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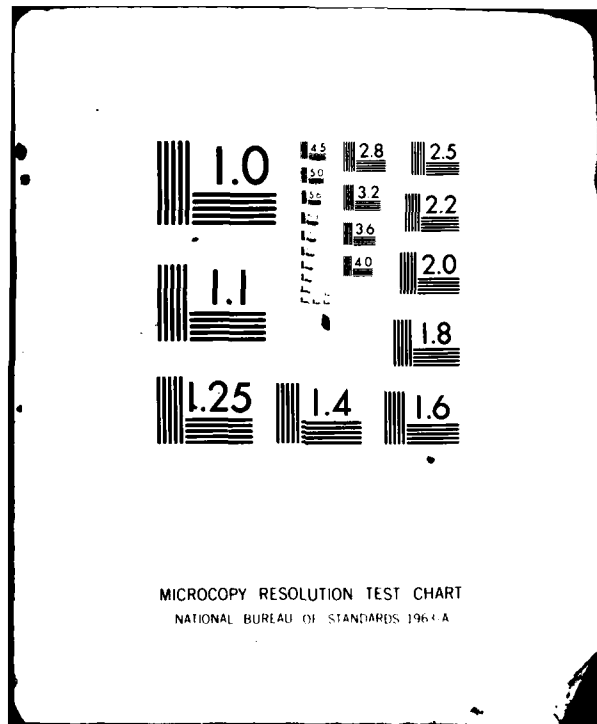
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MAMMALIAN TOXICOLOGY TESTING: PROBLEM DEFINITION STUDY

INHALATION CHAMBERS AND SUPPORTING EQUIPMENT SURVEY (U)

by

G. E. Schiefer and R. H. Reuter

March, 1981

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

Contract DAMD17-81-C-1013

Life Systems, Inc.
Cleveland, OH 44122

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER	2. GOVT ACCESSION NO. AD-A113 418	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) MAMMALIAN TOXICOLOGY TESTING: PROBLEM DEFINITION STUDY, INHALATION CHAMBERS AND SUPPORTING EQUIPMENT		5. TYPE OF REPORT & PERIOD COVERED Supporting Document 15 December 1980-5 April 1981
7. AUTHOR(s) G. E. Schiefer, R. H. Reuter		6. PERFORMING ORG. REPORT NUMBER LSI TR-477-26A
9. PERFORMING ORGANIZATION NAME AND ADDRESS LIFE SYSTEMS, INC. 24755 Highpoint Road Cleveland, OH 44122		8. CONTRACT OR GRANT NUMBER(s) DAMD17-81-C-1013
11. CONTROLLING OFFICE NAME AND ADDRESS US Army Medical Research and Development Command Fort Detrick Frederick, MD 21701		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS 62777A.3E162777A878.CC.208
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)		12. REPORT DATE March, 1981
		13. NUMBER OF PAGES 23
		15. SECURITY CLASS. (of this report) UNCLASSIFIED
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) Approved for Public Release; Distribution Unlimited		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES This report is one of 12 supporting documents to the final reports cited on the reverse side.		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Mammalian Toxicology Testing, Mammalian Toxicology, Toxicology, Mammalian, Mammalian Toxicology Facility, Toxicology Facility, Toxicology Testing Equipment		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Information on the inhalation chambers and supporting equipment needed for them are summarized in this report. This equipment represents a major expense that requires a tailored design and special fabrication to satisfy the Army's inhalation toxicology testing requirements. The data presented can be used for evaluating existing chambers and equipment and to assist in designing the special equipment or selecting equipment for an Army facility.		

18. continued-

Report Subtitle

Life Systems, Inc.
Report Number

Final Reports--

- Part 1. Comparative Analysis Report
- Part 2. Facility Installation Report
- Part 3. Impact of Future Changes Report

LSI-TR-477-2
 LSI-TR-477-3
 LSI-TR-477-4

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FOREWORD

Reports for this Contract, DAMD17-81-C-1013, consist of three major final reports and twelve supporting documents. The Contract title, MAMMALIAN TOXICOLOGY TESTING: PROBLEM DEFINITION STUDY, is the main title for all the reports. Individual reports are subtitled and referenced with Life Systems, Inc. report numbers as detailed below. Please note that the Life Systems report numbers in test references are shortened. In the Defense Technical Information Center (DTIC) data base the reports are identified by the complete report numbers (i.e., LSI-TR-477-XXX) and complete numbers must be used for retrieval.

