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THE EXPANSION PROJECT OF THE NATIONAL QUALITY CONTROL LABORATORY OF DRUG AND FOOD

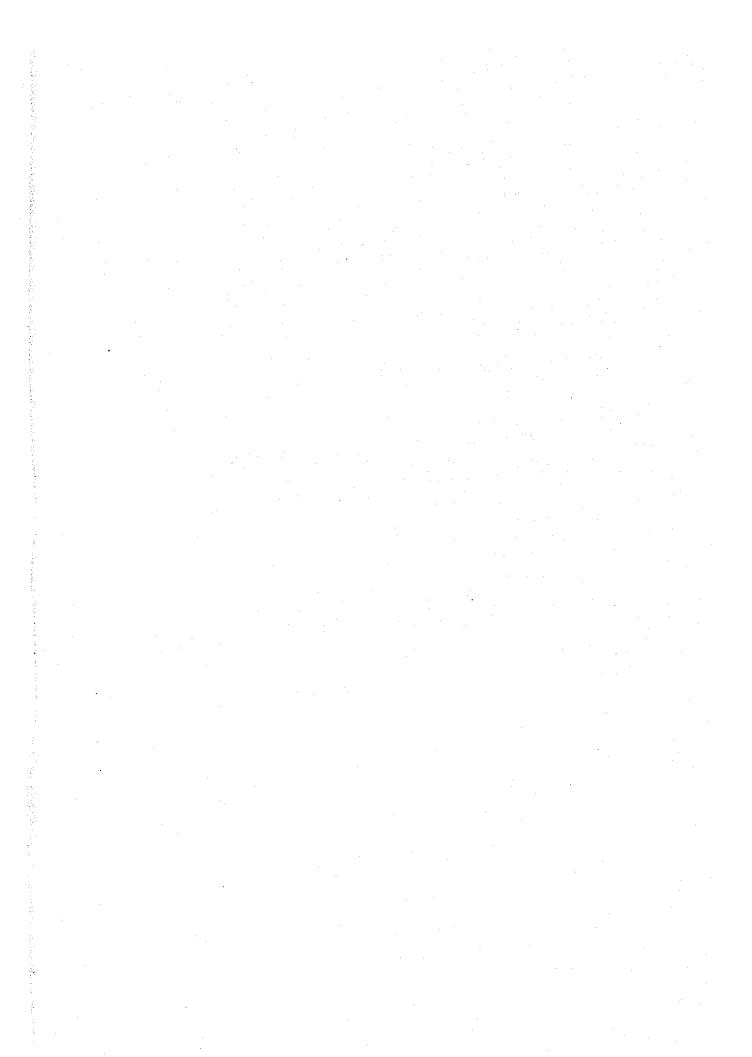
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THE REPUBLIC OF INDONESIA

AUGUST-1983

JAPAN INTERNATIONAL COOPERATION ASSECT





BASIC DESIGN STUDY REPORT

ON

THE EXPANSION PROJECT OF THE NATIONAL QUALITY CONTROL LABORATORY OF DRUG AND FOOD

IN

THE REPUBLIC OF INDONESIA

AUGUST 1983

JAPAN INTERNATIONAL COOPERATION AGENCY

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PREFACE

In response to the request of the Government of the Republic of Indonesia, the Government of Japan decided to conduct a survey on the Expansion Project of the National Quality Control Laboratory of Drug and Food and entrusted the survey to the Japan International Cooperation Agency (JICA). The JICA sent to Indonesia a survey team headed by Dr. Satoru TANAKA, Chief of Teratology and Reproduction Laboratory, Department of Pharmacology, National Institute of Hygienic Sciences from February 28th to March 29th, 1983.

The team had discussions with the officials concerned of the Government of the Republic of Indonesia and conducted a field survey. After the team returned to Japan, further studies were made and the present report has been prepared.

I hope that this report will serve for the development of the Project and contribute to the promotion of friendly relations between our two countries.

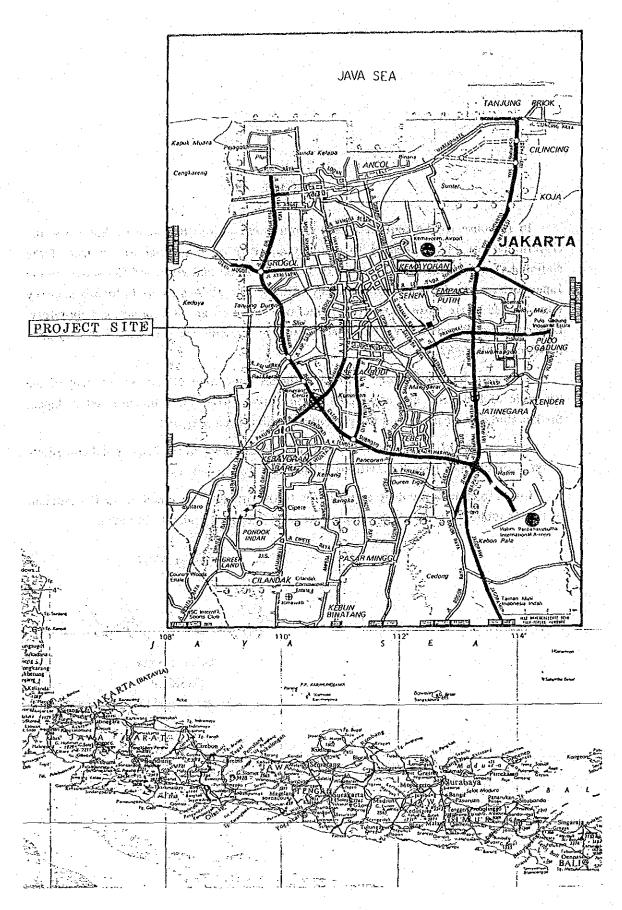
I wish to express my deep appreciation to the officials concerned of the Government of the Republic of Indonesia for their close cooperation extended to the team.

August 1983

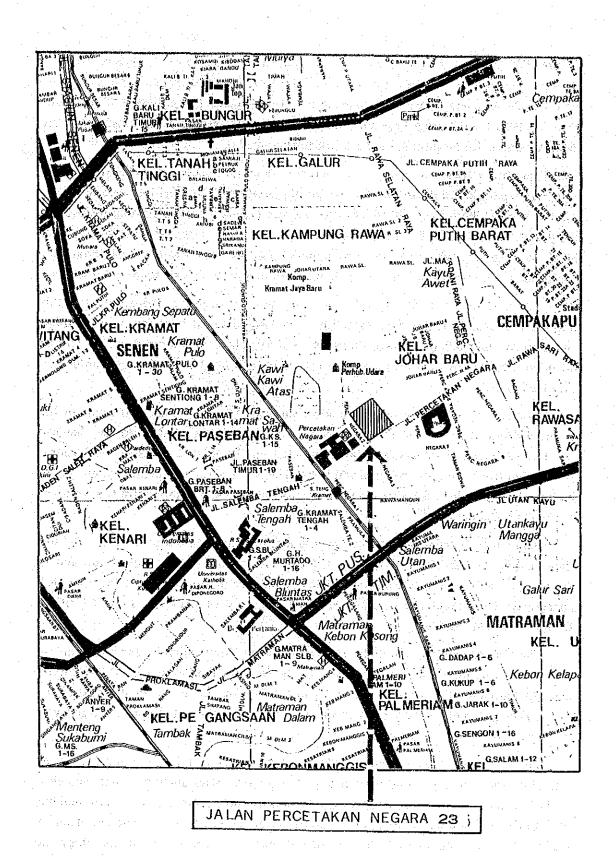
Keisuke Arita

President

Japan International Cooperation Agency



LOCATION MAP 1



LOCATION MAP 2

The Government of the Republic of Indonesia regards the policy of "Stable provision of the essential drugs both in quality and quantity" as one of the most important medical policies for promoting the health of the people.

There are various problems in the actual drug conditions of Indonesia such as the complete separation of dispensary from medical practice without health insurance system for the people, the price problem of drugs and the quality problem relating to its reliability and effectivity. As for quality for drugs on the actual market, effectivity and reliability of drugs depend on the maker's standards, so that ingredient and safety are not confirmed nor controlled by the Government according to unified standards.

This must be corrected urgently for promoting the health of the people. For this purpose it is mainly required to establish unified standards at least for essential drugs, and then to generalize them throughout the country. Thus, standardized quality will be introduced to the essential drugs and the effectivity and reliability will be guaranteed by the Government.

However, in order to establish quality standards for more than 200 items of the essential drugs, it is required to introduce new quality tests in addition to the chemical and physico-chemical tests now being conducted on the market drugs in the National Quality Control Laboratory of Drug and Food. The new tests above mentioned are microbiological test, biological test using experimental animals and comparative test with use of reference standards.

Under these circumstances, the Government of Indonesia has planned to intensify the function of the National Quality Control Laboratory of Drug and Food and to expand its facilities for establishing quality standards of drugs and training the staff concerned of the Provincial Quality Control Laboratory of Drug and Food to diffuse the established standards.

The Government of Indonesia has requested the Government of Japan a grant aid for the construction project for expansion of the facilities. On the request of the Government of Indonesia, the Government of Japan decided to conduct a basic design study on the project and sent a survey team through Japan International Cooperation Agency to Indonesia from February to March 1983.

The survey team confirmed the details of the request and collected necessary information for examining appropriateness of the project. After analysis of data and close study in Japan, the team prepared a plan for construction a reinforced concrete building of 3 stories and approx. 4000 sq.m of total floor area consisting of experimental animal facilities, laboratories for each division of pharmacology, toxicology, microbiology and biopharmacy, as well as rooms for reference standards, sterility, staff training, and so on.

Although the proposed facilities are possessed of minimum function required for above-mentioned aims, completion of the building makes possible comprehensive quality tests and staff training. It is the first step and at the same time the key of establishment of quality control system. The project is therefore very important for promoting the health of the people which is to be executed immediately.

The proposed facilities is the first laboratory to be introduced to Indonesia and some points are apprehended on operation and maintenance. The Government of Indonesia is intensely expected to operate the facilities after establishing a necessary organization and taking necessary measures for budget in accordance with the propositions mentioned at the end of this report to rise the effect of the project to be implemented by the Japanese grant aid.

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CHAPTER 1 INTRODUCTION

In the Indonesian Medical Policy aiming at improvement of the health of the people, "Stable Provision of the Essential Drugs" is one of the most important policies to be realized.

