Chapter 2

Rationale for particle size-selective air sampling

PAUL J. LIOY, Ph.D.,[A] MORTON LIPPMANN, Ph.D.[A] and ROBERT F. PHALEN, Ph.D.[B]
[A]Institute of Environmental Medicine, New York University Medical Center
[B]Department of Community and Environmental Medicine, University of California — Irvine

Introduction

The goal of particle size-selective sampling procedures in the work environment is to provide the most appropriate index of particle inhalation hazards by giving recognition to the fact that the size characteristics can greatly modify their regional deposition. The application of information on regional deposition of inhaled particles in the respiratory system to industrial hygiene sampling practice has only been done to a limited extent. Most cases in which particle size discrimination has been done addressed a limited number of specific problems.

In the context of the threshold limit values (TLVs) for certain particulate materials, respirable or total sampled mass has been used as the index of pollutant concentration. Unfortunately, use of total sampled mass concentration ignores the fact that toxicants captured at various sites in the upper respiratory tract or tracheobronchial tree may at times control the extent of the hazard. For example, based upon the recommendations of the International Standards Organization (ISO), particles can be divided into a number of deposition fractions which include gas exchange, tracheobronchial (T-B) and, head airways region. Collectively, these fractions, together with the exhaled particulate mass, constitute inspirable particulate mass (IPM).

On the basis that the aerodynamic size ranges associated with the specified deposition regions are valid for instances of occupational exposures, it was a major charge to the Air Sampling Procedures Committee to define size-selective air sampling equipment specifications and procedures required to evaluate potentially hazardous situations in the workplace. A framework for establishing TLVs with size discrimination for individual compounds will be outlined in terms of the physiological or biochemical responses or the pulmonary diseases associated with each. With the application of particle size-selective sampling criteria, future proposed and revised TLVs for particles would take into account not only the inherent toxicity of the particles, but also their particle size distributions, their patterns of deposition within within the respiratory tract, and the particle size related rate of dissolution and translocation to target tissues.

Present standards and criteria for respirable dust samplers

Size-selective standards have been established to address the problems associated with pneumoconiosis, and the development of standards for respirable dust are reviewed in this subsection. However, the limitations have not all been addressed because the information used to develop the standards was in most cases, quite limited.

British Medical Research Council

In 1952 the British Medical Research Council (BMRC) adopted a definition of "respirable dust" applicable to pneumoconiosis producing dusts. It defined respirable dust as that reaching the alveolar region. The BMRC selected the horizontal elutriator as a practical size selector, defined respirable dust as that passing an ideal horizontal elutriator, and selected the elutriator cut-off to provide the best match to experimental human respiratory tract deposition data available at that time. The same standard was adopted by the Johannesburgh International Conference on Pneumoconiosis in 1959.[1]

In order to implement these recommendations, it was specified that:

1. The estimation of airborne dust in its relation to pneumoconiosis, compositional analysis, or assessment of concentration by a bulk measurement such as that of mass or surface area, would represent only the "respirable" fraction of the cloud.
2. The "respirable" samples should be separated from the cloud while the particles

are airborne and in their original state of dispersion.

3. The "respirable fraction" was defined in terms of the settling velocity speed of the particles, by the equation $C/C_o = 1 - V/V_{2ST}$ where C and C_o are the concentrations of particles of falling speed V in the "respirable" fraction and in the whole cloud, respectively, and V_{2ST} is a constant equal to twice the settling velocity in air of a sphere of unit density 5 μm in diameter.

