Advisory Board on Toxic Substances and Worker Health Please place on record

Dear Chairman and members of the Board,

I would like to bring up several issues of concern and questions for the Board as the Board performs it's assigned tasks.

……the site exposure matrices of the Department of Labor;

42 USC 7384w–1. (Public Law 108 2004)

''**SEC. 3633. COMPLETION OF SITE PROFILES.**

''(a**) IN GENERAL**.—To the extent that the Secretary of Labor determines it useful and practicable, the Secretary of Labor shall direct the Director of the National Institute for Occupational Safety and Health to prepare site profiles for a Department of Energy facility based on the records, files, and other data provided by the Secretary of Energy and such other information as is available, including information available from the former worker medical screening programs of the Department of Energy.

''(b**) INFORMATION**.—The Secretary of Energy shall furnish to the Secretary of Labor any information that the Secretary of Labor finds necessary or useful for the production of such site profiles, including records from the Department of Energy former worker medical screening program.

''(c) **DEFINITION**.—In this section, the term **'site profile' means an exposure assessment of a facility that identifies the toxic substances or processes that were commonly used in each building or process of the facility, and the time frame during which the potential for exposure to toxic substances existed.**

''(d) TIME FRAMES.—The Secretary of Health and Human Services **shall establish time frames for completing site profiles for those Department of Energy facilities for which a site profile has not been completed.** Not later than March 1, 2005, the Secretary of Health and Human Services shall submit to Congress a report setting forth those time frames.''.

The OWCP determined that resources to be used in the "Site Exposure Matrix" and for the District Medical Consultants (since 2005) to include……

1. National Library of Medicine… pubmed
2. ATSDR toxicological profiles
3. National Toxicology Program-Report on carcinogens
4. International Agency for Research on Cancer
5. NIOSH…criteria documents…. Current intelligence bulletins
6. OSHA
7. TOXNET
8. HAZMAP
9. Site Exposures Matrix
10. *Textbook of Occupational and Environmental Medicine*
11. *Environmental and Occupational Medicine*
12. *Guides to the Evaluation of Permanent Impairment 5th Ed*

13. American Thoracic Society Position Statements
14. Current edition of the Merck Manual

A. Since the OWCP has established and approved the above references, why does the DEEOIC ignore the medical evidence and link to toxic substances when the claimant or the treating physicians uses the same reference?
B. Why does the SEM not list the health effects of radiation? Radiation is in the definition of toxic substances. Example: tritium goes to the whole body, radiation can cause damage to the DNA or cells and create non-malignant disorders. Optic neuropathy from plutonium and nitric acid vapors; thyroid disorders, parathyroid, etc.
C. The SEM addresses exposure assessment in the facility and in the processes, so who determines the health effects listed in the SEM and why is that factual determination not enough to accept a claim illness under Part E? Ex. Pulmonary disease, COPD, SEM lists over 30 toxic substances.
D. Who verifies the toxic substance and health effects? Ex. Bone cancer SEM could not verify that plutonium has a link to bone cancer.
E. Who decides what references will be used when claimants send in the information from peer reviewed articles?
F. NIOSH chemical guide and OSHA both inform the public of the target organs effected by a toxic substance. Can a claimant use the "target organ" of the toxic substance to provide a "scientific known link" of exposure and claimed illness? Can the treating physician use the "target organ" NIOSH chemical guide as a "Well rationalized report" reference?
G. DEEOIC has informed the Case Examiners that abstracts and Hazmap cannot be used for Part E. That only the SEM will be used. Yet the policy states that the Case Examiner cannot deny based on just SEM. Part E was to cover a broad array of illnesses. OSHA and NIOSH can only report hazardous substances after certain criteria have been met. SEM will not show aggravating or contributing to but only a "known link" of causation.
IF peer reviewed abstracts show an increase risk of a illness linked to a toxic substance, should that be enough under Part E?

……"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. "*

The Secretary of Labor has assigned OWCP with full authority to administer the EEOICP Act. Julia Hearthway is responsible for the administration of EEOICP Act. "Except as otherwise provided by law, the Director of OWCP and his/her designees have the exclusive authority to administer, interpret and enforce the **provisions of the Act." OWCP has interpreted that "at least as likely as not" to be more than a suspicion and less than the preponderance of the evidence. OWCP has defined significant factor to mean any factor. OWCP has determined that "aggravating" and "contributing to" is defined to be the same as in the workman compensation principles.** No where in the Act or the regulations is "significant level" of

exposure required. The regulations state proof of exposure is that the toxic substance was present and that the employee came into contact with the toxic substance.

The regulations do state, "*OWCP will consider the nature, frequency, and duration*" of the exposure to the toxic substance. The Industrial Hygienist can only address the nature… (the route of exposure inhalation, ingested, skin absorption, etc.; the soluble or insoluble,); the frequency (direct or indirect, chronic or acute, etc.) duration (daily, weekly, monthly, for how many years).

