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Dear Mr. Elliott:

I am pleased to respond to your letter of April 6 soliciting independent comments on the technical requirements of NIOSH relating to radiation dose under PL 106-398 and EO 13179. The responsibilities of NIOSH are addressed as enumerated in your letter. The information provided herein reflects solely my own experience and judgment.

1. Probability of Causation

The probability that a claimant's cancer was caused by exposure to radiation is dependent on radiation risk factors such as previously incorporated in radioepidemiological tables applied to the radiation dose (in rem) accrued. This concept is readily applied to a single, acute exposure. However, not all dose is equivalent in determining the probability of causation (PC) (also currently known as assigned share). The radiation risk for a given cancer depends on the worker's age at exposure, for example; the risk per rem varies throughout a working lifetime. Also, cancer latency may limit the interval during which exposure contributes to risk.

A confidence interval in the PC depends on the uncertainties in risk factors and dose. These uncertainties vary for additional parameters, such as type of radiation (via its quality factor). Thus, with respect to dose, the confidence interval in the PC is based on many discrete representations of dose, say annually by type, along with the estimated uncertainty distribution for each dose. The IREP software underlying the revision of the present radioepidemiological tables accommodates all of this information to arrive at the overall confidence interval in the PC appropriate to the worker's exposure history. One computer run with personal data and detailed dose information as inputs will suffice to arrive at a claimant's PC with confidence interval.

The determination of the confidence interval in probability of causation inextricably links radiation dose and risk; total dose is an ambiguous and unproductive end point.

In the cases of veterans, the Government takes pride that the process of dose determination is decoupled from the consideration of radiation risk and resulting compensation decisions. However, that these functions are accomplished by separate Executive departments does not appear to enhance the veterans' perception of their credibilty. These functions can be coupled through the new software, offering important economies in the processing of workers' claims. Through the Advisory Board and the information openness clause of Section 3623(e), PL 106-398 provides important safeguards against bias in claims processing. With the IREP software, it will frequently be possible to simplify the information requirements. The capability to perform a sensitivity analysis of dose attributes on the PC will demonstrate when even incomplete characterizations of dose will suffice to arrive at the correct compensation decision by law. For example, a claimant's recorded external doses alone, even if incomplete and without uncertainty information, may yield a qualifying PC. In this case, a requirement for further claim development, beyond what might be obtained directly from an existing DOE database, would be wasteful.

2. Dose reconstruction

The discussion of dose reconstruction herein covers both the employee categories identified in Section 3623(d) and the actual methods of dose reconstruction. In all cases, the reconstruction and/or interpretation of dose will be facilitated by an understanding of the dosimetric practices at each site. Therefore, such information should be collected beginning in advance of claims processing.

A. An employee not monitored for radiation, presumably meaning the lack of individual dosimetry or exposure potential

A determination must be made as to why the employee was not monitored. If this was because of the employee's job classification, the dosimetric practice pertaining to the lack of monitoring needs evaluation. What level of exposure was deemed not to require monitoring? What evidence is there that exposures were kept below such threshold? What statements has the claimant or his coworkers made regarding exposures?

If some of the employee's co-workers were monitored, their results should be substantially applicable to the employee. Adjustments may be required based on differences in work activities, and whatever inconsistency exists among coworkers' results contributes to the uncertainty in the employee's dose(s).

For other situations, the basic principles of dose reconstruction are required: the employee's activities are superposed on the radiation environment. The radiation environment may be well defined by non-individual dosimetric measurements (e.g., area monitoring data). The accuracy of such data and their pertinence to the employee's activities require evaluation. The employee's activities may be documented, substantially implied by his job classification and the known industrial processes at the site, and/or be recounted by the employee (and co-workers). In the absence of direct radiological data at the site, the dosimetric practices and industrial processes will provide some information on workers' exposure potential. In this case the associated uncertainty in dose is likely substantial, but the process in 1. accommodates it; further, the process in 3. (see below) by law must be based on some such exposure evaluation.

All available data pertinent to dose determination must be considered. While indirect measurements and/or auxiliary information tend to imply larger uncertainties in dose, they are also a valid part of the process, as are representations made by workers.

