NIOSH Radiation Dose Reconstruction Program

Ten Year Review – Phase I Report

Special Exposure Cohort (SEC)

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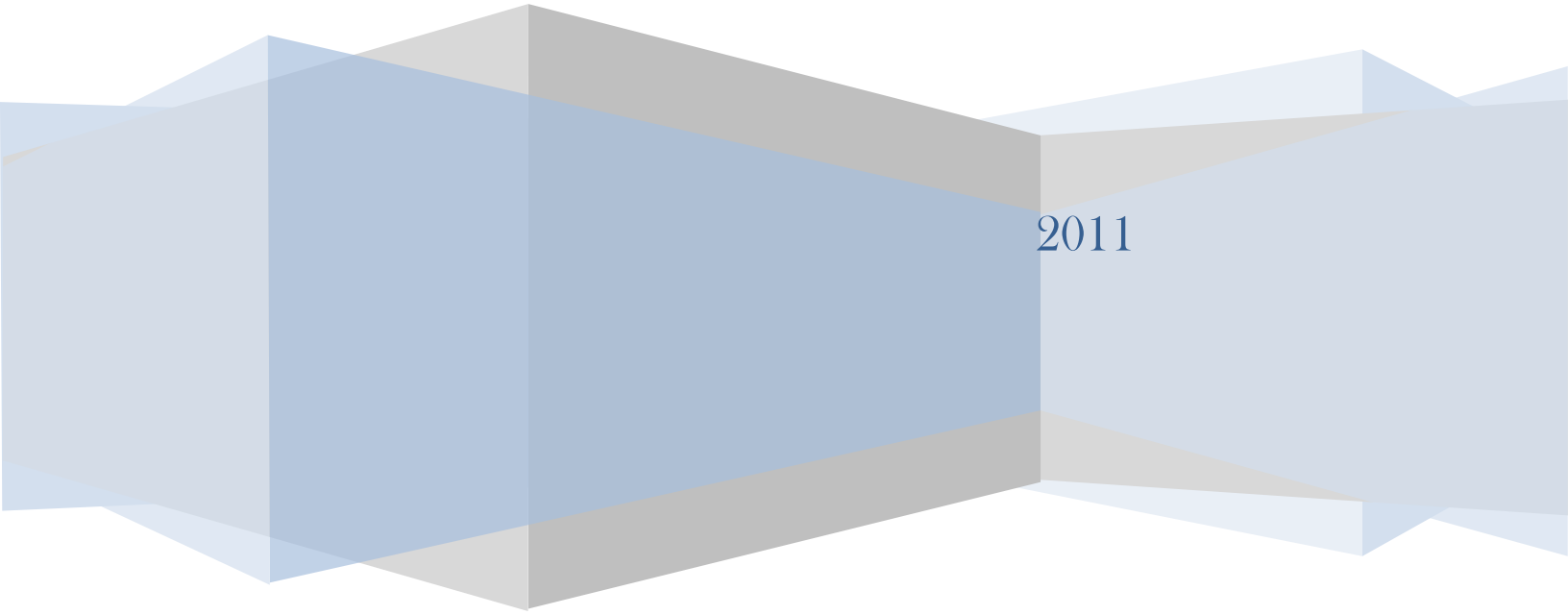

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SPECIAL EXPOSURE COHORT EVALUATION REPORT

Submitted By

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Ten Year Review of the NIOSH Radiation Dose Evaluation Program- Phase I Report

Special Exposure Cohort (SEC)

I. Introduction

Dr. Howard, Director of NIOSH, requested a review of NIOSH' implementation of EEOICPA during the last ten years, specifically "[t]he appropriateness and the consistency of decisions regarding petitions to add groups of claimants to the Special Exposure Cohort [SEC] established under the statute. "[2] This report responds to that request. It is not intended to be a primer on EEOICPA or its implementation, but assumes the reader has a working knowledge of the statute, its regulations, NIOSH policies, and Board processes. It addresses the SEC process; a separate report addresses the dose reconstruction (DR) process and this report makes no effort to capture the technical details of the DR process.

To complete this evaluation, Dr. Howard requested a review all of the documents relating to the evaluation and determinations of SEC petitions. He wanted a data-driven report. This report is based on review of thousands of pages of SEC Evaluation Reports (ERs), NIOSH policies, regulations, dozens of spreadsheets, and NIOSH presentations to, and Board debate on, many SEC petitions. The report is also based on interviews with Board members, advocates for claimants, present and former NIOSH staff, and other NIOSH contractors. Those interviewed are not identified in this report to ensure that their opinions remain confidential. The report does not analyze the merits of NIOSH's technical decisions, nor does it evaluate the rationale for site specific determinations. Rather, the goal was to look at broad program statistics to see what, if any, lessons can be learned from them. After reviewing hundreds of documents, and conducting many interviews, and despite Dr. Howard's request for a data driven report, the report finds that the available data do not provide a full picture of some of the concerns raised by the SEC process, the documents are scientifically complex and difficult for a layperson without scientific training to master, and do not directly answer the question of whether the SEC process provides "fairness and equity" to claimants. 42 U.S.C. 7384(a)(8).

This review is presented in five parts. Part II, summarizes the report's general findings on the SEC process. Part III, presents background statistics on the SEC process to provide the reader with necessary information for understanding the discussion which follows. Part IV discusses NIOSH's evaluation of SEC petitions and what the report identifies as NIOSH's failure adequately to address the role of scientific uncertainty in the SEC process, and the consequences of that failure. Part V highlights several other aspects of the SEC program.

[2] http://www.cdc.gov/niosh/review/public/194/

This review is focused on how NIOSH, not the Board, has implemented the SEC process. So, it includes only general observations about the give and take between the Board and NIOSH after its ER is presented and when the Board reviews a site profile. No recommendations regarding Board procedures are offered. However, changes in the pace of SEC review by NIOSH will have little impact on claimants unless the Board also evaluates the pace of its review, because lengthy deliberations over petitions by either NIOSH or the Board are inconsistent with Congress' goals of timely compensation.

This report assumes that, overall, more claims will be compensated at a site if a SEC is approved than if all claims were considered based on individual dose reconstructions. At sites where classes are included in the SEC, claims are approved at a rate of 64% (using claims data available via DOL as of July 29, 2010), even though some claims at the site may not be covered by the SEC. Claims at facilities where classes have not been added to the SEC have been approved at a rate of approximately 42% [3] (using claims data available via DOL as of July 29, 2010).[4]

However, some claimants at a site may not be better off if a SEC is granted. Under existing policy (but see discussion at pp. 44-45), for those claims which can only be granted based on a dose reconstruction --- and that is all claims not involving a "specified cancer" – NIOSH's determination that it cannot reconstruct some dose suggests that a claimant's total dose may be lowered by the amount of dose NIOSH cannot reconstruct. For these claimants, SEC status does not help and may hurt.

II. Summary of Conclusions

EEOICPA provides compensation to radiation exposed workers based on criteria which differ from those of other federal radiation or workers' compensation programs. NIOSH has no prior institutional experience administering compensation programs. NIOSH was given a difficult task in trying to develop a coherent compensation policy for EEOICPA. It has worked diligently to do so. In many respects it has succeeded. This report should not be viewed as criticism of those efforts. The purpose of the recommendations in this report is to help NIOSH learn from its experience over the past decade so it can improve the SEC program.

[3] http://www.dol.gov/owcp/energy/regs/compliance/statistics/Statistics.htmThe approval rate for statutory SECs may vary from administratively approved SECs because at the latter there may be more limitations on what time periods or buildings are covered by the SEC or which exposures are covered.

[4] Because this report was prepared over a period of time and the data on which it relies comes from different sources and was produced at different times, the data do not always match. For example, a summary of qualified petitions from April 2010 might indicate a different number of SEC evaluations than a summary of completed ERs from November 2010. The report indicates the source and date of the data on which it relies to help ease this problem.

Most SEC petitions have been approved. 68 classes at 52 facilities have been added to the SEC out of 109 qualified petitions and only 6 petitions have been denied as of December 31, 2010. For each of the 33 SEC petitions filed under section 83.14 on which the Board has voted, it has agreed with NIOSH's recommendation to add a class to the SEC. One 83.14 petition has been pending over several Board meetings. In 30 of 53 petitions filed under section 83.13, NIOSH has initially recommended adding a class to the SEC and the Board has always agreed. In these cases, which constitute 74% of all petitions, there has been little disagreement over the operation of the SEC process. Questions about methodology and delay have plagued the minority of petitions, 23 of 87, in which NIOSH initially concludes that it can feasibly reconstruct dose for the class.

The report concludes that a significant issue contributing to the methodological questions and delay which affects this minority of petitions is NIOSH's failure adequately to address the role of scientific uncertainty in the SEC process. (A more detailed discussion of the concept of scientific uncertainty and its relation to the EEOICPA program is included at pp. 11-32). This omission has had three significant adverse consequences for the program. First, NIOSH has placed undue deference on the expert judgment of scientists to make policy decisions. This over-reliance on scientific expertise to decide questions for which science cannot provide answers has delayed resolution of petitions. Deference to expert judgment has also resulted in seemingly unnecessary complexity in an area where there is already enough complexity. Finally, there is no way quantitatively to evaluate whether the exercise of expert judgment across SEC petitions has been consistent. Increased reliance on objective criteria or evidentiary presumptions to resolve issues of scientific uncertainty would ameliorate these effects.

In other areas of the SEC process, NIOSH has made improvements to the process internally, such as during the pre-qualification process and with its recent efforts to qualify petitions under 83.14 if dose reconstruction has not been completed within a fixed period of time. In other areas, such as completing site profiles so dose reconstruction and SEC petitions can be timely considered, NIOSH still faces challenges. These are areas where NIOSH might benefit from revised procedures.

III. **SEC Program Statistics**

NIOSH has received 182 SEC petitions through 2010. 109 petitions were qualified for further review; 64 petitions did not qualify or were withdrawn. Of those 109 qualified petitions, 35 were filed under 42 C.F.R. 83.14 and 147 were filed under 42 C.F.R. 83.13. At the end of 2010, 68 classes had been added to the SEC at 52 sites. 33 classes were added as a result of petitions filed under 42 CFR

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§83.14 and 35 as a result of petitions filed under 83.13. Six SEC petitions have been denied, a least one because DOE decided the site was not a covered EEOICPA facility. [5]

Data from November 2010 shows that among the 34 SEC classes originally qualified under 42 C.F.R. §83.14, in all cases, NIOSH initially recommended approval of the SEC and in each case where the Board has voted on the petition – and it has voted on all but one petition (GE Pet. No. 161) it has approved NIOSH's recommendation to add the site to the SEC. Among these 34 petitions, the Board requested SC&A review in 2 of 34 cases and in another 5 cases SC&A was involved in reviewing a site profile while a petition was pending. In 5 of 7 instances involving SC&A review, the Board voted to recommend granting the SEC petition before SC&A's review had been completed. In 31 of 34 cases, the Board considered the SEC petition at only one meeting; in two other cases the Board considered the petition at two meetings; one case is still pending. In all but two cases, both involving ongoing discussions with DOL about how to define the affected class, NIOSH has always met the 180 day time limit for evaluating petitions under §83.14. The average time from NIOSH ER to Board decision is 68.5 days.

