

Technical News feature

❖ Sampling for Respirable Cotton Dust

K.O. ROBERT, JR. and A. BARIL, JR., Southern Regional Research Center, Agricultural Research Service, USDA, New Orleans, LA 70179

ABSTRACT

The nature of sampling from a dust cloud containing fine dust and lint fragments is reviewed. The definition of "respirable cotton dust" in the OSHA Cotton Dust Standard is compared and contrasted with the quantity measured by the NIOSH (Lumsden-Lynch) vertical elutriator (VE) cotton dust sampler. Theoretical and empirical factors that affect the accuracy and precision of VE measurements are discussed. Technologies for alternative sampling strategies and for improving VE sampling are described.

INTRODUCTION

In 1978, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor promulgated standards for occupational exposure to airborne cotton dust (1). The OSHA standard was based on the criteria document (2), which was published in 1975 by the National Institute of Occupational Safety and Health (NIOSH).

In the criteria document, NIOSH (2) recommended criteria for protecting workers' health against cotton dust. Surprisingly, airborne cotton fibers (lint) were not identified at that time as an exposure pathway. So attention was focused on measuring "lint-free respirable" dust as an indicator of hazard during the processing of cotton.

NIOSH recommended that an environmental standard should be fixed. The stated purpose of NIOSH's recommended standard was to promote the development and installation of engineering controls, rather than to guarantee an absolute level of health protection.

Following the NIOSH recommendations, OSHA selected the quantity "lint-free respirable" dust as the hazard to be regulated. OSHA stipulated that no employee shall be exposed to 8-hr time-weighted average concentrations of this quantity in excess of: "(a) 750 micrograms/cubic m in slashing and weaving; (b) 200 micrograms/cubic m in yarn manufacturing, and; (c) 500 micrograms/cubic m in other industries wherein workers are exposed to cotton dust—including the delinting of cottonseed (1)." Application of the standard to cottonseed oil mills, however, was struck down by the DC Circuit Court in 1979. The court ruled that OSHA failed to show that the standard was economically feasible for the oilseed industry.

Cotton dust was defined in the standard (1) as any dust present in the air during the handling or processing of cotton. Most importantly, the OSHA standard stated that, "Lint-free respirable cotton dust" means particles of cotton dust of approximately 15 microns or less aerodynamic equivalent diameter (1)."

THE NIOSH-OSHA VERTICAL ELUTRIATOR

OSHA specified in the standard that the approved method for measuring lint-free respirable cotton dust was the NIOSH (Lumsden-Lynch) vertical elutriator (VE) air sampler (2,3) or its equivalent (1). The VE sampler is shown in Figure 1. It consisted of a membrane filter mounted in the convergent top section of a hollow can having a straight

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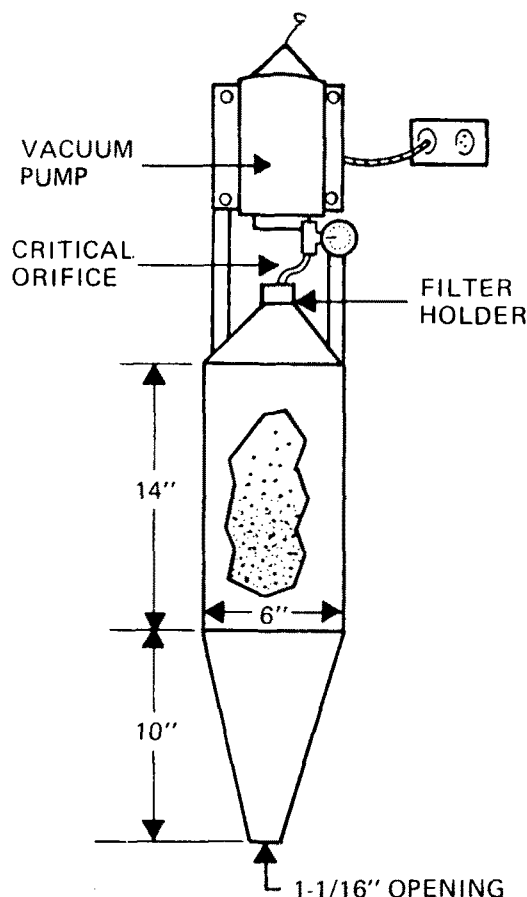


FIG. 1. VE Sampler, from NIOSH (2).

midsection, a tapered inlet section and an inlet at the very bottom of the device. Air was aspirated through the device by a suction pump connected to the filter cassette. Air flow rate was regulated by a device called a critical orifice, which was placed in the sampling line between the filter and the pump.

