

**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**

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DECEMBER 2002

JAPAN INTERNATIONAL COOPERATION AGENCY

NIHON SEKKEI, INC.

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).

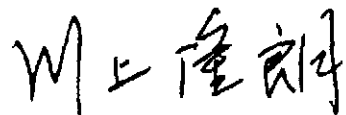
JICA sent to Kenya a study team from January 21st to February 16th, 2002.

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.

December 2002



Takao Kawakami

President

Japan International Cooperation Agency



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December 2002

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 January, 2002 to December, 2002. 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,

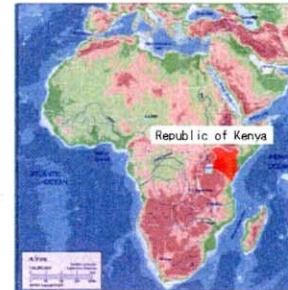
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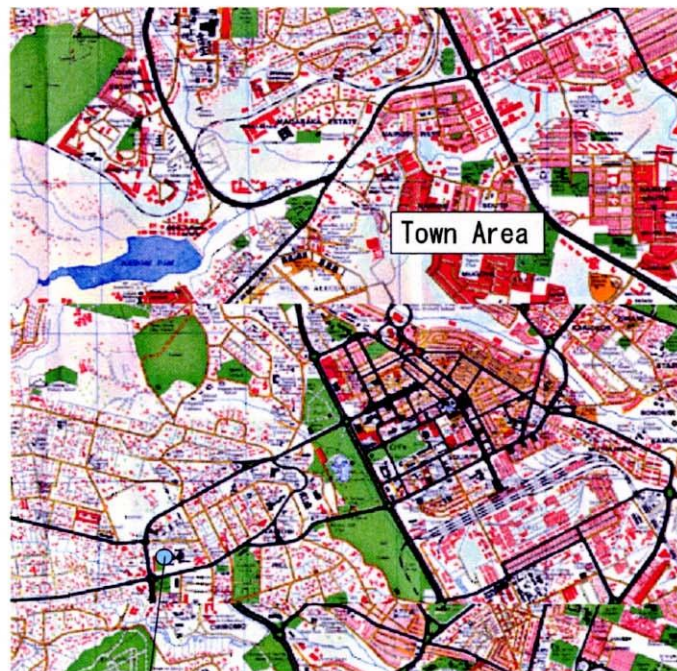
Nihon Sekkei, Inc.

