

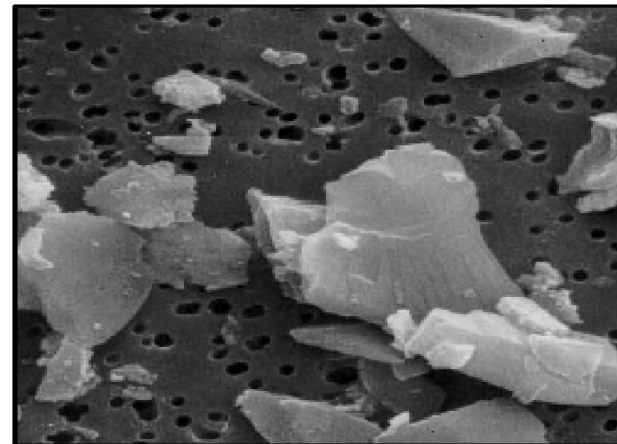
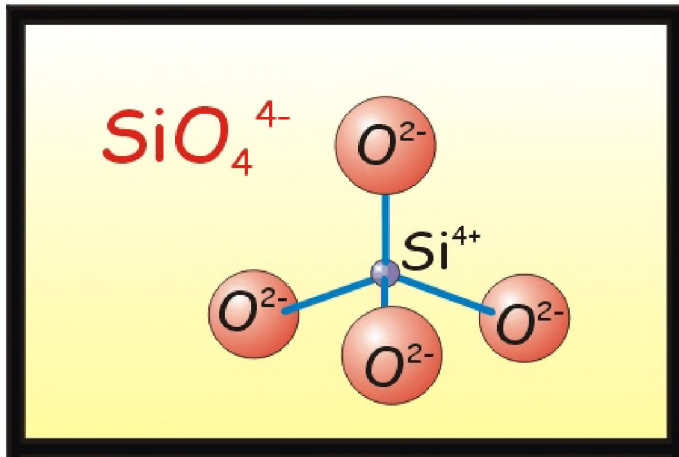
Crystalline Silica: Update on Toxicology, Regulation & Other Issues

September 30, 2005

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Crystalline Silica

- Silicon dioxide (SiO_2).
- Silica exists in two forms: amorphous & crystalline.
- Polymorphs: quartz, tridymite (rare) & cristobalite (rare).

