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DATE NOVEMBER 22, 1965

TO REFINERY MANAGERS

ANACORTES
HOUSTON
MARTINEZ
NORCO
WILMINGTON
WOOD RIVER
ODESSA/CINIZA

FROM MANAGER - MANUFAC
ENGINEERING DEPAR
HEAD OFFICE

SUBJECT HEALTH HAZARDS
FROM ASBESTOS

API Memo & rept on Asb. 1965 (Shell)

There has been considerable discussion in medical circles in recent years concerning the possibility of harmful effects to insulators from long-term exposure to asbestos. This matter has been a recent subject of an investigation by the API Central Committee on Medicine and Health. Attached is a report which summarizes the current status of the study which was presented at the mid-year API meeting of the Central Committee. It includes a summary of the findings from a recent survey of workers in the petroleum industry to determine if there were any potential problems from exposure to asbestos.

We thought you should be informed concerning this matter since work in progress by the U.S. Public Health Service and the medical profession is apt to focus increased attention on the health of workmen engaged in insulation activities.

You will note from the conclusions in the attached report that the data obtained to date is considered inadequate to resolve the question as to the degree of hazard posed to refinery insulators. For this reason, we see no cause for alarm at this time. However, you may wish to review the potential exposure to insulators from asbestos dust to determine if there are any situations where some additional precautions appear desirable.

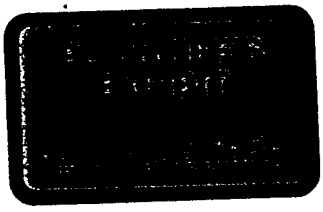
Subsequent to review of this report by the Committee on Industrial Hygiene of the Central Committee on Medicine and Health it was decided that, although the data so far accumulated was insufficient to draw any conclusions, a task force should be established to continue the review and make recommendations for future action. We will keep you advised if anything significant develops.

H. M. Karr

H. M. Karr

WCB:JC

Attachment



ABS-003995

MANAGEMENT REPORT

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May 31, 1979

Pref. Dego. Ex 1 to Ross Dego
1/28/88

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Section 1

BACKGROUND

Prior to 1963, insulators at Wood River were exposed to asbestos-containing materials although the crude estimates of exposure indicate that environmental levels were relatively low in relation to the present OSHA standards. Since 1963, Shell employees working at new construction projects have been exposed only to nonasbestos insulation materials; however, especially since 1970, the ripping out or stripping down of old units with insulation has continued to be a potential source of low-level asbestos exposure. A training program put into force in 1970 required that all Shell employees exposed to asbestos at Wood River learn wetting-down techniques prior to rip-out, and that they know how to bag and bury the material, as well as how to use a respirator.

In July 1972, the Shell corporate medical director issued a memo relative to the medical requirements of the OSHA asbestos standard. In December 1973, revisions were communicated by the corporate medical director; moreover, shortly thereafter, the General Manager Refining--Head Office issued a memo to all refinery managers informing them of the need to identify significant <u>past</u> exposures so as to assist in determining additional Shell employees who should be placed on medical surveillance.

In reviewing asbestos examinations in November of 1978, Dr. B. J. Kern, Shell Medical Director--Northern Region, noted several relevant items regarding the annual examination of current and former asbestos workers:

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- A questionnaire (described in a 1972 memo from the corporate medical director) is completed and signed by the "asbestos worker" in the medical department after a plant nurse checks the box marked "annual" and records the employee's name, number, date, work location, age, height, weight, and sex.
- Forced expiratory spirometry and a chest x-ray is obtained at a local hospital (at St. Joseph Hospital from 1973 to 1975 and at Alton Memorial Hospital from 1976 to 1978).
- A copy of a spirometry report, dated and signed by the technician, and a copy of the radiologist's interpretation are both mailed to the medical department at Wood River.
- A plant nurse transfers information from reports received in the mail, placing the data in the middle portion of a form entitled, "Special Medical Examination (Asbestos)."
- Dr. Michael F. Mitchell, plant physician, examines the patient, evaluates the reported information (as well as his own examination findings in relation to evidence of lung disease, limitations for respirator use, or the need for further clinical studies), and signs and dates the form.

