

ORIGINAL BOARD RECOMMENDATION (APRIL 2017)

Advisory Board on Toxic Substances and Worker Health Recommendations – Adopted at April 18-20, 2017 Meeting

Recommendation #1

Presumptions for Asbestos-related Diseases

1. All DOE workers who worked as a maintenance or construction worker at a DOE site for 250 days or more prior to January 1, 2005 and who are diagnosed 15 years or more after the initiation of such work with 1 of 5 asbestos-associated conditions will be presumed to have had sufficient asbestos exposure that it was at least as likely as not that asbestos exposure was a significant factor in aggravating, contributing to, or causing such asbestos-associated conditions. The five asbestos-associated conditions are asbestosis, asbestos-related pleural disease, lung cancer, and cancer of ovary and larynx.
2. All DOE workers who worked as a maintenance or construction worker at a DOE site for 30 days or more and who are diagnosed 15 years or more after the onset of such work with malignant mesothelioma of any bodily site will be presumed to have had sufficient asbestos exposure that it was at least as likely as not that asbestos exposure was a significant factor in aggravating, contributing to or causing the malignant mesothelioma.
3. All claims for one of the six asbestos-associated conditions named above that do not meet the exposure criteria described in items #1 and #2 above will be referred to an industrial hygienist for exposure assessment and to a CMC for evaluation of medical documentation and causation. These six conditions are asbestosis, asbestos-related pleural disease, malignant mesothelioma, lung cancer, and cancer of ovary and larynx.
4. Chronic obstructive pulmonary disease may have a contribution from asbestos exposure. However, claims for this disease should be evaluated as part of a broader set of presumptions for chronic obstructive pulmonary disease.

Exposure criteria	Asbestos-specific Diseases <u>Mesothelioma</u>	Asbestos-specific diseases <u>Asbestosis,</u> <u>Asbestos-related pleural disease</u>	Other Asbestos-related Cancers <u>Lung cancer,</u> <u>Cancer of ovary and larynx</u>
Duration	≥ 30 days	≥ 250 days	≥ 250 days
Job titles	Maintenance Construction	Maintenance Construction	Maintenance Construction
Calendar years	Pre-2005	Pre-2005	Pre-2005
Latency (minimum)	15 years	15 years	15 years

Rationale

The Departments of Labor and Energy recognize that asbestos was used extensively throughout the Departments of Energy (DOE) complex. The DOE Former Worker Program has documented that 11.9% of 78,894 DOE workers screened between 1998 and 2016 had chest x-ray evidence of non-malignant asbestos-related lung disease, including asbestosis and asbestos-related pleural disease (DOE Former Worker Program Annual Report, 2016). The prevalence of non-malignant asbestos-related lung disease varied considerably, as low as 4% to 5% at some DOE sites or up to one-quarter to one-third of production and construction workers, respectively, at other sites (DOE FWP Report). Recent published studies showed excess lung cancer, malignant mesothelioma (an asbestos-specific cancer), and asbestosis among DOE construction workers (Dement 2009; Ringen 2015). Additional published studies at DOE sites show excess lung cancer among sub-populations of the work force (Frome 1997; Richardson 1999; Silver 2013; Figs 2013).

Asbestos was used in over 3,000 products during the period when it was commonly manufactured in the United States, 1940's to 1980's. Some of its uses are well-recognized, including thermal insulation products, boards, textiles, friction products and cement. Other uses are less obvious, including laboratory counter tops, protective pads, filters, and others. Due to its frequency and sometimes occult nature of its use, proper investigation of a claim for any of the asbestos-related diseases, if consensus exposure

presumptions are not met, requires a detailed occupational history and evaluation by occupational health professionals with substantial knowledge of the asbestos exposure and related diseases.

There is a well-established medical literature documenting non-malignant and malignant asbestos-related diseases among construction workers and industrial and commercial maintenance workers in the United States. The asbestos-related disease experience among such workers at Department of Energy sites, thus, matches a much more comprehensive experience with general industry, which provides confidence in setting the recommended exposure presumptions based on the broad occupational groups (i.e., maintenance and construction) elaborated above.

