

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 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.

(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 kits 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 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 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 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.

Appendices

1. Member List of the Survey Team

Basic Design Survey (January 20 to February 18, 2002)

NAME	ROLE	INSTITUTION
Takashi KURIMURA	Leader	Professor Emeritus, Osaka University
Takuya SUGIE	Parasitic Diseases Control	Deputy Director, International Affairs Division, Ministry of Health, Labour and Welfare
Saeda MAKIMOTO	Planning Management	Grant Aid Management Department, Japan International Cooperation Agency
Masahiro IKAWA	Project Manager/ Architectural Planning	Nihon Sekkei, Inc.
Miki KUROBE	Architectural Designing	Nihon Sekkei, Inc.
Yukio ITO	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 (August 10 to August 26, 2002)

NAME	ROLE	INSTITUTION
Takashi KURIMURA	Leader	Professor Emeritus, Osaka University
Takuya SUGIE	Parasitic Diseases Control	Deputy Director, International Affairs Division, Ministry of Health, Labour and Welfare
Shinji TOTSUKA	Planning Management	Grant Aid Management Department, Japan International Cooperation Agency
Masahiro IKAWA	Project Manager/ Architectural Planning	Nihon Sekkei, Inc.
Miki KUROBE	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.

2. Survey Schedule

Basic Design Survey (January 20 to February 18, 2002)

No.	Date	Activity
1	JAN 20 (SUN)	Narita → London →
2	JAN 21 (MON)	→ Nairobi Discussion at JICA Office Courtesy call to Japanese Embassy
3	JAN 22 (TUE)	Courtesy call to MOH, NPLS, NACC Courtesy call to KEMRI/Nairobi
4	JAN 23 (WED)	Discussion and Survey at KEMRI Nairobi → Mombasa
5	JAN 24 (THU)	KEMRI/Kwale, Discussion and Survey Mombasa → Nairobi
6	JAN 25 (FRI)	Nairobi → Kisum KEMRI/Kisum, Discussion and Survey
7	JAN 26 (SAT)	Kisum → Busia KEMRI/Busia, Discussion and Survey, Busia → Kisum
8	JAN 27 (SUN)	Kisum → Nairobi Team meeting
9	JAN 28 (MON)	Discussion at KEMRI (Building, Equipment, Management) Soil Survey
10	JAN 29 (TUE)	Discussion at KEMRI (Building, Equipment, Management)
11	JAN 30 (WED)	Discussion at KEMRI (Building, Equipment, Management) Draft of Minutes of Discussion
12	JAN 31 (THU)	Signing of Minutes of Discussion Report to Japanese Embassy, JICA Office Members other than Consultants Departure from Nairobi → (Tokyo)
13	FEB 1 (FRI)	Discussion at KEMRI (Survey Schedule)
14	FEB 2 (SAT)	Team Meeting
15	FEB 3 (SUN)	Team Meeting Building Equipment Planner & Cost Planner (Nairobi → Mombasa)
16	FEB 4 (MON)	Discussion at KEMRI (Architectural Planning, Equipment Planning, etc.) Building Equipment Planner & Cost Planner • Survey at Kwale/KEMRI • Mombasa → Nairobi
17	FEB 5 (TUE)	Discussion at KEMRI (Architectural Planning, Equipment Planning, etc.) Building Equipment Planner & Cost Planner (Nairobi → Busia) • Survey at Busia/KEMRI • Busia → Kisum
18	FEB 6 (WED)	Architectural Plan, Equipment Plan Building Equipment Planner & Cost Planner (Kisum → Nairobi)
19	FEB 7 (THU)	Discussion at KEMRI (Architectural Plan, Equipment Plan)
20	FEB 8 (FRI)	Discussion at KEMRI (Architectural Plan, Equipment Plan) Survey for local building materials Discussion at JICA/KEMRI
21	FEB 9 (SAT)	Team meeting Survey for local building materials Architectural Designer and Production Designer Departure from Nairobi → (Tokyo)

No.	Date	Activity
22	FEB 10 (SUN)	Team meeting
23	FEB 11 (MON)	Discussion at KEMRI (Building Equipment Planning, Equipment Planning)
24	FEB 12 (TUE)	Discussion at KEMRI (Management, Operation) Discussion at Government Office concerned Survey for local materials
25	FEB 13 (WED)	Discussion at KEMRI, JICA/KEMRI , Discussion at Government Office concerned Hearing with Local constructor
26	FEB 14 (THU)	Discussion at KEMRI (Architectural plan, Equipment Plan) Signature of Technical Memorandum
27	FEB 15 (FRI)	Report to JICA
28	FEB 16 (SAT)	Departure from Nairobi →
29	FEB 17(SUN)	→ London →
30	FEB 18 (MON)	→ Narita

Explanation on Draft Report (August 10 to August 26, 2002)

No.	Date	Activity
1	AUG 10 (SAT)	Narita → London →
2	AUG 11 (SUN)	→ Nairobi Discussion with JICA/KEMRI
3	AUG 12 (MON)	Courtesy call to MOH, MOF Discussion at KEMRI Discussion at JICA Office Courtesy call to Japanese Embassy
4	AUG 13 (TUE)	Discussion at KEMRI (Explanation of Draft Report)
5	AUG 14 (WED)	Discussion at KEMRI (Explanation of Draft Report)
6	AUG 15 (THU)	Discussion at KEMRI (Explanation of Draft Report)
7	AUG 16 (FRI)	Signing on Minutes of Discussions Report to JICA Office Report to Japanese Embassy Members other than Consultants Departure from Nairobi → (Tokyo)
8	AUG 17 (SAT)	Confirm present condition of KEMRI Survey for Construction Industry, Equipment Procurement
9	AUG 18 (SUN)	Team Meeting
10	AUG 19 (MON)	Detailed Discussion at KEMRI
11	AUG 20 (TUE)	• Present condition of Existing Animal House
12	AUG 21 (WED)	• Present condition of Infrastructure
13	AUG 22 (THU)	• Re-survey of construction Site • Architectural plan, Equipment, Production system • Production Cost on Blood test kit • Operation system, budget, personnel plan • Schedule of After E/N conclusion
14	AUG 23 (FRI)	Report to JICA Office
15	AUG 24 (SAT)	Survey for Construction Materials, Equipment Procurement Departure from Nairobi →
16	AUG 25 (SUN)	→ London →
17	AUG 26 (MON)	→ 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

• 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 Resources

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. J. N. Kariuki	Chief Administrative Officer
Mr. J. K. Lelei	Principal Institute 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

Makoto Asami

Ambassador

Ryuhei Hosoya

Minister/Deputy Chief of Mission

Masanori Yuzawa

Second Secretary

• JICA Kenya Office

Masaaki Otsuka

Resident Representative

Shinichi Matsuura

Deputy Resident Representative

Tomoki Nitta

Deputy Resident Representative

Toru Shimoda

Assistant Resident Representative

• JICA Expert

Teruaki Amano

JICA/KEMRI Expert - Chief Adviser

Toshiki Awazawa

JICA/KEMRI Expert - Parasitic Diseases Control

Nobuyoshi Kobayashi

JICA/KEMRI Expert - Infectious Diseases Control

Yasukazu Omoto

JICA/KEMRI Expert - Infectious Diseases Control

Isao Oisi

JICA/KEMRI Expert - Infectious Diseases Control

Kozo Ono

JICA/KEMRI Project Coordinator

Tsutomu Kobayashi

JICA/KEMRI Project Coordinator

Makoto Shiraki

JICA/KEMRI Project Coordinator

Yasuhiro Hiruma

JICA/MOH Medical Equipment Management Adviser

4. Minutes of Discussions

(1) Basic Design Survey

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

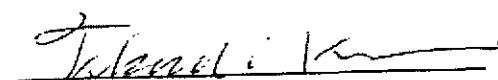
In response to a request from the Government of the Republic of Kenya (hereinafter referred to as "Kenya"), the Government of Japan decided to conduct a Basic Design Study on the Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute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

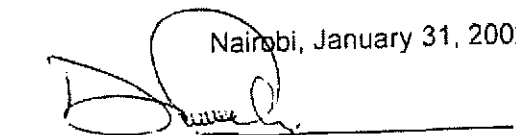
JICA sent to Kenya the Basic Design Study Team (hereinafter referred to as "the Team"), which is headed by Prof. Takashi Kurimura, professor emeritus of Osaka University, and is scheduled to stay in the country from January 21 to February 16, 2002.

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 on the attached sheets. The Team will proceed to further works and prepare the Basic Design Study Report.

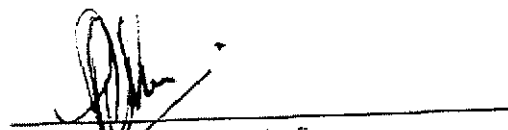
Nairobi, January 31, 2002


Prof. Takashi Kurimura
Leader
Basic Design Study Team
JICA


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

Countersigned by:


Prof. Julius S. Meme
Permanent Secretary
Ministry of Health
Republic of Kenya


Mr. Mwaghazi Mwachofi
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 of infectious and parasitic diseases in Kenya and the neighbouring countries through construction of new facilities and procurement of equipment for the Kenya Medical Research Institute (hereinafter referred to as "KEMRI").

2. Project sites

The sites of the Project are shown in Annex - 1.

3. Responsible and Implementing Agency

3-1. The Responsible Agency is the 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 Annexes - 2 and 3 were finally requested by the Kenya side. JICA will assess the appropriateness of the request and will recommend to the Government of Japan for approval as necessary.

4-1. Construction of the Building and Facilities

Details of items are listed in Annex - 2

4-2. Procurement of the Equipment

Details of items are listed in Annex - 3

5. Japan's Grant Aid Scheme

5-1. The Kenya side understands the Japan's Grant Aid Scheme explained by the Team, as described in Annex - 4.

5-2. The Kenya side will take the necessary measures, as described in Annex-5, 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 continue proceed to further studies in Kenya until February 16, 2002.

6-2. JICA will prepare the draft report in English and dispatch a mission to Kenya in order to explain its contents around May 2002.

6-3. In case that 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

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Government of Kenya by October 2002.

7. Other relevant issues

7-1. The Kenyan side requested consultant services for (1) setting-up of Blood Test Kit Production Unit and (2) maintenance of facilities and laboratory equipment as one of the components of the Grant Aid.

