Re-Estimated Benefits and Costs of OSHA's Proposed General Industry Standard for Occupational Exposure to Crystalline Silica

Executive Summary

Report for the American Chemistry Council Crystalline Silica Panel

January 27, 2016

Environomics, Inc.

EXECUTIVE SUMMARY

The American Chemistry Council's Crystalline Silica Panel (the Panel) commissioned Environomics to conduct a benefit-cost analysis of OSHA's proposed standard for occupational exposure to respirable crystalline silica for General Industry. In this analysis, we estimate the monetized benefits and costs of OSHA's proposed rule and compare our methodology and conclusions with the benefit-cost analysis for General Industry that OSHA included in its Preliminary Economic Analysis (PEA). Neither our analysis nor OSHA's includes the construction or hydraulic fracturing industries.[1]

Our analysis shows that the proposed standard -- including the proposed PEL of 50 ug/m^3, ancillary requirements and switch to the ISO/CEN monitoring protocol -- would entail costs that are many times larger than its monetized benefits, particularly if only the "incremental" costs and benefits of meeting the new standard relative to the existing standard are considered. We estimate incremental costs to be $4.7 billion/year compared against incremental monetized benefits of $71.7 million/year, a ratio of costs to benefits of more than 65 to1.

Table ES-1. Annualized Costs and Benefits of Proposed Silica Standard for General Industry and Maritime
(yr 2009 $ in millions/yr)

	Full Compliance With Current Standard (incl. PEL of 100 ug/m^3)	Increment: Reduce PEL from 100 to 50 ug/m^3 + ancillary req'ts + switch to ISO/CEN	Total for Proposed Standard: PEL of 50 ug/m^3 + ancillary req'ts + ISO/CEN
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Estimated Benefits**	$287.7	$71.7	$359.4
Ratio of Costs to Benefits	**4.9**	**65.9**	**17.1**
Net Benefits	**-$1,120.9**	**-$4,650.8**	**-$5,771.7**

* Estimated costs include only 19 General Industry sectors, excluding Maritime and 6 more sectors for which URS has not estimated costs (captive foundries, porcelain enameling, railroads, dental equipment, dental labs, refractory repair). URS believed that OSHA's estimates for the # of facilities in Maritime and the other 6 sectors were so inaccurate as to preclude estimating costs for them.

** Estimated benefits are for silica-exposed workers in all 25 General Industry sectors plus Maritime. Estimated benefits as shown above thus apply for a significantly larger universe of workers than is covered by the estimated costs.

OSHA's data indicate that many General Industry employers have not yet achieved compliance with the existing silica standard, including the current PEL of 100 ug/m^3. We estimate that substantial costs and benefits will accrue when all these employers achieve compliance with the existing standard. OSHA does not estimate these costs and benefits, choosing instead an analytical baseline assuming complete compliance with the existing standard and arguing that the only costs and benefits that need be considered now are those added incrementally by the proposed standard.

[1] In this analysis, we make extensive use of materials previously prepared for the Panel and now included in the rulemaking Docket, including estimates for the cost of the proposed standard that were developed by URS Corporation (URS, 2014), the Panel's Comments on silica risk issues (American Chemistry Council, 2014, pages 18 - 158), and the comments and testimony submitted by two consultants to the Panel on silica risk issues, Dr. Louis Anthony Cox, Jr. (Cox, 2014a and 2014b) and Dr. Peter Morfeld (Morfeld, 2014a and 2014b). In addition to this report, we are providing a large Excel workbook that details the data we used for our benefit-cost analysis, the steps in our calculations, and our results.

We disagree, and have chosen to estimate the costs and benefits of the proposed standard on both an incremental basis (as OSHA does) and on what we refer to as a "full" basis -- including both the yet-to-be-realized costs and benefits of complete compliance with the existing standard, and the incremental costs and benefits of the proposed standard relative to the existing standard.

In one sense our concern with both full and incremental costs and benefits and the broader purview of our analysis relative to OSHA's makes little difference. We estimate that the "full" costs of the proposed standard greatly exceed its "full" monetized benefits, just as we estimate that the *incremental* costs of the proposed standard greatly exceed its *incremental* monetized benefits.

In another sense, though, our more comprehensive approach allows us to reach an important conclusion that OSHA cannot investigate given the Agency's choice of baseline. In particular, we find that the great majority of the $359 million/year in monetized benefits of progressing from the current situation to compliance with the proposed standard ("full" benefits) would accrue when all General Industry employers are brought into compliance with the current standard and PEL. In contrast, the great majority of the $6.1 billion/year in costs of progressing from the current situation to compliance with the proposed standard ("full" costs) would accrue instead from the incremental/additional requirements of the proposed standard relative to the existing standard. Thus, OSHA would achieve a much more appropriate cost-benefit ratio by focusing its resources on bringing all employers into full compliance with the existing standard rather than by pushing forward with a very costly and more stringent new standard that will add only marginally to the benefits of achieving compliance with the current PEL.

While we find that the incremental costs of the proposed standard exceed the incremental benefits by a factor of more than 65, OSHA reaches the opposite conclusion, claiming that the incremental benefits of the proposed standard exceed incremental costs by a factor of more than eight. The reasons for these divergent conclusions relate largely to important shortcomings in OSHA's methodology and assumptions, as discussed in our report. Among these shortcomings are the following:

- ***OSHA underestimates costs for the engineering controls needed for compliance with the proposed standard.*** We use the cost estimates that URS Corp. developed. Among other things, URS emphasized the importance of estimating costs on a facility-by-facility basis. OSHA instead used a "cost per overexposed employee" approach, in which the Agency assumed generally that an average of four overexposed employees will be protected each time that an appropriate package of control measures is implemented. We found this assumption to be incorrect. It is one of numerous errors OSHA made in estimating compliance costs.

- ***OSHA greatly underestimates the incremental engineering control costs that would be needed to comply with the proposed PEL, because the Agency assumes employers would incur no such costs in the case of workers who are now exposed above the current PEL of 100 ug/m^3.*** This assumption rests on the belief that the actions employers would take to comply with the current PEL of 100 ug/m^3 would result in reducing the exposures of all workers who are now exposed above the current PEL to

levels below the proposed PEL of 50 ug/m^3. That belief is unfounded and counter-intuitive. After all, OSHA assumes that when employers seek to comply with the proposed PEL they will do so as inexpensively as possible, reducing exposures only to just below 50 ug/m^3. Why shouldn't employers be assumed to behave similarly when they seek to comply with the current PEL of 100 ug/m^3? OSHA's inappropriate assumption effectively eliminates any engineering control costs for those General Industry workers whose exposures exceed the current PEL of 100 ug/m^3. That group of workers represents roughly two-thirds of all General Industry workers whose current exposures exceed the proposed PEL of 50 ug/m^3. By excluding from consideration all engineering control costs for these overexposed workers, OSHA manages to ignore nearly 90% of the incremental exposure reductions that would be needed for compliance with the proposed PEL.

- ***OSHA fails to estimate the costs for the proposed change in monitoring protocol from the current ACGIH to ISO/CEN.*** This change will result in the capture of about 20% more crystalline silica in each sample without a corresponding 20% increase in the amount of workplace air sampled. As a result, exposures will need to be held below about 41.67 ug/m^3 using the proposed ISO/CEN protocol in order to keep them below a PEL of 50 ug/m^3 measured pursuant to the current ACGIH protocol. OSHA has not recognized the additional costs (and exposure reductions and benefits) inherent in this proposed change. Marginal costs of control will increase, and marginal benefits of control will decrease for this further effective reduction of the PEL.

- ***OSHA estimates benefits involving several illnesses that have not been adequately demonstrated to be caused by silica exposures at the low levels at issue for the proposed standard.*** OSHA believes that occupational exposure to respirable crystalline silica can cause five sorts of health effects and estimates risk reduction benefits by applying exposure-response functions for each of them. The Panel commented that none of these health effects are sufficiently well demonstrated to constitute a significant risk at exposure levels at or below the current PEL. Nevertheless, for three of these health effects– lung cancer mortality, silicosis mortality, and silicosis morbidity – we have calculated exposure-reduction benefits using what we believe to be the best single one or two of OSHA's exposure-response functions in each case.

  For the remaining two health effects – mortality from end-stage renal disease (ESRD) and mortality from non-malignant respiratory diseases (NMRD) other than silicosis – OSHA cites only a single exposure-response function as linking the effect to silica exposure. Dr. Cox and Dr. Morfeld did not find that these single studies established sound or persuasive relationships between silica exposure and the incidence of these health effects; consequently, we do not estimate benefits involving these two illnesses.

- ***OSHA ignores the fundamental differences between a significant risk determination and a benefit-cost analysis.*** When making the statutorily required significant risk determination, OSHA must assume that employees are exposed to crystalline silica for a full 45-year working lifetime. This necessarily produces the highest estimate of potential cumulative exposure, regardless of how likely or unlikely this scenario may be.

However, the Agency's aim in a benefit-cost analysis should be different -- to estimate benefits and costs as accurately as possible under the conditions that are likely to prevail in the real world.

Without further consideration, OSHA adopted for its benefits analysis most of the exposure-response relationships that it had used to make its significant risk determination. The epidemiological studies from which these relationships were derived investigated high cumulative lifetime exposures to respirable crystalline silica that occurred among workers many years ago and are not typical of current conditions of exposure or tenure. In summarily adopting these relationships for its benefits analysis, OSHA failed to consider many questions about whether extrapolating to the current very low range of workers' typical cumulative exposures is appropriate. In contrast to OSHA's 45-year working lifetime assumption, available data on worker tenure and turnover in the relevant industries suggests that the median duration of lifetime exposure is less than 10 years (with 4.5 times as many workers exposed over a 45-year period as OSHA assumes). The assumed average duration of exposure can have a very substantial impact on the risk reduction and monetized benefits that one calculates for the proposed standard.

- ***OSHA estimates that the monetary value of avoiding a non-fatal case of silicosis is within a range from $62,000 to $5.1 million per case. The upper end of this range and the $2.5 million midpoint value that the Agency uses as a point estimate for its benefits analysis are far too high.*** A more accurate estimate of $317,000 per case avoided was developed by the Agency's own contractor (Miller, 2005).

- ***OSHA then asserts that this inappropriately high range of values for an avoided case of non-fatal silicosis also should apply to each of the other diseases for which the proposed regulation is believed to cause reductions in morbidity.*** There is little reason why the amount of morbidity associated with a fatal case of these different illnesses should be similar to that for a non-fatal case of silicosis. Much more appropriate source material exists for estimating the value of any morbidity avoided for these other diseases. OSHA's approach results in inappropriate high-end ($13.8 million per case avoided) and mid-point ($11.2 million per case avoided) values for avoiding a fatal case of any of the diseases OSHA links to silica exposure.

The following table summarizes the likely impacts on OSHA's benefit and cost estimates if the Agency were to correct its analysis in some of the ways we have recommended.

Table ES-2. Approximate Changes to OSHA's Incremental Cost and Midpoint Benefits Estimates If Some of Our Recommended Changes Were Adopted

Suggested Change	Multiply OSHA Cost Estimate by*	Multiply OSHA Benefit Estimate by**
OSHA's cost estimate: $147 million/year		
Don't overestimate exposure reductions resulting from employer actions taken to comply with the current PEL	> 5	
Include costs for the switch to ISO/CEN	1.7	
Estimate costs on facility basis, not "per employee"	1.3	
Estimate costs for ancillary provisions more accurately	1.3	
Other	2	
Approximate Total for Costs	30	
OSHA's monetized midpoint benefit estimate: $1.2 billion/year		
#1. Assume there is no relationship between silica exposure and NMRD (other than silicosis) and ESRD		0.67
#2. Replace OSHA's wide range for the value of morbidity per case ($62 thousand to $5.1 million) for all avoided illnesses with the OSHA contractor's estimate for an avoided case of silicosis ($317,000)		0.46
#3. Lung cancer: replace OSHA's wide range of risk estimates with the point estimate from the single best exposure-response function; replace OSHA's wide range of morbidity values with a single estimate from EPA		0.86
#1 + #2 + #3. All of the above changes simultaneously.		0.10

* Individual changes to cost estimates are independent and can be multiplied together for total
** Individual changes to benefit estimates are not independent, and should not be multiplied

Conclusions

The great majority of the potential worker health benefits from OSHA's proposed new silica standard can be realized if all General Industry employers are brought into compliance with the existing standard. OSHA could accelerate this result by providing compliance assistance and effective enforcement. Any potential further health benefits from reducing the PEL below current levels and/or by switching to the ISO/CEN protocol would be relatively small and would come only at an excessively high cost.

OSHA has mistakenly concluded that the proposed standard has very large positive net benefits and is, therefore, justified from a monetized benefit-cost point of view. However, our benefit-cost re-calculations for General Industry indicate instead that the proposed standard would have costs far in excess of its monetized benefits and would represent an economically unsupportable investment of society's resources. This conclusion holds whether we measure the costs and benefits of the proposed standard on an incremental basis or on a "full" basis.

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Conclusions

The great majority of the potential worker health benefits from OSHA's proposed new silica standard can be realized if all General Industry employers are brought into compliance with the existing standard. OSHA could accelerate this result by providing compliance assistance and effective enforcement. Any potential further health benefits from reducing the PEL below current levels and/or by switching to the ISO/CEN protocol would be relatively small and would come only at an excessively high cost.

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I. INTRODUCTION AND SUMMARY

A. Introduction

In this report, we summarize the results of our analysis estimating the monetized benefits and costs of OSHA's Proposed Standard for occupational exposure to respirable crystalline silica in General Industry. We intend this analysis to compare with OSHA's benefit-cost analysis for General Industry that the Agency completed in 2013 and included in the Preliminary Economic Analysis (PEA) for the Proposed Standard.[2]

We conclude from our analysis that the Proposed Standard for General Industry (excluding hydraulic fracturing) would have costs far in excess of its benefits. This conclusion differs sharply from OSHA's conclusion in the Preamble to the Proposed Standard and in the PEA to the effect that benefits greatly exceed costs.

In the first chapter of this report we present our benefit and cost estimates and compare them with OSHA's estimates. We discuss why we have developed both incremental and "full" benefit and cost estimates. In Chapter 2 we provide a detailed summary of the methodology that we have used in developing our estimates and contrast our methodology with OSHA's.

B. Summary of Our Benefit-Cost Estimates and Comparison With OSHA's Estimates

We find it helpful in concept to view compliance with the proposed standard as consisting of two steps:

1. *A first step that includes the measures employers would undertake to achieve full compliance with the existing General Industry standard, including the current PEL of 100 ug/m^3.* OSHA's exposure information indicates that many General Industry employees are now exposed to silica levels in excess of the current PEL, and substantial costs and benefits will accrue when their employers reduce these employees' exposures sufficiently to comply fully with the current PEL and standard.

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[2] None of the cost and benefit estimates that OSHA provides in the main body of the PEA and that we cite in this report include the hydraulic fracturing industry. Similarly, none of our recalculated cost or benefit estimates that we reference in this report include the hydraulic fracturing industry. OSHA addressed the hydraulic fracturing industry in a separate appendix in the PEA. We do not address the hydraulic fracturing industry at all in this report.

This analysis likewise does not address the construction industry.

To our knowledge, neither the construction industry nor the hydraulic fracturing industry has yet developed a critique or re-analysis of OSHA's benefit-cost analysis for either of these industries. We surmise, though, if these industries were to review OSHA's benefit-cost analyses for construction and hydraulic fracturing, that they might conclude similarly as we have here to the effect that OSHA has underestimated the costs and overestimated the benefits of the proposed standards.

Both the construction industry and the hydraulic fracturing industry have filed comments to the effect that OSHA has underestimated costs. The respects in which we find in our analysis here that OSHA has overestimated benefits for General Industry (less hydraulic fracturing) seem likely to apply to construction and hydraulic fracturing also.

2. *A second step consisting of further actions employers would undertake to comply with the proposed standard, beyond those actions that they would take to comply only with the existing standard.* In our analysis, these additional actions include those necessary to: i) Reduce exposures to meet the proposed PEL of 50 ug/m^3 from a "baseline" where employers are assumed to have complied fully with the current PEL of 100 ug/m^3; ii) Comply with the new ancillary requirements proposed as a part of the new standard; and iii) Reduce exposures further as necessary to reflect the proposed change in exposure measurement approach from the ACGIH protocol to ISO/CEN, which is also a part of the proposed new standard.

In concept, the actions that employers will undertake to proceed from current conditions all the way to compliance with the proposed standard might be thought of as the sum of these two steps: 1) the actions needed to comply with the existing standard; plus 2) the incremental actions then needed to comply with the more stringent proposed standard.

In practical terms, though, an employer who has not yet achieved compliance with the existing standard would probably not comply with the proposed standard (if OSHA were to promulgate it) by taking exactly these two steps sequentially. In theory, there should be a single large step this employer could take to comply directly with the more stringent new standard that would be more efficient and less costly than to take our first step and then our second step in sequence.[3] But, given the substantial uncertainty about how well various potential exposure reduction measures will actually perform in the employer's particular facility, a "trial and error" approach involving perhaps several incremental steps and adjustments is much more likely. Having said that, it remains true that the specific two-step sequence in which the employer first tries to comply with the current PEL and then makes an entirely separate effort to comply with the new PEL is quite unlikely.

In our analysis for this report, we estimate three sets of benefits and costs in a way that reflects both: i) our interest in examining what would result from full compliance with the existing standard, which we see as a potentially attractive policy alternative to OSHA's proposed new silica standard; and ii) this recognition that employers would likely not comply with OSHA's proposed standard via the hypothesized two steps including complying explicitly with the existing standard along the way. In our analysis, we estimate:

1. *The costs and benefits of the actions that employers would take to proceed from the current state of affairs to full compliance with the proposed standard.* The current state of affairs includes some worker exposures that exceed the current PEL. Full compliance

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[3] For example, an employer who has not yet complied with either the current PEL or a known, lower new PEL would not choose as first step to install a ventilation system in his facility of a size sufficient to provide airflow to meet the current PEL, and then later to expand/retrofit that system or tear it out and replace it with a larger system sufficient to meet the lower new PEL.

The employer would instead prefer to estimate the size of the ventilation system that he needs to comply with the new standard, and then proceed directly to install a system of that size without explicitly stopping to comply with the existing standard along the way. In practice, however, even though identifying a single step to get all the way from the current situation to compliance with the new standard might seem the most efficient approach, the employer will rarely have sufficiently reliable information about the capabilities and performance of the various available exposure-reduction measures to support an attempt to take this single step.

with the proposed standard will require compliance with the proposed PEL at 50 ug/m^3, with the proposed ancillary requirements, and with the proposed new monitoring protocol (ISO/CEN), which will, in effect, result in a further reduction of about 20% in the proposed PEL relative to what the PEL would be if monitored pursuant to the current ACGIH protocol. We will refer to the costs and benefits of proceeding all the way from the current situation to compliance with the proposed standard as the "full" costs and benefits of the proposed standard.

2. *The costs and benefits of the actions that employers would take to proceed from the current state of affairs to full compliance with the existing standard.* We believe that compliance assistance and effective enforcement of the existing standard could represent an attractive policy alternative to promulgation of OSHA's proposed, more stringent standard. We therefor also estimate the costs and benefits of full compliance with the existing standard.

3. *The incremental costs and benefits of complying with the proposed standard*, beyond the costs and benefits of complying with the existing standard. We want to estimate what will be gained and what it will cost if employers were to comply with the proposed standard rather than to comply only with the existing standard. We estimate these costs and benefits -- what we will refer to as the "incremental" costs and benefits of the proposed standard -- by subtracting the costs and benefits of the existing standard (#2, above) from the "full" costs and benefits of the proposed standard (#1, above). By estimating the incremental costs and benefits of the proposed standard only as the difference between the costs and benefits of complying with the proposed standard and the costs and benefits of complying with the existing standard, we avoid making any assumptions about a specific path and steps by which employers will proceed from the current state of affairs to compliance with the proposed standard.

Our approach of estimating these three sets of costs and benefits contrasts with OSHA's approach. In the Preamble and the Preliminary Economic Analysis (PEA), OSHA estimates only what the Agency describes as the "incremental" costs and benefits of the proposed regulation. OSHA states that employers are already required to comply with the current PEL and that the only costs and benefits that need be considered now are those that would be added incrementally by the proposed new standard. OSHA thus chose not to estimate either the costs and benefits of compliance with the existing standard[4] or the "full" costs and benefits of the proposed standard, defined as we mean them to include proceeding all the way from current conditions to compliance with the proposed standard. OSHA's approach to the benefit-cost analysis is consistent with the Agency's approach in analyzing economic feasibility for the proposed standard, in which the Agency asks whether it is economically feasible for the affected General

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[4] In choosing not to estimate the costs and benefits of compliance with the existing standard, OSHA is unable then to examine the net benefits of full compliance with the existing standard in comparison to the net benefits of the incremental requirements inherent in the proposed standard.

OSHA cannot examine the question of whether it might be better to provide stricter enforcement and better compliance assistance for the existing standard than to tighten the standard and face the need to enforce and assist for a standard that will be much more difficult for General Industry employers to comply with. We have designed our benefit-cost analysis so as to shed some light on this important policy question.

Industries to pay only the incremental costs of compliance with the proposed standard -- excluding any costs that may yet be incurred for full compliance with the existing standard.

We disagree with OSHA's reasoning on this issue. We have provided economic arguments in our Docket submittals and testimony to the effect that the statutorily required judgments regarding economic and technological feasibility should turn on the full costs of a proposed new standard, not the incremental costs.

In our view, achievement of a proposed standard is economically feasible only if employers can afford the full costs of proceeding all the way from current conditions to compliance with all requirements of the proposed standard. In this instance, the costs (and benefits) for General Industry employers to comply fully with the proposed standard appear to be large, and they add meaningfully to the incremental costs (and benefits) attributable to the proposed regulation alone.

Likewise, both sets of costs and benefits are important in judging the economic desirability of the proposed standard. In our view, the costs and benefits of full compliance with the existing standard are important and should not be ignored as OSHA has done in its benefit-cost analysis of the proposed standard.

In any event, whatever the legal and conceptual merits of a "full" vs. incremental approach to assessing economic feasibility, we find that this issue has little impact on the results of our benefit-cost analysis. As the following Table 1 will indicate, we find that the benefits of the proposed standard are far short of costs, whether benefits and costs are estimated on a "full" basis or on an incremental basis.

We find further that the ratio of costs to benefits for the proposed standard is significantly higher ("worse") on an incremental basis than on a "full" basis. Compliance with the existing standard has a much higher ratio of benefits to costs than does the increment added by the proposed standard, so including the costs and benefits of compliance with the existing standard in the total costs and benefits of the proposed standard (as occurs with a "full" analysis) makes the proposed standard appear more justifiable from a benefit-cost point of view than it would appear on an incremental basis alone.

In sum, the difference of opinion that we have with OSHA about whether the economic feasibility of the proposed standard should be judged based on "full" costs or on incremental costs has little impact on the results of our benefit-cost analysis. The costs of the proposed standard exceed its benefits whether on a "full" basis or an incremental basis. Indeed, calculating costs and benefits in an incremental manner makes the ratio of costs to benefits even higher (worse) than calculating them on a "full" basis.

In our calculations, we estimate the costs[5] and benefits[6] for the two steps and for the entire proposed standard as follows:

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[5] Costs are as estimated by URS Corp. for the Panel (URS, 2014).

[6] Note that we have developed our benefit estimates using largely identical exposure information as that which OSHA used for the Agency's economic analysis. We also used what we believe to be the best of OSHA's chosen

Table 1. Annualized Costs and Benefits of Proposed Silica Standard for General Industry and Maritime
(yr 2009 $ in millions/yr)

	Full Compliance With Current Standard (incl. PEL of 100 ug/m^3)	Increment: Reduce PEL from 100 to 50 ug/m^3 + ancillary req'ts + switch to ISO/CEN	Total for Proposed Standard: PEL of 50 ug/m^3 + ancillary req'ts + ISO/CEN
Estimated Costs*	$1,408.6	$4,722.5	$6,131.1
Estimated Benefits**	$287.7	$71.7	$359.4
Ratio of Costs to Benefits	**4.9**	**65.9**	**17.1**
Net Benefits	**-$1,120.9**	**-$4,650.8**	**-$5,771.7**

* Estimated costs include only 19 General Industry sectors, excluding Maritime and 6 more sectors for which URS has not estimated costs (captive foundries, porcelain enameling, railroads, dental equipment, dental labs, refractory repair). URS believed that OSHA's estimates for the # of facilities in Maritime and the other 6 sectors were so inaccurate as to preclude estimating costs for them.

** Estimated benefits are for silica-exposed workers in all 25 General Industry sectors plus Maritime. Estimated benefits as shown above thus apply for a significantly larger universe of workers than is covered by the estimated costs.

We thus estimate that costs greatly exceed monetized benefits:

- for the increment associated with the proposed new requirements (by a factor of more than 65);
- for the proposed standard as a whole (by a factor of more than 17); and
- for full compliance with the existing standard (by a factor of nearly 5)

This is despite a mismatch between the larger number of affected General Industry sectors across which we estimate benefits relative to the smaller number of affected General Industry sectors across which we estimate costs, as explained in the one-starred note below Table 1.

Most of the benefits of progressing from current conditions to compliance with the proposed standard accrue from the first of our two steps: from complying with the current PEL. In contrast, most of the costs of progressing from current conditions to compliance with the proposed standard accrue from the second of the two steps: from the incremental/additional requirements of the proposed standard.

OSHA's benefit and cost estimates

The Agency provides the following estimates in the Preamble and PEA:

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exposure-response functions for lung cancer and for silicosis mortality and morbidity in developing our estimates of the monetized benefits from the lower silica exposures that would result from the proposed standard.

The Panel's risk consultants have argued strongly that OSHA's chosen exposure-response functions greatly overestimate the health risks of silica exposure and the benefits of reducing silica exposures. In using both OSHA's exposure information and the best of OSHA's chosen exposure-response functions to develop our benefits estimates, we therefore believe that we have produced an optimistic estimate for the benefits of the proposed rule.

Table 2. OSHA's Estimated Annualized Costs and Benefits of Proposed Standard (Incremental, not "Full")

General Industry & Maritime. 3% discount rate, yr 2009 $ in millions/yr

Total annualized costs	$143
Monetized annual benefits	$1,205
Net benefits	$1,062

OSHA estimates that the incremental benefits of the proposed standard exceed the incremental costs by a factor of more than eight.

