



Focus on —: Should Dust Samplers Mimic Human Lung Deposition?

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Should Dust Samplers Mimic Human Lung Deposition?

POINT

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Scientific Basis

The potential for adverse health effects resulting from exposure to toxic materials depends on the dose received. When inhaling airborne particles, the dose rate is the product of the volume of air inhaled each minute (minute volume), the airborne mass concentration, and the fraction of the inhaled mass that deposits (deposition efficiency). Deposition efficiency depends strongly on particle aerodynamic diameter and less strongly on the distribution of inhaled air between the nose and mouth, the mean inspiratory flow rate, breathing frequency, pause duration, airway dimensions, and residual volume. Deposition efficiency is independent of the chemical composition of the particles with some exceptions. For example, hygroscopic particles absorb water from the moist air in the respiratory tract. This causes the particle size to increase rapidly, so the particles deposit according to the size of the resulting water droplet rather than according to the size of the particle that was inhaled.

History

In the early days of industrial hygiene, the amount of airborne dust was evaluated by such methods as measuring the degree of darkening of a surface on which dust settled or the number of particles collected in a liquid impinger. These sampling methods were not directly related to airborne mass concentrations; thus, the resulting measures of dustiness were only indirectly related to the dose received by workers. After high-efficiency air filters became readily available, "total" mass concentrations were measured by analyzing filters through which a known volume of air had been drawn. That method is in wide use today.

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COUNTERPOINT

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Rationale

The first step in delivering a dose of particulate to the lungs, and potentially to other organs, is penetration of the particles. The next step is deposition. Penetration can be defined as the ability of a particle to reach but not necessarily deposit in a region of the lung. The current criteria for size-selective sampling are defined by penetration curves and are not predictive of deposited material. Criteria could be constructed based on the deposition curves for human subjects. The argument for using deposition curve criteria makes certain assumptions which should be examined from the outset:

1. Dose in the lung is a function of the fraction of particulate that is deposited.
2. A representative route of entry can be selected for the aerosol.
3. Deposition can be represented for the population by some "average" curve.
4. Measured exposure should be in constant proportion to dose.

Dose is a function of the size-fraction deposited.

This assumption is key to deposition-based criteria. For a particle to be a hazard to the lung, it must first come in contact with the lung. This occurs by deposition, with the other common assumption being that dose is a function of deposited mass. Even if the contaminant of interest occurs as a surface coating on the particle or is related to the number of particles, deposition would still be a necessary first step before surface contaminants could act. For penetration-type samplers to arrive at an estimate of hazard, it is necessary to assume that penetration will remain

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When measurements of the deposition efficiency of inhaled particles in the gas exchange region of human lungs became available, the practice of collecting respirable dust was instituted. Respirable dust samplers, such as the 10-mm nylon cyclone, do not allow inclusion in the sample of those particles that are too large to be likely to penetrate to the gas exchange region of the lungs. Measurements of respirable dust concentrations are considered appropriate for evaluating the hazard of breathing compounds that are relatively nontoxic if deposited in the head airways or ciliated airways of the lungs but are toxic if deposited in the gas exchange region of the lungs.

The American Conference of Governmental Industrial Hygienists (ACGIH) Air Sampling Procedures (ASP) Committee followed the lead of the International Organization for Standardization (ISO) and generalized the concept of respirable dust sampling when recommending that future Threshold Limit Values (TLVs) should be expressed for inspirable (now called inhalable), thoracic, or respirable particulate matter (IPM, TPM, or RPM).⁽¹⁾ The particle size dependence of the collection efficiency of an ideal IPM sampler approximates that of the inlet efficiency of the human nose and mouth. IPM-TLVs are appropriate for particulates that may cause adverse health effects if they deposit anywhere in the respiratory tract. An ideal TPM sampler collects most particles with aerodynamic diameters smaller than 10 μm and excludes most larger particles. TPM-TLVs are appropriate for materials that may be hazardous if they deposit anywhere in the lungs. An ideal RPM sampler collects most particles with aerodynamic diameters smaller than 3.5 μm (4 μm in a recent proposal⁽²⁾) and excludes most larger particles. RPM-TLVs are appropriate for materials which may be hazardous only if they deposit in the gas exchange region of the lungs.