B. An employee inadequately monitored, presumably meaning incomplete or poor quality monitoring

This individual could be a hybrid of the completely monitored and non-monitored employee; however, additional considerations might apply. It should be determined whether or not the monitored periods or activities are representative of the employee's overall exposures. Unless there is bias in what exposures are unmonitored, the recorded doses provide a basis for extrapolation to the unrecorded. Otherwise, the unmonitored exposures need to be reconstructed.

If the monitoring data are of insufficient quality to support a dose determination, this will be evident to the dose analyst and may require supersession by dose reconstruction. This may exist, for example, if dosimetry film is damaged such that readings are incompatible with the radiation environment; many archived films are available to substantiate such damage. Aspersions may be cast on data quality by claimants. If irregularities in recordkeeping indeed occurred, these should be revealed through inconsistencies discovered by dose analysts.

C. An employee whose records of exposure are missing or incomplete

Unless there are allegations that records are absent to conceal radiation exposures, the considerations of the first part of B. apply.

D. An employee whose records of exposure are complete according to current regulations

Although this category is not specified in PL 106-398, even an employee who was adequately monitored for exposure to radiation and whose records are complete requires an interpretation of

his/her doses. These doses are not reported with uncertainties. Internal exposures were recorded in quantities other than dose. Off-the-shelf internal dose software such as DOE presently utilizes provides doses as required by the CFR for radiation protection purposes, not the doses to specific organs in annual increments. This consideration also applies to any valid recorded portion of the dose for employees in the foregoing categories. Further, the quality of the recorded information, whether from original documents or databased distillations thereof, must be ascertained.

Methods of dose reconstruction

The methods of dose determination for the DOE worker population should largely be based on a fusion of the retrospective methods in use for the long past and the recent past. The exposures, radiation safety practices, and available records for the first two decades of nuclear weapons work, although varying widely among sites, are akin to those for the Department of Defense participants, principally veterans, in nuclear testing during that period. Doses for these veterans have been researched and reconstructed for over 20 years, and this is the only program to date providing doses for large numbers of individuals' radiation claims against the Government. In contrast, modern DOE practices provide the basis for current worker doses. Ideally, apart from uncertainty considerations, the tools supporting these practices require only conversion from radiation protection to retrospective dose determination applications. As indicated above, this involves the calculation of annual doses to specific body organs. The emphasis on dose reconstruction herein, therefore, involves the methods applicable to long-past exposures.

The methods of dose determination for veterans are principally as codified in 32 CFR Part 218 and developed in standard operating procedures for radiation exposure assessment (copy enclosed). These documents, as well as methodologies applied to a variety of external and internal exposure situations, extracted from several published reports, are publicly available per the Federal Advisory Committee Act from the National Academy of Sciences in conjunction with their current review of dose reconstruction (Dr. Evan Douple, study director). The thrust of the methods is synopsized below.

All available data pertinent to the veteran's radiation exposure are collected. Sample types of data include:

- Personal data — personnel information, unit affiliation, dates of participation, duty type, individual dosimetry records, personal statements
- Unit data — locations and movements, missions, specific activities, plans, after-action reports, unit histories, aggregated dosimetry records, statements by unit members
- Site data — physical/meterorological/geological characteristics, operational constraints, test schedule, detonation parameters, radiological safety programs, radiation field measurements.

To the degree feasible, unit and site data are collected in advance of individual claims traffic. In this case, personal parameters usually supply a degree of perturbation to doses already reconstructed for generic unit personnel. If this step has not been accomplished, personal, unit, and site data must be collected and evaluated concurrently. Although the thorough collection and evaluation of these data are time consuming, the dose determination for subsequent unit members is thereby expedited.

In general, film badge dosimetry data are used when they provide a valid representation of radiation exposure of the individual. Even these data require interpretation of their uncertainties, as based on the National Academy of Sciences report, "Film Badge Dosimetry in Atmospheric Nuclear Tests" (1989). Otherwise, indirect data are used to assess unbadged portions of the veteran's exposure. These may include any of the above types of data, including recorded doses of fellow unit members and other radiological measurements.

