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PLAINTIFF'S EXHIBIT

UC-3033

July 3, 1984

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SUBJECT: OSHA ASBESTOS STANDARD - Testimony by H. C. Lewinsohn, M.D.

The attached represents the "final" draft of the testimony, I propose to submit at the informal hearing in Washington, D. C. on July 12, 1984.

Your comments are still welcome!

H. C. Lewinsohn

Hilton C. Lewinsohn, M.D.

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MEDICAL EXAMINATIONS REQUIRED FOR ASBESTOS WORKERS

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Presentation to be made at the informal rulemaking hearing on the Proposed Rule on Occupational Exposure to Asbestos (29CFR, Parts 1910, Federal Register (1984) 49: 14116-14145) commencing on June 19, 1984.

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ABSTRACT:

The techniques which allow persons exposed to asbestos to be kept under surveillance will be briefly reviewed.

The pre-placement evaluation procedure and its usefulness are discussed.

The periodic medical evaluation is described and an outline of the essential requirements is given. The role of radiological surveillance is briefly discussed.

The point is made that both asbestos-exposed persons and their employers place reliance upon physicians to inform them of adverse findings so that decisions regarding alternative employment and future protection can be made in a sound and equitable manner.

Medical surveillance should ideally continue for the life-time of the individual once exposure has been documented.

The incidence of asbestos-related diseases can be greatly reduced by good work practices and engineering controls. The physician is able to intervene at the interface between worker and work and hopefully alter the final outcome to the good.

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INTRODUCTION

My name is Hilton C. Lewinsohn. I am licensed as a physician in the State of Connecticut, in which State I currently reside. My professional qualifications and achievements are recorded in my curriculum vitae previously submitted.

I wish to take this opportunity to place on record my comments on the proposal to revise the OSHA Standard on occupational exposure to asbestos, with particular emphasis on the subject of medical surveillance.

At the present time, OSHA is relying heavily upon a risk assessment based upon "studies of human worker populations and which includes a variety of industrial situations, processes, and fiber types." OSHA chooses to ignore many shortcomings of the studies upon which the risk assessment was based, some of which are the lack of measured exposure data, an inability to adequately define the number of exposed persons in the USA, different exposure experiences because of variations in processes and industrial uses in the populations studied, differences between data from different countries in terms of completeness and information sources and finally differences between statistical and epidemiological approaches used by the authors of the epidemiology studies considered in the assessment. As far as I am aware, no populations exist which can be accurately categorized according to exact exposure levels and fiber types to which they were exposed in the United States of America. Such evidence as does exist lacks information about

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persons exposed at the lowest levels of exposure achievable and most dose-response curves have been derived by extrapolating down from documented high exposure levels to theoretically derived lower limits of exposure.

OSHA's assessment of risk may be exagerated in the face of the many open-ended questions about the validity of the data upon which it is based. Commonsense dictates that if length of exposure, latency and respirable dust concentrations, not to mention fiber types which show differences in biological effects, are all factors to be considered, the current level of ignorance about most of these variables is such as to warrant proceeding with caution in the implementation of a more rigorous standard than now exists.

The evidence considered in other parts of the world should be carefully evaluated by OSHA. It would seem reasonable to accept the control limits set in Britain,(1) and recently proposed in Ontario,(2) based on thorough on-going assessment of the facts.

To quote directly from the Report of the Ontario Royal Commission:

> "We find in the cases of chrysotile mining and milling and of general chrysotile manufacturing that the disease risk associated with chrysotile exposure under a 1 f/cc control limit, effectively enforced, involves a projected mortality rate well below the mortality rate that results from industrial accidents in all Ontario manufacturing. It therefore falls well within the bounds of a societally acceptable industrial risk."