At a flow rate of 7.4 Lpm, the average upward air velocity in the straight midsection of the sampler was equal to the terminal velocity of a 15-micrometer diameter unit-density sphere in air. It was incorrectly assumed by NIOSH (2) that this uniform laminar air velocity is the same throughout the large-diameter midsection of the VE.

At the time that the OSHA standard was drafted, the VE sampler had the distinction of having been used as the basis for an important epidemiological survey (4) and engineering feasibility study (5). Although many investigators studied the precision (reproducibility) of VE measurements, definitive laboratory measurements of accuracy (correctness) were only attempted by Carson and Lynch (6). Their results were later revised (8) to take into account the existence of a systematic error in their experiment. Their revised data (6,8,9) indicated that the 50% cutoff of the VE was not 15 micrometers, but closer to 20 micrometers, for

the specific experimental conditions (isokinesis) they used.

The OSHA standard apparently relied, however, on the specious belief that the NIOSH VE could be counted on to always yield a 50% sampling cutoff of 15 micrometers, and that the VE was an accurate device for measuring OSHA's specified quantity: lint-free respirable (15-micrometer) cotton dust. In addition, OSHA mentioned the strong belief of certain industrial hygienists (19) that in spite of its shortcomings, the VE sampler was the best sampling device available at that time.

OSHA specified in the standard the methods to be used to calibrate the sampling instrument (1). This calibration actually referred to the regulation of air flow rate, not to the particle-collection efficiency of the device. The primary standard for this measurement was specified as a volume-displacement meter, e.g., a wet-test meter, spirometer, large bubble meter or dry gas meter.

The concentration of vertically elutriated dust is determined as the mass gain of the filter (initial weight minus final weight) divided by the product of the sample collection time and the flow rate, and expressed in units of micrograms per cubic meter.

INTERFERENCES IN VE SAMPLING

The Effects of Flow Separation

Robert (9,10), Claassen (11) and Marple and Tillery (12,13) performed fluid mechanical analyses of the flow regime inside the divergent inlet section of the VE. They all concluded theoretically that the average flow must separate near the inlet and must contain nonuniform vertical updraft components.

Claassen (11,14) used a 0.85-scale transparent model of the VE to observe experimentally the patterns of cool smoke and water mist introduced into the device. Robert and Hemstreet (20) used a laser Doppler anemometer (LDA) to measure the nonuniform velocity flow profile at the inlet plane of the VE. Marple and Tillery (12,13) employed a transparent hydraulic model and a dyetracing technique. The experimental studies showed that the flow separated near the inlet, persisted as separated laminar flow for a short distance, made a transition to large vortices and finally was distributed in turbulent eddying motion in the upper section of the VE.

Researchers have pointed out (5,10,16) that laminar flow—even if it could occur in the VE—would not have a uniform velocity profile, but would tend toward a parabolic profile. From the evidence reviewed above, however, the flow inside the VE clearly separates and eddies turbulently. The VE therefore does not meet the engineering design criterion of uniform laminar flow.

Particle-Size Dependence

At the time of the Merchant et al. (4) studies, the particle-size collection efficiency curve for the VE was unknown. Carson and Lynch (6) in 1973 reported measuring a sampling efficiency curve for the VE in a laboratory experiment.

Their data (6), corrected for inlet effects (10), suggested that the isokinetic sampling efficiency curve had a 50% cutoff at ca. 20 micrometers. In other words, the isokinetic VE was inaccurate and read high.

Barr et al. (5) in 1974 suggested that the flow inside the VE was not uniform, but somewhat parabolic. They deduced some upper limits to the collection efficiencies for particles of different sizes. In 1976, Matlock and Parnell (16) quoted Barr et al. (5) and pointed out that the assumption of fully developed laminar parabolic flow in the VE midsection corresponded to a maximum velocity (at the centerline) such that the maximum aerodynamic equivalent

size of the particles reaching the filter would be 20.9 micrometers.

