ORAL ARGUMENT NOT YET SCHEDULED

RECORD No. 16-1105(L) (consolidated with Nos. 16-1113, 16-1125, 16-1126, 16-1131, 16-1137, 16-1138, and 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 & HEALTH ADMINISTRATION, UNITED STATES DEPARTMENT OF LABOR,

Respondent.

On Petitions for Review of a Final Rule of the United States Occupational Safety and Health Administration

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JOINT OPENING BRIEF OF INDUSTRY PETITIONERS

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DATED MARCH 23, 2017

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Cir. R. 28(a)(1), Petitioners in Case Nos. 16-1125, 16-1126, 16-1131, 16-1137, 16-1138, and 16-1146 (jointly, "Industry Petitioners") state as follows:

A. Parties, Intervenors, and Amici

Because these consolidated cases involve direct review of final agency action, the requirement to furnish a list of parties, intervenors, and *amici curiae* that appeared below is inapplicable. These cases involve the following parties:

Petitioners:

No. 16-1105: North America's Building Trades Unions.

No. 16-1113: American Federation of Labor and Congress of Industrial Organizations; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC; International Union, United Automobile, Aerospace and Agricultural Implement Workers of America.

No. 16-1125: Associated Masonry Contractors of Texas DBA Texas Masonry Council; 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, Inc.; and Texas Association of Builders.

No. 16-1126: American Foundry Society Texas Region 3/Texas Chapter of the American Foundry Society; and Texas Association of Business.

No. 16-1131: National Stone, Sand & Gravel Association.

No. 16-1137: American Foundry Society; and National Association of Manufacturers.

No. 16-1138: American Road and Transportation Builders Association; American Society of Concrete Contractors; American Subcontractors Association; Associated Builders and Contractors; Associated General Contractors; Association of the Wall and Ceiling Industry; Building Stone Institute; Concrete Sawing & Drilling Association; Construction & Demolition Recycling Association; Interlocking Concrete Pavement Institute; International Council of Employers of Bricklayers and 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; Natural Stone Council; The Association of Union Constructors; and Tile Roofing Institute.

No. 16-1146: Brick Industry Association.

Respondents:

Respondents are the Occupational Safety and Health Administration, United States Department of Labor (in Nos. 16-1105, 16-1113, 16-1125, 16-1126, 16-1137, 16-1138); Occupational Safety and Health Administration (Nos. 16-1131, 16-1146); Thomas Perez, Secretary, United States Department of Labor (in Nos. 16-1125, 16-1126, 16-1137, 16-1138); and Secretary, Department of Labor (in Nos. 16-1131, 16-1146).

Intervenors-Petitioner:

The Chamber of Commerce of the United States of America, the State Chamber of Oklahoma, the Greater North Dakota Chamber of Commerce, the Portland Cement Association, and the National Concrete Masonry Association are all Intervenors for Petitioner Brick Industry Association.

Intervenors-Respondents:

National Stone, Sand & Gravel Association; American Foundry Society; National Association of Manufacturers; National Association of Home Builders; North America's Building Trades Unions; American Federation of Labor and Congress of Industrial Organizations; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC; International Union, United Automobile, Aerospace and Agricultural Implement Workers of America are Intervenors for Respondents.

***Amici Curiae*:**

The American Thoracic Society and the American College of Occupational and Environmental Medicine have been granted leave to file a brief as *amicus curiae* in support of Respondent OSHA.

B. Rulings Under Review

These consolidated cases involve petitions for review of the final rule titled "29 CFR Parts 1910, 1915, and 1926, Occupational Exposure to Respirable Crystalline Silica" (Docket No. OSHA-2010-0034, RIN 1218-AB70), promulgated by the Occupational Safety and Health Administration ("OSHA") of the United States Department of Labor ("DOL") on March 25, 2016, and published in the *Federal Register* at 81 Fed. Reg. 16,285 ("Silica Rule" or "Rule"). Because this is a direct appeal to this Court, as provided for in 29 U.S.C. § 655(f), there were no proceedings or disposition below.

C. Related Cases

This case was not previously before this Court. Certain Petitioners filed seven Petitions for Review of the Silica Rule in six different circuit courts of appeals (*i.e.*, Nos. 16-1105, 16-1112, 16-1113, 16-1114, 16-1125, 16-1126, 16-1131). Those Petitions were transferred to this Court per the Consolidation Order of the United States Judicial Panel on Multidistrict Litigation ("MDL"). *In re: Occupational Safety and Health Administration, U.S. Department of Labor, "Occupational Exposure to*

Respirable Crystalline Silica; Final Rule," March 25, 2016, MCP No. 139, Doc. 3 (J.P.M.L. April 12, 2016). Case Nos. 16-1137, 16-1138, 16-1146, and 16-1151 were filed in this Court after the MDL's April 12th Order.

All related cases pending in this Court (Nos. 16-1105, 16-1112, 16-1113, 16-1114, 16-1125, 16-1126, 16-1131, 16-1137, 16-138, 16-1146, and 16-1151), were consolidated under the lead docket number 16-1105 by the Court's Orders dated April 28, 2016, May 6, 2016, May 11, 2016, May 17, 2016, and May 25, 2016. Voluntary dismissal of three petitions (Nos. 16-1112, 16-1114, and 16-1151) was granted by the Court's Orders dated June 7, 2016 and June 9, 2016. The undersigned counsel is not aware of any other related case currently pending in this Court or any other court.

RULE 26.1 DISCLOSURE STATEMENTS

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, Industry Petitioners make the following statements:

No. 16-1125:

Associated Masonry Contractors of Texas DBA Texas Masonry Council ("TCM"): TMC is a non-profit national trade association incorporated in the State of Texas with headquarters located in Waco, TX. The TMC has no parent company, and no publicly held company has a 10% or greater ownership interest in TMC. TMC is a positive, professional, and financially-sound organization effectively

bringing many diverse people together to protect and strengthen the masonry industry, making masonry the dominant building material in Texas.

Associated Subcontractors Association of Texas, Inc. ("ASAT"): ASAT serves the commercial specialty trade construction industry of Texas through advocacy and education. ASAT is a nonprofit national trade association incorporated in the State of Texas with headquarters located in Horseshoe Bay, Texas. The ASAT has no parent company, and no publicly held company has a 10 perecent or greater ownership interest in ASAT.

Distribution Contractors Association ("DCA"): DCA is a non-profit national trade association incorporated in the State of Texas with headquarters located in Richardson, Texas. DCA has no parent company and no publicly held company has a 10 percent or greater ownership interest in the association. DCA represents contractors, suppliers and manufacturers who provide construction services including installation, replacement and rehabilitation of natural gas distribution systems and interstate gas transmission pipelines, as well as water, sewer and other utility systems. DCA has 200 members across the U.S.

Louisiana Associated General Contractors, Inc.: Louisiana Associated General Contractors is the only statewide, full-service construction trade association representing nearly 800 general contractors, subcontractors, suppliers and service firms throughout Louisiana. Louisiana Associated General Contractors' mission is

to be the voice of the Louisiana construction industry. The association offers a full range of services to its members to help them succeed and improve in their day-to-day operations. Together with its members, the Louisiana Associated General Contractors promotes skill, responsibility and integrity through construction and services that enhance the quality of life for those who live, work, or travel in Louisiana. Louisiana Associated General Contractors is a non-profit trade association incorporated in the State of Louisiana with headquarters located in Baton Rouge, LA. The Louisiana Associated General Contractors has no parent company, and no publicly held company has a 10% or greater ownership interest in Louisiana Associated General Contractors.

Mechanical Contractors Association of Texas, Inc. ("MCA of Texas"): MCA of Texas is a non-profit construction trade association. Its members are local associations from the major metropolitan areas of the State, including Austin, Dallas, Fort Worth, Houston and San Antonio. These local Associations represent mechanical contractors engaged in commercial and industrial mechanical construction and service. Most contractor members perform both mechanical construction and mechanical service work. All of the association's contractor members are union contractors. These member companies employ more than 10,000 union workers. MCA of Texas seeks to promote the mechanical construction and service contracting industry, to foster the exchange of ideas, to represent the

membership in its relations with its employees and any group or groups which may represent its employees so as to improve the character of work done and labor employed by the industry, and by better public service to contribute to the advancement of the industry in all its branches. MCA of Texas is a non-profit trade association incorporated in the State of Texas with headquarters located in Houston, Texas. MCA of Texas has no parent company, and no publicly held company has a 10% or greater ownership interest in MCA of Texas.

Mississippi Road Builders' Association ("MRBA"): The MRBA is dedicated to proactively serving its members across the state of Mississippi by promoting the building and maintenance of its roads and bridges to exemplary standards. MRBA is a nonprofit national trade association incorporated in the State of Mississippi with headquarters located in Jackson, Mississippi. The MRBA has no parent company, and no publicly held company has a 10% or greater ownership interest in MRBA.

Pelican Chapter, Associated Builders and Contractors, Inc.'s mission is to promote and protect the Merit Shop Philosophy and the principles of the free enterprise system in the construction industry. The Association will achieve the mission by enhancing the image of the construction industry and by providing craft training, political influence, and business opportunities for all of our members. The Association will be positioned so that others seek it out for its position on

construction-related industry issues and opportunities. Pelican Chapter, Associated Builders and Contractors is a non-profit trade association incorporated in the State of Louisiana with headquarters located in Baton Rouge, Louisiana. Pelican Chapter, Associated Builders and Contractors has no parent company, and no publicly held company has a 10% or greater ownership interest in ABC.

Texas Association of Builders ("TAB"): TAB is dedicated to creating a positive business environment for the housing industry by addressing the housing issues of the people of Texas. Founded in 1946, the Texas Association of Builders is an affiliate of the National Association of Home Builders and has 28 local home builders associations and nearly 10,000 members across Texas. Representing over 702,500 jobs and more than $31.1 billion annually in the Texas economy, the state and local associations play a crucial role in providing housing for Texans. TAB is a non-profit state trade association incorporated in the State of Texas with headquarters located in Austin, TX. The TAB has no parent company, and no publicly held company has a 10% or greater ownership interest in TAB.

No. 16-1126:

American Foundry Society Texas Region 3/Texas Chapter of the American Foundry Society: The Texas Chapter of the American Foundry Society is the Texas based metalcasting society, assisting member companies and individuals to effectively manage their production operations, profitably market their

products and services, and equitably manage their employees. The Texas Chapter of the American Foundry Society has no parent corporation, and no publicly held company has 10% or greater ownership in AFS.

Texas Association of Business: Texas Association of Business is a leading employer organization that represents companies from the largest multi-national corporations to small businesses in nearly every community of Texas. The Texas Association of Business works to improve the Texas business climate and to help make our state's economy the strongest in the world. It has no parent corporation, and no publicly held company has 10% or greater ownership in TAB.

No. 16-1131:

The **National Stone, Sand & Gravel Association ("NSSGA")** is a not-for-profit association organized under the laws of the District of Columbia which represents the crushed stone, sand and gravel-or-aggregates industries in legislative and regulatory arenas. NSSGA member companies produce more than 92 percent of the crushed stone and 75 percent of the sand and gravel consumed annually in the United States. NSSGA is a "trade association" within the meaning of Circuit Rule 26.1(b). NSSGA has no parent corporation and no publicly held company owns a 10 percent or greater interest in NSSGA.

No. 16-1137:

The **American Foundry Society ("AFS")**, founded in 1896, is the leading U.S. based metalcasting society, assisting member companies and individuals to effectively manage their production operations, profitably market their products and services, and equitably manage their employees. The association is comprised of more than 7,500 individual members representing over 3,000 metalcasting firms, including foundries, suppliers, and customers. AFS has no parent corporation, and no publicly held company has any ownership in AFS.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States. It is a national not-for-profit trade association representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private sector research and development. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. NAM has no parent company, and no publicly held company has a 10% or greater ownership interest in NAM.

No. 16-1138:

American Road and Transportation Builders Association ("ARTBA"): ARTBA is a federation whose primary goal is to aggressively grow and protect transportation infrastructure investment to meet the public and business demand for safe and efficient travel. From the beginning, ARTBA has been a major leadership force in the development of federal transportation policy. The association's 5,000+ private and public sector members are involved in the planning, designing, construction and maintenance of the nation's roadways, bridges, ports, airports and transit systems. The road and transportation industry generates more than $380 billion annually in U.S. economic activity and sustains more than 3.3 million American jobs. ARTBA is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Washington, D.C. ARTBA has no parent company, and no publicly held company has a 10% or greater ownership interest in ARTBA.

