Dragon, Karen E. (CDC/NIOSH/EID)

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To: NIOSH Docket Office (CDC)
Subject: 194 - Ten-Year Review of the NIOSH Radiation Dose Reconstruction Program
Attachments: BCTDcommentsCriteria to Evaluate OCAS Performance.doc

Attached are comments on NIOSH's plan for the 10-year review of the NIOSH radiation dose reconstruction program. These comments are respectfully submitted by the Building and Construction Trades Department, AFL-CIO.

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COMMENTS ON NIOSH'S PLAN FOR THE 10-YEAR REVIEW OF THE NIOSH RADIATION DOSE RECONSTRUCTION PROGRAM SUBMITTED BY
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THE BUILDING AND CONSTRUCTION TRADES DEPARTMENT, AFL-CIO
JUNE 3, 2010

The Building and Construction Trades Department, AFL-CIO is pleased to submit these comments in response to NIOSH's request (NIOSH Docket 194).

BCTD represents 13 international unions with more than 2,500,000 members. These comments are submitted on behalf of these unions and their members. There have been more building and construction trades workers employed at DOE facilities than any other occupational category. These workers have mostly been employed intermittently by construction contractors that have been hired as subcontractors to carry out new construction, maintenance, renovation, repair, emergency response clean-up, decommissioning and demolition.

GENERAL COMMENTS

It is not clear how this review will be conducted since NIOSH has not created any specific review criteria. In preparing these comments we have generally applied the criteria used by the National Academy of Sciences in their review of NIOSH programs. We believe that there are certain overriding issues that NIOSH needs to consider throughout this review.

- **Alternative Options:** The review should consider alternative options which were available to NIOSH for each of these components and whether or not alternative options might have produced better results. For instance, it is not clear that the selection of ORAU as the sole program support contractor benefitted NIOSH more than would have a net-work of academic based experts performing DRs.
- **Review of Program Components:** The review should examine the extent to which each of the different components of the program have been responsible for the outcomes:
    - NIOSH's internal oversight of DCAS[1] .
    - The leadership of DCAS.
    - The rules that were created to guide the work of the program.

[1] DCAS and the term "program" used throughout these comments refer to the NIOSH Division of Compensation Analysis and Support (DCAS)/Radiation Dose Reconstruction Program.

- The operational structure of the program and the decision to select one large contractor with lots of potential for conflict of interest.
- The execution of the operations.

- **Efficiency of the Operation:** How well have resources been optimized? Has there been waste?

RECOMMENDED REVIEW CRITERIA

Our position has been that where it is possible to settle compensation claims based on the individual claimant's history, it should be done, but there should be clear criteria to guide the process, including:

- ***Accuracy***: Is the dose given to a worker an accurate reflection of his or her experience?
- ***Fairness:*** Are cases similarly situated treated alike and given a similar outcome in the dose reconstruction process?
- ***Timeliness:*** Are cases processed in a timely manner?

For each of these criteria, there should be a separate analysis for:

- Claims submitted by ***workers*** and claims submitted by ***survivors***
- The overall program and each DOE/AWE site covered by the program
- The different occupational groups covered by the program
- The different time-periods covered by the program, beginning in 1943, and separately for at least each decade

To perform its review, NIOSH should consider the following issues

1. **Accuracy**: *Is the DR outcome a true reflection of exposure?*
    - **Dose Reconstructions**
        - **Initial Review**
            - Are the methods used consistent with the law?
            - Can DRs be verified (i.e., if you review a DR using the case documentation do you get the same POC as the official DR?)
            - Can DRs be independently replicated (i.e., if you take a case and perform a blind DR using DCAS procedures, do you get the same POC as the official DR?)
            - Are reports sent to claimants being prepared in such a way that they can be understood by a high school graduate, as is specified in both the 2002 and 2009 ORAU contracts?
        - **Reworks** (NOTE: This is a big issue. Half of all DRs have been reworked, some more than once.)

