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I. Summary

These conclusions are organized to answer the three questions posed in the Introduction and attached Protocol.

A. With respect to Protocol Question 1; regarding adherance to the Medical Surveillance Section of the Asbestos Standard:

1. Annual pulmonary function tests: Since 1973, 99.7% of required tests were performed.
2. Annual chest X-rays: Since 1973, 98.5% of required examinations were performed.
3. No effort was made to determine why the missing tests were not done.

B. With respect to Protocol Question 2; regarding quality of pulmonary function tests and X-rays:

1. One percent of the films selected for study were considered unreadable by at least two of the three "B" readers. This is comparable to the one percent unreadable films taken by NIOSH--Division of Respiratory Diseases in a large field study. We have not evaluated the quality of Company chest X-rays taken before 1976.
2. The pulmonary function testing equipment in use at the time of the study did not meet current NIOSH recommended standards.
3. The instructions and coaching techniques used by the nurse administering the pulmonary function tests were observed and found to be adequate.

4. Since 1979, all subjects performed at least 3 Forced Vital Capacity (FVC) maneuvers; however, before 1979 this was not always true. Ninety-eight percent of the complete sets of data (i.e., $\geq$3 curves) satisfied the NIOSH criteria (2) of three acceptable curves. If the American Thoracic Society guidelines (3) are used, ninety-one percent of the sets would be acceptable.
5. The normal standards for FVC used with the pulmonary function tests equipment came from an old study done with subjects in the supine position and give substantially lower values for "normal" compared to more recent, larger studies done with the subject in the upright position.

C. With respect to Protocol Question 3, regarding detection and notification of pulmonary abnormalities:

1. Detection--Pulmonary Function Tests:
   The normal values for FVC used by the Company would delay the detection of restrictive disease if compared to more recently derived values for normal. Detection of obstructive impairment by the use of the FEV_1/FVC ratio would be unaffected.
2. Detection--X-ray
   a. Instead of the ILO U/C 1971 classification, the Company reader used an old system in reading interstitial disease. Thus differences

between the Company and "B" readers in reading any pneumoconiosis and irregular opacities may be due to the system used rather than reader sensitivity.

b. Any pneumoconiosis: The Company reader called 11% of the films positive whereas the prevalence by median "B" reading was 35%.** The three individual "B" readers called 28%, 40%, and 46% of the films positive, all significantly different from each other. Using the median "B" reading, 11% of the films were category 1/1 or greater.

c. Irregular opacities: The Company reader called 11% of the films positive whereas the prevalence by median "B" reading was 21%.** The individual "B" readers called 20%, 22%, and 36% of the films positive, the last being significantly different from the first two. Using the median "B" reading, 7% of the films were category 1/1 or greater.

d. Pleural disease: The Company reader called 22% of the films positive and the median "B" reading was 40%.** The individual "B" readers

**Statistically significant difference, $p < .01$.

called 25%, 34%, and 87% of the films positive, all significantly different from each other. Because of its marked variance with the other two "B" readings, one must question the validity of the 87% value. It should be noted that the Company's reading of 22% positive is not significantly different from the 25% prevalence detected by one "B" reader.

e. Cancer: The Company reader called four films suspect or positive for cancer, and the median "B" reading called three suspect or positive; however, the suspect or positive films in each case were different. The individual "B" readers called three, six, and 34 films suspect or positive for cancer. Most of the 34 suspect or positive films read by one reader were not thought to show any evidence of cancer by the other two "B" readers, and most of the suspected lesions were interpreted to be normal markings or pleural changes when reviewed by two NIOSH chest physicians. One lung cancer noted by the median "B" reading and later clinically documented, was not detected by the Company

reader. The Company reader noted one coin lesion that was not detected by two "B" readers. All cases with suspected cancer (read by any of the three "B" readers) were notified to seek medical attention.

f. Precision: The data on the reading of individual cases of pneumoconiosis and pleural disease indicate that the Company reader agrees with the median "B" reading and the individual "B" readers as well as the "B" readers agree among themselves.

3. Notification--PFT's:

Employee notification of abnormal pulmonary function was not routine at the Johns-Manville Waukegan facility until the past two years. Only since January, 1979, has a sheet been added to the medical record which clearly indicates discussion of pulmonary function test results with the employee.

4. Notification--X-rays:

a. All of 36 red-tags (the Company designated indicating a possible work-related health problem) were notified; in 27 cases within two months of the red-tag-date; in 4 cases within 3-5 months, and in 5 cases within 8-12 months. The red-tag date was within 3 months of the date of the first abnormal film except when a repeat film was taken (3-9 months

after the first film) to confirm the radiologic abnormality. In one case, however, there was a delay in red-tagging of several years before the film, read as abnormal by two readers, was seen and read as such by the usual Company reader.

b. Notification of suspected cancer was apparently 100% although this fact could not be absolutely confirmed from the medical record data.

c. Pleural disease was not an indication for red-tagging, and only 20% of workers with pleural abnormalities were informed of the findings.

II. Introduction

This report presents the results of a NIOSH investigation of the Johns-Manville facility in Waukegan, Illinois, in response to a request for Technical Assistance from OSHA made in August, 1978. OSHA requested assistance in evaluating employee complaints regarding the Medical Surveillance program. In September, 1978, initial meetings among representatives of NIOSH, OSHA, Johns-Mansville and the International Chemical Workers Union Local 60 produced three questions to be addressed by the study:

1) Has the Company adhered to the medical monitoring requirements of the OSHA Asbestos Standard?
2) Do the equipment and procedures used in obtaining pulmonary function tests and chest X-rays meet current NIOSH recommended guidelines?
3) Is the medical surveillance program detecting pulmonary abnormalities at the appropriate time, and is proper notification being made once abnormalities are detected?

From this meeting and subsequent discussions, a protocol for the NIOSH study was made and is attached in the Addendum. A modification was outlined in a letter to all interested parties from Dr. Alan Engelberg dated April 10, 1979, also attached herein. Actual data gathering began in late April, 1979.

The summary for Parts III - VI are embodied in Part I.