Dr. Kern did not visit either hospital, nor did he discuss the procedures in detail with the plant physician or nurses. He did retrieve some medical data on smoking history, spirometry results, and chest x-ray interpretations from 1974 to 1978. On November 15, 1978, he submitted a memo to the corporate medical director. In this memo he reported his analysis of 41 workers who had asbestos examinations and compared the findings on these 41 employees with 41 other employees, selected randomly. The key findings noted by Dr. Kern were that a large fraction of workers had abnormal spirometry tests and the chest x-ray interpretations appeared to be inconsistent with previous readings. At that time Dr. Kern was unable to determine whether these findings represented a genuine health problem or were merely a procedural problem.

During Dr. Kern's analysis, Dr. C. E. Ross, Shell Medical Director, Occupational Health Surveillance, was completing a data processing task that involved abstracting certain data from all special medical examinations. The Wood River spirometry data in Dr. Ross's analysis differed in some respects from the spirometry data of Dr. Kern, especially in that the listing of Dr. Ross included tests obtained in January 1973, and the listing included 47 asbestos workers at Wood River.

On January 24, 1979, Dr. Ross issued a memorandum to Mr. R. L. Brunner, Manufacturing Safety and Health Manager, outlining plans for spirometry testing and quality assurance requirements for spirometry. In his memo, Dr. Ross made the following points:

- There are many ways to calculate predicted normals.
- Many different types and models of equipment are available for the test.
- Different levels of sophistication are required to use the equipment properly and to do the test properly.
- Requirements for a permanent record differ from case to case.
- Proper calibration of the equipment is required.
- A certified training program is needed for persons doing the test, whether they are Shell nurses or contractors.
- A computer program is needed to track the performance of such persons and to detect significant changes in function in individual asbestos workers (as well as groups or subgroups) at various locations.

Dr. Ross then referred to the Kerr report and noted certain steps to be taken by this consultant at Wood River.

Section 2

CONSULTANT'S EVALUATION

The following background information on spirometry is pertinent to my observations at Wood River and the three local hospitals.

The spirometry test for asbestos workers is intended primarily to detect restrictive dysfunctions (low forced vital capacity or FVC) associated with clinically significant lung fibrosis or scarring. The state-of-the-art for spirometry testing to detect this scarring has progressed in recent years such that three complementary techniques will yield the maximum for case detection at a minimum cost of false positives. The highlights for each of these techniques are presented below.

- FVC, when measured as the best trial or largest value ("BTPS corrected", or adjusted to standardize for climate and altitude) is generally reported as a percent of predicted value. Persons with clinically significant fibrosis usually have values below 70% of predicted for their age, sex, height, and race. Many persons may be mildly symptomatic and have objective evidence of asbestosis with FVC values between 70% and 80%. However, a single FVC value below 80% of predicted is not diagnostic of asbestosis, nor is a value of greater than 80% an absolute assurance that the individual is free of asbestosis.
- A second approach to the early detection of restrictive dysfunction is to measure accumulated or annual decrements in FVC. If a nonsmoker asbestos worker were to experience a decrement from year 1 to year 2 greater than 0.07 l and this decrement were to occur each year and accumulate for 5 years, then the accumulated decrement would be 0.35 l.

  (Note: The FVC could still be well above 80% of predicted, but a 0.35-l decrement would be about three times that expected for a nonsmoker. This 0.35-l decrement would be well beyond any combination of biological variation and reasonable calibration error.)

We recommend the use of an 8% decrease in FVC as a single-year "flag" indicating an excessive loss in volume of vital capacity (not an average decrement over several years). However,

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for accumulated decrements over 3 or more years, we recommend that a decrement in excess of 4% per year be flagged as indicating restrictive dysfunction irrespective of the calculated percent of predicted values. Thus, if the physician or clinician uses decremental dysfunction as an aid in the early detection of asbestosis, the accuracy of spirometry testing can be increased.

- A third approach to early detection of dysfunction is the epidemiologic detection method, wherein one examines grouped data by smoking category and exposure level. In this method, if a group of workers shows a greater FVC loss than expected, one can suspect an excessive exposure to asbestos. By means of a computer program now under development in the Shell corporate medical offices, occurrences of such losses in FVC will be flagged and local plant physicians notified. The algorithm for this technique is to be embodied in the biostatistics package.

