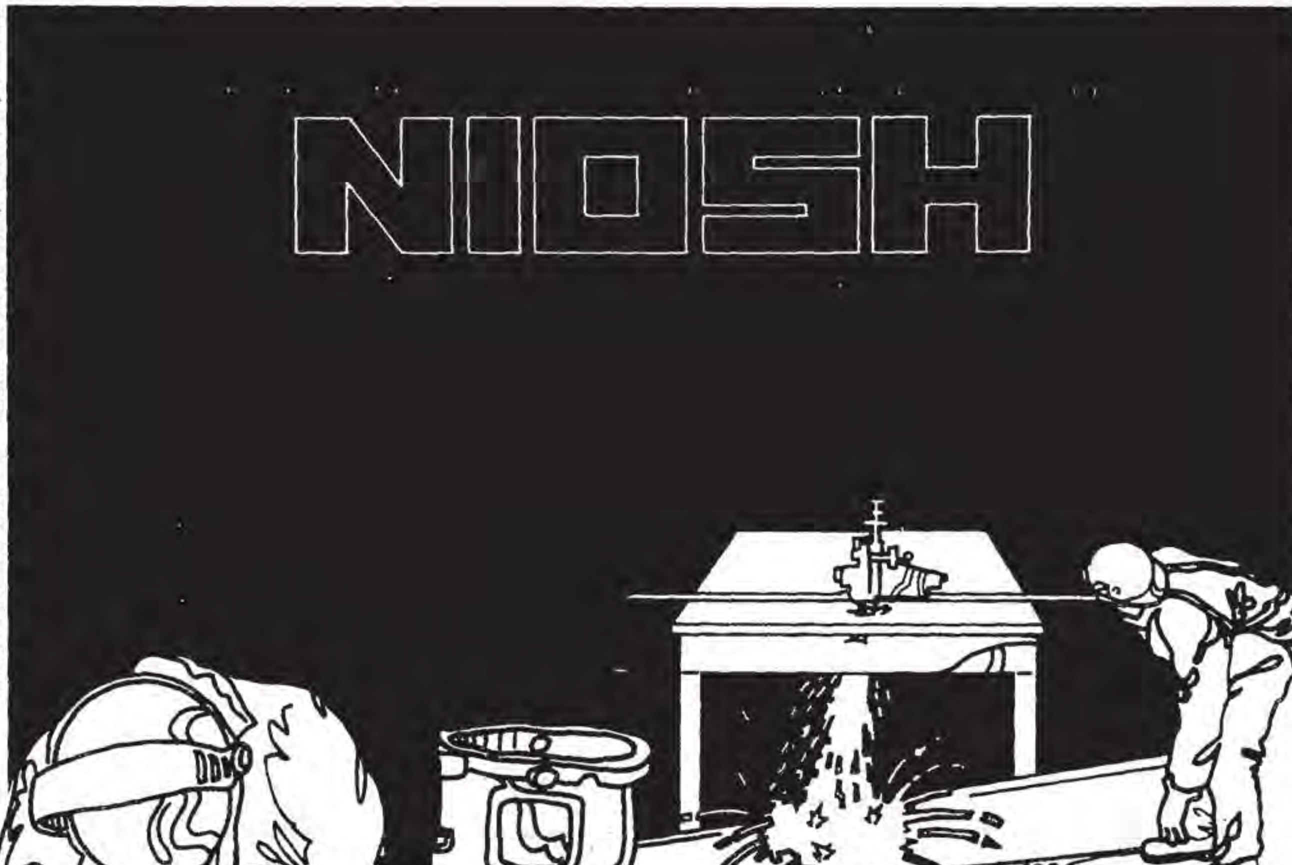
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 81-129-1455
CHEMICAL FABRICS CORPORATION
NORTH BENNINGTON, VERMONT

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. 669(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.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

HETA 81-129-1455
APRIL 1984
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I. SUMMARY

In December, 1980, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate reported impotence among employees of Chemical Fabrics Corporation, North Bennington, Vermont. This plant produces fabric reinforced with fluoropolymers by means of a high temperature process.

In January 1981, the Occupational Health Program at the Harvard School of Public Health, as part of a Cooperative Agreement with NIOSH, conducted an initial site visit at the plant. This was followed by more extensive industrial hygiene and medical surveys in late January 1981 and April 1981. These surveys included environmental monitoring for fluoropolymers and other organic chemicals which might be associated with the process; a questionnaire survey; physical examinations; and blood assays for testosterone and prolactin.

The medical interviews revealed that 5 of the 64 employees interviewed reported persistent erectile dysfunction, but in two of these workers, the onset of the dysfunction occurred prior to their work at the plant. This prevalence is less than that reported in the only published survey of impotence in the general population. There was no clear association between the occurrence of erectile dysfunction and work area at the plant, environmental exposures found in the industrial hygiene survey, a history of polymer fume fever, or the blood tests.

Six of the 28 workers interviewed in April 1981 reported episodes of polymer fume fever. The reported incidence of this disorder were higher among production workers and among cigarette smokers.

The analysis of the environmental samples were complicated by difficulties in identifying the fluoropolymers, pyrolysis products, and certain process chemicals. Since the prevalence of impotence was not excessive, the major effort necessary to determine the precise nature and concentrations of these chemicals was not undertaken.

On the basis of this evaluation, NIOSH concludes that an association between erectile dysfunction and occupational exposures at Chemical Fabric Corporation cannot be substantiated. Recommendations are included in this report to help reduce the incidence of polymer fume fever.

KEYWORDS: SIC 2295, (Textile goods, coated fabrics), erectile dysfunction, impotence, ploymer fume fever, fluoropolymers

II. INTRODUCTION

In December, 1980, the management of Chemical Fabrics in North Bennington, Vermont, requested a NIOSH health hazard evaluation of their plant producing fluoropolymer-reinforced architectural fabric. The purpose of the request was to evaluate complaints of impotence possibly related to workplace exposures among hourly and salaried employees. The onset of reports of sexual dysfunction had been within the past 36 months. The request was made by the ChemFab management following the general medical evaluation by a family practice physician including the initial reports of impotence. An investigation was conducted on January 6, 1981, January 19-21, 1981, and April 22, 1981, to ascertain the extent of the problem, th exact nature of the clinical complaints, the etiology of the symptoms and to characterize the workplace environment. Periodic reports were made to the plant and the employees on the progress of the evaluation.

III. BACKGROUND

The objective of the process is to coat fibrous glass or synthetic fabric with a fluorocarbon polymer to increase the strength and durability of the fabric. The fabric is drawn through an aqueous emulsion of fluoropolymer beads and then through a vertical tower oven, which sinters or melts the polymer into the fabric. The fabric comes in two widths, 3-4 feet and 15-20 feet, and is treated by the yarn manufacturer with an oil base sizig agent that must be burned off ("heat cleaned") prior to processing. This sizing is replaced with a silicone sizing agent that is applied in an aqueous emulsion (with or without fluoropolymer) and is sintered into the fabric.

The emulsions through which the silicone-treated fabric is drawn are aqueous dispersions of PTFE (polytetrafluoroethylene), FEP (fluorinated ethylene-propylene), silicone, or combinations thereof. The fluoropolymer emulsion also contains ammonium perfluoro octanoate and Triton X-100 (an emulsifier and surfactant). The silicone emulsion also included toluene. The behavior of these chemicals as they interreact at high temperatures is quite complex and poorly characterized. The emulsions are mixed and diluted to the required concentrations in a mixing room located off the process floor, and transported to the towers in 30 gallon drums.

