U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
DIVISION OF RESPIRATORY DISEASE STUDIES
MORGANTOWN, WEST VIRGINIA 26505

HEALTH HAZARD EVALUATION
HHE 80-134-986

PENNEX PHARMACEUTICALS
VERONA, PENNSYLVANIA

I. Summary

On June 24, 1980, the National Institute for Occupational Safety and Health (NIOSH)* received a request to evaluate the possible health effects of airborne talc dust to workers in the baby powder line (line #26) at Pennex Pharmaceuticals, Verona, Pennsylvania.

To evaluate the dust levels, industrial hygiene samples were collected in the mixing room and the baby powder line.

Personal and area samples were collected as well as bulk samples from the raw and finished products. The bulk samples were analyzed for asbestos and free silica content.

Medical evaluation was made via a telephone questionnaire.

Talc analysis of the raw and finished products revealed that it was non-asbestiform, contained no cristobalite or tridymite and that it contained less than one per cent quartz (crystalline silica). However, 60% of the respirable samples collected as personal and area samples exceeded the recognized Federal standard of 5 mg/m^3 for nuisance particulates with 80% of the samples exceeding the ACGIH standard recognized for respirable talc dust containing no fibers. See Table I.

*Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6), authorizes the Secretary of Health and Human Services, following a written request by an employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

II. INTRODUCTION

On June 24, 1980, a request was received by NIOSH in Morgantown, West Virginia to conduct a health hazard evaluation of the Pennex Pharmaceutical Plant in Verona, Pennsylvania. The request was made by one of three employees who work on the baby powder line, hereafter called line #26.

Employee concerns centered on excessive dust levels in the work environment and their possible adverse health effects. The initial walk through of the facility was conducted on September 18, 1980 with unannounced comprehensive surveys being conducted October 30, 1980 and February 23, 1981.

III. BACKGROUND

Pennex Pharmaceuticals is a family owned business employing in excess of 350 people and producing over 400 different products which are sold over the counter. Some examples of their products are: aspirin, cough medicine, saccharin, sleeping pills and baby powder. Pennex is a private label company that designs its own labels for the many chain stores which it supplies.

At Pennex, line #26 bottles perfumed baby powder and employs three people per each 8 hour shift. A total of 10 employees work in this production area.

One employee places empty plastic bottles on a conveyor system which moves under an overhead stainless steel hopper that meters out approximately 14 ounces (397 grams) of baby powder. Once filled, the bottles move to a Resina rotary bottle capping machine and then to a rotary table where the lot number is manually placed on the base of the bottles, which are then placed in a cardboard container for shipment. See Figure II.

The cosmetic talcum powder is initially prepared in a "mixing area". This area is in close physical proximity to "line #26" and was thus considered as part of the initial request for complete environmental evaluation.

The Pennex Pharmaceutical Company purchases its raw talc material from Whittaker, Clark and Daniels, Inc. of South Plainfield, NJ with the following requirements:

1) be free of gram negative bacteria

2) have a combined bacterial count of less than 500 micro-organisms per gram

3) silicon dioxide 57-61%

4) calcium oxide 0.7-1.5%

5) aluminum oxide 5-7.5%

6) magnesium oxide 29-32%

7) ferric oxide 0.3-.6%

8) moisture (less than) 0.6%

IV. METHODS AND MATERIALS

To ascertain the levels of free silica and respirable dust that was present in the mixing room and line #26 on October 30, 1980, air was drawn through a personal dust cyclone pre-selector and a 37mm filter cassette containing a pre-weighed 5 micrometer pore size FWSB filter. This was connected to a personal sampling pump calibrated at 1.7 liters per minute. This procedure was also used for several general area samples that were collected.

The silica samples were analyzed for the silica polymorphs (quartz, cristobalite and tridymite) by X-Ray Diffraction (XRD). The Physical and Chemical Analytical Method (P&CAM) #259 as described in NIOSH's "Manual of Analytical Methods" was the method used for silica analysis. A portion from each sample was ultrasonically wet sieved in isopropanol using a 10 micrometer pore size sieve. The fraction that passed through the sieve was collected, dried and used for quantitative analysis. From each sieved sample, two (2) milligram aliquots were weighed in triplicate, ultrasonically dispersed in isopropanol and deposited on 0.5 micrometer pore size silver membrane filters. Each filter was mounted on an XRD holder and was analyzed quantitatively for the quartz peaks.

The respirable dust samples collected used the same sampling train set up as mentioned above and at the same flow rate. The particulate material that was collected on the filter was post weighed to obtain the net weight. These levels are found in Table I. Two bulk samples, one of raw talc from Lot #17550 and one of the finished product (I23C), were submitted for asbestos determination by phase contrast microscopy and transmission electron microscopy.

Medical evaluation consisted of a telephone questionnaire of seven out of ten current employees in the filling and packing assembly line. A brief occupational history and respiratory questionnaire was also obtained.

V. EVALUATION CRITERIA

Evaluation criteria are obtained from various sources: Current American Conference of Governmental Industrial Hygienists Threshold Limit Values (ACGIH 1980 TLV), Code of Federal Regulations (Part 1910.1000, Title 29) and the National Institute for Occupational Safety and Health (NIOSH) Recommendations on Occupational Health Standards, 1978.

