMRI's blood screening kit has been granted the national approval by MOH, Kenya for manufacturing and marketing.

① PA kit

Positive factors for determining the number of PA kits to be manufactured are the following.

- The training courses held at KEMRI have been transferring the methods for using the kit to hospital laboratory technicians and other users.
- KEMRI has a function to provide consulting services on the blood screening, and is able to promptly respond to questions and inquiries from users of the PA kit.
- The PA kit is certified by NACC as being suited to testing AIDS.

The following are negative factors for determining the number of PA kits to be manufactured.

- There are as many as 28 competing products distributed in the market.
- The product has not been fully tried in competing sales and development.
- The PA kit is applicable only to HIV-1, and does not detect other strains (HIV-2, for example).
- KEMRI has not established a system to produce HIV by itself, but has to depend on private company for the supply of HIV.
- The government has not committed itself to purchase the product.

With the above factors duly taken into account, the number of the product to be produced in the initial year of the project completion is determined to be equivalent to two percent of the entire market demand, or 50,000 tests. With an

incremental rate of fifty percent of previous year assumed thereafter, the project is supposed to gain a share of approximately 10 percent of the market, or 250,000 tests, in five years. From this rationale, the number of the PA kits produced by the Project is determined at 250,000 tests/year. In the meantime, the production in laboratory in 2000 was 17,600 tests/year.

② HEPCELL kit

Positive factors for determining the number of HEPCELL kits to be manufactured are the following.

- The training courses held at KEMRI have been transferring the methods for using the kit to hospital test technicians and other users.
- There are only as few as three competing products distributed in the market.
- KEMRI has a function to provide consulting services on the blood screening, and is able to promptly respond to questions and inquiries from users of the HEPCELL kit.
- NPHLS has been using the HEPCELL kit.
- The HEPCELL kit is cheaper than competing products distributed in the market.
- The government is committed to buy 400,000 tests/year at present.

The following are negative factors for determining the number of HEPCELL kit to be manufactured.

- The product has not been fully tried in competing sales and development.
- The products already distributed in the market have been used in the Kenyan market. The expansion of sale of the HEPCELL kit will therefore take time.
- Due to lack of the government budget, the purchase by the government amounts only to 50,000 tests in 2002.

With the above factors duly taken into account, the number of the product to be produced in the initial year of the project completion is determined to be equivalent to five percent of the entire market demand, or 72,000 tests/year. With an incremental rate of fifty percent of previous year assumed thereafter, the project is supposed to gain a share of approximately 30 percent of the market, or 400,000 tests/year, in five years. From this rationale, the number of the HEPCELL kits produced by the Project is determined at 400,000 tests/year. In the meantime, the production in 2000 was 105,000 tests/year.

3) Performance of Blood Screening Kit

① PA kit

The PA kit shows a sensitivity*1 of 98.6 percent, a specificity*2 of 99.4 percent, and an accuracy of 99.2 percent, in comparison with other products marketed in Kenya. From this data, the PA kit is considered to be an excellent blood screening kit.

*1 Sensitivity : No. of HIV Positive bloods screened by PA kit / No. of HIV Positive bloods screened by standard kit × 100 (%)

*2 Specificity : No. of HIV Negative bloods screened by PA kit / No. of HIV Negative bloods screened by standard kit × 100 (%)

② HEPCELL kit

The present HEPCELL kit has exhibits a detection sensitivity of 10ng/mL (or 8 IU/mL), the value equivalent to those of blood screening kits being distributed in Japan for the same purpose.

4) Bio-material for Production of Blood Screening Kit

The bio-materials required for production of the PA kit and HEPCELL kit are as follows.

Table 2-6 Animal Species Used for Production of Kit

[PA kit]

Raw material	Animal species
Serum to be added to the extender	Rabbit
Gelatine particle	
HIV-1 antibody	

・ The shaded cells represent those to be provided by private company for ten years after signing on contract.
(based on the contract between KEMRI and private company)

[HEPCELL kit]

Raw material	Animal species
Anti-HBs antibody for reagin test	Guinea pig
Anti-HBs antibody for confirmatory test	Rabbit
Serum to be added to the extender	Rabbit
Erythrocyte for reagin test	Sheep

・ The shaded row represents procurement from other facilities of KEMRI.

5) Production Schedule

It is generally considered most desirable in Japan to manufacture these products four times a year from the standpoints of quality control and cost control. It may be considered most appropriate for the basic design, however, that KEMRI should manufacture each kit three times a year, and thus to ensure production of required amount for each product, in view of the KEMRI's experience and technical level.

The yearly production schedule shown below is established as a design condition. This production schedule supposes production of PA kit 250,000 tests/year (1,200 kits), HEPCELL kit 400,000 tests/year (2,000 kits), divided into three times a year.

Table 2-7 Production Schedule

HEPCELL kit : ▬▬ PA kit : ▬▬

Process/month	1	2	3	4	5	6	7	8	9	10	11	12
Preparation of component reagents	▬	▬			▬	▬			▬	▬		
Dispensing	▬	▬			▬	▬			▬	▬		
Freeze drying	▬	▬			▬	▬			▬	▬		
Capping	▬	▬			▬	▬			▬	▬		
Labeling	▬	▬			▬	▬			▬	▬		
Refining of HBs antigen	▬	▬			▬	▬			▬	▬		
Preparation of HBs antibody (immunoaffinity purification)	▪▪▪▪▪▪▪▪▪▪▪▪				▪▪▪▪▪▪▪▪▪▪▪▪				▪▪▪▪▪▪▪▪▪▪▪▪			
Fixation of sheep erythrocyte				▬				▬				▬
Preparation of erythrocyte for reagin test			▬				▬				▬	
Preparation of sensitized gelatin particles				▬				▬				▬
Cleaning of containers and equipment	▬			▬	▬			▬	▬			▬
Assemblage of kits		▬	▬			▬	▬			▬	▬	
Quality control	▬	▬ ▬	▬	▬	▬	▬ ▬	▬	▬	▬	▬ ▬	▬	▬
Preparation and putting to order of manufacturing record	▪▪▪▪▪	▪▪▪▪▪▪			▪▪▪▪▪	▪▪▪▪▪▪			▪▪▪▪▪	▪▪▪▪▪▪		
Animal raising and observation	▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪				▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪				▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪▪			

* The dotted lines indicate works lasting about one hour a day.

(3) Policy for the Training Programme

The policy for the training programme consists mainly of the following:

① To carry out third-country training courses on parasitic disease control for trainees from the East and South African countries as an element of the International Parasitic Disease Control Research and Training Centre Project,

② To carry out laboratory-work refreshing training on parasitology to the laboratory technicians and the students of the Kenya Medical Training College (KMTC), to promote parasitic disease control in Kenya,

③ To promote research activities aimed at developing parasitologists in Kenya, (to be expanded to neighbouring countries in the future), and

④ To conduct practical training on handling of the blood screening kits for entire Africa and Kenya as a measure for controlling infectious diseases.

(4) Policy for Natural Conditions

1) Temperature and Humidity

The monthly average temperature in Nairobi ranges from 15 to 20°C throughout the year. The temperature, however, can vary greatly within a day, even as much as over 20°C. The daytime temperature can become as high as 30°C.

The humidity is generally low, at about 50 percent in the dry season, and it seldom exceeds 70 percent even in the rainy season.

From the above, rooms except for those requiring air-conditioning or mechanical ventilation facilities because of their functions are designed to facilitate natural ventilation, with windows easy to open and to close.

2) Consideration to Daylight and Ultraviolet Ray

Nairobi is located close to the equator and hence the solar altitude is high. Therefore, the solar insulation on buildings from the above, east and west can be very intense depending upon the season. The design of buildings will give due consideration to the roofs, and walls on the east and west side for their thermal insulation. Nairobi is located on 1,798 meters above sea level; therefore, irradiation of the solar ultraviolet ray is stronger. The construction materials used for the portions exposed to the direct sunlight will be carefully selected considering the effects of the ultraviolet ray on the materials.

(5) Policy for Socioeconomic Conditions

Kenya, Nairobi in particular, is in a serious economic slump. In 2000 the nation registered a negative economic growth, or minus 0.3 percent, for the first time since independence as a result of drought. There seems to be no good sign of economic recovery, with suspension of finances from IMF and the World Bank, increasing unemployment rate resulting from decline of direct foreign capital investments, declining rate of growth of salaries, falling prices of real estate properties. Against such a background, the inflationary rate is relatively low for a developing country, ranging from 3 to 6 percent since 1998.

There are more skilled labours available than demanded under such a circumstance. Nevertheless, the project will pay due attention to workmanship of the workers and quality control of buildings. Over the past few years Kenya has been experiencing dearth of water and electric power; accordingly, the implementation schedule needs to have some allowance.

(6) Policy for Construction Business Conditions, Procurement Conditions or Particular Business Conditions, Trade Practices

The economic condition of Kenya is deteriorating, partly because of suspension of World Bank's finances. The construction business is in its worst condition. Under such a condition there are sufficient unemployed skilled workers available in Nairobi; therefore, it is relatively easy to secure skilled workers of a certain level or higher. It is also relatively easy to secure most construction materials and equipment that are needed.

However, in Kenya there are almost no skilled metalworking workers or factories that can produce high-level products. Even in the case of very general trades, efficiency will be greatly lowered compared with those in Japan if strict quality control is applied. Job-mixed concrete is the standard method in Kenya for pouring concrete because of ready-mixed concrete being not available. Job-mixed concrete is transported manually in bucket by lines of people, and consequently the amount of concrete that can be poured a day is very little.

(7) Policy for Employing Local Contractors

Registration with the Ministry of Public Works is necessary in order to conduct a construction business in Kenya. The registered contractors are classified into six ranks, A to F, according to their experienced and construction ability. The contractors are also classified according to their trades, like architecture or civil works for example, and recorded on the "Certificate." In addition, the contractor is required to make its business registration with such local authority as the Nairobi City Council to obtain a license for the business. The electric work, sanitary work and lift installation work all require different licenses from concerned authorities. The data for the year 2000 indicates that 60 contractors out of 200 registered companies fall into the A class category.

In implementation of construction works related to Japan's ODA projects, the Japanese contractor, a legal person registered in Japan, normally employs local contractors as subcontractors. In such a case, it is desirable to commission relatively large and capable contractors falling into the A or B category.

(8) Policy for Executing Agency's Managing and Maintenance Ability

Although buildings of KEMRI are 18 years old, their appearance and internals have been maintained rather well, indicating KEMRI's high managing and maintenance ability. Nevertheless, the project will be planned so as to facilitate maintenance and to reduce maintenance cost. Materials locally procurable will be preferentially adopted, while studying the breakage and wear of the construction materials and the equipment used in the existing buildings.

(9) Policy for Determination of Grade for Facility Installation and Equipment

1) Facility Plan

The grade for the production unit for the blood screening kits will be determined according to Japan's GMP voluntary standards for IVD: in vitro diagrostic medical device. The grade for the training unit will be determined referring to the grades of the existing facilities, and to facilitate smooth implementation of Japan's project-type technical cooperation.

2) Equipment Plan

① Equipment will be selected to meet the requirements for smooth implementation of the blood screening kit manufacturing plan and the training programme.

② Equipment relating to production of the PA kit and the HEPCELL kit will be selected so that one common equipment can be used for the production of both products, thereby enhancing the benefit cost effect of assistance. (This standard applies typically to the ultrapure water manufacturing unit and vacuum freeze-drying unit.) The specifications of the blood screening kit production unit will be determined to permit production of 400,000 tests a year.

③ In case of selecting equipment similar to those used by other concerned divisions of KEMRI, specifications similar to those of the existing ones will be selected to the extent possible, to facilitate operation and to improve maintenance efficiency.

④ The number and functions of training equipment will be selected to suit the training courses and curricula.

⑤ The existing equipment installed in other concerned divisions will not be transferred to the project facilities, because they will continuously be used by these divisions. However, provision will be made to allow these equipment to be used temporarily as found necessary in the project, in an emergency case where the equipment provided by this project fails.

⑥ Spareparts are not provided as part of the project. However, the study team will study possibility of including consumables in the list of provision to the extent necessary for test operation and training of the counterpart personnel on operation and maintenance.

(10) Policy for Method of Construction and Procurement, and Implementation schedule

1) Policy for Method of Construction

Manning plans of contractors and installation plans of temporary facilities will be fully examined to forestall problems in schedule control, quality control and safety control.

2) Policy for Method of Procurement

As a result of a study on distribution of construction materials in Kenya, it was learned that major materials are locally procurable with few exceptions. Presently, materials of various quality and specifications from South African and European countries are sold in the market and easily obtainable in Kenya. The materials and equipment to be employed will be locally procured to the extent possible in order to facilitate repairs, maintenance and management after commissioning of the facilities. However, quality and availability of the materials will be confirmed to avoid any adverse effect on the implementation schedule.

3) Policy for Implementation schedule

A one-fiscal-year budget can accommodate the implementation schedule of the Requested Japanese Assistance, judging from the scope and scale of the project.

2-2-2 Basic Plan

2-2-2-1 Overall Project Description (Study of the Request)

(1) Field Survey and Content of Final Request

Against the letter of request dated May 30, 2001 (original request), the Kenyan side presented a revised letter of request dated January 22, 2002 (revised request) at the initial meeting with the Kenyan side held on January 22, 2002. The study team discussed the items revised from the original request with the Kenyan side. After having surveyed the requested project site and made necessary studies, the study team confirmed the scope of the final request by affixing the team's signature on the minutes of meeting. The table below summarises the scope of the final request.

Table 2-8 Outline of the Scope of Final Request

	Final request
Nairobi	Production units for blood screening kit (PA kit, HEPCELL kit and traditional medicines), animal house attached to the production units, and training unit Equipment required for operation of the above facilities
Kwale	Training unit, accommodation facilities Equipment required for operation of the above facilities
Busia	Training unit, accommodation facilities Equipment required for operation of the above facilities

During the site survey, the study team learned that the Centre for Disease Control and Prevention (CDC) of the United States was carrying out a large-scale construction and modification of facilities as part of its endeavour to control AIDS. The study team confirmed with the general manager of the CDC Nairobi Office that CDC was promoting the project shown in the table below. It was also confirmed that the facilities being installed by CDC would be transferred to KEMRI after commissioning and that the CDC project would not affect the site of the Grant Aid Project.

Table 2-9 Outline of CDC's Project in KEMRI, Nairobi

Scope	Scale	Schedule
Administrative building (including some laboratories)	One-story building Total floor area: about 2,000 m^2	Start of construction work: July 2002 Construction period: 10 to 12 months

(2) Summary of Study for the Request

The study team studied the scope of the request by component for adequacy referring to the basic policy. The summary of the study results are presented in the table below.

Table 2-10 Summary of Study for the Request

Site	Name of facility (by building)	Requested scope (component)		Summary of the result of study
Nairobi	Production unit	PA kit production division (blood screening kit for HIV)	○	The project will formulate a plan for a system that can produce about 250 thousand tests five years after commissioning, and will develop a facility and equipment plans for the system, in cooperation with Japan's project-type technical cooperation. (Part of the line is shared by the HEPCELL kit production line.)
		HEPCELL kit production division (blood screening kit for HBV)	○	The project will formulate a plan for a system that can produce about 400 thousand tests five years after commissioning, and will develop a facility and equipment plans for the system, in cooperation with Japan's project-type technical cooperation. (Part of the line is shared by the PA kit production line.)
		Production division (Traditional medicine research and development unit)	×	KEMRI so far has identified eight plant extracts with antiviral effects. Japan's project-type technical cooperation will continue to be provided to this field. However, Japan's cooperation will be limited to the basic researches; therefore, the production unit was judged to be outside the scope of cooperation.
	Animal house	Attached animal house (Blood screening kit)	○	To secure biomaterials (serum, antibody) for manufacture of the blood screening kits, animal houses to raise two species of laboratory animals, the rabbit and guinea pig, will be provided.
		Attached animal house (Traditional medicine research and development unit)	×	The purpose of the traditional medicine research and development unit is not to produce and sell medicines on a large scale but is limited to researches, in which stage the research does not necessarily require confirmation of safety of medicines by animal trials. Therefore, animal houses associated with the traditional medicine research and development were judged to be outside the scope of the cooperation project.
	Training unit	Lecture (training) division	○	Three lecture rooms each accommodating about 16 persons will be installed according to the training programme. The partitions between rooms will be openable ones.
		Experiment (research) division	○	According to the training programme, two types of training experiment rooms each accommodating about 16 persons will be planned, one for parasitic disease and the other for infectious disease. Preparation rooms will also be installed for these experiment rooms.
		Information management division	○	One information management training room accommodating about 16 persons and others will be installed according to the training programme. The purpose is to let trainees develop programmes for parasitic disease control measures and plan sharing information through the computer network.
		Management and operation division	○	A division to facilitate execution of total training & research is also established.
Kwale	Training unit	Training & research division, Accommodation division	×	Since the daily activity (training) programme is not clarified at this moment, the usage rate of requested facilities would be lower. Therefore, the requested facilities are judged to be outside of the scope of the Grant Aid project.
Busia	Training unit	Training & research division, Accommodation division	×	Since the daily activity (training) programme is not clarified at this moment, the usage rate of requested facilities would be lower. Therefore, the requested facilities are judged to be outside of the scope of the Grant Aid project.

Note

○: Within the scope of the Grant Aid Project
×: Outside the scope of the Grant Aid Project

(3) Analysis of Content of Request

The contents of the request were analysed in detail as follows.

1) Facility Plan

① *Blood Screening Kit Production Unit*

PA and HEPCELL Kits Production Division

The government of Kenya recognises the increasing infection of HIV and HBV as serious threat to the nation's healthcare and medical service activities and socioeconomic activities, and hence is committed to implement effective measures against the infection. KEMRI, having succeeded in test production of the above-mentioned two blood screening kits (KEMRI kit: PA kit and HEPCELL kit, the latter with some market record), plans to embark on full-fledged commercial production of these kits, in order to play its legitimate role in the government effort. KEMRI forecasts the future demand to be one million tests for each kit.

The PA kit has been successfully commercially manufactured locally as HIV-1 detection kit (freeze-dried product with one-year effective period), with Japan's fourth project-type technical cooperation (from May 1996 to April 2001). Regarding the HEPCELL kit, Japan's third project-type technical cooperation (from May 1990 to April 1996) lead to successful preparation of raw materials. The subsequent fourth project-type technical cooperation (from May 1996 to April 2001) has achieved improvement of the kit (freeze-dried product with one-year effective period). The National Public Health & Laboratory Services (NPHLS) has committed itself to purchase 400 thousand tests of the HEPCELL kit to be used for testing of the blood for transfusion.

Since 1991 KEMRI has promoted activities for securing safety of blood through manufacture, distribution of the kits and holding of training courses, with the cooperation of JICA and other donors. KEMRI has held training courses for laboratory technicians and concerned people of Kenya and the neighbouring countries, thereby transferring the skill for using KEMRI kits together with education on viral infections. KEMRI kits are easy to use and not expensive; therefore, these kits are suited to Kenya and its neighbouring countries, all suffering from lack of fund.

From the above discussion, it may be considered perfectly adequate that KEMRI should install the blood screening kit production unit and establish a system for stable supply of blood screening kits as necessary.

Animal House attached to Production Unit

The animal house will be provided to raise animals and to obtain sera and antibodies, the main biomaterials for production of the blood screening kits by the renovation of the existing animal house.

② Traditional Medicine Research and Development Unit

In order for a new medicine to be subjected to a clinical trial in a given country, that country should in principle have an environment including a legal system that permits such clinical trials. However, such a legal system has not been established in Kenya; therefore, KEMRI exercises its own judgement to decide whether KEMRI should conduct a clinical trial. Accordingly, possibility of drug-induced suffering cannot be totally ruled out. The first thing that should be done, in such a circumstance, may be establishment in Kenya of a system for certifying new medicines.

Considering such a situation, it would be right to limit the cooperation for research and development of medicines to the extent possible with the project-type technical cooperation, or to researches. It would be a proper judgement to exclude installation of production unit and their associated animal houses from the scope of cooperation.

③ Training Unit (Nairobi)

KEMRI plans to implement training courses in Nairobi, with their particulars (trainees, number of trainees, objectives, schedules) shown in the table below. It may be noted from the table that the facility will be fully utilised for research activities and to the extent of about 60 percent for training activities.

Some of these courses are to be supported by third-country training courses by the project-type technical cooperation. Presently, KEMRI is not equipped with a training facility; therefore, installation of the training unit is considered to be indispensable to smooth implementation of project-type technical cooperation.

It should be remembered that the table shows the training plans of KEMRI only. Other concerned organisation, NPHLS, KMTC for example, are planning to use the facility after the facility is completed.

Table 2-11 Training Programme

Training Course	Months 1	2	3	4	5	6	7	8	9	10	11	12	No. of Trainee	period	Remarks
IPDCourse A,B,C													16	2 mths	◎
BS Course A													16	3 wks	◎
BS Course B													16	2wks	○
BS Course C													5	1wk	○
CFS Course													16	1 wk	◎
Training Activities	75	50	100	75	75	75	75	50	25	75	25	50	62.5%	Use Rate	
Research Activities	100	100	100	100	100	100	100	100	100	100	100	100	100.0%	Use Rate	

◎ : budget allocation courses by third-country training programme and with other institute
○ : planning stage (no budget allocation)

	Target Participant	Course Name (Purpose)	Third Countries Training
International Parasitic Disease Course A	Policy Maker	Sensitization on Parasitic Disease Problems	X
International Parasitic Disease Course B	Programme Manager	Planning, Operational Research and Control Strategy	X
International Parasitic Disease Course C	Technologist	Technical Aspects and Implementation	X
Blood Screening Course A	Technologist		X
Blood Screening Course B	Technologist in Kenya		
Blood Screening Course C	Technician		
Community Field Studies Course	Students for Local University and other Institutes - Jomo Kenyatta University of Agriculture and Technology - University of Nairobi - Moi University - Maseno University - Ministry of Health - Kenya Medical Training College		

The following training courses were held in KEMRI in Year 2000

Table 2-12 Training Courses held in KEMRI in Year 2000

Courses	A	B	C	D
1. Asthma Workshop for Nurses (2 weeks)	50	●		50
2. Training Workshop for Association of Kenya Medical Laboratory Scientific Officers (1 week)	150	●		
3. Medical Review Journal – Exhibitions for Scientists and Medical Practitioners (2 weeks)	100	●		
4. International Workshop of SONA (Society for Neuroscientists of Africa)	100		●	
5. Cancer Registrars Training Courses	16	●		16
6. Department of Epidemiology and Preventive Medicine –Moi University- Workshop (1week)	40	●		40
7. TB Diagnostics, kits demonstration and Laboratory Training (1 week)	50	●		50
8. Kenya Dental Association Workshop (1 week)	100	●		
9. International Course on Research Methods for Promotion of Lung Health	30	●		
10. Detection of Drug Resistance Malaria and TB	30		●	30
11. Industrial attachments of Students from Polytechnics and Universities	25	●		25
12. Third Country Training Programme on Blood Screening for HIV/AIDS and Viral Hepatitis	16		●	16
13. KEMRI Seminars organised on Monthly basis (total/year)	*(250)			
Total	723	561	146	227

The following courses are to be held after completion of the planned Training Unit

Other expected courses	A	B	C	D
14. ESACIPAC's (Eastern and Southern Africa Centre of International Parasite Control) expansion of activities could include training for Roll Back Malaria (RBM). RBM courses currently offered at Nazareth College in Ethiopia could be moved to ESACIPAC.	-	● (60)	● (16)	64
15. Courses by National Public Health Laboratory Services	-		●	15

A : Numbers of Participants
B : Domestic Courses
C : International Courses
D : Courses would be held in the planned Training Unit
* : Not included in Total Number

④ Training Units (Kwale and Busia)

The training units planned for Kwale and Busia (including accommodation facility) are considered inadequate to be included in the scope of the Grant Aid Project for the following reasons.

- The field station necessary for training of parasitic disease control may be placed in the existing facility of KEMRI at Kisumu.
- Since the daily activity (training) programme is not clarified at this moment, the usage rate of requested facilities would be lower. Therefore, the requested facilities are judged to be outside of the scope of the Grant Aid project.

2) Equipment Plan

Based on the rationale developed above, the equipment plan excludes the local training units and the traditional medicine research and development unit in Nairobi from the Grant Aid Project, as is the case with the facility plan.

① Study on Major Equipment

The results of the studies on major pieces of equipment are as follows.

- Ultrapure Water Manufacturing Unit

  This unit produces ultrapure water required for manufacture of kits. Ultrapure water is used for such purposes as preparation of buffer solutions and reagents, cleaning of antibodies. One cleaning operation requires about 400 litres to 500 litres of ultrapure water. A unit with a capacity of 10 litres/hour is selected, because the ultrapure water can be continuously produced and the produced ultrapure water is stored in a cool box.

- Lyophilizer

  Vacuum freeze drying is applied to dehydrating major reagents constituting the kits, an operation essential for long-term storage. The production of

blood screening kits is 400 thousand tests each, and one vacuum freeze-drying unit can easily cope with this number. The unit with the smallest dehydrating capacity among those with required performances (full capping function) will be studied for selection.

- Ultracentrifuge

  The ultracentrifuge is employed to obtain refined antigens from the plasma. The unit is used solely for this purpose because one operation could need a continuous operation of about 24 hours.

- Refrigerated Centrifuge

  This unit is used for such purposes as washing of separated antigens. This unit could be subjected to frequent and prolonged uses, and one operation handles a fluid of 1 litre (250 millilitres × 4); therefore, the unit is assigned exclusively to this purpose.

- Ultra Low Temperature Freezer

  This unit is used for such purposes as storage of blood containing antigens taken from subject animals. For the sake of ensuring stable supply of blood screening kits, it is necessary to store at all times about half the required amount. However, the volume to be stored is small, the smallest marketed product, with a capacity of 80 litres, will be selected. Different antigens should be stored in different freezers; therefore, two units are necessary, one for the PA kit and the other for the HEPCELL kit.

- Safety Cabinet

  This unit is used when titters of the positive control sera for the PA kit and the HEPCELL kit are adjusted. For the safety of operation, one person alone uses it at one time. The unit of smaller specifications (size) suffices.

- Microscope (for training purpose)

  Binocular microscopes, stereoscopic microscopes, inverted microscopes are used for training on parasitic diseases. Their specifications and numbers will be determined to suit to the needs of the training courses.

- Carbon Dioxide Incubator

  This unit is used for such purposes as training on cell culture. The unit of the specifications suited to training use and that designed to facilitate maintenance will be selected (capacity: 160 litres).

- Clean Bench

  This unit is needed for handling of bacteria in training. The unit cuts off inflow of ambient air to inside the equipment, thereby preventing entry of bacteria. This unit is used when seeding bacteria on the culture medium, for

example, in training on bacteria culturing. The trainee needs assistance of the instructor; therefore, the bench is sized to accommodate two persons.

- Personal Computer (training purpose)

  Report writing by personal computer is a must when a research work or training is done in the planned facilities. Training on the personal computer is also necessary. Personal computers of the minimum specifications good enough for the training purpose will be selected. The application software will be selected from those available in the market and suited to document preparation.

② Study from Equipment Selection Standards

Each piece of requested equipment was analysed for necessity and adequacy based on the equipment selection standards given below. The results of the analysis are shown in Table 2-13.

a) The equipment should be consistent with the scopes of the manufacturing work and the training in this project.

   ◎: Equipment judged to be highly needed

   ○: Equipment judged to be an essential one and needed

   △: Equipment judged to be inconsistent with the basic design policy

   ×: Equipment judged to be either not or little needed

b) The equipment should be consistent with the local conditions or the technical level of the subject facility

   ◎: Equipment judged to be operable by the technical level of the existing staff

   ○: Equipment for which operation may be instructed at the time of installation

   △: Equipment which requires technical training for a certain period before installation

c) The equipment should be maintainable.

   ◎: Equipment which does not require special maintenance or management

   ○: Equipment that may be maintainable by the present maintenance system and maintenance budget

   △: Equipment of which maintenance is expensive and therefore a special budgetary measure is required.

d) Equipment that may be dispensed with by sharing or effective utilisation of the existing equipment

×: Equipment that may be dispensed with by effective utilisation of the existing or the equipment to be procured for another division by this project

e) Equipment for which more than minimum required number has been requested

△: Equipment for which reduction in number is necessary (possible)

f) Equipment that should preferably be procured as part of the construction work

×: Equipment that may be regarded as office desk and chair, furniture or fixture

g) Equipment that may be procurable by the Kenyan side

×: Consumables and equipment for private needs that should be procured by the Kenyan side

h) Judgement and evaluation

○: Equipment for which procurement by this cooperation project is judged to be adequate

×: Equipment that should be excluded from the list of equipment to be procured by this cooperation project

Table 2-13 Study of Requested Equipment

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
Production unit											
HEPCEL and PA kit Production											
	Hepcell kit preparation room										
1	Refrigerated centrifuge	1	◎	○	○					○	1
2	Incubator	1	○	◎	○	×				×	0
3	Refrigerator	1	◎	◎	○					○	1
4	Fraction collectors	1	○	○	○					○	1
5	pH meter	1	○	○	○					○	1
6	Plate mixer	1	○	◎	◎					○	1
7	Peristaltic pumps	2	○	○	○		△			○	1
8	High vacuum aspirator machine	1	○	○	○	×				×	0
9	Affinity chromatography stand	1	◎	○	◎					○	1
10	Affinity chromatography column	5	◎	○	◎					○	5
11	Magnetic stineer	2	○	◎	◎	×	△			○	1
12	Safety cabinet	2	◎	○	○		△			○	1
13	Ultracentrifuge	1	◎	○	△					○	1
14	Auto clave	1	○	◎	○	×				×	0
15	Plasma separator	1	○	○	◎					○	1
16	Zonal rotor	1	◎	○	△	×				×	0
17	Swing bucket rotor	1	◎	○	○	×				×	0
18	Sonifier	1	○	○	○					○	1
19	Benches	6	○	◎	◎		△			○	2
20	Stools	3	○	◎	◎					○	3
PA kit preparation room											
1	Vortex mixer	2	○	◎	◎		△			○	1
2	Plate mixer	1	○	◎	◎	×				×	0
3	Peristaltic pumps	1	○	○	○					○	1
4	Filtration unit	1	△	○	○					×	0
5	Microwave unit	1	×	◎	◎					×	0
6	Benches	2	○	◎	◎		△			○	1
7	Stools	2	○	◎	◎					○	2
8	Safety cabinet	1	◎	○	○					○	1
9	Plasma separator	1	○	◎	◎	×				×	0
10	Automatic pipette aid - rechargeable	1	○	○	○					○	1

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
Hepcell kit manufacturing room											
1	Water bath	2	○	◎	◎					○	2
2	Refrigerated centrifuge	1	◎	○	○					○	1
3	Incubator oven	1	○	◎	○	×				×	0
4	Plate mixer	1	○	○	○	×				×	0
5	Mechanical crimpers	2	×	○	○	×				×	0
6	Calibrated autodispenser	1	×	○	○	×				×	0
7	Micro plate washer	1	○	○	○	×				×	0
8	Micro plate reader	1	○	○	○	×				×	0
9	Microplate mixer	2	○	○	○	×				×	0
10	Automatic pipette washer	1	×	○	○					×	0
11	PC + printer + UPS + desk + chairs	1	○	○	○	×				×	0
12	Benches	6	○	○	○		△			○	2
13	Stools	6	○	○	○		△			○	4
14	Haematocrit centrifuge	1	◎	○	○					○	1
15	Electronic balance	1	○	○	○					○	1
16	Suction unit	1	◎	○	○					○	1
PA kit manufacturing room											
1	Water bath	1	○	○	○					○	1
2	Rocking platform for vials	1	×	○	○					×	0
3	Automatic pipette aid - rechargeable	1	○	○	○					○	1
4	Mechanical crimpers	1	○	○	○					○	1
5	Sealing equipment	1	×	○	○					×	0
6	Benches	5	○	○	○		△			○	2
7	Stools	3	○	○	○					○	3
8	Refrigerated centrifuge	1	◎	○	○					○	1
Quality Control room											
1	Refrigerator	1	◎	○	○					○	1
2	Benches	2	○	○	○					○	2
3	PC + printer + UPS + desk + 2 chairs	1	○	○	○					○	1
4	Plate mixer	1	○	○	○					○	1
5	Automatic pipette aid - rechargeable	1	○	○	○					○	1
6	Micro plate washer	1	◎	○	○					○	1
7	Micro plate reader	1	◎	○	○					○	1

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
8	Deep freezer (-20℃)	1	○	○	○					○	1
9	Incubator with rocker	1	○	○	○					○	1
10	Camera illuminator & stand	1	◎	○	○					○	1
11	Bench top centrifuge	1	○	○	○					○	1
12	Electronic balance	2	○	○	○		△			○	1
13	Spectrodensitometer	1	○	○	○					○	1
14	pH meter	2	○	○	○		△			○	1
15	Refractometer	1	○	○	○					○	1
16	Spectrophotometer	1	○	○	○					○	1
Material room											
1	Water distiller / deioniser	2	◎	○	○		△			○	1
2	Refrigerator	2	◎	○	○					○	2
3	Deep freezer (-20℃)	2	×	○	○	×				×	0
4	Ultra low deep freezer	2	◎	○	○					○	2
5	Lockable cabinets	1	○	○	○					○	1
Dispense room											
1	Lyophilizer	2	◎	○	○		△			○	1
2	Benches	2	○	○	○		△			○	1
3	Dispenser	1	○	○	○	×				×	0
4	Automatic vial and filling machine	1	×	○	○	×				×	0
5	Benches for dispense	2	○	○	○					○	2
6	Automatic pipette aid - rechargeable	1	○	○	○					○	1
7	Plate mixer	1	○	○	○					○	1
Washing room											
1	Autoclave	1	○	○	○					○	1
2	Benches	2	○	○	○					○	2
3	Stools	2	○	○	○					○	2
4	Pass box	1	○	○	○					○	1
5	Drying machine	1	○	○	○					○	1
6	Ice making machine	1	○	○	○					○	1
Changing room											
1	Changing cabinets	6	○	◎	◎		△			○	4
Labelling room											
1	Labelling equipment	1	×	○	○					×	0
2	Batch printing machine	1	×	○	○				×	×	0

