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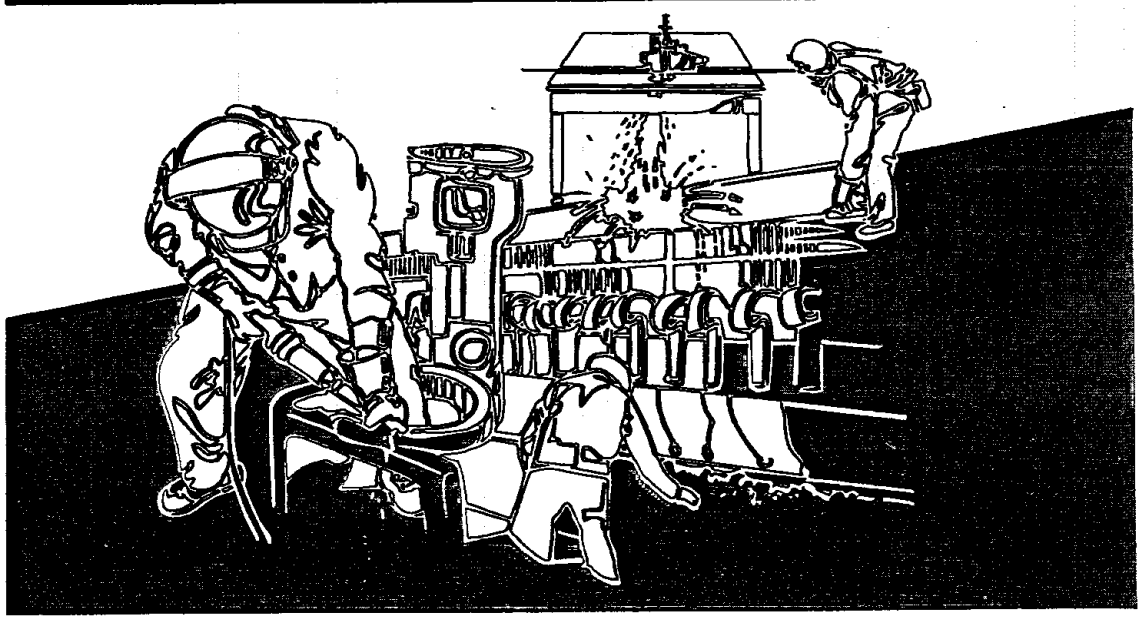
OSH HEALTH HAZARD EVALUATION REPORT

HETA 93-0795-2783
U.S. Silica - Columbia
Cayce - W. Columbia, SC

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

PREFACE

NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

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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 U.S. Silica Company - Columbia plant; Mine Safety and Health Administration; South Carolina Department of Health & Environmental Control; National Industrial Sand Association; Glass, Molders, Pottery, Plastics & Allied Workers International; General Teamsters and Allied Workers; PACE International; and other interested parties. 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 93-0795-2783
U.S. Silica - Columbia
Cayce - W. Columbia, SC
March, 2000

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 Columbia plant, in Cayce-W. Columbia, South Carolina.

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 February 24-25, 1994, a medical evaluation of current workers was conducted. Former workers were tested on February 26-27, 1994. 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.

Thirty-five (90%) of 39 current workers and 11 (65%) of 17 former workers who met the study criterion participated in the NIOSH medical evaluation. Of these 46, four (9%) had a chest x-ray consistent with silicosis. The highest median ILO profusion category was 2/2. Two of the four had a chest x-ray consistent with progressive massive fibrosis (PMF).

Twelve (27%) of the 45 participants who performed spirometry had abnormal patterns; all 12 exhibited an obstructive lung pattern. Abnormal spirometry patterns were present in all four of the 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.
Since 1990, the company reportedly sent chest x-rays initially classified 1/0 or greater by a single reader for additional classifications. Of the company records we reviewed, chest x-rays initially classified as negative (0/0 and 0/1) were not routinely sent for additional readings, and the practice of sending chest x-rays classified 1/0 or greater for additional readings was not consistent.

Four (9%) of the 46 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 or former workers with 15 or less years of employment; 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 may 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 Columbia plant, in Cayce -W. Columbia, South Carolina. 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 Columbia facility.

