Dose Reconstruction / Compensation Project

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Background

- October 2000
  - Congress passed the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)
  - Awards $150,000 and medical benefits for certain covered workers with cancer
- December 2000
  - the President issued Executive Order 13179 assigning policymaking and technical roles

Background (continued)

- EEOICPA administered by DOL
- HHS, DOE and DOJ have assigned roles under the Executive Order
- NIOSH assigned lead role for HHS
  - Reconstruction of doses
  - Evaluation of SEC petitions
  - Development of probability of causation guidelines

ORAU Partners

- Dade Moeller and Associates
  - Small business from Richland, WA
  - Extensive DOE site experience
  - External dose reconstruction
- MJW Corporation
  - Small business from Buffalo, NY
  - Performed Mound dose reconstruction project
  - Internal dose reconstruction
- Plus about 30 other subcontractors

Program goals

- Build public trust and confidence in the NIOSH dose reconstruction process
- Process claims as efficiently and accurately (i.e. compensability) as possible
- Protect claimant privacy
- Avoid actual conflict of interest and minimize perceived COI
- Use ORAU expertise to develop job-exposure matrices and improve efficiency

Dose Reconstruction Challenges

- Managing conflict of interest
- Hiring qualified personnel
- Changing the health physicist mindset
  - Need to determine if claim is compensable
  - Do not need to get dose exactly right
  - The enemy of “good” is “perfect”
- Timeliness

COI Management

- Full disclosure: “sunshine is the best disinfectant.”
- Detailed plan developed and submitted with proposal, incorporated into contract by reference
- No one will perform or review a dose reconstruction for a claimant from a site where he or she worked
- Post corporate and individual disclosures on project web page
- Same rules for site profiles and SEC reviews

NIOSH Cases Received

- Dose reconstruction: 18,800 (80% from top 18 sites)
  - –DOE employees: 84%
  - –AWE employees: 16%
  - –Survivors ~50%
- Telephone interviews completed: 24,900
- Final dose reconstructions sent to DOL: 8,600

Top 10 DOE Sites

Site	Claims
Y-12	2500
Savannah River	2339
Hanford	2173
ORGDP (K-25)	1343
ORNL	1292
Nevada Test Site	1117
Paducah GDP	1048
Rocky Flats	1017
Idaho Falls	808
Los Alamos	717
Total	14354

Top 10 AWE Sites

Site	Claims
Bethlehem Steel	624
Linde Ceramics	159
Blockson Chemical	112
NUMEC	108
Simonds Saw and Steel	98
Chapman Valve	93
Huntington Pilot Plant	67
Allied Chemical	65
DuPont Deepwater Works	56
W. R. Grace	55
Total	1437

Work Breakdown

- Task 1: Database management
- Task 2: Data collection for claims & petitions
- Task 3: Dose reconstruction research
- Task 4: Computer-assisted telephone interviews (CATI) with claimants
- Task 5: Dose estimation and reporting
- Task 6: Technical and program management support
- Task 8: Records management
- Task 9: Quality Assurance
- Task 10: SEC petition review

Task 5: Dose estimation and reporting

- Calculate internal and external radiation doses for each organ the claimant presents with a primary cancer
- Develop and include estimates of missed dose due to limitations of monitoring methods
- Collect and analyze all available information relevant for an individual claimant and produce a report providing dose estimates, uncertainty, methods, and factual basis, including a narrative report understandable to the claimant

Dose Parameter

- The only dose parameter of interest is the annual organ equivalent dose to the organ determined to be the origin of the cancer, from date of first employment to date of diagnosis
- IREP removes quality factor, then re-inserts it (with uncertainty) for POC calculation
- Annual doses from alpha, beta, photon (<30, 30-250, >250 keV) and neutron (<10, 10-100, 100-2000 keV, 2-20, >20 MeV) are entered; external dose includes an orientation factor
- Internal doses calculated by IMBA-NIOSH

Probability of Causation

- Determined by DOL using compute code IREP (Integrated Radio-Epidemiology Program)
- Cancer risk factors based on atomic bomb survivor data; corrections for race, gender, and age
- Convolutes uncertainty in risk factor with uncertainty in dose estimate (uncertainty in risk factor usually dominates)
- Claim is compensable if POC =/> 50% at the 99% CI

