

SURVEY REPORT
CONTROL TECHNOLOGY FOR MANUAL
POWDER WEIGH-OUT OPERATIONS

at

Merck & Company
Wilson, North Carolina

REPORT WRITTEN BY
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REPORT DATE
December 5, 1994

REPORT NO
ECTB 197-13a

U S Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
4676 Columbia Parkway - R5
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PLANT SURVEYED	Merck & Company 4633 Merck Road Wilson, North Carolina 27893
SIC CODE	2834
SURVEY DATE	June 7-8, 1994
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Summary

A commercially available booth for manually weighing out powdered materials was evaluated. In this operation, the worker used scoops to transfer material from drums, which ranged in height from 24 to 33 inches, to 17-inch high drums. All drums were lined with large plastic bags. A fan drew air through exhaust grates along the booth's back wall and then through filters. About two-thirds of this air was recycled through high efficiency particulate filters located in the ceiling of the booth. Thus, the ceiling of the booth served as an air shower. Flow visualization conducted with dry ice indicated an absence of eddies that could force contaminated air to flow into the worker's breathing zone. Aerosol instrumentation was used to identify activities that caused dust exposure. The worker's dust exposure was monitored with an aerosol photometer and an optical particle counter and the worker's activities were concurrently recorded on videotape. Dust exposure appeared to increase when the worker opened and closed the drum's plastic liner. In addition, dust exposure increased when the worker reached too far into the drum containing the powder.

INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) is the primary federal organization engaged in occupational safety and health research. Located in the Department of Health and Human Services, it was established by the Occupational Safety and Health Act of 1970. This legislation mandated NIOSH to conduct many research and education programs separate from the standard setting and enforcement functions conducted by the Occupational Safety and Health Administration (OSHA) in the Department of Labor. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards. The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering has been given the lead within NIOSH to study the engineering aspects of health hazards prevention and control.

Since 1976, ECTB has conducted several assessments of health hazard control technology based on industry, common industrial process, or specific control techniques. The objective of each of these studies has been to document and evaluate effective techniques for the control of potential health hazards in the industry or process of interest, and to create an awareness of the need for, or availability of, effective hazard control measures.

A study of manual dye weigh-out operations is being undertaken by ECTB to provide control technology information for the prevention of occupational disease in the textile industry. ECTB has been working on this project with the U.S. Operating Committee of the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD). ETAD is an international organization comprising representatives from various dye manufacturing companies. ETAD organized a steering committee that included members from ETAD, NIOSH, the U.S. Environmental Protection Agency (EPA), the American Textile Manufacturer's Institute (ATMI), the Amalgamated Clothing and Textile Worker's Union (ACTWU). This steering committee identified dye-weighing operations as requiring research to develop improved techniques to reduce worker exposure to dye dust.

The objective of the manual dye weigh-out study is to provide dye and textile shops with information about practical, effective engineering control methods that control worker exposure to air contaminants (dust). To develop this information, ventilation control methods need to be identified and evaluated in the workplace. This plant was selected for study because the controls used at this plant should be applicable for manual dye weigh-out operations in the dye and textile industries.

At this plant, manual powder weigh-out was conducted in a booth manufactured by Extract Technologies Ltd (Huddersfield, United Kingdom). The study was conducted to identify exposure sources that occur during the manual weighout of powders in this booth.

PLANT DESCRIPTION AND PROCESS DESCRIPTION

This pharmaceutical plant is 10 years old and it employs 300 people to manufacture tablets which contain medicine. The plant runs three shifts per day. The process of manufacturing tablets begins by weighing out batches of inert ingredients and active ingredients that are intended to have health effects. During the manual weighout operations involving active ingredients, workers are required to wear powered air purifying respirators. Because of Food and Drug Administration regulations, the powdered materials used in this facility cannot be treated with additives that suppress dust generation.

The weighout operation is conducted in an Extract Technologies 3m DX Booth shown in Figure 1. The worker places a drum containing powdered material onto the roller conveyor and pushes the drum through the plastic curtain until it is positioned under the baffle. Then, the worker takes the lid off the drum and opens the plastic liner, causing a visible dust cloud. Next, the worker uses one of several scoops to transfer material from the drum under the baffle to a second drum that also has a plastic liner. This second drum was 17-inches high and had a diameter of 17-inches. After completing the transfer operation, the worker ties the plastic liner shut and places the lid on the second drum. Between the time that the material transfer stops and the second drum is closed, the worker spends considerable time documenting the weighing process. Then, the liner for the drum under the baffle is tied shut and the lid is placed back on the drum.

Booth Description

The booth is located in a separate room for powder weighout as shown in Figure 2. Figures 3 and 4 present front and side views of the booth and provide the booths dimensions. In this booth, a fan draws air through the