U.S. Atomic Energy Commission

A second standard, established in January 1961 at a meeting sponsored by the U.S. Atomic Energy Commission (AEC), Office of Health and Safety[2] defined "respirable dust." In this report it referred to respirable particulate mass (RPM), as those portions of the inhaled dust which penetrate to the non-ciliated portions of the gas exchange region. This application of the respirable dust concepts and concomitant selective sampling was intended only for "insoluble" particles which exhibit prolonged retention in the lung. It was not intended to include dusts which have an appreciable solubility in body fluids and those which are primarily chemical toxicants. Within these restrictions, "respirable dust" was defined with a 50% respirable cut-size at an aerodynamic diameter of 3.5 μm. Other specified fractions were 0% at 2 μm, 25% at 2.5 μm, 75% at 5 μm, and 100% at 10 μm. The aerodynamic diameter, d_a, is the diameter of a spherical particle of physical density 1.0 g/cm^3 that has the same terminal settling speed in air as the particle in question, irrespective of the physical size, shape and density.

American Conference of Governmental Industrial Hygienists

Silica — crystalline

The ACGIH, at its annual meeting in St. Louis, Missouri, on May 13, 1968, announced in their "Notice of Intended Changes" alternate mass concentration TLVs for quartz, cristobalite and tridymite (three forms of crystalline free silica) to supplement the TLVs based on particle number count concentrations. For quartz, the alternative mass values proposed were:[3]

1. For respirable dust in mg/m^3: 10 mg/m^3/(% Respirable Quartz + 2)

   Note: Both concentrations and % quartz for the application of this limit are to be determined from the fraction that penetrates a size-selective sampler with the following characteristics.

d_a (μm) (unit density sphere)	<2.0	2.5	3.5	5.0	10
% Penetration	90	75	50	25	0

2. For "total dust" respirable and nonrespirable: 30 mg/m^3/(% Quartz +2)
3. For cristobalite and tridymite: Use one-half the value calculated from the count or mass formulae for quartz.

The size-selector chacteristic specified by ACGIH was almost identical to that of the AEC, differing only at 2 μm where it allows for 90% passing the first stage collector instead of 100%. The difference appears to be a recognition of characteristics of real particle separators. For practical purposes, the two standards may be considered equivalent.

The proposed mass concentration limits were obtained by a comparison of simultaneous impinger and size-selective samples collected in the Vermont granite sheds.[4] Since the original impinger sampling and microscopic particle counting standards were based on epidemiological investigations which has been performed 3 to 4 decades earlier in some of the same granite cutting sheds, it was possible to make a valid comparison of "respirable" mass and particle count.

Coal dust

The following values were suggested for coal dust:

2 mg/m^3, Respirable Particulate Mass Concentration (RPMC) with less than 5% SiO_2

or

10 mg/m^3/(% SiO_2 + 2) if respirable dust fraction was greater than 5% quartz

The coal dust standard was not well defined for all of the potential related diseases. It was developed to address the problem of pneumoconiosis, but did not deal with the industrial exposures leading to immunological effects and the onset of bronchitis.

Inert or nuisance dust

The following values were suggested for inert or nuisance dusts:

> 30 million particles per cubic foot (mppcf) or 10 mg/m^3 of total dust less than 1% quartz

or

> 5 mg/m^3 (RPMC)

The Federal Coal Mine Health and Safety Act of 1969[5] specified that:

> *"References to concentrations of respirable dust in this title means the average concentration of respirable dust if measured with an MRE instrument or such equivalent concentrations if measured with another device approved by the Secretary (of Interior) and the Secretary of Health, Education and Welfare. As used in this title, the term 'MRE' instrument means the gravimetric dust sampler with four channel horizontal elutriator developed by the Mining Research Establishment of the National Coal Board, London, England."*

While the 1969 Act specified the MRE instrument, which closely follows the BMRC sampling criteria, the Federal Mine Safety and Health Act of 1970,[6] which superceded it, does not. The National Research Council Committee on Measurement and Control of Respirable Dust in Mines[7] noted that it may be more appropriate to use the definition of respirable dust adopted by ACGIH, since human deposition data demonstrate that the ACGIH curve is a better representation of respirable dust than the BMRC curve.

