SURVEY OF BIOCLEAN FACILITIES

Volume I

GUIDELINES FOR EVALUATION, CONDUCT OF SURVEY, AND COST ESTIMATION FOR MODIFICATIONS

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FOREWORD

SURVEY OF BIOCLEAN FACILITIES

The future space exploration program will require a significant number of sterile spacecraft. An essential phase in the production of these sterile spacecraft will be their assembly in bioclean facilities, and preferably in qualified existing facilities rather than in structures specifically constructed for this purpose. Under Contract No. NASr-65(06), IITRI conducted a survey of a selected cross section of presently operating, contamination controlled areas to determine the requirements for their conversion to bioclean rooms for the assembly, checkout, and decontamination of small spacecraft.

This final report is issued in three volumes.

Volume I - Guidelines for Evaluation, Conduct of Survey, and Cost Estimation for Modifications

Volume II - Overall Conclusions, Recommendations, and Summaries of Individual Facilities

Volume III - Detailed Results and Evaluations of Individual Facilities.

Volume I will be made available generally. Volumes II and III will be restricted to use by NASA personnel only.

Each of the companies participating in the survey will receive a copy of Volume I and the results and evaluations of their particular facility as presented in Volume III.

ACKNOWLEDGEMENTS

The on-site surveys and evaluations were conducted by Charles Hagen, Sol Miller, Malcolm Nelson and John Stockham. The engineering cost estimates for those facilities which were deemed suitable for modification were prepared by Rudolf Zastera.

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Volume I

GUIDELINES FOR EVALUATION, CONDUCT OF SURVEY, AND COST ESTIMATION FOR MODIFICATIONS

1. INTRODUCTION

The Committee on Space Research (COSPAR) has recommended that Mars be declared a biological preserve to ensure that the biological objectives of missions to Mars receive first priority. A study group convened by COSPAR has recommended that the probability that a single viable organism be aboard any vehicle intended for planetary landing be less than 1×10^{-4} and that the probability of accidental planetary impact by an unsterilized fly-by or orbiter be less than 3×10^{-5} until the end of the initial period of planetary exploration by a landing vehicle.

The United States space program will therefore require a significant number of sterile spacecraft, and an essential part of the production of these sterile spacecraft will be their assembly in bioclean facilities. It is preferable that qualified existing facilities rather than specially constructed

structures be used for this purpose. Articles describing spacecraft sterilization standards and the microbial contamination in clean assembly areas have recently appeared in the literature or have been presented at technical meetings.[1-6]

IITRI was contracted by the NASA to perform an on-site survey of a selected cross section of presently operating clean assembly areas. These areas were to be evaluated to determine their suitability for conversion to bioclean rooms for the assembly, checkout, and decontamination of small spacecraft. The contract called for a survey of up to 23 clean room facilities. Visits were made to 25 companies in the aerospace field and a total of 32 clean room facilities were evaluated. A list of the companies visited is presented in Appendix A.

The on-site inspections were performed by two 2-man teams. One member of each team was a bacteriologist and the other a scientist from the Fine Particles Research Section. Each was well versed in contamination control and clean room design and operation.

A check list was completed for each facility inspected. The facility survey for each company was conducted in two phases over a period of one to two days. One phase consisted of discussions of the company's contamination control philosophy and a review of monitoring records and engineering drawings of the facility to be inspected. The second phase consisted of an inspection of the facility to verify and expand on the previous discussions. A report was prepared describing each

facility, detailing the results of the discussions, and presenting IITRI's evaluation as to the suitability for upgrading the facility to a bioclean assembly area. Where the evaluation indicated that a facility was suitably constructed and located for alteration to a bioclean area a cost estimate was prepared by IITRI for the modification requirements.

2. GUIDELINES FOR THE EVALUATION OF BIOCLEAN FACILITIES

An essential objective of the survey has been to evaluate, on a comparative basis, the suitability of the facilities visited for the bioclean assembly of spacecraft. Thus, it was essential to lay down a set of basic requirements which should be met by such facilities. These requirements or guidelines were reported in an interim report[7] and are summarized below. The need for a bioclean facility, as opposed to a reliability clean facility, is being questioned by the aerospace industry and the NASA. The question can probably only be resolved through comparing assays of items assembled in both types of facilities. NASA is well aware of the expense of a bioclean facility and the possible complications bioclean restrictions may have on the assembly of spacecraft. Bioclean requirements, therefore, are continually being revised as new information becomes available. The requirements as set forth below do not represent either the current or future specifications of the NASA. Nevertheless, they are sufficiently representative that they provide an adequate general background for the comparative evaluations.

2.1 Decomtamination and Sterilization of Spacecraft

Space probes which require bioclean assembly and sterilization will probably be assembled in laminar downflow clean rooms. Specifications for these clean areas are taken from two documents[8,9] published by the Sandia Corporation. These specifications suggest that the assembly area should meet the cleanliness requirements established for a Federal Standards 209, Class 100 clean area. The biocontamination in the room air should be 0.5 viable particles/ft^3 air with the ventilating system in operation, and with the room unoccupied except for the necessary test personnel.

Three types of sampling devices should be used to monitor the area. The total particulate airborne material, 0.5μ and larger, should be continuously monitored and continuously recorded using a light-scattering particle counter. The airborne biological material should be sampled in a biological slit impactor sampler with the biological media being trypticase soy agar and incubation being at 32°C for 72 hours. The viable particle fallout onto surfaces should be monitored using stainless steel strips, 1 x 2 x 0.06 in. The strips should be sterilized at 180°C for 90 minutes, and should be exposed from one to 52 weeks in the assembly area. Six of these strips from three locations should be removed twice a week and assayed by rinsing the strips in 1% peptone water and plating on soy agar.

The biocontamination of the garments worn in the clean

area should be monitored by sampling three garments each week. At least 10% of all parts passing into the assembly area should be assayed for biological load. These tests may be destructive to the parts tested.

