



AUG 23 2018

Dr. Steven Markowitz
Chair
Advisory Board on Toxic Substances &
Worker Health
Queens College, Remsen Hall
65-30 Kissena Boulevard
Flushing, NY 11367

Dear Dr. Markowitz:

I am pleased to send you the Department of Labor's response to the recommendations made by the Advisory Board on Toxic Substances and Worker Health, at the Board's January 2018 public meeting. The Department appreciates the dedication and expertise that the Advisory Board provides to the Energy Employees Occupational Illness Compensation Program and its stakeholders. Your important work is making a difference.

On behalf of the Department, the Office of Workers' Compensation Programs, the Energy program, and the communities we serve, I look forward to the continued efforts of the Advisory Board.

Sincerely,

A handwritten signature in black ink, appearing to read "Julia K. Hearthway".

Julia K. Hearthway
Director
Office of Workers' Compensation Programs

Enclosure

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

1. Comments on Recommendation: Incorporating Agency Health Effects Reviews Recommended by IOM Report into the SEM. The Advisory Board recommends that the program apply different data sources for expanding disease exposure links, including the following: International Agency for Research on Cancer (IARC), Integrated Risk Information System (IRIS), and the National Toxicology Program (NTP). The Board also recommends that the program identify a team that includes individuals with competence in toxicology, occupational medicine, and epidemiology to assess these sources.

DEEOIC recognizes that there are many potential sources of information regarding health effect data, including the specific items referenced by the Board (IARC, IRIS, and NTP). IARC is already an important source of data the program applies to populate the Site Exposure Matrices (SEM) health effect data. DEEOIC accepts all IARC Group 1 (Carcinogenic to human) data for toxins found at covered Department of Energy facilities, and applies that information to the claims adjudication process. Moreover, as IARC publishes updated epidemiological information (IARC Monographs), those publications are screened to determine whether reported SEM health effects require revision. IARC describes Group 1 as carcinogenic, meaning the medical condition was caused by exposure to certain toxic substances in humans. While IARC does provide other classifications of toxic agents, such as “probably carcinogenic” (Group 2A) and “possibly carcinogenic” (Group 2B), the program only applies IARC data that demonstrates a reliable and scientifically compelling *causal* connection between exposure and human health effects (Group 1). Moreover, program policy permits medical specialists wide latitude to make individual determinations regarding the *aggravating* or *contributory* effects of toxic substance exposure to diagnosed illnesses, absent epidemiologically established human health effects.

With regard to the application of the IRIS and NTP databases, the Board has suggested a process for evaluating health effect information maintained in each database. However, the Board does not offer its own analyses of either the credibility or scientific reliability of the materials underlying the findings presented within each database. Each database communicates voluminous and complex data on a range of toxic substance and health effect topics. DEEOIC does not believe it would be appropriate to add these health effect findings to the SEM in the absence of any rigorous and comprehensive investigation of those findings by the Board.

The Board has also recommended that DEEOIC identify a team that includes individuals with competence in toxicology, occupational medicine, and epidemiology to undertake a rigorous process for reviewing sources of information to be inputted into the SEM. However, the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) established an administrative program for the review and adjudication of individual claims, rather than scientific research. As a result, our primary mandate is to adjudicate those claims utilizing trained claims examiners.

While the Program has been able to supplement claims adjudication staff with policy analysts, communication specialists, IT professionals and some scientists, DEEOIC is not a research-centric

organization. Should the Board be in a position to offer more specific guidance regarding the content of data sources that are applicable and appropriate for administration of the EEOICPA, the program would consider that input.

2. Comments on Recommendation: Hiring Former DOE Workers to Administer the Occupational Health Questionnaire. The Advisory Board recommends the program hire former Department of Energy workers at the Resource Centers to better facilitate administration of the Occupational Health Questionnaire (OHQ). The Board also requested specific data regarding the work performed by the former DOE workers that the Resource Centers employ.

DEEOIC currently requires that the Resource Center contractor give hiring preference to qualified former DOE employees or contract staff who have experience working at covered facilities. However, contracting laws prohibit the program from requiring a contractor to hire *only* former DOE employees or contract staff. Although the government has a lot a latitude to require contractors to hire staff with specific skills or experience, federal law and regulations do not allow the government to require employment based solely on previous specific employers or locations of employment. Federal guidance stipulates that such requirements discriminate against potentially more qualified individuals who simply do not have that experience from a single employer or location. Contracting laws require hiring be based on skills, knowledge and experience which in turn leads to the most qualified candidates being selected for available jobs. Prior employer or previous location of employment can be qualifying factors, but not disqualifiers.

