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ESTABLISHMENT OF A PILOT PLANT FOR PESTICIDE FORMULATION

DP/MYA/80/011

UNION OF MYANMAR

Technical report: Pesticide quality control analysis*

Prepared for the Government of the Union of Myanmar
by the United Nations Industrial Development Organization,
acting as Executing Agency for the United Nations Development Programme

Based on the work of Brian Crozier, consultant in
pesticide quality control analysis

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Vienna

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* This document has not been edited.

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ABBREVIATIONS AND ACRONYMS USED

Local currency equivalent US $1=K5.9

ai	Active Ingredient
AOAC	Association of Official Analytical Chemists
CIPAC	Collaborative International Pesticides Analytical Council Ltd
EC	Emulsifiable Concentrate
GIFAP	International Group of National Associations of Agrochemical Manufacturers
GLC	Gas Liquid Chromatograph(y)
GLP	Good Laboratory Practice
HPLC	High Performance Liquid Chromatograph(y)
MAS	Myanmar Agricultural Service
PPPF	Pilot Plant for Pesticide Formulation
QC	Quality Control
RENPAP	Regional Network for Pesticides in Asia and the Pacific
SK	Superior Kerosene
TLC	Thin Layer Chromatography
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organisation
WHO	World Health Organisation (of the United Nations)
UV/VIS	Ultra-violet/Visible Spectrophotometer

ABSTRACT

Title: Pesticide Quality Control Chemist

Number: DP/MYA/80/011/11-56

Purpose: To establish a liquid formulation plant in Myanmar

Duration: Two months WAE 3 December 1992 to 10 February 1993

Conclusion: The laboratory now has all the instrumentation and equipment necessary to carry out its Quality Control responsibilities for the next five years. Consumable items, chemicals, solvents and spares will need to be maintained at a sufficient level during that period. Some other small pieces of laboratory equipment will be needed to continue the development of new formulations. Problems of recruitment and retention of suitably qualified staff need to be addressed.

Recommendations: Continued budget provision for spares and replacements is essential, replacement of major instrumentation must be considered at five yearly periods. Training of new staff needs to be undertaken. Some minor items are thought necessary for the expansion of the work into experimental granular formulations.

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INTRODUCTION

The Project is part of the Government of Myanmar's aim to maintain a relatively pest-free environment for the production of essential crops and to increase and intensify the cultivation of commodity crops including cotton, rice, pulses, vegetables and citrus for home consumption and export. The Project is intended to supply the needs of the country for liquid insecticide formulations and then to develop formulations based on locally available materials such as solvents and to identify alternative, cheaper sources of technical active ingredients and formulating agents. Further work foreseen is the production of granular formulations.
The PPPF has now been producing EC since June 1990 and the QC laboratory has continued to fulfill its function during the whole period.

This report has been written by Brian Crozier, Consultant in Pesticide Quality Control, based on the Job Description in Annex I.
The mission had three main aims, namely the training of laboratory staff in the use of new equipment and techniques to ensure the present and future requirements for QC of pesticide formulations produced; advice on further requirements for equipment and spares for the next five years and the establishment of foundations for good standard working practices based on GLP.
The Consultant had previously completed a mission at the Plant,and the report on that mission, dated August 1991, had made certain recommendations for purchase of major items of instrumentation which would enable the QC laboratory to continue to carry out analyses in the event of a major mal-function of existing instruments and which would be essential in the event of the projected widening of the range of active ingredients to be formulated.
The two major items recommended,an HPLC and a UV/VIS had been provided by UNIDO in late 1992 and were awaiting installation at the beginning of the mission.

I. ARRANGEMENT OF THE QC LABORATORY AT PPPF

A. Accomodation

As previously reported, the accomodation is satisfactory. There had been some rearrangement of the layout since 1991 which meant that the two rooms to be used for instrumental analyses were now on the upper floor, nearer the general laboratory where solutions for analysis are prepared. This was obviously an improvement.

B. Staff

The Laboratory Manager and his Deputy were as before; two of the three analysts had left, one to a less technically demanding but more lucrative position as analyst for a commercial company. One new analyst had been recruited towards the end of 1992 but left after only four months to a (more lucrative) administrative post.