The drugs on the present market are various in safety, effectivity and indication of component because both unified quality standards and test methods for drugs have not yet established in Indonesia, which has been a great obstruction in promoting the abovementioned policy.

In order to correct this defect, it is required first to establish quality standards basing on the results of the comprehensive quality tests on the marketing drugs which will be conducted by means of chemical, physico-chemical and biological analysis in the central laboratory, and second to develop a unified test method and extend it to the concerned staff of all the provincial laboratories. Thus, the established quality standards of drugs will be extended throughout the country and the people will be able to have quality controlled drugs.

The test for quality control are now conducted in the National Quality Control Laboratory of Drug and Food (hereinafter referred to as NQCL DF) and the Provincial Quality Control Laboratories of Drug and Food (hereinafter referred to as PQCL DF) mainly by means of chemical and physico-chemical tests and microbiological test on a small scale. But biological tests with the use of experimental animals is hardly realized at present in the NQCL DF.

The Government of Indonesia recognized that the expansion of the actual function of the NQCL DF is first of all required to establish a quality control system available for the whole country, and decided to extend its existing facilities to put new functions of comprehensive quality tests and staff training.

The Government of Indonesia has requested the Government of Japan a grand aid for the expansion project of the NQCL DF (hereinafter referred to as the Project).

On the request of the Government of Indonesia, the Government of Japan decided to conduct a basic design study on the Project and sent a survey team, headed by Ph. Dr. Satoru TANAKA, Division of Pharmacology, National Institute of Hygenic Sciences, Ministry of Public Health and Welfare, to Indonesia from 28 February to 29 March, 1983 for a field survey.

In Indonesia, the survey team confirmed the details of the request and collected necessary information for studying the function and size of the requested facilities and for examining appropriateness of the Project, such as the actual condition of the site, infrastructure and the construction industry; and also information on necessary budget and organization for the project to be prepared by the Government of Indonesia.

The study team and the concerned officials of the Government of Indonesia had close discussion on execution of the Project. The matters basically agreed through the discussion were summarized in the Minutes of Discussions, signed on March 12 between the representatives of the study team and Indonesian officials.

The study team, after the analysis of collected data, prepared a basic plan for the Project and reported it through this basic design study report to provide the necessary information for deciding implementation of the grant aid by the Japanese Government.

CHAPTER 2 PROJECT BACKGROUND

2-1 Present Conditions of Medical Service and Principles of the Health Policy

Since April 1979, the Government of Indonesia has been implementing the third 5 year Development Plan with the following seven targets:

- (1) Equal distribution of the development results
- (2) Attainment of high economic growth
- (3) Security and stabilization of the nation
- (4) Purification of administrative organizations
- (5) Realization of the 5 principles of the National Foundation (PANCA SILA)
- (6) Promotion of democracy
- (7) Independency in diplomacy

Details of the target "Equal distribution of the development results" are as follows:

- (1) Provision of food, clothing and housing for the nation
- (2) Equal opportunity in education and medical services
- (3) Equal distribution of national income
- (4) Equal opportunity of employment
- (5) Equal opportunity in economic activities
- (6) Equal opportunity of participation for juveniles and women, etc.
- (7) Abolition of regional disparities

In the background where the Indonesian Government set the "equal opportunity in medical services" as one of the essential targets of the Plan, the following situation of the actual medical service for the people is pointed out: absolute shortage of doctors and medical facilities and unestablished health insurance system have caused together with increased income disparities inversely proportionated by promotion of development policies that 80% of the total population are out of the benefit of modern medical services in Indonesia.

The number of doctors is 7 per 100,000 capita. This is extremely small compared with that of Japan, which is 121 per 100,000 capita. The number of medical beds in Indonesia is 60 per 100,000 capita, whereas in Japan it is about 1,400.

As for health insurance, a system called "ASKES" is established only for the government officials and the pensioned ex-officials and no system is still established for the people. In large scaled companies, some repayment system for the employee's medical expenses is provided as a part of the welfare measures. However, those are only a few of all the enterprises, and most of the people are not receiving such benefit of medical welfare.

It is said in Indonesia that the charge for a prescription by practitioners is 1,000 ~ 10,000 rupiah and the charge for drugs per prescription is about 5,000 rupiah. Medical expenses is, therefore, very high in comparison with income standards of the people and it is a heavy burden for low income earners to consult a doctor.

Under these circumstances, the Government of Indonesia has ordered all the doctors in active service to provide medical treatment in public medical facilities such as public hospitals and clinics at least in the morning in order to realize extension and equalization of medical services for the low income earners. The Government is also promoting the following policies: training medical staff, dispatching doctors to the provinces lacking medical service facilities, increasing public clinics and supplying drugs stably.

2-2 Present Condition of Drugs and Quality Control

The latest data show that there are 286 pharmaceutical manufacturers in Indonesia inclusive of national pharmaceutical corporations and 40 of them are the foreign affiliates established under the foreign investment law. The production has increased over 20% per year for these past few years and 7,200 kinds of drugs have already been registered to meet the domestic needs on the whole.

Complete separation of dispensary from medical practice is implemented in Indonesia. Consequently, the legend drugs used essentially for medical treatment are bought at pharmacies managed by pharmacists according to the prescription described by a doctor's diagnosis.

However, as the self-medication is becoming popular for treatment of simple diseases and health promotion in use of OTC (Over The Counter drugs) which can be bought at a drug store without a doctor's prescription, the market of OTC has been developing more rapidly than that of legend drugs. OTC includes vitamins, tonics and drugs for simple cold, headache, diarrhea and skin diseases. The present OTC market share is 50% of that of all the drugs. Foreign capitalized joint ventures supply $40 \sim 50\%$ of all the drugs including OTC and $60 \sim 70\%$ of legend drugs.

The qualities of these drugs are standardized by each firm: there is neither quality control on a uniformed basis nor full inspection of distribution process. As a result, many drugs of which ingredient, reliability and effectivity are not sufficiently confirmed are on the actual market. On the other hand, per capita consumption of drugs is smaller than in other neighbouring countries. This is not due to small need for drugs, but due to the fact that drugs are too expensive in the country as a whole considering the incomes of the people. The factors of high prices to be mentioned are dependence of the essential material on importation and the high distribution cost as well as large retail margins.

Under the circumstances, the Government of Indonesia has set out the following medicinal policies to solve the problems and to improve the health of the people.

- (1) To increase production of the essential drugs* at the national pharmaceutical corporations and to provide them stably at special prices to the public hospitals and clinics
 - * The essential drugs of Indonesia consist of drugs recommended by WHO in approximately 200 items and drugs specially selected considering the domestic health condition.
- (2) To achieve self-supply of raw material for essential drugs.
- (3) To extend the generic system, that is to sell drugs not in brand name but in name of the principal ingredient, by means of giving favourable treatment in terms of tax and/or registration procedure. Some of the drugs presently sold by brand name have extremely high profit margins because of their name value. To popularize them and to lower their prices, generic system is considered as an effective measure.
- (4) To establish strict inspection standards for the registration of products and to control the quality, price and distribution quantity.
- (5) To revive the original mission of pharmacy to supply drugs to the people increasing public pharmacys together with checking the distribution cost and retail margins,

It is indispensable to conduct the following measures for carrying out the abovementioned policies.

- (1) To establish quality standards for drugs and to confirm the reliability and effectivity through necessary tests based on the standards
- (2) To intensify the control system of production and distribution of drugs
- (3) To promote public relations and education of drugs

In other words, it is to establish and intensify the quality and distribution control systems of drugs.

Quality control in Indonesia is conducted in each Directorate of Drugs, Food and Beverages, Traditional Drugs, Cosmetics and of Narcotics and Dangerous Drugs under the Directorate General of Drug and Food Control, Ministry of Health. The National Quality Control Laboratory of Drug and Food (NQCL DF) has been established under the Directorate General to carry out tests and analyses necessary for quality control. The NQCL DF consists of five laboratories and twenty sections as is shown in the organization chart in Appendix.

In the seven main cities including Jakarta and Bandung and other twenty cities, two categories of PQCL DF have been respectively established conducting mainly chemical and physico-chemical test for drugs.

Quality control tests should be to confirm the reliability and effectivity of the test object and to guarantee the usefulness for the people. For this purpose, it is not sufficient to conduct merely chemical and physico-chemical analysis and tests. It is also required to introduce microbiological test, biological test using experimental animals and comparative test, using reference standards which are available for all the fields of chemical, physico-chemical and biological tests to examine the quality of drugs which are impossible to be examined its quality by ordinary means.

Accurate quality standards can only be determined by the data acquired as a result of such comprehensive tests.

For conducting quality control, it is required to prepare a nation-wide quality test network by developing unified test method for the PQCL DF and giving intensive training to the staff concerned after establishing the quality standards for drugs. This is the key for establishing a quality control system of drugs and the first step to be taken.

The Government of Indonesia has thus planned the expansion of the NQCL DF's functions in order to conduct comprehensive tests and staff training.

CHAPTER 3 OUTLINE OF THE PROJECT AREA

3-1 Project Site

3-1-1 Location

The construction site for the facilities is located inside of the building complex of the Directorate General of Drug & Food Control, Ministry of Health where the existing laboratory of the NQCL DF and other facilities are located. (See Fig. 3-1.)

The Directorate General of Drug & Food Control, Ministry of Health, is situated on the Percetakan Street, 4 km southeast of the Independent Square in the centre of Jakarta. Surrounded by the urban area, the location is convenient for both the staff's daily attendance and transportation of commodities. However, being only 3 km south from Kemayoran Domestic Airport and directly under the flight course of the domestic lines, the noise by aircraft is considerably loud. (See Location map.)