The historical trend has been to improve sampling procedures by instituting more appropriate measures of the mass concentration of airborne particles whose size would allow them to contribute to a potential adverse health effect of the compound. The specified collection efficiencies of IPM, TPM, and RPM samplers are intended to exclude particles considered too large to contribute to the hazard for materials capable of exerting toxic effects if deposited anywhere in the respiratory tract, in the lungs, and in the gas exchange region of the lungs, respectively. These samplers are not intended for accurate estimation of the dose deposited in the whole respiratory tract or any of its regions. Essentially all particles smaller than 4 μm are included in IPM and TPM samples, and essentially all those smaller than 2 μm are included in RPM samples. Since the lung deposition of particles having aerodynamic diameters less than 2 μm is known to be less than 100 percent, IPM, TPM, and RPM samples over-represent these particles compared to deposition in human lungs. It has been suggested that particle size-selective sampling for the purpose of hazard evaluation, i.e., for comparison of a measured airborne mass concentration to an allowable concentration to de-

termine whether exposures should be reduced, would be improved if the collection efficiencies of samplers were to more accurately reflect the population-mean, particle size-dependent deposition efficiency which has been measured in humans. For example, one could conceive of mean respiratory tract dose samplers for materials that exert their toxicity wherever they deposit in the respiratory tract, mean tracheobronchial dose samplers for materials that cause adverse health effects only when they deposit in the tracheobronchial region of the lungs, mean alveolar dose samplers for materials that exert their toxicity only when they deposit in the gas exchange region of the lungs, and possibly others. The ASP Committee has considered the idea of mean dose samplers in place of IPM, TPM, and RPM samplers and has not adopted it. The following discussion is based in part on ideas expressed during ASP Committee deliberations.

Epidemiology

The ASP Committee recognizes that in epidemiological studies, it is necessary to estimate the delivered dose as accurately as possible. This is probably best accomplished by sampling with a cascade impactor and determining the composition of the collected dust as a function of particle size. After thoroughly characterizing the airborne dust, it is reasonable to attempt to estimate delivered doses taking into account the workers' minute volumes, whether hygroscopic growth is likely to occur, whether volatile components may evaporate while airborne in the respiratory tract, the oral-nasal air flow distribution, and any other conditions which may be identified as potentially important.

One of the major difficulties of estimating doses from historical data is that very little detailed size distribution data are available. Size distribution data should probably be collected in each location where significant dust exposure may occur every two years and whenever a major process change is implemented. Such data would be invaluable for epidemiological studies since it could be used to make dose estimates and to estimate the mass concentration of any size fraction that might be of interest at some time in the future.

Hazard Evaluation

For routine monitoring to determine whether particle concentrations are below established health-based limits, the ASP Committee feels it is appropriate to characterize atmospheres using IPM, TPM, and RPM samplers. The collection efficiencies of ideal IPM, TPM, and RPM samplers were specified after considering characteristics of particle deposition in humans; specifically, the proportion of inhaled particles that can enter a region of the respiratory tract where they could exert their toxicity if they deposit. In addition, the characteristics of practical samplers and historical practice were considered. IPM, TPM, and RPM samplers are relatively simple conceptually and mechanically, require analysis of only one filter or other collection substrate, and avoid the important problem of collecting