III. Pulmonary Function Testing Program

The Asbestos Standard (1), mandates that yearly pulmonary function tests (PFT's) be given to all workers exposed to asbestos. The Standard does not contain guidelines for pulmonary function test procedures, equipment, interpretation, employee notification of results, or the action to be taken based on test results. This epidemiologic investigation not only includes a check of test dates, but also evaluates how PFT equipment and procedures in use by Johns-Manville at the Waukegan facility from 1970 to April 1979 compare to recent Department of Labor guidelines (2). These guidelines were recommended by NIOSH to the DOL, and are designed to assist medical practitioners by setting minimum standards for accurate pulmonary function testing.

A. Methods

A list of present employees hired before 1970 was obtained, and those working in non-asbestos-exposure areas were excluded. From the remainder, a random sample of 101 employees was selected, and dates for pulmonary function tests were found in the medical record. The dated spirometry tracing sheets were considered documentation that the testing actually had been performed. Only the month and year was recorded for this study. Testing was considered annual if there was at least one test within each calendar year. For tests that were performed near the change of a calendar year, a one-month leeway was allowed. Thus, if one test occurred in December, 1973 and the next in January, 1975,

this was considered as "annual." Dates were reviewed from 1971 through 1978.

The pulmonary function testing equipment was also examined, and the spirometric testing of one employee was observed. In addition, copies were made of the most recent PFT curves of the 101 sampled employees noted above. The method of calculating the results and their interpretation were ascertained through discussions with the Company nurse and physician.

B. Results

Dates of Pulmonary Function Tests: All of the 101 selected employees were working all years from 1971 to 1978, and thus there were 808 possible PFT dates (8 X 101).

Overall 166/808 = 21% of the dates were missed, but it was quite clear that most of this loss occurred in 1971 and 1972:

	1971-1972	1973-1978
Missing dates	164	2
Expected number of dates	202	606
Missing/expected	81%	0.33%

Thus from 1973 to the end of 1978, compliance with annual pulmonary function testing has been 99.7%.

Equipment and Data Calibration Procedures: A Jones Pulmonor waterless volume spirometer has been used at the plant since 1972. It is portable, but has not been carried

out of its room which is comfortably air conditioned. No documentation of routine calibration procedures was available. No means to measure the temperature inside the spirometer was available, and measured ambient temperature and barometric pressure were not used to correct values to body temperature and pressure, saturated with water vapor (BTPS) as recommended by NIOSH and published by the Department of Labor (2). (Instead, a fixed BTPS correction factor was used).

A volume-time curve is produced on a pen-graph recorder which has a time range of 0 to 8 seconds and a volume range of 0 to 6 liters.

The nurse at the facility administers the test. She has been employed for nearly 30 years at that plant, and is very familiar with the testing. During the observed spirometry tests, the technique (setting the graph, instructing the employee, use of noseclips, etc.) was adequate. Prior to January, 1979, one to three spirometry tracings were recorded. Since then, however, three or more tracings have been recorded on each testing date.

Analysis of the 101 sets of PFT's showed that 58 of the subjects performed three or more forced vital capacity (FVC) maneuvers. Of these, one (1) would not meet the NIOSH criteria (2) requiring the forced expiratory volumes in one second (FEV_1's) of the two largest curves to be within 10% or 100 ml of each other. The NIOSH guidelines do not set a maximal allowable variability in FVC, but the American Thoracic Society (3) requires that the two best of the three acceptable

curves not vary by more than 5% or 100 ml, whichever is greater. If this criterion is used, four (4) other sets of curves would be unacceptable.

Data Analysis and Interpretation: The start of the volume time curve (zero time) is set where the curve departs from the baseline. Although in most cases this point is clearly defined, back-extrapolation to the baseline using the steepest part of the curve is not done. The FVC is read from the highest point of the curve and FEV_1 is also visually read from the graph at a point 1 inch (= 1 second) from the start of the curve. On the back of the tracing the FVC is noted; the FEV_1 itself is not written down, but with the aid of a ruler designed for the tracing, the FEV_1/FVC % is obtained and recorded.

The Jones Pulmonor booklet includes an FVC-predicted value chart for males and females based on height and age and corrected to BTPS, which is used by Johns-Manville. The chart is based on prediction equations derived from a study done in the late 1940's in which the prediction equations were based upon the supine maximal breathing effort of a group of 92 subjects (4). The prediction values are low compared to those of much larger and more recent studies such as the one done by Knudson et al. in which subjects were tested in the upright position (5). For example, for a male age 42 and 172 cm tall:

Knudson, et al.: FVC = -5.4 + [(172)(0.0065)] = 4.50 liters

Reference 4: FVC = [27.63 - (0.112 x 42)] x 172 = 3.94 liters

Predicted Normal Chart used by Johns-Manville: FVC=3.95 liters

Thus, the normal prediction used by Johns-Mansville is approximately 12% below that derived from the work of Knudson et al. and the value of FVC meeting the criterion for restrictive impairment (see below) is likewise reduced. Use of the older prediction would have no effect on the detection of obstructive impairment by the criterion given below since it depends only on the ratio of FEV_1 to FVC.

The plant physician uses the following guidelines for interpreting the PFT results:

Restrictive impairment = FVC/FVC predicted <80%

Obstructive impairment = FEV_1/FVC <80% for teen-ager to mid-twenties;

= FEV_1/FVC <70% for those above mid-twenties

Also, if a forced expiratory maneuver takes greater than six seconds, a person may be considered obstructed.

Notification and Disposition: Employee notification of abnormal pulmonary function was not routine until the past two years. Only since January, 1979, has a sheet been added to the medical record which clearly indicates discussion of pulmonary function test results with the employee.

In some cases, employees are sent to Victory Memorial Hospital, Waukegan, for further pulmonary function work-up. Indications for this are: (1) new diagnosis of pneumoconiosis; (2) pneumoconiosis with impairment; (3) evaluation for disability.

C. Discussion

The results show that compliance with the pulmonary function portion of the Medical Surveillance requirement in the Asbestos Standard has been almost 100% at the Waukegan facility. However, the PFT equipment and procedures do not meet current NIOSH recommended standards (2) for the following reasons:

1. The vital capacity range of the spirometer is only 0-6 liters (0-7 liters is recommended).
2. The time range is only 8 seconds (10 seconds is recommended).
3. The system does not use measured spirometer temperature and barometric pressure to correct values to BTPS. (Instead a fixed BTPS correction factor is used).
4. No indication of daily volume calibration checks of the spirometer was found.
5. Until 1979, less than three acceptable curves were obtained.