American Society of Concrete Contractors ("ASCC"): ASCC was formed by and for concrete contractors and others who provide services and goods to the concrete construction industry. It is a powerful organization of contractors who share the same goals – to improve their businesses and their roles as contractors. Members include contracting firms, manufacturers, suppliers, designers and other professionals. There are approximately 500 member companies in the U.S. and

abroad in the American Society of Concrete Contractors. ASCC seeks to be the voice of the concrete contractor, serving as a collective instrument to give members of the concrete construction industry a stronger presence in the construction industry as a whole. ASCC is committed to helping members enhance the quality of their construction and their businesses. Members of this concrete contractor association become better equipped to improve all aspects of their performance with the help of valuable information and member interaction. ASCC has no parent company, and no publicly held company has a 10% or greater ownership interest in ASCC.

American Subcontractors Association ("ASA"): ASA is a national trade association representing subcontractors, specialty trade contractors, and suppliers in the construction industry. ASA's 5,000 members work in virtually all of the construction trades and on virtually every type of horizontal and vertical construction. ASA members frequently contract directly with a construction owner. More often, they serve as subcontractors dealing with the ultimate construction owner through a prime contractor. More than 60 percent of ASA members are small businesses. ASA is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Alexandria, VA. ASA has no parent company, and no publicly held company has a 10% or greater ownership interest in ASA.

Associated Builders and Contractors ("ABC"): ABC is a national construction industry trade association representing nearly 21,000 members. Founded on the merit shop philosophy, ABC and its 70 chapters help members develop people, win work and deliver that work safely, ethically, and profitably for the betterment of the communities in which ABC and its members work. ABC's membership represents all specialties within the U.S. construction industry and is comprised primarily of firms that perform work in the industrial and commercial sectors. ABC is a non-profit national trade association incorporated in the State of Maryland with headquarters located in Washington, D.C. ABC has no parent company, and no publicly held company has a 10% or greater ownership interest in ABC.

Associated General Contractors ("AGC"): AGC is a full service trade association representing nearly 30,000 firms in partnership with a network of 94 exceptional chapters throughout the United States. Among the association's members are approximately 7,500 of the nation's leading general contractors, more than 12,500 specialty contractors, and more than 13,000 material suppliers and service providers to the construction industry. AGC members play a powerful role in sustaining economic growth, in addition to producing structures that add to productivity and the nation's quality of life. AGC member firms engage in the construction of buildings, shopping centers, factories, industrial facilities,

warehouses, highways, bridges, tunnels, airports, waterworks facilities, waste treatment facilities, dams, hospitals, water conservation projects, defense facilities, multi-family housing projects, municipal utilities and other improvements to real property. And unlike many associations in the industry, AGC proudly represents both union and open-shop construction contractors. AGC is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Arlington, VA. The AGC has no parent company, and no publicly held company has a 10% or greater ownership interest in AGC.

Association of the Wall and Ceiling Industry ("AWCI"): AWCI is a trade association providing members with industry information, contacts and leadership for the wall and ceiling industries. Member companies are among the most successful in the industry. They are union and non-union wall and ceiling contractors of all sizes, manufacturers, suppliers and distributors throughout the world. AWCI represents 2,200 companies and organizations in the acoustics systems, ceiling systems, drywall systems, exterior insulation and finishing systems, fireproofing, flooring systems, insulation, and stucco contractors, suppliers and manufacturers and those in allied trades. AWCI's mission is to provide services and undertake activities that enhance the members' ability to operate a successful business. AWCI is a non-profit national trade association incorporated in the State of Delaware with

headquarters located in Falls Church, VA. The AWCI has no parent company, and no publicly held company has a 10% or greater ownership interest in AWCI.

Building Stone Institute ("BSI"): Since 1919, BSI has worked on behalf of the quarries, fabricators, retailers, importers, exporters, carvers, sculptors, restorers, designers, and installers that comprise its diverse membership. BSI provides programs and services that empower its member companies to offer the highest level of quality products and services. BSI resources are necessary tools that enable its members to educate the architectural and design communities on the benefits and uses of natural stone. BSI is a not-for-profit trade association dedicated to serving its member firms, and providing educational materials and continuing education on the uses and benefits of natural stone. BSI supports efforts to continually increase the quality of service, quality of products, and demand for stone. BSI is a non-profit national trade association incorporated in the State of Indiana with headquarters located in Chestertown, NY. The BSI has no parent company, and no publicly held company has a 10% or greater ownership interest in BSI.

Concrete Sawing & Drilling Association ("CSDA"): CSDA is a nonprofit trade association of contractors, manufacturers and affiliated members from the construction and renovation industry. The CSDA mission is to promote the selection of professional industry contractors and their methods. Diamond tools for projects requiring sawing, drilling, selective demolition, cutting and polishing offer the

construction industry many benefits including lower total project costs, precision cutting, maintenance of structural integrity, reduced downtime, reduced noise, dust and debris, limited access cutting and the ability to cut heavily reinforced concrete. CSDA offers its members access to multiple training programs and safety documents, as well as educational opportunities at its annual convention and online. Founded in 1972, CSDA has 500 member companies worldwide. CSDA is a non-profit national trade association incorporated in the State of Ohio with headquarters located in St. Petersburg, FL. The CSDA has no parent company, and no publicly held company has a 10% or greater ownership interest in CSDA.

Construction & Demolition Recycling Association ("CDRA"): CDRA promotes the recycling of materials generated from construction and demolition (C&D) projects. These materials can be generated from road, bridge, or building projects. The U.S. EPA estimates the amount of C&D material generated annually in the United States at 520 million tons, making it the largest individual material stream in the United States. For point of comparison, EPA estimates municipal solid waste generation to be around 240 million tons annually. The CDRA has 275 members throughout North America. Almost all these companies are privately held small businesses. Obviously the benefits of recycling all these companies bring to the environment is tremendous. For example, that 140 million tons of concrete recycled would otherwise go to landfills, quickly filling them up, while also

requiring an equal amount of mining activity to take place. In addition, the industry provides thousands of green jobs to the economy. CDRA is a nonprofit national trade association incorporated in the State of Illinois with headquarters located in Milwaukee, WI. The CDRA has no parent company, and no publicly held company has a 10% or greater ownership interest in CDRA.

Interlocking Concrete Pavement Institute ("ICPI"): As the leading technical organization on segmental concrete pavement systems, the Interlocking Concrete Pavement Institute provides substantial resources to concrete paver producers, contractors, suppliers, design professionals and distributors. Members representing this growing industry support the association's mission while utilizing its wealth of resources to gain a competitive business edge. ICPI began in 1993 with 66 charter members, since then membership has grown to over 1,000 companies. The diverse and unique membership represents manufacturers, contractors, industry suppliers and distributors. ICPI is a non-profit national trade association incorporated in the Commonwealth of Virginia with headquarters located in Chantilly, VA. The ICPI has no parent company, and no publicly held company has a 10% or greater ownership interest in ICPI.

International Council of Employers of Bricklayers and Allied Craftworkers ("ICE"): ICE is the only wholly union international masonry contractors' association, representing approximately 3,000 signatory contractors

who perform, brick, block, stone, tile, marble, terrazzo, cement masonry, plastering and restoration work. Its members employ the highest skilled, safest and best trained workers in the masonry industry. The primary purpose of ICE and its affiliate entities is to engage in labor relations matters with the International Union of Bricklayers and Allied Craftworkers (BAC) and its constituent local unions. The contractor members and officers of ICE are committed to working in harmony with the BAC to further the collective bargaining process, to enhance work opportunities for members of the union and to increase business opportunities for union contractors. ICE works with the BAC to provide union masonry craftworkers with the best training available, safe jobsites, pensions and healthcare. It works with its affiliates and other signatory contractors' associations to provide signatory masonry contractors with labor relations, education, staffing services and political advocacy specifically needed by the signatory contractor. ICE is a nonprofit national trade association incorporated in the District of Columbia with headquarters located in Pittsburgh, PA. ICE has no parent company, and no publicly held company has a 10% or greater ownership interest in ICE.

Leading Builders of America (“LBA”): LBA represents twenty of the nation’s largest homebuilding companies. Its members construct about one third of the new homes sold annually in the United States, generating over $33 billion in revenue and accounting for over 350,000 jobs through direct employment and the

engagement of subcontractors. LBA's primary goal is ensuring that new homes remain affordable for American families. LBA is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Washington, D.C. The LBA has no parent company, and no publicly held company has a 10% or greater ownership interest in LBA.

Marble Institute of America ("MIA"): Membership in MIA is worldwide and includes over 1,600 natural stone producers, exporters/importers, distributors/wholesalers, fabricators, finishers, installers, and industry suppliers committed to the highest standards of workmanship and ethics. MIA offers an industry accreditation program for fabricators and installers, markets a range of technical publications and consumer pamphlets on natural stone, sponsors business and technical meetings and seminars on industry-related topics, provides educational programming for architects and construction specification professionals, and conducts the annual Pinnacle Awards competitions recognizing outstanding natural stone projects worldwide. MIA is also a leading promoter of stone usage in the commercial and residential marketplaces, producing consumer education materials on the use of natural stone and its proper care and maintenance. MIA is a non-profit national trade association incorporated in the State of Michigan with headquarters located in Oberlin, Ohio. The MIA has no parent company, and no publicly held company has a 10% or greater ownership interest in MIA.

Mason Contractors Association of America ("MCAA"): MCAA is the national trade association representing all mason contractors both union and open shop. MCAA was incorporated in 1950. Its purpose is to help educate, train, and represent the mason contractor through its various programs aiding members to maintain their competitive edge against other construction methods. MCAA is a non-profit national trade association incorporated in the State of Illinois with headquarters located in Algonquin, IL. The MCAA has no parent company, and no publicly held company has a 10% or greater ownership interest in MCAA.

Mechanical Contractors Association of America is a non-profit construction trade association representing more than 2,400 members nationwide and overseas. More than 2,000 of the association's members are mechanical construction and/or service firms. Most contractor members perform both mechanical construction and mechanical service work. All of the association's contractor members are union contractors. These member companies employ more than 270,000 union workers; and the association has 85 local affiliates (chapters) throughout the United States and overseas. Mechanical Contractors Association of America is incorporated in the State of New York with headquarters located in Rockville, MD. Mechanical Contractors Association of America has no parent company, and no publicly held company has a 10% or greater ownership interest in Mechanical Contractors Association of America.

National Association of Home Builders ("NAHB"): Founded in 1942, NAHB represents more than 140,000 members involved in home building, remodeling, multifamily construction, property management, specialty trade contractor, design, housing finance, building products manufacturing, and all other aspects of the residential and light commercial construction industries. NAHB is affiliated with more than 700 state and local home builders associations (HBAs) located in all 50 states and Puerto Rico. NAHB's members touch on all aspects of the residential construction industry. About one-third of NAHB's members are home builders and/or remodelers. The others are associates working in closely related specialties such as sales and marketing, housing finance, and manufacturing and supplying building materials. Currently, the residential construction sector employs over 2 million people and NAHB's builder members will construct approximately 80 percent of the new housing units projected in the next 12 months, making housing one of the largest engines of economic growth in the country. The more than 14,000 members that belong to NAHB Remodelers Council comprise about one fifth of all firms that specify remodeling as a primary or secondary business activity. The NAHB Multifamily Council is comprised of more than 1,000 builders, developers, owners, and property managers of all sizes and types of multifamily housing comprising condominiums and rental apartments. NAHB is a non-profit national trade association incorporated in the State of Nevada with headquarters located in

Washington, D.C. The NAHB has no parent company, and no publicly held company has a 10% or greater ownership interest in NAHB.

National Demolition Association ("NDA"): Founded in 1973, NDA is the trade organization for the Demolition Industry in the United States, Canada and beyond. With over 800 members the organization represents the bulk of the entrepreneurial contractors and suppliers involved with the demolition process. In addition to structural dismantlement the industry is involved with implosions, asbestos, lead, and PCB abatement, the safe handling of hazardous and toxic materials, historic preservation, land clearing, facilities decontamination, specialized rigging, landfilling, C&D recycling, industrial recovery, scrap processing, trucking and general contracting. The Demolition Industry around the world is the largest source of feedstock for the scrap recycling industry and often recycles over 90% of the demolition debris in its material stream. The Association is the repository of safe work practice for the Demolition Industry on a global basis. Its Demolition Safety Manual, which was developed under an OSHA "New Directions" grant, is the bible of safe work practice for the industry around the world. The Association, as part of an OSHA Alliance, developed a Disaster Site Worker Training & Certification Program to train demolition workers as Second Responders at any man-made or natural disaster. NDA is a non-profit national trade association incorporated in the State of Massachusetts with headquarters located in Washington, D.C. The NDA has

no parent company, and no publicly held company has a 10% or greater ownership interest in NDA.

