From:	Stephanie Carroll
To:	DOL Energy Advisory Board Information
Subject:	Public Comments IH BeS Presumptions HFHL The Act
Date:	Wednesday, May 11, 2022 1:26:53 AM
Attachments:	OLD SEM 444 771 776 777 991.pdf
	Econometrica Report.pdf
	Pneumoconiosis Page 10.pdf

CAUTION - The sender of this message is external to the DOL network. Please use care when clicking on links and responding with sensitive information. Send suspicious email to spam@dol.gov.

# Stephanie M. Carroll

#### You have permission to release my PPI

Office: (303) 376-6215 Fax: (877) 467-9658 Email: <u>AtomicWorkerAdvocacy@gmail.com</u> Cell: 949-295-7593

To the Advisory Board on Toxic Substances and Worker Health,

Thank you for allowing me to make comments today. Earlier in the meeting Dr. Markowitz mentioned that there was a public comment that needed clarification. I believe that I was the commenter referred to.

#### **SEM Library**

I understand and have documentation of the records that are held by the DOL in support of the SEM. Documents were given to the DOL by DOE as mandated in support of this Program and all SEM results are supported by these documents. There is a DOL library, and all SEM results consist of documentation in support of the findings from the DOE. The library consists of unclassified DOE and FWP records. The DEEOIC may have turned the library over to Paragon in order to defy FOIA but the library exists and an index of supportive documentation may be of great help to the Board. See that the SEM lists references as DOL documents with a number and title. An index of the documents may help you with your SEM evaluations.

Example Rocky Flats Building 776/777 is supported by: DOL-05-00042 Title: Rocky Flats Overview" and DOL Doc #: DOL-05-00045 Title: "EG&G Industrial Hygiene Group"

See The attached SEM results prior to SEM becoming public.

See the Act and clear intent of Congress in relation to the mandated SEM (Site Profile) These profiles are clearly related to toxins not radiation. The SEM was intended to establish exposure and support approval of claims.

# §7384w–1. 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.

The SEM was mandated to support exposure to toxins at The DOE Sites. Industrial Hygiene records were mandated to be provided to the DEEOIC and Indexing and description of such records was required. The SEM library index is an invaluable resource.

See the Act 42CFR 7385s-10

# (c) Records

(1)(A) The Secretary of Energy shall provide to the Secretary all records, files, and other data, whether paper, electronic, imaged, or otherwise, developed by the Secretary of Energy that are applicable to the administration of this part, including records, files, and data on facility industrial hygiene, employment of individuals or groups, exposure and medical records, and claims applications.

(B) In providing records, files, and other data under this paragraph, the Secretary of Energy shall preserve the current organization of such records, files, and other data, and shall provide such description and indexing of such records, files, and other data as the Secretary considers appropriate to facilitate their use by the Secretary.

# The DEEOIC is not permitted under the APA to create presumptions more stringent than Congress intended.

# **Borderline BeS**

A test is done on each day at different levels of Beryllium Sulfate and one test showing a response that is abnormal fits the mandated criteria to establish a beryllium illness under Part B. See billing by National Jewish Health of 30.00 per test totaling 300.00 for the series. See the clear language of the Act:

(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).

Dr. Lee Newman prior to the enactment of this Program diagnosed one abnormal result (borderline) as abnormal and two abnormal results as "confirmed sensitized" The Program pays the bill for BeLPT's in segments of 30.00 payments for each assay/test. (300.00 for 6 assays/tests) This acknowledges that a result letter from NJH reports findings of <u>6 tests or assays</u>. The blood is assayed (tested) on each of 2 days at 3 different levels of Be Sulfate. An abnormal test (assay) preformed on blood is established sensitivity according to the clear language of the Act.

The false negative rate is quite high while the false positive rate is negligible and can only be explained by lab mistakes. (Contaminated equipment etc...) See Dr. Rossman University of Pennsylvania.

It is virtually impossible for lymphocytes to respond to beryllium without past exposure.

False negative tests can be explained by the following according to Dr. Rossman. In regard to the "normal" results "only a subpopulation of patients with cbd will test positive if their peripheral blood is studied for sensitivity to beryllium" (1) P. 170 "The BeLTT has a significant probability of a false negative result". (1) P. 189 Limitations can occur for the following reasons: "handling and transport cell death, immunosuppressive therapy can suppress the ability of the cells to respond, intercurrent viral infection can suppress the ability of the cells to respond, if an insufficient number of cells was obtained for study, or the test was assayed on the wrong day of in vitro culture and the peak response was missed". (1) P171

"Proliferation based assays might underestimate the frequency of Be Sensitization in the workplace" (6) Therefore the "normal" results are noted but do not exclude the diagnosis of established cbd

Further due to the immunogenicity of the BeLTT, there is indication that any positive value suggests Be sensitization.

