sampling strategies be designed to yield samples with fiber densities of at least 80 fibers per 100 fields when using the NIOSH 7400 method.

Intralaboratory Variability

NIOSH's statistical analysis of the Johns-Manville analytical data, and the resulting estimates of the precision of the P&CAM 239 method, were criticized by rulemaking participants, who believed NIOSH's estimates to be too low (Ex. 91–16, Tab D; 91–16, Tab F, 232–B, 233–B, 328; Tr. 7/6, p. 66). In summarizing the record evidence on intralaboratory variability, which was one of the three sources of variability included in NIOSH's overall estimate of precision for the method, the AIA concluded that ". . . NIOSH should . . . recognize a more reasonable CV value in the range of 0.2 to 0.3—a range which accords with the remainder of the evidence in the record on the best achievable total intralaboratory error" (Ex. 128, p. A–15). In arriving at this conclusion, the AIA relied on the following evidence:

- Testimony from Dr. Ogden stating that he had achieved intralaboratory CV's of approximately 0.2 in British laboratories.
- Analysis of the Johns-Manville data by Dr. Patrick Crockett, who projected a CV of over 0.31 for a total fiber count of 100.
- The study of the P&CAM 239 method by Chase and Rhodes (Ex. 86–002), who reported an intralaboratory CV of 0.38 for a total fiber count of 100.

OSHA has analyzed the evidence presented by the AIA and finds that these data do not necessarily refute NIOSH's estimates of the CV for samples analyzed by the P&CAM 239 or NIOSH 7400 methods. In fact, the evidence of Dr. Ogden cited by the AIA closely parallels the results obtained by Busch et al. (Ex. 84–62, Appendix C). Dr. Ogden examined intralaboratory variation among technicians analyzing 66 asbestos samples in British Health and Safety Executive (HSE) laboratories (Ex. 84–447). In this testimony about this work, Dr. Ogden stated that his investigation, as well as those from other laboratories, resulted in estimated intralaboratory CV's similar to the estimates obtained in the NIOSH study:

> There is a lot of evidence from different laboratories that repeated evaluation of the same asbestos-loaded membrane filter by the same counter, or by different counters closely linked within a laboratory, can give a coefficient of variation of between 10 and 20 percent. . . .
>
> Figure 1 [from Ex. 84–447] demonstrates results in our laboratory of a detailed study of one year's quality assurance results . . . . On the vertical axis we have the coefficient of variation of the repeated determination; and on the horizontal axis we have the mean number of fibers counted in that sample. . . .
>
> Since coming to the United States I have plotted the results on the same axis which were published by [Busch et al.] . . . . If we superimpose those, you can see they lie in very much the same kind of area. (Tr. 6/20, pp. 6–7)

Dr. Ogden's estimate of 0.2 as an average CV representing intralaboratory variability is a consequence of his use of a minimum fiber density of 50 fibers per 100 fields, in contrast with NIOSH's recommendation in the 7400 method that a minimum fiber density of 80 fibers per 100 field be used, which yields an estimated CV of 0.15. Therefore, OSHA finds that Dr. Ogden's results actually confirm NIOSH's estimates of the intralaboratory coefficient of variation for asbestos samples analyzed by phase contrast microscopy.

The AIA also relied on the analysis performed by Dr. Crockett (Ex. 312–A, Tab P) of the Johns-Manville data to refute NIOSH's estimate of the precision of the P&CAM 239 method (Ex. 328, pp. A–12 to A–15). The AIA explains Dr. Crockett's analysis as follows:

> Dr. Crockett identified and plotted . . . more than forty data points that were excluded from the NIOSH analysis. . . . In the very important range of 60 to 100 fibers counted, only six or seven of the eighteen data points [in this range] were included and the included points represented dramatically lower CV estimates than the excluded points . . .
>
> When Dr. Crockett applied a close reproduction of the NIOSH statistical method to the *entire* Johns-Manville data set, his projected CV for a total fiber count of 100 was over 0.31, about three times as high as NIOSH's result based on incomplete data. In any event, the published NIOSH method does not represent the original Johns-manville data base, but instead reflects only a subset of that database with much of the high variability data deleted. (Ex. 128, pp. A–13 to A–14)

When questioned as to why NIOSH eliminated some of the data points in the analysis, Ken Busch of NIOSH replied that these data were excluded because they were outside the fiber density range permitted by the "A" rules:

> I'm absolutely certain that there was no intent to eliminate counts which would be the cause of high variability. The elimination of counts . . . which were based on large numbers of fibers was simply because this procedure of counting more than 100 fibers did not correspond to the standard procedure for the NIOSH method. (Tr. 6/21, p. 192)

In addition, the statistical model developed by Busch et al. (Ex. 84–62, Appendix C) was developed to estimate the relationship between CV and number of fibers counted. As such, the model can only appropriately be applied to samples that were counted using the "100 fields" stopping rule of the set A rules (i.e., for samples with a fiber density of less than 1 fiber per field, 100 fields must be counted, and for samples with a fiber density of more than 5 fibers per field, 20 fields must be counted). For samples with fiber densities between 1 and 5 fibers per field, the NIOSH "A" rules require that enough fields be counted to yield 100 fibers. According to Busch et al. (Ex. 84–62, Appendix C, p. 75), calculating the overall CV for samples counted using the "100 fibers" stopping rule rather than the "100 fields" stopping rule cannot be done unless additional statistical techniques are developed, although "indications are that the '100 fibers' stopping rule [would] yields a CV_T similar to that for the '100 fields' stopping rule when 100 fibers are counted" (Ex. 84–62, p. 75). Both because of the uncertainty surrounding the calculation of a CV for samples counted using the 100 fibers stopping rule, as reported by Busch (Ex. 84–62, p. 75), and because the Johns-Manville data were appropriately excluded from the NIOSH analysis, OSHA disagrees with Dr. Crockett's contention that NIOSH's estimated CV is unreliable.

The final study cited by the AIA to support its contention that the intralaboratory CV associated with the P&CAM 239 method is higher than that estimated by NIOSH is the round robin study by Chase and Rhodes (Ex. 86–002), which reported a random intralaboratory CV of 0.38 for a total fiber count of 100. According to the AIA:

> This study included virtually all relevant error sources and of the studies in the record, is the most representative of everyday American experience with P&CAM 239 and commonly encountered workplace samples, and should be accorded significant weight by OSHA. (Ex. 328, p. A–11)

AIA did acknowledge that the study may overstate the magnitude of the "best achievable intralaboratory CV" because of the absence of quality control programs in some of the participating laboratories, and because some of the samples analyzed were difficult to count (Ex. 328, p. A–11, Footnote 17). The lack of quality control programs, as evidenced by the participation in the NIOSH PAT program of only 19 of the 46 laboratories included in the study, was one reason suggested by OSHA in the November proposal (48 FR 51136) for the Chase and Rhodes study's higher reported CV.

OSHA also believes that the design of the Chase and Rhodes study is deficient. The authors collected and analyzed a total of 1,774 full-shift samples, of which 541 were submitted for a second

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