U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
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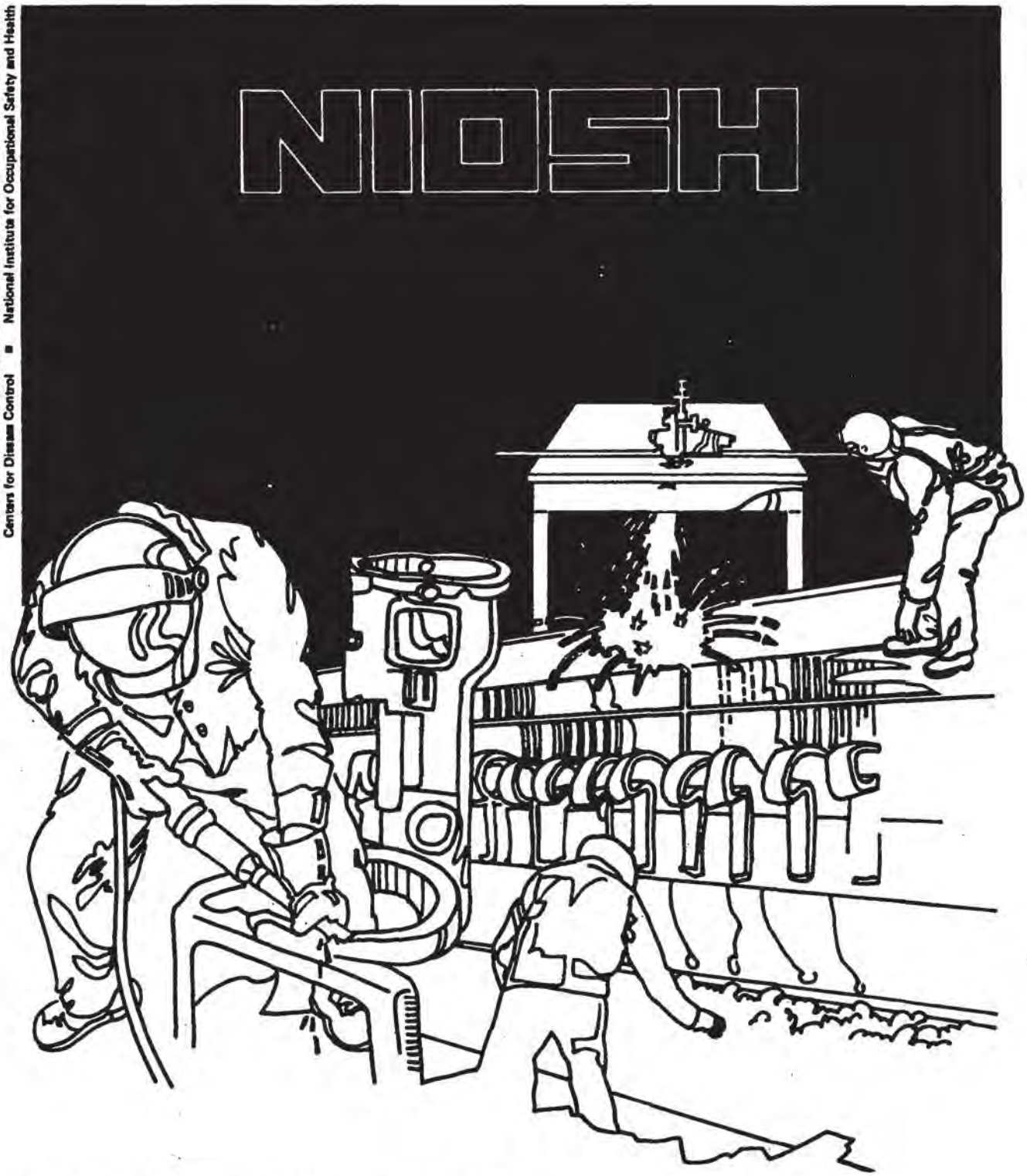
NIOSH



Health Hazard Evaluation Report

HETA 81-080-1146
PRECISION PLASTICS COMPANY
PHILADELPHIA, PENNSYLVANIA

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 81-080-1146
July, 1982
Precision Plastics Company
Philadelphia, Pennsylvania

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I. SUMMARY

On May 4, 1981, the National Institute for Occupational Safety and Health (NIOSH) was requested to evaluate several cases of breast cancer and uterine cancer among mold operators using polyvinyl chloride by Local 837 of the Industrial Workers Union at the Precision Plastics Company, Philadelphia, Pennsylvania.

