

# MSHA's Draft Quantitative Risk Assessment (QRA) of RCMD:

## Current flaws and possible fixes

Comments of  
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On behalf of  
The National Mining Association

2-15-11

*AB64-COMM-74-12*

# Outline

- Hazard identification
- Exposure assessment
- Exposure-response relationship
- Risk characterization
- Uncertainty characterization
- Conclusions and recommendations

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- Hazard identification → omitted
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- Exposure assessment → incorrect/irrelevant
- Exposure-response relationship → omitted
- Risk characterization → incorrect
- Uncertainty characterization → omitted
- Conclusions and recommendations
  - Risk if present standards enforced: not quantified
  - Probability that tightening standard will *not* decrease risk: Not quantified

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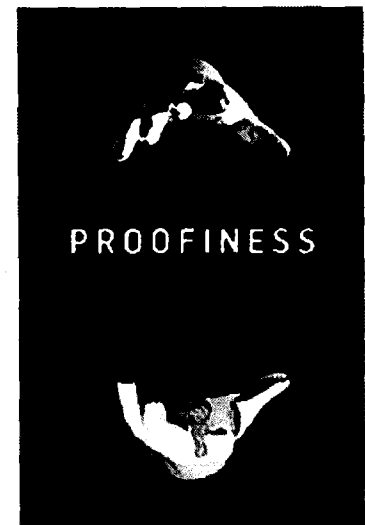
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- Conclusions and recommendations
  - Effects of single-shift sampling on risks, exposure threshold exceedance frequencies, enforcement error rates: not quantified

# Hazard identification

- Do *current levels* of RCMD create an excess risk of adverse human health effects?
  - What is the evidence, pro and con?
    - Toxicological, clinical, epidemiological
  - What is the weight of evidence?

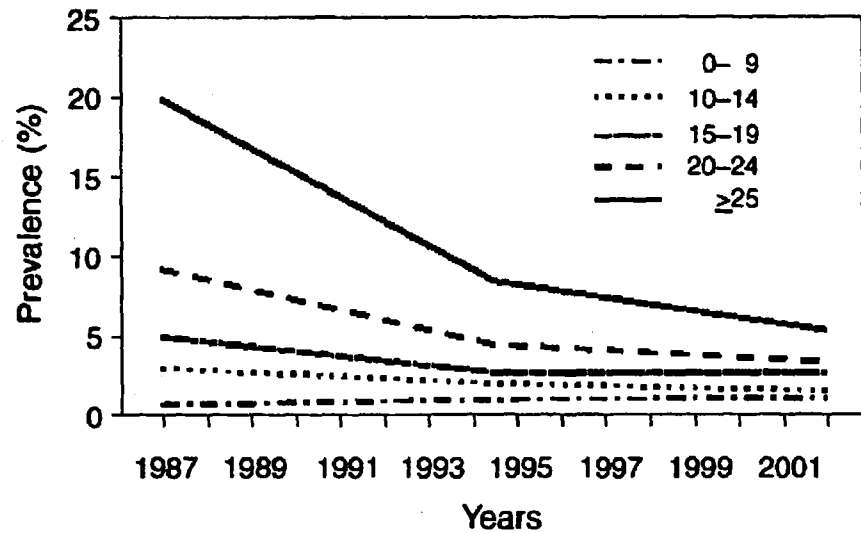
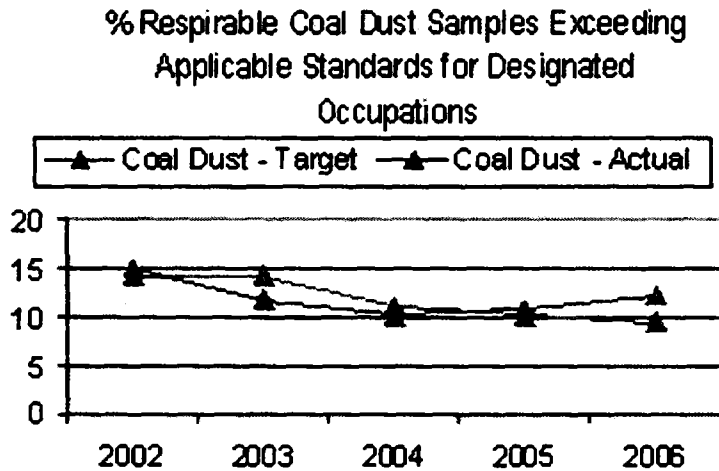
# Hazard identification

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  - What is the evidence, pro and con?
    - Toxicological, clinical, epidemiological
  - What is the weight of evidence?
- MSHA's QRA: *Assume yes*
- Supporting rationale/evidence/critical discussion: None
- QRA skips hazard identification
  - Proofiness: “The art of using bogus mathematical arguments to prove something that you know in your heart is true — even when it's not”