Tools should be bioassayed by impression plates, swab, or total immersion techniques. The personnel working in the assembly area should have their skin checked once a week for microbial quantity. The places checked should be the cheek, hair, chest, back, forearm, palm, and other places as required. Leakage around and in the filter system of the assembly area should be tested using a dioctylphthalate (DOP) smoke generator and an aerosol photometer. At the present time, no uniform leak check procedure has been accepted as standard by the contamination control industry.

Because a partially assembled spacecraft may be exposed to contamination during tests which may have to be performed in facilities that cannot be kept to bioclean room standards it will be necessary to decontaminate the spacecraft before they are returned to the bioclean area for further assembly work. For this purpose, each assembly area will require an ethylene oxide decontamination chamber of suitable size to contain a spacecraft.

By the use of clean assembly and decontamination techniques it is anticipated that a spacecraft can be brought to the point of terminal sterilization with not more than a total of 10^8 organisms on board.

The actual goal established by COSPAR* for Mars landers is a probability of less than 1 in 10,000 or 10^{-4} that a single organism will be on board. Laboratory studies of the kinetics of dry-heat sterilization with resistant microorganisms indicate that at 135°C a bacterial population would be reduced 1 logarithm (or a factor of 10 reduction) for every 1.8 hours of exposure. If, as assumed, a spacecraft would contain somewhere on the order of 10^{8} bacteria, then to achieve the desired probability level of 10^{-4} chances of a single viable cell remaining on the spacecraft a reduction of 12 logarithmic cycles would have to be effected.

It is presently assumed that all components will be made compatible with a terminal heat sterilization cycle. However, it is possible that no more than one heat sterilization cycle will be permitted for all components and this will presumably be the terminal cycle on the fully assembled spacecraft just prior to launch. In all probability the terminal heat sterilization will be performed at the launch site and will not be a part of the assembly area facilities.

2.2 The Size, Number, and Mobility of Spacecraft Components and Subassemblies

The components and subassemblies which will be received into a bioclean assembly area have been assumed to range in size from 1 in^3 to 1 ft^3 and weigh from 1 lb to 100 lb. These

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* COSPAR Resolution 26.5, 1965.

items will be received biologically packaged. They will have been assembled in a bioclean room and decontaminated with ethylene oxide but not sterilized. A surface decontamination process may be invoked on all parts received into the bioclean assembly area.

The completely assembled spacecraft is assumed to be in one of two approximate categories.

Category I - Shape: 60° cone
Size: 12 ft diameter at the base and 12 ft high
Weight: 1000 lbs.

Category II - Shape: 60° cone
Size: 20 ft diameter at the base and 20 ft high
Weight: 6000 lbs.

The clean room facilities are designated as suitable for modification for assembly of 1, 2 or 3 spacecraft in one of the above categories.

For each proposed mission there may be required a total of four flight units and one assay model. Furthermore, each of these units may require the use of a bioclean assembly area for a time period of 6 to 12 months. A very approximate annual output of one or two 12-ft spacecraft per year and two or three 20-ft spacecraft per year has been assumed. All spacecraft at any stage of assembly may be lifted and moved from underneath. Therefore, overhead cranes will not be essential to bioclean areas, although they may be beneficial.

Many tests on the spacecraft will be accomplished inside the bioclean area using portable equipment. Any single item of test equipment will not exceed 1/4 of the size of the spacecraft. However, it may be necessary to test the partially or fully assembled spacecraft outside the clean room, perhaps up to 3 times, throughout the course of assembly. All test equipment moved into the bioclean area will also require decontamination. Terminal sterilization of the spacecraft will be accomplished with dry heat.

2.3 Space Requirements for Bioassembly

The bioassembly of spacecraft will require three separate areas: (1) the assembly area, (2) the decontamination area, and (3) the support area. The assumed space requirements for these areas are shown in Table 1, and a possible layout is shown in Figure 1.

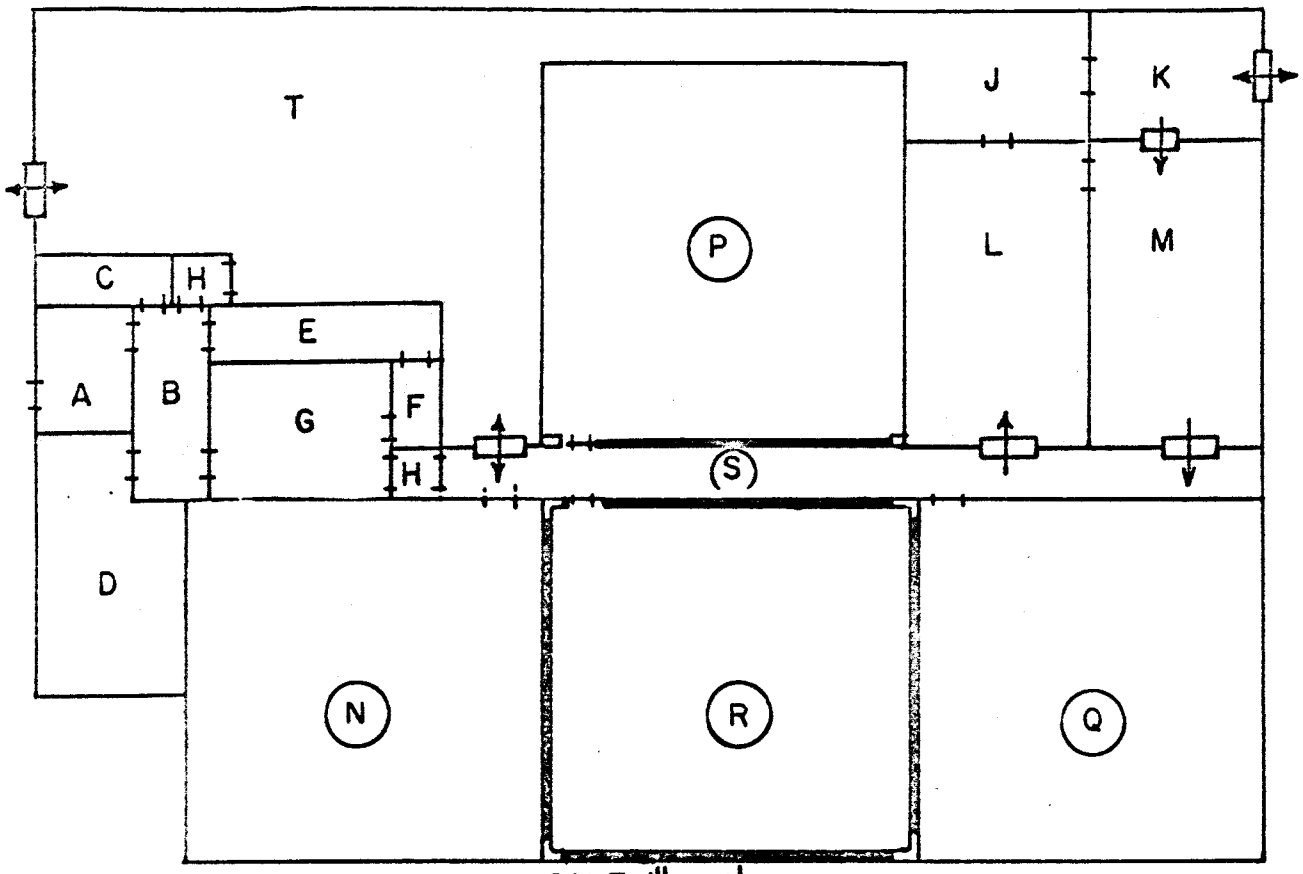
The assembly area will be laminar downflow with a grating floor and a ceiling composed of HEPA (High Efficiency Particulate Air) filters. Each assembly area for the 12-ft spacecraft will require floor dimensions of 20 ft x 20 ft and an interior vertical clearance of 15 ft. The absolute minimum exterior vertical clearance is 21 ft with 28 ft desirable. Thus, for a building to accept the assembly of this sized spacecraft it must have a clearance below the building trusses