7-2. The Kenyan side confirmed exemption from VAT on the purchase of project materials, equipment and services in accordance with the Japan's Grant Aid Scheme, and will take necessary measures to ensure prompt VAT returns to the contractors and suppliers.

7-3. The Kenyan side confirmed that the proposed facilities, including Production Unit, will be under KEMRI and will not be privatised in the future.

7-4. The Kenyan side promised adequate allocation for operational and maintenance costs and personnel to each proposed facility, including Kwale, and human resources for Production Units.

7-5. The Kenyan side shall remove existing buildings in project sites and utility piping and cabling if any at proper timing. The Kenyan side will prepare the necessary budget in the MTEF or through other scheme for construction costs covered by the Kenyan side.

7-6. The Ministry of Health has confirmed that HEPCELL II and PA Test Kits have been reviewed and approved for use in Kenya.

7-7. The Kenyan side should inform the Japanese side the schedule of other constructions in KEMRI compound as soon as possible and take necessary arrangement for harmonisation of such development.

7-8. The Team requested KEMRI to submit training schedules in each facility. The Kenyan side will submit them to the Team during their stay.

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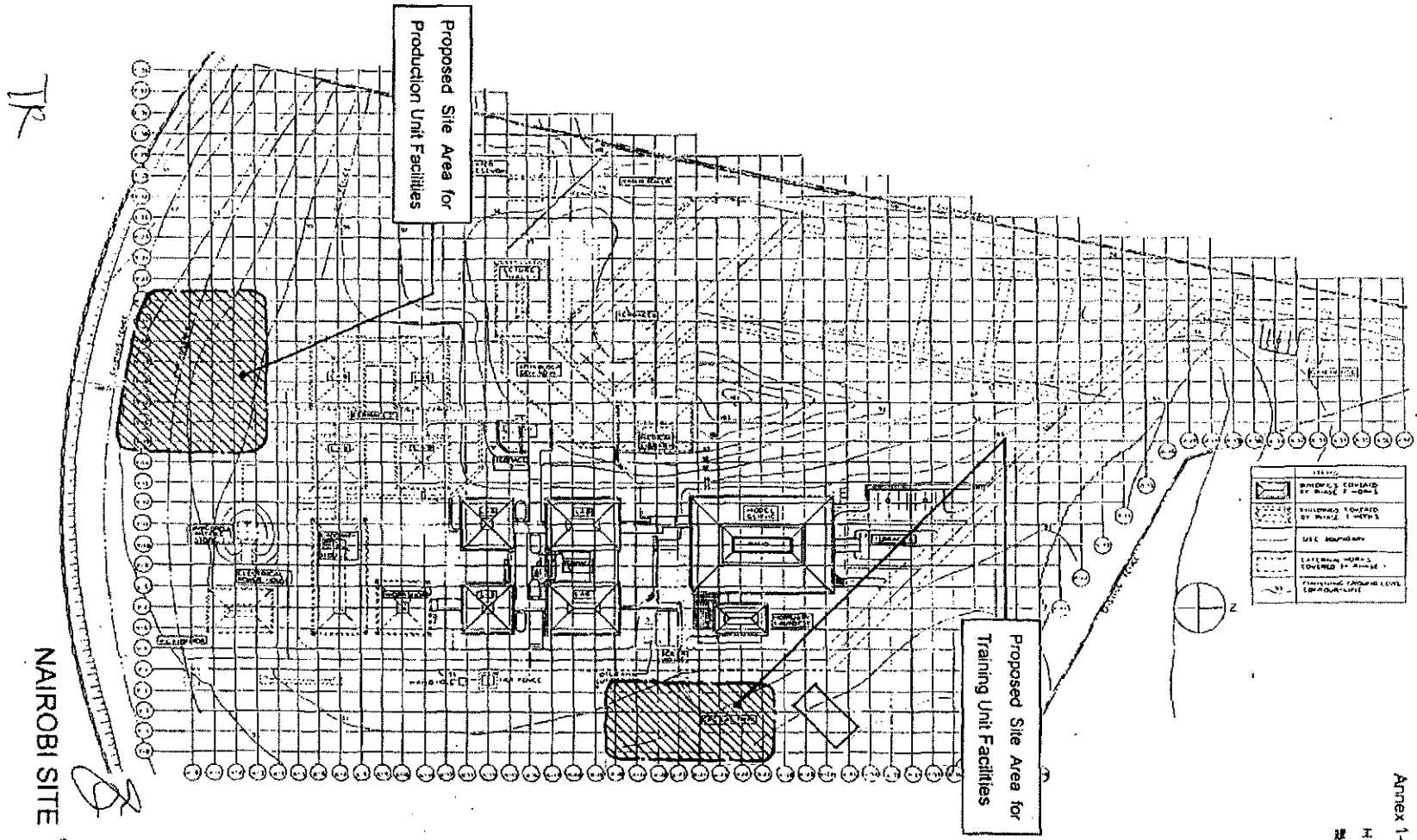
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Requested Project Sites

Project Sites
Nairobi (shown in Annex 1-1)
Kwale (shown in Annex 1-2)
Busia (shown in Annex 1-3)

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NAIROBI SITE

MIMON ARCHITECTS, ENGINEERS & CONSULTANTS, INC.

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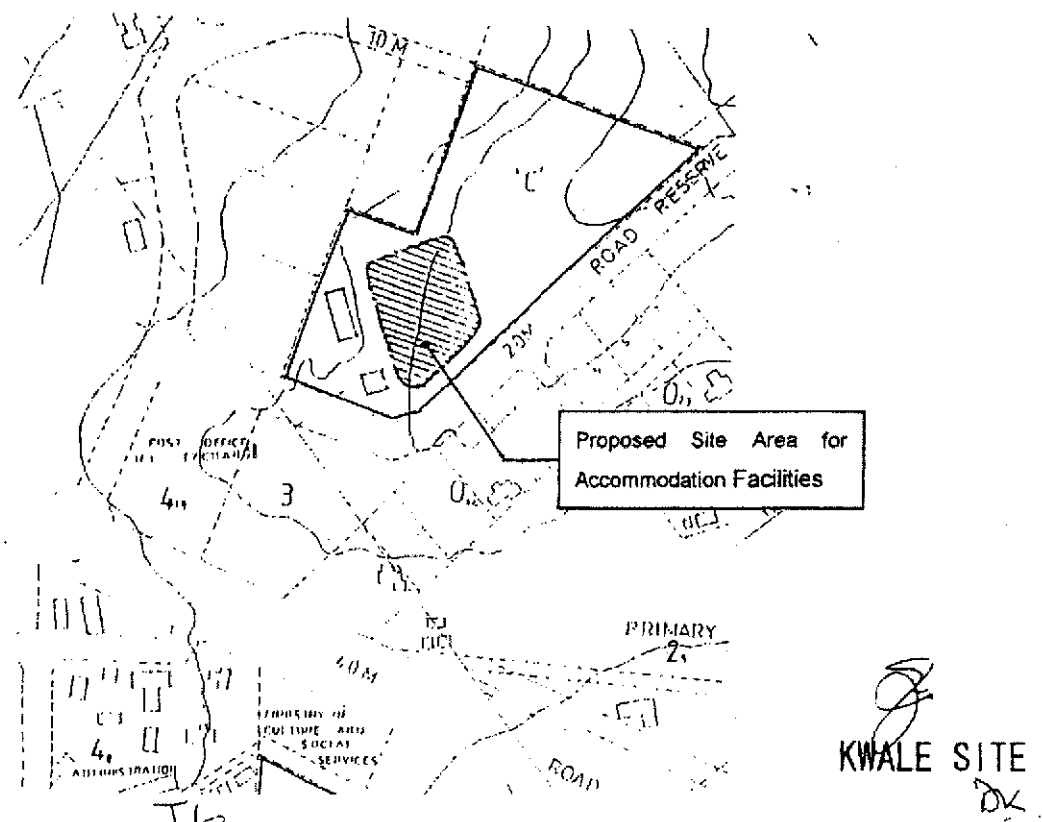
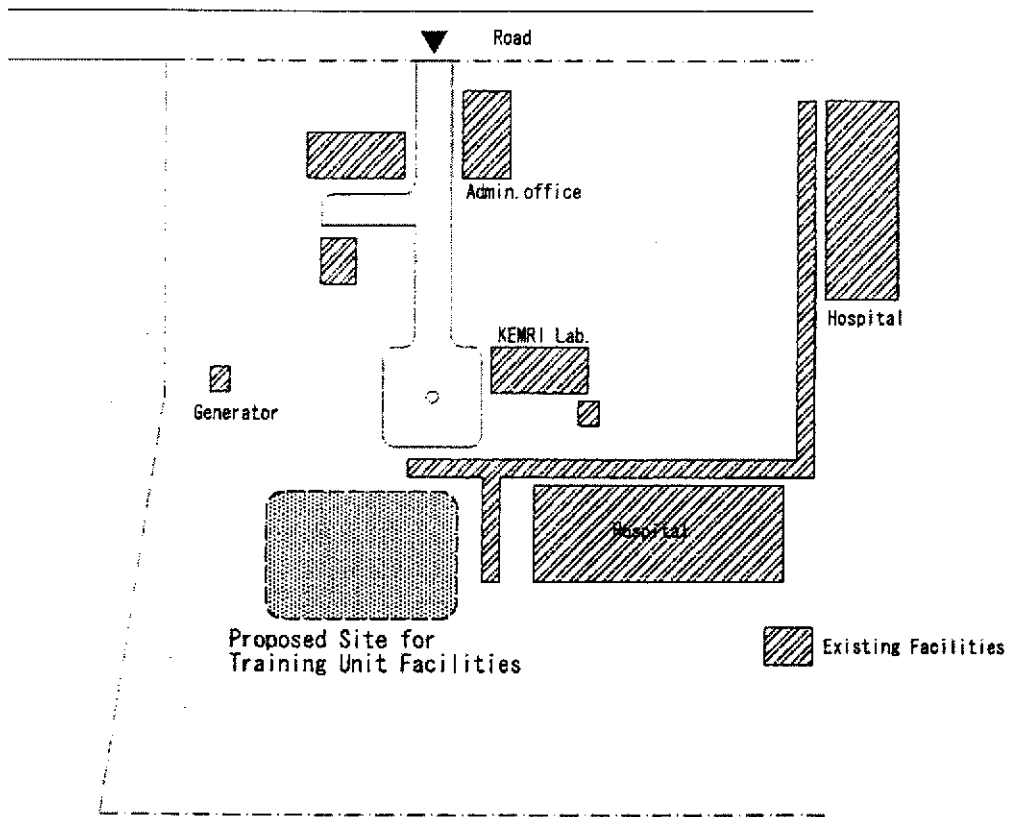
KENYA MEDICAL RESEARCH INSTITUTE PHASE 2