NIOSH provided data on 53 petitions filed under section 83.13 for which it had completed 57 ERs as of December 2010. [6] Of those 53 petitions, NIOSH initially concluded that dose reconstruction was not feasible in 30 of 53 or 56.6% of cases. NIOSH concluded that dose reconstruction was feasible in 23 of 53 or 43.4% of cases. In instances when NIOSH concludes dose reconstruction is not feasible and the Board has voted on the petition, the Board has always agreed with NIOSH's recommendation. Among 83.13 petitions where NIOSH initially concluded that dose reconstruction was not feasible, the average time for NIOSH to complete its ER is 195 days.[7] Among this subset, NIOSH has completed its ER within 180 days 14 of 30 times, or 46.6% The Board has completed its review in 29 of 30 petitions and the average time from filing of petition until Board recommendation is 280 days.

In 23 instances, NIOSH *initially* concluded that dose reconstruction was feasible. Of those 23 petitions, 14 are still pending and in 9 the Board has made a recommendation. In those 9 cases where the Board has voted, it has agreed with NIOSH's *initial* recommendation 3 times and disagreed 6 times. NIOSH, on average, took 247 days to complete its ER on these 23 petitions (min

[5] These numbers are based on data provided by NIOSH's Division of Compensation Analysis & Support (DCAS). The data were provided as of December 31, 2010.

[6] Of the 109 petitions qualified for evaluation, 57 were filed under 83.13. NIOSH has completed its review of 53 of those petitions as of December, 2010. Four petitions resulted in two ERs. So, NIOSH has completed its review of 53 petitions filed under 83.13 and generated 57 ERs in doing so.

[7] This subset of petitions includes some filed before 2004. EEOICPA was amended in 2004 to require that NIOSH's initial ER be completed within 180 days. Petitions filed after the amendments were effective are covered by the 180 day time limit.

29; max 547) and did so within 180 days in 7 of 23 instances or 30.4%. For petitions in this subset where the Board has made a final recommendation, the average time from petition filing to Board decision is 886 days. If the 14 petitions still pending before the Board were included in the calculation of the average time it takes to reach a decision about SEC status, the time petitions were pending before the Board would increase substantially.

Six petitions, or 5.5 percent of qualified petitions have been denied. Two were denied because the facility was not covered by EEOICPA or there was no exposure to radioactive materials during the period covered by the petition.[8] In the remaining 4 petition denials, NIOSH concluded that it had adequate data from which to reconstruct dose and the Board concurred.[9] In only one case, Rocky Flats, was the denial appealed under 42 CFR §83.18, and an internal HHS panel upheld the decision to deny adding a SEC class.

IV. SEC Petitions and The Role of Scientific Uncertainty

Among Congress' goals in passing EEOICPA was to ensure "fairness and equity" by providing claimants "efficient, uniform, and adequate compensation." 42 USC §7384(a)(8). NIOSH has established a goal of "uniform, fair and scientific consideration" of SEC petitions. 42 CFR §83.1; 69 Fed. Reg. 30765. EEOICPA promises "timely" compensation while NIOSH's regulations promise "timely" consideration of claims. The National Research Council has concluded, in commenting on the Radiation Exposure Compensation Act, that "to be equitable, any compensation program has to be based to a large extent on scientific criteria and has to make the criteria for inclusion and exclusion explicit. Eligibility for compensation needs to be assessed on the basis of criteria that support and are supported by the principle that "like cases are treated alike." [10]

Measured against these criteria, this report concludes, the SEC process needs improvement. NIOSH relies too heavily on the perception that science can answer SEC questions when the reality is that science can inform the evaluation of SEC petitions and narrow the areas of uncertainty, but in the

[8] DOE concluded that the National Bureau of Standards was not a covered facility under EEOICPA and the petition for the Iowa Ordnance Plant for 1946-1948 covered a period before the introduction of radioactive materials.

[9] The data on NIOSH's web page summarizing SEC decisions by site do not describe or provide links to transcripts discussing what, if any, concerns the Board expressed about NIOSH's recommendation to deny 3 of the 4 petitions. Those transcripts may be available elsewhere on NIOSH's web site. In each of these 3 instances, the Board's letter notes only that it "concurs" with NIOSH's recommendation. In the case of the petition on behalf of statisticians at Y-12, transcripts of Board discussion of each of several petitions at Y-12 are linked on the web page, but the transcript for the discussion about the class which was denied is not linked. Again, this transcript may be available elsewhere on the web site.

[10] National Research Council, ASSESSMENT OF THE SCIENTIFIC IFORMATION FOR THE RADIATION EPXOSURE SCREENING AND EDUCATION PROGRAM (2005) p. 3.

end the question (to a greater or lesser degree) of whether to add a class to the SEC turns on how to resolve scientific uncertainty and/or how much uncertainty to tolerate. NIOSH has opted for an evaluation process which relies heavily on the expert judgment of scientists, predominantly health physicists, to resolve issues which cannot be resolved by science, in the sense that science cannot offer quantitative or verifiable answers to the questions SEC petitions often pose. Some scholars refer to this as scientific uncertainty. The failure of NIOSH policies to distinguish between issues which science can resolve – and where the expert judgment of scientists is helpful – and those which science cannot answer has produced significant delay and disagreement between NIOSH and some members of the Board in the subset of petitions -- representing approximately one-quarter of SEC petitions -- where NIOSH initially concludes that dose reconstruction for a class is feasible (and hence the SEC petition should be denied). For these petitions, both NIOSH evaluation and Board review is more prolonged and the number of revisions to NIOSH's methodology greater than with other petitions. Scientific uncertainty is present in the three-quarters of petitions which have been resolved more expeditiously,[11] but in these instances agreement among NIOSH staff and its contractors, a group composed mostly of health physicists, about how to resolve questions of uncertainty, or more often why questions about uncertainty cannot adequately be resolved, has meant fewer delays during the SEC process.

A. EEOICPA Statutory Criteria

EEOICPA includes four classes of employees in a statutorily defined SEC. 42 U.S.C. §7384l(14)(A). These statutory SEC classes cover workers at three gaseous diffusion plants in Paducah, KY, Portsmouth, OH, and Oak Ridge, TN (specifically K-25) and also workers at Amchitka Island, AK. Workers at other locations may be added to the SEC administratively if the Secretary of HHS determines: (1) that "it is not feasible to estimate with sufficient accuracy the radiation dose" claimants received; and (2) that the health of the claimants may have been endangered by the exposure. 42 U.S.C. §7384q. A claim for a "specified cancer" at a non-SEC site, or any claim for a cancer other than a "specified cancer" will only be compensated if an individual dose reconstruction shows a probability of causation ≥50%.

EEOICPA is one of four statutes Congress has enacted to compensate American citizens exposed to radiation. [12] Two statutes compensate veterans exposed to radiation during military service. Both

[11] This subgroup includes petitions where the Board votes to recommend or deny a SEC petition at the first meeting where it is presented. Ordinarily, no work group is formed to consider these petitions, they are not referred to SC&A, and the Board generally agrees with NIOSH's recommendation.

[12] For citations to each of these statutes and a description of its provisions, see generally, National Academy of Sciences, ASSESSMENT OF THE SCIENTIFIC INFORMATION FOR THE RADIATION EXPOSURE SCREENING AND EDUCATION PROGRAM 37-41 attached at Appendix A.

statutes relating to veteran's compensation include a list of diseases for which certain veterans are entitled to presumptive compensation; in each case the statute assumes that if a veteran were exposed in certain defined situations, the veteran had enough radiation exposure to warrant compensation. Another statute, Radiation Exposure Compensation Act (RECA), provides compensation to persons living or working in certain places during atmospheric nuclear tests and who have been diagnosed with one of several diseases listed in the statute. As originally enacted, RECA paid compensation based on radiation dose for certain covered workers. In 2000, however, Congress amended RECA to make length of employment the relevant compensation criteria for covered diseases. According to the NAS, "length of employment gained support because of the lack of exposure measurements and the uncertainty associated with the extrapolations needed to calculate reconstructed exposure times." [13]

EEOICPA is thus the only radiation compensation statute which includes no statutory presumption that certain cancers are compensable and which bases compensation for all cancers, in the absence of an SEC class, on individual dose reconstruction. And, since claimants are included in an administrative SEC only when NIOSH cannot feasibly complete dose reconstruction for such claims, it is also the only radiation exposure program where compensation eligibility turns, as a practical matter, on whether radiation exposure records were created and/or retained and, if so, whether those records are reliable. In most programs, compensation is provided either to those with the greatest degree of impairment, the greatest economic loss, the highest cumulative exposures, or the greatest risk of disease. Congress chose not to apply these factors to the SEC approval process.

EEOICPA directs the President to develop methods for arriving at "reasonable estimates of radiation dose." 42 U.S.C. §7384(l). It also authorizes the President to add additional classes of employees to the Special Exposure Cohort if the President determines that "it is not feasible to estimate the radiation dose received by such class *with sufficient accuracy*." *Id.* The President delegated this authority to HHS in Executive Order 13179; the Secretary of HHS has delegated certain of her responsibilities under EEOICPA to the Centers for Disease Control and Prevention, of which NIOSH is a part. The Secretary retains the responsibility for making final determinations on whether or not to add a class of employee to the SEC. 42 C.F.R. §83.16(b).

B. NIOSH Regulatory Criteria

NIOSH first published proposed rules governing the SEC petition process in 2002, 67 Fed. Reg. 42962 (June 25, 2002), and revised its proposal in response to comments the next year. 68 Fed. Reg. 11294 (March 7, 2003). It published final rules to govern the SEC process on May 28, 2004. 69 Fed. Reg. 30765. Shortly thereafter NIOSH published an interim final rule and request for comments to

[13] Id. at 23.

implement statutory deadlines and other changes included in Congress' 2004 amendments to EEOICPA. 70 Fed. Reg. 75949 (Dec. 22, 2005). NIOSH published a final amendment to the SEC regulations on July 10, 2007. 72 Fed. Reg. 37455.

