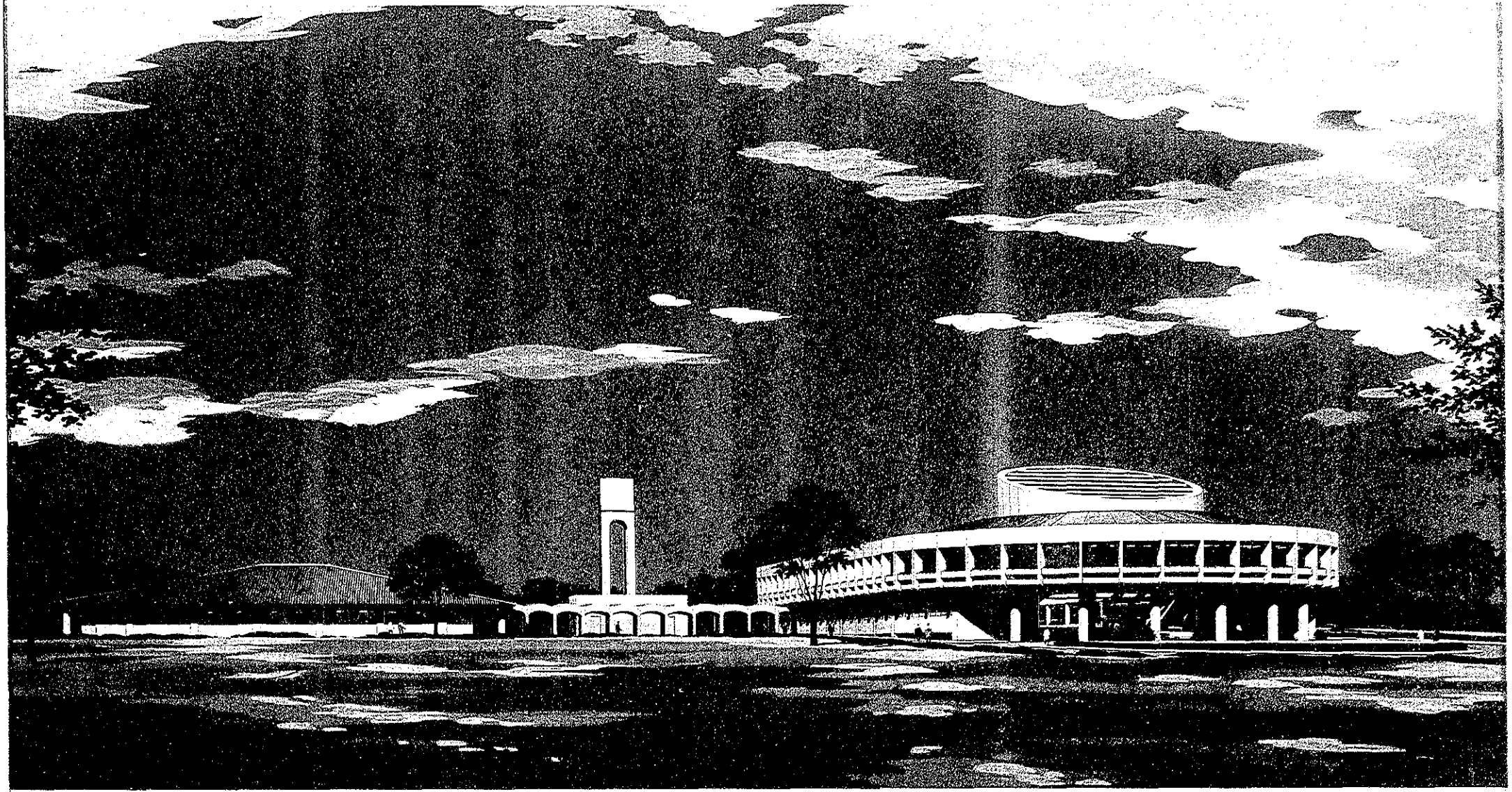
NO. 4

BASIC DESIGN STUDY REPORT
ON
THE ESTABLISHMENT PROJECT FOR
FOOD AND DRUGS LABORATORIES
IN
THE REPUBLIC OF THE PHILIPPINES

OCTOBER, 1985

JAPAN INTERNATIONAL COOPERATION AGENCY



PREFACE

In response to the request of the Government of the Republic of the Philippines, the Government of Japan decided to conduct a Basic Design Study on the Establishment Project of the Food and Drugs Laboratories and entrusted the study to the Japan International Cooperation Agency (JICA).

JICA sent to the Philippines study team headed by Dr. Shigeo IWAHARA, Director of Food and Environmental Division, Hatano Research Institute, Food and Drug Safety Center, from June 10 to June 28, 1985.

The team had a series of discussions on the Project with the officials concerned of the Government of the Philippines and conducted a field survey in Alabang Area, Muntinglupa City, Metro Manila.

After the team returned to Japan, further studies were made and the present Report has been prepared.

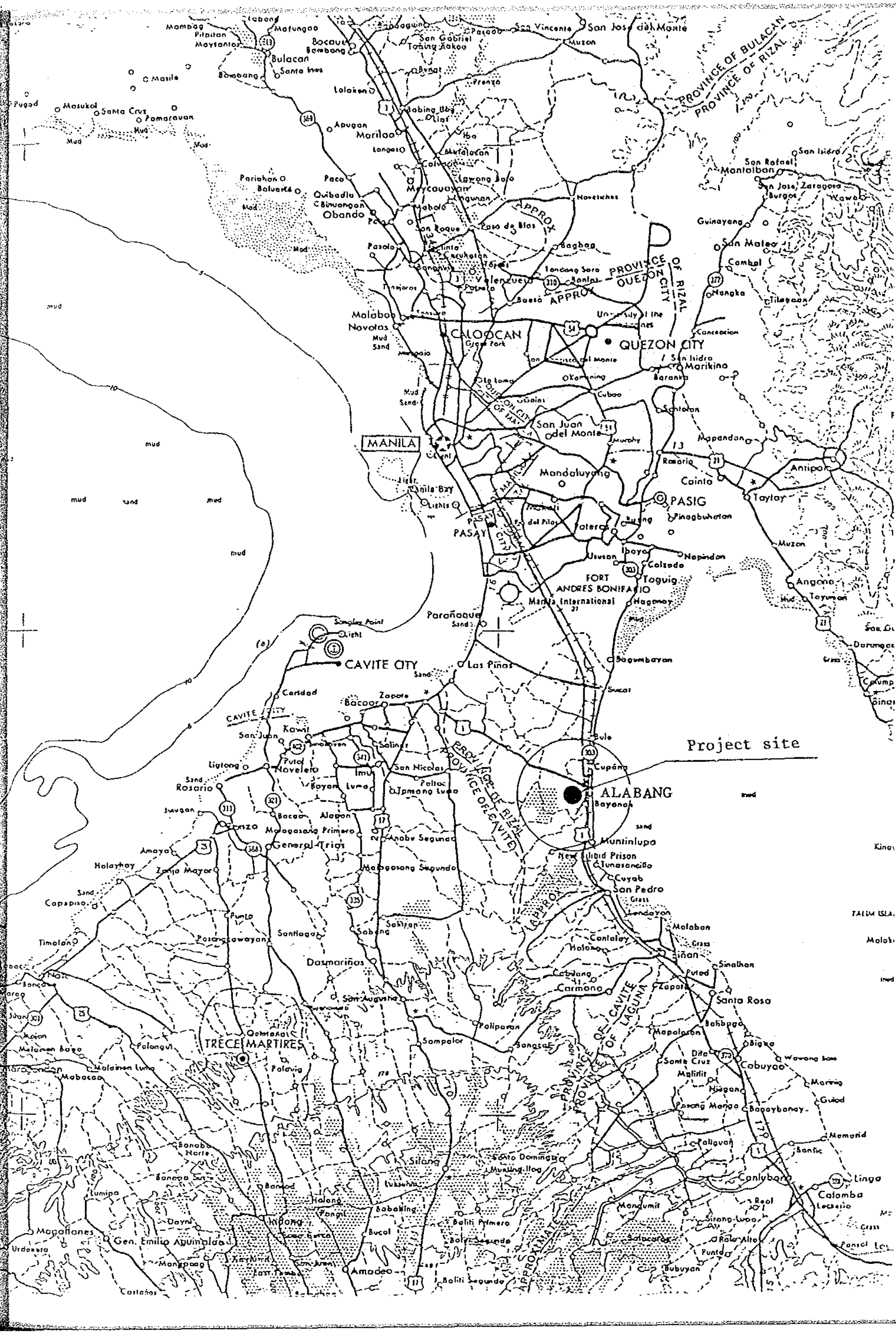
I hope that this Report will serve for the development of the Project and contribute to the promotion of friendly relations between our two countries.

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

October, 1985

Keisuke Arita

Keisuke ARITA
President
Japan International Cooperation Agency



Project site
ALABANG
MANILA
QUEZON CITY
CALOOCAN
PASAY
PASIG
CAVITE CITY
TRECE MARTIRES
FORT ANDRES BONIFACIO
Manila International
PROVINCE OF BULACAN
PROVINCE OF RIZAL
PROVINCE OF RIZAL
PROVINCE OF CAVITE
PROVINCE OF CAVITE
PROVINCE OF LAGUNA
San Jose del Monte
Bulacan
Bocaue
Marilao
Meycauayan
Obando
Malabon
Navotas
Valenzuela
Montalban
San Mateo
Marikina
San Juan del Monte
Mandaluyong
Cainta
Taylay
Antipolo
Angono
Taguig
Parañaque
Las Piñas
Bacoor
Kawit
Noveleta
Rosario
General Trias
Imus
Dasmariñas
Muntinlupa
New Bilibid Prison
San Pedro
Biñan
Carmona
Santa Rosa
Cabuyao
Silang
Amadeo
Naic
Gen. Emilio Aguinaldo
Magallanes
Canlubang
Calamba

SUMMARY

The Government of The Philippines has an important policy for checking the safety, and maintaining the quality of foodstuffs and pharmaceuticals that have a strong relationship to the health of the people of the nation. As outlined in the Updated National Health Plan (for the years 1984 - 1987), the fundamental policy of the Ministry of Health deals with the establishment of the examination and inspection and other facilities necessary for the monitoring, inspection and registration of manufacturing facilities, and also for the registration of pharmaceuticals. This is being done as part of the fundamental strategy to maintain the quality and safety of pharmaceuticals and foodstuffs.

The present state of quality control of pharmaceuticals and foodstuffs cannot be said to be favorable. For examples, in 1984 the Ministry of Health's Bureau of Food and Drugs (BFAD) carried out inspections of some 64,000 factory-processed foods, and instances of solar bacteria, improper additives and rust and other container faults were detected in more than 400 cases.

At the present stage, domestic production alone is not sufficient to manufacture the types and quantities of medicines necessary to maintain the health of the nation's people and some imports must be relied upon to fill the gap. Because of the economic dipression and the ensuing foreign exchange situation in recent years, the Government of the Philippines is encouraging the production and usage of traditional medicines. However, the safety and quality testing for these traditional medicines consists only of tests for accute toxicity at the present stage and testing for chronic toxicity and microanalysis has not been performed.

In order to improve the situation, the Government of the Philippines has been carrying out various policies relating to the safety of pharmaceuticals and foodstuffs. In particular, Presidential Decree No. 851 of December, 1982 ordered the Bureau of Food and Drugs of the Ministry of Health to perform inspection, evaluation and registration of the facilities related to the production and sales of pharmaceuticals and foodstuffs, and also to perform the examinations and tests necessary for the registration of pharmaceuticals. However, the insufficiency of laboratory facilities and

the testing technology due to the lack of facilities, are causing the insufficient responce at the administrative level.

In order to solve the situation and to implement the Updated National Health Plan, the Government of The Philippines proposed the establishment of the Food and Drugs Laboratories and has requested that the Government of Japan to provide grant-in-aid cooperation for its realization.

The Government of Japan received the request from the Government of The Philippines and decided to conduct a basic design study of the Project, and entrusted the study to the Japan International Cooperation Agency (JICA). In January 1985, JICA dispatched the Preliminary Study Team to the Philippines in order to study the feasibility and the scope of the grant-in-aid cooperation. After this, the Basic Design Study Team was dispatched to the Philippines from June 10th to June 28th in order to confirm the contents of the request in detail and to conduct the necessary study for the Basic Design.

After their return to Japan, the Basic Design Study Team studied the materials it had collected in The Philippines and consulted with the authorities concerned to determine the feasibility of the project in the scale and grade. And also examined the proposed operation and management systems. Based on these studies, the necessary facilities and equipment were determined as described in this Report.

The purpose of this plan is to improve BFAD Laboratories in quality and quantity and to make it the core experimental and research facility relating to pharmaceuticals and foodstuffs in The Philippines.

The facility is to be composed of 1) Microbiology section, 2) physico-chemical analysis section, 3) Toxicology section, 4) Animals breeding section, 5) Common equipment section, 6) Inspection & Evaluation section, and 7) Administrative section. A careful study was on the Toxicology section and for the Animal Breeding section, since the BFAD at present has neither of these facilities. In addition, the basic design of the facility paid careful consideration to its size for efficient operation and management.

The following is the outline of the project.

Implementing body:	Bureau of Food and Drugs, Ministry of Health
Construction site:	Within the compound owned by the Ministry of Health, in Alabang, Muntinlupa City, Metro Manila.

Facility outline: Main building: 4,475.0 m^2, 2-storey, reinforced concrete
Animal house: 1,160.0 m^2, 1-storey, reinforced concrete
Energy building: 120.0 m^2, 1-storey, reinforced concrete
Storehouse: 10.0 m^2, 1-storey, reinforced concrete
Waste water treatment plant: 15.0 m^2, 1-storey, reinforced concrete
TOTAL: 5,780.0 m^2

Equipment: Necessary equipment realating to microbiology, physicochemical analysis, toxicology inspection and evaluation.

It is estimated that the facilities to be constructed by the Philippines Government will cost one million pesos. The construction period for the whole project will be 14 months.

This project is intended to reinforce the functions of the BFAD in line with the health policies of the Government of The Philippines which is planning a drastic improvement in the maintenance of the quality, and checking of the safety of pharmaceuticals and foodstuffs. Accordingly, the implementation of this project will prove beneficial in raising the level of safety of pharmaceuticals and foodstuffs in The Philippines, confirm the effectiveness of pharmaceuticals, and will also raise the level of reliance of the contents indications of pharmaceuticals and foodstuffs. Therefore, the project is expected to make a great contribution to increase the level of health of the people of The Philippines.