Table 1

SUGGESTED SPACE REQUIREMENTS FOR BIOASSEMBLY

Area Designation	Horizontal Clearance		Vertical Clearance	
	Dimension ft	Area ft^2	Interior ft	Exterior ft
1. Assembly Area				
12' craft laminar downflow assembly area	20 x 20	400	15	21-28*
20' craft laminar downflow assembly area	30 x 30	900	25	31-38*
2. Decontamination Area				
Ethylene oxide (ETO) decontamination area	Identical in size to assembly area			
3. Support Area				
a. Personnel Support Area		approx. 800	8.5-10	
Reception area, 80 ft^2 Change room, 20 lockers, 130 ft^2 Toilets and lavatory area, 60 ft^2 Rest area, 250 ft^2 Shower, 6 heads, 80 ft^2 Personnel dryer, 28 ft^2 Bioclean dressing room, 20 sterile lockers, 160 ft^2 Air shower				
b. General Support Area	30 x 30	900	8.5-10	
Parts & component receiving, 100 ft^2 Parts & component storage, 200 ft^2 Parts & component cleaning, 200 ft^2 Cleanliness inspection, particle monitoring, 200 ft^2 Miscellaneous, 200 ft^2				
c. Biological Support Area	32 x 32	1024	8.5-10	
Media dispensing, sample storage, 384 ft^2 Exposed sample preparation incubation & counting, 384 ft^2 Media preparation, 128 ft^2 Glassware washing & cleaning, 128 ft^2				

* The lower figures represent minimum design requirements, the upper figure represents a comfortable design requirement.



SCALE: 1" = 16'

A. RECEPTION AREA
B. LOCKER ROOM
C. TOILET
D. REST AREA
E. WATER SHOWER
F. PERSONNEL DRYER
G. BIOCLEAN LOCKER ROOM
H. AIR SHOWERS
J. GLASSWARE WASHING
K. MEDIA PREPARATION
L. EXPOSED SAMPLE ASSAY
M. MEDIA DISPENSING
N. ASSEMBLY AREA NO. 1
30 x 30 x 25
P. ASSEMBLY AREA NO. 2
30 x 30 x 25
Q. ASSEMBLY AREA NO. 3
30 x 30 x 25
R. ETO AREA
30 x 30 x 25
S. HALL, 25' CEILING
T. GENERAL SUPPORT AREA

PASS-THRUS
DOORS
HIGH BAY DOORS
HIGH BAY

FIGURE 1. SUGGESTED BIOCLEAN FACILITY FLOOR PLAN FOR ASSEMBLING 20' DIAMETER SPACECRAFT

of at least 21 feet. The assembly of the 20 ft spacecraft will require floor dimensions of 30 ft x 30 ft with an interior vertical clearance of 25 feet. The minimum exterior height of this assembly area will be 31 ft with 38 ft desirable.

The decontamination area will require the same space requirements as the assembly areas. Since it essentially serves as an airlock in addition to a decontamination chamber it should be able to meet clean room requirements, and thus it should also be a laminar downflow room. Minimum humidity requirements of 35% should be met, and provision must be made for injecting and exhausting ethylene oxide into and from the system. The use of the entire room as a decontamination chamber has not been critically evaluated by IITRI. However, if it should prove impractical to maintain the required ethylene oxide concentration within the entire room, a plastic curtain or shroud could be provided to surround the spacecraft during the decontamination to reduce the gas volume required.

The total support functions for the bioclean assembly areas will require approximately 3000 ft^2 of floor area with normal ceiling heights, 8-1/2 to 10 feet. These areas could be either conventional flow or laminar flow types. Federal Standard 209, Class 10,000 should be satisfactory for the operations to be performed in the support area. The support area can be subdivided into three functional areas (a) personnel support, (b) general support, and (c) biological support.

These areas do not necessarily require division by physical walls but the advantage of doing so is clear.

The personnel support area will require approximately 800 sq ft and will include such functions as a reception area, locker room, toilets, water shower, personnel dryer, rest room, bioclean dressing room with sterile lockers, and air shower. Although these survey guidelines and cost estimates include a water shower for employees, it is possible that a shower will not be recommended because of the increased shedding of skin particles during the period a few hours immediately after showering. If employees of both sexes are used in the facility the personnel support area will have to be expanded to include additional toilets, lockers, and showers.