National Electrical Contractors Association ("NECA"): NECA began in 1901 when a group of electrical contractors met in Buffalo, NY to form an association that could help in the fostering of trade among electrical contractors and reform abuses in the electrical industry. Part of its mission was to settle differences between its members and promote more enlarged and friendly discourse among its members. Today over 3500 NECA members from around the country count on NECA to deliver the resources that help them make better business decisions, provide excellent customer service, and take advantage of innovative technology. NECA's national office and local chapters advance the electrical construction industry through advocacy, education, research, and standards development. NECA works with members, contractors, building owners, developers, manufacturers, business development staff and NECA chapters to produce training programs, tools, publications and promotional material that position NECA contractors as a customer's full service energy solutions provider. NECA is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Bethesda, MD. NECA has no parent company, and no publicly held company has a 10% or greater ownership interest in NECA.

National Utility Contractors Association ("NUCA"): NUCA is the largest and most influential national trade association working solely for the excavation and utility construction markets. NUCA represents contractors, manufacturers, suppliers, and other service providers engaged in the water, sewer, gas distribution, electric, communications, construction site development and excavation industries. Founded in 1964, NUCA is entering its 50th year of leadership providing high quality safety services, craft training, management education, and advocacy. NUCA is a non-profit national trade association incorporated in the District of Columbia with headquarters located in Fairfax, Virginia. The NUCA has no parent company, and no publicly held company has a 10% or greater ownership interest in NUCA.

Natural Stone Council ("NSC"): NSC was formed in 2003 to unite a diverse industry of natural stone producers, fabricators and related affiliates to actively promote the attributes of natural stone in commercial, residential, government, institutional, educational and all types of applications interior and exterior, and to proactively position natural stone as the premier construction material. The NSC is comprised of twelve affiliates representing every type of dimensional stone quarried and fabricated in the United States. The NSC affiliates have a combined membership over 2,200 whose companies' employee in excess of 40,000 workers. The dimension stone industry is a major part of the nation's economy. According to recent Department of Labor figures, 4,380 stone quarries themselves directly employ

35,248 workers, and 2,125 fabrication facilities directly employ 23,666 workers. Additional indirect employment is estimated to be greater than 100,000 people with a total estimated payroll for the industry approaching $4 billion annually. NSC is a non-profit national trade association incorporated in the State of Ohio with headquarters located in Hollis, NH. The NSC has no parent company, and no publicly held company has a 10% or greater ownership interest in NSC.

The Association of Union Constructors ("TAUC"): TAUC is made up of more than 2,000 contractor companies that utilize union labor for their projects, as well as local contractor associations and vendors in the industrial maintenance and construction fields. TAUC's mission is to act as an advocate for union contractors and enhance cooperation between the three entities involved in the successful completion of construction projects: the union, the contractor and the owner-client, the company for which the work is being completed. By encouraging this "tripartite dialogue," many potential issues and delays are eliminated before work even begins. TAUC is a non-profit national trade association incorporated in the State of Delaware with headquarters located in Arlington, VA. TAUC has no parent company, and no publicly held company has a 10% or greater ownership interest in TAUC.

Tile Roofing Institute ("TRI"): Founded in 1971, TRI has been the leading voice for the concrete and clay tile Industry. The TRI has over 95% of the capacity

for roofing tiles within its ranks and has several hundred roofing contractors, distributors and suppliers of related materials. The primary focus of the TRI has been in the development of technical manuals, industry positions and research studies for code language and preferred installation practices within all the major code bodies nationwide. TRI has played a major role in establishing tile performance and recommendations for severe weather, fire and seismic conditions, as well as developing legislation of building codes. TRI is a non-profit national trade association incorporated in the State of California with headquarters located in the state of Washington. The TRI has no parent company, and no publicly held company has a 10% or greater ownership interest in TRI.

No. 16-1146:

The **Brick Industry Association ("BIA")** is a not-for-profit, national trade association representing clay brick manufacturers, distributorships, and their suppliers. Two-thirds of all brick shipped in North America is manufactured by BIA members. BIA is a "trade association" within the meaning of Circuit Rule 26(b)(1). It has no parent corporation, and no publicly held company owns a 10 percent or greater interest in BIA.

The **Portland Cement Association ("PCA")** is a not-for-profit association that represents companies responsible for more than 92 percent of the cement production capacity in the United States. PCA is a "trade association" within the

meaning of Circuit Rule 26.1(b). It has no parent corporation, and no publicly held company owns a 10 percent or greater interest in PCA.

The **National Concrete Masonry Association ("NCMA")** is a not-for-profit trade association that represents the interests of manufacturers of concrete block and related dry-cast concrete products. NCMA represents about 60 percent of the production capacity of concrete masonry products in the United States. NCMA is a "trade association" within the meaning of Circuit Rule 26.1(b). It has no parent corporation, and no publicly held company owns a 10 percent or greater interest in NCMA.

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GLOSSARY

ACC	American Chemistry Council
APA	Administrative Procedures Act
BCTD	Building and Construction Trades Department
CFM	Cubic feet per minute
Doc.ID.	Document Identification Number
DOL	Department of Labor
ERG	Eastern Research Group
FEA	Final Economic Analysis and Final Regulatory Flexibility Analysis
FQRA	Final Quantitative Risk Assessment
FTE	Full time equivalent employee
GM	Geometric mean
GSD	Geometric standard deviation
JA	Joint Appendix
LEV	Local exhaust ventilation
µg/m³	Micrograms per cubic meter of air
NAICS	North American Industrial Classification System
NIOSH	National Institute for Occupational Safety and Health
NMRD	Non-malignant respiratory disease
OIS	OSHA Information System

OSHA	Occupational Safety and Health Administration
OSH ACT	Occupational Safety and Health Act of 1970
PEA	Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis
PEL	Permissible exposure limit
PQRA	Preliminary Quantitative Risk Assessment
SBREFA	Small Business Regulatory Enforcement and Fairness Act
TWA	Time-weighted average

REASONS WHY ORAL ARGUMENT SHOULD BE PERMITTED

Pursuant to Rule 34(a) of the Federal Rules of Appellate Procedure, Industry Petitioners respectfully request that this Court hear oral argument. This case presents important questions of law arising under the Occupational Safety and Health Act of 1970. Oral argument will assist this Court in reaching a full understanding of the issues presented and the underlying facts. Moreover, oral argument will allow the attorneys for both sides to address any outstanding legal or factual issues that the Court deems relevant.

JURISDICTIONAL STATEMENT

These consolidated cases seek review of the final rule titled "29 C.F.R. Parts 1910, 1915, and 1926, Occupational Exposure to Respirable Crystalline Silica" (Docket No. OSHA-2010-0034, RIN 1218-AB70),[1] promulgated by the Occupational Safety and Health Administration ("OSHA") of the United States Department of Labor ("DOL") on March 25, 2016, and published in the *Federal Register* at 81 Fed. Reg. 16,285 ("Silica Rule" or "Rule") (JA0001-JA0606). This Court has jurisdiction under Section 6(f) of the Occupational Safety and Health Act ("OSH Act"), 29 U.S.C. §655(f). Petitions for review were filed within the 60-day period provided by the Act. *Id*.

STANDARD OF REVIEW

Judicial review of OSHA standards is governed by Section 6 of the OSH Act. 29 U.S.C. § 655. OSHA bears the burden of proving the validity of an occupational health and safety standard. *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 653 (1980) (plurality opinion) ("*Benzene*"); *AFL-CIO v. OSHA*, 965 F.2d 962, 973 (11th Cir. 1992) ("*Air Contaminants*"). OSHA must do so with substantial evidence, which test is applied to both OSHA's factual findings and its policy decisions. 29 U.S.C. § 655(f); *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S.

[1] As used herein, "Doc.ID.####" refers to documents contained in Docket No. OSHA-2010-0034.

490, 522 (1981) ("*Cotton Dust*"); *AFL-CIO v. Marshall*, 617 F.2d 636, 648 n.43 (D.C. Cir. 1979). The "substantial evidence" test requires "stringent" judicial review of OSHA standards and provides for closer scrutiny of OSHA's action than review under the more deferential arbitrary and capricious standard. *AFL-CIO v. Marshall*, 617 F.2d at 648-49; *Asbestos Info. Ass'n v. OSHA*, 727 F.2d 415, 521 (5th Cir. 1984).

Section 6(e) of the OSH Act provides that "[w]henever the Secretary promulgates any standard . . . he shall include a statement of the reasons for such action, which shall be published in the Federal Register." 29 U.S.C. § 655(e). The "reasons" must include the facts relied upon, methodologies used, and explanations as to why alternatives were not adopted. *AFL-CIO v. Marshall*, 617 F.2d at 651 ("To facilitate this review of the record, the agency must pinpoint the factual evidence and the policy considerations upon which it relied. This requires explication of the assumptions, underlying predictions or extrapolations, and of the basis for its resolution of conflicts and ambiguities.") (footnotes omitted). The record, and specifically the reasons in that record, forms the basis of judicial review. *Benzene*, 448 U.S. at 631 n.31 ("The validity of an agency's determination must be judged on the basis of the agency's stated reasons for making that determination."); *Color Pigments Mfrs. Ass'n v. OSHA*, 16 F.3d 1157, 1160 (11th Cir. 1994) (noting that judicial review of OSHA standards entails both a "review [of] the sufficiency of the evidence presented and the procedure used in promulgating the standard.").

Thus, OSHA's conclusions must be adequately supported in the administrative record, and the reasons for its decisions must be adequately explained.

In promulgating a standard under the Act, OSHA must demonstrate that (1) the standard will substantially reduce a significant risk; (2) compliance is technologically feasible; (3) compliance is economically feasible; (4) the standard employs the most cost-effective protective measures capable of reducing or eliminating significant risk; (5) for any standard differing from an existing national consensus standard, must publish its reasons why the standard would better effectuate the purposes of the Act; and (6) support the standard with substantial evidence in the rulemaking record and explain any inconsistency with prior agency practice. *Int'l Union, United Auto., Aero. & Agric. Implement Workers of Am., UAW v. OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994) ("*Lockout/Tagout II*") (internal citations omitted).

STATEMENT OF ISSUES

1. Whether OSHA has demonstrated, through substantial evidence, a significant risk of material harm warranting a revision of the permissible exposure limit ("PEL") for respirable crystalline silica from 100 micrograms per cubic meter (µg/m³) of air to 50 µg/m³ as an eight-hour, time-weighted average ("TWA"), in all industries covered by the Rule, and whether reducing the PEL to 50 µg/m³ would substantially reduce any such risk that might exist.

2. Whether OSHA has demonstrated, through substantial evidence, that the Rule is technologically and economically feasible in the foundry, hydraulic fracturing, and construction industries.

3. Whether the Rule's ancillary requirements prohibiting dry sweeping and brushing, and prohibiting employers from receiving important work-related health information from health care professionals are supported by substantial evidence and are reasonably necessary and appropriate to effectuate the purposes of the Rule.

4. Whether OSHA's rulemaking procedures violated Section 6 of the OSH Act and Section 553 of the Administrative Procedure Act ("APA") by depriving the public of a meaningful opportunity to comment on significant exposure data that OSHA relied on in promulgating the Rule and by relying on information from its contractor Eastern Research Group ("ERG") that was unsupported and unavailable for meaningful public review and comment.

5. Whether OSHA has demonstrated, through substantial evidence, that the reduced PEL will result in materially increased health benefits for workers in the brick industry when the toxicity of silica in brickmaking clays and shales is significantly reduced by aluminum occlusions of the quartz particles.

6. Whether OSHA's decision not to exempt the brick industry from the new silica standard is supported by substantial evidence and otherwise consistent with law.

7. Whether OSHA has shown by substantial evidence that the implementation of the new silica standard by the brick industry is economically feasible.

STATUTORY PROVISIONS

This case involves regulations promulgated pursuant to a claim of authority under Section 6 of the OSH Act, 29 U.S.C. § 655, and Section 553 of the APA, 5 U.S.C. § 553. The relevant statutes and regulations are reproduced in the Addendum.

STATEMENT OF THE CASE

The Silica Rule is one of the most far-reaching health standards promulgated by OSHA in the last two decades. The Rule involves two separate standards regulating employee exposure to respirable crystalline silica[2] at worksites across the country: one applicable to "general industry and maritime" and one applicable to

[2] "Respirable crystalline silica" is defined to mean "quartz, cristobalite, and/or tridymite contained in airborne particles that are determined to be respirable" by certain designated sampling devices. *See* 29 C.F.R. § 1910.1053(b); 81 Fed. Reg. at 16,712 (JA0428). In this brief, the terms "respirable crystalline silica," "crystalline silica," and "silica" are generally used interchangeably, with the latter two terms being understood to refer to the first, unless the context indicates otherwise.

