A STUDY OF ODOR AND IRRITANT EFFECTS IN A POPULATION RESIDING NEAR A BARREL AND PAIL MANUFACTURING PLANT IN JERSEY CITY

Prepared by:

The Office of Occupational and Environmental Medicine
and
The Environmental Health Service

Division of Occupational and Environmental Health
New Jersey Department of Health
Trenton, New Jersey

January 1988

ACKNOWLEDGEMENTS

Special thanks to John Demjanick and Gary Garetano of the Hudson County Regional Health Commission and the administration and staff at Our Lady of Mercy School, especially Sister Rose Mary Collins, for their invaluable assistance in planning and carrying out this investigation. We would also like to extend our gratitude to the study participants, who waited through heat and waded through puddles to participate in this project.

SUMMARY

Jersey City residents living near the Van Leer Containers Company (the plant), a barrel and pail manufacturing plant, have been reporting for several years odors and symptoms of eye, nose, and throat irritation, headache, and nausea. In response to citizen complaints and a New Jersey Department of Health (NJDOH) study suggesting an abnormal pattern of nosebleeds in children attending Our Lady of Mercy School which is across the street from the plant, NJDOH conducted a cross-sectional study comparing two groups of adults, one living downwind from the plant (target population) and the other living outside the target area (comparison population).

Eighty-three (83) parents of children attending the school (47 in the target group and 36 in the comparison group) underwent a clinical nasal examination in an attempt to measure potential effects of low-level irritants and unpleasant odors. The examination included an extensive questionnaire, an odor identification test, physical examination of the nasopharynx and cytologic examination of cells obtained by nasal swab.

Analysis of the data indicated that the target population had a consistent pattern of increased symptoms of eye, nose and throat irritation, compared with the comparison population, that may be related to exposure to low-level irritant emissions and/or noxious odors emanating from the plant. Headache was the only complaint that was reported at a statistically significantly ($p=0.038$) higher rate in the target population compared with the comparison population.

With regard to the nasal physical examination, redness of the internal lining of the nostrils was observed more frequently in the target population

than in the comparison population. There were no differences between the groups in their responses to the remaining parameters in the nasal speculum and fiberoptic examinations and cytology, and odor identification test.

Redness of the internal lining of the nostrils is not considered to have clinical significance. The absence of any correlation with other symptoms or clinical endpoints suggests that the increased redness in the target group may not be related to the exposure of interest. However, because of the absence of adequate personal exposure data, a relationship between the plant's emissions and redness cannot be ruled out.

The increased complaints of headache and the more frequently observed redness of the internal lining of the nostrils in the target group, if indeed caused by the exposure under consideration, would be expected to improve as the emissions are abated, with no residual ill effects. The fact that these headache complaints did not persist away from home strongly suggests that they do not represent an irreversible problem. If these headaches are related to outdoor air contaminants, the mechanism for the cause-effect relationship is unclear. Exposure to low-level irritants is not reported to directly cause headaches, although stress related to the exposure might result in a headache. Noxious odors have been linked with headaches, but without much substantiating evidence.

The eye, nose, and throat symptoms experienced by the residents should not be dismissed lightly, since they may have considerable impact on quality of life. The increased complaints of headaches in the target population is of particular concern, since any type of headache, whether or not it is associated with a serious medical condition, can adversely affect an individual's ability to function.

There are many problems inherent in designing and carrying out an investigation of this type. The small number of study participants makes it difficult to arrive at strong indications of a causal relationship between the exposure under consideration and any adverse health effect. Assignment to exposure categories was very crude since no objective exposure measurements were available. Adding to the difficulty is the nonspecific or easily subjective nature of the health endpoints which may be caused by other factors independent of the plant's emissions. There might be other relevant endpoints which were not investigated, either because they are as yet unrecognized or they are impossible to detect by currently available screening techniques. Another problem with studies of this type is selection bias, i.e., there is a greater tendency for symptomatic individuals to participate.

Despite the limitations of the study, and despite the fact that no single study of any type can ever definitively rule out a health effect, the absence of increased nosebleeds and other nasopharyngeal abnormalities in the target group remains reassuring. Consequently, excess symptoms related to exposure to emissions from the plant may decline as the emissions are controlled. On the other hand, it is precisely because of these limitations, that it is important to identify and reduce chemical exposures and eliminate hazards instead of waiting for the results of health studies to determine actions.

The findings of this study support the efforts the New Jersey Department of Environmental Protection and the community have taken to bring the emissions from the plant under control through consent orders. Clearly, the

quality of life of the neighborhood in the immediate vicinity of the plant was impacted by the perception that the emissions were affecting them, in addition to any direct effect of the actual exposure.

RECOMMENDATIONS

This study was undertaken to determine if any of the following three actions are indicated:

1. Immediate intervention to reduce exposure,
2. Clinical intervention to alleviate current or to prevent future diseases, and
3. Further studies or actions stemming from initial results.

Based on the results of this study, none of these three actions are warranted because of a) the absence of excess of objective indications of physical damage such as nosebleeds and other nasopharyngeal abnormalities in the target group, and 2) the plant terminated its operations on October 5, 1987 due to economic considerations. Excess self-reported symptoms that may be related to exposure to emissions from the plant are expected to decline as the result of the plant's closure. In addition, each participant received a letter from NJDOH containing the individual's results and, where indicated, recommending additional clinical follow-up with the individual's personal physician.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