Permissible Standard*

Substance	OSHA	NIOSH	ACGIH
Asbestos	2 fibers/cc > 5um/cc	0.1 fiber/cc > 5um/cc	0.5 fiber/cc > 5um/cc
Respirable Free Silica	$\frac{10mg/m^3}{\%SIO_2+2}$	$.05mg/m^3$	$\frac{10mg/m^3}{\%SIO_2+2}$
Respirable Talc Dust	$5mg/m^3$	---	**$2mg/m^3$ < 1% silica

*Note: Standard not to be exceeded in any 8-hour shift of a 40-hour work week.
**Note: 1980 ACGIH TLV's ® Notice of Intended Changes

Common cosmetic grade talc ranges in particle size from 0.3-50um in size with only a minor fraction of this, by weight, consisting of particles considered to be of respirable size. Although industrial grade talcs may contain significant concentrations of asbestos or free crystalline silica, the major cosmetic manufacturers in the United States, as represented by the Toilet Preparations Federation and the Cosmetic, Toiletry and Fragrance Association have established more strict specifications for cosmetic grade talc which helps ensure the absence of asbestos.

The normal consumer use of cosmetic talc has not been associated with any measurable loss of lung function or with any increased incidence of lung cancer.(9)

VI. RESULTS

A. Environmental

Two bulk samples of talc powder collected on October 30, 1980 and again on February 23, 1981 as a follow up revealed that there was no asbestos or crystalline silica polymorphs in the raw or finished product. However, the respirable dust samples collected from Workers A and B on October 30, 1980 exceeded the OSHA and ACGIH standard for respirable nuisance dust containing no fibers. On the follow up sampling conducted on February 23, 1981, Worker A did not exceed the OSHA standard, but did exceed the ACGIH standard, while Worker B exceeded both standards again.

B. Medical

A total of seven out of ten workers employed on the filling and packing assembly line were given a telephone interview. Exposure history for current workers interviewed ranged from 2 months to 5 years. Four out of seven workers felt that their work environment was not dusty. They denied any respiratory effects including cough, phlegm production, wheezing, shortness of breath or nasal symptoms.

Three out of seven workers interviewed felt that there were significant dust concentrations in their work environment. One worker experienced mild pruritis in the neck and face during intermittent dust exposure. One worker described symptoms of a "dry throat" after exposure to airborne talc dust, although this worker denied cough and sputum production. One worker experienced a non-productive cough after the work shift, accompanied by nasal congestion. These symptoms subsided completely one to two hours after leaving the work environment.

VIII. DISCUSSION AND CONCLUSIONS

Several unannounced visits were made to Pennex Pharmaceuticals in order to monitor line #26 and determine the dust levels, but on each occasion line #26 was not working and air samples could not be obtained. However, with each unannounced visit, the mixing room was monitored to obtain personal and area respirable samples.

On the October 30 visit, both mixers in the mixing room were exposed to high levels of talc dust as a result of breaking open 50 pound bags of talc and pouring these into the large 6000 pound mixer. Once the mixer has been filled with certain proportions of talc and a perfumed master blend, the mixer then runs for a set period of time. The mixed ingredients are then emptied into what is called a "tote". This tote is a stainless steel container with a 3000 pound capacity. When full, it is transferred by a fork lift to line #26 where it is set up to feed by a screw conveyor to a Mateer-Burt dispenser that in turn deposits 14 ounces of baby powder into a plastic bottle moving on a conveyor system below. See Figure II.

The two processes in the mixing room in which dust is generated are the (1) breaking open of 50 pound bags of talc which are spread across a grid (36"x36") that is located over the mixer door and (2) filling either the totes or 55 gallon drums. The only control we noted on our visit was personal protection and this was inadequate for the following reasons:

a) improper respirator cartridges were being used (organic vapor cartridge R51 was used for talc dust),

b) lack of written procedures governing the selection, use and maintenance of respirators,

c) lack of training and fit testing for employees,

d) respirators were stored on tables and hooks in the work area and had not been cleaned from the previous days use,

e) respirators were being used by more than one person and were not disinfected,

f) the respirators being used (AO R6000) had gaskets missing on the inlet and outlet areas.

g) of the two strap disposable masks that were also used, one strap would either be broken or un-used. This prevents the mask from providing a proper seal around the nose and mouth.

At the end of the shift, the NIOSH investigator mentioned to the workers in the mixing room, the union safety director and the plant manager that the respirators were not being used properly. I was informed by the plant manager that the situation would be corrected. It was on this visit that I was asked to return in January of 1981 to evaluate a new local exhaust ventilation system that would be installed.

On February 23, 1981, a NIOSH team again made an unannounced visit and again was not able to monitor line #26. Personal samples were again taken in the mixing room, this time with a working local exhaust system. See Table II for the environmental results.

The new local exhaust system is set up to exhaust across the mixer door away from the workers breathing zone. Branch take-offs from the main duct are used to exhaust talc dust from the totes or 55 gallon drums when being filled. The hood type used with this system are plain openings. See Figure III.

The average face velocity of the hood which is 20 inches from the mixer door measured 215 feet per minute with the dimensions of 24"x44", which indicates that the exhaust system was not working effectively. Worker B continued to have an exposure to dust levels exceeding the current federal standard. From the observations made by the NIOSH team the reasons for exposures are two fold: first, work practices of the mixers enhance their exposures, and second, the hood capture velocity is too low. Capture velocity is the velocity at <u>any</u> point in front of the hood necessary to overcome opposing air currents and capture the contaminant. Based on the face velocity of the hood, two feet from the duct, the capture velocity is estimated to be only 21.5 feet per minute (fpm). The Industrial Ventilation[1] manual recommends that the capture velocity should be between 100-200 feet per minute for this type of operation. To have this capture velocity, the hood face velocity must be 1000-2000 feet per minute. This is five times more than what is presently being exhausted. Thus, the talc dust is not being exhausted across the length of the grid on the mixer door resulting in continued worker exposure.

