



Comments on Quantitative Risk Assessment for Coal Dust Rule

Richard Reiss, ScD and Ken Bogen, DrPH

Disclaimer

- **Drs. Reiss and Bogen are with Exponent and were asked to independently review the quantitative risk analysis (QRA) for proposed MSHA Rule**
- **Exponent received funding from Murray Energy Corporation to conduct this independent review**
- **The opinions and comments presented herein reflect the independent scientific assessment of Drs. Reiss and Bogen**

Qualifications

- **Dr. Reiss is a Principal Scientist at Exponent and an expert in risk assessment and air quality**
 - Editorial Board, *Risk Analysis: An International Journal*
 - Fellow and Past-President, Society for Risk Analysis
- **Dr. Bogen is a Managing Scientist at Exponent and an expert in risk assessment and biomathematics**
 - Member of NRC committee *Science and Judgment in Risk Assessment*
 - Author of RiskQ software

Introduction

- **The QRA provides the basis for estimating the reduced incidence of respiratory disease associated with the proposed rule. The parts include:**
 - Estimation of the reduced level of coal dust for compliance with rule
 - Based on an analysis of 2004-2008 MSHA inspector and operator-collected data
 - Estimation of the reduced incidence of respiratory disease associated with the dust level reduction
 - Based on published epidemiologic studies for pneumoconiosis, emphysema, and mortality

Overall Impression

- **The QRA represents a significant work effort using advanced mathematical tools; however, the unnecessary complexity of the assessment makes it less transparent**
- **Health benefits are based on an irrelevant population comparison**
- **The QRA may significantly underestimate the coal dust reduction required to meet the exposure limit of the standard**
- **QRA would be strengthened by inclusion of quantitative uncertainty analysis**

Basis for Health Benefits Assessment

Workers exposed to
2 mg/m³ standard
for career

versus

Workers exposed to
1 mg/m³ standard
for career

- No current worker is exposed to 2 mg/m³ standard for their entire working lifetime
- Full estimated benefits will not be realized for 45 years
- Acknowledgment in prior rulemaking; should be acknowledged here

Underestimation of Required Coal Dust Concentration Reductions

Changes Affecting Dust Concentrations	Accounting in QRA
Level from 2 mg/m ³ to 1 mg/m ³	Yes
5-shift average to 1-shift exceedance	Partially, but underestimates
Number of required samples	No

Methodology to Evaluate RCMD Reductions Needed to Comply with Proposed Standard

- **Statistically simulate RCMDs from the distribution of inspector data**
 - Use Longwall Operators as an example (highest exposed)
 - Assume mixed lognormal distributions (excellent fit)
- Draw sample sizes in relation to expected number of samples to be collected under current and proposed standard
- Simulate 5-shift average and single shifts
- Estimate reduction necessary to attain high rate of compliance
 - Assume shape of RCMD distribution is unchanged as concentrations are reduced