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The level at which the standard should be set cannot be accurately determined because of the multitude of conflicting data and the numerous mathematical manipulations of statistical data which have been undertaken. Attainment of this level would be based on personal sampling to be used to obtain measurements of employee exposure. Suggestions which have been made to incorporate a "Permissable Airborne Concentration" should not even be entertained.(3) The present standard has not been in effect for long enough to determine its effect on the incidence rates of asbestos-related conditions. All the data considered is old and relates to happenings during the past 30 or 40 or even 50 years. Political pressures, not scientific considerations, have forced OSHA to propose a new standard. If a new standard is set, it should be one which is feasible and demonstrated as being necessary in the light of current scientific knowledge. Industry has demonstrated that it can meet the present standard. (4)

MEDICAL SURVEILLANCE

I should now like to consider the medical surveillance of persons exposed to asbestos. This dissertation on the medical surveillance of persons exposed to asbestos is in response to OSHA's request for comments in Section VI of the Proposal, namely: "Summary and Explanation of the Proposed Amendments and Other Issues Relevant to the Permanent Standard." Paragraph 11 (Medical Surveillance Program) on page 14126 discusses the proposed action level which will trigger the need for a medical surveillance program (a), and itemizes a number of proposed policy decisions [(b) - (e)]. These proposals are

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discussed in this document although not necessarily in the same sequence as in the NPR.

Exposure to asbestos in various industries and occupations has been associated with three major lesions involving the intrathoracic organs.

Asbestosis, first recognized at the beginning of this century, is a form of interstitial pulmonary fibrosis which has been shown to be related to the airborne asbestos levels in the workplace and to be dependent upon the duration of such exposure.

Lung cancer in heavily exposed workers in industries such as insulation, construction, ship-building and asbestos textiles manufacture, has been adequately documented and related to asbestos exposure.[5] Asbestos exposed persons who smoke cigarettes appear to have a 50 times greater chance of dying from lung cancer than non-smoking non-asbestos exposed persons.[6]

The third condition to be associated with exposure to asbestos is diffuse malignant mesothelioma of the pleura (or peritoneum).[7] Unlike asbestosis and lung cancer, this rare tumor has been more difficult to characterize in terms of dose-response and pathologic features.

Less clear-cut associations have been described by some observers between asbestos exposure and cancers involving the gastro-intestinal tract[8,9] and cancers in other organs such as the larynx[10] or renal organs.[11]

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Cancer of the ovary in women has been ascribed to asbestos exposure.(12) It is suggested that the cases described were actually of peritoneal origin and due to malignant mesothelioma of the peritoneum.(13) It may be difficult to distinguish ovarian carcinoma from peritoneal mesothelioma.

The asbestos-related diseases are not readily amenable to therapy. Asbestosis is slowly progressive, the outlook for the person with lung cancer is very poor and diffuse malignant mesothelioma of the pleura or peritoneum is invariably fatal within a short period of time after diagnosis. The physician practicing in the industrial environment can, with diligence and perseverence, exert a positive influence on the protection of the health of exposed workers.

Physicians whose practice includes providing a service to industry must have the confidence of workers and management, must be completely familiar with the properties of asbestos in use, must understand the manufacturing processes in the plant and have a clear concept of the plant design and layout. The doctor who has taken the trouble to become knowledgeable in this way will be better equipped to assist in the management or the health of people at work. In addition to gaining practical experience of the workplace the physician also needs to gain a thorough working knowledge of the etiology, pathogenesis, epidemiology and therapy of asbestos-related diseases. The physician should acquire a working knowledge and appreciation of the theory and practice of industrial hygiene, including an understanding of sampling and monitoring procedures.

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The role of the physician is to assist industry to employ people who are suited to the tasks required of them, and to provide for their continued medical surveillance.

PRE-PLACEMENT MEDICAL EVALUATION OF PERSONS EXPOSED TO ASBESTOS

In general the pre-placement medical evaluation is designed to determine the suitability of the prospective employee for the job under consideration. When asbestos exposure is likely, the workplace conditions must be known before intelligent decisions can be reached concerning a prospective employee with medical contra-indications to such employment. As the result of experience already gained in the development of medical surveillance programs, the suitability of prospective employees for the specific tasks in question may be estimated and based upon defined selection criteria.[14] Applicants should be evaluated regarding their suitability for employment in an occupation with potential asbestos exposure and where appropriate if any restrictions need to be imposed on medical grounds they should be indicated to the applicant and the employer prior to placement. There are certain broadly defined conditions which may contraindicate employment which need to be carefully evaluated: a history of previous work in another industry with a recognized dust hazard, any existing impairment of pulmonary function, the presence of obstructive airways disease with or without emphysema, asthma, and organic heart disease. Other suggested contraindications are: (1) Nasal obstruction or deformity of such a degree as to make the wearing of a dust mask difficult or impossible, (2) gross physicial deformity of the chest such

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as scoliosis or kyphosis, or as a result of thoracic surgery, (3) chronic bronchitis, bronchiectasis or emphysema, (4) gross hypertension with cardiac impairment and (5) the presence of rheumatoid arthritis. (15,16)

Apart from identifying people who should not be employed in dusty work, the pre-placement evaluation serves the purpose of establishing base-line data for longitudinal prospective follow-up. The data which should be incorporated in the medical records for this purpose are summarized in Tables 1 and 2.

