Report of the WHO Collaborating Centre for Quality Assurance of Essential Drugs

By Drs. R. Pandjaitan
(Head, National Quality Control Laboratory of Drug and Food)

I. Introduction.

National Quality Control Laboratory of Drugs and Food (NQCL DF) is a central quality control laboratory for pharmaceuticals and food commodities under the supervision of the Director General of Drug and Food Control, Ministry of Health.

Based on the Ministry of Health Act No. 145/Menkes/IV/1978, in 1978, NQCL DF was established. In the same year 27 Provincial Quality Control Laboratory of Drug and Food (PQCL DF), in each province in Indonesia were also established based on the Ministry of Health Act No. 146/Menkes/IV/1978. The objective of NQCL DF are:

1. To protect the consumers from adulterated or misbranded pharmaceuticals and food commodities.
2. To evaluate and to accredit the quality control laboratories of pharmaceuticals and food commodities.
3. To control and give guidance to all quality control laboratories of drug and food.
4. To stimulate the quality of domestic products of pharmaceuticals and food commodities to promote the volume of exports.

To meet these objective some activities which have been done are as follows:

1. As a referral laboratory to carry out specific tests.
2. To analyze the validity of the test result carried out by PQCL DF.
3. To support these tests, NQCL DF established method of analysis, national reference standards and regional reference standards.
4. For the purpose of microbiological test, NQCL DF also established freezed dried microorganisms.
5. For the biological test laboratory animals were breeded supported with and animal food fabrication.

To improve the capability of the personal from NQCL DF and PQCL DF training were held in NQCL DF. As a WHO Collaborating Centre for Quality Assurance of Essential Drugs, fellows from countries i.e. Nepal, Vietnam, Sri Lanka were trained.

II. Organization of NQCL DF.

National Quality Control Laboratory of Drug and Food is headed by a Director, has one Secretariat with 3 subdivision and 5 division, each with 4 sections.

(see Annex 1)

Human Resources.

National Quality Control Laboratory of Drug and Food has 192 personells and the
ARTIKEL

Provincial Quality Control Laboratory of Drug and Food have totally about 1,700 personells. In general those personells consist of about 40% university degrees, 40% analysts and technicians and about 15 - 20% administration and laboratory messengers.

Table 1

<table>
<thead>
<tr>
<th>No.</th>
<th>Education Qualification</th>
<th>Persons</th>
<th>Field (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Doctor degree</td>
<td>2</td>
<td>Chemical Synthesis and Microbiology</td>
</tr>
<tr>
<td>2.</td>
<td>Master degree</td>
<td>2</td>
<td>Pharmaceutical sciences and master of public health</td>
</tr>
<tr>
<td>3.</td>
<td>University degree</td>
<td>91</td>
<td>Pharmacist, veterinarian, biologist, chemist.</td>
</tr>
<tr>
<td>4.</td>
<td>Bachelor degree</td>
<td>10</td>
<td>Chemist, biologist, nutrition, finance</td>
</tr>
<tr>
<td>5.</td>
<td>Laboratory analyst</td>
<td>42</td>
<td>Pharmacist assistant, chemist technician</td>
</tr>
<tr>
<td>6.</td>
<td>Technician (technical)</td>
<td>3</td>
<td>Electrical and mechanical technician</td>
</tr>
<tr>
<td>7.</td>
<td>Laboratory Technician</td>
<td>16</td>
<td>Vocational, training</td>
</tr>
<tr>
<td>8.</td>
<td>Administration</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>192</td>
<td></td>
</tr>
</tbody>
</table>

III. Objectives.

1. To protect the consumers from adulterated or misbranded pharmaceuticals and food commodities.

2. To evaluate and to accreditate the quality control laboratories of pharmaceutical and food commodities.

3. To control and to give guidance to all quality control laboratories of drug and food.

4. To stimulate the quality of domestic products of pharmaceuticals and food commodities to promote the volume of exports.

IV. Functions of NQCL DF.

To achieve the objectives mentioned above National Quality Control Laboratory of Drug and Food has several functions as follows:

1. **Testing on Surveillance.**

To monitor the quality and the safety of pharmaceuticals and food commodities distributed in the market by testing.

   a. Validation Test.

