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Subject: PACE comments on NIOSH Proposed Rules on Dose Reconstruction

I am attaching the PACE comments on the proposed rules. Please let me know if you have any questions.

Sylvia Kieding

PACE Comments on NIOSH Proposed Dose Reconstruction Regulations: 42 CFR Part 82: Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000

The Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) represents 320,000 workers nationwide in oil, chemical, pulp, paper, auto parts and nuclear industries. We represent workers at eleven (11) Department of Energy sites in the nuclear complex and workers at a number of current and former beryllium and other atomic weapons suppliers. PACE also represents tens of thousands of former workers potentially affected by this proposed rule. The NIOSH Proposed Regulations on Dose Reconstruction will be critical in determining the outcome of cancer claims filed under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICP). Thus, PACE wants to ensure that workers or former workers who file claims for radiation-related cancers are afforded an accurate and comprehensive assessment of their past exposures. To this end

The following comments follow the specific content rather than the generic implications of the rule. PACE is concerned about a number of the issues raised in the **Background** section of the proposed rules.

Section C:

PACE is concerned about the phrase: "particularly when radiation monitoring is unavailable, incomplete, or of poor quality". While this may not limit the scope of dose reconstruction, nothing should be left to question or interpretation. It should be clearly stated that dose reconstruction would be conducted for ALL claimants. All workers filing claims want and deserve an "independent" assessment of their past exposures.

Section D:

NIOSH needs to exercise care when adding "missed doses" based on detection limits for a given monitoring period. The use of additional facility or individual monitoring data may show that the "missed dose" times the number of monitoring periods significantly exceeds the actual dose detection limit for the entire monitoring period. This could well be true in many cases such as:

- The case of long-lived radionuclides, sampled infrequently but routinely;
- For instances where detection limits improve over time;

When well-placed area monitors and/or individual badges are collected at different frequencies and source term data indicate that exposures could not have been routinely at the detection limit for all of the shorter monitoring periods.

PACE feels strongly that extensive "research and analysis" may be required for examination of both external and internal doses. While this section seems to reflect this view PACE feels strongly that NIOSH must review all records with a critical eye. For example, in plants where neutron exposures were expected but not included in the individual dose records, research into the original glow curve data from the TLDs may shed some light on the potential likelihood and significance of neutron exposures. Another example, PACE knows of many cases of individuals who were assigned doses different from their TLD reading during an accident (usually lower). Thus, verifying the assigned dose may involve fairly extensive research. Another example occurred at the Paducah site where database records for the individuals did not include some of the elevated results (usually associated with incidents) identified in health physics monthly reports.

NIOSH needs to clarify and explain what they mean by the statement, "conducting a variety of complex analyses to interpret the data compiled or estimated." What complex analyses does NIOSH mean?

Section E, Paragraph 1

While the importance of timely assessment is understood, the need for accurate assessments is at least equally important. Because of the ambitious schedule for these assessments, there needs to be an allowance for the assessor to redo an assessment if additional data becomes available that results in modification of the initial dose assessment assumptions. Examples of this might be improved characterization of source term, additional programmatic data showing work restrictions, etc., or incident data that reveals peculiar characteristics of the exposure for a particular group of workers. While not all assumption changes will result in significant dose changes, the most accurate historical record is the one that should be preserved. The only reference to reopening the dose reconstruction is 82.10 (0) where DOL must request a reopening under 20 CFR part 30. Also, it is our opinion that re-assessment should not necessarily have to be based on the appeal of an individual claimant but rather situations may arise where better data is identified after an assessment has been completed.

Section 82.2

“The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment” PACE does not think most internal dosimetrists would take this approach. Sounds like a traditional IH approach. We strongly support the approach and believe this is an important element and should be closely analyzed in parallel with the assessment of personal monitoring records. This introductory section seems to be contradictory to 82.2 (a).

Section 82.2, (a)

“If found to be complete and adequate individual worker monitoring such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure.” “These monitoring data are interpreted using additional data characterizing the workplace radiation exposures”.