A general support area of approximately 900 square feet will be required for such functions as parts receiving, storage, cleaning, inspection, and particle monitoring.

A biological support area of approximately 1,000 sq ft will be required for such functions as glassware washing, media dispensing, sample storage, and incubation, and counting of exposed samples.

3. COST ESTIMATES FOR MODIFICATION OF FACILITIES

The basis for the structural cost estimates for modifying facilities to the bioclean assembly areas are presented in Tables 2 and 3. Cost estimates include material, labor and equipment costs based upon averaged prices over twenty-six major cities.[10] Costs in specific localities may vary by as

Table 2

BASIS FOR STRUCTURAL COST ESTIMATE

LAMINAR DOWNFLOW ASSEMBLY AREA

Item	Unit	$ Cost Per Unit	For 12' Spacecraft		For 20' Spacecraft	
			Units Req'd	Cost, $	Units Req'd	Cost, $
Steel framing, 20' x 20' x 28' or 30' x 30' x 38'	ton	264	1.5	400	4.5	1,200
Wall, 5/8" gypsum board, 2 x 4 studs, 4 x 6 sills, 7 oz. vinyl cover, 6-1/2'stainless steel wainscot	ft^2	0.80	2,000	1,600	4,000	3,200
Ceiling, 2' x 2' x 1/2' HEPA filters with steel frames and aluminum separators including supporting structure and plenum	ft^2	23.20	400	9,300	900	20,900
Floor, elevated steel grating over existing concrete including sealing, supporting frame and louvers	ft^2	9	400	3,600	900	8,100
Large door, electrically operated, rolling, 16' x 16' or 24' x 24' opening	ea	-	1	2,200	1	5,000
Small door, 3' x 7' stainless steel over wood with window	ea	200	3	600	3	600
Observation windows, 3' x 3'	ea	100	4	400	4	400
Lights, including wiring	ea	115	20	2,300	42	4,800
Power installation excluding air handling requirements	ft^2	6	400	2,400	900	5,400
Plumbing	ft^2	3	400	1,200	900	2,700
Vacuum system	ea	1,500	1	1,500	1	1,500
Ductwork, galvanized steel	lb	0.90	12,000	10,800	18,000	16,200
Communication system	ea	800	1	800	1	800
	Total Cost of Assembly Area			$37,100		$70,800
	Cost per ft^2, $/$ft^2$			92.75		78.67

Table 3

BASIS FOR STRUCTURAL COST ESTIMATING

SUPPORT AREA

Item	Cost
a. Personnel Support Approximately 800 ft^2 of floor area; 5/8" gypsum board, 2 x 4 studs, 7 oz. vinyl cover, porcelain enameled ceiling panels, recessed ceiling lights, doors, ductwork, utilities, vinyl floor cover, conventional air circulation	$27,000
b. General Support Approximately 900 ft^2 of floor area, 5/8" gypsum board, 2 x 4 studs, 7 oz. vinyl cover, porcelain enameled ceiling panels, recessed ceiling lights, ductwork, utilities, vinyl floor cover, conventional or horizontal laminar flow air circulation	31,600
c. Biological Support Approximately 1024 ft^2, 5/8" gypsum board, 2 x 4 studs, 7 oz. vinyl cover, porcelain enameled ceiling panels, recessed ceiling light, ductwork, utilities, vinyl floor cover, conventional or horizontal flow air circulation	33,500
Total Cost of Support Area	$92,100
Cost per ft^2, $/$ft^2$	33.81

much as +27% to -13% of the national averages. The high bay laminar downflow area for each 12 ft spacecraft have been estimated to cost approximately $37,100 or $92.75 per square foot. For the 20 ft spacecraft the estimated total cost of each assembly area is $70,800 or $78.67 per square foot. These figures have been rounded off to $40,000 and $80,000 respectively.

The total support area has been estimated to cost approximately $92,100 or $33.81 per square foot. The cost estimates were based on a wall structure of 5/8" gypsum board over 2 x 4 studs with an outer covering of 7 oz. vinyl. In the conventional flow support areas the ceilings are porcelain enameled panels and the floor is sheet vinyl over the sealed surface of the existing concrete floor. In the laminar flow areas the ceiling is composed of HEPA filters with aluminum separators and metal frames. The survey showed that there are a number of construction materials and methods used in clean rooms, and apparently they make little difference in room air quality.

The cost estimates do not include subcontractors' overhead or profit, nor any contingency allowance. The subcontractors' overhead and profit can be expected to increase the cost by as much as 25 percent on the subcontracted item. A reasonable contingency allowance on alteration jobs of this type is 10 percent. The estimates also assume that the basic air handling and conditioning equipment in the plant has sufficient capacity to supply the needs for the assembly and support areas. The cost incurred for the removal of equipment presently occupying

the space slated for the bioclean area is also excluded. The estimates therefore, represent a minimal figure.

No reliable cost estimate for the ethylene oxide decontamination chamber could be obtained. Therefore, all cost estimates must be increased by a sum equal to the cost of this facility.

In addition to the structural alteration costs, the cost of some basic biological assay and particulate cleaning and monitoring equipment is required. These basic equipment needs are presented in Tables and . The major biological equipment costs is for ethylene oxide/steam autoclave pass-through units. Four of these pass-throughs are required at a unit cost of $8,000. One will be used within the biological support area and one will service each of the three assembly areas. The equipment cost for the biological support area only is $19,700. The cleaning and particulate monitoring equipment includes an ultrasonic cleaner, four laminar flow work stations, a light scattering aerosol monitor, membrane filtration kit for monitoring aerosols and uniforms, and another filtration kit for monitoring the cleanliness of liquids. A DOP smoke generator and an aerosol photometer is included so that the filter installation may be periodically leak checked. The total estimate for the cleaning and particulate equipment is $24,500.

