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

Attachments

1. **Comments on Recommendation: Incorporating Agency Health Effects Reviews Recommended in IOM Report into the SEM**
   (Originally approved as Recommendation #2 at the October 2016 Board meeting)

2. **Comments on Recommendation:** Hiring Former DOE Workers to Administer the Occupational Health Questionnaire
   (Originally approved as Recommendation #3 at the October 2016 Board meeting)

3. **Comments on Recommendation: Claimant Information sent to Industrial Hygiene and Medical Consultants**
   (Originally approved as Recommendation #8 at the October 2016 Board meeting)

4. **Revised Recommendation: Presumptions for Asbestos-related Diseases**
   (Originally approved as Recommendation #1 at the April 2017 Board meeting)

5. **Comments on Recommendation: Presumptions for Work-Related Asthma**
   (Originally approved as Recommendation #2 at the April 2017 Board meeting)

6. **Revised Recommendation: Presumptions for Chronic Obstructive Pulmonary Disease Diseases**
   (Originally approved as Recommendation #3 at the April 2017 Board meeting)

7. **Comments on Recommendation: Revisions of the Occupational Questionnaire (OHQ)**
   (Originally approved as Recommendation #4 at the April 2017 Board meeting)

8. **Comments on Recommendation: Enhancing the Science and Technical Capacity in EEOICP**
   (Originally approved as Recommendation #5 at the April 2017 Board meeting)

9. **Revised Recommendation: Quality Assessment of Contract Medical Consultants and Industrial Hygienists**
   (Originally approved as Recommendation #7 at the April 2017 Board meeting)

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

Comments on Recommendation: Incorporating Agency Health Effects Reviews Recommended in IOM Report into the SEM
(Originally approved as Recommendation #2 at the October 2016 Board meeting)

ABTSWH response to DOL's comments

The Advisory Board had recommended that DEEOICP incorporate the disease exposure links identified by the sources listed in table 3-1 of the Institute of Medicine report. DEEOICP requested that the board narrowed the list to the sources the board believes are most relevant, with recommendations as how they could be used in the SEM. DEEOICP reported they found the list of 11 sources to be redundant or contradictory

The Board continues to believe that all these 11 sources would be useful, but to make the task feasible for DEEOICP we have developed a more limited set of databases that can be incorporated. Those recommendations are attached here. The additional sources in the table from IOM can be reviewed and added at a future time.

The ABTSWH recommends that EEOICP use IARC as the source for information on causal links for carcinogens, use IRIS (EPA) to develop causal links between exposures in the DOE complex and non-cancer endpoints, and use NTP as an additional source for both cancer and non-cancer endpoints. Although the other databases listed in the Institute of Medicine report may contain additional causal links, these three data sources are likely to be the ones that are most comprehensive and best supported as causing human health effects. Once the addition of hazardous agents identified by IARC, IRIS and NTP to the SEM is complete, the ABTSWH can reevaluate the necessity for review of additional databases.

IARC is an agency within the World Health Organization whose mission is to continuously assess available evidence and identify which chemicals are known and probable human carcinogens.

IRIS is a database maintained by EPA which identifies chemicals that are determined to have potential human health effects. Attached is a short description of the process by which EPA develops these risk assessments. On the IRIS website, a detailed summary is available for each chemical; this includes a discussion of the underlying scientific basis for the health assessment. The Board recommends that EEOICP rely upon IRIS because of the extensive research and multilayers of review that go into each document. Because EPA has determined that every agent listed by IRIS has potential human health effects the board recommends that all these agents should be linked in SEM to those health effects.

The National Toxicology Program is an interagency program established in 1978 to coordinate toxicology research and testing across the Department of Health and Human Services. The program was also created to strengthen the science base in toxicology, to develop and validate improved testing methods, and to provide information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public.

Recommended process

1. DEEOICP should identify a team that will implement these recommendations and that includes individuals with competence in toxicology, occupational medicine, and epidemiology.

2. The Board recommends that DEEOICP make this a transparent process, with a report to the Board at each semiannual meeting on agents and health effects added to SEM and those under review.

3. DEEOICP should review SEM to be sure that all the IARC group 1 (known human carcinogens) are included in SEM, and are links to all the specific cancers known to be caused by that chemical based on the IARC report.

4. DEEOICP should add the IARC group 2a carcinogens (probable human carcinogens) using the same process as above.

5. DEEOICP should add agents identified as causing non-cancer end points based on the IRIS database from EPA.

    a. Review the list of agents evaluated in IRIS and identify the ones that result in non-cancer endpoints. (IRIS has a total of 511 chemicals that have been assessed)

    b. Match this list against SEM.

    c. For those agents in the SEM, add the non-cancer endpoints as causal links. Each IRIS assessment identifies which specific health effects are caused by that agent. To identify all the health effects, it is necessary to read the entire document. The summary may only list the critical health effect (the health effect found at the lowest dose which then determines the Rfd set by EPA) but the full document lists all the potential health effects. If necessary or helpful the reviewers could use the available ATSDR Toxicological Profiles to identify health effects for agents in IRIS.

    d. As new exposures are added to SEM, repeat this process.