Furthermore, the organic linking of this core facility with regional health offices will enable it to contribute to raising the level of health and hygiene across the entire country.

Moreover, the Government of The Philippines has also made a request for project-type technical cooperation and so the more efficient functioning of the entire facility can be expected if the training for counterparts and dispatch of exparts were realized for cooperation in the running of the facility and also for the and inspection and evaluation technology.

CONTENTS

CHAPTER 1 INTRODUCTION

In order to improve the level of food hygiene and to maintain the quality and safety of pharmaceuticals, the Government of The Philippines invoked Presidential Decree No. 851 in December, 1982 to regulate the manufacture, sales and distribution of foodstuffs and pharmaceuticals. This decree determined that the Bureau of Food and Drugs (BFAD) of the Ministry of Health, perform the laboratory tests necessary to inspect, evaluate and register establishments of the manufacture and sales of foodstuffs and pharmaceuticals and also to register products.

The present state of the BFAD is such that both the building and the facilities are deteriorated and that it is rather difficult to acquire new laboratory equipments because of the foreign exchange situation. Aside from this, the volume of inspection work is increasing yearly and the types of inspections are also becoming more complex. In a situation like this, the Government of the Philippines planned the establishment of Food and Drugs Laboratories and requested that the Government of Japan provide grant-in-aid cooperation for their construction.

Upon receipt of this request, the Japan International Cooperation Agency (JICA) dispatched Preliminary Survey Team to the Philippines in February of this year. This group held meetings with the authorities concerned of the Government of the Philippines, inspected the essential facilities and collected the necessary informations, which were carefully analyzed after their return to Japan. A careful study of the appropriateness of the project for the grant-in-aid cooperation was made along with a study on the scope of the cooperation.

After these studies the Basic Design Study Team headed by Dr. Shigeo Iwahara (Director of Food & Environmental Division, the Hatano Research Institute, the Food and Drug Safety Center) was dispatched to the Philippines from June 10 to June 28, 1985 in order to confirm the results of the Preliminary Survey and to confirm the content of the project in detail.

After their return to Japan, the Basic Design Study Team compiled a report containing an analysis and investigation of the materials and information that the group had collected in the course of discussions with their counterparts, and from the site surveys.

At the end of this report, along with the List of Members of the Study Team and their study schedule, the Minutes of Discussion and other materials are attached.

CHAPTER 2 BACKGROUND TO THE PROJECT

1. The Importance of Food Hygiene and Pharmaceutical Quality Control in the National Health Plan

The Philippine Ministry of Health formulated the Updated National Health Plan for 1984-87 to promote the safty and health of the people. Under this plan, it was expected that the increase of 2.4 percent a year in the population which stood at 48.3 million as of 1980 would drop to 2.1 percent and that the average life expectancy would rise from 61.6 years to 64.6 years in 1987.

As regards the age-structure of the population, it was projected that the percentage of people, 15 years old and below would decline from 40 percent in 1980 to 35 percent in 1987 and that of 50-years and above would slightly rise from 10.3 percent in 1980 to 12 percent in 1987. As a whole, there are signs of a rise in age, but compared with Japan (where 15-year-olds and below are 23 percent and 50-year-olds and above are 23.8 percent in 1980), it can be said that the Philippines shows an extremely young age composition. In order to reduce the disease prevalence and the mortality per 1,000 population from 8.3 persons to 7.2 persons in 1987, it is an urgent task to reduce the infant mortality, which is 10 times as high as in Japan, and improve the health of the younger generation. The principal diseases which are responsible for this high incident rate of mortality are; mainly those of the respiratory system, such as tuberculosis, pneumonia and bronchitis, and of the digestive system, such as gastritis and colonitis, and contagious diseases, such as malaria, filariasis and schistosomiasis. For the extermination of these diseases, it is an urgent task to diffuse city water systems and hygienic lavatories.

The Updated National Health Plan calls for the deployment of primary health care facilities and personnel, which will constitute basics for community medicine and health care. In order to eliminate negative factors for the health and welfare of the people, it is also urged that all related institutions of the government should cooperate with one another in giving full support to their functions.

For the promotion of the people's health, there would be a need, directly, to expand medical care facilities and, indirectly, to develop a hygienic living environment. The Bureau of Food and Drugs, the main entity

to grant-in-aid cooperation, is an integral part of the Ministry of Health and assumes the responsibility for the safety of food and drugs.

2. The Role of the BFAD in Food and Drug Administration

Under the Food, Drug and Cosmetic Act (Republic Act No. 3720), the Food and Drug Administration was established in 1963 to take charge of food, drugs and cosmetics. In conjunction with the changes brought in the people's living mode by an increase in population, the organization was expanded to take charge of the Household Hazardous Substance Decree (Presidential Decree No. 881), part of the Pharmacy Act (Republic Act No.5921), and the Simplification of Export Procedures Decree (Presidential Decree No. 930) and other acts, and the BFAD came into existence under the Presidential Decree No. 851 dated December 2, 1982. This institution is now staffed by nearly 300 persons, including pharmacists, chemists, nutritionists, medical care technicians and the like.

What BFAD aims at is to assure the safety of food and drugs including traditional medicine household items, medical supplies, cosmetics and hazardous items, and supervise their production, sales and distribution in order to protect the people's health. To achieve this purpose, the aforementioned plan incorporates the following action guidelines.

1) Establishment of criteria for uniformity, purity and quantity
2) Inspect and evaluate establishments and make them to register
3) Random sampling and laboratory tests of their products
4) Screening and registration of products
5) Determination and collection of fees for inspection of establishments and analytical testing of products.
6) Testing prior to and after registration of products
7) Establishment of a system of surveillance on side effects of drugs
8) Establishment of an effective system to prevent false indications and impurities in the marketed products.
9) Collection of statistical data from related industries
10) Enactment of ordinances and regulations against extravagant advertisements
11) Personnel training
12) Establishment of standards for labels of household items, including hazardous items
13) Inspection evaluation and registration of the producers and wholesalers of the above household products

3. Situation of Related Institutions

(1) Inspection and Research Institutes Related to Food Hygiene and Pharmaceutical Quality Control

Other than the BFAD, the government institute that deal directly with the management of hygiene for food supply within The Philippines include the Environmental Health Division of the Bureau of Health Services, as well as the National Meat Inspection Commission.

The Environmental Health Division of the Bureau of Health Services is responsible for the planning and inspection of food hygiene management throughout the country while the National Meat Inspection Commission performs the management of slaughterhouses and meat processing facilities and also conducts inspections for meat quality.

The inspection of food processing, etc. at marketplaces and restaurants is performed by provincial health offices under the jurisdiction of regional health offices.

Furthermore, testings for toxicity, pyrogens, sterility and microbiological analysis that cannot be performed presently at the BFAD, are entrusted to the institutes such as the National Bureau of Investigation and the National Institute of Science and Technology.

The BFAD also maintains a close working relationship with the following organizations in order to avoid the one-sided decisions.

* Bureau of Fisheries and Agriculture Research (BFAR)
* Institute of Food Trading (FTI)
* National Food Authority (NFA)
* National Institute of Science and Technology (NIST)
* Bureau of Plant Industry (BPI)
* Product Standards Association (PSA)

(2) Present State of Private Enterprises

The laboratories we have visited are United Laboratories, Inc., (pharmaceutical maker), Magnolia Dairy Products (maker of dairy products) and California Manufacturing Co. They are topclass makers in the Philippines, and hygiene and quality control are in the satisfactory condition.

Aside from Uni-Lab in which control is exercised with priority in the research and testing sections, other food makers have only adopted existing

production lines from industrially developed countries, and by faithfully following these processes, a basic level of hygiene is sustained.

The existence of facilities of such a high level will presumably bring about favorable impacts on fellow manufacturers in the Philippines, but it is not conceivable that the industry as a whole has attained this level now.

Even though it could be said that the level is high, it does not seem that the hygienic conditions of these facilities are perfect. Presumably, the reason for this is the availability of relatively cheap and abundant manpower and a considerable degree of production is done manually. In terms of regional factors, it is surmisable that the hygienic conditions of these workers' living environment and their living practices reflect the production environment. Consequently, there seems to be a lack of basic hygienic education to cope with these factors.

The findings of the survey at the visited firms are given below:

1) United Laboratories, Inc.

The drug production complex of this firm is well equipped and controled according to the Good Laboratory Practice, and its facilities and management are efficient. But the animal test facility is small in scale. The laboratory rooms are readily visible from the corridor through windows. The rooms as a whole are not so big in area.

It was told that a wide variety of toxicological experiments is done and two veterinarians are engaged in the experiments.

2) Magnolia Dairy Products Plant, San Miguel Corporation

Situated in Quezon City in Metropolitan Manila, this is a large plant with an area of 5.2 hectares. It was established in 1971 as the dairy products plant of San Miguel Corporation which is known for its production of San Miguel Beer.

The line of products includes long-life milk, icecream, cheese, butter, margarine, fruit juice, etc.

The plant facilities and machinery are updated and excellent, and the stirring, sterilization, molding and apportionment of raw materials are automatically done in almost every case. Homemade milk (Magnolia Farm) is used for raw materials and dairy products as raw materials are imported from New Zealand. Philippine sugar is also used. Hygienic quality

standards are set forth for all these raw materials, and an inspection is conducted for each lot and unqualified raw materials are not used.

The quality control sector consists of a chemical laboratory and a bacteriological laboratory. In the inspection of accepted raw materials and particularly in the bacteriological tests, sampling is done and tests are conducted, according to the process flow, in an attempt to attain a high quality.

In the use of synthetic resins, polyethylene is used for containers and polystyrene for their covers. These resins contain the least amounts of additives, which is acceptable. In-house inspections are conducted on them and they are subject to the random sampling by BFAD.

In an overall perspective, the machinery and facilities, work process and quality control stand in comparison with those of similar plants in Japan.

In the icecream filling work, tops are manually put into place, but from a hygienic point of view, it is desirable to automate this work. Although such manual work might be something inevitable in a country where manpower has to be fully utilized.

All products except icecream are filled automatically.

3) California Manufacturing Co.

The firm produces a wide variety of food. The Study Team visited its production complex. It has a large-capacity automatic noodle-making system to produce macaroni and spaghetti. In some part of the complex, powdered chicken soup is produced. Boiled chicken is manually separated from the bones.

In general, the equipment is of the latest, high-performance type but precautions against the flies are insufficient.