In preparing the modification cost estimate, each facility was given credit for their present facilities provided

Table 4

BIOLOGICAL SUPPORT AREA
EQUIPMENT REQUIREMENTS

Equipment Item	Size, ft l x h x d	Number Required	Total Cost
Ethylene oxide-steam autoclave pass-through	2 x 2 x 3	4*	32,000
Germidical immersion tank pass-through	2 x 2 x 3	1	400
Standard clean room benches	-	4	1,600
Drying ovens	2 x 2 x 2	2	1,200
Miscellaneous glassware	-	-	2,000
Incubator	4 x 6 x 7-1/2	2	5,000
Refrigerator	14 ft^3	2	400
Water still	-	1	400
Microscope	-	1	700
		Total	$43,700

* One pass-through is used within the biological support area and one pass-through is to service each of three assembly areas.

Table 5

CLEANING AND PARTICULATE MONITORING AREA
EQUIPMENT REQUIREMENTS

Equipment Item	Size, ft l x h x d	Number Required	Total Cost
Ultrasonic cleaner, spray rinse, dryer	2 x 2 x 3	1	2,500
Laminar flow clean work stations	10 x 2 x 2	4	12,000
Light scattering aerosol monitor	-	1	7,000
Clean room sampling kit (millipore xx 71-047-30 or equivalent)	-	1	700
Contamination analysis kit (millipore xx 71-047-10 or equivalent)	-	1	300
DOP smoke generator and aerosol photometer	-	1	2,000
		Total	$24,500

they were adequate. Where they were considered inadequate the cost estimate included a sum for their enlargement or upgrading.

In this survey, the cost of modifying an existing facility has been compared to the cost of an all new bioclean sub-facility. The new sub-facility is a clean room complex, built inside an existing structure and making use of all the utilities and air handling equipment which are assumed to be available in the existing structure. Table 5 shows the estimated total cost of this sub-facility. The layout is shown in Figure 1.

For further comparison an estimate has been made for constructing a complete bioclean facility including the outer structure and utilities. No architectural study has been performed although a basic layout has had to be assumed. The cost estimate for this complete facility is summarized in Table 7 and is presented in more detail in Appendix B.

It should be stated that although considerable effort has been expended in making the cost estimates realistic, their primary value lies in their consistency and hence their usefulness for comparison with each other and with the estimated cost of a new sub-facility or complete facility.

Table 6

SUMMARY OF ESTIMATED COST OF
A NEW BIOCLEAN SUB-FACILITY*

	20' Spacecraft	12' Spacecraft
Laminar downflow assembly areas	$210,000	$120,000
Personnel support area	27,000	27,000
General support area	31,600	31,600
Biological support area	33,500	33,500
Personal support equipment (showers, lockers, etc.)	20,000	20,000
General support equipment (laminar flow benches, pass-thrus, etc.)	15,000	15,000
Biological support equipment	43,700	43,700
Cleaning and particulate monitoring	24,500	24,500
	$435,300**	$315,300**

* Exclusive of outer structure, air conditioning and contingency allowances.

** No estimate is included for the large ETO decontamination chamber.

Table 7

SUMMARY OF ESTIMATED COST OF A COMPLETE BIOCLEAN FACILITY*

Exterior construction**		$93,740
Interior construction		218,800
Air conditioning		343,000
Utilities		192,400
Lighting	$36,000	
Power (electric)	81,000	
Plumbing	38,000	
Central vacuum system	28,000	
Communications system	9,400	
Equipment		103,200
Subtotal		$951,140
+10% contingency		95,114
+4% cost rise factor		38,046
+ profit and overhead		180,700
		$1,265,000***

* Area of facility = 7,400 sq ft. Total floor area = 18,600 sq ft. See Appendix B for approximate layout.

** For assembly of three 20' spacecraft.

*** No estimate is included for the large ETO decontamination chamber.

4. GENERAL COMMENTS ABOUT THE SURVEY

Some general comments of the survey team members who conducted the facility survey are enumerated below. These comments are not reflections from a single inspection but are the impressions that the team members obtained atter visiting 32 facilities. The comments suffer the same disadvantage as all generalizations in that notable exceptions do exist and the validity of the sample on which they are based must always be questioned.

1. There is not a laminar downflow area of sufficient size to meet the space requirements for the assembly of either the 12 ft craft or the 20 ft craft.
2. The facilities and plants of the Aerospace Industry are extremely adaptable and building modifications are readily accomplished.
3. The quality assurance personnel in industry seem to be well versed in comtamination control.
4. Industry is just beginning to think seriously about the bioclean assembly of equipment. Despite some competent and complete life sciences divisions within their corporate structure, the contamination control engineer and biological scientists do not yet appear to have combined their talents in a manner that would be required for successful bio-assembly.
5. There appears to be an interest in contamination control but mainly as a contractual obligation. Thus contamination control requirements must be spelled out in detail in all contracts.

6. Industry seems ready to provide the facilities which will meet contractual obligations within the framework of contamination control.

7. Except in a general way there is no knowledge of how upgrading the work assembly environment aids or promotes reliability.

8. Many companies tend to classify their rooms at a design level rather than an operating level. Many indicated that their present clean rooms could be upgraded considerably in quality by tightening controls, but they have never actually operated the rooms at the indicated level. Such claims were usually rejected by the IITRI survey teams and the room cleanliness potential was evaluated independently by the teams.

9. There appears to be a tendency to overcrowd clean rooms with both personnel and instrumentation so that the rooms have a very cluttered appearance and the air quality is compromised.

10. The horizontal laminar flow rooms did not meet Federal Standards Class 100 clean room classification past the first work station and degradation can be quite rapid as a function of room length.

11. HEPA filters with aluminum separators and metal frames* have been found to be satisfactory for Class 100 clean rooms. Other types of filter construction should be carefully assessed before being specified.

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* We have recently become aware of difficulties with obtaining leakproof media to metal frame joints.[11]

12. Training programs for clean room personnel should be expanded and medical check-ups initiated.

13. In most instances the personnel working within a clean area obey the rules and regulations laid down for them in the company's procedural manual.