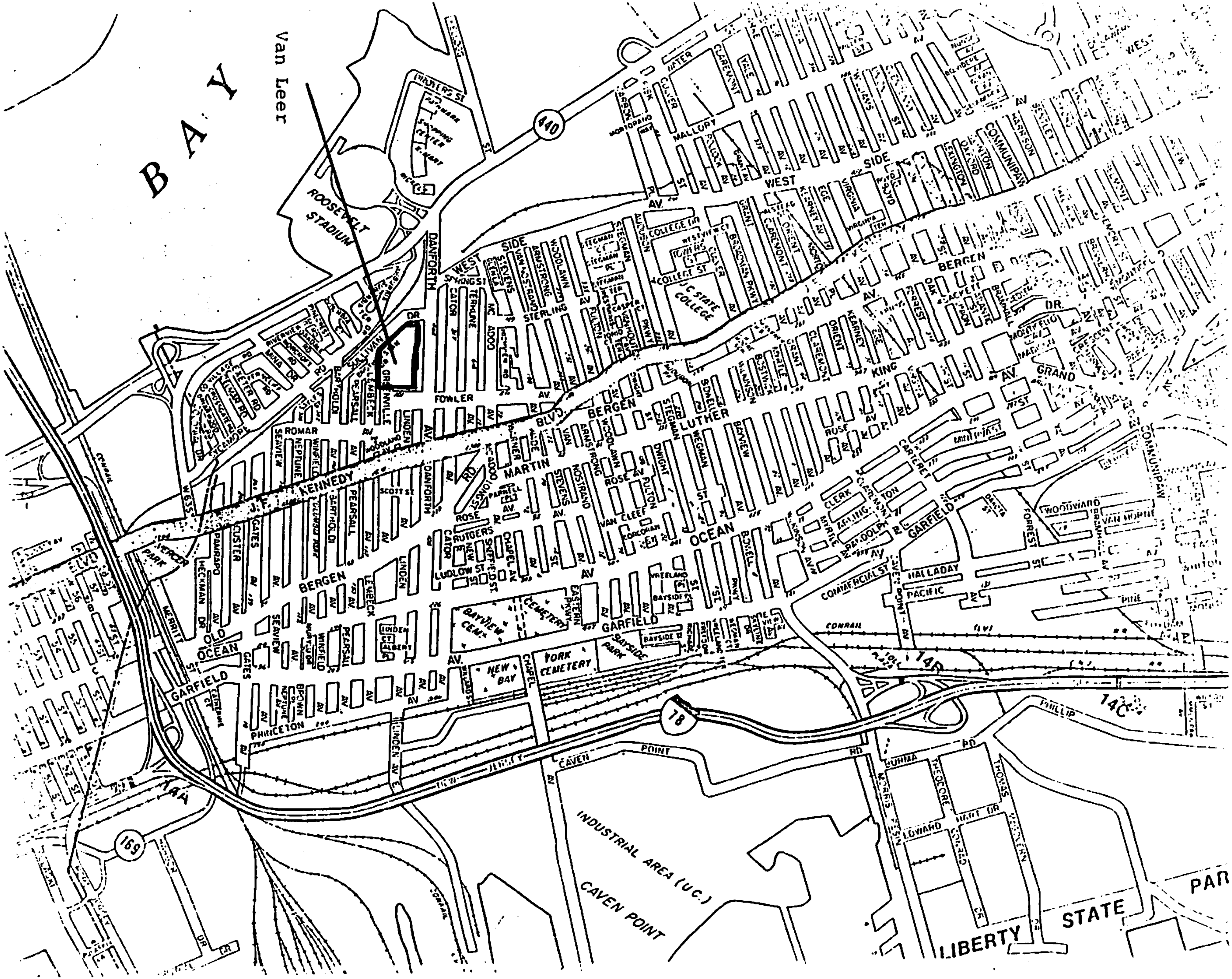
LIST OF APPENDICES

INTRODUCTION

Van Leer Containers Company (the plant) which is more than 100 years old, is located in a residential area in Jersey City (Figure 1). Prior to terminating its operations in October, 1987, pails and barrels where manufactured and painted with a normal daily production rate of 3,500 pails and 15,000 barrels (OSR/NJDEP, 1986). Coatings were put on products by the plant using paint spray, lacquer spray and lithograph roller booths. The lithograph and part of the pail lines were vented to two separate exhaust incinerators. However, a considerable amount of vapors from the plant's operations were fugitive. According to the records of the Hudson County Regional Health Commission (HCRHC) and the New Jersey's Right-to-Know Program, the paint products utilized by the plant contained at least the following solvents: acetone, methylethylketone, methylisobutylketone, butanol, ethanol, isopropanol, butylacetate, Ektasolve, xylenes, and toluene (Appendix A).

Odors resulting from the plant could be detected as far as 1 mile from the manufacturing site. Residents living in the vicinity of the plant have complained of symptoms of upper airway irritation, nausea and headaches. The residents have associated these symptoms with the emissions from the plant. In the fall of 1985, HCRHC requested assistance from the New Jersey Department of Health (NJDOH) and New Jersey Department of Environmental Protection (NJDEP) in evaluating the citizens' complaints.

In November of 1985, the NJDEP's Office of Science and Research (OSR) collected and analyzed air samples to determine upwind, downwind and maximum impact data for volatile organic compounds (VOCs) on the plant's emissions



BAY
Van Leer
ROOSEVELT STADIUM
SHOPPING CENTER
440
WEST SIDE AV
DANFORTH
J.F. KENNEDY BLVD
BERGEN AV
MARTIN LUTHER KING DR
OCEAN AV
OLD OCEAN AV
GARFIELD AV
COMMUNIPAW
J.C. STATE COLLEGE
GRAND
MERCER PARK
BAYVIEW CEM.
CEMETERY
NEW BAY
YORK CEMETERY
BAYSIDE PARK
CONRAIL
14B
14C
78
169
CAVEN POINT RD
PHILLIP
INDUSTRIAL AREA (U.C.)
CAVEN POINT
LIBERTY STATE
PAR

(OSR/NJDEP, 1986; Appendix B). The results of the air sampling indicated that downwind concentrations were significantly elevated over upwind concentrations. No VOCs were measured at levels known to be associated with adverse health effects. The report noted, however, that unknown organic compounds were not the focus of the study and, therefore, it is uncertain whether high levels of other odorous materials were being emitted from the plant (OSR/NJDEP, 1986).

NJDOH initially focused on complaints of excess nosebleeds among school children at Our Lady of Mercy School, located across the street from the plant (Figure 1). Some parents and the school nurse felt that there was an excess of upper and lower airway irritant symptoms, especially nosebleeds, among the children. Nosebleeds were selected for investigation because this was felt to be the most objective endpoint available. Staff of NJDOH's Division of Occupational and Environmental Health reviewed the nurse's logs at Our Lady of Mercy and compared the incidence and prevalence rates and pattern of nosebleeds with that recorded in the nurses' logs at three parochial elementary schools in Bayonne.

The results of the study indicated that, although there was no excess of nosebleeds among the children in Our Lady of Mercy school, there was a difference in the seasonal distribution of the bleeding episodes. More nosebleeds occurred among the children in Our Lady of Mercy school in the warmer months when windows were open and the children played outdoors more often. This was in contrast to the expected increase in nosebleeds during the winter, when the risk factors of low indoor humidity and upper respiratory infections are most prevalent. Indeed, children in the three comparison schools had more nosebleeds in the winter months.