On February 10,1994, two NIOSH representatives met with company representatives, the facility's Miners' Representative, several employees, and a MSHA representative to discuss logistical and administrative considerations of the NIOSH evaluation. On February 23, 1994, an opening meeting was held with company representatives, the Miners' Representative, 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 plant.

On February 24-25, 1994 the medical evaluation of current workers was conducted. Former workers were tested on February 26-27, 1994. All study participants received written notification of their spirometry results in March, 1994. 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 December, 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 Columbia plant. 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 Columbia plant was constructed in 1962 and has been in operation since then. Beginning with two grinding mills, U.S. Silica (formerly Pennsylvania Glass Sand) increased its silica-grinding capacity in the 1960's and again in the 1970's with the installation of a total of four additional grinding mills. In 1994, U.S. Silica's Columbia plant was the largest producer of industrial ground silica in the United States. A miners' representative, selected by the employees, represented employees at this plant. At the Columbia plant, silica sand is mined from a nearby open-pit operation and transported by overland conveyor to the plant for processing. After removing impurities, the sand is dried, classified, and milled. The bagging operation was eliminated in 1980, and all products are bulk-loaded into railroad cars or trucks. At the time of our survey in 1994, the plant operated production processes 24 hours a day, seven days a week, with 8-hour shift schedules. Four 5-person production teams rotated periodically to cover the seven-day operations. Maintenance personnel worked 8 a.m. - 4 p.m. five days a week.

Maintenance occurred weekly on Mondays during the first (daylight) shift. No milling or grinding took place while maintenance activities were performed. A total of 48 employees (including clerical and salaried employees) worked at the Columbia plant. The departments that were part of the Columbia operation were Production, which included mining, milling, and load-out; Maintenance; and Administrative/Clerical staff. The main job categories affected by the grinding process were Control Room Operator, Mill Helper (Mill Helper duties include working in the mill and clean-up), Bulk Loader, Lab Technician, Maintenance (mechanics and electricians), and Supervisory personnel (e.g., shift supervisor or foreman).

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. 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 the company, 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, company information, and/or company records which were subsequently provided. 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		
0/-	0/0	0/1	1/0	1/1	1/2

2			3		
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 (FEV_1) 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 FEV_1/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, NISA 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:

Form	Time to Onset	Intensity of Exposure
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 <1cm 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 who remained to make up the study population.

Of 48 current employees, eight current workers were determined to be ineligible (i.e., they did not meet the study criterion) and were excluded from the study population. Eligibility could not be determined by NIOSH for one participating current worker. A total of 39 current workers were eligible for inclusion in the study population.

Of 42 former workers identified, 24 were determined to be ineligible, and the records for one worker were missing. Eligibility could not be determined by NIOSH for one participating former worker whose name was not listed on the company roster. A total of 17 former workers were eligible for inclusion in the study population.

Of the 39 current workers eligible for inclusion in the study population, 35 (90%) participated in the medical survey. Of the 17 eligible former workers, 11 (65 %) participated. Thus, of 56 eligible workers, 46 (82%) participated (Table 2).

Medical Evaluation

The following discussion of results concerns the 46 participants who met the study criterion. All data were collected by NIOSH.

Demographics

Forty-five (98%) of the 46 participants were males. Twenty-nine (63%) were white and 17 (37%) were African-American. Age, tenure, and cigarette smoking status of the participants are presented in Table 3. Current and former workers differed primarily with regards to tenure and cigarette smoking status. Former workers were employed for a shorter median length of time (6 years) than current workers, who were employed for a median of 15 years. Fourteen (40%) of the 35 current workers were employed for 10 years or less, four (11%) were employed between 11 and 15 years, eight (23%) were employed between 16 to 20 years, and nine (26%) were employed for over 20 years. Among former workers, 10 (91%) of the 11 were employed for 10 years or less, and one former worker was employed for over 15 years. A greater proportion of former workers were current smokers (55%), and former workers had a slightly higher median number of packyears (one pack-year is equal to smoking an average of one pack of cigarettes per day for a year). However, a greater proportion of current workers (71%) were "ever" smokers (that is, either a current smoker or a former smoker) than former workers, 64% of whom were "ever' smokers. An average (mean) of 10 years had passed since former workers had left employment. The median number of years since leaving employment was eight, and former workers had left the Columbia plant between four

months and 20 years prior to the time the NIOSH evaluation was conducted.