C. Equipment

Laboratory instrumentation and equipment is sufficient for the next few years provided adequate spares are on hand and replacements for the inevitable breakages and chemical and solvent usage are obtained.

For formulation development work a laboratory ball mill or grinder is needed.

As previously reported there are some deficiencies in safety and medical facilities and supplies.

The library has been stocked up; revisions of and additions to standard pesticide analytical texts should be obtained when available.

D. Services

Services are basically adequate but there remains a need for a hot water supply for glassware washing.

E. Facilities

Bulk solvents and retained samples are presently stored in rooms in the laboratory building; it is preferable that these are stored outside. A well-ventilated, lockable two room brick store, approximately 4m X 4m fitted with shelves and placed about 20m away from the laboratory building would add to the overall safety of the Plant.

II. ACTIVITIES

The activities undertaken corresponded to the three aims of the mission:

A. Training of Laboratory Staff

The recently acquired UV/VIS spectrophotometer was installed and tested. Several small experiments were carried out to explain the different modes of usage of the instrument which would be likely to be needed; these included the photometric, spectrum and quantitative modes. The other available modes, namely time scan, kinetic and multicomponent were briefly explained but it is expected that relatively little use will be made of them. The recently acquired HPLC instrument required installation and comissioning by the manufacturer in order not to invalidate the guarantee. Unfortunately due to changing arrangements by the manufacturer, the engineer had not arrived by the end of this mission. It happened that the consultant remained in Myanmar for a further three weeks on a separate, but associated, mission and so was able to give some basic instruction in the use of the equipment. Analyses and recovery experiments were carried out on the waste water from the Production Plant lagoon and the Laboratory waste lagoon. Results were encouraging - in the PP lagoon no pesticides were found above the Limit of Determination (0.3 to 0.8 mg l^{-1}), with recoveries in the range 85 to 112%. Thus indications for the disposal of this water were promising. The waste water from the laboratory showed some evidence of pesticide contamination at levels of approximately 1 to 2 mg l^{-1}. This level of contamination is easily treated by the Sentinel Waste Treatment Plant.

As well as bench training a number of lectures on various aspects of the analytical chemistry and registration of pesticides were given to the staff and to associated staff within MAS, see Annex III

B. Further Requirements

The activities undertaken by the QC laboratory were evaluated with the purpose of assessing usage of consumable equipment, spares and chemicals. Whilst it obviously impossible to foresee breakages and increased usage of

chemicals, particularly solvents, it was feasible to give an approximate value to the budgetary requirements for the next five years. These are given in Section IV Findings and Conclusions, Part C Equipment and are based on the information in Annex IV which gives a list of basic equipment and associated spares recommended for a pesticide QC laboratory.

C. Good Working Practices

During training in the laboratory safe working practices and standard laboratory techniques were stressed. The importance of recording actions and observations at the time of their performance was emphasised.

A lecture on Good Laboratory Practice was given but it was noted that full implementation of such a scheme was unlikely for a lengthy period.

III. THE FUTURE OF THE QUALITY CONTROL LABORATORY

The present set-up of the QC laboratory, instrumentation, equipment and projected staff complement should be adequate to carry out its functions of Quality Control of Plant formulations and formulation development using new supplies of raw materials.

This is not to say that there needs to be no furter expenditure since an analytical laboratory using a number of different techniques has a continuing need to replace consumable items and to provide for running repairs (and sometimes major replacements) to instruments. An annual budget of the order of US $8000 is likely to cover running costs and a sum of US $50000 allowed every five years to replace one of the major instruments so that the laboratory does not fall behind in the technological developments in the field of pesticides analytical chemistry.

The laboratory has recently had some sucess in formulating the five pesticides with which they are familiar (cypermethrin, diazinon, endosulfan, fenitrothion and phenthoate) using locally available SK as a partial or total replacement for imported xylene as solvent. It has also produced laboratory scale batches of formulations of new active ingredients (deltametrin, fenvalerate, esfenvalerate, fenpropathrin and monocrotophos) which have been tested satisfactorily by MAS. The laboratory intends to carry on this type of formulation development and also to investigate alternative, cheaper sources of ai.