This statement seems inconsistent with the introductory statement. PACE believes all data should be considered and weighted based on site or individual specific cases.

What are “reasonable and scientific” assumption? This needs to be clarified and defined.

Section 82.2, c

“If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model”. PACE does not disagree with this approach but would add two comments: 1) NIOSH should consider process information and source term information in the two (a and b) sections above -- you may have cases where monitoring is adequate for some internal exposure sources or external exposures but not for others (Paducah transuranics question); and (2) At what point does NIOSH decide that a reasonable estimate of dose cannot be made. The statute states that NIOSH shall “establish by regulation methods for arriving at reasonable estimates of the radiation doses received by an individual....” Further the statute says within section 3626 (a) under designation of the additional members to the special exposure cohort that individuals or groups can be given SEC status when “it is not feasible to estimate with sufficient accuracy the radiation doses they received”. PACE believes the two underlined clauses need to be defined within the regulations.

Additionally understanding the process and source term is important to more realistically assessing the data. An example of this is when increasing and then decreasing Pu results are assumed to be a chronic exposure, when in reality they represent an acute exposure to Pu-238 oxide. The determination that the exposure is more likely acute comes from Radiation Work Restriction documentation and

incident/occurrence reports, as well as knowledge of the actual composition of the source term. This could be completely mis-interpreted if that data was not reviewed along with the bioassay data for the individual.

82.3

The first paragraph has three groups of individuals requiring dose reconstruction. It implies dose reconstruction only for those individuals for which records are missing or monitoring was inadequate. PACE believes that it should include all individuals who are filing for compensation for a radiation-related cancer. While the second sentence seems to imply that all individuals will be reviewed the statement needs to be made stronger – NIOSH (who is independent) will do dose reconstruction for ALL individuals filing a claim.

Section 82.5(a)(1)

All exposures to radioactive materials and radiation from atomic weapons employment should be included. "Handled" should be added in addition to "Processed or produced". "Equipment" that emitted ionizing radiation should also be added to this section.

Section 82.5(d)

Is the definition of "covered employee" sufficiently broad to ensure that all individuals exposed as a result of their employment involving radiation and/or radioactive material exposures associated with atomic weapon R&D and production are covered?

Section 82.5(q)

Is the type of distribution being specified? If not how will this be determined?

Section 82.10(a)

The more specific the employment history is, the more useful it may be in dose reconstruction. Additionally, it is important to look at all data (source term, other employees exposure data, process information, bioassay analysis methods and modifications, etc.) for a given facility to get the best understanding of what actually occurred 10 to 60 years earlier.

Information regarding radiation incidents, occurrences, and other unusual situations (that may not have been classified as an incident or an occurrence at the time) should also be included in the claims packet.

Information regarding work restrictions should also be included. This should include programmatic information on how work was restricted and what the restriction meant at a given facility, as well as, data on individuals work restrictions.

Also this section states that NIOSH "may compile data". PACE recommends that NIOSH use all available data, NOT just what DOE provides. All data should be put through the same verification and validation process, BUT all data should be considered. Other sections of the regulation seem to suggest a broader vision of what data will be included -- 82.10 (e) for example. It is critical that ALL data go through the same verification and validation process. Section 82.10 (e) seems to suggest that data provided by the claimant will be put under greater scrutiny than the data provided by DOE. All records should initially be given equal weight when initiating the assessment. Section 82.10 (e) clearly indicates that, if other data is to be introduced into the assessment process, it will be put under greater scrutiny and the burden of proof of the validity of the data is on the claimant. The phrase "substantial evidence" clearly sets the burden of proof on the claimant.

Section 82.10(a)

How will exposures from medical screening be determined?

Will medical staff exposures from the medical screening be considered?

Section 82.10(e)

What will the criteria be for "substantial" evidence? See comments for section 82.10(a) above. PACE wants to stress that all data should be given equal weight at the beginning of the assessment and all data should be verified and validated through the same approaches.