   To analyze the validaty of the test result a carried out by PQCL DF. Substandard commodities are analyzed in NQCL DF to get the validated result as the basic consideration for further action by the Director General of Drug and Food. These sample are sent by PQCL DF and the validation test is decided by the Director of NQCL DF after requested by the related Directorate of Control.

   b. Referral Test.

   NQCL DF as a referral laboratory tested assential drugs including raw materials and finished product. Essential drugs mentioned in list C produced by non-governmental manufacture are tested by PQCL DF before distributed to hospital and other health care services. Several dosages forms from these essential drugs list and trade name such as antibiotics injection, infusion, oxytocin injection need biological tests that can not be done by PQCL DF such as abnormal
toxicity test, pyrogen test, potency of oxytocin, histamin test etc. This test are directly requested by PQCL DF and carried out in NQCL DF.


To test the quality of pharmaceuticals and food commodities in the process of registration and to validate the method of analysis used by the manufacturer.

3. Testing for Certification.

a. Essential drugs produced by the governmental manufactures and several non-governmental manufacturer designated by the Ministry of Health mentioned in list A1, B1, B2 are tested in NQCL DF for certification. These drugs consist of drugs, vaccines and medical devices and were released by the Quality Control Laboratory from each manufacturer.

b. Generic drugs produced by governmental manufacturer were tested especially on dissolution for certification before distributed in the market and hospitals. The product were tested by the producers on the same specification and were released before sending to NQCL DF for certification.

c. Pharmaceuticals and food commodities for exports require certificate from NQCL DF.

4. Establishment of Method of Analysis.

To obtain the same result of testing in NQCL DF and all PQCL DF. NQCL DF has to provide good reproducible method of analysis to test specification of pharmaceuticals and food commodities. These methods of analysis are developed especially for drug and medical devices which monographs are not mentioned in the pharmacopoeia and for other pharmaceuticals and food commodities which method are not mentioned in the official literature or other standards.

Each year NQCL DF establishes 100 method of analysis for drugs, traditional drug, food and beverage, cosmetic, medical device, narcotic, psychotropic and hazardous substances.

The studies of method of analysis consist of theoretical and practical aspect. National Quality Control Laboratory of Drug and Food collaborates with the universities such as Bandung Institute of Technology, University of Gajah Mada, and other Institute of Research such as Indonesian Institute of Sciences in establishing the method of analysis.

The aim of establishing method of analysis are:

a. To fullfill the needs of NQCL DF and PQCL DF in method of analysis of new substances, new dosage from new formula or new commodities.

b. To modify existing methods to be a better and more reproducible method.

c. To validate the existing method of analysis.


NQCL DF establishes and distributes working reference standards for all PQCL DF, pharmaceutical industries, and other institution. Every year NQCL DF produces about 100 chemical reference standard substances consist of drug substances, cosmetic active ingredients, food additives, pesticides, etc.

Until November 1992 more than 390 reference substances were established especially drug, food additives and cosmetic ingredient.
reference substances. NQCL DF participated on the establishment of ASEAN Reference Substances.

NQCL DF also distributes bacterial reference standard. Besides, NQCL DF also joint ASEAN Collaboration for the establishment ASEAN Reference Standards Substances.

NQCL DF calibrates the working standards with the WHO, USP, BP, European Pharmacopoeia or NIHs primary reference standard substances. Pesticides working standards are calibrated to Environmental Protecting Agency Pesticides primary reference standards. Biological primary reference standards are provided by Staaten Serum Institute Denmark and NIBS London.

The activities under the ASEAN TCDC Project, until 1992, 65 substances as ASEAN Reference Standard. The production and utilization of ASEAN reference substances in coordinated by Thailand. The activities consists: collaboration laboratory studies, supplies the bulk material and some instruments.


NQCL DF participates in establishing quality standards or specification and its method of testing. In standardization process NQCL DF has close cooperation with Standardization Council of Indonesia


a. One of the important function is to provide continuity of education and training of staffs from National and Provincial Quality Control Laboratories of Drug and Food.

b. To train nationals of the countries of the region in drug analysis.

8. WHO Collaborating Centre.

Since January 1986, WHO designated NQCL DF as WHO Collaborating Centre for quality assurance of essential drugs four years and renewed in 1990.