Primary Job and Dustiest Job

Overall, 16 (35%) of the 46 participants reported holding their primary job (the job held for the longest period of time) in Maintenance, 10 (22%) reported working as a Mill Helper, 9 (20%) reported a primary job as a Control Room Operator, four (9%) reported a primary job in a supervisory position, and three (7%) of the participants reported working as a Lab Technician. The four remaining participants reported Loading or working as a Miner in the quarry as a primary job. Maintenance was reported by 13 (37%) of the 35 current workers as their primary job, and eight (23%) reported Control Room Operator. Five (45%) of the 11 former workers reported Mill Helper as their primary job, while three (27%) reported working in Maintenance.

Both Mill Helper and Maintenance were reported with the greatest frequency by current workers as the single dustiest job at the plant. Mill Helper was reported by former workers as the single dustiest job. Maintenance and maintenance activities, such as repairing or changing the bags in the dust collectors, followed in frequency for both current and former workers.

Other Dusty Jobs

A total of 31(67%) of the 46 participants reported prior or subsequent employment in occupations or industries that might have been associated with exposure to fibrogenic dusts. These included 22 (63%) of the 35 current workers and nine (82%) of the 11 former workers. When the information was examined by employment status and reported tenure in such jobs, 10 (45%) of the 22 current workers and three (33%) of the nine former workers reported employment in such jobs for five years or less, and eight (36%) current workers and two (22%) former workers reported working at such jobs between six to 10 years. Four (18%) of the 22 current workers and four (44%) of the nine former workers reported employment at such jobs for over 10 years. The type of work reported included construction, road work, mining and/or quarry work, and welding.

Chest X-Ray Results

All Participants

Overall, four (9%) of the 46 participants had a chest x-ray consistent with silicosis. The highest ILO small opacity profusion category among the participants was 2/2. Two of the four had a chest x-ray consistent with PMF: one had "B" size large opacities noted by all three readers, and the second had large opacities noted by two readers (one read them as "A" size, the other as "B"). All of the chest x-rays were taken by NIOSH. Forty-three (93%) had a median film quality score of 1 (the highest), two (4%) had a median quality score of 2, and one had a median score of 3.

The predominant shape of the small opacities was examined in relation to cigarette smoking status for the four participants with x-ray evidence of silicosis. All four of the participants were "ex-smokers," and the chest x-rays of all four showed small opacities that were predominantly rounded and affecting the upper zones.

Of the four 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 Control Room Operator, and one held a supervisory position. The pattern of primary jobs for these four participants is similar to, and a reflection of, the pattern observed among all 46 participants. The median age of the four participants was 56 years and their median tenure was 26 years. Three of the four participants with a positive chest x-ray reported working at another dusty job. Two of the three worked for less than five years, and one worked for over 10 years.

Current Workers

Table 4 lists the chest x-ray results by reader for the 35 currently working participants. The prevalence of silicosis among currently working participants was 9% (3/35). None of the 18 current workers employed 15 years or less had a positive chest x-ray, while three (18%) of the 17 participants employed over 15 years had a positive chest x-ray. All three were 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 11 participating former workers. One (9%) former worker had x-ray evidence of silicosis. None of the 10 former workers employed 15 years or less had a positive chest x-ray. The one former worker with a positive chest x-ray was employed over 15 years and was over 60 years old.

Chronic Symptoms

A total of 15 (33%) of the 46 participants reported a chronic symptom or health effect, as defined in the "Evaluation Criteria" section of this report; eight were current workers and seven were former workers. Dyspnea (shortness-of-breath) was reported by eight of the participants, and six reported chronic bronchitis. Four participants reported chronic phlegm, and two reported chronic cough. Twelve (80%) of the 15 symptomatic participants were "ever" smokers. Three of the four participants with a positive chest x-ray were symptomatic. The most frequently reported primary job held by symptomatic participants was Maintenance, and their median tenure at the Columbia plant was seven years. The median tenure of the 31 asymptomatic participants was 12 years, but the difference in tenure between them and symptomatic participants (seven years) was not statistically significant ($p=0.87$, Wilcoxon rank-sum). Symptomatic participants had a longer median tenure in other dusty jobs (4 years) than asymptomatic participants (2 years), but this difference was not statistically significant ($p=0.22$, Wilcoxon rank-sum) either.