Recommendations in Section VIII will address the altering of the present ventilation system in order to obviate the need for personal respiratory protection.

Until such time as the ventilation system is modified, respirator usage should be continued.

VIII. RECOMMENDATIONS

A. Baby Powder Line (line #26)

On the three visits, this operation appeared to produce minimal chances for exposure because its mainly an enclosed system. No recommendations are warranted.

B. Mixing Room

1) Respiratory Protection - a respiratory protection program meeting the requirements of Title 29-1910.134 of the Code of Federal Regulations should be established and enforced.

While this program is not meant to replace engineering controls, it should be established for the plant where respirators are currently in use. A respiratory protection program will alleviate all of those discrepancies noted in the discussion section which deal with improper respirator utilization. Please see the enclosed xeroxed articles on employer-employee respiratory protection and the CFR 1910.134.

2) Ventilation System - after the October 30 visit to Pennex, a local exhaust system was designed by the NIOSH investigator that would take care of the talc dust being generated. The ventilation system installed by Clean Air Systems of Gibsonia, Pennsylvania was close to the one proposed in the original NIOSH design before Clean Air installed the system. See Figure I.

On the February visit after the new system was installed, the air flow was measured and found to not be exhausting adequately. This conclusion was based on measurements taken with a Thermoanemometer air meter and the personal sampling results.

In order to create a capture velocity capable of removing the contaminant at the source, the far side of which, is approximately 3 feet from the hood, two recommendations will be presented which may be used to modify the present system.

The first is the simplest, most effective and least costly and should eliminate the need for respiratory protection at the mixer. See Figure IV. The dotted lines indicate the suggested modification.

The second modification will also be effective, but requires major changes. These are:

a) reduce the hood width dimension from 24 inches down to 4 inches,

b) provide a flange to the perimeter of the hood to eliminate air flow from ineffective areas around the hood where no contaminant exists,

c) increase the air flow in the system to provide a duct velocity of 3100-3500 fpm.

d) The present fan capacity may be inadequate to increase the system flow through RPM alteration, thus necessitating the selection of a new fan/motor.

e) once a-d have been initiated, there should be a capture velocity of 100 fpm 3 feet from the hood. This, of course, is on the low side of the recommended range, but should eliminate employee exposure and their need to wear respirators, provided there are no strong side drafts.

f) on the lower side of the mixer, when filling the 55 gallon drums or the totes, either system as shown in Appendix A print no. VS-303 should be utilized.

g) an alternative to (f) above would be to have the Pennex maintenance department or Clean Air Systems fabricate a spout that would fit the tote opening better. The reason for this is that the present male-female connection between the mixer and totes does not fit and allows for talc "splash backs".

h) the "DustKop", see Appendix C, is a fabric type collector. The company, Clean Air Systems, has advised that this collector be shaken at the end of the shift. However, it should be noted that as dust on fabric collectors builds up, the resistance to air flow increases, decreasing the quantity of air flowing through the system with a subsequent loss of dust collection efficiency. If continuous cleaning is not possible, pressure drop should be monitored with a water gauge. The cleaning mode should be initiated when the pressure drop indicates a decrease in system flow of approximately 20%.

i) for additional construction specifications that may be considered, see the rest of Appendix B.

IX. ACKNOWLEDGEMENTS

Report prepared by:

Rick Ferguson
Industrial Hygienist
Environmental Investigations Branch
Morgantown, West Virginia

Originating Office:

Alan Engelberg, M. D.
Coordinator
Mining Health Hazard Evaluations
Morgantown, West Virginia

Environmental Evaluation:	Rick Ferguson Industrial Hygienist Environmental Investigations Branch Morgantown, West Virginia
Analytical Laboratory Service:	John Palassis, Marilyn Hawkins Chemists Division of Physical Sciences and Engineering Cincinnati, Ohio
	Joe Burkhart Industrial Hygienist Environmental Investigations Branch Morgantown, West Virginia
Report Typed By:	Patty Tiberio Secretary Environmental Investigations Branch Morgantown, West Virginia

X. REFERENCES

1. Industrial Ventilation, A Manual of Recommended Practice, 15th Edition, 1978, by the American Conference of Governmental Industrial Hygienists.

2. Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment, 1980, by the American Conference of Governmental Industrial Hygienists.

3. Code of Federal Regulations, Title 29, Part 1910.1000, November 7, 1978.

4. NIOSH Recommendations for Occupational Health Standards, October, 1978.

5. NIOSH Criteria for a Recommended Standard -- Occupational exposure to Crystalline Silica, HEW Publication No. (NIOSH) 75-120. 1974.

6. NIOSH Criteria for a Recommended Standard -- Revised Recommended Asbestos Standard. HEW Publication No. (NIOSH) 77-169. December 1976.

7. The Industrial Environment - its Evaluation and Control, USDHEW, PHS, NIOSH, 1973.

8. P&CAM Method No. 259. Free Silica in Airborne Dust. NIOSH Manual of Analytical Methods, Vol. 1, DHEW Publication No. (NIOSH) 77-157-A. 1977.

9. The Lancet, editorial, June 25, 1977, pages 1348-49.

TABLE I

PENNEX PHARMACEUTICALS

RESPIRABLE DUST SAMPLES

Date/Shift	Location	Sample Number	Sample Time (mins)	Total (Liters) Volume	Final Weight (mg.)	TWA mg/m^3
10/30/80 - Day	Worker A	234 Personal	427	726	1340	1845
10/30/80 - Day	Worker B	Personal 163	435	740	16.38	22.13
10/30/80 - Day	Column to right of mixer	Area 180	425	723	2.46	3.40
10/30/80 - Day	Railing at top of stairs	246 Area	425	723	3.94	5.45
10/30/80 - Day	Baby Powder Line	Area 166	375	638	.09	.14

Evaluation Criteria: Threshold Limit Value (TLV) ® for talc dusts (containing no fibers) at which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effects is 2 mg/m^3.

