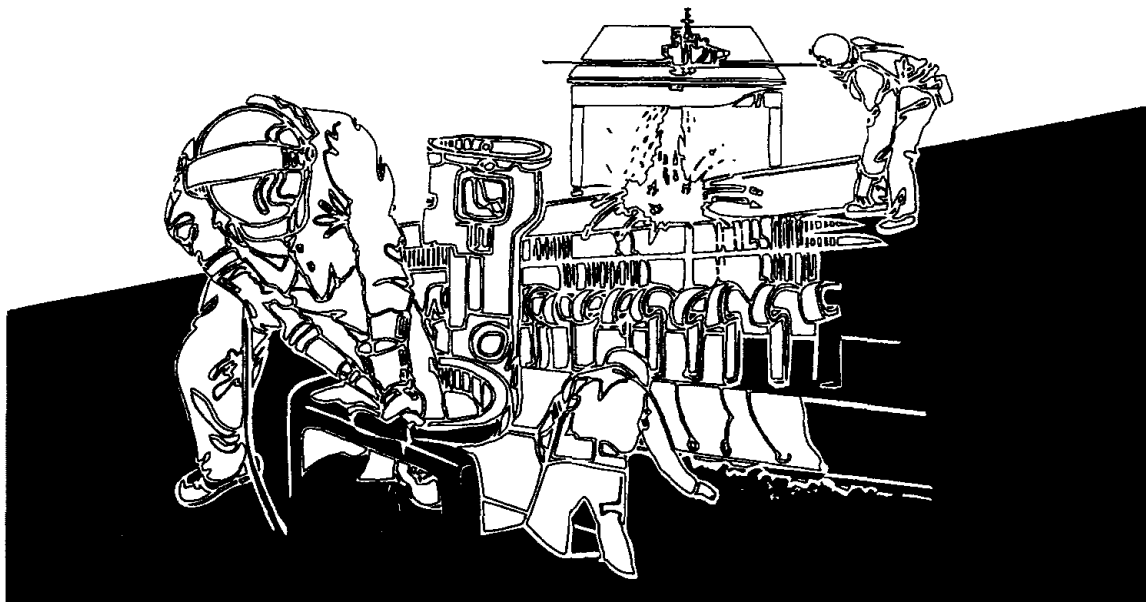




NIOSH HEALTH HAZARD EVALUATION REPORT

HETA 93-0790-2760
U.S. Silica Company, Mill Creek Plant
Mill Creek, Oklahoma

Margaret S. Filios, SM, RN



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



FOREWORD

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ACKNOWLEDGMENTS AND AVAILABILITY OF REPORT

This report was prepared by Margaret S. Filios, SM, RN of the Surveillance Branch, Division of Respiratory Disease Studies (DRDS). Assistance was provided by Jean Cox-Ganser, Ph.D., Field Studies Branch, DRDS, and Ken Ream, DRDS. Analytical support was provided by Kathleen Fedan, BS, Field Studies Branch, DRDS. Desktop publishing was performed by Terry Rooney.

Copies of this report have been sent to employee and management representatives at U.S. Silica Company, and the U.S. Silica Company - Mill Creek plant; Glass, Molders, Pottery, Plastics Allied Workers, Local 286; Glass, Molders, Pottery, Plastics & Allied Workers International; Mine Safety and Health Administration; Oklahoma State Department of Health; National Industrial Sand Association; General Teamsters and Allied Workers; and Oil, Chemical and Atomic Workers International; and Laborers' Health and Safety Fund of North America. This report is not copyrighted and may be freely reproduced. Single copies of this report will be available for a period of three years from the date of this report. To expedite your request, include a self-addressed mailing label along with your written request to:

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**Health Hazard Evaluation Report 93-0790-2760
U.S. Silica Company, Mill Creek plant
Mill Creek, Oklahoma
November, 1999**

Margaret S. Filios, SM, RN

SUMMARY

In July 1991, the National Institute for Occupational Safety and Health (NIOSH) received a request for technical assistance from the Mine Safety and Health Administration (MSHA) to estimate the prevalence of silicosis among active and retired miners at U.S. Silica Company's Mill Creek plant, in Mill Creek, Oklahoma.

Current and former workers with one year or greater cumulative tenure since 1970 in the grinding area of the mill or in areas downstream (by material processing) of the grinding process represented the population of primary interest. On August 10-12, 1993, a medical evaluation of current workers was conducted. Former workers were tested on August 13-14, 1993. The medical evaluation included a questionnaire, spirometry, and a single view posterior-anterior (PA) chest x-ray. Chest x-rays were independently classified according to the 1980 International Labour Office (ILO) system by three NIOSH-certified B readers who were unaware of the participant's age, occupation, occupational exposure, smoking history, or any identifying information. For the purposes of this evaluation, silicosis was defined on the basis of a chest x-ray with median small opacity profusion classification of category 1/0 or greater.

Twenty-nine (57%) of 51 current workers and 20 (33%) of 61 former workers who met the study criterion participated in the NIOSH medical evaluation. Of these 49, five (10%) had a chest x-ray consistent with silicosis. The highest median ILO profusion category was 2/2. One of the five had a chest x-ray consistent with progressive massive fibrosis (PMF), with "B" size large opacities as classified by all three readers.

Four (9%) of the 46 participants who performed spirometry had abnormal patterns; three exhibited an obstructive lung pattern and one exhibited a combined restrictive and obstructive pattern. An abnormal spirometry pattern was present in one of the five participants with a positive chest x-ray.

U.S. Silica's medical monitoring includes all of the screening tests recommended by the National Industrial Sand Association (NISA) as well as those recommended by NIOSH for workers exposed to ground silica. NISA's current guidelines also recommend multiple readings of all chest x-rays with a small opacity profusion classification of 1/0 or greater and 5-10% of those chest x-rays classified as 0/1 based on a single reading. Of the company records we reviewed, company chest x-rays initially classified as negative (0/0 and 0/1) were not routinely sent for additional readings. Since 1990, the company reportedly sent chest x-rays initially classified 1/0 or greater by a single reader for additional classifications.

Five (10%) of the 49 survey participants who met the study criterion were found to have chest x-ray findings consistent with silicosis. These results are consistent with patterns of crystalline silica dust exposure at this facility. There were no cases of silicosis among current workers with 10 or less years of tenure; however, because of the long latency usually associated with chronic silicosis, this finding is not sufficient to conclude that current crystalline silica dust exposure levels are without adverse effect.

The company medical monitoring practice of obtaining additional B reader classifications of those chest x-rays initially classified 1/0 or greater will produce an estimated prevalence no higher than and possibly lower than that obtained with a single reading, and those workers with a positive chest x-ray whose chest x-rays are initially read as 0/0 or 0/1 will not be identified.

Recommendations are presented in this report and include obtaining at least two readings of all chest x-rays regardless of the initial small opacity profusion classification, increasing the frequency of medical monitoring examinations, and modification of the baseline and routine examinations to include skin testing for tuberculosis (TB).

Keywords: SIC 1446 (Industrial Sand), Silica, Silicosis, Mineral processing, Ground silica, Silica flour

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INTRODUCTION

In July 1991, the National Institute for Occupational Safety and Health (NIOSH) received a request for technical assistance from the Mine Safety and Health Administration (MSHA) to estimate the prevalence of silicosis among active and retired miners at U.S. Silica Company's Mill Creek plant, in Mill Creek, Oklahoma. The medical evaluation was part of a joint project between MSHA and NIOSH to study silica exposures and the prevalence of silicosis in workers in a number of ground silica mills. A protocol outlined the responsibilities of each agency (see Appendix I). MSHA selected the nine sites for this study and was responsible for the evaluation of crystalline silica dust exposures as well as dust control methods. NIOSH was responsible for conducting medical evaluations at each site. This is the final report of the NIOSH medical evaluation conducted at U.S. Silica Company's Mill Creek facility.

On July 28, 1993, a NIOSH representative met with company and union representatives, several employees, and a MSHA representative to discuss logistical and administrative considerations of the NIOSH evaluation. A second NIOSH representative participated in this meeting via telephone. On August 9, 1993, an opening meeting was held with company and union representatives and a representative from MSHA to discuss the ensuing evaluation and to address any last minute questions. The meeting concluded with a walk-through of the South plant portion of the Mill Creek facility, where ground silica is produced.

On August 10-12, 1993, the medical evaluation of current workers was conducted. Former workers were tested on August 13-14, 1993. All study participants received written notification of their spirometry results in September, 1993. All chest x-rays were promptly reviewed by a pulmonary physician for evidence of acute health problems upon return to NIOSH and prior to the classification process. All study participants received written notification of their chest x-ray results in October, 1994.

In 1993, each company with a site, or sites, selected by MSHA for evaluation, was asked by NIOSH to provide medical and personnel records of current and former employees who had worked at least one year since 1970. Of the nine sites, three were U.S. Silica operations, one of which was the Mill Creek facility. In March of 1995, following negotiations and legal proceedings, a settlement was reached concerning NIOSH access to company medical and personnel records. U.S. Silica agreed to extract, copy, and provide the records of current and former workers whom the company determined had met the NIOSH criterion for entry into the study population (i.e., one year or greater cumulative tenure since 1970 in the grinding area of the mill or in areas downstream by material processing of the grinding process). The production of records for all three U.S. Silica sites began in July 1995, and was completed in November 1996.

BACKGROUND

U. S. Silica Company's Mill Creek facility consists of two plants located 5-6 miles apart: the North plant, which processes whole grain sand from an on-site, open-pit mine, and the South plant, which produces ground silica. U.S. Silica Company, formerly known as Pennsylvania Glass Sand Corporation, has owned and operated the facility at Mill Creek since 1937. The Glass, Molders, Pottery, Plastics & Allied Workers Union, Local 286, represents employees at this plant and was chartered in 1937. Raw material is transported via rail from the mine at the North plant to the South plant for processing; where it is crushed, dried, milled, and screened. The ground silica product is then bagged into 50-pound or 2000-pound bulk bags or bulk-loaded into trucks or railroad cars. At the time of our survey in 1993, the South plant operated production processes 24 hours a day, five days a week, with three 8-hour shifts. Selected production personnel rotated every two weeks to the evening or night shift. The majority of hourly workers and salaried personnel worked during the day shift, 8 a.m. - 4 p.m. Ten hourly employees worked 4 p.m. - 12 midnight, and 12 worked 12 midnight to 8 a.m. Maintenance occurred during the

day shift and on an 'as-needed' basis. A total of 66 employees (including clerical and salaried employees) worked at the Mill Creek facility (both North and South plants combined). The departments at the North plant were Mining, Drying, Shipping, and Maintenance; the departments at the South plant were Production, Load-out, Packaging (Bagging), and Maintenance. Supervisory/Administrative personnel offices were located at the South plant, with Supervisory personnel duties covering both plants. The main job categories affected by the grinding process at the South plant were Miller, Assistant Miller or Mill Helper (duties included loading railroad cars and trucks and clean-up), Bagger, Utility Operator, Maintenance, and Supervisory personnel (e.g., shift supervisor).

