

**Analysis of the Institute of Medicine's Review of Department of Labor's  
Site Exposure Matrix  
And  
Department of Labor's Response to the Recommendations**

Prepared by

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In September 2011 the Department of Labor's Division of Energy Employees Occupational Illness Compensation Program (DOL) contracted with the National Academy of Sciences' Institute of Medicine (IOM) to review the Site Exposure Matrix (SEM) and to make recommendations for improving the database. [http://eecap.org/PDF\\_Files/EECAP/NAS\\_contract.pdf](http://eecap.org/PDF_Files/EECAP/NAS_contract.pdf)

#### **DOL'S TASK TO IOM**

DOL tasked IOM to "review the scientific rigor and organization of the Department of Labor's Site Exposure Matrix (SEM) database. The SEM is a repository of site-specific information gathered from a variety of sources regarding toxic substances present at Department of Energy and Radiation Exposure Compensation Act facilities covered under Part E of the Energy Employees Occupational Illness Compensation Program Act. The focus will be on how workplace chemical usage and exposure link to certain diseases as well as the NIH's and National Library of Medicine's (NLM) review process for Haz-Map, the database that helps link jobs and hazardous tasks with occupational diseases and their symptoms. The committee also will examine the review process used by the Haz-Map developer when including information in the Haz-Map database and identify strengths and weaknesses of the SEM in order to make recommendations. Additionally, the report will consider the following:

1. What, if any, occupational diseases that might have affected the DOE contractor workforce are missing from SEM?
2. What, if any, links between occupational diseases and toxic substances present at DOE sites are missing from SEM?
3. Is there additional literature that might be incorporated into SEM to strengthen or add to the existing links between toxic substances and occupational diseases? Are the existing links sufficiently robust?
4. What, if any, other occupational disease databases might be used to supplement the Haz-Map information in SEM?
5. How scientifically rigorous are the disease links contained in the SEM and Haz-Map?
6. What are the strengths and weaknesses of the NIH/NLM peer review process with regard to Haz-Map? How might this process be improved?
7. Can any known (epidemiologically significant) synergistic effects between multiple chemicals or chemicals and radiation be placed in SEM? If so, what are the sources of these links and are they occupational in nature?
8. What consistent process or approach could be used to consider a disease or cancer established when studies are inconclusive, inconsistent or conflicted in some way?"

#### **IOM PROVIDES DOL WITH 3 "OVERARCHING" RECOMMENDATIONS TO IMPROVE SEM**

1. Add supplemental information sources to the health effects information imported from Haz-Map
2. Improve the structure and function of SEM, including the addition of available exposure information
3. Use an external advisory panel to review the health effects information in SEM

The Alliance of Nuclear Worker Advocacy Groups (ANWAG) has reviewed the IOM report and DOL's response. We offer a brief analysis and our conclusions.

## EXTERNAL ADVISORY PANEL AND PEER REVIEW

We will begin with IOM’s recommendations which we consider the most important, that being Recommendation #1, “Add supplemental information sources to the health effects information imported from Haz-Map” and Recommendation #3, “Use an external advisory panel to review the health effects information in SEM”. These two recommendations are closely intertwined

The IOM Report repeatedly stresses the need for an external advisory panel; one that is not only independent of DOL but is also independent of the DOL’s sub-contractors responsible for SEM and Haz-Map.

IOM’s report offers recommendations on the makeup of this panel and as well as the tasks that the panel should undertake. While DOL acknowledged this recommendation, they clearly show their reluctance to accept this recommendation. Instead of immediately initiating the process that would help establish the external board, DOL intends to “evaluate the options for developing such a process.” DOL also stated, in response to Recommendation #1, they would reach out to other agencies “to determine whether there are possibilities for collaboration or information gathering as a starting point.” DOL’s ideas for establishing an external advisory panel do not concur with IOM’s well rationalized recommendations.

Below is a side by side comparison between the IOM report and DOL’s proposal.

<b>IOM Recommendations</b>	<b>IOM Report</b>	<b>DOL Proposal</b>
Peer review of its toxic substance–occupational disease links.	Yes	No
Broad-based Expert Advisory Panel	Yes	No
Expert Advisory Panel external to DOL.	Yes	No
Expert Advisory Panel also external to current SEM contractor.	Yes	No
Membership should include experts in epidemiology, occupational medicine, toxicology, industrial hygiene, claimants, and advocacy organization representation.	Yes	No
Expert Advisory Panel would establish the criteria for the evidence base for causal links between exposure to a toxic substance and an occupational disease.	Yes	No
Expert Advisory Panel would determine the information sources that might be reviewed to identify information on possible links.	Yes	No
Expert Advisory Panel would develop a worksheet or other documentation to capture the evidence taken from each information source, including Haz-Map.	Yes	No
Expert Advisory Panel would oversee revisions of SEM to add appropriate fields for capturing supplemental information.	Yes	No
Expert Advisory Panel would peer review all new links in SEM that are based on both Haz-Map and the supplemental information.	Yes	No