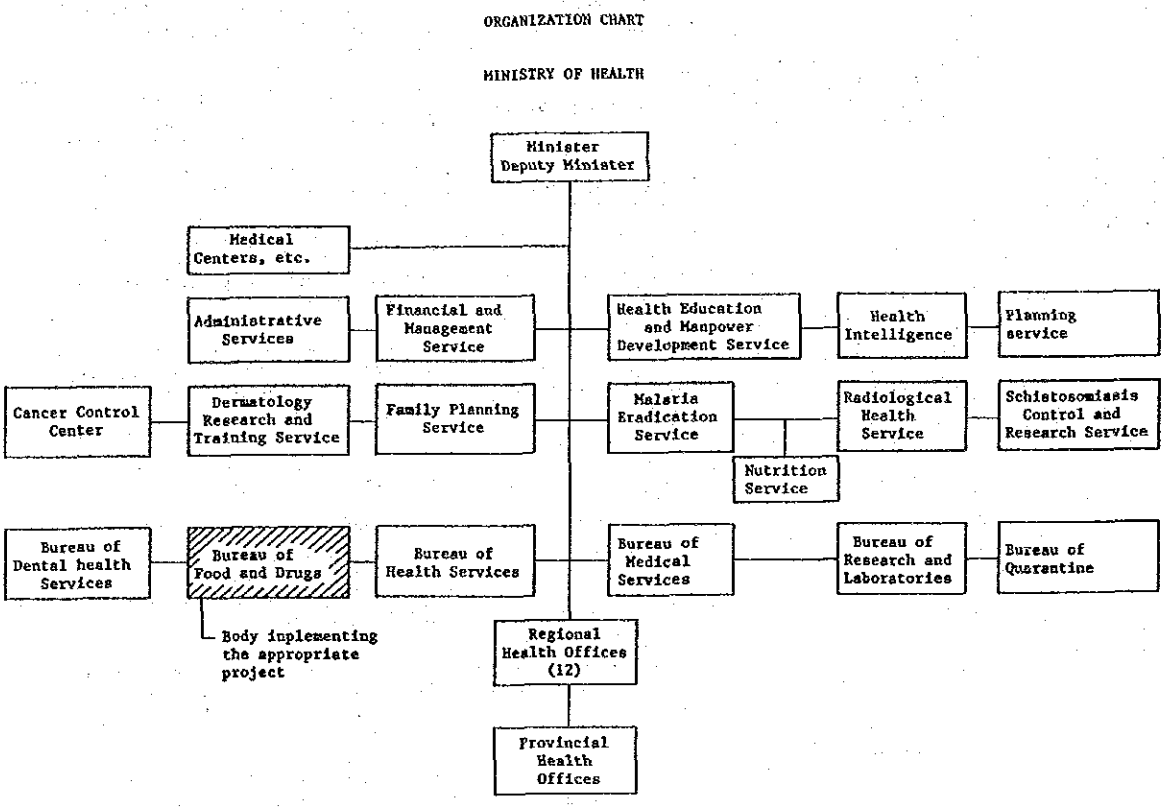
4. Present State of BFAD

(1) Organization

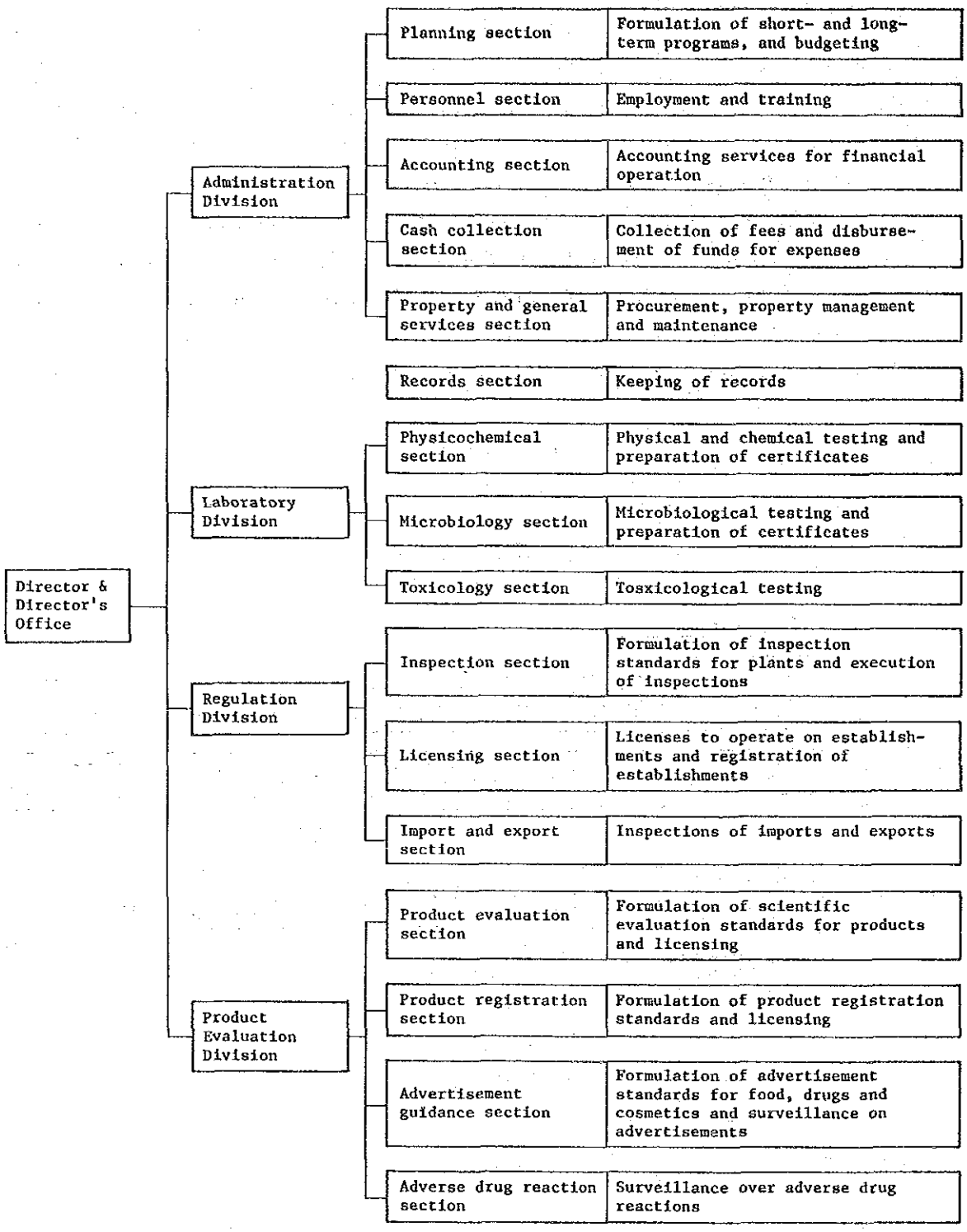
The BFAD, as a part of the Ministry of Health, is responsible for the quality control of food and drugs.

This institution carries out all kinds of laboratory-like experiments and tests on food and drugs (tests on the pesticide residues of pershables are done by a separate institution associated with the Ministry of Agriculture and Food) and also performs all sorts of inspection, evaluation, control and guidance in regard to their directly linked food and drugs (surveillance over narcotics and eating and drinking establishments is done by a separate organization of the same Ministry).

The organization and line of business are shown in the following table:



Organization chart of BFAD



(2) Activities

1) Microbiological Tests

The samples in BFAD's microbiological tests in 1983 ran up to 20,000, or half of all samples used by the Bureau. Broken down, they consisted of about 12,000 foods and drugs and about 10,000 antibiotics. Of the former, exported foods accounted for about 80 percent.

Categorized, the tests center on the counting of general bacteria and the detection of colon bacilli. The detection of bacteria responsible for food poisoning, such as salmonellae and staphylococci, is also included. However, the measures taken for the seorological differentiation of salmonellae and the differentiation of pathogenic yellow staphylococci seem to be inadequate. As regards the true fungi (mold and yeast), the number of fungi is counted but no further steps are taken.

In terms of testing, various antibiotics account for about half of all samples. Tilter tests are conducted in most cases but few germless tests are carried out.

Those tests are conducted according to the Bacteriological Analytical Manual (USFDA) for food and according to the United States Pharmacopoeia (USP).

The equipment needed for the execution of the aforementioned line of work are generally deteriorated, especialy the autoclave which has been used for more than 20 years and, quantitatively, there seems to be an acute shortage. The supply of culture grounds, glass implements and other expendables is also inadequate.

In terms of facilities, the laboratories are combined large room system, as the result that heterogeneous works which should have essentially separated in different rooms are done in one large room. The airtightness of doors and windows is also inadequate because the building has been deteriorated.

2) Biological Tests Using Test Animals

a. BFAD's biological tests

BFAD has neither animal house nor animal breeding facilities, so that neither biological test assays nor toxicological tests are conducted. Nor has it any experience in this milieu. The passive notion has prevailed in the past that when there arises a need for an animal test,

the University of the Philippines or some other institutions may be asked to do it.

A reactive variation test using microorganisms, one of the hereditary toxicology tests, has never been carried out though the bureau wishes to do it.

b. Supply of test animals

In the Philippines, there is no dealer who may supply mice and rats as far the Study Team knows. The institutions which have animal breeding facilities (United Lab., U.P., National Science and Technology Authority and RITM) breed them by themselves.

3) Chemical Analyses of Food

The following four activities are the main activities that are presently performed by the food section of the BFAD. Together, they constitute approximately 99% of the work of the sections related to food.

- o Food components: Water content, sugar content, starch content, total nitrogen content, oils and ash, etc.
- o Infinitesimal nutrients: Vitamins, heavy metals (iron, calcium, magnesium, zinc, nickel, etc.)
- o Food additives: Pigments, sodium benzoate, salt, ion nitric acid, ion nitrous acid, etc.)
- o Borax

The remaining one percent work includes analyses of hazardous contaminants in food. The percentage of this work in all types of work is extremely small not because this work is not necessary but because given the present number of staff and facilities, it is impossible to carry out this work. In fact, samples for an analysis of hazardous contaminants are sent to other institutions.

Work for the analysis of harmful contaminants can be broadly divided into the three types of artificial contaminants, natural contaminants and those relating to the container.

(a) Artificial hazardous pollutants

a) Polynuclear aromatic compound (ex. benzopiren):

At present, these are analyzed by the National Bureau of Investigation (NBI).

b) Pesticides: Organochlorine pesticides, organo-phosphorous pesticides, cabamate, etc.

At present, pesticides are analyzed by the Bureau of Plant and Industry and the University of the Philippines. For rice, wheat, corn, etc., pesticides are analyzed by institutions related to the Ministry of Agriculture and Food, whereas those in processed food are analyzed by BFAD.

Consequently, the types of pesticides which may be analyzed are limited.

c) Hazardous metals: Pb, Cd, Hg, As, etc.

(b) Hazardous natural substances

a) Micotoxin (Afratoxin B_1, B_2, G_1, G_2, etc.):

Until January this year (1985), only afratoxin had been analyzed, but at present, the number of micotoxins which should be analyzed has increased to 13. The number of samples processed a week is 10-15.

As no densitometer is available, it is impossible to make any analysis high in precision. As only one HPL chromatograph is available, it is not used for the analysis of micotoxin.

Micotoxin is analyzed mainly by the FNRI (Food and Nutrition Research Institute).

Southeast Asia is an area where food is contaminated with afratoxin, the most powerful carcinogen. Consequently, it is desirable that a testing system be completed as soon as possible.

b) Poisoning with fishes and shellfishes:

Samples are tested mostly by the BFAR (Bureau of Food and Aquatic Resources) and partly by the University of the Philippines.

BFAD has not grasped the number of cases poisoned with fishes and shellfishes. In future, it is desirable that BFAD take the lead in conducting tests, come to accurate grips with incidences of poisoning and work out measures for the prevention of poisoning.

c) Analyses of histamin

Chemical analytical method for histamin has been established, but BFAD is still using bioassays with cats.

(c) Packing of containers

Melting tests are performed for the most part, but there is a desire to analyze monomer, etc.

In addition to the above, inspections for contaminants also include impurity testing through floccation, although few products are tested in this manner.

4) Physicochemical Analysis of Drugs

There are 44 members staff in the inspection section of the BFAD, and of these 15 are engaged in the physico-chemical analysis of drugs, cosmetics and foodstuffs. The content of the work they are presently engaged in is as follows:

* Titer testing
* Checking the indications of contained quantities
* Component analysis testing
* Tests for the state of bacteria removal

Moreover, testing for biological agents cannot be performed because of insufficient facilities, while medical devices and quasi-drugs are not an object of investigation at present.

The manufacture of reference material and standard is being carried out in the ASEAN countries with Thailand being the center for such activity. The Philippines is participating in this joint project for the manufacture of reference material and standard and test work for (raw material) supplied by WHO, is being performed as part of physico-chemical analysis work for drugs.

There is a considerable lack of experimental facilities and equipment that can be illustrated by the fact that the spectrophotometers that are frequently used in drug analysis, the inspection section has while only one that is of the single beam type purchased eight years ago. In addition, HLP chromatographs that have recently come to be used in the analysis of drugs but the only one present was provided by WHO a year and a half ago. The column is a negative-phase- sequence column, but there is only one.

5) Inspection, Licensing and Administration

a. Inspection and licensing division

In order to assure the quality and safety of food, drugs, medical devices cosmetics, etc., this division carries out the inspection and licensing of facilities, disposition of grievances and take charge of accidents.

(a) Licensing of facilities for food, drugs, etc.

Licensing is done by screening facilities and applications. As regards facilities for drugs, licenses are awarded to manufacturers, importers, exporters, pharmacies, drugstores, etc. As for facilities for food, cosmetics and hazardous household items, licenses are awarded to manufacturers or processors, importers, exporters and repackers.

The facilities for which licenses are granted consist of 17,000 facilities for food (6,000 in Metropolitan Manila) and 10,000 facilities for drugs (3,000 in Metropolitan Manila).

The license is valid for a period of one year and renewed, depending on the findings of an inspection and a test of the sampled products. A license will be issued one week after an application at the earliest.

(b) Inspection of facilities for food, drugs, etc.

The facilities for which licenses are to be granted are inspected. In the Manila area, inspections are directly done by BFAD officials, but in other areas, they are done by officials of the RHO (Regional Health Offices), regional branches of the Ministry of Health, as the nation is divided into 12 blocs. The inspection reports and product samples of the RHOs are sent to BFAD.

It is a rule to inspect each facility at least once a year. A check is made to see if the facility is in line with legislation, regulations and GMP (Good Manufacturing Practices), information is exchanged and guidance is provided on the control of manufacture.

When an inspection is made, reference is made to the GMP and inspection guideline. GMP comes in separate general practices for food and drugs, and it is also stipulated for individual items. The

inspection guideline also differs, depending on the item, incorporating important check points.

The findings of an inspection are compiled in an inspection report, and recommendations, etc., are made, if necessary.

The inspections are well developed in terms of the system, to be sure, but it might not be said that an efficient inspection is done as there is a lack of mobility and equipment. A problem is also posed as to the degree to which guidance is provided from a hygienic point of view in an actual inspection.

(c) Others

As regards food poisoning, there is neither a system nor any other means whereby notice may be made, and virtually no countermeasures are in effect.

b. Product evaluation division

The main line of administration for this division is to inspect and register food, drugs, medical devices and cosmetics. It also carries out the surveillance of advertisements and take other measures.

(a) Registration

All food for export and import are required to register. As regards drugs, registration must be done for new drugs for which new efficacious components, new use method and volume are formulated and also for their modifications. Registration is also required for cosmetics and hazardous substances.

Registration is made by writing the appellation, components, etc., on a card.

About 1,550 drugs (of which 1,150 drugs were renewed) and 2,000 foods were registered in 1982. The number of registered drugs stood at 7,684 as of January 1985.

Radiotherapeutic drugs, vaccine and other biochemical drugs are also registered, although they come under the jurisdiction of other ministries and agencies.

(b) Licensing of drugs

A guideline which provides data necessary for the registration is well prepared. The guideline on IND (Investigational New Drugs) is

also presented. The number of materials in applications for new drugs seems to be virtually the same as in Japan. But only one licensing official is available.

(c) Standards for food and food additives

At present, provision of standards are now under preparation. How standardized items are managed is not clear.

(d) Others

A committee, known as the Board of Food and Drugs Inspection, is established as the Philippine equivalent of the Central Pharmaceutical Council and the Food Hygiene Research Council in Japan, and this board is made up of representatives from the Ministry of Health, Ministry of Agriculture and Food, Ministry of Trade and Industry, Medical Associations, Dental Associations, pharmacists and the like. The board meets when new standards, etc., are to be formulated.

c. Administration division

This division formulates short-term and long-term programs, compiles budgets, takes charge of personnel affairs, trains staff personnel, controls office supplies and equipment and does simple repair work on research equipment, etc.

(3) Present State of Facilities

The facilities of the BFAD are presently located in the old part of Manila City in one part of the San Lazaro Compound occupied by the Ministry of Health headquarters and its affiliated bodies.

The existing buildings are of two-storey (and part of three-storey) reinforced concrete construction and are considerably deteriorated since they were constructed more than 40 years ago. The facility has the management and product evaluation sections on the first floor, the Bureau Director's room, the inspecting and licensing section, and the testing section on the second and third floors. The scale of the facility is as follows.

First floor	approximately	800 m^2
Second floor	approximately	800 m^2
Third floor	approximately	250 m^2
TOTAL AREA	approximately	1,850 m^2

Section Areas	
Management section	413 m^2
Product evaluation section	247 m^2
Inspecting and licensing section	135 m^2
Testing section	552 m^2
Bureau Director's room	105 m^2

The present facility is located in a high-density part of the city and all of the rooms are therefore provided with window air conditioners.

The floor of the interior is finished with P-tiles and the ceilings with handboard, while the walls are either mortar-covered concrete block or timber partitions.

Many of the building fittings are either timber or steel fittings which do not offer ample airtightness. The present facility was not planned originally to incorporate the testing section and so there is considerable strain upon the electrical, water supply, drainage and ventilation facilities. Much provisional work has been done to accommodated the better laboratory work. Nevertheless, there is considerable obstruction for efficient work and the accuracy of the work.