Although the VE was designed to exclude lint, observations that the device in practice collected some lint and other fragments larger than 15 micrometers prompted Bethea and Morey (17,18) by the mid-1970's to suggest lowering the flow rate of the VE to 4 Lpm in order to collect a more lint-free fraction.

At any rate, the VE appeared—at least under some conditions—capable of collecting size fractions much larger than its design limit. These problems tended to focus attention on the fact that the VE sampling efficiency curve was in doubt. This led Robert (9,10), at the Southern Regional Research Center (SRRC), to develop a theoretical model of the isokinetic VE based on the phenomenon of turbulent flow separation at the inlet. A striking result of the VELUT model was the prediction of appreciable collection efficiencies for aerodynamic equivalent diameters above 25 micrometers. The transmission of some fiber fragments to the filter was clearly predicted by that model. Robert and Thibodeaux (7) used the VELUT model to compare theoretically the results of an isokinetic VE with the results of an hypothetical device having an ideal cutoff at an aerodynamic equivalent diameter of 15 micrometers. They found that the respirable content of a dust cloud, as measured by an ideal 15-micrometer cutoff device, was a strong function of both the mass-median aerodynamic diameter (MMAD) and the geometric standard deviation (GSD) of the assumed dust size distribution.

Marple and Tillery (12,13) used the Walton (42) equation and their theoretical laminar solution of the fluid motion inside the VE to estimate the particle-size collection curve. They concluded that the 50% cutoff of the standard isokinetic VE was ca. 28 micrometers (13).

Claassen (11), at SRRC, examined experimentally the question of whether particulates known to have aerodynamic equivalent sizes greater than 15 micrometers could indeed penetrate the VE and be captured on the filter. He used pollens of nearly unit specific gravity. He reported (11) that aerodynamic sizes greater than 15 micrometers could indeed be collected by the VE.

Problems with Crossflows

The deleterious effects of crossdrafts or updrafts in the sampling of cotton dust with a VE were pointed out by Neefus et al. (22) and are generally known to workers in the field. Neefus et al. (22) stated that air currents in the vicinity of the elutriator can disturb the laminar flow in the elutriator chamber. They suggested that if sampling sites with greater than 0.508 m/sec (100 fpm) crossflow cannot be relocated, then the inlet of the VE should be protected with a funnel.

Robert (24) considered the NIOSH VE cotton-dust sampler under the 2 modern criteria for proper air sampling and found that the VE sampler meets neither the condition of isoaxiality (25) nor isokinesis (25) when used as an area monitor according to the OSHA (1) protocol. The VE was not designed with those inlet considerations in mind.

Claassen (28) stated that the VE inlet satisfies the Davies (26) calm-air criterion for particles under 35 micrometers, and meets the less restrictive Agarwal and Liu (27) calm-air criterion for particle sizes below 65 micrometers. Claassen pointed out that work areas in cotton processing areas may not meet either criterion if lint fragments reach the inlet.

Robert (24) investigated the Davies (26) criterion for sampling from a moving stream. He found that the VE is a permissible sampler under that criterion only for wind velocities below ca. 0.002 m/sec (24). Thus, in VE sampling a strong distinction must be made between isokinetic sam-

pling, calm-air sampling and sampling from a crosswind (24).

Researchers at the Los Alamos Scientific Laboratory (LASL) (15) reported the results of theoretical studies of the sampling efficiency of the VE. A calm-air sampling-efficiency curve, based on an equation from Davies (26), was proposed. Aspiration efficiency curves were given for the VE in crossflow according to the theories of Levin (31) and Raynor (30); Rajendran (39) discussed similar considerations for personal aerosol samplers. Robert (24) predicted from available aerosol theory the possibility of significant changes in the collection efficiency of the VE if it is sampling from a laminar crossflow.