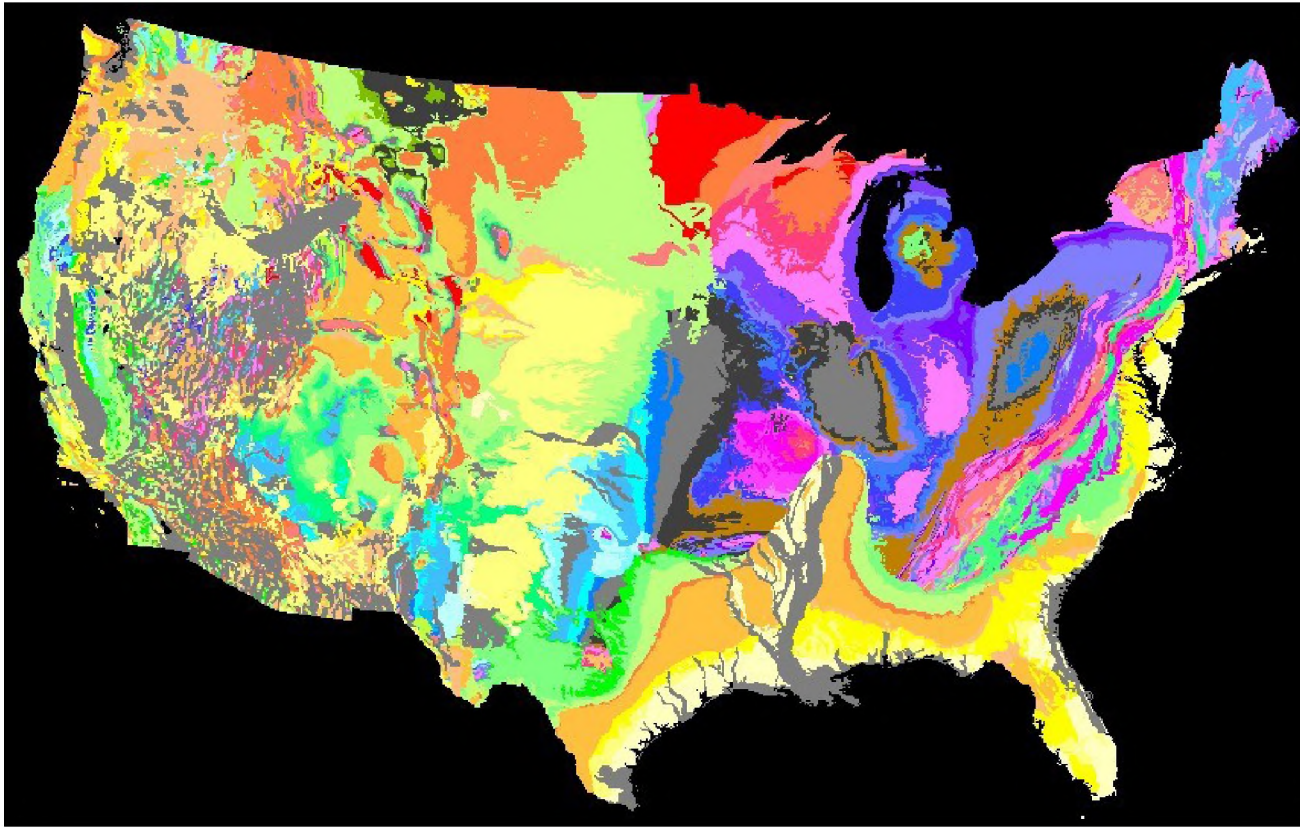


Key Polymorphs

- Alpha & beta quartz
- Cristobalite
- Tridymite
- Keatite
- Coesite
- Stishovite
- Moganite



Natural Occurrence of Crystalline Silica



Most common mineral in the Earth's crust

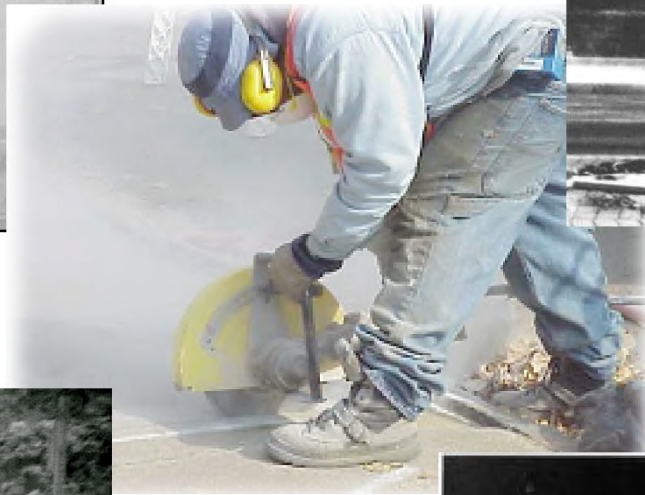
Crystalline Silica Occurrence

Sand	Sandstone	Siltstone
Gravel	Shale	Silt
Limestone*	Schist	Gneiss
Slate	Quartzite	Marble*
Granite	Obsidian	Rhyolite
Pumice	Conglomerates	Breccia

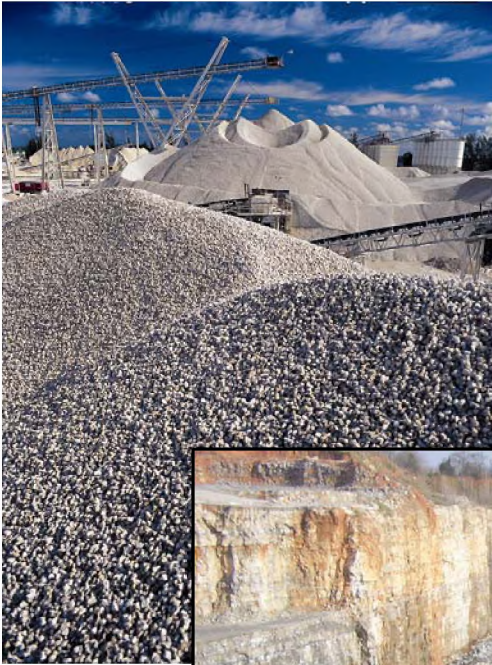
General Dust Sources in the U.S.

Sources of Fugitive Dust (PM ₁₀)	Percentage of Total Dust Generation
Unpaved roads	28%
Construction	23%
Agriculture	19%
Paved roads	15%
Wind erosion	5%
Mining/Quarrying	1%

