

STUDY REPORT  
ON  
THE PROJECT FOR  
STRENGTHENING  
PROVINCIAL LABORATORIES FOR  
QUALITY CONTROL  
IN  
THE REPUBLIC OF INDONESIA

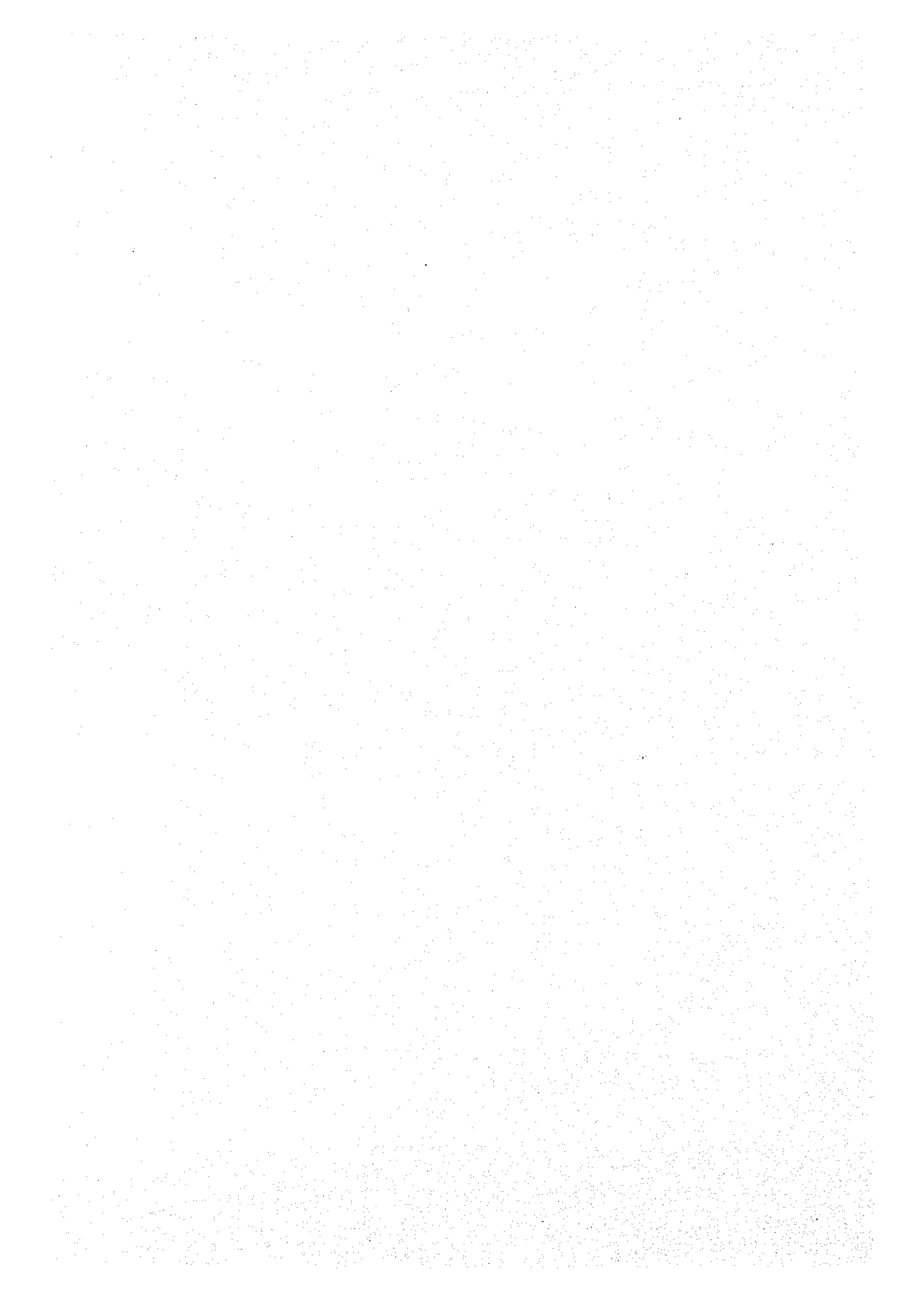
February 1995



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Japan International Cooperation Agency (JICA)