Probability of Causation

PoC = ERR/(1+ERR)

ERR = PoC/(1-PoC)

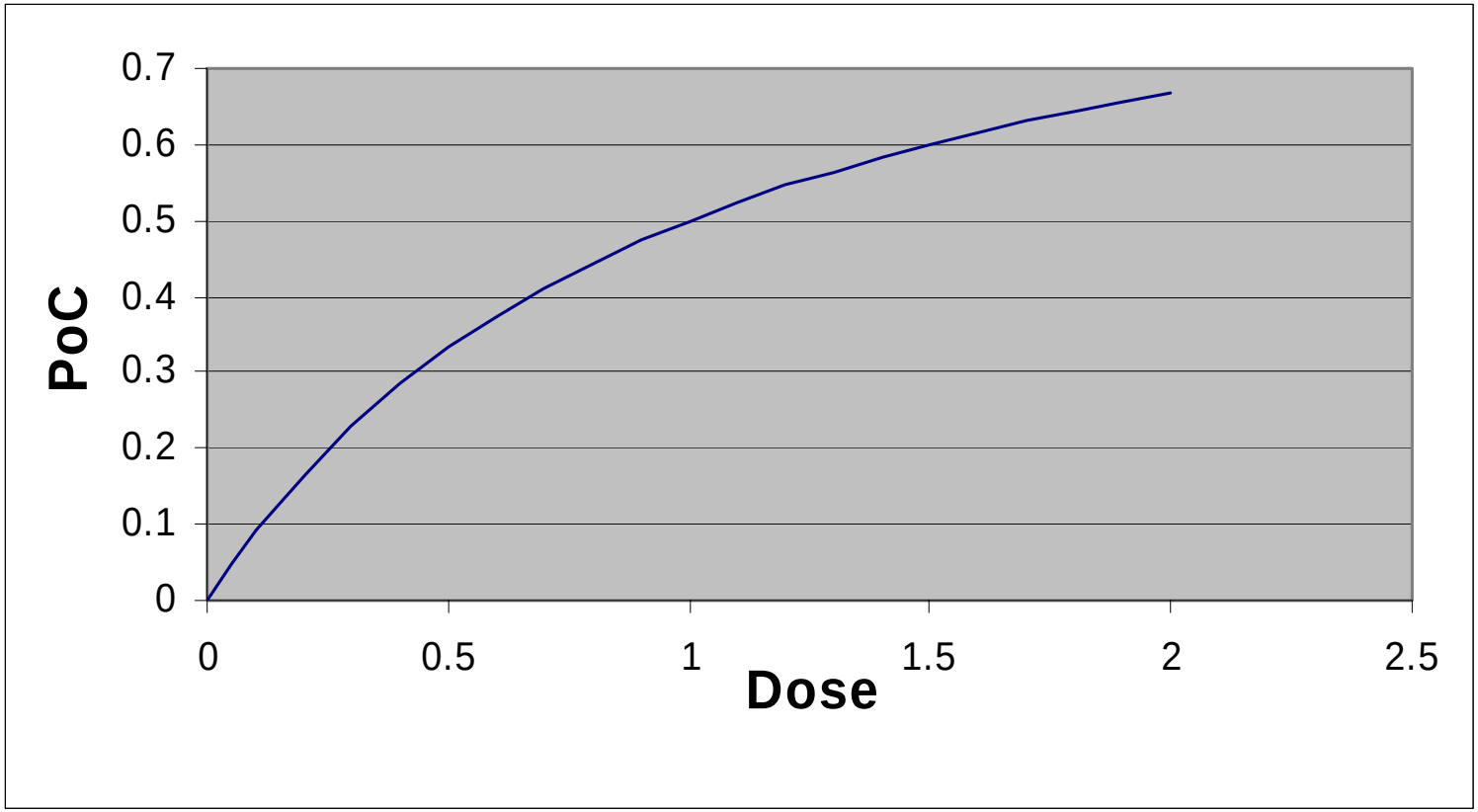
PoC = 45% ERR = .82

Dose must increase by 22% to reach a PoC of 50%

Applicable only to a given case

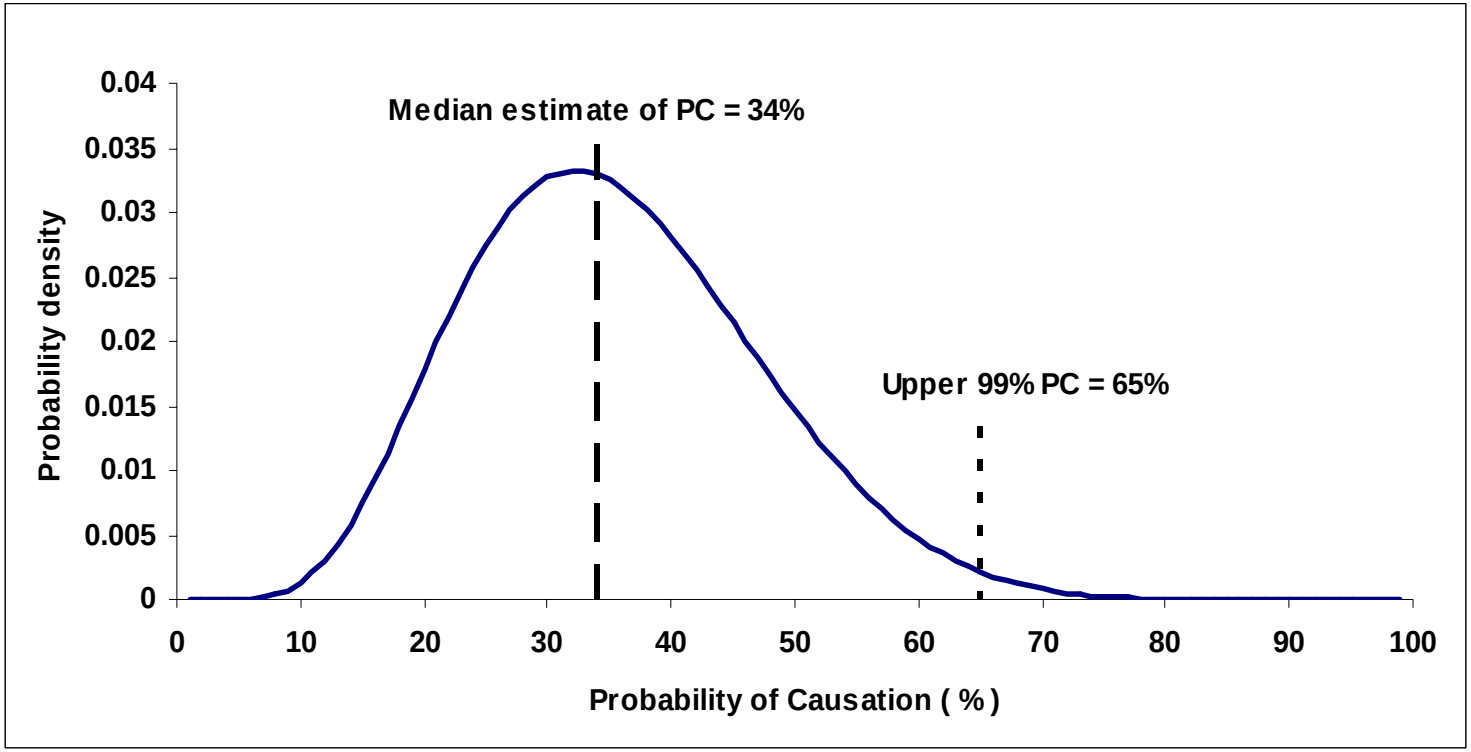
Probability of Causation

- PoC is not a linear value



PC uncertainty for leukemia

example: man exposed to 11 rem age 40, diagnosed age 50



Uncertainty Analysis

- In general, uncertainty is assessed by Monte Carlo sampling of the uncertainty distributions of each independent variable
- The question is determining the appropriate uncertainty distribution: Gaussian, log-normal, triangular
- Composite distributions tend to have long right-hand tails, so 5,000 runs may be needed for adequate sampling