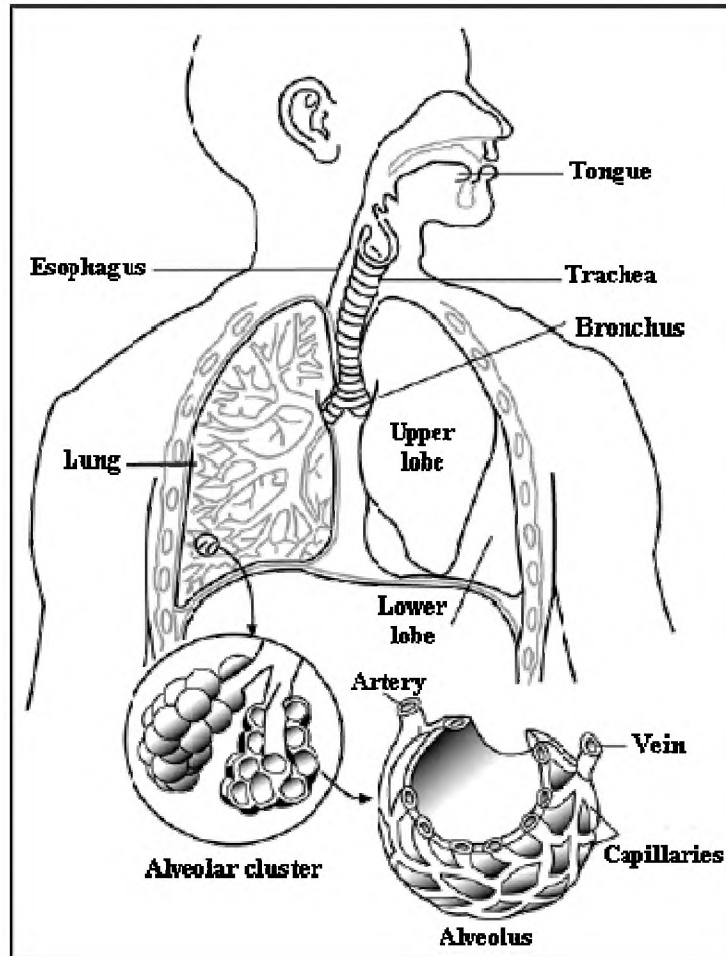
Crystalline Silica Exposures



Occurrence in Industry



Pulmonary Toxicology



- Particle size is critical.
- Peak dust inhalation occurs with particles having a diameter of 0.5 to 3 microns (μm).
- RCS is invisible to the human eye.
- Pulmonary clearance mechanisms: macrophages & the mucociliary escalator.

Silicosis Defined

- Progressive form of diffuse, nodular, interstitial, pulmonary fibrosis resulting from the inhalation of respirable crystalline silica (RCS).
- Symptoms: shortness of breath, reduced pulmonary function, chronic cough, may also involve fever & weight loss. Cardiac complications in advanced cases.
- Treatment: No specific treatment. Cessation of exposure. Smoking cessation if relevant. Antibiotics. Anti-tuberculosis drugs. Lung transplant is rarely attempted.

Crystalline Silica: Silicosis Defined

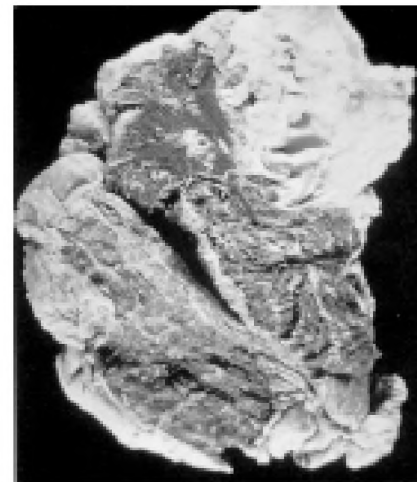
- Chronic (simple) silicosis: Most common form. Caused by exposure to respirable crystalline silica over periods that are generally longer than 20 years. Often more prominent in the upper lobes. Nodules are usually small (< 1 cm).
- Usually involves exposures to dusts containing less than 30% RCS concentrations.
- Silicosis is often confused with other dust disease miliary tuberculosis, siderosis, sarcoidosis, coal miner's pneumoconiosis, etc.

Crystalline Silica: Silicosis Defined

- Accelerated silicosis: Occurs after exposure to higher concentrations of RCS over shorter periods relative to the chronic form, e.g., 5 – 15 years. Inflammation, scarring and symptoms occur faster than in chronic silicosis.
- Acute silicosis: Results from short-term exposure to very high concentrations of RCS. Can occur after massive exposures of several weeks to less than two years.

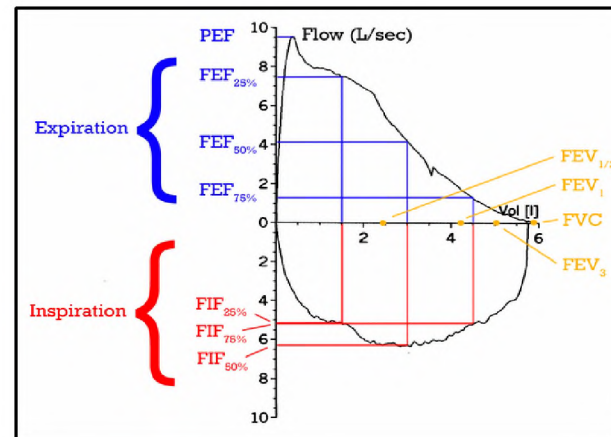
Medical Surveillance

- Occupational history.
- Medical examination.
- Chest x-ray.
- Pulmonary function test (PFT).
- Less common: baseline TB skin test.



Pulmonary Function Testing (PFT)

- PFT testing can only find defects consistent with silica exposure and that can be found in many other diseases.
- There is no PFT that can diagnose silicosis.
- More sophisticated testing available: diffusing capacity.