82.10(h)

The phrase "certification from DOE that record searches have been completed" is very troubling. This seems to indicate that NIOSH and their contractors will be one step away from the actual records. DOE field people have their pre-conceived ideas of what data NIOSH will need and not need to do their job. It is critical that NIOSH (and their contractor) have a very good understanding (on the ground) of what data is available, where it is, etc. and not be solely reliant on DOE field office guidance. I know NIOSH has great experience in this area but NIOSH needs to have some kind of direct check or review of this process.

Further, stronger language needs to be included in this section such as: "DOE shall provide all applicable records or access to all records potentially related to radiation dose reconstruction."

Section 82.10(i)

Assessing the effect of non-uniformity and geometry for external exposures could be a formidable task

How does NIOSH know when they are unable to estimate a dose "with reasonable certainty"? This has to be addressed somewhere.

Section 82.10(j)

The word "impute" has a negative connotation. Perhaps "assigned" or "ascribed" would be better.

Section 82.12 (c)

It seems that it may not be always reasonable to deny a claim based on the inability of NIOSH to complete a dose reconstruction. Please elaborate. What recourse does the claimant have? Section (d) says that the claimant "may" have recourse under the Special Exposure section of the Act but does not say anything about when NIOSH will say that it can not estimate dose with reasonable certainty.

This seems to read that if we can't determine your dose than we are not going to be able to assess your claim – forcing DOL to deny the claim. This is unacceptable. Obviously, the claimant will not automatically be given special exposure cohort status. Once again this puts the burden of proof on the individual to prove that he/she deserves SEC status. In this case NIOSH should automatically file a petition on behalf of the individual and notify the claimant. At this point the Advisory Board would review the petition in accordance with section 3626 (a).

Section 82.14(c)

Blood results were also frequently collected in the early days and may provide useful information.

Section 82.14(c)(4)

As well as incident investigation reports, a report documenting unusual circumstances and associated related data should also be made available.

Section 82.14(d)(3)

There has been much debate on what detection limits might have been for the early bioassay programs and how to determine these. (examples: no background recorded, no negative values recorded, no count times, no chemical recovery data recorded, thus you can not calculate the detection limits). Have examples of procedures suggesting longer count times than were really used. Resolving this can be a very complicated process. May really end up having to "select" a "conservative" estimate of the detection limit.

Information regarding *in vivo* detection limits is also necessary.

Section 82.14(e)

Information regarding locations of air sampling heads for both workplace and BZA samplers is important. Information regarding particle sizes would be useful. Airflow patterns in relation to locations (3D) of the sampling heads are also important. Information regarding facility specific interpretation of air monitoring data is important (sample flow rate, filter type, filter size, collection efficiency, dustiness of environment, frequency of filter change, filter analysis method(s), etc.)

Section 82.14(g)(1)

Information regarding physical forms would also be useful, e.g., solid, particulate, solution, vapors, etc.

Section 82.16(a)

It seems like the determination of "missing" is a tough one. NIOSH must also consider why they are missing. Was the individual involved in any kind of accident or special work that may have resulted in greater dose than would be assigned if "normal tasks" were assumed?

Section 82.16(b)

NIOSH should also ensure that sample collection practices are examined and that actual practices, not just those described in procedural documents, are considered while interpreting the data. This must be verified since it is one of the things most commonly reported at all DOE sites – "according to procedures we were supposed to do it one way but what really happened was different". (See DOE Portsmouth, K-25 and Paducah investigation reports)

"Minimum Detectable Dose" based on a given monitoring period is a useful concept. The use of the words "missed dose" can have many connotations and should NOT be used in this context. Also, for internal doses, in many cases, the minimum detectable dose cannot be simply added for the monitoring periods to determine an upper limit for an extended period. The minimum detectable dose should be based on the actual data available. For example a radionuclide exposure measured using urinalysis may have a MDD of 3 rem per quarter but that does not necessarily mean that there would be an annual MDD of 12 rem.