Asbestos-related diseases generally increase in frequency with increasing exposure to asbestos (Algrante 2016; Markowitz 2016). As such, setting a specific period of exposure (e.g., 250 days) is approximate but reasonable for the purpose of setting an exposure presumption. It should not be construed as representing a precise limit separating those with risk from those without risk. It accords with the underlying scientific knowledge and represents a practical element for application of a set of presumptions to claims evaluation. Recommending such a time limit should not be construed as signifying that asbestos exposure for less than the specified time period is without risk. For claims with asbestos exposure less than the recommended period, evaluation of a history of asbestos exposure by an industrial hygienist will yield information about frequency and intensity of exposure, in addition to exposure duration, and allow a more informed decision about the claim.

Malignant mesothelioma is known to occur following relatively brief exposure to asbestos, thus permitting the setting of a shorter period of exposure as a presumption of significant exposures (i.e., 30 days) (Helsinki 1997; Welch 2007; Markowitz 2015). A minimum latency of 15 years for all asbestos-related diseases is supported as a presumption by extant medical literature; claims asserting a latency period less than 15 years can be evaluated on an individual basis.

Setting a calendar year as representative of a specific time demarcation when exposure was categorically lowered is inherently problematic. It is highly attractive for assessing exposure in claims evaluation but fails to recognize that exposure reduction occurs over time, usually a number of years. However, entirely disregarding calendar years in assessing exposure for the purpose of establishing presumptions fails to recognize that exposure to asbestos has, for many workers, diminished over time. A feasible and knowledge-based compromise is to build in a safety margin in setting a calendar time element in exposure presumptions. In 1994, OSHA lowered the permissible exposure level of asbestos in the workplace. In 1995, DOE issued a new order regarding occupational health and safety in the DOE complex. It is reasonable to posit that it required a decade of dissemination and diffusion of knowledge, attitudes and practice with regard to asbestos use such that exposure to asbestos was decisively diminished across the vast majority of workers at DOE facilities. Thus, we recommend 2005 as a year to demarcate likely significant asbestos exposure, recognizing that exposures after

2005 might be significant and will be evaluated by occupational health professionals as part of the individual claims evaluation.

Chronic obstructive pulmonary disease may have a contribution from asbestos exposure but is better evaluated in the claims process in accordance with a broader policy that addresses the large number of exposures that can aggravate, contribute to, or cause chronic obstructive pulmonary disease.

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Department of Labor Responses to Recommendations from the April 2017 Public Meeting of the Advisory Board on Toxic Substances and Worker Health

Response:

With regard to Recommendation #1-1, OWCP agrees that the 250-day aggregate duration of exposure is a reasonable standard to apply when assessing presumptive standards for asbestos related health effects pertaining to the following five asbestos-associated conditions: asbestosis, asbestos-related pleural disease, lung cancer, and cancer of ovary and larynx.

OWCP currently makes a distinction between *exposure* presumptions and *causation* presumptions. The Division of Energy Employees Occupational Illness Compensation (DEEOIC or the program) has determined that certain presumptions may be made as to the nature, frequency, and duration of a specific *exposure*. Presumptions are based on knowledge and evidence OWCP has obtained through industrial hygiene, knowledge of labor categories and work processes, and environmental health and safety practices in existence. Therefore, OWCP's exposure presumptions are specific to certain labor categories, work processes, and/or timeframes. If an exposure presumption exists, the claims examiner will apply the criteria to the specified toxic substance. As long as all criteria have been met, the case does not need to be reviewed by an industrial hygienist. With regard to exposure to asbestos specifically, the program recognizes that asbestos is a toxic material that was present in all DOE facility locations; however, OWCP assumes different levels of exposure depending on the employee's labor categories and years of employment. The program has developed a list of labor categories considered to have had significant exposure to asbestos at high or low levels (referred to by the Board as "Attachment 1.") If an employee worked in one of these labor categories before December 31, 1986, the program considers that he or she had significant exposure at high levels. If the employee worked in one of the labor categories between 1987 and 1995, in one of these labor categories, the employee is presumed to have significant exposure to asbestos at low levels. While employees in all other labor categories or during other years of employment are assumed to have had some level of exposure to asbestos, the level of exposure is determined by guidance from an industrial hygienist on a case-by-case basis. OWCP applies these exposure presumptions before applying any causation presumptions.

