Nano-Materials & Health

"An Industrial Hygiene Update"

Donald H. Ewert

EH&S Manager: Oso BioPharmaceuticals Manufacturing
Vice-Chairman; AIHA Nanotechnology Working Group

Industrial Hygienist

"Within a short time, everything that can be known, will be known, and anything that is possible within the laws of physics will be achievable."

(Daniel G. Clemmensen; Singularity Action Group)

Don Ewert; Industrial Hygienist – EH&S Department Manager

30+ Years Experience as a Practicing Industrial Hygienist

Radiation Safety Officer at NDSU – Biochemistry/Physics Departments

Environmental Sampling of the Twin Towers During the Late 80's

Environmental Remediation of Guantanamo Bay's Medical Center in the Late 80's

Creation of the First EPA-NIST Certified Mobile Laboratory for On-Site Environmental Assessments (AHERA Regulations)

Development of Three OSHA and EPA Laws Involving Industrial Hygiene & Environmental Sampling

20 Years as an Expert Witness in the Field of Forensic Toxicology (Post-Injury Analysis)

Research Scholar - Center for Environmental Toxicology & Technology at Colorado State University

Vice-Chair of the AIHA Nanotechnology Working Group

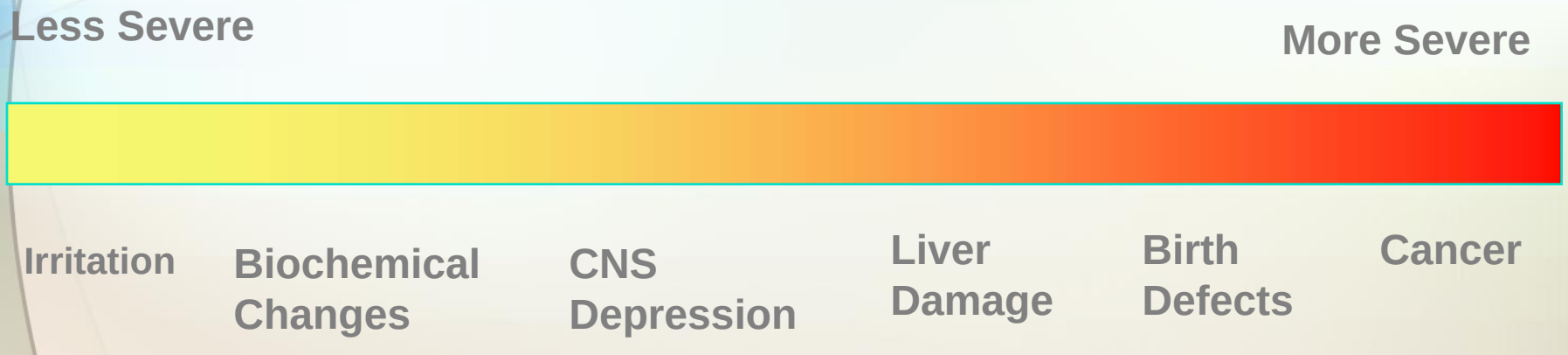
Nanotechnology

What Are The Health Risks?

Physiological Risks (*Hazard = Toxicity x Exposure*)

- *Cancer & Tumors*
- *Developmental*
- *Reproductive*
- *Cardiovascular or Blood*
- *Endocrine*
- *Gastrointestinal or Liver*
- *Immunosuppressant*
- *Kidney*
- *Musculoskeletal*
- *Neurological*
- *Respiratory*
- *Skin or Sensory Organ*

Hazard Continuum



Risk = f (Hazard, Exposure)

Hazard = the potential for a compound to produce harm.

Exposure = Contact with a compound.

Risk = the probability that a substance will produce harm under specified conditions of exposure.

Safety = perception that a substance will not produce harm under specified conditions.

Compound Characteristics that Affect Exposure

Low	Risk	High
Wet	Physical Form	Dry
Large	Particle Size	Small
Dense	Density	Light
Spherical	Particle Shape	Feathery
No	Electrostatic	Yes
Limited	Routes of Ingestion	Unlimited
Low	Bio Availability	High
Fast/ Reversible	Acute / Chronic	Slow / Irreversible
None	'gens	All

Process Characteristics that Affect Exposure

Less	Action	More
Closed	Operation	Open
Low Energy / Velocity	Process	High Energy / Velocity
Low Δ p/ Temp	Pressure	High Δp/Temp
None	Transfers	Multiple
Well	Training	Poorly
None Required	Operator Skill	Highly Dependent
Routine	Task Type	Non Routine
Short	Duration	Long
One Operation	Frequency	Multiple Operation

Facility Characteristics that Affect Exposure

Better	Feature	Worse
- Ve to Corridor	Pressure	+ ve to Corridor
Two stage + ve buffer	Airlock	Single stage no buffer
Isolator	ECM	LEV
HEPA Terminals	Filtration	No HEPA
Away from Access	Airflow	Towards Access

Nanotechnology

Toxicology Update

Toxicology Update

Nano-Materials (General)

- ***Toxicity Remains Dependant Upon the Physicochemical Properties of the Material***
- ***Nanoscale Materials Demonstrate Increased Ability to Penetrate the Body at Mucous Openings***
- ***30%-50% of Inhaled Nanoscale Materials are Deposited to the GI Tract due to Lung Clearance***
- ***Varying Particle & Toxicity Characteristics Prevent us From Grouping Health Effects***

Metal Oxide Powders

- ***Inflammatory Response from Inhaled TiO2 is Less Than the Response Associated with Exposure to Silica***
- ***Low Toxicity Inhaled Particles are Easily Cleared Through Macrophage Action***
- ***Physiological Response to Agglomerated Particles is Dependant Upon the Toxicity of the Material***
- ***Dermal Response Remains Dependant Upon Material Toxicity Characteristics***

Toxicology Update

Carbon Nanotubes

- ***Cytotoxic Characteristics Increase with Increased Iron Content (up to 30% Fe)***
- ***Studies With Pure SWCNT Show a Reduction in the Adverse Physiological Effects Over CNT Material Containing Fe***
- ***Macrophage Recognition and Subsequent Lung Clearance is Lower for SWCNT than for MWCNT***
- ***Oxidative Stress & Fibrosis are the Most Common Physiological Reactions to CNT***
- ***Fibrosis Development is Sensitive to SWCNT Concentration, Exposure Frequency, & Duration***
- ***Repeated Inhalation Exposure Causes Increased Aortic Plaque Formation***
- ***Dermal Response to SWCNT Shows a Dependence on Fe Content***

Quantum Dots

- ***Inhalation Studies Show Macrophage Recognition in the Lungs & Blood Clearance Within 24 Hours***
- ***Organ Retention is Highly Dependant Upon Physicochemical Properties (Protein Interaction at Surfaces)***

Toxicology Topic of the Week

Nature

Carbon nanotubes, introduced into the abdominal cavity of mice, show asbestos-like pathogenicity in a pilot study.

The New York Times

Researchers Find Nanotubes May Pose Health Risks Similar to Asbestos

BBC News

'Asbestos warning' on nanotubes

Washington Post

Effects of Nanotubes May Lead to Cancer

http://www.nanotechproject.org/multimedia/flash/mwcnt/mwcnt.html

ICON™ INTERNATIONAL COUNCIL ON NANOTECHNOLOGY
A partnership for nanotechnology stewardship and sustainability

Interview with Dr. Günter Oberdörster, D.V.M., Ph.D.