The evaluation of recorded data, which may contain misinterpretations, clerical errors, or biases, as well as the competent use of indirect data have proven to require sound professional judgment. A thorough understanding of the physical, analytical, and operational linkages and constraints among ostensibly disparate data are essential to quality, defensible dose reconstructions. For example, how can an internal dose be related to a film badge reading or the disintegrations counted in a urine sample?

Such linkages involving internal dose are made and quantified with the assistance of biokinetic methods and data established by radiation protection organizations such as the ICRP and NCRP. In general, the methods of ICRP Publication 30 have the common ground of current use in both veterans' dose reconstruction and DOE regulations, but updates are feasible. Care is needed in applying ICRP and like methods developed for radiation protection purposes. They may contain biases appropriate for radiation protection but not for retrospective dose determination. Because these radiation protection methods do not require data on all organ doses, dose conversion factors are not published for all organs pertinent to the cancers covered under PL 106-398. Factors for the remaining organs must be otherwise determined.

The determination of internal dose from even decades-old exposures may be buttressed in some instances with present bioassay. Urine bioassay for plutonium-239 has been applied with the fission track method (the basis is described in Boecker et al., *Health Physics Journal*, 1991) to Marshallese Islanders, veterans, and Rocky Flats downwinders. It has also been applied successfully to Nevada Test Site worker plaintiffs via surrogate workers in *Prescott v. USA* (1994). Other state-of-the-art urine bioassay methods, including thermal ionization mass spectroscopy and accelerator mass spectroscopy, provide information on additional radionuclides. Urine bioassays could provide the worker compensation program opportunities to

reduce uncertainty in PC for certain claims, verify the application of internal dose reconstruction methodology in a sampling of claims, bound the internal dose to certain generic worker classes, and contribute to the resolution of contested compensation decisions. The strengths and limitations of these advanced techniques warrant further review regarding their feasibility for widespread application to retrospective dose assessment at DOE sites.

Application of dose reconstruction methods

Unlike for the veterans, the DOE worker compensation program is expected to involve a large number of claims early in the program. It is therefore judicious to consider what dose-related strategies might facilitate timely claims processing while preserving the accuracy of compensation decisions and fairness to all parties.

Compassionate priorities should be developed among claims; simple first-in-first-out may not be equitable and not practical because of disparate dose information requirements. The current estimates for likely compensable claims based on radiation doses and PC amount to a low percentage of all claims — perhaps just a few percent of eligible cancers. If so, the claim types most likely to result in compensation should be identified for special action, based on the premise that such claimants deserve compensation promptly if at all.

Even simple screening may identify claimants with a strong potential for compensation. This may involve total recorded dose, radiogenicity of the cancer, young age at diagnosis, job category, the known presence of high doses at the site, or some combination of these. Criteria for some combinations could be established with the aid of the PC software. Classes of workers may be identifiable for whom even lower-bound doses would qualify for compensation.

Other screening may serve to identify the claimant classes least likely to have meritorious claims. Low priority might be designated based on a site with low recorded doses, no alleged high doses, the industrial processes and radionuclides involved, and job category. For example, many temporary waste remediation workers may be covered by bounding. Generic dose reconstructions based on sites and activities may suffice to bound the PC for workers for whom details on their individual exposure situations are unavailable. Clearly, data that are collected on sites and their practices in advance of active claims processing will facilitate claim prioritization. Further, a comprehensive review of the radiological history of each site will be a crucial foundation to dose reconstruction in general.

Even for the typical claimant, collection of the full information accommodated in the PC software may not be necessary. Whatever can be accomplished to streamline the inputs without skewing the compensation decision will be fruitful. For example, as indicated previously, incomplete data

such as the recorded external dose information alone may suffice to justify compensation. Insertion of this with personal information into the PC software might be a useful first step in general.

Whether limited dose information may correctly imply a denial of compensation is far less certain and requires careful professional judgment and review. However, early scoping could be made of what information covering missing external doses, internal doses, or uncertainties would be required to achieve compensability. Experience that will be developed from similar cases, as well as partial reconstruction of the missing information, may lead to defensible compensation decisions.

