Cr(VI) exposures and the confidence limits around the projected risks from the two data sets do not overlap. This indicates that the maximum likelihood estimates derived from one data set are unlikely to describe the lung cancer mortality observed in the other data set. Despite this statistical inconsistency between the risk estimates, the differences between them are not unreasonably great given the potential uncertainties involved in estimating cancer risk from the data (see section VI.G). Since the analyses based on these two cohorts are each of high quality and their projected risks are reasonably close (well within an order of magnitude), OSHA believes the excess lifetime risk of lung cancer from occupational exposure to Cr(VI) is best represented by the range of risks that lie between maximum likelihood estimates of the Gibb and Luippold data sets.

Table VI-7

OSHA Estimates of Excess Lung Cancer Cases per 1000 Workers[a] Exposed to Various Eight Hour TWA Cr(VI) With 95 Percent Confidence Interval Comparisons by Cohort

Exposure Level (μg/m³)	Best Estimates of Risk	Preferred Cohorts		Additional Cohorts		
		Gibb	Luippold	Mancuso	Hayes	Gerin
0.25	0.52-2.3	2.3 (1.0-3.9)	0.53 (0.31-0.79)	1.7 (1.0-2.7)	0.45 (0.31-0.75)	0.2 (0.0-0.7)
0.5	1.0-4.6	4.6 (2.0-7.8)	1.1 (0.62-1.6)	3.5 (2.0-5.4)	0.90 (0.62-1.5)	0.5 (0.0-1.4)
1.0	2.1-9.1	9.1 (4.0-16)	2.1 (1.2-3.1)	7.0 (4.1-11)	1.8 (1.2-3.0)	0.9 (0.0-2.8)
5.0	10-45	45 (20-75)	10 (6.2-15)	34 (20-52)	9.0 (6.1-15)	4.5 (0.0-14)
10	21-86	86 (39-142)	21 (12-31)	n/a	18 (12-30)	9.0 (0.0-29)
20	41-164	164 (76-256)	41 (21-60)	n/a	36 (24-51)	18 (0.0-54)
52	101-351	351 (181-493)	101 (62-147)	293 (188-403)	88 (61-141)	46 (0.0-130)

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level. All estimates were recalculated using year 2000 U.S. reference rates, all races, both sexes, for lung cancer and all causes, except for those from Mancuso, for which 1998 rates were used.

[b] OSHA finds that the estimates of risk best supported by the scientific evidence are the ranges bounded by the maximum likelihood estimates from the linear relative risk models presented in Table VI-2 (Baltimore reference population/exposure grouping with equal person-years) for the Gibb cohort and Table VI-6 for the Luippold cohort.

[c] The confidence intervals for the Gibb and Luippold cohorts are from Tables VI-2 and VI-6. The confidence intervals for the Mancuso and Gerin cohorts are derived from parameters reported by Environ (2002, Ex. 33-15). All are from the best fitting linear relative risk models and are 95% confidence intervals. The confidence interval for the Hayes cohort was calculated from the 90 percent confidence interval on the dose coefficient for the linear relative risk model reported by the K.S. Crump Division (1995, Ex. 13-5).

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OSHA's best estimates of excess lung cancer cases from a 45-year working lifetime exposure to Cr(VI) are presented in Table VI–7. As previously discussed, several acceptable assessments of the Gibb data set were performed, with similar results. The 2003 Environ model E1, applying the Baltimore City reference population and ten exposure categories based on a roughly equal number of person-years per group, was selected to represent the range of best risk estimates derived from the Gibb cohort, in part because this assessment employed an approach most consistent with the exposure grouping applied in the Luippold analysis (see Table VI–6). To characterize the statistical uncertainty of OSHA's risk estimates, Table VI–7 also presents the 95% confidence limits associated with the maximum likelihood risk estimates from the Gibb cohort and the Luippold cohort.