Chest X-Rays

- Routine chest x-rays may or may not find silicosis when an employee is beginning to have symptoms. Symptoms are non-specific (cough, shortness of breath, etc).
- Only when the typical findings of silicosis are present can the diagnosis be comfortably made.
- Chest x-rays, however, can identify employees who have early disease, and allow for intervention.
- CT-scans may be useful.
- Silicosis may progress after removal from exposure.

Normal vs. Silicotic Lung



Normal



Advanced chronic silicosis

Toxicology of Crystalline Silica

- Particle surface characteristics affect fibrogenic activity, e.g., freshly cleaved particle potency.
- Quartz is not mutagenic, i.e., negative Ames test.
- Reproductive & developmental effects unknown.
- Mechanisms of action: cellular inflammation, nodule formation, suppressed immune function, alveolar proteinosis.
- Carcinogenicity: direct genotoxic effect for quartz not established.

Autoimmune Disease

- Immune activation by occupational exposure to RCS may be linked to scleroderma, rheumatoid arthritis, polyarthritis, mixed connective tissue disease, lupus erythematosus, polymyositis, fibritosis & glomerulonephritis.
- Some research suggests that $\approx 10\%$ of silicotics will develop clinically detectable autoimmune disease or "abnormal immune tests".
- The cellular mechanism that leads from RCS exposure to these autoimmune diseases is not known and has not been clinically substantiated.

Crystalline Silica Epidemiology

- Lung cancer standard mortality ratios (SMR's) for crystalline silica have slight but consistent elevations.
- The relationship between silica and lung cancer in the absence of silicosis is unclear.
- Some studies have verified the exposure response relationship between silicosis and tuberculosis, etc.
- Confounding factors, e.g., tobacco, poorly controlled or assessed in most studies.

Criteria for Carcinogenicity

- Strength of association (high relative risk)
- Dose response relationship
- ✓ Consistency of findings
- ✓ Temporal cogency (exposure before disease)
- ✓ Biological plausibility & experimental evidence
- Control of confounding & bias
- Specificity

Carcinogenicity Designations

- Suspect lung carcinogen:
 - OSHA: Suspected
 - MSHA: No designation
 - ACGIH: A2 (Suspected)
 - IARC: 1 (Confirmed in humans)
 - NIOSH: Potential (human)

Historical Exposure Assessment

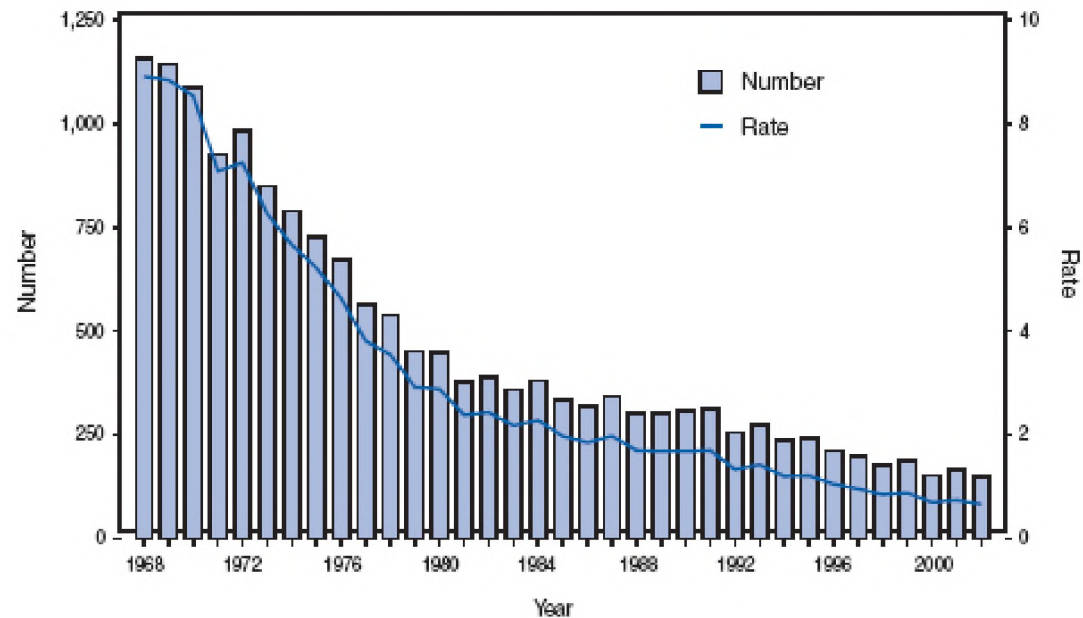
- Different sampling methods used: konimeter, impinger, gravimetric without size selection, gravimetric analysis with cyclones, x-ray diffraction.
- Conversion factors have been proposed, but correlation between dust particle number and size is difficult.
- Until recently, different criteria were used to define the respirable fraction of RCS, e.g., ISO, ACGIH.
- Current consensus: 50% cut point for particles of 4 μm aerodynamic diameter.