The Occupational Safety and Health Act of 1970[8] has led to the adoption of only a few permanent standards, and none of them address the issue of respirable dust. As a result, the Occupational Safety and Health Administration (OSHA) is enforcing numerous interim standards including 22 Maximum Acceptable Concentrations (MACs) of the American National Standards Institute (ANSI) and approximately 280 of the ACGIH 1968 TLVs[3] including the silica TLVs which specify either dust counts or respirable mass concentrations. The Mine Safety and Health Adminstration (MSHA) of the Department of Labor operates under different enabling legislation, and uses the 1973 TLVs which, for silica, are the same as the 1968 values.

Standards and criteria for sampling particles which deposit in the head and tracheobronchial airways

Comprehensive definitions are clearly needed for particles which deposit in the head airways and T-B regions, and cause diseases such as nasal and bronchial cancers, and chronic bronchitis. Two groups have addressed this need in recent years. The first was the U.S. Environmental Protection Agency (EPA) on the basis of its responsibility to protect the public health from diseases associated with the inhalation of airborne particles. The second was the International Standards Organization (ISO), on the basis of their desire to have better sampling specification for test methods used to determine potential inhalation hazards in both the workplace and general community atmospheres.

U.S. Environmental Protection Agency

In addressing its responsibility to develop primary ambient air quality standards to protect the public health, scientists in EPA concluded that the diseases that could be related to the inhalation of ambient aerosols were associated with particles which penetrated through the upper respiratory tract and were available for deposition in the tracheobronchial and/or gas exchange regions. They initially called this fraction "inhalable" dust.[9] Since they were only concerned with those particles which enter the trachea, they took a conservative position on the selection of the appropriate cut-size for a pre-collector, proposing a d_{50} (50% cut-size) at a d_a 15 μm. This was based on published data which indicated that about 10% of the particles of this size could enter the trachea of a mouth breathing person. The use of the word "inhalable" to designate particles penetrating through the upper respiratory airways and entering the thorax was in conflict with the usage of the word in Europe, where it was defined as the particles which entered the nasal or oral air passages.[10,11]

The Office of Air Quality Planning and Standards recommended to the EPA Administrator, in July 1981, that the revised particulate matter primary standard for ambient air should include a less conservative d_{50} of 10 μm. The size cut was the basis for the particulate matter standard proposed by the administrator in the *Federal Register*, No. 49, page 10408 on March 20, 1984. The fraction below

the 10 μm cut-size, defined by ISO as thoracic particulate (TP) matter or by EPA as PM_{10} (particulate matter below a 10 μm cut-size) would replace total suspended particulate (TSP) as the basic ambient air particulate pollution parameter. This recommendation was intended to provide for the collection of ambient air particle concentration data that were more relevent to potential inhalation hazards. In the context of the present analysis the PM_{10} fraction represents what this Committee refers to as Thoracic Particulate Mass (TPM), i.e., the fraction of the particulate material penetrating to the tracheobronchial and gas exchange regions.

International Standards Organization

Technical Committee 146 — Air Quality of the ISO appointed an ad hoc working group to prepare recommendations on size definitions for particle sampling to be used in preparing standard methods for the sampling and analysis of air contaminants in both occupational and general environmental settings. The working group used the available human regional depositon data to define a series of aerosol fractions related to particle deposition within specific regions of the human respiratory tract. The fraction drawn in by the nose or mouth was called "inspirable"; that part collected in the head was called "extra-thoracic"; while that part penetrating through the larynx was called "thoracic," and was further subdivided into "tracheobronchial" and "alveolar." Their recommendations were presented with two options. One, with a d_{50} cut of 15 μm for penetration into the trachea, and one with a d_{50} cut of 10 μm. The 15 μm cut would have been consistent with the recommendations of Miller *et al* of U.S. EPA[9] and, therefore, conservative for lung diseases. The 10 μm cut gave a more unbiased cut between head and chest fractions. Eighty-eight percent of the national membership of ISO, voted for the 10 μm cut size. Fortuitously, this turned out to be consistent with the concurrent recommendation of the EPA Clean Air Scientific Advisory Committee for a $d_{50} = 10$ μm as the index for the primary particulate matter air quality standard.