OSHA finds that the most likely lifetime excess risk at the previous PEL of 52 $\mu g/m^3$ Cr(VI) lies between 101 per 1000 and 351 per 1000, as shown in Table VI–7. That is, OSHA predicts that between 101 and 351 of 1000 workers occupationally exposed for 45 years at the previous PEL would develop lung cancer as a result of their exposure. The wider range of 62 per 1000 (lower 95% confidence bound, Luippold cohort) to 493 per 1000 (upper 95% confidence bound, Gibb cohort) illustrates the range of risks considered statistically plausible based on these cohorts, and thus represents the statistical uncertainty in the estimates of lung cancer risk. This range of risks decreases roughly proportionally with exposure, as illustrated by the risk estimates shown in Table VI–7 for working lifetime exposures at various levels at and below the previous PEL.

The risk estimates for the Mancuso, Hayes, and Gerin data sets are also presented in Table VI–7. (As discussed previously, risk estimates were not derived from the Alexander data set.) The exposure-response data from these cohorts are not as strong as those from the two featured cohorts. OSHA believes that the supplemental assessments for the Mancuso and Hayes cohorts support the range of projected excess lung cancer risks from the Gibb and Luippold cohorts. This is illustrated by the maximum likelihood estimates and 95% confidence intervals shown in Table VI–7. The risk estimates and 95% confidence interval based on the Hayes cohort are similar to those based on the Luippold cohort, while the estimates based on the Mancuso cohort are more similar to those based on the Gibb cohort. Also, OSHA's range of best risk estimates based on the two primary cohorts for a given occupational Cr(VI) exposure overlap the 95 percent confidence limits for the Mancuso, Hayes, and Gerin cohorts. This indicates that the Agency's range of best estimates is statistically consistent with the risks calculated by Environ from any of these data sets, including the Gerin cohort where the lung cancers did not show a clear positive trend with cumulative Cr(VI) exposure.

Several commenters remarked on OSHA's use of both the Gibb cohort and the Luippold cohort to define a preliminary range of risk estimates associated with a working lifetime of exposure at the previous and alternative PELs. Some suggested that OSHA should instead rely exclusively on the Gibb study, due to its superior size, smoking data, completeness of follow-up, and exposure information (Tr. 709–710, 769; Exs. 40–18–1, pp. 2–3; 47–23, p. 3; 47–28, pp. 4–5). Others suggested that OSHA should devise a weighting scheme to derive risk estimates based on both studies but with greater weight assigned to the Gibb cohort (Tr. 709–710, 769, Exs. 40–18–1, pp. 2–3; 47–23, p. 3), arguing that ''the use of the maximum likelihood estimate from the Luippold study as the lower bound of OSHA's risk estimates * * * has the effect of making a higher Permissible Exposure Limit (PEL) appear acceptable'' (Ex. 40–18–1, p. 3). OSHA disagrees with this line of reasoning. OSHA believes that including all studies that provide a strong basis to model the relationship between Cr(VI) and lung cancer, as the Luippold study does, provides useful information and adds depth to the Agency's risk assessment. OSHA agrees that in some cases derivation of risk estimates based on a weighting scheme is an appropriate approach when differences between the results of the two or more studies are believed to primarily reflect sources of uncertainty or error in the underlying studies. A weighting scheme might then be used to reflect the degree of confidence in their respective results. However, the Gibb and Luippold cohorts were known to be quite different populations, and the difference between the risk estimates based on the two cohorts could partly reflect variability in exposure-response. In this case, OSHA's use of a range of risk defined by the two studies is appropriate for the purpose of determining significance of risk at the previous PEL and the alternative PELs that the Agency considered.

Another commenter suggested that OSHA should derive a ''single 'best' risk estimate [taking] into account all of the six quantitative risk estimates'' identified by OSHA as featured or supporting risk assessments in the preamble to the proposed rule, consisting of the Gibb and Luippold cohorts as well as studies by Mancuso (Ex. 7–11), Hayes (Ex. 7–14), Gerin (Ex. 7–120), and Alexander (Ex. 31–16–3) (Ex. 38–265, p. 76). The commenter, Mr. Stuart Sessions of Environomics, Inc., proposed that OSHA should use a weighted average of risk estimates