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
3	Benches	1	○	○	○					○	1
4	Stools	2	○	○	○					○	2
PA kit store											
1	Refrigerator	1	◎	○	○					○	1
Hepcell kit store											
1	Refrigerator	1	◎	○	○					○	1
Packing room											
1	Benches	2	○	◎	◎					○	2
2	Lockable cabinets	3	○	◎	◎		△			○	2
3	Cabinets	3	○	◎	◎		△			○	2
4	Refrigerator	2	◎	○	○					○	2
Office											
1	PC + printer +UPS	6	○	○	○		△			○	2
2	Desks	12	○	◎	◎		△			○	6
3	Chairs	24	○	◎	◎		△			○	6
4	Photocopier	1	○	○	○					○	1
Staff room											
1	Table + 6 chairs	1	○	◎	◎					○	1
2	Side bench	1	×	◎	◎					×	0
3	Refrigerator	1	×	○	○					×	0
4	Lab coat + head cap + sandals set	100	○	◎	◎				×	×	0
General manager room											
1	Desks	1	○	◎	◎					○	1
2	Chairs	1	○	◎	◎					○	1
Marketing manager room											
1	Desks	1	○	◎	◎					○	1
2	Chairs	1	○	◎	◎					○	1
Animal House											
Washing room											
1	Autoclave	2	○	○	○			△		○	1
2	Benches	2	○	◎	◎					○	2
3	Stools	2	○	◎	◎					○	2
Preparation room											
1	Benches	2	○	◎	◎					○	2

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
2	Stools	2	○	◎	◎					○	2
3	Scale	1	○	◎	◎					○	1
4	Breeding tool set	1	○	◎	◎					○	1
Breeding room											
1	Cage cabinets	4	○	◎	◎					○	4
2	Animal cages	125	○	◎	○					○	125
Quarantine room											
1	Desk + 2chairs	1	○	◎	◎					○	1
Training Unit											
Lecture room											
1	Student desks and chairs for trainees	120	○	◎	◎		△			○	48
2	Chairs	72	○	◎	◎					○	72
3	Lecturer tables	4	○	◎	◎		△			○	3
4	Visual-audio system	2	○	○	○		△			○	1
5	Multi purpose board (black, white and screen)	1	×	○	○					×	0
6	Notice boards	2	○	◎	◎	×			×	×	0
7	White boards	4	○	◎	◎			×		×	0
8	Slide projectors	1	○	○	○	×				×	0
9	Computer projectors and note type computers	2	○	○	○		△			○	1
10	Overhead projectors	2	○	○	○		△			○	1
Parasitic Lab.											
1	Laboratory tables and 4 chairs	4	○	◎	◎					○	4
2	Binocular microscope	25	○	○	○		△			○	16
3	Demonstrating microscope connecting to video camera	1	○	○	○					○	1
4	24 inches colour televisions for demonstrating	3	×	○	○					×	0
5	Discussion microscopes (for 5 persons)	1	○	○	○	×				×	0
6	Dissecting binocular microscope (×0.5 - 30, sliding)	25	○	○	○		△			○	16
7	Low speed centrifuges (table type)	3	○	○	○					○	1
8	Slide staining sets (including bottles and vats)	6	○	○	○				×	×	0
9	Micrometers and manometers	25	○	○	○					○	8
10	Hotplates for protozoa examination	6	○	○	○					×	0
11	Water baths	3	○	○	○		△			○	1
12	Incubators	3	○	○	○		△			○	1
13	Cabinets for storage of microscopes and materials	4	○	○	○					○	4

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
14	Bench	1	○	◎	◎					○	1
15	Stool	1	○	◎	◎					○	1
Infectious Lab.											
1	Water baths , small	2	○	○	○		△			○	1
2	ELISA readers connecting to computer diskettes	3	○	○	○	×				×	0
3	Shakers	6	○	○	○		△			○	3
4	*Auto-pipettes (different sizes)*	30	○	○	○		△			○	3
5	Multiple pipettes	6	○	○	○		△			○	1
6	Refrigerators	3	○	○	○		△			○	2
7	Incubators	2	○	○	○		△			○	1
8	pH meter	3	○	○	○		△			○	2
9	Spectro photometer	1	○	○	○					○	1
10	Magnet stirrers	6	○	○	○		△			○	2
11	Electronic balances (until 31g)	3	○	○	○		△			○	1
12	Electronic balances (until 310g)	3	○	○	○		△			○	1
13	Balance (until 2 kg)	1	○	○	○					○	1
14	Laboratory tables and 4 chairs	4	○	◎	◎					○	4
15	Electrophoresis sets	6	○	○	○					×	0
16	Microscopes for cell cultures	6	○	○	○		△			○	3
17	CO2 Incubators	2	○	○	○					○	2
18	Clean benches and aspirators	2	○	○	○					○	2
19	Aspirator	1	○	○	○	×				×	0
20	Slide glass, cover glass, ELISA plate, pipette, chips and dilution bottles	1	○	◎	◎				×	×	0
21	Autoclave for dissecting	1	○	○	○	×				×	0
22	Bench	1	○	◎	◎					○	1
23	Stool	1	○	◎	◎					○	1
Preparation room											
1	Gel-electrophoresis	1	×	○	○					×	0
2	Deep freezer	2	×	○	○					×	0
3	Ultra low deep freezer	2	○	○	○					○	2
4	Ultracentrifuge	1	×	○	○	×				×	0
5	PCR sets	2	×	○	○					×	0
6	Amplifiers	1	×	○	○					×	0
7	Sequencers	1	×	○	○					×	0
8	Fluorescence-Activated Cell Sorter	1	×	○	○					×	0

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
9	Ultra-homogenizer	1	○	○	○					○	1
10	Magnet stirrers	3	○	○	○		△			○	1
11	Freeze dryer	1	×	○	○					×	0
12	Clean bench	1	○	○	○					○	1
13	Low centrifuge with temperature control system	1	○	○	○					○	1
14	Cell culture equipment	1	×	○	○					×	0
15	Water bath	1	○	○	○					○	1
16	Sample stock cages	2	○	◎	◎					○	2
17	Glass tube washing machine	1	×	○	○					×	0
18	Dryer	1	×	○	○					×	0
19	Autoclave	1	○	○	○					○	1
Dark room											
1	Fluorescent microscopes	3	○	○	○		△			○	1
2	Chairs and tables	3	○	◎	◎		△			○	1
Culture room											
1	Chairs and tables	5	○	◎	◎		△			○	2
2	Fluorescent microscope with camera	1	○	○	○	×				×	0
3	Binocular microscope with camera	1	○	○	○	×				×	0
4	Binocular microscope with computer system	1	○	○	○					○	1
5	Dissecting microscope with camera	1	○	○	○					○	1
6	Microscope for cell culture with camera	1	○	○	○					○	1
Data processing room											
1	Chairs and tables	30	○	◎	◎		△			○	16
2	Lecturer's table and chair	1	○	◎	◎					○	1
3	Multi board (screen and white board)	1	×	○	○					×	0
4	White board	1	○	◎	◎					○	1
5	Projector connected to computer	1	○	○	○	×				×	0
6	Computers for trainees	25	○	○	○		△			○	8
7	White and black printers	4	○	○	○		△			○	1
8	*Colour printer*	1	○	○	○	×				×	0
Network room											
1	Computers	3	○	○	○					○	3
2	System reservoir	1	×	○	○	×				×	0
3	Cabinet for mechanical parts	1	○	◎	◎					○	1
4	CD-maker	1	○	○	○	×				×	0

No.	Description	Q'ty of request	Selection standard								Q'ty of plan
			a	b	c	d	e	f	g	h	
5	Desk and chairs	4	○	◎	◎					○	4
6	Cabinets for computer data	3	○	◎	◎		△			○	1
7	Cabinets for administrative documents	1	○	◎	◎					○	1
Office											
1	Vehicle(4WD)	1	×	○	○					×	0
2	Minibus	1	×	○	○					×	0
3	Saloon car	1	×	○	○					×	0
4	Office desks and chairs	8	○	◎	◎					○	8
5	Meeting table and chairs	1	○	◎	◎					○	1
6	Cabinets for office	4	○	◎	◎					○	4
7	Sofa set	1	×	◎	◎					×	0
8	White boards	2	○	◎	◎					○	2
9	Black board	1	×	◎	◎					×	0
10	Notice boards	2	◎	◎	◎					×	0
11	Photocopy machine (black and white)	2	○	○	○					○	2
12	Printing machine (colour)	1	○	○	○					○	1
13	Office-book-binding machines	2	○	○	◎		△		×	×	0
14	Bookstand	1	○	◎	◎				×	×	0
15	Fax machine	2	○	○	○				×	×	0

2-2-2-2 Site Plan

(1) Blood Screening Kit Production Unit

Considering the nature of the facility to be operated by the Blood Screening Kit Production Division, the facility will be laid out as a separate building from, rather than as an extension of, the existing KEMRI's facility, the latter consisting mainly of research facilities. The blood screening kit production unit will not be visited by a large number of various people; therefore, the facility does not need to be conspicuous. This is also right for security reason. Accordingly, the facility will be located on the hilly place in the southernmost part of the KEMRI's premises. At this location the facility would have a minimum impact upon the traffic lines of KEMRI.

The planned site is close to the southern boundary of the premises and faces the railroad of the Kenya Railways Corporation. Since construction of a building on the 100-feet belt along the railroad area is not permitted, such exteriors of the building as runways or parking areas will be planned on the side of the railroad, and the building is planned apart from the railroad. To prevent the traffic line for cars bringing in and out of the raw materials and the finished kits and that for persons from crossing each other, the design will separate their traffic lines.

CDC plans to expand KEMRI's facility to the northwest of the planned site, however, the details of the plan and schedules are not known. It is possible that construction works of both project be done in the same period; therefore, the layout will be planned to minimise impacts of CDC's works on the project. Reconciliation between the cooperation project and CDC's project will be necessary to avoid mutual interference on such matters as traffic lines of construction and after commissioning, for example.

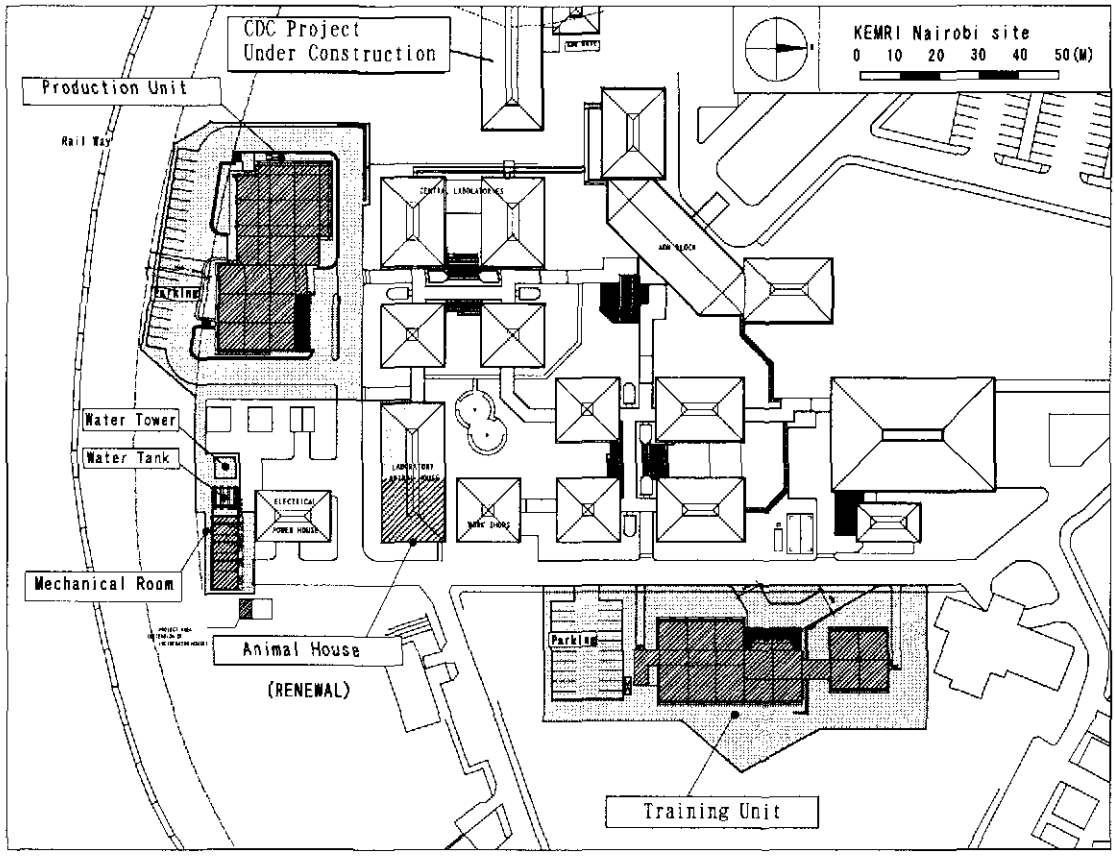


Figure 2-1 Layout Plan

(2) Animal House attached to the Production Unit

The location of the animal house should preferably be located as close to the production unit as permissible, from the viewpoint of the production process of the blood screening kits.

(3) Training Unit

Unlike the production unit of the blood screening kits, the training unit is to be used by a large number of people visiting various training courses, including seminar and Japan's third-country training courses by project-type technical cooperation. The training & research facility will therefore be laid out to be rather outstanding within the entire KEMRI plan. To satisfy these requirements, the training unit will use a portion of the large open space on the eastern part of the premises. This site is situated just the opposite of the existing hospital ward across the road and is on the highest point of the sloping open space.

2-2-2-3 Architectural Plan

(1) Design Conditions

Details and scale of the facility are determined on the basis of the following design conditions.

1) Blood Screening Kit Production Unit

① Voluntary GMP (Good Manufacturing Practices) Standards

Normally, establishment and management of a facility to manufacture medicines are required to satisfy the "GMP for pharmaceutical products" which specifies strict standards for hardware aspect and software aspects. The purposes of the GMP are, among others, to minimise human errors, to prevent contamination of medicines from the environment and facilities and deterioration of the quality, and to prepare a system to assure quality of medicines.

The blood screening kits to be produced by this project fall into "in vitro diagnostic medical device (IVD)" of medicines. Since Kenya dose not have such kind of standard, the voluntary GMP standards, which is commonly used in Japan, of the JAPAN ASSOCIATION OF CLINICAL REAGENTS INDUSTRIES (JACR), different from the GMP for pharmaceutical products that are orally taken or injected or vaccines, will be applied to the facility of this project.

② Classification of Production Area

The production area may be broadly classified into the clean production area, or the area covering the processes from the raw material storage room to the final dispensing operation, and the normal production area covering the operations from assemblages after dispensing and vacuum freeze drying to box packing.

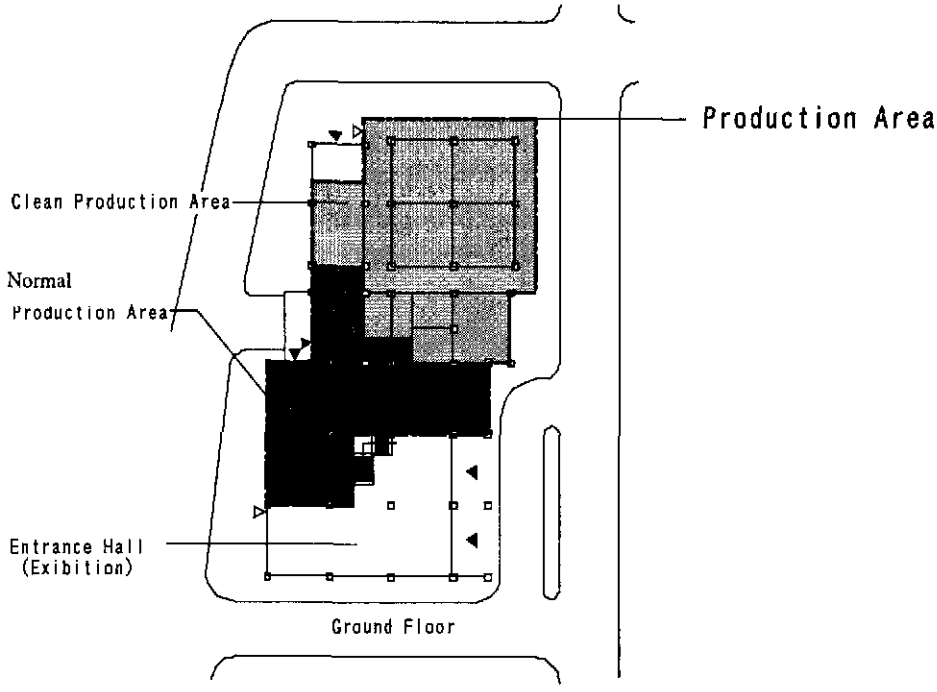
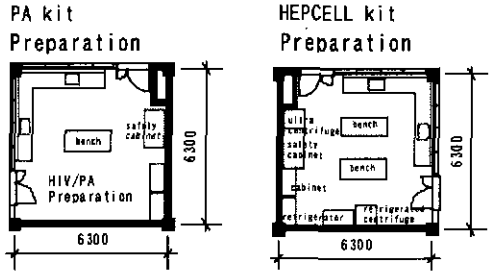


Figure 2-2 Zoning Plan of Production Area

③ Function and Scale of Room in the Production Area

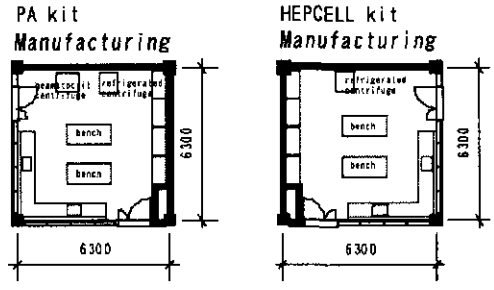
- Kit Preparation Room

The kit preparation rooms conduct various preparatory treatments of raw materials before they are fed to the manufacturing process. To avoid complex contamination, different rooms are assigned to different operations. Safety cabinets are provided for handling of such hazardous items as virus.



- Kit Manufacturing Room

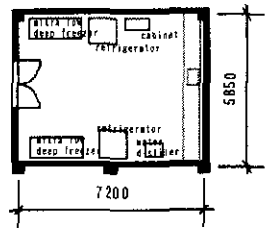
The kit manufacturing rooms manufacture parts necessary for manufacturing the kits. To avoid complex contamination, different rooms are assigned to different operations.



· Material Room

The raw material storage room stores the raw materials, parts prepared by the kit preparation rooms and the kit manufacturing rooms until the time these substances are demanded by the subsequent processes to be processed into the final products.

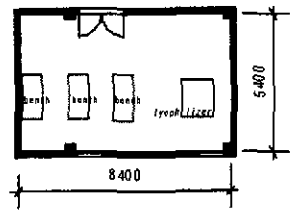
Material room



· Dispense Room, Freeze Drying Room

Dispensing and freeze-drying operations are done. The semi-products after these processes are transported out of the clean production area to the specified storage house to be stored there.

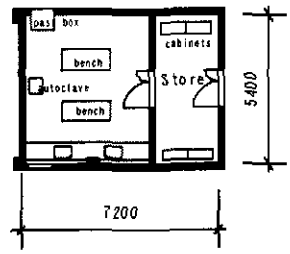
Dispense Room



· Washing Room

This room receives vials for products, washes them and transports them to the clean production area through the pass box. The cleaning and transportation operations are done as necessary to fit the dispensing operation schedule.

Washing room



· Locker Room

It is necessary to change clothes before entering and leaving the clean production area. Separate locker rooms are installed for men and women.

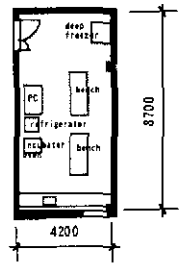
· Pre-clean Room

The pre-clean room is installed at the interface between the clean production area and the exterior. The locker rooms are installed in front of the pre-clean rooms.

· Quality Control Room

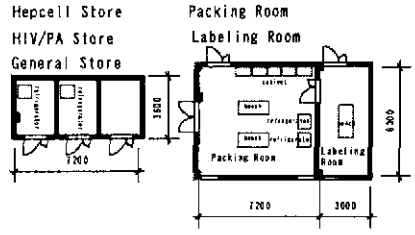
Quality control is applied not only to the finished products but to the in-process parts as found necessary to confirm their qualities.

Quality control Room



・ Special Store, Labelling Room, Packing Room

Separate special store will be prepared for the PA kit and HEPCELL kit. On completion of all manufacturing works in the clean production area, the PA kit and HEPCELL kit are transferred to their respective special store, where these kits are stored in refrigerators. Thereafter, these kits are subjected to the labelling operation and packing operation according to the delivery schedule.



④ Functions and Scales of Various Rooms outside the Production Area

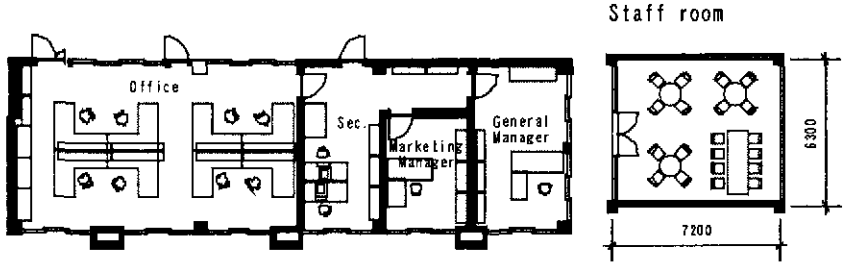
The rooms outside the production area may be broken down into the product exhibition space and the administration area.

・ Product Exhibition Space

As part of sales activities, panels showing the blood screening kits and their manufacturing processes, etc. will be exhibited.

・ Administration Area

The private offices of the manufacturing manager and marketing managers, and working spaces for their secretaries and clerks (the latter assumed to be eight persons) will be provided. A staff room will also be provided as place for resting for those working for the production unit.



⑤ Traffic Line Plan for the Production Unit

The table below shows the manufacturing processes of the blood screening kits.

In these processes, Processes 2 to 9, corresponding to the processes to manufacture parts of the blood screening kits, represent the HEPCELL kit manufacturing process which has more processes than the PA kit. In other words, these processes include the processes for manufacturing the PA kits. The processes 11 and onward apply to both PA kit and HEPCELL kit. Therefore,

the facility plan will be formulated based on the traffic line plan for the HEPCELL kit shown in the Appendices.

Table 2-14 Manufacturing Process and Various Rooms Used (HEPCELL kit)

Step	Stage	Detail	Rooms
1	Unloading	· Material unloading	Material Room/Storage/Packing Room
2	Elements preparation (HEPCELL kit)	· Purification of HBs antigen	Material Room/Preparation Room
3		· Preparation of immunogen	Material Room/Preparation Room
4		· QC for antisera of animal antiHBs antibody	Quality Control Room
5		· Antisera separation by centrifugation	Material Room/Manufacturing Room
6		· Purification of antiHBs by affinity column.	Material Room/Manufacturing Room
7		· Fixation of Sheep red blood cells	Material Room/Manufacturing Room
8		· Sensitisation	Material Room/Manufacturing Room
9		· Preparation of Positive control	Material Room/Preparation Room
10	Kit Manufacturing	· Preparation of kit components	Material Room/Manufacturing Room
11		· Dispense/Vials cleaning	Washing Room/Dispense Room
12		· Dispense of kit component	Dispense Room
13		· Capping	Dispense Room/Storage
14		· Labelling	Labelling Room/Storage
15	Shipping	· Assemble of kit/shipping	Packing Room

The design policy calls for production of 400 thousand tests (2,000 kits) a year of HEPCELL kits and 250 thousand tests (1,200 kits) a year of PA kits. Installation of separate lines for these two kits, as indicated by the request from the government of Kenya, would raise the construction cost, maintenance and management cost, and reduce operation efficiency. Therefore, whatever the elements in the manufacturing line that can be shared by both kits should be used by both kits. For this purpose, Processes 11 to 14 mentioned above should have only one line which should however be sized to be capable of producing 400 thousand tests, which can naturally accommodate 250 thousand PA kits.

2) Animal House attached to Production Unit

① Species and Number of Animals

In five years after completion of this project, to secure production of these amounts of kits, the project needs 30 guinea pigs a year and 10 rabbits a year as shown in the table below.

Table 2-15 Species and Number of Animals Required

Animal	Purpose	Requirement (per year)	Number to be grown (per year)	Maximum number of animals kept at the same time (within the cage)	Method for procurement	Rationale
Guinea pig	HEPCELL kit (HBs antibody for sensitisation)	Antibody, 100 mg	80	30	Number to be bred in the facility 60	Since 5mg of antibody may be taken from one guinea pig, collection of 100mg of antibody needs 20 guinea pigs. Generally, however, the yield from refining to sensitisation is 25%; therefore, 80 guinea pigs are necessary.
Rabbit	HEPCELL kit (fluid for confirmation)	Antibody 150mℓ	3	10	Procurement from outside: 3 to 10 per year (Breeding in the facility is planned for the future.)	Since 50mℓ of antibody is obtainable from one rabbit, three rabbits are required.
	HEPCELL kit (Addition of liquid to dilute the serum)	Serum 500mℓ	10			Since 50 mℓ of serum is obtainable from one rabbit, 10 rabbits are necessary. About 200 kits may be manufactured from 50 mℓ of serum.
	PA kit (Addition of liquid to dilute the serum)	Serum 500mℓ	10			Since 50mℓ of serum is obtainable from one rabbit, 10 rabbits are necessary. About 126 kits may be manufactured from 50mℓ of serum.

② Traffic Line Plan and Breeding Area

The 60 percent of existing animal house will be renovated, with installation of a new entrance separated from the existing one. With this renovation, the existing animal house will be used exclusively for the production unit, completely separated from the one for the research purpose. Separate traffic lines are needed for the production works and the research works.

The contaminated wastes from the new breeding area will be removed to the outer corridor through the pass room. One-way traffic line is planned to permit returning from the outer corridor to the washing room, thereby keeping the inside of breeding area uncontaminated.

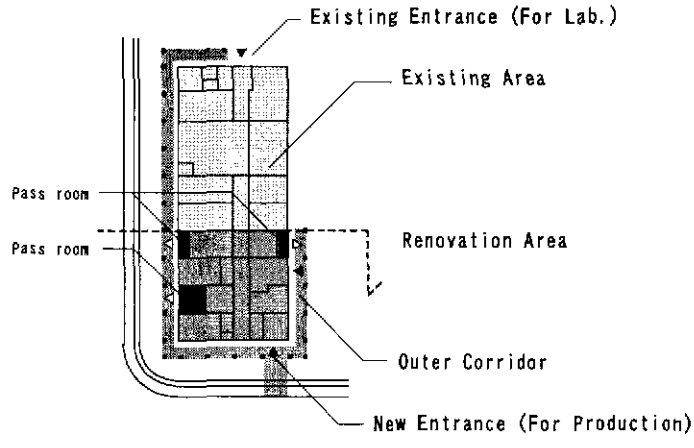


Figure 2-3 Zoning Plan of Animal House

3) Training Unit

① Zoning

The training unit consists of the entrance area, the training areas, and the office area. As shown in the figure below, the training area and the office area are laid out apart, with the entrance area in between.

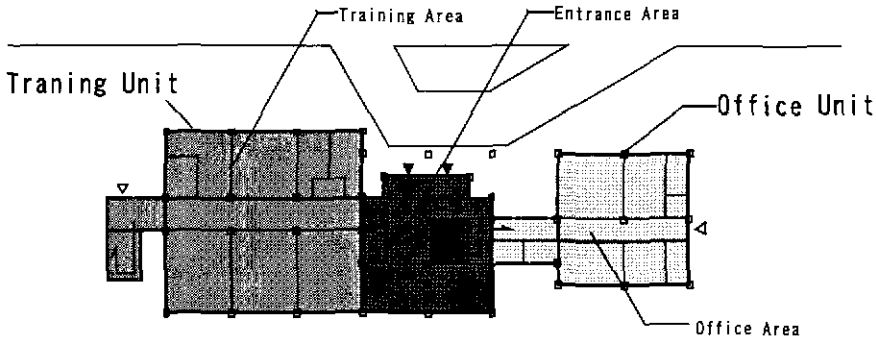


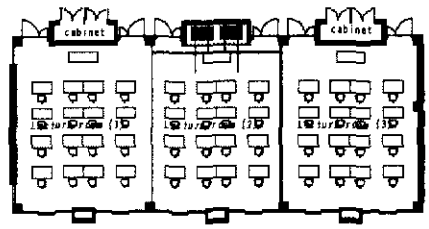
Figure 2-4 Zoning Plan of Training Unit

② Function and Scale of Room

- Lecture Room

Since two or more lecture rooms may be necessary at the same time, three lecture rooms each accommodating about 16 persons will be installed. The partitions between rooms will be openable ones, to make one big lecture room that can accommodate 30 or more persons.

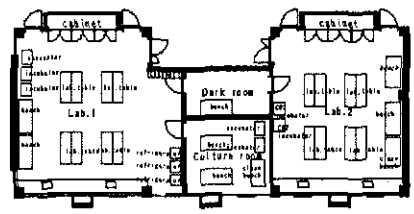
Lecture room



- Training Laboratory

Two training laboratories, one for parasitic and the other for infectious diseases, will be provided. Both are sized to accommodate 16 persons and to permit them to conduct their own experiments simultaneously.

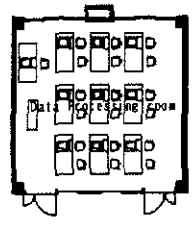
Training Laboratory



- Data Processing Room

An data processing room will be provided for analysis of epidemiological data and for drafting of parasitic disease control by computer. The room will be sized

Data Processing Room

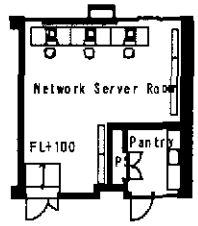


to accommodate about 16 persons, according to the training programme.

- Network Room

  It is an important that KEMRI be equipped with functions to collect and transmit information as a centre of parasitic disease control in East Africa. For this purpose a network room will be provided to manage and transmit information.

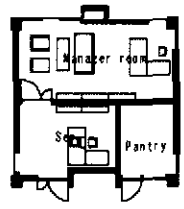
Network Room



- Administration Area

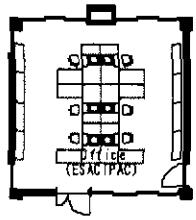
  An administration office will be provided for the general manager of the training unit, the head of the unit, their secretaries and clerks. Also planned are rooms for instructors and programme supervision rooms. The administration space is not partitioned to be used as a big open space which flexibly permits alteration of layout to meet various needs.

Manager room

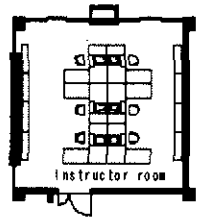


Secretary room

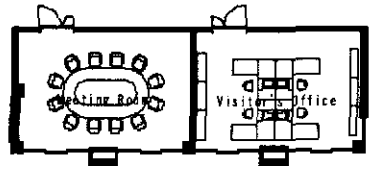
Office



Instructor room



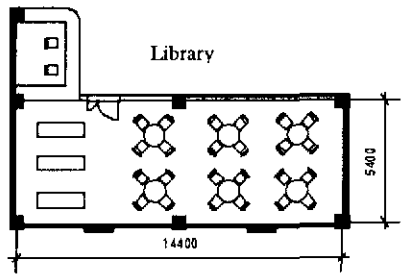
Meeting room / Visitor's Office



- Library

  The library will be deigned to be a multi-purpose space holding literature, showing various exhibits and panels, and providing a space for reading and studying of trainees. The number of books regarding parasitic and infectious disease control to be shelved will be 700 to 800.

Library



(2) Required Floor Area

The details and scale of the facility plan formulated on the above conditions are given below.

