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# BASIC DESIGN STUDY REPORT
# ON
# THE PROJECT FOR IMPROVEMENT OF FACILITIES
# FOR
# CONTROL OF INFECTIOUS AND PARASITIC DISEASES
# AT KENYA MEDICAL RESEARCH INSTITUTE
# IN
# THE REPUBLIC OF KENYA

NOVEMBER 2003

JAPAN INTERNATIONAL COOPERATION AGENCY

NIHON SEKKEI, INC.

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## PREFACE

In response to a request from the Government of the Republic of Kenya, the Government of Japan decided to conduct a basic design study on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute and entrusted the study to the Japan International Cooperation Agency (JICA).

JICA sent to Kenya a study team from August 24th to September 9th, 2003.

The team held discussions with the officials concerned of the Government of Kenya, and conducted a field study at the study area. After the team returned to Japan, further studies were made. Then, a mission was sent to Kenya in order to discuss a draft basic design, and as this result, the present report was finalized.

I hope that this report will contribute to the promotion of the project and to the enhancement of friendly relations between our two countries.

I wish to express my sincere appreciation to the officials concerned of the Government of the Republic of Kenya for their close cooperation extended to the teams.

November 2003

Kunimitsu Yoshinaga
Vice President
Japan International Cooperation Agency

November 2003

**Letter of Transmittal**

We are pleased to submit to you the basic design study report on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute in the Republic of Kenya.

This study was conducted by Nihon Sekkei, Inc., under a contract to JICA, during the period from August, 2003 to November, 2003. In conducting the study, we have examined the feasibility and rationale of the project with due consideration to the present situation of Kenya and formulated the most appropriate basic design for the project under Japan's grant aid scheme.

Finally, we hope that this report will contribute to further promotion of the project.

Very truly yours,

Masahiro Ikawa
Project Manager

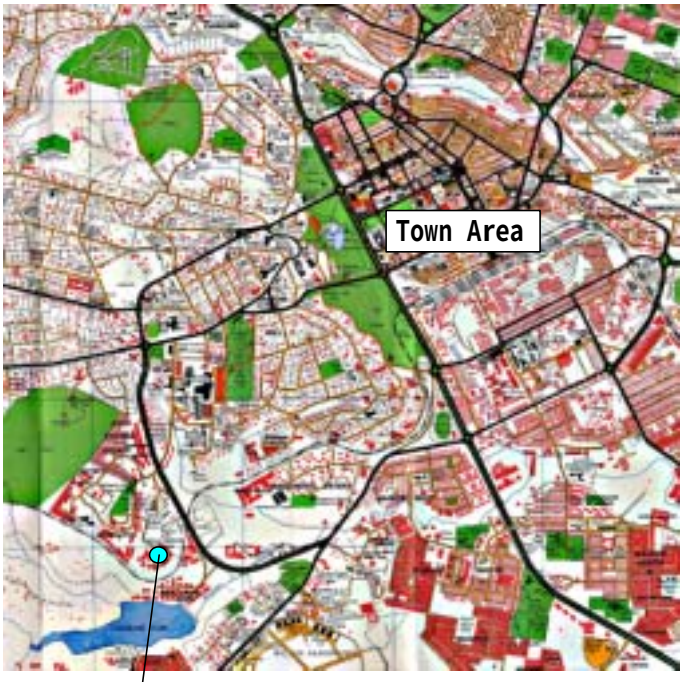
Basic Design Study Team on
the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases
at Kenya Medical Research Institute

Nihon Sekkei, Inc.

Location Map



Kenya and Neighouring Countries

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# ABBREVIATION

| | |
|---|---|
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **BS** | British Standard |
| **CDC** | Centres for Disease Control and Prevention |
| **HB** | Hepatitis B |
| **HBV** | Hepatitis B Virus |
| **HIV** | Human Immunodeficiency Virus |
| **ITROMID** | Institute of Tropical Medicine and Infectious Diseases |
| **JIS** | Japan Industrial Standard |
| **KEMRI** | Kenya Medical Research Institute |
| **KPLC** | Kenya Power and Lighting Company |
| **KMTC** | Kenya Medical Training College |
| **MOF** | Ministry of Finance |
| **MOH** | Ministry of Health |
| **NACC** | National AIDS Control Council |
| **NPHLS** | National Public Health & Laboratory Services |
| **PA** | Particle Agglutination |
| **VCT** | Voluntary Counselling and Testing |

**Summary**

The Republic of Kenya (hereinafter referred to as Kenya) is situated on the equator on the East Coast of the African Continent facing the Indian Ocean. The total area is about 580 thousand square kilometres, or about 1.5 times the area of Japan. The population is about 30 million (as of 2000). Nairobi, the capital of Kenya, where the subject project is situated has a population of about 1.8 million. Nairobi is 1,798 meters above sea level. Because of its high altitude, the annual mean temperature is about 18°C, though it is located on the equator. However, the daytime temperature can rise as high as 30°C, and the temperature can vary more than 20°C between the daytime and night. The annual precipitation is about 1,000mm in Nairobi. There are two rainy seasons in Kenya, the major one from March to May and the other minor one from October to December. During the rainy season, rail falls mostly in the morning and at night, only seldom throughout the day. Consequently, the humidity does not exceed 70 percent and a relatively dry climate prevails.

Kenya is relatively industrialised in Africa, though the economy depends mainly on agriculture. The agricultural sector employs about 80 percent of the population, accounting for 24 percent of GDP, and 60 percent of the export value. Kenya is world's third largest exporter of black tea. Tourism accounts for 19 percent of GDP, ranks second in foreign currency earning, next only to black tea. Kenya has been experiencing stagnation in its socioeconomic development since the 1990s. As a result, more people now fall under the poverty stratum and the country is suffering from serious unemployment and inflation problems. There are a number of factors that may explain the downturn of Kenya's economy, including the poor harvest and export of crops caused by abnormal climate, stagnation of economic activities caused by such factors as deteriorating security, suspension of finances by the International Monetary Fund and the World Bank, and decline of direct investments from abroad. In 2000, Kenya registered a negative economic growth, -0.3 percent, for the first time since independence, as a result of a severe drought etc. Kenya's GDP per capita as of 1999 was US Dollars 360.

In "9th National Development Plan" (2002 – 2008), the government of Kenya attaches particular importance to prevention of HIV infection, showing particular concern to the adverse effects of AIDS on healthcare and Kenya's socioeconomic activities and the problem of occurrence of AIDS orphans. Also, the diseases caused by Hepatitis type B Virus (HBV) are in serious condition and the infection by blood transfusion has been increasing. Under such a condition, it is regarded as urgent to prevent the infection by screening of blood for transfusion. On the other hand, the government of Kenya established "Malaria Office" in MOH for the

purpose of reduction of parasitic diseases and aims at reducing the infection rate and death rate of malaria as of 1999 by 30 % respectively in 2004. The government of Japan proposed to the Birmingham Summit in 1998 to establish centers for “human resource development” and “network construction” in Asia and Africa for intensifying international movements for controlling parasitic diseases. Kenya Medical Research Institute (KEMRI) has been named as one of the centres in Africa.

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. 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. 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 in Kenya.

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

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 technical cooperation project. 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. Similarly, as control for infectious and parasitic diseases, research in these fields and development of researchers have been promoted at KEMRI, also by the Japanese Technical Cooperation for the Research and Control of Infectious Diseases Project. 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. Against such a background, construction and extension of the facilities to smoothly carry out the above-mentioned manufacturing plan and training plan (blood screening kit production unit, training unit, etc.) are urgently needed in Kenya.

For the purpose of achieving the targets set forth by the preceding plan, the government of Kenya has formulated “The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute”. The project aims to intensify controls on infectious diseases and parasitic diseases in Kenya and neighbouring countries by strengthening the facilities in the premises of KEMRI for infectious disease and parasitic disease control, while maintaining collaboration with the technical cooperation project of Japan. However, the government of Kenya found it difficult to execute the project of its own because of the financial and other difficulties, and accordingly filed a request with the government of Japan for grant aid cooperation for implementation of this project.

In response to it, the first Basic Design Study was conducted from January to December of 2002. This basic design study is intended to establish a full-fledged manufacturing facility of blood test kits and training facilities for parasitic and infectious diseases, linked with technical cooperation project which is in operation. The study team has confirmed the necessity of the improvement of facilities for control of infectious and parasitic diseases at Kenya Medical Research Institute. The study has reached a conclusion that, to realise it, it is necessary to construct or rehabilitate the blood screening kit production unit, attached animal unit, training unit in the premises of KEMRI in Nairobi, and to procure and install the necessary equipment. In the basic design study, the demands for blood test kits for HIV of 250,000 tests/year and those for hepatitis B virus of 400,000 tests/year were estimated, and the manufacturing facility for these capacities was designed.

However, after the study was completed, the government of Kenya decided the policy of using the test kit which can test both HIV-1 and HIV-2 in response to "Recommendation Relating to Using of Test Kits for HIV (Using of test kits which can test both HIV-1 and HIV-2)" by WHO. KEMRI HIV-PA kits which are manufactured in this project can test HIV-1 but can not test HIV-2. Therefore the project was obliged to amend the policy of production, from "manufacturing and sales" to "manufacturing for research," and to review demand estimated and others.
Under such a circumstance, a study team was dispatched again in May 2003 to Kenya to confirm the policy direction for this project. As a result, the concerned parties agreed on the amendment of the manufacturing policy, from " manufacturing and sales" to " manufacturing for research" and, along with it, the necessity of reduction of maintenance and management costs due to the review of the floor planning and others of manufacturing facility of blood test kits and air-conditioning system.

So, the government of Japan decided to conduct the Basic Design Study, and Japan International Cooperation Agency (JICA) dispatched the basic design study team in August of 2003. After the consultation with the concerned parties of Kenya, check of the related facilities, collection of

necessary data, investigation of planned construction site, the confirmation of change of demand estimated, the study team analyzed them in Japan and decided to conduct the reduction of production which resulted from the change to "manufacturing for research" of KEMRI HIV-1 PA kit (decrease from 250,000 tests / year to 50,000 tests / year), the reduction of the unit size due to the review of floor planning of manufacturing facility of blood test kits (including animal unit), and the change of air-conditioning system of the facility. After the basic design synoptic document was explained on site in October of 2003, the study team compiled the report on the Basic Design Study.

The following is the outline of “The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute”.

Responsible Organisation: Ministry of Health (MOH)
Implementation Organisation: Kenya Medical Research Institute (KEMRI)

Project Schedule: After E/N, the project schedule is estimated 18 months before the completion of the Project. The estimated terms necessary are 4 months for detailed design stage, 3 months for tender stage and 11 months for construction stage.

Construction Site: Premises of KEMRI, Nairobi

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| Structure: | Production Unit (New construction) | Reinforced concrete structure with 2 stories |
| | Animal Unit (Renovation) | Concrete block structure with 1 story |
| | Training Unit (New construction) | Reinforced concrete structure with 2 stories |

| | | |
|---|---|---|
| Floor Area: | Production Unit | 1,479.9 m² (Site Area : 3,288 m²) |
| | Animal Unit | 246.6 m² (Site Area : 612 m²) |
| | Training Unit | 2,083.3 m² (Site Area : 3,457 m²) |
| | Total Floor Area | 3,809.8 m² |

Content of the Project

| | | |
|---|---|---|
| Construction of Building | Production Unit<br>First floor： General Manager room, Marketing Manager room, Secretary room, Office, Staff room, Changing room, Pantry, Mechanical room, and etc.<br>Ground floor： HEPCELL Ⅱ Preparation room, HIV/PA Preparation room, HEPCELL + HIV/PA Manufacturing room, Material room, Dispense room, Washing room, Quality control room, Packing room, Labelling room, Clean corridor, Store, WC, Corridor, and etc.<br>(*including Mechanical House and Water Supply Facility)<br>Animal Unit<br>Ground floor： Guinea pig room, Rabbit room, Inoculation room, Quarantine room, and etc.<br>Training Unit<br>First floor： Lecture room, Data processing room, Network room, Project Supervision, Instructor room, Meeting room, Specialist room, Lounge, and etc.<br>Ground floor： Parasitic Lab., Infectious Lab., Preparation room, Culture room, Office, Manager room, Secretary room, Entrance hall, Library, and etc. | |
| 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.) |

PA: Particle Agglutination Hepcell: "KEMRI HEPCELL" Productoin Name

The management and maintenance cost after completion of the Grant Aid project is estimated about 6.2 million Kenyan Shilling (hereinafter referred to as KShs) per year. It is equivalent to approximately 84% (approximately 76% in only maintenance cost of facility) of annual management and maintenance cost which was estimated in the first Basic Design Study. Of this amount, the management and maintenance cost for the facilities is 4.2 million KShs, and for the equipment is 2 million KShs. This total cost for the management and maintenance is equivalent to 0.86 percent of the total annual budget of KEMRI (717 million KShs in fiscal 2002/2003). The increased manpower after completion of this project is 20 persons. The personnel cost for these people is estimated about 14 million KShs a year. This amount is equivalent to 1.95 percent of the KEMRI's annual budget as well. Since both KEMRI and MOH assure to secure such necessary budget and manpower, the project will not meet difficulty in management and maintenance in the future.

Implementation of this project (including the Japanese and Kenyan scope of works) is expected to bring about the following direct merits.

① Increase of quantity of production and number of check of blood screening kit

In this project, the manufacturing facility of blood screening kits for HIV and HBV will be constructed, which develops the manufacturing system of blood screening kit which is

low-priced and whose quality is guaranteed, supplies blood screening kit stably, and increases the number of check of HIV and HBV.

② Improvement of screening rate of blood for transfusion

It is said that the infection rate of HIV is approximately 13% and that of HBV is approximately 4% in Kenya. The low-priced blood screening kit and its stable supply would improve the screening rate of blood for transfusion. And the transfusion of blood which is tainted with HIV and HBV decreases and the infection can be prevented furthermore.

③ Increase of personnel who gets the training of infectious diseases and parasitic diseases

In this project, the training facility for infectious and parasitic diseases will be constructed, which will increase the number of personnel at home and from abroad who gets the training, and can further promote the countermeasures of parasite and infectious diseases not only in Kenya but also in neighbouring nations.

KEMRI has a function to provide consulting services on the blood test. KEMRI is able to promptly reply to questions, etc. of KEMRI HIV-1 PA kit users.

④ Implementation of smooth technology transfer

In the two technical cooperation projects which are in operation, technical aid will be conducted in manufacturing technology of blood screening kit and training activities on infectious diseases and parasitic diseases. And the use of the facilities which will be constructed in the project will make the activities smoother.

Through the training activities which will be held at the training facility, the technology of use of KEMRI Kit can be transferred to laboratory engineers and others of hospitals at home.

Implementation of this project will intensify control measures for infectious and parasitic diseases not only for Kenya, with a population of about 30 million, but also for neighbouring countries, with a population amounting to about 100 million. In this context, implementation of this project under Japan’s grant aid programme is worthwhile, and the adequacy and necessity of this project are justifiable with a high decree of certainty.

It is essential that the Kenyan scope of works has been timely done before cooperation project is commenced. What is more important, such works as demolishing and removal of the existing facilities in the construction site, land grading, (including temporary relocation of the existing

animal unit) must have been completed before the works of the Japanese side can start. In order for the project to be smoothly and effectively managed, it is recommended that the following improvements or arrangements be made.

1) Presently in Kenya, blood screening kits are manufactured on a laboratory scale. Management of the new blood screening kit production unit to be installed by this project will require process control and quality control on the basis of voluntary GMP standard. The project also requires establishment of management method for the attached animal unit and acquisition of such skills by the local staff. In these respects, technology transfer by technical cooperation project is much desired. Most importantly, KEMRI should by its own effort ensure that the human resource developed through such a technology transfer, in turn, transfers their skills to other technicians and specialists, thereby establishing a system for sustainable development of KEMRI. Through such endeavours, KEMRI would be able to effectively utilise the blood screening kit production unit, and to realise KEMRI's own technological developments.

2) On KEMRI HEPCELL II kit of blood screening kits, acquisition of national approval and blanket purchase by MOH are promised. On the other hand, on KEMRI HIV-1 PA kit, MOH and others express that they will purchase them in a lump when screening kits of HIV-1 and HIV-2 are developed in technical cooperation project and national approval is acquired. So, it is desired that screening kits of HIV-1 and HIV-2 are developed promptly in KEMRI with the technical cooperation project and the production technology is transferred.

3) The government of Japan proposed to the 1998 Birmingham Summit (G8 Summit) to intensify international movements for controlling parasitic diseases by establishing centres for human resource development and network building in Asia and Africa. Regarding this proposal, Kenya (KEMRI), Ghana and Thailand are considered as locations of such centres. KEMRI is expected to establish the network and effectively promote activities for human resource development, in close collaboration with the other centres.

4) It is important that necessary manpower be secured to maintain the facilities and equipment. This is essential to keep the facilities constructed and equipment procured by this project in good conditions, the air-conditioning facilities for production unit in particular, so that they may be used in good conditions for a long period.

5) When the equipment is procured, the maintenance and inspection manual, operation manual, circuit diagram, etc. are provided. In addition, a technical guidance by the supplier will be done. Therefore, effective use of these materials is necessary to realise good maintenance control of the equipment. It is desired to keep tracks of dates of delivery, frequency of use, repair history, etc. and record these events on a ledger (record book) for each equipment. It is also desired to formulate a spareparts purchase plan and equipment renewal plan, and to formulate long and medium-range budgets based on these plans.

6) It is desired that, after completion of the project, the annual report be prepared every year on the management and operation of the project. The preparation of the annual report will help understand the management and operation of the subject facilities, and the report will serve as a reference for planning improvements.

7) It is desired that a system for monitoring the effects of the use of blood screening kits be established in collaboration with other medical institutions. The monitoring system should facilitate collection of information that serve as indicators of the effects of kits, and studies on diseases of AIDS and HB after blood transfusions.

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# Chapter 1. Background of the Project

## CHAPTER 1. BACKGROUND OF THE PROJECT

KEMRI, the executing agency of this project, is a medical research institute established in 1979 within the Ministry of Education, Science and Technology of Kenya. KEMRI's parent organisation is believed to be the East Africa Medical Institute (Nairobi) established by UK in the 1950s for Kenya, Uganda and Tanzania. The headquarters of KEMRI was shifted in 1981 to the former East Africa Medical Institute.

Construction of the headquarters' facilities of KEMRI (research rooms, laboratories, diagnostic facilities, administrative facilities, animal experiment rooms) was completed in 1985 by Japan's grant aid programme. Concurrently with the grant aid programme, Japan's technical cooperation project, "The Research and Control of Infectious Diseases Project in Kenya," was carried out. Thereafter, four technical cooperation projects have been done since then, utilising these facilities.

The table below summarises technical cooperation projects and grant aid programmes Japan has extended to KEMRI over the past 20 years.

**Table 1-1 Outline of Japan's ODA to KEMRI**

| Technical cooperation project | | Grant aid programme | |
|---|---|---|---|
| Project period | Project name and scope | Project period | Project name and scope |
| 1979 to 1984 | First: The Research and Control of Infectious Diseases Project in Kenya<br>Diarrhoea, schistosomiasis | 1981 to 1985 | The Project for Construction of Kenya Medical Research Institute<br>Construction of the KEMRI headquarters<br>Project cost: 2,745 million yen |
| 1985 to 1990 | Second: Kenya Central Medical Institute Project<br>Virology (diarrhoea, hepatitis), parasitology (schistosomiasis), bacteriology (diarrhoea)<br>→ Test manufacture of the HB blood screening kit | | |
| 1990 to 1996 | Third: The Research and Control of Infectious Diseases Project in Kenya<br>Addition of parasitology (filariasis) to the above<br>→ Manufacture of the HB blood screening kit | | |
| 1996 to 2001 | Fourth: The Research and Control of Infectious Diseases Project in Kenya (Phase 2)<br>Acute Respiratory Infection, viral hepatitis, HIV/AIDS<br>→ Improvement of the HB blood screening kit and manufacture of the HIV blood screening kit | 1997 to 1999 | The Project for Improvement of Kenya Medical Research Institute<br>Modification of laboratories to P3 bio-hazard protection level<br>Project cost: 234 million yen |
| 2001 to 2006 | Fifth: Project for Control of Infectious and Parasitic Diseases<br>Addition of parasitic diseases (malaria, schistosomiasis, etc.) | | |

As shown in the above table, Japan's technical cooperation began in 1985 with measures against HB, and developed the blood screening kit for HB (KEMRI HEPCELL Ⅱ kit) at its third and fourth stage projects. The fourth technical cooperation from 1996 constructed physically enclosed highly bioclean laboratories called "closed laboratory at P3 level" using Japan's grant aid (1999), and developed HIV blood screening kit (KEMRI HIV-1 PA kit) through researches into HIV/AIDS. The Ministry of Health of Kenya granted a national license to KEMRI HEPCELL Ⅱ kit and committed itself to purchase the product. Subsequently, the ministry also granted a national license to the KEMRI HIV-1 PA kit.

It will be possible to lower the infection rates of HB and AIDS by commercialising these blood screening kits by implementation of third-country training not only in Kenya but East African countries. It is urgently desired for this purpose to establish a system whereby these kits are reliably supplied.

Presently, cooperation on the following three items are underway in the fifth technical cooperation project, "Project for Control of Infectious and Parasitic Diseases."

- Measures to ensure blood safety considering HIV/AIDS and viral hepatitis
- Measures for prevention and therapy of opportunistic infections associated with HIV/AIDS, and application development of traditional medicines
- Human resource development and establishment of a network as part of The Global Initiative for Parasitic Disease Control.

The project was divided into "The Japanese Technical Cooperation for the Research and Control of Infectious Diseases Project" and "The Japanese Technical Cooperation for the International Parasite Control Project" in April of 2003.

Construction of the facilities and procurement of equipment are planned by the Government of Kenya to smoothly implement these measures with Japan's technical cooperation project. The government of Kenya has filed a request with the government of Japan for grant aid cooperation because of the lack of necessary fund.

# Chapter 2. Contents of the Project

## CHAPTER 2. CONTENTS 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 technical cooperation project "The Research and Control of Infectious Diseases Project in Kenya." Thereafter, Japan has extended technical cooperation project four times. Specifically, the cooperation was aimed at prevention of hepatitis and diarrhoea. The fourth technical cooperation project (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 technical cooperation project 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 technical cooperation project, "Project for Research on Control of Infectious and Parasitic Diseases," has started, expected to last for five years. The fifth technical cooperation project 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.

In "9th National Development Plan" (2002 – 2008), the government of Kenya attaches particular importance to prevention of HIV infection, showing particular concern to the adverse effects of AIDS on healthcare and Kenya's socioeconomic activities and the problem of occurrence of AIDS orphans. Also, the diseases caused by Hepatitis type B Virus (HBV) are in serious condition and the infection by blood transfusion has been increasing. Under such a condition, it is regarded as urgent to prevent the infection by screening of blood for transfusion. On the other hand, the government of Kenya established "Malaria Office" in MOH for the purpose of reduction of parasitic diseases and aims at reducing the infection rate and death rate of malaria as of 1999 by 30 % respectively in 2004. The government of Japan proposed to the Birmingham Summit in 1998 to establish centers for "human resource development" and "network construction" in Asia and Africa for intensifying international movements for controlling parasitic diseases. Kenya Medical Research Institute (KEMRI) has been named as one of the centres in Africa.

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. 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. 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 in Kenya.

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

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 technical cooperation project. 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. Similarly, as control for infectious and parasitic diseases, research in these fields and development of researchers have been promoted at KEMRI, also by the Japanese Technical Cooperation for the Research and Control of Infectious Diseases Project. 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. Against such a background, construction and extension of the facilities to smoothly carry out the above-mentioned manufacturing plan and training plan (blood screening kit production unit, training unit, etc.) are urgently needed in Kenya.

For the purpose of achieving the targets set forth by the preceding plan, the government of Kenya has formulated "The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute". The project aims to intensify controls on infectious diseases and parasitic diseases in Kenya and neighbouring countries by strengthening the facilities in the premises of KEMRI for infectious disease and parasitic disease control, while maintaining collaboration with the technical cooperation project of Japan. However, the government of Kenya found it difficult to execute the project of its own because

of the financial and other difficulties, and accordingly filed a request with the government of Japan for grant aid cooperation for implementation of this project.

In response to it, the first Basic Design Study was conducted from January to December of 2002. This basic design study is intended to establish a full-fledged manufacturing facility of blood test kits and training facilities for parasitic and infectious diseases, linked with technical cooperation project which is in operation. The study team has confirmed the necessity of the improvement of facilities for control of infectious and parasitic diseases at Kenya Medical Research Institute. The study has reached a conclusion that, to realise it, it is necessary to construct or rehabilitate the blood screening kit production unit, attached animal unit, training unit in the premises of KEMRI in Nairobi, and to procure and install the necessary equipment. In the basic design study, the demands for blood test kits for HIV of 250,000 tests/year and those for hepatitis B virus of 400,000 tests/year were estimated, and the manufacturing facility for these capacities was designed.

However, after the study was completed, the government of Kenya decided the policy of using the test kit which can test both HIV-1 and HIV-2 in response to "Recommendation Relating to Using of Test Kits for HIV (Using of test kits which can test both HIV-1 and HIV-2)" by WHO. KEMRI HIV-PA kits which are manufactured in this project can test HIV-1 but can not test HIV-2. Therefore the project was obliged to amend the policy of production, from "manufacturing and sales" to "manufacturing for research," and to review demand estimated and others.
Under such a circumstance, a study team was dispatched again in May 2003 to Kenya to confirm the policy direction for this project. As a result, the concerned parties agreed on the amendment of the manufacturing policy, from " manufacturing and sales" to " manufacturing for research" and, along with it, the necessity of reduction of maintenance and management costs due to the review of the floor planning and others of manufacturing facility of blood test kits and air-conditioning system.

So, the government of Japan decided to conduct the Basic Design Study, and Japan International Cooperation Agency (JICA) dispatched the basic design study team in August of 2003. After the consultation with the concerned parties of Kenya, check of the related facilities, collection of necessary data, investigation of planned construction site, the confirmation of change of demand estimated, the study team analyzed them in Japan and decided to conduct the reduction of production which resulted from the change to "manufacturing for research" of KEMRI HIV-1 PA kit (decrease from 250,000 tests / year to 50,000 tests / year), the reduction of the unit size due to the review of floor planning of manufacturing facility of blood test kits (including animal

unit), and the change of air-conditioning system of the facility. After the basic design synoptic document was explained on site in October of 2003, the study team compiled the report on the Basic Design Study.

The purposes of the field survey for the basic design (final) done from August 24 to September 9, 2003, were to: (1) finalize the demand forecasts of both blood test kits, while considering the results of the basic design study (first), and (2) conduct a design commensurate with the revised forecast demands, to develop the content and capacity of the manufacturing facility. Regarding the training facilities for which no revision was made since the first field survey, it was agreed that the cost estimation would be reviewed with the updated data.

The objectives of the project are to establish the manufacturing system of blood test kits and to improve the training functions by developing and expanding the manufacturing facility of blood test kits and the facilities for infectious and parasitic diseases in the premises of KEMRI, and in addition, to strengthen the measures to parasitic and infectious diseases in Kenya and surrounding countries, linked with technical cooperation project.

**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 (KEMRI HIV-1 PA kit) | 1,479.9 *including machine room and water supply facility | Manufacturing capacity: 50,000 tests equivalents/year |
| | Blood screening kit production division for HB (KEMRI HEPCELL Ⅱ kit) | | Manufacturing capacity: 400,000 tests/year |
| Animal Unit | Animal breeding division | 246.6 | Rabbits, guinea pigs |
| Training Unit | Lecture division | 2,083.3 | 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 | | 3,809.8 | |

## 2-2 Basic Design of the Requested Japanese Assistance

### 2-2-1 Design Policy

(1) Basic Policy

1) Presently, Japan's two technical cooperation projects "The Research and Control of Infectious Disease Project for Kenya Medical Research Institute" and "International Parasitic Disease Control Project"[*)] are underway. Therefore, 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 technical cooperation project for KEMRI, "Project for Control of Infectious and Parasitic Diseases".

2) The process of developing the basic design considers the maintenance and 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, in addition to lowering the maintenance and management cost of the facilities and equipment.

3) The basic policy of manufacturing facility of blood screening kit (hardware aspect) is to make a plan in which the quality level suited to the future mass production and mass sale and the reduction of maintenance cost are estimated.

4) 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., including (CDC facilities completed in 2003 with the assistance of the United States) and other future plans (ITROMID, etc. of the master's courses of the Jomo Kenyatta University).

5) The design of facilities will give sufficient considerations to security of the inside and outside of the planned buildings, in view of the security situation in Nairobi and the security measures adopted in the facilities recently installed in the premises of KEMRI.

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*) The technical cooperation project "The Project for Research and Control of Infectious and Parasitic Diseases" was agreed by the R/D of April 12, 2001 and was initiated on May 1, 2001. However, this project was divided into the two projects on April 1, 2003 mentioned above.

6) The technology transfer on the management and operation of the blood screening kit manufacturing facilities (preparation of manuals for the manufacturing processes and quality control) will be done while confirming actual operations of the processes after commissioning of the facilities. 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 this cooperation project. Nevertheless, the technology transfer to the management and operation 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.

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 and Manufacturing Plan

① KEMRI HIV-1 PA kit

Demand Forecast

The following table shows the forecast annual demand for the blood screening kits for HIV.

**Table 2-2 Forecast Annual Demand for Blood Screening Kit for HIV**

| Purpose of screening | Number of tests |
|---|---|
| Blood transfusion | 300,000 |
| VCT | 200,000 |
| Diagnosis | 3,000,000 |
| Total | 3,500,000 |

Information from NPHLS (Letter to KEMRI on 25th June, 2003).

Of the total, 500,000 kits for blood transfusion and VCT contribute to the KEMRI HIV-1 PA kit demand. The table below shows the annual consumption of the HIV screening kits by the Ministry of Health of Kenya.

**Table 2-3 Annual Consumption of HIV Screening Tests by the Ministry of Health**

| Screening kits | Number of tests | Purpose of use |
|---|---|---|
| Determine HIV 1 and 2 (abbot) | 1,000,000 | VCT |
| Uni-Gold HIV 1 and 2 | 1,000,000 | VCT |
| Enzygnost (Behring) | 100,000 | Diagnosis/confirmation test |
| Vironostika HIV Uni-form IIAg/Ab | 200,000 | Blood transfusion |
| Total | 2,300,000 | |

Presently, 43 kinds of test kits are allowed for marketing in Kenya. The four kits shown above dominate the Kenyan market.

The following kits for 300,000 tests are used by NPHLS for blood transfusion and confirmation tests.

**Table 2-4 Test Kits Used for NPHS**

| Test kits | Number of tests |
|---|---|
| Vironostika HIV Uni-Form ⅡAg/Ab | 200,000 |
| Enzygnost (Behring) | 100,000 |
| Total | 300,000 |

The KEMRI HIV-1 PA kit developed by KEMRI is capable of detecting HIV-1 but not HIV-2. WHO, however, recommends that test kits capable of detecting both HIV-1 and HIV-2 be used. Therefore, this KEMRI HIV-1 PA kit is used only for research purposes. The annual demand for the KEMRI HIV-1 PA kit for research purpose is equivalent for 50,000 tests as shown in the table below.

**Table 2-5 Forecast Annual Demand for the KEMRI HIV-1 PA kit for KEMRI's Research Purpose**

| Purpose | Number of kits (200 tests/kit) |
|---|---|
| Third country training | 20 |
| Practical training of medical technicians of Kenya | 79 |
| Provision of kits to hospitals, practical training | 102 |
| Quality control and research at KEMRI | 14 |
| Total | 215<br>(47,300 tests) |

A report by KEMRI (Production forecast for the KEMRI HIV-1 PA kit)

Future Plan

KEMRI is now in the process of developing a test kit capable of detecting both HIV-1 and HIV-2 with the assistance of Japan's technical cooperation project. NPHLS has announced an intention of procuring 200,000 kits per year of the PA test kit capable of detecting both HIV-1 and HIV-2 to replace the test kit presently procured with World Bank's loan assistance, upon approval by the government of Kenya.

From the above, the annual demand for the KEMRI HIV-1 PA kit capable of detecting both HIV-1 and HIV-2 may be forecast as shown in the table below.

**Table 2-6 Forecast Annual Demand for the KEMRI HIV-1 PA kit Capable of Detecting Both HIV-1 and HIV-2**

| Purpose of the use | Number of tests |
|---|---|
| Uses by the government-related organizations | 200,000 |
| Training of inspectors, quality control and research | 47,300 |
| Total | 247,300 |

The screening kits presently used in Kenya are almost all imported products provided by assistance. In order for the government of Kenya to establish an independent and sustainable system of diagnosis and test, Kenya needs domestic production of a KEMRI HIV-1 PA kit having the following advantages.

- The KEMRI HIV-1 PA kit has been given the national license by the Ministry of Health for manufacture and marketing
- The product is domestically produced and not expensive. Hence, it allows the government to establish a sustainable system of supply in the future.
- The kit is easy to use and does not require a power source for testing. In addition, the kit is totally self-contained without requiring any other test equipment.

And the merits of blood screening kit of KEMRI are as follows:

- Technology transfer is being done to medical technicians, etc. of domestic hospitals on the use of the kit through training at KEMRI.
- KEMRI has a function to provide consulting services on the blood test. KEMRI is able to promptly reply to questions, etc. of KEMRI HIV-1 PA kit uses.

Planned number of production

The initial production is set at 50,000 tests equivalent, considering the forecast demand for the KEMRI HIV-1 PA kit in Kenya, and that the kit now used only research purpose is expected to be much demanded in future. The capacity of the facility will include a provision for expansion to allow addition of a modicum of facilities to meet possible increase in future production by increasing operation frequencies.

② KEMRI HEPCELL Ⅱ kit

Demand Forecast

The forecast annual demand for the test kit for hepatitis B virus is shown below.

**Table 2-7 Forecast Annual Demand for the Test Kit for Hepatitis B Virus**

| Purpose of test | Number of tests |
|---|---|
| Blood transfusion | 300,000 |
| Diagnosis | 600,000 |
| Maternity health checkup | 1,500,000 |
| Total | 2,400,000 |

A KEMRI's report (Justification for the market forecast for KEMRI HEPCELL and KEMRI HIV-1 PA kits)

The Ministry of Health of Kenya will demand the following amount of the test kit for hepatitis B virus every year.

**Table 2-8 Use of Test Kit for Hepatitis B Virus by the Ministry of Health**

| Purpose of test | Number of tests |
|---|---|
| Blood transfusion | 200,000 |
| Maternity health checkup | 150,000 |
| Diagnosis and quality control | 50,000 |
| Total | 400,000 |

Information from NPHLS: (Procurement of KEMRI HEPCELL Ⅱ test kits; Letter of 1st July, 2003)

KEMRI provided NPHLS with 90,000 tests equivalent of KEMRI HEPCELL Ⅱ kits (or 22% of 400,000 tests) in 2002. NPHLS purchased other test kits from the market to meet the rest of the requirement, or 78%, with a World Bank's grant aid program. However, this aid program terminated in September 2002, and no sign of the program being extended was seen during the field survey of this project conducted in 2003.

Therefore NPHLS was obliged to prepare a budget for purchasing the KEMRI HEPCELL Ⅱ kits equivalent to 400,000 tests in 2003.

Besides, KEMRI is planning to enter the market for general hospitals (market scale: 2,000,000 tests equivalent) in addition to provision to the official organizations. KEMRI sold the 10,000 KEMRI HEPCELL Ⅱ kits to general hospitals in 2002.

Comparison of market prices

The table below compares prices of various products in the Kenyan market.

**Table 2-9 Test Method and Product Prices of Various Test Kits in the Kenyan Market**

| Kit | Test method | Price (KSH) |
|---|---|---|
| **Celia-Hep B** | **Rapid** | **130** |
| CDI | Rapid | 100 |
| Nerugost | Rapid | 140 |
| Rialab | Rapid | 160 |
| **KEMRI HEPCELL II kit** | **Screening and Confirmation** | **50** |
| Eurotec | Rapid | 70 |
| ELISA | ELISA | 100 |

As may be noted from the table, KEMRI HEPCELL Ⅱ kit is the cheapest in the Kenyan market. Besides price, the following are favourable factors in the estimation of manufactured quantity.

- The product has been granted the license for manufacture and marketing by the Ministry of Health of the government of Kenya.
- KEMRI is conducting technology transfer on the method of using the kit to the medical technicians, etc. by means of training.
- KEMRI has a function to provide consulting services on the blood test, and is in a position to promptly respond to questions from the HEPCELL users.
- The product has been and will be used by NPHLS.
- The product is domestically produced and is therefore not expensive. It is possible to establish a sustainable system of supply.
- The product is easy to use, and it does not require an outside power source. The kit is self-contained and does not require any other testing apparatus.

Planned number of production

In view of the demand forecast of KEMRI HEPCELL Ⅱ kit by MOH and the competition in the market in Kenya, the annual production quantity will be set at 400,000 tests. The capacity of the facility will include a provision for expansion to allow addition of a modicum of facilities to meet possible increase in future production by increasing operation frequencies.

2) Performance of Blood Screening Kit

① KEMRI HIV-1 PA kit

The KEMRI HIV-1 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 KEMRI HIV-1 PA kit is considered to be an excellent blood screening kit.

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

[*2] Specificity： No. of HIV Negative bloods screened by KEMRI HIV-1 PA kit / No. of HIV Negative bloods screened by standard kit × 100 (%)

② KEMRI HEPCELL Ⅱ kit

The present KEMRI HEPCELL Ⅱ 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.

3) Animal Species for Blood Screening kit

The bio-materials required for production of the KEMRI HIV-1 PA kit and KEMRI HEPCELL Ⅱ kit are as follows.

**Table 2-10 Animal Species Used for Production of Kit**

[KEMRI HIV-1 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)

[KEMRI HEPCELL Ⅱ 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.

4) Production Schedule

In Japan it is generally considered appropriate to produce the product four times a year from the quality control or cost viewpoints. It would be appropriate, however, to design the facilities so that three-times-a-year operation and two-times-a-year operation respectively of the KEMRI HEPCELL Ⅱ kit facilities and of the KEMRI HIV-1 PA kit facilities can produce the design quantities of the two products, if KEMRI's past experiences, technological level and production quantities are considered perspectively.

The annual production schedule as part of the design condition is shown in the table below. This schedule contemplate producing 50 thousand tests equivalent (about 230 kits) of the KEMRI HIV-1 PA kits and 400 thousand tests equivalent (about 2,000 kits) of the KEMRI HEPCELL Ⅱ kits.

**Table 2-11 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),

④ To conduct practical training on handling of the blood screening kits, etc. for African countries and Kenya as a measure for controlling infectious diseases, and

⑤ To cover the Tropical Medicine and Infectious Disease Department of the Jomo Kenyatta University (ITROMID), one of its master course.

(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

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. Economic growth is still hampered by the suspension of finances from IMF and the World Bank, the decline of direct foreign

capital investments and high unemployment rate. Against such a background, the inflationary rate is relatively low for a developing country ranging from 3 to 6 percent since 1998. The new government, which was formed after the General Elections in December 2002, announced Economic Recovery Measures to improve economic growth.
Rural workers concentrate on Nairobi under such economic recession, which results in temporary buyers market. Nevertheless, due attention should be paid to skills and quality in the procurement of workers, materials and equipment. 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 construction industry in Kenya belongs to English System. Building Standard Law and Construction Specifications of Kenya are established according to BS Standard, so the design is based upon the domestic law and BS standard.
In working circumstances, we can say that the total working population is surplus. However, most of them are unskilled workers, while skilled workers are insufficient in both quality and quantity. Even the productivity of them is thought to be one-third or one-fourth of that of Japanese as compared to the ability of skilled workers in the industrialized countries.

Cutting down of trees has been basically prohibited in Kenya, and this regulation has been intensified since 2003. Consequently, wood products have become scarce in Nairobi City, and the price has increase by more than 30 percent. In many cases, construction work uses imported wood products. The local technological level of wood processing is very low, and care must be exercised in procurement of locally made wooden fixtures. The construction work will exercise the utmost supervision to enforce strict quality control on carpentry and reinforcing bar works. Naturally, efficiency of skilled workers would be lower than their Japanese counterparts.

Regarding concrete works, there is no ready-mixed concrete dealer in Kenya. Therefore, the job-mixed concrete work is a common, though there are some contractors who have batcher plants. The mixed concrete is conveyed in bucket by rows of people; naturally, the amount of concrete to be poured in a day is limited. Therefore the process planning needs to have some allowance.

(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 applying contractors are classified into six ranks, A to F, according to their construction experience and construction ability. In addition, the contractors are classified according to their category of 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 business. The electric work, sanitary work and lift installation work require different licenses from concerned authorities. The data for the year 2000 indicates that 60 contractors out of 200 registered companies fall under the A class category.

In implementation of construction works related to Japan's ODA projects, the Japanese contract, a juridical 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 under the A or B category.

It is a common that the local labor asks the employer to guarantee the minimum wage when employing a local. It should be remembered that labor cost for works by Japanese or third-countries entities may be set at higher levels.

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

Although buildings of KEMRI are 20 years old or older, their appearance and internals have been maintained rather well, indicating KEMRI's high managing and maintenance ability. In the facility plan, the budget burden should be reduced basically by facilitating maintenance and reducing running cost to acquire the personnel required for operation and maintenance. Materials locally procurable will be preferentially adopted, while studying the present state of breakage and wear, etc. of the construction materials and the equipment used in each of the existing buildings.

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

1) Facility Plan

① Facility for Manufacture of the Blood Test Kit, and Animal Unit Attached to the Manufacturing Facility

Presently, KEMRI manufactures the blood test kits in the laboratory. The blood test kit has been approved by the Ministry of Health of the government of Kenya, and granted the license for manufacture, sale and use, indicating the approval of

quality. Therefore, the design conditions will be based on the indoor environmental conditions of the laboratory, but at the same time will realize the quality level suited to the mass production and sales in the future, and will permit reduction of maintenance and management cost.