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Table 1

Identification characteristics for the establishment of a data base for long term follow-up of asbestos workers.

A. 1. Name (include maiden name, if any, for married women)
   2. Identification number (social security number, etc.)
   3. Date of Birth
   4. Place of Birth
   5. Address

B. 1. Name of spouse
   2. Identification number of spouse (social security number, etc.)
   3. Spouse's date of birth

C. 1. Names, dates of birth, addresses and identification number of children

D. 1. Employee's company I.D. number (clock no., etc.)*
   2. Employee's occupation (job description, including raw materials handled)
   3. Latest dust levels in job department

* The employee I.D. number should never change and should be reallocated to the same employee upon rehiring after termination of employment.

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Table 2

Minimum information to be recorded to establish a data base for long term follow-up of asbestos workers.

Complete, detailed, occupational history since leaving school

Family history

Smoking history

Social history (drugs, alcohol, etc.)

Previous illnesses of note, especially respiratory ailments

Detailed respiratory symptoms history (MRC or ATS Respiratory Symptoms Questionnaire or modification thereof)

Vital and physical signs

Special investigations: 17" x 14" Postero-anterior chest roentgenogram*

Measurement of lung function (ventilatory capacity, lung volumes, gas transfer, etc.)

Sputum cytology (optional test, value not proven)

Measurement of angle between nail and cuticle to document appearance of clubbing of fingers.

* Oblique views, and occasionally lateral views, may be required to clarify pleural abnormalities.

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Where appropriate, the physician should take the opportunity to counsel and advise regarding the known facts about asbestos-related diseases. It is essential to emphasize the special risks the person will run if he or she works with asbestos and smokes cigarettes. Every effort should be made to discourage the tobacco habit.

It has previously been pointed out that the pre-placement medical evaluation "is an essential tool for use in the medical supervision of asbestos workers because it establishes the principles upon which future management will be based. It gives the prospective applicant an insight into the seriousness of the problem and enables the physician to recommend suitability, limited suitability or total unsuitability of the individual for the job. The opportunity which the pre-placement physical examination provides for the medical staff to counsel the individual and establish rapport is unique and should not be missed. This period in the career of the job applicant provides the best opportunity for the recording of identification details and verifying them, in order to establish the data base for long-term follow-up."[16]

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PERIODIC MEDICAL EVALUATION

Persons exposed to asbestos in their occupation should be kept under medical surveillance. The object of periodic examinations is not only to determine changes in the physical condition, physiological status or radiological appearances of the exposed person but also to re-evaluate the workplace conditions and the individual's suitability to continue doing the same job. Medical findings can be recorded on an ongoing basis to allow comparison from one examination to the next. The periodicity of the evaluation process will depend upon demonstrated need and regulatory requirements.

The Occupational Safety and Health Administration promulgated the Asbestos Standard (CFR 1910.1001) in July 1972. [17] Section 1001 (j) (3) requires that every employer shall provide, or make available, comprehensive medical examinations to each of his employees engaged in occupations exposed to airborne concentrations of asbestos fibers. Such annual examinations shall include, as a minimum, "a chest roentgenogram (posterior-anterior 14 x 17 inches), a history to elicit symptomatology of respiratory disease, and pulmonary function tests to include forced vital capacity (FVC) and forced expiratory volume at 1 second ($FEV_{1.0}$)."

Periodic medical evaluation is designed to detect the biological effects of inhalation of asbestos as early as possible, and hopefully, at a stage when removal from further occupational exposure to asbestos may arrest or

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significantly delay the progress of asbestosis or the occurrence of other asbestos-related conditions.[18]

The periodic evaluation should include a physical examination even though the present OSHA standard does not specify it. The examiner should concentrate on the physical signs associated with pulmonary fibrosis such as bilateral end-inspiratory fine crackles at the lung bases, finger-clubbing and breathlessness. Transient pleural effusions occur in asbestos workers. In the case of long-service employees, especially heavy-smokers, the possibility of lung cancer should always be borne in mind.