Respiratory Illnesses and Conditions

Physician-diagnosed asthma was reported by three participants. Chronic bronchitis, emphysema, and tuberculosis (TB) were each reported once. Seven participants reported other physician-diagnosed lung conditions: one reported unspecified chest x-ray changes, a second reported a fungal infection, and five reported silicosis. Of the five participants who reported physician-diagnosed silicosis, four had a positive chest x-ray. Thirty-four (74%) of the participants reported no physician-diagnosed respiratory illness or condition.

Spirometry

Forty-five (98%) of the 46 participants performed spirometry, and 12 (27%) of those had results that fell below the normal range. These included seven (20%) of the 35 current workers and five (50%) of 10 former workers. All four of the participants with a positive chest x-ray had abnormal spirometry results. All 12 of the participants with abnormal spirometry exhibited an obstructive pattern. Eleven (92%) of the 12 with abnormal patterns were 'ever' smokers: six were ex-smokers and five were current smokers. Five of the 12 participants with an abnormal pattern held their primary job in Maintenance, three worked as Mill Helpers, and two reported Control Room Operator as a primary job. The two remaining participants reported working as a Lab Technician or in a supervisory position. The median tenure of the 12 participants with abnormal patterns was 10 years – no different from the median tenure (10 years) of the 33 participants with normal spirometry results. The median tenure in other dusty jobs for those with abnormal patterns was 9 years, which was different statistically ($p=0.04$, Wilcoxon rank-sum) from participants with normal lung function (whose median tenure in other dusty jobs was one year).

Company Records

Company records contained information on age, tenure, cigarette smoking history, work in other dusty jobs, and small opacity profusion classification for all 39 (100%) of the eligible current workers. All eligible current workers were male. Race was recorded for 17 (44%) of the 39 eligible current workers. Fifty-nine percent (10/17) of the current workers were white and 41% (7/17) were African-American.

The records of former workers were less complete. Of the 17 eligible former workers, records were entirely missing for four participants. Race was recorded for only one of the 17 eligible former workers, and of the 13 former workers for whom information on sex was available, 11 (85%) 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 four non-participating current workers differed from the 35 participating current workers with regards to median age and length of employment 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. Non-participating current workers were slightly younger than the participants and had less than half their median tenure. Of the four non-participating current workers, one had a positive chest x-ray (classified 2/1), one had a chest x-ray classified 0/1, and two were classified 0/0. Three participants had positive chest x-rays (one was classified 1/2 with 'A' size large opacities, and two were classified 2/1 with 'A' and 'B' sized large opacities, respectively). Of the 32 remaining chest x-rays, 9 were classified 0/1 and 23 were classified 0/0. The chest x-rays were classified by the same B reader between 1990 and 1994.

Non-participating former workers differed from participating former workers for each characteristic or variable examined. Non-participating former workers were older and were employed for more than twice the median tenure of the former workers who participated. Based on the 13 available ILO classifications, none of the non-participating former workers had a positive chest x-ray, while one participating former worker had a positive chest x-ray (classified 1/2 with 'B' size large opacities). Of the 12 remaining chest x-rays, three had a small opacity profusion classification of 0/1 and nine 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.

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 Columbia plant since 1962. 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 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 by a

physician in Columbia, 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 1994. 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 receipt of his or her 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 35 of the participating current workers and seven out of 10 participating former workers reported taking part in either pre-placement or routine medical monitoring offered by the company. (The results for one former worker were not included based on the questionnaire response). Forty-one of the 45 participants reported having had a chest x-ray as part of a past company evaluation. Twenty-seven (77%) of the 35 current workers and three former workers were able to recall their company chest x-ray results. Eight current workers, one of whom had a positive company chest x-ray, either didn't know or didn't recall their company chest x-ray results at the time of our survey. Eight former workers reported having had a recent chest x-ray, but for other reasons.

Subsequent to the NIOSH survey, U.S. Silica implemented NISA'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 by a physician in Columbia. Skin testing for tuberculosis (TB) was not one of the screening tests offered in 1994, 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

Four (9%) of the 46 current and former workers who participated in the medical evaluation were found to have changes on their chest x-ray consistent with silicosis; two of the four had PMF. The prevalence among currently working participants was 9% (3/35). The four participants with a positive chest x-ray had been employed for a median of 26 years and their median age was 56. All four of the participants with a positive chest x-ray were ex-smokers.