9. National Pharmacopoeia

To assist in preparation of National Pharmacopoeia.

V. Cooperation and Collaboration.

To support the functions of NQCL DF, a cooperation with several scientific institution was established since 1983 as follows:

1. National Institute of Hygienic Sciences (NIHS), Japan

NIHS is the scientific counterpart of NQCL DF in executing the programmre of the technical cooperation between the government of Japan and Indonesia for strengthening the capability of NQCL DF.

NIHS dispatch their experts to train staffs in NQCL DF to coordinate the execution of training of NQCL DF staffs in Japan, exchange scientific information and to select the laboratory equipment to be dispatched to NQCL DF.

NIHS trains NQCL DF staffs in the field of food microbiology, sterility test, preparation and analysis of reference standards substances, toxicology, biopharmacy, pharmacology, hormone, bioassay, pathology, clinical chemistry, teratogenic, mutagenic, fungi identification, animal care, animal food fabrication, pyrogen test, etc.

2. National Institute of Health (NIH), Japan

NIH trains NQCL DF staffs in the field of
vaccine quality control especially tetanus, diphtheria, and pertussis vaccine, antibiotic potency test, and animal care. NIH is scientific counterpart of NQCL DF in the field of vaccine quality control.

3. Zentrallaboratorium Deutscher Apotheker, Eschborn West Germany.

This laboratory trains NQCL DF staffs mostly in the field of chemical analysis, such as multicomponent drug analysis, pesticides analysis, fat and fatty acid analysis. This laboratory is the scientific counterpart of NQCL DF in the field of chemical analysis within the technical cooperation.

4. Paul Enrich Institute Frankfrut, West Germany.

Training in the field of Polio vaccine quality control.

5. University of Miami, USA

Training in the field of pesticide residue analysis in pharmaceuticals and food commodities.

6. Institute CIVO-Toxicology and Nutrition TNO Zeiss The Netherland.

Training in the field of food additives analysis.


ITB is scientific counterpart of NQCL DF in Indonesia especially in collaborative study of method of analysis, reference standard substances analysis, provides training for NQCL DF staffs in chemical analysis and microbiological analysis. Several staffs of the Pharmacy Department are appointed as WHO National Consultants for NQCL DF.

8. University of Gadjah Mada

Training of NQCL DF and PQCL DF staffs in physico-chemistry analysis.

9. University of Airlangga

Training of NQCL DF and PQCL DF staffs in physico-chemistry analysis.

10. Biofarma

Biofarma is governmental institution that produces vaccines in Indonesia. With Biofarma NQCL DF has effective collaboration in vaccine quality control.

11. Staatens Serum Institute, Copenhagen Denmark.

Training the field of BCG vaccine quality control.

12. Apoteksbolaget AB Centrallaboratoriet, Stockholm, Sweden

Training in the field of the production chemical reference substances and supporting the International Chemical Reference Substance.


Training in the field of the production of antibiotic Reference Substances and supporting the International Biological Reference Substances.

14. Department of Medical Sciences, Bangkok, Thailand.

Collaborative Study in the production of ASEAN Reference Substances.

---

Media Litbangkes Vol. II No. 04/1992
ARTIKEL

15 National Pharmaceutical Control Laboratory, Selangor, Malaysia.

Collaborative Study in the Production of ASEAN Reference Substances and Training Course in Laboratory Quality Control of Pharmaceutical - ASEAN.

16 Department of Scientific Services - Ministry of Health - Singapore.

Collaborative study in the production of ASEAN Reference substances.

17 Bureau of Food and Drug - Manila - Philippines.

Collaborative study in the production of ASEAN Reference substances.

18 Public Health Research Institute of Kobe City, Kobe-Japan.

Training in the field of Mycotoxin and Food Additives Analysis.

19 Osaka Prefectural Institute of Public Health, Osaka-Japan.

Training in the field of Food Additives Analysis.

20 Kobe Womens College of Pharmacy, Kobe - Japan.

Training in the field of Food Microbiology Control.

21 Kobe Quarantine Station Laboratory, Kobe - Japan.

Training in the field of Food Microbiology Testing.

22 Pasteur Institute of India, Coonoor - India

Training in the field of DPT, Polio, Measles and Rabies Vaccine.