A. Why does the IH determine the "significant level" when the Act does not require it?
B. How can an IH reconstruct the "level" of exposure when there is no data?
C. The FECA has developed an Occupational Disease check lists. The lists addresses
   Nature of exposure… **primary**, normal duties require direct exposure;
   Secondary, normal duties and working along other workers
   Intermittent, normal duties irregularly involve exposures
   Environmental, normal duties around ambient levels
   Degree of exposure….heavy, medium, light, ambient
   Frequency.. hours per day
   Can a simple form be created for the IH to be used in the EEOICP program?

42 USC 7385 …''**SEC. 3671. DEFINITIONS**. ''In this subtitle:

(1) The term 'covered DOE contractor employee' means any Department of Energy contractor employee **determined under section 3675 to have contracted a covered illness through exposure at a Department of Energy** facility. ''

(2) The term '**covered illness' means an illness or death resulting from exposure to a toxic substance. ''**

(3) The term 'Secretary' means the Secretary of Labor.

''**SEC. 3675. DETERMINATIONS REGARDING CONTRACTION OF COVERED ILLNESSES.**

'(c) OTHER CASES.—

(1) In any other case, a Department of Energy contractor employee **shall be determined** for purposes of this subtitle 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. ''

(2) A determination under paragraph (1) **shall be made by the Secretary**.

The Contract Medical consultants, (CMC), have no authority to decide the facts in a case. The Case Examiners has the duty to develop the claim and create a Statement of Accepted Facts, (SOAF). The SOAF must be objective and contain accurate facts. The CMC's report must contain the same information contained in the SOAF. The CMC must rely on the SOAF, they cannot go

outside the information or questions provided to them. The CMC may state whether the accepted exposure was competent to produce the claimed illness. The Case Examiner should submit medical questions which are case specific. The Case Examiner cannot ask the CMC whether or not the DEEOIC should accept the claimed illness or consequential illnesses, or to decide the facts of the case.

A. Since the CMC must address only the SOAF, should the SOAF be sent to the treating physician as well as the claimant before the CMC issuing a report to check the SOAF for accuracy and objectivity?
B. The determination of Part E is the at least as likely as not standard. Should the CMC report state that more than a suspicion but less than 50%, the toxic substance has the potential to be a factor in aggravating the claimed illness because of XXXXX, it may contribute to the claimed illness because of XXXXX, and it may have a casual link to the claimed illness based on the increased risk and target organ of the toxic substance?
C. Why does the CMC address the IH's report of exposure when that is not under the expertise of the CMC?
D. Can a form be created for the CMC/ treating physician to address Part E such as.. "Based on the SOAF, the claimant/employee was a DOE contractor/subcontractor that worked from XXXX to XXX. The work duties exposed the employee to several toxic substances specifically but not limited to xxxxxx. The employee has claimed the illness of XXXXXX. Based on XXXXXXX it is established that the toxic substance has the potential because of it's nature to aggravate, the claimed illness OR contribute to the claimed illness OR cause the claimed illness.
Absent relevant evidence to the contrary, it is at least as likely as not……."

……medical guidance for claims examiners for claims under this subtitle with respect to the weighing of the medical evidence of claimants;

Determining the weight of evidence for claimants should be as objective as possible. Please note it is the "**medical evidence**" and not medical "**well rationalized report**". The burden of medical evidence is listed in 20 CFR 30.114. The diagnosis from the treating physician should out weight a physician that did not physically see the claimant or the medical records. The Former Worker Screening should be treated as objective medical evidence, as well as the medical records from work. The CMC must be an expert in the area of concern. A physician that is just a Occupational Medical Doctor must also be aware of chemical toxicity, biological toxicity, and radiological toxicity, and not just fractures, sprains, etc.

A. Medical conclusion unsupported by rationale are of little probative value. A physician's opinion must be one of reasonable medical certainty and must be supported with affirmative evidence, explained by the medical rationale and based on a complete and accurate medical and factual background. Should the Case Examiner send a copy of the SOAF to the treating physician when the CE needs a "well rationalized report"?

B. Should the treating physician be informed that this is not a workers compensation, but a federal compensation? And the at least as likely as not criteria.
C. What are the elements in a "well rationalized report"?
D. Can a form be created for both the CMC and the treating physician that would be consistent for all claimants?
E. Physician's statement SHOULD contain…
    1. An affirmation that the physician treated the employee for the claimed illness
    2. A statement that the requested medical records are no longer available
    3. A discussion that includes the diagnosis and date of diagnosis
    4. The physician's signature and the date signed
    5. The date of most recent examination
    6. The results of recent objective testing
    7. Physical examination findings
    8. Well reasoned medical opinion supported by the physical findings and objective testing as to whether the current conditions is related to the employment
    9. What work restrictions would be involved
    10. The type and frequency of medical treatment being provided or recommended

Please address a form for a medical narrative for OWCP to address……..