The availability of recent (1990-94) ILO classifications for all 39 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 39 current workers. Based on company records and classification by a single B reader, four (10%) of the 39 current workers had x-ray evidence of silicosis (defined as small opacity profusion 1/0 or greater). Although the company

reportedly sent chest x-rays with small opacity profusion classification 1/0 or greater for additional readings beginning in 1990, only one of these four chest x-rays (all four chest x-rays were dated 1992 - 1993) had more than one classification completed. A total of three readings were completed for this one chest x-ray, and the median classification remained ≥1/0. Thus, even when additional classifications were taken into consideration, the number of eligible current workers with x-ray evidence of silicosis remained the same (4). It is not known if any of the 35 remaining chest x-rays classified 0/0 or 0/1 would have been reclassified as positive (1/0 or greater) had they been sent for additional readings. Considering just the 35 participating current workers in the NIOSH survey, the prevalence of silicosis in company chest x-rays was 9% (3/35). The three participating current workers identified in company records as having a positive chest x-ray also had positive NIOSH chest x-rays.

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. For eligible current workers, available data on age and tenure indicate that participants were older, had worked longer, and had more x-ray evidence of silicosis than non-participants (see Table 6). However, the lowest possible silicosis prevalence estimate among all eligible current workers would be 8% (3/39) if all four of the non-participants had a negative chest x-ray. Thus it appears that the NIOSH silicosis prevalence estimate of 9% represents a reasonable estimate for eligible current workers. The lower participation rate among eligible former workers (65%), and reliance on company-provided information for non-participating former workers, are potential sources of bias. Combined with the obvious degree of abnormality among those for whom company chest x-ray information was available (of the five with small opacities, three were classified major profusion category "2," and four had PMF), the higher median age and tenure among non-participating former workers, and the possibility of progression and appearance of clinical changes consistent with silicosis since the time the company chest x-rays were taken, the NIOSH silicosis prevalence estimate of 9% is probably an under-estimate of prevalence in the study population as a whole.

The study population prevalence of x-ray-defined silicosis among the 56 eligible current and former workers could, in theory, range from 9 - 20% depending upon the number of cases among non-participating former workers, the source of the 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 company records, a total of five workers had a positive chest x-ray: three currently working participants, one of the four non-participating current workers, and one of the seven participating former workers for whom records were available. Assuming the four participating former workers with no records and the six non-participating former workers had no radiographically-defined evidence of silicosis, the lower boundary of the prevalence estimate would be 9% (5/56).

To determine the upper boundary of the prevalence estimate, both sources of information were used to count the number of cases. Four cases out of 46 participants were identified during the NIOSH evaluation and one additional case among the 10 non-participants (four current workers and six former workers) was identified from available company records. Assuming the six non-participating former workers <u>had</u> x-ray evidence of silicosis the highest estimate would be 20% (11/56).

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 among "ever" smokers, and those with longer tenure in other dusty work. However, there was no clear association between years of employment and lung function. Symptoms appeared related to cigarette smoking but not to length of employment at the plant or at other dusty jobs. Among the 12 participants with abnormal spirometry patterns, five reported shortness-of-breath, three had chronic bronchitis, three reported chronic phlegm, one reported chronic cough. 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 all four participants with positive chest x-ray's.

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 the rate 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 all four positive chest x-rays was rounded, and all four workers were "ever" smokers. Cigarette smoking alone would not explain the observed chest x-ray abnormalities. There is no evidence that smoking can cause small rounded opacities.[43] 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]

MSHA's current standard for respirable dust containing crystalline silica came into effect July 1974. As reported in the MSHA environmental study, MSHA has documented past episodes of non-compliance with its respirable crystalline silica dust standard at the Columbia plant. During the period 1988 to June 7, 1994, 15% (9/59) of personal samples collected by MSHA inspectors in the mill area or affected downstream operations were citable under the MSHA standard for respirable crystalline

silica.[44] All four participants with a positive chest x-ray began working at the Columbia plant between three to nine years before MSHA's current silica dust standard came into effect in July 1974, and all four were employed for 15 years or more. Three of the four participants with a positive chest x-ray reported previous or subsequent work at other dusty jobs. Only one of the three reported employment of a length (≥5 years) that may have made a major contribution to signs of silicosis seen on his chest x-ray, although the degree to which this participant's other dust exposure contributed to the abnormalities seen on his 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.[30,45]