Several policy choices made by NIOSH in adopting the regulations have the practical effect of elevating scientific consideration of claims above the goals of uniform and timely consideration of SEC petitions. These include the decisions (1) to defer to the expert judgment of scientists; (2) to encourage the development of an extensive reliance on analytic models to bridge data gaps and (3) to fail to give independent meaning to the statutory phrase "*with sufficient accuracy.*"

NIOSH's regulations place primary emphasis on the case-by-case exercise of expert judgment by its scientists. In response to its proposed SEC regulations, for example, several commentators suggested that NIOSH adopt a regulatory time limit on how long dose reconstruction should take. If dose reconstruction were not complete after a certain period of time, comments suggested, then NIOSH should recommend a SEC. NIOSH rejected this suggestion because a time limit would "eliminate flexibility" and "could delay compensation for claimants." 69 Fed. Reg. 30765. Other comments suggested that NIOSH define "plausible circumstances" as the term is used in the regulations. Again, NIOSH declined, citing the need for "expert judgment." 69 Fed. Reg. 30770. [14] NIOSH was also asked to more clearly define when it could estimate dose with "sufficient accuracy." Again, it declined, citing as one of two reasons its "expert judgment" in making claimant friendly assumptions about dose. NIOSH opined that the provisions of EEOICPA relating to dose reconstruction and those relating to SEC petitions "address different but complementary circumstances." 69 Fed. Reg. 30769. In each of these instances, NIOSH was asked to provide transparent and objective criteria for how it would exercise its discretion in evaluating petitions and in each of these instances it declined to do so.

NIOSH instead announced that it would publish "internal guidelines" on how its scientific discretion would be exercised. These guidelines[15] primarily address process issues -- how to evaluate a petition, what documents to review, how to draft an ER. The guidelines contain limited guidance on how to resolve substantive dose response questions. Instead they note:

[14] NIOSH opined that "plausible" circumstances refers to "how doses would be estimated." It means that "NIOSH is not required to utilize unlikely, unreasonable, or illogical scenarios to estimate radiation doses." 67 Fed. Reg. 30770. The Board, in its policy on surrogate data, adopted in August 2010, takes a broader view of "plausibility." In the Board policy, plausibility refers not only to whether the exposure scenario being reconstructed is plausible, but also to whether the analytic methods used to reconstruct dose are scientifically plausible.

[15] Office of Compensation Analysis and Support, Document Number OCAS-PR-004.

"adequacy" and "credibility" are not judgments subject to any rigid criteria; because each case is likely to be unique, "adequacy" and "credibility" will be determined on a case-by-case basis, based on the totality of the circumstances. (OCAS –PR-004 at p.8).

C. The Role of Scientific Uncertainty

In implementing the SEC program, NIOSH has not adequately addressed the role scientific uncertainty plays in its evaluations. The concept of scientific uncertainty, as used in this report, refers to factual uncertainty which the scientific community has not been able to resolve and, therefore, must be resolved for administrative purposes partially on policy grounds.[16] NIOSH policy emphasizes getting the radiation science "right." Institutionally, it seems to believe that if it applies equal scientific rigor to each petition, its evaluation has been fair and uniform and that with additional time it can develop models which will answer radiation dose questions. This is so regardless of how much uncertainty its models introduce into the dose reconstruction process. Sometimes data is adequate and science can provide quantitative estimates of dose. But, when the data is limited or its reliability questionable, science (as used here meaning verifiable) does not provide a basis for dose reconstruction. Science can inform the appropriate choice of models or estimating techniques, but, the question of what data is "sufficiently accurate" to make compensatory decisions is essentially a policy choice. NIOSH chose not to give added meaning to the phrase "with sufficient accuracy" when adopting the SEC regulations. 69 Fed. Reg. 30769. That failure meant that NIOSH did not adopt policies to adequately address, on a uniform and consistent basis, the role of scientific uncertainty in SEC decision making. Instead, NIOSH has implemented the SEC process as a predominately scientific exercise guided by the opinions of its analysts. Doing so has had at least three significant consequences for the SEC program: (1) policy decisions, shrouded in scientific complexity, are made by scientists; (2) decisions across SECs are not based on objective criteria and are, therefore, potentially inconsistent; and (3) SEC petition evaluation is delayed awaiting "scientific" estimates of past exposures. [17]

NIOSH's emphasis on science is not surprising. NIOSH is a scientific research agency. Scientists are trained to search for scientific truths – results which can be verified through experimentation.

[16] *See generally,* McGarrity, "Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA," 67 Geo. L. J. 729(1979).

[17] This report refers to the absence of objective criteria and the exercise of expert opinion as subjective decision-making criteria. By subjective, the report does not mean to suggest that NIOSH or other scientists arbitrarily arrive at dose reconstruction methodologies. Rather, the term "subjective" as used in this report refers to situations where, based on some scientific information, a scientist reaches one conclusion while, based on the same scientific information, another scientist reaches a different conclusion, and there is no objective basis for concluding that one interpretation is "better" than the other. Elsewhere in this report, such a circumstance is identified as a "trans-scientific" or science policy issue. See p. 14.

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DCAS employs dozens of health physicists and its' contractors scores more. By profession, health physicists are trained to, among other things, develop models by which to estimate radiation exposures. EEOICPA's emphasis on individual dose reconstruction (as opposed to other radiation compensation statutes) lends support to that emphasis.

Where resolution of a SEC petition turns on ascertaining scientific facts, this emphasis on getting the science right seems reasonable. Unfortunately, science cannot answer the questions raised by many SEC petitions for several reasons. In many instances, NIOSH cannot determine what the facts are because no monitoring was performed at the time of radiation exposure or if it was, it is too sparse or unreliable to give a reasonable snapshot of occupational exposure for a class of workers. There are no experiments NIOSH could conduct which will tell it what exposures were 60 years ago in facilities which either no longer exist or whose processes have been substantially modified. Even when NIOSH can determine the radiation dose "facts," these facts provide only part of the answer to the broader policy judgment of what data are adequate (or in the statutory phrasing "sufficiently accurate") for dose reconstruction.

Scholars have recognized that in the field of occupational and environmental health, scientific uncertainty is inevitable. [18] That is so because agencies must predict the public health impacts of exposure to latent hazards and such effects are difficult to quantify. So, scientists often rely on models to estimate what exposure might have been in the past, what health effects may be expected at various exposure doses, or what technology may be required to reduce exposures. Efforts by EPA, OSHA, or other regulatory agencies to quantify risks posed by toxic exposures in many ways are similar to NIOSH's task under EEOICPA because in each instance an agency is called upon retrospectively to reconstruct exposures to hazardous materials. Scholars argue that agencies, such as EPA or OSHA, make policy choices, not scientific choices, when selecting among various models to extrapolate either dose or response. While the choice may be informed by science, these "science policy"[19] decisions "share in common the fact that ultimately, policy considerations must dominate their resolution." Professor McGarity, for example, has identified several types of science policy questions which regulatory agencies may face in quantitatively assessing dose and response. Different science policy questions should, he maintains, each be resolved differently. Because the evaluation of SEC petitions requires that NIOSH address the same types of science policy questions which EPA and OSHA routinely confront, Professor McGarity's analysis could inform NIOSH's handling of SEC petitions.

[18] *See e.g.,* McGarity, Shapiro & Bollier, SOPHISTICATED SABOTAGE (Env. L. Inst. 2004); Thomas McGarity, "Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA," 67 Geo. L. J. 729 (1979); Wendy Wagner, "The Science Charade in Toxic Risk Regulation," 95 Col. L. Rev. 1613 (1995).
[19] McGarity, 67 Geo. L. J. at 732.

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SEC petitions closely resemble trans-scientific issues "that are cast in scientific terms" but which "cannot for various practical or moral reason be answered by science." [20] Trans-scientific issues include "significant splits in the scientific community that are identified by scientists as major controversies over 'scientific judgment.'" [21] For these issues, "a regulatory agency [has no] legitimate excuse for delaying a decision" because "by definition, scientific experimentation is incapable of resolving trans-scientific issues."[22] SEC questions are similar to trans-scientific issues for several reasons. First, when exposure data are missing or unreliable, science cannot verify what past exposures might have been. Science can inform the development of analytic models, but the models nevertheless represent predictions – based in science but not scientifically verifiable --about past exposures. Indeed, the protracted discussions between SC&A and NIOSH over the interpretation of data and development of models illustrate the uncertain nature of the exercise.

A different science policy issue exists when NIOSH must make a decision based on insufficient data where the missing data could be obtained with sufficient time and resources.[23] In such cases, Professor McGarity suggests regulators weigh the benefits of prompt action against the costs of delay. NIOSH has faced this dilemma explicitly in the case of Malincrodt (SEC Petition No.00012-1) where it recommended a SEC even though its evaluation was incomplete. On the other hand, NIOSH has waited years in some cases before it concludes that dose reconstruction is not feasible and a section 83.14 petition is appropriate. [24] The Board has been reluctant to approve a SEC at General Electric (SEC Petition No. 161) believing better data might be available with more research. Each of these SEC petitions involves a different weighing of the costs and benefits of delay.

A significant omission from NIOSH's SEC evaluation process is its failure to distinguish between issues where reliance on expert judgment to resolve scientific questions has merit, for example the resolution of fact issues like determining which source materials were used at a facility, and science policy issues where science cannot provide answers, and for which deferring to the expert judgment

[20] McGarity, 67 Geo. L. J. at 733. Moral values prevent NIOSH from purposefully exposing workers to radiation to gain data from which to estimate what exposures might have been in the past.
[21] Wagner, "The Science Charade" 95 Colum. L. Rev. at 1620 n. 22.
[22] McGarity, 67 Geo. L. J. at 734, 736.
[23] Id. at 736.
[24] In its ER for Petition No. 00012-1, NIOSH observed: "NIOSH is issuing this report because NIOSH has established that it cannot conduct complete dose reconstructions for the class of DOE or DOE contractors or subcontractors employees who worked at the Mallinckrodt Destrehan Street facility within Plants 1, 2, or 4 during the period from 1942 through 1945. NIOSH has also made a health endangerment determination with respect to this class of employees. Issuing a report of these findings immediately will allow the Advisory Board on Radiation and Worker Health (the Board), the Director of NIOSH, and the Secretary of HHS to make recommendations and decisions Concerning this class of employees, as provided under 42 C.F.R. Part 83, without delay.

of scientists masks value judgments behind a veil of scientific complexity. Professor Wendy Wagner has summarized a similar dilemma in cancer regulation as a "science charade." By "science charade," Professor Wagner is referring to that aspect of environmental standard-setting "where agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions." [25]

In a perfect world, scientists and policy specialists would strive to separate trans-scientific issues that can be resolved with scientific experimentation. Policy choices would be made at each trans-scientific juncture, the basis for each choice would be explained, and the public would find the agency policy decisions clear and accessible.