# Regression of trends $\neq$ causation

**FIGURE 2. Trends in coal workers' pneumoconiosis prevalence by tenure among examinees employed at underground coal mines — U.S. National Coal Workers' X-Ray Surveillance Program, 1987–2002**



Exposure down

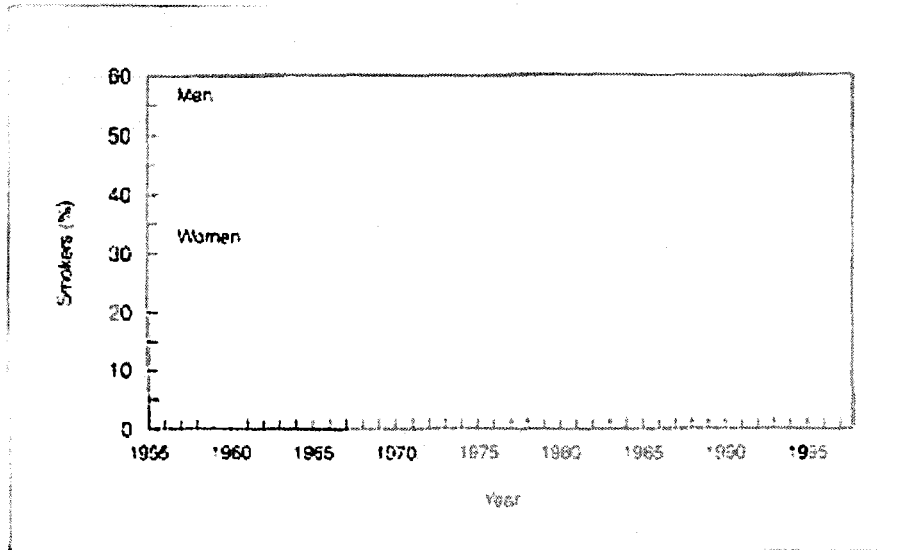
? → ?

Disease down

Proofiness: Attribute decline in lung diseases to tighter RCMD standards



# Regression of trends $\neq$ causation



**Figure 2: Trends in Cigarette Smoking Among Persons > 18 Years Old, by Gender—United States, 1955-1997**—Before 1992, current smokers were defined as persons who reported having smoked  $\geq 100$  cigarettes and who currently smoked. Since 1992, current smokers have been defined as persons who reported having smoked  $\geq 100$  cigarettes during their lifetime and who reported smoking every day or some days. Source of data: 1955 Current Population Survey, National Interview Survey, 1965-1997.

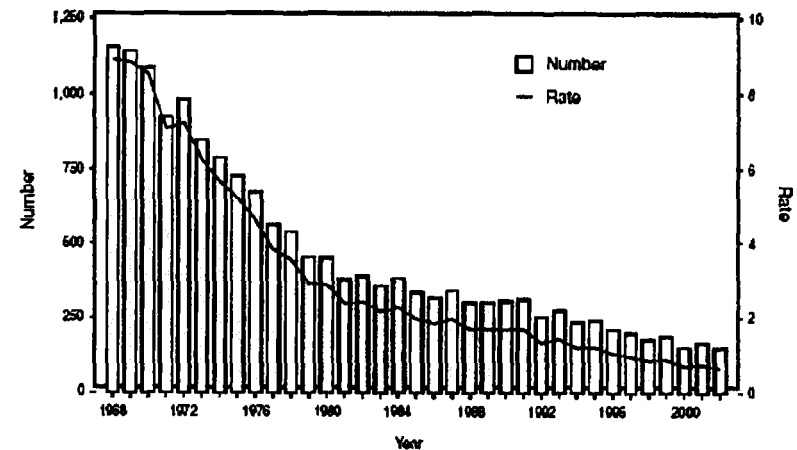
Smoking down

?  $\rightarrow$  ?