# Presumptions under part E

*OWCP* is relying on impermissible factors when adjudicating claims using the presumptions. Hearing Loss is an example of the Agency not following the clear language of the Act. (See language below) Presumptions have already been established by Congress. See the sense of Congress as quoted from the Act.

#### §7384. Findings; sense of Congress

Federal nuclear activities have been explicitly recognized under Federal law as activities that are *ultra-hazardous*. Recurring exposures to radioactive substances and beryllium that, *even in small amounts*, can cause medical harm. Over the past 20 years, more than two dozen scientific findings have emerged that indicate that certain of such employees are *experiencing increased risks of dying from cancer and non-malignant diseases*. Studies indicate than 98 *percent of radiation-induced cancers* within the nuclear weapons complex have *occurred at dose levels below existing maximum safe thresholds*.

Because of long latency periods, the uniqueness of the hazards to which they were exposed, and inadequate exposure data, many of these individuals have been unable to obtain State

#### workers' compensation benefits.

Under the Administrative Procedures Act if Congress has clearly spoken on an issue the Agency is not permitted to rely on factors that do not have a reasonable relationship to statutory purposes or requirements. Requiring that an IH determine

According to the Act:

# 7385s-4. 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 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.

(A) Is referring to the toxic substance being likely to cause, contribute to, or aggravate an illness. (B) refers to the probability that exposure to such toxin was as a result of employment at a DOE Site.

Any presumptions have been addressed in 2005 with the implementation of Part E. The FWP phase 1 Needs Assessments have established the most common toxic exposures and illnesses related to DOE employment. It is the basis of the protocol used in the Former Worker Program. Econometrica is a contracted report used by OWCP in the adjudication of Part E claims and was completed in 2005 in order to assist CE's. It was the basis for the matrixes found in the PM which have been changed without reason. The Matrixes addressed evidence sufficient to establish a covered condition under Part E. (presumptions)

DEEOIC would like you to spend your valuable time recreating "presumptions" that are often in direct conflict with past Agency decisions and in violation of the clear intent of Congress. It is arbitrary and capricious for an Agency to preclude the unambiguous text of the statute by creating more stringent criteria (presumptions) under Part E.

High Frequency Hearing Loss has a very stringent presumption. See the Procedure Manual which does not bind the public in any way according to the cover of PM 4.1.

See the section on challenges to the presumption. *PM* 6.1

d. Challenges to the DEEOIC Standard. <u>This standard described in this section represents the</u> <u>sole evidentiary basis a CE</u> is to use in making a decision concerning whether it is "at least as likely as not" that an occupational exposure to a toxic substance was a significant factor in aggravating, contributing to or causing a diagnosed bilateral sensorineural hearing loss. Claims filed for hearing loss that do not satisfy the standard outlined in this section cannot be accepted, because it represents the <u>only scientific basis for establishing work-related hearing</u> <u>loss due to exposure to a toxic substance</u>. As is usual for all claims, the CE is to undertake development on any hearing loss claim that does not meet the criteria described in this procedure, which entails communicating to the claimant the evidence necessary to meet the <u>standard</u> (medical+employment+exposure). As part of that development, the CE is to notify the claimant of his or her ability to challenge the scientific underpinnings of the DEEOIC hearing loss standard.

My client was not informed and no development in line with the statute was preformed. Contemporaneous exposure evidence in conflict with the presumption was never considered. It consisted of Job Descriptions (not listed in the presumption) with *frequent* Solvent exposure, Evidence as a "Hazardous Waste Worker" defined by DOE as *exposed to hazards above standards for 30 days or more per year*. There were Medical records of exposure to Trichloroethylene at high levels. His probative contemporaneous exposure evidence was ignored by the CE and he was denied benefits. None of the evidence he provided was analyzed or acknowledged including the OHQ. There is DOE evidence of the use of Trichloroethylene for the entire life of building 771 well beyond 1990. . His job titles/descriptions support solvent exposure as a Filter Tech, NDT Tech and an RCT.