To determine if the cancer cases could be related to exposures, NIOSH reviewed the reports on air samples for measurement of airborne vinyl chloride monomer and polyvinyl chloride dust which were taken at the plant by the Occupational Safety and Health Administration (OSHA) on June 3, 1981. The data showed no detectable levels of vinyl chloride monomer in personal breathing zone samples taken on two injection mold operators and one helper and 0.1 mg/m^3 of polyvinyl chloride dust was found when an area sample was taken. This is below the OSHA standard for nuisance particulates (15 mg/m^3 for 8 hours).

To determine if the number of cases of breast cancer and uterine cancer was higher than the number that would be expected among women in the general population of the same age and race as those at the plant, NIOSH conducted a site visit on July 28, 1981. NIOSH investigators performed a walk-through survey and recorded information from the personnel records of all hourly employees (125) who worked five years or longer. On July 29, 1981, NIOSH investigators checked this list of employees against a file of claims made to the Local 837 Health and Welfare Fund, looking for medical claims which listed breast or uterine cancer as the diagnosis. Claims for three cases of breast cancer and two cases of cervical cancer were found.

Following the July visit, NIOSH investigators carried out a historical cohort morbidity analysis to calculate the number of cases of breast cancer (0.986 cases) and cervical cancer (0.428 cases) that would have been expected at the Precision Plastics Company. The overall standard incidence ratios (calculated by dividing the observed number of cases by the expected number of cases and then multipling by 100) were calculated as 304 for breast cancer and 469 for cervical cancer. The two standard incidence ratios indicated an excess risk of more than three-fold for breast cancer and an excess risk of more than four-fold for cervical cancer for women who worked at the Precision Plastics Company for at least five years. The standard incidence ratios, however, were not statistically significant--$p=0.078$ for breast cancer, $p=0.069$ for cervical cancer (p=values less than or equal to 0.05 are generally considered significant). This means that the excess risks noted might reasonably have occurred by chance. Apparent excess risks will often be statistically nonsignificant when the number of cases is small.

Based on these results, NIOSH concluded that the cases of breast and cervical cancer observed at the Precision Plastics Company were not demonstrably due to occupational exposures to polyvinyl chloride dust or vinyl chloride monomer. Although little assessment of past exposures to employees was possible, NIOSH concluded that the 1981 levels of vinyl chloride monomer and polyvinyl chloride dust did not exceed current OSHA regulations. Because the risk of breast and cervical cancer among employees was elevated, albeit nonsignificantly, NIOSH recommends that the employer, the union, and the employees keep track of future cases of these cancers among active and, if feasible, terminated employees and request that NIOSH conduct another Health Hazard Evaluation if several new cases occur.

Keywords: SIC 3079 (Miscellaneous Plastics Products), injection molding, vinyl chloride monomer, polyvinyl chloride dust, polystyrene, breast cancer, uterine cancer, cervical cancer.

II. INTRODUCTION

In May 1981, NIOSH received a request for a health hazard evaluation at Precision Plastics Company, Philadelphia, Pennsylvania. The request was initiated by the President of Local 837 of the Industrial Workers Union which is affiliated with the International Brotherhood of Teamsters. At that time, NIOSH was also provided with information on eight possible breast cancer cases and two possible uterine cancer cases. The requestor asked NIOSH to evaluate the possible breast and uterine cancer hazards of polyvinyl chloride (PVC) exposure to injection mold operators.

III. BACKGROUND

The Precision Plastics Company, which has been at its present location, 4655 Stenton Avenue, Philadelphia, Pennsylvania, since 1940, is a plastic injection molding operation which has also done limited extrusion molding. Since 1940 the company has expanded and contracted in adjustment to its markets and changing product line. Today, the company's products include louvers, seats and consoles.

The Precision Plastics Company presently employs 36 workers divided into three shifts; about 31 of these work in production areas. The company did, however, maintain a workforce of about 90 workers throughout the 1950's and over 100 workers throughout the 1960's. Up until 1965 the workforce was entirely white but the present racial breakdown is about 40% nonwhite and 60% white.