particles that are too large to contribute to the hazard. When formulating allowable concentrations, characteristics of the sampler and, when possible, characteristics of the toxic dust are taken into consideration. For example, it might be reasonable to assume that 30 percent of all submicron particles deposit in the alveolar region when setting a numerical value for an exposure standard for an aerosol that is known to be submicron.⁽³⁾ In the absence of particle size information or when the material may occur in a wide range of particle sizes, it would be appropriate to base standards on the assumption that 100 percent of all collected particles could deposit. Basing standards on such assumptions, it is unlikely that IPM, TPM, and RPM samples would lead to significantly underestimating the potential hazard of breathing an atmosphere containing submicron particles. However, reliance on IPM, TPM, and RPM data can result in overestimating the potential hazard or in not recognizing changes in the potential hazard when aerosol size distributions change. For example, changes in the size distribution of a submicron aerosol might increase or decrease the deposited dose without changing the IPM, TPM, or RPM concentration. If appropriate assumptions were used in setting the standard, a hazard evaluation based on IPM, TPM, or RPM samples would always overestimate the hazard although by a different amount before and after the size distribution changed. When the level of ambiguity inherent in using IPM, TPM, and RPM samplers is judged to be unacceptable, it is logical to propose the use of mean dose samplers.

Mean dose samplers would be intended to simulate the particle size dependence of deposition in a region of the human respiratory tract and would appear to provide improved information on which to base hazard evaluations. However, replacing IPM, TPM, and RPM samplers with mean dose samplers would have several disadvantages. A population-mean deposition efficiency curve for each region of the respiratory tract would have to be agreed upon. This would necessarily be a compromise, since there is wide variability in deposition efficiencies among individuals arising from such important, but difficult to measure, quantities as airway dimensions and the distribution of inhaled air between the nose and mouth. Individual differences would cause individual doses to vary significantly around estimates based on data from mean dose samplers. If the toxic particles are hygroscopic and larger than about 0.3 μm or attach to ubiquitous hygroscopic particles, deposition would tend to occur with greater efficiency and higher in the respiratory tract than would be expected based on the material's behavior in a sampler. Mean dose samplers would lead to underestimates of the hazard of breathing such particles, a situation to be avoided. Dust concentrations obtained using mean dose samplers would provide a false sense that accurate dose estimates could be made since there would be significant random variation of individual doses about the mean and there would be significant bias in estimating mean doses for some dusts. Mean dose samplers would be at least somewhat more complicated than IPM, TPM, and RPM samplers because their collection ef-

ficiencies must approximate more complicated functions of particle size. Analysis of more than one filter or other collection substrate would probably be required.

The main advantage of mean dose samplers over IPM, TPM, and RPM samplers would be that they would not over-represent smaller particles compared to their expected deposition in the respiratory tract. However, there are few situations in which such an advantage would outweigh the disadvantages of having to use a more complicated sampler, having to analyze more than one collection substrate, and risking underestimates of some hazards. The advantages of mean dose samplers would be strongest when most of the toxic material occurs in nonhygroscopic submicron particles. This does not normally occur when dust is generated mechanically, but it does occur when particles are formed by cooling hot vapor, e.g., diesel exhaust particles and metal fumes.

When ambiguities in basing hazard evaluations on IPM, TPM, and RPM sampling data are judged to be unacceptable, an alternative to developing mean dose samplers would be to measure particle size distributions. Particle size distributions could be measured by techniques similar to those which are necessary for epidemiological studies; standards that relate to those sampling results could be established. One possibility would be to require occasional high-resolution size distribution measurements, such as can be obtained from a cascade impactor containing several stages, and routine IPM, TPM, or RPM measurements. The numerical value of the exposure standard that the IPM, TPM, or RPM measurements are required to meet could depend on the results of the particle size distribution measurements. Another possibility would be to require routine low-resolution particle size distribution measurements, such as might be obtained with a two- or three-stage device, and apply a mathematical weighting to the amount collected in each stage when calculating a concentration to compare to a standard. Low-resolution size distribution samplers might be mechanically similar to mean dose samplers except that the aim would be to collect all the submicron particles in appropriate size fractions and then mathematically apply appropriate relative weights to them rather than attempting to collect only the desired relative amounts in the sampler. The advantage of a low-resolution size distribution sampler over a mean dose sampler would be that the raw data would provide valid size distribution information.