It is also intended to try to prepare on a small scale a batch of diazinon granules using locally available chalk stone as carrier. For such laboratory scale formulation a ball mill or small grinder or crusher will be needed. If this preparation is successful then a small expansion of the Plant to enable granules to be prepared on a commercial scale (ca 5 tons pa) is foreseen. Further advice from an expert in pesticide formulation would be of benefit in this case.

IV. FINDINGS AND CONCLUSIONS

A. Accommodation

The laboratory accommodation is satisfactory.

B. Staff

The projected complement of a total of five staff for QC will be sufficient for the present and foreseen workload. However the recent turnover of junior staff points to possible difficulties in future recruitment of suitably qualified, graduate staff and their subsequent retention for a sufficient period to enable them to be fully trained and capable of taking over the running of the laboratory when the senior staff take retirement. Training on-the-job can take some time, even well qualified recent graduates need a number of years experience before they can be relied upon to carry out the full range of tasks expected from the QC and formulation development laboratory.

C. Equipment

See detailed list in Annex IV.

1. Instrumentation

No further purchases of any new major instrumentation should be required during the next five years. However the Perkin Elmer 8500 GC is now about five years old which, in terms of analytical chemistry instrumentation, is a long time as new developments are announced each year. It should be serviceable for that period but provision must be made for its replacement before it becomes unserviceable; manufacturers normally stock spares for at least ten years. US $50000 /5years

There must be an annual budget for replacement of spares and consumable items. US $1000 pa

Expansion into regular residue analyses will require an increase in the budget.

2. Glassware

The stock of glassware provided for the laboratory has been found to lack no major items but an annual provision must be made for replacement

of breakages and purchase of minor additional items.

3. Chemicals

This is liable to be the major area of expenditure in the next five years since, with the purchase of the HPLC, the usage of solvents will increase and a wider range will need tc be stocked. Other chemicals and reagents should be replaced as they are used or as their shelf life is exceeded. This latter point is important in the context of GLP. US $2000 pa

4. Instrumental Accessories and Small Equipment

Briefly mentioned under C 1 above, consumable items for the major instruments are listed in AnnexIV and adequate stocks must be maintained.

HPLC columns are difficult to pack in an analytical laboratory and must be purchased from manufacturers. US $2000 pa

The Nitrox nitrogen and air generator has recently developed a fault which, although a temporary repair has been effected, may be recurrent. The manufacturers have been contacted and have remarked that parts of this model generator are now obsolescent and newer models have replaced them. The generator can be reconditioned by the manufacturers and should then be expected to perform as a new machine. When the HPLC is fully running and routine analyses for the products have been developed, the Nitrox generator should be returned for reconditioning. US $ _____

A ball mill or laboratory grinder is included under this item.

5. Pesticide standards and special chemicals

At regular intervals, depending on the manufacturers recommended shelflife, stocks of primary analytical standards need to be replaced. Only a small quantity is needed as batches of technical material can be calibrated as secondary standards. The manufacturers should be approached first for supplies.

Special chemicals such as recommed internal standards or derivatizing reagents will need to be bougnt from time to time. See 3 above

6. Protective/Safety Equipment

Emergency eyewash bottles are essential in all rooms in which chemicals are used.

The Medical Room has a few supplies, a complete First Aid kit (and full time Occupational Health Nurse?) is essential. US $1000 pa

7. Literature

The library has a selection of suitable texts. Any amendments or additions to series need to be obtained. US $1000 pa

8.Tools

Probably adequate but some extra items would not be too expensive and would make maintenance etc. much easier.

D. Services

An automatic start-up for the stand-by emergency generator would prevent loss of vital parameters stored in the memory of instruments (and personal computers). Such instruments have a back-up battery supply lasting for about 30 minutes only.

E. Facilities

A source of hot water for thoroughly washing glassware is still needed.

An external store for bulk solvents and retained samples would add to overall safety.

F. Training

Any new recruits should attend a suitable RENPAP organized course as well as receiving on-the-job training from more experienced colleagues.

The laboratory should get in touch with CIPAC and take part in any suitable collaborative trials to widen their experience of analysis.

G. Good Laboratory Practice

Whilst it is unlikely that full GLP can be established at the Laboratory for a number of years, it is essential that the staff and any new recruits get into the habit of recording all actions and observations in a permenent form at the time they occur.