Expert Advisory Panel would assess occupational diseases that might result from complex exposures.	Yes	No
Expert Advisory Panel would identify potential new links and track them for possible future inclusion in SEM.	Yes	No
Expert Advisory Panel would review existing causal links in SEM that are based solely on Haz-Map.	Yes	No
Expert Advisory Panel would do periodic review of a sample of the toxic substance–disease links from both accepted and rejected claims to determine whether SEM links are actually assisting in the claims process.	Yes	No

<b>DOL Press Release</b>	<b>IOM Report</b>	<b>DOL Proposal</b>
DOL suggests having a panel of unnamed scientific and medical experts review the SEM links and substances.	No	Yes
DOL suggests possibly contracting with an unnamed scientific or academic organization to do the work.	No	Yes
DOL suggests possibly utilizing the services of scientific experts employed by other Federal agencies to do the work.	No	Yes
DOL suggests possibly creating a peer review process by unnamed individuals with recognized scientific expertise to independently review the SEM. Didn't IOM just do this?	No	Yes

One of the recommended panel's main tasks would be to provide a peer review of the scientific research that is used in SEM to ensure SEM contains the best science for use by the claims examiners (CE). DOL does "recognize the value of a process for review of the SEM links and substances by a panel of scientific and medical experts". However, their plan for this review is quite different from what IOM suggests.

The IOM Report supplies the National Research Council's definition of peer-review on page 45. The peers performing the review must not have a conflict of interest and need to be free of bias from personal, work, or financial concerns.

As we have seen in the IOM Report neither the Site Exposure Matrix (SEM) nor Haz-Map has been peer-reviewed. Evidence sent to DOL to be reviewed for inclusion in the SEM is currently evaluated by [Paragon Technologies](#). DOL has paid this contractor over \$12 million to manage the SEM. The information in Haz-Map is evaluated by [Dr. Jay Brown](#), a Paragon contractor and the individual owner of Haz-Map.

Possible Routes to Peer Review	IOM Recommends	DOL Recommends
An Expert Advisory Panel reviews only evidence used for the Haz-Map links that are incorporated into the SEM "Specific Health Effects" field	Yes	No
Expert Advisory Panel review Haz-Map links incorporated into SEM then directs DOL contractor to make changes.	Yes	No
DOL Contractor prepares profile for each substance in SEM, including any information Expert Advisory Panel decides must be added. Contractor would make recommendations. Expert Advisory Panel would review. Link entered into SEM by Contractor.	Yes	No
Contractor prepares profile for each toxic substance but does not make any recommendation. Expert Advisory Panel would review profiles using weight of evidence and make determination. Determination would be reviewed by External peer reviewers. Expert Advisory Panel reviews.	Yes	No
Peer review of all new links in SEM	Yes	Yes
Peer review of SEM's toxic substance–occupational disease links	Yes	Yes

A SEM Source needs
To use weight-of-evidence evaluations for occupational health effects and exposures
To be peer reviewed externally
To be easy to use
To be transparent with methods clearly described
For field contents to be appropriately referenced
To communicate the toxic substance–disease linkages clearly and accessibly to non-expert audiences
To be publicly available for free or minimal cost
To be comprehensive

Why the SEM needs to be Peer Reviewed
Increase public confidence in its accuracy
Increase public confidence in its comprehensiveness
Help ensure SEM contains the most current information available

The IOM Report leaves no doubt that the SEM and Haz-Map, as SEM's only source of illness/exposure information, need to be peer-reviewed. The report states peer-review is "critical if the SEM is to provide both DOL claims examiners and claimants with comprehensive, accurate, and understandable information." This is a very strongly worded recommendation and DOL cannot afford to ignore it.

One of the best known sources of peer reviewed medical research articles is [PubMed](#). This is a resource that many claimants and advocates turn to when they need to research links between occupational illnesses and toxic exposures. PubMed can be accessed through the Haz-Map database. However, the IOM report notes (Page 59) that DOL's Claims Examiners' Procedure Manual forbids the claims examiner to utilize this resource when adjudicating claims.

The IOM Review also pointed out that DOL is misleading the public and DOL personnel on the National Library of Medicine's involvement with review of SEM (Page 101). This issue has been raised multiple times by ANWAG. DOL insists that peer review of the SEM is not necessary because the National Library of Medicine (NLM) reviews it.