Effective Health Effect-related Dust Sampling

One advantage of measuring size distributions with high- or low-resolution devices instead of developing mean dose samplers is that all dust sampling for epidemiological studies and for routine hazard evaluations would require only two types of hardware and expertise in their use. IPM, TPM, and RPM samplers could be used for routine hazard evaluation in most situations. Samplers measuring particle size distributions could be used for epidemiological studies and for routine hazard evaluations in those situations where the extra effort is judged to be necessary in order

to decrease ambiguity.

A worthwhile goal would be to develop the capability to measure high- or low-resolution particle size distributions and IPM, TPM, and RPM concentrations in all areas where dust exposures occur. In most situations, infrequent size distribution measurements and routine IPM, TPM, and RPM concentration measurements would provide the information necessary for valid hazard evaluations and possible future epidemiological studies. In some situations, it might be judged worthwhile to increase the frequency of size distribution measurements and include those results in routine hazard evaluations.

Comments

Please address comments and suggestions on this or other air sampling issues to the Chair of the Air Sampling Procedures Committee: Sidney C. Soderholm, Environmental Health Sciences Center, University of Rochester Medical Center, Rochester, New York 14642.

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proportional to deposition which, in turn, will be proportional to dose.

A representative route of entry can be selected.

There are two choices for the route of entry into the lungs: the nose or the mouth. Selection of either one would cause less bias in determination of the deposited mass than would selection of the penetration criteria. A curve that averaged the deposition for the two routes might be the best alternative. Little information exists on the percent of time workers spend breathing through either nose or mouth. Assuming a 50 percent split would not introduce as large a bias, regardless of whether the actual split was heavily weighted toward one route or the other, when compared to the difference between the penetration and deposition values.

Deposition can be represented by some average curve.

The major difficulty in selecting a deposition curve is the lack of information on deposition based on any studies of large populations. This is a difficulty shared by the penetration criteria, however. We have recently begun conducting tests in large populations on the variability of deposition.⁽¹⁾ For 0.5 μm particles, the mean value of nearly 200 subjects was not significantly different from that published by other studies of smaller populations.⁽²⁾ Although any deposition curve may be a relatively poor predictor for an individual, the population mean can be well defined. This is equivalent to using a "reference individual," which is the concept behind many risk analyses. While more work is needed to test other particle sizes in a large population, an average deposition curve can represent the population average. The breathing pattern (volume and frequency) would conform to an average pattern as described by Jones *et al.*⁽³⁾ in their study of breathing differences in miners. The curve would not be applicable to those with existing lung disease, but standards are usually developed for populations without pre-existing disease.

Measured exposure should be in constant proportion to dose.

The most important assumption for this argument is that the measured exposure, when based on penetration, is not always in constant proportion to dose. It may be a common misconception that because respirable dust levels and certain pneumoconioses are correlated, respirable dust measures are always good predictors of deposition in the gas exchange region. For submicrometer aerosols with a geometric standard deviation of 1.5, the ratio of penetration to deposition can have a two- to sixfold range depending on the median size of the aerosol⁽⁴⁾ and result in an extremely variable dose-response relationship if penetration is used. The difference between penetration and deposition thereby dwarfs the difference between the choice of nose or mouth breathing for deposition.

Application

Given the previous rationale, what are the arguments surrounding application of a deposition criteria? The strongest argument against adoption is that instruments matching a penetration curve already exist. It should not be overlooked that these instruments, themselves, replaced earlier, less appropriate techniques. There should be a natural evolution to more biologically plausible methods. As the penetration criteria devices replaced particle counting and "total dust" measurements so, eventually, can deposition criteria-based instruments be used in place of the penetration devices.

Are there instruments that can be designed to meet a deposition curve, regardless of which curve is chosen? We have reported a possible design that matches the deposition curve and assume other designs would become available if the need existed.⁽⁴⁾ The instrument, which was designed to match a selected gas exchange region deposition curve, required analysis of either two or three substrates depending upon what information was desired. Other designs may be possible that would require only analysis of a single substrate. Because the generation mechanisms (grinding and crushing produce large aerosols; vaporization and condensation produce smaller aerosols) for aerosols in different size ranges vary, so would the type of aerosol. Instruments that separate the various aerosols by size regime could add to the available information classifying the source of the dust on the basis of size using only an additional substrate weight. Thus, having a choice of one or more substrates is not necessarily a disadvantage.