In general, the curves were of good quality, with only one set out of 58 (that had 3 or more curves) not meeting NIOSH criteria for acceptibility. However, as noted, four others would not pass the criteria recommended by the American Thoracic Society (3).

The criteria for obstruction and restriction used by Johns-Mansville are commonly used and accepted (6). The normal values for FVC, however, are derived from a small and outdated study in which tests were done in the supine position. This

is not justified when there are several much larger and more recent population studies in which spirometry was performed with the workers upright. As noted, the normal values used were substantially lower than those derived from one of the more recent studies of a healthy population.

IV. X-ray Program

A. Compliance with Requirement for Annual Chest X-ray

Using an analysis similar to that for PFT's, the missing X-ray dates were determined for the 324 present and past employees included in the study. (See Section V for population selection factors). This data is tabulated in Table 1. It can be seen that since the Asbestos Standard has been in effect (1973), 1.6% of the required X-ray examinations have not been obtained on the employees studied. It should be noted that retirees in 1974 or 1975 were not studied. Since 1973, only in one case were two consecutively missing X-ray dates noted.

B. X-ray Equipment and X-ray Quality

No formal check was made of the X-ray equipment to determine if it would comply with NIOSH recommendations. However, on visual inspection the unit was modern and made by a reputable company. The X-ray unit has evidently passed Illinois state inspections. The X-rays are taken by a trained technician.

Of the 319 films sent to all three "B" readers, three, or one percent were classified as unreadable due to poor quality by at least two of the readers. This can be compared to a similarly derived value of 1% for X-rays taken by the NIOSH field team in the second round of the National Coal Study (M.R. Petersen, unpublished data). The number of unreadable films is well within the 5% maximum allowed by NIOSH in its surveillance program for coal miners (7).

V. Comparison of "B" Readers' and and Company X-ray Readings

A. Background and Methods

The original protocol for evaluating the Company X-ray readings was modified because of delays in the Company-sponsored "B" reading program. However, this was described in Dr. Engelberg's letter to all involved parties dated April 10, 1979. As he noted, a random sample of 200 present employees (excluding those in the refractory felt area) plus all workers with greater than five years of service who terminated employment at the plant between January 1, 1976, and December 31, 1978, were selected. Their latest chest X-rays were sent to 3 NIOSH-selected "B" readers who used the ILO U/C 1971 international classification (8), and their findings were compared to those of the Company reader as described below. The actual population sample consisted of 195 present employees, 42 workers who retired in 1975, 41 who retired in 1976, and 46 who retired in 1977. Five films of this total of 324 were not obtained, and are not included in the analysis of X-ray reading. The Company had read these films as showing: lung cancer--two, pneumoconiosis--three, negative--one.

The X-ray reading comparison is made difficult by the fact that the Company reader does not use the ILO U/C 1971 classification. Instead he uses an outdated system evidently developed in a series of Saranac Laboratory Symposia on Silicosis

which were initiated in 1934. In brief, he used four categories of interstitial findings, each with three grades of severity as indicated by subscripts:

- $P_{1,2,3}$ (Peribronchial markings)
- $A_{1,2,3}$ (Asbestosis)
- $S_{1,2,3}$ (Silicosis)
- $M_{1,2,3}$ (Mixed)

In a few cases, a comment was made after a "P" reading such as "p (or q,r) and/or s(or t,u) densities present." These readings using the size and shape designations from the ILO U/C 1971 classification seem to be the counterpart of the ILO U/C 1971 "0/1" readings; i.e., negative but the reader considered calling the film positive. In addition, pleural changes (sometimes only described as "pleural thickening") and any other findings are noted.

In an effort to compare the readings, criteria for a "positive" film were defined. With regard to any interstitial findings, a Company reading of "negative" or "P" was considered negative, and "A," "S," or "M" (of any grade) considered positive. Empirically, this was the Company interpretation as well, since "P" readings were not "red-tagged," i.e., were not labeled by the Company as indicating a possible work related health problem. On the other hand, "A," "S," and "M" readings of any grade were red-tagged. A "B" reading of rounded or irregular or combined opacities (i.e. any pneumoconiosis) of $\geq$1/0 profusion was considered positive.

The use of category 1/0 to define pneumoconiosis follows the NIOSH guidelines for coal workers' pneumoconiosis (9). If two or all three of the "B" readers called a film positive, it was considered positive (i.e., a median "B" reading was used). In a separate analysis the number of films with a profusion of $\geq$1/1 was arbitrarily used to compare with the Company readings. This was done in order to estimate how much of the difference between the Company and "B" readings could be due to a single step in the 12-point ILO U/C classification scale.

Since asbestosis classically presents with irregular interstitial markings, this feature was separately examined. Here a Company reading of "A" or "M" (but not "S") was considered positive, as was a "B" reading of $\geq$1/0 profusion for irregular type opacities. As before, the analysis was then repeated comparing the number of films with profusion $\geq$1/1 to the company readings.

Unfortunately, the Company did not always classify positive pleural findings as to location or whether they were bilateral or not. (These features are important in trying to assess the possible relationship to asbestos exposure.) Therefore, all pleural changes recorded except pleural effusion were considered positive for both the Company and "B" readers. Specifically, if a "B" reader recorded the extent of pleural thickening or pleural calcification to be $\geq$1, or if he noted "pq" (pleural plaque, uncalcified) in the "other symbols" section of the ILO U/C 1971 form, his reading was considered positive.

An analysis similar to those described above was also done for cancer. Here a note of cancer or possible cancer by the Company reader was considered positive, and a "B" reader's report was considered positive if he noted "Ca" (cancer) in the "other symbols" section of the ILO U/C form.