"construction." 81 Fed. Reg. at 16,286 (JA0002). By OSHA's estimates, the Rule will affect nearly 700,000 establishments in the United States and over 2.3 million workers. *Id.* at 16,418 (JA0134). The Rule lowers the "permissible exposure limit" or "PEL" for silica exposures to 50 μg/m^3 as an eight-hour, TWA across all industries. This is a 50% reduction of the previous general industry PEL, and an 80% reduction of the previous construction and maritime industry PELs.[3] The Rule also requires that employers comply with numerous ancillary requirements, many of which are triggered by exposures above the "action level" ("AL") of 25 μg/m^3. *Id.* at 16,287 (JA0003).

I. SILICIA AND ITS USES

Crystalline silica, a compound consisting of the first and second most abundant elements in the Earth's crust (oxygen and silicon), makes up about 12 percent, by weight, of the Earth's crustal mass.[4] It has been described as one of the building blocks of our planet.

Crystalline silica is perhaps the most common construction and manufacturing material in the world. It is a major component of most building products – including brick, concrete, ceramic tile, mortar, shingles and other items that are used in the

[3] OSHA's previous PEL for silica in General Industry was approximately 100 micrograms of respirable crystalline silica per cubic meter of air ("100 μg/m^3"), and the previous PEL for construction (and maritime) was approximately 250 micrograms per cubic meter of air ("250 μg/m^3").

[4] *See* 78 Fed. Reg. 56,295 (Sept. 12, 2013) (JA0629); OSHA, Controlling Silica Exposures in Construction. OSHA 3362-04 (2009) (JA1774-JA1845).

construction of all homes and commercial buildings. *See, e.g.*, Doc.ID.4247, pp. IV-107,124, and 578 (JA6097, JA6108, JA6300). Silica is a critical component of the Nation's transportation infrastructure. It is present in the crushed stone, sand, and gravel that make up the bulk of the asphaltic and Portland cement concrete used to construct roads, airport runways, parking lots, and many other hard-surfaced areas. Doc.ID.4247, pp. IV-96, 124, and 480 (JA6086, JA6108, JA6289). Unbound crushed stone supports thousands of miles of railroad ties and track and forms breakwaters that protect our Nation's ports, shores, and other waterways. Doc.ID.4247, pp. IV-96, 124, 462, and 480 (JA6086, JA6108, JA6278, JA6289).

In addition, silica is an important component in manufacturing operations. Foundries use silica-containing materials to make the molds and cores used to produce thousands of metal products. Doc.ID.4247, p. IV-225 (JA6130). Silica sand plays an important role in the production of natural gas and oil through the process of hydraulic fracturing where it is used as proppant to hold open cracks and fissures created by hydraulic pressure. Finally, silica is ubiquitous in everyday life; for example, beach sand is comprised almost completely of crystalline silica.

II. SILICA AND HUMAN HEALTH

In light of its widespread presence in rocks, sand, and soils, occupational exposure to silica is certainly nothing new. Silicosis, the form of pneumoconiosis associated with prolonged breathing of air with high levels of crystalline silica, is an ancient occupational disease that has come under significant control in developed

countries. Reflecting this, the Centers for Disease Control and Prevention's analysis of silicosis mortality trends in the United States shows a decline of more than 90 percent in the overall silicosis mortality rate from 1968-2010, as the number of annual deaths with silicosis listed as either the underlying or a contributing cause decreased from 1,065 in 1968 to 101 in 2010.[5] Over that same time period, there was a similar decline of approximately 90 percent in the annual Years of Potential Life Lost attributed to silicosis as either the underlying or a contributing cause of death.[6] Concurrently, the age-adjusted death rate for silicosis (as either an underlying or a contributing cause) declined by 95 percent, falling from 8.21 per million population in 1968 to 0.39 per million population in 2010.[7]

III. OSHA'S HISTORY OF REGULATING OCCUPATIONAL EXPOSURE AND RULEMAKING

OSHA's initial standards for respirable crystalline silica were established in 1971. 81 Fed. Reg. at 16,294 (JA0010). Based on the form of the standard used at the time, the PEL for General Industry was approximately equivalent to 100 $\mu g/m^3$, expressed as an eight-hour TWA, and the PELs for construction and maritime were

[5] *See* Centers for Disease Control and Prevention, National Occupational Respiratory Mortality System: National Database Query Results on May 17, 2013. available at http://webapp.cdc.gov/ords/norms.html.

[6] *Id.*

[7] *Id.*

approximately 250 µg/m³. *Id.* As noted above and addressed in greater detail below, these standards have virtually eliminated silicosis in the American workplace. In January 2010, OSHA completed a draft Health Effects Analysis and Preliminary Quantitative Risk Assessment ("PQRA") for respirable crystalline silica. *Id.* at 16,297 (JA0013). OSHA also completed a Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis ("PEA") which examined the technological and economic feasibility of the proposed rule. The PQRA and PEA were incorporated into the proposed rule which was issued on September 12, 2013. 78 Fed. Reg. 56,273 (JA0607-JA0838). OSHA invited comments on the proposed rule and its preliminary determinations that (1) employees exposed to respirable crystalline silica at the then-current PELs faced a significant risk to health, (2) making the PELs more stringent would substantially reduce that risk, and (3) the proposed PEL of 50 µg/m³ was technologically and economically feasible. 81 Fed. Reg. at 16,297 (JA0013).

Following the close of the comment period, a public hearing on the proposed rule was held in Washington, D.C. from March 18, 2014 through April 4, 2014. *Id.* at 16,298 (JA0014). Thereafter, post-hearing briefs and supplemental comments and other information were placed into the administrative record. OSHA published the final Rule on March 25, 2016. 81 Fed. Reg. 16,285 (JA0001-JA0606).

IV. THE SILICA RULE

The Silica Rule sets a comprehensive regulatory scheme for affected industries. OSHA estimates that the Rule potentially affects 2.3 million workers and 676,000 business establishments.[8] As described above, the Rule establishes a new PEL of 50 μg/m^3 for all industries. *Id*. at 16,286 (JA0002). A 25 μg/m^3 "action level" makes the Rule even more stringent: for employees who are reasonably expected to be exposed to silica at or above the action level, General Industry and maritime employers are required to use engineering and work practice controls to ensure compliance with the PEL. *Id*. at 16,862-63 (JA0578-JA0579). Respiratory protection cannot be used to meet the PEL unless the employer has exhausted all other feasible options. *Id.*

In addition to the PEL, the Rule imposes ancillary requirements regarding exposure assessment, respiratory protection, medical surveillance, hazard communication, recordkeeping, and housekeeping. *Id*. at 16,863-65 (JA0579-JA0581) and 16,879-82 (JA0595-0598). The Rule essentially prohibits standard housekeeping practices like dry sweeping and the use of compressed air for cleaning. *Id*. at 16,864, 16,880 (JA0580, JA0596). In addition, the Rule prohibits employers from receiving information gathered during medical surveillance to help protect

[8] OSHA Fact Sheet, "Frequently Asked Questions: Respirable Silica Rule" at 4, www.osha.gov/silica (explaining that the total compliance cost of the Rule is so high because the standards are among the broadest OSHA has issued) (JA7280).

employees from continued exposure to silica if they develop silica-induced disease. *Id*. at 16,864-65, 16,881 (JA0580-JA0581, JA0597).

For the construction industry, OSHA has adopted a first of its kind approach for compliance with the PEL through the adoption of "Table 1." Table 1 sets forth 18 specific construction "equipment/tasks" and describes the engineering and work practice control methods and respiratory protection required for those tasks. *Id*. at 16,877-79 (JA0593-JA0595). For example, all handheld power saws (except those used to cut fiber-cement board) must be equipped with an integrated water delivery system that continuously feeds water to the blade. *Id*. at 16,877 (JA0593). If an employee is using the saw outdoors for less than four hours in an eight-hour work day, the employee does not have to wear respiratory protection. However, if the employee is using the saw outdoors for more than four hours, or indoors for any period of time, he or she is required to wear respiratory protection. *Id.* When employers follow the procedures outlined in Table 1, they do *not* have to comply with the PEL or follow the exposure monitoring requirements. *Id*. at 16,879 (JA0595); 29 C.F.R. § 1926.1153(c), (d).

Employers in the construction industry must comply with the standard by June 23, 2017. 81 Fed. Reg. at 16,882 (JA0598). General Industry employers are required to meet the standard by June 23, 2018, except for employers in the hydraulic fracturing industry which are given five years to comply with the PEL and engineering control provisions. *Id*. at 16,865 (JA0581).

A. OSHA's Risk Analysis

OSHA's Final Quantitative Risk Assessment ("FQRA"), published in conjunction with the promulgation of the Rule, on March 16, 2016 reiterates the findings and conclusions of the PQRA. Among other things, OSHA concludes that employees exposed to silica at the exposure levels permitted under the prior PELs were at significant risk of developing silicosis and other non-malignant respiratory disease, lung cancer, kidney effects, and immune system effects. OSHA further asserted that these material health risks would be substantially reduced by adoption of a PEL of 50 $\mu g/m^3$.

B. OSHA's Feasibility Analysis

OSHA's Final Economic Analysis and Final Regulatory Flexibility Analysis ("FEA") was also published in conjunction with the promulgation of the Rule. The FEA generally echoes the Preliminary Economic Analysis ("PEA"), concluding that the Rule is technologically and economically feasible, while also carrying forward many of the same assumptions from the PEA. *Id.* at 16,399 (JA0115).

OSHA made the universal conclusion that the Rule is technologically feasible for most operations in affected industries. *Id*. at 16,287 (JA0003). OSHA used 2,483 data samples from general industry and 881 samples from construction in its final feasibility analysis. Of those 3,364 samples, 699 were placed into the record at the end of the post-hearing submission period. Doc.ID.3958 (JA4954-JA5205).

OSHA also concludes that the standard is economically feasible, comparing its cost estimates of the Rule's impact against the revenues and profits of affected industries. OSHA estimated costs of $1.03 billion *annually* across all industries. 81 Fed. Reg. at 16,400 (JA0116). That includes costs of $371 million to all General Industry establishments and $659 million for construction. *Id*. at 16,467-68 (JA0183-JA0184).

Finally, in promulgating both the proposed and final rules, OSHA relied upon data collected and analyzed by its government contractor, Eastern Research Group ("ERG"). OSHA also relied on private interviews with ERG personnel to support a variety of assumptions made throughout the analysis. No ERG witness was available for cross examination at the public hearing.

SUMMARY OF THE ARGUMENT

This regulation is a solution in search of a problem. Silicosis mortality rates have declined more than 90 percent in this country (a decrease from 1065 deaths in 1968 to 101 in 2010). OSHA nevertheless asserts that this new standard is justified because of its evaluation of five disease endpoints (silicosis mortality, non-malignant respiratory disease mortality, silicosis morbidity, silica related lung cancer, and renal disease).

On closer scrutiny, it is evident that OSHA's conclusions regarding respiratory disease – four of the five endpoints – are not supported in the record

because OSHA fails to recognize a threshold above the prior PEL below which no disease endpoint will manifest. Similarly, OSHA's exclusive reliance on a cumulative exposure model for its risk assessment completely disregarded the impact that short term intensive exposure has on disease outcome. Finally, OSHA's conclusions regarding renal disease are so flawed as to fall far short of the requisite best evidence.

OSHA concedes that many of the silica-related deaths during the preceding decades were among workers whose main exposure to respirable crystalline silica "probably occurred before introduction of national silica standards" by OSHA in 1971. 81 Fed. Reg. at 16,306 (JA0022). It further acknowledges that its own enforcement data demonstrate that exposures in excess of the prior PEL are widespread in both general industry and construction, and the severity of these overexposures is, in many cases, very high. 81 Fed. Reg. at 16,296-297 (JA0012-JA0013). These concessions by OSHA resoundingly support Petitioners' contrary conclusion on disease causation; to wit, that the silica related disease that has existed – and continues to exist – from occupational silica exposure is related exclusively to exposure above the prior PEL.