② Training Facility

The training facility will be designed to maintain the level of functions and quality to enable the Japan's technical cooperation project to be executed smoothly, and to maintain harmony with the design, quality, etc. of the existing facilities.

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 KEMRI HIV-1 PA kit and the KEMRI HEPCELL Ⅱ 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

Due consideration will be given to the quality control plan of the construction work, proper manning and manpower deployment by the construction contractors, and formulation of rational temporary work plan so that problems with schedule control, quality control and safety control may not arise.

2) Policy for Method of Procurement

The materials and equipment will be locally procured to the extent possible to facilitate repair, maintenance and control of the facilities after completion. However, locally produced products may often have quality problems. The delivered products could have great variances in quality. Care must be exercised to these points. The imported products locally marketed are generally available in small quantities, and delivery of such products could take two to three months after orders. The procurement will be planned not to adversely affect the construction work, while confirming qualities and supplies of the materials and equipment.

3) Policy for Implementation schedule

The implementation schedule of this cooperation project would not be not achievable, without proper managerial and technological supports of Japan's ongoing technical cooperation project. Judging from the content and scale of this project, the buildings should preferably be completed before April 2006 when the technical cooperation project will end.

### 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 2-12 Outline of the Scope of Final Request**

| | Final request |
|---|---|
| Nairobi | Production units for blood screening kit (KEMRI HIV-1 PA kit, KEMRI HEPCELL Ⅱ kit and traditional medicines), animal unit attached to the production units, and training unit<br>Equipment required for operation of the above facilities |
| Kwale | Training unit, accommodation facilities<br>Equipment required for operation of the above facilities |
| Busia | Training unit, accommodation facilities<br>Equipment required for operation of the above facilities |

During the site survey in January 2002, 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.

The study team confirmed during the field survey of August 2003 that these facilities were completed and in operational stage.

The study team also visited CDC facilities to confirm the suppliers and condition of construction materials and equipment and the security measures. The security measures which CDC implements are as follows:

1） Establishment of bars on all exterior fixtures (windows and others)
2） Use of the laminated glass on interior and exterior fixtures
3） Control of entrance and exit by using card reader
4） Establishment of security camera

**Table 2-13 Outline of CDC's Project in KEMRI, Nairobi**

| Scope | Scale | Schedule |
|---|---|---|
| Administrative building (including some laboratories) | One-story building<br>Total floor area: about 2,000 $m^2$ | Start of construction work: July 2002<br>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 2-14 Summary of Study for the Request**

| Site | Name of facility (by building) | Requested scope (component) | Summary of the result of study | |
|---|---|---|---|---|
| Nairobi | Production unit | KEMRI HIV-1 PA kit production division (blood screening kit for HIV) | ○ | The project will formulate a plan for a system that can produce about 50 thousand tests equivalent after commissioning, and will develop a facility and equipment plans for the system, in cooperation with Japan's technical cooperation project. (Part of the line is shared by the KEMRI HEPCELL Ⅱ kit production line.) |
| | | KEMRI HEPCELL Ⅱ kit production division (blood screening kit for HBV) | ○ | The project will formulate a plan for a system that can produce about 400 thousand tests after completion of the facilities, and will develop a facility and equipment plans for the system, in cooperation with Japan's technical cooperation project. (Part of the line is shared by the KEMRI HIV-1 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 technical cooperation project 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 unit | Attached animal unit (Blood screening kit) | ○ | To secure biomaterials (serum, antibody) for manufacture of the blood screening kits, animal units to raise two species of laboratory animals, the rabbit and guinea pig, will be provided. |
| | | Attached animal unit (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 units 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. |

| Site | Name of facility (by building) | Requested scope (component) | Summary of the result of study | |
|---|---|---|---|---|
| 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

KEMRI HIV-1 PA and KEMRI HEPCELL Ⅱ 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 HIV-1 PA kit and KEMRI HEPCELL Ⅱ 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.

The KEMRI HIV-1 PA kit has been successfully manufactured locally as HIV-1 detection kit (freeze-dried product with one-year effective period), with Japan's fourth technical cooperation project (from May 1996 to April 2001). Further, the test kit capable of detecting HIV-1 and HIV-2 is under development with manufacturing scheduled to start in 2006. Further Regarding the KEMRI HEPCELL Ⅱ kit, Japan's third technical cooperation project (from May 1990 to April 1996) lead to successful preparation of raw materials. The subsequent fourth technical cooperation project (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 KEMRI HEPCELL Ⅱ kit to be used for testing of the blood for transfusion. And also, on KEMRI HIV-1 PA kit, it is expressed that 200 thousand tests / year will be purchased at the stage of the development of HIV-1 and HIV-2 test kit.

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 Unit attached to Production Unit

The animal unit 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 unit.

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 technical cooperation project, or to researches. It would be a proper judgement to exclude installation of production unit and their associated animal units 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.

**Table 2-15 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<br>- Jomo Kenyatta University of Agriculture and Technology<br>- University of Nairobi<br>- Moi University<br>- Maseno University<br>- Ministry of Health<br>- Kenya Medical Training College | | |

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

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. It was found out in the field survey of August 2003 that the Tropical Medicine and Infectious Disease Department of the Jomo Kenyatta University (ITROMID) and KEMRI will use the facilities in their Joint project.

The following training courses were held in KEMRI in Year 2002.

**Table 2-16 Training Courses held in KEMRI in Year 2002**

| Courses | A | B | C | D |
|---|---|---|---|---|
| 1. 2 Day Workshop – Nurse Training Workshop on TB | 45 | ● | | 45 |
| 2. KEMRI/JICA Third Country Training Programme (TCTP) | 16 | | ● | 16 |
| 3. Workshop Organized by Radiography Society | 40 | | ● | |
| 4. Workshop Organized by Dentist Board | 80 | ● | | |
| 5. International Symposium on Parasitic Diseases Control Programme in Eastern and Southern Africa (ESACIPAC) | 76 | ●(60) | ●(16) | 76 |
| 6. Cancer Registry Scientific Training | 98 | | ● | 98 |
| 7. Acacia Consultant to examine Effectiveness of Japanese Technical Assistance | 30 | | ● | 30 |
| 8. Transport of Biomedical Material Course | 102 | | ● | |
| 9. Private Public Partnership in Product Development in Kenya | 30 | ● | | |
| 10. The Potential for Probiotics in Desease Privention and Health Management | 200 | ● | | |
| 11. Industrialization of Medicinal and Aromatic Plants | 141 | ● | | |
| 12. Industrial Attachments of Students from Polytechnics and Universities | 50 | ● | | 50 |
| 13. Conducted Tours and Training for Students from Institutions of Learning | *(100) | | | |
| 14. KEMRI Seminars organised on Monthly Basis (total/year) | *(260) | | | |
| Related to the Project (Total) | 217 | 155 | 62 | 217 |
| Total | 908 | 606 | 302 | |

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

| Other expected courses | A | B | C | D |
|---|---|---|---|---|
| 15. Courses by National Public Health Laboratory Services | - | | ● | 15 |
| 16. ITROMID:Institute of Tropical Medicine and Infectious Diseases (Master Science Degree Programmes) | - | | ● | N/A |

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

⑤ 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

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 by using extremely high rotations. The unit must be capable of continuous operation of about 24 hours. The ultracentrifuge will be used exclusively for this purpose to forestall mixing with other raw materials.

・ 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 large fluid volume 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 KEMRI HIV-1 PA kit and the other for the KEMRI HEPCELL Ⅱ kit.

・ Safety Cabinet

This unit is used when titters of the positive control sera for the KEMRI HIV-1 PA kit and the KEMRI HEPCELL Ⅱ 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 indispensable 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 adequate 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

The study team discussed with and confirmed with the Kenyan side each piece of the requested equipment and its number. In such processes, their necessity and relevance was studied from the viewpoints of the manufacturing system and facility plan of the kits, and also based on the selection standard given below. The results of such study are shown in the table below. The number in the column "Planned number" indicates proposed deployment in each room.

1) 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

2) 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

3) 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.

4) The requested number should be relevant
   - ◎ Minimum required number of equipment is requested.
   - △ The reduction in number is necessary (possible) for the equipment.

5) Judgment and evaluation
   - ○ Equipment for which procurement in this cooperation project is judged to be relevant
   - × Equipment for which procurement in this cooperation project is not done

**Table 2-17 Study of Requested Equipment**

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| 1-1 Manufacturing facility | | | | | | | | |
| HEPCELL II and HIV/PA kits manufacturing division | | | | | | | | |
| ・ HEPCELL II Preparation room | | | | | | | | |
| 1 | Refrigerated centrifuge | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Cool box | 1 | ◎ | ◎ | ○ | ◎ | ○ | 1 |
| 3 | Fraction collector | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | pH meter | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Plate mixer | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 6 | Fluid pump | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 7 | Affinity column stand | 1 | ◎ | ○ | ◎ | ◎ | ○ | 1 |
| 8 | Affinity column | 5 | ◎ | ○ | ◎ | ◎ | ○ | 5 |
| 9 | Magnetic stineer | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 10 | Safety cabinet | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 11 | ultracentrifuge | 1 | ◎ | ○ | △ | ◎ | ○ | 1 |
| 12 | Plasma separator | 1 | ○ | ○ | ◎ | ◎ | ○ | 1 |
| 13 | ultrasonic homogenizer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 14 | Vortex mixture | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 15 | Bench | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 16 | Stool | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| ・ HIV/PA preparation room | | | | | | | | |
| 1 | Vortex mixer | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 2 | Fluid transfer pump | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 4 | Stool | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 5 | Safety cabinet | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Automatic pipette, rechargeable | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Manufacturing room (equipment for the HEPCELL II kit) | | | | | | | | |
| 1 | Thermostatic bath | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| 2 | Refrigerated centrifuge | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Bench | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 4 | Stool | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 5 | Hematocrit centrifuge | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Electro-balance | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 7 | Aspirator | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| ・ Manufacturing room (equipment for HIV/PA kit) | | | | | | | | |
| 1 | Thermostatic bath | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Automatic pipette, rechargeable | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Capping unit, manual | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | Bench | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 5 | Stool | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 6 | Refrigerated centrifuge | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| ・ Quality control room | | | | | | | | |
| 1 | Refrigerator | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Bench | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 3 | Stool | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 4 | Personal computer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Printer (monochromatic) | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Plate mixer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 7 | Automatic pipette, rechargeable | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 8 | ELISA washer | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 9 | ELISA reader | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 10 | Freezer (upright) | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 11 | Incubator | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 12 | Photographic unit | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 13 | Centrifuge, desk top | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 14 | Electro-balance | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 15 | Densitometer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 16 | pH meter | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 17 | Refractometer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 18 | Spectrophotometer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Raw material storage room | | | | | | | | |
| 1 | Freezer | 2 | ◎ | ○ | ○ | ◎ | ○ | 2 |
| 2 | Ultra low temperature freezer, 300 liters | 2 | ◎ | ○ | ○ | ◎ | ○ | 2 |
| 3 | Storage room | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| ・ Dispense room | | | | | | | | |
| 1 | Vacuum freeze drying | 1 | ◎ | ○ | △ | ◎ | ○ | 1 |
| 2 | Bench | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 3 | Stool | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 4 | Automatic pipettes, rechargeable | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Plate mixer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Washing room | | | | | | | | |
| 1 | Autoclave | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Bench | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Stool | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | Pass box | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Drying machine | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Ultrapure water manufacturing unit | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| 7 | Ice making machine | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Locker room | | | | | | | | |
| 1 | Locker | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| ・ Labelling room | | | | | | | | |
| 1 | Bench | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Stool | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| ・ HIV/PA kit storage room | | | | | | | | |
| 1 | Cool box | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| ・ HEPCELL kit storage room | | | | | | | | |
| 1 | Refrigerator | 1 | ◎ | ○ | ○ | ◎ | ○ | 1 |
| ・ Packing room | | | | | | | | |
| 1 | Bench | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 2 | Storage cabinet A | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 3 | Storage cabinet B | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 4 | Refrigerator | 2 | ◎ | ○ | ○ | ◎ | ○ | 2 |
| ・ Office | | | | | | | | |
| 1 | Personal computer | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 2 | Printer (monochromatic) | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Desk | 6 | ○ | ◎ | ◎ | ◎ | ○ | 6 |
| 4 | Chair | 6 | ○ | ◎ | ◎ | ◎ | ○ | 6 |
| 5 | Photocopier, monochromatic | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Staff room | | | | | | | | |
| 1 | Table, chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ General manager room | | | | | | | | |
| 1 | Desk | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| 2 | Chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Marketing manager room | | | | | | | | |
| 1 | Desk | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 2 | Chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| Animal unit | | | | | | | | |
| ・ Washing room | | | | | | | | |
| 1 | Autoclave | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 3 | Stool | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 4 | Animal raising tool set | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Blood collection room | | | | | | | | |
| 1 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 2 | Stool | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 3 | Balance | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Breeding room | | | | | | | | |
| 1 | Cage cabinet | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| 2 | Animal cage | 125 | ○ | ◎ | ○ | ◎ | ○ | 125 |
| ・ Office | | | | | | | | |
| 1 | Desk, chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| | | | | | | | | |
| 1-2 Training equipment | | | | | | | | |
| ・ Lecture room | | | | | | | | |
| 1 | Desk, chair | 48 | ○ | ◎ | ◎ | ◎ | ○ | 48 |
| 2 | Chair | 72 | ○ | ◎ | ◎ | ◎ | ○ | 72 |
| 3 | Lecture table | 3 | ○ | ◎ | ◎ | ◎ | ○ | 3 |
| 4 | Audio unit | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Projector, note-type personal computer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Overhead projector | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Laboratory 2 (Parasitic laboratory) | | | | | | | | |
| 1 | Laboratory table, chair | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| 2 | Binocular microscope | 16 | ○ | ○ | ○ | ◎ | ○ | 16 |
| 3 | Demonstrating microscope | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | Stereoscopic microscope | 16 | ○ | ○ | ○ | ◎ | ○ | 16 |
| 5 | Centrifuge, desk top | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Micrometer | 16 | ○ | ○ | ○ | ◎ | ○ | 16 |
| 7 | Thermostatic bath | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 8 | Incubator | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 9 | Storage room | 4 | ○ | ○ | ○ | ◎ | ○ | 4 |

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| 10 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 11 | Stool | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Infectious laboratory 1 | | | | | | | | |
| 1 | Thermostatic bath | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Vortex mixer | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 3 | Automatic pipette, rechargeable | 5 | ○ | ○ | ○ | ◎ | ○ | 5 |
| 4 | Pipettes of various types | 5 | ○ | ○ | ○ | ◎ | ○ | 5 |
| 5 | Refrigerator | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 6 | Incubator | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 7 | pH meter | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 8 | Spectrophotometer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 9 | Plate mixer | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 10 | Electro-balance A | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 11 | Electro-balance B | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 12 | Balance | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 13 | Laboratory table, chair | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| 14 | Inverted microscope | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 15 | Carbon dioxide incubator | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 16 | Clean bench | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 17 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 18 | Aspirator | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Preparation room | | | | | | | | |
| 1 | Ultra low temperature freezer | 2 | ○ | ○ | ○ | ◎ | ○ | 2 |
| 2 | Ultrasonic homogenizer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 3 | Plate mixer | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | Clean bench | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Centrifuge, with temperature setting function | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Thermostatic bath | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 7 | Sample cabinet | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 8 | Autoclave | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 9 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Dark room | | | | | | | | |
| 1 | Fluorescence microscope | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 2 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 3 | Stool | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Microscope room | | | | | | | | |
| 1 | Bench | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |

| No. | Equipment | Q'ty requested | Selection standard | | | | | Planned number |
|---|---|---|---|---|---|---|---|---|
| | | | 1. Indispensable | 2. Technology level | 3. Maintenance | 4. Relevant in number | 5. Judgment and evaluation | |
| 2 | Stool | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 3 | Binocular microscope equipped with a computer system | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 4 | Stereoscopic microscope | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 5 | Inverted microscope equipped with a photographic system | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Data processing training room | | | | | | | | |
| 1 | Chairs and a table (for two persons) | 8 | ○ | ◎ | ◎ | ◎ | ○ | 8 |
| 2 | Lecture table, chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 3 | Personal computer for the trainee | 8 | ○ | ○ | ○ | ◎ | ○ | 8 |
| 4 | Printer, monochromatic | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| ・ Network server room | | | | | | | | |
| 1 | Personal computer | 3 | ○ | ○ | ○ | ◎ | ○ | 3 |
| 3 | Cabinet for parts | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 5 | Table and chair | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| 6 | Cabinet for computer data | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 7 | Cabinet for document | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| ・ Training facility manager room, secretariat room, conference room, office, visitors office | | | | | | | | |
| 1 | Desk, chair | 8 | ○ | ◎ | ◎ | ◎ | ○ | 8 |
| 2 | Conference table, chair | 1 | ○ | ◎ | ◎ | ◎ | ○ | 1 |
| 3 | Storage cabinet | 4 | ○ | ◎ | ◎ | ◎ | ○ | 4 |
| 4 | White board | 2 | ○ | ◎ | ◎ | ◎ | ○ | 2 |
| 5 | Copier, monochromatic | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |
| 6 | Printer, color | 1 | ○ | ○ | ○ | ◎ | ○ | 1 |

### 2-2-2-2 Site Plan

(1) Blood Screening Kit Production Unit

The blood test kit manufacturing facility, one of the subject facilities, is different from the existing laboratories modified to fit research objectives, in role and nature of the facilities. It is also necessary to prevent cross contamination to the extent possible. For these reasons, these facilities need to be planned as separate buildings from the existing ones. The facilities are not intended to be frequently used by a large number of unspecified persons. It is therefore important that entry to and exit from the facilities be made easy, provided that visitors are limited.

Upon such premises, the construction site of the facilities will be on the part of the southernmost end of the KEMRI's premises. This site is also favourable from the viewpoint of traffic lines.

This site faces the railroad of the Kenyan Railways Cooperation, and construction of buildings on the 50-feet belt along the railroad area is not permitted. Therefore, the layout plan calls for placing facilities other than buildings, such as roads and parking spaces, on this belt along the railroad.

In addition, to prevent the traffic lines of vehicles for delivery of the raw materials for the kits and for shipping of the finished products from becoming too complicated, exclusive yards for vehicles for delivery and shipping are planned to separate the traffic lines of vehicles from those of men.

The CDC of the United States has constructed and commissioned a research facility in the back of the planned manufacturing facility. It is mandatory that the construction of the planned facility ensure safety to the vehicle and people visiting and leaving the CDC's facility. In addition, study team has requested KEMRI to relocate the security gate to the CDC's facility already installed in the planned site by the time construction of the planned facilities starts.

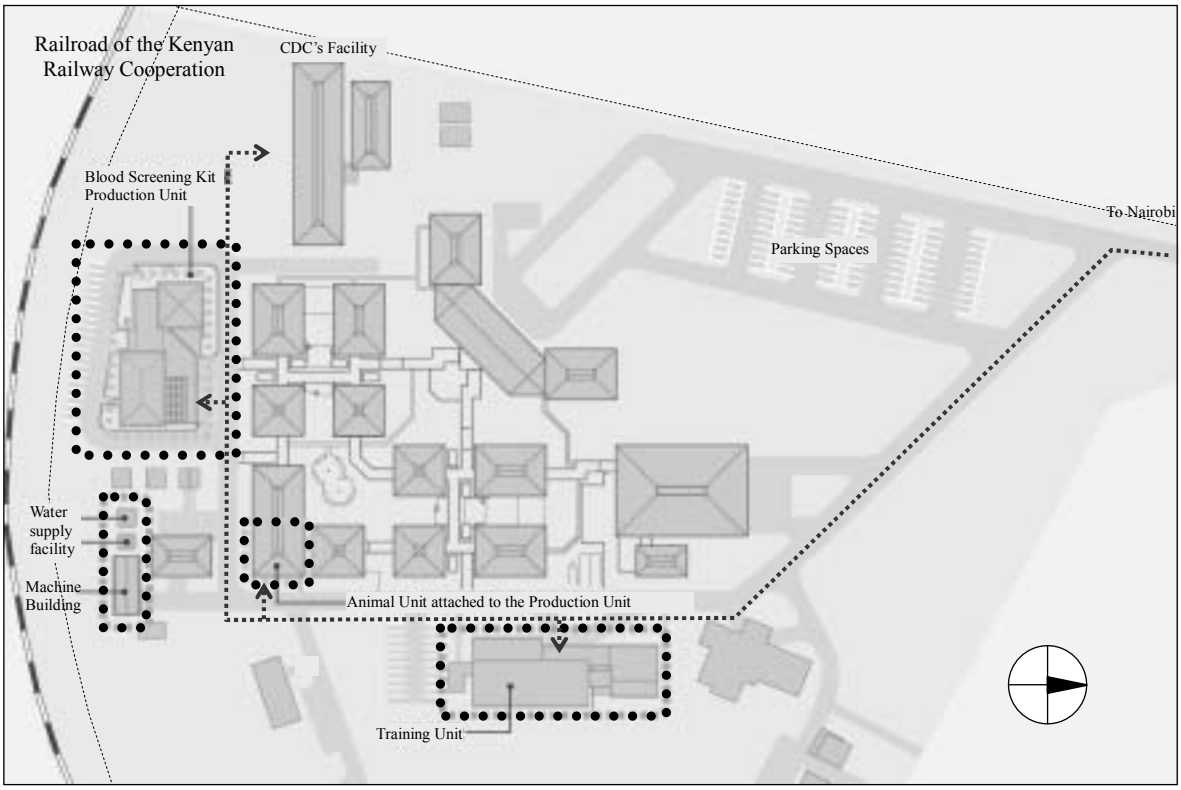



**Figure 2-1 Layout Plan**

(2) Animal Unit attached to the Production Unit

Considering the manufacturing scale of the blood test kits by the planned facilities, the animal unit of this project will be provided by partially modifying the KEMRI's existing animal unit. The role of the animal unit in the manufacturing process of the test kits would require the animal unit to be as close to the manufacturing facilities as possible. The locations of the manufacturing facilities and the existing animal unit satisfy this requirement.

(3) Training Unit

Training by the Japan's technical cooperation project, third-country training and other various training are planned. Accordingly, the training unit will be visited by a large number of people, not necessarily belonging to KEMRI. The training facility should therefore be planned in the facility layout plan for the KEMRI's premises to be easy to access, and be independent of the existing facilities. The large unused space on the east side of the premises satisfies such a requirement, the training unit will be constructed in a most conspicuous part of the KEMRI's premise.

### 2-2-2-3 Architectural Plan

(1) Blood Screening Kit Production Unit

1) Design Premises

① Design Standard

As mentioned above, the indoor environmental conditions of the existing laboratory will be adopted for the manufacturing facilities, the quality of the test kits will be made fit to mass production and sale, and the reduction of the maintenance and operation cost of the entire facility will be planned. For these purposes, the following three items are established as design standards.

- To minimize crossing of manufacturing process lines to the extent possible
- To clearly delineate the clean production area for prevention of contamination of bacteria and foreign materials
- To restrict the entry and exit of people and materials not concerned with manufacturing

② Manufacturing Process and Required Rooms

The following schedule chart applies to the manufacturing process of the KEMRI HEPCELL Ⅱ kit. Development of the floor plan for concerned rooms, traffic lines, etc. should be based upon a thorough study and understanding of each step of the manufacturing process so that the blood test kits may be smoothly manufactured.

The manufacturing process of the KEMRI HIV-1 PA kit is identical with that of the KEMRI HEPCELL Ⅱ kit from Step (11) and downward. In the Steps (2) to (10) where reagents for blood test are manufactured, the only difference from the process of KEMRI HEPCELL Ⅱ kit is that the number of processes is fewer, and contains no process of different nature.

**Table 2-18 Manufacturing Process and Various Required Rooms Used (KEMRI HEPCELL Ⅱ kit)**

| Step | Stage | Detail | Required rooms |
|---|---|---|---|
| 1 | Unloading | ・Material unloading | Material Room/Storage/Packing Room |
| 2 | Elements preparation (KEMRI HEPCELL Ⅱ 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 number of test kits required to be manufactured a year is 400 thousand tests equivalent (2,000 kits) for the KEMRI HEPCELL Ⅱ kit and 50 thousand tests equivalent (1,200 kits) for the KEMRI HIV-1 PA kit. If two separate trains are installed for the two products, as indicated in the request document of the Kenyan government, the construction cost and maintenance and operation cost would be high, and operation rate would below.

For the above two reasons, the scales of the facilities are designed in such a way that the HEPCELL train and the PA train will share the same facilities to the extent possible. As a result, one train capable of manufacturing in principle 400 thousand tests equivalent of KEMRI HEPCELL Ⅱ kits will be installed. Rooms in which cross contamination is possible if commonly used will be separated.

2) Floor Planning

① Facility Configuration

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.

The manufacturing facilities are housed in an independent building, and are also clearly distinguished in the floor plan. The plan facilitates entry and exit control of men and articles.

The manufacturing facilities may be broadly classified into the following three areas according to the function.

a. Manufacturing Area

This area covers the entire manufacturing process from storage of raw materials to packing of the finished products. This area may be further broken down into the "clean production area" and "sub clean production area" by the nature of work.

- Clean production area

  The clean production area conducts storage of the raw materials, dispensing into vials, freeze drying, capping, the manufacturing operations requiring higher degrees of cleanliness.

- Sub clean production area

  This zone conducts assembling of various kinds and packing the products into boxes. These works are downstream of capping; therefore, a high degree of cleanliness is not required.

b. Entrance Area

The entrance area will have the function of entry to and exit from the building. Besides, this area will have a space for exhibiting the test kit products.

c. Administration Area

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


**Figure 2-2 Zoning Plan of Production Area**

② Installation of Clean Production Area

The clean production area and other parts will be separated by the pre-clean room or the pass room. Clean production areas will have either one air conditioning system for each clean production area, or have a common air conditioning system exclusively for clean production areas. Windows will be fixed type (not openable) to prevent bacteria and foreign materials from entering from outside.

Operators can enter the clean production area only through the locker room and the pre-clean room. The operators should change their clothes and shoes in the locker rooms, and wash their hands in the pre-clean room. The operation in the clean production area is predetermined according to the production plan. When the work is finished, the operators should promptly leave the clean production area.

The raw materials are brought into the clean production area through the pass room. The vials and associated equipment are washed in the washing room and disinfected in an autoclave, and brought into the clean production area via the pass box.

③ Planning of Traffic Line in the Manufacturing Area

The clean production area consists of the preparatory room, kit manufacturing room, clean corridor, raw material storage room, dispensing/freeze drying room. The operators, materials, parts move along the traffic line for each stage of the manufacturing process.

The materials and parts that have been subjected to dispensing, freeze drying, capping processes are brought out of the clean production area, and placed in the storage cabinet. Subsequently, these semi-finished products are assembled and labeled into finished products, and stored in the refrigerator in the assembling room. The finished products are shipped from the truckyard according to the delivery plan.

The “Traffic Line in the Blood Test Kit Manufacturing Facility” attached in the Reference schematically show the above traffic lines. It may be noted from this that the traffic lines are planned not to cross each other at each manufacturing line.

④ Safety Plan

Two exits are planned for the manufacturing room and the preparatory room, (one directly to the corridor and the other to the next room) to enable the operators to evacuate in case virus dispersion occurs while the test kits are being manufactured.

The operators reaching the corridor shall go outdoors through the corridor between the dispensing room and washing room. Showers and eye washers will be installed near the exit to be used in case operators are sprayed with chemicals.

3) Room Plan

The functions of planned rooms explained below.

(Reference should be made to floor plans on Pages 89 and 91 for scales and equipment layout.)

① Function and Scale of Room in the Production Area

・ Preparation Room for HEPCELL+HIV/PA

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.

・Manufacturing Room for HEPCELL+HIV/PA

The parts to be used for the kits are manufactured. The parts that have already been subjected to preparation process are not liable to cross contamination. The manufacturing processes of the KEMRI HEPCELL Ⅱ kit and the KEMRI HIV-1 PA kit are placed in a common room.

・Material Room

The raw material storage room stores the raw materials, parts prepared by the kit preparation rooms and the kit manufacturing rooms. The parts for the KEMRI HEPCELL Ⅱ kit and the KEMRI HIV-1 PA kits are placed in clearly distinguished places so that they may not be mixed.

・ Dispense 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.

・ Washing Room

The vials (bottles) for the products are purchased and temporarily stored in the vial storage room. The vials are brought into the clean production area through the pass box after having been washed. The equipment once used in the

manufacturing process is disinfected in the autoclave of the washing room and return to the clean area.

・Locker Room, Pre-clean Room

The benches in the locker room will be placed to partition the locker room into two spaces, one for outdoor-shoe area and the other indoor-shoe area. The operators entering the locker room sit on the bench to remove the outdoor shoes and turn the bodies while sitting on the bench to the indoor-shoe area to put on indoor shoes. Then the operator puts on work outfits, enter the pre-clean room, and wash their hands.

・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.

・HEPCELL and PA Storage Room/ Labelling Room, Packing Room

The finished kits are stored in the refrigerators in the warehouse after all operations of the manufacturing processes have been completed.

The finished products are labeled and assembled according to the delivery plan. The products are tentatively stored in the refrigerator in the assembly room until shipment.

② Functions and Scales of Various Rooms outside the Production 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.

・Toilet

To secure a minimum required cleanliness, toilets with natural ventilation are planned. The men's toilet is equipped with two wash basins, two urinals, and two closet bowls. The women's toilet is equipped with two wash basins and three closet bowls.

4) Elevation Plan (design and finish)

The external wall will be of concrete rigid frame structure, common in Kenya, with masonry of Nairobi stone. The columns and beams will have mortar substrates finished with paints. The exterior walls are finished with chipped Nairobi stones. The kinds of Nairobi stones that match the appearances of the existing facilities will be selected.

The roofs will be slanted roofs made of concrete slabs so that the roofs may maintain good water resistance over a long period of time. Asphalt roofing will be applied to the roof. Further, to protect the asphalt roofing from deterioration by ultraviolet rays, concrete roof tiles will be used.

The window frames will be of aluminum so that they may have good weatherability under intense direct sunshine. Outside the windows will be installed louvers to shield the sunshine. This design helps reduce the air-conditioning load while giving a unique appearance to the building.

5) Section Planning

The space just below the slanted roof above the manufacturing area will be used to place a room for the air conditioner machine. The ducts for air supply and exhaust air ducts will be placed in this space. This space will be used also as a maintenance work area.

Below the sinks in the manufacturing area and toilets will be installed underground pits, to facilitate maintenance area.

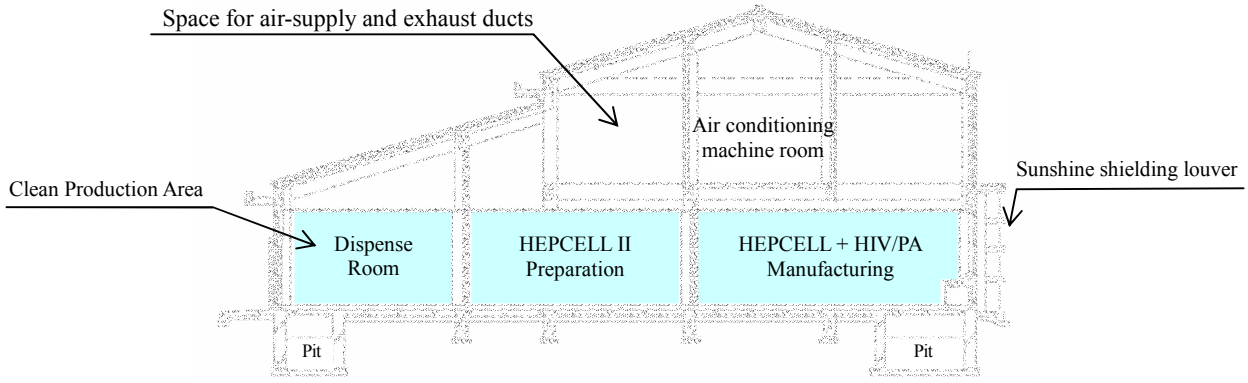



**Figure 2-3 Cross-sectional View of Production Area**

6) Anticrime Measures

The steel anticrime frame (burglar proof) shall be installed in all the window frames.

(2) Animal Unit attached to Production Unit

1) Design Premises

① Product Quality

The animal unit constitutes an important component of the test kit manufacturing train. Naturally, the serum for the purpose of mass producing test kits must always be of higher quality than that of the sera now being taken by KEMRI for experimental and research purposes. Therefore, importance is attached to the following two items, in view of the design conditions established for the manufacturing facilities.

- To prevent infections from outsides, the animal raising zone for kit manufacturing purpose should be clearly defined.
- Entry and exit of persons and articles not concerned with manufacturing should be restricted.

② 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 2-19 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 | KEMRI HEPCELL Ⅱ 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 | KEMRI HEPCELL Ⅱ 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. |
| | KEMRI HEPCELL Ⅱ 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. |
| | KEMRI HIV-1 PA kit (Addition of liquid to dilute the serum) | Serum 100ml/ year | 2 | | | Since 50ml of serum is obtainable from one rabit, 2 rabits are necessary. About 126 kits may be manufactured from 50mℓ of serum. |

2) Floor planning

The existing animal unit for keeping experimental animals will be modified to the extent of about 40 percent to be converted into the animal unit for blood kit manufacturing. The purpose of the animal unit is to collect sera and other raw materials to be used by the manufacturing facility from rabbits and guinea pigs. Breeding of guinea pigs will also be done in the animal unit.

① Partition from the Existing Animal Unit

The animal unit will be planned as an independent and separated from the existing animal unit to facilitate control on entry and exist. The partition wall with the existing animal unit will extend to the space below the room and a new entrance exclusively for the new animal unit will be installed. In this way, the new animal unit will be an animal unit exclusively for the manufacturing facility, completely separate from the existing animal unit for experimental purpose.

② Component of the Facility

This facility may be broken down into the area for raising animals and to collect sera and the area where the operators work. Further, the corridor in the center of the animal unit will serve as a buffer space.

The operators and articles enter the washing room from the entrance of the office through the locker room. The rabbit and Guinea pig are brought into through the animal entrance. The animals are continuously watched for health conditions from the adjacent quarantine room.

The animal unit is protected from contamination by bacteria and foreign materials from outside by means of the measures mentioned above.

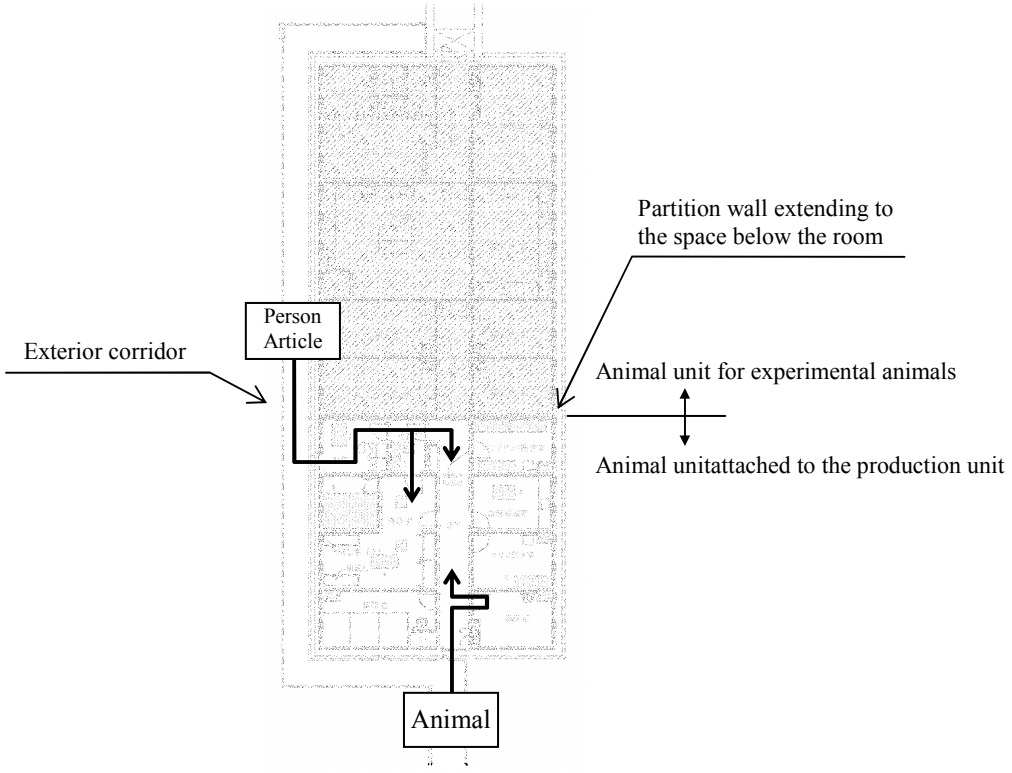



**Figure 2-4 Zoning Plan of the Animal Unit**

3) Elevation Planning, (Shape, Finishing Material)

The existing animal unit will be modified, and the interior finishing and other works will be applied. Since the inside corridor will be cut, a new entrance will be installed. A louver will be installed below the eaves of the existing building, and a new connecting breezeway will be installed so that people may be able to reach the animal unit from the existing KEMRI facilities without getting wet on rainy days.

4) Section Planning

The air conditioning machine for the modified animal unit will be installed in the attic of the modified portion. In order for the noise and vibration not to disturb the animals, the machine area will not be located above the breeding area. An accommodation ladder will be provided for entering and leaving the attic.

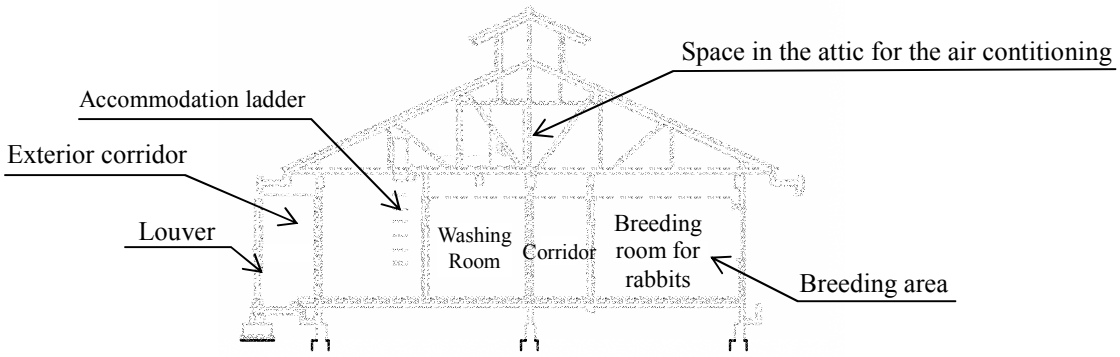



**Figure 2-5 Cross-sectional View of the Animal Unit**

5) Anticrime Measures

The steel anticrime frame (burglar proof) shall be installed in all the window frames.

(3) Training Unit

1) Zoning

The training unit consists of the entrance area, the training areas, and the office area. As shown in Figure 2-6 (sic) below, the training area and the office area are laid out apart, with the entrance area in between.

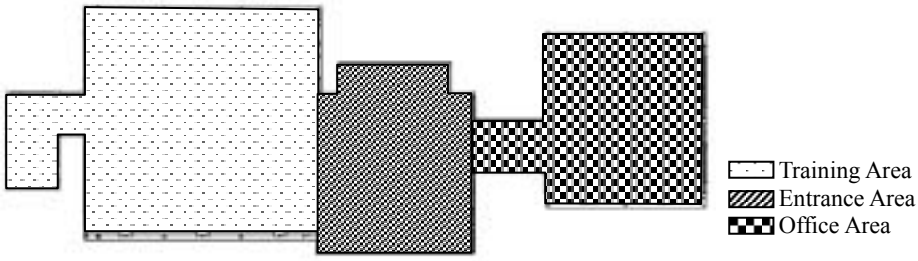



**Figure 2-6 Distribution of Function and Zoning Plan of Training Unit**

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 technical cooperation project 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.

2) Function and Scale of Room

The following are the functions of the rooms to be installed. (Reference should be made to the floor plans on Pages 101 and 103 for scales of the rooms and equipment layout.)

- 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.
- Laboratory 1 (Infectious Disease) and Laboratory 2 (Parasites)

  These two training laboratories are for parasitic diseases and infectious diseases. Both will be wide enough to accommodate 16 persons.
- Data Processing Room

  A 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 to accommodate about 16 persons, according to the training programme.
- Network Server Room

  It is 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.
- 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.

- 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 are assumed to be 700 to 800.

3) Elevation Plan (design and finish)

There is a difference in ground height between the training area (including the entrance area) for the third country training, etc. and the administrative area. However, these two portions are contained in one structure with the same and continuous roof.

The policy applied to the test kit manufacturing facility will also be applied to the exterior wall, roof, window, etc.

4) Section Planning

There is an about 1.4-meter difference in height of the ground level between the northern and southern ends of the planned building site, because of irregularity of the topography. This difference in height will be accommodated by installing a skipped steps in the breeze way connecting the entrance area and the administration area.

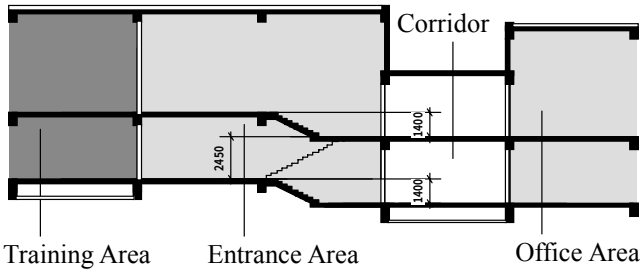



**Figure 2-7 Cross-sectional View of the Training Unit**

5) Anticrime Measures

The steel anticrime frame (burglar proof) shall be installed in all the window frames.

