NIOSH OCAS Trip Report
Discussion with AFL/CIO representatives of NIOSH role and plans for EEOICPA

Date/Location of Meeting: May 16, 2001, 1:00 - 5:00 pm, NIOSH Headquarters, Hubert H. Humphrey Building, Room 735G, Washington, D.C.

Attendees (Affiliation):

Larry Elliott, Ted Katz, Alice Kelley, Greg Lotz, Jim Neton, Mary Schubauer-Berigan (NIOSH)
Jim Ellenberger, Jordan Barab, Bill Kojola (AFL/CIO)
Scott Schneider (Laborers Health & Safety Fund)
James Platner, Knut Ringen (CPWR)
Liz Bottinger, Pete Strader (PACE)
Mark Griffin (CPS/PACE)
Mike Watson (Teamsters S&H)
David Mallino, Jim Melius (LIUNA)
John Morawetz (ICWUC)
Joe Abshire (IAM & AW)
Bob Alvarez (IPS)
Larry Edginton (IUOE)
David Michaels (George Washington University)

Objective: Provide an overview of NIOSH activities under OCAS and obtain stakeholder input from organized labor representatives on the program and NIOSH efforts.

Meeting Summary: The NIOSH team, led by Larry Elliott, Jim Neton, Mary Schubauer-Berigan, and Ted Katz provided a briefing of the labor representatives that consisted of an overview of the NIOSH activities under the (EEOICPA) compensation program, the general issues and plans for the dose reconstruction rule, and the general issues and plans for the rule for probability of causation, and comments on the rule for Special Exposure Cohort (SEC) consideration. Stakeholder representatives were afforded the opportunity to ask questions and make suggestions. Ideas were exchanged in a fruitful discussion. The information received by the NIOSH team will be used in the further development of the rules and guidelines for this program.

Specific issues discussed:

A. **General overview**, presented by Larry Elliott, with questions raised and comments received.

The basic approach for NIOSH is one that is claimant-friendly, interactive, based on a principle of reasonableness, and gives the benefit of the doubt to the claimant. NIOSH will contact the claimant, and use a computer-assisted telephone interview (CATI) to collect information the claimant has to provide.

The following points summarize the questions or comments raised in the meeting.

1. There was concern about whether the NIOSH CATI would be redundant with efforts by the DOE Office of Worker Advocacy (OWA) and whether there will be interagency coordination. The DOE former worker surveillance program may also be gathering similar information.

2. **Will we focus on only individual DR or also consider collective DR?**
   N: Both. We will have periodic updates on DR, with internal quality assurance checks on the work of contractors. Each DR will be reviewed by our NIOSH technical experts.

3. **How is NIOSH involved in the physician panels to be set up under EEOICPA?**
   N: NIOSHis to appoint physicians to those panels, which are set up, funded and operated by DOE.

4. **What is happening with respect to the Radiation Worker Advisory Board, and it's role in rule development under EEOICPA?**
   N: The Advisory Board has not yet been appointed. Recommendations for that Board have been forwarded to HHS for action. NIOSH is still deliberating over the sequence of the review by the Board in the development of the regulations, but is proceeding with that development so that they will be ready when the Board is appointed.

5. **What is the projected timeline for NIOSH development of the dose reconstruction (DR) and probability of causation (PC) rules?**
   N: The goal at this time is to get a draft of the two regulations into HHS review by 6/15.

6. **What is the projected length of time to process a dose reconstruction after the claim is received by NIOSH?**
   N: This will vary widely, depending on the complexity of the case, but NIOSH projects that it will take 2 to 8 weeks to process a claim. NIOSH is working to design a process that is as efficient as possible.

7. **Will the appeals of DR results go to DOL or NIOSH?**
   N: DOL.

B. **Presentation on plans for the DR regulation and procedures**, by Jim Neton.
Powerpoint slides were used for this presentation and accompany this summary. Copies of those slides were made available to the participants in this discussion. The following summary does not reiterate the basic points of that presentation, but covers the questions and comments that were made in the discussion of that presentation.

1. What if there are no exposure records? What are some of the tools for dealing with missed dose? How will NIOSH integrate knowledge of work processes into the DR effort? Will NIOSH report a range of doses or a single value?

