

ORAL ARGUMENT NOT YET SCHEDULED

No. 16-1105

consolidated with Nos. 16-1113, 16-1125, 16-1126, 16-1131, 16-1137, 16-1138, 16-1146

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NORTH AMERICA’S BUILDING TRADES UNIONS,

Petitioner,

v.

**OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR,**

Respondents.

**On Petition for Review of OSHA’s Final Rule on
Occupational Exposure to Respirable Crystalline Silica,
81 Fed. Reg. 16285 (March 25, 2016)**

BRIEF FOR RESPONDENTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**(A) Parties and Amici****Petitioners:**Case No. 16-1105

North America's Building Trades Unions

Case No. 16-1113

American Federation of Labor & Congress of Industrial Organizations
United Steel, Paper and Forestry, Rubber, Manufacturing, Allied-Industrial and
Service Workers International Union
International Union and United Automobile, Aerospace and Agricultural
Implement Workers of America

Case No. 16-1125

Associated Masonry Contractors of Texas
Associated Subcontractors Association of Texas, Inc.
Distribution Contractors Association
Louisiana Associated General Contractors, Inc.
Mechanical Contractors Association of Texas, Inc.
Mississippi Road Builders Association
Pelican Chapter, Associated Builders and Contractors
Texas Association of Builders

Case No. 16-1126

American Foundry Society Texas Region 3/Texas Chapter of the American
Foundry Society
Texas Association of Business

Case No. 16-1131

National Stone, Sand & Gravel Association

Case No. 16-1137

American Foundry Society
National Association of Manufacturers

Case No. 16-1138

American Road & Transportation Builders Association

American Society of Concrete Contractors
American Subcontractors Association
Associated Builders & Contractors
Associated General Contractors
Association of the Wall & Ceiling Industry
Building Stone Institute
Concrete Sawing & Drilling Association
Construction & Demolition Recycling Association
Interlocking Concrete Pavement Institute
International Council of Employers of Bricklayers & Allied Craftworkers
Leading Builders of America
Marble Institute of America
Mason Contractors Association of America
Mechanical Contractors Association of America
National Association of Home Builders
National Demolition Association
National Electrical Contractors Association
National Utility Contractors Association
National Stone Council
Association of Union Constructors
The Roofing Institute

Case No. 16-1146

Brick Industry Association

Respondents:

U.S. Department of Labor
Occupational Safety & Health Administration
United States Secretary of Labor, Thomas E. Perez

Intervenors for Petitioners:

Portland Cement Association
National Concrete Masonry Association
Chamber of Commerce of the United States of America
State Chamber of Oklahoma
Greater North Dakota Chamber of Commerce

Intervenors for Respondents:

National Stone, Sand & Gravel Association
American Foundry Society

National Association of Manufacturers
National Association of Home Builders
American Federation of Labor & Congress of Industrial Organizations
United Steel, Paper and Forestry, Rubber, Manufacturing, Allied-Industrial
and Service Workers International Union
International Union and United Automobile, Aerospace and Agricultural
Implement Workers of America
North America's Building Trades Unions

Amicus Curiae for Respondents:

American Thoracic Society

American College of Occupational & Environmental Medicine

(B) Rulings Under Review

These cases involve challenges to a final occupational safety and health standard, "Occupational Exposure to Respirable Crystalline Silica," issued by the Occupational Safety and Health Administration on March 25, 2016. 81 Fed. Reg. 16285.

(C) Related Cases

These matters have not previously been before this Court or any other court. The undersigned counsel are not aware of any other related cases currently pending in this Court or any other court.

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GLOSSARY

AFS:	American Foundry Society
cfm:	Cubic feet per minute
ERG:	Eastern Research Group
Fracking:	Hydraulic Fracturing
HEPA:	High-efficiency particulate air
LEV:	Local exhaust ventilation
IARC:	International Agency for Research on Cancer
NAICS:	North American Industry Classification System
NIOSH:	National Institute for Occupational Safety and Health
OMB:	Office of Management and Budget
OSHA:	Occupational Safety and Health Administration
OSH Act (or Act):	Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678
$\mu\text{g}/\text{m}^3$	Micrograms per cubic meter of air
PEL:	Permissible exposure limit
Preamble:	Preamble to Occupational Exposure to Respirable Crystalline Silica; Final Rule, 81 Fed. Reg. 16285 (March 25, 2016)
Secretary:	The United States Secretary of Labor
SBREFA:	Small Business Regulatory Enforcement Fairness Act of 1996

Silica: Respirable crystalline silica

Silica Rule: Occupational Exposure to Respirable Crystalline Silica;
Final Rule, 81 Fed. Reg. 16285 (March 25, 2016)

JURISDICTIONAL STATEMENT

On April 1, 2016, North America's Building Trades Unions filed a petition in this Court (Docket No. 16-1105) seeking review of the final rule governing occupational exposure to respirable crystalline silica (Silica Rule), issued by the Occupational Safety and Health Administration (OSHA) on March 25, 2016. *See* 81 Fed. Reg. 16285 (March 25, 2016) (Preamble). This Court has jurisdiction over the petition under section 6(f) of the Occupational Safety and Health Act of 1970 (the Act or the OSH Act), 29 U.S.C. § 655(f). Between April 1 and April 4, 2016, six other challenges to the Silica Rule were filed in other federal courts of appeals; on April 12, 2016, the Judicial Panel on Multidistrict Litigation consolidated those challenges with Docket No. 16-1105 in this Court. *See* 28 U.S.C. § 2112(a). The Court then dismissed Docket Nos. 16-1112 and 16-1114 at the petitioners' request. Thereafter, three additional petitions for review were timely filed in this Court. An untimely challenge (Docket No. 16-1151) was subsequently dismissed at the petitioners' request.

STATEMENT OF ISSUES

1. Whether substantial evidence supports OSHA's findings that workers exposed to silica at the prior exposure limits suffer significant risk of material impairment of health and that the Silica Rule's new exposure limit will

substantially reduce that risk, where numerous studies, scientists, peer reviewers, and public health organizations confirm OSHA's findings and overall conclusions.

2. Whether OSHA correctly found that the Silica Rule is technologically feasible for foundries, hydraulic fracturing (fracking), and construction, where substantial evidence supports OSHA's conclusion that silica exposures can be reduced to the new exposure limit in most operations most of the time.

3. Whether OSHA correctly found that the Silica Rule is economically feasible for foundries, fracking, and construction, where OSHA made a reasonable, evidence-based assessment that the likely costs of the rule do not threaten the existence or competitive structure of those industries.

4. Whether the Court should uphold OSHA's decisions with respect to medical surveillance, medical removal protection, and housekeeping, where OSHA considered the arguments raised by petitioners before issuing the Silica Rule and thoroughly explained the reasons for its decisions in the Rule's preamble.

5. Whether OSHA provided stakeholders with sufficient information and time to allow for meaningful comment, where industry petitioners have failed to demonstrate harm related to the length of the briefing period and where all information gathered by OSHA's consultant and considered by OSHA was available to stakeholders for review and comment prior to the Silica Rule's post-hearing briefing period.

STATUTES AND REGULATIONS

All applicable statutes and regulations are included in the Addenda to the Joint Opening Brief of Industry Petitioners and the Joint Brief of Union Petitioners.

STATEMENT OF THE CASE

I. Procedural History

This case involves eight consolidated challenges to OSHA's Silica Rule – two on behalf of union petitioners and six on behalf of industry petitioners.

Several parties filed motions to intervene on OSHA's behalf, which were granted by the Court. The Court also granted a motion filed by the United States Chamber of Commerce and other parties, as well as a motion filed by the Portland Cement Association and the National Concrete Masonry Association, to intervene on behalf of petitioners. The American Thoracic Society and the American College of Occupational and Environmental Medicine are amici curiae in support of OSHA.

II. Statement of Facts

A. *The Hazards of Respirable Crystalline Silica*

The serious health effects associated with silica¹ exposure have been recognized “since the time of the ancient Greeks,” making silica one of the oldest

¹ Silica is a compound composed of silicon and oxygen. Preamble at 16298. The most common crystalline form of silica found in workplaces is quartz. *Id.*; *see also* 29 C.F.R. §§ 1910.1053(b), 1926.1153(b) (definition of respirable crystalline silica). Quartz is present in natural materials such as rock, sand, and gravel, and in building materials, such as concrete and brick. Preamble at 16298-99. Crystalline

known occupational hazards. *See* Ex. 0388, pp. 18-20; Ex. 2339, p. 2.² Although medical study of these effects began as early as the seventeenth century, silica-related disease first came to widespread attention in this country during the 1930s, after more than 750 unprotected workers died, and at least 1500 more were disabled, from silicosis contracted during excavation of the Hawks Nest tunnel through high-silica content rock in Gauley Mountain, West Virginia. *See* Ex. 0333, p. 2; Ex. 0388, p. 19; Ex. 3450; Ex. 3637, p. 5-3. Silicosis is a progressive, irreversible lung disease caused by the inflammatory effects of silica in the lungs, which leads to reduced pulmonary function, disability, and, sometimes, death. Preamble at 16305. In 1938, then-Secretary of Labor Frances Perkins warned the nation about the dangers of silica and called for protective action. *See Stop Silicosis*, U.S. Dep't of Labor (1938), <https://www.youtube.com/watch?v=pHwvKKQ5WtI> (last visited Jan. 19, 2017); *see also* Preamble at 16302.

Despite this warning and growing knowledge of the hazards posed by silica, widespread protections against silica exposure did not arrive until passage of the

forms of silica are respirable only when they appear as very small particles. Preamble at 16305, 16440. All references to “silica” in this brief refer to the respirable crystalline form of the silica compound.

² Throughout this brief, exhibit numbers are referred to in the form Ex. XXXX, where XXXX reflects the last four digits of the full document number (OSHA-2010-0034-XXXX).

OSH Act in 1970. Reductions in exposures since then have prevented similar large-scale tragedies, but workers continue to suffer from the effects of silica exposures at work. *See, e.g.*, Tr. 2504-12.³ During the rulemaking hearing, 48-year old foundry worker Alan White described being diagnosed with silicosis when he was just 44 years old, and the devastating effect the disease has had on his life. By the time he testified, Mr. White's silicosis had progressed so much that he struggled to walk up two flights of stairs and to talk while walking. *Id.*; Ex. 3477; Statement of Alan White, <http://www.osha.gov/silica/AlanWhite.pdf> (last visited Jan. 19, 2017); *see also* Ex. 4032, Attachment 1 (describing former glass industry worker's death from silicosis). Mr. White has been told he will die as a result of the silica dust he inhaled on the job. Statement of Alan White, <http://www.osha.gov/silica/AlanWhite.pdf> (last visited Jan. 19, 2017).

Although occupational silica exposure is the only known cause of silicosis, *see* Preamble at 16302, research in the last half century has shown that silicosis is not the only, or even the most lethal, consequence of silica exposure. Inhalation of silica particles significantly increases a worker's risk of experiencing multiple serious health effects, including the silicosis suffered by Mr. White. These health effects include other non-malignant respiratory diseases, such as emphysema and

³ "Tr." cites are to the transcript of the hearing, available at Exhibits 3576 through 3589.

chronic bronchitis; lung cancer, which has a five-year survival rate of only 15.6%; and kidney disease, such as chronic renal disease and end-stage renal disease.

Preamble at 16300-305, 16310, 16381-84; *see also infra* pp. 24-34 (risk assessment).

Over two million workers in the United States are currently exposed to silica. *See* Preamble at 16408-18 (Table VII-3). Construction workers are often exposed to silica dust during the cutting, drilling, grinding, or demolishing of materials such as concrete, stone, and mortar. *See* Preamble at 16299. Workers in general industry are exposed to silica in many different contexts, including through the use of silica sand in foundries, fracking, and glass manufacturing facilities. *See* Preamble at 16299, 16401-18.

B. *History of the Silica Rule*

The OSH Act authorizes the Secretary to promulgate occupational safety and health standards “to provide safe or healthful employment and places of employment.”⁴ 29 U.S.C. § 652(8); *see also id.* §§ 654(a)(2), 655. Section 6(a) of the Act gave OSHA two years following the effective date of the statute to promulgate “start-up” standards, on an expedited basis, without public input. *See*

⁴ The Secretary has delegated his rulemaking authority to the Assistant Secretary for Occupational Safety and Health, who heads OSHA. *See* Secretary’s Order 1-2012, 77 Fed. Reg. 3912 (Jan. 25, 2012). The terms Secretary and OSHA are used interchangeably in this brief.

id. § 655(a). Since then, standards must be promulgated pursuant to the rulemaking procedures in section 6(b) of the OSH Act. *See id.* § 655(b).

OSHA adopted its previous standards for silica in 1971 pursuant to section 6(a) of the Act. *See* Preamble at 16294. Those standards set formula-based permissible exposure limits (PELs) for silica, expressed as time-weighted averages, that were approximately equivalent to 100 $\mu\text{g}/\text{m}^3$ (micrograms per cubic meter of air) for general industry and between 250 $\mu\text{g}/\text{m}^3$ and 500 $\mu\text{g}/\text{m}^3$ for construction and shipyards. *See* Preamble at 16294, 16311, 16384. The 1971 PELs did not require particular exposure controls and did not include the types of additional protective provisions, such as training and medical surveillance requirements, that are typical of comprehensive health standards promulgated pursuant to section 6(b) of the Act. *See* Preamble at 16293-94.

The 1971 PELs, which were based on voluntary or national consensus standards that relied on science from the 1960s or earlier, *see* Preamble at 16294, quickly became outdated. In 1974, the National Institute for Occupational Safety and Health (NIOSH)⁵ recommended a time-weighted average PEL for silica of 50 $\mu\text{g}/\text{m}^3$ – roughly half of OSHA’s original general industry PEL and one-fifth of

⁵ NIOSH, an agency within the Centers for Disease Control and Prevention, Department of Health and Human Services, was created by the OSH Act to conduct research and recommend standards for occupational safety and health hazards. *See* 29 U.S.C. § 671.

OSHA's original PEL for construction and shipyards. *See* Preamble at 16294, 16300; Ex. 2177, Attachment B, p. 2. NIOSH also recommended requiring exposure monitoring and medical surveillance, among other ancillary provisions. *See* Preamble at 16294; Ex. 0388. OSHA published an Advance Notice of Proposed Rulemaking soliciting public comments on whether OSHA should issue a new silica standard based on the NIOSH recommendations, but OSHA did not pursue further rulemaking on silica at that time. *See* 39 Fed. Reg. 44771 (Dec. 27, 1974); Preamble at 16294.

As research on the health effects of silica exposures developed during the 1980s and 1990s, national and international organizations increasingly recognized silica as a human carcinogen. *See* Preamble at 16294. In 1987, the International Agency for Research on Cancer (IARC) within the World Health Organization determined that silica was probably carcinogenic to humans. *See* Preamble at 16294-95. Approximately ten years later, IARC concluded, more definitively, that “crystalline silica inhaled . . . from occupational sources is *carcinogenic to humans*.” Ex. 2258, Attachment 8, p. 211; *see also* Preamble at 16295, 16302, 16330; Ex. 1473, p. 396. The National Toxicology Program at the U.S. Department of Health and Human Services found, in 1991, that silica was reasonably anticipated to be a human carcinogen, and in 2000, upgraded its classification of silica to “known to be a human carcinogen” based on “sufficient

evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure . . . and increased lung cancer rates in workers exposed to crystalline silica dust.” Ex. 1417, p. 1; *see also* 66 Fed. Reg. 29340 (May 30, 2001); Preamble at 16295, 16302, 16330 (citing Ex. 1164, p. 1). In 2000, the professional organization American Conference of Governmental Industrial Hygienists listed silica as a suspected human carcinogen, and adopted a threshold limit value (*i.e.*, a recommended occupational exposure limit) of 50 $\mu\text{g}/\text{m}^3$, reduced to 25 $\mu\text{g}/\text{m}^3$ in 2006. *See* Preamble at 16295 (citing Ex. 1503, pp. 1, 15), 16300.

In 1997, OSHA, concluding that “there [would] be no significant progress in the prevention of silica-related diseases without the adoption of a full and comprehensive silica standard[,]” announced plans to publish a proposed rule. 62 Fed. Reg. 57755, 57758 (Oct. 29, 1997). OSHA held stakeholder meetings in 1999 and 2000 to obtain input from the regulated community on the upcoming rulemaking and, in 2003, initiated Small Business Regulatory Enforcement Fairness Act (SBREFA) proceedings to elicit input from small businesses. *See* Preamble at 16295-96 (citing 68 Fed. Reg. 30583 (May 27, 2003) and Ex. 0937).

In 2010, OSHA initiated the “peer review” process required by the Office of Management and Budget (OMB), during which independent scientific experts reviewed a draft Health Effects Analysis and Preliminary Quantitative Risk Assessment prepared for inclusion in a proposed silica rule. *See* Preamble at

16297, 16300-301 (citing Ex. 1336), 16398-99; *see also* 70 Fed. Reg. 2664 (Jan. 14, 2005). The peer review panel consisted of seven experts in, among other areas of study, occupational epidemiology, biostatistics, and risk assessment. Preamble at 16300 n.2. They responded to questions from OSHA and commented on various aspects of the draft analyses. *See* Preamble at 16301; Ex. 1716. Following peer review, OSHA revised the draft analyses and responded to the panel's comments. *See* Ex. 1711, pp. 379-99; Preamble at 16301. The updated versions of the health effects analysis and risk assessment were used as the basis for the proposed silica rule and were available to the public for review and comment as part of the rulemaking docket. *See* Preamble at 16297, 16301; Ex. 1711.

OSHA published its proposed rule for silica on September 12, 2013. 78 Fed. Reg. 56274 (Sept. 12, 2013); *see also* Preamble at 16297. In the proposal, OSHA preliminarily determined that employees exposed to silica at the 1971 PELs faced a significant risk to their health and that the proposed standards would substantially reduce that risk. *See* 78 Fed. Reg. at 56275-76; *see also* Ex. 1711. OSHA proposed a PEL of 50 $\mu\text{g}/\text{m}^3$ for general industry, maritime, and construction, as well as ancillary provisions, including medical surveillance and training requirements, to supplement the PEL. *See* 78 Fed. Reg. at 56275. Also, in an effort to simplify compliance for construction work, OSHA proposed a compliance option in the construction standard (Table 1) that listed specific construction

activities and controls employers could use to reduce silica exposures for employees performing those activities. *See id.* at 56496-99.

OSHA provided five months, until February 11, 2014, for the public to comment on the proposed rule, and held informal public hearings on the proposal from March 18 through April 4, 2014. *See* Preamble at 16297-98. During the hearings, OSHA heard testimony from hundreds of stakeholders representing more than seventy organizations, including public health groups, industry trade associations, labor unions, and individual companies and workers. *Id.* at 16298. Hearing participants had two months following the hearings (until June 3, 2014) to submit additional evidence and data to the record, and an additional eleven weeks (until August 18, 2014) to submit final briefs, arguments, and summations. *Id.* Stakeholders thus had nearly a year in which to submit pre- or post-hearing comments, and OSHA received more than 2000 comments on the proposed rule. *See id.* Five of the seven peer reviewers who had commented on OSHA's draft health effects and risk analyses attended the hearings on the proposed rule and filed post-hearing comments. *See id.* at 16301 (citing Ex. 3574).

On March 25, 2016, after considering the entire rulemaking record, OSHA promulgated its final Silica Rule governing occupational exposure to silica. 81 Fed. Reg. 16285. OSHA made numerous changes to the proposal in response to comments received during the rulemaking, but retained a PEL of 50 $\mu\text{g}/\text{m}^3$ for all

covered industry sectors and (with some modifications) the Table 1 compliance alternative for construction. *See infra* pp. 12-15 (summary of the rule). OSHA reaffirmed its preliminary finding that silica exposures at the previous PELs resulted in a significant risk of material impairment of health, and concluded that the new Silica Rule will substantially reduce that risk. *See* Preamble at 16302, 16399. OSHA estimates that the Silica Rule will prevent 642 deaths and 918 new cases of silica-related disease each year, which results in an estimated monetized annual benefit (using widely-accepted approaches for valuing the avoidance of fatalities and illnesses) of over \$8.6 billion. *See* Preamble at 16399-400, 16582-615.

C. *The Silica Rule*

The Silica Rule contains two standards – one that regulates general industry and maritime (29 C.F.R. §§ 1910.1053, 1915.1053), and one that applies to construction (29 C.F.R. § 1926.1153).⁶ The standards cover all non-agricultural (and non-mining) occupational exposures to silica, with the exception of exposures that result from the processing of sorptive clays. 29 C.F.R. § 1910.1053(a)(1)(ii)-

⁶ While the maritime standard is technically a separate standard, it is identical to the general industry standard. *See* 29 C.F.R. § 1915.1053 (cross-referencing 29 C.F.R. § 1910.1053). The two standards will therefore be referred to collectively as the “general industry/maritime” standard, and references to that standard will use the general industry standard citations.

(iii). In addition, both standards contain an exemption for situations in which exposures will remain below $25 \mu\text{g}/\text{m}^3$ as an eight-hour time-weighted average under any foreseeable conditions. 29 C.F.R. §§ 1910.1053(a)(2), 1926.1153(a). OSHA denied a request for an exemption for exposures to silica-containing brick clay. *See* Preamble at 16376-79.

Each standard sets a PEL of $50 \mu\text{g}/\text{m}^3$ and an action level of $25 \mu\text{g}/\text{m}^3$, expressed as eight-hour time-weighted averages.⁷ 29 C.F.R. §§ 1910.1053(b)-(c), 1926.1153(b), (d)(1). OSHA adopted a PEL of $50 \mu\text{g}/\text{m}^3$ for silica in light of findings that: (1) the prior exposure limits for silica resulted in a significant risk of material health impairment to exposed workers; (2) lowering the PEL to $50 \mu\text{g}/\text{m}^3$ will substantially reduce that risk; and (3) a PEL of $50 \mu\text{g}/\text{m}^3$ is the lowest level that is both technologically and economically feasible for all covered industries. *See* Preamble at 16755.

With some exceptions (discussed below), employers must assess silica exposures for employees who are or may reasonably be expected to be exposed at or above the action level. 29 C.F.R. §§ 1910.1053(d)(1), 1926.1153(d)(2). These assessments can be done using exposure monitoring, objective data, or a combination of the two. 29 C.F.R. §§ 1910.1053(d), 1926.1153(d)(2). Once

⁷ The “action level” triggers requirements for exposure assessment and, in the general industry/maritime standard, medical surveillance. *See* Preamble at 16707.

exposures have been assessed, employers must implement feasible engineering and work practice controls when necessary to lower exposures to the PEL or below. 29 C.F.R. §§ 1910.1053(f)(1), 1926.1153(d)(3)(i). If feasible engineering and work practice controls cannot reduce exposures to the PEL or below, the employer must use controls to reduce exposures to the extent feasible and then provide respirators as supplementary protection. 29 C.F.R. §§ 1910.1053(f)(1), 1926.1153(d)(3)(i).

The most significant difference between the general industry/maritime standard and the construction standard is the extra “Table 1” compliance option in the construction standard. Titled “Specified Exposure Control Methods When Working With Materials Containing Crystalline Silica,” 29 C.F.R.

§ 1926.1153(c)(1), the table lists eighteen types of equipment or tasks, and, for each one, specifies control methods employers can use to protect construction workers from silica exposures. *Id.* For most Table 1 entries, OSHA determined that the specified controls, which generally include using water or ventilation, will keep exposures at or below the PEL most of the time. *See* Preamble at 16716, 16785. When OSHA determined that the specified controls will not reduce exposures to the PEL most of the time under particular circumstances (*e.g.*, indoors or outdoors for more than four hours), Table 1 requires respiratory protection in addition to the designated engineering and work practice controls. 29 C.F.R. § 1926.1153(c)(1); Preamble at 16458. Compliance with Table 1 is a “safe harbor”

in that it satisfies an employer's duty to achieve the PEL and the employer does not have to perform separate exposure assessments. Preamble at 16458.

Both silica standards contain ancillary provisions, such as requirements for housekeeping (29 C.F.R. §§ 1910.1053(h), 1926.1153(f)), medical surveillance (29 C.F.R. §§ 1910.1053(i), 1926.1153(h)), hazard communication and training (29 C.F.R. §§ 1910.1053(j), 1926.1153(i)), written exposure control plans (29 C.F.R. §§ 1910.1053(f)(2), 1926.1153(g)), and recordkeeping (29 C.F.R. §§ 1910.1053(k), 1926.1153(j)). These provisions supplement the protection provided by the PEL.

Both standards became effective on June 23, 2016. For the general industry/maritime standard, compliance obligations generally begin on June 23, 2018; however, medical surveillance obligations are phased in, with full enforcement starting on June 23, 2020, and a delayed compliance date of June 23, 2021, is set for implementing engineering controls in fracking. 29 C.F.R. § 1910.1053(l). For the construction standard, compliance obligations begin on June 23, 2017, although OSHA will not enforce requirements governing the analysis of exposure monitoring samples until June 23, 2018. 29 C.F.R. § 1926.1153(d)(2)(v), (k).

SUMMARY OF THE ARGUMENT

The record evidence overwhelmingly supports OSHA's promulgation of the Silica Rule. It is undisputed that silica causes serious, even fatal, health effects in exposed workers. More than 1 in every 1000 workers exposed to silica at the previous general industry PEL of $100 \mu\text{g}/\text{m}^3$ will become seriously ill or die as a result of their exposure. Substantial evidence supports OSHA's conclusions about these health risks and demonstrates that the lives, health, and livelihoods of America's silica-exposed workers depend on this new Rule. Attempts by industry petitioners and intervenors to portray silica-related diseases as problems of the past are belied by the large body of scientific evidence, including many peer-reviewed epidemiological studies, linking silica exposures at, and even below, the previous PELs with increased rates of illness and death.

Substantial evidence also supports OSHA's finding that the new PEL of $50 \mu\text{g}/\text{m}^3$ is technologically feasible for all industries affected by the Rule. Industry petitioners challenge these findings in the foundry, fracking, and construction industries, but have not presented a single valid basis on which this Court can set aside OSHA's feasibility findings. To the contrary, OSHA's finding that these industries are capable of reducing exposures to the PEL for most operations most of the time is based on one of the most extensive databases of information OSHA

has ever used to evaluate the effectiveness of exposure controls and is entitled to an extreme degree of deference.

In addition, OSHA established that the Silica Rule is economically feasible by creating a reasonable estimate of the likely costs of the rule and demonstrating that those costs will not threaten the existence or competitive structure of any affected industries. Industry petitioners raise a laundry list of weakly-developed challenges to OSHA's economic analysis as it pertains to foundries, fracking, and construction. In all cases, however, OSHA's analysis is reasonable and supported by the best available, and substantial, evidence in the record.

Challenges by industry and union petitioners to some of the Silica Rule's ancillary provisions merit even less attention under the applicable substantial evidence standard. OSHA considered each of the arguments raised by the petitioners before setting the final standards and thoroughly explained the reasons for its decisions in the preamble to the final rule. And, in promulgating the Silica Rule, OSHA scrupulously followed OSH Act and Administrative Procedure Act rulemaking procedures, providing stakeholders with ample time and sufficient information to allow for meaningful comment on all evidence in the rulemaking record.

ARGUMENT

I. Statutory Background and Standard of Review

An occupational safety and health standard is a rule “which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.” 29 U.S.C. § 652(8). When OSHA issues standards “dealing with toxic materials or harmful physical agents” it must “set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.” *Id.* § 655(b)(5). The Supreme Court has interpreted the OSH Act to require OSHA to demonstrate that the standards it promulgates are reasonably necessary and appropriate to remedy a significant risk of material harm. *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst. (Benzene)*, 448 U.S. 607, 614-15, 639-40, 642-43 (1980) (plurality opinion). The Supreme Court noted in *Benzene* that a reasonable person might consider risk to be “significant” if the odds are one in 1000 that exposure to a hazardous substance will be fatal. *Id.* at 655.

Moreover, OSHA must minimize the risk of exposure to the relevant hazard as far as economically and technologically feasible. 29 U.S.C. § 655(b); *Am.*

Textile Mfrs. Inst., Inc. v. Donovan (Cotton Dust), 452 U.S. 490, 509 (1981) (Congress “place[d] the ‘benefit’ of worker health above all other considerations save those making attainment of this ‘benefit’ unachievable.”); *United Steelworkers of Am., AFL-CIO-CLC v. Marshall (Lead I)*, 647 F.2d 1189, 1251 (D.C. Cir. 1980) (OSHA must reduce risk “as far as it c[an] within the limits of [technological and economic] feasibility.”). A PEL is technologically feasible if there is “a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.” *Am. Iron & Steel Inst. v. OSHA (Lead II)*, 939 F.2d 975, 980 (D.C. Cir. 1991) (per curiam) (internal quotation marks omitted). A standard is economically feasible if it does not “threaten massive dislocation to, or imperil the existence of, [an] industry.” *Lead I*, 647 F.2d at 1265 (internal citations and quotation marks omitted); *see also Lead II*, 939 F.2d at 980.

Under the OSH Act, the Secretary’s regulatory determinations are “conclusive if supported by substantial evidence in the record considered as a whole.” 29 U.S.C. § 655(f). This Court “has acknowledged the difficulties of applying the substantial evidence test ‘to regulations which are essentially legislative and rooted in inferences from complex scientific and factual data, and which often necessarily involve highly speculative projections of technological development in areas wholly lacking in scientific and economic certainty.’” *Nat’l*

Oilseed Processors Ass'n v. OSHA, 769 F.3d 1173, 1178 (D.C. Cir. 2014) (quoting *Lead I*, 647 F.2d at 1206-207). The Court's role on review of OSHA standards is "to ensure the agency has acted within the scope of its authority, followed . . . statutory and regulatory procedures, explicated the bases of its decision, and adduced substantial evidence in the record to support its determinations." *Id.* In conducting this review, the Court looks simply to see whether "the agency [has] identif[ied] relevant factual evidence, . . . explain[ed] the logic and the policies underlying any legislative choice, . . . state[d] candidly any assumptions on which it relies, and . . . present[ed] its reasons for rejecting significant contrary evidence and argument." *Id.* (quoting *Lead I*, 647 F.2d at 1207).