Disease down

Proofiness: Attribute decline in lung diseases to tighter RCMD standards

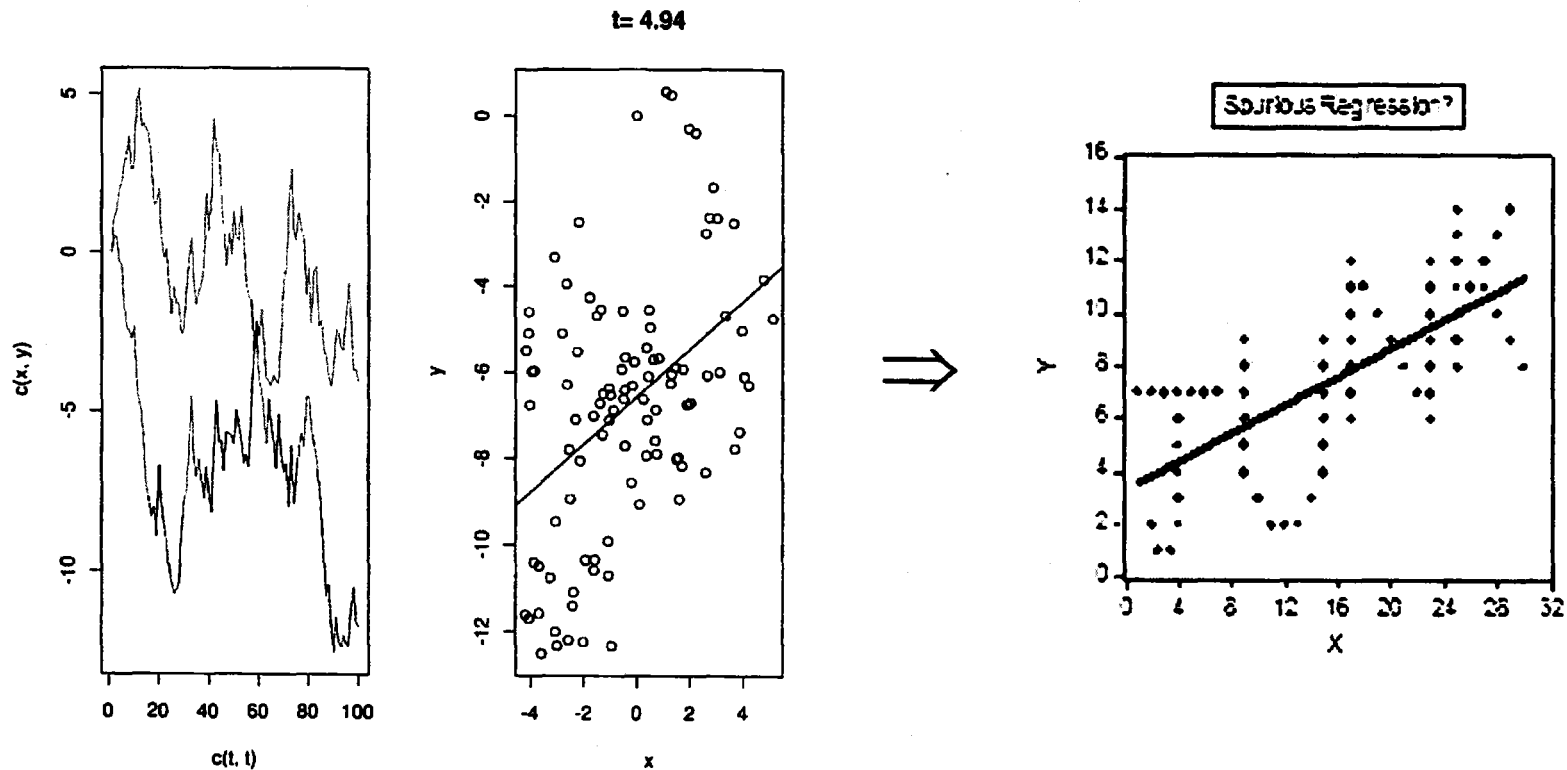
**FIGURE 1. Number of silicosis deaths and age-adjusted mortality rate\*, by year — National Occupational Respiratory Mortality System, United States, 1968-2002**



\* Per million persons aged  $\geq 15$  years.

# Regression: Wrong tool for the job

- Regressing *trend variables* against each other makes even independent variables (random walks) look “significantly correlated”!



# Hazard identification

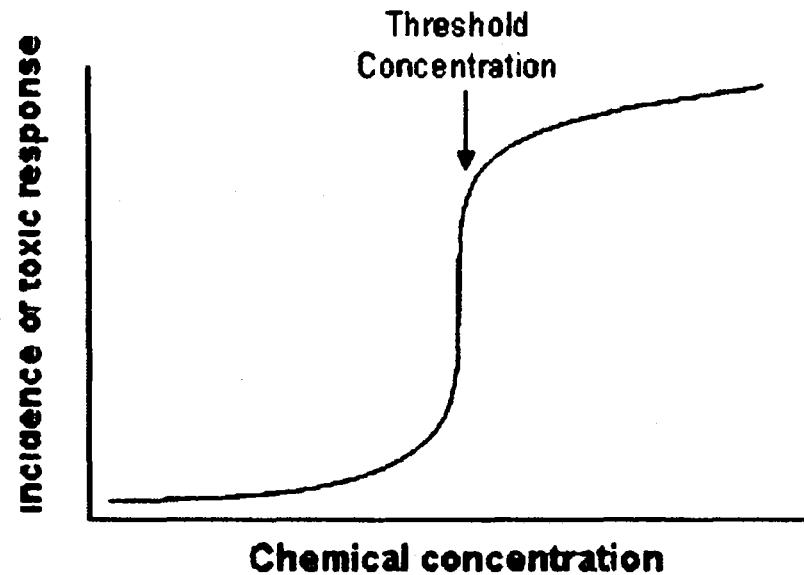
- What would a sound hazard identification show?
- Weight of evidence is that inflammation-mediated lung diseases caused by poorly soluble particulates have *exposure-response thresholds*.
  - E.g., “Tissues and cells respond to mild oxidative stress by increasing antioxidant defenses. However, high levels of ROS/RNS may overwhelm antioxidant defenses, resulting in oxidant-mediated injury or cell death” (Comhair and Erzerum 2002)

