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PROGRAMME "BIOMED"

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MONGOLIA

Technical report: "Strengthening of Maintenance Facilities
at the Institute of Biological Products and Blood Transfusion
Ulan Bator"*

Prepared for the Government of the Mongolian People's Republic
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

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ABSTRACT

Programme "Biomed": Strengthening of Facilities for Production and Quality Control of Gamma-globulin and Albumin at the Institute of Biological Products and Blood Transfusion

Project Number DP/MCN/82/004/11-C3

Some essential installations (electric, cooling) in the Blood Fractionation Unit were found inadequate. These installations had to be reconstructed before the mounting of the new equipment could be started. The available old equipment needed repair, which was also done.

The equipment supplied by UNIBO for the implementation of the project to enlarge and modernize the production of gamma-globulin and albumin from placental materials was examined, tested, installed and put into regular operation.

There were some difficulties with the installation and putting into action of the lyophilization apparatus which had suffered substantial damage during transportation. The repair work was successful and it was also put into operation.

Local personnel was trained in the operation and maintenance of the new equipment supplied for the project.

A list of the available spare parts and a list of the parts which may be worn out and would need replacement soon were made. Spare parts should be ordered on time so that the maintenance of the equipment is ensured.

INTRODUCTION

Before the implementation of the project the Blood Fractionation Unit at the Institute for Biological Products and Blood Transfusion had old, worn out equipment of low productivity and that was why it had the production capacity to process not more than 1500 l retroplacental serum per year for the production of gamma-globulin and albumin. It was not possible to carry out a large scale fractionation because of the lack of modern equipment. Such equipment was supplied by UNIDO with the purpose to develop the technological capabilities and skills for local production of blood derivatives at the Institute of Biological Products and Blood Transfusion.

The author's duties were to:

- examine the situation concerning the equipment supplied;

- install and put into action all the equipment for the fractionation of retroplacental serum and placentae, for lyophilization and quality control;

- train local personnel on operation and maintenance of the equipment;

- prepare list of spare parts needed for the repairs of the equipment.

These duties were fulfilled as described further on.

ACTIVITIES CARRIED OUT

The work was started under the guidance of the Chief Technical Adviser and in cooperation with the expert in blood derivatives production with the examination of the production premises. It was found that the needed conditions to begin with the installation of the new equipment were not created. Almost complete reconstruction of the electric net (new lines were also installed) was necessary in order to ensure the safe work of the machines and personnel. Serious repair work had to be done on the high speed centrifuges (rotors had to be balanced also), which had to be used in the fractionation department before the implementation of the project. The available cooling installation had to be repaired also in order to ensure the proper cooling of the equipment for the fractionation.

The reconstruction of the cooling installation included repair of compressors and cooling lines; centrifuges and reactors had to be connected to the cooling system. The centrifuges were mounted so to meet safety regulations.

Electrotechnical works were carried out under my guidance and with my personal participation. These included: installation of one main control panel, four switchboards, outfitting of 300 m electric cables, installation of 50 monophase and 10 threephase sockets, installation of electric lines and lighting in the cold room.

All these unforeseen activities needed lot of work and time. They were successfully performed but delay in the activities was formed. Additional problems were created with the difficult supply of the needed electric materials and the lack of local workers experienced to carry out this type of work.

The examination of the newly delivered equipment showed that some parts of the ultrafiltration apparatus were missing. This hindered the putting of the apparatus into action.

The delivery of the decanting centrifuge was delayed

and it was not available at the beginning of my term.

The freeze-dryer was not unpacked till the arrival of the expert in lyophilization (November 1986). The examination of the machine upon unpacking showed that it had suffered serious damage during transportation. The state of the machine was described in a protocol of 24 November 1986.

A number of apparatuses (filters, centrifugal pumps, peristaltic pumps, pressure vessels, colloid mill, etc.) were installed, tested and put into action after the work on the electric net was completed. Simultaneously the author trained the local personnel attached to me on the operating principles, installation and maintenance of this equipment.

In cooperation with the quality control expert the set of apparatuses for automatic chromatography analysis was put into operation.