TABLE II

PENNEX PHARMACEUTICALS

RESPIRABLE DUST SAMPLES

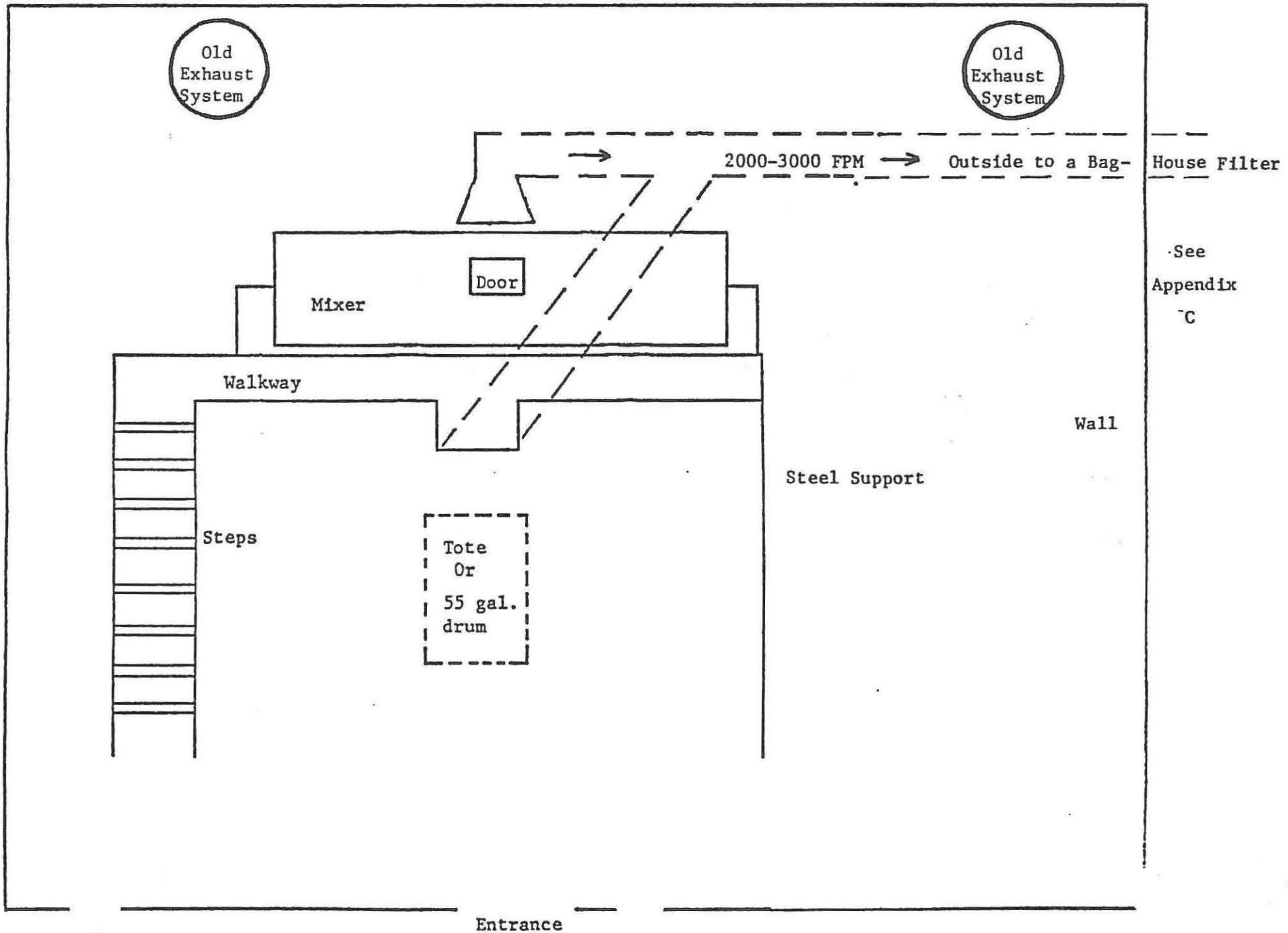
Date/Shift	Location	Sample Number	Sample Time (mins)	Total (Liters) Volume	Final Weight (mg.)	TWA mg/m^3
2/23/81 - Day	Worker A	1419	455	773.5	1.68	2.18
2/23/81 - Day	Worker B	1422	447	759.9	30.83	40.57

Evaluation Criteria: Threshold Limit Value (TLV) ® for talc dusts (containing no fibers) at which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effects is 2 mg/m^3.