METHODS

Study Objective

The primary objective of the study was to estimate and report the prevalence of silicosis among participating current and former employees in the grinding area and/or downstream (by material processing) of the grinding area, by tenure and job, if feasible. To assess any bias in the prevalence estimate caused by lack of full participation in the medical survey, demographic characteristics and disease status of participants and living non-participants who met the study criterion were compared using information obtained from company records.

Company medical monitoring programs and practices were also examined and evaluated as factors that affect silicosis prevalence and contribute towards its prevention.

Study Population

The study population was defined as all current workers and living former workers who had one year or greater cumulative tenure since 1970 in the

grinding area of the mill or in areas downstream of the grinding process.

The company provided a roster of all current workers and a roster of former workers employed for one year or more since 1970. The union provided rosters of current and former workers. We mailed letters to the workers on these rosters inviting them to participate in the medical evaluation. Additionally, advertisements were placed in local newspapers to reach those workers who may have moved within the local area or otherwise may have failed to receive a letter. To avoid inadvertent oversight of an eligible worker with prior experience in the grinding area or areas downstream of the grinding process, all identified workers were invited to participate regardless of work area or length of employment. For current workers who chose to participate, eligibility for inclusion in the study population was determined using information from discussions with company representatives, company records, the medical evaluation, and MSHA. For former workers who chose to participate and were listed on the company roster, eligibility was determined using information from the medical evaluation, company records, and company information regarding eligibility when no records were provided (i.e., correspondence). If a former worker was not listed on the company roster, eligibility was determined using information from the medical evaluation followed by a review of company records which we subsequently requested. We relied on the company to identify eligible non-participating current and former workers and provide their records.

Data Collection

Posterior-Anterior Chest X-Ray

Chest x-rays were taken on a full size (14 x 17 inch) film. All chest x-rays were read independently by three B readers who, without knowledge of the participant's age, occupation, occupational exposure, smoking history, or any identifying information, classified the films according to the 1980 ILO International Classification of Radiographs of

Pneumoconioses.⁽¹⁾ A B reader is a physician who has demonstrated the ability to classify chest x-rays for the pneumoconioses (dust diseases of the lung) using the ILO Classification System by passing a certification examination administered by NIOSH.

The NIOSH-certified B readers used in this project had each classified at least 500 chest x-rays for the 4th round of the NIOSH Coal Workers' X-Ray Surveillance Program. They had also participated in a pilot study which entailed a reading trial of over 400 films of anthracite miners in preparation for a current exposure-response study using National Study for Coal Workers' Pneumoconiosis films. After determining that NIOSH B reader certification was not due to expire any time between June 1993 and December 1994, the readers were contacted and interest and availability to read chest x-rays for the present study were ascertained. The same three B readers were used throughout the entire project.

The ILO classification method is used for epidemiological research, for the surveillance of workers in dusty occupations, and for clinical purposes. The method recognizes two major categories of opacity size: small (≤ 1 centimeter) and large (> 1 centimeter).⁽²⁾

The profusion (i.e., number) of small opacities are recorded using a graduated 12-point scale within four major categories (0, 1, 2, 3). A major profusion category of 0 indicates no apparent abnormality, while 3 indicates substantial abnormality. Film classification is achieved by comparing the subject film with the appearance of "standard films" which define small opacity profusion. In classifying small opacity profusion, the final determination of major category is listed first. If a higher or lower major category has also been seriously considered, this category is also listed after a slash mark. If there is no question as to major category, the two listed numbers are identical.^(1,2)

Thus, the small opacity profusion scale is as follows:

0			1			2			3		
0/-	0/0	0/1	1/0	1/1	1/2	2/1	2/2	2/3	3/2	3/3	3/+

Size and shape of the small opacities are also classified, both being differentiated using the letters of the alphabet. Two letters are used to record size [in millimeters (mm)] and shape, the first listed letter indicating the predominant type.^(1,2)

Classification of Small Opacity Type

Shape	Size		
	Up to 1.5 mm	1.5 - 3 mm	3-10 mm
Rounded	p	q	r
Irregular	s	t	u

To record the distribution of the small opacities, the lungs are divided into six zones--three on the left and three on the right, for the upper, middle, and lower portions of the lungs.^(1,2)

Three categories are used to define large opacities according to size [measured in centimeters (cm)]: A, B, and C.⁽¹⁾ Category A is specified as an opacity > 1 cm but < 5 cm, or several opacities > 1 cm whose combined diameters are < 5 cm; Category B is one or

more opacities >5 cm whose combined area is less than the equivalent area of the right upper lung zone; Category C is one or more opacities whose combined area is greater than the equivalent area of the right upper lung zone.^(1,2)

The technical quality of the chest x-ray (or film quality) is graded and recorded using four scores, 1, 2, 3, or 4. A "1" represents the highest quality, while a "4" represents a chest x-ray considered by a reader as "unacceptable" or "unreadable" for classification purposes.^(1,2)

Spirometry

Spirometry was performed using a dry rolling-seal spirometer interfaced to a dedicated computer. At least five maximal expiratory maneuvers were recorded for each person. All values were corrected to BTPS (body temperature, ambient pressure, saturated with water vapor). The largest forced vital capacity (FVC) and forced expiratory volume in one second (FEV₁) were the parameters selected for analysis, regardless of the curves on which they occurred. Testing procedures conformed to the American Thoracic Society's recommendations for spirometry.⁽³⁾ Predicted values were calculated using the Knudson reference equations.⁽⁴⁾ Predicted values for African-Americans were determined by multiplying the value predicted by the Knudson equation by 0.85.⁽⁵⁾

Questionnaire

A modified version of the Medical Research Council (MRC) questionnaire⁽⁶⁾ on respiratory symptoms, supplemented with questions concerning demographic information, work history, cigarette smoking habits, physician-diagnosed respiratory illness, frequency and content of company medical evaluations, and participant's knowledge of prior test results, was administered by trained NIOSH personnel.

Medical and Personnel Records

Each company was asked to provide medical and personnel records of current and former employees who had worked at least one year since 1970.

Three types of company-held documents were identified from which the presence or absence of silicosis was ascertained – ILO classifications, clinical radiology reports (a chest x-ray report by a radiologist), and miscellaneous documents (e.g., CT scan results, letters from physicians, etc.). The following case definitions for silicosis were established for each type of document:

1. An ILO small opacity profusion classification of 1/0 or greater on the most recent chest x-ray.
2. A clinical radiology report which contained explicit words or phrases indicating the presence of silicosis (e.g., "silicosis" or "pneumoconiosis"), or other descriptions considered consistent with silicosis (see "Results" section).
3. A physician diagnosis of silicosis, or a diagnosis of pneumoconiosis if silicosis was considered in the differential diagnosis.

The case definition used in the analysis depended on the type of records obtained from the company. ILO classifications were considered ideal and the preferred document type for definition, followed by clinical radiology reports, and finally miscellaneous documents. Therefore, if all three types of documents were available for an individual, ILO classifications were used to identify silicosis (case definition 1). If company records only contained clinical radiology reports and miscellaneous documents, case definition 2 was used. Case definition 3 was used when only miscellaneous documents were available.

Medical Monitoring

The 1981 NIOSH recommendations for medical monitoring of workers exposed to ground silica (silica flour),⁽⁷⁾ and the recommendations published

by the National Industrial Sand Association (NISA) for workers exposed to crystalline silica^(8,9) were used as the basis to evaluate company medical monitoring practices.

EVALUATION CRITERIA

Chest X-Ray

A chest x-ray was defined as consistent with silicosis if the median, or middle, classification of small opacity profusion by the three B readers was 1/0 or greater. For cases where only one reader considered a film of unacceptable quality, an additional classification was sought. If the film was considered unacceptable a second time, it was then classified as unreadable (UR). However, if the film was able to be classified, this classification was used to determine the median, and the results were subsequently used in the data analysis. This procedure was followed so as not to give undue weight to the judgement of a single reader. Progressive massive fibrosis (PMF) was defined as the presence of large opacities of ILO category A, B, or C classified by at least two readers.

The overall shape of the small opacities was based on the predominant shape (i.e., the first listed letter) classified by two or more readers. If only two readers classified shape and the predominant type differed, the shape was considered "mixed."

Spirometry

To identify participants with abnormal spirometry patterns of obstruction and restriction, each examined worker's test results were compared to the 95th percentile lower limit of normal (LLN) values obtained from Knudson's reference equations.⁽⁴⁾ Five percent of a normal population will have predicted values that fall below the normal range, or LLN, while 95% will have predicted values above the lower limit.

Using this comparison, obstructive and restrictive patterns were defined as:

Obstruction: Observed ratio of FEV₁/FVC% below the LLN.

Restriction: Observed FVC below the LLN.

Questionnaire

The following definitions were established for the purpose of questionnaire analysis:

Chronic Cough a cough on most days for as much as 3 months during the year.

Chronic Phlegm the production of phlegm on most days for as much as 3 months during the year.

Dyspnea shortness-of-breath walking with individuals of similar age on level ground.

Chronic Bronchitis cough and phlegm on most days for as much as 3 months for 2 or more years.

Medical Monitoring

The 1981 NIOSH recommendations for medical examinations of ground silica workers include a medical and occupational history, chest x-ray, and pulmonary function testing (spirometry) for all workers prior to job placement and annually thereafter.⁽⁷⁾ The 1977 NISA guidelines recommended obtaining a medical and occupational history, physical examination, and pulmonary function testing every two years. A chest x-ray was also recommended, but frequency was not discussed.⁽⁸⁾ The current NISA medical monitoring guidelines, part of NISA's Silicosis Prevention Program which was established in 1993 and published in 1997, recommend a medical and

occupational history and physical examination prior to job placement and at least every two years thereafter; pulmonary function testing and a pre-placement skin test for tuberculosis (TB) are optional components of the medical monitoring program. A chest x-ray is also recommended, with frequency determined by worker age, time since first exposure to crystalline silica dust, or as determined by a physician if a worker has any signs or symptoms of silicosis.⁽⁹⁾ For a worker who is 35 years of age or less, or over 35 years with 8 years or less since first exposure, NIOSH guidelines recommend a chest x-ray every 4 years. The frequency increases to every 2 years for workers over 35 years of age with more than 8 years since first exposure.⁽⁹⁾ The current guidelines also recommend multiple readings of all chest x-rays with a small opacity profusion classification of 1/0 or greater and 5-10% of those chest x-rays classified as 0/1 based on a single B reading.⁽⁹⁾

Silicosis

Silicosis, a form of pneumoconiosis, is a chronic fibrotic pulmonary disease caused by the inhalation,

deposition, and retention of dust containing crystalline silica.⁽¹⁰⁾ Silicosis is usually diagnosed through chest x-ray and occupational history of exposure to silica-containing dust. In nodular silicosis, lung tissue reacts to the presence of crystalline silica dust by forming nodules, which on chest x-ray typically appear discrete, round, and more prominent in the upper zones, although other patterns have been described.^(7,11,12,13,14,15) Such radiographic abnormalities are often the first sign of silicosis.