N: if no worker data, use co-worker data, or environmental surveys, air sampling, etc. In case where there is no monitoring program at all, we would have to go back to process knowledge. Process information, including source term, will be used if there is no monitoring information - how much, isotopic composition, location. Construct a deterministic model. Precision would be imprecise but we would develop a range. For missed dose, there was a NIOSH workshop that dealt with those tools, including. statistical methods, and NIOSH would use the tools addressed in the proceedings of that workshop. [attendees asked for copies of that workshop proceedings, which were later sent to them by mail.] A list of information developed by NIOSH that indicated what would be needed or thought to be valuable was also discussed. This list had been provided previously to DOE, and was subsequently provided to participants of this meeting as well.

2. What happens to the dose range?

N. we will provide a knowledge of central tendency - best estimate, but include uncertainty, or a range. That will be the input data to the PC calculation.

3. Has there been a discussion of the role sharing between NIOSH and DOE on development of DR information for a claim?

N: Yes. It is anticipated that a MOU will be created, defining this arrangement, so that NIOSH can get the information it needs for DR efforts from DOE records.

Comment: the bigger problem will be with data for DR for subcontractors at DOE site, not simply with outsourcing contractors (e.g. AWEs).
Comment: use the more current data from site abatement survey results to give insight into the value of older surveys on the same site.

4. Questions regarding the sample report slide of hypothetical DR results:

a. Could you have multiple acute exposures in one year?
N: Yes. This example was simple with plutonium in mind.

b. What does this report mean to the claimant? Will the outreach offices have staff that can explain it?
N: You can tell total dose, but you can't tell what the outcome of the claim will be. It's not likely that the outreach offices will have staff who can explain it, at least not in first few years. We'll have to develop ways to explain where these numbers come from.
Comment: this report will lead the claimant to see affirmation by the government that he has a covered illness, that he was exposed, and thus, should receive compensation. Denials will then lead to resentment and outcry.

Comment: the report needs to have a detailed explanation with it to explain where these results come from.

5. What models are being used to calculate internal dose? How will NIOSH deal with insoluble alpha emitters, where the issue of dose heterogeneity to the organ is of concern?

N: The models NIOISH will use are based on ICRP 66. We are having a software program rewritten to calculate individual annual doses to individual organs. ICRP 66 models are particularly valuable in dealing with insoluble alpha emitters, which are a concern in this worker population. ICRP 66 has better lung model, and that gives you more flexibility of solubility, organ distribution, etc.

6. Discussion on comparisons to DOD/VA experience with Atomic Veterans.

Comment: the VA compensation program did not begin in 1979 when dose reconstruction work began. Compensation effort didn't begin until 1990's. Instead there was resistance to compensation all that time.

7. Discussion of NIOSH gathering of information and records related to exposures.

a. Will NIOSH conduct a standardized interview with the claimant?

N: yes, but not until after we get the initial records.

b. Will we consider work history for the individual?

N: yes.

c. Can the individual submit information obtained from union health and safety records (e.g., for construction workers, whose work history was transient on many sites.)

N: Yes, those sources will be acceptable.

N: how difficult is it to access union holdings?

A. generally only get information on which employer the person was sent to work for, not very helpful detail on what they did.

d. Who will pay for getting information (records) from the DOE sites? Hw will NIOSH deal with it when the site says they don't have the funds to complete the records research needed?

N: NIOSH has the understanding that DOE has the funds in the EEOICPA to pay for this. Issues of supporting the work at the sites will to be covered in the MOU and get DOL involved, if necessary.

e. What if the employee worked in the nuclear power industry as well?

N: That is not covered by EEOICPA. Only exposures that resulted from work in the nuclear weapons programs are covered by the Act.

8. How transparent will your process be to the outside? Will the records be accessible? Will the individual worker have access to this process?

N: The intent is to have the program be very transparent. NIOSH will share the

supporting information that we have obtained. This will be like the system of records the research at NIOSH is done from, so a grantee or coop agreement holder will be able to get it. Workers' privacy will be protected, but the worker will be about to access the information for their own records and their case.