OWCP currently applies a *causation* standard to the conditions of asbestosis, laryngeal cancer, ovarian cancer, and mesothelioma, using criteria specific to each of these conditions. For all four conditions, in order to apply a presumption that the condition is related to exposure to asbestos under Part E, there must be a medical diagnosis of the condition, and the employee must have been employed in a job that would have brought him or her into contact with significant exposure to asbestos on a day-by-day basis for at least 250 aggregate work days. The exposure can be determined by existing asbestos exposure presumptions, as outlined above, or through an industrial hygiene assessment. The program also applies varying latency periods to each of these conditions: for asbestosis, latency is 10 years after initial exposure; for laryngeal cancer, it is 15 years; for ovarian cancer, it is 20 years; and for mesothelioma, it is 30 years. The program

has not yet created a presumption for lung cancer as it relates to exposure to asbestos; however, OWCP agrees that sufficient literature exists to develop one. OWCP reviewed the Board's recommendation that the latency period for all of the listed conditions be 15 years and agrees to change existing latency standards for all conditions except asbestosis. Since the current latency period of 10 years for asbestosis is more claimant friendly, and OWCP's research confirms this period is scientifically valid, OWCP will retain the existing 10-year latency period.

In developing the labor categories for use in the asbestos exposure presumption, the program primarily relied on the scientific research conducted and compiled by the Agency for Toxic Substances and Disease Registry (ATSDR) within the Department of Health and Human Services (HHS). They published a booklet on January 29, 2014, entitled *Case Studies in Environmental Medicine, Asbestos Toxicity*. Pages 31-32 include a list of occupations they determined to entail significant asbestos exposures. OWCP worked with its contractor, Paragon (who created the SEM) to review the list and tailor it to the labor categories relevant to the DOE complex. The scientists at Paragon are former DOE nuclear workers and very familiar with labor categories at the DOE facilities. OWCP included in its policy more specific definitions where appropriate (like maintenance mechanic instead of maintenance worker), excluded some on the ATSDR list that were clearly not DOE-related (like longshoremen), and further tailored the list to DOE job descriptions.

In determining the causation standards, the program also relied on this publication, along with updated information from the *International Agency for Research on Cancer (IARC)* and articles and publications based on human studies, including the *American Journal of Epidemiology*, the *American Journal of Respiratory and Critical Care Medicine*, the *American Journal of Industrial Medicine*, and the *Journal of Occupational Medicine and Toxicology*.

In reference to the Board's Recommendation #1-2, to apply an asbestos presumption to "all DOE workers who worked as a maintenance or construction worker at a DOE site," OWCP needs additional information and clarification. Included in the Board's reference materials was a listing of 17 construction and trade worker labor categories related to asbestos exposure, 15 of which are already included in DEEOIC's presumptive labor category listing. The two remaining categories include "Teamsters" and "Administrative/scientific/security" jobs. OWCP requests that the Board clarify whether their recommendations are that OWCP should include these remaining two labor categories and whether there are additional specific labor categories that the Board believes should be included in the listing. OWCP also requests that the Board provide the research relied upon that supports the inclusion of the proposed new labor categories.