In acute silicosis, the lung is overwhelmed by crystalline silica particles, and a proteinaceous fluid accumulates in the lungs as a reaction to the silica dust.^(7,10,16,17) On chest x-ray, the appearance is different from that of nodular silicosis, with very little of the typical nodular scarring.^(7,18,19) Consequently, it may often be mis-diagnosed as pulmonary edema or pneumonia.

The following table summarizes the clinical forms of silicosis:

<u>FORM</u>	<u>TIME TO ONSET</u>	<u>INTENSITY OF EXPOSURE</u>
NODULAR		
-Chronic	10+ years	Low
-Accelerated	5-10 years	High
ACUTE	weeks-4 or 5 years	Extremely High

Each form is differentiated by time to onset of clinically apparent disease after initial exposure (induction period), intensity of exposure, and the rate at which the disease progresses.^(7,10,12,18) The percentage of crystalline silica in the dust, size of the dust particle, form of crystalline silica, and length of exposure also affect disease onset and progression.^(7,19,20) Ground silica (silica flour) consists of essentially pure crystalline silicon dioxide particles (the quartz polymorph), of respirable size (< 10 micrometers).^(21,22) Particles of this size may be invisible to the naked eye and are small enough to be deposited in the alveoli. Freshly ground, or fractured, crystalline silica -- which is a typical form of silica in ground silica facilities -- may be more

toxic or fibrogenic (i.e., produce more scarring of the lungs) than aged silica.^(23,24,25)

A continuum is thought to exist between the chronic and accelerated forms of nodular silicosis. Factors determining the progression of disease are unclear.⁽¹⁴⁾ *Chronic silicosis* (the presence of detectable, discrete, nodules <1 cm in diameter on chest x-ray) is the most common form of silicosis and usually becomes evident after 10 years or more of exposure to dust containing crystalline silica.^(10,11,26) There may be few, if any, clinical symptoms; the most common symptoms are cough, with or without sputum production, and shortness of breath. There may be little or no decrement in pulmonary function.

Accelerated silicosis is associated with higher exposures to crystalline silica and has a shorter induction period than chronic silicosis. Chest x-ray abnormalities usually appear within 5-10 years.⁽²⁶⁾ This form of silicosis often progresses after exposure has been discontinued. *Acute silicosis* may develop in a few weeks to 4 or 5 years after initial exposure and is associated with exposures to extremely high concentrations of crystalline silica.^(10,11,26) Respiratory impairment is severe with acute silicosis, and the disease is usually fatal within a year of diagnosis.^(18,19)

Both chronic and accelerated silicosis can become complicated by the development of infection and/or progressive massive fibrosis (PMF). Infections (e.g., tuberculosis and/or fungal infections) are believed to result from the inability of the overwhelmed lung scavenger cells (macrophages) to kill the organisms that cause these diseases.^(27,28) Progressive massive fibrosis (PMF) has at times been called "complicated" silicosis, and is the result of silicotic nodules fusing into large masses. PMF profoundly affects both the structure and function of the lungs.^(10,11,12,18)

Recently, the International Agency for Research on Cancer (IARC) reclassified crystalline silica (quartz or cristobalite) from occupational sources as a substance "carcinogenic to humans," and evidence suggests that individuals with silicosis are at increased risk for lung cancer.^(29,30) NIOSH currently recommends that crystalline silica be considered a potential occupational carcinogen.^(31,32)

RESULTS

The Study Population and Participation

Table 1 outlines the number of current and former workers who were originally identified for study, the number of workers excluded (and the reasons), and the total number of workers that remained to make up the study population. Of 66 current employees,

15 were determined to be ineligible (i.e., they did not meet the study criterion) and were excluded from the study population. A total of 51 current workers were eligible for inclusion in the study population.

Of 103 former workers identified, 28 were determined to be ineligible, and the records for another three were reported missing. Eligibility could not be clearly or fully determined by NIOSH for one participating former worker for whom records were provided, and seven non-participating former workers whose names appeared on the union roster but did not appear on the company roster. Finally, three deceased former workers were excluded. A total of 61 former workers were eligible for inclusion in the study population.

Of the 51 current workers eligible for inclusion in the study population, 29 (57%) participated in the medical survey. Of the 61 eligible former workers, 20 (33%) participated. Thus, of 112 eligible workers, 49 (44%) participated (Table 2).

Medical Evaluation

The following discussion of results concerns the 49 participants who met the study criterion. All data were collected by NIOSH.

Demographics

All of the participants were men and most, 94% (46/49), were white. Selected characteristics of the participants are presented in Table 3. Current and former workers differed primarily with regards to tenure, cigarette smoking status and pack-years (one pack-year is equal to smoking an average of one pack of cigarettes per day for a year). Although fewer current workers were current smokers, their median number of pack-years was the same (26) as that of the former workers in the same smoking category. However, the median number of pack-years for former workers who were "ever" smokers (that is, either a current smoker or an ex-smoker) was nearly double that of the current workers. Former workers were employed for a shorter median length of time (4.5 years) than current workers, who were

employed for a median of 13 years. Sixteen (80%) of the 20 former workers were employed for 10 years or less, 1 (5%) was employed between 11 and 15 years, and three (15%), were employed for over 15 years. Among current workers, eight (28%) were employed for 10 years or less, 12 (41%) were employed between 11 and 15 years, and 9 (31%), were employed for over 15 years. An average (mean) of 12 years had passed since former workers had left employment. The median number of years since leaving employment was also 12, and former workers had left the Mill Creek plant between 6 months and 21 years prior to the time the NIOSH evaluation was conducted.

Primary Job and Dustiest Job

Overall, 19 (39%) of the 49 participants reported holding their primary job (the job held for the longest period of time) in Maintenance, 12 (24%) reported working as a Miller or Mill Helper, six (12%) reported a primary job as a Utility Man or Utility Operator, five (10%) of the participants reported working as a Bagger, and four (8%) worked in supervisory positions. The three remaining participants reported Quarry Pumper or Dryer as a primary job. The proportion and distribution of participants in each of these jobs was remarkably similar for current workers and former workers alike. Eleven (38%) of the 29 current workers reported their primary job as Maintenance, while eight (40%) of the 20 former workers reported this as their primary job. A slightly higher proportion of current workers reported primary jobs as Miller (28%) and Utility Man (14%) than former workers, 20% and 10% of whom, respectively, reported holding these same jobs. Working as a Maintenance Man, and engaging in activities such as repair and maintenance of the dust collectors, was reported with the greatest frequency by current workers as the single dustiest job at the plant. Former workers reported working as a Bagger as the single dustiest job. Working as a Miller, or Mill Helper, followed in frequency for both current and former workers.

Other Dusty Jobs

A total of 38 (78%) of the 49 participants reported prior or subsequent employment in occupations or industries other than a ground silica operation that might have been associated with exposure to fibrogenic dusts. These included 19 of the 29 current workers and 19 of the 20 former workers. When the information was examined by employment status, 11 (58%) of the 19 current workers reported employment at such jobs for less than five years, versus three (16%) of the 19 former workers. The opposite was true for participants who reported working at other dusty jobs for 15 years or more; three (16%) of the current workers reported such employment for 15 years or more versus six (32%) of the former workers. The type of work reported included construction, mining and/or quarry work, welding, and road work, among others.

Chest X-Ray Results

All Participants

Overall, five (10%) of the 49 participants had a chest x-ray consistent with silicosis; of these, two (4%) had primarily round small opacities and three (6%) had primarily irregular small opacities. The highest ILO profusion category among the participants was 2/2. One of the five had a chest x-ray consistent with PMF, with "B" size large opacities noted by all three readers. All of the chest x-rays were taken by NIOSH. Forty-four (90%) had a median film quality score of 1 (the highest), three (6%) had a median quality score of 2, and two had a median score of 3.

The predominant shape of the small opacities was examined in relation to cigarette smoking status for the five participants with x-ray evidence of silicosis. Four of the five participants were "ever" smokers and one had never smoked. The chest x-rays of two of the four "ever" smokers showed small opacities that were predominantly rounded; the two other chest x-rays had predominantly irregular small opacities. The predominant shape of small opacities on the chest x-ray of the "never" smoker was irregular.

Of the five participants with a positive chest x-ray, two reported holding a primary job (the job held for the longest period of time) in Maintenance, one reported a primary job as a Utility Operator, one was a Miller, and one held a supervisory position. Four of the five participants with a positive chest x-ray reported working at another dusty job, none over 10 years. Two worked for three years or less, and the other two worked from five to 10 years. None of these five participants reported working with asbestos.

Current Workers

Table 4 lists the chest x-ray results by reader for all 29 currently working participants. The prevalence of silicosis among currently working participants was 10% (3/29). One of these three participants had primarily round small opacities and two had primarily irregular small opacities. None of the eight participants employed 10 years or less had a positive chest x-ray, while three (14%) of the 21 participants employed over 10 years, had a positive chest x-ray. Two of these three were employed between 11 to 20 years and one was employed for over 20 years. One of the three participants with a positive chest x-ray was between 40 and 49 years of age, and two were over 50 years old.

Former Workers

Table 5 lists the chest x-ray results by reader for the 20 participating former workers. Two (10%) former workers had x-ray evidence of silicosis. One former worker had primarily round small opacities and one had primarily irregular small opacities. None of the 16 participants employed 10 years or less had a positive chest x-ray. Both of the former workers with a positive chest x-ray were employed over 15 years and one was employed for over 20 years. One of these two participants was less than 40 years of age and the second was over 60 years old.

Chronic Symptoms

A total of 11 participants reported a chronic symptom or health effect, as defined in the

"Evaluation Criteria" section of this report; three were current workers and eight were former workers. Chronic bronchitis was reported by five participants, and four reported dyspnea (shortness-of-breath). Two participants reported chronic phlegm, and one reported chronic cough. Eight of the 11 symptomatic participants were "ever" smokers. Only one of the participants with a positive chest x-ray was symptomatic. The most frequently reported primary jobs held by symptomatic participants were Maintenance and Miller, and their median tenure at Mill Creek was four years. The median tenure of the 38 asymptomatic participants was 12 years, and the difference in tenure between symptomatic and asymptomatic participants was statistically significant ($p=0.0175$, Wilcoxon rank-sum). Symptomatic participants had a longer median tenure in other dusty jobs (12 years) than asymptomatic participants (3.5 years), but this difference was not statistically significant ($p=0.2187$, Wilcoxon rank-sum).

Respiratory Illnesses and Conditions

Physician-diagnosed emphysema was reported once, chronic bronchitis was reported by three participants, and asthma was reported by five participants. Other physician-diagnosed lung conditions that were reported were pneumonia and silicosis, among others. None of the participants reported a physician diagnosis of tuberculosis (TB). Thirty-two (65%) of the participants reported no physician-diagnosed respiratory illness or condition.

Spirometry

Forty-six (94%) of the 49 participants performed spirometry, and four (9%) of those had results that fell below the normal range. Three of these participants exhibited an obstructive lung pattern, and one exhibited a combined obstructive and restrictive pattern. Of the four participants with abnormal patterns, one had never smoked cigarettes, one was an ex-smoker, and two were current smokers. Only one of the five participants with a positive chest x-ray had abnormal spirometry results.