During application, the emulsions are placed in a long trough at the base of the oven. The fabric is drawn through the trough and coated, and then through the oven, where it encounters successively hotter zones. The processing of a single roll can involve as many as twelve successive dips at different process temperatures. On successive runs the emulsion water is evaporated, then the surfactant is pyrolyzed, and finally the polymer is sintered into the fabric.

This operation is called a fuse-dip. The operator controls the thermostats on the heating zones, adjusting the gas or electric heaters to maintain proper temperature.

After the polymer processing is completed, further operations may be necessary to finish the product. Two of these operations involve high temperature and/or pressure.

The first of these involves heat-sealing the edges of the wide fabric product with a two-ply PTFE/FEP tape. This is done with a hot (370 - 400 degrees C) press as well as with a pair of hand-held heated pliers. The other finishing operation involoving potential exposure is the lamination of precut one meter squares of product in a high pressure and temperature platform press. These laminates are sawed into smaller pieces and used as structural support elements in circuit boards and instrument panels.

The manufacturing processes are conducted in a large, open area approximately 130 feet wide, 300 feet long, and 20-30 feet high (Figure 1). At one end of the building there are two floors of enclosed offices, an enclosed quality control laboratory and an employee lunch area that is not enclosed. At the other end of the area are the maintenance shops, a large R & D laboratory and mixing rooms and storage areas which are accessible through two sets of doors, but which are not open to the general platn atmosphere. There are no structural barriers to air circulation except for the office and laboratory enclosures, and there is considerable air movement inside the building. To the extent that the offices and laboratories are not airtight and that there is traffic in and out of the offices, mixing of the production area air and the office air can occur.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

1. Sources

Six sources of exposure were identified and targeted for sampling and observation. these sources differ from each other in terms of magnitude, method of heat generation and type of operation. (Figure 1):

Source 1: Towers F and H are electrically heated narrow fabric towers. During the time of the site visit, only Tower H was operating. This tower is adjacent to the slitting department, in which tape is cut to width and rerolled, and is also adjacent to the calender process. Any contaminant generated by Source 1 at ground level would give the highest exposure to the tower operator. The contaminant may also drift into the slitting department and the calender press area, and then enter the general atmosphere of the plant.

Source 2: Towers A-D are narrow fabric, gas-heated towers. The calender press operator also assisted in this area. These men would incur highest exposure in the event of ground level contaminant generation at Source 2, after which the contaminant would be dispersed.

Source 3: Tower E is the older of the two wide-fabric, gas-heated towers. Exposure from this source would initially be experienced most intensely by the two tower operators, and to a lesser degree by the two workers in the adjacent rerolling area.

Source 4: Tower G is the new wide-fabric, gas-heated tower. This tower is located near the loading docks, the belting department, management offices and the employee lunch area.

Source 5: The heat sealer is in the belting department. Local exhaust ventilation was recently installed at the heat press, but the hand-held pliers have no ventilation. The exposures in this area are silicone fumes and pyrolysis products of PTFE and FEP fluoropolymers from the release papers.

Source 6: Laminating occurs only every few weeks for a one-week period. The press is in an isolated area and exposures beyond the immediate area are small. Localized exposures to vaporized fluoropolymer and pyrolysis products could be significant under some circumstances.

Miscellaneous Sources: There are other potentially important exposures that we observed at the plant, particularly air contaminants from the cold emulsions. Volatile compounds are added to the emulsions by the manufacturers and can be smelled during liquid dilution and transfer. Exposures to various chemicals during the maintenance and failure of the abator are also possible.

2. Sampling Methods

Six types of sampling were conducted during the three-day exposure evaluation. Throughout the sampling, pump flow rates were periodically checked for accuracy. Observations of individual work practices were made and amnufacturing process changes were noted.

a. Respirable Mass

Membrane filters were pre-loaded by Millipore into three-piece cassettes. The cassettes were placed into 10 mm nylon cyclones and attached via tygon tubing to personal sampling pumps calibrated at 1.7 liters per minute. The cassettes were capped and frozen until analysis.

b. Total Particulate

Total particulate samples were collected on membrane filters in closed face cassettes, through which air was drawn at 1.7 liters per minute. The used filters were frozen until analysis.

c. Total Particulate Sampling (High Volume)

A high volume sampler was used to collect the total particulate on glass fiber filters. The flow rate was 40 cubic feet per minute. Sampling was done for approximately 8-hour periods coinciding with the 8-hour work shifts.

Two sets of hi-vol filters were used. One set was taken during the evaluation period of January 19-21. The hi-vol sampler was raised approximately twenty feet above floor level at a site directly across from the belt department, on the opposite side of the storage racks. This site was used for all samples.

The second set of samples collected in March, 1981, were pre-weighed, then reweighed to measure their total weight gain. Used filters were wrapped in foil and frozen until analysis.

d. Organic Vapors

Area samples were collected on silica gel and charcoal tubes using low flow pumps (100 cubic centimeters per minute). On the first sampling day, samples were collected for 1-4 hours alternately using silica gel and charcoal tubes at each location. On the second and third days of sampling, silica gel and charcoal tube samples were collected in parallel. All used tubes were sealed and frozen until analysis.

e. Total Particulate and Organic Vapors

Area samples were taken using large charcoal tubes in line with cellulose membrane fiters at a flow rate of 780 cubic centimeters per minute. The filters were placed in front of the charcoal tubes in order to remove any particulates that could have collected on the charcoal. The tubes and filters were capped after use and frozen.

3. Analytical

a. Sample Preparation

The personal filters were cut in two. Because the health complaint of sexual dysfunction was possibly neurologically based, lipid soluble compounds were examined by extracting the filters in toluene. To one half filter, 10 ml of toluene was added and the samples were ultrasonicated for 30 minutes. Four ml of the solution were pipefitted into a vial and then evaporated to dryness. The sample was then dissolved in 2 ml of methanolspiked with .437 mg benzene per liter added as an internal standard and separated by liquid chromotography.

Discs of 37 mm diameter were cut from the high volume filters. These were then treated in the same manner as the personal sample halves.

Material which had condensed in the ductwork leading to the combuster of Tower G was collected as possibly representative of some of the air contaminants. This black material was dissolved in toluene. Aliquots were deposited on filters, which were treated as the personal samples.

To prepare solutions of the raw materials used in the process, 0.4 ml of material was added to 8 ml of methanol containing 0.5 mg benzene per ml methanol. This suspension was extracted ultrasonically for 10 minutes. To remove those materials which would be retained on the liquid chromography column, the mixture was then passed through a C_{18} SepPak from Waters Associates. The eluting solutions were then chromatographed.

b. Gas Chromatography

First, an SE 30 Hiplate column was used to attempt separation of sample components. A flame ionization detector was used, and the chromatographs were run both isothermally at 250 degrees C and with temperature programming starting at 56 degrees C and rising at 10 degrees per minute to 35 degrees C, where the temperature was held for ten minutes. Samples from the high volume filters extracted in carbons disulfide, DMSO, and diethyl ether were injected.

