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June 17, 2001

Larry Elliott
NIOSH
Robert Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Mr. Elliott:

In response to your letter of March 21, 2001 requesting input, attached please find detailed recommendations to NIOSH related to the development of regulations to implement the Energy Employees Occupational Illness Compensation Program Act of 2000. These recommendations were developed through a workshop convened at the Government Accountability Project on May 30, 2001 in Washington, DC involving representatives of stakeholder groups who were involved in the development of the Act and experts on the issues of science and policy related to dose estimation and the NCI-CDC radioepidemiology tables.

As part of the workshop, we invited Dr. Charles Land to present the recent update of the Working Group to Revise the 1985 NIH Radioepidemiology Tables and respond to questions about the assumptions and methods underlying the report.

Those participating included: Mark Griffon, a health physicist who has performed dose assessments and risk mapping work within the DOE nuclear weapons complex; Arjun Makhijani, a physicist with the Institute for Energy and Environmental Research who has done extensive dose assessment work at Fernald and other weapons supplier facilities; Robert Alvarez with the Institute for Policy Studies and a former Senior Policy Advisor to the Secretary of Energy; David Michaels, associate professor at George Washington University and former Assistant Secretary of Energy for Environment, Safety and Health; David Richardson, Department of Epidemiology at University of North Carolina; Jordan Barab, consultant to the AFL-CIO and former senior advisor to the Assistant Secretary of Labor for Occupational Safety and Health; Dan Guttman, former Executive Director for the President's Advisory Committee on Human Radiation Experiments; Jaya Tiwari, Physicians for Social Responsibility; and staff from the Government Accountability Project (GAP) including Louis Clark, Richard Miller, Bob Stix and Frank Morales.

GAP advocates for whistleblowers within the workplace, and has dedicated significant resources to investigating worker health and safety problems in the DOE nuclear weapons complex. GAP has initiated a project to evaluate and communicate on the challenges and opportunities facing the implementation of the Energy Employees Occupational Illness Compensation Program Act of 2000. This landmark legislation presents significant challenges to

the four agencies charged with its implementation if it is to benefit those it is intended to serve. To this end, GAP looks forward to working with and supporting the efforts of NIOSH with its major responsibilities.

As a follow-on to this set of recommendations, we would welcome the opportunity to brief you and those charged with drafting regulations.

Sincerely,

Richard Miller
Policy Analyst

cc: Kathleen Rest, Acting Director, NIOSH
Workshop Participants

RECOMMENDATIONS OF THE GOVERNMENT ACCOUNTABILITY PROJECT TO NIOSH IN THE IMPLEMENTATION OF THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT (EEOICPA) OF 2000

These recommendations analyze 3 major areas: Dose Reconstruction, the Application of NCI-CDC Radioepidemiological Tables and IREP Model, and Eligibility for the Special Exposure Cohort. They were prepared by the staff of the Government Accountability Project (GAP), in consultation with David Richardson, University of North Carolina, Mark Griffon, CPS Environmental, Arjun Makhijani, Institute for Energy and Environmental Research, Robert Alvarez, Institute for Policy Studies, Dan Guttman, former Director of the President's Advisory Committee on Human Radiation Experiments, and David Michaels, George Washington University.

I. RECONSTRUCTING THE RADIATION DOSE

Section 3623(d) of the EEOICPA requires the President to establish, by regulation, methods for arriving at reasonable estimates of the radiation doses received by an individual at their place of employment, including employees who were not monitored, inadequately monitored or whose records are missing or incomplete. Executive Order No. 13179 assigned this responsibility to the Department of Health and Human Service ("HHS"). EEOICPA assigned responsibilities given to HHS to the National Institute for Occupational Safety and Health ("NIOSH").

The challenges to "reasonable" dose estimates outlined below should be addressed in regulations:

- There is inadequate internal dosimetry data on worker exposure to radiation at many sites, and the quality and reliability is uneven, at best. Thus, there should be no presumption of regularity in terms of adequacy in monitoring practice, unless otherwise demonstrated through investigation. Dose records are frequently unreliable or inaccurate. Even up to the current time frame, DOE radiation protection programs are marked by deficiencies, according to audits by the Price Anderson Enforcement Program

- Access to records is complicated by changes in DOE contractors and lack of a chain of custody. DOE has also blocked researchers' and workers' access to records.

- DOE vendors in most cases did not retain records, and in numerous cases, the plants no longer exist and have been bulldozed. Access to some records will be complicated by clearance issues related to the data of interest or the document which contains the data of interest (e.g., K-25, Mound, Portsmouth, Paducah). Declassification of the documents is a time consuming and costly process and it may cause problems with the interpretation of the data of interest. Additionally, some records may have been transferred to other repositories. This may further complicate the identification and recovery of pertinent documents. This caused extensive delays in the Mound dose reconstruction project.