…at best only a minimal fraction of inhaled MWCNTs depositing in the deep lung is likely to translocate to pleural sites, heavily agglomerated structures, *i.e.*, larger clumps, will not. At inhaled concentrations of 50 µg/m^3 – a concentration found in a simulated carbon nanotube workplace scenario by Dr. Maynard and colleagues – the i.p. doses of 3 mg/mouse used in the Takagi *et al*. study would never have been achieved in the pleural cavity, even under continuous exposure conditions.

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Interview with Dr. Günter Oberdörster, D.V.M., Ph.D.

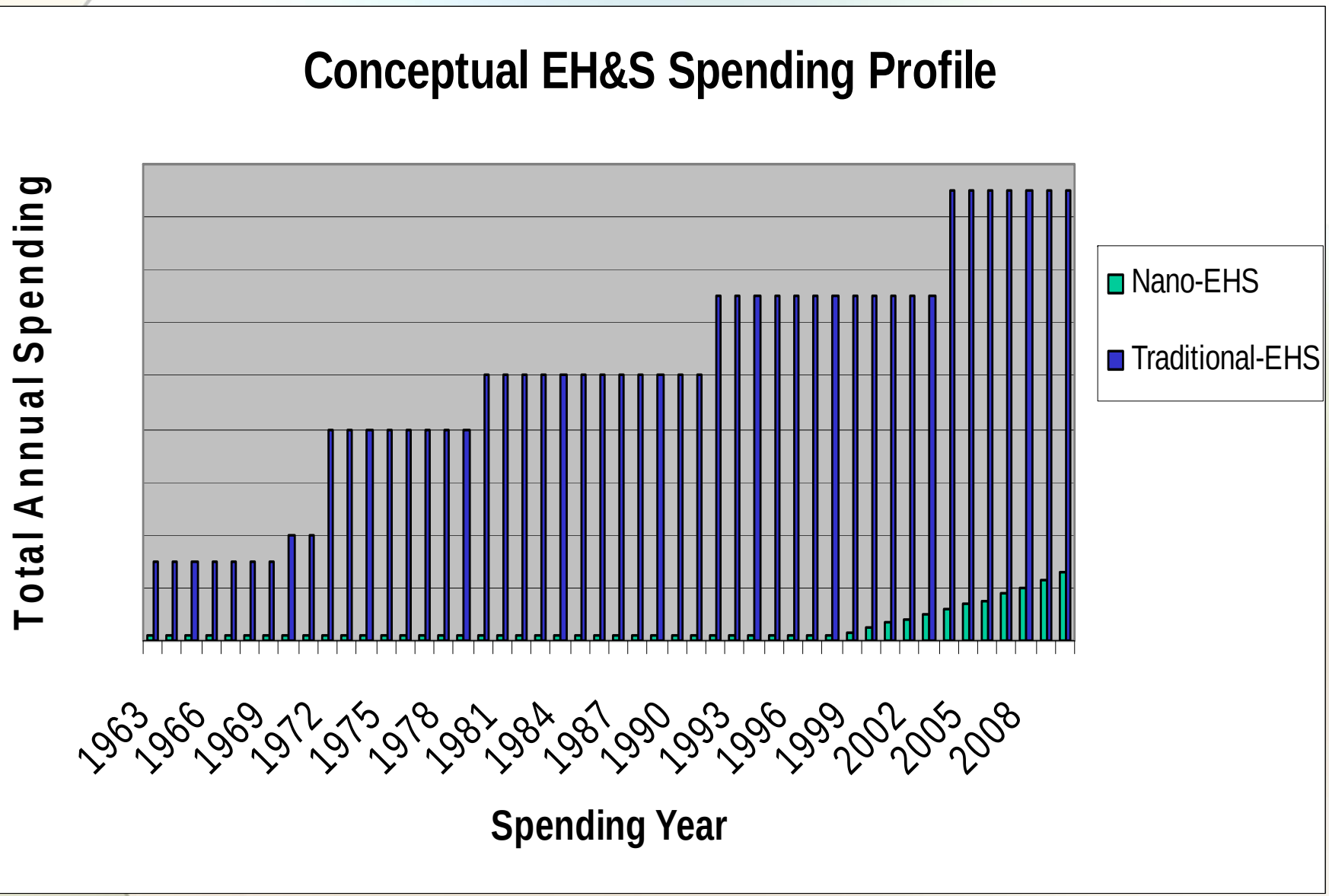
Three milligrams i.p. is a huge amount for a mouse as well as a rat. Regarding the injected numbers of 10^9 fibers, given the uncertainty of the method that was used to count fibers, it is very difficult in my view to even estimate the number of fibers per milligram MWCNT. The material that was injected was highly agglomerated, unlike what the European regulations dictate… …In this case, it appears there were only a few non-agglomerated individual fibers; most were big clumps of materials, and it's hard to discern how many fibers were in those clumps. So what we are dealing with is a mix of very large agglomerates and a few individual fibers. That raises another issue, namely – as is well-known from earlier studies where investigators injected simultaneously asbestos fibers and non-fibrous particles (even benign ones) – that even benign spherical particles together with a carcinogenic fiber cause an increase in tumor induction. They act synergistically. Moreover, even a biosoluble fiber – which is not carcinogenic by inhalation – when injected i.p. into rats at an extremely high dose – comparable to the present mouse study – induced mesothelial tumors in an earlier study.

Can We Manage Exposures?

Absolutely!

What Methods Are Available?

The Same Ones We're Already Applying!


Conceptual EH&S Spending Profile
Total Annual Spending
Nano-EHS
Traditional-EHS
1963
1966
1969
1972
1975
1978
1981
1984
1987
1990
1993
1996
1999
2002
2005
2008
Spending Year

Environmental Health & Safety - The 21st Century

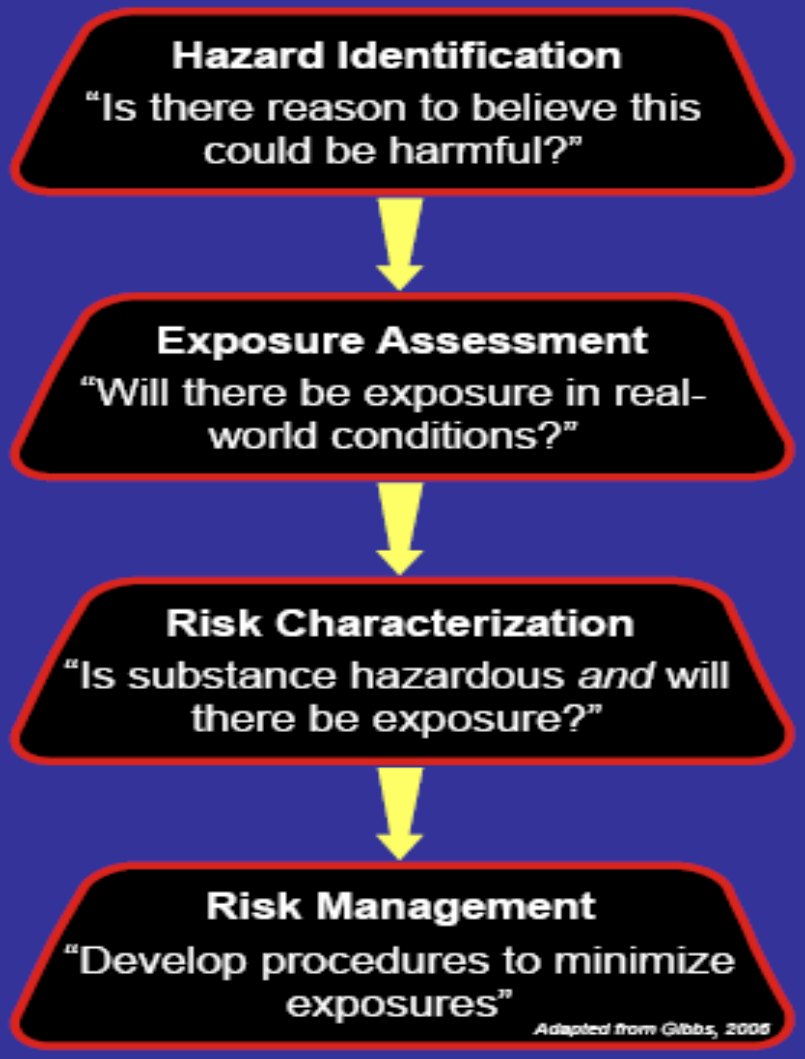
Nanoproduct manufacturing has now moved beyond hype and into active commercialization. A report by the National Center for Manufacturing Sciences reveals that within the next 3 years, 58% of all manufacturers will have some form of nanomanufactured product available in the market. Given this rapid penetration, worker and public health are a major consideration. To minimize potential exposures to unbound nanoparticles, historically validated pharmaceutical control methods such as process safety, chemical hygiene, product stewardship, and control banding are available and effective. Thus, manufacturers and public health professionals who are familiar with and apply these techniques can generally assure an anxious public that nano risks are manageable, health and safety considerations are defined, and controls have been implemented.

