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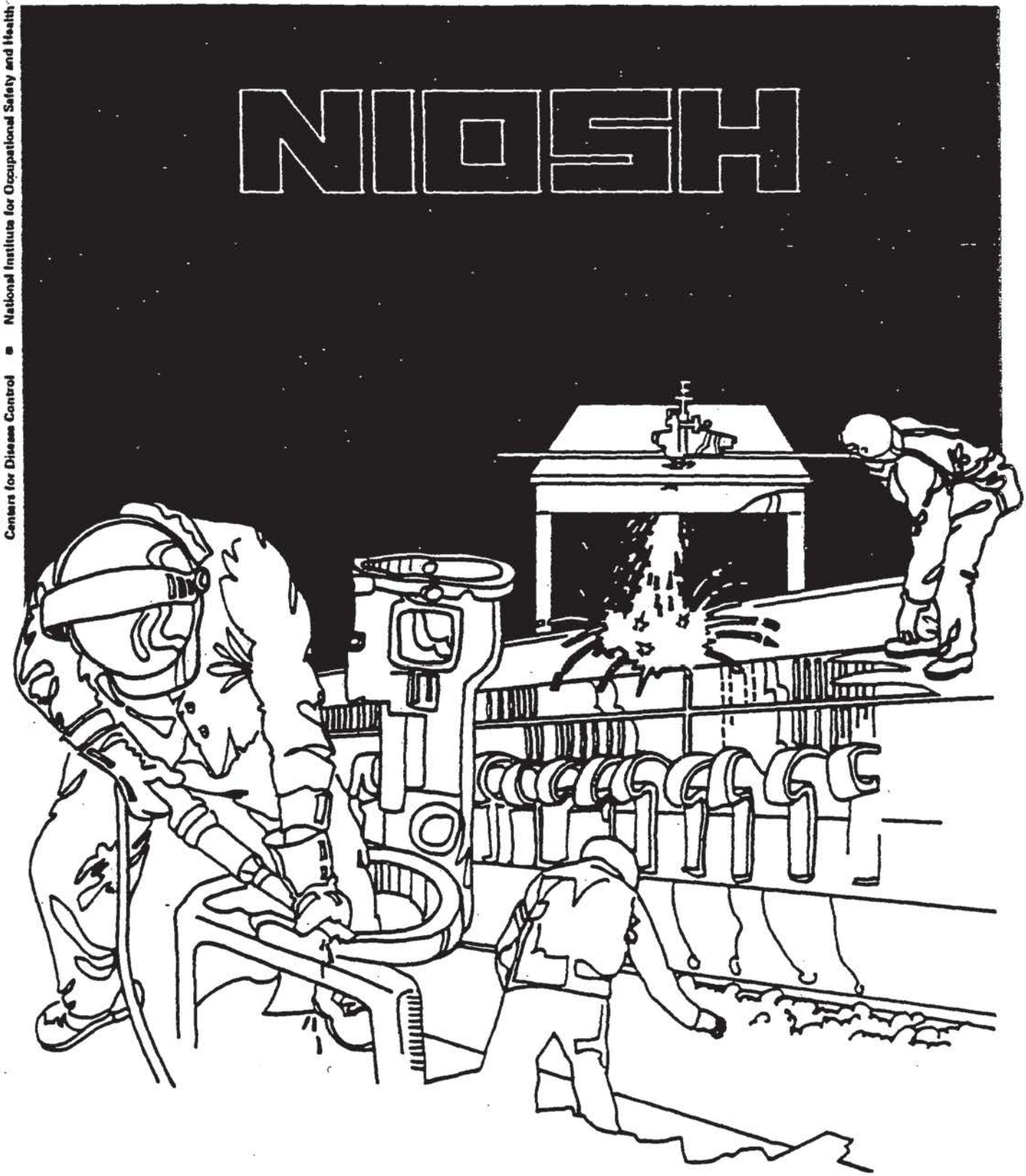

Health Hazard Evaluation Report

HETA 83-301-1478
LION UNIFORM COMPANY
BEATTYVILLE, KENTUCKY

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.

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LION UNIFORM COMPANY
BEATTYVILLE, KENTUCKY

NIOSH INVESTIGATORS:
David B. McAuley, M.D.
Paul Blanc, M.D.

I. SUMMARY

On June 3, 1983, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Kentucky Department of Labor to evaluate the occurrence of dermatitis and other symptoms in employees of Lion Uniform Company, Beattyville, Kentucky. Lion Uniform produces firefighters' jackets from Nomex(TM) fabric which has been treated with acetophenone and melamine-formaldehyde resin.

Thirteen employees, who were exposed to the fabric at different stages in the manufacturing process, reported the occurrence of skin irritation during late 1982 and early 1983. Twelve of these employees had visited local physicians at least once during the first two weeks of April. Their rashes had been diagnosed as either allergic dermatitis or urticaria. These physician visits were more frequent on colder days, suggesting a possible association with decreased fresh air ventilation inside the plant. In response to a self-administered questionnaire inquiring about symptoms during the first two weeks in April, 1983, five employees reported rash and eye irritation, three reported throat irritation, headaches, and dizziness; and two reported sleep disturbances and nausea.

Personal monitoring for exposure to formaldehyde was conducted by the Kentucky Department of Labor on three employees. Airborne formaldehyde levels ranged between 0.15 and 0.23 ppm; eight-hour time-weighted averages were 0.15 to 0.18 ppm. Bulk fabric samples were analyzed by NIOSH and found to have residual formaldehyde levels between 260 to 450 ppm, and acetophenone levels between 33.5 to 46.5 mg/g (33,500 - 46,500 ppm).

Symptoms observed are compatible with formaldehyde exposure at the levels found in our study; however, the levels of acetophenone may also have contributed to the occurrence of symptoms. Acetophenone toxicity has not been well-studied, but there is evidence that it has primary skin and eye irritant effects. Recommendations include increased fresh air ventilation, cooperation with textile mills to acquire fabrics with the lowest possible levels of latent formaldehyde and acetophenone, and airing of fabrics to allow off-gassing of these chemicals.