# Hazard identification

- What would a sound hazard identification show?
- Weight of evidence is that inflammation-mediated lung diseases caused by poorly soluble particulates have *exposure-response thresholds*.
- A useful risk assessment should address how current and proposed future standards affect exposures compared to such exposure-response thresholds (or steep nonlinearities).
  - Would tighter standards create incremental health benefits, beyond those from enforcing current standards?
  - MSHA's QRA does not address thresholds → No answer

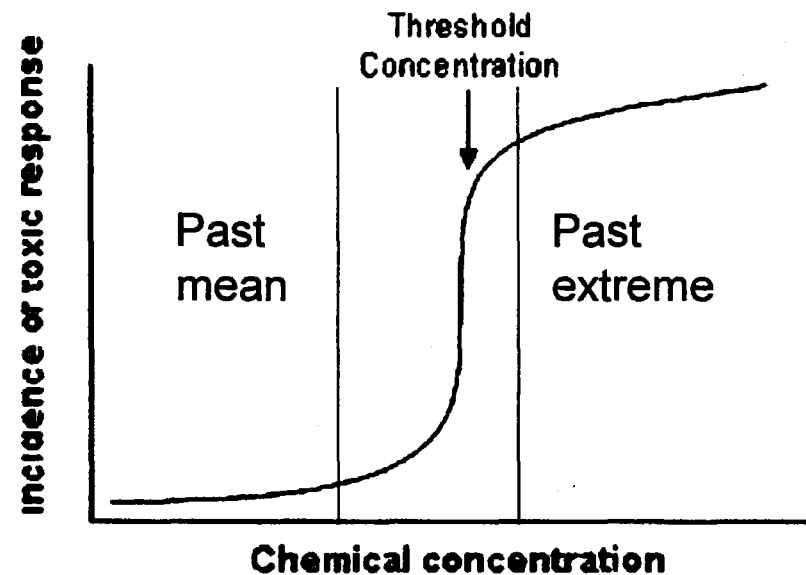
# Exposure assessment

- *Key question: Do currently permitted levels of exposure increase risk of harm?*



# Exposure assessment

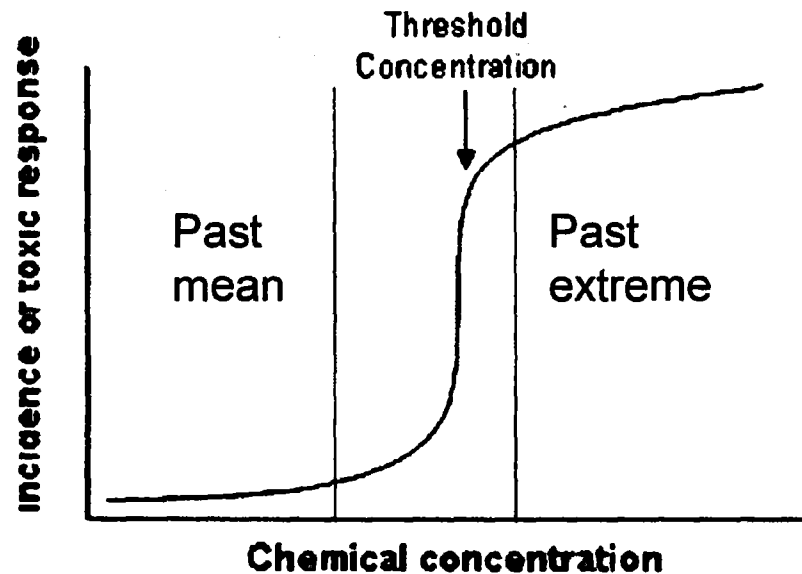
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Risks attributed to past *mean* cumulative exposures may have been caused by much higher *extreme* cumulative exposures.