Thus, three ways are available to identify significant ventilatory restriction: (1) an individual has an FVC level less than 80% (70% for persons without any other findings) of predicted FVC; (2) a decrement of 4% per year occurs over several years (or an 8% decrement occurs in any single year), and (3) mean FVC values decrease more than expected, depending on the size and characteristics of the risk group. Persons described in items (1) or (2) would generally be flagged for special clinical review and subsequent annual reviews; persons in item (3) would be flagged for special studies if the entire group showed gradual, but excessive, losses in FVC values.

Since spirometry measurements also include obstructive indicators--such as an 80% of predicted forced expiratory volume in the first second of effort ($FEV_{1.0}$) or an $FEV_{1.0}$/FVC ratio less than 0.70—the same sort of analysis can be made for obstructive diseases of non-occupational origin so as to provide some specificity to the surveillance. For persons having "mixed flags" (both a flag for FVC and either of the obstructive cutoff flags), the first action should be no different than for a restrictive dysfunction problem. When the only flag is obstructive, the action should be directed to smoke cessation, if applicable, and/or a referral for pulmonary workup for other non-occupation causes.

The technique for performing forced expiratory spirometry is not easily learned from a syllabus but requires practical instruction and practice with a wide variety of workers, all of whom have their individual motivations, language problems, educational level, etc. Our experience indicates some technicians never learn this technique, even after several hours of lecture and 8 hours of small group instruction. Appendix 1, a 1978 report of an ad hoc committee, includes their minimum criteria for a training course and lists the course objectives. This committee, recently reconstituted into a new Council on Occupational Respiratory Disease (CORD) has developed a course certification program, as well as other guidelines for developing ORDS. This committee also prepared the syllabus material in Appendix 2. These documents will be further developed by CORD, and NIOSH will be publishing a revised version of this syllabus shortly. A 100-page booklet providing a broader perspective of ORDS is being considered by CORD for publication.

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Section 3

PRELIMINARY STUDIES OF DATA RETRIEVED BY DR. KERN

As indicated above, Dr. Kern audited the medical records of 41 asbestos workers and a random sample of 41 nonasbestos workers at Wood River, who had spirometry tests as a part of the voluntary periodic examination program. For each asbestos worker, Dr. Kern made a data sheet with a column for each year and a note on the right side indicating the worker's age in 1978 and his or her smoking history (years and packs per day). In each column he listed the laboratory-reported measured FVC and $FEV_{1.0}$ (liters to the nearest tenth), predicteds, percent of predicteds, ratio of the $FEV_{1.0}$ to FVC, and a brief summary of the chest x-ray report.

My analysis of this data differed somewhat from Dr. Kern; however, we reached similar conclusions. I noted that among the asbestos workers, 29 of 41 were below 80% of predicted FVC at one or more of the annual spirometry tests. I doubted that the predicted values were accurate (perhaps the values were from different equations, retrieved erroneously, or recorded incorrectly at the laboratory). In my tabulation of the results from 41 nonasbestos workers, 31 of the 41 had FVC values less than 80% of predicted. I found about the same fraction of current or former smokers among the two groups (21/31 in nonasbestos workers and 21/29 in asbestos workers).

In scanning the FVC and $FEV_{1.0}$ measured data on the asbestos workers, I noted that most of the low FVC values (compared with predicteds or compared with previous years' measured FVCs) had occurred in the past 2 years. I also noted that in the first year in which the new machine was used at Alton Memorial Hospital (1976), many asbsetos workers who had been tested 2 years previously at St. Joseph Hospital had significant increases in FVC. This increase indicated that the tests at Alton may

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have been inaccurate in one direction in 1976 because of a problem in calibration equipment and in another direction in 1977 and 1978 because of premature terminations (or submaximal efforts) due to poor technician performance. To test this hypothesis, I identified 21 of the 41 asbestos workers who had spirometry data all 5 years.

The 5-year grand mean for FVC was 3.74 l, and for FEV, 2.96 l. The expected age decrement for FVC would be about 0.20 and 0.35 l, respectively, for the 5-year period (this estimate would depend greatly on the level of cigarette smoking for the 21 persons, plus the "aging effect" on an active working population of males at average age of 50.7 ± 9.7 years). Thus, one would expect the asbestos workers, if no asbestosis were occurring, to show 1974-initial FVC values of about 3.84 l and 1978 values of 3.64 l--the difference of 0.20 l being due to aging and smoking. This population showed a remarkably higher average decrement of 0.91 l (from 3.90 to 2.99 l). The $FEV_{1.0}$ decrement from 3.08 to 2.65 l (or 0.43 l) is not unexpected. These results are consistent with the hypothesis that 1978 FVC values are artifacts due to premature terminations of effort.