KEYWORDS: SIC 2328 (Men's, Youth's, and Boy's Furnishings, Work Clothing, and Allied Garments), formaldehyde, acetophenone, dermatitis, upper-respiratory irritation, textile mill, clothing manufacturing.

II. INTRODUCTION

On June 3, 1983, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation from the Kentucky Department of Labor requesting medical assistance in evaluating the occurrence of dermatitis among employees of the Lion Uniform Company in Beattyville, Kentucky. Personal communications and exchange of industrial hygiene data allowed NIOSH to conduct its investigation based on the Kentucky Department of Labor's preliminary findings.

III. BACKGROUND

Lion Uniform manufactures firefighter jackets from DuPont-licensed Nomex(TM) fabric, which is supplied by several different textile mills. These mills treat the Nomex fabric with acetophenone, a carrier for the dyes, and melamine-formaldehyde resin, a polymer which provides wear and crease resistance, water repellancy, increased fabric stiffness, and aids in dye fixation. In addition, other chemicals are added to promote water-proofing, fire retardance, and polymerization of the melamine resin, and to recover and recycle expensive chemicals. The fabric is cured in ovens, rolled onto bolts and shipped to the manufacturer.

Lion Uniform employs approximately 100 people, most of whom are females working on a piece-work basis. There is one shift per day. It takes approximately 1 to 2 months for a bolt of fabric to be used from the first cutting to the last cut. The manufacture of a single uniform may take from 1 to 3 weeks from the initial cutting to the final garment, which includes storage time of the preassembled pieces.

The manufacturing process is contained within one building. The bulk material is received from the textile mills on bolts containing approximately 1000 yards of Nomex fabric. It is stored in one end of the building wrapped in its shipping cover, which is either paper or plastic, depending on the supplier. The storage period is variable. Almost one half of the building is devoted to storage and cutting. The fabric is cut to order, and the various pieces are stored in bins awaiting assembly by the sewers. The sewing operation is located in the other half of the building, with a small section devoted to the manufacture of other non-Nomex uniforms (e.g., service station uniforms). The sewing operators are responsible for making one part of the jacket; they locate and sew the pieces needed to make this part (e.g., a collar or a sleeve). This completed piece is then passed on to the assembly people who sew the pieces together, add linings, pockets, collars, sleeves, and buckles until a jacket has been completed. The completed jacket is then passed on to another area for quality control checking.

IV. EVALUATION DESIGN AND METHODS

A. Environmental

1. Formaldehyde

NIOSH conducted bulk sample analysis for residual acetophenone and formaldehyde in three samples of fabric obtained from Lion Uniform. The age of the materials was unknown. In order to assess the levels of free formaldehyde and acetophenone in the fabric as it emerges from the resin curing process, we obtained three more samples directly from one of the textile mill suppliers. This second analysis was conducted to observe the rate of "off-gassing" of acetophenone and formaldehyde over a period of several months.

An inside and outside piece of each sample was analyzed for formaldehyde immediately, 2 1/2 to 3 weeks later, and again 2 1/2 months later. Two methods for latent formaldehyde analysis were used. The first method was the Burlington Industries standard method for latent formaldehyde. In this method the samples are heated to drive all of the formaldehyde from the samples. An inside and outside piece of each sample was cut and weighed, placed in separate Mason jars on a wire mesh screen suspended above 50 ml of distilled water, and capped and placed in an oven set at 50°C for 20 hours. A blank consisting of 50 ml of distilled water in a Mason jar was also prepared for comparison. After heating, the jars were removed and cooled to room temperature for 1 1/2 hours. The cloth samples were removed, the lids replaced, and the jars shaken. Aliquots were treated with 10% chromotropic and concentrated sulfuric acids at 95°C for 30 minutes, then cooled in an ice bath. When thoroughly cooled the flasks were filled to volume with distilled water and mixed well. The absorbance of each sample, standard, and blank was then measured at 570 nm using a Spectronic 20 spectrophotometer and compared with controls of known formaldehyde concentration.

In the second method, the samples were not heated, and therefore monitored for the formaldehyde given off at room temperature but not, as in the method described above, the total latent formaldehyde present. An inside and outside piece of each cloth was weighed and placed in a screw-cap jar containing 100 mg of N-benzylethanolamine-coated XAD-2 resin. Three blanks consisting of 100 mg of the above sorbent placed in similar jars were also prepared. The jars were capped and allowed to stand for 8 hours at room temperature. The cloth was then removed, and the sorbent samples and blanks were desorbed in a sonic bath for 45 minutes with 2 ml of isooctane. They were then analyzed by gas chromatography (FID) for 3-benzyloxazolidine, the product resulting from the reaction of formaldehyde with BEA, using a 25-meter Carbowax 20M fused silica capillary column.

2. Acetophenone

The analysis for acetophenone was conducted with "fresh" material and again 2 1/2 weeks later. Bulk samples weighing 0.14-0.15 g were cut and weighed. Samples were taken from both from the inside and outside layers of the samples. Each portion was soaked overnight in 5 ml methanol and sonicated for 30 minutes the following morning. The methanol extract was then removed and stored in sealed vials in a freezer until analysis was performed. Spiked solutions of acetophenone in methanol were also prepared and stored to make sure there was no loss upon storage. The remaining portions of the bolts of cloth were left uncovered on a benchtop. A second set of samples were weighed and treated identically 2 1/2 weeks later. All analyses for acetophenone were performed on the same day using gas chromatography (FID) on a 30-meter DB-1 bonded-phase, fused-silica capillary column.

3. Analyses by others

The Kentucky Department of Labor conducted personal breathing zone formaldehyde sampling on May 27, 1983 on four employees who had experienced symptoms in April. In addition, seven samples of scrap fabric were analyzed for latent acetophenone.

Lion Uniform arranged to have one of their textile mill suppliers analyze bulk samples for both acetophenone and formaldehyde. These fabrics were obtained from their own, as well as several other, textile mills.

DuPont also conducted a separate analysis of the Nomex fabrics used at Lion uniform. The DuPont lab conducted two separate analyses of Nomex fabrics obtained from various textile mills. The first analysis was an extraction analysis of seven samples to discover what compounds were present. The second analysis was a quantitative analysis for residual formaldehyde in four of these samples using a 1% sodium bisulfite extraction procedure, which is not directly comparable to the Burlington method.