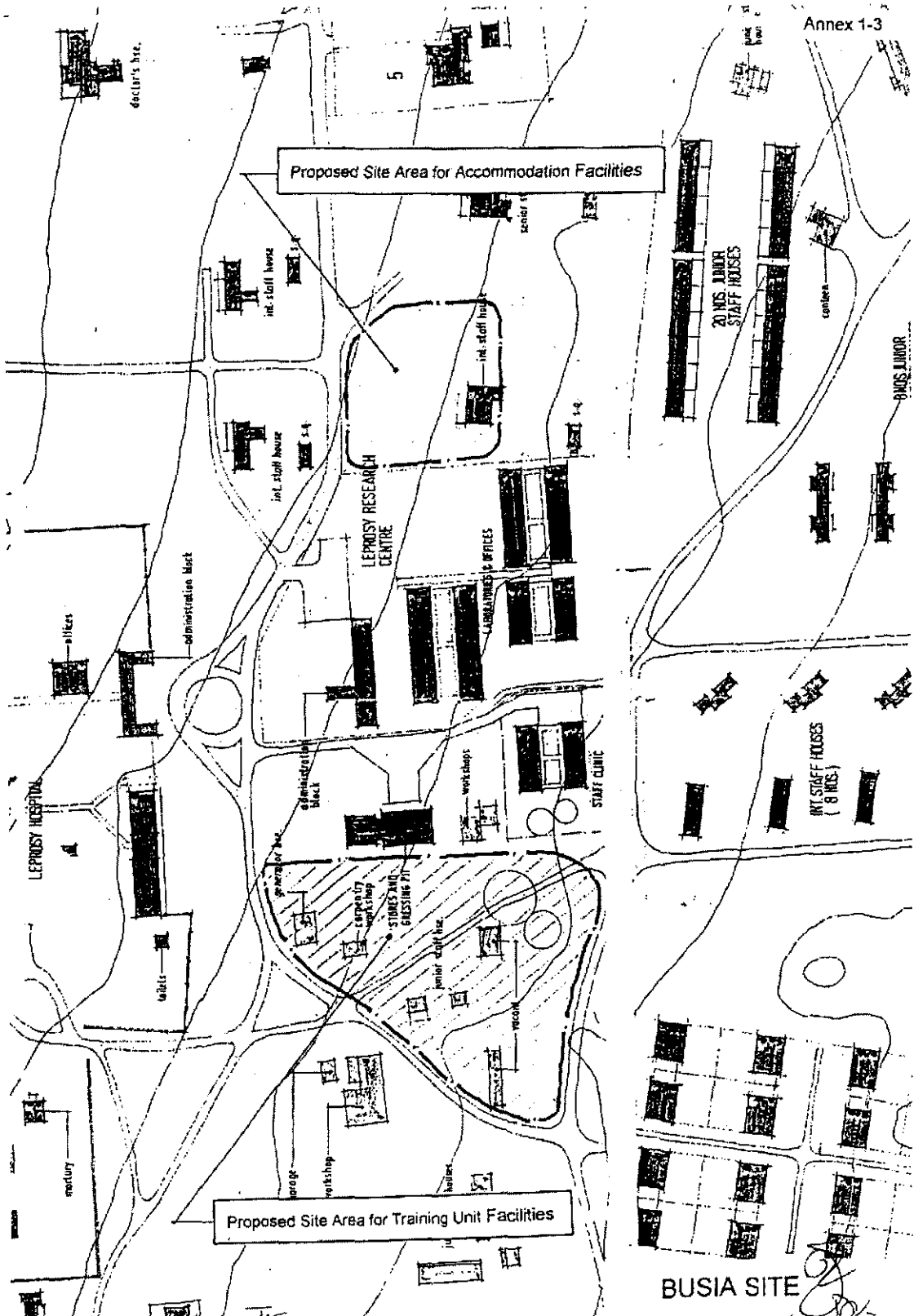
LAYOUT PLAN

DATE 1/5/00

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Annex 1-1





Annex 1-3

Proposed Site Area for Accommodation Facilities

Proposed Site Area for Training Unit Facilities

BUSIA SITE

Construction of the Building and Facilities

1. Nairobi SiteApprox. 3400m²

1-1 Production Unit

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> a) Pharmaceutical Production <ul style="list-style-type: none"> • Raw material receiving and preparation section • Manufacturing section • Quality control section • Distribution room • Other facilities
 c) Animal House <ul style="list-style-type: none"> • Sterilization room • Preparation room • Bleeding room • Experimentation room | <ul style="list-style-type: none"> b) Hepcell II and HIV PA Kit Production <ul style="list-style-type: none"> • Material preparation section • Manufacturing section • Quality control section • Serum preparation room • Other facilities
 d) Common Facilities for Production Unit <ul style="list-style-type: none"> • Dry equipment room • Wet equipment room • Administrative offices • Other facilities |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

1-2 Training Unit

- Lecture rooms
- Laboratories
- Information network section
- Administrative offices
- Other facilities

2. Kwale SiteApprox. 2000m²

2-1 Training Unit

- Lecture rooms
- Research Laboratories
- Administrative offices
- Other facilities

2-2 Accommodation Facilities

- Guesthouse for trainees
- Guesthouse for trainers
- Other facilities

3. Busia SiteApprox. 1600m²

3-1 Training Unit

- Lecture rooms
- Research Laboratories
- Meeting rooms
- Counseling room
- Administrative offices
- Other facilities

3-2 Accommodation Facilities

- Guesthouse for trainees
- Guesthouse for trainers
- Other facilities

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NO.	DESCRIPTION
1. Nairobi Site	
1-1 Production unit	
a) Pharmaceutical production	
- Raw material receiving and preparation section	
1	Preparative HPLC system
2	High capacity freeze dryer
3	Benches
4	Desk + 2 chairs
5	Deep Freezer, -20°C
6	Heavy duty scale or top loading balance
7	Lab. Glassware and plastic ware
8	PC + Printer + UPS
- Manufacturing section	
1	Benches
2	Stools
3	Gas cookers
4	Gas cylinders
5	Filtration unit
6	Refrigerator
7	Fume hood
8	Dry granulator
9	Powder mixer
10	Tablet coating
11	Tabletting machine
12	Strip packing machine
13	Fluid bed dryer
14	Tablet hardness tester
15	Capsule filling machine
16	Dust extractor
17	Homogenizer
18	Tube filling machine
19	Batch printing machine for bottles
20	Drying oven
21	Top loading analytical balance (in-process control)
22	PC +Printer + UPS + desk + 2 chairs
- Quality control section	
1	Thin layer chromatography system
2	Tablet hardness tester
3	Disintegration / dissolution tester
4	Suppository tester
5	Temperature-controlled shaking bath
6	Table top centrifuge
7	Stirrer / heater
8	Rotary evaporator with vacuum pump
9	Refrigerator
10	Drying oven
11	Benches
12	Fume hood
13	Stool
14	Vortex mixer
15	PC + printer + UPS +desk + 2 chairs
16	Zoom stereomicroscope
17	Microplate reader
18	Incubator oven

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NO.	DESCRIPTION
19	Magnetic stirrer / heater
· Distribution room	
1	Benches
2	Stools
· Other facilities	
1	Benches
2	Stools
3	Large glassware washing sink
4	Convection drying oven
5	Lockable cabinets
b) HEPCELL II and HIV PA kit Production	
· Materials preparation section	
1	Refrigerated centrifuge
2	Haematocrit centrifuge
3	Incubator oven
4	Refrigerator - large capacity
5	Fraction collectors with optical units
6	pH meter
7	Magnetic stirrer / heater
8	Peristaltic pumps
9	High vacuum aspirator machine
10	Affinity chromatography stand
11	Affinity chromatography column
12	Vortex mixer
14	Ultracentrifuge
15	Autoclave
16	Plasma separator
17	Zonal rotor
18	Swing bucket rotor
19	Safety cabinet
20	Sonifier
21	Benches
22	Stools
23	Water filtration unit
24	Microwave unit
· Manufacturing section	
1	Water bath
2	Bench top centrifuge
3	Incubator oven
4	Magnetic stirrer / heater
5	Mechanical crimpers
6	Calibrated autodispenser
7	ELISA reader
8	ELISA washer
9	Microplate mixer
10	Automatic pipette washer
11	Batch printing machine
12	Automatic vial and filling machine
13	PC + printer + UPS + desk + 2 chairs
14	Benches
15	Refrigerated centrifuge
16	Rocking platform for vials
17	Automatic pipette aid - rechargeable

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NO.	DESCRIPTION
18	Dispenser
19	Hand crimper (capping apparatus)
20	Sealing equipment
21	Labeling equipment
22	Stools
Quality control section	
1	Refrigerator
2	Benches
3	PC + printer + UPS + desk+ 2 chairs
4	Plate mixer
5	Automatic pipette aid - rechargeable
6	ELISA washer
7	ELISA reader
8	Deep freezer (-20°C)
9	Incubator with rocker
10	Camera illuminator & stand
11	Bench top centrifuge
Serum preparation room	
1	Safety cabinet class II B
2	Plasma expresser
3	Automatic pipette aid - rechargeable
4	Benches
5	Stools
Other facilities	
1	Autoclave
2	Benches
3	Stools
4	Lockable cabinets
5	Cabinets
6	Changing cabinets
c) Animal House	
Sterilization room	
1	Autoclave
2	Benches
3	Stools
Preparation room	
1	Benches
2	Stools
3	Scale
4	Breeding tool set
Bleeding room	
1	Cage cabinets
2	Animal cages
Experimentation room	
1	Desk + 2 chairs