Two of the four participants with an abnormal pattern held their primary job in Maintenance, one worked as a Utility Operator, and one held a supervisory position. The median tenure of the four with abnormal patterns was 10.5 years – not substantially (or statistically) different from the median tenure (10 years) of the 42 participants with normal spirometry results.

Company Records

Company records contained information on age, tenure, cigarette smoking history, work in other dusty jobs, and small opacity profusion classification for all 51 (100%) of the eligible current workers. All eligible current workers were male. Only the information on 'race' was incomplete; 47 (92%) of the 51 records contained information concerning race. Ninety-one percent (42/47) of the current workers were white.

The records of former workers were less complete. The table below summarizes the proportion of information available from the records of eligible former workers for each of the variables listed.

Eligible Former Workers N = 61		
Variable	Number of Records with Information	Percent
Age	59	97 %
Tenure	60	98%
Cigarette Smoking History	40	66%
Other Dusty Jobs	41	67%
ILO classification	40	66%
Race	15	25%
Sex	39	64%

Of the information on race and sex available for former workers, 87% (13/15) were white and all (39/39) were male.

Age, tenure, cigarette smoking habit, work in other dusty jobs, and chest x-ray information was examined by employment status for both participants and non-participants (Table 6). The 22 non-participating current workers differed little from their participating counterparts with regards to median age, tenure, and proportion of workers with an indication of work in another dusty job, or jobs. The non-participants differed in terms of the proportion of current and ex-cigarette smokers (i.e., "ever" smokers), and the number of individuals with a positive chest x-ray (defined as small opacity profusion of 1/0 or greater) based on a single B reading. Two of the non-participating current workers had a positive chest x-ray, with small opacity profusion classifications of 1/0 and 1/1, versus five participants with positive chest x-rays (four were classified 1/0, and one was classified 2/2 with 'A' size large opacities). Of the 44 remaining chest x-rays, 11 were classified 0/1, and 33 were

classified 0/0. The chest x-rays were classified by the same B reader between 1989 and 1993.

Except for cigarette smoking and the number of individuals with a positive chest x-ray, non-participating former workers differed little from participating former workers. For former workers for whom cigarette smoking information was available, non-participants had a slightly higher proportion of current smokers than those who chose to participate (29% versus 25%), while a larger proportion of participating former workers (40%) had never smoked cigarettes. Based on available ILO classifications, three of the non-participating former workers had a positive chest x-ray versus one participating former worker. All four former workers had a small opacity profusion classification of 1/0. Of the 36 remaining chest x-rays, four had a small opacity profusion classification of 0/1, and 32 were classified 0/0. These chest x-rays were classified between 1979 and 1993 by the same B reader who classified all of the chest x-rays of the eligible current workers. A clinical radiology report of the non-participating former worker for whom there were no ILO classifications was negative.

Because the company sent chest x-rays with small opacity profusion classification 1/0 or greater for additional readings beginning in 1990, the classifications from these additional readings were used to develop a single classification, and this data is also presented in Table 6. Nine of 11 workers with a positive chest x-ray based on a single B reading had more than one ILO small opacity profusion classification completed. Of these nine, seven were current workers (five participants and two non-participants), and two were former workers (one participant and one non-participant). Eight of the nine workers had a total of three classifications completed, and one worker had one additional classification. For the worker with one additional classification, the second classification did not differ from the first. However, for those workers where the consensus classification was the median classification, three changed status (i.e., the median small opacity profusion classification was less than 1/0). Thus, the number of individuals with a positive chest x-ray decreased from five to three among

participating current workers and from two to one among non-participating current workers. For the two former workers, the additional information did not result in any change of status. The four participants identified in company records as having a positive chest x-ray also had positive NIOSH chest x-rays.

U.S. Silica Company has consistently used standard forms to collect medical and work history information. Except for chest x-ray information, the portions of the forms used from 1979 onward and received by NIOSH were, for the most part, filled out by the individual worker. The work history information found in these forms was often incomplete. Personnel records provided by the company were used in conjunction with these standard forms, and others, to assemble work histories and supplement other missing information whenever possible.

Company Medical Monitoring

Routine medical monitoring has been conducted at the Mill Creek plant since at least 1950. The initial monitoring was offered annually and included a physical examination and a chest x-ray that was reviewed by a contract radiologist. Employee participation in the medical monitoring was optional up until 1979, at which time the company (known at that time as Pennsylvania Glass Sand) adopted the 1977 National Industrial Sand Association (NISA) occupational health program guidelines and recommended medical monitoring. Participation by hourly employees in the monitoring then became mandatory. Medical monitoring consistent with these guidelines (see Evaluation Criteria), including a chest x-ray, was conducted every two years. Office and administrative employees were examined every 4 years. Examinations were completed at a hospital in Mill Creek, and all company chest x-rays were sent to the same B reader for classification. A company representative reported that beginning in 1990, chest x-rays with small opacity profusion classification 1/0 or greater were sent for additional readings to other B readers. An annual chest x-ray

was obtained if a chest x-ray was classified 1/0 based on a consensus of the additional readings. This was the medical monitoring in place at the time of our survey in 1993. The medical records, except for chest x-rays, were kept at U.S. Silica's corporate offices in locked files separate from personnel records. Chest x-rays were kept by the B reader. No medical records were maintained at the plant site. A company representative reported that the company medical director forwarded narrative reports of test results in sealed envelopes to the plant manager, who ensured that each employee signed a document indicating that he or she had received their individual medical test results. Employees with abnormal test results were encouraged to see their personal physician or to call the company medical director to discuss their results.

All 29 participating current workers and eight participating former workers reported taking part in either pre-placement or routine medical monitoring offered by the company. Twenty-two (76%) of the 29 current workers and four of the former workers were able to recall their chest x-ray results from the company monitoring. Seven current workers and four former workers either didn't know or didn't recall their company chest x-ray results. Seven former workers reported also having had a chest x-ray, but for other reasons. Participants reported that the company medical monitoring was offered every two years. One participant reported he was notified there was "no change" on his chest x-ray but did not know, or was unable to recall, his original chest x-ray results.

Subsequent to the NIOSH survey, U.S. Silica implemented NIOSH's voluntary Silicosis Prevention Program and its medical monitoring guidelines. The monitoring consists of a medical and occupational history, physical examination, chest x-ray, and spirometry prior to job placement as baseline, and every other year. Chest x-rays continue to be sent to, and kept by, the same NIOSH-certified B reader who has classified chest x-rays for the company since 1979. Since November 1994, U.S. Silica has utilized the services of a mobile health testing company to conduct its routine medical monitoring.

Pre-placement examinations continue to be conducted at a hospital in Mill Creek. Skin testing for tuberculosis (TB) was not one of the screening tests offered in 1993, either as part of the pre-placement examination or the routine medical monitoring. Currently, a TB skin test is obtained if an employee's chest x-ray is classified 1/0. Medical data from the routine medical monitoring are kept by the mobile health testing company in electronic form. Original examination results, except for chest x-rays, continue to be maintained at U.S. Silica's corporate offices in separate locked files with access limited to the medical director, the vice president of administration and his staff, and the legal department. The procedure for notifying individual employees of their test results has remained the same as it was in 1993.

DISCUSSION

Five (10%) of the 49 current and former workers who participated in the medical evaluation were found to have changes on their chest x-ray consistent with silicosis; one of these five had PMF. Two of these five participants had primarily round small opacities, and three had primarily irregular small opacities. These five participants had been employed at the U.S. Silica Mill Creek plant for 15 years or more, and two were employed for over 20 years. One of the participants was less than 40 years old, one was between 40 and 49 years of age, two were 50-59 years, and one was over 60. Four of the five participants with a positive chest x-ray were current or ex-smokers.

The availability of recent (1989-93) ILO classifications for all 51 eligible current workers from company records permits a comparison of the estimated prevalence of chest x-ray-defined silicosis with the results from the NIOSH medical survey. The company-based readings are not biased by selective participation, since ILO classifications were available for all 51 current workers. Based on company records and classification by a single B reader, seven (14%) of the 51 current workers had x-ray evidence of silicosis (defined as small opacity

profusion 1/0 or greater), but when the additional readings were used to determine a single classification, four (8%) had x-ray evidence of silicosis. Since the company routinely sent only those chest x-rays initially classified 1/0 for additional readings, it is not known if any of the 44 remaining chest x-rays classified 0/0 or 0/1 would have been reclassified as positive (1/0) had they also been sent for additional readings. Considering just the 29 participants in the NIOSH survey, the prevalence of silicosis in company chest x-rays was 17 % (5/29) based on the single reading and 10% (3/29) based on additional readings. Thus, it appears that the initial difference in prevalence between company-based results and the results from the NIOSH evaluation for the 29 participating current workers (17% from company records versus 10% from the NIOSH survey) may be a result of a difference in procedure (i.e., classification by a single B reader versus the use of the median classification from three B readings).

A population prevalence estimate based on the results from a sample of volunteer participants may result in an over-estimate, if those who choose to participate are less healthy than those who do not participate. Available data on age and tenure indicate that participants and non-participants for whom data were made available are alike, and among current workers there is more x-ray evidence of silicosis among those who chose to participate (see Table 6). Therefore, for all 51 eligible current workers a prevalence of 10% may be an over-estimate. However, the low participation rates among eligible former workers (33%), and the reliance on company-provided information for non-participating former workers, is a potential source of bias and limits the ability to state whether the NIOSH prevalence estimate of 10% represents an over-estimate or an under-estimate as applied to the study population as a whole. Despite these limitations, a perspective can be gained by examining the possible ranges of the prevalence.

The study population prevalence of x-ray defined silicosis among the 112 eligible current and former workers could, in theory, range from 5% - 42% depending upon the number of cases among non-

participating former workers, the source of information (company records or the NIOSH evaluation), and the number of cases counted from each source. An explanation of how these upper and lower boundaries on the estimate were obtained follows.

Using the company records and limiting the number of cases of silicosis to those determined by consensus, a total of six workers had a positive chest x-ray: three currently working participants, one of the 22 non-participating current workers, one of the 20 participating former workers, and one of the 41 non-participating former workers. Assuming the remaining 40 non-participating former workers (15 of whom had no chest x-ray results available and the one who did not have an ILO classification) had no radiographically-defined evidence of silicosis, the lower boundary of the prevalence estimate would be 5% (6/112).

To determine the upper boundary of the prevalence estimate, both sources of information were used to count the number of cases. Five cases out of 49 participants were identified during the NIOSH evaluation and two additional cases out of a total of 48 non-participants with chest x-ray results (22 current workers and 26 former workers) were identified from available company records. Assuming the 40 non-participating former workers had x-ray evidence of silicosis the highest estimate would be 42% (47/112). A more realistic upper boundary may be found by applying the proportion of cases identified, 7/97 (7%) to the 15 non-participants for whom chest x-ray results were missing. One of these 15 non-participants would then be assumed to have silicosis in addition to the seven already identified. The upper boundary of the prevalence estimate would then be 7%, or 8/112.