B. Medical

Informal interviews with 9 of the 13 employees who had reported symptoms were conducted on the day of the NIOSH visit. In addition, medical reports from two local physicians were obtained regarding the visits of these employees during April 1983. A self-administered questionnaire was mailed to the 13 employees to obtain a more complete picture of the symptoms experienced and the dates of their occurrence.

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. Formaldehyde

1. Overview

Overview of the medical/scientific literature, related to formaldehyde dermatitis in the finished textile industry, can be summarized as follows:

1) Airborne levels of formaldehyde less than 1 ppm have been associated with occupational dermatitis among textile workers.

2) Bulk samples of fabric involved in these outbreaks have generally had latent formaldehyde levels below 750 ppm (by weight).

3) Formaldehyde assessment in bulk samples is complicated by the dissipation, over time, of retained formaldehyde.

4) Airborne formaldehyde determinations may be an indirect indicator of latent bulk fabric formaldehyde concentrations; however, these two methods of sampling may not be directly related due to different resin formulations, types of fabric, and local environmental conditions which may influence the rate of off-gassing.

5) Occupational dermatitis has been associated with airborne formaldehyde levels as low as 0.08 ppm and with bulk fabric sample latent formaldehyde concentrations as low as 200 ppm (by weight).

6) The threshold exposure level of formaldehyde necessary to produce primary skin sensitization, either by inhalation or by skin absorption, has not been determined.

7) The threshold exposure level of formaldehyde necessary to cause dermatitis in individuals with prior sensitization, either by inhalation or by skin absorption, has not been determined.

8) Occupational dermatitis in textile workers exposed to melamine-formaldehyde resin may be secondary to formaldehyde alone, but other undetermined resin contaminants may also be involved.

2. Review of Scientific Literature

Formaldehyde has long been known to be a skin sensitizer and contact allergen [5,12]. It is well appreciated that numerous textile finishing agents contain formaldehyde and that a variety of finished textiles and manufactured garments may contain varying amounts of free formaldehyde [8]. Many reports, particularly in the European literature, document contact dermatitis among workers or consumers exposed to such fabrics. Such studies have shown positive allergen testing to formaldehyde, the parent formaldehyde-containing resin, or both [7,11,23].

An exposure limit for formaldehyde in air of one part per million (ppm) was recommended by NIOSH to protect against a variety of toxic effects, including the development of formaldehyde related dermatitis in individuals not previously sensitized [25]. The NIOSH document supporting this recommendation specifically sites a study of eight permanent-press fabric plants with airborne formaldehyde concentrations ranging from 0.3 - 2.7 ppm which did not find occupational dermatitis [25,41]. Mucous membrane irritation and disturbed sleep were noted at these levels [41]; however, it is noted that exposure to 10.5 ppm by air or to a 0.5 ppm solution (1:5,000,000 dilution) could cause dermatitis in individuals with prior sensitization [12,25].

The NIOSH recommended standard was felt to protect against formaldehyde dermatitis caused by inhalation in non-sensitized individuals. The document supporting the standard stated, "This recommended standard is not designed to protect an individual already sensitized to formaldehyde. Such workers should not be exposed to formaldehyde." [25] Although the standard outlines pre-employment histories emphasizing prior atopy, there is no recommendation for patch test screening in those workers [25]. In fact, patch testing with formaldehyde containing textiles has been shown to be inaccurate in predicting formaldehyde sensitivity [8,23]. Furthermore, the standard as proposed does not deal directly with liquid rather than airborne exposures, although it does call for protective clothing when contact with formaldehyde (no level stated) is likely [25].

Since publication of the original NIOSH Criteria Document, positive carinogenicity bioassay results prompted NIOSH to recommend an exposure limit for formaldehyde as low as achievable [25]. This document recommends engineering controls and substitution where possible, but does not address problems of the textile industry specifically.

Since publication of the recommended standard in 1976, the Hazard Evaluation and Technical Assistance Branch of NIOSH has investigated numerous workplace environments with potential formaldehyde exposures; four of these investigations were specifically concerned with contact dermatitis in finished textile apparel manufacturing. One study in 1977 involved an investigation of a uniform manufacturer using a formaldehyde impregnated, glyoxal-based resin, DMDHEU [26]. Twenty-six of 210 employees (12.4%) were identified as having work-related formaldehyde exposure symptoms, 15 of these (7.1%) specifically experiencing skin problems. Skin reactions were described as erythematous or urticarial without frank eczema. Airborne sampling showed concentrations of 0.13 - 0.57 ppm (mean value = 0.25 ppm). Latent formaldehyde levels in fabric tested ranged from 580 - 938 ppm by weight. An 86 - 91% reduction in detectable formaldehyde was noted after three weeks of storage and repeat analysis. The report recognized an association between rash and an air concentration below 1 ppm and suggested airing fabric sufficiently prior to apparel manufacture in order to reduce worker exposure.

In April, 1982 NIOSH began another investigation in a uniform manufacturer to assess worker exposure to formaldehyde [27]. Cloth used was also impregnated with a formaldehyde, glyoxal-based resin. Forty-four of 56 employees (78.6%) experienced eye irritation, while 18 of 56 workers questioned (32%) complained of skin rash, most frequently rash of the forearms. Eleven of these cases were verified by physical examinations. Breathing zone sampling detected formaldehyde in levels ranging from 0.08-0.44 ppm (mean value = 0.26 ppm). Fresh samples of cloth had a latent formaldehyde level ranging from 329 - 339 ppm by weight, stored samples ranged from 146 - 255 ppm. This report also recognized symptoms at a level below the recommended NIOSH standard and suggested better over-all ventilation.

A third study done in August, 1982 in a clothing manufacturer, investigated skin rashes in employees who sewed cotton shirts impregnated with a formaldehyde resin [28]. Over a one year reporting period, 107 of 120 employees (89%) reported eye irritation and 70 of 120 (58%) reported skin rash. Airborne levels of formaldehyde ranged from 0.12 - 0.53 ppm (mean = 0.34 ppm); personal 8 hour TWA samples ranged from 0.11 - 0.27 ppm (mean = 0.17 ppm); bulk samples of the cloth contained 200 - 500 ppm by weight.

