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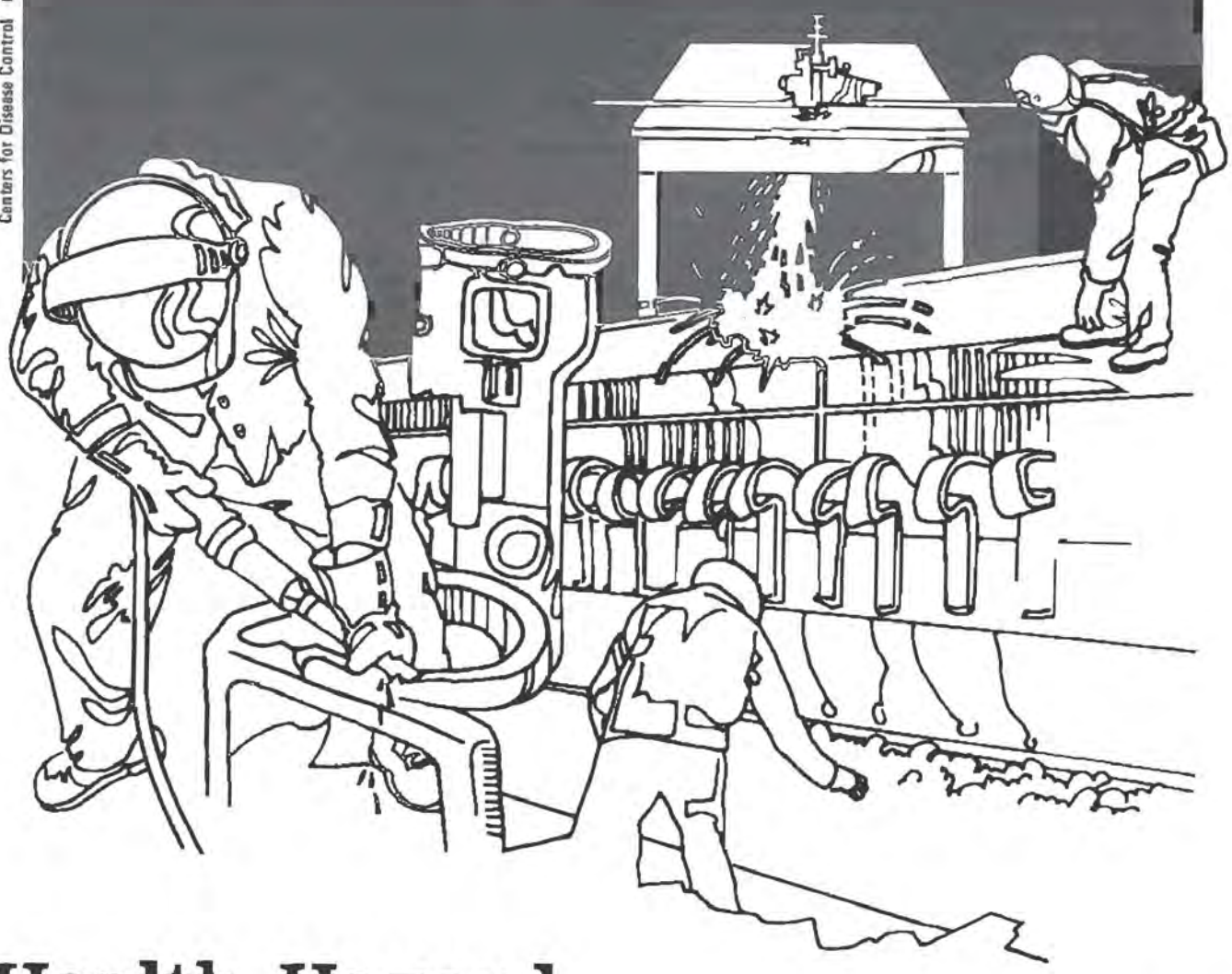

Health Hazard Evaluation Report

HHE 80-023-804
BECTON-DICKINSON COMPANY
COLUMBUS, NEBRASKA

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 699(a)(6), which authorizes the Secretary of Health and Human Services, following a written request from any 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.