6. DEEOICP should follow this same process for toxic agents identified by the National Toxicology Program.

Comments on Recommendation: Hiring Former DOE Workers to Administer the Occupational Health Questionnaire
(Originally approved as Recommendation #3 at the October 2016 Board meeting)

ABTSWH response to DOL's comments

DOL's response indicates that there is clear agreement between the Board and DOL that having former DOE workers administer the Occupational Health Questionnaire (OHQ) is beneficial in the claims evaluation and decision-making process. The Board also recognizes the stated commitment by DOL to encourage the hiring of former DOE workers at the Resource Centers. It is encouraging that over one-quarter of contractor Resource Center employees are former workers. To clarify the current status and to understand the likely future direction on this issue, the Board requests additional information.

- How many of the 17 former DOE workers currently employed at the Resource Centers spend at least one-third of their time administering the OHQ to claimants during the past year?
- What percentage of the OHQ's was administered by former DOE workers during the past year?
- What job titles did the Resource Center-employed former DOE workers have when they worked at DOE?
- Are there any Resource Centers where there is a below average number of employed former DOE workers or a below average number of OHQ's administered by former DOE workers?
- Do the Resource Center job vacancy notices and recruitment methods specifically address the desirability of applications by former workers and reach out to former workers to encourage them to apply?
- Does the contract with the Resource Center contractor prioritize the hiring of former DOE workers over other applicants?

Such information will be useful to better understand the extent to which former DOE workers at the Resource Centers actually participate in the OHQ administration and to serve as indicators to assess future changes in these parameters.

Comments on Recommendation: Claimant Information sent to Industrial Hygiene and Medical Consultants
(Originally approved as Recommendation #8 at the October 2016 Board meeting)

ABTSWH responses to DOL's comments

The original Board recommendation is as follows:

> *"We recommend that the entire case file should be made available to both the industrial hygienists and the contract medical consultants when a referral is made to either, and not be restricted to the information that the claims examiner believes is relevant. The claims examiner should map the file to indicate where relevant information is believed to be."*

The Department of Labor's response was to reject the recommendation for the following reasons:

1. It is inappropriate and inefficient.

2. The current claims evaluation process relies on the CEs as the finders of fact, which would be undermined if the Industrial Hygienist and CMC develop or substitute their own facts.

3. Claimants submit voluminous amounts of medical information, not all of which is pertinent to the claim.

4. When a claims examiner refers a case to an IH or CMC, they are seeking guidance on a particular set of circumstances from which specific questions are derived.

5. It is the claims examiners' responsibility to determine which questions are asked.

6. The contractors doing the work do not want to sift through all of the information.

First, the Board notes that the Board was unanimous in this recommendation. Specifically the Board's industrial hygienists and the physicians all indicated that the professional standard, which they apply to the maximum extent possible, is to receive and review all available medical and exposure records in conducting reviews and expressing opinions about the work-relatedness of health conditions of individuals.

Second, we respond to each reason presented by the Agency in its response:

Issues 1 and 3: are easily resolved with a case index or case map. The contractor can review the CE's findings of accepted facts and then review the case index to see if there is any other information they wish to review. The board strongly recommends that

the agency develop a system by which all case files are provided to CE, IH and CMC in searchable pdf format to improve searching efficiency.

Issue 2: While the CE's are well trained to extract information based on agency protocol, they are not experts in IH or occupational medicine and may sometimes not recognize important links between seemingly unrelated parts of a case. We do not believe the agency wishes their experts to form professional opinions based on incomplete or inaccurate information. The entire reason for referring to experts is that their expertise augments what is known by the CE. Denial of a claim based on CE misjudgment about the relevance of medical or exposure information would be unfair to claimants. In addition, finders of fact in our legal system are typically not experts, and we do not believe that using experts undermines the role of the finders of fact. Finders of fact (like judges and juries) often rely on expert evidence. The finders of fact then weigh the evidence to determine the facts that they will use in rendering an opinion.

Issues 4 and 5: These are essentially the same issue. It would be inappropriate for the IH or CMC to render an opinion on a specific question when they are not permitted to review documents that were not provided to them but are pertinent to the claim. To do so creates "tunnel vision" on the part of the expert and a faulty opinion may be the result. Again, this is unjust to the claimant. In addition, the Board's recommendation does not affect the CE's ability to ask specific questions of the IH or CMC. It provides these consultants with the opportunity to use their expertise identify information relevant to the CE's questions that was not recognized as such by the CE.

Issue 6: It should be noted that these same contractors provide expert medical opinions to other federal agencies where they are required to receive the entire claims folder. It should be the responsibility of the IH or CMC to determine if the statement of accepted facts is complete and accurate enough for them to render an opinion, or if they need to review additional information in the claims folder.