Several groups have made experimental measurements of VE efficiency curves under various crossflow conditions. The LASL group (15) collected cotton dust samples from crossflow conditions at 2 southwestern saw gins processing spindle-picked cotton. The crosswind velocities at the sampling locations were measured. The wind velocities varied greatly with both location and time, and ranged from ca. 0.1 m/sec to 6 m/sec with gusts in excess of 10 m/sec. Results (12,13,15) for VE efficiency were obtained by taking the ratio of the impactor distributions, with and without VE's on the front end of the impactor. Under the experimental conditions, the experimentally determined 50% cutoff was ca. 7 micrometers. The experimenters (13) concluded that the shape of the curve was not characteristic of the VE's design operation, and clearly showed that particles larger than 15 micrometers penetrated the elutriator.

Claassen (28) at SRRC measured the experimental relative collection efficiency of a standard VE against a hooded, downward-facing 37-mm filter. The filter hood was geometrically similar to the inlet of the VE. These 2 devices took samples from a turbulent monodisperse particle cloud that was stirred. The stirring velocities varied between 0.2 m/sec and 2.2 m/sec. Claassen (28) found that the 50% cutoff point of the VE was between 11 and 12 micrometers. Although Claassen described his experiment as a calm-air experiment, he compared his results with the theoretical isokinetic curve (10) and found poor agreement. Claassen's (28) data actually correlated much better with the calm-air efficiency curve given by Robert (24). Because Claassen (28) used stirred air with average velocities well in excess of the Robert-Davies (24) criterion of 0.002 m/sec, however, his results should probably be treated as a case of crossflow.

Robert (35) performed a crossflow experiment in which a standard VE operating at 7.4 Lpm was mounted at the exhaust near the axis of a laminar duct. The efficiency of the VE for 10-micrometer DOP spheres was found to depend on crossflow velocity as predicted by the VELUT (24) model. The theoretical values from the VELUT (24) code apply only to uniform laminar crossflow. The effect of turbulence seems to be to decrease the collection efficiency below the laminar estimate.

McFarland et al. (29) conducted an experimental study to characterize the particle-selection biases of a VE sampling controlled particles from a turbulent crossflow. Monodispersed oil droplets were introduced into a 0.3 m × 0.3 m horizontal wind tunnel, passed through a baffle to obtain a uniform concentration profile across the central area of the wind tunnel and drawn past a standard VE that was mounted vertically. At a wind speed of 0.56 m/sec (110 fpm), McFarland et al. (29) reported that the experimental 50% cutoff point of the VE was 8.5 micrometers.

²Laboratory and Theoretical Calibration of Cotton Dust Samplers, Cooperative Research Agreement No. 58-7B-30-0249 between the USDA-SEA-AR and the University of Minnesota, V.A. Marple, Principal Investigator, September, 1980.

A cooperative research project² between SRRC and the University of Minnesota was recently initiated. One of the objectives of that study is to elucidate the size-selection mechanisms of the VE.

Lint Fragments

Neefus et al. (22) reported that failure to keep the VE chamber clean resulted in "lint balls" being deposited on the filter and producing unexpectedly high results. Neefus (21) presented photomicrographs of filters from a VE and an impaction sampler. The VE filter showed: "...many particles of lint exceeding the calculated 15-micrometer cutoff. The weight contribution of these aerodynamically unpredictable particles is not known (23)."

The importance of lint fragments in cotton-dust sampling was also demonstrated experimentally by Claassen and Baril (32). They used a 2-part sampling arrangement to separate the lint fragments from the fine dust in a card waste duct. Most of the mass was found to reside in the lint fragments. They also conducted a test with downward-faced filters to determine the changes in measured dust concentration and size distribution resulting from changes in the sampling flow rate. The results indicated that area samples drawn from still air could not measure the dust concentration in the undisturbed air when lint fragments were present.

Robert (33) studied hypothetical dust and lint distributions and found that lint fragments in the sampled air introduced a substantial bias into the result of the measurement. Even modest amounts of lint fragments or variations in the fraction caused errors in excess of the OSHA criterion of ±25% for acceptability of a cotton dust sampler.

Thibodeaux (34) described some results from a cooperative study between the USDA-ARS-SRRC and Texas Tech University³ aimed at characterizing occupational dust control equipment used in cottonseed oil mills, and providing engineering specifications on such equipment. The major objective of the research reported was to use image analysis to characterize the physical parameters of particulates collected on selected VE filters obtained during the mill study. In many of the samples studied, a considerable fraction of the total accumulated mass was attributable to lint and lint fragments, as well as to large particles. Thibodeaux (34) concluded that airborne dust collected by a VE in cottonseed oil mills was not limited to lint-free respirable dust.