9. **Re: claims volume and efficiency of processing them:**

a. How long do we anticipate processing a claim before deciding whether or not it's feasible to complete DR? How will we decide when the site has given all the records they have?

N: That's not been determined at this point, on either question. It will be done on a case-by-case basis.

b. What will we do if we later unearth new information? Who will notify claimant that we have new science to address claims?

N: NIOSH will have to go back when we unearth new information. And there is a need to have an automated system to keep track of that.

Comment: perhaps we should prioritize claims with respect to health status - e.g., alive or dead.

Comment: can't emphasize enough the importance of setting up formal arrangements with DOE to get this process (records retrieval) as soon as possible.

c. Will you go back (update) to claims that you already processed?

N: Yes, but only those that were denied.

d. Who will do notification if we have new science to address claims?

N: That will be DOL's responsibility. NIOSH would inform them and ask them to refer cases denied back to us.

C. **<u>Presentation on Probability of Causation (PC) rule</u>** by Mary Schubauer-Berigan: Powerpoint slides were used for this presentation and accompany this summary. Copies of those slides were made available to the participants in this discussion. The following summary does not reiterate the basic points of that presentation, but covers the questions and comments that were made in the discussion of that presentation.

1. **Will we do this for those seeking compensation under state programs?**
   N: No, only those coming in from the federal program.

2. **How will we deal with individual susceptibilities in the calculation of PC?**
   N: No consideration of this in these models. Factors of age and gender are included. Smoking has been included for lung cancer only. Q. what about asbestos or other

chemical exposures? N. Interactions with other agents (besides radiation) are not included in the models at this point.

3. **What will the input data be for PC calculation by IREP, e.g., median dose?**
N: Not just the median dose, but using the input uncertainty as well. Q. Is the distribtuion the uncertainty of dose ? N. it includes all the uncertainties related to that model, not just that in dose.

4. **Discussion of DDREF considerations, e.g., wrt thermal neutrons.**

Why does IREP (NCI version) use lower RBE for neutrons than used by ICRP?
Comment: NIOSH needs to include protons because of many DOE accelerators.
N: It's factors like this why NIOSH will not use the NCI IREP directly, but instead will produce a NIOSH IREP that addresses unique aspects of DOE worker exposures and illnesses.

5. **Discussion of modification and use of IREP by NIOSH for EEOICPA use.** This dicussion included the hypothetical example of the use of IREP for case in which we know DOE workers have increased risk of cancer, e.g. multiple myeloma.

a. Does smoking adjustment make a big difference for lung cancer?
N: Yes.

b. What will you do with a case that has the upper bound on PC at 49%?
N: that would be one to be revisited on appeal.

c. Will DOL use the NCI or NIOSH version of IREP?
N: NIOSH-IREP.

d. What will NIOSH do if there is a dispute between the claimant information on exposure and theDOE or obtainable records information?
N: Process will be designed to give worker benefit of the doubt, but ultimately, if the dispute cannot be resolved, a third party review might be used.

d. What would be used if claimant had two cancers?
N: If there are two primary cancers, NIOSH will provide an organ-specific process to calculate the PC for each, and a statistical process to use both to determine a final PC. If only one cancer is a primary cancer (the other is secondary), then only the primary cancer site is considered.

Comment: NIOSH should look at the paper by Tom Mancuso on Hanford workers that found that death ertificates underreported cancer.
Comment: NIOSH needs to carefully justify any changes from the NCI IREP, or the HP community will fight the NIOSH changes (e.g. in RBE).

7. **What if child claims cancer from in utero exposure?**
N: That would not be covered. Offspring are not "covered employee."

8. What's the timeline for the NIOSH version of IREP, to be reviewed and in place? What is the process for getting that reviewed and approved?

N: Hopefully by mid-summer, but the over-riding goals is to have it ready when we start processing claims. Advisory Board will be the stamp of approval; It doesn't have to run through OMB because it's policy, not rule. The Adv. Bd meeting on that would be public meeting.

D. <u>Other (miscellaneous) items</u>:

1. Discussion of relationship between NIOSH/HERB and NIOSH/OCAS.

a. Will NIOSH utilize information and coordinate studies from the existing NIOSH/DOE epidemiological studies (NIOSH/HERB) with the compensation effort?

