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MALVERN MINERALS COMPANY
HOT SPRINGS, ARKANSAS

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I. 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 at specific ground silica operations by conducting a medical evaluation of active and retired miners.

On August 4-7, 1993, NIOSH conducted a medical survey at Malvern Minerals Company in Hot Springs, Arkansas. The survey included a questionnaire, spirometry, and a single view (posterior-anterior) chest x-ray.

The criterion for inclusion in the study population was one year or greater cumulative tenure since 1970 in the grinding area of the mill or in areas downstream of the grinding process. Twelve of 15 (80%) eligible current workers and eleven of 30 (37%) eligible former workers participated in the medical survey.

A chest radiograph was defined as consistent with silicosis if the median, or middle, classification of small opacity profusion was 1/0 or greater. Overall, 39% (9/23) of the participants had a chest radiograph considered consistent with silicosis; the prevalence among current workers was 50% (6/12). The highest International Labour Office (ILO) small opacity profusion category among the group was 3/2. Two of these individuals had radiographs consistent with progressive massive fibrosis (PMF), both with "B" size large opacities. Four of the nine participants with x-ray evidence of silicosis were less than 40 years old at the time of the medical survey. Five of the nine had been employed less than 20 years.

Pulmonary function testing revealed that 26% of participants had abnormal patterns, including five participants who exhibited an obstructive lung pattern and one participant who exhibited a restrictive lung pattern. Three out of the nine participants with a positive chest radiograph had abnormal pulmonary test results.

There was a substantial prevalence of silicosis among current and former ground silica workers at Malvern Minerals Company. Nine of the 23 (39%) survey participants were found to have radiographic changes consistent with silicosis; this includes 6 of the 12 (50%) current workers.

Even if all non-participants are assumed to have negative chest x-rays, and even if 3 participants with exposure to fibrogenic dusts at other jobs are excluded, the study population prevalence of radiographically-defined silicosis would be 13% (6/45). Recommendations are presented in Section IX of this report and include instituting a medical monitoring program.

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

II. 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 at specific ground silica operations by conducting a medical evaluation of active and retired miners.

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). Briefly, MSHA selected nine sites and was responsible for evaluation of silica dust exposures and dust control methods, while NIOSH was responsible for conducting medical evaluations at each site. This is a final report of the NIOSH medical evaluation conducted at Malvern Minerals Company in Hot Springs, Arkansas.

On July 27, 1993, a NIOSH representative met with company and employee representatives, along with an MSHA representative, to discuss logistical and administrative considerations of the survey. A second NIOSH representative participated in the meeting via telephone.

On August 3, 1993, an opening meeting was held with company and employee 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 plant. On August 4-7, 1993, the medical survey was conducted. All study participants received written notification of their spirometry results in August 1993. All chest x-rays were promptly reviewed by a pulmonary physician for 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.

III. BACKGROUND

Malvern Minerals Company began operation in April 1947. Raw material is brought from the quarry to the plant for processing, where it is crushed, dried, classified, and bagged. At the time of the survey, the company employed a total of 21 workers in three departments: production; maintenance; and office (salaried and clerical personnel). The plant operates production processes four days a week, with two 10-hour shifts. Maintenance personnel work five days a week, 8 hours a day. Workers often share many of the same tasks in addition to their usual job duties (e.g., running the forklift, clean-up, and light maintenance work). The four main job categories were Bagging Machine Operator, Dryer Operator, Lab Manager, and Maintenance.

IV. 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 of the grinding area at each operation by tenure and job, if feasible.

Although not a primary objective, of interest for discussion was the study population prevalence based on living participants and non-participants who met the study criterion. To assess the direction and magnitude of possible bias in this prevalence estimate, demographic characteristics and disease status of participants and non-participants were compared using company records.

Study Population

The criterion for inclusion in the study population was one year or greater cumulative tenure since 1970 in the grinding area of the mill or in areas downstream of the grinding process. Company records were used to verify dates of employment for participants. Tenure data from company records were considered more accurate than information obtained by questionnaire during the medical survey, which is subject to errors from recall. Jobs within and downstream of the grinding circuit were ascertained using information from both the medical survey and company records and verified with MSHA.