Location Map



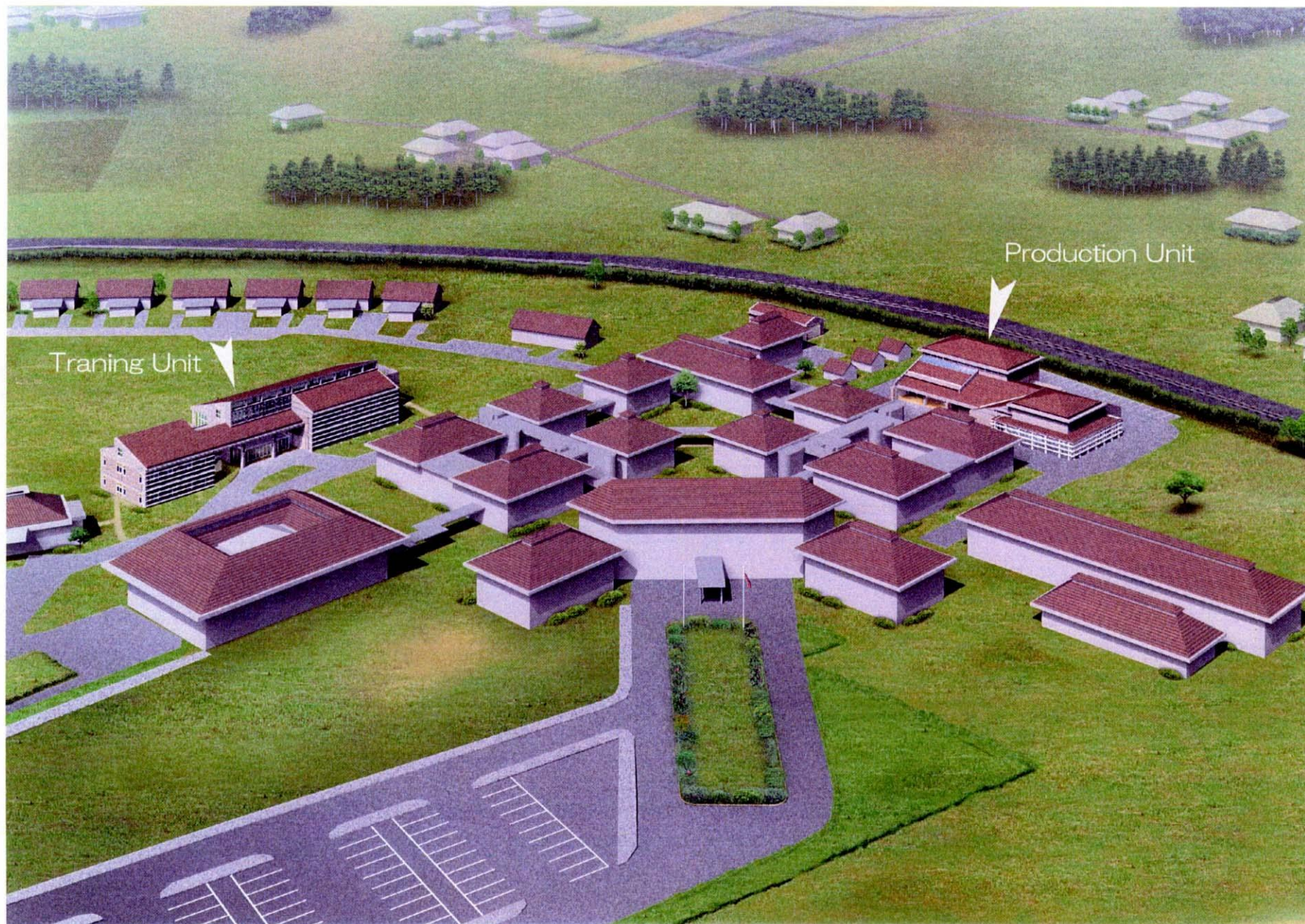
Republic of Kenya

Kenya and Neighbouring Countries



KEMRI Site

Nairobi City Map



Perspective

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ABBREVIATION

AIDS	Acquired Immunodeficiency Syndrome
BS	British Standard
CDC	Centers for Disease Control and Prevention (USA)
GMP	Good Manufacturing Practices
HB	Hepatitis B
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
JIS	Japan Industrial Standard
KEMRI	Kenya Medical Research Institute
KMTC	Kenya Medical Training College
MOF	Ministry of Finance and Planning
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 was 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, rain 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.

Worried about the effect the AIDS epidemic may have on the nation's healthcare and medical service, socioeconomic activities, and on the increasing AIDS orphans, the government of Kenya attaches a particular important to prevention of HIV infection in the 8th National Development Plan (1997 to 2001). In addition, the president himself has named spread of AIDS as a national emergency, and has stressed the need to establish a system for testing and surveillance, and to do everything to stop further infection. The government of Kenya, in response to the president's remark, has established the National AIDS Control Council (NACC), reporting directly to the president, with the objective of reducing the HIV infection rate, now estimated at 13 to 14 percent, to 10 percent by 2004. The diseases caused by Hepatitis B Virus

(HBV) infection are also serious in Kenya. Especially the number of HBV infectious cases through blood transfusion is increased. Therefore, the infectious control by blood screening is urgently necessary. Also, the government of Kenya has established the Division of Malaria Control in the Ministry of Health (MOH), with a view to reducing parasitic diseases. The objective is to reduce both the infection rate and mortality rate of malaria by 30 percent by 2004 from the levels of 1999. 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. The 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 project-type technical cooperation. Hereafter, steady and stable production of these quality-assured blood screening kits is required so that these blood screening kits may be extensively used as necessary. Similarly, as control for infectious and parasitic diseases, research in these fields and development of researchers have been promoted at KEMRI, also by Japan's project-type technical cooperation. Hereafter, it is necessary to make the achievements of the research available to all levels of concerned people, in Kenya as well as in neighbouring countries, such as policy makers, engineers, medical technicians, students, by training and other means. 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 project-type technical cooperation 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 this request, the government of Japan decided to conduct a basic design study, and the Japan International Cooperation Agency (JICA) dispatched a basic design study team in January 2002. The basic design study team had discussions with the concerned officials of the Kenyan side, investigated the concerned facilities, collected necessary materials, and surveyed the proposed construction site. After having conducted necessary studies in Japan, the basic design study team presented the draft report of basic design study in August 2002, and has finally completed this basic design study report.

The basic design study team has confirmed the necessity of “The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute”. The study has reached a conclusion that, to realise the project, it is necessary to construct or rehabilitate the blood screening kit production unit, attached animal house, training unit in the premises of KEMRI in Nairobi, and to procure and install the necessary equipment. The request from the government of Kenya originally included improvement of training unit and accommodations at Kwale and Busia, both local sites. It has been agreed between both parties, however, that these facilities are not included in the project, on the ground that regular use of these facilities is not clearly foreseen at this moment, and the utilisation rate is judged to be low.