Not surprisingly, in the real world a completely different picture emerges. Agency scientists and bureaucrats engage in a "science charade" by failing first to identify the major interstices left by science in the standard-setting process and second to reveal the policy choices made to fill each trans-scientific gap. [26]

The task of separating science and policy is made more difficult by the fact that "even for those questions that cannot be resolved by science, science plays a small but important role in defining the scientifically plausible default options available at each trans-scientific juncture." [27] As a result, scientists should play an important role in the SEC process to identify which questions science can answer and to distinguish between science and policy.

[25] The phrase "science charade" is borrowed from an article by Wendy Wagner, "The Science Charade in Toxic Risk Regulation," 95 Colum. L. Rev. 1613 (1995).
[26] Id. at 1628.
[27] Id.

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Observations/Recommendation

1. Using the NAS definition of equity in RECA compensation suggests that the criteria for inclusion or exclusion from the SEC should be explicit and applied consistently. NIOSH should seek to develop consistent, objective criteria which it can apply across SEC petitions to ensure fairness and uniformity. . Expert judgment is not an objective criterion.

2. NIOSH should revisit its interpretation of the statutory phrase "with sufficient accuracy" to give fuller effect to the role of scientific uncertainty.

3. NIOSH should recognize that SEC petitions often raise science policy questions, where science can inform NIOSH's policy choice, but science may not provide "facts" to govern those choices.

4. NIOSH should clearly articulate these policy choices. It should compare the policy choices it makes in reconstructing radiation dose across SEC petitions and against other occupational health policy choices. Where radiation dose reconstruction justifies different policy choices than NIOSH relies on in other areas of occupational health, NIOSH should explain why the different choice is appropriate.

Special Exposure Cohort

1. Over Reliance on Scientific Expertise

Assuming that science can answer questions which it cannot encourages over-reliance on scientists generally and, in the case of SEC petitions, health physicists specifically, who have no professional expertise in deciding what is "fair and equitable." Over-reliance on scientific expertise diminishes the possible contribution of others, trained in different disciplines, to contribute to compensation policy choices. It also vests in the hands of career scientists policy decisions which would otherwise be made by higher level agency policymakers.

All experts bring with them some bias, either explicit or unintentional, which results from their technical background.

Agency officials cannot be perfect and cannot escape their own interests. They sometimes opt for the path of least resistance in order to avoid pressure and conflict, or pursue a course that allows them to obtain rewards or recognition. Additionally, budget constraints impose limitations upon the full potential of agency expertise. Even the hypothetical selfless, perfectly competent agency official cannot escape the limitations of formal expertise. After all, even the most technical issues involve value judgments and therefore raise political questions beyond the ken of agency expertise. Moreover, a pure expertise model presumes an objectivity that is increasingly subject to question. [28]

Since the inception of the SEC program at NIOSH, it has relied heavily on the expert judgment of a group of scientists who are predominantly health physicists. NIOSH could have relied upon a broader array of occupational health knowledge – epidemiologists, toxicologists, risk assessors, and compensation claims experts in establishing its dose reconstruction program. Several of these disciplines are represented on the Board. Had it done so, the feasibility and uncertainties of radiation dose reconstruction might have been viewed through a wider lens and in a broader context. For example, are the assumptions used to reconstruct dose in the EEOICPA program similar to those NIOSH countenances in epidemiology studies it conducts or funds. If not, what are the reasons for the differences? Health physicists, industrial hygienists, epidemiologists, physicians and lawyers are all likely to view dose reconstruction with a different professional bias.

Over-reliance on health physicists serves to exclude the policy values held by non-experts or other types of experts. In the case of the SEC process, claimants have voiced the concern, both publicly at Board meetings and privately, that they often feel they have not been heard or that NIOSH is acting as an advocate against them. This perception may be a result of NIOSH's heavy reliance on health physicists.

[28] McGarity, Shapiro & Bollier, SOPHISTICATED SABOTAGE at 52-53.

The point is neither to malign experts nor to disparage an agency attempting in some fashion to respond to environmental inequities, but to recognize that everyone, including the expert, is influence by her own experiences. If experiences of outsiders remain peripheral to the expert's vision, the expert-generated standards might be inadequate to protect excluded groups, regardless of the good intentions of the regulators. [29]

Observations/Recommendation

1. NIOSH should consider relying on a multi-disciplinary approach to SEC evaluation. By relying on a broader range of experts to evaluate the data on radiation exposures at a site, NIOSH can take steps to minimize any unconscious bias in the SEC evaluation process. A multidisciplinary approach would also ensure that NIOSH applies consistent science policies across its programs.

2. Health physicists have no special expertise in setting compensation policy. Health physics can inform decisions about what science can tell us about past radiation doses. Over-reliance on health physics in instances where science does not provide quantitative answers reduces NIOSH's accountability for its policy choices. .

3. NIOSH should recognize that scientific expertise can be used to mask professional bias and take steps to minimize that effect. All professionals have some form of unconscious biases. Because DCAS is staffed overwhelmingly with health physicists, the biases of that profession dominate NIOSH's evaluations. Broader participation of other disciplines in SEC decision would likely bring with it a broader range of policy perspectives.

[29] Id. at 54.

2. Delay in the SEC Process

Scholars have observed that the failure adequately to address scientific uncertainty results in "administrative delays bordering on paralysis as experts debate incomplete science." [30] Professor Wagner comments that scientists may prolong the "science charade" by "embarking on an endless search for nonexistent scientific answers." [31] These observations about the effect of scientific uncertainty in other programs seemingly describe the SEC review process as well where delay has been significant at three junctures. First, there has been significant delay in the time it takes NIOSH to conclude individual dose reconstruction is not feasible and a petition under 42 CFR 83.14 is warranted. (See discussion at pp. 33-35). Second, there have been significant delays in SEC petitions where NIOSH initially concludes that dose reconstruction is feasible, and the Board initiates a detailed review. In such cases, the extended back and forth between NIOSH, SC&A and a work group, which often results in multiple revisions to NIOSH's dose reconstruction methodology causes delay (See discussion at pp. 5-6). Third, there has been significant delay in evaluating SEC petitions when they are presented to the Board while its review of a site profile for the same facility is still ongoing (See discussion at pp. 42-43).

NIOSH's experience and its regulations suggest that there are several ways that the perceived tension between full scientific analysis and timely evaluation of SEC petitions could be eased. NIOSH could pursue the best scientific evaluation possible, without regard to time. Or, it could pursue the best scientific evaluation within a fixed or reasonable amount of time. NIOSH has implicitly chosen the former in most cases, but chose the latter in at least one case, Malincrodt (SEC Petition 0012-1), where it split the petition into two SEC classes and recommended granting one SEC before its evaluation of the second SEC class was completed. The Board noted the delays in considering a different Malicrodt class (SEC Petition 0012-2) as one of several justifications for its recommended approval of a SEC class.

The question of when an evaluation is good enough and the time has come to move forward with a decision is not unique to the EEOICPA program. It is a recurrent issue in setting standards under section 6(b)(5) of the OSH Act. OSHA regulates on the basis of the "best available evidence" a phrase one court has interpreted to mean that OSHA cannot "let workers suffer while it awaits the Godot of scientific certainty" even if that means potentially over-regulating workplaces. [32] Under the OSH Act, courts have criticized OSHA for "delay in pursuit of certainty" and observed that "imperfect analysis" does not justify an "indefinite delay" of nine years.[33] NIOSH might consider

[30] Wagner, 95 Col. L. Rev. at 1617.
[31] Id. at 1633.
[32] *See* Rabinowitz, Ed. OCCUPATIONAL SAFETY AND HEALTH LAW SECOND ED., (BNA 2002) at 443-45.
[33] *Public Citizen Health Research Group v. OSHA,* 314 F.3d 143 (3rd Cir. 2002).

whether similar reliance on the "best available evidence" approach is appropriate in evaluating SEC petitions.

Second, NIOSH could declare that dose reconstruction is not feasible because it will not have timely access to information necessary to complete DR. NIOSH added language to the rule, 42 C.F.R. 83.13(b), which provides that the Director of DCAS may determine that "records and/or information requested from [various sources] will not be available on a timely basis." NIOSH has never exercised this authority. It should explore when to do so.

Third, the SEC rule provides:

> NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition. Each evaluation plan will include the following elements:. .. (2) A list of activities for evaluating the radiation exposure potential of the class and the adequacy of existing records and information needed to conduct dose reconstructions for all class members under 42 CFR Part 82.42 C.F.R. §83.12(c).

Currently, NIOSH forwards an evaluation plan to the petitioner and Board after a petition is qualified. The plans NIOSH currently uses are largely pro-forma, reiterating its internal operating procedures. Currently, the plans do not include timelines for completing an evaluation. Reliance on more detailed evaluation plans, particularly in complex cases, would create a framework for petition evaluation and allow the Board to voice its expectations about what the evaluation should consider early on in the process.

Finally, NIOSH could treat its evaluation of a SEC petition more like a rule --- in the sense that NIOSH reviews the petition, issues its proposed recommendation, solicits comments from claimants and the Board, prepares a final ER and submits it to the Board for a vote. In some instances, every time NIOSH's analytic methods are criticized by SC&A or the Board, or new information comes forward, NIOSH proposes different methods. Once NIOSH suggests a new method, either SC&A, the Board, or claimants need time to review and evaluate those methods. Since Board or workgroup meetings occur only once every few months, each revision to NIOSH's methods may add several months of review. NIOSH could reduce these delays by limiting the number of times it revises its methods.

Special Exposure Cohort

Observations/Recommendation

1. The SEC rule envisions that NIOSH will make timely decisions based on the best evidence available to it within a reasonable time frame. NIOSH has taken steps internally to implement that goal. It should continue to do so. There is no inherent tension between robust scientific analysis of dose for a class and timely evaluation of petitions.

2. NIOSH should rely on the authority in 42 CFR 83.13(b) in appropriate cases to declare that data will not be available for dose reconstruction.

3. When evaluation of a SEC petition is complex, NIOSH could present a detailed, petition-specific evaluation plan to the Board and seek its agreement on how to proceed.