- At many of the sites, internal dosimetry programs, especially prior to 1989, have been determined to be inadequate for the detection of all potential significant internal doses. Existing bioassay data, in many cases, will be difficult to use for estimating dose due to insufficient information regarding critical parameters such as specific radionuclide of interest, solubility, particle size, date of intake, type of intake (chronic or acute), etc. Often only net counts are available with no indication of isotope, solubility, particle size, or detection efficiency.

- There are numerous examples within the DOE of radiation monitoring programs which inadequately monitored for potentially significant exposures or did not monitor individuals who were potentially exposed to significant levels of radiation. Several studies have revealed inadequacies in historical radiation monitoring programs by comparing monitoring programs (actual implementation of the documented programs) over time against the radiological hazards over time. The inadequacies identified included: field practices not consistent with procedures, significant hazards not being monitored, inadequate detection capabilities, instruments were not calibrated, samples left unanalyzed, etc. Review of the personnel dosimetry records alone would not have uncovered these cases of potentially significant unmonitored exposures and would have resulted in an underestimate of dose. Testimony of the General Accounting Office before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, March 17, 1994; Testimony of Richard Miller before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, June 29, 1999; Portsmouth Mortality Study, NIOSH 1996; *Paducah Exposure Assessment Project Report*, DOE, PACE and University of Utah, January 2001; *INEEL Risk Mapping Session*, June 2001,Griffon; *Evaluation of Protection, Bioassay, and Dose Assessment Programs for Internal Radiation Exposure at the Nevada Test Site Particularly With Respect to Three Exposure Situations*, Prepared for REECO, French, Skrable, September 30, 1995. (Also see: hearing records from Senate Government Affairs Committee, March 23, 2000, Senate Government Affairs Committee, August 2, 1989, Senate Health, Education and Labor Committee, May 15, 2000, DOE Tiger Team Reports.)

- Even in the most ideal situations, the radiation dose reconstruction process is a very uncertain science. This is true for dose estimates of both external radiation exposures as well as internal radiation exposures, although the uncertainties in the internal dose estimates are generally believed to be greater *(Procedures for Assessing Occupational Radiation Monitoring Data for Use in Epidemiologic Studies*, Crawford-Brown, Watson, Strom, Tankersley, ORAU, 1989). The uncertainties of concern regarding dose reconstruction include:

  - » Appropriateness of monitoring program for the hazards.

  - » Uncertainties in the metabolic and dosimetric models used for calculating the dose. These models rarely are based on a detailed understanding of how the radiation interacts with the human body and often are formed on the basis of limited data

(*Procedures for Assessing Occupational Radiation Monitoring Data for Use in Epidemiologic Studies, Crawford-Brown*, Watson, Strom, Tankersley, ORAU, 1989).

- Uncertainties in the modeling parameters including assumption of "reference" individual, uncertainties with the biokinetic parameters (fl, fu, etc.), breathing rates, organ sizes, etc. These parameters vary among individuals and within an individual over time (*Evaluating Reliability of Biokinetic and Dosimetric Models and Parameters Used to Assess Individuals for Risk Assessment Purposes*, NCRP No.15)

- Uncertainty regarding the quality of the data reporting system. The best measurement schemes can be negated if one has no confidence that the results were correctly recorded (*Paducah Exposure Assessment Project*, Department of Energy, PACE and University of Utah, January 2001).

- Uncertainty in measurement procedures (*Paducah Exposure Assessment Project*, Department of Energy, PACE and University of Utah, January 2001).

- Uncertainties in the bioassay and air sampling data including sample size (collection period, volume, etc.), chemical yield, interference from other radionuclides, counting efficiencies, background, etc.

- Uncertainty in defining the exposure scenario including the mode of exposure (chronic or acute), the date or period of exposure, the knowledge regarding the source term, the chemical form and the particle size (*Paducah Exposure Assessment Project*, Department of Energy, PACE and University of Utah, January 2001).

- African Americans and other minorities may have been subjected to harsher working conditions with far less extensive exposure monitoring. Subcontractors may have followed different monitoring protocols when compared with M&O contractors.

- Uncertainty analysis for most dosimetric data at the DOE sites does not exist. Further, it is unlikely that data will be available for quantifying the uncertainties for all parameters of concern such as counting result, particle size, solubility, chemical yields, calibration error, and biokinetic model parameters. There is wide variability between the results produced by internal dosimetrists because of the varying use of "expert" assumptions," even when working with a given set of assumptions up front. In some situations, usually involving potentially high doses, health physicists have used an independent review process for purposes of quality assurance. (Mound Roundtable Meeting, 2001) Differences in dose estimates of 100% are not unlikely.

Recommendations:

1. **Independent auditing and oversight--**To address this major and complex task, a strong

scientific underpinning and public credibility are essential elements of quality control and quality assurance. (A good model that could achieve these objectives of a scientific and fair process has been demonstrated at the Los Alamos National Laboratory in the context of federal Clean Air Act radionuclide emission standards. This endeavor included an independent technical audit that was reviewed by stakeholder experts relative to workscope, ongoing analysis and final work product. The process yielded multiple benefits relative to achieving and validating Clean Air Act compliance in a way that now has strong public and laboratory support.) This same approach could be adapted to apply to the multi year NIOSH dose reconstruction contract.

