Radiation Dose Reconstruction and Probability of Causation for Compensation

James W. Neton, Ph.D., CHP
Associate Director for Science
Division of Compensation Analysis and Support
U.S. National Institute for Occupational Safety and Health

September 20, 2018
Reference Documents
Background

• October 2000
  • U.S. 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
  • President issued Executive Order 13179 assigning policymaking and technical roles
Background
(continued)

• EEOICPA administered by the U.S. Department of Labor
• The U.S. Department of Health and Human Services and Department of Energy 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
Covered Population

• U.S. Department of Energy workers and contractors involved in nuclear weapons development and production
• Approximately 600,000 DOE workers and contractors eligible to apply
• Atomic Weapons Employees also eligible
• All cancers eligible for compensation – including chronic lymphocytic leukemia
Criteria for Award

• Dose reconstruction must result in probability of causation (PC) ≥ 50% at the 99% credibility limit

• PC determined using Interactive RadioEpidemiology Program (NIOSH-IREP)
  • Based on program originally developed by the U.S. National Cancer Institute
  • Web based software accessible to the public at www.cdc.gov/niosh/dcas
Dose Reconstruction Process

- **Dose Reconstruction**
  - Claimant Interviews
  - Technical Basis Documents
  - Site/Complex Strategy
  - TBDs
  - Data
  - Claimants
  - Complex-wide/Site Prioritization
  - Claims from DOL

- **Claimant Records**
  - DR Reports to claimants

**Steps:**
1. **Claims from DOL**
2. **Complex-wide/Site Prioritization**
3. **Claimant Records**
4. **Technical Basis Documents**
5. **Site/Complex Strategy**
6. **TBDs**
7. **Data**
8. **Claimants**
9. **Claimant Interviews**
10. **Dose Reconstruction**
11. **DR Reports to claimants**

**Related Terms:**
- Claims
- DOL
- DR Reports
- Site/Site Prioritization
- TBDs
- Data
- Claimants
- Technical Basis Documents
Technical Approach

• Evaluate all doses of record for data quality shortcomings
  • Assess capability of external dosimetry programs over time
  • Assess quality of radiochemical techniques for bioassay samples
• Evaluate potential for undetected dose
  • Missed dose for external exposure estimated by LOD/2
  • Minimum detectable internal dose based on bioassay program capability
Technical Approach (cont.)

• Use recommendations established by national and international organizations
  • ICRP 66 Lung Model for inhalation exposures
  • More recent ICRP recycling models adopted for internal dose estimates
  • ICRP 74 used for external dose evaluation
• Preferentially use individual monitoring data if available and of sufficient quality
• As necessary, use area dosimeters, radiation surveys and air sampling data to augment individual monitoring data
• If no individual monitoring data, use available data on source term, etc.
Examples of Information Types Used in Dose Reconstruction

- Claimant interviews
- External dosimeter readings
- Pocket ionization chamber data
- Bioassay sample results
- *In Vivo* exam results
- Incident investigation reports
- Nasal smear results
- External contamination measurements
- Surface contamination surveys
- General area air samples
- Area radiation survey results
- Fixed location dosimeter results
- Breathing zone air sample results
- Source term characterization data
- General process descriptions
Processing Strategy

• Start conservatively simple using available monitoring data
• Perform initial evaluation using worst case assumptions
• If case has a low estimated POC, dose reconstruction is complete
• If not, perform more detailed analysis
Determine organ of interest and most probable mode of exposure. Perform dose evaluation using worst case assumptions.

Low probability?

Perform dose evaluation using a conservatively low estimate.

High probability?

Perform dose evaluation using conservatively low estimate for the other mode of irradiation. Combine both doses.

Low probability?

Perform evaluation using worst case assumptions for other mode of exposure. Combine both doses.

High probability?

Perform dose reconstruction using complete data and information.

Yes

No

Dose reconstruction complete.

Yes

No

Yes

No

High probability?
Compensation vs. Regulatory Dose

- Compensation dose evaluation limited to period of covered employment
- Includes internal, external and some occupationally required medical sources of exposure
- Annual Dose required for PC estimate
- Committed Effective Dose Equivalent concept not applicable
- For external exposures, concept of deep dose equivalent not necessarily applicable
- Undetected dose is an important factor
- Uncertainty distributions can be used
- Can take advantage of recent scientific developments
Special Exposure Cohort

- Original legislation included Special Exposure Cohort (SEC) status for four sites
  - Certain cancers considered presumptive
  - No dose reconstruction required
- Additional classes of workers can be added through a petition process
  - Many additional classes of workers have been added to the SEC
  - Several petitions currently under review
Probability of Causation under EEOICPA

• 42 CFR Part 81 published May 2, 2002 by the U.S. Dept. of Health and Human Services (HHS)

• Title: “Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule”

• Promulgated the “at least as likely as not” criterion for compensation under Subtitle B of EEOICPA
Probability of Causation

- The likelihood (expressed as a percentage between 0% and 100%) that the cancer was “at least as likely as not” caused by occupational radiation exposure
- Often abbreviated as “PC” or “PoC”
- Some prefer the use of “Assigned Share” (AS)
- Each individual PC result depends on circumstances unique to the claim, such as radiation dose, type of cancer, etc.
PC/AS Calculation

Risk of cancer from occupational radiation exposure

Total risk of cancer*

*Total risk of cancer = Risk from occupational radiation exposure + risk from all other sources

PC = ERR/(EER+1) = (RR-1)/RR = ERR/RR
NIOSH-IREP
(IREP = Interactive RadioEpidemiological Program)

• NIOSH-IREP is the online software tool that implements the Probability of Causation rule
• Computerized, updated version of radio-epidemiological risk tables developed in 1985
• Maintained by NIOSH for use by DOL; available to the public and requires no password
• Programmed with 35 different cancer risk models
  • Based mostly on Japanese A-bomb survivor studies, adjusted for U.S. cancer rates and dose-response factors
What Does NIOSH-IREP Do?

