PHC 162

PROJECT PLAN
FOR
ESTABLISHMENT OF A FACILITY
TO
PRODUCE TETANUS TOXOID
AT
THE NATIONAL INSTITUTE OF HEALTH
ISLAMABAD, PAKISTAN

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Ottawa, Canada

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INDEX

GLOSSARY OF TERMS AND ABBREVIATIONS

- Basic Production	- Manufacture of the final, ready-for-use product from seed
- DPT	- Diphtheria and Tetanus Toxoids combined with Pertussis Vaccine
- EPI	- Expanded Program on Immunization
- GMP	- Good Manufacturing Practices Code
- GON	- Government of the Netherlands
- GOP	- Government of Pakistan
- HVA	- Heating, Ventilation, Air-conditioning/purification
- Intermediate Production	- Manufacture of the final ready-for-use product from imported bulk concentrate
- K	- Thousands
- Lf	- Floculating Unit -(measure of potency of T.T.)
- NIH	- National Institute of Health, Islamabad
- NNT	- Neonatal Tetanus
- MV	- Measles Vaccine
- OPV	- Oral Polio Vaccine
- Q.A.-	- Quality Assurance
- Q.C.-	- Quality Control
- RHDC-	- Rabies Vacine, Human Diploid Cell Origin
- RIV	- Rijksinstituut Voor Volksgezondheid
- S.O.	- Senior Officer
- SOP	- Standard Operating Procedures
- T.T.	- Tetanus Toxoid
- USAID	- U.S. Agency for International Development
- WHO	- World Health Organization

1. EXECUTIVE SUMMARY

- The Project comprises the establishment of an up-to-date facility at NIH to produce T.T for the prevention at NNT (See Section 2).

  The GOP requested the assistance from USAID in the form of a 150-litre Fermentor.

  In April 87, the Consultant visited NIH to ascertain NIH's capability of undertaking such a Project. He recommended at the time that NIH prepare a detailed Project Plan prior to the purchase of a Fermentor be undertaken by USAID (See Section 3).

  As such a Project Plan had not been developed by NIH, the Consultant visited Islamabad from January 20 to 29, 1988 to undertake this task in collaboration with NIH staff.

  The maximum annual rated capacity of this Project is 18 million doses of T.T (Section 5).

  The Project is expected to take from Feb 1988 to July 1990 (Section 7).

  The recommended staffing of the facility was established and job descriptions prepared (Section 8)

  The existing technical expertise was assessed by the Consultant (Section 9).

  An appropriate lay-out of the Facility was developed (Section 11).

  A detailed list of equipment required for the Project was prepared (Section 12).

  A series of recommendations on Project Management, Training and Intermediate Production have been made (Section 15).

2. BRIEF DESCRIPTION OF PROJECT

- To provide the National Institute of Health, Islamabad, Pakistan ("NIH") with the capacity to locally manufacture Tetanus Toxoid ("TT") for prevention of neonatal tetanus ("NNT") of a quality meeting (or exceeding) WHO specifications in sufficient quantity to satisfy all Pakistan's requirements and to ensure that such production is carried out in premises conforming to pertinent WHO specification and under conditions conforming to a Good Manufacturing Practices code.

3. PROJECT BACKGROUND

- The incidence of neonatal tetanus (NNT) in Pakistan is high. (see page 9 of Dr. N. Hirschhorn's report dated April 2-13 '87.)
- Consequently Pakistan desires to commence an Accelerated Tetanus Toxoid Initiative for married women of childbearing age as well as pregnant women.

- In line with the GOP's policy of vaccine self-sufficiency, the GOP approached USAID to fund the purchase of a fermentor to manufacture T.T. locally.

- At the request of USAID, the Consultant visited NIH in April'87 to review the request for a 150 litre fermentor.

- At that time the Consultant's basic recommendation was that USAID inform NIH that the former is prepared to assist in the establishment of basic T.T. production by providing a fermentor as well as selected other equipment and materials subject to NIH developing an integrated Project Plan for the execution thereof.

- As of January '88, NIH had not developed such a Project Plan.

4. LOCATION OF THE FACILITY

- The facility will be located at the NIH and will occupy the space currently used for TT production plus an extension therof which is to be erected.

5. MAXIMUM ANNUAL CAPACITY OF THE FACILITY

- The facility will be designed to provide a maximum annual output of 18 million doses of T.T.

6. FINAL PRODUCT PRESENTATIONS

- The final ready-for-use product will be presented in 10-dose (10 Lf/dose of 0.5 ml.) glass vials, stoppered, capped and labelled.

- These vials will be boxed as follows:

6 - vial carton	(60 doses)
10 - vial carton	(100 doses)
20 - vial carton	(200 doses)

- Three direction inserts will be packed per carton.

7. ESTIMATED PROJECT TIME-FRAMES

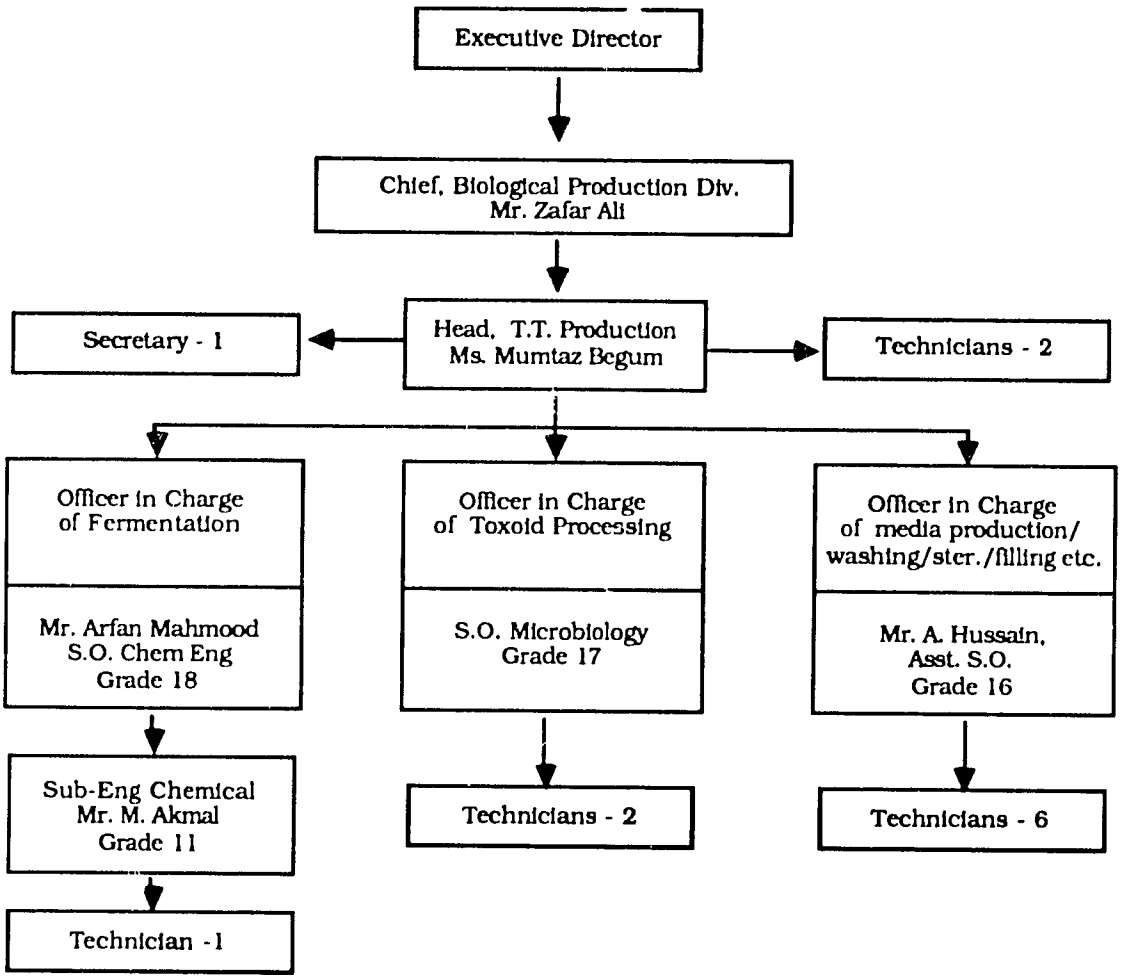
- The Project is estimated to take a total of 29 months, i.e. from February 1, 1988 to June 30, 1990.

- Appendix I details, in bar-chart form, the estimated time-frames of the major activities.

8. RECOMMENDED STAFFING OF THE FACILITY

8.1 *Organizational Structure*

- The following organizational structure has been agreed upon:



8.2 *Notes:*

- Head of T.T. Production proposed currently is in charge of the same.
- Mr. Mahmood is eminently qualified to be the Officer-in-charge of Fermentation. However the Consultant has a concern about a work-overload for Mr. Mahmood , as he also supervises the fermentation of Cholera, Typhoid and Paratyphoid A & B Vaccines, production of dialysis fluid preparations and the maintenance of equipment in the Bacterial Department.

- Consequently it is recommended that Mr. Mahmood be relieved of his supervisory duties for dialysis fluids and maintenance, commencing immediately.
- It is further recommended thi Mr. Mahmood be named as the Project Manager responsible for overseeing the building erection/ modification and installation of equipment. Past Connaught experience with the Polio, Measles and Rabies facilities has shown the necessity for a Project Manager.
- The post of Officer in charge of Toxoid Processing creates a major concern as, apparently, this function cannot be filled by an existing NIH staff member who has had hands-on experience. Instead NIH currently is interviewing a microbiologist from outside with no production experience.

8.3 Job Descriptions

- These have been developed between Mr. Zafar Ali and the Consultant and are listed in Appendix II(A).

8.4 Qualifications and Experience of Senior Staff

- These are described in Appendix II(B).

9. EXISTING TECHNICAL EXPERTISE

9.1 Preparation of Production Seed lots

- Expertise to undertake this is available in N.I.H.

9.2 Media Production

- The NIH expertise is weak in this area.
- Hence it is recommended that training be obtained for this purpose abroad.

9.3 Toxoid Processing

- The NIH expertise is weak in this area as well, especially for large-scale production.
- Hence it is recommended that training be obtained abroad in this field.

9.4 *Q.C. (in process and final container) and Q.A.*

- Expertise exists in NIH

9.5 *Washing and Sterilization*

- It is recommended that the T.T. staff be trained in this area by NIH members of the MV plant.

9.6 *Filling, Stoppering, Labelling and Packaging*

- As for 9.5 above

9.7 *Record Keeping*

- As for 9.5 above

9.8 *Production Scheduling*

- As for 9.5 above

9.9 *Maintenance*

- Following the visit of Mr. Mahmood to the New Brunswick Co. coupled with existing expertise in maintenance of the OPV and MV facilities, it is deemed that sufficient in-house experience is available.

10. STAFF TRAINING

10.1 *Training Abroad*

- As it is deemed likely that the Rijksinstituut Voor Volksgezondheid (RIV) will eventually provide technology transfer for DPT production to the NIH with funding by the GON, coupled with the fact that NIH currently uses seed from the RIV as well as their formulation for media, it is recommended that training in these areas listed in Section 9 be obtained at the RIV.
- Appendix III outlines the current status of the RIV DPT project.

10.2 *In-House Training*

- It is strongly recommended that NIH develop, a formal, precisely defined, in-house training program.

10.3 Timing of Training

- These are specified in Appendix I.

11. LAY-OUT OF THE FACILITY

11.1 Interior Lay-Out

- The lay-out submitted by NIH was discussed and radically changed. (See Appendix IV).
- This lay-out will be discussed by the Consultant with staff of Connaught as a double-check.
- Following this it is recommended that NIH send the lay-out to Dr. Magrath, Chief of Biologicals, WHO, with a request for comments and/or approval.

11.2 Interior Finishes

2.1 Sterile Areas

- All joins (e.g. corners, ceiling to wall, wall to floor) should be coved.
- Hanging panelled ceilings are not permitted.
- Walls and ceiling are to be painted twice with a washable epoxy paint.
- Floors should either be epoxy covered or made out of large terrazo slabs with joins between the slabs being grouted level with the slabs.

2.2 Windows and Doors

- Windows should have aluminum frames, should be double-glazed and such that they cannot be opened.
- Doors and door frames should be made from aluminum and glassed in (semi or total).

12. EQUIPMENT

12.1 General

- Although NIH previously submitted a list of required equipment, the Consultant, jointly with Messrs Zafar Ali, Mahmood and Akhtar have gone through the entire production process to ensure that all required

equipment was included as well as to define the type (model # etc.) of each.

- All effort has been made to provide as much uniformity of equipment as possible with the existing OPV, MV and RHDC plants to facilitate stocking of spare parts and maintenance.
- Based on previous experience, it is recommended that relatively fragile prices of equipment (such as the vial filler/stoppering machine, and the labeller) be despatched by air.
- In addition, it is recommended that delicate electronic controls be removed from the pieces of heavy equipment and the former shipped by air.
- Quotations should include sea-worthy export packing and, in the case of the fermentor, the service of a member of the fermentor company on site to assist with the installation and run-up.

12.2 *General Specifications for Equipment with Electric Motors etc.*

- The motors etc should be tropicalized.
- They should be designed for 220 V. 3 phase, 50 cycles.
- Due to relatively frequent brown-outs and complete power loss of the electrical grid, major pieces of equipment should be provided with a stabilizer as well as a cut-off in case one of the three phases fails.
- Appendix V states the list of equipment and their specifications, (in so far as they could be ascertained) as well as suggested manufacturers in the U.S.

13. INTERMEDIATE PRODUCTION

- It is recommended that following the validation and commissioning of the facility, intermediate production be commenced and continued until three consecutive lots of basic production have successfully passed Q.C. testing.

- This system, successfully proven by Connaught Laboratories Ltd. Toronto, Canada for the establishment of the OPV and MV (and currently the RHDC operations), has the following major advantages:

- it permits the training of personnel in washing, sterilizing, dilution, filling, packaging and final Q.C. testing under actual operating conditions;
- it allows testing of major pieces of equipment, the HVA system etc. under actual operating conditions;
- it permits NIH to supply large quantities of T.T. to the EPI bearing NIH's name. This has been shown, in the case of OPV, to provide a major stimulus to the immunization program.

- Intermediate production will require the provision of 10 months' supply of bulk concentrated T.T. which, at an estimated 25% coverage, will total:

  22,000 K. : 25% coverage: 10/12 + 10% overfill and testing samples = 5,040 K doses or 50,400 K Lf of bulk concentrated T.T.

14. BASIC PRODUCTION

- It is recommended that the 16-litre New Brunswick fermentor currently located in the Cholera/Typhoid facility be moved to the T.T. plant.

- It can then be used to commence pilot scale basic production without wasting large quantities of media.

- Once pilot production is working satisfactorily, trial production can commence in the 150 litre fermentor.

- Basic production shall be deemed to be fully operational only once three consecutive full-scale production lots have been manufactured which pass Q.C.

- It is recommended that these lots not be released for distribution until samples of all three lots have passed Q.C. by WHO Geneva.