Table 2-16 Required Floor Area

Production Unit

Area	Room name	No.	m^2/room	m^2	Remark
Entrance	Entrance hall	1	85.8	85.8	14.5m×7m
	Reception	1	5.0	5.0	6m×2m
	Exhibition	1	45.4	45.4	12.5m×3.6m
	Lounge	1	45.4	45.4	12.5m×3.6m
	Subtotal			181.6	
Office Area	General Manager room	1	22.7	22.7	7m×3.2m
	Marketing Manager room	1	16.2	16.2	7m×3.2m
	Secretary room	1	25.9	25.9	
	Office	1	71.3	71.3	14.5m×6.3m
	Changing room	2	9.5	19.0	5m×4m
	Staff room	1	45.4	45.4	6.3m×7.2m
	Pantry	1	8.6	8.6	2m×4m
	Subtotal			209.1	
Clean Production Area	PA kit Preparation room	1	39.7	39.7	6.3m×6.3m
	PA kit Manufacturing room	1	39.7	39.7	6.3m×6.3m
	Hepcell kit Preparation room	1	39.7	39.7	6.3m×6.3m
	Hepcell kit Manufacturing roo	1	39.7	39.7	6.3m×6.3m
	Material room	1	41.8	41.8	6.3m×7.2m
	Dispense room	1	45.4	45.4	8.5m×5.4m
	Changing room	2	14.8	29.5	7.2m×4m
	Ante room	1	10.2	10.2	4.5m×2m
	Pass room	1	5.7	5.7	4.5m×2.5m
	Clean corridor	1	145.7	145.7	width 1.8m & width 2.7m
	Subtotal			437.1	
Attached Production Area	Washing room	1	25.9	25.9	4.5m×5.4m
	Quality control room	1	36.8	36.8	4.5m×8.5m
	Labeling room	1	18.9	18.9	3m×6.3m
	Packing room	1	45.4	45.4	7.2m×6.3m
	Hepcell kit store	1	8.2	8.2	2.5m×3.5m
	PA kit store	1	8.2	8.2	2.5m×3.5m
	Vial store	1	13.7	13.7	3m×5.4m
	Store	2	8.2	16.5	2.5m×3.5m
	WC	1	35.8	35.8	7m×4m
	Subtotal			209.4	
Common Area	Corridor	1	165.0	165.0	
	Canopy	1	51.8	51.8	
	Exterior corridor	1	148.1	148.1	
	Terrace	1	38.5	38.5	
	Mechanical room	1	83.2	83.2	
	Subtotal			486.6	
Total				1,523.8	

Animal House

Area	Room name	No.	m^2/room	m^2	Remark
Breeding Area	Corridor	1	17.0	17.0	1.8m×12.5m
	Rabbit room	1	15.1	15.1	4.8m×3.2m
	Guinea pig room	1	15.1	15.1	4.8m×3.2m
	Breeding room	1	16.1	16.1	3.6m×3.2m
	Inoculation room	1	10.4	10.4	3.3m×3.2m
	Pass room	5	4.2	22.8	1.5m×3.2m×5
	Ante room	1	9.5	9.5	3.0m×3.2m
	subtotal			106.0	
	Washing room	1	15.9	15.9	4.5m×3.2m
	Preparation room	1	12.5	12.5	4.5m×3.2m
	Quarantine room	1	10.4	10.4	2.3m×3.2m
	Changing room	1	5.0	5.0	2.3m×3.2m
	subtotal			43.8	
Common	Office	1	9.1	9.1	4.5m×3.2m
	Canopy	1	102.9	102.9	1.8m×1.7m
	Subtotal			112.0	
Total				261.8	

Training Unit

Area	Room name	No.	m^2/room	m^2	Remark
Entrance Area	Entrance hall	1	60.2	60.2	14.5m×9.6m
	Reception	1	8.9	8.9	3.6m×2.7m
	Lounge	1	52.6	52.6	14.5m×3.5m
	Library	1	77.7	77.7	14.5m×5.5m
	Subtotal			199.4	
Office Area	Manager room	1	25.9	25.9	7.2m×5m
	Secretary room	1	16.9	16.9	7.2m×5m
	Office	1	51.8	51.8	7.2m×12m
	Visitor's Office	1	35.6	35.6	7.2m×4.5m
	Specialist room	1	22.2	22.2	4.5m×5m
	Project Supervision	1	35.5	35.5	7.2m×5m
	Instructor room	1	51.8	51.8	7.2m×7.2m
	Meeting room	2	33.8	69.4	7.2m×4.5m
	Print room	1	13.3	13.3	2.7m×5m
	Pantry	2	7.5	16.5	2.5m×3m
	Store	1	10.5	10.5	2.5m×4.2m
	WC	2	18.4	36.7	7.2m×2.4m
	Subtotal			386.1	
Training Area	Parasitic Lab.	1	83.8	83.8	7.2m×9m
	Infectious Lab.	1	68.9	68.9	7.2m×9m
	Preparation room	1	55.9	55.9	7.2m×7.2m
	Culture room	1	21.2	21.2	5m×4.2m
	Dark room	1	13.9	13.9	5m×2.5m
	Lecture room	3	68.3	204.9	7.2m×9m×3
	Data processing room	1	51.8	51.8	7.2m×7.2m
	Network room	1	43.6	43.6	5m×7.2m
	Changing room	2	12.0	24.0	2.5m×5m ×2
	Shower room	1	5.5	5.5	2.5m×2.5m ×2
	Pantry	2	8.7	17.3	2m×2m
	WC	2	29.9	59.8	7.2m×5.5m
	Store	2	10.0	25.6	3m×6.5m
	Subtotal			676.2	
Common	Corridor	1	471.1	471.1	
	Canopy	1	69.1	69.1	
	Exterior corridor	1	135.7	135.7	
	Terrace	1	137.2	137.2	
	Mechanical room	1	8.5	8.5	
	Subtotal			821.6	
Total				2,083.3	

Mechanical House

Area	Room name	No.	m^2/room	m^2	Remark
	Mechanical room	1	129.0	129.0	
	Exterior corridor	1	23.1	23.1	
	Subtotal			152.1	
Total				152.1	*Mechanical Room is included Production Unit

Water Supply Facility

Area	Room name	No.	m^2/room	m^2	Remark
	Water tower	1	36.0	36.0	
	Water tank	1	25.0	25.0	
	Subtotal			61.0	
Total				61.0	*Water Supply Unit are included Production Unit

(3) Facility Component (Function)

Components of each facility are as follows.

Production Unit (New Construction Work: Reinforced Concrete Structure with 2 stories)

Floor	Contents
Ground Floor	PA kit Preparation room, Hepcell kit Preparation room, PA kit Manufacturing room, Hepcell kit Manufacturing room, Material room, Dispense room, Changing room, Ante room, Pass room, Clean corridor, Quality control room, Washing room, Vial store, PA kit store, Hepcell kit store, Store, Packing room, Labelling room, WC
First Floor	Office, Staff room, General Manager room, Marketing Manager room, Secretary room, Changing room, Pantry, Entrance hall, Reception, Corridor, Mechanical room

Animal House (Renovation Work: Concrete Block Structure with 1 story)

Floor	Contents
Ground Floor	Rabbit room, Guinea pig room, Breeding room, Inoculation room, Washing room, Pass room, Changing room, Corridor, Quarantine room, Office, Preparation room, WC
Loft	Mechanical room

Training Unit (New Construction Work: Reinforced Concrete Structure with 2 stories)

Floor	Contents
Training Unit / Ground floor	Parasitic Lab., Infectious Lab., Preparation room, Culture room, Dark room, Changing room, Shower room, WC, Store, Pantry, Mechanical room, Entrance hall, Reception, Library, Corridor
Training Unit / First floor	Lecture room, Data processing room, Network room, WC, Store, Pantry, Lounge, Corridor
Office Unit/ Ground floor	Office, Visitor's office, Manager room, Secretary room, Meeting room, Store, WC, Pantry, Corridor
Office Unit/ First floor	Project Supervision, Instructor room, Meeting room, Specialist room, Print room, Store, Corridor

(4) Floor Planning

1) Blood Screening Kit Production Unit

The production unit may be broadly divided by function into the following three areas.

① Production Area

Clean Production Area

The clean area is maintained at the degree of cleanliness equivalent to those of similar Japanese facilities.

Normal Production Area

The portions of the manufacturing process for which high cleanliness is not necessarily required are laid out outside the clean production area to reduce the operation and maintenance costs of the facility.

② Entrance Area

The entrance area will have a space to exhibit finished blood screening kits, in addition to normal entrance function of a building.

③ Administration Area

The Administration area will also have rooms for manufacturing manager, marketing manager, and manufacturing staff.

A portion of the building will be of two-story structure, due to constraints of the site and to make the traffic line on the site as compact as possible. The ground floor will have the entrance and the exhibition space, the entire production unit, and receiving and shipping functions directly to and from the runway level. The Administration Division will be placed on the first floor. Thus, the total traffic line will be shorter than would be if all functions were laid out on the same floor.

Entry to and exit from the production clean area are, in principle, done either through the pre-clean room (in the case of the operation staff) or through the pass room and pass box (in the case of raw materials, vials, etc.). The pre-clean room is equipped with locker rooms for men and women, who are obliged to enter the pre-clean room carrying their clothes to change. The works they have to do after entering the production clean area have been determined according to the manufacturing plan. On completion of the work, the working staff is required to leave the manufacturing area promptly. In the production clean area are laid out the preparatory room, kit manufacturing room, clean side walkway surrounding the kit manufacturing room, raw material storage room, dispensing/freeze drying room. The operating staff and

materials move along the traffic line connecting the manufacturing processes as works are being done.

Parts that have gone through the dispensing and freeze drying operation are discharged from the clean production area to their respective special storage to be stored until they are sent out for labelling and packing. The finished products are shipped from the packing room through the truck yard.

2) Animal House attached to the Production Unit

The purpose of the animal house is to collect sera and other raw materials from rabbits and guinea pigs. Breeding of guinea pig is also done in this animal house. To assure quality of raw materials for the blood screening kits, this animal house will be installed as a separate facility from the production area.

3) Training Unit

The training unit consists of the following three areas.

① Training Area

The training laboratories and lecture rooms are planned for this area. These rooms are used for training on parasitic diseases and infectious diseases. During the period when training is not done, these rooms are used for researches.

② Entrance Area

In addition to the function of the entrance area, a library for shelving literature mainly for infectious and parasitic diseases and a lounge to provide relaxation are planned.

③ Administration Area

The Administration Division responsible for smoothly managing training & research facility, and the associated administration division responsible for smooth implementation of project-type technical cooperation will be accommodated.

For the sake of effective utilisation of limited available land, a two-story building is planned. The ground floor will hold the training laboratories and the first floor will hold the lecture rooms, to clearly distinguish the functions of the ground and first floors. The three lecture rooms will be planned. The partitions between the lecture rooms will be of openable structure to make a large room to be used in such cases as opening ceremony of the facility, for example.

(5) Elevation Plan (design and finish)

1) Blood Screening Kit Production Unit

The outer wall will be of Nairobi stone, which is commonly used in Kenya, though paint-finished mortar will be used partially. Basically, the finishing materials will be selected with due consideration given to harmony wit the existing KEMRI's facilities. The roof will be slanted and tiled similar to the existing building. Louvers will be placed on the external windows to shield intense sunlight and hence reduce the load of air conditioning, as are the case with the existing buildings.

2) Animal House attached to the Production Unit

Since the existing animal house for research purpose will be modified, the number of openings to the exterior will increase. To enclose such openings, an outer cloister will be installed. The outer cloister (to connect these openings) is planned to be equipped with wooden louvers to serve as blinds. The cloister and louvers will be placed under the eaves of the existing buildings.

3) Training Unit

Training area is used for the third-country training & others. The training unit constitutes a space having the entrance lounge function. The associated administration function is given to the separate administration block. These two blocks will be built on grounds at different elevations. However, the roofs of these two buildings are connected to form one structure. The design applied to the external wall of the blood screening kit production unit will also be applied to the external wall of this building.

(6) Section Plan

1) Blood Screening Kit Production Unit

The administration area only will be placed on the first floor of the building. For the production area, the loft space beneath the slanted roof is used as space for installing the air-conditioning machine. The ducts for intake and exhaust air will be installed in this space. This space will also be effectively utilised for maintenance space.

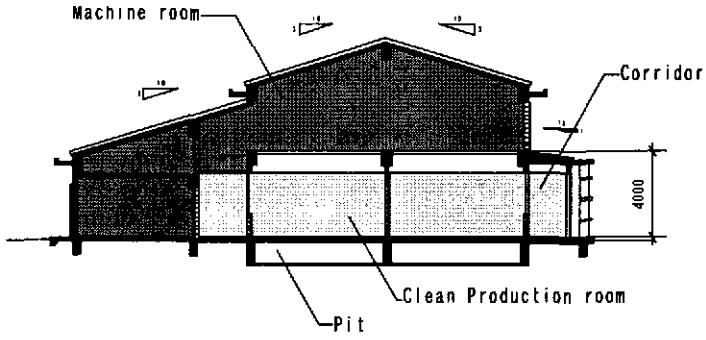


Figure 2-5 Cross-sectional View of the Production Unit

2) Animal House attached to the Production Unit

An air-conditioner machine room of steel frame structure will be installed in the loft space of the existing animal house. The modified portion of the animal house will be air conditioned (heating and cooling). The breeding area and the machine space are planned not to be overlapping vertically to protect the breeding area from the noise or vibration. A gangway ladder will be used to access to the loft space.

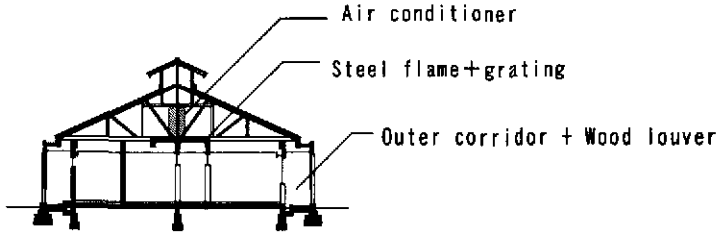


Figure 2-6 Cross-sectional View of the Animal House

3) Training Unit

There is a difference in level of about 2.1 meters between the northern and southern ends of the site for the planned facility. This difference in level is coped with by installing skipped steps on the connecting corridor between the entrance area and the administration area.

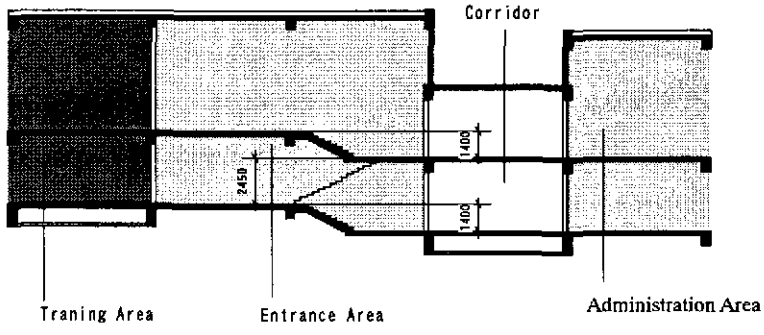


Figure 2-7 Cross-sectional View of the Training Unit

2-2-2-4 Structural Plan

(1) Geological Structure of the Site

The construction site is a gentle hill situated about 3 kilometres to the southwest of Nairobi downtown. The ground conditions are good. The buildings of KEMRI built in the premises do not show any sign of land deformation as of subsidence.

The ground structure of the entire site is such that the ground is generally solid with baserock lying about 1.0 to 2.0 meters deep from the ground surface. The planned buildings are two-story ones, and they can stand on spread foundations (independent footings). Shallow as it is, excavation of the baserock will present a difficulty; therefore, the foundations must be designed with due consideration given to the depth distribution of the baserock.

(2) Outline of Geological Study

A plate loading test was conducted to measure depth of the bearing ground and to figure out the bearing strength. In this test, a disk of 45 centimetres across was placed at a depth of one meter, and increasing loads were placed on the disk in a stepwise fashion. The degree of subsidence was measured for each load.

The plate loading test was done at the indicated location where the training unit is to be built.

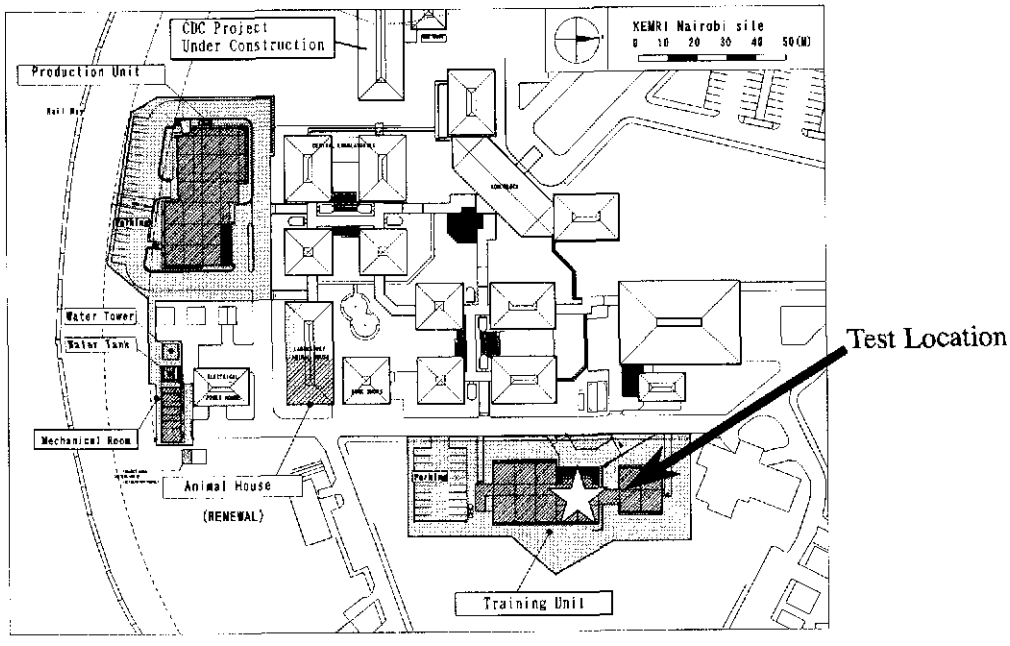


Figure 2-8 Plate Loading Test Location Map

The following Table shows the results of the plate loading test. A maximum subsidence of 0.44mm was recorded against the maximum load of 201.6kN/m^2 (20.6t/m^2). Normally, the amount of load that causes a subsidence of 1cm is regarded as the ultimate strength, and one-third of the ultimate strength is used as the long-term load bearing strength of the ground. It was confirmed from this test that the long-term load bearing strength of more than 200.0kN/m^2 may be expected.

Table 2-17 Results of Plate Loading Test

Load (kN)	Intensity (kN/m^2)	Immediate Settlement (mm)	Delayed Settlement (mm)
(LOAD/SETTLEMENT)			
1.5	9.45	0.00	0.00
2.0	12.6	0.01	0.01
4.0	25.2	0.07	0.07
6.0	37.8	0.10	0.10
8.0	50.4	0.11	0.11
10	63.0	0.12	0.14
12	75.6	0.15	0.15
14	88.2	0.16	0.17
17	107.1	0.19	0.22
19	119.7	0.23	0.24
21	132.3	0.26	0.26
23	144.9	0.27	0.28
25	157.5	0.29	0.31
27	170.1	0.33	0.36
30	189.0	0.38	0.41
32	201.6	0.43	0.44
(REBOUND)			
23	144.9	0.42	0.42
13	81.9	0.40	0.39
1	6.3	0.32	0.21

Date : 6th March 2002
Test Depth: GL-1.0m、Diameter of Test Plate: 0.45m、Dead Load: 1.0kN

(3) Foundation Plan

A spread foundation (independent footing) with its bearing layer at a depth of around GL−1.0m will be used for both the production unit and the training unit. The long-term load bearing strength was set at 200.0 kN/m^2.

(4) Structural Plan

The building for the production unit and that for the training unit will both be two-story without basement, of reinforced concrete of moment-resisting frame structure.

(5) Design Standard

The buildings will be designed first to the Building Code Republic of Kenya, and also to the Code of Practice for the Design & Construction of Buildings & Other Structures in relation to Earthquakes and the General Specification for Building Works Republic of Kenya. The BS Standards will also be used. As found necessary, the Japanese design standards will be referred to.

The following are major standards to be observed in construction of the buildings.

a. Building Code Republic of Kenya (1968)
b. Code of Practice for the Design & Construction of Buildings & Other Structures in relation to Earthquakes (1973)
c. General Specification for Building Works Republic of Kenya (1976)
d. Load conditions of the BS Standards
e. Reinforced concrete building structure of the BS Standards
f. Various standards of the Architectural Institute of Japan

(6) Design Load

1) Fixed Load

The fixed load is calculated from the weights of structural materials, finishing materials, other items fixed to the building like piping and ducts.

2) Live Load

The values indicated in the Building Code Republic of Kenya are used as design live load. Regarding other loads, corrections will be made from the load conditions of the BS Standards. Live loads for main rooms are specified as shown in the table below.

Table 2-18 Live Load of Main Room

Building	Room	Live load (kg/m^2)
Production Unit	Manufacturing room	500
	Raw material storage room	500
	Dispensing room	300
	Administration room	300
	Machine room	500
Training unit	Laboratory	500
	Lecture room	300
	Storage	1,000
	Library	800

3) Wind Load

The wind load is set at 33.1kg/m^2 according the BS Standards.

4) Earthquake Load

The earthquake load is set according to the Code of Practice for the Design & Construction of Buildings & Other Structures in relation to Earthquakes of Kenya. The design of low-rise buildings does not need to consider the earthquake load; therefore, earthquake resisting walls of reinforced concrete are not considered in the design.

(7) Materials and their Strengths

The buildings will basically use Kenya-made structural materials. The facility will use the following structural materials, in consideration of availability, quality, workability, price, etc.

- Concrete

  Kind: normal concrete, Class 20

  Strength: 205kg/cm^2 (4-week strength)

  Aggregate: Coarse aggregates will be crushed stones and fine aggregates will be river sand, pit sand, and fine sand, all conforming to the BS882.

- Reinforcing bar

  Mild steel bars, D6, D10, D12

  High yield steel bars, D16, D20, D25

2-2-2-5 Mechanical and Electrical Plan

(1) Electrical Facility

1) Power Substation

According to the Kenya Power and Lighting Company, the KEMRI can have two electric power receiving lines. In addition to the existing high-voltage receiving line, a new power receiving line will be provided from another substation from the northern boundary of the site, and a new high-voltage panel will be installed. The main switching system for the two receiving lines will be installed by KPLC (Kenyan side). The construction from this high-voltage transmission terminal to the KEMRI's existing 1,000 kVA transformer and to the 500 kVA transformer for the subject project will be the work of the Japanese side.

The electric power for internal distribution is at 3 ϕ 4W 415/240V, that for power at 3 ϕ 3W 415V and that for lighting at 1 ϕ 2W 240V.

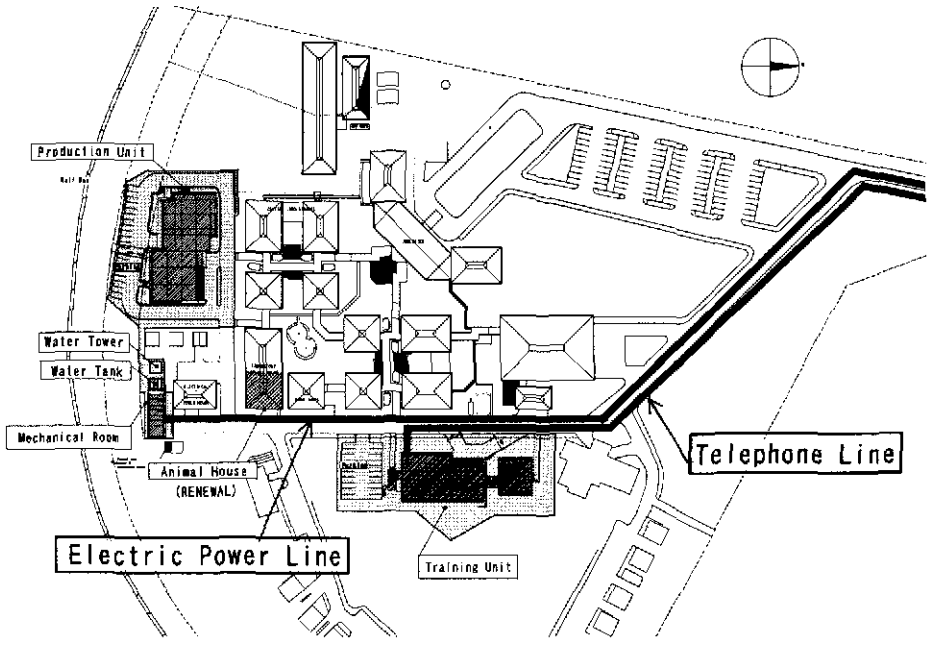


Figure 2-9 Trunk Power Wiring Plan

2) Emergency Electric Power Facility

Power failure occurs very frequently and voltage fluctuation is also large in Kenya. The power failure can seriously affect the operation of the production unit, it can degrade the quality of the product, or even worse, the power failure affect the animals for blood collection. A diesel-powered generator of about 200kVA will be installed

for the production unit and for particular air-conditioning machines which need stable supply of electric power. To limit the capacity of the generator, the supply of emergency power will be limited to such essential facilities as the production unit, particular air conditioning machines, emergency facilities, and disaster prevention devices.

The electric power condition for existing laboratories at the P3 level laboratory are inadequate, with the faulty UPS and the existing power generator that often fails to start at frequent power failures. The electric power demand by the P3-level laboratories is not very large, the amount that can be supplied by the generator to be installed by this project without upgrading its specifications. The electric power supply to these facilities will be more reliable by supplying electricity from the circuit of this project's generator accordingly.

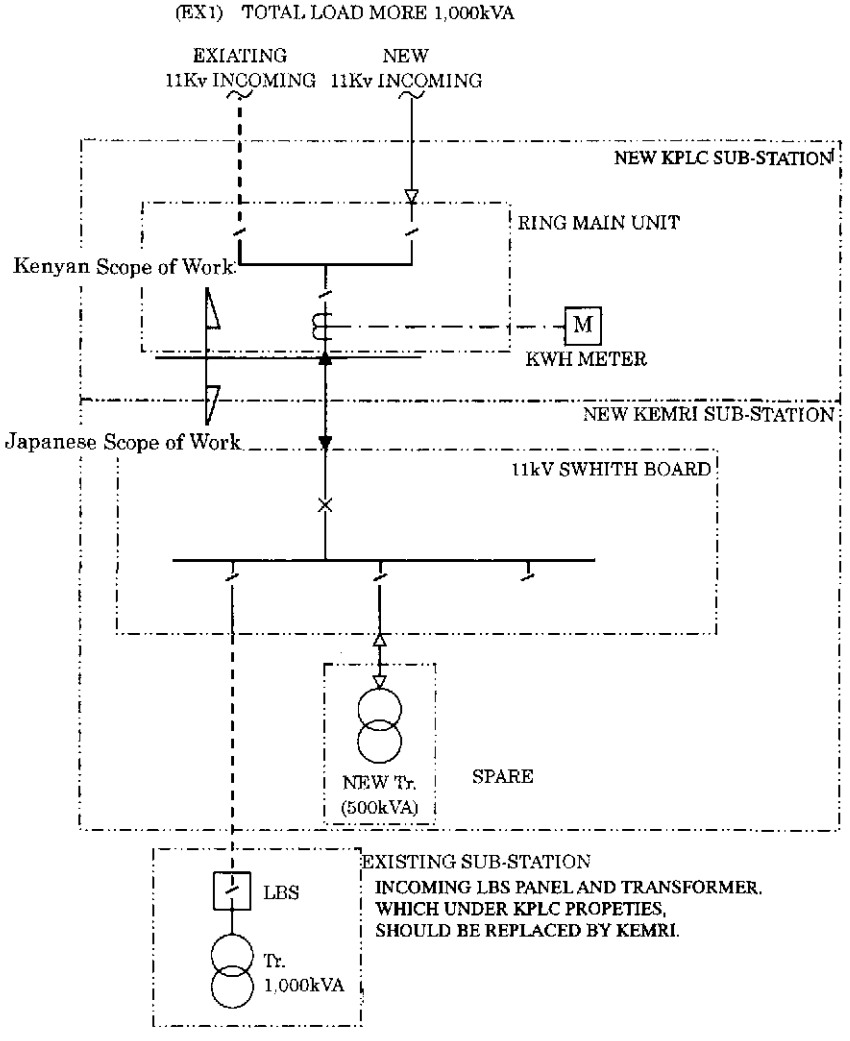


Figure 2-10 One-line Wiring Diagram

3) Main Power Line, Electric Power Facility

Dual distribution systems, one being public utility power distribution system and the other being public utility power/generator distribution system, are planned. General uses are supplied from the public utility power distribution system, but the important uses of the production unit and disaster prevention facilities are supplied from the public utility power/generator distribution system.

4) Lighting and Receptacle

Fluorescent lamps are used mainly as lighting equipment because of their relatively low maintenance cost. The illuminance will be set at 50 to 70 percent of the JIS standards, considering the local conditions. For outdoor lighting, mercury lamps commonly used locally will be used.

Three types of power receptacle will be used depending upon the use; namely, general purpose, equipment purpose and emergency purpose. The receptacle for emergency purpose (including machine driving purpose) only are connected with the generator distribution system.

5) Lightning Arrester

A lightning arrester is installed on the elevated water tank.

6) Telephone System

Due to the scale of the subject facility, about 10 independent outside lines and about 40 inside lines are conceived. The system design will consider interlocking with the existing systems. The switchboard will be placed at the ground floor reception desk and will be operated by the receptionist. The exchange will be placed in the server room.

The Japanese scope of work is limited to installation of cable rack or cable conduit pipe to the connecting point with the existing facility.

7) Public Address System

The main part of the public address system will be installed in the ground floor administration room of the training unit, because the system will be operated by the receptionist. Speakers will be installed at appropriate places of the planned facility to enable paging and emergency announcing to the entire buildings.

The emergency announcing will be done by person; therefore, an automatic announcing system will not be provided.

8) Central Monitoring System

The central monitoring system will be installed, one each for the administration room of the production unit, and the administration room of the training unit, to monitor the operation of equipment and to indicate alarms. The system will also indicate alarms in the control room of the existing KEMRI facilities, with other alarms. The function of the central monitoring system will be in principle limited to monitoring and indication of alarms.

9) Fire Alarm System

The fire alarm system will be designed to the BS standards or the Japanese standards. The receiver of the system will be placed in the administration room of the production unit and in the administration room of the training unit. The alarm is indicated in the control room of the existing facilities with other alarms.

10) LAN System

The Japanese scope of work is limited to connection with the existing LAN system and installation of cable conduit pipe within the subject project area.

11) Common TV Receiving Facility

Cable dusts only will be installed as a Japanese scope of work, as a provision for facilitating receiving both satellite and surface TV broadcasting after commissioning of the facility.

(2) Mechanical Facility

1) Water Supply System

The water main is tapped from the trunk line buried in the road (Mbagathi Way) to the west of the construction site, and stored in the receiving tank. The design consumption is set at about $40m^3$/day from the scale of the project facility.

The capacity of the receiving tank is equivalent to one day's consumption to accommodate scheduled supply shortage. The tank is made of FRP, and is placed aboveground close to the production unit. Water is pumped up to the elevated water tank and water is supplied to the production unit, the training unit and animal house

by gravity. A plan to drill new deep well at the cost of the Kenyan side has been confirmed as an emergency usage against water supply shortage. This water from new well will be used also for the existing buildings. Only branch piping is to be provided for new well water. A piping between new well and new water reservoir shall be provided by Kenyan side.

2) Drainage

The soil water and the miscellaneous wastewater are mixed outdoor and discharged to the sewer main pipe running along the eastern boundary of the construction site. Since the ground level of the production unit is a little lower than that of the existing buildings, a new sewer pipe will be laid to the boundary of the site as Japanese scope of work. A neutralisation tank will be installed to neutralise wastewaters from the production unit and laboratory before they are discharged to the sewer main pipe. An exclusive sterilisation tank will be installed for wastewater from the animal house. After treatment, wastewater is discharged to the sewer main.

3) Hot Water Supply

Hot water supply systems will be installed to the planned facilities. Supply of large amount of steam is not needed, all the hot water supply systems will be locally installed. Hot water suppliers of storage or instantaneous electric type are installed where they are needed.

Hot water supply systems will be installed at the following locations.

- Production unit
  Washing room, pantry, quality control room
- Animal house
  Washing room, preparation room, inoculation room
- Training unit
  Shower room, pantry

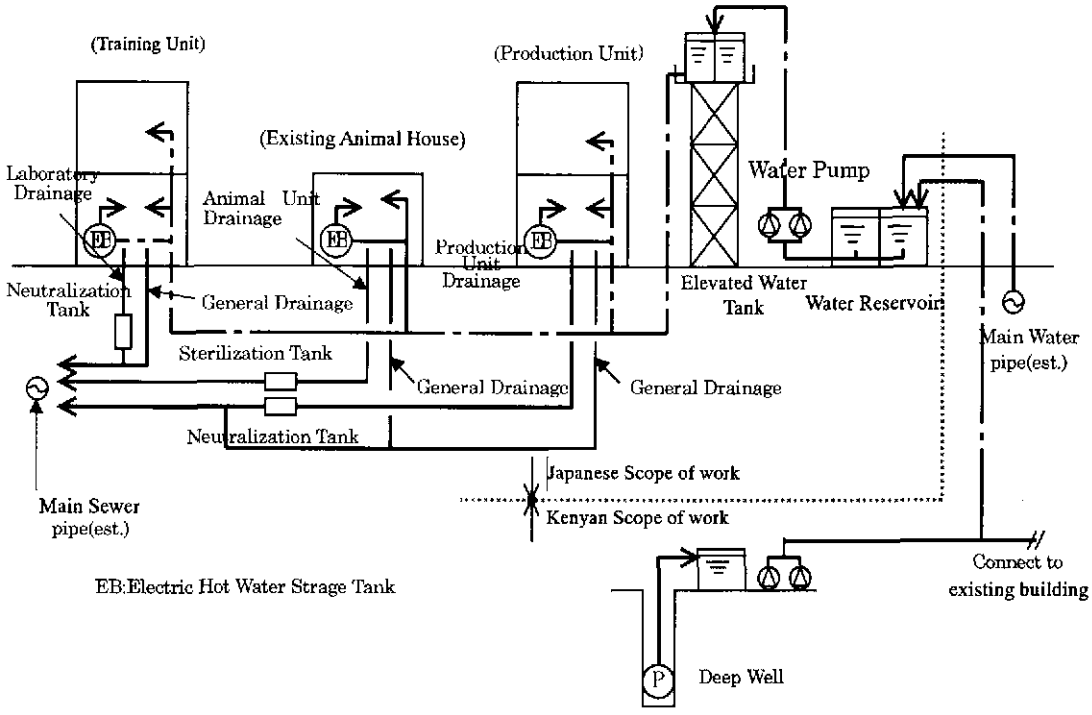


Figure 2-11 Water Supply, Hot Water Supply, Drainage System Plans

4) Sanitary Fixture

Water closet is to be of Western style with a low tank similar to the existing facilities. Urinals will be either of floorstanding type or of wall hung type, with flush valves. Hot water and water will be supplied, with a mixing valve as necessary. Every laboratory table will be equipped with a wash basin for experiment, and provision of a handle-lever type faucets will be studied for the sinks in the production unit and the training unit. The drainpipes from the laboratory table and animal house are equipped with traps as necessary.