Complying with Proposed Standard will be Nearly Impossible—Longwall Operator

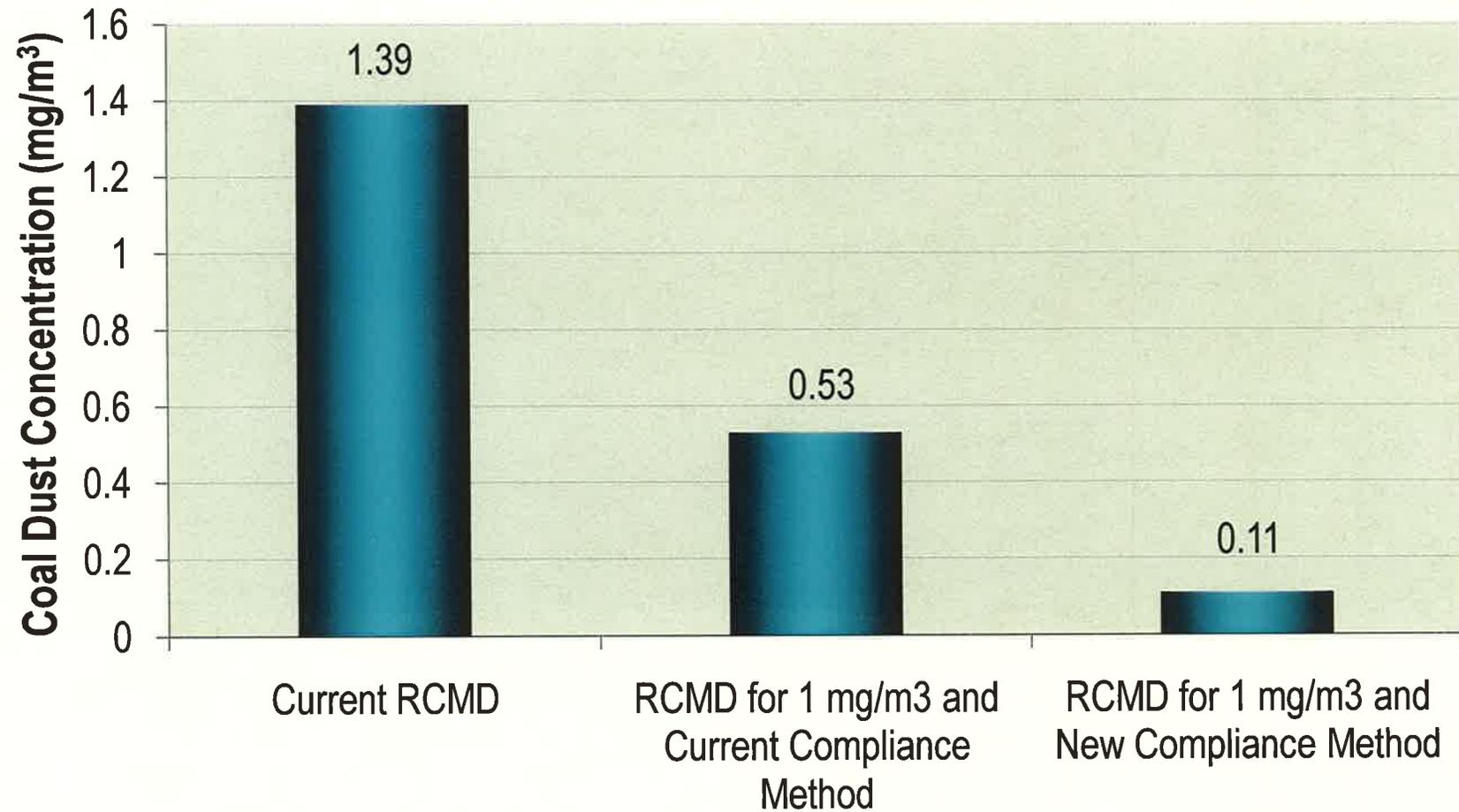
RCMD for Standard (mg/m ³)	Compliance Method	Annual Non-Compliance Rate at Current Levels	% RCMD Reduction for 99% Annual Compliance	Mean RCMD Concentration for 99% Annual Compliance (mg/m ³)
1 (proposed)	Current	100%	62%	0.53
2 (current)	Proposed	100%	84%	0.22
1 (proposed)	Proposed	100%	92%	0.11

Compliance Method:

Current: Maximum of 5-shift average per 2-month period

Proposed: Maximum of 3 shift/day and 120 days/quarter = 360 samples/quarter

Mean Levels Needed to Comply with Proposed Standard



Longwall Operator – Concentrations Needed for 95% Compliance

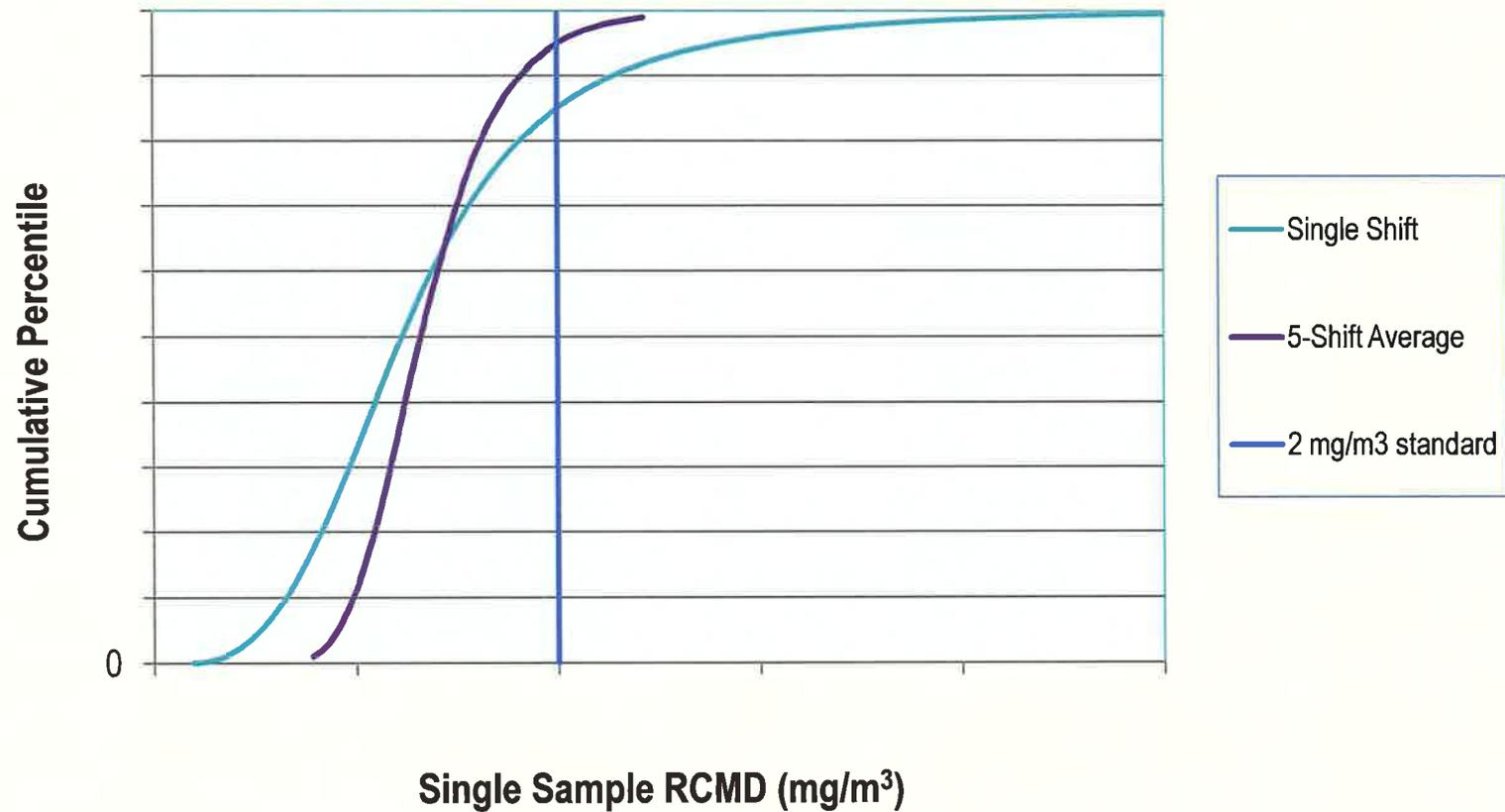
RCMD for Standard (mg/m ³)	Compliance Method	Annual Non-Compliance Rate at Current Levels	% RCMD Reduction for 95% Annual Compliance	Mean RCMD Concentration for 95% Annual Compliance (mg/m ³)
1 (proposed)	Current	100%	56%	0.87
2 (current)	Proposed	100%	80%	0.28
1 (proposed)	Proposed	100%	90%	0.14

Compliance Method:

Current: Maximum of 5-shift average per 2-month period

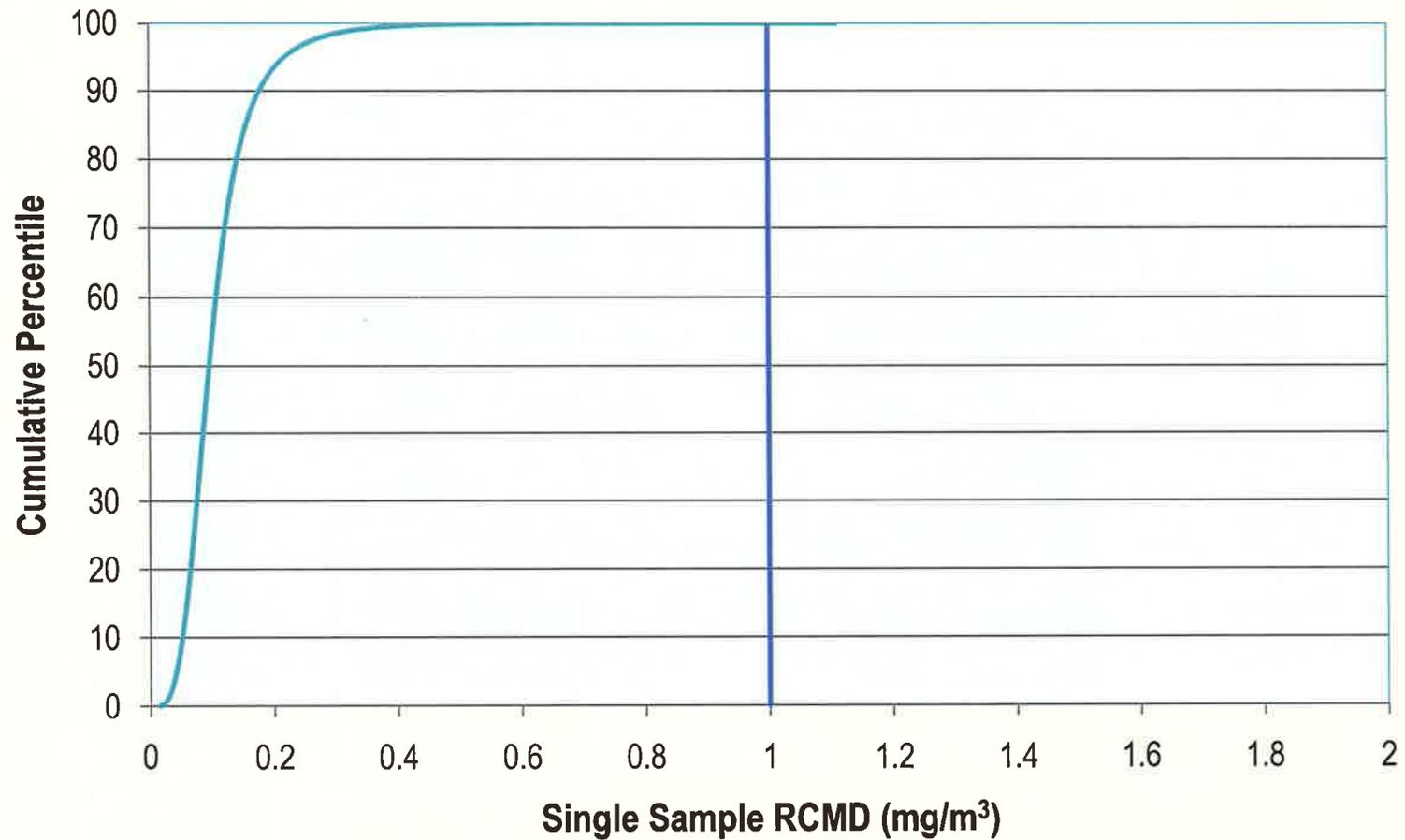
Proposed: Maximum of 3 shift/day and 120 days/quarter = 360 samples/quarter