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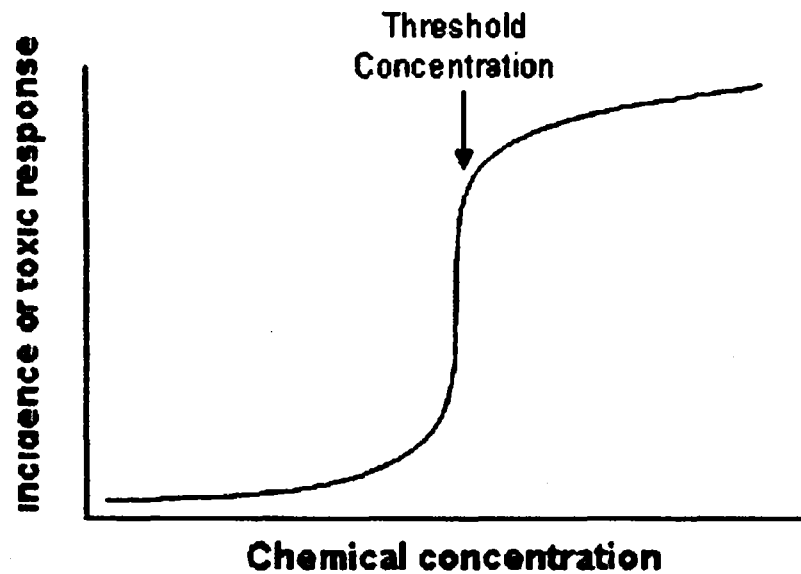
# Exposure assessment

- *Key question: Do currently permitted levels of exposure increase risk of harm?*
- QRA does not actually address this question
  - QRA estimates future cumulative mean exposures, but not past variances or response thresholds
    - Cumulative mean exposures have no known relevance to risk
  - QRA simply assumes that the answer is yes.
    - Attributes harm to RCMD, without showing any causation
- Past harm may have resulted from higher-than-currently-permitted exposures
  - Such exposures have not been estimated



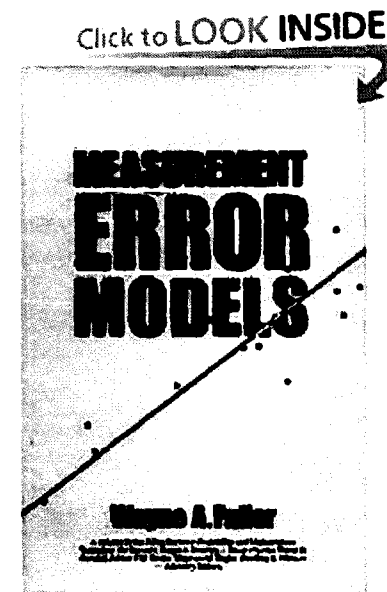
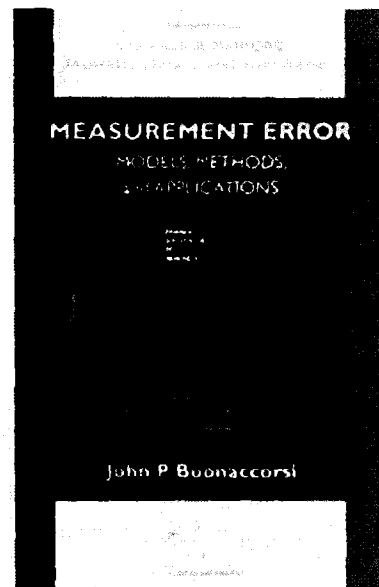
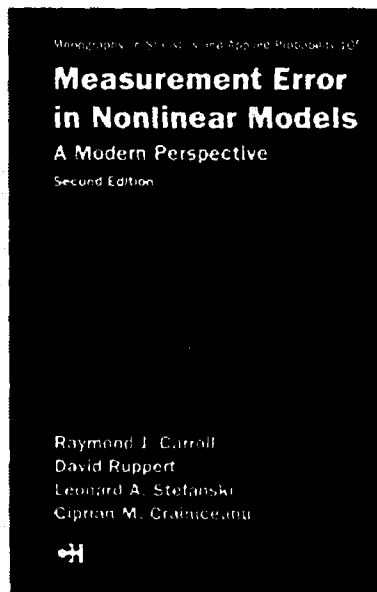
# Exposure assessment

- Estimates of mean cumulative exposures are inappropriate for risk assessment
  - Proposed measures that decrease exposure mean but increase variance could still increase risk
  - Need to quantify *upper tail* of exposure distribution



# Exposure assessment

- MSHA inflates its exposure estimates
  - One-way “adjustments”
  - Why not two-way?
  - Neglects to counter-adjust exposure-response estimates
  - Ignores measurement errors in exposure estimates → biases