23 Central Drug Research Institute, Calcutta, Calcutta - India.

Training in the field of Drug Analysis.


25 Yonsei University, Seoul, Korea.

26 Landesuntersuchungsinstitut für Lebensmittel, Arzneimittel und Tiereseuchen Berlin (LAT) Berlin.

27 Division of Drug Analysis, Food and Drug Administration, St. Louis, Missouri, USA.

VI. Types of Testing.
1. Chemical-physicochemical testing.
   a. Titration
      • Non aqueoustitration
      • Potentiometry
      • Karl Fisher
      • Complexometry
      • Nitrimetri
      • etc.
   b. Chromatography
      • Paper Chromatography
      • Thin Layer Chromatography
      • Gas Chromatography-GC-massspectrophotometry
      • High Pressure Chromatography.
   c. Spectrophotometry
      • Ultraviolet and vissible spect
      • Atomic absorption spect
      • Spectrofluorometry.
   d. Spectrophotodensitometry.
   e. Thermal analysis
   f. Polarimetry
   g. Optical rotation.
2. Phytochemistry/Pharmacognosy
   • Identification of active substances.
   • Determination of volatile oil
   • Identification of simplicia.
   • Determination of traditional medicine composition.

3. Biopharmacy
   • Dissolution test.
   • Bioequivalency test.
   • Bioavailability test.

4. Microbiological Test
   a. Contamination
      • Total plate number
      • MPN Coliform
      • Fungi number and Mycotoxin
      • Yeast
   b. Identification of Pathogenic Bacteri
      • Salmonella
      • E. Coli
      • Streptococcus aureus
      • Clostr. botulinum
      • Clostr. perfringens
      • Pseudomonas aeruginosa
      • Vibrio cholerae
      • Vibrio parahaemolyticus
      • Bacillus cereus
   c. Phenol coefficient
   d. Sterility test
   e. Antibiotic potency test
   f. Effectiveness of preservatives
   g. Mutagenic test

5. Biological Test
   1. Pyrogen test
      • Rabbit test
      • LAL test
   2. Bioassay
      • Insulin
      • Vasopressine
      • Oxytocine
      • Digitalis
      • Heparine
   • Corticotropine

3. Toxicology
   • Abnormal toxicity test
   • Acute toxicity
   • Sub-acute toxicity test
   • Teratogenic test

4. Vaccine
   • Identity
   • Chemicals
   • Potency
   • Abnormal toxicity test
   • Specific toxicity test
   • Sterility test

VII. Courses and Training

Annually National Quality Control Laboratory of Drug and Food provides courses and training for staffs of Provincial Quality Control Laboratory of Drg and Food and other institutions.

The main objective of this training is to provide basic practical guidance on the analysis of pharmaceuticals and food commodities. The topics of regular courses and training available in NQCL DF as group as well as individual training are as follows:

1. Titrimetric and Related Method
   • Acid - base titration
   • Oxidation - reduction titration
   • Non - aqueous titration
   • Complexometric titration
   • Karl Fisher titration
   • Determination of Iodine value
   • Determination of Saponification and acid values
   • Nitrogen assay by the Kjeldahl method

2. Spectrophotometric Techniques
   • Ultraviolet - visible
   • Infrared
ARTIKEL

• Atomic absorption
• Fluorescence

3. Potentiometric Techniques.
• Thin layer chromatography/spectrophotodensitometry
• Paper chromatography
• Column chromatography
• Gas chromatography
• High performance liquid chromatography.

5. Traditional Drug Analysis.
• Microscopic examination
• Phytochemical evaluation
• Physical evaluation (ash value, moisture content, extractive value, etc)
• Physicochemical and chemical assay of chemical substance additives
• Residue of pesticide analysis.

• Dissolution test
• Bioavailability and bioequivalence test
• Stability test.

7. Microbiology.
• Determination of Total Plate Count Bacteria Contamination
• Identification of pathogenic bacteria contamination (Food, Traditional Drug and Cosmetics)
• Antibiotic potency test
• Sterility test
• Effectiveness of antimicrobial preservatives
• Identification of fungi/mycotoxin (Food Traditional Drug and Cosmetics)
• Phenol coefficient test for disinfectant.