15. RECOMMENDATIONS

15.1 Project Management

- Appointment of Mr. Arfan Mahmood as Project Manager.
- Establishment of a Working Group consisting of the Project Manager, the Chief of Biological Products Division and the Head of MV Production.
- Regular monthly (and, if need be, more frequent) reporting by the Working Group to Maj. Gen (Retd) M.I. Burney (Ex-Executive Director at NIH and current Honorary Consultant on Vaccine Production at NIH) and to the new Executive Director (once appointed).
- Continued involvement of the Consultant throughout the Project duration.

15.2 Training

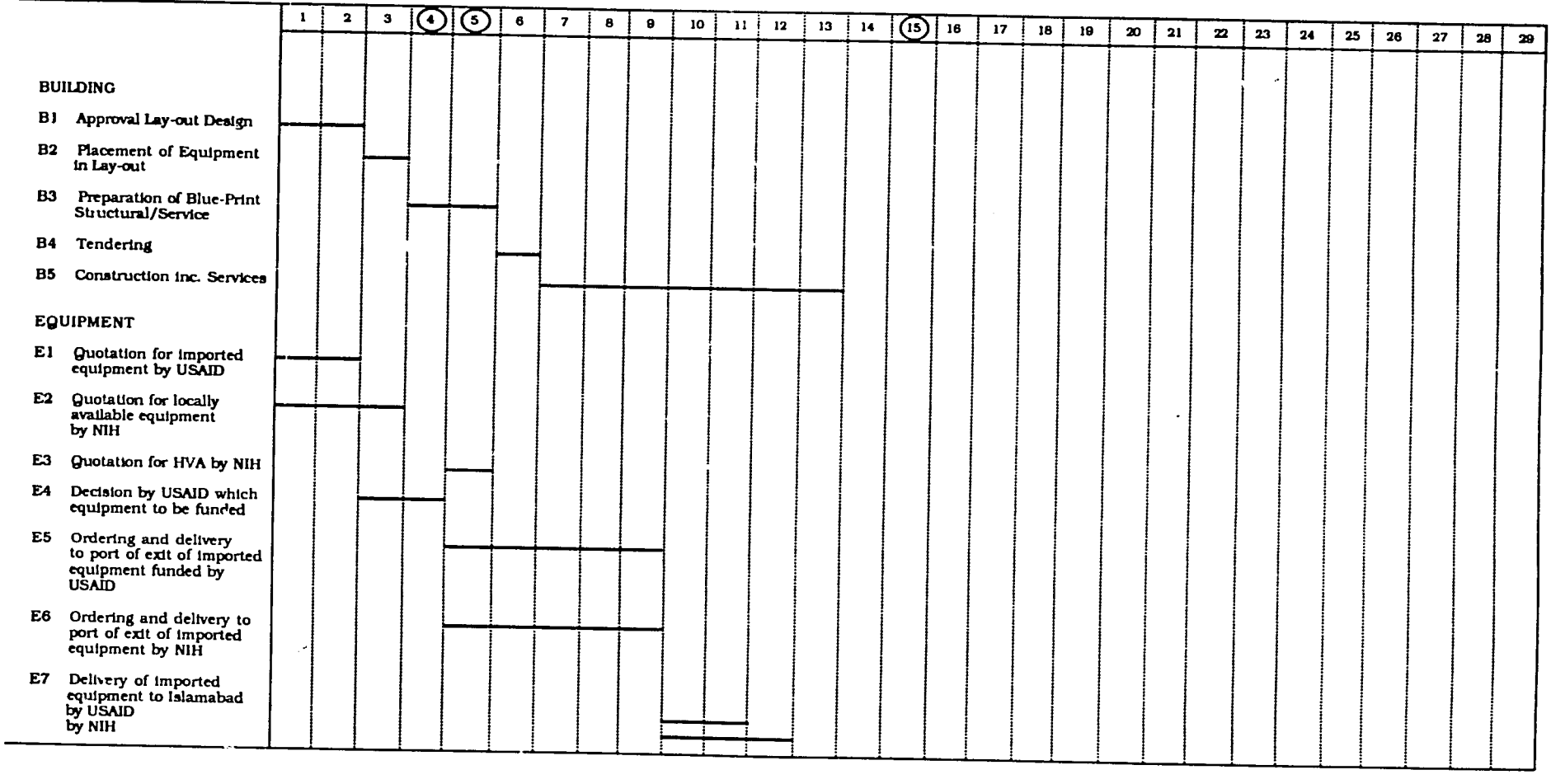
- Establishment of a Formal, in-house training program.
- Training of the officer in charge of Toxoid Processing and the one in charge of Media Productions, etc at RIV.

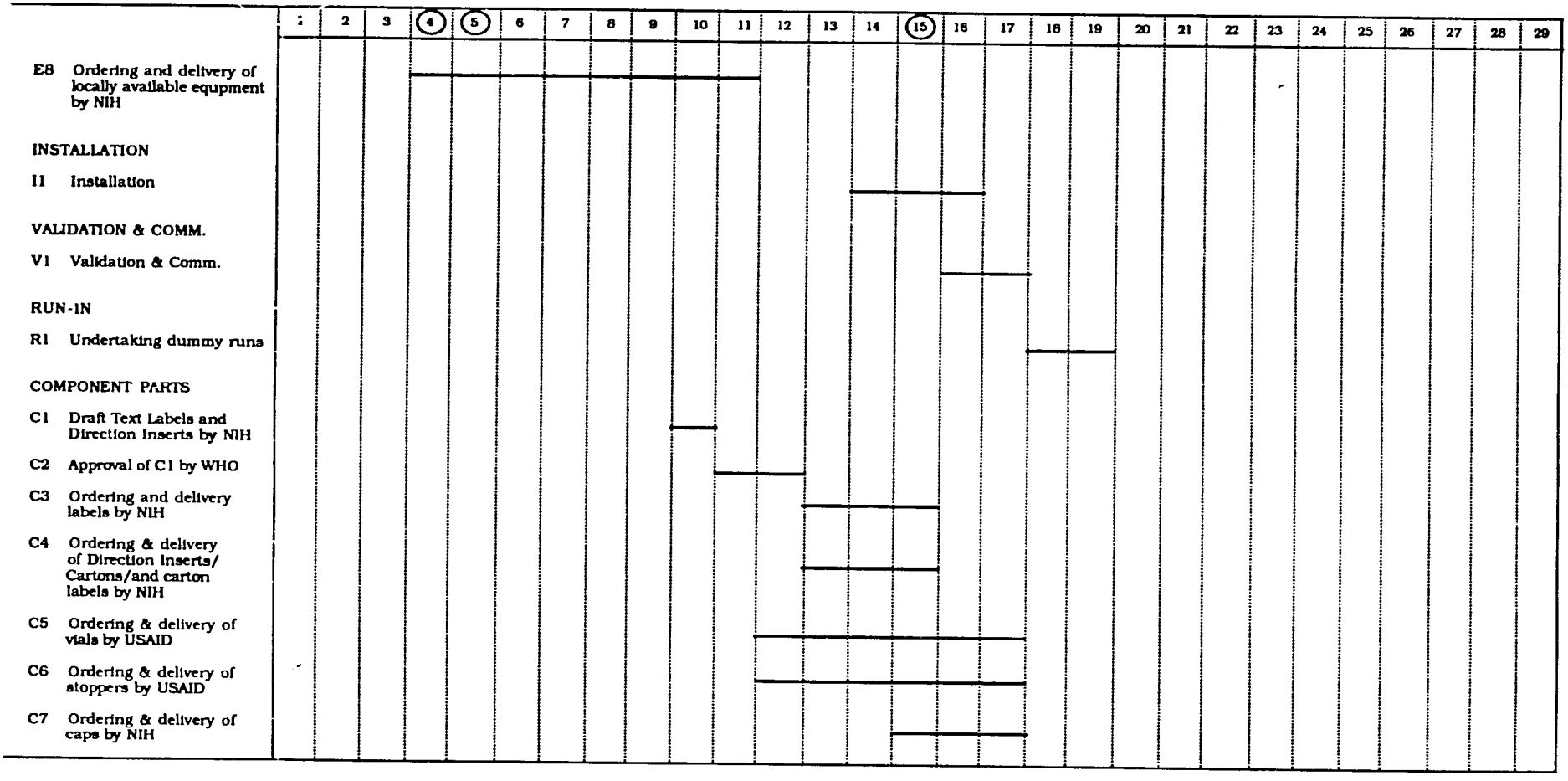
15.3 Intermediate Productions

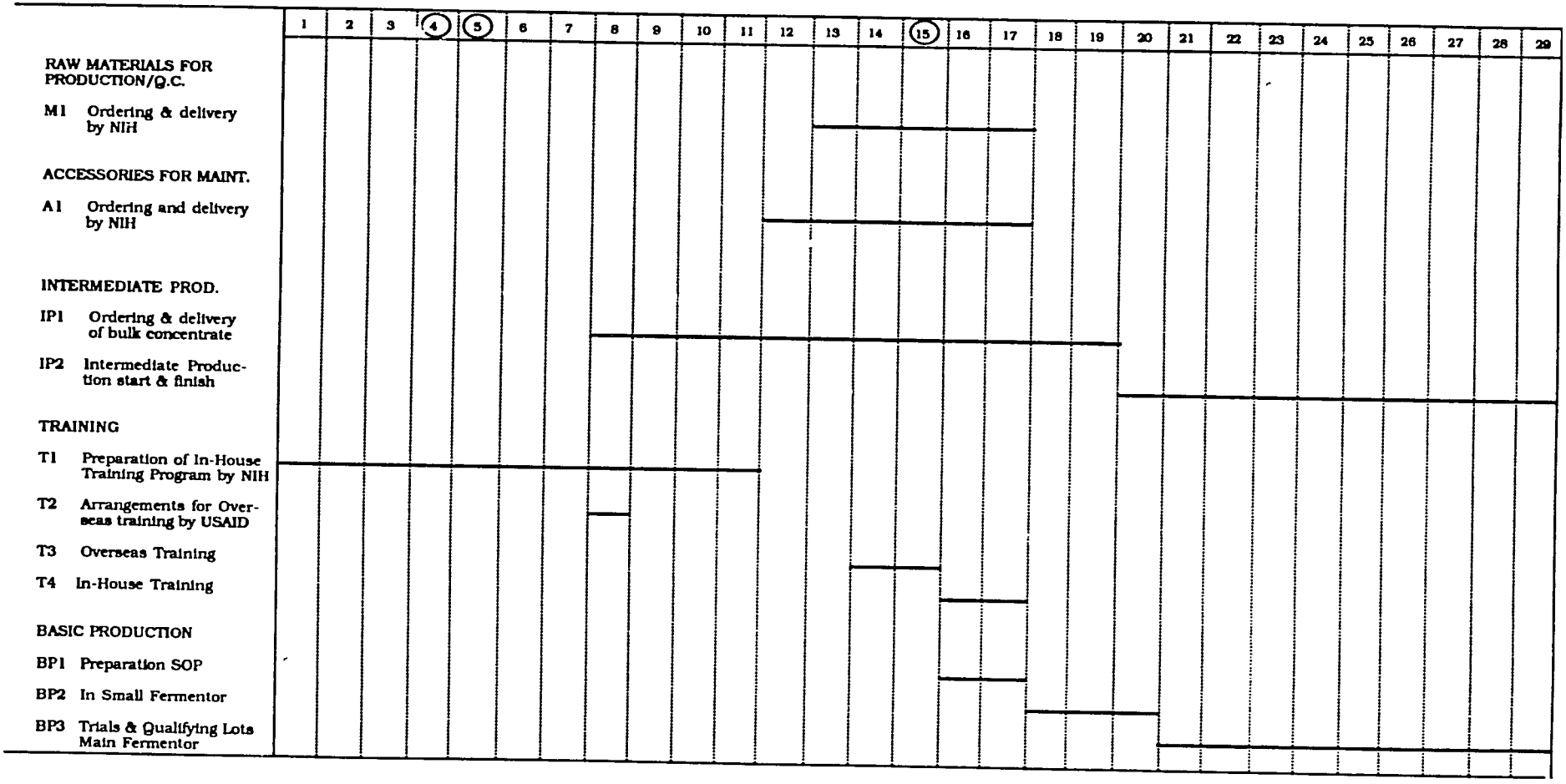
- Establishment of intermediate production by the provision to NIH of a pre-determined quantity of bulk concentrated T.T by an, as yet to be established, donor agency.

APPENDIX 1

ESTIMATED TIME FRAMES




1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29
E8 Ordering and delivery of locally available equipment by NIH
INSTALLATION
I1 Installation
VALIDATION & COMM.
V1 Validation & Comm.
RUN-IN
R1 Undertaking dummy runs
COMPONENT PARTS
C1 Draft Text Labels and Direction Inserts by NIH
C2 Approval of C1 by WHO
C3 Ordering and delivery labels by NIH
C4 Ordering & delivery of Direction Inserts/ Cartons/and carton labels by NIH
C5 Ordering & delivery of vials by USAID
C6 Ordering & delivery of stoppers by USAID
C7 Ordering & delivery of caps by NIH


1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29
RAW MATERIALS FOR PRODUCTION/Q.C.
M1 Ordering & delivery by NIH
ACCESSORIES FOR MAINT.
A1 Ordering and delivery by NIH
INTERMEDIATE PROD.
IP1 Ordering & delivery of bulk concentrate
IP2 Intermediate Production start & finish
TRAINING
T1 Preparation of In-House Training Program by NIH
T2 Arrangements for Overseas training by USAID
T3 Overseas Training
T4 In-House Training
BASIC PRODUCTION
BP1 Preparation SOP
BP2 In Small Fermentor
BP3 Trials & Qualifying Lots Main Fermentor

APPENDIX II(A)

JOB DESCRIPTIONS

1. *In-Charge T.T Production*

1.1 Overall Responsibility:

- Total responsibility and accountability for the proper functioning of the T.T laboratory, including the administration.

1.2 Specific Responsibilities

- Production scheduling;
- ordering of raw materials, component parts, etc. to permit scheduled production;
- ensures full compliance to Standard Operating Procedures (SOP), amends SOP when required and obtains approval for such changes from Chief, Biological Products Division and the Q.C. division;
- ensures compliance to the Good Manufacturing Practices code (GMP);
- prepares the production seeds;
- supervises two technicians in the execution of in-process Q.C;
- supervises the transfer of quarantined finished goods to the released goods storage area;
- preparation and maintenance of appropriate reference standards;
- handles personnel matters.

1.3 Reporting Relationship

- this function reports to the Chief, Biological Products Division.

2. *In Charge of Fermentation/ Project Manager*

2.1 Overall Responsibility

- Total responsibility for the operation of the Fermentation unit and maintenance of the T.T Facility.