# <u>PM 6.1 continued guidance for challenging the presumption.</u>

<u>If the claimant wants to challenge</u> one or more of the criteria of the standard, the claimant has the burden of establishing, through the submission of probative scientific evidence, that the criteria used by the program do not represent a reasonable consensus drawn from the body of available scientific data. If a claimant seeks to argue that the standard is not based on a correct interpretation of available scientific evidence, or that a toxic substance that is not listed as having a health effect of hearing loss exists, he or she will need to provide probative epidemiological data to support the claim. At a minimum, the claimant must produce epidemiological evidence (medical health science journals, articles, periodicals or other peerreviewed publications) that specifically identifies or references a toxic substance, as defined by DEEOIC's regulations, which the evidence describes as having a health effect of bilateral sensorineural hearing loss.

This is burdensome and unfair. There are many studies that show CNS effects from heavy metals and the list of solvents in the presumption are just the tip of the iceberg for known solvent hearing loss effects. It would burden the claimant less if the scientific data supporting the presumption were cited. This is being withheld from the claimants and renders any challenge to the presumption impossible. It is unfair.

The presumption for High Frequency Hearing Loss is contradicted elseward in the PM 6.1.

# See Chapter 15 – Establishing Toxic Substance Exposure

Medical evidence specific to the individual. Individuals can have unique medical responses to different toxic substance exposures. SEM and scientific studies may not show a causal connection, but the claim may still be compensable based on an employee's unique biology and the employee's physician's opinion regarding causation. This is untrue for HFHL under **Part E** Medical evidence specific to the individual can also be important regarding claims of aggravation and contribution as SEM and the Toxicologist only provide associations as relating to direct cause (i.e., human epidemiological evidence that a toxic substance is known to cause an illness)

The PM and Agency guidance notes that SEM and the toxicologist only provide associations relating to <u>direct cause</u>. The claims must be adjudicated in a fair and consistent manner in line with the clear language of the Statute.

HFHL is being denied ameliorating the cost of medical devices, which can be expensive.

Congress has clearly spoken to the qualifications required for approval of benefits under part E. It is arbitrary and capricious for the Agency to change the requirements for certain conditions without going through the rulemaking process.

# <u>IH reports</u>

The Act does not require an opinion as to the nature, frequency and duration of exposure to meet the employment criteria under Part E.

*See the Act:* (*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.* 

The templatized IH reports state that "this document is for the purpose of providing supplemental information for use by the CE in the development of this specific claim" "It is not intended for use on other claims" The template is the same for all claimants and all references are to SEM and four publications on Industrial Hygiene and toxicology (none specific to the DOE) The new language on the mid 1990's health standards is being added to *all* IH reports. It is a waste of resources for the same language and references to be used in all claims and yet they cannot be used interchangeably. The IH will never interview the claimants because the Program does not believe in the value of interviewing the workers to form the basis of Industrial Hygiene which contradicts one of the main tenants of a good IH program. There is never any substantive reference to any OHQ in the IH reports. The Program believes that workers will lie about their jobs. The OHQ is never given any probative value. The lack of discussion of the OHQ supports that it is not analyzed. I have heard Agency personnel state that workers very often answer that they were exposed to all toxins which in my experience is untrue. This culture of mistrust forms the basis of the refusal to accept the OHQ and the resistance to interviewing the workers. The culture within the DEEOIC is not in line with Congressional intent of the Act.

In conclusion it is imperative that we all recognize the clear intent of the US government when enacting the EEOICPA. It is expressed beautifully in the Executive Order in support of the Act.

It reads: While the Nation can never fully repay these workers or their families, they deserve recognition and compensation for their sacrifices. Since the Administration's historic announcement in July of 1999 that it intended to compensate DOE nuclear weapons workers who suffered occupational illnesses <u>as a result of exposure to the unique hazards</u> in building the Nation's nuclear defense, it has been the policy of this Administration to support fair and timely compensation for these workers and their survivors. The Federal Government should provide necessary information and otherwise help employees of the DOE or its contractors determine if their <u>illnesses are associated with conditions of their nuclear weapons-related</u> work; it should provide workers and their survivors with all pertinent and available information necessary for evaluating and processing claims, and <u>it should ensure that this program minimizes the administrative burden on workers and their survivors and respects their dignity and privacy.</u>

You have my permission to release all PPI found in the Comments.

Thank you for your continued work on behalf of all nuclear workers,

Stephanie Carroll Authorized Representative 949-295-7593