In addition, two sets of filters with charcoal tubes were sent to MetPath Environmental Laboratory for gas chromatography mass spectrometry analysis. One was an area sample from the heat seal press and the other an area sample from Tower G. Both the charcoal and the filter were desorbed with carbon disulfide and the resulting solutions were injected directly into a gas chromatograph. A flame ionization detector and a mass spectrometer were used with a 10% AT-100 column. A mass spectometer detector was also used with a Chromosorb 102 and a 3% SP-2250 DB column. All columns were 6 ft. x 2 mm ID, and the temperature program increased at 10 degrees per minute to 220 degrees C, except for the 3% SP-2250 DB column, which reached 260 degrees C.

c. Liquid Chromatography

All samples and material were chromatographed on a Waters Associates high performance liquid chromatograph. The separation was carried out on a umBondpac C_{18} column, 3.9 mm ID x 30 cm, 10 um particle size. The gradient was program 2, going from 75% methanol/25% water to 100% methanol. Initially, 50 ul injections were made, but these were soon increased to 200 ul, which were used for most analyses.

Samples were automatically injected by the 710B WISP, pump by the model 6000 and model 45 solvent delivery systems controlled by the Model 660 Solvent Programmer. The eluting compounds were monitored with a Model 440 Absorbance detector at 254 mm and 280 mm with the use of the model 730 data module, which printed the chromatograms, determined retention times, integrated the areas under the peaks, and calculated the amount of material present using the benzene internal standard and assuming a response factor of 0.1010 for all compounds. All samples were run in duplicate and the concentration results were averaged.

B. MEDICAL

During the initial walk-through site visit, three of the affected men were interviewed. This initial interview served as a guide for constructing a focused health and work history questionnaire and survey conducted three weeks later. At this time, all available employees were asked to volunteer to be interviewed concerning job description, smoking and hygiene habits, general medical history, respiratory, neurologic, and genito-urinary symptoms. They completed the American Thoracic Society (ATS) Respiratory Questionnaire (14), as well as the Profile of Mood States (15). They were also interviewed by a physician regarding specific medical and sexual histories, alcohol and drug use, and job-exposure description. Each step of the medical evaluation with the exception of the medical interview was performed with the examiner "blinded" as to which individual was symptomatic or not.

Medical examination was performed on all volunteering subjects. This included vital signs, vascular and general neurological exam. Males were also examined for sensation to the penis and saddle regions, testicular size, and Bulbocavernosus Reflex. The Bulbocavernosus Reflex is a segmental polysynaptic reflex with cross-over in the sacral spinal cord and is tested by compression of the glans penis, grading the reflex contraction of the external sphincter ani from 0 to 2+(16), where 0 is decreased, and 2+ is normal.

Laboratory investigation included complete blood count, differential white blood cell count, erythrocyte sedimentation rate, and serum levels of BUN, creatinine, glucose, SGOT, LDH, SGPT, alkaline phosphatase, uric acid, bilirubin, globulin, albumin, calcium, phosphorus, iron, testosterone, and prolactin. Urine was collected for the 16 hours away from work for creatinine and drug analysis, as well as flouride analysis (total and organic). Urine and serum samples were obtained for spectrographic and chromatographic "finger-printing" analysis.

A follow-up survey was conducted in April, 1981, after preliminary results of the initial health survey served to focus attention on several specific areas: the exact nature of exposures in the plant, prior jobs (in and out of this plant), details of the sexual history, polymer fume fever history, duration of sexual symptoms and fume fever symptoms in relation to exposure. The follow-up survey focused on the 10 male subjects reporting sexual dysfunction on the first survey plus 18 other men who were symptom-free but similar in age and duration of work.

A case of male erectile dysfunction was defined as difficulty in getting an erection either during sexual intercourse or masturbation except on rare occasions (17). The time course of symptoms of erectile dysfunction and its persistence or resolution were documented during the follow-up survey (April). All male employees who worked at the plant were assumed to be at risk except those with known erectile dysfunction prior to exposure.

The medical evaluation revealed that a number of men had experienced episodes of polymer fume fever. A case of polymer fume fever was defined as shaking chills, myalgias, shortness of breath or chest tightness and malaise with or without measured increase in temperature occurring near the end of or after a work shift, and complete recovery within 24 hours (18). "Incomplete" or "partial" polymer fume fever is defined as a combination of myalgias or headache or chest tightness, throat irritation and/or cough, but no shaking chills or measured increase in body temperature and quickly aborted by 10-30 minutes of fresh air.

V. EVALUATION CRITERIA

A. Environmental Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended standards, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet only those levels specified by an OSHA standard.

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 or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

B. MEDICAL/TOXICOLOGAL

Male erectile dysfunction induced by exposure to workplace toxins has not been reported in the absence of bladder dysfunction. Kreiss et al., reported a bladder neuropathy due to dimethylaminoproprionitrile (DMAPN) which caused severe bladder symptoms, most of which were reversible after removal from exposure to the catalyst (1). Some of the men affected by the bladder neuro-toxin, which caused bladder sensorimotor neuropathy, also complained of erectile dysfunction which did not necessarily improve when exposure ceased and bladder function improved (1). Siroky et al., performed Sacral Signal Tracing on a patient with erectile dysfunction after perchlorethylene exposure, but this patient also complained of urinary retention, and had a toxic peripheral neuropathy (3).

Proper sexual function depends on a sexually mature state (psychological), effective vasocongestive action (erection), adequate androgenic hormones, and ejaculation. Erection and ejaculation are complicated reflex responses involving both divisions of the autonomic nervous system (4). In man, efferent neural impulses for erection are thought to arise from parasympathetic fibers in sacral cord roots S_2, S_3 and S_4. These are the same spinal roots that provide efferent (paraysympathetic) supply to the detrusor muscle of the urinary bladder and to the distal colon and rectum (5). Thus, the pelvic nerves from the sacral cord segments conduct the parasympathetic impulses for erection, urination, and defecation. Men with partial spinal cord injuries but intact pelvic nerves frequently have a dissociation of bladder, bowel, and erectile function e.g., normal bladder and bowels, but erectile dysfunction. Similarly, damage to nerves in the pelvis may alter one of these physiologic functions without affecting the others. Hence, although the neural pathways may be similar, they are not identical. In increasing order of vulnerability are bowel, bladder, then erection (6).

Research on the role of higher centers and other spinal cord segments reveal that an outflow from the thoracolumbar cord acts synergistically with the spinal parasympathetic outflow to mediate penile erections (5,6). The sacral erection center receives reflex-arc input from both local stimuli (via the pudendal nerves) and from psychic (mental) stimuli originating in the higher centers of the CNS. The thoracolumbar center receives reflex-arc input from the higher centers of the CNS but not directly from reflexogenic stimuli (4). The failure of direct electrical stimulation of these nerves (in animals) to produce penile erection may be attributed to simultaneous stimulation of the antagonistic fibers. Presumably an erection-mediating (vasodilator) component is selectively activated by erotic stimuli. In normal males it is difficult to assess the relative contributions of the thoracolumbar (sympathetic) and sacral centers (parasympathetics) in producing erections, but it is clear that in cases of complete impotence the outflow from both centers must be compromised.