2.2 Specific Responsibilities

- Ensures that fermentation takes place in accordance with the production schedule and SOP;
- ensures adherance to GMP in the Department;
- supervises the preventive (and where possible) corrective maintenance of the T.T. equipment and Facility itself;
- maintains an adequate supply of spare parts and accessories;
- during the period of erection at the T.T. Facilities, acts as Project Manager for the supervision of the construction of the building, installation of services and equipment in which task the Project Manager shall be assisted by the Head of MV production and the Chief, Biological Products Division;
- supervises the working of a Sub-Engineer and 1 technician.

2.3 Reporting Relationship

2.3.1 During Erection of T.T Facility

- this function will report directly to the Chief, Biological Products Division

2.3.2 After Erection of the T.T. Facility

- this function will report to the Head, T.T. Production.

3. *In Charge of Toxoid Processing*

3.1 Overall Responsibility

- Total responsibility for the processing of the toxin from the fermentor stage to the diluted bulk stage.

3.2 Specific Responsibilities

- Ensures that pre-filtration, detoxification, ultra-filtration, dilution and mixing takes place in accordance with the production schedule and SOP;
- maintains an adequate supply of production accessories and pertinent chemicals;
- prepares the aluminum phosphate gel according to the SOP;

- ensures adhere to GMP in the department;
- supervises the working of two technicians.

3.3 Reporting Relationship

- this function will report to the Head, T.T. Production.

4. *In Charge at Washing/Sterilizing and Finishing Operations*

4.1 Overall Responsibility

- Total responsibilities for the washing, sterilizing, media production, and finishing operations.

4.2 Specific Responsibilities

- Ensures adequate supplies of sterile goods to other Departments and his own;
- prepares media in accordance to the production schedule and the SOP;
- ensures the filling, stoppering, capping, labelling and packaging in accordance with the production schedule and the SOP;
- maintains an adequate stock of component parts, chemicals for media production and related accessories;
- is in charge of the proper functioning of the component parts, chemicals and accessories store;
- ensures adherence to GMP in the department;
- supervises the working of six technicians.

4.3 Reporting Relationship

- this function will report to the Head, T.T. Production.

APPENDIX II(B)

QUALIFICATIONS AND EXPERIENCE OF SENIOR STAFF

1. Head T.T. Production - Ms. Mumtaz Begum

- Qualifications:
  - M.Sc; M.Phil (Microbiology); Diploma Medical Biology.

- Experience:
  - Seven years experience in production and Q.C of bacterial vaccines and sera at NIH Islamabad.

2. Officer in Charge of Fermentation - Mr. Arfan Mahmood

- Qualifications:
  - B.Sc (Chem. Engineering); D.R.A.C; F.L.C.P.

- Experience;
  - 3 years experience at NIH in installation, operation and maintenance of Fermentor;
  - 8 years experience in private pharmaceutical industry in Pakistan;

3. Officer in Charge of Washing/Sterlizing and Finishing Operations - Mr. Abid Hussain.

- Qualifications:
  - B.Sc

- Experience:
  - 20 years experience in all aspects of production of bacterial vaccines at NIH Islamabad.

APPENDIX III

POTENTIAL DPT PRODUCTION AT NIH WITH GON FINANCIAL ASSISTANCE

- For a number of years the GOP and the GON have been holding discussions on GON funding local production of DPT at NIH.

- As such a venture will produce, amongst other biologicals, T.T. as well, and as such potentially could lead to a duplication of facilities for T.T. manufacture, it was deemed essential to ascertain the current status of this project.

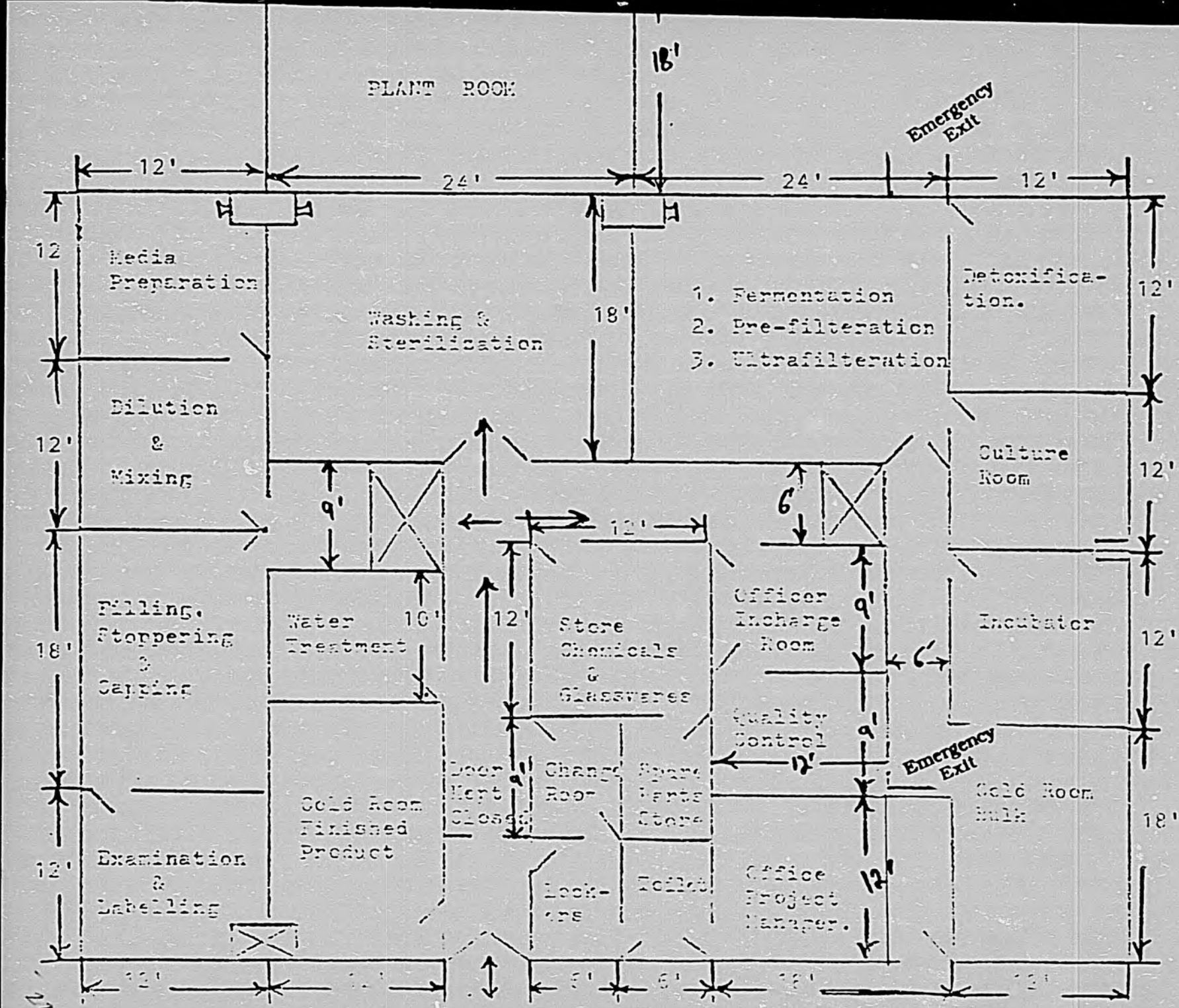
- During the last Bilateral Consultations on the development cooperation between the GOP and the GON, on December 9 and 10 '87, the GON's potential aid funding was increased from Dfl.14 million to Dfl.20 million. However the Netherlands delegation reported that approval of the project by the Netherlands has been delayed due to its apparent low cost/benefit ratio.

- On January 5, 1988 a committee consisting of representatives of NIH, the GOP Planning Division and the Netherlands Embassy met and submitted a report on additional benefits of such a Project.

- To date no reaction to this report has been received from the GON.

- Should the GON approve the project in, say, February '88, it appears unlikely that the M.O.U. between the two Governments could be signed until say June or July '88.

- As the total project has an estimated duration of 84 months, it seems reasonable to assume that the commencement of basic production of T.T. would not be at least until mid- 1994 versus an estimated completion date of the T.T. project by Sept.'90.


PLANT ROOM
18'
Emergency Exit
12'
24'
24'
12'
12
Media Preparation
Washing & Sterilization
18'
1. Fermentation
2. Pre-filteration
3. Ultrafilteration
Detoxification.
12'
Dilution & Mixing
12'
Culture Room
12'
9'
12'
6'
Filling, Stoppering & Capping
18'
Water Treatment
10'
12'
Store Chemicals & Glasswares
Officer Incharge Room
9'
6'
Incubator
12'
Quality Control
9'
12'
Emergency Exit
Door Kept Closed
9'
Change Room
Spare Parts Store
Cold Room Finished Product
Cold Room Milk
18'
12'
Examination & Labelling
Lock-ers
Toilet
Office Project Manager.
12'
12'
12'
6'
6'
18'
12'

APPENDIX V

LIST OF EQUIPMENT AND THEIR SPECIFICATIONS

Note: (I) denotes equipment to be imported
(L) denotes equipment which can be procured locally

1. WASHING & STERILIZING:

1.1 Vial Washing

- Vial Washer semi automatic Metromatic products Corp. 10 Audrey Ave., Oyster Bay NY 11771, Model No. for 7 ml vials.		1 unit	(I)
Filters			
- Manufacturer Pall Corp.			
Filter Housing for:	Town Water P/N - SANT 2G723 S/N - 5H5 G 1396-1	1 unit	(I)
	Distilled Water Same as above	1 unit	(I)
	Air P/N SANT 1G723 S/N 5HS F2002 -1	1 unit	(I)
	Steam VCL 1002C16H S/N E1621-83	1 unit	(I)
Cartridges for:	Town Water AB2NR7P 0.2/µm	12 Nos.	(I)
	Distilled Water AB2NR7P 0.2/µm	12 Nos.	(I)
	Air AB1FR7PV	12 Nos.	(I)
	Steam VCL 1002C16H S/N E1621-83	6 Nos.	(I)

1.2 Washing of Equipment

Stainless Steel Sink	See attached drawing	1 unit	(I)

1.3 Washing of Sterility suits/coats etc.

Household type washer	1 Unit	(L)
Household type dryer	1 Unit	(L)

1.4 Autoclaving of Equipment

Autoclave for small equipment (Double door - Steam operated) Make: AMSCO Model: Eagle 2023	01 Unit	(I)
Autoclave for 150 Lt. tanks (Double door - Steam operated) Make: AMSCO Model: Eagle 2051 Size: 24 x 36 x 60	2 Units	(I)
Trollies for conveying tanks to Autoclave (Carriage)	1 Unit	(I)
Loading Car	2 Units	(I)

1.5 Sterilization of Gowns, Vials

Hot Air Oven (Pass through Sterilizer Double door) Model: 1257 - Temp. up to 280°C Make: BDK Temperature System 208 Toryork Drive, Weston, Ontario M9L 1Y2 (416) 749-9789 / 745-6821	1 Unit	(I)

2. FILLING, STOPPERING, CAPPING, LABELLING, EXAMINING.

2.1 Filling/Stoppering of Vials

Filling/Stoppering machine Make: Cozzoli Model: FSV 30/PS10 C	1 Unit	(I)
Unscrambling Tables Make: Cozzoli Model: UT 30	2 Units	(I)

2.2 Capping of vials

Capping machine Make: West Coy Phoenixville, U.S.A. Model: PW500	1 Unit	(I)
Unscrambling Table Make: Cozzoli Model: UT 30	1 Unit	(I)

2.3 Labelling of vials

Labelling Machine Newman Labelling Machine Ltd., Queen Rd. Barnet, Herts, U.K. EN5 4DL UK Model: 5 VA Facilette	1 Unit	(I)

2.4 Sterile air

Laminar Flow Hood Make: Envirco (New Mexico, U.S.A.) Model: 802030 S/N: 83060266	1 Unit	(I)

2.5 Examination:

Conveyor Belt	1 Unit	(I)
Table, Light & Background	1 Unit	(L)

3. PRODUCTION

3.1 Storage of Seed Culture

Upright Deep Freezer - 70 to 80°C Autocharge performance monitor Forma Scientific Division of Millinkrodt Inc. Box 649 Marietta, USA. Model: 8300 (8318) 13 cu. ft.	1 Unit	(I)

3.2 Manufacture of Production Seed:

Laminar Flow Unit - Bench Model Thomas Scientific, 99 High Hill Rd. AT1-295. P.O. Box 99 Swedesboro,. N.J. 08085-0099 USA 609-467-2000 Model: 5170-C40 Flow Station LF-630, 6 ft. Volt: 230, 50HZ	1 Unit	(I)
Laboratory Binocular Microscope Fisher or any other	1 Unit	(I)

3.3	Incubation:		
	Incubator Room	1 Unit	(L)
3.4	Media Preparation		
	20 Ltr. bottles for preparation of Aluminium Phosphate Gel	20 Units	(I)
	Mixing Tank with Stirrer Stainless Steel - 100 litres.	3 Units	(I)
	pH meter Corning Model: 140 (Corning 475372) Digital pH meter Ref. No. 4135-G40	1 Unit	(I)
3.5	Fermentation		
	150 ltr. fermentor with accessories and spares: New Brunswick Scientific Corp. Specification: See Appendix.	1 Unit	(I)
3.6	Pre-filteration		
	Millipore filters 0.45/µm (see Appendix) - do - 0.22/um (- do -)		(I)
3.7	Ultra Filteration		
	Amicon Filter Specification: (See Appendix)		(I)
3.8	Bulk concentrate Production/Storage		
	6 ltr. Pyrex Graduated bottles	15 Units	(I)
3.9	Dilution		
	Stainless Steel Tanks 100 Lit. Cap.	6 Units	(I)
3.10	Filling		
	Stainless Steel Tanks 50 Lit. cap. (Design as per Appendix)	10 Units	(I)

4. INPROCESS QUALITY CONTROL

Details attached

5. SERVICES

5.1 Steam

Steam Boiler 2.5 ton	1 Unit	(L)
Steam Filter Pall Main Line Steam Filter S/N 7AMG 4737M Model: SMX 1120 H 32J.7	1 Unit	(L)

5.2 Electricity

Electricity from Grid		
Stand-by Generator GEC Dorman Diesel Capacity: 200 KVA Diesel Operated Automatic starter within 10 seconds from Grid failure	1 Unit	(L)

5.3 Gas

Natural Gas available		(L)

5.4 Compressed Air

Air Compressor Local made (PWD)	1 Unit	
Air Dryer Model A35., S/N: 240 Kel Air U.S.A.	1 Unit	(L)

5.5 Heating/Ventillatin/Airconditioning/Purification

As per design by P.W.D.		(L)

5.6 Water

Town Water from main supply		
Booster Pump	2 Units	(L)

5.7 Water Treatment

Pre-filter (design by Mr. Arfan)	1 Unit	(L)
De-ionizing Unit Culligan	1 Unit	(I)
Model: DB 16W	1 Unit	(I)
DB 16S	1 Unit	(I)
Hi-flow filter	1 Unit	(I)
Still AMSCO Steam powered Still Capacity: 600 Gal. per/hr. Steam: 450 lts./hr Appropriate accessories	1 Unit	(I)
Distilled Water Storage Tank Make: AMSCO Jacketted Steam heated Capacity: 450 Lit. Appropriate Accessories	1 Unit	(L)