To avoid inadvertent oversight of eligible current workers with prior experience in these areas, all current workers were invited to participate regardless of work area or length of employment. Using rosters provided by the company, letters were mailed inviting current and former workers to participate in the medical survey. 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. No further follow-up was made to eligible workers who chose not to participate in the medical survey. Current and former workers who met the study criterion are the focus of this report.

Data Collection

Posterior-Anterior (PA) Chest Radiograph

Chest radiographs were either taken by NIOSH, or provided by the worker or the company, or both. Workers with a recent chest radiograph were permitted to either furnish their own or could elect to use a company radiograph (if made available by the company) for classification, provided the radiograph had been taken within one year of the date of the survey and was of adequate quality.

NIOSH radiographs were taken on a full size (14 x 17 inch) film. All radiographs 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⁾

The NIOSH-certified pneumoconiosis B Readers used in this project had each classified at least 500 radiographs for the 4th round of the NIOSH Coal Workers X-Ray Surveillance Program (CWXSP). 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 (NSCWP) 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 radiographs 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 and large.⁽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
Round	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)

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 each time spirometry was performed. 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, or subsequent to the opening of a plant.

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.

OR

2. A clinical radiology report which contained explicit words or phrases (e.g., "silicosis" or "pneumoconiosis"), or other descriptions considered consistent with silicosis (see "Results" section).

OR

3. A physician diagnosis of silicosis, or a diagnosis of pneumoconiosis if silicosis was considered as part of 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 contained both clinical radiology reports and miscellaneous documents, case definition 2 was used. Case definition 3 was used when only miscellaneous documents were available.

The 1981 NIOSH recommendations for medical monitoring of workers exposed to ground silica (silica flour), and recommendations published by the National Industrial Sand Association (NISA) for workers exposed to crystalline silica were used as the basis to evaluate company medical monitoring practices.

V. EVALUATION CRITERIA AND TOXICOLOGY

A. Criteria

Chest Radiograph

A chest radiograph was defined as consistent with silicosis if the median, or middle, classification of small opacity profusion was 1/0 or greater. For cases where only one reader considered a film of unacceptable quality, an additional classification was sought if the participant met the criterion for inclusion in the study population. 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.

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

Each examined worker's test results were compared to the 95th percentile lower limit of normal (LLN) values obtained from Knudson's reference equations to identify participants with abnormal spirometry patterns of obstruction and restriction.⁽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 are defined as:

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

Restriction: Observed FVC below the LLN; and FEV₁/FVC% above 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.

Chronic 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⁾ NIOSH guidelines recommend a medical and occupational history, physical exam, and pulmonary function testing every two years. A chest radiograph is also recommended, although frequency is not discussed.⁽⁸⁾

B. Silicosis

Silicosis, a form of pneumoconiosis, is a chronic fibrotic pulmonary disease caused by the inhalation, deposition, and retention of dust containing crystalline silica.⁽⁹⁾ Silicosis is usually diagnosed through chest radiograph and occupational history of exposure to silica-containing dust. Lung tissue reacts to the presence of silica dust in the lung by forming nodules, which on chest radiograph typically appear discrete, round, and more prominent in the upper lobes, although other patterns have been described.^(7,10,11,12) Such radiographic abnormalities are often the first sign of silicosis. The following summarizes the clinical forms of the disease:

<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.^(7,9,11,13) 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.^(7,14,15) Ground silica (silica flour) consists of essentially pure crystalline silicon dioxide (quartz) particles, of respirable size (< 10 micrometers).^(16,17) 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.^(18,19)

A continuum is thought to exist between the chronic and accelerated forms of nodular silicosis. Factors determining the progression of disease are unclear.⁽¹²⁾

Chronic silicosis (the presence of detectable, discrete, nodules <1cm in diameter on chest radiograph) is the most common form of silicosis and usually becomes evident after 10 years or more of exposure to dust containing crystalline silica.^(9,10,20) 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. Radiographic abnormalities usually appear within 5-10 years.⁽²⁰⁾ 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.^(9,10,20) 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.^(7,9,21,22) Radiographically, the appearance is different from that of nodular silicosis, with very little of the typical nodular scarring.^(7,13,15) Consequently, it may often be mis-diagnosed as pulmonary edema, pneumonia, or tuberculosis. Respiratory impairment is severe with acute silicosis, and the disease is usually fatal within a year of diagnosis.^(13,15)