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NO.	DESCRIPTION
d) Common Facilities for Production unit	
· Dry equipment room	
1	Analytical electronic balance (4 decimal digits)
2	UV / Vis spectrophotometer
3	Spectrodensitometer
4	Flame photometer
5	pH meter
6	Stools
7	Benches
8	Refractometer
9	Lab. trolleys
· Wet equipment room	
1	Large capacity water distiller / deioniser
2	Large capacity lyophilizer
3	Cold room (4°C)
4	Cold room (-20°C)
5	Ultra low deep freezer
6	Lockable cabinets in cold room
· Administrative offices	
1	PC + printer +UPS
2	Desks
3	Chairs
4	Photocopier
· Other facilities	
1	Benches
2	Table + 6 chairs
3	Side bench
4	Refrigerator
5	Lab coat + head cap + sandals set
6	Servers
7	Stools
8	Chairs
9	Desk + chair
10	Network setting material
1-2 Training unit	
· Lecture rooms	
1	Student desks and tables for trainees
2	Lecturer tables (and desks) with control system
3	Visual-audio system
4	Multi purpose board (black, white and screen)
5	Notice boards
6	Black boards
7	Slide projectors
8	Computer projectors and note type computers
9	Overhead projectors
· Laboratories	
1	Laboratory desks and chairs
2	Binocular microscope
3	Demonstrating microscope connecting to video camera
4	24 inches color televisions for demonstrating
5	Discussion microscopes (for 5 persons)
6	Dissecting binocular microscope (×0.5 - 30, sliding)
7	Low speed centrifuges (table type) and balance
8	Slide staining sets (including bottles and vats)

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NO.	DESCRIPTION
9	Micrometers and manometers
10	Hotplates for protozoa examination
11	Water baths
12	Cabinets for storage of microscopes and materials
13	ELISA readers connecting to computer diskettes
14	Shakers
15	Auto-pipettes (different sizes)
16	Multiple pipettes (for 6 lanes)
17	Refrigerators
18	Incubators
19	Water baths
20	pH meter
21	Photometer
22	Electronic balances (until 20g)
23	Electronic balances (until 200g)
24	Balance (until 2 kg)
25	Electrophoresis sets
26	Fluorescent microscopes
27	Microscopes for cell cultures
28	CO2 Incubators and gas cylinders
29	Clean benches and aspirators
30	Slide glass, cover glass, ELISA plate, pipette, chips and dilution bottles
31	Chairs and tables
32	Deep freezer (-40°C)
33	Ultra low deep freezer
34	Fluorescent microscope with camera
35	Binocular microscope with camera
36	Binocular microscope with computer system
37	Dissecting microscope with camera
38	Microscope for cell culture with camera
39	Ultracentrifuge
40	Gel-electrophoresis
41	PCR sets
42	Amplifiers
43	Sequencers
44	FACS calibrator
45	Ultra-homogenizer
46	Magnet stirrers
47	Autoclave for dissecting
48	Freeze dryer
49	Clean bench or safety cabinet
50	Low centrifuge with temperature control system and balance
51	Cell culture equipment
52	Aspirator
53	Sample stock cages
54	Glass tube washing machine
55	Dryer
56	Autoclave
Information network section	
1	Chairs and tables
2	Lecturer's table and chair
3	Multi board (screen and white board)
4	White board
5	Projector connected to computer

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NO.	DESCRIPTION
6	Computers for trainees
7	White and black printers
8	Color printer
9	Computers
10	System reservoir
11	Cabinet for mechanical parts
12	CD-maker
13	Desk and chairs
14	Cabinets for computer data
15	Cabinets for administrative documents
- Administrative offices	
1	Vehicle(4WD)
2	Minibus
3	Saloon car
4	Office desks and chairs
5	Meeting table and 10 chairs
6	Cabinets for office
7	Sofa set
8	White boards
9	Black board
10	Notice boards
11	Photocopy machine (black and white)
12	Photocopy machine (color: connecting to computer)
13	Office-book-binding machines
14	Bookstand
15	Fax machine
- Computer services section	
1	Servers + UPS
2	Network setting material
3	Laserjet printers
4	CD-maker

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NO.	DESCRIPTION
2. Kwale Site	
2-1 Training unit	
· Lecture rooms	
1	Discussion tables
2	Chairs
3	Black boards
4	White boards
5	Projector-connected to computer
6	Overhead projector
7	Screen
8	24 inches color television with videocassette recorder
· Research laboratories	
1	Binocular microscope with camera
2	Binocular microscope with connection to computer
3	Fluorescent microscope
4	Low centrifuge (on table)
5	Balance
6	Low centrifuge with setting temperature
7	Ultra low deep freezers (-80°C)
8	Cabinets for storage
9	Electronic balances (less 20g less than 200g)
10	Balance (less than 3 kg)
11	Echo machine for abdominal examination
12	Scales for weight
13	Table
14	Chairs
15	Low centrifuges
16	Binocular microscope
17	Dissecting microscopes
18	ELISA reader with connection to computer
19	Refrigerator
20	Deep freezer (-40°C)
· Administrative offices	
1	Desk and chairs
2	Photocopy machine (black & white)
3	Cabinet for business records
4	Fax machine
5	Computers
6	Printer (black & white)
7	Color printer
8	Sofa set
· Other facilities	
1	Vehicles
2	Minibus


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2-2 Accommodation Facilities

- Guesthouse for trainees
 - 1 Beds
 - 2 Desks
 - 3 Chairs
- Guesthouse for trainers
 - 1 Beds
 - 2 Desks
 - 3 Chairs

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3. Busia Site**3-1 Training unit**

- Lecture rooms
 - 1 Discussion tables
 - 2 Chairs
 - 3 Black boards
 - 4 White boards
 - 5 Projector connected to computer
 - 6 Overhead projector
 - 7 Screen
 - 8 24 inches color television with videocassette recorder
- Research laboratories
 - 1 Binocular microscope with camera
 - 2 Binocular microscope
 - 3 Fluorescent microscope
 - 4 Low centrifuge (on table)
 - 5 Balance
 - 6 Low centrifuge with setting temperature
 - 7 Refrigerator
 - 8 Ultra low deep freezers (-80°C)
 - 9 Cabinets for storage
 - 10 Electronic balances (less 20g less than 200g)
 - 11 Balance (less than 3 kg)
 - 12 Table
 - 13 Chairs
- Meeting rooms
 - 1 Table
 - 2 Chairs
 - 3 White boards
- Counseling room
 - 1 Table
 - 2 Chairs
- Administrative offices
 - 1 Desk and chairs
 - 2 Photocopy machine (black & white)
 - 3 Cabinet for business records
 - 4 Fax machine
 - 5 Computers
 - 6 Printer (black & white)
 - 7 Color printer
- Other facilities
 - 1 Vehicles
 - 2 Minibus

3-2 Accommodation Facilities

- Guesthouse for trainees
 - 1 Beds
 - 2 Desks
 - 3 Chairs
- Guesthouse for trainers
 - 1 Beds
 - 2 Desks
 - 3 Chairs

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Japan's Grant Aid Program

1. Japan's Grant Aid Procedures

(1) The Japan's Grant Aid Program is executed by 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 the Cabinet of Japan)

Determination of Implementation (Exchange of Notes between both Governments)

Implementation (implementation of the Project)

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

Secondly, JICA conducts the study (Basic Design Study), using (a) Japanese consulting firm(s).

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

Fourth, the project approved by the cabinet becomes official with the Exchange of Notes signed by the Government of Japan and the recipient country.

Finally, for the implementation of the Project, JICA assists the recipient country in preparing contracts and so on.

2. Contents of the Study

(1) Contents of the Study

The purpose of the Basic Design Study conducted by JICA on a requested project is to provide a basic document necessary for appraisal of the project by the Japanese Government. The contents of the Study are as follows:

a) confirmation of the background, objectives, benefits of the project and also institutional capacity of agencies concerned of the recipient country necessary for project implementation,

b) evaluation of the appropriateness of the project for the Grant Aid Scheme from a technical, social and economical point of view,

c) confirmation of items agreed on by the both parties concerning a basic concept of the project,

d) preparation of a basic design of the project,

e) estimation of cost 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

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is confirmed considering the guidelines of Japan's Grant Aid Scheme.

Final project components are subject to approval by the Government of Japan and therefore may differ from an original request. Implementing the project, the Government of Japan requests the recipient country to take necessary measures involved which are itemized on Exchange of Notes.

(2) Selection of Consultants

For smooth implementation of the study, JICA uses (a) registered consulting firm(s). JICA selects (a) firm(s) based on the proposals submitted by the interested firms. The firm(s) selected carry (ies) out a Basic Design Study and write(s) a report, based upon terms of reference set by JICA.

The consulting firm(s) used for the study is (are) recommended by JICA to a recipient country after Exchange of Notes, in order to maintain technical consistency and also to avoid any undue delay in implementation should the selection process be repeated.

3. Japan's Grant Aid Scheme

(1) What is Grant Aid?

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

(2) Exchange of Notes (E/N)

Both Governments concerned extend Japan's Grant Aid in accordance with the Exchange of Notes 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 Aid" means one Japanese fiscal year that the Cabinet approves the Project for. Within the fiscal year, all procedure such as Exchange of Notes, concluding a contract with (a) consulting firm(s) and (a) contractor(s) and a final payment to them must be completed.

(4) Under the Grant, in principle, products and services of origins of Japan or the recipient country are to be purchased.

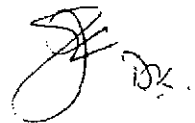
When the two Governments deem it necessary, the Grant may be used for the purchase of products or services of a third country.

However the prime contractors, namely, consulting, contractor 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 the "Verification"

The Government of the recipient country or its designated authority will conclude contracts denominated in Japanese yen with Japanese nationals. The Government of Japan shall verify those contracts. The "Verification" is deemed

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necessary to secure accountability to Japanese taxpayers.

(6) Undertakings Required to the Government of the Recipient Country

In the implementation of the Grant Aid project, the recipient country is required to undertake such necessary measures as the following:

a) to secure land necessary for the sites of the project prior to the installation work in case the project is providing equipment,

b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities in and around the sites,

c) to secure buildings prior to the installation work in case the project is providing equipment,

d) to ensure all the expenses and prompt execution for unloading, customs clearance at the port of disembarkation and internal transportation of the products purchased under the Grant Aid,

e) to exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which will be imposed in the recipient country with respect to the supply of the products and services under the Verified Contracts,

f) to accord Japanese nationals whose services may be required in connection with the supply of the products and services under the Verified Contracts, such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work.

(7) Proper Use

The recipient country is required to maintain and use the equipment purchased under the Grant Aid properly and effectively and to assign staff necessary for the operation and maintenance as well as to bear all 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 shall open an account in the name of the Government of the recipient country in a bank in Japan. The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by 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 issued by the Government of the recipient country or its designated authority.