We believe, though, that OSHA has made numerous errors in developing estimates for these incremental costs and benefits. In our view, the estimates that OSHA develops do not accurately represent the incremental costs and benefits of the proposed standard either conceptually or quantitatively. We believe that our estimates for the benefits and costs of the proposed standard, whether on an incremental basis or a "full" basis, are much more accurate than OSHA's.

C. OSHA's Suggestion that it has Developed Both Incremental and "Full" Estimates for Benefits and Costs is Misleading

Notwithstanding what we have said previously, OSHA includes in the Preamble and PEA tables and text that do appear to provide estimates for compliance with the current PEL and for the incremental requirements of the proposed standard in a manner consistent with our "two-step" formulation for benefits and costs. The following is a simplified version of OSHA's Table VII-22 in the Preamble and Table VII-7B in the PEA:

Table 3. Annualized Costs, Benefits and Incremental Benefits of Alternative Silica Standards at 100 ug/m^3 and 50 ug/m^3

OSHA Estimates. General Industry & Maritime. 3% discount rate, yr 2009 $ in millions/yr

	100 ug/m^3	Incremental Costs/Benefits	50 ug/m^3
Total annualized costs	$36	$106	$143
Monetized annual benefits	$69	$1,135	$1,205
Net benefits	$33	$1,029	$1,062

This information that OSHA provides in the Preamble and PEA seems to show that:

1. The benefits of compliance with the current PEL at 100 ug/m^3 are about twice the costs of doing so ($69 million/year in benefits vs. $36 million per year in costs);

2. The incremental benefits of reducing the PEL from 100 ug/m^3 to 50 ug/m^3 are more than ten times the incremental costs of doing so ($1,135 million/year in benefits vs. $106 million per year in costs); and

3. The benefits of the proposed standard are more than eight times the costs ($1,205 million/year in benefits vs. $143 million/year in costs).

4. The great majority of the benefits (and costs) accrue from reducing the PEL from 100 ug/m^3 to 50 ug/m^3 rather than from obtaining full compliance with the current PEL ($1,135 million/year in benefits vs. $69 million/year in benefits).

In fact, though, the table and figures that OSHA provides are quite misleading and do not support any of these four apparent conclusions.

In the table above, OSHA continues with the Agency's approach of estimating only the *incremental* costs and benefits of the proposed standard, while ignoring the costs and benefits of compliance with the existing standard and not estimating the *full* (i.e., all the way from the current state of affairs to compliance with the proposed standard) costs and benefits of the proposed standard.

The column of Table 3 above labeled 100 ug/m^3, does not represent the costs and benefits of compliance with the existing standard at 100 ug/m^3, but instead represents the estimated incremental costs and benefits relative to the existing standard of a potential new standard that OSHA defines as: i) including the proposed ancillary requirements and ii) simply reiterating the current General Industry PEL at 100 ug/m^3. In effect, this column of OSHA's table (with the $36 million/year cost figure) represents only the incremental costs and benefits of adding the proposed ancillary requirements to the existing standard. It does not include any engineering control costs to reduce worker exposures as would be necessary for many employers to comply fully with the current PEL at 100 ug/m^3. (Again, OSHA assumes, consistent with the Agency's incremental approach, that all costs necessary for compliance with the current PEL are attributable to the existing standard and thus are not relevant to decisions regarding a potential new standard.)

How can OSHA then estimate positive benefits of $69 million/year in this column of the table as resulting from $36 million/year in ancillary requirement costs? If the hypothetical new standard that OSHA is analyzing in this column includes only:

i. the proposed ancillary requirements; and
ii. reiteration of the current PEL at 100 ug/m^3, and thus no need for incremental exposure reductions,

then we cannot understand how there can be any incremental worker health effects prevented by such a new standard that would give rise to the monetized health benefits of $69 million/year that OSHA has shown in this column of the table.

Unfortunately, OSHA does not in the PEA or elsewhere in the Docket explain what these projected benefits consist of or how they have been estimated. Perhaps OSHA believes that employer compliance with one or more of the proposed ancillary requirements will somehow reduce the incidence of silica-related health effects, but without employers needing to incur any costs for additional engineering controls. Nowhere in the Preamble, PEA, economic analysis spreadsheets or other docket materials can we find that OSHA has provided information to indicate which ancillary requirements the Agency believes give rise to health benefits or other avoided costs, or how the estimates were derived.

The other columns of the Agency's table (our Table 3) are as follows:

- The column titled "Incremental Costs/Benefits" provides OSHA's estimates for the incremental costs and benefits that would result from reducing the PEL to 50 ug/m^3 relative to the costs and benefits of a hypothetical regulation that reaffirms the current PEL at 100 ug/m^3 and establishes the proposed set of ancillary requirements (represented by the leftmost numerical column).

- The column titled "50 ug/m^3" apparently provides OSHA's estimates for the summed costs and benefits of compliance with both the proposed ancillary requirements and the proposed PEL of 50 ug/m^3 (ignoring the ISO/CEN provisions), incremental to an assumed baseline of full compliance with the current PEL. Although the format of OSHA's table makes it appear that this column instead represents the "full" costs and benefits of both i) compliance with the current PEL at 100 ug/m3 and ii) the incremental requirements of the proposed standard, this column nevertheless still represents only the increments beyond an assumed baseline of full compliance with the current PEL .

Thus, despite the text of what OSHA says in the benefit-cost chapter of the PEA and what the appearance of OSHA's tables seems to suggest, the Agency's Preamble and PEA do not include any estimates for the costs and benefits of full compliance with the existing silica standard. Nor does OSHA provide any estimates for the full costs and benefits of the proposed standard relative to a baseline assumed at the current state of the world.

OSHA thus does not provide any benefit-cost information bearing directly on what we view as one of the most important policy questions regarding a potential new silica standard -- should OSHA promulgate a new standard with a lower PEL, or should the Agency instead emphasize compliance assistance and enforcement for the existing PEL, including a requirement for exposure monitoring?

D. Conclusions From Our Re-Analysis of Benefits and Costs

Based on the Agency's benefit-cost calculations, OSHA's Preamble (table VII-22) and PEA (table VII-7B) suggest that, for General Industry, the proposed standard has very large positive net benefits and is justified from a benefit-cost point of view.

As demonstrated by our benefit-cost re-calculations, this conclusion by OSHA is incorrect. Contrary to what OSHA suggests, we find for General Industry that:

1. The proposed standard would have costs far in excess of its benefits and would represent a misallocation of society's resources. This conclusion holds whether we measure the costs and benefits of the proposed standard on an incremental basis or on a "full" basis.

2. The great majority of the potential worker health benefits from OSHA's proposed new silica standard would be realized when all employers comply fully with the existing standard. OSHA can accelerate compliance with the existing PEL by requiring employers to monitor and control exposures and by providing compliance assistance and

effective enforcement. Any potential further health benefits from reducing the PEL below current levels and/or by switching to the ISO/CEN protocol would be relatively small and would come only at an excessively high cost.

E. Additional Materials that Support Our Re-Analysis of Benefits and Costs

In the next chapter of this report we provide a thorough discussion on the major methodological differences between OSHA's benefit-cost analysis and ours. In addition, we are providing separately a large Excel workbook titled Silica Benefit-Cost Calculations 12-10-15.xls that includes our calculations and results. The workbook includes 30 sequential worksheets that lay out the data we use, the calculation steps, explanations for each step, and our results. In many instances, the formulas and notes in the worksheets provide additional explanation beyond that provided in this report.

The worksheets begin with OSHA's and our assumptions regarding current silica exposures for General Industry workers, and then address exposure-response functions for the health effects that OSHA contends are caused by silica exposure; risk estimates; calculation of avoided health effects; monetization of avoided health effects; timing, discounting and annualization; cost estimates (both OSHA's and ours); and comparisons between estimated benefits and costs.

Our worksheets are nearly completely linked, such that a user may alter one of the data elements or assumptions or steps in an early worksheet, and the resulting changes to the overall cost and benefit estimates for General Industry would then be shown automatically in the later worksheets. This makes it easy for the user to change assumptions, to assess the impact of alternative assumptions or to perform sensitivity analyses.

We have also included as Appendix 1 to this report a document that we prepared previously discussing our questions about the exposure assumptions that OSHA applied in the Agency's benefit-cost analysis.

We include this for two reasons: 1) to indicate how we have interpreted the poorly documented and unclear exposure assumptions and confusing discussion that the Agency provides on this issue in the PEA; and 2) to provide a guide to a set of issues that need clarification if OSHA seeks to improve its benefit-cost analysis and documentation in an Economic Analysis supporting a final rule.

We conclude in Appendix 1 that the number of workers across whom OSHA appears to have estimated benefits is larger than the number of workers across whom OSHA appears to have estimated costs. If true, this serious mismatch should be corrected for the final Economic Analysis.

In developing our benefit-cost calculations, we also conducted an extended investigation into the particular exposure-response function that OSHA had chosen and that we use for silicosis mortality (deriving from studies by Mannetje, and Toxichemica/Steenland and Bartell). We have been unable to replicate the exact equation and risk estimates that OSHA cites as deriving from applying this function.

Accordingly, we contracted with an epidemiologist to investigate this issue. Ms. Qin concluded that the researchers had made a questionable decision in fitting a particular function to their data that was anchored to only a small portion of it. She instead fit a modified function to the entire set of data, and we used that function for our calculations. We have included as Appendix 2 an amalgamation of two documents written by the epidemiologist on this issue.

II. Detail on Key Methodological Differences Between OSHA's Benefit-Cost Analysis and Ours

In this chapter, we provide a thorough discussion on the major methodological differences between OSHA's benefit-cost analysis and ours. This chapter is organized by topic in an order that generally matches the sequence of calculation steps by which we develop our estimates of benefits and costs in the Excel workbook that we are providing.

A. Scope of the Analysis

OSHA estimates costs and benefits for General Industry less the hydraulic fracturing industry. OSHA estimates costs and benefits for hydraulic fracturing in a separate appendix in the PEA; we do not estimate costs and benefits for this industry at all in this report.

We estimate benefits for all of General Industry less hydraulic fracturing (26 sectors), but we estimate costs for only the 19 General Industry sectors for which URS was able to estimate costs for the Panel. (URS could not estimate costs for 6 General Industry sectors plus the Maritime sector because they found OSHA's estimates for the numbers of facilities in each of these sectors to be grossly incorrect.)

Therefore, we estimate benefits for more sectors and workers than those for which we estimate costs, which results in mismatched comparisons that overstate benefits relative to costs.

OSHA estimates that there are 19,125 employees exposed at levels exceeding the proposed PEL in the six General Industry sectors plus Maritime for which URS has not been able to estimate costs, while there are 103,343 employees exposed at levels exceeding the proposed PEL in the nineteen General Industry sectors for which URS was able to estimate costs. If the seven sectors for which URS was unable to estimate costs were to have the same cost per overexposed employee as the sectors included in URS' cost analysis, the cost estimate that we use for our analysis in this report would increase by 18.5%, (by $883 million/year) if we were to extend it to all of General Industry and Maritime so as to match the scope of our benefits estimate.

B. Baseline Assumed For the Benefit-Cost Analysis

We assume the current state of the world as the baseline for our analysis. We estimate two sets of costs and benefits starting from this baseline: i) costs and benefits of achieving full compliance with the *existing* PEL; and ii) costs and benefits of achieving full compliance with the *proposed* standard (including the lower PEL, the ancillary requirements, and the switch to ISO/CEN. We refer to this second set of costs and benefits as the "full" costs and benefits of the proposed standard.

We estimate a third set of costs and benefits, the "incremental" benefits of the proposed standard, as the difference between the "full" costs and benefits of the proposed standard and the costs and benefits of full compliance with the existing standard. In our analysis, the incremental costs and benefits of the proposed standard consist of (ii) minus (i).

OSHA assumes full compliance with the existing standard as the baseline for the Agency's analysis. OSHA then estimates benefits and costs only for the increment between the existing

standard (the Agency's analytical baseline) and the proposed standard (but ignoring the proposed change in monitoring protocol to ISO/CEN).

With OSHA's choice of baseline, the Agency's analysis cannot shed any light on the question of whether compliance assistance and more effective enforcement of the existing standard might be a more efficient and cost-effective approach to improving worker health than promulgating a tighter PEL.

C. Health Effects From Silica Exposure and Exposure-Response Functions For Them

OSHA estimates monetized benefits as the summed value of avoided cases of: 1) Lung cancer mortality; 2) Mortality from silicosis and other non-malignant respiratory diseases (NMRD); 3) Silicosis morbidity; and 4) Renal disease mortality (end-stage renal disease, or ESRD).

For each of these four health effects,[7] OSHA selected between one and five studies that have estimated exposure-response functions relating a worker's cumulative silica exposure to the likelihood of the worker suffering the health effect in question.[8] The Agency performed quantitative risk analysis using these 13 exposure-response relationships in attempting to make the legally required case that there are significant risks to workers exposed for a 45-year working lifetime at the current PEL and that these risks would be meaningfully reduced if their working lifetimes were spent instead with exposure at the proposed PEL.

OSHA chose to use these 13 selected studies/exposure-response relationships for its benefits analysis as well, *i.e.*, to estimate the numbers of cases of these health effects that would be avoided if worker exposures were reduced from the levels assumed in the Agency's analytical baseline to the levels that might prevail after compliance with the proposed standard. In fact, though, benefits analysis represents a rather different purpose for selecting and using exposure-response functions than evaluating the significance of estimated risks at the current and proposed PEL over a nominal 45-year working lifetime.

Many of the exposure-response relationships that OSHA selected for the significant risk determination have important shortcomings when they are applied in the much lower cumulative

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[7] Both we and OSHA sometimes refer to non-malignant respiratory diseases, consisting of silicosis and non-malignant respiratory diseases other than silicosis, as one sort of disease or illness and sometimes as two sorts of diseases or illnesses, distinguishing silicosis from other NMRD We may in this paper thus refer to four health effects addressed in the benefits analysis or to five.

[8] OSHA used 5 studies for lung cancer mortality, 1 for silicosis mortality, 1 for non-malignant lung disease mortality, 5 for silicosis morbidity, and 1 for renal disease mortality, for a total of 13 studies. In several instances a study that OSHA chose offers more than one estimated exposure-response relationship (e.g., multiple different functional forms, lag times, exposure metrics, etc.). Sometimes OSHA chose a single relationship from a study that offers more than one relationship, and sometimes OSHA chose multiple relationships from such a study, thereby representing the study as providing a range of risk estimates.

Across the 13 studies that OSHA selected, the Agency uses 18 relationships for its risk determination, chosen from at least 50 different exposure-response relationships that the studies had estimated. The Agency made all of their selections -- among studies and among relationships estimated in each study -- with a view toward demonstrating significant risks and without considering the appropriateness of the chosen relationships for benefits analysis, a purpose that should be viewed as quite different from demonstrating significant risks.

exposure region--as is necessary for a benefits analysis reflecting exposures at current levels. Yet, OSHA disregarded this issue in choosing the studies/functions that it used for the benefits analysis.[9]

From among the 13 studies/exposure-response relationships that OSHA used for demonstrating significant risks, we chose 4 to use in re-estimating benefits. These include:

- 2 relationships for estimating lung cancer benefits. These two relationships yield an upper and a lower estimate for lung cancer benefits. In the point estimate results that we presented earlier in this report, we chose the midpoint between the upper and the lower estimates.

- 1 relationship for estimating silicosis mortality benefits. We did not choose any relationship from Park et al., 2002, the only study that OSHA had used to estimate

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[9] The Panel's risk consultants have provided much evidence to the effect that the exposure-response functions that OSHA has chosen are inappropriate for silica risk assessment in general, and the Panel has expressed its position forcefully on this issue. We have additional, somewhat different arguments against using many of these chosen functions also for benefits assessment at much lower cumulative exposure levels.

Most of the epidemiological studies that OSHA chose to use in attempting to demonstrate significant risk (and then adopted for the benefits analysis without further consideration) investigated very high worker cumulative exposures to respirable crystalline silica that occurred many years ago and are not typical of workplace exposures now.

For example, more than half of the workers in the six cohorts studied by Mannetje, et al (2002) (the original source for most of the exposure-response relationships that OSHA considered for silicosis mortality) had cumulative exposure to crystalline silica exceeding 7 mg/m^3-years, or average exposures at about 700 ug/m^3 for the median exposure duration of about 10 years among the workers in this study's database. The median cumulative exposure among workers in the cohorts studied by Steenland, et al (2001) that provides several of the exposure-response functions that OSHA used for lung cancer mortality was about 4.9 mg/m^3-years. OSHA used exposure-response functions derived from these and other databases to estimate risks at exposures of 100 ug/m^3 and 50 ug/m^3 for 45 years (cumulative exposures of 4.5 or 2.25 mg/m^3-years) in the Agency's significant risk discussion.
In applying these relationships for benefits analysis in the case of workers who on average now are exposed to silica for fewer than 10 years and at concentrations at or below the proposed new PEL, OSHA is applying the relationships to cumulative exposures below nearly the entire exposure ranges in the original studies from which they were developed. For example, a worker exposed now at the level of the proposed PEL (after the impact of the proposed change to ISO/CEN) of about 0.041mg/m^3 for what we estimate to be the current average lifetime duration of exposure of 9.5 years would have a cumulative exposure at the end of his silica-exposed working lifetime of only about 0.4 mg/m^3-years; roughly one-twentieth of that for the median worker in the Mannetje et al. study and one-tenth of that for the median worker in the Steenland et al. study.

OSHA has paid no attention to many questions about whether extrapolating to this very low dose range is appropriate: is the functional form that the researchers chose to fit at the high historical cumulative exposure range appropriate also in the current very low dose range? What is the curvature of the chosen function at this very low dose range, and is this biologically plausible? Is the estimated excess incidence of the health effect significantly different from zero in a statistical sense in this very low dose range? Is cumulative lifetime exposure the only meaningful exposure metric, or could there be some evidence of a dose-rate effect?

Again, OSHA neither asked nor attempted to answer such questions about whether the functions derived at very high doses several decades ago and chosen for use in the significant risk investigation were appropriate to use also for benefits analysis at the far lower cumulative exposure levels that now prevail.

benefits involving non-malignant respiratory disease mortality,[10] which is a broader and more inclusive category than mortality from silicosis only. This leaves our estimate for silicosis mortality benefits smaller than OSHA's estimate for benefits from reduced mortality from silicosis and other non-malignant lung diseases. We rejected the Park et al. study for several reasons that we will describe subsequently, including the particularly strong objections to this study from Drs. Cox and Morfeld.

- 1 relationship for estimating silicosis morbidity benefits.

- We chose to use no relationships for estimating renal disease mortality benefits. Drs. Cox and Morfeld viewed the only study that OSHA used to quantify renal disease risks (Steenland, et al, 2002) as failing to establish a persuasive relationship between silica exposure and renal disease mortality. We agreed with that view.

In sum, among the many exposure-response relationships that OSHA uses in the Agency's significant risk analysis, we choose to apply the following four in our benefit-cost reanalysis when estimating risks and benefits for the various health effects that OSHA quantifies.

Table 4. Exposure-Response Functions We Use in Estimating Risks and Benefits

Health Effect	Exposure-Response Functions That We Use
Lung cancer	Two functions: 1. Linear relative risk model based on untransformed cumulative exposure that was developed by Steenland and Bartell for the IARC pooled analysis (Steenland, et al. 2001a -- 10 cohorts) and reported in Steenland, personal communication, 2010 2. A relationship developed for a cohort of British coal miners that was not among those included in the IARC pooled analysis, drawn from Miller and MacCalman (2009), and cited as particularly strong by OSHA
Silicosis or NMRD mortality	Mannetje et al. (2002b) (as updated by Toxichemica/Steenland and Bartell, 2004) for silicosis mortality. We do not use Park, et al, (2002) for the broader category of NMRD mortality. We thus estimate risks and benefits for silicosis mortality only, and not additionally for mortality from other NMRD.
Renal disease mortality	None. No exposure-response relationship between silica exposure and renal disease mortality has been established
Silicosis morbidity	Exponential exposure-response relationship from Buchanan et al. (2003) for exposures at concentrations less than 2 mg/m^3

[10] Non-malignant respiratory diseases may also be referred to as lung diseases other than cancer (LDOC).

In selecting what we view as the better among the exposure-response functions that OSHA has developed, we do not mean to imply that these exposure-response functions provide the best estimates of silica-related risks at exposure concentrations below 100 $\mu g/m^3$. To the contrary, the Crystalline Silica Panel's comments point out numerous shortcomings in those exposure-response functions and make a persuasive case for the existence of a concentration threshold above 100 $\mu g/m^3$. Nonetheless, we believed our analysis would be more credible to the Agency if we were to limit our selections to exposure-response relationships that OSHA itself had chosen to use.

1. Exposure-response functions we use for lung cancer

Function from Steenland, et al. (2001a)

As a first function that we use in estimating risks and benefits involving lung cancer, we select a relationship based on the Steenland, et al. (2001a) pooled analysis of 10 cohorts that was supported by IARC. We prefer this study as a source of aggregated relationships over the relationships from any of the 10 cohorts individually. The pooled analysis is far larger than the individual cohort studies, and most of the cohort studies are included in the pooled analysis, meaning that the pooled analysis draws conclusions reflecting the aggregated data across most of the individual studies.

The peer reviewers of OSHA's draft quantitative risk assessment also recommended that OSHA use the results from the pooled cohort analysis as the basis for "best" estimates of lung cancer risk, in contrast to OSHA's range approach where the pooled analysis provided lower risk estimates and some of the individual cohort studies provided an upper end for the range.[11]

In the risk assessment document, OSHA has chosen to provide three different risk estimates derived from the pooled analysis data set:

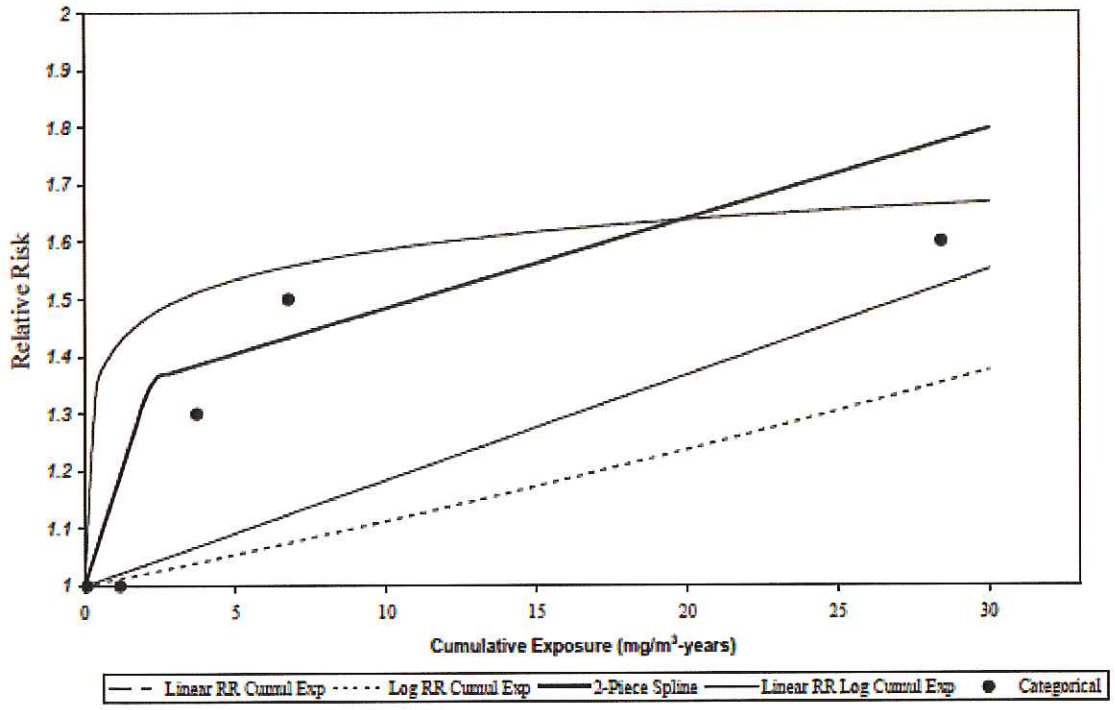
- log-linear model based on log cumulative exposure from Steenland et al.'s original analysis as modified in the Toxichemica, Inc. (2004) reanalysis;
- linear model based on log cumulative exposure, developed by Steenland (Steenland, personal communication, 2010) in response to peer review comments that OSHA had received "questioning the appropriateness of relying on non-linear models and log transformation of exposure"; and
- 2-piece linear spline model based on untransformed cumulative exposure, also developed by Steenland (Steenland, personal communication, 2010) in response to the peer review comments.

[11] See page 397 of OSHA: *Occupational Exposure to Respirable Crystalline Silica – Review of Health Effects Literature and Preliminary Quantitative Risk Assessment.* We will refer to this document as OSHA's "risk assessment document", and may also refer to it as OSHA does as the "QRA".

OSHA chose to present alternative risk estimates for the pooled dataset based on these three particular models for two reasons. First, their very steep early slope supposedly matches the pattern that Steenland et al. (2001) observed in their original categorical analysis of the pooled dataset. See the risk analysis document, text on page 276, and Figure II-2 on page 278 and copied below. (Model b is the solid line curve toward the top of the figure, while model c is the two-piece solid line in the figure. Model a is not shown in the figure.)

Second, two of the three chosen models tend to reduce the heterogeneity of parameter and risk estimates among the individual studies (cohorts) comprising the pooled data set. In effect, the log transform of cumulative exposure (chosen models a and b) reduce the impact of the data points in the high cumulative exposure range on the parameter estimates (see the risk assessment document at page 273). (OSHA does not say anything about whether the third model the Agency chose to present -- the two-piece spline model -- also reduces the heterogeneity of the estimates for individual cohorts.)

Figure II-2. Plot and Parameters of Relative Risk Models Fit to the Pooled Cohort Data Originally Analyzed by Steenland et al. (2001a)



OSHA chose not to present in the risk assessment document additional estimates based on either of the other two models developed in Steenland (personal communication, 2010), shown in the figure as the lower two straight line relationships. This is evidently because the lower two lines/models do not show the steep early slope as originally estimated in Steenland et al. (2001a) and because they yield lifetime excess risk estimates at the current PEL that are substantially lower than the risk estimates generated by the three other models in Steenland (personal communication, 2010) that OSHA did choose to present in the risk document.