5.8 Stainless Steel Pipe with S.S. fittings

Stainless Steel Pipe 1/2" Dia.	400 ft.	(I)
Stainless Steel Pipe 3/4" Dia.	100 ft.	(I)
Elbow 1/2" Dia.	60	(I)
Elbow 3/4" Dia.	15	(I)
Tee 1/2 " Dia.	60	(I)
Tee 3/4" Dia.	15	I)
Union 1/2" Dia.	60	(I)
Union 3/4" Dia.	15	(I)
Nipple 1/2" Dia.	60	(I)
Nipple 3/4" Dia.	15	(I)
Valve 1/2" Dia.	60	(I)
Valve 3/4" Dia.	15	(I)
Socket 1/2" Dia.	60	(I)
Socket 3/4" Dia.	15	(I)

6. CHEMICALS AND REAGENTS

Details attached (I) & (L) NIL

7. COMPONENT PARTS

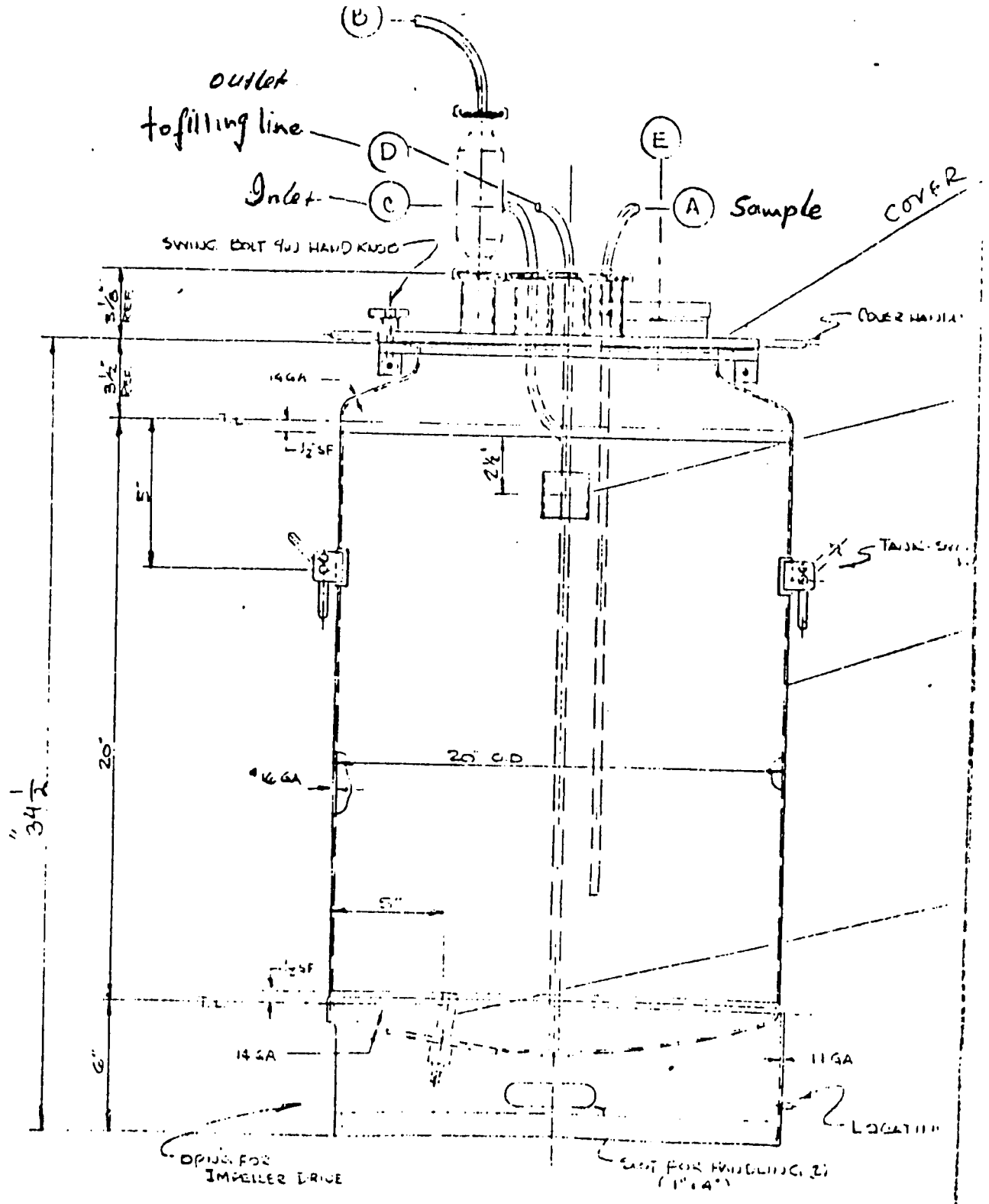
As per list given in F -1 form for: Fermentor, (L)
Cepa Centrifuge, Amicon filter, Nutrient Sterilizer, Rapid Chiller.
List of other part will follow soon.

MICROFILTERS FOR TETANUS TOXOID PRODUCTION
LABORATROY AT N.I.H. ISLAMABAD

NAME OF APPARATUS	MODEL/CAT NO.	FILTER TYPE	QTY
316 Stainless Sanitary Disc Holder 193 mm.	YY3029316 Millipore		12
Replacement Parts			
1. Adapter 1/2" TC to 9/16" ID	YY2004076		12
2. 1 1/2" TC Gasket Silicone	YY2004055		10
3. Clamp 1 1/2" TC	YY2004045		12
4. Vent/relief valve	YY3029366		12
5. Hand wheel bolt	YY2229357		72
6. Inlet Plat	000551		12
7. 0-ring, filter sealing Teflon	YY2229353		12
8. Inlet flow defloctor	YY3029307		12
9. Teflon-faced support Screen with 0-ring	YY3029354		12
10. Under drain support	YY3029358		12
11. 0-ring, Teflon (support screen)	YY3029360		12
12. Outlet Plate	000552		12
13. Plate Alignment Stud	YY2229370		12
14. Legs with nylon Pads	YY2229359		12
15. Hand wheel wrench	YY2229352		06
Accessories			
1. 1 1/2" TC Gasket, Teflon	YY2004057		04
2. 0-ring, filter sealing Silicone	YY2229374		12

3.	O-ring , Silicone (support screen)	YY2229375	12
4.	O-ring filter Sealing Vitron	YY2229361	12
5.	O-ring, Viton (support screen)	YY2229362	12
6.	PVC Tubing 1/2" ID x 10' with Clamps (not autoclabable)	XX6700035	12
7.	Back Pressure Support Screen, stainless	YY4025764	12
8.	Back Pressure support screen, Teflon coated	YT4025759	12
9.	Maximum Registering Thermometer	YY3000010	12
10.	Helicoil insert kit	YY3339311	12
11.	Helicoil inserts	YY2229312	12
Filter type 0.22 mm.		GS/FV	400
Filter type 0.45 mm.		HA/HV	400

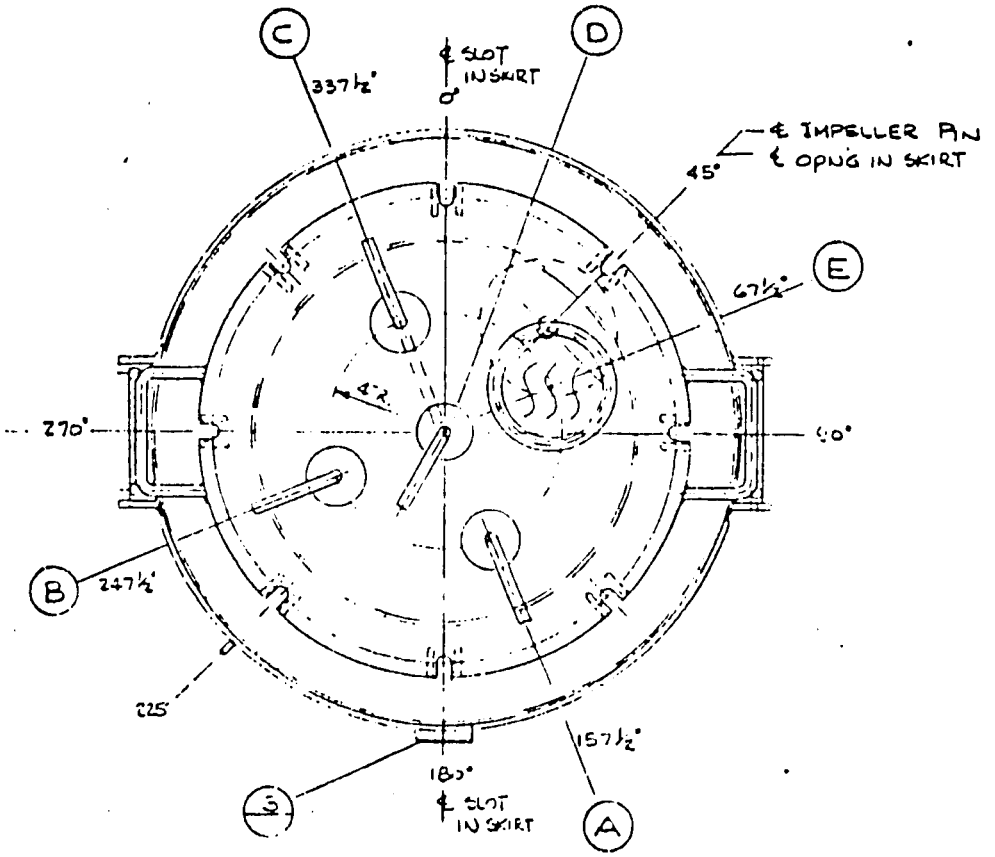
S.,No.	NAME OF APPARATUS	MODEL/CAT NO.	FILTER TYPE	QTY
01.	Dia Filteration/ Concentration system Air Operated system with Pump type LP30A	DC30A AMICON	5402	02
02.	Lollow Fiber Cartridges	H5P30-45	1875	50
03.	Replacement Kit for LP30A Pump	RKLP30A	7036	10
04.	Automatic Pressure Shut off	-	54357	10
05.	End-point Controller for liquid level shut off	EC22M	6053	10



Capacity = 120 Litters

(See Section)

(For Top View See Below View A)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℄ IMPELLER PAN & OPNG IN SKIRT
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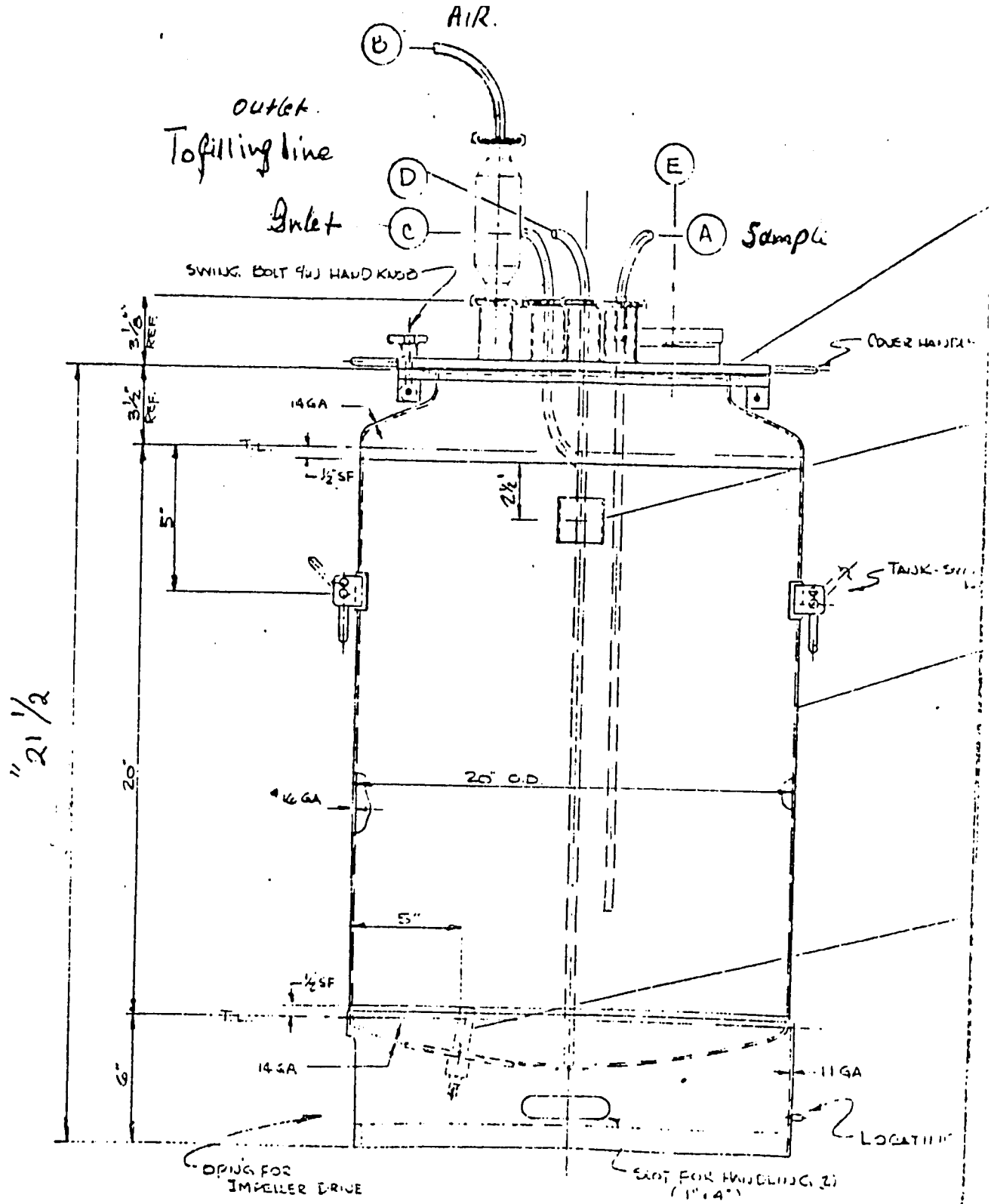
A

FULL VIEW



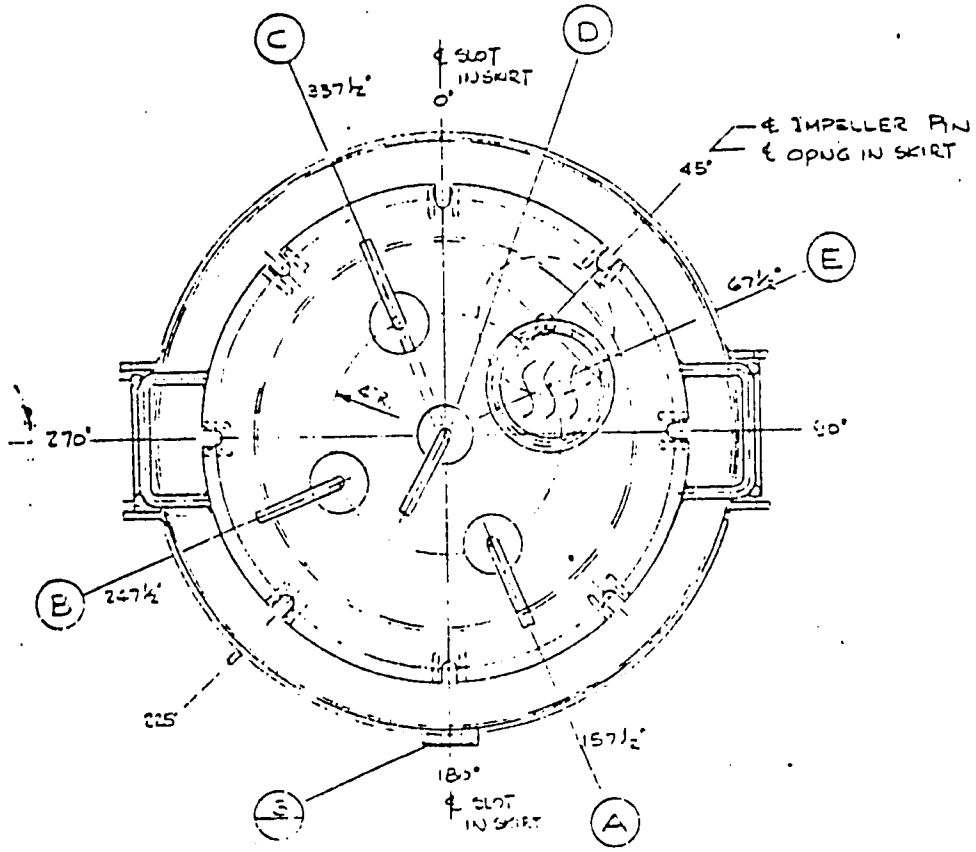
SIDE ELEVATION

(FOR TRUE OR FRONT VIEW SEE PLAN VIEW)

Capacity 60 Liters

CHEMICAL AND REAGENTS REQUIRED FOR BIOLOGICAL TESTING OF IN PROCESS CONTROL OF T. TOXOID FOR ONE YEAR.