Section 82.17(b)

Insert the words "and radioactivity" or "and radioactive contamination" between "radiation" and "survey".

Section 82.18(a)

All of the data (including that mentioned in 82.17(b) and 82.17(c) should be considered when performing the dose reconstruction. It would be inappropriate to use isolated bits of data to determine and later justify the determination of a given dose.

Where bioassay data are unavailable, dose reconstruction should not be limited to relying on air monitoring data. Data regarding source term, process knowledge, external contamination levels, etc. should be considered when available.

82.18(b)

"When NIOSH cannot establish exposure conditions with sufficient specificity" -- again, this seems similar to "with reasonable certainty". At what point does NIOSH decide that the dose determination cannot be completed? "The dose calculation will assume exposure conditions that maximize the dose to the organ under consideration" -- even in this phrase, there have to be a lot of assumptions made to get to the "maximal dose". Again, at what point are the estimates too uncertain to complete a "reasonable estimate".

Individual specific models should be allowed if available data supports -- rather than just relying on ICRP data

Section 82.18(c)

It is not clear what value the calculation of yearly exposure dates will have for this process. Because methods of interpreting data will be based on numerous assumptions, including protracted and acute exposures, exposures calculated for a given year are unlikely to represent reality. It is clear that it will be useful to determine the exposure for the purpose of PC determination to some date that is not necessarily 50 years. This can be done without estimating annual doses. The error associated with any given year's calculated dose will be typically significantly higher than that associated with the overall assessment, and could be the basis for significant disagreement in dose determinations. The resulting arguments will not serve anyone and this extraneous and non-meaningful requirement should be eliminated.

Only having results every six months (bioassay measurements) can make it very difficult in determining annual doses.

Section 82.19

This section must outline how the uncertainty in dose will be determined. This section should detail the parameters that must be considered in the determination of the uncertainty including but not limited to the following: counting result, particle size, solubility, chemical yields, calibration errors, biokinetic parameters, etc. This section also must establish the confidence interval which should be reported for the dose estimate which will be used in the probability of causation analysis. This section also needs to define "reasonable certainty" as outlined in the statute. It must include something about relative error. Is an error of 2 or 3 times the dose reasonable? Annual uncertainty is not a useful concept for these historical internal dose assessments. Often, assumptions of chronic exposures are used to characterize a series of acute intakes. Relatively small exposures in a given year may not be directly accounted for and early data is sometimes over or underestimated to allow for a best fit to the data with simplifying assumptions. While the concept of uncertainty is certainly important and the uncertainty of these assessments should be characterized, it should be characterized over the period of interest. Typically the period of interest will be at least 5 years and may be more than 20, 30 or 50 years.

Section 82.26(b)(2)

As noted above, because of the need for simplifying assumptions to assess historical bioassay data, the importance of providing separate realistic dose estimates for acute and chronic exposures is negated and has little meaning in reality. The total dose to a specified tissue for some relevant time period is what should be considered in the end. The importance of acute and chronic exposures is only meaningful in terms of modeling the data, not in terms of reporting the actual truth, which is an unknown.

The wording in this sentence makes it look like separate estimates for each radiation type, and exposure pathway and exposure period are what are required. This does not appear to be meaningful. Why can't the dose from alphas plus x-rays be combined? Why would it be necessary to report these separately, especially in the case of internal dose?

Section 82.26(3)

How are the word "as necessary" interpreted in association with determining when an uncertainty distribution must be performed for a given dose estimate? Is this contradictory to section 82.19?

Section 82.27(b)

What is this section saying?

82.28

Does not include anything about required advisory committee review of some percentage of cases as specified in the statute.

There is nothing in the regulation about updating assessments when additional data is identified by or provided to NIOSH – what is the process for this? Again, this should not be solely a claimant appeals process but should be a NIOSH commitment to do the best possible job in estimating each individual's dose.