5. GENERAL CONCLUSIONS

A total of ten of the thirty-two facilities visited were found to be suitable for modification to bioclean assembly areas for the 20' spacecraft. An additional six were suitable for modification to bioclean assembly areas for the 12' spacecraft. The estimated cost saving (excluding the ETO decontamination chamber) resulting from the use of existing facilities ranged from 10-40% compared to the cost of a new sub-facility for 12' spacecraft, 7-29% of a new sub-facility for 20' spacecraft and 68-76% of a new complete facility for 20' spacecraft.

No facility had a Class 100 laminar downflow clean room of adequate size for the simple reason that there has been no previous requirement for such stringent cleanliness in such large assembly areas. Thus, in all cases the cost of modification has to include laminar downflow high bay clean rooms. Furthermore, it is the lack of high bay space adjacent to existing facilities which has been the major reason for listing so many as unsuitable for the modification. The fact that there will now be a requirement for these facilities is being recognized by the industry and they are clearly prepared to provide the necessary bioclean rooms.

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Appendix A

ORGANIZATIONS VISITED FOR BIOCLEAN ROOM SURVEY

(Selected as a cross section of industrial facilities)

Company	Location
Bell Aerosystems Company	Buffalo, New York
Bendix Corporation	Teterboro, New Jersey
Boeing Company	Seattle, Washington
Chrysler Corporation	New Orleans, La.
Douglas Aircraft	Santa Monica, Calif.
Eastman Kodak Company	Rochester, New York
General Dynamics Corp.	Pomona, California
General Electric	Valley Forge, Pa.
Grumman Aircraft Engineering Corporation	Bethpage, L.I., N.Y.
Honeywell Aeronautical Division	St. Petersburg, Fla.
Hughes Aircraft Company	El Segundo, Calif.
Ling-Temco-Vought, Inc.	Dallas, Texas
Lockheed Aircraft Corp.	Van Nuys, Calif.
Martin Marietta Corp.	Baltimore, Maryland
Marquardt Corporation	Van Nuys, California
McDonnell Aircraft Corp.	St. Louis, Missouri

Company	Location
Middletown Air Materiel Area	Olmsted Air Force Base
NASA-Marshall Space Flight Center	Huntsville, Alabama
Northrop Space Laboratories	Hawthorne, California
Radio Corporation of America	Princeton, New Jersey
Republic Aviation Corp.	Farmingdale, L.I., New York
North American Aviation Inc., Rocketdyne Div.	Canoga Park, Calif.
Sandia Corporation	Albuquerque, N. M.
TRW	Redondo Beach, Calif.
United Aircraft Corp., Norden Division	Norwalk, Connecticut

Appendix B

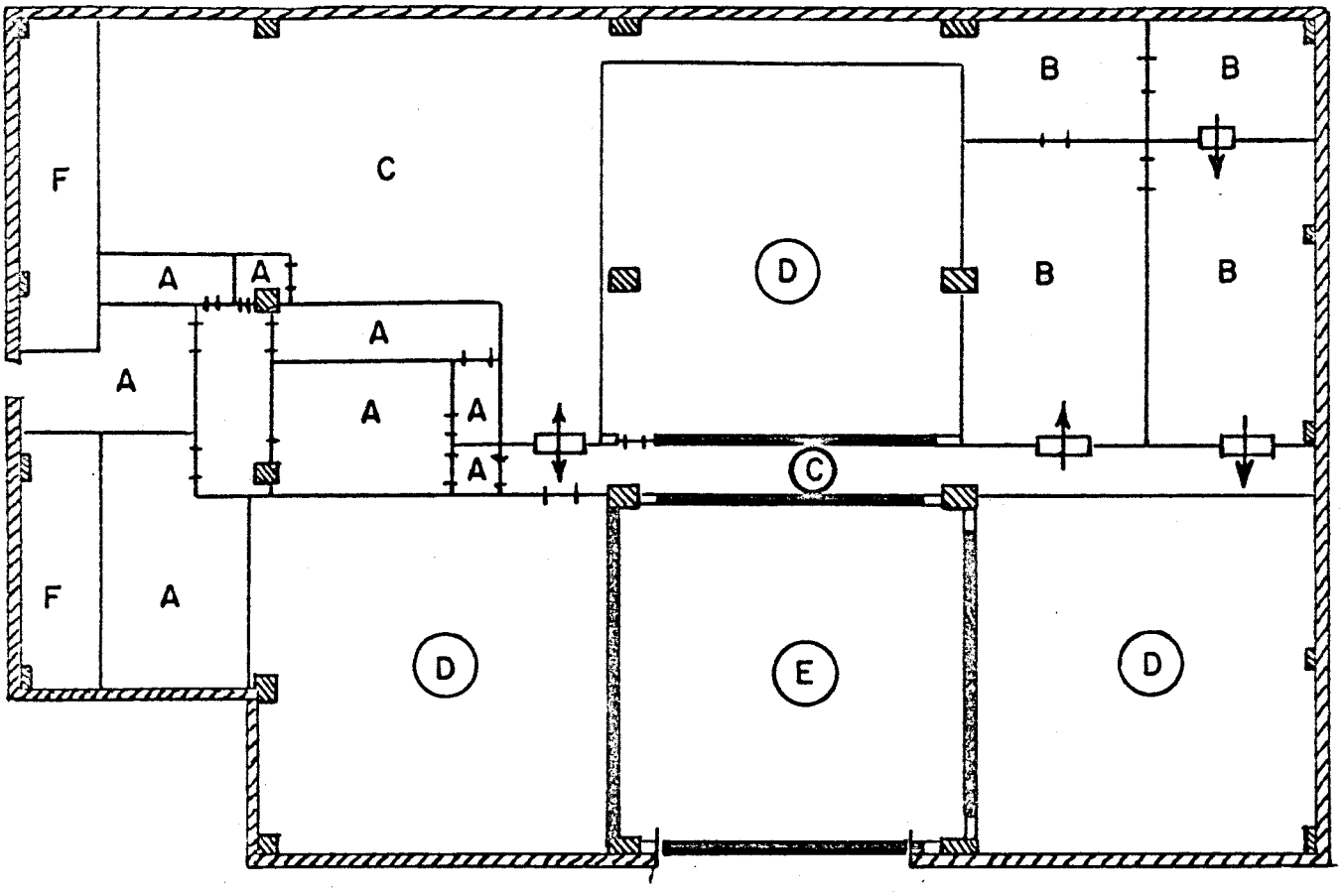
COST ESTIMATE FOR THE CONSTRUCTION OF A COMPLETE BIOCLEAN FACILITY

An estimate has been prepared for the construction of a building structure to house the bioclean facility discussed earlier and shown in Figure 1. An outline of the building is given in Figure B-1 which has been drawn only for the purpose of estimating costs. This figure represents neither an architectural design nor a recommended structure. A sketch of the building is shown in Figure B-2.