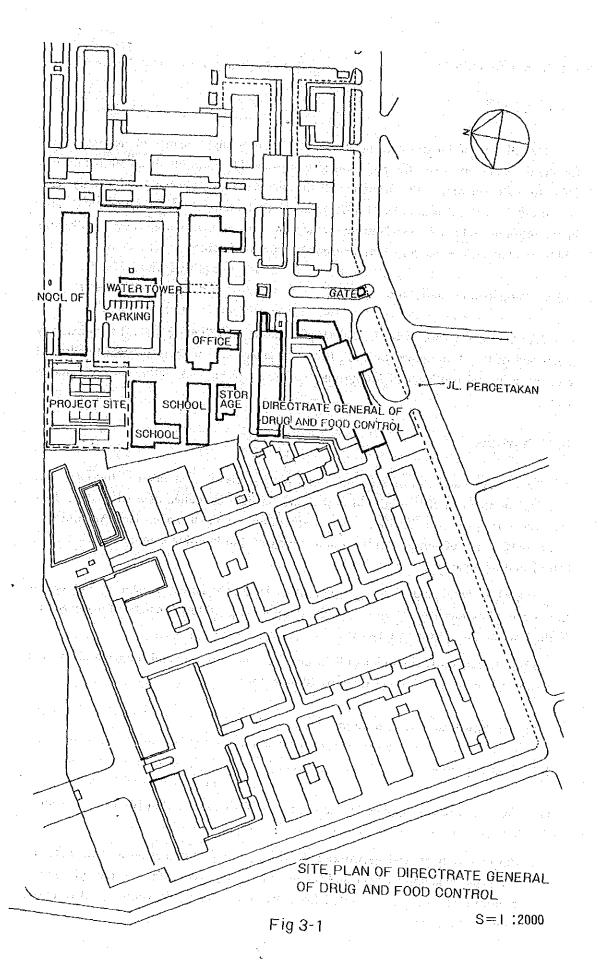
3-1-2 Present situation

As is shown in Fig. 3-1, the proposed site is adjacent to the existing laboratory of the NQCL DF on the eastern side and to the school for chemical analyst on the southern side.

The land is flat and square in shape with an area of approximately 2,200sq.m. Being used mainly as a tennis court at present, it is equipped with a storehouse, net fence, a clothing-change house and so on. No special land formation is therefore required except finish grading after demolition and removal of those facilities.

Access to the site is through the pilotis of the administration building of two stories located 70 m in front of the main gate of the complex facing on the Percetakan Street. After the pilotis, there is a courtyard composed of parking area and green belts where a water supply tower and a green house is located. The courtyard is surrounded by the training school, the existing laboratory of NQCL DF, the canteen and the mosque in addition to the administration building.

The pilotis, the only access for common use of both pedestrians and vehicles, is so narrow (width: 4.3m, height: 3.5m) that it is a matter to be taken into due consideration to use the pilotis for transportation of the materials and passage of the vehicles for construction purpose.



3-2 Natural Conditions

3-2-1 Climate

The climate of Jakarta is tropical oceanic. There is slight change of seasons except for the difference between the rainy and dry seasons. The monthly mean temperature is 26°C to 30°C showing little difference all through the year. However, as for daily temperature difference, it is considerably remarkable as the temperature is below 25°C early in the morning and nearly 33°C during the daytime. The annual rainfall is over 2,000 mm and it concentrates in the rainy season from October to March.

3-2-2 Topographic conditions

Jakarta is a city formed on the alluvial plain along the Ciliwung River. Its topography is flat and of $0 \sim 8$ m above sea level. From the geological survey result near the Project site, the principal top layer of the ground is clay $3 \sim 7$ m thick with sand layer underneath.

3-2-3 Disasters

There have been almost no remarkable natural disasters in Jakarta. Indonesia is a volcanic country and Java Island, in particular, has high incidence of earthquakes. However, the earthquakes in Jakarta are not frequent and of small magnitudes. Accordingly, shear coefficiency of seismic force recommended by the building standards of Jakarta is half of that of Japan.

Regarding wind and flood damage, there is no particular damage except casual floods caused by localized downpour in the rainy season and low capacity of drainage due to the low and flat altitude all over the city.

There is frequently thunder and lightning in the rainy season and there are occasional damages such as electric failure caused by thunderbolts.

3-3 Present Situation of Infra-structure

3-3-1 Electric power

- (1) Electric power is supplied by the national electric corporation (Perusahaan Umum Listrik Negara=P.L.N.).
- (2) Power supply is well networked. However, voltage fluctuation is sharp between the peak consumptive time and the rest of the day. Power failures take place once a month on an average resulted from lightnings and repair troubles, not from the shortage of supply.

- (3) The supply voltage is 220V/380V, 50Hz.
- (4) There is no problem for supply to the Project site, as an aerial cable of 20 KV is installed on the Percelakan Street.

3-3-2 Water supply

- (1) Water is supplied by the national water supply corporation (Persahaan Air Minum D.K.I. Jaya=P,A.M.).
- (2) Water supply pipes are distributed in the main parts of Jakarta, but many of them are old from the days of Dutch rules, with much water leakage. Average supply pressure is 0.5 kg/cm², which is so low that water pollution is anticipated in the water distribution process. Moreover, water supply failure takes place frequently. To cope with the situation, well water and city water are commonly used at the same time in Jakarta.
- (3) Water qualities of both the city and well waters are not suitable for drinking without treatment.
- (4) Only underground water is supplied for the existing facilities of the Directorate General from the well in the premises and there is no city water supply at present. The water from the existing well is not expected to be used for the Project, but city water from the main pipes (150 mm & 200 mm in diameter) of the Percetakan Street is possible to be supplied for the proposed facilities.

3-3-3 Sewerage system

- (1) In Jakarta, there is no urban sewerage system with a sewage disposal plant. Sewage is generally treated in the individual septic tank installed for each building and is discharged to the drainage ditch or penetrated naturally in percorating basin.
- (2) Consequently, rivers and drainage ditches in the city are considerably polluted,
- (3) There is no particular regulation regarding sewage disposal at present.
- (4) In the facilities of the Directorate General of Drug & Food Control sewage is permiated into the earth in the percolating basins after treated in the septic tanks installed for each building.
 - There is a reservoir called WADUK in the premises. It is connected to the outside drain ditches through covered conduits. Discharging the treated water from the proposed facilities to Waduk is possible.

3-3-4 City gas

- (1) City gas is supplied by the national gas corporation (Persusahaan Gas Negara=P.G.N.).
- (2) Natural gas with calorie of 5,000 kcal/cu m is supplied at pressure of 60 mm Aq.
- (3) Pipes of 50 mm in diameter are installed in the premises of the Directorate General and 100 mm diameter pipes are laid under the Percetakan Street.

3-4 Construction Conditions

3-4-1 General conditions of construction

(1) Construction Material

There is no problem of procuring ordinary materials, as many of structural and finishing materials as well as material and equipment for building installations are domestically produced. Besides, imported products are sufficiently on the market.

(2) Labour and the any end of the design of the rest of the second of th

Construction has been booming due to the increase of development investment since 1980 and the construction industry has become active. Consequently, absolute quantity of labour is short to some extent and it must be noted to secure necessary labour force.

(3) Transporation

It takes about two weeks to transport construction material and equipment from Japan. Cargo is unloaded directly at Tanjonpuriok Port in Jakarta. It is less than one hour from the port to the Site. Two to four weeks are usually required for going through the customs clearance. Custom duty exemption will be applied for the imported materials for the Project. However, it will be estimated to take the same amount of days to go through the necessary procedure.

3-4-2 Building regulations

(1) Building Regulations and Design Standards

There are a number of regulations and standards regarding structural, material, building equipment and fire protection, as well as the National Architectural Regulations (Peaturan Bangunan Nasional 1978). They are not particularly strict as compared with the Japanese regulations and standards.

(2) Procedures for Permission

Those who are going to construct a building should apply for permission according to the Regulations for Building Permission (Izin Bangunan). A qualified engineer's signature is required on the attached drawings. In case that the cost of construction works ordered by the Government exceeds 500 million Rupiah, the details of the contract should be examined by the State Department (Secretariat Negara).

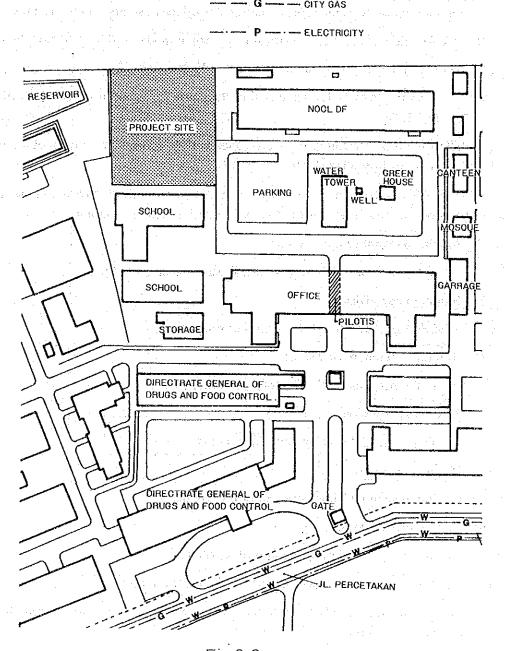


Fig 3-2

CHAPTER 4 PROJECT SUBSTANCE

4-1 Objectives and Outline of the Project

The aim of the Project is to establish a network of quality control test by adding the following functions to the existing laboratory of the NQCL DF. It is, as mentioned in the chapter 2, the first step and the key for the "Establishment of quality control system for drugs" required for stable provision, quantitively as well as qualitatively, of the essential drugs to the people.

- (1) The function of the biological tests such as pharmacological, toxicological and immunological tests in use of experimental animals and microbiological tests.
- (2) The function of biopharmaceutical tests such as in vivo and in vitro examinations.
- (3) The functions of producing reference standards.
- (4) The function of developing available standards for test and analysis of drugs for the PQCL DF.
- (5) The function of training the staff concerned to improve their technology of test and analysis in the PQCL DF.

The Project in concrete terms is to construct a laboratory building consisting of necessary rooms and facilities for the following divisions and common use.

(1) Animal care and supply division:

Breeding rooms, Holding rooms, Washing room and others

(2) Biopharmacy division:

Biopharmacy laboratory and other rooms

(3) Reference standards division:

Reference standard laboratory and other rooms

(4) Toxicology division:

Toxicology laboratory and other rooms

(5) Pharmacology division:

Pharmacology laboratories and other rooms

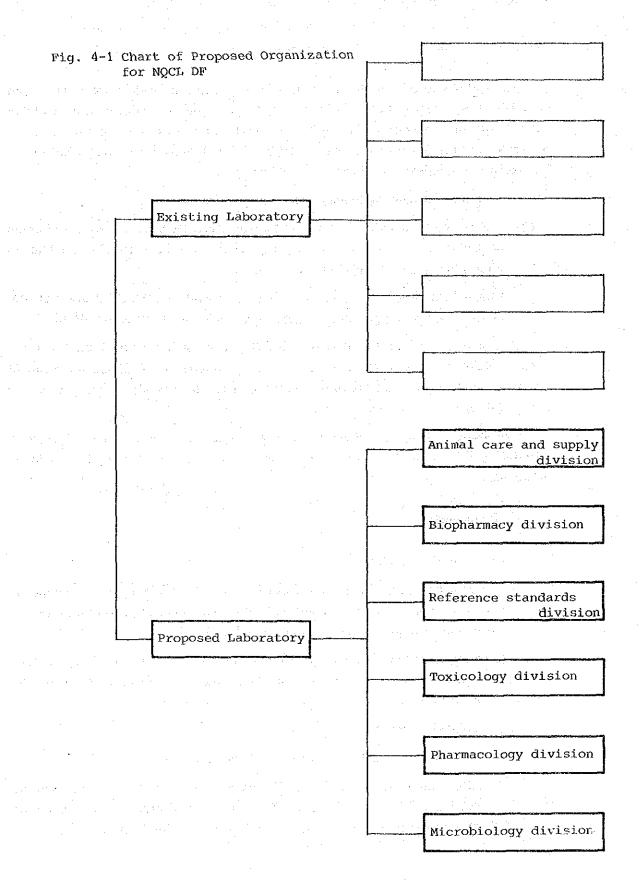
(6) Microbiology division:

Microbiology laboratories and other rooms

(7) The following are the necessary rooms for common use:

Administration office, Library, Conference room, Training room, Building installation rooms and others.