N: Yes, key staff are from HERB and our understanding of compensation issues can now be used to drive HERB research agenda.

b. What sites does NIOSH/HERB have good data on?

N: Hanford, Idaho, Fernald, SR, Rocky Flats, others.....

c. Did we revisit the DOE data we inherited? Verify back to hard copy data?

N: yes, those data were revisited, and this included looking at the dosimetry program records, including things like administratively assigned dose.

Comment: only thing that NIOSH should look into that they have not in this presentation is the adjustment for smoking in the IREP.

2. SEC process: What's the time frame for this?

N: after we get the other 2 reulations out of the gate. NIOSH expects in early July to ask these folks to get together again. Need additional discussion on this, but they will be called back later for that step.

3. Physician Panels: Where are we in this process? Have we received many nominations?

N: Request for nominations was sent out widely - June 15 due date. Then NIOSH will set up a selection process, working with DOE to plan for appointments. DOE plans to have 10 "virtual" panels, with 3 members per panel, with an option for specialists on an "as needed" basis. DOE is producing the guidelines for panels.

Comment: Please send the draft request for nominations to Knut Ringen.

Submitted by Greg Lotz

NIOSH & AFL-CIO Meeting on EEOICPA

Hubert H. Humphrey Building, Room 735G
1:00 - 5:00, May 16, 2001

I. Introductions & Overview

II. Rule for Dose Reconstructions

a. Basics of dose reconstruction for compensation
b. Federal experience - Department of Defense
c. Similarities and differences for DOE workers
d. Duration of dose reconstructions
e. Claims volume and efficiency
f. Readiness to conduct dose reconstructions
g. Periodic updates resulting from progress in science

III. Rule for Probability of Causation

a. Basics of probability of causation for compensation
b. Federal experience - NIH/Department of Veteran Affairs
c. Update of NCI epidemiologic tables and IREP
d. Limitations of IREP for DOE workers
e. Strategy for meeting the needs of DOE workers
f. Periodic updates resulting from progress in science

IV. Special Exposure Cohort Procedures

a. Timing
b. Form of policy (rule or internal policy)
c. Specified cancers: leukemia under RECA

– ADJOURN –

Rule for Dose Reconstruction

Energy Employees Occupational
Illness Compensation Program Act
(EEOICPA)

CDC

NIOSH

Basics of Dose Reconstruction

- Use all available worker and workplace information to reconstruct dose
- Evaluate all doses of record for data quality shortcomings
- Evaluate potential for undetected dose
- Use recommendations established by national and international organizations

Dose Reconstruction (continued)

- Preferentially use individual monitoring data if available and of sufficient quality
- Use standard tools to evaluate "missed dose"
- Rely on use of area dosimeters, radiation surveys and air sampling if individual data not available
- If no monitoring data, use available data on source term, etc.

Examples of Information Types

- 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

Dose Reconstruction (continued)

- Annual organ doses will be computed from date of first employment to date of diagnosis
- When possible, provide an estimate of uncertainty
- Dose output will be compatible with the probability of causation software (IREP)

****** FOR INTERNAL USE ONLY ******

Example Dosimetry Report for Probability of Causation Calculation

Name: John Q. Doe

SSN: 000-00-0000

Sex: Male

Cancer: Leukemia

Organ: Red Bone Marrow

Year of Diagnosis: 1958

Year of First Exp.: 1951

Year	Internal Dose (rem)	RBE	Type	External Dose (rem)	Type
1951	Lognormal (0.051, 2.1)	20	Chronic	Normal (0.200, 0.030)	Acute
1952	Lognormal (0.072, 2.1)	20	Chronic	Normal (0.300, 0.045)	Chronic
1953	Lognormal (0.100, 2.1)	20	Chronic	Normal (0.010, 0.002)	Acute
1954	Lognormal (0.102, 2.1)	20	Chronic	Normal (0.205, 0.031)	Acute
1955	Lognormal (0.103, 2.1)	20	Chronic	Normal (0.565, 0.085)	Chronic
1956	Lognormal (0.104, 2.1)	20	Chronic	Normal (0.100, 0.015)	Acute
1957	Lognormal (0.106, 2.1)	20	Chronic	Normal (0.030, 0.005)	Acute
1958	Lognormal (0.107, 2.1)	20	Chronic	Normal (0.050, 0.008)	Acute