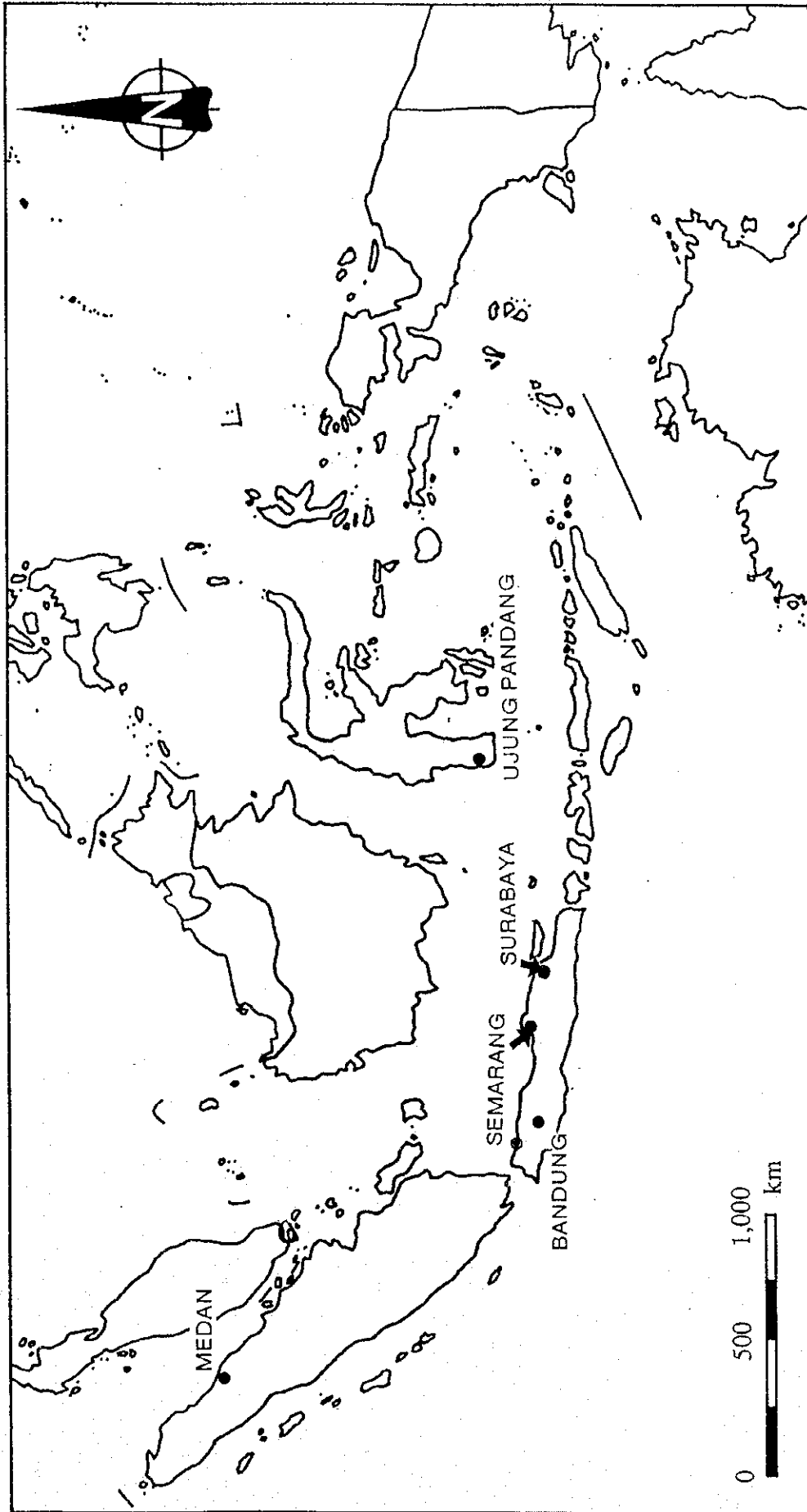
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## Chapter 1 Background of the Project

### 1. Background of the Request

#### (1) National Land and Natural Conditions

The Republic of Indonesia (hereinafter referred to as Indonesia) is located between Lat.  $06^{\circ} 08' N.$  and Lat.  $11^{\circ} 15'$ , and between Long.  $94^{\circ} 45'$  and  $141^{\circ} 05' E.$  The country is composed of 13,667 large and small islands, however, of these only 922 or 7% are inhabited with the rest being uninhabited.