U.S. Silicosis Mortality 1968 - 2002

Medscape®

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FIGURE 1. Number of silicosis deaths and age-adjusted mortality rate*, by year — National Occupational Respiratory Mortality System, United States, 1968–2002



* Per million persons aged ≥ 15 years.

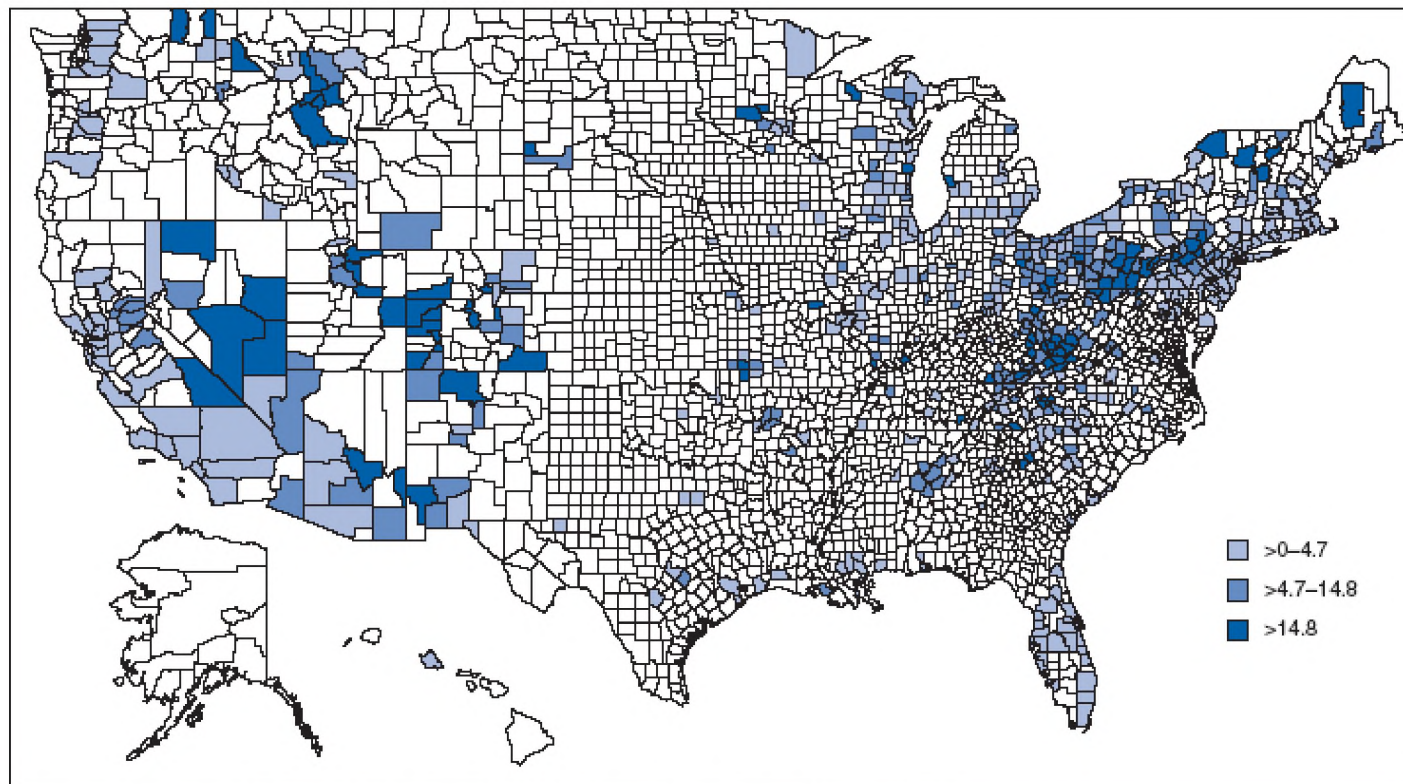
Source: MMWR © 2005 Centers for Disease Control and Prevention (CDC)

Distribution of Silicosis Deaths

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FIGURE 2. Geographic distribution of age-adjusted silicosis mortality rates*, by county — National Occupational Respiratory Mortality System, United States, 1968–2002



* Per million persons aged ≥ 15 years. Rates were not calculated for counties with fewer than five deaths.