When contracting for dose estimation services, NIOSH should provide two levels of quality control/quality assurance and a process to disqualify firms and individuals with a potential conflict of interest.

Level I: Models for dose estimation should be set up by a competent consortium working closely with NIOSH staff. These models and procedures can then be implemented by other contractors, provided there is adequate QA/QC, so that judgement calls can be made in advance on each group of workers. Models should also be made available to the Advisory Board.

Level II: A stakeholder technical review group with expertise in DOE's radiation dosimetry should be assembled and retained by NIOSH to provide QA on the work of Level 1 contractors. This group should be given full access to workers, the models, and the data. Their analysis should also be made available to the Advisory Board. Level 1 contractors would have to respond to questions and critiques of the stakeholder technical review group and NIOSH would oversee this process.

Conflict of interest: Both actual and perceived conflict of interest should not be allowed to taint the credibility of the dose estimates. For example, if individuals or companies performing dose estimates for NIOSH have been under contract or subcontract to DOE, those individuals or contractors who may be placed in the position of reviewing, re-estimating or critiquing their current or former radiation dosimetry work, or have a potential liability associated with radiation exposure, or have been retained by the DOE or its contractors to serve as experts on ongoing litigation that involves radiation, should be precluded from this contract.

2. **Worker History is Essential to Reconstruct Dose** –Worker history will need to be taken with respect to job hazards, industrial processes, work practices, history of monitoring (internal and external), isotopes known, location of external badges with respect to radiation hazard, air monitoring (breathing zone and area), and the history of contamination control practices. As part of the interviews, individual and group history will need to be taken to determine respirator availability, quality of equipment with respect to the hazard (particle size), equipment hygiene, and the extent to which such equipment was used. Assessing the

quality and use of respirators is a major assumption when estimating internal radiation dose. One effective way to encourage worker participation is to work in cooperation with the union(s), where present (similar to the methods used by the DOE in gathering data for oversight reports at the three enrichment plants). Both open meetings and one-on-one interviews should be used.

3. NIOSH should provide workers/claimants the opportunity to review the paper history provided by DOE/contractor or vendor to NIOSH, and then compare this paper record against their recollection. Where there is a divergence, workers should be afforded the opportunity to provide an affidavit to NIOSH that records the knowledge of the worker and the inconsistencies with the paper record. The affidavit should be included as part of the administrative record in the case.

4. Where there is a succession of contractors/vendors, NIOSH must ascertain whether is there a chain of custody for the records. NIOSH must identify if there are gaps in the work history for certain contractors. Where data gaps exist that cannot impair the ability to estimate dose with sufficient accuracy, then NIOSH should flag data this major data gap as a possible predicate for including such individuals or groups of workers in a special exposure cohort. NIOSH needs to record and catalogue such findings or flags, as these have legal significance. History must be evaluated for individuals where there is multi site exposure (i.e. both Y-12 and K-25) or multi facility (i.e., at Hanford PFP and PUREX). As part of the process, NIOSH must insist through documentation that the DOE has looked for and produced all records (to avoid loss of credibility when other records surface later on).

5. NIOSH should seek out historical data that may be available from DOE medical surveillance grantees, and incorporate where applicable.

6. **NIOSH Should Not Presume Adequacy of the Dose Record**--Individual exposures contained in the employee's record, although potentially useful, should not be deemed a "reasonable" estimate without first validating the dose against air monitoring data, radiation surveys, thorough knowledge of work practices, analysis of the source term, and, if available and reliable, co- located worker exposure data. For example, where individual records show no internal dose, but the air monitoring or rad surveys show the presence of high alpha contamination, then NIOSH needs to perform a job task analysis, conduct source term analysis, look at air sampling data and breathing zone data, and estimate dose accordingly. This scenario was identified at a major DOE site, casting doubt on the credibility of the internal dose records. Likewise, at the uranium enrichment plants and certain vendor-operated uranium processing sites, worker dosimetry did not account for uptakes of insoluble Y-Class transuranics, leading to substantial missed dose in the paper record. Instead, the paper record assumes almost exclusively soluble uranium compounds. This deficiency caused historic dose estimates to be understated by at least an order of magnitude for hundreds of workers.

7. **NIOSH Must Account for Uncertainty in Dose Estimates When Establishing a "Reasonable" Estimate–** Uncertainty and sensitivity analysis should be conducted on all parameters, when possible. It is unlikely that data will be available for quantifying the uncertainties for all parameters of concern (see above). Quality assurances (described above in recommendation #1 (Level II)) which are transparent to the claimant and the public should be included as part of the process. While the conclusions may be subjective in nature, introducing the steps formally within the regulation will assure that all documentation is scrutinized.