The islands of this great island nation stretch 5,110 km from east to west and 1,888 km from north to south, and the national land area is 191,944,300 ha.

As Indonesia is situated between the two continents of Asia and Australia, dry easterly seasonal winds give it a dry season lasting from June to September, and moist westerly seasonal winds give it a rainy season from December to March. April, May, October and November are intermediary periods between the two main seasons. The country lies within the marine tropical belt, giving it a mean temperature of  $27^{\circ}C$  and a mean maximum temperature and mean minimum temperature on the plains of  $33^{\circ}C$  and  $27^{\circ}C$  respectively. These temperatures are not as high compared with those of a continental tropical climate. Humidity, however, ranges from between 60% to 100% with a mean value of 78%.

#### (2) National Economy

The major issues currently facing the economy of Indonesia can be summarized as follows.

- a) The international balance of payments and the fiscal balance are deteriorating and cumulative liabilities are becoming a serious problem. In an effort to counter these problems, the Government of Indonesia is planning structural adjustment programs (reconstruction of the monetary system, control of fiscal expenditure, the delay of liability repayments and the

- promotion of non-oil product exports etc.) in response to recommendations from the IMF and World Bank etc.
- b) The inefficiencies of the manufacturing, agricultural and other production sectors which received moderate protection during the period of stable growth of the oil revenue are becoming apparent. In response to this problem, the Government of Indonesia is examining and implementing measures such as the reduction of various subsidies and the reexamination of preferential financing and import and export regulations etc.

The fifth five-year national development plan, which targeted the period between April 1989 and March 1994, was the final plan within the first 25-year long-term development plan and aimed to lay the foundations for the second long term plan, which will commence with the implementation of the sixth-five-year development plan. If the fifth plan achieves its objectives, it is expected that Indonesia will achieve further economic growth during the sixth plan, although the country is facing a number of serious problems as it prepares to commence the sixth plan. The greatest of these is the fact that the country must achieve a real economic growth of 5% per year in order to provide ample employment opportunities for its working population, which is rapidly expanding in line with the growing national population. For this purpose, the industrial sector in particular needs to make large advances.

With the prospects of oil and gas products not looking very optimistic, increased exports of non-oil and gas products and greater general tax revenue must be largely relied upon in order to secure funds for the investment that is necessary to achieve the desired economic growth. Exports of non-oil and gas products must at least double and general tax revenue must roughly triple over the next five years. Moreover, private sector investment must be relied upon in order to make up for those areas which cannot be covered by government investment. Thus, the policies



which have been implemented since 1985 must be bolstered in order to give an impetus to private sector corporate activity. Following that, aid from foreign countries will have to be relied upon to make up any remaining deficit. It is estimated that the total amount of investment that is required to ensure an annual average economic growth of 5% will be Rp. 239.1-trillion over the five years of the sixth development plan.

The rate of investment in the final year of the fourth development plan (FY 1988) was 22.7% of the GDP. This had grown to 27.7% by the final year of the fifth plan (FY 1993). The mean investment rate for the five years of the sixth plan is planned at 26.4%.

The total amount of expenditure in the development budget of the fifth development plan was Rp. 107.5-trillion, which represented an increase of 126.3% over the Rp. 47.5-trillion in the fourth plan. Similarly, the development budget for the first year of the fifth plan (FY 1989) was Rp. 13.1-trillion or an increase of 47.2% over the Rp. 8.9-trillion for the final year of the fourth plan (1988).