Other Interferences

Batra et al. (36) pointed out that in addition to the problems previously discussed, the VE had other limitations. First, it could be used effectively only in vertical orientation. Second, the physical size of the device made use in limited-access spaces (such as ducts) virtually impossible. The size and weight of the sampler imposed a particular burden on industrial hygienists or researchers who must transport a large number of the instruments between sampling sites.

Suh and Neefus (23) studied the statistical variance in VE readings. They identified contributions to the observed variations because of sampling equipment, location, time and repeated sampling. They reported that 3 hr sampling was superior to 6 hr sampling at moderate dust levels, but inferior at low dust levels. The sampling errors because of replication overshadowed instrument errors, location errors

³Evaluation of Occupational Cotton Dust Control Technology in Cottonseed Oil Mills, Cooperative Research Agreement No. 58-7B30-9-123 between USDA-SEA-AR and the Texas Tech University, R.M. Bethea, Principal Investigator, September, 1979.

and time-dependent errors and made them difficult to study. They concluded that the VE sampler had an inherent statistical variance that was large in comparison with the small average values being made.

Suh et al. (37) elaborated on the problems caused by the irreproducibility of VE readings. They stated that, "It is generally known by users of the large VE (LVE) that it yields a high coefficient of variation (37)." With respect to OSHA's criterion of $\pm 25\%$ "accuracy and precision," (1) the authors stated that, "Interestingly, it is noted that the LVE itself often will not meet all the criteria when strictly interpreted (37)." They went on to say that the 95% confidence level for reproducibility of a single VE measurement was ca. $\pm 20\%$.

Neefus et al. (22) found that a poor fit between the filter cassette and the neck of the VE will cause a partial bypass of the total air volume. They also stated that a poor seal between the sections of the cassette, or between the cassette and filter, allowed air or dust to bypass the VE filter. Dust deposited in the critical orifice caused erroneous results.

Olin (38) pointed out that although a VE critical orifice regulated flow rate independently of the vacuum pump inlet pressure, the flow rate was still directly proportional to the pressure upstream of the orifice. Because the filter in the VE was located between the orifice and essentially atmospheric pressure, any variation in the pressure drop across the filter changed the inlet pressure of the critical orifice, thus changing the flow rate. Olin (38) reported tests that showed the flow rate of VE's controlled by critical orifices dropped below 7.2 Lpm when the pressure drop across the filter exceeded 1 inch of Hg. Olin (38) described a flow-control system that avoided this problem.

Recently, OSHA issued an advisory notice (44) pointing out that the electric motors on most VE's had not been approved for use in Class III hazardous environments, as required by Article 503 of the 1971 National Electrical Code (45). Because most areas in textile mills were potential Class III locations, OSHA (44) advised employers to ensure that cotton-dust monitoring equipment used in such locations were rated for Class III service. OSHA emphasized that the electrical requirements were not new, but that they predated the Cotton Dust Standard. OSHA (44) also advised that the sampling procedures specified in Appendix A of the Cotton Dust Standard (1) were not mandatory.

RESEARCH ON BETTER SAMPLING TECHNOLOGY

The SRRC Cotton Dust Sampler

During the course of an SRRC-sponsored research program⁴ at the Battelle Memorial Institute (BMI), a device having a 15-micrometer aerodynamic equivalent cutoff was designed and built (43). The device was called the "precutter." Laboratory tests performed at BMI with monodisperse aerosols indicated that the capture efficiency of the precutter was zero for 10-micrometer particles, 50% for 15-micrometer particles and 100% for 20-micrometer particles.

At SRRC, the precutter design was converted into a sampling device for cotton dust. The resulting device was called the SRRC sampler. The self-cleaning impaction principle of the device was patented (44).

The SRRC sampler (Figure 2) consisted essentially of an inlet tube, an impaction platform and an outlet filter. The inlet tube accommodated a circular jet of carefully controlled diameter. The air impacted abruptly on the platform

⁴Highly Efficient Dust Filtration System for Use in Cotton Textile Mills, Research Contract No. 12-14-7001-365 between USDA-SEA-AR and the Battelle Memorial Institute, Columbus, R.B. Reif, Principal Investigator, June, 1984.