The Fig. 4-1 shows a proposed organization for the NQCL DF and its new facilities.



4-2 Planning and Design

4-2-1 Design policy

The features to be specially mentioned for the proposed facilities are to breed and hold laboratory animals inside facilities and to carry out the construction works in parallel with daily activities of the other existing facilities because the site is located in the precinct of the Directorate General of Drug and Food Control, Ministry of Health. The facilities are designed considering the following.

- (1) Architectural planning to realize an easy care of animals.
- (2) Full air-conditioning for 24 hours to the animal care facilities and positive adoption of daylighting and natural ventilation system to the other parts of the building to reduce the operation and maintenance costs.
- (3) Design to have less effect of the construction works on the environmental condition of the existing facilities together with a relevant construction planning.

It is a matter of course of respect the National Building Regulations and other related building codes and standards established in Indonesia on designing, but in case of no technical standards available to be applied, design will be conducted on the basis of the related Japanese standards.

The proposed building is designed so as to facilitate the maintenance and repair by introducing familiar materials which are generally used and fit for the local skills in Indonesia.

4-2-2 Site planning

(1) Process of site selection

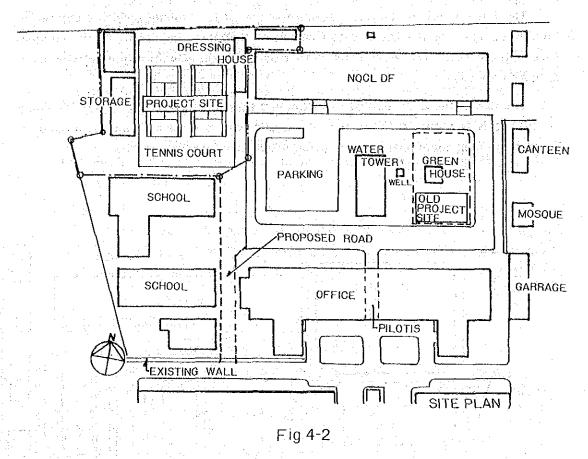
The land first proposed for the construction of the building by the Indonesian Government is a part of the courtyard before mentioned in the center of which a green house is at present found as shown in Fig. 4-2.

However, as some defects had been found on the land as pointed below, the study team proposed to use the tennis courts as a building site after full examination of the site conditions.

The pointed defects are:

- 1) The land is too small for the estimated size of facilities.
- After completion, the clearance between the proposed facilities and the
 existing facilities will be too narrow, which will probably worsen the environmental conditions on the mutual landscape, ventilation and so on.

3) The center courtyard will be occupied by construction machinery and materials throughout the construction period, which will not only prevent safety of pedestrians but also will cause a deteriolation of the environmental conditions having a bad influence upon daily activities of the existing facilities.



After close discussion the proposed land was agreed and decided to be the project site.

(2) Land renovation

The site is flat and needs no land forming with cut and fill but it is required to remove the existing facilities of the tennis court such as the net fence, the lighting equipment and the brick house used for a changing room and the brick storage as well as the wooden house used for a shopping stand.

(3) Access road

In case any path for access is not newly provided, all access to the site should be done through the pilotis of the administration building. As it is dangerous to use the pilotis to carry in and out the construction machinery and materials, an access road is planned to be provided removing a part of the existing wall as shown in Fig. 4-2 and 4-3.

The proposed road will be available for cars to access to the courtyard after completion of the construction and the pilotis will be in exclusive use for pedestrian

4-2-3 Layout of building

The building for the Project is planned as one of the buildings which compose the building-complex of the Directorate General, so that the components of the complex such as the parking area, green belts, inner road and main gate are required to be shared as much as possible.

The size of the site is limited to a minimum scale to construct the required building, so that it is laid out in the center of the site with necessary clearances around the building for construction works and operation and maintenance activities.

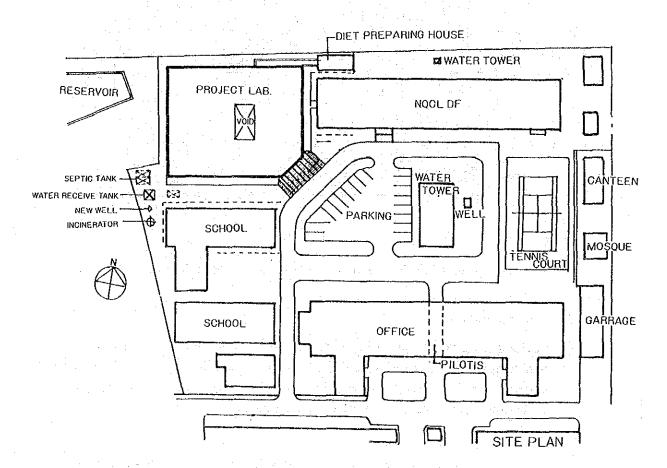


Fig 4-3

4-2-4 Plan of building

(1) Size and structure

The size of the building required for the activities in the laboratory is estimated at a minimum of 4,000 sq.m of total floor area. It is calculated from the results of the study on the details of the plan prepared by the Indonesian side considering the actual condition of quality test technology in Indonesia.

The Committee of the Co

It is desired to design the building in low-rise considering its principal purpose of use and that the existing buildings are of two stories in majority. Comparing the site area of 2,000 sq.m. and the required total floor area of 4,000 sq. m. it is adequate to design a three story building for the Project.

A reinforced concrete structure is considered most adequate for the proposed building from the geological data, the principal purpose of use and the structure of surrounded similar buildings.

In general it is recommended to introduce a slope-roof to building in such a rainy region as Jakarta, but from the necessity of installing air-conditioning and ventilation equipment on the roof the building is designed to be of a flat-roof. It is a matter of course to take care of waterproofing and drain system design.

(2) Composition of facilities

The most characterized features of the building is to breed and hold the experimental animals inside the building as mentioned in 4-2-1. The animal care and test facilities are therefore planned to be concentrated on the ground floor to facilitate the animal care and test.

Laboratory animal feed is prepared by weighing, mixing and pressing such raw materials as wheat and corn in the preparation room. Green feed for rabbits is stored in the storage room. It is difficult to keep these rooms clean as required to the animal care and test facilities, so these rooms are planned to be detached from the main building, but connected with a covered passage.

The building installation rooms for heavy and vibratile machines are also laid out on the ground floor.

On the second floor, biological test laboratories and related rooms are laid out together with common use rooms such as a library, a document room, a conference room and so on.

On the third floor, a training room and rooms for the microbiology division are arranged. The area of the microbiology division is off-limits except to concerned specialists by the door installed in the corridor. At the center part of the building on the second floor a light-court of open well style is planned for the purpose of daylighting and natural ventilation.

(3) Detail of planned rooms

1) Ground floor

a) Animal breeding and holding rooms

To keep required sanitation of the rooms, one way systems are introduced to the flow of men, animals and goods as well as the flow of conditioned air. The following rooms are planned for animal care.

Rabbits & guinea pigs breeding room
Mice breeding room
Rats breeding room
Rabbits holding room
Guinea pigs holding room
Mice holding room x 2
Rats holding room
Washing & sterilizing room
Sterilized cage & diet storage room
Animal care administration room

b) Laboratories

The following rooms are planned for animal using tests
Pharmacology laboratory (in Vivo)
Pyrogen test room
Body temperature measuring room
Animal dissection and treatment room x 2

c) Machine rooms

Power inlet switchboard room
Transformer room
Fire hydrant pump room
Boiler room
Generator room
Water treatment room
Air conditioning machine room
Tools & parts storage room

2) Second floor

a) Pharmacology division

A pharmacology laboratory is planned to be provided for tests of drug effectivity in vitro. A pathology laboratory and a clinical bio-chemistry laboratory are planned to be shared with the toxicology division.

b) Toxicology division

A toxicology laboratory is planned for teratology tests and intensive toxicology tests.

c) Biopharmacy division

Biopharmacy laboratory
Weighing room
Analizing room

d) Reference standard division

Reference standard laboratory Packing room Storage room Weighing room Analizing room

e) Common facilities

Administration office room
Conference room
Library cum meeting room
Air-conditioning machine room
Dressing room

3) Third floor

a) Microbiology division

The microbiology division is planned to be situated on the 3rd floor, offlimits to the general staff considering the spread of dangerous microbes. The following laboratory and rooms are planned to be laid out separated from common facilities by doors installed in the corridor.

Microbiology laboratory x 4
Clean room x 3
Media preparation cum Washing room
Culture collection room
Low temperature laboratory
Analyzing room
Weighing room
Photo-techno room
Staff rest room

b) Common facilities

Reference room
Dark room
Photographing room

Ice & pure water maker room
Lecture & training room
Experts room

(4) Materials

The local materials are planned to be fully utilized except in case which adequate materials are not produced in Indonesia. In this case necessary materials will be imported from Japan.

(5) Principles of structural design

1) General

- a) The building is planned to be of three stories reinforced concrete structure.
- b) The spread foundation is adoptable for the proposed building on the clay layer of 2m under ground level because the bearing capacity of soil is expected over 10t/sq.m from the boring data of the adjacent land.
- c) The building is planned to be of Rahmen rigid frame structure aiming at free layout planning.

2) Design standards and basic materials

The structural members are designed and calculated according to both the "Standards for structural calculation of reinforced concrete structure", Architectural Institute of Japan and the Indonesian related regulations and standards.