4. NIOSH should consider limiting the number of revisions it makes to its SEC petition analysis.

Special Exposure Cohort

3. Lack of Objective Decision Making Criteria

Two consequences flow from NIOSH's heavy reliance on expert judgment for SEC policy decisions. First, different experts view the same facts differently. Second, deference to expert judgment means that NIOSH has developed few objective decisional rules to guide evaluation of SEC petitions. Case-by-case judgments about what data are "sufficiently accurate" to reconstruct dose are unlikely to be uniform across dozens of SEC petitions, but it is not possible quantitatively to measure the extent of any inconsistency.

In the SEC process, NIOSH views its procedures as consistent and fair if it has pursued an equally rigorous scientific effort to reconstruct dose at each site. But looked at from a different perspective – are similarly situated workers, such as those exposed for equal periods to radiation or exposed to similar radionuclides, treated similarly – it is far less apparent that the SEC process is consistent or uniform. (These are the criteria used by NIOSH to describe the goals of the 10 year review). NIOSH has established internal controls designed to ensure consistency across its evaluations. It has also published many policies to cover recurring scientific issues. The CDC contractor assigned to provide technical support to the Board, SC&A, also reviews NIOSH evaluations for, among other issues, consistency. Each of these reviews mitigates the possibility of inconsistency across SEC evaluations. But, adding layers of expert review by different health physicists does not fully addresses the concern that the perspective of the health physics profession is too dominant in the SEC process. Nor does agreement among several health physicists mean their judgments represent science rather than policy. For even with these internal controls, the process still lacks objective criteria to guide the exercise of discretion and the criteria or inclusion or exclusion from the SEC are not explicit.

a. Uniformity

For petitions requesting approval of an SEC covering a class of workers exposed to radiation during the 1940s, NIOSH has usually found that radiation exposure records are too sparse or of such poor quality that they are inadequate for some or all aspects of dose reconstruction. So most SEC petitions covering workers during the 1940s have been approved, at least in part. However, in at least four instances NIOSH has concluded that it could feasibly reconstruct radiation doses from the 1940s (Bethlehem, Electro-Met, Hooker Chemical, Chapman Valve). Three of these petitions are still pending; in one the Board rejected NIOSH's recommendation. NIOSH also usually recommends granting a SEC for petitions covering workers exposed during the 1950s – 1960s. In contrast, in only 11 instances have SEC classes been approved covering time periods beyond 1970.

When each SEC petition is viewed in isolation, there may be technical reasons for concluding that records from the 1940s or 1950s are reliable enough in one case, but not in another. But, when viewed across SECs, the result is that workers exposed to radiation during the 1940s -- when health

physics programs were primitive and records sparse – are treated differently. Claimants view such results as inequitable.

A difference in results across SECs exists when the petition requires NIOSH to bound internal exposures to radionuclides other than uranium. Seventeen SECs have been granted because NIOSH could not bound internal thorium (or other "exotic") exposures. Yet, in at least three instances, NIOSH has concluded that it could use internal uranium doses to bound thorium dose. (SRS, Mound, Fernald). None of these recommendations has been approved by the Board.

Several other areas of potential inconsistency were suggested by others, but none demonstrated any statistically significant differences in treatment. To evaluate whether differences existed in the evaluation of "large" sites or classes compared with "small" sites, the report compares the total number of DOL claims at sites with either pending SEC petitions or SEC petitions which had been approved. DOL claims are an imperfect proxy for site size, since there can be many reasons why few claims would be pending at a site, including widespread knowledge among former workers that NIOSH has not completed a site profile so is not processing dose reconstructions. In addition, at smaller sites which stopped operating years ago, claimants may be unaware of the EEOCIPA program or pending SEC petition. Despite the limits of the data on total DOL claims, it is the only proxy for site size available. The analysis found the size of a pending SEC class is not statistically different from the size of an approved SEC class. [34] A comparison of the rate of approval of SEC petitions from DOE sites with those from AWE sites was also completed. DOE sites represent 37% (123 out of a total of 328) of the EEOICPA covered sites, but 61% (32 out of a total of 52) of sites with SECs**.** One possible explanation for this finding is that AWE sites were more likely to work only with uranium than with other source terms and that NIOSH and the Board have developed a consensus on how to estimate uranium exposures. So, SECs at uranium only sites may be approved less frequently than are SECs at sites where workers were exposed to multiple radionuclides.

[34] The median number of claims received by DOL at closed sites was 625 while at open sites the median number of claims received by DOL was 474

Special Exposure Cohort

Observations/Recommendations

1. NIOSH's heavy reliance on expert judgment to evaluate SEC petitions is an inherently subjective criterion, in the sense that reasonable experts can reasonably disagree about the outcome of any petition. NIOSH should consider developing objective criteria to limit the exercise of expert discretion so that similarly documented exposures are treated similarly across sites. NIOSH regulations do not anticipate such an inquiry.

2. Applying an equally rigorous effort to reconstruct dose across SEC petitions may be one measure of "fairness and equity" but other measures, such as developing objective criteria to guide science policy decisions or increasing the use of presumptions in SEC evaluation, are available as well. Application of an equal measure of scientific rigor to SEC petitions may not ensure that similarly situated workers – in terms of year of exposure, type of exposure, or degree of risk – are treated similarly.

b. Surrogate Data

The role of surrogate data in NIOSH evaluations of SEC petitions is controversial. NIOSH endorsed reliance on surrogate data in its SEC regulations which authorize, but do not require, that it rely only on exposure information from the site being evaluated. Under NIOSH policy, there must be some data -- monitoring, process, source, or source term data -- from the site where the employee worked on which to base a dose reconstruction. 42 USC 83.13(c)(1). If there is no such data, dose reconstruction is not feasible. OCAS PR 004 p, 16. If there is any such data, NIOSH is not limited "to using only or primarily information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked." 42 CFR 83.13(c)(1)(i). There is no policy requiring a consistent amount of data from a site for dose reconstruction.

NIOSH's implementation of its policy on surrogate data illustrates some of the dilemmas posed by scientific uncertainty. By definition, NIOSH relies on surrogate data when it lacks representative data for the affected workers. Surrogate data represents an inferential bridge between what is known about the exposures --- actual monitoring data or source term and process information – and what can be inferred about exposures at the site from what is known about other sites. The validity of these assumptions may be grounded in science, but the accuracy of such models cannot be scientifically validated. The decision to rely on surrogate data necessarily involves policy choices: is there some

minimum quantum of data at a site that is necessary before relying on surrogate data; must it be consistent across sites to be fair and equitable; what quality data may serve as surrogate data; must the data be verifiable; etc.

NIOSH's surrogate data policy does not address these choices. [35] Instead, the policy authorizes NIOSH reliance on surrogate data "when necessary" "as appropriate" when it "may be possible." Others have been tasked with reviewing the scientific merits of the policy. For the purposes of this review, however, NIOSH's surrogate data policy is notable because it contains no objective criteria to guide analysts in deciding what data is a reasonable surrogate and when to rely on such data. Instead, the policy relies on expert judgment. Surrogate data allows NIOSH to take two petitions which are similarly situated – in terms of the actual exposure data available to calculate dose – and treat them differently, filling in the blanks in some cases, but not in others.

[35] Office of Compensation Analysis and Support "The Use of Data from Other Facilities in the Completion of Dose Reconstructions Under the Energy Employees Occupational Illness Compensation Program Act" OCAS-IG-004 (2008).

Among health physicists there seems to be a consensus on some uses of surrogate data, but on many issues it appears that reasonable health physicists can disagree about what inferences to draw when scientific "facts" do not fully answer the questions put to them. For example, the use of surrogate data to add a medical x-ray dose to the radiation dose of workers participating in medical surveillance appears to have wide support within NIOSH and among Board members. On the other hand, NIOSH has proposed several models for estimating doses at Linde Ceramics, but as of December 2010, there had been no agreement between the Board and DCAS on how to proceed, suggesting that the models represent science policy judgments.

If the decision on whether to rely on surrogate data and if so, when to so rely, is one of policy not science, then DCAS might benefit from the full range of NIOSH's broader experience advising OSHA and MSHA. For the question of what data are adequate to retrospectively estimate occupational exposures is not unique to radiation dose reconstruction. Even though epidemiologists often retrospectively estimate exposures to determine whether exposure is causally related to certain health effects in some cases such data may not be sufficiently accurate for deriving a quantitative dose response curve for regulatory purposes. *See* 52 Fed. Reg. 46,221-223 (1987) (OSHA discussion of why it chose to rely on animal data rather than human data quantitatively to estimate the risks of formaldehyde). Or, data may show that a relationship exists between two types of sampling methods, but doubts remain about whether the data are adequate to conclude that such a relationship holds true across all exposure levels. 70 Fed. Reg. 32870(2005) (MSHA discussion of the relationship between total carbon and elemental carbon across a range of exposures). And, although exposure data from one plant may generally describe exposures at another, such data may not be accurate enough to regulate the second facility. See Rabinowitz, Ed., OCCUPATIONAL SAFETY AND HEALTH LAW 2D Ed. at 447. (discussing 5th Circuit decision rejecting OSHA reliance on Italian studies to show risk at American cotton ginning facilities).

Each of these examples represents occupational health dilemmas faced by either OSHA, NIOSH, or MSHA in other contexts. Each has similarities to policy issues DCAS must address. These examples all suggest that models which are adequate for one purpose, such as assigning workers to an exposure cohort in an epidemiology study, may not be "sufficiently accurate" for another purpose, such as quantitatively estimating exposures for standard-setting or compensation decisions.

Claimants repeatedly voice skepticism over NIOSH's reliance on surrogate data. For many claimants, filing a SEC petition under EEOICPA is another step in a long, frustrating battle. When there are no exposure records for a site, but NIOSH nevertheless concludes that it can reconstruct radiation dose, and therefore, recommends denying a SEC petition, claimants may see NIOSH as an adversary. Historically, DOE fought all claims for compensation from radiation exposed workers. 42 USC §7384(a)(4). Although NIOSH played no part in that policy, when reliance on surrogate data limits

compensation, claimants may be skeptical about whether past governmental policies have changed. While this is a problem of perception, it can be made worse if NIOSH is not transparent about the policy choices underlying its reliance on surrogate data and their effect.

At its August 2010 meeting, the Board adopted its own policy on the use of surrogate data. The Board's policy identifies specific considerations which it will rely upon in deciding whether reliance on surrogate data is appropriate. If the Board policy has the effect of requiring NIOSH to articulate whether its reliance on surrogate data in each case meets certain criteria, then the policy should improve uniformity across SEC decisions.