In formulating its risk assessments for silica exposure, OSHA makes the unsupportable assumption that there is no threshold exposure level for silica-related respiratory disease – that is, no level of exposure at which a person will not become

ill. This simply cannot be so. Humans are exposed to silica every day, but do not become ill as a result. Further, many studies submitted into the rulemaking record show that the threshold for silica-related illness exceeds the prior PEL of 100 µg/m³. Rejecting these studies, OSHA decided not to recognize a threshold for silica-related disease, and instead constructed a risk assessment based on a hypothetical worker who will be exposed to either 100 µg/m³ or 50 µg/m³ of silica over a work life of 45 years. And, this risk assessment does not factor in – at all – the disease impact from short term extremely high concentration exposure above that threshold.

These errors are in full relief when focusing on the individual disease endpoints. All the respiratory disease conditions are flawed due to OSHA's rejection of the threshold evidence. Moreover, OSHA's projections that exposure to respirable crystalline silica at the prior PEL puts workers at risk for a variety of respiratory and non-respiratory disease conditions are neither credible nor reliable, even if (contrary to the facts) a threshold is assumed not to exist.

For example, in its analysis of the risk of silicosis or other non-malignant respiratory mortality, OSHA relies upon the study of diatomaceous earth workers by Park, *et. al.* That study includes an express acknowledgement of the likelihood that exposures were not properly classified due to lack of reliable data. Thus, OSHA is relying for its conclusion that there is a significant risk of material impairment of health at the prior PEL on a study that contains exposure above that PEL, which

cannot be disaggregated from lower level exposure. This falls far short of OSHA's requisite substantial evidence standard.

OSHA's conclusions with respect to silicosis morbidity also are based upon studies that include exposure above the prior PEL and fail to account for high-concentration, short-term exposure. Also, with respect to OSHA's conclusion regarding the number of workers who will develop silicosis, the studies that OSHA relies upon contradict *each other*. Finally, OSHA's conclusions regarding silica related lung cancer are flawed for the additional reason that substantial evidence does not support a conclusion that silica exposure directly increases the risk of lung cancer in the absence of silicosis.

With respect to renal disease, OSHA acknowledges that its projection of renal disease mortality was based upon limited data from studies with large exposure uncertainties. Indeed, its projections are at odds with numerous studies that find no causal association at all between silica exposure and renal disease mortality. While Petitioners' arguments with respect to a threshold for harmful silica exposure do not dispose of this disease endpoint, if OSHA is left with only renal disease as the basis of this Rule, this slim reed of speculative evidence cannot possibly sustain this Rule.

In summary, Petitioners do not dispute that occupational exposure to silica can result in disease and death. Petitioners' argument is that the prior PEL was protective because a threshold for harmful silica exposure exists above the prior

PEL, and disease manifestation results either from cumulative exposure above that threshold or short-term, high-concentration exposure. OSHA cannot establish a conclusion to the contrary with substantial evidence because not one study in the record reliably separates out exposure above the prior PEL with exposure at or under the current PEL. Therefore, OSHA has not supported with substantial evidence that silica causes material impairment of health at an exposure level of 100 µg/m^3 or that any significant improvement in already low silica disease rates would be accomplished by lowering that exposure level to 50 µg/m^3.

Furthermore, substantial evidence in the rulemaking record does not demonstrate that OSHA's PEL is technologically and economically feasible in the foundry, hydraulic fracturing, and construction industries. OSHA ignores substantial evidence of exposure variability in operations that generate silica. The evidence in the rulemaking record shows convincingly that this variability is often outside the control of the employer and impacts the extent to which an employer can consistently meet any exposure level. The best available evidence in the rulemaking record demonstrates that, in order to ensure compliance with the PEL, employers must reach an exposure level far below 50 µg/m^3. OSHA never establishes that a lower PEL can be met and, in fact, states the opposite: that the record does *not* establish that employers can meet this lower level.

For foundry operations, OSHA completely ignores the best available evidence of exposure variability, a study applying a National Institute for Occupational Safety and Health ("NIOSH") strategy for assessing the variability seen in repetitive sampling to determine the statistical confidence of reaching a reduced PEL for silica in the foundry environment. OSHA also ignores substantial evidence presented in the rulemaking record of foundries that have been unable, in the course of OSHA inspections, to meet the prior PEL of 100 µg/m³ with engineering and work practice controls.

For hydraulic fracturing operations, OSHA concludes that the reduced PEL can be met reliably despite there being little to no evidence in the record showing that to be the case. OSHA explored several different control methods to reduce exposures to silica in the key job classifications in hydraulic fracturing, only to find that these methods could not even reach the prior PEL of 100 µg/m³.

OSHA's economic feasibility findings for these industries is similarly flawed. OSHA adopts a model for the costs of employers to implement engineering controls in General Industry that is not supported by the rulemaking record and is completely at odds with the real world of compliance. The adoption of this model, along with several unsupported cost inputs, leads to an overall assessment of feasibility that is not supported by substantial evidence.

OSHA does no better in its analysis of the feasibility of construction employers to comply with the Rule. In addition to ignoring exposure variability, OSHA adopts assumptions throughout its technological feasibility analysis that have the effect of systematically skewing the extent of exposures in construction and the effectiveness of controls.

Despite these unsupported assumptions, on its face, OSHA's technological feasibility analysis does not show that the Rule can be met in most construction operations most of the time. In fact, OSHA's adoption of a PEL of 50 µg/m³ will require almost 300,000 construction employees to wear respirators for at least 30 days per year and will require respirator use for a third of the tasks analyzed by the Agency.

OSHA's findings regarding economic feasibility in construction also suffer from assumptions that make no sense in real life. For example, OSHA assumes with little to no evidence that construction work that generates silica is only performed for 150 days a year, which is significantly below the number of days worked in construction.

Additionally, several ancillary provisions in the Rule are not reasonably necessary and appropriate to effectuate the purposes of the standard. OSHA essentially prohibits the practice of dry sweeping or dry brushing material that could contain silica. It has done so without a sufficient showing that the prohibition of this

common practice will result in any safety and health benefits for employees. Further, in a deviation from its past practice in health standards, OSHA prohibits employers from receiving key work-related health information from health care professionals that examine employees for silica-related disease.

Finally, the rulemaking process itself was flawed. In particular, to show feasibility, OSHA relies on a significant number of exposure samples placed into the rulemaking record toward the very end of the rulemaking process, depriving the public of a meaningful opportunity to review the evidence and place contrary evidence into the record. In addition, throughout the rulemaking process, OSHA relied on a contractor to provide "evidence" supporting its findings. This "evidence" was often nothing more than the opinion of ERG staff. OSHA did not make ERG available for cross-examination at the hearing and did not otherwise provide an opportunity to meaningfully analyze ERG's findings and conclusions.

STANDING

OSHA identifies various North American Industrial Classification System ("NAICS") industry sectors as affected by the Rule. 81 Fed. Reg. at 16,406-16,407 (JA0122-JA0123). Industry Petitioners are trade associations and industry groups whose members are classified as one of the affected NAICS sectors. *See* Rule 26.1 Corporate Disclosure Statement, *supra*. Petitioners' members therefore have individual standing as a result of concrete and particularized injuries which are fairly

traceable to the Rule, and as to which there is a substantial probability of redress by a decision that sets the Rule aside. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992) (noting that, when a party is the object of government regulation, "there is ordinarily little question that the [governmental] action . . . has caused him injury").

As trade associations representing members in the General Industry or construction sectors, Industry Petitioners have standing in this litigation because (1) their individual members are directly and adversely affected by the Rule and have standing to sue in their own right, (2) the interests Petitioners seek to protect are germane to their organizational purposes, and (3) neither the claims asserted nor the relief requested requires the participation of their individual members. *See Hunt v. Wash. St. Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). Industry Petitioners also participated in the rulemaking process, by submitting comments and data and offering expert testimony. Thus, Industry Petitioners' standing is self-evident based on the administrative record. *See, e.g., Lujan,* 504 U.S. at 560-62 (1992); *Sierra Club v. EPA*, 292 F. 3d 895, 899-900 (D.C. Cir. 2002).

ARGUMENT

I. OSHA HAS FAILED TO MEET ITS BURDEN OF SHOWING THAT A SIGNIFICANT RISK OF MATERIAL HEALTH IMPAIRMENT EXISTS AT A PEL OF 100 µG/M^3 OR THAT, IF SUCH A RISK DOES EXIST, IT WILL BE SUBSTANTIALLY REDUCED AT A PEL OF 50 µG/M^3.

OSHA concluded that exposure to respirable crystalline silica "increases the risk" of a variety of respiratory and non-respiratory diseases. 81 Fed. Reg. at 16,300 (JA0016). However, that conclusion alone cannot justify the revised standard at issue here. Rather, OSHA must show, by the best available evidence, that employees were exposed to a significant risk of material health impairment at the prior PEL of 100 µg/m^3, and that the reduction in the PEL to 50 µg/m^3 will substantially reduce that risk. At the same time, OSHA must establish that implementation of the new standard is technologically and economically feasible. 29 USC § 655(b)(5); *Benzene*, 448 U.S. at 642.

In making its material harm and significant risk determinations, OSHA must rely on "a body of reputable scientific thought," and those determinations must be supported by substantial evidence. *Benzene*, 448 U.S. at 656. OSHA must show "empirical evidence" of an actual risk. *Am. Petroleum Inst. v. OSHA*, 581 F.2d 493, 503 (5th Cir. 1978), *aff'd*, 448 U.S. 607. Courts may review the quality of OSHA's evidence. *Id.* at 506-508. Where there is disputed scientific evidence, OSHA is to review both sides of the dispute and "reasonably resolve" it. *Pub. Citizen Health*

Research Grp v. Tyson, 796 F.2d 1479, 1500 (D.C. Cir. 1986); *Bldg. & Constr. Trades Dep't. v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988).

Although OSHA is entitled to some leeway where "its findings must be made on the frontiers of scientific knowledge," *Benzene*, 488 U.S. at 656, the Agency is not free to conduct a results-oriented investigation in which it seeks and selects only studies with results that support its stated policy goals. That is, OSHA is not permitted to engage in "confirmation bias."

Here, OSHA's risk assessment seeks to justify the reduction of the silica PEL from 100 μg/m^3 to 50 μg/m^3 by assessing five disease endpoints – silicosis morbidity, silicosis mortality, lung cancer, other non-malignant respiratory disease mortality, and renal disease. OSHA's assessment with respect to each of these endpoints is flawed. As is explained below, instead of conducting an objective analysis, OSHA engaged in confirmation bias by either ignoring or giving short shrift to studies with results that did not support its stated goal of further regulating silica exposure, and unlawfully discounted competing evidence and points of view.

A. OSHA Improperly Rejected Evidence of a Threshold for Silica-Related Respiratory Disease.

OSHA did not factor a disease-related threshold exposure level into its risk assessment. The Agency concluded that a significant risk exists based on the cumulative exposure over a 45 year working life of exposure at 100 and 50 μg/m^3, but selected 50 as appropriate because it concluded that it was the lowest level

feasible for the affected industries. The best evidence, which OSHA is legally obligated to follow, establishes the contrary conclusion: specifically, that there is a safe dose level of silica at 100 $\mu g/m^3$ or higher. Similarly, OSHA relies exclusively on a cumulative exposure model that does not consider the impact of short term high concentration silica exposure on disease outcomes. The conclusion that silica related disease results from exposure to a threshold level higher than the prior PEL, including short-term exposure of extremely high levels of silica, is supported by studies in the record and by the declining rates of silica related diseases at the prior PEL.

Numerous studies show the existence of a threshold exposure level for silica-related disease – that is, a level of exposure (in terms of either concentration or cumulative exposure) such that no individual whose exposure is below that level would be expected to develop an adverse health effect. Evidence shows that there is low-level silica exposure in ambient air generally, yet the overwhelming majority of people do not develop silicosis. Accordingly, "it's important to consider or to test those response models that include the possibility of exposure concentrations of respirable crystalline silica below which there are no anticipated health effect[s], the so-called no adverse effect level." Doc.ID.3576, Hearing Transcript March 19, 2014, Testimony of Dr. Peter Valberg, p. 311 (JA4285).

At the hearing, Dr. Valberg discussed animal studies which show the development of a "lung overload" condition characterized by persistent inflammation. He argued that persistent inflammation is a key threshold-exposure-level element for respiratory disease. *Id.* at 310-13 (JA4284-4287). Given this biological disease mechanism (the existence of which is widely accepted by health experts, including OSHA's expert, Dr. Kyle Steenland),[9] many commenters argued that OSHA should have factored a disease-related exposure threshold level into its risk assessment.