• Food additives analysis
• Toxic substances analysis:
  - heavy metals
  - aflatoxin
  - etc.
• Residual pesticide analysis

• Testing for pyrogens
• Bioassay of hormones
• Abnormal toxicity testing
• Acute toxicity testing

10. Training Course for WHO-Fellowship.
• Mr. Ha Dac Bien, National Institute of Drug Quality Control - Vietnam; July 27 to September 24, 1992, topic: repairing and maintenance of laboratory analytical instrument.
• Mr. A. Gamaethige and Mr. G. Premachandra, Ministry of Health - Colombo-Sri Lanka; April 13-24, 1992, topic: Quality Control of Drug and Food.
• Mr. U Nyi, Dr. Thant Syn, Mr. Khin Maung Aye and Mr. U Tha Lwin, Ministry of Health Republic of Myanmar, August 24-25, 1992, topic: Quality Control of Drug and Food.

VIII. Standards Used in NQCL DF and PQCL DF.

Standards and its method of testing use for the quality testing for pharmaceuticals and food commodities are decided by the Director General of Drug and Food Control. Those books of standards for related commodities are stated in Table 2.
<table>
<thead>
<tr>
<th>No</th>
<th>Commodities</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Dosage form</td>
<td>b. USP XXII</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. BP 1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td>d. International Pharmacopoeia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e. Other literatures (designated by NQCL DF)</td>
</tr>
<tr>
<td>2</td>
<td>Food and Beverages</td>
<td>a. Indonesia Food Codex</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Codex Alimentarium commission</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Regulation of Minister of Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>d. WHO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e. Other literatures (designated by NQCL DF)</td>
</tr>
<tr>
<td>3</td>
<td>Traditional drugs</td>
<td>a. Indonesia Pharmacopoeia Ed. III, 1979</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Indonesian Materia Medika</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Regulation of Minister of Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>d. Other literatures (Designated by NQCL DF)</td>
</tr>
<tr>
<td>4</td>
<td>Cosmetics</td>
<td>a. Indonesian Cosmetic Codex</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Regulation of Minister of Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Other literatures (Designated by NQCL DF)</td>
</tr>
<tr>
<td>5</td>
<td>Medical Devices</td>
<td>a. Indonesia Pharmacopoeia Ed. III, 1979</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. USP XXI/XXII</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. BP 1980, 1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td>d. Other literatures (Designated by NQCL DF)</td>
</tr>
<tr>
<td>6</td>
<td>Hazardous Substances</td>
<td>a. Specification for pesticides used in public health (WHO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Other Literatures (Designated by NQCL DF)</td>
</tr>
<tr>
<td>7</td>
<td>Vaccines</td>
<td>WHO</td>
</tr>
<tr>
<td>8</td>
<td>Cigarette/Tobacco</td>
<td>International Standard Organization (ISO)</td>
</tr>
</tbody>
</table>

IX. Commodities to be Tested.

1. Drug and Narcotics.

The quality of drug substance and drug dosage forms is tested according to the Indonesian Pharmacopoeia, or other standads designated by the Director General of Drug and Food Control. The analysis include chemical, microbiological, pharmaceutical and biological analysis.

2. Traditional Drug

Several testing are implemented for traditional drug, such as microorganism contamination; identification of pathogenic bacteria; identification of chemical substances additives, acute and subchronic toxicity; identification of aflatoxin, microscopic and phytochemistry examination.

3. Food and Beverages

Food additives such as preservatives anti oxidants, colouring materials artifical sweetener, and others are analysed. Determination of toxic substances such as heavy metals, aflatoxin, pesticide residue. Isolation, counting, identification and study of bacteria from food products.

4. Hazardous Substances

Determination of hazardous substances contaminats. Toxicity studies such as acute, sub acute and chronic tests. Toxic effects are established by the usual physiological, haematological, biochemical and pathological criteria.

5. Cosmetic

Identification of toxic substances or prohibited chemical substances in cosmetic preparation. To determine the concentration
of limited amount of chemical substance in cosmetic preparation.

Isolation, counting, identification and further study of bacteria. Microbiological tests for evaluation of disinfectant and toxicity studies in cosmetic.