Both chronic and accelerated silicosis can become complicated by the development of infection and/or progressive massive fibrosis (PMF). Infections (i.e., 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.^(23,24) 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.^(9,10,11,13)

Evidence suggests that crystalline silica is a potential occupational carcinogen,⁽²⁵⁻²⁷⁾ and NIOSH currently recommends that crystalline silica be treated as a potential occupational carcinogen.^(28,29)

VI. RESULTS

A. Participation

Of 21 current employees, 15 were eligible for entry into the study population; 12 (80%) participated in the medical survey. The company provided NIOSH with a list of 102 living former workers; these included full-time, part-time, and temporary employees, both hourly and salaried workers. Of the 30 who were eligible for entry into the study population, 11 (37%) participated in the medical survey. The total number of workers in the study population was 45: 23 were participants and 22 were non-participants (Table 1). Job history information was missing or incomplete in company records for eight non-participants, one current worker and seven former workers. In these cases, inclusion in the study population was based solely on tenure.

B. Medical Survey

The following discussion of results will be limited to those 23 participants who met the study criterion. All of the participants were men, and the majority (70%) were white. Selected characteristics of the participants are presented in Table 2. Current and former workers differed primarily with regards to cigarette smoking status, pack-years (a pack-year is equivalent to smoking an average of one pack per day for a year), and tenure. Fewer former workers were "ever smokers" (i.e., current smokers and ex-smokers combined) than current workers. The median number of pack-years for former workers who were "ever smokers" was 26, nearly three times that of the current workers. Former workers were employed for a shorter length of time (nine years) than current workers (16 years). An average (mean) of six years had passed since former workers had left employment at Malvern Minerals, and the median number of years since leaving employment was seven years.

Overall, 39% (9/23) of the participants had a chest radiograph considered consistent with silicosis; the prevalence among current workers was 50% (6/12). The highest ILO profusion category among the group was 3/2. Two of the nine had radiographs consistent

with PMF, both with “B” size large opacities classified by at least two readers (Table 3). All of the radiographs were taken by NIOSH, and all 23 had a median quality score of 1 (the highest). Four of the nine with x-ray evidence of silicosis were less than 40 years old at the time of the medical survey, two were between 40 and 50 years old, two were between 50 and 59 years of age, and one individual was over 60 years.

Table 4 presents the distribution of radiographic results by tenure for all 23 participants. Of 18 participants with less than 20 years employment, 5 (28%) had a positive radiograph, two of whom were employed for less than 10 years. Of the five participants with greater than 20 years employment, four (80%) had a positive radiograph.

Table 5 summarizes the predominant shape of the small opacities by cigarette smoking status for the nine participants with x-ray evidence of silicosis. Eight of the nine participants with a positive radiograph were “ever smokers.” Seven radiographs showed small opacities that were predominantly rounded, two were mixed, and none were irregular.

Five of the nine participants with a positive radiograph reported previous work in occupations or industries other than a ground silica operation that might have been associated with exposure to fibrogenic dusts. For one participant, that employment was less than six months. For another participant, it was two years. Two participants worked in other dusty jobs between 5 to 10 years; the duration of employment at Malvern Minerals was over 5 years for the first and over 20 years for the second. The remaining participant worked in such jobs for over 15 years, and had over 30 years of tenure at Malvern Minerals. Neither of the individuals with PMF reported working in any other dusty job.

Seventy percent (16/23) of the participants reported holding their primary job (the job held for the longest period of time) in production, 17 percent (4/23) worked in maintenance, and 13 percent (3/23) worked in supervisory or administrative positions. Privacy concerns preclude reporting the prevalence of disease as seen on chest x-ray by either current job or primary job. However, when examined by department, 6 of 16 (38%) with a primary job in production, 2 of 3 (67%) working in supervisory or administrative positions, and 1 of 4 (25%) with a primary job in maintenance had a positive chest radiograph. Bagging Machine Operators made up the largest proportion of workers in production, 63% (10/16), and participants reported Bagging or Packing work most frequently as the single dustiest job at the plant. The process of loading a mixer for surface modification of the ground silica, and maintenance activities such as cleaning and repairing the dust collector, dust lines, and other machinery followed in frequency.