(4) Present State of the Existing Equipment

1) Microbiology Section

Incubator (West German)		1
Incubator (American)	-out of order-	2
Refrigerator (American)		1
Water bath (U.K.)		1
Colony counter (American)	-out of order-	1
Beam balance (American)		1
Fume hood, biohazard (American)	-out of order-	1
Autoclave (American)		1
Autoclave (American)		1
Pipet can		8
Glassware for cultivation (American)		some
Glass pipets etc. (American)		some
Binocular microscope (American)		1
pH meter (American)		1
Timer (American)		1

Mechanical analytical balance (Swiss)	1
Pipet washer (American)	1

There is a considerable degree of equipment deterioration and there are frequent breakdowns. In addition, the equipments are not sufficient.

2) The Present Chemical Analysis Section

Physico-chemical analysis of foodstuffs, cosmetics and pharmaceuticals

Mechanical analytical balance (Swiss)	2
Rotary evaporator (Swiss)	1
pH meter (American)	1
Hand refractometer (American)	1
Paper chromatograph equipment (American)	1
Pipet washer (American)	1
Weight balance (West German)	1
Water bath, ring type (American)	1
Incubator (West German)	1
Refrigerator (American)	1
Freezer (American)	1

Mechanical analysis techniques are presently the major means of analysing tests and bodies in the technologically-advanced countries but at the BFAD, testing and analysis is still being performed using glassware equipment and manual techniques.

3) Toxicity Testing Section

The major tests for toxicity are not presently conducted at the BFAD and so there is no equipment for analysis testing.

4) Other commonly-used analytical equipments

HPL chromatograph (American)		1
Spectrcphotometer (visible) (American)		1
AA spectrometer (American)		1
Gas chromatograph (American)	-out of order-	1
IR spectrometer (American)	-out of order-	1
Centrifuge (American)	- out of order-	1
Vacuum dryer (American)		1
Kjeldahl's apparatus (Swiss)		1

Soxhlet's apparatus (American)	1
Muffle furnace (American)	1
Crucible furnace (American)	1
Tube furnace (American)	1
Hotplate (American)	1
Water still (American)	1
Glassware processing & repair apparatus (American)	1

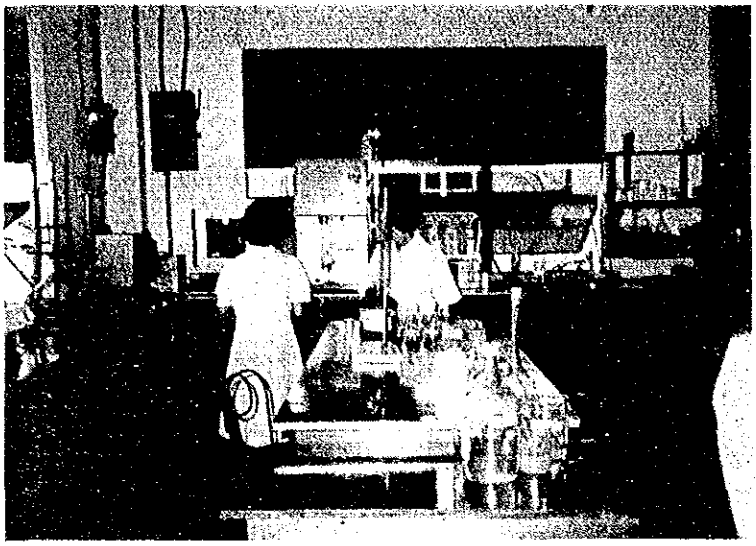
The equipment used in common by all the sections is largely of American or Europian manufacture and there are many items intended for testing and analysis such are out of use because of the insufficiency of spare parts for repairs and also because they have been used for many years.

5) Animal Testing Section

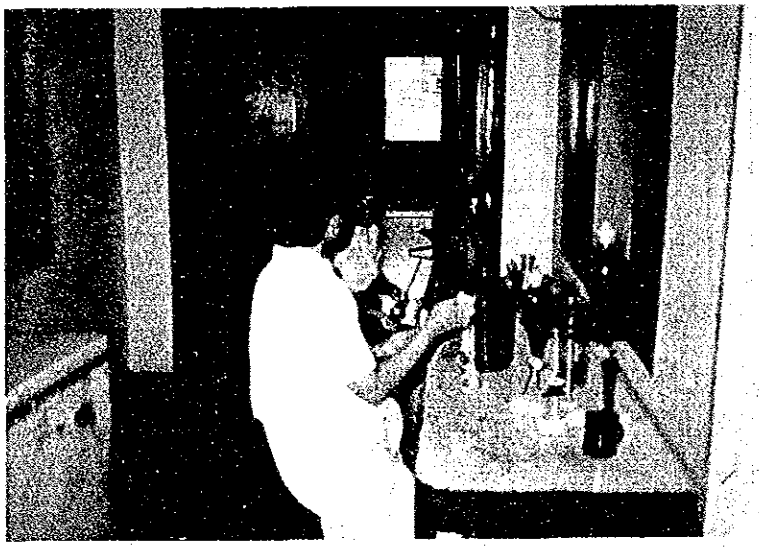
The BFAD does not possess pharmaceutical and toxicity test facility using animals, and also has no facilities for the breeding and raising of animals for such purposes.

6) Monitoring and Inspection Section

There are five manual typewriters (American) for the compilation of reports but there is no equipment for the collection of materials.