5) Gas

The production unit and the laboratories are supplied with LP gas by a centrally supplied LP gas system.

6) Waste and Rubbish

General wastes are considered to be collected by the city authority as are done now. The medical wastes from the production unit will be burned in the existing oil-fired incinerator. Animal carcasses from the animal house will be burned in the existing P3 laboratory incinerator. Special hazardous substances will be stored in the storehouse for hazardous substance in KEMRI and duly treated.

7) Firefighting System

Local standards are not provided for firefighting system; therefore, these will be designed in conformity with the BS standards or Japanese standards.

Considering the scale of the facility, fire alarms, indoor hydrants and fire extinguishers will be installed exclusively for the project facility.

8) Air Conditioning

Natural ventilation will be generally applied to each room. On rooms where heat, steam, odours are generated or rooms directly receiving afternoon solar radiation mechanical ventilation will be considered to these rooms.

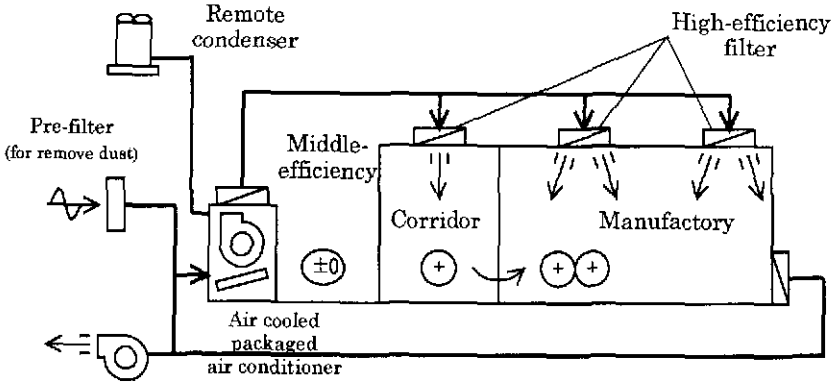
The manufacturing rooms or animal house, where a degree of cleanliness must be secured, will be provided with air conditioning, equipped with high efficiency or medium efficiency filters, and the inside is maintained at positive pressures. On network room and the data processing room, air condition is to be provided.

Air conditioning will be done by air-cooled air-conditioning system. Semi-central or individual systems will be used.

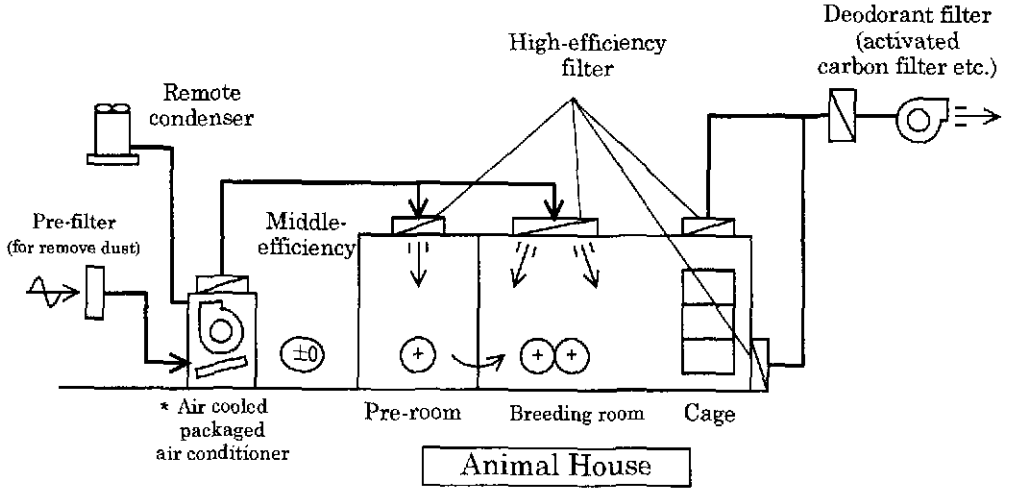
Table 2-19 Air Conditioning System and Area by Application

Room name			Cooling Semi-central	Cooling Inde-pendent	Positive Pressure	High-performance air-filter	Medium-performance air-filter
Production Unit	Production Area	Preparation (HIV・HEPCELL)	○		○	○	
		Manufacturing (HIV・HEPCELL)	○		○	○	
		Corridor	○		○	○	
		Material room		○			○
		Dispense room		○			○
		Washing room		○			
		Packing room		○			
		Labelling room		○			○
	Administration Area	Quality control		○			○
Animal House		Quarantine room	○*			○	
		Breeding room	○*			○	
		Rabbits, Guinea pigs room	○*			○	
		Inoculation Room	○*			○	
		Washing room		○			
		Preparation		○			
		Office		○			
Training Unit		Lab 1		○			
		Culture room		○			
		Preparation room		○			
		Lecture room 1,2,3		○			
		Data processing room		○			
		Network Server		○			

* including Heating System

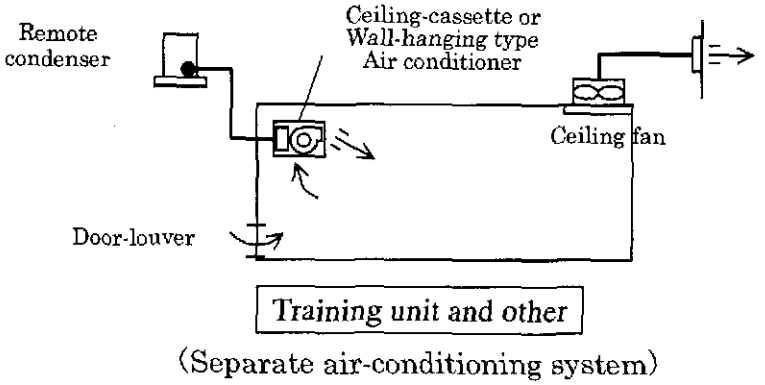


(Semi-central air-conditioning system)



(Semi-central air-conditioning system)

*including Heating System



(Separate air-conditioning system)

Figure 2-12 Conceptual Diagram of Air Conditioning

2-2-2-6 Construction Material Plan

In selecting construction materials, the materials and construction methods established in Kenya will mainly be selected for the sake of facilitating maintenance.

The following are basic considerations in the selection of construction materials.

(1) Exterior Finishing Material

1) Roof

The roof of the facility will be design to be a slanted one, the shape to be in harmony with the surrounding buildings. The flat roofs to be used partly will have a gradient of about 1/50 to facilitate drainage. The asphalt waterproofing material distributed in the local market will be used. The roofing material will be selected from those available in the local market while considering harmony with the existing buildings.

2) Exterior Wall

The Nairobi stone will be used mainly. This material is available in the local market at low prices and the masonry technique for this material is established. The Nairobi stone is used for the existing buildings, and is easy to maintain. Portions partitioned by beam columns will be filled by the masonry structure and the concrete portion will be finished by painted mortar.

(2) Interior Finishing Material

1) Floor

The terrazzo blocks easily obtainable from the local market will be used. Such small areas as storage and pantry will be given local terrazzo finish. Ceramic tiles are used for such areas as entrance hall and its surroundings where traffic of persons is busy to facilitate cleaning.

2) Wall

The partition walls in the buildings will be of concrete block construction. The concrete substrate will be mortared and paint finished. Those portions which tend to be stained like toilets or hot water service rooms will use tiles.

3) Ceiling

The light gauge steel structures generally used locally, with rock wool sound insulation board applied on them, will be used.

4) Doors and Windows

Aluminium sashes are used for exterior fixtures (for windows) for their water-tightness and air-tightness. The doors facing the exterior will be of aluminium or steel. Of interior fixtures, those doors which are used in the production clean area will be airtight steel doors to ensure airtightness of the space. For other purposes, wooden fixtures will be used.

The finishing materials to be used and methods for application are summarised in the table below.

Table 2-20 Finishing Material and Method for Application

Building element	Method applied locally (including the existing building)	Method adopted	Rationale for adoption
Roof	Slanted roof Flat roof (gravel-held asphalt waterproofing)	Slanted roof Flat roof (gravel-held asphalt waterproofing)	This method is generally adopted locally and easy to maintain after completion.
Exterior wall	Masonry (Nairobi stone) Mortared and paint finished	Masonry (Nairobi stone) Mortared and paint finished	This method is generally adopted locally and easy to maintain after completion.
Floor	Tile Terrazzo block Terrazzo finish	Tile Terrazzo block Terrazzo finish	This material is generally used locally, and easy to maintain and clean after completion.
Interior wall	Tile Paint	Tile Paint	These materials are generally used locally, and easy to maintain after completion.
Ceiling	Rock wool sound insulating board Partly painted	Rock wool sound insulating board Partly painted	These materials are generally used locally and are easy to maintain after completion. The ceilings are covered with boards to increase the air-conditioning efficiency, to cover piping and the likes, and to prevent dust from accumulating.
Doors and Windows	Aluminium made Steel made Wooden	Aluminium made Steel made Wooden	These are generally used locally. Doors required of airtightness will be steel airtight fixtures.

2-2-2-7 Equipment Plan

(1) Purpose of Equipment, Judgement of Necessity and Adequacy

Based on the results of "Overall Project Description (Study of the Request)", the purpose of equipment, judgement of necessity and adequacy are developed as shown in the following table.

Table 2-21 Study on the Purpose of the Equipment Requested

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
Production unit					
HEPCELL and PA kit Production					
Hepcell kit preparation room					
1	Refrigerated centrifuge	1	1	Used for washing of raw materials	Equipment indispensable to manufacture of the blood test kit
2	Refrigerator	1	1	Used for concentration of plasma after fibrin has been removed	Equipment indispensable to manufacture of the blood test kit
3	Fraction collectors	1	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
4	pH meter	1	1	Used to adjust pH value when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
5	Plate mixer	1	1	Used to stir plate-shaped specimens like the blood test kit	Equipment indispensable to manufacture of the blood test kit
6	Peristaltic pumps	2	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
7	Affinity chromatography stand	1	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
8	Affinity chromatography column	5	5	Used when proteins are removed from human plasma and different columns are needed for different substances removed	Equipment indispensable to manufacture of the blood test kit
9	Magnetic stineer	2	1	Used for various works	Essential equipment
10	Safety cabinet	2	1	Used to adjust the titre of the positive control serum before dispensing	Equipment indispensable to manufacture of the blood test kit
11	Ultracentrifuge	1	1	Used to refine the HBs antigen from human plasma	Equipment indispensable to manufacture of the blood test kit
12	Plasma separator	1	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
13	Sonifier	1	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
14	Benches	6	2	Used to place various pieces of equipment, used for various works	Essential equipment
15	Stools	3	3	Used for various works	Essential equipment
PA kit preparation room					
1	Vortex mixer	2	1	Used to stir test tubes for various works	Essential equipment
2	Peristaltic pumps	1	1	Used when proteins are removed from human plasma	Equipment indispensable to manufacture of the blood test kit
3	Benches	2	1	Used to place various pieces of equipment, used for various works	Essential equipment
4	Stools	2	2	Used for various works	Essential equipment

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
5	Safety cabinet	1	1	Used to adjust the titre of the positive control serum before dispensing	Equipment indispensable to manufacture of the blood test kit
6	Automatic pipette aid - rechargeable	1	1	Used for dispensing of 1mℓ or less	Equipment indispensable to manufacture of the blood test kit
Hepcell kit manufacturing room					
1	Water bath	2	2	Used for sensitisation of anti-HBs antibody, and for pretreatment of immobilised sheep erythrocyte before sensitisation	Equipment indispensable to manufacture of the blood test kit
2	Refrigerated centrifuge	1	1	Used for preparation of HBs antibody and cleaning of total sheep blood	Equipment indispensable to manufacture of the blood test kit
3	Benches	6	2	Used to place various pieces of equipment, used for various works	Essential equipment
4	Stools	6	4	Used for various works	Essential equipment
5	Haematocrit centrifuge	1	1	Used for concentration adjustment of immobilised sheep erythrocyte and gelatine particles	Equipment indispensable to manufacture of the blood test kit, and used as equipment for HIV
6	Electronic balance	1	1	Used for weighing minute specimens	Essential equipment
7	Suction unit	1	1	Used for various works	Equipment indispensable to manufacture of the blood test kit
PA kit manufacturing room					
1	Water bath	1	1	Used for thawing of frozen specimens and slow heating of specimens	Essential equipment
2	Automatic pipette aid - rechargeable	1	1	Used for dispensing of 1mℓ or less	Equipment indispensable to manufacture of the blood test kit
3	Mechanical crimpier	1	1	Crimpier for vials	Essential equipment
4	Benches	5	2	Used to place various pieces of equipment, used for various works	Essential equipment
5	Stools	3	3	Used for various works	Essential equipment
6	Refrigerated centrifuge	1	1	Used for HIV antigen sensitisation and post-cleaning, for cleaning of concentration adjusted gelatine particles before pretreatment for HIV antigen sensitisation	Equipment indispensable to manufacture of the blood test kit
Quality Control room					
1	Refrigerator	1	1	Used for storing for a given period quality-assured test kits and for storing testing reagents	Long-term storage of sample is essential for confirmation of long-term stability of the test kits. Hence, equipment indispensable to accuracy control of the test kits
2	Benches	2	2	Used to place various pieces of equipment, used for various works	Essential equipment
3	PC + printer + UPS + desk + 2 chairs	1	1	Used for storing the quality control data and other data	Equipment indispensable to accuracy control of the blood test kit
4	Plate mixer	1	1	Used to stir plate-shaped specimens like the blood test kit	Essential equipment
5	Automatic pipette aid - rechargeable	1	1	Used for dispensing of 1mℓ or less	Essential equipment

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
6	Micro plate washer	1	1	Used for accuracy control test of the blood test kit	Equipment indispensable to accuracy control of the blood test kit
7	Micro plate reader	1	1	Used with Micro plate washer	Equipment indispensable to accuracy control of the blood test kit
8	Deep freezer (-20?)	1	1	Used for storing specimens of antigens and antibodies used for quality control	Equipment indispensable to accuracy control of the blood test kit
9	Incubator with rocker	1	1	Used for quality control test of the blood test kit	Essential equipment
10	Camera illuminator & stand	1	1	Used for making photographic records of the accuracy of the blood test kit	Equipment indispensable to accuracy control of the blood test kit
11	Bench top centrifuge	1	1	Used for isolation of components in specimens	Essential equipment
12	Electronic balance	2	1	Used for weighing minute specimens	Essential equipment
13	Spectrodensitometer	1	1	Used for purity certification of the blood test kit	Equipment indispensable to accuracy control of the blood test kit
14	pH meter	2	1	Used for confirming pH values of blood diluents and others	Equipment indispensable to accuracy control of the blood test kit
15	Refractometer	1	1	Used for confirming concentrations of various solutions in the blood test kit	Equipment indispensable to accuracy control of the blood test kit
16	Spectrophotometer	1	1	Used for measuring (optical) absorbencies of various solutions in the blood test kit	Equipment indispensable to accuracy control of the blood test kit
Material room					
1	Water distiller / deioniser	2	1	Used for preparing water for cleaning equipment for manufacturing, for water for the diluent and solutions	Equipment indispensable to manufacture of the blood test kit
2	Refrigerator	2	2	Used for temporary storing of HIV antigen sensitised particles and various erythrocytes cleaned in the manufacture of the HIV and HEPCELL kits	Equipment indispensable to manufacture of the blood test kit
3	Ultra low deep freezer	2	2	Used for cyropreservation of raw materials for manufacture (human and animal blood)	Equipment indispensable to manufacture of the blood test kit
4	Lockable cabinets	1	1	Used for storing consumables of the ultrapure water manufacturing unit	*Essential equipment*
Dispense room					
1	Lyophilizer	2	1	Used for freeze-drying under vacuum anti-HBs antibody sensitised erythrocytes, HIV antigen sensitised particles, which are unstable and difficult to store, to enable their long-term storage	Equipment indispensable to manufacture of the blood test kit
2	Benches for freeze dry	2	1	Used to place various pieces of equipment, used for various works	Essential equipment
3	Benches for dispense	2	2	Used to place various pieces of equipment, used for various works	Essential equipment
4	Automatic pipette aid - rechargeable	1	1	Used for dispensing of 1mℓ or less	Equipment indispensable to manufacture of blood test kit

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
5	Plate mixer	1	1	Used to stir plate-shaped specimens like the blood test kit	Equipment indispensable to manufacture of blood test kit
Washing room					
1	Autoclave	1	1	Used for disinfecting various pieces of manufacturing equipment	Essential equipment
2	Benches	2	2	Used to place various pieces of equipment, used for various works	Essential equipment
3	Stools	2	2	Used for various works	Essential equipment
4	Pass box	1	1	Used for transporting cleaned vials within the manufacturing unit	Necessary to maintain required degree of cleanliness of the manufacturing unit
5	Drying machine for vials	1	1	Used for drying cleaned vials to be used to manufacture the blood test kit	Necessary to maintain required degree of cleanliness of the manufacturing unit
6	Ice making machine	1	1	Used for various works	Equipment indispensable to manufacture of blood test kit
Changing room					
1	Changing cabinets	6	4	Used for changing clothes for *manufacturing works of the* blood test kit	Essential equipment
Labelling room					
1	Benches	1	1	Used for placing the label print/apply unit and for labelling operation	Essential equipment
2	Stools	2	2	Used for labelling operation	Essential equipment
PA kit store					
1	Refrigerator	1	1	Used for storing parts (vials, etc.) before and after labelling	Equipment indispensable to manufacture of the blood test kit
Hepcell kit store					
1	Refrigerator	1	1	Used for storing parts (vials, etc.) before and after labelling	Equipment indispensable to manufacture of the blood test kit
Packing room					
1	Benches	2	2	Used for preparation for shipping of the blood test kit	Essential equipment
2	Lockable cabinets	3	2	Used for storing containers, etc. of the blood test kit	Essential equipment
3	Cabinets	3	2	Used for storing shipping materials, etc.	Essential equipment
4	Refrigerator	2	2	Used for storing the blood test kit before shipping	Equipment indispensable to manufacture of the blood test kit
Animal House					
Washing room					
1	Autoclave	2	1	Used for disinfecting equipment	Water washing is enough for the cage and autoclave is not studied for this purpose.
2	Benches	2	2	Used to place various pieces of equipment, used for various works	Essential equipment
3	Stools	2	2	Used for various works	Essential equipment
Preparation room					
1	Benches	2	2	Used to place various pieces of equipment, used for various works	Essential equipment
2	Stools	2	2	Used for various works	Essential equipment
3	Scale	1	1	Used for weighing specimens	Essential equipment
4	Breeding tool set	1	1	Equipment for animal raising, the cutter used for preparing *feed for example*	Essential equipment

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
Breeding room					
1	Cage cabinets	4	4	Used to place the cage	Equipment indispensable to manufacture of the blood test kit
2	Animal cages	125	125	Cages for guinea pigs and rabbits, used for raining animal to collect the antibody	Equipment indispensable to manufacture of the blood test kit
Quarantine room					
1	Desk + 2chairs	1	1	Used for such operations as blood collection	Essential equipment
Common use					
Office					
1	PC + printer +UPS	6	2	Used for manufacturing control, tabulation, report making	Equipment indispensable to systematic manufacturing control
2	Desks	12	6	Used for various works	Essential equipment
3	Chairs	24	6	Used for various works	Essential equipment
4	Photocopier	1	1	Used for manufacturing control, tabulation, report making	Equipment indispensable to systematic manufacturing control
Staff room					
1	Table + 6 chairs	1	1	Used for meetings, for data and material compiling	Essential equipment
General manager room					
1	Desks	1	1	Used for various works	Essential equipment
2	Chairs	1	1	Used for various works	Essential equipment
Marketing manager room					
1	Desks	1	1	Used for various works	Essential equipment
2	Chairs	1	1	Used for various works	Essential equipment
Training Unit					
Lecture room					
1	Student desks and Chairs for trainees	120	48	Used for training at KEMRI	Essential equipment
2	Chairs	72	72	Used for training at KEMRI	Essential equipment
3	Lecturer tables	4	3	Used for training at KEMRI	Essential equipment
4	Visual-audio system	2	1	Used for training at KEMRI	Television sets and videocassette recorders are necessary for presenting research activities and training activities
5	Computer projectors and note type computers	2	1	Used for training at KEMRI	Equipment needed for presenting research activities and training activities
6	Overhead projectors	2	1	Used for training at KEMRI	Equipment needed for presenting research activities and training activities
Parasitic Lab.					
1	Laboratory tables and 4 chairs	4	4	Used for training practice	Essential equipment
2	Binocular microscope	25	16	Used for observation of such minute specimens as infectious bacilli	Equipment necessary for effective observation training,
3	Demonstrating microscope connecting to video camera	1	1	Used for training on observation of minute specimens	Equipment necessary for effective training on observation
4	Dissecting binocular microscope (×0.5 - 30, sliding)	25	16	Used for microdissection on training on such parasites as mosquito	Equipment necessary for effective training on equipment operation
5	Low speed centrifuges (table type)	3	1	Used for obtaining supernatant or precipitate from various specimens	Essential equipment

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
6	Micrometers	25	16	Used for measuring dimensions of minute specimens	Essential equipment
7	Water baths	3	1	Used for thawing of frozen specimens and slow heating of *specimens*	Essential equipment
8	Incubators	3	1	Used for culturing aerobic bacteria	Essential equipment
9	Cabinets for storage of microscopes and materials	4	4	Used for storing microscopes	Microscopes must be stored in special storing boxes when not in use.
Infectious Lab.					
1	Water baths , small	2	1	Used for thawing of frozen specimens and slow heating of specimens	Essential equipment
2	Shakers	6	3	Used to stir specimens contained in such vessels as test tube	Essential equipment
3	Auto-pipettes (different sizes)	30	3	Used for weighing minute liquid specimens	Essential equipment
4	Pipettes	6	5	Used for dripping of reagents on plates like blood test kit	Equipment indispensable to the training on the use of the blood test kit
5	Refrigerators	3	2	Used for storing the test kit for accuracy control, also used for storing reagents used in training	Equipment necessary for storing reagents for testing and the blood test kit, necessary also for temporarily storing distilled water prepared in other divisions when distilled water is needed
6	Incubators	2	1	Used for culturing aerobic bacteria	Essential equipment
7	pH meter	3	2	Used for preparation of reagents and others	Essential equipment
8	Spectro photometer	1	1	Used for preparation of reagents, identification of components of specimens	Essential equipment
9	Magnet stirrers	6	2	Used to stir plate-shaped specimens like the blood test kit	Essential equipment
10	Electronic balances (until 31g)	3	1	Used for weighing minute specimens, unit 1 mg	Essential equipment
11	Electronic balances (until 310g)	3	1	Used for weighing a small amount of specimens, unit 100 mg	Essential equipment
12	Balance	3	3	Used for weight specimens, unit gram	Essential equipment
13	Laboratory tables and chairs	4	4	Used for training practice	Essential equipment
14	Microscopes for cell cultures	6	3	Used for observation of specimens under minutely controlled conditions, for distinguishing suspended cells, and for training	Equipment necessary for effective training on equipment operation
15	CO2 Incubators	2	2	Used for culturing anaerobic bacteria	Essential equipment for such training as culture practice
16	Clean benches and aspirators	2	2	Used for preparation of specimen, confirmation of specimen after culturing after culturing, for training	Essential equipment for such training as culture practice

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
Preparation room					
1	Ultra low deep freezer	2	2	Used for storing specimens that require cryogenic conditions for storage	Equipment to store various specimens and blood samples that have to be stored for a long period while they are used for training
2	Ultra-homogenizer	1	1	Used to crush parasite specimens or to stir liquid specimens	Essential equipment
3	Magnet stirrers	3	1	Used to stir plate-shaped specimens like the blood test kit	Essential equipment
4	Clean bench	1	1	Used to prepare specimens used for culture practice	Essential equipment for such training as culture practice
5	Low centrifuge with temperature control system	1	1	Used for obtaining supernatant or precipitate from various specimens	Essential equipment
6	Water bath	1	1	Used for thawing of frozen specimens and slow heating of specimens	Essential equipment
7	Sample stock cabinet	2	2	Used for storing specimens that can be kept at ambient temperature	Essential equipment
8	Autoclave	1	1	Used for disinfecting used equipment and used specimens, etc.	Essential equipment
Dark room					
1	Fluorescent microscopes	3	1	Preparation of materials for training on fluorescent antibody technique and for identification of infectious bacillus	Equipment required for identifying object substance by fluorescent antibody technique by using a fluorescent substance
2	Chairs and tables	3	1	Used for fluorescent microscope operation	Essential equipment
Culture room					
1	Chairs and tables	5	2	Used for operations with various microscopes	Essentially necessary
2	Binocular microscope with computer system	1	1	Used for preparation of data obtainable under microscope to be used in training, etc.	Equipment necessary for preparation of data for training, etc.
3	Dissecting microscope with camera	1	1	Used for preparation of materials for training	Essential equipment for preparation of specimens, etc.
4	Microscope for cell culture with camera	1	1	Used for preparation of materials for training	Equipment used for minute control of specimen chamber and for distinguishing suspended cells and necessary for preparing materials for training
Data processing room					
1	Chairs and tables	30	8	For trainees	Essential equipment
2	Lecturer's table and chair	1	1	For lecturers	Essential equipment
3	Computers for trainees	25	8	Used for training on report preparation, etc.	This item is studied in this Equipment Plan. The computer is necessary in research and training in KEMRI, and the computer is used for training on such skills.
4	White and black printers	4	1	Used for training on report preparation, etc.	This item is studied in this Equipment Plan. The computer is necessary in research and training in KEMRI, and the computer is used for training on such skills.

No.	Description	Q'ty of request	Q'ty of plan	Purpose of the use	Judgement on necessity and adequacy
Network room					
1	Computers	3	3	Used for management of research data of KEMRI	Equipment necessary for managing research and third-country training data, an initial stage work toward functioning as core of the East African network
2	Cabinet for mechanical parts	1	1	Used for storing computer-related equipment	Essential equipment
3	Desk and chairs	4	4	Used for computer works and other works	Essential equipment
4	Cabinets for computer data	3	1	Used for storing such memory devices as FDs and CD-Rs	Essential equipment
5	Cabinets for administrative documents	1	1	Used for storing books, literature and printed documents	Essential equipment
Office					
1	Office desks and chairs	8	8	Used for clerical works for training, etc.	Essential equipment, the number will be confirmed with respect to the number of clerks during the during the draft presentation survey
2	Meeting table and chairs	1	1	Used for confirmation of the training plan, etc.	Essential equipment, the number will be confirmed with respect to the number of clerks during the during the draft presentation survey
3	Cabinets for office	4	4	Used for storing training records or prepared materials	Essential equipment
4	White boards	2	2	Used for discussions on training plan and entering schedules, etc.	Essential equipment
5	Photocopy machine (black and white)	2	1	Used for printing training records or materials	Equipment necessary for preparation of written materials for training
6	Printing machine (colour)	1	1	Used for printing training records or materials	Necessary because such materials as specimens need to be printed in colour

(2) Equipment List and Specifications

The planned equipment list is shown in the Table 2-22 and the specification for major equipment is also shown in the Table 2-23.

Table 2-22 Equipment List

No.	Description	Production unit	Animal house	Training unit	Total
1	Water distiller/deionizer	1			1
2	Lyophilizer	1			1
3	Ultra Centrifuge	1			1
4	Refrigerated Centrifuge	3			3
5	Autoclave	1	1	1	3
6	Safety Cabinet	2			2
7	Clean Bench			3	3
8	Incubator	1		2	3
9	Refrigerator	8		2	10
10	Freezer (vertical type)	1			1
11	Ultra Low Deep Freezer	2		2	4
12	CO2 Incubator			2	2
13	Passbox	1			1
14	Drying machine for vials	1			1
15	Laboratory Tables			8	8
16	Benches	17	4	5	26
17	Stools	16	4	8	28
18	Desk and Chair for office	6	1	12	19
19	Desk and Chair for trainees (for 1 person)			48	48
20	Desk and Chair for trainees (for 2 person)			8	8
21	Chair			72	72
22	Desk and Chair for Manager	2			2
23	Lecture Table			4	4
24	Meeting Table and Chair	1		1	2
25	Whiteboard			2	2
26	Cage Rack		4		4
27	Balance A			3	3
28	Balance B		1		1
29	Personal Computer	3		11	14
30	Photocopy Machine, Black and White	1		2	3
31	Printer, Colour			1	1
32	Printer, Black and White	2		1	3
33	Computer projectors and note type computers			1	1
34	Overhead projectors			1	1
35	AV Equipment			1	1
36	Storage Cabinet A	1			1
37	Storage Cabinet B	2			2
38	Storage Cabinet C	2			2

No.	Description	Production unit	Animal house	Training unit	Total
39	Storage Cabinet D			4	4
40	Storage Cabinet E			4	4
41	Changing Cabinet	4	2		6
42	Material Storage Cabinet			1	1
43	Computer Data Storage Cabinet			1	1
44	Document Storage Cabinet			1	1
45	Sample Stock Cabinet			2	2
46	Demonstrating microscope			1	1
47	Dissecting binocular microscope			17	17
48	Binocular microscope			16	16
49	Microscope for cell culture			3	3
50	Fluorescent Microscope			1	1
51	Binocculer Microscope with computer system			1	1
52	Microscope for cell culture with Camera			1	1
53	Centrifuge with Temperature Control			1	1
54	Hematocrit Centrifuge	1			1
55	Table Top Centrifuge	1		1	2
56	Densitometer	1			1
57	Refractometer	1			1
58	Spectrophotometer	1		1	2
59	Electric Balance A	2		1	3
60	Electric Balance B			1	1
61	Fraction Collector	1			1
62	pH Meter	2		1	3
63	Plate Mixer	3		3	6
64	Peristaltic pump	2			2
65	Vortex Mixer	1		1	2
66	Magnetic stineer	1		2	3
67	Automatic Pipette Aid-rechargeable	4		5	9
68	Water Bath	3		3	6
69	Micro plate Washer	1			1
70	Micro plate Reader	1			1
71	Camera Illuminator & Stand	1			1
72	Micrometer			16	16
73	Ultrasonic Homoginizer	1		1	2
74	Animal Caring Set		1		1
75	Animal Cage		125		125
76	Affinity Chromatography Stand	1			1
77	Affinity Chromatography Column	5			5
78	Pipette			5	5
79	Suction unit	1			1
80	Plasma separator	1			1
81	Mechanical crimpers	1			1
82	Ice making machine	1			1

Table 2-23 Specification of Major Equipment

No.	Description	Specification
1	Water distiller/deionizer	RO + deion water Capacity：10litre/h
2	Lyophilizer	Capacity：8 litre/time or more
3	Ultra Centrifuge	Zonal rotor Max rpm：32,000
4	Refrigerated Centrifuge	250cc×4 bottle
5	Autoclave	Capacity：50 litre Temperature115℃、121℃
6	Safety Cabinet	Width inner 120cm、 Inner material ：stainless steel
7	Clean Bench	Width inner 120cm、 Inner material ：stainless steel
8	Incubator	Capacity：150 litre、 Temperature range：room＋5℃～60℃
9	Refrigerator	Capacity：300 litre、 Temperature range：＋2℃～14℃
11	Ultra Low Deep Freezer	Capacity：80 litre、 Temperature range：－20℃～－90℃
15	Laboratory Tables	Size：1500×1500mm,with sink with stool
16	Bench	Size：1500×750mm
29	Personal Computer	CPU：Pentium Ⅳ
33	Computer projectors and note type computers	CPU：Pentium Ⅲ、projector for personal computer
46	Demonstrating microscope	Type：Trinocular, with light source, CCD camera, monitor
47	Dissecting binocular microscope	Type：Binocular, with light source, Objective lens：0. 67×,1×,2×,4×
48	Binocular microscope	Type：Binocular, with light source, Objective lens：4×,10×,40×, 100×
49	Microscope for cell culture	Type：Binocular, with light source
50	Fluorescent Microscope	Type：Binocular, with light source
51	Binocculer Microscope with computer system	Type：Trinocular, with light source
52	Microscope for cell culture with Camera	Type：Trinocular, with light source

2-2-2-8 Blood Screening Kit Production System Design

(1) Production System Design

In this project, the kinds of reagents constituting the PA kit and HEPCELL kit are set as follows.