Within the legal requirements described above, the DEEOIC requires the Resource Centers to give preferential treatment to hiring former DOE employees and contractors. Per your request for specific data, we are providing more information herein. The position descriptions for the contract employees typically include experience or qualification requirements that read similar to the following: "At least 3 years' experience providing assistance for a federal, private or state workers' compensation program, or working at or for a Department of Energy facility covered by the program." Another statement typically found in the position descriptions for resource center staff is, "Preference given to staff with prior experience working at or for a Department of Energy facility covered by the program." These requirements allow DEEOIC's contractor to hire the most qualified individuals available in any given workforce market where the Resource Center is hiring, while recognizing that if a qualified candidate also has DOE employee or contractor experience, they should receive preference.

The current Resource Center contractor has 13 staff, nationwide, who are also former DOE employees or contractors, and 12 of those are in positions where they assist with completion of the Occupational Health Questionnaires. That means approximately 20% of the current Resource Center workforce has previous DOE employee or contractor experience. The average time spent on completing an Occupational Health Questionnaire is about one hour, but can be longer depending on the amount of information in possession of the respondent or the complexity of the employee's work history.

3. Comments on Recommendations: Claimant Information sent to Industrial Hygiene and Medical Consultants. The Advisory Board recommends that the program provide copies of entire case files to subject matter experts such as industrial hygienists and medical consultants. The Advisory Board further recommends that the claims examiner map the file to indicate where relevant information is believed to be.

The requirements for adjudicating claims for benefits under EEOICPA is a complicated administrative process. The volume of documents associated with claims differ according to the nature of the claim. In some instances, a case file can comprise thousands of documents spanning many decades worth of medical and employment records. Case files can include documents relating to any number of claims filed on behalf of a former employee or survivors of deceased employees.

DEEOIC provides guidance to its staff to best facilitate thorough, and effective, examination of case referrals by medical health experts. The claims examiners often must adjudicate new and varying issues at different times throughout the life of a case. This may include initial decision, subsequent decisions for consequential conditions, evaluation of impairment, and wage loss. It is important that once a decision on one part of a case is made, it is not re-adjudicated in a referral to a specialist on another issue or decision. Therefore, the type of information referred will differ depending on the reason for the referral. With all referrals, whether to scientific or medical specialists, the claims examiner includes a Statement of Accepted Facts (SOAF), in which the claims examiners outline the facts of the case that have been gathered or determined already (e.g. employment and exposure information, conditions already accepted etc.). In addition, with each referral, the claims examiners ask specific questions which require an educated response from the specialist (including references to conflicts in medical opinions already in the file). In those situations, where a claims examiner is seeking a medical opinion in connection with a diagnosis clarification, the examiner is to provide the physician with any medical documentation relating to the condition since its first identification or reference. For all initial causation referrals to a Contract Medical Consultant (CMC), DEEOIC instructs its staff to include in its referral *all* medical records relating to the claimed medical condition, exposure documentation obtained from development, and fact-finding documents prepared by the Claims Examiner. Referrals to Industrial Hygienists include all exposure records obtained from development including claimant submitted evidence, employer information, and any evidence produced by the Claims Examiner, such as Site Exposure Matrices research outputs. For impairment ratings, DEEOIC uses the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, Fifth Edition (the *Guides*), and CMC's must have appropriate training before conducting impairment evaluations. Per the *Guides*, there are very specific medical documents required in order to complete an evaluation for any particular organ. DEEOIC requires that the claims examiners provide these specific relevant documents to the physicians in order for them to complete their reports for impairment.

The program considers its existing referral process to be sufficiently robust in providing the available documents to subject matter experts necessary to produce a rationalized response to the matter under review. In those situations where the industrial hygienist or medical consultant requires clarification or seeks additional information, program guidance encourages them to contact the claims examiner for assistance.

In order to be fully compliant with the statute and regulations, it is vitally important that claims examiners remain the finders of fact regarding the elements of the claim, including determinations regarding verified employment and covered conditions. Providing CMCs with the entire case file could potentially circumvent the claims examiners' ability to support their role as sole fact finders, as CMCs could inadvertently accept employment or other allegations made by the claimant as fact, thereby diminishing the value of their reports. For those reasons, DEEOIC cannot accept the Board's recommendation on this point.

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.

