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Sent: Monday, May 03, 2010 12:17 PM
To: Silvey, Patricia - MSHA
Cc: Chovanec, Marie I. (CDC/NIOSH/OMSH)
Subject: FW: MSHA coal risk assessment

Hi Pat,

This is the final revised version of our comments related to the QRA document.

Thanks,

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This is a very thorough and detailed quantitative risk assessment (QRA). It is structured in three main parts: 1) the derivation of coal mine dust concentrations for U.S. coal mines that are intended to be free of artifacts introduced by the compliance process; 2) an examination of pertinent exposure-response models; 3) the application of the data from 1) and 2) in order to derive the reduction in excess risk that would result through application of the lower recommended dust standard and associated rules. Full and detailed appendices that cover further issues and expositions of the methods are supplied.

In the first part, recognition is taken of the factors that can impact measurements made in the course of enforcing dust regulations. These extend to the issues engendered by the current sampling process, involving both operator and inspector sampling, as well as the fact that the current procedures do not rely on single samples. Sophisticated methods are used to resolve these issues, as far as they can be resolved, coupled with careful selection of data so as to exclude samples that are potentially likely to be unrepresentative (e.g., inspector follow-up samples).

The second part presents information on the exposure-response models used. This material is up-to-date and the information is interpreted correctly as well as employed properly. There is a proper focus on different health outcomes, including both coal workers' pneumoconiosis (CWP) and chronic obstructive pulmonary disease (COPD). End outcomes include both morbidity and mortality, and within each type of outcome, various endpoints are considered (e.g., simple CWP and PMF, or ventilator function and pathologic emphysema).

The final part derives information on the benefits to be gained by adopting the proposed new coal mine dust standard and associated regulations. The logic behind this is to derive the distribution of recent exposure levels (using information from the first part), the distribution of exposure levels expected by imposition of the proposed standard, and compute the benefit in terms of numbers of cases that would be prevented by the reduction in exposure levels. The report properly concerns itself with sample distributions rather than a restricted focus on mean levels, and pays great attention to valid methods of estimation.

Overall, the QRA indicates that the proposed coal mine standard would have the effect of substantially reducing the number of occupational respiratory disease cases. This is the same conclusion that NIOSH came to in 1995 using much of the same epidemiologic information. It therefore is consistent not only with NIOSH policy but is based on the same basic approach employed by NIOSH.

Comment on format

The document is well-written and I could find only a few typos and inaccuracies. Nevertheless, it is a large and detailed document, full of facts and data, and it is very hard to digest. Even though I have been intimately involved in most of the studies and with the data, I found it hard to determine the broad analytical approach. In this, the style of the document is discursive, rather than directive. For example, in part 1, the data are described, discussed, decisions made, and then further issues are raised and decisions made, and we finally get to the estimates that are employed. In part 3, the text starts with a description of the method used by NIOSH, rather than getting directly to the chosen approach by MSHA. In both cases, it would be better to tell us about the MSHA approach, and later compare it to prior or

alternative approaches, citing the pros and cons, of course. Overall, the pace of the document is rather slow and the text tends to belabor points that should be familiar to the expected readership of this document.

Overall, it would be much better to get to the main points much more directly, so the reader can rapidly comprehend the whole process. One way to do this is including some summary material, presented initially in each chapter, which gives the objective, issues, and a brief overview of the methods employed. This would outline the steps of the analysis based on the final data and methodology chosen for the analysis. Any justification would be brief, with references made to the later sections where the topic is handled in detail. Having understood from that how the whole analysis is put together, the reader can then choose to read further as needed. Perhaps in this, there is room for more of the discursive text to be moved to further appendices.

Major comments on methods

As noted above, great attention was paid to assessing recent dust levels in U.S. mines. The various reasons why certain data might be biased were presented, discussed, and, where necessary, appropriate steps were taken to adjust or exclude potentially biased measurements. However, at NIOSH we have been concerned over the last few years that something is gravely wrong in certain areas concerning how well the U.S. underground coal mine environment has been controlled. In this respect, various papers and reports have been published on hot spots of CWP prevalence or progression. More recently, we have been investigating the observed CWP prevalence in comparison with the prevalence that might be expected given dust concentration levels derived from the same dataset employed in this QRA. Overall, we have found that in certain coal mining regions considerably more CWP has been recorded than is predicted using the reported dust levels in the MSHA dataset. There are a number of potential explanations for the observed phenomenon:

1) the epidemiologic models employed in the published papers might be wrong;
2) dust levels have systematically been under-reported;
3) longer working hours have effectively been increasing overall exposures;
4) some other constituent of the dust, such as silica, is at work;
5) all of the above factors, including underestimation, are at work.

The fact that the effect is absent in some coal mining regions (that is, observed and predicted prevalences are similar to each other) appears to rule out reason 1).