Table 2-24 Kinds of Reagents Constituting One Kit

[PA kit (220 tests/kit)]

Sensitised gelatine particle	Unsensitised gelatine particle	Serum extender	Diluent	Control serum
1.5mℓ × 4 vials	2mℓ × 4 vials	40mℓ × 1 bottle	18mℓ × 1 bottle	0.6mℓ × 1 vial

・ The reagents in the shaded cells require freeze-drying operation.

[HEPCELL kit (200 tests/kit)]

Erythrocyte for reagin test	Extender	Fluid for confirmation	Control serum
2.5mℓ × 2 vials	50mℓ × 1 bottles	10mℓ × 2 bottles	1.5mℓ × 1 vial

・ The reagent in the shaded cell requires freeze-drying operation.

In order to manufacture the above kits in a stepwise fashion, the range of production number, from 100,000 to 800,000 tests per year, is divided into four stages. The reagents to be produced for one manufacturing processing for each stage are shown in the table below.

Table 2-25 Production Number for One Manufacturing Processing

[PA kit]

Production number	Sensitised gelatine particle 1.5mℓ×4 vials	Unsensitised gelatine particle 2mℓ×4 vials	Serum extender 40mℓ×1 bottle	Diluent 18mℓ×1 bottle	Control serum 0.6mℓ×1 vial
100,000 tests or less	4 vials×152 kits = 608 vials	4 vials×152 kits = 608 vials	1 bottle×152 kits = 152 bottles	1 bottle×152 kits = 152 bottles	1 vial×152 kits = 152 vials
200,000 tests or less	4 vials×304 kits = 1,212 vials	4 vials×304 kits = 1,212 vials	1 bottle×304 kits = 304 bottles	1 bottle×304 kits = 304 bottles	1vial ×304 kits = 304 vials
400,000 tests or less	4 vials×608 kits = 2,424 vials	4 vials×608 kits = 2,424 vials	1 bottle×608 kits = 608 bottles	1 bottle×608 kits = 608 bottles	1 vial×608 kits = 608 vials
800,000 tests or less	4 vials×1,212kits = 4,848 vials	4 vials×1,212kits = 4,848 vials	1 bottle×1,212kits = 1,212 bottles	1 bottle×1,212kits = 1,212 bottles	1 vial×1,212kits = 1,212 vials

・ Manufacturing will be done three times a year.
・ The processes in the shaded cells need mechanisation.

[HEPCELL kit]

Component reagent	Erythrocyte for reagin test 2.5mℓ × 2 vials	Extender 50mℓ × 1 bottles	Fluid for confirmation 10mℓ × 2 bottles	Control serum 1.5mℓ × 1 vial
100,000 tests or less	2 vials×170 kits = 340 vials	1 bottles×170 = 170 bottles	2 bottles×170 kits = 340 bottles	1 vial×170 kits = 170 vials
200,000 tests or less	2 vials×340 kits = 680 vials	1 bottles×340 = 340 bottles	2 bottles×340 kits = 680 bottles	1 vial×340 kits = 340 vials
400,000 tests or less	2 vials×680 kits = 1,360 vials	1 bottles×680 kits = 680 bottles	2 bottles×680 kits = 1,360 vials	1 vial×680 kits = 680 vials
800,000 tests or less	2 vials×1,360kits = 2,720 vials	1 bottles×1,360kits = 1,360 bottles	2 bottles×1,360kits = 2,720 vials	1 vial×1,360 kits = 1,360 vials

As the number of vials used in one manufacturing operation increases, manual production becomes inefficient and installation of additional equipment, automatic capping machine for example, becomes necessary.

The table below shows equipment that may be considered necessary for the four stages of production from 100,000 to 800,000, and specifications of these equipment.

Table 2-26 Equipment Required by Production Scale

Process	100,000 tests or less	200,000 tests or less	400,000 tests or less	800,000 tests or less
Sterilisation after filtration	Instrument	Instrument	High-pressure equipment	High-pressure equipment
Dispensing of component reagents	Manual method	Electric motor driven pump	Electric motor driven pump	Automatic dispenser
Half capping (rubber cap)	Manual method	Manual method	Manual method	Automatic capping machine
Freeze drying, litre	3ℓ	5ℓ	10ℓ	10ℓ
Aluminium cap seaming	Manual method	Manual method	Manual method	Automatic seamer
Screw cap seaming	Manual method	Manual method	Seamer	Automatic seamer
Labelling	Manual method	Manual method	Label print/ apply unit	Automatic printer

The grand aid project is designed on the basis of 400,000 tests a year. Even with this design, the system can produce as many as about 800,000 tests a year by increasing number of operations per year, and also by adding the machines shown in the shaded cells of the above table.

The following pages show process flows of PA kit and HEPCELL kit.

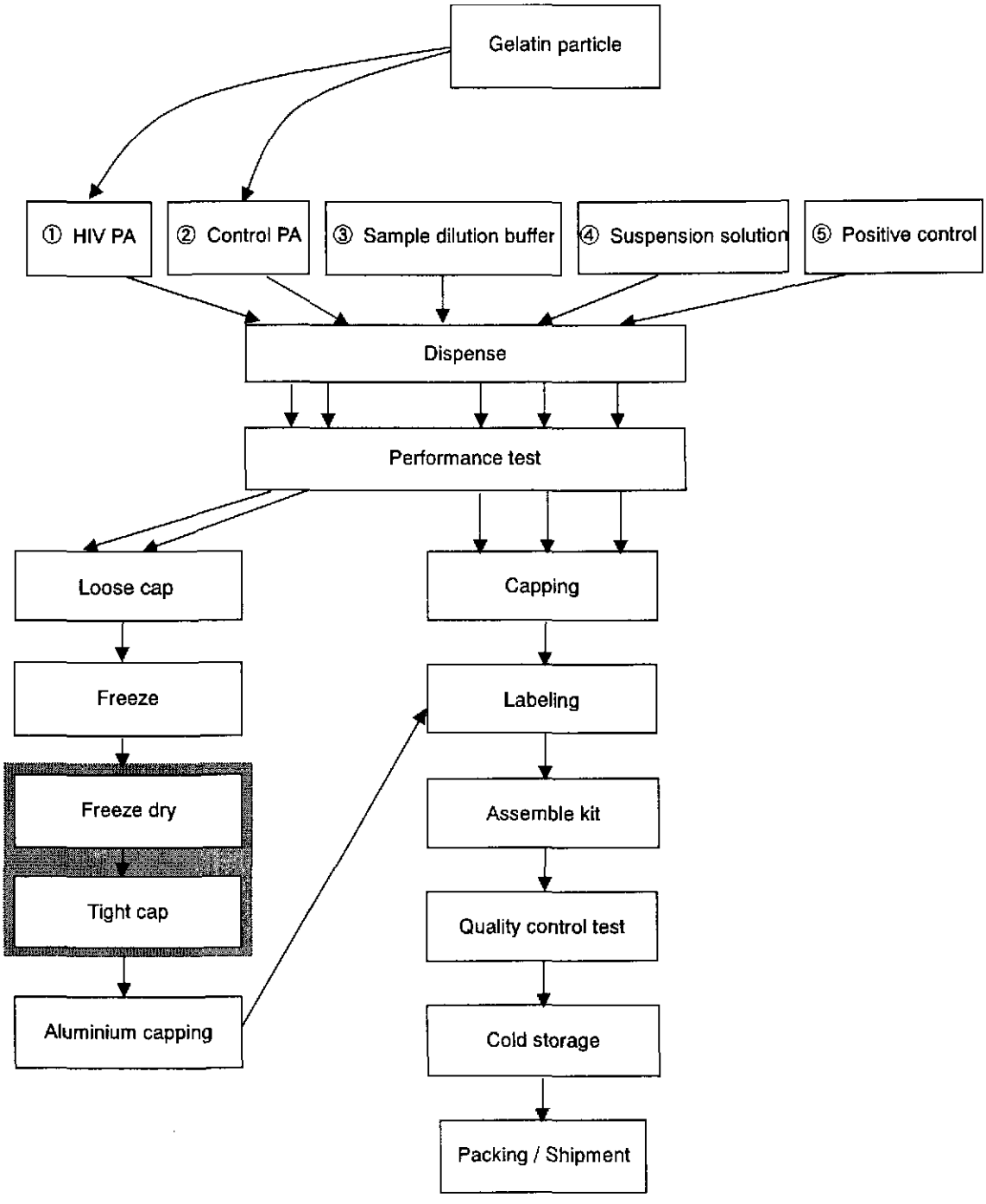


Figure 2-13 Process Flow (PA kit)

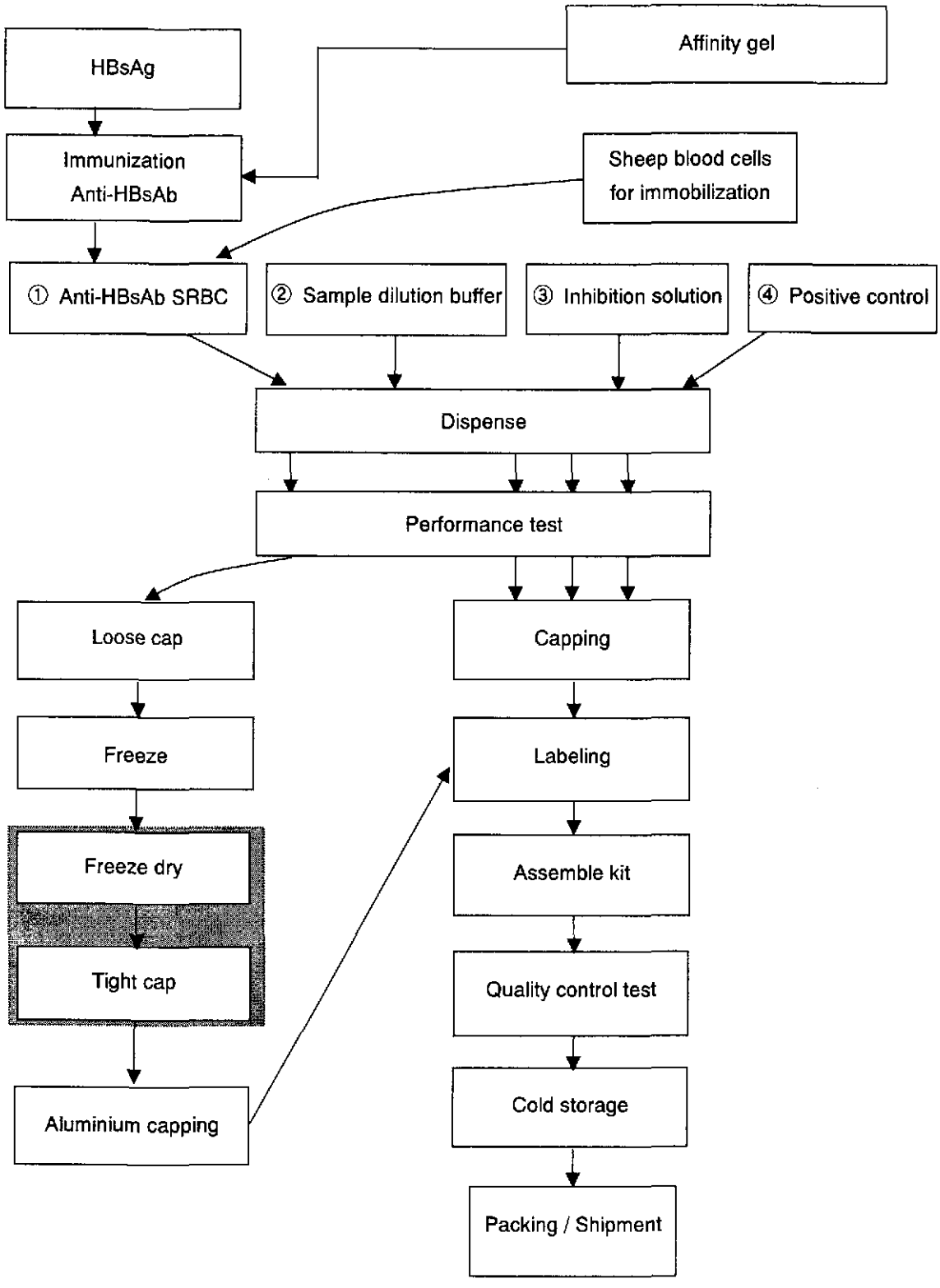


Figure 2-14 Process Flow (HEPCELL kit)

(2) Estimate for Production Cost

KEMRI estimated the costs of the blood screening kits as shown in the table below, according to the request.

Table 2-27 Cost of Blood Screening Kits Estimated by KEMRI

KShs/test

	PA kit per test	HEPCELL kit per test
Manufacturing cost estimated by KEMRI	50.00	25.28

Table 2-28 shows the manufacturing cost, which the study team estimated on the following conditions.

Conditions for calculation

- Biomaterials and chemical materials will be in principle procured from the KEMRI's own facility or from the Kenyan market.
- Notwithstanding the above, the main biomaterials for the PA kit will be imported from the private company of Japan.
- Vials of the same specifications will be used for both kits. Presently, one HEPCELL kit consists of one 5-mℓ vial, but both kits will consist of two 2.5-mℓ vials.

Table 2-28 Cost of Blood Screening Kits Estimated by the Study Team

KShs/test

	PA kit per test	HEPCELL kit per test
Manufacturing cost estimated by the study team	49.05	26.37

A more detailed comparison is given in the Appendix.

For the purpose of reference, prices of other test kits marketed in Kenya are given in the table below.

Table 2-29 Reference Price of Other Blood Screening Kits in Kenya

KShs/test

	HIV screening kit per test	HBV screening kit per test
Reference price of marketed product A	179.17	187.50
Reference price of marketed product B	107.29	117.97

KEMRI's kits will be sold at prices which represent manufacturing costs plus expenses. However, KEMRI may be considered to be able to sell its products at prices lower than these reference prices.

2-2-3 Basic Design Drawings

Table 2-30 *List of* Drawings

	Unit Name	Drawing Name	Scale	Page
1	Building Layout	Site Plan	1/1000	83
2	Production Unit	Production Unit Ground Floor Plan	1/200	85
3		Production Unit First Floor Plan	1/200	87
4		Production Unit Elevation	1/200	89
5		Production Unit Section	1/200	91
6	Animal House	Animal Unit Ground Floor Plan, Roof Plan	1/200	93
7		Animal Unit Ground Elevation, Section	1/200	95
8	Training Unit	Training Unit Ground Floor Plan	1/200	97
9		Training Unit First Floor Plan	1/200	99
10		Training Unit East and West Elevation	1/200	101
11		Training Unit North and South Elevation	1/200	103
12		Training Unit Section	1/200	105

Production Unit

CDC Unit(2002.08 Under construction)

Rail Way

Project Area

PARKING
20 CARS

CENTRAL LABORATORIES

ADM. BLOCK

KEMRI EXISTING FACILITIES

LABORATORY
ANIMAL HOUSE

ELECTRICAL
POWER HOUSE

WORK SHOPS

Water Tank
15,420
50feet

Water Tower

Mechanical Unit

Animal Unit (Renovation)

PARKING
20 CARS

Traning Unit

Project Aera

N

KEMRI Nairobi Site		
TITLE: Layout Plan	SCALE: 1/1000	PAGE: 83

CDC Unit New Way(2002.08 Under Construction)

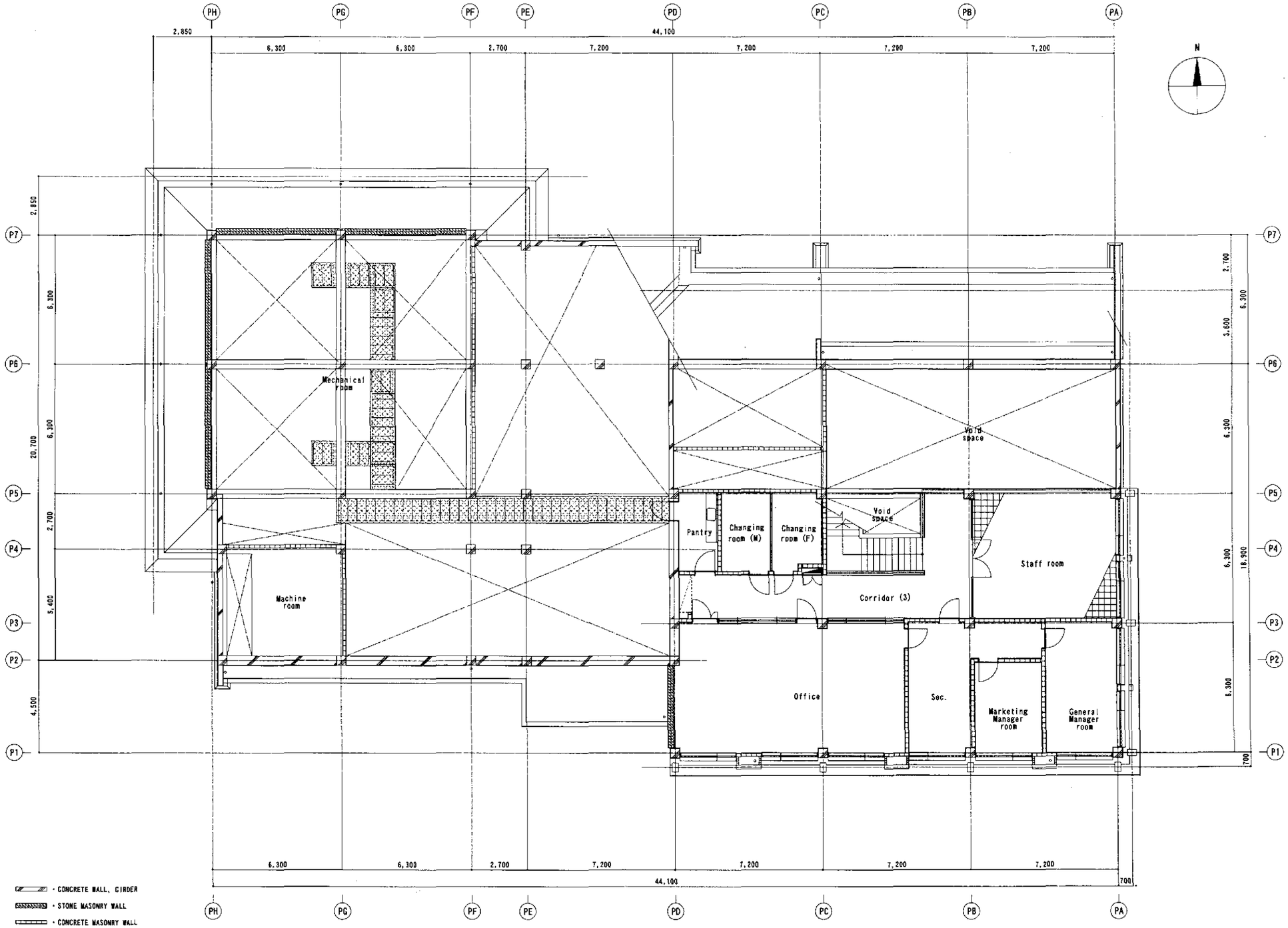
N

HIV/PA Preparation
Hepcell II Preparation
HIV/PA Manufacturing
Hepcell II Manufacturing
Material room
Changing room (F)
Changing room (M)
Ante room
Pass room
Shower
Corridor (1)
Mechanical room
Dispense room
Washing room
Store (4) Vial
Port
WC (F)
WC (M)
PS
Store (5) General
Reception
GFL=1001.15
(1FL=1000.65)
Exhibition-2
Entrance Hall
Store (1) Hepcell
Store (2) HIV/PA
Store (3) General
Corridor (2)
Lounge
Packing room
Labeling room
Quality control room
Exhibition-1
• 1001.10
• 1000.65
• 1001.00
• 1001.15

- CONCRETE WALL, GIRDER
- STONE MASONRY WALL
- CONCRETE MASONRY WALL
- HOLLOW CLAY BRICK
- PRECAST CONCRETE
- INTERLOCKING BLOCK
- CERAMIC FLOOR TILE
- CONCRETE METAL TROWELED
- GRAVEL
- ASPHALT PAVING
- SODDING
- PLANT
- NAIROBI STONE CURB
- NAIROBI STONE WALL
- PRECAST CONCRETE CURB

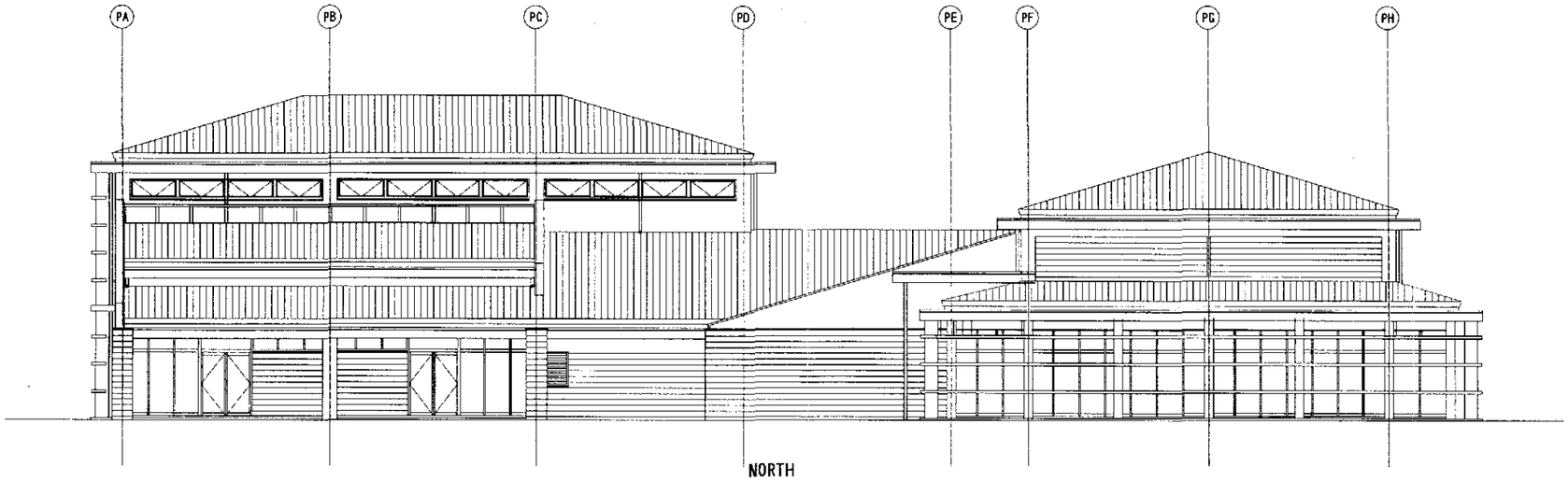
Production Unit

TITLE	SCALE	PAGE
Ground Floor Plan	1/200	85

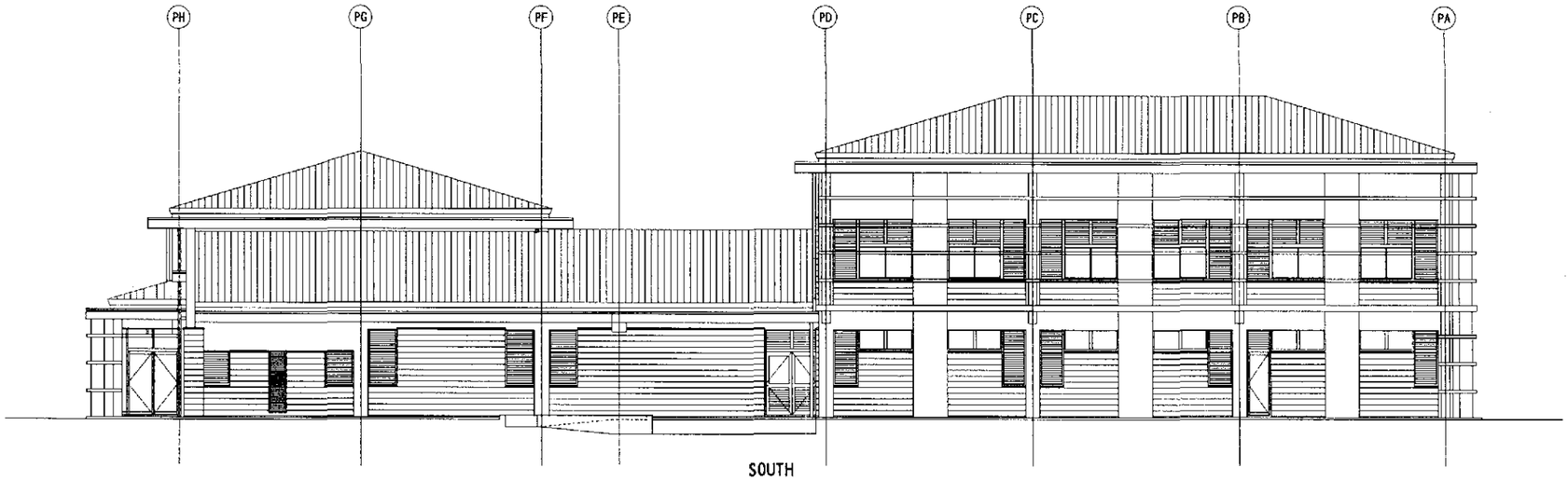


Production Unit

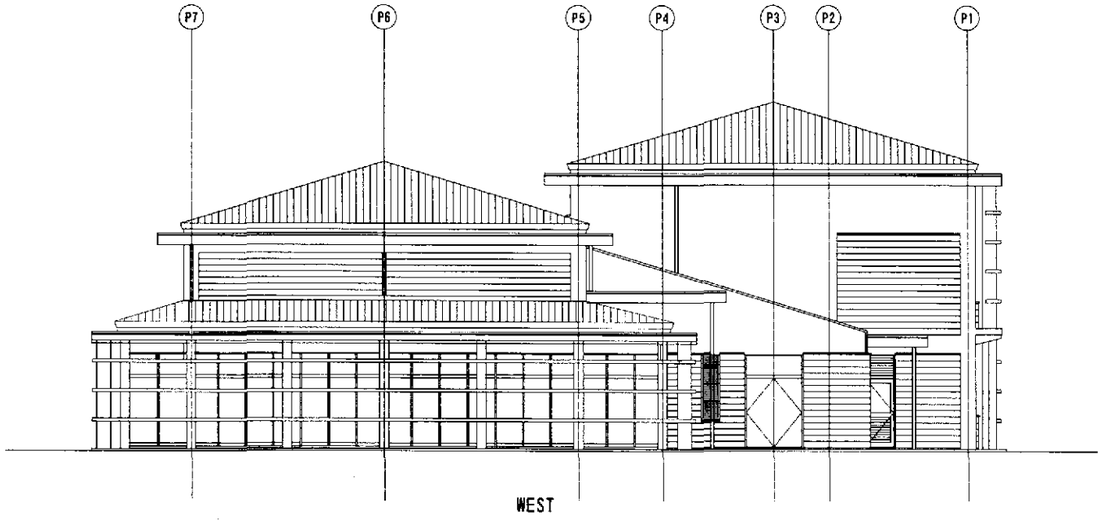
TITLE	SCALE	PAGE
First Floor Plan	1/200	87



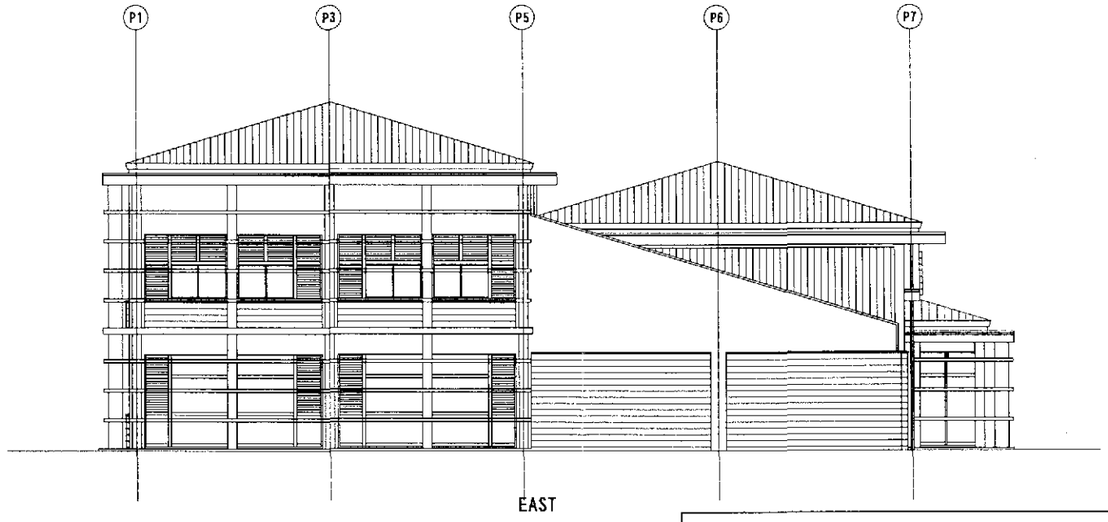
NORTH



SOUTH

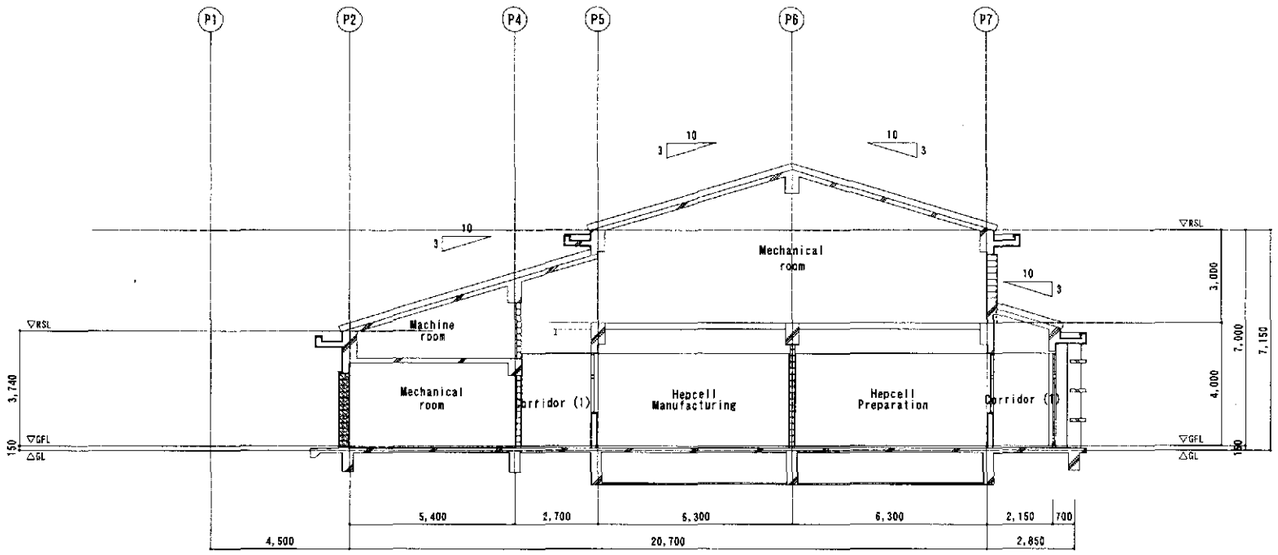


WEST

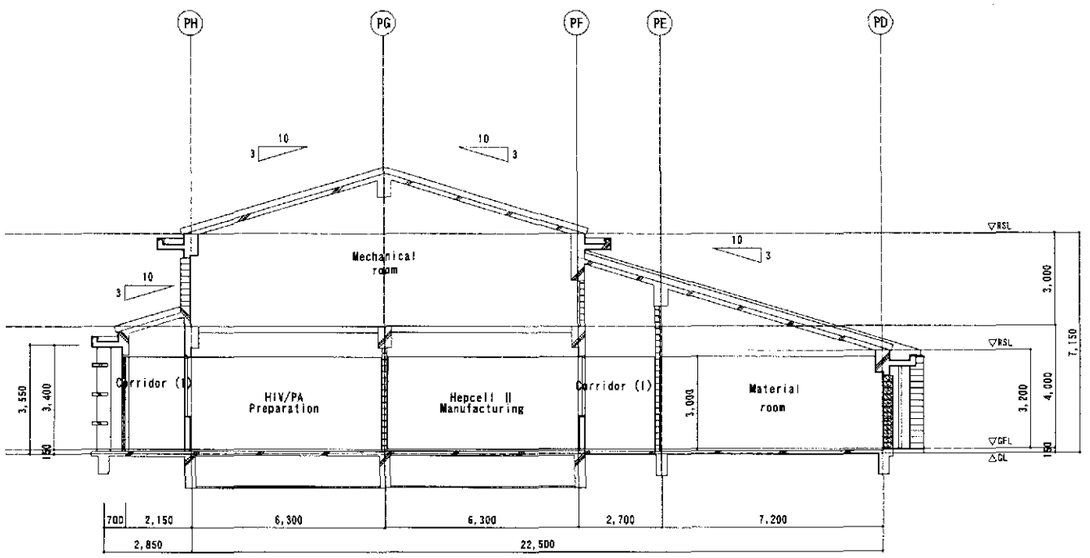


EAST

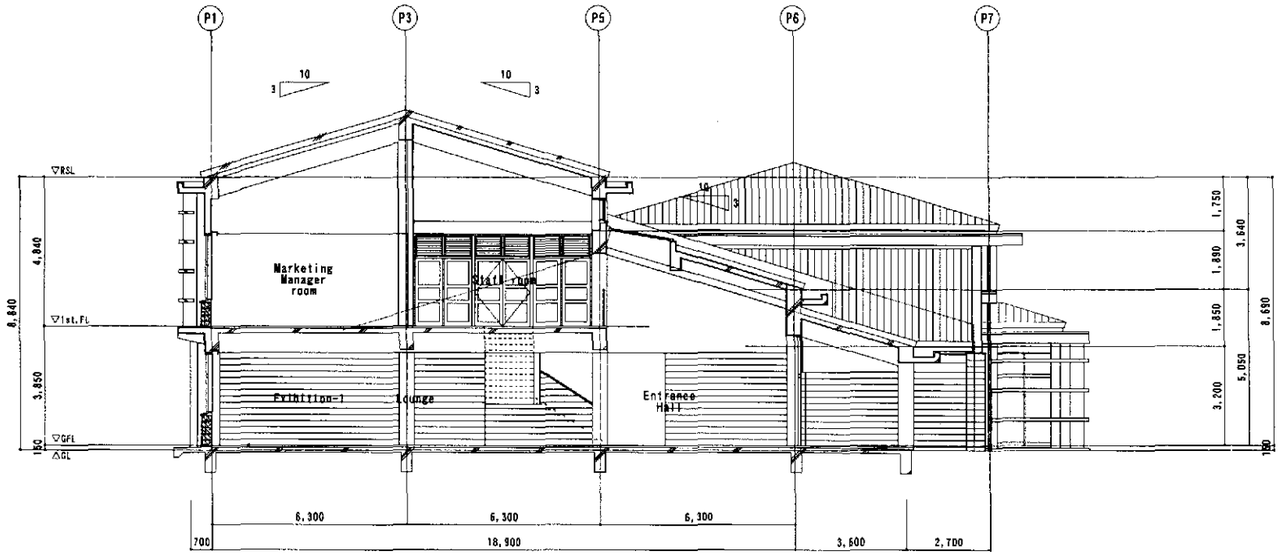
Production Unit			
TITLE	SCALE		PAGE
Elevation	1/200		89