HE 80-023-804
January 1981
Becton-Dickinson Company
Columbus, Nebraska

NIOSH INVESTIGATORS:
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I. SUMMARY

On November 8, 1979, the Becton-Dickinson Company requested the assistance of the National Institute for Occupational Safety and Health (NIOSH) in an evaluation of potential adverse health effects associated with the use of glass containing antimony and cerium oxide in the production of hypodermic syringes in their Columbus, Nebraska, plant. Approximately thirty-five employees per shift are involved in the production of syringes by cutting, heating and shaping glass tubing. Until August 10, 1979, this product had been manufactured with a standard glass (Type 7800). On August 10 a new style glass (Type 7802) was introduced which contained small amounts of antimony and cerium oxide. During a short run of the new glass, some employees noted an unusual odor, itching, or irritation of the upper respiratory tract. Use of the new glass was discontinued.

To investigate this episode, NIOSH researchers interviewed employees and management, and conducted environmental measurements on November 29 through December 1, 1979. On December 1, type 7802 glass was reintroduced into production for one day by management volunteers. Environmental measurements made on that day for antimony, cerium, stibine, and dust were compared with similar measurements made the previous day during normal production of 7800 glass. Also, samples were collected both days for qualitative analysis, and long path-length infrared scans were made at several points throughout the workplace.

Environmental concentrations of antimony, stibine and cerium were approximately mately one percent of the recommended maximum concentration of 0.5 mg/M^3, 0.1 ppm, and 5 mg/M^3 respectively. One sample for total particulate was approximately 50 percent of the recommended maximum of 10 mg/M^3, but all others were in the one percent range. Qualitative and infrared measurements did not detect any change in the composition of the environment during the run of 7802 glass compared with the run of 7800 glass.

Employee interviews indicated that significantly more smokers than non-smokers experienced symptoms during the August episode, and that there was a geographical grouping of job sites of those employees experiencing symptoms. Measurements of atmospheric contaminants indicated no difference in air quality between the normal run on November 30 and the test run of 7802 on December 1. No symptoms were noted on December 1.

Based on the information collected during this evaluation, it is not possible to define a causative agent for the symptoms experienced during the August 1979 run of Type 7802 glass. Available information does not indicate that either antimony or cerium oxide would cause such problems in concentrations measured in November or December. Temperature and humidity are thought to be possible contributing factors. If Type 7802 glass is reintroduced into production, a follow-up request could be submitted and NIOSH investigators could be on-site for observation and measurements.

KEYWORDS: SIC 3841 (hypodermic syringe), antimony, cerium, stibine, particulate, glass.

II. INTRODUCTION

On November 8, 1979, a request was received from the management of the Becton-Dickinson Company to conduct a Health Hazard Evaluation in their Columbus, Nebraska, plant. The request expressed concern about employees working with glass containing cerium oxide and antimony in the production of glass syringes. A combined medical/industrial hygiene study was conducted on-site from November 29 through December 1, 1979, to determine if symptoms exhibited by employees were due to exposure to substances in the workplace.

Preliminary environmental results were provided on February 19, 1980, followed by correspondence in March and August detailing the findings of the on-site evaluation, as well as information obtained on the toxicology of the compounds of interest and the experience of other manufacturers with similar processes.

III. BACKGROUND

The Glass Manufacturing Department (Department 251) of the Becton-Dickinson plant in Columbus, Nebraska, produces glass syringes. On Friday, August 10, 1979, a new glass (Type 7802) was introduced on day shift at the horizonal glass cutting machine. Some employees working at or near the process noted an unusual odor, itching, or irritation of the upper respiratory tract. On Monday, August 13, cutting continued and the cut glass was processed through two of the form, flange, and tip machines (also called lamp machines). Several employees at or near both those processes noted an odor, itching, or upper respiratory irritation; and use of the glass was discontinued early Monday afternoon.