- What is the basis for rework (number of cases by cause, site, type of cancer, time period of exposure, etc.)?
- Can DRs be verified?
- Can DRs be independently replicated?

- **SEC Determinations**
  - Are cases that cannot yield a valid POC referred to the SEC?
  - Are claimants automatically notified when their case has been denied because POC is <50 and when a SEC is established?

2. **Fairness:** *Are cases similarly situated treated alike and do they have similar outcomes in terms of POC or referral to SEC*?
   - **Dose Reconstruction**
     - **Initial review**
       - Are the applied methods consistent between cases regardless of site?
       - What is the statistical sensitivity/predictive value of the DR (i.e., how often does a DR result in a POC<50% when it should not, by DOE sites, type of cancer, occupation, time period of exposure, etc)?
       - Is the rationale for referring cases to the SECs applied consistently (i.e., by DOE and AWE sites, type of cancer, occupation, time period of exposure, etc)?
       - Is there a clear and rationale approach for using surrogate/co-worker data when data are missing for a worker?
       - Has NIOSH exceeded its authority in using surrogate data?
       - Does the statute authorize the use of other facility data in the first place with respect to the definition of "such facility" within the statute?
     - **Reworks**
       - Are all cases eligible for rework identified and included?
       - What is the statistical specificity/predictive value of the reworked DR (i.e., how often does a DR result in a POC<50% when it should not, by DOE sites, type of cancer, occupation, time period of exposure, etc)?
   - **SEC Determinations**
     - **Referrals**
       - Is the rationale for referring cases to the SECs applied consistently (e.g., by DOE and AWE sites, type of cancer, occupation, time period of exposure, etc?)

- **Petitions**
  - Are reviews and determinations for petitions performed consistently (by DOE or AWE site, type of cancer, occupation, time period of exposure, etc?)
  - Is NIOSH's policy on Conflict of Interest adhered to for SEC reviewers?
  - What steps will be taken by NIOSH to review the process by which ORAU evaluates worker statements/affidavits in the SEC evaluation process to ensure that ORAU is investigating any and all potential exposure issues raised by workers?

3. **Timeliness:** *Are claims processed in a timely manner?*
   - What is the duration from receipt to closure (by sites, type of cancer, occupation, time period of exposure, etc?) NOTE: Closure means either a POC determination or a referral to SEC?
   - What is the duration from time an SEC petition is received until it is adopted or rejected by NIOSH?

COMMENTS ON THE FIVE "ASPECTS OF THE RADIATION DOSE RECONSTRUCTION PROGRAM" NIOSH HAS IDENTIFIED

These comments will address each of the five "aspects of the Radiation Dose Reconstruction Program" that NIOSH listed in the announcement of the review:

1. **The quality of science practiced in the program at the current time as well as throughout the evolution of the program.**

   Many claimants believe that NIOSH's approach is bogus. This question cannot be settled without performing two tests which are commonly used in any program evaluation:
   - ***A quality review of claims files***. NIOSH should select a representative sample of files and perform a quality assurance evaluation, much like a chart review is performed in medical Q/A, to determine:
     - Whether the files are complete, accurate, and documented.
     - Whether the findings are presented correctly.
   - ***A statistical analysis of the claims outcomes***. These evaluations are quite common in occupational health and are applicable to the DCAS review. The dose reconstruction process can be analyzed on its own merits in the same way the predictive value of a medical screening test is evaluated.

   The hallmark of science is that results are replicable. To date, DCAS hasn't been subjected to a true test of replication. The review should take a representative sample

of cases and perform a blinded DR to see what the results are. These reviews should be done by a panel of 3-5 qualified individuals, who have no ties to DCAS/ORAU, with each reviewer working independently, and using DCAS procedures. This type of review is also quite common in occupational health. It would be similar to the type of review that is performed, for instance, to validate B-reader findings based on their reviews of radiographic images.