OSHA is thus entitled to "an extreme degree of deference" when it is "evaluating scientific data within its technical expertise." *Nat'l Mining Ass'n v. Sec'y, U.S. Dep't of Labor*, 812 F.3d 843, 883-84 (11th Cir. 2016) (quoting *Kennecott Greens Creek Mining Co. v. MSHA*, 476 F.3d 946, 954-55 (D.C. Cir. 2007)). In recognition of "both OSHA's superior technological capacity and its broad legislative mandate," OSHA need not "support its findings . . . with anything approaching scientific certainty." *Bldg. & Constr. Trades Dep't, AFL-CIO v. Brock (Asbestos)*, 838 F.2d 1258, 1264 (D.C. Cir. 1988) (internal citation and quotation marks omitted). Moreover, the "possibility of drawing two inconsistent conclusions from the evidence does not prevent [the] agency's finding from being

supported by substantial evidence.” *Cotton Dust*, 452 U.S. at 523 (internal quotation marks omitted); *see also Lead II*, 939 F.2d at 982 (the Court’s “function is not to decide what assumptions or findings [it] would make were [it] in the Secretary’s position”) (internal citations omitted). Numerical standards, such as PELs, must be upheld as long as they fall within a “zone of reasonableness.” *Lead I*, 647 F.2d at 1207 (internal citation and quotation marks omitted).

II. Substantial Evidence Supports OSHA’s Finding that Exposure to Silica at the Prior PELs Causes Significant Risks of Death and Serious Disease.

OSHA properly determined that workers face significant health risks from silica exposure at the prior PELs. Namely, workers exposed, over a working lifetime, to average silica concentrations at and above 100 $\mu\text{g}/\text{m}^3$ are at risk of developing silicosis, lung cancer, other non-malignant respiratory diseases, and renal disease as a result of their exposure. These risks are substantially lower, though still significant, at the new PEL of 50 $\mu\text{g}/\text{m}^3$. OSHA’s risk determinations elicited the support of many expert commenters, including public health agencies, scientific and occupational health experts, and independent peer reviewers. OSHA’s findings of significant risk are supported by substantial evidence in the record and demonstrate that the Silica Rule is necessary to protect America’s workers.

To promulgate a new health standard, OSHA must determine that there is a significant risk of material impairment of health at the existing exposure limit and that issuance of a new, more protective, standard will substantially reduce or eliminate that risk. *See* 29 U.S.C. § 655(b)(5); *Cotton Dust*, 452 U.S. 490; *Benzene*, 448 U.S. at 639, 642, 655-56 (“[i]t is the Agency’s responsibility to determine, in the first instance, what it considers to be a ‘significant’ risk.”). Based on the Supreme Court’s *Benzene* decision, OSHA generally finds risk to be “significant” when at least one exposed worker in 1000 will suffer a particular, material harm as a result of exposures experienced over his or her working lifetime. *Benzene*, 448 U.S. at 655.

While OSHA’s risk determination must be supported by substantial evidence, OSHA “is not required to support its finding that a significant risk exists with anything approaching scientific certainty” and may rely on “conservative assumptions in interpreting the data . . . risking error on the side of overprotection.” *Id.* at 656. A reviewing court must “give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.” *Id.* Additionally, as this Court has stated, OSHA may act with a “pronounced bias towards worker safety” in making its risk determinations, *Asbestos*, 838 F.2d at 1266, and may incorporate “a fully adequate margin of safety.” *Nat’l Mining Ass’n v. MSHA*, 116 F.3d 520, 528 (D.C. Cir. 1997) (analyzing a mine safety

standard under the *Benzene* significant risk test). The identification of risks and how to reduce them are judged as “technical decision[s] entrusted to the expertise of the agency.” *Id.* at 528. If a scientific question lacks a clear answer, OSHA is entitled to “reasonably resolve the matter” after reviewing all the evidence. *Pub. Citizen Health Research Grp. v. Tyson (Ethylene Oxide)*, 796 F.2d 1479, 1500 (D.C. Cir. 1986). “[T]he court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute.” *Lead I*, 647 F.2d at 1263.

Despite OSHA’s well-reasoned and well-supported analysis showing significant risks at the prior PELs and below, industry petitioners and intervenors attempt to dismiss silica-related diseases as relics of the past. *See* Industry Br. at 8 (silicosis is an “ancient occupational disease that has come under significant control”); *see also id.* at 22-52; Chamber Br. at 11-20. Specifically, they argue that a “threshold” of silica exposure, below which no silica-related respiratory disease can occur, exists at an average concentration exposure of 100 $\mu\text{g}/\text{m}^3$ or higher, making the new PEL of 50 $\mu\text{g}/\text{m}^3$ unnecessary. *See* Industry Br. at 23-30; Chamber Br. at 16-20. Industry petitioners claim that lung cancer cannot occur in the absence of silicosis and that, therefore, the threshold applies to lung cancer as well. Industry Br. at 46-48. Intervenors point to surveillance data on silicosis deaths that they claim refute OSHA’s showing of significant risk under the prior

general industry PEL. Chamber Br. at 11-16; *see also* Industry Br. at 8. Industry petitioners further allege that OSHA's risk analysis is tainted by "confirmation bias" and relies on an exposure metric that ignores the effects of high, short-term exposures on risk. *E.g.*, Industry Br. at 23, 27-28, 43, 47-48. And, industry petitioners argue that OSHA failed to demonstrate significant risk of material impairment of health for the brick industry and thus erred in including that industry within the scope of the Silica Rule. Industry Br. at 123-31. Every single one of these arguments was addressed comprehensively by OSHA in the preamble to the final rule. Because OSHA's analysis on all points is amply supported by substantial evidence, industry petitioners' and intervenors' scattershot attacks on OSHA's findings must be rejected by the Court.

A. *OSHA's Finding of Significant Risk at the Previous PELs Is Solidly Grounded in Scientific Evidence and Should Be Upheld.*

The best available evidence demonstrates clearly significant risks of silicosis, other non-malignant respiratory diseases, lung cancer, and renal disease for workers exposed to silica at the previous PELs. These risks will be substantially reduced at the new PEL. OSHA therefore correctly concluded that the Silica Rule was "reasonably necessary and appropriate to remedy a significant risk of material health impairment." *Benzene*, 448 U.S. at 639; *see also* 29 U.S.C. § 652(8).

OSHA conducted a lengthy and thorough risk assessment of the health effects associated with silica exposure. As explained in detail in the preamble to the Silica Rule, OSHA reviewed extensive toxicological, epidemiological, and experimental studies and research pertaining to the adverse effects of silica, including silicosis, other non-malignant respiratory diseases, lung cancer, and autoimmune and renal disease. *See* Preamble at 16299-399. This body of evidence establishes that inhalation exposure to silica at 100 $\mu\text{g}/\text{m}^3$ increases the risk of these adverse health effects, each of which constitutes a material impairment of health. These diseases make it difficult or impossible to work and result in significant and permanent functional limitations, reduced quality of life, and premature death. *Id.* at 16381. Using the information collected during its review, and applying widely-accepted methods of statistical analysis, OSHA developed quantitative estimates of the risk of mortality and morbidity (*i.e.*, disease) at the previous and new silica PELs and the new action level, assuming forty-five years of exposure.⁸ *See id.* at 16300-304, 16380-99.

The studies OSHA relied on to assess the risks of mortality and morbidity caused by silica exposure constitute the best available evidence for quantitative risk assessment. These studies of worker populations (cohorts) contained adequate

⁸ OSHA uses forty-five years to reflect “the period of [the employee’s] working life.” 29 U.S.C. § 655(b)(5); *see also Asbestos*, 838 F.2d at 1264-65.

quantitative information on exposure and disease risks. They also met OSHA's rigorous quality standards; using a weight-of-evidence approach, OSHA evaluated the studies based on stringent selection criteria, including: (1) whether the study population was sufficiently large to detect low levels of risk; (2) the duration of follow-up of the study population; (3) whether the study either adjusted for or otherwise adequately addressed confounding factors, such as smoking and exposure to other carcinogens; (4) the potential for study bias; (5) the adequacy of underlying exposure information for examining exposure-response relationships; and (6) whether the cumulative exposure levels experienced by the cohorts were relevant to the levels of exposure permitted under the former and new PELs. *See id.* at 16302-10, 16317, 16362, 16387-89. The studies that most adequately met these criteria were deemed to be the best available evidence for risk assessment purposes. *See id.* at 16304.

OSHA estimated the risk of silica-related diseases and death assuming exposure over a working life to 25, 50, 100, 250, and 500 $\mu\text{g}/\text{m}^3$ silica, which represent the new action level, the new PEL, the prior PEL for general industry, and the prior range of PELs (250 to 500 $\mu\text{g}/\text{m}^3$) for construction/shipyards, respectively. For its excess mortality risk estimates, OSHA used life table analysis; for silicosis morbidity, it relied on the risk models

from published, peer-reviewed studies.⁹ These estimates show clearly significant risks of disease and death from silicosis, and death from other non-malignant respiratory diseases, lung cancer, and renal disease for silica-exposed workers. The numerous studies OSHA relied on, as well as its final risk estimates, are listed below in Table A. *See* Preamble at 16386-87 (Table VI-1).

⁹ Life table analysis, used by OSHA to estimate the lifetime excess risk of death from silica-related diseases, is a generally-accepted and frequently-used method of risk analysis developed by the National Research Council (part of the National Academy of Sciences and the National Academy of Engineering). *See* Preamble at 16300, 16311-12, 16373-74. It allowed OSHA to incorporate background mortality data (*i.e.*, deaths unrelated to silica exposure) as well as consistent assumptions for the length of a lifetime and duration of exposure. *Id.* For silicosis morbidity, OSHA based its risk estimates on the cumulative risk models used in the best available published, peer-reviewed studies of silicosis to develop quantitative exposure-response relationships. *See id.* at 16300, 16373. These models characterized the risk of developing silicosis, as detected by chest x-ray, up to the time that study participants, including both active and retired workers, were last examined. *See id.*

Table A: Risk Estimates for Respirable Crystalline Silica Exposure					
Health Endpoint (Source)	Risk Associated with 45 Years of Occupational Exposure (per 1,000 Workers)				
	Crystalline Silica Exposure ($\mu\text{g}/\text{m}^3$)				
	25	50	100	250	500
Lung Cancer Mortality (Lifetime Risk)					
Pooled Analysis (Steenland, <i>et al.</i> , 2001; ToxaChemica, 2004)	10-21	16-23	20-26	24-30	32-33
Earth Worker study (Rice <i>et al.</i> , 2001)	8	15	30	72	137
U.S. Granite Worker study (Attfield and Costello, 2004) **	10	22	54	231	657
North American Industrial Sand Worker study (Hughes <i>et al.</i> , 2001)	7	14	33	120	407
British Coal Miner study (Miller and MacCalman, 2009)	3	5	11	33	86
Silicosis/NMRD Mortality (Lifetime Risk)					
Pooled Analysis (Mannetje <i>et al.</i> , 2002; ToxaChemica, 2004) (silicosis)	4	7	11	17	22
Diatomaceous Earth Worker study (Park <i>et al.</i> , 2002) (NMRD) **	22	44	85	192	329
Renal Disease Mortality (Lifetime Risk)					
Pooled study (Steenland <i>et al.</i> , 2002a)	25	32	39	52	63
Silicosis Morbidity (Cumulative Risk)					
Chest x-ray category of 2/1 or greater (Buchanan <i>et al.</i> , 2003)	21	55	301	994	1,000
Silicosis mortality and/or x-ray of 1/1 or greater (Steenland and Brown, 1995b) **	31	75	440	601	634
Chest x-ray category of 1/1 or greater (Hnizdo and Sluis-Cremer, 1993)	6	127	773	995	1,000
Chest x-ray category of 1 or greater (Chen <i>et al.</i> , 2001) **	40	170	590	1,000	1,000
Chest x-ray category of 1 or greater (Chen <i>et al.</i> , 2005) **					
Tin miners	40	100	400	950	1,000
Tungsten miners	5	20	120	750	1,000
Pottery workers	5	20	60	300	700
** Indicates that the study was challenged by industry petitioners as being inappropriate for inclusion in OSHA's risk assessment.					

Table A demonstrates that silica exposure at the previous PELs (100 $\mu\text{g}/\text{m}^3$ for general industry; 250 $\mu\text{g}/\text{m}^3$ to 500 $\mu\text{g}/\text{m}^3$ for construction and shipyards) results in clearly significant risks of death and serious illness, which are substantially reduced at the new PEL of 50 $\mu\text{g}/\text{m}^3$.¹⁰ *See Benzene*, 448 U.S. at 642 (requiring a finding that a workplace is “unsafe-in the sense that significant risks are present and can be eliminated or lessened by a change in practices”). For example, given a working lifetime of silica exposure at the previous general industry PEL of 100 $\mu\text{g}/\text{m}^3$, OSHA estimated a lifetime mortality risk of eleven deaths per 1000 workers from silicosis, as well as excess lifetime mortality risks of eleven to fifty-four deaths per 1000 workers from lung cancer and eighty-five deaths per 1000 workers from non-malignant respiratory diseases.¹¹ Preamble at

¹⁰ Industry petitioners appear to assume that the prior general industry PEL of 100 $\mu\text{g}/\text{m}^3$ is the only PEL that was affected by the Silica Rule. *See, e.g., Industry Br.* at 15 (referring to the “prior PEL of 100 $\mu\text{g}/\text{m}^3$ ”), 17. Petitioners ignore the much higher construction/shipyard PELs of between 250 and 500 $\mu\text{g}/\text{m}^3$ – which applied to more than 85% of workers protected by the new standard, Preamble at 16418 – seemingly conceding the existence of significant risk at those higher PELs. *See supra* Table A.

¹¹ OSHA’s mortality risk estimates generally represent “excess” risks in the sense that they reflect the risk of dying from silica-related disease over and above that of persons who are not exposed to silica. Preamble at 16391. OSHA calculated absolute rather than excess risks for silicosis because silicosis is caused only by exposure to silica (*i.e.*, there is no background rate of non-occupational silicosis in the general population). *Id.* at 16312. The risk estimates for the different health endpoints are not additive because some workers may suffer from more than one silica-related illness. *Id.* at 16391.

16386. The risks are even higher at the previous construction/shipyard PELs. *Id.* OSHA also determined that risks are substantially reduced at the new PEL of 50 $\mu\text{g}/\text{m}^3$, with seven deaths per 1000 workers from silicosis, five to twenty-three excess deaths per 1000 workers from lung cancer, and forty-four excess deaths per 1000 workers from non-malignant respiratory diseases. *Id.* The estimated excess lifetime risk of renal disease mortality is thirty-nine deaths per 1000 workers at the previous general industry PEL and thirty-two at the new PEL of 50 $\mu\text{g}/\text{m}^3$.¹² *Id.*

The reduction in risk of silicosis morbidity achieved by lowering exposures to the new PEL of 50 $\mu\text{g}/\text{m}^3$ is even starker. At the previous general industry PEL, OSHA estimated that the risk of developing silicosis is, at the lowest, sixty cases per 1000 workers. *Id.* The risk at the new PEL of 50 $\mu\text{g}/\text{m}^3$ is reduced by two-thirds or more, to as low as twenty estimated cases of silicosis per 1000 exposed workers. *Id.* Even these reduced risks of illness and death achieved by lowering the PEL to 50 $\mu\text{g}/\text{m}^3$ are well above one in 1000 workers, which is the level of risk

¹² Industry petitioners allege that OSHA's estimates of renal disease mortality are unsupported by the record. Industry Br. at 49-52. Although OSHA grounded these estimates in the best available evidence, specifically a large pooled study that found statistically-significant relationships between silica exposure and deaths from renal disease, it acknowledged in the final rule that the evidence underlying its estimates for renal disease is less robust than for lung cancer and non-malignant respiratory diseases (including silicosis). *See* Preamble at 16342-45. Thus, OSHA relied more heavily on its risk estimates for the other health endpoints as the bases for the Silica Rule.

the Supreme Court indicated a reasonable person would consider unacceptable.¹³ *See Benzene*, 448 U.S. at 655. OSHA's estimated risks, therefore, plainly demonstrate that the Silica Rule is not, as industry petitioners claim, a "solution in search of a problem." Industry Br. at 13. Rather, the Rule represents American workers' greatest hope of relief from the significant risks of death and disease caused by workplace silica exposure.

OSHA's risk assessment garnered overwhelming support from the medical, public and occupational health, and scientific communities.¹⁴ *See* Preamble at 16300-301. As the American Public Health Association commented, "OSHA has thoroughly reviewed and evaluated the peer-reviewed literature on the health effects associated with exposure to . . . silica. OSHA's quantitative risk assessment is sound." Ex. 2178, Attachment 1, p. 1; *see also* Ex. 2373, p. 1 (National

¹³ Although significant risk remains even at the Action Level of 25 $\mu\text{g}/\text{m}^3$, OSHA was unable to conclude that an exposure limit below 50 $\mu\text{g}/\text{m}^3$ would be technologically feasible. Preamble at 16461-62; *see Cotton Dust*, 452 U.S. at 509 (OSHA's statutory mandate to set the standard that "most adequately" protects workers is limited only by what is feasible.).

¹⁴ Ironically, despite industry petitioners' constant refrain that OSHA engaged in "cherry picking," *see* Industry Br. at 30, 47, 62, they reference only a few selective comments from individual peer reviewers in an attempt to obscure the peer reviewers' overall support for OSHA's analysis. *See* Ex. 1711, p. 381; Preamble at 16301. Similarly, they make several references to NIOSH's testimony, *e.g.*, Industry Br. at 48, without acknowledging NIOSH's strong support for OSHA's risk conclusions and the Silica Rule. *See, e.g.*, Ex. 2177, Attachment B, p. 2; Tr. 125-26.

Consumers League saying same). Dr. Franklin Mirer, who has served on several National Academy of Sciences committees tasked with setting risk assessment guidelines, opined that OSHA's risk analysis is "scientifically correct, and consistent with [the] latest thinking on risk assessment." Ex. 2256, Attachment 3, p. 3; *see also* Tr. 935-36. NIOSH stated that "[t]he adverse health effects of exposure to . . . silica are well-known, long lasting, and preventable," and the American Society of Safety Engineers commented that "reduction of the . . . [PEL] to that recommended for years by [NIOSH] is long overdue." Ex. 2177, Attachment B, p. 2; Ex. 2339, p. 2. Dr. David Goldsmith compared silica to asbestos and cigarette smoking, in that, "exposure clearly increases the risk of many diseases. There have been literally thousands of research studies on exposure to crystalline silica in the past 30 years. Almost every study tells the occupational research community that workers need better protection to prevent severe chronic respiratory diseases, including lung cancer."¹⁵ Preamble at 16372 (quoting Tr. 865-66).

Just as significantly, OSHA's risk assessment was fully vetted by a panel of seven independent peer reviewers in accordance with OMB's "Final Information

¹⁵ Dr. Goldsmith is a Ph.D. scientist on the faculties of George Washington and Georgetown Universities. Ex. 3426, p. 1. He has spent nearly his entire academic career studying the health effects of silica exposure, including co-authoring the first study linking silica exposure to lung cancer in 1982. *Id.*

Quality Bulletin for Peer Review.” Preamble at 16300-301. The peer reviewers were recognized experts in occupational epidemiology, biostatistics and risk assessment, animal and cellular toxicology, and occupational medicine. Preamble at 16300 n.2. They found that OSHA was very thorough in its review of the literature and was reasonable in its interpretation of the studies with regard to the various endpoints examined. Ex. 1711, p. 381. They also found the conclusions about risk at the prior and new PELs to be reasonable. *See* Preamble at 16301.

Disputing or ignoring the opinions of most expert commenters and the peer reviewers, industry petitioners and intervenors argue that OSHA’s risk assessment is unsupported by substantial evidence and riddled with errors. Industry Br. at 22-52; Chamber Br. at 11-20. Taken together, their many challenges constitute a demand that OSHA meet a higher legal standard than that described by the Supreme Court in *Benzene* or than that utilized by scientific and public health experts. In *Benzene*, the Court stated that OSHA must rely on a “body of reputable thought,” but did not require OSHA “to support its finding that a significant risk exists with anything approaching scientific certainty.” *Benzene*, 448 U.S. at 656. In addition, OSHA may act with a “pronounced bias towards worker safety” in making risk determinations. *Asbestos*, 838 F.2d at 1266. In the Silica Rule, as in the ethylene oxide standard reviewed by this Court, OSHA went “to great lengths to calculate, within the bounds of available scientific data, the significance of the

risk presented by” silica in order to demonstrate that “exposure presents a substantial risk of harm on the basis of record evidence.” *Ethylene Oxide*, 796 F.2d at 1499. Because OSHA has made its “findings of fact on the basis of substantial evidence and has provided a reasoned explanation for [its] policy assumptions and conclusions,” this Court must uphold OSHA’s findings and conclusions regarding the significant risks of silica-related health effects. *Asbestos*, 838 F.2d at 1266.

B. *Substantial Evidence Supports OSHA’s Threshold Assessment.*

Industry petitioners and their intervenors also assert that OSHA committed a crucial error in its risk assessment by finding that there is no threshold – or a very low threshold – for diseases caused by silica exposure.¹⁶ Industry Br. at 14; Chamber Br. at 6. They claim that the scientific evidence demonstrates a threshold that is – conveniently for them – at or above OSHA’s prior PEL for general industry of 100 $\mu\text{g}/\text{m}^3$, and that OSHA simply ignored this evidence. *See, e.g.*, Industry Br. at 24. The location of this alleged threshold above 100 $\mu\text{g}/\text{m}^3$, according to their argument, demonstrates that OSHA’s findings of significant risk at levels at and below 100 $\mu\text{g}/\text{m}^3$ are unsupported by the record. *Id.* at 14-15. In

¹⁶ A threshold in this context refers to a level of exposure below which nobody becomes sick. *See* Preamble at 16351.

fact, according to petitioners, there can be no risk at all of silica-related lung disease below $100 \mu\text{g}/\text{m}^3$. *Id.* at 24.

These assertions are strongly contradicted by the record evidence. Petitioners fail to acknowledge OSHA's lengthy, thorough, and credible assessment of the evidence on thresholds, and the support for OSHA's conclusions from peer reviewers and other expert commenters. Moreover, industry petitioners and intervenors ignore the evidence – discussed at length by OSHA in the preamble – that many workers have become sick and died after experiencing silica exposures *below* the threshold level alleged by petitioners. *See* Preamble at 16352-59.

Under section 6(b)(5) of the OSH Act, 29 U.S.C. § 655(b)(5), OSHA must regulate on the basis of the “best available evidence” when that evidence “indicates a serious threat to the health of workers,” even if such evidence is incomplete. *AFL-CIO v. Marshall*, 617 F.2d 636, 651 (D.C. Cir. 1979), *aff'd in relevant part by Cotton Dust*, 452 U.S. 490. Where OSHA “has exercised [its] expertise,” as it has here, “by carefully reviewing the scientific data,” this Court demands only “that OSHA review all sides of the issue and reasonably resolve the matter.” *Ethylene Oxide*, 796 F.2d at 1500. That demand is met when OSHA has “explained the evidence it used, the reasons for its conclusions, and its responses to the industries’ evidence and objections.” *AFL-CIO*, 617 F.2d at 668 (stating no more is expected

from an agency “entrusted with regulating risks on the frontiers of scientific and medical knowledge”).

Industry petitioners’ assertion that OSHA “ducked the question” is absurd. Industry Br. at 29. OSHA spent abundant effort reviewing and addressing the issue of whether a threshold for silica-related health effects exists and, if it does, whether it can be quantified. *See* Preamble at 16348-59. After evaluating the best available scientific evidence on both sides, OSHA found that there is considerable scientific uncertainty about whether there is a threshold below which silica exposures will not cause *any* adverse health effects to any exposed worker, but concluded that if there is such a threshold, it is likely well below the new PEL of $50 \mu\text{g}/\text{m}^3$.¹⁷ *See id.* at 16319, 16348-59.

Consistent with OSHA’s conclusion, several studies in the record that examined this precise issue found either no evidence of a threshold or evidence of a possible threshold well below the new PEL. *See* Preamble at 16351, 16356; Kuempel *et al.* (2001), Ex. 1082 (possible threshold around $36 \mu\text{g}/\text{m}^3$); Steenland

¹⁷ Industry petitioners and intervenors focus on the fact that low-level ambient exposures to silica, estimated between 1 and $3 \mu\text{g}/\text{m}^3$, do not cause illness among the general population. Industry Br. at 27; Chamber Br. at 19. As an initial matter, this level of ambient exposure may be an overestimate because the source they primarily relied on, a 1996 Environmental Protection Agency study, Ex. 3637, reported estimates that captured more than just respirable silica dust. *See* Preamble at 16758. Further, rather than supporting their argument, these estimated ambient levels are consistent with OSHA’s conclusion that a threshold, if one exists, would be well below $50 \mu\text{g}/\text{m}^3$. *See* Preamble at 16351.

and Deddens (2002), Ex. 1124, p. 781 (possible threshold around $10 \mu\text{g}/\text{m}^3$).

Findings from the European Commission's Scientific Committee on Occupational Exposure Limits included a "No Observed Adverse Exposure Level" for silica somewhere below $20 \mu\text{g}/\text{m}^3$, but could not identify a clear threshold. Preamble at 16350 (discussing Mossman and Glen (2013), Ex. 4070, p. 655). Other studies, including one that specifically looked for a threshold for lung cancer and silicosis in a pooled set of cohorts, ToxaChemica (2004), Ex. 0469, found the evidence either consistent with the absence of a threshold or inconsistent with the existence of a threshold at the new PEL or above. Preamble at 16353. Mannelje *et al.* (2002), Ex. 1089, for instance, studied a population of over 18,000 workers, including four of six cohorts with significant numbers of workers with median cumulative and/or average exposures below the levels associated with OSHA's previous general industry PEL. Preamble at 16352-53. According to NIOSH, the results of Mannelje *et al.* "suggest the absence of [a] threshold at the lowest [cumulative] exposure analyzed," which was "the equivalent of 45 years of exposure at $11.1 \mu\text{g}/\text{m}^3$ silica."¹⁸ *Id.* at 16353 (quoting Ex. 4233, pp. 34-35).

¹⁸ Cox (2011), a theoretical piece written by an expert hired to comment on the rule by the American Chemistry Council, suggested there could be a threshold for crystalline silica above $100 \mu\text{g}/\text{m}^3$ based on animal studies of non-reactive and poorly soluble particles, such as carbon black and titanium dioxide. *See* Ex. 1711, Attachment 1, pp. 37-39 (discussing Ex. 1470). OSHA discounted Dr. Cox's hypothesis because, among other major flaws, silica is not a non-reactive, poorly

OSHA's conclusions on the threshold issue were supported by the peer reviewers, including Dr. Kenneth Crump, a Ph.D. scientist specializing in risk assessment, who stated that "OSHA is on very solid ground in the . . . statement that 'available information cannot firmly establish a threshold exposure for silica-related health effects.'" *Id.* at 16351-52 (quoting Ex. 3574, p. 17).

Importantly, the argument for a threshold above the previous PEL depends on there being no cases observed below it. *See id.* at 16352; Tr. 403 (Dr. Cox agreeing it is possible to rule out a threshold based on observed illness). As part of its evaluation of the best available evidence on thresholds, however, OSHA reviewed multiple studies involving workers exposed below the alleged "safe dose level of silica at 100 $\mu\text{g}/\text{m}^3$ or higher," Industry Br. at 24, and found substantial evidence of illnesses and deaths. *See* Preamble at 16352-59. Studies of industrial sand workers, *e.g.*, Hughes *et al.* (2001), Ex. 1060; McDonald *et al.* (2005), Ex. 1092, showed elevated lung cancer risk among workers with cumulative exposure levels below that which would result from forty-five years of exposure to the previous PEL of 100 $\mu\text{g}/\text{m}^3$ (*i.e.*, 4.5 $\text{mg}/\text{m}^3\text{-yrs}$). Preamble at 16357. In addition, Steenland and Sanderson (2001) identified seven deaths from silicosis among

soluble particle. *See* Preamble at 16349-50. Thus the approach used by Dr. Cox, according to OSHA as well as the International Life Sciences Institute and the European Centre for Ecotoxicology and Toxicology of Chemicals, was not appropriate. *Id.* at 16350 (citing Ex. 3897, p. 5; Ex. 3906, p. 1).

workers whose cumulative exposures were below $1.28 \text{ mg/m}^3\text{-yrs}$, which is equivalent to an average exposure concentration of about $28 \text{ }\mu\text{g/m}^3$ (*i.e.*, just above the action level) over a period of forty-five years. *See id.* at 16353 (citing Ex. 0455, p. 700); *see also* Ex. 0456. The pooled cohorts in Mannelje *et al.* (2002) included seventeen silicosis deaths among workers with even lower cumulative exposures – at most $0.99 \text{ mg/m}^3\text{-yrs}$ (equivalent to an average exposure concentration of $22 \text{ }\mu\text{g/m}^3$). *See* Ex. 1089. A Steenland and Brown (1995) study of gold miners showed twenty-five cases of silicosis among miners with cumulative exposures up to $1.0 \text{ mg/m}^3\text{-yrs}$ (average exposure concentration of $22.2 \text{ }\mu\text{g/m}^3$), ten of which were among those with exposures of at most $0.5 \text{ mg/m}^3\text{-yrs}$ (average exposure concentration of $11 \text{ }\mu\text{g/m}^3$). *See* Ex. 0451. These identified cases of silica-related illnesses and deaths at cumulative exposures well below that which would accrue at the petitioners’ alleged threshold of $100 \text{ }\mu\text{g/m}^3$ – and even below the Silica Rule’s action level of $25 \text{ }\mu\text{g/m}^3$ – compellingly refute the claim by industry petitioners and intervenors that there is a threshold above that level. *See infra* pp. 60-63 (“dose-rate effect” cannot explain these cases).

Remarkably, in another study of silicosis morbidity by Morfeld *et al.* (2013), Ex. 3843, which was touted by the industry petitioners as proof of a threshold around $250 \text{ }\mu\text{g/m}^3$, Industry Br. at 37, 17.5% of illnesses occurred in workers whose highest annual silica exposures were below $250 \text{ }\mu\text{g/m}^3$, and 12.5% of

illnesses affected workers whose highest exposures were under $100 \mu\text{g}/\text{m}^3$.¹⁹ *See* Preamble at 16354-55 (citing Ex. 4224, p. 3; Ex. 4233, pp. 57-58 (NIOSH recommending that these results be discounted)). Dr. Morfeld explained that this threshold estimate was meant to describe a “population average,” which would not be expected to characterize risk for all individuals in the population. *See* Preamble at 16354 (quoting Ex. 4003, p. 5). OSHA, however, is charged with protecting all workers for the duration of their working lives. *See* 29 U.S.C. § 655(b)(5) (“no employee” shall suffer material impairment of health); *see also Lead I*, 647 F.2d at 1309 (OSH Act “requires OSHA to protect all workers”). This acknowledgement that some people are more susceptible to illness than others further undermines petitioners’ argument for a bright-line threshold and is consistent with OSHA’s conclusion that, if a level exists below which *nobody* gets sick, it is well below the new PEL.