The aim of radiologic surveillance of asbestos workers is to compare serial roentgenograms taken throughout the exposure period at regular intervals in order to detect the earliest changes. Radiographic evidence of predominantly basal diffuse interstitial fibrosis is the characteristic change seen in asbestosis. The Medical Advisory Panel (MAP) of the Asbestos International Association has prepared a document entitled "Criteria for the Diagnosis of Asbestosis and Considerations in the Attribution of Lung Cancer and Mesothelioma to Asbestos Exposure".[19] MAP recommends that to ensure comparibility of radiographs they must be of good technical quality, of full size (14"x17") and both costo-phrenic angles should be visible. Ideally, inspiration should be such as to have brought the diaphragm below the fifth rib anteriorly and the tenth rib posteriorly. The recording of changes on the radiograph should be in accordance with the ILO International Classification of Radiographs of Pneumoconioses (1980).[20]

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Pleural lesions are often the first radiological indicator of exposure to asbestos. These changes may consist of diffuse or localized pleural thickening. Circumscribed pleural plaques, with or without calcification, may occur and may not be associated with obvious parenchymal fibrosis. The pleural abnormalities can be sufficiently extensive to obscure the lung fields and may, in rare cases, lead to impairment of lung function.

Pleural plaques develop in the parietal pleura, seldom cause disability, and are not considered to be a compensable condition in certain countries, eg. Britain. Pleural effusions may be transient but some are chronic and may recur.

Diffuse pleural thickening associated with exposure to asbestos has become increasingly recognized. Both pleural layers are affected and restrict the expansion of the lung. The diagnosis depends on the exclusion of other causes such as tuberculosis and other infections, collagen diseases, trauma, chronic uraemia, and drug induced fibrosis.

It has been shown that whereas parenchymal radiographic patterns change in relationship to dust concentrations experienced over the course of time, pleural changes are related to length of exposure, irrespective of dose. Pleural changes probably represent an important radiologic sign which is part of a constellation of changes observed in low-grade exposure groups where parenchymal effects are less likely to be seen.(21)

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Weill[22] has attempted to evaluate the basis for clinical decision making by the physician evaluating patients who have had occupational exposure to asbestos. In an asbestos worker definite radiographic evidence of diffuse pulmonary fibrosis, even if it is minimal in profusion or extent, should be an indication to advise the individual that further exposure to asbestos may increase the probability that the condition will progress with time. The greater the past cumulative exposure, the higher the probability of progressive pulmonary fibrosis according to Weill. Cessation of exposure is thought likely to minimize the degree of progression of fibrosis and, because the excess risk for development of respiratory cancer has been shown to be dose-related, this may also be minimized by not adding further to the lung burden of individuals with radiographic signs of asbestosis.

Pleural thickening and pleural plaques are apparently related to length of exposure and the lapsed time period since first exposure, but not to dose, and are not therefore likely to be influenced by modest additional exposure. Weill believes that when only pleural stigmata of asbestos exposure are present, continued medical surveillance and periodic evaluation are necessary but job transfer is not required. The individual should be told about the pleural lesions which have been noted so that any subsequent election to change to a job without further asbestos exposure can be considered if so desired.

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In the periodic medical evaluation of asbestos exposed persons it is recommended that tests of lung function be used to determine the earliest possible effects resulting from such exposure. The measurement of the timed vital capacity components, namely, forced vital capacity (FVC), forced expiratory volume in the first second of expiration ($FEV_{1.0}$) and the ratio of these ($FEV_{1.0}/FVC$), should be routinely recorded. A restrictive pattern is consistent with the development of pulmonary fibrosis (asbestosis) but other causes should first be ruled out. A predominantly obstructive pattern is uncommon in the absence of a smoking history. A comparison of periodic lung function test results over a number of years is of much greater value in the follow-up of an individual than a single observation where comparisons can only be made with the "predicted normal value". Where facilities exist for more complete studies they should at least include measurement of lung volumes and the single-breath carbon monoxide diffusing capacity.