OSHA thus chose in the risk assessment document to present risk estimates for the pooled analysis data set based on three models: two from Steenland (personal communication, 2010) and one from Steenland et al. (2001a), as updated by Steenland and Bartell (Toxichemica, 2004). OSHA chose to omit estimates based on the two other models that were newly developed and included in Steenland (personal communication, 2010).

However, in the context of a benefits analysis rather than a significant risk determination, we believe there are two good arguments for preferring the two omitted risk models over the three included risk models and making an exactly opposite choice from that which OSHA has made:

- First, Steenland and Bartell (Toxichemica, 2004) cautioned that a very steep early slope at low cumulative exposure levels – such as is shown in each of the three models that OSHA chose to present in the risk assessment document – may not be plausible. With respect to the log-linear model based on log cumulative exposure from Steenland et al.'s original analysis (model a in OSHA's risk document) and a spline model that was also included in the original analysis (different from and much less steeply sloped than the new spline model – model c – that was included in the risk document), Steenland and Bartell said:

  > "We believe the risk estimates from the [original} spline model are to be preferred, in that the slope of the log cumulative exposure curve increases very rapidly at low doses, such as those for which we are calculating excess risk, and this rapid increase may not be plausible" (Toxichemica, 2004, page 20)

  In choosing among the various possible lung cancer risk models, OSHA appears in the risk assessment document to have overlooked or ignored this issue. In our view, the steepness of the exposure-response function in the "low dose" range is an extremely important issue for benefits analysis, whereas it is a much less significant issue for risk assessment for exposure over a full working lifetime, which is OSHA's primary focus in the risk assessment document. This is because, by our estimate, the great majority of current General Industry workers that could benefit from the proposed standard (as opposed to those who could benefit from strict compliance with the current standard) incur lifetime cumulative respirable silica exposures that are substantially less than 1 mg/m^3-years – and thus exposures that are only at the very far left of Figure II-2. [12]

[12] Later in this paper, we develop estimates showing that the median duration of lifetime exposure to respirable crystalline silica among General Industry workers is less than seven years and the average duration is less than ten years. Assuming ten years as the average duration of occupational exposure, the average General Industry employee exposed at the current PEL will accrue cumulative exposure of 1 mg/m^3-years – the maximum baseline exposure concentration assumed in OSHA's analysis for General Industry and the highest concentration at which workers who will benefit from the proposed standard are assumed to be exposed.

Other General Industry employees who are assumed to accrue benefits from the Proposed Standard in OSHA's analysis will have cumulative exposures in the baseline averaging less than 1 mg/m^3-years – if they are exposed in the baseline at the level of the proposed PEL on average they will accrue benefits when their cumulative exposures are reduced below 0.5 mg/m^3-years; if they are exposed in the baseline at the proposed Action Level on average they will accrue benefits when their cumulative exposures are reduced below 0.25 mg/m^3-years.

For benefits analysis the important range of cumulative exposure is from zero to about 1 mg/m^3-years. For risk assessment over a full working lifetime the important range is from about 1 mg/m^3-years (0.025 mg/m^3 [proposed Action Level] x 45 years) to about 11 mg/m^3-years (0.25 mg/m^3 [current construction PEL] x 45 years).

OSHA's concern regarding choosing risk models that reduce the heterogeneity across estimates from individual studies for cohorts in the pooled data set is an issue only for the higher cumulative exposure ranges that prevailed in the worker exposure data underlying these studies; in effect at cumulative exposures exceeding about 15 mg/m^3-years and very far to the right in the figure.

The extremely steep exposure-response relationships in the very low cumulative exposure range that characterize all three of OSHA's selected lung cancer risk models for the pooled data would greatly inflate the estimated benefits for the proposed rule when calculations are performed that recognize the facts cited in the footnote above.

In choosing a lung cancer risk model to use for benefits analysis, OSHA should be particularly concerned that the model yield plausible results in the low dose range below 1 mg/m^3-years in cumulative lifetime exposure, and should not be concerned at all about the heterogeneity of different models' projections at cumulative exposures exceeding 15 mg/m^3-years.

- A second point that OSHA also appears to ignore in selecting the three models used for lung cancer risk assessment are the Agency's external peer reviewers' "comments questioning the appropriateness of relying on non-linear models and log transformation of exposure over the more preferred linear model for estimating cancer risks."[13] These comments prompted OSHA to request Drs. Steenland and Bartell to "conduct additional analyses with linear relative risk models on the pooled data set"[14], resulting in the four new models provided in Steenland (personal communication, 2010). But then, after apparently recognizing the peer reviewers' preference for: a) linear models involving b) untransformed cumulative exposure, OSHA selected for the Agency's lung cancer risk estimates three models that did not meet both criteria of the reviewers:

Despite the fact that the proposed standard will require exposure reductions only for those workers now exposed above the proposed new PEL, the compliance measures that employers will implement will result as frequently or more frequently in exposure reductions for workers now exposed near or below the proposed PEL as for workers now exposed far above the proposed PEL. This is because the engineering controls that employers in general industry will implement to protect overexposed workers will also reduce exposures for the large number of workers who are not overexposed but work in the same areas of the facilities where the exposure-reduction measures will be implemented.

In sum, the great majority of the exposure reductions that will occur as a result of the proposed rule will be at the far left of the figure. The shape of the lung cancer exposure-response function in this range will be critically important in estimating benefits. An implausibly steep curve in this range will result in substantially overestimated lung cancer benefits.

[13] Risk assessment document, page 275.
[14] Risk assessment document, page 275.

- One model the Agency selected involves both log-transformed cumulative exposure and a non-linear (log-linear) format (model a, the log-linear model based on log cumulative exposure from Steenland et al.'s original analysis as modified in the Toxichemica, Inc. (2004) reanalysis), thus failing to meet both of the reviewers' criteria.

- The second model the Agency selected involves log-transformed cumulative exposure and a linear format (model b, linear model based on log cumulative exposure, developed by Steenland, personal communication, 2010), thus failing to meet one of the reviewers' two criteria; and

- The third model the Agency selected does not apply a log-transformation to cumulative exposure, but adopts a piecewise linear format (linear spline with one knot) rather than a simple linear format (model c, 2-piece linear spline model based on untransformed cumulative exposure from Steenland [personal communication, 2010]), thus (arguably) also failing to meet one of the reviewers' criteria.

At the same time, OSHA did not choose to use in risk assessment the only model that meets both of the reviewers' criteria – the linear relative risk model based on untransformed cumulative exposure (the uppermost of the two straight lines in Figure II-2) which had been developed specifically in response to OSHA's request (Steenland, personal communication, 2010).

In conclusion, in estimating lung cancer risks for our benefits analysis, *we have chosen to use this latter model: the linear relative risk model based on untransformed cumulative exposure that was developed by Steenland and Bartell and reported in Steenland, personal communication, 2010.* This particular model is the only one among those that have been applied to the IARC pooled data set that: a) Has a plausible and not excessively steep slope in the critically important low-dose range; and b) Meets both of the criteria suggested by the external peer reviewers. It also has additional credibility for use in this critique of OSHA's benefit-cost analysis insofar as it was developed pursuant to OSHA's request.

We applied this relationship in order to estimate lifetime lung cancer mortality risks at various levels of cumulative exposure by using OSHA's life table approach shown in the risk assessment document Appendices A-1 through A-3 on page 361 through 366, but with column L revised to reflect the different lung cancer hazard rate calculated using the linear relative risk model based on untransformed cumulative exposure lagged 15 years.

Function from Miller and MacCalman (2009)

Miller and MacCalman (2009) studied a cohort of British coal miners that was evaluated later and was not included as one of the ten cohorts addressed in the IARC pooled study (Steenland, et al 2001a). OSHA believes this study is particularly strong in assessing the relationship between exposure to crystalline silica and lung cancer.

> Three of the strengths of this study are the availability of detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. (Risk assessment document, page 288)

and

> OSHA believes that these coalminer-derived estimates are quite credible because of the quality of several study factors relating to both study design and conduct. In terms of design, the cohort was based on union rolls with very good participation rates and good reporting. The study group was also over 17,000 with an average of nearly 30 years of follow-up, and about 60 percent of the cohort had died. Just as important was the high quality and detail of the exposure measurements, both of total dust and quartz. (Risk assessment document, page 289)

We have used as a second source for risk and benefits estimates involving lung cancer the particular relationship that OSHA selected from among those developed by Miller and MacCalman (2009) -- expressing lung cancer mortality risk as a function of 15-year lagged cumulative exposure to quartz and coal mine dust. We applied this relationship in order to estimate lifetime lung cancer mortality risks at various levels of cumulative exposure using OSHA's life table approach shown in the risk assessment document Appendix A-7 on page 373.

> OSHA's inappropriate procedure for estimating lung cancer risks and benefits after applying multiple exposure-response functions

We thus applied two exposure-response functions to estimate lung cancer risks -- 1) The linear relative risk model based on untransformed cumulative exposure described in Steenland (personal communication, 2010); and 2) The relationship developed by Miller and MacCalman (2009) that OSHA had selected and applied in both the risk assessment document and the PEA. These two relationships yield an upper and a lower estimate for lung cancer risk reductions and lung cancer benefits attributable to the proposed standard. In the point estimates that we present in this report, we chose the midpoint between the upper and the lower estimates.

OSHA similarly applied multiple exposure-response functions in estimating lung cancer risks and benefits, and reported a point estimate at the midpoint between the Agency's upper and lower estimates. However, OSHA applied 7 different functions (from 5 studies) in deriving its range,[15] while we applied only two in developing our range. We believe OSHA's procedure of developing a point estimate at the midpoint of a range when the range results from the application of many different functions is inappropriate.

When one converts a range to a point estimate in this manner, if the high end of the range is much higher than the low end of the range, the midpoint estimate as a matter of mathematics becomes close to half of the high end of the range. In using this approach to generate a point estimate from a range, OSHA essentially ignored the information inherent in all the estimates comprising the range except for the highest single estimate. The point estimate for benefits that OSHA derived is roughly half of the high end of the range, and this estimate is minimally

[15] See pages VII-3 and 4 of the PEA and Table II-2 of the risk assessment document.

affected by how low the low end of the range is and is not affected at all by what the intermediate values are in the range.[16]

Moreover, OSHA's procedure for converting benefits that are initially estimated as a range into a single point estimate causes the Agency's benefits estimates to inflate as the Agency increases the number of studies/functions that are considered in estimating risks for the avoided health effect.[17]

OSHA's approach is particularly inappropriate for benefits analysis when the key risk study for a health effect is a pooled study or meta-analysis that includes multiple cohorts (e.g., the Steenland/Toxichemica pooled analysis for lung cancer mortality and arguably also the Mannetje/Toxichemica pooled analysis for silicosis mortality) and the additional relationships that OSHA considers as providing additional risk estimates address individually one or more of the cohorts that are included in the pooled study. In this instance, the midpoint risk estimate that OSHA uses for the reported benefits estimate is roughly half of the risk for whatever particular cohort in the pooled study shows the highest risk.

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[16] Here's an example. In estimating the number of deaths from lung cancer that will occur from 45 years of silica exposure at 250 ug/m^3, OSHA in the QRA (Table II-2) cites the results from five studies (7 exposure-response relationships) yielding a range from 27 lifetime cases per thousand workers (one of three candidate relationships drawn from Steenland and Bertell/Toxichemica, 2004) up to 250 lifetime cases per thousand workers (the single relationship drawn from Attfield and Costello, 2004). When OSHA then uses these risk calculations in estimating monetized benefits involving avoided lung cancers, the Agency presents estimates based on the midpoint in this range ([27 + 250]/2 = 138.5 lifetime excess lung cancer deaths per 1,000 workers). This estimate of 138.5 is approximately half (55.4%) of the 250 high-end estimate. If the low-end risk estimate were, for example, 13.5 rather than 27 cancer deaths per 1,000 workers, only half of the low-end risk that OSHA actually calculated, the calculated midpoint estimate would decline from 138.5 to 131.75, only a 5% decline resulting from a 50 % reduction in the low-end value. Similarly, if the low-end risk estimate were 40.5 rather than 27, the calculated midpoint estimate would increase from 138.5 only to 145.25, only a 5% increase from a 50% increase in the low-end value. When the high-end estimate for the range is much higher than the low-end estimate for the range, the midpoint will always be slightly more than half of the high-end estimate. The midpoint value is only minimally affected by what the low-end value is, and not at all affected by what the other values are between the low and the high.

[17] For example, if OSHA were to add an eighth exposure-response relationship to the seven that the Agency used in estimating lung cancer risks, there would be three possibilities:

- The additional relationship might project risks at a lower level than the lower end of the seven-relationship range, in which case the midpoint for the new eight-relationship range would be very slightly lower than the midpoint for the seven-relationship range.
- The additional relationship might project risks at a level between the lower and the higher ends of the seven-relationship range, in which case the midpoint for the eight-relationship range would be unchanged from the midpoint for the seven-relationship range.
- The additional relationship might project risks at a higher level than the high end of the seven-relationship range, in which case the midpoint for the eight-relationship range would move up to about half of whatever the additional risk projection is. If the eighth study estimated risks at, for example, 500 lifetime cancer deaths per 1,000 workers in our illustration (twice the original high-end risk estimate), the midpoint estimate would increase by 90% from 138.5 cases per 1,000 workers to 263.5 cases per 1,000 workers.

Adding a further relationship to the set of relationships considered in establishing a risk range (where the high end of the range is a substantial multiple of the low end of the range) could thus increase the midpoint estimate substantially but could not decrease the midpoint estimate substantially. As more studies are added to the set that is considered as establishing the risk range, the midpoint estimate that OSHA reports for the range will tend to increase.

In OSHA's benefits analysis for lung cancer, the relationship drawn from the Attfield and Costello (2004) study of a cohort of U.S. granite workers provides the high end of the Agency's benefits range (e.g., 2,636 lung cancers avoided at a PEL of 50 ug/m^3 -- see pages VII-3 and VII-4 of the PEA). This cohort is included in and comprises only about 8% of the worker population covered by the 10-cohort Steenland/Toxichemica pooled analysis. The pooled analysis provides relationships accounting for both the low end (238 cancers avoided) and two intermediate estimates within OSHA's risk range, yet OSHA's approach makes the nearly 12 times larger pooled analysis nearly irrelevant in determining the results of the benefits analysis. The single relationship drawn from the Attfield and Costello study essentially determines the results of the Agency's analysis, while the large pooled analysis, other cohorts within the pooled analysis, and other studies/relationships the Agency includes all have virtually no impact. This result is particularly troubling because the Attfield and Costello (2004) study has been superseded by a subsequent, updated, and more comprehensive study of the Vermont granite worker cohort that found no causal association between silica exposure and lung cancer risk.

In using this multiple-study approach, OSHA's benefits estimate for lung cancer depends largely on whatever perhaps anomalous study result OSHA has found that shows the highest risk estimate. The more studies and relationships that OSHA considers, the higher this risk estimate is likely to be. OSHA's reported monetized benefits estimate involving lung cancer does not fairly portray the range of uncertainty about the lung cancer impact of silica exposure or reasonably reflect any central tendency across this range of uncertainty. Instead, OSHA's benefits estimates for lung cancer represent figures that are mathematically about half of whatever benefits might be calculated based upon the highest risk estimates that researchers have developed and that the Agency has chosen to include for some particular group of workers.

While we oppose this procedure that OSHA follows in developing many risk estimates and choosing the midpoint between the lowest and the highest, we nevertheless follow such a procedure (though to a much lesser degree) in our benefits calculations for lung cancer risks. We choose two exposure-response functions and report the midpoint values resulting from these two functions, in contrast to OSHA using eight functions from five studies. We choose these two functions because: a) the Steenland, et al pooled lung cancer study is the largest lung cancer study by far, including 10 cohorts and most of the other individual cohorts/studies selected by OSHA; yet b) it does not include the British coal miner cohort addressed in Miller and MacCalman (2009) which OSHA believes in several other ways to constitute the strongest of the lung cancer studies. In our analysis using these two relationships, the highest benefits estimate (from Miller and MacCalman, 2009) is a little less than three times the lowest benefits estimate (from the pooled study), not a particularly wide range. In OSHA's analysis using eight relationships there is a much wider range: the highest benefits estimate (from Attfield and Costello, 2004) is more than eleven times the lowest benefits estimate (from the pooled study) for a PEL of 50 ug/m^3 and nearly fifty times the lowest benefits estimate for a PEL of 100 ug/m^3.

2. Exposure-response function we use for silicosis mortality or non-malignant respiratory disease mortality

In the QRA, OSHA estimated risks involving these health effects by applying the relationships estimated in two studies:

- OSHA's first estimate is for silicosis mortality, derived from the Mannetje, et al. (2002b) study estimating silicosis mortality across six of the ten cohorts that had been included in the IARC/Steenland, et al (2001a) lung cancer pooled analysis. OSHA contracted for the original analysis developed by Mannetje, et al. (2002b) to be updated/corrected using a nested case-control approach rather than the original Poisson regression and correcting for two types of measurement error, resulting in risk estimates that are about 20 – 25% lower than the original estimates (Toxichemica/Steenland and Bartell, 2004).

- OSHA's second estimate is for total mortality from non-malignant and non-infectious respiratory causes of death (non-malignant respiratory diseases, or NMRD), thus including deaths from, for example, emphysema, chronic bronchitis, and COPD in addition to those from silicosis and other pneumoconioses. This estimate is based on the Park et al. (2002) analysis of California diatomaceous earth workers, one of the six cohorts also included in Mannetje, et al. (2002b). The cohort studied by Park et al accounts for 13% of the workers, 9% of the silicosis deaths and 11% of the total deaths in the Mannetje, et al. pooled analysis. Rather like the situation for lung cancer, then, for silicosis mortality OSHA derives a lower estimate from a large, multi-cohort pooled analysis, while the Agency derives a higher estimate from a study addressing a single one of the pooled cohorts. (Though the approach for NMRD mortality is different than for lung cancer in the sense that the individual study assessed risks for a larger set of health endpoints than did the pooled study.)

OSHA's higher mortality risk estimate based on Park et al. (2002) is about 5 to 16 times higher than the lower mortality risk estimate based on Mannetje, et al. (2002b), for 45 years exposure at levels ranging from 25 to 500 ug/m^3.

In contrast to the Agency's approach for lung cancer, for the monetized benefits analysis OSHA chose to use only the higher risk estimate from Park et al. (2002) that addresses mortality from many non-malignant respiratory diseases in addition to silicosis. OSHA's rationale was:

- Other studies have documented increases in non-silicosis NMRD mortality among silica-exposed workers in several industry sectors;

- Silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis (and thus presumably Mannetje, et al. 2002b underestimate the number of silicosis deaths);

- The diatomaceous earth worker cohort included too few deaths attributed to silicosis for analysis of silicosis mortality.

We make several arguments against OSHA's judgments that: i) silica exposure causes NMRD mortality in addition to that from silicosis; and ii) Park et al. (2002) should be used to quantify this relationship:

- Studies investigating the relationship between silica exposure and NMRD and NMRD mortality are quite mixed in the conclusions they draw (see pages 181 – 208 of the risk assessment document). There are several studies with negative findings. Many studies have difficulty distinguishing effects of silica exposure from those due to dust exposure more generally. Several studies found effects in smokers but not in non-smokers.

- Exposure estimates in the Park at al. (2002) study are very uncertain, and there was the possibility of significant confounding by smoking.

- Dr. Cox and Dr. Morfeld strongly criticized Park et al. (2002):

    - General dust exposures are widely agreed to cause NMRD, and toxicological considerations argue in favor of a threshold effect for these endpoints. But Park et al. (2002) did not account for the effect of general dust exposure, nor did the researchers consider potential thresholds in any exposure-response relationship;

    - The researchers used *ad hoc* and inadequately justified procedures for selecting the various forms of models to consider, and for the final choice of a particular model used to quantify risk;

    - The researchers did not address uncertainties in the exposure data and in the chosen model; and

    - A significant share of the dataset (all cumulative exposures exceeding 10 mg/m^3-years, accounting for 16% of the total NMRD deaths in the cohort) was inappropriately excluded from the analysis in order for the researchers to obtain a monotonically increasing exposure-response relationship

Drs. Morfeld and Cox both concluded that OSHA's NMRD mortality risk estimates based on Park et al. (2002) are "unsupported". Mannetje et al. (2002b) is a far stronger study addressing mortality from silica exposure than is Park et al. (2002). We *thus choose to use Mannetje et al. (2002b) (as updated by Toxichemica/Steenland and Bartell, 2004) as the source of the exposure-response function for NMRD mortality in our re-estimation of the benefits analysis*. Our benefits analysis for NMRD mortality will thus be limited to silicosis mortality.

Relative to Park et al. (2002), Mannetje et al. (2002b):

- Deals with silicosis mortality, which is much more consistently recognized as an end point attributable to silica exposure than is mortality from emphysema, chronic bronchitis and COPD;

- Involves six worker cohorts across four industries and three countries in contrast to one cohort for Park et al. (2002);

- Involves about 8 times as many workers and about 10 times as many attributable deaths;

- Does not resort to the very questionable deletion of a substantial share of the study dataset in order to obtain a smoothly fitting exposure-response relationship; and

- Is not limited to cristobalite alone as the form of crystalline silica that is investigated.

We chose to use the same exposure-response function from Mannetje et al. (2002b) for estimating the risk of silicosis mortality as OSHA did. OSHA and we both chose the continuous (as opposed to categorical) relationship developed from the nested case control analysis using conditional logistic regression with two sources of measurement error corrected by OSHA's consultants Toxichemica/Steenland and Bartell, 2004.

Correction of the two sources of measurement error caused the estimated rate ratio for log-transformed cumulative exposure to decrease from 2.08 to 1.74 (Toxichemica, 2004, Table 6, page39). The researchers estimated the full risk equation by assuming the silicosis mortality rate observed for the least exposed group of workers in the study (rate of 0.000047 per person-year at a cumulative exposure of 183.5 mg/m^3-[days+1]) as a "referent rate" and then estimating the resulting equation for a rate ratio of 1.74.

The epidemiologist that we contracted with to review OSHA's work with this exposure-response function objected to this procedure of anchoring the estimated function to the observed rate for a single group among the 10 cumulative exposure groups in the study, instead preferring to estimate a risk equation with a rate ratio of 1.74 that best fit the observed risks across all ten of the cumulative exposure groups. This resulted in an estimated constant for our equation of -1.5.

Mannetje et al. estimated risks assuming worker exposure to crystalline silica for 365 days per year, and it is not clear what assumptions were made by Toxichemica and by OSHA in the risk assessment document, though we guess 365 days/year again. Mannetje et al. calculated risks through age 65, Toxichemica estimated risks through age 75, and OSHA and we then estimated risks through age 85. We assumed a more realistic value of 250 days per year.

The silicosis mortality risk estimates that we ultimately calculated via our adaptation of the modified Mannetje, et al. equation were only slightly different than those that OSHA calculated when cumulative exposure was expressed in mg/m^3-[days+1]. See our workbook for details.

3. Exposure-response function we use for silicosis morbidity

In the risk assessment document, OSHA provides a range of silicosis morbidity risk estimates based on exposure-response relationships estimated in six cumulative risk studies with post-employment follow-up. OSHA prefers cumulative risk studies (where radiographs are taken at multiple points in a subject's lifetime) over cross-sectional studies (radiograph taken only at a single point in a subject's lifetime) because the cumulative risk studies can evaluate disease onset and progression over time. OSHA prefers studies with post-employment follow-up because they get closer to being able to estimate long-term risks and ultimate disease incidence.

The risk estimates varied widely across the six cumulative risk studies with post-employment follow-up (8 exposure-response relationships). For 45 years exposure at 100 ug/m^3, the number

of projected silicosis cases ranged from 6 to 77 per 100 workers. For 45 years exposure at 50 ug/m^3, the number of projected silicosis cases ranged from 2 to 17 per 100 workers (risk assessment document, page 337).

OSHA believes that two studies of a group of Scottish coal miners (Miller et al. 1998, and further analysis in Buchanan et al. 2003) are the most reliable of the silicosis morbidity studies "because of high-quality exposure data, post-exposure follow-up, and extensive analysis" (risk assessment document, page 358). OSHA's table summarizing available silicosis morbidity risk estimates portrays these two studies as finding estimated lifetime risks in roughly the middle of the range across the six cumulative risk studies (8 exposure-response relationships) with post-employment follow-up.

In OSHA's more condensed tables summarizing selected risk estimates for all of the quantified health effects from silica exposure, OSHA presents for the Scottish coal miner studies a single set of risk estimates based on a particular exponential exposure-response relationship that OSHA selected from among those estimated in Buchanan et al. 2003 (risk assessment document, page 351).[18] *We choose to use this particular equation in estimating silicosis morbidity risks and benefits in our revised benefit-cost analysis.*

In estimating the number of cases of silicosis prevented at a PEL of 50 ug/m^3, OSHA showed a range across eight risk models from a low of 218 cases per year to 5,212 cases per year, a figure more than 20 times larger. In then monetizing the benefits of avoiding this wide range of claimed prevented silicosis cases, though, OSHA recognized that all but two of these eight models estimated the numbers of cases of 1/0 silicosis, and that most of these cases were likely non-symptomatic. OSHA thus chose to address in the monetized benefits analysis only the more severe and more clearly symptomatic cases of 2/1+ silicosis. Only two of the eight risk models that OSHA chose provide risk estimates for 2/1+ silicosis, and the second of these two models (Buchanan, 2003) represents an update after extended follow-up of the cohort addressed in the first of these two models (Miller, 1998). OSHA thus had only a single reasonable candidate model for estimating the risks of more serious 2/1+ silicosis.

In estimating monetized benefits, OSHA then paired an estimate for the number of cases of 2/1+ silicosis avoided that is derived from the Buchanan (2003) model with estimates of the dollar value of avoiding such a more severe case of silicosis drawn from the literature.

