Alliance of Nuclear Worker Advocacy Groups

Presentation to National Academy of Sciences Institute of Medicine
January 23, 2012
The DOL rule fails to define how site profiles/exposure matrices will be used to assist claimants, and it does not set forth a clear basis for deciding claims when no reliable toxic exposure monitoring was conducted by the DOE or its contractors.

The rule places a burden on a claimant to establish proof that toxic substances were "present at the facility" and "that employee came into contact with such substance." Even though exposure site profiles are underway. Exposure monitoring records exist for few toxic substances - even for current operations. Further, claimants do not have ready access to records that do exist, and survivors have no first-hand knowledge of working conditions. Exposure assessments should be identified as a DOL requirement in developing a claim where there is inadequate information to render a decision, and be used as a source of information to supplement the information provided by claimants. Claimants should be assured the right to review these site profiles/exposure matrices.
ANWAG’s Comment on Interim Final Rules

1. Develop a matrix of toxic substances (DOE workers were known to have had exposures to) and all the diseases and/or conditions these toxins were known to aggravate, contribute to or cause. Verification of these toxic substances on site should be developed through the occupational histories already submitted by claimants or by DOE's contribution to the claim, or by other means such as purchase orders for these toxins, DOE “Tiger Team Reports”, and DOE Independent Investigation Health and Safety Reports, all other federal and state monitoring agencies.
ANWAG’s Comment on Interim Final Rules (cont.)

2. A disease list should use the MSDS of each toxic substance, medical literature, federal monitoring agency reports and any other credible source of information. If an agency or credible medical study shows that a toxic exposure aggravated, contributed to or caused a disease it needs to be listed in the matrix. Waiting for a consensus between agencies or the medical community will conflict with Congressional intent for timely compensation. Each toxic substance should be listed with the maximum exposure effects, as monitoring these substances was either limited or non-existent. Many of these substances have since been banned from the workplace, due to their dangerous health effects. MSDS recommendations were not always followed. For example, TCE (trichloroethylene), now banned was recommended as a coolant for machine tooling and diluted according to MSDS. However, it was often used undiluted to degrease parts. Consequently, assuming maximum concentration will be claimant friendly.
ANWAG’s Comment on Interim Final Rules (cont.)

3. EEOICPA has adopted the policy that each worker at a facility where beryllium was present had the potential of exposure because of dust, vapor or liquid dispersion. This policy was developed because office workers, etc. have been diagnosed with Chronic Beryllium Disease, in addition to the trades that worked with the metal. It has therefore been assumed that winds and water supplies as well as workers carrying the beryllium on the clothes and in their hair exposed the entire facility. The same policy should be used to assume that all workers had the potential exposure to other toxins.

4. Anything less than an all inclusive matrix applied by well trained claims examiners familiar with using such a matrix would not comply with the Department of Labor’s intent for this to be a claimant-friendly program.
What the Site Exposure Matrix says:

- [http://www.sem.dol.gov/Dis.cfm](http://www.sem.dol.gov/Dis.cfm)

Stomach cancer (also known as Cancer of stomach; Gastric cancer; Gastric neoplasms)

Toxic substances with an established causal link to the diagnosed illness as accepted by NLM

(Note: EEOICPA evaluates toxic substance exposure that was a significant factor in aggravating or contributing to employee illness or death and is done on a case-by-case basis.):

No toxic substances in the SEM database show an established causal link to the selected occupational disease at this time.
What the Agency for Toxic Substances & Disease Registry says:

Human Carcinogenic Agent

<table>
<thead>
<tr>
<th>Organ</th>
<th>Known</th>
<th>Suspected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomach</td>
<td>Zinc chromate</td>
<td>Ethylene oxide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PAHs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tetrachloroethylene</td>
</tr>
</tbody>
</table>

What the International Agency for Research on Cancer (IARC) says

Inorganic and organic lead compounds

2.1.3 Lead chromate pigment production
Workers producing lead chromate pigments have been the subject of two cohort studies focused on possible lung carcinogenicity resulting from exposure to hexavalent chromium, which was classified as Group 1 human carcinogen by IARC (IARC, 1990).
What the International Agency for Research on Cancer (IARC) says (cont.)