The American Chemistry Council's Crystalline Silica Panel presented several studies that place the threshold exposure level for silicosis above the prior PEL of 100 µg/m³. Comments of the American Chemistry Council Crystalline Silica Panel, February 11, 2014, Doc.ID 2307 ("ACC Comments") at 91-102 (JA3058-JA3069).[10] The starting point for this analysis is the finding, in a number of studies, that intensity of exposure (*i.e.*, the duration and levels at which exposures are received) affects the risk of contracting silicosis. That risk increases more steeply when the same cumulative exposure is received in a shorter period of time at a higher intensity, than

[9] *See* Steenland, K. & Ward, E. Silica: A Lung Carcinogen. CA CANCER J CLIN 2013; 00:00-00 (JA7810-JA7826).

[10] A number of the Petitioners and Intervenor-Petitioners here, including the American Foundry Society, the Brick Industry Association, the NSSGA, the Portland Cement Association, and the National Concrete Masonry Association, are either members of the ACC Silica Panel or members of other industry groups that are members of the Silica Panel.

when it results from longer exposure at a lower average concentration.[11] Indeed, because silica-related lung cancer and silicosis appear to evolve from the same inflammatory process in the lungs, essentially the same concentration threshold is expected for these two disease endpoints.[12] Dr. Anthony Cox posits a "tipping point" exposure threshold above 100 μg/m^3 for the risk of any malignant as well as non-malignant respiratory pathologies that may be associated with prolonged exposure to crystalline silica.[13] Numerous studies support this proposition.[14]

Contrary to this evidence, OSHA asserted there "likely" is no threshold for silica-related disease, and if there is one, it is "likely" lower than 50 μg/m³. 81 Fed. Reg. at 16,359 (JA0075). In OSHA's view, a threshold below 100 μg/m³ cannot exist, because workers reportedly continue to become ill at cumulative or average exposure levels permitted under the prior PEL. Consequently, OSHA used only non-threshold exposure-response models in its risks assessments for silicosis and lung cancer. 81 Fed. Reg. at 16,351 (JA0067).

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[11] *See* ACC Comments at 91-94 (JA3058-JA3061).

[12] *See* ACC Comments at 56-59, 101 (JA3023-JA3026, JA3068); Comments of Dr. Peter Morfeld on Epidemiological Issues Related to OSHA's Proposal of an Occupational Health Standard for Crystalline Silica ("Morfeld Comments"), Attachment 2 to ACC Comments (Doc.ID.2307A) at 21-22 (JA3216-JA3217).

[13] Cox, L.A. Jr., An Exposure-Response Threshold for Lung Diseases and Lung Cancer Caused by Crystalline Silica. Risk Analysis. 2011; 31(10): 1543-1560 (cited in ACC Comments, Doc.ID 2307, p.55) (JA3022).

[14] ACC Comments at 97-99 (JA3064-JA3066).

OSHA's reasoning fails for several reasons. First, it is at odds with common sense: if there is no silica-disease threshold, or if a threshold exists but at a very low level, then a substantial group of individuals, regardless of occupational exposure, would be at risk of silica related diseases by reason of ambient levels of silica. Presumably, consistent with OSHA's cumulative impact reliance, the impact would be greatest on the elderly who would have had a lifetime of low level exposure. But record evidence does not show that silica-related disease occurs in the general population resulting from non-occupational exposure.

Second, OSHA fails to account for the factors that drove the dramatic decrease in silicosis mortality. Current silicosis cases very likely are the result of intense exposure decades earlier, prior to institution of the prior 100 $\mu g/m^3$ PEL, and many newer cases relate to exceedances of that PEL, which could be prevented with better compliance and enforcement. The ACC points out that, if there were not a threshold exposure level above 100 $\mu g/m^3$, silicosis rates would not have declined by 90 percent since implementation of that PEL.

Similarly, OSHA's risk assessment is based exclusively on cumulative exposure. The Agency does not account adequately for the role played by intensity of exposure. OSHA peer reviewer Kenneth Crump, Ph.D., stated that "[n]ot accounting for a dose-rate effect . . . could overestimate risk at lower concentrations" Doc.ID.4016, p.2 (JA5246), citing Doc.ID.1716, pp.165-167 (JA2567-JA2569). If

a dose-rate effect exists for silicosis morbidity, logically it exists for silicosis mortality and other silica-related respiratory diseases.[15]

OSHA acknowledges these concerns have merit, but claims that "the best available studies use cumulative exposure as the exposure metric." 81 Fed. Reg. at 16,375 (JA0091). This statement is incomplete. Viewed together or separately, threshold and dose effect can explain the decline in silica related disease. Moreover, but for non-compliance with the prior PEL, the rate would have declined even further. ACC Comments at 99-102 (JA3066-JA3069).

Third, OSHA's position is inconsistent with mounting judicial skepticism of "no safe dose" or "no threshold dose" arguments. *See, e.g.*, *Bartel v. John Crane, Inc.*, 316 F.Supp.2d 603 (N.D. Ohio 2004) (no safe dose theory not supported by medical literature); *Parker v. Mobil Oil Corp., et al.*, 857 N.E.2d 1114 (N.Y. 2006) (upholding Appellate Division's decision to exclude expert testimony that, in part, concluded that there is no threshold for benzene exposure below which leukemia would not occur, questioning scientific reliability of that methodology); *Benz v. Pneumo-Abez*, 615 Pa. 504, 44 A.3d 27 (2012) (addressing discrepancy in expert testimony to the effect that any exposure to asbestos fiber causes disease and admission that lifetime of background exposure does not). *See also McClain v.*

[15] ACC Comments at 94-95 (JA3061-JA3062), quoting peer review comments of Dr. Crump (Doc.ID 1716, p.167) (JA2569).

Metabolife Int'l, Inc., 401 F.3d 1233, 1242 (11th Cir. 2005) (dose-response relationship is hallmark of basic toxicology).

OSHA ultimately ducked the question, saying "there is a great deal of argument and analysis directed at the question of thresholds in silica exposure-response relationships, but nothing like a scientific consensus about the appropriate approach to the question has emerged." 81 Fed. Reg. at 16,359 (JA0075). After criticizing and deflecting studies showing the importance of the dose-response relationship and the existence of threshold exposures for silica, OSHA concluded that "common issues with epidemiological studies limit the Agency's ability to determine whether and where a threshold effect exists for silicosis and lung cancer." *Id*.

In short, in the face of science that it perceived to be uncertain, OSHA concluded that it should treat any silica-related respiratory disease as having no dose effect or exposure threshold. But, that conclusion is flawed because it plainly is not based on substantial evidence – indeed, it is a default position taken for *lack* of substantial evidence. No study exists in the record that addresses exposure only at 100 or 50 $\mu g/m^3$.

The Agency cannot meet its "substantial evidence" burden by picking one group of inconclusive studies over another, which is what it has done here. To ascertain whether OSHA has met it burden of supporting the rule with substantial

evidence, this Court, "after considering the inferences that can be drawn from the studies supporting" OSHA, as well as "those [studies] opposing" it, must then "decide whether the *cumulative* effect of *all this evidence*, and not the effect of *any single bit of it*, presents a rational basis" for the rule. *Pub. Citizen Health Research Grp.*, 796 F.2d at 1495 (emphases added). And while it is not the job of this Court to "reweigh the evidence and come to [its] own conclusion," it is tasked with "assess[ing] the reasonableness of OSHA's conclusion." *Id.* Here, OSHA has resorted to a highly selective, cherry-picked record to support its action, the very opposite of reasoned decision making, OSHA's failure to recognize a threshold invalidates its conclusions as to *all* respiratory disease endpoints.

B. Workers Do Not Face a Significant Risk of Silicosis or Other Non-Malignant Respiratory Disease Mortality at a PEL of 100 µg/m^3.

OSHA estimates the "lifetime silicosis mortality risk" at the prior general industry PEL of 100 µg/m^3 to be "11 deaths per 1,000 workers" exposed for a 45-year working lifetime, an alleged risk that OSHA finds will be reduced to "7 deaths per 1,000 workers" at its new 50 µg/m^3 PEL. 81 Fed. Reg. at 16,303 (JA0019). With respect to non-malignant respiratory disease ("NMRD") mortality,[16] OSHA calculates a risk of "85 deaths per 1,000 workers" at the prior PEL, and projects "44 deaths per 1,000 workers at the revised PEL." *Id.* These estimates of risk at the

[16] NMRD includes silicosis, chronic obstructive pulmonary disease, chronic bronchitis, and emphysema. *See* 81 Fed. Reg. at 16,309 (JA0025).

prior 100 μg/m^3 PEL are not supported by substantial evidence, and so OSHA has failed to meet its burden of demonstrating that lowering the PEL is warranted.

As was previously discussed, OSHA has failed to rebut the claim, made by ACC and others, that there is a *threshold* for crystalline silica exposure, below which the risk for developing lung pathologies, including silicosis and other non-malignant respiratory diseases is negligible, if it exists at all. That threshold is likely to be well *above* 100 μg/m^3, meaning that the new 50 μg/m^3 PEL will serve only to impose enormous new costs on industry with no cognizable health benefits for workers at all.

This issue aside, OSHA's projections of mortality risk for silicosis and other non-malignant respiratory diseases at exposures below 100 μg/m^3 are neither credible nor reliable. As ACC explained, OSHA's preliminary risk projection, derived from the study of diatomaceous earth workers (*i.e.*, the study by Park *et al.* (2002)), rested more on speculation than any solid evidence. *See* ACC Comments at 102-115 (JA3069-JA3082). This was due to, among other things, the large uncertainty in the exposure assessment used by Park *et al.* and the high likelihood of exposure misclassification. When individuals in an epidemiologic study are wrongly classified with respect to the level or nature of their exposure, this will compromise comparisons of relative risk between groups or exposures, producing either spurious differences or masking true differences.

Notably, Park *et al.* themselves acknowledged the likelihood of exposure misclassification, with such misclassification more than likely being driven by the fact that there was no dust monitoring data for the years before 1948, and as a consequence exposure estimates for the earlier years could be derived only by estimation.[17] There was also uncertainty about converting exposure estimates made before 1948 (by counting dust particles) to exposure estimates made after 1963 (by weighing the particles).[18]

Evidence that exposure misclassification has distorted the conclusions reached by Park *et al.* is in the fact that the silicosis incidence rate in the 1942-1954 period was 13.3 times higher than in later years, even when comparing workers in both periods supposedly having the same cumulative exposures. Further, Park *et al.* found *no deaths* from non-malignant respiratory disease in the *highest cumulative exposure group*. Yet, none of the models that Park *et al.* considered took account of such exposure estimation errors or uncertainties. *See* Cox Comments at 31

[17] *See* Park, R. *et al.* (2002), Exposure to crystalline silica, silicosis, and lung disease other than cancer in diatomaceous earth industry workers: A quantitative risk assessment. Occu Environ Med 59:36-43 at 41 (Doc.ID.0405) (JA7400).

[18] *See* Checkoway, H. *et al.* (1997), Dose-response Associations of Silica with Nonmalignant Respiratory Disease and Lung Cancer Mortality in the Diatomaceous Earth Industry. Am J Epidemiol 145:680-688 at 685 (Doc.ID.0326) (JA7340).

(JA3301). Rather, those models assume that the estimated cumulative exposures correspond to the actual exposure values. *Id.*[19]

Moreover, the mean estimated respirable crystalline silica exposure level in the diatomaceous earth worker cohort as a whole was at least three times the prior general industry PEL of 100 μg/m^3. *See* ACC Comments at 105 (JA3072). The mean estimated exposure of the silicosis cases may well have been almost *10 times* the level of the prior PEL. *Id.* Given this, extrapolating risks from the high exposure levels of the diatomaceous earth worker cohort to the significantly lower levels that had to be maintained to comply with the prior 100 μg/m^3 PEL (much less the new 50 μg/m^3) is not supportable.

In response, OSHA has to "acknowledge that there is some uncertainty in using models" that, in OSHA's own words, are "heavily influenced by exposures above the previous PEL due to potential deviance at areas of the relationship with fewer data points." *See* 81 Fed. Reg. at 16,318 (JA0034). OSHA expresses its "belie[f]," however, that the "ACC's characterization of exposures" in the Park *et al.* study as "vastly higher than the final and former PELs" is "incorrect." *Id.*

[19] Potentially compounding this problem of uncertainty is a lack of clarity regarding the silica percentage assumed to be present in respirable dust. Park *et al.* (2002) appear to have used values ranging from one percent to 25 percent, which differs from the values used in other studies and which would tend to understate silica exposures based on low estimates of silica content. *See* ACC Comments at 104 (JA3071).