As part of estimating uncertainty NIOSH should evaluate:

a. The completeness and appropriateness of the facility radiation monitoring program over time along with the radiological hazards over time to ensure that the instrumentation and methods employed (actual practices in the field) were capable of measuring significant exposures. Additionally, consideration should be given to the question of the extent to which the radiation hazards were identified with acceptable precision and completeness. If these facts can not be determined than there is a question as to whether the measured values are representative of actual exposures.

b. Quantitative analysis of the uncertainty of the metabolic and dosimetric models should be performed. All relevant models should be used for dose estimation purposes. The model selected for the final dose calculation should be noted and an explanation for the model selection should be provided.

c. NIOSH, or contractors should used validation and verification procedures to assure the accuracy and completeness of the dosimetric records.

4. **Determining What is a "Reasonable" Dose for DOL to Use in Ascertaining Eligibility–** If the average dose estimate does not render a claimant eligible for compensation, then NIOSH should determine whether a claimant would be eligible if the estimate falls within a range of uncertainty around the mean dose estimate. For example, NIOSH could modify the IREP model to apply the upper 95% or 99% confidence interval of the dose estimate instead of the average (mean) dose. However, if the uncertainties are so large (i.e., the 99% confidence interval is 6-10 times greater than the average) then NIOSH may want to flag this claimant as a candidate for the special exposure cohort. The reason is that it isn't feasible to estimate dose with "sufficient accuracy." However, the fact that a dose can be estimated without excessively wide confidence intervals, does not mean that the employee monitoring program was appropriate and adequate for the hazards over time and may not be reasonable.

5. All isotopes and types of ionizing radiations should be considered. Where there is a possibility of decay products affecting dose estimates, these should be taken into account.

6. Correction factors were used by DOE contractors which had the effect of reducing external dose estimates–in some cases, to less than zero. Where there is doubt about the validity of external dose badge data, NIOSH should seek to obtain the film badges and have them read to cross check and validate. (Dose badge re-reading was performed at Rocky Flats where neutron exposures were systematically underestimated, and dose estimates were revised at Portsmouth after it was determined that a radiation dose was administratively "assigned" when badges would not read out on automated reading equipment). External dose readings should not be used as a proxy for internal dose.

7. **External Dosimetry**--Neutron exposures were not accounted for at a number of DOE sites. Examination of hard copies of early TLD glow curve data, radiation surveys, and records on neutron poisons should be conducted, where appropriate, in determining if significant neutron exposures existed. Dose badges were not necessarily located on the parts of the worker where individuals may have received dose. For example, workers may have had their dose badges on a pocket that was shielded by lead when the face of person received intense gamma emissions from a dissolution tank while inserting a fuel rod. A popular photo shows a worker sitting on a uranium derby at Fernald when the dose badge is on his shirt, rasing questions about the dose to the gonad. Workers who routinely carried "hot" samples from their left hand may not have recorded an accurate dose when the dose badges were always pinned to the right pocket. Interviews will assist in ascertaining the potential for missed dose.

8. **Group Dose Estimates May Be Required**--When adequate individual information is not available, NIOSH should consider grouping like workers based on job category, department or building information to assist in dose estimation.

9. **Air Monitoring Data, if Available, Should be Used**-- Air monitoring data, where available, should be used to estimate dose (using area and breathing zone data) or validate dosimetry. In many cases this will require determining source term composition, since the air sampling was likely not isotopic specific. In some cases assumptions which were made were erroneous and could have great consequences with regard to internal doses. At the Mound site in Ohio, all early data was assumed to be plutonium. The rationale behind this was that it was the most conservative assumption. Subsequently, however, many of these areas were determined to have actinium-227 and high fired plutonium oxides (both more restrictive cases with regard to internal exposures). If source term composition cannot be validated for each work activity over time, potentially significant uncertainties will result.

10. **NIOSH Should Use Committed Dose Estimates**--NIOSH should aggregate internal and external dose into annual committed dose equivalents for use in the IREP model from the date of exposure through the diagnosis of the illness.

11. **Consultation with the Advisory Committee**--Before the dose estimate regulations are promulgated in either an Interim or Final Rule, they should be reviewed by the Advisory

Board on Radiation and Worker Health. Issuance of an Interim Rule should not be used to circumvent the consultation process, as this review is required by law, is essential to assuring public confidence and providing a means for public involvement.

II THE REVISED RADIOEPIDEMIOLOGICAL TABLES SHOULD BE MODIFIED TO ADDRESS WEAKNESSES IN THE USE OF ATOMIC BOMB SURVIVOR DATA, THE CORRELATION TO US POPULATION, THE ABSENCE OF WORKER EPIDEMIOLOGY AND OTHER LIMITATIONS

Section 3623(c) of the EEOICPA requires the President to establish guidelines to determine whether a covered employee's cancer was at least as likely as not caused by their occupational exposure to radiation. The statute requires use of radio epidemiological tables (at the upper 99 percent confidence interval of the probability of causation), plus consideration past health-related activities (such as smoking), information on risk of developing a radiation related cancer from occupational exposure, and other relevant factors. Executive Order No. 13179 assigned this requirement to the Department of Health and Human Service ("HHS"). NIOSH will develop the regulation.