Some variability between the Company and median "B" reading, as between any two readers, was expected. In an effort to better interpret these differences, the variability among the three "B" readers (labeled "X,"Y," and "Z") was also analyzed for comparison. In the first analysis, the reading of any pneumoconiosis (i.e., any type of opacity) $\geq$1/0 profusion was considered positive; in the second, the reading of any irregular opacities $\geq$1/0 profusion was considered positive; and in the third any pleural disease (except pleural effusion) was considered positive. It will be noted that these same criteria were used in part of the Company versus "B" reader studies, thus permitting direct comparisons to be made. Chi-square analysis was done in all cases to determine if a statistically significant difference was present.

It should be noted that agreement on the total percentage of positive films does not necessarily mean agreement on each individual film.[a] To test this aspect of precision, the

[a] In fact, it is possible that two readers might both call one-half of a set of 100 films positive, and yet not agree on any individual film. That is, reader "1" might call films 1 to 50 positive, while reader "2" might call films 51 to 100 positive.

agreement on individual films was calculated for the Company reader versus the median "B" reading and the individual "B" readers, with the agreement among the three "B" readers serving as a control. In each pairing, the agreement was equal to the number of films called positive by both readers, plus the number of films both called negative, divided by the total number of films read by both. This number was then multiplied by 100 to give percentage agreement.

B. Results

Tables 2-6 compare the Company versus the median "B" reading; Tables 7-9 compare the three "B" readers to each other, and Table 10 summarizes the data on the reading of pneumoconiosis and pleural disease. The agreement among the readers is shown in Tables 11-13, and the cancer data is presented in Table 14.

The Company reader called 11% of the films positive for any pneumoconiosis, and all but one of these films had either Asbestos ("A") or a Mixed ("M") reading. Using the ILO U/C 1971 category 1/0 (or greater) as indicating a positive film, the median "B" reading considered 35% of the films positive (Table 2). This is significantly different from the Company reading ($p < .01$). If one compares the number of films with category $\geq$1/1 to the Company readings, then the Company and median "B" readings are almost identical (Table 3).

Table 4 and 5 make similar comparisons, looking only at irregular opacities. Using category $\geq$1/0 as positive, the median "B" reading of 21% positive is significantly ($p < .01$) greater than the 11% positive read by the Company reader (Table 4). If one compares the number of films with category $\geq$1/1, the median "B" reading drops to 7% positive, slightly but not statistically below that of the Company result (Table 5).

The median "B" reading considered almost twice as many films positive for pleural disease (40%) as did the Company reader (22%) (Table 6). However, as can be seen in Tables 9 and 10, and Graph 1, reader "Z" was clearly out of line with the other two "B" readers, reading over 2 1/2 times and almost 3 1/2 times as much pleural disease as readers "Y" and "X," respectively. There is no significant difference between the Company's 22% positive result and reader "X"'s result of 25% positive.

Table 7 shows the large variability among the "B" readers if one accepts category 1/0 or greater as indicating a positive film for any pneumoconiosis. The three readers' results are 40%, 28%, and 46% positive, all significantly different from each other as well as from the Company reading of 11% positive. This variability is eliminated if one compares the films classified as category 1/1 or greater giving "B" readings of 14%, 15% and 14% positive (Table 10). Here only the 15% value is significantly different from the Company reading.

A similar analysis for irregular opacities is shown in Table 8. Here two "B" readers agree (20% and 22% positive), but both are significantly lower than the third (36%). As with "any pneumoconiosis," all three readers found significantly more disease than the Company reader who noted 11% positive films. Interestingly, if one compares category 1/1, two different "B" readers agree, (11% and 10%) but differ from the third (5%) (Table 10).

Table 9 compares the "B" readers' findings for pleural disease. All three values for percent positive (25%, 34%, and 87%) were significantly different from each other, with the last being remarkably different, as noted above.

Tables 11-13 address the question of the Company reader's precision. Most of the data presented is obtained from Tables 2-9. Table 11 looks at the reading of any pneumoconiosis. Here one finds an agreement between the Company reader and the median "B" reading of 74% if category 1/0 is accepted as positive. For category $\geq$1/1, there is 95% agreement. The final two sections of the table compare the "B" readers to themselves and to the Company reader, using 1/0 criteria for positive. All comparisons show a reading agreement of 63% to 79%. Table 12 shows a similar analysis, looking at irregular opacities. Here again the Company reading agrees with the median "B" reading or individual "B" readers as well as the "B" readers agree among themselves.

For pleural disease, the Company reading agreed with the median "B" reading 74% of the time, as shown in Table 13. Reader "X," "Y" and the Company reader agreed among each other approximately 78% of the time, and each one showed poor agreement with reader "Z." The poor agrement is due to the extremely high number of films called positive by reader "Z" as noted before.

Table 14 shows that the Company and median "B" reading agreed on 98% of films in diagnosing cancer, yet the actual positive cases were different. Of the four Company "positives," two were not read as positive by any of the "B" readers. One of these had had surgical excision of his cancer before the 1979 film read by the "B" readers. The second employee had some pleural abnormalities and was throught to have a mesothelioma, evidently partly on clinical grounds. Two Company "positives" were also considered positive for cancer by one "B" reader. One showed a somewhat poorly visualized coin lesion, and the other showed a density in the right cardiophrenic angle.

All three "B" readers considered one film positive for cancer. This person had a somewhat poorly visualized coin lesion. He died two years later and the autopsy report noted a bronchogenic adenocarcinoma. The other two positive cases were considered positive by two "B" readers; one shows an extensive right pleural lesion as well as thoracotomy sutures, and the other shows enlarged hila with a questionable right hilar mass.

It should be noted that there was a large variability in the number of films considered suspect or positive for cancer. Thus while the Company reader called four films suspect or positive, Reader "X" read three, Reader "Y" read six, and Reader "Z" read 34 films suspect or positive for cancer. Most of the suspect or positive films noted by Reader "Z" were not thought to show any evidence of cancer by the other two "B" readers, and most of the suspected lesions were interpreted to be normal markings or pleural changes when reviewed by two NIOSH chest physicians.

C. Discussion

With regard to the reading of interstitial disease, it should be emphasized that the comparison between the Company and the "B" readers is also a comparison of two different classification systems. Thus differences in results may well be due to the system used rather than reader sensitivity.