FIGURE I

Pennex Pharmaceuticals

Proposed Ventilation System



_FIGURE__II_

Pennex Pharmaceuticals

Baby Powder Line

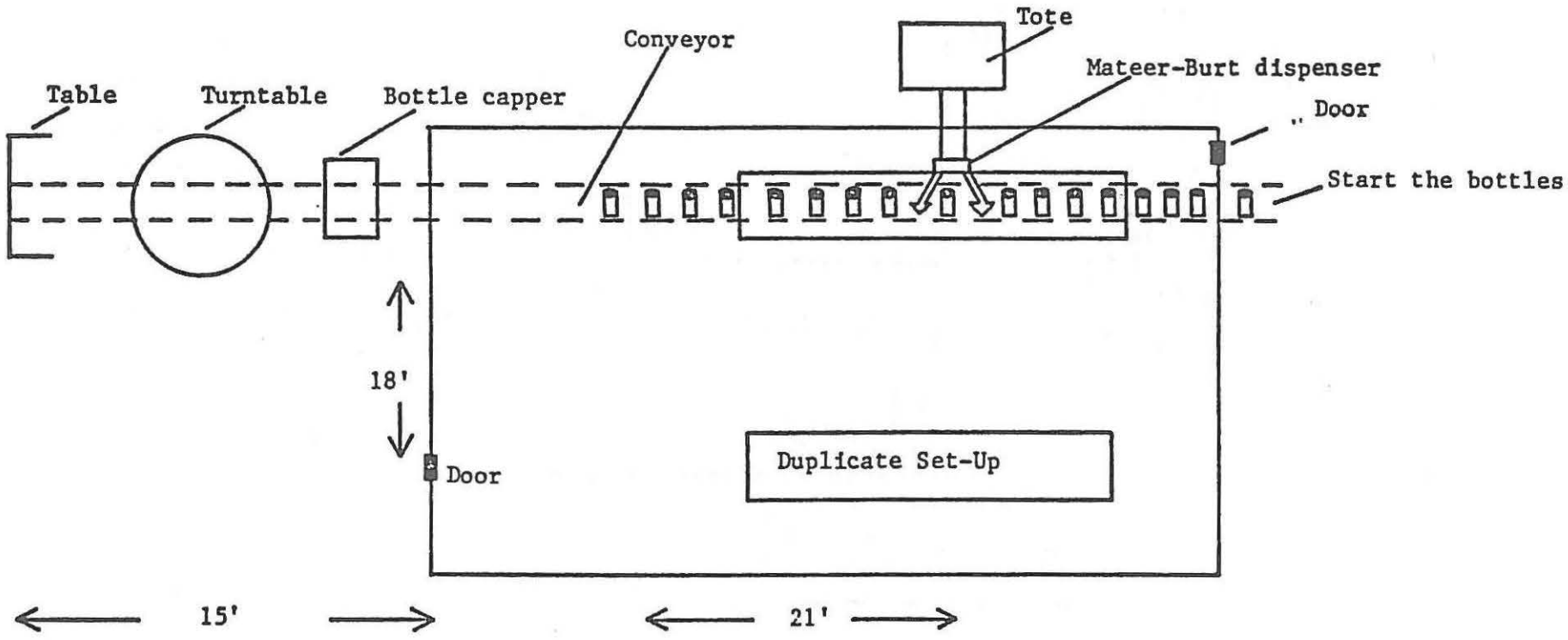


FIGURE III

Pennex Pharmaceuticals

Existing Ventilation System

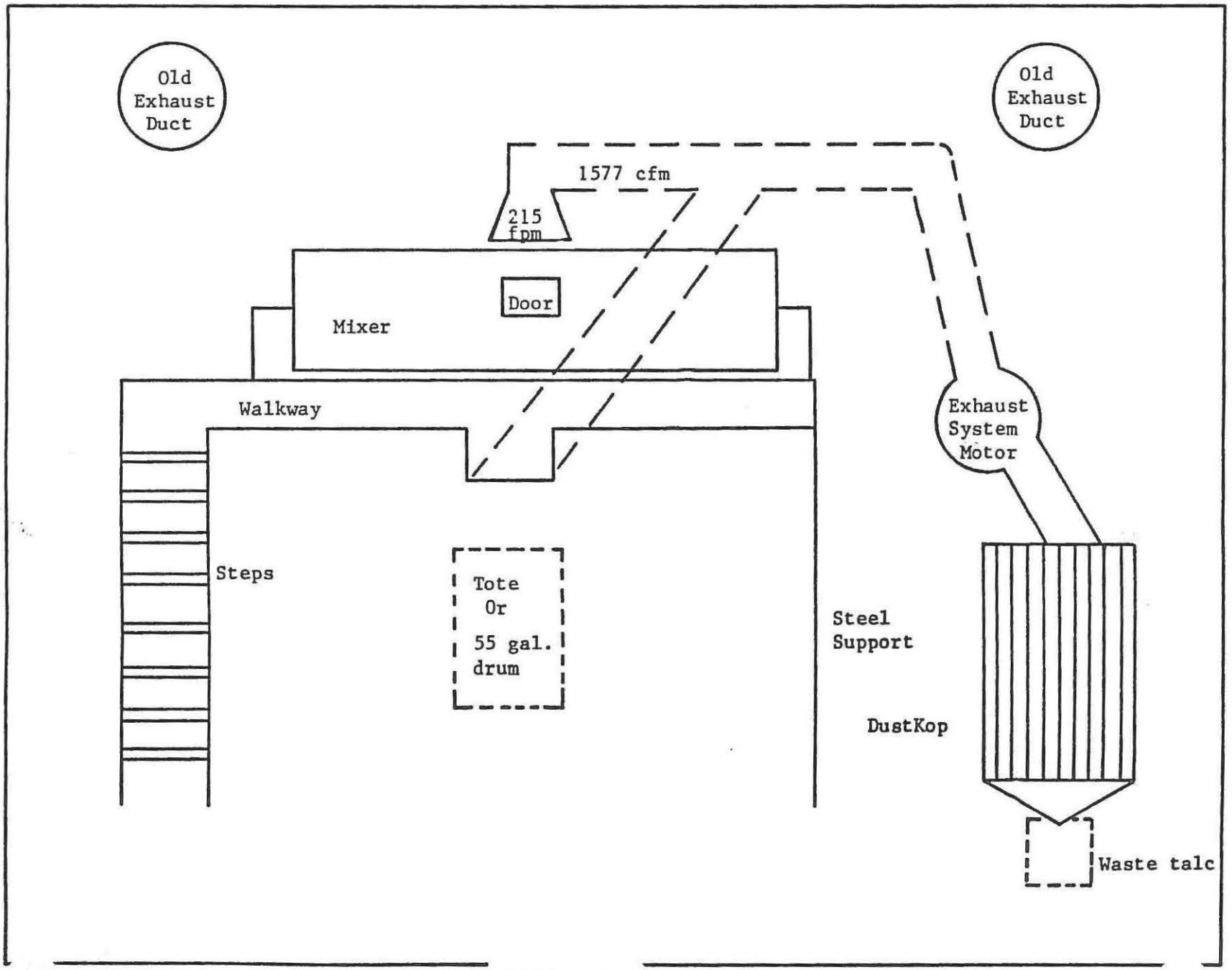
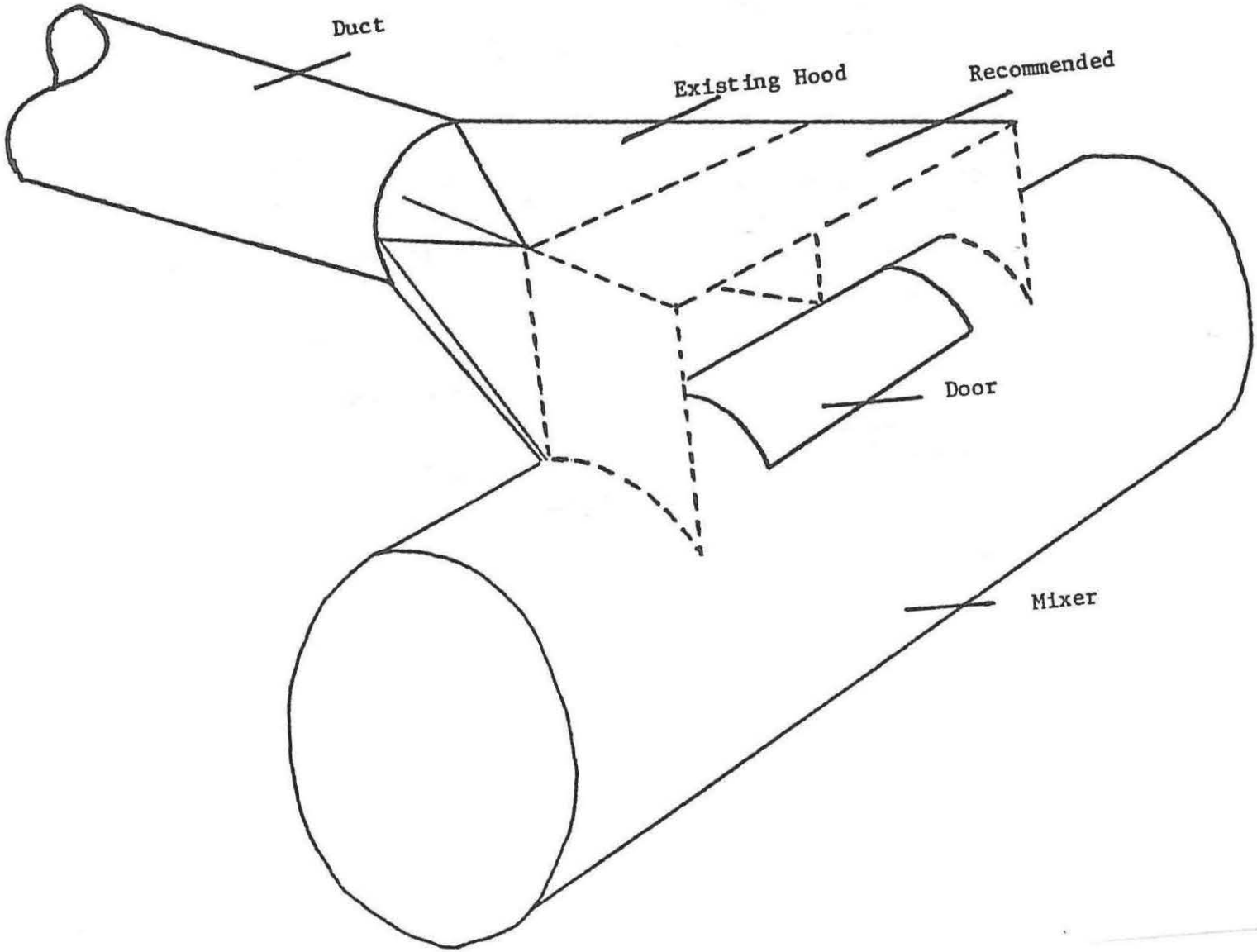