Briefly, the injection molding process using polyvinyl chloride (PVC) is as follows: 1) bags of solid PVC pellets are slit and the pellets are scooped into a Gaylord box, 2) the pellets are transferred to the injection molding machine by a vacuum tube, 3) the pellets are heated to 320°F by electrically-heated, pressurized water, 4) when the plastic is fluid, it is forced by a plunger mechanism into the mold where it cools and hardens, 5) the mold opens automatically and the operator removes the formed louver and excess plastic from the mold, 6) the louver is placed on a conveyer and goes through a water wash to cool, 7) a second operator completes the trimming and packages the product for shipment. Since use of PVC began eight years ago, it has been used four times for about three weeks on each occasion. The total amount of PVC used over this time period was 3000-4000 pounds. PVC was molded in one of two large injection molding machines presently in service and in two of about 20 smaller machines which were previously in service.

Polystyrene is the primary plastic which is presently used. Rubber modified styrene, polymethyl methacrylate, polypropylene and polyethylene are also used, and for three to four years acryl nitrilate was used to manufacture lenses for swim masks. During the 1950's and 1960's cellulose acetate and cellulose acetate butyrate were used. There is also a urethane operation. The main solvents used by the company are toluene and acetone.

Prior to November 1980, female workers at the Precision Plastics Company became aware of several cases of breast and uterine cancer among the workforce. Knowledge of the potential hazards of exposure to vinyl chloride monomer prompted workers to request both a NIOSH Health Hazard Evaluation and an OSHA inspection.

IV. MATERIALS AND METHODS

A. Environmental

In assessing the exposure to vinyl chloride monomer (VCM) which might have occurred between 1972 and 1981, NIOSH investigators considered the following sources of information: 1) the extent of PVC louver production at the company, 2) the process and raw material information including changes which might have occurred, 3) the company's monitoring data from 1978 and, 4) OSHA's monitoring data from 1981.

On June 3, 1981, OSHA collected personal and area samples to evaluate present employee exposures. OSHA investigators obtained personal samples by attaching a battery powered pump to the worker's belt with the sampling media in a holder attached to the worker's shirt to obtain a representative breathing-zone sample. These personal samples were taken to represent an 8-hour exposure. The general area samples were obtained near operator positions.

OSHA investigators obtained full-shift personal breathing-zone samples for VCM for two PVC injection molding operators and one helper. As required by the vinyl chloride standard (29CFR 1910.1017)[1], OSHA obtained these samples using a duPont pump calibrated at 50 cc/min and equipped with two charcoal tubes in series. Air volume per sample ranged from 1.0 to 7.2 liters. OSHA desorbed the samples with carbon disulfide and analyzed them with gas chromatography. The limit of detection for one liter of air was 0.25 ppm.

OSHA investigators obtained area samples with direct-reading vinyl chloride detector tubes at the operator position during injection molding. Detector tubes are used to establish the presence and general concentration range of an air contaminant. Detector tube results do not represent personal 8-hour exposures. The company conducted area samples for VCM on June 28 and July 21, 1978. Using the Chemist-In-A-Can method (an instantaneous grab sample which then undergoes direct gas chromatographic analysis), air samples were taken near the injection nozzle and in the operator's work area.

OSHA obtained a general area sample of PVC dust in the vicinity of the PVC pellet pulverizing operation. OSHA collected this sample using a MSA Model G pump calibrated at 2.0 liters per minute and equipped with a polyvinyl chloride filter. The sample was taken continuously for seven hours and the filter was analyzed gravimetrically.

B. Medical

During the plant visit on July 28, 1981, NIOSH investigators encountered about 2,700 personnel records, each record consisting of a five by seven inch sheet containing basic employment and personal information for hourly personnel. Upon sampling of these records, NIOSH investigators determined that there was a very high proportion of short-term employees. In order to reduce the 2,700 to a more manageable number while maintaining a high probability of detecting possible occupational cancer, NIOSH investigators decided to include only hourly workers whose first date employed and last date employed were at least five years apart. It was reasoned that such workers would have the greatest exposures and therefore be at greatest risk. These criteria reduced the number of workers to 125. These criteria also eliminated two cases of breast cancer; one had worked less than five years and one was not an hourly production employee.