Contrary to the claim – made by both industry petitioners and intervenors – that case law indicates “mounting judicial skepticism” of a “no threshold dose” model of disease, *Industry Br.* at 28-29; *Chamber Br.* at 17-18, courts have accepted no-safe-dose assumptions in the context of OSHA rulemaking, especially

¹⁹ Morfeld *et al.* (2013) also used exposure measurements collected using German dust samplers, which have been shown to collect twice as much dust as samplers used in the United States, meaning that any estimated threshold from this study would need to be cut in half to be applicable to OSHA’s analysis. *See* Preamble at 16354 (citing Ex. 4233, p. 21).

when carcinogens like silica are involved. The attempt by industry petitioners and intervenors to direct the Court to toxic tort case law is particularly disingenuous given the decisions from this and other courts that are directly on point.²⁰ *See Ethylene Oxide*, 796 F.2d at 1499-1501 (approving OSHA’s no-threshold assumption for ethylene oxide despite stakeholder comments supporting a threshold); *see also ASARCO, Inc. v. OSHA*, 746 F.2d 483, 492–93 (9th Cir. 1984) (rejecting an industry challenge to OSHA’s reliance on a no-threshold, cumulative-dosage model for its arsenic risk assessment). Regarding thresholds in particular, this Court specified that OSHA “must be given leeway when regulatory subject matter is not subject to strict proof one way or the other.” *Ethylene Oxide*, 796

²⁰ The cases cited by petitioners and intervenors were products liability actions, where courts rejected expert testimony that every instance of a plaintiff’s workplace exposure to a toxic substance triggered liability. *See* Industry Br. at 28-29; Chamber Br. at 17-18. These decisions are not applicable in the OSHA regulatory context for many reasons, including the different burdens of proof in toxic tort products liability actions, the different requirements for admissibility of expert testimony, and the different disease mechanisms involved. Importantly, while OSHA must demonstrate significant risk by showing 1/1000 employees are at risk, *see Benzene*, 448 U.S. at 655, plaintiffs in toxic tort actions must show they themselves were sickened by a particular exposure. Moreover, many courts have accepted the no-threshold/general causation model even in toxic tort cases. *See, e.g., In re Zicam Cold Remedy Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 09-MD-2096-PHX-FJM, 2011 WL 2784803, at *1 (D. Ariz. July 15, 2011) (noting that “the majority of courts that have considered the issue of general causation in the context of pharmaceutical products liability litigation have not required a toxic dose showing”); *Davis v. Honeywell Int’l Inc.*, 245 Cal. App. 4th 477, 493–94 (Cal. Ct. App. 2016), *review denied* (May 25, 2016) (accepting no-threshold theory and noting that causation requirements in toxic torts cases vary widely).

F.2d at 1499 (citing *Benzene*, 448 U.S. at 655-56). Thus, the efforts by industry petitioners and intervenors to discredit OSHA's well-reasoned analysis on the threshold issue are unavailing, especially where the record includes evidence of illness and death at exposure levels that are well below the petitioners' alleged threshold.

C. *Substantial Evidence Supports OSHA's Finding that Silicosis Is Not a Necessary Precursor to Silica-Related Lung Cancer.*

Industry petitioners separately argue that silicosis is a necessary precursor of lung cancer (*i.e.*, silica-related lung cancer cannot occur unless a person first has silicosis). *See* Industry Br. at 46-48. According to petitioners, because (1) silicosis requires a certain threshold of silica exposure (allegedly at least 100 $\mu\text{g}/\text{m}^3$), and (2) only people with silicosis get lung cancer, then silica-related lung cancer also has an exposure threshold. Industry Br. at 46. Substantial evidence, however, refutes petitioners' claims and supports OSHA's finding that silicosis is not a necessary pre-cursor to lung cancer.

Petitioners' argument that nobody gets silica-related lung cancer without first getting silicosis only matters if the evidence indicates a threshold for silicosis above 100 $\mu\text{g}/\text{m}^3$, which it does not. *See supra* pp. 34-42. The argument is also internally contradictory because industry petitioners' brief first states that it is

“widely accepted” that silicosis must precede development of lung cancer,²¹ Industry Br. at 46, then, just two pages later, approvingly quotes several scientists who believe that this particular question is, to quote one of them, “unanswerable.” *Id.* at 48. Finally, it is unsupported because industry petitioners fail to identify a single study that proves this alleged “necessary precursor” effect. Preamble at 16331, 16342.

This is precisely the type of scientific debate Congress anticipated when it passed the OSH Act. The “best available evidence” standard, rather than constraining OSHA, “was intended to permit the agency to act immediately to protect workers from a disease even when contemporary science does not fully comprehend how the disease develops.” *Lead I*, 647 F.2d at 1228 n.54. This Court, in looking at the Act’s legislative history, stated that “Congress did ‘not [intend] that the Secretary be paralyzed by debate surrounding diverse medical opinions.’” *Ethylene Oxide*, 796 F.2d at 1497 (quoting H.R.REP. NO. 91–1291, 91st Cong., 2d Sess. 18 (1970), *reprinted in* Legislative History of the Occupational Safety and Health Act of 1970 at 848 (1971)).

²¹ Even the article cited by industry petitioners for the proposition that Dr. Kyle Steenland agrees with this view of the mechanism, *see* Industry Br. at 46, in fact supports OSHA’s finding that lung cancer can occur in the absence of silicosis. The article states: “New studies have also shown that excess lung mortality occurs in silica-exposed workers who do not have silicosis.” Steenland and Ward (2013), Ex. 2340, p. 68.

OSHA relied upon multiple studies showing increased lung cancer risk in the absence of silicosis, evidence from animal studies indicating the mechanisms by which tumors may form, and supportive testimony from peer reviewers and NIOSH scientists. After extensive analysis of this body of evidence, OSHA found that the best available evidence indicates several possible mechanisms that may cause lung cancer in workers exposed to silica. *See* Preamble at 16328-49. This credible scientific evidence shows that lung cancer can develop without the presence of chronic inflammation and silicosis, as both genotoxic (*i.e.*, causing damage to cellular DNA) and non-genotoxic mechanisms triggered by early responses to silica exposure at the cellular level, prior to development of silicosis, can contribute to silica-induced lung cancer. *Id.* at 16342, 16346.

The epidemiological evidence OSHA examined includes Checkoway *et al.* (1999), Ex. 0327, which showed a statistically significant exposure-response relationship for lung cancer among diatomaceous earth workers without silicosis. Preamble at 16309; *see also* Cassidy *et al.* (2007), Ex. 0313; Cherry *et al.* (1998), Ex. 0335; Hnizdo *et al.* (1997), Ex. 1049; McLaughlin *et al.* (1992), Ex. 0372; Liu *et al.* (2013), Ex. 2340. The evidence on the mechanisms that cause silica-related lung cancer, which industry petitioners largely ignore, includes the latest review of the carcinogenicity of silica by IARC, which discussed early genotoxic and non-genotoxic responses that occur once lung cells are exposed to silica

particles. These early responses at the cellular level include damage to DNA, oxidative stress, cytotoxicity, and cell proliferation that can lead to neoplastic (*i.e.*, tumor-forming) transformation and development of lung cancer. The early neoplastic events precede the chronic inflammation that develops from silica overexposure and do not depend on silicosis to be present. *See* Ex. 1473, pp. 391-96; *see also* Knaapen *et al.* (2002), Ex. 1076; Johnston *et al.* (2000), Ex. 1070; Porter *et al.* (2002), Ex. 1114; Vallyathan *et al.* (1995), Ex. 1128; Castranova *et al.* (1996, 2004), Exs. 0314, 0315; Shoemaker *et al.* (1995), Ex. 0437. Studies exposing animal and human cells to silica *in vitro* also demonstrate that silica may have a direct effect on epithelial cells (which line the air sacs in the lungs), causing neoplastic transformations in the absence of inflammation. *See* Ex. 1473, pp. 390-92; Ex. 1711, pp. 244-57 (discussing studies). These studies support OSHA's conclusion that malignant tumors may form through genotoxic as well as non-genotoxic mechanisms that result from silica interaction with lung cells in the absence of silicosis. Preamble at 16348.

OSHA's findings are bolstered by the conclusions of medical and scientific experts, with Dr. David Weissman – Director of the Division of Respiratory Disease Studies at NIOSH – testifying that “there's quite a bit of reason . . . to think that the two processes [development of silicosis and development of lung cancer] don't require each other.” Preamble at 16331 (quoting Tr. 247); *see also*

Tr. 246-47 (testimony of Robert Park, an epidemiologist in the Risk Evaluation Branch of NIOSH). IARC noted in its latest comprehensive review of the evidence for the carcinogenicity of silica that a direct mechanism for lung cancer cannot be ruled out. Preamble at 16309 (citing Ex. 1473). Finally, Checkoway and Franzblau (2000), Ex. 0323, who reviewed the epidemiological literature addressing this topic, recommended that silicosis and lung cancer be treated in risk assessments as ““separate entities whose cause/effect relations are not necessarily linked.”” Preamble at 16331 (quoting Ex. 0323, p. 257). OSHA properly followed this recommendation given that the best available evidence indicates that lung cancer can develop in the absence of silicosis. *See Benzene*, 448 U.S. at 656 (reviewing courts shall “give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.”); *Cotton Dust*, 452 U.S. at 523 (the “possibility of drawing two inconsistent conclusions from the evidence does not prevent [the] agency’s finding from being supported by substantial evidence.”).

D. *The Silicosis Surveillance Data Do Not Undermine OSHA’s Risk Assessment.*

Intervenors claim that silicosis surveillance data from death certificates showing declining cases of silicosis in the United States rebut OSHA’s finding of significant risk at the previous PELs. Chamber Br. at 16. However, as explained at length in the preamble, these data are both irrelevant to OSHA’s risk assessment for the Silica Rule and entirely inadequate to quantify the health risks associated

with occupational silica exposure. *See* Preamble at 16322-30. Thus, OSHA properly rejected intervenors' claim that the surveillance data undermine OSHA's conclusion that workers face significant risks to their health at the prior PELs. *See Nat'l Mining Ass'n*, 812 F.3d at 883 (once significant risk is demonstrated, it is of no import that the incidence of illness may be declining).

As described fully in the preamble, the silicosis mortality data are collected by the National Center for Health Statistics (part of the Centers for Disease Control and Prevention) from death certificates reported to state vital statistics offices; NIOSH then compiles the data for its database on occupational respiratory diseases. Preamble at 16306, 16322-30; Ex. 0319, p. 1. These data are gathered on a nation-wide basis and report cases where silicosis is listed as a contributing or underlying cause of death on a death certificate.²² Significantly, these data pertain only to deaths from silicosis,²³ which make up but a small proportion of the estimated risks in OSHA's risk assessment, and show merely that there has been a

²² The data are general population data, in the sense that any death certificate listing silicosis as a cause of death is included in the database. *See* Preamble at 16324-25. However, because silicosis is an occupational disease, all reported deaths likely occurred among people exposed to silica at work. *See id.* at 16306, 16328-29.

²³ The data do not include silicosis illnesses or deaths from non-malignant respiratory diseases, cancer, or renal disease. Preamble at 16306, 16322-30.

significant decline in silicosis mortality since the late 1960s.²⁴ *Id.*; *see also supra* Table A. According to the Centers for Disease Control and Prevention, this decrease in the annual number of silicosis deaths – from 1157 in 1968 to 161 in 2005 – is probably due to a decline in employment in high-exposure industries like foundries as well as a decrease in exposure levels once the previous PELs went into effect.²⁵ Preamble at 16306; Exs. 0319, 1308. Despite this decrease in mortality and a high rate of underreporting, the data show a continuing high death toll from silicosis, with OSHA noting that “silicosis deaths among workers of all ages result in significant premature mortality; between 1996 and 2005, a total of 1,746 deaths resulted in a total of 20,234 years of life lost from life expectancy,

²⁴ Intervenors’ argument focuses exclusively on the data on mortality related to “occupational lung diseases, including silicosis.” Chamber Br. at 12 (quoting Preamble at 16306). The argument does not at all address the silicosis morbidity data that OSHA considered, *see* Preamble at 16306, 16325, which show that, nationwide, the number of hospitalizations related to silicosis remained constant from 1993 to 2011 (notwithstanding a decrease in the population at risk, *see infra* n.25). *See* Preamble at 16327-28 (discussing Ex. 3425). And despite intervenors’ loose references to “respiratory mortality data” and “silica-related deaths,” Chamber Br. at 12, the mortality data come from death certificates on which silicosis was listed as a cause of death. *See* Preamble at 16323. Thus, intervenors’ argument that these data undermine OSHA’s risk estimates, even if assumed to be correct, would not affect OSHA’s risk findings for silicosis morbidity, or for mortality from lung cancer or other non-malignant respiratory diseases.

²⁵ By one credible estimate, “almost all” of the decrease in silicosis deaths is attributable to a decrease in the population at risk. Preamble at 16326 (quoting Ex. 3425, pp. 3-4).

with an average of 11.6 years of life lost.” Preamble at 16306; *see also* Preamble at 16322-30.

OSHA also examined more recent silicosis death certificate data covering 2005 through 2013 and found “that the decline in the number of deaths with silicosis as an underlying or contributing cause has leveled off in more recent years, suggesting that the number of silicosis deaths being recorded and captured by death certificates may be stabilizing after 30 or more years of decline.”²⁶ Preamble at 16324. Dr. Robert Cohen, representing the American Thoracic Society, emphasized this levelling-off as well, stating ““we are concerned that [silicosis mortality] has been the same without any further reduction for more than 20 years.””²⁷ *Id.* at 16325 (quoting Tr. 775).

The salient point about the mortality data, moreover, is that they are only as reliable as the death certificates from which they are taken. The fact is that death

²⁶ This stabilization is likely due, at least in part, to the increased use of new materials and methods, *e.g.*, in road building and construction, that generate increased silica exposures. *See* Preamble at 16327. Furthermore, deaths of workers in newer industries with high silica exposures, like fracking, may not yet be reflected in the data because of the lengthy latency period for respiratory diseases like silicosis. *Id.*

²⁷ This plateau is ignored in intervenors’ brief. While intervenors point out that the year 2014 had the fewest recorded silicosis deaths (84), Chamber Br. at 13, the recently-released data for 2015 show a significant uptick, to 105. *See* Centers for Disease Control and Prevention WONDER database, *available at* <http://wonder.cdc.gov/mcd-icd10.html> (last visited Jan. 18, 2017).

certificates are notoriously unreliable with respect to the listed cause of death, especially when a chronic occupational disease is involved. Preamble at 16328-29. The problem is two-fold: silicosis can easily go undetected and be mistaken for a different respiratory disease; and, even if diagnosed, the health professional entering information on the certificate may be unaware of the diagnosis and misclassify the cause of death as, for example, emphysema or heart failure. *See id.* at 16328-29, 16382. One analysis by Dr. Kenneth Rosenman, a physician, epidemiologist, and professor at Michigan State University, demonstrated that silicosis is only listed as a cause of death for 14% of individuals with confirmed silicosis, suggesting that up to 86% of deaths may be missing from the mortality data on which intervenors focus. *See* Preamble at 16328 (citing Tr. 854).²⁸

Significant underestimation is therefore a given for the silicosis mortality data, and not a “mere supposition.” Chamber Br. at 15. But even if underestimation were to be removed from consideration, and even if silicosis mortality were the only health endpoint of regulatory concern, intervenors fail to prove their point that the mortality surveillance data in the record should substitute for OSHA’s epidemiology-based quantitative risk assessment, which was peer-

²⁸ A different analysis, Rosenman *et al.* (2003), based on Michigan’s silicosis surveillance activities, estimated that silicosis cases (both diseases and deaths) were understated by a factor of between 2.5 and 5. *See* Preamble at 16306 (discussing Ex. 0420).

reviewed, thorough, transparent, and in accordance with standard scientific practice; nor do the data “*refute* OSHA’s conclusions that employees face significant risks under the existing PEL of 100 $\mu\text{g}/\text{m}^3$.” *Id.* at 16. This is because these data do not contain sufficient information to be used for quantitative assessment of the relationship between silica exposures and deaths from silicosis.

Unlike epidemiological studies used for risk assessments, death certificate data often lack information on usual industry, occupation, and, most importantly, exposures experienced by the deceased individuals; thus data drawn from death certificates “cannot be directly compared in any meaningful way” with OSHA’s quantitative risk findings. Preamble at 16322-23. For this reason, NIOSH – the agency responsible for compiling and analyzing the surveillance data – testified that relying on the data to show that there is no need for a lower PEL or that there is no significant risk at 100 $\mu\text{g}/\text{m}^3$ would be “a misuse of surveillance data,” primarily because the surveillance data contain no information whatsoever about exposure. *Id.* at 16326 (quoting Tr. 167); *see also* Tr. 248. The National Academy of Sciences agreed that surveillance data are not appropriate for use in risk assessment for occupational hazards. *See* Preamble at 16326-27 (citing Ex. 4204, p. 21). OSHA thus rationally concluded that these data “are inadequate and inappropriate for estimating risks or benefits associated with various exposure

levels, as is required of OSHA's regulatory process."²⁹ *Id.* at 16323.

E. *Petitioners' Criticism of OSHA's Reliance on Particular Studies Does Not Undermine OSHA's Overall Finding of Significant Risk.*

Industry petitioners claim that OSHA relied on studies that were “cherry-picked” for their results, *see* Industry Br. at 30, 47, despite alleged flaws in several of the studies. *See* Industry Br. at 31-46. These same criticisms were a focus during the rulemaking, with certain industry stakeholders claiming that biases and uncertainties in the studies OSHA used for its quantitative risk assessment fundamentally undermine OSHA's conclusions on risk. *See, e.g.*, Ex. 2330; Ex. 2307, Attachments A, 4.

OSHA carefully evaluated and disposed of petitioners' criticisms in the preamble. The so-called “flaws” highlighted by petitioners affect all retrospective epidemiological studies to varying degrees. Because the potential biases and uncertainties of concern to industry petitioners are well known in epidemiology, scientists who conduct the studies and subject them to peer review before

²⁹ Intervenors' attempt to estimate a death rate for silicosis – measured against the general population – is completely beside the point. *See* Chamber Br. at 12. Because the general population is not at risk of silicosis, *see* Chamber Br. at 19, the denominator in intervenors' calculation is many times larger than appropriate for the silica-exposed working population addressed in this rulemaking. Moreover, their calculation only purports to estimate the rate of silicosis deaths in a single year (2014, which had the fewest silicosis deaths ever recorded). In contrast, a true risk assessment estimates the rate of excess deaths in a worker population after they have experienced cumulative exposures throughout a working life of forty-five years and requires data on what those exposures were.

publication take these issues into account in evaluating the quality of the data and analysis. *See, e.g.*, Tr. 894-95. Thus, despite the recognized possibility for biases and uncertainties in these studies (which were exhaustively catalogued by industry commenters during the rulemaking process, *see, e.g.*, Ex. 2307, Attachment 4), “mainstream scientific thought holds that valid conclusions regarding disease causality can still be drawn” from them. Preamble at 16359 (quoting Ex. 4233, p. 32). Indeed, according to peer reviewer Dr. Gary Ginsberg, although “epidemiology studies will always have issues of exposure misclassification,” these types of error may also underestimate true risk. Ex. 3574, p. 23.

Exposure uncertainty, which industry petitioners suggest infects both Park *et al.*'s 2002 study of non-malignant respiratory diseases and Steenland and Brown's 1995 study of silicosis, *see* Industry Br. at 31-36, 41-42, is common and mostly unavoidable in occupational epidemiology. The exposure data used by the studies in OSHA's risk assessment are based on either direct measurements of airborne respirable silica for a sample of workers or on measured airborne dust concentrations for specific jobs. Preamble at 16314. Despite these measurements, exposures dating back decades – sometimes to the 1930s – obviously cannot be confirmed with absolute certainty. Nor can the effect of exposure uncertainty on exposure-response relationships be known definitively, although comments and testimony during the rulemaking indicated that such uncertainty is equally (or

more) likely to result in underestimation of risk as in overestimation. *See, e.g.*, Preamble at 16340, 16365-66; Tr. 358-59, 1266-67; Ex. 3574, p. 21; Ex. 3606, p. 646. Tellingly, one industry expert, Dr. Long, testifying on behalf of the Chamber of Commerce, was unable to identify a single study that he believed was not tainted by exposure uncertainty. *See* Preamble at 16366 (citing Tr. 356-57).

The “best available evidence” standard does not expect the studies OSHA relies on to achieve a level of perfection or certainty that does not exist in the real world. *See Benzene*, 448 U.S. at 656. Nevertheless, OSHA commissioned a separate quantitative analysis – ToxaChemica (2004), Ex. 0469 – to study the possible effects of exposure uncertainty (both in terms of random error in individual workers’ exposure estimates and error in the conversion of dust measurements to respirable silica concentrations) on OSHA’s risk estimates. *See* Preamble at 16365-69; Ex. 1711, pp. 299-314. This analysis found that neither random error in the underlying exposure estimates nor hypothetical systematic errors in exposure estimation is likely to have substantially influenced the risk estimates for lung cancer derived from the pooled data in Steenland *et al.* (2001), Ex. 0452. *See* Preamble at 16314-15. For silicosis mortality, modeling these errors had more of an effect; therefore, OSHA incorporated the simulated error into its risk estimates, based on Marnett *et al.* (2002), Ex. 1089, for this endpoint. Preamble at 16314-15. Thus, to the extent possible, OSHA analyzed and

accounted for exposure estimation error in its risk estimates, concluding that such error did not substantially affect the results in the majority of studies examined. *See* Preamble at 16314-15, 16365-69, 16395; Ex. 1711, pp. 299-314. Industry petitioners acknowledge neither this analysis nor OSHA's extensive evaluation of whether its risk estimates were affected by other potential sources of bias and uncertainty, including model specification bias, study selection bias, data selection bias, and model selection bias. *See* Preamble at 16360-65, 16395-97.

Industry petitioners' other arguments regarding the Park *et al.* study, Industry Br. at 31-36, lack merit. The allegation that the models used in the study "simply assumed no . . . threshold" is untrue. Rather, the authors performed a categorical analysis that indicated no threshold at 25 ug/m³. Preamble at 16319. Below this level, "the data lacked the power" to indicate any possible threshold. *Id.* (citing Ex. 4233, p. 27); *see also supra* pp. 34-42 (thresholds). With respect to the exposure levels of workers in the Park study population, OSHA continues to believe, as stated in the preamble, that "the ACC's characterization of exposures in the Park *et al.* (2002) study as vastly higher than the final and former PELs is incorrect." Preamble at 16318. While the ACC focuses on the average concentration exposures experienced by workers in the study population, Industry Br. at 33-34, those workers actually had cumulative exposures in the range of interest for this rulemaking, making significant extrapolation unnecessary.

Preamble at 16318. Because cumulative exposure is an appropriate exposure metric for epidemiological studies of silica-related health effects, *see infra* pp. 60-63, the authors' approach was valid. Preamble at 16318.

Similarly, the study's authors (and OSHA) already addressed petitioners' challenges regarding confounding by smoking. *See* Industry Br. at 34-35. Park performed "internally standardized analyses," which are "less susceptible to confounding by smoking" because they compare the mortality of groups of workers within the study population rather than comparing the mortality experience of the study population with an external population. The results of these analyses suggested that the risk of death from non-malignant respiratory disease "based on this cohort are not likely to be exaggerated due to cohort members' smoking habits." Preamble at 16318. The results were also consistent with a study of the same cohort by Checkoway *et al.*, which found it was "very unlikely" smoking could explain the association between non-malignant respiratory disease mortality and silica exposure. *Id.* Finally, OSHA's decision to rely on the Park study is supported by the Mannelje *et al.* study of silicosis mortality, which included several cohorts of workers who had exposures relevant to this rulemaking and showed clearly significant risks of silicosis and other non-malignant respiratory disease at the previous PELs. Preamble at 16320.

Industry petitioners also argue, unconvincingly, that OSHA should have relied on Vacek *et al.* (2011), Ex. 1486, which found no statistically significant link between lung cancer and silica exposure among Vermont granite workers, instead of the Attfield and Costello (2004) study, Ex. 0543, which did find such a link in the same population.³⁰ *See* Industry Br. at 43-46. Petitioners' brief does not disclose that the Vacek study was financed by the American Chemistry Council's Crystalline Silica Panel, an organization that vehemently opposes OSHA's Silica Rule.³¹ *See* Ex. 1486, p. 318. Regardless of funding, OSHA comprehensively addressed the attributes and drawbacks of both Vacek *et al.* (2011) and Attfield and Costello (2004) in the preamble to the final rule. *See* Preamble at 16335-38. Among other things, Vacek *et al.* (2011) found a statistically significant excess of

³⁰ Similarly, industry petitioners accuse OSHA of “systematically dismiss[ing] . . . studies that cast doubt on the theory that silica exposure causes lung cancer.” Industry Br. at 43. As an illustration, they point to OSHA's treatment of the studies reviewed by Gamble (2011), which re-evaluated the studies relied upon by IARC as the basis for that agency's 2012 reaffirmation that silica exposure causes lung cancer. *See id.* Although IARC found that this body of evidence supported a finding of carcinogenicity, Gamble (2011) came to the opposite conclusion. *See* Ex. 1711, Attachment 1, p. 13. In weighing the studies included in the Gamble review, OSHA considered only the best-designed studies. *Id.* at 36. In contrast, Gamble simply totaled the number of positive and negative studies to draw his conclusion on causation. *See id.* OSHA's approach was more analytically appropriate and the fact that its conclusion on causation is in accordance with that of IARC, the most authoritative cancer agency in the world, lends it legitimacy.

³¹ Many of the Panel's members are also petitioners in this litigation. *See* Ex. 2307, Attachment A, n.1; Industry Br. at i-ii.

lung cancer (almost 100 excess lung cancer deaths) in the cohort that the authors could not explain. *See* Preamble at 16335. In contrast to Attfield and Costello, the Vacek study also failed to account for a healthy worker survivor effect,³² even though an independent analysis found evidence of this effect in the Vermont granite worker cohort.³³ *See* Preamble at 16336-38. OSHA was particularly concerned that the exposure estimate in the Vacek study for “channel bar operators” was much lower than the Attfield and Costello study’s estimate (from Davis *et al.* (1983), Ex. 0999) for this job category. *Id.* Because this job occurred frequently, changing the exposure estimate for channel bar operators could have, according to NIOSH, “‘major consequences’ on the exposure-response analysis.” Preamble at 16337 (quoting Ex. 4233, p. 22). In any event, the Vacek study found a statistically significant association between cumulative silica exposures and death from both silicosis and other non-malignant respiratory diseases in the cohort of granite workers it studied. *See* Ex. 1486, p. 312. Therefore, even if the Vacek

³² The healthy worker survivor effect occurs when less healthy workers transfer into less labor-intensive jobs due to illness or decreased physical fitness, or leave the workforce early due to exposure-related illness prior to the start of follow-up in the study. Preamble at 16336. As a result, the healthier workers accumulate the highest exposures such that the risk of disease at higher exposures may appear to be constant or decrease. *Id.*

³³ The approach taken by Attfield and Costello (2004) is supported by Applebaum *et al.* (2007), which found that a healthy worker survivor effect was present in the data relied upon by Attfield and Costello (2004). *See* Preamble at 16336-37; Applebaum *et al.* (2007), cited in Ex. 2307, Attachment 6, p. 3.

study does not support a direct link between silica and lung cancer, it supports OSHA's overall finding of significant risk of material harm for workers who are exposed to silica.

Moreover, the Attfield and Costello study is not the only study OSHA relied on in estimating lung cancer risk. As summarized in Table A and explained above, OSHA's conclusions regarding disease risk from silica exposure within the ranges of regulatory interest (25 $\mu\text{g}/\text{m}^3$ to 500 $\mu\text{g}/\text{m}^3$) are based on its analyses of numerous epidemiological studies and were finally formed only after the peer review and public comment processes concluded. *See* Preamble at 16380-81. In choosing the body of studies on which to rely, OSHA used rigorous, objective criteria for study selection precisely to avoid the type of "confirmation bias" industry petitioners accuse the Secretary of applying.³⁴ *See, e.g.*, Industry Br. at 23, 43, 48; *supra* pp. 24-34.

³⁴ As to industry petitioners' criticism of the range of silicosis risks estimated based on the two Chen *et al.* studies (2001, 2005), the range is not as great as petitioners attempt to make it out to be; nor is it obviously out of line with the risks estimated based on other studies. *See* Industry Br. at 37-39. For example, at 25 $\mu\text{g}/\text{m}^3$, the risks based on Chen 2001 and 2005 range from 5 to 40 workers out of 1000; at 50 $\mu\text{g}/\text{m}^3$, the range is from 20 to 170. *See supra* Table A. The estimates from the other three studies range from 6 to 31 at 25 $\mu\text{g}/\text{m}^3$ and from 55 to 127 at 50 $\mu\text{g}/\text{m}^3$. *Id.* Regardless, the critical point is that both Chen studies demonstrate clearly significant risks in the worker populations they studied, as do the multiple other studies OSHA used to estimate silicosis morbidity risks. *Id.*

In making its risk determinations, OSHA may – as it did here – rely on the cumulative evidence found in a body of studies; courts do not “seek a single dispositive study that fully supports [OSHA’s] determination.” *Ethylene Oxide*, 796 F.2d at 1495 (OSHA’s “decision may be fully supportable if it is based . . . on the inconclusive but suggestive results of numerous studies”). Indeed, as recognized by the American Public Health Association, “[t]he agency has relied on the best available evidence and acted appropriately in giving greater weight to those studies with the most robust designs and statistical analyses.” Preamble at 16362 (quoting Ex. 2178, Attachment 1, p. 1). Thus, even if the studies that petitioners allege are particularly afflicted by uncertainty and bias (marked with asterisks in Table A) are discounted, the remaining studies would provide adequate support for OSHA’s overall conclusion that significant risk exists at the former PELs.

F. *Substantial Evidence Supports OSHA’s Use of Cumulative Exposure as an Appropriate Exposure Metric.*

Industry petitioners also criticize OSHA for its use of cumulative exposure (average exposure concentration multiplied by duration of exposure) as the exposure metric to quantify exposure-response relationships in OSHA’s risk assessment. They claim that this metric ignores the role of short-term, high exposures in causing disease. *See* Industry Br. at 16-17, 24, 27-28. This so-called “dose-rate effect” refers to “a non-linearity in the exposure-response whereby a

given increase in intensity of exposure will cause a greater than proportional increase in risk.”³⁵ Ex. 1716, p. 166. Petitioners argue, without supporting evidence, that more recent cases of silicosis are caused not by regular exposures at levels near the former and new PELs but by shorter-term, higher exposures above those PELs. *See* Industry Br. at 24-30.