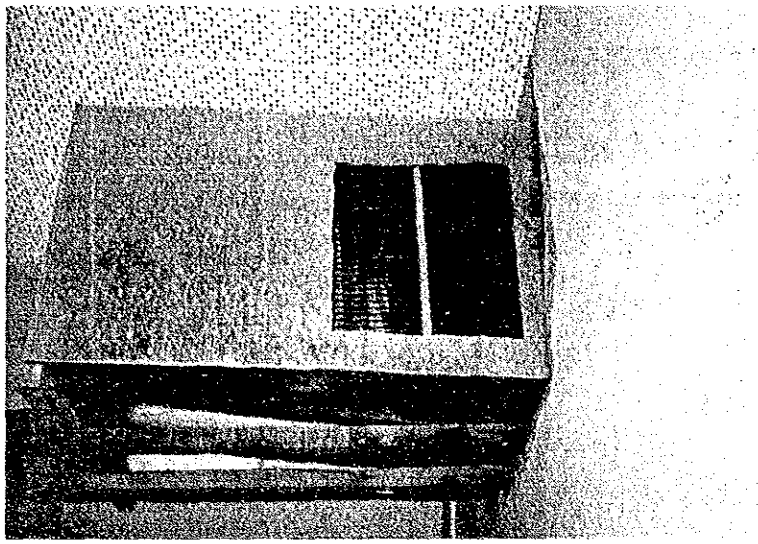


Physico-chemical testing room



Test being conducted in the corridors because of the lack of rooms

Monitoring and inspection section

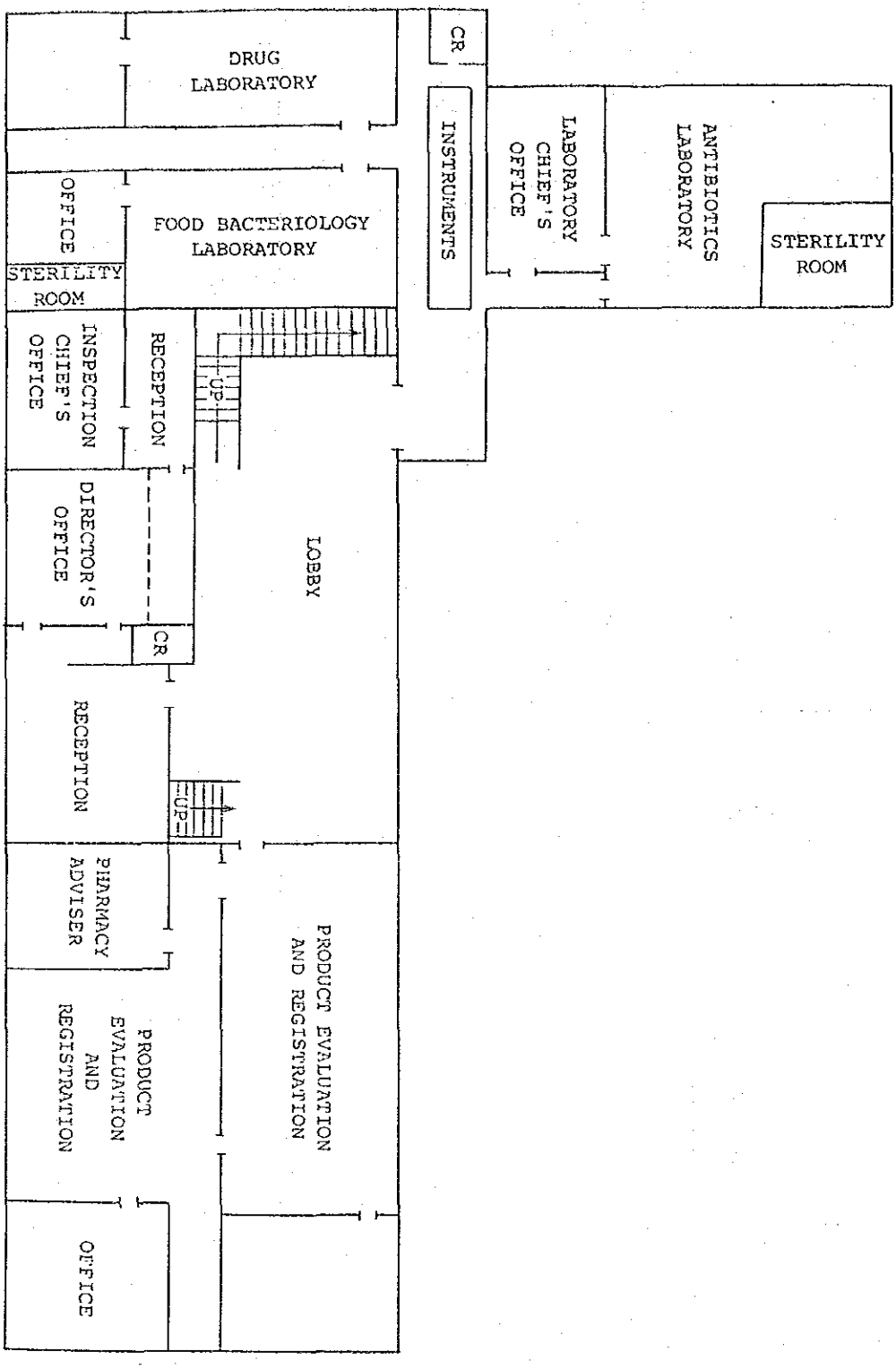


Exhaust duct installed as an urgent, temporary measure

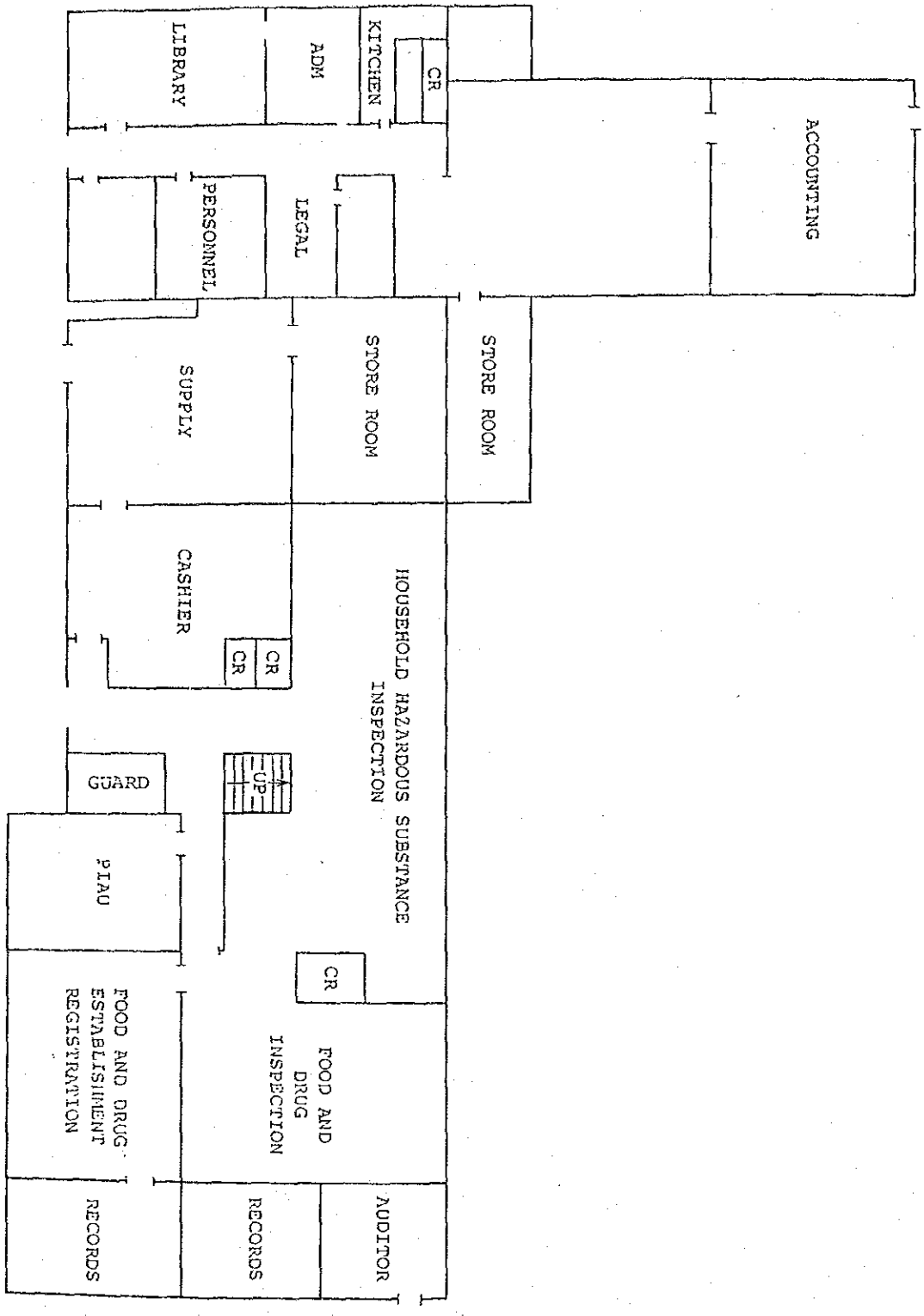
Measuring room

External view of BFAD

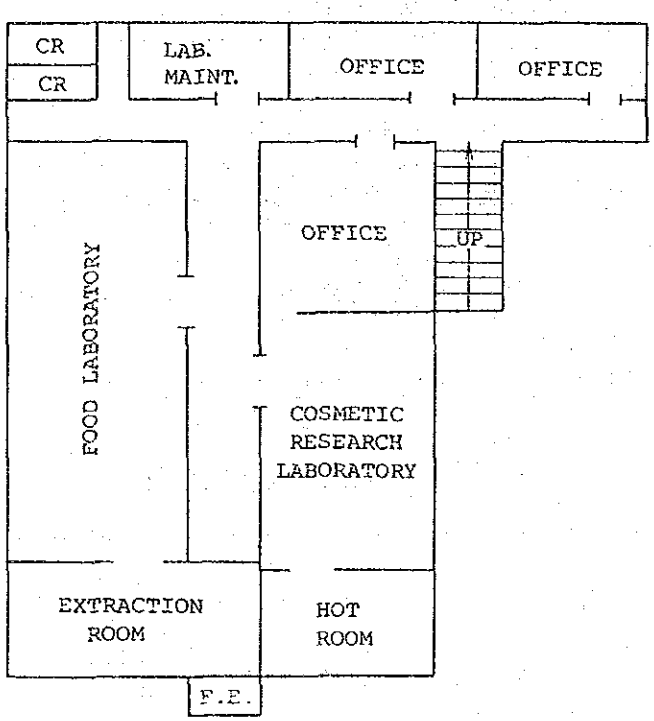
Present condition of BFAD building



1st floor plan



2nd floor plan

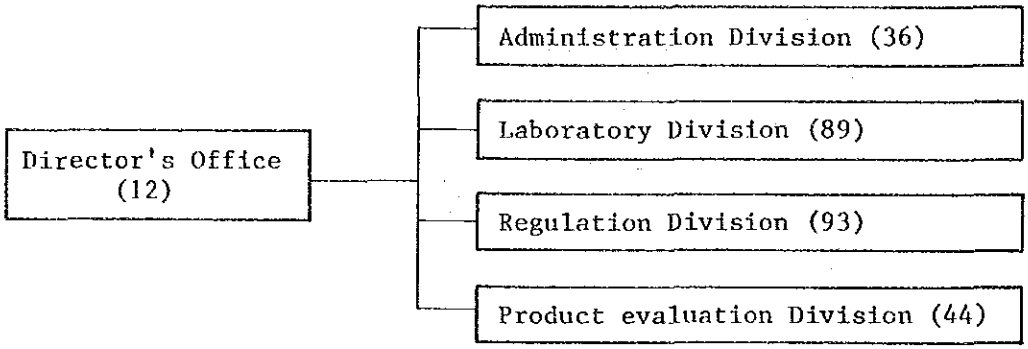


3rd floor plan

(5) Management System and Budget

At present, the management of the BFAD has been conducted with the previously described configuration.

The situation as regards the placement of personnel in each of the sections is shown in the following diagram. In all, there is a total of 274 personnel, of which 172 are engaged in research, 39 in office and administrative duties and a further 63 in auxilary work.



The following is the BFAD annual budget for the year fiscal 1985.

BFAD's Budget for CY 1985

	Breakdown			Total
	Wage	Allowance	Equipment, material, light and heating	
Laboratory Division	1,133,000	264,000	835,000	2,232,000
Regulation Division	1,163,000	267,000 *281,000	562,000	2,273,000
Product Evaluation Division	631,000	220,000	498,000	1,349,000
Total	* Official travel expenditure			5,854,000 Peso (76,100,000 Yen)

5. Scope and Content of the Request

(1) Scope of the Request

In order to maintain the safety and quality of foodstuffs and pharmaceuticals which have an intimate relationship with the health of the people of the nation where there has been a remarkable development of the foodstuff and pharmaceutical industries in recent years, the Government of the Philippines is creating laws to regulate the manufacture, sales and distribution of such products, and the Bureau of Food and Drugs (BFAD) of the Ministry of Health is being placed in charge of the inspection, monitoring and registration of manufacturing facilities and is also responsible for the necessary testing and inspections of the registration of products.

However, the existing inspection and testing facility of the BFAD has much equipment that is in a state of deterioration, and the level of the technology used is rather low. These and other problems mean that a sufficient administrative response to the situation cannot be made at the present stage.

Because of this, the Government of the Philippines has formulated a plan for the establishment of a food and drugs laboratories, and has submitted a request to the Government of Japan for grant-in-aid cooperation in order to realize the project.

(2) Content of the Request

1) Purpose

a. A project for the purposes of providing a good facility for the related sections dealing with the analysis and inspection of foodstuffs, pharmaceuticals, quasi-drugs and medical devices, as well as the section dealing with the breeding and raising of animals for testing purposes.

b. A suitable facility for the purposes of managing the sections required to assist the testing work.

This will include the following functions. Inspection and evaluation of products, their registration, field testing and licensing, the formulation of policies and standards, and the formulation of long-term plans, etc.

2) Outline of the Project

It is required that the construction of facilities and procurement of equipment satisfy the following sections and their functions.

a. Microbiology section

* Isolation and identification of particular bacteria
* General isolation and identification
* Setting of microbacteria quality standards for individual foodstuffs
* Establishment of methods for the detection of toxic substances within foodstuffs
* Establishment of microbacteria testing methods with respect to foodstuffs, pharmaceuticals and cosmetics

b. Physico-chemical analysis -- phamaceutical-related section

* Improvement of the methods of analysis for foodstuffs, heavy metals and impurities, etc.
* Analysis of food additives
* Analysis of foodstuffs with respect to environmental contamination

c. Physico-chemical analysis -- foodstuffs-related section

* Cosmetics-related
  - Receptivity and allergy testing
  - Mucosa stimulation testing
* Harmful substances
  - Inflammability testing
  - Toxic substances research
* Plastics-related
  - Polymer allowable quantities testing
  - Danger testing for residual substances
* Pharmaceutical additives
  - Inspection of new additives
* Diagnostic test pharmaceuticals-related
  - Inspections of marketed products (imported and domestic products)
  - Development of methods for the disposal of harmful test pharmaceuticals

d. That related to the use of animals for testing

* Breeding and raising of test animals
* Establishment of an animal testing system
  - Pyrogen testing experiments
  - Allergy testing
  - Histamin test
  - Receptivity testing
  - Skin and mucosa stimulation testing
  - General (violent) toxicity testing, etc.
  - Insulin activity testing
  - Testing of substances causing high blood pressure
  - Testing physical appropriateness of proteins

e. That related to testing, inspections and management

* Testing section
  - Establishment of a system for food poisoning, monitoring and reporting
  - Exports and imports inspections
  - Inspection of enterprises relating to foodstuffs and additives
  - Inspections of pharmaceuticals and cosmetics, etc.
* Inspection section
  - Inspections of foodstuffs and food additives
  - Inspections relating to the side effects of pharmaceuticals
* Management section
  - Data processing

CHAPTER 3 DESCRIPTION OF THE PROJECT

1. Purpose

The purpose of this project is to upgrade the standard of quality control of Food and Drugs in the Philippines. This is to say that the project seeks to replenish the functions of the BFAD through the construction of a building to house the Food and Drugs Laboratories and to provide them with the necessary equipment. For this purpose, an investigation into the necessity and appropriateness of the plan was conducted with respect to the items listed below.

(1) This laboratory will become the core facility for the analysis and testing of food and drugs in the Philippines.

(2) It will serve to upgrade the testing functions to a level at par with that of the technologically-advanced countries.

(3) The results of previous testing and analysis had a considerable degree of error because of the manual methods used, will now become officially recognized precision values due to the employment of a testing system based on mechanical analysis.

(4) The use of the mechanical analysis will mean that the testing and evaluation work will be speeded up, and that a target of 375,000 test items can be covered in one year.

(5) To perform the collection and analysis of standard numerical data for ratings and standards for food and drugs, etc., for confirmation testing regulations, and for purity testing, etc.

(6) To achieve the strengthening and improvement of the system for the monitoring of all stages of foodstuffs and pharmaceuticals manufacture, distribution, export and import.

(7) To organize the training of regional staff in order to upgrade health in regional areas.

2. Study of the Project Proposal

As we have already seen in the chapter on the background for this Project, the findings of the Preliminary Study Team and the Basic Design Study Team suggest in terms of manpower that researchers are well acquainted with the substance of their work and seem to be carrying out their tests in a faithful manner. However, the equipment which is used to carry out the test, for example the autoclaves which have been used for the last 20 years, are already outdated, and they need replacement. The BFAD building, originally not built for inspections and tests, is not only inconvenient, narrow and small, but may pose many problems for the efficiency and credibility of its tests.

Given this situation, there arises the need to construct a new building, and in this conjunction, it is deemed appropriate to renew and replenish equipment in physicochemistry, microbiology, toxicology and other millieus.

Animal tests are indispensable for the qualitative improvement of food and drugs, therefore, it is to be strongly hoped that animal testing facilities be installed.

In the following, the test and inspection items which seem to be necessary for each sector are illustrated.

(1) Microbiology Section

1) Isolation and Identification of Food Poisoning Bacterium

The information available in The Philippines about food poisoning is fragmentary and there is a lack of accurate statistical data. Judging from the general state of hygiene, it is surmisable that there is a considerable number of patients with food poisoning. The substance of the tests which are being carried out by BFAD at present seems to be inadequate.

Therefore, it is also necessary to cover the following fields of analysis.

* Bacterial food poisoning
* Yellow staphylococci
* Salmonella pathogenic, toxin pathogenic colon bacilli
* Isoration and identification of enteritis vibrios (including serological type differentiation)

2) Establishment of Quality Standards and Testing Methods for Microbacteria with respect to Foodstuffs, Pharmaceuticals and Cosmetics

* Development of testing methods
* Accumulation of test results for the establishment of the quality standards.

The testing method practiced at the BFAD for foodstuffs and pharmaceuticals is the methods of other countries. The Philippines have not developed any quality standards of her own either.

At present, an investigation into testing methods is being concurrently performed along with the implementation of testing for various types of products in The Philippines in an attempt to set quality standards based on the results of the data accumulated.

3) Establishment of microbacteria standards for one antibiotics (National standards relating to strength and sterilization testing)

At the BFAD, strength test and sterilization test using microbacteria is being implemented with respect to certain antibiotics but there is no national standards for such at present. The number and the types of antibiotics in The Philippines is increasing and it is necessary to establish microbiological standards in early stage.

4) Mold fungus testing

Isolation and identification of fungii

* Isolation and identification of mycotoxin-producing mold fungus
* Establishment of methods for the detection of minute quantities of mycotoxin-producing substances

Improvement and quantitative replenishment of the general purpose equipment relating to these items.

The mold fungus testing that is currently being implemented at the BFAD is limited to the quantification of fungii, and their isolation and identification are not implemented. By considering the high temperatures and humidity conditions of The Philippines, it is considered important that methods for the isolation and identification of mycotoxin-producing substances be established along with the methods for their detection.

(2) Physicochemical Analysis (Food) Section

The main work by food section is the analysis of:

(a) Food ingredients
(b) Infinitesimal nutrients
(c) Food additives
(d) Borax

The above work consists of 99 percent of all work done by BFAD's food section.

The remaining one percent includes analyses of hazardous contaminants in food. The percentage of this work in all types of work is extremely small. However it does not mean this work is not necessary, but it is because of the present number of staff and the present facilities. In fact, samples for an analysis of hazardous contaminants are sent out to other institutions.

It is necessary that hazardous pollutants should be analyzed by BFAD, which is the core of administration for food hygiene. From the standpoint of view of food hygiene, BFAD has the intention of analyzing hazardous contaminants in a positive manner.

Accordingly, it is necessary that the following fields be implemented.

1) Qualitative and Quantitative Analyses and determination of the structure of Super-Infinitesimal Components

* Environmental pollutants
* Natural pollutants
* Causative toxins
* Food ingredients
* Food additives

2) Establishment of Speedy Routine Analytical Method

In particular, an efficient mechanical analysis is desirable because of the large quantity of analytical work is required.

(3) Physicochemical Analysis (Drug) Section

As regards the tests on drugs, the realization of this project will enable BFAD to carry out tests necessary for its reasonable administration, especially of the testing methods enumerated in the Pharmacopeia Americana. The feasible main testing items are given below:

Liquid chromatography
Gas chromotography
Ultraviolet ray spectrum assay
Infrared ray sepctrum assay
Thermal analysis
Potentimetry
Atomic absorption spectrophotography
Measurement of polarity
Measurement of osmotic pressure
Measurement of viscosity
Measurement of moisture
Measurement of melting point
Tests on elution
Tests on crumbling
Tests on stability
Tests on containers

As regards tests on non-medical items, the project will make it possible to establish testing methods necessary for the authorization, surveillance and guidance of non-medical items in the Philippines.

With respect to the production of standardized items, the project will enable the Philippines to carry out in a smooth manner its share in the five ASEAN member nations' project for the production of standardized items, and also to produce standardized items for the analysis of drugs for distribution in the nation.

(4) Biological Tests Using Test Animals

In order to enable BFAD to carry out animal tests as it hopes to do, it is indispensable that animal raising facilities and animal test rooms be prepared. The availability of animal raising facilities would form the basis on which BFAD could strengthen its toxicology section and carry out a variety of safety and toxicity tests. In order to assure a stable supply of superior and uniform animals and feed, with due consideration given to the present situation of test animals in The Philippines, it is necessary to produce them at its own facilities. However, as it is considered impossible to propagate and rear animals, carry out animal tests, produce feed at such a small scale as cabinet type. The best alternative would be to construct an animal house. And an animal house must have the following functions:

(a) Raising and breeding of mice, rats, rabbits and guinea pigs
(b) Cleaning and sterlization of raising equipment
(c) Production of feed
  a. Storing of equipment and feed at low temperature (15°C)
(d) Animal tests
(e) Anatomy, animal control, sample preparation
(f) Others

The operation of following items is necessary.

1) Development of Animal Testing and Toxicology Section

* Biological testing and analysis
* Allergy tests
* Sensitivity test
* Stimulus test

In the animal tests, the immediate targets would be the biological tests assay indicated in USP, allergy tests, sensitivity tests and stimulus tests. When general toxicity (acute toxicity) tests are taken into consideration, it is necessary to consider the possible expansion of the safety and toxicity tests in future.