What about the alternative of using an impactor or other classifying devices for obtaining the size distribution and then applying the appropriate criteria? It may be possible to monitor the size distribution on an occasional basis and derive weighting factors if it can be shown that the process does not change. It would then be appropriate to do regular sampling with a device that gave the same total mass as the impactor or other classifying device. Using a penetration criteria device for comparison would perhaps require additional conversion factors and result in additional error. This approach also assumes that the process being monitored will not change. If it changes, there may be no obvious cue to the hygienist that anything has changed. This limits the applicability of the penetration method to those cases where a change in size distribution is not crucial or dangerous. For epidemiology, past practice has been to adopt the method of measurement that was used to develop the standard for enforcement of the standard. This practice is not absolutely necessary for size-selective standards. Epidemiologic studies should, however, provide as much information as possible on the complete size distribution where that seems to be a relevant factor in the dose-response relationship.

Adoption of deposition-based criteria rather than penetration criteria would result in different standards, but are deposition and penetration criteria translatable from one to the other? Under certain circumstances, they may

be. For respirable dust, if the particle size is large enough, there is a good chance that deposition and penetration criteria would be proportional to one another. For submicrometer dusts, which would include most fumes, both metal and organic, there is less likelihood of finding a correlation between penetration and deposition criteria for respirable particles.⁽⁵⁾ Work is under way by groups both in the United States and in Europe to reach a consensus on the penetration criteria. This consensus will result in adoption of penetration-based standards for a number of countries. Regardless of the current trend toward penetration criteria, deposition criteria could still be considered in certain situations. Because the deposition criteria represent an approach better approximating what occurs in the lung, the likelihood of obtaining better correlation with disease is good. For the large, mechanically-generated dusts, there may still be good correlation between deposition and penetration. For submicrometer aerosols and for tracheobronchial deposition, a switch to deposition criteria could offer an improvement. This may present an economic advantage to those countries that hesitate to adopt the penetration criteria.

We have been well served by the penetration-based standards for coal and silica. Since coal and silica are predominantly large aerosols, penetration and deposition should be well correlated and thus the standards could remain as they are. Before particle size-selective criteria are applied to other dusts, particle size information will be required to change old "total dust" standards to the new size-selective standards. As that information is collected, it will afford the scientific community a chance to determine dose-response curves using both penetration and deposition criteria. If there is no difference in the correlation between measurements based on both criteria, it will make no difference which is adopted. If a better correlation between response and exposure (characterized by deposition criteria) occurs, deposition-based criteria seem the reasonable choice. For example, recent evidence from measurements in lead acid battery workers⁽⁵⁾ indicates that a higher degree of correlation is obtained with blood lead levels, for lead fume exposure, using deposited mass calculated from size distribution measurements rather than the penetration criteria, respirable mass.

Neither the penetration nor the deposition criteria address the other physical characteristics that may alter the toxicity of a particle. Aerosol growth is not currently accounted for nor are surface characteristics, such as area or surface coatings. Solubility and clearance must also be considered in arriving at a better understanding of the response function. However, determining the likelihood of deposition based on airborne size can be the first step in the environmental portion of the assessment.

Summary

1. Deposition-based, size-selective sampling criteria should present a more plausible biological analog to the first step in eliciting a response to inhaled aerosols than

penetration criteria.

- It appears feasible to develop a standard curve for average deposition in a population.
- It also appears to be feasible to develop instruments that conform to the deposition curve.
- Future investigations leading to development of particle size-selective sampling criteria should determine the size distribution of the aerosol and apply both deposition and penetration criteria to determine if the correlation between measured exposure and response can be enhanced.

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