Federal Experience
Department of Defense

- Process outlined in 32 CFR 218
- Benefit of doubt applied in reconstructions
- Contracted dose reconstruction effort
- Independently reviewed by National Academy of Sciences
- Claimant involvement found to be critical and beneficial to both parties

Comparison to DOE Workers

- Claimants assertions to be provided the benefit of the doubt
- Claimant will have a standard role
- DOE workplace exposure potential more diversified
- Internal dose a more significant component in DOE workers
- Required medical screening x rays to be included

Duration of Dose Reconstruction

- Like VA process, startup time needed at beginning
  - Characterize workplaces
  - Evaluate monitoring programs
- Individual claims may vary depending on complexity (days to months)
- Additional time required for previously unexamined locations and processes

Claims Volume and Efficiency

- DOL estimates 22,500 claimants to file dose reconstruction consent form
- Methods needed to efficiently process claims
- Some possibilities include:
  - Characterize site monitoring program capabilities to develop pre-defined dose distributions for workers with censored monitoring data
  - Make use of existing data in NIOSH's Health-Related Energy research Branch files
  - Develop, in conjunction with DOL, threshold dose values for certain cancers.

Readiness to Conduct Dose Reconstructions

- Internal dose software under development
- Investigating records availability
- Developing statements of work for contractors
- Actively working on staffing

Periodic Updates

- Periodically reevaluate science behind models and dose reconstruction procedures
- Revise procedures as necessary to accommodate advancement in knowledge
- Develop method to assess the effect of changes on previously denied claims

Probability of Causation Guidelines under EEOICPA

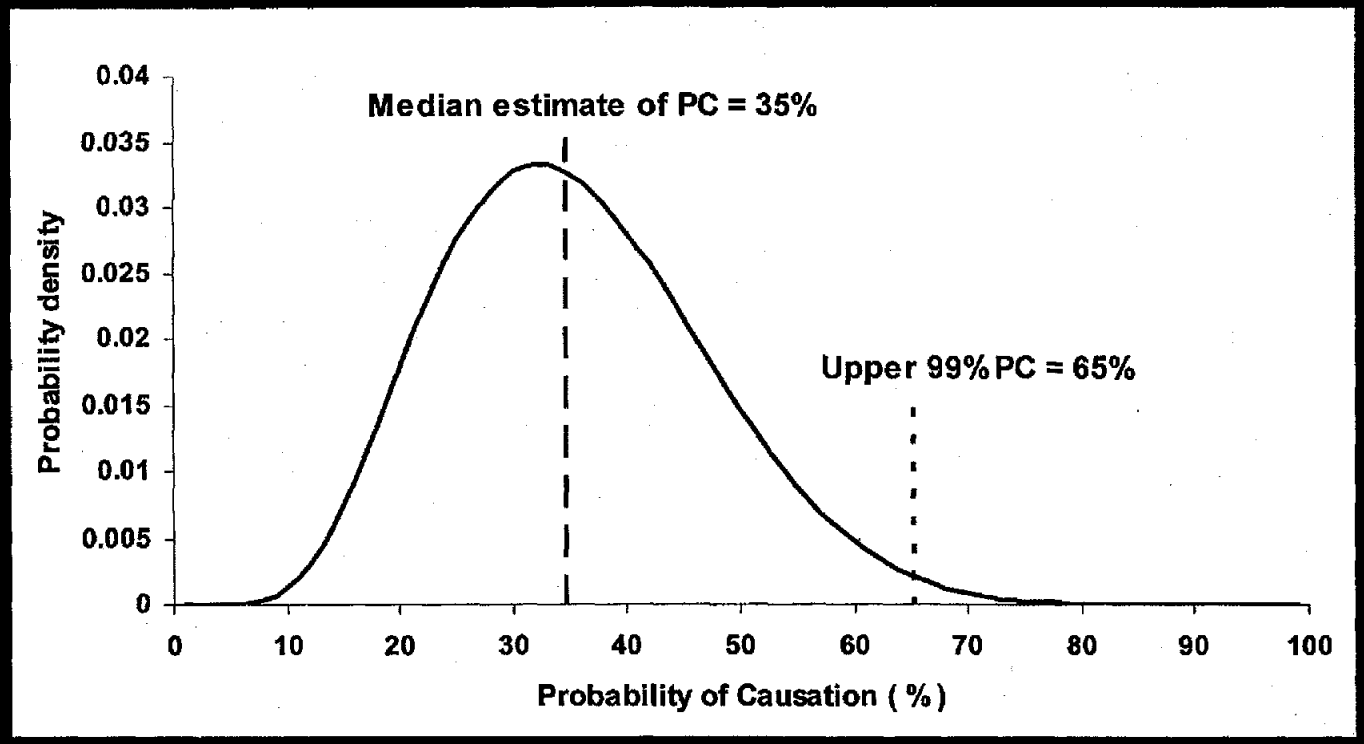
- Basics of probability of causation (PC) for compensation
- Federal experience - Department of Veterans' Affairs
- NCI update of radioepidemiologic tables (IREP)
- Limitations of IREP for DOE workers
- Strategy for meeting the needs of DOE workers
- Periodic updates resulting from progress in science