When likely minor pieces of data are absent, sensitivity testing with the PC software will readily demonstrate whether the missing information could have any bearing on the compensation decision. As with the veterans, many situations may arise where the lowest doses are the least documented. The IREP software may be able to justify not devoting disproportionate resources to further evaluation of minor contributions to dose.

Unlike for veterans, regulations are being developed concerning Energy workers' doses without the benefit of much experience in dose determination for individuals of this claimant population. Therefore, the initial regulations should not be expected to be of the same quality and durability as those for the veterans. The fewest problems will arise if the regulations err on the side of underspecification and if they contain their own mandate and mechanism for improvement and augmentation (in the manner of PL 106-398 itself).

The regulations will need to cover an even greater breadth of situations than exist for veterans. They need to cover the range extending from:
• modern workers exposed to one radionuclide with complete individual monitoring data in full compliance with current DOE regulations and modern health physics practice
to:
• workers of decades ago potentially exposed to over 100 fission product and actinide radionuclides (as at the Nevada Test Site) with spotty available individual dose data obtained under outmoded radiation safety practices that require further research to make dose interpretations (e.g., of internal dose) from indirect data.

One size cannot fit all workers. Regulations need a wide latitude for professional judgment in dose determination, the appropriateness of which is subject to review by the Advisory Board.

3. Special Exposure Cohort

Classes of workers for potential inclusion in the Special Exposure Cohort require consideration under Section 3626 of PL 106-398. Simply stated: the consideration is to involve exposure assessments; if the radiation dose to the class is not determinable with sufficient accuracy, and if such dose has a reasonable likelihood of health effects, then the class is eligible for inclusion in the Cohort. Note that "class," "sufficient accuracy," and "reasonable likelihood" are undefined.

In the above context, "class" logically refers to a set of workers whose similar exposure conditions led to a similar probability of causation for their cancers. Because of the wide variations of cancer radiogenicity, a class should not be defined solely in terms of workplace parameters. For example, in the related program at VA, the equivalent of the Special Exposure Cohort is defined for eligible participants according to cancer type.

The process in 1. tends to obviate the need to define "sufficient accuracy." The wider the confidence interval in dose, the wider the confidence interval in the individual's PC. Therefore, with increasing uncertainty in dose comes increasing benefit of doubt that is resolved in favor of the claimant.

Potential augmentation of the Special Exposure Cohort is useful if substantial disagreements regarding the best estimate or uncertainties in doses cannot be resolved. This could occur as the result of review by the Advisory Board or if an impasse occurs from a contested compensation decision. Recourse to the Special Exposure Cohort provision would eliminate the need to revisit the disputed area in other claims of a suitably defined class of co-workers.

In these situations, "sufficient accuracy" is that for which the disputed range of best-estimate dose or its uncertainty distribution does not skew the compensation decision. A dose may be sufficiently high that even its minimum possible value is sufficient to support compensation; conversely, even a worst-case dose may be insufficient to support compensation. Although each of these doses may be highly uncertain, they have sufficient accuracy for the purpose intended. For the intermediate situation, it should be noted the uncertainties in PC based on radiation risk factors alone are considerable. Therefore, when uncertainties rather than best estimates are at issue, doses with lesser uncertainties than exist for the risk factors are unlikely to influence the compensation decision and should be deemed sufficiently accurate.

"Reasonable likelihood" of the health effect is applicable in unresolved dose situations. If the PC for the higher-dose position exceeds 50 percent (or alternatively if some to-be-defined confidence interval in PC for the higher-dose position includes 50 percent), then there may be deemed a reasonable likelihood of the health effect having occurred from radiation exposure during

qualifying employment. In arriving at an appropriate definition, it should be noted that the class is perforce based on parameters pertinent to the index claimant, some of which may not fully apply to other members of the class.

The existence of large uncertainty in dose should not in itself warrant consideration by the Advisory Board under Section 3626; only unresolved doses with bearing on compensation decisions should lead to augmentation of the Special Exposure Cohort. Note that this process is reactive, stimulated by individual claims, and is distinct from the proactive screening/bounding processes in 2.

Sincerely,

W. Jeffrey Klemm

W.Jeffrey Klemm, Ph.D.

Enclosure as stated