Revised Recommendation: Presumptions for Asbestos-related Diseases
(Originally approved as Recommendation #1 at the April 2017 Board meeting)

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** Mesothelioma	**Asbestos-specific diseases** Asbestos, Asbestos-related pleural disease	**Other Asbestos-related Cancers** Lung cancer, Cancer of ovary and larynx
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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Comments on Recommendation: Presumptions for Work-Related Asthma
(Originally approved as Recommendation #2 at the April 2017 Board meeting)

ABTSWH responses to DOL's comments

The Board's April 2017 Recommendation on Presumptions for Work-Related Asthma (WRA) contained 4 parts. Each initial recommendation is provided bolded, followed by a summary of the DOL's response, and additional comments of the Advisory Board to the DOL to add further clarity or, where indicated, help the DOL implement the Recommendation.

The OWCP indicated that changes in response to Recommendation #2 have already been incorporated into the most recent revision of the Procedure Manual (Procedure Manual 1.1; Appendix 1, 9/2017; sections related to WRA). Relevant sections of the Procedure Manual were also reviewed to assess how the recommended changes were incorporated.

Recommendation #2-1

DOL should use the generally accepted unifying term, work-related asthma (WRA) for claims evaluation and decision-making. Work-related asthma includes: a) occupational asthma (OA), or new onset asthma that is initiated by an occupational agent, and b) work-exacerbated asthma (WEA), which is established asthma that is worsened by workplace exposures. The recognition of both forms of work-related asthma should be communicated to claimants, their physicians and consulting IH's and CMC's.

The Advisory Board appreciates that OWCP agrees with this recommendation and has implemented it in the most recent Revision of the Procedure Manual (Procedure Manual 1.1; Appendix 1, page)

Recommendation #2-2

Medical criteria for the diagnosis of asthma: The diagnosis of asthma by a treating or evaluating physician should be sufficient for the recognition that the claimant has asthma. Bronchodilator reversibility of FEV1 and/or a positive methacholine challenge test may be helpful but should not be required to accept the diagnosis of asthma, which is made by a health care provider.

The Advisory Board appreciates that OWCP agrees that *"a diagnosis of asthma by a treating physician should be sufficient, without specific reference to the tests listed" (spirometry, methacholine challenge test).* The Advisory Board agrees with OWCP that *"the physician's opinion should include appropriate medical rationale, based on objective findings, to support the diagnosis."*

The Advisory Board also appreciates that OWCP has attempted to implement this recommendation in the most recent Revision of the Procedure Manual (Version 1.1).

However, a review of the relevant sections of the Procedure Manual that describe the criteria for the diagnosis of asthma reveals sections that are confusing, do not appear to incorporate the above recommendation, and do not reflect current clinical practice. For example,

Procedure Manual 1.1, Appendix 1 (9/2017), page 524 states that:

"The criteria for accepting a Part E claim for asthma are:

a. The employee has a period of covered Part E contractor or subcontractor employment.

b. A qualified physician has diagnosed the employee with asthma. A medical diagnosis for asthma should be made when the physician is able to identify the presence of intermittent respiratory and physiologic evidence of reversible or variable airways obstruction including positive methacholine challenge test or post-bronchodilator reversibility. However, a physician can also rely on other clinical information to substantiate his or her diagnosis of asthma. ***For example, spirometry for measurement of FEV1 and FVC is the most reliable method for assessing airway obstruction****. The response to inhaled bronchodilator administration has been used as a measure of airway hyperresponsiveness. A 12% improvement in FEV1 of at least 200 mL after inhaled bronchodilator is how the American Thoracic Society defines a significant improvement indicative of hyperresponsive airways."*

This wording adds unnecessary confusion, especially the "For example" section. As noted in the Advisory Board's recommendation above the diagnosis of asthma by a treating or evaluating physician should be sufficient to recognize that a claimant has asthma for multiple reasons. Asthma is a condition that is episodic and variable over time. Spirometry testing is generally not performed during symptomatic exacerbations and can be normal when patients are not having exacerbations. Bronchodilator testing can be falsely negative, especially if performed after a patient has been started on standard asthma treatment such as inhaled steroids or long acting beta-agonists. Methacholine challenge testing can also have false negatives (and positives), entails risk of inducing an asthma attack, and is not widely available, especially in many outpatient office settings. Thus asthma is commonly diagnosed and treated <u>without</u> documentation of a positive bronchodilator response or methacholine challenge testing. The diagnosis is usually based on the patient's history, clinical presentation, specific symptoms, triggers, physical exam findings and response to treatment.

Documentation of specific asthma symptoms (e.g. wheeze, cough), symptom triggers, and physical exam findings (e.g. wheezing) are objective findings that are used to identify the presence of reversible airflow obstruction, and would be better examples of *"other clinical information to substantiate his or her diagnosis of asthma"* than those provided (spirometry, bronchodilator and methacholine challenge testing).