## IMPROVING THE STRUCTURE OF SEM

The final broad recommendation IOM had to improve SEM is for DOL to improve the structure and function and to include available exposure information. IOM identified the strengths of this database

<b>Site Exposure Matrix Strengths</b>
Contains occupational diseases linked to toxic substances used at DOE sites.
Developed in consultation with DOE experts and former facility workers.
Attempts to be comprehensive for all toxic substances used at DOE sites.
Includes 65% DOE facilities covered by EEOICPA Part E.
Publicly available on the Internet.
Allows searches for a variety of information within a specific DOE facility.
Updated approximately every 6 months.
Provides a way for the public to submit site and disease related information.

DOL has agreed to search for additional exposure records. DOL disagreed with the recommendation that a universal SEM be developed so that the public could access general information on job titles and the potential toxic substances that would have been present. ANWAG agrees with DOL that the claims examiners need the site specific SEM because each site had unique processes. However, we were disappointed that DOL dismissed this recommendation out of hand without further study into the feasibility and cost effectiveness of having such a universal SEM. It is interesting to note that the SEM does provide a general list of toxic substances for each site.

DOL also stated in their response to Recommendation #2 that “Haz-Map database does contain source references to each link that is in that database”. Unfortunately, the claims examiners are not permitted to search Haz-Map for that information.

IOM also suggested ideas that would make SEM more user-friendly. Some of the suggestions can be implemented quite easily. For instance, IOM suggested that the search box be placed near the top of the page instead of at the bottom. Another suggestion was to notify the public of the specifics of the updated information. The National Institute for Occupational Safety and Health Division of Compensation and Analysis Support does supply these details when they update their website. DOL does not address these recommendations in their response.

<b>Recommendations to improve the Structure and Function of SEM</b>
Links between toxic substance and occupational disease must be appropriately referenced
Include appropriate citations
Remove misleading statement from SEM Homepage*
Remove misleading statement from Occupational illnesses and toxic substances page*2
Provide direct link on SEM homepage to universal expanded database ( <a href="http://www.sem.dol.gov/expanded">http://www.sem.dol.gov/expanded</a> )
Provide specification in SEM indicating what field was updated or changed as well as date changed
Improve search function to include toxic substances at more than one site at a time
Improve search function to enable user to search for all toxins by job category
Improve search function to enable user to search for multiple filter at one time, ie. job description, site and disease
Peer review process
Quality control review of all SEM records to insure proper citing
Quality control review of all SEM records to insure there are no typographic errors
Quality control review of all SEM records to insure no important information is omitted
Quality control review of all SEM records to insure that no information has been taken out of context
Conduct feasibility study to determine if the following can be added to SEM
Include information on occupational exposure to help determine duration of exposure
Include information on occupational exposure to help determine intensity of exposure
Include information on occupational exposure to help determine frequency of exposure
Include information on occupational exposure to help determine routs of exposure
Include other sources than HazMap into SEM
Call SEM a "hazardous substance" rather than an "exposure" database
DOE epidemiological studies results considered by Advisory Board for addition to SEM
Better and more comprehensive use of data sources, such as IARC, ATSDR, NTP, IRIS, Cal/EPA OEHHA
Make SEM links for mixtures more robust
Peer review of HazMap
Include research on synergistic chemical interactions for evaluation for claimants
Expert Advisory Panel should watch evidence of chemical-radiation synergism as it develops over time
Expert Advisory Panel should review evidence of potential toxic substance disease links to access for inconclusive, inconsistenet or conflicted studies.
*The relationship between toxic substances and diagnosed illnesses shown in SEM is derived from records of research by recognized medical authorities maintained by the National Library of Medicine. DOL continually updates these relationships as new disease associations are recognized by NLM. The causal links provided by NLM do not represent an exclusive list of the pathways necessary for an affirmative Part E causation determination.
*2 "Toxic substances with an established causal link to the diagnosed illness as accepted by NLM." Page 101 of IOM report

In preparing this paper ANWAG has discovered two issues concerning the structure of SEM that were not addressed in detail by IOM. The more serious of the two is that there are sites that are missing from SEM. Some of these sites such as Dayton Project and the Uranium sites have only been designated as a DOE facility within the past year. However, some sites such as the Kirtland Air Force Base Hanger 481 and Oak Ridge Hospital have been designated as a DOE facility for a number of years. A complete list of the missing sites can be found at the end of this paper.

The other issue is the extreme difficulty in locating the expanded SEM for uranium mines. Before the user can search for the name of the mine the location of the mine (state *and* county) must first be known and entered. These steps seem unnecessary when that information is not needed when searching for DOE sites.