Six participants (26%) had pulmonary function results that fell below the normal range, including five participants who exhibited an obstructive lung pattern and one participant

who exhibited a restrictive lung pattern. Of the six participants with abnormal patterns, one had never smoked cigarettes, two were current smokers, and the remaining three were former smokers. Only three of the nine participants with a positive chest radiograph had abnormal pulmonary function test results. Neither of the participants with PMF had abnormal pulmonary function test results.

Eight of 23 (35%) participants reported the chronic symptom of dyspnea (shortness-of-breath), and 6 (26%) reported cough. Chronic bronchitis and chronic phlegm were each reported by three (13%) of the participants. Asthma was the most frequently reported physician-diagnosed respiratory condition (6/23, 26%), followed by two reports of tuberculosis. Four of the six participants who reported a physician diagnosis of asthma had a positive radiograph. One of the two participants who reported tuberculosis had a positive radiograph. One participant reported being diagnosed with chronic bronchitis and one with pneumonia. The remaining 13 reported no physician-diagnosed respiratory illness or condition.

C. Company Records

Information on age was available from company records for 96% of participants and 82% of non-participants, and tenure was available for the entire study population. The data was examined by employment status for both participants and non-participants (Table 6). The three eligible non-participating current workers were of similar median age (36 years) to their participating counter-parts (39 years) but differed in length of employment, with a median of 7 years versus 16 years. The median age of non-participating former workers was 38 years and of participants was 44 years; median tenure was 2 years versus 9 years.

Company records contained primarily personnel records. Information on sex was missing from the company records for 41% (9/22) of the non-participants and 70% (16/23) of the participants. The remaining participants and non-participants had records indicating they were male. Data regarding race was available for only two former workers, one participant and one non-participant, both of whom were white. Smoking status was entirely unrecorded for both groups. Information on prior work history was available for seven participants and five non-participants. Records of four participants and four non-participants indicated work in jobs with a potential for dust exposure.

Only miscellaneous documents were available from which silicosis might be ascertained. Chest x-ray results were available for only 2 of the 23 participants and 4 of the 22 non-participants as part of what appeared to be a pre-employment physical exam (those records with dates were from the late 1970's). The chest x-ray results, as noted, were

“normal” for all six. One additional participant and one non-participant had evidence of having had a chest x-ray, but no results were found in their files.

D. Company Medical Monitoring

Routine medical monitoring of workers was not conducted at this facility. Company representatives did report that medical evaluations of workers had taken place on three separate occasions in the past -- once in 1979, some time in the early 1980's, and again in 1985. Participation was voluntary, and included pulmonary function testing and chest x-ray. The x-rays were reviewed by a radiologist, but the company did not know if they were classified by a B Reader. Results of these evaluations were kept by a local physician, and the company reported being unable to obtain these records when the physician died. Company representatives did report being in possession of the chest radiographs from the 1985 evaluation, however.

Approximately 10 participants reported taking part in at least one of the medical evaluations. Only two recalled their chest x-ray results. The others either didn't know or remember the results, or reported that they did not receive their results. Currently, pre-employment exams are conducted by a local free-standing clinic. The company described the present exam as very basic, with x-rays taken for the sole purpose of evaluating the spine. The company does not receive detailed exam results, other than information as to ability to work. According to the company, the clinic does not notify the workers of the results of this exam.

VII. DISCUSSION

Nine (39%) of the 23 workers who participated in the medical survey and who met the study criterion were found to have radiographic changes consistent with silicosis; 2 had PMF. The majority were current workers, were of a relatively young age (four were less than 40 years old), were “ever smokers,” and most had been employed less than 20 years.

Five out of the nine individuals with a positive chest radiograph reported previous work in occupations that might have resulted in exposure to fibrogenic dusts. One of these participants was employed less than six months in his previous dusty job, and a second was employed for over 20 years at Malvern Minerals but only two years at a prior dusty job (in a quarry). Only three of these individuals had prior dusty job employment of a length (> 5 years) that would likely have contributed substantially to radiographic signs of silicosis. Previous reported dusty jobs included work in construction, welding, and a limestone quarry. Excluding these three individuals, the prevalence would be 26% (6/23).