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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 / deep well if necessary		●
	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	●	

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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		●



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(2) Explanation on Draft Report

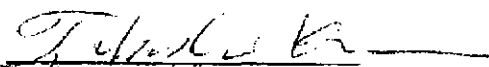
**MINUTES OF DISCUSSIONS
ON THE BASIC DESIGN STUDY
ON THE PROJECT FOR IMPROVEMENT OF FACILITIES FOR CONTROL OF
INFECTIOUS AND PARASITIC DISEASES
AT KENYA MEDICAL RESEARCH INSTITUTE
IN THE REPUBLIC OF KENYA
(EXPLANATION ON DRAFT REPORT)**

From January through February 2002, 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") in the Republic of Kenya (hereinafter referred to as "Kenya"), and has prepared the draft report of the study through discussion, field survey, and technical examination of the results in Japan.

In order to explain and to consult with 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 was headed by Dr. Takashi Kurimura, professor emeritus of Osaka University from August 11, 2002 to August 24, 2002.

In the course of discussions, both parties confirmed the main items described on the attached sheets.

Nairobi, August 16, 2002



Prof. Takashi Kurimura
Leader
Draft Report Explanation Team
Japan International Cooperation Agency



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

Countersigned by:



Prof. Julius S. Meme
Permanent Secretary
Ministry of Health
Republic of Kenya



Mr. Joseph K. Kinyua
Permanent Secretary
Ministry of Finance and Planning
Republic of Kenya

ATTACHMENT

1. Components of the Draft Report

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

2. Japan's Grant Aid Scheme

- 2-1. The Kenyan side understood the Japan's Grant Aid Program described in Annex-5 explained by the Team.
- 2-2. The Kenyan side will take the necessary measures described in Annex-3, for smooth implementation of the Project on condition that the Japan's Grant Aid is executed to the Project.

3. Schedule of the Study

- 3-1. The consultant members will proceed to conduct further study in Kenya until August 24, 2002.
- 3-2. JICA will complete the final report in accordance with the confirmed items and send it to the Government of Kenya around January 2003.

4. Other Relevant Issues

- 4-1. The parties agreed that the construction of the Training Unit and Production Unit, and procurement of necessary equipment for each facility described in Annexes-1 and 2 are included in the Project .
- 4-2. The Kenyan side shall secure and allocate enough qualified staff and budgets to operate and maintain the facilities and equipment procured through the Grant Aid properly and effectively.
- 4-3. The Ministry of Health has agreed to secure and allocate enough budget to carry out the preparatory works described in Annex-4 and has agreed to carry out all of those preparatory works in accordance with the schedule of the Project.
- 4-4. The Kenyan side confirmed exemption from 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.
- 4-5. The Kenyan side agreed to carry out the following work regarding 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 existing Animal House before implementation of the construction.

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- 4-6. The Kenyan side requested the following items.
- To provide the air conditioning in the 3 (three) lecture rooms of Training Unit.
 - To provide teachers rooms in the Training Unit.
 - To provide necessary spare parts for equipment.
- 4-7. The Kenyan side requested counterpart training under the Grant Aid for (1) setting-up of Blood Test Kit Production Unit and (2) maintenance of facilities and laboratory equipment.
- 4-8. The Kenyan side expressed desire to develop HIV-2-TYPE kit utilizing the planed 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 Major undertaking to be taken by each government
- Annex-4 Preparatory works to be carried out by the Kenyan side
- Annex-5 Japan's Grant Aid Program

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Description of the Construction of Facilities Confirmed by both Sides

A) Production Unit		Total floor area: approx. 1,448m²
1 Hepcell preparation room	13 Quality control room	
2 Hepcell manufacturing room	14 Stores	
3 HIV/PA preparation room	15 Toilets	
4 HIV/PA manufacturing room	16 Entrance hall	
5 Material room	17 Exhibition space	
6 Dispensing room	18 Office	
7 Ante room	19 General manager's room	
8 Changing room	20 Marketing manager's room	
9 Pass room	21 Secretary's office	
10 Washing room	22 Staff room	
11 Packing room	23 Pantry	
12 Labeling room	24 Mechanical room	
B) Training Unit		Total floor area: approx. 2,042m²
1 Laboratories 1and 2	14 Library	
2 Preparation room	15 Lounge	
3 Culture room	16 Pantry	
4 Dark room	17 Office	
5 Changing room	18 Secretary's office	
6 Store	19 Manager's room	
7 Toilets	20 Connecting corridor	
8 Shower room	21 Instructor's room	
9 Lecture rooms 1~3	22 Meeting room	
10 Data Processing room	23 Program supervision's room	
11 Network server room	24 Specialist's room	
12 Teachers room	25 Print room	
13 Entrance hall		
C) Animal House		Renovation floor area: approx. 166m²
1 Guinea pigs room	7 Office	
2 Rabbit room	8 Changing room	
3 Breeding room	9 Preparation room	
4 Innoculation room	10 Washing room	
5 Ante room	11 Quarantine room	
6 Pass room	12 Toilets	
D) Other Facilities		Total floor area: approx. 213m²
1 Mechanical house		
2 Water supply tank		
3 Water supply tower		
A)~D) Total floor area: approx. 3,869m²		

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Description of the list of Major Equipment

No.	Description	Specification
1	Water distiller/deionizer	RO + deion water Capacity : 10litre/h
2	Lyophilizer	Capacity : 5 litre/time or more
3	Ultra Centrifuge	with Zonal rotor MAX rpm : 50,000
4	Refrigerated Centrifuge	with rotor Rotor capacity: 250cc× 4 bottle
5	Autoclave	Capacity : 50 litre Temperature 115°C, 121°C
6	Safety Cabinet	Inner material : stainless steel
7	Clean Bench	Width inner 120cm, Inner material : stainless steel
8	Incubator	Capacity : 150 litre, Temperature range : room + 5°C ~ 60°C
9	Refrigerator	Capacity : 300 litre, Temperature range : + 2°C ~ 14°C
10	Ultra Low Deep Freezer	Capacity : 80 litre, Temperature range : - 20°C ~ - 90°C
11	CO2 Incubator	Capacity : Approx. 160 litre, Temperature range : room + 5°C ~ 50°C
12	Laboratory Table	Size : 1800×1500mm, with sink with stool
13	Bench	Size : 1500×750mm
14	Personal Computer	CPU : Pentium III
15	Computer projectors and note type computer	CPU : Pentium III, projector for personal computer
16	Demonstrating microscope	Type : Trinocular, with light source, CCD camera, monitor
17	Dissecting binocular microscope	Type : Binocular, with light source, Objective lens : 0. 67×, 1×, 2×, 4×
18	Binocular microscope	Type : Binocular, with light source, Objective lens : 4×, 10×, 40×, 100×
19	Microscope for cell culture	Type : Binocular, with light source
20	Fluorescent Microscope	Type : Binocular, with light source
21	Binocular Microscope with computer system	Type : Binocular, with light source
22	Microscope for cell culture with Camera	Type : Binocular, with light source

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Major Undertakings to be taken by Each Government

No.	Items		
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 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 the Japanese bank for the banking services based upon the B/A		
	1) Advising commission of A/P		●
	2) Payment commission		●
9	To ensure unloading and customs clearance at port of disembarkation in recipient country		
	1) Marine (Air) transportation of the products from Japan to the recipient	●	
	2) Tax exemption and custom 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 contracts		●
12	To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant		●
13	To bear all the expenses, other than those to be borne by the Grant, necessary for construction of the facilities as well as for the transportation and installation of the equipment		●

(B/A: Banking Arrangement, A/P: Authorization to pay)

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Preparatory works to be carried out by the Kenyan side

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

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Japan's Grant Aid Program

1. Japan's Grant Aid Procedures

(1) The Japan's Grant Aid Program is executed by 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 the Cabinet of Japan)

Determination of Implementation (Exchange of Notes between both Governments)

Implementation (implementation of the Project)

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

Secondly, JICA conducts the study (Basic Design Study), using (a) Japanese consulting firm(s).

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

Fourth, the project approved by the cabinet becomes official with the Exchange of Notes signed by the Government of Japan and the recipient country.

Finally, for the implementation of the Project, JICA assists the recipient country in preparing contracts and so on.

JICA

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2. Contents of the Study

(1) Contents of the Study

The purpose of the Basic Design Study conducted by JICA on a requested project is to provide a basic document necessary for appraisal of the project by the Japanese Government. The contents of the Study are as follows:

- a) confirmation of the background, objectives, benefits of the project and also institutional capacity of agencies concerned of the recipient country necessary for project implementation,
- b) evaluation of the appropriateness of the project for the Grant Aid Scheme from a technical, social and economical point of view,
- c) confirmation of items agreed on by the both parties concerning a basic concept of the project,
- d) preparation of a basic design of the project,
- e) estimation of cost 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.

Final project components are subject to approval by the Government of Japan and therefore may differ from an original request. Implementing the project, the Government of Japan requests the recipient country to take necessary measures involved which are itemized on Exchange of Notes.

(2) Selection of Consultants

For smooth implementation of the study, JICA uses (a) registered consulting firm(s). JICA selects (a) firm(s) based on the proposals submitted by the interested firms. The firm(s) selected carry (ies) out a Basic Design Study and write(s) a report, based upon terms of reference set by JICA.

The consulting firm(s) used for the study is (are) recommended by JICA to a recipient country after Exchange of Notes, in order to maintain technical consistency and also to avoid any undue delay in implementation should the selection process be repeated.

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3. Japan's Grant Aid Scheme

(1) What is Grant Aid?

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

(2) Exchange of Notes (E/N)

Both Governments concerned extend Japan's Grant Aid in accordance with the Exchange of Notes 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 Aid" means one Japanese fiscal year that the Cabinet approves the Project for. Within the fiscal year, all procedure such as Exchange of Notes, concluding a contract with (a) consulting firm(s) and (a) contractor(s) and a final payment to them must be completed.

(4) Under the Grant, in principle, products and services of origins of Japan or the recipient country are to be purchased.

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

However the prime contractors, namely, consulting, contractor 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 the "Verification"

The Government of the recipient country or its designated authority will conclude contracts denominated in Japanese yen with Japanese nationals. The Government of Japan shall verify those contracts. The "Verification" is deemed necessary to secure accountability to Japanese taxpayers.