The radio epidemiological tables were originally mandated by the Orphan Drug Act, which required that the HHS develop a systematic guide for determining the causal connection between exposure to radiation and cancer. The original tables from 1985 were based on atomic bomb survivor data at Hiroshima and Nagasaki. An update was prepared the National Cancer Institute-Centers for Disease Control in May 2000. The quantitative basis for these updated radio epidemiological tables is, again, the study of atomic bomb survivors in Hiroshima and Nagasaki. These updated tables (a) do not incorporate the results of epidemiological studies of workers, (b) pertain to a select population of Japanese survivors of an atomic blast and subsequent depravation, in a situation where radiation doses were primarily received as an acute exposure resulting from an atomic bomb blast instead of a long term, low-dose exposures typically received over a working lifetime, and (c) are based on a study that primarily concerns the effects of external exposures to photons rather than internal exposure to alpha particles which were the largest sources of radiation dose at many of the DOE sites under consideration.

These tables should be revised to better account for the experiences confronted by populations in the nuclear weapons complex. To obtain credibility, NIOSH should not promulgate regulations or issue interim regulations until it has resolved the major deficiencies in the radio-epi tables and the supporting interactive computer program (IREP).

A. The following parts of the IREP Model rely on questionable assumptions (citations are referenced in end notes to this section):

1. The radio epidemiological tables assume that the effectiveness of radiation at causing cancers decreases at low doses. For chronic exposures, the IREP model specifies a dose and dose-rate effectiveness factor (DDREF) with a value that is distributed around 2, even though

analyses of the atomic bomb survivor data (which are the quantitative basis for these tables) suggest that there is no reduction in effectiveness at causing cancer at low doses (indicating a DDREF of 1). Furthermore, the radio epidemiological tables are applied to workers who were exposed to alpha and neutron radiation as well as gamma radiation, and who will report a dose in units of Sv. There is no empirical basis for a DDREF value greater than unity when doses were due to high-LET exposures (in fact, the literature suggests a DDREF value of less than unity for high-LET exposures).

Epidemiological analyses of atomic bomb survivors do not support the conclusion that the dose-response relationship for solid cancers departs from linearity (that is, the atomic bomb survivor study does not support a DDREF greater than unity for solid cancers).(1,2) Analyses of leukemia among atomic bomb survivors have been interpreted as supporting a DDREF greater than unity, although there is substantial uncertainty in estimates of the excess relative risk for leukemia in the low dose range of the Life Span Study (LSS) data; and, when broader groups of solid cancers are examined there is strong evidence of linearity. The authors of the radio epidemiological tables largely rely on evidence from radiobiological studies to support the decision to apply a DDREF value of approximately 2 for all chronic and low dose exposures. This evidence from studies of chromosomal damage, and animal experimentation (often evaluating non-cancer outcomes), is of questionable relevance to radiation-induced cancer in humans. Epidemiological studies of populations other than the Japanese atomic bomb survivors offer minimal support for a DDREF greater than unity. Studies of breast cancers among tuberculosis patients who were exposed to multiple chest fluoroscopies, for example, have ben considered in evaluations of the effect fractionation of low-LET radiation doses. There is no evidence in these studies of a reduction in breast cancer risk with protracted exposure.(3) Some have argued that a lack of a dose-related excess of lung cancer among tuberculosis patients suggests a DDREF greater than unity for that cause of death (4); however, necrosis and surgical removal of lung tissue among tuberculosis patients (related to risk of lung cancer and duration of treatment) precludes any clear interpretation of dose, or dose-rate, effects on lung cancer. (5,6)

Given the epidemiological findings of linearity in the atomic bomb survivor study, which is used as the quantitative basis for the risk estimates in these tables, there is little support for the decision to divide risk estimates by a factor of approximately 2 for purposes of compensation.

In addition, the radio epidemiological tables are to be applied in decision making for workers exposed to high-LET radiation as well as low-LET radiation. Doses will be reported in units of Sv, combining different radiation types. There is little support for the assumption that low doses of high-LET radiation, or chronic exposure to high-LET sources of radiation, are less biologically effective than higher doses or acute exposures. To the contrary, studies of exposure to alpha-radiation among miners suggest an inverse exposure rate effect (that is, radiation effects were of larger magnitude when doses were accrued at lower dose rates).(7) Similarly, a recent review concluded that there is no evidence of a reduction in effectiveness

of neutrons at low doses or low dose rates, and that effects may be larger for neutron doses accrued at lower rates.(8)

2. The IREP model assumes that there is a systematic underestimation of atomic bomb survivors' radiation doses that can be accounted for by dividing all DS86 doses by a factor of approximately 1.1 (to account for bias in gamma dose estimates) and by a factor of approximately 1.1 (to account for bias in neutron dose estimates). This is done in the radio epidemiological tables by dividing all radiation risk estimates by a factor of approximately 1.1, and again by a factor of approximately 1.1. The naïve reduction of these risk estimates by a simple multiplier (and consequently a simple reduction in risk estimates) is an unsupported approach to addressing problems of non-random measurement error in gamma and neutron dose estimates.