Environmental Health & Safety Control Methods

1) Process Safety Management
2) Chemical Hygiene Programs
3) Product Stewardship Principles
4) Control Banding

Steps to Protect Nanotechnology Workers

Process Safety



Process Safety Management

* *Process safety management is the proactive identification, evaluation and mitigation or prevention of chemical releases that could occur as a result of failures in process, procedures or equipment.*

* *The major objective of process safety management of highly hazardous chemicals is to prevent unwanted releases of hazardous chemicals especially into locations which could expose employees and others to serious hazards.*

* *The various lines of defense incorporated into the design and operation of each process, to prevent or mitigate the release of hazardous chemicals, needs to be evaluated and strengthened to assure effectiveness at all levels.*

* *An effective process safety management program requires a systematic approach to evaluating the whole process.* Using this approach the process design, process technology, operational and maintenance activities and procedures, nonroutine activities and procedures, emergency preparedness plans and procedures, training programs, and other elements which impact the process are all considered in the evaluation.

Chemical Hygiene Programs

Chemical Hygiene Programs

* *Components of a Chemical Hygiene Program*
  - Basic Rules and Procedures
  - Chemical Procurement, Distribution, and Storage
  - Environmental Monitoring
  - Housekeeping, Maintenance and Inspections
  - Medical Program
  - Personal Protective Apparel and Equipment
  - Records
  - Signs and Labels
  - Spills and Accidents
  - Training and Information
  - Waste Disposal

* *Minimize all chemical exposures*. Because few chemicals are without hazards, general precautions for chemical handling should be adopted, rather than specific guidelines for particular chemicals. Skin contact with chemicals should be avoided as a cardinal rule.

Chemical Hygiene Programs

* *Avoid underestimation of risk.* Even for substances of no known significant hazard, exposure should be minimized; for work with substances which present special hazards, special precautions should be taken. One should assume that any mixture will be more toxic than its most toxic component and that all substances of unknown toxicity are toxic.

* *Provide adequate ventilation.* The best way to prevent exposure to airborne substances is to prevent their escape into the working atmosphere by use of hoods and other ventilation devices.

* *Institute a viable chemical hygiene program.* A mandatory chemical hygiene program designed to minimize exposures is always necessary; it should be a regular, continuing effort, not merely a standby or short-term activity.

* *Observe PELs and TLVs.* The Permissible Exposure Limits of OSHA and the Threshold Limit Values of the American Conference of Governmental Industrial Hygienists should never be exceeded.

Chemical Hygiene Programs

* *Responsibility for chemical hygiene rests at all levels*. Chemical hazards have no selectivity. Every member of the organization is responsible for assuring the safe handling and application of chemicals including the:

1) *Chief Executive Officer*, who has ultimate responsibility for chemical hygiene and must, along with other administrators, provide continuing support for chemical hygiene.

2) *Supervisor of the department or other administrative unit*, who is responsible for chemical hygiene in that unit.

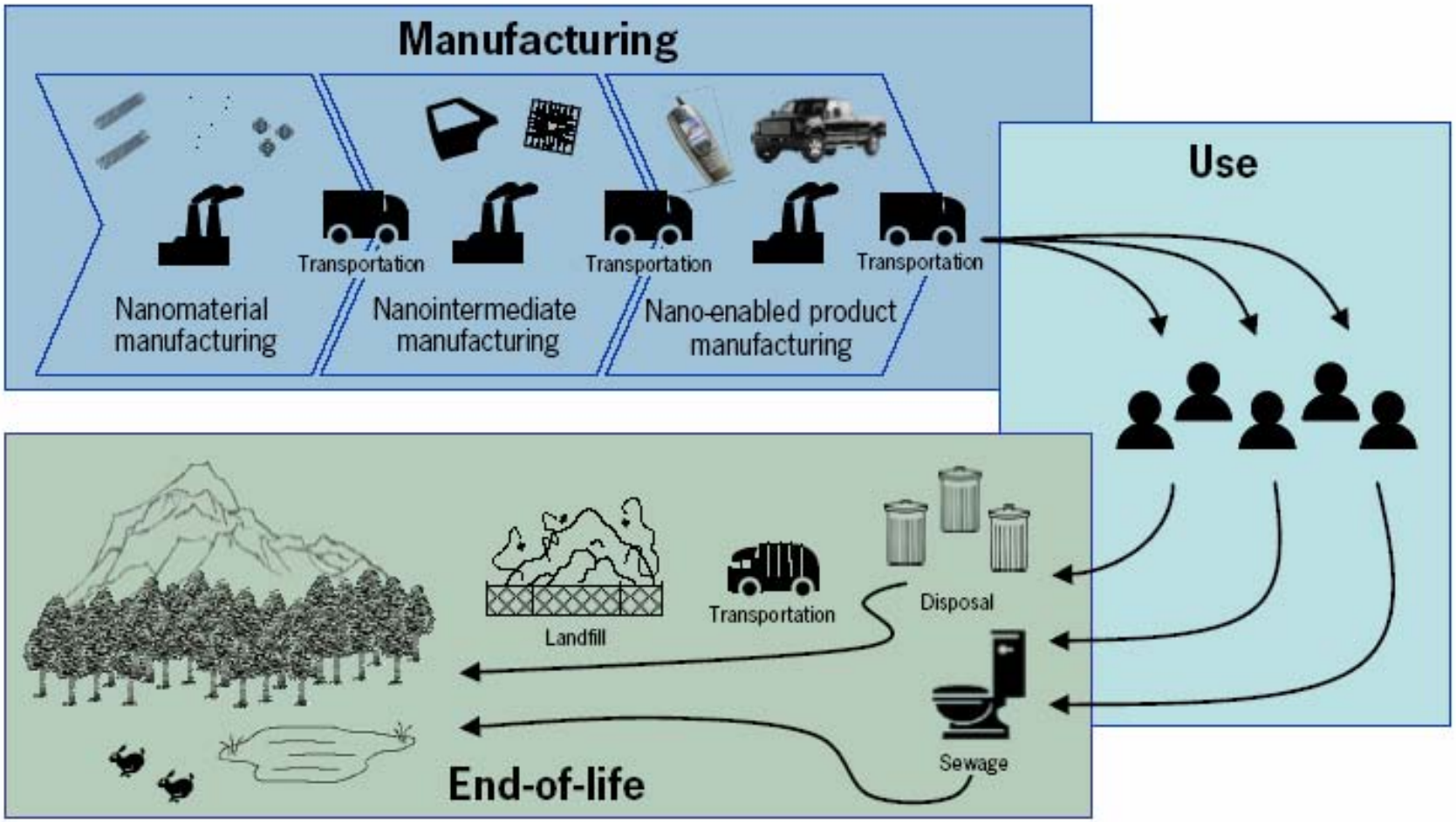
3) *Chemical Hygiene Officer(s)*, whose appointment is essential and who must work with administrators and other employees to develop and implement appropriate chemical hygiene policies and practices.