Until August 10, 1979, the employees in this plant had been producing the same product, using the same equipment, at the same rate, under the same operating condition, for several years. The only discernible difference was in the composition of the glass. The 7802 glass contained small amounts of cerium oxide and antimony which the old glass did not. The old glass, type 7800, contained a small amount of chlorine which the new glass did not.

IV. EVALUATION DESIGN AND METHODS

Following receipt of this request from Becton-Dickinson, a meeting was arranged at the corporate headquarters in New Jersey for November 19, 1979. At this meeting, the NIOSH project officer discussed the work process, materials and unexplained symptoms with members of the company industrial hygiene and engineering staff. Subsequent to that meeting, information was collected on the composition of materials, operating parameters, toxicity of various suspected substances, and symptoms exhibited by employees.

A decision was made to conduct a joint environmental/medical investigation at the Columbus, Nebraska plant. To investigate the August episode, department employees were interviewed on Thursday, November 29 through Saturday, December 1, 1979. The department generally employs about 35 workers on the day shift, with a total work force of about 110 people. Forty-seven employees (36 day shift, eight evening, three night shift) were interviewed. Four employees who were not working on August 10 or 13 were excluded from analysis.

To document any change in environmental conditions created by production with type 7802 glass, air tests were made during normal operation on Friday, November 30, when 7800 glass was being worked, and on Saturday, December 1, when 7802 glass was being worked. The Saturday operation was manned by management with the voluntary assistance of one set-up man and one mechanical technician. All other operations were shut down during this one day run of 7802 glass. The only people present other than those running the operation were NIOSH medical and environmental investigators, and a company industrial hygienist.

Personal and area air samples were collected on filters and on activated charcoal on Friday, and in as far as practical these samples were duplicated on Saturday. These samples were returned to the laboratory to be quantitated for antimony, total dust, stibine, and cerium. They were qualitated for crystalline compounds by X-ray methods and for organic compounds by gas chromatography and mass spectrometry. On-site, long path infrared spectral scans were made of air from several points, including personal breathing zones and suspected high emission process points, on both days for the purpose of comparison.

Subsequent to the on-site evaluation, the NIOSH medical officer contacted other researchers investigating effects of exposure to antimony in similar industrial applications.

V. EVALUATION CRITERIA

A maximum atmospheric concentration for antimony (1,2,3) and stibine (1,2) of 0.5 milligrams per cubic meter (mg/M^3) and 0.1 parts per million (ppm), respectively, for an eight hour time weighted average occupational exposure is recommended. Exposure to antimony compounds above the recommended maximum concentration can cause headaches, sleeplessness, vertigo, muscle pain and loss of appetite(4). Antimony has been shown to cause dermatitis in concentrations greater than approximately 5 mg/M^3. Stibine at high concentrations can be a lung irritant and can cause liver and kidney damage(2).

According to NIOSH (5), "No local effects have been reported due to cerium and its compounds," although in high concentrations a pneumoconiosis is suspected due to inhalation. No occupational exposure standard has been established for cerium by OSHA, nor has one been recommended by NIOSH, or the American Conference of Governmental Industrial Hygienists (ACGIH). Sax (6) has given this compound a toxicity rating of 0 ("no toxicity") to 1 ("slightly toxic"). This is similar to the rating of iron oxide which has a TLV of 5 mg/M^3.

The evaluation criteria for airborne particulate or "nuisance dust" is based on its ability to reduce workplace visibility, create unpleasant deposits in the ears, eyes and nasal passages, or cause injury to the skin or mucous membranes by chemical or mechanical action per se or by the rigorous cleansing procedures necessary for its removal. The ACGIH (2) recommends a concentration of 10 mg/M^3 as a maximum acceptable level for total particulate in air.