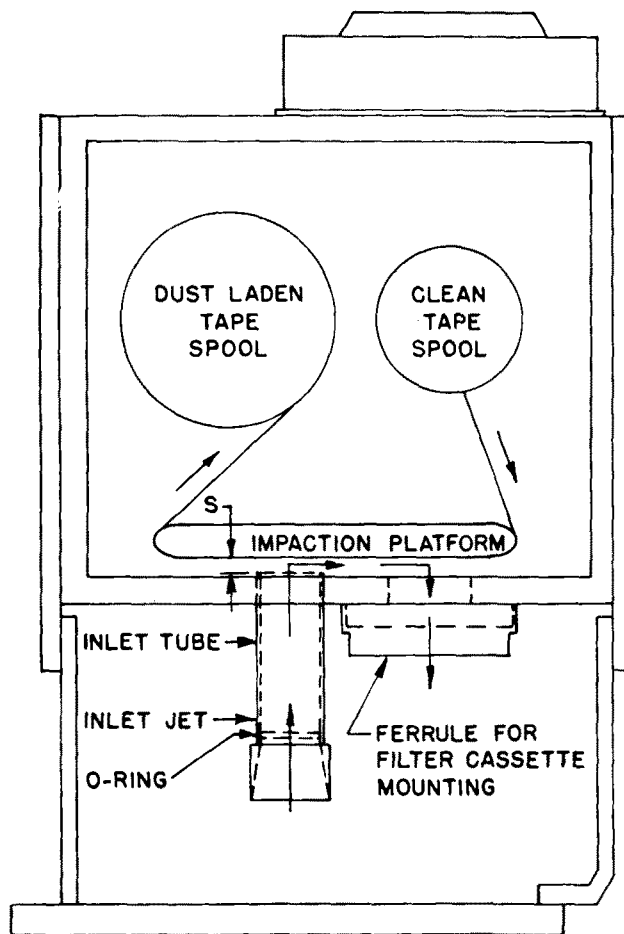


FIG. 2. The SRRC Cotton Dust Sampler.

and flowed in a U-shaped path to the outlet tube. Two spindles held a supply spool and take-up spool for a transparent adhesive tape that traveled slowly over the impaction platform, sticky-side-up. The take-up spindle was driven by an electric motor. A ferrule on the outlet held a 37-mm filter cassette.

Large-diameter particles impacted on the platform, adhered to the tape and were continually carried away from the impaction zone, thus avoiding the buildup of lint in the impaction zone. Smaller particles remained coupled to the air stream until collected on the filter at the outlet. The concentration of small particles in the air stream was determined by weighing the filter in exactly the same manner as a VE filter.

The SRRC cotton dust sampler was evaluated in a cooperative study⁵ at North Carolina State University. During that study, the SRRC sampler was investigated as a possible substitute for the VE. Side-by-side measurements were made with the SRRC sampler and the VE sampler in the NCSU Model Card Room. Batra et al. (45) reported that the VE and the 15-micrometer cutoff SRRC device were not equivalent, and that the VE generally read higher. The differences between the samplers were interpreted (36,45,46) as arising from the SRRC sampler's better lint rejection. Thus the SRRC sampler was perhaps the more accurate sampler, but because of that fact, it could not generally replicate VE readings.

Further experimentation was performed at NCSU with

⁵SRRC Cotton Dust Precutter Sampler, Cooperative Research Agreement No. 58-7B30-8-24 between USDA-ARS-SRRC and North Carolina State University, S.K. Batra and S.P. Hersh, Principal Investigators, August, 1978.

larger jet sizes (which corresponded to nominal cutoff sizes of 20 and 28 micrometers). Equivalence was approached with the largest size used. The investigators concluded that designing the SRRC sampler to measure dust concentration statistically equivalent to that measured by the VE might be possible with a grounded metal platform and increasing the jet size to permit a larger amount of cotton lint to escape capture by the adhesive tape and instead be deposited on the filter. But they warned that: "Achievement of this equivalence would be, however, incongruous because an attempt would be made to match a faulty technique in the name of consistency (45)."