It is necessary that each facility to clear at least the GLP standard. (GLP = Good Laboratory Practice)

2) Offer of Animals (Colony for Breeding)

3) Technical Training of Breeders and Personnel in Charge of Animal Tests

(5) Management, Inspection and Evaluation

1) Data Processing

It is indispensable to computerize licensing, registration and other matters, which are presently processed with cards, and test data.

2) Dissemination of Information

To be an efficient BFAD, it would be important to disseminate information within the bureau. It is desirable, therefore, that copying machines, typewriters and other basic office machines be prepared.

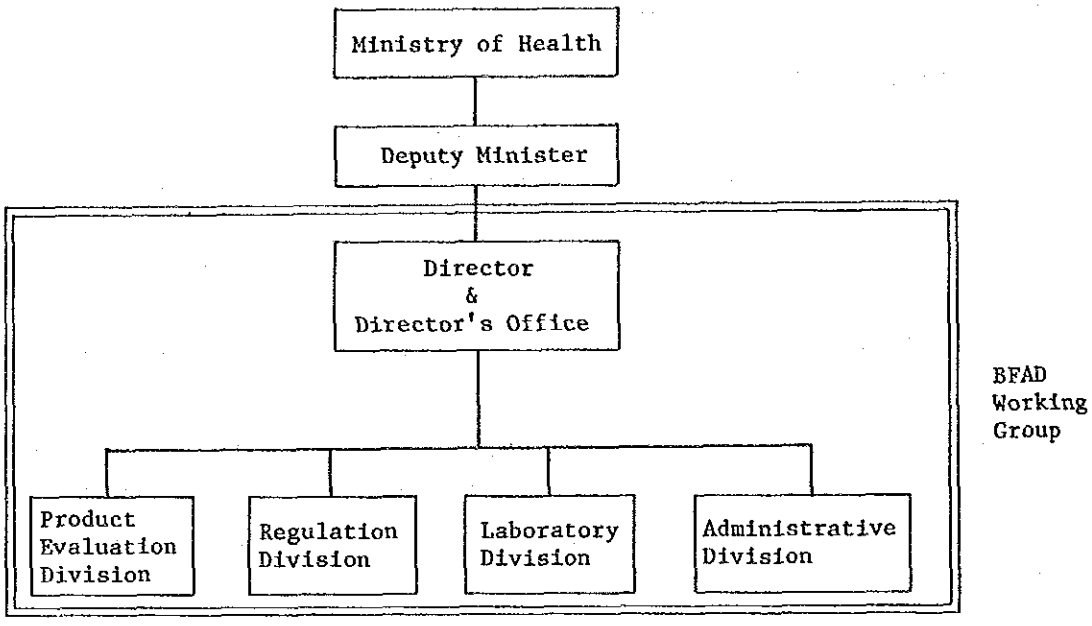
3) Others

BFAD consists of the Laboratory sector and Inspection and Evaluation sector. BFAD takes direct charge of establishments in the Manila area, and the collection of samples, testing, licensing, registration and certification are done with close coordination between both sections. For the efficient administration, it would be better to place both sections close by.

3. Outline of the Project

(1) Enforcing Organization and Management System

The management of the implementation of this project is to be entrusted to the Bureau of Food and Drugs of the Ministry of Health. The organization of this is as follows.



(2) Determination of the Scope of the Project

When the present situation of BFAD in the Philippines was surveyed, it was found out that BFAD's program for tests and analysis is insufficient, as the various types of equipment which they have and presently being used are extremely outdated and are not adequate enough to cope up with increasing tests and analysis.

Since good quality test animals are absolutely indispensable for biological and microbiological tests, including pharmacological, immunological and toxicological tests, it is necessary to establish an animal house with sufficient facilities.

The establishment of this animal house would bring BFAD's testing and analytical technology to the level of industrially developed countries and contribute greatly to an enhancement of the health and welfare of the people of the Philippines.

In the following, the tests and analyses conducted by each sector and the composition of rooms are enumerated.

Functions of Each Section

a. Microbiology section

Isolation and identification of bacteria in food, and bacteria in the intestines. Isolation and identification of true fungi, culture mediums and infinitesimal toxins.

Detection of clinical bacteria, sera, fluorescent antibodies and parasites.

b. Physicochemical section

(a) Food

Analysis of super-infinitesimal components with equipment.

Food analysis, food chemistry, chemistry of hazardous substances and chemistry of poisoning Chemical analysis of milk, meat, fishes and shellfishes.

Studies on methods to test food additives in food and to carry out quality control.

Food contamination with chemicals, carcinogens, minute particles of metals, pesticide residues, antibiotics, etc.

Instruments for food and packing of containers.

(b) Medical supplies

Tests on drugs, violent poisons, and drugs for injection.

Methods to evaluate.

Retrieval of cosmetics, non-medical articles, medical care instruments, household goods and hazardous substances.

Development of testing methods.

c. Pharmacology, immunology and Toxicology Sector

For safety tests on food and drugs, the following tests will be conducted with superior test animals:

* Tests on drug metabolism
* General tests on toxicology
* Tests on functional toxicity

* Tests on carcinogenicity
* Pathological examinations with anatomy of internal organs
* Tests on pyrogenicity
* Tests on stimulation to skin and membrane
* Allergy tests
* Histamin pressure-falling tests
* Measurement of insulin activity

d. Biology Sector

Good quality animals will be bred as test animals.

(3) Outline of the Facilities and Equipment

1) Facilities

Building: Floor area (including balconies and pilotis, etc.) ..... 5,780.0 m^2

a. Main building ..... 4,475.0 m^2
b. Animal house ..... 1,160.0 m^2
c. Energy building ..... 120.0 m^2
d. Storage ..... 10.0 m^2
e. Waste water treatment facility (building) ..... 15.0 m^2

Other facilities:

a. Waste water treatment facility (processing tank)
b. Waste substance treatment facility

2) Composition of Each Section

The configuration of each section is as follows.

a. Microbiology section

* Microbiological testing room (incubator, anaerobic jars)
* Clean room (NASA Class 100 clean benches)
* Culture room, bacteria preservation room, testing room (CO_2 incubator, colony counter)
* Low-temperature room, washing room (refrigerator, washer)

b. Physicochemistry section (Food and Drugs)

* General research and testing room
* Analytical instruments room (spectrophotometer, high-speed liquid chromatograph, spectrophotometer, gas-mass analyzer)

* Clean room (NASA Class 100 clean benches)
* Pyrostat analysis room (a): (Gas chromatograph, AA spectrometer)
  Hot room (b): (Muffle furnace, crucible furnace, soxhlet's apparatus, hot plates)

c. Toxicology section

* Animal test room (Polygraph including an electromagnetic shield)
* Pyrogenic test room, body temperature measurement room, general (acute) toxicity test room (Pyrogen tester)
* Allergy test room, skin and mebrane stimulation test room (incubator box, organic photographing set)
* Histamin test room (animal restraining cage)
* Animal dissecting room, specimen preparation and storing room (dissecting table, microtome)

d. Test animal breeding and propagation section

* Rabbit breeding room, propagarion room (Breeding propagation cage)
* Mouse breeding room, propagarion room (Breeding propagation cage)
* Rat breeding room, propagarion room (Breeding propagation cage)
* Guinea pig breeding room, propagation room (Breeding propagation cage)
* Cat breeding room (Breeding cage)
* Passroom (pass box)
* Equipment washing and sterlization room (Cage rack washer, large autoclave)
* Feed production and storing room (Pellet machine, mixer, drier)
* Incidental facilities: Incinerator, waste water disposal facilities

e. Commonly used rooms

* Cold room (-10°C), Low-temperature room (+5°C), analytical balance room (Analitical balance, balance bench), electro-microscope room (Electro-microscope; scanner type)
* Pure water production (Water still apparatus, ION exchange equipment), darkroom

f. Surveillance and Screening Sector (Audiovisuals, typewriter, TV unit)

g. Administration Sector (Computer unit)

(4) Location and Conditions of Project Site

1) Outline of Project Site

The site of this project is situated in the Alabang area, Muntinlupa City, Metropolitan Manila, about 20 kilometers south from the center of Manila City (about half an hour by car along National Highway No. 1).

The proposed site for this project is situated within the compound of the Ministry of Health's auxiliary facility complex with an area of 246 hectares, which faces the Alabang Interchange of the said highway. Within the compound, there are many existing facilities including the Research Institute for Tropical Medicine (RITM), completed in 1983 with Japanese Grant Aid Assistance, the Biological Laboratory and the BCG Laboratory.

The project area slopes towards the east (2.5 percent purchased on the average), about 200 m × 200 m, in the eastern section of the Ministry of Health's compound which faces the highway. The Lagna Lake is situated about 700 meters east of the site (the Lagna Lake is 1.6 m above sea level) but there is no danger of inundation.

The site is a pasture at present. There are 10 - 15 tall trees (7 - 12 m), which do not form a thick foliage. It is possible to leave the trees as they are, depending on the location of facilities. There are also no obstacles. As the slope is appropriate, there is no need to do any excavation works. Nor is there any problem with the infrastructure to which reference will be made later. It might be said therefore, that the site is appropriate with little construction cost to the Philippine Government.

However, there is noise (estimated at 60 - 70 db) coming from the highway, however there is a distance of more than 50 meters between the border of the site and the motorway, it is possible to cope with it by appropriately locating the building.

As the premises road leading from the main gate of the Ministry of Health's Division of Biology compounds which faces the old highway about 200 meters from the Alabang Interchange, can be used there would be no problem with the access to the site. The Ministry of Health has plans to

move the main gate closer to the interchange, but the schedule and the exact location are yet to be decided.

2) Transit

In case the facilities in this project are constructed at the project site, the aforementioned highway or the parallel old national highway will be used to link Quezon City, Manila City and Makati City for the comutation of workers and the transport of samples. Owner-driven passenger cars, buses, and jeepnies as means of public transit will be used.

The road system between the center of Manila City and the project site are well developed, and there will be no bottleneck to traffic during and after the construction period.

3) Future City Planning for the Perimeter

BFAD has been asked to provide detailed materials, but considering the current trend of events, it looks like there are no programs for the perimeter (road, railway, public sewerage system, the high-voltage iron tower and land utilization programs, etc.) which would produce a great impact on this project and other future programs.

4. Technical Cooperation

When the Philippines is viewed from the point of manpower, there are insufficiencies in some specialized fields, but it may be concluded that a minimal number of personnel, including those with an educational carrier, is maintained. In terms of a willingness to do work, there seems to be no specific problem, but it is also conceivable that the impact from the physical retardation is greater than expected and it is keenly felt that there is a need to render technical cooperation.

The request by the Government of the Philippines for technical cooperation is quite an extensive one which cannot be definitely stated without ranking the contents in terms of their necessity. As a result of the preliminary study, the Japanese side considers that technical cooperation is necessary for the following fields but the final definite plan will be compiled through a process of discussion with the counterparts. Technical cooperation fields:

(1) Dispatch of Experts and Provision of Equipment

1) Microbiological Testing

* Establishment of microbiological testing standards with respect to foodstuffs, pharmaceuticals and cosmetics, and the setting up of quality standards for these products.
* Isolation and separation of food-poisoning bacteria within food.
* Testing relating to antigen substances
* Mold testing

2) Rearing of Test Animals and Biological Testing of Such

* Animal breeding and rearing
* Animal tests (bioassays, allergy tests, receptivity tests, stimulus and toxicity testing)

3) Physico-chemical Analysis of Foodstuffs and Pharmaceuticals

* Analysis of food components and food additives
* Physico-chemical analysis of foodstuffs and pharmaceuticals, etc.

4) Inspection and Evaluation

* Monitoring of foodstuffs and pharmaceuticals and the monitoring of imports and exports
* Product evaluation

(2) Acceptance of Trainees (the following fields are to be given high priority)

1) Test animal rearing and breeding fields
2) Foodstuff and pharmaceutical monitoring and inspection
3) Experiment and testing section

CHAPTER 4 BASIC DESIGN

1. Design Policies

The following items determine design policies which the deisign will take, in accordance with the results of the Basic Design Study.

1) A functional plan allowing the high-level and prompt performance of the inspections and evaluations accompanying the progress in food and drugs
2) A plan which can easily correspond to future change
3) A plan that considers the prevention of laboratory disasters and that also considers 'clean' and 'dirty' zones
4) A plan that is based on natural illumination and ventilation to the greatest possible extent, with the aim of reduction of building running costs in this hot and humid country
5) A plan that has a reasonable frame structure and that is appropriate from the point of view of construction cost and construction period
6) A materials plan that provides for easy cleaning and maintenance

2. Study of the Design Conditions

The design conditions are all of those conditions that must be satisfied and include those relating to the fundamental design policies, the natural environmental conditions and the various types of regulations, as well as those concerning the purpose of use of the spaces (noise, heat and light insulation). They also include management and operating conditions from the point of view of the owner, and given conditions such as the site ground, slope, relation to roads and the infrastructure. Other conditions also include those born of the living customs and practises while there are also other design conditions imposed by the level of construction and production technology. The building cost can also be considered to be a design condition.

Those of the above conditions that are taken to be major conditions in this design are as follows.

(1) Conditions resulting from the Design Policies

- o Selection of the planning, structural system and materials is to be made so that flexibility with respect to future change is emphasized so that additions, rearrangement of room partitions and relocation or extention of the facilities and services are all possible.
- o The prevention of laboratory disasters is also given primary importance by having a plan with a safe plan for evacuation and that enable a clear separation between 'clean' and 'dirty' zones.
- o Reduction of the building running cost is also planned for with a plan and section planning that allows for natural illumination and ventilation.

(2) Meteorological and Natural Environment Conditions

- o The room placement and section planning will be such that the strong sunlight from the east and west does not enter the rooms directly.
- o The room placement and section planning, and the directions of prevailing winds will be considered so that natural ventilation is easily secured and so that odors from the animal house do not flow into rooms for general use.
- o The rooftop, roof, section and materials planning are to be considered to prevent the strong sunlight and heavy rain.

(3) Room Usage Conditions

- o The materials planning is to allow for easy sanitary management.
- o The laboratories are to have modular coordination allowing a high degree of freedom as regards the use of laboratory benches, shelves, sinks and other equipment.

(4) Conditions Generating from Local Customs and Manners

- o There are no points that are particularly different from a building in Japan but the plan should have a flat floor, be able to be partitioned into small spaces, and should also consider security.