4) *Supervisor(s)*, who have overall responsibility for implementing and monitoring chemical hygiene.

5) *Project Director or director of other specific operation*, who has primary responsibility for chemical hygiene procedures for that operation.

6) *Worker(s),* who are directly responsible for chemical handling.

Product Stewardship Principles



Product Stewardship Principles

* *The responsibility for reducing product impacts is a shared responsibility.* The greater the ability an entity has to minimize a product's life-cycle impacts, the greater its degree of responsibility, and opportunity, for addressing those impacts.

* *All product lifecycle costs - from using resources, to reducing health and environmental impacts throughout the production process, to managing products at the end-of-life-cycle should be included in the total product cost. The environmental costs of product manufacture, use, and disposal should be minimized, to the greatest extent possible, for local and state governments, and ultimately shifted to the manufacturers and consumers of products. Manufacturers should thus have a direct financial incentive to redesign their products to reduce these costs.*

* *Those that are responsible for reducing the health and environmental impacts of products should have flexibility in determining how to most effectively address those impacts.* The performance of responsible parties shall be measured by the achievement of goal-oriented results.

Product Stewardship Principles

* *Policies that promote and implement product stewardship principles should create incentives for the manufacturer to design and produce "cleaner" products - ones made using less energy, materials, and toxics, and which result in less waste energy to operate (through reduction, reuse, recycling, and composting).* These policies should also create incentives for the development of a sustainable and environmentally-sound system to collect, reuse, and recycle products at the end of their lives.

* *Industry should provide leadership in realizing these principles.* Government will provide leadership in promoting the practices of product stewardship through procurement, technical assistance, program evaluation, education, market development, agency coordination, and by addressing regulatory barriers and, where necessary, providing regulatory incentives and disincentives. Industry and government shall provide - and consumers should take full advantage of - information needed to make responsible environmental purchasing, reuse, recycling, and disposal decisions.

Control Banding

* *Courtesy of NIOSH; Control Banding Presentation by:*

Mark D. Hoover, PhD, CHP, CIH

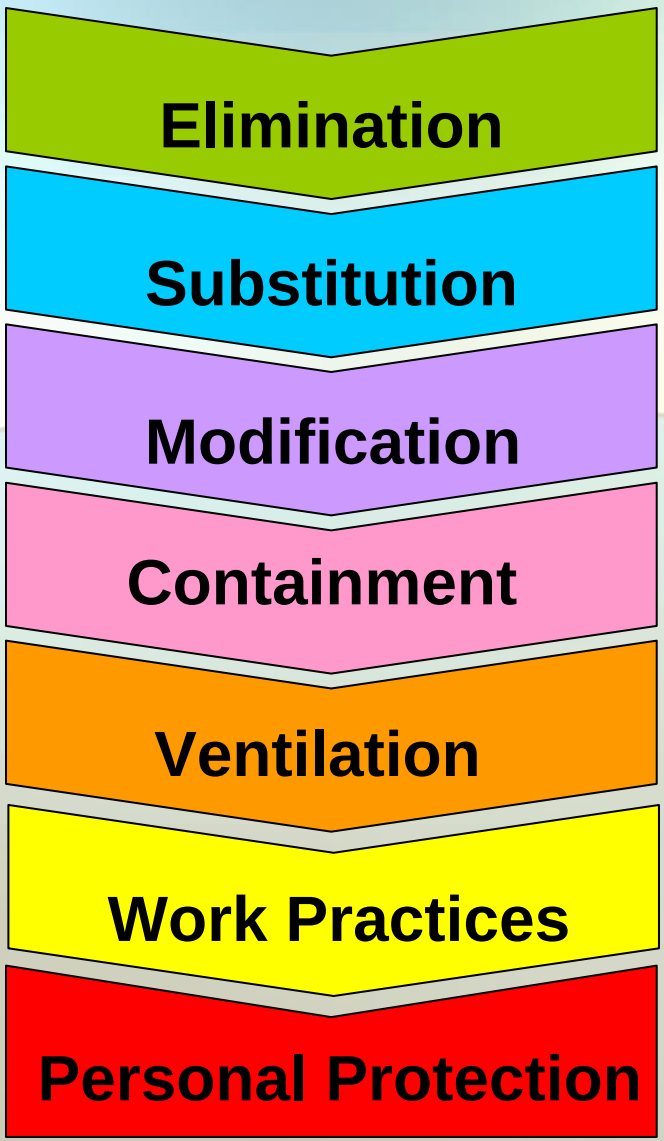
Control Banding

* *Control Banding is a complementary approach to protecting worker health by focusing resources on exposure controls*. Since it is not possible to assign a specific Occupational Exposure Limit to every chemical in use, a chemical is assigned to a "band" for control measures, based on its hazard classification according to international criteria, the amount of chemical in use, and its volatility/dustiness.

* *The outcome is one of four recommended control strategies:*
  - *Employ good industrial hygiene practice*
  - *Use local exhaust ventilation*
  - *Enclose the process*
  - *Seek the advice of a specialist*

* *Industrial hygiene expertise is not replaced - specific operating knowledge and professional judgment are required for implementation of the best "reasonably practicable" combination of controls to minimize risks to workers.*

Traditional Hierarchy of Exposure Control Practices



“Traditional” Control banding concept for exposure management

	Low Dustiness	Medium Dustiness	High Dustiness
Hazard Group A			
Small	1	1	1
Medium	1	1	2
Large	1	2	2
Hazard Group B			
Small	1	1	1
Medium	1	2	2
Large	1	3	3
Hazard Group C			
Small	1	1	2
Medium	2	3	3
Large	2	4	4
Hazard Group D			
Small	2	2	3
Medium	3	4	4
Large	3	4	4
Hazard Group E			
For all hazard group E substances, choose control approach 4			