If one considers the median "B" reading as the "true" reading, and accepts ILO U/C 1971 category 1/0 (or greater) as positive, then the Company detects only one-third of the pneumoconiosis present and only one-half of the cases with irregular opacities. The Company reading was also significantly less than each individual "B" reading. However, one should note that with the 1/0 criteria there are substantial reading differences for any pneumoconiosis and irregular opacities even among the "B" readers.

Although the Company--median "B" reading differences are large, the data comparing category 1/1 show that the Company is only reading one minor category above the "B" readers. It should also be noted that because of reader variability at least some experts have found the early categories of irregular opacities to be very non-specific (10). The analysis shows that although the Company reader has a higher threshold for "positive," from the standpoint of precision he cannot be differentiated from the "B" readers.

The data for pleural disease shows that the Company reader is no different from the lower of the two acceptable "B" readers, and agrees on individual films with these two as well as they agree between themselves. One could emphasize the fact that the Company reads only one-half of the pleural disease present (22% vs. Median "B" reading of 40%, from Table 10). However, reader "Z"'s result of 87% positive is well outside the range of the other two "B" readings and should be excluded from the analysis.

Although the analysis of the reading of cancer shows a high degree of agreement (98%) between the Company and median "B" reading, any mistakes in this area may have serious consequences. The coin lesion read as cancer by all three "B" readers and not detected by the Company reader did turn out to be a lung cancer as shown at autopsy two years later. The coin lesion noted by the Company reader and not detected by two "B" readers is presently being further evaluated to determine if it is a cancer. All cases with

suspected cancer (read by any of three "B" readers) were notified to seek medical attention.

VI. Notification of Employees of Radiologic Abnormalities

A. Findings

Thirty-four of the 324 charts reviewed had red-tags. These included all of the readings of "A," "S," or "M," with the exception of one chart whose film was read as "A_{0-1}" by the Company and one case called "A_1" where the employee retired before he was re-examined. It is not known whether this last man was notified of his X-ray abnormality. All 34 employees with red-tagged charts plus 2 others whose red-tag status was later removed were notified; in 27 cases within 2 months of the red-tag date, in 4 cases within 3 to 5 months, and in 5 cases within 8 to 12 months.

The time interval between the date of the first positive film and the red-tag date was not obtained in many cases. When obtained, it was usually less than three months. In five cases, a repeat X-ray was taken 3 to 9 months later, and the employee notified that month when the reading remained positive. One film was noted to show "A_2" as read by two different readers four and three years before the usual Company reader saw the film. It was only when this last reader called the films positive that the employee was (promptly) red-tagged and notified. One additional film was read as "asbestosis" by someone other than the usual Company reader, and his chart was not red-tagged nor was he informed. Prior to this he had been clearly informed about a lung cancer, however.

None of the four films with suspected cancer without pneumoconiosis were red-tagged but there was evidence suggesting that all the employees were notified. One chart clearly noted that the man was informed. Two had surgical excision of the tumor, one within two weeks of the abnormal X-ray. The last chart noted that it had not been determined whether the abnormality (a coin lesion) was a primary or metastatic tumor. In only one of the four charts was it explicitly stated that the X-ray findings were discussed with the employee, however.

None of approximately fifty subjects with isolated pleural disease were red-tagged, and forty were not notified of their abnormalities.

B. Discussion

In the sample of workers studied, review of the medical charts indicate that all persons who were red-tagged were notified of their X-ray abnormalities. In one-quarter of the cases the delay between red-tagging and employee notification was excessive (greater than two months).

Repeating a chest X-ray to confirm or refute a questionable abnormality is a common clinical practice, and cannot be criticized as such. In this setting, however, it is felt that a period of 3-6 months would be adequate for resolution of any intercurrent disease process which might mimic pneumoconiosis.

There is evidence suggesting that the X-ray reports of readers other than the usual Company readers were not always detected or used by Johns-Manville in its red-tagging procedure. In one case this caused a delay of several years in notifying an employee of a radiographic abnormality.

Notification of suspected cancer was apparently 100%, although this could not be absolutely confirmed from the medical record data.

Certain types of pleural thickening, calcification, and plaques can usually be considered as an indication of asbestos exposure, but they may produce few if any symptoms and little physiologic impairment. It is not clearly known what effect a change of asbestos exposure has on these lesions. Therefore, it is difficult to comment on whether employees with such lesions should be removed from all further asbestos exposure. While some pleural lesions, such as apical or unilateral pleural thickening are usually not asbestos related in non-selected populations, others such as bilateral thickening and pleural calcification without other obvious cause are quite likely to be asbestos related. In such circumstances, it would seem reasonable to notify the worker of this fact, although one should note that the Asbestos Standard does not require employee notification of any findings.

VII. Recommendations

A. Pulmonary Function Tests:

1. A spirometer system which would meet NIOSH recommended standards should be used, and NIOSH recommended procedures as published in the Federal Register, 43(80), April 25, 1978, Part IV, Appendix B, should be followed.
2. Standards for normal pulmonary function should be selected from any one of several recent large studies of normal populations.

B. X-ray Program

1. The Company should ensure that its X-ray equipment and practices meet NIOSH recommendations, as published in the Federal Register, 43(149), August 1, 1978.
2. The use of the ILO U/C 1971 (and the ILO 1980 classification when available) system is recommended.
3. All chest X-rays should be read by at least two radiologists, one of whom should be a "B" reader.

C. Notification:

1. Individuals with abnormal spirometry or chest radiographs should be notified within two months. For radiographic abnormalities suggestive of conditions requiring

immediate medical attention (e.g. lung cancer, active tuberculosis) the individual should be notified as soon as possible.

2. Certain pleural findings (such as bilateral pleural thickening or pleural calcification without any other obvious cause) are quite likely to be related to asbestos exposure, and should be considered evidence of potentially hazardous exposure to asbestos. Employees with these abnormalities should be so notified.