(4) 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 | HEPCELL Ⅱ Preparation room, HIV/PAPreparation room, HEPCELL+HIV/PA Manufacturing room, Material room, Dispense room, Washing room, Quality control room, Packing room, Labelling room, Clean corridor, Store, WC, Corridor |
| First Floor | General Manager room, Marketing Manager room, Secretary room, Office, Staff room, Changing room, Pantry, Mechanical room |

Animal Unit (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 |

(5) Required Floor Area

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

**Table 2-20 Planned Facility and Scale**

Blood screening kit production unit

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Entrance | Entrance hall | 170.5 | |
| | Exhibition lounge | 41.4 | 211.9 |
| Manufacturing area (clean production area) | HIV/PA preparatory room | 37.4 | |
| | HEPCELL preparatory room | 57.0 | |
| | HEPCELL＋HIV/PA manufacturing room | 72.3 | |
| | Raw material storage room | 44.7 | |
| | Dispensing room | 46.3 | |
| | Rocker rooms (men and women) | 37.9 | |
| | Pre-clean room | 24.8 | |
| | Pass room | 1.6 | |
| | Clean corridor | 65.8 | 387.8 |

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Manufacturing area (sub clean room) | Washing room | 36.8 | |
| | Quality control room | 40.2 | |
| | Labeling room | 21.3 | |
| | Assembly room | 47.2 | |
| | HIV/PA storage room | 13.4 | |
| | HEPCELL storage room | 13.4 | |
| | Vial storage room | 16.9 | |
| | Common storage room | 12.9 | |
| | Men' and women's toilets | 51.2 | |
| | Common corridor, etc. | 64.8 | 318.1 |
| Common area | Canopy | 37.4 | |
| | Storage room | 9.7 | |
| | Balcony | 28.1 | |
| | Machine room, etc. | 25.7 | 100.9 |
| Administration area | Manufacturing general manager's room | 20.6 | |
| | Sales manager's room | 14.5 | |
| | Secretary's room | 29.1 | |
| | General office | 75.3 | |
| | Locker room | 20.5 | |
| | Officer's room | 27.3 | |
| | Hot water service room | 9.7 | |
| | Corridor | 51.1 | 248.1 |
| Total | | | 1,266.8 |

Aminal house attached to the production unit

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Breeding area | Common corridor | 24.6 | |
| | Rabbit breeding room | 14.2 | |
| | Guinea pig breeding room | 14.2 | |
| | Breading room | 19.8 | |
| | Blood collection room | 14.2 | |
| | Quarantine | 14.2 | 101.2 |
| Office area | Washing room | 39.7 | |
| | Locker room | 6.3 | |
| | Office | 11.7 | 57.7 |
| Common area | Exterior corridor | 87.7 | 87.7 |
| Total | | | 246.6 |

Training unit

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Entrance | Entrance hall | 60.2 | |
| | Reception desk | 8.9 | |
| | Lounge | 52.6 | |
| | Library | 77.7 | 199.4 |
| Office area | Training facility manager's officer | 25.9 | |
| | Secretary's room | 16.9 | |
| | (ESACIPAC) | 51.8 | |
| | Visitor's office | 35.6 | |
| | Professional's office | 22.2 | |
| | Project control room | 35.5 | |
| | Lecturer's room | 51.8 | |
| | Conference room | 69.4 | |
| | Printing room | 13.3 | |
| | Hot water service room | 16.5 | |
| | Storage room | 10.5 | |
| | Toilet | 36.7 | 386.1 |
| Training area | Laboratory 1 (infectious disease) | 83.8 | |
| | Laboratory 2 (Parasite) | 68.9 | |
| | Preparatory room | 55.9 | |
| | Microscope room | 21.2 | |
| | Dark room | 13.9 | |
| | Lecture room | 204.9 | |
| | Training room for information processing | 51.8 | |
| | Network server room | 43.6 | |
| | Locker room | 24.0 | |
| | Shower room | 5.5 | |
| | Hot water service room | 17.3 | |
| | Toilet | 59.8 | |
| | Storage room | 25.6 | 676.2 |
| Common area | Common corridor | 471.1 | |
| | Canopy | 69.1 | |
| | Bern, etc. | 135.7 | |
| | Terrace, etc. | 137.2 | |
| | Machine room, etc. | 8.5 | 821.6 |
| | Total | | 2,083.3 |

Machine Building

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Energy supply | Machine room | 129.0 | |
| | Bern, etc. | 23.1 | 152.1 |

Water supply facility

| Area | Room | $m^2$/room | $m^2$ |
|---|---|---|---|
| Water supply | Elevated cistern | 36.0 | |
| | Water tank | 25.0 | 61.0 |

### 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.

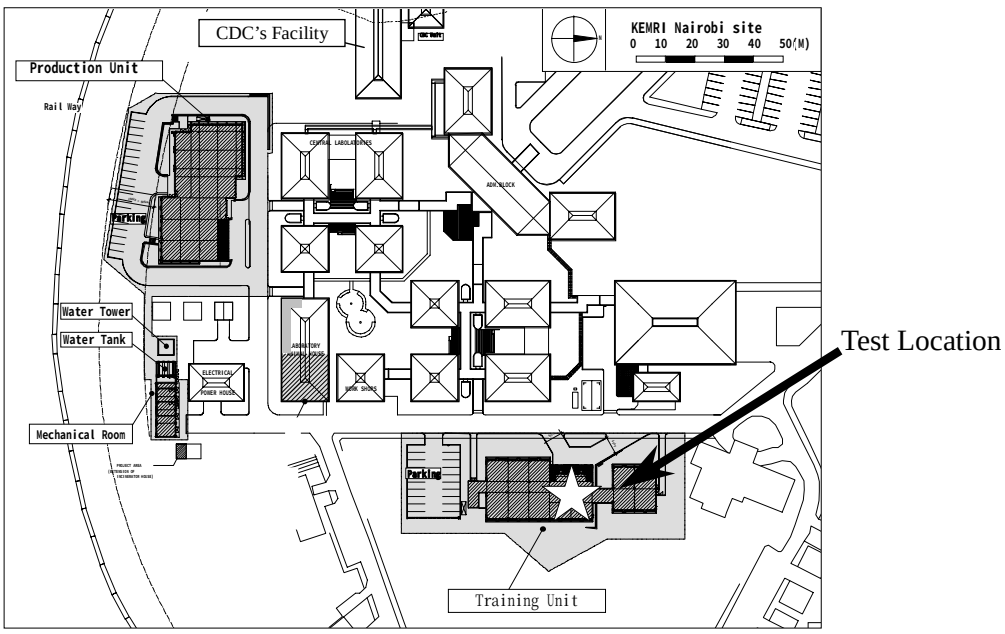



**Figure 2-8 Plate Loading Test Location Map**

The results of the loading test are shown in the following table. The sinkage to the upper limit of live load of 201.6 kN/$m^2$ (20.6t/$m^2$) was low value of 0.44mm. Usually the load that the sinkage reaches 10mm is the yield strength to the limit, and one-third of it is long-term allowable soil pressure. In consideration of these things - Supporting soil is rock and no creep subsidence is found, long-term allowable soil pressure of more than 200.0kN/$m^2$ can be sufficiently expected.

**Table 2-21 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 2-22 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) Receiving and Transforming Facility

The capacity of the existing low-voltage transformer (1000kVA) is not enough for the power supply to the project facilities. So considering the future power consumption, the power system of the entire facilities will be changed into the high-voltage receiving system. According to the survey of 2002, KPLC reported that the two receiving lines were quite good, but in the meeting with KPLC in august of 2003, we found that the two receiving lines to the KEMRI were in a difficult situation due to the shortage of the capacity of the main substation.

In case of the existing transformer, if the power capacity in this project is added, the capacity of it runs short. So the following project was designed: KPLC will install high-voltage receiving ・transforming panel for leading of high-voltage power by using the existing receiving lines, and KPLC will install the transformer for housing in it. And the construction of receiving ・ transformer room will be the work of the Japanese side.

The construction of high-voltage panel with which the power is supplied from this high-voltage receiving panel to the KEMRI's existing 1,000 kVA low-voltage transformer and to the 500 kVA transformer for the project facilities will be included in the work of the Japanese side.

The electric power for internal distribution will be 3φ4W 415／240V, and that at 3φ 3W 415V for power, and that at 1φ2W 240V for lighting will be supplied.

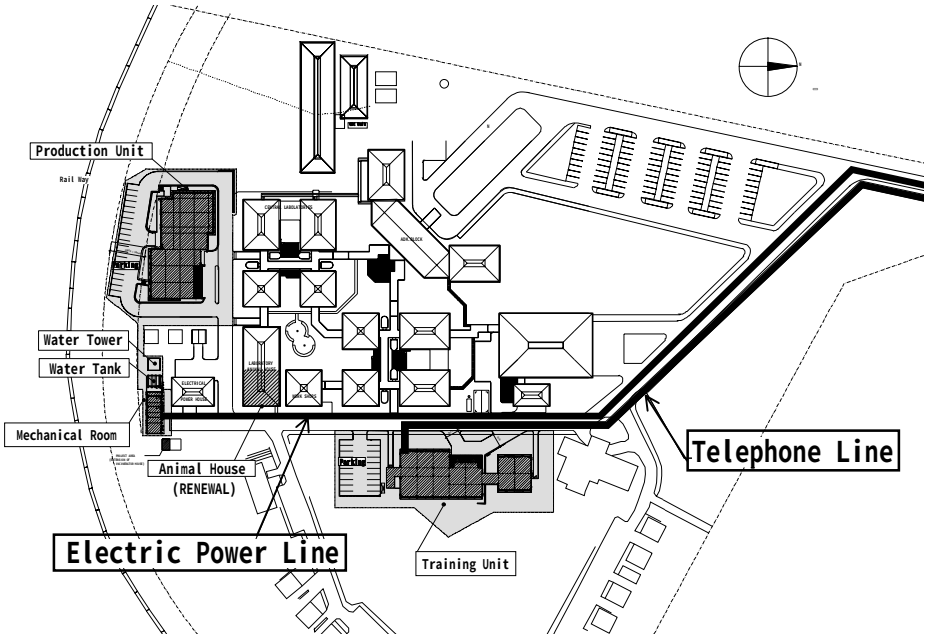



**Figure 2-9 Trunk Power Wiring Plan (leading them in the future)**

2) Emergency Electric Power Facility

Power failure occurs very frequently and voltage fluctuation is also large in Nairobi. Especially in the production unit and others, the power failure may degrade the quality of the product, and may bring the death of the animals for blood collection. So a diesel-powered generator of about 200kVA will be installed for the instruments for production 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 instruments for production, 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 capacity of this project's generator is enough for it and accordingly we will try to support the supply of electricity form the circuit of this project's emergency generator.

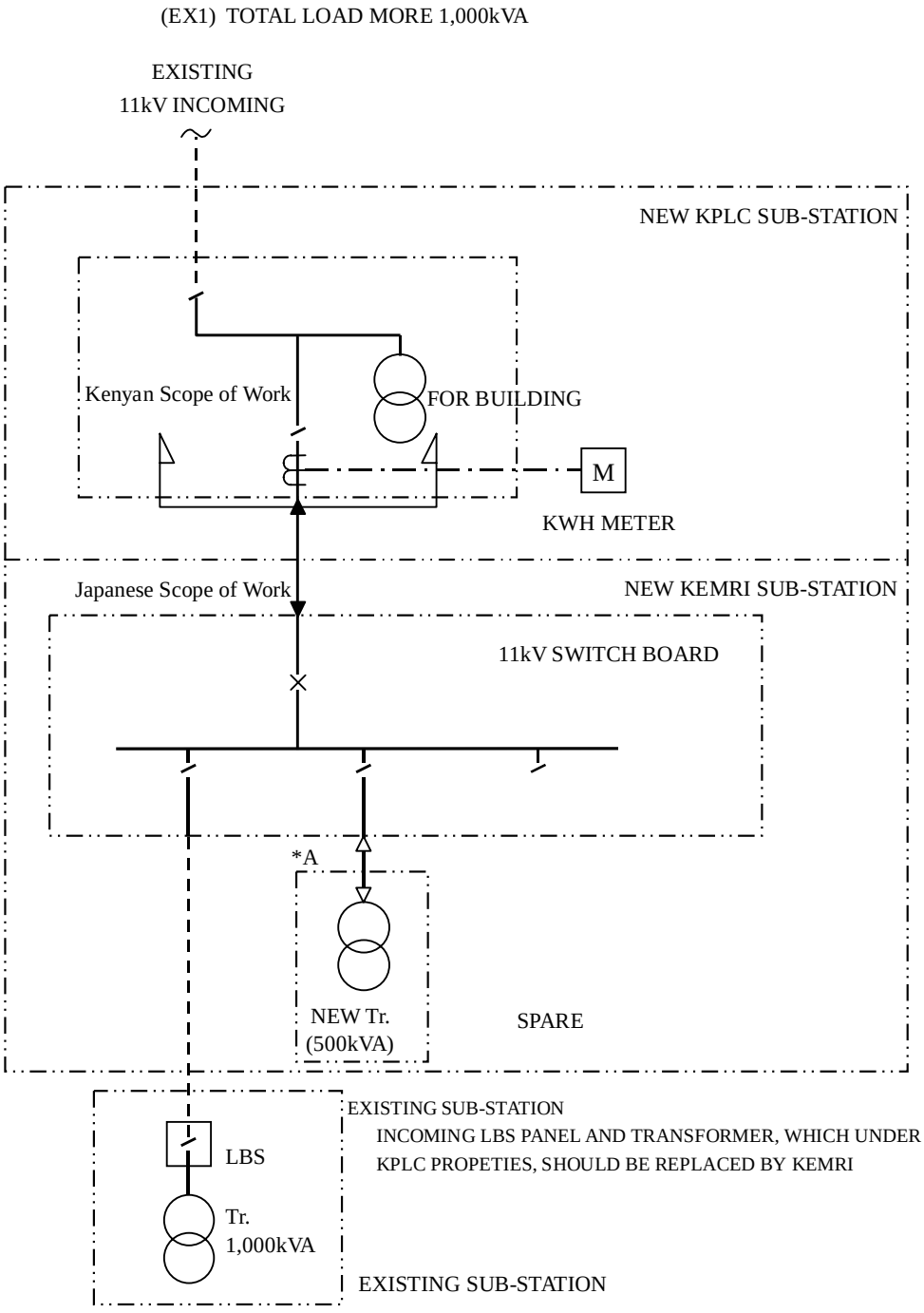



**Figure 2-10 One-line Wiring Diagram**

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 facility are supplied from the public utility power/generator distribution system.

4) Lighting and Receptacle

Fluorescent lamps will be used mainly as lighting equipment because of their relatively low maintenance cost. The illumination 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. In production unit and laboratories, wiring of receptacle will be set at the floor or the ceiling.

Two types of power receptacle are available: general purpose and emergency purpose. The receptacle for emergency purpose (including instruments for production) only will be connected with the circuit of the generator.

5) Lightning Arrester

A lightning arrester will be installed on the elevated water tank.

6) Telephone System

Due to the scale of the facilities, about 20 independent outside lines and about 70 inside lines are conceived. And in the system design, interlocking with the existing systems will be considered. The translator will be placed at the ground floor reception desk of the training unit because the receptionist will operate it. The switchboard will be placed in the server room.

The Japanese scope of work is limited to installation of cable rack and cable conduit pipe to the existing facilities for connecting with internal line.

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 receptionist will operate it. Speakers will be installed at appropriate places of the project facilities to enable paging and emergency announcing to the entire buildings. Microphones and public address device will be installed in the 1st floor for the training unit.

The emergency announcing will be done by person in the project facilities; therefore, an emergency announcing system will not be installed.

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 each equipment and to indicate alarms. And also the system will be designed to transmit alarms to all control rooms of the existing KEMRI facilities. However, the function of the above system will be in principle limited to monitoring and indication of alarms.

9) Manually-operated Fire Alarm System

The fire alarm system will be designed according to the BS standards or the Japanese standards. The receivers of the system will be placed in the administration room of the production unit and in the administration room of the training unit. The system will be designed to transmit alarms to all control rooms of the existing facilities.

10) LAN System

On the connection with LAN system of the existing facilities and LAN system within the project facilities, the Japanese scope of work is limited to installation of cable rack and cable conduit pipe.

11) Common TV Receiving Facility

The Japanese scope of work is limited to installation of conduit so that common TV receiving facility of satellite and surface TV broadcasting can be installed easily in the training unit after the completion of the facility.

(2) Mechanical Facility

1) Water Supply System

The water supply is restricted in Nairobi. So the trunk line will be newly branched from the primary side of HILL TOP Tank which is the water supply source of the KEMRI, and it will be tapped from the western road of the site (Mbagathi Way) to the project facilities exclusively to store water in the existing receiving tank and supply to the project receiving tank. The construction of this tapping will be included in the Kenyan scope of the work.

Considering the scale of the facility in the project, water supply will be 40$m^3$ / day. The capacity of the receiving tank is equivalent to one day's consumption to accommodate scheduled supply shortage, and the FRP tank will be placed aboveground close to the production unit. Water is pumped up to the elevated water tank with the lifting pump and it is supplied to the production unit and the training unit by weight.

In preparation of water failure, the conduit which comes to the existing receiving water tank from the deep well which was established by using 2nd KR will be connected with the receiving tank for the project facilities in the side of the KEMRI. For emergency, the branch line will be established to connect with the existing facilities.

2) Drainage

The soil water and the miscellaneous wastewater will be mixed outdoor and the wastewater pipe from the production unit will be connected with the existing drainage main pipe running near the dining hall in the southern boundary of the site. The wastewater pipe from the training unit will be connected with the existing drainage main pipe running along the northeast boundary of the site. A neutralisation tank will be installed for the drainage from the production unit and laboratory, and from it the wastewater is discharged to the sewer main pipe. An exclusive sterilization tank will be installed for wastewater from the animal house. After treatment, the wastewater is discharged to the sewer main pipe.

3) Hot Water Supply

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

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

- Production unit
  Washing room, quality control room, pantry
- Animal house
  Washing room, blood collection room
- Training unit
  Shower room, pantry

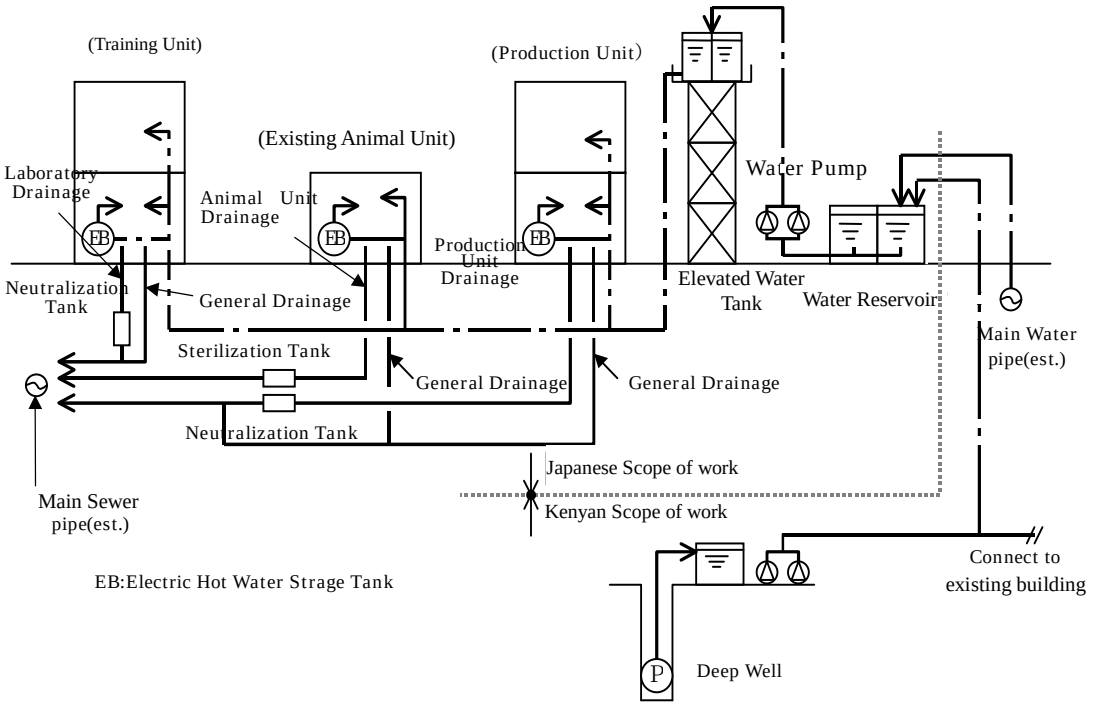



**Figure 2-11 Water Supply, Hot Water Supply, Drainage System Plans**

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 floor standing type or of wall hung type, with flush valves. Water and hot water will be supplied at the places where sterilization wash basin is required. And furthermore a mixing valve with automatic temperature control device will be installed. 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 will be equipped with traps as necessary.

5) Gas

The safety cabinets of the production unit and the laboratories will be supplied with LP gas by a semi-centrally supplied LP gas system.

6) Waste and Rubbish

General wastes are collected by the city authority of Nairobi 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 fire fighting system; therefore, these will be designed in conformity with the BS standards or Japanese standards. And considering the scale of the project facilities, manually-operated fire alarms, indoor hydrants and fire extinguishers will be installed exclusively.

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.

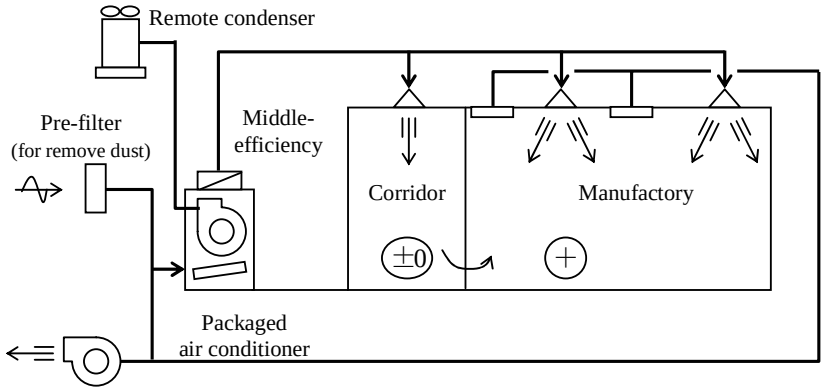
The rooms such as production unit and an animal house which require the cleanliness will be air-conditioned by the system with medium performance air filter (Filter efficiency of approximately 90% to bacteria) and the rooms will be maintained at positive pressures. In network rooms, data processing rooms, practical rooms and others where computers and the like are installed, the equipment of air-conditioner in each room will be considered.

Air conditioning will be done by air-cooled air-conditioning system which is popular at the location. Individual or semi-central systems will be used.

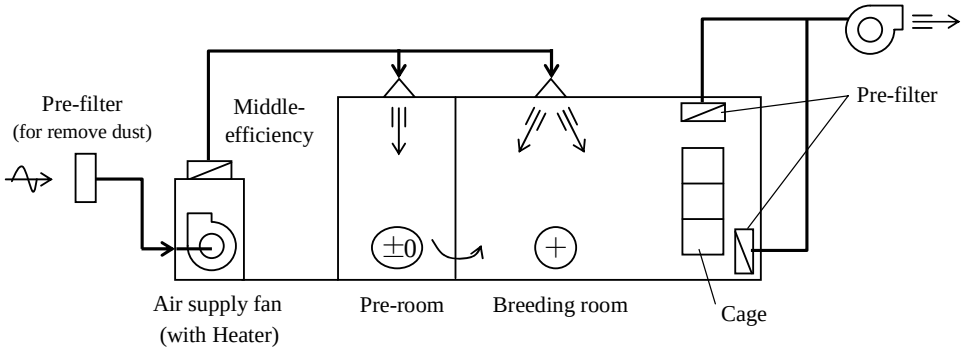
## Table 2-23 Air Conditioning System and Area

| Room Name | | | Cooling Semi-Central | Cooling Independent | Positive Pressure | Mechanical Ventilation | Medium-performance Air Filter |
|---|---|---|---|---|---|---|---|
| Production Unit | Production Area | Preparation Room (HIV・HEPCELL) | ○ | | ○ | | ○ |
| | | Manufacturing Room (HIV・HEPCELL) | ○ | | ○ | | ○ |
| | | Corridor | ○ | | ○ | | ○ |
| | | Material Room | | ○ | | | ○ |
| | | Dispense Room | | ○ | | | ○ |
| | | Washing Room | | ○ | | | |
| | | Packing Room | | ○ | | | |
| | | Labelling Room | | ○ | | | ○ |
| | Administration Area | Quality Control Room | | ○ | | | ○ |
| Animal House | | Quarantine Room | | | ○ | ○※ | ○ |
| | | Breeding Room | | | ○ | ○※ | ○ |
| | | Rabbits, Guinea Pigs Room | | | ○ | ○※ | ○ |
| | | Blood Collection Room | | | ○ | ○※ | ○ |
| | | Washing Room | | | | ○ | |
| | | Preparation Room | | | | ○ | |
| | | Office | | | | ○ | |
| Training Unit | | Lab 1 | | ○ | | | |
| | | Microscope Room | | ○ | | | |
| | | Preparation Room | | ○ | | | |
| | | Lecture Room (1) (2) (3) | | ○ | | | |
| | | Data Processing Room | | ○ | | | |
| | | Network Server Room | | ○ | | | |

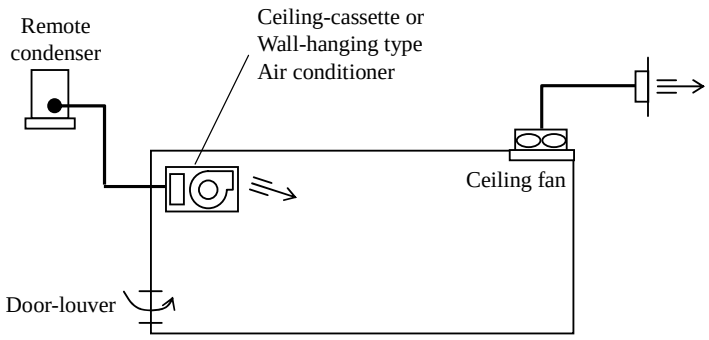
※ The room is not air-conditioned, but needs heating system.




Production unit
(Semi-central air-conditioning system)




Animal House
(Semi-central air-conditioning system)




Training unit and other
(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

To secure long-term waterproof performance and to form the shape which is in harmony with the surrounding buildings (roof pitch of 3/10), the roof will be designed to be a slanted roof whose material is concrete slab and asphalt roofing will be spread. The facility will be roofed with tiles to prevent the asphalt roofing from being damaged by ultraviolet rays. 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 mainly used for the existing buildings, and is easy to maintain. Portions partitioned by beam columns will be filled by the masonry structure using block or brick 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 for general rooms. Dust- proof coating will be given for stores. Porcelain tiles will be used for such areas entrance hall and its surroundings where traffic of persons is busy, and places equipped with a water supply such as rest rooms, and the material which makes us facilitate cleaning will be used. PVC sheet will be used for the production clean area to secure high standards of cleanliness.

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 porcelain tiles.

3) Ceiling

Grid system ceiling which is generally used locally will be used. In the production clean area which will be maintained at positive pressure, the traditional method of construction (putting rock wool sound insulating board on plasterboard base) which is airtight will be used.

4) Doors and Windows

Aluminium sashes are used for exterior fixtures (for windows) for their water-tightness, air-tightness and weather proof. The doors facing the exterior will be of aluminium or steel. Of interior fixtures, those doors which will be used in the production clean area will be airtight aluminium 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 following table.

**Table 2-24 Finishing Material and Method for Application**

| Building element | Method applied locally (including the existing building) | Method adopted | Rationale for adoption |
|---|---|---|---|
| Roof | Slanted tile roof (asphalt roofing)<br>Flat roof (gravel-held asphalt waterproofing) | Slanted concrete slabroof (asphalt roofing, tile)<br>Flat roof (gravel-held asphalt waterproofing) | This method is highly waterproof and becomes popular locally, and relatively easy to maintain after completion. |
| Exterior wall | Masonry Construction (Nairobi stone)<br>Mortared and paint finished | Masonry Construction (Nairobi stone)<br>Mortared and paint finished | This method is generally adopted locally and they are accustomed to the maintenance. |
| Floor | Tile<br>Terrazzo block<br>Terrazzo finish at site | Tile<br>Terrazzo block<br>PVC sheet (welding method) | This material is generally used locally and easy to maintain and clean after completion.<br>PVC sheet is used to secure the high standards of cleanliness of production unit. |
| Interior wall | Tile<br>Paint | Tile<br>Paint | These materials are generally used locally and easy to maintain after completion. |
| Ceiling | Grid system ceiling (rock wool sound insulating board)<br>Traditional method (putting rock wool sound insulating board on plasterboard ) | Grid system ceiling (rock wool sound insulating board)<br>Traditional method (putting rock wool sound insulating board on plasterboard) | These materials are generally used locally and easy to maintain after completion.<br>The ceilings are covered with boards to increase the air-conditioning efficiency, cover piping and the likes, and to prevent dust from accumulating. |
| Doors and Windows | Aluminium made<br>Steel made<br>Wooden | Aluminium made<br>Steel made<br>Wooden | These are generally used locally.<br>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 matters examined in "Overall Project Description (Study of the Request)", the purpose of equipment, judgement of necessity and adequacy are developed as shown in the following table. The number of equipment in each room is the study plan of arrangement.

**Table 2-25 Study on the Purpose of the Equipment Requested**

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| HEPCELL Ⅱ and HIV PA kit production | | | | |
| · HEPCELL Ⅱ preparation room | | | | |
| 1 | Refrigerated centrifuge | 1 | Used for washing of raw materials | Equipment indispensable to manufacture of the blood test kit |
| 2 | Refrigerator | 1 | Used for concentration of plasma after fibrin has been removed | Equipment indispensable to manufacture of the blood test kit |
| 3 | Fraction collectors | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 4 | pH meter | 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 | Used to stir plate-shaped specimens like the blood test kit | Equipment indispensable to manufacture of the blood test kit |
| 6 | Peristaltic pumps | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 7 | Affinity chromatography stand | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 8 | Affinity chromatography column | 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 stinger | 1 | Used for various works | Essential equipment |
| 10 | Safety cabinet | 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 | Used to refine the Hobs antigen from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 12 | Plasma separator | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 13 | Signifier | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |
| 14 | Vortex mixer (mixer for test tube) | 1 | Used to mix matters in the test tube in various operations | Essential equipment |
| 15 | Benches | 2 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 16 | Stools | 2 | Used for various works | Essential equipment |
| · HIV/PA preparation room | | | | |
| 1 | Vortex mixer | 1 | Used to stir test tubes for various works | Essential equipment |
| 2 | Peristaltic pumps | 1 | Used when proteins are removed from human plasma | Equipment indispensable to manufacture of the blood test kit |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| 3 | Benches | 1 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 4 | Stools | 2 | Used for various works | Essential equipment |
| 5 | Safety cabinet | 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 | Used for dispensing of 1mℓ or less | Equipment indispensable to manufacture of the blood test kit |
| ・ Manufacturing room (equipment for production of Hepcell kit) | | | | |
| 1 | Water bath | 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 | Used for preparation of HBs antibody and cleaning of total sheep blood | Equipment indispensable to manufacture of the blood test kit |
| 3 | Benches | 2 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 4 | Stools | 2 | Used for various works | Essential equipment |
| 5 | Haematocrit centrifuge | 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 | Used for weighing minute specimens | Essential equipment |
| 7 | Suction unit | 1 | Used for various works | Equipment indispensable to manufacture of the blood test kit |
| ・ Manufacturing room (equipment for production of PA kit) | | | | |
| 1 | Water bath | 1 | Used for thawing of frozen specimens and slow heating of specimens | Essential equipment |
| 2 | Automatic pipette aid - rechargeable | 1 | Used for dispensing of 1mℓ or less | Equipment indispensable to manufacture of the blood test kit |
| 3 | Mechanical crimpier | 1 | Crimpier for vials | Essential equipment |
| 4 | Benches | 2 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 5 | Stools | 2 | Used for various works | Essential equipment |
| 6 | Refrigerated centrifuge | 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 | 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 | 3 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 3 | Stools | 3 | Used for various works | Essential equipment |
| 4 | Computer | 1 | Used to store the records and the likes in the quality control | Equipment indispensable to accuracy control of the blood test kit |
| 5 | Printer (black and white) | 1 | Used to store the records and the likes in the quality control | Equipment indispensable to accuracy control of the blood test kit |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| 6 | Plate mixer | 1 | Used to stir plate-shaped specimens like the blood test kit | Essential equipment |
| 7 | Automatic pipette aid - rechargeable | 1 | Used for dispensing of 1mℓ or less | Essential equipment |
| 8 | Micro plate washer | 1 | Used for accuracy control test of the blood test kit | Equipment indispensable to accuracy control of the blood test kit |
| 9 | Micro plate reader | 1 | Used with Micro plate washer | Equipment indispensable to accuracy control of the blood test kit |
| 10 | Deep freezer (-20°C) | 1 | Used for storing specimens of antigens and antibodies used for quality control | Equipment indispensable to accuracy control of the blood test kit |
| 11 | Incubator with rocker | 1 | Used for quality control test of the blood test kit | Essential equipment |
| 12 | Camera illuminator & stand | 1 | Used for making photographic records of the accuracy of the blood test kit | Equipment indispensable to accuracy control of the blood test kit |
| 13 | Bench top centrifuge | 1 | Used for isolation of components in specimens | Essential equipment |
| 14 | Electronic balance | 1 | Used for weighing minute specimens | Essential equipment |
| 15 | Spectrodensitometer | 1 | Used for purity certification of the blood test kit | Equipment indispensable to accuracy control of the blood test kit |
| 16 | pH meter | 1 | Used for confirming pH values of blood diluents and others | Equipment indispensable to accuracy control of the blood test kit |
| 17 | Refractometer | 1 | Used for confirming concentrations of various solutions in the blood test kit | Equipment indispensable to accuracy control of the blood test kit |
| 18 | Spectrophotometer | 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 | Refrigerator | 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 |
| 2 | Ultra low deep freezer | 2 | Used for cyropreservation of raw materials for manufacture (human and animal blood) | Equipment indispensable to manufacture of the blood test kit |
| 3 | Lockable cabinets | 1 | Used for storing consumables of the ultrapure water manufacturing unit | Essential equipment |
| · Dispense room | | | | |
| 1 | Lyophilizer | 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 | 2 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 3 | Benches for dispense | 2 | Used to place various pieces of equipment, used for various works | Essential equipment |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| 4 | Automatic pipette aid - rechargeable | 1 | Used for dispensing of 1mℓ or less | Equipment indispensable to manufacture of blood test kit |
| 5 | Plate mixer | 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 | Used for disinfecting various pieces of manufacturing equipment | Essential equipment |
| 2 | Bench | 1 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 3 | Stool | 1 | Used for various works | Essential equipment |
| 4 | Pass box | 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 | 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 | Water distiller | 1 | Used to make wash water, solution for dilution, and solution for dissolution which are essential in production | Equipment indispensable to manufacture of the blood test kit |
| 7 | Ice making machine | 1 | Used for various works | Equipment indispensable to manufacture of blood test kit |
| ・ Locker Room | | | | |
| 1 | Lockers | 4 | Used for changing clothes for manufacturing works of the blood test kit | Essential equipment |
| ・ Labeling room | | | | |
| 1 | Bench | 1 | Used for placing the label print/apply unit and for labelling operation | Essential equipment |
| 2 | Stools | 2 | Used for labelling operation | Essential equipment |
| ・ HIV/PA store | | | | |
| 1 | Refrigerator | 1 | Used for storing parts (vials, etc.) before and after labelling | Equipment indispensable to manufacture of the blood test kit |
| ・ HEPCELL store | | | | |
| 1 | Refrigerator | 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 | Used for preparation for shipping of the blood test kit | Essential equipment |
| 2 | Lockable cabinets | 2 | Used for storing containers, etc. of the blood test kit | Essential equipment |
| 3 | Cabinets | 2 | Used for storing shipping materials, etc. | Essential equipment |
| 4 | Refrigerator | 2 | Used for storing the blood test kit before shipping | Equipment indispensable to manufacture of the blood test kit |
| ・ Office | | | | |
| 1 | Computers | 2 | Used for manufacturing control, tabulation, report making | Equipment indispensable to systematic manufacturing control |
| | Printer (black and white) | 1 | Used for manufacturing control, tabulation, report making | |
| 2 | Desks | 5 | Used for various works | Essential equipment |
| 3 | Chairs | 5 | Used for various works | Essential equipment |
| 4 | Photocopy machine, black and white | 1 | Used for manufacturing control, tabulation, report making | Equipment indispensable to systematic manufacturing control |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| ・ Staff room | | | | |
| 1 | Meeting table, chair | 1 | Used for meetings, for data and material compiling | Essential equipment |
| ・ Production unit chief's room | | | | |
| 1 | Desk | 1 | Used for various works | Essential equipment |
| 2 | Chair | 1 | Used for various works | Essential equipment |
| ・ Marketing manager room | | | | |
| 1 | Desk | 1 | Used for various works | Essential equipment |
| 2 | Chair | 1 | Used for various works | Essential equipment |
| ・ Secretary's room | | | | |
| 1 | Desk | 1 | Used for various works | Essential equipment |
| 2 | Chair | 1 | Used for various works | Essential equipment |
| Animal house attached to the production unit | | | | |
| ・ Washing room | | | | |
| 1 | Autoclave | 1 | Used for disinfecting equipment | Water washing is enough for the cage and autoclave is not studied for this purpose. |
| 2 | Bench | 1 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 3 | Stools | 2 | Used for various works | Essential equipment |
| 4 | Breeding tool set | 1 | Equipment for animal raising, the cutter used for preparing feed for example | Essential equipment |
| ・ Blood collection room | | | | |
| 1 | Bench | 1 | Used to place various pieces of equipment, used for various works | Essential equipment |
| 2 | Stool | 2 | Used for various works | Essential equipment |
| 3 | Scale | 1 | Used for weighing specimens | Essential equipment |
| ・ Breeding room | | | | |
| 1 | Cage stands | 4 | Used for installation of animal cages will be installed | Equipment indispensable to manufacture of the blood test kit |
| 2 | Breeding cages | 125 | Cages for guinea pigs and rabbits, used for raising animal to collect the antibody | Equipment indispensable to manufacture of the blood test kit |
| ・ Office | | | | |
| 1 | Desk, Chair | 1 | Used for such operations as blood collection | Essential equipment |
| ・Locker room | | | | |
| 1 | Lockers | 2 | Used for changing clothes for manufacturing works of the blood test kit | Essential equipment |
| 1-2 Training unit | | | | |
| ・ Lecture room | | | | |
| 1 | Student desks and Chairs for trainees | 48 | Used for training at KEMRI | Essential equipment |
| 2 | Chairs | 72 | Used for training at KEMRI | Essential equipment |
| 3 | Lecturer tables | 3 | Used for training at KEMRI | Essential equipment |
| 4 | Visual-audio system | 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 | 1 | Used for training at KEMRI | Equipment needed for presenting research activities and training activities |
| 6 | Overhead projectors | 1 | Used for training at KEMRI | Equipment needed for presenting research activities and training activities |
| ・ Lab 2 (Parasite) | | | | |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| 1 | Laboratory tables and 4 chairs | 4 | Used for training practice | Essential equipment |
| 2 | Binocular microscope | 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 | Used for training on observation of minute specimens | Equipment necessary for effective training on observation |
| 4 | Dissecting binocular microscope (×0.5 - 30, sliding) | 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) | 1 | Used for obtaining supernatant or precipitate from various specimens | Essential equipment |
| 6 | Micrometers | 16 | Used for measuring dimensions of minute specimens | Essential equipment |
| 7 | Water baths | 1 | Used for thawing of frozen specimens and slow heating of specimens | Essential equipment |
| 8 | Incubators | 1 | Used for culturing aerobic bacteria | Essential equipment |
| 9 | Cabinets for storage of microscopes and materials | 4 | Used for storing microscopes | Microscopes must be stored in special storing boxes when not in use. |
| 10 | Bench | 1 | For instructors | Essential equipment |
| 11 | Stool | 1 | For instructors | Essential equipment |
| ‧ Lab 1 (Infection) | | | | |
| 1 | Water baths , small | 1 | Used for thawing of frozen specimens and slow heating of specimens | Essential equipment |
| 2 | Shakers | 3 | Used to stir specimens contained in such vessels as test tube | Essential equipment |
| 3 | Electric pipette, charging type | 5 | Used for weighing minute liquid specimens | Essential equipment |
| 4 | Pipettes | 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 | 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 | 1 | Used for culturing aerobic bacteria | Essential equipment |
| 7 | pH meter | 1 | Used for preparation of reagents and others | Essential equipment |
| 8 | Spectro photometer | 1 | Used for preparation of reagents, identification of components of specimens | Essential equipment |
| 9 | Magnet stirrers | 2 | Used to stir plate-shaped specimens like the blood test kit | Essential equipment |
| 10 | Electronic balances (until 31g) | 1 | Used for weighing minute specimens, unit 1 mg | Essential equipment |
| 11 | Electronic balances (until 310g) | 1 | Used for weighing a small amount of specimens, unit 100 mg | Essential equipment |
| 12 | Balance | 3 | Used for weight specimens, unit gram | Essential equipment |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| 13 | Laboratory tables and 4 chairs | 4 | Used for training practice | Essential equipment |
| 14 | Microscopes for cell cultures | 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 | Used for culturing anaerobic bacteria | Essential equipment for such training as culture practice |
| 16 | Clean benches and aspirators | 2 | Used for preparation of specimen, confirmation of specimen after culturing after culturing, for training | Essential equipment for such training as culture practice |
| 17 | Bench | 1 | For instructors | Essential equipment |
| 18 | Stool | 1 | For instructors | Essential equipment |
| ・Preparation room | | | | |
| 1 | Ultra low deep freezer | 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 | Used to crush parasite specimens or to stir liquid specimens | Essential equipment |
| 3 | Magnet stirrers | 1 | Used to stir plate-shaped specimens like the blood test kit | Essential equipment |
| 4 | Clean bench | 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 | Used for obtaining supernatant or precipitate from various specimens | Essential equipment |
| 6 | Water bath | 1 | Used for thawing of frozen specimens and slow heating of specimens | Essential equipment |
| 7 | Sample stock cabinet | 2 | Used for storing specimens that can be kept at ambient temperature | Essential equipment |
| 8 | Autoclave | 1 | Used for disinfecting used equipment and used specimens, etc. | Essential equipment |
| 9 | Bench | 1 | Used for various works | Essential equipment |
| ・ Dark room | | | | |
| 1 | Fluorescent microscopes | 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 | Bench | 1 | Used for fluorescent microscope operation | Essential equipment |
| 3 | Stool | 1 | Used for fluorescence microscope operation | Essential equipment |
| ・ Microscope room | | | | |
| 1 | Bench | 1 | Used for operation of various microscopes | Essential equipment |
| 2 | Stools | 2 | Used for operation of various microscopes | Essential equipment |
| 3 | Dissecting microscope with camera | 1 | Used for preparation of materials for training | Essential equipment for preparation of specimens, etc. |
| 4 | Microscope for cell culture with camera | 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 |

| No. | Description | Q'ty of plan | Purpose of the use | Judgement on necessity and adequacy |
|---|---|---|---|---|
| ・ Data processing room | | | | |
| 1 | Chairs and tables (for 2 persons) | 8 | For trainees | Essential equipment |
| 2 | Lecturer's table and chair | 1 | For lecturers | Essential equipment |
| 3 | Computers for trainees | 8 | Used for training on report preparation, etc. | This item is studied in this Equipment Plan.<br>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 | 1 | Used for training on report preparation, etc. | This item is studied in this Equipment Plan.<br>The computer is necessary in research and training in KEMRI, and the computer is used for training on such skills. |
| ・ Network server room | | | | |
| 1 | Computers | 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 | Used for storing computer-related equipment | Essential equipment |
| 3 | Desk and chairs | 4 | Used for computer works and other works | Essential equipment |
| 4 | Cabinets for computer data | 1 | Used for storing such memory devices as FDs and CD-Rs | Essential equipment |
| 5 | Cabinets for administrative documents | 1 | Used for storing books, literature and printed documents | Essential equipment |
| ・ Training unit director room, Secretary’s room, Meeting room, Office, Visitors office | | | | |
| 1 | Office desks and chairs | 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 chair | 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 | Used for storing training records or prepared materials | Essential equipment |
| 4 | White boards | 2 | Used for discussions on training plan and entering schedules, etc. | Essential equipment |
| 5 | Photocopy machine (black and white) | 1 | Used for printing training records or materials | Equipment necessary for preparation of written materials for training |
| 6 | Printing machine (colour) | 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 2-26 and the specification for major equipment is also shown in the Table 2-27. The arrangement plan of each room in "Table 2-17 Study of Requested Equipment" and "Table 2-25 Study on the Purpose of the Equipment Requested" is created based on the number of the following equipment.