The recommendations of the ISO working group also provide a basis for a thorough re-examination of air concentration limits for occupational exposures. For some, such as droplets or soluble components of solid particles, deposition anywhere within the respiratory tract leads to absorption by the tissues, and the current total concentration limits may be appropriate. For other types of particles, biological effects may depend on the region of deposition. For example, particles depositing in the head airways region which are not expelled through the nose or mouth are likely to be swallowed and may cause a hazard by absorption through the gastrointestinal mucosa. Particles depositing in the tracheobronchial region and cleared by the mucociliary escalator are also likely to be swallowed, so that gastrointestinal absorption is also a possible route for these particles. Particles depositing in the gas exchange region may also be cleared by this route, or through the lymphatic system, or may remain for long periods in the gas exchange region itself.

Size-selective criteria for specific occupational hazards

Other criteria have been adopted for cotton dust and asbestos. However, these are different than the ones in the previous section, since each is based on criteria other than aerodynamic particle size (d_a). A brief review of the rationale and practice used for each of these materials follows.

Cotton dust sampling

Since byssinosis, or "brown lung" is characterized by an allergic response producing airway constriction, it was recognized that particles depositing in the tracheobronchial airways should not be excluded. Thus, conventional "respirable" dust criteria were judged to be inappropriate. On the other hand, the mass of the dust in cotton ginning and textile operations tends to be dominated by very large cotton fibers which were too large to be inspirable. These considerations led to the recommendation of a vertical elutriator with a nominal 50% cut-size at 15 μm as the precollector of a standard sampler.[13] The second stage filter is analyzed for the mass concentration of the particles judged most likely to be related to the health effects.

Asbestos sampling

For asbestos and other mineral fibers, size-selection is applied after air sampling. There is no sampling selectivity specified in the NIOSH[14] or ACGIH-AIHA[15] sampling recommendations, although the specified inlet configurations to the

filter holders will, of course, impose some. In the analyses by phase contrast optical microscopy, there is an effective lower limit for fiber diameter imposed by the resolving power of the optical system. There are also other limits specified by the methods, whereby particles with an aspect ratio (length to diameter) of less than 3, or a length of less than 5 μm, are not counted. The rationale for these exclusions is based on toxicological and epidemiological studies which showed that the toxic effects were primarily associated with long thin fibers. Asbestosis, a fibrotic disease, and mesothelioma, a cancer of the pleural or peritoneal surfaces, are presumably related to long fibers depositing in the gas exchange regions. Bronchial cancer may be related to the long fibers depositing on bronchial airways.

Regional deposition and clearance dynamics

Definitions

Deposition: Refers specifically to the collection of inhaled airborne particles by the respiratory tract and to the initial regional patterns of these deposited particles.

Clearance: Refers to the subsequent translocation, transformation and removal of deposited particles from the respiratory tract.

Retention: Refers to the temporal distribution of uncleared material.

For the purpose of estimating toxic dose from inhaled particles, the respiratory tract can be divided into a number of functional regions, which differ grossly from one another in retention time at the deposition sites and along the elimination pathway, and to some extent pathologic response. These are:

1. Head airway region
   a. Anterior unciliated nares (for nose breathing).
   b. Ciliated nasal passages (for nose breathing).
   c.1. Oral cavity, pharynx and larnyx (for mouth breathing).
   c.2. Nasopharynx, pharynx and larynx (for nose breathing).
2. Tracheobronchial region (for both nose and mouth breathing).
3. Gas exchange region (for both nose and mouth breathing).

The fractional deposition in each of these regions is dependent on particle aerodynamic size and the subject's airway dimensions and breathing characteristics (flowrate, breathing frequency, tidal volume, etc.).

The air sampling data collected using the procedures recommended by this committee could provide data on the deposition to be expected in each functional region. However, at a minimum, the sampling should be selective for regions 1, 2, and 3, inclusive.