The results of the nosebleed study should not be taken to suggest that the plant emissions was responsible for the seasonal shift in nosebleeds among the children attending Our Lady of Mercy.

Nosebleeds could be caused by several factors which include low humidity, upper respiratory infections, and genetic susceptibility to bleeding of varying degrees. The frequency and the severity of the nosebleeds would depend on individual variability. A review of the scientific literature revealed little information on possible relationships between nosebleeds and the chemicals emitted from the plant and little objective information concerning adverse effects of human exposure to unpleasant odors or low-level irritants. Exposure to unpleasant odors is widely reported to cause nausea and headache, but no well-documented investigation of this was found. Exposure to low-level irritants is a recognized cause of eye, upper airway (nose and throat) and, possibly, lower airway (bronchial tree and lungs) irritant symptoms. However, no epidemiologic investigation utilizing objective parameters (such as physical examination or upper airway physiologic studies) was found.

One of the major difficulties in drawing conclusions regarding cause-effect relationships based only on symptoms such as headaches and tightness of the chest is that these symptoms are self-reported, and therefore, cannot be documented by available medical tests. Such self-reported symptoms are called "subjective" illnesses, whereas illnesses which can be documented by medical tests are called "objective" illnesses. In studies of communities concerned about their health because of emissions from chemical facilities or hazardous waste sites, "subjective" illnesses are usually carefully interpreted since the assumed "exposed" population may

have a heightened awareness of their medical conditions compared with the "unexposed" population. This heightened awareness may overemphasize the magnitude of the true effect from the exposure. Although there are analytical tools for analyzing the data which take account of heightened awareness, the problem cannot be ruled out confidently. It is for these reasons that "subjective" illnesses are not highly regarded as parameters to consider in health studies of communities concerned about chemical exposures.

There is need for recognition that, although self-reported illnesses cannot be verified by objective means, these illnesses require no verification to the the individual residing in the community under investigation and impact heavily on the individual's and the community's quality of life. Additionally, in order to develop a risk communication/outreach program for the community and its residents with some hope for success, knowledge of the community's general concern for health should include information on both "subjective" and "objective" illnesses.

Even with paucity of information on the relationship between chemical exposure and nosebleeds and the difficulty in drawing conclusions regarding cause-effect relationship based only on "subjective" symptoms, the nosebleed complaints suggested that the plant's emissions might be affecting the health of the children and adults in the immediate vicinity of the plant. Because of this concern, NJDOH decided to undertake an investigation, which was cross-sectional in nature, comparing a group of residents living in the immediate vicinity of the plant with a group living further away from the facility. The study focused on the detection of irritant and odor effects resulting from exposure to low-level irritants and unpleasant odors. The

deprivation. Alone, the odor test can provide meaningful information only for an individual's ability to detect odors. When combined with nasal examination and nasal cytology, however, the odor test could provide meaningful information on the biological relationship between chemical exposure and effects on nasal function.

deprivation. Alone, the odor test can provide meaningful information only for an individual's ability to detect odors. When combined with nasal examination and nasal cytology, however, the odor test could provide meaningful information on the biological relationship between chemical exposure and effects on nasal function.