Generally, testing of active workers or recently active workers can result in an under-estimation of prevalence due to a "healthy worker survivor effect." This effect, or bias, is a pattern typically found in working populations where healthy people are employed and remain employed, while individuals who are less healthy tend not to be employed in the first place, and those who become ill tend to leave

employment over time. Cases of silicosis that may have occurred among deceased former workers were not included in this evaluation. Again, the low participation rate (33% among eligible former workers), selection bias, and the study design itself, may have had an effect and reduced the likelihood of identifying more cases of silicosis. Additionally, the low median tenure (3 years) in non-participating former workers is indicative of a high turnover rate, and as a result, x-ray evidence of silicosis may have been less likely to have occurred.

Occupational exposures to mineral dust have been associated with airflow limitation and chronic obstructive pulmonary disease.^(30,33,34) Published studies suggest that pulmonary impairment and chronic respiratory symptoms are associated with both cigarette smoking and cumulative dust exposure, and may be greater among dust-exposed workers who smoke.^(34,35,36) We found, as expected, that abnormal patterns occurred more frequently in "ever" smokers. However, there was no clear association between years of employment and lung function when this relationship was examined. Symptoms appeared related to cigarette smoking but surprisingly not to a greater number of years of employment at the plant or at other dusty jobs. Among the four participants with abnormal spirometry patterns, one reported shortness of breath, two had chronic bronchitis, and three reported a physician-diagnosed respiratory disease or illness (emphysema, bronchitis, and/or asthma). Pulmonary impairment can exist irrespective of the presence or absence of abnormalities detected on a chest x-ray.^(30,34,35,36) Abnormal pulmonary function test results were identified in only one of the five participants with a positive chest x-ray.

Cases of silicosis are not rare among workers currently or formerly employed at facilities that produce ground silica; workers at these facilities are, and have historically, been considered to be at high risk for silicosis. A NIOSH evaluation at a silica mining and milling operation in 1979 found that 7 (27%) of 26 participating current and former workers with one or more years exposure had chest x-ray changes consistent with silicosis.⁽³⁷⁾ Three cases were identified among 15 current workers, and four

cases were identified among 11 former workers. The participation rate among all current workers (i.e., including those with less than one year of exposure) was 83% (25/30), and among former workers with one year or more exposure was 35% (11/31).

A similar evaluation at the same time at another silica mining and milling operation found that 17 (44%) of 39 participating current and former workers with one or more years exposure had chest x-ray changes consistent with silicosis; three cases were identified among 15 current workers and 14 cases were identified among 24 former workers.⁽³⁸⁾ The participation rate among all current workers was 73% (30/41), and among former workers with one year or more exposure the rate was 47% (24/51).

In 1980, a NIOSH evaluation at a plant in New Jersey found six (13%) radiographically-defined cases of silicosis among 47 participating current and former workers.⁽³⁹⁾ Five out of the six cases identified during this evaluation were current workers. The participation rate for all current workers was 87% (26/30), and among former workers with one year or more employment since January 1, 1972, the rate was 70% (21/30).

These previous investigations utilized similar procedures and the standard pneumoconiosis classification of the time, the 1971 ILO-U/C.⁽⁴⁰⁾ More recently, Johnson and Busnardo⁽⁴¹⁾ described a case of silicosis in a maintenance mechanic employed from 1976 - 1981 at a plant that manufactures ground silica. By way of comparison, a 1985 study involving the classification (ILO-U/C 1971) of chest x-rays of 1422 blue-collar workers not exposed to dust or other respiratory hazards found only three (0.21%) chest x-rays with a median small opacity profusion of 1/0 or greater.⁽⁴²⁾ This study found only one chest x-ray with irregular small opacity profusion of 1/0, and no chest x-rays with rounded small opacity profusion of 1/0 or greater among over 700 males.

In the present evaluation, the predominant shape of small opacities on two of the five positive chest x-rays was rounded, and three showed predominantly irregular small opacities. Silicosis is usually

manifested as rounded opacities on chest x-ray, but it can present as predominantly irregular opacities, especially when the affected individual has been exposed to other dusts in addition to silica.^(12,13,26)

Although four of the five participants with positive chest x-rays were "ever" smokers, cigarette smoking alone does not explain the observed chest x-ray abnormalities. First, smoking clearly cannot explain the irregular opacities seen in one participant who had never smoked cigarettes. Second, smoking cannot explain the small rounded opacities seen in two other participants who were smokers, because there is no evidence that smoking can cause small rounded opacities.⁽⁴³⁾ Finally, although some have suggested that smoking may cause small irregular opacities, studies of large groups of workers exposed to silica have failed to show a significant effect of smoking on the presence of small irregular opacities classified according to the ILO system.⁽⁴³⁾ In summary, the irregular patterns noted in our survey are consistent with silicosis. However, other possibilities, such as exposure to another type of dust in addition to crystalline silica prior to, during, or after employment at Mill Creek, or a respiratory illness that is not work-related, cannot be ruled out.

MSHA's current standard for respirable dust containing crystalline silica came into effect July 1974. Since that time, MSHA has documented periods of non-compliance with its respirable crystalline silica dust standard at US Silica's Mill Creek operation (see Appendix I, Attachments 1 and 2). Two participants with a positive chest x-ray began working at Mill Creek between five to 10 years before MSHA's current silica dust standard came into effect in July 1974, two began working several months before July 1974, and one began working after July 1974. All five of these participants were employed for 15 years or more. Four of the five participants with a positive chest x-ray reported previous work at other dusty jobs. Two of these four participants with other dusty jobs had prior or subsequent employment of a length (≥ 5 years) that may have made a major contribution to signs of silicosis on their chest x-ray, although the degree to which these participant's other dust exposure contributed to the abnormalities seen on

their chest x-ray cannot be determined. The development of chest x-ray abnormalities is known to be related to both duration of exposure and to intensity of exposure, together known as cumulative exposure. A relationship between exposure to increasing levels of crystalline silica dust and the prevalence of chest x-ray evidence of silicosis is accepted, although the precise relationship is unknown.^(30,44)

Routine medical monitoring has been available to employees of the Mill Creek plant since 1950, is currently conducted every two years, and includes all of the screening tests recommended by NISA as well as those recommended by NIOSH based on the 1981 recommendations for workers exposed to ground silica. Chest x-rays are classified by a NIOSH-certified B reader and have been sent to the same reader since 1979. A company representative reported that since 1990, chest x-rays classified 1/0 or greater have been sent for additional classifications. Company chest x-rays classified as negative (0/0 and 0/1) by a single reader were not routinely sent for additional readings. The inconsistency of chest x-ray classification among B readers is well documented,^(2,45,46,47) and use of a single reader has consequences, intended or not, for the individual worker as well as groups of workers. For example, had "Reader 3" been the only reader for this NIOSH evaluation three (60%) of the five workers identified as having silicosis based on a median of three readings would have initially been considered to have a negative (0/0) chest x-ray, and the prevalence of silicosis among participants would have been 4% (2/49) (see Tables 4 and 5). Alternately, had "Reader 2" been the only reader, an additional 17 participants would have been considered to have silicosis and the prevalence among all participants would have been 49% (22/49). Obtaining multiple readings on *all* chest x-rays is one way of minimizing reader variability and reduces both 'false positive' (i.e., a chest x-ray wrongly classified as positive) and 'false negative' (i.e., a chest x-ray wrongly classified as negative) results. Obtaining multiple readings for the screening of chest x-rays for pneumoconiosis is standard practice for NIOSH studies,⁽⁴⁸⁾ and the federally mandated Coal Workers' X-ray

Surveillance Program (CWSP)⁽⁴⁹⁾ although NIOSH has not formally recommended multiple readings for the medical monitoring of workers exposed to silica.^(7,12,13,20,26)

Additionally, the frequency of the medical monitoring at Mill Creek differs from the frequency recommended by NIOSH for ground silica workers, and screening for TB was not reported to be part of the baseline examination or the routine medical monitoring. Pre-placement and annual medical examinations are recommended by NIOSH for all workers who manufacture, use, or handle ground silica or materials containing ground silica.⁽⁷⁾

CONCLUSIONS

1. It is reasonable to conclude that the abnormalities seen on these chest x-rays are attributable, at least in part, to past crystalline silica dust exposure at this facility. This conclusion is supported by MSHA documentation of prior periods of non-compliance with its respirable silica dust standard. There were no cases of silicosis among current workers with 10 or less years of tenure; however, because of the long latency usually associated with chronic silicosis, this finding is not sufficient to conclude that current crystalline silica dust exposure levels are without adverse effect.

2. The company medical monitoring practice of obtaining additional B reader classifications only for those chest x-rays initially classified 1/0 or greater will produce an estimated prevalence no higher than and possibly lower than that obtained with a single reading. This practice fails to identify positive chest x-rays among workers whose chest x-rays are initially read as 0/0 or 0/1.

RECOMMENDATIONS

The following recommendations are based on findings of the medical evaluation conducted by NIOSH at U.S. Silica, Mill Creek, MSHA

regulations, and NIOSH policy. Recommendations regarding primary prevention through engineering controls will be provided by MSHA in a separate report.

1. The medical examination and screening tests should be available to all workers who work in or downstream of the grinding mill prior to job placement and annually thereafter.⁽⁷⁾ However, medical monitoring should not be used as a substitute for environmental controls to reduce worker exposure to crystalline silica.
2. The current practice of obtaining an additional B reading only for those x-rays with a positive first reading creates a negative bias in the evaluation of workers for silicosis. To avoid this bias, ideally, all chest x-rays should be sent for a second B reading regardless of the initial classification, and for a third B reading if there is disagreement between the first two readings.
3. Skin testing for tuberculosis (TB) should be conducted prior to job placement and annually thereafter,^(12,13,26,50,51) with appropriate follow-up for definitive diagnosis and medical treatment, as indicated. The association of TB with silicosis and silica exposure is well-known.^(29,52,53) Skin testing procedures should be in accordance with CDC guidelines.^(54,55)
4. Each employee should receive a written copy of his medical examination results in full detail, whether or not the results are abnormal, in addition to a summary narrative. Results should be provided directly to the employee by the medical facility or contractor responsible for the examination, and employees should have the opportunity to review the results with a health care professional at the time they receive them.
5. Medical records should continue to be maintained separately from personnel records in a confidential manner. The access to medical records should be limited to health care personnel, such as the medical director.