A minimal type of design concept was assumed, i.e., a concept including minimal, but adequate, floor area and facilities. These are enumerated as follows:

1. Floor Plan

In general, the floor plan is the same as was recommended for modifying existing facilities. The overall area was increased somewhat to make room for vertical runs of air-conditioning ductwork.



A. PERSONNEL SUPPORT AREA
B. BIOLOGICAL SUPPORT AREA
C. GENERAL SUPPORT AREA
D. LAMINAR DOWN FLOW ASSEMBLY AREA. 25 FOOT CEILING HEIGHT
E. ETO DECONTAMINATION CHAMBER. 25 FOOT CEILING HEIGHT
F. RETURN AIR DUCTS

PASS-THRUS
DOORS
HIGH BAY DOORS
HIGH BAY

FIGURE BI: GROUND FLOOR PLAN OF COMPLETE BIOCLEAN FACILITY
SCALE: 1"= 16'

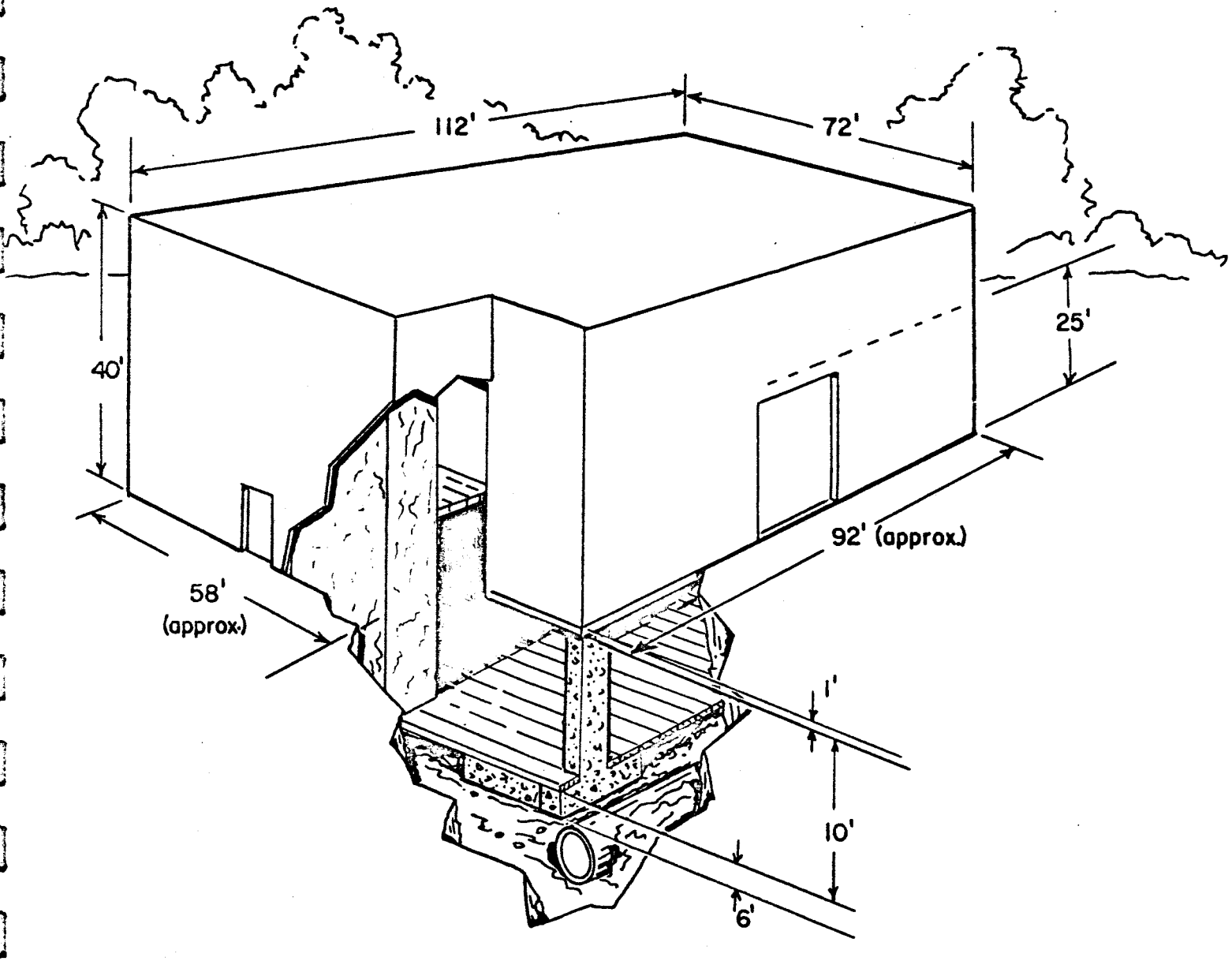


FIGURE B2: ARTIST'S CONCEPTION
OF COMPLETE BIOCLEAN FACILITY

2. Facilities

One consideration of the minimal design is that the installation will be used by personnel of the same sex (men). Thus, only one set of toilet, shower room, locker room, personnel dryer, and bioclean locker room facilities has been provided. If employees of both sexes will be required, dual facilities will be needed.

3. Decontamination Chamber

The decontamination chamber serves as an egress for the spacecraft at various times during assembly for test purposes. Upon return of the spacecraft it can be decontaminated with ethylene oxide and cleaned in this chamber before being readmitted to the assembly areas.