In the preamble to the SEC final rule, NIOSH predicted that its reliance on analytic models would not delay dose reconstruction decisions. 69 Fed. Reg. 30768. But, NIOSH reliance on surrogate data often triggers detailed Board review of SEC petitions and such review delays final resolution of claims. Data are not available to compare the time it takes to resolve a petition relying on surrogate data with the time it takes to resolve a petition which does not rely on surrogate data. NIOSH should evaluate whether its reliance on surrogate data has affected the timeliness of decisions on SEC petitions or individual dose reconstructions.

Special Exposure Cohort

Observation/Recommendation:

1. NIOSH should develop objective criteria to guide when it relies on surrogate data and, if it does so rely, what type of data is accurate enough to serve that purpose. NIOSH has begun taking steps internally to do so. It should continue those.

2. NIOSH should review whether its reliance on surrogate data is consistent across SEC petitions, in the sense that workers with comparable exposure records are treated similarly. NIOSH should be more aware of whether its decisions are uniform and fair across SEC petitions.

3. NIOSH should also consider whether its use of surrogate data in the radiation dose reconstruction program is consistent with its treatment of such data in other areas of occupational health. Any differences in the way it approaches such data across programs should be consistent with relevant statutes or justified by explicit policy choices.

4. NIOSH should better explain its judgments about the use of surrogate data.

5. NIOSH should evaluate whether its reliance on surrogate data speeds or delays resolution of claims.

c. Upper Bound Estimates

Under its regulations, NIOSH estimates individual dose either by calculating an upper bound estimate of dose or, where data are available, a more precise estimate of dose. NIOSH uses this same approach to evaluate SEC petitions. 42 C.F.R. §83.13(c)(1). NIOSH relies on an upper bound to ensure that it does not underestimate the dose received by the claimant. An upper bound is not designed to accurately describe dose, but instead to set an outer boundary on the highest doses which might have been received. If NIOSH is unsure of the dose an individual received, or when it is criticized for underestimating dose, NIOSH's response is to add a dose assumption to its estimate. If it can construct a curve which does not underestimate the dose to anybody in the affected class, it recommends denying a SEC petition. By consistently overestimating individual dose, NIOSH believes it has constructed a "claimant friendly" approach to individual dose reconstruction.

There are several aspects of this policy which are likely to result in inconsistent results. An upper bound estimate is higher than a best estimate and requires less data from a site to calculate. So, at sites where little data exists and NIOSH must rely on an upper bound estimate, claimants benefit from higher dose estimates than at sites where more data is available. No objective criteria exist to guide the decision as to what quantum of data is enough to rely on a best estimate of dose rather than an upper bound. No objective criteria exist to decide what exposure scenarios should plausibly be estimated. 6 9 Fed. Reg. 30770.

Furthermore, even among upper bound estimates, there are no objective guidelines to guide how "claimant friendly" the dose NIOSH relies upon will be. There are numerous possible upper bound curves among which NIOSH could select. Sometimes NIOSH points to documentation on which it bases its "claimant friendly" assumptions. Other times, NIOSH just asserts that it added some extra dose to make its assumptions "claimant friendly." There is no data to quantitatively compare how "claimant friendly" various NIOSH assumptions are or whether they are all comparably "claimant friendly." Further, the degree to which an added dose is "claimant friendly" is not a matter of science -- in the sense that it cannot be tested and verified – but of science policy.

Adding a dose assumption to ensure that NIOSH does not underestimate dose is similar to the practice of safety and health professionals of incorporating a safety factor into decisions about safe levels of exposure. For example, when EPA calculates safe doses of chemicals, it relies on a consistent safety factor of 10.[36] Conversely, when OSHA attempted to revise its permissible exposure limits and it relied on varying safety factors without explaining why, its decision was

[36] *See* *http://www.epa.gov/raf/publications/review-reference-dose.htm*

rejected as impermissible. [37] NIOSH should consider whether there are objective criteria which would allow it to make its assumptions about dose more uniform.

Another area where inconsistent results are likely is the degree of acceptable uncertainty surrounding NIOSH's dose estimates. Even when the assumptions in an analytic model have a valid scientific basis, each assumption in a model adds some uncertainty to dose estimates. The use of multiple models multiplies the uncertainty. The National Academy of Science, in reviewing the use of dose reconstruction in radiation epidemiology, recommended that the uncertainty surrounding dose reconstruction be expressed quantitatively. [38] While NIOSH takes uncertainty into account in completing individual dose reconstructions, it rejected the idea that it quantitatively assesses uncertainty in its SEC recommendations, because it believed there was no valid scientific basis for doing so. 69 Fed. Reg. 30770.

Observation/Recommendation

1. NIOSH should reconsider whether its heavy reliance on expert judgment to decide when to rely on upper bound estimates and, if so, how it decides how claimant friendly to make its assumption is uniform or fair.
2. NIOSH should develop objective criteria, where possible, to guide the exercise of expert judgment.
3. NIOSH should give greater consideration to the uncertainties associated with its dose estimates.

[37] *See* Rabinowitz, Ed. OCCUPATIONAL SAFETY AND HEALTH LAW at 454 (discussing the 11th Circuits' criticism of OSHA's reliance on inadequately explained, varied safety factors in setting permissible exposure limits). .
[38] National Research Council, RADIATION DOSE RECONSTRUCTION FOR EPIDEMIOLOGY USES (NAS Press 1995) at pp. 48-49.

d. Increased Reliance on Presumptions

NIOSH could ensure greater uniformity in the SEC decision making process if it placed increased reliance on presumptions in evaluating data. In the context of SEC petition evaluation a presumption can be thought of as a default assumption -- an explicit statement of policy describing how NIOSH will handle a recurring science policy question – absent evidence that unique circumstances justify a departure from the default assumption. Such explicit policy presumptions should be contrasted with the expert, case-by-case assumptions on which NIOSH often relies. Increased reliance on presumptions to resolve science policy questions would substitute objective criteria for expert judgment to resolve issues of uncertainty and would facilitate comparison of SEC decisions across petitions.

Other compensation programs rely on presumptions to bridge gaps when scientific evidence is too uncertain to resolve questions of causation or exposure. For example, The Veteran's Administration has a long history of extensive reliance on presumptions "when data are not sufficient . . . to describe a specific service member's service exposure history." [39] Particularly in the area of radiation, where evidence suggests exposures were low, the VA relies on presumptions because "there remain numerous uncertainties, particularly with respect to estimation of an individual's exposures." Id. at 90. The Vaccine Injury Compensation Program, established in the National Childhood Vaccine Injury Act of 1986, also relies on presumptions to bridge gaps caused by uncertainties about causation. Presumptions may be a function of statute, regulation, or agency policy. They promote accuracy and consistency in adjudications by requiring similar treatment in similar cases.[40] NIOSH, too, relies on presumptions in other contexts such as when it prefers engineering controls over personal protective equipment.

Below are listed several issues for which presumptions might be developed. They are meant as illustrations.

- Lack of internal dosimetry. Overwhelmingly, SECs are approved because NIOSH lacks adequate internal dosimetry records for radionuclides other than uranium. It has recommended SEC status for 17 out of 109 qualified petitions on this basis (as of April 2010). In four instances NIOSH has concluded that it could bound such exposures. [41] NIOSH might develop a uniform

[39] Institute of Medicine, IMPROVING THE PRESUMPTIVE DISABILITY DECISION-MAKING PROCESS FOR VETERANS (National Academy Press 2008) at 237.
[40] Report of the Veteran's Commission on Disability (2007).
[41] The four instances include" Savannah River, Weldon Springs, Fernald, and Los Alamos (post 1975). Personal Communication from LaVon Rutherford, 11/20/10.

policy on the circumstances under which it will estimate internal doses for source terms other than uranium if no internal dose records are available.

- Early Exposures. In 51 of 109 qualified petitions, NIOSH has been unable to reconstruct dose for classes exposed during the 1940s through some period in the early 1950s. Data from the next two decades is often sparse and of varying quality. And, at some point, usually in the 1960s or 1970s, covered facilities implemented mature health physics programs which permit dose reconstruction. In only 11 instances where NIOSH has recommended granting a SEC does the covered time period extend beyond 1970. Thus, in almost 80% of cases covering earlier periods, NIOSH has found the exposure data from the early years inadequate to set upper bounds on some portion of radiation dose. However, in at least 4 instances, Bethlehem Steel, Chapman Valve, Hooker Electrochemical , and Electromet, NIOSH concluded initially that the data from the 1940s was adequate to reconstruct dose. The Board has not agreed. It rejected NIOSH's conclusion in Bethlehem Steel and the other three petitions were pending as of December 2010. NIOSH could adopt an explicit policy indicating what type and quantum of data from this period are viewed as "sufficiently accurate" for dose reconstruction.

- Location at the Site. EEOCIPA's statutory SECs covered individuals who were or should have been monitored. NIOSH approved several early SECs which were defined by job or assigned location (i.e., radiographers in Building 12). In these early petitions, NIOSH assumed that access controls were adequate to distinguish those who were exposed in certain locations from those who were not. But, over time, NIOSH's view of this issue has evolved. In several instances, DOL has not been able to administer SECs as approved by NIOSH because employment records were not detailed enough to know who worked where or in which job. Recently, NIOSH has assumed limited access controls to buildings, absent specific evidence of an access control policy. As a result, NIOSH has recommended broader SEC classes recently than it had in previous years. NIOSH has recently conducted an internal review of the evolution of SEC class definitions, so that it can make its policy more consistent in this regard. [42] This NIOSH-initiated effort to make SEC class definitions consistent is the type of presumption suggested here.

- Reliability of Data. When NIOSH has access to the result of individual monitoring data, it usually relies on it for dose reconstruction. Sometimes, however, NIOSH relies on summaries of monitoring data without reviewing the underlying data itself. In other instances, NIOSH has expressed doubts about the reliability of monitoring summaries. Can general rules about what data is reliable and what verification is needed be developed?

[42] DCAS Assessment Report – Review of SEC Class Definitions (Nov. 3, 2010).

- Quantum of Data. The actual quantum of data needed to reconstruct dose varies widely, depending on what is known about the facility's processes and the quantity of radioactive material used. In other instances, where a similar amount of data is available, NIOSH concludes it is inadequate to reconstruct dose. Valid technical reasons may exist for these differences, but NIOSH may want to evaluate whether its policy is consistent -- in the sense that petitions based on a similar quantum of data, from the facility, the time period, or the source term in question, are treated similarly.

Observation/Recommendation

1. NIOSH should consider creating presumptions to be applied across all SEC petitions. Such presumptions should be based on objective criteria. Increased use of presumptions would create more timely, uniform decisions on SEC petitions.

