

the AIA's CV estimate for intersample variability necessarily reflects a random error that is intrinsic to the P&CAM 239 or NIOSH 7400 methods, finding instead that nonrandom error, caused by inadequate sampling times, low fiber counts, etc. accounts for what the AIA terms intersample variability. OSHA thus rejects the argument that intersample variability may be a more significant source of sampling and analytical error than intra- or interlaboratory errors.

Summary of Evidence on Sampling and Analytical Variability

In the preceding discussion, OSHA reviewed the rulemaking evidence describing the sources and extent of sampling and analytical error associated with measuring airborne asbestos concentrations using the NIOSH P&CAM 239 or NIOSH 7400 methods. The major sources of sampling and analytical variability described by the AIA (Ex. 328) include intralaboratory variability, interlaboratory variability, and intersample variability. Together, AIA estimated that these sources of variability result in an overall CV for the NIOSH P&CAM method ranging from 0.45 to 0.65 (Ex. 328, p. A-23). Based on this estimate for total CV, the AIA argued that

OSHA must recognize that this unique variability limits the degree to which the asbestos PEL can be reduced, calls for more than usual enforcement flexibility, and, at the same time, assures that workplaces in compliance with a PEL will keep average exposures much lower than the PEL. (Ex. 328, p. A-1)

The AIA further argued that, given the high variability of the NIOSH P&CAM 239 and NIOSH 7400 methods, promulgation of a 0.2 f/cc PEL would not leave an adequate margin between the PEL and the "practical limit of detection" (Ex. 328, p. 11-18), and that employers would thus not be able to reliably determine whether their employees' exposures are in excess of the PEL.

OSHA rejects these arguments for two reasons. First, OSHA does not agree with the AIA's estimate of the overall precision of the NIOSH P&CAM 239 method. As discussed in the section above, the data relied upon by the AIA do not predominantly reflect random sources of sampling and analytical error; instead, they reflect nonrandom error caused by the use of different monitoring methods and quality control programs by laboratories participating in the study. On the other hand, the study by Busch et al. (Ex. 84-62) of the precision of the NIOSH P&CAM 239

method reflects a truer estimate of the random variability of the method because of the greater degree of consistency in laboratory practices and training between the different Johns-Manville laboratories that generated the sampling data. NIOSH's estimate of the overall precision of the phase contrast method of asbestos analysis are similar to the estimates reported by Ogden (Ex. 84-448), who also studied analytical results from laboratories that implement similar training and laboratory practices. OSHA believes that, by promulgating requirements for specific monitoring procedures and quality control measures, it is possible to limit sources of sampling and analytical error to those that are random. Therefore, OSHA finds that NIOSH's estimates for the overall precision of the P&CAM 239 method, and consequently for the NIOSH 7400 and OSHA Reference methods, are the most reliable estimates in the record of the random sampling and analytical variability of these methods. As long as samples are obtained with a fiber density of 80-100 fibers per 100 fields counted, OSHA believes that the standard analytical error (SAE) of the ORM will be between 18.9 and 21.3 percent, with an upper estimate of 24.7 percent, based on the analysis of Dr. Ogden. This SAE coincides with the SAE of 25 percent currently used by OSHA for evaluating compliance samples of airborne asbestos. Therefore, OSHA will retain the SAE for asbestos at 25 percent. The Agency also finds that use of the ORM will not require employers to reduce their employees' exposures to levels substantially below the PEL of 0.2 f/cc to ensure that they are in compliance with the new PEL.

Reliable Limit of Detection

NIOSH has reported that the 7400 method for asbestos sampling and analysis has a reliable limit of detection of 0.02 f/cc, based on collecting a 1,920-liter sample (i.e., collecting an 8-hour sample using a flow rate of 4 lpm) and obtaining the minimum acceptable fiber density of 80 fibers per 100 fields. Using the formulas for calculating limits of detection (Exs. 84-444, 84-478), OSHA has determined that the reliable limit of detection for the ORM is 0.03 f/cc, based on obtaining a fiber density of 80 fibers/100 fields from a 1,200-liter sample (2.5 lpm over 8 hours); the limit of detection for the ORM is thus well below the 0.1 f/cc action level included in the revised standards for general industry and construction.

The AIA argued that, because of the problem of nuisance dust obscuring

asbestos fibers on a filter, the practical limit of detection for the NIOSH 7400 method is much higher:

... The practical limit of reliable detection incorporates important practical factors that prevent the theoretical detection limit from being achieved such as reasonable sampling times, reasonable pumping rates and filter loading with nuisance dust. Problems with nuisance dust loading will vary from one atmosphere to another and may seriously limit the range of the method.

A number of measurement methods in the record have suggested that practical limits of reliable detection fall in the range of 0.1 f/cc to 0.5 f/cc. In fact, P&CAM 239 establishes 0.1 f/cc as its lower bound even though exposure levels well below this may be obtained using the method. NIOSH's new Method 7400 does claim a lower value, 0.02 f/cc, but made clear that this is only a theoretical limit of detection by stating that it applies only in the absence of excessive nuisance dust loading. NIOSH has not explained why it chose to depart in Method 7400 from the practical limit of reliable detection employed in P&CAM 239. Considering the total absence in the record of any published testing results on Method 7400, there has never been any demonstration that it is practical to achieve the claimed value in manufacturing workplaces (Ex. 128, pp. A-24 through A-27).

Dr. Chatfield also expressed this view at the hearing, stating that the higher flow rates permitted by the NIOSH 7400 method "... will result in [the] capture of even larger pieces of nuisance dust than are collected currently using P&CAM 239 adding further to the filter obstruction problem" (Tr 7/6, p. 64).

In his testimony, Dr. Taylor stated that NIOSH intended the higher flow rates permitted by the 7400 method to be used for taking clearance samples and not for the routine monitoring of airborne asbestos levels in workplaces (Tr. 6/21, p. 161). OSHA agrees that the higher flow rates permitted by the 7400 method may contribute to filter overload or interference by other particles, and has therefore limited the ORM's flow rate to 2.5 lpm. Although OSHA believes that limiting flow rate will, in the great majority of cases, eliminate the filter overload problem, the ORM does permit the use of a 37-mm diameter filter in specific instances where filter overloading may be a problem. However, since the use of the 37-mm diameter filter doubles the limit of detection that can be achieved with the smaller filter, the larger filter may only be used if employers provide a written justification for its use. OSHA believes, based on testimony presented by Drs. Ogden and Taylor to the effect that nuisance dust overload is a rare