In this monetization step, however, OSHA again drew multiple estimates from the literature, cited the range from the lowest cost per case to the highest, and provided a point estimate at the midpoint between the low and high ends of the range. Similarly as for the lung cancer risk estimates, the high end of OSHA's risk range for the value of an avoided case of silicosis is a large multiple of the low end (the high estimate is more than 80 times larger than the Agency's low estimate), and the midpoint valuation that OSHA chose is thus essentially half of the single high end estimate. We believe, and will discuss this later in this paper, that OSHA's high end

[18] The particular relationship chosen by OSHA estimates the risks while workers are exposed to quartz concentrations below 2 mg/m^3 and the additional risks while workers are exposed to concentrations above 2 mg/m^3. Only the portion of the equation for exposures below 2 mg/m^3 is relevant to and used for risk analysis relating to the Proposed Standard, since no General Industry workers are thought currently to be exposed to concentrations exceeding 2 mg/m^3.

cost per case estimate is wholly inappropriate as an estimate for the value of preventing a case of silicosis, and that OSHA's valuation procedure has made irrelevant a very reasonable intermediate value estimate (but near the low end) that was developed by an OSHA contractor, as well as the several other estimates the Agency offered.

In estimating the monetized benefits of avoided silicosis morbidity for our analysis, we avoid the problems inherent in OSHA's approach involving the wide and inappropriate range of values per case avoided. We combine the Buchanan (2003) estimate for the number of cases of more severe silicosis that are avoided with the single most reasonable figure for the value of an avoided case.

4. Exposure-response function we use for renal disease mortality

OSHA estimated the risk of renal disease mortality as a function of silica exposure based on a single study: a case-control study performed by Steenland et al. (2002) after pooling three of the ten cohorts included in the IARC/Steenland et al. (2001) lung cancer study. For reasons noted below and discussed at greater length at pages 140-157 of the Panel's Comments, we do not believe that occupational exposure to crystalline silica has been shown to cause an excess risk of renal disease mortality. We therefore apply no exposure response function relating silica exposure to renal disease mortality, and we estimate that there will be no benefits in terms of reduced renal disease mortality.

In the draft risk assessment document provided for peer review in 2010 or so, OSHA preliminarily determined that data were insufficient to support a quantitative assessment of renal effects from silica exposure. Three OSHA-selected peer reviewers subsequently agreed with this view. Another reviewer also agreed that the data were insufficient to support a quantitative assessment of renal risks, but stated further that "... if one were required, it would be feasible, given the available studies." Two reviewers held opposite opinions, that the data were sufficient and would support a quantitative assessment. (See the risk assessment document, page 388.)

Despite the majority of the reviewers thus recommending against quantitative risk assessment for renal effects, OSHA changed course since the peer review draft and elected to include renal disease mortality among the end points for which risks from silica exposure are quantified.

Avoided renal disease mortality accounts for a meaningful share of the total benefits that OSHA estimates for the proposed rule. By OSHA's calculation, depending on which combinations of studies are used to estimate risks for the various silica-related health impacts, somewhere between about 35% and 99% of total estimated benefits for the proposed rule derive from avoided mortality in contrast to avoided morbidity.

For General Industry and Maritime, OSHA estimates that avoided renal disease mortality accounts for 19% of the total number of fatal illnesses prevented by the Proposed Standard (PEA, Table VII-1, page VII-4, total number of avoided cases, midpoint estimate).

OSHA's shift in opinion between 2010 and now about quantification of renal disease impacts thus has a moderate impact in increasing the benefits estimated for the proposed rule.

Drs. Cox and Morfeld offered in their testimonies several objections to OSHA's conclusions (1) that silica exposure causes a significant increase in renal disease, and (2) that the Steenland et al. (2002) pooled analysis provides a credible quantitative estimate of this relationship.

First, there has not been an adequate explanation for why Steenland/IARC's pooled lung cancer study includes ten cohorts, yet the pooled analysis for silicosis mortality makes use of only six of these cohorts and the renal disease analysis includes only three. There is no reason not to evaluate kidney disease mortality on the basis of all available cohorts/studies. This raises the possibility of study selection bias. (The three cohorts chosen for the renal disease study were evidently the only cohorts for which information on renal disease had been included when recording all contributing causes of death, though additional cohorts were available for which renal disease had been considered when investigating only a single underlying cause of death.) This is a particular concern, since numerous studies have failed to find an association between silica exposure and renal disease mortality. (Panel Comments, pages 140-145).

Second, it is uncertain whether the three cohorts pooled in Steenland et al.'s (2002) renal disease mortality study would now support a finding of significantly elevated mortality risk if the data were appropriately updated and re-analyzed:

- The largest of the original pooled cohorts -- Vermont granite workers, accounting for 42% of the workers with exposure information in the pooled study – has been updated, expanded and re-studied recently. In that analysis, Vacek et al. (2011) could find no associations between silica exposure and renal disease mortality.

- The second of the original cohorts included 3,328 South Dakota gold miners. The exposure assessment in that study suffers from enormous uncertainty, and there is a high likelihood that exposures were underestimated. Analyzed by itself, the entire gold miner cohort showed no statistically significant relationship between silica exposure and increased mortality from chronic renal disease. A significant relationship between silica exposure and renal disease mortality was found only for workers hired before 1930 when silica exposures were much higher (median intensity of silica exposure estimated to be 150 $\mu g/m^3$), suggesting the existence of an exposure threshold above 150 $\mu g/m^3$. (Risk assessment document, page 214; Panel Comments, pages 146-147).

- In the final cohort consisting of North American industrial sand workers (Steenland et al. 2001), mortality from acute renal disease as the underlying cause (which should be viewed as the relevant mortality metric) was not significantly increased, and there was only a marginally significant increase in mortality for chronic renal disease. Moreover, there were large uncertainties in the exposure assessment for this cohort, and a comparison with the more carefully derived exposure assessment for a second, largely contemporaneous study of North American industrial sand workers (McDonald et al. 2005) suggested that exposure estimates in the Steenland et al. 2001 study were understated. In addition, the second study by McDonald *et al.* (2005) found *decreasing* odds ratios for chronic non-malignant renal disease mortality with increasing cumulative

exposure to silica. (Risk assessment document, page 215; Panel Comments, pages 148-152).

Dr. Cox argues with respect to the relationship between silica exposure and renal disease mortality that:

> "The use of a log-transform for estimated cumulative exposures introduces unknown and uncorrected biases and errors into the estimate of the coefficient, due to the fact that the log transformation is applied to (unknown and uncharacterized) errors in cumulative exposure estimates. The log-linear model used is mis-specified (e.g., no terms for errors in estimated exposures) and thus ... its conclusions may bear no resemblance to the truth." (Cox, written comments, page 96)

Steenland and Bartell (Toxichemica, 2004) reviewed the available studies on renal impacts and concluded there was insufficient data for quantitative risk assessment:

> "For renal disease, there are two cohort studies (one mortality, one incidence) with exposure-response data, based on 51 renal deaths (Steenland et al. 2002) and 23 renal cases (Steenland et al. 2001). This amount of data is insufficient to provide robust estimates of risk, and is considerably less than what is available for silicosis mortality or lung cancer mortality ..." (page 27)

We assume for our benefits calculations that there is no relationship between silica exposure and renal disease mortality. There are significant uncertainties about whether any such relationship exists, and significant questions about the single study (Steenland et al., 2002) that OSHA cites as quantifying such a relationship.

In sum, we will use the following exposure-response functions in estimating risks and benefits for the four health effects that OSHA believes are caused by occupational exposure to crystalline silica:

Table 4 (repeated). Exposure-Response Functions We Use in Estimating Risks and Benefits

Health Effect	Exposure-Response Functions That We Use
Lung cancer	Two functions: 1. Linear relative risk model based on untransformed cumulative exposure that was developed by Steenland and Bartell for the IARC pooled analysis (Steenland, et al. 2001a -- 10 cohorts) and reported in Steenland, personal communication, 2010 2. A relationship developed for a cohort of British coal miners that was not among those included in the IARC pooled analysis, drawn from Miller and MacCalman (2009), and cited as particularly strong by OSHA
Silicosis or NMRD mortality	Mannetje et al. (2002b) (as updated by Toxichemica/Steenland and Bartell, 2004) for silicosis mortality. We do not use Park, et al, (2002) for the broader category of NMRD mortality. We thus estimate risks and benefits for silicosis mortality only, and not additionally for mortality from other NMRD.
Renal disease mortality	None. No exposure-response relationship between silica exposure and renal disease mortality has been established
Silicosis morbidity	Exponential exposure-response relationship from Buchanan et al. (2003) for exposures at concentrations less than 2 mg/m^3

D. Exposure Information Used for the Benefit-Cost Analysis

We have accepted and used for our benefit and cost estimates most of OSHA's exposure information, including OSHA's estimates for the numbers of workers in General Industry exposed to respirable crystalline silica at various levels. We did so despite some indication that current worker exposure levels are not as high as they were during the period over which OSHA developed much of the Agency's exposure information

In general, the URS cost estimates are premised on OSHA's exposure information (e.g., number of facilities and number of workers currently exposed above the proposed PEL and needing exposure reductions if the proposed standard were promulgated). Consequently, we cannot alter OSHA's exposure information in our benefit-cost analysis without similarly altering URS' cost estimate, and we do not want to do this.

URS, however, believed that OSHA's estimates for the number of facilities and exposed employees were grossly incorrect for 6 of the 25 General Industry sectors and for the Maritime industry, and URS did not estimate compliance costs for these 7 sectors/industries. We have used URS' cost estimates for the 19 General Industries for which URS was able to estimate costs in our recalculated benefit-cost analysis.

We would like to perform our benefits calculations for this same set of 19 General Industries as those for which URS estimated costs, so that our benefit and cost estimates will be for identical sets of workers. However, we cannot with a reasonable level of effort disaggregate OSHA's exposure data to pull out the information for the employees in the 7 sectors/industries for which URS did not estimate costs.

As a result, our analysis compares estimates of the benefits of the proposed rule for all 25 General Industries plus Maritime (with an estimated 295,000 silica-exposed employees) against the costs that URS estimated only for 19 General Industry sectors (with 220,000 exposed employees). The set of workers across which we estimate benefits is thus about 1/3 larger than the set of workers across which we estimate costs.[19]

Our conclusion that costs greatly exceed benefits is particularly striking in view of this mismatched comparison.

While we accept OSHA's estimates for the numbers of General Industry workers currently exposed within the various concentration ranges for use in our benefit and cost calculations, we have made changes to OSHA's choices about the specific single weighted average concentration levels to use in representing all the concentrations within a range.

Table 5. Different Assumptions Regarding Point Estimates to Represent Ranges of Current/Baseline Silica Exposures for General Industry Employees

Group of workers in terms of baseline exposure (ug/m^3)	# of General Industry workers	OSHA's assumed single exposure level for group (ug/m^3)	Our assumed single exposure level for group (ug/m^3)
Exposed at ≥ 250	48,956	?	434
Exposed between 100 - 250	31,775	125*	150
Exposed between 50 - 100	41,741	62.5*	75
Exposed between 25 - 50	53,329	?	37.5
Exposed between 0 - 25	119,085	?	12.5
Total	294,886		

? = OSHA does not specify any estimate or assumption

* OSHA cites these assumptions at one point in the PEA text, but there are reasons to doubt this statement. OSHA does not present sufficient detail in the Docket about the Agency's benefits calculations to indicate whether these particular figures or others were used.

For example, OSHA estimates that there are 41,741 General Industry workers who are now exposed at between 50 and 100 ug/m^3. In then applying exposure-response functions to estimate risks and benefits involving this particular group of workers, OSHA assumes that all 41,741 of these workers are exposed at some particular single exposure level within this range, rather than assuming that a few of these workers are exposed at 50 ug/m^3, a few more at 51 ug/m^3, etc., and

[19] Though the workers in the sectors for which URS does not estimate costs are, on average, exposed at somewhat lower levels than the workers in the sectors for which URS does estimate costs. See the discussion on page 11.

performing a large volume of calculations and summing the results across all the various workers/exposure levels within this range.

While we agree that this sort of computational shortcut is reasonable, we disagree with OSHA's choices of specific single exposure levels with which to represent each of the concentration ranges. Table 5 shows in the rightmost column the single exposure levels that we chose for our analysis in contrast to those OSHA chose. We chose these figures for the following reasons:

- For exposure ranges up to the current General Industry PEL, we chose a representative figure at the midpoint of each exposure range. This follows OSHA's practice in the Agency's 2003 benefits analysis, but diverges perhaps from OSHA's choice in the 2013 analysis, where OSHA indicates in the PEA that the Agency has chosen 62.5 ug/m^3 to represent the range from 50 ug/m^3 to 100 ug/m^3. Note that we need to assign figures for the ranges below the proposed PEL because we assume that some workers in these ranges will incur some collateral exposure reduction as employers address overexposures of workers in higher exposure ranges at the same facilities as the workers in ranges below the proposed PEL.

- For exposures in the range from 100 ug/m^3 to 250 ug/m^3, we chose a single value at 150 ug/m^3. This is short of the midpoint at 175 ug/m^3, but higher than the figure of 125 ug/m^3 that OSHA indicates in the PEA the Agency may have chosen for the 2013 benefits analysis. In our view, 125 ug/m^3 is unrealistically low. Our rationale for 150 ug/m^3 is: a) Assuming the distribution of exposures is lognormal, in exposure ranges that approach being in the upper tail of the distribution, the geometric mean of all the values within a range will be at less than the midpoint of the range; b) NIOSH has stated that the distribution of worker exposures in any industry is typically lognormal, and NIOSH and statisticians generally agree that, for a lognormal distribution, the geometric mean is the best measure of central tendency for the entire distribution or for parts of the distribution (Leidel and Busch, 1975); c) In the sample of individual exposure values between 100 ug/m^3 and 250 ug/m^3 that we compiled from OSHA's exposure information for General Industry (see below), the arithmetic mean was 155 ug/m^3, the geometric mean was 149 ug/m^3 and the median was 140 ug/m^3. All these values are not much different from 150 ug/m^3

- For exposures exceeding 250 ug/m^3, we chose a value of 434 ug/m^3. We derived this value as follows. We found all individual sample values for General Industry workers exceeding 100 ug/m^3 that we could from among easily-accessed Docket and other materials. The materials that we accessed included: OSHA's 2003 and 2008 Technological Feasibility reports for General Industry (for a few of the industries, these reports included appendices that cite every data value among the exposure samples available for the industry), a special analysis that we did in 2011 on the Structural Clay Products industry where we determined the value of every exposure sample that OSHA had assembled for this industry, and 2 sets of NIOSH site visit reports where they cite each individual data point among a large number of samples taken at refractories and iron foundries. We thus accumulated 134 such data points. 71 of these exposure data points exceeded 250 ug/m^3. 25 of the 71 are for the Ready-Mix concrete industry and involve extremely high exposures in instances where various employees had been sampled for

single shifts or parts of shifts while chipping concrete out of cement trucks. This task is not one that employees perform more than a couple times a year, and no employee performing this task is likely to do it for 30 or more days per year. We reasoned that this task, and the samples obtained from the Ready-Mix industry involving this task, are not representative of average or long-term exposure for any General Industry employees. We excluded the 25 Ready-Mix samples exceeding 250 ug/m^3 from the 71 original data points exceeding 250 ug/m^3, resulting in a sample of 46 data points exceeding 250 ug/m^3. Among these 46 data points, the maximum was 1,900 ug/m^3, the arithmetic mean was 493 ug/m^3, the geometric mean was 434 ug/m^3, and the median was 382 ug/m^3. The exposure data from which these results were obtained is shown in the tab titled "Current Exposures > 100" in the Excel workbook that we are providing that shows all of our calculations and results for our analysis of benefits and costs. We chose the geometric mean value from among these data points as the representative figure for our analysis because the geometric mean is a better measure of central tendency than the arithmetic mean or other measures.

In Table 5, we also show what we believe are the single exposure values that OSHA chose for the Agency's benefit-cost analysis -- although we are quite uncertain about these values. In Appendix A to this report, we include several pages of discussion about the values that OSHA may or may not have chosen.

This discussion, among other points, highlights the lack of precision and transparency in OSHA's benefit-cost analysis. As best we can tell -- OSHA's analysis is opaque and the Agency nowhere presents their full calculations -- OSHA appears to have estimated total industry-wide exposure reductions for the benefits analysis that greatly exceed the total industry-wide exposure reductions that drive the Agency's cost analysis.[20]

Thus, the Agency's cost and benefits analyses are mismatched -- OSHA has estimated the monetary benefits for a large amount of exposure reductions, and compared that against the dollar costs needed to achieve a smaller amount of exposure reductions. We suspect that one of the reasons for this mismatch involves conflicting choices in the Agency's benefits and cost analyses regarding the particular exposure levels chosen as representative of the various ranges shown in Table 5. More discussion of this issue is provided in Appendix A.

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[20] By "total industry-wide exposure reductions" we mean to sum the exposure reductions provided for every affected employee in General Industry. Thus, if one employee accrues a reduction in exposure from 300 ug/m^3 to 50 ug/m^3 and another employee accrues a reduction from 100 ug/m^3 to 50 ug/m^3, then the total exposure reduction for these two employees is 300 ug/m^3 (250 ug/m^3 for the first employee, plus 50 ug/m^3 for the second employee).

It is apparent in OSHA's analysis that the total exposure reduction that drives the Agency's cost analysis is significantly smaller than the total exposure reduction that drives the Agency's benefits analysis, but we can't tell exactly what the particular figures are that OSHA has estimated in order to generate this result

We want to note specifically that the reason why OSHA has estimated a larger total exposure reduction for the benefits analysis than the cost analysis is **not** because of what we term later in this paper "collateral" exposure reductions -- which can result when a control measure that is implemented to reduce the exposure of a particular employee who is exposed at a level exceeding the PEL has the "collateral" effect of also reducing the exposures of other employees at the facility who are not exposed at levels exceeding the PEL.

Thus, in broad overview, there are two ways in which our calculations match costs against benefits in a manner different from how OSHA has done it in the Agency's analysis. First, we compare costs for 19 affected General Industry sectors and 212,000 exposed employees against benefits for all 25 General Industry sectors plus Maritime with an estimated 295,000 silica-exposed employees. Second, we take pains to ensure (for the 19 sectors for which we estimate both costs and benefits) that the estimated total industry-wide exposure reductions that serve to drive the cost analysis match the estimated total industry-wide exposure reductions that kick-off the benefits analysis.

In addition, while we use no exposure data other than that which is provided by OSHA , we interpret OSHA's data as suggesting higher current exposures levels than the Agency does (see Table 5). Both we and OSHA then estimate the costs to implement engineering controls to bring these exposures down below the proposed PEL. Given the higher current exposures that we assume, the exposure reductions that we estimate will be needed to attain the proposed PEL are larger than the exposure reductions that OSHA estimates will be needed. Thus, while the engineering control costs that we estimate are much higher than OSHA's, the exposure reductions that we estimate are significantly higher also. We think we are being much more realistic than OSHA in both respects.

E. Minimum Effectiveness of Engineering Controls Needed to Reduce Exposures to Below the Proposed PEL

We assume in our analysis that the exposure reductions necessary to meet the proposed standard will be much larger than OSHA assumes for the Agency's analysis. This is in part because we assume that current exposures are higher than OSHA assumes, as discussed above. But we also assume that the reductions will need to be deeper than OSHA estimates, for several reasons:

- First, for any group of workers that is overexposed relative to a PEL, the average exposure among members of this group will have to be reduced to half or less of the PEL in order to provide a high level of confidence that employee exposures will comply with the "never-to-be-exceeded" PEL all of the time after controls are implemented. We thus assume in meeting the current PEL of 100 ug/m^3 that employers with overexposed employees will need to reduce these employees' average exposures to 50 ug/m^3 or below. Similarly, average exposures will need to be reduced to 25 ug/m^3 or below in order to leave little likelihood that some employees will remain exposed above a PEL at 50 ug/m^3. OSHA, in contrast, presumes in the Agency's engineering cost analysis that controls need to be sufficient only to reduce average exposures exactly to the level of the PEL.

- Second, the shift to the ISO/CEN monitoring protocol as an element of the proposed standard will result in the capture of about 20% more respirable silica than would be the case under the current ACGIH protocol. To meet a PEL of 50 ug/m^3 with monitoring required pursuant to ISO/CEN, we assume that employers will need to achieve average exposures of 25 ug/m^3 (half of this PEL), which is equivalent to achieving average exposures of 20.83 ug/m^3 via the ACGIH protocol that OSHA currently employs.

URS developed their cost estimates for engineering controls, which we use for the cost portion of our benefit-cost analysis, in a manner that reflects only the second of these two points. URS has estimated costs to obtain exposure reductions consistent with the *de facto* lower standard entailed by the proposed switch to the ISO/CEN sampling protocol. URS has not, however, estimated costs for engineering controls in a manner that explicitly recognizes the need to reduce average exposures to half or less of any potential new PEL instead of reducing average exposures only to just below the new PEL (see, e.g., pages 18-19 of URS, 2014) .

Had URS estimated costs for engineering controls sufficient to reduce average exposures to well below the PEL, as we believe is necessary to avoid occasional exposures exceeding the PEL (and as we assume for our benefits estimates), URS would have estimated higher costs than they did. This represents another respect in which we estimate benefits for a quantity of employee exposure reductions that exceeds the quantity of employee exposure reductions that we/URS have presumed in estimating costs.

We make another assumption consistent with the URS cost analysis that further increases the exposure reductions that drive our benefits analysis. URS emphasized the importance of estimating costs for the engineering controls needed for compliance with the current or the proposed PEL on a facility-by-facility basis.

URS and we argued strongly against OSHA's "cost per overexposed employee" approach in which the Agency assumed that there is an average of four overexposed employees who will be protected each time that an appropriate package of control measures is implemented. Among other objections to this approach, for most of the small and very small affected facilities in General Industry, there are many fewer than four overexposed employees in each job category or area of a facility where a worker is overexposed and controls will be needed.

We believe that a facility-by-facility approach is much more appropriate for estimating how often controls will need to be implemented, based on information about how many workers at each type/size of facility are in each job category and how many of them are likely to be overexposed.

Consistent with this costing approach and contrary to OSHA's approach, we believe that controls that are implemented to reduce exposures for one or more overexposed employees will sometimes also reduce exposures collaterally for additional employees who are not overexposed but perform the same functions in the same area of a facility as the overexposed workers targeted with the controls.

For example, in a small facility where there are two employees in a particular job category or in the same area and only one of them is overexposed relative to the proposed PEL, the package of controls that will be implemented to reduce the exposure of the overexposed employee to below the proposed PEL will also reduce the exposure of the second employee, even though the second employee is exposed at a level that does not exceed the proposed PEL.

We make several assumptions in the course of estimating these "collateral" exposure reductions in our benefits calculations:

Table 6. Assumptions That Generate Estimated "Collateral" Exposure Reductions

% of General Industry facilities estimated now to have at least one worker exposed at ≥ 100 ug/m^3	30%
% of General Industry facilities estimated now to have at least one worker exposed at ≥ 50 ug/m^3	65%
% of General Industry facilities estimated now to have their most exposed workers exposed at between 50 and 100 ug/m^3	35%

Step 1 "collateral" reduction: average assumed exposure reduction that will occur for workers who are not overexposed currently, at facilities where compliance efforts will occur to get below current PEL at 100 ug/m^3	20%
Step 2 "collateral" reduction. After compliance has been achieved with the current PEL. Average assumed exposure reduction that will occur for workers who are not overexposed relative to the proposed new PEL, at facilities where compliance efforts will occur to get below the proposed new PEL at 50 ug/m^3	20%

The first set of assumptions is based roughly on URS' estimates obtained by applying "binomial expansion" techniques so as to convert OSHA's projections regarding worker exposures into estimates regarding compliance by facilities with the current and proposed PELs. The second set of assumptions represents our current estimates about the collateral or incidental exposure reductions that might occur among employees who are not targeted for exposure reductions at facilities where exposure reduction measures will need to occur because some employees are overexposed relative to a PEL and targeted for reductions.

F. We Estimate Much Larger Aggregate Reductions in Exposure Than OSHA Does

In our benefit-cost calculations, we combine all of the foregoing points regarding baseline exposures and exposure reductions with engineering controls into a series of tables like the one below:

Table 7. Exposure Reductions Involved in Compliance w/the Current PEL

Group of Workers in Terms of Current/Baseline Exposure (ug/m^3)	# Workers in General Industry	Assumed single exposure level for group (ug/m^3), after compliance
Exposed at ≥ 250	48,956	50
Exposed between 100 - 250	31,775	50
Exposed between 50 - 100 (at facilities w/exposures >100)	12,522	60
(at facilities w/out exposures > 100)	29,219	75
Exposed between 25 - 50 (at facilities w/exposures > 100)	15,999	30
(at facilities w/out exposures > 100)	37,330	37.5
Exposed between 0 - 25 (at facilities w/exposures > 100)	35,726	10
(at facilities w/out exposures > 100)	83,360	12.5
Total	294,886	

% of General Industry facilities now estimated w/exposures > 100:	30.0%
Avg. assumed exposure reduction for workers who are not overexposed currently, at facilities where compliance efforts occur to get below 100:	20.0%

In the following paragraphs, we will explain a few of the rows in the foregoing table showing the exposure reductions that we believe will be needed for employers to comply with the current PEL at 100 ug/m^3:

- First row: OSHA estimates there are 48,956 General Industry employees who are currently exposed at $\geq$ 250 ug/m^3. We estimate that these employees are exposed at a geometric mean of 434 ug/m^3. After their employers comply with the current PEL, these employees will be exposed at an average of 50 ug/m^3 (we assume that average exposure must be reduced to half of the PEL in order for individual workers only rarely to be exposed above the PEL).

- Second row: OSHA estimates there are 31,755 General Industry employees who are currently exposed between 100 and 250 ug/m^3. We estimate that these employees are exposed at an average of 150 ug/m^3. After their employers comply with the current PEL, these employees will be exposed at an average of 50 ug/m^3 (half of the current PEL, as for the previous group of employees).

- Third and fourth rows: OSHA estimates there are 41,741 General Industry employees who are currently exposed between 50 and 100 ug/m^3. We estimate that these employees are exposed at an average of 75 ug/m^3. We assume that 30% of all General Industry facilities with silica-exposed workers have worker exposures exceeding 100 ug/m^3, and that these facilities will need to implement engineering controls to reduce the exposures of their overexposed workers to below the current PEL. We assume that the 30% of facilities that will need to implement exposure reduction measures to comply with the current PEL also account for 30% of all workers. Thus, among the 41,741 General Industry employees who are currently exposed at between 50 and 100 ug/m^3, we estimate that 30% of them (12,522) are at facilities that will need to undertake measures to address overexposures relative to the current PEL and the remaining 70% (29,219) are at facilities where no exposure reduction measures will be needed.