In reference to the Board's recommendation to apply an exposure presumption prior to January 1, 2005, as indicated above OWCP currently has guidance concerning presumptions to be made regarding the level of exposure to asbestos. Our Procedure Manual states that the claims examiner is to assume high or low levels of significant exposure to asbestos depending on the years of exposure. Anything after 1995 is referred to an industrial hygienist for an individual assessment and then a physician must conduct a medical assessment. Then the program reviews the evidence for causation presumptions, depending on the latency periods. In the Board's presumptions, it is suggesting not only that a presumption be made that the claimant was significantly exposed to asbestos before 2005, but also that the exposure was sufficient to

presume that the asbestos exposure was at least as likely as not a significant factor in aggravating, contributing to, or causing the listed asbestos-associated conditions. While OWCP rescinded EEOICPA Circular No. 15-06, that Circular simply stated that claims examiners should presume that any exposure after 1995 was within safety regulatory limits and therefore need not be reviewed by an industrial hygienist. That Circular did not address causation, and the program has continued to refer cases for an exposure and causation assessment for the listed conditions prior to accepting for causation, where the employee was employed after 1995. The Board recommends changing current guidance to allow for acceptance of these medical conditions under broader circumstances. OWCP agrees to changing current latency periods for all of the conditions as recommended, and to changing the duration of mesothelioma to greater than or equal to 30 days. However, with regard to the 2005 date, OWCP seeks additional clarity as to the underlying research and the rationale supporting the selection of that date as a temporal basis for application in the Board's presumption. While OWCP agrees with the Board that it is difficult to assign a temporal threshold for use in a presumption, more specific documented basis supporting the date of 2005 is necessary to satisfy the legal requirement that all presumptions must have sufficient scientific rationale to withstand judicial scrutiny. Our research indicates that DOE's predecessor, the Atomic Energy Commission, began developing health and safety standards as early as 1973, after the Occupational Safety and Health Act of 1970 was passed. Those standards became longer and more detailed as the dissemination and enforcement of enhanced safety measures progressed over the next two decades. Those safety measures were standardized in 1995 with the issuance by DOE of Order 440.1, and accordingly, we could agree that 1995 creates a clear demarcation date for causation purposes with a solid supporting rationale that would withstand judicial scrutiny. To move that date out to 2005, on the assertion that it likely took another decade for exposure levels to be significantly lower, is much more problematic. The 2005 date, without additional support, places OWCP in a position of being unable to legally defend the presumption, should it be challenged by an employee who only worked *after* 2005. Accordingly, OWCP requests that the Board provide more substantive medical health science justification or specific DOE operational data that supports the scientific basis for its selection of January 1, 2005 as the exposure demarcation date for use in the recommended presumption.

In response to Recommendation #1-3, OWCP agrees that all claims for the six asbestos-associated conditions named above, that do not meet the exposure criteria, should be referred to an industrial hygienist and to a CMC, as appropriate. By way of further answer and clarification, OWCP currently stipulates in program policy that any case assessed for causation under Part E that does not satisfy an established presumptive standard must undergo a case-specific assessment including review by an industrial hygienist and a qualified physician (Reference Guidance in the Procedure Manual, Exhibit 15-4).

The Program addresses Recommendation #1-4 in its answer to the Board's Recommendation #3 regarding chronic obstructive pulmonary disease (COPD) below.

REVISED BOARD RECOMMENDATION (FEBRUARY 2018)

Advisory Board on Toxic Substances and Worker Health, Department of Labor

Revised Recommendations and Comments on Board's October 2016 and April 2017

Recommendations and the Department of Labor Responses

Issues for Consideration by the Future Advisory Board on Toxic Substances and Worker Health