Control Approach

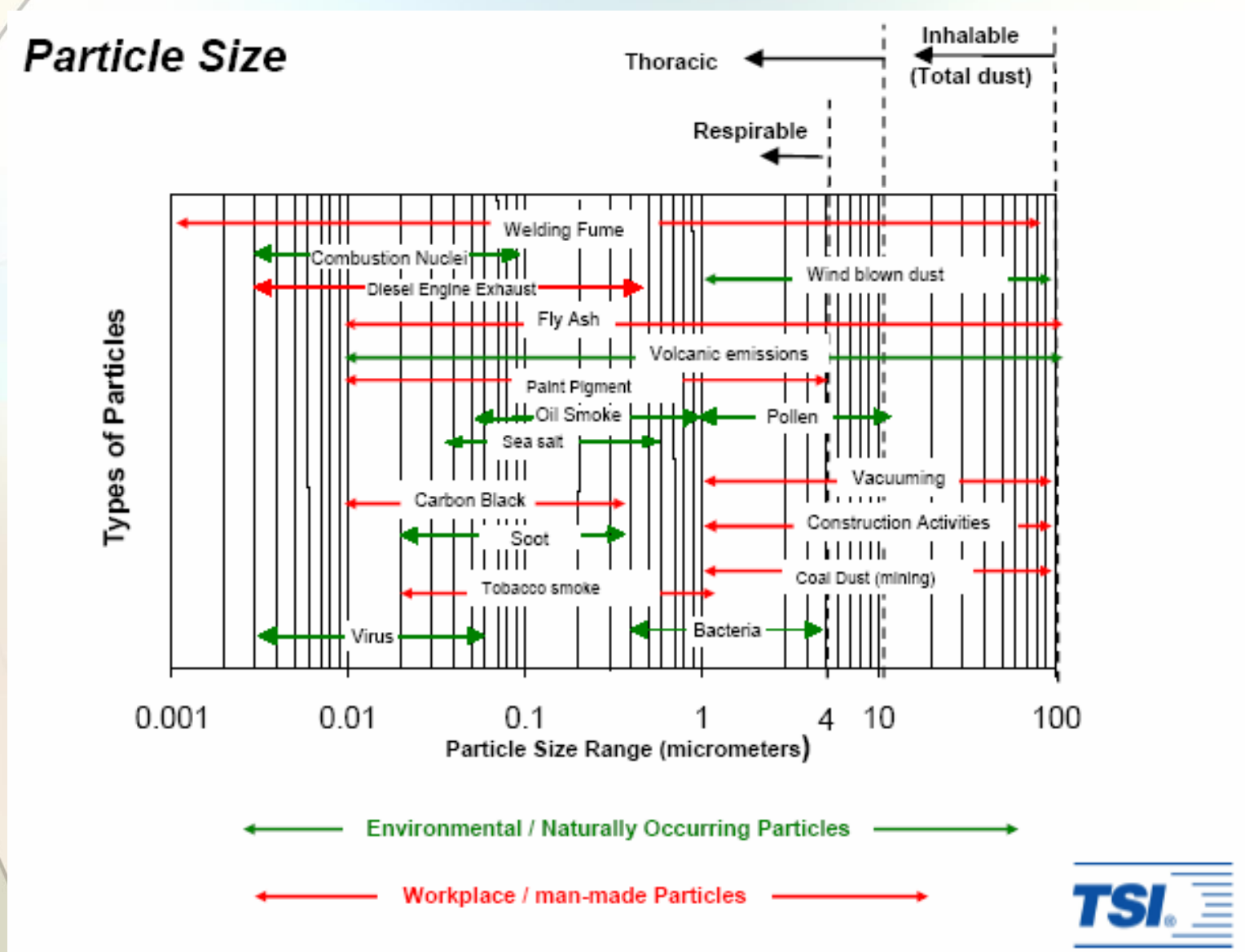
1. General Ventilation
2. Engineering Control
3. Containment
4. Specialist Advice

Possible Hazard Band Scheme for Nanoparticles in the Workplace

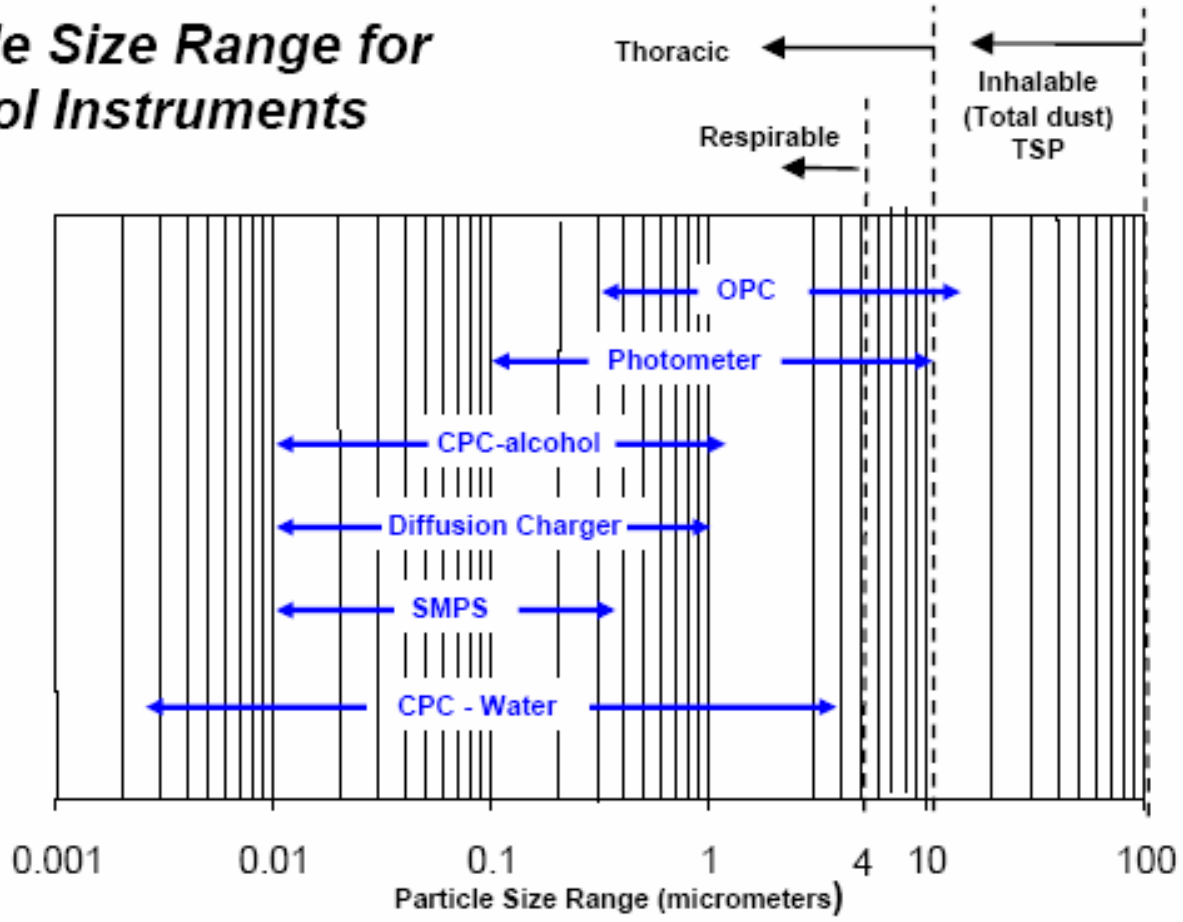
Hazard Band	Range of Exposure Concentrations	Type or Degree of Hazard	General Character of Control Band
A	100 to 500 µg/m^3 dust *? Other criteria ?*	Slight and reversible ?	Good industrial hygiene practice with open handling or local exhaust ventilation
B	10 to 100 µg/m^3 dust *? Other criteria ?*	Moderate and reversible ?	Local exhaust ventilation or enclosed processes.
C	1 to 10 µg/m^3 dust *? Other criteria ?*	Severe and reversible or moderate and irreversible ?	Enclosed processes.
D	<1 µg/m^3 dust *? Other criteria ?*	Severe and irreversible ?	Isolated or remote handling.