METHODS

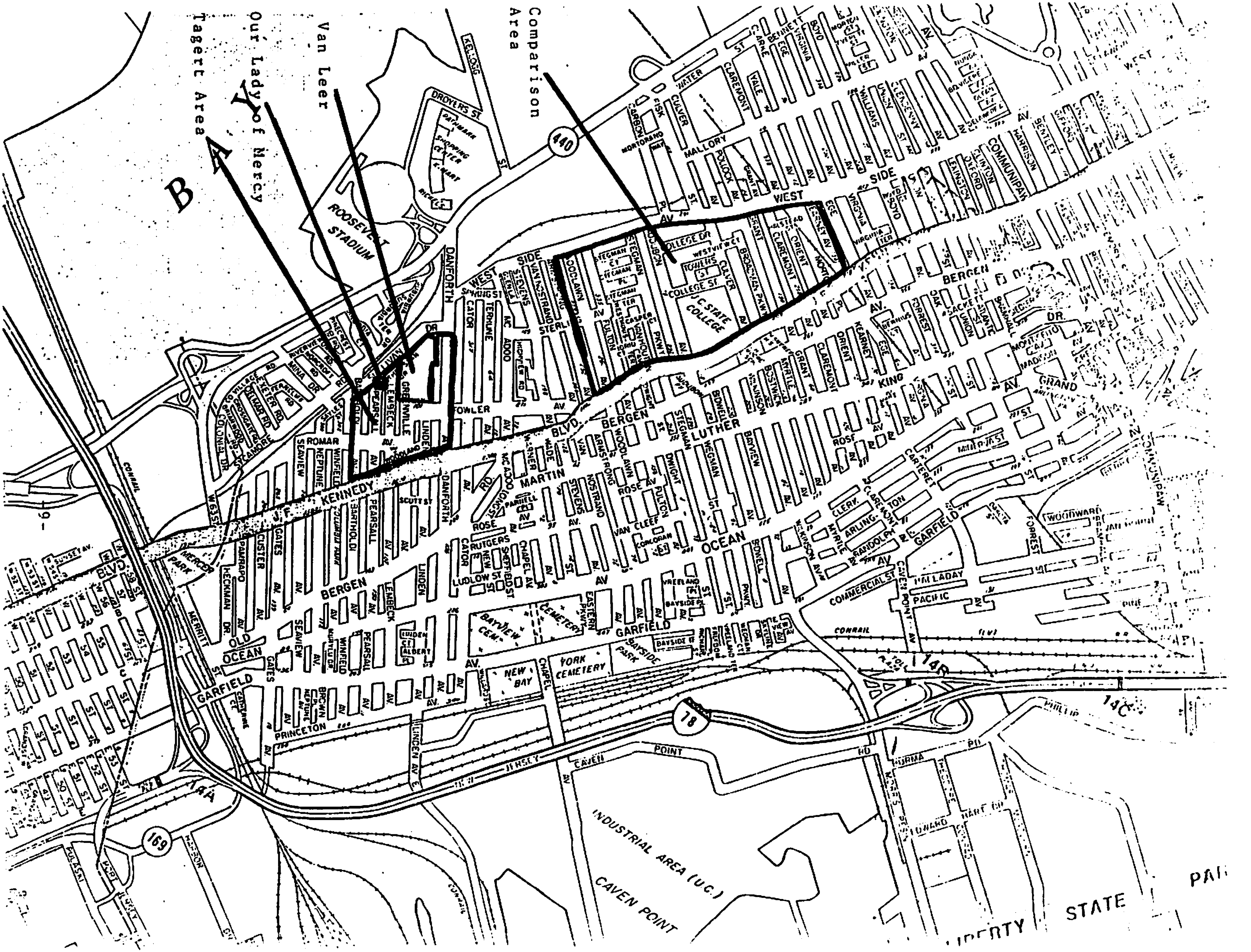
Study Participants

Study participants were recruited from among parents of children attending Our Lady of Mercy School. Two groups of parents were identified on the basis of a) proximity to the plant, b) information provided by the OSR study, and c) known wind direction (ascertained with the assistance of the Hudson County Regional Health Commission). In the absence of individual exposure data, the target population was defined as those living in areas downwind from the plant and the comparison population was defined as those living upwind or in areas not expected to be impacted by the plant's emissions (Figure 2). The target area was defined to be as small as possible to minimize misclassification of individuals in the target and comparison groups.

All potential participants received a letter (Appendix C) informing them of the project, and follow-up phone calls were made to elicit their participation. Anyone with heart problems was excluded from the study because of the slight possibility that the nasal spray used during the examination might exacerbate any existing problems with their heart's rhythm.

Power Calculation

One of the paramount considerations in designing a health study is the study's statistical power; in other words, the study's ability to accurately estimate differences in frequencies or mean values between two or more study groups, and to rule out chance as a likely explanation of such differences. A study's power depends on, among other factors, the number of participants.



Comparison Area
Van Leer
Our Lady of Mercy
Tagert Area
BAY
ROOSEVELT STADIUM
J.C. STATE COLLEGE
J.F. KENNEDY BLVD.
WEST SIDE AV.
BERGEN AV
OCEAN AV
GARFIELD AV.
MARTIN LUTHER KING DR.
MERCER PARK
BAYVIEW CEM.
NEW BAY CEMETERY
YORK CEMETERY
BAYSIDE PARK
INDUSTRIAL AREA (U.C.)
CAVEN POINT
STATE
440
78
169

The greater the size of the population investigated, the greater the confidence one will have that a small difference, or that a lack of measurable difference is real. Since the focus of this study is on the nasopharyngeal examinations and odor identification, the power calculation indicated that a minimum of 44 participants in each group was necessary to give 90% assurance that a 30% absolute difference in responses between the target group and the comparison group would be detected with less than 5% probability of this difference, or a greater difference, is due to chance alone. The designation of a target area of limited size still afforded the possibility of recruiting 44 study participants. It is important to note that the power calculation values assume that there is no bias in estimation of effect caused by misclassification of exposure status, i.e., that everyone in the exposure group is truely exposed and everyone in the comparison group is truely not exposed.

Symptoms Questionnaire and Nasopharyngeal and Odor Examinations

The overall examination consisted of a questionnaire focusing on symptoms related to eye, nose, throat and lung irritation and nonspecific odor effects; a test of the sense of smell, and a nasal examination.

The questionnaire was designed to elicit information regarding symptoms of irritation of the eyes (two questions), irritation of the nose (eight questions), irritation of the throat (three questions), nausea (one question), and headache (one question) (Appendix D). For any positive response to the initial general question, multiple follow-up questions were asked to learn more details about the symptom. The remainder of the questionnaire focused on factors other than potential exposure to plant emissions that might be related to these symptoms, such as workplace and

home exposures to chemicals, smoking history, and pre-existing medical problems. Questions were also asked regarding each participant's sense of smell (Appendix E).

The nasal exam consisted of an initial visualization of both nostrils through a speculum (Appendix F) followed by a fiberoptic nasal examination of one nostril to look farther up the nose (Appendix G). A cytologic specimen was obtained by nasal swab during the speculum examination (Appendix H). Local anesthesia was used for the fiberoptic examination.

Questionnaires and smell tests were administered by trained personnel from the NJDOH and the Hudson County Regional Health Commission. The nasal examinations were conducted by third-year residents from the Division of Otolaryngology at UMDNJ-New Jersey Medical School under the direction of Division Chairman Dr. Anthony Jahn. Examination of the cytologic specimens was performed by Dr. Neana Mirani of the Department of Pathology, United Hospitals, Newark.

All interviewers and examiners and field personnel were deliberately kept unaware of whether the individual participants resided in the target or comparison areas.

Clinical and statistical interpretations of study results were performed by NJDOH in consultation with Drs. Jahn and Mirani. Prodas and SPSS/PC+ softwares were used for the statistical analyses.

Statistical Interpretation of Data

The data presented in this report were statistically evaluated by using two measures, the p-value and the 95% confidence interval. It is common in most epidemiologic studies to calculate the probability that any differences found between two study groups occurred merely on the basis of chance rather

than because there was any real difference between the two groups. This calculation provides the investigator with an estimate of the "statistical significance" of the findings. Usually a result is considered statistically significant if the observed difference or a greater difference would be expected by chance less than 5% of the time (i.e, the p-value is less than 0.05).

The 95% confidence interval is another measure used by investigators to estimate the range a particular result represents 95% of the time. The evaluation of the confidence interval is very important for studies with small population sample sizes in which a slight change in the number of individuals with a particular symptom can drastically change the size of the difference between two study groups. Generally, the smaller the population sample size, the larger the range of the confidence interval for a particular effect, and the less confident the investigator feels that a large difference in a response between two study groups is real.

Collectively, the p-value and the 95% confidence interval provide investigators with reasonable methods for determining how likely it was that the observed differences between two study groups could have occurred by chance alone.

RESULTS

Characteristics of Study Participants

The characteristics of the study populations are summarized in Table 1. The target group consisted of 47 adults, including fourteen married couples, and the comparison group included 36 adults with eight married couples. Although the required minimum number of 44 participants was not attained for the comparison group, the available small sample size was still sufficient to detect a 30% absolute difference in responses on the nasal examinations between the groups.

The two groups were similar with regard to age, sex, employment, and years of formal education. The proportion of whites was statistically significantly ($p=0.006$) higher in the target population compared with the comparison population. Average years of residence was slightly higher in the comparison group although the range was similar in both groups. These differences should not have any affect on the endpoints under investigation in this study.

Occupational and Residential Exposure Experiences

Forced air was used overwhelmingly ($p=0.005$) as the major type of residential heat in the residences of the target population compared with the comparison population. No differences were noted between populations in occupational and smoking experiences, or in the other parameters of residential exposure experience.