The main purpose of development expenditure is the achievement of balanced growth in the sectors of industry and agriculture. The main objectives in the field of agriculture are the securing of self sufficiency in foodstuffs and the increase in production of export products and raw materials for industry. The main objectives in the field of industry are the expansion of exports, the bolstering of domestic demand, the promotion of employment and the expansion of private sector operations. Other objectives include infrastructure development in such areas as irrigation, transportation, communications, power and water works etc., and the diversification of energy sources for industrial development is a particular goal.

### (3) Outline of the Sector

One of the policies of the fourth five-year development plan (Pelita IV), which started in 1984, dealt with family planning

works, improvement of the national standard of health and raising of the level of medical care services .The basic policies for this were made the five major objectives of the National Health System (commonly known as SKN). The five objectives can be summarized as follows:

- a) The creation of a climate in which citizens strive to maintain their own health,
- b) The strengthening in the quality and quantity of medical care workers,
- c) The securing of drug and food supplies and stronger monitoring of harmful substances,
- d) Improvement in the nutrition levels and nutritional condition of citizens, and
- e) The preparation and implementation of related laws.

Moreover, drugs are regarded as strategic items for raising the health standards of citizens and improving medical care services, and their importance is prescribed as follows in the National Drug Policy (commonly known as KON):

- a) Contribution to the welfare of citizens through ensuring the stable supply of essential drugs and preventing unfair rises in medical charges,
- b) Self sufficiency in the production of raw materials for important drugs,
- c) The natural selection of drug items and types through stricter registration, authorization and review of existing drugs, and the strengthening of price and quality monitoring,
- d) The protection of citizens' benefits through proper adjustment of distribution.

In accordance with these basic policies, the Government of Indonesia has, since the fourth five-year national development plan, advanced the strengthening of the National Quality Control Laboratory of Drug and Food (NQCL-DF), which is the central agency for the achievement of the objectives of ensuring a

stable supply of cheap and good quality drugs, establishing a setup to monitor poor quality drugs, and establishing a setup to monitor the safety levels of drugs that are available on the market etc. In 1985, a new laboratory was constructed through Japanese grant aid, and following that, technical assistance via the dispatch of specialists in the six fields of experimental animal management, pharmacology, toxicity, microbiology, biological pharmacology and standard items was carried out until March 1989. During the period of technical assistance, 21 trainees from Indonesia were invited to Japan and a total of 48 long-term and short-term specialists were dispatched to Indonesia, and the assistance covered a number of wide ranging areas. Moreover, various analysis and investigation equipment, totalling approximately 300-million yen in value, was provided to the NQCL-DF. In this way, the assistance strengthened the functions of the said agency in terms of both software and hardware. The NQCL-DF is the superior agency for the Provincial Quality Control Laboratories of Drug and Food (PQCL-DF) located in each of the country's 27 provinces, however, it does not carry out all of the ordinary analysis work. The NQCL-DF is responsible for establishing experiment methods and manufacturing and distributing standard items, which are required by the PQCL-DF, carrying out the training and education of PQCL-DF employees, and performing pyrogen and germ free experiments which cannot be carried out by the PQCL-DF.

It can thus be seen that the monitoring system of quality and safety levels at the central level has been firmly established, however, at the provincial level where each PQCL-DF performs sampling of products taken from the manufacturing and distribution stages, and performs actual analyses and investigations based upon the methods that have been established by the NQCL-DF, the state of preparation of analysis equipment and facilities is backward and the analysis and investigation implementation setups are lacking compared with the central NQCL-DF.

Meanwhile, the population of Indonesia in 1990 was measured to be 179-million and this is expected to increase to 215-million by 2000. The demand for drugs and food etc. is increasing every year in line with the growing population, and the number of drugs registered with the Ministry of Health as of 1994 amounts to 13,645 items. Furthermore, the number of food and drink items registered with the Ministry between 1988 and 1993 amounted to 14,260. Under these circumstances, it is necessary that the quality and safety levels of drugs and food etc. be inspected and confirmed in the manufacturing and distribution stages, and that proper administrative guidance be provided to companies. Such activities are the responsibility of the PQCL-DF, the role of which is thus becoming extremely important.