   The IREP model assumes that gamma radiation dose estimates, as indicated by DS86, systematically underestimate the true gamma exposure of survivors. The authors of the IREP model divide estimates of the excess relative risk per unit dose by a factor with a value centered around 1.1 (with an uncertainty distribution ranging from 1.0 to 1.4). This is not an acceptable approach, and is not supported by empirical evidence. There is little evidence that gamma doses in Nagasaki are underestimated by DS86; and errors in gamma dose estimates for survivors in Hiroshima are unlikely to be proportional to total dose (for example, errors may be greater for survivors with low doses than for survivors with high doses, as suggested by Maruyama et al., 1987). While we agree that errors in radiation dose estimates are an important concern in the LSS study, the naïve use of a single factor applied to all dose estimates will not necessarily reduce bias (and may in fact increase the bias in radiation risk estimates.)

   Similarly, the IREP model assumes that neutron radiation dose estimates, as indicated by DS86, systematically underestimate the true exposure of survivors. The authors of the IREP model divide estimates of the excess relative risk per unit dose by a factor with a value centered around 1.1 (with an uncertainty distribution ranging from 1.0 to 1.3). Again, errors in neutron dose estimates may differ by city (as indicated by some empirical evidence), and the magnitude of error may vary with DS86 dose; it has been noted that further investigation of measurement techniques for evaluating the contribution of the neutron component of dose in each city, and at varied distances, is needed to understand the error distribution.(9) A simple inflation of all doses by a fixed correction factor is an inadequate assumption about the distribution of measurement error.

3. In applying epidemiological risk estimates from the study of Japanese atomic bomb survivors to United States populations, NCI uses a model that leads to an estimate with a value between the additive and multiplicative relative risk approaches. Current radiation protection guidelines are premised on a multiplicative model in which it is assumed that excess relative risk (ERR) estimates derived from the LSS can serve as a quantitative basis for worker protection. The same should be said for issues of worker compensation. We

recommend that NIOSH apply the multiplicative approach for all cancers. The assumption that a multiplicative relative risk model is valid has been argued in much of the literature on radiation effects. Further, there is substantial scientific literature that examines the application of estimates derived from the LSS under a multiplicative relative risk model to other populations, such as patients exposed to medical irradiation that supports the conclusion that a multiplicative model is appropriate for transferring epidemiological results between populations.(10,11) Furthermore, the multiplicative model would give the benefit of doubt to the claimant in a situation where there is scientific uncertainty.

4. Under the current radio epidemiological tables, the probability that a worker's cancer was caused by radiation tends to be lower for workers exposed at older ages than for workers exposed at younger ages, in contrast to recent occupational epidemiological studies that indicate the opposite pattern of association. Studies of US radiation workers suggest that older adults are more vulnerable to the cancer causing effects of ionizing radiation than young adults (6); most studies of other chemical and physical hazards find a similar pattern of increasing vulnerability to hazards in later life.(12,13)

   For issues of workers compensation, we are concerned with variation in sensitivity to the effects of ionizing radiation at adult ages (e.g., age 18+ years). The slope of the age-at-exposure term may be predominantly influenced by the relatively high radiosensitivity of children, which is not relevant to the issues under consideration.(14) Several epidemiological studies (including worker studies) suggest that among sensitivity to the carcinogenic effects of radiation may increase in adulthood with older ages at exposure (suggesting a non-linear trend in sensitivity across the lifespan).(15-19)

5. A number of recent studies have concluded that there is convincing evidence that mortality following the bombings of Hiroshima and Nagasaki left a select group of healthy survivors. These analyses of radiation effects clearly pertain to a highly select population. Furthermore, there is evidence that this selection was dose-related, such that people in the high dose categories were more select than people in lower dose categories. Overall mortality rates, for example, in the first 15 years after the bombing, are negatively associated with dose.(20) Such a pattern is consistent with a healthy survivor effect in the cohort, and would lead to a downward bias in radiation risk estimates.(21,22)

B. Recommendations to modify the IREP Model:

Short term recommendations--

1. In the face of the epidemiological findings of linearity in the atomic bomb survivor study, which is used as the quantitative basis for the risk estimates in these tables, there is little support for the decision to divide risk estimates for all chronic and low dose exposures by a factor of approximately 2.0 for purposes of compensation. In addition, the radio epidemiological tables are to be applied in decision making for workers exposed to high-LET radiation as well as low-LET radiation. There is little support for the assumption that low doses of high-LET radiation, or chronic exposure to high-LET sources of radiation, are less

biologically effective than higher doses or acute exposures. To the contrary, studies of exposure to alpha-radiation among miners suggest an inverse exposure rate effect (that is, radiation effects were of larger magnitude when doses were accrued at lower dose rates).(3) We therefore recommend that the DDREF should either be equal to 1.0, or follow a distribution centered around 1.0 with associated uncertainty (e.g. 90% confidence bounds at 0.67 – 1.50).