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(6) Undertakings Required to the Government of the Recipient Country

In the implementation of the Grant Aid project, the recipient country is required to undertake such necessary measures as the following:

- a) to secure land necessary for the sites of the project prior to the installation work in case the project is providing equipment,
- b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities in and around the sites,
- c) to secure buildings prior to the installation work in case the project is providing equipment,
- d) to ensure all the expenses and prompt execution for unloading, customs clearance at the port of disembarkation and internal transportation of the products purchased under the Grant Aid,
- e) to exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which will be imposed in the recipient country with respect to the supply of the products and services under the Verified Contracts,
- f) to accord Japanese nationals whose services may be required in connection with the supply of the products and services under the Verified Contracts, such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work.

(7) Proper Use

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

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(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 shall open an account in the name of the Government of the recipient country in a bank in Japan. The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by 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 issued by the Government of the recipient country or its designated authority.

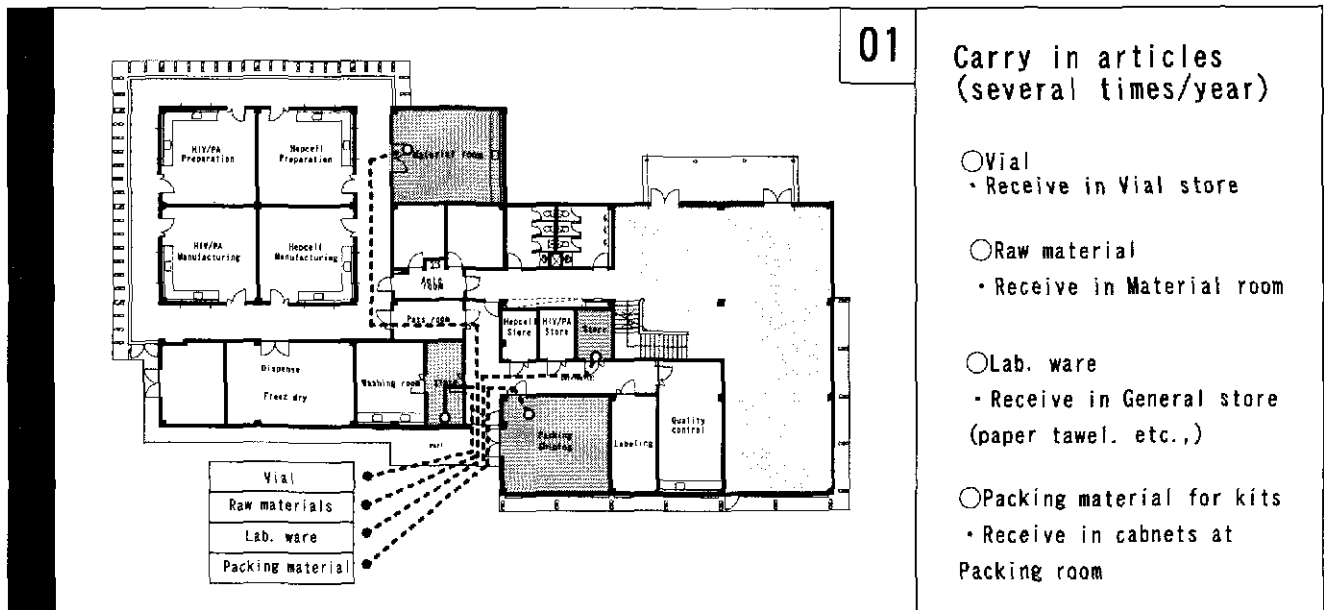
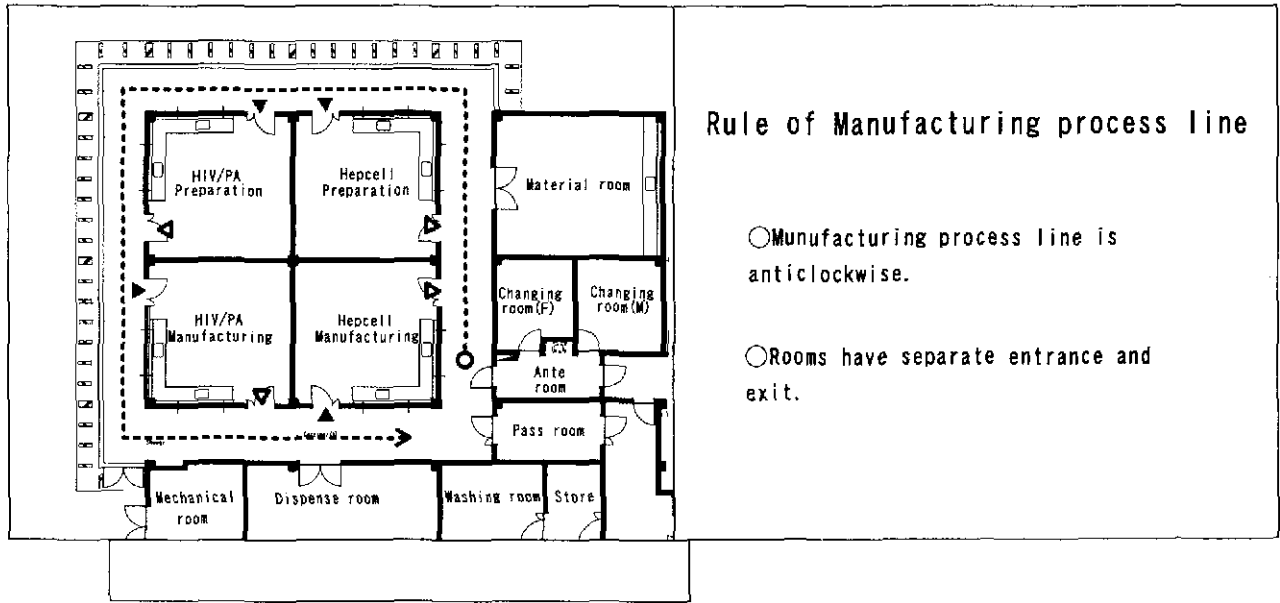
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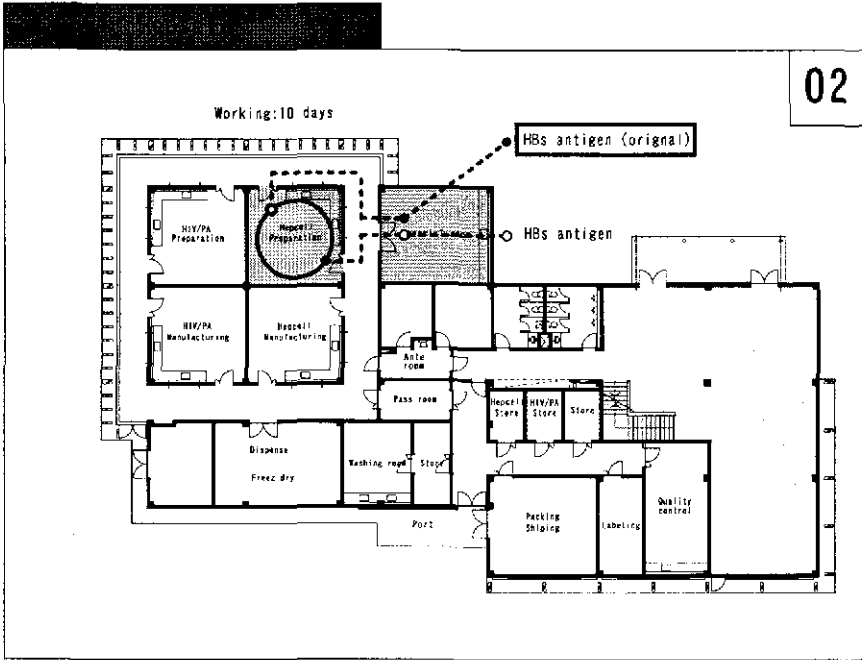
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5. OTHER DOCUMENTS

Flow Diagram for Blood Screening Kit Production Unit

1. [Production Unit] Manufacturing process Line (Hepcell II kit Production)

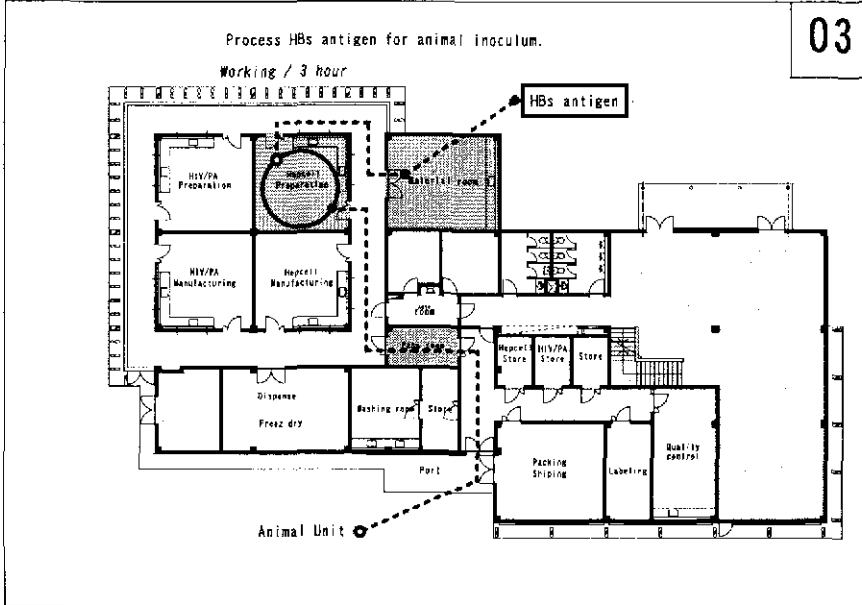




02

Preparation of HBs antigen

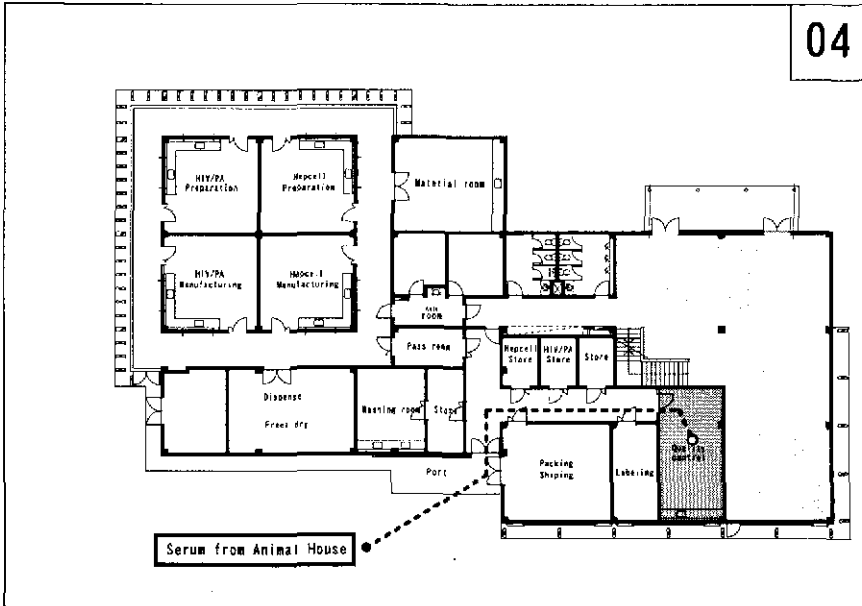
- Material room
 - HBs antigen (original)
- ↓
- Hepcell Preparation
 - Purification of HBs antigen
 - Working, 10 days
- ↓
- Material room
 - After make out, HBs antigen are refrigerated