A-A Section



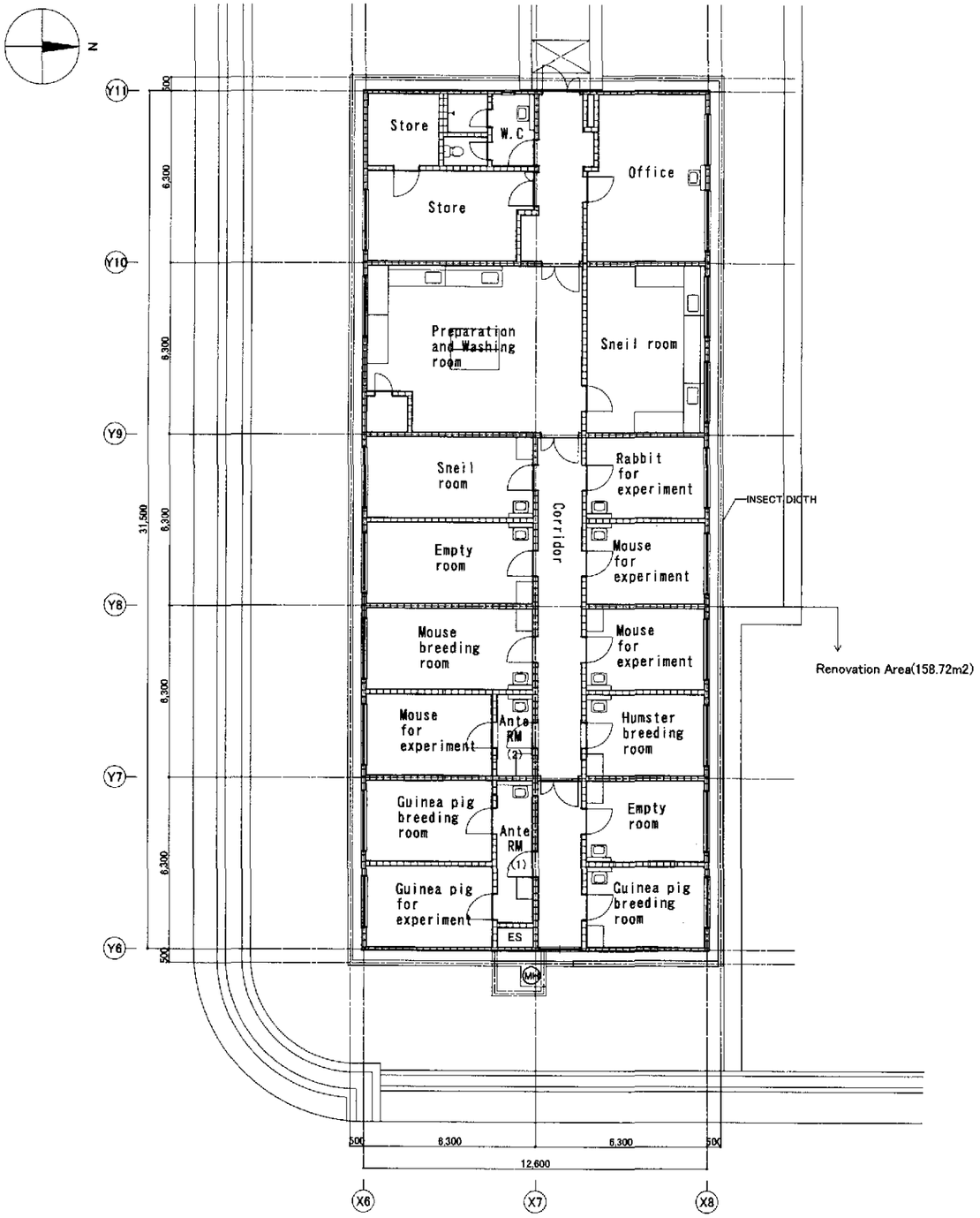
C-C Section



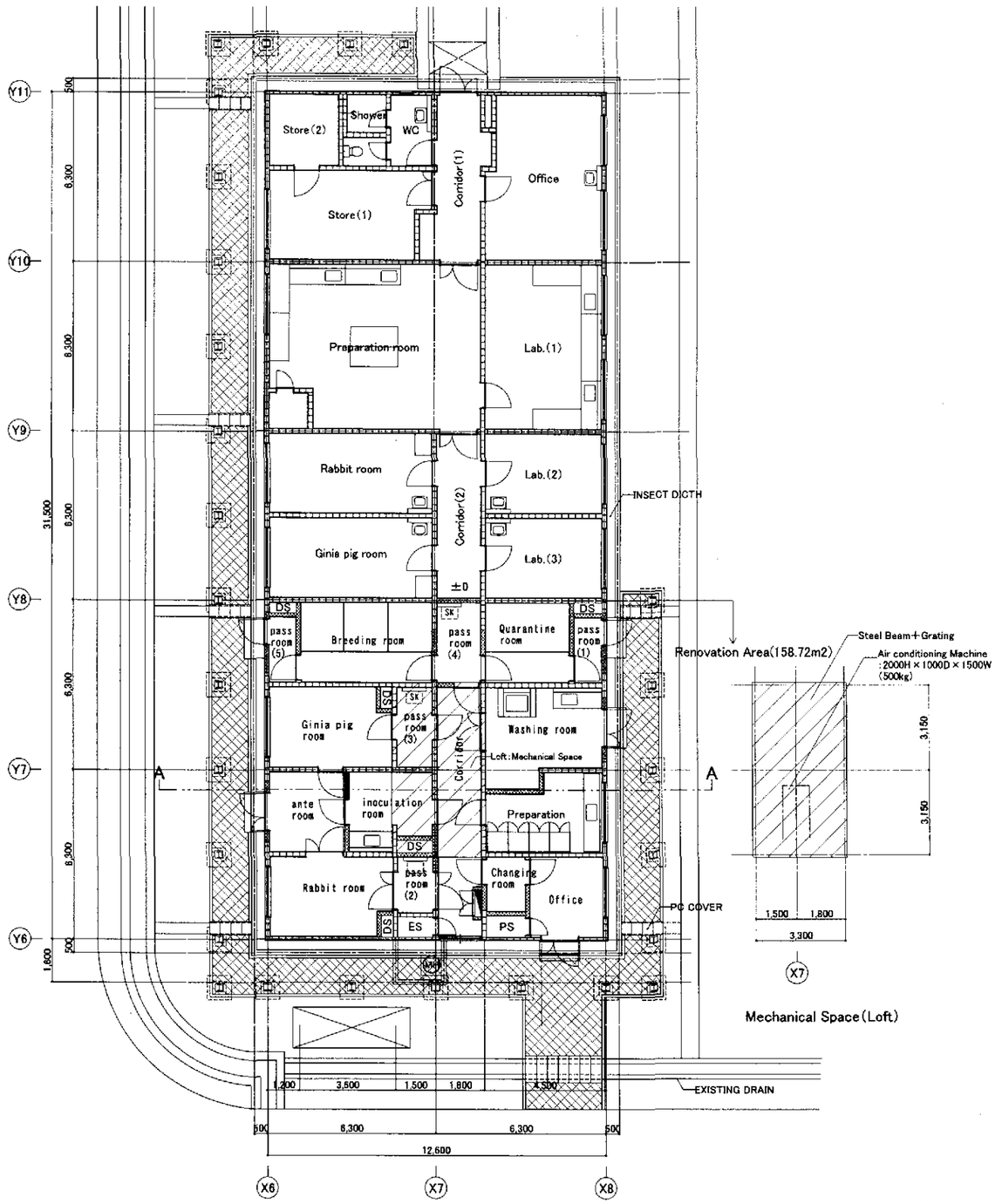
B-B Section

- CONCRETE WALL, GIRDER
- STONE MASONRY WALL
- CONCRETE MASONRY WALL
- HOLLOW CLAY BROCK
- PRECAST CONCRETE

Production Unit		
TITLE: Section	SCALE: 1/200	PAGE: 91

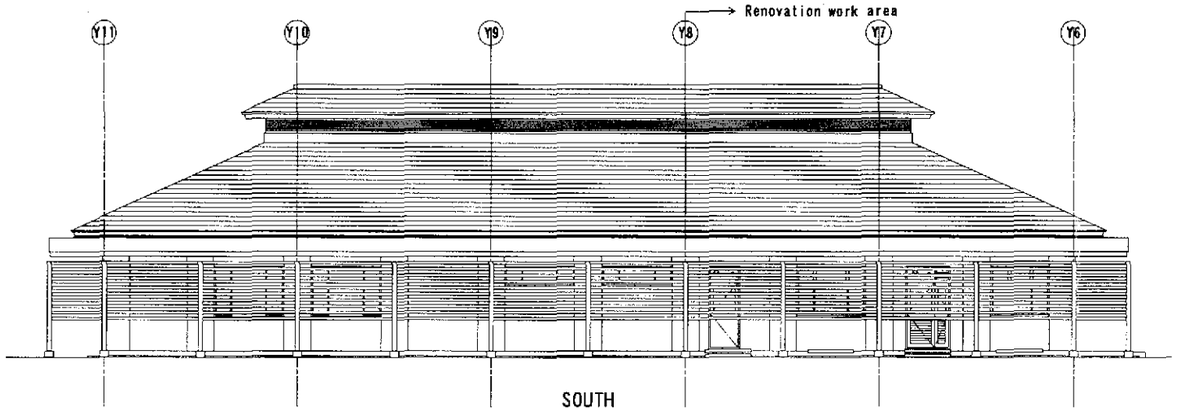


Before

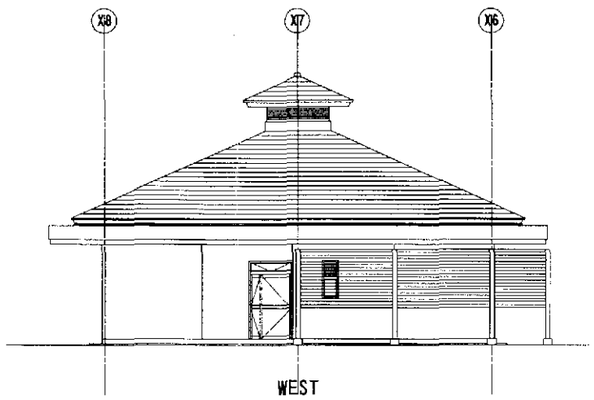


After

Animal Unit (Renovation)		
TITLE: Ground Floor Plan	SCALE: 1/200	PAGE: 93



SOUTH



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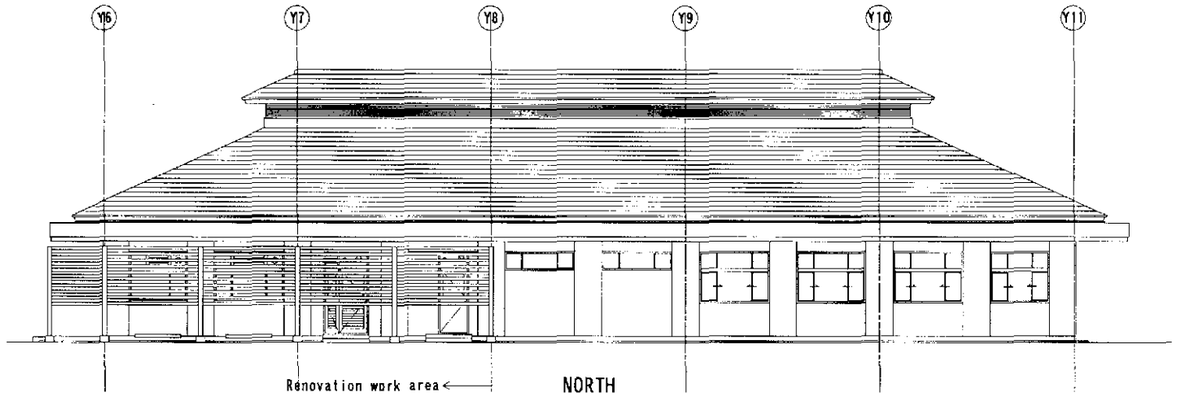

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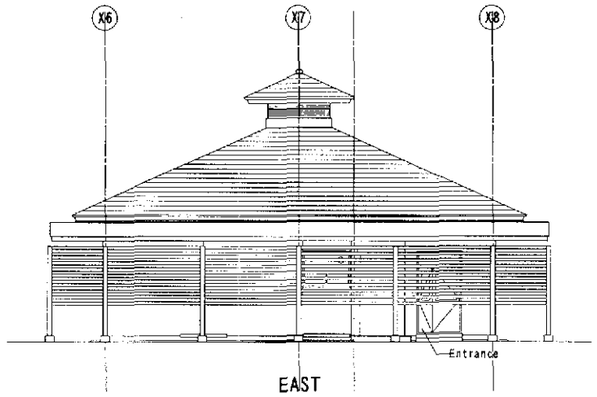
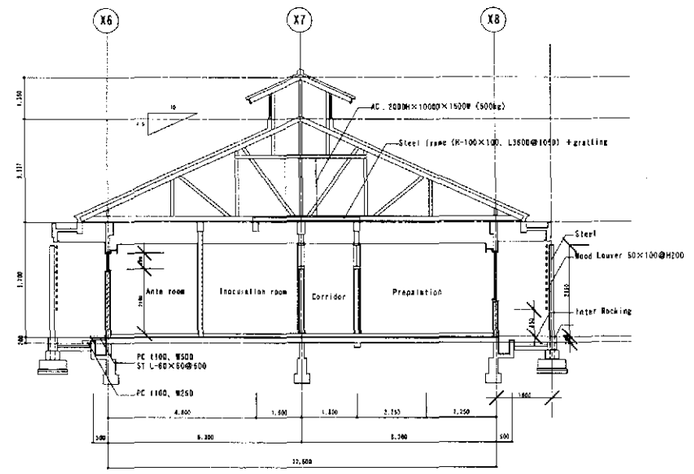


EAST



A-A' SECTION

Animal Unit (Renovation)		
TITLE Elevation・Section	SCALE 1/200	PAGE 95

T1 T2 T3 T4 T5 T6 T7 T8 T9

57,600

7,200 7,200 7,200 7,200 7,200 7,200 7,200 7,200

N

TH TG TF TE TD TC TB TA

A B C

Stair Case (2)
UP
Store
ES
Preparation room
cabinet
Changing room (F)
Changing room (M)
Pantry
PS
Corridor (3)
cabinet
cabinet
WC (M)
WC (F)
Parking
Dark room
Lab.1
Lab.2
Culture room
GFL=1001.65
Entrance Hall
GFL=1000.25
UP
Corridor (1)
Stair Case (1)
DN
GFL=1000
Library
Connecting Corridor
GFL=1000.25
WC (F)
PS
WC (M)
Office (ESACIPAC)
Manager room
Secretary room
Pantry
Corridor (2)
GFL=1000.25
Meeting room
Visitor's Office

4,800 2,700 7,200 7,200 7,200 7,200 57,600 7,200 7,200 7,200

1001.50 1000.50 999.50 999.00 998.50 998.00 997.50

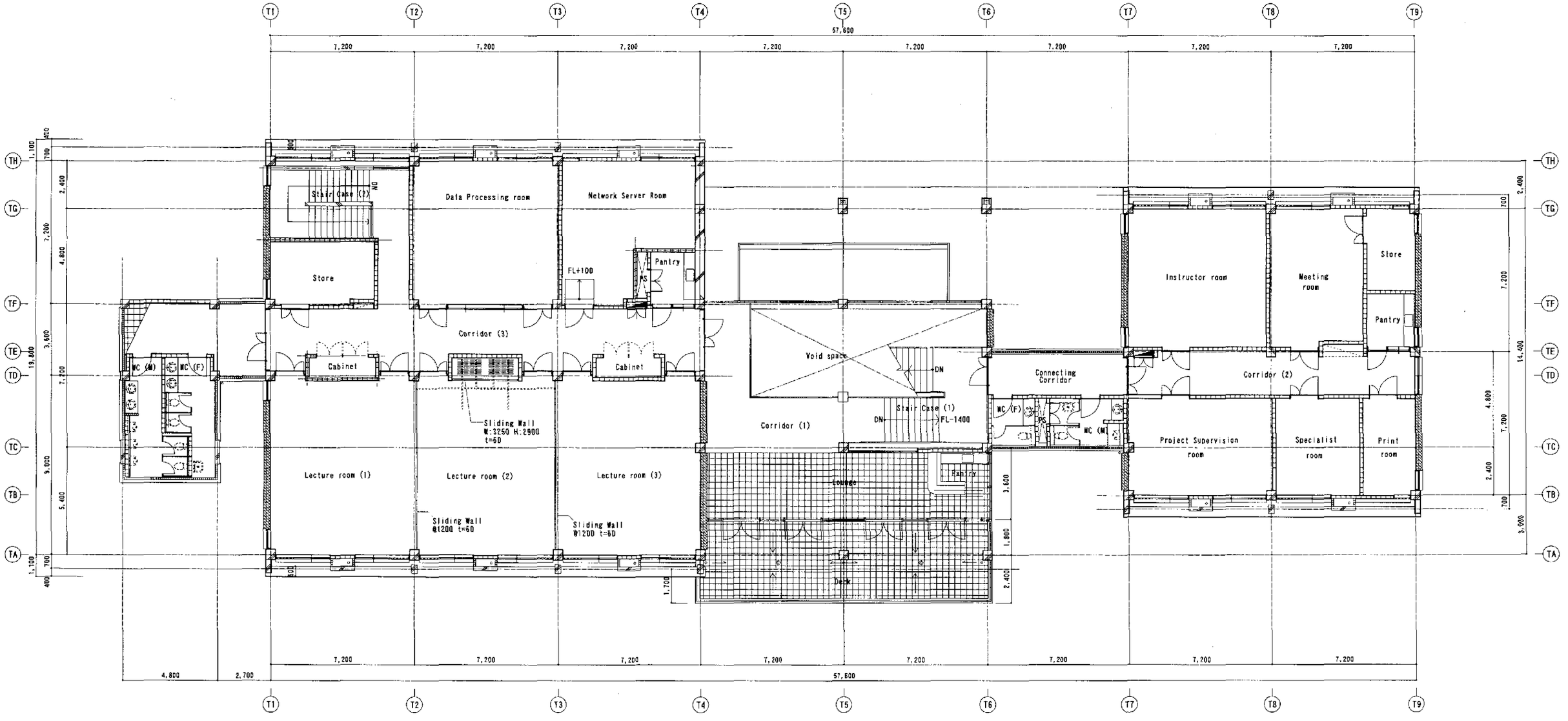
1階平面図

- CONCRETE WALL, GIRDER
- STONE MASONRY WALL
- CONCRETE MASONRY WALL
- HOLLOW CLAY BROCK
- PRECAST CONCRETE

- INTERLOCKING BLOCK
- CERAMIC FLOOR TILE
- CONCRETE METAL TROWELED
- GRAVEL
- ASPHALT PAVING
- SODDING
- PLANT
- NAIROBI STONE CURB
- NAIROBI STONE WALL
- PRECAST CONCRETE CURB

Traning Unit

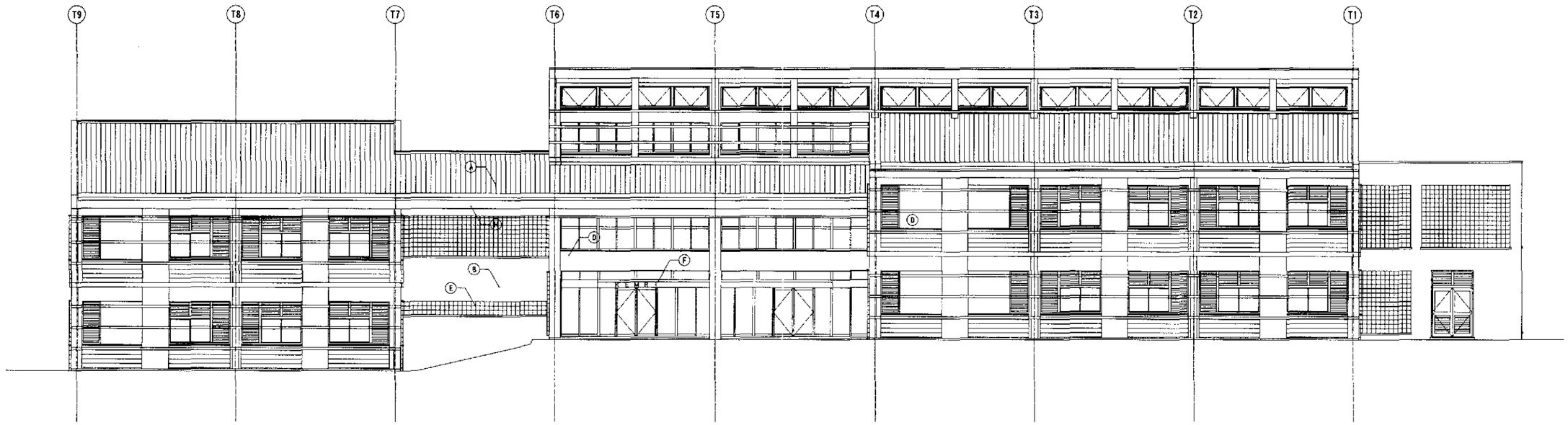
TITLE	SCALE	PAGE
Ground Floor Plan	1/200	97



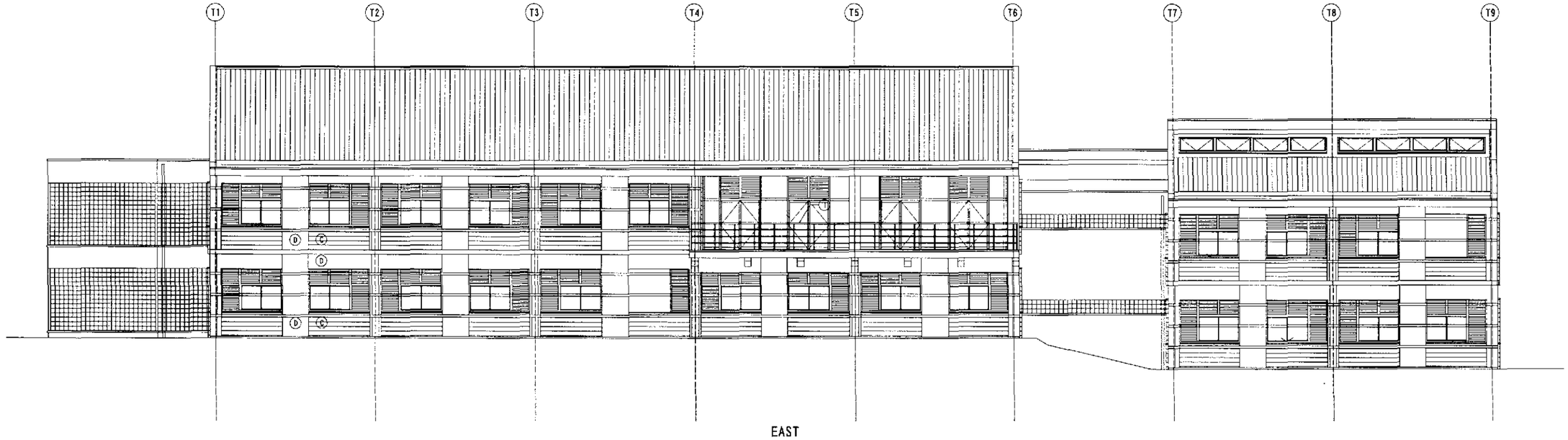
2階平面図

- CONCRETE WALL, GIRDER
- STONE MASONRY WALL
- CONCRETE MASONRY WALL
- HOLLOW CLAY BROCK
- PRECAST CONCRETE

Traning Unit		
TITLE: First Floor Plan	SCALE: 1/200	PAGE: 99



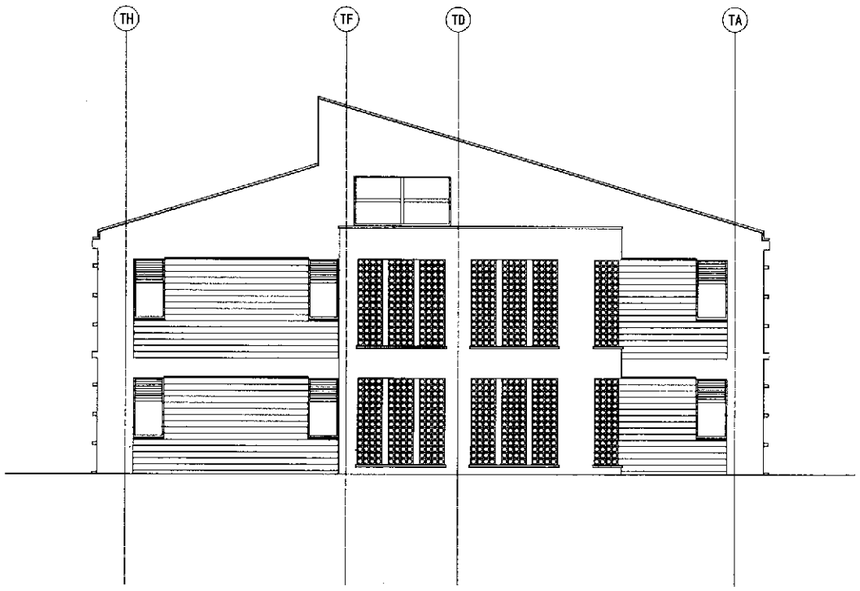
WEST



EAST

- (A) · CONCRETE ROOF TILE
- (B) · MORTAR METAL TROWELLED FINISH
- (C) · NAIROBI STONE(HAND CUT) COURSED ASHLAR MASONRY
- (D) · CEMENT PLASTER PAINTED
- (E) · HOLLOW CLAY BROCK
- (F) · CANOPY
- (G) · LOUVER
- (H) · EAVES GUTTER
- (I) · HAND RAIL
- (J) · PC COPING

Traning Unit		
TITLE: Elevation East & West	SCALE: 1/200	PAGE: 101



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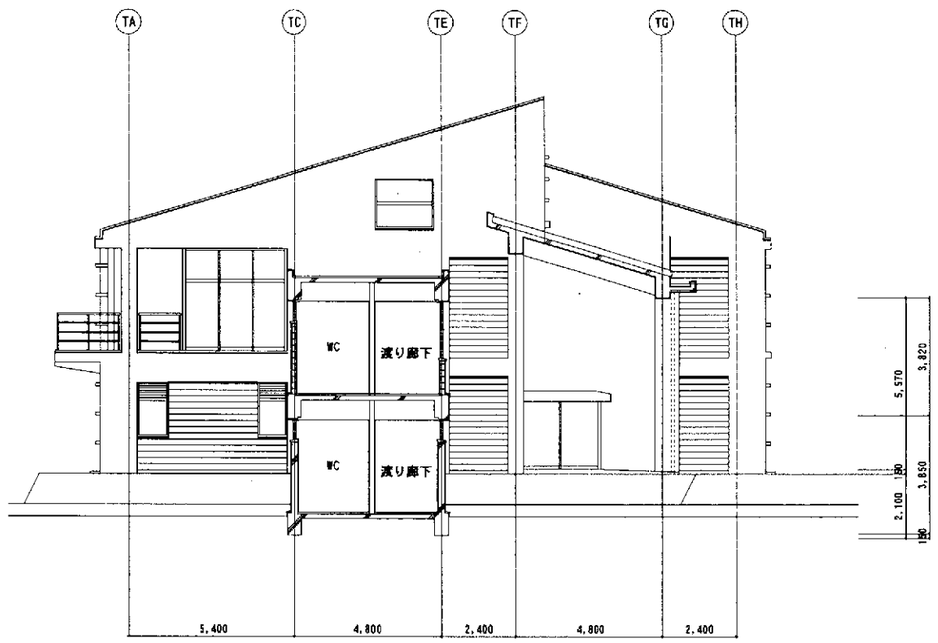

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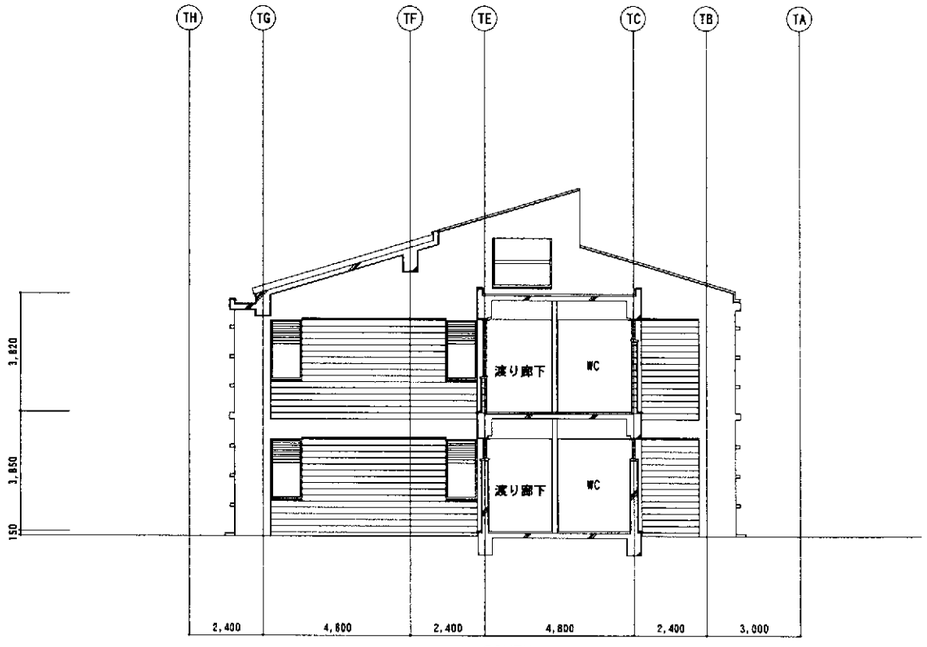