As for seismal force it will be calculated using the formula $Ci=Z \cdot PtAiCo$ of the above Japanese standards on the assumption of Z=0.375, because Jakarta is situated in the seismal category 4 and the basic seismal force co-efficient is of C=0.05 in the Indonesian aseismatic structure design standards.

Standards for basic materials of structure will be accorded with the following Indonesian standards

Concrete: K 225 Steel bar: II U32

3) Design load

The live loads for the building are assumed according to the Indonesian load regulations as follows

Laboratory	250 kg/m.sq.	
Office room	ditto	
Library	400 kg/m sq.	
Stair	300 "	
Machine room	soo »	

Mitigation factors of live load for calculation of members and force are shown in the following table.

	Factor for calculation of			
Room	Beam & Rahmen	Seismal force		
Laboratory	0.6	0.3		
Office room	0.6	0,3		
Stair	0.75	0,5		
Library	0,8	0.5		
Machine room	0.8	0.5		

4-2-5 Building installation planning

(1) Air condition and ventilating installations

1) The animal laboratory area

a) The environmental condition for laboratory animals is required to be maintained within the following range for 24 hours to ensure the objectivity of the test result. Air conditioning is planned to be provided in this area.

Dry bulb temperature $24 \pm 2^{\circ}$ C Relative humidity $60 \pm 10\%$

b) The air conditioning system shall be a central air duct system in order to remove animal odor. Waste heat utilizing equipment shall be provided.

Electrical terminal reheater shall be installed.

c) Refrigerating machines shall be provided as the cooling source. Two of each machine, with half the required capacity respectively shall be installed to avoid a full stop during breakdown, replacement and maintenance.

2) The sterility room

The sterility rooms are rooms where room temperature, humidity, degree of

air purity and air movement are controlled. Air conditioning is required to be provided as following conditions.

a) The clean room (1)

The degree of air purity

NASA Class 100

Dry bulb temperature

24 ± 2°C

Relative humidity

60 ± 10%

b) Clean room (2) and (3)

The degree of air purity

NASA Class 10,000 (2)

100,000 (3)

Dry bulb temperature

24 ± 2°C

60 ± 10%

Relative humidity

3) The cooling service for special laboratories

Cooling service for 24 hours is required for the following laboratories to guarantee the normal functioning of the test equipment.

a) Second floor:

Packing and storage room for reference standards, Clinical bio-chemistry laboratory, Analyzing room, Weighing

room

b) Third floor:

Instrument room, Weighing room

4) The low temperature laboratory

The low temperature laboratory shall be air conditioned normally and a cooling unit will be installed in because it is required to keep the freezing chamber temperature at 5°C.

5) The general cooling service

The package type air conditioner shall be installed and the room temperature shall be kept under 28°C.

- 6) Ventilation
 - a) The exhaust air from the animal laboratory

The exhaust air from the animal laboratory shall be discharged at the roof. The animal odor in the exhaust air will be diluted with other air and diffused after being discharged. Therefore, no deodorizer tower shall be provided.

b) The exhaust air from the draft-chamber

The exhaust air from the draft-chamber shall be discharged at the roof. The exhaust air will be diluted with other air and diffused after being discharged. Due to the system configuration, no scrubber tower shall be provided.

REFRIGERATION PLANT

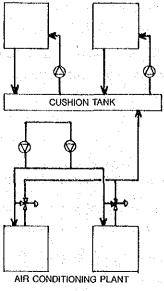


Fig 4-2-5a

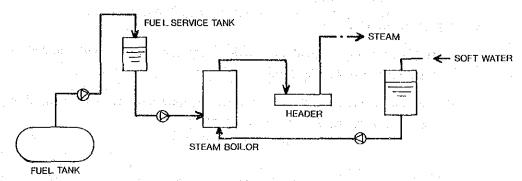


Fig 4-2-5b

DUCTING FLOW DIAGRAM

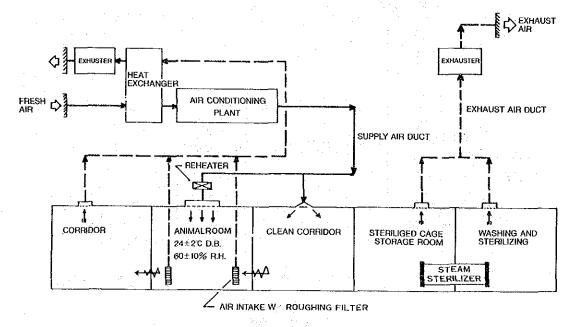


Fig 4-2-5c

c) The required ventilating equipment shall be provided in the following rooms.

Electrical room, Boiler room, Toilets, Shower rooms, Air conditioning machine room for the animals, Kitchenette, Dark room, Storage, and so on.

(2) Plumbing and gas installations

1) Water supply

- a) City water and well water shall be supplied to the receiving tank.
- b) The receiving tank shall consist of a detritus tank and two reserve tanks to be prepared for supply cut-off and cleaning.
- c) Water supply to the building shall be made from the elevated water tank after filtration by a sand filter and sterilization by chlorine to prevent water contamination.

2) Hot water supply

- a) Hot water supply shall be provided for the cage washer installed in the washing and sterilizing room.
- b) Hot water outlets shall be equipped in some laboratories for washing and testing apparatus.

WATER SUPPLY AND DRAINAGE SYSTEM FLOW DIAGRAM

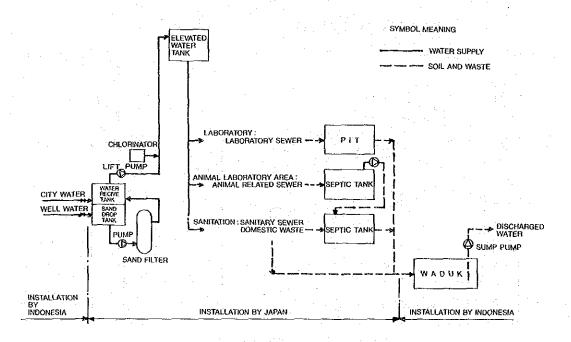


Fig 4-2-5d

3) Waste water drainage

- a) The drainage system shall be separated into the following five flows.
 - i) Domestic waste
 - ii) Sanitary sewer
 - iii) Animal sewer
 - iv) Laboratory sewer
 - v) Rainwater
- b) The sanitary sewer shall be treated in a septic tank.
- c) The animal sewer from the animal facilities shall be treated in another septic tank after removal of solid excrement and fur.
- d) The sewer from the laboratory shall be retained temporarily in the pit located outside and then discharged into the catch basin.
- e) All sewers shall be collected into one catch basin and then discharged through WADUK into the gutter outside the premises.

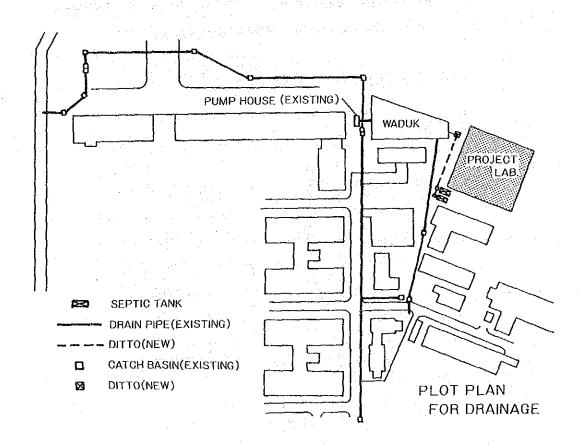


Fig 4-2-5e

4) City gas services

Gas service shall be provided in the laboratories and the kitchenettes.

5) Indoor fire hydrants

Indoor fire hydrants shall be provided at a circle of 25m in diameter according to the code of Indonesia.

6) Fire extinguisher

2 sets of fire extinguisher shall be installed in the corridor of every floor.

(3) Electrical installation

1) Power receiving

Three phase, three line 50Hz power supply of 20 Kv shall be provided and necessary wiring and connecting works to the switchboard shall be implemented by the Indonesian side.

2) Transforming

- a) Two transformers of 250 KVA shall be provided for parallel operation.
- b) Power load is estimated approximately as follows:

ELECTRIC POWER FLOW DIAGRAM

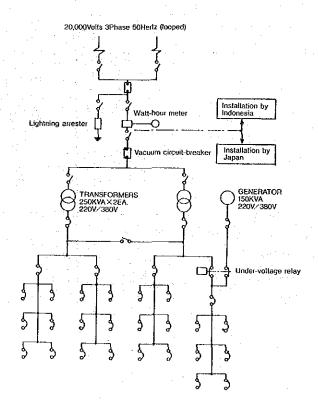


Fig 4-2-5f

Lighting and power outlets
Air conditioning and ventilation
Water supply and drainage
ventilation
Testing apparatus
Others

Total

60 KVA
380 KVA
40 KVA
40 KVA
540 KVA

c) Important testing apparatus that may be affected by voltage fluctuation are to be provided with an automatic voltage adjuster, and this shall be excluded from the building work.

3) Emergency power generator

- a) A power generator shall be provided as a standby power source for the important power requirement.
- b) Loads to be serviced by the power generator are calculated as follows:

Animal laboratory air conditioner 115 KVA
Water pump 5 KVA
Fire pump 10 KVA
Special testing apparatus 10 KVA
Emergency equipment such as emergency lighting 10 KVA
Total 150 KVA

4) Power distribution system

Trunk lines shall be as follows:

For motors

Three phase, 380 V

For lighting

Three phase, four lines, 380/220V

5) Lighting and receptacles

- a) Lighting fixtures shall be generally fluorescent lamps and incadescent lamps shall be used as required.
- b) Illuminance average shall be as follows.

Animal dissection room $400 \sim 500 \text{ Lux}$ Laboratories $200 \sim 300 \text{ Lux}$ Office, library and conference room $100 \sim 200 \text{ Lux}$ Animal care rooms $100 \sim 150 \text{ Lux}$ Corridors, staircase, toilets $50 \sim 100 \text{ Lux}$ Storage rooms, dressing rooms $30 \sim 50 \text{ Lux}$

c) Lighting in the animal room shall be controlled by an automatic on-off device equipped with a timer, and at the same time provided with the manual device operatable by the switch.

- d) Selective switching for the perimeter zone and the interior zone in the working area shall be made possible.
- e) Emergency lighting and exit lights shall be made able to receive power from the generator in case of an emergency.

6) Telephone services

A cross-bar type telephone exchanger for 25 to 30 extensions shall be installed in the administration office room on the second floor.