Presumptions for Asbestos-Related Diseases

1. All DOE workers who worked as a maintenance or construction worker at a DOE site for 250 days or more prior to December 31, 1995 and who are diagnosed 15 years (or 10 years in the case of asbestosis) or more after the initiation of such work with 1 of 5 asbestos-associated conditions will be presumed to have had sufficient asbestos exposure that it was at least as likely as not that asbestos exposure was a significant factor in aggravating, contributing to, or causing such asbestos-associated conditions. The five asbestos-associated conditions are asbestosis, asbestos-related pleural disease, lung cancer, and cancer of ovary and larynx.
2. All DOE workers who worked as a maintenance or construction worker at a DOE site for 30 days or more prior to December 31, 1995 and who are diagnosed 15 years or more after the onset of such work with malignant mesothelioma of any bodily site will be presumed to have had sufficient asbestos exposure that it was at least as likely as not that asbestos exposure was a significant factor in aggravating, contributing to or causing the malignant mesothelioma.
3. All claims for one of the six asbestos-associated conditions named above that do not meet the exposure criteria described in items #1 and #2 above will be referred to an industrial hygienist for exposure assessment and to a CMC for evaluation of medical documentation and causation. These six conditions are asbestosis, asbestos-related pleural disease, malignant mesothelioma, lung cancer, and cancer of ovary and larynx.
4. Chronic obstructive pulmonary disease may have a contribution from asbestos exposure. However, claims for this disease should be evaluated as part of a broader set of presumptions for chronic obstructive pulmonary disease.

Rationale

In their response to this Board recommendation, DOL raised several issues:

1. DOL distinguishes between exposure and causation presumptions.

2. DOL requests documentation to justify expansion of List A job titles to the broader categories of “maintenance and construction” titles, as the Board recommended.
3. DOL requests evidence that 2005 should be a threshold date before which significant asbestos exposure can be presumed for selected job titles.

Table: Summary of Recommended Presumptions for Asbestos-related Diseases

Exposure criteria	Asbestos-specific Diseases <u>Mesothelioma</u>	Asbestos-specific diseases <u>Asbestosis,</u> <u>Asbestos-related pleural disease</u>	Other Asbestos-related Cancers <u>Lung cancer,</u> <u>Cancer of ovary and larynx</u>
Duration	≥ 30 days	≥ 250 days	≥ 250 days
Job titles	Maintenance, Construction	Maintenance, Construction	Maintenance, Construction
Calendar years	≤ 1995	≤ 1995	≤ 1995
Latency (minimum)	15 years	10 years	15 years

Board’s Approach to DOL Concerns

1. DOL’s distinction between exposure and causation presumptions represents mainly a linguistic and procedural difference in approach from the Board’s recommendation. The Board’s recommendation essentially modifies DOL’s exposure presumption to define sets of exposure conditions that are sufficient to meet exposure requirements of a causal standard.
2. The Board and DOL agree on the following time-related exposure parameters: >250 days (except for mesothelioma, 30 days) minimum employment; and 15 years of latency, or time between onset of work in a listed job title at DOE and the date of diagnosis of N asbestos-related disease (except for asbestosis, 10 years).

3. The Board provides scientific publications in support of including all DOE-relevant job titles in the maintenance and construction categories in this presumption (see below).
4. The Board has not yet identified surveillance information that supports use of 2005 as a threshold date for presumed significant asbestos exposure. As a default and until such information is identified, the Board recognizes that DOE Order 440.1 issued in 1995 likely served as an important stimulus for change in DOE health and safety policy and procedures. The Board, therefore, agrees to the use of 1995 as a threshold date before which sufficient asbestos exposure occurred among maintenance and construction job titles, assuming the temporal requirements noted above, to meet a presumption of asbestos-related disease.

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**DOL Responses to Advisory Board on Toxic Substances and Worker Health
February 16, 2018 Clarifications to Recommendations**

4. Comments on Recommendation: Revised Recommendation: Presumptions for Asbestos-related Diseases. The Advisory Board recommends that the program add or modify presumptive standards relating to several Asbestos-related diseases. The five conditions are asbestosis, asbestos-related pleural disease, lung cancer, and cancer of the ovary and larynx. The Board also recommends applying the presumption to all DOE workers who worked as a maintenance or construction worker and it has suggested that the presumption standard use 1995 as a threshold date before which sufficient asbestos exposure occurred.

In review of the other recommended presumptions for Asbestos-related diseases, the DEEOIC responds to each as follows:

1. Asbestosis

DEEOIC's existing presumption for asbestosis, that the employee must establish a diagnosis of asbestosis, significant occupational exposure to asbestos for at least 250 aggregate workdays and a 10-year latency requirement, comports to the recommendation of the Board.