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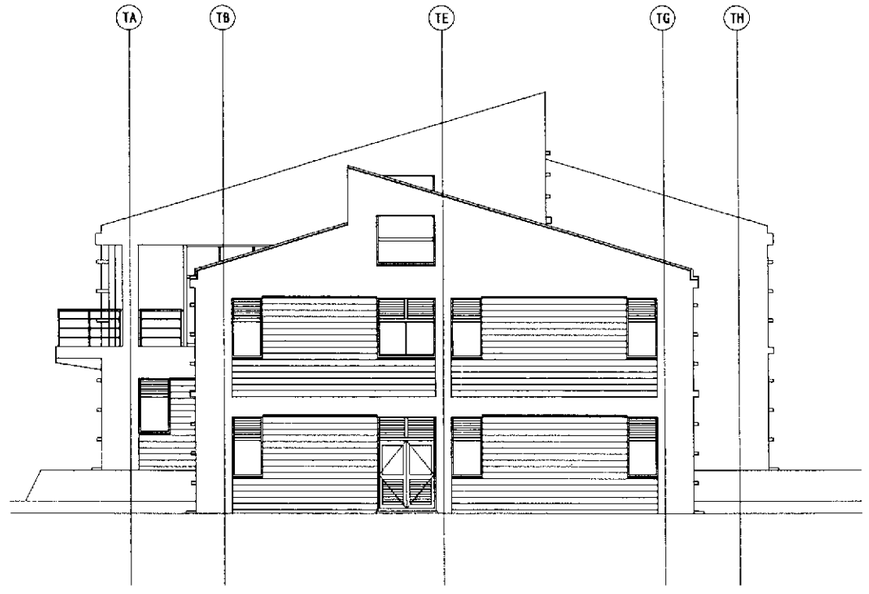
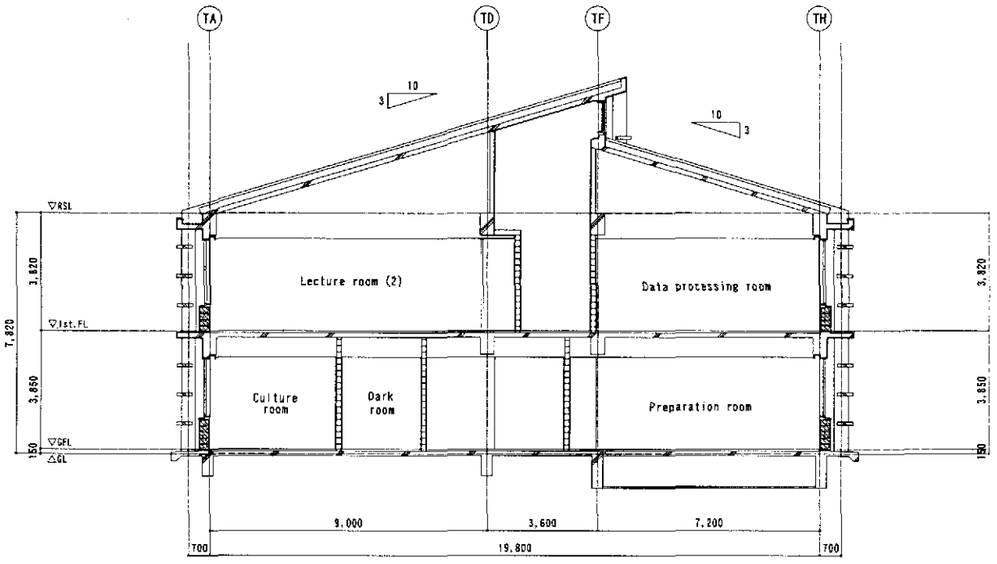


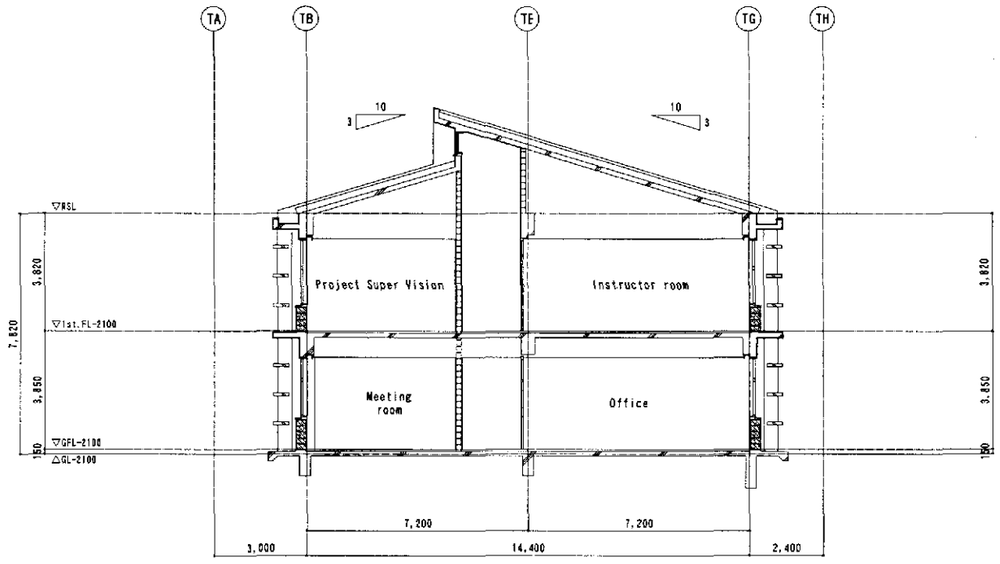
NORTH

- CONCRETE WALL, GIRDER
- STONE MASONRY WALL
- CONCRETE MASONRY WALL
- HOLLOW CLAY BROCK
- PRECAST CONCRETE

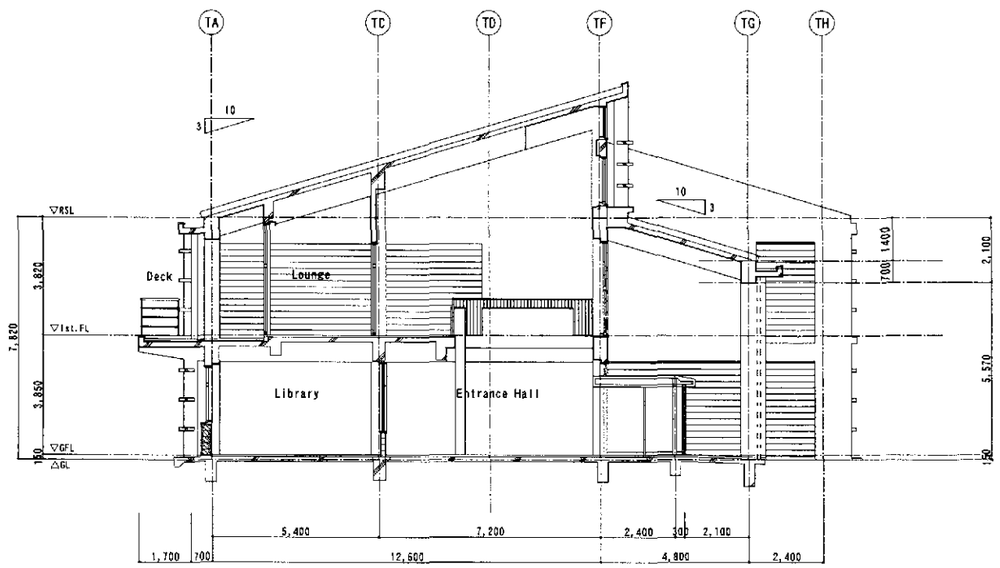
Traning Unit		
TITLE: Elevation North & South	SCALE: 1/200	PAGE: 103



A-A Section



C-C Section



B-B Section

ECONCRETE WALL&GIRDER
ESTONE MASONRY WALL
ECONCRETE MASONRY WALL
EHOLLOW CLAY BROCK
EPRECAST CONCRETE

Traning Unit		
TITLE: Section	SCALE: 1/200	PAGE: 105

2-2-4 Implementation Plan

2-2-4-1 Implementation Policy

(1) Implementation System

The Project will be implemented under Japan's grant aid system, after the Exchange of Notes (E/N) is signed on the Project, by and between the Governments of Japan and the Republic of Kenya after the decision by the Cabinet of the Government of Japan. The implementation system of the Project in Kenya is shown in the Figure 2-15.

The Ministry of Health (MOH) will remain the agency of the Republic of Kenya responsible for the implementation of the Project. The implementing organisation is KEMRI. The contracting party on the Kenya side, which is KEMRI (Director), will sign a consultant agreement and construction contracts concerning the Project, and will perform the Kenyan scope of work.

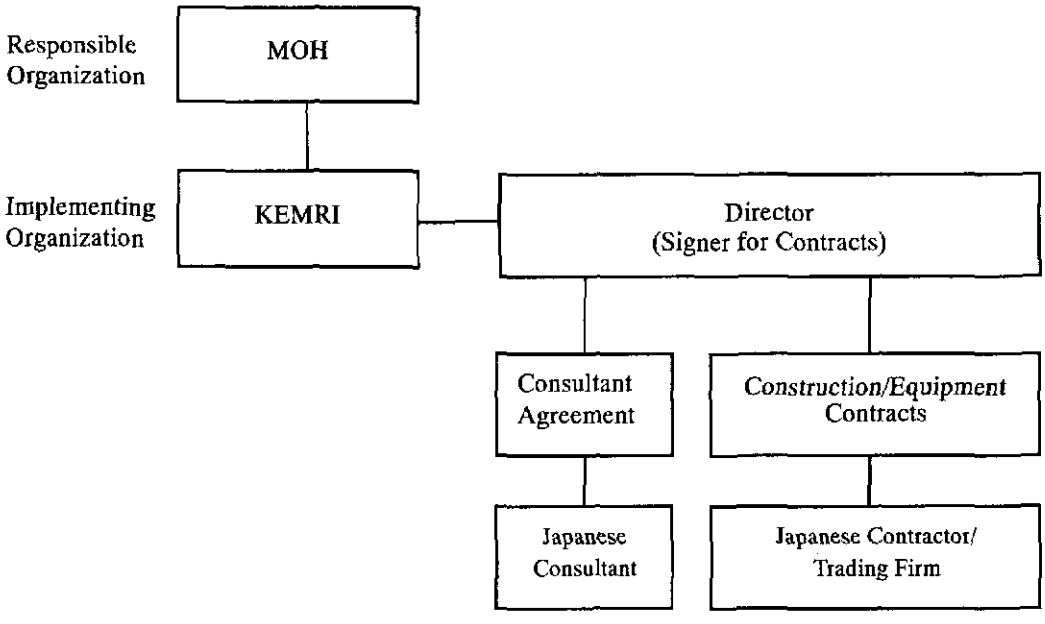


Figure 2-15 *Implementing Organisation*

In order for smooth implementation of the Project, the Grant Aid Project Steering Committee on the Kenyan side has been established. The members of the Committee are as follows:

Members of Grant Aid Project Steering Committee will be as follows:

KRMRI

- Director, KEMRI
- Deputy Director (Administration & Finance)

- Deputy Director (Research & Development)
- Deputy Director (Corporate Affairs)
- Coordinator (Blood Screening Kit Production Unit)
- Coordinator (Parasitic Diseases Control Training Unit)
- Production Manager
- Marketing Manager
- Finance Officer
- Director of Centre for Virus Research

National Public Laboratory Services

- Person in Charge

Major Functions

- Implementation of the Project, including Tender
- Getting tax exemption, building permission and other necessary permissions
- Provision of registered persons and fee in relation to the Project

Examination of the contents of tender documents (detailed design drawings, specifications, etc.) and inspection of construction work will be conducted by authorities concerned through the Project Steering Committee and KEMRI will finally make approval. Figure 2-16 shows the flow of these procedures.

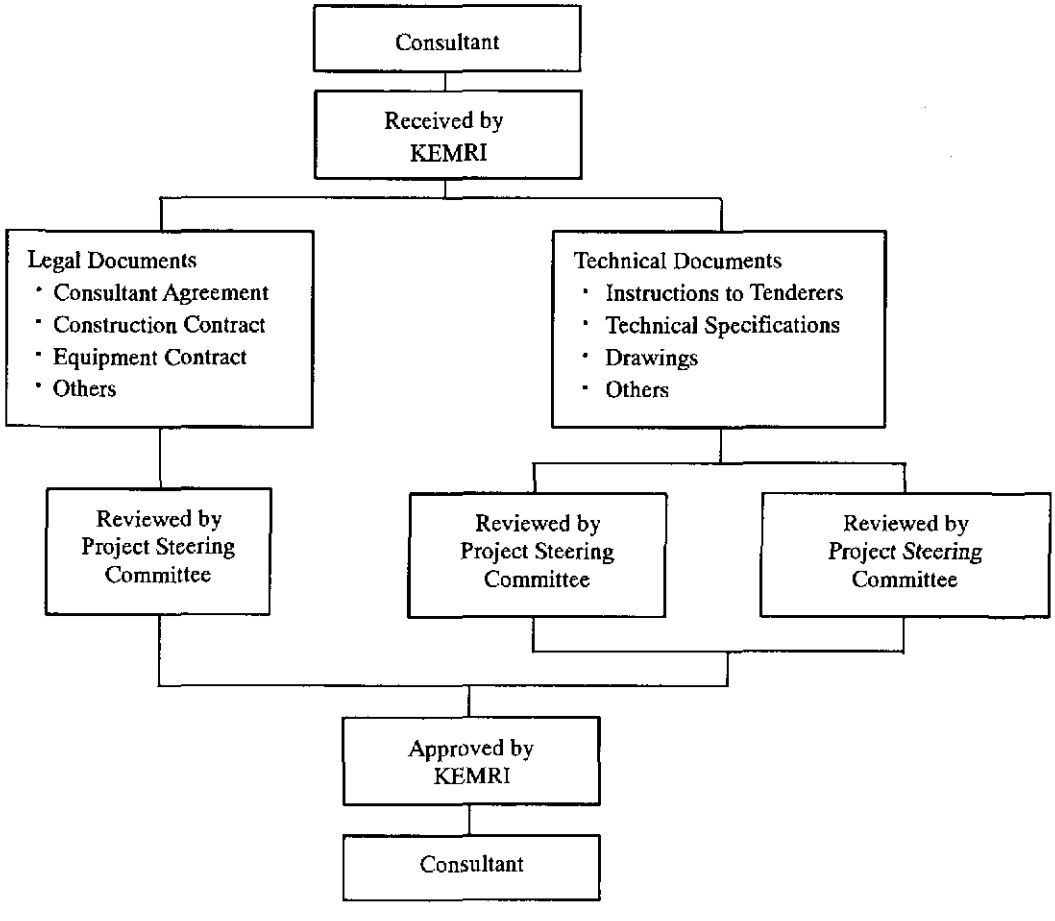


Figure 2-16 Approval Procedures

(2) Consultant

After the E/N is concluded, KEMRI concludes a consultant agreement with a Japanese consultant, regarding detailed design and construction supervision, and receives the Japanese government's verification of the agreement. For the smooth implementation of the Project, it is important to conclude a consultant agreement as early as possible after the conclusion of the E/N. After concluding the agreement, the consultant prepares detailed design drawings (Tender Documents) on the basis of the Basic Design Study Report and with the consent of KEMRI. Then KEMRI will make approval on tender documents, in accordance with the procedures mentioned above. The consultant carries out the assistant services of tender and the construction supervision services based on the agreement.

(3) Contractor

The Works relevant to the Project includes construction work (building) and equipment work (procurement and installation). The contractors will be appointed from among qualified Japanese legal persons through the open competitive tender with restriction on tender's qualifications.

KEMRI will conclude contracts on construction and equipment works with the successful tenderers, and receives the verification on the contracts from the Government of Japan.

(4) Use of Local Consultants

Two or more buildings will be constructed simultaneously; therefore, employment of local building engineers is necessary to supplement a limited number of the Japanese resident supervisors. The Grant Aid project includes a facility for manufacturing blood screening kits. The building housing the processes to manufacture them requires more mechanical and electric works than do other buildings. The building requires a certain degree of cleanliness. Accordingly, the construction requires Mechanical/Engineers.

(5) Use of Local contractors and Dispatch of Japanese Engineers

Typical top-level Kenyan construction companies have a manpower of about 3,000, a staff of 21 engineers, and an annual construction sales amount of about 800 million yen. Unlike Japanese construction companies, some local companies have their own wood-working and metal-working factories and their own woodworkers and metalworkers.

Even top-level Kenyan companies have as few as 20 to 30 engineers, far less compared with the Japanese companies. Under such a situation, the main contractor (a Japanese

legal person) of this project is required to employ local engineers reporting to the Japanese engineers, and to minutely instruct them on implementation and confirmation of schedule control, quality control and safety control.

Since the production unit of the Grant Aid project has clean area, the construction work is required of advanced quality control. The technical instruction and construction management by experienced Japanese professional engineers are indispensable to satisfactory completion of such speciality works.

2-2-4-2 Implementation Conditions

(1) Temporary Work Plan

The planned facility will be built on the same site but will be in distributed in more than one building. The construction work will be done while other research institutes are normally in operation. In order to prevent accidents involving injuries to third party persons, temporary enclosures and drop prevention devices will be appropriately installed. The vehicles for the construction work will be common types of vehicles and will share the same runways with other vehicles; therefore, watchmen will be deployed at appropriate places to prevent accidents. The temporary work plan will be so designed to minimise the crossings of the traffic lines of the vehicles and persons for the construction work and those of the KEMRI staff. The locations of construction material stockyard, assembly yard and temporary office should be determined after full discussions with KEMRI so that these may not interfere with the research and other activities of various facilities.

The planned facility will be build partly on the plot after the existing building on the plot have been removed. Proper precautions may be made to selection of the bearing ground for the building, and also to measures to avoid excessive excavation during demolition of the existing building.

It has been confirmed that CDC of the United States is implementing a large-scale construction and modification project in the KEMRI Nairobi premises. It is necessary to confirm whether the CDC's project and the Grant Aid project will overlap in site or to cause connection problems to each other. It is also necessary to confirm CDC's site and construction schedule.

(2) Material Procurement

Given the present conditions of the Kenyan construction material market, almost all major materials may be locally procurable. Presently, products of various qualities and specifications from South African and European countries are being marketed to be easily obtainable.

To facilitate repairs, maintenance and management of the facility after commissioning, the materials and equipment to be used for the project will be procured locally to the extent possible. However, precautions will be exercised to select goods of reliable quality and supply to forestall any adverse effects on the construction schedule. Locally produced

metal fixtures, glued laminated wood, plywood are not necessarily satisfactory in quality; therefore, products imported from third countries will be used.

Procurement of Japanese products for the Grant Aid project will be minimised, limited only to speciality equipment, because procurement from Japan will be disadvantageous not only in cost and schedule control but also in maintenance and management, because of transportation over the very long distance separating Kenya and Japan.

(3) Special Construction Method

There is no ready-mixed concrete plant in Nairobi; therefore, a batcher plant will be temporarily installed on the construction site. Here, concrete is transported for pouring manually in bucket by lines of people, and consequently, the amount of concrete that can be poured is limited to a maximum of 20 m^3 a day.

In Kenya it is common, in forming building frames, to use a two-step pouring method in which concrete is first poured to pillars to the height of beams and second to beams and slabs. Local construction companies are accustomed to this method but not to the monolithic pouring in which concrete is poured to the form enclosing pillars, beams and slabs, commonly adopted in Japan. Accordingly, the subject cooperation project will adopt the two-step pouring method.

2-2-4-3 Scope of Works

For the smooth implementation of the Project, it is important to define Japanese and Kenyan undertakings. The scope of works is mentioned as follows.

Table 2-31 Scope of Works

Works to be borne by Japanese side	Works to be borne by Kenyan side
1. Building construction work (including standard fix furniture, fixtures).	1. Preparation of construction site Preparation of construction site and site clearance (including clearance of existing woods), demolition of existing structure (including gas tank and gas piping) and demolition of existing substructure (including relocation of existing sewer pipes)
2. Electrical Work Electrical system, power and main wiring system, lighting and socket outlet system, telephone system, paging system, and automatic fire alarm system, lightning protection system	2. Lead-in and connection work Electricity: up to new electrical room constructed by Japanese side incoming LBS panel, transformer 1000 kVA at existing substation as necessary, Telephone: up to existing new MDF room constructed by Japanese side, and up to existing MDF, Water supply: up to new water reservoir constructed by Japanese side from city water main and existing well
3. Mechanical work Water supply system, drainage system, hot water supply system, gas supply system, sanitary fixtures, fire protection system, air conditioning and ventilation system.	3. Landscape work Road outside the Project Site, gardening, planting
4. Special work Generator system, sewage treatment system,	4. Furniture and equipment Curtain for windows (rail work will be done by Japanese side), blind, ordinary furniture.
5. Landscape work Road and parking inside the Project Site, outside lighting fixtures.	
6. Equipment work *Procurement and installation of equipment*	

Electrical system, Generator system, lightning protection system, water supply system (water reservoir) and so on, listed in "Works to be borne by Japanese side", will not be constructed for each unit (namely blood screening kit production unit, animal house, training unit) as attached facilities, but be constructed for all planned facilities.

2-2-4-4 Consultant Supervision

The Japanese consultant concludes a consultant agreement with KEMRI, and carries out the detailed design (Tender Documents) and supervision for the Project.

The purpose of supervision is to ascertain that construction/equipment works are in conformity with the drawings and specifications. The consultant will provide guidance and advice, and coordinate works throughout the construction period, from a fair standpoint for the proper implementation of the contents of the contract, and thereby to raise the quality of construction /equipment works. As such, the consultant will carry out the services mentioned below.

1) Cooperation in tendering and concluding a contract

   The consultant prepares the tender documents necessary for deciding contractors for construction work and equipment work, gives a tender notice, accepts applications for tendering, examines the applicants' qualifications, holds an explanatory meeting for tendering, deliveries tender documents, and accepts and evaluates tenders. The consultant gives advice to KEMRI and the successful tenderer on the conclusion of contracts.

2) Guidance, advice and coordination for contractor

   The consultant gives guidance and advice to the contractor and coordinates works, by examining the construction process, the progress schedule, the construction material procurement plan, the medical equipment procurement and installation plan, etc.

3) Inspection and approval of working drawings manufacture drawings, etc.

   The consultant examines the working drawings, the manufacture drawings and other documents presented by the contractor, and gives approval, with the necessary instructions.

4) Confirmation and approval of construction materials and equipment

   The consultant confirms conformity between the contracts and the construction materials/equipment, which the contractors wish to procure. Then the consultant will approve the procurement plan.

5) Inspection of the work

The consultant attends, as necessary, inspections and test carried out in plants where construction materials and equipment are manufactured, in order to ascertain that they possess the required quality and performance.

6) Report on the progress of the works

The consultant reports the progress and conditions of the works to the parties concerned of both countries.

7) Completion inspection and trial run

The consultant conducts completion inspections on the buildings and ancillary facilities as well as equipment installations, conducts trial runs to ascertain that the performances are secured as described in the contract, and hands in a certificate of the completion of inspection to KEMRI.

8) Consultant supervision system

In view of the scale of the Project, the consultant assigns one (1) resident supervisor, who perform the above-mentioned activities. In addition, the consultant sends experts in relevant fields to the site, as necessary in the progress of the works, for discussions, inspections, guidance and coordination necessary for the Project implementation. The consultant is prepared to dispatch additional experts where necessary, and establishes a back-up system, by assigning experts also in Japan. The consultant reports to the parties concerned of the Kenyan and Japanese governments on progress in the Project implementation and other necessary matters such as the procedure of payments and handing over upon completion.

The following figure shows the supervision system in Japan and Kenya.

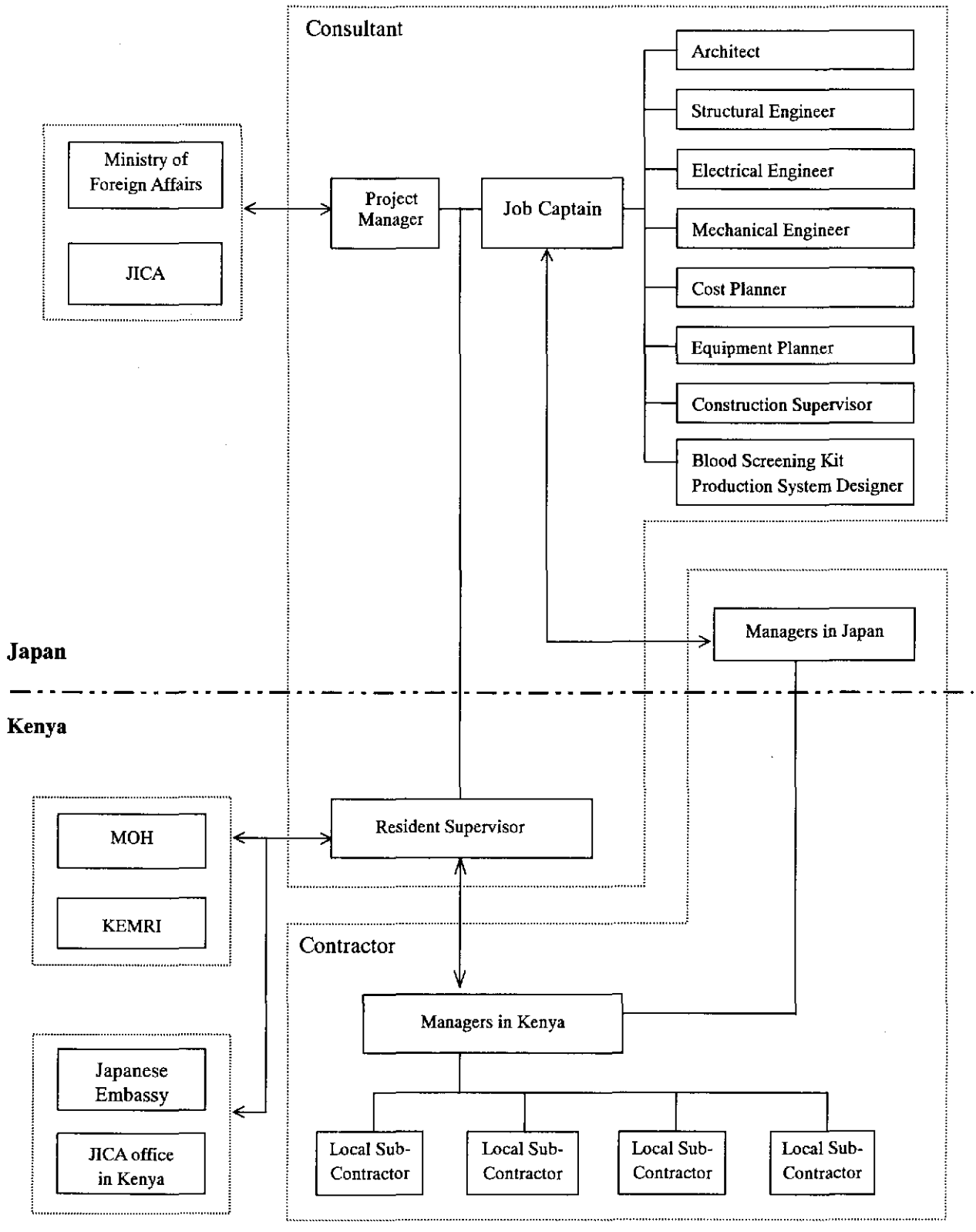


Figure 2-17 Supervision System

2-2-4-5 Quality Control Plan for Concrete

(1) Material

Cement: Cement meeting the British Standard or the Kenyan Standards is locally manufactured.

Aggregate: Local aggregates are insufficient in terms of both quality and quantity. They are characterised by low strength, and are unsuited for use for high-strength concrete.

Water for mixing: Tap water will be used.

Admixture: As a general rule, concrete is mixed at the construction site in Kenya. Therefore admixtures are not used.

(2) Mixing

As a rule, concrete is mixed at the construction site using rotary mixers. Since the components of concrete will be mixed by volume, their weights and specific gravities must be controlled minutely. Control on curing of cement and management of materials, aggregate for example, are important. Mixing time of longer than ten minutes must be secured in principle.

(3) Pouring of Concrete

Generally, concrete is poured from carts. Since concrete is mixed at the construction site, the workability will not be good. Therefore, utmost care will be needed to secure good compaction of concrete. Use of such machines as vibrator will be planned to secure compact pouring of concrete.

In Kenya the general procedure is to pour concrete to the pillars first, and then to assemble beams and floor frames and to finish the bar arrangements, and finally to pour concrete.

(4) Strength

The strength of the Kenyan Standard, 20 to 40N/mm^2 (28 day cube strength) is applied to structures. Considering the conditions of aggregates and scales of buildings, the design will be based on the strength specification of 25 to 30N/mm^2.

Strength control is done for 7day strength = 0.65Fc and 28 day strength = 1.0Fc.

(5) Quality Control of the Subject Cooperation Project

The quality control of concrete will be done according to the procedure generally followed in Kenya. However, the control method of the Japanese Architectural Standard Specification, Reinforced Concrete Work, (JASS5) will be applied as found appropriate.

The required strength for proportioning will be set according to the Kenyan Standard and the Japanese Architectural Standard Specification, Reinforced Concrete Work, (JASS5).

2-2-4-6 Procurement Plan

(1) Construction Material and Equipment

The Grant Aid project is construction of facilities to manufacture blood screening kit, and implement training and research. The procurement plan intends to select materials and equipment meeting the purpose of the facility, namely, those easy to be kept clean and sturdy. Specifically, the procurement policy may be explained by the following.

1) Local procurement

The materials and equipment will be procured locally to the extent possible to facilitate repairs, maintenance and management after commissioning. In so doing, care will be exercised to confirm their quality and availability for procurement to ensure that the locally materials and equipment may not adversely affect the construction schedule and other important elements of construction. Those imported materials and equipment which are procurable without restriction (those always available in the Kenyan market without taking importation procedure) are regarded as local products.

The greatest care must be paid to the quality and delivery schedule of the goods to be procured. The quality variance of the local products tends to be great; therefore, efforts will be made to assure quality, by examining the samples beforehand for example, and to cautiously watch delivery period, which tends to be delayed, to secure necessary amounts of materials and equipment.

2) Procurement by Importation

The materials and equipment considered difficult to locally procure, or for which the local products are considered not to meet the quality requirements or not to reliable in supply, will be procured by importation from Japan or third countries. In such cases the general contractor should see to it that all procedures for customs clearance be done smoothly, well coordinating with the concerned offices of the government of Kenya. The South Africa is a candidate source of import; however, delivery period and documentation are said to be not well done regarding importation from South Africa. Importation from Singapore will be studied along with that from South Africa.

In case the list price plus the packaging and transportation cost of a commodity procured from Japan or a third country is found to be lower the price of local procurement, the procurement by importation will be opted.

3) Transportation Plan

The materials and equipment procured from Japan and third countries will be transported by sea to the Port of Mombasa, Kenya. From Mombasa the goods will be transported on land by freight cars to the construction site in Nairobi. Procurements by air transportation direct to the Nairobi Airport will not be rare. The road conditions and security along the road are so bad that most constructors have experienced accidents or robberies.

Some of the materials and equipment to be procured are very susceptible to shocks, high humidity and high temperature to such extents that their functions may be impaired. Accordingly, these will be well packed to be able to withstand long-time transportation.

4) Procurement Plan

Major construction materials and equipment are shown in the following broken down by procurement sources: local market, Japan and third country, with rationale supporting the selection of procurement source.

Table 2-32 Procurement Plan for Major Construction Materials and Equipment

Type of work	Material	Procurement source			Note
		Local market	Japan	Third country	
Reinforced concrete work	Portland cement	○			The local products (Nairobi, Mombasa) meeting with BS and Kenyan Standards are available. The local products are satisfactory.
	Fine aggregate	○			The local materials will be used. However, materials are poor in both quality and quantity.
	Coarse aggregate	○			ditto
	Ready-mixed concrete	○			The local products will be used. There is no ready-mixed concrete plant. Some constructors have their own plants.
	Deformed bar		○		The local manufacturer has shut down the plan. The products will be procured from Japan.
	Form	○			The local products will be used.
Steel work	Steel frame member		○		The light gauge steel is only made locally. Heavy steel members will be procured from Japan.
Masonry work	Concrete block	○			The local products are produced under the BS standard. However, variance of strength is large due to faulty process control, in curing for example. They cannot be used for bearing wall.
	Brick	○			The local products will be used.
Waterproofing work	Asphalt waterproofing	○			The local products will be used. The special attention is necessary on local contractors work because of poor experience.
	Liquid-applied membrane waterproofing	○			This method is not virtually practised in Kenya, though there seem cases of application.
	Sealing compound		○		The products available in the market have mostly been stored for a long time, and have problems with quality (in weatherability in particular). The products will be procured from Japan.
Plaster works	Cement mortar	○			Unlike Japanese practice, the scratch coating and middle coating are not done by trowel but by pushing mortar on the substrate and the finish coating only is done by trowel.
Tile work	Earthenware tile			○	The local products do not have lugs and are not precise in dimensions. The products will be procured from Thailand.
	Porcelain tile			○	ditto

Type of work	Material	Procurement source			Note
		Local market	Japan	Third country	
Stone work	Stone	○			Nairobi stones are locally available.
	Terrazzo	○			Terrazzo is locally available.
Wood working	Wood	○			The local materials will be used. However, the special attention is necessary because the local products are poor in quality.
	Glued laminated wood	○			ditto
	Plywood	○			ditto
Metal working	Light-weight ceiling substrate			○	The products will be procured from Thailand because the local products are poor in quality and strength.
	Decorated metal, handrail		○	○	The products will be procured either from third countries or Japan, because the local products are poor in quality.
Wooden fixture work	Door, fixture frame			○	The products will be procured from Thailand, because the local products are poor in quality.
Metal fixture work	Aluminium fixture			○	The products will be procured from Singapore, because locally assembled products are inferior in air-tightness and water-tightness.
	Steel fixture			○	The products will be procured from Thailand, because the local products have problems in quality and precision.
Glazing work	Glass pane		○		There is no local product. The products will be procured from Japan.
	Glass block		○		ditto
Paining work	Internal painting	○			The local products are satisfactory. Epoxy paints are used in place of dust-proof paints.
	External painting	○			Speciality paints are not locally available. However, suitable local products will be used for maintenance sake.
Interior finish work	Plaster board		○		There is no local product. The products will be procured from Japan.
	Rock wool sound insulating board		○		ditto
	Rock wool		○		ditto
	Flexible board		○		ditto
	Decorated plywood		○		The local products are poor in quality. The products will be procured from Japan.

Type of work	Material	Procurement source			Note
		Local market	Japan	Third country	
Finished units installation work	Sink, medical sink		○		The local products are poor in quality. The products will be procured from Japan.
	Overhead closet		○		ditto
	Wooden furniture		○		ditto
	Sign		○		Products are procured from Japan.
Exterior work	Paving material	○			The imported local products are available in the market.
	Interlocking block	○			The local products are not uniform in size. However, the local products will be procured for the sake of maintenance.
	Curb	○			The local products are satisfactory.