7) Interphone services

Interphones shall be provided at the following locations as an exclusive communication facility,

a) First floor: Between the washing & sterilizing room and sterilized cage storage room

b) Third floor: Between clean rooms mutually

8) Communication system

- a) A broadcasting system shall be provided for communication within the building.
- b) Microphones and amplifiers shall be installed in the administration office room for convenience of communication.
- c) Speakers shall be installed on the ceiling of corridors at intervals of 20 m in principle.

9) Automatic fire alarm system

- a) An automatic fire alarm system shall be installed according to the Indonesian standards.
- b) The control panel shall be installed in the office room.
- c) Water proof fixed temperature detectors shall be provided in the animal rooms where the chemical spraying for disinfection is conducted, and in the washing sterilizing room where the temperature and the humidity is high.

10) Lightning arrester

An arresting spit shall be installed at the highest part of the penthouse and a set of grounding wire shall be laid around on the parapet of the building.

4-2-6 Plan of equipment

The equipment to be mentioned in this paragraph is neither building equipment nor equipment available for various tests in the proposed facilities which will be provided under the technical cooperation program. The equipment to be covered by grant aid includes the equipment related with animal care and tests, pyrogen test equipment and draft-chambers. The required equipment listed below shall be imported from Japan. Specification and quantity are decided considering details of the technical cooperation.

(1) Animal care equipment

Auto cage washers

Steam sterilizers

Incinerator for animal sewage

Animal cages

Cage stands

Animal cage carriers

Working tables

Balances for animal

Steel boxes for tip sterilization

Sterilizers for animal room

Stands for hand sterilization

Carcass freezer

(2) Feed preparation equipment

Crushers

Mixers

Pellet mills

Dryers

Balances

Cutters

Stands

Hardness tester

Moisture meter

Trolley

(3) Pyrogen test equipment

Digital data logger (auto voltage stabilizer)

Thermister sensors

Rabbit holding boxes and stands

Balance for rabbit (auto voltage stabilizer)

Electric sterilizer

Ultrasonic glassware cleaner

Steel shelves

Syringe container

Syringe sterilizing box Climate recorder Small water purifier

(4) Miscellaneous

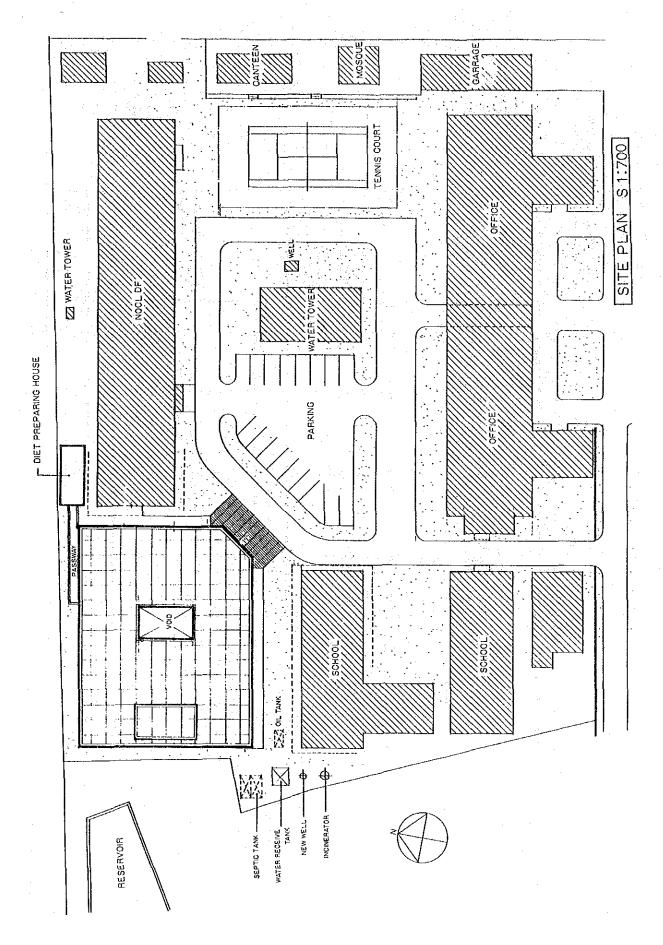
Draft-chambers

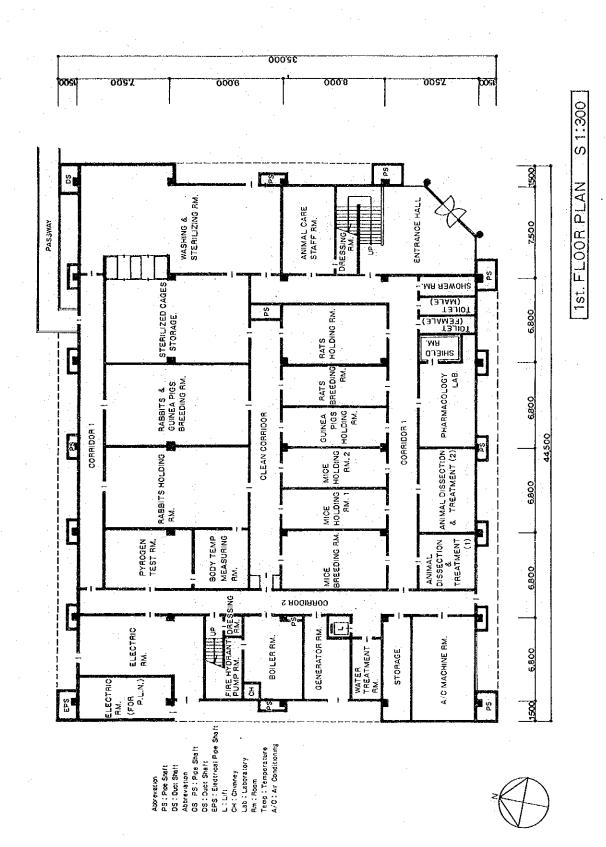
Large water purifier

Ice maker

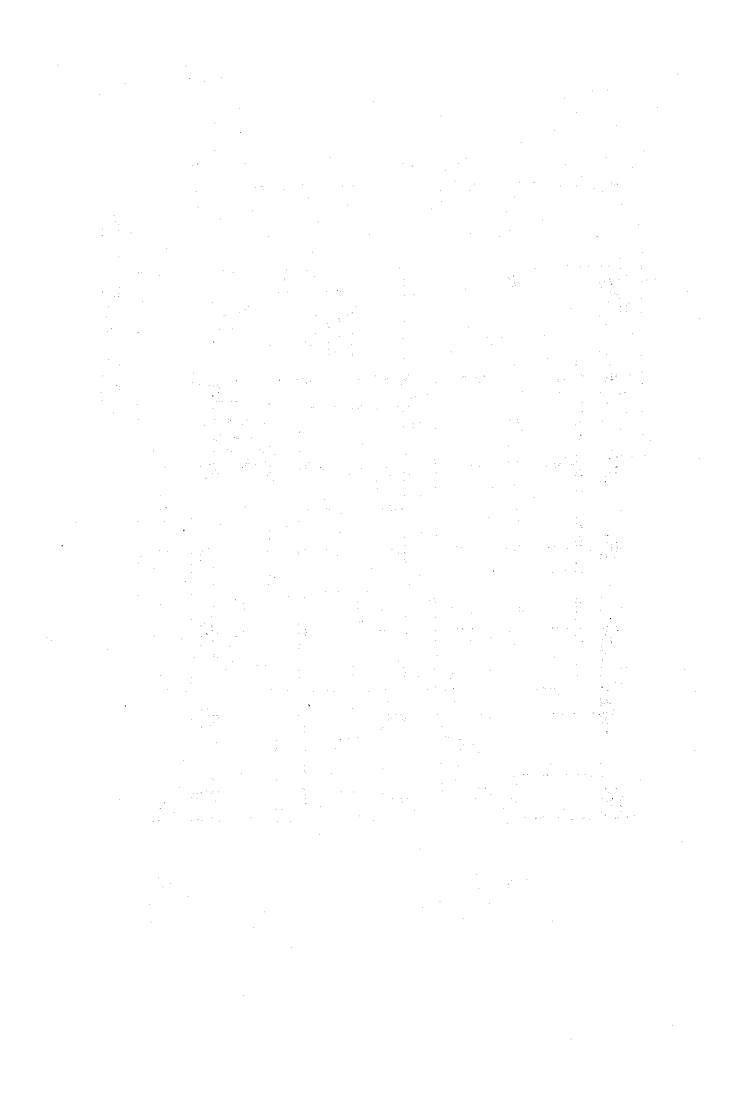
SITE PLAN 1ST. FLOOR PLAN 2nd. FLOOR PLAN 3rd. FLOOR PLAN ROOF FLOOR PLAN SOUTH & EAST ELEVATION NORTH & WEST ELEVATION

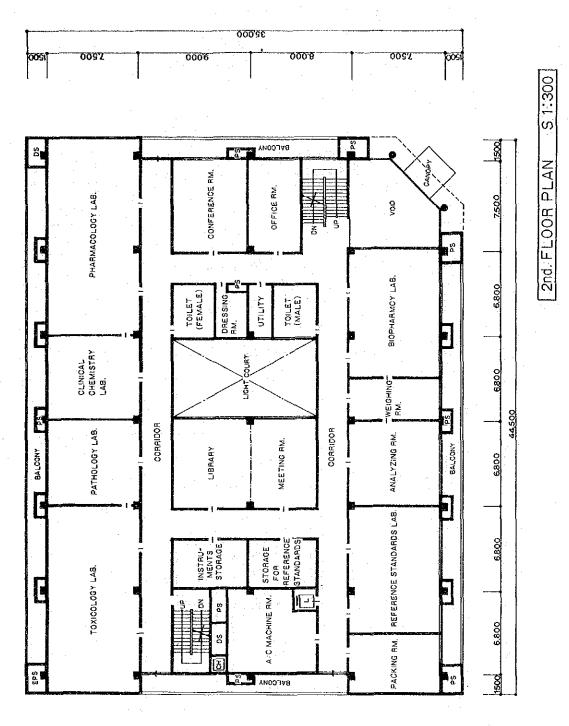
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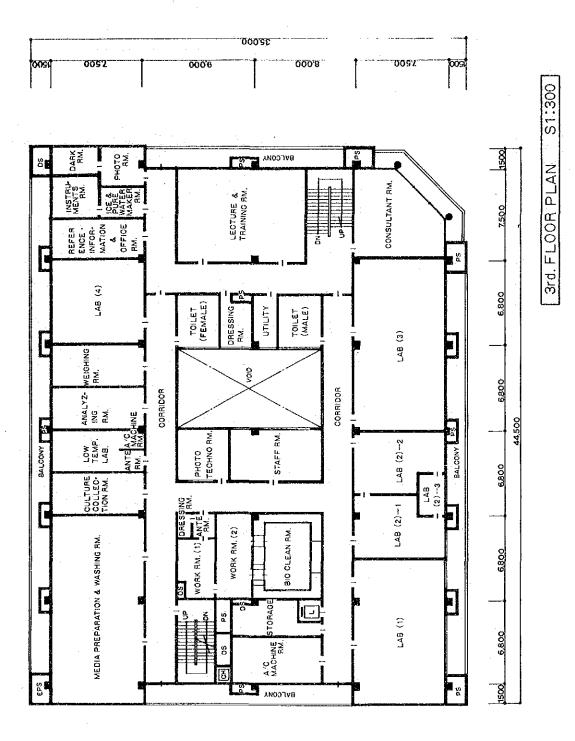