As noted above, the higher centers, or cerebral contribution to erection, is also important. The cerebral localization of penile erections in humans is not clear. Indeed, little is known about the physiologic mechanisms and anatomic pathways that mediate cerebral inhibitation of erection. This information would be essential in understanding the psychological causes of erectile dysfunction (7).

Hormonal factors also contribute to normal erections. A sufficient amount of circulating androgen is required to permit adequate male functions. However, normal adult men show a wide range in plasma testosterone concentrations and the mechanism by which androgens influence male sexual function is unclear.

Circulating testosterone levels are not stable and are characterized by fluctuations superimposed on a circadian rhythm with peak testosterone concentrations occurring in early morning (8). There is also recent evidence that psychological/psychosocial stress may depress plasma testosterone (8,9). However, there is as yet no evidence for a relation between circulating androgen levels and differences in sexual behavior (10).

The last essential factor for normal erections is normal hemodynamics. The actual transformation of the penis from a flaccid to an erect state is a vascular pphenomenon. Blood reaches the penis via terminal branches of the right and left pudental arteries. These arteries carry blood to the "erectile tissues" of the penis, the corpora cavenosa which lie side by side on the dorsal aspect of the penis. The corpus spongiosa surrounds the urethra. During erection, these vascular spaces are transformed into large cavities distended with blood at high pressures because the rate of arterial inflow is temporarily greater than venous outflow, thus causing an increase in penile volume (4). A steady-state is reached, where the rates of inflow and outflow are equal and the penis will no longer increase in size but remains rigid. Detumescence results from vasoconstriction of the penile arteries with subsequent decrease of arterial blood flow, decrease in pressure, and release of compressed veins (5).

There are a number of organic causes of erectile dysfunction. Broadly characterized, these include: systemic disease with diabetes mellitus being the most common, but also alcoholism (via 2^o hypogonadism, not cirrhosis (11)), hypopituitarism, etc.; local disorders such as congenital abnormalities and inflammatory lesions; vascular disease such as spinal cord lesions or toxic neuropathy, drugs such as antihypertensives; and surgical procedures such as prostatectomy. Endocrinopathies such as hyperprolactinemia and hyperthyroidism are also well-documented causes.

DMAPN is unique among neurotoxins in that it produces mainly bladder dysfunction, possibly by a urine-concentrating effect and in a minority of cases, male sexual dysfunction. To produce erectile dysfunction in the absence of bladder dysfunction would imply an even more specific, purely autonomic toxin, which affected erectile function but not bladder or bowel function (4,5,6,12,13).

VI. RESULTS

A. ENVIRONMENTAL

1. Observations during the Environmental Survey

Source 1: Over the course of the three days that we spent in the plant, Tower H was the only tower operating in Source 1 that was doing dry-fuse and fuse drip runs. At no time was visible contaminant generation noticed, and discussions with the operator, the only female operator in the plant, indicated no unusual process conditions.

Source 2: The four gas heated narrow fabric towers (A-D) were all operating during the observation period. No visible contaminant generation was observed here, although the marks on the ceiling near the towers indicate that emissions may have occurred in the past.

Source 3: No complaints were received from either of the two operators of the old wide tower (E). No smoke was generated when this tower was operating during either of the surveys.

Source 4: The new wide fabric (Tower G) was observed to produce significant amounts of visible emission. Five minutes after start-up, the center portion of the tower, between the ascending and descending fabric, began to fill up with smoke near the Local Exhause Ventilation (LEV) takeoff. In a few minutes the entire center portion would be quite smoky, and the contaminant would begin to flow out from beneath the baffle that surrounded the tower and hung from the ceiling to within 15 feet of the floor. The smoky emissions were hot, and flowed up to the ceiling by convection. Within 15-20 minutes, a distinctly visible white haze was apparent at the end of the plant near Tower G. Workers in the lunch area, the loading docks, the belting department, and management offices were exposed to the contaminants reaching ground level. The emissions from Tower G accumulated near the ceiling so the workers who spend time near the ceiling, e.g., maintenance workers doing work at the top of the ovens, would have the highest exposure. No runs with silicone were made during the time of the survey, but it was reported that smoke generation during these runs is worse than that observed.

It was observed that the plant atmosphere cleared quickly when the loading dock doors were opened, allowing escape of the warm contaminated air through the roof vent. It also appeared that the smoke generation at the tower was reduced. An undesirable side effect was that the temperature inside the plant was noticeably lower in the winter.

Source 5: The heat sealing procedure was observed twice during the survey. The highest exposure occurred when the hand-held pliers were used to melt the PTFE/FEP onto the product. This operation is unventilated, and visible fumes drift upward into the breathing zones of men performing the operation and those nearby. Most of the heat-sealing, however, is done in a three-foot long horizontal press, which was unventilated until immediately after the January 6, 1981 visit to the plant, when a small hood was installed over the press. Although it is not 100% effective in eliminating exposure, exposure has been reduced.

The men in the belting department were aware of the irritating effects of the smoke. They also reported that the fumes generated when fresh silicone paper was used to cover the heated elements of the press were especially irritating.

Source 6: The laminating press was not observed in operation by industrial hygiene personnel. It is quite possible that contaminants could be produced during this process since it uses high temperature, the working surface is at breathing level, and the press area is unventilated.

There are several process parameters which vary from one run to the next, and they could affect the amount and the nature of the contaminants generated from Sources 1-4:

- Use of emulsion: in general, contaminant generation rate will increase as the amount of pyrolyzable material on the fabric increases. Any run in which an emulsion is used will generate more smoke than a dry (no emulsion) run. The important exception to this is the "heat clean," in which large amounts of oil base starch are pyrolized off.

- Silicone: workers reported that more contaminant is reportedly generated in a dip through an emulsion containing silicone.

- Fabric fiber weight: more contaminant is expected to be generated with small fiber weights and tighter weaves due to increased surface area available for absorption of emulsion.

- TDype of fluoropolymer: product information from Vermont shows that FEP decomposes much more rapidly than PTFE at elevated temperatures. Increased FEP concentration in the emulsion will increase the contaminant generation rate.

- Sequence of dips: it was reported that the earlier dips on a roll of fabric tended to be more smoky than the late dips.

It is known that many of these variables change from run to run, but it would be impossible to suggest what the overall effect would be. It is possible, however, to predict that some emulsion treatments, e.g., a high specific gravity silicone/fluoropolymer dip run at high temperature, could be expected to generate more contaminant than other treatments.

On a more general level, there were many opportunities for skin contamination and the ingestion of chemicals. Much splashing and skin contact occurred during liquid transfer, and employees ate, drank, and smoked at their work stations.

It was also observed that the potential exists for hazardous exposure during abator maintenance. With some types of emulsion runs, the catalyst must be removed and cleaned weekly. Cleaning, which is accomplished by blowing off the silica that forms on the catalyst with compressed air in an unventilated area, is a very dusty operation. The white silica that clogs the catalyst was reported to be an oxidation product of the silicone compounds. Further discussions with several plant personnel provided different reports of how much respiratory protection is used during catalyst cleaning. As a result, exposure to silica dust may occur to a greater extent than work practices are designed to permit.