6. Medical Device

The quality medical of devices is tested according to Indonesian Pharmacopoeia, or other pharmacopoeia such United State Pharmacopoeia XXII. British Pharmacopoeia 1988, or other standars. The medical devices tested in NQCL DF are pure cotton, sterile cotton, bandage, sterile bandage, absorbant gauze, infusion set, disposable syringe, condom, gibs-bandage etc

7. Vaccine (will be described specially in No. XII)

X. Type of Laboratories

The laboratories which already exist to support the implementation of the objective and the function of NQCL DF are:

1. Laboratory of drug analysis
2. Laboratory of cosmetic and medical device analysis
3. Laboratory of microbiology analysis, consists of:
   - Laboratory Bacteriological contamination analysis (food product, traditional drug product, cosmetic product).
   - Laboratory of microbiological assay of antibiotics.
   - Laboratory of fungi (isolation and identification of toxin, detection of aflatoxin from aspergillus flavus in food and traditional drug product).
   - Bioclean room for sterility test.
   - Room for media preparation and sterilization.

 • Room for freezed dried bacteria and fungi production.

4. Laboratory of toxicology consists of:
   - Laboratory of Anomol Pathology.
   - Laboratory of Clinical Chemistry
   - Laboratory of Mutagene
   - Laboratory of Teratology

5. Laboratory of Pharmacology
6. Laboratory of Biossay
7. Laboratory of Biopharmacy
8. Laboratory of Pyrogenic testing
9. Laboratory of Experimental Animal consists of:
   - Laboratory of Mice, Rat, Guinea-pig, Rabbit breeding.
   - Laboratory of Experimental animal diseases control.
   - Experimental animal food fabrication.

10. Laboratory of traditional drug analysis
11. Laboratory of chemical analysis of food
12. Laboratory and production of reference standard substances
13. Laboratory of Tobacco and cigarette analysis
14. Laboratory of vaccine quality control
15. Laboratory of aflatoxin analysis
16. Laboratory of gelatine identification

XI. Laboratory Animals

For biological tests such as abnormal toxicity test, pyrogen test, bioassay for hormones, vaccine quality tests, pharmacological tests, NQCL DF needs several kinds of pure strain laboratory animals. All tests stated above are routine work, therefore in order that all tests can be carried out continually, NQCL DF breeds several laboratory animals imported from Japan maintained under clean system. The animals are:

Mice Strain ddy (Deutsche yoken)
Rats  | Strain  | SD (Spraque Dawley)
Guinea Pigs | Strain  | Hartley
Rabbits | Strain  | Japanese white

XII. Vaccine Quality Control at the National Quality Control Laboratory of Drug and Food

National quality control laboratory of drug and food has carried out the quality control tests of EPI vaccines routinely according to the WHO Requirements, with the following history.

1986  Vaccine laboratory was established, beginning with the quality control of Diptheria, Pertussis and Tetanus vaccine (DT, TT and DPT vaccines)

1988  The quality control of DT, TT and DPT vaccines were established.

1990  The quality control of BCG and Polio vaccine were established.

1991  The quality control of measles and rabies vaccine, tetanus and diphtheria antitoxin were established.

1993  The quality control of Hepatitis B vaccines will be established.

In order to promote those above activities several staffs have been trained abroad in the vaccine quality control laboratory which is recommended by WHO.

1. Capabilities
   a. Potency test
      • Pertussis vaccine  150 batch/year
      • Diphtheria vaccine  25 batch/year
      • Tetanus vaccine    50 batch/year
      • BCG vaccine        80 batch/year
      • Polio vaccine      200 batch/year
      • Measles vaccine    300 batch/year
      • Rabies vaccine        15 batch/year
      • Diphtheria and Tetanus antiserum  10 batch/year

All the method used for testing according to WHO Requirement, except for Diphtheria vaccine, using Indonesia Pharmacopoeia.

b. Other test for quality control of final products of vaccine
   • Identity test
   • Sterility test
   • chemical test
   • Toxicity test