WHO, WHAT, WHEN, WHERE, WHY and HOW

….**evidentiary requirements for claims under subtitle B related to lung disease;**

" To ensure fairness and equity, the civilian men and women who, over the past 50 years, have performed duties uniquely related to the nuclear weapons production and testing programs of the Department of Energy and its predecessor agencies **should have efficient, uniform, and adequate compensation for beryllium-related health conditions and radiation-related health conditions."**

Chronic beryllium disease and silicosis have a legal diagnosis and not a medical diagnosis. Under the statute, covered beryllium disease is defined as

42 USC 7384l (8) The term "**covered beryllium illness**" means **any** of the following:

(A) Beryllium sensitivity as established by an abnormal beryllium lymphocyte proliferation test performed on either blood or lung lavage cells.

(B) Established chronic beryllium disease.

(C) Any injury, illness, impairment, or disability sustained as a consequence of a covered beryllium illness referred to in subparagraph (A) or (B).

(13) The term "established chronic beryllium disease" means chronic beryllium disease as established by the following:

(A) For diagnoses on or after January 1, 1993, beryllium sensitivity (as established in accordance with paragraph (8)(A)), together with lung pathology consistent with chronic beryllium disease, including—

(i) a lung biopsy showing granulomas or a lymphocytic process consistent with chronic beryllium disease;

(ii) a computerized axial tomography scan showing changes consistent with chronic beryllium disease; **or**

(iii) pulmonary function or exercise testing showing pulmonary deficits consistent with chronic beryllium disease.

(B) For diagnoses **before January 1, 1993**, the presence of—

(i) occupational or environmental history, or epidemiologic evidence of beryllium exposure; and

(ii**) any three of the following** criteria:

(I) Characteristic chest radiographic (or computed tomography (CT)) abnormalities.

(II) Restrictive or obstructive lung physiology testing or diffusing lung capacity defect.

(III) Lung pathology consistent with chronic beryllium disease.

(IV) Clinical course consistent with a chronic respiratory disorder.

(V) Immunologic tests showing beryllium sensitivity (skin patch test or beryllium blood test preferred).

(e) CHRONIC SILICOSIS—For purposes of this subchapter, the term "chronic silicosis" means a non- malignant lung disease if—

(1) the initial occupational exposure to silica dust preceded the onset of silicosis by at least 10 years; **and**

(2) a written diagnosis of silicosis is made by a medical doctor and is accompanied by—

(A) a chest radiograph, interpreted by an individual certified by the National Institute for Occupational Safety and Health as a B reader, classifying the existence of pneumoconioses of category 1/0 or higher;

(B) results from a computer assisted tomograph or other imaging technique that are consistent with silicosis; **or**

(C) lung biopsy findings consistent with silicosis.

The law only requires that the evidence be consistent with CBD and not definitive CBD. The biokinetics of CBD include the liver, skeleton, etc. Please verify that the correct ICD-10 code is the correct coded and that the liver, skeleton, etc. should be addressed in the medical coverage and the impairment.

A. What is the correct ICD10 code for CBD to included all of the biokinetics linked to CBD?
B. Since CBD has asthma like symptoms, should the asthma chart be used in the impairment?
C. Should CBD impairment include home health, in the activities of daily living as well as depression and anxiety? Guides allow for pain, 3%
D. What is a lymphocytic process consistent with CBD?
E. What is a lung pathology consistent with CBD? Give examples
F. If a claimant has been diagnosed with BeS, but has an abnormal pulmonary function, is that BeS or CBD ?

G. What are characteristics of an x-ray or CT scan for CBD? Should the policy state “but not limited to” when listing the x-rays/CT scans characteristic CBD?
H. Is calcified granulomas consistent with CBD?

The CASE EXAMINER develops the claim. The Case Examiners issue the Recommended Decisions. IN 2009, **“This material revises the requirements for demonstrating Chronic Beryllium Disease, and clarifies that satisfaction of either the pre-1993 or post-1993 is sufficient to allow for a diagnosis of CBD under the EEOICPA.”**
Rachel P. Leiton Director, Division of Energy Employees Occupational Illness Compensation

I. The pre-1993 is used if there is evidence of being treated for, tested for, or diagnosed with a chronic respiratory disorder. John Vance has stated that an upper respiratory infection, URI, is not a chronic respiratory disorder. However, an acute beryllium disorder is an inflammation of the upper respiratory. So based on objective facts and not speculations, can a URI be evidence of exposure to a inflammatory toxin, such as beryllium?

J. The OWCP has never defined Chronic respiratory disorder. IS it reasonable to use the World Health Organization’s definition of Chronic respiratory disorder?

Thank you for your time and help in clarify the issues that are of concern.

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