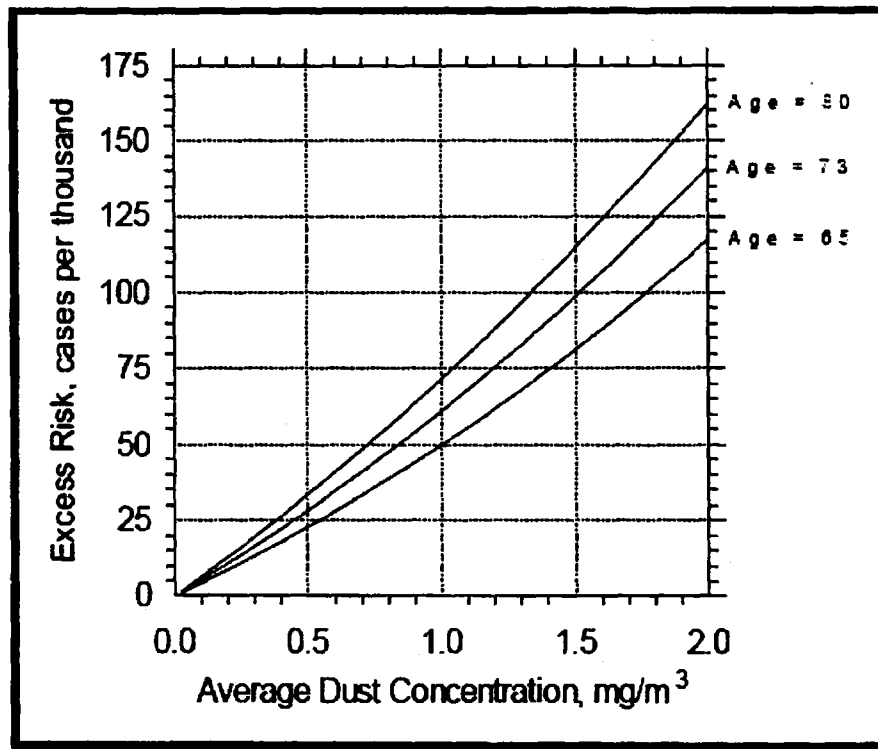


# Exposure-response modeling

- *Purpose:* Quantify the probability that each exposure level causes illness
- *Status:* Not done.
  - QRA uses statistical (descriptive) regression equations, not causal (predictive) models, to attribute risk to exposure
  - No exposure-response relation established
  - Exposure estimation uncertainty not accounted for
    - Treats estimated exposures as true exposures
    - Creates potentially large, unquantified biases

# Exposure-response modeling

- This is *not* an exposure-response relation!



Plotting predicted hypothetical responses against hypothetical mean exposures does not create (or provide evidence of) a valid exposure-response relation.

Figure 14. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and excess risk of developing emphysema severity corresponding to FEV<sub>1</sub> < 65% of predicted normal value, for white, never-smoking U.S. coal miners at ages 65, 73, and 80 years.

# Attribution vs. Causation

- The risk “*attributable*” to a source (in epidemiology) is not the risk *caused* by it (and is often much larger)
  - The QRA treats them as the same thing
  - Attributes a relative risk of 4.4 to coal even when exposure = 0
    - Use with caution (MSHA QRA) vs. Don’t use!
  - Assigns some risks from smoking to RCMD
  - Attributable risk can be positive even when exposure does no harm

# Risk characterization

- *Purpose:* Show the frequency and severity of health effects with and without proposed rule.
- *Status:* MSHA has not performed a risk characterization for effects of proposed action
  - Estimates are provided only for hypothetical exposure scenarios and obsolete conditions (smoking, etc.).
  - No causal modeling → No accurate or validated predictions