2. In developing presumptions under EEOICPA, NIOSH should take steps to ensure that its policy choices under this program are either consistent with its policies on related issues in other occupational health contexts or justified by the different statutes and regulations for each program.

V. Other SEC Process Issues.

A. Petition Qualification

NIOSH has received 182 petitions as of December 2010. 64 petitions (35%) either did not qualify or were withdrawn. 109 petitions (or 60%) were qualified for further evaluation. Five petitions were not qualified because they were filed before the SEC rule was finalized; four are pending. If NIOSH determines that a petition does not qualify, the petitioning party may seek review of OCAS' decision. Review is completed by HHS staff. 42 C.F.R. §83.11(d). Review has been sought in 9 cases or 5% of all petitions. On review, NIOSH's decision not to qualify a petition has been overturned three times. Information on the outcome of qualification appeals is not available on NIOSH's web site.

Of the 56 petitions qualified for further evaluation under 42 C.F.R §83.13 (as of April 2010), NIOSH modified the proposed class definition in 18 petitions; NIOSH expanded the class definition in 4 cases; NIOSH narrowed the class definition in 13 cases; and NIOSH has subdivided the class into one or more smaller groups in 1 cases. In one case, the timing was adjusted but the time span of the class definition was neither expanded nor narrowed.

DCAS staff indicated that when the SEC rule was first published, if a petition had any technical deficiencies, NIOSH would deny the petition, often without fully explaining why to the petitioner. Since 2006, when NIOSH hired an SEC petition counselor, NIOSH staff believes it has taken a more cooperative approach to qualifying petitions. According to NIOSH staff, when a petition has technical deficiencies, NIOSH now works with the petitioner to explain the problem and help the petitioner fix it. The SEC petition counselor also explains the process to claimants. Other DCAS staff also counsel petitioners informally.

The impression that NIOSH's approach to qualification has softened is difficult to quantify. Data on the rate at which petitions were qualified before and after 2006 shows the rate remains the same. The time between petition filing and qualification decision has decreased since 2006, but that may be the result of statutory changes. (Adams Draft) The Board reviewed the qualification process and many of its recommendations suggest better cooperation between NIOSH and petitioners and better communication about the SEC process. [43]

[43] Summary from Working Group on SEC Petitions that Did Not Qualify NIOSH (Taft Labs), Cincinnati, Ohio, November 9, 2006

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Observation/Recommendation

1. NIOSH's decision to add a SEC Petition Counselor was a sound one, transforming a function that had become adversarial into a more cooperative function.

2. NIOSH should continue and expand its efforts to cooperate with petitioners. Such efforts increase petitioners' knowledge of what is needed to gain SEC approval and should aid NIOSH in more quickly obtaining whatever information petitioners have about exposures and practices at potential SEC sites.

B. 180 Day Statutory Deadline for SEC Petition Recommendation

EEOICPA requires NIOSH to make a recommendation on a SEC petition within 180 days. 42 U.S.C. §7384q (c). Under interim regulations, NIOSH did not start the 180 clock until a petition qualified for evaluation. 70 Fed. Reg. 75950 (Dec. 12, 2005). NIOSH changed this aspect of its rules in response to comments. NIOSH rules now provide that a SEC petition evaluation should be complete 180 days from the day it is received by NIOSH. 42 C.F.R. §83.13(e). 72 Fed. Reg. 37456.[44] Congress did not, however, impose any time limit on Board review and deliberation and NIOSH regulations anticipate revisions to the ER in response to Board comments. 42 C.F.R §83.15(c)-(d).

Of 87 petitions qualified under section 83.13 since July 2007 (petitions no. 66 forward) NIOSH has met the 180 day deadline 50 of 87 times or 57% of the time. NIOSH has exceeded the 180 day deadline for 27 of these 87 petitions; when it has done so the average time until its ER is completed is 278 days. The data show that for 34 petitions under section 83.14, NIOSH has met the 180 day deadline for making a recommendation to the Board in 32 of 34 instances, or 94% of the time. The average time until an ER is approved for petitions under 83.14 between 2005 and present is 76.7 days.[45]

Several petitioners have criticized NIOSH for failing to meet the 180 day deadline. However, NIOSH has overwhelmingly met the 180 day deadline. In cases where NIOSH has not met the 180 day deadline, there has also been extended Board review, suggesting that the delays occur in complex cases. In such cases, 180 days is often an inadequate amount of time for NIOSH to obtain relevant radiation exposure records and complete the type of detailed ER contemplated by its regulations.

Observations/Recommendations:

1. NIOSH usually meets the 180 day time limit.

2. For SEC petitions requiring complex analysis, NIOSH should submit a comprehensive plan to evaluate a SEC petition for Board approval and evaluate a petition consistent with that plan. 42 C.F.R. §83.12(c).

3. NIOSH should utilize the authority provided in 42 C.F.R. 83.13(b) and avoid delay when data necessary to evaluate a petition is not forthcoming in a timely manner.

[44] Petitions 1-65 fall into the first group, which were governed by NIOSH's Interim Final Rule implementing the 2004 amendments to EEOICPA. *See* 70 Fed. Reg. 75949. Petitions 66 and above fall into the second group, which are governed by NIOSH final amendments to the SEC rule, published on July 10, 2007. *See* 72 Fed. Reg. 37455.

[45] Adams, Draft Report on Timeliness, p. 33

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C. Petitions Under 83.14

Once NIOSH concludes that it cannot complete an individual dose reconstruction for a claimant, it then considers whether there is a class of similarly situated workers. If there is, NIOSH will encourage the claimant to file a SEC petition under section 83.14. NIOSH has evaluated 34 petitions under 83.14; one is pending before the Board (as of December, 2010). In each 83.14 petition, NIOSH has recommended approving a SEC. In all cases where the Board has voted, it has agreed with NIOSH's recommendation. In most cases, NIOSH recommended adding a SEC class because it lacked enough data to bound internal doses, usually where a source term other than uranium was involved. In 10 cases it has also concluded that it lacked enough data to bound external doses and in 1 additional case NIOSH did not conduct an "exhaustive review" of its ability to bound external doses because of its inability to bound internal doses. In 13 cases, NIOSH concluded that it could set an upper bound on external dose, in some instances for exposures as early as 1942.

Several factors about the 83.14 petition process are noteworthy. Petitions under 83.14 are evaluated expeditiously by NIOSH and resolved promptly by the Board because in these cases, NIOSH has already concluded that it cannot adequately resolve the issues of scientific uncertainty it presents. Instead, for these petitions, significant delay usually precedes the filing of a SEC petition. Petitions under section 83.14 result from individual claims which have been pending, on average, for 1454 days from the time a claim was initially filed with DOL until NIOSH concluded that it could not reconstruct dose. [46] NIOSH data do not indicate what caused these delays. Recently, Dr. Howard instructed OCAS staff to complete DRs which had been pending at NIOSH for more than one year. This instruction has resulted in an increase in the number of SEC petitions under section 83.14, as NIOSH concludes that DR is not feasible at a number of sites.

Even though petitions under section 83.14 involve claims which, on average, have been pending for four years, NIOSH regulations require the same comprehensive evaluation report that NIOSH would prepare in any other case. NIOSH internal policies suggest that a modified ER is appropriate for petitions under section 83.14, but in practice those reports are as long as those for petitions under section 83.13. OCAS PR 004 p. 22.

[4646] Personal communication from Nancy Adams, Consultant to NIOSH. DOL's website suggests that claims sent to NIOSH are completed in an average of about 1000 days. In the early days of the Black Lung program, by contrast, claims processing was average 630 days and Congress responded by tripling the claims processing staff. Peter Barth, THE TRAGEDY OF BLACK LUNG (Upjohn Inst. 1987).

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

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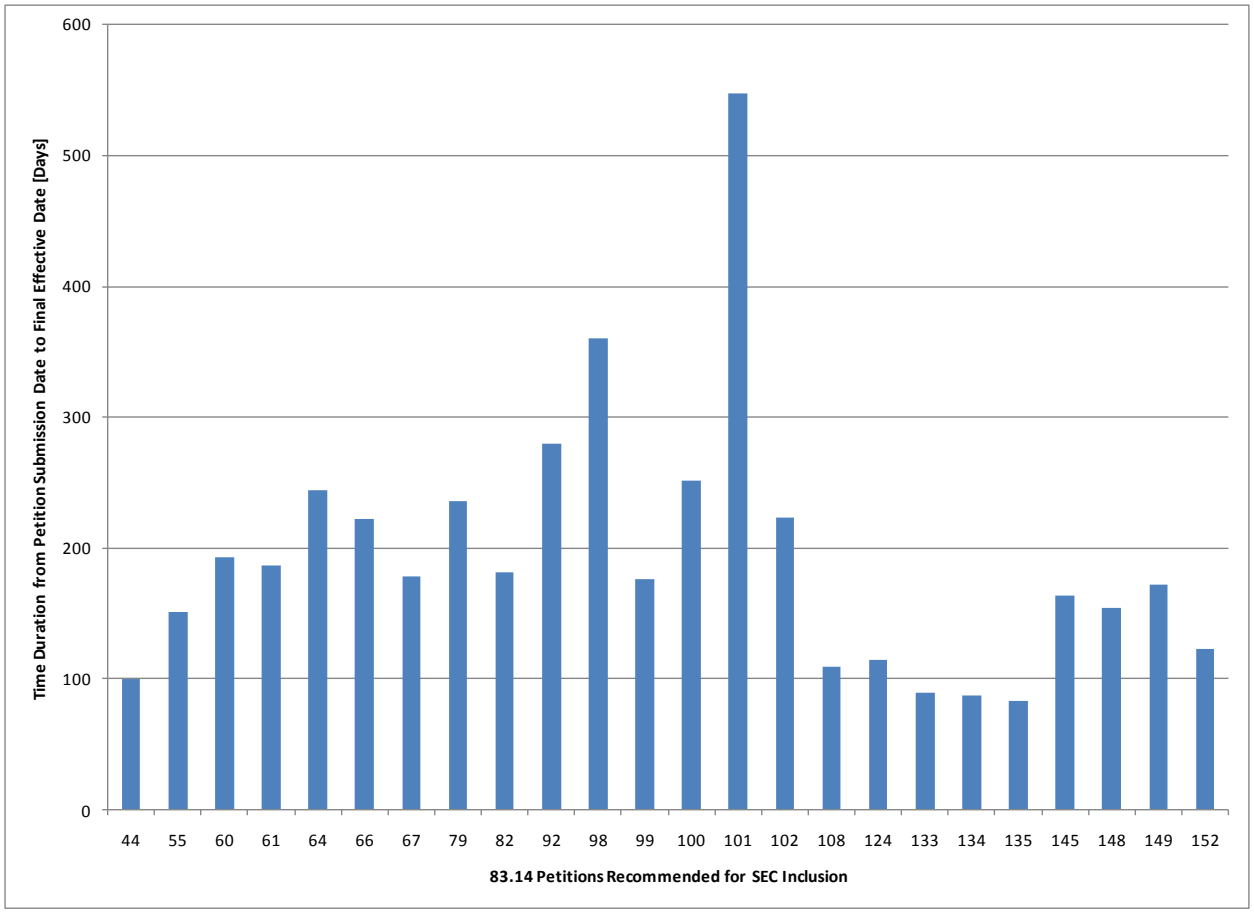
Table 1 83.14 Petitions Submission Until SEC Effective [Days]



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Observations/Recommendations

1. NIOSH should reduce delay between filing of a claim and a decision that a petition under 83.14 is proper by setting an internal deadline on when it will decide that DR is not feasible and a section 83.14 SEC should be considered.