VI. RESULTS AND DISCUSSION

A. Environmental

Tables I through III give results of samples which were analyzed for antimony and total particulate, stibine, and cerium. As can be seen from these tables, the concentrations of these substances was consistently below the recommended criteria, in most cases by several orders of magnitude. As a matter of curiosity, it will be noted that the highest concentrations of cerium and the second highest concentration of antimony were measured on the day that the type 7800 glass (containing neither of these compounds) was being used. The reason for this apparent indiscrepancy is that the analyses were done at the limit of detection of the analytical method and under these conditions the quantitation is not as precise as when optimum conditions exist.

Results of qualitative analysis on three charcoal tubes indicate all three samples were identical in composition. This includes one sample taken each day near the cutting machine and a sample taken on December 1, near the #12 forming machine. Major peaks identified by GC/MS (gas chromatography/mass spectrometer) were Freon 113, 1,1,1-trichloroethane, perchloroethylene, butyl cellosolve and alphaterpineol. Due to the method of desorption and analysis employed on these samples, stibine would not have been detected.

Six filter samples (three taken Friday and three taken Saturday) were submitted for qualitative analysis by X-ray diffraction (XRD) and X-ray fluorescence (XRF). XRD detected no crystalline compound (such as antimony oxide). XRF indicated the following compounds in some or all of the filters: silicon, sulfur, chlorine, potassium, and iron. There was no significant difference in the analysis of filter samples taken Saturday compared with those taken Friday. If anything, there was more material detected on the Friday samples, as would be expected on a day with more work activity.

Environmental analysis by long path infrared spectrometry at several worksites showed no detectable change in air composition during the run of #7802 glass as compared with a run of #7800 the previous day. Samples were taken on both the test day and on the comparison day at three points and scanned from 2.5 to 14.5μ (4000 to 700 CM^{-1}) at a path length of 8.25 M. There was no discernible difference in the spectra between the two scans.

Detector tube measurements for carbon monoxide and hydrocarbons on both days at various points throughout the workplace showed nothing above background levels.

Observations were made regarding general exhaust ventilation. There was no local exhaust ventilation on the cutting machine or the lamp machines 15 to 23. Air flow measurements, as shown by arrows in Figure 1, indicate a general movement of air during the December study from the machines which were processing the 7802 glass toward the area where cases (see definition below for affected workers) had worked. As will be discussed later, Figure 1 also shows normal location of both affected and unaffected employees and general plant layout. There was no specific air flow pattern in the area of lamp machines 15 to 23.

B. Medical

The medical evaluation of the August episode was a retrospective investigation to determine the number of cases and delineate common factors. A case was defined as a day shift employee of Department 251 who had noted a peculiar odor, itching, or irritation of eyes, nose, mouth or throat on August 10 and/or August 13. Eleven cases were identified (Table IV).

Employees were also asked if they had noticed similar symptoms at work any other time. Eight of 11 cases (73%) responded yes, compared to 17 of 25 other day shift employees (68%) and 19 of 35* other employees on all shifts (54%). The differences were not statistically significant.

Compared to other day shift workers, there was a statistically significant excess of smokers among the cases ($p< 0.05$). The difference was not significant when cases were compared with workers on all shifts (Table V).

A diagram of the department (Figure 1) reveals a geographic clustering of cases in the area around the cutting machine and the involved lamp machines. There is a statistically significant difference between cases and other day shift workers with respect to working in this "exposed" area ($p< 0.01$). If the three day shift employees who did not recall in which area they worked on August 10 or August 13 are excluded from analysis, the difference is not statistically significant. Comparing cases to workers on all shifts, with respect to the exposed area, there is a statistically significant difference even if all evening and night shift workers are considered in the exposed area ($p <0.01$). The difference remains significant if the three who did not recall are excluded from analysis ($p <0.05$) or are added to the exposure group ($p <0.05$) (Table 5).