Nanotechnology

Sampling & Exposure Monitoring


Particle Size
Thoracic
Inhalable
(Total dust)
Respirable
Welding Fume
Combustion Nuclei
Diesel Engine Exhaust
Fly Ash
Volcanic emissions
Paint Pigment
Oil Smoke
Sea salt
Carbon Black
Soot
Tobacco smoke
Virus
Wind blown dust
Pollen
Vacuuming
Construction Activities
Coal Dust (mining)
Bacteria
Types of Particles
0.001
0.01
0.1
1
4
10
100
Particle Size Range (micrometers)
Environmental / Naturally Occurring Particles
Workplace / man-made Particles
TSI

Particle Size Range for Aerosol Instruments



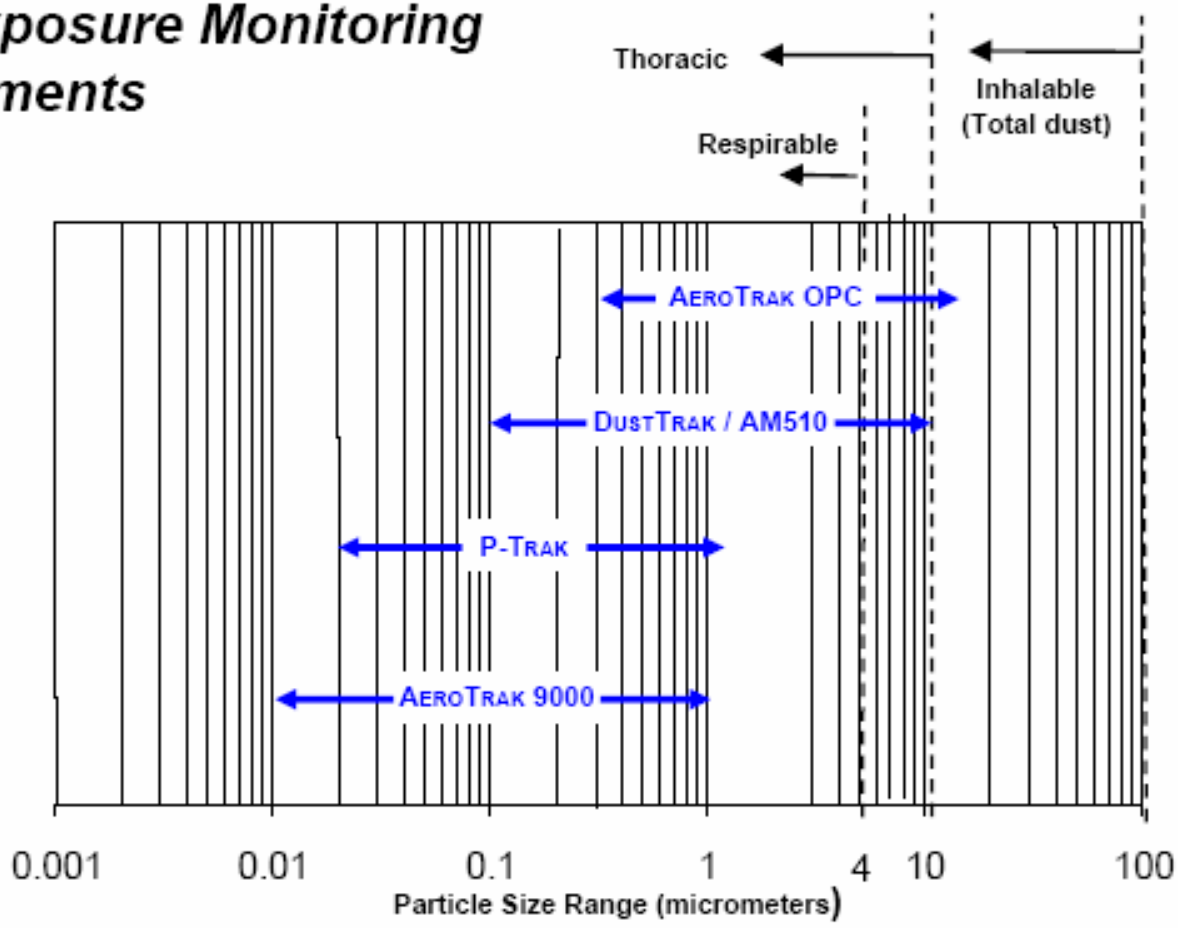
OPC: Optical Particle Counter

CPC: Condensation Particle Counter

SMPS: Scanning Mobility Particle Sizer

TSI

Particle Size Range for TSI Exposure Monitoring Instruments



TSI

Gravimetric Sampling Systems

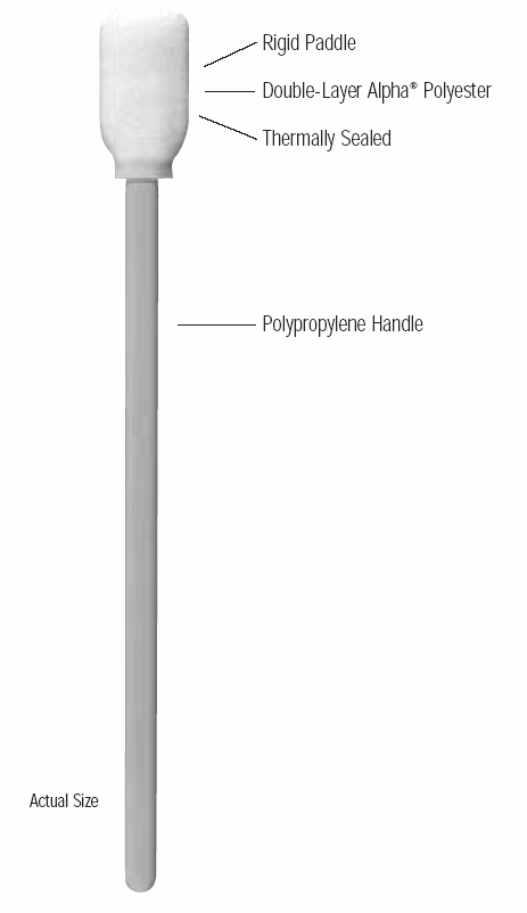
SIDEPAK™
Personal Aerosol Monitors (Photometer)

Model AM510

- Measure aerosol mass concentrations in real time
- Small, lightweight and quiet
- PM10, PM2.5, PM1.0 and respirable fractions
- Belt mounted for personal sampling
- Battery operated
- Data logs and downloads to a PC for analysis and reporting

Model AM510

Surface Sampling Supplies



Selecting Nanoscale Monitoring Instruments

Photometers, Optical Particle Counters (OPCs) and Condensation Particle Counters (CPCs) all measure airborne particles in real time. Each technology has a unique sensitivity to specific particle characteristics such as size, mass and refractive index. Table 1 summarizes the basic performance differences. Note in particular the size ranges and upper airborne contamination limits associated with OPCs and CPCs.

TABLE 1. Comparison Chart—Real Time Particle Measurement Technologies

	Photometer	OPC	CPC
Typical Size Range	0.1 to 10 μm	0.3 to 20 μm	0.02 to 1.0 μm
Measures Particle Mass	Yes	No	No
Measures Particle Size	No	Yes	No
Detects Single Particles	No	Yes	Yes
Typical Mass Concentration Range	0.01 to 100 mg/m^3	N/A	N/A
Typical Number Concentration, Upper Limit	N/A	2×10^6 Particles/ft^3 70 Particles/cm^3	1.5×10^{10} Particles/ft^3 500,000 Particles/cm^3

Photometers

Often used for industrial workplace studies and emissions monitoring, photometers are well-suited for assessing human exposure to specific size fraction aerosols in real time. They use conventional lightscattering technology to closely estimate particulate mass concentrations.