The name, social security number, date of birth, race, sex, marital status, first date employed and last date employed were recorded for each of the 125 workers. To identify cases of breast and uterine cancer that occurred among these 125 workers during their employment at the Precision Plastics Company, NIOSH investigators checked their names against the medical claim files of the Local 837 Health and Welfare Fund on July 29, 1981. Photocopies of all records with even remote mention of breast and uterine disease were taken for further medical review.

Upon return from the field, NIOSH investigators assembled a computer data file from the personnel and morbidity data. The file included breast and cervical cancer cases (and dates of diagnosis) which were determined to be valid. Male workers and women who, upon re-checking, were found not to have worked for at least five years were removed from this data file prior to analysis. NIOSH investigators then performed two separate modified life table analyses on these workers' records using the Monson Lifetable Program and age-specific breast and cervical cancer incidence rates for the years 1940 to 1981 for females of all races from the Connecticut Tumor Registry. The rates for the period 1970 to 1974 were used for all periods after 1974. Cervical cancer was not considered an endpoint for person-time calulation in the breast cancer analysis and vice versa. Standard incidence ratios (SIR's) were derived for both cervical and breast cancer and 95% confidence limits were calculated for these SIR's using the Fisher exact method. NIOSH investigators also calculated Fisher one-sided p-values for the SIR's. In these analyses, workers were considered at risk only after five years of employment at the company and were not considered at risk when they left the coverage of the Local 837 Health and Welfare Fund. Thus, only female hourly workers who were union members were eligible for entry into this cohort. The begin study date was January 25, 1944 (earliest first employment date observed) and the end of study date was July 28, 1981 (date of the NIOSH on-site investigation).

V. EVALUATION CRITERIA

A. Environmental

Vinyl chloride monomer, one of the substances for which samples were taken, is known to be a carcinogenic agent. It causes angiosarcoma of the liver, a rare form of liver cancer, and possibly other site-specific malignancies. NIOSH states in the Recommended Standard for Occupational Exposure to Vinyl Chloride [2], "there is probably no threshold for carcinogenesis although it is possible that with low concentrations, the latency period might be extended beyond the life expectancy". In view of these considerations and NIOSH's inability to describe a "safe" level as required in Section 20(a)(6) of the Occupational Safety and Health Act of 1970, NIOSH rejects the concept of a threshold limit for carcinogens such as vinyl chloride. As a result, the NIOSH Recommended Standard for Occupational Exposure to Vinyl Chloride states that worker exposure to vinyl chloride monomer should not exceed levels that are detectable by the recommended methods of sampling and analysis. The OSHA standard (29 CFR 1910.1017) for vinyl chloride monomer is 1 ppm averaged over any 8-hour period and 5 ppm averaged over any period not exceeding 15 minutes.

The polymerization of vinyl chloride to form polyvinyl chloride is an irreversible reaction. PVC is a solid over wide ranges of temperatures and pressures and cannot be converted back to VCM. However, residual VCM can be entrapped in PVC. PVC is regulated as a nuisance particulate and the OSHA permissible exposure limit for nuisance dust is 15 mg/m^3 during an 8-hour workday. Although PVC is currently considered a nuisance particulate, data exist relating it to pneumoconiosis, pulmonary X-ray opacities, and lung cancer [3-6].

B. Medical

NIOSH investigators considered a relationship between occupational exposure to vinyl chloride monomer and breast cancer possible, based on evidence from experimental studies on mice reported by Maltoni[7] and Lee et al.[8]. NIOSH investigators were not aware of evidence relating uterine or cervical cancer to VCM exposure and considered this relationship unlikely. Breast cancer is not generally thought to be related to occupational risk factors but is, instead, more commonly related to personal risk factors. Kelsey[9] provided a review of factors which are thought to increase the risk for breast cancer including:

1. old age
2. family history of premenopausal bilateral breast cancer
3. history of cancer in one breast
4. history of fibrocystic disease
5. history of primary cancer in ovary or endometrium
6. any first degree relative with breast cancer
7. large doses of radiation to the chest
8. upper socioeconomic class
9. age greater than 30 at first birth
10. obesity

These personal risk factors, however, fall far short of explaining the occurrence of all breast cancer; hence we remain constantly alert in attempting to identify other risk factors, including occupational ones.