OSHA’s use of the cumulative exposure metric was appropriate for several reasons. First, cumulative exposure is a driver of chronic diseases such as silicosis and lung cancer. Preamble at 16368, 16374-75. Second, cumulative exposure was used by each of the key epidemiological studies OSHA relied upon to estimate risks. *Id.* at 16374-75. Third, using a cumulative exposure metric (expressed as $\text{mg}/\text{m}^3\text{-yrs}$) accounts for both exposure intensity and duration, while using an exposure intensity metric (expressed as $\mu\text{g}/\text{m}^3$) alone ignores the influence of exposure duration. *Id.* at 16375. As peer reviewer Dr. Kenneth Crump noted, “[e]xposure to a particular air concentration for one week is unlikely to carry the same risk as exposure to that concentration for 20 years, although the average exposures are the same.” Preamble at 16375 (quoting Ex. 1716, p. 166); *see also* Tr. 127 (NIOSH concurring).

³⁵ A dose-rate effect is said to exist when short-term exposure to high concentrations results in greater risk than longer-term exposure to lower concentrations although both result in the same cumulative exposure. Preamble at 16375.

Many experts supported OSHA's reliance on cumulative exposure, with NIOSH calling cumulative exposure a "very high confidence choice." See Preamble at 16363 (quoting Tr. 150-51). Dr. Kyle Steenland, author of numerous studies on the health effects of silica exposure, referred to cumulative exposure as "the best predictor of chronic disease." *Id.* at 16375 (quoting Tr. 1227). Thus, substantial evidence amply supports OSHA's use of cumulative exposure as a reasonable exposure metric on which to base estimates of risk to silica-exposed workers.

Although it is difficult to analyze for a dose-rate effect,³⁶ OSHA reviewed two studies – Buchanan *et al.* (2003), Ex. 0306; Hughes *et al.* (1998), Ex. 1059 – that examined dose-rate effects on silicosis exposure-response relationships; neither found a dose-rate effect relative to cumulative exposure at silica concentrations anywhere near 100 $\mu\text{g}/\text{m}^3$.³⁷ See Preamble at 16375 (citing Ex. 1711, pp. 342-44). In addition, NIOSH conducted a dose-rate analysis for silicosis

³⁶ NIOSH stated that a "detailed examination of dose rate would require extensive and real time exposure history which does not exist for silica (or almost any other agent)." Preamble at 16375 (quoting Ex. 4233, p. 36). Peer reviewer Dr. Crump concurred that "it may be difficult to account for [a dose-rate effect] quantitatively." *Id.* at 16375 (quoting Ex. 1716, p. 167).

³⁷ These studies did observe a dose-rate effect, but only at silica concentrations far above the previous PEL. See Preamble at 16375. OSHA used the model from the Buchanan study in its silicosis morbidity risk assessment to account for possible dose-rate effects at very high average silica concentrations. *Id.*

incidence with data from a Chinese tin miners cohort, and concluded that the best fit to the data was cumulative exposure with no dose-rate effect. *See* Preamble at 16375 (citing Ex. 4233, pp. 36-39). Accordingly, OSHA properly determined that record evidence does not support a dose-rate effect at exposure concentrations relevant to the Silica Rule and clearly elucidated its reasoning in the Rule's preamble. *See AFL-CIO v. Marshall*, 617 F.2d at 651-52 (in reviewing an OSHA standard, "the court does not reach out to resolve controversies over technical data," instead requiring "[e]xplicit explanation for the basis of the agency's decision.").

G. *Substantial Evidence Supports OSHA's Inclusion of the Brick Manufacturing Industry in the Scope of the Silica Rule.*

Industry petitioners assert that brick manufacturing facilities should be exempt from the scope of the general industry standard because unique properties of the silica used in brick manufacturing – including that the quartz particles are coated in aluminum-rich clay – reduce its toxicity such that it does not pose a significant risk to workers. *See* Industry Br. at 122-31. This issue was thoroughly considered during the rulemaking, *see* Preamble at 16376-79, and OSHA's decision not to exempt brick manufacturing (*i.e.*, exposures from silica-containing brick clay) from the scope of the standard is supported by substantial evidence and is reasonable. *See Lead I*, 647 F.2d at 1309 (OSH Act requires OSHA to protect all workers).

Contrary to petitioners' assertion that OSHA ignored data relevant to the brick industry, Industry Br. at 129, OSHA in fact "gave separate consideration to every point raised before it" by the industry. *See Am. Dental Ass'n v. Martin*, 984 F.2d 823, 826-27 (7th Cir. 1993). As the industry itself acknowledged, *see* Tr. 679, 692, only one study – Love *et al.* (1999), Ex. 0369, a study of silicosis among almost 2000 workers at brick plants in England and Scotland – presented exposure-response information specific to this industry. Although this study did not examine effects among retirees, which results in underestimated risks, it still reported sufficient cases of silicosis to exceed OSHA's 1 in 1000 (0.1%) benchmark for significant risk.³⁸ *See* Preamble at 16378; Ex. 0369. In workers aged fifty-five and older – the age category most likely to have had sufficient time since first exposure to develop detectable lung abnormalities – prevalence of abnormal x-rays ranged from 2.9% (at relatively low cumulative exposures) to 16.4% (at higher exposures). *Id.* at 16378 (citing Ex. 0369, Table 4). Notably, the study's authors stated that their findings "suggest[ed] considerable risks of radiological abnormality" at the prior general industry PEL of 100 $\mu\text{g}/\text{m}^3$. *Id.* at 16378 (quoting Ex. 0369, p. 132). Therefore, although OSHA is not required to

³⁸ Because there is no dispute that the Love study is the best available evidence regarding silica risk specific to the brick industry, *Tex. Indep. Ginners Ass'n. v. Marshall*, 630 F.2d 398, 407 (5th Cir. 1980), poses no obstacle to OSHA's determination of significant risk for the industry. *See* Industry Br. at 125.

“disaggregate the risk industry by industry,” *American Dental Ass’n*, 984 F.2d at 827, the best available evidence specific to the brick industry supports a finding of significant risk at the previous PEL, consistent with OSHA’s overall risk assessment for general industry. Accordingly, OSHA was required to include silica exposure in brick manufacturing within the scope of the Silica Rule.³⁹ *See Nat’l Cottonseed Prod. Ass’n v. Brock*, 825 F.2d 482, 485 n.1 (D.C. Cir. 1987) (once a significant risk is demonstrated, OSHA is compelled to adopt regulations providing maximum protection feasible); *United Steelworkers of Am. v. Auchter*, 763 F.2d 728, 738 (3d Cir. 1985) (“the Secretary may exclude a particular industry only if he informs the reviewing court, not merely that the sector selected for coverage presents greater hazards, but also why it is not feasible for the same

³⁹ The cases cited by industry petitioners – *National Grain & Feed Ass’n v. OSHA*, 866 F.2d 717 (5th Cir. 1988) and *American Dental Ass’n*, 984 F.2d 823 – do not undermine OSHA’s treatment of the brick industry. In *National Grain & Feed Ass’n*, the court upheld OSHA’s exclusion of grain mills from an action level for certain limits on dust accumulation in part because the exclusion was based on a rational conclusion that mill workers, unlike grain elevator workers, were both less at risk and sufficiently protected from explosion hazards due to different working conditions and other requirements in the rule. *See* 866 F.2d at 735-37. The court in *American Dental Ass’n* upheld OSHA’s decision not to exclude the dental industry from the bloodborne pathogens standard because dentists, like hospital workers, face a “nontrivial” risk of infection from splattered blood. *See* 984 F.2d at 827-28. In those cases, as in the Silica Rule, OSHA included provisions to protect workers who were found to be at significant risk.

standard to be applied in other sectors where workers are exposed to similar hazards”).⁴⁰

OSHA’s exemption of “[e]xposures that result from the processing of sorptive clays” from the general industry standard, 29 C.F.R.

§ 1910.1053(a)(1)(iii), only underscores the care with which OSHA made its decisions regarding the scope of the standard. *See* Industry Br. at 127-29. Like the brick industry, the Sorptive Minerals Institute argued that the silica in sorptive clays does not pose the same health risk as the silica encountered in other types of work.⁴¹ Preamble at 16379-80. After extensive analysis, OSHA found there was insufficient evidence on the magnitude of the lifetime risk resulting from exposure to silica in sorptive clays, and therefore decided to retain the previous PEL for that industry. *See id.* at 16376-80, 16398; 29 C.F.R. §§ 1910.1000 Table Z-3, 1910.1053(a)(1)(iii). OSHA did not similarly exempt exposure to silica from brick

⁴⁰ The footnote in *Industrial Union Department, AFL-CIO v. Hodgson*, 499 F.2d 467, 480 n.31 (D.C. Cir. 1974) cited by industry petitioners is distinguishable because it concerns differentiating industries based on compliance capabilities, not significant risk.

⁴¹ Sorptive clays come from bentonite deposits, which contain “geologically ancient” quartz. Preamble at 16376-77, 16379. Products in the sorptive clay industry are not heated to high temperatures or fractured as part of the manufacturing process, distinguishing them from brick and pottery clays. *Id.* at 16376-77. Because of these factors, among others, OSHA believes “that silica in bentonite clay is of lower toxicologic potency than that found in other industry sectors.” *Id.* at 16379.

clay because the best available evidence demonstrates significant risk in brick manufacturing.⁴² *See Benzene*, 448 U.S. at 656; *Cotton Dust*, 452 U.S. at 491-92; *Nat'l Cottonseed Prod. Ass'n*, 825 F.2d at 485 n.1.

III. Substantial Evidence Supports OSHA's Finding that the Silica Rule Is Technologically Feasible for Foundries, Fracking, and Construction.

After extensive review of the evidence, OSHA determined that the typical firm in all industries affected by the Silica Rule will be able to reduce exposures to the PEL in most operations, most of the time. These technological feasibility findings should be affirmed by the Court. In promulgating standards dealing with toxic materials or harmful physical agents, including silica, the OSH Act requires OSHA to set the standard that eliminates the risk of material health impairment "to the extent feasible." 29 U.S.C. § 655(b)(5). The Supreme Court has broadly interpreted feasibility to mean "capable of being done" both technologically and economically. *Cotton Dust*, 452 U.S. at 509-10.

⁴² Because substantial evidence supports OSHA's determination that workers in the brick manufacturing industry are indeed exposed to significant risk from silica, industry petitioners' cost argument concerning the brick industry, Industry Br. at 130-31, is foreclosed absent a showing of economic infeasibility for this industry. *See Cotton Dust*, 452 U.S. at 491 (OSHA may not base a health standard on a cost-benefit analysis); *Pub. Citizen v. OSHA (Chromium)*, 557 F.3d 165, 189 (3d Cir. 2009) (argument that OSHA failed to show reasonable relationship between compliance costs and benefits to workers "predicated on a clear misstatement of law").

Courts have interpreted technological feasibility to mean that a typical firm in each affected industry will reasonably be able to implement engineering and work practice controls that can reduce workers' exposures to a PEL in most operations most of the time. *See Lead II*, 939 F.2d at 990 (“[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time”); *Lead I*, 647 F.2d at 1272 (“OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.”). However, “insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA’s concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility.” *Lead I*, 647 F.2d at 1272.

OSHA standards may be “technology forcing,” *i.e.*, where OSHA gives an industry a reasonable amount of time to “develop and diffuse new technology[,]” OSHA is not bound by the “technological status quo.” *Id.* at 1264. A standard limiting toxic chemical exposures is technologically feasible if “modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.” *Lead II*, 939 F.2d at 980 (quoting *Lead I*, 647 F.2d at 1266). OSHA is “not obliged to provide detailed solutions to every engineering

problem,’ but only to ‘give plausible reasons for its belief that the industry will be able to solve those problems in the time remaining.’” *Kennecott Greens Creek*, 476 F.3d at 957 (citation omitted).

Because OSHA’s feasibility analysis typically requires projections from the known to the unknown, the Court “cannot require of OSHA anything like certainty.” *Lead I*, 647 F.2d at 1266. Courts grant OSHA significant deference when reviewing technological feasibility findings. *See Lead II*, 939 F.2d at 980 (“If OSHA makes reasonable predictions based on ‘credible sources of information’ (e.g., data from existing plants and expert testimony), then the court should defer to OSHA’s feasibility determinations.”) (quoting *Lead I*, 647 F.2d at 1266). Any uncertainty in OSHA’s feasibility determination is counterbalanced by flexibility in the standard’s enforcement, as a finding by OSHA that a standard is feasible does not preclude an employer from raising a defense of infeasibility in an enforcement proceeding. *See Lead II*, 939 F.2d at 980 (possibility of reexamining feasibility during an enforcement action “greatly ease[s] OSHA’s preliminary burden of proving feasibility”) (citation and quotation marks omitted).

Industry petitioners do not challenge OSHA’s overall technological feasibility findings or methodology. Instead, their challenge is confined to OSHA’s technological feasibility findings with respect to the foundry, fracking, and construction industries. *See Industry Br.* at 55-69, 85-105. As explained

below, OSHA's technological feasibility findings for these industries are supported by substantial evidence in the record, and the industry petitioners' claims lack merit.

A. *OSHA Performed a Comprehensive and Legally Sufficient Technological Feasibility Analysis.*

Fulfilling its mandate to set the standard that eliminates the risk of material impairments "to the extent feasible," 29 U.S.C. § 655(b)(5), OSHA performed a technological feasibility analysis for twenty-four industry sectors in general industry and maritime, and twelve "application groups" (reflecting specific activities performed) in construction.⁴³ See Preamble at 16433, 16433 n.21, 16455 (Table VII-8), 16459 (Table VII-9). Within each industry sector and application group, OSHA identified the job categories or tasks that involve silica exposure. OSHA then developed exposure profiles quantifying workers' current levels of exposure in those jobs or tasks, identified the jobs or tasks for which employers

⁴³ OSHA's complete technological feasibility analysis is at Chapter IV of the Final Economic Analysis, Ex. 4247. A summary is found at Preamble pages 16432-62. OSHA identified affected general industry sectors primarily based on the type of product manufactured (*e.g.*, concrete products, pottery, glass) or type of process used (*e.g.*, foundries, mineral processing, refractory repair). Preamble at 16433, 16455. For the construction industry, OSHA identified application groups based on the activities, tasks, or equipment associated with silica exposures. *Id.* at 16433. By using application groups, OSHA was able to group employees who perform the same types of activities across all segments of the construction industry. *Id.* at 16434.

will need additional controls to comply with the new PEL, and, for each affected job or task, evaluated the ability of engineering and work practice controls to reduce current exposures to or below the PEL.⁴⁴ *See id.* at 16432-36; *see also* Ex. 4247, Ch. IV.

In characterizing baseline (current) exposures, OSHA relied on information and exposure measurements from OSHA's extensive inspection database, over 200 reports from inspections conducted under OSHA's Special Emphasis Program for silica,⁴⁵ almost 100 NIOSH reports, site visits conducted by NIOSH and OSHA's contractor, and materials from other federal and state agencies, labor organizations, industry associations, and equipment manufacturers. Preamble at 16433-34. OSHA also reviewed studies evaluating the effectiveness of engineering controls and work practices and considered the extensive testimony and comments submitted to the record. *See id.* at 16433. The resulting exposure profiles reflect the results of 3364 personal breathing zone air samples obtained on worksites throughout the United States. Ex. 4247, Ch. IV, p. 22.

⁴⁴ Engineering controls address silica-containing dust particles at the source of exposure. Preamble at 16781-82, 16784. Work practice controls systemically modify how employees perform an operation, and often relate to the way employees use engineering controls. *Id.* at 16785.

⁴⁵ In 1996, OSHA initiated a Special Emphasis Program for silica enforcement in an effort to reduce workers' silica exposure. Preamble at 16295.

To determine whether the new PEL is technologically feasible for each job and task, OSHA evaluated the extent to which engineering and work practice controls can reduce workers' baseline silica exposures to 50 $\mu\text{g}/\text{m}^3$ or below. Preamble at 16436. For each job or task, OSHA either identified controls that have been demonstrated to reduce exposures to the PEL or evaluated the extent to which baseline exposures would be reduced after applying a percentage reduction in exposures that has been demonstrated for a given control in the job or task at issue or in analogous jobs or tasks. *Id.* OSHA found that controls – most commonly, local exhaust ventilation (LEV) or wet methods – will generally reduce silica exposures for most operations to the new PEL. *Id.* at 16453-54.

In general industry and maritime, the additional controls OSHA identified consist of equipment and work practices that OSHA determined are widely available and already used in many applications. *See id.* at 16436. For all twenty-four industry sectors (and eighty-seven of the ninety job categories in those sectors) in general industry and maritime, OSHA found that it is technologically feasible (*i.e.*, achievable for most operations or job categories, most of the time) to reduce exposures to the new PEL using engineering and work practice controls. *Id.* at 16454-55.

For construction, OSHA found that the controls listed on Table 1 are either commercially available from tool and equipment manufacturers or (in the case of

jackhammers) can be fabricated from readily-available parts. *Id.* at 16436, 16458.

It further found that available engineering and work practice controls can reduce exposures to or below the new PEL most of the time for the vast majority of tasks (nineteen of twenty-three) performed across the twelve application groups, and for almost all of the application groups overall, and thus concluded that the PEL is technologically feasible for the construction industry as a whole.⁴⁶ *Id.* at 16458-59.

Relying on one of the largest databases OSHA has ever used to evaluate the feasibility of a health standard, OSHA concluded the new PEL is technologically feasible for all affected industries. *See id.* at 16433, 16455-61. OSHA's findings for all affected industries that workers' exposures can be reduced to the new PEL in most operations most of the time, is therefore supported by substantial evidence in the record and should be upheld. *See Lead II*, 939 F.2d at 990.

B. *The Silica Rule Is Technologically Feasible for the Foundry Industry.*

Foundries melt and cast metal into molds to produce castings; depending on the casting processes used, foundry workers are exposed to silica-containing materials. *See Ex. 4247*, Ch. IV, pp. 225-26. Industry petitioners contend that

⁴⁶ In the limited situations where OSHA expects exposures to remain above 50 $\mu\text{g}/\text{m}^3$ even after implementation of Table 1 controls, Table 1 requires respiratory protection. *See* 29 C.F.R. § 1926.1153(c). Based on the typical location and duration of Table 1 activities (*e.g.*, outdoors, for four hours or less), most of the time respirators will not be necessary to reduce exposures to the new PEL. *See Preamble* at 16458, 16724, 16730-31.

demonstrating feasibility of the PEL requires OSHA to demonstrate it is feasible to reduce exposures well below the PEL virtually all the time. *See, e.g.*, Industry Br. at 57-58. This argument lacks any basis in law or logic. OSHA's feasibility findings were based on the best available evidence – including the American Foundry Society's (AFS) own data, which show that foundries already have reduced exposures to the new PEL in most operations, most of the time.

1. OSHA Reasonably Found that the Foundry Industry Can Meet the New PEL in Most Operations, Most of the Time.

OSHA evaluated the feasibility of the new PEL in the foundry industry by analyzing three subsectors – ferrous, nonferrous, and non-sand casting – which are distinguished by the types of metals and processes used to cast molds. *See* Ex. 4247, Ch. IV, pp. 225-353. Within each of these subsectors, OSHA evaluated twelve affected job categories, or operations. *See* Preamble at 16455; *see also*, *e.g.*, Ex. 4247, Ch. IV, pp. 230-31. The record evidence demonstrates that the new PEL is technologically feasible for all twelve operations in all subsectors. *See* Preamble at 16454-55; Ex. 4247, Ch. IV, pp. 225-353.

To characterize workers' exposures in these twelve job categories, OSHA compiled data from industrial hygiene literature, exposure monitoring from visits to worksites, OSHA Special Emphasis Program inspection reports, NIOSH reports, state program reports, and OSHA enforcement data. Ex. 4247, Ch. IV, pp. 231-32. In total, OSHA evaluated 1267 personal breathing zone samples from nearly 100

foundries. Ex. 4247, Ch. IV, p. 232. OSHA also considered summary data submitted by the United Auto Workers and a survey submitted by AFS. *See* Ex. 4247, Ch. IV, p. 232-33. Notably, the survey submitted by AFS showed that most affected foundry workers (67%) are already exposed to silica at or below 50 $\mu\text{g}/\text{m}^3$. *See* Ex. 2379, Attachment B, p. 27, Table 6; Ex. 4247 Ch. IV, p. 233.

OSHA concluded that the new PEL is technologically feasible for all three subsectors because employers can reduce exposures to 50 $\mu\text{g}/\text{m}^3$ using engineering and work practice controls for all twelve job categories in each subsector, most of the time. *See* Preamble at 16454-55; *Lead II*, 939 F.2d at 990 (PEL is feasible if it can be met in “most operations most of the time”). Included within the finding of overall technological feasibility for foundries was a finding that some supplemental respirator use may be necessary for a limited number of employees performing certain tasks. *See* Preamble at 16454. This supplemental use of respirators, however, does not “undermine th[e] general presumption in favor of feasibility.” *See Lead I*, 647 F.2d at 1272.

2. Exposure Variability Does Not Render the New PEL Infeasible.

Notwithstanding OSHA’s finding – and the AFS survey’s showing – that 50 $\mu\text{g}/\text{m}^3$ can be achieved for most operations most of the time in the foundry industry, industry petitioners argue that OSHA has not demonstrated that the PEL is feasible because OSHA has not proved that foundries can reduce exposures to 50 $\mu\text{g}/\text{m}^3$ on a

“consistent basis.” Industry Br. at 57-58. According to industry petitioners, to demonstrate that $50 \mu\text{g}/\text{m}^3$ is feasible, OSHA must prove that employers can reduce exposures far below $50 \mu\text{g}/\text{m}^3$, *e.g.*, to $20 \mu\text{g}/\text{m}^3$, in order to have 84% confidence that they would never exceed the PEL due to alleged unpredictable exposure variations. *See id.*; *see also* Ex. 2379, Attachment B, p. 14 (“compliance requires reducing the mean exposure far enough below the PEL to assure compliance [in every sample] with some level of confidence”).

Petitioners’ argument that the PEL is only feasible if exposures in the workplace are below the PEL virtually all of the time reflects a fundamental misunderstanding of the legal test for technological feasibility. *See Lead I*, 647 F.2d at 1270 (“the court would not expect OSHA to prove the standard certainly feasible for all firms at all times in all jobs.”). Rather, feasibility depends on whether the PEL can be met “in most operations *most of the time.*” *Lead II*, 939 F.2d at 990 (emphasis added). The existence of variability does not change the legal test for technological feasibility. *See Asbestos*, 838 F.2d at 1268 (applying *Lead I* test to find PEL feasible despite presence of random exposure variability). And industry petitioners cite no law in support of their argument that OSHA must prove that some level of exposure significantly (and consistently) *lower* than $50 \mu\text{g}/\text{m}^3$ is feasible to demonstrate that the PEL of $50 \mu\text{g}/\text{m}^3$ is feasible.

Further, the record does not support industry petitioners' claim that exposure variability poses a challenge unique to the foundry industry.⁴⁷ Industry Br. at 55-56 (referencing AFS testimony that foundries are "particularly susceptible to significant and unpredictable swings in exposure to silica"). The cited testimony from AFS's Director of Marketing, Communications, and Public Relations does not mention any unpredictable exposure swings unique to the foundry industry. *See* Tr. 2633-34. Moreover, AFS's own guidance document on controlling silica exposures identifies process variables and activities affecting exposure, indicating the industry has a well-developed understanding of typical exposure sources and how to minimize exposure variability. *See* Ex. 3733, pp. 2-4 to 2-5.

Rather than ignore exposure variability, *see* Industry Br. at 59, OSHA thoroughly addressed variability in finding the PEL feasible.⁴⁸ Preamble at 16459-60; Ex. 4247, Ch. IV, pp. 9-11. OSHA acknowledged that environmental factors (such as wind, humidity, and silica content of the material used) can affect exposure levels, but determined that not all variability is due to random variation

⁴⁷ The existence of exposure variability is not unique to silica: OSHA has considered it in other rulemakings involving toxic chemical exposures where the same issue was raised. *See* Ex. 4247, Ch. IV, p. 9.

⁴⁸ Given that OSHA analyzed 1267 personal breathing zone samples from almost 100 foundries, any variability in sampled exposures was necessarily part of OSHA's evaluation. *See* Ex. 4247, Ch. IV, pp. 231-32.

or environmental factors; much of the variability observed for silica exposures is predictable and within the employer's control, and the consistent use of engineering controls reduces overall variability. Preamble at 16460; Ex. 4247, Ch. IV, pp. 9-11; Ex. 4234, Attachment 2, pp. 31-39; Tr. 971, 4251-52. OSHA relied on studies in the record reporting that up to 80% of variability in silica exposures can be attributed to factors that are observable and controlled by the employer (*e.g.*, whether the work is performed indoors or outdoors, the type of equipment used, and the type of controls used).⁴⁹ Preamble at 16460; Ex. 4247, Ch. IV, p. 10; Exs. 3608, 3803, 3956, 3998, Attachments 5h, 13i.

OSHA recognized that controls cannot eliminate *all* variability, however. *See* Preamble at 16460. OSHA therefore committed to a flexible enforcement policy giving OSHA inspectors discretion to conduct a follow-up inspection rather than issuing a citation when an employer's air monitoring data suggest that sampling results obtained during an OSHA inspection are not representative of normal exposure levels at the site. *Id.* at 16460, 16757-58. This discretion is in addition to OSHA's standard practice of accounting for sampling and analytical

⁴⁹ OSHA did not find, as industry petitioners claim, that "lower exposure levels are associated with reduced variability." Industry Br. at 59. Rather, based on several studies using multivariate statistical models and testimony from industrial hygienists, OSHA found that the consistent use of engineering controls and appropriate work practices reduces exposure variability. Ex. 4247, Ch. IV, p. 10.

error by providing a margin of error above the PEL before OSHA issues a citation for violating the PEL. *Id.* at 16447. Given the extent to which controls can reduce variability and its flexible enforcement policy, OSHA found that the potential for exposure variability did not undermine its technological feasibility findings.

Preamble at 16460; *Asbestos*, 838 F.2d at 1268 (PEL feasible despite presence of random exposure variability, particularly in light of OSHA's enforcement policy allowing it to account for uncontrollable fluctuations before issuing a citation).⁵⁰

Finally, OSHA's finding that the new PEL is feasible does *not* mean that an employer violates the standard whenever silica exposures exceed the PEL. The Silica Rule explicitly contemplates that the PEL may not always be achieved through engineering and work practice controls, and an employer can avoid citation by showing that controls to achieve the PEL are infeasible in its particular workplace. 29 C.F.R. § 1910.1053(f)(1). Accordingly, industry petitioners' argument that an employer will be cited for violating the PEL when unpreventable exposure variability renders the PEL infeasible, *see* Industry Br. at 58, is wrong. Moreover, although petitioners do not mention it, the ability to raise an infeasibility defense in an

⁵⁰ Industry petitioners' attempts to distinguish *Asbestos* lack merit. *See* Industry Br. at 60-61 n.43. In the asbestos rulemaking, like the silica rulemaking, industry argued that variability rendered the PEL effectively infeasible. *See Asbestos*, 838 F.2d at 1267. Contrary to petitioners' claim, there is nothing to support their argument that exposure variability was "not at all as significant" in the asbestos rulemaking, Industry Br. at 60, n.43, and OSHA has clearly articulated its enforcement position in the preamble. *See* Preamble at 16757-58.

enforcement action “greatly ease[s] OSHA’s preliminary burden of proving feasibility.” *Lead II*, 939 F.2d at 980 (citation and quotation marks omitted).

3. OSHA Relied upon the Best Available Evidence in Determining that the New PEL Is Feasible for the Foundry Industry.

Industry petitioners argue that the best available evidence in the record shows that the PEL of 50 $\mu\text{g}/\text{m}^3$ is infeasible because numerous foundries were unable to comply with the prior PEL of 100 $\mu\text{g}/\text{m}^3$. *See* Industry Br. at 61-63. Quite the contrary: the best available evidence in the record – including AFS’s own data – demonstrates the foundry industry’s ability to reduce the exposures to 50 $\mu\text{g}/\text{m}^3$ in most operations most of the time. Contradicting petitioners’ argument, AFS’s own data show that 87% of exposure samples in the foundry industry were at or below the prior PEL, even before accounting for the possibility of additional controls to further lower exposure levels. *See* Ex. 4247, Ch. IV, p. 234.

The three Special Emphasis Program reports that the industry petitioners rely on do not show that the prior PEL was infeasible.⁵¹ *See* Industry Br. at 61-62. In the first place, none of the reports actually shows an inability to comply with the prior PEL. *See* Exs. 0028, 0130, 0132. The first report, Ex. 0130, stated that the

⁵¹ To the extent that industry petitioners seek to incorporate AFS’s comments during the rulemaking, *see* Industry Br. at 63-64, in which AFS identified purported flaws in the studies used by OSHA, OSHA fully responded to these comments in the Final Economic Analysis. Ex. 4247, Ch. IV, pp. 225-353.

foundry evaluated was able to reduce a sand system operator's exposures to 20 $\mu\text{g}/\text{m}^3$ and 24 $\mu\text{g}/\text{m}^3$ after installing LEV; AFS claimed that it "learned that this foundry . . . has not been able to achieve compliance without respiratory protection[,]'" but AFS provided no basis for this claim. Industry Br. at 61 (citing Ex. 2379, Appendix. 2, p. 3). The second report noted that follow-up sampling revealed "no employee over-exposure . . . to respirable silica dust on the day of the survey."⁵² Ex. 0132, p. 241. Finally, the third report, Ex. 0028, contained three samples that indicated compliance with the prior PEL. Given the extensive body of evidence, including AFS evidence, that OSHA relied upon in making its feasibility findings, there is ample evidence demonstrating that the typical foundry can reduce exposures to the new PEL. *See Lead I*, 647 F.2d at 1272 ("OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.").

Industry petitioners also broadly argue that OSHA relies on "wholly unpersuasive data" in making its feasibility findings, and suggest that none of OSHA's feasibility findings for the twelve job categories evaluated are supported by substantial evidence. *See* Industry Br. at 63. However, industry petitioners

⁵² A follow-up letter a year later indicated that only one job (a wheelabrator, which is a shot blasting operation) was not under the prior PEL. *See* Ex. 0132, p. 17.

only specifically challenge findings related to two job categories – sand system operators and finishers.⁵³ *See id.* at 64-65. But even if the PEL were infeasible for two job categories in each of the foundry subsectors, which it is not, the PEL would still be feasible for each foundry subsector overall. *Lead II*, 939 F.2d at 990 (“[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time”). Here, petitioners do not challenge, and thus leave undisturbed, OSHA’s determination that the general industry/maritime standard is technologically feasible for the other ten (of twelve) job categories in each foundry subsector.