No mention has been made thus far of the role of sputum examination for exfoliative cytology. A proposal has been made in the United States that this should be performed routinely on persons with 10 or more years of exposure to airborne concentrations of asbestos fibers or who are 45 years of age or older.[23] A large-scale multi-institutional program designed to evaluate periodic screening for early stage bronchogenic carcinoma among asymptomatic asbestos workers is currently in progress.[24] Interim results do not indicate that sputum cytology is of overall benefit for screening individuals and "early data from studies of smoking men at high risk of lung cancer indicate that only one fourth of asymptomatic lung cancers are detected by

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sputum cytology and the remainder are detected by chest radiography." At this point in time, sputum cytology should not be included in the routine medical surveillance of asbestos workers.

The value of the periodic medical evaluation depends upon the manner and thoroughness with which it is performed. The standardization of the protocol will enhance its early diagnostic capabilities.[25] The strictest attention must be paid to the detail of radiologic and physiologic methods employed.

CONTENT OF A MEDICAL SURVEILLANCE PROGRAM

Table 3 illustrates the complexity of designing an adequate medical surveillance program which satisfies the needs described in the preceding pages of this document.

The periodicity of the various components of the surveillance program is based on current thoughts and understanding of the subject within the international medical community. These thoughts are set forth in Table 4 - 7 which summarize the data in Table 3 according to the type of examination, its content and periodicity.

It has been known for many years that asbestosis is one of the effects of exposure to respirable airborne concentrations of asbestos fibers. Furthermore, it is accepted that a dose-response relationship can be demonstrated for the radiologic features of asbestosis in terms of length of

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TABLE 3

PROPOSED MEDICAL SURVEILLANCE OF PERSONS EXPOSED TO ASBESTOS: PERIODICITY OF PROCEDURES

TYPE OF PROCEDURE	PRE-EMPLOYMENT OR PRE-ASSIGNMENT	PERIODIC					
		AGE			EXPOSURE		
		35	35-45	45	5	5-10	10
Medical History (Respiratory Symptoms Questionnaire See Ap. B1 & B2)	Obligatory	ANNUAL	ANNUAL	ANNUAL	ANNUAL	ANNUAL	ANNUAL
Physical Examination	Obligatory To include examination of Respiratory System and Digestive System	Every 5 Years	Every 2 Years	ANNUAL	Every 5 Years	Every 2 Years	ANNUAL
Chest Radiology (PA view 14" x 17") See Appendices C1 & C2)	Obligatory (Not required if recent film available, i.e., within preceding 12 months)	Every 5 Years	Every 2 Years	ANNUAL	Every 5 Years	Every 2 Years	ANNUAL
Pulmonary Function (FEV_1, FVC, FEV_1/FVC %) See App. D1 & D2	Obligatory	Every 5 Years	Every 2 Years	ANNUAL	Every 5 Years	Every 2 Years	ANNUAL
Other e.g., Sputum Cytology	Voluntary	N/A	N/A	ANNUAL	N/A	N/A	ANNUAL

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exposure and levels of exposure. Similar dose-response relationships have been demonstrated for lung function and physical findings such as basal rales (crackles). These facts have recently been well summarized.[26,27]

Based upon the knowledge of the dose-response relationship demonstrated, it would appear that the traditional routine of performing an annual medical evaluation of each and every asbestos worker is unnecessary and burdensome upon both employer and employee. With this in mind, the scheme suggested in Table 3 has been proposed to lessen the frequency of medical surveillance procedures by stipulating a periodicity based on either age or length of exposure at or above the proposed action level. It is apparent that young people will be examined less frequently than older persons unless length of exposure overrides age considerations. It is considered reasonable that the annual medical evaluation not be obligatory until either after age 45 or 10 years exposure, whichever occurs sooner.[28]

These suggestions are in keeping with current medical practice especially with regard to the frequency and periodicity of chest x-rays which may pose their own health hazards by unnecessarily exposing employees to radiation, among other reasons.[29,30,31])

The approach adopted is that the employer shall incorporate certain procedures in the medical surveillance of persons exposed to asbestos at or above the proposed action level. These mandatory procedures for pre-employment or pre-assignment examinations, periodic examinations and

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termination examinations are the obtaining of a medical history, which include a respiratory symptoms questionnaire, physical examination of the respiratory system and digestive system, chest radiology and pulmonary function tests.