2. The factor used to adjust for systematic bias in DS86 gamma dose estimates should be modified. The authors of the IREP model divide estimates of the excess relative risk per unit dose by a factor with a value centered around 1.1 (with an uncertainty distribution ranging from 1.0 to 1.4). This is not an acceptable approach, and is not supported by empirical evidence. We recommend treating the DS86 doses as the current best estimate of the survivors' true doses (this factor be assigned a value of unity). If the authors of the radio epidemiological tables wish to account for uncertainty in risk estimates due to uncertainties in this component of dose, since it is not clear at this time whether these errors in dosimetry would lead to inflation or attenuation of risk estimates, we would suggest that any adjustment factor should have be centered around 1.0 with a symmetric error distribution.

   Similarly, the IREP model assumes that neutron radiation dose estimates, as indicated by DS86, systematically underestimate the true exposure of survivors. The authors of the IREP model divide estimates of the excess relative risk per unit dose by a factor with a value centered around 1.1 (with an uncertainty distribution ranging from 1.0 to 1.3). We recommend treating the DS86 doses as the current best estimates of survivors radiation doses. If the authors of the radio epidemiological tables wish to account for uncertainties in estimates of excess relative risk per Sv due to uncertainties in this component of dose, we would suggest that any adjustment factor should be centered around 1.0 with a symmetric error distribution.

3. Current radiation protection guidelines are premised on a multiplicative model in which it is assumed that ERR estimates derived from the LSS can serve as a quantitative basis for worker protection. The same should be said for issues of worker compensation. We recommend that NIOSH apply the multiplicative approach for all cancers.

4. A linear term is used in the IREP model to describe changes in sensitivity to the effects of ionizing radiation with age-at-exposure over the entire human lifespan. It is known that infants and young children are especially vulnerable to ionizing radiation when compared to adults. For issues of workers compensation, however, we are concerned with variation in sensitivity to the effects of ionizing radiation at adult ages (e.g., age 18+ years). We recommend that the IREP model include categorical parameters for age at exposure, or else limit analyses to a range of ages at exposure that is directly relevant to workers. We also suggest that NIOSH conduct further investigation into the use of data from occupational cohort studies to inform these radiation risk estimates, and understand variation in risk estimates with age at exposure.

5. The IREP Model should require the input of committed effective internal dose from the date of exposure(s) to the date of disease, particularly for isotopes that have high energy potential or are not soluble. Failure to use committed dose estimates in the IREP model will result in the potential for significant amounts of missed dose.

Intermediate Term Recommendations--

6. Account for bias and uncertainty due to selective survival in the atomic bomb survivor cohort. There is evidence selective survival was dose-related, such that people in the high dose categories were more select than people in lower dose categories.(20) Such a pattern is consistent with a healthy survivor effect in the cohort, and would lead to a downward bias in radiation risk estimates.(21,22) We recommend that NIOSH develop and include a correction factor for this source of bias and associated uncertainty.(23)

7. The decision to divide the lung cancer radiation risk estimate approximately in half for all workers who ever smoked should be questioned. We recommend that NIOSH re-evaluate the logic and justification for applying a factor which leads, at the median level, to the ERR at 1 Sv for lung cancer among ever-smokers to be half as large as the estimate for never smokers. This decision has little support from empirical evidence; as the authors of the report acknowledge, much of the epidemiological evidence is consistent with a multiplicative model. Apparently, the authors of the updated Tables have followed a precedent set in the 1985 radio epidemiological tables-- despite the lack of empirical evidence supporting this approach. In contrast, as a basis for using a multiplicative model, one might draw a parallel to the use of a multiplicative model for describing the effect of radiation with increasing age at risk, which presumably is also associated with an increase in cancer due to the accrual of damage from environmental exposures (and for which radiation effects are routinely described as multiplicative). Furthermore, the authors show little sensitivity to the misclassification that arises if workers are simply classified as ever or never smoked.

8. We recommend that NIOSH develop an approach to use data from occupational cohort studies of nuclear workers to further inform risk estimation and to address potential variation in risk estimates with age at exposure.

9. NIOSH should examine, in detail, the entire IREP model. This should include review of raw LSS incidence data and DS-86 dosimetry data which was used to determine the model.

10. Segregate types of cancers where possible (i.e. do not lump cancers such as leukemia together, rather, when data allows, break them into subgroups of various types of leukemia).