Another factor which might have contributed to the symptoms of transient irritation experienced by employees in the plant during the initial run of 7802 in August was the weather. In spite of cooling equipment in operation in this plant, temperature and humidity would be expected to be significantly higher in August than in December. High temperature and humidity may have been at least in part a factor in creating discomfort, although these were probably not the sole causative agents of the symptoms experienced in August, 1979.

VII. RECOMMENDATIONS

As noted in preliminary reports on this evaluation, if the 7802 glass is reintroduced for production of syringes, NIOSH investigators are prepared to respond to a new Hazard Evaluation request. The continued involvement of Becton Dickinson corporate medical and industrial hygiene staff as well as employee representatives, in this process is recommended.

*One night shift employee noted an unusual odor on November 30, 1979 when he was near the glass that was to be used for the trial run the following day. He was excluded from this analysis.

It is suggested that, if the 7802 glass is reintroduced into this plant, consideration be given to the ambient temperature and humidity. In order to eliminate these factors as possible contributors to discomfort, the glass could be reintroduced during mild weather. Measurements of temperature and humidity both inside and outside the building would be interesting data should an episode of irritation recur.

VIII. REFERENCES

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5. Occupational Diseases, A Guide to Their Recognition, U.S. Department of Health and Human Services, No. (NIOSH) 77-181, 1977.

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IX. AUTHORSHIP AND ACKNOWLEDGEMENTS

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X. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Services, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22151. Information regarding its availability through NTIS can be obtained from the NIOSH Publications Office at the Cincinnati address.

Copies of this report have been sent to:

1. Becton Dickinson Company
2. NIOSH, Region VII
3. OSHA, Region VII

For the purpose of informing the affected employees, copies of the report shall be posted by the employer in a prominent place accessible to the employees, for a period of 30 calendar days.

Table I

Antimony and Total Dust Concentrations
Becton Dickinson Company
Columbus, Nebraska

Nov 30 - Dec 1, 1979

DESCRIPTION	DATE	DURATION	ANTIMONY CONCENTRATION	DUST CONCENTRATION
In Area of Forming Machines #10 & 11	12/1	8:45 a.m. - 2:55 p.m.	0.002 mg/M^3	N.D.*
Operator, Forming Machines #20 & 21	12/1	8:15 a.m. - 11:45 a.m.	0.0002	4.7 mg/M^3
Cutting Machine Operator	12/1	8:05 a.m. - 11:45 a.m. 12:30 p.m. - 2:45 p.m.	N.D.*	0.1
Cutting Machine Operator	11/30	9:05 a.m. - 11:25 a.m. 12:10 p.m. - 4:00 p.m.	N.D.	0.4
Operator, Forming Machines #10 & 11	11/30	10:45 a.m. - 11:25 a.m. 1:30 p.m. - 4:05 p.m.	0.001	0.1
Operator, Forming Machines #20 & 21	11/30	9:20 a.m. - 11:25 a.m. 12:10 p.m. - 3:55 p.m.	N.D.	0.2
Recommended Maximum Concentration (8 hour Time Weighted Average)			0.5	10.0

* None Detected - Limit of Detection: 0.000025 MG Antimony per sample
0.01 MG dust per sample

Table II

Stibine Concentrations
Becton Dickinson Company
Columbus, Nebraska

December 1, 1979

LOCATION	DURATION	CONCENTRATION
In Area of Forming Machines #10 & 11	8:45 a.m. - 2:55 p.m.	0.001 ppm
In Area of Forming Machine #20	8:55 a.m. - 3:10 p.m.	N.D.*
In Area of Cutting Machine, Near Packer	9:05 a.m. - 3:00 p.m.	0.002