**Table 2-26 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 | 2 | 5 | 24 |
| 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 |
| 39 | Storage Cabinet D | | | 4 | 4 |
| 40 | Storage Cabinet E | | | 4 | 4 |

| No. | Description | Production unit | Animal house | Training unit | Total |
|---|---|---|---|---|---|
| 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 | 2 | | 1 | 3 |
| 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 2-27 Specification of Major Equipment**

| No. | Description | Main Specification |
|---|---|---|
| 1 | Water distiller/deionizer | RO + deion water<br>Capacity：10litre/h |
| 2 | Lyophilizer | Capacity：8 litre/time or more |
| 3 | Ultra Centrifuge | Zonal rotor<br>Max rpm：32,000 |
| 4 | Refrigerated Centrifuge | 250cc×4 bottle |
| 5 | Autoclave | Capacity: less than 200 l (Animal house), less than 50 l (Others)<br>Including preset temperature of 121℃ |
| 6 | Safety Cabinet | Width inner : About 100cm、<br>Inner material ：stainless steel |
| 7 | Clean Bench | Width inner 120cm、<br>Inner material ：stainless steel |
| 8 | Incubator | Capacity：150 litre、<br>Temperature range：room＋5℃～60℃ |
| 9 | Refrigerator | Capacity：300 litre、<br>Temperature range：＋2℃～14℃ |
| 11 | Ultra Low Deep Freezer | Capacity：80 litre、<br>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 |
| 30 | Photocopy machine (black and white) | A3 |
| 33 | Computer projectors and note type computers | CPU：Pentium Ⅲ、projector for personal computer |
| 35 | Audio-video equipment | Monitor, Video camera, Videocassette recorder |
| 46 | Demonstrating microscope | Type：Trinocular, with light source, CCD camera, monitor |
| 47 | Dissecting binocular microscope | Type：Binocular, with light source,<br>Objective lens：0. 67×,1×,2×,4× |
| 48 | Binocular microscope | Type：Binocular, with light source,<br>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 KEMRI HIV-1 PA kit and KEMRI HEPCELL Ⅱ kit are set as follows.

**Table 2-28 Kinds of Reagents Constituting One Kit**

[KEMRI HIV-1 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.

[KEMRI HEPCELL Ⅱ 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 from 50,000 to 800,000 tests per year, is divided stepwise. The number of reagents to be produced for one manufacturing processing for each stage is shown in Table 2-29.

**Table 2-29 Production Number for One Manufacturing Processing**

[KEMRI HIV-1 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 |
|---|---|---|---|---|---|
| 50,000 tests or less | 4vial×76kit =302vial | 4vial×76kit =304vial | 1 bottle×76kit =76 bottles | 1 bottle×76kit =76 bottles | 1vial×76kit =76 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 |

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

[KEMRI HEPCELL Ⅱ 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 2-30 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 2-30 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 |

As a grant aid, the production system in which the annual production number of KEMRI HIV-1 PA kit is 50,000 tests and that of KEMRI HEPCELL II kit is 400,000 tests will be designed. And according to the increase of demand, the number of test kit which is shown in the above table can be produced by the increase of annual production times and the addition of necessary equipment (screened parts).

Figures 2-13 and 2-14 in the following pages show process flows of KEMRI HIV-1 PA kit and KEMRI HEPCELL Ⅱ kit.

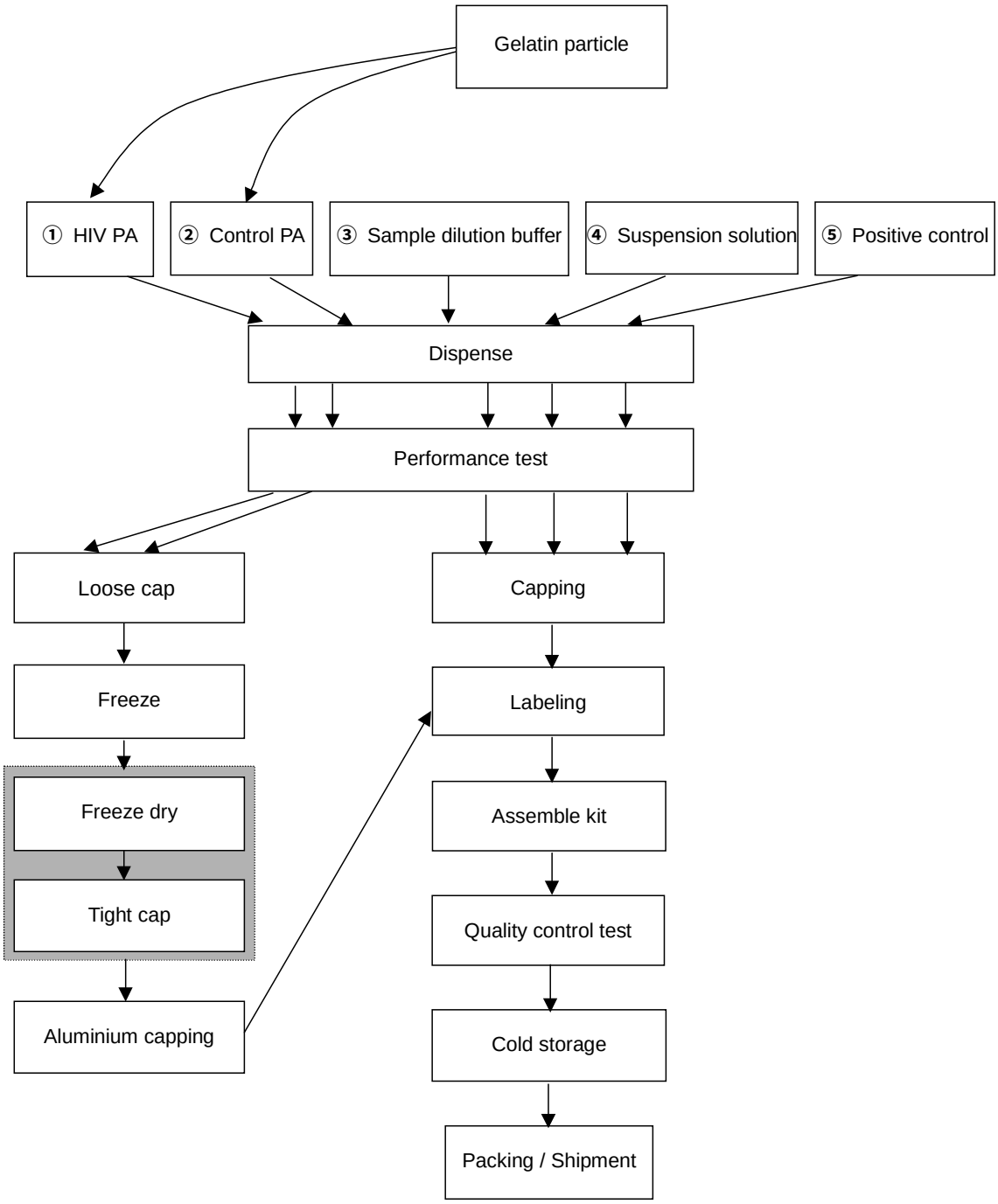



**Figure 2-13　Process Flow（KEMRI HIV-1 PA kit）**

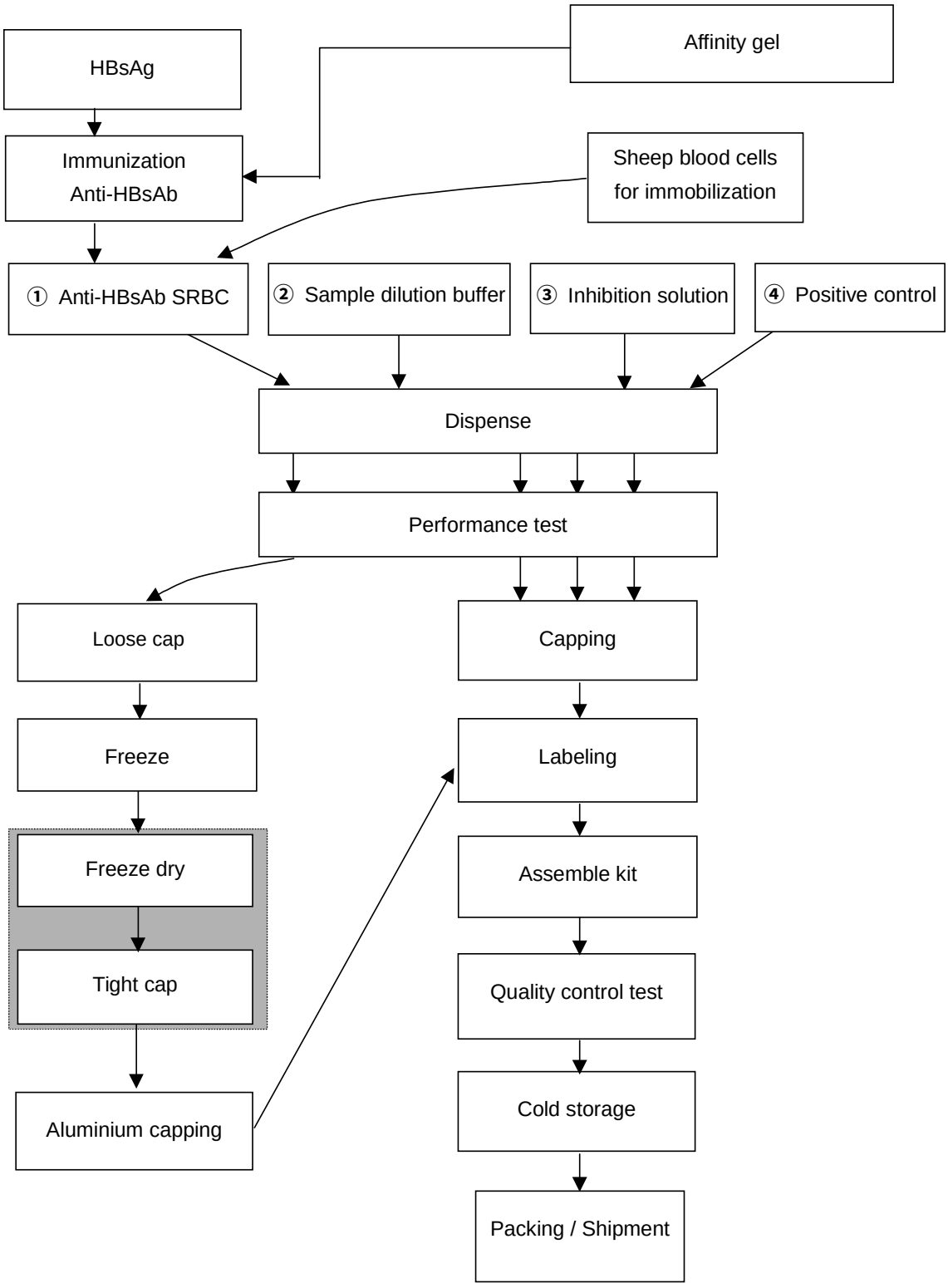



**Figure 2-14　Process Flow（KEMRI HEPCELLⅡ kit）**

(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 2-31 Cost of Blood Screening Kits Estimated by KEMRI**

KShs/test

| | KEMRI HIV-1 PA kit per test | KEMRI HEPCELL Ⅱ kit per test |
|---|---|---|
| Manufacturing cost estimated by KEMRI | 50.00 | 25.28 |

The manufacturing cost which the study team estimated based on the following conditions by referring to it is as follows.

Conditions for calculation

- The annual number of production of KEMRI HIV-1 PA kit will be 1,200, and that of KEMRI HEPCELL Ⅱ kit will be 2,000.
- 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 KEMRI HIV-1 PA kit will be imported from the private company of Japan.
- Vials of the same specifications will be used for both kits. Presently, one KEMRI HEPCELL Ⅱ kit consists of one 5-mℓ vial, but both kits will consist of two 2.5-mℓ vials.

**Table 2-32 Estimation of Manufacturing Costs**

KShs/test

| | KEMRI HIV-1 PA kit per test | KEMRI HEPCELL Ⅱ kit per test |
|---|---|---|
| Manufacturing cost estimated by the study team | 48.32 | 23.86 |

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 2-33 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 2-34 List of Drawings**

| | Unit Name | Drawing Name | Scale | Page |
|---|---|---|---|---|
| 1 | Building Layout | Site Plan | 1/1000 | 87 |
| 2 | Production Unit | Production Unit Ground Floor Plan | 1/200 | 89 |
| 3 | | Production Unit First Floor Plan | 1/200 | 91 |
| 4 | | Production Unit Elevation | 1/200 | 93 |
| 5 | | Production Unit Section | 1/200 | 95 |
| 6 | Animal Unit | Animal Unit Ground Floor Plan | 1/200 | 97 |
| 7 | | Animal Unit Ground Elevation, Section | 1/200 | 99 |
| 8 | Training Unit | Training Unit Ground Floor Plan | 1/200 | 101 |
| 9 | | Training Unit First Floor Plan | 1/200 | 103 |
| 10 | | Training Unit East and West Elevation | 1/200 | 105 |
| 11 | | Training Unit North and South Elevation | 1/200 | 107 |
| 12 | | Training Unit Section | 1/200 | 109 |
| 13 | Mechanical Unit | Mechanical Unit Ground Floor Plan, Elevation and Section | 1/200 | 111 |

TO RELOCATED THE CDC'S EXISTING SECURITY GATE BY KEMRI

CDC Unit

Production Unit

Rail Way

Project Area

PARKING
20 CARS

CENTRAL LABOLATORIES

MDL BLOCK

KEMRI EXISTING FACILITIES

Water Tank

15,420
50feet

Water Tower

Animal Unit

LABORATORY
ANIMAL HOUSE

ELECTRICAL
POWER HOUSE

WORK SHOPS

Project Aera

M and E Unit

TO RELOCATED THE EXISTING LABORATRY WASTE BY KEMRI

TO RELOCATED THE EXISTING GAS TANK BY KEMRI

TO RELOCATED THE EXISTING SHEEP SHED BY KEMRI

PARKING
20 CARS

Training Unit

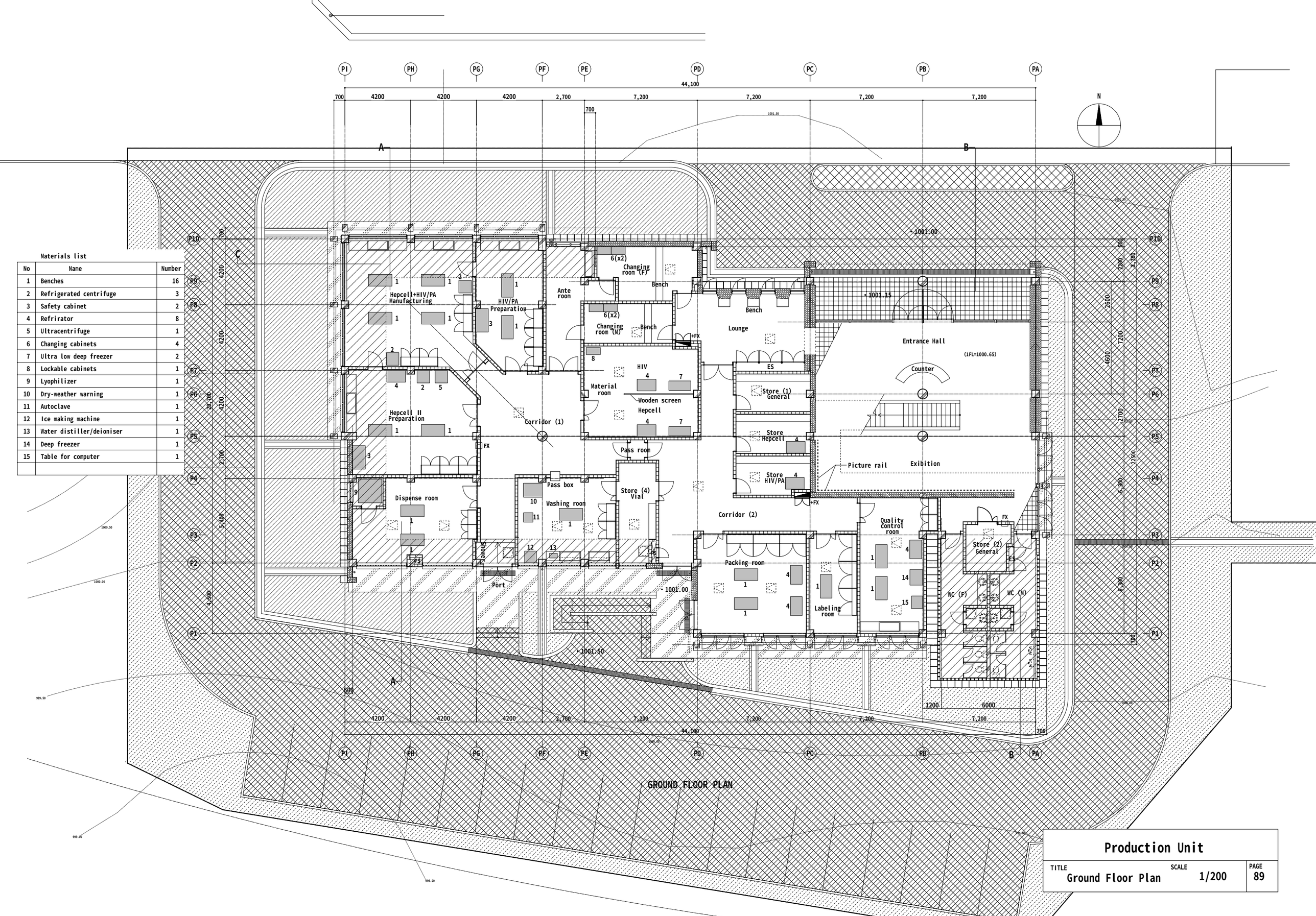
Project Aera

N

| | |
|---|---|
| KEMRI Nairobi Site | |
| TITLE: Layout Plan | SCALE: 1/1000 |
| PAGE: 87 | |

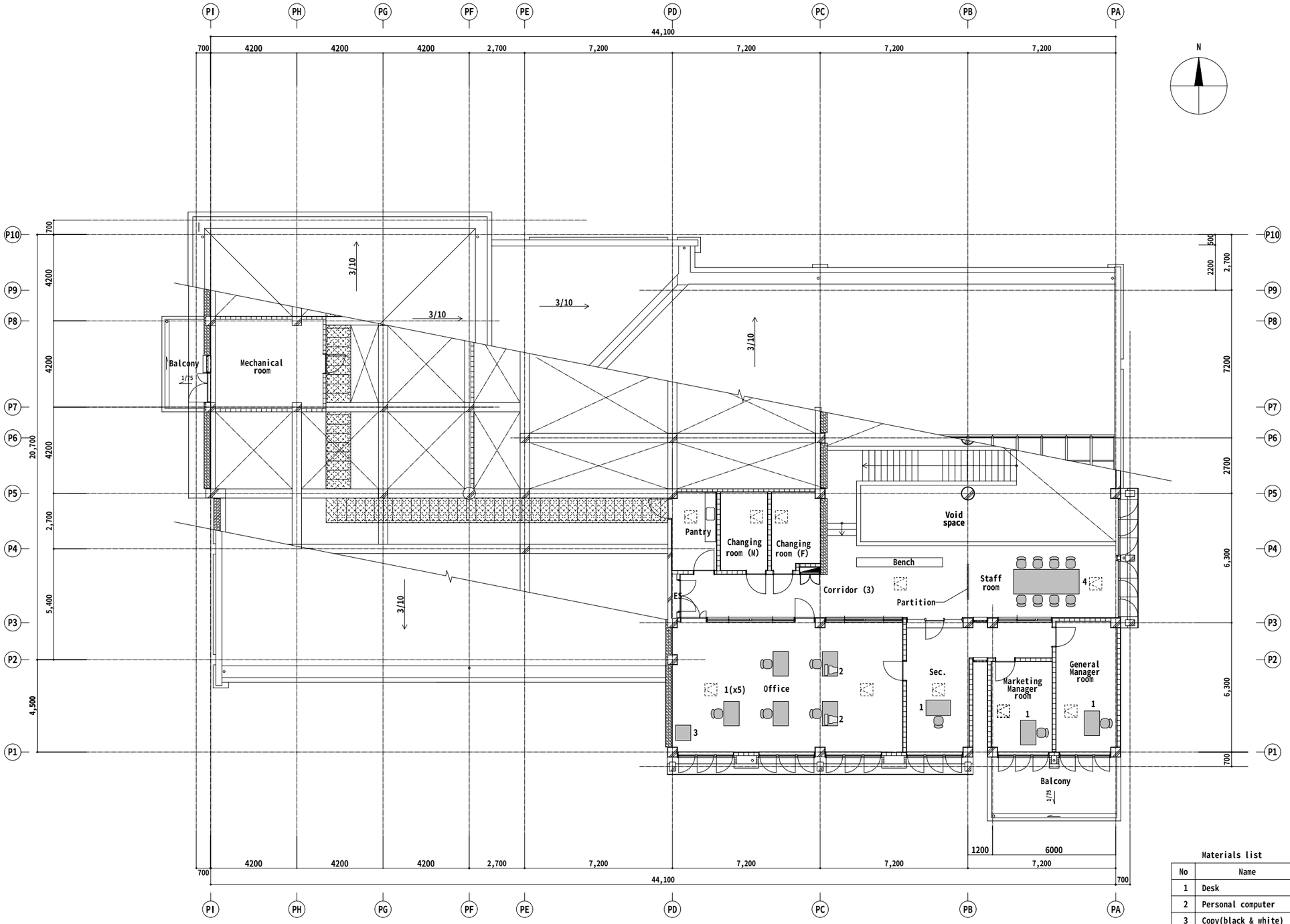
Materials list

| No | Name | Number |
|---|---|---|
| 1 | Benches | 16 |
| 2 | Refrigerated centrifuge | 3 |
| 3 | Safety cabinet | 2 |
| 4 | Refrirator | 8 |
| 5 | Ultracentrifuge | 1 |
| 6 | Changing cabinets | 4 |
| 7 | Ultra low deep freezer | 2 |
| 8 | Lockable cabinets | 1 |
| 9 | Lyophilizer | 1 |
| 10 | Dry-weather warning | 1 |
| 11 | Autoclave | 1 |
| 12 | Ice making machine | 1 |
| 13 | Water distiller/deioniser | 1 |
| 14 | Deep freezer | 1 |
| 15 | Table for computer | 1 |
| | | |




**Production Unit**

| TITLE | SCALE | PAGE |
|---|---|---|
| Ground Floor Plan | 1/200 | 89 |



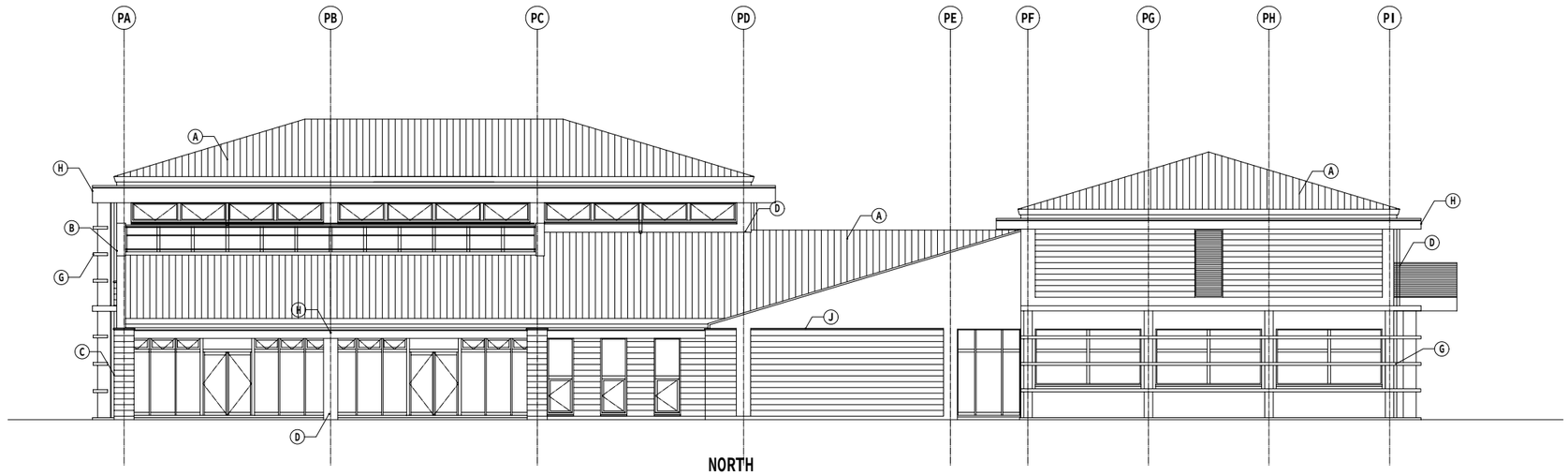

FIRST FLOOR PLAN

Materials list

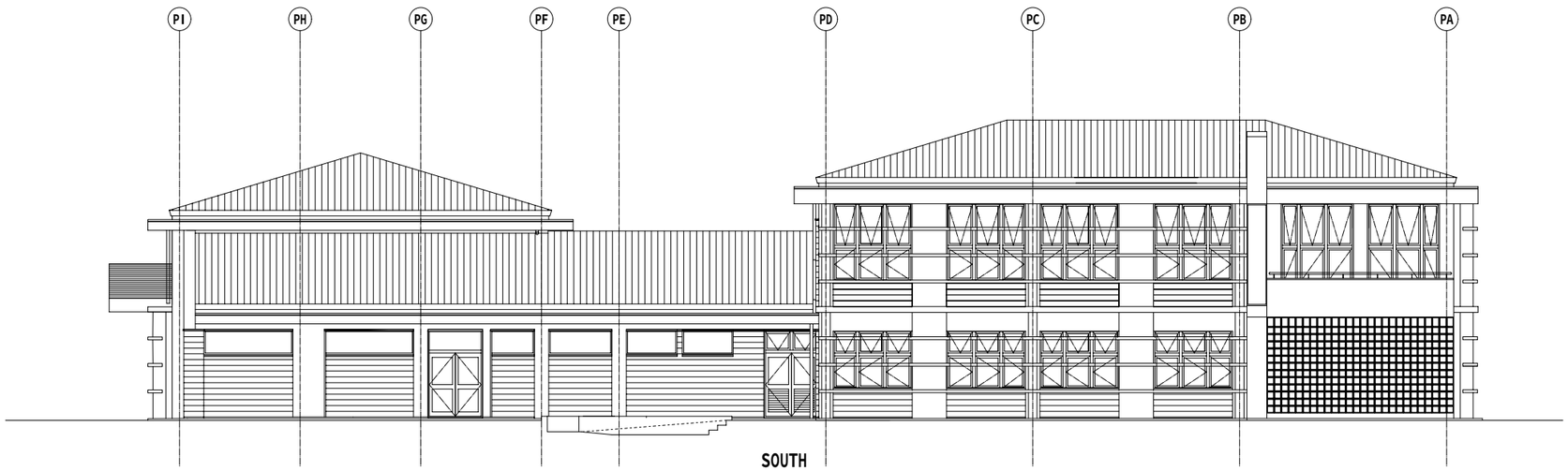
| No | Name | Number |
|---|---|---|
| 1 | Desk | 8 |
| 2 | Personal computer | 2 |
| 3 | Copy(black & white) | 1 |
| 4 | Table | 1 |
| | | |

**Production Unit**

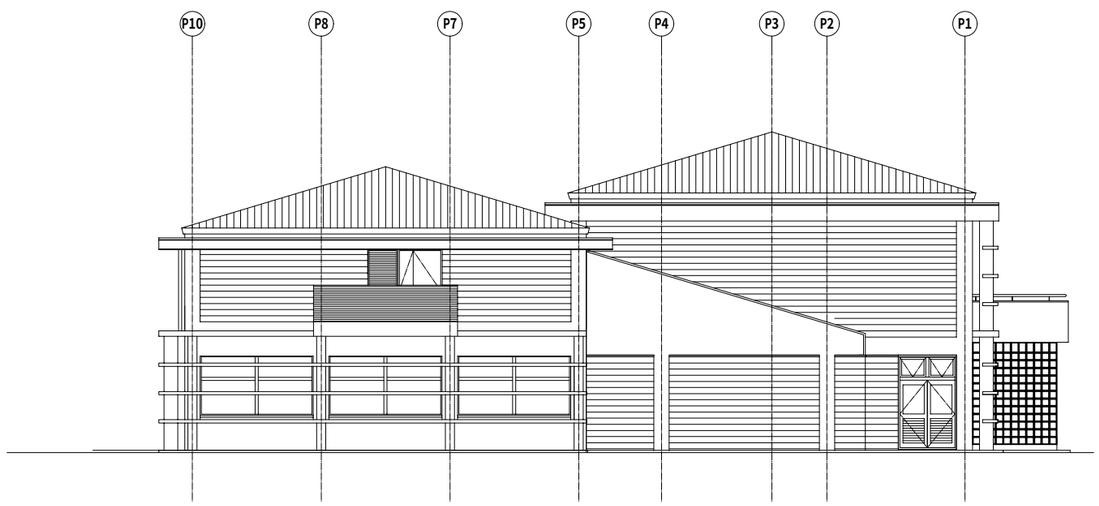
| TITLE | SCALE | PAGE |
|---|---|---|
| First Floor Plan | 1/200 | 91 |



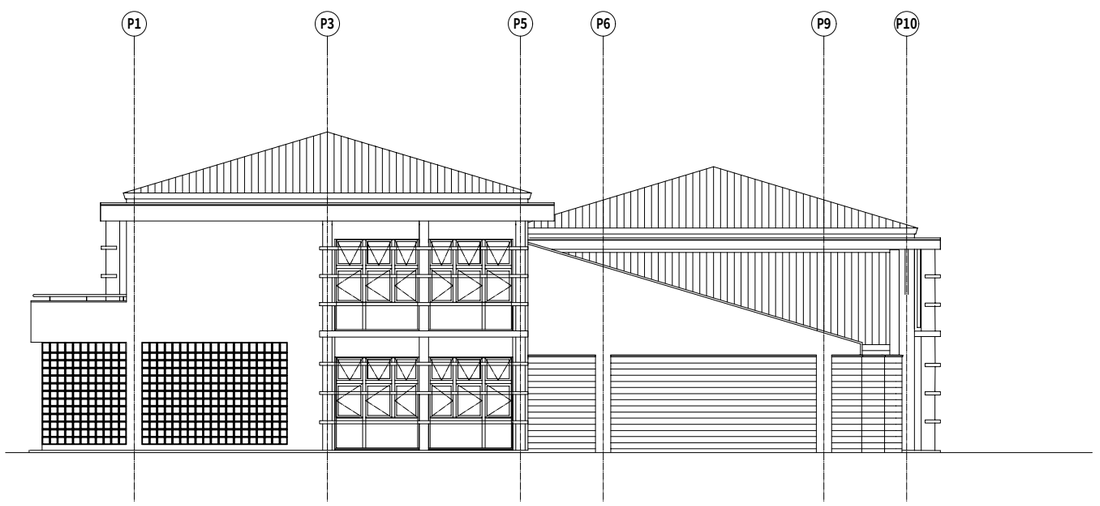

NORTH




SOUTH

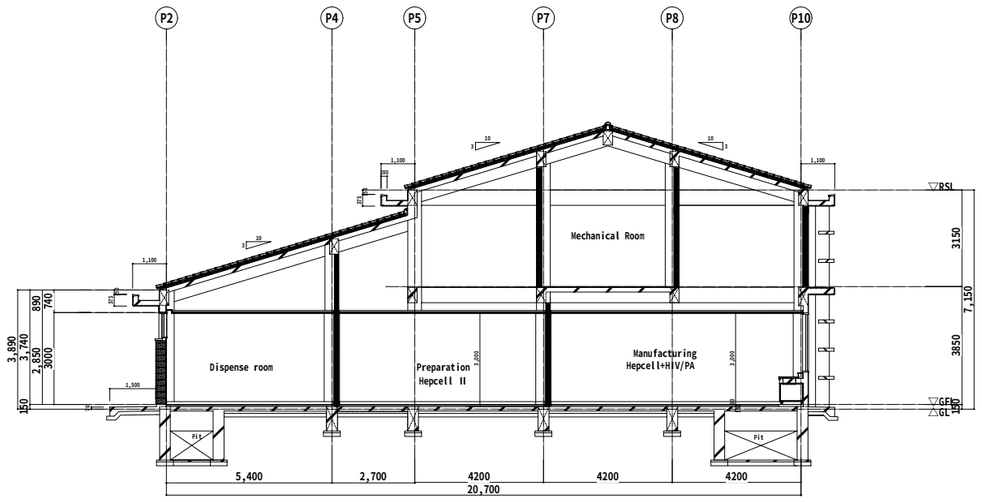



WEST

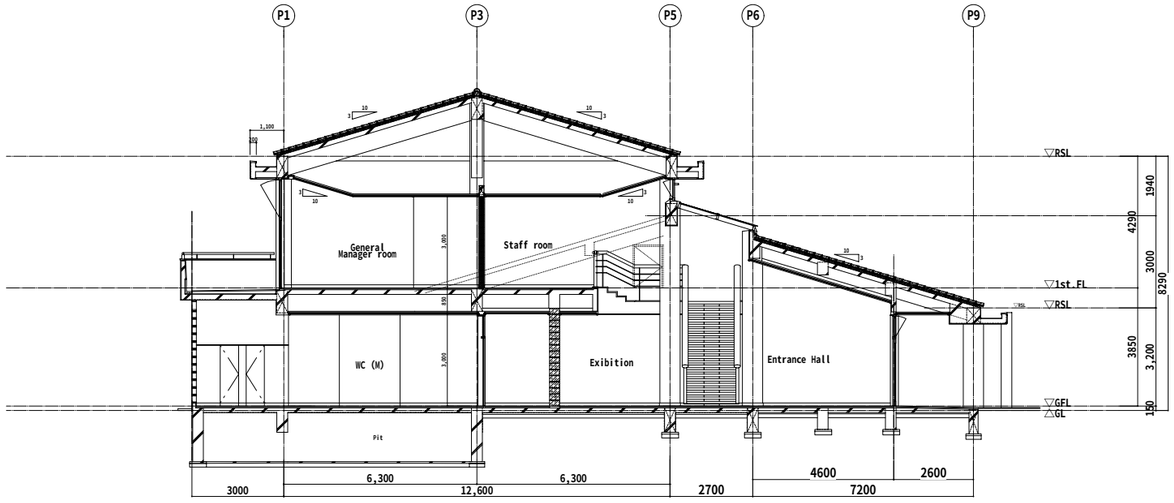



EAST

| Production Unit | | |
|---|---|---|
| TITLE: Elevation | SCALE: 1/200 | PAGE: 93 |