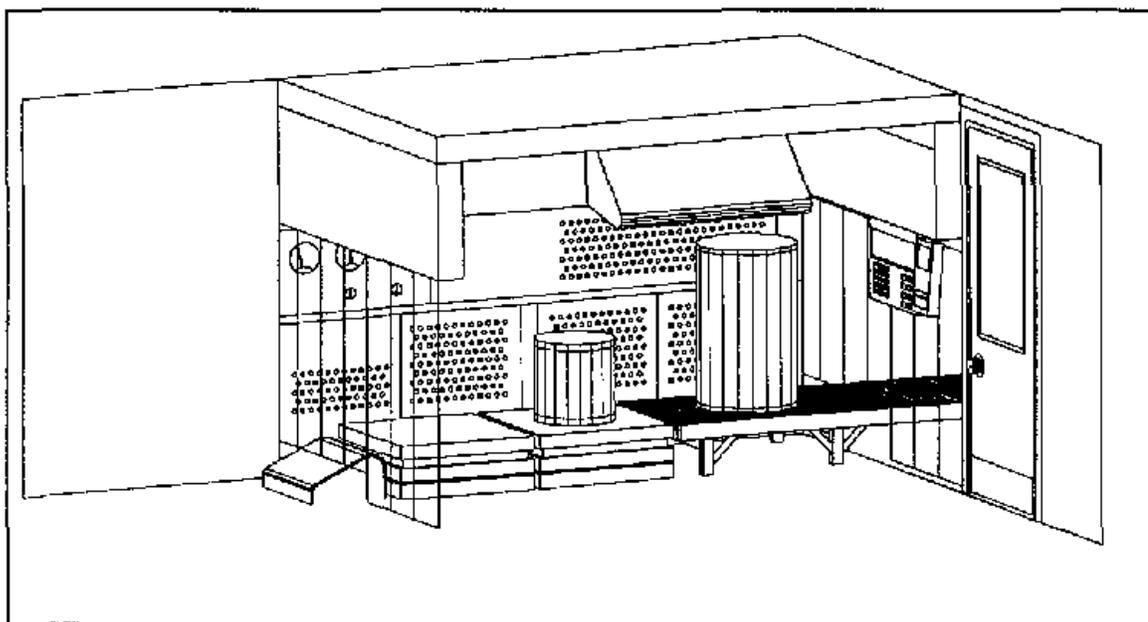


Figure 1 Three dimensional illustration of Extract Technology Booth

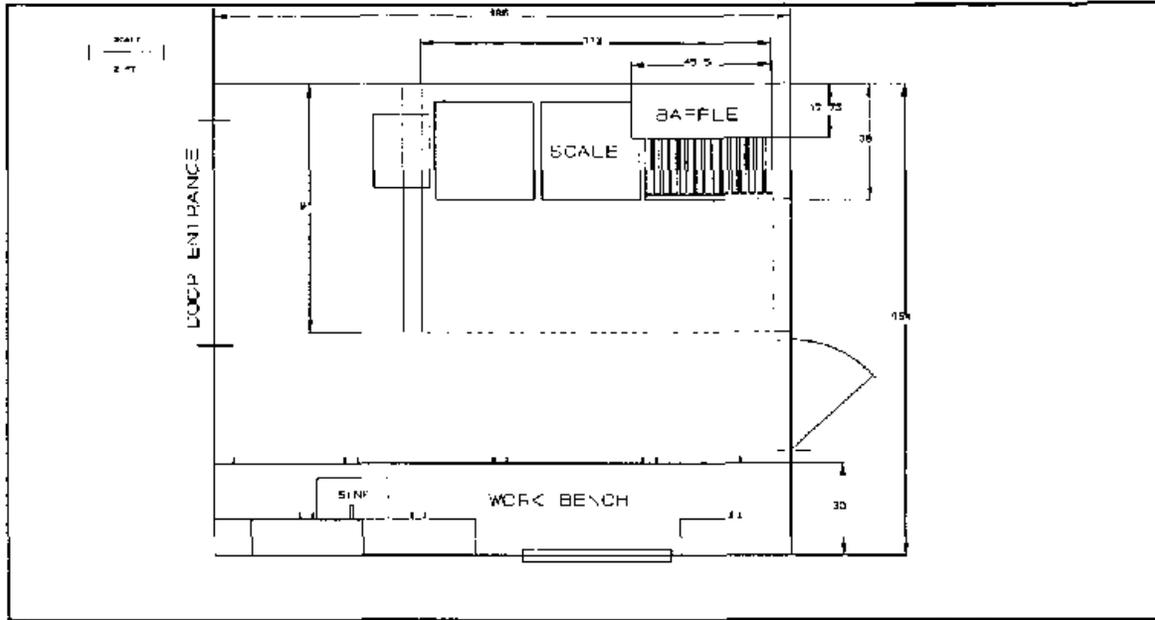


Figure 2 Plan view of weighout room and booth

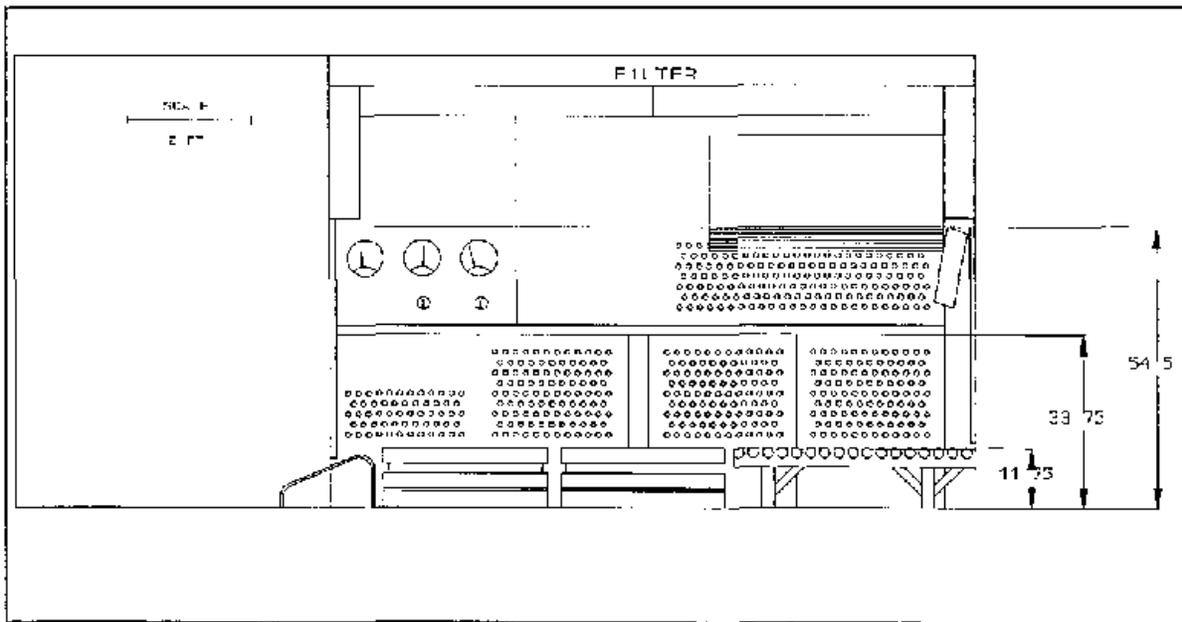


Figure 3 Front view of weighout booth

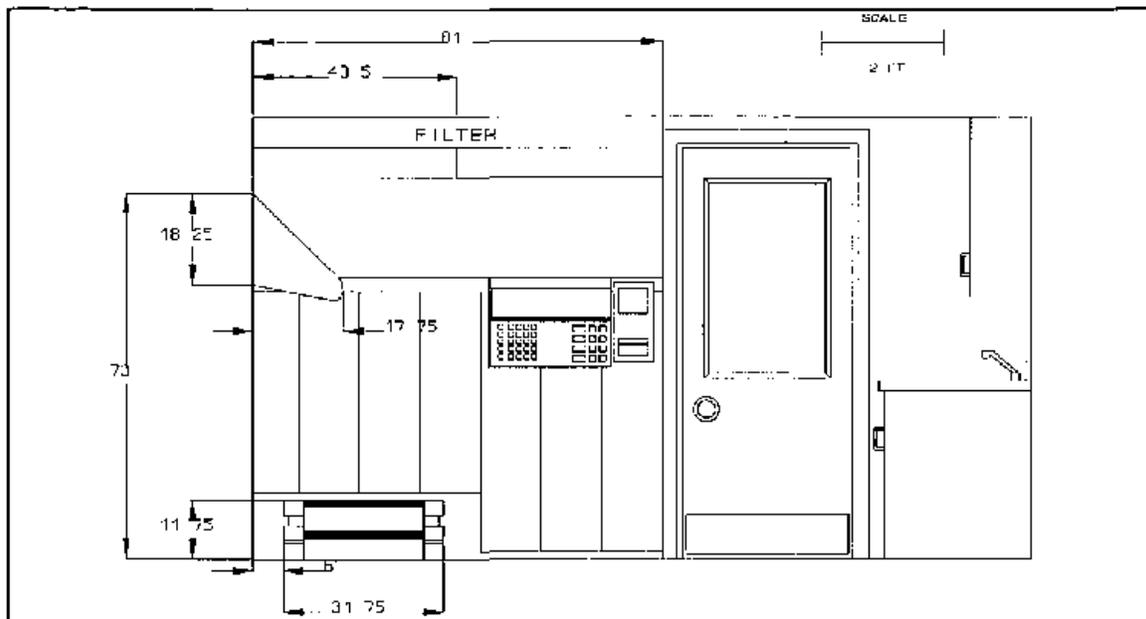


Figure 4 Side view of booth

exhaust grates and filters that are behind the exhaust grate. The fan discharges about one-third of this air to the outdoors and the remaining air is recycled through high efficiency particulate filters located in the ceiling of the booth.

EXPOSURE EVALUATION CRITERIA

As a guide to evaluating hazards posed by workplace exposures such as those from manual weigh-out operations, NIOSH field staff employs environmental evaluation criteria. The primary sources of environmental evaluation criteria in the United States that can be used for the workplace are (1) NIOSH Recommended Exposure Limits (RELs), (2) the American Conference of Governmental Industrial Hygienists's (ACGIH) Threshold Limit Values (TLVs), and (3) the U.S. Department of Labor (OSHA) Permissible Exposure Limits (PELs). The OSHA PELs are required to consider the feasibility of controlling exposures in various industries where the agents are used, the NIOSH RELs, by contrast, are based primarily on the prevention of occupational disease. ACGIH Threshold Limit Values (TLVs) refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. ACGIH states that the TLVs are guidelines. The ACGIH is a private, professional society. It should be noted that industry is legally required to meet only those levels specified by OSHA PELs.

A Time-Weighted Average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits (STEL) or ceiling values that are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

The overall objective of this study is to control worker exposure to dust generated by manual powder weigh-out activities. The powders used during this testing were pharmaceutical fillers (e.g., starch and magnesium stearate). These fillers are believed to pose minimal health hazards. Thus, exposure limits for total dust are used as the criteria for evaluating whether the exposures are excessive. The PELs established by OSHA require industry to control the 8-hour time-weighted average (TWA) of total dust to 15 mg/m³. The TLVs suggested by ACGIH are set at a 10 mg/m³ TWA for total dust.¹ The NIOSH REL for total dust is 10 mg/m³.²