  We then further assume that at facilities that do undertake exposure reduction measures, each of the workers who is not overexposed currently will accrue a "collateral" exposure reduction of 20% when the employer implements measures to reduce exposures for the employees who are overexposed. Thus, we estimate that all of the 12,522 employees at facilities where exposure reduction measures will be implemented will accrue the 20% collateral exposure reduction, from an assumed 75 ug/m^3 in the baseline to 60 ug/m^3. The remaining 29,219 employees out of this group of 41,741 (all those at facilities that do not have workers exposed above 100 ug/m^3 currently, and thus all those at facilities that do not need to implement exposure reductions) will accrue no collateral exposure reductions, and their exposures will remain at an average of 75 ug/m^3.

In our attached Excel workbook providing the calculations for our benefit-cost reanalysis, we include five tables of this sort that we use to estimate the exposure reductions associated with the various policy steps under consideration (see the tab titled "Reductions with Proposed PEL"). The five tables include:

1. Table 7, above, which shows the exposure reductions that we estimate will accrue when General Industry employers reduce their worker exposures from current levels to full compliance with the existing standard. This corresponds to the first step in our "two-step" conceptual approach that we describe beginning on page 2.

2. A second table that shows the incremental exposure reductions that we estimate will accrue when employers reduce exposures further, after they comply fully with the existing standard, to meet the proposed revised PEL at 50 ug/m^3.

3. A third table that shows another set of incremental exposure reductions that we estimate will accrue when employers reduce exposures even further, after they comply with the proposed revised PEL at 50 ug/m^3 measured pursuant to the traditional ACGIH protocol, to meet instead the proposed PEL when measured pursuant to the ISO/CEN protocol. The sum of these second and third tables corresponds to the second step in our "two-step" analysis -- the increment between compliance with the current PEL and compliance with the proposed standard.

4. A fourth table that shows the sum of our two steps together -- the exposure reductions that we estimate will result when employers progress all the way from current exposure levels (including some noncompliance with the current PEL) to compliance with the proposed standard, including both the reduced PEL and the requirement to sample using the ISO/CEN protocol. Interestingly, the summed exposure reductions that we estimate will occur from the two steps taken sequentially are slightly larger than the estimated exposure reductions shown in this fourth table when employers progress all the way from current exposures to compliance with the proposed standard in one step. Taking the two steps sequentially rather than in one large step involves slightly different and larger collateral exposure reductions.[21]

5. A fifth table that shows the exposure reductions that OSHA appears to estimate in the Agency's benefit-cost analysis.

In sum, in our calculations reanalyzing benefits and costs, we make several major changes to OSHA's approach for estimating exposures and exposure reductions that have the effect of

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[21] Again, as we mentioned previously, we do not believe that employers will explicitly take these two steps sequentially, in the sense of installing equipment and taking other measures as necessary to comply fully with the current PEL, and then altering or removing this equipment and installing new equipment and taking additional measures as necessary to comply fully with the proposed PEL. Taking these two steps sequentially would likely require expenditures somewhat larger than taking the aggregate of these two steps in one step.

Similarly, we do not mean to imply in our analytical discussion on the preceding page regarding the various increments of exposure reduction (e.g., the increment necessary to comply with the proposed PEL with monitoring conducted pursuant to the ISO/CEN protocol rather than the ACGIH protocol) that these increments will be achieved sequentially. Employers will likely aim to take the series of steps or achieve the series of exposure reductions in a least-cost manner, aiming to proceed directly from the current state of affairs to compliance with all of the requirements of the standard in one comprehensive set of actions. Again, though, as we discussed previously, employers will likely not have sufficiently accurate *ex ante* knowledge about the costs and performance of controls to support taking a single large step to achieve compliance, and a more incremental, "trial and error" approach is more probable.

making our estimates of the exposure reductions associated with the proposed rule much larger than OSHA's estimates.

First, we estimate the "full" exposure reductions associated with the proposed standard, consisting of two steps: i) from current exposures to compliance with the existing standard; and ii) from compliance with the existing standard to compliance with the proposed standard, including ISO/CEN. OSHA, in contrast:

- Addresses in the benefit-cost analysis only the incremental step from compliance with the existing standard to compliance with the proposed standard.

- Fails to recognize and estimate the additional exposure reduction needed with the proposed change to the ISO/CEN protocol.

- Assumes that employers will comply with the current PEL by reducing to levels below the proposed PEL the exposure of all 80,731 workers estimated as now exposed above the current PEL of 100 ug/m^3. OSHA should instead assume that, if the current PEL were strictly enforced with the aid of compliance assistance, employers would comply by reducing exposure for these currently overexposed workers only to below 100 ug/m^3, not below 50 ug/m^3. As a result of this error, OSHA wrongly attributes to the existing standard much of the incremental exposure reduction that would instead be required by the proposed new standard. OSHA ultimately estimates the incremental exposure reduction required by the proposed new standard as consisting of only the reduced exposures among the estimated 41,741 General Industry employees who are currently exposed at between 50 ug/m^3 and 100 ug/m^3. The incremental exposure reduction required by the proposed new standard also should include the reduction in exposure from 100 ug/m^3 to 50 ug/m^3 that will be needed for the 80,731 workers estimated as now exposed above the current PEL. OSHA has estimated that the proposed new standard will require incremental exposure reductions for only about 1/3 as many employees as will actually need such reductions.

Second, based on statistical reasoning and some analysis of OSHA's exposure data, we assume higher values than OSHA assumes as representing the typical or mean exposure levels within a range of current worker exposures, as discussed earlier (see Table 5).

Third, we assume that engineering controls will need to reduce the average exposure of overexposed employees to half of the PEL in order for the exposures of all employees to be maintained reliably at levels below the PEL. OSHA's analysis, by contrast, presumes (at least implicitly) that the average exposure level for overexposed employees needs to be reduced only to the PEL.

Fourth, we assume realistically that engineering controls implemented to reduce the exposure of overexposed employees at a facility will also "collaterally" reduce the exposure of other employees at the facility who are not overexposed. OSHA assumes that engineering controls are so precise as to reduce exposures only for the particular overexposed employees who are targeted with the controls.

Some of these larger exposure reductions that we estimate relative to OSHA's estimate are a consequence of the more intensive/extensive and more costly engineering controls that URS has estimated will be needed relative to OSHA's estimate -- the additional controls, additional costs and additional exposure reductions that we estimate when we consider in our analysis the proposed switch to ISO/CEN, for example.

But others of the additional exposure reductions that we estimate relative to OSHA's estimate are, in a sense, costless. We simply believe that it is realistic to recognize the "collateral" exposure reductions for workers who are not overexposed that will result from the engineering controls that we and OSHA have costed out to reduce exposures for overexposed workers. There is no additional cost for these collateral exposure reductions.

Nor has URS estimated costs in a manner that recognizes the likely higher costs that would be required if engineering controls were selected and sized so as to reduce exposures on average to half of the PEL rather than only to the PEL or slightly below.

Table 8, following, shows the much greater exposure reductions that we estimate in our benefit-cost reanalysis relative to OSHA's estimates. For Table 8, we have created an "index" of exposure reduction, which is measured in units of (ug/m^3) x (workers/1,000). For example, two thousand workers each getting an exposure reduction of 1 ug/m^3 will yield an index value of 2, as will one thousand workers each of whom get an exposure reduction of 2 ug/m^3.

Table 8. We Estimate Much Larger Reductions in Worker Exposures than OSHA Does [measured as an index expressed in units of (ug/m^3) x (workers/1,000)]

Action that is Analyzed	Exposure Reduction (Index Value)
Our estimates:	
Full compliance w/current PEL/standard (from current exposures) -- Step 1	22,391
Increment from current standard to proposed standard (incl ISO/CEN) -- Step 2	5,330
Total for both steps sequentially -- "Full" exposure reduction	27,720
From current exposures to proposed standard (incl ISO/CEN) -- "Full" exposure reduction, but for the aggregate of both steps	27,460
OSHA's estimates:	
Full compliance w/current PEL (from current exposures) -- Step 1	Not estimated
Increment from current PEL to proposed PEL (not incl ISO/CEN) (*sic* *) -- Step 2	522
Increment from current PEL to proposed PEL (not incl ISO/CEN)** -- Step 2	4,558

* OSHA wrongly assumes that workers now exposed above the current PEL will have their exposures reduced all the way below the proposed PEL when employers fully comply with the current PEL. To the contrary, if OSHA were to enforce the current PEL and provide compliance assistance rather than establish the lower proposed PEL, employers would reduce exposure for their currently overexposed workers only to below the current PEL, not the proposed PEL. The proposed standard will require further, incremental reductions in exposure for these workers. OSHA thus estimates wrongly that the proposed standard will require incremental exposure reductions only for workers now exposed at between the current and the proposed PELs.

** This is what OSHA would estimate if the Agency were to assume properly that workers now overexposed relative to the current PEL will have their exposures reduced only to the current PEL when their employers fully comply with the current PEL. The proposed standard will require incremental exposure reductions for these workers (from 100 to 50), as well as for workers now exposed at between the current and the proposed PELs.

It would require many pages to explain all the reasons why our estimates differ from OSHA's, largely because we have made numerous revisions to OSHA's exposure analysis in our calculations. Some of our revisions cause the estimated exposure reductions to increase and others cause the estimated exposure reductions to decrease, and it is difficult to disentangle the often countervailing impacts of the individual revisions.

We will provide only a couple of relatively straightforward observations:

- According to our estimates, more than 80% of the exposure reductions that the proposed standard might generate relative to current worker exposures will derive from full compliance with the current PEL (22,391/27,460 = 81.5%). The incremental requirements of the proposed standard (reduced PEL and switch to ISO/CEN) will add relatively little further reduction in exposures to what would be accomplished upon full compliance with the current PEL. (This pattern is the opposite of that for costs -- 77% of

the costs derive from Step 2, and only 23% derive from compliance with the current PEL. See Table 1.)

OSHA's analysis appears to provide an opposite conclusion, suggesting instead that the great majority of the exposure reduction would accrue from reducing the PEL from 100 ug/m^3 to 50 ug/m^3 rather than from full compliance with the current PEL. See OSHA's summary table, shown as Table 3 in this report. However, OSHA's table is misleading, and the Agency's analysis does not support this conclusion.[22]

OSHA's errors in accurately projecting what General Industry employers will need to do to meet the additional requirements of the proposed standard (relative to the existing standard) are sufficiently large as to result in underestimating the incremental exposure reductions by a factor of nearly 10 (522 vs. 4,558), without even considering the further exposure reductions needed with the proposed shift to ISO/CEN.

- OSHA judges wrongly what employers will likely do to comply with the existing standard, overestimating the exposure reductions that will be accomplished via compliance with the current PEL and thereby underestimating the additional exposure reductions that will be needed for compliance with the proposed PEL. The Agency wrongly estimates that the proposed new standard will require exposure reductions and impose costs only with respect to the 42,000 workers now exposed at between 50 and 100 ug/m^3, overlooking the much larger exposure reductions and costs for the 80,000 General Industry workers now exposed at levels exceeding 100 ug/m^3. See the * and ** notes for Table 8, above. OSHA also fails to account for the impact of the proposed switch to ISO/CEN as an element of the proposed new standard, which will require further exposure reductions and costs.

G. Assumed Duration of a Worker's Lifetime Exposure to Crystalline Silica

For how long, on average, does a silica-exposed General Industry worker remain exposed to crystalline silica? The health risks associated with crystalline silica exposure and the benefits of any tighter standard depend to some degree on whether turnover in the workforce exposed to crystalline silica is slow or rapid; on whether the total number of labor hours that workers spend exposed to crystalline silica consists of many workers who spend relatively few years performing

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[22] Although OSHA's summary table (shown in this report as Table 3) appears to portray the benefits and costs of compliance with the existing standard in comparison to the incremental benefits and costs stemming from the proposed standard, this appearance is misleading. The comparison actually shown in OSHA's table is between the benefits and costs of a hypothetical regulation that reiterates the current PEL and establishes the proposed set of ancillary requirements, and the incremental benefits and costs of tightening that hypothetical standard by reducing the PEL to 50 ug/m3.

In fact, nowhere in OSHA's analysis does the Agency develop an estimate of the benefits or the exposure reduction that will accrue from full compliance with the existing standard. OSHA's analysis addresses only the incremental exposure reduction benefits and costs of the proposed new standard relative to the existing standard.

silica-exposed jobs, or conversely fewer workers who spend many more years -- perhaps even their full working lives -- performing silica-exposed jobs.

OSHA conducts the Agency's benefits analysis assuming that all silica-exposed work in General Industry is performed by individuals who spend an entire 45-year working lifetime, from ages 20 to 65, performing this work.

As a sensitivity analysis in the risk analysis and the benefits analysis the Agency assumes alternate shorter average durations of employment -- 25 years, 13 years and 6.6 years. The more rapid rate of employee turnover reflected by these shorter assumed durations implies a corresponding increase in the total number of exposed workers over time such that the total number of exposed worker-years remains constant.

In reviewing the results of the Agency's sensitivity analyses assuming this range of alternative durations from 6.6 to 45 years, OSHA concludes that: "The aggregate estimated benefits of the rule appear to be relatively insensitive to implicit assumptions of average occupational tenure." (PEA, page VII-6)

In fact, depending on the nature of the exposure-response function being considered, the assumed duration of exposure -- fewer workers for many years each, or more workers for fewer years each, with the total number of worker-years remaining constant -- can make a very large difference in estimating current/baseline risks and the risk reduction associated with the proposed standard.

For example, as discussed in the box below, using one of OSHA's chosen exposure-response relationships, revising the assumed average duration of exposure from 45 years downward to 9 years (while assuming five times as many workers) will reduce the risks that are estimated among the two different populations of workers by more than 80%.

This is a comparison of the silicosis mortality risks faced by two different hypothetical populations of General Industry workers. At company A, 50 workers are each exposed to crystalline silica at a constant 200 ug/m^3, and each worker works a full 45 years at this exposure level, as OSHA assumes. After the 45 years ends, each of these workers at company A has cumulative exposure of 9 mg/m^3-years, and has faced a lifetime risk of silicosis mortality of 2.42 x 10^{-2}, as calculated from the Mannetje et al. (2002) categorical exposure-response function, one of those cited by OSHA in the risk assessment. The population risk for all 50 company A workers is thus 50 x 2.42 x 10^{-2}, or 1.21 expected silicosis fatalities over the 45 years.

Company B is nearly identical to company A. As at company A, at B there are 50 workers employed at any one time, and each of them is exposed to crystalline silica at the same constant level of 200 ug/m^3. However, at company B, each worker leaves after 9 years of employment and takes some other non-silica-exposed job elsewhere for the remainder of his working life (9 years is close to, actually a little longer than the median duration of lifetime silica exposure that we estimate now prevails in the industries potentially affected by the proposed standard). Over the next 45 years, in each job slot at company B there will thus be a succession of 5 workers, each leaving and being immediately replaced after 9 years. Company B thus has 250 workers over the 45 years that we are considering, each exposed for 9 years at a constant 200 ug/m^3, for a cumulative exposure of 1.8 mg/m^3-years for each of them. Based on OSHA's chosen exposure-response function, each of these workers would face a lifetime risk of silicosis mortality of 8.76 x 10^{-4}. The population risk for all 250 company B workers is thus 250 x 8.76 x 10^{-4}, or 0.219 expected silicosis fatalities over the 45 years.

In sum, the aggregate population risk for the larger number of shorter-term workers at company B is less than 1/5th that for the smaller number of longer-term workers at company A, despite the exposure concentrations and the total number of work-years being the same at the two companies. If OSHA is going to use an exposure-response function that estimates a worker's risk as a function of his cumulative dose or exposure, the Agency should use accurate assumptions about workers' job tenure and turnover rates. Blindly assuming that all workers work for a full 45-year working lifetime can lead in such a case as this one to greatly overestimating the risk reduction and benefits that will result from a potential new silica regulation.

Alternatively, in an instance where an exposure-response function has a shape/curvature opposite to that of the categorical function estimated in Mannetje et al. (2002) and used in this example, the opposite result could occur -- total risks across an entire worker population could decrease rather than increase assuming fewer workers but with each exposed for a full 45 year working lifetime. The duration of employment and exposure to silica is important and the risk and benefits assessments should reflect the best data possible on what the duration of employment actually is.

In the example discussed above, the Mannetje et al. (2002) categorical exposure-response function estimates the silicosis mortality rate or risk as a convex function of cumulative exposure across nearly the entire relevant range of cumulative exposures.[23] An exposure-response function that is convex with respect to cumulative exposure will result in an increase in estimated population risks as the set of exposed workers turns over less frequently and works longer. For such a function, when OSHA assumes unrealistically that all exposed workers will continue in

[23] A function is said to be convex in a range if, over that range, it has a slope that is monotonically increasing or if the second derivative of the function is positive. One can think of a convex exposure-response function as having the property that, over the relevant range, if one doubles the exposure that a worker receives, the risk faced by the worker will more than double. The Mannetje et al. exposure-response function for silicosis mortality is convex over the range from zero cumulative silica exposure through 9.58 mg/m^3-years, or up to the cumulative exposure that would be received by a worker working a full 45-year working lifetime at a crystalline silica concentration of 213 ug/m^3. In other words, the Mannetje et al. function is convex over nearly the entire range of possible relevant current worker exposures.

their jobs for an entire 45-year working lifetime, OSHA will overestimate risks and benefits -- sometimes very substantially if the convexity is significant, as in the example.

On the other hand, an exposure-response function that is concave with respect to cumulative exposure will result in a reduction in estimated population risks as the set of exposed workers turns over less frequently and works longer, and when using a concave function OSHA will underestimate risks and risk reduction by assuming unrealistically that all workers will continue in their jobs for an entire 45-year working lifetime.

In sum, when OSHA finds in the Agency's sensitivity analysis that benefits appear relatively insensitive to average tenure, this finding has resulted only because some of the particular exposure-response functions the Agency chose predict larger population risks with less worker turnover and others predict the opposite.

It is only due to happenstance that the several of the Agency's chosen exposure-response functions that make risk a convex function of cumulative exposure are roughly counterbalanced by the several others of the Agency's chosen exposure-response functions that instead make risk a concave function of cumulative exposure. For a different set of exposure response functions (and perhaps for the specific, more limited set that we have chosen for our reanalysis of benefits and costs), the results could be very different.

OSHA notes in the PEA that the Agency is required by the OSH Act to assume that workers will remain exposed to silica at the level in question for a full working lifetime in determining whether a significant risk exists. The Agency cites this direction as then also justifying the assumption of exposure for a full working lifetime for the Agency's benefits analysis:

> "Given that it is necessary for OSHA to reach a determination of significant risk over a working life, it is a logical extension to estimate what this translates into in terms of estimated benefits for the affected population over the study period." (PEA, page VII-5)

We disagree. Benefits analysis is conducted as a portion of a benefit-cost analysis for reasons other than assisting in the significant risk determination. The Agency's aim in a benefit-cost analysis should be to estimate benefits and costs as accurately as possible under the conditions that are likely to prevail in the real world. For the benefits analysis, OSHA should estimate risks and risk reduction using assumptions about employee tenure that are as accurate as possible rather than assuming inaccurately that all employees remain exposed over a full working life.

For our recalculation of benefits, we would like to estimate baseline risks and risk reduction using more accurate data about the durations of affected workers' silica exposures. Such data is difficult to find. The ideal would probably be data from employers in the affected industries on the lengths of time that their employees in jobs with silica exposures have been in these jobs. Such data do not appear to be available.

The best we have been able to do is to access data collected every two years by the Bureau of Labor Statistics (BLS) on "employment tenure", defined as the length of time that an employee has been employed by his current employer. Information on workers' employment tenure in

industries with silica exposure probably provides a rough guide to how long workers who are exposed to silica remain exposed:

- On the one hand, a worker's duration of silica exposure may be longer than his or her employment tenure if s/he switches from one silica-exposed job with one employer to a different silica-exposed job with another employer. While this is undoubtedly common among construction workers, we judge it as much less common among General Industry workers. OSHA estimated in the PEA that about 295,000 individuals worked in silica-exposed jobs in General Industry in 2006. The great majority of these individuals were production workers. BLS' Occupational Employment Statistics for 2006 shows 10.3 million workers in production occupations in that year, meaning that there were about 34 production worker jobs without exposure to crystalline silica for every one job with exposure to crystalline silica (10,000,000/295,000 = 34:1). While there is perhaps some tendency for a silica-exposed production worker in General Industry to switch to a similar job that also involves silica exposure when he or she changes jobs to a different employer, most of these jobs are not very highly skilled and the sheer number of non-exposed production jobs suggests that the great majority of job changes by exposed workers will be to other production jobs without exposures.

- On the other hand, a worker's duration of silica exposure may be shorter than his or her employment tenure if s/he switches from a silica-exposed job to a non-silica-exposed job with the same employer. OSHA estimated in the PEA that there were 4.4 million jobs in the General Industries within which the 295,000 silica-exposed employees worked. In OSHA's Technological Feasibility studies in 2003 and 2008, the Agency provided estimates for most of the General Industries for both the number of production workers in the industry and the number of production workers in each industry who were judged at risk of silica exposure. Table 9 below shows the percentage of production workers in each General Industry that OSHA judged to be at risk of silica exposure.

Table 9. Many Production Jobs in General Industry are Not at Risk of Silica Exposure

Industry	% of Production Workers at Risk
Structural clay products	46
Pottery	62
Concrete products	61
Glass products	6
Jewelry	41
Paints and coatings	33
Cut stone products	47
Refractory products	35
Foundries other than captive	42

For most of these industries, OSHA judged that there are more production workers not exposed to silica (at risk) than are exposed to silica. We believe this suggests that there is substantial opportunity for a production worker in General Industry to spend some of his

or her tenure with a particular employer in a silica-exposed position and some in a different position that is not-silica exposed.

On balance, we believe that these two factors might approximately offset each other, and the BLS figures for employment tenure in an industry could thus roughly match the average duration over which a silica-exposed worker in that industry is exposed to silica during his or her working life.

In the first row of data in Table 10, below, we show the most recent BLS data (reflecting January, 2014) on employment tenure for all employed U.S. male workers over the age of 16. This row shows, for example, that only 10.6 % of all such workers have been employed by their current employer for 20 years or more -- a figure suggesting the wide magnitude of error in OSHA's assumption that 100% of silica-exposed workers remain so for 45 years.

Table 10. Distributions of Employment Tenure in January, 2014

	Percentage of employed workers by tenure with current employer										
Group	12 months or less	12 - 23 months	2 - 3 years	3 - 4 years	5 - 9 years	10 - 14 years	15 - 19 years	20 years or more	Total	Median Years	Average Years
BLS: All male workers, age 16 and over	21.3	6.4	5.3	16.5	21.5	12	6.5	10.6	100	5.1	8.3
BLS: All male workers, age 20 and over	19.7	6.2	5.2	16.8	22.2	12.3	6.7	10.9	100	5.5	8.5

Median tenure by industry, age 16 and over:	
Manufacturing	5.9
Nonmetallic mineral products	7.6
Primary metals and fabricated metal products	6.1
Electrical equipment and appliances	5.8
Miscellaneous manufacturing	5.1
Petroleum and coal products	6.1

Source: U.S. Bureau of Labor Statistics. Economic News Release. Employee Tenure in 2014. September 18, 2014

The particular General Industries that will be affected by the potential new silica standard undoubtedly have employment tenure distributions that differ from the economy-wide figures shown in the first row.

There are a variety of reasons why one industry may generally have more or less experienced workers than another industry, including skill requirements, whether the industry is new or mature and is growing or shrinking, the degree of unionization, etc.

BLS does not provide employment tenure data for individual industries at the same level of detail as it does for the entire economy. For individual industries, BLS provides only information on median employee tenure, and not the information on the full distribution of employment across various tenure categories as shown on the first row.

The second portion of Table 10 shows the data reported by BLS for those individual industries or aggregations relevant to the affected General Industries. Median employee tenure is shown for manufacturing generally and for each of the aggregated industries within which one or more of

the affected General Industries is included. We take the following steps in estimating from the data in Table 10 what tenure might be in the affected General Industries:

- We believe that the focus of the BLS data on employment tenure for male workers only is probably acceptable for extrapolation to the General Industries insofar as the vast majority of General Industry production workers are male.

- The data for workers age 20 and over is more relevant to our concerns here than is the data for workers age 16 and over. However, the BLS does not provide industry-specific information for workers age 20 and over, instead providing industry-specific data only for workers age 16 and over, as shown in the bottom portion of Table 10. It appears that median and average tenure for workers age 20 and over may be 0.2 to 0.4 years longer than the comparable figures for workers age 16 and over.

- For our risk and benefits calculations, we need information on average worker tenure rather than information on median worker tenure. BLS does not provide information on average worker tenure. However, we estimated average worker tenure from the BLS data by assuming that all individuals in each tenure group are employed for a duration equal to the midpoint of the tenure group range.[24] The resulting figures shown in the rightmost column as "Average Years" thus derive from our calculations and have not been reported by BLS.

- The five aggregated industries within which the General Industries are included and for which BLS reports median tenure information (bottom five rows of Table 10) have average median tenure of 6.14 years. We will assume this figure represents the median tenure for workers 16 years and older for the General Industries affected by the Proposed Standard. This median tenure figure for the General Industries is 1.04 years higher than the corresponding median tenure figure of 5.1 years for workers 16 years and older as reported by the BLS for the entire economy.

- To the estimated average tenure for male workers age 20 and over across the entire economy -- 8.5 years -- we add this figure of 1.04 years to reflect the typically longer tenure in General Industry relative to the economy as a whole. The result is a preliminary estimate that average tenure for workers age 20 and older in General Industry is about 9.54 years.

We suppose as discussed earlier that the average duration of silica-exposed employment in General Industry is approximately equal to the average tenure of a worker in General Industry with that worker's current employer. We thus might assume that the average duration of silica exposure for a General Industry worker who is exposed to crystalline silica is 9.54 years. For our calculations, we will round this figure upward to 10 years. We will thus assume that General Industry workers who are exposed to crystalline silica will incur an average of 10 years of exposure during their working lifetimes. We believe this assumption is much more realistic than

[24] For our calculations, for example, for workers age 16 and over in the 5 - 9 years tenure group, we assume that this 21.5 % of workers has all been employed for 7 years, the midpoint between 5 and 9 years. For the ≥ 20 years group, we assumed based on fitting a lognormal distribution to the data, that the average tenure is 31.5 years.