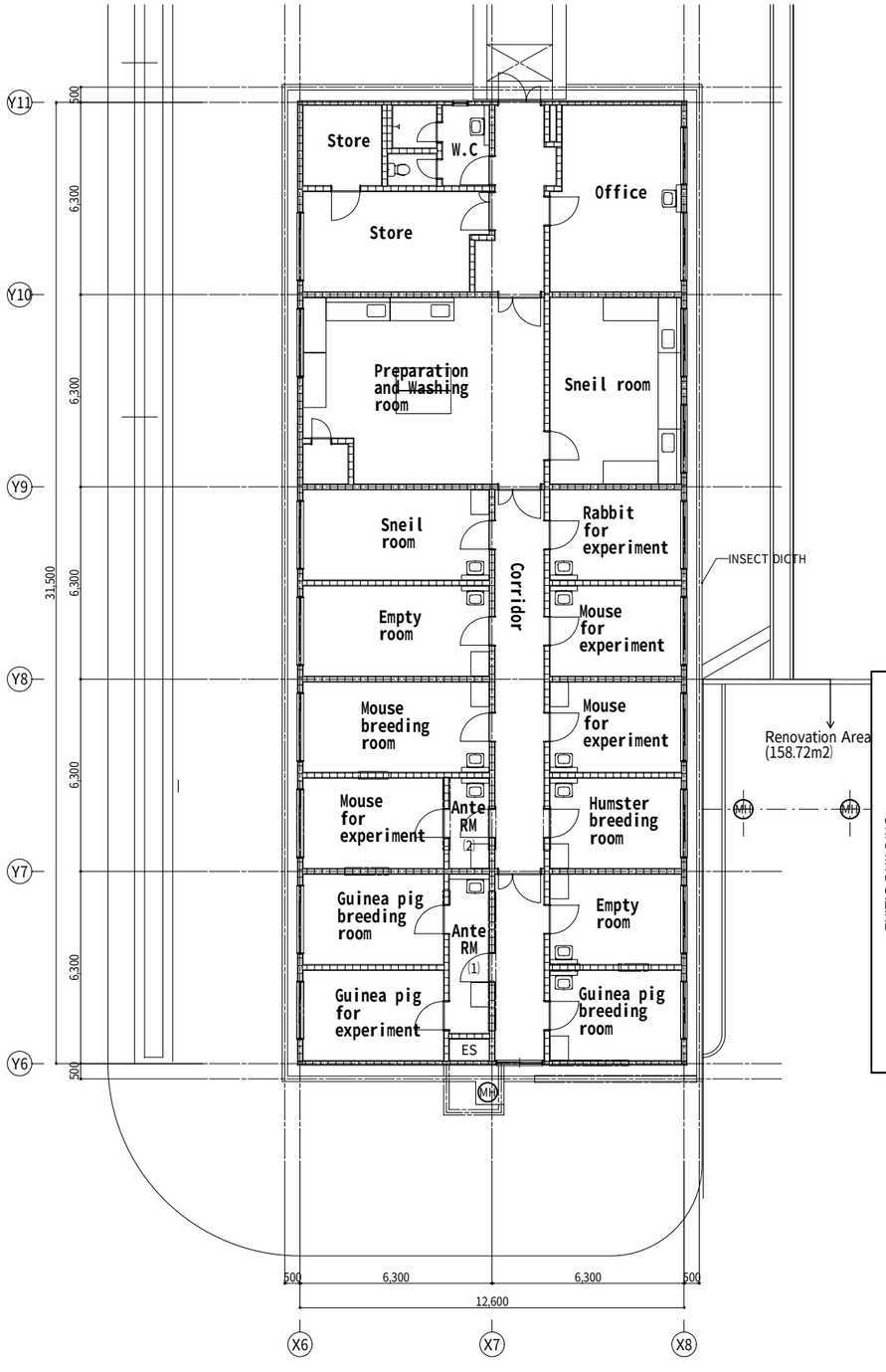



A-A SECTION

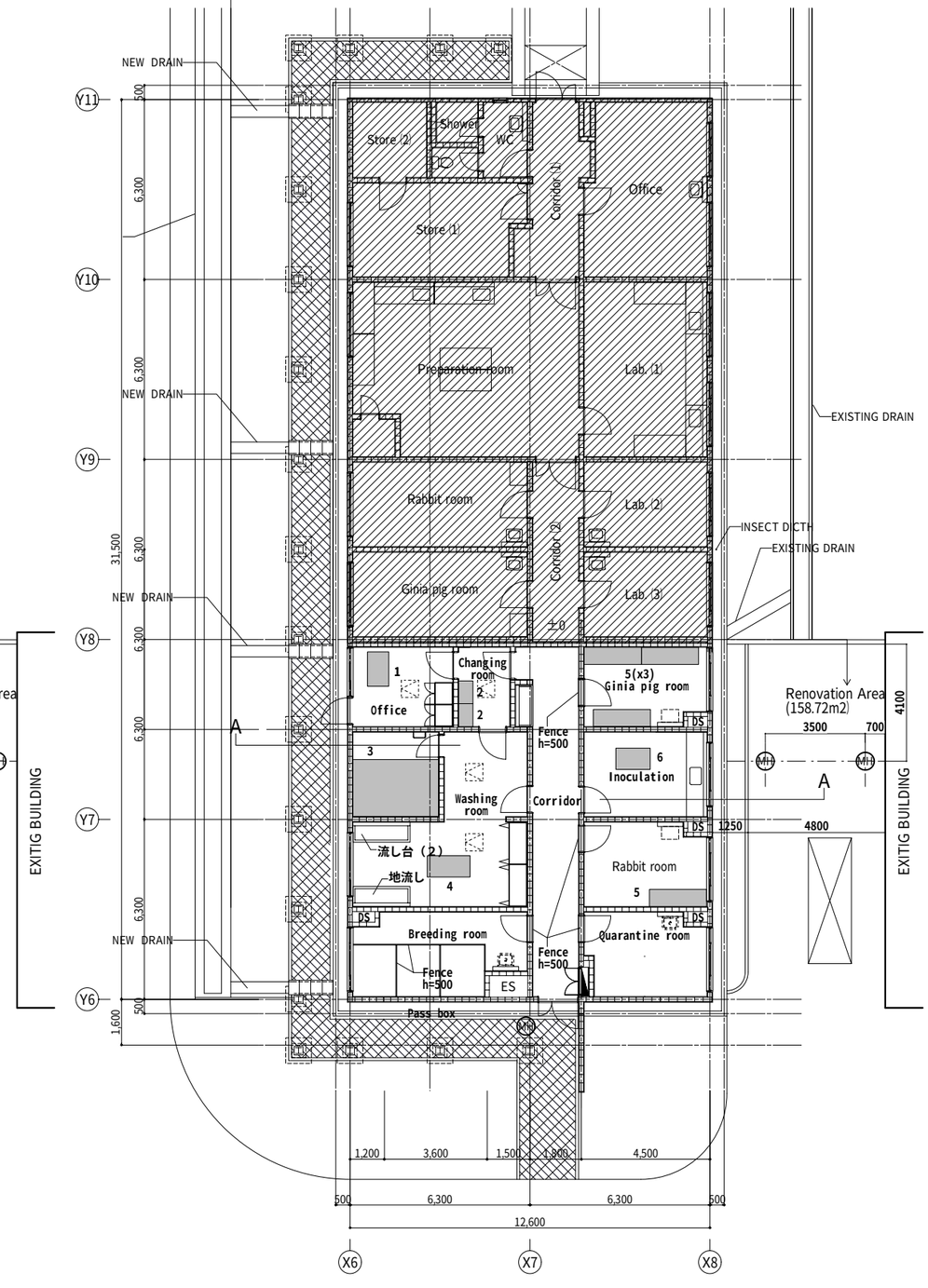



B-B SECTION

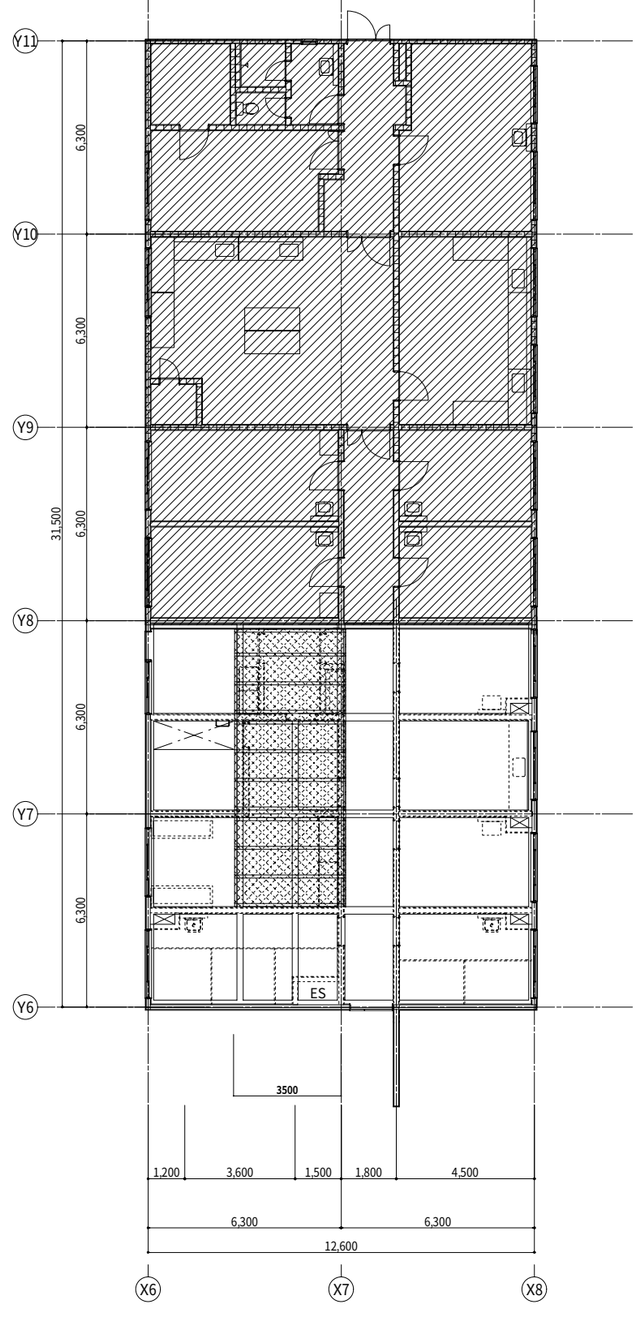
| Production Unit | | |
|---|---|---|
| TITLE: Section | SCALE: 1/200 | PAGE: 95 |



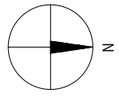

Before




After




Mechanical Space (Loft)




**Materials list**

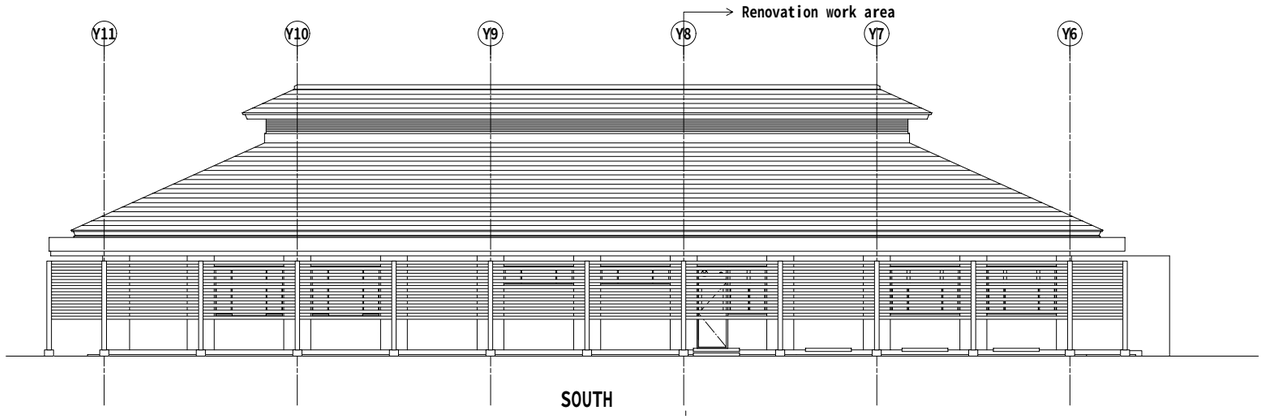
| No | Name | Number |
|---|---|---|
| 1 | Desk | 1 |
| 2 | Changing cabinets | 2 |
| 3 | Autoclave | 1 |
| 4 | Benches | 1 |
| 5 | Animal cage | 4 |
| 6 | Table | 1 |

# Animal Unit (Renovation)

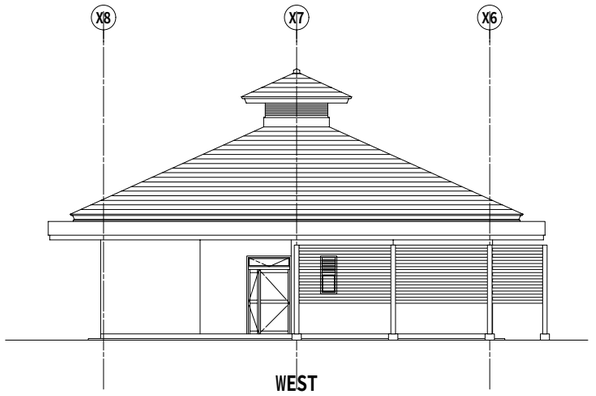
TITLE: Ground Floor Plan

SCALE: 1/200

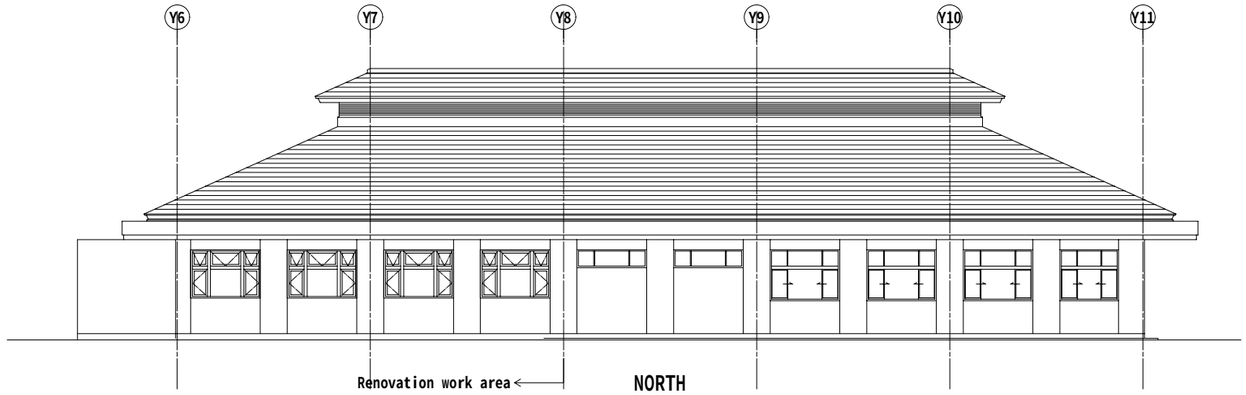
PAGE: 97



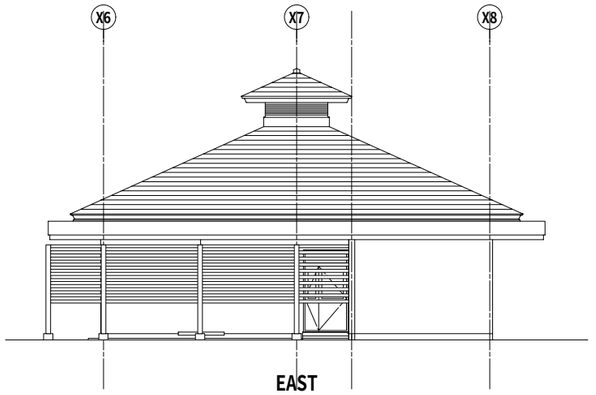

SOUTH



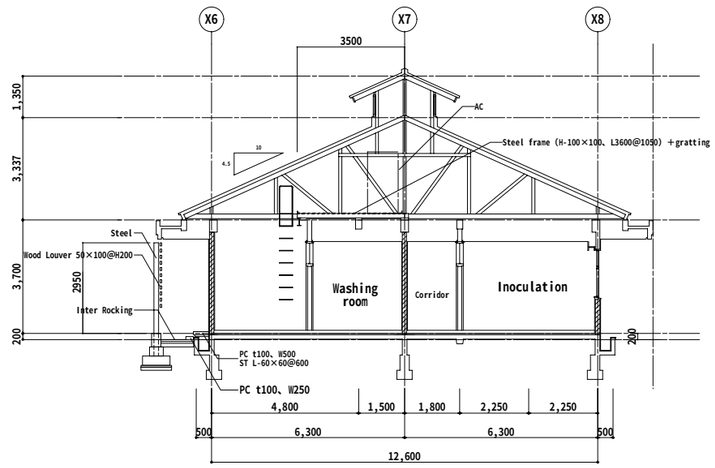

WEST




NORTH




EAST




A-A' SECTION

| Animal Unit (Renovation) | | |
|---|---|---|
| TITLE<br>Elevation・Section | SCALE<br>1/200 | PAGE<br>99 |


Materials list

| No | Name | Number |
|---|---|---|
| 1 | Incubator | 2 |
| 2 | CO2 Incubator | 2 |
| 3 | Clean bench | 2 |
| 4 | Refregerator | 2 |
| 5 | Cabinet | 10 |
| 6 | Lecturer table | 2 |
| 7 | Bench | 3 |
| 8 | Laboratory table with sink | 8 |
| 9 | White board | 2 |
| 10 | Office desk | 8 |
| 11 | Meeting table | 3 |
| 12 | Photocopy machine black and white | 1 |
| 13 | Ultra low deep freezer | 2 |
| 14 | Autoclave | 1 |

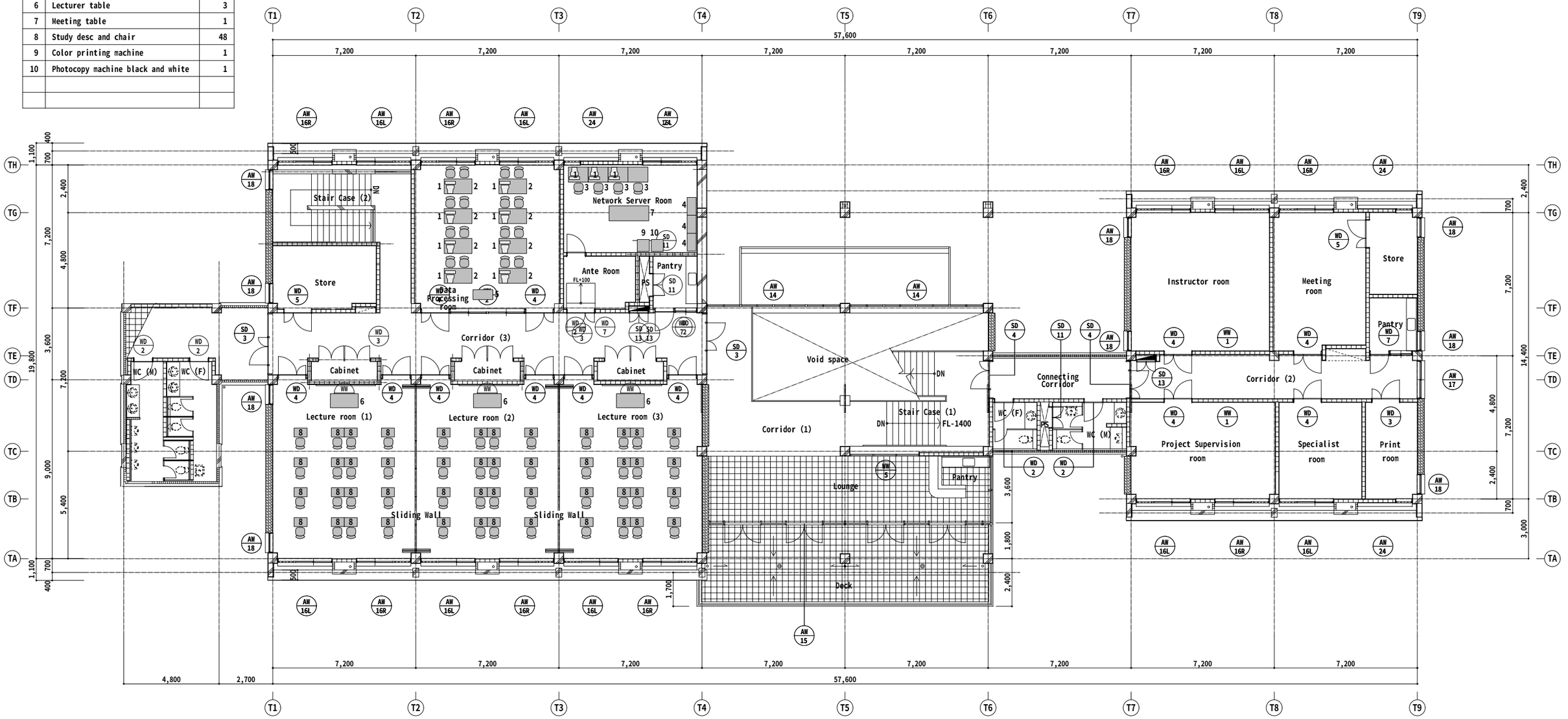
Ground Floor Plan

**Traning Unit**

| TITLE | SCALE | PAGE |
|---|---|---|
| Ground Floor Plan | 1/200 | 101 |

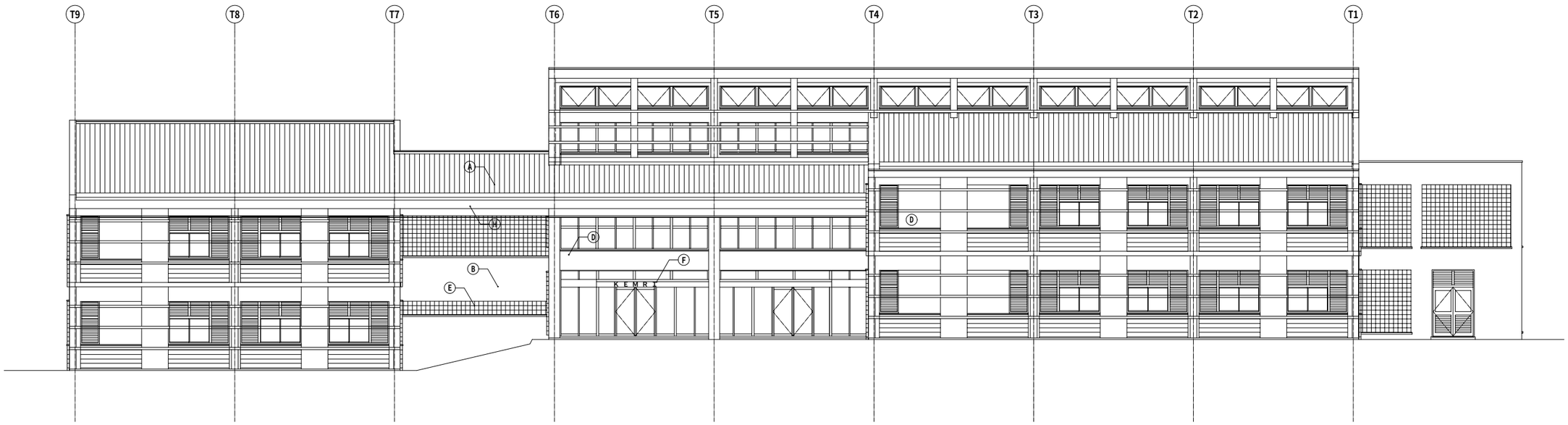
Materials list

| No | Name | Number |
|---|---|---|
| 1 | Computer | 11 |
| 2 | Desc and 2 chairs | 8 |
| 3 | Desc and chair | 4 |
| 4 | Cabinet | 3 |
| 5 | Lecturer table | 1 |
| 6 | Lecturer table | 3 |
| 7 | Meeting table | 1 |
| 8 | Study desc and chair | 48 |
| 9 | Color printing machine | 1 |
| 10 | Photocopy machine black and white | 1 |
| | | |
| | | |

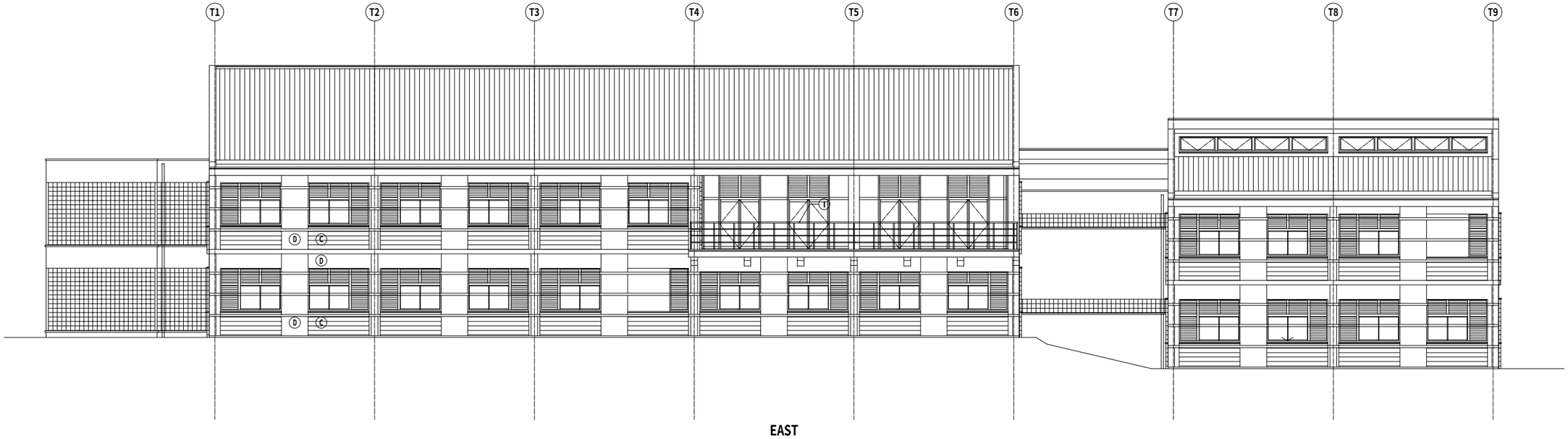



Fist Floor Plan

| Traning Unit | | |
|---|---|---|
| TITLE: First Floor Plan | SCALE: 1/200 | PAGE: 103 |

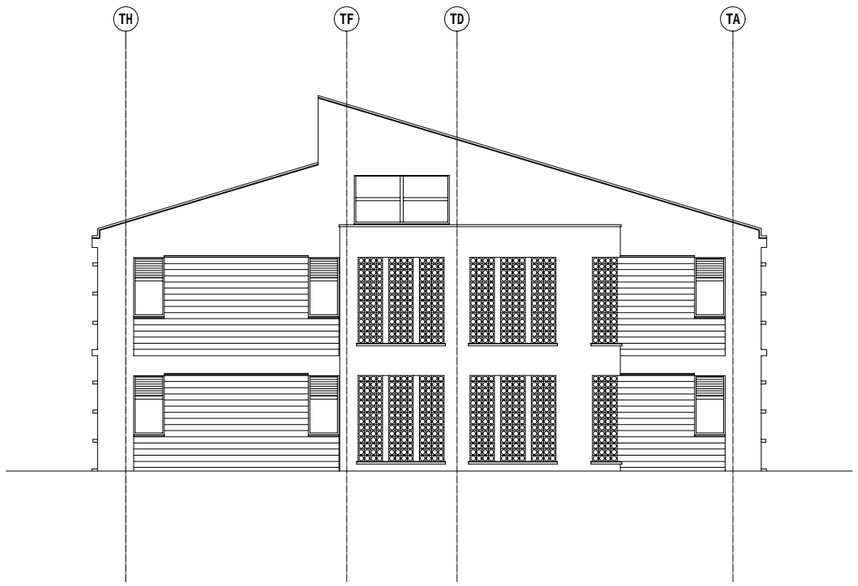



WEST

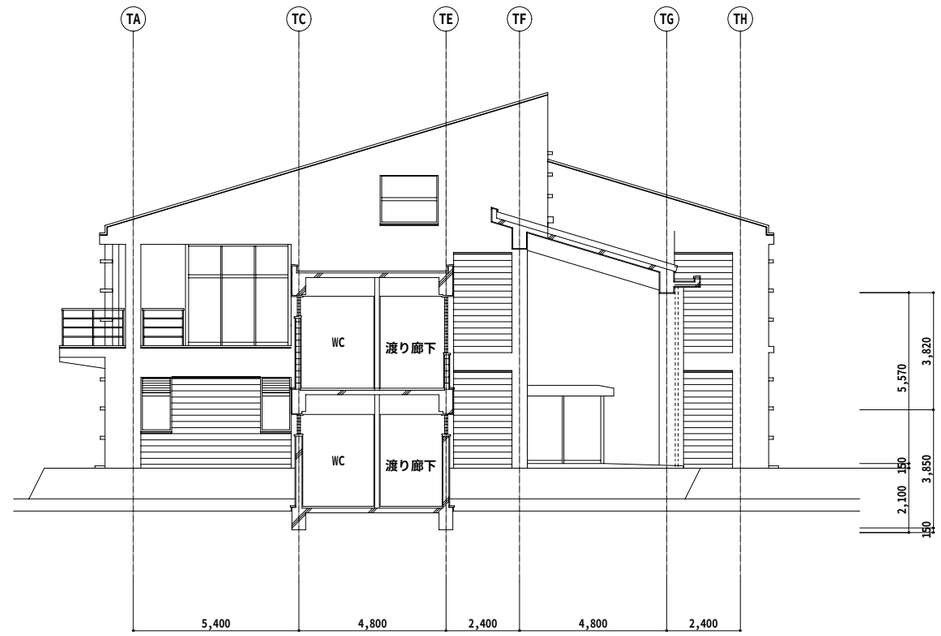



EAST

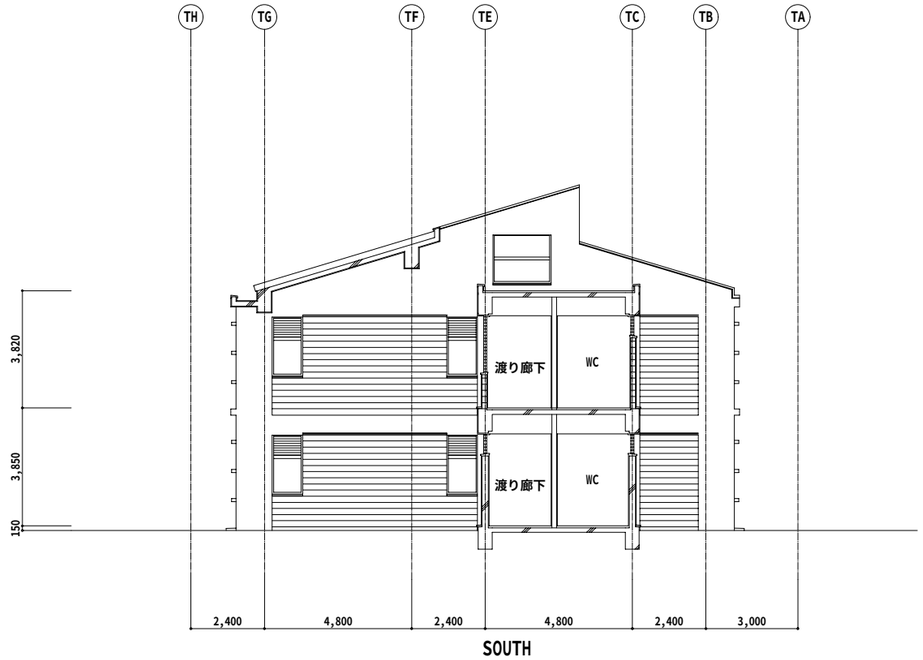
| Traning Unit | | |
|---|---|---|
| TITLE: Elevation East & West | SCALE: 1/200 | PAGE: 105 |



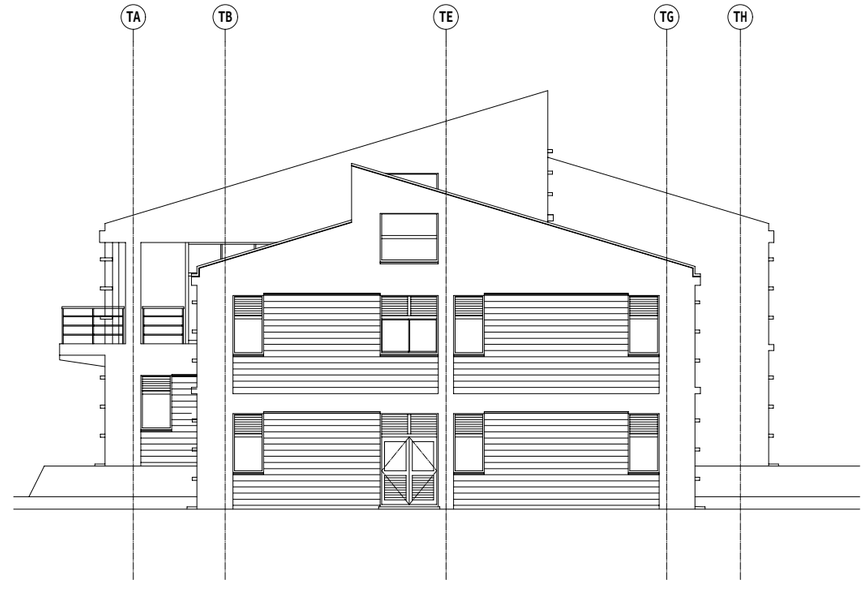

SOUTH




NORTH

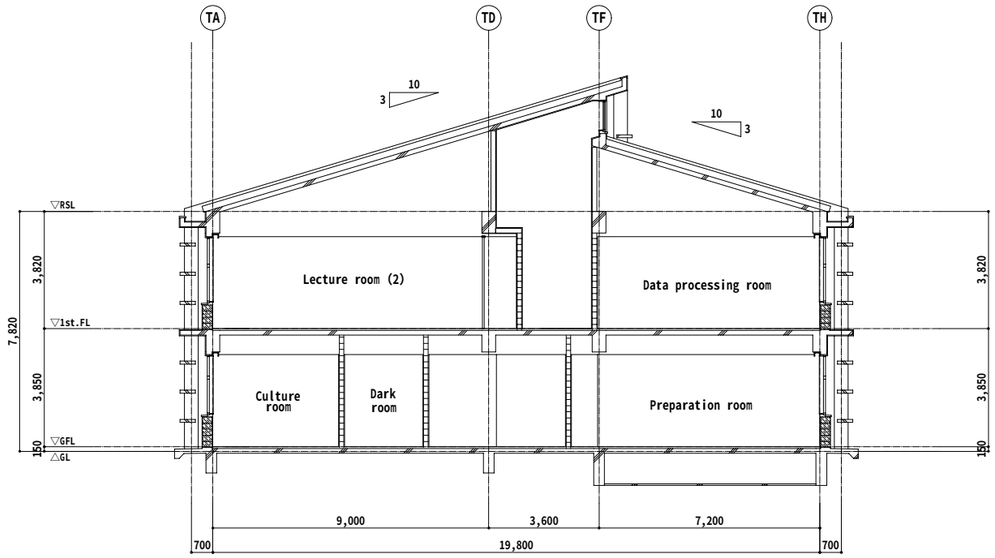



SOUTH

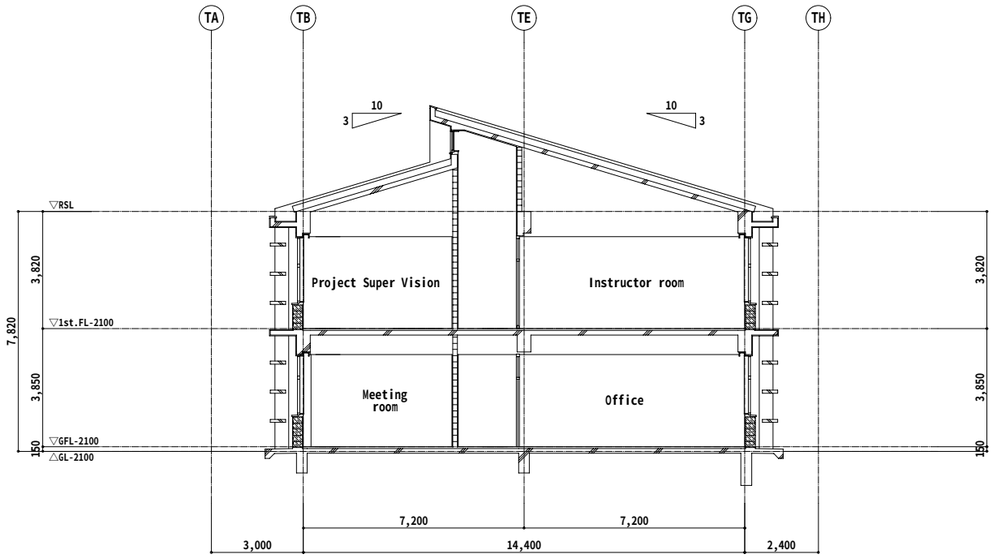



NORTH

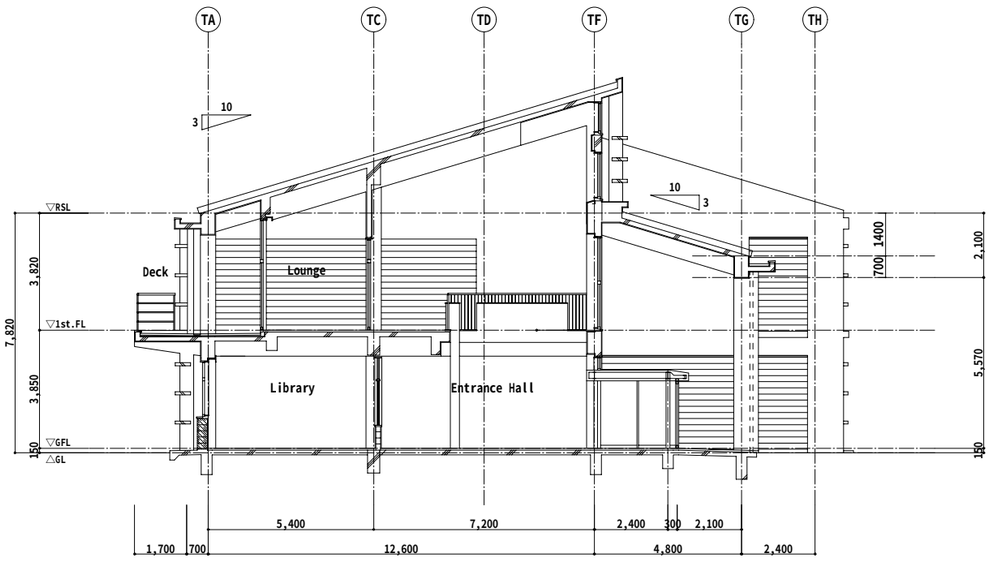
| Traning Unit | | |
|---|---|---|
| TITLE<br>Elevation North & South | SCALE<br>1/200 | PAGE<br>107 |




A-A Section

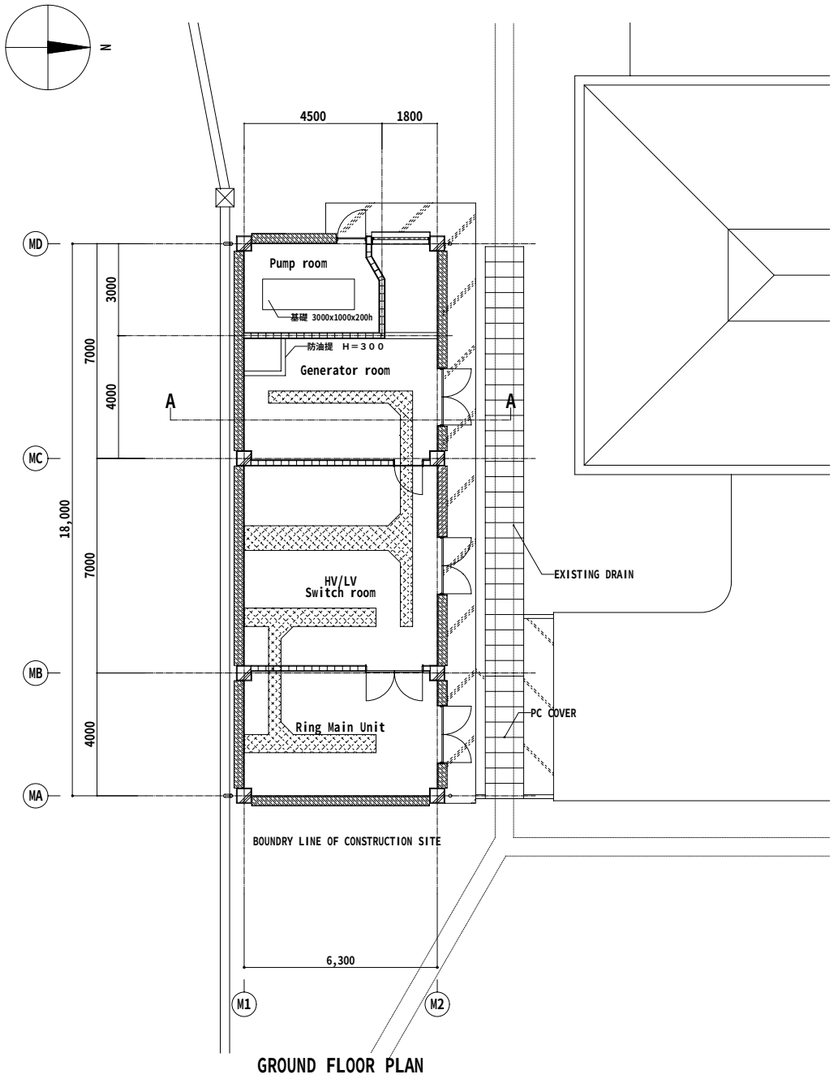



C-C Section

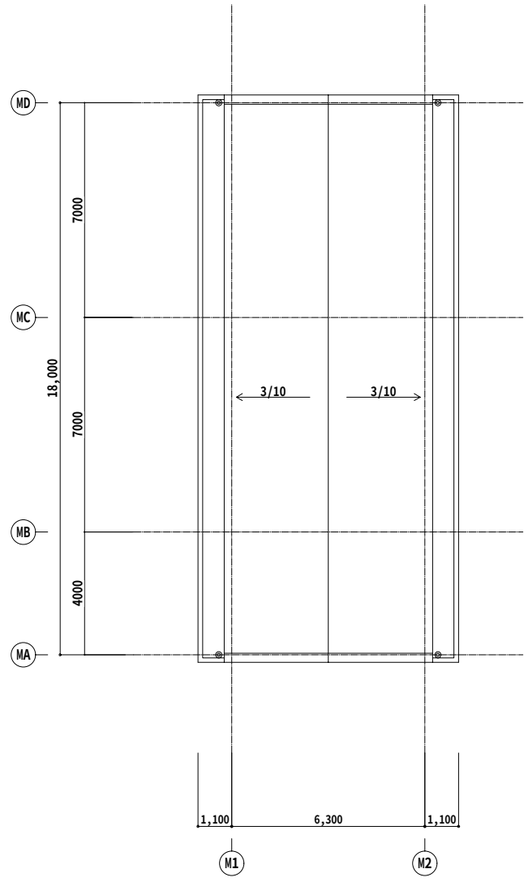



B-B Section

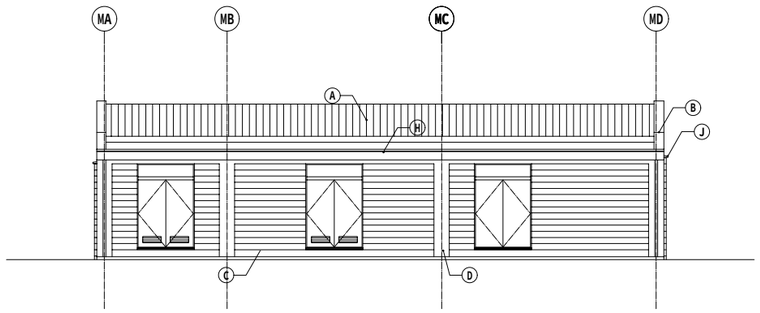
| Traning Unit | | | |
|---|---|---|---|
| TITLE Section | | SCALE 1/200 | PAGE 109 |



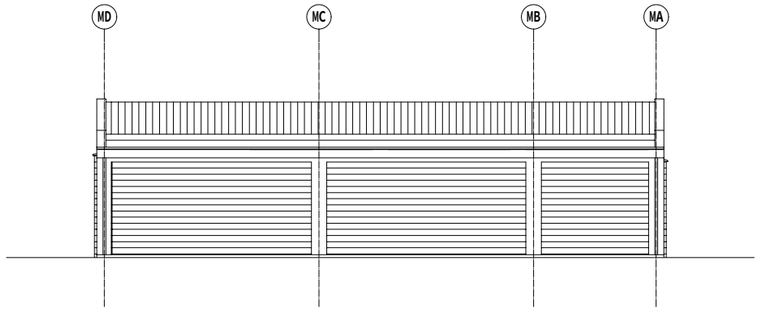

GROUND FLOOR PLAN



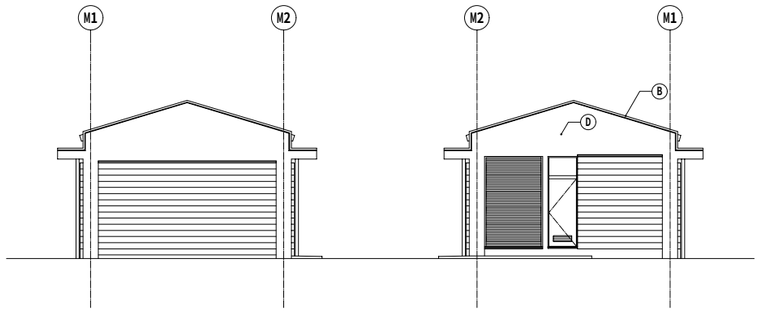

ROOF PLAN



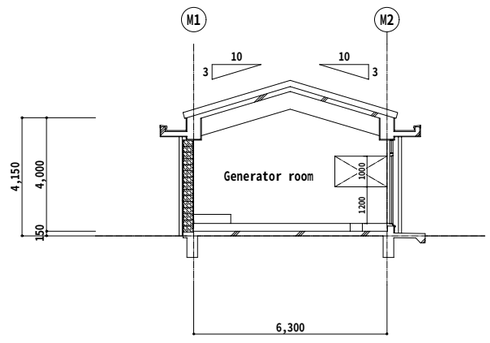

NORTH




SOUTH




EAST WEST




A-A SECTION

| Mechanical Unit | | | |
|---|---|---|---|
| TITLE Ground Floor Plan Elevation,Section | SCALE 1/200 | PAGE 111 | |

### 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.

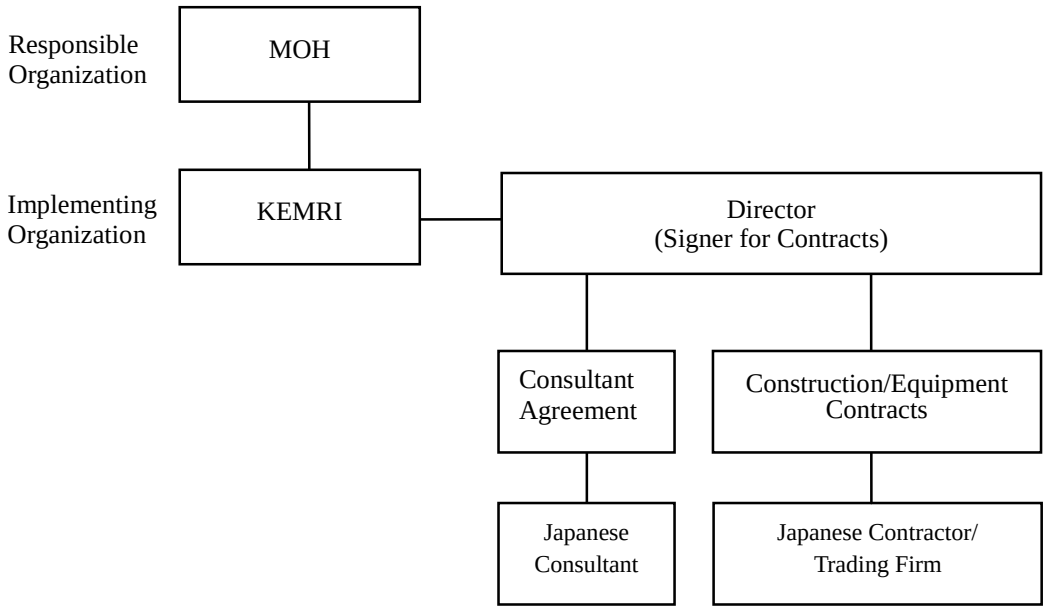



**Figure 2-15 Implementing Organisation**

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.