Type of work	Material	Procurement source			Note
		Local market	Japan	Third country	
Mechanical work	Air-conditioning machine			○	Although local products are available in the markets, Singapore products will be procured especially for medical purposes.
	Fans			○	Since local products are poor quality and poor durability, Singapore products will be procured.
	Air inlet and outlet			○	ditto
	Filter			○	Since local products (but poor in variety) are available in the markets, Singapore products will be procured.
	Duct material		○		Since local products are poor quality and poor durability, Japanese products will be procured.
	Pump			○	Since local products are poor quality, Singapore products will be procured.
	Electrical water heater			○	ditto
	Sanitary fixture			○	Since local products are poor quality & quantity, and poor durability, Singapore products will be procured.
	FRP panel tank			○	Since local products are poor quality and poor durability, Singapore products will be procured.
	Copper pipes		○		Since local products are poor quality, Singapore products will be procured.
	Steel pipes		○		ditto
	PVC pipes		○		Since local products are poor quality & quantity, and poor durability, Japanese products will be procured.
	Insulating material		○		ditto
	Fire extinguisher			○	Since local products are poor quality and poor durability, Singapore products will be procured.
	Water treatment		○		Since there are no local made products, Japanese products will be procured.

Type of work	Material	Procurement source			Note
		Local market	Japan	Third country	
Electrical work	Transformer			○	Since local products are poor quality, Singapore products will be procured.
	Electric power generator	○			Although imported products are available in the markets, local products will be procured due to smooth maintenance.
	AVR		○		Since local products are poor quantity, Japanese products will be procured.
	Boards			○	Since local products are poor quality, Singapore products will be procured.
	Conduit tube		○		Since local products are poor quality & quantity, Japanese products will be procured.
	Boxes		○		Since local products are poor quality & quantity, Japanese products will be procured.
	Electric wire		○		Since local products are poor quality & quantity, Japanese products will be procured.
	Cable		○		ditto
	Lighting equipment		○	○	Since local products are poor quality, Singapore products will be procured. Such special ones as with clean specifications are Japanese products.
	Wiring accessory		○		Since local products are poor quality, Japanese products will be procured.
	Telephone equipment	○			Since imported products are available in the market, local (imported) products will be procured.
	Public address system		○		Since local products are poor quality, Japanese products will be procured.
	Fire alarm system		○		Since JIS is applied for design and no locally made product are available, Japanese products are procured
	UPS	○			Although imported products are available in the local markets, local products will be procured due to smooth maintenance.

* The country, in which equipment are procured, was decided after comparison of prices in Japan and other countries.

(2) Equipment

All pieces of existing equipment used by KEMRI (which have been procured mainly under Japanese assistance programmes) are generally maintained well without major troubles. Some pieces of equipment (mainly in Production Unit) to be procured under this project need periodic inspections, at the beginning and ending of the manufacturing process for example, in order to be able to ensure stable supplies of the PA kit and HEPCELL kit, while assuring their quality. No one but technicians with professional skill can do such periodic inspections and replacement of parts of equipment, the compressor for example. Ideally, such skilled technicians with professional knowledge are secured in KEMRI. If not, such pieces of equipment should be procured from manufactures, including their agents, which station in Kenya such skilled technicians with professional knowledge.

Sources of procurement could be third countries for certain equipment, in case a fair competitive bidding cannot be expected if the source is limited to Japan, in such a case as competitive bidders being less than three for example.

Table 2-33 Equipment by Third Country Procurement

Equipment	Reason
Lyophilizer, Ultracentrifuge	Skilled technicians with professional knowledge of manufactures (or agents) need to be stationed in Kenya.
Lyophilizer, Ultracentrifuge, Water distiller , Refrigerated centrifuge, Ultra low deep freezer, Electronic balance, Fraction collectors, pH meter, Plate mixer, Vortex mixer, Magnetic stineer, Micro plate washer, Micro plate reader, Sonifier, Computers, Photocopy machine, Printing machine, Note type computers	Fair competitive bidding may not be realised if country of origin for procurement is limited to Japan.

2-2-4-7 Implementation Schedule

The implementation schedule following conclusion of the Exchange of Notes (E/N) for the Project is illustrated in the next page. It is divided into three (3) Stages: detailed design stage, tender stage and construction stage as follows.

(1) Detailed design stage

KEMRI and a Japanese consultant make an agreement on the consultant services for the Project. The verification of the agreement will be received from the Government of Japan. The consultant will prepare documents of the detailed design in accordance with the results of this Basic Design Study Report. Following discussions with KEMRI, tender documents will be prepared, and approval from KEMRI will be obtained.

The estimated terms necessary for detailed design stage (including the preparation of tender documents) are 4 months.

(2) Tender stage

The estimated terms necessary for tender stage are 3 months.

(3) Construction stage (construction and equipment works, and consultant supervision)

After the contracts are finalised, verification is obtained from the Government of Japan, and then the works can begin. The consultant will carry out the supervision.

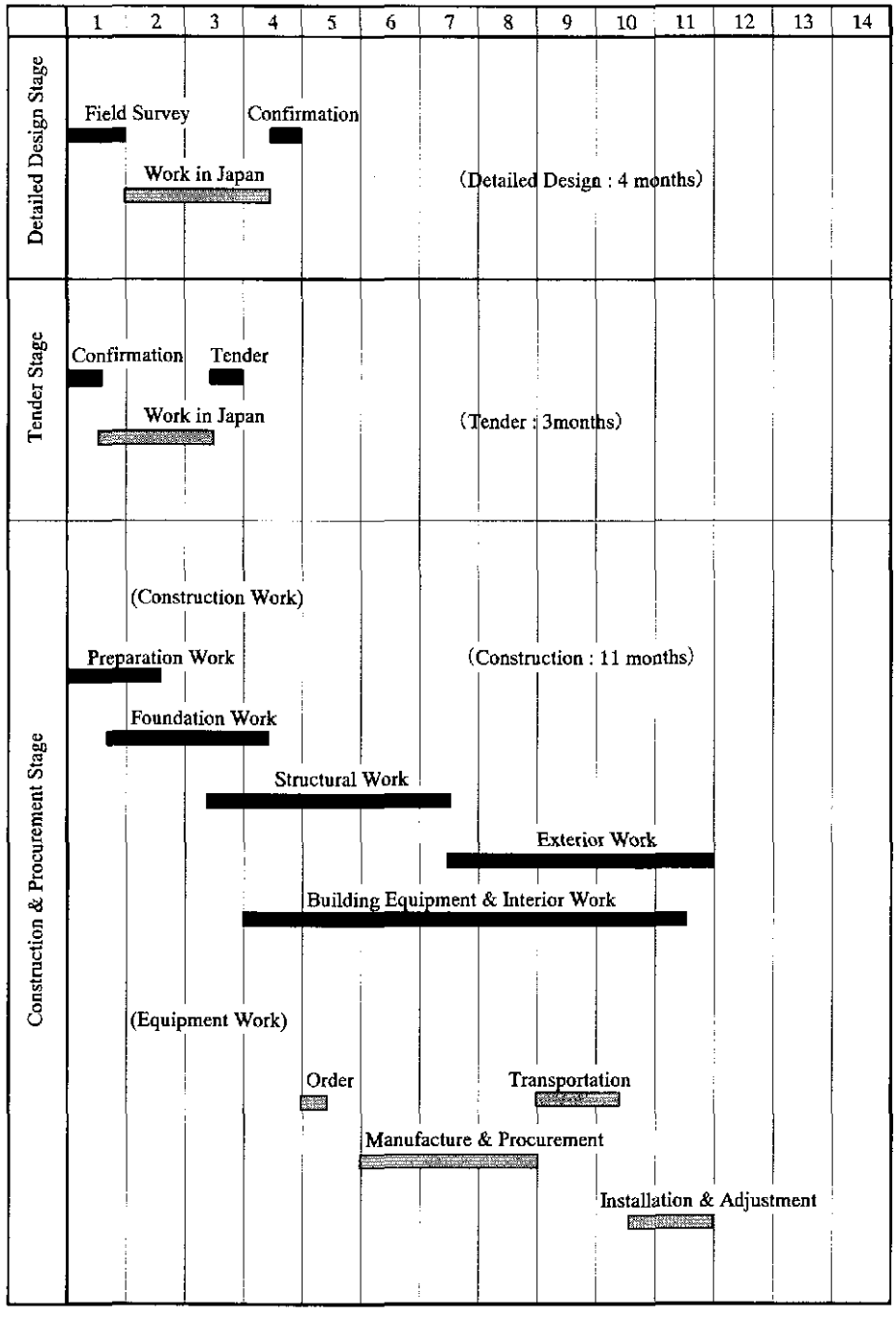
The estimated terms necessary for construction and equipment works are 11 months.

The outline of the Project is shown in the following table under the Japan's Grant Aid System.

Table 2-34 Construction and Equipment Work

Construction of Building	Production Unit (1,737 m²) First floor : General Manager room, Marketing Manager room, Office, Staff room, and so on Ground floor : PA kit Manufacturing room, Hepcell kit Manufacturing room, Material room, Dispense room, Quality control room, and so on Animal House (262 m²) Ground floor : Guinea pig room, Rabbit room, Inoculation room, Quarantine room, and so on Training Unit (2,083 m²) First floor : Lecture room, Data processing room, Network room, Project Supervision, Instructor room, Meeting room, Specialist room, Lounge, and so on Ground floor : Parasitic Lab., Infectious Lab., Preparation room, Culture room, Office, Manager room, Secretary room, Entrance hall, Library, and so on	
(Total area)	(4,082 m²)	
Supply of Equipment	The Equipment, which is necessary for the production unit. (Lyophilizer, Ultracentrifuge, Refrigerated centrifuge, Refrigerator, Ultra low deep freezer, Safety cabinet, etc.)	The Equipment, which is necessary for the training unit. (Binocular microscope, Fluorescent microscope, Dissecting binocular microscope, CO2 Incubators, Clean benches, etc.)

Table 2-35 Implementation Schedule



2-3 Obligations of Recipient Country

(1) Major Undertakings

The following items are major undertakings by the Kenyan side.

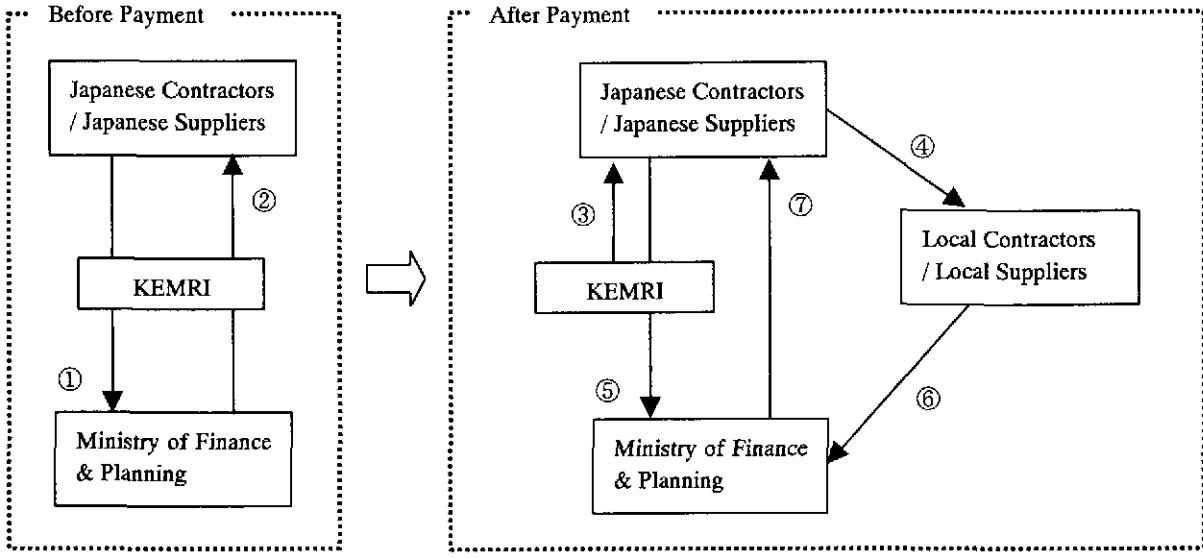
1) Exemption of the taxes relevant to the Project.

For VAT (Value Added Tax), which is one of the taxes imposed in Kenya, the following reimbursement system will be applied.

Person in charge

Deputy Director (Administration & Finance) of KEMRI

Basic Procedure (for VAT)



① Submit application letter for "Zero Rate Basic Certificate" through KEMRI
② Issue Zero Rate Basic Certificate
③ Payments (by Japan's Grant Aid) without VAT under the Construction/Equipment Contracts
④ Payments with VAT
⑤ Application Letters for Reimbursements (VAT-Return) with "Zero Rate Basic Certificate" through KEMRI
⑥ VAT to Ministry of Finance & Planning
⑦ Reimbursements (VAT-Return) shall be made within one (1) month after the date of application letters

2) To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contact such facilities as may be necessary for the their entry into the recipient country and stay therein for the performance of their work.

3) To exempt Japanese nationals from custom duties, internal taxed and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contracts.

4) Guarantee of the prompt landing of materials and equipment at the port of destination, tax exemption and customs clearance, and overland transportation.

5) Application for and acquisition of the government approval of the construction of buildings and facilities under the Project.

6) Issuance of Banking Arrangement (B/A) and Authorisation to Pay (A/P), and the bearing of the fees for them.

7) Budgetary measures for the effective operation, maintenance and management of the facilities built and the equipment procured under Japan's grant aid system

(2) Cost Estimate for the Scope of Kenyan Works

The scope of works to be borne by the Government of Kenya is estimated in the following Table.

Table 2-36 Expenses borne by the Government of Kenya

Items	Expenses
1. Site clearance, Demolition of existing facilities and trees	2,400,000 KShs
2. Relocation of existing function of Animal house	1,000,000 KShs
3. Landscape work	2,000,000 KShs
4. Infrastructure connection work	13,400,000 KShs
5. Furniture and equipment	3,000,000 KShs
Total	21,800,000 KShs

Scope of Kenyan Works is shown in Appendices.

2-4 Project Operation Plan

(1) Personnel Plan

The table below summarises the personnel plan of the project after commissioning.

Table 2-37 Personnel Plan

(Blood Screening Kit Production Unit including Animal House)

Job Title	Number of Staff			Annual Salary (KShs/y)		
	Present	After Completion	±	Salary /Person	Total	Increase
Manager	2	2	±0	1,037,000	2,074,000	0
Assist. Manager	1	2	+1	974,000	1,948,000	+974,000
Researcher	0	0	±0	974,000	0	0
Technologist	2	2	±0	895,000	1,790,000	0
Technician	7	7	±0	504,000	3,528,000	+1,008,000
Staff	2	4	+2	504,000	2,016,000	+2,016,000
Total	14	17	+3		11,356,000	+1,982,000

(Training Unit)

Job Title	Number of Staff			Annual Salary (KShs/y)		
	Present	After Completion	±	Salary /Person	Total	Increase
Manager	1	1	0	1,037,000	1,037,000	0
Assist. Manager	2	2	0	974,000	1,948,000	0
Researcher	0	2	+2	974,000	1,948,000	+1,948,000
Technologist	0	6	+6	895,000	5,370,000	+5,370,000
Technician	0	6	+6	504,000	3,024,000	+3,024,000
Staff	2	5	+3	504,000	2,520,000	+1,512,000
Total	5	22	+17		15,847,000	+11,854,000

It may be noted that 17 people and 22 people will be needed for production unit and training unit, respectively, after commissioning.

The net increases in manpower and in personnel cost for the production unit will be 3 people and about 2 million KShs (about 3 million yen). The persons engaged in the production unit will be assigned exclusively to it. The net increases in manpower and in personnel cost for the training unit will be 17 people and about 12 million KShs (about 20 million yen). After completion of the Project, the total personnel cost will be about 14 million KShs (about 23 million yen)

The personnel plan for the production unit, for which exclusive assignment is planned, is shown in the table below. As may be noted from this table, some of the jobs shown in the

table do not necessarily require full-time exclusive assignment, or those who are assigned to such jobs can do other jobs part-time.

Table 2-38 Personnel Plan for Production and Sales Promotion for Screening Kit

Technical Staff	Number	Full/Part time (%)
(PA Kit)		
Preparation. of HIV antigens	1	100
Prep. of Sensitised Gelatine particles	1	
Prep. of other kit reagents	1	
Assemble	1	
Technician (Animal maintenance)	2	75
Quality control	2	50
(HEPCELL Kit)		
Preparation. of HBs antigens	1	100
Prep. of anti-HBs antibody	1	
Prep. of Affinity Gel	1	
Prep. of fixed red blood cells	1	
Prep. of Sensitised red blood cells	1	100
Prep. of other kit reagents	1	100
Assemble	1	100
Administrative Staff		
Manager	2	20
Assist. Manager	2	100
Person in charge for Procurement	1	100
Person in charge for Sales	2	100
Person in charge for Scientific Affairs	1	20
Total	17	

- Assist. Manager is also working as Production staff.
- Number (persons) in shadow are working for both production lines for PA/HEPCELL Kit.

(2) Maintenance and Management Plan

1) Present Status of Maintenance and Management

Presently, the Engineering and Maintenance Division in the General Affairs Department of KEMRI is in charge of maintenance of facilities and equipment. To the Technology and Maintenance Management Section are assigned 2 group leaders; namely, the Facility Maintenance Group and the Machine/Equipment Maintenance Group. The Facility Maintenance Group maintains buildings, landscape, water supply and wastewater facilities. On the other hand, the Machine/Equipment Maintenance Group maintains electric facilities, air-conditioning and refrigerating facilities, and research and medical equipment.

The Facility Maintenance Groups has 4 carpenters, 2 masons, 2 plumbers, 3 metal workers, 1 painter under the group leader, or the group has a total of 13 persons. The Machine/Equipment Maintenance Group has 1 mechanic, 5 persons for electronic and medical equipment, 3 electricians under the group leader, or the group has a total of 10 persons. Thus, with 24 persons (including manager), the Technology and Maintenance Management Section maintains the entire KEMRI, including scheduled maintenance and unscheduled repairs.

The workshop belonging to the Technology and Maintenance Management Section is situated in the block of the research building of KEMRI. In the workshop are installed lathes, screw cutting lathes, welders, cutting machines, etc. and such works as duct processing, piping and equipment repair are done rather smoothly. However, generators, air-conditioners, and medical and research equipment are apparently not maintained as required because of difficulty with timely procurement of materials and spareparts for maintenance.

2) Maintenance and Management Plan

a) Facility

To proceed smoothly with the maintenance of the planned project facility, the production unit including the animal house in particular, it is essential that the indoor environment be maintained clean by an air conditioning system. To maintain a portion of the facility clean, a system is required whereby that particular portion is maintained at a pressure higher than the surroundings to prevent inflow of air, and the air supplied to that portion is rid of fine particles by filtration. The filter becomes clogged after being used for a certain period and,

therefore, the filter has to be periodically cleaned or replaced. For this purpose, the conditions of the air conditioning system has to be understood at all times.

No doubt KEMRI well understands the importance of proper maintenance mentioned above. However, the skill to maintain such machines and equipment is different from that for the existing facilities. Therefore, in the maintenance of the production unit including the animal house in particular, it is desirable that a right person be named responsible for maintenance and management of air-conditioning machines and refrigerators.

Regarding such strengthening of maintenance force, the reinforcement should be given training on the method of maintenance, even before commissioning of the project. The responsible person should be named at an early stage.

b) Equipment

The production unit should maintain a stable operation while producing the blood screening kits of assured quality as saleable product. Suspension of operation resulting from equipment failures should be prevented by all means. Therefore, routine inspections and periodic maintenance are important. Under such a circumstance, it is desired that a right person be named responsible for maintenance control of equipment. In addition to daily routine inspections, he/she named responsible for this job should always get hold of the status of every piece of equipment, in order to be able to systematically and smoothly control and replenish consumables, procure and replace spareparts.

Certain pieces of equipment are relatively complicated and difficult for KEMRI to maintain, like the freeze-drying unit. Regarding those pieces of equipment of which maintenance is considered beyond the ability of KEMRI, KEMRI should preferably conclude a maintenance agreement with the local dealer in Kenya of the supplier of such a particular equipment.

(3) Operation and Maintenance Cost

1) Maintenance and Management Cost

The estimated cost for maintenance and management after completion of the Project is shown in the following tables.

Table 2-39 Maintenance and Management Cost

First year after completion (unit : KShs)

Items	Production Unit	Anima House	Training Unit	Total
① *Electricity Charge*	1,599,360	574,908	835,680	3,009,948
② Telephone Charge	191,040	17,520	491,040	699,600
③ Fuel Expenses for Generator	136,224	41,280	53,664	231,168
④ Water Charge	47,532	51,792	100,656	199,980
⑤ Butane Gas Charge	115,200	0	57,600	172,800
⑥ Building Maintenance Expenses	0	0	0	0
⑦ Air Filter Expenses	0	0	0	0
Facility Maintenance Cost (①~⑦)	2,089,356	685,500	1,538,640	4,313,496
⑧ Equipment Maintenance Cost	510,000	0	300,000	810,000
Total (①~⑧)	2,599,356	685,500	1,838,640	5,123,496

Second year and after

Items	Production Unit	Anima House	Training Unit	Total
① Electricity Charge	1,599,360	574,908	835,680	3,009,948
② Telephone Charge	191,040	17,520	491,040	699,600
③ Fuel Expenses for Generator	136,224	41,280	53,664	231,168
④ Water Charge	47,532	51,792	100,656	199,980
⑤ Butane Gas Charge	115,200	0	57,600	172,800
⑥ Building Maintenance Expenses	166,100	16,600	204,200	386,900
⑦ Air Filter Expenses	187,000	488,000	0	675,000
Facility Maintenance Cost (①~⑦)	2,442,456	1,190,100	1,742,840	5,375,396
⑧ Equipment Maintenance Cost	1,570,000	176,500	300,000	2,046,500
Total (①~⑧)	4,012,456	1,366,600	2,042,840	7,421,896

① Electricity Charge ····· 3,009,948 KShs/year

In accordance with the size of the Grant Aid project, the contract load capacity is estimated as follows. Average electricity usage is estimated at approximately 60% of the contract load.

Table 2-40 Estimated Load Capacities

	Contract Load (kW)	Usage Load (kW)
Production Unite	160	100
Animal House	50	30
Training Unit	90	50
Total	300	180

Basic Charge 300 KShs/kW

Usage Charge 10.66 KShs/kWh

Production Unit

Basic Charge 300KShs/kW×160kW/month×12months = 576,000 KShs/year

Usage Charge 10.66KShs/kWh×100kW×8h×240days×0.5 = 1,023,360 KShs/year

Sub-total 1,599,360 KShs/year

Animal House

Basic Charge 300KShs/kW×30kW/month×12months = 108,000 KShs/year

Usage Charge 10.66KShs/kWh×20kW×10h×365days×0.6 = 466,908 KShs/year

Sub-total 574,908 KShs/year

Training Unit

Basic Charge 300KShs/kW×90kW/month×12months = 324,000 KShs/year

Usage Charge 10.66KShs/kWh×50kW×8h×240days×0.5 = 511,680 KShs/year

Sub-total 835,680 KShs/year

Total 3,009,948 KShs/year

② Telephone Charge ····· 699,600KShs/year

Telephone Charge is estimated in accordance with basic call charges as follows.

Domestic Call Charge	Nairobi	1.6 KShs/min
	Other cities	70 KShs/min
International Call Charge		180 KShs/min

Production Unit

Nairobi 1.6KShs/min × 3min/call × 20calls/day × 240days = 23,040 KShs/year

Outside Nairobi 70KShs/min × 5min/call × 2calls/day × 240days = 168,000 KShs/year

Sub-total 191,040 KShs/year

Animal House

Nairobi 1.6KShs/min × 3min/call × 10calls/day × 365days = 17,520 KShs/year

Sub-total 17,520 KShs/year

Training Unit

Nairobi 1.6KShs/min × 3min/call × 20calls/days × 240days=23,040 KShs/year

Other Nairobi 70KShs/min × 5min/call × 3call/day × 240days=252,000 KShs/year

International 180KShs/min × 5min/call × 1call/day × 240days=216,000 KShs/year

Sub-total 491,040 KShs/year

Total 699,600 KShs/year

③ Fuel Expenses for Generator ····· 231,168 KShs/year

In KEMRI, there are 4 times/month of Power offs in 2001. It is assumed that Power offs is 2 hours/time, and 96 hours/year. Diesel oil is to be used as the fuel for the emergency generator. The consumption of fuel is estimated 56 litters/hour with 200kVA generator engine.

Unit price of diesel oil 43 KShs/litter

Production Unit 43KShs/litter × 33litters × 8h × 12months = 136,224 KShs/year

Animal House 43KShs/litter × 10litters × 8h × 12months = 41,280 KShs/year

Training Unit 43KShs/litter × 13litters × 8h × 12months = 53,664 KShs/year

Total 231,168 KShs/year

④ Water Charge ····· 199,980 KShs/year

Water consumption is estimated as follows.

Table 2-41 Estimater Water Charge

	Water Consumption/day (m^3/day)	Annual Consumption 20days × 12months (m^3/year)
Production Unit	8.5	2,040
Animal House	6.5	* 2,340
Training Unit	18	4,320
Total	36	8,640

* 30days/month for Animal House

Water Usage Charge 19.8 KShs/m^3

Water Basic Charge 70 KShs/month/m^3

Production Unit

Usage Charge 19.8KShs/m^3×2,040 m^3/year = 40,392 KShs/year

Basic Charge 70ksks/month×8.5m^3×12months/year = 7,140 KShs/year

Sub-total 47,532 KShs/year

Animal House

Usage Charge 19.8KShs/m^3×2,340m^3/year = 46,332 KShs/year

Basic Charge 70ksks/month×6.5m^3×12months/year= 5,460 KShs/year

Sub-total 51,792 KShs/year

Training Unit

Usage Charge 19.8KShs/m^3×4,320m^3/year= 85,536 KShs/year

Basic Charge 70ksks/month×18m^3×12months/year= 15,120 KShs/year

Sub-total 100,656 KShs/year

Total 199,980 KShs/year

⑤ Butane Gas Charge ····· 172,800 KShs/year

Butane Gas will be used in Laboratory and Production Unit. The gas consumption will be estimated as follows.

Table 2-42 Estimated Bitane Gas Consumption

	Purpose	Daily Consumption (kg/day)	Annual Consumption 20day×12months (kg/year)
Production Unit	Laboratory & Production	6	1,440
Training Unit	Training Laboratory	3	720
Total		9	2,160

Butane gas unit price 80 KShs/kg

Production Unit 80KShs/kg×1,440KShs/year = 115,200 KShs/year

Training Unit 80KShs/kg×720 KShs/year = 57,600 KShs/year

Total 172,800 KShs/year

⑥ Building Maintenance Expenses ····· 386,900 KShs/year

Interior and exterior finishing materials with easy maintenance and management were chosen for the planned Project. It is assumed that building maintenance expenses, including the expenses for interior/exterior finish and repair work of electrical equipment, plumbing equipment and air-conditioners, will be 100KShs/m^2/year. This is about 1/2 to 1/3 of maintenance cost in Japan.

Production Unit	1,661m^2 × 100 KShs/m^2/year =	166,100 KShs/year
Animal House	166m^2 × 100 KShs/m^2/year =	16,600 KShs/year
Training Unit	2,042m^2 × 100 KShs/m^2/year =	204,200 KShs/year
	Total	386,900 KShs/year

⑦ Air Filter Expenses ····· 675,000 KShs/year

High and medium performance air filter will be used in the Production Unit and Animal House. Activated carbon air filter is also used in Animal House for deodorization. Pre air filter will be installed in each air conditioner.

Air filter will be replaced as follows.

Pre air filter	2 times/year
Medium performance air filter	1 times/year (10,500 KShs/filter)
High performance air filter	0.5 times/year (14,500 KShs/ filter)
Activated carbon air filter	1 times/year (190,000 KShs/filter)

Since Pre air filter is reusable type, replacement will not be necessary.

Production Unit

Medium performance air filter	4filters/year × 10,500 KShs/filter =	42,000 KShs/year
High performance air filter	10filters/year × 14,500 KShs/filter =	145,000 KShs/year
	Sub-total	187,000 KShs/year

Animal House

Medium performance air filter	2filters/year × 10,500 KShs/filter =	21,000 KShs/year
High performance air filter	6filters/year × 14,500 KShs/filter =	87,000 KShs/year
Activated carbon air filter	2filters/year × 190,000 KShs/filter =	380,000 KShs/year
	Sub-total	488,000 KShs/year
	Total	675,000 KShs/year

⑧ Equipment Maintenance Cost ····· 2,046,500 KShs/year

First year after completion 810,000 KShs/year

Equipment for Production Unit

The equipment adjustment cost to be used properly, and the replacement cost of cartridge (remove chlorine from city water) will be necessary. The cartridge cost of the pure water manufacture device and the half price of whole consumables are necessary for the maintenance cost in the first year.

Second year and after

Water distiller/deionizer device		
(adjustment, spareparts replacement)	1 time/year × 100,000KShs =	100,000 KShs/year
(Cartridge)	9 time/year × 30,000KShs =	270,000 KShs/year
Lyophilizer device		
(adjustment, spareparts replacement)	1 time/year × 200,000KShs =	200,000 KShs/year
Ultra Centrifuge device		
(check, drive part replacement)	1 time/year x 400,000KShs =	400,000 KShs/year
Other material replacement (*1)	1 time/year x 120,000KShs =	120,000 KShs/year
Consumables (*2)	12 time/year x 40,000KShs =	480,000 KShs/year
	Total	1,570,000 KShs/year

First year after completion

Water distiller/deionizer device		
(Cartridge)	91 time/year x 10,000KShs =	270,000 KShs/year
Consumables (*2)	12 time/year x 20,000KShs =	240,000 KShs/year
	Total	510,000 KShs/year

*1. The following costs will be necessary from the second year.
The compressor for the freezer, HEPA filter for the safety cabinet, the optical photometer and the electronic balance calibration
*2. The cleaning consumables (ex. Paper towel) is included.

Equipment for Animal House

A heater and door packing for steam sterilised device will be replaced once in two years.

High pressure steam sterilised device		
(spareparts replacement)	0.5time/years x 353,000KShs =	176,500 KShs/year

Equipment for Training Unit

The following consumable items would periodically be necessary.

Valve (microscope), the filter (clean bench) and so on		= 200,000 KShs/year
Cover glass, the slide glass and so on		= 100,000 KShs/year
	Total	300,000 KShs/year

(4) Financial Conditions for Maintenance and Management Cost

The maintenance and management cost of the Grant Aid project after commissioning is estimated at about 7.4 million KShs every year, of which facility maintenance and equipment maintenance are estimated at 5.4 million KShs and 2 million KShs, respectively.

The fiscal year of Kenya begins on July 1 and ends on June 30 of the following year.

The national budget on expenditure base declined from 1997 to 1999 as shown in the table below. In 2000, the national budget sharply increased over the preceding year, by about 30 percent, to about 270,000 million KShs (about 500,000 million yen). The budget for MOH shows a similar trend to that of the national budget. It was 13,500 million KShs (about 25,000 million yen), representing an increase of 35 percent over the previous year's budget. The KEMRI's budget shows a steady increase over the years irrespective of ups and downs of the national budget or MOH's budget. KEMRI's budget for 2000 was 512 million KShs (about 900 million yen), representing about 4 percent of the MOH's budget. KEMRI is an independent legal person under the jurisdiction of MOH; therefore, it is in a position to secure funds, including assistance, for itself, without regard to MOH's budget.

Table 2-43 MOH's and KEMRI's Budget

(Unit: Million KShs)

Expenditure base	1997/1998	1998/1999	1999/2000	2000/2001
National budget	291,064	222,650	205,795	270,038
MOH's budget	12,883	10,449	10,054	13,500
(MOH' budget/National budget) × 100, %	4.43	4.69	4.89	5.00
KEMRI's budget	290.20	306.80	436.03	512.04
(KEMRI's budget/MOH's budget) × 100, %	2.25	2.94	4.34	3.79

(Source: KEMRI, Economic Survey 2001, Ministry of Finance and Planning)

The KEMRI's budget shows a steady increase over the past five years. The personnel expense and research expense are the two major items, the former accounting for about 50 percent and the latter about 47 percent, or the total of about 97 percent. KEMRI's budgets for the past two years (1999/2000 and 2000/2001) registered an increase of 42 percent and 17 percent over the preceding year, respectively. As indicated above KEMRI's budget for 2000/2001 is about 512 million KShs. Against this budget, the estimated maintenance and management cost (7.4 million KShs) for the project is 1.44 percent and the estimated personnel cost (14 million KShs) is 2.73 percent of the KEMRI's 2000/2001 budget (512 million KShs).

Table 2-44 Breakdown of KEMRI's Budget

(Unit: Million KShs)

Expenditure base	1997/1998	1998/1999	1999/2000	2000/2001
Personnel expense	187.40	195.40	197.00	258.60
Research expense	94.80	99.70	229.00	239.00
Facility and equipment procurement expense	4.70	7.20	6.50	10.40
Training expense	1.30	1.50	0.83	0.64
Maintenance and management cost	2.00	3.00	2.70	3.40
Total	290.20	306.80	436.03	512.04
Rate of increase, %	-	5.7	42.1	17.4

(Source: KEMRI)

The maintenance and management cost of the project account for a fraction of KEMRI's total budget as shown in the above table. With these taken into consideration, KEMRI may be considered to be able to bear the increasing cost of the project.