V. ACKNOWLEDGEMENTS

The Consultant would like to thank and acknowledge the help and advice received from all persons with whom he came into contact which helped to make the mission enjoyable.

Dr I Bendefy, CTA, was at the Plant for part of the mission and provided a never-ending fund of information of all kinds, both about the Plant and life in Hmawbi and Yangon.

National Project Director, U Win Kyi, and project staff provided help and hospitality whenever requested; U Maung Maung Tin and MAS staff provided useful information and staff of the Programme and Finance Sections of UNDP were always ready to help overcome any problems.

RECOMMENDATIONS

1. Thought given to recruitment and retention of suitably qualified new staff with such a timescale that any change of leadership is smoothly effected.

2. Continue to provide a suitable budget for the purchase of sufficient quantities of:-

   a) instrumental spares and consumables

   b) replacement glassware

   c) chemicals and solvents

   d) safety and disposable items

   e) pesticides analytical standards (unless supplied by manufacturer)

3. Refurbish Nitrox generator at a convenient time.

4. Establish a reliable, well-staffed medical facility.

5. Update reference texts as available.

6. Install instantaneous water heater for cleaning glassware.

7. Staff to attend suitable RENPAP training and take part in suitable CIPAC collaborative analyses.

8. Make provision for replacement of one major instrument (GLC and HPLC) at intervals of approximately five years, ie., projected lifetime of each instrument about ten years.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

JOB DESCRIPTION

DP/MYA/80/011/11-02/B

Post title: Quality Control Specialist

Duration: 2.0 m/m

Date required: October 1992

Duty station: Yangon, Myanmar

Purpose of project: To assist the country to establish a liquid pesticide formulation plant in Myanmar.

Duties: The expert, in collaboration with his counterpart, will supervise the overall operation of the analytical laboratories, assist in the operation of the newly installed analytical equipment (HPLC), give on the job training in operating various analytical equipment. In this he will take into account the work carried out during his previous assignment.

He is expected to write a report giving instructions to long term operation of laboratories according to the standard practice and mentioning list of equipment, spare parts etc. they should carry for short-medium term basis (1-5 years).

Qualifications	Highly qualified chemist with extensive experience in industry or institution dealing with quality control of pesticides. Should be familiar with the international practice in running of a quality control laboratory. Experience in a developing country would be an advantage.
Language	English
Background information	The backbone of Burma's economy is agriculture and the staple crops are rice, cotton and sugar cane. At one time Burma was a major exporter of rice but now, due to lack of fertilizers and pesticides, the productivity in agriculture has declined considerably. The country has to import all its pesticide requirements as finished products. Due to shortage of foreign exchange, supply of pesticides has been erratic and always below the requirements. Having realized the importance of proper supply of pesticides, the Government of Burma approached UNDP/UNIDO for technical assistance in the establishment of a pesticide formulation plant. Based on various studies conducted by UNDP and UNIDO, it has been decided to set up a liquid formulation plant (E.C) making use of the locally available solvents as much as possible in combination with standard solvents such as xylene. The project will be executed by UNIDO with the Pharmaceutical Industries Corporation (PIC) as the National Counterpart Agency. The plant will be established at 50 km north of Rangoon, and a site is being made ready for the plant. The basic infrastructure is being created by providing all utility services, analytical laboratory, a small pilot plant, trained staff and the necessary safety precautions.

ANNEX II

INSTITUTIONS AND PERSONS CONTACTED

United Nations Personnel

Mr J Raheem	Resident Representative
Mr R Sethna	Deputy Resident Representative
Mr A Sissingh	Senior Industrial Advisor
Ms M Magellanes	Head, Programme Section
	Backstopping Officer, UNIDO
Dr I Bendefy	Project CTA
Ms F Lemmonaire	Programme Section
U Htin Aung	Programme Officer
Dr T Prvulovic	WHO Public Health Administrator

Myanmar Agricultural Service (MAS)

U Tin Hlaing	Managing Director
U Maung Maung Tin	Dy GM, Head Plant Protection Service

Project Personnel

U Win Kyi	National Project Director
U Myint Swe	Project Manager
U Aung Min	Planning Manager
U Saw Moo Ler	Laboratory Manager
U Mon Tin Win	Dy Laboratory Manager
U Saw Win	Production Manager
U Nyo Lay	Maintenance Manager