Suggested alternate wording (major changes are underlined) to the current Procedure Manual 1.1 (pages 524-5) is as follows:

"A medical diagnosis for asthma should be made when the physician is able to identify the presence of intermittent respiratory and physiologic evidence of reversible or variable airways obstruction including post-bronchodilator reversibility on spirometry or a positive methacholine challenge test. However, a physician can also rely on other clinical information to substantiate his or her diagnosis of asthma, such as the findings from a detailed medical history and physical examination. Documentation of recurrent symptoms of airflow obstruction or airway hyper-responsiveness, such as episodic cough, chest tightness or shortness of breath, or symptomatic improvement following treatment for asthma (e.g. inhaled bronchodilator or steroids) supports a diagnosis of asthma. Physical examination findings such as wheezing on lung examination, nasal swelling and drainage, or use of chest muscles to breath also support a diagnosis of asthma.
The response to inhaled bronchodilator administration has also been used as a measure of airway hyperresponsiveness. A 12% improvement in FEV1 of at least 200 mL after inhaled bronchodilator is how the American Thoracic Society defines a significant improvement indicative of hyperresponsive airways. However, a negative bronchodilator test does not rule out a diagnosis of asthma, especially if the patient is on medical treatment for asthma."

Recommendation #2-3. Work-related asthma, whether OA or WEA, is defined as the presence of medically-diagnosed asthma that is associated with worsening of any one or more of the following in relation to work: asthma-related symptoms, asthma medication usage or asthma-related health care utilization temporally related to work, or change in peak expiratory flows associated with work. Such a history should be documented by a treating or evaluating health care provider, or addressed by a CMC if consulted in a claim evaluation.

The Advisory Board appreciates that OWCP agrees with this recommendation. The Advisory Board recognizes that implementation of the recommendation by the DOL will likely be challenging, as it will require education of claims examiners and treating and consulting physicians about WRA, including causative substances and diagnostic criteria.

Recommendation #2-4. The same criteria for WRA should be used in evaluating asthma claims whether the claim is made contemporaneous with the period of DOE employment or after the end of that period of employment. A specific triggering event causing onset of WRA may occur but is not typical or necessary. Inciting exposures such as dusts, fumes, heat or cold or others should be specifically identified when possible, but should not be required for the diagnosis of WRA.

OWCP's response to this recommendation notes that *"The policy (=updated Procedure Manual) differs slightly from Recommendation #2-4 by requiring a triggering mechanism that occurred to cause, contribute to, or aggravate the condition. Legally, OWCP must require evidence that the toxic substance was the likely trigger for the condition because a condition can only be accepted as a compensable "covered illness" if "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.*

A mere temporal association, without identification of a toxic substance, would not satisfy the statutory requirement for eligibility. In addition, neither "heat" nor "cold" can be defined as a "toxic substance" under this definition."

The Advisory Board understands that under Part E of the EEOICPA, an illness can only be accepted as a compensable covered illness if *"exposure to **a toxic substance** at a covered DOE facility was "at least as likely as not" a significant factor in aggravating, contributing to or causing the illness."* The Advisory Board also acknowledges that heat and cold should not be considered causative exposures for work-related asthma.

However, a review of the updated Procedure Manual 1.1 (see below) indicates that OWCP's current criteria for WRA differ more than "slightly" from the Advisory Board's recommendation and are not consistent with current knowledge and clinical practice regarding WRA. The primary area of discrepancy relates to the criteria regarding the physician's documentation of the exposure that likely caused the claimant's WRA.

A better understanding of what is meant by the phrase *"a toxic substance"* and also what is known about the causes of WRA provides greater clarity and should resolve this discrepancy. The U.S. National Institute of Health (NIH) (and others) define a toxic substance as:

> ***"A toxic substance** is simply a material which has toxic properties. It may be a discrete toxic chemical or **a mixture of toxic chemicals**. For example, lead chromate, asbestos, and gasoline are all toxic substances. More specifically:*
>
> - *Lead chromate is a discrete toxic chemical.*
> - *Asbestos is a toxic material that does not consist of an exact chemical composition but **a variety of fibers and minerals**.*
> - *Gasoline is also **a toxic substance** rather than a toxic chemical in that it contains **a mixture of many chemicals**. Toxic substances may not always have a constant composition. For example, "the composition of gasoline varies with octane level, manufacturer, time of season, and other factors." https://toxtutor.nlm.nih.gov/01-002.html*

There are numerous other examples of well-known toxic substances that are mixtures of many chemicals, particles or fumes, such as cigarette smoke, coal dust, diesel exhaust, degreasing solvents, combustion products or dust from the World Trade Center attacks. These exposures are well recognized to be toxic, even though they are not a single specific toxic chemical or a mixture of chemicals with unvarying composition. Stating that EEOICPA Part E requires identification of a specific exposure or exposure event in order to consider a condition to be compensable is a misunderstanding of the EEOICPA statutory requirement. Rather EEOICPA requires identification of work exposure(s) that on an at least as likely as not basis were a significant factor in aggravating, contributing to or causing the illness.

Multiple different potentially toxic substances can cause or exacerbate WRA, including various irritants, allergens, dusts, fumes, vapors and gases. This is acknowledged in the current Procedure Manual page 524: "*The CE does not apply a toxic substance exposure assessment to a*

claim for work-related asthma, including the application of the SEM or IH referral process, because any dust, vapor, gas or fume has the potential to affect asthma."