In determining the feasibility of the PEL for sand system operators, OSHA evaluated baseline exposure levels and the effectiveness of additional controls to reduce exposures to 50 $\mu\text{g}/\text{m}^3$ or below. Ex. 4247, Ch. IV, pp. 239-40, 260-63.

OSHA concluded that the PEL was feasible for sand system operators, relying

⁵³ Industry petitioners’ arguments appear to focus on the ferrous foundry subsector, perhaps because OSHA’s findings that sand system operators’ and finishers’ exposures can be reduced to the new PEL most of the time in the other subsectors are clearly supported by overwhelming evidence. In nonferrous foundries, 80% of sand system operator exposures have already been reduced to 50 $\mu\text{g}/\text{m}^3$ or below, and 75% of finishing operator exposures have already been reduced to 50 $\mu\text{g}/\text{m}^3$ or below. *See* Ex. 4247, Ch. IV, pp. 323, 329. In non-sand casting foundries, although OSHA was unable to identify any exposure data for sand system operators, OSHA determined these workers’ exposures would likely be lower due to the reduced use of sand. *See* Ex. 4247, Ch. IV, p. 336. In non-sand casting foundries, over 85% of finishing operator exposures have already been reduced to 50 $\mu\text{g}/\text{m}^3$ or below. *See* Ex. 4247, Ch. IV, pp. 346-47.

primarily on an OSHA Special Emphasis Program report and a NIOSH evaluation. Ex. 4247, Ch. IV, pp. 260-63, 303-304.

The Special Emphasis Program report showed that sand system operators' exposures could be reduced up to 82% by implementing several controls, including installing LEV and fixing leaks in the mixer, along with other controls, such as replacing existing equipment with completely enclosed or pneumatic sand processing and transportation equipment, and improving work practices and housekeeping. Ex. 4247, Ch. IV, pp. 260-63, 303-304. In the steel foundry analyzed in the report, this combination of controls effectively reduced exposure to $28 \mu\text{g}/\text{m}^3$. Ex. 4247, Ch. IV, p. 303. The NIOSH evaluation found exposure results below $30 \mu\text{g}/\text{m}^3$ for workers in areas where sand transportation systems were isolated and mullers (mixers) were fitted with ventilation. Ex. 4247, Ch. IV, pp. 240, 303. OSHA determined that an 82% reduction in the exposures currently faced by sand system operators would result in 88% of sand system operators' exposures being at or below new PEL. Ex. 4247, Ch. IV, p. 304.

Industry petitioners raise no issues with the Special Emphasis Program report; instead, they challenge OSHA's reliance on the NIOSH study, arguing that the automation described in it could not be replicated. Industry Br. at 64. AFS raised these same concerns during the rulemaking, and OSHA thoroughly addressed them in the Final Economic Analysis. Ex. 4247, Ch. IV, pp. 261-62.

OSHA noted that AFS did not provide any evidence showing that automation could not be replicated, NIOSH made no mention of it, and automation had been observed in multiple other foundry studies. *Id.* at p. 261-62. Notably, industry petitioners have pointed to no other evidence in the record that OSHA should have considered. OSHA's finding that sand system operators' exposures can be reduced to 50 $\mu\text{g}/\text{m}^3$ most of the time is reasonable, based on credible information, and entitled to deference. *See Lead II*, 939 F.2d at 980 ("If OSHA makes reasonable predictions based on 'credible sources of information' (e.g., data from existing plants and expert testimony), then the court should defer to OSHA's feasibility determinations.").

Likewise, OSHA's finding that the PEL is feasible for cleaning/finishing operators is also based on the best available evidence. OSHA determined that most cleaning/finishing operators' exposures can be reduced to 50 $\mu\text{g}/\text{m}^3$ or below most of the time by pre-cleaning castings, installing LEV, eliminating compressed air cleaning, and using wet methods. Ex. 4247, Ch. IV, pp. 282-90, 312-14. AFS's own survey shows that 62% of cleaning and finishing operators have already achieved exposure levels of 50 $\mu\text{g}/\text{m}^3$ or less. *See* Ex. 4247, Ch. IV, p. 312.

Industry petitioners incorrectly claim that OSHA primarily relied on evidence from non-foundry operations in making its findings. Industry Br. at 64-

65. In fact, OSHA relied primarily on evidence from several NIOSH and OSHA Special Emphasis Program reports from foundries. Ex. 4247, Ch. IV, pp. 282-90, 312-14; Exs. 0081, 0268, 0511, 0718, 1287, 1373, 1381. Petitioners again ignore AFS's own data and other evidence in the record that show the new PEL is feasible and fail to point to any data that OSHA did not consider.⁵⁴ OSHA's findings are reasonably based on studies and data from foundries and are entitled to deference. *See Lead II*, 939 F.2d at 980; *Asbestos*, 838 F.2d at 1266 (“When called upon to review technical determinations on matters to which the agency lays claim to special expertise, the courts are at their most deferential.”).

C. *The Silica Rule Is Technologically Feasible for the Fracking Industry.*

While the fracking industry has existed for decades, the extent of the silica hazard in the industry has only been widely recognized since publication of a NIOSH report in 2010. *See* Preamble at 16456. Nonetheless, substantial progress has already been made in protecting fracking workers from silica. This progress, combined with longstanding precedent that OSHA standards may be technology-

⁵⁴ The only “evidence” petitioners point to is AFS's prehearing comment, which criticized a particular NIOSH foundry study. *See* Ex. 2379, Appendix 2, p. 3. Contrary to petitioners' claim, *see* Industry Br. at 65, the study does not show that the foundry was unable to meet the prior PEL. *See* Ex. 0268. In fact, all samples for cleaners were below 50 $\mu\text{g}/\text{m}^3$, and out of sixty-one samples obtained at this foundry, only three exceeded the previous PEL. *Id.* at pp. 6, 11. NIOSH concluded that “[t]he control systems that are in place appear to be effective at controlling exposures in a difficult work environment.” *Id.* at p. 11.

forcing (*see Lead I*, 647 F.2d at 1264), provides substantial evidence to support OSHA's finding that the industry will be able to comply with the standard within the three additional years – for a total of five years – allowed for this industry.

OSHA reasonably found that the fracking industry can meet the new PEL within the Silica Rule's fracking-specific, five-year compliance deadline. OSHA determined that some engineering controls are already commercially available, and others under development have demonstrated promise. Preamble at 16455.

Although engineering controls have not been widely implemented on fracking sites, OSHA found that almost one-third of all sampled workers were already exposed at or below the new PEL, and determined that the growing availability of controls, further development of emerging technologies, and better use and maintenance of existing controls will be able to reduce exposures to or below the PEL for the remaining operations. Preamble at 16455-56. Given the ongoing progress in the development of controls, OSHA concluded that it is appropriate to provide the fracking industry five years to implement engineering controls.

Preamble at 16455. This extended time period makes petitioners' burden in challenging OSHA's feasibility finding particularly high. *Kennecott Greens Creek*, 476 F.3d at 957 (agency is obliged only to provide "plausible reasons for its belief that the industry will be able to solve [its engineering] problems *in the time remaining*") (citation omitted; emphasis added).

Abundant evidence supports OSHA's determination that the significant efforts currently being made to develop more effective dust controls in the fracking industry will be effective by 2021. *See* Preamble at 16456. A number of effective controls are already commercially available or will be soon. *Id.* at 16455-56; *see also* Ex. 4247, Ch. IV, pp. 642-69. KSW Environmental reported that its LEV system, which controls emissions at several exposure points on a fracking site, has been tested and reduced exposures below 50 $\mu\text{g}/\text{m}^3$. Preamble at 16455. J&J Bodies reported that its dust control system is in use at ten different fracking sites with good results. *Id.* at 16455-56. SandBox Logistics, a manufacturer of a containment system that eliminates most dust emission points on fracking sites, reported that its system is currently in use and its engineers believe the system can be further refined to reduce exposures to the new PEL. Ex. 4247, Ch. IV, pp. 652-54; *see also* Preamble at 16456. OSHA considers other control systems, including dust suppressants and a NIOSH-designed baghouse that has been evaluated in a field test with an industry partner, to be on the "horizon." Preamble at 16456; Ex. 4247, Ch. IV, pp. 649-52, 659-62.

OSHA based the five-year compliance time frame on the substantial progress and innovation displayed since NIOSH publicized findings about widespread overexposure in the industry in 2010. Preamble at 16456. Almost immediately, the fracking industry, through the National Service, Transmission,

Exploration & Production Safety network's Respirable Silica Focus Group, began taking steps to reduce silica exposure on fracking sites, and in 2012, started facilitating and evaluating the development of engineering controls. *Id.* at 16456-57. Since then, the silica control field has grown rapidly, resulting in the development and deployment of the new technologies described above. *Id.* at 16457. For example, SandBox Logistics stated that it took only three years to develop its technology and make it commercially available. *Id.* In light of this substantial progress already made in developing controls in the fracking industry, OSHA considers the silica standard more "market-accelerating" than "technology-forcing." *Id.* OSHA's finding that the new PEL can be achieved within five years is reasonable and therefore valid. *See Lead I*, 647 F.2d at 1264.

Moreover, while industry petitioners allege OSHA did not rely on the best available evidence, Industry Br. at 65-68, they fail to point to any other data that OSHA should have considered. Nor did they supply any useful data in response to OSHA's requests for additional information on current exposures and dust control practices on fracking sites. *See Preamble* at 16456. Even now, industry petitioners provide no evidence for their claim that the PEL is not, and may never be, achievable.⁵⁵ Industry Br. at 69. Their argument ignores the standard for

⁵⁵ While petitioners question the industry's ability to ever reach the PEL, others in the industry expressed confidence that the industry could develop controls to

technological feasibility, which is that a PEL is feasible for an industry if “modern technology has at least conceived some industrial strategies or devices which are likely to be capable of meeting the PEL and which the industries are generally capable of adopting.” *Lead II*, 939 F.2d at 980 (citing *Lead I*, 647 F.2d at 1266).

In contrast, OSHA has demonstrated the rule’s feasibility by “identif[ying] the major steps for improvement and giv[ing] plausible reasons for its belief that the industry will be able to solve those problems in the time remaining.”

Kennecott Greens Creek, 476 F.3d at 957, 960 (mine safety agency provided “more than enough evidence” of feasibility by “identif[ying] several types of control technologies that are effective at reducing . . . exposure,” to conclude that the industry could comply with the two-year implementation date of a technology-forcing standard) (internal citation omitted).

OSHA is not bound by the “technological status quo,” and the Court “cannot require of OSHA anything like certainty” in making its feasibility projections. *Lead I*, 647 F.2d at 1264, 1266. Further, any uncertainty in OSHA’s feasibility finding for the fracking industry is counterbalanced by flexibility in the standard’s enforcement, as an employer may raise an infeasibility defense in an enforcement proceeding. *Id.* at 1273.

reduce exposure to the PEL. As Kenny Jordan of the Association of Energy Service Companies testified at the hearing, “I believe there will be a solution found eventually We’ll depend on good old American ingenuity.” Tr. 4087.

Finally, to the extent that industry petitioners argue that the fracking industry should not have been included in the rule because the industry did not participate in the pre-proposal review process under SBREFA, there is no legal basis for such claim. Under SBREFA, OSHA and the Small Business Administration identify “individuals representative of affected small entities” to provide advice and recommendations to OSHA, but there is no legal requirement that all affected industries be included. *See* 5 U.S.C. § 609(b)(2), (b)(4); Preamble at 16632. Nor is the SBREFA review process judicially reviewable. *See* 5 U.S.C. § 611(a). Moreover, the fracking industry’s absence from SBREFA did not impede its participation in the rulemaking: as Wayne D’Angelo of the American Petroleum Institute testified, the industry “fully participated” in the rulemaking and submitted “extensive comments.” Tr. 4024. OSHA’s findings are based on the data in the record relevant to fracking, are entitled to deference, and should be upheld. *See Kennecott Greens Creek*, 476 F.3d at 954-55; *Lead II*, 939 F.2d at 980.

D. *The Silica Rule Is Technologically Feasible for the Construction Industry.*

A number of silica-generating tasks are performed in the construction industry, often for short periods of time and outdoors. *See* Preamble at 16435, 16724. To simplify compliance for construction employers, OSHA adopted a novel regulatory approach for this industry. The construction standard contains two compliance options: employers must either fully and properly implement the

controls on Table 1, or they may independently assess and reduce workers' silica exposures to the PEL. 29 C.F.R. § 1926.1153(c), (d). Compliance with Table 1 is a "safe harbor" in that it satisfies an employer's duty to achieve the PEL.

Preamble at 16458. Relying on extensive exposure data, industrial hygiene studies, and testimony from industry and worker representatives, OSHA analyzed twenty-three common construction tasks (within twelve application groups) with substantial silica exposure, and reasonably concluded that compliance with both options is technologically feasible. Preamble at 16458-61.

Nineteen of the tasks performed in the construction industry are on Table 1.⁵⁶ 29 C.F.R. § 1926.1153(c)(1)(i)-(xviii). OSHA found that the engineering controls listed on Table 1 are either commercially available from tool and equipment manufacturers or (in the case of jackhammers) can be fabricated from readily-available parts. Preamble at 16458. OSHA therefore determined that the vast majority of employers will follow Table 1 for most tasks, and that use of the Table 1 controls will, with few exceptions, reduce exposures to 50 $\mu\text{g}/\text{m}^3$ most of the time. *Id.* at 16436, 16458. Where OSHA found, in those few exceptions, that exposures would exceed 50 $\mu\text{g}/\text{m}^3$ despite full and proper implementation of the

⁵⁶ Although there are eighteen individual entries on Table 1, one additional task (performed by ground crew assisting equipment operators) is included in the entries for heavy equipment and utility vehicles (29 C.F.R. § 1926.1153(c)(1)(xvii)-(xviii)). *See* Ex. 4247, Ch. IV, pp. 715-35.

controls specified on Table 1, OSHA identified the required level of respiratory protection. *Id.* at 16724.

To analyze feasibility of the PEL for each construction task and determine when respiratory protection is needed, OSHA analyzed personal breathing zone samples and studies in the record. *See* Ex. 4247, Ch. IV, pp. 675-1029. Although construction tasks are often performed outdoors for short durations, higher exposures result if tasks are performed indoors or for long durations; accordingly, whether respiratory protection is required may depend on the location and duration of the task. *See* Preamble at 16724, 16779. OSHA also analyzed typical work patterns to determine how regularly workers would need to use respiratory protection. Ex. 4247, Ch. IV, pp. 675-1029. Based on this analysis, OSHA concluded that most tasks are performed for four hours or less and/or outdoors, and that respiratory protection will not be necessary for the most commonly-encountered work situations and environments specified on Table 1. Preamble at 16458, 16724, 16730-31.

OSHA determined that available engineering and work practice controls can reduce exposures to or below the PEL for the vast majority of tasks (nineteen of twenty-three) performed across the twelve application groups, and nearly all of the application groups overall. Preamble at 16458-59. Substantial evidence supports

this determination. OSHA therefore reasonably concluded that the PEL is technologically feasible for the construction industry. *See* Preamble at 16458.

Industry petitioners raise several arguments attacking OSHA's feasibility findings for the construction industry. Industry Br. at 85-105. They claim that OSHA's findings regarding exposure variability and work patterns are not supported by substantial evidence, and that the PEL is infeasible because respirator use is necessary for some operations and wet methods are not always practical. These claims are contrary to the evidence and controlling legal standards.

1. Exposure Variability Does Not Render the New PEL Infeasible.

Industry petitioners ignore that the Table 1 compliance option does not require separate compliance with the PEL, and thus resolves industry petitioners' exposure variability concerns. *See* Ex. 4247, Ch. IV, p. 11. Instead, petitioners largely repeat the same arguments raised for the foundry industry, claiming that OSHA ignored the best available evidence of exposure variability in the construction industry and contending that construction employers actually need to reduce exposures well below $50 \mu\text{g}/\text{m}^3$ so that 95% of exposures are at or below the PEL. *See* Industry Br. at 86. These arguments are as unpersuasive for construction as they are for foundries.

In any event, OSHA thoroughly considered evidence related to exposure variability, and addressed variability issues specifically related to the construction

industry.⁵⁷ *See* Ex. 4247, Ch. IV, pp. 9-11. OSHA acknowledged that environmental factors can affect employee exposure, but determined that much of the variability observed is predictable and within the employer's control. *See* Preamble at 16459-60; Ex. 4247, Ch. IV, pp. 9-10; Ex. 4234, Attachment 2, pp. 31-39; Tr. 971, 4251-52. Comments from industrial hygienists and several studies using multivariate statistical models showed that up to 80% of variability can be attributed to factors that are observable and controlled by the employer. *See* Ex. 4247, Ch. IV, p. 10. OSHA therefore found that the consistent use of engineering controls and appropriate work practices reduces exposure variability. *Id.*

This finding is reasonable. First, as fully explained above, *supra* pp. 75-76, technological feasibility depends not on whether the PEL can be achieved 95% of the time, but on whether the PEL can be met “in most operations most of the time.” *Lead II*, 939 F.2d at 990. The existence of variability does not change the legal test for technological feasibility. *See Asbestos*, 838 F.2d at 1268 (PEL feasible despite random exposure variability).

Second, for employers not utilizing Table 1, as explained above, pp. 78-79, OSHA has committed to a flexible enforcement policy to allow it to take exposure variability into account before issuing a citation. *See* Preamble at 16460, 16757-

⁵⁷ Given that OSHA analyzed almost 900 samples from construction sites, OSHA's evaluation necessarily took exposure variability into consideration. *See* Ex. 4247, Ch. IV, p. 22.

58. Thus, to the extent Table 1's elimination of the need to comply separately with the PEL for most tasks does not fully dispose of the variability issue, OSHA has reasonably addressed exposure variability through its enforcement policy. *See Asbestos*, 838 F.2d at 1268 (standard's feasibility is bolstered by enforcement policy that acknowledges PEL cannot be achieved at all times and takes account of uncontrollable fluctuations at pre-citation stage).

Third, industry petitioners' attacks on the evidence OSHA relied on relating to exposure variability in construction are misguided. *See Industry Br.* at 86-90. Contrary to petitioners' claim, two of the four studies specifically analyzed variability of silica exposures in construction. *See Exs.* 3608, 3803. The other two studies are also relevant because they show that much of the day-to-day variability in occupational exposures to air contaminants is caused by known and observable factors. *See Exs.* 3956, 3998, Attachment 5h.

One study of silica exposure in the construction industry created a statistical model to predict exposures over a range of tasks as a way to "anticipate, evaluate, and control" exposure in the industry – undermining industry petitioners' claim that exposure is unpredictable and uncontrollable in the construction industry. *Ex.* 3803, p. 441. Another study evaluating silica exposure in stone restoration work quantified the amount of variability attributable to different factors and developed models to predict exposure levels. *See Ex.* 3608. These studies are relevant and

credible, and it was reasonable for OSHA to rely upon them. *See Lead II*, 939 F.2d at 980.

Fourth, industry petitioners' similar criticism of OSHA's reliance on testimony from "representatives of labor unions" is baseless. Industry Br. at 89. In making its feasibility findings, OSHA considered all comments related to exposure variability, including testimony from Dr. Frank Mirer, Professor of Environmental and Occupational Health at CUNY School of Public Health and Scott Schneider of the Laborers' Health and Safety Fund of North America. *See* Preamble at 16301, 16460; *see also* Ex. 4247, Ch. IV, p. 10. Dr. Mirer and Mr. Schneider are both industrial hygienists with many years of experience and expertise assessing and controlling silica, Tr. 915-16, 4179-80, and it was entirely reasonable for OSHA to credit their testimony that most variability can be controlled.⁵⁸ *See Lead II*, 939 F.2d at 980 (court defers to OSHA's feasibility determinations when they are based on "credible sources of information").

Finally, industry petitioners take NIOSH's testimony completely out of context to argue that the testimony shows the need to reduce exposures greatly

⁵⁸ Industry petitioners reference three excerpts of hearing testimony in arguing that OSHA should have relied on "numerous rulemaking participants" who said that exposure variability was a significant issue. Industry Br. at 89 (citing Ex. 4217, pp. 11-12). Only one of the referenced participants testified about the compliance challenge due to exposure variability – and he was referring to the challenges of reducing exposure to the *action level* of 25 $\mu\text{g}/\text{m}^3$. *See* Ex. 4217, pp. 11-12 (citing Tr. 2938).

below the PEL in order to meet the PEL. *See* Industry Br. at 86-87. Responding to a question, Frank Hearl of NIOSH was simply describing a statistical model recommended for the analysis of lognormally distributed exposure data⁵⁹ – not testifying that construction (or any other) employers need to reduce exposures well below the PEL to meet either of the standard’s compliance options, or that exposure variability is largely unpredictable or uncontrollable. *See* Tr. 187-88. Moreover, Mr. Hearl’s testimony that variability increases if a worksite is poorly controlled, *see* Tr. 187, supports OSHA’s finding that variability is reduced when engineering controls are implemented.

2. OSHA’s Work Pattern Assumptions Are Well-Supported by the Record Evidence.

The sampling results in OSHA’s construction industry exposure profiles reflect a wide variety of work patterns, consisting of both shorter-duration task-based samples and samples from eight-hour work shifts. *See* Ex. 4247, Ch. IV, p. 39. Of the nearly 900 samples OSHA considered, 70% were more than 240 minutes and about 43% were more than 360 minutes. *See* Ex. 4247, Ch. IV, p. 42.

⁵⁹ Mr. Hearl explained that exposures are often lognormally distributed with a geometric standard deviation of two, which can be used to determine the upper and lower bounds of where most exposures are expected to occur. *See* Tr. 187. Although this means that employers who reduce exposures significantly below the PEL would be 95% confident that they will not exceed the PEL, *see* Tr. 147-48, 188, as explained above, this is not the legal standard for setting a PEL. *See Lead II*, 939 F.2d at 990.

OSHA assumed the sample reflected the worker's full exposure during a work shift unless there was evidence in the record that exposure continued during any unsampled portion of time. *See* Preamble at 16435. Industry petitioners argue that this assumption underestimated actual exposures in the construction industry, undermining OSHA's feasibility findings. *See* Industry Br. at 90-94.

OSHA's assumption, however, is consistent with its approach for calculating the eight-hour time-weighted average when determining compliance with a PEL. *See* Ex. 4247, Ch. IV, p. 41. When OSHA compliance officers collect partial shift samples during an inspection, they calculate eight-hour time-weighted average exposures using the assumption that no further exposure occurred during the unsampled period. *Id.* Accordingly, OSHA's methodology is completely consistent with its approach during enforcement.

Moreover, this assumption makes sense for the construction industry and is supported by substantial evidence.⁶⁰ Unlike tasks in general industry, construction industry tasks are typically performed for varying amounts of time, and are often

⁶⁰ In general industry, the exposure profiles consist mainly of full-shift samples collected over periods of 360 minutes or more. *See* Ex. 4247, Ch. IV, pp. 38-40. When OSHA obtained samples shorter than 480 minutes in general industry, OSHA assumed that the same level of exposure measured during the sampled portion of the shift continued during the unsampled portion of the shift. This assumption reflects OSHA's finding that most job activities in general industry occur at a fixed location and involve processes that remain constant over a full shift. *See* Preamble at 16435.

performed on an intermittent basis. *See* Ex. 4247, Ch. IV, pp. 39-40. OSHA found that the sample durations included in the exposure profiles more accurately reflect the actual duration of tasks in the construction industry than would an assumption of continued, constant exposure. *See* Ex. 4247, Ch. IV, pp. 40-41.

Relying on data in Flanagan *et al.* (2003), Ex. 0676, a study that reported the average percentage of time a worker in the construction industry performed a silica-generating task, OSHA determined that average task durations ranged from 150 to 240 minutes. *See* Ex. 0676, pp. 320-23; Ex. 4247, Ch. IV, pp. 40-41. Based on a large set of silica data from the construction industry, OSHA determined that silica-generating tasks are often performed on an intermittent basis.⁶¹ *See* Ex. 0677; Ex. 4247, Ch. IV, p. 40. Additionally, Susi *et al.* (2000) developed a task-based exposure assessment model combining sampling data with task observations and durations; when applied to masonry jobsites, the model showed that workers spent much of their shifts performing non-silica-generating tasks. *See* Ex. 4073, Attachment 8c; Ex. 4247, Ch. IV, p. 42.

⁶¹ Petitioners' argument that this study contradicts OSHA's finding, *see* Industry Br. at 93, is incorrect. The study included worksite observations on the amount of time actually spent on a silica-generating task. For example, the median task time of demolition activities with handheld power tools like jackhammers was 231 minutes, and the median time spent using stationary masonry saws was 69 minutes. *See* Ex. 0677 and Ex. 0677, Attachment 2; Ex. 4247, Ch. IV, pp. 760, 834.

In addition to the studies in the record, OSHA received comments from both labor and industry supporting OSHA's understanding of typical work patterns in construction. For example, the Building and Construction Trades Department of the AFL-CIO commented that construction workers often spend significant time engaged in tasks that do not generate silica exposure, including setting up and installing equipment and materials, waiting for supplies or instructions, and picking up and packing tools. *See* Ex. 4223, p. 16; Ex. 4247, Ch. IV, p. 42. Mason Contractors Association of America's testimony indicates OSHA's estimates are conservative: "90 minutes is actually a really long time to be cutting something. The vast majority of [cuts] are under 15 minutes in any given day." Ex. 4247, Ch. IV, p. 783 (quoting Tr. 2911). Gary Fore from the National Asphalt Pavement Association testified that small milling machines are typically used for a "very short duration" during a shift. *Id.* at p. 879 (quoting Tr. 2213); *see also* Tr. 2216-17. Additionally, a number of industry groups asked OSHA to exclude short-term tasks (*e.g.*, 90 minutes or less) from Table 1 – presumably because a meaningful number of construction industry tasks are performed for such short periods. *See* Preamble at 16725.

Although industry petitioners criticize the evidence OSHA relied upon in estimating construction industry exposures, they point to no other evidence in the record that OSHA should have considered instead, nor did they provide any despite

being asked to do so. *See, e.g.*, Preamble at 16401; Ex. 4247, Ch. IV, p. 14.

OSHA relied on the best available evidence and made reasonable assumptions in estimating current levels of exposure. *See Ethylene Oxide*, 796 F.2d at 1499 (“If Congress had intended to require the agency to ‘prove’ all of its assumptions, Congress would not have allowed the agency to rely on the ‘best available evidence’ and the ‘latest available scientific information.’”) (internal citation omitted).

3. Industry Petitioners’ Other Feasibility Arguments Lack Merit.

Industry petitioners also argue that the PEL is infeasible because (1) too many employees will need to wear respirators when following Table 1; (2) wet methods are not always feasible⁶²; and (3) OSHA’s feasibility findings for four individual tasks lack record support. These arguments are unavailing.

Industry petitioners claim that the PEL is infeasible because one-third of the tasks on Table 1 require respiratory protection when the task is performed for more

⁶² Although industry petitioners only specifically challenge the feasibility of the PEL compliance option, *see* Industry Br. at 95-105, they also seem to argue Table 1 is infeasible inasmuch as it is not always feasible to implement wet methods. *See id.* at 97-99. Despite claiming that the record is “replete with instances where Table 1 cannot be followed,” *id.* at 99, industry petitioners fail to identify the infeasibility of any controls other than wet methods in certain circumstances and make no argument that Table 1 is infeasible most of the time. And, as explained *infra* pp. 103-104, it is feasible to implement wet methods most of the time.

than four hours.⁶³ *See* Industry Br. at 95. In fact, for most of the tasks/equipment on Table 1 (thirteen of nineteen), respiratory protection is never required, regardless of the duration and location of the task. 29 C.F.R. § 1926.1153(c)(1)(i), (iii), (v), (vi), (vii), (ix), (xiii)-(xviii). Additionally, industry petitioners grossly overstate the amount of respirator use required when following Table 1 by assuming – without any evidence – that workers will typically be performing a silica-generating task for more than four hours. But record evidence shows that construction workers typically perform silica-generating tasks for *less than* four hours a shift, and OSHA found that most of the tasks on Table 1 will be performed for four hours or less and/or outdoors. *See* Preamble at 16724; Ex. 4247, Ch. IV, pp. 40-41. Just two of the nineteen tasks on Table 1 require respirator use when the task is performed outdoors for less than four hours. 29 C.F.R. § 1926.1153(c)(1)(viii) and (xi). Substantial evidence therefore supports OSHA’s finding that most of the time employees are performing tasks on Table 1, respiratory protection will not be required. *See* Preamble at 16724.

Industry petitioners also claim that OSHA’s medical surveillance cost estimates support their argument that the PEL is technologically infeasible due to

⁶³ Industry petitioners incorrectly claim there are thirty-one tasks on Table 1. Petitioners inflated the number of tasks (and number of tasks when respiratory protection is required) by double-counting the task when it has multiple control options, and counting the task again when it has different specifications for working indoors and outdoors.

excessive reliance on respirators. Industry Br. at 96. In calculating medical surveillance costs for the construction industry, OSHA estimated that 270,581 construction workers would be eligible for medical surveillance because they will wear a respirator for thirty or more days per year.⁶⁴ Preamble at 16625. But this just means that out of 2.02 million construction workers covered by the rule, roughly 13% are expected to wear a respirator at some point. *See* Preamble at 16508. This small amount of respirator use hardly undercuts OSHA's finding that the construction industry can comply with the PEL for "most operations most of the time." *See Asbestos*, 838 F.2d at 1267-68 (PEL feasible when it did not require the "regular use of respirators").

The argument concerning wet methods is that the PEL is infeasible because such methods cannot always be used. Industry Br. at 97-99. Industry petitioners claim that the fact that OSHA did not include a dust collection system as an alternative control option for several tasks on Table 1 means the PEL is infeasible when wet methods are infeasible. *See id.*

⁶⁴ Moreover, this overestimates the number of employees who will wear a respirator for thirty or more days. Without information in the record regarding how many workers would need to wear a respirator for thirty or more days a year, OSHA conservatively estimated – for costing purposes only – that any worker who needed to wear a respirator even once would wear it for thirty or more days per year. *See* Ex. 4247, Ch. V, pp. 370-71.

That is not the case. When following the PEL compliance option, employers do not have to use the wet methods specified on Table 1 and may use alternative controls like LEV. Preamble at 16461. Moreover, many of the barriers to wet dust suppression have been overcome in various construction settings. Preamble at 16460-61. For example, if water is unavailable at a worksite, *see* Industry Br. at 98, Fann Contracting explained that it uses water trucks to haul water to worksites and includes the cost of doing so when bidding projects. Preamble at 16460; Ex. 2116, p. 33. Similarly, evidence in the record shows that heated water or heated shelters can be used if construction work is being performed in freezing temperatures. *See* Preamble at 16460; Tr. 3095-96. OSHA's determination that wet methods are feasible most of the time is thus supported by substantial evidence. *See* Ex. 4247, Ch. IV, pp. 848-50.