Compensability Trends

Cancer	% compensable
Lung	69.8%
Acute LL	66.7%
Chronic ML	61.1%
Leukemia not CLL	55.6%
Liver	40.0%
AML	34.3%
Other endocrine	20.0%
Other respiratory	19.7%
Skin BCC	16.9%
Thyroid	13.6%

Compensability Trends

Cancer	% compensable
Oral & pharynx	9.1%
Skin--melanoma	8.0%
Bone	7.1%
Urinary not bladder	7.1%
Gallbladder	5.0%
Urinary bladder	3.4%
Colon	1.8%
Esophagus	1.5%
Skin—SCC	1.0%
Stomach	0.9%
Lymphoma & mult.myel.	0.7%
Breast	0.3%

Efficiency in DR

- For lung cancers (and other systemic organs) in claimants with inhalations of radioactive materials, calculate internal dose first; if POC > 50% at 99% CI, DR is complete
- Similarly, for leukemias, lymphomas, skin, and breast cancers, calculate external exposure first; if compensable, DR is complete
- If not, combine internal and external dose
- If still not compensable, add other exposures: environmental dose received on the job, missed dose, medical x-rays if a condition of employment.

Example of Minimum Dose

- Hanford engineer diagnosed with lung cancer.
- Ten positive plutonium urinalysis results
- Confirmed intake of plutonium nitrate
- Intake calculated by IMBA from bioassay results = 520 nCi
- Total lung dose equivalent = 88 rem
- Probability of causation = 66% at 99% CI

Maximum Dose Protocol

- Potentially non-compensable cases
  - Low exposure potential
  - Zero or minimal recorded internal and external dose
  - Cancer of a non-metabolic organ, e.g. prostate
- Assign average of maximum intakes for all workers at site for all radionuclides except tritium
- Assign maximum missed dose for tritium
- Assign maximum missed external dose
  - (n x LOD)
- Assign maximum medical X-ray and environmental doses