A fourth study, done in June of 1983, examined symptoms in employees exposed to a glyoxal-based formaldehyde resin in a permanent-press trouser manufacturing plant [29]. 44 of 64 questioned employees (69%) reported eye irritation, while skin problems were reported in 15 of 64 (23%). While exposure data was not specifically collected for these employees, formaldehyde sampling done elsewhere in the plant showed airborne levels of 0.34-0.53 ppm (mean = 0.47 ppm). Latent formaldehyde levels were measured in four fabric samples of unknown age. Three of these samples had non-detectable levels (level of detection = 150 ppm), while one sample had a level of 200 ppm.

These studies are summarized in Table I.

Two NIOSH walk-through surveys of a shirt manufacturer, in 1980 and 1981, have also shown similar formaldehyde levels [30,31]. The 1980 study showed area samples ranging from 0.07 - 0.34 ppm (mean value = 0.20 ppm) [30]. The 1981 study showed personal monitoring levels with a range of 0.15 - 0.30 ppm (mean value = 0.23 ppm) [31]. Neither of the walk-through surveys evaluated current health complaints among workers, including possible dermatitis.

In the cases of formaldehyde dermatitis cited previously, formaldehyde concentrations of less than 1 ppm have corresponded to fabric latent formaldehyde levels of 200 - 938 ppm by weight. There have been several studies that have addressed the issue of exposure levels of latent formaldehyde as a percentage or ppm by weight of extractable formaldehyde in cloth.

Fisher examined this question in 1962 [8]. The author theorized that the paucity of formaldehyde-textile dermatitis reports in the American literature might reflect lower exposure levels rather than poorer reporting. Because information obtained from U.S. manufacturers showed a ceiling of residual free formaldehyde of 0.075% by weight (750 ppm), and because twenty patients with known formaldehyde senstivity that the author tested did not react to fabric that was positive in a qualitative formaldehyde assay, the author concluded that 750 ppm was a level below which contact dermatitis was not produced. Based on this study, a 750 ppm level has entered the literature as a threshold for fabric formaldehyde skin sensitization. Partly because of the lack of quantification in the Fisher study, Schorr in 1974 attempted to analyze American cloth for its free, or latent, formaldehyde content [40]. Of 112 fabric samples Schorr examined, all contained free formaldehyde, with values ranging from 1 - 3517 ppm. Eighteen (16%) had a latent formaldehyde content greater than 750 ppm. The author conservatively states, "The threshold level of free formaldehyde in clothes that will produce clinical dermatitis in a formaldehyde-allergic patient is, to our knowledge, unknown" [40]. This does not, it should be noted, address the question of formaldehyde sensitization among those without prior formaldehyde exposure; nor does this study examine fabric by surface treatment applied (e.g., urea-formaldehyde, glyoxal-based, or melamine-formaldehyde). A more recent Polish study, presumably of European textiles, found 30% of 1005 fabrics analyzed to have formaldehyde levels greater than 750 ppm, roughly consistent with Schorr's findings [24].

Melamine-formaldehyde resin is widely used industrially but textile coating is a small portion of its end-use market: 4% of consumption (5 million pounds) in 1978 with little increase expected by 1983 [51]. In textile treatment it is used to impart crease resistance, water repellancy, to stiffen synthetics, or to fix dyes [51]. The melamine monomer precursor used in melamine-formaldehyde production is a reactive intermediate currently under investigation in the National Toxicology Program of the National Cancer Institute [32].

There have been no reports examining the potential for residual melamine monomer exposure in polymerized resin; however, melamine-formaldehyde resin has been examined for its ability to produce contact dermatitis in individuals with and without known or suspected skin sensitivity. Andersen showed that of 184 patients tested, three reacted positively in patch testing to melamine-formaldehyde resin [2]. All three positive reactors were among 15 with known textile dermatitis; other control eczema patients did not react. It is interesting to note that one of these three patients reacted strongly to two other textile resins but only weakly to a 2% formaldehyde solution. The other two melamine-formaldehyde positive patients cross-reacted with a variety of textile finishes and to 2% formaldehyde solution as well [2].

In an earlier study, Malten showed that 9 out of 25 textile dermatitis patients tested were reactive to melamine-formaldehyde [22]. Three of these nine patients did not react to 5% formaldehyde skin testing; one of these patients also was not cross-reactive with other formaldehyde con- taining resins [22]. Cross-reactivity of melamine-formaldehyde resin sensitive individuals with formaldehyde and/or other formaldehyde containing resins has thus been shown to be common but not universal. This may reflect testing difficulties, or possibly sensitization to other components of melamine-formaldehyde resin such as to melamine monomer or to reaction contaminants or by-products. In addition to human data, at least one animal study has examined melamine-formaldehyde resin treated fabrics and found them to have an irritating effect [3]. This study recommended that such fabrics should not be used for medical purposes.

In another study from the Eastern European literature, an attempt was made to gauge human exposure to formaldehyde from melamine-formaldehyde treated textiles, by measuring air levels of formaldehyde in the space between body surface and the clothing in question [15]. This investigation found air levels of 0.6 - 1.3 micrograms/Liter (0.6 - 1.3 ppm), with levels nearly double that if an outer garment was worn over the resin-treated clothing. When sampled by flow-through air, measurments were 0.43 - 8.75 micrograms/Liter (0.36 - 7.3 ppm). This investigation found 1.78 - 3.46 mg/g (1780 - 3460 ppm by weight) extractable formaldehyde in bulk samples, levels within range of other studies [15,24,40]. This study also found considerable reduction in measurable formaldehyde after sixty days of storage, consistant with other observations [26].

C. Acetophenone

1. Overview

Overview of the medical/scientific literature relating to acetophenone can be summarized as follows:

1) Acetophenone, a chemical used in a variety of commercial settings, as well as, a food and cosmetic additive, is a known irritant and of potential but little studied chronic risk. Standards in the U.S. for safe exposure have neither been recommended nor instituted.