6. All cases of silicosis should be reported to MSHA by the company, and to the Oklahoma State Department of Health by the examining physician, health care provider, contractor, and/or radiologist, as required. MSHA requires operators to report any miner with small opacity profusion of 1/0 or greater on chest x-ray, or a diagnosis of silicosis, or an award of compensation. Silicosis is a reportable condition in Oklahoma.^(56,57) To enhance the uniformity of reporting, NIOSH has developed reporting guidelines and a surveillance case definition for silicosis (Appendix II). This definition and guidelines are recommended for surveillance of work-related silicosis by state health departments and regulatory agencies receiving reports of cases from physicians and other health care providers.^(12,13,26)

REFERENCES

1. International Labour Office [1980]. Guidelines for the use of ILO international classification of radiographs of pneumoconioses. Revised Ed. 1980. Geneva, Switzerland: International Labour Office, (International Labour Office Occupational Safety and Health Series No. 22, Rev 80).
2. Morgan RH [1986]. Radiology. In: Merchant JA, Boehlecke BA, Taylor G, Pickett-Harner M (eds). Occupational Respiratory Diseases. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health DHHS (NIOSH) Publication No. 86-102.
3. American Thoracic Society [1987]. Standardization of spirometry - 1987 update. Am Rev Respir Dis 136:1258-1298.
4. Knudson RJ, Lebowitz MD, Holberg CJ, Burrows B [1983]. Changes in the normal maximal expiratory flow-volume curve with growth and aging. Am Rev Respir Dis 127:725-734.
5. Lanese RR, Keller MD, Foley MF, Underwood, EH [1978]. Differences in pulmonary function tests among whites, blacks, and american indians in a textile company. J Occup Med 20:39-44.
6. Medical Research Council's Committee on the Etiology of Chronic Bronchitis [1960]. Standardized questionnaire on respiratory symptoms. Br Med J 2:1665.
7. NIOSH [1981]. Current Intelligence Bulletin 36: silica flour: Silicosis (crystalline silica). Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 81-137.
8. National Industrial Sand Association [1977]. Occupational health program for exposure to free crystalline silica. Prepared by Clayton Environmental Consultants.
9. National Industrial Sand Association [1997]. Occupational health program for exposure to crystalline silica in the industrial sand industry. 1st ed. National Industrial Sand Association, Inc.
10. Ziskind M, Jones RN, Weill H [1976]. Silicosis. Am Rev Respir Dis 113:643-665.
11. Peters JM. [1986]. Silicosis. In: Merchant JA, Boehlecke BA, Taylor G, Pickett-Harner M (eds). Occupational Respiratory Diseases. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 86-102.
12. CDC (Centers for Disease Control) [1990]. Silicosis: clusters in sandblasters-Texas, and occupational surveillance for silicosis. MMWR 39 (25):433-437.

13. NIOSH [1996]. NIOSH Alert: request for assistance in preventing silicosis and deaths in construction workers. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 96-112.
14. Weill H, Jones RN, Parkes WR [1994]. Silicosis and related diseases. In: WR Parkes, eds. Occupational Lung Disorders. 3rd ed. Oxford: Butterworth-Heinemann, Ltd., pp. 285-339.
15. Fraser RG, Paré JAP, Paré PD, Fraser RS, Genereux GP [1990]. Pleuropulmonary disease caused by inhalation of inorganic dust (pneumoconiosis). In: Diagnosis of diseases of the chest. 3rd ed. Vol.3. Philadelphia: W.B. Saunders Company, pp. 2289-2300.
16. Silicosis and Silicate Disease Committee [1988]. Diseases associated with exposure to silica and nonfibrous silicate minerals. Archives of Pathology and Laboratory Medicine 112:673-720.
17. Beuchner HA, Ansari A [1969]. Acute silico-proteinosis. Disease of the Chest 55:274-285.
18. Sheppard D, Hughson WG, Shellito J [1990]. Occupational lung diseases. In: J. LaDou, ed. Occupational Medicine. Norwalk, CN: Appleton & Lange, pp. 221-236.
19. Wegman DH, Christiani DC [1995]. Respiratory disorders. In: BS Levy & DH Wegman, eds. Occupational Health: Recognizing and Preventing Work-Related Disease. 3rd ed. Boston: Little, Brown and Company, pp. 427-454.
20. NIOSH [1974]. NIOSH criteria for a recommended standard: occupational exposure to crystalline silica. Washington, DC: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 75-120.
21. NIOSH [1984]. Health hazard control technology assessment of the silica flour milling industry. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 84-110.
22. Hinds, WC [1982]. Respiratory deposition. In: Hinds, WC, Aerosol Technology: Properties, Behavior, and Measurement of Airborne Particles. New York: Wiley-Interscience Publishers, p. 219.
23. Vallyathan V, Xianglin S, Dalal, NS, Irr W, Castranova V [1988]. Generation of free radicals from freshly fractured silica dust: potential role in acute silica induced lung injury. Am Rev Respir Dis 138:1213-1219.
24. Vallyathan V, Kang JH, Van Dyke K, Dalal, NS, Castranova V [1991]. Response of alveolar macrophages to in vitro exposure to freshly fractured versus aged silica dust: the ability of prosil 28, an organosilane material, to coat silica and reduce its biological reactivity. J Tox Environ Health 33:303-315.
25. Vallyathan V, Castranova V, Pack D, Leonard S, Shumaker J, Hubbs AF, Shoemaker DA, Ramsey DM, Pretty JR, McLaurin JL, Khan A, Teass A [1995]. Freshly fractured quartz inhalation leads to enhanced lung injury and inflammation. Am Rev Respir Crit Care Med 152:1003-1009.
26. NIOSH [1992]. NIOSH Alert: request for assistance in preventing silicosis and deaths in rock drillers. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 92-107.
27. Allison AC, Hart PD [1968]. Potentiation by silica of the growth of *mycobacterium tuberculosis* in macrophage cultures. Brit J Exper Pathology 49:465-476.

28. Ng TP, Chan, SL [1991]. Factors associated with massive fibrosis in silicosis. *Thorax* 46 (4):229-232.
29. International Agency for Research on Cancer (IARC) [1997]. IARC monographs on the evaluation of carcinogenic risks to humans: silica, some silicates, coal dust and para-Aramid fibrils. Vol 68. Lyon, France: World Health Organization.
30. American Thoracic Society [1997]. Adverse effects of crystalline silica exposure. *Am J Respir Critical Care Med* 155:761-768.
31. NIOSH [1988]. NIOSH testimony to the U.S. Department of Labor: statement of the National Institute for Occupational Safety and Health. Presented at the public hearing on OSHA PELs/Crystalline Silica, July 1988. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health.
32. NIOSH [1992]. NIOSH recommendations for occupational safety and health: Compendium of policy documents and statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 92-100.
33. Becklake MR [1985]. Chronic airflow limitation: its relationship to work in dusty occupations. *Chest* 88:608-617.
34. Oxman AD, Muir DC, Shannon HS, Stock SR, Hnizdo E, Lange HJ [1993]. Occupational dust exposure and chronic obstructive pulmonary disease: a systematic overview of the evidence. *Am Rev Respir Dis* 148:38-48.
35. Hnizdo E, Baskind E, Sluis-Cremer GK [1990]. Combined effect of silica dust exposure and tobacco smoking on the prevalence of respiratory impairments among gold miners. *Scand J Work Environ Health* 16:411-422.
36. Wiles FJ, Baskind E, Hessel PA, Bezuidenhout B, Hnizdo E [1992]. Lung function in silicosis. *Intl Arch Occup Environ Health* 63:387-391.
37. NIOSH [1979]. Health hazard evaluation and technical assistance report: Tammsco, Inc., Tamms, Illinois. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 79-104-107.
38. NIOSH [1979]. Health hazard evaluation and technical assistance report: Illinois Minerals Company, Elco, Illinois. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 79-103-108.
39. NIOSH [1980]. Health hazard evaluation and technical assistance report: Unisil Corporation, Millville, New Jersey. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 80-103-04M.
40. Jacobsen G, Lainhart WS, eds. [1972]. ILO U/C 1971 International classification of radiographs of the pneumoconioses. *Med Radiogr Photogr* 48(3):65-110.
41. Johnson WM, Busnardo, MS [1993]. Silicosis following employment in the manufacture of silica flour and industrial sand. *J Occup Med* 35(7):716-719.
42. Castellan RM, Sanderson WT, Petersen MR [1985]. Prevalence of radiographic appearance of pneumoconiosis in an unexposed blue collar population. *Am Rev Respir Dis* 131:684-686.

43. Blanc PD, Gamsu G [1989]. Cigarette smoking and pneumoconiosis: structuring the debate (editorial). *Am J Ind Med* 16:1-4.
44. Hughes JM [1995]. Radiographic evidence of silicosis in relation to silica exposure. *Appl Occup Environ Hyg* 10(12):1064-1069.
45. Attfield MD, Althouse R, Reger RB [1986]. An investigation of inter-reader variability among x-ray readers employed in the underground coal miner surveillance program. *Ann Am Conf Gov Ind Hyg* 14: 401-409.
46. Ducatman AM [1991]. Variability in interpretation of radiographs for asbestosis abnormalities: problems and solutions. *Annals of the New York Academy of Sciences*. 643:108-120.
47. Attfield MD, Wagner GR [1992]. A report on a workshop on the National Institute for Occupational Safety and Health B reader certification program. *J of Occ Med* 34(9): 875-879.
48. Attfield MD, Castellan RM [1992]. Epidemiological data on US coal miners' pneumoconiosis, 1960 to 1988. *Am J Public Health* 82:964-970.
49. Code of Federal Regulations [1978]. 42 CFR 37 - Specifications for medical examinations of underground coal miners. Washington, DC: U.S. Government Printing Office, Federal Register.
50. American Thoracic Society and Centers for Disease Control [1994]. Treatment of tuberculosis and tuberculosis infection in adults and children. *Am J Respir Crit Care Med* 149:1359-1374.
51. CDC (Centers for Disease Control and Prevention) [1995]. Screening for tuberculosis and tuberculosis infection in high-risk populations; recommendations of the advisory council for the elimination of tuberculosis. *MMWR* 44 (No. RR-11): 19-34.
52. Snider, DE Jr. [1978]. The relationship between tuberculosis and silicosis. *Am Rev Respir Dis* 118: 455-460.
53. Chen GX, Burnett CA, Cameron LL, Alterman T, Lulich NR, Tanaka S, Althouse R [1997]. Tuberculosis mortality and silica exposure: a case-control study based on a national mortality database for the years 1983-1992. *Int J Occup Environ Health* 3:163-170.
54. American Thoracic Society/CDC [1990]. Diagnostic standards and classification of tuberculosis. *Am Rev Respir Dis* 142:725-35.
55. CDC [1994]. Guidelines for preventing the transmission of *mycobacterium tuberculosis* in health-care facilities. *MMWR* 43 (No. RR-13).
56. Freund E, Seligman PJ, Chorb TL, Safford SK, Drachman JG, Hull HF [1989]. Mandatory reporting of occupational diseases by clinicians. *J Am Med Assoc* 262 (21): 3041-3044.
57. CDC [1990]. Mandatory reporting of occupational diseases by clinicians. *MMWR* 39 (No. RR-9):19-28.