Head airways region

Nasal passages

Air enters through the nares or nostrils, passes through a web of nasal hairs, and flows posteriorly toward the nasopharynx while passing through a series of narrow passages winding around and through shelflike projections called turbinates. The air is warmed and moistened in its passage and partially depleted of particles. Some particles are removed by impaction on the nasal hairs and at bends in the air path, and others by sedimentation. Except for the anterior nares, the surfaces are covered by a mucous membrane composed of ciliated and goblet cells. The mucus produced by the goblet cells is propelled toward the pharynx by the beating of the cilia, carrying deposited particles along with it. Particles deposited on the anterior unciliated portion of the nares and at least some of the particles deposited on the nasal hairs usually are not carried posteriorly to be swallowed, but rather are removed mechanically by nose wiping, blowing, sneezing, etc.

Oral passages, pharynx, larynx

During mouth breathing, some inhaled particles are deposited, primarily by impaction, in the oral cavity and at the back of the throat. These particles are rapidly eliminated to the esophagus by swallowing.

Tracheobronchial tree

These airways taken collectively have the appearance of an inverted tree, with the trachea

analogous to the trunk and the subdividing bronchi to the limbs. The branding pattern normally asymmetric in a regular pattern, as described by Horsfield *et al.*[16] However, for purposes of discussion, it will be clearer if we adopt Weibel's simplified anatomic mode in which there are 16 generations of bifurcating ciliated airways.[17] The diameter decreases from generation to generation, but because of the increasing number of tubes, the total cross section for flow increases and the air velocity decreases toward the ends of the tree. In the larger airways, particles too large to follow the bends in the air path are deposited by impaction. At the low velocities in the smaller airways, particles deposit by sedimentation and, if small enough, by diffusion.

Ciliated and mucus secreting cells are found at all levels of the tracheobronchial tree. Within hours, inert non-soluble particles deposited in this region are thus carried towards the larynx on the moving mucus sheath which is propelled proximally by the beating of the cilia. Beyond the larynx, the particles enter the esophagus and pass through the gastrointestinal tract.

Persistent defects in clearance of particles from the bronchial tree would also lead to increased residence times for particles containing toxic and carcinogenic chemicals. This increases the dose to the underlying tissues from those chemicals and resulting in increased systemic uptake. Consequently, defective clearance may contribute to a variety of disease conditions.

Gas exchange region

The region beyond the terminal bronchioles, which includes the alveoli and associated ducts and bronchioles, is the region in which the gas exchange takes place. The epithelium is non-ciliated and, therefore, insoluble particles deposited in this region by sedimentation and diffusion are removed at very slow rates, with clearance half-times on the order of a month or more. The mechanisms for particle clearance from this region are only partly understood and their relative importance is a matter of some debate. Some particles are engulfed by phagocytic cells which are transported onto the ciliary "escalator" of the bronchial tree in an undefined manner. Others penetrate the alveolar wall and enter the lymphatic system. Still others dissolve slowly *in situ*. Even "insoluble" particles have some finite dissolution rate, which is greatly enhanced for smaller particles by their large surface to volume ratio. Morrow *et al*[18] demonstrated that the clearance half-times of many "insoluble" dusts in the lung are proportional to their solubilities in simulated lung fluids. It has also been demonstrated that the gas exchange region clearance mechanisms may function differently for different dusts and concommitantly inhaled gaseous contaminants.

It is difficult to believe that prolonged retention of particles in the gas exchange region of the lungs is beneficial. Prolonged retention of the inhaled particles in the gas exchange region increases the doses of those particles to the underlying tissues as well as the potential for systemic uptake. If the particles are fibrogenic, this could contribute to the development of pneumoconiosis and emphysema. Cigarette smoke from either passive or active smoking contain a variety of carcinogens, and greater retention in the alveoli could cause an increased risk from both lung cancer and cancer in other organs which accumulate these chemicals after their dissolution in the lungs.

Limitations of selective sampling and samplers

The effective application of size-selective sampling procedures to respiratory hazard evaluation requires: 1) adequate knowledge of the regional deposition and clearance of particles in people, and 2) practical, reliable, reproducible, and accurately calibrated size-selective samplers.