A population prevalence estimate based on 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 suggest that 39% may be an over-estimate, since non-participants have a lower median age and tenure than participants. The study population prevalence among the 45 participants and non-participants could range from 13-69% depending on the number of cases. Assuming all 22 non-participants had no radiographically-defined evidence silicosis and excluding the 3 participants with exposure to fibrogenic dusts at other jobs yields the most conservative estimate, 13% (6/45). Conversely, assuming all 22 non-participants had radiographic evidence of silicosis and including all 9 participant cases yields the highest estimate, 69% (31/45). The “true” study population prevalence lies somewhere in between these two estimates.

Generally, testing of active workers or recently active workers can result in an under-estimation of a 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. Both the healthy worker survivor effect and the relatively low proportion (37%) of former workers who participated in the medical survey may have reduced the likelihood of identifying more cases of silicosis. Additionally, the fact that only 30 non-participating former workers out of 102 met the study criterion, and the low median tenure (2 years), is indicative of a high turn-over rate, and as a result disease may have been less likely to have occurred in non-participants.

Pulmonary function testing revealed that 26% of participants had abnormal patterns. Three of the nine participants with a positive chest radiograph had abnormal pulmonary test results, and neither of the participants with PMF had abnormal results. The chronic symptoms reported most frequently were dyspnea and cough. These findings are consistent with results reported by others, and possibly reflect more of an association of pulmonary impairment with the combined effects of cigarette smoking and dust exposure, rather than radiographically detectable silicosis.^(30,31)

A 1979 NIOSH evaluation at two silica mining and milling operations in Illinois found 23 of 61 (38%) participating current and former workers with one year or more exposure had radiographic changes consistent with silicosis.⁽³²⁾ A NIOSH evaluation at a plant in New Jersey in 1980 found six radiographically-defined cases of silicosis (13%) among 47 participating current and former workers.⁽³³⁾ Both previous investigations utilized similar procedures and the standard pneumoconiosis classification of the time, the 1971 ILO-U/C.⁽³⁴⁾

In contrast to this study and to the studies referred to above, a 1985 study involving the classification (ILO-U/C 1971) of 1422 chest radiographs of non-exposed blue-collar workers found only 3 (0.21%) radiographs with a median small opacity profusion of 1/0 or greater.⁽³⁵⁾ The 1985 study also found only one radiograph with irregular small opacity profusion of 0/1 and no radiographs with rounded small opacity profusion of 1/0 or greater among over 700 males. The predominant shape of small opacities on the radiographs in this evaluation was rounded, and shape did not appear to be related to cigarette smoking status. Although eight of the nine participants with a positive radiograph were “ever smokers,” cigarette smoking alone does not explain the observed chest x-ray abnormalities. There is little evidence in the literature to support a smoking effect without occupational exposure, and the abnormality that has been observed has been predominantly irregular, not rounded.⁽³⁶⁾

In the present evaluation, five of the participants with a positive radiograph began working at Malvern Minerals before MSHA’s dust standard came into effect (July 1974), and four began working after 1974. Of the nine, one participant began working prior to 1970, four began working during the years 1970 and 1974, and the four remaining participants began working at the company after 1974. Johnson and Busnardo⁽³⁷⁾ describe a case of silicosis in a maintenance mechanic employed from 1976 -1981 at a plant that manufactures silica flour.

At the time of the survey no routine medical monitoring program was in place, and only three medical evaluations had taken place in the past. Recommendations for the medical monitoring of workers exposed to silica have been available since the mid-to late 1970's from both government and industry sources. In 1974, NIOSH made recommendations for the medical monitoring of workers exposed to crystalline silica.⁽¹⁴⁾ Medical examinations

(including a medical and occupational history, chest x-ray, and pulmonary function testing--spirometry) were recommended for all workers prior to job placement and at least once every 3 years thereafter. In 1977, NISA published recommended medical monitoring guidelines as part of an "Occupational Health Program"⁽⁸⁾ for its member companies. In 1981, NIOSH published medical monitoring recommendations specifically directed toward ground silica (silica flour) workers.⁽⁷⁾ Preplacement and annual medical examinations, as described above, were recommended for all workers who manufacture, use, or handle ground silica or materials containing ground silica.