2. Analytical

a. Gas Chromatography

Only the solvent peaks were detected in the gas chromatography on the SE 30 Hiplate column. MetPath Evironmental Labs reported that five different components were separated from the filter samples, but only toluene was identified. Six components were detected in the charcoal tube samples, but again only toluene was identified. Reportedly the concentration of the other components was too low for satisfactory mass spectra.

b. Liquid Chromatography

Liquid chromatography was used to separate the components of the air samples as well as the raw materials. The methanol extracts of air samples were separated into between 11 and 24 different components; the raw materials were separated into between 12 and 21 chromatographic peaks; and the chromatogram of the black condensate had 22 peaks.

Almost all the chromatographic peaks found in the exposure samples match the rentention times of the components of the raw materials. The major exception was the material which eluted at 2.08 minutes; this material was found in about two-thirds of the samples, often as a large peak. The only other exception was a very small peak with rentention time of 6.5 minutes, which was found in one personal sample from the slitters, one from the calendar operator, one area sample and a personal sample from Tower G, and an area sample from the heat seal press.

Qualitatively the chromatograms of the air samples are remarkably similar to each other. This similarity is probably due to the fact that the air mixes and flows throughout the building. Only ten rooms, offices and labs, are enclosed. During the walk-through of the production facility one could see that the ventilation system was not capturing all the emissions. This mixing and free flow of air probably makes exposure qualitatively homogeneous throughout the plant, excluding the work stations immediately adjacent to contaminant sources.

From Table 1 one can see which job categories or areas of the plant have relatively high exposure to the compounds represented by the rentention times given. The cutoff values used for each peak are given at the bottom of the page. At least half of the samples in each category had to be above the cutoff level of a given peak in order for exposure to be designated as high (H).

The major area of variability which can be seen from inspection of the chromatograms is the area of the peaks with retention times 1.68, 2.08, and 2.28. For instance, the twelve personal samples taken from near the towers (Towers E, G, B and the gas Towers) were quite similar to each other, and the eight area samples from all the towers were quite similar, but the area samples had much smaller peaks at 1.68, 1.08, and 2.28 than the personal samples. By contrast, the tower area samples had a large peak with retention time 4.35, which was larger than the personal samples. Samples taken from near the heat seal press have larger peaks with retention times of 7.2 and 7.7 than do any of the other samples.

During the walk-through inspection of the plant, three basic sources of exposure were identified: the towers in which the fabric was actually coated, the heat sealing operation in the belt department, and the laminating operation. Both the area and the personal samples taken in the laminating area contain relatively high levels of components with retention times of 1.68, 2.08, 2.28, and 4.35 minutes; the area samples also included one with a 5.80 minute retention time. The area sample from the heat seal press was high in all these compounds as well as in those eluting at 7.1 and 7.85 minutes. Two of th personal samples were low in all these compounds, but the third was high in the components with retention times of 2.08 and 5.80 minutes. These results are probably due to the employees not working adjacent to the heat seal press at all times.

Because smoke was emanating from Tower G and some people had reported that the health effects started after the new wide tower G began operation, a comparison of air levels near this tower with those from the old wide Tower E, was undertaken. Generally, the levels of materials averaged over a work shift near Tower G were slightly but not significantly higher than the average levels near Tower E, in spite of our observation of occasionally large amounts of visible emissions from Tower G. This may not accurately reflect the quantity of emissions because the samplers were not placed to measure the emission rates, but rather to measure area levels. Also, these electric tower emissions were not very different from those of the gas Towers A, B, C, and D.

The offices on the second floor had lower levels of exposure to the components studies. The cafeteria had higher levels of components with retention ties of 1.68, 2.08, and 2.28, but other components were at lower levels.

B. MEDICAL

Of the 100 plant employees, 86 participated in the January survey. Five of the 86, however, refused to answer questions regarding sexual function. Of the remaining 14 non-participants, 11 were women either away on vacation or declining participation. Thus, 81 percent of the total employees and 96 percent of the male employees were surveyed in January 1981. The January survey included complete health, smoking and work questionnaires, a physical exam with attention to the genito-urinary and neurologic systems, and blood assays of testosterone and prolactin as well as complete blood counts and chemical screen were completed on all 86 participants.

A follow-up survey was performed in April, 1981. Complete questionnaires were obtained on 28 male employees; ten of these were employees who had been identified as having erectile dysfunction during the January survey, and 18 were a stratified sample of the remainder of the work force similar to each other in age and type of employment at the plant.

1. Erectile Dysfunction

Ten of the 64 males surveyed in January responded positively to questions regarding sexual dysfunction within the preceding 36 months. Three of these males had returned to normal function at the time of the January survey. Two others had normalized between January and April. Therefore, as of April, five men met our case definition of persistent erectile dysfunction, and five others were classified as transient erectile dysfunction that had resolved at the time of the resurvey. Two of the persistent cases revealed that the onset of erectile dysfunction preceded their employment at Chemical Fabrics.

The onset and duration of persistent and transient erectile dysfunction among employees is displayed in Tables 2 and 3. As displayed, four of the five transient cases, and one of the three persistent cases associated with employment had onset within six months of the January survey.

Cases of persistent erectile dysfunction have been reviewed in detail. All of the cases except one had normal physical exams and chemical tests; this one employee had atrophic testes and a mildly elevated prolactin level and had undergone evaluation for impotence prior to his employment at Chemical Fabrics. Likewise, another employee had noted onset of sexual problems prior to employment at Chemical Fabrics. Of the cases with onset since employment at Chemical Fabrics, two worked in the belting department, and one worked in maintenance. No obvious cause of erectile dysfunction unrelated to their employment was discovered in the physical exams, blood studies of these cases or psychological profiles.

Cases of transient erectile dysfunction were also reviewed. All cases of transient erectile dysfunction reported normalization of function as of the April survey. All had normal physical exams and blood tests except one who had an elevated blood glucose. All abnormal test results have been communicated directly to the employees involved, and to their physicians if so indicated by the employee.

Exposures measured on the days surveyed were not correlated with the occurrence of erectile dysfunction. The three cases of persistent erectile dysfunction (from the maintenance and beltmaking departments) worked in areas with relatively low general exposures on the days surveyed.

Since the available data suggests that the prevalence of erectile dysfunction increases with age, we stratified by age and prevalence of erectile dysfunction on the study population (Table 4). This table demonstrates that the overall prevalence of persistent erectile dysfunction (including those with "pre-exposure" erectile dysfunction) was 7.8 percent. When the "pre-exposure" cases of erectile dysfunction are excluded the prevalence drops to 4.8 percent.

In order to further explore a possible relationship between erectile dysfunction and plant exposures, we divided the cohort into "production area" jobs and "non-production area jobs" based on the approximate number of hours spent on the general shop floor per week. The overall prevalence for the production area was 10.5%, including pre-exposure cases (one from the production area, one from the non-production area), and was 3.8% for the non-production area.

Age stratification revealed that in only one of the cases of persistent erectile dysfunction that had occurred since employment was the worker under 50 years of age. The age specific prevalence rates are reported in Table 5.

Female participants in this survey, which included two production area workers and 15 office workers, all gave negative histories for bladder or sexual dysfunction, peripheral neuropathy, or polymer fume fever symptoms.