Routine medical monitoring has been available to employees of the Columbia plant since 1962. It 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. However, in the process of reviewing company records, it was noted that this practice was not consistent; chest x-rays with an initial classification of major category "2" were not sent for additional readings. Moreover company chest x-rays classified as negative (0/0 and 0/1) by a single B reader were not routinely sent for additional readings. The inconsistency of chest x-ray classification among B readers is well documented,[2,46,47,48] 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 2" been the only reader for this NIOSH evaluation, an additional 17 participants would have been considered to have silicosis, and the prevalence among all participants would have been 46% (21/46) (see Tables 4 and 5). 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[49] and the federally mandated Coal Workers' X-ray Surveillance Program (CWXSP),[50] although NIOSH has not formally recommended multiple readings for the medical monitoring of workers exposed to silica.[7,12,13,20,26]

The frequency of the medical monitoring at the Columbia plant 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 periodic 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. Four (9%) of the 46 survey participants had a chest x-ray consistent with silicosis. Cases of silicosis occurred among workers who were older and employed for a longer period of time. Available data on age and tenure for non-participating former workers, the degree of disease found in available company records, and other factors, such as selection bias, suggest that 9% may be an underestimate as applied to the study population as a whole.

2. It is reasonable to conclude that the abnormalities seen on these chest x-rays are attributable to past crystalline silica dust exposure at the Columbia plant, although time worked at other dusty jobs may have contributed to the abnormalities observed in at least one case. This conclusion is supported by MSHA

documentation of prior episodes of non-compliance with its respirable silica dust standard. There were no cases of silicosis among current and former workers with 15 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.

3. 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's Columbia plant, MSHA regulations, and NIOSH policy. Recommendations regarding primary prevention through engineering controls have been 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. Any employee with chest x-ray evidence of silicosis or pneumoconiosis or those employees with pulmonary function impairment and/or symptoms of respiratory distress (for example, shortness-of-breath), should be referred for a more thorough medical evaluation. The evaluation should be conducted by a physician qualified to advise the employee and the company whether continued work-related exposure to crystalline silica dust at the Columbia plant would be associated with an increased risk of impairment of respiratory health.

3. The current reported practice of obtaining additional B reading only for those x-rays with a positive first reading creates a negative bias in the evaluation of workers for silicosis. This bias persists even if chest x-rays with a major profusion category greater than 1 are not sent for additional readings. 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.

4. Skin testing for tuberculosis (TB) should be conducted prior to job placement and annually thereafter,[12,13,26,51,52] with appropriate follow-up for definitive diagnosis and medical treatment, as indicated. The association of TB with silicosis and silica exposure is well-known.[30,53,54] Skin testing procedures should be in accordance with CDC guidelines.[55,56]

5. Each employee should receive a written copy of their 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.

6. 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.

7. All cases of silicosis should be reported to MSHA by the company, and to the South Carolina Department of Health & Environmental Control 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 South Carolina.[57,58] 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]

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TABLE 1
Determination of the Study Population
U.S. Silica - Columbia
HETA 93-0795

	CURRENT WORKERS		FORMER WORKERS		Total
	Participants	Non-participants	Participants	Non-participants	
Number of Workers Originally Identified	39	9	23	19	90
Reason for Exclusion from Study Population					
- Not eligible based on job and/or tenure	3	—	10	—	13
- Company determined worker not eligible	—	5	1	13	19
- NIOSH unable to verify eligibility	1	—	1	—	2
Number of Workers Remaining for Study	35	4	11	6	56

TABLE 2
Study Population and Participation Rate By Employment Status
U.S. Silica - Columbia
HETA 93-0795

Employment Status	N	Total # Eligible	Number Eligible Participants	Number Eligible Non-Participants	Participation Rate (%)
Current Worker	48	39	35	4	90
Former Worker	42	17	11	6	65
TOTAL	90	56	46	10	82

TABLE 3
Characteristics of 46 Participants by Employment Status
U.S. Silica - Columbia
HETA 93-0795

	EMPLOYMENT STATUS								
ıRACTERISTIC	35 CURRENT WORKERS			11 FORMER WORKERS			TOTAL		
(yrs) [median]	42			40			41		
Range (yrs)	25 - 59			27 - 66			25 - 66		
ure (yrs) [median]	15			6			10		
Range (yrs)	2 - 32			2 - 17			2 - 32		
arette Smoking Status	Number	%@	Pack-years [median]	Number	%	Pack-years [median]	Number	%	Pack-years [median]
lever smoker	10	29%	—	4	36%	—	14	30%	—
;urrent smoker	10	29%	15.5	6	55%	23.5	16	35%	19.5
:x-smoker	15	43%	21	1	9%	—	16	35%	22
k - Years (median), r smokers			20			23			20.5

Smokers = Current smokers and ex-smokers combined.
rcentages do not add to 100 due to rounding.