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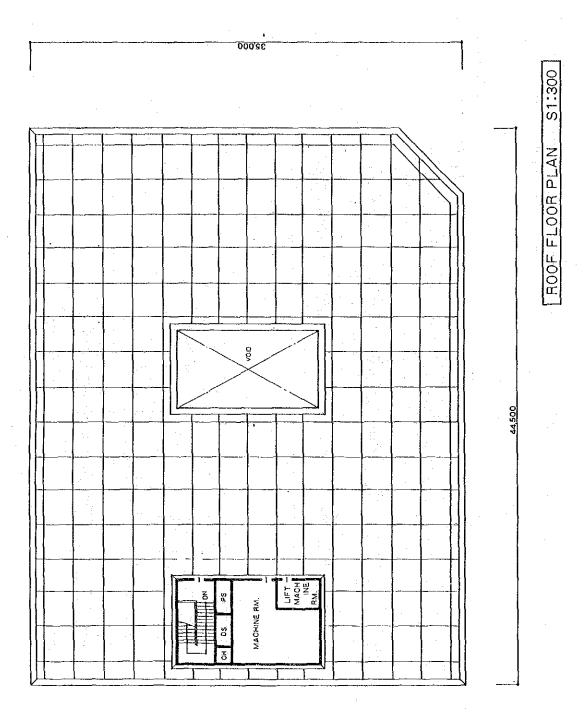




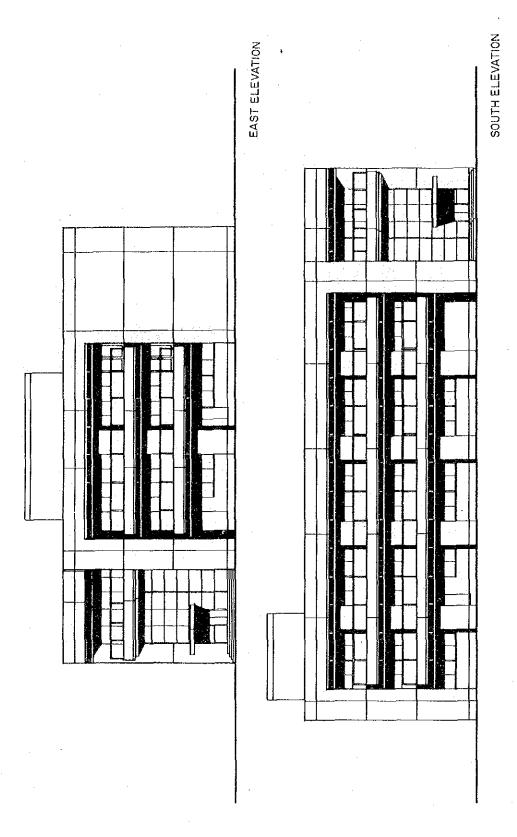




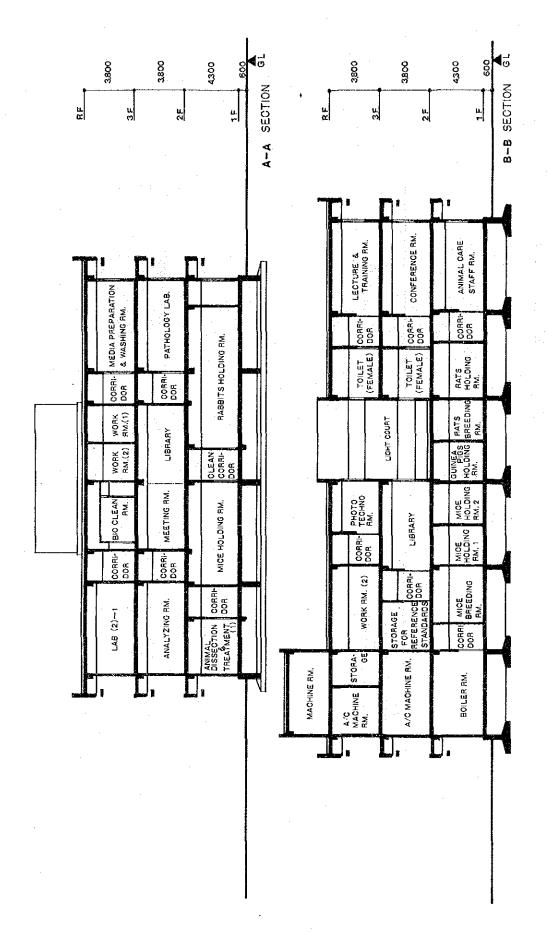


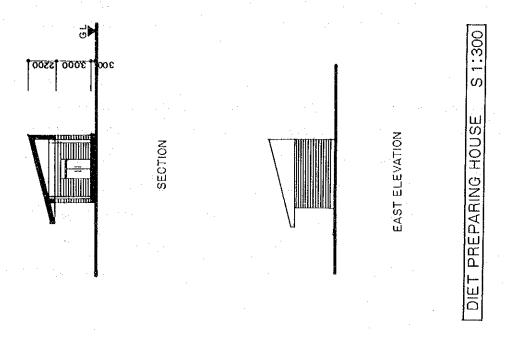


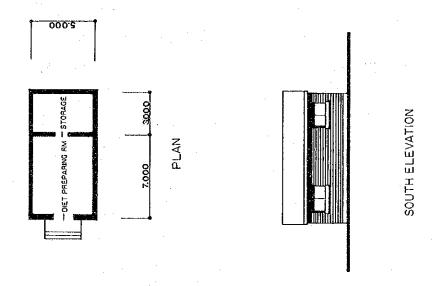




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4-3 Construction Cost

4-3-1 Japanese portion

The construction cost including that of necessary equipment shall be covered by the grant in accordance with the scope of work to be mentioned in section 5-3.

4-3-2 Indonesian portion

The construction costs of the works to be conducted by the Indonesian Government according to the scope of work are estimated as follows.

(1) Welling work

Rp. 30,000,000

(Including pumps and tax.)

(2) Water supply work

Rp. 15,000,000

(50mm pipe, 200M, including beneficiary charge)

(3) City gas work

Rp. 15,000,000

(ditto)

(4) Electrical work

Rp. 132,000,000

(Beneficiary charge for 500 KVA, materials for underground burial cable of 220 m)

(5) Drainage work

Rp. 3,000,000

(Remodeling work of existing drain of 200 m and drainage pumps)

(6) Telephone work

Rp. 5,100,000

(100 m cable, stainless steel pipe 42 mm, 3 handholes)

(7) Demolition and Removal

Rp. 3,650,000

- 1) Brick house of 160 sq.m
- 2)

48 "

3)

12 "

- 4) Wooden house of 80 sq.m
- (8) Road remodeling

Rp. 6,300,000

(Repavement of 700 sq.m)

(9) Removal of Tennis court

Rp. 5,500,000

(Lighting poles and lamps, fences)

(10) Funitures

Rp. 32,000,000

TOTAL

Rp. 247,550,000

CHAPTER 5 PROJECT EXECUTION PROCEDURE

5-1 Implementing Organization

The Project shall be implemented by the Government of Indonesia. The expected objectives of the Project will be realized by both the smooth promotion of construction works and the adequate operation and maintenance of the facilities. For this purpose it is necessary for promoting the grant aid procedure smoothly to confirm in advance the responsible organization both for the construction term and for the operation term after completion of the facilities.

At the meeting for explanation of the draft final report of the Project, held on July 1983 between the Indonesian concerned officials and the study team, both parties reconfirmed that the responsible staff members for the Project are nominated as follows:

- (1) The highest executive is Dr. Midian SIRAIT, Director General of Drug and Food Control
- (2) The project director is Dr. Charles SIREGAR, Director of NQCL DF
- (3) The staff of the technical department of the Ministry of Health will be responsible on the following technical matters such as check of the drawings, legal procedure, supervision of the construction works and execution of the works to be covered by the local fund.

5-2 Construction Planning

The project site is surrounded by existing buildings as mentioned earlier. And the area is not enough for construction works. The construction planning should therefore be prepared in careful consideration of the influences of works on the surrounding area.

The outlines of the consideration are given below.

- (1) To provide a new passage for construction works between the school located on the southern side and the administration building to secure safety of the complex.
- (2) To use the clearance of 3 m wide kept around the building as much as possible as a passage and/or a working space.
- (3) The foundation shall be without piling so as to minimize vibration and noise as much as possible.
- (4) The parking area in the courtyard shall be utilized as a place for keeping the construction materials and equipment.
- (5) Consideration shall be given fully to the students of the school. Arrangements for working schedule shall be made not so as to disturb the class as much as possible in addition to taking necessary measures for safety of construction works.

It will take approximately two months for concrete placing work for one story area of 1,300 sq.m. and it will take six months and a half altogether for three stories including works for the penthouse. Considering excavation and foundation works to be executed during the rainy season, 15 months shall be estimated as the least term for construction work.

5-3 Scope of Work

The scopes of work to be covered by the Japanese grant and to be executed on the responsibility of the Government of Indonesia are shown below.