2. Polymer Fume Fever

Detailed respiratory, smoking, and polymer fume fever histories were obtained on the 28 males in the April survey because of concern about polymer fume fever symptoms revealed during the January survey. As mentioned, polymer fume fever (PFF) was defined as shaking chills, myalgias, shortness of breath, chest tightness, and malaise with or without a measured increase in body temperature, which occurred near the end or soon after the end of a workshift, and had complete resolution of the symptoms within 24 hours (19). This syndrome is reported only in workers that are exposed to the pyrolysis products of fluorocarbon polymers, but is otherwise similar in presentation to metal fume fever (20).

Six of the 28 male employees in the April survey had experienced between one and ten episodes of classical PFF since the plant's relocation in 1978. Smokers in the production area (27.8 percent) are the most likely to get symptoms of PFF (Table 5). No non-smokers, and only one smoker from the non-production area gave histories of classical PFF.

Information was also obtained on a symptoms complex referred to as "partial" or "incomplete" PFF. This complex was characterized by a combination of myalgias, headaches, or chest tightness, throat irritation and/or cough, but no shaking chill or measured increase in body temperature, and with symptoms subsiding after 10-30 minutes exposure to fresh air.

Fourteen of 28 employees reported between one and "100" episodes of partial PFF since 1978. All of the cases occurred in workers from the production area and were evenly divided between cigarette and non-cigarette smokers.

VII. DISCUSSION AND CONCLUSIONS

1. Erectile Dysfunction

The purpose of this health hazard evaluation was to investigate the possibility of workplace exposures causing an increased prevalence of sexual dysfunction in the male workers. If exposure does lead to erectile dysfunction, an increased prevalence among exposed workers compared to unexposed workers in the same factory (if indeed such groups can be identified that are otherwise comparable in terms ofage, race, education, etc.) would be expected. An increased prevalence in comparison to otherwise similar bur unexposed working "control" groups in other factory situations might also be expected.

Unfortunately, no data were available on the expected prevalence of erectile dysfunction in working populations. The only prevalence data that is available stems from the kinsey data collected between 1933 and 1968 in which working populations were relatively under-represented. Kinsey's data showed a prevalence of "erectile impotence" of 18.9 percent in white, non-college educated males, and 5.6 percent in college educated males where "erectile impotence" is defined as "impotence other than incidental", and "incidental" pertains to: 1) justifiable due to drunkenness, fatigue, interruption, and, 2) impotence which occurs rarely or infrequently (17).

Our study showed an overall prevalence of persistent erectile dysfunction (essentially equivalent to Kinsey's "erectile impotence") of 7.8 percent (5/64) for all male employees, and 10.5 percent (4/38) in production area workers. Since none of the production area workers had college degrees, and all were white, the prevalence in the production area workers, and the employees as a whole, was not elevated when compared to Kinsey' data.

As with Kinsey's data, our data indicated an increasing prevalence of persistent erectile dysfunction with age.

No data were available, from Kinsey or otherwise, on the expected incidence or prevalence of transient erectile dysfunction. Psychologic causes of transient impotence have been described previously. Undoubtedly, organic causes of such transient dysfunction (such as drug induced) also exist and it is therefore conceivable for a transient syndrome to be caused by workplace exposures. However, since all of these cases of transient erectile dysfunction resolved without any changes in exposures, and there was no obvious "clustering" of cases by work area, it is doubtful that a workplace exposure is responsible. It is possible the clustering time in the six months preceding our investigation is likely to be due to short term recall which might over-represent recent reports of impotence. It is also possible that an unidentified source of exposure was responsible for the clustering. This does suggest the need for surveillance to determine whether this is the expected frequency of reports of transient erectile dysfunction implicated from this study.

The process of identifying the agents(s) associated with partial PFF was begun in this study. It is clear from the analytical results that there are many air contaminants in the production area, and there was no simple means of identifying which might have contributed the effects. We concluded it would be a major undertaking to perform the necessary industrial hygiene, analytical chemistry and toxicological work to determine the precise nature of the air contaminants and their individual and joint effects. We were not able to demonstrate any association between episodes of classical or partial PFF and erectile dysfunction.

We conclude that the prevalence of erectile dysfunction in this working population in comparison with available data is not elevated and thus an association with workplace exposures is not substantiated.

2. Polymer Fume Fever

The finding of an association between cigarette smoking and classical PFF in this population was not surprising. This has been a frequently noted aspect of polymer fume fever since the syndrome was first described in 1951 (18,21). It is thought that the high temperatures at the burning end of a cigarette cause pyrolysis of fluorocarbons that have contaminated the cigarettes in the workplace (22). Polymer fume fever is generally thought to be a "self-limited: and therefore, a "benign" illness. At least one report, however, suggests that recurrent episodes of PFF may lead to pulmonary fibrosis and the "alveolar-capillary block syndrome" (23).

To our knowledge, information on "partial" PFF has yet to be reported. Based on what is known about classical PFF, the partial syndrome appears to be a self-limited illness which may be associated with pyrolysis products of fluorocarbons. Partial PFF may essentially represent an "aborted" case of classical PFF. However, this may also represent a totally new problem unrelated to PFF.

We concluded that "partial" PFF was also work-related. The significant association of partial PFF to the production area environment and lack of association with smoking supports our supposition of exposures to some agent(s) in the production area. It also suggests that the partial syndrome is a response to work exposures to which smokers and non-smokers are equally susceptible. There are, however, a variety of materials other than fluorocarbon polymers in this work area and so pyrolysis products of the fluorocarbons alone cannot be on the shop floor. Hand washing before smoking and eating should be strongly encouraged, and the cafeteria should be located in an enclosed area that does not receive air from the production floor. No cigarettes should be carried in work clothes, because they may become contaminated.

The occurrence of partial polymer fume fever (PFF) was related to work in the production area, particularly in the work area of material used or formed in the production operation. General improvement in the collection of air contaminants may reduce the occurrence of partial PFF. More detailed industrial hygiene evaluation of air contaminant levels, their sources, and relationship to production activities would be helpful in guiding the choice of a control strategy. Based on our limited visual observations, Tower G appeared to be a major source of air contaminants, therefore improvements in ventilation on Tower G may help reduce the general air contamination level.

As noted previously, considerable industrial hygiene work and toxicological research would be needed to identify the agent(s) that cause partial PFF. This level of effort is beyond the scope of the HHE program. Given that the syndrome is mild, self-limiting, and clears up spontaneously, it may not warrant a major research effort to identify the causes. Since there is a remote possibility of subtle cumulative effects that may lead tochronic respiratory impairment with long-term exposures, the annual physical examinations should also include pulmonary function testing and a brief questionnaire on respiratory symptoms. Then a periodic (every five years) epidemiologic review of the experience of the workers in the production area could detect any subtle long-term effects, if they occur.

VIII. RECOMMENDATIONS

1. We recommend that the cases of persistent erectile dysfunction be advised to seek evaluation by an endocrinologist or urologist expert in problems of sexual dysfunction. Reports of our findings and data have been communicated to these affected workers and they have been advised to obtain further evaluation.

2. To protect against the small possibility that the cluster of transient erectile dysfunction is work related we recommend that the annual physical exams and health histories include details on sexual and neurological functioning. Records should be kept to document the prevalence and detect any clustering of sexual dysfunction for the next three to five years. This should provide adequate warning if any clustering is real. Since partial and classical polymer fume fever were observed, we suggest that the annual history should also include questions about episodes of polymer fume fever.