(4) Background of the Project

PQCL-DF are located in each of the 27 provinces within Indonesia, and according to the size of their supervision districts, they are divided into either type-B PQCL-DF (in eight provinces) and type-C PQCL-DF (19 provinces). Incidentally, the NQCL-DF is the solitary type-A body. The major functions of both the type-B and type-C PQCL-DF can be summarized as follows:

- a) To carry out administrative guidance to manufacturers and distributors in order to control the quality and safety levels of drugs and food etc. in the stages of manufacturing, distribution and storage,
- b) To carry out analysis and investigation of drug and food samples taken from the manufacturing, distribution and storage stages, in order to confirm the quality and safety levels of the products, and
- c) In cases where products fail to meet quality and safety levels as a result of the analysis and investigation, to recommend to manufacturers the stoppage of production and the recall of the problem products etc.

The five PQCL-DF which have been targeted under the Project are required to carry out analysis and investigation of more than 5,000 drug samples, 5,000 food and drink samples, 2000 cosmetic samples etc. and 1,000 samples of traditional and herbal medicines every year. However, the capacity of each PQCL-DF to analyze and investigate the ever growing numbers of drugs and foods etc. is steadily declining due to inadequate equipment and facilities and insufficient staff training. The analysis and investigation performance of the five targeted laboratories is not only well below the aforementioned required targets, but the analysis and investigation capacity of the laboratories is also well below that of other type-B PQCL-DF.

The improved training of staff and the improvement and preparation of analysis and investigation equipment in each PQCL-DF are indispensable and strongly desired in raising the analysis and investigation capacity and accuracy levels. However, due to an insufficient budget at the Ministry of Health, budgetary measures for the improvement of the PQCL-DF cannot be taken, and the resolution of the current conditions with the present implementation setup is extremely difficult.

Under these circumstances, the Government of Indonesia, realizing that the strengthening of equipment and facilities and the development of staff at the PQCL-DF were the most vital measures needed to strengthen and improve the system of drug and food investigation etc., compiled the Project and then requested the Government of Japan to provide grant aid for its implementation.

## 2. Contents of the Request

The requested items are as follows.

| <u>No.</u> | <u>Requested Equipment</u>              | <u>Quantity</u> |
|------------|---|-----------------|
| 1          | High performance liquid chromatographer | 5               |
| 2          | UV-VIS spectrophotometer                | 5               |

|    |  |    |
|----|--|----|
| 3  | TLC scanner                                | 5  |
| 4  | Gas chromatographer                        | 5  |
| 5  | Atomic absorption spectrophotometer system | 5  |
| 6  | Dissolution tester                         | 3  |
| 7  | Spectrofluorophotometer                    | 4  |
| 8  | Kjeldahl nitrogen determination            | 4  |
| 9  | Potentiograph                              | 4  |
| 10 | Polarographic analyzer                     | 3  |
| 11 | Disintegration tester                      | 5  |
| 12 | Karl Fisher titator                        | 3  |
| 13 | Polarimeter                                | 4  |
| 14 | Refractometer                              | 3  |
| 15 | Fume hood                                  | 1  |
| 16 | Clean bench                                | 3  |
| 17 | Autoclave                                  | 2  |
| 18 | Colony counter                             | 5  |
| 19 | Stomacher                                  | 5  |
| 20 | Filtering apparatus for sterility test     | 5  |
| 21 | Low temperature incubator                  | 5  |
| 22 | Platinum wire loop                         | 20 |
| 23 | Water distillation apparatus               | 4  |
| 24 | Water purifier apparatus                   | 4  |
| 25 | Microwave digestion                        | 5  |

## Chapter 2 Contents of the Project

### 1. Objectives of the Project

The Project aims to achieve the following objectives by preparing and strengthening the analysis and investigation equipment at the PQCL-DF located in the major cities of Bandung, Semarang, Surabaya, Ujung Pandang and Medan:

- a) To strengthen the analysis and investigation capacity of each PQCL-DF in both quantity and quality terms and so enable each laboratory to achieve its yearly analysis and investigation sample quota,
- b) To standardize the analysis capacity of each PQCL-DF by prescribing standard analysis and equipment lists and facilities,
- c) To strengthen the setup for monitoring harmful drugs and foods etc. by establishing a network between the NQCL-DF and each PQCL-DF, and
- d) By achieving the above mentioned objectives, to aim for the supply of good quality, fairly priced and safe drugs and foods etc. onto the market, and the establishment of a food hygiene system.