Nonetheless, OSHA recognized that there could be limited instances when wet methods may not be feasible, such as where they could create a greater hazard. *Id.* at 15-16. In these situations, alternative controls such as LEV and the supplemental use of respiratory protection, as needed, may be used. Preamble at 16461; Ex. 4247, Ch. IV, pp. 848-50. OSHA's finding that wet methods are not always feasible does not undermine OSHA's finding that the PEL is achievable in most operations, most of the time. *See Lead I*, 647 F.2d at 1272.

Finally, industry petitioners' argument concerning the four construction tasks is that OSHA failed to rely on the best available evidence in determining technological feasibility. *See* Industry Br. at 99-105. In each case, however, OSHA's finding that exposures can be reduced to 50 $\mu\text{g}/\text{m}^3$ most of the time is supported by substantial evidence and entitled to deference. *See Lead II*, 939 F.2d at 980.

Hole Drilling. With respect to hole drilling using handheld or stand-mounted drills, OSHA found that exposures could be reduced to 50 $\mu\text{g}/\text{m}^3$ when drills are equipped with commercially-available shrouds with dust collection systems and filters with 99% or greater efficiency, and high-efficiency particulate air (HEPA)-filtered vacuums are used to clean debris from holes. Ex. 4247, Ch. IV, pp. 758-59. Although industry petitioners challenge the number of samples in the record as too few to make a feasibility finding, and argue that reliance on two laboratory studies to evaluate the effectiveness of controls is inappropriate, *see* Industry Br. at 100, they point to no other evidence OSHA should have considered. As OSHA stated in the Final Economic Analysis, the twenty-one sample results in the record are the best available evidence.⁶⁵ Ex. 4247, Ch. IV, pp. 742-43.

⁶⁵ Contrary to industry petitioners' argument that OSHA should have assumed exposure during the unsampled portion for hole drilling samples, *see* Industry Br. at 100, OSHA had no reason to assume continued exposure for hole drilling. The exposure profile contains two full-shift samples, consistent with OSHA's finding

OSHA also fully addressed critiques of its reliance on two laboratory studies to evaluate the effectiveness of LEV, explaining that these studies are relevant because they measured how well a control method works in an environment where other sources are also controlled. *See* Ex. 4247, Ch. IV, pp. 746-49. OSHA further noted that the conditions of one laboratory study – small and enclosed areas with poor circulation – resemble drilling in real-world conditions. Ex. 4247, Ch. IV, pp. 748-49.

Jackhammering. Based on the evidence in the record, including data from its exposure profile and the data from Flanagan *et al.* (2006), Ex. 0677, OSHA found that jackhammering is most often conducted outdoors and for fewer than four hours, and exposures can be reduced to 50 $\mu\text{g}/\text{m}^3$ using water spray systems or LEV under typical conditions. Ex. 4247, Ch. IV, pp. 772-74. Industry petitioners point to no contrary evidence.

Stationary masonry cutting. OSHA's exposure profile showed a median silica exposure of 34 $\mu\text{g}/\text{m}^3$ when wet methods were used; based on this data and other record evidence, OSHA found that exposures during stationary masonry cutting could be reduced to 50 $\mu\text{g}/\text{m}^3$ or below, most of the time. *See* Ex. 4247, Ch. IV, pp. 831-59. Industry petitioners argue that the PEL is not feasible because

that “[d]rilling may be performed only briefly or intermittently or might be done continuously during the work shift.” Ex. 4247, Ch. IV, p. 736.

the identified engineering control – wet methods – cannot always be used.

Industry Br. at 98, 102-103. As OSHA explained above, *supra* pp. 103-104, wet methods are feasible most of the time. *See* Ex. 4247, Ch. IV, pp. 848-50. Industry petitioners point to no evidence to the contrary. Moreover, OSHA also evaluated the feasibility of LEV and determined that it could be used to reduce exposure to the PEL. Ex. 4247, Ch. IV, pp. 850-59.

Mobile crushing machine operators and tenders. OSHA found that crusher operator and tender exposures can be reduced to 50 $\mu\text{g}/\text{m}^3$ through the use of water spray or mist delivered at the crusher and other points where dust is generated and a remote control station or ventilated booth that provides fresh, climate-controlled air to the operator.⁶⁶ Ex. 4247, Ch. IV, pp. 967-68.

Industry petitioners argue that a single full-shift result of 54 $\mu\text{g}/\text{m}^3$ shows the PEL is infeasible. *See* Industry Br. at 103-105. Contrary to industry petitioners' claim that this work was performed with "extensive control measures" under "almost ideal conditions," OSHA noted that only one water spray nozzle was used, and the operator spent much of the shift inside a poorly-sealed booth equipped with foam (instead of a high-efficiency filter), left the booth frequently, and shoveled

⁶⁶ Industry petitioners argue that there is no evidence regarding tenders' exposures. *See* Industry Br. at 103. While OSHA has no samples for workers who performed only tending tasks, OSHA's exposure profile includes results for workers who performed both operating and tending tasks. *See* Ex. 4247, Ch. IV, p. 953.

dry crushed concrete without dust suppression. Ex. 4247, Ch. IV, p. 959.

Particularly where the exposure result barely exceeded the PEL, OSHA reasonably concluded that if a finer mist and other water sprays had been used so that the operator did not need to shovel dry material, the operator's exposure would have been reduced to 50 $\mu\text{g}/\text{m}^3$ or below. *See id.* at 959-60.

Far from "simply speculating" that these measures would reduce exposures to 50 $\mu\text{g}/\text{m}^3$, Industry Br. at 105, OSHA relied on additional evidence in the record to support its conclusion, including guidance from the Health and Safety Executive of Great Britain, NIOSH's Dust Control Handbook, and a progress report from an ongoing study of demolition dust and silica dust control. Ex. 4247, Ch. IV, pp. 960-62.

Petitioners are therefore wrong that OSHA failed to establish that the standard is feasible for these four construction tasks. In any event, they do not argue that the standard is infeasible for fifteen (of twenty-three) other construction tasks. *See* Preamble at 16458-59. Thus, the standard would be feasible for the construction industry as a whole, even if substantial evidence were lacking for the feasibility for these four tasks. *See Lead II*, 939 F.2d at 990.

IV. Substantial Evidence Supports OSHA's Finding that the Silica Rule Is Economically Feasible for Foundries, Fracking, and Construction.

After an extensive analysis, OSHA reasonably concluded that the final rule is economically feasible for all covered industries. *See* Preamble at 16755. An

OSHA standard is economically feasible for an industry “if the costs it imposes do not ‘threaten massive dislocation to, or imperil the existence of’” that industry.

Lead II, 939 F.2d at 980 (quoting *Lead I*, 647 F.2d at 1265). “A standard is not infeasible simply because it is financially burdensome or even because it threatens the survival of some companies within an industry.” *Lead I*, 647 F.2d at 1265 (citation omitted); *see also Cotton Dust*, 452 U.S. at 519-20 (“Congress understood that the [OSH] Act would create substantial costs for employers, yet intended to impose such costs when necessary to create a safe and healthful working environment.”). Indeed, even if the costs of an OSHA rule appear “frightening,” those costs must be examined “in relation to the financial health and profitability of the industry” to determine the feasibility of the rule. *Lead I*, 647 F.2d at 1265.

This Court does “not require[] [OSHA] to prove economic feasibility with certainty,” *Lead II*, 939 F.2d at 980, or in any “particular way.” *Lead I*, 647 F.2d at 1267. Rather, OSHA must “use the best available evidence” to “construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.” *Lead II*, 939 F.2d at 980-81 (citations and quotation marks omitted). As detailed below, OSHA met these legal requirements in promulgating the Silica Rule, and the Court must defer to OSHA’s conclusion that the rule is economically feasible for all affected industries, including foundries, fracking, and construction.

A. *OSHA Conducted a Thorough and Legally Sufficient Analysis of the Economic Feasibility of the Silica Rule.*

At the outset of its economic analysis, OSHA identified job categories and activities affected by the Silica Rule and the industries in which those job categories and activities are performed.⁶⁷ Preamble at 16401-19. Then OSHA classified affected industries using the North American Industry Classification System (NAICS) Manual, *id.*, and estimated the costs that will be incurred by establishments in the affected industries.⁶⁸ *Id.* at 16462-68. For each industry, OSHA also compared estimated annualized costs with annual revenues and profits.⁶⁹ Preamble at 16535-44, 16572-73.

⁶⁷ OSHA's complete analysis of compliance costs and economic feasibility is at Chapters V and VI of the Final Economic Analysis, Ex. 4247. A summary is found at preamble pages 16462-582.

⁶⁸ The estimated costs of the rule represent the additional costs necessary for employers to achieve full compliance with the Silica Rule. They do not include costs employers must incur to comply with OSHA's prior PELs for silica or with other OSHA requirements, nor do they include costs associated with voluntary steps employers may have taken previously that will achieve compliance with the new standard. Preamble at 16463, 16471. OSHA's cost estimates do not reflect the possibility that employers may find ways to reduce compliance costs (by, *e.g.*, assigning work so that fewer employees are exposed to silica or by developing cost-reducing compliance technology), and they do not account for any cost savings employers may achieve due to compliance with the rule (*e.g.*, capturing silica dust at its source can reduce clean-up costs and extend the useful life of equipment). *See id.* at 16471, 16527.

⁶⁹ OSHA used the latest-available industry-specific revenue data (from 2012) and profit rate (profits as a percentage of revenues) data averaged across the years 2000

Consistent with past analyses, OSHA presumed for screening purposes that the Silica Rule is economically feasible for any industry in which estimated compliance costs are less than 1% of revenues and 10% of profits.⁷⁰ *Id.* at 16533. OSHA found that in every construction sector affected by the Silica Rule, costs are below both these revenue and profit thresholds. *Id.* at 16572-73. In general industry and maritime, OSHA identified no industries in which the costs of the Silica Rule exceed 1% of revenues, but eight industries – not including foundries, fracking, or construction – in which costs are greater than 10% (up to 31%) of profits. *Id.* at 16535-44; Ex. 4247, Ch. VI, pp. 14. OSHA looked more closely at those eight industries – accounting for year-to-year variations in profit rates and the impact of international trade – and concluded that the costs of the final rule are below any level that could threaten their economic viability. Ex. 4247, Ch. VI, pp. 15, 70. OSHA also did a screening analysis, using the same revenue and profit

to 2012 (to encompass both the highs and lows of a normal business cycle – including two recessions and two periods of sustained growth). Preamble at 16531.

⁷⁰ Retrospective studies of prior OSHA standards have shown that potential impacts of less than 1% of revenues are unlikely to eliminate an industry or significantly alter an industry's competitive structure. Preamble at 16533. OSHA found 10% to be a modest threshold for profit impacts given that normal year-to-year variations in profit rates can exceed 40%. *Id.*; *see also, e.g.*, Ex. 4247, Ch. VI, pp. 48-62 (Table VI-5). When costs do not exceed 10% of profits, firms can easily cover first-year costs out of current profits without having to access capital or credit markets or facing short-term insolvency. *See* Preamble at 16533.

thresholds, for small businesses in affected industries, and concluded that the costs of the rule are unlikely to threaten the survival of small or very small entities in, or consequently to alter the competitive structure of, any affected industries.⁷¹

Preamble at 16551-72, 16575-78.

Industry petitioners challenge OSHA's economic feasibility finding for two industrial groups in general industry (foundries and fracking) and for construction. Industry Br. at 69-85, 105-10. For those industrial groups, OSHA's final economic impact estimates are as follows:

⁷¹ To test the strength of the economic analysis, OSHA performed a sensitivity analysis of its cost estimates by evaluating the impact of modifying certain unit cost estimates. *See* Preamble at 16616. The sensitivity tests resulted in only very minor changes to total costs. *See id.* For example, OSHA found that doubling its estimate for the amount of time it will take employers to familiarize themselves with the new rule increased total estimated costs by less than 2%. *Id.* at 16617-19. The sensitivity analyses resulted in OSHA concluding that its cost analysis was "reasonably robust." *Id.* at 16616. OSHA also performed a "break-even" analysis and determined that the estimated costs of the rule would need to increase by approximately 740% (or \$7.7 billion) for estimated costs to equal the projected benefits of the rule. *Id.* at 16619-21.

Industry⁷²	Costs as a Percentage of Revenues	Costs as a Percentage of Profits
Iron Foundries NAICS 331511	0.22%	4.96%
Steel Foundries NAICS 331513	0.25%	5.62%
Support Activities for Oil and Gas Operations (Fracking) NAICS 213112	0.56%	7.94%
Construction – Foundation, Structure, and Building Exterior Contractors NAICS 238100	0.12%	3.66%

For all of these industries, OSHA's economic impact estimates fall significantly below OSHA's screening thresholds for economic feasibility.

Industry petitioners do not challenge OSHA's screening thresholds or argue that OSHA's cost impact estimates for foundries, fracking, and construction rise to

⁷² The figures in this table are from Table VII-18 (Preamble at 16536-44) and Table VII-21 (Preamble at 16573). The two foundry industries listed are the ones specifically mentioned by industry petitioners in their brief. *See* Industry Br. at 70-71. Foundation, Structure, and Building Exterior Contractors is included because it is the construction industry for which OSHA estimated the greatest economic impact. *See* Preamble at 16572-73.

the level of economic infeasibility.⁷³ Instead they allege that parts of the methodology OSHA used for its economic analysis, some of OSHA's unit cost estimates, and a few of OSHA's assumptions led OSHA to underestimate overall economic impacts for foundries, fracking, and construction. In every instance, however, the discussion below in parts B through D shows that OSHA's analysis is reasonable and supported by substantial evidence in the record. Furthermore, even petitioners recognize that changing just one part of OSHA's analysis would not necessarily alter the ultimate outcome. *See* Industry Br. at 110.

⁷³ Industry petitioners note that OSHA's estimated cost impacts for very small iron and steel foundries (10.03% and 12.27% of profits respectively) and for small and very small fracking entities (18% and 29% of profits respectively) "surpass[]" the "thresholds denoting infeasibility." Industry Br. at 71; *see also* Industry Br. at 85; Preamble at 16553-71 (Tables VII-19 and VII-20). However, an economic impact that exceeds OSHA's screening thresholds does not necessarily "denote" infeasibility. OSHA uses its screening thresholds to separate industries for which it can assume economic feasibility from industries that require more scrutiny, and may find a rule economically feasible for an industry even when cost impacts exceed its screening criteria. *See* Preamble at 16533; *see also, e.g.*, 71 Fed. Reg. 10100, 10272-80, 10300-02 (Feb. 28, 2006) (chromium (VI) standard economically feasible for industrial groups with costs exceeding revenue and profit thresholds). Moreover, OSHA evaluates the economic impact of the rule on small and very small entities to assess whether the rule is likely to alter the competitive structure of an industry. Preamble at 16551-52. For all sectors in which costs for small or very small entities exceed the screening criteria, OSHA determined that the cost impacts of the rule on smaller businesses are not significant enough to threaten the competitive structure of the relevant industries. *See id.* at 16552. *Cf. Lead II*, 939 F.2d at 1003-04 (affirming OSHA's finding that a rule was economically feasible for an industry even though it could cause some small businesses to close).

B. *OSHA's Economic Analysis for Foundries Is Sound.*

1. OSHA's Approach for Estimating the Costs of Controls Is Reasonable and Supported by Substantial Evidence.

Arguing that OSHA's methodology for estimating the costs of the Silica Rule for foundries was "incorrect," Industry Br. at 72, petitioners challenge two elements of OSHA's methodology – the "per-worker" approach to estimating the costs of controls and the assumption that half of all control costs are attributable to reducing exposures to the prior PEL of 100 $\mu\text{g}/\text{m}^3$ (as opposed to reducing exposures from the prior PEL to the new PEL). *Id.* at 73-77. Both parts of OSHA's analysis are reasonable, well-explained, and well-supported.⁷⁴

(a) "Per-Worker" Approach

OSHA estimated the costs of silica controls for most of general industry (including foundries) on a per-worker basis. Preamble at 16469. OSHA derived its per-worker costs by dividing the overall cost of each control by the number of workers impacted by that control. For example, if a control costs \$20,000 and can reduce the silica exposures of four employees, OSHA assigned the control a per-

⁷⁴ Although OSHA did not adopt all of the recommendations proffered by industry representatives during the rulemaking, it did make numerous adjustments to its economic analysis in response to industry comments. *See, e.g.*, Preamble at 16490 (adding occupations to the analysis), 16509-11 (adding costs for self-employed workers on multi-employer worksites), 16513 (increasing industrial hygiene costs for exposure monitoring), 16515 (adding costs for employers to familiarize themselves with the new rule), 16531 (revising method for calculating profit rates to include unprofitable firms).

worker cost of \$5000. *Id.* OSHA could then multiply the per-worker control cost by the number of workers exposed above the new PEL to arrive at an estimate of total control costs. *Id.*

Industry petitioners argue that OSHA erred by using this approach in lieu of the approach that was described in an analysis submitted to the rulemaking record by URS Corporation. Industry Br. at 73-76 (discussing Ex. 2307, Attachment 8b). OSHA provided two important reasons for rejecting the URS approach. Preamble at 16469-71.

The URS approach assumes employers will install a full set of new controls whenever any worker in a job category is overexposed to silica, effectively disregarding the presence and impact of any existing controls. Preamble at 16470-71, 16478; Tr. 2108-10. While URS's approach might be appropriate in scenarios where there are no controls in place and most workers are overexposed by a large margin, it does *not* accurately reflect the costs employers will incur in other situations. Preamble at 16470. Substantial evidence in the record (as well as common sense) establishes that when there are controls already in place, or only some workers are overexposed, employers can frequently reduce exposures by means short of (and less expensive than) installing a complete slate of new controls, *e.g.*, by modifying work practices, making minor design modifications to existing controls, or improving repair and maintenance procedures or

housekeeping protocols. *Id.* at 16470-71, 16478-79; *see also, e.g.*, Ex. 1365, p. 3-20; Ex. 1992, p. 6; Ex. 4204, p. 40. Accordingly, OSHA reasonably concluded that its approach (estimating costs by assigning per-worker costs of engineering controls to workers exposed above the PEL), and assuming that employers will opt for the control(s) with the lowest per-worker unit cost, was “much more likely to be accurate than estimates based on URS’s suggestion that all controls are needed whenever one worker is exposed above the PEL.” Preamble at 16471.

Second, OSHA rejected the URS approach because it erroneously assumed that the presence of existing controls in a facility has no bearing on workers’ likely exposure levels (*i.e.*, exposure levels are randomly distributed in every facility).⁷⁵ Preamble at 16469-70. In reality, workers in facilities with controls in place are more likely to have exposures that reflect the presence of those controls than they are to exhibit a random distribution of exposures. *Id.* This common sense notion

⁷⁵ Industry petitioners state, with no support or clarifying discussion, that the URS approach does *not* presume randomness in the distribution of exposures. *See* Industry Br. at 75. However, they acknowledge that the URS model “assign[ed] groups of overexposed workers *statistically*.” *Id.* (emphasis added); *see also* Ex. 2307, Attachment 8b, p. 7 (explaining that URS’s methodology was based on the creation of “statistical binomial distributions”). OSHA is aware of no reading of “statistically” in this context that would imply anything other than a random assignment of values. A fundamental assumption of a binomial distribution is that each observation (*e.g.*, whether a worker is overexposed) is statistically independent of every other observation. *See* <http://www.dictionary.com/browse/binomial-distribution> (last visited Jan. 19, 2017).

is reflected in OSHA's operative "least cost" assumption in its per-worker approach and is supported by evidence in the record showing that establishments with low exposures are much more likely to have controls in place than establishments with very high exposures. *Id.*; *see also, e.g.*, Ex. 4247, Ch. IV, pp. 236-39.

OSHA gave serious consideration to URS's methodology and provided an extensive rationale, supported by substantial evidence in the record, for rejecting it. *See* Preamble at 16469-71. Thus, it cannot be said that URS's approach constituted the best available evidence or that OSHA erred by failing to adopt it.

(b) Fifty-Percent Assumption

Industry petitioners also challenge OSHA's assumption that half of the foundry industry's control costs incurred to reduce current exposures to the new PEL represent the costs of implementing controls needed to go from an uncontrolled situation to the prior PEL of 100 $\mu\text{g}/\text{m}^3$ (costs *not* attributable to the new Silica Rule) and half represent costs for implementing controls necessary to reduce exposures from the prior PEL to the new PEL (costs that *are* attributable to the new rule).⁷⁶ Industry Br. at 76-77; *see also* Preamble at 16473. Petitioners

⁷⁶ OSHA adopted the 50% assumption because there is no evidence that would allow it to distinguish the specific types of controls necessary to comply with the prior PEL from the additional types of controls necessary to comply with the new

allege that OSHA's assumption was not supported by the record because evidence shows that the costs of coming into compliance with the new PEL exceed the costs of achieving the prior PEL of 100 $\mu\text{g}/\text{m}^3$. Industry Br. at 77. Petitioners cite only to a URS analysis asserting that “[w]hile large reductions in silica exposure are possible when concentrations are high, control costs increase exponentially as facilities seek to achieve lower and lower exposure levels.” *Id.* (quoting Ex. 2307, Attachment 8b, p. 11). OSHA's analysis shows, however, that its 50% assumption is actually a *conservative* assumption that results in an *overstatement* of costs attributable to the Silica Rule. Preamble at 16473-74. And, as described below, the 50% assumption is entirely consistent with the concept of rising incremental costs.

OSHA specifically assessed whether more control costs are necessary to meet the preceding PEL or the new PEL. Preamble at 16473-74. According to exposure data in the record, the average general industry worker exposed to silica levels above the prior PEL of 100 $\mu\text{g}/\text{m}^3$ is exposed above 300 $\mu\text{g}/\text{m}^3$. Preamble at 16473. This evidence led OSHA to conclude that the typical “uncontrolled” situation involves very high levels of exposure that can typically be addressed only through the implementation of the types of controls that provide the greatest

PEL. Preamble at 16473; *see also* Preamble at 16471-72 (rationale for excluding costs of compliance with prior PEL).

reductions in exposure – namely LEV or wet methods, with some improvement in housekeeping practices. *Id.* Those types of controls account for a significant majority of the costs associated with controlling silica. Data in the record show that across all general industry/maritime sectors and occupations, LEV *alone* accounts for an average of over 60% of all control costs; wet methods and ventilation, together, account for more than three-quarters of control costs, on average; and housekeeping costs represent nearly one-quarter of control costs, on average. *Id.*; *see also* Ex. 4249, Attachment 8 (costs tab). Accordingly, because employers already need to implement the most expensive types of controls to comply with the prior PEL, and only less expensive actions (*e.g.*, modifying maintenance or work practices) will be necessary to reduce exposures further to the new PEL, OSHA found that, in actuality, *more* than 50% of all control costs will be incurred to reduce exposures to 100 $\mu\text{g}/\text{m}^3$. Preamble at 16473. Thus, the assumption petitioners are challenging, which assigns a full 50% of control costs to the new rule, likely overstates, rather than understates, the costs employers will incur to comply with the new PEL of 50 $\mu\text{g}/\text{m}^3$. *Id.* at 16473-74.

OSHA confirmed this finding in two ways. First, it looked specifically at data from eight ferrous sand casting foundry facilities – four of which had relatively few workers exposed above 50 $\mu\text{g}/\text{m}^3$ and the other four of which had many exposures over 100 $\mu\text{g}/\text{m}^3$. Preamble at 16473; *see also* Ex. 4249,

Attachment 7. OSHA found that the “high exposure” facilities generally had little or no LEV in place, poor housekeeping, no worker enclosures, and poor maintenance. Preamble at 16473. In contrast, the foundries with lower exposures generally had working LEV and good housekeeping and maintenance practices. *Id.* Second, OSHA looked at all of the exposure measurements in the record for which it had control descriptions and found that exposures above $250 \mu\text{g}/\text{m}^3$ occurred in uncontrolled situations or situations in which installed controls were not in use, whereas exposures between $50 \mu\text{g}/\text{m}^3$ and $100 \mu\text{g}/\text{m}^3$ were typically associated with the implementation of some controls (usually LEV). *Id.* These additional sources of data confirmed that the controls making up the bulk of control costs (generally LEV and housekeeping) are essential to meeting the prior PEL of $100 \mu\text{g}/\text{m}^3$, and thus that the decision to attribute half of control costs to reducing exposures from the prior PEL to the new PEL is a conservative one that likely overestimates the costs of the Silica Rule. *See id.* at 16473-74.

As part of its analysis, OSHA addressed the claim, now asserted by petitioners, that the 50% assumption failed to account for the fact that “control costs increase exponentially as facilities seek to achieve lower and lower exposure levels.” Industry Br. at 77 (quoting Ex. 2307, Attachment 8b, p. 11). OSHA explained that allocating half of control costs to reducing exposures from over $250 \mu\text{g}/\text{m}^3$ to $100 \mu\text{g}/\text{m}^3$, and the other half to reducing exposures (to a more limited

extent) from 100 $\mu\text{g}/\text{m}^3$ to 50 $\mu\text{g}/\text{m}^3$, inherently accounts for the rising incremental costs of controls. Preamble at 16474 n.32.

OSHA's methodology for allocating control costs between the prior and new PELs for silica was plainly reasonable and supported by substantial evidence in the record. The petitioners' challenge to that approach must be rejected. In any event, OSHA determined that its overall cost estimates for controls in general industry were not highly sensitive to shifts in the allocation assumption; each change of five percentage points in the assumption changed overall control costs by less than six percent. Preamble at 16474.

2. OSHA's Economic Analysis Appropriately Accounted for the Control Costs Likely to Be Incurred by the Typical Foundry.

Industry petitioners argue that "the largest issue" with OSHA's economic analysis for foundries is its failure to account for the costs of *every* control method mentioned in the technological feasibility analysis (in particular, the costs of substituting silica-free materials for materials containing silica). Industry Br. at 77-80. This argument has no merit because it would not be rational to account for the costs of *all* potential controls – many of which are redundant.⁷⁷

⁷⁷ For example, petitioners fault OSHA for failing to account for the costs of both process automation and the substitution of silica-free for silica-containing materials. Industry Br. at 79. However, no employer would invest in both types of controls, as the implementation of one renders the other unnecessary.

Simply because a control is mentioned in OSHA's technological feasibility analysis as a potentially feasible option for reducing silica exposures to the PEL does not mean that every employer must implement that control. Preamble at 16482. The general industry/maritime rule does not require employers to adopt any particular controls, but rather gives employers discretion to adopt the controls that will most efficiently reduce silica exposures below the PEL in their facilities. Thus, OSHA "developed cost estimates [for foundries] based on the lowest cost combination of controls that allows [foundry] employers to . . . meet[] the new PEL[,]” or in other words, the controls a typical foundry employer will likely implement to comply with the new rule. *Id.* This Court affirmed precisely this type of "typical employer" analysis in *Lead II*, 939 F.2d at 1005 (upholding cost estimates "based on the controls that [OSHA] believed a typical employer would need to implement.").

With respect to substitution in particular, OSHA explained that it did not account for substitution costs because "in most situations, substitution is not the least costly method of achieving the . . . new PEL." Preamble at 16476 (citing Ex. 2379, Attachment B, p. 6). Petitioners acknowledge as much, but nonetheless assert that OSHA should have accounted for substitution costs because in individual cases OSHA might expect employers to consider substitution as part of the hierarchy of controls (presumably when other, less expensive control options

are not available that can reduce exposures to 50 $\mu\text{g}/\text{m}^3$). Industry Br. at 79-80. But OSHA's technological feasibility analysis for foundries shows that controls other than substitution can be used to comply with the new PEL most of the time. *See* Ex. 4247, Ch. IV, pp. 225-353; *see also* Ex. 4247, Ch. IV, p. 258 (noting that "none of [OSHA's technological] feasibility findings are based on substitution"). Given the relative expense of substitution and the ready availability of alternative control options in most cases, it was entirely reasonable for OSHA to conclude that the typical foundry employer will not use substitution to comply with the Silica Rule.

3. OSHA's Unit Cost Estimates for Ventilation and Housekeeping Are Reasonable and Supported by Substantial Evidence.

Industry petitioners assert that OSHA's economic analysis should have used AFS-developed unit cost estimates for ventilation and housekeeping. Industry Br. at 80-82. In both cases, however, OSHA adopted unit cost estimates that were reasonable and well-supported, and adequately explained its rationale for rejecting the higher alternatives presented by AFS.

(a) Ventilation

To calculate the cost of ventilation enhancements for the Silica Rule, OSHA used a unit cost input representing the average annual cost of such enhancements per cubic foot per minute (cfm) of air flow. *See* Preamble at 16477. OSHA's overall unit estimate for annual ventilation costs includes a component for

annualized capital costs, a component for annual operating costs, and an additional factor to account for maintenance costs. Preamble at 16477-78. For the preliminary economic analysis accompanying the proposed silica rule, OSHA estimated annualized capital costs of \$1.83 (based on non-annualized capital costs of \$12.83), operating costs of \$2.22, and maintenance costs of \$1.28, for total annual costs per cfm of just over \$5.00. *Id.*; *see also* Ex. 1720, p. V-14.

The estimate of \$12.83 for capital costs (\$1.83 when annualized) was based on an analysis developed by OSHA's contractor, Eastern Research Group (ERG). *See id.*; *see also* Ex. 1608, pp. 3-5 to 3-10; Ex. 1720, p. V-14. ERG "worked with industrial hygienists and plant ventilation engineering specialists to derive . . . costs of LEV enhancements" and "determined that over a wide range of circumstances" the capital costs associated with "ventilation enhancement . . . varied from roughly \$8 per cfm . . . to perhaps \$16 per cfm." Ex. 1608, p. 3-5. Based on the data collected, ERG concluded that \$11 per cfm was a "reasonable overall representation of the likely capital costs of ventilation enhancements," Ex. 1608, p. 3-6; this value converted to \$12.83 in 2009 dollars (as used in the preliminary economic analysis). Ex. 3983.

For operating costs, ERG's engineering consultants "analyzed the costs of heating and cooling system operation for 12 widely distributed US cities," which were also in very diverse climates. Ex. 1608, p. 3-6; *see also* Ex. 1608, pp. 3-6 to

3-9; Preamble at 16477. The analysis looked separately at the heating and cooling requirements for operations that run sixty hours a week and operations that run continuously and, for both types of operations, accounted for the presence or absence of recirculated air. (Recirculation results in significantly lower operating costs.) Ex. 1608, p. 3-6. Based on these data, OSHA estimated an average annual operating cost per cfm of \$2.22 across all facilities.⁷⁸ See Preamble at 16477-78.