OSHA's 45-year assumption, and the difference between these two assumptions may cause a substantial difference between the baseline risks and regulatory benefits that we estimate and that OSHA estimates.

The age at which occupational exposure to crystalline silica begins also has some impact on the estimated risks, though not nearly as large an impact as the duration of exposure. In general, the later that exposure is assumed to begin, the lower the resulting lifetime risks through any particular age (e.g., through age 85 as OSHA and we presume when applying the exposure-response function for silicosis mortality from Mannetje et al. (2002)).

OSHA assumes that the 45-year full working lifetime of exposure that the Agency applies in risk calculations begins at the employee's age 20. We assume that the 10-year average working lifetime of exposure that we apply begins at the employee's age 30. In our attached Excel workbook showing our benefit-cost calculations, we show the results for some alternative assumptions regarding the age at which employee exposure begins. In general, if we were to assume that the 10 years' worth of exposure begins at age 20 rather than at age 30, the risks that we estimate would increase by less than 5%.

H. Dollar Values For Each of the Avoided Health Effects

In order to express benefits in monetary terms so that they may be compared directly against costs that are expressed in monetary terms, both OSHA and we must assign values to each of the sorts of health effects that may be avoided as a result of the proposed standard. The following table summarizes the values for each avoided health effect that OSHA applied in the Agency's analysis and that we applied in ours.

Table 11. Unit Values for Avoided Health Effects (in 2009 dollars)

Avoided Health Effect	OSHA's Valuation	Our Valuation
Death from lung cancer or silicosis	$8.7 million in 2009 dollars per avoided fatality (value of a statistical life – VSL), based on Viscusi and Aldy (2003) updated to 2009. Sensitivity analysis is performed to reflect potential future increase in VSL with increasing per capita real income. OSHA suggests assuming VSL will increase in the future at 2%/yr.	We use a lower VSL value of $7.96 million in 2008 dollars as recommended by the US EPA. We apply OSHA's suggested increase of 2%/yr.
Death from NMRD other than silicosis or from renal disease	Same as above	Values for mortality from NMRD other than silicosis and from renal disease are not needed since we do not believe these conditions are caused by silica exposure.
Silicosis morbidity	Range from low estimate of $62,000 per case to high estimate of $5.1 million per case. Midpoint is $2.58 million per case.	Most of OSHA's estimates, including the low and high estimates, are for illnesses other than silicosis and are inappropriate. OSHA's high estimate is particularly inappropriate. We use the best one of OSHA's estimates, $317,000, from Miller (2005) for a case of moderately severe silicosis.
Morbidity prior to death from lung cancer, NMRD other than silicosis, renal disease	The same values are applied for morbidity prior to death from these diseases as for silicosis. Range from low estimate of $62,000 per case to high estimate of $5.1 million per case. Midpoint is $2.58 million per case.	Values for morbidity prior to death from NMRD other than silicosis and from renal disease are not needed since we do not believe these conditions are caused by silica exposure. We add $51,211 (1996$) for avoided health care costs prior to death from lung cancer (EPA, 2007).

Below we provide comments on these chosen values.

1. Value of avoided mortality

In valuing the deaths prevented by the proposed standard, OSHA applies a value of a statistical life (VSL) of $8.7 million in 2009 dollars, drawn from an analysis of wage-risk studies by Viscusi and Aldy (2003) and then updated to 2009 by using the gross domestic product (GDP) deflator.

The U.S. Environmental Protection Agency has performed extensive work on the issue of valuing mortality risks that has included consideration of the Viscusi and Aldy study and contingent valuation-based estimates as well as wage-risk studies, and recommends in the Agency's updated Guidelines for Preparing Economic Analyses a default value of $7.9 million in 2008 dollars. EPA's air office often uses a value of $6.3 million in 2000 dollars (equivalent to $7.6 million in 2009 dollars). Other meta-analyses (Mrozek and Taylor, 2002, and Kochi, et al. 2006) have derived VSL figures lower than the estimate that OSHA draws from Viscusi and Aldy. For our analysis we have applied the EPA's recommended default figure of $7.9 million

in 2008 dollars which, when updated to 2009 dollars by applying the GDP deflator becomes $7.96 million.

We agree with OSHA that it would be appropriate to increase the VSL figure to reflect expected future growth in real income. For our calculations, we have accepted OSHA's suggested approach of increasing this value by 2% per year. Research sponsored by the U.S. EPA indicates, however, that the income elasticity of willingness to pay (WTP) for health risk reductions is substantially less than unity, and it is lower for less severe health effects than for more severe health effects (see, for example, U.S. EPA, 2014, pages 5-71 through 5-75). We suggest that OSHA review the literature on income elasticity of WTP for health risk reductions and projections regarding future growth in real income and develop an appropriate estimate. We suspect that this estimate will be somewhat less than 2% per year.

2. Value of an avoided case of silicosis

OSHA's range of estimated values for an avoided case of silicosis is inappropriate. The Agency's low estimate of $62,000 per case of silicosis avoided derives from studies of what OSHA terms "simple accidents", but these have nothing to do with silicosis. These studies actually estimated the value of avoiding an on-the-job injury, and we see little reason why the average cost of an on-the-job injury or the average value of avoiding an on-the-job injury should be similar to the average cost per case of silicosis or the average value of avoiding a case of silicosis.

OSHA's high estimate of $5.1 million per avoided case of silicosis represents 58.3% of the Agency's assumed VSL of $8.7 million, with the 58.3% figure deriving from one study's estimated value of avoiding a non-fatal case of cancer (lymphoma, specifically) relative to the value of avoiding a fatal case of that cancer. The 58.3 % figure derives from old research (Magat, Viscusi and Huber, 1996) that has very occasionally been used by EPA to value avoided non-fatal cancers, but to our knowledge EPA has never used this approach to value any avoided health effects other than cancers. More particularly, the 58.3% figure was not developed (and has not previously been used) to value the avoidance of silicosis.

OSHA appears to suggest also a mid-range estimate for valuation of health impairment due to silica exposure of approximately $460,000 in 2009 dollars for a case of chronic bronchitis. This figure reflects an EPA estimate that OSHA had used as the basis for comparison with less severe lung impairments from diacetyl exposure in the Agency's analysis supporting a standard for this substance. Again, OSHA has not indicated how or why the value of avoiding a case of chronic bronchitis or a case of a less severe lung impairment from diacetyl exposure should be similar to the value of avoiding a case of silicosis from exposure to respirable crystalline silica.

The only reasonable estimate that OSHA presents for the value of an avoided case of silicosis that was developed for this disease specifically was developed by Miller (2005), a researcher under contract to OSHA. This estimate is $265,808 per case in 2002 dollars, or $317,000 in the 2009 dollars that OSHA uses for the PEA analysis. The estimate is specific to silicosis and is quite comprehensive, including amounts for medical costs, productivity losses (work loss, long-term disability plus household productivity losses), administrative/legal costs and quality-of-life decrements based on willingness to pay estimates. It is intended to reflect the lifetime value to

both the afflicted individual and to society at large of avoiding a case of silicosis. The inclusion of values to society at large as well as to the ill individual is commendable and relatively rare among estimates that have been developed for the value of avoiding a case of a chronic illness. In our view, the Miller estimate would represent an excellent single choice as the value of an avoided case of silicosis, far preferable to OSHA's range from $62,000 per case (for accidents, with no relation to silicosis) to $5.1 million (for nonfatal lymphoma, again with no relation to silicosis).

The Miller (2005) estimate is based specifically on the value of avoiding a case of silicosis that results in hospitalization, and thus is perhaps most applicable for a silicosis case with severity greater than that on average for an individual with a 2/1+ radiograph, as would be needed to mesh with the number of cases as estimated using the one of OSHA's chosen silicosis morbidity exposure-response functions (Buchanan, 2003) that both OSHA and we have chosen for benefits analysis. This estimate does not include any component reflecting the fraction of cases that prove to be fatal or any associated VSL figure. It thus reflects the cost/case for a nonfatal but relatively severe case of silicosis. Note that the cost per case developed by Miller (2005) would be much too high to represent the average cost per case for the often non-symptomatic cases with radiographs of only 1/0 or 1/1 as are quantified by the various silicosis morbidity exposure-response functions that OSHA presents other than Buchanan (2003). Miller's estimated value per case avoided would thus not be appropriate for OSHA to use in valuing the mild cases of silicosis projected using most of OSHA's silicosis morbidity exposure-response relationships.

It is debatable whether the value per case for silicosis developed by Miller (2005) should be increased for future years to reflect projected increasing real incomes. It is thought generally that the components of a value per case avoided that are based on willingness to pay will increase over time as the income of those who provided the WTP information increases, but components of value based on other measures (e.g., cost of illness, averting cost) will not increase with income. A relatively small share of the Miller (2005) value for an avoided cost of silicosis is based on WTP, so we have chosen not to increase this value in future years.

Having valued an avoided case of silicosis as within a range spanning nearly two orders of magnitude from $62,000 to $5.1 million, OSHA makes the same error as in others of the Agency's calculations by developing a point estimate at the midpoint of the range. Again, when the low end value for a range is a small fraction of the high end value for the range, the midpoint estimate necessarily approaches half of the high end value, and all estimates for the value in question other than the highest estimate become nearly irrelevant. OSHA's point estimate for the value of an avoided case of silicosis becomes about $2.5 million, approximately half of the high end value of $5.1 million, reflecting Magat, Viscusi and Huber's estimate to the effect that the value of an avoided case of non-fatal lymphoma is 58.3% of the VSL. OSHA's point estimate for the value of an avoided case of silicosis thus reflects a single estimate for the value of avoiding an entirely different disease, and ignores the much more appropriate estimate specifically for silicosis that was developed by OSHA's contractor, Miller.

3. Value of avoided morbidity associated with diseases other than silicosis that OSHA contends are caused by silica exposure

In our view, then, the range of values and the point estimate that OSHA applies in valuing an avoided case of silicosis are inappropriate in application to silicosis. However, OSHA goes further by contending that this range also represents the value of the morbidity that will be avoided when a case of any other illness that OSHA contends is caused by silica exposure is avoided. OSHA thus applies this range and the $2.5 million point estimate to represent the value of the morbidity avoided when a case of lung cancer is avoided, when a case of end-stage renal disease is avoided, or when a case of non-malignant respiratory disease (NMRD) is avoided. We have several objections to this approach.

First and most obviously, these three sorts of diseases that OSHA is seeking to value are, like silicosis also, substantially different from the particular diseases for which the valuation figures were derived. OSHA has provided no persuasive reasoning as to why the morbidity associated with a case of lung cancer, renal disease or NMRD should be similar to the morbidity associated with non-fatal lymphoma or occupational accidents. Rather than blindly assuming that the morbidity valuations for these diseases are identical, OSHA would be much better served by developing valuation estimates for these three sorts of diseases specifically. Substantial literature exists regarding the valuation of morbidity for each of these three sorts of diseases, some of which literature OSHA references – but then fails to use – in the PEA. A few examples of this literature:

- For lung cancer (as well as respiratory illnesses), EPA has compiled information on morbidity values in the Agency's "Cost of Illness Handbook" (U.S. EPA, 2007). See also Yabroff, et al., (2011).

- For renal disease, OSHA cites one estimate in the PEA (page VII-15). See also Khan and Amedia (2008) and materials referenced by the American Society of Nephrology.[25]

- For non-malignant respiratory diseases, OSHA cites three estimates in the PEA, one for chronic bronchitis (page VII-14), one for less severe lung impairments from diacetyl exposure (page VII-14) and one for pneumoconioses other than silicosis (page VII-15). EPA provides many value estimates for illnesses and conditions resulting from inhalation of respirable particles in the Agency's economic analysis relating to the National Ambient Air Quality Standards for particulate matter (U.S. EPA, 2012).

We do not believe OSHA is accurate in stating in the PEA that "... measures of the benefits of avoiding these illnesses are rare and difficult to find ..." (page VII-14). We believe that the Agency could develop reasonable valuation estimates specific to these particular illnesses without undue difficulty.

[25] Begin with https://www.asn-online.org/policy/webdocs/KD%20Growing%20Public%20Health%20Threat.pdf

4. Value of avoided morbidity associated specifically with avoided fatal cases of diseases that OSHA contends are caused by silica exposure

In our view, OSHA also makes a more subtle error in further extending the Agency's estimated range and point values for the morbidity avoided when a case of lung cancer, end-stage renal disease or NMRD is avoided to the specific circumstances when the avoided case of one of these diseases would have been fatal and the avoided morbidity is that which would have occurred before the afflicted individual's death from the disease. EPA and many analysts make an important distinction between fatal and non-fatal cases of an illness when valuing the morbidity that is avoided when a case of the illness is avoided. OSHA does not appear to recognize the import of this distinction.

In OSHA's benefits analysis, the Agency believes it needs to estimate morbidity values for four sorts of avoided diseases: for all cases of avoided moderate-to-severe silicosis, for fatal cases of lung cancer, for fatal cases of renal disease, and for fatal cases of NMRD other than silicosis.

At the high end of the Agency's range, OSHA values each avoided fatal case of one of these diseases at $13.8 million in 2009 dollars, consisting of $5.1 million in estimated avoided morbidity that would have occurred before the death (by assigning the estimated value of avoided non-fatal lymphoma equal to 58.3% of the VSL), and $8.7 million in VSL, or WTP to avoid the fatality. At the low end, OSHA values an avoided fatal case at $8.8 million, consisting of $62,000 in morbidity value from the study of industrial accidents plus the $8.7 million VSL. For a point estimate, OSHA values an avoided fatal case at $11.2 million, consisting of roughly $2.5 million in morbidity value (essentially half of the $5.1 million figure representing 58.3% of the VSL) plus the $8.7 million VSL. OSHA summarizes these estimates in the PEA as follows:

> In summary, the various studies presented in this section suggest that the imputed value of avoided morbidity associated with silica exposure, both for cases preceding death and for non-fatal cases, ranges between $62,000 and $5.1 million. The Agency believes this range of estimates is descriptive of the value of preventing morbidity associated with moderate-to-severe silicosis, as well as the morbidity preceding mortality due to other causes enumerated here—lung cancer, lung diseases other than cancer, and renal disease. OSHA is therefore applying these values to monetize the benefits of all these cases of avoided silica-related morbidity resulting from the proposed rule … For the purpose of simplifying the calculation of the monetized benefits of avoided illness and death, OSHA simply added the monetized benefits of morbidity preceding mortality to the monetized benefits of mortality at the time of death … (PEA, page VII-15)

This approach where OSHA adds a WTP-based pre-death morbidity value that is a high fraction of the mortality value is unprecedented in our experience in reviewing valuations of fatal health effects by regulatory agencies. Commonly, regulatory agencies value the avoided morbidity impacts prior to an avoided fatality by applying cost-of-illness approaches, figuring the medical costs, and perhaps lost earnings, caregiver costs, etc. before death occurs. Typically the avoided pre-death morbidity costs are estimated at an amount much, much less than the VSL applied for the avoided death itself, an amount not nearly large enough to equal 29% (at OSHA's point estimate) or 58% (at OSHA's high-end estimate) of the VSL. The following are two specific examples involving the source material for OSHA's (inappropriate) high-end estimate to the effect that the avoided pre-death morbidity should be valued at 58.3% of the VSL:

- Magat, Viscusi and Huber (1996) is the source of the estimate to the effect that the value of an avoided nonfatal case of lymphoma is 58.3% of the value of an avoided fatal case of lymphoma. The researchers estimated this figure by presenting subjects with a series of alternatives where the subjects were asked in essence to trade off the risk of having terminal (incurable) lymphoma against the risk of certain death in an automobile accident and then to trade off the different risk of having curable lymphoma again against the risk of certain death in an auto accident. One of the researchers' findings was that the median respondent assigned curable lymphoma 58.3% as much disutility as was assigned to terminal lymphoma. Based on this finding, in the instance that OSHA cites in the PEA, EPA estimated the value of avoiding the morbidity associated with a nonfatal case of another form of cancer at 58.3% of the value of avoiding a fatal case of that form of cancer. Note, though, that Magat, Viscusi and Huber did not find in their study what OSHA has assumed that they found. They did not find that the disutility of the pre-death morbidity that would be incurred in the course of an eventually fatal case of lymphoma amounted to 58.3% as much total disutility as was ascribed to all attributes of the fatal case of lymphoma.

  To the contrary, the researchers found that the median subject assigned exactly as much disutility to the eventually fatal case of lymphoma as s/he assigned to immediate and certain death in an auto accident. The disutility of terminal lymphoma that the researchers found in this study was exactly equal to the VSL, not nearly as much as the VSL plus the value of avoided morbidity associated with a case of curable lymphoma. For the Agency's high end estimate, OSHA makes the value of avoiding a fatal case of silicosis, lung cancer, NMRD or end-stage kidney disease equal to 1.583 times the VSL (the VSL plus the value of avoided pre-death morbidity assumed to equal 0.583 times the VSL), but the Magat, Viscusi and Huber study from which OSHA draws the 58.3% factor makes the value of the avoided fatal illness equal only to 1.0 times the VSL.

- OSHA's approach of assigning avoided pre-death morbidity a value equal to 58.3% of the VSL is also contrary to what EPA did in the reference that OSHA wrongly cites (page VII-14 of the PEA) as the instance in which EPA supposedly applied this value. In EPA's Final Economic Analysis for the Stage 2 Disinfection Byproducts regulation, the Agency did indeed develop an estimate in which the morbidity associated with an avoided *non-fatal* case of bladder cancer was valued at 58.3% of the VSL. (U.S. EPA, 2005, pages 6-82 - 6-84) But EPA did not, as OSHA wrongly presumes, then value an avoided *fatal* case of bladder cancer at 1.583 times the VSL (consisting of 0.583 times the VSL intended to represent the value of avoided morbidity before the avoided death, plus 1.0 times the VSL intended to represent the value of the avoided death itself).

  Instead, EPA valued an avoided *fatal* case of bladder cancer by adding a relatively small morbidity increment of $93,927 in 1996 dollars to the VSL of $4.8 million in 1990 dollars. This increment was intended to represent the medical cost likely associated with a fatal cancer case. EPA ultimately valued an avoided fatal case of bladder cancer at 1.016 times the VSL, and not by adding a vastly larger pre-death morbidity increment so as to reach 1.583 times the VSL as OSHA has presumed. In EPA's view, in the rare instances when the Agency has used this approach, the 58.3% of VSL figure is intended

to represent the WTP to avoid a nonfatal case of a cancer, not the pre-death morbidity costs that should be added to the VSL when valuing an avoided fatal case of the cancer.

5. Impact of OSHA's inappropriate approach for valuing avoided morbidity on total benefits estimated for the proposed rule

The approach that OSHA has taken in valuing avoided morbidity is inappropriate and accounts for the Agency's extremely high estimates for the morbidity benefits of the regulation:

- At the high end of the morbidity valuation range and assuming the midpoint estimate for cases avoided for each illness, OSHA estimates that "the majority of benefits are related to morbidity ($6.9 million out of $10.3 billion …)"

- At the midpoint of the morbidity valuation range (i.e., at just short of half the $5.1 million per nonfatal case and just short of half the $5.1 million in morbidity costs prior to death per fatal case) and assuming the midpoint estimate for cases avoided for each illness, OSHA estimates that "$3.4 billion in benefits are related to mortality, $1.0 billion are related to morbidity preceding mortality, and $2.4 billion are related to morbidity not preceding mortality … " (i.e., silicosis morbidity). (see page VII-16 of the PEA)

In these two examples, the high end of OSHA's morbidity valuation range yields morbidity benefits estimated at $6.9 billion and the midpoint of the valuation range yields morbidity benefits estimated at $3.4 billion (very slightly less than half the high end, as we have discussed will be the case when the high end is much larger than the low end). OSHA's estimated morbidity benefits for the proposed standard would be drastically reduced (to a level less than $0.25 billion) if the Agency were instead to value avoided morbidity at the Miller (2005) figure specific to silicosis of $317,000 per case avoided.[26]

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[26] In these examples, at the high end of OSHA's morbidity valuation range, total morbidity benefits are estimated at approximately double the total monetized mortality benefits for the proposed standard. At the midpoint of OSHA's morbidity valuation range, total morbidity benefits are estimated as approximately equal to total mortality benefits. If OSHA were instead to value morbidity benefits using the much more reasonable Miller (2005) figure specific to silicosis, total morbidity benefits would in contrast be less than 8% of total mortality benefits. As far as we know, all the large, well-respected, U.S. government-supported analyses of regulatory benefits or disease burdens that value mortality risks using a VSL approach find similarly that mortality benefits far outweigh morbidity benefits. OSHA's estimates in the PEA are aberrant in this respect due largely, we believe, to OSHA's inappropriate methodology for valuing morbidity risks. See, for example, the following studies:

- In EPA's most recent report on the benefits and costs of the Clean Air Act (U.S. EPA, 2011), the Agency projects that monetized morbidity benefits in 2020 will amount to only about 4% as much as the projected monetized mortality benefits.
- Similarly, in EPA's regulatory impact analysis for the air quality standards addressing respirable particulate matter, the Agency found that "mortality benefits account for 98% of total monetized benefits." (U.S. EPA, 2012, page 5-73).
- In summarizing many other studies, three researchers from the National Cancer Institute and a co-author estimated that VSL-based mortality costs for cancers in the U.S. were $961 billion in the year 2000 and would increase to $1.473 trillion in 2020 (Yabroff, et al. 2011, with 2020 projections from Yabroff, et al. 2008). In contrast, the direct medical costs of cancer care were estimated at $124.5 billion in 2010 and $157.8 billion in 2020 (Yabroff, et al. 2011).

Because we do not believe that a causal relationship has been established between silica exposure and renal disease mortality or non-malignant respiratory diseases other than silicosis, we have not estimated any value for avoided morbidity (or mortality) associated with these diseases. For silicosis we have estimated morbidity values based on the estimate that OSHA's contractor, Miller (2005), developed specifically for that disease. For fatal lung cancers, we have applied EPA's estimate for the value of the pre-death medical costs that will be avoided with an avoided case of fatal lung cancer, *i.e.*, $51,211 in 1996 dollars, updated to $66,768 in 2009 dollars (EPA, 2007).

I. Compliance Cost Estimates

We adopt for our analysis here the compliance cost estimates developed by URS Corp. for the Panel.

URS developed estimates for: i) the cost of the steps that employers will undertake to comply fully with the existing standard with a PEL of 100 ug/m^3; ii) the cost of the incremental steps that employers will need to take after complying with the existing standard in order to comply additionally with the Proposed Standard with a PEL of 50 ug/m^3, ancillary requirements, and a switch to ISO/CEN; and iii) the "full" costs of the entire proposed rule, including both (i) and (ii). OSHA estimates only the incremental costs of the proposed rule, failing to estimate the costs of either (i) or (iii).

We focus in this discussion particularly on URS and OSHA's incremental cost estimates. URS and OSHA have developed the following estimates for the incremental costs of the proposed standard.

Table 12. Incremental Cost Estimates for General Industry and Maritime (in millions of 2009$/year) -- URS vs. OSHA
(7%/yr discount rate)

	URS: Increment from Current PEL to Proposed PEL + ISO/CEN + Ancillary Req'ts	OSHA: Increment from Current PEL to Proposed PEL + Ancillary Req'ts
19 General Industry sectors with costs estimated by URS	$4,722.4	$114.7
6 additional General Industry sectors + Maritime	---	$32.4
Total	**$4,722.4**	**$147.0**

URS' cost estimate is more than 30 times larger than OSHA's cost estimate for the incremental requirements of the proposed standard relative to the existing standard. We explained briefly in the Executive Summary some of the reasons for this difference and we provide some further discussion here. For further detail on URS' cost estimates we refer the reader to the URS comments to the Docket and testimony (URS, 2014).

URS was able to estimate costs for only 19 of the 25 General Industry sectors. URS could not estimate costs for 6 General Industry sectors (captive foundries, porcelain enameling, railroads, dental equipment, dental laboratories, refractory repair) plus the Maritime sector because they found OSHA's estimates for the numbers of facilities in each of these sectors to be grossly

incorrect. OSHA's cost estimate for all 25 General Industry sectors plus Maritime is about 28% higher than the Agency's cost estimate for the 19 sectors addressed by URS. If URS were to find a similar 28% increase in addressing all the sectors, URS' cost estimate might increase from $4.7 billion/year to $6.1 billion per year

In estimating the incremental engineering control costs of the proposed standard, OSHA assumed that the actions employers would take to comply with the current PEL would result in reducing the exposures of all the estimated 80,731 workers who are now exposed above the current PEL to levels below the proposed PEL. URS assumed instead that employers would comply with the current PEL by reducing exposures for these workers only to below the current PEL, not to below the proposed PEL. OSHA should have assumed likewise. As a result of this error, OSHA wrongly attributes to the existing standard much of the incremental exposure reduction that will instead be required by the proposed new standard.

OSHA ultimately estimates costs incrementally attributable to the proposed standard for only the 41,741 employees estimated as now exposed at levels between the current and the proposed PEL -- only about 1/3 of all the employees who will actually need exposure reductions as a result of the incremental requirements of the proposed standard. URS (if they were to have addressed all 26 sectors) would have estimated costs for all 122, 472 employees who will need exposure reductions if the proposed PEL were to be promulgated.

Not only did OSHA fail to estimate any engineering control costs for 2/3 of all the workers who will need exposure reductions as a result of the proposed standard, but the average amount of exposure reduction needed for the workers that OSHA omitted from the cost analysis will substantially exceed the average exposure reduction needed for the workers that OSHA included in the Agency's cost analysis.[27] Were OSHA to make the correct assumption about what

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[27] OSHA assumes that the proposed standard will require incremental exposure reductions only for the 41,741 employees now estimated as exposed at between 50 ug/m^3 and 100 ug/m^3. OSHA appears to assume (see Appendix 1) that these employees are now exposed at an average of 62.5 ug/m^3. OSHA assumes that the proposed standard will require a reduction in these employees' exposures to just below the proposed PEL of 50 ug/m^3, for a total exposure reduction of 41,741 x 12.5 ug/m^3 = 522,000 person-ug/m^3. OSHA estimates engineering control costs of $101 million/year to achieve this quantity of total exposure reductions.