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III. ESTABLISHING SPECIAL COHORTS

Under section 3623(b) of the EEOICPA provides that the President may, in consultation with the Advisory Board, designate additional classes of workers for designation as a Special Exposure Cohorts (SEC). The statute states: "[m]embers of a class of employees at a Department of Energy facility maybe treated as members of the Special Exposure Cohort for purposes of the compensation program if the President, upon recommendation of the Advisory Board of Radiation and Worker Health, determines that–(1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received, and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of the workers. Once in the Special Exposure Cohort, claimants receive an irrebuttable presumption of workplace causation for one of a list of 22 covered cancers. We strongly recommend that NIOSH convene a workshop to explore this issue in more detail before issuing draft regulations.

A. When The Process of Dose Estimation Indicates that a Special Exposure Cohort Designation may be Triggered, the Rule Should Flag These Cass for Designation in the SEC

In the regulation, NIOSH should establish a procedure for reporting "flags" or indicators that arise during the dose estimation process which suggest that a reasonable dose estimate is not going to be feasible, including very large uncertainties in the estimate (greater than a rule of thumb) or inadequacy of the data. At the point a flag goes up, NIOSH will need to review the case to determine whether dose estimation may need to stop. If it appears fruitless to continue with a dose estimate, NIOSH should notify claimants so they may be advised of the process to petition to be included in a special exposure cohort. In the alternative, NIOSH should initiate the process of evaluating a group for inclusion in the special exposure cohort. This will prevent claimants from being denied based on the inability to estimate dose.

B. Definition of "feasibility."

How long should a claimant have to wait to obtain a reasonable dose estimate? If it takes more than 6 months from the time DOL refers the dose estimation work to NIOSH for NIOSH (or its contractors) to acquire the data, interview workers and calculate estimates, prepare a dose estimate for an individual or group, and have it reviewed for quality control/quality assurance by NIOSH, then it should not be deemed "feasible" for purposes of the statute to estimate the dose.

Likewise, if the costs of dose estimation is so large relative to the group of eligible workers, it may be a waste of resources to invest in dose estimates. For example, if the cost to estimate

radiation dose is 50% of more of the benefits potentially payable to a claimant or a group of claimants (based on expected excess relative risk), it should not be deemed feasible to estimate dose.

Further, if data needed to estimate a dose with reasonable confidence does not exist-- a list of this essential data should be developed--in the time periods when the claimant was employed in a covered facility performing work functions that may have endangered their health, then it should be deemed not feasible to estimate dose.

C. Definition of "sufficient accuracy."

This should be defined by the degree of confidence in the estimates. If the data collected is such that the calculated uncertainty at ~3 times the standard deviation (99% confidence interval) is, for discussion purposes, 6-10 times the size of the mean, then NIOSH should conclude that the dose cannot be estimated with "sufficient" accuracy (unless the mean dose estimate establishes eligibility).

D. Definition of "may have been endangered."

EEOICPA (Section 3621(14)) requires dosimetry badging as a criteria for members of Special Exposure Cohorts at 4 sites (Paducah, Portsmouth, Oak Ridge and Amchitka Island). In drafting the legislation, dosimetry badging and term of employment was used as a proxy for whether the worker "may have been endangered". The purposes of using a dose badge as a threshold was a crude way to exclude those who were presumed not to be at material risk. Specifically, the law requires that the covered employee:

> "was monitored through the use of dosimetry badges for exposure at the plant of the external parts of employee's body to radiation; or worked in a job that had exposures comparable to a job that is or was monitored through the use of dosimetry badges."

The use of dosimetry as a proxy should be expanded to include workers who were monitored through a radio bio-assay program or worked in a job that had exposure comparable to a job that is or was monitored through the use of radio bioassay programs. (The DOE criteria for film badging is the individual's potential to receive 100 mrem occupational dose in a year.)

E. Development of an Administrative Process for Receiving and Rendering a Determination.

What documentation should petitioners have to submit? Should there be a minimum size to a Special Exposure Cohort? What happens to people in groups whose size that fall below the minimum? Are there any classes of cases that automatically fall into the Special Exposure Cohort?

Petitions should be reviewed and decided in a 120 day period, with time extensions provided only with the concurrence of the Advisory Board. The petitioner(s) should be afforded the right to a public hearing, and to receive all of the documentation that went into a recommendation prior to a draft decision or recommendation being sent to the advisory board. Petitioners should be permitted to present their case to the Advisory Board. Petitions to the Secretary of HHS should be sent to the

advisory board upon receipt. A process must be established for the Advisory Board to evaluate and make recommendations on expanding the special exposure cohort after receiving recommendations from NIOSH, and input from the petitioner(s) if so requested.

An added eligibility issue need to be addressed by NIOSH and DOL: Can a covered employee (or their claimant) who was denied compensation after dose reconstruction be subsequently included as a member of a Special Exposure Cohort?