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

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

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

Floor Area: Production Unit 1,737 m² (Site Area : 3,288 m²)
 Animal House 262 m² (Site Area : 612 m²)
 Training Unit 2,083 m² (Site Area : 3,457 m²)
 Total Floor Area 4,082 m²

Content of the Project

Construction of Building	Production Unit First floor : General Manager room, Marketing Manager room, Office, Staff room, and so on Ground floor : PA kit Manufacturing room, Hepcell kit Manufacturing room, Material room, Dispense room, Quality control room, and so on (*including Mechanical House and Water Supply Facility)	
	Animal House Ground floor : Guinea pig room, Rabbit room, Inoculation room, Quarantine room, and so on	
	Training Unit First floor : Lecture room, Data processing room, Network room, Project Supervision, Instructor room, Meeting room, Specialist room, Lounge, and so on Ground floor : Parasitic Lab., Infectious Lab., Preparation room, Culture room, Office, Manager room, Secretary room, Entrance hall, Library, and so on	
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 this project is estimated about 7.4 million Kenyan Shilling (hereinafter referred to as KShs) per year. Of this amount, the management and maintenance cost for the facilities is 5.4 million KShs, and for the equipment is 2 million KShs. This total cost for the management and maintenance is equivalent to 1.44 percent of the total annual budget of KEMRI (512 million KShs in fiscal 2000/2001). 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 2.73 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 in Number of Blood Screening Kits Manufactured and in Number of Tests

This project will install HIV and HBV blood screening kits (in vitro diagnostic medical device) production units. The facilities are designed and operated on the basis of voluntary GMP (Good Manufacturing Practices), a standard applied to the design of production unit of such products as “in vitro diagnostic medical device” to secure the quality of the product. By this way, a large-scale system for manufacturing blood screening kits, inexpensive and quality secured, will be established. More blood screening kits will be manufactured, and blood tests for HIV and HBV will be increased.

2) Increase in Blood Screening Rate for Blood Transfusion

In Kenya, the infection rate of HIV and HBV are reportedly 13 and 4 percent, respectively. If blood screening kits are steadily supplied at low prices, it would increase the blood screening rate for blood transfusion, and this will enable prevention of further infection of HIV and HBV.

3) Increase in Number of Trainees for Control of Infectious and Parasitic Diseases

The training unit for control of infectious and parasitic diseases will be constructed under the project. This project will increase the number of trainees coming from within Kenya and from neighbouring countries. This will help enable further promotion of control measures for infectious and parasitic diseases, not only in Kenya but also in neighbouring countries.

4) Smooth Implementation of Technology Transfer

Technical cooperation will be provided by the ongoing Japan's project-type technical cooperation in such fields as manufacturing technology for blood screening kits, training for control infectious and parasitic diseases. Effective utilisation of facilities and equipment to be provided by this project would facilitate the activities for technology transfer.

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 degree 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 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 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 house and acquisition of such skills by the local staff. In these respects, technology transfer by project-type technical cooperation 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) Of the blood screening kits, the HEPCELL kit (for HB) was granted a national license (for sales in the domestic market) and the Ministry of Health committed itself to purchase the product in lump sum. The PA kit (for AIDS) was also granted a national license, but is not at present guaranteed of a lump-sum purchase by the Ministry of Health or other organisations. Accordingly, further effort should be made to realise a lump-sum purchase by the Ministry of Health or other organisations.
- 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 infection of AIDS and HB after blood transfusions.

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- 2. Study Schedule**
- 3. List of Parties Concerned in Recipient Country**
- 4. Minutes of Discussions**
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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 project-type technical cooperation project, "The Research and Control of Infectious Diseases Project in Kenya," was carried out. Thereafter, four project-type technical cooperation projects have been done since then, utilising these facilities.

The table below summarises project-type 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

Project-type technical cooperation		Grant aid programme	
Project period	Project name and scope	Project period	Project name and scope
1979 to 1984	<u>First: The Research and Control of Infectious Diseases Project in Kenya</u> Diarrhoea, schistosomiasis	1981 to 1985	<u>The Project for Construction of Kenya Medical Research Institute</u> Construction of the KEMRI headquarters Project cost: 2,745 million yen
1985 to 1990	<u>Second: Kenya Central Medical Institute Project</u> Virology (diarrhoea, hepatitis), parasitology (schistosomiasis), bacteriology (diarrhoea) → Test manufacture of the HB blood screening kit		
1990 to 1996	<u>Third: The Research and Control of Infectious Diseases Project in Kenya</u> Addition of parasitology (filariasis) to the above → Manufacture of the HB blood screening kit		
1996 to 2001	<u>Fourth: The Research and Control of Infectious Diseases Project in Kenya (Phase 2)</u> Acute Respiratory Infection, viral hepatitis, HIV/AIDS → Improvement of the HB blood screening kit and manufacture of the HIV blood screening kit	1997 to 1999	<u>The Project for Improvement of Kenya Medical Research Institute</u> Modification of laboratories to P3 bio-hazard protection level Project cost: 234 million yen
2001 to 2006	<u>Fifth: Project for Control of Infectious and Parasitic Diseases</u> 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 (HEPCELL kit) at its third and fourth stage projects. The fourth technical cooperation from 1996 constructed physically enclosed highly bio-clean laboratories called "closed laboratory at P3 level" using Japan's grant aid (1999), and developed HIV blood screening kit (PA kit) through researches into HIV/AIDS. The Ministry of Health of Kenya granted a national license to HEPCELL kit and committed itself to purchase the product. Subsequently, the ministry also granted a national license to the 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.

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.