EVALUATION PROCEDURES

The study's objective was to identify tasks which elevate worker dust exposure during the weighout of powder at the ventilated booth manufactured by Extract Technologies. During selected weighout operations at this booth, video exposure monitoring was conducted to study the association between weigh out tasks and the response of an aerosol photometer and an optical particle counter. Ventilation measurements were made to document the air flow rates and the air flow patterns around the worker.

VIDEO EXPOSURE MONITORING

Video exposure monitoring was used to study in greater detail how specific tasks affected the worker's exposure to air contaminants.^{3,4} While a video camera recorded workplace activities, an aerosol photometer and an optical particle counter were concurrently monitored aerosol concentrations on the worker. This aerosol instrumentation along with a data logger and personal sampler pump were mounted on a backpack frame that the worker wore.

An optical particle counter (Model 227, Met One, Grants Pass, OR) was mounted on the frame. This instrument sampled at a rate of 2.83 liters per minute (lpm). A 30-cm length of 5-mm inside diameter Tygon[®] tubing was used to transport the aerosol from the cowl to the instrument. The optical particle counter was used with following settings:

- 1 sampling period - 1 minute,
- 2 time between sampling periods - 1 second, and
- 3 lower size limit for second channel - 3 μm

The Met One optical particle counter continuously recorded the number of particles counted during a series of consecutive one minute sampling periods that are separated by one second. Two channels store the number of particle counts in a time interval. One channel stores the total number of particles counted by the instrument. The particles are all larger than approximately 0.3 μm. The second channel was set to count the number particles larger than 3.0 μm. The particles are sized based upon the amount of scattered light detected by a photodetector. In reality, the magnitude of the light pulse scattered by the particles varies with particle size, optical properties, and surface roughness.