TABLE 1

CHECK OF RADIOGRAPH DATES

Present Employees (N = 195)

1971-1972	1973-1978
dates missing = 147	dates missing = 5
possible dates = 390	possible dates = 1170
(38% missing dates)	(0.4% missing dates)

1976 to 1978 Retirees (N = 129)

1971-1972	1973 to date of retirement
dates missing = 72	dates missing = 22
possible dates = 258	possible dates = 520
(28% missing dates)	(4.2% missing dates)

TOTALS

1971-1972	1973 +
dates missing = 219	dates missing = 27
possible dates = 648	possible dates = 1690
(34% missing dates)	(1.6% missing dates)

TABLE 2

COMPANY VS. MEDIAN "B" READING*

ANY PNEUMOCONIOSIS ($\geq$ 1/0 PROFUSION)

		Median "B" Reading +	Reading −	Totals
Company Reading	+	31	3	34(11%)
	−	80	200	280(89%)
Totals		111	203	314
		(35%)	(65%)	(100%)

Results show statistically significant difference, $p < .01$.

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-).
A "B" reading of ILO U/C 1971 category 1/0 or greater was considered positive.

TABLE 3

COMPANY VS. MEDIAN "B" READING*

ANY PNEUMOCONIOSIS ($\geq$ 1/1 PROFUSION)

		Median "B" Reading $\geq$1/1	<1/1	Totals
Company Reading	+	26	8	34(11%)
	-	9	272	281(89%)
Totals		35	280	315
		(11%)	(89%)	(100%)

No statistically significant differences.

*See text for explanation
Numbers represent films read in each category. 1/1 refers to the ILO U/C 1971 classification category.

TABLE 4

COMPANY VS. MEDIAN "B" READING*

IRREGULAR OPACITIES ($\geq$ 1/0 PROFUSION)

		Median "B" Reading +	Reading −	Totals
Company Reading	+	21	12	33(11%)
	−	45	236	281(89%)
Totals		66	248	314
		(21%)	(79%)	(100%)

Results show a statistically significant difference ($p < .01$).

*See text for explanation
Numbers represent films read as Positive (+) or Negative (-).
A "B" reading of ILO U/C category 1/0 or greater was considered positive.

TABLE 5

COMPANY VS. MEDIAN "B" READING*

IRREGULAR OPACITIES ($\geq$ 1/1 PROFUSION)

		Median "B" $\geq$1/1	Reading <1/1	Totals
Company Reading	+	17	16	33(10%)
	-	4	278	282(90%)
Totals		21	294	315
		(7%)	(93%)	(100%)

No statistically significant differences.

*See text for explanation
Numbers represent films read in each category. 1/1 refers to the ILO U/C 1971 classification category.

TABLE 6

COMPANY VS. MEDIAN "B" READING*

PLEURAL DISEASE

		Median "B" Reading +	Reading -	Totals
Company Reading	+	57	12	69(22%)
	-	68	175	243(78)
	Totals	125	187	312
		(40%)	(60%)	(100%)

Results show a statistically significant difference ($p < .01$).

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-).

TABLE 7

COMPARISON OF THREE "B" READERS*

(LABELED "X," "Y," AND "Z")

ANY PNEUMOCONIOSIS ($\geq$ 1/0 PROFUSION)

		Reader "X" +	Reader "X" -	Totals
Reader "Y"	+	62	23	85(28%)
	-	60	159	219(72%)
Totals		122(40%)	182(60%)	304(100%)

Results show statistically significant difference, $p<.01$.

		Reader "X" +	Reader "X" -	Totals
Reader "Z"	+	92	48	140(47%)
	-	29	130	159(53%)
Totals		121(40%)	178(60%)	299(100%)

Results show statistically significant difference, $p<.05$.

		Reader "Y" +	Reader "Y" -	Totals
Reader "Z"	+	75	67	142(46%)
	-	13	156	169(54%)
Totals		88(28%)	223(72%)	311(100%)

Results show statistically significant difference, $p<.01$.

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-). A "B" reading of ILO U/C 1971 category 1/0 or greater was considered positive.

Note: Totals for each reader may vary because films called unreadable were deleted from each analysis.

TABLE 8

COMPARISON OF THREE "B" READERS*

(LABELED "X," "Y," AND "Z")

IRREGULAR OPACITIES ($\geq$1/0 PROFUSION)

		Reader "X" +	Reader "X" -	Totals
Reader "Y"	+	44	20	64(21%)
	-	66	174	240(79%)
Totals		110(36%)	194(64%)	304(100%)

Results show statistically significant difference, $p<.01$.

		Reader "X" +	Reader "X" -	Totals
Reader "Z"	+	43	17	60(20%)
	-	66	173	240(80%)
Totals		109(36%)	190(64%)	304(100%)

Results show statistically significant difference, $p<.01$.

		Reader "Y" +	Reader "Y" -	Totals
Reader "Z"	+	31	31	62(20%)
	-	36	213	249(80%)
Totals		67(22%)	244(78%)	311(100%)

No statistically significant differences.

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-). A "B" reading of ILO U/C 1971 category 1/0 or greater was considered positive.

Note: Totals for each reader may vary because films called unreadable were deleted from each analysis.

TABLE 9

COMPARISON OF THREE "B" READERS*

(LABELED "X," "Y," AND "Z")

PLEURAL DISEASE

		Reader "X" +	Reader "X" -	Totals
Reader "Y"	+	55	40	101(33%)
	-	21	182	203(67%)
Totals		76(25%)	228(75%)	304(100%)

Results show statistically significant difference, $p<.01$.

		Reader "X" +	Reader "X" -	Totals
Reader "Z"	+	73	187	260(87%)
	-	3	36	39(13%)
Totals		76(25%)	223(75%)	299(100%)

Results show statistically significant difference, $p<.01$.

		Reader "Y" +	Reader "Y" -	Totals
Reader "Z"	+	103	166	269(86%)
	-	3	39	42(14%)
Totals		106(34%)	205(66%)	311(100%)

Results show statistically significant difference, $p<.01$.

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-).

Note: Totals for each reader may vary because films called unreadable were deleted from each analysis.

TABLE 10

SUMMARY OF X-RAY READING OF PNEUMOCONIOSIS

AND PLEURAL DISEASE*

		Any Pneumoconiosis		Irregular Opacities		Pleural Disease
	Reading	Positive†	≥1/1††	Positive†	≥1/1††	
"B" Readers	"X"	40	14	36	11	25
	"Y"	28	15	22	10	34
	"Z"	46	14	20	5	87
	Median "B"	35	11	21	7	40
	Company	11		11		22

*Numbers represent the percent of the films read that were in each category.