OSHA's analysis generally adopted the preliminary unit cost estimate for ventilation (updated only to reflect more recent energy prices and 2012 dollars), finding it "to be a reasonable average across a very wide variety of circumstances." Preamble at 16480; *see also* Preamble at 16648 (Table VII-38a, n.[a]). OSHA also compared its final estimates to the ventilation costs presented in the economic analysis for OSHA's chromium (VI) rule (promulgated in 2006) and concluded that the two reflected "approximately the same" annualized costs for ventilation. See Preamble at 16480.

AFS submitted comments to the rulemaking asserting that "[a] group of foundry ventilation managers and ventilation experts estimated the annual cost per [cfm] at \$20 for exhaust alone and another \$6-10 for makeup air." Ex. 2379, Appendix 3, p. 9. AFS provided minimal detail (just three interview quotes,

⁷⁸ OSHA used an annual maintenance factor equivalent to 10% of capital costs (\$1.28 in the preliminary economic analysis). Preamble at 16478.

providing very little context) in support of its alternative estimate. *See id.* OSHA explained that it could not “make use of [these] estimates . . . without [more] information” – such as information about the size of the facilities in question. Preamble at 16479; *see also* Tr. 2773-74. And at the hearing on the Silica Rule, OSHA representatives asked Tom Slavin, Chair of the AFS Health and Safety Committee, to provide additional information about the AFS estimate. In particular, OSHA asked for a breakdown of the AFS estimate among capital costs and operating costs. Tr. 2779-85; *see also* Preamble at 16479. Mr. Slavin was unable to provide an adequate response to OSHA’s questions at that time, so OSHA asked Mr. Slavin to submit the requested clarification to the record following the hearing. Tr. 2784. AFS never responded to OSHA’s request. Preamble at 16479.

Given the paltry detail AFS provided in support of its alternative estimate, and its failure to provide the additional information OSHA requested at the hearing, the AFS estimate hardly constituted the best available evidence on ventilation costs, and OSHA’s choice not to adopt it was not erroneous. *See, e.g., AFL-CIO*, 617 F.2d at 661 (“The very nature of economic analysis frequently imposes practical limits on the precision which reasonably can be required of the

agency. This is especially the case where . . . the industry chooses to withhold from the agency part of the data underlying the industry's cost estimates.”⁷⁹

(b) Housekeeping⁸⁰

Industry petitioners argue that OSHA erred by estimating the cost of a thorough initial cleaning at \$0.15 per square foot (annualized at \$0.02 per square foot), *see* Preamble at 16481-82, instead of adopting the AFS-proffered estimate of \$1.00 per square foot. *See* Industry Br. at 82 (citing Ex. 2379, Appendix 3, pp. 13, 29). This argument has no merit.

OSHA's estimate is based on evidence from a Midwestern firm that specializes in cleaning foundries. *See* Preamble at 16481; Ex. 3817. The cleaning company charges between \$2200 and \$3500 for a team of two technicians to clean a 210,000 square foot sand foundry every two to three weeks. Preamble at 16481; Ex. 3817. On the high end this represented cleaning costs of \$0.02 per square foot. *See* Preamble at 16481. OSHA then estimated that it would take four to five days to perform a thorough initial cleaning to remove all visible silica dust; \$0.02 per

⁷⁹ Annual ventilation cost estimates submitted to the record by URS were much closer to OSHA's estimate (in the \$5.00-\$6.00 range) than to the estimate presented by AFS (over \$20.00). *See* Ex. 2307, Attachment 8j (estimating costs of between \$8.00 and \$9.00 per cfm on an annualized basis).

⁸⁰ The general industry/maritime rule does not require housekeeping in any particular conditions. Rather, OSHA included costs for housekeeping where housekeeping is expected to be used as a control method for complying with the PEL.

square foot per day over five days led to a total estimated cost of \$0.10 per square foot (converted to \$0.12 per square foot in 2012 dollars) for an initial cleaning. *See id.* OSHA then added an additional 25% (or \$0.03 per square foot) as an additional factor to ensure that its estimate allowed for “cleaning [that] was sufficiently thorough to achieve compliance.” *Id.* Thus, OSHA arrived at a final estimate of \$0.15 per square foot. *See id.*; *see also id.* at 16482.

AFS’s estimate of \$1.00 per square foot was based on one cleaning quote received by one foundry, which projected a cost of \$23,872.50 for three service technicians (plus a lead technician) to clean an area of 17,710 square feet over a 46-hour period. *See Ex. 2379*, Appendix 3, pp. 13-14, 29-30.⁸¹ OSHA rejected the estimate of \$1.00 per square foot on the basis that it would be unrealistic to adopt an estimate for initial cleaning that was fifty times the cost OSHA estimated for a more basic cleaning. *See Preamble* at 16481. OSHA explained that the greater accumulations of dust present during an initial cleaning would not justify that large a multiplier, as “much of the cost of the initial cleaning will be due to the time spent going over the entire facility with the appropriate cleaning devices – a cost that is fixed by area and not by accumulation.” *Id.*

⁸¹ URS also provided comments estimating cleaning costs of \$1.00 per square foot, but OSHA rejected the URS estimate in part because it was based solely on a general reference to “communications with several industries.” *Ex. 2307*, Attachment 8, p. 24; *see also Preamble* at 16481.

Petitioners suggest that their estimate was preferable to OSHA's estimate because OSHA's estimate was based on a quote for "routine superficial" cleaning, not a "deep" initial cleaning. Industry Br. at 82. However, as described above, OSHA accounted for this by multiplying the cost per square foot for a regular cleaning (\$0.02) by the greater number of days (five) it takes to do a thorough initial cleaning as compared to a more regular cleaning, and adding on an additional 25%. *See* Preamble at 16481-82.

Petitioners provide no other rationale for why their estimate, which was based on a quote provided by one cleaning company to one foundry, constitutes better evidence than OSHA's estimate, which was based on information from a different cleaning company.⁸² In such circumstances, OSHA acted within its discretion in rejecting the AFS estimate.⁸³ *See Nat'l Grain*, 866 F.2d at 740

⁸² The quote relied on by AFS is arguably implausible on its face insofar as it suggests that three service technicians will work for 138 total man-hours to clean an area of 17,710 square feet – a cleaning pace of one-man-hour per approximately 128 square feet (equivalent to a small 11 x 11 room). The pace is even slower if one accounts for any additional work done by the lead technician on the job. *See* Ex. 2379, Appendix 3, pp. 29-30.

⁸³ Petitioners also briefly contend that OSHA's estimate of \$3500 for a 15-gallon HEPA vacuum system was too low, citing AFS comments stating that in some cases employers would use systems costing upwards of \$40,000. *See* Industry Br. at 81-82 (citing Ex. 2379, Appendix 3, p. 12); *see also* Ex. 4229, p. 23. OSHA explained, however, that large, expensive systems like those described by AFS would generally be used to address the tremendous volumes of sand used in foundries *irrespective* of the Silica Rule, and that the housekeeping costs OSHA

("[W]hen available evidence of equivalent quality is conflicting, a finding by OSHA in accordance with one view or the other should be considered to be supported by substantial evidence.") (internal citations and emphasis omitted). *Cf. Lead I*, 647 F.2d at 1263 ("[T]he court must not second-guess the particular way the agency chooses to weigh . . . conflicting evidence or resolve the dispute.").

C. *OSHA's Economic Analysis for Fracking Is Sound.*

With respect to fracking, petitioners first argue that OSHA erred because the controls included in the economic analysis for fracking did "not come close to matching the controls discussed in the technological feasibility analysis as potentially being needed to meet the PEL." *Industry Br.* at 83. This argument fails in the fracking context for the same reasons it failed with respect to foundries. Many controls are redundant, and OSHA adequately accounted for the control

attributed to the new rule are limited to those for *improved* housekeeping, beyond what foundries otherwise have to do to control sand. *See* Preamble at 16480-81. OSHA estimated the costs of additional housekeeping "as those necessary for overexposed workers to spend [ten] minutes vacuuming their immediate work areas with a 15-gallon HEPA vacuum," but acknowledged that some large firms could find it more cost-effective to install a dust-handling system or a central vacuum system in lieu of having individual workers regularly spend time cleaning with small vacuums. *Id.*

costs that will be incurred by the typical fracking employer.⁸⁴ *See supra* pp. 122-24; *see also Lead II*, 939 F.2d at 1005.

Second, petitioners argue that OSHA's economic impact estimates for fracking (which show costs significantly below 1% of revenues and 10% of profits) are faulty because they are based on revenue data from 2012 (supplemented with data through the early part of 2014) that do not account for more recent falling oil prices. *See* Industry Br. at 84-85; *see also* Preamble at 16549. But OSHA both used the most up-to-date revenue data in the record and provided an extra analysis, supported by substantial evidence, concluding that the Silica Rule would not jeopardize the fracking industry, even in light of current conditions.⁸⁵

The economic data OSHA used for its fracking analysis was the most up-to-date information in the record at the time OSHA prepared the Final Economic

⁸⁴ OSHA's cost estimates for fracking do not account for any new, more cost-effective, control measures that may be developed before June of 2021, when fracking employers must implement engineering controls. *See* 29 C.F.R. § 1910.1053(l)(3)(ii); *see also* Preamble at 16483; *Lead I*, 647 F.2d at 1265 (delayed compliance deadlines can "enhance economic feasibility generally").

⁸⁵ An explanation of OSHA's methodology for estimating fracking revenues and profits can be found in the Final Economic Analysis, Ex. 4247, Ch. III, pp. 124-43, which describes a variety of ways in which OSHA's final estimates were more conservative than the preliminary estimates that accompanied the proposed silica rule. Petitioners do not challenge the methods used to derive industry profits and revenues other than to suggest that OSHA did not account for the most recent conditions in the industry.

Analysis for the Silica Rule. Preamble at 16549. OSHA recognized that oil prices dropped between 2012 (when oil prices were between \$90 and \$100 per barrel) and 2015 (when oil prices ranged from \$45 to \$60 per barrel), leading to bankruptcies and closures throughout the oil industries. *Id.* And in light of these “major change[s] in the industry,” OSHA conducted a thorough analysis (beyond what it did for any other industry affected by the Silica Rule) to confirm that the rule remained economically feasible for fracking considering current industry conditions. *Id.*

OSHA found that while there has been an overall reduction in the number of operational oil rigs, fracking still accounts for roughly half of the country’s oil and natural gas output.⁸⁶ *Id.* Furthermore, projections from the United States Energy Information Administration, available at the time OSHA prepared the Final Economic Analysis for fracking, forecasted the price of oil to rise to over \$70 per barrel by 2020, and to over \$100 per barrel by 2028. *See id.* at 16549-50. Thus, OSHA noted that the implementation of engineering controls for fracking in June of 2021 “may come during a period of much higher and rising energy prices.” *See id.* at 16550.

⁸⁶ In February 2015, fracking accounted for 49% of oil production and 54% of natural gas output. *See* Preamble at 16549.

OSHA also found that the projected costs of the Silica Rule are “a minor issue” when compared with the effect of fluctuating energy prices on the demand for fracking services, and that even if oil prices stay low, the Silica Rule will not “impos[e] significant costs, caus[e] massive economic dislocations to the . . . industry, or imperil[] the industry’s existence.” *Id.* OSHA noted reports indicating that oil companies are developing and using new technologies that are improving production and efficiencies in the industry. *See id.* These new technologies include lasers and high-tech equipment and data analytics that can be used prior to drilling to ensure new wells deliver the most crude for the investment cost, fiber-optic tools that can monitor a well to ensure it is working, and new techniques for stimulating microbes that break up oil and make it easier for crude to flow through rock. *Id.* Indeed, productivity and efficiency are already improving in the industry, while the overall costs of fracking are going down. *See id.* (describing indicators of improvements in the industry). Given these positive developments, OSHA’s special analysis for fracking led it to conclude that nothing about the current state of the industry undermines its conclusion (based on the standard comparison of estimated costs to industry revenues and profits) that the rule is economically feasible for fracking. *Id.*

Petitioners challenge OSHA’s analysis of current industry conditions only by calling it “unconvincing.” Industry Br. at 85. They cite to no record evidence,

or any other sources, that contradict OSHA's findings. OSHA's conclusion with respect to the state of the fracking industry is therefore a reasonable prediction based on the best available evidence. This Court recognizes that "[t]o protect workers from material health impairments, OSHA must rely on predictions of possible future events[,]” and “complete factual support in the record . . . is not possible or required where assessments of future events are at issue.” *AFL-CIO*, 617 F.2d at 651, 670 n.211 (citations and quotation marks omitted). Moreover, because a finding of economic feasibility at this stage creates only a presumption of feasibility that can be rebutted in individual enforcement actions (*e.g.*, if OSHA's predictions about the future of the industry prove inaccurate), this Court does not require OSHA to “prove [its] standard[s] certainly feasible for all firms at all times in all jobs.” *Lead I*, 647 F.2d at 1270.

D. *OSHA's Economic Analysis for Construction Is Sound.*

1. OSHA's Cost Estimates for Construction Are Reasonable.

Most of the costs associated with the Silica Rule in construction (roughly 65% of total costs) are control costs. *See* Ex. 4247, Ch. V, pp. 403-404. In estimating control costs, OSHA assumed that *all* construction employers with employees performing any of the tasks covered on Table 1 (not just those with employees exposed above the new PEL) will implement the controls specified for

those tasks.⁸⁷ Preamble at 16486. Also, due to a lack of relevant data, OSHA did not reduce its cost estimates to account for construction employers that will be exempt from the Silica Rule because their workers' exposures will remain below the action level of 25 $\mu\text{g}/\text{m}^3$ under any foreseeable conditions. *Id.*; *see also* 29 C.F.R. §1926.1153(a). Thus, OSHA likely *overestimated* the costs of controls for construction employers. *See* Preamble at 16486. And even using OSHA's conservative cost estimates, the construction sector most affected by the Silica Rule (NAICS 238100, Foundation, Structure, and Building Exterior Contractors) is projected to incur costs equivalent to just 0.12% of revenues and 3.66% of profits – figures that do not come close to approaching OSHA's screening thresholds (1% and 10%, respectively). *See supra* pp. 111-14; *see also* Preamble at 16573 (Table VII-21).

Industry petitioners challenge OSHA's cost estimates showing annualized costs per establishment of under \$1000 for five construction industries. *See* Industry Br. at 106-107; *see also* Preamble at 16573 (Table VII-21). These estimates are not unreasonable, however. First, the estimates in question reflect

⁸⁷ This assumption reflected a change from the preliminary economic analysis that accompanied the proposed rule. In the preliminary analysis, OSHA assumed that only employers with workers currently exposed above the PEL would implement additional controls. In the final analysis, OSHA accounted for baseline compliance, not by excluding any group of employers, but rather by assuming that 44% of construction workers currently exposed at or below the new PEL are already using controls that comply with Table 1. *See* Preamble at 16486.

average costs per establishment. *See* Preamble at 16572. Some establishments will spend more, and some will spend less. Second, the estimates reflect *annualized* costs following promulgation of the rule.⁸⁸ OSHA recognizes that first year costs will be significantly higher than costs in subsequent years (and higher than the estimates of annualized costs). Preamble at 16529-30. Third, establishments in the cited industries have three or fewer workers affected by the standard.⁸⁹ *See* Preamble at 16408 (Table VII-3). Fourth, most of those few affected workers spend just a small fraction of their working time performing tasks involving silica exposures (and requiring silica controls). In the industries referenced by petitioners, the average at-risk worker will spend between 7% and

⁸⁸ OMB Circular A-4 states that agencies “should present annualized . . . costs . . . begin[ning] in the year in which the final rule will begin to have effects.” 2003 WL 24011971, at *42 (Sept. 17, 2003). Annualized costs represent the constant annual stream of costs that, at a given discount rate, is equal in value to the actual irregular stream of costs incurred. Annualized cost typically include an annualized component for one-time capital and initiation costs, the annual operating costs, and a component for maintenance of equipment. For this rulemaking, OSHA developed both annualized costs and a yearly distribution of costs for years one through ten of the rule. *See* Preamble at 16526 (Table VII-15), 16530 (Table VII-17).

⁸⁹ Dividing total affected employment by the number of total affected establishments for each industry, using the data provided in Table VII-3 (Preamble at 16408), leads to the following results: (1) Electric Utilities – 1.4 workers per establishment; (2) Residential Building Construction – 1.4 workers per establishment; (3) Land Subdivision – 2.7 workers per establishment; (4) Building Equipment Contractors – 2.3 workers per establishment; (5) Building Finishing Contractors – 1.8 workers per establishment.

36% of his or her working time performing silica-related work.⁹⁰ *See* Ex. 4247, Ch. V, pp. 293 (Table V-39), 304 (Table V-42). Finally, controls for construction generally consist of inexpensive water-based dust suppression systems or ventilation systems that are integrated into hand tools and heavier equipment. *See* Preamble at 16436; 29 C.F.R. § 1926.1153(c)(1) (Table 1); *see also* Ex. 4247, Ch. IV, pp. 675-1029 (technological feasibility analysis); Ex. 4247, Ch. V, pp. 231-34 (Table V-32) (showing daily costs of control equipment ranging from \$0.61 per day to \$168.38 per day, with the vast majority of controls (17 of 23) costing less than \$15.00 per day (including maintenance and operating costs)).

Petitioners assert only that OSHA's cost estimates appear unrealistic. *See* Industry Br. at 106-107. Such bare allegations are no justification for rejecting OSHA's finding that the Silica Rule is economically feasible for construction, especially for the reasons explained above.⁹¹ Petitioners further alleged only two

⁹⁰ Dividing the total number of full-time-equivalent workers from Table V-39 (Ex. 4247, Ch. V, p. 293) by the total number of affected workers from Table V-42 (Ex. 4247, Ch. V, p. 304) provides the average amount of time an at-risk worker spends performing silica-related work. The results for the five industries listed in petitioners' brief are as follows: (1) Electric Utilities – 36%; (2) Residential Building Construction – 8%; (3) Land Subdivision – 27%; (4) Building Equipment Contractors – 7%; and (5) Building Finishing Contractors – 8%.

⁹¹ Petitioners assert, with little discussion, that an alternative overall cost estimate prepared by the Construction Industry Safety Coalition shows that using "real assumptions and real construction working conditions" would result in estimated costs almost eight times greater than OSHA's estimates. Industry Br. at 110.

specific errors in OSHA's economic analysis for construction; as explained below, neither have merit.

2. OSHA's Assumption of 150 Workdays per Year Is Reasonable, and Assuming More Workdays per Year Would Result in Lower Estimated Costs for Construction Employers.

For purposes of estimating the costs of the Silica Rule for construction, OSHA assumed for some purposes that each year there are 150 workdays (or thirty workweeks) when silica controls will be needed. *See* Preamble at 16490 n.38, 16494-95. Industry petitioners argue that this assumption is unsupported and led OSHA to significantly underestimate costs for the construction industry. *See* Industry Br. at 107-108. Petitioners are wrong on both counts.

OSHA adequately explained its rationale for the 150-day assumption. OSHA noted that it reduced its assumption about working days in construction to 150 based on comments received from industry representatives during the SBREFA panel convened prior to issuance of the proposed silica rule.⁹² *See*

OSHA gave serious consideration to the Coalition's alternative analysis, adopting some of the Coalition's recommendations and explaining its rationale for rejecting others. *See, e.g.,* Preamble at 16490-92, 16497-98, 16502-03, 16508-10, 16531, 16580, 16582.

⁹² At page 16494 of the preamble, OSHA refers to Exhibit 0968 as the source of the relevant small business comments. Petitioners point out, and OSHA acknowledges, that this citation is wrong. *See* Industry Br. at 107. The correct supporting document is Exhibit 0004. *See* Preamble at 16490 & 16490 n.38

Preamble at 16490 n.38, 16494; *see also* Ex. 0004, p. 578; Ex. 1709, pp. 4-54 to 4-55; Ex. 1720, p. V-169. OSHA also explained that it found the 150-day assumption reasonable because of “winter weather slowdown[s] in many parts of the country, as well as general weather conditions (such as rain) that can interfere with many construction processes.”⁹³ Preamble at 16494.

More important, an assumption of 250 workdays for construction would *not* increase overall projected costs. Petitioners point to the only three elements of OSHA’s cost analysis for construction that are affected by the 150-workday assumption: (1) respiratory protection costs; (2) the costs of exposure control plans; and (3) engineering control costs. *See* Industry Br. at 108. Petitioners are correct that increasing the assumption from 150 to 250 workdays would increase OSHA’s estimated costs for respirators and exposure control plans, albeit by a

(discussing small business panel comments, which led to downward adjustment of usage assumption).

⁹³ Publicly available information supports OSHA’s assumption. *See, e.g.*, Missouri DOT Engineering Policy Guide ch. 237.8, Contract Time, http://epg.modot.mo.gov/index.php?title=237.8_Contract_Time (last visited Jan. 19, 2017) (showing average number of working days for six types of construction jobs across various geographic regions in the state; almost all below 150 days per year); Report, VDOT-VT Partnership for Project Scheduling, A Review of State DOT Methods for Determining Contract Times 4 (March 2005) www.virginiadot.org/business/resources/const/0501_statedotmethods.pdf, p. 4 (last visited Jan. 19, 2017) (review of state department of transportation methods for determining contract times; noting that Tennessee and Arkansas assume 150 working days per year).

fairly modest amount. For control costs, however, OSHA used the 150-day assumption only as a *divisor* to calculate the daily cost of some types of control equipment when it already had evidence of the total cost of that equipment. To obtain the daily cost, OSHA divided the total cost of the control by the number of working days it expected the equipment would be used; therefore, increasing the assumption from 150 to 250 days for purposes of calculating the daily rate would actually *lower* the daily cost of the control equipment, *decreasing* overall control costs. *See* Preamble at 16490; *see also* Preamble at 16490 n.38 (noting that the initial change in OSHA's assumption from 250 to 150 days *increased* the daily cost of control equipment).⁹⁴

Control costs constitute the majority of overall costs for construction (64%), whereas respirators (3.4%) and control plans (6%) account for less than 10% of the total. *See* Preamble at 16525-26. Thus, changing the working-day assumption so as to decrease daily control costs would decrease overall costs for construction, even if it also led to moderate increases in OSHA's cost estimates for respirators

⁹⁴ OSHA determined the total overall costs for these controls on the basis of full-time-equivalent employees, where a full-time-equivalent worker represents 2000 work hours (or 250 workdays). *See* Ex. 4247, Ch. V, p. 293 (Table V-39). While the full methodology OSHA used to estimate control costs is quite complex, it is described at length in the preamble at pages 16487-88.

and engineering controls.⁹⁵ For this reason, there is no merit to the petitioners' suggestion that adopting the 150-day assumption led OSHA to *underestimate* costs.

3. OSHA's Economic Analysis Appropriately Reflects the Costs Likely to Be Incurred by the Typical Construction Employer.

Employers that fully and properly implement the engineering controls, work practices, and respiratory protection specified in Table 1 of the construction standard are not also required to assess workers' silica exposures or separately ensure compliance with the PEL. *See* 29 C.F.R. § 1926.1153(c), (d). And as discussed above, OSHA found that the controls specified in Table 1 are technologically feasible (meaning employers using the equipment and performing the tasks covered by the table can use the specified controls most of the time). *See supra* pp. 92-93, 101 n.62.

Because following Table 1 allows employers to minimize (or eliminate) monitoring costs, provides a safe harbor from PEL requirements, and is generally

⁹⁵ In response to petitioners' argument, OSHA conducted an analysis to mathematically determine the impact of changing the working-day assumption from 150 to 250 days. OSHA determined that control costs would decrease by 2.6% (for a reduction in annualized costs of approximately \$11,000,000), while respirator costs would increase by 9.5% (for an increase in annualized costs of approximately \$2,000,000) and control plan costs would increase by 4.2% (for an increase in annualized costs of roughly \$2,000,000). Thus, changing the assumption would have the net effect of *decreasing* total annualized costs by approximately \$7,000,000, or less than 2%.

feasible from a technological perspective, OSHA assumed, for costing purposes, that employers performing the tasks and using the equipment listed on the table will follow Table 1 instead of using the more traditional compliance option. *See, e.g.,* Preamble at 16458, 16460, 16486, 16790, 16816, 16858. OSHA included regular monitoring/exposure assessment costs in its analysis only for operations not listed on Table 1 (*e.g.,* tunnel boring and abrasive blasting). Preamble at 16486, 16514. In addition, OSHA assumed that 1% of construction employers will conduct initial sampling to determine whether their workers' exposures are below the action level (rendering compliance with any of the Silica Rule unnecessary), and included corresponding monitoring costs in its analysis. *See id.*

Industry petitioners argue that OSHA improperly underestimated construction costs by failing to account for the regular exposure monitoring costs employers will incur in situations in which they cannot (or do not) fully and properly implement the protective measures called for by Table 1. *See* Industry Br. at 109. However, as discussed above, OSHA's technological feasibility analysis adequately determined that most construction employers will be able to comply with Table 1 most of the time. *See supra* pp. 92-93. Accordingly, while OSHA acknowledges that employers may encounter problems implementing Table 1 controls from time to time, those cases will be isolated. And OSHA did not err by excluding the monitoring costs associated with those isolated cases from its

analysis. As discussed previously with respect to foundries and fracking, OSHA satisfied its legal obligation by accounting for the costs likely to be encountered by the *typical* construction employer. *See Lead II*, 939 F.2d at 1005.

V. OSHA's Decisions on Four Ancillary Provisions Challenged by Petitioners Were Reasonable and Are Supported by Substantial Evidence in the Record.

Petitioners object to four of OSHA's decisions on ancillary provisions included in the final rule. First, union petitioners argue that OSHA impermissibly failed to provide construction employees with adequate protection when it chose to trigger medical surveillance in the construction standard based on respirator use for thirty or more days per year. *See Union Br.* at 33-44. Second, industry petitioners claim that OSHA's deviation from past practice regarding what employee medical information is provided to employers without employee consent is unjustified. *See Industry Br.* at 111-14. Third, union petitioners maintain that OSHA failed to adequately justify its decision not to include medical removal protection in the general industry standard. *See Union Br.* at 21-33. Fourth, industry petitioners contend that the Silica Rule's housekeeping provisions are overly broad and not supported by substantial evidence. *See Industry Br.* at 114-16.

OSHA considered and reasonably rejected each of petitioners' arguments before setting the final standards. OSHA's determinations are based on substantial evidence and its rationales are thoroughly presented in the preamble. Therefore,

the Court must uphold them since, in each instance, OSHA adequately met its obligation “to ‘identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument.’” *UAW v. Pendergrass (Formaldehyde)*, 878 F.2d 389, 392 (D.C. Cir. 1989) (quoting *Asbestos*, 838 F.2d at 1264).

A. *OSHA’s Decision to Trigger Medical Surveillance in the Construction Standard Based on Respirator Use for Thirty or More Days per Year Was Reasonable and Is Supported by Substantial Evidence.*

Under the final rule, construction employers that fully implement the protections specified in Table 1 are not required to assess employee exposures or take any other steps to assure compliance with the PEL. 29 C.F.R.

§§ 1926.1153(c)(1), (d); Preamble at 16714. Employers will, therefore, not know the exact exposure level of employees working under the provisions of Table 1. Preamble at 16815. And, as noted above, OSHA expects the vast majority of construction employers to utilize the Table 1 option.

As a result, OSHA could not implement the proposed requirement to offer medical surveillance to each employee exposed to silica above the PEL for thirty days or more per year in construction. *Id.* at 16815. Instead, OSHA reasonably chose to trigger medical surveillance for construction employees based on

respirator use, which OSHA determined is generally equivalent to a PEL trigger.

Id. at 16815-16.

OSHA chose to retain the thirty-day (duration-based) portion of the proposed trigger. *See id.* at 16814. Union petitioners claim that this decision denies “large numbers of construction employees medical surveillance at *any* level of exposure.” Union Br. at 43. They argue that OSHA should have required employers to offer medical surveillance to each construction worker who would be required under to use a respirator at any point during a year (without regard to exposure-duration). *See id.* at 38. As explained in the preamble, however, OSHA rejected this suggestion, in part, to ensure medical surveillance is focused on employees who are most at risk of developing silica-related disease.⁹⁶ *See* Preamble at 16814.

Silica-related health effects typically occur as a result of repeated exposures. *Id.* at 16816. Therefore, a trigger based on exposure duration focuses on employees who are more likely to experience adverse health effects. *Id.*; *see also id.* at 16814 (finding that a thirty-day trigger is a reasonable benchmark for

⁹⁶ Union petitioners also assert that employers can easily manipulate the duration of employment through layoffs and job rotation to avoid providing medical exams. Union Br. at 38. OSHA reasonably rejected this argument, finding that employers are unlikely to base employment and placement decisions on the thirty-day exposure-duration trigger because the cost of medical examinations is modest and employers would incur costs if they have to continually train new employees. Preamble at 16817, 16819.

capturing cumulative effects caused by repeated exposures). Workers only occasionally requiring a respirator to protect them from silica exposure would not likely receive the expected benefits from medical surveillance due to the infrequency of their exposures.

Union petitioners argue that expanding medical surveillance to any employee who is required to wear a respirator under this standard at any point during a year is necessary to cover workers who would not wear a respirator for thirty days or more during their employment with any particular employer, but might wear one for thirty days working for multiple employers over the course of a year.⁹⁷ Union Br. at 36-37. Although the available evidence indicates that up to 20% of construction workers may work for more than one employer during a year, *see* Union Br. at 37 (citing Ex. 1620), union petitioners have not pointed to any evidence showing that any of those workers would wear a respirator for thirty days or more in a year under this standard (without meeting the thirty-day threshold for any one employer) or that this is a common occurrence requiring the unions' overinclusive solution. *See Asbestos*, 838 F.2d at 1271 (“[P]arty challenging an

⁹⁷ Union petitioners have not challenged OSHA's decision that “exposures occurring with past employers do not count towards the 30-day-per-year exposure-duration trigger with the current employer (*i.e.*, the trigger is for employment with each particular employer)”. Preamble at 16817.

OSHA standard must bear the burden of demonstrating that the variations it advocates will . . . provide more than a *de minimis* benefit for worker health.”).