The operation of a typical photometer is shown in Figure 1. **A sample is drawn into the instrument by a continuously running pump. The size fraction of interest is aerodynamically "cut" from the air stream at the sample inlet using either an impactor or a cyclone. The size fractions of most interest are respirable, thoracic, PM10, PM2.5 and PM1.0.**

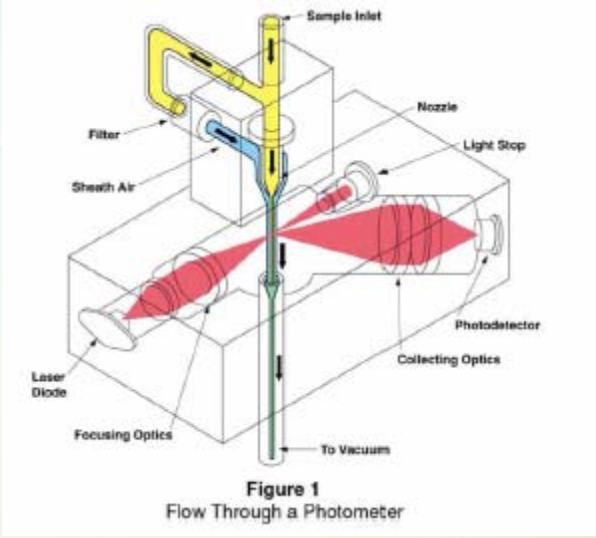


Figure 1
Flow Through a Photometer

Photometers typically measure particle size ranges from 0.1 to 10 µm diameter with concentrations ranging from 0.01 to 100 mg/m3 or more. Photometers cannot "see" particles below 0.1 µm (ultrafine particles) because the particles are too small to scatter detectable quantities of light. Photometers measure the aggregate signal from a "cloud" of particles and are not designed to detect individual particles, even when they are relatively large.

Most photometers are calibrated against a standard test dust, commonly referred to as Arizona Road Dust. This calibration is a good approximation for most ambient aerosols. Because optical measurements are dependent upon particle size and material properties, there may be times in which a custom calibration would improve the accuracy for a specific aerosol.

Optical Particle Counters

Optical particle counters measure particle size and number concentration by detecting the light scattered from individual particles. They were traditionally used for clean room monitoring, but have more recently found application in filter testing, outdoor environmental monitoring, and indoor air quality studies.

Single particles are drawn through a focused laser beam and produce a flash of light, as illustrated in Figure 2. The intensity of the scattered light is a complex function of the diameter, shape and refractive index of the particle as well as light wavelength and geometry of the optical detector. A photodetector measures the amount of light that each particle scatters and records a count for each calibrated size range or bin.

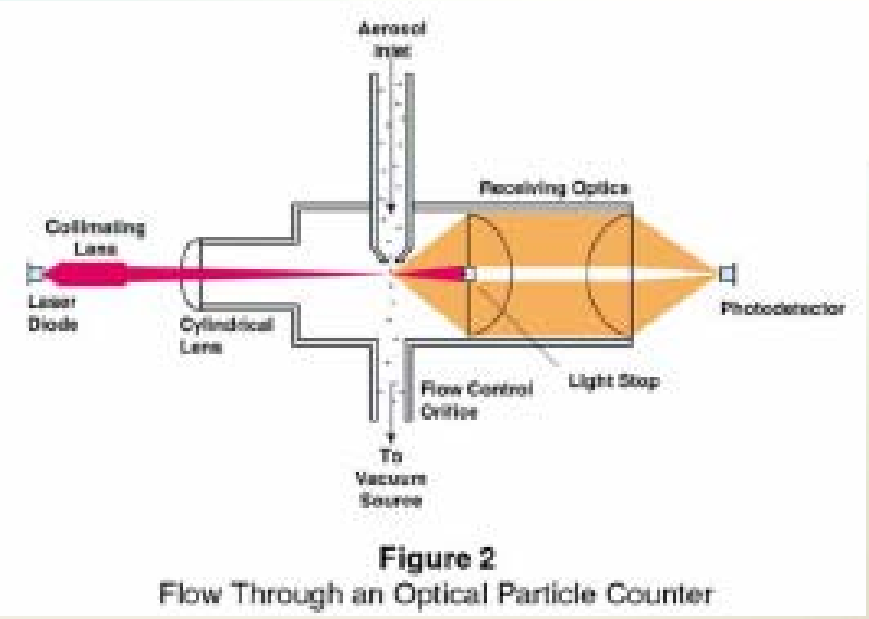


Figure 2
Flow Through an Optical Particle Counter

The measured size range is typically 0.3 to 20 µm diameter, and the number concentration is limited to a maximum of 2,000,000 particles/ft3 (70 particles/cm3). OPCs are calibrated with perfectly uniform, spherical polystyrene latex bead particles of known refractive index. The measured size of an unknown particle is therefore the "light-scattering equivalent size" as compared to the known calibration particle. The actual physical size may be quite different from this.

Condensation Particle Counters

Condensation particle counters, sometimes referred to as condensation nuclei counters, are specialized instruments that first enlarge very small particles to an optically detectable size. They excel at counting particles in size ranges that are invisible to OPCs and photometers. CPCs are used for a variety of applications ranging from respirator fit testing to environmental air pollution studies to basic research. They are particularly well-suited for tracking indoor pollutants to their source.

As depicted in Figure 3, particles are continuously drawn into the instrument and passed through a warm alcohol vapor. The mixture then flows through a condenser section where the alcohol vapor condenses onto the particles and "grows" them into larger droplets. The individual droplets then pass through the focal point of a laser beam, producing a flash of light. Each light flash is counted as one particle.

The measured size range is typically from below 0.02 to above 1.0 µm diameter. Number concentration ranges from zero to more than 500,000 particles/cm3 (15,000,000,000 particles/ft3). The concentration measurement does not depend on the size or material properties of the particle.

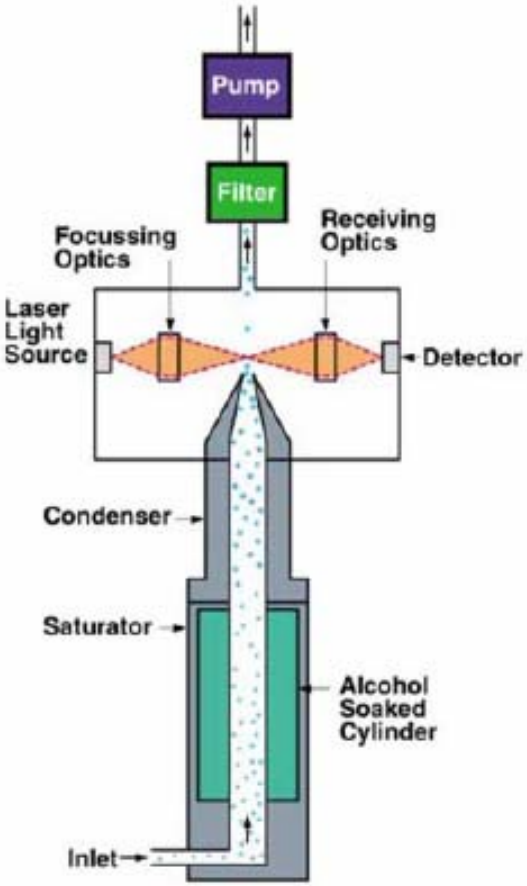


Figure 3
Flow Through a Condensation Particle Counter

Model 8520

DustTrak™ Aerosol Monitor (Photometer)

Model 8520

- Measures aerosol mass concentrations in real time
- PM10, PM2.5, PM 1.0 and respirable size fractions
- Portable, battery operated
- Long-term unattended sampling
- Data logs and downloads to a PC for analysis and reporting

AeroTrak™ Handheld Opticle Particle Counters (OPC)

Model 8220

Model 8220

- Count and measure size in up to 6 channels from 0.3 to 10 microns
- User selectable and adjustable size channels
- Measure filter efficiency to ensure optimal HVAC performance
- Data logs and downloads to a PC for analysis and reporting

P-TRAK™ Ultrafine Particle Counters (CPC)

Model 8525

- Counts ultrafine particles less than 1 micron diameter in real time
- Tracks particles to the source
- Portable, battery operated
- Data logs to document results

Model 8525

Hand-held Condensation Particle Counter

Model 3007

A portable, battery-powered CPC that detects particles down to 10 nm!