2. Lung Cancer

The Board recommended adding a presumption for lung cancer as a health effect of asbestos exposure. DEEOIC agreed to evaluate the matter. DEEOIC's assessment is complete and it will add a presumption to its published procedures. The presumption will stipulate that the employee must establish a diagnosis of lung cancer and that the employee had significant occupational exposure to asbestos for at least 250 aggregate workdays. DOL concurs with the Board's recommendation to apply a 15-year latency requirement.

3. Mesothelioma

DEEOIC agrees to the Board's recommendation to reduce the latency period for the presumption from the current 30 years to 15 years. DEEOIC will also change the exposure duration to ≥ 30 workdays from the current ≥ 250 workdays.

4. Asbestos-Related Pleural Disease

DEEOIC agrees to the Board's recommendation to reduce the latency period for the pleural plaque presumption from the current 20 years to 10 years.

5. Ovarian Cancer

DEEOIC agrees to the Board's recommendation to reduce the latency period for the presumption from the current 20 years to 15 years.

6. Laryngeal Cancer

DEEOIC's existing presumption for Laryngeal Cancer, that the employee must establish a diagnosis of laryngeal cancer, had significant occupational exposure to asbestos for at least 250 aggregate workdays and a 15-year latency requirement, comports to the recommendation of the Board.

The existing presumptions for the asbestos-related diseases already contain the stipulation that the employee had significant occupational exposure to asbestos for at least 250 aggregate workdays. This component of the presumptions matches the Board's recommendation.

DEEOIC continues to have concerns with regard to overly broad labor categorizations, *i.e.*, all maintenance and construction workers, that the Board uses in this recommendation. DEEOIC's current asbestos exposure presumption references a comprehensive listing of *specific* labor categories with significant asbestos exposure. It is the program's position that its existing policy offers more specificity for identifying the particular jobs that had significant asbestos exposure. Moreover, as was explained in DOL's November 9, 2017 response to the Board on this topic, one of the documents the Board references for identifying construction and maintenance labor categories actually lists the same labor categories (except for two) that DEEOIC lists in its presumption. DEEOIC requests that the Board provide any additional, specific labor categories that the Board believes should be included in the existing presumption and the research relied upon that supports the inclusion of the proposed new labor categories.

With regard to the threshold date for presumed significant asbestos exposure, DEEOIC concurs with the Board's recognition that DOE Order 440.1 issued in 1995 likely served as an important stimulus for change in DOE health and safety policy. As the Board agrees to use of 1995 as the threshold date before which sufficient asbestos exposure occurred in qualifying labor categories necessary to make a presumption of asbestos-related disease, there will be no changes to the threshold date in the current DEEOIC presumption.

In consideration of the Board's input, there is a distinction in Part E of EEOICPA between exposure and causation. These are two interrelated, albeit separate and distinct aspects of the overall eligibility question for Part E, as highlighted by the placement of these two issues in separate subsections of 42 U.S.C. § 7385s-4(c)(1) by Congress. For reference, the pertinent section of § 7385s-4, "Determinations regarding contraction of covered illnesses," is as follows: subsection A relates to causation and subsection B concerns exposure. The law combines these two statutory segments with the word "AND," which means that claimants must show both exposure and causation in order for there to be a legally compensable claim:

(c) OTHER CASES.—(1) In any other case, a Department of Energy contractor employee shall be determined for purposes of this part to have contracted a covered illness through exposure at a Department of Energy facility if—

(A) it is at least as likely as not that exposure to a toxic substance at a Department of Energy facility was a significant factor in aggravating, contributing to, or causing the illness; and

(B) it is at least as likely as not that the exposure to such toxic substance was related to employment at a Department of Energy facility.

DEEOIC's claim adjudication processes for Part E focuses on both aspects of this legal stipulation. It is not a matter of "linguistics;" rather, Congress has established, and DEEOIC cannot ignore, the two-pronged eligibility requirement of Part E.