<u>Report Subtitle</u>	<u>Life Systems, Inc. Report Number</u>
Final Reports--	
Part 1. Comparative Analysis Report	LSI-TR-477-2
Part 2. Facility Installation Report	LSI-TR-477-3
Part 3. Impact of Future Changes Report	LSI-TR-477-4
Supporting Documents--	
Technology Changes Impact on Testing Requirements	LSI-TR-477-14
Quality Assurance Plan	LSI-TR-477-17A
Capability Modules	LSI-TR-477-19B
Technical Plan	LSI-TR-477-20A
Equipment Plan	LSI-TR-477-21A
Personnel Plan	LSI-TR-477-23A
Inhalation Chambers and Supporting Equipment Survey	LSI-TR-477-26A
Equipment List for Modules	LSI-TR-477-28B
AMTR Protocol/Pricing Report	LSI-TR-477-29A
Global Army Toxicology Requirements	LSI-TR-477-31A
Comparison Toxicology Test Costs	LSI-TR-477-36A
Annual Testing Capacity	LSI-TR-477-38A

SUMMARY

During this program undertaking the study and defining the Army's requirements for Applied Mammalian Toxicology Research/Testing, a survey was made of the inhalation chambers and supporting equipment needed. These items, called the inhalation toxicology system, represent a major equipment expense for the Facility. They will require tailor designing and special fabrication to satisfy the Army's testing needs.

The special design requirements result from the Army unique exposures that exist.

Sixteen toxicology facilities were contacted concerning their inhalation toxicology Systems. Six manufacturers were contacted that supply such systems. Worksheets were prepared to ensure all the important information was acquired during each contact.

Much significant information resulted from the survey. Manufacturers, for example, do not limit themselves to specified, off-the-shelf design; a major difference in chambers is the shape and subsequent ability to expose either the whole animal, just their noses, etc. A total of 16 summarizing conclusions were presented.

A highlight of the report is a table summarizing inhalation chamber characteristics starting with approximate volume, dimensions, and shape/type to animal capacity/species, construction material, operational status, delivery, cost and special features.

Equally important were the inhalation chamber operating procedures defined for each of the 16 facilities. Such parameters as temperature, relative humidity range, computer monitoring, etc. are cited.

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INTRODUCTION

A program was undertaken to study and define the Army's requirements for Applied Mammalian Toxicology Research (AMTR) and methods for meeting the requirements. Inherent in the latter is the consideration of the facility, equipment and expendables, personnel, quality assurance and resources needed for the design, construction and operation of such a facility.

Scope of Document

This document was conceived and prepared to accumulate in one spot information on the inhalation chamber and supporting equipment (hereafter referred to as the Inhalation Toxicology System). The Inhalation Toxicology System is a major equipment expense that will require a tailored design and special fabrication to satisfy the Army's inhalation toxicology testing requirements. All information considered critical to evaluating existing systems has been assembled in a standardized format in this document.

The Inhalation Toxicology System will determine to a great extent the inhalation testing the AMTR facility can perform. The system will directly determine the testing protocols that can be performed by influencing or fixing:

1. The number and types of animals that can be used.
2. The exposure pattern that can be used (intermittently or continuously).
3. The distribution of the test agent within the chamber.
4. The control and monitoring of the test agent.

Objective

The objective of this document is to assemble the data that can be used for evaluation of existing inhalation systems in order to assist in design of special equipment or the selection of existing equipment for an Army AMTR facility. The data base represents information provided from equipment manufacturers and from facilities with good systems selected by a group of inhalation toxicologist consultants.