Also included in my analysis of these 21 asbestos workers was a comparison of mean $FEV_{1.0}$ and mean FVC values. This comparison was performed to identify any trends for each year of spirometry testing. For $FEV_{1.0}$ the first 3 years are all similar, but the next 2 years appear to show a remarkable decrement. The only additional observation on $FEV_{1.0}$ is the remarkable increase in standard deviation for 1976, suggesting some difficulty with the electronics of the spirometer during the first few weeks of its use at Alton Memorial Hospital. The more impressive results are evident in the FVC mean values for 5 years: the highest value was in 1976 and the standard deviations for 1976 and 1977 are both much higher than usually observed in a male workforce. Again, the suspicion of equipment problems in 1976 is evident from scanning across the 5 years of FVC values for each person, noting how frequently the value for that year appears to be an outlier.

In summary, I reviewed a recent audit of Dr. B. J. Kern. In general, Dr. Kern and I agreed that something was peculiar in the spirometry data. In the 1976 data I found an increase in spirometry variance, associated with numerous high outliers and high mean values, all of which suggest equipment and calibration errors. I also noted low FVC values in 1977 and 1978, which strongly suggests poor technician performance because of premature terminations. The principal question at the time of my visit to Wood River on February 8, 1979, was whether Dr. Mitchell was aware of the above audit problems, whether his lack of any clinical diagnoses of restrictive lung disease reflected this lack of confidence, and whether we could confirm that the spirometry data collected at Alton Memorial were as deficient as they appeared. The general thrust of the above analysis was reviewed with Dr. Ross on February 7, 1979, and plans were made for meetings and data collection the next day at the Wood River refinery.

Section 4

OBSERVATIONS OF SPIROMETRY TESTING AT THE THREE HOSPITALS

On February 8, 1979, Dr. Ross and I met with the company representatives most reponsible for plant safety and health: Messrs. Porter Slack, Jim Gibson, Perry Rawlins, and Dr. Mitchell. After brief introductions I asked Dr. Mitchell to review the Occupational Respiratory Disease Surveillance (ORDS) program and his assessment of it. Dr. Mitchell stated his deep concern about the validity of the spirometry data obtained at Alton Memorial, and also suggested that he might have more confidence in spirometry as a tool if Dr. Mohyuddin, an internist specializing in pulmonary diseases at St. Joseph and St. Anthony hospitals, were to help direct the pulmonary laboratory technician providing these data. He reported discussions with the Alton technician, J. Dingerson, suggesting that she had difficulty in obtaining good patient cooperation in the time available. We discussed several other background issues, and then proceeded to Alton Memorial, St. Anthony, and St. Joseph hospitals where I asked each technician to perform spirometry tests on me.

At Alton Memorial, after the results of my first trial were recorded, I was instructed by the technician, J. Dingerson, that no further trial was necessary since my results were well above 50% of predicted for both $FEV_{1.0}$ and FVC. The predicteds came from a sliderule estimate, not from tables provided by corporate medical offices. I purposely gave a submaximal effort on this trial, and asked her if she noted anything on the test. She only repeated that the results were good, based on the 50% rule-of-thumb provided to her by an anesthesiologist who is her advisor. I asked her about mechanical calibration and a graphic record and found she was unfamiliar with the need for either. Since I knew the reported $FEV_{1.0}$ and FVC values were low, I asked if I could do the test again; when my second trial results were more than 22% better, I asked for her comment. She reported that she did not feel

that another trial would be necessary, not understanding the fact that reproducibility is the hallmark of maximal effort. Since my true FVC value (BTPS corrected) is 7% lower than that reported by Ms. Dingerson, based upon my second trial at Alton Memorial, I judged the equipment to be out of calibration and that it was consequently over-estimating true volumes considerably. Since the $FEV_{1.0}$ reading on the spirometer was 16% too high, the equipment may have had a 1-second trigger delay.

At St. Anthony and St. Joseph hospitals, the technicians had better equipment, knew how to do a reasonably good test, and recognized my submaximal effort on the first trials. At neither hospital was the equipment calibrated by approved techniques, however.