TABLE 1

Characteristics and Exposure Experiences of Study Participants

	Target Group No. (%)	Comparison Group No. (%)	p-value*
Number of subjects	47 (100%)	36 (100%)	
Male	17 (36%)	13 (36%)	ns
Female	30 (64%)	23 (64%)	ns
White	41 (87%)	21 (58%)	0.006
Black	0	5 (14%)	nt
Other	6 (13%)	10 (28%)	ns
Average age (range)	37 (30-59)	37 (28-48)	ns
Average yrs education (range)	13.1 (8-17)	13.8 (9-17)	ns
Yrs at current address (range)	7.6 (0-30)	10.4 (1-38)	ns
Currently employed	36 (76.6%)	29 (80.5%)	ns
Second job	3 (6.4%)	6 (16.7%)	ns
Homemaker	11 (23.4%)	6 (16.7%)	ns
Occupational and Residential Exposure Experiences			
Average number of hours away from neighborhood (range)			
Mon-Fri	6 (0-12)	6.4 (0-12)	ns
Sat-Sun	4 (0-24)	5.3 (0-48)	ns
Exposed to chemicals for more than 1/2 hour per day	15 (31.9%)	8 (22.2%)	ns
metal dust	1 (2.1%)	0	nt
acid fumes	13 (27.6%)	8 (22.2%)	ns
industrial solvents	4 (8.5%)	0	nt
cleaning products	10 (21.3%)	6 (16.7%)	ns
herbicides/pesticides	0	1 (2.8%)	nt
other	6 (12.8%)	1 (2.8%)	ns
Type of Residential Heat			
forced air	14 (29.8%)	2 (5.5%)	0.005
steam or hot water	25 (53.2%)	26 (72.2%)	ns
built-in electric unit	0	0	nt
other	8 (17%)	8 (22.2%)	ns

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

TABLE 1 (continued)

Characteristics and Exposure Experiences of Study Participants

	Target Group No. (%)	Comparison Group No. (%)	p-value*
Number of subjects	47	36	
Fireplace or a Wood Stove	2 (4.2%)	0	nt
Kerosene Heater	1 (2.1%)	0	nt
Humidifier	12 (25.5%)	8 (22.2%)	ns
Air Conditioned Home	43 (91.4%)	31 (86.1%)	ns
Air Purifier	3 (6.4%)	3 (8.3%)	ns
Smoking Experience			
Used tobacco on a regular basis for at least 3 months	31 (66%)	18 (50%)	ns
Do you smoke or use tobacco now?	17 (36.2%)	11 (30.5%)	ns
cigarettes	31 (66%)	17 (47.2%)	ns
cigars	0	0	nt
pipes	0	1 (2.8%)	nt
chewing tobacco/snuff	0	0	nt
Does anyone else smoke in your home?	21 (44.7%)	12 (33.3%)	ns

* X^2-test, one-tailed, ns = not significant: $p > 0.05$, nt = not tested

Symptoms Questionnaire

As shown in Table 2, the crude rates for the various self-reported illnesses include new, existing, and reoccurring cases of illnesses or medical conditions. In other words, the illness rates in the table are a snapshot (cross sectional) description of the health status of the study groups. Overall the health status of the target and comparison groups were not dissimilar based on the prevalence rates of reported illnesses. However, the target group demonstrated elevated rates (not statistically significant) of itchy/burning eyes, watery eyes, cough, dry throat, nausea, and headache.

The data were analyzed further by defining a symptom case which could be considered to be compatible with exposure to airborne irritants from outside the house. A symptom was considered compatible with exposure if the respondent described it as:

1. occurring only at home;
2. not related to clearly identifiable colds or allergies or known chemical exposures in the home;
3. not related to any particular season; and
4. occurring weekly or daily (rather than monthly or seldom).

A symptom had to have all four of these characteristics before it was considered "positive" for the purposes of this study. This stringent criteria was necessary because the symptoms used for analysis were very nonspecific and quite common in the general population. Nosebleeds were included in the analysis if they were not related to any particular season. Winter is when adult nosebleeds occur most frequently and are commonly related to colds and dry indoor air. Using these criteria, the number of

TABLE 2

Crude Rates of Illnesses Reported by Study Participants

	Target Group	Comparison Group	Rate Ratio	95% Conf. Interval	p-value*
Number of subjects	47	36			
Ever had asthma					
confirmed	5 (10.6%)	2 (5.5%)	1.93	0.32 - 51.3	ns
still present	2 (4.2%)	1 (2.8%)	1.55	0.04 - 61.1	ns
Allergy					
affecting nose	9 (19%)	11 (30.5%)	0.62	0.17 - 1.65	ns
food	4 (8.5%)	5 (13.9%)	0.61	0.11 - 2.75	ns
medication	13 (27.6%)	2 (5.5%)	5.02	1.24 - 31.9	0.008
as a child	6 (12.8%)	3 (8.3%)	1.54	0.32 - 41.3	ns
Nose-related symptoms:					
runny nose	25 (53%)	18 (50%)	1.06	0.43 - 2.97	ns
itchy nose	18 (38%)	13 (36%)	1.05	0.41 - 2.97	ns
sneezing	17 (36%)	19 (53%)	0.68	0.19 - 1.34	ns
dry nose	15 (32%)	11 (30.5%)	1.05	0.37 - 3.02	ns
crusting	9 (19%)	8 (22%)	0.86	0.25 - 2.74	ns
pain	3 (6.4%)	2 (5.5%)	1.16	0.14 - 2.96	ns
nasal obstruction	12 (25.5%)	11 (30.5%)	0.84	0.27 - 2.27	ns
sinus pain	19 (40.4%)	16 (44.4%)	0.91	0.32 - 2.24	ns
nosebleeds	9 (19%)	9 (25%)	0.76	0.22 - 2.28	ns
Eye-related symptoms:					
itchy/burning eyes	28 (59.6%)	15 (41.7%)	1.43	0.78 - 5.5	ns
watery eyes	20 (42.5%)	10 (27.8%)	1.53	0.69 - 5.43	ns
Throat-related symptoms:					
cough	11 (23.4%)	5 (13.9%)	1.68	0.53 - 7.11	ns
sore/scratchy throat	15 (31.9%)	16 (44.4%)	0.72	0.21 - 1.58	ns
dry throat	18 (38.3%)	8 (22.2%)	1.72	0.74 - 6.5	ns
Nausea	12 (25.5%)	4 (11.1%)	2.3	0.71 - 11.3	ns
Headache	30 (63.8%)	15 (41.6%)	1.53	0.93 - 6.7	0.07
High blood pressure					
Yes	9 (19%)	5 (13.9%)	1.37	0.39 - 5.7	ns
don't know	1 (2.1%)	0	-	-	nt
Diabetes	0	0	-	-	nt
Epileptic seizures	1 (2.1%)	1 (2.8%)	0.76	0.27 - 2.09	ns
Kidney disease	1 (2.1%)	2 (5.5%)	0.38	-	ns
Bleeding problems	3 (6.4%)	4 (11.1%)	0.58	0.09 - 3.17	ns
More than 6 colds/year	3 (6.4%)	2 (2.8%)	2.9	0.14 - 2.96	ns