The following sources were contacted to obtain information:

A. Facilities contacted:

1. Brookhaven National Laboratory
2. Chemical Industry Institute of Toxicology
3. National Institute of Environmental Health Sciences
4. Environmental Protection Agency, Research Triangle Park
5. Environmental Protection Agency, Center Hill Facility, Cincinnati
6. National Institute for Occupational Safety and Health, Cincinnati

7. Lovelace Inhalation Toxicology Research Institute
8. Hazelton Laboratories, Inc.
9. Battelle Columbus Laboratories
10. U.S. Army Environmental Hygiene Agency
11. Toxigenics, Inc.
12. Litton Bionetics, Division of Litton Corporation
13. IIT Research Institute
14. Monsanto Company
15. The Upjohn Company
16. University of California, Davis

B. Manufacturers contacted:

1. Charles Spengler and Associates
2. Hazelton Systems, Inc.
3. King-Lar Company
4. Wahmann Manufacturing Company
5. Young & Bertke Company
6. The Upjohn Company

Data Sought

The data sought is enumerated in the work sheets used for the inhalation chamber inventory in Appendix 1. When several sources (a manufacturer and one or more facilities) provided information on the same system, the information was checked for validity. If the information obtained from a manufacturer and a facility differed, information from the facilities with the systems was used. It was reasoned that manufacturers would be less likely to point out deficiencies or shortcomings in their system (most manufacturers are involved in only making some of the system components, not complete systems, therefore, it was necessary to contact several parties to get complete data on a system).

Results of Survey Inventory

The results of the inventory are summarized in Appendix 2.

Table A2-1 lists the sources of information in a matrix of the 16 AMTR facilities and the 6 manufacturers (both listed above). Table A2-2 and A2-3 provide a tabulation of data on the chambers' characteristics and operating procedures.

A summary of the data follows:

1. Manufacturers do not limit themselves to specified, off-the-shelf designs. For most applications a basic design concept is tailored to the specific needs of the facility by getting input from a consultant or the purchaser.
2. If chamber reliance is discounted as a variable, the major differences in chambers (not chamber systems) are their shape, their ability to expose either the whole animal or just their nose, and their design features to accommodate loading and unloading of the animals and animal care.
3. Inhalation chamber fabrication and design is a business with a small market, measured in both number of transactions and total dollars. Hazelton Systems, Inc. is the largest business (based on total sales) active in chamber fabrication.
4. Rack and cages should be either purchased in conjunction with the chambers or the specifications of existing cages (and cages that will be used) should be determined to avoid a compatibility problem. Certain special racks are available to reduce the effect of uneven distribution of the test agent inside the chamber and intercage contamination by feces and urine droppings from upper cages to lower ones.
5. Chamber manufacturers routinely fabricate chambers to the buyers' specifications. Average lead time of three months was quoted by the manufacturers for up to 15 chambers. Longer periods would be required if more than 15 chambers were ordered from a single manufacturer. Purchases of chambers indicated that six months, not three, is the average delivery time they experienced. With an adequate specification package, several manufacturers could fabricate identical units--one manufacturer could make the acute chambers, another the subchronic, and a third the chronic.
6. A special team of chamber design experts and toxicologists should be used to design the chamber systems for the special Army requirements associated with troop exposures that are characterized by short-term, intermittent, high-level exposures. The chamber system will be influenced by the inhalation toxicology protocols used. Therefore, a protocol determination must precede chamber design.
7. Support equipment has probably a greater impact on chamber system capability than the chamber design.
8. Upjohn is patenting a new chamber design that has as one of its major features a lower height to chamber volume ratio. This is particularly attractive to accommodating chambers into existing buildings, such as LAIR, that may not have sufficient floor to ceiling distance to accommodate certain typical chamber designs.
9. Chambers can be categorized into those that are movable (routinely put through a washer) and those that are fixed in place (built-in) equipment.