3. Although there are warning labels on the equipment and materials, workers should be made aware of the symptoms and signs of polymer fume fever as well as its close association with cigarette smoking. All smoking should be prohibited.

4. Since some workers, particularly maintenance workers, may spend time at the top of the towers where hot air contaminants may accumulate, they should be provided with respiratory protection during these times, such as half mask respirators with cartridges approved for organic vapors and fumes. They may be at risk of both PFF and partial PFF in these areas.

IX. REFERENCES

See Appendix I.

X. AUTHORSHIP AND ACKNOWLEDGEMENTS

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Division of Surveillance, Hazard Evaluations, and Field Studies

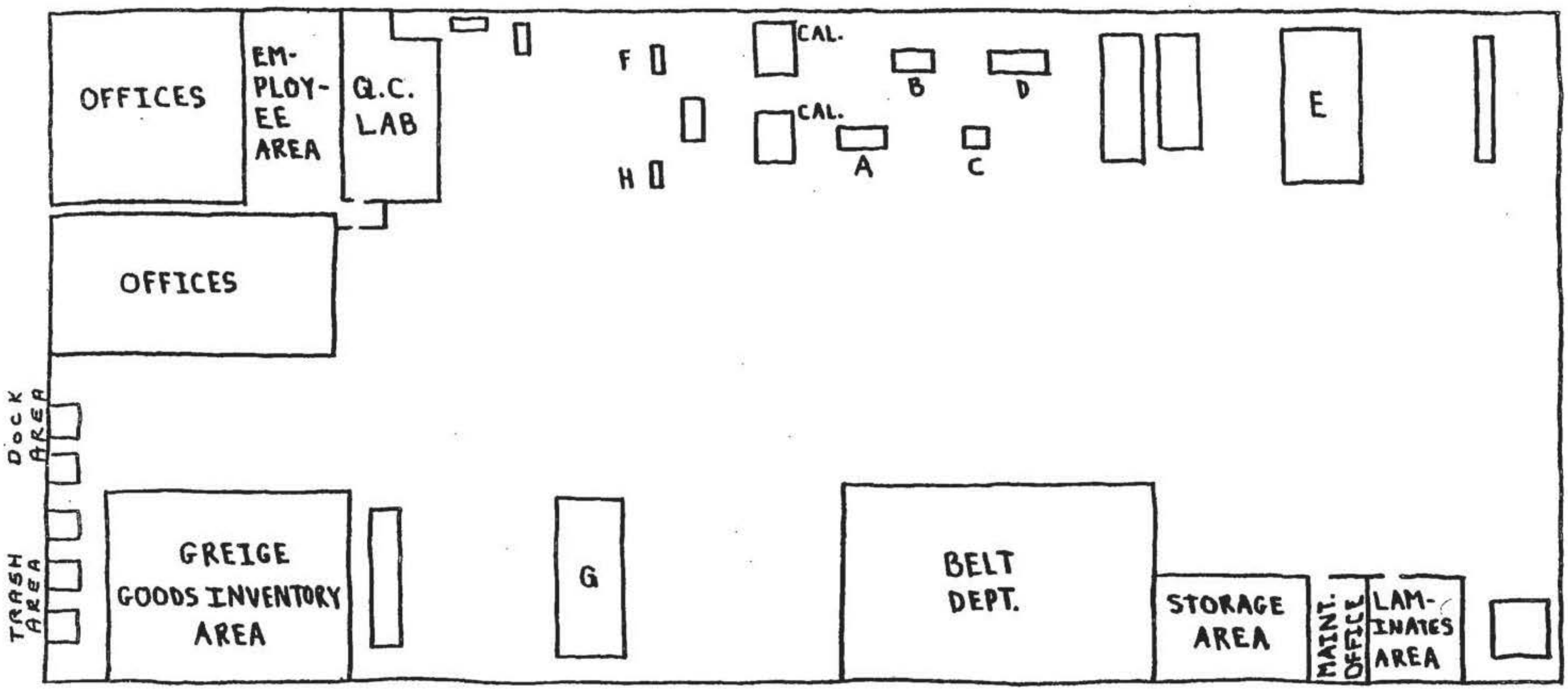
XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Publications 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, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. Chemical Fabrics
2. NIOSH, Region I
3. OSHA, Region I

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

FIGURE 1



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Fire Safety Plan
Scale, 1" = 30'

TABLE 1 - AREA AND JOB CATEGORY SAMPLES WITH HIGH CONCENTRATIONS AT MAJOR RETENTION TIMES

JOB/AREA	NO. SAMPLE	RETENTION TIMES 1.68	2.08	2.28	4.35	5.80	7.10	7.85	8.85	9.35
Slitter	6P	--	--	--	--	--	--	--	--	--
Gas Tower	3P	--	H	--	--	H	--	--	--	--
Tower E (old wide)	3P	H	H	H	--	--	--	--	--	--
	3A	--	--	--	H	--	--	--	--	--
Tower G (new wide)	6P	H	H	H	--	--	--	--	--	--
	2A	--	--	--	H	--	--	--	--	--
Tower B	3A	--	--	--	--	--	--	--	--	H
Calendar Operator	3P	H	H	H	--	--	--	--	--	--
Maintenance	1P	--	--	--	--	--	--	--	--	--
Laminator	2P	H	H	H	H	--	--	--	--	--
	2A	H	H	H	H	H	--	--	--	--
Cutter	3P	H	--	H	--	--	--	--	--	--
Leader Belt Dept.	2P	--	--	--	--	H	--	--	--	--
Heat Seal Press	3P*	--	IH	--	--	IH	--	--	--	--
	1A	H	H	H	H	H	H	H	--	--
Fork Lift	3P	--	--	--	--	--	--	--	--	--
Ceiling Bean 8	1A	--	--	--	--	--	--	--	--	--
QC Room	1P	--	H	H	--	--	--	--	--	--
1st Fl. Exec. Office	2A	--	--	--	--	--	--	--	--	--
2nd Floor Office	1A	--	--	--	--	--	--	--	--	--
Switchboard	2A	H	H	H	--	--	--	--	--	--
Cafeteria	2A	H	H	H	--	--	--	--	--	--
Electric Oven Abator	3A	H	H	H	H	--	--	--	H	--
Black Abater Residue					H					
CUT OFF FOR H		100,000	100,000	100,000	100,000	5,000	6,000	1,000	200	100