### 2. Outline of the Project

#### (1) Responsible and Executing Agency of the Project

The Responsible and Executing agencies for the Project are as follows:

- 1) Responsible Ministry: Ministry of Health
- 2) Executing Agency: Directorate General of Drug and Food Control

The agencies targeted for Project implementation are the aforementioned five Provincial Quality Control Laboratories of Drugs and Food which are attached to the Directorate General of Drug and Food Control.

## (2) Maintenance Plan

It is judged that the five targeted PQCL-DF independently purchase the minimum test samples and equipment etc. required for performing analyses and investigations, and that they take the minimum required budgetary measures.

In the event where new analysis and investigation equipment is procured through the Project, budgetary measures for the maintenance of the new equipment will be taken. Moreover, until now, the training of the PQCL-DF staff has been periodically carried out at the NQCL-DF, however, in the event where the new analysis and investigation equipment is procured, it is planned to increase the number of trainees from the target PQCL-DF and carry out thorough training in the handling of the new equipment. For this reason, it is planned that the extra training costs be included within the bounds of an increased NQCL-DF budget.

## 3. Design Concept

### (1) Examination of Basic Conditions

The Project is designed to carry out the preparation and strengthening of analysis and investigation equipment at five PQCL-DF, which are responsible for investigating and confirming the quality and safety levels of drugs and foods etc. in the manufacturing and distribution stages. The methods of drug and food investigation that are adopted by the PQCL-DF are all based upon mainly those methods which have been developed by the NQCL-DF. Therefore, the selection of the equipment to be introduced has been made conditional upon, as a minimum, the NQCL-DF already possessing the equipment and the investigation methods used with the equipment having already been established.

In carrying out the Project, the Indonesia side is planning to improve the capacity levels of the PQCL-DF without resorting to staff increases. For this reason, each item of analysis and investigation equipment shall be provided with an attached data



processor to perform the rapid processing of analysis results etc.

(2) Examination of Equipment

|      | Equipment Category               | Main Purposes of Use  |
|------|----------------------------------|---|
| I.   | Chemical-Physical Test Equipment | Identification investigations and strength tests etc. of drugs; identification and strength tests etc. of food and drink additives, aflatoxines, residual agricultural chemicals, heavy metals and lard etc., and identification and strength tests etc. of traditional and herbal medicines etc. |
| II.  | Microbiology Test Equipment      | Strength tests, germ free tests and pyrogen tests of drugs, and germ free tests etc. of foods, drinks and cosmetics etc.  |
| III. | General Equipment                | General equipment required for performing chemical analysis   |