5. Comments on Recommendation: Presumption for Work-Related Asthma. The Advisory Board recommends language changes to procedural guidance relating to the existing presumption for occupational asthma. As part of this recommendation, the Board has offered an alternative definition of the term, "toxic substance."

The DEEOIC implemented several updates to program procedure derived from input from the Board on work-related asthma. The focus of the agreed-to changes centered on clarifying the terminology of work-related asthma. Additional input from the Board, which the DEEOIC has not yet applied procedurally, relates to advice regarding clinical interpretation of medical evidence and wording changes regarding a physician's assessment of toxic substance linkage to work-related asthma. The DEEOIC agrees to make additional changes given the Board's input on these two topics, as long as it does not overly restrict the physician's ability to make his/her own medical assessment.

With regard to the Board's definitional guidance regarding the phrase "a toxic substance," the Department of Labor has defined what is meant by the statutory term "toxic substance" through rulemaking, which provides the basis for these definitions. This has the force and effect of law and it cannot consider how other entities define that term for purposes other than the adjudication of claims under Part E of EEOICPA.

6. Revised Recommendation: Presumption for Chronic Obstructive Pulmonary Disease (COPD). The Advisory Board recommends modifications to the presumptive standard for evaluating claims involving COPD. In particular, the Board recommends that exposure to "vapors, gases, dust and fumes (VGDF)" has a COPD health effect. It also recommends changing the period of exposure necessary to trigger the presumption from 20 to 5 years.

The current list of toxic substances in SEM with a COPD health effect represents a set of named toxic substances or work processes known to have a COPD health effect (including those that are part of the broad categories of vapors, gases, dusts, or fumes), while still offering DEEOIC the specificity needed for case adjudication. DEEOIC believes that using the phrase "vapors, gases, dust and fumes" (VGDF) is overly broad and not legally permissible. However, DEEOIC would

welcome input on additional specific toxic substances encompassing VGDF that it should add to the COPD health effect listing in SEM.

Concerning the duration of exposure to trigger the presumption, DEEOIC has reviewed the Board's literature. DEEOIC maintains that 5 years of exposure is insufficient to meet the causation threshold.

7. Comments on Recommendation: Revisions of the Occupational History Questionnaire. The Advisory Board recommends several revisions to the Occupational History Questionnaire.

DEEOIC is continuing to review revisions to the OHQ and it will consider the suggestions of the Board.

8. Comments on Recommendation: Enhancing the Science and Technical Capacity in the EEOICP. The Advisory Board recommends that the program expand its use of subject matter and organizational expertise relating to the fields of disease causation, epidemiology, and occupational medicine.

DEEOIC has implemented many changes to the claim adjudication process with input from stakeholders, including the Board. While the DEEOIC recognizes that it is the claimant's burden of proof to establish and support his/her claim for benefits, over the years the program has taken various steps to assist in this process beyond simply reviewing evidence submitted. Shortly after Congress passed Part E, the DEEOIC realized that one of the most difficult components to adjudicating these cases is establishing exposure and causation. As a result, DEEOIC entered into a contract with a company made up of former DOE employees, epidemiologists, and industrial hygienists to develop the SEM. This contract included a subcontract with the physician who created *Hazmap*, which is the database that links occupational exposures to known health effects. The Program has also consulted with preeminent pulmonologists at the National Jewish Hospital, University of Pennsylvania, and University of Iowa on an ad hoc basis, as appropriate, to assist in the development of procedures related to lung conditions. DEEOIC will continue to utilize the services of the SEM contractor to conduct research and update the SEM as possible. In addition, the DEEOIC evaluates peer-reviewed literature regarding toxic substances and health effects on a regular basis, through research by the toxicologist, updates by IARC, and claimant or advocate-submitted information. It will continue to use stakeholder feedback to enhance the application of medical health science to serve the claimant community while adhering to the legal requirements of the Act.

9. Revised Recommendation: Quality Assessment of Contract Medical Consultants and Industrial Hygienists. The Advisory Board recommends improvement to the quality of Contract Medical Consultant auditing.

DEEOIC conducts objective and systematic reviews of the application of medical health science through annual accountability reviews and recurring audits by the DEEOIC Medical Director. The DEEOIC believes there is sufficient internal oversight to ensure compliance with legal requirements and programmatic policy. DEEOIC also questions whether the Board is straying

from its legal mandate with its focus on the quality assessment of medical evidence provided by physicians *other* than those submitting medical evidence in support of a claim.