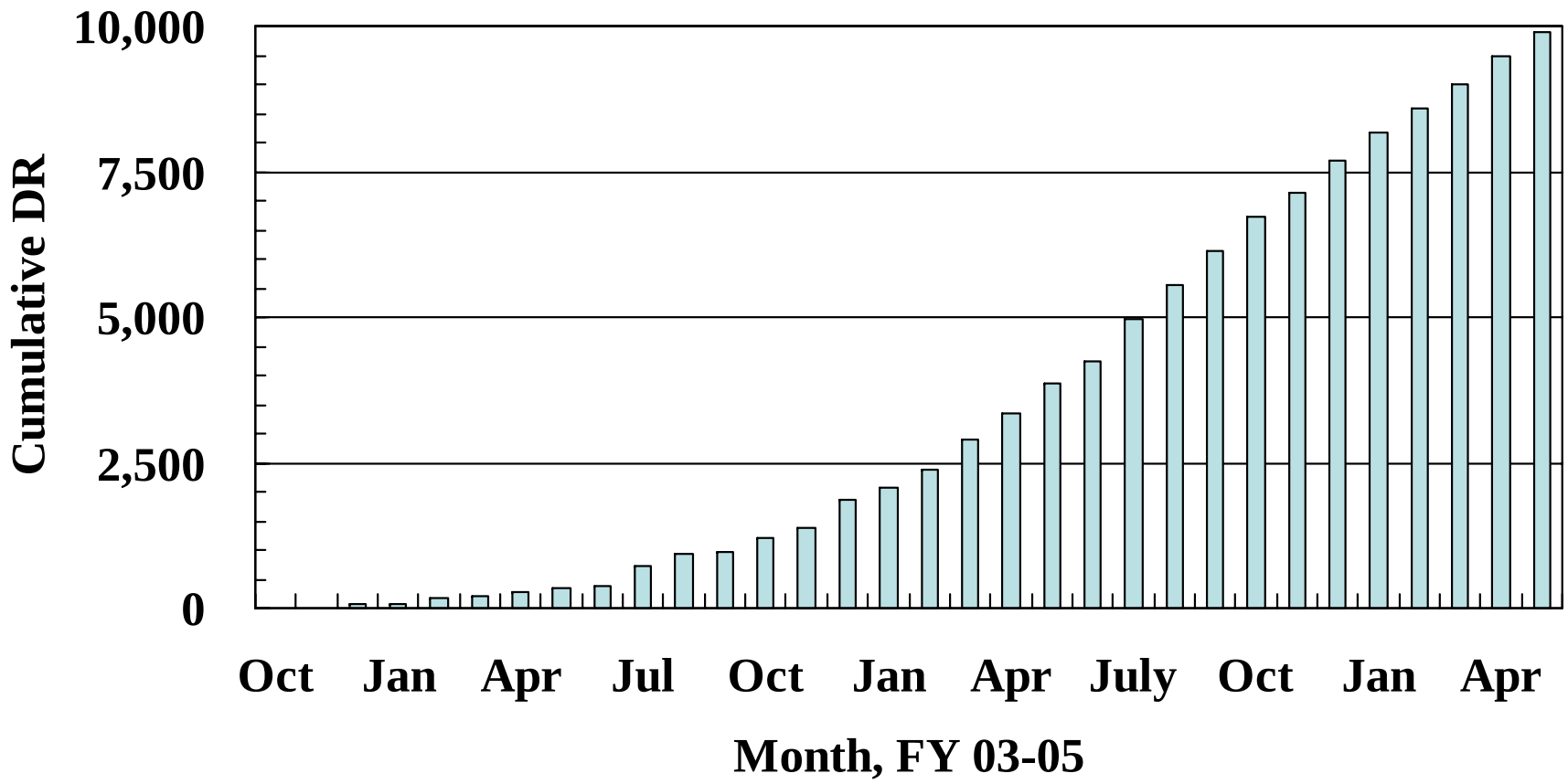
Maximum Dose for SRS

- ORAUT-OTIB-0001, approved 7/15/03
- Averaged the five highest reported intakes ever on the site for Co-60, Zn-65, Sr-90, Nb-95, Zr-95, Ru-106, Cs-137, Ce-144, U-234, U-235, U-238, Np-237, Pu-238, Pu-239, Pu-241, Am-241, Cm-242, Cm-244, and Cf-252
- Claimant favorable assumptions for particle size and clearance type
- To qualify, predicted bioassay results must always exceed observed results and MDA