1.	Tetanus Anti-toxin for Flocculation (International standard)	200 ml.
2.	Tetanus Challenge Toxin(Int'l std.)	200 ml/mg.
3.	Tetanus Toxoid 120 Iu/ampule (Adsorbed) (Int'l. std.)	5 ampules.
4.	Tetanus Toxoid 833 Iu/ampule (Plain) (Int'l. std.)	5 ampules.
5.	Thioglycollate Broth (Difco)	15 Kg.
6.	Soyabean Casein digest broth (Difco)	15 Kg.
7.	Tri-sodium hydrogen phosphate(Na_3Po_4) (E.Merk)	230 Kg.
8.	Aluminium Chloride ($Alcl_3$) (E.Merk)	150 Kg.
9.	Disinfectant (Wascodyne)	50 Lit.
10.	Standard Buffer (PH=4, PH=7, PH=9)	100 Tab.each.
11.	Disposable Syringes (1ml, 2ml, 2.5ml, 5ml, 10ml)	500 Nos.each.
12.	Pipetts disposable (0.1ml, 1ml, 2ml, 5ml. & 10 ml)	500 Nos. each
13.	Samples Bottles (Nalgen) 25ml, 50ml & 100 ml.	100 Nos. each.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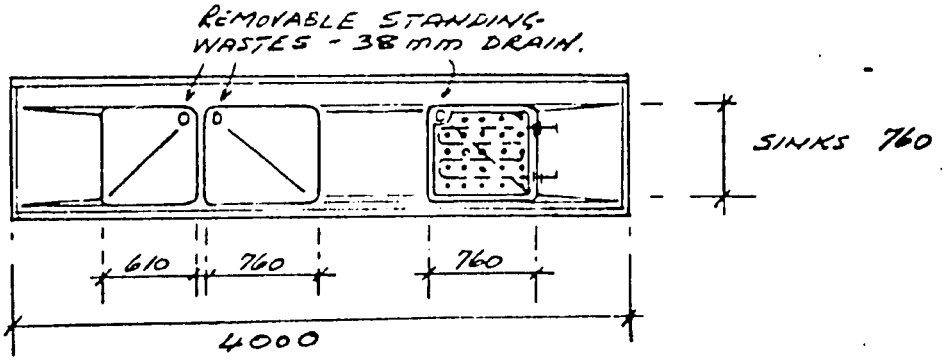
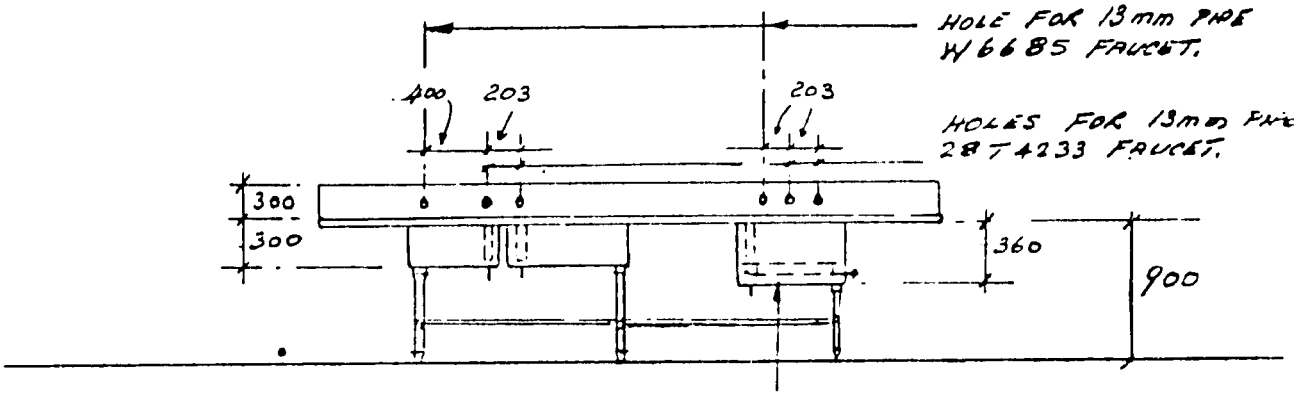
157½°
180°
℄ SLOT IN SKIRT

FOUR VIEW





REMOVABLE S.S. PERFORATED PLATE - 25ø S.S. REMOVABLE PIPE COIL AND FITTINGS. SUITABLE FOR 35kPa (5PSI) STE

SINK UNIT. ITEM 33.6

CONSTRUCTED FROM 316 S.S. 14 GAUGE. 'Z' BAR SUPPORTS WELDED TO UNDER SIDE OF TOP. PROVIDE SOUND DEADENER

FRONT EDGES SYTLE 7 MARINE ROLLED

BACK ROLLED AND RETURNED STYLE 4A.

TUBULAR LEGS WITH SADDLE SUPPORT - S.S. - 14 S.S. SADDLES ADJUSTABLE FT.

ALL WELDS GROUND SMOOTH AND POLISHED.

CONNAUGHT LABORATORIES LIMITED

TITLE: MEASLES VACCINE LABORATORY - ISLAMABAD - PAKISTAN

McGREGOR - ALLSOP LIMITED
Consulting Engineers Mechanical Electrical
1295 Bellamy Road North - Scarborough, Ontario M1H 1H9
Tel (416) 438-9725

REVISION: 'A'	JOB NO.: 2773
DATE: FEB. 1983	SCALE: 1 - 50
APPRV'D BY:	DWG NO.: M 100

→HPN

UNITED STATES GOVERNMENT

memorandum

DATE: November 1, 1987

REPLY TO ATTN OF: Robert W. Nachtrieb, Chief/PDM

SUBJECT: Primary Health Care Project (391-0475)

TO: OCC/CMO - Mr. A.T. Bilecky

Attached for your necessary action is a PIO/C No. 391-0475-4-70280 dated October 30, 1987, issued under the subject project, for the procurement of one Bacterial Fermentor (IF-150) required for the National Institute of Health (NIH), Islamabad. A copy of the Justification for Proprietary Procurement to the file is also attached for the specified model of Bacterial Fermentor (IF-150).

Please take appropriate action. Thank you.

ENC: a/s

cc: HPN - H. Goldman
PDM - S. Khan
FM - D. Pratt
} with attachments

PDM:Shaukat

AID 1370-1 (10-79)

PIO/C

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT IMPLEMENTATION ORDER/COMMODITIES

/ / Worksheet /X/ Issuance

1. Cooperating Country: Pakistan

2. PIO/C Number: 391-0475-4-70280

3. Project Number and Title: 391-0475 Primary Health Care

4. Appropriation Symbol	5. Allotment Symbol and Charge	6. Funds Allotted to
72-1171021	QDHA-87-27391-KG13	/ / AID/W /X/ Mission

7. Obligation Status: / / Administrative Reservation /X/ By Agreement

8. /X/ Original or Amendment Number _____

9. Authorized Agent: USAID/Pakistan

10. Method of Financing: A. /X/ US Government B. / / Direct Letter of Commitment

11. Contracting Period (Mo. Day. Year)	12. Delivery Period (Mo. Day. Year)	13. Project Assistance Completion Date (Mo. Day. Year.)
From: To:	From: To:	March 31, 1989

14. Area of Source: U.S. (Code 000)

15. Dollar Value

A. Previous Total	B. Increase	C. Decrease	D. Total to Date
-	586,866	-	586,866

16. Quantity, Description, Specification, Instructions and Special Provisions:

A. This procurement is subject to the provisions of Federal Acquisition Regulations, or Host Country Contracting procedures, AID HB 11, Ch. 3.

B. This authorization may be used to finance commodities and related services including transportation as approved for payment by A.I.D.

C. Project Commodities: One (1) Bacterial Fermentor (IF-150) from New Brunswick Scientific Co. Inc., with specifications as per details on the proposal at Attachment 1, in accordance with budget estimates provided under item 'J' on page 2. This Bacterial Fermentor is required for the National Institute of Health (NIH), Islamabad.

D. Delivery: As soon as possible.

17. MISSION REFERENCES

18. MISSION CLEARANCES	Date	MISSION CLEARANCES	Date
PDM - Shahabuddin Khan	10/15/87	HPN - Heather Goldman	10/15/87
O/CC(CMO) - A.T. Bilecky	10/18/87	FM A. Dean Pratt	10/19

19. Date of Original Issuance: --

20. Date of this Issuance: October 30, 1987

21. For the Cooperating Country - The terms and conditions set forth herein are hereby agreed to:

Signature: Col. M. Akram Khan Date: Oct 28 87

Title: National Manager EPI, NIH, Islamabad

22. For the Agency for International Development

Signature: Robert W. Nachtrieb

Title: Chief/PDM, USAID/Pakistan

Date: 30 OCT 87

E. Addressee for Mailing Documents: Documents Distribution and Shipping Instructions attached.

F. Shipping Instructions: U.S. Flag Vessels and/or Pakistan Flag Vessels

Port of Entry: Karachi, Pakistan

Ship to: National Institute of Health (NIH)
Islamabad, Pakistan
(PIO/C No. 391-0475-4-70280)
Via Karachi, Pakistan

G. Marking: Containers must be marked in accordance with AID marking requirements and include:

i. Application of AID Clasped Hands Emblem
ii. PIO/C No. or P.O. Number

H. Special Instructions:

All material on order must be suitably export packed before placing the items in the containers in order to avoid damage in transit due to rough handling. Shipments should be consolidated where possible.

I. Insurance:

All items are to be insured with U.S. marine insurance coverage including "all risk" and "war" on a warehouse to warehouse basis at 115% of the C&F value of the shipment. Claims must be payable in U.S. dollars.

J. Budget Estimates:

Estimated cost of Bacterial Fermentor (CIF/Karachi) (as per pages 22 & 23 of Attachment 1: Proposal of New Brunswick Scientific Co.)	=	$ 410,015
Estimated cost of Spare Parts (List of Spare Parts is provided as Attachment 2)	=	75,000
Sub-Total	=	$ 485,015
Estimated charges of handling, forwarding, marine insurance, export packing and shipment; to be charged at actuals (10% of total cost)	=	48,500
Total	=	$ 533,515
Contingency (10%)	=	53,351
Grand Total	=	$ 586,866

K. All items to be procured under this PIO/C shall be turned over to the GOP Ministry of Health, National Institute of Health (NIH), Islamabad, immediately upon receipt in country.

L. The supplier shall send a Non-negotiable Rated Ocean Bill(s) of Lading applicable to each invoice to the Office of Commodity Management, Transportation Support Division, Agency for International Development, Washington, D.C. 20523. The supplier shall certify on each invoice requesting payment for commodities that he/she has sent the Bill(s) of Lading as required. The supplier is also required to send such Bill(s) of Lading to the Maritime Administration, Division of National Cargo, 400 Seventh Street, S.W. Washington, D.C. 20590.

M. Ocean Transportation Special Provisions attached.

OCEAN TRANSPORTATION SPECIAL PROVISIONS
(For USG Authorized Agents)

1. The costs of ocean transportation and of other delivery services for the authorized commodities are eligible for reimbursement, except that air transportation is eligible only if specified in the PIO/C. Delivery services means the services customarily performed in an export transaction which are necessary to effect a physical transfer of commodities to the cooperating country. Examples of such services include export packing, local drayage in the source country (including waiting time at the dock), ocean and other freight, loading, heavy lift, wharfage, tollage, switching, dumping and trimming, lighterage, insurance, commodity inspection services, and services of a freight forwarder. Delivery services may also include work and materials necessary to meet AID marking requirements.

2. To be eligible for reimbursement, ocean transportation of authorized commodities must be on vessels under flag registry of countries included in the Area of Source. When the Area of Source is AID Geographic Code 941, vessels under flag registry of the cooperating country may be used as well as U.S. flag vessels and vessels under flag registry of other Code 941 countries.

3. In the event a contracting officer of the authorized agent determines there are no eligible vessels as stipulated in paragraph 2 available to make timely delivery, the contracting officer should contract the Office of Commodity Management, Transportation Support Division, to request a waiver authorizing use of any free world flag vessel.

ID:3102S

UNITED STATES INTERNATIONAL DEVELOPMENT COOPERATION AGENCY
AGENCY FOR INTERNATIONAL DEVELOPMENT

DOCUMENT DISTRIBUTION AND SHIPPING INSTRUCTIONS

1. DATE: October 30, 1987 | PAGE 5 OF 5 PAGES

2. U.S. AID ORDERING OFFICE:
USAID Mission to Pakistan
O/HPN, Islamabad

IMPORTANT: This form shall be completed by the U.S. AID Ordering Office and attached to all requests for commodities (PA's and PIO/C's) submitted for supply action. A separate form is required for each ultimate consignee receiving material.