The aerosol photometer (Hand-held Aerosol Monitor (HAM), PPM Inc., Knoxville, TN), has a detached sensor and an electronics module. The sensor was placed

on the worker's chest and the electronics module was mounted on the backpack frame. The analog output of the HAM was recorded with a data logger, (Rustrak® Ranger, Gulston, Inc., East Greenwich, RI) which was mounted on the backpack frame. When the data collection was completed, the data logger was downloaded to a personal computer for storage and analysis.

In the HAM, light from a light-emitting diode is scattered by the aerosol, and forward-scattered light is detected by the HAM. The amount of scattered light is proportional to the analog output of the HAM. However, the calibration of aerosol photometers varies with aerosol properties such as refractive index and particle size³. Therefore, HAM measurements are reported as "the HAM analog output" which has units of volts.

A calibration manifold was placed on the HAM's sensor section. A preweighed filter was attached to this manifold. Tygon® tubing connected the outlet of the filter holder to the inlet of a battery operated pump (SKC Inc., Eighty Four, PA). This pump drew 5 lpm of air through the HAM's sensing chamber and the preweighed filter. This filter was used to measure the total dust concentration. The filter's weight gain was determined by using NIOSH Method 0500⁵. To compute the total dust concentration, the filter's weight gain, which was adjusted for the weight change of blank filters, was divided by the product of the sampling rate and a task time. This time interval was from the start of the weighing activities to the removal of the backpack at the end of the sampling period.

VENTILATION MEASUREMENTS

Air velocity at the filters in the ceiling of the booth were measured using a hot wire anemometer (model 8357, TSI, St Paul, MN). This instrument was operated with a time constant of 10 seconds. In addition, air velocities around a drum in the booth were measured. Dry ice was used to document air flow patterns because FDA regulations preclude the use of smoke to trace air flow patterns.

Results and Findings

Ventilation Measurements

The supply air flow from the ceiling of the booth was measured to be 4,900 cubic feet per minute (cfm). Merck indicated that the supply flow rate from the ceiling of this booth is 3000 cfm and the total exhaust flow rate into the grates in the back of the booth is 4200 cfm. The reason for the discrepancy in the flow rates from the ceiling of the booth is not known. When a person stood in front of the baffle in Figure 5, the air flowed away from the worker's breathing zone. The air flow patterns appear to separate the worker from the dust generated in the drum. No eddies were observed which would force contaminated air back into the worker's face.

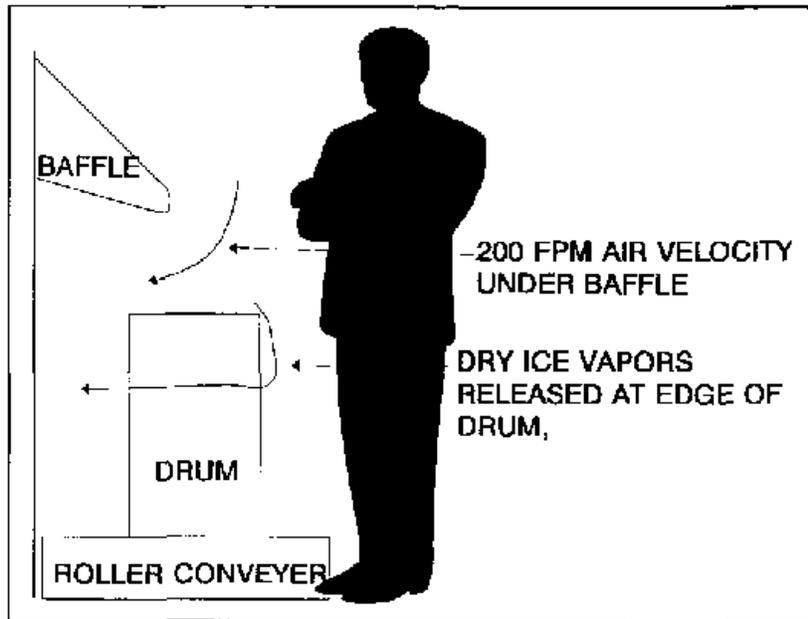


Figure 5 Air flow around the drum

Video Exposure Monitoring and Total Dust Concentrations

The total dust concentrations and the activities occurring during each sampling run are listed in Table 1. Video exposure monitoring was successfully conducted during the second and third sampling sessions listed in Table 1.

During the first sampling session, a 33" long scoop, shown in Figure 6, was used to remove material from the bottom of the 33" high, tilted drum depicted in Figure 7.

During the second sampling session in Table 1, the optical counter ran continuously. The response of the optical particle counters to particles larger than 3 μm was analyzed because these particles probably contain most of the aerosol's mass. The raw data from the optical particle counter is listed in Appendix 1. The videotape was viewed and the worker's activities were categorized as follows:

Table 1 Short-term, total dust concentrations measured on the worker

Session	Activity	Time (min)	Concentration (mg/m ³)
1	scooping material from the bottom by tilting the drum and using a long-handled scoop The worker weighed out three batches of material from a 33 inch high drum	21	2.84
2	Scooping material from near the top of 33 and 24 inch high drums	43	1.95
3	Scooping material from the top of a 33 inch high drum	8	3.96