2) Acute toxicity studies for acetophenone have demonstrated an oral LD_{50} with a range of 0.9 to 3.2 g/kg conducted in three different studies. A dermal LD_{50} has been estimated to be greater the 20 ml/kg. An inhalation LC_{50} was found to be 244,000 ppm. Acetophenone is also readily absorbed through the skin.

3) Subchronic toxicity studies in test animals have shown pathologic and physiologic changes at exposure levels as low as 140 ppm by inhalation and 0.5 mg/kg orally.

4) A respiratory irritant threshold in humans has been cited as 7.2 ppm. Acetophenone is classified as a mild skin irritant and a severe eye irritant. Positive human patch testing has been reported.

2. Review of Scientific Literature

Toxicologic characterization of acetophenone has been very limited. The most widely quoted literature citations are of a series of acute toxicological assesments performed by Smyth and Carpenter. In a 1944 study they estimated an LD_{50} (LD_{50} = Lethal dose for 50% of animals exposed), using small groups of Wistar rats with actephenone administered by gavauge, of 3.0 gram/kilogram [42]. In a later paper they revised this dosage to a more toxic level, the LD_{50} being 0.9 gram/kilogram (Sherman rat) with a 95% confidence range of 0.81-1.00 gram/kilogram [43]. A more recent study by other investigators found an LD_{50} (Osborne-Mendel rats; gavauge) of 3.2 gram/kilogram with 95% confidence limits of 2.46-4.16 gram/kilogram [14]. Acute inhalation toxicity in white mice was reported as an LC_{50} of 1.2 mg/liter (244,000 ppm) [18]. A dermal LD_{50} in guinea pigs was reported as greater than 20 ml/kilogram [42], but immersion of mice tails in acetophenone for four hours caused 100% mortality in another study, indicating effective skin absorption [17]. Aquatic toxicity studies have shown an LC_{50} for the fathead minnow of 200 mg/liter for 1-24 hours exposure [46]. Acetophenone was also investigated for possible synergistic effects at acutely toxic dosages. Overall, when tested with 26 other chemicals in equal ratios, acetophnone was found to have more than additive toxicity with 13 of the chemicals [44]. Two of these ratios were significantly elevated: in combination with acetonitrile and with tetra-chloroethylene (at more than three times expected additive toxicity). When tested with formalin, acetophenone's toxicity was greater than twice expected but was not statistically significant [44].

Sublethal acute effects of acetophenone are predominantly that of a central nervous system depressant (for which it was originally considered as a possible anaesthetic) and as an irritant [38]. Its irritating effects on skin have been described as mild [20]; eye irritation is classified as severe [20], with an irritant effect equivalent to formaldehyde [4]. It is interesting to note that the chemical irritant alpha- or 2-chloroacetophenone is a halogenated analogue of acetophenone and the principle component of the chemical lacrimator "Mace" [50].

Studies of chronic acetophenone toxicity are much less adequate. In spite of its approved use as a food additive, the Food and Drug Administration background file for acetophenone lists only five relevant studies, all of which are considered by FDA to be of "C" or poor quality [49]. The FDA itself undertook a study feeding twenty rats a 1% diet of acetophenone for 17 weeks: no microscopic or macroscopic adverse effects were noted [9]. However, the study did note a 31% loss of the test compound from the animal feed over a seven day period. Another study did find changes in conditioned reflex activity in rats fed 0.05 mg/kilogram for 6 months [18]. Rabbits at a similar exposure level showed growth inhibition, a "moderate decrease in blood glucose levels" and chronic nephritis [18].

Inhalation of 0.077 mg/liter (1700 ppm) for 3.5 months caused a variety of changes in exposed rats, including decreased blood cholinesterase, dystrophic changes in the liver and central nervous system, and "hemodynamic and vascular disorders in the internal organs" [18]. Inhalation of 0.015 mg/liter (3000 ppm) for 5.5 months was associated with urinary coproporhyrin excretion, accelerated extinction of developed conditioned reflexes, and "disorders in the chronaxy of antagonist muscles" in exposed rats and rabbits. Seventy day inhalation of 0.00007 mg/liter (140 ppm) acetophenone reportedly caused similar changes in exposed rats, while an exposure at one-tenth that level had no observed effect. On necroscopic examination the rats in the 140 ppm exposed group again showed "dystrophic" changes in the liver and "hyperemia" in cardiac vessels.

There have been no chronic exposure studies of acetophenone that meet current National Cancer Institute guidelines for carcinogenesis bioassay. In-vitro mutagenesis bioassay has been limited to a report of DNA breakage with combined photosensitization and acetophenone exposure [36]. Reported teratogenic studies are limited to a negative finding of embryotoxicity after 0.48 gram/kilogram dermal exposure of rats during days 10-15 of gestation [18].

Human toxicity data for acetophenone are extremely limited. Threshold for odor and reflex effects of eye photosensitivity are reported at 0.01 mg/cubic meter (2 ppm); cerebral electrical activity in humans was affected at doses of 0.007 mg/cubic meter (1.4 ppm) [18]. Another source references odor threshold to be 0.0039 ppm with a mean threshold of 0.17 ppm [47]. The threshold for respiratory irritation has been reported as 0.035 mg/cubic meter (7.2 ppm) [18]. Although skin irritation in humans has been reported [16], in another report 2% dermal application in 48-hour closed patch testing found no irritation in 25 subjects [34].

In summary, toxicologic data indicate minimal acute lethal mammalian toxicity, but irritant effects, particularly to the eye and potentially to the skin and respiratory tract, are possible at moderately low dosage. Adequate chronic toxicity studies, including carcinogenesis bioassay, have yet to be completed. Subchronic studies, most notably of inhalation exposure, are suggestive of low level adverse effects.

The metabolism of acetophenone has been delineated in certain systems, although not in humans. In bacteria, acetophenone has been shown to be metabolized via phenylacetate to phenol catechol. The first step is a proposed oxygen insertion by an enzyme, acetophenone oxygenase, requiring O_2 and NADPH [6]. In mammalian species (dog and rabbit), metabolism has been via methylphenylcarbinol (the reduced alcohol of the acetophenone ketone) and mandelic acid to benzoic acid [34]. In rats, metabolism was carried on from benzoic to hippuric acid with urinary excretion of this metabolite [33]. In-vitro rat metabolism also included oxidation to alpha-hydroxyacetophenone. Acetophenone has also been shown to be a step in the metabolic pathway of ethylbenzene, via equilibrium conversion with methyl-phenylcarbirol, a major metabolite of ethylbenzene. 60% of an inhaled dose of ethylbenzene in humans is converted to mandelic acid (via methylphenylcarbirol), but humans apparently lack the ability to convert mandelic to benzoic acid [33]. A similar human metabolic pathway for acetophenone would be expected.