5-3-1 Scope of work to be covered by the grant

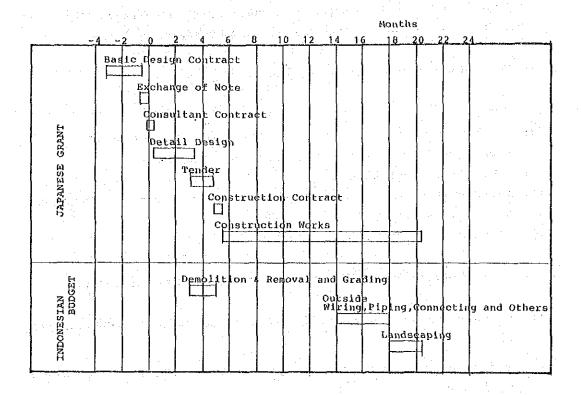
- (1) Building
- (2) Electrical installation
- (3) Plumbing installation including septic tanks and Gas installation
- (4) Air-conditioning installation
- (5) Experimental equipment to be fixed to the structure such as draft-chambers and examination tables
- (6) Equipment regarding animal care facilities

5-3-2 Scope of work to be executed at the expense of the Government of Indonesia

- (1) Removing obstructions and finish grading of the site before commencement of the Work,
- (2) Wiring work for power supply and connecting work to the inlet switchboard in the building.
- (3) Welling and piping work for water supply up to the receiving water tank to be covered by the grant.
- (4) Piping and connecting works for city gas supply to the main pipe of the building.
- (5) Wiring and connecting works for telephone services to the terminal in the building.
- (6) Drain piping work to the Waduk from the catch basin included to the scope of work to be covered by the grant and remodeling work of drainage installations after Waduk.
- (7) Repairing and remodeling works for inner roads and parking areas
- (8) Landscaping and gardening
- (9) Fencing and external lighting
- (10) General furnishings (carpets, chairs, tables, etc.)

5-4 Working Schedule

The schedule laid out below is proposed for execution of the Project according to the procedures of the Japanese grant aid. The works to be performed under the direct responsibility of the Government of Indonesia as mentioned in 5-3-2, shall be carried out also according to this schedule.



5-5 Operation and Maintenance of the Facilities

 $(x_1,x_2) \in \{x_1,x_2,\dots,x_n\} \times \{x_1,x_2,\dots,x_n\}$

After completion of the building, the operation and maintenance of the facilities will be conducted by the Government of Indonesia. The outline of the operation and maintenance is considered as follows.

5-5-1 Maintenance of the building and installations

(1) Building

Maintenance of the building is mainly daily cleaning and repair of worn and deteriorated parts. Especially, remodelling and repairing of the interior finish and facing will be the main work. For maintenance, it is recommended first to use the building with care and to clean it frequently and second to repair simple damage at the time of its occurance. Maintenance staff is required to be manned for that purpose.

(2) Building installations

The machinery for the building installation is selected on the basis of the safety, reliability and popularity. However, it is still important to carry out daily inspection and maintenance. Technicians with professional knowledge on electrical, mechanical and sanitary installations are required to engage in daily operation, inspection and repair of the building.

It is a matter of course that equipment used over its own life for use should be changed or overhauled. Average lives of main machines are given below for reference.

Boiler	15 years
Refrigerating machine	10 years
Cooling tower	10 years
Pump	15 years
Fan	15 years
Air-conditioner	10 years
Generator	15 years
Fluorescent lamp ballast	7 ∼ 8 years
Lift	20 years

5-5-2 Staff planning

In order to make the proposed facilities fulfill their function satisfactorily, it is indispensable to secure the professional staff for operation and maintenance of the building and installations as well as the staff of laboratories and for administration. However the professional staff is not always required to be in full service for the proposed facilities. They shall be secured for all the facilities of Directorate General.

(1) Administration Staff

10 pers,

(2) Laboratory Staff

Division	Researcher	Assist. Researcher	Sub-total	
Microbiology	10	15	25	
Reference Standards	3	5	8	
Biopharmacy	4	6	10	
Pharmacology & Toxicology	14	13	27	
Animal Care	4	16	20	
Total	35	55	90	

(3) Staff for operation and maintenance

Electrician	1	Assistant	1
Refrigerator Engineer	1	33	1
Boiler Engineer	1	**	1
Building Maintenance Engineer	1	"	2 · · · · · · · · · · · · · · · · · · ·
Total	4	,,	5

5-5-3 Operation, maintenance and management cost

The annual O-M-M cost is estimated based on the prices in March 1983 as follows. The actual O-M-M cost shall be therefore adjusted taking into consideration the price escalation.

(1) Operation cost

The operation cost includes the water and energy rates as shown below:

Total			Rp.	70,600,000	}
Water rate			Rp.	1,900,000)
City gas rate	* .		Rp.	1,600,000) 1
Power rate		27.5	Rp.	60,000,000)
Fuel			Rp.	7,100,000)

(2) Maintenance cost

The maintenance cost includes the expendable parts of mechanical installations, the cost of repairs of building and installations and personnel expenses of O-M staff.

Expendable parts	Rp.	2,000,000
Air filters	Rp.	2,900,000
Cost of repairs	Rp.	3,700,000
Total	Rp.	8,600,000

(3) Management cost

The management cost is calculated as follows:

Personnel expenditure	Rp. 138,600,000		
Testing expenses	Rp. 168,000,000		
Animal care expenses	Rp. 19,600,000		
Test equipment	Rp. 14,000,000		
Administration expenses	Rp. 9,800,000		
Total	Rp. 350,000,000		

(4) Grand total

$$(1) + (2) + (3) =$$
 Rp. 429,200,000

5-6 Procurement of Material

5-6-1 Procurement of main construction material

Procurement of construction materials selected considering the following factors are planned as shown in the table below: the mentioned factors are construction technology, quality and price of material, purpose of use, limit of construction terms and others

	Indonesian Material	Japanese Material
Building Works	Scaffold, Sand, Gravel, Cement, Steel bar, From, Steel-frame, Brick, Concrete brick, Paint, Terrazo, Tile, Marble, Wood, Plywood, Spraying, Asbestos board, Vinyl wall covering, Glass, Rock wool sound absorbent board, Heat insulation material Wooden door and window, Light partition, Built-in furniture	Waterproofing material, Steel door, Aluminum door & window, Finish hardware, Metal work material, Cast iron material (roofdrain, etc.)
Electric Installation	Lamps, Switch, Receptacle, Wire & Cable, Distribution board, Vinyl conduit pipe	Steel conduit pipe, Telephone equipment, Loud speaker, Ampli- fier, Lighting fixture, Generator Fire alarm system, Lift, Control switch board,
Air-conditioning installation	Ventilating fan	Refrigerator, Boiler, Cooling tower, Pump, Steel pipe, Packaged air-conditioner, Air handling unit, Automatic control system Duct material, Fan, Valve, Air filter, Air outlet & inlet louver
Plumbing installation	Sanitary fixture, Hume concrete pipe, Vinyl pipe (below 100mm DIA)	Reservoir tank, Fire hydrant box, Pump, Steel pipe, Sewage treat- ment system, Water treatment system, Incenerator, Floor drain Valve, Plumb pipe, Copper pipe, Experimental sink

5-6-2 Procurement labour

It should be taken into full consideration that procurement of the necessary labor power is not easy because labor supply is short as mentioned in paragraph 3-4-1. The labor capability is relatively low in comparison with that of Japan and it should be supplemented by increasing the quantity. However, in some category of work, laborers should be secured not by quantity but by skill as a matter of course.

CHAPTER 6 PROJECT ASSESSMENT

A development project is evaluated in general from economic and social view points by mean of economic analysis method comparing the benefit to be brought with the cost to be invested. As of this project, its principal aim is the promotion of the health of the people and it is difficult to state the benefit in figures and also inadequate to evaluate its appropriateness from economic point of view. Accordingly, the Project will be assessed and examined on its feasibility, after clarifying the necessity of the Project and the effect to be brought by the proposed facilities, comparing them with the details of the planning studied for execution of the Project.

It is a matter of course that safety and effectivity of drugs should be fully guaranteed. But the quality of drugs is not adequately controlled by the Government in Indonesia, because any of the facilities in which comprehensive quality test for drugs can be conducted is not yet established and the number of staff concerned is not sufficiently secured. This is a problem to be urgently solved for the health of the people,

Investigation of the actual situation of quality control of drugs both in factories and in distribution process made clear that the examination of safety and effectivity of drugs and confirmation of the ingredients were not satisfactorily conducted due to the lack of both the unified quality standards and the test methods.

Under the circumstances, extension of the existing facilities of the NQCL DF, that is to introduce new functions of biological tests and training of technical staff in addition to the actual functions of chemical and physico-chemical tests, is required at a minimum for establishing a quality control system for drugs in Indonesia.

After confirming the details of the request and analizing the collected data during the field survey, the study team prepared a plan of construction for a reinforced concrete building of 3 stories and approx. 4,000 sq.m for total floor area consisting of laboratory animal facilities, laboratories for each division of pharmacology, toxicology, microbiology and biopharmacy, reference standards rooms, sterility rooms, staff training room and other rooms.

Completion of the facilities having minimum functions required for performing the above-mentioned aim is the first step and the key as well to establish a quality control system, and it will realize the following effects:

- (1) The biological tests consisting of animal tests and microbiological tests will be available for quality control tests.
- (2) Using reference standards to be produced in the proposed facilities, comparative tests for drugs will be introduced to chemical, physico-chemical and biological test.

(3) The quality standards of drugs will be general in all the laboratories through developing unified test methods and training them to the technical staff of the PQCL DF.

The facilities are composed of such specialized rooms in function as sterility rooms, animal breeding and holding rooms and other air-conditioned laboratories, so that the operation and maintenance cost such as personnel expenditure, running cost of building equipment and repairing expenditure are, therefore, estimated considerably high in comparison with other ordinary buildings, and it can be easily forecasted that management and operation of the facilities would be rather difficult.

However, if the Indonesian Government manages and operates relevantly the facilities with necessary budget, the matters above-mentioned in three items will be performed and as a result, quality of drugs will be well controlled.

After all, penetration of medical care for the people will be realized through improvement of quality and stable provision of drugs and finally the health of the people will be promoted.

The proposed building is designed to be functionally equipped with the necessary and sufficient rooms, facilities and equipment, however it is designed so as to reduce the construction cost sharing the parking area, green belt, main gate and so on with the existing facilities, and adopting local materials and skills as many as possible. At the same time the design makes the operation and maintenance cost to be cheaper by means of positive adoption of daylighting and natural ventilation system together with that of local materials.

From due consideration as mentioned above, it is finally judged that the planned facilities are at least necessary for conducting the quality control tests in Indonesia and the effects of the Project are highly expected. Moreover, the Indonesian burden for management, operation and maintenance of the facilities is not too large but appropriate comparing with the effects.