For further information concerning breast cancer detection, interested persons may write for a free copy of "Breast Exams: What You Should Know" to:

Office of Cancer Communications
National Cancer Institute
Bldg. 31, Rm 10A18
Bethesda, Maryland 20205

VI. RESULTS

A. Environmental

OSHA detected no VCM in any of the personal breathing-zone samples for PVC mold operators from the sampling on June 3, 1981. The Precision Plastics Company also detected no VCM from the area air samples taken on June 28 and July 21, 1978. OSHA's area sample for PVC nuisance dust yielded a level of 0.1 mg/m^3. Past usage of PVC was 3000-4000 pounds between 1972 and 1981 on four three-week occasions. Based on available measurements, the process seemed to provide adequate exposure protection.

B. Medical

NIOSH investigators eliminated the 17 men from the 125 workers whose personnel records were abstracted along with six women who were later found not to have worked for at least five years and one woman whose date of birth was missing. Thus, 101 women were included in the modified lifetable analysis. Of the 101 women, 90 were white and 11 were nonwhite; 92 were married at least once, 8 were single and the marital status was unknown for 1; 15 were currently employed, 33 left employment between 1970 and July, 1981, and 53 left employment before 1970. The following statistics further characterize the cohort.

TABLE 1: Characteristics of the 101 Women in the Cohort

Variable	Mean	Median	Standard Deviation	Maximum	Minimum
Year of Birth	1920.9	1920	13.2yrs	1952	1888
Year First Empl.	1957.2	1955	7.8yrs	1974	1944
Year Last Empl.	1969.5	1968	8.7yrs	1981	1952
Age First Empl.	36.3yrs	36.6yrs	8.5yrs	61yrs	9yrs
Age Last Empl.	48.6yrs	47.9yrs	10.1yrs	67yrs	17yrs
Duration Employment	12.3yrs	11.3yrs	5.6yrs	28yrs	5yrs
Person-Years at Risk	7.3yrs	6.3yrs	5.6yrs	23yrs	0yrs*

*Indicates less than one but more than zero person-years at risk

From the Local 837 Health and Welfare Fund, NIOSH investigators documented three cases of breast cancer and two cases of cervical cancer among the 101 women selected for analysis. The following data further characterize these five cases.

TABLE 2: Characteristics of the 5 Cancer Cases Among the 101 Women

Case No.	Diagnosis	Year of Diagnosis	Age at Diagnosis	Duration Employed at Diagnosis	Race	Marital Status
1	Infiltrating ductal carcinoma of right breast	1975	60 yrs	23 yrs	White	Single
2	Infiltrating ductal carcinoma of left breast	1979	56 yrs	11 yrs	Nonwhite	Married
3	Adenocarcinoma of left breast	1979	45 yrs	11 yrs	White	Married
4	Infiltrating cancer of cervix (Invasive squamous carcinoma)	1979	45 yrs	17 yrs	White	Married
5	Focal cervical carcinoma in situ	1975	45yrs	9 yrs	Nonwhite	Married

NIOSH investigators found medical records in the Local 837 Health and Welfare Fund files for 37 of the 101 women who comprise the cohort. No records were found for 64 women. Records would not be present for women who filed no health claims during their coverage.

NIOSH investigators were originally alerted to the possibility of eight cases of breast cancer and two cases of uterine (cervical) cancer. Upon further medical follow-up, NIOSH investigators found that of the eight possible breast cancer cases: three were confirmed, three were found not to be breast cancer, and two did not meet the criteria for entry into the cohort. No previously unknown breast cancer cases were discovered. Upon further medical follow-up, NIOSH found that of the two possible cases of cervical cancer: one was confirmed and one was found not to be cervical cancer. One previously unknown cervical cancer case was discovered.

Of the two cases of breast cancer that did not meet the criteria for entry into the cohort, one occurred in an employee who had not worked at the company for five years and the other occurred in an employee who did not work in a production area. While the exact diagnoses were not known for these two cases, NIOSH did learn that they resulted in mastectomies in 1973 and 1980 respectively.

The modified lifetable analyses yielded the following results.