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

people in each group reporting the symptoms selected as potential effects of exposure to unpleasant odors and low-level irritants are summarized in Table 3.

For the results presented in Table 3, it is important to note that the number of individuals reporting symptoms compatible with exposure to a nearby source was reduced by applying the above stringent criteria. Under these conditions, only the headache rates were statistically significantly ($p=0.038$) higher in the target population compared with the comparison population. Despite the lack of statistical significance for the other individual symptom complaints, however, a glance at the data reveals a clearcut trend toward more symptom in the target group (i.e., rate ratios greater than 1.0).

The headache finding led to further scrutiny of this data. The single headache complainant in the comparison group was female and could identify no cause for her headaches. The eight headache complainants in the target group included six women and two men. One person attributed her headaches to previous head trauma, one to migraines, two to stress/tension, one to sinus problems, two to environmental exposures, and one to unknown causes.

Symptoms a) occurring in a location other than work and b) occurring more frequently in a particular season, did not provide additional findings different from those described in Table 3. Additional analysis failed to demonstrate correlations within the reported symptoms and between the symptoms and occupational, smoking, and residential exposure experiences including forced air.

TABLE 3

Rates of Illnesses Compatible with Exposure

	Target Group	Comparison Group	Rate Ratio	95% Conf. Interval	p-value*
Number of subjects	47	36			
Asthma	1 (2.1%)	0	-	-	nt
Allergy	0	1 (2.8%)	-	-	nt
Nose-related symptoms:					
runny nose	5 (10.6%)	1 (2.8%)	3.8	0.43 - 80	ns
itchy nose	5 (10.6%)	3 (8.3%)	1.3	-	ns
dry nose	6 (12.8%)	2 (5.5%)	2.3	0.41 - 29	ns
nasal obstruction (both nostrils)	2 (4.2%)	4 (11.1%)	0.38	0.02 - 2.46	ns
one or more nose-related symptoms	15 (31.9%)	5 (14%)	2.3	0.85 - 10.5	ns
sinus pain	0	2 (5.5%)	-	-	nt
nosebleeds	1 (2.1%)	1 (2.8%)	0.76	0.28 - 2.08	ns
Eye-related symptoms:					
itchy/burning eyes	1 (2.1%)	1 (2.8%)	0.76	0.28 - 2.08	ns
watery eyes	2 (4.2%)	2 (5.5%)	0.76	0.28 - 7.25	ns
one or more eye-related symptoms	10 (21.2%)	3 (8.3%)	2.55	0.67 - 15.3	ns
Throat-related symptoms:					
cough	4 (8.5%)	0	-	-	nt
sore/scratchy throat	2 (4.2%)	3 (8.3%)	0.5	0.005 - 3.9	ns
dry throat	5 (10.6%)	1 (2.8%)	3.8	0.43 - 80	ns
one or more throat-related symptoms (all participants)	14 (29.7%)	6 (16.6%)	1.8	0.65 - 7.17	ns
one or more throat-related symptoms (non-smokers only)	8/30 (27%)	5/25 (20%)	1.35	0.35 - 6.23	ns
One or more nose, eye, or throat-related symptoms	26 (55%)	15 (42%)	1.73	0.66 - 4.6	ns
Nausea	1 (2.1%)	1 (2.8%)	0.76	0.28 - 2.08	ns
Headache	8 (17%)	1 (2.8%)	6.07	0.83 - 68	0.038

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

ODOR IDENTIFICATION TEST

Only two study participants performed abnormally on the odor identification test. One of the two had problems with sense of smell since birth and the other, who performed the test abnormally in just one nostril, had a cold at the time of the examination and denied any problems in her usual healthy state. Thus, there were no differences between the two examination groups.

NASAL EXAMINATION

Of the 83 participants who completed the questionnaire and odor identification test, 81 underwent the nasal speculum examination and 79 underwent the fiberoptic nasal examination. Multiple endpoints were recorded during both the speculum and fiberoptic nasal examinations.

Of the results presented in Table 4, erthyema (redness) of the nasal mucosa (internal lining of the nose) was observed more frequently in the target population (12 for 27% in the left nostril and 11 for 25% in the right nostril) compared with the comparison population (3 for 8% in both nostrils). The redness in both nostrils was not consistently accompanied by redness in other parts of the nose nor by an increase in any other abnormality (such as nasal swelling, increased secretions, dryness) consistent with an irritant effect. Nor did the presence of redness correlate with nasal symptoms.

There were no consistent differences nor any pattern of findings suggestive of differences between the target and the comparison groups on either the speculum or the fiberoptic examinations (Table 5) for the other nasal parameters investigated.

TABLE 4

Nasal Speculum Examination

	Target Group (44)	Comparison Group (36)	p-value*
External Examination			
Nasal tenderness	0	0	nt
Sinus tenderness	0	0	nt
Evidence of bleeding			
Both nostrils	0	1 (2.8%)	nt
Neither	44 (100%)	34 (100%)	nt
Evidence of discharge			
Both nostrils	0	1 (2.8%)	nt
Neither	44 (100%)	34 (100%)	nt
Significant external abnormalities			
Yes	4 (9.1%)	5 (14%)	ns
No	30 (68%)	23 (64%)	ns
Internal Examination			
<u>Mucosa</u>			
normal -right	23 (52.3%)	22 (61%)	ns
-left	23 (52.3%)	23 (64%)	ns
pale -right	7 (16%)	7 (19.4%)	ns
-left	7 (16%)	7 (19.4%)	ns
edematous-right	4 (9.1%)	6 (16.7%)	ns
-left	3 (6.8%)	5 (14%)	ns
erthyema -right	11 (25%)	3 (8.3%)	ns
-left	12 (27.3%)	3 (8.3%)	0.06
dry -right	7 (16%)	3 (8.3%)	ns
-left	8 (18.2%)	3 (8.3%)	ns
crusted -right	1 (2.3%)	2 (5.5%)	ns
-left	3 (6.8%)	1 (2.8%)	ns
erosion -right	0	0	nt
-left	0	0	nt
bleeding -right	0	0	nt
-left	0	0	nt
vessel -right	0	0	nt
-left	1 (2.3%)	0	nt
<u>Septum</u>			
midline	17 (38.6%)	10 (27.8%)	ns
deviated -right	9 (20.4%)	11 (30.5%)	ns
-left	12 (27.3%)	9 (25%)	ns
perforation	0	0	nt