(5) Local Construction Technology and Production Technology Conditions

- o Special systems of construction (such as suspended, prestressed and prefabricated structures) shall be avoided.
- o The use of steel-frame construction should be avoided as much as possible (for reasons of cost).
- o Local materials and construction systems shall be positively incorporated.
- o materials and equipments shall be selected for easy maintenance.

(6) Conditions Relating to the Architectual Design

This facility will give consideration to the appearance from the nearby expressway since it will be able to be clearly seen from persons traveling in automobiles along the expressway.

In particular, the roof, the facility layout and the view from above are considered important since the facility will be seen from above by persons using the Alabang Interchange.

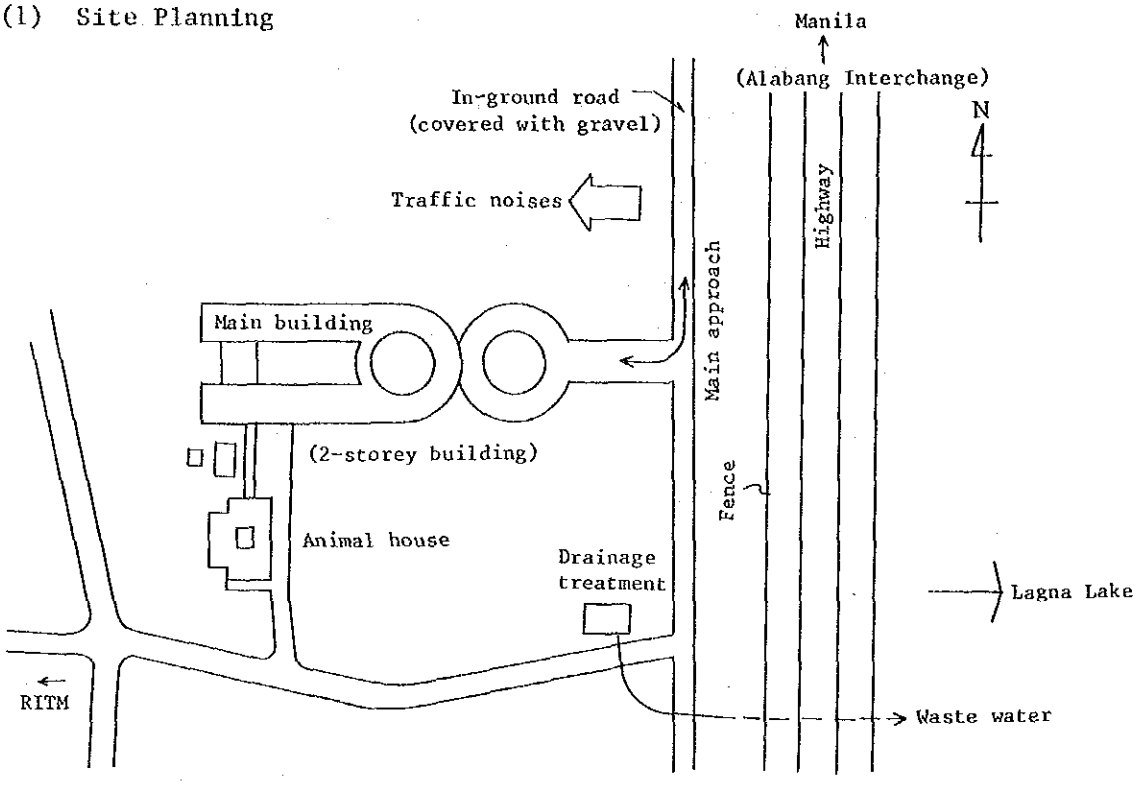
Another important design condition is that the building interior be both easy to use and easy to maintain in a clean state.

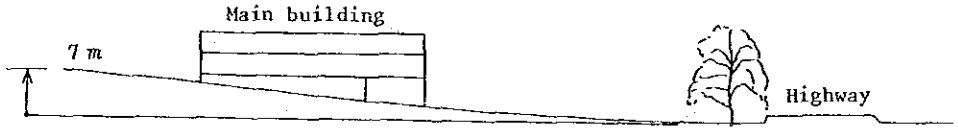
(7) Other Conditions

- o An air conditioning system that can be operated within the limits of the maintenance and operation budget of the owner, and that allows for future extension shall be installed.
- o The site planning, the site landscaping and infrastructure shall be interconnected so that the load to be borne by the Government of the Philippines is held to the minimum.

3. Basic Design

(1) Site Planning





The points to be noted in the placement of the building are as follows.

1) The building axis is such that sunlight from the east and west is not received. (Blocking the sun from the west is important for the energy conservation.)
2) The building axis is such that natural ventilation due to the prevailing winds is possible throughout the year.
3) The building axis is such that the natural slope (approximately 2.5°) of the land is used.
4) The building is palced so that it can be well attracted from the Highway and from the Alabang Interchange in particular.

5) The building is placed so that the facility and electrical service lines are short and have a rational distribution.

As shown in the diagram above, the building axis is east-west so that sunlight from these directions does not enter the rooms, and so that natural ventilation is possible.

In addition, having an east-west axis enables the slope of the site to be utilized for natural drainage of rainwater and waste water. This water flows to the south-east corner of the site where it can be led to a treatment facility. The building location has the inspection, evaluation, registration and management sections in the one building, while the animal house that requires contact with the ground and also has frequent comings and goings of goods and people is a separate building for the purposes of management. Also, the transformer, pumps, water treatment, generator unit and other main equipment is combined into an energy plant that has a separate building to enable easy correspondence to future extension.

(2) Architectural Planning

The broad organization of the BFAD is as follows.

1) Management Services	Office of the Director
	Administrative Division
2) Technical Services	Product Evaluation Division
	Inspection Division
3) Laboratory Division	

The functions of each of these are as follows.

a. Management Services:

This has the core functions of the facility and has planning, accounting, personnel management and purchasing functions as well as equipment for final determination.

b. Technical Services

Performs approvals, guidance and registration with respect to the manufacture of drugs, food and quasi-drugs handled by the B.F.A.D., and also performs inspection, guidance and sampling with respect to manufacturing facilities. It is the division that links the center with the facilities it administers.

c. Laboratory Division

Here, the sampled drugs, food and quasi-drugs are given physico-chemical tests, biological tests and toxicological tests to determine whether or not they conform to standards.

The animal house belongs to this division.

The facility constitution is as follows.

Building: Building floor area (including balconies, piloties, etc.)	5,780 m^2
a) Main building	4,475
b) Animal house	1,160
c) Energy plant	120
d) Dangerous good storage	10
e) Sewage treatment plant (Building part)	15

Other facilities:

a) Sewage treatment plant (related to treatment tank)
b) Waste disposal facility

1) Floor Planning

The floor plans of this facility give precedence to the functions of the previously mentioned sections while maintaining good interrelationships between them as far as the flow of goods and people is concerned.

As can be seen from the appended drawings, the first floor utilizes the lowest part of the site. People are led from the main gate to the approach leading to the piloti section which houses the Technical Services section and the Administrative Section, which both have a relatively high frequency of outside visitors. Although it is desirable that the Laboratory Division also be located on the first floor in consideration of the bringing in and out of equipment and the relationship to the animal house, it was placed on the second floor for reasons of sanitation, ease of air supply and discharge and ease of plumbing and wiring and also because priority was given to clear access to persons visiting the

building. Furthermore, the Director's Office, the library, conference room and other common rooms were placed on the second floor.

The animal house has a clear separation between 'clean' and 'dirty' zones, while consideration was also given to achieving natural illumination and ventilation for each room.

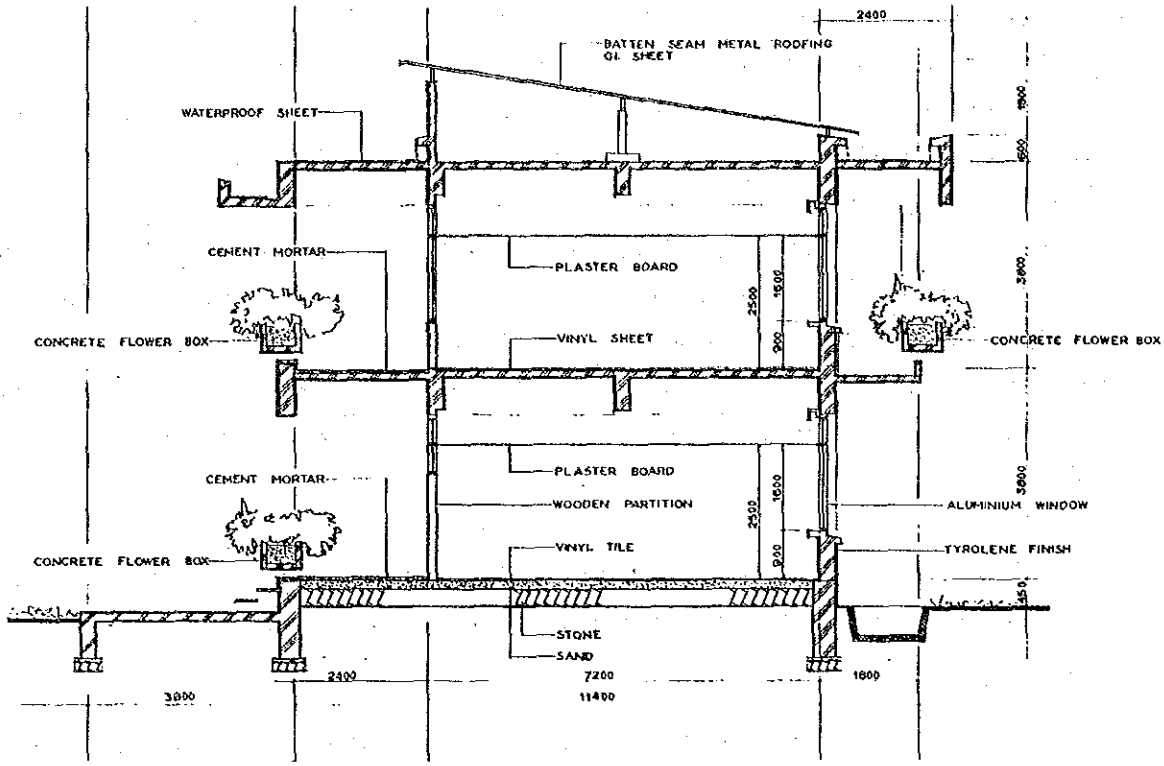
The room size and the column span was based on the method in which the laboratories are to be used and the dimensions that resulted from an investigation into the standard facilities in the many existin laboratories, the placement of the laboratory benches and the energy lines, etc. were 6,400 mm by 7,200 mm. The sizes of the rooms are based on these dimensions.

Moreover, the one-sided corridor method was used to facilitate natural illumination and ventilation, and balconies were provided on the outside to provide safety, flexibility and to block direct sunlight.

2) Section Planning

The section of the main building is as shown in the following diagram. The floor height is sufficient (3,800 mm) to facilitate natural ventilation while balconies are provided on the second floor to block the sunlight, prevent rain from being carried inside and to provide emergency exits. There is a double roof for added thermal insulation and to provide an extra waterproof layer.

The laboratories that house the central functions of this facility are placed on the second floor where the discharge of laboratory air, ventilation and drainage are facilitated.



3) Structural Planning

a. Design policies

The Philippines lies along the circum-Pacific earthquake belt and is subject to frequent earthquakes of considerable magnitude. The design earthquake force is slightly smaller than that for Tokyo but still necessitates adequate earthquake design.

The Philippines adopts the U.S. standards for all calculations standards relating to earthquakes. These codes are well provided provisions and are contained in "The National Building Code," and "The National Structural Code for Buildings." Metropolitan Manila contains many hotels, department stores and office buildings, etc. which have all been constructed according to these codes. This building for the project shall also be constructed in conformity with the same codes.

b. Foundation planning

The results of a boring survey and test excavation on the site showed that black topsoil was present to a depth of between 0.5 m and 1.0 m. Digging deeper showed the presence of a light yellow and highly-clayey soil known locally as 'adobe.' The results of standard penetrometer tests showed that the N-value was above 10, thus indicating that the soil is extremely compacted and clayey. A boring survey was carried out to a depth of 15 m and the 'adobe' turned to shale and it is assumed that a thick soil lies deeper.

The upper 'adobe' layer is sufficient for the support of this building. Direct foundation method will be used. From the survey it was also apparent that the clayey soil exhibits no particular swelling when it absorbs water.

c. Frame planning

This facility is divided into the three buildings of the main building, the animal house and the energy plant. The main building is a two storey structure while the animal house and the energy plant are both single-storey structures. These buildings have expansion joints and are structurally three separate buildings.

The three buildings are built of reinforced concrete with a steel roof shading. The floor plan is designed on the basic dimensions of 6,400 mm by 9,600 mm. These dimensions give a reasonable structural span which is not particularly difficult at any part.

The building is in Alabang area which is in Wind Zone II, having wind speeds of up to 175 km/hour (48.6 m/sec) that must be withstood. The design was performed using 0,15 as the base shear coefficient with respect to the seismic forces.

4) Facility Planning

a. Electrical planning

The electrical equipment and machinery shall form a system that is reliable and durable, safe to operate and easy to maintain and manage.

(a) Power supply system

A line is taken from the 34,500 V overhead line of the National Power Corporation to the south of the site and led to a concrete pole provided with a transformer to drop to voltage on the secondary side to 3-phase, 3-wire 220 V 60 Hz that is led to the transformer room.

(b) Substation system

The necessary main cables are run from the electrical room which is supplied with an AVR (Automatic voltage Regulator) to keep the power at the required load.

(c) Generator system

A generator unit is provided as a backup against power failure, and also for use as a power source in case of emergency, for preservation and for special equipment.

(d) Main line and motor control system

The power supplied consists of general use power, power for use in laboratories, and lighting and outlets. The motor control system is simple and takes both the operation and the maintenance into acount.

(e) Lighting and outlet system

General lighting within the building is by flourescent lamps while outlets are to be selected according to how they are to be used.

(f) Public address system

A public address system will be installed for the entire part of the building.

(g) Electric clock system

Electric clocks will be installed at necessary places in the buildings.

(h) Telephone system

A PABX will be provided so that both internal and external calls can be made.

(i) Master TV antenna system

The building will be provided with a television antenna and TV outlets will be provided where thought necessary.

(j) Interphone system

Interphone are provided at the necessary places for use in building maintenance and management.