OSHA also reasonably determined that employers will be able to offer surveillance to the second group of workers the union claims will go unprotected: those who consistently work for a single employer, but are engaged in different combinations of tasks, in different locations, under different working conditions. *See* Union Br. at 37. OSHA found that employers should generally be able to estimate whether a particular worker is likely to require respiratory protection on a given day based on previous experience and all other available information. *See, e.g.*, Preamble at 16725-26. Likewise, OSHA expects that employers will know whether their workers are likely to perform the types of tasks for which respiratory protection may be needed. *See* Preamble at 16726, 16815-16 (citing Tr. 3008-10). Most construction employers should already be familiar with this type of requirement, as several OSHA construction standards require employers to consider whether employees are or may be exposed to a certain substance at a certain level for thirty or more days in a year. *See, e.g.*, 29 C.F.R. §§ 1926.1126(i)(1)(i)(A) (chromium (VI)), 1926.1127(l)(1)(i)(A) (cadmium), 1926.62(j)(1)(ii) (lead). This consistency also makes the thirty-day trigger more convenient for the construction industry, especially as union petitioners present no

evidence that employers have had difficulty making such determinations under other standards.⁹⁸ *See* Preamble at 16816-17.

Moreover, OSHA reasonably accounted for the fact that employers may not always be able to anticipate employee respirator use due to unexpected circumstances. Preamble at 16818. In those cases, OSHA directed employers to offer medical surveillance as soon as it becomes apparent that the employee will be required to wear a respirator for thirty or more days per year. *See id.*

Consequently, in the unusual situation where a construction employer is unable to anticipate future respirator use and offer medical surveillance prospectively, the employer can still track actual respirator use and offer surveillance when the employer realizes that the duration-trigger is likely to be met. *See* Preamble at 16815-16 (citing Tr. 1535-36, 3008-10) (some employers are already tracking a variety of similar, and in some cases far more complex, issues in the workplace).

⁹⁸ Union petitioners also argue that OSHA impermissibly balanced risks to employee health against employer administrative burdens. *See* Union Br. at 38-39 (quoting Preamble at 16816). This argument takes the quoted statement out of context. In context, OSHA was merely responding to employer comments about such burdens as part of a discussion on what is reasonable and practical given the risks associated with occasional versus repeated exposure. Preamble at 16816.

B. *OSHA's Evidence-Based Determination Regarding Which Private Employee Medical Information Should Be Provided to Employers Must Be Upheld.*

Medical surveillance provisions in OSHA standards typically require the employer to obtain a written medical opinion that includes private employee medical information from the physician or other licensed health care professional performing a required examination. *See, e.g.*, 29 C.F.R. § 1910.1026(k)(5)(i) (chromium (VI)). The proposed silica rule followed this convention. *See* 78 Fed. Reg. at 56500. For example, the employer would have learned whether the health care professional recommended referral to a pulmonary specialist, regardless of whether the employee wanted the employer to know or planned to visit the specialist. *See id.*

In the final standards, OSHA took “a more privacy- and consent-based approach . . . compared to the proposed requirements and earlier OSHA standards” “in response to the weight of opinion in [the silica] rulemaking record and to evolving notions about where the balance between preventive health policy and patient privacy is properly struck.” Preamble at 16831. Industry petitioners assert that this decision was unjustified and runs “counter to the primary purposes of medical surveillance.” Industry Br. at 112; *see also* Industry Br. at 111-14. The Court must reject industry petitioners’ challenge because OSHA appropriately explained and justified its reasons for adopting a more privacy-protective model,

including its reasons for finding that the change from prior practice and the proposal does not detract from, and may actually increase, the benefits of medical surveillance. *See Formaldehyde*, 878 F.2d at 392. *See generally* Preamble at 16830-36.

OSHA's decision was based chiefly on record evidence that employees would refuse to participate in medical surveillance due to privacy concerns. Preamble at 16834. Various stakeholders, including labor unions, physicians, and employees, expressed concern that employees' current or future employment might be jeopardized if medical information is reported to employers without employee consent.⁹⁹ Preamble at 16831-32 (citing, *e.g.*, Ex. 2282, Attachment 3, p. 20; Ex. 4203, pp. 6-7; Ex. 4214, pp. 7-8; Tr. 1582, 2470-71, 3053-54, 3245, 3881-82, 4227-28, 4294-95). Employees must choose to participate in medical surveillance in order for it to be successful, and employees' reluctance to let employers know about their health status may result in their refusal to participate in medical surveillance. Preamble at 16832 (citing Tr. 169, 819-20, 1657, 3053-54; Ex. 4219, p. 31; Ex. 4223, p. 131).

OSHA fully considered and adequately explained its rejection of the arguments raised by industry petitioners here. For example, industry petitioners

⁹⁹ Testimony from industry representatives indirectly confirmed that employee fears of discrimination are not unwarranted. Preamble at 16832 (citing Ex. 4217, pp. 22-23).

claim that the withholding of employee medical information will prevent employers from “understand[ing] the effects that hazards in the work environment are having on the health of their employees and . . . mak[ing] necessary changes to the worksite.” Industry Br. at 112. OSHA addressed this argument in the preamble, explaining that “because of the long latency period of most . . . silica-related diseases, a diagnosis of such an illness . . . will not provide useful information about current controls or exposure conditions.” Preamble at 16833. Thus, OSHA reasonably found that employee health information would provide employers with little to no information on current exposures in the workplace.

OSHA also addressed the argument that withholding detailed medical information from employers might leave employers with no medical basis to aid in employee placement.¹⁰⁰ See Industry Br. at 112-13; see also Preamble at 16833.

On this point, OSHA credited testimony opposing employers making job

¹⁰⁰ Industry petitioners rely on OSHA’s statement in the chromium (VI) rulemaking explaining that OSHA required the health care professional to give the medical opinion to the employer “to provide the employer with a medical basis to aid in the determination of placement of employees and to assess the employee’s ability to use protective clothing and equipment” and stating that the denial of this information “would diminish one of the main benefits of the medical surveillance requirements of this standard.” Industry Br. at 113 (quoting 71 Fed. Reg. at 10365). Under the Silica Rule, the medical opinion for the employer must contain any recommended limitations on the employee’s respirator usage. See Preamble at 16835; 29 C.F.R. § 1926.1153(h)(6)(i)(C). Thus, employers will still have the information necessary to assess their employees’ ability to use the only personal protective equipment required by the Rule.

placement decisions based on employees' medical findings. Preamble at 16833 (citing Ex. 2371, Attachment 1, pp. 45-46; Ex. 4214, pp. 7-8; Ex. 4219, pp. 31-32; Ex. 4223, p. 133; Tr. 1656). Specifically, OSHA was persuaded "that employees have the most at stake in terms of their health and employability, and they should not have to choose between continued employment and the health benefits offered by medical surveillance." Preamble at 16833. OSHA also reasonably concluded that before employees make employment decisions that take into account the risks of silica exposure, they "need to have confidence that participation in medical surveillance will not threaten their livelihoods." *Id.*

Finally, OSHA considered and reasonably rejected the contention that OSHA lacks the legal authority to require employers to pay for ongoing medical surveillance with, allegedly, no nexus to the workplace. Preamble at 16833-34. OSHA properly found that "the medical surveillance requirement in this rule, and every OSHA rule, [has] a nexus to the workplace." Preamble at 16834. The nexus to the workplace in the silica rule "is that exposure in the workplace can result in or exacerbate disease and that medical surveillance information will allow employees to make health and lifestyle decisions that will benefit both them and the employer." *Id.* OSHA noted that medical surveillance unqualifiedly "provides the employer with information on fitness to wear a respirator, which is vitally important because of risks to employees who wear a respirator when they should

not do so because of medical reasons.” *Id.* OSHA’s determination that the medical surveillance provisions in the Silica Rule strike the proper balance between encouraging employee participation and providing the employer with needed information to protect its employees is rational and supported by substantial evidence, and thus should be upheld by this Court.

C. *OSHA Properly Omitted Medical Removal Protection from the Final General Industry/Maritime Standard.*

Some OSHA health standards contain “medical removal protection” provisions that require employers to remove employees from exposure, with maintenance of pay and other benefits, when removal is recommended by a health care provider. *See, e.g.*, 29 C.F.R. § 1910.1025(k) (lead). OSHA did not include medical removal protection in the Silica Rule primarily because it did not expect that the health of a significant number of employees would benefit from temporary removal from their jobs as a result of medical surveillance findings. Preamble at 16840. It also reasonably found that workers’ compensation is the appropriate recourse if permanent removal is required. *See* Preamble at 16839. Union petitioners challenge this decision as it relates to the general industry/maritime standard.¹⁰¹ Union Br. at 21-33. The challenge is unpersuasive.

¹⁰¹ Without explanation, union petitioners do not challenge OSHA’s decision as to the construction standard. Union Br. at 24 n.13.

In *Asbestos*, this Court held that “a party challenging an OSHA standard must bear the burden of demonstrating that the variations it advocates will be feasible to implement and will provide more than a *de minimis* benefit for worker health.” 838 F.2d at 1271. *Only* if the challenging party produces such evidence should the reviewing court consider the agency’s decision not to institute the suggested alternative. *See id.* (finding that cost estimates and evidence of worker health benefits submitted by the challenging party were enough to trigger OSHA’s duty to justify non-adoption of the alternative proposal). Here, union petitioners have not offered any evidence of medical removal protection costs or otherwise demonstrated that it would be economically feasible. Therefore, the Court need not even consider OSHA’s reasons for not adopting the alternative proposal. However, as shown below, OSHA’s decision was eminently reasonable.

Union petitioners point to two situations in which they claim that temporary removal would benefit worker health. First, they argue that it “would be beneficial where an employee has been referred to a specialist for further evaluation and the [referring health care professional] has recommended that the individual be removed from exposure pending the specialist’s determinations.” Union Br. at 30. In support of this argument, they point to other OSHA standards that allow for temporary removal. *Id.* However, they fail to point to any evidence of how removal pending evaluation by a specialist would benefit employees in *this*

rulemaking. On the contrary, the available evidence suggests that, given the slow progression of silica-related diseases, “there is no urgent need for removal from . . . exposure while awaiting a specialist determination.” Preamble at 16840.

Second, union petitioners claim that temporary removal is warranted where a health care professional has determined that temporary removal would improve employee health. *See* Union Br. at 28-30. They offer only one example in support of this argument: situations in which temporary removal might alleviate exacerbated symptoms of non-malignant respiratory diseases, such as chronic obstructive pulmonary disease. *Id.* at 29. However, chronic obstructive pulmonary disease is not reversible. Preamble at 16839. Periods of exacerbation would likely continue to recur absent *permanent* removal. *Id.* Temporary removal would offer little more than a repeated, short-term reprieve from symptoms of a permanent health condition that would recur upon re-exposure. *See id.*

While acknowledging that removing some employees from silica exposures might help prevent or delay progression of silica-related disease, OSHA found that because such diseases are permanent, removals would also need to be permanent to have a beneficial effect. Preamble at 16839. Absent special circumstances, OSHA views medical removal protection as appropriate for dealing with temporary removals only, and considers workers’ compensation the appropriate recourse if

permanent removal from exposure is required.¹⁰² *Id.* OSHA explained that the primary objective of medical removal protection provisions “is to prevent permanent health effects from developing by facilitating employee removal from exposure at a point when the effects are reversible,” and that such an objective “cannot be met where the effects are already permanent.”¹⁰³ *Id.* OSHA properly declined to adopt removal protection provisions in other health standards, such as its chromium (VI), ethylene oxide, and 1,3-butadiene standards, for similar reasons. Preamble at 16839; *see also, e.g.*, 71 Fed. Reg. at 10366-67.

OSHA also considered other criteria it has previously applied to determine the necessity for medical removal protection and found that they do not support including such provisions in the Silica Rule. Preamble at 16840 (incentives for employer compliance in lead standard not applicable to silica context), 16839-40

¹⁰² The argument that this Court’s decision in *Formaldehyde* compels a remand of OSHA’s decision not to require removal of employees suffering from permanent silica-related health effects is misplaced. *See* Union Br. at 27 (citing 878 F.2d at 400). The remand in *Formaldehyde* occurred primarily because OSHA did not appropriately explain its decision in the preamble. *See* 878 F.2d at 400 (finding “allusions to ‘non-specificity’ of symptoms too vague and obscure either to show consistency with OSHA’s prior stance or to justify a reversal of position”). Remand is not necessary here because OSHA’s decisions are carefully explained and consistent with many of its previous standards.

¹⁰³ Given that removal protections are designed to protect workers for a temporary period of time, OSHA health standards that contain removal protection provisions limit available benefits to a maximum, specified period of time. *See, e.g.*, 29 C.F.R. §§ 1910.1027(l)(12) (cadmium), 1910.1028(i)(9) (benzene), 1910.1052(j)(12) (methylene chloride).

(medical removal protection necessary in formaldehyde standard because the availability of medical surveillance in that standard depended on employee actions). Importantly, the Silica Rule allows employees to choose whether to give their private health information to their employers. In past standards, employee health information passed to employers without employee consent. Therefore, a key factor employees considered in deciding whether to participate in surveillance was whether they wanted to give their private health information to their employers. In this context, medical removal protection reassured employees that they would not immediately lose their livelihood if they chose to participate in medical surveillance. *See id.* at 16839-40 (discussing employee sabotage of blood lead levels). In the Silica Rule, OSHA concluded that the incentive for employee cooperation that wage protection crucially provides in other situations was adequately addressed by the enhanced privacy protection afforded in the medical surveillance provision. *See Preamble* at 16840.

OSHA's reasons for including a medical removal protection provision in the recent beryllium standards are also not applicable to the Silica Rule. OSHA found that such a provision was important in the beryllium standards because removal of a sensitized employee may prevent the development of chronic beryllium

disease.¹⁰⁴ 82 Fed. Reg. 2470, 2721 (Jan. 9, 2017). Silica-related lung diseases, however, are detectable only when a worker has already developed some degree of lung damage or lung function loss. *See, e.g.*, Preamble at 16823, 16837, 16831. Thus, once silica-related disease has been detected, removal would not prevent disease.¹⁰⁵ Preamble at 16839; *see also* 82 Fed. Reg. at 2720-2721 (discussing other reasons for medical removal protection in beryllium standards that are inapplicable to silica, *i.e.*, financial incentive for employers and partial dependency on employee cooperation).

Finally, contrary to union petitioners' argument, Union Br. at 31-32, OSHA's decision not to include medical removal protection for employees who are exposed above the PEL but cannot wear a respirator is reasonable and supported by substantial evidence. OSHA determined that such a provision was unnecessary for the Silica Rule because OSHA has revised its respirator standard to address the "problem of employees who are medically unable to wear negative pressure

¹⁰⁴ Sensitization to beryllium is an essential step in the development of chronic beryllium disease. 82 Fed. Reg. at 2492.

¹⁰⁵ A diagnosis of chronic beryllium disease also triggers medical removal protection in the beryllium standards. Although chronic beryllium disease is an irreversible condition, there is some evidence that medical removal could prevent its progression. 82 Fed. Reg. at 2721. Moreover, because workers with chronic beryllium disease will also have been sensitized, not including chronic beryllium disease as a trigger for medical removal would have served as a disincentive to sensitized workers to be tested for chronic beryllium disease.

respirators by requiring the employer to provide a powered air-purifying respirator.” Preamble at 16840 (citing 29 C.F.R. § 1910.134(e)(6)). OSHA cited to record evidence indicating that “[s]uch an approach has been used by employers who are unable to move employees to jobs with lower exposure.” Preamble at 16840 (citing Ex. 3577, p. 610).

Union petitioners contend that some employees who are medically unable to use a negative pressure respirator will also not be able to use a powered air-purifying respirator. Union Br. at 31-32. In support of this argument, they reference OSHA’s finding in the preamble to its respirator standard that “*many* workers who are medically unable to use a negative pressure respirator will be able to use a [powered air-purifying respirator]” and discussion in the silica preamble noting “medical disqualifications” as one of the disadvantages of negative pressure respirators that also apply to powered air-purifying respirators. *Id.* (citing 63 Fed. Reg. 1152, 1221 (Jan. 8, 1998) and Preamble at 16780). They also cite to testimony that “it would be almost virtually impossible to wear [a powered air-purifying respirator] and perform [particular tasks].” Union Br. at 32 (citing Preamble at 16780).

In essence, union petitioners fault OSHA for not providing medical removal protection for an unknown number of employees who may be: (1) in general industry, (2) exposed to silica levels above the PEL, (3) unable to wear a negative

pressure respirator, and (4) unable to wear a powered air-purifying respirator.

However, they have neither attempted to quantify the number of employees who might meet these criteria, nor pointed to any evidence that such employees even exist.

Union petitioners also claim that OSHA's justifications for this decision are at odds with OSHA's prior statements. Union Br. at 32-33 (citing OSHA's brief in *Cotton Dust*, 452 U.S. at 539). However, the referenced statement was made seventeen years *before* OSHA revised its respirator standard. And OSHA's statements in the preamble to the chromium (VI) standard, which is the only other OSHA standard to address this issue since the respirator standard's revision, mirror those provided in the preamble to this rule. *See* 71 Fed. Reg. at 10367. Thus, OSHA's rationale here is consistent with the only relevant statement it has made on this issue.

D. *OSHA's Decision to Limit Dry Sweeping and the Use of Compressed Air Was Reasonable Where Substantial Evidence Shows that These Practices Contribute to Employee Exposures.*

The proposed Silica Rule would have prohibited the use of compressed air and dry sweeping to clean clothing or surfaces contaminated with silica where such activities could contribute to employee exposure to silica that exceeds the PEL. Preamble at 16794. It also would have required employers to ensure that accumulations of silica are cleaned by HEPA-filter vacuuming or wet methods

where such accumulations could, if disturbed, contribute to employee exposure to silica that exceeds the PEL. *Id.*

Stakeholders submitted a variety of conflicting opinions on these proposed provisions. For example, some stakeholders, including some of the industry petitioners, argued that wet methods and HEPA-filtered vacuums are not safe and effective in all situations. Preamble at 16794-95. Other stakeholders, including some of the union petitioners, argued that dry sweeping and compressed air should be prohibited at any exposure level, not just where the use of such measures contributes to exposures that exceed the PEL. Preamble at 16796. Some of these stakeholders maintained that lower exposures should trigger the provisions because exposure at the PEL still poses a significant risk to workers. *Id.* Still other stakeholders, including some of the industry petitioners, argued that a general prohibition on the use of compressed air, dry brushing, and dry sweeping to clean areas where silica-containing material has accumulated is too broad, and not directly related to a particular exposure risk. *Id.*

OSHA revised the proposed provisions in response to these comments. Preamble at 16795-96. The final standards prohibit dry sweeping “where such activity could contribute to employee exposure to . . . silica unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of

exposure are not feasible.”¹⁰⁶ 29 C.F.R. §§ 1910.1053(h), 1926.1153(f); *see also* Preamble at 16795. They also prohibit the use of compressed air to “clean clothing or surfaces where such activity could contribute to employee exposure to . . . silica unless: (i) [t]he compressed air is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air; or (ii) [n]o alternative method is feasible.” 29 C.F.R. §§ 1910.1053(h), 1926.1153(f); *see also* Preamble at 16795.

Industry petitioners argue that OSHA’s decision to allow dry sweeping and compressed air only where wet sweeping, HEPA-filtered vacuuming, or other methods that minimize the likelihood of exposure are not feasible does not “account for the practical implications of the proposal.”¹⁰⁷ Industry Br. at 115. However, all of the examples industry references to support its objections are addressed by the feasibility exception in the final rule. *See id.*; *see also* Preamble at 16795-96 (discussing situations raised in industry petitioners’ brief). OSHA’s

¹⁰⁶ This provision also prohibits dry brushing. However, this activity was not mentioned in the industry’s brief and, thus, remains unchallenged.

¹⁰⁷ Industry petitioners also complain that the rule does not define what is feasible in any particular situation. Industry Br. at 115. While the regulatory text does not define the term, OSHA’s intent is clear from the preamble. Indeed, industry’s brief uses the preamble’s definition. *Id.* at 115-16 (“the employer . . . will then have to convince a compliance officer . . . that using a wet method or vacuum system ‘would not be effective, would cause damage, or would create a hazard in the workplace.’”).

method of resolving these concerns was reasonable, whereas industry commenters (and now petitioners) did not offer OSHA an alternative method that would have alleviated their concerns and appropriately protected employee health. OSHA's chosen solution encompasses the situations industry raises and is flexible enough to encompass other, unexpected situations.¹⁰⁸ Thus, the Court must reject this argument. *See Formaldehyde*, 878 F.2d at 392.

Industry petitioners also argue that the provisions are unreasonably broad, *i.e.*, not reasonably necessary to protect against a silica-related health risk. *Industry Br.* at 116. However, as noted above, some stakeholders objected to triggering cleaning-related provisions at the PEL because exposure at the PEL still poses a significant risk to workers. OSHA agreed with these commenters and revised the rule accordingly, stating that “the risk of material impairment of health remains significant at and below the revised PEL of 50 $\mu\text{g}/\text{m}^3$, including at the new action level of 25 $\mu\text{g}/\text{m}^3$.” Preamble at 16796. OSHA intended the revised housekeeping triggers to minimize this risk. *Id.*; *see also Asbestos*, 838 F.2d at 1269 (“[I]t is [the Secretary’s] duty to keep adding measures so long as they afford

¹⁰⁸ Industry petitioners oddly ignore the Silica Rule’s new exception for the use of compressed air where it is used in conjunction with a ventilation system that effectively captures the dust cloud created by the compressed air. *See* 29 C.F.R. §§ 1910.1053(h)(2)(i), 1926.1153(f)(2)(i). This change provides employers with additional opportunities to use compressed air without compromising employee health. *See* Preamble at 16795-96.

benefit and are feasible, up to the point where he no longer finds significant risk.”). But OSHA also narrowly tailored the final provision to “not only balance the concerns of employers with the need to protect employees, but align the rule with the realities of the workplace, which do not always lend themselves to the method that produces the lowest silica exposure.” Preamble at 16796. This decision was reasonable and the resulting final provisions are appropriately narrow so as to protect employees from cleaning methods that can lead to unnecessary employee exposure, while allowing employers flexibility.

To the extent industry petitioners’ real concern is that employers must bear the burden of convincing an OSHA compliance officer that using a wet method or vacuum system would be infeasible, Industry Br. at 115-16, the argument fails as a matter of law. First, the burden of proof is appropriately placed on the employer to make and support a claim of infeasibility because the employer has better access to information specific to the particular cleaning need or method in the particular workplace that is relevant to the issue of feasibility. *Cf. Brock v. Dun-Par Engineered Form Co.*, 843 F.2d 1135, 1138-1139 (8th Cir. 1988) (burden on employer to show infeasibility of compliance with OSHA standard). Second, OSHA gave clear guidance to both employers and compliance officers in the final rule’s preamble, spelling out the types of situations that would qualify as infeasible. *See* Preamble at 16794-96. Third, if employers disagree with OSHA’s

determination that a particular cleaning method is feasible in a given situation, they can challenge the citation. Fourth, such a claim is not ripe for review. Whether any specific OSHA finding conflicts with the guidance OSHA has provided in the final rule's preamble will depend on the specific facts of each case. *See Munsell v. Dep't of Agric.*, 509 F.3d 572, 585 (D.C. Cir. 2007) (“[R]ipeness inquiry springs from the Article III case or controversy requirement that prohibits courts from issuing advisory opinions on speculative claims”) (citation omitted).

VI. OSHA Provided Sufficient Time and Information to Allow for Meaningful Comment on the Silica Rule.

Industry petitioners argue that OSHA deprived the public of: (1) notice and an opportunity to comment on exposure data that OSHA relied on in the final rule and (2) a meaningful opportunity to comment on and examine information supplied by OSHA's contractor. Industry Br. at 116-21. The Court should reject both of these allegations because OSHA provided stakeholders with sufficient time and information to allow for meaningful comment.

A. Rulemaking Participants Had Ample Time to Review and Provide Meaningful Comment on OSHA Information System Data.

Following its five-month prehearing comment period and three-week informal public hearing, OSHA provided stakeholders with a four-and-a-half-month post-hearing comment period: sixty days in which to submit additional information and data, followed by seventy-six days to file final briefs, arguments,

and summations.¹⁰⁹ Exs. 3569, 4192; Preamble at 16297-98. On the last day of the data submission period, but *before* the additional briefing period, OSHA submitted recent data from the OSHA Information System to the docket.¹¹⁰ *See* Ex. 3958 (posted June 3, 2014). Industry petitioners argue that OSHA's actions denied them the ability to comment meaningfully. Industry Br. at 118.

The Court should reject industry petitioners' arguments for three reasons. First, seventy-six days is ample time for stakeholders to review the data submitted during the data period and file their final briefs.¹¹¹ Second, the OSHA Information System data was added to supplement the record in response to stakeholder comments regarding the accuracy of older exposure data and did not contradict OSHA's preliminary feasibility findings in the proposal. *See* Preamble at 16632 (citing Ex. 2349, p. 4); Tr. 33-34 (hearing participant asking OSHA for more

¹⁰⁹ OSHA initially provided stakeholders with forty-five days in which to file final briefs, arguments, and summations, but it extended that period by thirty-one days in response to stakeholder requests, allowing for a total briefing period of seventy-six days. Exs. 3569, 4192.

¹¹⁰ The OSHA Information System data is from OSHA inspections conducted during OMB's review of the proposed rule (which began in 2011) and after the proposed rule had been published, until April 17, 2014. *See* Ex. 3958.

¹¹¹ The Administrative Conference of the United States recommends a minimum comment period of sixty days to allow meaningful comment on significant regulatory actions. *See* Administrative Conference of the United States Recommendation 2011-2, Rulemaking Comments (June 16, 2011), 76 Fed. Reg. 48789, 48792 (Aug. 9, 2011).

recent inspection data); *see Chamber of Commerce of U.S. v. S.E.C.*, 443 F.3d 890, 900 (D.C. Cir. 2006) (further notice and comment not required when additional fact gathering merely supplements information in the record without changing methodology).

Third, industry petitioners have failed to demonstrate how they were harmed by OSHA's choice not to further extend the post-hearing briefing period. *See Fla. Power & Light Co. v. United States*, 846 F.2d 765, 772 (D.C. Cir. 1988) (petitioners' challenge not meritorious where no substantive challenges that differ in kind from original comments were raised). Therefore, the claim that the post-hearing briefing period was not sufficient to allow meaningful comment on the OSHA Information System data is entirely without merit.

B. *OSHA Did Not Deprive the Public of Notice of or the Opportunity for Meaningful Comment on the Data Provided by Its Contractor.*

During the silica rulemaking, OSHA hired an outside contractor, ERG, with extensive scientific and technical expertise, to assist in the rulemaking. *See, e.g.*, Ex. 4190. ERG gathered information, conducted site visits, interviewed experts, analyzed data in the rulemaking record, and otherwise advised OSHA as an expert consultant in the development of the preliminary and final economic analyses.¹¹²

¹¹² ERG's role in this rulemaking was typical. In past rulemakings, OSHA has employed expert consultants, like ERG, to gather and analyze information. *See, e.g.*, Methylene Chloride Final Economic Analysis, Docket ID OSHA-H071B-

See, e.g., Exs. 1365, 1431. Industry petitioners claim that OSHA deprived the public of a meaningful opportunity to comment on and examine the information supplied by ERG. *See* Industry Br. at 121. For example, they argue that OSHA should have made ERG available at the public hearing for “cross-examination and questioning.” *Id.*; *see also* Industry Br. at 120 (“The source data OSHA cites for [interviews conducted by ERG] does not include the names of the individuals interviewed, the individuals’ qualifications, or the name of the facility.”).

The Court should reject this argument for five reasons. First, industry petitioners have not demonstrated that they asked OSHA to make ERG available at the hearing or that they specifically asked OSHA for the information they now claim is critical.¹¹³ *See Tex Tin Corp. v. EPA*, 935 F.2d 1321, 1323 (D.C. Cir. 1991) (“Absent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue.”); *Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 602 (D.C. Cir. 2015) (“The question in determining whether an issue was preserved, however, is not simply whether it was raised in some fashion, but whether it was raised with sufficient

2006-0839-0121 (noting that OSHA’s consultant conducted a survey on the use of methylene chloride, the results of which were the bases for exposure assessments). This practice is expressly authorized by the OSH Act. *See* 29 U.S.C. § 656(c); *see also Lead I*, 647 F.2d at 1216-17.

¹¹³ Neither the Administrative Procedure Act nor the OSH Act requires OSHA, its consultants, or any other party to appear at the informal hearing.

precision, clarity, and emphasis to give the agency a fair opportunity to address it.”).

Second, OSHA placed all of the evidence it considered in this rulemaking into the record for stakeholder review and comment. Industry petitioners have not suggested otherwise. *See, e.g.*, Industry Br. at 119-120 (citing discussion in Ex. 4247 that, in turn, cites to exhibits that were placed in the record more than two years prior to the proposal’s publication); *see also* Exs. 1365, 1431 (reports prepared by ERG for OSHA’s use in its preliminary technological feasibility analysis, entered into the record before the proposal’s publication, along with reports from ERG site visits and dozens of interviews with industry consultants and equipment manufacturers).

Third, as to industry petitioners’ claim that OSHA failed to disclose the bases for ERG’s estimates, it is clear from their brief that their issue is not lack of disclosure, but rather whether the bases were sufficient. *See, e.g.*, Industry Br. at 121 (“OSHA provided no scientific basis or reasonable justification for ERG’s opinion”); *see also id.* at 120 (quoting ERG’s estimate in Ex. 4247, Ch. V, p. 251, but omitting the next sentence in the exhibit, which explains the reasons for the estimate, and ignoring the table on the previous page, which summarizes the productivity impact estimates and cites to the source document). However, petitioners neither explain why they believe the given bases to be insufficient nor

point to alternative evidence on which OSHA should have relied. And, even if the bases of ERG's opinions were insufficient, which they are not, industry petitioners have failed to demonstrate what affect, if any, these alleged insufficiencies would have on OSHA's feasibility findings.

Fourth, as to the bits of evidence petitioners mention that were not disclosed, *i.e.*, "the names of the individuals interviewed, the individuals' qualifications, or the name of the facility," Industry Br. at 120, petitioners have not demonstrated harm, especially given that OSHA did not consider this information. *See First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) ("As incorporated into the [Administrative Procedure Act], the harmless error rule requires the party asserting error to demonstrate prejudice from the error.") (citations and quotation marks omitted). Finally, the OSH Act requires OSHA to make its decisions based on "the best available evidence." 29 U.S.C. § 655(b)(5). OSHA cannot disregard the best (and, in some cases, only) available evidence on a particular topic merely because it does not answer every possible question a stakeholder may have.

CONCLUSION

For the foregoing reasons, the Silica Rule should be upheld in its entirety and the petitions for review should be denied.

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CERTIFICATE OF COMPLIANCE

I hereby certify that Respondents' brief complies with the Court's Order of October 13, 2016, because it contains 41,921 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(f).

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Dated: January 19, 2017

CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of January, 2017, a copy of the foregoing Brief for Respondents was filed electronically via the Court's CM/ECF Electronic Filing System. All registered counsel will be served via operation of the Court's CM/ECF Electronic Filing System.

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