In summary, we visited three hospitals and found the required instrument calibration procedures were not in force at any of the pulmonary laboratories. The equipment that we were tested upon at St. Anthony and St. Joseph hospitals was almost identical except for the fact that the spirometer at St. Joseph had been inactivated and may have had a drag on the timing gears that would be repairable. The equipment at Alton Memorial Hospital was grossly inadequate and appeared to be 7% out of volume calibration and probably had an additional delay in the 1-second trigger. No graphic record was provided from tests at Alton, whereas the records at the other two hospitals were available for me to check on equipment and technician. The technician performance at St. Anthony and St. Joseph hospitals was excellent but could be improved. The technician performance at Alton Memorial was grossly inadequate.

Section 5

RECOMMENDATIONS

Proposed Spirometry Standards and Related Support for ORDS

The Wood River ORDS program should be integrated into a corporate-wide medical program, which would include the following points:

- For spirometry testing of asbestos workers, the technicians/nurses performing the test must be certified, which would establish that they had a basic, practical understanding of the quality testing and calibrating requirements.
- The equipment must also be certified and maintained in calibration.
- The test results must be reviewed for reliability and interpretation, using locally understood endpoints, plus a corporate technician and computer system to recheck calculations and inferences.
- The local plant physicians must learn to interpret test results and know what followup studies are indicated.
- The medical supervisors of these physicians must provide guidance and support for the program, both in the field as well as in the corporate facility.
- Nonmedical employees and managers must have a written plan for developing these needs and maintaining the ORDS program.

Certification of spirometry testing personnel: We recommend a corporate-wide training course be held in Houston under the CORD certification program. Prior to this course, certain information should be gathered from all locations having an asbestos ORDS program. Where appropriate, the plant physicians should be included in a portion of the 2-3-day program. A Shell syllabus should be circulated prior to the first training program, and a pretest examination might also be useful. *I urge that no spirometry testing under the Shell ORDS be done in 1980 by noncertified persons.*

Certification of equipment and implementation of a calibration program: The first step in equipment calibration would be to adopt minimum equipment requirements consistent with the ATS and ACCP standards for forced expiratory spirometry. One way would be to purchase a small calibration packet with instructions and mail the packet from one place to another for local use. Another way would be to detail this packet together with a technician or nurse who would check the calibration and also check the examination, techniques, calculations from graphs, and the interpretation of data. I recommend that equipment requirements and calibration procedures be prepared and signed by the corporate medical director prior to the training course. *I urge that testing in 1981 and thereafter be performed only on certified equipment that has a current calibration.*

Corporate interface and software support: The Ross system must be expanded to handle the broader list of raw data indicated in the previous section, as well as to provide algorithms to verify local reliability checks and rating flags. The role of corporate and regional offices would need to be defined with respect to feedback of the data base to the users at the local level in a manner that promotes morale. *I recommend a well-documented computer program be prepared and that the corporate software package and documentation be in regular use for all data obtained in 1980 and thereafter.*

Physician diagnostic criteria and referral assistance: Integration of the various portions of ORDS program is essential, not only regarding clinical criteria but also for the local chest consultants who may be called to assist when needed. *I recommend that data be gathered from all Shell plant physicians regarding the diagnostic criteria that they are using, as well as the local chest consultants they are using. These data should be analyzed by corporate medical staff and disseminated back to the local physicians.*

Management support: As a followup to the memorandum of January 4, 1974, I believe a communication from corporate to local managers would be helpful if it would focus on spirometry testing and its importance in asbestos ORDS. The memo should outline some of the above plans and accomplishments.

Data Obtained in Wood River

Retrospective--1978 data and all prior data: Based upon my analysis to date, I have much less confidence in the 1976-78 spirometry data than in the 1974 and 1975 data. I am unsure as to how data was collected in 1973, but my presumption is that it is equivalent in quality to that obtained in 1974 and 1975. To be sure about the data in 1973-75, I recommend that samples of the graphs for these years be copied and reviewed.

With respect to the 1976-78 examinations, I urge that all spirometry data be declared invalid. Specifically, the medical charts should be so noted and all computer-processed data should be asterisked, indicating it as unreliable. Communications to workers, managers, and local community physicians should be planned, as appropriate, based upon further studies of the data and recommendations herein.