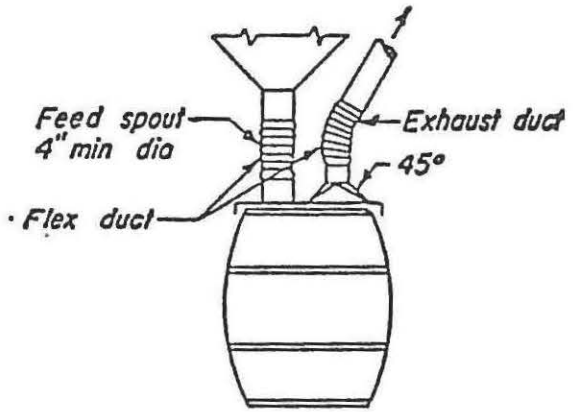
FIGURE IV

Pennex Pharmaceutical

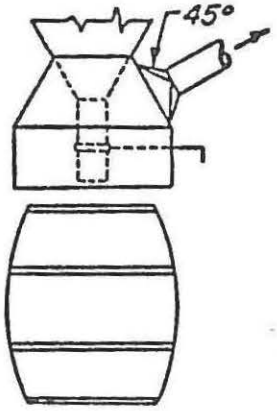


APPENDIX A

PENNEX PHARMACEUTICALS



Q = 50 cfm x drum dia (ft) for weighted lid
150 cfm x drum dia (ft) for loose lid
Duct velocity = 3500 fpm minimum
Entry loss = 0.25 VP