#### 4. Basic Design

| No. | Name of Equipment                          | Specifications & Contents   | Q'ty |
|-----|--|---|------|
| 1   | High performance liquid chromatographer    | Data processor, four types of detector (UV-VIS, RI, FP, ECD), and system controller               | 5    |
| 2   | UV-VIS spectrophotometer                   | Data processor and auto sampler   | 5    |
| 3   | TLC scanner                                | Data processor and one spreading and developing set   | 5    |
| 4   | Gas chromatographer                        | Data processor and detectors (type A: ECD & FPD, type B: FID & FTD)                               | 5    |
| 5   | Atomic absorption spectrophotometer system | Frameless type with data processor  | 5    |
| 6   | Dissolution tester                         | Six shafts and temperature adjustment (RT-50 °C)  | 3    |
| 7   | Spectrofluorophotometer                    | Measuring wavelength range: 220-700 nm, fluorescence holographic, data processor                  | 4    |
| 8   | Kjeldahl nitrogen determination            | Dissolution, distillation, titration and quantity recorder  | 4    |
| 9   | Potentiograph                              | Potentiometric titration apparatus, titration control apparatus, graphic printer and auto viewlet | 4    |
| 10  | Polarographic analyzer                     | X-Y recorder  | 3    |
| 11  | Disintegration tester                      | Toyama type   | 5    |
| 12  | Karl Fisher titator                        | Measurement range: 1-100mg, 0.001-100%  | 3    |
| 13  | Polarimeter                                |   | 4    |
| 14  | Refractometer                              |   | 3    |
| 15  | Fume hood                                  | Water supply piping and gas piping  | 1    |
| 16  | Clean bench                                | Air capacity: 20 m <sup>3</sup> /min.   | 3    |
| 17  | Autoclave                                  | 100-129 °C, 0-1.67 kg/cm <sup>2</sup>   | 2    |
| 18  | Colony counter                             | 4-digit LED display, ring-type fluorescent lamp   | 5    |
| 19  | Stomacher                                  | 80-100 ml   | 5    |
| 20  | Filtering apparatus for sterility test     | Six branches, washing pipe  | 5    |
| 21  | Low temperature incubator                  | 254 liters, -10 - +50 °C  | 5    |
| 22  | Platinum wire loop                         |   | 20   |
| 23  | Water distillation apparatus               | Electric heating, 10 liters/hour  | 4    |
| 24  | Water purifier apparatus                   | Ion exchange type, 1.8 liters/hour  | 4    |
| 25  | Microwave digestion                        | 600 PSI, 12 samples   | 5    |

## Chapter 3 Project Evaluation and Recommendation

### 1. Project Effect

The analyses and investigations of drugs and foods etc. performed at the five targeted PQCL-DF account for roughly 40% of the analyses and investigations carried out in all Indonesia. The remaining 60% or so are shared by the other 22 PQCL-DF. It can thus be seen that the role played by the five target PQCL-DF is very important, and it is absolutely vital that as well as preparing and strengthening the equipment and facilities of each, the training of the laboratory staff also be carried out, in order to enable the laboratories to handle the drug and food analysis and investigation work which is expected to further increase in the future. Bearing in mind these circumstances, it is thought that preparation of analysis and investigation equipment at the PQCL-DF in Bandung, Semarang, Surabaya, Ujung Pandang and Medan will make a major contribution to improving the setup for investigating the quality and safety levels of drugs and foods etc. available on the market.