Source: MMWR © 2005 Centers for Disease Control and Prevention (CDC)

Exposure Limits & Guidelines

Agency	Country	Limit (mg/m ³)	Averaging
OSHA	U.S.	0.1*	8-hour TWA
MSHA	U.S.	0.1	8-hour TWA
NIOSH	U.S.	0.05	8-hour TWA
ACGIH	U.S.	0.05	8-hour TWA

*10 mg/m³/(% SiO₂+ 2)

Proposed Regulation: OSHA

- Published a draft proposed standard 10/03.
- SBREFA review subsequently conducted.
- General industry, maritime & construction versions.
- Reduction in PEL, e.g., construction:

PEL

0.1 mg/m³

0.075 mg/m³

0.05 mg/m³

Action Level

0.05 mg/m³

0.04 mg/m³

No separate AL

Proposed Regulation: OSHA

- Engineering & work practice: primary controls
- Employee rotation unacceptable (carcinogen)
- Exposure assessment & regulated areas
- Two options for sampling:
 - (1) If PEL = 0.05 mg/m³ trigger for quarterly sampling
 - (1) If PEL > 0.075 mg/m³ semiannual sampling
 - (2) Periodic enough to ensure proper controls
- Designated competent persons
- Respiratory protection & other PPE.
- Housekeeping & hygiene
- Medical surveillance, education & training

Proposed California OSHA PEL

- Air Contaminants Advisory Committee (ACAC).
- Recommended reduction in PEL to 0.01 mg/m³.
- Applies to all forms of respirable crystalline silica.
- Based on risk assessment work from S. Africa.
- Recommendation forwarded to CDOSH (OSHA).

ACGIH TLV NIC 2004

- Would reduce the TLV from 0.05 to 0.025 mg/m³.
- Applicable to quartz and cristobalite.
- "Intended to prevent pulmonary fibrosis that may be a risk factor for lung cancer."
- A2 suspect carcinogen designation.
- "Evidence that levels of silica exposure leading to fibrosis are required for increase risk for lung cancer."
- ACGIH is currently being sued over its TLV process.

ASTM E1132-99a

- "Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica."
- Voluntary consensus standard.
- OSHA & MSHA required to be considered. Judicial notice.
- Comprehensive control structure:
 - Exposure assessment
 - Engineering, administrative & PPE controls
 - Hygiene facilities
 - Respiratory medical surveillance & medical protection
 - Worker training & education
 - Warning signs & labels
- Does not include a recommended exposure standard.

Current Sampling Methodologies

- NIOSH 7500: Pre-tarred PVC filter w/ 10 mm cyclone with x-ray diffraction. Most widely used and recognized. (NIOSH 7500 = OSHA 142). LOD: 0.005 mg.
- NIOSH 7601: Visible absorption spectrophotometry. Does not differentiate between quartz, cristobalite and tridymite.
- NIOSH 7602: Infrared spectrophotometry. Can distinguish between quartz and cristobalite, but not tridymite. LOD: 0.005 mg.
- Watch for interferences, e.g., silicates, feldspars, micas, potash, graphite, etc.

Air Sampling Challenges

- Are the existing crystalline silica standards consistent?
- Recent research looked at crystal morphology, surface area, particle size distribution, elemental composition for <4.5 μm Silver Bond B, <10 μm Silver Bond B, NIST 1878, NIST 1878a.
- Used a variety of laboratories and reference methods.
- Differences were significant. Publication to follow.

Air Sampling Challenges

- Airborne concentrations of RCS below 0.05 mg/m³ collected via 1.7 lpm cyclone and analyzed by x-ray diffraction or IR offer insufficient precision and accuracy.
- NIOSH: "...current methods do not meet appropriate accuracy criterion to quantify exposures at concentrations below 0.05 mg/m³."
- Issues: Dust loads below 40 µg, limits of detection, overall RSD as measured by NIOSH PAT program.

Litigation: Recent Developments

- Silica the second wave following asbestos litigation.
- 2005: Judge Janis Graham presiding over multidistrict litigation in Corpus Christi, Texas.
- Sent 90 cases representing 10,000 plaintiffs back to their states of origin.
- Called into question plaintiff's evidence of injury.
- Expected to have wide-ranging consequences on mass tort litigation involving silica.
- Adding momentum to state legislative efforts to require prima facie evidence of injury to justify litigation.

Tort Reform Legislation

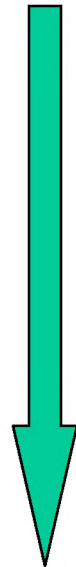
Florida

- "Asbestos & Silica Compensation Fairness Act of 2005"
- Requires plaintiffs to make prima facie showing of physical impairment based on specific medical criteria for nonmalignant asbestos, asbestos-related lung cancer claim and certain silica-related disease.
- Two disease rule: claims arising from a nonmalignant condition and cancer are separate actions.
- No punitive damages awarded for silica-related claims.
- No damages for "fear of cancer" claims.