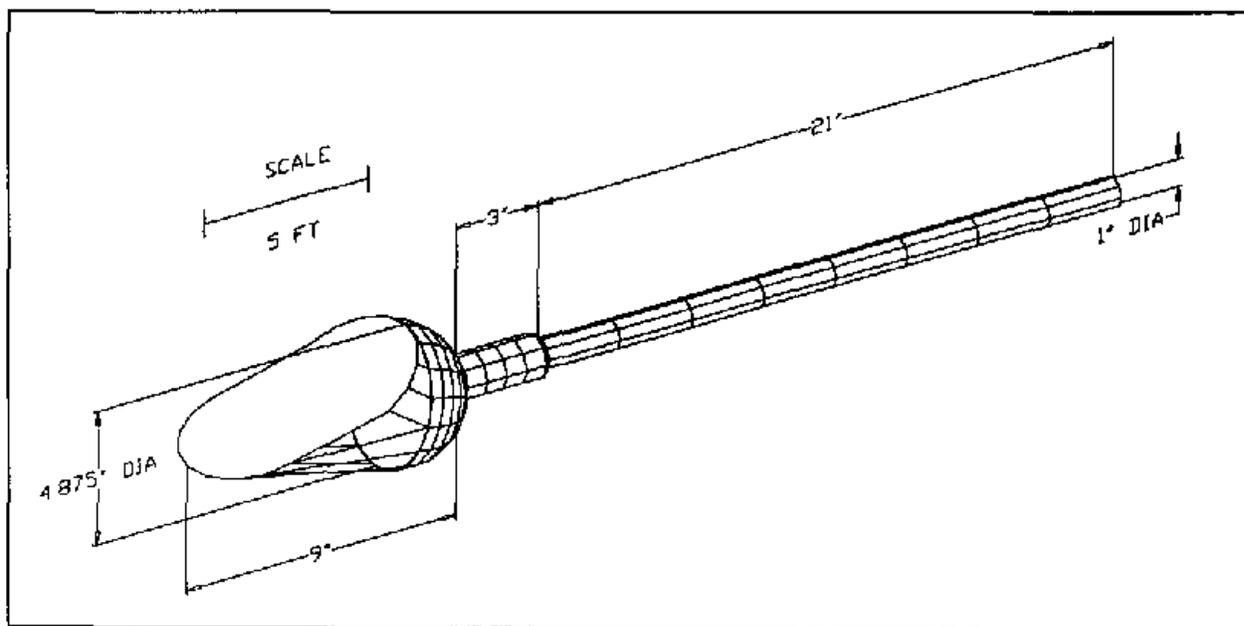


Figure 6 Schematic of long-handle scoop used to remove material from the bottom of a drum

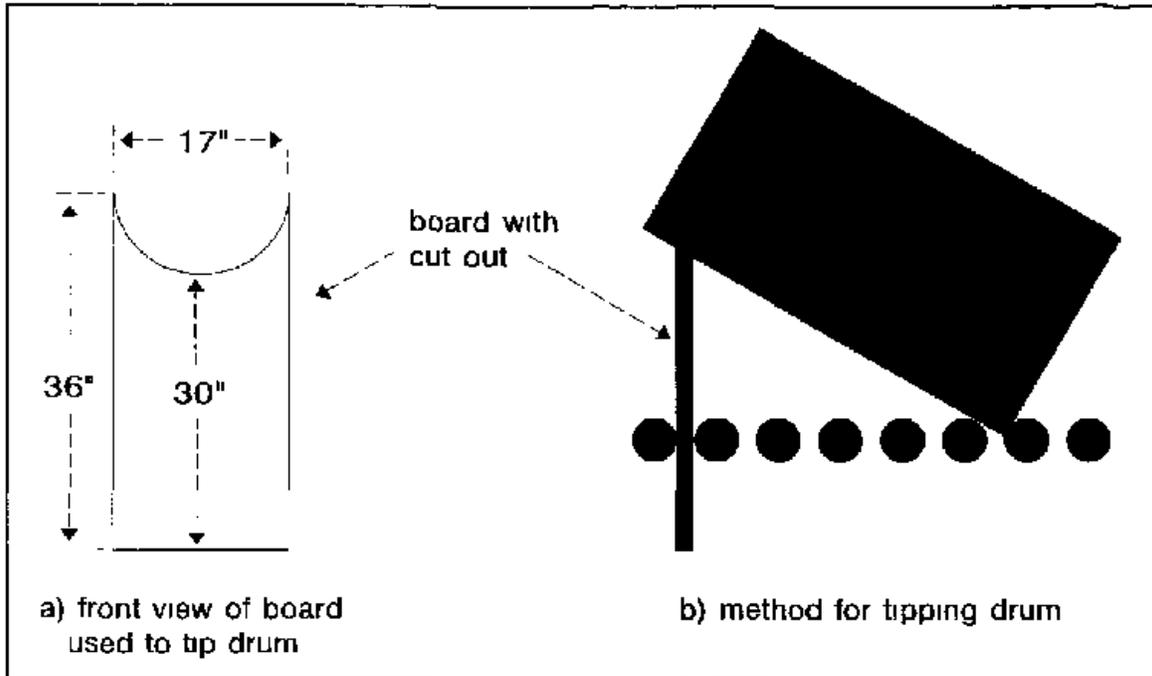


Figure 7 Schematic illustration of cut-out board used to tip drum
This board is placed between the rollers

- 1 Closing the drum During this activity, the worker squeezed the air out of the plastic liner and tied the liner shut. In the videotape, the airborne dust appeared to puff into the worker's face. If this activity occurred during the one minute sampling period, the exposure was attributed to "closing drum."
- 2 Scooping During this activity, the worker was manually transferred the powder from a large drum to a smaller container. If this activity occurred during the sampling period and Activity 1 did not occur during the sampling period, the exposure was attributed to "scooping."
- 3 Other This describes activities away from the weighing booth. If this activity did occur during the sampling period and Activities 1 and 2 did not occur, the exposure was attributed to "other."
- 4 Writing The worker spent much of his time in the weigh booth documenting the weigh-out process. If Activities 1, 2, and 3 did not occur during the sampling, the worker's exposure was attributed to "writing."

Figure 8 shows that much of the dust exposure is caused by closing the drum. During this activity, the worker squeezed the air out of the plastic drum liner and this directed a flow of dusty air into the worker's face. The contribution of "closing drum" to the workers dust exposure may be understated.