Most cases of WRA result from repeated inhalational exposures over months to years, rather than a specific exposure incident. In the great majority of cases of WRA diagnosed in the US, a single specific causative agent or specific exposure event is not identified, nor a triggering mechanism, even when patients are evaluated by occupational lung specialists. Commonly identified exposures that contribute to WRA include dusts, fumes, chemicals, cleaning products, and pyrolysis products.(1-5) Also of note, the mechanisms by which most exposures cause or exacerbate asthma remain poorly defined.

The criteria to diagnose WRA that are described in newly revised Procedure Manual 1.1, Appendix 1, pages 524-5 (noted below), differ more than slightly from Recommendation #2-4, are not reflective of current knowledge and practice regarding WRA, and contain internal inconsistencies:

> ***"Asthma**: Work-related asthma includes: a) occupational asthma; or new onset asthma that is initiated by an occupational agent, and b) work-exacerbated asthma, which is established asthma that is worsened by work place exposures. The CE does not apply a toxic substance exposure assessment to a claim for work-related asthma, including the application of the SEM or IH referral process, because any dust, vapor, gas or fume has the potential to affect asthma. Given the scope of potential occupational triggers that can affect asthma, the CE relies exclusively on the assessment of the medical evidence by a qualified physician to arrive at a determination of compensability. The criteria for accepting a Part E claim for asthma are:*
>
> *a. The employee has a period of covered Part E contractor or subcontractor employment.*
> *b. A qualified physician has diagnosed the employee with asthma ..... (see above).*
> *c. Once having established covered Part E contractor or subcontractor employment and a diagnosis of asthma, the following criteria are available to demonstrate that the employee has work related asthma (as defined above):*
>
> *i. A qualified physician, who during a period contemporaneous with the period of covered Part E employment, diagnosed the employee with work-related asthma or;*
> *ii. After a period of covered employment, a qualified physician conducts an examination of either the patient or available medical records and he or she concludes that the evidence supports that the employee had asthma and that an occupational exposure to a toxic substance was at least as likely as not a significant factor in causing, contributing to or aggravating the condition.* ***The qualified physician must provide a well-rationalized explanation with specific information on the mechanism for causing, contributing to, or aggravating the conditions. The strongest justification for acceptance in this type of claims is when the physician can identify the asthmatic incident(s) that occurred while the employee worked at the covered work site and the most likely toxic substance trigger. A physician's opinion that does not provide a clear basis for***

> ***diagnosing asthma at the time of covered employment or the physician provides a vague or generalized opinion regarding the relationship between asthma and occupational toxic substance exposure will require additional development including the CE's request for the physician to offer further support of the claim***. *If the CE is unable to obtain the necessary medical evidence from the treating physician to substantiate the claim for work-related asthma, the CE will need to seek an opinion from a CMC. If a CMC referral is required, the CE will need to provide the CMC with the relevant medical evidence from the claim file and provide a detailed description of the employee's covered employment which must include each covered worksite, dates of covered employment, labor categories, and details about the jobs performed."*

The above criteria for WRA would more accurately reflect the medical literature and current practice if the sections that are bolded were eliminated.

Also of note, the updated Procedure Manual refers to Exhibit 18-1; Matrix for Confirming Sufficient Evidence of Non-cancerous Covered Illnesses; Asthma, Occupational (page 568) for further guidance. This Table (page 568; dated 9/2017) summarizes the criteria to diagnose Asthma and WRA. It does not reflect the Procedure Manual text, contains inaccurate medical information, and requires revision.

The Advisory Board, which has substantial expertise in WRA, is willing to provide the DOL additional guidance on updating the Procedure Manual and implementation of the WRA Presumption.

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Revised Recommendation: Presumptions for Chronic Obstructive Pulmonary Disease Diseases
(Originally approved as Recommendation #3 at the April 2017 Board meeting)

ABTSWH comments on OWCP's response regarding the causal link between COPD and VGDF

OWCP did not accept the Board's recommendation to add a section on reported exposure to vapors, gases, dust, and fumes (VGDF) based on the following reasoning:

1. EEOICPA specifically states that a condition can only be accepted as a compensable covered illness if it is at least as likely as not that exposure to a toxic substance was related to employment at a Department of Energy facility.

2. The program has defined a 'toxic substance" -- as "any material that has the potential to cause illness or death because of its radioactive, chemical, or biological nature".

3. VGDF lexicon is a broad reference that encompasses many different toxic substances that exist in either occupational or non-occupational settings.

4. The current presumption for COPD requires 20 years of exposure to asbestos while the Board recommended that five years of exposure to VGDF should be sufficient in a presumption. OWCP stated that this recommendation conflicts with the literature on which OWCP developed its presumption and requested additional documentation.

5. OWCP also requested clarification of the labor categories, which is being addressed in response to recommendation #1 from April 2017.

Regarding (1) and (2) above: The Board agrees that VGDF exposure can contain a range of different individual toxic agents. The Board notes that OWCP does accept claims for disease resulting from exposure to complex mixtures such as welding fume and wood dust, and from work processes that do not contain one specific toxic substance, such as: Blast, drill, remove, or crush rock; Dry clean with organic solvents; Clean equipment with solvents; Paint or varnish, oil-based. The Board notes these examples to point out that OWCP has found ways to accommodate exposure to complex mixtures.