TABLE 4
Chest X-ray Results by Reader for 35 Participating Current Workers
U.S. Silica - Columbia
HETA 93-0795

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			1/1	st	2,3,5,6	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	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
0/0			1/0	st	2,3,5,6	0/0			0/0	1
0/0			0/0			0/0			0/0	2
1/2	rq	1,2,4,5	1/1, A	pr	All	2/1, B	rr	1,4,6	1/2 ◆	1
0/0			1/1	st	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
2/1	qr	1,2,4,5	2/2	qr	All	2/2, A	rq	1,2,4,5	2/2	1
0/0			0/0			0/0			0/0	1
2/1	ru	All	2/1	pq	All	1/2	qr	All	2/1	1
0/0			1/1	st	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			1/1	st	All	0/0			0/0	1
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

◆ PMF by consensus

TABLE 4 (continued)
Chest X-ray Results by Reader for 35 Participating Current Workers
U.S. Silica - Columbia
HETA 93-0795

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

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

TABLE 5
Chest X-ray Results by Reader for 11 Participating Former Workers
U.S. Silica - Columbia,
HETA 93-0795

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
1/2, B	qt	1,2,3,4,5	1/0, B	pp	1,2,4,5	1/0, B	rq	1,4	1/0, B	1
0/0			0/0			0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/1	st	All	0/0			0/0	1
0/0			0/0			0/0			0/0	1
0/0			1/2	st	All	0/0			0/0	1
0/0			1/0	st	2,3,5,6	0/0			0/0	1
0/0			1/1	sp	All	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

* 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 - Columbia
HETA 93-0795

	CURRENT WORKERS				FORMER WORKERS			
	Participants N=35		Non-participants N=4		Participants N=11[a]		Non-participants N=6	
(yrs) [median]	42		38		39[a]		47	
Range (yrs)	25-59		35-61		27-66		37-65	
re (yrs) [median]	16		7		6[a]		13	
Range (yrs)	2-32		3-24		3-17		2-21	
Dusty Job (s)	Number	%	Number	%	Number	%	Number	%
Yes	28	80	3	75	6	55	5	83
No	7	20	1	25	—	—	1	17
Unknown	—	—	—	—	1	9	—	—
No Record	—	—	—	—	4	36	—	—
ette Smoking	Number	%	Number	%	Number	%	Number	%@
Current smoker	9	26	1	25	4	36	2	33
Ex - smoker	15	43	2	50	1	9	2	33
Never smoker	11	31	1	25	2	18	2	33
No Record	—	—	—	—	4	36	—	—
l Opacity ision ≥ 1/0* le B reading)	Number	%	Number	%	Number[a]	%	Number	%
	3	9	1	25	1	9	0	—

ords were missing for 4 participating former workers. Numbers apply to 7 of 11 workers for whom records were available.
centages do not add to 100 due to rounding
etermined by the ILO classification closest in time prior to the NIOSH survey by a single B reader

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.

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 MSHA 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, when 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 selected as well as a summary report.

   (c) Each agency will review and comment on all reports prior to release.

(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.

(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).

APPENDIX I (con't)

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

	Northeastern District		Employees
46-02805	U.S. Silica Co.	Berkeley Plant	102
	Southeastern District		
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
	North Central District		
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
	South Central District		
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

			Employees
	Northeastern District		
46-02805	U.S. Silica Co.	Berkeley Plant	102
	Southeastern District		
38-00138	U.S. Silica Co.	Columbia Plant	50
40-02937	Nicks Silica Co.	Nicks Silica Co.	13
	North Central District		
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
	South Central District		
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 ≥ 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 or 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

For Information on Other Occupational Safety and Health Concerns

Call NIOSH at:
1-800-35-NIOSH (356-4674)
or visit the NIOSH Homepage at:
http://www.cdc.gov/niosh/homepage.html

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