With respect to dust levels (point 2), one tabulation undertaken for West Virginia miners has shown that mean concentration levels of 3 mg/m^3 or higher would have had to been experienced to get the CWP prevalences observed. These levels are more consistent with the example given of the continuous miner job in Table 29 of the QRA than the <1 mg/m^3 level given in Table 6, and point to a consistent underestimation of the actual coal mine dust levels in recent years. It seems that these NIOSH findings regarding observed and predicted CWP prevalences ought to be mentioned in the QRA. They do not undercut the QRA at all – if underestimation of dust concentrations is a major problem, it is clear that

adoption of the new dust limits, ***if effectively enforced***, would lead to considerably greater benefits than are indicated in this QRA.

The QRA comments on the impact of longer hours. Although, there are no epidemiologic or other data that conclusively implicates working longer hours as a factor in the development of CWP, it seems prudent to suspect it does. The QRA comments on this issue and correctly notes that its results are conservative in this regard.

Lastly, there is the issue of silica exposure. This is not dealt with at all in the QRA, which has a focus totally on mixed mine dust. To a large extent, this focus is reasonable – historically silica exposure has not featured greatly in findings concerning CWP development (at low levels it did not appear as a major predictor) – and there are no epidemiologic models from the U.S. that include silica exposure as a predictor variable. Ultimately, this QRA accomplishes what it is intended to do – to justify a reduction in the dust standard for mixed coal mine dust. This is the same conclusion as promulgated by NIOSH in 1995. However, in concentrating on this particular exposure-response relationship with coal mine dust, we must not forget that miners today are being exposed to excess silica levels, particularly in thinner seam and small mines, and that this situation could well get worse as the thicker seams are mined out. Hence, since silica is more toxic than mixed coal mine dust, tomorrow's miners could well be at greater risk, despite a reduction in the mixed coal mine dust standard. It seems appropriate that this fact should be noted in the QRA.

My second major concern relates to the outcome endpoints being set for miners at fairly advanced age. Not only does a focus on 80-year old miners undercut the obvious seriousness of the intent of the QRA – some might wonder why, if a miner can reach to his 80s, whether there could be anything seriously wrong! But, more importantly, extrapolating the epidemiologic findings well beyond the age range of the study participants stretches credibility. All of the morbidity studies were based on coal miners of working age, often with an average age of around 45, with only a minority close to retirement age. In essence, we don't know much about about the disease status of retired coal miners. Although it does seem very plausible that occupational respiratory disease, once it has developed, could well exacerbate without further exposure, there is little solid evidence on this. Consequently, I have a concern that the validity of the results could be questioned by those opposed to change. Using only the age 73 outcome would minimize the possibility of this type of criticism.

Other comments

a) On p. 37 the text notes:

"Therefore, MSHA classified each WL as belonging to one of three coal rank categories — anthracite, high-rank bituminous, or low/medium rank.[35] *At most work locations in U.S. underground coal mines, exposures are to high rank coal dust. Except for District 1 (all anthracite), it was assumed that exposures at surface mines and facilities are to low/medium rank coal mine dust."*

This may be a matter of definition, but my understanding is that most coal that is mined underground is low/medium rank. High rank coal, by my definition, is only mined underground in western Virginia and

the very south-east of West Virginia. In fact, that coalfield actually includes some semi-anthracite coal (although I do not know if it is mined currently). My definitions come from a reference book on coal, that is, in Table 1.5 of Speight *The chemistry and technology of coal* [1]. Here, I equate high rank with low- and medium-volatile coal. My understanding is that the majority of coal mined underground in the U.S. is high-volatile bituminous coal, which I equate with low/medium rank.

b) There is no reference to the Miller et al. (2007) report. I suspect it was an Institute of Occupational Medicine technical report. I also suspect that the Miller and MacCalman [2](2009) publication contains the essentials of the report (although not the modeling coefficients used in this QRA).

c) It would be good to have some words interpreting Table 37. The caption says that the figures are relative to the first day. If this is so, the first day should be 0 (exp(0)=1). If they are not relative to the first day, then it seems that subsequent measurements are higher than those from the first day (-1.0353>-1.2201), which seems contrary to the supposition that the inspector returned to sample because dust levels were high and had then been corrected.

d) On p. 27 the text says:

"Attfield and Seixas used two or three specially selected B readers…"

This appears to make the methods look rather casual. The text of the paper notes that three readers were used and that the median reading of the three was taken. (Fewer *readings* might have been available if one or more readers found the radiograph to be unreadable, but these cases were few.)

e) The Kuempel et al. coal risks paper [3], which provides more information on the risk assessment used in the NIOSH criteria document should be cited. The fact that the procedures passed peer review for publication adds validity to those results, and by implication, to those of the QRA.

References

[1] Speight,J.G. The chemistry and technology of coal, Marcel Dekker, New York, 1994.

[2] Miller,B.G., MacCalman,L. Cause-specific mortality in British coal workers and exposure to respirable dust and quartz, Occup. Environ. Med.(2009).

[3] Kuempel,E.D., Smith,R.J., Attfield,M.D., Stayner,L.T. Risks of occupational respiratory diseases among U.S. coal miners, Appl. Occup. Environ. Hyg. 12 (1997) 823-831.