## **CONCLUSIONS**

ANWAG is grateful to DOL for contracting with IOM to review the SEM. We are very pleased with IOM's evaluation. We concur with their recommendation that an external advisory panel be formed to review the health effects information and other deficiencies IOM identified. We would like to take this one step forward and add responsibilities to this proposed panel to advise DOL on other areas of the program.

DOL contract with IOM cost over \$1 million. ANWAG thinks that was money well spent. However, we are disappointed in DOL's response to the recommendations. Most of the recommendations are ignored. While DOL offers to research various options for other entities to review the information in SEM, it is not clear whether the review will be open to the public as an external advisory board's deliberations would be. It is crucial that this process be transparent and open to scrutiny. We urge Congress to introduce and pass legislation that would create this independent advisory board as quickly as possible.

**DEPARTMENT OF ENERGY FACILITIES WITHOUT SITE EXPOSURE MATRICES**

<b>DOE Facilities without Site Exposure Matrices</b>	<b>DOE Site</b>	<b>DOE dates</b>	<b>In SEM</b>
Albuquerque Operations Office	Yes	1942-present	No
BONUS Reactor Plant (Puerto Rico)	Yes	1964-1968	No
Climax Uranium Mill in Grand Junction. CO	Yes	Dec. 1988-Aug. 1994	Different name suspected
Clinton Engineer Works Oak Ridge, TN	Yes	1943-1949	No
Colonie Site (National Lead) Albany, NY	Yes	1984-1998	No
Elk River Reactor, MN	Yes	1962-1968	No
Environmental Measurements Laboratory - NY	Yes	1946-2003	No
Grand Junction Operations Center - CO	Yes	Aug. 1943–Oct. 2001	Possible different name used
Green Sludge Plant In Uravan Co. - CO	Yes	1943-1945	No
Hallam Sodium Graphite Reactor - NE	Yes	1960-1971	No
Hood Building - MA	Yes	1946-1963	No
Kirtland Air Force Base Hanger 481 - NM	Yes	Mar. 1, 1989-Feb. 29, 1996	No
Kirtland Operations Office- Kirtland Air Force Base - NM	Yes	1964 - Present	No
Laboratory for Biomedical + Environmental Sciences - CA	Yes	1947-present	No
Laboratory for Energy-Related Health Research - CA	Yes	1958-1989; 1991-present	No
Laboratory of Radiobiology and Environmental Health- University of California	Yes	1951-1999	No
Lacrosse Boiling Water Reactor - WI	Yes	1967-1969	No
New Brunswick Laboratory - NJ	Yes	1948-1977	No
New Uranium Mill in Rifle, CO	Yes	Sept. 1988-Sept. 1989; April 1992-Oct. 1996	No
Oak Ridge Hospital	Yes	1943-	No

		1959	
Office of Scientific and Technical Information - TN	Yes	1957 - Present	No
Old Uranium Mill in Rifle, CO	Yes	Sept. 1988-Sept. 1989; April 1992-Oct. 1996	No
Puerto Rico Nuclear Center	Yes	1957-1976; 1987	No
St Louis Airport Storage Site (SLAPS)	Yes	Jan. 3, 1947 - 1973; 1984-1998	No
Thomas Jefferson National Accelerator Facility, VA	Yes	1994-present	No
Uranium Mill and Disposal Cell in Lakeview, OR	Yes	1986-1989	
Uranium Mill at Shiprock, NM	Yes	Oct. 1984-Nov. 1986	No
Uranium Mill in Converse County, WY	Yes	April-Sept. 1989	No
Uranium Mill in Falls City, TX	Yes	Jan. 1992-June 1994	No
Uranium Mill in Gunnison, CO	Yes	Sept. 1991-Dec. 1995	No
Uranium Mill in Lowman, ID	Yes	1992; 1994 - present	No
Uranium Mill in Maybell, CO	Yes	May 1995 – Sept. 1998	No
Uranium Mill in Mexican Hat, UT	Yes	July-Oct. 1987; Sept. 1992-Feb. 1995	No
Uranium Mill in Monument Valley, AZ	Yes	May 1989-Feb. 1990; Sept. 1992-May	No

		1994	
Uranium Mill in Naturita, CO	Yes	May- Nov. 1994; June 1996- Sept. 1998	No
Uranium Mill in Riverton, WY	Yes	May 1988- Sept. 1990	No
Uranium Mill in Tuba City, AZ	Yes	Jan. 1985- Feb. 1986; Jan. 1988- April 1990	No
Uranium Mill No. 1 in Slick Rock (East), CO	Yes	1995- 1996	No
Uranium Mill No. 2 in Slick Rock (West), CO	Yes	1995- 1996	No
Winchester Engineering and Analytical Center - MA	Yes	1952- 1961	No