Insufficient positive evidence exists for the obligatory incorporation of sputum cytology in the medical surveillance program. In the NPR the question is asked as to whether it would be appropriate to screen asbestos exposed persons for colo-rectal cancer, including tests for occult blood in the feces. This question may well be redundant since colo-rectal screening by means of occult blood tests is a routine procedure already incorporated into many employers' medical programs. Recent evidence tends to suggest that the epidemiologic evidence for an association between asbestos exposure and gastro-intestinal tract cancer is very weak and the reason for mandating the incorporation of colo-rectal screening is inadequately supported on these grounds alone.[32] These procedures should not be a mandatory requirement of the proposed medical surveillance program.

On page 14131-2 comments on issues pertaining to medical examinations in the construction industry including, those listed in the general industry discussion, are solicited. In this section of the OSHA proposal the logistic difficulties involved in developing an adequate medical surveillance program are discussed and it is suggested by OSHA that attention should be directed toward developing a generic standard for physical examinations and the identification and documentation of hazardous materials, processes, and work practices in the industry. We cannot support the concept of a generic standard for physical examinations on scientific grounds since it may be contrary to achieving the goals of good medical practice.

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COMMENTS

The prevention of asbestos-related diseases depends upon engineering technology, work practices, administrative controls and use of protective equipment for achieving dust control. The role of the physician is to aid in the prevention of ill-suited job-placement and intervene in a timely manner at the interface between worker and work. The technique of medical surveillance is merely one cog in the wheel which comprises the total effort required to safeguard employee health. The active collaboration of employer, physician and employee in the surveillance program may allow the achievement of significant results which could be of benefit to both.

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TABLE 4

MEDICAL SURVEILLANCE OF PERSONS EXPOSED TO ASBESTOS:

PRE EMPLOYMENT OR PRE-ASSIGNMENT

- MEDICAL HISTORY - RESPIRATORY SYMPTOMS QUESTIONNAIRE
- PHYSICAL EXAMINATION
- CHEST X-RAY (PA VIEW 14" X 17")
- PULMONARY FUNCTION TESTS (FEV_1, FVC, FEV_1/FVC%)
- SPUTUM CYTOLOGY IF INDICATED AND FEASIBLE

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TABLE 5

MEDICAL SURVEILLANCE OF PERSONS EXPOSED TO ASBESTOS:

PERIODIC EVALUATION : 35 YEARS OF AGE OR 5 YEARS EXPOSURE

- o MEDICAL HISTORY - RESPIRATORY SYMPTOMS QUESTIONNAIRE: ANNUALLY
- o CHEST X-RAY - (PA VIEW 14" x 17")
- o PHYSICAL EXAMINATION EVERY 5 YEARS
- o PULMONARY FUNCTION TESTS (FEV_1, FVC, FEV_1/FVC%)
- o SPUTUM CYTOLOGY - NOT INDICATED

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TABLE 6

MEDICAL SURVEILLANCE OF PERSONS EXPOSED TO ASBESTOS:

PERIODIC EVALUATION : AGES 35-45 YEARS OR 5-10 YEARS EXPOSURE

- o MEDICAL HISTORY - RESPIRATORY SYMPTOMS QUESTIONNAIRE: ANNUALLY
- o PHYSICAL EXAMINATION
- o CHEST X-RAY - (PA VIEW 14" x 17") EVERY 2 YEARS
- o PULMONARY FUNCTION TESTS (FEV_1, FVC, FEV_1/FVC%)
- o SPUTUM CYTOLOGY - IF INDICATED BY SMOKING HISTORY OR OVER AGE 40 YEARS

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TABLE 7

MEDICAL SURVEILLANCE OF PERSONS EXPOSED TO ASBESTOS:

PERIODIC EVALUATION : 45 YEARS OF AGE OR 10 YEARS EXPOSURE

- MEDICAL HISTORY - RESPIRATORY SYMPTOMS QUESTIONNAIRE: ANNUALLY
- PHYSICAL EXAMINATION: ANNUALLY
- CHEST X-RAY - (PA VIEW 14" x 17"): ANNUALLY
- PULMONARY FUNCTION TESTS (FEV_1, FVC, FEV_1/FVC%): ANNUALLY
- SPUTUM CYTOLOGY - IF FEASIBLE: ANNUALLY

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