Based on particle-size distribution analyses, Batra et al. suggested (45) that the SRRC sampler might be capable of sampling the same respirable dust fraction as the VE, but with the inclusion of much less interference from lint, lint fragments, and large particles. Impaction mechanisms yield inherently steeper cutoff curves than elutriation processes. Thus, based on accuracy, the SRRC sampler would seem to be the better way to measure respirable cotton dust.

VE-Equivalent Samplers

The OSHA Cotton Dust Standard (1) attempted to sever the description of cotton dust from the type of device or method of measurement employed. OSHA explained that, in requiring the VE as the approved sampling device for cotton dust, OSHA was not eliminating the use of other sampling devices where equivalency could be demonstrated (47). The exact wording of the standard was, "The sampling device to be used shall be either the VE cotton dust sampler or a method of equivalent accuracy and precision (1)."

But OSHA defined the VE sampler in a very general manner: "VE cotton dust sampler" means a dust sampler which has a particle size cut-off at approximately 15 microns aerodynamic equivalent diameter when operating at the flow rate of 7.4 ± 0.2 Lpm (1)." None of the experimental data reviewed by the present authors indicated that the NIOSH VE cutoff was 15 micrometers. As was the case with the OSHA's definition of lint-free respirable cotton dust, the word "approximately" was not defined.

OSHA specified 3 conditions for equivalency of the alternative cotton dust sampler.

The first requirement meant that the equivalent sampler collected the same size fraction as the VE. The second requirement meant that the equivalent sampler collected the same gravimetric fraction as the VE. The practical interpretation of the third requirement was that the equivalent sampler would differ by no more than $\pm 25\%$ from the VE reading in at least 95% of side-by-side tests.

Previously Neefus (23) described an alternative device based on a coal dust sampler. Neefus (21) used a miniature 2.78-inch diameter elutriator (the "tennis-ball-can" elutriator) as a preseparator for the coal-dust unit. The nominal cutoff of the mini-VE was 17 micrometers. This sampler had the advantage of yielding short-term sampling results (7 min). Neefus (21) reported a good relationship between the coal-dust and the VE sampler at cotton-dust readings below 0.7 mg/cubic m. At dust readings above 1.0 mg/cubic m, the relationship was less consistent. In general, the VE read higher, because of its poorer rejection of lint and large particles (23). Although equivalency with the standard VE was claimed for this device during the hearings on the OSHA Cotton Dust Standard, OSHA cited opposing NIOSH testimony, and emphasized that, "... only devices which positively demonstrate equivalency with the standard VE ... will be accepted as alternative sampling devices. The burden of proving equivalency of alternative

methods rests with the employer utilizing an alternative device (47)."

More recently, a commercially available cotton dust sampler (CAM) was developed specifically for equivalency to the VE. The CAM sampler used a one-quarter-scale VE in conjunction with an optical scattering sensor, as described by Shofner et al. (48). The electrical signal from the light sensor was converted by a microprocessor to an estimate of the mass of respirable particles per unit volume of air. This device was also available in a single-sensor portable version (PCAM), or for operation with multiple remote sensors.

Studies of the equivalency of the CAM and VE samplers were reported by Shofner et al. (48,49), Suh et al. (37), Kriekebaum et al. (50) and Neefus et al. (51). These investigators reported that although the CAM was capable of equivalence to the VE, the demonstration of equivalence was very difficult because of the irreproducibility of the VE. They found using a bank of four VE's surrounding the CAM sampler in side-by-side measurements was necessary. By using the average of the 4 VE readings for comparison with the CAM sampler, they were able to reduce the variance in the VE reading. Applying a small correction (ERF) procedure to CAM readings was necessary to obtain general equivalence (49). Another procedure, Gravimetric Certification, was recommended as a method for periodically checking the calibration of CAM units without side-by-side equivalency measurements with a standard VE (49).

Burlington Industries has acquired simultaneous side-by-side CAM/PCAM and large-VE data from a typical cotton manufacturing plant (49). OSHA and NIOSH reviewed the procedures and the data and, "OSHA issued Burlington a statement that the CAM/PCAM method was capable of equivalence (49)." Specific equivalency demonstration requirements are discussed in detail by Shofner et al. (49).

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