VIII. CONCLUSIONS

There was a substantial prevalence of silicosis among current and former workers at Malvern Minerals Company. Nine of the 23 (39%) survey participants who met the study criterion (one year or greater cumulative tenure since 1970 in the grinding area of the mill or in areas downstream of the grinding process) were found to have radiographic changes consistent with silicosis; the proportion among current workers was 50% (6/12). Even if all non-participants are assumed to have negative chest x-rays, and even if three participants with exposure to fibrogenic dusts at other jobs are excluded, the study population prevalence of radiographically-defined silicosis would be 13% (6/45). These findings should be of serious concern to workers, management, and MSHA. Concerted efforts should be made by all parties to ensure the health of current and future workers at this site.

IX. RECOMMENDATIONS

The following recommendations are based on findings of the medical evaluation conducted by NIOSH at Malvern Minerals Company.

1. Current workers without detectable disease may be at high risk of developing silicosis in the future. The company should institute a medical monitoring program and provide medical examinations annually for all employees to facilitate early detection of silicosis.^(7,20) However, medical monitoring should not be used as a substitute for environmental controls to reduce worker exposure to crystalline silica. Each employee should receive their individual medical exam results. Medical examinations should include at a minimum:
 - A. A medical and occupational history to collect data on worker exposure to crystalline silica dust, and signs and symptoms of respiratory disease.
 - B. A chest radiograph (posterior-anterior 14" x 17") classified by a B reader, according to the 1980 ILO International Classification of Radiographs of Pneumoconioses (or revision thereof, whichever is current at the time of the examination).
 - C. Pulmonary function tests including forced vital capacity (FVC) and forced expiratory volume at one second (FEV₁) using equipment and methods consistent with ATS recommendations.⁽³⁾
 - D. Skin testing for tuberculosis,⁽³⁸⁾ with appropriate follow-up for definitive diagnosis and medical treatment, as indicated. The association of tuberculosis with silicosis and silica exposure is well known.
2. Any employee with radiographic evidence of pneumoconiosis or who has respiratory distress and/or pulmonary function impairment should be notified and fully evaluated by a physician qualified to advise the employee and the company whether occupational exposure to silica dust at Malvern Minerals would be associated with increased risk of impairment of respiratory health.
3. All cases of silicosis should be reported to MSHA by the company, and to the Arkansas State Health Department by the examining physician or health care provider, 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. Reporting of silicosis is mandatory in the state of Arkansas.⁽³⁹⁾ 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.⁽¹¹⁾

4. Company personnel records should be updated regularly to ensure they are complete and accurate. Once a medical monitoring program has been established, these records should be maintained separately from the personnel records and kept in a confidential manner with access limited to health care personnel. Both personnel and medical records should be maintained for at least 30 years following an employee's termination of employment.
5. The company should provide each employee with instruction on the potential hazards associated with crystalline silica, the necessary work practices needed to reduce exposures, and the use of protective equipment.
6. A plant-wide no-smoking policy should be implemented if one is not already in place.
7. X-rays of the spine should be eliminated from the pre-employment physical. Such x-rays are of little value in controlling or predicting back injury and expose employees to unnecessary radiation.⁽⁴⁰⁾

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1. Malvern Minerals Company
2. Miners Representative, Malvern Minerals Company
3. Mine Safety and Health Administration
4. Arkansas Department of Health
5. Bureau of Mines
6. National Industrial Sand Association
7. Glass, Molders, Pottery, Plastics & Allied Workers International
8. General Teamsters and Allied Workers
9. Laborers' Health and Safety Fund of North America
10. Oil, Chemical and Atomic Workers International

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

TABLE 1
 Study Population and Participation Rate By Employment Status
 Malvern Minerals Company
 HETA 93-0796

Employment Status	N	Total # Eligible	Number of Participants	Number of Non-Participants	Participation Rate (%)
Current Worker	21	15	12	3	80
Former Worker	102	30	11	19	37
TOTAL	123	45	23	22	51

Table 2
 Characteristics of 23 Participants by Employment Status
 Malvern Minerals Company
 HETA 93-0796

CHARACTERISTIC	EMPLOYMENT STATUS		TOTAL	
	12 CURRENT WORKERS	11 FORMER WORKERS	Number	%
Age (yrs) [median]	37	43	41	
Range (yrs)	28-62	28-59	28-62	
Tenure (yrs) [median]	16	9	10	
Range (yrs)	1-35	1-20	1-35	
Cigarette Smoking Status				
Ever	10	6	16	70
Never	2	5	7	30
Pack - Years (median)	9	26	13	