2. NIOSH should consider the use of summary reports on its evaluation of petition under section 83.14 to reduce the size and complexity of the evaluation reports it produces for each SEC petition.

D. Development of the Dose Reconstruction Methodology for a Site

The interplay between development of site profiles and evaluation of SEC petitions has created uncertainty and delay in both the SEC process and the completion of individual dose reconstructions. These complications arise, at least in part, because NIOSH and the Board have taken a long time to develop dose reconstruction methodologies for covered sites.

In the early years of the program, NIOSH expected concurrently to complete dose reconstructions and site profiles, but it concluded that it should first complete site profiles "to avoid having to collect site-related information on a case by case basis."[47] Dr. Ziemer, then Chair of the Board, reported to the Secretary of HHS in January 2010 that 75 site profiles had been prepared by NIOSH and the Board has been involved in reviewing 34. He reported that work had been completed on only 3 site profiles.[48]

A NIOSH site profile is intended to be a comprehensive analysis of how to approach dose reconstruction at a site. A draft site profile is often submitted to the Board which reviews NIOSH's proposed methodology. The Board may question NIOSH's approach and may refer the site profile to its contractor, SC&A, for review. SC&A has been involved in reviewing NIOSH's dose reconstruction methodology at 26 sites. The process of reconciling NIOSH drafts with comments from SC&A and the Board can be time consuming. Often SC&A prepares a matrix and NIOSH, SC&A and work group members seek consensus resolution of items on the matrix. NIOSH often makes multiple revisions to the site profile. Most revisions are accomplished when NIOSH posts a notice on its web site announcing the change with little explanation of why the revision was made. The process is technically public, but the scope and complexity of the deliberations have the effect of masking the rationale for many changes. When all concerns over dose reconstruction methodology have been fully resolved, NIOSH has a site profile it can reasonably rely upon for dose reconstruction and to evaluate any SEC petition it may receive. This is important, because NIOSH does not control when it receives a SEC petition.

When NIOSH receives a SEC petition covering a site for which the site profile remains incomplete, it does not have an agreed upon dose reconstruction methodology on which it can rely to evaluate that petition. Nevertheless, the 180 day deadline for NIOSH to complete its evaluation is running. In such cases, questions about the site profile, dose reconstruction methodology, and propriety of

[47] GAO, **E**nergy Employees Compensation: Actions to Promote Contract Oversight, Transparency of Labor's Involvement, and Independence of Advisory Board Could Strengthen Program, , October 26, 2007)

[48] Draft Report on Dose Reconstruction p. 7. Dr. Ziemer also reported that 20 Site profiles were undergoing active review by a work group, SC&A had initially reviewed another 8 site profiles, but no work group had yet been established, and another 3 site profiles had just been assigned to SC&A for review.

granting a SEC essentially merge. SC&A has reviewed NIOSH's ER for 17 sites with pending SEC petitions – 15 petitions were filed under 83.13 and 2 under 83.14. In 12 instances, SC&A review of SEC petition overlaps with its review of a site profile. For 8 sites, SC&A review of the site profile is not associated with a pending SEC petition. In several instances, the Board has voted to approve a SEC petition before SC&A review of the site profile has been completed.

Each time a revision to the site profile is proposed, claimants must been given an opportunity to comment, often a work group evaluates comments, and NIOSH's SEC recommendation must be revisited. In many cases, this process of response and revision goes on repeatedly. For the 17 petitions with SC&A review, 10 have final Board decisions. The average time between NIOSH ER and final Board decision in these cases is 464 days. During this period of response and revision, NIOSH may suspend work on dose reconstructions not wanting to deny claims on the basis of a methodology which is likely to change. Repeated revisions to the site profile once a SEC petition has been qualified, accompanied by multiple updates to the SEC ER place a heavy burden on claimants who try to participate in the deliberations.

The process of repeated revisions, review, comments, and updates could be limited. If site profiles or SEC petitions were considered in the same manner as regulations, there would be fewer revisions on which the Board and claimants were expected to comment. And, each change might be accompanied by an understandable explanation for why it is being made. Using this regulatory analogy, NIOSH could make public its site profile or ER, the Board (acting through SC&A) and claimants could comment and NIOSH would issue a final "decision" or recommendation. If the Board voted promptly on whether to accept or reject NIOSH's decision, such a procedure might reduce the delays caused by multiple revisions to documents describing NIOSH's methods.

Observations/Recommendations

1. DCAS should prioritize completion of site profiles, particularly in cases where the absence of a final site profile has delayed resolution of individual dose reconstructions or decisions on SEC petitions.

2. NIOSH should minimize revisions to site profiles while a SEC petition is pending.

E. The Relationship Between Dose Reconstruction and SEC Approval

NIOSH has linked its dose reconstruction procedures directly to SEC evaluation. In the preamble to the SEC rule, NIOSH concluded it was "not authorized under EEOICPA to administratively assign radiation doses to employees for whom radiation doses cannot be estimated using methods of dose reconstruction." 69 Fed. Reg. 30776. Under this interpretation, dose reconstruction is a zero sum game -- if NIOSH can't reconstruct all doses, some claimants will benefit by being included in a SEC and obtaining presumptive compensation, but others will lose because their total dose will not include any radiation exposure which NIOSH cannot reconstruct.

NIOSH staff repeatedly voiced a concern that if they give up on dose reconstruction too soon, or conversely recommend SEC approval too quickly, claimants with cancers other than "specified cancers" would be adversely affected. In other words, in the view of many NIOSH staff, an extended effort to develop models to estimate dose is done for the benefit of claimants even though some claimants and their representatives argue otherwise.

NIOSH's practice, however, seems at odds with the view taken in the preamble to its final rule or the concerns raised by many staff. NIOSH's internal guidelines, for example, instruct analysts evaluating a SEC petition to limit records requests to those necessary to evaluate issues relating to the class. NIOSH observes that "the purpose of requesting records is *not* to obtain all the records that might be required to actually conduct dose reconstructions for members of the class of employees." OCAS PR 004 p. 17. NIOSH routinely includes a statement in its SEC evaluation report noting that its SEC recommendation does not mean it cannot reconstruct dose for individual members of the class. (p. 19). And, NIOSH ERs indicate that, even in cases where NIOSH recommends a SEC, it may also be able to complete individual dose reconstructions.

These internal policies raise the question about the extent to which approval of a SEC petition affects the outcome of individual claims from others at that facility with cancers other than "specified cancers?" What proportion of doses at a site does NIOSH attempt to reconstruct before recommending a SEC? Where an SEC is granted, how often are individual DRs incomplete for non-specified cancers because NIOSH has concluded that dose reconstruction is not feasible? Because this 10 year review requested separate analyses of DR and SEC processes, it may not fully explore the relationship between the two. But, if the tension between the ability to complete individual dose reconstructions and the approval of a SEC is more perceived than real, NIOSH's rationale for the extended time it takes and the analytic modeling relied upon to complete individual dose reconstructions over SECs would be weaker.

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Observation/Recommendation

1. Because NIOSH did not give added meaning to the phrase "with sufficient accuracy" in the SEC regulations, it has created a "zero sum game" where approval of a SEC petition is beneficial for some while at the same time limiting the dose considered in the claims of others. NIOSH should revisit whether this policy choice is reasonable.

2. NIOSH should evaluate how its policy has impacted the claims of individuals with cancers other than "specified cancer" at SEC sites.

F. Transparency

The SEC program produces a lot of information about sites where petitions have been filed. Most of this information is technically complex. Many of the reports, site profiles, and other information are available on NIOSH's web site. The information disclosed by NIOSH on its SEC website is sometimes incomplete or its technical rationale inadequately explained. Members of the public may have to search elsewhere to find complete information about NIOSH and Board consideration of SEC petitions.

Using data from NIOSH's web site, it is difficult to distinguish between petitions for which NIOSH initially concluded it could feasibly reconstruct dose and those for which it initially determined it could not. The former are likely to be more controversial and debate over them is likely to extend over a longer period of time.

An example illustrates the problem. Several people interviewed observed that the debate over whether to approve a SEC at the Nevada Test Site was controversial. But, the documents on NIOSH's web site provide little insight into the nature of the debate over NTS. http://www.cdc.gov/niosh/ocas/nts.html#sec Public documents show a NIOSH recommendation to grant petition #55 in April 2006 which the Board promptly approved. NIOSH's web site suggests a second ER was presented to the Board at its January 2008 meeting, but notes the ER is "not available at this time" and no link to the transcript of the January 2008 meeting is provided. NIOSH posted a January 2010 ER which recommends approving SEC petition #84 and Board approval of that petition in February of 2010. These documents disclose no controversy over the NTS SEC. But, a separate section labeled "previous versions" of documents suggests a fuller debate, and reveals a September 2007 ER – which reached the opposite conclusion of the January 2010 ER. This document appears below 11 revisions to the NTS site profile. While all of the transcripts can be found somewhere on the website, NIOSH's failure to include all documents on the site describing the decision about NTS creates the impression of consensus when it did not exist.

Much of the information disclosed is a recitation of facts, the relevance of which is sometimes not clear. NIOSH's ERs contain much of the "who, what, and where" of a site's radiation history. They often contain little explanation of the "why" behind NIOSH's conclusion. This is particularly true when NIOSH changes its dose reconstruction methodology. Sometimes the explanation can be discerned after reading transcripts from work group and Board meetings. Little written explanation is for how the new approach differs from the old approach and why the change was made. Such a reasoned explanation for agency action would be required during rulemaking.

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Observation/Recommendations

1. NIOSH should explain the rationale for its decisions, and its change of position, clearly and succinctly. The rationale behind its choices should be transparent.