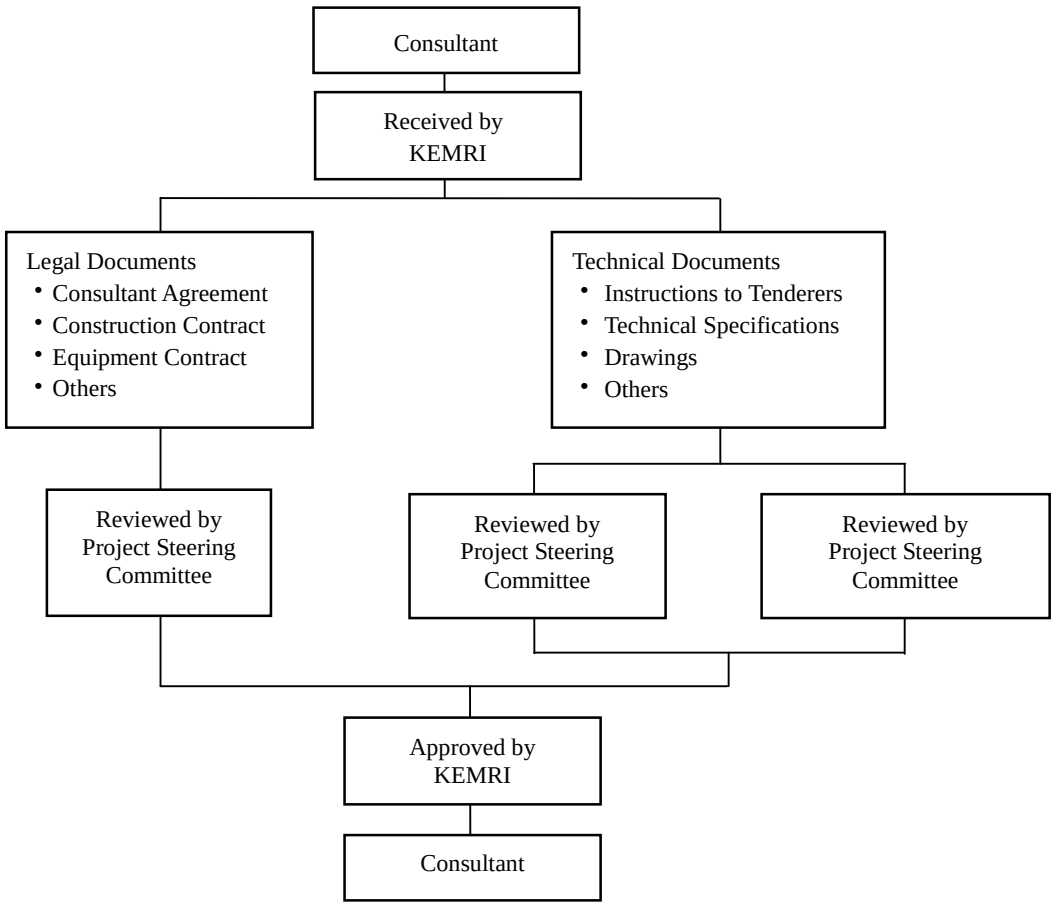



**Figure 2-16 Approval Procedures**

(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 Engineers

On care of work, plural buildings will be constructed simultaneously, therefore, two local engineers will be required to supplement the Japanese resident managers. The Grant Aid project includes a facility for manufacturing blood screening kits. So the rate of construction in mechanical equipment and electrical equipment is higher than that of general buildings, and the building requires cleanliness. Accordingly engineers for each equipment will be required.

Engineers for calculation will be required for the estimate of actual number and the management of budget. Furthermore accountants, designers, security officers for safety management, store keepers, clerks and drivers will be required.

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

Typical top-level Kenyan construction companies have manpower of about 3,000, a staff of about 20 engineers, and an annual construction sales amount of about 800 million yen. Unlike Japanese construction companies, some local companies have their own woodworkers and metalworkers, and their own manufacturing plants.

Even top-level Kenyan companies have 20 to 30 engineers in total as above, and they employ only a few engineers. Under such a situation, the main contractor (a Japanese corporate body) of this project is required to employ local engineers under the Japanese engineers, to minutely implement checks in process, quality control and safety control, and to instruct them.

Since the production unit has clean area in the project facilities, advanced quality control is required for the construction work. The construction management by experienced Japanese professional engineers are indispensable to satisfactory completion of such special works.

### 2-2-4-2 Implementation Conditions

(1) Temporary Work Plan

The security situation in Nairobi deteriorates year by year. Enough attention should be paid to robbories of materials and equipment in the construction sites. Now security officers are always deployed at the entrance of temporary enclosures around the building under construction, and at the security gate to the site even vehicles of acquaintances are checked.

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. At the entrance of the site from a main road, the vehicles for the construction work will cross other vehicles and pedestrians, and they will share the same runways with other vehicles and pedestrians; therefore, safety roads will be secured and watchmen will be deployed at appropriate places.

Attention will be paid to cleaning of roads in the site. 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 site includes 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.

Furthermore, next to the production unit, U.S. established newly large-sized research facilities. And the flow lines of the vehicles for construction and the user of the facilities overlap. Therefore, to users of the facilities, the security measures such as establishment of security road and deployment of guard officer are required.

(2) Material Procurement

To facilitate repairs, maintenance and management of the facility after commissioning, the materials and equipment will be procured locally to the extent possible. Presently, products of various qualities and specifications from South African and European countries are being marketed in addition to the materials made in Kenya. However, the number of imported materials is limited, so precautions will be required at the order at the location. Many materials trend to be in short supply. Accordingly you have to allow enough time to

plan to avoid disturbing the construction schedule and also have to pay attention to variation of quality.

Local procurement of imported materials and equipment is expensive, so you have to select them after comparing the price of them with that of articles procured from Japan and third countries.

(3) Special Construction Method

In Nairobi, only two local construction companies have the plants for ready-mixed concrete for themselves, so the price of ready-mixed concrete is very high. The standards such as JIS are not established, so orderers specify the mixture. Accordingly the thorough quality control of concrete is important.

Like the common construction in Kenya, in this project construction, temporary batcher plant will be established in the construction site. 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 $10m^3$ 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 two-step pouring method is adopted in this construction.

### 2-2-4-3 Scope of Works

For the smooth implementation of the Grant Aid project, each undertaking of Japan and Kenya is defined. The contents are as follows.

**Table 2-35 Scope of Works**

| Works to be borne by Japanese side | Works to be borne by Kenyan side |
|---|---|
| 1. Building Construction Work<br>（including standard fix furniture, fixtures） | 1. Preparation of construction site<br>・Preparation of construction site and site clearance(including cutting of woods and clearance of existing woods)<br>・Demolition of existing structure (gas tank/gas piping, wastewater treatment tank/pipes, and goat house)<br>・Removal of buried equipment (replacement of drainage pipe/water-supply pipe, electric wiring and the likes)<br>・Removal of the function of the existing facilities during the construction and after completion of animal unit.<br>・Removal of Gates and gatehouses which were constructed by CDC. |
| 2. Electrical Work<br>Electrical system, power and main wiring system, lighting and socket outlet system, telephone system, paging system, automatic fire alarm system, and lightning protection system | 2. Lead-in and connection work of each infrastructure<br>Electricity: Replacement of high voltage distribution boad / household transformers and the existing transformers of 1000kVA by KPLC<br>Telephone: Lead-in and connection up to new electrical room and wiring of inside and wiring of internal line to the existing telephone are constructed by Japanese side<br>Water supply: Installation of an exclusive city water intake main to the new water receiving tank to be installed by the Japanese side, and installation of pipes connecting with the existing well water system |
| 3. Plumbing sanitary・airconditioning and ventilation construction<br>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<br>Gardening, planting, road outside the project site, stone wall on the southern side (for security) |
| 4. Special work<br>Generator system, sewage treatment system | 4. Furniture・household articles・equipment<br>Curtain (rail work will be done by Japanese site), blind, and ordinary furniture. |
| 5. Land scape work<br>Road and parking inside the project site, outside lighting fixtures | |
| 6. Equipment work<br>Procurement and installation of equipment | |

Especially, electrical system, generator system for emergency, lightning protect system, water supply system (water reservoir and elevated water tank) among the works by Japan, will not be installed in each building of three target facilities (production unit, animal house and training unit),but they will be installed as objects of the entire three buildings.

### 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.

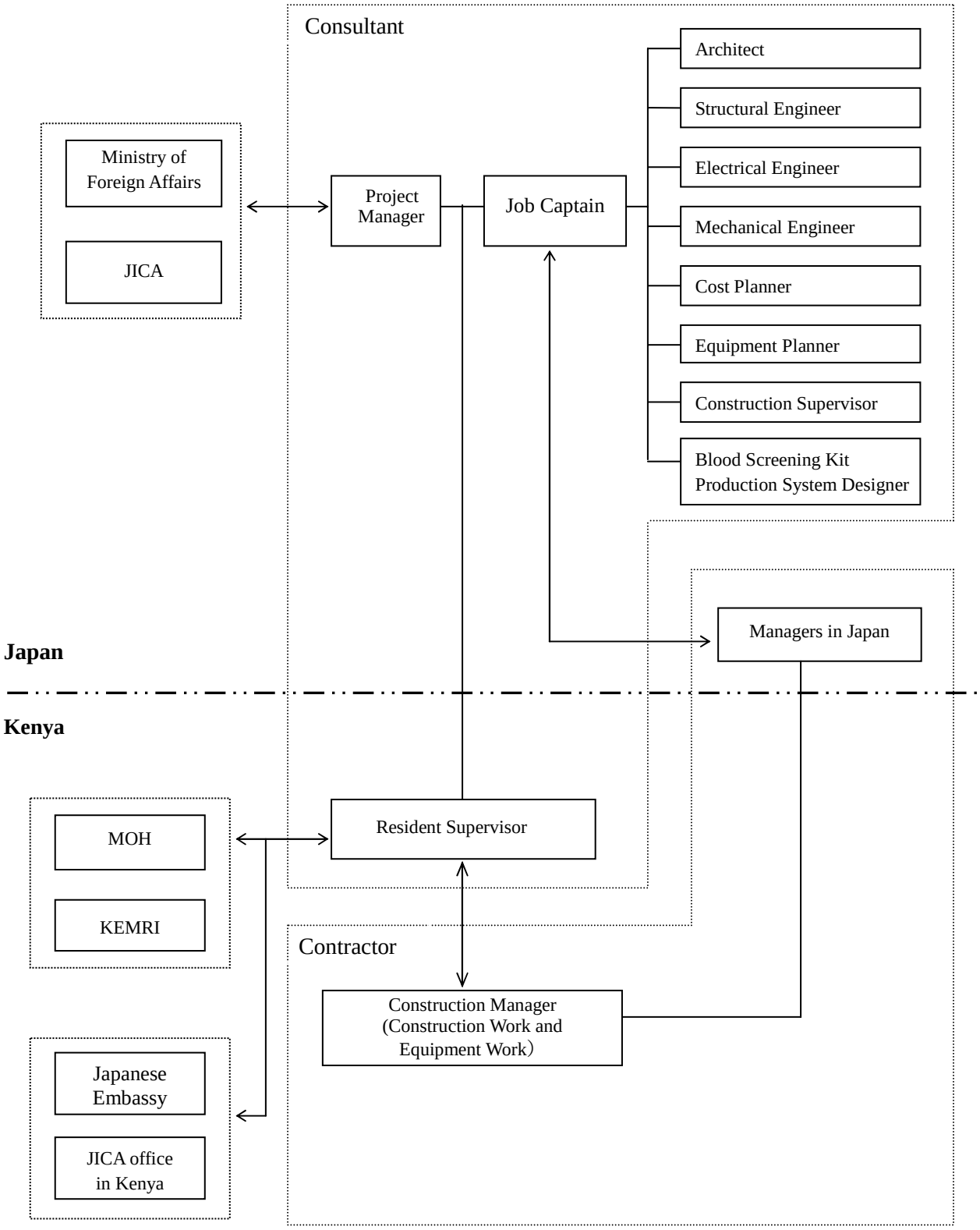



**Figure 2-17 Supervision System**

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

(1) Material

Cement: Cement meeting the British Standard or the Kenyan Standards is manufactured in Kenya. Portland cement and its equivalent production are generally used.

Aggregate: Local aggregates are insufficient in terms of both quality and quantity. Problems are found in size distribution, so they 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. Appropriate mixing time that the local weather conditions are considered must be secured.

(3) Pouring of Concrete

Generally, concrete is poured from carts. In the local weather, drying shrinkage is small. Since concrete is mixed at the construction site, we cannot say that the workability will be good. Therefore, utmost care will be needed in the filling of concrete. We plan to certainly pour the concrete by using vibrators and others.

It is a common procedure in Kenya 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 the production unit of blood screening kit, the training unit and the likes, so on the procurement of material and equipment, the articles which can be kept clean, are easy to clean, and are solid will be selected to meet the purpose of the facilities. And the materials which Kenya side can maintain enough after the completion will be selected. The policy of procurement is as follows:

1) Local procurement

In the facility of CDC of U.S. which were established in the site, much materials except for glasses and furniture are procured locally. However wooden goods and interior materials which are used are poor in quality. Accordingly in this project, the procurement of the goods made in third countries and Japan is considered to keep the performance of use of building materials including these materials.

When we researched the local manufacturer of imported materials, we found that most of materials were imported from Europe and other countries. In that case, they receive orders and then they arrange the goods. They are hardly in stock. If the items are out of stock, it often takes a few months to obtain them, so care should be paid not to influence the schedule of the construction. And also there is much price difference between local items and imported ones.

Furthermore, even though we consider the procurement from third country on an article, we try to consider the use of imported material obtainable in the local market in the light of maintenance. It is necessary to consider enough the use of the local items because they are of uneven quality and the materials used have many problems.

2) Procurement by Importation

Even though the materials and equipment are good in quality and performance and can be obtained locally, we must consider the procurement if those of third countries are more inexpensive. However they must be materials which can be obtained easily in case of considering repair.

Timber is marketed at a high price under the influence of strengthening of cutting prohibition in Kenya, so it is important to compare domestic timber with imported one.

On glasses, domestic ones are poor in quality, so in most of main buildings in Nairobi including the facilities of CDC the glasses made in third countries are used. In this project, the glasses of third countries will be procured.
Shopwork metal such as manhole and access port is article made in third countries. Steel products are in short supply in Kenya, so they will be procured in third countries.

Most types of heavy machine for construction can be procured in Kenya, but rental fees are extremely expensive. So we will compare the rental fees with the procurement cost from third countries.
As a general trend, products whose accuracy is required are not manufactured in Kenya, so they will be procured from third countries.

3) Transportation Plan

The materials and equipment procured from third countries are shipped to Port of Mombasa. On inland transportation from Port of Mombasa to the construction site of KEMRI in Nairobi, motor trucks are used. It takes one or two days to transport them by land from Mombasa to Nairobi, 500km. The conditions of roads and security deteriorate, and most constructors have got involved accidents or been stolen during the transport by land. Considering these circumstances enough, the transportation program must be created.

Some 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 packed to be able to withstand long-time transportation.
Since the number of days required for the procurement from third countries may be uncertain due to the conditions of suppliers, such as for one month or two months, enough attention must be paid to that point.

On the transportation by ship from Japan, the liner leaves Yokohama Port once a month. And tram vessels goes to Nairobi 2 or 3 times a month. It takes about one month to go to Nairobi.

4) Procurement Plan

Major construction materials and equipment to be procured are divided into three: local procurement, third countries procurement, and Japan procurement. And the items and the reason to select are described at the following table. (If areas of procurement overlap, it is finally decided after considering mainly the cost.)

**Table 2-36 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 (Mombasa, Nairobi) meeting with BS and Kenyan Standards are available. The local products are satisfactory. |
| | Fine aggregate | ○ | | | Local products will be used, but they cannot be supplied sufficiently so that we must include the procurement period in the production control. |
| | Coarse aggregate | ○ | | | ditto |
| | Ready-mixed concrete | ○ | | | There is no ready-mixed concrete plant. Some constructors have their own plants. The purchase price is high. |
| | Deformed bar | | ○ | ○ | The local manufacturer has shut down. The products will be procured from Japan or third countries. |
| | Form | ○ | | | The number of diversion is rather low. |
| Steel work | Steel frame member | | ○ | ○ | The local manufacturer has shut down. The products will be procured from Japan or third countries. |
| Masonry work | Concrete block | ○ | | | They are produced under the BS standard. However, variance of strength is large due to faulty of process control, in curing for example. They cannot be used for bearing wall. |
| | Brick | ○ | | | The local products are satisfactory. |
| Waterproofing work | Asphalt waterproofing | ○ | | | The special attention is necessary on local contractors work because of lack of technical knowledge such as construction technique. |
| | Liquid-applied membrane waterproofing | ○ | | | This method is not virtually practiced 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). |
| Plaster works | Cement mortar | ○ | | | The local products do not have lugs and are not precise in dimensions. So the imported products form Europe and others are marketed. But they are in short stock, and we will consider the procurement from third countries. |

| Type of work | Material | Procurement source | | | Note |
|---|---|---|---|---|---|
| | | Local market | Japan | Third country | |
| Tile work | Earthenware tile | ○ | | ○ | ditto |
| | Porcelain tile | ○ | | ○ | Local Nairobi stones are marketed at the low price |
| Stone work | Stone | ○ | | | Terrazzo is generally used locally. |
| | Terrazzo | ○ | | | The local products do not have lugs and are not precise in dimensions. So the imported products form Europe and others are marketed. But they are in short stock, and we will consider the procurement from third countries. |
| Wood working | Wood | ○ | | ○ | Attention is necessary because the local products are in short stock and the procurement is difficult. |
| | Glued laminated wood | ○ | | ○ | ditto |
| | Plywood | ○ | | ○ | ditto |
| Metal working | Light-weight ceiling substrate | | | ○ | The local products are poor in quality and strength, so the products will be procured from third countries. |
| | Decorated metal, handrail | | ○ | ○ | The local products are poor in quality. |
| Wooden fixture work | Door, fixture frame | | | ○ | The local products are poor in quality, so the products will be procured from third countries. |
| Metal fixture work | Aluminium fixture | | | ○ | The local products are inferior in an accuracy, air-tightness and water-tightness, so the products are procured from third countries. |
| | Steel fixture | | | ○ | The local products are poor in accuracy and quality, so the products are procured from third countries. |
| Glazing work | Glass pane | | ○ | ○ | There are not many kinds of local products, and they have variation in quality. The products will be procured from Japan or third countries. |
| | 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 | | ○ | ○ | The local products have variation in quality, and it is difficult to adopt them. |
| | Rock wool sound insulating board | | ○ | ○ | The only local products are 600-panel type. |
| | Rock wool | | ○ | ○ | There is no local product. |
| | Flexible board | | ○ | ○ | ditto |
| | Decorated plywood | | ○ | ○ | The local products are poor in quality, so the products will be procured from Japan or third countries. |

| 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, so they are not adopted. Because it is used in medical scene, the products will be procured from Japan. |
| | Overhead closet | | ○ | | ditto |
| | Wooden furniture | | ○ | | ditto |
| | Sign | | ○ | | The products will be procured from Japan. |
| Exterior work | Paving material | ○ | | | The imported materials are available in the market. |
| | Interlocking block | ○ | | | Attention must be paid to the local products because they have variation in dimension and accuracy. |
| | Curb | ○ | | | The local products are satisfactory. However, there are no side ditch. |
| Mechanical work | Air-conditioning machine | ○ | | ○ | Although imported products are available in the local agent, there is no special type (medical purpose) .The products will be procured from Singapore. |
| | Fans | | | ○ | The local products are poor in quality and endurance, so the products will be procured from Singapore. |
| | Air inlet and outlet | | ○ | ○ | ditto. However, special goods will be procured from Japan. |
| | Filter | ○ | ○ | ○ | There are no local products and the imported products are available. In principle the products will be procured from Singapore, and special products will be procured from Japan. |
| | Duct material | | ○ | ○ | The local products are poor in quality and endurance, so the products will be procured form Singapore or Japan. |
| | Pump | | ○ | ○ | ditto |
| | Electrical water heater | | ○ | ○ | ditto |
| | Sanitary fixture | ○ | ○ | ○ | The local products are poor in quality and endurance and the items of the products are limited, so in principle the products will be procured form Singapore. Special products will be procured from Japan. |
| | FRP panel tank | | | ○ | The local products are poor in quality and endurance, so the products will be procured form Singapore. |
| | Copper pipe | | ○ | | The local products are poor in quality, the heat insulating field copper pipes will be procured from Japan. |
| | Steel pipe | | ○ | ○ | The local products are poor in quality and endurance and the items of the products and the size are limited, so the products will be procured from Singapore or Japan. |
| | PVC pipe | | ○ | ○ | ditto |
| | Insulating material | | | ○ | The local products are poor in quality and endurance, so the products will be procured from Singapore. |

| Type of work | Material | Procurement source | | | Note |
|---|---|---|---|---|---|
| | | Local market | Japan | Third country | |
| Mechanical work | Fire extinguisher | | | ○ | ditto |
| | Wastewater treatment | | ○ | | There are no locla products, and considering the medical purpose, the products will be procured from Japan. |
| Electrical work | Transformer | | | ○ | The locla products are poor in quality, so the products will be procured from Singapore. |
| | Electric power generator | ○ | | | Although imported products are available in the markets, local products will be procured due to smooth maintenance. |
| | AVR | | ○ | | The type of high-capacity products is limited, so the products will be procured from Japan. |
| | Boards | | | ○ | The local products are poor in quality, so the products will be procured from Singapore. |
| | Conduct tube | | ○ | ○ | The local products are poor in quality and the items of the products and the size are limited, so the products will be procured from Singapore or Japan. |
| | Boxes | | ○ | | The local products are poor in quality and the items of the products are limited, so the products will be procured from Japan. |
| | Electric wire | | ○ | | The local products are poor in quality and the size of the products is limited, so the products will be procured from Japan. |
| | Cable | | ○ | | ditto |
| Electric installation work | Lighting equipment | ○ | ○ | ○ | Some local products are poor in quality, so the products will be mainly procured from Singapore. Such special ones as with clean specifications will be procured from Japan. |
| | Wiring accessory | ○ | ○ | | The local products are poor in quality, so the products will be procured from Japan. |
| | Telephone equipment | ○ | | | Since the imported products are marketed in the local agent, the products will be procured locally. |
| | Public address system | | ○ | | The local products are poor in quality, so the products will be procured from Japan. |
| | Fire alarm system | | ○ | | Since JIS is applied, the products will be procured from Japan. |

Note） If plural products have the same conditions such as quality, we selected one whose price is lower.

(2) Equipment by Third Country Procurement

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 KEMRI HIV-1 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 2-37 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, | 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.

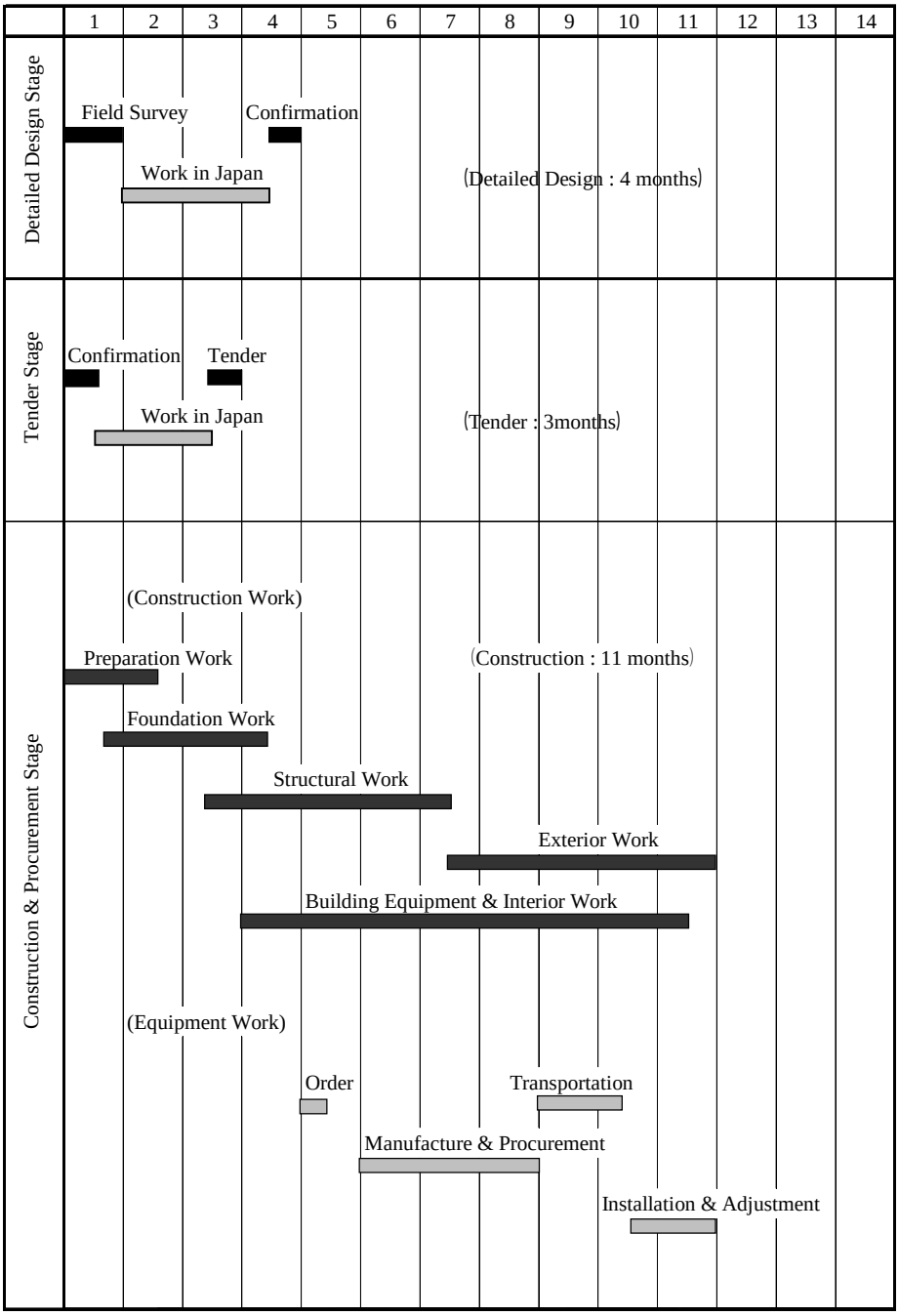
The estimated terms necessary for construction and equipment works are 11 months.

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

**Table 2-38 Construction and Equipment Work**

| | | |
|---|---|---|
| Construction of Building | Production Unit（1,479.9 $m^2$）<br>First floor： General Manager room, Marketing Manager room, Secretary room, Office, Staff room, Changing room, Pantry, Mechanical room, and etc.<br>Ground floor：HEPCELLⅡ Preparation room, HIV/PAPreparation room, HEPCELL+HIV/PA Manufacturing room, Material room, Dispense room, Washing room, Quality control room, Packing room, Labelling room, Clean corridor, Store, WC, Corridor, and etc.<br>Animal House（246.6 $m^2$）<br>Ground floor：Guinea pig room, Rabbit room, Inoculation room, Quarantine room, and etc.<br>Training Unit（2,083.3$m^2$）<br>First floor： Lecture room, Data processing room, Network room, Project Supervision, Instructor room, Meeting room, Specialist room, Lounge, and etc.<br>Ground floor：Parasitic Lab., Infectious Lab., Preparation room, Culture room, Office, Manager room, Secretary room, Entrance hall, Library, and etc. | |
| (Total area) | (3,809,8 $m^2$) | |
| 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 2-39 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.

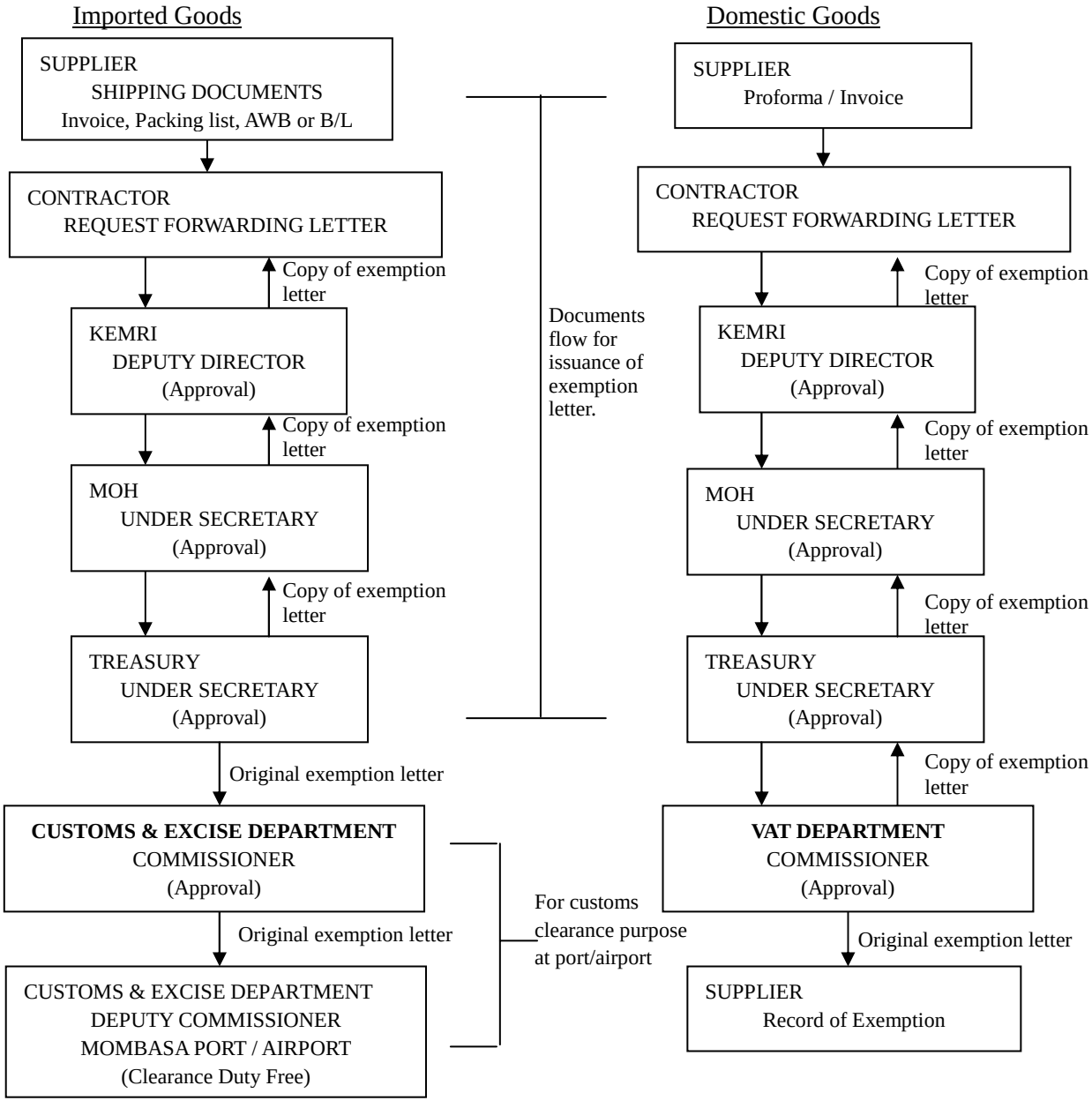
The exemption procedure of tax which is imposed in Kenya changed from the reimbursement system which had been conducted till 2002, and the change is shown in the figure below.

Exemption Method

| Import Procurement | |
|---|---|
| Customs Duties | Exemption |
| VAT | Exemption |

Exemption Method

| Local Procurement | |
|---|---|
| VAT | Exemption |



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 2-40 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<br>(about 34,400,000 yen) |

## 2-4 Project Operation Plan

### 2-4-1 Approximate Cost of the Cooperation Project

The cost to be borne by the Japanese side is as follows.

**Table 2-41 Approximate Cost of the Japanese Obligation Works**

(Approximate 1,082 million yen)

Nairobi Three buildings (Total Floor Area: approximate 3,810m$^2$)

| Item of Expenditure | | Approximate Cost (million yen) | | |
|---|---|---|---|---|
| Facilities | Production Unit | 284 | 699 | 886 |
| | Animal Unit | 53 | | |
| | Training Unit | 362 | | |
| Equipment | Production Unit | 101 | 187 | |
| | Animal Unit | 19 | | |
| | Training Unit | 67 | | |
| Detailed Design / Construction Supervision | | | | 196 |

This cost estimate is provisional and would be further examined by the Government of Japan for the approval of the Grant.

### 2-4-2 Project Operation and Maintenance Plan

(1) Personnel Plan

Table 2-42 below summarises the personnel plan of the project after commissioning.

**Table 2-42 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 |

According to this table, 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 19 million yen). After completion of the Project, the net total personnel cost will be about 14 million KShs (about 22 million yen).

The personnel plan for the production unit, for which exclusive assignment is planned, is shown in Table2-43. 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 2-43 Personnel Plan for Production and Sales Promotion for Screening Kit**

| Technical Staff | Number | Full/Part time (%) |
|---|---|---|
| (KEMRI HIV-1 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 |
| (KEMRI HEPCELLⅡ 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 KEMRI PA / HEPCELLⅡ Kit.

(2) Maintenance and Management Plan

1) Present Status of Maintenance and Management

Presently, the Technology 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 Division are assigned 2 group leaders. (the Facility Management Maintenance Group and the Machine/Equipment Maintenance Group)

The Facility Management Maintenance Group maintains buildings, landscape, water supply and wastewater facilities. The Machine/Equipment Maintenance Group maintains electric facilities, air-conditioning and refrigerating facilities, and research and medical equipment. The Facility Maintenance Group 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.

On the other hand, 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 Division maintains the entire KEMRI, including scheduled maintenance and repairs at failure.

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

2) Maintenance and Management Plan

a) Facility

To proceed smoothly with the maintenance of the planned project facility, especially the production unit (including animal house), it is essential that the indoor environment be maintained clean by an air conditioning system. To maintain a portion of the production unit clean, a system is required whereby that pertinent portion is maintained at a pressure higher than the surroundings

(positive pressure) to prevent inflow of air from the outside, 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. Therefore the filter has to be periodically cleaned of replaced. For this purpose, it is the point that the operating 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-conditioners, refrigerators and others.

Maintenance force is required to accurately acquire the maintenance and management method before the completion of the planned facilities. Therefore it is important that the responsible person is named at an early stage and maintenance force is strengthened.

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 spare parts.

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 particular equipment.

### 2-4-3 Management, Maintenance and Operation Costs

(1) Maintenance and Operation Costs

The annual maintenance and operation cost at the second year and after that was estimated in the first Basic Design Study conducted from January to December 2002 was approximately 7.4 million KShs ( the maintenance cost for facility was approximately 5.4 million KShs).

Ant in the (final) Basic Design Study which started in August 2003, the reduction of electric charge due to the adaptation of high voltage receiving system and the efficiency of air conditioning system and the study on the rational use of various filters based on the minute study of required degree of cleanliness of each room were conducted. As a result of it, the annual maintenance and operation cost at the second year and after was approximately 6.2 million KShs (the maintenance cost for facility was approximately 4.1 million KShs) as shown in Table 2-44. It reduced by 16% compared to the figure in the first Basic Design Study and the maintenance cost for only facility reduced by 24%.

The results of estimation of annual maintenance and management cost of the facilities of the Grant Aid program at the first year after completion and the second year and after are shown in the table below.

**Table 2-44 Maintenance and Management Cost**

Unit：KShs

| Items | First year after completion | | | |
|---|---|---|---|---|
| | Production Unit | Animal House (Improvement) | Training Unit | Total |
| ① Electricity charge | 1,040,928 | 430,368 | 588,960 | 2,060,256 |
| ② Telephone charge | 222,000 | 23,725 | 438,000 | 683,725 |
| ③ Fuel expenses for generator | 145,728 | 44,160 | 57,408 | 247,296 |
| ④ Water charge | 57,630 | 65,130 | 122,040 | 244,800 |
| ⑤ Butane gas charge | 127,200 | 0 | 76,320 | 203,520 |
| ⑥ Building maintenance expenses | 0 | 0 | 0 | 0 |
| ⑦ Air filter expenses | 0 | 0 | 0 | 0 |
| Subtotal ①～⑦ (Facility maintenance cost) | 1,593,406 | 563,383 | 1,282,728 | 3,439,597 |
| ⑧ Equipment maintenance cost | 510,000 | 0 | 300,000 | 810,000 |
| Total ①～⑧ | 2,103,406 | 563,383 | 1,582,728 | 4,249,597 |

| Items | Second year and after | | | |
|---|---|---|---|---|
| | Production Unit | Animal House (Improvement) | Training Unit | Total |
| ① Electricity charge | 1,040,928 | 430,368 | 588,960 | 2,060,256 |
| ② Telephone charge | 222,000 | 23,725 | 438,000 | 683,725 |
| ③ Fuel expenses for generator | 145,728 | 44,160 | 57,408 | 247,296 |
| ④ Water charge | 57,550 | 65,130 | 122,040 | 244,720 |
| ⑤ Butane gas charge | 127,200 | 0 | 76,320 | 203,520 |
| ⑥ Building maintenance expenses | 166,100 | 16,600 | 204,200 | 386,900 |
| ⑦ Filter | 216,000 | 108,000 | 0 | 324,000 |
| Subtotal ①～⑦ (Facility maintenance cost) | 1,975,506 | 687,983 | 1,486,928 | 4,150,417 |
| ⑧ Equipment maintenance cost | 1,570,000 | 176,500 | 300,000 | 2,046,500 |
| Total ①～⑧ | 3,545,506 | 864,483 | 1,786,928 | 6,196,917 |

① Electricity charge .....2,060,256 KShs/year

The contract demand of the facilities of Grant Aid project can be estimated in accordance with the size of the facilities and the contents as shown in Table 2-45. Average electricity usage is estimated at approximately 60% of the contract demand. That of animal house will be estimated at 80%.

**Table 2-45 Estimated load capacity**

| | Contract load(kW) | Used load(kW) |
|---|---|---|
| Production unit | 150 | 90 |
| Animal house | 30 | 20 |
| Training unit | 90 | 50 |
| Total | 270 | 160 |

Basic charge (1) 2,000 KShs/month

Basic charge (2) 300 KShs/kW

Usage charge 4.6 KShs/kWh

Basic charge (1)

Annual basic charge (1) 2,000KShs/month×12months＝24,000 KShs/year

Basic cost (1) will be added to the production unit.