The ampoule filling and sealing machine was mounted, the laminar flow hood was attached to it and the machine was connected to sources of propane and oxygen. Following the instructions of the Chief Technical Adviser and the expert in blood protein fractionation the dosage of the machine was adjusted according to the needs of the local production. Special attention was paid to training of local personnel to use the ampoule filling and sealing machine. The trainees got acquainted with the operation principles, the different adjustments, running and maintenance of the machine and safety measures during operation (especially safety of work with the ignition gases).

Laminar flow hood for sterile manipulations was also installed and put into action.

The installation and putting into action of the lyophilization apparatus was connected with overcoming of many difficulties. It was mentioned above that the apparatus had suffered substantial damage during transportation (this was described in a protocol). Great efforts were made to remove the damages, some essential units like the temperature controller were replaced (it was

good that the most essential spare parts were delivered with the apparatus). The air injection system had to be modified. Additional difficulties were created by some wrong electric connections in the apparatus itself. One could have in mind that normally this kind of apparatuses are installed and put into action by a representative of the firm. Probably this was one of the reasons that some wrong connections were left. It took time to find them and make the appropriate electric connections to ensure the regular operation of the freeze-dryer. In spite of the described difficulties, in cooperation with the expert in lyophilization the apparatus was put into action. Local personnel was trained on the operation and maintenance of the basic units of the freeze-dryer.

After the delivery of the centrifuge CEPA-Technicum TE-3, it was also installed and put into action.

A list of the available spare parts was made. The basic items of equipment were supplied with enough spare parts to last several years. A list of details which could be worn out during operation was also prepared. The lists were handed over to the specialists concerned. The spare parts should be ordered in time to ensure the regular work of the apparatuses over the years.

CONCLUSIONS

The duties of maintenance engineer specified in the job description were fulfilled:

The existing situation at the beginning of my term enforced the reconstruction of the electric installation, the reconstruction of the cooling system and repair of the available (before the implementation of the project) equipment.

The newly supplied equipment for the fractionation, lyophilization and quality control was examined, installed and put into regular operation.

Local personnel was trained in the operation and maintenance of equipment.

A list of spare parts delivered with the basic items of the equipment and a list of details which could be worn out during operation were prepared (to be considered when spare parts are ordered). The lists were handed over to local specialists.

RECOMMENDATIONS

The Blood Fractionation Unit is not fully ensured with technical, sufficiently qualified staff for the repair and maintenance of the supplied equipment for the implementation of the project. At present only the person who takes the position of fractionation engineer had the needed technical qualification. That is why, it is recommended that an experienced mechanic is appointed to take care of the routine repairs and maintenance of equipment. Spare parts for the equipment should be timely ordered and supplied.

Annex - Programme for training of Mongolian personnel on operation of the equipment in the Blood Fractionation Unit

PROGRAMME FOR TRAINING OF MONGOLIAN PERSONNEL ON OPERATION OF THE EQUIPMENT IN THE BLOOD FRACTIONATION UNIT

1. Mounting, installation, operation and maintenance of the equipment in the cold room (reactors, filters, pumps, etc.)
2. Mounting, installation, operation and maintenance of the equipment in the room for the preparation of placental extract (decanting centrifuge, pumps, etc.)
3. Mounting, installation, operation and maintenance of the lyophilization equipment
4. Mounting, installation, operation and maintenance of membrane filters, pressure vessels, pumps (equipment for clarifying and sterile filtration)
5. Maintenance, installation, operation of the laminar flow hood
6. Mounting, installation, operation and maintenance of the ampoule filling and sealing machine
7. Mounting, installation, operation and maintenance of the equipment for control of biopreparations
8. Mounting, installation, operation and maintenance of the ultrafiltration apparatus
9. Preparation of a list of spare parts for the equipment and training local personnel to this end

In-service training was carried out during mounting and operation of equipment. The technical staff participated in the training. Once a week discussions were held on the work done and on maintenance problems.

The following persons participated in the training programme: Ganbat, Bajarsaikhan, Ganbold, Boldbaatar