H = High

* = Analysis with 50 µl injection

IH = One sample value was high

TABLE 2: TIME OF ONSET AND DURATION OF

TRANSIENT AND PERSISTENT ERECTILE DYSFUNCTION

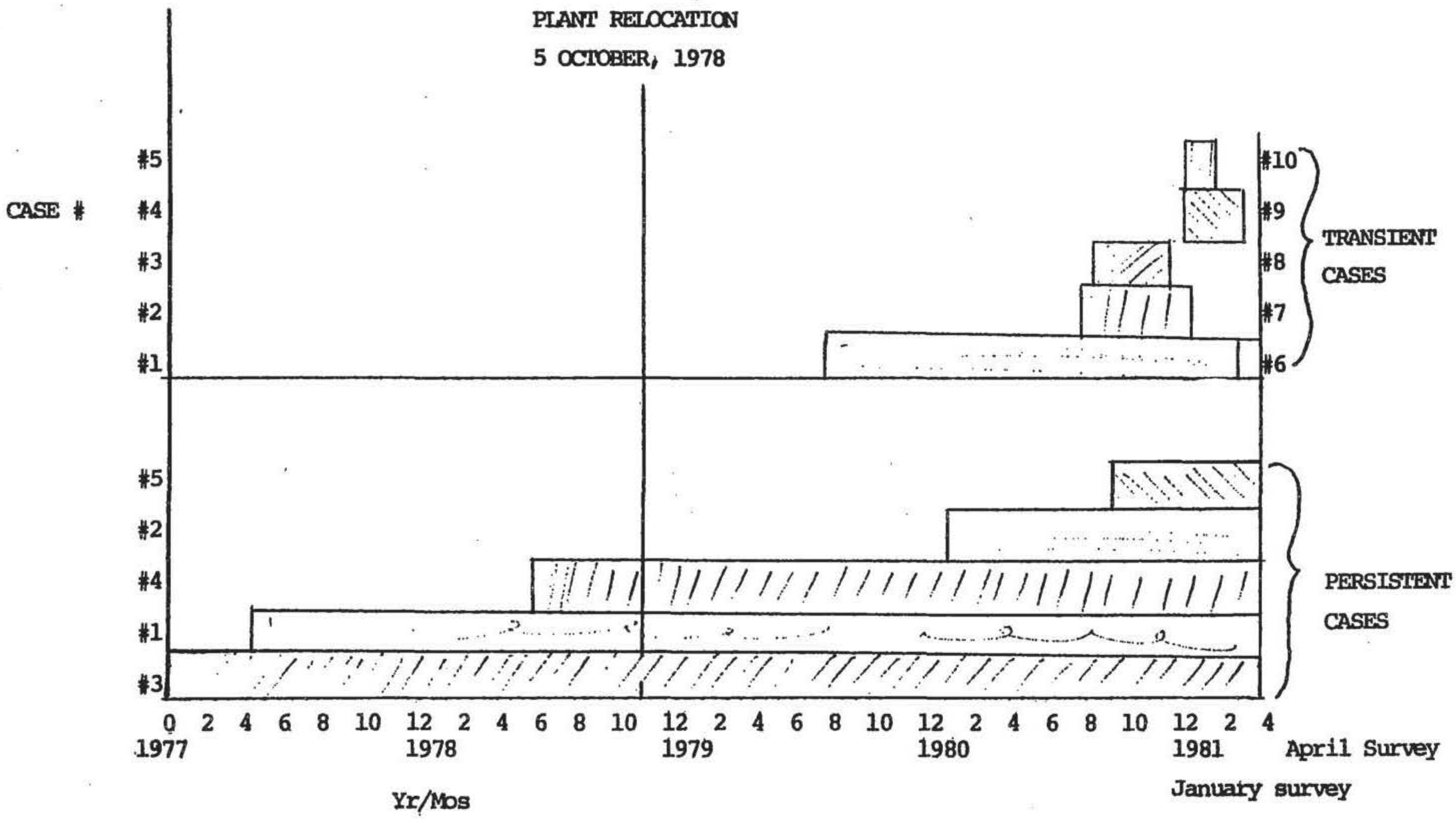

TABLE 3: INCIDENCE OF ERECTILE DYSFUNCTION

DATE OF ONSET

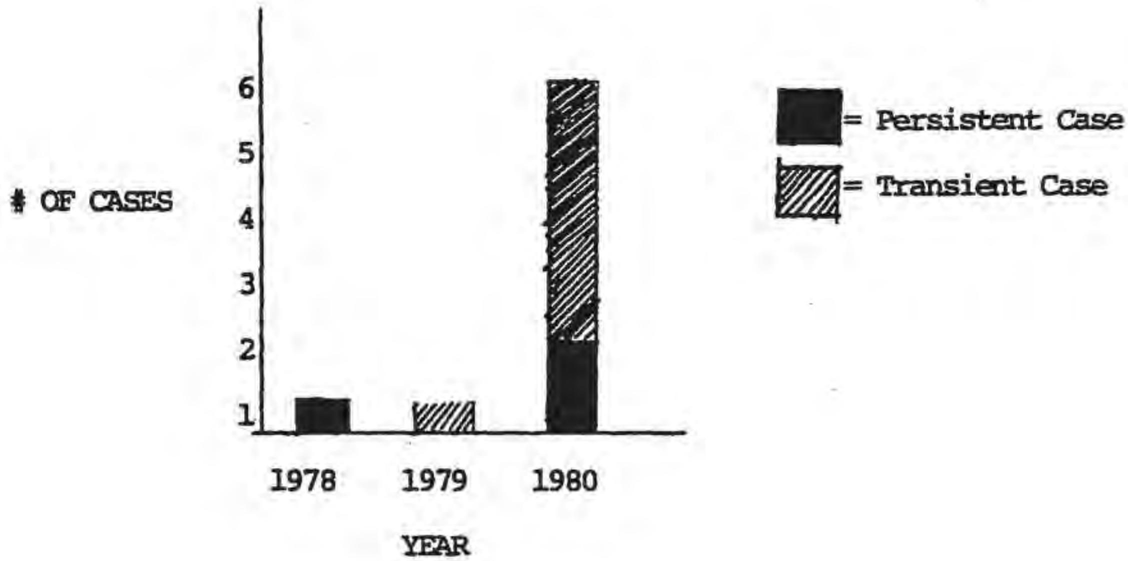

TABLE 4: PREVALENCE OF PERSISTENT ERECTILE DYSFUNCTION

(APRIL SURVEY) BY AGE

Age	All Employees	(Excluding pre-existing E.D.) All Employees	Production Area (Previous E.D. excluded)	Production Area (Previous E.D. included)	Non-Prod. Area (Previous E.D. included)
30	0/25 (0%)	0/25 (0%)	0/19 (0%)	0/19 (0%)	0/6
30-39	1/20 (5%)	1/20 (5%)	1/8 (12.5%)	1/8 (12.5%)	0/12
40-49	1/10 (10%)	0/9 (0%)	0/5 (0%)	1/6 (16.6%)	0/3
50	3/9 (33%)	2/8 (25%)	2/5 (40%)	2/5 (40%)	1/4 (25%)
Total	5/64 (7.8%)	3/62 (4.8%)	3/37 (8.1%)	4/38 (10.5%)	1/26 (3.8%)

TABLE 5: POLYMER FUME FEVER - CLASSICAL AND PARTIAL

FREQUENCY BY PRODUCTION AREA, STRATIFIED BY SMOKING

	Frequency of Classical PFF (1 or more episodes)	Frequency of Partial PFF
<u>Non-Production Area</u>	1/10 (10%)	0/10 (0%)
Smokers	1/3 (33%)	0/3 (0%)
Non-Smokers	0/7 (0%)	0/7 (0%)
<u>Production Area</u>	5/18 (27.8%)	14/18 (77.8%)
Smokers	4/8 (50%)	7/8 (87.5%)
Non-Smokers	1/10 (10%)	7/10 (70%)
<u>All Areas</u> (April survey)	6/28 (21.4%)	14/28 (50%)
All Smokers	5/11 (45.4%)	7/11 (63.6%)
All Non-Smokers	1/17 (5.9%)	7/17 (41.2%)

APPENDIX 1

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