2. Activities which has already done
   a. Routine activities
      • Certification of EPI vaccine by checking the documents analysis of vaccine before marketed
      • Routine quality control testing for final products of EPI vaccines and other vaccines.
      • Tests of vaccine in the case of "cold-chain-break", with the request from the communicable diseases centre (CDC) (DPT and polio vaccines)
      • Establishing the working and national reference standard in cooperation with Perum Bio Farma. (tetanus and pertussis working standard are under establishment).
      • To improve the capability of the staffs by training abroad and advanced studying to get degree.
   b. Cooperative activities
      • Institution in the country
         1. Communicable disease research centre and communicable disease centre.
            Information and experience in the case of quality control of vaccine, also to perform the test of vaccine from the field which is taken by the communicable disease centre (CDC).
          2. Perum Bio Farma
Bio Farma prepares the candidate of reference standard and collaborative testing for the determination of its potency. In order to achieve the same technique of testing for vaccine which is recommended by WHO, NQCL DF does the technical cooperation with Perum Bio Farma. Collaboration study for the potency test of BCG vaccine is on going project.

To achieve the effectiveness of training, before sending the staffs to study the quality control of vaccine abroad, they were trained first in Bio Farma (for the technique which available in Bio Farma).

-Institutions abroad


To get the reference standards for vaccine and information concerning to the quality control of vaccines, and training for the staffs


Transfer technology for vaccine quality control either by sending the staff to Japan or Experts comming to NQCL DF.

XIII. The Future Programme

1. Training course

It is needed for NQCL DF and PQCL DF staffs to improve their knowledge and capability of laboratory analysis. Training for NQCL DF staffs are expected to be conducted in leading/developing countries by WHO fellowship, while PQCL DF staffs training are held by NQCL DF or WHO fellows.

2. Reference substances

a. Increasing the number national reference substances and primary reference substances

b. Training the staffs of the reference standard (substances) laboratory, to improve their capability of the reference substances production and analysis

c. Supplying analysis instruments and computer for data handling.

3. General Instrument supplying:
Improving the analysis of drug and food.

4. Laboratory Accreditation
Assessing the capability of drug analysis for PQCL DF and Pharmaceutical Industries laboratory

5. Bioavailability.

6. The programe of vaccine quality control is as follows

a. Quality control of Hepatitis B vaccine will be carried out in 1993.

b. To establish the working and national reference standard, and collaborative study for the determination its potency, with institutions in the country (i.e communable diseases research centres) and institutions abroad. Beside that also carrying out the stability test of the reference standard.

c. To establish the potency tests of Diphtheria vaccine using "vero-cell method" (at present we are still using "Indonesian Pharmacopoeia" method.

d. To increase the types of vaccine to be tested and capability of the staffs for the quality control test of vaccine by
training in the laboratory which is recommended by WHO

e. To increase the capability of testing by establishing new animal rooms if the budget is available.

XIV. Proposal in Order to Increase the Cooperation

In order to increase the activities and get current information and knowledge, involving to the other collaborative action should be promoted i.e.

a. Joining to the collaborative study for vaccine quality control which is held by WHO.

b. Inviting the collaborative study with institution abroad for testing the reference standard for vaccine which is produced by our institute.

c. As the quality control laboratory for EPI vaccine, we hope that we could have routine information concerning to the requirements, current publications etc. from the WHO.

d. The role of WHO Collaborating Centre training and testing of vaccine used in EPI should be clarified and formulated in order to get a good achievement.

e. Comparison study and information or experience exchange with other institution should be promoted.

Annex I

Diagram showing the organizational structure of various divisions and departments, including:

- Division of Drug Quality Testing
  - Section: 1. Physicochemistry
  - 2. Microbiology
  - 3. Pharmacology
  - 4. Biopharmacy

- Division of Food and Beverages Testing
  - Section: 1. Physicochemistry
  - 2. Microbiology
  - 3. Toxicology
  - 4. Nutrition

- Division of Narcotic and Hazardous Substances Testing
  - Section: 1. Narcotics
  - 2. Psychotropics
  - 3. Hazardous Substances
  - 4. Forensic

- Division of Cosmetic and Medical Devices Testing
  - Section: 1. Chemistry
  - 2. Microbiology
  - 3. Toxicology
  - 4. Pysic

- Division of Traditional Drug Quality Testing
  - Section: 1. Pharmacognosy
  - 2. Phytochemistry
  - 3. Galenic
  - 4. Toxicology