†Positive for the "B" readings is defined as ILO U/C 1971 profusion category 1/0 or greater.

††1/1 refers to the ILO U/C 1971 classification category--see text.

TABLE 11

ANY PNEUMOCONIOSIS

Company vs. Median "B" Reading

1/0 = Positive

Company	Median "B"	No. Films	
Positive	Positive	31	231
Negative	Negative	200	
Positive	Negative	3	$\frac{231}{314} \times 100 = 74\%$ Agreement
Negative	Positive	80	
	Total =	314	

Comparing films ≥1/1

Company	Median "B" Reading ≥1/1?	No. Films	
Positive	yes	26	298
Negative	no	272	
Positive	no	8	$\frac{298}{315} \times 100 = 95\%$ Agreement
Negative	yes	9	
	Total =	315	

Agreement Among "B" Readers: All pneumoconiosis ≥ 1/0

"X" vs. "Y"	73%
"X" vs. "Z"	74%
"Y" vs. "Z"	74%

Agreement Between Company and Individual "B" Readers: All Pneumoconiosis ≥ 1/0

Company vs. "X"	79%
Company vs. "Y"	70%
Company vs. "Z"	63%

TABLE 12

IRREGULAR OPACITIES

Company vs. Median "B" Reading

1/0 = Positive

Company	Median "B"	No. Films	
Positive	Positive	21 }	257
Negative	Negative	236 }	
Positive	Negative	12	$\frac{257}{314}$ x 100 = 82% Agreement
Negative	Positive	45	
	Total =	314	

Comparing films ≥ 1/1

Company	Median "B" Reading ≥1/1?	No. Films	
Positive	yes	17 }	295
Negative	no	278 }	
Positive	no	16	$\frac{295}{315}$ x 100 = 94% Agreement
Negative	yes	4	
	Total =	315	

Agreement Among "B" Readers: Irregular Opacities > 1/0

"X" vs. "Y"	72%
"X" vs. "Z"	71%
"Y" vs. "Z"	78%

Agreement Between Company and Individual "B" Readers: Irregular Opacities ≥ 1/0

Company vs. "X"	70%
Company vs. "Y"	82%
Company vs. "Z"	78%

TABLE 13

PLEURAL DISEASE

Company vs. Median "B" Reading

Company	Median "B"	No. Films		
Positive	Positive	57 }	232	
Negative	Negative	175 }		
Positive	Negative	12	232	= 74% Agreement
Positive	Negative	68	312	
	Total	312		

Agreement Among "B" Readers

"X" vs. "Y"	78%
"X" vs. "Z"	36%
"Y" vs. "Z"	46%

Agreement Between Company and Individual "B" Readers

Company vs. "X"	79%
Company vs. "Y"	77%
Company vs. "Z"	32%

TABLE 14

COMPANY VS. MEDIAN "B" READING*

CANCER

		Median "B" Reading +	Reading -	Totals
Company Reading	+	0	4	4(1%)
	-	3	307	310(99%)
Totals		3	311	314
		(1%)	(99%)	(100%)

No statistically significant differences.

*See text for explanation.
Numbers represent films read as Positive (+) or Negative (-).

GRAPH 1

PLEURAL DISEASE

Individual readings of percent of films read positive
(Expressed as 95% confidence range)

Company

"X"

"Y"

"Z"

0 10 20 30 40 50 60 70 80 90 100

IX. References

1. Standard for Exposure to Asbestos Dust. 29 CFR 1910-1001 Federal Register 37(No. 110):(Wednesday, June 7, 1972), 11318-11322.
2. Standards for Determining Coal Miner's Total Disability or Death Due to Pneumoconiosis; and Review of and Claims for Benefits. Federal Register 43(No. 80):(Tuesday, April 25, 1978), 17728-17729, (Appendix B).
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7. Specifications for Medical Examinations of Underground Coal Mines. Chest Roentgenographic Examinations. Federal Register 43(No. 148):(August 1, 1978), 33713-33720.

8. Jacobson, G., and Lainhart, W.S., Ed. ILO U/C 1971 International Classification of Radiographs of the Pneumoconises. Medical Radiography and Photography 48 (No. 3):65-110, 1972.

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ADDENDUM

PROTOCOL FOR NIOSH TECHNICAL ASSISTANCE TO OSHA REGARDING JOHNS-MANVILLE MEDICAL SURVEILLANCE PROGRAM

The NIOSH investigation of the Johns-Manville asbestos-related medical records and program will attempt to answer the following questions:

(1) Is the medical surveillance program adhering to the OSHA Asbestos Standard requiring annual chest radiograph and pulmonary function tests?

(2) Do the equipment and procedures for obtaining pulmonary function data meet NIOSH recommendations to the Department of Labor as published in "Standards for Determining Coal Miners Total Disability or Death Due to Pneumoconiosis "(CFR Vol. 43(80)), April 25, 1978, Part IV, Appendix B); do the equipment and procedures for obtaining x-ray data meet the NIOSH "Chest Roentgenographic Examination Standards" (CFR, Vol. 43 (148), August 1, 1978)?

(3) Is the medical surveillance program detecting pulmonary abnormalities suggestive of asbestos-related disease or mixed dust-related disease at the appropriate time, and is there medical-record evidence that individual employees are being notified of these abnormalities at the appropriate time?

It should be made clear that answers to Questions 2 and 3 go beyond the requirements of the asbestos standard, and are being sought in the interests of the general health and welfare of the employees. The standards mentioned in Question 2 are for the guidance of physicians and technicians to insure that the best medical data will be obtained. Investigation of Question 3 will detect if there are deficiencies in interpretation of the medical data and with notification of the employee of asbestos-related abnormalities.

Procedures for answering the questions:

Question 1: Obtain a random sample of 50 current employees who are exposed to asbestos. The sample will be determined from assigning random numbers to the alphabetically-listed medical records. If an employee who works in a department that has no asbestos exposure (Department 280 - Refractory Felt) is selected, his record will be rejected and the next randomly selected record will be used. This pattern will be followed until 50 employees' records are obtained. Each record will then be reviewed for the initial date of employment, and for the dates of all pulmonary function testing and chest radiography as far back as the date of enactment of the Asbestos Standard, to see whether these tests have been given at least yearly.