# Risk characterization: Bogus claims

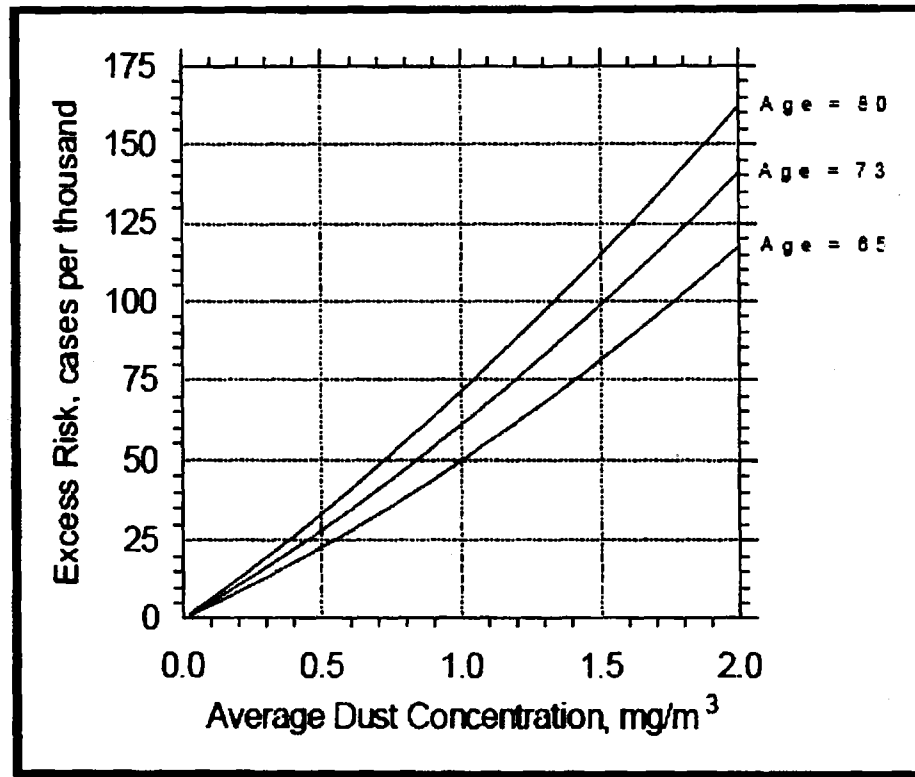


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Thresholds?

Confounding?

- Smoking
- SES

High exposures?  
(Right tail)

Variance?

Uncertainties?

- Confidence?
- Model?

Proofiness: Hypothetical statistical relation presented as real causal relation.

# Risk characterization

- *Recommendations:*
  - Extend risk characterization to address realistic frequency distributions of exposure histories and smoking histories.
  - Remove effects of confounders, estimation errors, etc.
  - Use validated causal models instead of attribution



# Uncertainty characterization

- MSHA's QRA omits this step.

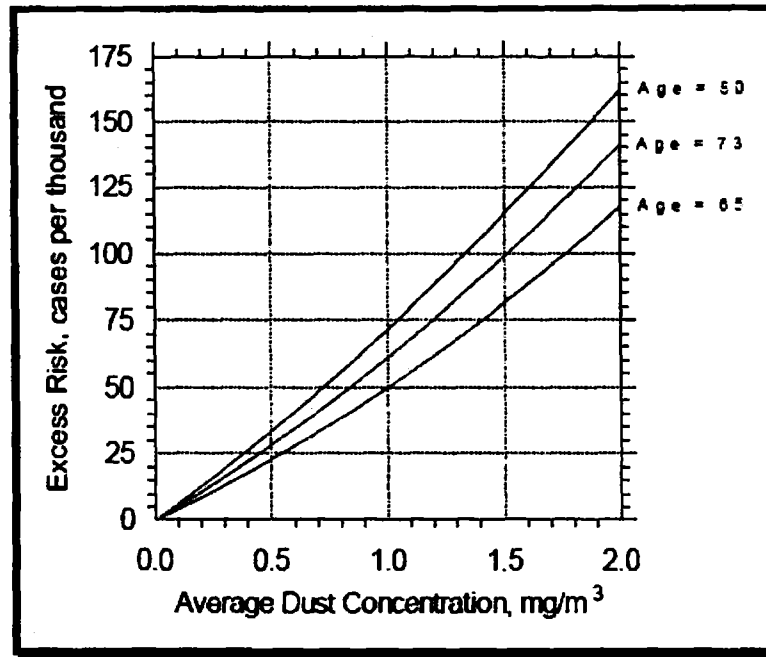


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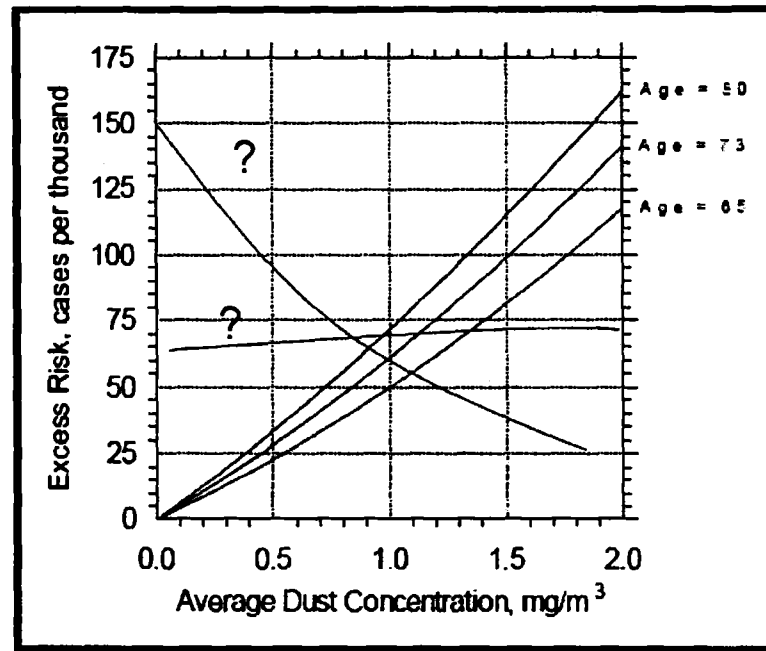


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What is probability that the proposed measure would...