10. The Hazelton 1000 chamber appears to be the chamber that is currently being produced in the greatest numbers. Because of its popularity there may be back orders. One of the principal features of the Hazelton 1000 is the use of catch pans to avoid droppings from the animals in higher cages upon lower ones and to maintain an even distribution of the test agent in the filled chamber.
11. One of the features desired in chambers used for certain Army tests is the ability to achieve a designated level of test agent concentration rapidly and maintain it in the chamber. The best approach for achieving this is to utilize an interactive computer which manipulates the input of the test agent and input air volume, and reduces the time to equilibrium concentration to less than two minutes. If a computer is not used it may require 30 minutes or more to bring the chamber up to its desired concentration.
12. Air handling systems, both entrance air and treatment of exhaust air, and the monitoring and control equipment are normally not provided by chamber manufacturers.
13. Chamber manufacturing remains a highly specialized field with relatively few manufacturers, and numerous tailored but basically similar units.
14. As concern for environmental quality, quality assurance and personnel safety increase, the inhalation chamber systems have moved to improved double filtration systems of exhaust air, automated monitoring and control with data storage retrieval and alarms. The chambers are frequently housed inside of separate rooms or hood enclosures with air pressure relationships which provide a double safeguard of protection (the chamber having the lowest pressure, the enclosure the next lower pressure and the general room area the highest pressure). This provides for inward air flow into areas with greatest contamination. Some chambers are serviced by special mobile service modules that provide protection to the ambient air during servicing of the chamber.
15. There have been some measures taken to provide inhalation exposures by means other than a chamber. For primates and certain other larger animals, the animals wear special exposure helmets. This type of system is adequate for short-term exposures, but is not practical for long-term studies.
16. The current chamber designs accommodate the numbers and types of animals called for in standard protocols. The chambers used for regulatory testing compliance purposes must be able to handle the standard number of animals and have a sufficient number of chambers (one per dose and one for control).

Assumptions

1. The Army's AMTR facility will consider inhalation studies for both the standard industrial occupational exposures and special exposures encountered by soldiers during training and combat.
2. Inhalation studies will include acute, subchronic and chronic durations, the use of rodents and primates, and the full spectrum of toxicology outcomes.
3. In some cases the studies will be for submission to regulatory agencies. In other cases, the studies will be performed for non-regulatory Army requirements.

CONCLUSIONS

The survey performed of the Inhalation Toxicology Systems provided a comprehensive and detailed collection of information and data. It provides a data base, identifies sites that can be visited and manufacturers that can be contacted to assist in the development of the Army's AMTR facility system's specification package, the system design or system fabrication and installation.

APPENDIX 1

INHALATION CHAMBER INVENTORY FORM

Inhalation Chamber Code Number _____

Instructions for Inhalation Chamber Inventory

1. Name, address, phone number of organization contacted:

ph. () _____

2. Name of individual contacted and department:

3. Assign code number to the chamber which is to be discussed and complete appropriate columns. Number should be in sequence with previous contacts.

Model Name _____ Number _____

Model Type _____

4. Complete survey form through those categories which apply, e.g., if chamber only, fill out chamber characteristics section.
5. Ask for specifications sheet. If available, have it sent to:

Mr. Greg Schiefer
Life Systems, Inc
24755 Highpoint Road
Cleveland, OH 44122

INHALATION CHAMBER INVENTORY

Code for Differing Chamber Types

Chamber Characteristics

1. Package
 - Chamber unit only
 - Four or more additional equipment items required
 - Less than four additional equipment items required
 - Complete system with all required peripherals

2. Capacity (Volume, m³ or l)
 - Cubic Meters, m
 - Liters, l
 - Weight, kg

3. Size (Dimensions, m)
 - Length x Width x Height, m
 - Diameter x Height, m
 - Shape
 - Cylindro-conical
 - Cylindrical
 - Square
 - Rectangular
 - Hexagonal
 - Spherical

4. Animal Capacity (Approx. No. of)
 - Mouse
 - Rat
 - Guinea Pig
 - Hamster
 - Rabbit
 - Dog
 - Primate
 - Monkey
 - Baboon
 - Chimpanzee

5. Major Material of Construction
 - Stainless Steel/Glass
 - All Stainless Steel
 - All Glass
 - Aluminum
 - Plastic (e.g., Lucite)
 - Fiberglass

continued-

APPENDIX 2

RESULTS OF SURVEY INVENTORY

<u>TABLE</u>		<u>PAGE</u>
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TABLE A2-1