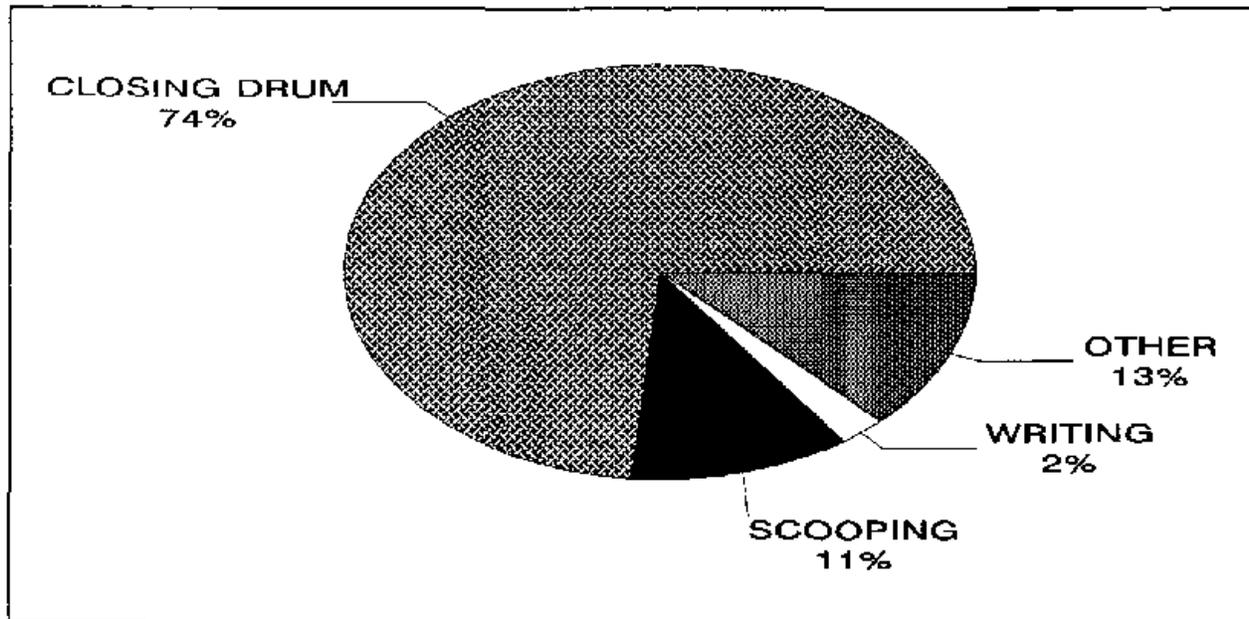


Figure 8 Effect of activity upon percent of total exposure to particles greater than $3 \mu\text{m}$ as measured by the optical particle counter during second sampling session

in Figure 8 because of coincidence effects⁶. During interval number 38 listed in Appendix 1, the particle number concentration was 620,000 particles/cubic foot. According to the instruction manual for the optical particle counter, coincidence losses are less than 5 percent at concentrations less than 300,000 particles/cubic foot.

The HAM was in operation for 29 minutes of the second session listed in Table 1. The effect of worker activity upon the HAM's analog output is depicted in Figure 9. Because the HAM's output was recorded in 1-second increments, the worker's activities are more finely classified here than in Figure 8. Furthermore, only one activity occurs during the 1-second increment. These additional activities were included:

1. Opening drum: The worker takes the lid off the drum and opens the plastic liner.
2. Off screen: The worker is not visible in the videotape, but is in the weighing room and is not handling powders.
3. Left room: The worker left the room to get additional drums of powder. The activities "off screen" and "left room" were used in place of the activity "other."

In Figure 9, the HAM's analog output is just above the limit of detection, which is 0.01 volts. Opening and closing drums and scooping material out of the drum caused noticeable increases in the HAM's analog output as compared to writing or leaving the weighout room. While opening and closing the drum, the worker manipulated the plastic liner.

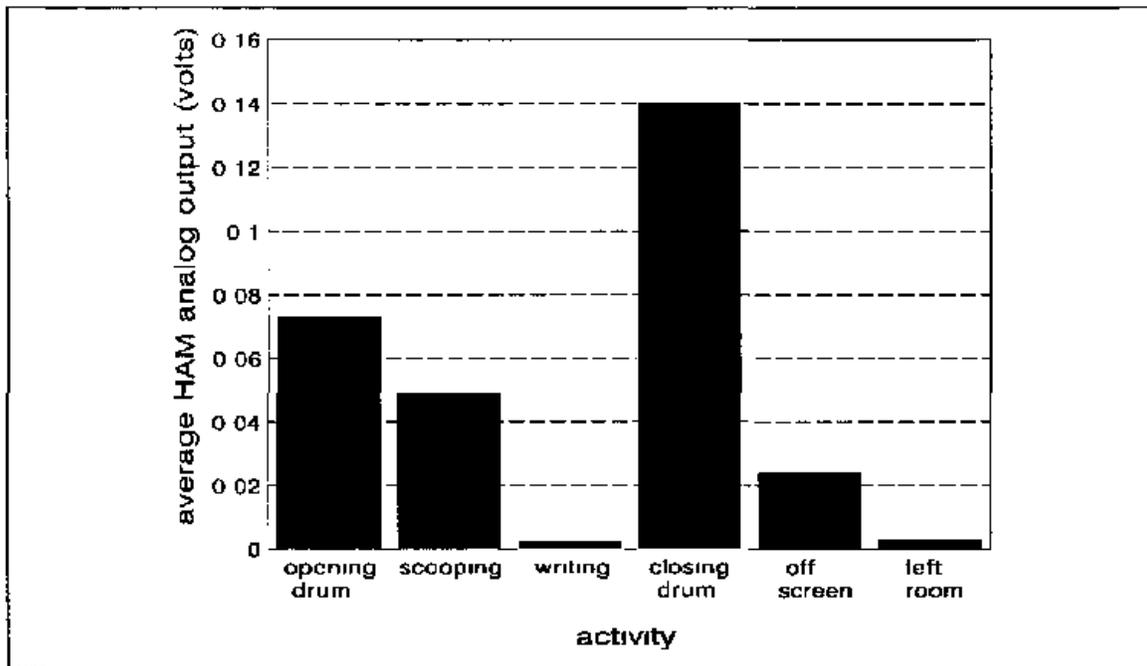


Figure 9 During second session, effect of activity upon HAM's analog output. Note, the HAM's battery failed during this session.