Question 2: For pulmonary function guidelines, obtain list of equipment that is used, how it is used, and the qualifications of the persons who administer the tests. Compare this information to the proposed standard mentioned above. From the same 50 randomly selected employees' records obtain the latest volume-time curves and the notes interpreting these curves. Check these curves for determination and calculation of the largest FVC and FEV_1; correction for BTPS; and for the interpretation of the FVC/FVC-predicted ratio and the FEV_1/FVC ratio. Check the medical record to determine if there is any note indicating that the employee has been notified of any abnormal pulmonary function result. Abnormal results will be based upon the Intermountain Thoracic Society recommendations of FVC/FVC-predicted $<.81$ and FEV_1/FVC, $<.70$. These are the guidelines currently followed by NIOSH-ALOSH in notifying coal miners studied in the National Coal Study of PFT abnormality.

For x-rays, obtain a list of equipment that is used, how it is used, and the qualifications of the persons who use the equipment. Compare this information to the NIOSH standard mentioned above.

Question 3: For pulmonary function surveillance, see procedure for Question 2. For radiographic surveillance, this question will be answered in the following sequence of steps:

1. Obtain the protocol and results of the company-sponsored "B" reader review of the most recent chest x-rays of all present employees at the Waukegan plant. Obtain copies of the individual reading reports that the "B" readers have sent to the company. From these reports classify the workers as to whether their radiographic findings are suggestive of asbestos-related lung disease or mixed-dust related pneumoconiosis according to the following definitions:

   (1) Highly suggestive of Asbestos-Related Lung Disease--

      (a) Small-irregular opacities of profusion Category 1/0 or greater, or

      (b) bilateral pleural thickening or pleural calcification of grade 1 or greater, or

      (c) findings suggestive of primary lung carcinoma or mesothelioma

   (2) Possible asbestos-related disease--unilateral pleural thickening or calcification of grade 1 or greater .

   (3) Suggestive of non-asbestos related lung disease--small rounded opacities of Category 1/0 profusion or greater.

2. Since only one "B" reader will have read any given film, the group of x-rays suggestive of the above abnormalities will be sent to a NIOSH-selected "B" reader for his interpretation. To minimize bias a 10% sample of the latest chest x-ray films of workers with no suggestive findings will also be sent to this "B" reader. Consensus will be achieved if both the company "B" reader and the NIOSH "B" reader agrees on whether a film fulfills any of the above criteria. A chi-square test will be done to determine whether the disagreement is statistically significant.

NIOSH "B" reader	Company "B" reader: suggestive findings	Company "B" reader: no suggestive findings
suggestive findings		
no suggestive findings		

In those cases where there are disagreements, the disputed films will be sent to a second NIOSH-selected "B" reader. Consensus will then be by agreement between 2 of the readers, and a final set of film with suggestive abnormalities will be established.

3. For individuals with suggestive abnormalities on their most recent radiographs all radiographs taken since the implementation of the OSHA asbestos standard will be sent to another "B" reader. To minimize bias twenty individuals whose latest films are negative for the abnormalities will be randomly selected and their radiographs dating back to the asbestos standard implementation will also be sent to the "B" reader. These films will be randomly interspersed with the suggestive films, so that the reader will not know whether he is reading a "positive" or "negative," current or old film.

Names and dates will be obliterated and a code devised to sort the films after they have been read. In this way it will be determined which radiograph the "B" reader has detected the earliest evidence of abnormalities. The medical record will then be reviewed to see whether the local radiologist-consultant's narrative report for that radiograph indicated the presence of a comparable abnormality. If so, indication of worker notification will be sought. If the radiologist-consultant's narrative report for that radiograph did not indicate the presence of a comparable abnormality, later reports will be checked to determine if the abnormality was found subsequently, and if the individual was notified at that time.

April 19, 1979

Mr. John Svalina
Occupational Safety and Health Administration
Aurora Area Office, Region V
364 Smoke Tree Business Park
North Aurora, IL 60542

Dear John

I thought I would outline for you NIOSH's plan to study the medical surveillance system of the Johns-Manville plant in Waukegan. This plan takes into account the responses of OSHA, the ICWU and Johns Manville to my first protocol, as well as further thought we at NIOSH have given on the matter. Furthermore, since J-M has failed to begin its review of of the radiographs at the Waukegan plant, our sampling scheme has been changed so that it is not dependent on J-M's review.

The study will include the following:

(1) Random selection of 100 present employee's records, excluding employees in Refractory Felt and those hired since 1970. Their latest pulmonary function tracings will be copied, and the dates of PFTs and chest radiographs since 1971 will be noted. The calculation and the interpretation of the pulmonary functions as done by J-M staff will be noted. Interviews with the staff regarding the equipment and operation of the pulmonary function tests will be conducted.

(2) Dr. Pitts and Dr. Culmer will be interviewed about the equipment and procedure for taking, reading and interpreting chest x-rays.

(3) A random sample of 200 present employees, plus all workers with greater than five years of service who terminated employment at the plant between January 1, 197X and December 31, 197X, will be selected. Their latest chest x-rays will be sent to 3 NIOSH selected B readers for reading. Those found by consensus to have evidence of pneumoconiosis, pleural disease, primary lung cancer or mesothelioma will be considered positive and their chest radiographs dating back to 1971 will then be sent to another B reader. Randomly interspersed will be present and back x rays of 20 negative employees, to minimize bias. Results of these records to determine when the abnormality was first detected by the local radiologist, and for evidence in the record that the employee was notified.

All records with personal identifiers will be kept strictly confidential, according to OSHA and NIOSH regulations and guidelines.

I have contacted Drs. William Paul and John Culmer to begin the study during the week of April 26th.

Sincerely,

Alan L. Engelberg, M.D.
Medical Officer, CIB, DRDS

cc:
Dr. William Paul, Johns-Manville, Denver, CO
Dr. John Culmer, Johns-Manville, Waukegan, IL
Mr. James Middleton, International Chemical Workers Union, Local 69, Waukegan, I

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