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

TABLE 4 (continued)

Nasal Speculum Examination

		Target Group (44)	Comparison Group (36)	p-value*
Turbinates				
normal	-right	19 (43.2%)	18 (50%)	ns
	-left	16 (36.5%)	18 (50%)	ns
pale	-right	10 (22.7%)	8 (22.2%)	ns
	-left	9 (20.4%)	8 (22.2%)	ns
bluish	-right	0	3 (8.3%)	nt
	-left	2 (4.5)	3 (8.3%)	ns
edematous	-right	11 (25%)	9 (25%)	ns
	-left	14 (31.8%)	10 (27.8%)	ns
granular	-right	4 (9.1%)	1 (2.8%)	ns
	-left	4 (9.1%)	1 (2.8%)	ns
polypoid	-right	0	2 (5.5%)	nt
	-left	1 (2.3%)	1 (2.8%)	ns
eroded	-right	2 (4.5%)	0	nt
	-left	2 (4.5%)	0	nt
hyper-trophied	-right	5 (11.4%)	1 (2.8%)	ns
	-left	5 (11.4%)	0	nt
Secretions				
none	-right	19 (43.2%)	13 (36%)	ns
	-left	20 (45.5%)	13 (36%)	ns
scant	-right	19 (43.2%)	16 (44.4%)	ns
	-left	17 (38.6%)	17 (47.2%)	ns
profuse	-right	0	0	nt
	-left	0	0	nt
watery	-right	7 (16%)	3 (8.3%)	ns
	-left	5 (11.4%)	3 (8.3%)	ns
mucoid	-right	4 (9.1%)	6 (16.7%)	ns
	-left	6 (13.6%)	5 (14%)	ns
purulent	-right	0	0	nt
	-left	0	0	nt

* χ^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

TABLE 5

Nasal Fiberoptic Examination

	Target Group (44)	Comparison Group (36)	p-value*
Sinus orifices			
clear	35 (79.5%)	25 (69.4%)	ns
mucoid discharge	9 (20.4%)	9 (24%)	ns
pus	0	0	nt
Nasal cavity			
patent	37 (84%)	30 (83.3%)	ns
obstructed	7 (16%)	6 (16.7%)	ns
Nasopharynx			
normal	25 (56.8%)	16 (44.4%)	ns
erythema	9 (20.4%)	6 (16.7%)	ns
pale	7 (16%)	11 (30.5%)	ns
polypoid	3 (6.8%)	5 (14%)	ns
edema	3 (6.8%)	2 (5.5%)	ns
crusted	0	1 (2.8%)	nt
other	2 (4.5%)	2 (5.5%)	ns
Eustachian tube orifices			
clear	38 (86.4%)	28 (77.8%)	ns
obstructed	5 (11.4%)	7 (19.4%)	ns
Nasopharyngeal vault			
adenoid - none	21 (47.7%)	18 (50%)	ns
- minimal	20 (45.4%)	14 (39.7%)	ns
- more	2 (4.5%)	3 (8.3%)	ns
other	2 (4.5%)	3 (8.3%)	ns

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

CYTOLOGY

Potential findings which could have been interpreted as consistent with chemical irritation (although most commonly caused by other factors) were an increase in neutrophils of 1+ or greater, an increase in goblet cells of 3+ or greater, and the presence of atypical (possibly precancerous) cells. Neutrophils are inflammatory cells which increase in number with infection, allergy, and, possibly, chemical irritation. Goblet cells produce mucus and are thought to increase with any type of nasal insult, including allergy, infection, and possibly, chemical irritation. Cellular atypia has been reported with chronic usually high-level exposure to some chemicals.

Seventy-one (71) slides were available for evaluation; nine of the 80 people from whom nasal scrapings were obtained had slides which could not be interpreted for technical reasons.

No participants in either group were found to have atypical cells in their specimens (Table 6). Seventy-nine (79%) percent of each group (30/38 in the potentially exposed group, 26/33 in the comparison group) had increased neutrophils. An increase in goblet cells was found in 7/38 of the target group (18%) and in 4/33 of the comparison subjects (12%). The difference between study groups was not statistically significant and was not considered biologically important. There was no correlation between increased neutrophils or goblet cells, nasal symptomatology or redness, or any other finding on nose examination including self-reported symptoms.

TABLE 6

Summary of Nasal Cytology Examination

Cell Type	Target Group (38)	Comparison Group (34)	p-value*
Eosinphils			
0	7 (18.4%)	12 (35.3%)	ns
1	24 (63%)	19 (55.9%)	ns
2	5 (13%)	2 (5.3%)	ns
3	1 (2.6%)	1 (2.9%)	ns
4	1 (2.6%)	0	nt
Neutrophils			
0	8 (21%)	8 (23.5%)	ns
1	21 (55.3%)	19 (55.9%)	ns
2	4 (10.5%)	3 (8.8%)	ns
3	1 (2.6%)	2 (5.3%)	ns
4	4 (10.5%)	2 (5.3%)	ns
Basophils/mast cells			
0	12 (31.6%)	16 (47%)	ns
1	22 (57.9%)	14 (41.2%)	ns
2	3 (7.9%)	3 (8.8%)	ns
3	1 (2.6%)	1 (2.9%)	ns
Mononuclear cells			
0	13 (34.2%)	15 (44.1%)	ns
1	25 (65.8%)	19 (55.9%)	ns
Columnar cells			
ciliated			
0	1 (2.6%)	1 (2.9%)	ns
1	4 (10.5%)	6 (17.6%)	ns
2	5 (13.1%)	5 (14.7%)	ns
3	9 (23.7%)	8 (23.5%)	ns
4	19 (50%)	14 (41.2%)	ns
non-ciliated			
0	13 (34.2%)	17 (50%)	ns
1	13 (34.2%)	7 (20.6%)	ns
2	8 (21%)	5 (14.7%)	ns
3	4 (10.5%)	5 (14.7%)	ns
CCP			
0	38 (100%)	34 (100%)	nt
metaplastic			
0	9 (23.7%)	9 (26.5%)	ns
1	24 (63%)	18 (52.9%)	ns
2	4 (10.5%)	7 (20.6%)	ns
3	1 (2.6%)	0	nt

0=none, 1=occassional too few cells, 2=moderate number, 3=many easily seen, 4=large numbers, may cover entire field.