TABLE 3
Radiological Results* by Reader for 23 Participants
Malvern Minerals Company
HETA 93-0796

READER A			READER B			READER C			MEDIAN
Profusion	Size/Shape	Zone(s)**	Profusion	Size/Shape	Zone(s)	Profusion	Size/Shape	Zone(s)	
3/2	pq	All	3/3	pq	All	3/2	qt	All	3/2
2/2, B	ps	All	2/1, B	pq	All	1/1, B	qr	1,4	2/1, B
0/1	st	2,3,5,6	0/0			0/0			0/0
1/0	qp	1,2,4,5	1/1	pq	All	0/1	qq	1,2,4,5	1/0
1/1	qt	All	1/2	qr	All	1/2	qq	1,4	1/2
1/1	qr	All	1/1	qp	All	1/2	qq	1,2,4,5	1/1
0/0			0/0			0/0			0/0
0/0			0/0			0/0			0/0
1/0	qs	1,2,4,5	1/2	st	2,3,5,6	0/0			1/0
0/0			0/0			0/0			0/0
0/0			0/0			0/0			0/0
0/0			0/0			0/0			0/0
0/1	qs	1,2	1/0	ps	All	0/0			0/1
0/0			0/0			0/0			0/0
1/0	qt	1,2,4,5	1/1	st	All	0/0			1/0
0/0			0/0			0/0			0/0
1/1, B	qr	All	1/1, B	qp	All	1/0, C	rr	1,4	1/1, B
0/0			1/0	ss	5,6	0/0			0/0
0/1	qs	1,2,3,5,6	1/0	st	2,3,5,6	0/1	qq	2,5	0/1
0/0			0/0			0/0			0/0
1/2	rt	All	2/2	qp	All	2/2	qq	1,2,4,5	2/2
0/0			1/2	sp	All	0/0			0/0
0/0			1/0	st	2,3,5,6	0/0			0/0

*All 23 radiographs had a median film quality score of 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 4
 Distribution of Radiographic Results by Tenure
 Malvern Minerals Company
 HETA 93-0796

MAJOR PROFUSION CATEGORY	TENURE (years)			TOTAL	
	1-9	10-19	≥ 20	n	(%)
0	9	4	1	14	(61)
1	1	2	3*	6	(26)
2	1	1*	--	2	(9)
3	--	--	1	1	(4)
Total	11	7	5	23	(100)

* Progressive Massive Fibrosis (PMF)

TABLE 5
 Distribution of Small Opacity Shape by Cigarette Smoking Status
 For Participants with ≥ 1/0 Small Opacity Profusion
 Malvern Minerals Company
 HETA 93-0796

Opacity Shape*	CIGARETTE SMOKING STATUS		Total
	Ever N = 16	Never N = 7	
ROUND	6	1	7
MIXED	2	--	2
IRREGULAR	--	--	--
TOTAL	8	1	9

* Predominant shape classified by 2 or more readers

TABLE 6
 Age and Length of Employment from Company Records
 by Participation and Employment Status
 Malvern Minerals Company
 HETA 93-0796

	PARTICIPANTS		NON-PARTICIPANTS	
	Current Worker N = 12	Former Worker N = 11	Current Worker N = 3	Former Worker N = 19
AGE (yrs) [median]	39*	44	36	38*
Range (yrs)	28-62	28-60	28-42	25-55
TENURE (yrs) [median]	16	9	7	2
Range (yrs)	1-35	1-21	6-12	1-20

*Age missing for 1 participating current worker and 4 non-participating former workers.

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.

APPENDIX I (con't)

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.

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.

APPENDIX I (con't)

- (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 radiographs 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.

APPENDIX I (con't)

- (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.

APPENDIX I (con't)

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.

APPENDIX I (con't)

(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.

APPENDIX I (con't)

III . REFERENCES

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APPENDIX I (con't)

ATTACHMENT 1

GROUND SILICA MILLS - 1991

Northeastern District

Employees

46-02805	U.S. Silica Co.	Berkeley Plant	102
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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

Northeastern District

Employees

46-02805	U.S. Silica Co.	Berkeley Plant	102
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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 $\geq 1/0$ 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 ⁽¹¹⁾

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