TABLE 1
Determination of the Study Population
U.S. Silica - Mill Creek
HETA 93-0790

	CURRENT WORKERS		FORMER WORKERS		Total
	Participants	Non-participants	Participants	Non-participants	
Number of Workers Originally Identified	37	29	30	73	169
Reason for Exclusion from Study Population					
- Not eligible based on job and/or tenure	8	—	6	4	18
- Company determined worker not eligible	—	7	3	15	25
- Missing records	—	—	—	3	3
- NIOSH unable to verify eligibility	—	—	1	7	8
- Deceased	—	—	—	3	3
Number of Workers Remaining for Study	29	22	20	41	112

TABLE 2
Study Population and Participation Rate By Employment Status
U.S. Silica - Mill Creek
HETA 93-0790

Employment Status	N	Total # Eligible	Number of Participants	Number of Non-Participants	Participation Rate (%)
Current Worker	66	51	29	22	57
Former Worker	103	61	20	41	33
TOTAL	169	112	49	63	44

TABLE 3
 Characteristics of 49 Participants by Employment Status
 U.S. Silica - Mill Creek
 HETA 93-0790

	EMPLOYMENT STATUS						
CHARACTERISTIC	29 CURRENT WORKERS			20 FORMER WORKERS			TOTAL
Age (yrs) [median]	38			39			39
Range (yrs)	24-58			31-66			24-66
Tenure (yrs) [median]	13			4.5			11
Range (yrs)	2-32			1-27			1-32
Cigarette Smoking Status	Number	%	Pack-years [median]	Number	%	Pack-years [median]	Number % Pack-years [median]
Never smoker	10	34%	—	9	45%	—	19 39% —
Current smoker	4	14%	26	8	40%	26	12 24% 26
Ex-smoker	15	52%	9	3	15%	21	18 37% 13
Pack - Years (median), Ever smokers	13			24			18

Ever Smokers = Current and Former smokers combined.

TABLE 4
Chest X-ray Results by Reader for 29 Participating Current Workers
U.S. Silica - Mill Creek
HETA 93-790

READER 1			READER 2			READER 3			MEDIAN	
Profusion	Size/Shape	Zone(s)*	Profusion	Size/Shape	Zone(s)	Profusion	Size/Shape	Zone(s)	Profusion	Film Quality
0/0			1/0	ss	2,3,5,6	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/0	pp	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
2/2, B	pq	All	2/1, B	qp	All	2/3, B	qr	All	2/2, B	3
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
1/0	st	2,3,5,6	2/1	st	2,3,5,6	0/0			1/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/1	ps	1,2,4	1/0	pp	All	0/0			0/1	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
1/1	st	2,3,4,5,6	2/1	st	2,3,5,6	0/0			1/1	2
0/0			1/0	st	All	0/0			0/0	1
0/0			1/0	ss	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1

* 1, 2, and 3 correspond to the right upper, middle, and lower zones, respectively; while 4, 5, and 6 correspond to the left upper, middle, and lower zone

TABLE 4 (Continued)
Chest X-ray Results by Reader for 29 Participating Current workers
U.S. Silica - Mill Creek
HETA 93-790

READER 1			READER 2			READER 3			MEDIAN	
Profusion	Size/Shape	Zone(s)*	Profusion	Size/Shape	Zone(s)	Profusion	Size/Shape	Zone(s)	Profusion	Film Quality
0/0			0/0			0/0			0/0	3
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1

* 1, 2, and 3 correspond to the right upper, middle, and lower zones, respectively; while 4, 5, and 6 correspond to the left upper, middle, and lower zones.

TABLE 5
Chest X-ray Results by Reader for 20 Participating Former Workers
U.S. Silica - Mill Creek
HETA 93-790

READER 1			READER 2			READER 3			MEDIAN	
Profusion	Size/Shape	Zone(s)*	Profusion	Size/Shape	Zone(s)	Profusion	Size/Shape	Zone(s)	Profusion	Film Quality
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/1	ss	All	0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
1/0	st	2,3,5,6	1/0	ss	2,3,5,6	0/0			1/0	2
0/0			1/1	pp	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/1	st	3,6	1/1	st	2,3,5,6	0/0			0/1	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
1/1	qt	1,2,4,5	1/1	qr	1,2,4,5	2/1	rq	1,4	1/1	1
0/1	qr	1,4	1/1	st	All	0/0			0/1	1
0/0			0/0			0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
0/0			0/0			0/0			0/0	2
0/0			0/0			0/0			0/0	1

* 1, 2, and 3 correspond to the right upper, middle, and lower zones, respectively; while 4, 5, and 6 correspond to the left upper, middle, and lower zones

TABLE 6
Age, Length of Employment, Experience in Other Dusty Jobs, Cigarette Smoking,
and Small Opacity Profusion from Company Records
by Employment Status and Participation
U.S. Silica - Mill Creek
HETA 93-0790

	CURRENT WORKERS		FORMER WORKERS	
	Participants N=29	Non-participants N=22	Participants N=20	Non-participants N=41
Age (yrs) [median]	38	38	39 ^a	39 ^a
Range (yrs)	24-58	20-60	20-60	23-73
Tenure (yrs) [median]	13	14	4 ^b	3
Range (yrs)	2-31	1-38	1-28	1-41
Other Dusty Job (s)	Number %	Number %	Number %	Number %@
Yes	21 72	17 77	10 50	20 49
No	8 28	5 23	5 25	6 15
Unknown	— —	— —	5 25	15 37
Cigarette Smoking	Number %@	Number %	Number %	Number %@
Current smoker	7 24	9 41	5 25	12 29
Ex - smoker	12 41	13 59	2 10	3 7
Never smoker	10 34	— —	8 40	10 24
Unknown	— —	— —	5 25	16 39
Small Opacity Profusion ≥ 1/0* (single B reading)	Number %	Number %	Number ^c %	Number ^c %
	5 17	2 9	1 5	3** 7
Small Opacity Profusion ≥ 1/0 (using additional B readings)	3 10	1 4.5	1 5	1 2

a Missing age for 1 participating and 1 non-participating former worker

b Missing tenure for 1 participating former worker

c ILO Classification missing for 5 participating and 16 non-participating former workers

@ Percentages do not add to 100 due to rounding

* As determined by the classification closest in time prior to the NIOSH survey by a single B reader

** Two non-participants had a single ILO classification

APPENDIX I
PROTOCOL
MSHA/NIOSH GROUND SILICA MILL STUDY

This protocol describes a joint Mine Safety and Health Administration (MSHA) and National Institute for Occupational Safety and Health (NIOSH) project to study silica exposure and the prevalence of silicosis in workers in ground silica mills. MSHA selected the mill portions of nine ground silica operations, based on one or more of the following criteria: (1) one or more outstanding violations of MSHA's respirable silica standard and a history of overexposure to respirable silica; (2) size of the mills, both large and small, based on number of employees; (3) use of advanced control technology; and (4) a representative number of ground silica mills from each Metal and Nonmetal Mine Safety and Health District. Nine mills were chosen for the study rather than all sixteen because of the two year time frame (fiscal years 1993 - 1995) planned to complete the study. A list of the sixteen mills is provided in Attachment 1 and a list of the nine selected mills is given in Attachment 2. Noncompliance with MSHA's respirable silica standard is indicated on the attachments.

In late 1991, when the selection was made, six of the sixteen mills were selected using criteria number one. U.S. Silica Company's Berkeley Mill and Columbia Mill, and the Nicks Silica Company Mill had no outstanding respirable silica violations. The Berkeley Mill uses many advanced controls and is the largest mill. The Columbia Mill, a large mill and Nicks Silica Company, a small mill in MSHA's Southeastern District, were selected using criteria number two and four. There are ground silica mills in four of the six Metal and Nonmetal Mine Safety and Health Districts and each of these four Districts are represented in the study. Three mills were selected from the South Central District and North Central District, two mills were selected from the Southeastern District, and one mill was selected from the Northeastern District.

MSHA will evaluate silica dust exposures in the 9 selected ground silica mills. NIOSH will estimate the prevalence of silicosis in active and former workers in the same 9 mills. At the completion of the study, MSHA will issue a report on findings of each mill and a summary of all mills.

I. BACKGROUND

Ground silica particles are hazardous due to their respirable size and high concentration of crystalline silica, a known cause of nonmalignant respiratory disease (silicosis) and possible cause of lung cancer. A NIOSH feasibility study of the adequacy of company records for a proposed NIOSH study of silicosis was released in 1990. Examination of four industrial sand facilities' B Reader reports found 27% of workers with > 20 years work experience had small opacities on x-ray.¹ The feasibility study was of industrial sand mills of which ground silica was a subset.

APPENDIX I (con't)

II. PROTOCOL OBJECTIVES & METHODS

The following protocol describes the joint MSHA/NIOSH study and identifies responsibilities for each part of the project.

1. NIOSH and MSHA will inform management and employee representatives about the project prior to initiation.
 - (a) Entrance and close-out meetings will be held with local management and employees or employee representatives at each site.
 - (b) All current and former employees will receive invitations from NIOSH to participate in the medical portion of the study.
2. NIOSH will radiographically examine current and former employees at the 9 selected ground silica mills for evidence of silicosis.
 - (a) Posterior-anterior radiographs will be taken, randomly mixed, and independently classified for pneumoconiosis according to the 1980 ILO system by two NIOSH certified B Readers. If the two readings do not agree on small opacity profusion, a third reading will be obtained and the median reading will be used to define an abnormality. A chest x-ray showing opacities of profusion category $\geq 1/0$ in a ground silica mill worker will be categorized as consistent with silicosis. The B Readers will not be informed of any exposure history and the films will be masked of identifying information. The same three B Readers will be used throughout the entire project.
 - (b) Participants with a recent chest x-ray (within 1 year of the current NIOSH survey) may provide the chest x-ray to NIOSH to be read, rather than have a new chest x-ray taken during this evaluation.
 - (c) All participants will receive written notification of their chest x-ray results. Persons found to have abnormal chest x-rays will be encouraged to consult their personal physician.
3. NIOSH will administer a questionnaire which elicits occupational history, demographic information, respiratory symptoms, and smoking history.
4. NIOSH will obtain pertinent records held by the companies.
 - (a) NIOSH will copy pertinent medical and personnel records.
 - (b) Review company medical records for diagnoses suggestive of silicosis.
 - (c) Collect personnel records showing detailed work histories for current and former workers.

APPENDIX I (con't)

5. NIOSH will evaluate the pulmonary function status of the participants through spirometry testing.
 - (a) Spirometry will conform to the American Thoracic Society's criteria for screening spirometry.
 - (b) All participants will receive written notification of their spirometry results. Persons found to have abnormal results will be encouraged to consult their personal physician.
6. MSHA will determine exposure levels of employees at the 9 ground silica mills.
 - (a) Obtain and compare records of past respirable silica dust sampling performed by MSHA and the ground silica mill operators.
 - (b) Sample all job classifications in the mill portion of the nine selected ground silica mills.
 - (c) Cite, under MSHA regulations, any overexposure to respirable silica dust determined from MSH samples.
7. MSHA Technical Support will evaluate the effectiveness of dust controls in the selected mills.
 - (a) Observe and measure the performance of dust controls. Evaluate maintenance, housekeeping and work practices and how they effect dust control.
8. MSHA will evaluate respiratory protection programs at the 9 ground silica mills.
 - (a) Evaluate respiratory programs to determine if they meet the minimum requirements of ANSI Z88.2-1969, Practices For Respiratory Protection, as mandated by Title 30 CFR, Part 56.5005. whe respirators are required. The minimum requirements are listed in Attachment 3.
9. NIOSH and MSHA will report results of their surveys as follows:
 - (a) NIOSH reports will summarize findings of medical surveys, including the prevalence of silicosis among participants overall, by mill, job, and tenure if feasible.
 - (b) MSHA will issue reports combining findings of NIOSH and MSHA for each of the 9 mills selectex as well as a summary report.
 - (c) Each agency will review and comment on all reports prior to release.