During the scooping activity, the HAM's analog output increased when the worker's head was next to or below the baffle. The magnitude of this effect is illustrated in Figure 10. As shown in Figure 11, the HAM's response is delayed by one to two seconds because time is required to transport the airborne dust into the worker's breathing zone and into the instrument.⁷ When the exposure peaks caused by placing her head next to the baffle or below the level of the baffle are removed, the average HAM analog output is only 0.02 volts.

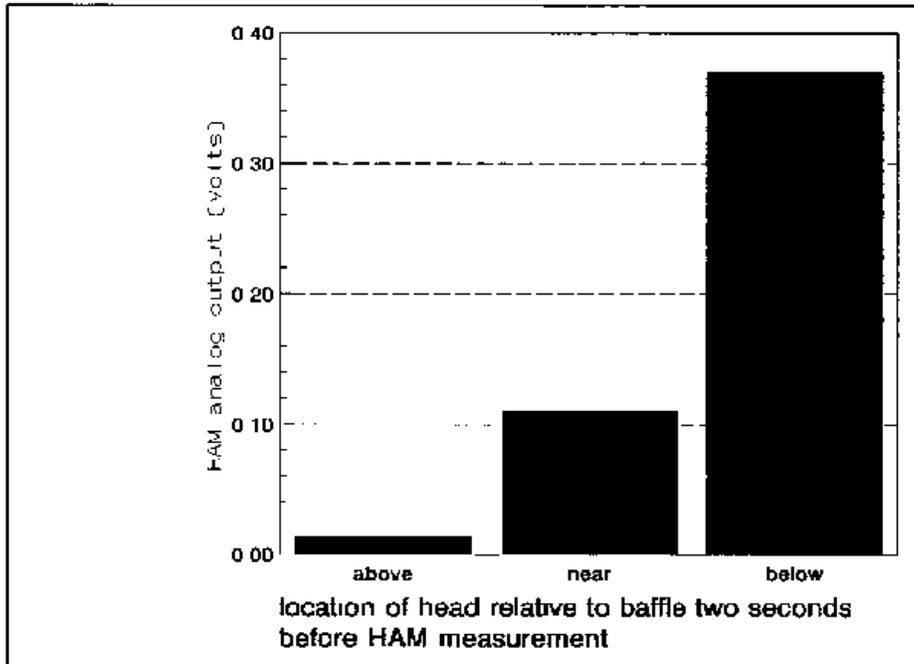


Figure 10 Placing head below baffle increases dust exposure (Data collected during second sampling session)

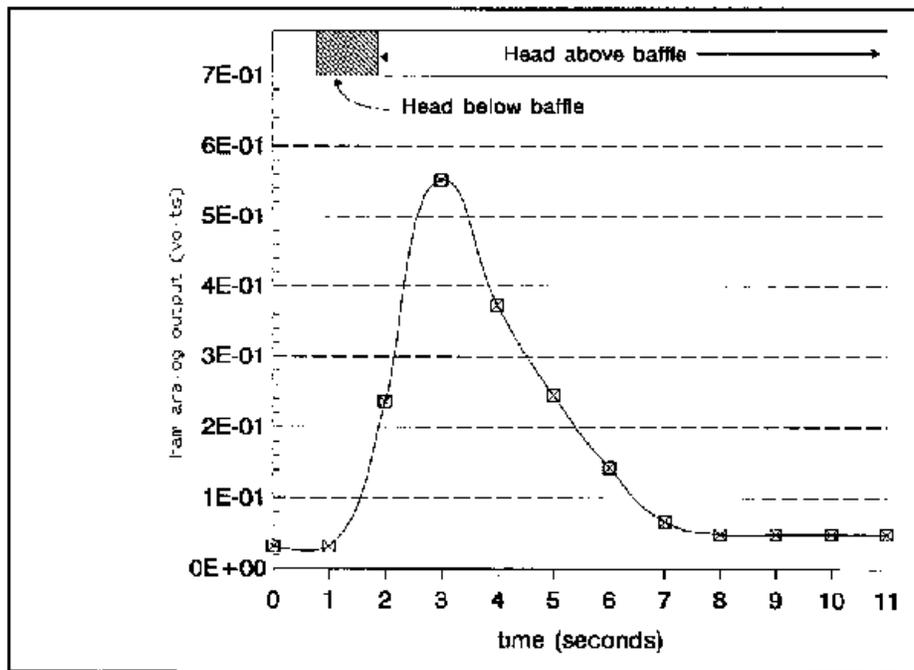


Figure 11 There is a delay between act of placing the head below the baffle and the transitory increase in HAM analog output

During the third sampling session described in Table 1, the worker transferred 3 kilograms of magnesium stearate from a 33 inch high drum to a 17-inch high, 17-inch diameter plastic drum. Only one batch was weighed out. The optical particle counter readings are presented in Figure 12. These results indicate that about 90 percent of the worker's dust exposure is caused by opening and closing the drum's plastic liner.