4. Shipping and Receiving Area

The assumption was made at the onset of this program that the components and subassemblies to be received into the bioclean facility will be less than 1 ft^3 in size and less than 100 lbs. in weight; thus, no receiving docks or elaborate materials receiving provisions were incorporated into the design. Similarly, no "shipping department" was provided for, since the bioclean assembly building was considered as an additional building to an existing manufacturing complex which already contains a complete shipping and receiving facility.

5. Basis of Cost Estimate

Since a detailed design was not prepared but only a hasty, rudimentary design concept, the cost estimate had to be based upon block figures and known percentages for the most part. For large construction projects of this type, however, this method is considered to give reasonably accurate results. The main source of errors will stem from an erroneous estimate of the building size; therefore, this factor should be carefully evaluated. With regards to this particular estimate, where the objective was a minimal design and where design details were not completely worked out, the estimated building size may be too low.

6. Construction Features

The following brief descriptions of construction features were the basis of this cost estimate.

a) Foundation

Reinforced concrete floor and walls, floor surface hardened and dust proofed with two coats of liquid dust proofing. Finishing of foundation walls consists of breaking ties, patching, and carborundum rub where needed. Exterior surface of walls and floor are waterproofed with 3 ply fabric membrane.

b) Floor Construction

Ground floor construction consists of metal pan concrete slab in all areas other than the laminar downflow areas. Concrete is surface hardened, dust proofed, and covered

with 1/8 inch thick sheet vinyl. All joints are sealed and corners are coved. In laminar downflow areas, the floor consists of 1-1/2 inch deep stainless steel grating supported on epoxy coated structural steel beams to minimize dust and facilitate cleaning. Second floor construction consists of metal pan concrete slab, surface hardened, and dust proofed. Vinyl covering was not considered on the second floor.

c) Building Enclosure

Consists of structural steel framing supporting exterior walls of aluminum sandwich construction, 3 inches thick insulated, and with a porcelain enameled finish on the inside surface and a baked enamel finish on the outside. All joints are sealed with plastic caulking and taped to present a smooth surface.

The roof is comprised of 2 inch precast gypsum planking supported by structural steel roof joists and covered with 5 ply built-up roofing.

d) Interior Walls

These consist of 5/8 inch vinyl covered gypsum board on metal studs with all joists sealed and taped. Horizontal laminar flow areas have one wall (supply wall) comprised of HEPA filters connected by stainless steel supply plenum and an opposite wall (return wall) comprised of roughing filters set into a stainless steel return air plenum.

e) Ceilings

The ceilings in the laminar downflow rooms consist of HEPA filters set in a steep supporting grid which, in turn, is supported by the roof trusses. Fluorescent lighting troffers with glass prism lenses are recessed flush with the ceiling in continuous illuminated strips about one foot wide and spaced about 5 feet apart. The lights and HEPA filters are serviced from appropriate catwalks within the supply air plenum above the ceiling. This plenum (about 5 feet high) is formed of sheet aluminum and is supported by the roof trusses.

The ceilings in the other areas consist or porcelain enameled panels in a supporting steel grid with strip lighting similar to that of the laminar downflow rooms.

f) General

The 10 foot deep basement provides space for air-conditioning ductwork, piping, miscellaneous service lines and mechanical equipment, such as pumps, compressors, steam generators, ETO system, controls for louvers regulating laminar downflow, etc. The second floor provides space for air handling and air-conditioning equipment and for ductwork.

COST ESTIMATE

a. External Construction

Earthwork (clear, excavate trench, lay sewers, backfill and tamp)	10,640
Concrete (foundations, footings, columns, basement floor, surface finish, waterproof)	22,300
Building frame (steel framing)	14,200
Exterior walls (aluminum sandwich panels 3" thick, porcelain enamel finish inside, baked enamel outside. Joints caulked and taped)	40,800
Roof (2" precast gypsum planking covered with 5 ply built-up roofing)	5,800
Total for exterior construction	$93,740

b. Interior Construction

1st floors (metal pan concrete slab 6" thick. Surface hardened, dust-proofed covered 1/8" vinyl.)	16,500
1st floor (stainless steel grating in assembly areas)	10,800
2nd floor (metal pan concrete slab 6" thick. Surface hardened, dust-proofed.)	6,100
Partitions (5/8" vinyl covered gypsum board on both sides of metal studs, joints sealed and taped.)	11,300
HEPA filters (with plenum in horizontal laminar flow rooms, with frames in vertical laminar flow areas)	98,300
Roughing filters	20,000
Plenum (above vertical laminar flow areas, including catwalk)	6,800

b. Interior Construction (Cont'd)

Ceiling (in horizontal flor rooms, porcelain enamel panels in steel support grid)	13,000
Large doors (24' x 24')	25,000
Accessories (standard doors, viewing windows, stairs, etc.)	11,000
Total for interior construction	$218,800

c. Air Conditioning

Main unit (heating, cooling, cooling tower, pumps, piping, air handling)	242,000
Major ducts (galvanized steel)	62,000
Control (louvres and balancing valves and mechanisms)	14,000
Control panel (recorders and continuous control)	25,000
Total for air conditioning	$343,000

d. Utilities

Lighting (fixtures and wiring)	36,000
Power (electric materials and installation)	81,000
Plumbing (miscellaneous materials and installation)	38,000
Vacuum (central system)	28,000
Communication (TV monitor, visual, intercom)	9,400
Total for utilities	$192,400

e. Equipment

Personnel support area (showers, lockers, etc.)	$20,000
General support area (laminar flow benches, pass-thrus, etc.)	15,000
Biological support area (glassware, ovens, incubator, immersion tank, etc.)	43,700
Cleaning and particulate monitoring equipment	24,500
Total for equipment	$103,200
Estimated total cost of complete facility	$951,140

It should be noted that no estimate has been included for the large ETO decontamination chamber. Further, this estimate represents a minimal cost for such a facility.

Additional allowances of 10% for contingencies, 4% as a cost rise factor and 25% for a profit and overhead allowance on all costs except the air-conditioning estimate bring the overall estimated total cost to $1,265,000.