Production unit

Annual basic charge (1) 2,000KShs/month×12months＝24,000 KShs/year

Annual basic charge (2)

300KShs/kW×150kW/month×12 months＝540,000 KShs/year

Annual usage charge

4.6KShs/kWh×90kW×8h×240days×0.6＝476,928 KShs/year

Subtotal 1,040,928 KShs/Year

Animal house

Annual basic charge (2)

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

Annual usage charge

4.6KShs/kWh×20kW×12h×365day×0.8＝322,368 KShs/year

Subtotal 430,368 KShs/year

Training unit

Annual basic charge(2) 300KShs/kW×90kW/月×12months＝ 324,000 KShs/year

Annual usage charge

4.6KShs/kWh×50kW×8h×240days×0.6＝ 246,960 KShs/year

Subtotal 588,960 KShs/year

Total 2,060,256 KShs/year

② Telephone charge .....683,725 KShs/year

Since the telephone charge depends on the number of use, we assume the frequency of use in each facility and imitate as below.

| | | |
|---|---|---|
| Domestic call charge | Nairobi | 6.5 KShs/3min |
| | Other cities | 23 KShs/min |
| International call charge | | 180 KShs/min |

Production unit

Nairobi 6.5KShs/3min×20calls/day×240days＝ 31,200 KShs/year

Outside Nairobi 23KShs/min×5min/call×3calls/day×240day＝82,800 KShs/year

International

180KShs/min×5min/call×0.5calls/day×240day＝108,000 KShs/year

Subtotal 222,000 KShs/year

Animal house

Nairobi 6.5KShs/3min×10calls/day×365days＝23,725 KShs/year

Subtotal 23,725 KShs/year

Training unit

Nairobi 6.5KShs/3min×20calls/day×240days＝31,200 KShs/year

Outside Nairobi 23KShs/min×5min/call×3calls/day×240days＝82,800 KShs/year

International

180KShs/min×5min/call×1.5calls/day×240days＝324,000 KShs/year

Subtotal 438,000 KShs/year

Total 683,725 KShs/year

③ Fuel expenses for generator.....247,296 KShs/year

In Kenya, there are 4 times/month of Power offs in 2001. It is assumed that Power offs is 2 hours/time, and 96 hours/year. We will estimate the fuel cost based on the assumption.

The capacity of generator in this program is estimated to be 200kVA.

| | |
|---|---|
| Consumption of fuel for generator | 56 ℓ/h |
| Unit price of fuel | 46 KShs/ℓ |

Production unit

Annual consumption of fuel for generator

46 KShs/ℓ×28ℓ×8h×12months＝123,648 KShs/year

Animal house

Annual consumption of fuel for generator

46 KShs/ℓ×11ℓ×8h×12months＝48,576 KShs/year

Training unit

Annual consumption of fuel for generator

46 KShs/ℓ×17ℓ×8h×12months＝75,072 KShs/year

Total 247,296 KShs/year

④ Water charge .....244,800 KShs/year

Water consumption in the facilities of the Grant Aid program T is estimated as follows.

**Table 2-46 Estimated water charge**

| | Water consumption/day ($m^3$/day) | Water consumption/ year 20days×12months ($m^3$/year) |
|---|---|---|
| Production unit | 8.5 | 2,040 |
| Animal house | 6.5 | 2,340 ※ |
| Training unit | 18.0 | 4,320 |
| Total | 33.0 | 8,700 |

※30 days/month for Animal house

The current water charge depends on water usage, and the payment method is as below.

| | |
|---|---|
| Water usage charge （Average） | 27 KShs/$m^3$ |
| Water basic charge | 25 KShs/month・$m^3$ |

Production unit

Usage charge 27 KShs/$m^3$×2,040$m^3$/year＝55,080 KShs/year

Basic charge 25 KShs/month×8.5$m^3$×12months/year＝2,550 KShs/year

Subtotal 57,630 KShs/year

Animal house

Usage charge 27 KShs/m3×2,340m3/year＝63,180 KShs/year

Basic charge 25 KShs/month×6.5m3×12months/year＝1,950 KShs/year

Subtotal 65,130 KShs/year

Training unit

Usage charge 27 KShs/m3×4,320m3/year＝ 116,640 KShs/year

Basic charge 25 KShs/month×18m3×12months/year＝5,400 KShs/year

Subtotal 122,040 KShs/year

Total 244,800 KShs/year

⑤ Butane gas charge.....203,520 KShs/year

Butane gas is used for experiments and production. The gas consumption will be estimated as follows.

**Table 2-47 Estimated Butane gas consumption**

| Name of Facility | Purpose | Daily consumption (kg/day) | Annual consumption (20days×12months) (kg/year) |
|---|---|---|---|
| Production unit | Experiment and production | 5 | 1,200 |
| Training unit | Training | 3 | 720 |
| Total | | 9 | 1,920 |

Butane gas charge 106 KShs/kg

Production unit

Annual Butane gas charge 106 KShs/kg×1,200 KShs/year＝127,200 KShs/year

Training unit

Annual Butane gas charge 106 KShs/kg×720 KShs/year＝76,320 KShs/year

Total 203,520 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 the purchase cost of repair parts and replacement parts of electrical equipment, plumbing equipment and air-conditioners, will be 100KShs/㎡/year. This is about 1/2 to 1/3 of maintenance cost in Japan.

| | |
|---|---|
| Production unit | 1,661 ㎡×100 KShs/㎡/year＝166,100 KShs/year |
| Animal house | 166 ㎡×100 KShs/㎡/year＝16,600 KShs/year |
| Training unit | 2,042 ㎡×100 KShs/㎡/year＝204,200 KShs/year |
| | Total 386,900 KShs/year |

⑦ Cost of replacement parts (Exchange of filter).....324,000 KShs/year

Medium performance air filter will be installed in the air conditioners in the production unit and the animal house.

Prefilter will be installed in each air conditioner.

We assume the frequency of exchange of each filter as below. And we assume that prefilters is recyclable and exchange cost is not required

| | |
|---|---|
| Prefilter | 2 times/month Cleaning |
| Medium performance air filter | 1 time/year（27,000 KShs/filter） |

Production unit

Medium performance air filter

8 filters/year×27,000 KShs/filter＝216,000 KShs/filter

Animal house

Medium performance air filter

4filters/year×27,000 KShs/filter＝108,000 KShs/filter

Total 324,000 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) are 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 |

(2) Financial Conditions for Maintenance and Management Cost

The maintenance and management cost of the Grant Aid project after commissioning is estimated at about 6.2 million KShs every year, of which facility maintenance and equipment maintenance are estimated at 4.2 million KShs and 2 million KShs, respectively.

The trend of the budget of KEMRI reduced by 0.8% in 2001/ 2002, but it shows high increase of 64.1% in 2002/2003. And the estimated maintenance cost (6.2 million kShs) in the project accounts for 0.86% of KEMRI budget (717 million KShs) in 2002/2003. On the other hand, the estimated labor cost (net increase) is 14 million KShs and accounts for 1.95% of the budget.

**Table 2-48 Breakdown of KEMRI's Budget**

(Unit: Million KShs)

| Expenditure base | 1999/2000 | 2000/2001 | 2001/2002 | 2002/2003 |
|---|---|---|---|---|
| Personnel expense | 197.00 | 258.60 | 223.7 | 417.0 |
| Research expense | 229.00 | 239.00 | 204.9 | 280.3 |
| Facility and equipment procurement expense | 6.50 | 10.40 | 6.0 | 13.4 |
| Training expense | 0.83 | 0.64 | 0.5 | 1.4 |
| Maintenance and management cost | 2.70 | 3.40 | 2.0 | 5.6 |
| Total | 436.03 | 512.04 | 437.1 | 717.7 |

(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.

# Chapter 3. Project Evaluation and Recommendations

# CHAPTER 3. PROJECT EVALUATION AND RECOMMENDATIONS

## 3-1 Project Effect

(1) Expected Direct Effect

This project is expected to bring about the following direct effects.

1) Increase of quantity of production and number of check of blood screening kit

In this project, the manufacturing facility of blood screening kits for HIV and HBV will be constructed, which develops the manufacturing system of blood screening kit which is low-priced and whose quality is guaranteed, supplies blood screening kit stably, and increases the number of check of HIV and HBV.

2) Improvement of screening rate of blood for transfusion

It is said that the infection rate of HIV is approximately 13% and that of HBV is approximately 4% in Kenya. The low-priced blood screening kit and its stable supply would improve the screening rate of blood for transfusion. And the transfusion of blood which is tainted with HIV and HBV decreases and the infection can be prevented furthermore.

3) Increase of personnel who gets the training of infectious diseases and parasitic diseases

In this project, the training facility for infectious and parasitic diseases will be constructed, which will increase the number of personnel at home and from abroad who gets the training, and can further promote the countermeasures of parasite and infectious diseases not only at home but also in neighbouring nations.

And KEMRI has a function to provide consulting services on the blood test. KEMRI is able to promptly reply to questions, etc. of KEMRI HIV-1 PA kit users.

4) Implementation of smooth technology transfer

In the two technical cooperation projects which are in operation, technical aid will be conducted in manufacturing technology of blood screening kit and training activities on infectious diseases and parasitic diseases. And the use of the facilities which will be constructed in the project will make the activities smoother.

Through the training activities which will be held at the training facility, the technology of use of KEMRI Kit can be transferred to laboratory engineers and others of hospitals at home.

(2) Expected Indirect Effect

Execution of this project will improve the facilities for prevention of infectious and parasitic diseases. It is expected naturally that the policy measures of Kenya regarding infectious and parasitic diseases control will be improved.

Regarding infectious diseases, control Kenya's own blood screening kids suited to the conditions of Kenya will be mass-produced. The blood screening kits will be used by a number of hospitals, blood banks and related facilities. This will increase the number of blood tests, not only for the purpose of transfusion but also for the purpose of maternal and child health checks. Coupled with proper measures for preventing the already infected persons from further spreading the diseases, use of HIV and HBV blood screening kits will help reduce mother-to-bay infection rate, for example.

Regarding parasites, disease control with a background of intensifying international cooperation, this project will conduct training for parasitologists, clinical technologists, medical students of Kenya and neighbouring countries. This will contribute greatly to human resource development in this region, and hence reduction of infection rates of parasitic diseases.

(3) Use of Performance Indicator

The evaluation of this project will use the number of blood screening kits, number of blood tests, rate of screening for blood transfusion, trend in the number of participants in training courses for infectious diseases and parasitic diseases.

### 3-2 Recommendations

It is essential that the works of Kenyan portion have been timely done before cooperation project is commenced. What is more important, such works as demolishing and removal of the existing facilities in the construction site, land grading, (including temporary relocation of the existing animal house) must have been completed before the works of the Japanese side can start. In order for the project to be smoothly and effectively managed, it is recommended that the following improvements or arrangements be done.

(1) Presently in Kenya, blood screening kits are manufactured on a laboratory scale. Management of the new blood screening kit production unit to be installed by this project will require process control and quality control on the basis of voluntary GMP standard. The project also requires establishment of management method for the attached animal house and acquisition of such skills by the local staff. In these respects, technology transfer by technical cooperation project is much desired. Most importantly, KEMRI should by its own effort ensure that the human resource developed through such a technology transfer, in turn, transfers their skills to other technicians and specialists, thereby establishing a system for sustainable development of KEMRI. Through such endeavours, KEMRI would be able to effectively utilise the blood screening kit production unit, and to realise KEMRI's own technological developments.

(2) On KEMRI HEPCELLII kit of blood screening kits, acquisition of national approval and blanket purchase by MOH are promised. On the other hand, on KEMRI HIV-1 PA kit, MOH and others express that they will purchase them in a lump when screening kits of HIV-1 and HIV-2 are developed in technical cooperation project and national approval is acquired. So, it is desired that screening kits of HIV-1 and HIV-2 are early developed in KEMRI with the technical cooperation project and the production technology is transferred.

(3) The government of Japan proposed to the 1998 Birmingham Summit (G8 Summit) to intensify international movements for controlling parasitic diseases by establishing centres for human resource development and network building in Asia and Africa. Regarding this proposal, Kenya (KEMRI), Ghana and Thailand are considered as locations of such centres. KEMRI is expected to establish the network and effectively promote activities for human resource development, in close collaboration with the other centres.

(4) It is important that necessary manpower be secured to maintain the facilities and equipment. This is essential to keep the facilities constructed and equipment procured by this project in good conditions, the air-conditioning facilities for production unit in particular, so that they may be used in good conditions for a long period.

(5) When the equipment is procured, the maintenance and inspection manual, operation manual, circuit diagram, etc. are provided. In addition, a technical guidance by the supplier will be done. Therefore, effective use of these materials is necessary to realise good maintenance control of the equipment. It is desired to keep tracks of dates of delivery, frequency of use, repair history, etc. and record these events on a ledger (record book) for each piece of equipment. It is also desired to formulate a sparepart purchase plan and equipment renewal plan, and to formulate long- and medium-range budgets based on these plans.

(6) It is desired that, after completion of the project, the annual report be prepared every year on the management and operation of the project. The preparation of the annual report will help understand the management and operation of the subject facilities, and the report will serve as a reference for planning improvements.

(7) It is desired that a system for monitoring the effects of the use of blood screening kits be established in collaboration with other medical institutions. The monitoring system should facilitate collection of information that serve as indicators of the effects of kits, and studies on diseases of AIDS and HB after blood transfusions.

# Appendices

## 1. Member List of the Survey Team

Basic Design Survey (August 24 to September 9, 2003)

| NAME | ROLE | INSTITUTION |
|---|---|---|
| Takashi KURIMURA | Leader | Professor Emeritus,<br>Osaka University |
| Masahiro IKAWA | Project Manager/<br>Architectural Planning | Nihon Sekkei, Inc. |
| Noki TOMINAGA | Architectural Designing | Nihon Sekkei, Inc. |
| Toshio NIIZUMA | Blood Screening Kit Production System Designing | Nihon Sekkei, Inc. |
| Takahisa ISOBE | Facility Planning | Nihon Sekkei, Inc. |
| Hiroaki NAKATANI | Equipment Planning | Nihon Sekkei, Inc. |
| Yoichi UCHIHARA | Cost and Procurement Planning | Nihon Sekkei, Inc. |

Explanation on Draft Report (October 20 to October 29, 2003)

| NAME | ROLE | INSTITUTION |
|---|---|---|
| Masaaki OTSUKA | Leader | Resident Representative<br>JICA Kenya Office<br>Japan International Cooperation Agency |
| Masahiro IKAWA | Project Manager/<br>Architectural Planning | Nihon Sekkei, Inc. |
| Toshio NIIZUMA | Blood Screening Kit Production System Designing | Nihon Sekkei, Inc. |

## 2. Survey Schedule

Basic Design Survey (August 24 to September 9, 2003)

| | | | | |
|---|---|---|---|---|
| 1 | Aug 24 Sun | | Narita → Amsterdam | |
| 2 | Aug 25 Mon | | → Nairobi<br>Courtesy call to JICA Office<br>Discussion at KEMRI | |
| 3 | Aug 26 Tue | | Discussion and Survey at KEMRI | |
| 8 | Aug 27 Wed | Leader<br>Narita → | Courtesy call to MOH<br>Courtesy call to Japanese Embassy<br>Discussion at KEMRI | |
| 5 | Aug 28 Thu | → Nairobi | Courtesy call to JICA Office<br>Discussion at KEMRI（Mr. KURIMURA)）<br>Discussion at KEMRI | Cost and Procurement Planning<br>Narita → |
| 6 | Aug 29 Fri | Discussion at KEMRI<br>(Production Syste, Architectural Plan,Air Conditioning Plan） | | → Nairobi |
| 7 | Aug 30 Sat | Market Survey（local building materials） | | |
| 8 | Aug 31 Sun | Team meeting | | |
| 9 | Sep 1 Mon | Discussion at KEMRI<br>（Architectural Plan, Project Operaton Plan）<br>KEMRI (Draft of Minutes of Discussions) | | |
| 10 | Sep 2 Tue | Signing of Minutes of Discussion<br>Report to Japanese Embassy, JICA Office | | |
| 11 | Sep 3 Wed | | Discussion at KEMRI<br>(Blood Screening Kit Production System Design, Training Unit/Equipment Plan） | |
| 12 | Sep 4 Thu | | KEMRI (Operation & Maintenance Plan, Budget & Personnel Plan) | |
| 13 | Sep 5 Fri | | Discussion at KEMRI<br>Report to JICA | |
| 14 | Sep 6 Sat | | Market Survey | |
| 15 | Sep 7 Sun | | Team Meeting<br>Departure from Nairobi → | |
| 16 | Sep 8 Mon | | → Return Trip → | |
| 17 | Sep 9 Tue | | → Narita | |

Explanation on Draft Report (October 20 to October 29, 2003)

| | | |
|---|---|---|
| 1 | 10/20 Mon. | Narita → |
| 2 | 10/21 Tue. | → Nairobi Courtesy call to JICA, Meeting with Project Experts, Courtesy call to EOJKEMRI |
| 3 | 10/22 Wed. | Explanation of Draft Report to KEMRI (Production System, Architectural Plan) |
| 4 | 10/23 Thu. | KEMRI (Production System, Architectural Plan, Scope of Works, Total Schedule) |
| 5 | 10/24 Fri. | KEMRI (, Operation & Maintenance Plan, Budget & Personnel Plan) |
| 6 | 10/25 Sat. | KEMRI (Draft of Minutes of Discussions) |
| 7 | 10/26 Sun. | Team Meeting/Market Survey |
| 8 | 10/27 Mon. | Signing of Minutes of Discussionsat MOH, Report to JICA / EOJ Nairobi → |
| 9 | 10/28 Tue. | Return trip |
| 10 | 10/29 Wed. | → Narita |

**3. List of Party Concerned in the Recipient Country**

Kenyan Side

■Kenyan Government (Ministry of Health)

| | |
|---|---|
| Prof. J. S. Meme | Permanent Secretary |
| Dr. I. B. Arnira-Ag | Director of Medical Services |
| Dr. O. Muga | Director of Medical Services |
| Dr. K. C. Koskei | Chief Pharmacist |
| Mr. Wellington, P, Godo | Permanent Secretary |
| Mr. John Gakuo | Senior Deputy Secretary |
| Ms Janet Mugo | Representative person in charge of JICA Project |

・National Public Health Laboratory Services

Dr. J. A. Nyamongo

・National AIDS Control Council

| | |
|---|---|
| Dr. Margaret Gachara | Director |
| Dr. P. A. Orege | Deputy Director, Technical |

■Kenyan Government (Ministry of Finance)

・Department of External Resourses

| | |
|---|---|
| Mr. D. K. Kibera | Director of External Resources Department |
| Ms. Anne Olubendi | Desk officer Asia/Pacific |
| Mr. M. O. Ochieng | Deputy Desk officer Asia/Pacific |

■Kenyan Government（Kenya Medical Research Institute：KEMRI)

| | |
|---|---|
| Dr. Davy K. Koech | Director |
| Mr. D. M. Ngumo | Deputy Director, Finance and Administration |
| Dr. W. M. Kofi-Tsekpo | Assistant Director |
| Dr. P. Josior | Chief Research Officer (Corporate Affairs) |
| Dr. Solomon Mpoke | Coordinator of Infectious Diseases, KEMRI/JICA Project |
| Dr. N. Wamae | Principal Research Officer, Director, Centre for Microbiology Research, Director, ESACIPAC |
| Dr. C. S. Mwandawiro | Principal Research Officer |
| Dr. W. Rono | Marketing Manager |
| Mr. Davis Mkuji | Information Officer |
| Mr. J. N. Kariuki | Chief Administrative Officer |
| Mr. J. K. Lelei | Principal Institute Engineer |
| Mr. J.K. Mutegi | Electrical Engineer |
| Mr. J. Kanyeki | Maintenance Officer |

| | |
|---|---|
| Dr. Pesuu | Director of CGMRC, KEMRI, Kilifi |
| Dr. Joseph M. Vulule | Director of CVBCR, KEMRI Kisumu |
| Dr. Nick Abungo | Director of CIPDCR, KEMRI Busia |
| Mr. Simon Woods | Consultant Architect, KEMRI |

Japanese Side

■Japanese Government

・Embassy of Japan

| | |
|---|---|
| Masanori Yuzawa | Second Secretary |

・JICA Kenya Office

| | |
|---|---|
| Masaaki Otsuka | Resident Representative |
| Tomoki Nitta | Deputy Resident Representative |
| Shinichi Matsuura | Deputy Resident Representative |
| Takayuki Nakagawa | Assistant Resident Representative |

・JICA Expert

(Infectious Diseases Control Project)

| | |
|---|---|
| Isao Oisi | JICA/KEMRI Expert - Infectious Diseases Control |
| Yasukazu Omoto | JICA/KEMRI Expert - Infectious Diseases Control |
| Kozo Ono | JICA/KEMRI Project Coordinator |

(Parasitic Diseases Control Project)

| | |
|---|---|
| Teruaki Amano | JICA/KEMRI Expert - Chief Adviser |
| Toshiki Awazawa | JICA/KEMRI Expert - Parasitic Diseases Control |
| Makoto Shiraki | JICA/KEMRI Project Coordinator |
| Tsutomu Kobayashi | JICA/KEMRI Project Coordinator |

**Appendices 4**

## 4-1 MINUTES OF DISCUSSION

**MINUTES OF DISCUSSIONS**
**ON THE BASIC DESIGN STUDY**
**ON THE PROJECT FOR IMPROVEMENT OF FACILITIES FOR CONTROL OF INFECTIOUS AND PARASITIC DISEASES**
**AT KENYA MEDICAL RESEARCH INSTITUTE**
**IN THE REPUBLIC OF KENYA**

The Japan International Cooperation Agency (hereinafter referred to as "JICA") dispatched Basic Design Study Teams on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute (hereinafter referred to as "the Project") in the Republic of Kenya (hereinafter referred to as "Kenya") from January through February 2002 and August 2002 and prepared the report of the study form discussions, field surveys, and technical examination of the results. JICA also dispatched the Basic Design Study Team in May 2003 in order to reconfirm the situation, namely of the estimation of the projected number of kits for production and the purchase of blood screening test kits by the Government of Kenya.

In order to re-examine the basic design based on the results of previous study teams, JICA sent to Kenya the Basic Design Study Team (hereinafter referred to as "the Team"), which was headed by Prof. Takashi Kurimura, Professor Emeritus of Osaka University, from August 25, 2003 to September 3, 2003.

The Team held discussions with the officials concerned of the Government of Kenya and conducted a field survey at the study area.

In the course of discussions and field survey, both parties confirmed the main items described in the attached sheets. The Team will proceed with further studies and prepare the Basic Design Study Report.

Nairobi, September 2, 2003

Prof. Takashi Kurimura
Leader
Basic Design Study Team
Japan International Cooperation Agency

Dr. Davy K. Koech
Director
Kenya Medical Research Institute
Republic of Kenya

Countersigned by:

Mr. Wellington P. Godo
Permanent Secretary
Ministry of Health
Republic of Kenya

Mr. Joseph M. Magari
Permanent Secretary
Ministry of Finance and Planning
Republic of Kenya

ATTACHMENT

1. Objective of the Project

The objective of the Project is to strengthen control and research on infectious and parasitic diseases in Kenya and the neighboring countries through construction of new facilities and procurement of equipment for the Kenya Medical Research Institute (hereinafter referred to as "KEMRI").

2. Project site

The site of the Project is Nairobi.

3. Responsible and Implementing Agency

3-1. The Responsible Agency is Ministry of Health.

3-2. The Implementing Agency is KEMRI.

4. Items requested by the Government of Kenya

After discussions with the Team, the items described in Annex-1 and 2 were finally requested by the Kenyan side.

4-1. Construction of the Buildings and Facilities

Details of items are listed in Annex-1.

4-2. Procurement of the Equipment

Details of items are listed in Annex-2.

5. Japan's Grant Aid Scheme

5-1. The Kenyan side understands the Japan's Grant Aid Scheme explained by the Team, as described in Annex-3.

5-2. The Kenyan side will take the necessary measures, as described in Annex-4, for smooth implementation of the Project, as a condition for the Japanese Grant Aid to be implemented.

6. Schedule of the Study

6-1. The consultants will proceed with further studies in Kenya until September 7, 2003.

6-2. JICA will prepare the draft report in English and dispatch a mission in order to explain its contents around October 2003.

6-3. In case the contents of the report are accepted in principle by the Government of Kenya, JICA will complete the final report and send it to the Government of Kenya by January 2004.

7. Other relevant issues

7-1. Both sides reconfirmed the contents of the Minutes of Discussions of the Basic Design Study Team signed on May 15, 2003.

7-2. Both sides confirmed that the design of Production Unit and Animal House would be revised as described in Annex-1 from the result of Basic Design Study Team in 2002.

7-3. The Kenyan side presented the annual demand forecast in the target market and projected number of blood screening tests using KEMRI HEPCELL II kit and KEMRI HIV-1 P.A. kit.

| | |
|---|---|
| KEMRI HEPCELL II kit : | 400,000 tests/year (for sales purposes) |
| KEMRI HIV-1 P.A. kit : | 50,000 tests/year (only for research purposes) |

TK

The Kenyan side explained the development plan of an HIV blood screening kit, which can detect both HIV-1 and HIV-2 antibodies utilizing the planned facilities.

7-4. The Government of Kenya commits itself to continue purchasing the blood screening test kits from KEMRI as mentioned below:

KEMRI HEPCELL II kit : 400,000 tests/year

7-5. The Kenyan side agreed to carry out the following work regarding the Animal House

- To prepare the necessary facilities (including insect and snail rooms etc.) during construction period and after completion of the Project.
- To remove the functions of the existing Animal House before implementation of the construction.

7-6. The Training Unit, described in Annex -1, will be constructed in accordance with Minutes of Discussions signed on August 16, 2002 between the Leader of Draft Report Explanation Team and the Director KEMRI.

7-7. The Kenyan side requested for technical cooperation as well as technical training in 1)setting up of Blood Test Kit Production Unit and 2)maintenance of facilities and laboratory equipment.

7-8. The Kenyan side confirmed exemption from the Value Added Tax (VAT) on the purchase of project materials, equipment and services related to the Project in accordance with the Japan's Grant Aid Scheme, and will take necessary measures to ensure prompt VAT returns to the contractors and suppliers.

7-9. The Kenyan side shall secure and allocate enough qualified staff and budgets to operate and properly and effectively maintain the facilities and equipment procured through the Grant Aid.

7-10.Electrical Power and Water Supply

7-10-1 Electrical Power Supply

- The Kenyan side shall provide the additional main distribution line to the site in addition to the existing main line.

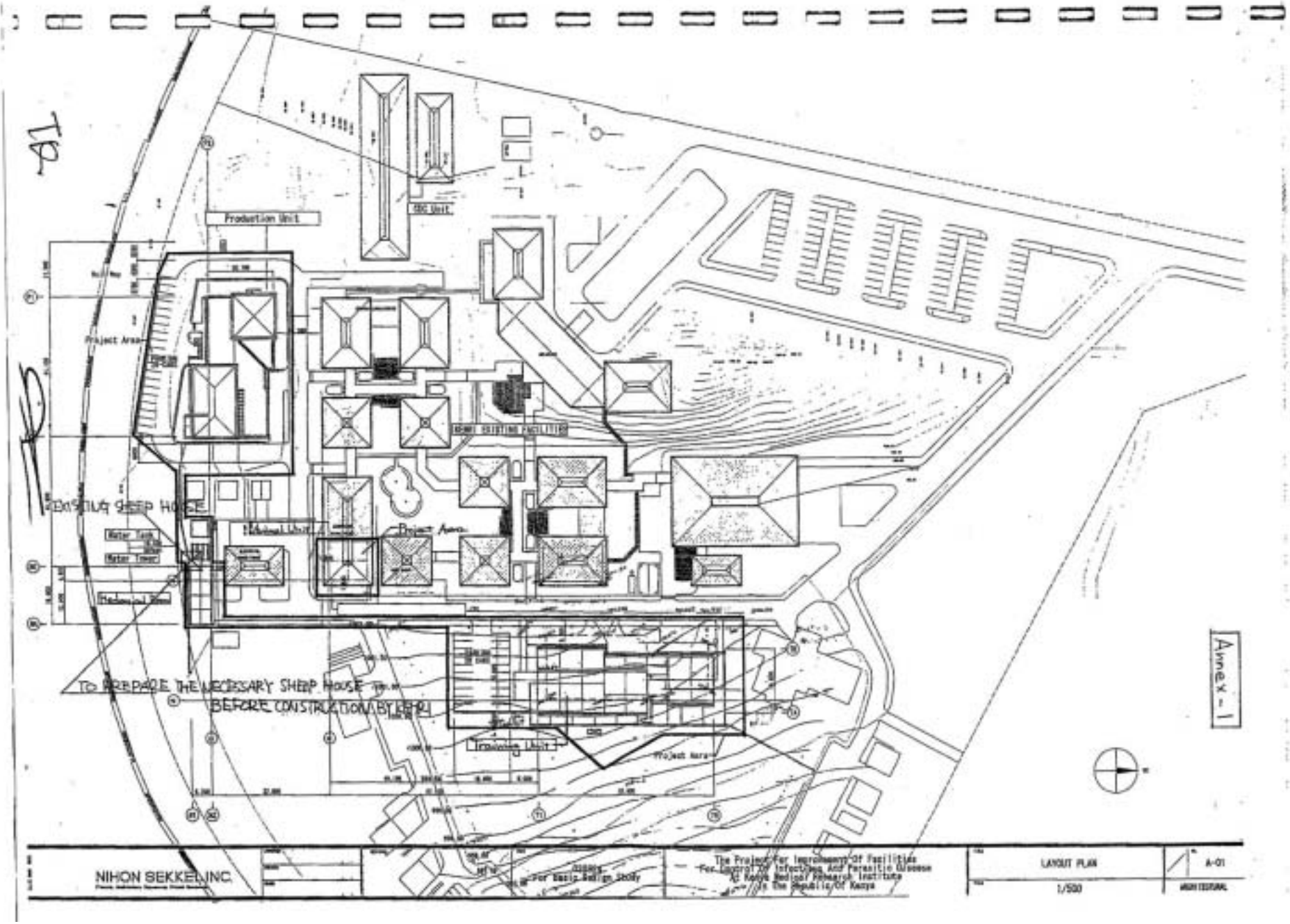
7-10-2 Water Supply

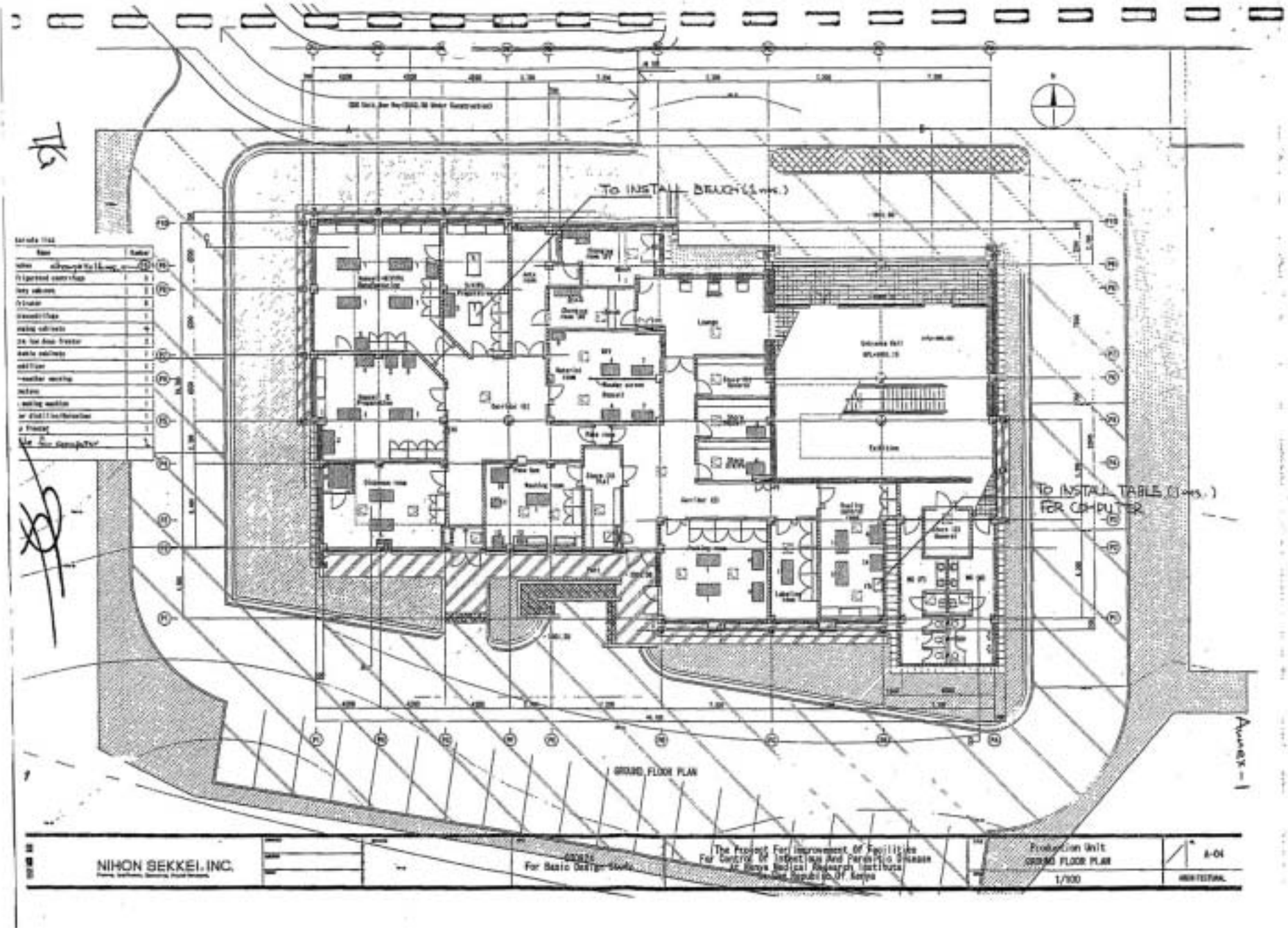
- The Kenyan side shall provide the additional direct water main line to the site in addition to the existing main line.
- The Kenyan side shall provide the deep well piping line to the Project.

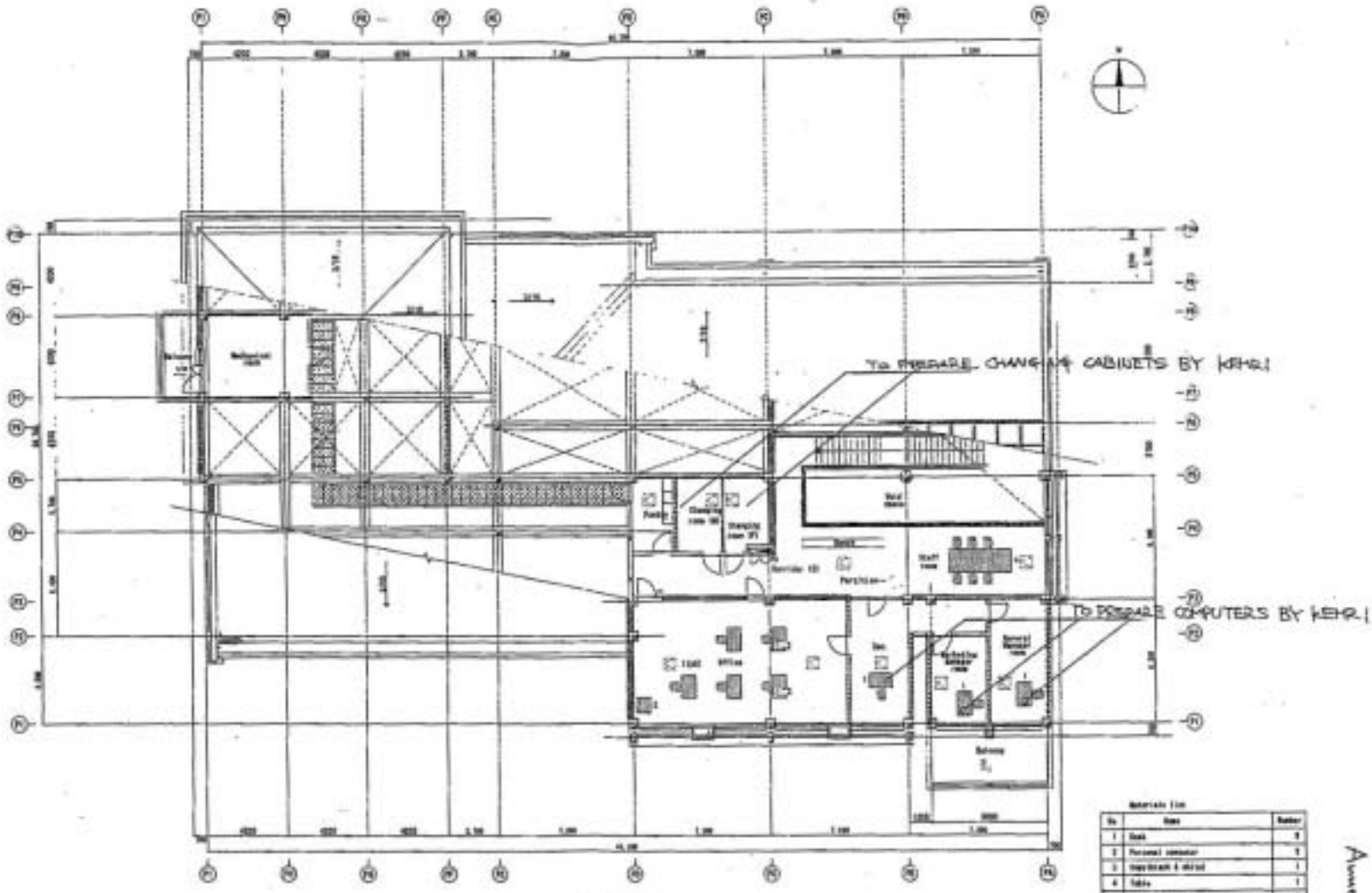
7-11.Both sides agreed that additional works need to be undertaken to strengthen security of the planned facilities.