3. U.S. AID PROCUREMENT REQUEST NO.: PIO/C 391-0475-4-70280

4. DOCUMENT CONTROL NO. (Leave Blank)

SHIPPING

5. CONSIGN SHIPMENT TO:
Liaison Officer
USAID/Karachi
1, SMCH Society
Karachi, Pakistan

6. MARK FOR (Final Destination):
National Institute of Health (NIH)
Islamabad, Pakistan

7. PARTIAL DELIVERY ACCEPTANCE
☒ a. YES ☐ b. NO

DOCUMENTATION

8. ADDRESS TO RECEIVE INFORMATION REGARDING STATUS OF PROCUREMENT REQUEST*
USAID Mission to Pakistan
Attn: Commodity Management Officer
P. O. Box 1028
Islamabad/Pakistan

9. ADDRESS TO WHICH BILLING DOCUMENTS ARE TO BE SENT
Office of Financial Management
USAID/Islamabad
18, 6th Avenue, Ramna 5
Islamabad/Pakistan

10. SHIPPING DATA (Insert complete address(es) below, items a through c, to receive shipping documents in the number of copies indicated.)

	ADDRESS	OCEAN BILL OF LADING NEGOTIABLE	OCEAN BILL OF LADING COPY	AIR FREIGHT B/L	PACKING LISTS	EXPORT INVOICE
a.	Liaison Officer USAID/Karachi 1, SMCH Society Karachi, Pakistan	One original	N/A	One original	One orig.	One original
b.	USAID Mission to Pakistan Attn: Commodity Management Officer P. O. Box 1028 Islamabad/Pakistan	N/A	Three (alongwith copy of Insurance Certificate	Three	Three	Three
c.	Office of Financial Management USAID/Islamabad 18, 6th Avenue, Ramna 5 Islamabad/Pakistan (a/w	copy of I	Non-negotiable Insurance	Non-negotiable Cert. &	Origi- request	Origina for pa

11. SPECIAL DOCUMENTATION (Identify any special documents required, such as import licenses, certificates of origin, etc.)

* Supply documents furnished to the addressee will serve to inform the ordering office of the status of the procurement request during the export processing cycle.

ATTACHMENT 1 TO
PIO/C No. 391-0475-4- 70280

NEW BRUNSWICK SCIENTIFIC CO., INC.

PROPOSAL

COVERING THE

MODEL IF-150

FULLY EQUIPPED INDUSTRIAL FERMENTOR

and

Analog Instrumentation

PREPARED FOR:

NATIONAL INSTITUTE OF HEALTH
(US - AID Mission/Pakistan)

DATE: January 6, 1987

ENG. REF. NO.: P-3032

EXP. REF. NO.: X-9228

Ivan Vazquez

1.0 INTRODUCTION

The engineering embodied in the New Brunswick Scientific Co., Inc. Industrial Fermentors represents the accumulation of many years experience and achievement in the field of pilot and industrial size fermentation equipment. The equipment has a history of successful performance in diverse pilot plant and industrial applications, and should give years of trouble-free operation, if properly operated and maintained.

The fermentors are fabricated in a modern plant under the control of a quality assurance system approved for the manufacture of ASME Sec. VIII Coded Vessels.

All Industrial Fermentors undergo at least one 72-hour continuous sterility test before shipment.

A staff of professional field specialists operating from key centers in the United States, and in most principal cities throughout the world, is available for technical assistance. Our service specialists are trained to diagnose problems and to adjust and service equipment promptly and efficiently in the field. We maintain a separate inventory of spare parts designated for rapid shipment to be used for service purposes, should the need arise.

2.0 GENERAL DESCRIPTION AND OPERATION

2.1 DESCRIPTION

The Model IF-150 Industrial Fermentor is a manually sterilized system consisting of an open-frame, skid-mounted piping console and stainless steel vessel mounted on the left of the piping. The skid includes all of the piping and valves for sterilization, cooling, and operation of the fermentor. The fermentor vessel is a jacketed pressure vessel with ports and wells sufficient to insert all the required sensors; provide aeration and agitation; and permit the heating and cooling necessary for in-place sterilization and fermentation. The fermentor vessel and all piping are mounted on a single skid.

2.2 OPERATION

Typically, the fermentor is filled through a combination Viewing Window/Filling Port (located in the headplate), manually raised to sterilization temperature while the contents of the vessel are being agitated; automatically held at sterilization temperature for an operator determined period; manually cooled to operating temperature; maintained at fermentation temperature, pressure and sparge rate for an operator determined period; harvested and shut-down.

Addition of aseptic inoculum as well as aseptic sampling may be accomplished by the use of the Steam-Resterilizable Addition and Sampling Ports.

3.0 SPECIFICATIONS

3.1 Vessel

Conforms to latest issue of ASME, Sect. VIII Pressure Vessel Code. Supplied with copies of the Manufacturer's Data Report (U-1) which is also registered with the National Board of Boiler and Pressure Vessel Inspectors. Includes ASME-Code Stamp.

3.1.1 Vessel Dimensions

Capacity: 150 liters (39.6 gals.)
Maximum Working Capacity: 115 liters (30.4 gals.)
Nominal Size: 18" O.D. by 40" long (45.7 cm x 101.6 cm)
L/D = 2.2

3.1.2 Materials and Finish

All surfaces in contact with the culture liquid including the headplate are fabricated of type 316L stainless steel. All interior surfaces are polished to a #4 or better finish. Exterior is polished to a #3 or better finish (except if insulated).
The jacket is fabricated of type 304 stainless steel.
Gaskets and "O" Rings are Ethylene Propylene.

3.1.3 Design Pressure

The Vessel design pressure is 40 psig (2.7 ATM gauge).
The Jacket design pressure is 35 psig (2.4 ATM gauge).
The Vessel and Jacket are tested at 50% over-pressure including the assumption that full vacuum may occur in the vessel interior.
The design temperature of vessel and jacket is 300°F (149°C).

3.1.4 Ports and Penetrations

All vessel piping, unions and fittings utilize standard U.S. design.

3.1.4.1 Vessel Headplate

The vessel headplate is fabricated with double "O" Ring grooves, with a channel in-between for an optional steam seal. An ethylene propylene "O" Ring is provided.

3.1.4.2 Vessel Head Openings and Appurtenances

1. Filling/View Port - 2.5" (6.4 cm) used for both filling and viewing.
2. Light Port - 1-7/8" (4.8 cm) diameter.
3. Spare penetrations drilled, tapped, plugged - (1) 1/8" FNPT, (1) 3/8" FNPT, (1) 3/4" FNPT.
4. Head Bolts - ASME Code hex head bolts.
5. ASME Coded Rupture Disc. The outlet of the rupture disc is piped from the top of the vessel to approximately 6" above the skid.
6. (1) Penetration drilled, tapped, and plugged for installation of a Foam Sensor - 1/8" FNPT.
7. Air/Gas Outlet with Exhaust Condenser
8. Penetration drilled, tapped and plugged for installation of an NBS D.O. electrode - 3/8" FNPT.
9. Diaphragm-type Pressure Gauge.
10. Penetration (plugged) for Mechanical Foam Breaker (bottom-drive only).
11. Penetration for Agitation System (top-drive only).

3.1.4.3 Ports and Lines Located in Upper Side-Wall of Vessel

1. (1) 25 mm Steam-Resterilizable Inoculation Port - 1/2" hose barb fitting.
2. (2) Air/Gas Inlets for sparge and overlay - 1/2".
3. (5) 19 mm Addition Ports (for acid, base, antifoam and (2) spares).

3.1.4.4 Rectangular Viewing Window

1. The window is 2-1/2" wide x 11-1/2" long.
2. A 1/4" Steam Inlet Port with valve is located along-side the window for window cleaning.

3.1.4.5 Ports and Wells Located in Lower Side-Wall or Dished Head of Vessel

1. (1) 19 mm Temperature Sensor Well.
2. Steam-Resterilizable Bottom Drain Port - (1" flush-mounted ball valve, cavity filled) - 3/4" hose barb fitting. Port is modified to allow sterile transfer of product.

4/6

3. (1) 19 mm Steam-Resterilizable Bottom Sample Port - 1/8" hose barb fitting.
4. (1) 19 mm Port (Plugged) for optional spare steam-resterilizable sample port.
5. (1) 19 mm Thermometer Well.
6. (4) 25 mm Fitting and plug assemblies for installation of an Ingold side-mounted pH Electrode and future electrodes.
7. Penetration for Agitation System (plugged on top-drive unit).

NOTE: All 19 mm and 25 mm ports are double "O" ring sealed Ingold-type ports.

3.1.4.6 Jacket

1. (2) Coolant inlet and outlet ports - 1/2" FNPT.
2. Pressure relief valve port - 3/4" FNPT. (Outlet of relief valve is piped to approximately 6" above the skid)

3.1.5 Vessel Legs

Each vessel leg will be provided with a spacer to allow for future installation of an individual load cell. The Load Cell Weight Measurement System is available as an option.

3.2 PIPING MODULE

3.2.1 Skid and Piping

All copper piping for steam, instrument air and water is color coded and located in a skid-mounted, piping module. Filters, controls, and measurement devices are piped-in with union connections to permit easy field service when required. Hand valves for sequencing the various phases of the sterilization procedure and process cycle are easily accessible and identified for easy operation. The rugged skid is designed to withstand deformation during shipment and is coated with baked-on chemically resistant paint. Steam piping on the exterior portion of the piping skid is insulated. All steam traps are brought to a common header and are fed separately into the header. A stainless steel cover is positioned beneath the vessel to facilitate cleaning.

3.3 INSTRUMENTATION

Monitoring and recording instrumentation as well as electrical controls are mounted in a separate Instrument Console. Details on these instruments are in succeeding sections of this proposal.

3.4 **BASIC SERVICE REQUIREMENTS** (for Model IF-150)
(Prefilters, regulators and pressure gauges are provided on the fermentor piping skid for utility steam, sparge air, instrument air and water.)

3.4.1 Utility Steam

Required steam supply:	125 lbs/hr (57 Kg/hr) at 60-80 psig (4.1 - 5.4 ATM gauge)
Inlet service connection:	3/4" FNPT.

3.4.2 Process Steam

Required steam supply:	25 lbs/hr (11 Kg/hr) at 60-80 psig (4.1 - 5.4 ATM gauge)
Inlet service connection:	1/2" FNPT.

3.4.3 Process Air (for Sparge and Overlay)

Required air supply:	7.1 SCFM (200 SLPM) at 60-80 psig (4.1 - 5.4 ATM gauge)
Inlet service connection:	1/2" FNPT.

3.4.4 Instrument Air (for Air Operated Valves)

Required air supply:	2.0 SCFM (56 SLPM) at 50-100 psig (3.4 - 6.8 ATM gauge)
Inlet service connection:	3/8" FNPT.

3.4.5 Water

Required water supply:	At least 6 GPM (23 LPM) at 60-80 psig (4.1 - 5.4 ATM gauge)
Inlet service connection:	1/2" FNPT.

3.4.6 Electrical

Electrical wiring will be in conformance with latest National Electrical Code requirements and require the following power:

	220 Volts, 50 Hz, Single Phase
Service connection:	Fused main disconnect box with at least 35 AMPS capacity.

42

(NOTE: Any electrical codes other than the National Electrical Code must be specified and provided to NBS. An additional charge may be required to meet alternate codes.)

3.4.7 Drains/Exhaust

1. Contaminated condensate trapped, as required, to a 1" FNPT drain line.
2. Clean condensate trapped, as required, to 1" FNPT drain line.
3. Water Return Line - 3/4" FNPT.
4. Exhaust Air/Gas Line - 3/4" FNPT.

4.0 FUNCTION OF VARIOUS SUBSYSTEMS

4.1 Utility Steam System

Steam flows from the inlet port on the top of the piping skid through:

1. Shut off valve;
2. Pressure gauge #1;
3. 20 micron sintered stainless steel prefilter;
4. Steam regulator (factory set to 30 PSIG);
5. Pressure gauge #2;
6. Steam is then used for sterilization of the vessel and vessel contents and as a source of heat for the jacket water when operating at fermentation temperatures.

All copper steam lines are painted red. Steam lines on the exterior portions of the piping skid are insulated.

4.2 Process Steam System

Steam flows from the inlet port on the top of the piping skid through:

1. Shut off valve;
2. Pressure gauge #1;
3. Steam regulator (factory set to 30 PSIG);
4. Pressure gauge #2;
5. Steam is then used for sterilization of the air inlet and exhaust lines and the various steam-sterilization ports.

All steam lines that are used to sterilize the air inlet system and steam-resterilizable ports are fabricated of stainless steel (i.e. steam that sterilizes components entering the fermentor).

4.3 Cooling Water

Cooling water flows from the inlet port on the top of the piping skid through

1. Shut off valve;
2. Water pressure gauge #1;
3. 20 micron prefilter;
4. Water pressure gauge #2;
4. Water pressure regulator (factory set to 30 PSIG)
5. Water pressure gauge #3;
6. Water then is used for temperature control of the fermentor.

All copper water lines are painted green.

4.4 Temperature Control

1. Temperature control is accomplished by the use of a solid-state, on-off controller using a temperature sensor in a thermal well in the lower side of the vessel. Operating temperature is set on the front panel of the Instrument Console. Temperature control range is 5°C above water supply temperature to 60°C, ±0.25°C. Temperature is digitally displayed.

2. Sterilization of vessel, piping and contents is accomplished by manually applying steam to the vessel jacket and all components making up the fermentation enclosure. When 121°C is reached, the vessel contents are automatically controlled at this temperature by the opening and closing of an automatic steam valve.

   At expiration of an operator determined sterilization time, cooling water is manually admitted to the jacket of the vessel, through a circulation pump via valving to rapidly reduce temperature to desired fermentation conditions.

   NOTE: A completely Automatic Sterilization/ Cooling System is available as an option.

3. At fermentation temperature, the controller will automatically a) turn on steam to a heat exchanger which will heat the water circulating to the jacket of the vessel or b) will inje t cooling water into the jacket circulation system, as required.

4.5 **Agitation System** (Controlled by an Agitation Controller mounted in the Instrument Console.) Top- or Bottom-entering Agitation System (please specify) including:

1. 3 HP, variable speed D.C. motor, driving three Rushton-type, 6-bladed turbine impellers at 45 to 450 RPM.
2. Adjustable variable speed control with feed-back to hold RPM constant within ±2% RPM.
3. Digital display of RPM.
4. Ball bearing shaft and housing with rotating mechanical seal (carbon-to-tungsten carbide), double sealed with sterile condensate lubrication.
5. Four, type 316 stainless steel removable baffles.
6. A pressure regulator and gauge shall be installed on the double seal assembly to indicate seal condensate pressure, thereby, indicate proper sealing.
7. Impellers are adjustable in position along the shaft, alternate types of impellers can be substituted. (Marine propellers, pitched blade, draft tube, etc.)

4.6 **Aeration System**

1. Air flow passes from an inlet port on the top of the piping skid through:

   1) Shut-off valve

   2) Air pressure gauge #1.

   3) Air for instrumentation is split, passing through prefilter then to air operated valves.

   4) Air for sparger and overlay passes through combination prefilter/regulator (factory set to 35 PSIG).