WHO Local Personnel

Dr Ohn Kyaw	Project Officer, Malaria Control

ANNEX III

LECTURES GIVEN TO STAFF OF PPPF AND MAS

1. Good Laboratory Practice
2. Trends in Pesticide Formulation
3. Chromatography
   - General Introduction and Overview
   - Maintenance
   - Troubleshooting
4. High Performance Liquid Chromatography
   - Equipment
   - Methods
   - Developments
5. Registration of Pesticides
   - Need, Objectives, Responsibilities
   - Data Requirements
   - Trials
   - Assessment
   - Post-Registration Activities
   - ADI and MRL
6. Specifications for Pesticides
   - Description
   - Physical Requirements
   - Tolerances
7. Gas Liquid Chromatography
   - Introduction; Components of the System
   - Stationary Phases
   - Special Techniques

ANNEX IV

MINIMUM BASIC INSTRUMENTATION AND EQUIPMENT FOR A PESTICIDE QUALITY CONTROL LABORATORY

Main items listed together with suggested spares and consumables

1. Major Instrumentation with Accessories and Spares

Gas Liquid Chromatograph, fitted with packed and capillary injectors, FID and other suitable detector.

- Gas supplies, Nitrox generator with maintenance kit
- Gas filters for oxygen and moisture
- Gas supply of hydrogen
- Glass columns, ready packed or empty together with suitable liquid phases and support materials
- Capillary columns, bonded phase
- Injection port liners
- Septa, silanized glass wool, O rings, syringes, ferrules, copper tubing, Swagelock fittings, chart paper
- Manufacturer's recommended service kit

High Performance Liquid Chromatograph, with variable wavelength UV detector

- Selection of columns of various length and packings
- Guard columns
- Degasser/debubbler for solvents
- Syringes, injection loops
- Swagelock fittings and connectors, ferrules, stainless steel and PTFE tubing, chart paper
- Solvents
- Manufacturer's recommended service kit

UV/Visible Spectrophotemeter, scanning range 200 to 1100 nm

- Spectrophotometer cells, various sizes
- Spare deuterium and tungsten bulbs
- Chart paper
- Manufacturer's recommended service kit

Infrared recording spectrophotometer, double beam

Sodium chloride cells, various path lengths

Chart paper

Manufacturer's recommended service kit

2. Laboratory Apparatus and Small Instruments

Balance, analytical, 200g X 0.1mg, with tare

Balance, laboratory, 2kg X0.1g, with tare

pH meter/potentiometric titrator

electrodes, buffer powders

Karl Fischer titration apparatus

solvents, reagents

Deioniser, spare cartridges or resins

Melting point apparatus, tubes

Flash point apparatus

Ultrasonic bath

Microwave oven

Centrifuge

assorted tubes and 100ml IP75 tubes

Sieve shaker and range of sieves

Laboratory ovens X 2

Furnace with crucibles and tongs

Steam bath, thermostatted water bath, cooled bath, water bath for emulsion stability test

Refrigerator/ deep freezer

Liquidizer/ homogenizer/ blender

Vegetable/ fruit chopper

Tissue grinder

Hotplate/magnetic stirrer with fleas

Rotary shaker

Orbital shaker

Ball grinding mill with containers and balls

Rotary evaporator with spare clips and flasks

Heating mantles of various sizes

Vacuum pump/compressor

Water vacuum pump

Whirlimix

Desiccators

Stirrer motors and rods with varying lengths and paddles

Hair dryer

Viscometer, or range of viscometer tubes

TLC plate maker (or plates), tanks, sprayer etc

UV lamp

Stop clock, stop watch, interval timer

Thermometers, general and melting point

3. Glassware etc

Volumetric flasks and stoppers to fit

1,5,10,20,25,50,100,200,250,500,1000 ml

Graduated cylinders, lipped and stoppered

5,10,25,50,100,200,250,500,1000 ml

250 ml for suspensibility test

tap density cylinders

Pipettes, bulb and graduated

1,2,5,10,20,25,50 ml

pipette fillers

Pasteur pipettes and teats

Burettes

10,25,50 ml

Beakers, squat and tall form

10,25,50,100,250,500,1000 ml

Quickfit glassware

Adaptors, condensers, distillation columns, flasks (round bottomed, one and two necked, 50,100,250,500 ml), still heads, splash heads, chromatography columns, separating funnels, thermometers, gas adsorption apparatus, Dean and Stark fitments, Soxhlet extractor with thimbles, conical flasks (25,50,100,250,500 ml), Iodine flasks (250 ml), range of stoppers