SOURCES OF INFORMATION

AMTR Facilities	Manufacturers					
	Charles Spengler and Associates	Hazelton Laboratories, Inc.	King-Lar Co.	Wahmann Manufacturing Co.	Young and Bertke Co.	The Upjohn Co. (a)
1. Army Environmental Hygiene Agency			X			
2. Battelle Columbus Laboratories	X					
3. Brookhaven National Laboratory	X					
4. Chemical Industry Institute of Toxicology	X	X				
5. Environmental Protection Agency, Center Hill Facility, Cincinnati					X	
6. Environmental Protection Agency, Research Triangle Park					X	
7. Hazelton Laboratories, Inc.	X					
8. IIT Research Institute	X					
9. Lovelace Inhalation Toxicology Research Institute	X					
10. Litton Bionetics, Division of Litton Corporation	X					
11. Monsanto Company		X	X			
12. National Institute of Environmental Health Sciences					X	
13. National Institute of Occupational Health and Safety, Cincinnati, Ohio	X				X	
14. Toxigenics, Inc.						
15. The Upjohn Company						X
16. University of California at Davis					X	

(a) Upjohn is attempting to secure a licensee for their system, they do not plan to be a manufacturer.

INHALATION CHAMBER CHARACTERISTICS(a)

Manufacturer/ Designer	Approx. Volume (m ³)	Dimensions (L x W x H cm, Diam x H cm)	Shape/Type	Animal Capacity No. Species	Major Materials of Construction	Operational Status	Delivery (mo.)(b)	Cost (\$000)	Special features (see list)
Charles Spengler and Associates	0.25	46 x 46 x 120	Square/Minners	24 mice	Stainless Steel/Glass	Operating	2-5	—	3,8
	0.50	62 x 52 x 130	Square/Minners	48 mice	Stainless Steel/Glass	Operating	2-5	—	3,8
	1	92 x 92 x 200	Square/Minners	96 mice	Stainless Steel/Glass	Operating	2-5	—	5,8
	1.5	—	Square/Minners	75 rats	Stainless Steel/Glass	Operating	6-8	—	6
	3.7	150 x 150 x 350	Square/Minners	200 rats	Stainless Steel/Glass	Operating	—	—	6,8
	6	180 x 180 x 350	Square/Minners	250 rats	Stainless Steel/Glass	Operating	6-8	10 ^(c)	6,8
	(d)	62 x 124	Hexagon/Nose Only	12 rodents	Stainless Steel	Operating	3	7.9	9
Hazelton Systems, Inc.	0.4	68 x 68 x 210	Square/Minners	40 rats	Stainless Steel/Lucite ^(e)	Operating	—	3 ^(f)	3,5
	0.6	82 x 82 x 210	Square/Minners	60 rats	Stainless Steel/Lucite	Operating	—	5 ^(f)	6
	1.0	92 x 92 x 210	Square/Rochesto-	90 rats	Stainless Steel/Glass	Operating	—	7 ^(f)	6
	1.5	91 x 180 x 210	Rectangle/Minners	120 rats	Stainless Steel/Lucite	Operating	—	7 ^(f)	6
	2.2	127 x 132 x 210	Square/Battelle ^(g)	170 rats	Stainless Steel/Glass	Operating ^(h)	1-2	9 ^(f)	1,3-8
	6.0	180 x 180 x 340	Square/Minners	240 rats	Stainless Steel/Lucite	Operating	—	10 ^(f)	2,8
	(d)	—	Nose Only	200 rats	Stainless Steel	Design Stage	—	3-5 ^(f)	—
King-Lar Co.	8	180 x 220 x 350	Nose Only	—	Stainless Steel	Design Stage	3-6	—	5,5
	16	250 x 280 x 350	Nose Only	400 rats	Stainless Steel	Design Stage	3-6	—	5,6
The Upjohn Co.	0.15	—	Cubical/Leong ⁽ⁱ⁾	—	—	Ready for Manufacturer ^(j)	—	—	1,3,7,10,11,12
	0.9	—	Cubical/Leong ⁽ⁱ⁾	—	—	Ready for Manufacturer ^(j)	—	—	1,3,7,10,11,12
	6	—	Cubical/Leong ⁽ⁱ⁾	—	—	Ready for Manufacturer ^(j)	—	—	1,3,7,10,11,12
Wannam Mfg. Co.	0.2	—	Square/Minners	—	Stainless Steel/Glass	Operating	6	—	5
	1	—	Square/Minners	—	Stainless Steel/Glass	Operating	6	—	5
	2.5	110 x 120 x 250	Square/Minners	60 rats	Stainless Steel/Glass	Operating	6	—	5
	8	220 x 180 x 340	Rectangle/Minners	200 rats	Stainless Steel/Glass	Operating	6	—	2,5,6
Young and Bertke Co.	0.33	70 x 70 x 200	Square/Minners	30 rats	Stainless Steel/Glass	Operating	3-6	1,6 ^(f)	3,5
	1.3	90 x 90 x 300	Square/Minners	108 rats	Stainless Steel/Glass	Operating	3-6	2,0 ^(f)	5
	2.9	140 x 140 x 330	Square/Minners	144 rats	Stainless Steel/Glass	Operating	3-6	3,6	5
	3.3	150 x 150 x 340	Square/Minners	15 monkeys	Stainless Steel/Glass	Operating	3-6	4,4 ^(f)	5,6