Recommended Maximum Concentration (8 hr Time Weighted Average) 0.1

*None Detected - Limit of Detection: 0.00005 MG stibine per sample

Table III

Cerium Concentrations
Becton Dickinson Company
Columbus, Nebraska

Nov 30 - Dec 1, 1979

DESCRIPTION	DATE	DURATION	CERIUM CONCENTRATION
Glass Packer	11/30	9:05 a.m. - 11:25 a.m. 12:15 p.m. - 4:00 p.m.	0.01 mg/M^3
Mechanical Technician	11/30	9:15 a.m. - 11:30 a.m. 12:35 p.m. - 4:00 p.m.	0.02
Mechanical Technician	12/1	8:05 a.m. - 11:40 a.m. 12:35 p.m. - 3:20 p.m.	less than 0.01*
Glass Packer	12/1	8:15 a.m. - 11:50 a.m. 12:35 p.m. - 2:40 p.m.	less than 0.01*

Recommended Maximum Concentration — None given

* 0.01 mg/M^3 is the lower limit of detection

Table IV

Epidemologic Features of Cases and Other Workers
Dept. 251, Becton Dickinson Company
Columbus, Nebraska

	Age (years)		Sex		Smoking History		
	Mean	Range	M	F	Yes	No	Former
Cases (11)	48.5	(27-63)	7	4	5	4	2
All other day-shift workers (23)	44	(28-64)	9	14	2	12	9
Non-case day-shift workers who were in "exposed" area (15)	45.1	(28-57)	9	6	2	5	8
Evening* and night-shift workers (8)**	40.3	(21-64)	5	3	2	4	1
Trial Run 12/1/79 (6)	39.8	(29-52)	6	0	3	1	2

For analysis, former smokers were considered non-smokers.

*One evening-shift worker (47 years old, female, non-smoker) noted a peculiar odor on Friday evening, August 10. Therefore, she was included as a "case" when evening and night-shift workers were compared to cases, and she was excluded from this analysis of evening and night-shift workers.

**One evening-shift worker gave no smoking history

Table V

Statistical Analyses of Cases and Other Workers
With Respect to Smoking and Working Areas
Dept. 251, Becton Dickinson Company
Columbus, Nebraska

Smoking: Comparing cases to other day-shift workers

Smoke	Case	Control	
Yes	5	2	7
No	6	21	27
	11	23	34

$p < .05$

Smoking: Comparing cases to other workers on all shifts

Smoke	Case	Control	
Yes	5	4	9
No	7	26	33
	12	30	42

$p < .05$

Exposed Area: Comparing cases to other day-shift workers

Exposed	Case	Control	
Yes	11	15	26
No	0	8	8
	11	23	34

$p < .05$

Exposed Area: Cases vs. other day-shift workers (exclude "do not recall")

Exposed	Case	Control	
Yes	11	15	26
No	0	5	5
	11	20	31

$p < .05$

Exposed Area: Comparing cases to other workers on all shifts

Exposed	Case	Control	
Yes	12	19	31
No	0	12	12
	12	31	43

$p < .01$

Exposed Area: Cases vs. other workers on all shifts (exclude "do not recall")