Regulatory control of acetophenone is minimal. As a food additive, it is approved for use by the FDA under 21 CFR 121.1164. The FDA has not promulgated food tolerances for acetophenone, but an industry survey found maximum uses to range from 0.98 ppm (by weight) for beverages to 20 ppm in chewing gum [10]. Other uses include ice-cream, candy, baked goods, and gelatin. In cosmetics, final product concentrations were reported to have maximum concentrations of 300 ppm for creams and lotions to 2000 ppm for perfume, with usual concentrations about one-tenth those levels [34]. The Council of Europe has listed an ADI (Adult Daily Ingestion) limit of 1 mg/kg [34].

OSHA has not promulgated any standard for occupational exposures to acetophenone, nor has NIOSH or the ACGIH recommended threshold limits for safe exposure to acetophenone. The USSR has a maximum allowable concentration of 5 mg/M^3 (1000 ppm) [18], but at least one Soviet study recommends 0.003 mg/M^3 (0.61 ppm) as a 24 hour average maximum allowable concentration, based on a minimal concentration of 0.007 mg/cubic meter being capable of causing "reflex effects on electro-cortical brain activity" in humans [13].

Some industry guidelines for acetophenone do exist. Southern Mills recommends an allowable ambient concentration of 300 ppm in its production facilities [21]; Rhone-Poulenc recommends a TLV of 20 ppm in its material safety data sheet [37]. There has been little environmental sampling to determine typical levels of current industrial exposure. One study of 2 styrene-resin manufacturing plants found personal monitoring levels of acetophenone ranging from 0.05 to 0.47 ppm and area samples ranging from 0.05 to 0.39 ppm [35].

The Environmental Protection Agency has not promulgated any water quality standards for acetophenone [47], but acetophenone does fall under general provisions of The Resource Conservation and Recovery Act (RCRA).

5) No adequate carcinogenesis bioassay has been reported.

6) No official exposure limits have been set for acetophenone in the United States. The USSR has set a standard of 1000 ppm. One study recommends an exposure limit of 0.61 ppm. Two U.S. companies, experienced with acetophenone, have in-house standards of 20 and 300 ppm.

VI. RESULTS AND DISCUSSION

A. Environmental

Three fabric samples obtained by NIOSH from Lion Uniform contained 100 - 600 ppm by weight of formaldehyde (mean = 300 ppm) and 24 - 45 mg/g of acetophenone (mean = 34 mg/g, 34,000 ppm). Three other samples obtained directly from Southern Mills, a textile mill, after the curing process, were analyzed by two separate methods. The Burlington Industries standard method for latent formaldehyde, involving heating the fabric to 100 degrees Farenheit, found formaldehyde levels of 260 - 450 ppm (mean = 311 ppm). The BEA process, which extracted formaldehyde at room temperature, found latent formaldehyde levels of 3.2 - 10.0 ppm (mean = 7.26 ppm). Both of these analyses were performed on samples of cloth from the outside and the inside of the bolts (the bolts were simulated by rolling each 3-square-yard sample into a small roll). These two analyses were repeated to estimate the rate of "off-gassing" of formaldehyde and acetophenone. The BEA method was repeated three weeks later, and no detectable formaldehyde was found. The Burlington method was repeated 2 1/2 months later, and the levels were essentially unchanged from the previous analysis: range = 280 - 440 ppm (mean = 324 ppm). The acetophenone analysis found levels of 33.5 - 46.5 mg/g (mean=39.3 mg/g, 39,300 ppm), and 2 1/2 weeks later the levels were essentially unchanged: range = 33.2 - 48.8 mg/g (mean=39.2 mg/g, 39,200 ppm).

Southern Mills conducted an independent analysis of a different set of bulk fabric samples. Eight different samples were obtained from Lion Uniform and from several different processing mills; the acetophenone levels ranged from 33.5 - 46.5 mg/g (mean = 39.3, 39,300 ppm). The formaldehyde analysis used employed a different method than the NIOSH methods and attempted to approximate potential airborne levels in the plant. Vapor-phase formaldehyde levels ranged from 0.01 - 0.71 ppm (mean = 0.19 ppm).

The Kentucky Department of Labor analyzed some fabric samples of unknown age for acetophenone. They utilized a different extraction procedure than NIOSH, so the levels are not directly comparable. The levels ranged from 0.27 - 4.2 mg/g (mean = 1.81 mg/g, 1,800 ppm). On May 27, 1983 they also performed personal monitoring and area sampling for airborne levels of formaldehyde in the plant. Four employees who had experienced symptoms were monitored. Area samples ranged from 0.15 - 0.23 ppm (mean = 0.18 ppm), and personal 8-hour TWA levels ranged from 0.15 - 0.18 ppm (mean = 0.16 ppm).

DuPont conducted another analysis for formaldehyde, on a different set of fabric samples, but employed an extraction process using 1% sodium bisulfite, so again these levels are not directly comparable to the NIOSH analysis. Levels ranged from 0.05 - 0.13 ppm (mean = 0.08 ppm). Quantitative analysis for acetophenone was not performed.

B. Medical

Thirteen of 102 plant employees (13%) reported symptoms to the management during the first two weeks of April 1983. (A complete medical survey of the plant was not conducted, so this is a conservative estimate of the percentage of employees affected.) Symptoms reported included rash of the face, neck, arms, and legs; itching; eye and throat irritation; headaches; dizziness; nausea; and sleep disturbance. Only five of the thirteen NIOSH questionnaires were returned (38.5%), so percentages of reported symptoms may not accurately reflect the true prevalences. All five employees experienced rash, itching, and eye irritation (100%). Three experienced throat irritation, headaches, and dizziness (60%). Two experienced sleep disturbances and nausea (40%).