(a) Blank spaces in table indicate information not collected.

(b) Does not include any time for special design.

(c) For chamber with special features 1, 2, 6 and 8.

(d) Nose-only exposure

(e) Heat transfer problems and solvents might react with lucite.

(f) Approximate price, not a quoted or catalog price.

(g) Hazelton 100 design by Dr. Owen Moss at Battelle Northwest.

(h) Some concern about getting homogenous particle distribution within chambers.

(i) Chambers designed by Dr. Basil Leong at Upjohn.

(j) No manufacturer at this time.

SPECIAL FEATURES LIST

1. Designed to run with animal waste catch pans in place during exposures.
2. Cage racks can be rolled into and out of chambers.
3. Designed to be movable. These are either self-contained units or have quick disconnects.
4. Designed to be cleaned in tunnel type rack washer.
5. Have internal spray rings for cleaning and flushing.
6. Available as knockdown units for construction in selected location.
7. Designed to fit into rooms with ceiling heights of 10 feet.
8. Available as a complete system with air handling and filtration (input and exhaust)(does not include monitoring equipment).
9. Modular construction.
10. Transfer of animals to temporary housing unit without exposing handlers to test agent.
11. Atmosphere generating equipment contained inside chamber.
12. Built-in exhaust air handling system.

TABLE A2-3

INHALATION CHAMBER OPERATING PROCEDURES

Parameter	Facilities Providing Information(a)															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Temperature °C (range)	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22
Relative Humidity % (range)	50 (45-55)	50 (40-70)	50 (40-65)	50 (40-65)	50 (40-65)	50 (30-70)	50 (60-70)	50 (60-70)	50 (60-70)	50 (60-70)	50 (60-70)	50 (60-70)	50 (20-80)	50 (20-80)	50 (20-80)	50 (20-80)
Pressure cm H ₂ O (range)	-1	-2.5	0.25-0.5	-1	-0.5	-0.5	-1.2 (-1to-2.5)	-1.2 (-1to-2.5)	-1	-1	-1	0.5 (0.5to 1)	2.5	2.5	2.5	0.5 (0.25to 1)
Light Intensity (ft candles)			Optimal for species													(100)
Internal lighting	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
Air changeshr.	-	15-20	12-18	15	5-60	15	20	15	15	10-15	10-15	17	17	17	10-15	10-15
Computer monitoring	Yes	Yes	No	-	-	Yes	No	No	No	Yes	No	No	No	Yes	No	No
Computer feedback control	Yes	Yes	No	-	-	No	No	No	No	Yes	No	Yes	No	Yes	No	No
Cleaning Time (min)	15	15-30	10-15	Hose	-	-	5	15	15	-	-	10-15	10-15	10-15	15	15
Equipment	Hose	Pruss hot water Solvent	Hose	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Pruss hot water
Connections	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water	Water
Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain	Drain
Prepared	Prepared	Prepared	Prepared	Room air	Room air	Room air	Room air	Room air and prepared	Room air	Room air	Room air	Room air	Room air	Room air	Room air	Room air
Type filters	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	HEPA
Exhaust air Separate system for each chamber	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	Charcoal	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA	HEPA
Type filters	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
Personnel required to operate (b) No. chambers and scrubber	2/4	2/8	2/8	2/8	2/8	2/8	2/8	2/8	2/8	2/4	2/4	4/8	2/4	2/4	2/4	3/10
Personnel required to operate (b) No. chambers and scrubber	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6	3/6

(a) See Sources of Information Table for names of facilities
(b) Supervisory and maintenance personnel not included

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