Prospective--1979 data and henceforth: Two long-term alternatives would be to internalize spirometry testing or to obtain such data by contract from one of the three hospitals visited in Alton. Dr. Mitchell and plant management at Wood River should select either of the two laboratories other than Alton Memorial and proceed to obtain 1979 spirometry testing after the selected laboratory technician telephones me for instructions. I believe it more important to solidify the raw data aspect and to defer temporarily the central software package. This would mean an early corporate decision on a training program and whether or not internalizing is possible at Wood River. If the nursing staff is stable and reasonably facile, I would suggest that equipment be purchased and that training be planned for having spirometry done at

the plant dispensary by plant nurses who would be certified this June. *I recommend that no testing in 1980 be done under any contract arrangement without having a satisfactory equipment package (including frequent calibrations) and a fully trained technician, both equivalent to certification (ATS and CORD, respectively).*

After spirometry testing problems have been resolved and standards agreed upon, the data should be fowarded to Dr. Mitchell for his prompt analysis and appropriate action. Dr. Mitchell has suggested that he have a designated chest physician for backup; this suggestion seems sound and should be explored further. Corporate offices need to be advised as to all actions taken by these physicians.

Section 6

SUGGESTIONS FOR FURTHER WORK

Analysis of All ORDS Data on Ten Selected Persons

Prior to my visit to the Wood River refinery and to the three hospitals in Alton, I examined data prepared by Drs. Kern and Ross. I concluded that both the spirometry and the x-ray results were suspect. During my visit, I was only able to assess spirometry equipment and technique, confirming that these data were very likely unreliable for the past 3 years of ORDS. To confirm that the previous spirometry data were satisfactory would require my examining, on a sample basis, the 1973 to 1975 spirograms, if available. The second aspect, that of chest film results, adds two new questions:

- Are the films generally of adequate quality?
- Do the generally negative interpretations stand up under qualified review?

Before leaving the refinery, I left the names of 10 employees and indicated that as a supplement, I would be requesting <u>all</u> raw and derived data on these persons (copies of graphs of spirograms from St. Joseph Hospital, 14 x 17 inch chest x-rays from the two hospitals, and copies of the entire medical records in the refinery medical department). A report on my findings would be submitted within 45 days of my receiving these records. I selected these persons because of the questionable findings reported--thus, they are not a random sample, but a selection of problem cases. The names and basic data are as follows:

Employee	X-ray 1973	1974	1975	1976	1977	1978	Dates Spirometry Performed	Spirometry Results
1	•	+	+	+	-	-	1973-1978	OK
2	•	+	+	+	+	+	1973-1978	Obstructive? Restrictive?
3	•	-	-	-	-	-	1974-1978	Obstructive? Mixed?
4	•	-	-	-	-	-	1973-1978	Restrictive
5	•	-	-	-	-	-	1973-1978	OK
6	•	+	+	+	+	-	1973-1978	Restrictive?
7	•	+	+	-	-	-	1973-1978	Obstructive? Restrictive?
8	•	+	+	+	+	+	1973-1978	Restrictive? Obstructive?
9	•	+	+	-	+	-	1973-1978	Restrictive? Obstructive?
10	•	•	•	•	-	-	1973-1978	Restrictive? Obstructive

+ = clinically significant finding.
- = no clinically significant finding.
• = status uncertain.

Assistance on ORDS at Other Locations, as Needed

The basic thrust of this preliminary report responds to Shell ORDS development at all locations. As I complete the supplemental phase above, I can see benefits in my briefly visiting other locations and helping corporate medical staff in planning a course for all nursing personnel, as well as some plant physicians. As a first step, I have prepared for your office a suggested communication to the various Shell plant physicians. This memo begins with a statement of the general problem of spirometer and technician quality control. An attachment to this is a questionnaire which would give Shell Corporate Medical staff

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certain basic information from each plant location. A followup communication might deal with guidelines and standards that you wish them to follow and the forms to use.

Backup for the Asbestos Surveillance Examinations at Wood River in 1979

Assuming that these examinations are completed by July 1, I would be able to evaluate the spirograms, chest x-rays, and medical examination forms by approximately August 1, 1979. In addition to evaluating the quality of each person's examination, I would make a brief general report on the overall performance of 1979 studies. I would anticipate that this would require approximately 20-25 hours of my time.