Q = 300-400 cfm
Duct velocity = 3500 fpm min
Entry loss = 0.25 VP

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BARREL FILLING	
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APPENDIX B

PENNEX PHARMACEUTICALS

CONSTRUCTION SPECIFICATIONS FOR LOCAL EXHAUST SYSTEMS

Correct design and competent installation of sheet steel ducts and hoods are necessary for the proper functioning of any exhaust system. The following minimum specifications are recommende

General

All exhaust systems shall be constructed with the materials recommended herewith and shall be installed in a permanent and workmanlike manner. Interior of all ducts shall be smooth and free from obstructions with joints either welded or soldered air-tight.

Materials

1. Ducts shall be constructed of black iron welded or of galvanized sheet steel riveted and soldered unless the presence of corrosive gases, vapors and mists, or other conditions makes such material impractical. Galvanized construction is not recommended for temperatures exceeding 400 F. Welding of black iron lighter than 18 gauge is not recommended.

2. For average exhaust systems on non-corrosive applications, the following metal thicknesses shall be supplied:

Diameter of Straight Ducts	MINIMUM* U. S. Standard Gauge for Steel Duct		
	Class I	Class II	Class III
to 8"	24	22	20
Over 8" to 18"	22	20	18
Over 18" to 30"	20	18	16
Over 30"	18	16	14

Class I. Includes non-abrasive applications such as paint spray, woodworking, pharmaceutical and food products; discharge ducts from dust collectors.

Class II. Includes non-abrasive material in high concentration (low pressure pneumatic conveying); moderately abrasive material; and highly abrasive materials in light concentrations. Typical examples are conveying of chemicals and wood dust; exhaust of grain dusts; buffing and polishing.

Class III. Includes all highly abrasive materials in moderate to heavy concentrations and moderately abrasive materials in heavy concentrations such as low pressure conveying of tobacco; exhaust systems from sand and grit blasting, abrasive cleaning operation, rock and ore screening, crushing, dryers and kilns; fly ash from boiler stacks; foundry shakeouts and sand handling systems; coal crushing and screening; and grinding.

Brown and Sharpe gauge numbers have been used to indicate thickness of aluminum sheet as compared with U. S. Standard gauges for steel sheet. Where aluminum duct is indicated, the following equivalent B & S gauges should be used:

Steel - U. S. Standard Gauge	26	24	22	20	18	16	14
Aluminum - B & S Gauge	24	22	20	18	16	14	12

3. For exhaust systems on corrosive applications, consideration should be given to non-corrosive materials or coatings.

4. Elbows and angles shall be a minimum of two gauges heavier than straight lengths of equal diameter.

5. Hoods shall be a minimum of two gauges heavier than straight section of connecting branches.

6. Where flexible piping is necessary, a non-collapsible type of flexible piping shall be used and it shall be kept at a minimum.

*Except in certain heavy industries such as high production grey iron foundries and steel mills has lead to adoption of heavier gauges. A typical specification:

Diameter of Pipe	Gauge No.
Up to 18"	16
Over 18" to 30"	14
Over 30"	12

Construction

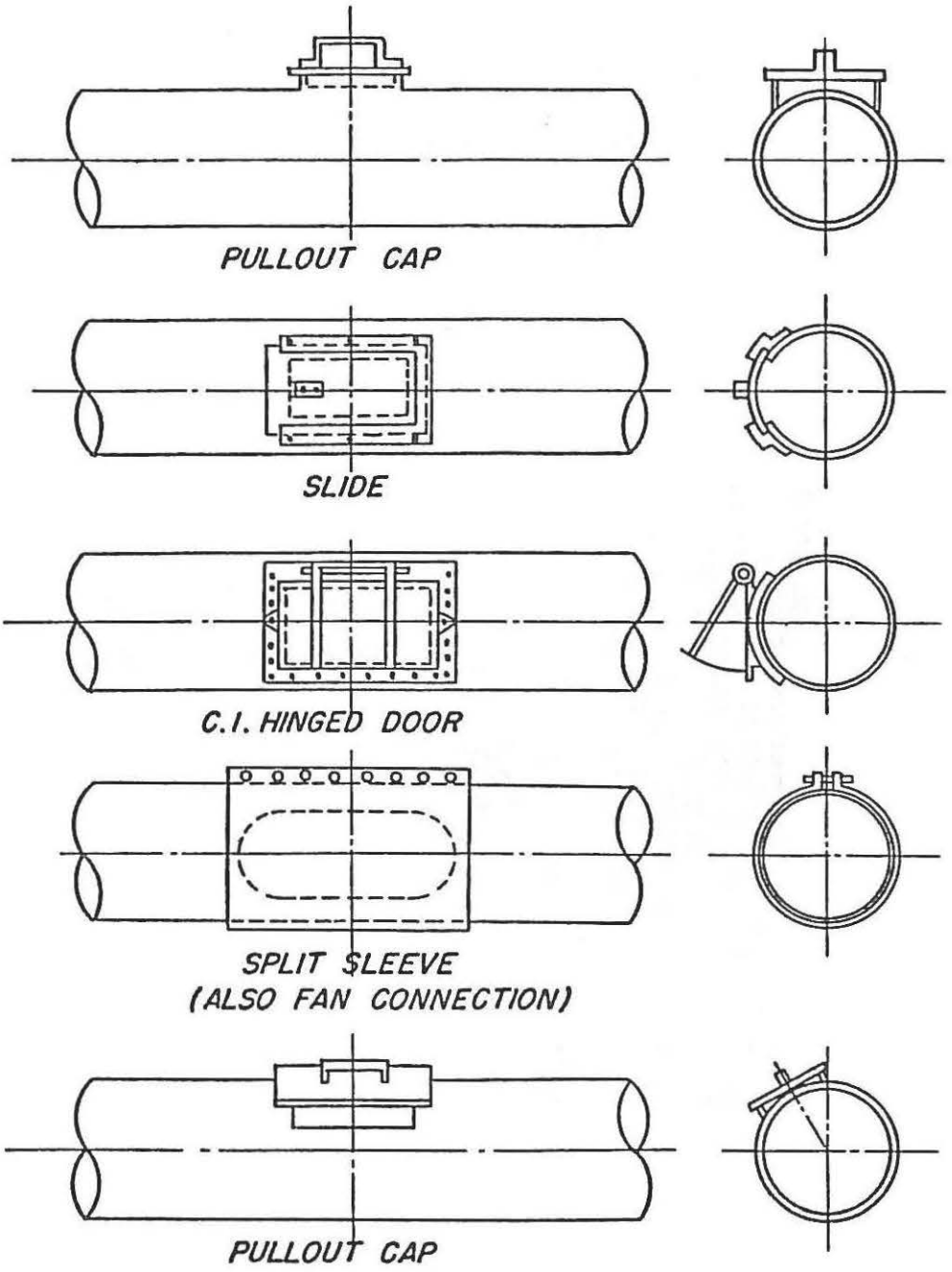
1. Longitudinal joints of ducts shall be lapped and riveted or spot welded on 3" centers maximum. Double-lock seams may be used on Class I application only.
2. Girth joints of duct shall be made with inner lap in direction of air flow, with 1" lap, diameters to 19", and 1-1/4" laps for diameters over 19".
3. Elbows and angles shall have a centerline radius of two pipe diameters whenever possible. Large radii are recommended for heavy concentrations of highly abrasive dusts. Construct elbows 6" or less in diameter of at least five sections, over 6" diameter of seven sections. Prefabricated elbows of smooth construction may be used. Angles pieced proportionately.
4. Hoods must be free of sharp edges or burrs and reinforced to provide necessary stiffness.
5. Use straight-through weather caps unless otherwise specified.

System Details

1. Connect duct to fan inlet with split sleeve drawband at least one pipe diameter long, but not less than 12".
2. Transitions in mains and sub-mains to be tapered; taper 5" long for each 1" change in diameter when possible.
3. All branches shall enter main at the large end of transition at an angle not to exceed 45°; 30° is preferred. Connect branches only to top or sides of main with no two branches entering diametrically opposite.
4. Provide dead-end caps within 6" from last branch of all mains and sub-mains.
5. Provide access openings or cleanouts every 10' and near each elbow, angle or duct junction in horizontal sections, except for non-corrosive gases and vapors containing no particulate matter.
6. Support ducts sufficiently to place no load on connecting equipment and to carry weight of system if plugged with material. Maximum supporting interval 12' for 8" or smaller ducts, 20' interval for larger ducts.
7. Provide 6" minimum clearance between ducts and ceiling, wall or floors.
8. Where blast gates are used for adjustment of system, place near connection of branch to main. Provide means of locking after adjustments have been made. Butterfly-type dampers shall not be permitted.
9. Fire dampers, explosion vents, etc., should be installed in accordance with National Fire Protection Association Codes or local fire ordinances.
10. Rectangular ducts can be used only when clearance prevents the use of round ducts. Rectangular ducts must be made as nearly square as possible. Weight of metal, lap and other construction details are to be equal to round duct construction whose diameter equals the longest side.
11. Support fans and motors on common vibration absorbing mounting.
12. Exhaust fans installed in a hazardous area shall be spark-resistant and shall have non-ferrous blade or wheel and a non-ferrous ring about the opening through which shaft passes. Provide electrical grounding for all fan parts.
13. Where state or local laws conflict with above specifications, the more stringent regulation shall be followed, Any other deviation must be approved before installation.

Testing

Measure the air flow in the system with a standard pitot tube to determine whether it is functioning in accordance with design specifications. See Section 9.



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CLEANOUT OPENINGS

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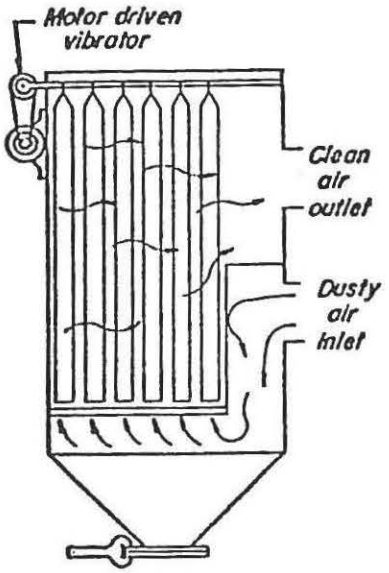
APPENDIX C

PENNEX PHARMACEUTICALS

"Dustkop"



CLOTH TUBE OR STOCKING TYPE

This Fabric Collector or Baghouse as is sometimes called is similar to the one at Pennex Pharmaceutical.

AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS	
FABRIC COLLECTORS	
DATE 1-68	Fig. II-5