Current Conditions – Longwall Operator

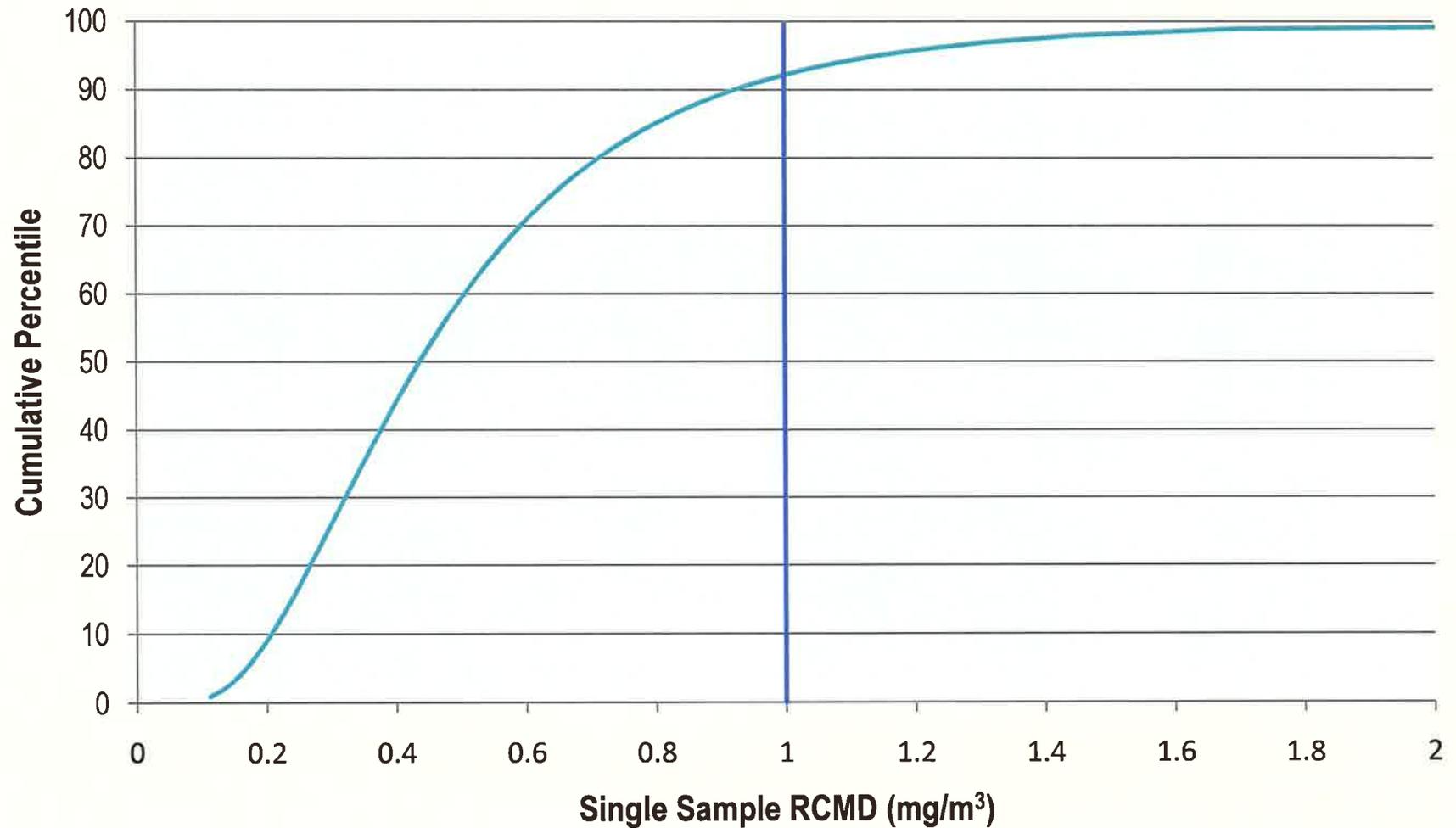


Doesn't account for increase number of samples

Conditions Needed for 99% Compliance with Proposed Standard – Longwall Operator



What If Longwall Operator Average is Reduced to 0.5 mg/m^3 ? – Still Significant Non-Compliance



Unnecessary Complexity in Coal Dust Model

- **All data were transformed (using “Box-Cox” method) prior to analysis**
 - Data are mixed normal; transformation unnecessary
- **Statistical model is extremely complicated (>20,000 parameters)**
 - Statistical theory advises using the most parsimonious model
- **Operator data prior to 2008 was not used due to conclusion that there was a downward trend**
 - The trend analysis did not account for smaller sample sizes through time, leading to a spurious result
 - More data could have been used in the analysis

Lack of Quantitative Uncertainty Analysis

- **QRA provides the reader little basis for assessing the uncertainty of its estimates**
- **The variability in exposure is readily available; one estimate of effect variability can be gleaned from regressions used for effect estimates**
- **Also, the QRA acknowledges that there may be a threshold effect**
 - Peaks in concentrations “may overload the respiratory system’s clearance mechanisms” (p.59)
 - Analysis to assess the potential effect of a threshold would aid decision-makers

Conclusions and Recommendations

- **Should make clear that benefits may not be realized until well into the future**
- **The QRA does not provide a realistic estimate of the changes needed to comply with the standard**
 - Thorough analysis needed to understand required reductions
- **Reduce complexity of statistical model**
- **Perform a quantitative uncertainty analysis**