Cancer Mortality in pigment plant utilizing lead and zinc chromates

Several studies of workers exposed to various forms of chromium compounds have suggested an increased incidence of respiratory cancers. Lead and zinc chromates were among the chromium compounds implicated. The Department of Preventive Medicine and Community Health of the New Jersey Medical School undertook a detailed mortality study of a pigment plant in Newark which utilized both of these compounds. We compared observed deaths from each cause among 1296 white and 650 non-white males who were employed at the plant between January 1, 1940 and December 31, 1969, with expected deaths, as computed from cause-, age-, and time-specific standard death rates for the United States. A statistically significant relative risk of 1.6 for lung cancer among white male employees was found, as well as among the cohorts of white males employed 10 yr or more. A relative risk of 1.9 was noted for individuals employed at least 2 yr who were at least moderately exposed to chromates. An increased incidence of lung cancer among non-white males and stomach and pancreatic cancer among the total cohort was also evident.

What the International Agency for Research on Cancer (IARC) says (cont.)

- Sheffet et al. (1982) studied mortality among 1296 white and 650 non-white men in a pigment plant producing lead and zinc chromates in the USA who were employed for at least 1 month between 1940 and 1969, and followed through 31 March 1979. Moderate exposure was defined as work in jobs with an average exposure of 0.5–2 mg/m³ airborne chromium, while high exposure was defined as > 2 mg/m³ airborne chromium; 76% of the cohort had high or moderate exposure. A statistically significant relative risk of 1.6 (95% CI, 1.1–2.2; 31 deaths) for lung cancer was found among male employees, increasing to a significant 1.9 for those exposed for at least 2 years to moderate or high exposure. Stomach cancer had a SMR of 2.0 (95% CI, 0.9–3.6; 8 deaths).

http://monographs.iarc.fr/ENG/Monographs/vol87/mono87-7.pdf
HazMap is inappropriate for EEOICPA

- No value for Toxicologist
  - Animal studies not considered.
- No value for Epidemiologist
  - Depends on causation only. No contributing or aggravating factors considered.
- No value for Occupational Physician
  - Contains no combinations of chemicals, radiation, or pre-existing medical conditions.
- No value for evidence based review
  - Does not follow IOM rules of weighing evidence protocol - peer review, grading of evidence or grading of conclusions.
  - [Link](https://download.nap.edu/catalog.php?record_id=13059)
- No value for EEOICPA
  - Too subjective for complex claims
What the District Medical Consultant Manual says


Legal Standards of Certainty and Concepts

- **Highest** - beyond a reasonable doubt (e.g., used to determine guilt in criminal cases);
- **Clear** and convincing evidence (e.g., used in special civil cases such as commitment determinations);
- **Mid** - preponderance of evidence (usual standard in civil cases and usually means more likely than not);
- **Low** - reasonable suspicion;
- **Lowest** - mere suspicion (hunch).

In the EEOICP the causation standard for Part E seems to fall between level c and d (above).
What the law says:

• § 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.
“The DOL rule applies the wrong standard of causation for radiation related cancers.
The standard of causation under Subtitle E is whether exposure to a toxic substance is "a significant factor which aggravated, contributed to or caused the illness." DOL follows this contributory standard for all toxic substances, except radiation-related cancers. For radiation related cancers, DOL's interim rule requires the Subtitle E claimant to prove that "it is at least as likely as not that exposure to radiation caused the illness." These two standards of causation are not the same, and DOL is not at liberty to modify the statute through rulemaking. DOL's preamble states that to apply the law, as written, will require decisions to be based on a "substantial speculative component." The contributory standard under Subtitle E is applied in numerous state jurisdictions, and the DOL uses it for all other toxic substance claims under Subtitle E. DOL's rule applies the contributory standard when there are mixed exposures involving both radiation and toxic substances. DOL should set forth a contributory standard for radiation related cancers of less than 50% (at the upper 99% confidence interval) which is guided by science.”
Standards for Peer Review

- The peer review process must be independent and without significant conflicts of interest...
  [ICMJE](http://www.icmje.org/ethical_3peer.html)

- National Academy of Sciences Standards for Systemic Reviews
  [NAP](http://www.nap.edu/catalog.php?record_id=13059)

- Closely aligned reviewers tend to render favorable reviews
  [JAMA](http://jama.ama-assn.org/content/295/3/314.full.pdf+html)