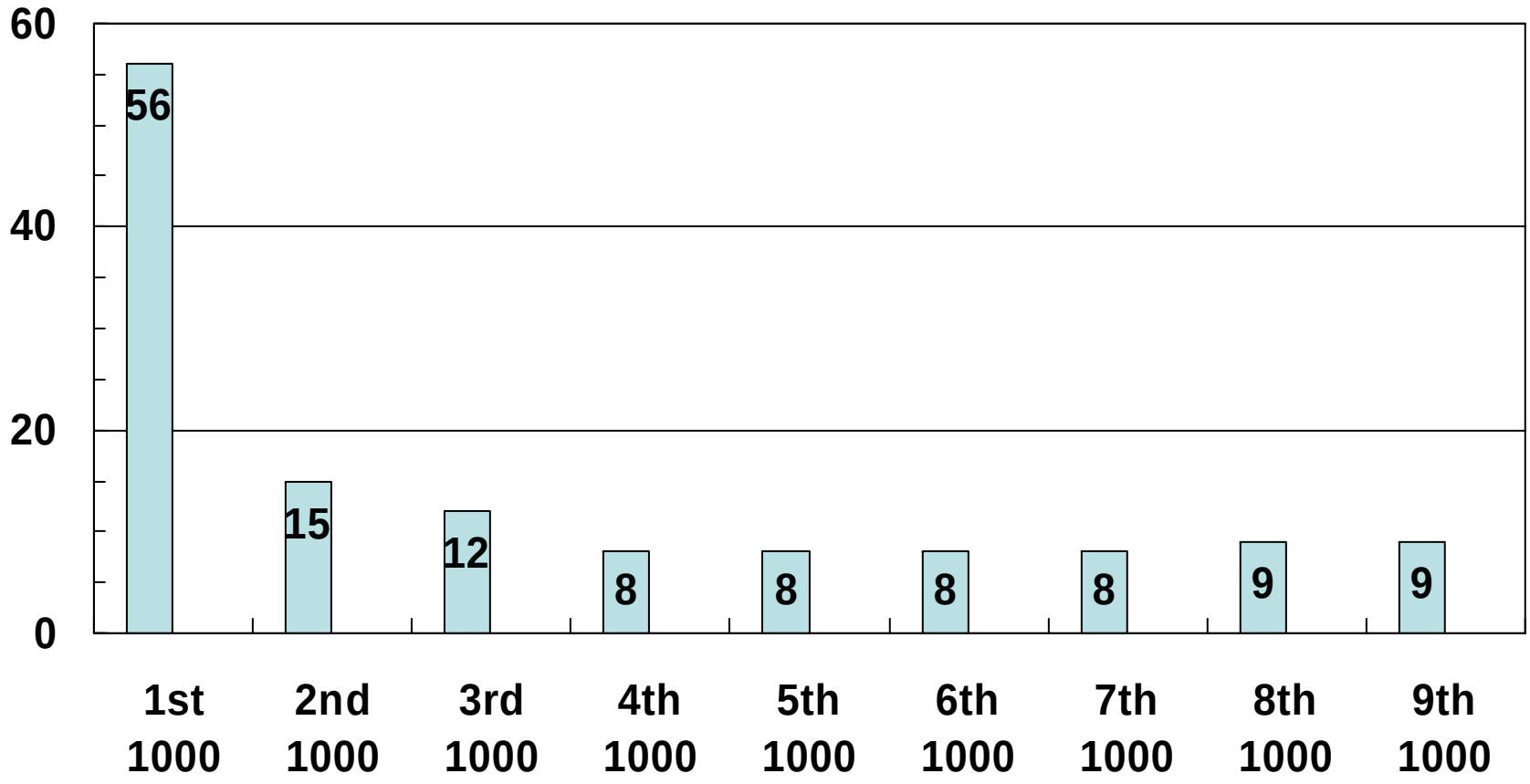
Example Max. Dose for SRS

- Claimant with breast cancer
- External dose (rem):
  - Monitored: 0.1 deep, 0.45 shallow
  - Missed: 0.29
  - Max. ambient: 2.22
  - Max X-ray: 0.10
- Internal Dose (rem):
  - Missed tritium: 0.55
  - Max intake: 0.82
- Total dose 4.53 rem; POC = 8.23% at 99% CI

Cumulative DR Production (Rev. 0)



Weeks per 1,000 Rev. 0 DRs



Special Exposure Cohort (SEC)

- The Act established the SEC to include the 3 GDPs and the Amchitka Island test site
- Any one of 22 cancers is presumed to be radiation induced, so award is made without dose reconstruction
- Medical coverage for an additional non-SEC cancer does require DR

SEC Petitions

- 42CFR83 permits individuals or groups to petition to be added to the SEC
- The criterion is adequacy of exposure data to at least set an upper limit on dose to ALL of the organs with covered cancers
- NIOSH presents evaluation to Advisory Board, who advises Secretary of HHS, who makes a recommendation to Congress

SEC Petition Reviews

- 34 petitions received, covering 18 sites
- 14 administratively closed as not qualified
- 3 merged with others
- 18 in qualification process
- 3 evaluations sent to Board, 1 in process
- Internally generated reviews of MED sites underway

Changes to the Act

- Subtitle D (workers' comp) moved from DOE to DOL and becomes federal program (Subtitle E)
- Period of covered employment at AWE sites extended to residual contamination era
- Non-weapons related exposures included (radiography, TENORM, etc.)

Outlook for the Future

- Current claim submittal rate is about 60 per week
- Expect to reach steady state in about 12 months
- Potential influx of cases with exposure to residual contamination only
- DOL outreach efforts for Subpart E may increase submittal rate of Subpart B claims

Information Resources

- NIOSH: www.cdc.gov/niosh/ocas
- ORAU: www.oraucoc.org
- DOE: tis.eh.doe.gov/advocacy/index.html
- DOL: www.dol.gov/esa/regs/compliance/owcp/eeoicp/main.htm