Reagent bottles, labelled, 500,1000 ml

Buchner flasks and funnels with range of papers

Sintered glass funnels, range of porosities

Filter funnels, varying sizes, range of papers to fit

Test tubes and racks

Mortars and pestles, various sizes

Polythene squeeze bottles

Tubing: glass, polythene, rubber, vacuum and tubing clips

Glass rods

Weighing bottles and funnels; disposable weighing boats

Glass vials, varying sizes with screw caps

Glass jars, varying sizes with screw caps

4. General Equipment

Spatulas, palette knives, scoops, spoons

Forceps

Scissors

Bowls and buckets, polythene

Cleaning brushes (bottles, burette, stiff, bristle, soft)

Paint brushes, various sizes

Aluminium foil

Cotton wool

Glass wool

Cork rings

Paper tissues

Butane burner with cartridges, tripods and gauzes

Vials, caps and liners

Crimper/decapper

Retort stands, clamps (various), bosses, rings

Scaffold rods

Laboratory jacks

Multimeter

Assorted tools

Knives

Self-seal polybags or polybags and sealer

5. Safety and disposable items

First aid kits

Eye wash bottles

Safety glasses and goggles

Safety Shields

Dust masks

Ear defenders

Laboratory coats

Protective gloves (nitrile, polythene, heat resistant)

Solvent store cupboard

Acid store cupboard

6. Special chemicals etc

GC phases and supports

Silylating agents

Aluminium oxide, silica gel (various grades)

CVS solutions

Indicator papers, pH papers

MAJOR EQUIPMENT OF THE LABORATORY

Item	Description	Supplier	Model	No	Received	Condition *
1	Abbe refractometer	Fisher	LR45302	1	1985	
2	Rotary evaporator	Buchi	RE 111/A	1	1985	
3	Analytical balance	Sartorius	1702 MP 8	2	1985	One item needs new chip
4	pH meter	Corning	140	1	1985	Irreparable
5	Balance	Ohaus	760	1	1985	
6	Oven	Fisher	127G	2	1985	
7	Microscope	Olympus	CHB	1	1985	
8	Microscope	Kolb	Wetzlar	1	1985	
9	Water bath	Gallenkamp	Grant SE15	1	1985	
10	Flash point apparatus	SETA	ASTM D93-IP34	1	1985	
11	Flash point apparatus	SETA	ABEL PEH-670-M	1	1986	
12	Sieve shaker	Endecotts	SW19-3BR	1	1986	
13	Gas chromatograph	Perkin Elmer	8500	1	1988	
14	Nitrox generator	Nitrox Ltd	ANG 750/1	1	1989	Needs refurbishment
15	Balance	Mettler	PM4000	1	1990	
16	TLC starter kit	Spectroline	Q/22 SN-5	1	1991	
17	Spectrophotometer	Shimadzu	UV 160A	1	1992	
18	HPLC	Shimadzu	LC 9	1	1992	
19	Electronic typewriter	IBM	6784	1	1989	
20	Plain paper copier	Canon	NP 3225	1	1989	
21	Overhead projector	AVD	3 M 2170	1	1992	
22	Slide projector	Kodak	S-AV 1030	1	1992	

* Good unless otherwise stated

UNIDO COMMENTS

The report gives a complete run down of the work carried out by the expert in assisting the counterparts in the day-to-day running and maintenance of the analytical laboratory.

The author has also given experimental details on the amount of pesticides present in the waste water coming out of the analytical laboratory and the formulation plant. The in-depth training given by the expert would be very valuable to the project.

The expert's recommendation to keep stock of essential items and providing an annual budget should be seriously considered by the project authorities. In addition, there should be more analytical chemists provided to the project to take care of the analytical laboratory in the absence of the senior chemist.