According to OSHA, whereas ACC had focused on the "mean exposure *concentrations*" that had been reported by Park *et al.* to "make this argument," the "mean *cumulative* exposure of the cohort was … lower than what the final rule would permit over 45 years of exposure." *Id.* (emphases added). Thus, according to OSHA, "whereas some participants in the Park *et al.* study had higher average 8-hour exposures than were typical under the previous PEL" – this, in itself, is quite an understatement, given that the levels have been estimated to be between three and 10 times the 100 μg/m^3 level of the prior PEL – those exposures were "quite comparable to the exposures workers might accumulate over their working lives under the final PEL of 50 μg/m^3. OSHA's conclusion fails to respond to ACC's actual claim because OSHA assumes that cumulative exposure is the only relevant metric, whereas, as discussed earlier, the impact of short-term, high level exposure should have been considered. Further, OSHA here again ignores the matter of there being a threshold below which risks are negligible or non-existent. The models on which Park *et al.* relied simply assumed no such threshold. ACC Comments at 85 (JA3052).

The ACC also observed that the results reached by Park *et al.* very possibly reflected confounding by smoking. ACC Comments at 108 (JA3075). The Park *et al.* study had available to it data on smoking habits for only 50 percent of the cohort, and even those data were on an "ever-versus-never" smoked basis. *Id.* Of particular

significance, smoking habits were unknown for some 67 percent of the workers who died from non-malignant respiratory disease. *Id.* Moreover, what is known from this incomplete data is that there was a lower prevalence of smoking in workers with the lowest cumulative exposures, which obviously could have confounded the internal comparisons in the diatomaceous earth worker cohort. *Id.*

Here, too, OSHA's response does not rise to the level of substantial evidence. OSHA responds to the fact that there was no smoking data for two-thirds of the cohort who died from non-malignant respiratory disease with the simple observation that the "[s]moking habits of a third of the individuals who died from NMRD *were* known in the Park *et al.* (2002) study." 81 Fed. Reg. at 16,319 (emphasis added) (JA0035). Park *et al.* drew on that admittedly "partial knowledge" of these workers smoking habits and developed "analyses indicating that confounding by smoking was unlikely to significantly impact the observed relationship between cumulative exposure to crystalline silica and NMRD mortality." *Id.* While OSHA had to agree that "comprehensive smoking data would be ideal," the Agency "believes that the approach taken by Park *et al.* to address this issue was reasonable." *Id.*

It is understandable that OSHA would find the approach taken by Park *et al.* to be "reasonable," insofar as the results it produced affirms the conclusion that OSHA has reached. The question is whether this constitutes substantial evidence to support the new PEL. Given that OSHA itself had previously stated that "it appears

that the silica-related risk [of NMRD mortality] is strongly influenced by smoking, and the effects of smoking and silica exposure may be synergistic,"[20] the Agency's acceptance that the possible confounding effects of smoking have been accounted for adequately by Park *et al.*, even in face of admittedly "partial" data, is inconsistent, ultimately unsupportable, and certainly not based on substantial evidence.

C. OSHA's Projections of Silicosis Morbidity Risks at Exposure Levels Below 100 μg/m^3 Are Neither Credible nor Reliable.

According to OSHA, "[c]umulative risk estimates for silicosis morbidity are … well above 1 case per 1,000 workers exposed at the previous PELs." 81 Fed. Reg. at 16,300 (JA0016). "At the revised PEL of 50 μg/m^3 respirable crystalline silica," it continues, this estimated risk is "substantially reduced." *Id.* Thus, OSHA concludes that the "new PEL … provides a large reduction in the lifetime and cumulative risk posed to workers exposed to respirable crystalline silica." *Id.* As is explained below, OSHA's projections of silicosis morbidity risks at exposure levels below 100 μg/m^3 are not credible, having been derived from studies that cannot be considered reliable.

[20] Occupational Exposure to Respirable Crystalline Silica – Review of Health Effects Literature and Preliminary Quantitative Risk Assessment ("Health Effects Review"), Doc. ID 1711, p. 206 (JA2284).

OSHA projected that, after 45 years of occupational exposure to respirable crystalline silica at a concentration of 100 μg/m^3, anywhere from 60 out of 1,000 workers (an estimate derived from a study of the Chinese pottery industry) to 773 out of 1,000 workers (based on a study of South African gold miners) will develop radiological silicosis.[21] As discussed below, these projections lack credibility, and OSHA's reliance on the studies that produced these projections is ill-founded. OSHA's conclusion, therefore, that the new PEL "provides a large reduction in the lifetime and cumulative risk posed to workers" with respect to silicosis morbidity is not supported by substantial evidence.

First, as has already been explained, the best available evidence indicates that there is an exposure concentration threshold above 100 μg/m^3 for silicosis and other respiratory conditions involving an unresolved chronic inflammatory/fibrotic response. The best estimate for that threshold is 250 μg/m^3. See Morfeld Comments. Accordingly, whatever validity OSHA's risk estimates for silicosis might or might not have for workers exposed to high concentrations of respirable crystalline silica, they have no validity with respect to workers whose exposures do not exceed the former general industry PEL of 100 μg/m^3.

Second, at the 100 μg/m^3 level, OSHA's projections of silicosis morbidity risks span more than an order of magnitude. Such a vast range of estimated risks

[21] Health Effects Review at 351-52, Table II-12 (JA2429-JA2430).

cannot be reconciled with the assertion that the projections themselves were well-founded. While these varying estimates are derived from studies which claim to have obtained statistically significant results, as Dr. Cox observed, "obtaining *significant* results is not the same as obtaining *correct* results," and the "fact that [the studies] disagree with each other suggests that none of them is a reliable guide to a correct quantification of [exposure response] associations." Cox Comments at 98 (emphases in original), (JA3368).

Tellingly, nowhere in the final rule does OSHA address this simple point. To the contrary, OSHA states that the "risk values derived from the Chen *et al.* studies *do not differ remarkably* from other silicosis morbidity studies used in the risk assessment." 81 Fed. Reg. at 16,321 (emphasis added) (JA0037).[22] The "other silicosis morbidity studies" to which OSHA refers – *i.e.*, Buchanan *et al.* (2003); Steenland and Brown (1995); and Hnizdo and Sluis-Cremer (1993) – project the risk associated with 45 years of exposure at 100 μg/m^3 to be 301 workers out of 1,000, 431 workers out of 1,000, and 773 workers out of 1,000, respectively. Contrast those estimated risks to the estimate of 60 out of 1,000 workers in Chen *et al.*'s 2005 study

[22] At an exposure level of 100 μg/m^3, Chen *et al.* (2001) estimated the risk associated with 45 years of exposure to be 590 workers out of 1,000 for tin miners. Chen *et al.* (2005) estimated the risk to be 60 out of 1,000 (for pottery workers), 120 out of 1,000 (for tungsten miners), and 400 out of 1,000 (for tin miners). *See* Health Effects Review at 352, Table II-12 (JA2430).

of Chinese pottery workers. The assertion that these projected risks "do not differ remarkably" reflects arbitrary and capricious reasoning on OSHA's part.

Moreover, the silicosis risks estimated in the Chen *et al.* studies themselves differ internally by a factor of 10, varying from 60/1,000 workers in the 2005 pottery workers study to 590/1,000 workers in the 2001 tin miners study. And in the Chen *et al.* 2005 study, the silicosis risk for tin miners was almost three times higher than the risk for tungsten miners, even though the tungsten miners had higher silica exposures than the tin miners.[23] That is the opposite of what one would expect under OSHA's theory, and the Agency is forced to admit that "[t]here is no apparent explanation for why tungsten miners appeared to have lower silicosis risk than tin miners. . . ."[24]

Moreover, the ACC Silica Panel in its comments on the proposed rule set forth, in considerable detail, the various flaws it had identified in the three studies on which OSHA relied that had produced the highest projections of silicosis morbidity.[25] OSHA acknowledges the challenges to the validity of those studies that were raised in the ACC's comments and attempts to rebut at least some of them.

[23] *See* ACC Comments at 134-135 (JA3101-JA3102).

[24] Health Effects Review at 341-42 (JA2419-JA2420).

[25] *See, e.g.*, ACC Comments at 117; *id.* at 124; *id.* at 132 (JA3084; JA3091; JA3099).

Ultimately, however, OSHA is left to argue little more than that the "uncertainty" associated with these studies was unavoidable.

For example, with respect to the Chen *et al.* studies, the exposures assigned to cohort members were based on "total dust samples" (*i.e.*, samples that contained non-respirable silica and other airborne substances) from which respirable crystalline silica levels were estimated by applying an across-the-board mathematical "conversion factor" which assumed that respirable crystalline silica constituted 3.6% of the total dust. ACC Comments at 132-133 (JA3099-JA3100). OSHA concedes that neither Chen *et al.* study "expressed reason to be concerned about the non-silica portion of the dust samples,"[26] even though, as had been pointed out, insofar as "[n]o information was provided on the composition of the remaining ~96% of the total airborne mixed dust," the "radiographic findings in these workers possibly reflect a certain amount of mixed dust fibrosis, rather than [findings] purely due to crystalline silica." *See* ACC Comments at 133 (JA3100). In defense, OSHA can only muster the generalized suggestion that "uncertainty about potential unknown exposures exists in retrospective studies, which describes most epidemiological research." 81 Fed. Reg. at 16,321 (JA0037).

Taken to its logical end, this view that epidemiological research will always involve "uncertainty" would give OSHA license to place its reliance on whatever

[26] 81 Fed. Reg. at 16,321 (JA0037).

study it might choose, regardless of the study's evident flaws or questionable findings. OSHA is not entitled to such leeway, because it must make its "findings of fact on the basis of substantial evidence" and must "provide[] a *reasoned explanation* for [its] policy assumptions and conclusions." *Bldg. & Constr. Trades Dep't. v. Brock*, 838 F.2d 1258, 1266 (D.C. 1988). Here, OSHA's conclusion that it is "unlikely that an unknown compound significantly impacted the exposure-response relationships reported in both Chen studies" cannot be attributed to any "substantial evidence" found in the record. To the contrary, the contrasting risk estimates for the tin and tungsten mines in Chen *et al.* 2005 suggest that some other compound in the mixed dust did indeed impact the exposure-response relationships.

In a similar vein, OSHA dismisses the ACC's explanation that the exposure assessment in the Steenland and Brown study "suffers from enormous uncertainty and a high likelihood of underestimation," due to the absence of data for years prior to 1937 and after 1975. *See* ACC Comments at 124 (JA3091). Again, OSHA acknowledges that there are "potential sources of uncertainty in the exposure estimates," but then takes refuge in the assertion that "exposure uncertainty" is a "common occurrence in occupational epidemiological studies." 81 Fed. Reg. at 16,321 (JA0037). While it may be a "common occurrence," the degree of exposure uncertainty in the Steenland and Brown study was exceptional. *See* ACC Comments at 124-130 (JA3091-3097). For OSHA, though, it is enough that the "authors used

the best measurement data available to them in their study." *Id.* But, of course, the issue is whether the conclusions reached by a given study are derived from valid data, are credible, and are thus entitled to weight. While OSHA's candor here is commendable,[27] "substantial evidence" is not assessed against some "they-did-the-best-they-could-with-what-they-had" standard.

D. Workers Do Not Face a Significant Risk of Silica-Related Lung Cancers at a PEL of 100 µg/m^3.

OSHA's risk assessment for lung cancer mortality at the former PEL (between 11 and 54 deaths per 1000 workers, 81 Fed. Reg. at 16,338 (JA0054), hinges on the assumption that silica exposure directly increases the risk of lung cancer, even in the absence of silicosis, and that there is no threshold for lung cancer risk. Although these assumptions have been demonstrated to be untenable by many epidemiologic studies (contained in the rulemaking record),[28] OSHA summarily dismissed these studies, unabashedly setting aside studies with which it disagreed.

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[27] *Cf. United Steelworkers of Am.*, 647 F.2d at 1207 (Among other things, OSHA is required to "explain the logic and the policies underlying any legislative choice," and to "state candidly any assumptions on which it relies.").

[28] These studies are cited in the ACC Comments at 35-36, 48 (JA3002-JA3003, JA3015).

1. OSHA Gave Inadequate Consideration to Substantial Evidence That There Is No Conclusive Link Between Silica Exposure and Lung Cancer in the Absence of Silicosis.

Many meta-reviews of epidemiological studies exploring the link between silica exposure and lung cancer failed to find a direct relationship between the two.[29] OSHA largely disregarded these studies, and addressed in detail only the meta-review conducted by Gamble (2011).[30] OSHA's treatment of Dr. Gamble's review is telling, as clearly shown by a chart prepared by OSHA which compared its position on each of the studies to Gamble's. *Id.* at pp. 14-23 (JA2531-JA2540). The chart shows that OSHA systematically dismissed the studies that cast doubt on the theory that silica exposure causes lung cancer.