OSHA attributes no incremental engineering control costs to the proposed standard for the 80,731 General Industry workers who are estimated to be exposed now above the current PEL, assuming wrongly that employers will reduce their exposures all the way to below the proposed PEL in the course of complying with the current PEL. A far more accurate assumption would be that employers will reduce their exposures only to just below the current PEL in the course of complying with the current standard. In this case, these 80,731 employees would need further exposure reductions from just below the current PEL to just below the proposed PEL if the proposed standard were to be promulgated. This additional exposure reduction that OSHA omits from its incremental cost analysis amounts to 80,731 workers x (100 ug/m^3 - 50 ug/m^3) = 4,037,000 person-ug/m^3.

OSHA thus estimates incremental costs for engineering controls sufficient to achieve only some 522,000 units of exposure reduction, whereas it should estimate incremental costs for engineering controls that are sufficient to achieve approximately 4.5 million units of exposure reduction, a figure nearly nine times higher. If OSHA were to correct this error in predicting what employers will do to comply with the current PEL, the Agency's incremental cost estimate for engineering controls might increase by a factor of roughly nine relative to the current estimate of $101 million/year. The new engineering control cost estimate might be about $900 million/year, bringing the total incremental cost estimate to roughly $947 million per year (including $46 million/year for the ancillary

General Industry employers will do in complying with the current PEL, the Agency's cost estimate for engineering controls would not only triple as the number of employees would suggest, but would likely increase instead by a factor of roughly nine. The total incremental costs that OSHA estimates for the proposed standard, including costs for both engineering controls and the ancillary requirements, would likely increase by a factor of at least five.

OSHA fails to recognize also the cost implications of the proposed change in monitoring protocol from the current ACGIH to ISO/CEN. This change will result in the capture of about 20% more crystalline silica in each sample. In effect, exposures will need to be held below about 41.67 ug/m^3 using the proposed ISO/CEN protocol in order to keep them below a PEL of 50 ug/m^3 measured pursuant to the current ACGIH protocol. OSHA has not recognized the additional exposure reductions and costs inherent in this proposed change, while URS has done so.

If OSHA were to recognize the implications of the proposed change to the ISO/CEN protocol, the Agency would need to add costs to achieve exposure reductions for an additional 18,000 or so General Industry employees now thought to be exposed between 41.67 ug/m^3 and 50 ug/m^3. Furthermore, the amount of the exposure reduction needed for all employees now exposed at levels exceeding the proposed PEL of 50 ug/m^3 measured pursuant to ACGIH would increase as reductions to below 41.67 ug/m^3 (per ACGIH) would be required rather than only to below 50 ug/m^3 (per ACGIH). We estimate that OSHA would calculate the total incremental exposure reduction required by the proposed standard to increase by about 86% if the implications of the change to ISO/CEN were properly recognized, and the Agency's total cost estimate for the proposed standard might increase by about 68%.[28]

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requirements), a six- to seven-fold increase over OSHA's current incremental cost estimate of $147 million per year. We are going to refer to this increase conservatively as "at least a factor of five."

[28] As per the previous footnote, OSHA in effect assumes for its analysis of engineering control costs that 522,000 units of exposure reduction will be needed -- to reduce the exposure of the 41,741 employees now thought to be exposed at between 50 ug/m^3 and 100 ug/m^3 from an average level assumed at 62.5 ug/m^3 to just below 50 ug/m^3. Upon recognizing the implications of the switch to ISO/CEN, OSHA would estimate that these employees would need a further reduction of exposure to below 41.67 ug/m^3, for an additional 41,741 x 8.33 = 348,000 units of exposure reduction.

In addition, the roughly 17,776 employees now estimated to be exposed at between 41.67 ug/m^3 and 50 ug/m^3 (assuming the 53,329 employees that OSHA estimates as exposed at between 25 ug/m^3 and 50 ug/m^3 are evenly distributed across that range) would need exposure reductions totaling 74,000 units (from an average of 45.84 ug/m^3 [midway between 41.67 ug/m^3 and 50 ug/m^3] to below 41.67 ug/m^3).

The exposure reductions required by the proposed switch to ISO/CEN would add 422,000 units (348,000 + 74,000) to the 522,000 units that OSHA estimated as needed without considering the proposed switch, an 86% increase. Marginal costs would presumably increase as employers need to reduce exposures to 41.67 ug/m^3 rather than only to 50 ug/m^3, so total costs for engineering controls would likely increase by more than 86%. We'll presume that OSHA's estimated engineering control costs might increase by 100% rather than 86%, adding another roughly $100 million per year to the $101 million per year that OSHA has estimated. This $100 million/year increase in costs for engineering controls would represent an increase of 68% relative to OSHA's current estimate of $147 million per year for total incremental costs including the ancillary requirements.

URS emphasized the importance of estimating costs for the engineering controls needed for compliance with the current or the proposed PEL on a facility-by-facility basis. URS has argued strongly against OSHA's "cost per overexposed employee" approach in which the Agency assumed instead that there is an average of four overexposed employees who will be protected each time that an appropriate package of control measures is implemented.

Among other objections to this approach, most of the small and very small affected facilities in General Industry have fewer than four overexposed employees in each job category or area of the facility where a worker is overexposed and controls will be needed. In the majority of instances, a package of controls to protect an overexposed worker in a particular job category in a particular facility will protect only that single overexposed worker, not four such individuals. As a result, engineering controls will be needed far more often than OSHA has estimated -- at many more facilities and much more often in total across General Industry -- and costs will be correspondingly higher.

URS has estimated much larger costs for compliance with the proposed ancillary requirements than has OSHA. URS estimates costs of $778 million per year while OSHA estimates only $46 million per year. Among other errors in estimating costs for the proposed ancillary requirements, OSHA failed to include any costs for the annual professional facility cleaning that the Agency cited in Chapter IV of the PEA as necessary in order for many General Industry sectors to comply with the proposed standard.[29] OSHA indicated that the Agency would include costs for professional cleaning as a housekeeping measure when estimating costs for the ancillary requirements, but the Agency failed to do so. URS identified many other respects in which OSHA underestimated costs for the ancillary requirements including underestimating the unit costs and numbers of employees who will need to be covered by the monitoring and medical surveillance provisions, and more. See the URS cost report for further details.

URS also cited additional objections to OSHA's procedures for estimating costs, including overestimating the effectiveness of control technologies, failing to recognize increasing marginal costs as controls are implemented to achieve lower silica concentrations, underestimating unit costs, and more.

The following table indicates the approximate impact on OSHA's incremental cost estimate of $147 million per year if the Agency were to correct its cost analysis to reflect these various changes suggested by URS.

[29] See the following pages of the PEA: IV-80, 83, 91, 92 for concrete products; IV-166, 168, 173 for foundries; IV-232 for mineral processing; IV-245, 246, 247 for porcelain enameling; IV-262, 267, 270, 271 for pottery; and IV-357, 365, 366, 367, 368, 369 for structural clay.

Table 13. Approximate Increases in OSHA's Incremental Cost Estimate ($147 million/yr) if URS Changes Were Adopted

Suggested Change	Multiply OSHA Cost Estimate by
Don't overestimate exposure reductions resulting from employer actions taken to comply with the current PEL	5+
Include costs for the switch to ISO/CEN	1.7
Estimate costs on facility basis, not "per employee"	1.3
Estimate costs for ancillary provisions more accurately	1.3
Other	2
Approximate Total (based on multiplying the independent factors)	30

J. Time Frame for the Analysis and Time Path of Costs and Benefits

Both OSHA and we estimate costs in an annualized manner. Although the actual costs incurred to comply with the proposed standard will vary from year to year in the future, all these costs have been aggregated, discounted back to a base year, and converted into an equivalent stream of payments that is equal from year to year.

In both OSHA's and our analyses, we assume that this "annualized" cost stream will continue at this level each year forever. For the increment from the existing standard to the proposed standard, OSHA estimates that the costs for General Industry will be $147 million per year in 2009 dollars, continuing at this level forever. In contrast, we estimate that the comparable costs for the 19 General Industry sectors for which URS estimated costs will be $4.7 billion per year in 2009 dollars, also continuing at this level forever.

OSHA and we make different assumptions about the manner in which to analyze future benefits, however.

In projecting benefits in future years, OSHA describes how the annual stream of avoided silica-related illnesses will eventually reach a "steady state," when all the exposed workers will spend the entire period during which they are exposed at the lower risk levels that will prevail after employers comply with the proposed standard.

Assuming that all workers are exposed for a full working lifetime of 45 years from age 20 to age 65, OSHA indicates that the steady state will not occur for silica-related non-cancer diseases until 45 years have passed.

In the first year following compliance with the standard, for example, nearly all of the exposed workers will have spent their career to date exposed at the higher silica concentrations that existed prior to compliance, and will have only one year of exposure at the lower silica concentrations that exist after compliance. Risks will be only very slightly reduced from pre-regulatory baseline levels, and benefits will be small in this first year.

As the years pass, exposed workers will spend an increasing portion of their working lives exposed at the lower post-compliance levels, and benefits will gradually increase year by year. After 45 years have passed following compliance, all the exposed workers will have spent their entire 45-year working lives exposed at the lower post-compliance levels, and annual benefits will have reached their maximum. For years more than 45 years in the future beyond the year of compliance, benefits will continue each year at the same steady state maximum annual level as was reached following year 45.

For lung cancer, benefits will similarly increase to the steady state level, but this increase will not begin until 15 years after compliance is achieved and will not reach the steady state level until 60 years after compliance is achieved. This lagged accrual of benefits involving lung cancer relative to the timetable for other health effects is due to the 15-year lag in the exposure-response relationships that OSHA chooses for lung cancer, in which risk is a function of cumulative exposure lagged 15 years.

OSHA chooses a 60-year time horizon for the Agency's benefit-cost analysis, thereby estimating benefits for each future year until the steady-state has been reached for both non-cancer health effects (steady state is reached after 45 years) and lung cancer effects (steady state is reached after 60 years).

We make a different choice of time frame for our benefit-cost analysis. Using more realistic assumptions about the duration of General Industry employees' exposure to crystalline silica than OSHA's 45-year assumption, we assume an average duration of exposure of only 10 years.

With the 15-year lag when using two of OSHA's chosen exposure-response functions for lung cancer, in our analysis the transition period continues for 25 years following compliance. Over this period, annual benefits grow year by year to their maximum. We choose to run our analysis for the steady state period after this 25-year transition period has ended.

More specifically, we run our analysis for a cohort of workers that begins work during the steady state period after the transition period, and we follow these workers for their silica-exposed working lifetimes (assumed to be 10 years) plus the remainder of their lifetimes after their silica-exposed employment is presumed to end (including the post-exposure lag period, and continuing up to the workers' deaths, as given by OSHA's life tables).

Our cohort of workers spends their entire working lifetime at the lower exposure levels that prevail post-compliance; the regulatory benefits in our analysis are the reductions in health effects expected over the remainder of these workers' lifetimes, and OSHA's life tables tell us, in effect, when these workers will die.

The regulatory costs in our analysis are the costs necessary to yield the exposure reductions these workers accrue over their assumed ten year silica-exposed working lifetime – these costs are ten years' worth of the annualized costs that URS has estimated. We determine the year-by-year schedule of these benefits and costs in the years after compliance has been achieved and risk reduction has reached its maximum; we then discount these costs back to the start of the steady state period and determine a present value; and we then annualize both costs and benefits over

the ten-year period during which compliance expenditures and exposure reduction have occurred.

Benefits accrue at varying levels over the years during which the cohort of workers live following the beginning of their ten years of silica-exposed employment. Costs accrue for ten years at the annualized cost level that URS has estimated. The result after we have discounted and then annualized both costs and benefits is a comparison between the levelized annual benefits and costs of the proposed regulation during the steady state period.

We chose a time frame for our analysis that focuses on the steady state period after benefits have grown to their maximum so as to provide the highest possible estimated ratio of benefits to costs and thus to portray the proposed standard in its most favorable possible light.

K. Choice of Discount Rate for the Analysis

OSHA performs the Agency's analysis using several alternative real discount rates: zero percent, 3%, and 7% per year.

We perform our analysis using a real discount rate of 7% per year. We choose this rate to reflect the opportunity cost of the General Industry capital investments that will be displaced by compliance spending pursuant to the proposed standard. 7% is also one of two discount rates that OMB recommends using for Federal agency economic analyses.

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APPENDIX 1: DISCUSSION ON EXPOSURE ASSUMPTIONS USED IN OSHA'S BENEFITS ANALYSIS

OSHA's benefits analysis is thinly documented, and we have difficulty understanding what the Agency assumed regarding current exposures for General Industry employees and the degree to which these exposures will be reduced if their employers were to comply with the proposed standard.

As best we can tell, the Agency's benefits analysis appears to have estimated a larger quantity of exposure reductions from the proposed regulation than the quantity of exposure reductions that drives the Agency's cost analysis. OSHA's cost and benefits analyses do not appear to have been generated in a consistent manner. If so, the Agency's cost estimate cannot legitimately be compared against the Agency's benefits estimate. We discuss in this Appendix how we have reached this tentative conclusion.

Table A-1 below shows OSHA's estimates and assumptions regarding current or baseline worker exposure to crystalline silica in: a) the Agency's benefits analysis conducted for the 2003 SBREFA process; and in b) the Agency's benefits analysis in 2013 as shown in Chapter VII of the PEA.

Table A-1. OSHA Baseline Exposure Assumptions for Two Benefits Analyses

OSHA's Assumptions in 2003 Analysis		
Group of Workers in Terms of Baseline Exposure (ug/m^3)	General Industry # Workers	Assumed single exposure level for group (ug/m^3)
Exposed at > 100	53,550	125
Exposed between 75 - 100	19,164	87.5
Exposed between 50 - 75	25,811	62.5
Exposed between 40 - 50	12,013	45
Exposed between 0 - 40	?	?
Total	110,000+	

OSHA's Assumptions in 2013 Analysis		
Group of Workers in Terms of Baseline Exposure (ug/m^3)	General Industry # Workers	Assumed single exposure level for group (ug/m^3)
Exposed at ≥ 250	48,956	?
Exposed between 100 - 250	31,775	125*
Exposed between 50 - 100	41,741	62.5*
Exposed between 25 - 50	53,329	?
Exposed between 0 - 25	119,085	?
Total	294,886	

? = OSHA does not specify any estimate or assumption
* OSHA cites these assumptions at one point in the text, but gives no evidence of using these assumptions in any analysis

In each of these two analyses, OSHA expressed the Agency's exposure profiles in ranges, indicating the numbers of workers estimated as exposed within a particular range of concentrations. In order to apply the exposure-response functions and estimate risks for employees exposed at these levels and then to estimate presumed benefits as employees are exposed at lower levels, OSHA assumed single point estimates to represent the typical exposure level within each range. Applying an exposure-response function to a point estimate of exposure will require many fewer calculations to estimate risks and benefits than treating all exposures as ranges. We do likewise in our analysis: for each range of exposure we assume a single representative exposure figure rather than deal with the entire range.
OSHA divided the exposure profile into different ranges in the Agency's 2003 and 2013 analyses, and made differing assumptions about point estimates with which to represent the various ranges.

These differences are partly a function of the differing regulatory alternatives that OSHA was considering at the two times. Exposures at 75 ug/m^3 and 40 ug/m^3 were of interest in 2003 because the Agency was considering a PEL and an Action Level at those points. Exposures at 250 ug/m^3 and 25 ug/m^3 were of interest in 2013 because the Agency is now considering a PEL (for construction) and an Action Level at these different points.

In OSHA's 2003 SBREFA benefits analysis, the Agency assumed a single exposure figure at the midpoint of each exposure range, with the exception of the > 100 ug/m^3 range, where OSHA assumed a "conservative" value of only 125 ug/m^3.

OSHA provides no definitive statement for the 2013 benefits analysis as to how the Agency dealt with the various exposure ranges. Its only statement on this issue in the PEA is in footnote #3 on page VII-2 of the PEA:

> Based on available data, the Agency estimated the weighted average for the relevant exposure groups to match up with the quantitative risk assessment. For the 50-100 μg/m^3 exposure range, the Agency estimated an average exposure of 62.5 μg/m^3. For the 100-250 μg/m^3 range, the Agency estimated an average exposure of 125 μg/m^3.

This statement of OSHA's raises several issues:

- What did the Agency assume as representative figures for the exposure ranges below 50 ug/m^3 and above 250 ug/m^3? Did the Agency not address exposures within either of these ranges in the benefits analysis?

- Did the Agency assume 62.5 ug/m^3 as the representative figure for the range from 50 ug/m^3 to 100 ug/m^3, while in 2003 the Agency assumed the same value of 62.5 ug/m^3 as the representative figure for the more limited range from 50 ug/m^3 to 75 ug/m^3? Why did the Agency in 2013 change their approach from 2003, when they took the midpoint of each range? Did the Agency mean to make this change in 2013, or could the footnote statement perhaps be a mistake?

- Did the Agency assume 125 ug/m^3 as the representative figure for the range from 100 ug/m^3 to 250 ug/m^3, while in 2003 the Agency assumed 125 ug/m^3 as the representative figure for the entire range exceeding 100 ug/m^3, including for values exceeding 250 ug/m^3? Did the Agency mean to do so? How did the Agency address the workers exposed above 250 ug/m^3 in 2013? Or did the Agency in the 2013 analysis perhaps decide explicitly not to consider benefits for workers exposed above 250 ug/m^3?

- What does the Agency mean by suggesting that these figures of 62.5 ug/m^3 and 125 ug/m^3 were chosen "to match up with the quantitative risk assessment"? The 2013 QRA document presents no risk calculations for exposure levels at 62.5 ug/m^3 or 125 ug/m^3, nor do the PEA or any of OSHA's benefits calculation spreadsheets present any risk calculations at either of these exposure levels.

Unfortunately, the Excel spreadsheets that OSHA placed in the docket to document the 2013 benefits calculations provide no help in answering these questions. The benefits spreadsheets all show calculations that begin after the point at which the number of health effects prevented has been estimated. There is no indication about the antecedents to these calculations: the amounts by which exposure has been assumed to be reduced and the numbers of workers for whom exposure has been reduced by these amounts.

Neither is it clear how the Agency combined assumptions regarding exposure reductions and numbers of affected workers to estimate the number of silica-related diseases purportedly avoided by the proposed standard.

In an effort to understand OSHA's benefits calculations in this regard, we offer the following comments and questions about OSHA's text description on pages VII-1 through VII-4 of the PEA.

OSHA begins by saying:

> "OSHA estimated the benefits associated with the proposed PEL of 50 $\mu g/m^3$ and, for economic analysis purposes, with an alternative PEL of 100 $\mu g/m^3$ for respirable crystalline silica by applying the dose-response relationships developed in OSHA's quantitative risk assessment (QRA) to exposures *at or below the current PELs* [emphasis added]. OSHA determined exposure levels *at or below the current PELs* by … By applying the dose-response relationships to estimates of exposures *at or below the current PELs* across industries, it is possible to project the number of cases …" (PEA, page VII-1)

In using this "at or below the current PELs" language, OSHA appears to say that the Agency did not estimate benefits or apply dose-response relationships for any exposure levels *exceeding* the current PELs. This seems odd: why wouldn't OSHA estimate benefits involving workers who are now exposed at levels exceeding the current PELs?

For General Industry, why wouldn't OSHA estimate the benefits of reducing exposures down to the proposed PEL of 50 ug/m^3 for those workers who are now exposed above 100 ug/m^3? These General Industry workers now exposed above 100 ug/m^3 would seem to be the General Industry workers who would accrue the largest exposure reduction benefits from the proposed PEL; certainly larger than the benefits that purportedly will be accrued by the much smaller estimated number of General Industry workers now exposed at between 50 ug/m^3 and 100 ug/m^3 (per OSHA's exposure profile).

The reason for OSHA's "at or below the current PELs" language may be that OSHA conducted the benefits analysis in the same "incremental" manner as the Agency conducted the cost analysis.[30] Workers currently exposed at levels exceeding the current PEL may not be relevant in an "incremental" analysis as OSHA defines it, neither in the cost analysis nor perhaps also in the benefits analysis. In OSHA's "incremental" cost analysis for General Industry, it is clear that workers now exposed at levels exceeding the current PEL of 100 ug/m^3 are not considered as entailing any costs -- they are assumed wrongly to have their exposures reduced below the proposed new PEL at 50 ug/m^3 when employers implement measures to comply fully with the current PEL at 100 ug/m^3.

[30] Note our comments earlier to the effect that OSHA has badly overestimated the exposure reductions that employers will likely accomplish to comply with the current PEL and thus grossly underestimated the incremental exposure reductions and costs that will be needed for compliance with the proposed PEL.

It appears perhaps that OSHA has conducted the Agency's benefits analysis in the same manner. Incremental benefits attributable to the proposed standard are perhaps not estimated for the General Industry workers now exposed at levels exceeding 100 ug/m^3 because all of these workers are assumed to be "taken care of," with their exposures reduced below 50 ug/m^3, when employers comply fully with the current PEL.

In fact, further along in the benefits section of the PEA, OSHA appears to confirm our supposition that the Agency has conducted the benefits analysis in a similar "incremental" manner as the Agency conducted the cost analysis. In the paragraph running between pages VII-1 and VII-2 of the PEA, OSHA says:

> "The estimated benefits for the proposed silica rule represent the additional benefits derived from employers achieving full compliance with the proposed PEL relative to the current PELs. They do not include benefits associated with current compliance that has already been achieved with regard to the new requirements or benefits obtained from future compliance with current silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements."

This language parallels OSHA's language elsewhere to describe the Agency's cost analysis and to indicate that the cost analysis has been conducted as an "incremental" analysis. We interpret this benefits language, as well as the accompanying footnote #3, to indicate that the Agency's benefits analysis has also been conducted in an "incremental" manner. A long footnote on page VII-2 can be interpreted to mean that the 2013 analysis was conducted in an "incremental" manner and the 2003 analysis was not.

At this point, we are inclined to believe that OSHA estimated benefits for the proposed General Industry PEL in the Agency's "incremental" manner as consisting of the benefits only for the group of General Industry workers now exposed at between 50 ug/m^3 and 100 ug/m^3. All General Industry workers now exposed at levels exceeding 100 ug/m^3 appear to be considered as not relevant in the Agency's benefits analysis, based on an assumption that their exposures will be reduced to the level of the proposed PEL as General Industry employers comply with the current PEL.

Likewise, for Construction, it appears to be only the construction workers exposed at between 50 ug/m^3 and 250 ug/m^3 who are relevant in the benefits analysis. OSHA appears to assume that construction exposures above 250 ug/m^3 will be reduced to 50 ug/m^3 as construction employers eventually comply with the current Construction PEL of 250 ug/m^3.

This interpretation of OSHA's benefits analysis seems *consistent* with the Agency's cost analysis and additional remarks in the PEA benefits chapter:

- This interpretation could explain why OSHA says they apply exposure-response functions and estimate benefits only for exposure levels at or below the current PELs. General Industry employees with exposures above the current PEL of 100 ug/m^3 are not relevant and are not addressed in the benefits analysis for General

Industry. Construction employees with exposures above the current PEL of 250 ug/m^3 are similarly not relevant in the benefits analysis for Construction.

- This interpretation could also explain why OSHA cited 62.5 ug/m^3 and 125 ug/m^3 as the only two figures chosen to represent broad exposure ranges. Exposures exceeding 100 ug/m^3 for General Industry or exceeding 250 ug/m^3 for construction don't need single value assumptions because exposures exceeding the current PELs are not relevant in the benefits analysis. Exposures below 50 ug/m^3 for either General Industry or Construction also do not need any single value choices because: a) as OSHA says on page VII-2 of the PEA, "OSHA assumed that compliance with the ... proposed rule would result in reductions in exposure levels to exactly the ... proposed PEL" and not to below it; and b) OSHA assumes that employees currently exposed at below 50 ug/m^3 will not be affected (and thus benefits for them are not at issue) by employers' efforts to comply with either the current PELs or the proposed new PEL.

However, this interpretation of OSHA's benefits analysis seems *inconsistent* with other Agency remarks in the benefits chapter .

The exact quotation on page VII-2 of the PEA that we referenced immediately above, without the deletions indicated by ..., is: "OSHA assumed that compliance with the existing and proposed rule would result in reductions in exposure levels to exactly the existing standard and proposed PEL, respectively."

The portion of this statement that is inconsistent with our initial attempts to understand how OSHA conducted its 2013 benefits analysis relates to OSHA's assumption regarding the current rule: "OSHA assumed that compliance with the existing ... rule would result in reductions in exposure levels to exactly the existing standard ... "

If this statement is indeed accurate about how OSHA performed the 2013 benefits analysis, it is inconsistent with how OSHA performed the 2013 cost analysis.

In OSHA's 2013 "incremental" cost analysis, the Agency assumed that employers' efforts to comply with the existing standard would reduce exposures that exceed the current PEL to or below the proposed PEL, not just to the current PEL.

For the 2013 benefits analysis, in contrast, are we to understand from this quotation that OSHA assumed differently: that employers' efforts to comply with the current PEL would reduce exposures only to the current PEL rather than to or below the proposed PEL?

If so, OSHA would then presumably estimate benefits attributable to the proposed standard when employers comply with the new standard by reducing these employees' exposures incrementally from the level of the current to the proposed PEL. Is OSHA thus saying on page VII-2 that the Agency did the 2013 benefits analysis in a different and non-comparable way from how the Agency did the 2013 cost analysis? Is OSHA saying, in effect, that it estimated costs for the proposed standard as consisting, for

General Industry, of the costs to reduce exposures for the roughly 42,000 General Industry workers currently exposed between 50 ug/m^3 and 100 ug/m^3, while the Agency estimated benefits for the proposed standard for General Industry instead as consisting of those realized by:

- The same 42,000 workers for whom costs were estimated,

  plus additional benefits for

- Some 81,000 General Industry workers currently exposed in excess of 100 ug/m^3? Per OSHA's quoted statement on page VII-2, these workers' exposure will be reduced to the level of the existing standard (100 ug/m^3) as a result of compliance with the existing PEL and then further to 50 ug/m^3 as a result of the proposed standard.

Based on OSHA's quoted statement on page VII-2, the Agency estimated costs for reducing the exposures of 42,000 General Industry workers, but estimated benefits from exposure reductions for roughly 123,000 General Industry workers. If so, the Agency appears to have compared costs estimated for this smaller group of workers against benefits for a group three times as large.