03

Preparation of immunogen

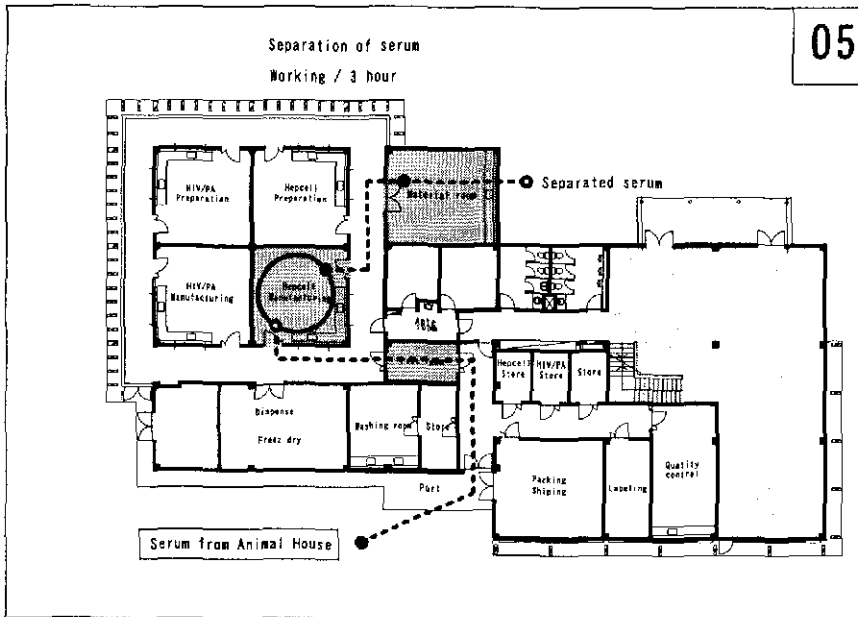
- Material room
 - HBs antigen
- ↓
- Hepcell Preparation
 - Process HBs antigen for animal inoculum.
 - Working / 3 hour.
- ↓
- Animal House
 - After make out, HBs antigen are carried in Animal House.



04

Quality test of serum.

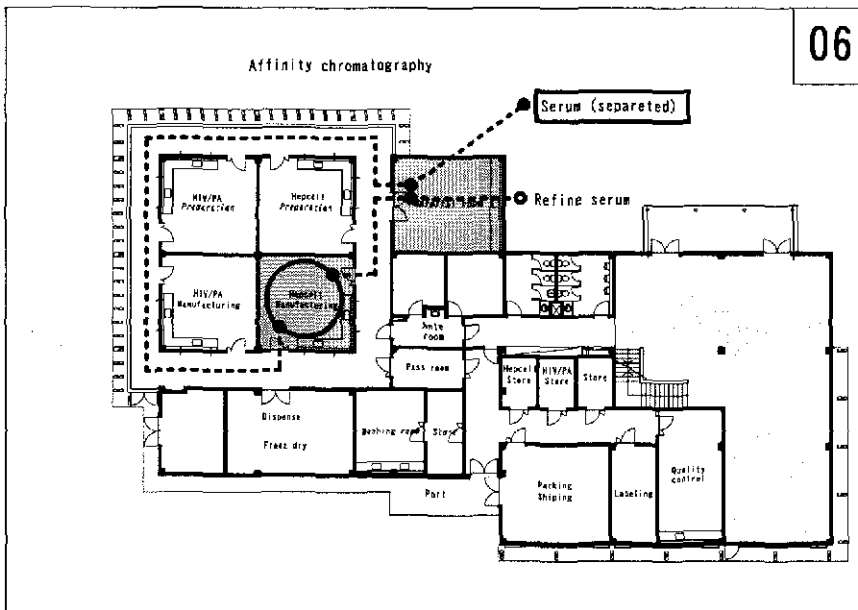
- Animal House
 - Serum
- ↓
- Quality Control
 - Quality test of serum.



05

Separation of serum

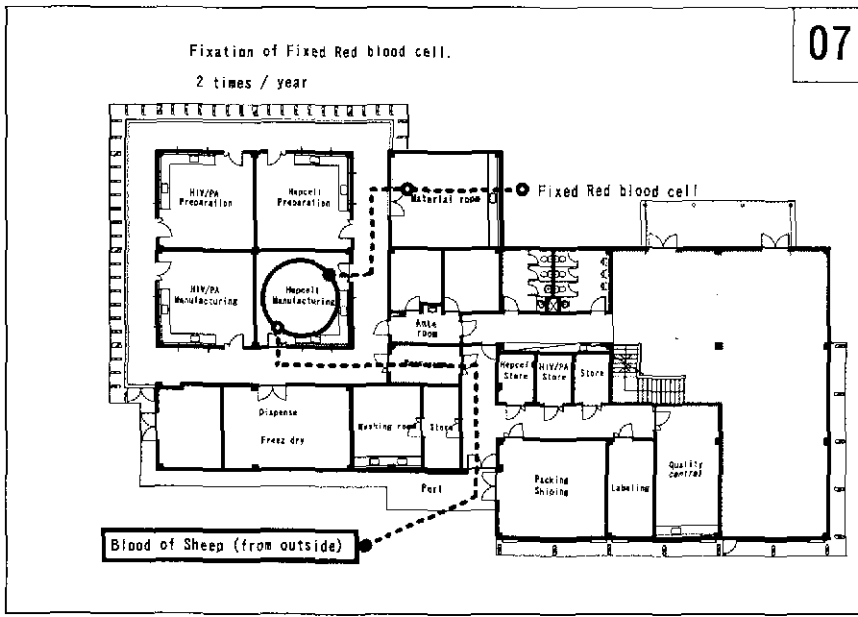
- Animal House
 - Serum.
- ↓
- Hepcell Manufacture
 - Separation of serum
 - Working / 3 hour.
- ↓
- Material room
 - After make out, Separated serum are refrigerated



06

Manufacturing of Purified antibody

- Material room
 - Separated serum
- ↓
- Hepcell Manufacture
 - Affinity chromatography
 - Working/ 3days
- ↓
- Material room
 - After make out, Purified antibody are refrigerated

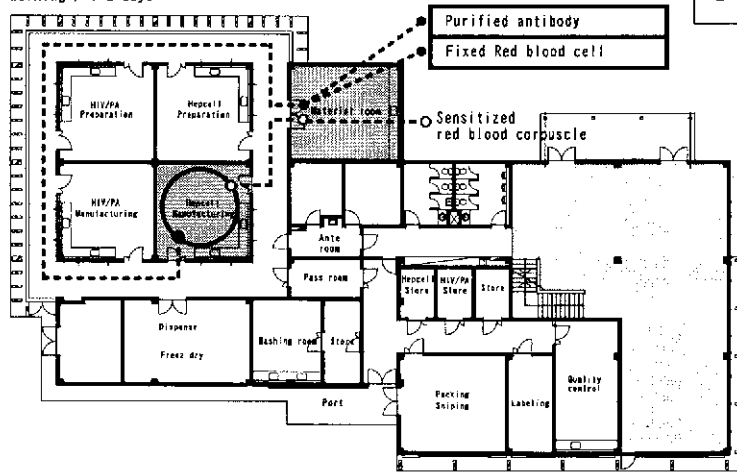


07

Preparation of Fixed Red blood cell

- Out side
 - Blood of sheep
- ↓
- Hepcell Manufacture
 - Fixation of Fixed Red blood cell.
 - 2 times / year
 - Working / 2-3 days
- ↓
- Material room
 - After make out, Fixed Red blood cell are refrigerated

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

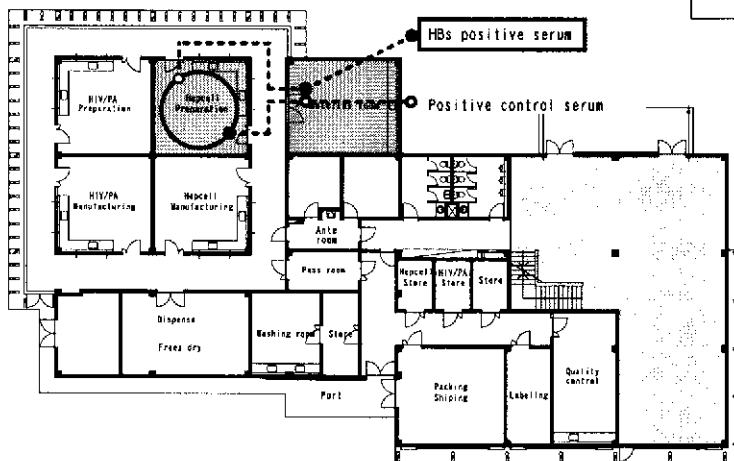


08

Manufacturing of Sensitized red blood cell

- Material room
 - Purified antibody.
 - Fixed red blood cell
- ↓
- Hepcell Manufacture
 - Manufacturing of Sensitized red blood cell
 - Working / 1-2 days
- ↓
- Material room
 - After make out, Sensitized red blood cell are refrigerated.