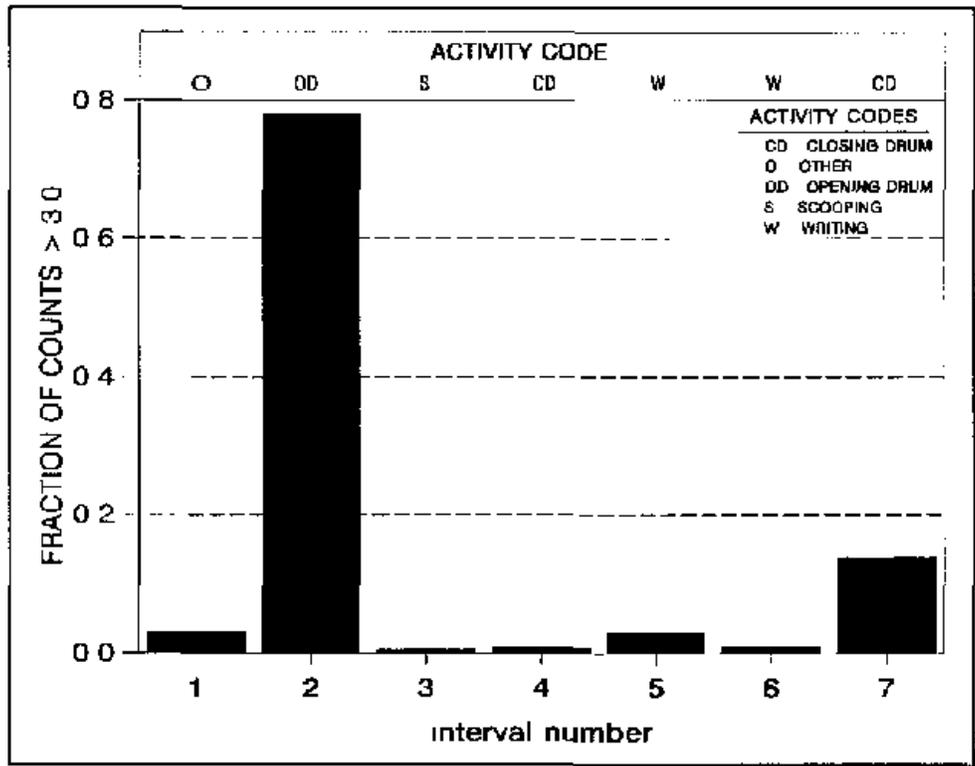


Figure 12 Activity code and fraction of total exposure to particles greater than 3 μm measured by the optical particle counter during the third sampling session

Anthropometric Considerations

The work station and the drums need to be configured so that the worker does not need to place his face next to or below the baffle. This would greatly reduce the dust exposure from transferring material from one drum to another. Drums should be sized so that the worker does not need to place the upper body into the drum to remove powder from the bottom of the drum. Thus, drum height should not exceed the forward functional reach of a 5th percentile female. For females, the 50th percentile distance from the shoulder to a pinch of the thumb and index finger is 24.6 inches with a standard deviation of 1.3 inches.⁸ For the 5th percentile female, this distance is 22 inches. This distance describes "how far forward a person can reach into a porthole or other access hole." In order for the ventilation system to keep the airborne dust out of the worker's breathing zone, the worker's face must be separated by some distance from the top of the drum. By using scoops and tipping the drum as illustrated in Figure 7 and keeping the drum depth less than 22 inches, there may be sufficient separation between the worker's face and the top of the drum to keep the airborne dust out of the worker's breathing zone. However, data needs to be collected to evaluate the validity of the preceding statement.

The anthropometric table cited in the preceding paragraph suggests that a drum depth of 32 inches is excessive. The shoulder to forward functional pinch for a 95th percentile male is 30.3 inches.⁸ In order to scoop material from the bottom of the drum, practically all workers would need to place their upper body very close to the drum's opening or inside the drum.

Discussion and Conclusions

The dust exposures measured on the worker listed in Table 1 were less than the NIOSH REL for total dust of 10 mg/m³. However, the booth does not completely isolate the worker from dust exposure during the manual powder weighout process. The video exposure monitoring revealed that two tasks appear to increase dust exposure:

1. Opening and closing the plastic liner inside the drums. Compressing the plastic bags and opening these bags can disperse dust directly into the worker's face.
2. Placing one's head below the baffle to scoop material out of the drum.

If these exposure sources were controlled, the total dust exposures in listed in Table 1 would be much lower. The optical particle counter results suggest that about 80-90 percent of the worker's dust exposure is due to the manipulation of the drum's plastic liner.

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Appendix 1 Listing of Counts from Optical Particle Counter

Activity	Interval Number	Number of Particles >0.3 μm	Number of Particles > 3.0 μm
Second Sampling Session			
background, no activity	1	322	56
background, no activity	2	210	31
scooping from drum	3	59	7
scooping from drum	4	179	27
scooping from drum	5	560	57
writing, closing small drum	6	499	78
writing, off screen,	7	633	100
writing, scooping from drum	8	617	76
scooping from drum	9	383	76
scooping from drum	10	2200	872
scooping, off screen, closing drum	11	789	147
closing drums	12	1151	338
writing	13	423	52
writing	14	278	41
outside of room	15	998	186
outside of room	16	431	36
outside of room	17	1016	101
outside of room	18	951	52
outside of room	19	1586	184
writing	20	178	16
writing	21	581	116
writing, off screen, scooping from drum	22	2243	311
scooping from drum	23	4514	1108

To obtain concentration, divided the number of counts by the product of interval width (1 minute) and sampling rate (0.1 cubic feet per minute)

scooping from drum closing drum	24	8669	3366
closing drum	25	15036	6686
writing	26	241	23
writing	27	399	48
outside of room	28	11821	2130
outside of room	29	2267	358
outside of room	30	1622	167
outside of room	31	1603	95
outside of room	32	1146	92
outside room, writing	33	2161	97
writing	34	255	40
writing, scooping from drum	35	1359	173
scooping from drum	36	2110	569
scooping from drum	37	2309	619
scooping, closing drum Big puff of dust observed when closing drum liner Measurement probably low due to coincidence losses	38	62266	37493
closing drum	39	5722	2044
writing	40	658	126
writing	41	1855	621
outside of room	42	14344	1964
outside of room	43	11698	2551
Third Sampling Session			
set up	1	589	156
opening drum, scooping from drum	2	5995	3946

To obtain concentration, divided the number of counts by the product of interval width (1 minute) and sampling rate (0.1 cubic feet per minute)

scooping from drum	3	223	26
closing drum, writing	4	290	44
writing	5	688	147
writing	6	154	45
closing drum	7	1740	696

To obtain concentration, divided the number of counts by the product of interval width (1 minute) and sampling rate (0.1 cubic feet per minute)