Features and Benefits

- Battery-powered operation
- Programmable data-logging capabilities
- Particle size range of 0.01 to >1.0 µm
- Concentration range of 0 to 100,000 particles/cm³
- Built-in LCD display
- RS-232 serial data port

Model 3550 Nanoparticle Surface Area Monitor

AEROTRAK™ 9000 Nanoparticle Aerosol Monitor

These 10-1000nm Nanoparticle Surface Area Monitors measure the human lung-deposited surface area of particles (reported as $\mu m^2/cm^3$) corresponding to tracheobronchial (TB) and alveolar (A) regions of the lung. The instruments do not measure total surface area of particles suspended in air. Rather they measure the surface area of that fraction of material that is capable of depositing in the TB or A region of the human respiratory tract. Their operating principle is based on diffusion charging of sampled particles, followed by detection of the aerosol using an electrometer.

Electrostatic Classifiers and Differential Mobility Analyzers

In a particle sizing system, the Electrostatic Classifier separates particles by size for high-resolution measurements of particle size distribution. When used in Scanning Mobility Particle Sizer (SMPS) systems, monodisperse aerosol exiting the Electrostatic Classifier passes to a Condensation Particle Counter (CPC), which measures particle number concentration. By scanning quickly through the size range from 3 to 1000 nanometers, the SMPS measures the size distribution of the aerosol precisely.

Sample charged particles from the output of a Differential Mobility Analyzer (DMA), onto various sample substrates for analysis.

Exposure Assessment Strategies for Nano-Materials

Sampling Conditions:

- Botulinum Toxin Type B (Neurobloc™)
- Category 5 Potent Compound
- 1ng lethality – Invisible & Serious
- 10ng/ml analytical detection limit
- Undetectable by standard Gravimetric sampling methods
- Concentrations too low for traditional monitoring methods

The Sampling Strategy

Background, Background, Background

- Surface Sampling (floors, mobile equipment, fixtures, etc.)
- Long Term High Flow Gravimetric Sampling

Process Sampling

- Personal gravimetric sampling to meet regulatory requirements
- High Flow gravimetric sampling to capture real-time releases
- OPC, CPC continuous monitoring for releases

Post-Process Sampling

- Surface Sampling (floors, mobile equipment, fixtures, etc.)

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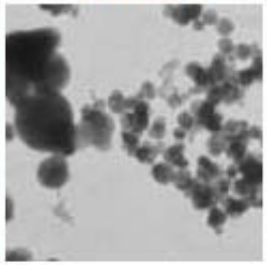
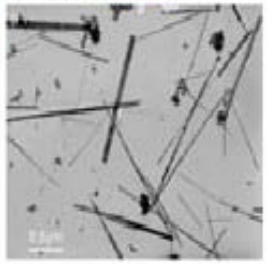
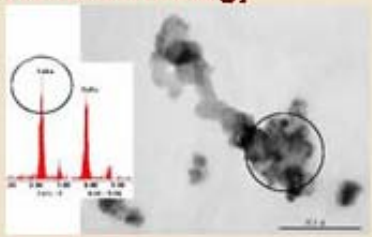


Pam Drake and Doug Scott at the NIOSH Spokane Research Lab are more...



Single-crystalline barium titanate nanowires are synthesized more...

Nanotechnology



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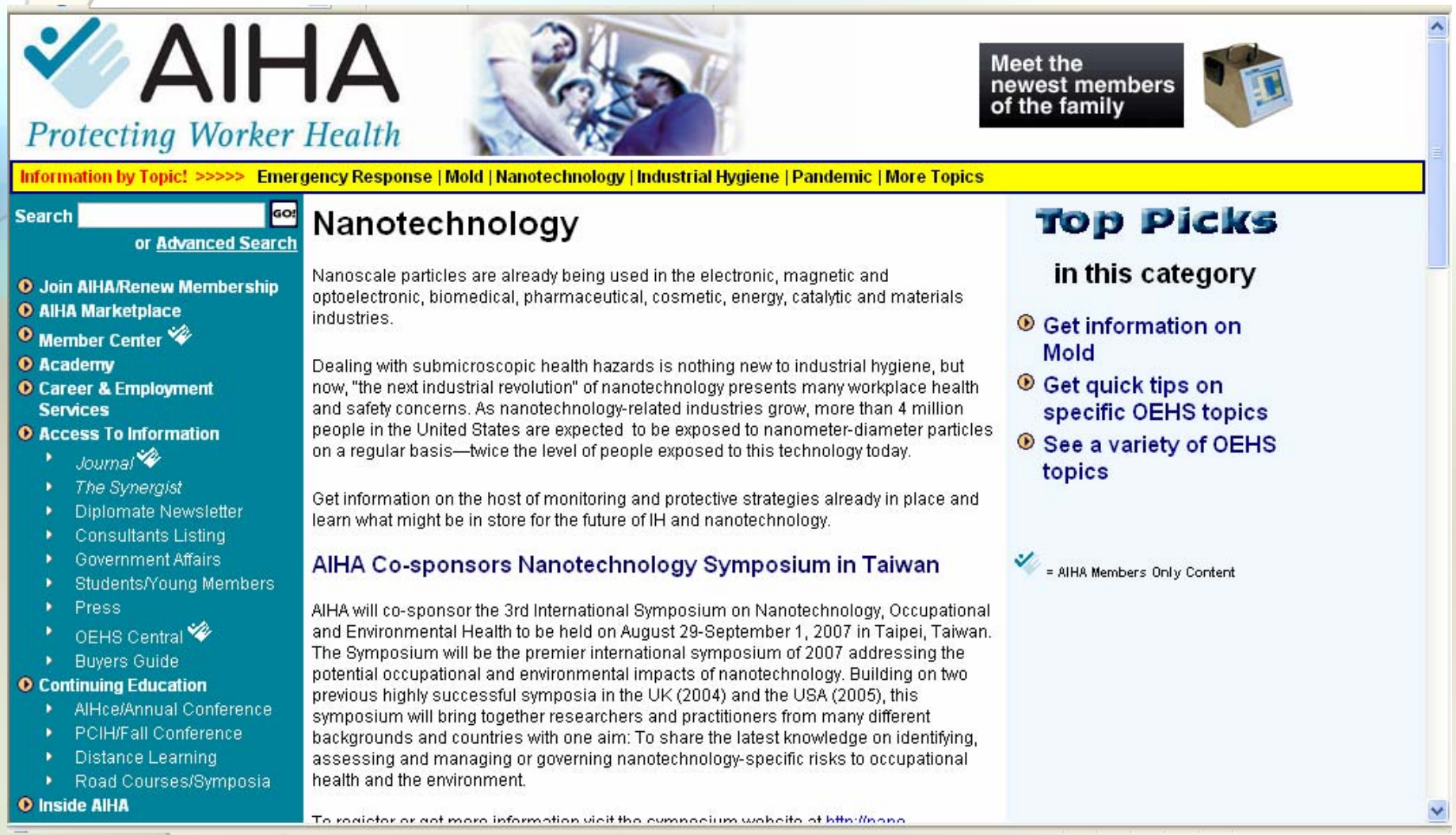
American Industrial Hygiene Association



Thank You For Participating!