It is apparent from reviews of human deposition and clearance data and models that regional deposition is not fully understood and that the predictive models are at best approximations. Furthermore, there are very large variations in both regional deposition efficiencies and clearance rates among normal people and within individuals at different stages of activity. Thus, even if the data were highly precise and reproducible and population average figures met with general acceptance, the individual risks from the inhalation of a given aerosol would vary over a wide range.

The technology for designing a size-selective sampler and characterizing its collection characteristics is relatively more advanced than that for determining regional deposition and clearance dynamics in the human respiratory tract. Yet, even

here, there are many conflicting data in the literature, and many instrument designs have required modifications to meet their original specifications. Some of these instruments, especially those most applicable to the charge of the committee, are reviewed within the sections of Chapters 5.A, 5.B and 5.C. Also, much laboratory calibration data were not matched by instrument performance under field test conditions. Therefore, the recommendations made here are based upon present state of the art, with a full awareness of the need for further research.

In addition, size-selective sampling performance procedures are necessary to properly insure the instrumentation used will be in conformance with boundaries defined by the lung deposition criteria found in Chapters 4.A and 4.B.

Within this document the features of particle size-selective sampling systems are reviewed and generic size-selective sampling system requirements have been described for use in situations where toxic particles are present in the workplace. The analysis which follows attempts to include size-selection of the particle ranges that can penetrate or deposit and have a biological effect on various regions within the pulmonary system. The procedures have been designed with sampler size cuts for IPM, TPM and RPM. Since we are approximating the potential dose of the material to the respiratory system, the procedures use integrated mass collection devices. The strengths and weaknesses of the individual samplers are described and the efficiency of the collection curves are presented and evaluated for approximation to the shape of the sampling efficiency curves for the appropriate regions of the human respiratory tract.

Chemical composition vs. particle size

Since the deposition of particles in the respiratory system varies according to the aerodynamic particle size, collection and analysis of size segregated samples by the specified procedures can be used to determine how much of a chemical substance will be deposited in the interior regions of the respiratory system and compared to appropriate size-selective TLVs. Unfortunately, as has been shown in many industrial situations, the particles often will not have a homogeneous chemical composition and a substance will not necessarily be distributed uniformly, as a percentage of the mass, over the range of particles found in a particular work setting. Examples for various materials are illustrated in Chapter 6.

The diversity of chemical and physical characteristics of individual particles requires the development of compound and particle size-selective TLVs (PSS-TLVs). Sampling procedures are identified for use in instances where one or more particle size ranges are expected to contain a particular compound. However, knowledge of the dissolution rate and volatility of each compound are also required in order to evaluate the potential for toxicological impact at various target sites within the body after inhalation and deposition in the respiratory tract. The latter point will necessitate the acquisition of further information for inclusion in the TLV background documation.

The process of defining a TLV has always dealt with the assimilation of information on the diseases associated with a particular substance. It should now be apparent that for particles, the development of TLVs appropriate for protection of workers requires even more information. The PSS-TLV must include information of the particle size associated with a substance, its effects after deposition, and its rate of dissolution in the various regions of the lung. To facilitate these evaluations, this Committee proposes a decision flow diagram for use in establishing PSS-TLVs. It encompasses both the present TLV procedure and a new procedure for determining the physical and chemical nature of a substance and the potential deposition regions. The approach recommended by this Committee is outlined and illustrated in Chapter 6.

Summary

The development of particle size-selective occupational threshold limit values has not proceeded in a consistent fashion in the past. The development of a reliable data base on size-selective particle deposition in the human respiratory tract in recent years has created a basis for the specification of additional PSS-TLVs. These should consider the diseases associated with the inhaled substance, and should be based upon the physical characteristics of the lung, size-mass distribution and dynamics of particles, the physical and chemical composition of particles emitted by varying

processes, and other factors including dissolution rates in the lung.

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