- Increase risk?
- Leave it unchanged?

MSHA's QRA does not show policy makers *any* uncertainties

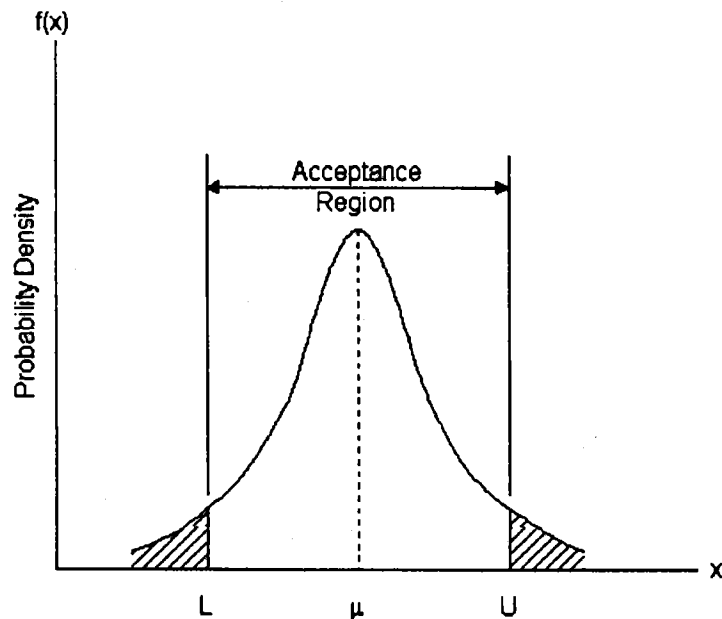
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# Single-Shift Sampling: A bad idea

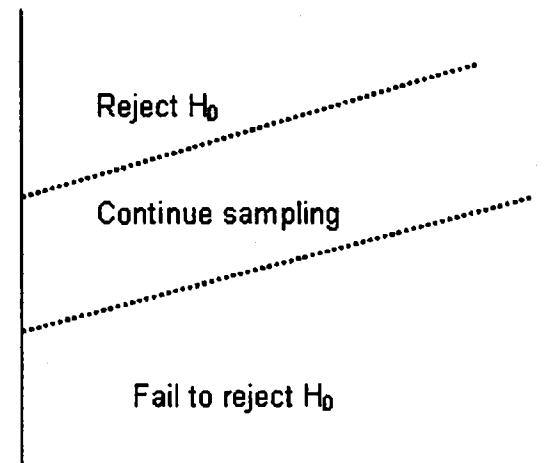
- QRA does not address *sample variance* around estimated means
- QRA provides no basis for risk-informed decisions.
  - Type 1 vs. type 2 errors?
  - Frequency of exceeding threshold?
  - Sampling and decision rules not designed to minimize errors or total cost/harm
- Basing enforcement criteria on less data is undesirable

# Single-Shift Sampling: A bad idea

- *Recommendation:* Replace proposed single-shift sampling with well-designed *statistical sampling and decision rules* that reduce errors, rather than increasing them.



Sequential Probability Ratio Test



# Summary

- Hazard identification → omitted
- Exposure assessment → incorrect/irrelevant
- Exposure-response relationship → omitted
- Risk characterization → incorrect
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# Conclusions and Recommendations

- Correct or withdraw misleading claims and language. MSHA's QRA...
  - Does not obtain unbiased estimates
  - Does not assess risk from current exposures
  - Does not assess reduction in risk from reduction in exposure (causal effect)
- Add missing hazard identification section
- Add missing exposure-response modeling
- Add missing uncertainty characterization

**Thanks!**

# Additional Materials



# MSHA's QRA biases exposure and risk estimates upward

- Excludes post-abatement measurements
- “Adjusts” exposures upward, but not downward
  - Takes higher of two estimates
  - Creates an upward bias, even when current estimates are unbiased
- Does not counter-adjust the estimated exposure-response relations to reflect adjustments on exposure inputs
  - Creates upward bias in risk estimates

# MSHA QRA's models are not validated for use in QRA

- Models produce conflicting predictions, so not all of them can be correct
- Models attribute risks to coal even when exposure is zero, so not good causal models
- Models use attribution formulas for \*single\* factors, but multiple factors (age, smoking, exposure, perhaps income and location) contribute to risk.
- Models do not explain historical data; not validated
  - Historical declines in exposure, changes in smoking, recent increases in risk