Dust Exposure Controls

- Material substitution (e.g., sandblasting)
- Isolation (enclosures)
- Process modification
- Ventilation (general vs local)
- Suppression (water)
- Administrative procedures (time, rotation)
- Personal protective equipment (respirators)

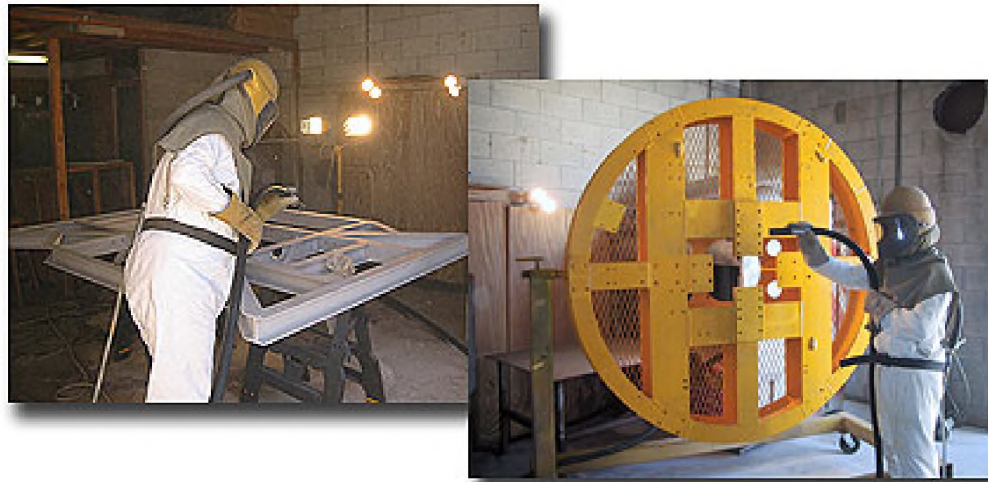
Most
desirable



Least
desirable

Special Case: Sandblasting

- Must use silica substitute, e.g., garnet.
- Requires air-line respirator.



Process Control/Design



Mobile & Fixed Equipment Enclosures



Road Dust Suppression

Water trucks



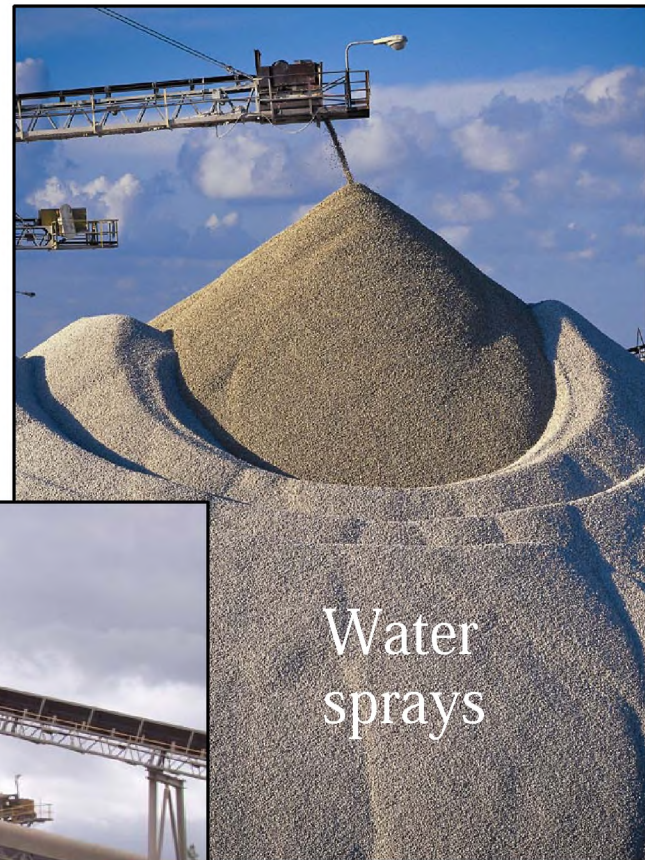
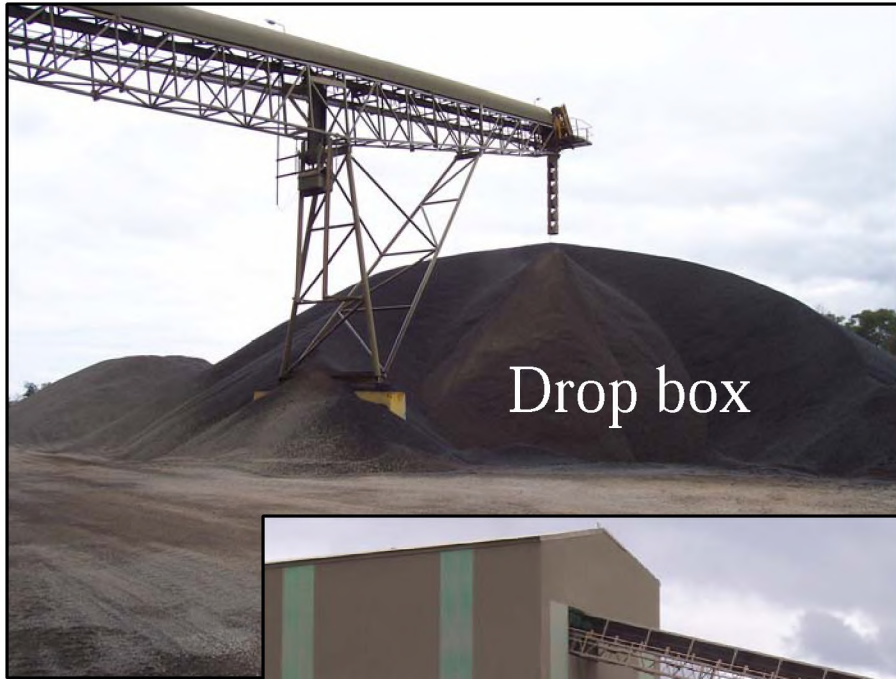
Surfactants