According to information from Lion Uniform, and medical reports obtained from two local physicians who saw most of the thirteen employees, nine employees had multiple visits to these physicians for the occurrence of a fine, red, maculopapular rash; three had one visit for the rash; and one employee experienced a rash but did not see a physician. The rash was diagnosed in five of these employees as allergic dermatitis or urticaria; the diagnosis for the other cases is unknown. Two of these 13 employees had a history of prior allergies or atopy.

Twelve of the thirteen employees with symptoms were referred to local physicians during the first two weeks of April 1983. There were multiple visits by many of these employees on different days, resulting in a total of 32 physician visits. There was a strong relationship between the number of physician visits and the local temperature for that day (correlation coefficient = -0.65, p=0.08). Employees tended to make visits to the physicians on cold days as opposed to warmer days (Figure I). This could mean that on colder days the ventilation in the plant was less than on the warmer days, providing for higher concentrations of formaldehyde and acetophenone within the building. It is not clear whether this relationship was due to the use of the heating system in aiding the volatilization of these chemicals, the lack of sufficient outside air for dilution or exhaust because windows were kept closed on these colder days, or a combination of both.

Another interesting point is that the employees most affected worked with nearly finished jackets or were involved in the assembly of these jackets. This would provide for both greater direct contact and greater surface area of fabric for off-gassing of formaldehyde and acetophenone into the local air. This is compatible with other reports of symptoms resulting from both direct contact and airborne exposure.

C. Conclusions

The symptoms experienced at this plant are compatible with formaldehyde exposure in fabrics with these latent or residual formaldehyde concentrations (average concentration = 300 ppm) and the airborne formaldehyde levels (area samples 0.15 - 0.23 ppm, mean = 0.18 ppm, and personal 8-hour TWA levels from 0.15 - 0.18 ppm, mean = 0.16 ppm). This relationship has been well-documented in the scientific literature, as well as in other NIOSH studies. In addition, because of the relatively high levels of residual acetophenone in these fabrics (average concentration = 34,000 ppm), and the little known hazards of acetophenone exposure, we are unable to ascertain the contribution of acetophenone in the occurrence of these symptoms. It is possible that formaldehyde and acetophenone may additively contribute to both eye irritation and dermatitis, and because of the presence of both chemicals in this fabric, we are unable to determine the role of each.

The levels of formaldehyde in the Nomex cloth, as it is supplied from the textile mills, are comparable with levels found in other studies of dermatitis and upper respiratory irritation in textile plants. These other studies have demonstrated that 7 - 32% of employees exposed to air levels between 0.08 and 0.57 ppm will develop formaldehyde-related symptoms. This investigation found similar results. Analysis of Nomex cloth over a period of time, in order to determine the rate of off-gassing, showed that the easily volatilized formaldehyde decreased, at room temperature, from 200-600 ppm to non-detectable levels over a period of three weeks. The less easily volatilized latent formaldehyde and

acetophenone was still present in the cloth when extracted at high temperatures after 2 1/2 months. This would seem to indicate that the possibly airborne-related formaldehyde irritation (e.g., eye and throat irritation) may be lessened if the cloth were allowed to off-gas for 2-3 weeks.

The levels of acetophenone are much greater, by a factor of 100, than the levels of formaldehyde in the cloth, and although the hazards of acetophenone exposure are not well known, it has been demonstrated to be an eye and skin irritant. The higher prevalence of symptoms in employees working with finished and nearly finished coats would seem to implicate both direct contact with cloth containing high levels of formaldehyde and acetophenone, as well as higher airborne concentrations in the vicinity of the larger amounts of cloth. The skin irritation may be the result of direct contact with the cloth, and the levels of latent formaldehyde and acetophenone did not decrease even after 2 1/2 months. This exposure and the resulting dermatitis may not be alleviated by off-gassing and storage of the cloth. Prevention of symptoms related to direct contact may only be prevented by decreasing the amount of contact or using cloth with lower levels of these chemicals.

More frequent visits to physicians, assuming a higher prevalence of symptoms on these days, seems to be inversely related to the average daily temperature. Because of the lack of an exhaust ventilation system, at the time of our visit, there may be a correlation between symptoms experienced and the use of windows to provide adequate ventilation. On colder days, there may be less tendency to open windows, thereby preventing dilution or exhaust ventilation from lowering the levels of formaldehyde and acetophenone within the building.

VII. RECOMMENDATIONS

1. Efforts should be made to encourage the textile mills to supply information concerning formaldehyde and acetophenone concentrations in their fabrics. Additionally, periodic sampling could be conducted for airborne formaldehyde and acetophenone to determine if there is a relationship between a particular supplier, type, or color of fabric and increased levels of formaldehyde and acetophenone at times when irritant symptoms are present. This information could be retained along with other information about that lot of fabric, so that if problems recur this information could be correlated to determine if symptoms were related to a particular lot or type of fabric.

2. If possible, arrangements should be made to have fabric known to be high in formaldehyde set aside for 2 - 3 weeks to provide for some off-gassing of the more volatile formaldehyde. It should be noted, however, that according to our analysis, there will still be a significant amount of formaldehyde in the fabric available for direct skin contact, and this off-gassing may only lessen the non-dermatitis symptoms.

3. Exhaust ventilation should be provided, with a corresponding make-up dilution ventilation comprising at least 15% fresh (outside) air, especially at areas where there is the greatest quantity of fabric being handled. There is a greater chance of releasing formaldehyde in the jacket assembly area than in the storage area because the fabric is handled and thrown around, thereby exposing more of the fabric to the air and enabling greater release of formaldehyde vapors.

4. Long-sleeve shirts may help alleviate the contact dermatitis on the forearms, especially in the assembly area where there is intimate contact with large, bulky coats. However, this will not prevent dermatitis on the hands, and it is not known whether individuals can develop dermatitis as a result of indirect exposure through inhalation.

5. Ultimately, the best solution is to obtain fabrics with the lowest concentrations of these chemicals that still meet the standards of Lion Uniform in terms of fabric quality, water resistance, fire retardance, and other attributes. This is consistent with the current NIOSH recommendation that formaldehyde levels be maintained at levels as low as acheivable.