   5) Air pressure gauge #2

   6) Sparge and overlay air then flows through air control system. System includes a rotameter and manual control valve.

   7) Installed in the inlet sparge/overlay air line is a steam-sterilizable cartridge-type sterile filter that removes continuously 100% of all viable organisms. (Relative humidity, must be less than 95%.) The standard filter is manufactured by Domnick-Hunter. Alternate filter vendors can be provided.

2. All piping, valves and fittings in the air system are fabricated of stainless steel.

3. All necessary valves, steam traps, check valves are provided for sterilization of the air inlet system.

4. Flow rate is adjustable from 15 to 160 liters/minute by a valve mounted after the rotameter. Accurate control is maintained when the vessel pressure is changed, the differential pressure across the control valve is regulated by a flow controller.

5. Sparge - Air is introduced at the bottom of the vessel through a ring sparger. Sparger can be removed and replaced with an alternate type sparge system (single orifice, sintered disc, etc.)

6. Overlay - Air can also be added through an air overlay system. Air is added above the liquid volume. Selector valves are provided to choose between addition via sparge, overlay or both simultaneously.

4.7 Vessel Pressure and Exhaust System

1. Vessel pressure is regulated by the use of a stainless steel trim pressure regulator in the exhaust line.

2. A sealed diaphragm-type pressure gauge is mounted on the fermentor headplate.

3. A safety relief blow-out rupture disc mounted on the fermentor vessel protects the vessel from accidental over-pressure.

4. Exhaust gas flows from from the outlet port on the fermentor headplate through:

   1) A stainless steel exhaust condenser mounted on the fermentor headplate. Cold water circulates through a stainless steel coil in the condenser dropping out entrained water and much of the water vapor back into the fermentor.

2) A diaphragm-type pressure transducer.

3) A stainless steel double pipe heat exchanger which heats the exhaust gas above its dew point.

4) A steam-sterilizable, cartridge-type sterile filter that removes continuously 100% of all viable organisms.

5) Exhaust Pressure Gauge

6) Exhaust gas then flows through the vessel pressure regulator.

5. All piping, valves and fittings are fabricated of stainless steel.

6. The exhaust system is sterilized simultaneously with other fermentor components.

4.8 Mechanical Head Lift

The vessel head (with all its appurtenances) is provided with a motor driven mechanism which lifts the head sufficiently to provide access to the vessel interior for cleaning and/or adjustment of the impellers and baffles. Safety interlocks prevent operation of the mechanical foam breaker (if provided) and agitator when the head is not in its operating position.

NOTE: Head Lift adds approx. 26" to the standard height of the fermentor when head is in the fully-raised position.

4.9 Addition Vessel Skid

(In-lieu of the peristaltic pumps detailed in para. 6.1 through 6.3, Addition Vessels with solenoid valves are provided for acid and base addition.)

1. The Addition Vessel Skid contains (2) 15-liter stainless steel Addition Vessels for acid and base.

2. Each Vessel is permanently piped directly to the fermentor for sterilization and pressurized transfer. Stainless steel piping is provided.

3. The Addition Vessels are fabricated of type 316 stainless steel and each is furnished with a constant speed agitator to ensure good heat transfer during sterilization and cool-down.

4. Each vessel is designed and fabricated to ASME Pressure Vessel Code specifications and each is supplied with a removable headplate to facilitate filling and cleaning.

5. Each 15-liter vessel is sterilized by flowing steam through a stainless steel coil mounted in the vessel.

6. Automatic valves are furnished for sterilization and cooling each vessel and an in-line air filter is installed to sterilize make-up air. A timer is provided to set duration of sterilization cycle. Automatic cycle is actuated by a switch.

7. Solenoid valves are mounted after each vessel's discharge port. Valves are actuated by the pH and Antifoam Controller.

   NOTE: (1) Addition Vessels are designed for sterilization of reagents which contain a minimum of 40-50% water. If higher concentrations of reagents (lower concentrations of water) are used, a separate steam supply may be required to properly sterilize the air filter.

   (2) Use of Hydrochloric Acid or Sulfuric Acid will cause corrosion at a rate dependent on concentration and temperature and should not be used. Acids such as Phosphoric and Nitric have no appreciable effect on type 316 stainless steel.

8. Each vessel includes a level probe calibrated to indicate reagent level.

9. Service Requirements (Piped from Fermentor Piping Skid by NBS)

   Air: 1/2" FNPT - 2.0 SCFM (56 SLPM) @ 80-100 PSIG
   Water: 1/2" FNPT - 1 GPM (3.8 LPM) @ 25-30 PSIG
   Steam: 1/2" FNPT - 45 lbs/hr (20.4 Kg/hr) @ 25-30 PSIG
   Electric: 220 Volts, Single Phase

Filters and Regulators will be provided for each of these services on the fermentor piping skid.

10. Dimensions and Weight (Addition Vessel Skid)
40" WIDE X 24" DEEP X 50" HIGH
(100 cm WIDE X 68 cm DEEP X 127 cm HIGH)

Shipping Weight: 600 lbs (270 Kg)
Net Weight: 500 lbs (225 Kg)

5.0 SIZE AND WEIGHT

5.1 Dimensions (of combination fermentor vessel and piping skid)
Skid: 95" Wide x 30" Deep x 80" High
(238 cm Wide x 77 cm Deep x 203 cm High)

NOTE: Height of vessel with Head Lift raised with Foam Breaker is 106". Depth at vessel is 46".

5.2 Weight (of combination fermentor vessel and piping skid) (Approximate)
Shipping Weight: 2300 lbs (1044 Kg)
Net Weight: 1700 lbs (770 Kg)

5.3 Dimensions (of Instrument Console)
22" Wide x 24" Deep x 76" High
(56 cm Wide x 62 cm Deep x 195 cm High)

5.4 Weight of Instrument Console (Approximate)
Shipping Weight: 400 lbs (182 Kg)
Net Weight: 300 lbs (136 Kg)

6.0 DESCRIPTION OF INSTRUMENTATION (Mounted in Floor Standing Instrument Console)

6.1 pH Control System

1. A signal from a pH electrode is conditioned and amplified for inputting to a recorder and contacting meter which monitors pH in the fermentor vessel.

2. An Ingold combination pH electrode is furnished for side-mounting in a mating penetration in the lower side-wall of the fermentor vessel. The electrode assembly is steam-sterilizable-in-place at the same time the medium and vessel are sterilized. Provided are double-bridged electrode, housing, cable, pressure gauge, air pump, and electrolyte.

3. When the pH exceeds the desired value (as preset) a timed addition of acid is introduced automatically into the vessel; when pH is too low, a timed addition of base is introduced automatically into the vesse. An addition timer and mixing timer are incorporated in the system to control the duration of each acid or base addition and to permit sufficient time for the acid or base to be properly mixed with the fermentation broth prior to a subsequent addition.

4. 4-20 mA recorder output.

5. The pH value is also continuously displayed on a 5" Indicator also having a range from 2 to 12 pH.

6. Two peristaltic addition pumps are furnished; one for acid addition and one for base addition. The customer provides sterile acid and base reagent. The pumps are mounted on the fermentor frame along side of the vessel.

7. Two steam-sterilizable capped ports with appropriate valving and traps are installed in (2) 19 mm addition ports in the upper side-wall of the vessel for introduction of the acid or base to the fermentor vessel.

8. Two 250 ml reagent flasks and silicone tubing are provided. A shelf is provided to store the reagent flasks.

6.2 Dissolved Oxygen Control

1. A top-entering dissolved oxygen electrode (Johnson, Borkowski and Engblom type), with replaceable membrane and cathode, inserted in the lower side-wall of the vessel through a mating penetration, generates a current signal which is amplified and conditioned to become the input to a recorder and a contacting meter which monitors the dissolved oxygen.

2. Dissolved oxygen is read on a scale of 0-100% which represents the % of saturation at a particular pressure and temperature of the medium. Range and zero adjustments are provided to easily calibrate the instrument to the desired pressure and temperature.

3. 4-20 mA recorder output.

4. When the dissolved oxygen level deviates from the desired value, the controller changes the agitation rate by adjustment of the speed control potentiometer and the aeration rate by remote adjustment of the air flow control system.

   Four modes may be selected:

   a) Control of aeration only
   b) Control of agitation only
   c) Control of aeration and agitation simultaneously
   d) Control of both sequentially

   The control action is integrating (floating), in that a timed adjustment is made whenever a deviation from set point occurs. The controller continues to make adjustments as long as it detects a deviation.

5. The Galvanic probe is steam-sterilizable-in-place at the same time the medium and vessel are sterilized. Cable is provided.

6.3 **Chemical Foam Control System**

1. A stainless steel conductivity-type foam sensing probe with Teflon cover is installed through a compression fitting in the headplate of the fermentor.

2. Contact with foam activates a peristaltic pump to introduce to the fermentor a chemical defoaming agent. The pump is mounted on the fermentor frame along side of the vessel. The control circuit includes a sensitivity adjustment to prevent minor splashing from causing spurious operation and a percentage timer which divides a fifteen second interval into addition and mixing time, as desired.

3. The customer provides antifoam.

4. A 19 mm steam-sterilizable addition port is provided in the upper wall of the vessel for antifoam entry.

5. A 250 ml reagent flask and silicone tubing is provided. A shelf is provided to store the reagent flask.

6.4 Six-Channel Recorder

Recorder will record in 6-colors, with colored description for each variable, colored numerical axis for each variable, time of day, date, chart speed and fermentor ID number.

A six-channel recorder will be supplied to record the following variables:

1. Vessel Temperature (°C)
2. Dissolved Oxygen (%)
3. pH of Fermentor Medium
4. Spare
5. Spare
6. Spare

Recorder has (6) 100 mm scales.

7.0 OPTIONAL INSTRUMENTATION

7.1 Insulation of the Vessel

The outer surface of the fermentor vessel is insulated with 1-1/2" of composition material covered with latex painted canvas cloth and covered with a stainless steel band over the jacket portion.

7.2 CO_2 Addition Gas System

The Addition Gas System incorporates the necessary valves, rotameter and piping to introduce a separate gas (e.g. CO_2) into the sparge air stream prior to (upstream of) the air inlet filter. Rotameter range: 0-10 CFM.

7.3 Turbidity Monitor TD-20

A culture sample is continuously drawn from the lower section of the fermentation vessel by means of a peristaltic pump, passed through the optical sensing system of the analyzer, and returned to the upper portion of the fermentor. A debubbler chamber in the connection lines removes entrained gas bubbles which interfere with the turbidity measurement. The output of the optical system which senses the optical density (OD) is impressed on a 4" Recorder and Circulating Pump which is factory calibrated with a 0-100 scale corresponding to an OD of 0-46 (0-20 absorbance). The customer may field calibrate the output to increase the instrument sensitivity to provide full scale output for an OD differential as low as 5 e.g., 5-10, 25-30, etc.

7.4 Dual Air Incinerator CN-20 (both inlet and exhaust)

The Dual Air Incinerator is used to provide the added precaution of sterilization of both inlet air and exhaust gases. One channel of the dual system is connected to the air inlet line and the second channel is connected to the exhaust line.

Temperature of the air or gas is raised to 370°C (700°F) by stainless steel heaters, and then lowered to the approximate temperature of the fermentor (or room) in a water-cooled stainless steel heat exchanger. Incineration and outlet temperatures are adjustable for air volumes up to 10 SCFM (280 SLPM).

The gas is first preheated and then incinerated. It is fed around a series of baffles to a central heating chamber and is then recycled through a coil inside the chamber in the path of the incoming gas.

The incinerator is connected to steam and water services. It is steam-sterilizable for initial start-up to eliminate any possible contamination in the after cooler. Incinerator temperature is controlled by an indicating pyrometer. A safety control is incorporated for automatic air shut-off in the event of power or control failure. A limit-switch, incorporated in the heater circuit, protects against heater burn-out.

Power:	6 KVA, at 220 Volts, 50 Hz.
Dimensions:	17" WIDE X 42" HIGH X 30" DEEP
Weight:	400 lbs. (182 Kg.)

7.5 Rapid Chiller System (Model RC-100)

The Rapid Chiller System includes a separate, stainless steel heat exchange coil mounted inside the fermentation vessel. Coil can be removed, ports are then plugged. Its use permits rapid cooling of the contents of the fermentor to arrest any further metabolic activity. It may also be used to maintain the fermentor contents at a temperature as low as 5°C for extended period of time.

When used in the rapid cool mode, the refrigeration system is turned on three or four hours before the expected end of the fermentation. This time period is used to cool 100-liters of a glycol-water mixture to -30°C. At the end of the fermentation, the cold glycol-water mixture is circulated through the coil in the main fermentor, chilling the fermentor contents to a temperature near 10°C in a time dependent on the main fermentor contents.

When used in the controlled temperature mode, the jacket circulation of the fermentor is stopped and the medium temperature is maintained at a temperature between 2° and 18°C by using the cooling coil to abstract the heat of agitation, the heat absorbed from ambient by the vessel and any heat resulting from exothermic reactions in the fermentor.

A 1-1/2 HP circulation-pump is provided. Insulated lines connecting RC-100 and fermentor are also provided (distance less than 10 feet). Ethylene Glycol is not provided (32.4 gallons is necessary).
Reservoir capacity is 55 gallons
Refrigeration System: 2 HP semi-Hermetic Compressor
Electrical Specifications: 220 Volts, 50 Hz., 1 Phase 3-wire (approx. 21 Amps)
Approx. Dimension: 34" wide x 36" deep x 59" high

7.6 **CEPA Model LE Centrifuge**

CEPA Model LE Electrically Driven Rapid Centrifuge. Unit includes XLE-K Clarifying Bowl with a universal motor providing stepless speed control from 15,000 - 40,000 RPM. Maximum G Force at 40,000 rpm is 39,300. Motor is 220 Volt, 50 Hz., A.C. with regular starter. Unit includes feeder and collecting cover fabricated of type 316 stainless steel.

8.0 QUALITY ASSURANCE

All phases of manufacture from the purchase of raw materials and components through the fabrication of the individual parts and assemblies to final inspection of the fermentor are under the control of our Quality Control Department. The quality assurance procedures permit us to manufacture the vessels in accordance with the requirements of the ASME Boiler and Pressure Vessel Codes and assure the quality of other components of the fermentor as well as of the fermentor system.

Each fermentor is fully inspected and operated as an integral system to assure:

a) Proper calibration of the instrumentation.
b) Control within guaranteed specification limits.
c) Maintenance of sterility during extended fermentation and during inoculum addition, sampling and harvesting.

9.0 SPARE PARTS

New Brunswick Scientific Co., Inc., considers the ready availability of spare parts important to the economical operation of this equipment. A complete spare parts list is an integral part of the instruction manual supplied with each unit. Most components are readily available for immediate shipment. A recommended list of spare parts will be prepared as part of the engineering phase of this project.

10.0 WARRANTY

All equipment is warranted to be free from defects in material and workmanship for 15 months from the date of shipment from NBS or 12 months from the date the customer accepts the equipment, whichever comes first. The exceptions to this warranty are:

A. All glass parts, which carry no warranty.
B. All electrodes which are warranteed for 15 months from the date of shipment from NBS or 6 months from the date the customer accepts the equipment, whichever comes first.