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

TABLE 6 (continued)

Summary of Nasal Cytology Examination

Cell Type	Target Group (38)	Comparison Group (34)	p-value*
Goblet cells			
0	2 (5.3%)	2 (5.3%)	ns
1	10 (26.3%)	13 (38.2%)	ns
2	19 (50%)	14 (41.2%)	ns
3	3 (7.9%)	4 (11.8%)	ns
4	4 (10.5%)	1 (2.9%)	ns
Squamous cells			
mature			
0	24 (63%)	17 (50%)	ns
1	7 (18.4%)	9 (26.5%)	ns
2	5 (13.1%)	7 (20.6%)	ns
3	2 (5.3%)	1 (2.9%)	ns
anucleate			
0	33 (86.8%)	23 (67.6%)	ns
1	4 (10.5%)	7 (20.6%)	ns
2	1 (2.6%)	4 (11.8%)	ns
atypical			
0	38 (100%)	34 (100%)	ns
Bacteria			
0	36 (94.7%)	32 (94.1%)	ns
1	2 (5.3%)	0	nt
3	0	1 (2.9%)	nt
4	0	1 (2.9%)	nt

0=none, 1=occassional too few cells, 2=moderate number, 3=many easily seen, 4=large numbers, may cover entire field.

* X^2-test, one-tailed, ns = not significant: $p>0.05$, nt = not tested

DISCUSSION AND CONCLUSIONS

The study's principal findings are as follows:

1. Redness of the internal lining of the nostrils was observed more frequently in the target group compared with the comparison group. The absence of any correlation with other endpoints suggests that the increased nasal mucosal erythema in the target group may not be related to the exposure of interest. However, in the absence of individual exposure data, a relationship between erthyema in the target population and the plant's emissions cannot be ruled out. Erythema of the nasal mucosa is not consider to have clinical importance even if it was indeed a result of environmental exposure.
2. No clinical abnormalities were detected either in the physical examination of the nose and nasopharynx or in the nasal cytology evaluation which appeared to be related to low-level irritant exposure to the plant's emissions.
3. There was no increase in nosebleeds which appeared to be attributable to the chemical exposure of concern.
4. The target group had more complaints of eye, nose and throat irritation and a statistically significant higher incidence of headache complaints compared with the comparison group.

The absence of abnormal physical and cytologic findings attributable to the exposure should help to reassure both public health officials and the citizens who live in the area that there appear to be no serious adverse health effects on the upper airway that may be related to exposure to the plant's emissions.

It is important to note that the study group downwind from the plant did have a consistent pattern of increased symptoms of eye, nose and throat irritation as well as a far higher incidence of headaches that may be attributable to exposure to low-level irritant emissions and/or noxious odors emanating from the plant. Such symptoms should not be dismissed lightly, since they may have considerable impact on the quality of life. The increased complaints of headaches in the target population is of particular concern, since any type of headache, whether or not it is associated with a serious medical condition, can adversely affect an individual's ability to function.

The increased complaints of headache and the more frequently observed redness of the internal lining of the nose in the target group, if indeed related to the exposure under consideration, would also be expected to improve as the emissions are abated, with no residual ill effects. The fact that the headache complaints did not persist away from home strongly suggests that they do not represent an irreversible problem. If these headaches are related to outdoor air contaminants, the mechanism for the cause-effect relationship is unclear. Exposure to low-level irritants is not reported to directly cause headaches, although stress related to the exposure might result in a headache. Noxious odors have been linked with headaches, but without much substantiating evidence.

There are many problems inherent in designing and carrying out an investigation of this type. The small number of study participants makes it difficult to arrive at strong indications of a causal relationship between the exposure under consideration and any adverse health effect. Adding to

the difficulty is the nonspecific or easily subjective nature of the health endpoints, with numerous important confounders.

Assignment to exposure categories was very crude since no objective exposure measurements were available. Because of the small study size and the lack of objective exposure measurements, the participants were divided into two groups. This dichotomous distinction may mask important differences within each exposure group.

Another problem with studies of this type is selection bias; there is a greater tendency for symptomatic individuals to participate. In addition, there might be other relevant endpoints which were not investigated, either because they are as yet unrecognized or they are impossible to detect by currently available screening techniques. (It is important to note that the investigators themselves are not aware of any such endpoints relevant to this investigation.)

Despite all these limitations, and despite the fact that no single study of any type can ever definitively rule out a health effect, the absence of increased nosebleeds and other nasopharyngeal abnormalities in the potentially exposed group remains reassuring. Consequently, excess symptomatology related to exposure to emissions from the plant may decline as the emissions are controlled. On the other hand, it is precisely because of these limitations, that it is important to identify and reduce chemical exposures and eliminate hazards instead of waiting for the results of health studies to determine actions.

The findings of this study support the efforts the New Jersey Department of Environmental Protection and the community have taken to bring the emissions from the plant under control through consent orders. Clearly, the

quality of life of the neighborhood in the immediate vicinity of the plant was impacted by the perception that the emissions were affecting them, in addition to any direct effect of the actual exposure.

RECOMMENDATIONS

This study was undertaken to determine if any of the following three actions are indicated:

1. Immediate intervention to reduce exposure,
2. Clinical intervention to alleviate current or to prevent future diseases, and
3. Further studies or actions stemming from initial results.

Based on the results of this study, none of these three actions are warranted because of a) the absence of excess of objective indications of physical damage such as nosebleeds and other nasopharyngeal abnormalities in the target group, and 2) the plant terminated its operations on October 5, 1987 due to economic considerations. Excess self-reported symptoms that may be related to exposure to emissions from the plant are expected to decline as the result of the plant's closure. In addition, each participant received a letter from NJDOH containing the individual's results and, where indicated, recommending additional clinical follow-up with the individual's personal physician.