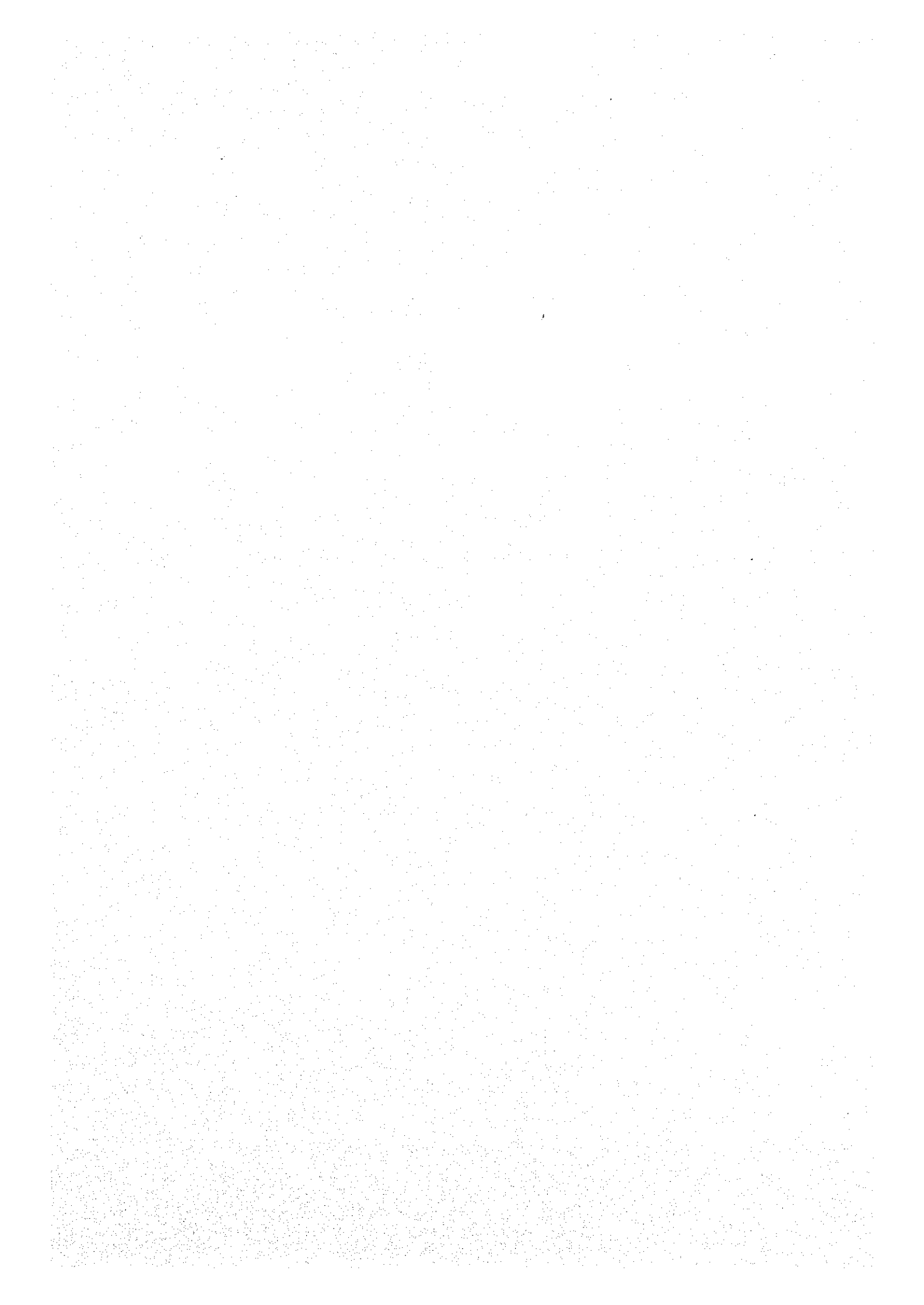
Implementation of the Project is expected to bring about the following specific effects:

- a) The strengthening of the analysis and investigation capacity of each PQCL-DF, which confirms and investigates the quality and safety levels of drugs and foods etc., in both quantity and quality terms, to thus enable each laboratory to achieve its yearly quota of analysis and investigation samples and items,
- b) The standardization of the analysis capacity of the PQCL-DF by prescribing standard analysis and investigation equipment lists and facilities, to achieve the consequent improvement in the accuracy of analysis and investigation results,
- c) The strengthening of the setup for monitoring harmful drugs and foods etc. by establishing a network between the NQCL-DF and each PQCL-DF, and
- d) The supply of good quality, fairly priced and safe drugs and foods etc. onto the market, and the establishment of a food

hygiene system through the achievement of a) - c)

## 2. Recommendation

- 1) Of the five targeted PQCL-DF, those in Bandung and Semarang are situated close to the capital Jakarta and can easily receive service from the equipment agents in Jakarta. The level of maintenance of the analysis equipment in these two laboratories is thus relatively good. However, the other three PQCL-DF (Surabaya, Ujung Pandang and Medan) are far away from Jakarta, and because much time and cost is required for the repair of equipment, breakdowns of equipment are greatly hindering the activities of each laboratory. It is therefore the wish of the Indonesia side to send employees for training in equipment makers in Japan and other foreign countries, in order to develop equipment maintenance staff. However, because almost all of the equipment breakdowns are caused by simple operational errors, it is considered that the thorough training of employees in basic equipment handling would be more effective than developing maintenance staff.
- 2) In view of the fact that items of precision machinery are included in the requested equipment, budgetary measures for maintenance and the purchase of spare parts are required to ensure the long-term and effective utilization of the machinery.
- 3) The Indonesia side has requested the dispatch of one long-term specialist in the field of chemical analysis as backup to the Project.



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