List of Annexes

| | |
|---|---|
| Annex-1 | Description of the construction of facilities confirmed by both sides |
| Annex-2 | Description of the list of major equipment confirmed by both sides |
| Annex-3 | Japan's Grant Aid Program |
| Annex-4 | Major Undertakings by each government |


Production Unit
BSC Unit
Project Area
Project Area
Project Area
Project Area
Animal Unit
Animal Unit
Water Tank
Water Tower
To DEMOLISH THE UNNECESSARY SHEEP HOUSE BEFORE CONSTRUCTION BY KEMRI
Annex-1
NIHON SEKKEI INC.
Design
Per Basic Design Study
The Project For Improvement Of Facilities For Control Of Infectious And Parasitic Diseases At Kenya Medical Research Institute In The Republic Of Kenya
LAYOUT PLAN
1/500
A-01
ARCHITECTURAL


TO INSTALL BRACKET(
TO INSTALL TABLE (
FOR COMPUTER
GROUND FLOOR PLAN
Annex-1
NIHON SEKKEI, INC.
The Project For Improvement Of Facilities
For Control Of Infectious And Parasitic Diseases
At Kenya Medical Research Institute
Republic Of Kenya
Production Unit
GROUND FLOOR PLAN
1/100
A-04

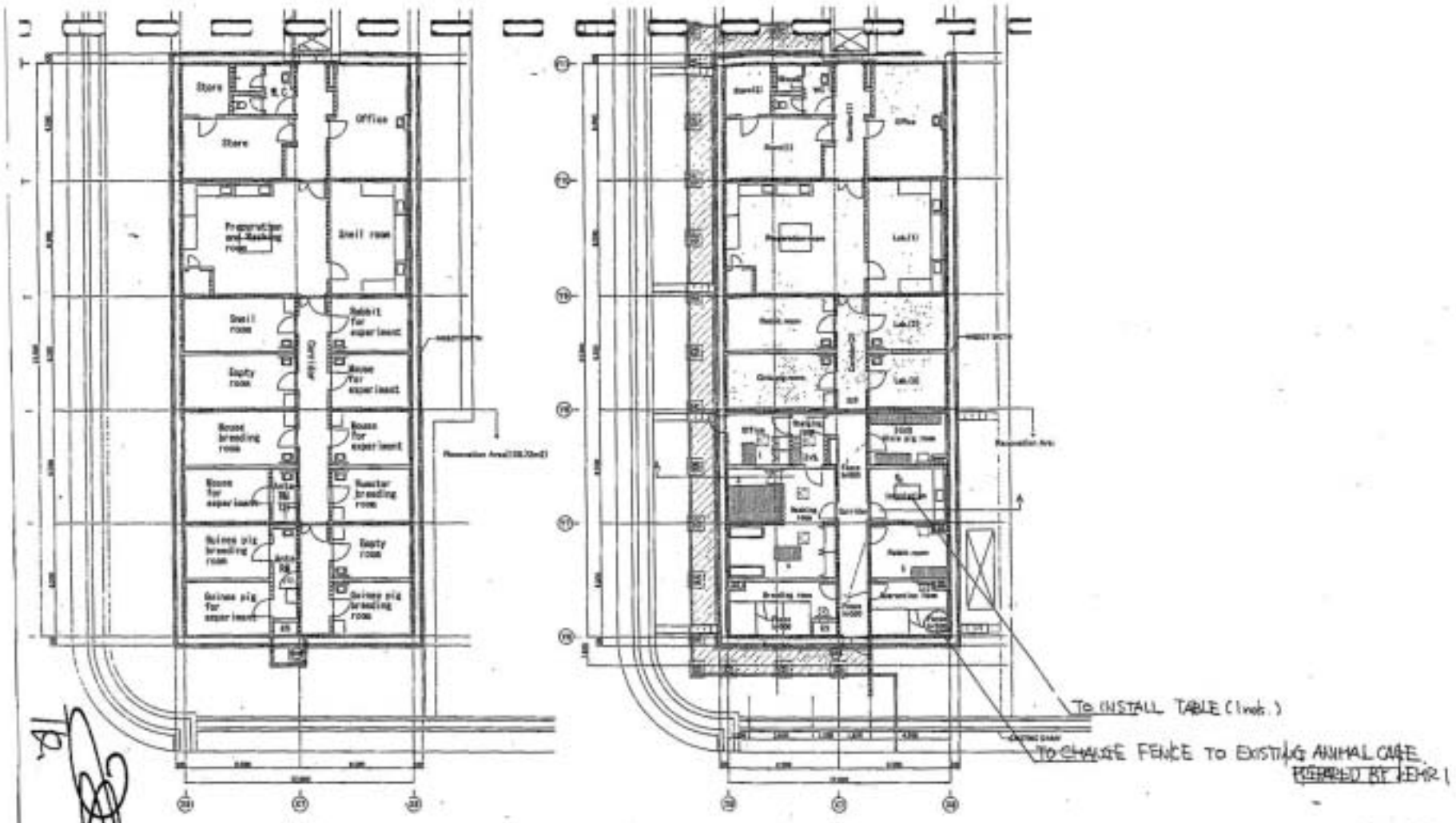



FIRST FLOOR PLAN

| No. | Name | Number |
|---|---|---|
| 1 | Desk | 9 |
| 2 | Personal computer | 9 |
| 3 | Copy machine & shredd | 1 |
| 4 | Table | 1 |
| 5 | Changing cabinets | 3 |

Annex - 1

| | | | | | |
|---|---|---|---|---|---|
| NIHON SEKKEI, INC. | | 050824 For Basic Design Study | The Project For Improvement Of Facilities For Control Of Infectious And Parasitic Diseases At Kenya Medical Research Institute In The Republic Of Kenya | Production Unit FIRST FLOOR PLAN | A-105 |
| | | | | 1/100 | ARCHITECTURAL |




| NIHON SEKKEI, INC. | | | 03082N For Basic Design Study | The Project For Improvement Of Facilities For Control Of Infectious And Parasitic Disease At Kenya Medical Research Institute In The Republic Of Kenya | Animal Unit (Renovation) GROUND FLOOR PLAN, ROOF PLAN | A-19 |
|---|---|---|---|---|---|---|
| | | | | | 1/200 | ARCHITECTURAL |

**Equipment List (Production Unit and Animal House)**

| No. | Description | Production unit | Animal house | Q'ty of 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 | 2 |
| 6 | Safety cabinet | 2 | | 2 |
| 7 | Incubator | 1 | | 1 |
| 8 | Refrigerator | 8 | | 8 |
| 9 | Freezer (vertical type) | 1 | | 1 |
| 10 | Ultra low deep freezer | 2 | | 2 |
| 11 | Passbox | 1 | | 1 |
| 12 | Drying machine | 1 | | 1 |
| 13 | Benches | 19 | 2 | 21 |
| 14 | Stools | 16 | 4 | 20 |
| 15 | Desk and chair for office | 6 | 1 | 7 |
| 16 | Desk and chair for manager | 2 | | 2 |
| 17 | Meeting table and chair | 1 | | 1 |
| 18 | Cage rack | | 4 | 4 |
| 19 | Balance | | 1 | 1 |
| 20 | Personal computer | 3 | | 3 |
| 21 | white | 1 | | 1 |
| 22 | Printer, black and white | 2 | | 2 |
| 23 | Storage cabinet A | 1 | | 1 |
| 24 | Storage cabinet B | 2 | | 2 |
| 25 | Storage cabinet C | 2 | | 2 |
| 26 | Changing cabinet | 4 | 2 | 6 |
| 27 | Hematocrit centrifuge | 1 | | 1 |
| 28 | Table top centrifuge | 1 | | 1 |
| 29 | Densitometer | 1 | | 1 |
| 30 | Refractometer | 1 | | 1 |
| 31 | Spectrophotometer | 1 | | 1 |
| 32 | Electric balance A | 2 | | 2 |
| 33 | Fraction collector | 1 | | 1 |
| 34 | pH meter | 2 | | 2 |
| 35 | Plate mixer | 3 | | 3 |
| 36 | Peristaltic pump | 2 | | 2 |
| 37 | Vortex mixer | 2 | | 2 |
| 38 | Magnetic stineer | 1 | | 1 |
| 39 | Automatic pipette aid-rechargeable | 4 | | 4 |
| 40 | Water bath | 3 | | 3 |
| 41 | Micro plate washer | 1 | | 1 |
| 42 | Micro plate reader | 1 | | 1 |
| 43 | Camera illuminator & stand | 1 | | 1 |
| 44 | Ultrasonic homoginizer | 1 | | 1 |
| 45 | Animal caring set | | 1 | 1 |
| 46 | Animal cage | | 125 | 125 |
| 47 | Affinity chromatography stand | 1 | | 1 |
| 48 | Affinity chromatography column | 5 | | 5 |
| 49 | Suction unit | 1 | | 1 |
| 50 | Plasma separator | 1 | | 1 |
| 51 | Mechanical crimpers | 1 | | 1 |
| 52 | Ice making machine | 1 | | 1 |

TD.

JAPAN'S GRANT AID SCHEME

1. Grant Aid Procedure

1) Japan's Grant Aid Program is executed through the following procedures.

| | |
|---|---|
| Application | (Request made by a recipient country) |
| Study | (Basic Design Study conducted by JICA) |
| Appraisal & Approval | (Appraisal by the Government of Japan and Approval by Cabinet) |
| Determination of Implementation | (The Notes exchanged between the Governments of Japan and the recipient country) |

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

Secondly, JICA conducts the study (Basic Design Study), using Japanese consulting firms.

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

Fourthly, the project, once approved by the Cabinet, becomes official with the Exchange of Notes signed by the Governments of Japan and the recipient country.

Finally, for the implementation of the project, JICA assists the recipient country in such matters as preparing tenders, contracts and so on.

2. Basic Design Study

1) Contents of the Study

The aim of the Basic Design Study (hereinafter referred to as "the Study"), conducted by JICA on a requested project (hereinafter referred to as "the Project"), is to provide a basic document necessary for the appraisal of the Project by the Government of Japan. The contents of the Study are as follows:

a) confirmation of the background, objectives and benefits of the Project and also institutional capacity of agencies concerned of the recipient country necessary for the Project's implementation;
b) evaluation of the appropriateness of the Project to be implemented under the Grant Aid Scheme from the technical, social and economic points of view;
c) confirmation of items agreed on by both parties concerning the basic concept of the Project;
d) preparation of a basic design of the Project; and
e) estimation of costs of the Project.

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

TK

The Government of Japan requests the Government of the recipient country to take whatever measures are necessary to ensure its self-reliance in the implementation of the Project. Such measures must be guaranteed even though they may fall outside of the jurisdiction of the organization in the recipient country actually implementing the Project. Therefore, the implementation of the Project is confirmed by all relevant organizations of the recipient country through the Minutes of Discussions.

2) Selection of Consultants

For the smooth implementation of the Study, JICA uses a consulting firm selected through its own procedure (competitive proposal). The selected firm participates in the Study and prepares a report based upon the terms of reference set by JICA.

At the beginning of implementation after the Exchange of Notes, for the services of the Detailed Design and Construction Supervision of the Project, JICA recommends the same consulting firm which participated in the Study to the recipient country, in order to maintain the technical consistency between the Basic Design and Detailed Design as well as to avoid any undue delay caused by the selection of a new consulting firm.

3. Japan's Grant Aid Scheme

1) Grant Aid

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

2) Exchange of Notes (E/N)

Japan's Grant Aid is extended in accordance with the Notes exchanged by the two Governments concerned, in which the objectives of the project, period of execution, conditions and amount of the Grant Aid, etc., are confirmed.

3) "The period of the Grant" means the one fiscal year which the Cabinet approves the project for. Within the fiscal year, all procedures such as exchanging of the Notes, concluding contracts with consulting firms and contractors and final payment to them must be completed.

However, in case of delays in delivery, installation or construction due to unforeseen factors such as weather, the period of the Grant Aid can be further extended for a maximum of one fiscal year at most by mutual agreement between the two Governments.

4) Under the Grant, in principle, Japanese products and services including transport or those of the recipient country are to be purchased.

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

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

5) Necessity of "Verification"

The Government of the recipient country or its designated authority will conclude contracts

denominated in Japanese yen with Japanese nationals. Those contracts shall be verified by the Government of Japan. This "Verification" is deemed necessary to secure accountability of Japanese taxpayers.

6) Undertakings required to the Government of the recipient country

a) to secure a lot of land necessary for the construction of the Project and to clear the site;

b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities outside the site;

c) to ensure prompt unloading and customs clearance at ports of disembarkation in the recipient country and internal transportation therein of the products purchased under the Grant Aid;

d) to exempt Japanese nationals from customs duties, internal taxes and fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contracts;

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

f) to ensure that the facilities constructed and products purchased under the Grant Aid be maintained and used properly and effectively for the Project; and

g) to bear all the expenses, other than those covered by the Grant Aid, necessary for the Project.

7) "Proper Use"

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

8) "Re-export"

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

9) Banking Arrangement (B/A)

a) The Government of the recipient country or its designated authority should open an account in the name of the Government of the recipient country in an authorized foreign exchange bank in Japan (hereinafter referred to as "the Bank"). The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by the Government of the recipient country or its designated authority under the verified contracts.

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

T.K.

D.K.

Major Undertakings by each Government

| NO | Items | To be covered by Grant Aid | To be covered by Recipient side |
|---|---|---|---|
| 1 | To secure land | | • |
| 2 | To clear, level and reclaim the site when needed | | • |
| 3 | To construct gates and fences in and around the site | | • |
| 4 | To construct the parking lot | • | |
| 5 | To construct roads | | |
| | 1) Within the site | • | |
| | 2) Outside the site | | • |
| 6 | To construct the building | • | |
| 7 | To provide facilities for the distribution of electricity, water supply, drainage and other incidental facilities | | |
| | 1)Electricity | | |
| | a.The distributing line to the site | | • |
| | b.The drop wiring and internal wiring within the site | • | |
| | c.The main circuit breaker and transformer | • | |
| | 2)Water Supply | | |
| | a.The city water distribution main to the site | | • |
| | b.The supply system within the site ( receiving and/or elevated tanks ) | • | |
| | 3)Drainage | | |
| | a.The city drainage main ( for storm, sewer and others ) to the site | | • |
| | b.The drainage system ( for toilet sewer, ordinary waste, storm drainage and others ) within the site | • | |
| | 4)Gas Supply | | |
| | a.The city gas main to the site | | • |
| | b.The gas supply system within the site | • | |
| | 5)Telephone System | | |
| | a.The telephone trunk line to the main distribution frame / panel (MDF) of the building | | • |
| | b.The MDF and the extension after the frame / panel | • | |
| | 6)Furniture and Equipment | | |
| | a.General furniture | | • |
| | b.Project equipment | • | |
| 8 | To bear the following commissions to a bank of Japan for the banking services based upon the B/A | | |
| | 1) Advising commission of A/P | | • |
| | 2) Payment commission | | • |
| 9 | To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country | | |
| | 1) Marine(Air) transportation of the products from Japan to the recipient country | • | |
| | 2) Tax exemption and customs clearance of the products at the port of disembarkation | | • |
| | 3) Internal transportation from the port of disembarkation to the project site | (•) | (•) |
| 10 | To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contract such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work | | • |

T.Ito

| | | | |
|---|---|---|---|
| 11 | To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contract | | • |
| 12 | To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant Aid | | • |
| 13 | To bear all the expenses, other than those to be borne by the Grant Aid, necessary for construction of the facilities as well as for the transportation and installation of the equipment | | • |

## 4-2 MINUTES OF DISCUSSION

**MINUTES OF DISCUSSIONS**
**ON BASIC DESIGN STUDY**
**ON THE PROJECT FOR IMPROVEMENT OF FACILITIES FOR CONTROL OF INFECTIOUS AND PARASITIC DISEASES**
**AT KENYA MEDICAL RESEARCH INSTITUTE**
**IN THE REPUBLIC OF KENYA**
**(EXPLANATION ON DRAFT REPORT)**

In August 2003, the Japan International Cooperation Agency (hereinafter referred to as "JICA") dispatched a Basic Design Study Team on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute (hereinafter referred to as "the Project") to the Republic of Kenya (hereinafter referred to as "Kenya"), and through discussion, field survey, and technical examination of the results in Japan, JICA prepared a draft report of the study.

In order to explain and to consult the Kenyan side on the components of the draft report, JICA sent to Kenya the Draft Report Explanation Team (hereinafter referred to as " the Team "), which is headed by Masaaki Otsuka, Resident Representative, JICA Kenya Office, from 21st October to 27th October.

As a result of discussions, both parties confirmed the main items described on the attached sheets.

Nairobi, October 27, 2003

Mr. Masaaki Otsuka
Leader
Draft Report Explanation Team
Japan International Cooperation Agency

Dr. Davy K. Koech
Director
Kenya Medical Research Institute
Republic of Kenya

Countersigned by

Mr. Wellington P. Godo
Permanent Secretary
Ministry of Health
Republic of Kenya

Mr. Joseph M. Magari
Permanent Secretary
Ministry of Finance
Republic of Kenya

ATTACHMENT

1.Components of the Draft Report

The Government of Kenya agreed and accepted in principle the components of the draft report explained by the Team.

2.Japan's Grant Aid scheme

Kenyan side understands the Japan's Grant Aid Scheme and the necessary measures to be taken by the Government of Kenya as explained by the Team and described in Annex-1 and Annex-2.

3.Schedule of the Study

JICA will complete the final report in accordance with the confirmed items and send it to the Government of Kenya by the end of January 2004.

4.Other relevant issues

4-1. Regarding the request for technical cooperation by the Kenyan side as described in the Minutes of Discussions signed on September 2, 2003, both sides agreed that requested contents would not be included in the soft component program of the project. The requested contents would be considered to be conducted by the KEMRI experts dispatched from JICA.

4-2. For the purpose of strengthening the security of the facilities, both sides agreed that burglar proof bars would be set up on windows and entrances of the facilities.

OK.

JAPAN'S GRANT AID SCHEME

1. Grant Aid Procedure

1) Japan's Grant Aid Program is executed through the following procedures.

| | |
|---|---|
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4) Under the Grant, in principle, Japanese products and services including transport or those of the recipient country are to be purchased.

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

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

5) Necessity of "Verification"

The Government of the recipient country or its designated authority will conclude contracts

denominated in Japanese yen with Japanese nationals. Those contracts shall be verified by the Government of Japan. This "Verification" is deemed necessary to secure accountability of Japanese taxpayers.

6) Undertakings required to the Government of the recipient country

a) to secure a lot of land necessary for the construction of the Project and to clear the site;

b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities outside the site;

c) to ensure prompt unloading and customs clearance at ports of disembarkation in the recipient country and internal transportation therein of the products purchased under the Grant Aid;

d) to exempt Japanese nationals from customs duties, internal taxes and fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contracts;

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

f) to ensure that the facilities constructed and products purchased under the Grant Aid be maintained and used properly and effectively for the Project; and

g) to bear all the expenses, other than those covered by the Grant Aid, necessary for the Project.

7) "Proper Use"

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

8) "Re-export"

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

9) Banking Arrangement (B/A)

a) The Government of the recipient country or its designated authority should open an account in the name of the Government of the recipient country in an authorized foreign exchange bank in Japan (hereinafter referred to as "the Bank"). The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by the Government of the recipient country or its designated authority under the verified contracts.

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

Annex-2

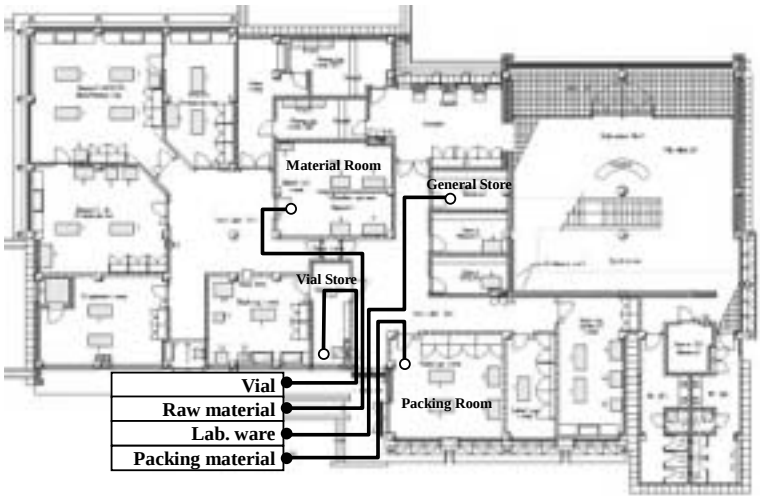
## Major Undertakings to be taken by Each Government

| No | Items | To be covered by Grant Aid | To be covered by Recipient side |
|---|---|---|---|
| 1 | To secure land | | • |
| 2 | To clear, level and reclaim the site when needed | | • |
| 3 | To construct gates and fences in and around the site | | • |
| 4 | To construct the parking lot | • | |
| 5 | To construct roads | | |
| | 1) Within the site | • | |
| | 2) Outside the site | | • |
| 6 | To construct the building | • | |
| 7 | To provide facilities for the distribution of electricity, water supply, drainage and other incidental facilities | | |
| | 1)Electricity | | |
| | a. The distributing line to the site | | • |
| | b. The drop wiring and internal wiring within the site | • | |
| | c. The main circuit breaker and transformer | • | |
| | 2)Water Supply | | |
| | a. The city water distribution main to the site | | • |
| | b. The supply system within the site ( receiving and/or elevated tanks ) | • | |
| | 3)Drainage | | |
| | a. The city drainage main ( for storm, sewer and others ) to the site | | • |
| | b. The drainage system ( for toilet sewer, ordinary waste, storm drainage and others ) within the site | • | |
| | 4)Gas Supply | | |
| | a. The city gas main to the site | | • |
| | b. The gas supply system within the site | • | |
| | 5)Telephone System | | |
| | a. The telephone trunk line to the main distribution frame / panel (MDF) of the building | | • |
| | b. The MDF and the extension after the frame / panel | • | |
| | 6)Furniture and Equipment | | |
| | a. General furniture | | • |
| | b. Project equipment | • | |
| 8 | To bear the following commissions to a bank of Japan for the banking services based upon the B/A | | |
| | 1) Advising commission of A/P | | • |
| | 2) Payment commission | | • |
| 9 | To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country | | |
| | 1) Marine(Air) transportation of the products from Japan to the recipient country | • | |
| | 2) Tax exemption and customs clearance of the products at the port of disembarkation | | • |
| | 3) Internal transportation from the port of disembarkation to the project site | • | |
| 10 | To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contract such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work | | • |
| 11 | To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contract | | • |
| 12 | To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant Aid | | • |
| 13 | To bear all the expenses, other than those to be borne by the Grant Aid, necessary for construction of the facilities as well as for the transportation and installation of the equipment | | • |

## 5. OTHERS

### Flow Diagram for Blood Screening Kit Production

**01** Carry in Articles (several times/year)



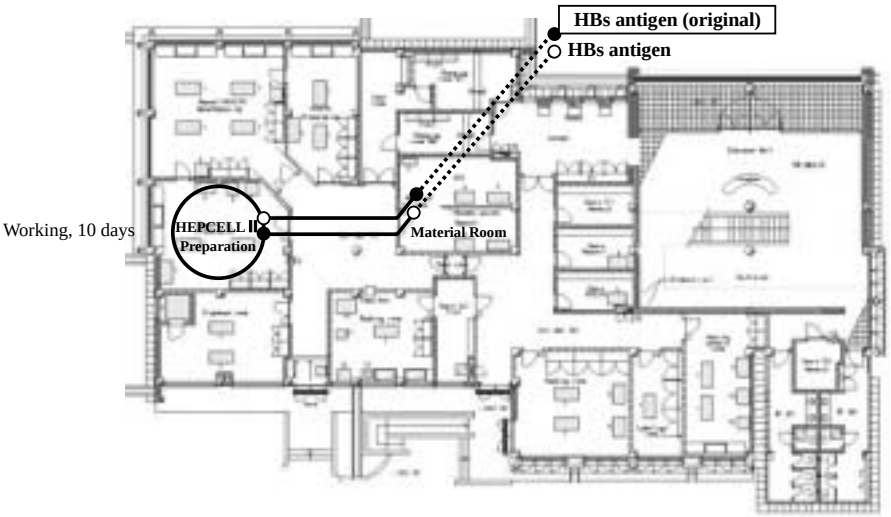

○Vial
- Receive in Vial Store

○Raw Material
- Receive in Material room

○Lab. Ware
- Receive in General store (paper towel, etc.)

○Packing Material for Kits
- Receive in cabinets at Packing room

**02** Preparation of HBs Antigen

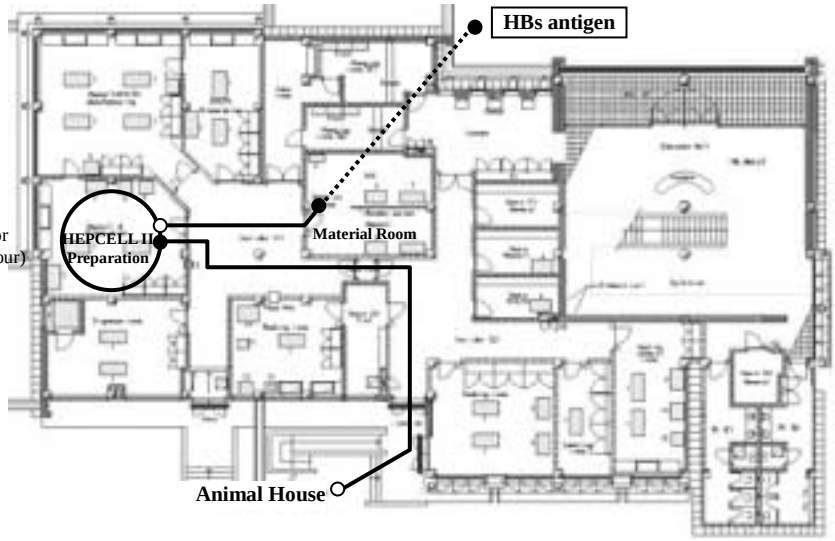



○Material Room →
- HBs antigen (original)

○HEPCELL II Preparation →
- Purification of HBs antigen
- Working, 10 days

○Material Room
- After make out, HBs antigen are refrigerated

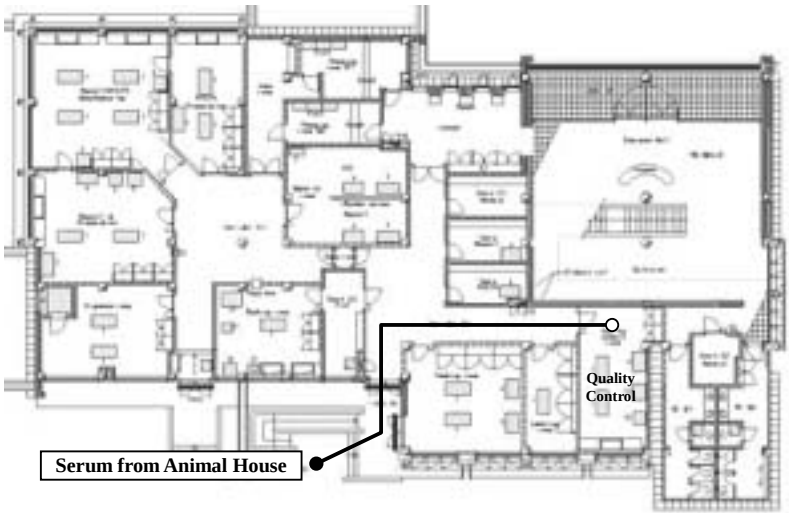
## 03 Preparation of Immunogenic




○Material Room → ○HEPCELL Ⅱ Preparation → ○Animal House

- HBs antigen
- Process HBs antigen for animal inoculums.
- Working / 3 hour
- After make out, HBs antigen are carried in Animal House.

## 04 Quality Test of Serum

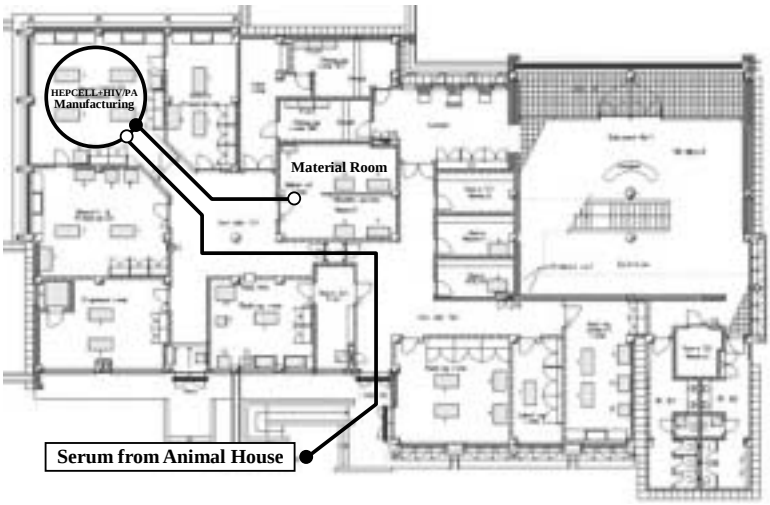



○Animal House → ○Quality Control

- Serum
- Quality test of serum

## 05 Separation of Serum

Separation of serum
Working / 3 hour




○Animal House
• Serum

→

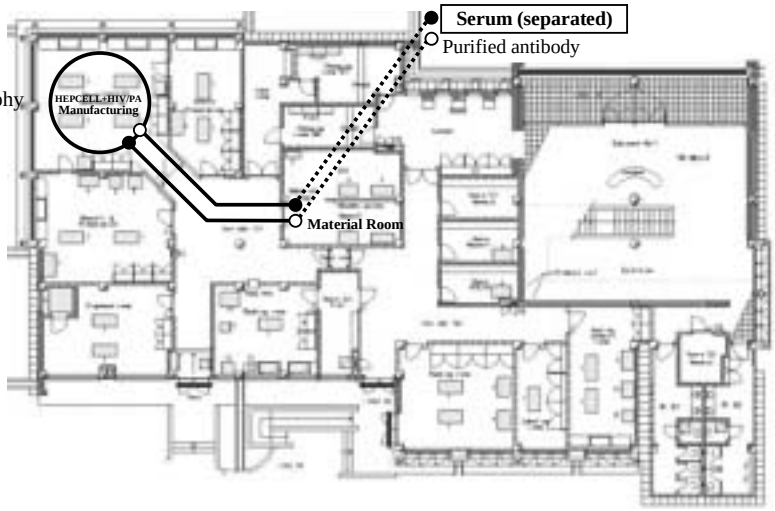
○HEPCELL + HIV/PA Manufacturing
• Separation of serum
• Working / 3 hour.

→

○Material Room
• After make out, separated serum are refrigerated.

## 06 Manufacturing of Purified Antibody

Affinity chromatography




○Material Room
• Separated serum

→

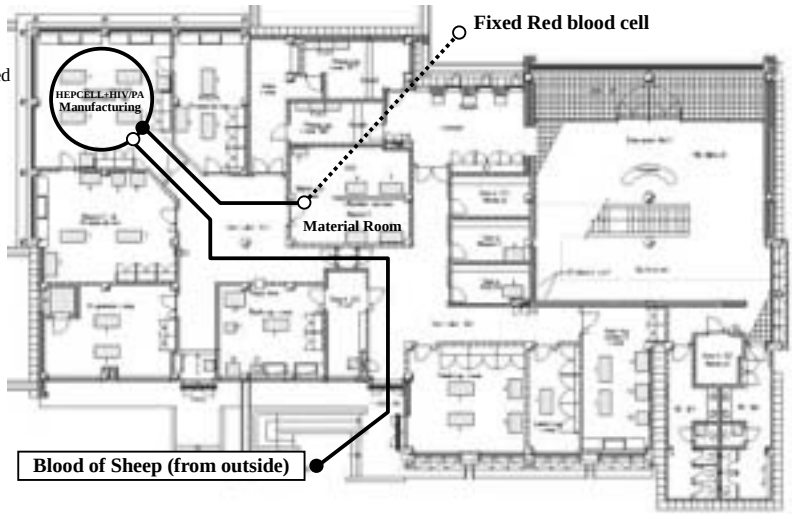
○HEPCELL + HIV/PA Manufacturing
• Affinity chromatography
• Working / 3 days

→

○Material Room
• After make out, purified antibody are refrigerated.

## 07 Preparation of Fixed Red Blood Cell

Fixation of Fixed Red blood cell.
2 times/year



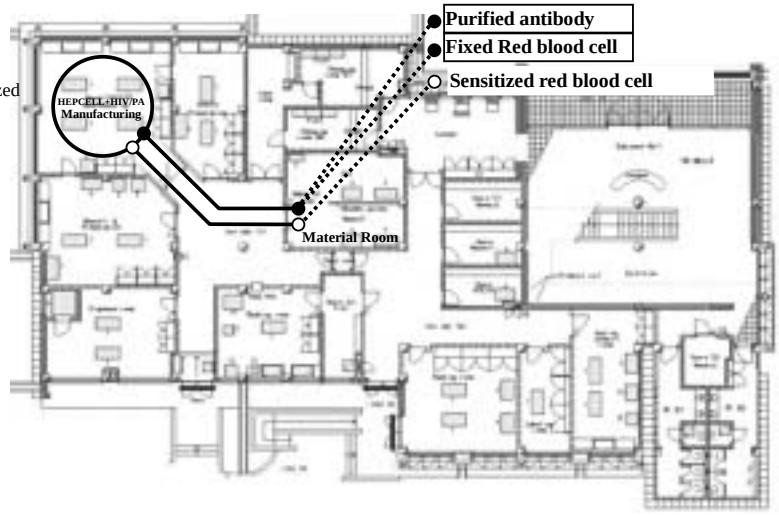

○Outside
- Blood of sheep

→ ○HEPCELL + HIV/PA Manufacturing
- Fixation of Fixed red blood cell
- 2 times/year
- Working / 2-3 days

→ ○Material Room
- After make out, fixed red blood cell are refrigerated.

## 08 Manufacturing of Sensitized Red Blood Cell

Manufacturing of Sensitized red blood cell
Working / 1-2 days



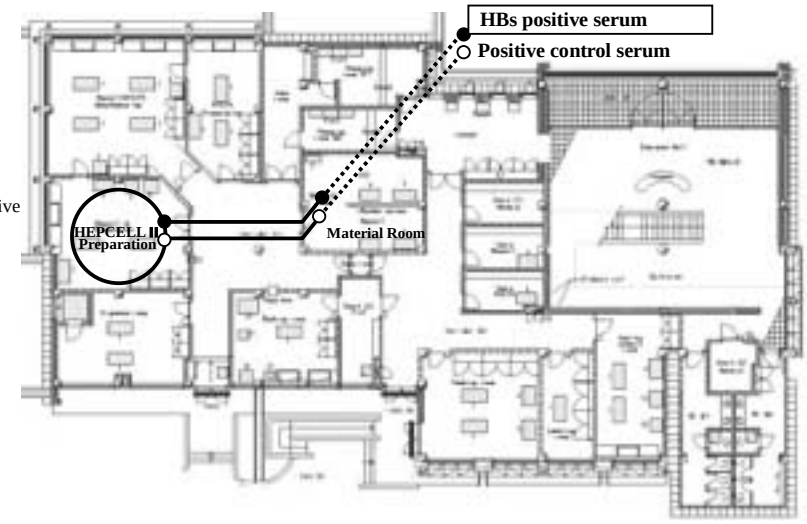

○Material Room
- Purified antibody
- Fixed red blood cell

→ ○HEPCELL + HIV/PA Manufacturing
- Manufacturing of Sensitized red blood cell
- Working / 1-2 days

→ ○Material Room
- After make out, sensitized red blood cell are refrigerated.

## 09 Manufacturing of Positive Control Serum

Manufacturing of Positive control serum.
Using, safety cabinet



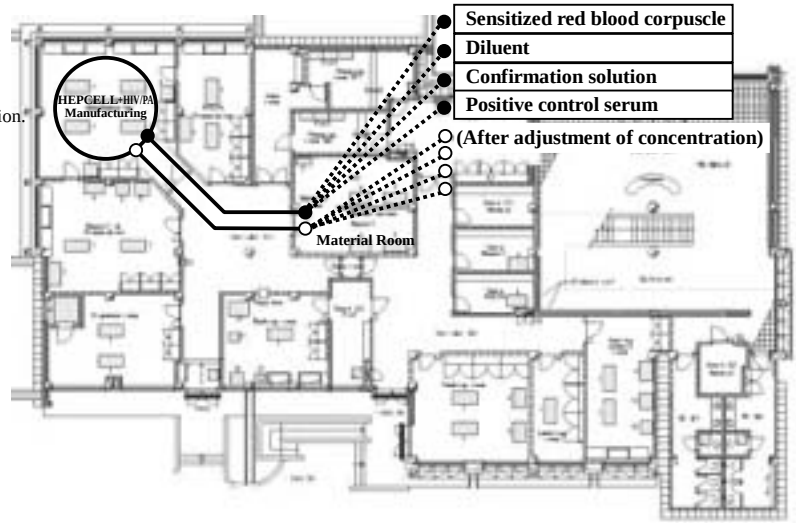

○Material Room
- HBs positive serum

→ ○HEPCELL II Preparation
- Manufacturing of positive control serum
- Using, safety cabinet

→ ○Material Room
- After make out, positive control serum are refrigerated.

## 10 Adjustment of Concentration

Adjustment of concentration.
Working / several day

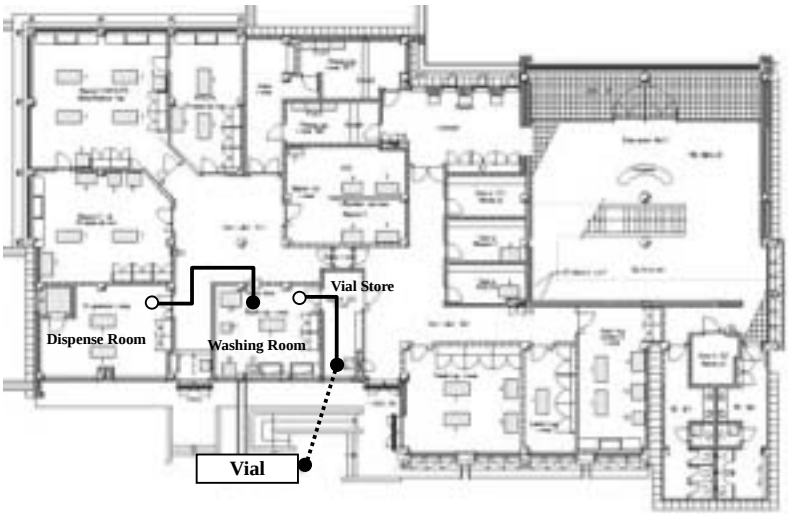



○Material Room
- Sensitized red blood cell
- Diluents
- Confirmation solution
- Positive control serum

→ ○HEPCELL + HIV/PA Manufacturing
- Adjustment of concentration, severally
- Working / several day

→ ○Material Room
- After adjustment of concentration, they are refrigerated.

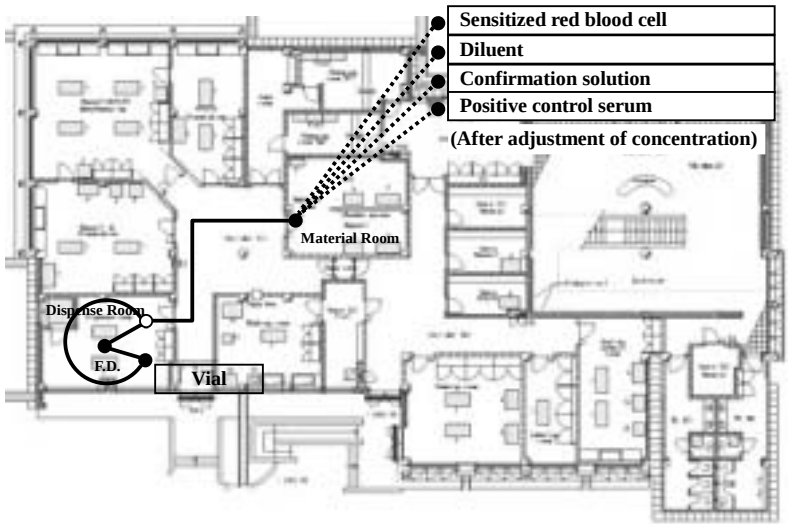
## 11 Dispense Working 1/3




○Vial Store → ○Washing Room → ○Pass Box → ○Dispense Room

- Vial
- Vial are washed
- Vial are carried in manufacturing area
- Using, passbox
- Vial are kept in cabinets.

## 12 Dispense Working 2/3



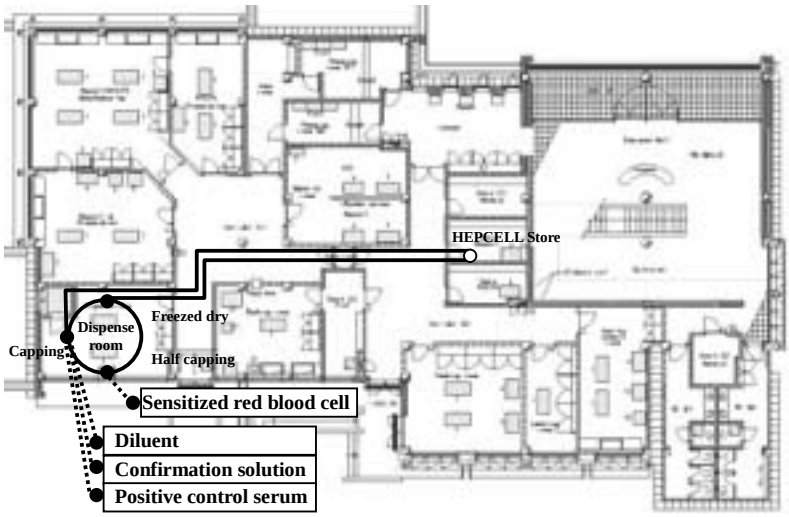

○Material Room

- Sensitized red blood cell
- Diluents
- Confirmation solution
- Positive control serum

○Dispense Room

- Dispense Working, severally

## 13 Dispense Working 3/3



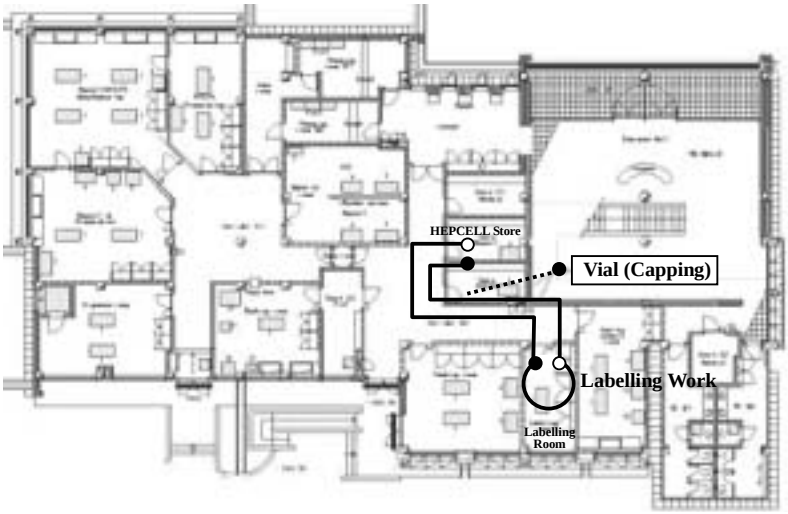

○Dispense Room → ○Dispense Room → ○HEPCELL Store

- Sensitized red blood cell are half capping.
- Diluents, Confirmation solution, Positive control serum are capping.

- Sensitized red blood cell are freezed dry. (Capping, lyophilizer use)

- After capping, they are refrigerated.

## 14 Labelling Work



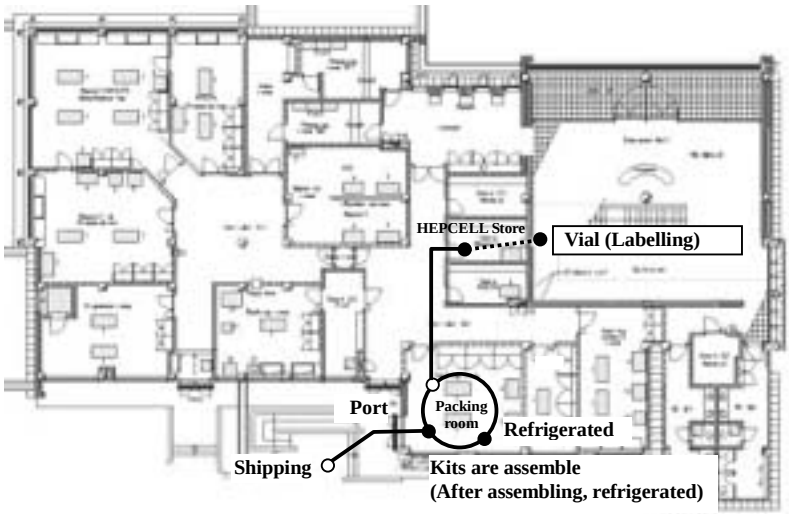

○HEPCELL Store → ○Labelling Room → ○HEPCELL Store

- Capped vial are carried out.

- Labelling work

- Labelled vial are refrigerated.

## 15 Pre-Shipping Work ～ Shipping




○HEPCELL Store
- Labelled vial are carried out.

→ ○Packing Room
- Kits are assembling.
- After assembling, refrigerated until shipping.

→ ○Shipping Port
- Shipping