There are several specific issues that should be included in the review of the quality and application of science in the program to determine whether or not any of them have had a material impact on DR outcomes:

- We think NIOSH's use of the terms "co-worker" and "surrogate data" have been overextended, and as a result, the extrapolations derived from them may not be scientifically supported. We do not believe it was ever the intent of Congress that exposure data from one DOE facility could be used to make dose determination at an entirely different facility, and that if the records at one facility were so deficient, the case should have been referred to the SEC. We do not believe reliance on "source terms" is valid for extrapolations.
- DCAS has added a massive number of new procedures over its existence, yet it is not evident that it has systematically applied procedures that each case affected by the new procedures would be appropriately identified and reworked.
- The high number of reworks in the program is a special concern and should be reviewed and reported on separately. It is not clear what caused all the reworks to be done. It is also not clear that every claimant that was affected by something that required a rework received one.
- There have been many claims that both DCAS and ORAU have consistently violated the conflict of interest policies. This should be reviewed.

2. The timing of the accomplishment of NIOSH's program tasks.

Whatever timeliness means, it is not the 3-6 years it has taken NIOSH to complete a DR or the 2-4 years to review a SEC petition.

This is one of the most difficult criterions to define, since (except for the review of SEC petitions) neither the law nor NIOSH's regulations establish any enforceable time limit. NIOSH has consistently refused to set time limits on its duties or where one exists (such as for the review of SEC petitions), it has been routinely been ignored. Unless NIOSH sets a time limit, how can timeliness be evaluated?

In its review, NIOSH should determine if claims have systematically been placed on the "backburner" because DCAS lacks data to process them. The review should determine and identify any disparities in any group of claimants. Also, the underlying documents used in the DR process, such as site profiles, should be reviewed.

In CPWR's employment verification contract with DOL to research union records that produce employment verification evidence on claimants for which DOE cannot establish an employment relationship, CPWR has 30 business days from the time it gets the claim to produce whatever it can.

NIOSH should have an established time limit as well and it should not be a "goal." DCAS should be able to complete a DR in 90 days from the time it receives the case. If it can't get it done in that time period, then it should refer the case to the SEC.

3. **The appropriateness and the consistency of decisions regarding petitions to add groups of claimants to the Special Exposure Cohort (SEC) established under the statute.**

   The term "appropriateness" is meaningless until NIOSH defines it. There is evidence that NIOSH has more readily approved SECs where there has been substantial political demand. It also seems NIOSH has been ready to adopt SECs for AWE sites than for DOE sites. DCAS has typically limited SEC petitions to certain time periods, buildings, and occupations. These narrow perimeters put a heavy burden on the claimant (and survivor).

4. **The appropriateness and the consistency of decisions on individual dose reconstructions.**

   The term "appropriateness" is meaningless until NIOSH defines it. We have heard repeatedly from our members that "Joe" worked right next to "Jim" doing exactly the same work in the same location, yet they received very different dose reconstruction outcomes. That complaint needs to be investigated.

   We also urge NIOSH to review whether or not the case files for all the claimants affected by a policy or procedure update, or other requirements for reworking, have been identified and properly updated, and whether or not the claimants and DOL have been informed of such updates.

5. **The quality and timing of service provided to claimants and petitioners, and their representatives.**

   We hear several repeated complaints from claimants. These complaints are well documented in the DOL Ombudsman's Annual Report, and include:

   a. NIOSH staff does not listen to the claimants.
   b. NIOSH demands too much evidence from claimants, especially survivors.
   c. NIOSH presents its decisions in language a majority of people do not understand.
   d. NIOSH's processes are never-ending.
   e. NIOSH fails to keep SEC petitioners informed about the process.

NIOSH would do well to create a quality and satisfaction survey, and administer it to a representative sample of claimants.

NEED FOR SEPARATE REVIEW FOR DIFFERENT OCCUPATIONAL GROUPS

We hope NIOSH will take our recommendations seriously and conduct this review in a manner that can identify any disparities existing in the experience of different occupational groups under the program. We would welcome such a review for building and construction trades workers.