Basics of probability of causation

- Used for non-SEC cancer claims only
- Based on epidemiologic models of dose and effect
  - Atomic bomb survivor data
  - Separate models are produced for each cancer
- Uses "as likely as not" standard (50% PC)
- Allows for incorporation of uncertainty in dose, dose-response relationship and other factors

PC uncertainty for leukemia

example: man exposed to 10 rem age 40, diagnosed age 50



Federal experience – Department of Veterans' Affairs

- NIH developed radioepidemiologic tables in 1985
  - Method approved by NAS
  - Based on epidemiologic analyses: 14 cancers modeled
  - Assumes linear-quadratic dose-response for all cancers but breast and thyroid
  - No direct dose-rate adjustment
  - Constant relative risk model used (except for leukemia & bone), transferred additively to the U.S. population
  - Poor assessment of PC from high-LET dose (radon-lung and radium-bone only)
  - Incorporated uncertainty rather crudely
  - Were meant to be updated every few years
- Good fit to dose scenario for "atomic veterans"
- Expert judgment frequently used
- Currently processing 300-400 claims/year

NCI update of radioepidemiologic tables

- Availability of new data (A-bomb incidence through 1987)
- More cancer sites modeled (33 total)
- Directed toward VA "atomic veterans" compensation
- Eliminated radon and bone cancer models
- Improved computational methods
- More detailed uncertainty analysis
- Addition of DDREF and RBE factors
- Interactive Radio-epidemiological Program rather than tables
- PC changes from 1985 tables
  - PC increased: leukemia, stomach, colon, kidney and liver (men)
  - PC decreased: thyroid, salivary gland, esophagus, lung, breast, liver and pancreas (women)
- Status: draft (expect final end of June 2001), incorporating some NIOSH suggestions

Limitations of IREP for DOE workers

- Weakness in applicability for high-LET exposures
  - No radon and lung models
  - RBE values highly uncertain for bone marrow and other sites
  - Inverse DDREF not addressed
- Cancer models omitted (skin, bone, male breast)
- Models unlikely to result in compensable claim for some cancers shown to be elevated in DOE workforce
- Temporal changes in U.S. cancer rates not considered
- How to handle metastatic cancers when primary site is unknown

Strategy for meeting needs of DOE claimants

- Discussion with subject matter experts to resolve issues
- Identifying short-term vs. long-term solutions
- Participating in final software development
  - May result in EEOICPA-specific program
- Documenting guidance on applying PC program to DOE workforce
- Remaining involved in developing long-term solution to PC problems for DOE workers

Periodic updates resulting from progress in science

- NCI PC program is interim
- Long-term changes for some issues
- BEIR VII updates
- Input from NIOSH epidemiologic studies of DOE workers
- Advisory board's recommended changes
- Changes in dosimetry practices