Another statement by OSHA on page VII-2 may confirm the possibility that the Agency assumed that compliance with the current PELs will reduce workers' exposures only to the current PELs and not to the proposed PELs:

> In order to examine the effect of simply changing the PEL, OSHA compared the number of various kinds of cases of silica-related disease that would occur if workers were exposed for an entire working life to PELs of 50 μg/m^3 or 100 μg/m^3 to the number of cases that would occur at levels of exposure at or below the current PELs. The number of avoided cases over a hypothetical working life of exposure for the current population at a lower PEL is then equal to the difference between the number of cases at levels of exposure at or below the current PEL for that population minus the number of cases at the lower PEL.

If, as we have initially supposed, workers exposed above the current PELs are simply omitted from OSHA's benefits analysis because the Agency has adopted an identical "incremental" approach to benefits as well as costs, why, then, does OSHA show in Table VII-1 of the PEA (page VII-4) in the columns for a PEL of 100 ug/m^3 and GI & Maritime that there are avoided cases and positive benefits?

Furthermore, OSHA says they chose the figures of 62.5 ug/m^3 and 125 ug/m^3 to represent ranges in order to "to match up with the quantitative risk assessment" (footnote 3 on page VII-2). If 62.5 ug/m^3 and 125 ug/m^3 really were used as benchmark figures in the benefits analysis, one would expect that somewhere in the documentation for the proposed standard (perhaps in the QRA), OSHA would have estimated using the various exposure-response functions under consideration the risks that would be expected for a worker exposed for a lifetime at these two particular exposure levels. However, neither the QRA, nor the PEA, nor the benefits calculation spreadsheets the Agency has placed in

the Docket, show the risks that would result at these particular levels as calculated using any of the exposure-response functions that OSHA selects.

OSHA also provides no further text beyond page VII-2 in the benefits chapter of the 2013 PEA to clarify:

1. Which point estimates have been assumed to represent the various possible ranges in OSHA's exposure profile;

2. Whether employers' efforts to comply with the current PELs are assumed to reduce the exposures of their currently overexposed employees to the proposed PEL (in which case there should be no benefits estimated as attributable to the proposed standard for this group of employees) or instead compliance with the current PELs is assumed to reduce exposures only to the levels of the current PELs (in which case benefits attributable to the proposed standard will accrue when these employees' exposures are further reduced from the current PELs to the proposed PEL); and

3. More generally, which groups and numbers of employees are assumed to accrue benefits due to the proposed standard, and by how much will their exposures be reduced.

We tried to shed further light on these issues by attempting to replicate some of OSHA's benefits estimates (number of purportedly avoided illnesses) for the proposed standard (as shown in Table VII-1 on page VII-4) by trying out various assumptions that OSHA might have made about the effects of compliance with the current PELs and about single exposure values to substitute for ranges. More specifically, we:

1. Replicated in an Excel worksheet the Steenland, et al. (2002) log-linear exposure-response function for lung cancer mortality (lagged 15 years and as corrected by Toxichemica (2004)) such that we could calculate lifetime risks for any desired level of crystalline silica exposure. OSHA states on Page VII-3 of the PEA that this particular model gives the "lowest estimate of lung cancers avoided from lowering the PEL to 50 ug/m^3 …" OSHA's benefits estimates from applying this exposure-response function are shown in Table VII-1 on the line titled "Lung Cancers: Low".

2. Assumed OSHA's exposure distribution for General Industry and Maritime employees, as shown in Table III-6 of the PEA (page III-58) and as reproduced in Table 5 of this report.

3. Made the various possible assumptions that we believe OSHA might have used in the Agency's benefits analysis regarding: a) the effects of compliance with the current PELs (e.g., will General Industry exposures that exceed the current PEL be reduced to 100 ug/m^3 or to 50 ug/m^3?); and b) what single exposure values have been substituted for exposure ranges (e.g., did OSHA substitute 62.5 ug/m^3 or perhaps 75 ug/m^3 for the range between 50 ug/m^3 and 100 ug/m^3? Did OSHA

assume that the 125 ug/m^3 figure applied for the 100-250 ug/m^3 range would represent the exposure also for all the workers now exposed above 250 ug/m^3?).

4. Using a new Excel worksheet, estimated the risk reduction that would ensue given steps #1 through #3.

5. Compared the resulting estimated risk reductions against OSHA's risk reduction conclusions shown in Table VII-1, specifically against the numbers OSHA shows in this Table on the line titled "Lung Cancers: Low" and in the columns for a PEL of 50 ug/m^3 for GI & Maritime and for a PEL of 100 ug/m^3 for GI & Maritime. More specifically, we compared the various risk reduction estimates that we generated in the spreadsheet against OSHA's estimated benefit figures of 238 cases of lung cancer mortality incrementally prevented by a PEL at 50 ug/m^3, and 6 cases of lung cancer mortality incrementally prevented by a PEL at 100 ug/m^3.

As shown in a pair of worksheets (titled Steenland Lung Cncr Log-linear and Try replicate OSHA reprtd rslt) in the accompanying workbook, we were unable to replicate OSHA's benefits estimates using any of the various possible sets of assumptions that we surmise OSHA may have applied. (See the various comparisons between our calculated results in green and OSHA's conclusions as shown in the PEA in red). OSHA may have performed the benefits analysis using some combination of assumptions and approach that is different from the various possibilities that we have been considering after carefully reading the benefits chapter of the PEA.

A further conclusion that we draw from our worksheet results is that OSHA cannot have derived the Agency's benefits estimates for the proposed PEL by estimating risk reductions among only the set of employees now exposed between the proposed and current General Industry PELs. (Note that this set of employees is the only General Industry group for whom OSHA estimates that employers will incur engineering control costs as a result of the proposed standard.)

Whether OSHA represented the current exposure for this set of employees as 62.5 ug/m^3 (as the Agency stated on page VII-2) or as 75 ug/m^3 (as the Agency might have done if making the same assumption as in 2003) or even as 100 ug/m^3 (an odd alternative possibility), benefits for this group due to a PEL at 50 ug/m^3 would be much less than the incremental benefits that OSHA estimated in Table VII-1 for General Industry workers due to the proposed PEL.

Using the Steenland log-linear exposure-response function, OSHA estimated that the proposed standard would avoid an incremental 238 lifetime cases of lung cancer mortality. Our worksheet calculations show, however, that among this group of General Industry employees, 46 cases would be avoided if their assumed baseline exposure was 62.5 ug/m^3, 84 cases would be avoided if their assumed baseline exposure was 75 ug/m^3, and 144 cases would be avoided if their assumed baseline exposure was100 ug/m^3.

It appears that OSHA must have estimated incremental benefits from the proposed standard for a larger group of employees than this one. Given that this is the only group

of General Industry employees for whom OSHA estimated costs, the Agency appears to have performed the benefits analysis in a manner inconsistent with how the Agency estimated costs.

OSHA estimated that more workers (apparently many more workers) will accrue benefits from a PEL at 50 ug/m^3 than the workers for whom OSHA estimated that employers will need to incur engineering control costs.[31] Or, said another way, OSHA estimated engineering control costs for one set of workers, but then estimated benefits for a much larger set of workers -- the first set for whom costs had been estimated, plus many more workers.

[31] OSHA might appropriately estimate exposure reduction benefits for a larger set of employees than the set for which engineering control costs have been estimated *if* the Agency were to assume some sort of "collateral" exposure reduction. If, for example, the Agency were to assume that exposure reduction efforts pursuant to the proposed PEL for exposures between 50 ug/m^3 and 100 ug/m^3 would also result in exposure reductions for employees now exposed at less than 50 ug/m^3 at the same facilities. However, OSHA explicitly assumes that no such "collateral" exposure reductions occur.

APPENDIX 2: PAPER FROM EPIDEMIOLOGIST ON EXPOSURE-RESPONSE FUNCTION FOR SILICOSIS MORTALITY

(The author of this paper is T. Qing. References in the paper to "I" or "me" or "my" refer to Ms. Qing. References in the paper to "you" or "your" refer to staff of Environomics, Inc. This paper relates to Mannetje, et al. 2002. All references in this paper to page numbers or tables or formulas are to those in Mannetje, et al. 2002)

HIGHLIGHTS

- The risk calculation on page 726 was based on adjusted mortality rate in Table 2, not based on Table 3.
- Conditional logistic regression assumes a "set-specific" intercept (often not estimated from the model), and a common slope (log rate ratio) of the exposure for each set.
- The interpretation of RR=2.08 in Table 3 is that with one-unit increase in log cumulative exposure, the odds of death will increase by 2.08 folds.

1. Risk Calculation

On page 725, last paragraph before results section, the authors introduced the method for calculating the cumulative risk (CR): "*Risk assessment was based on absolute rates of silicosis by cumulative exposure (adjusted for age, calendar time and study).*" This suggests that their calculation was based on the adjusted mortality rate in Table 2, rather than Table 3. Table 3 did not adjust for any confounders, but rather eliminated confounding by matching. This paragraph also provided the formula for risk calculation: risk=1-exp(Σtime*rate), which is the classic formula for converting incidence rate (IR) to CR. Since the IR is not constant over time but rather depends on the cumulative exposure, the risk calculation needs to account for this by looking at each year.

Please refer to my worksheet for the complete calculation. Below I just tabulate a small proportion of the worksheet for illustration. At year 19, the cumulative exposure is 1.9 mg/m^3-year, if the exposure intensity is 0.1 mg/m^3 every year. This cumulative exposure lies in the interval of 0.99-1.97 (first column of Table 2), so the corresponding mortality rate for year 19 is 15.9 (fourth column of Table 2) per 100,000 py. In year 20, however, the cumulative exposure exceeds 1.97 and lies in the interval of 1.97-2.87, so the corresponding mortality rate increases to 29.2. Then I sum over all the ICs over years to get Σtime*rate, and thereby computed the risk.

Year	Cumulative exposure	Adjusted IC
…	…	…
18	1.8	15.9
19	1.9	15.9
20	2	29.2
21	2.1	29.2
22	2.2	29.2

23	2.3	29.2
24	2.4	29.2
25	2.5	29.2
26	2.6	29.2
27	2.7	29.2
28	2.8	29.2
29	2.9	44.2
...	...	...

The risk calculation matches the results in the paper: 12.5 per 1000 subjects with an exposure of 0.1 mg/m^3 and 5.8 per 1000 subjects with an exposure of 0.05 mg/m^3. The paper got 13 and 6, which might be either due to rounding up the CR to a larger integer or the rounding errors of the IR in Table 2.

2. Conditional Logistic Regression

The paper performed a nested case-control analysis, where each of the 170 cases was matched with 100 controls by race, sex, date of birth and study. I'll use the following notation to describe conditional logistic regression:

$s = 1, \ldots, 170$: the index for the matched sets each containing one case and 100 controls.
$i = 1, \ldots, 101$: the index for subjects within in each matched set, with the first one being the case.
X_{si}: the log cumulative exposure for subject i in set s.
p_{si}: the probability that subject i in set s has an event (death).

The formulation of the conditional logistic regression is

$$\log(p_{si}/(1- p_{si})) = \alpha_s + \beta X_{si},$$

which assumes that the log odds ratio of having an event with one-unit increase in the exposure X is the same across all the matched sets, but the intercept, or baseline log odds α_s is set-specific. A heuristic explanation is that each matched set shares common characteristics because of matching, and different sets have different "baseline" odds of having an event. For example, a set with older workers could have elevated risk of an event. This is analogous to a random effects model, where α_s can be viewed as the random intercept describing the between-cluster/set variability. In estimating the model, only β is estimated by maximizing a so-called "conditional likelihood", given as follows:

$$CL(\beta) = \prod_{s=1 \; to \; 170} \frac{\exp(\beta X_{s1})}{\sum_{i=1}^{101} \exp(\beta X_{si})}.$$

Inside the product, the numerator corresponds to the case ($i = 1$), and the denominator corresponds to all 101 subjects in the matched set. This function has the same form as the conditional likelihood for a Cox regression (stratified by matched set). The case is the subject who had an event, while the controls can be viewed as 100 censored subjects (those who only contributed to the "at-risk" set). Therefore, people may also view β as the log hazard ratio, interpreted as the instantaneous risk ratio with one-unit increase in X. The interpretation of RR=2.08 in Table 3 is that with one unit increase in log cumulative exposure, the log odds (or hazard rate) of death will increase by 2.08 fold.

It should be noted that α_s is not estimated from the conditional logistic regression, and therefore we could not say anything about the baseline rate of an event. Only in a cohort study (such as the life table analysis and Poisson regression in Table 2), can one obtain the IR and then calculate the CR. In a case-control setting (regardless of nested or not), we do not have the denominator for calculating IR without using an external data source. What we can conclude is only the ratio of IRs (a.k.a, hazard ratio, odds ratio, rate ratio – just different names).

HIGHLIGHTS

- With rare events, the odds ratio, CR ratio, and IR ratio are all approximately identical. The interpretation of β in the conditional logistic regression could be log odds ratio, or log CR ratio (relative risk), or log IR ratio (hazard rate ratio) with one unit increase in log cumulative exposure.
- The risk of death will reduce by 39.8%, if the exposure reduces by half from 0.1 to 0.05mg/m^3.
- The CR can only be estimated from the full cohort, not from the conditional logistic regression. However, I roughly guessed the "baseline" CR according to the categorical results in Table 2. With cumulative exposure of 0.8 and 0.4 mg/m^3 – year over 8 years, CR(8) is 0.6 and 0.36 per 1000, respectively.

3. Some Mathematical Derivations with Heuristics

Hopefully this section will help you understand the conditional logistic regression and its interpretation. The formulae given here also lead to the risk calculation in the next section.

The "discrete" version of the cumulative risk (CR) calculation is given in the paper as below:

$$CR(u) = 1 - \exp\left(-\sum_{t=0}^{u} \mathrm{IR(t)}\Delta\mathrm{t}\right),$$

where u is the time interval of exposure, i.e., 45 years, Δt is a small time interval (a year in the paper) for evaluation, and IR(t) is the incidence rate at time t (based on certain cumulative exposure levels, e.g., 0.1 mg/m^3 every year). If the incidence rate is a step function (e.g., Table 2 of the paper), it's fine to use the discrete CR formula. But if we estimate the IR as a continuous curve over time (such as in Table 3, it would be better to use a "continuous" version of the CR calculation, where we cut the interval Δt to very small pieces, and replace the summation with the integration:

$$CR(u) = 1 - \exp\left(-\int_0^u \mathrm{IR(t)dt}\right). \quad (1)$$

The conditional logistic regression indeed estimates

$$\mathrm{IR(t)} = \exp\left(\alpha_s + \beta\, \mathrm{X(t)}\right), \quad (2)$$

where α_s is set-specific intercept determined by the intrinsic characteristics of the matched set, and β is log(2.08) as shown in Table 3. (*Note: with the rare disease, the incidence rate is about the same as the*

odds ratio. So this expression does not contradict the formula in my previous report.) Here X(t) is the log cumulative exposure at time t, so we have

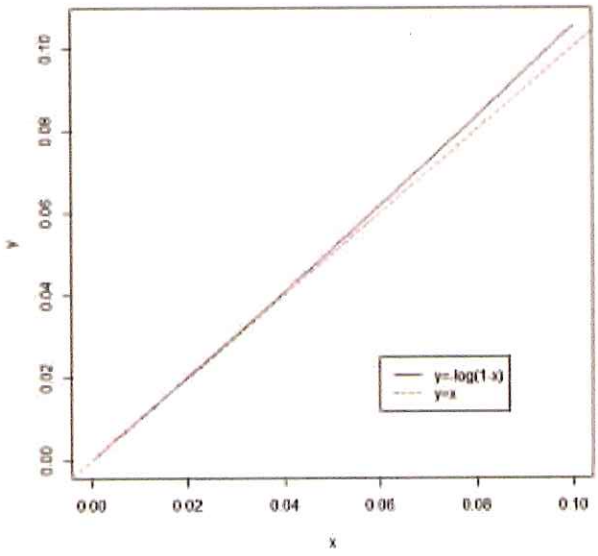
$$\mathrm{X(t)} = \log\left(\frac{T\times 365}{u}t + 1\right), \tag{3}$$

where T is the cumulative exposure over u years (e.g., $T = 4.5\ \mathrm{mg/m^3} - \mathrm{year}$ over $u = 45$ years). (*Note: 1 is added to avoid taking log of zero.*)

Now I'm going to work out the $CR(u)$ expression by substituting (2) and (3) into (1) and do the integration. I'm not showing you the detailed steps, which is messy; trust me, here is the ugly but correct result:

$$-\log\big(1 - CR(u)\big) = \frac{\exp(\alpha_s)u}{365(\beta+1)T}\big[(365T + 1)^{\beta+1} - 1\big]. \tag{4}$$

With the rare event, we have $-\log\big(1 - CR(u)\big) \approx CR(u)$, which works well when $CR(u)$ is less than 0.1 (100 deaths per 1000), as you can see from the next figure.



Although we cannot calculate $CR(u)$ because of the unknown α_s, we could calculate their ratios:

$$\frac{CR_1(u)}{CR_2(u)} \approx \frac{-\log\big(1 - CR_1(u)\big)}{-\log\big(1 - CR_2(u)\big)} = \frac{\frac{\exp(\alpha_s)\,u}{365(\beta+1)T_1}\big[(365T_1 + 1)^{\beta+1} - 1\big]}{\frac{\exp(\alpha_s)\,u}{365(\beta+1)T_2}\big[(365T_2 + 1)^{\beta+1} - 1\big]} = \frac{(365T_1 + 1)^{\beta+1} - 1}{(365T_2 + 1)^{\beta+1} - 1} \times \frac{T_2}{T_1}$$
$$\approx \left(\frac{T_1}{T_2}\right)^{\beta} \tag{5}$$

The last approximation follows because $+1$ and -1 are negligible compared to $365T_1$. Because of the rare event, CR ratio (which is a relative risk) is well approximated by the odds ratio.

Again, according to (2) and (3), we have the IR ratio:

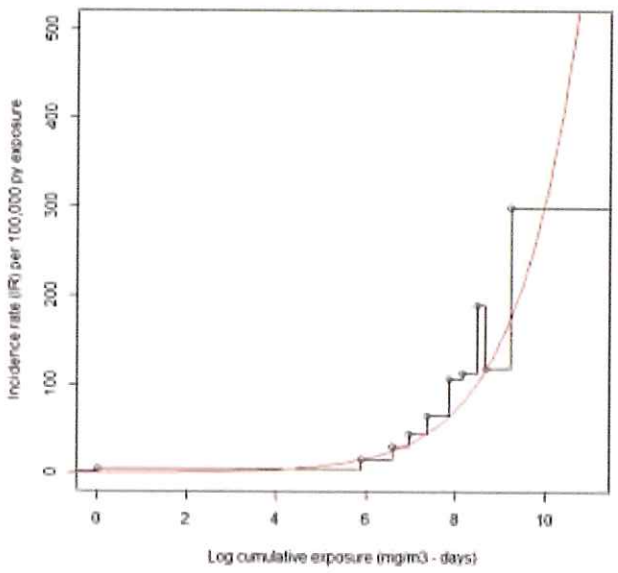
$$\frac{IR_1(t)}{IR_2(t)} = \frac{\left(\frac{365T_1t}{u}+1\right)^{\beta}}{\left(\frac{365T_2t}{u}+1\right)^{\beta}} \approx \left(\frac{T_1}{T_2}\right)^{\beta}.$$

Therefore I have shown that the odds ratio, CR ratio, and IR ratio are all approximately identical. The interpretation of β in the conditional logistic regression could be log odds ratio, or log CR ratio (relative risk), or log IR ratio (hazard rate ratio) with one unit increase in log cumulative exposure. For example, for cumulative exposures $T_1 = 0.8\ \text{mg/m}^3 - \text{year}$ and $T_2 = 0.4\ \text{mg/m}^3 - \text{year}$ over $u = 8$ years, we have the odds ratio, CR ratio and IR ratio to be $\left(\frac{0.8}{0.4}\right)^{\log(2.08)} = 1.66$. In other words, the risk of death will reduce by 39.8% (=1-1/1.66), if the exposure reduced by half from 0.1 to 0.05mg/m^3.

Note: in the paper, the CR ratio for exposure of 4.5 and 2.25 $mg/m^3 - year$ is 13/6=2.17, which is somewhat different from the theoretical value of 1.66. A reason might be that the categorical life table analysis in Table 2 is a rather crude approximation of the continuous exposure analysis.

4. A Rough Guess of CR

First, I plot out the IR as a step function based on Table 2. Then a smoothed curve (red line) is superimposed taking the form of $IR = \exp(-1.6 + \log(2.08) \times \log \text{cumulative exposure})$. The slope $\log(2.08)$ matches the rate ratio in Table 3, while the intercept -1.6 is just a crude guess, so that the figure resembles the "Figure 5" you sent me in the word document. The intercept can be viewed as an average of all set-specific intercepts α_s in the conditional logistic regression. It is not estimable from the conditional logistic regression; it can only be estimated from the original cohort data. But keep in mind that the conditional logistic regression is estimating the same association parameter as if we had fit the ordinary logistic regression using the full cohort. Hence if we plot out the incidence rate curve, it should be close to the step function.



Note: I wasn't able to fully replicate Figure 5. The y-axis in Figure 5 is odds ratio, or approximately, IR ratio. If I divide the IR by 4.7 (the reference group) in the above figure, the IR ratio for the highest exposure group would be 63.63 (as in Table 2), but in Figure 5, the odds ratio is less than 30. With the limited descriptions, I don't know how exactly they plotted the curves in Figure 5.

With the guessed IR curve, we would be able to roughly calculate the risk by equation (4):

$$CR(u) = 1 - \exp\left\{-\frac{\exp(-1.6)\,u}{365(\log(2.08)+1)T \times 100000}\left[(365T+1)^{\log(2.08)+1} - 1\right]\right\}.$$

The results for different u and T are listed as follows:

u (years)	T (mg/m^3 − year)	CR(u) per 1000
45	4.5	11.8
45	2.5	7.1
8	0.8	0.60
8	0.4	0.36

As we can see, with cumulative exposures of 4.5 and 2.5 mg/m^3 − year over 45 years, the CR(45) is calculated to be 11.8 and 7.1 per 1000, respectively, which are close to the results in the paper. With the same exposure intensities over 8 years, the CR(8) is 0.6 and 0.36 per 1000. The CR ratio is always around 1.66 (11.8/7.1=0.6/0.36=1.66) when the cumulative exposure level doubles.

$ in millions/yr

	Engr Controls	Ancillary Reqts	Total	Ratio new total to old total, each change separately	Engr control costs, cumulatively
Base estimate	101.1	45.6	146.7		
Don't overestimate impact current PEL	900	45.6	945.6	6.4	900
Include ISO/CEN	200	45.6	245.6	1.7	1,780
Est costs on facility basis	144	45.6	189.3	1.3	2,531
Est ancillary provisions more accurately	101.1	778	879.1	1.3	

Assume the changes relating to engineering control costs do not affect ancillary provisions costs, and vice versa

OSHA's General Industry Benefits Estimates

	Low	High	Midpoint
Lung Cancer deaths/yr avoided	5	59	32
Value of avoided instant deaths	$43,500,000	$513,300,000	$278,400,000
Addl value of morbidity avoided	$310,000	$300,900,000	$150,605,000
Total value	$43,810,000	$814,200,000	$429,005,000
NMRD deaths/yr avoided			65.0
Value of avoided instant deaths			$565,500,000
Addl value of morbidity avoided	$4,030,000	$331,500,000	$167,765,000
Total value	$569,530,000	$897,000,000	$733,265,000
ESRD deaths/yr avoided			23
Value of avoided instant deaths			$200,100,000
Addl value of morbidity avoided	$1,426,000	$117,300,000	$59,363,000
Total value	$201,526,000	$317,400,000	$259,463,000
Silicosis cases/yr avoided			504
Value of morbidity avoided	$31,248,000	$2,570,400,000	$1,300,824,000
Total value	$31,248,000	$2,570,400,000	$1,300,824,000
Grand total value	$846,114,000	$4,599,000,000	$2,722,557,000

	Low	High	Midpoint
VSL estimate			$8,700,000
Morbidity value	$62,000	$5,100,000	$2,581,000
	$62,000	$5,100,000	

Silicosis only deaths avoided (Mannetje): 7.2

Park's estimates are about 8 to 9 times higher than those calculated by Mannetje et al.

Excess deaths per 1,000 workers

	at 50 ug/m3	at 100 ug/m3	Reduction
Mannetje	7	11	4
Park	43	83	40

I thus estimate that Mannetje's risk reduction is about 1/9 Park's risk reduction

Results of various potential changes:

				Reductions from OSHA's base midpoint estimate
OSHA's PEA estimate approximately*	$846,114,000	$4,599,000,000	$2,722,557,000	---
1. Drop ESRD and NMRD xcept silicosis	$138,339,111	$3,484,266,667	$1,811,302,889	0.67
2. Replace OSHA estimate/case for all morbidity w/OSHA contractor est. for avoided case of silicosis	$998,349,000	$1,485,267,000	$1,241,808,000	0.46
3. Lung cancer: replace risk range with result from single best exposure-response function; replace inappropriate estimate for pre-death morbidity	$846,137,840	$3,828,633,840	$2,337,385,840	0.86
#1 + #2 + #3	$268,724,618	$268,724,618	$268,724,618	0.10

* This represents a way of approximately calculating what OSHA would estimate benefits to be, assuming our time horizon, time path of annual benefits, and discounting. We assume that each change that we have addressed here would have the same proportional impact on OSHA's benefits calculated as the Agency does it as the proportional impact that we calculate here for this different way of calculating the benefits that OSHA would estimate.

Distribution of Workers Exposed >50 ug/m3 by # in the Same Job Category and Facility

# workers in job category & facility:	< 0.5	0.5 to 1.0	1 to 2	2 to 3	3 to 4	4 to 6	6 to 8	> 8	All
Very Small Establishments	4,854	3,259	2,853	177	0	0	0	0	11,143
Small Establishments	2,749	4,175	3,435	5,289	9,525	4,350	15,996	3,507	49,026
Large Establishments	1,392	897	2,981	2,747	2,131	16,338	3,275	17,981	47,742
Total # workers	8,996	8,332	9,269	8,213	11,655	20,687	19,271	21,488	107,912
Percentage	8.3%	7.7%	8.6%	7.6%	10.8%	19.2%	17.9%	19.9%	100.0%

# of control pkg installations -- OSHA	2,249	2,083	2,317	2,053	2,914	5,172	4,818	5,372	26,978	26,978
# of control pkg installations -- actual	8,996	8,332	6,179	3,285	3,330	4,137	2,753	1,343	38,356	38,356