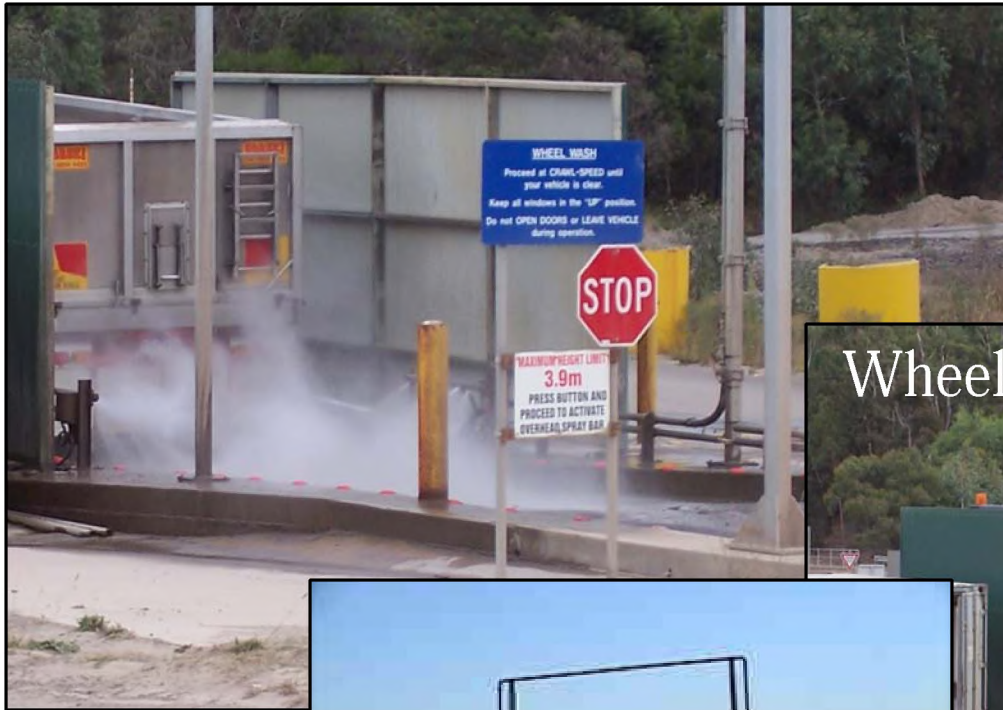
Surfaced mine roads



Conveyor Drop Points



Truck-borne Dust



Wheel wash station



Truck wash

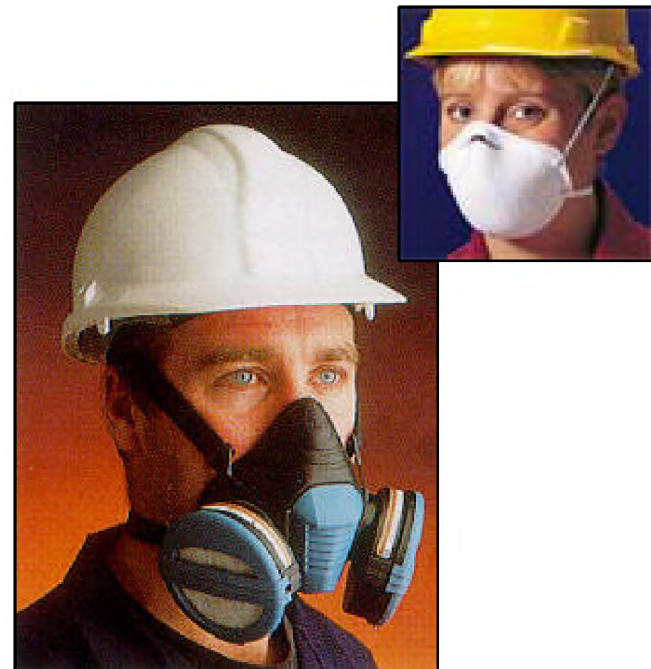


Vacuuming & Wet Sweeping



Respiratory Protection

- Respirator type based on silica air concentration.
- Air-purifying vs air-supplying.
- Requires medical qualification & fit-testing.



A View to the Future

- Increasing regulation at the state & federal level.
- On-going & unresolved debate over dose response.
- Increasing focus on ambient issues.
- Watch for "mixed dust pneumoconiosis."
- Improved screening & diagnosis techniques.
- Improved epidemiology.

Thank You for Your Attention

- Comments, questions, additions?