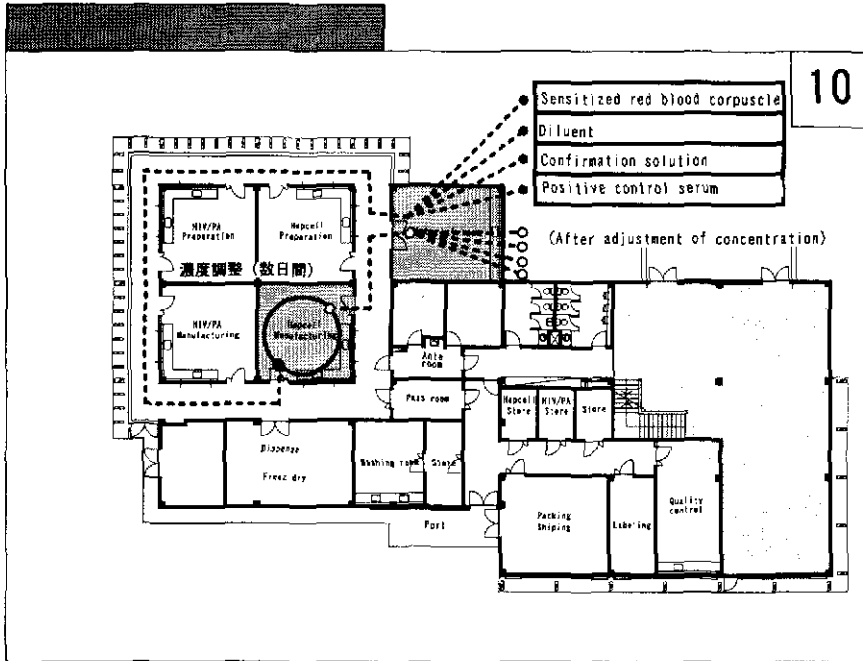
• Manufacturing of Positive control serum
• Using, safety cabinet



09

Manufacturing of positive control serum

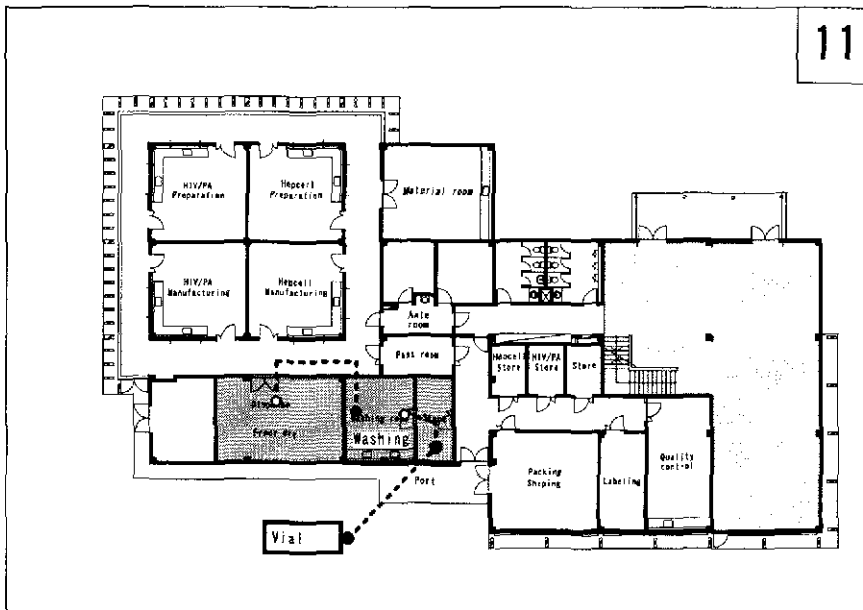
- Material room
 - HBs positive serum
- ↓
- Hepcell Preparation
 - Manufacturing of positive control serum
 - Using, safety cabinet.
- ↓
- Material room
 - After make out, Positive control serum are refrigerated.



10

Adjustment of concentration

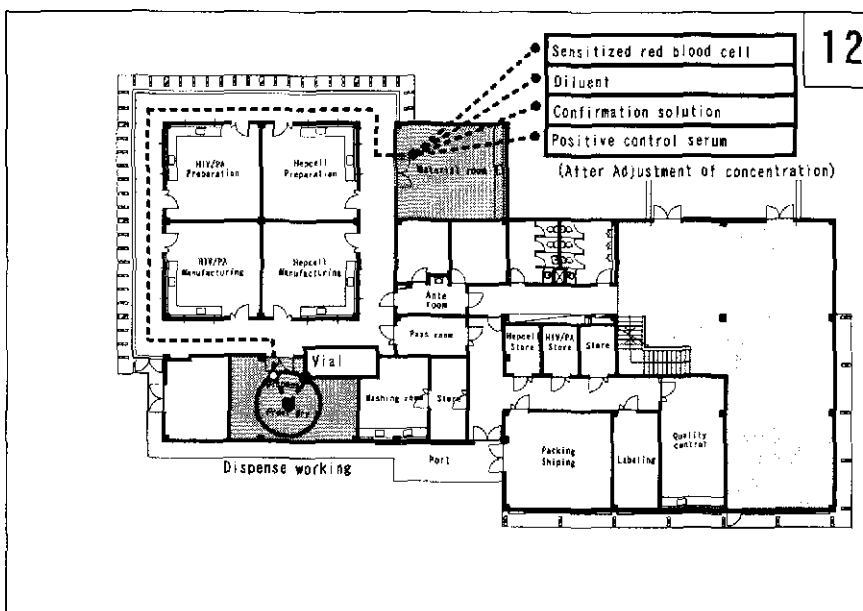
- Material room
 - Sensitized red blood cell,
 - Diluent,
 - Confirmation solution,
 - Positive control serum
- ↓
- Hepcell Manufacture Adjustment of concentration, severally
 - Working / several daya
- ↓
- Material room
 - After make out, they are refrigerated.



11

Dispense Working 1/3

- Store
 - Vial
- ↓
- Washing room
 - Vial are washed
- ↓
- Pass box
 - Vial are carried in manufacturing area
 - Using, passbox
- ↓
- Dispense room
 - Vial are kept in cabinets



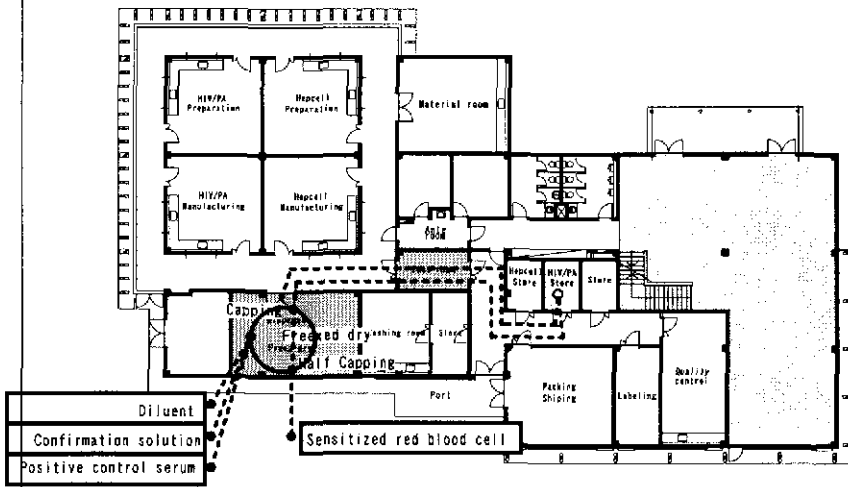
12

Dispense working 2/3

- Material room
 - Sensitized red blood cell,
 - Diluent,
 - Confirmation solution,
 - Positive control serum
- ↓
- (After Adjustment of concentration)
- Dispense room
 - Dispense Working, severally

13

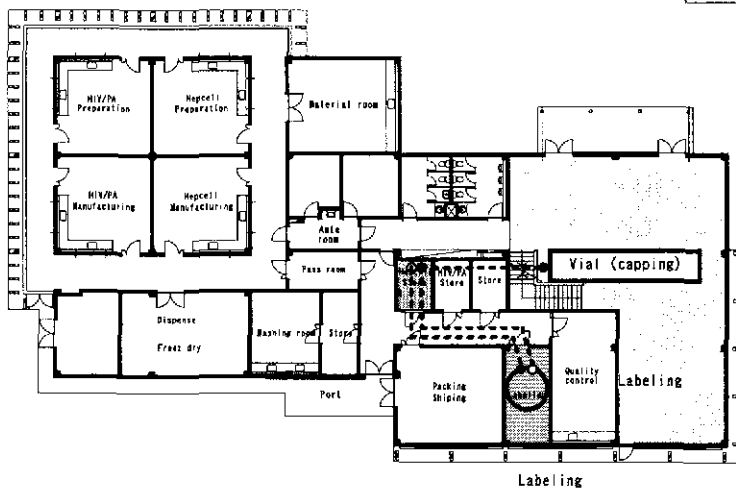
Dispense working 3/3



- Dispense room
 - Sensitized red blood cell are half capping.
 - Diluent, Confirmation solution, Positive control serum are capping
- ↓
- Dispense room
 - Sensitized red blood cell are Freezed dry (Capping, lyophilizer use)
- ↓
- Hepcell Store
 - After capping, they are refrigerated.

14

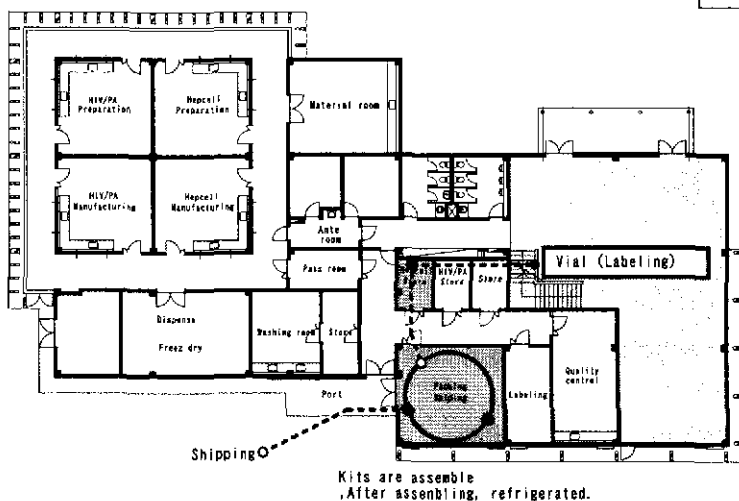
Labeling work



- Hepcell Store
 - Capped vial are carried out
- ↓
- Labeling
 - Labeling work
- ↓
- Hepcell Store
 - Labeled vial are refrigerated.

15

Pre-shipping work ~ shipping



- Hepcell Store
 - Labeled vial are carried out.
- ↓
- Packing
 - Kits are assembling
 - After assembling, refrigerated until shipping.
- ↓
- Shipping Port
 - Shipping