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IX. AUTHORSHIP AND ACKNOWLEDGEMENTS

Report Prepared by:

David B. McAuley, M.D.
Medical Officer
Medical Section

Paul Blanc, M.D.
Guest Researcher

Originating Office:

Hazard Evaluations and Technical Assistance Branch
Division of Surveillance, Hazard Evaluations, and Field Studies

X. 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. Lion Uniform Company
2. Kentucky Department of Labor
3. NIOSH, Region IV
4. OSHA, Region IV

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.

TABLE I

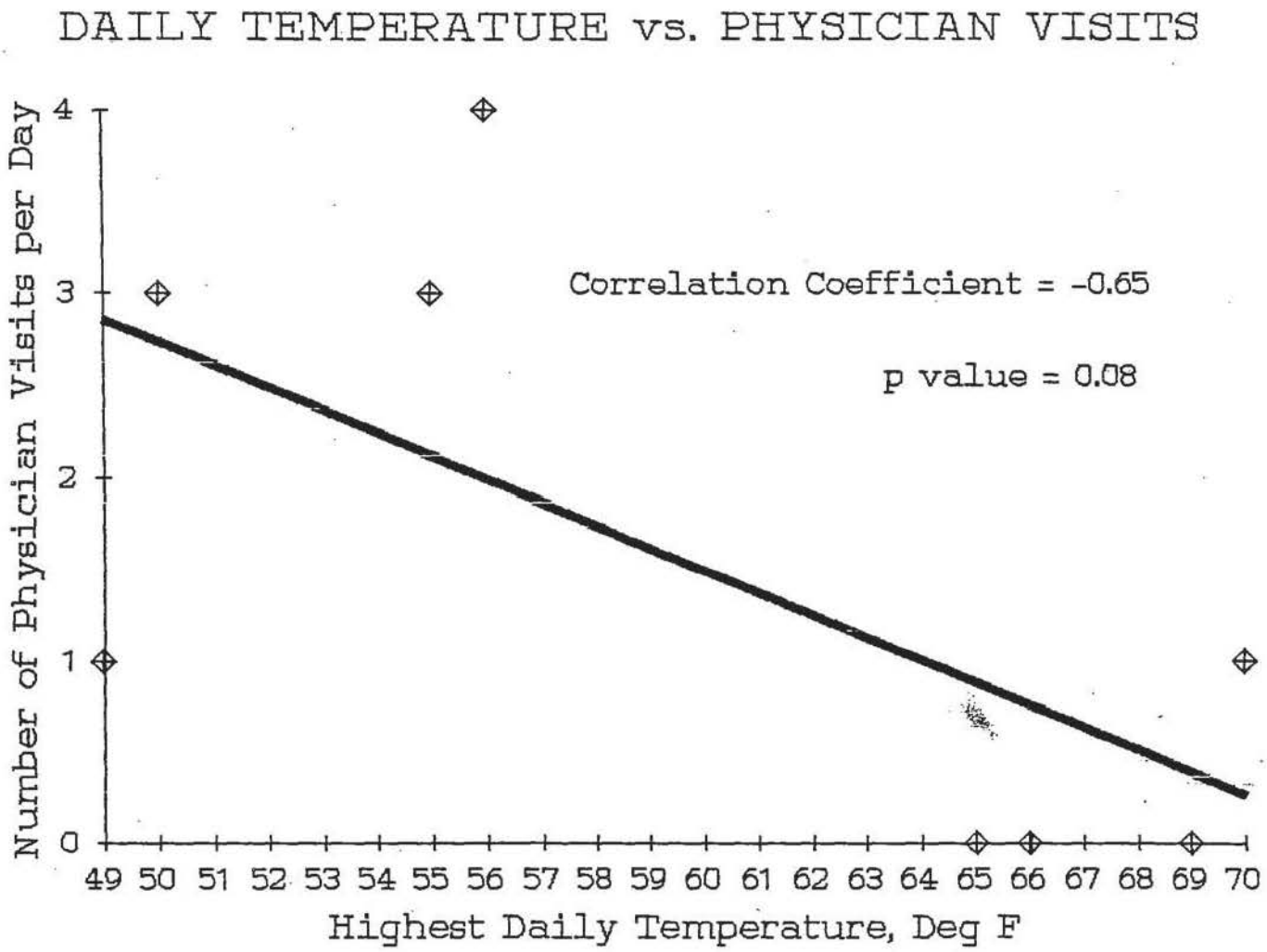
Comparison of NIOSH Studies in Textile Mills
-- Symptoms and Formaldehyde Levels --

	Number of Employees (%) Reporting Symptoms	Air Levels (avg) (Formaldehyde)	Bulk Samples (Formaldehyde)
Study 1.	26/210 (12.4%) all symptoms 15/210 (7.1%) skin irritation	0.13-0.57 ppm (.27)	580-938 ppm
Study 2.@	44/56 (78.6%) eye irritation 18/56 (32.1%) skin irritation	0.08-0.44 ppm (.26)	329-339 ppm
Study 3.*	107/120 (89%) eye irritation 70/120 (58%) skin irritation	0.12-0.53 ppm (.36) 0.11-0.27 ppm TWA	200-500 ppm
Study 4.	44/64 (69%) eye irritation 15/64 (23%) skin irritation	0.34-0.53 ppm (.47)	200 ppm
Study 5.#	13/102 (13%) all symptoms 13/102 (13%) skin irritation	0.15-0.23 ppm (.18) 0.15-0.18 ppm TWA	260-450 ppm
Study 6.	Not reported	0.07-0.34 ppm	
Study 7.	Not reported	0.15-0.30 ppm	

@ 2 month reporting period
* 1 year reporting period
# 2 week reporting period

1. HE 77-74-720
2. HETA 82-200-1233
3. HETA 82-349-1332
4. HETA 83-254-1393
5. This study
6. IWS 125.12
7. IWS 125.17

Figure 1


DAILY TEMPERATURE vs. PHYSICIAN VISITS
Number of Physician Visits per Day
0
1
2
3
4
Correlation Coefficient = -0.65
p value = 0.08
49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70
Highest Daily Temperature, Deg F