APPENDIX I (con't)

(d) Individual mill reports and summary report will be provided to the industry associations, national unions representing workers in the ground silica industry, participating mill management and employee representatives, and other interested parties.

III. STUDY POPULATION

All current (estimated 332) and former workers (estimated number unknown) of the 9 mills to be studied will be invited to participate. No further follow up will be made to eligible individuals who do not participate.

ADDENDUM: FURTHER STUDIES OF TWO SOUTHERN ILLINOIS GROUND SILICA MILLS PREVIOUSLY STUDIED BY NIOSH IN 1979 (11-01982 AND 11-02051)

I. BACKGROUND

In 1979, NIOSH was requested to provide Technical Assistance to MSHA at two ground silica mills.^(2,3) Through medical and environmental surveys, NIOSH determined that a significant health hazard existed at these mills due to overexposure to respirable quartz. Forty-four percent of workers with greater than a year experience in one mill were found to have x-ray evidence of silicosis. Twenty-seven percent of the workers with similar work histories in the other mills were also found to have x-ray evidence of silicosis. Of 65 current and former workers with ≥ 1 year exposure studied in the two mills, 7 cases of progressive massive fibrosis were discovered by NIOSH.

In response to these findings, NIOSH in 1981 issued Current Intelligence Bulletin 36, "Silica Flour. Silicosis (Crystalline Silica)", describing a significant respiratory hazard in silica flour mills from respirable quartz.⁽⁴⁾

II. OBJECTIVES AND METHODS

1. NIOSH will estimate the incidence of new cases of silicosis among workers at the two mills.
 - (a) The x-rays of current and former employees of the two mills will be compared with those previously taken in 1979 to identify any new cases of silicosis developing since 1979.
2. NIOSH will compare the prevalence estimates of silicosis found in the 1979 Technical Assistance surveys of two southern Illinois ground silica mills to the current estimates of prevalence for those two mills.
 - (a) Methods 2 (a) and (b) discussed in the study protocol.

APPENDIX I (con't)

(b) Reclassify the x-rays taken by NIOSH in 1979 at these two mills according to the 1980 ILO classification system. (The films taken in 1979 were classified used the 1971 ILO classification system). The B Readers will not be made aware when more than one film on an individual is to be classified. The films will be randomly mixed and classified independently. The same three B Readers will be used throughout the entire project.

3. NIOSH will evaluate the change in spirometry results among the workers previously examined in 1979.

(a) Compare an individual worker's 1979 spirometry results to those obtained in this study.

4. NIOSH will review the implementation of recommendations made in the 1979 NIOSH Technical Assistance survey reports (HETA Nos. 79-103-108 and 79-104-107). The following recommendations were made: engineering and work practice improvements to reduce free silica exposures below the NIOSH REL; periodic environmental monitoring of silica exposures by the operator; respiratory protection while the effectiveness of the engineering controls are evaluated; all workers exposed to silica dust not examined in the NIOSH study should undergo comprehensive medical examinations; workers with radiographic evidence of silicosis should be given the opportunity to transfer to jobs without silica exposure; current workers with pulmonary function impairment be evaluated by a qualified physician and advised whether to continue in a dusty trade; medical examinations should be performed at first exposure to silica dust and at yearly intervals; bagged silica flour should be correctly labeled and contain appropriate health warnings.

- (a) Review company industrial hygiene records.
- (b) Review company respiratory protection program.
- (c) Review employee medical and personnel records.
- (d) Review product bag labels.

III . REFERENCES

1. Amandus H [1990]. A feasibility study of the adequacy of company records for a proposed NIOSH study of silicosis in industrial sand workers. Final report to Director, NIOSH. Morgantown, WV: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, DHHS (NIOSH).
2. NIOSH [1979]. Hazard evaluation and technical assistance report: Tammsco, Incorporated: Tamms, Illinois. Morgantown, WV: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NIOSH Report No. HHE 79-104-107.
3. NIOSH [1979]. Hazard evaluation and technical assistance report: Illinois Minerals Company: Elco, Illinois. Morgantown, WV: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NIOSH Report No. HHE 79-103108.
4. NIOSH [1981]. Current Intelligence Bulletin 36: silica flour; silicosis (crystalline silica). Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 81-137.

APPENDIX I (con't)

ATTACHMENT 1

GROUND SILICA MILLS - 1991

	<u>Northeastern District</u>		<u>Employees</u>
46-02805	U.S. Silica Co.	Berkeley Plant	102
	<u>Southeastern District</u>		
38-00027	Spartan Minerals Co.	Pacolet Mill	21
38-00138	U.S. Silica Co.	Columbia Plant	50
38-00299	Unimin Corp.	Unimin-Lugoff	19
40-02937	Nicks Silica Co.	Nicks Silica Co.	13
	<u>North Central District</u>		
11-01013	U.S. Silica Co.	Ottawa Plant	94
11-01580	Unimin Corp.	Troy Grove Plant	18
11-01981	Unimin Specialty Min.	Plant (NC)	30
11-02051	Unimin Specialty Min.	Plant/Mill (NC)	22
33-01354	Central Silica Co.	Glass Rock Quarry (NC)	34
33-01355	Central Silica Co.	Millwood Sand Div.	25
	<u>South Central District</u>		
03-00299	Malvern Minerals	Malvern Minerals Sandstone (NC)	19
23-00504	American Tripoli, Inc.	American Tripoli, Inc. (NC)	12
23-00544	U.S. Silica Co.	Pacific Plant	30
34-00377	U.S. Silica Co.	Mill Creek Plant (NC)	50
41-01059	Unimin (Texas) Corp.	Unimin (Texas)	20

NC - Noncompliance

APPENDIX I (con't)

ATTACHMENT 2

GROUND SILICA MILLS - 1991

	<u>Northeastern District</u>		<u>Employees</u>
46-02805	U.S. Silica Co.	Berkeley Plant	102
	<u>Southeastern District</u>		
38-00138	U.S. Silica Co.	Columbia Plant	50
40-02937	Nicks Silica Co.	Nicks Silica Co.	13
	<u>North Central District</u>		
11-01981	Unimin Specialty Min.	Plant (NC)	30
11-02051	Unimin Specialty Min.	Plant/Mill (NC)	22
33-01354	Central Silica Co.	Glass Rock Quarry (NC)	34
	<u>South Central District</u>		
03-00299	Malvern Minerals	Malvern Minerals Sandstone (NC)	19
23-00504	American Tripoli, Inc.	American Tripoli, Inc. (NC)	12
34-00377	U.S. Silica Co.	Mill Creek Plant (NC)	50

NC - Noncompliance

APPENDIX I (con't)

ATTACHMENT 3

Minimum Requirements of ANSI Z88.2-1969

(1) The operator must establish a written standard operating procedure governing the selection and use of the respirator.

(2) The operator must select the respirators on the basis of the hazards to which the worker is exposed. The respirator must be MSHA/NIOSH approved for the specific hazards.

(3) The respirator user shall be instructed and trained in the proper use of respirators and their limitations. The minimum training shall include the following (as quoted from ANSI Z88.2-1969):

- a. Instruction in the nature of the hazard, whether acute, chronic, or both, and a complete appraisal of what may happen if the respirator is not used.
- b. Explanation of why more positive control is not immediately feasible. This shall include recognition that every reasonable effort is being made to reduce or eliminate the need for respirators.
- c. A discussion of why this is the proper type of respirator for the particular purpose.
- d. A discussion of the respirator's capabilities and limitations.
- e. Instruction and training in actual use of the respirator (especially a respirator for emergency use) and close and frequent supervision to ensure that it continues to be properly used.
- f. Classroom and field training to recognize and cope with emergency situations.
- g. Other special training as needed for special use.

Training shall provide the employees an opportunity to handle the respirator, have it fitted properly, test its facepiece-to-face seal, wear it in normal air for a long familiarity period, and, finally, to wear it in a test atmosphere.

APPENDIX I (con't)

(4) Fit testing

All respirator wearers must be fit tested before using negative pressure respirators. ANSI Z88.2-1969 does not require fit testing of positive pressure respirators. Use a validated protocol for fit testing.

(5) The operator must keep records to show that the proper respirator was issued to the respirator wearer. This is usually accomplished by recording the fit test results for each wearer, along with the date that the wearer received the respirator.

(6) Respirators shall be cleaned and disinfected. Respirators used routinely shall be inspected during cleaning. Worn or deteriorated parts shall be replaced to maintain MSHA/NIOSH approval. ANSI states that cleaning and maintenance shall be done "as frequently as necessary to ensure proper protection is provided to the wearer."

(7) Emergency-use respirators must be thoroughly inspected at least once per month and after each use. Keep a record of the inspection dates and findings.

(8) Respirators shall be stored in a convenient, clean and sanitary location. The respirators must be stored in a manner that protects them against contamination, temperature extremes, and other potentially damaging conditions.

(9) A single individual must administer the respiratory protection program. This individual shall regularly evaluate the effectiveness of the program. Monitoring will be conducted regularly to ensure that the selected respirators continue to provide appropriate protection to the wearer.

APPENDIX I (con't)

ATTACHMENT 4

PART II 2 (a) OBJECTIVES AND METHODS

Posterior-anterior radiographs will be taken, randomly mixed, and independently classified for pneumoconiosis according to the 1980 ILO system by three NIOSH certified B Readers. The median reading will be used to report an abnormality. A chest x-ray showing opacities of profusion category $\geq 1/0$ in a ground silica mill worker will be categorized as consistent with silicosis. The B Readers will not be informed of any exposure history. The films will be masked of identifying information. The same B Readers will be used throughout the entire project.

APPENDIX II ⁽¹²⁾

SURVEILLANCE GUIDELINES: SILICOSIS

Reporting Guidelines

State health departments and regulatory agencies should encourage physicians (including radiologists, pathologists, and other health care providers) to report all diagnosed or suspected cases of silicosis. These reports should include persons with

- a physician's provisional or working diagnosis of silicosis, OR
- a chest radiograph interpreted as consistent with silicosis, OR
- pathologic findings consistent with silicosis

To set priorities for workplace investigations, State health departments and regulatory agencies should collect appropriate clinical, epidemiologic, and workplace information about persons reported to have silicosis.

Surveillance Case Definition

- A. 1. History of occupational exposure to airborne silica dust

AND

2. Chest radiograph or other imaging technique interpreted as consistent with silicosis

OR
- B. Pathologic findings characteristic of silicosis