(k) Lightning protection system

A lightning rod will be provided on the elevated water tank.

(l) Fire alarm system

An automatic fire alarm system is provided for quickly detecting and notifying of fire and preventing enlargement of the area sustaining damage.

b. Water supply and drainage planning

The system is to be one which is easy and inexpensive to operate and maintain.

(a) Water supply system

Well water is used after softening and sterilizing. A gravity method water supply system is used to simplify the sytsem.

(b) Drainage system

General purpose and animal waste water is discharged after treatment in a sewage treatment plant. The waste water from laboratories is given primary treatment and then sent to the treatment plant and discharged along with the general purpose waster water. Rainwater is directly discharged.

(c) Gas supply system

Gas is supplied from the LPG central devices to each of the laboratories by a central piping system.

(d) Firefighting system

A firefighting system such as indoor fire hydrants, etc. are provided in accordance with the local regulations after discussions with the Local Fire Department.

(e) Sewage treatment system

The method of sewage treatment is a combined system. This biological treatment system is easy to operate and maintain. The discharge water quality is BOD 20 ppm.

(f) Incineration system

A incinerator is provided for the combustion of waste such as animal corpses and beds, etc. of animals.

c. Air conditioning planning

The Philippines are a country with high temperatures and high humidity that means air conditioning expenses form a considerable portion of the maintenance expenses. This plan utilizes natural ventilation to the greatest degree possible while cooling is only performed for special areas. The use of GLP (Good Laboratory Practice) is considered for part of the laboratories.

(a) Air conditioning facilities

The types of air conditioners that are commonly used in The Philippines include the air cooled window type and the air cooled separate type. The individual type is chosen because of energy conservation and the purpose of use. Parts of the building that are not cooled, are provided with ceiling fans to promote cooling by ventilation.

(b) Ventilating system

Mechanical exhaust fans are provided in places (such as toilets, electrical room, etc.) where there is the concentrated generation of heat or odors.

(c) Air conditioning of animal house

The animal house is designed to correspond to SPF (Specific Pathologen Free) animals in the future but only the following air conditioning methods will be used partially for the present.

a) Air conditioning by natural ventilation only
b) Supply of pressurized, clean air to clean zones
c) Individual cooling and partial ventilation

5) Construction Materials and Equipments

Reinforced concrete was chosen as the material for the structure of the building because of its economy, durability and the local level of technology.

As is mentioned in the section dealing with the local technical level, that relating to the RC technical level is quite high. The external walls of the building are therefore to be made of exposed concrete, and finished with either an epoxy or acryl spray tile in considration of waterproofing and design.

The roof is to be a double roof because of the need for thermal insulation. The top is covered with concrete slab as a waterproof sheet and a steel roof erected over this.

Internal finishes are chosen in consideration of future flexibility, sanitation and ease of maintenance, while RC partition walls are avoided wherever possible, and substituted with timber ones.

Floors in the laboratories are to be long lengths of vinyl chloride linoleum because it is chemical-resistant, water-proof and sanitaton, with part of the floors being covered in PVC tiles.

The materials are chosen in consideration of local materials and methods.

Materials for the facilities and the electrical facilities shall be imported from Japan for reasons of longevity, reliability and economy. However, in the case of repairs or other management being necessary after completion, the part shall be taken to a local repair agency and repairs made using the materials at hand.

(3) Equipment Planning

1) Basic Policies

The following points will be given priority in the selection of the testing and analysis equipment so that the most suitable apparatus can be chosen.

a. Equipment will be chosen so that it will be suited to the technical level of the BFAD testing and analysis personnel.
The testing and analysis personnel in The Philippines are mainly persons who have graduated from the pharmaceutical departments of universities and have a fairly high level of technical training. There are also persons who have received training at the American FDA (Food and Drug Administration) and training in the clinical inspection departments of hospitals in Japan.

b. The testing and analysis items at the BFAD are based on those of the USP (United States Pharmacopoeia) and so the testing and analysis equipment was selected to be in conformity with the USP.

c. BFAD has an important role as the central facility with respect to the 12 regional health laboratories, and the laboratory facility is to be one equipped with modern equipment that can be used in the joint projects carried out by the ASEAN countries.

d. In the selection of the equipment, it is necessary that adequate thought be given to the equipment maintenance and management once the testing laboratories have been completed. Considering the technical level of the machine analysis technicians at the testing laboratory, the personnel configuration, and the maintenance and management expenses, it is desirable that the major items of equipment be durable, easy to maintain, and difficult to break down. Also, in the selection of the electronic equipment, the plan was made after confirmation of the frequency of use, the conditions for maintenance in The Philippines, the technical service, the electricity supply, and the stability of the voltage. In particular, computerized equipment having power stabilizers and power supply devices was chosen in order that loss of data and misoperation could be avoided.

e. The supply of distilled water is an important factor affecting the testing and analysis. Looking at the operations of hospitals and similar laboratories in The Philippines, the water quality is not particularly good and so this laboratory will be provided with its own water purification equipment in two stages so that the water is initially processed and then passed on to a distillation unit for the supply of distilled water.

f. In recent years, testing and analysis work in the technologically-advanced technologically countries is being conducted using electronic equipment and disposable products. However, in consideration of the conditions regarding the replenishment of disposable products and the maintenance and management environment for the facility after its completion, the basic testing and analysis methods that have been conventionally used will be kept, and the machines and equipment will be chosen with basic testing and analysis equipment constituting the main. Because of this, it will be possible to obtain similar parts in The Philippines for use as temporary substitute parts when machine parts and consumables have to be repurchased for replenishment at a later stage.

In view of the above, a survey was carried out for companies and agencies handling such machines in The Philippines, and the equipment selected on the results of the survey.

2) Selection of Equipment for Each Section

The functions of each section, the major equipments requried for the smooth and effective execution of the testing activities and the reasons for selecting the equipments are described below:

a. Micro-biology section

Major functions

- o Separation and identification of bacteria in foods and drugs
- o Separation and identification of food poisoning bacteria, Eumycetes, and Mycotoxins
- o Potency tests and axenic tests of antibiotics

Major equipments

Incubators, Axenic clean benches, Carbon dioxide incubators, Anaerobic jars, Culture type microscopes, Ovens, Balances, Stereoscopic type microscopes, Autoclaves, pH meters

Separation and identification of enteritis Vibrios, yellow staphylococcus, Salmonellas, and Escherichia coli., which account for food poisoning bacteria in The Philippines, are urgent concerns. In order to execute these tests and inspections, a micro-biology laboratory, a mutagenicity laboratory and an axenic laboratory equipped with incubators, axenic clean benches (NASA 100) and others are required to incubate and test a variety of bacteria. For anaerobic bacteria, carbon dioxide incubators and anaerobic jars are necessary to incubate and test.

Tests with optical microscopes are most commonly practiced in the micro-biology section, and so inverted culture type microscopes used only for incubation and stereoscopic microscopes with transmission light are necessary.

In addition, micro-biology tests require highly efficient incubators, clean boothes and low temperature containers for storage of strains and test samples. The provision of these equipments will greatly contribute micro-biology testing through correct sepration and identification of Eumecetes, Mycotoxins and mycotoxin producing molds.

b. Physico-chemical analysis section (food analysis)

Major functinos:

- o Instrumental analysis of ultramicro constituents
- o Chemical analysis of foods, toxic substances, and poisonous substances
- o Chemical analysis of milk, foods and fishes
- o Examination of quality control of food additives and testing methods for additives in foods
- o Testing and analysis of food pollution by chemical compounds and carcinogens
- o Analysis of trace heavy metals and residual agricultural chemicals

o Detection of harmful substances contained in tools and packages for foods

Major equipments:

Electron microscope, HPL chromatographs, Double wave double beam spectrophotometer, Gas chromatograph-mass spectrometer, Atomic absorption spectrometer, Gas chromatographs (FID, ECD, FPD), IR spectrophotometer, Fluorescence spectrophotometer, Spectrophotometers, Dual wave scanner, electrophoresis sets, Centrifuge, Balances for chemical analysis

Major analytical items conducted with the above listed equipments:

The gas chromatograph-mass spectrophotometer is used to determine accumulating subsances which remain in foods, drugs and the human organs and to monitor ultramicro organic substances.

The electron microscope (scan type) perform observation of biological samples such as bacteria, virus, tissues, non-biological chemical substances, metal particles, foreign substances in foods and durgs and of steric structure on a sample surface. The selected electron microscopes of a convenient scan type have the maximum magnifications of 150,000 and can cover areas where optical microscopes can not be used.

c. Physico-chemical analysis section (drug analysis)

Major functions:

a) Testing of drugs, toxics and poisons, crude drugs and injection drugs
b) Development of quality, safety and testing methods of medicinal substances
c) Monitoring cosmetics, quasi-drugs, medical devices and toxic substances, and development of testing methods
d) Quality evaluation of crude drugs

Major equipments and testing items:

Since equipments and testing items used in this section are the same with those for the food analysis in (3)-2)-b, they are not especially mentioned here.

However, in instrumental analysis the instruments listed below require special accuracy and so special rooms only for these instruments are provided:

a) Electron microscopes
b) Gas chromatograph-mass spectrometers
c) Optical microscopes
d) Balances for chemical analysis
e) Centrifuge
f) Equipments for chemical analysis

d. Toxicology section

In order to perform safety tests for foods and drugs, the following tests are conducted using good quailty test animals.

Major functions:

Drug metabolism testing
General toxicity testing
Functional toxicity testing
Carcinogenicity testing
Pathological inspection by dissection of internal organs
Pyrogenecity tests
Skin mucosae stimulation tests
Allergy tests
Histamine-induced blood pressure reduction tests
Insulin activity determination

Major equipments:

Pyrogen testing units, Refrigerators, Dissecting tables, Photographic set (for viscers), Micro-slide manufacturing unit, Microtome sets, Plygraph unit, Binocular microscopes, Centrifuges, Incubators

Good quality test animals (mouse, rat, guinia pig and rabbit) which are bred in the test animal house are used to perform safety, carcinogenicity, general toxicity, allerginicity and pyrogenecity tests for foods and drugs.

e. Animal house

The usefullness of foods and drugs is generally evaluated based on the balance between the effectiveness and the safety.

Any drugs have to assure 100% safety and effectiveness to "human body" and avoid any side effects in the course of development and use.

However, drugs are mostly foreign to human body by nature, and thus any misuse could lead to cancellation of the aimed effectiveness with high risks of the side effects.

The recent thalidomide tragedy gave us a rare chance to reconsider and improve safety of drugs.

Current development tests for drugs are based on the above mentioned basic idea, and this requires facilities which can thoroughly perform safety tests.

For these reasons, a test animal facility which is well managed to provide high quality test animals is required. This facility has to be organized in coherence from animal raising, breeding to manufacturing of feeds.

Major equipments for test animals

Cages for raising and breeding (for mouse, rat, guinea pig, rabbit, cat, monkey)
Large autoclave (double door type)
Cage washer
Pass box
Work tables
Fooder manufacturing unit

f. Management, Monitoring and Inspection Section

It is necessary that these sections handle a great volume of data and so the introduction of computers is desirable.

3) Equipment list

a. Microbiology section

Optical microscope, system type
Optical microscope, culture type
Optical microscope, binocular type
Optical microscope, stereoscopic type
Centrifuge
Incubator CO_2
Anaerobig jar
pH meter
Hot air sterilizer
Autoclave
Incubator
Water bath
Rotary evaporator
Oven
Refrigerator
Freezer
General laboratory equipments
Laboratory bench
Side bench
Sink units
Laboratory cabinet
Fume cupboard
Fume hood, biohazard

b. Physico-chemical analysis section (foods)

Hot air sterilizer
Refractometer, ABBE
Stereoscipic microscope
Autoclave
Crusher
Shaker
Incubator
Water bath
Spectro meter
Spectro color meter
Centrifuge
Homogenizer
pH meter
Rotary evaporator
Oven
Refrigerator
Freezer
General laboratory equipments
Laboratory bench
Side bench
Sink units
Laboratory cabinet
Fume cupboard

c. Physico-chemical analysis section (drugs)

Polarimeter
Thin layer apparatus
Hot air sterilizer
Refractometer, ABBE
Stereoscopic microscope
Autoclave
Vacuum oven
Centrifug
Homogenizer
Balance
pH meter
Rotary evaporator
Oven
Refrigerator
Crusher
Shakerer
Incubator
Water bath
Spectro meter
Spectro color meter
Freezere
General laboratory equipments
Laboratory bench
Side bench
Sink units
Laboratory cabinet
Fume cupboard

d. Toxicilogy section

Binocular microscope
Centrifuge
Homogenizer
pH meter
Thin layer apparatus
Oven
Refrigerator
Freezer
General laboratory equipments
Laboratory bench
Shaker
Incubator
Water bath
Rotary evaporator
Side table
Sink units
Laboratory cabinet
Fume cupboard

e. Other equipment analysis sections

Electron microscope, scanning type	Fluores microscope
Gass chromatograph-mass spectro	Polarizing microscope
HPL chromatograph	Metallic microscope
DW, doublebeam	Water still unit
Spectrometer	ION exchange water
Atom absorption spectrometer	Analytical balance
Gas chromatograph (FID)	General laboratory equipments
Gas chromatograph (ECD)	Low temperature room (5°C)
Gas chromatograph (FPD)	Cold room (-10°C)
IR spectrometer	Icemachine
Fluorescence spectrometer	Fume cupboard
Dual wave scanner densitometer	Fume hood, biohazard
Muffle furnaces	Laboratory bench
Centrifuge, ultra	Side bench
Ditto, large-capacity	Sink units
Ditto, refregerated	Laboratory cabinet
Research microscope unit	Bench, for balance

f. Animal house section

Animal cage, mouse
Animal cage, rat
Animal cage, guinea pig
Animal cage, rabbit
Animal cage, cat
Animal cage, monkey
Large autoclave
(double door type)
Cage washer
Pass box
Work table
Fooder manufacturing unit
Dissecting table
Photographic set (for viscers)
Micro-slide manufacturing unit
Microtome set
Polygraph unit
Hot air sterilizer
Autoclave
Binocular microscope
Centrifuge
Homogenizer
Incubator
General laboratory equipments
Balance
Pyrogen testing unit
Refrigerator
Laboratory bench
Laboratory cabinet
Photo develop equipment

g. Inspection section

Audio-visual aids
Photocopy machine
Electric typewriter
Computer unit
TV and video cassette
Darkroom equipments