TABLE 3: Results of Modified Lifetable Analyses

	Breast Cancer (7th ICD, 170)	Cervical Cancer (7th ICD, 171)
Total Person-Years at-Risk	730.1	727.6
Total Expected Number of Cases	0.986	0.428
Total Observed Number of Cases	3	2
Overall Standard Incidence Ratio (SIR)	304	469
Fisher Exact 95% Confidence Limits for SIR	63-889	57-1686
Fisher One-Sided p-value for SIR*	0.078	0.069

*A p-value less than or equal to 0.05 is generally considered significant.

VII. DISCUSSION AND CONCLUSIONS

From the environmental evaluation, NIOSH found that: 1) under 1981 production procedures and as far back as 1978 when the company sampled, vinyl chloride monomer probably did not occur in detectable levels, 2) 1981 polyvinyl chloride dust levels were below OSHA's permissible exposure limit and, 3) the maximum possible length of exposure to VCM and PVC to workers at the company was about twelve weeks. From the medical evaluation, NIOSH found that: 1) three cases of breast cancer and two cases of cervical cancer occurred within a study population of 101 female workers during their period of employment, 2) these cases constituted an excess risk of over three-fold for breast cancer and over four-fold for cervical cancer when compared to the expected number of cases and, 3) these excesses were not statistically significant which means they might reasonably have occurred by chance.

Based on these findings of no exposures to PVC or VCM above the regulatory limits and of excesses that were not significant for breast or cervical cancer, NIOSH concluded that:

1) the cases of breast and cervical cancer which NIOSH observed at the Precision Plastics Company were not demonstrably due to occupational exposures to PVC or VCM.

2) the 1981 PVC and VCM exposures at the company did not constitute a hazard to workers on the basis of current occupational health standards and knowledge of the effects of exposure to PVC and VCM.

3) the past exposures at the company to PVC and VCM did not appear to constitute a hazard to workers on the basis of current occupational health standards and knowledge of the effects of exposure to PVC and VCM.

Because breast and uterine cancer had not been strongly associated with occupation, NIOSH adopted a strategy for this investigation which would be likely to uncover evidence of occupational cancer without immediately committing large amounts of resources to long-range and possibly fruitless investigation. Thus NIOSH investigators limited case-finding follow-up to the period covered by the Local 837 Health and Welfare Fund which was essentially the period of employment. NIOSH chose this follow-up period because it was pertinent, available and inexpensive. Obviously, an average follow-up of only 7.3 years is insufficient for a comprehensive incidence study of breast or uterine cancer. NIOSH did assume, however, that a follow-up period through the end of employment was sufficient to detect a real cluster of breast or uterine cancer among active employees.

In this investigation, NIOSH began follow-up after five years of employment at any time and not only after 1972 which was the year in which PVC was first used. NIOSH chose this follow-up scheme in order to characterize the overall experience of the female employees at Precision Plastics with respect to breast and uterine cancer. While commencing follow-up only after the introduction of PVC might be more technically correct and might have produced significantly elevated standard incidence ratios for breast and uterine cancer, NIOSH's conclusions would still not have changed because of the low level of PVC and nondetectable levels of VCM measured at the plant. The fact that all five cases occurred after 1972, however, does raise suspicions and NIOSH investigators advise continued observation for cases and for occupational exposures, including those other than PVC.

In the current investigation, NIOSH investigators agreed that the small numbers of observed cases did not provide sufficient impetus to undertake difficult and expensive long-term follow-up of the 101 women in the cohort. NIOSH felt that an epidemiologic study undertaken among so small an employee population could not possibly result in firm conclusions. If, in the future, new and compelling evidence relating exposure to PVC, or other plastics used in injection molding, to breast and uterine cancer becomes known, NIOSH would probably recommend that an industrywide study of injection molding be undertaken.

VIII. RECOMMENDATIONS

NIOSH recommends that the company, the union, and the employees keep track of future cases of breast, uterine and cervical cancer among active and, if feasible, terminated employees of the Precision Plastics Company, and request that NIOSH conduct another Health Hazard Evaluation if several new cases occur.

IX. REFERENCES

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XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available, upon request, from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia 22161.

Copies of this report have been sent to:

1. Authorized Representative of Employees, Local No. 837, Industrial Workers Union.
2. President of Precision Plastics Company, Philadelphia, Pennsylvania.
3. NIOSH, Region III.
4. OSHA, Region III.
5. City of Philadelphia, Department of Public Health, Philadelphia, Pennsylvania.

For the purpose of informing the 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.