• Computes the statistical probability that a cancer was caused by occupational radiation exposure
  • Upper 99% credibility limit determines claim outcome

• Uses probability distributions to account for the uncertainty (inexact data) associated with dose reconstruction and risk modeling

• Calculates each individual probability of causation and displays results on printable summary report
Cancer Risk Models in NIOSH-IREP

- Based mainly on the Japanese A-bomb survivors study, but also other epidemiological studies
- Adjustments for
  - The U.S. population, based on U.S cancer rates
  - Low dose and low dose-rate exposure situations
  - The effectiveness of different radiation types
- 35 different cancer risk models
- Some types of cancers require running more than one IREP model to see which one produces the highest PC
Propagating the Uncertainty

Cancer Risk Model Distribution

Reconstructed Radiation Dose Distribution

PC Distribution
Information Needed to Calculate PC (NIOSH-IREP Inputs)

- Gender, year of birth, & year of diagnosis
- Cancer type (organ site & ICD-9 code)
- Ethnicity, if skin cancer; smoking history, if lung cancer
- Organ dose, may be entered as a specific value or as an uncertainty distribution
- Years of exposure, radiation energy and type, and exposure rate (acute or chronic)
- Data are uploaded into NIOSH-IREP via an Excel spreadsheet, but may also be entered manually
## Example NIOSH-IREP Spreadsheet

### PERSONAL INFORMATION

<table>
<thead>
<tr>
<th>Claimant Name</th>
<th>Claim #</th>
<th>Claimant SSN</th>
<th>DOL Claim Center</th>
<th>Gender</th>
<th>Birth Year</th>
<th>Year of Diagnosis</th>
<th>Cancer Model</th>
</tr>
</thead>
</table>

### CLAIMANT CANCER DIAGNOSES

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Primary Cancer #1</th>
<th>Primary Cancer #2</th>
<th>Primary Cancer #3</th>
<th>Secondary Cancer #1</th>
<th>Secondary Cancer #2</th>
<th>Secondary Cancer #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>Lung</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Date of Diagnosis</td>
<td>1985</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### EXPOSURE INFORMATION

<table>
<thead>
<tr>
<th>Exposure #</th>
<th>Exposure Year</th>
<th>Exposure Rate</th>
<th>Radiation Type</th>
<th>Dose Distribution Type</th>
<th>Parameter 1</th>
<th>Parameter 2</th>
<th>Parameter 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1965</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>4.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>2</td>
<td>1966</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>3</td>
<td>1967</td>
<td>acute</td>
<td>electrons (tritium)</td>
<td>Triangular</td>
<td>1.000</td>
<td>2.000</td>
<td>3.000</td>
</tr>
<tr>
<td>4</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>5</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>6</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>7</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>8</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>9</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>10</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
<tr>
<td>11</td>
<td>1970</td>
<td>chronic</td>
<td>electrons</td>
<td>Lognormal</td>
<td>2.000</td>
<td>2.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>
The Use of “Credibility Limits”

- To merit compensation, the cancer had to have been “at least as likely as not” caused by occupational radiation exposure (PC≥50% at upper 99th percentile C.L.)

- Example: male exposed to 60 mSv at age 40, diagnosed with leukemia at age 50
  - Before application of credibility limits, PC = 34% (claim would not qualify for compensation)
  - Apply credibility limits (place confidence interval around PC value)
  - PC at upper 99th percentile C.L. = 65% (claim now qualifies for compensation)
Applying Credibility Limits
(Male exposed to 60 mSv at age 40, diagnosed with leukemia at age 50)

Central estimate of PC = 34%

Upper 99% C.L: PC = 65%
Additional Procedures

• Guidelines often require running 2 or more risk models and using the highest PC value

• Claims with >1 cancer require use of a special equation to calculate the probability that at least one of the cancers might have been caused by radiation

• Claims with PC result between 45% and 52% require 30 IREP runs: average (arithmetic mean) PC value determines claim outcome
How to Access NIOSH-IREP

http://www.cdc.gov/niosh/dcas
Claim Information  
(as of September 2018)

• Almost 50,000 cases received by NIOSH for dose reconstruction since October 2001

• Current rate of receipt ~200 per month

• Current compensation rate is around 28%  
  • Varies depending on cases being processed
Additional Information

• The NIOSH Division of Compensation Analysis and Support’s website is located at:
  
  www.cdc.gov/niosh/dcas

• E-mail can be sent to: dcas@cdc.gov