Our obligation under this warranty is limited to repairing parts or providing replacement parts at no charge which prove to be defective during the warranty period. A part shall be considered defective after inspection of NBS' technical staff. At NBS' option,

we will repair or replace any defective part which is returned to our plant in Edison, New Jersey, U.S.A., freight prepaid. The cost of shipping the repaired or replacement part will be borne by NBS. Should the services of an NBS Engineer or Technician be required to effect the repair, travel time and expenses to and from the job site will be charged at the rates which prevail at that time. This warranty does not extend to equipment or parts which have been subjected to misuse, neglect, accident or improper installation or application; nor shall it extend to equipment or parts which have been repaired or altered outside the NBS plant without prior approval by NBS.

11.0 PRICES AND CONDITIONS

11.1	Price for Model IF-150 Industrial Fermentor with Analog Instrumentation System (as described in paragraphs 2.0 through 6.4 of the preceding proposal):	$116,500
11.2	Optional Instrumentation	
	1. Insulation of the Vessel (para. 7.1)	$ 4,100
	2. CO_2 Gas Addition System (para. 7.2)	$ 3,265
	3. Turbidity Monitor TD-20 (para. 7.3)	$ 8,855
	4. Dual Air Incinerator (para. 7.4)	$ 9,075
	5. Rapid Chiller (RC-100) (para. 7.5)	$ 19,45[illegible]
	6. CEPA Model LE-Centrifuge (para. 7.6)	$ 7,450
	a. XLE-K Clarifying Bowl	$ 1,800
	b. XLE-CP Cooling Coil, Copper, installed	$ 1,035
	c. XLE-TE Electric Tachometer, 50,000 RPM range, installed	$ 1,675
	NOTE: The LE-Centrifuge is manufactured in Germany, IT IS NOT OF USA ORIGIN.	
11.3	(10) 20-Liter Heating Bottles for inactivation of Bacterial Vaccination @ $4,550	$ 45,500
11.4	(10) 50-Liter Heating Bottles for inactivation of Bacterial Vaccination @ $4,725	$ 47,250
11.5	(3) 100-Liter Storage Tanks @ $32,500	$ 97,500
11.6	(1) Sterilization console for above	$ 9,375
11.7	20 Meters Silichem Tubing code "V"	$ 116
	20 Meters Silichem Tubing code "AB"	$ 169
	20 Meters Silichem Tubing code "AH"	$ 297
	20 Meters Silichem Tubing code "AN"	$ 465
11.8	One Lot of Spare Parts	$ 15,800

TOTAL F.O.B. PLANT - Edison, NJ	$389,677
Export Packing/Inland Freight to New York Pier	$ 5,988
Forwarding/Handling	$ 250
TOTAL F.A.S. NEW YORK - PIER	$395,915
Estimated Ocean Freight	$ 5,825
TOTAL C & F KARACHI	$401,740
Estimated Insurance	$ 8,275
TOTAL C.I.F. KARACHI	$410,015

NOTE: All prices are exclusive of all applicable taxes and duties.

12.0 Proforma is valid until March 31, 1987.

12.1 Delivery: 5-6 months after receipt of a firm order.

12.2 Payment Terms: Net 30 Days

12.3 Training:

Included in the price is up to one week of training at NBS in Edison, New Jersey by one professional including room and board. customer pays for airfare expenses.

ATTACHMENT 2 TO
PIO/C No. 391-0475-4-70280

LIST OF SPARE PARTS FOR BACTERIAL FERMENTOR

Quantity	Part No.	Description
	SPARE PARTS FOR MODEL IF-150 (FERMENTOR)	
1	M1088-0700	Cavity Fillers
1	P0220-3059	Seal Kit
1	P0220-8862	"O" Ring for Cover Plate.
3	P0280-5392	"O" Ring.
2	H-1259	Ferrule, Front
2	H-1260	Ferrule, Rear.
1	P0280-6752	"O" Ring
1	P50-175	Foam Probe
12 Rolls	P0540-1010	Chart Paper for Oxygen Recorder.
2	P0280-5442	"O" Ring for Seal Steam.
1	P0700-6294	Belt , 3V, 750 for Drive,AssemblyM
20ft.	P0740-2391	Silicone Tubing, .065 I.D x.195 OD
1	M1041-0520	Gasket
2	M1041-0540	Gasket.
1	H1001	Glass.
2	M1041-0610	Gasket
1	H-793	Glass.
2	P0620-0289	Repair Seals for Centrifugal Pump P0620-0281.
1	P0200-0233	Filter Element for Inlet Filter P0200-0241.
2	P0200-0230	Filter Element for Exhaust Filter P0200-0220
3	P0200-0229	Seal Kit for Exhaust Filter P0200-0220.
1	P0280-5432	"O" Ring.
3	P0200-0090	Filter Element for Water Filter P0200-0080.
1	H-1303	Washer.
1	R-223	Gasket.
1	R-224	Gasket.
1	R-225	"O" Ring.

Quantity	Part No.	Description
4	R-100	Rubber for Steam Lock Port.
4	R-101	Rubber Bushing Atlantic.
3	P0200-0250	Filter Element for Inst. Air Filter H-1071.
2	P0280-6842	"O" Ring for 1/2" & 1" Steam Lock Ports.
1	P0280-6762	"O" Ring
1	P0280-5432	"O"Ring.
6	P280-5932	"O" Ring.
12 Rolls	H1282	Chart Paper for pH.
3	P0200-0090	Replacement Element for Filter P0200-0080.
1	P0220-3102	Ball Valve, 1/2"
2	P0220-4200	Check valve, 1/2" Brass
3	P0220-3159	Repair Kit for Ball Valve P0220-3150.
1	P0220-4201	Check Valve, 1/2", S.S.
1	P0280-4240	Check Valve, 1/8", S.S. Repair Kit for H-1069.
1	P0220-5239	Repair Kit for Plug Valve, P0220-5230
2	H-742	Check Valve, 3/4" Brass
2	P0220-3102	Ball Valve, 1/2"
2	P0280-1080	Rupture Disc.
2	H-742	Check Valve, Brass.
2	P0220-3159	Repair Kit for Ball Valve P0220-3150.
7	P0220-4139	Repair Kit for Steam Trap. P0220-4130.
3	P0220-5239	Repair Kit for Plug Valve P0220-5230.
2	P0220-6028	Repair Kit for Air Valve P0220-6021.
1	P0220-6048	Repair Kit for Air Valve P0220-6041.
1	P0220-0298	Spare Parts Kit for Solenoid Valve P0220-0291.
1	P0220-0180	Replacement Coil for

Quantity	Part No.	Description
1	P0220-1770	Timer.
5	EP-135	Fuse.
5	EP-104	Fuse.
1	P0460-0170	Control Module.
1	P0440-1331	Meter.
1	P0460-2020	Circuit Card.
1	M1054-0310	Circuit Card Assembly.
1	P0380-0030	Pilot Light,115V.White.
1	P0380-3070	Fuse.
2	B-109	Bearing.
2	R-263	"O" Ring.
2	R-153	"O" Ring.
2	P0280-0120	Seal Assembly
1	P0180-0270	Bearing
1	P0180-0063	Bearing.
1	P0280-4140	V-Ring Seal
1	P0280-6342	"O" Ring.
1	P0280-6322	"O" Ring.
1	R-145	"O" Ring
1	P0280-0131	Mechanical Seal
1	P0280-4190	Seal
1	Special Order	Spare Brushes & Bearing 1-1/2 HP Agitation Motor (Motor Spec. Y-11852)
2	ES-111	Toggle Seitch, SPST.
1	P0400-2041	Contactor, 3 pole
1	EL-107	Lamp, 115VAC,30 Watt.
1	ES-110	Switch, SPST.
1	EF-109	Fuse - 4A - FRN 4.
2	P0380-3370	Fuse - 1/2 A-FRN 0.5
4	EF-108	Fuse - 8A-FRN 8
1	EF-106	Fuse - 1A - FRN 1
1	EP-110	Fuse, 7A, FRN-7
5	P0380-0170	Pilot Light, Amber
1	P0280-0170	Pilot Light, Red.

(HPN)

UNITED STATES GOVERNMENT

memorandum

DATE: December 27, 1987 (PDM)

REPLY TO ATTN OF: Robert W. Nachtrieb, Chief/PDM

SUBJECT: Primary Health Care Project (391-0475)

TO: Mr. A.T. Bilecky, CMO

Attached for your necessary action is Amendment No. 1 to PIO/C No. 391-0475-4-70280, dated December 22, 1987, issued under the subject project to include the procurement of equipment, spares and accessories required for Bacterial Fermentor (1F-150) requested in the original PIO/C.

Please take appropriate action. Thank you.

ENC: a/s

cc: HPN - H. Goldman
PDM - S. Khan
FM - D. Pratt
} with a copy of PIO/C

PDM:Shaukat

PIO/C

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT IMPLEMENTATION ORDER/COMMODITIES

☐ Worksheet ☒ Issuance

1. Cooperating Country: Pakistan

2. PIO/C Number: 391-0475-4-70280

3. Project Number and Title: 391-0475 Primary Health Care

4. Appropriation Symbol: 72-1171021

5. Allotment Symbol and Charge: QDHA-87-27391-KG-13

6. Funds Allotted To: ☐ AID/W ☒ Mission

7. Obligation Status: ☐ Administrative Reservation ☒ By Agreement

8. ☐ Original OR Amendment Number 1

9. Authorized Agent: USAID/Pakistan

10. Method of Financing: A. ☒ U.S. Government B. ☐ Direct Letter of Commitment

11. Contracting Period (Mo., Day, Yr.) From: To:

12. Delivery Period (Mo., Day, Yr.) From: To:

13. Project Assistance Completion Date (Mo., Day, Yr.): March 31, 1989

14. Area of Source: U.S. (Code 000)

15. DOLLAR VALUE

A. Previous Total	B. Increase	C. Decrease	D. Total to Date
586,866	-	-	586,866

16. Quantity, Description, Specifications, Instructions and Special Provisions

1. The purpose of this PIO/C amendment is to include the procurement of equipment, spares and accessories, as per details on pages 2-3, required for Bacterial Fermentor (IF-150) requested in the original PIO/C. No additional funds are required for this procurement.

2. All other provisions of the original PIO/C remain unchanged.

17. MISSION REFERENCES

HWGoldman/ RWNachtrieb memo dated 12/15/87

18. MISSION CLEARANCES	DATE	MISSION CLEARANCES	DATE
PDM - Shahabuddin Khan	12/15/87	HPN - Heather Goldman	12/15/87
OCC - A.T. Bilecky	12/15/87	FM - A. [illegible]	12/20

19. Date of Original Issuance: October 30, 1987

20. Date of this Issuance: December 22, 1987

21. For the Cooperating Country - The terms and conditions set forth herein are hereby agreed to:

Signature: Col. M. Akram Khan Date:

Title: National Manager EPI, NIH, Islamabad

22. For the Agency for International Development

Signature: Robert W. Nachtrieb

Title: Chief, Office of PDM USAID/Pakistan

Date: 22 DEC 87

AID 1370-1 (10-79)

LIST OF EQUIPMENT (TO BE SUPPLIED BY U.S. AID)
IN RESPECT OF THE PROJECT "TETANUS TOXOID PRODUCTION
FOR THE INSTALLATION OF FERMENTOR (BIO-REACTOR)"
NATIONAL INSTITUTE OF HEALTH, ISLAMABAD

S.No.	Name of Equipment	Qty	
1.	"4 x 12" rectangular vertical viewing window	1	
2.	Mechanical Foam Breaker	1	
3.	Stainless Steel Exhaust Line	1	
4.	Additional Gas System	1	
5.	Model DO&82 D.O. Controller System Ser#6801100	1)	
	M1016-5005 D.O. Probe	1)	LOT
	M1093-7470 D.O. Cable	1)	
6.	PH-172 PH Controller System with two 15L addition vessels (M1092-3001) Ser#6801355	1	LOT
7.	XpH-75 PH Probe	1)	
	TD-20 Turbidity Monitor Ser#6802100	1)	
8.	M1023-5001 Rapid Chiller-RC100 with coil 220V 50Hz	1	
9.	Vial Washer	1	
10.	Vial Filling, Stoppering & Sealing Machine	1	
11.	Vial Printing machine	1	
12.	Autoclave Double Door	2	
13.	Vial Oven	2	
14.	Laminar Flows		
	a) Hanging type	2	
	b) Bench type 3' area	1	

LIST OF SPARES AND ACCESSORIES FOR FERMENTOR, CENTRIFUGE FILLING MACHINE, SEALING MACHINE, AUTOCLAVES AND CHEMICALS, TO BE SUPPLIED BY U.S. AID IN RESPECT OF PROJECT "TETANUS TOXOID PRODUCTION FOR THE INSTALLATION OF FERMENTOR (BIO-REACTOR)" NATIONAL INSTITUTE OF HEALTH ISLAMABAD

Spares parts:

S. No.	Item	Part No.	Qty
1.	CEPA Laboratory Centrifuge with Electric Drive:	-	1 No.
2.	Spring	2045 PO160-8103	10 Nos.
3.	Gasket	2059 PO280-1630	10 Nos.
4.	Belt	2049 PO700-4000	10 Nos.
5.	Guide Ring	1790 PO160-6100	10 Nos.
6.	Bearing	4858 PO180-0224	10 Nos.
7.	Ball Bearing	4852 PO180-0220	10 Nos.
8.	Coupling Spring	4433 PO160-8100	10 Nos.
9.	3/8 Fiber Washer	PO100-9030	24 Nos.
10.	D.O. Memrance Kit	PO200-0360	6 Nos.
11.	D.O. Probe 17	M1016-5002	2 Nos.
12.	O-Ring	PO280-5972	6 Nos.
13.	D.O. Probe 12"	M1016-5001	2 Nos.
14.	O.Ring (Cathode)	PO280-5865	6 Nos.
15.	Cathode Glass 17"	PO720-5236	2 Nos.
16.	O.Ring (holding Cap)	PO280-5236	2 Nos.
17.	PH Amp. Circuit	A-4177	4 Nos.
18.	Rapid Chiller for Fermentor		1 No.

Chemicals	Manufacturer
1. Trayptone	Sheffield Products/marcor
2. Beef Heart infusion	Local supplier
3. Glucose	Difco
4. NaCl	Merck
5. Na_2HPO_4	Merck
6. KH_2PO_4	BDH
7. $MgSO_4\ 7H_2O$	Merk
8. $FeSO_4\ 7H_2O$	-do-
9. L-Cystine	-do-
10. Tyrosine	-do-
11. Uracil	-do-
12. Ca-D-Pantothenate	Fluke
13. Thiamine Dihydrochloride	Merk
14. Riboflavin	-do-
15. Pyridoxine hydrochloride	-do-
16. D-Biotin	-do-
17. HCl concentrate	BDH