Exposed	Case	Control	
Yes	12	19	31
No	0	9	9
	12	28	40

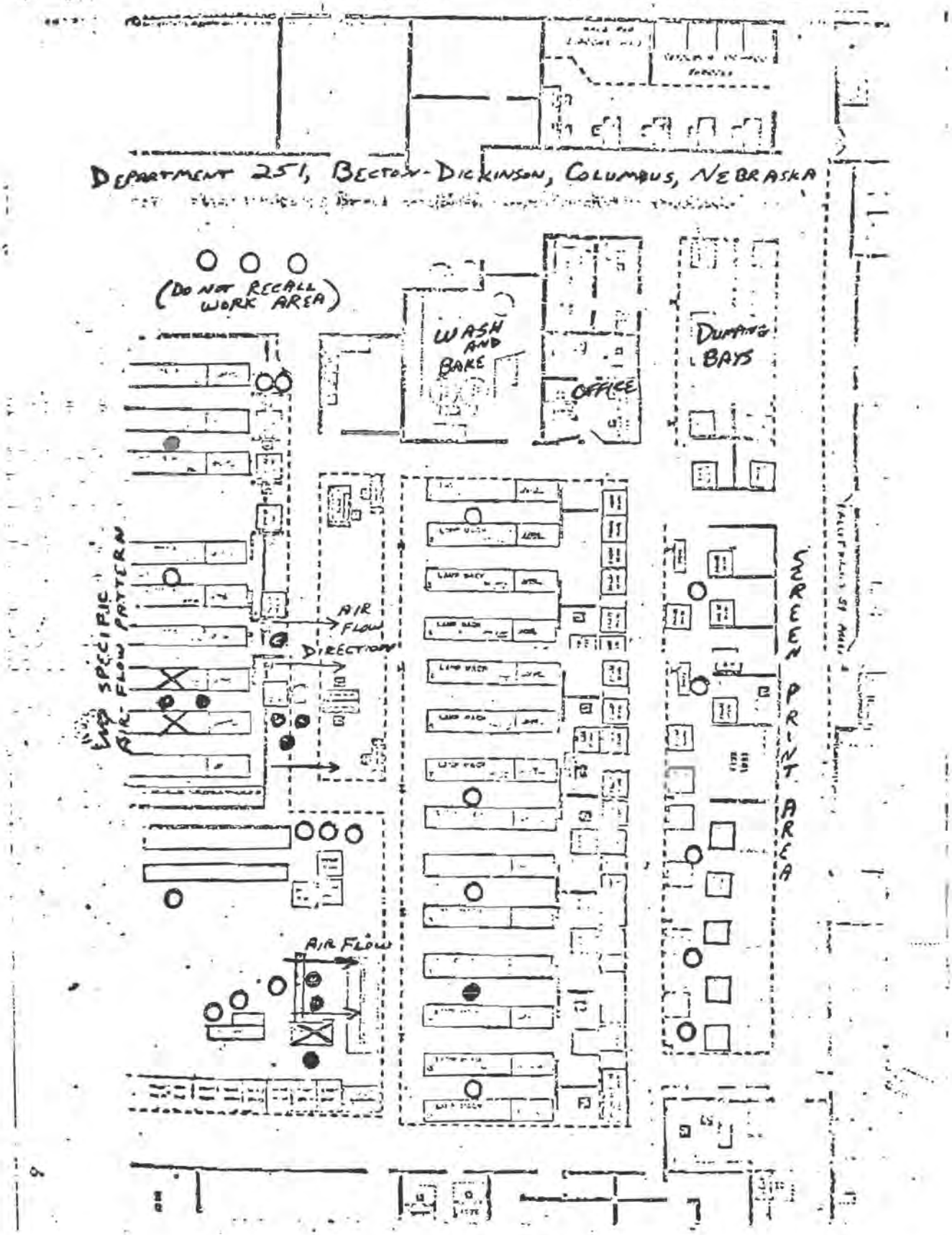
$p < .05$

Exposed Area: Cases vs. other workers on all shifts (add "do not recall" to exposed group)

Exposed	Case	Control	
Yes	12	22	34
No	0	9	9
	12	31	43

$p < .05$

FIGURE 1


DEPARTMENT 251, BECTON-DICKINSON, COLUMBUS, NEBRASKA
(DO NOT RECALL WORK AREA)
WASH AND BAKE
OFFICE
DUMPING BAYS
SCREEN PRINT AREA
AIR FLOW DIRECTION
AIR FLOW

Explanation of Figure 1

Figure 1 - Diagram of Department 251

Darkened circles represent cases and empty circles represent other employees.

An "X" marks the horizontal cutting machine and the two involved lamp machines.

Circles are placed in the approximate areas where day shift employees recalled working on August 10 and 13. Two supervisors and one set-up instructor (all non-cases) are represented in the area near the involved machines, although their jobs involve circulating through the entire department.

Three workers who did not recall in which area they worked on August 10 or 13 are represented in the upper left of the diagram.

The "exposed" area was designated as the area including the cutting machines and all lamp machines (excludes wash and bake area, offices, screen print area, and dumping bays).

Arrows indicate general direction of air movement.

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