Regarding (3), to be responsive to the request to provide a narrower list of toxic exposures, we have added a list to the presumption recommended in October 2016; see below

Regarding (3) above, the intent of the Board's recommendation is to have OWCP compensate workers with occupational exposure to VGDF that occurred during their work in the DOE weapons complex, not from more general non-occupational exposure. The Board stands behind the opinion that the literature provided to OWCP shows a clear causal link between VGDF exposure and COPD in an occupational setting, and this causal link is accepted by the American Thoracic Society, the premier US organization of professionals in the area of respiratory disease.

Regarding (4) above, the Board would need to review the research referenced by OWCP. However, that review would not change the recommendations made here, since OWCP's references presumably are specific asbestos.

Revised Recommendation: Presumptions for Chronic Obstructive Pulmonary Disease Diseases

The Board recommends that DOL adopt the following:

1. A determination by DOL that chronic occupational exposure to toxic substances or vapors, gases, dusts, or fumes (VGDF) at DOE sites where toxic substances were or are used can cause, contribute, or aggravate COPD,

2. Presumption of Chronic Exposure to Toxic Substances

   Claimants will be presumed to have had chronic occupational exposure to one or more toxic substances at a Department of Energy facility that was sufficient to aggravate, contribute to, or cause COPD if they meet any one of the following conditions:

   a. 5 years of work at a DOE site with exposure to one or more of the following toxic substances, as identified on the EE-3 or the OHQ: asbestos; silica; cement dust; engine exhausts; acids and caustics; welding, thermal cutting, soldering, brazing; metal cutting and grinding; machining aerosols; isocyanates, organic solvents, wood dust, molds and spores; and particulates not otherwise regulated (PNOR[1]), or

   b. 5 years of work in any one of the maintenance or construction job titles at a DOE site if the claimant's job title(s) is linked to one or more toxic substances in the SEM, or

   c. 5 years of exposure to VGDF during DOE employment as reported in a revised OHQ that assesses VGDF exposures and the SEM shows that his/her job title or tasks are linked to agents in one or more of the following SEM toxic substance groups:

      i) Acids/caustics/reducing and oxidizing agents
      ii) Dusts and fibers
      iii) Gases
      iv) Metals
      v) Solvents

[1]PNOR includes all mineral and inorganic "inert or nuisance dusts" without specific individual U.S. Occupational Safety and Health Administration Permissible Exposure Limits (PEL). See OSHA. *Chemical Sampling Information: Particulates Not Otherwise Regulated (Total Dust)* Washington, DC. 2015; *NIOSH Pocket Guide to Chemical Hazards: Particulates not Otherwise Regulated.* Atlanta, GA, 2015.

3. Timing of exposure: Because exposures to toxic substances continue to take place at DOE sites and many of them are unregulated, it should be presumed that reported exposures to toxic substances that cause, contribute to or aggravate COPD at any period of employment covered by EEOICPA, up to the present time, are contributory exposures.

4. Duration of exposure. Based on the evidence presented in the Dement 2015 study, a cumulative duration of 5 years of reported exposures to VGDF can be presumed to aggravate, contribute to, or cause COPD.

5. Time since last exposure: The committee does not recommend specifying any minimum or maximum time since last exposure to a toxic substance. COPD is a slowly progressive disease and individuals are often not diagnosed until the disease is advanced, or an intervening infection makes the diagnosis more apparent. Since it would not be possible to determine in retrospect when a case of COPD could have been first diagnosed, and since exposure to VDGF involving toxic substances is a contributory cause to COPD, it is reasonable to assume that VGDF exposure contributed to any diagnosed case even if the disease is diagnosed after the worker has left employment

6. Additionally, claims examiners should not deny claims for COPD if the worker had fewer than 5 years of exposure; for example, a claimant who has experienced high intensity exposures to VGDFs involving toxic substances during work in a covered facility would have an equivalent exposure. Claims that do not meet the requirements set forth here but do have reported exposure to VGDF should be sent for IH and/or CMC review under the policy established in Bulletin 16-03.

Scientific Rationale

Substantial medical literature has investigated the etiology of COPD among general populations in the U.S., Italy, New Zealand, Poland, Australia, Spain, and elsewhere (see reviews in ATS Statement, Balmes 2003; ATS Statement, Eisner 2010).

In 2003, the American Thoracic Society, which is the preeminent respiratory disease organization in the United States, published the enclosed paper concluding that occupational exposures were responsible for a substantial fraction of COPD in the United States (Balmes 2003). Another paper from the American Thoracic Society published in 2010, with Eisner as the lead author and the title "An Official American Thoracic Society Public Policy Statement: Novel Risk Factors and The Global Burden of Chronic Obstructive Pulmonary Disease," (Eisner 2010) describes that there is a very strong and well accepted relationship between occupational exposures to vapors, gases, dusts and fumes (VGDF) and COPD; [see the section starting on page 704]. This document states that it is a strong causal relationship and describes other literature that has identified some specific agents that are part of the overall occupational exposures to vapors gases dust and fumes. Table 5 in this paper lists some studies that have identified specific agents, including asbestos and quartz (quartz is another name for as crystalline silica).

Other primary research studies have defined the causative occupational exposures as a combined exposure VGDF. These large studies of varying study designs have consistently shown that occupational exposures defined as "gases, dusts, vapors, and fumes" increase the risk of COPD. A dose-response relationship has been seen (Weinmann 2008, Mehta 2012), and the effect is observed among both smokers and non-smokers (Blanc 2009, Dement 2010). The effect of smoking and occupational exposures appears to be additive. A recent study by Dement et al looked at COPD and occupational risks in DOE facilities specifically, and found that VGDF significantly increased the risk for COPD (Dement 2015).

The specific agents listed in 2(a) have been shown to cause COPD with these studies:

asbestos [ATS, 2004; Dement et al., 2010; Glencross et al., 1997];

silica [Dement et al., 2010; Hnizdo and Vallyathan, 2003; Oliver and Miracle-McMahill, 2006; Rushton, 2007b; Tse et al., 2007]

cement dust [Abrons et al., 1988; Dement et al., 2010; Fell et al., 2010; Mwaiselage et al., 2004; Rushton, 2007a]

diesel exhausts [Hart et al., 2009; Hart et al., 2006; Tuchsen and Hannerz, 2000; Ulvestad et al., 2000; Weinmann et al., 2008]

welding and cutting gases and fumes [Balmes, 2005; Bradshaw et al., 1998; Dement et al., 2010; Hunting and Welch, 1993; Koh et al., 2015; Mastrangelo et al., 2003; Szram et al., 2013]

metal cutting, grinding, and machining aerosol, **paint-related aerosols** [Glindmeyer et al., 2004; Hammond et al., 2005; Mastrangelo et al., 2003; Pronk et al., 2007]\

organic solvents [Ebbehoj et al 2008; Heederik et al 1989; Melville 2010; Post et al 1994; Suadicani P, 2001; Valcin M, et al. 2007; Alif et al, 2017]

wood dust [Jacobsen et al., 2008; Dement et al., 2010]

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Comments on Recommendation: Revisions of the Occupational Questionnaire (OHQ)
(Originally approved as Recommendation #4 at the April 2017 Board meeting)

ABTSWH responses to DOL's comments

The Advisory Board made several specific recommendations for revision of the current occupational history questionnaire at the April 2017 meeting. The DOL response to the Advisory Board's recommendation contains the following specific points:

1. OWCP has already developed a revised OHQ that:
    - Provides space for workers to provide free text descriptions of how they were exposed.
    - Provides space to record union membership and participation in a Former Worker Program.
    - Reduces the lists of toxic substances and instead lists categories under which the claimant may provide specific toxic substances.

2. OWCP did not accept the Board's recommendation to add a section on reported exposure to vapors, gases, dust, and fumes (VGDF) based on the following reasoning:
    - EEOICPA specifically states that a condition can only be accepted as a compensable covered illness if it is at least as likely as not that exposure to a specific toxic substance was related to employment at a Department of Energy facility.
    - The program has defined a "toxic substance" - as "any material that has the potential to cause illness or death because of its radioactive, chemical, or biological nature".
    - VGDF lexicon is a broad reference that encompasses many different specific toxic substances that exist in either occupational or non-occupational settings.

The Advisory Board discussed the OHQ recommendations and the OWCP response in detail at the meeting held in November 2017. The Board's recommendation to add questions concerning VGDF exposures is tied to the recommended presumption for COPD and will be addressed in the responses to the COPD recommended presumption.

The Advisory Board's recommended OHQ revisions are closely tied with other recommendations intended to improve the quality of claimant-provided exposure information and use of this information during claim adjudication. These other Advisory Board recommendations include:

1. Use of former DOE workers to assist claimants in completing the OHQ, and

2. Providing industrial hygienist the opportunity to speak directly with claimants to clarify information provided in the OHQ.

The Advisory Board was provided and did review the revised draft of the OHQ in the process of developing its specific OHQ recommendations. The Board believes that there remains considerable room for improvement in the draft OHQ. The draft OHQ is largely a form that allows the claimant space for recording free text descriptions of their exposures. While recording free text descriptions of work performed is helpful, the draft OHQ does not provide sufficient structure and 'memory triggers' to help claimants recall specific tasks and exposures at DOE sites. Experience gained through the Former Worker Programs including the Building Trades National Medical Screening Program (BTMed) has shown that listings of materials and tasks on the OHQ provide memory triggers often useful in stimulating recall of exposures that may have occurred decades in the past. Furthermore, industrial hygienists use tasks and materials collectively as indicators of exposure and exposure intensity. In addition to asking about materials and tasks, the Advisory Board recommended that a scale of task frequency be included the OHQ. The BTMed program has found that tasks and task frequency by job, in combination with job duration, can be used to generate exposure indices that are indicative of risk for occupational diseases such as pulmonary fibrosis and COPD.

The Advisory Board acknowledges that the BTMed list of tasks is largely specific to construction and maintenance workers. A similar list is not available for production workers and production tasks are likely to differ substantially by DOE site. Acknowledging this limitation, the Advisory Board recommended that the OHQ provide space to record free text descriptions of tasks associated with recorded exposures. This would allow industrial hygienists reviewing the claimant file better information to assess the likely range of exposure intensity. Additionally, this free text description could provide a useful flag to industrial hygienists when the task description is insufficient and discussion with the claimant for clarification is needed.

Comments on Recommendation: Enhancing the Science and Technical Capacity in EEOICP
(Originally approved as Recommendation #5 at the April 2017 Board meeting)

ABTSWH responses to DOL's comments

The Board recommended that the DEEOICP enhance its scientific and technical capabilities to address selected gaps in current capacity, namely, to implement the recommendations developed in the 2013 IOM report on the SEM; to update and keep current the exposure-disease links based originally on Haz-Map in the SEM; to ensure that that program policies reflect state-of-the-art science; to address the continuing challenge of evaluating claims for diseases for which knowledge is actively evolving; and others. The Board acknowledges the current in-house and contracted expertise that OWCP has at present in the EEOICP. However, the issues that the IOM report raised remain relevant, and the problems that the Board itself has identified in its work on selected issues such as occupational asthma, asbestos-related diseases, occupational hearing loss, and chronic obstructive pulmonary disease, illustrate that OWCP needs additional organizational expertise in disease causation, epidemiology, and occupational medicine that can participate in the OWCP on a sustained and regular basis. The Board remains willing to assist on an ad hoc and advisory basis, but the program need is too multi-dimensional and ongoing to rely on the Board to fulfill this function.

Revised Recommendation: Quality Assessment of Contract Medical Consultants and Industrial Hygienists
(Originally approved as Recommendation #7 at the April 2017 Board meeting)

ABTSWH responses to DOL's comments

The Board takes note that the EEOICP Medical Director conducts audits of approximately 40 CMC reports on a quarterly basis and that follow-up is conducted on problems that are thereby identified. However, the Board raises the concern that the audit process itself is flawed and fails to address major questions concerning quality. The Board recommends the following three changes in the process as relatively straightforward ones that could be implemented immediately to improve quality assessment:

1. The initial question for the medical reviewer to address is whether the CE included all relevant information in the information sent to the CMC/IH. Note that this recommendation is not necessary if the Board's overarching recommendation to provide the entire file to CMC and IH consultants is approved.

2. The main quality question for the medical reviewer is whether the CMC's written medical opinion was based on established DOL guidance and on the latest scientific evidence.

3. A review process in which reviews are conducted by two medical experts with subsequent comparison of results should be implemented.

The Board takes the position that it cannot properly advise the Secretary regarding the fourth task of its mission concerning "the work of industrial hygienists and staff physicians and consulting physicians of the Department and reports of such hygienists and physicians to ensure quality, objectivity, and consistency' without conducting an independent review of a substantial number of claims. In the second half of 2016, the Medical Director found problems in 13 of 82 reviewed CMC reports, representing 1 of every 6 (16%) CMC reports. This finding represents a significant proportion of reports with errors, reinforcing the Board's desire to take an independent look at a large number of claims. In addition, the Medical Director's review did not address the issue of consistency across reports, an issue that is key to quality and fairness of EEOICP. The Board has not been provided of a quality assessment of the IH reports.

Revised Recommendation

Given the number of CMC's and IH's, the different types of their evaluations, the different types of claims, and other factors, the Board requests that it oversee the review of CMC and IH reports that were developed in several hundred claims. The exact number awaits a fuller understanding of the variation in the factors identified above.

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

The following is a number of issues raised by Board members in its last two meetings that might be considered by the next appointed Board. They are not ordered in priority and are not intended to be comprehensive.

1. How to interpret and apply the standard: aggravated, contributed to, or caused by an exposure.

2. Revisit the SEM at a broad level and assess and monitor DEEOIC's relationship with HAZ-MAP. In addition, making sure that exposure assessment in the claims process continues to improve, including a focus on tools that are outside the SEM. How to ensure that the employment history of claimants is well-documented.

3. Look more deeply at the available claims data – particularly continuing with the analysis that Member Dement did of the data relating to pat B claims.

4. Look at the topic of durable medical equipment authorization.

5. Examine EEOICP's performance on impairment ratings.

6. The new Board should look at the list of conditions for the most commonly denied claims, and, additionally, neurologic illnesses, cancer, and endocrine conditions.

7. More interaction with physicians from DOL would be helpful.

8. It would also be helpful for the next Board to have refresher presentations from DOL and the NIOSH Board.

9. Be involved in evaluating the pilot data from the re-drafted OHQ questionnaire.

10. Follow up on Board recommendations.

11. Monitor the outcomes of changes made by DOL in response to Board recommendations, including the claims process and outcomes.

12. Examine and encourage additional continuing education, credentialing, and career progression for Claims Examiners and other staff.

13. Ensure that public comments are appropriately tracked and subsequently integrated into Board discussions.

14. Review of the latest procedure manual, circulars, bulletins, and training materials for accuracy and consistency.