Nowhere is this "confirmation bias" more evident than in OSHA's treatment of two major studies of Vermont granite workers, one by Attfield and Costello (2004)[31] and a more recent, larger study by Vacek *et al.* (2011).[32] The Vacek study

[29] These studies are cited in the ACC Comments at 31-33 (JA2998-JA3000). *See* also Report of Dr. Patrick Hessel, May 2005, Attachment 5 to ACC Comments, at 4-5 (JA3378-JA3379).

[30] Supplemental Literature Review of Epidemiological Studies on Lung Cancer Associated with Exposure to Respirable Silica (Doc.ID.1711, Attachment A) (JA2516-2562).

[31] Attfield, M.D. & Costello, J. (2004). Quantitative exposure-response for silica dust and lung cancer in Vermont granite workers. Am J Ind Med 45:129-138 (Doc.ID.0543) (JA7456-JA7465).

[32] Vacek, P., Verma, D., Graham. W. & Gibbs, G., Mortality in Vermont granite workers and its association with silica exposure. Occup. Environ. Med. 2011; 68:312-318, available online at http://dx.doi.org/10.1136/oem.2009.054452, Doc.ID.1486 (cited in ACC Comments) (JA2047-JA2053).

did not find significant associations between respirable silica exposure and mortality from lung cancer; the Attfield and Costello study did.

Several commenters (including Dr. Cox and Dr. Morfeld) found that the more recent Vacek study was stronger than the Attfield and Costello study, and essentially superseded it, because: (1) the Vacek study included more workers (7052, compared to 5414 in the Attfield study) and covered a wider range of years; (2) the Vacek study had a ten-year longer follow-up period (*i.e.*, ten additional years during which any cancers might manifest); (3) although both studies used employment information collected as part of a Vermont Department of Industrial Health ("DIH") surveillance program, the Vacek study re-examined these data and augmented them with information from other sources, which revealed that the DIH information on which Attfield relied was incomplete for many workers; (4) Vacek used more detailed information about the measurements of crystalline silica particles; and (5) Vacek used more complete work histories for each worker, meaning that the silica exposures in Attfield were less reliable. *See* ACC Comments at 37-38 (JA3004-JA3005). These commenters noted that the lung cancer findings in the Vacek study were consistent with two other studies on which Attfield and Costello relied for their exposure information. *Id.* at 40 (JA3007).

Nonetheless, OSHA rejected the Vacek study in favor of Attfield and Costello, and, based on the latter, estimated a strongly increased lung cancer risk for

silica-exposed workers. OSHA's stated reasons for doing so reveal the bias it brought to this risk assessment. For example, OSHA argued that the categories of exposure ("quintiles") studied by Vacek were higher than the categories used in other studies; however, it did not explain why this should be considered problematic. OSHA also published a table purporting to compare the exposure categories of the Vacek and Attfield and Costello studies. Supplemental Literature Review Doc.ID.1711, Attachment A at p. 4, Table 1 (JA2521). However, as the ACC noted, the table compared Vacek's *silicosis* exposure categories with the *lung cancer* exposure categories used by Attfield and Costello – an "apples and oranges" comparison. Vacek's categories for the lung cancer assessment actually were quite similar to Attfield and Costello's. ACC Comments at 42 (JA3009).

OSHA also argued, without any support, that the regression models used in the Vacek studies exhibited signs of "uncontrolled confounding" – that is, unaccounted-for external factors that might have affected the causal analysis. 81 Fed. Reg. at 16,335 (JA0051). OSHA did not explain what these confounding factors might be, and in fact, had deemed the cohort in question free of confounding exposures for purposes of the Attfield and Costello study.[33]

[33] Attfield and Costello noted that the cohort consisted of "workers exposed almost exclusively to rock dust containing silica and no other major occupational confounding exposures."

OSHA thus demonstrated an inconsistent, results-oriented approach to data analysis in the two studies. It criticized the Vacek study for including data from the highest exposure group (quintile), ostensibly because it "suppress[ed] a linear trend from being observed."[34] At the same time, OSHA endorsed the decision by Attfield and Costello to exclude the highest exposure group from the analysis, because there was no significant exposure-response trend for lung cancer when that quintile was included. Supplemental Literature Review at 3 (JA2520); ACC Comments at 44 (JA3011). The rejection of data based on personal opinions or preconceptions is scientifically unsound. OSHA's endorsement of this approach reveals the bias with which it approached the epidemiological literature, and fundamentally undermines its conclusion that silica exposure causes lung cancer.

2. Risk of Silica-Related Lung Cancer Depends on Pre-Existing Silicosis.

Medical and epidemiological literature indicates that if silica exposure increases lung cancer at all, it does so through an inflammation-mediated mechanism, in which silicosis first manifests. This view is widely accepted, including by one of OSHA's consultants, Dr. Kyle Steenland. ACC Comments at 54, n.124 (JA3021). That in turn implies that there is "a threshold for any causal association between silica exposure and risk of lung cancer." Morfeld Comment at

[34] Supplemental Literature Review, Doc.ID.1711, Attachment A, p. 3 (JA2520).

5-7 (JA3200-3202). Numerous studies submitted into the rulemaking record supported this proposition.[35]

OSHA acknowledged that "uncertainty remains about what percentage of lung cancers in silica-exposed workers are independent of silicosis," 81 Fed. Reg. at 16,331 (JA0042), but nonetheless cherry-picked the epidemiological literature to find five studies that it deemed to support a direct relationship between silica exposure and lung cancer. OSHA flatly rejected Dr. Cox's extensive criticism of the methodologies used in these studies, which revealed study selection bias and data selection bias on OSHA's part. Many of the studies on which OSHA relied tried different combinations of research protocols and modeling choices (including alternative exposure metrics, different time lags, alternative mathematical models, different subsets of data, or models that were biased toward false positives); but the researchers did not conduct additional statistical tests for "model selection bias" (*i.e.*, bias in study results that may arise when researchers seek the research protocol or mathematical model that best supports the conclusions they hope to find). ACC Comments 65-72 (JA3032-JA3039). As a result, the Final Quantitative Risk Assessment offers causal conclusions that are unsupported. *Id.*

At bottom, OSHA's risk analysis for lung cancer is fraught with uncertainty, and an association with lung cancer, in and of itself, cannot be deemed to be the best

[35] These studies are cited in the ACC Comments at 56-61 (JA3023-JA3028).

available evidence in support of a reduction of the PEL. Dr. Robert Park of the National Institute for Occupational Safety and Health ("NIOSH") stated at the hearing that it is difficult to resolve the issue of whether silicosis is a necessary precursor to development of lung cancer; the diseases may have a similar pathway and can develop independently, but appear correlated. Transcript of March 18, 2014, Doc.ID.3579, p.246-47 (JA4486-4487). He added, "[t]o really separate those two, you'd have to do a really big study. You'd have to have some measures, independent measures of lung physiological pathology, and see what's going on.…" *Id.* at 247 (JA4487). Dr. Brian Miller, an OSHA peer reviewer from the Institute of Occupational Medicine, testified, "I consider this issue unanswerable, given that we cannot investigate for early fibrotic lesions in the living, but must rely on radiographs." In light of this testimony, OSHA has not mustered substantial evidence to support its risk assessment for lung cancer, and its new silica standard cannot be justified on an association with lung cancer.[36]

[36] OSHA relied heavily on a study of Chinese pottery workers and miners by Liu *et al.* (2013) for the proposition that silica exposures cause lung cancer in the absence of silicosis, but, as is explained in the ACC Comments at 49-51 (JA3016-JA3018), significant defects in that study render it unreliable – and certainly not the best available evidence on the subject. OSHA's reliance on the Liu study to support its lung cancer argument illustrates its own confirmation bias.

E. Workers Do Not Face a Significant Risk of Renal Disease Mortality at a PEL of 100 µg/m^3.

OSHA estimates the "lifetime renal disease morality risk" for "45 years of exposure" to the former general industry PEL of 100 µg/m^3 to be "39 deaths per 1,000 workers." 81 Fed. Reg. at 16,342 (JA0058). For the new PEL, it is "32 deaths per 1,000 workers." *Id.* At the same time, OSHA "acknowledges that there are considerably less data for renal disease mortality," and, thus, the "risk findings based on them are less robust" than the findings OSHA has made for silicosis, lung cancer, and non-malignant respiratory disease mortality. *Id.* In fact, the record reveals that OSHA's conclusion with regard to renal disease are not robust at all.

In its comments on the proposed rule, the ACC Silica Panel explained at length that OSHA's projection of renal disease mortality was based on limited data from studies with very large exposure uncertainties, and that, at the same time, it ran counter to numerous studies showing no causal association between silica exposure and renal disease morality at all. *See* ACC Comments at 139-157 (JA3106-JA3124). Ultimately, the ACC concluded that it was "absurd to pretend that OSHA's projections … are anything other than rank speculation." *See* ACC Post-Hearing Comments at 96 (JA5520). In defense of its projections in the final rule, OSHA offers little to unsettle that conclusion.

Indeed, OSHA all but concedes that it has provided nothing in the way of substantial evidence in support of its findings, taking pains at one point to note that

"even if the risk of renal disease mortality is discounted, there would remain clearly significant risks of lung cancer mortality, silicosis and [non-malignant respiratory disease] mortality, and silicosis morbidity," these supposedly having "more robust risk estimates based upon a larger amount of data from numerous studies." 81 Fed. Reg. at 16,342 (JA0058). As has been explained previously, OSHA's claim that it has established, on the basis of substantial evidence, "clearly significant risks" with respect to these other disease conditions does not itself withstand scrutiny. That aside, what is otherwise clear is that OSHA itself has little apparent confidence that it has made out a credible case with respect to renal disease mortality.

Particularly significant in this regard is OSHA's treatment of the fact that no fewer than ten separate studies that were brought to its attention indicate no causal association between silica exposure and renal disease mortality. *See* ACC Comments at 140-145 (JA3017-3112); 81 Fed. Reg. at 16,344 (JA0060). While OSHA asserts that it has performed an "overall analysis of the literature, including the negative studies," and on that basis has "concluded that there was substantial evidence suggesting an association between exposure to crystalline silica and increased risk of renal disease," notably, in the final rule preamble, OSHA discusses only four of the aforementioned 10 "negative studies" – *i.e.*, Birk *et al.*; Mundt *et*

al.; Vacek *et al.*; and Cherry *et al.*[37] As for the other studies, if OSHA has some principled basis for rejecting them, it fails to explain what that might be.

This failure is particularly significant given that, Kyle Steenland, the principal author of the study on which OSHA has based its estimate of renal disease mortality, concedes in a 2013 article that the evidence for a causal association of silica exposure and renal disease is only "suggestive."[38] At the public hearing on the proposed rule, Steenland acknowledged that the question whether silica exposure causes renal disease mortality "is a little more complicated," and there "there is more uncertainty."[39] In a candid moment, Dr. Steenland added: "Two of the [three] studies relied on [to estimate the risks of renal disease mortality] were mine, so I have to support them."[40] Indeed, Dr. Steenland stated that the "amount of data is insufficient to provide robust estimates of risk."[41]

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[37] 81 Fed. Reg. at 16,345 (JA0061).

[38] Steenland, K. & Ward, E. Silica: A Lung Carcinogen. CA CANCER J CLIN 2013;00:00-00, Doc.ID.2340. Available online at http://dx.doi.org/10.3322/caac.21214 (first published on-line Dec. 10, 2013) (JA7810-JA7826).

[39] Testimony of Dr. Kyle Steenland, Transcript of Public Hearing, March 24, 2014, Doc.ID.3580, p. 1245 (JA4513).

[40] *Id.*

[41] Steenland, N.K. & Bartell, S.M. Silica Exposure: Risk Assessment for Lung Cancer, Silicosis and Other Diseases. Prepared under contract to OSHA by ToxaChemica International, Inc. (Draft Final, December 7, 2004) at 27. Doc.ID.0469 (JA1721).

OSHA argues that its "decision may be fully supportable if it is based … on the inconclusive but *suggestive* results of *numerous* studies." 81 Fed. Reg. at 16,360 (emphases added) (JA0076). The problem is, even if the studies on which OSHA relies can be said to provide results that are "suggestive" with respect to a causal association between silica exposure and renal disease, it is at a minimum questionable that *three* such studies constitute a "numerous" array of studies constituting substantial evidence in support of OSHA's findings. And given that those three studies run counter to a much larger number of studies in which a causal association was not found, attributing a high risk of renal disease mortality to silica exposures at the former PEL of 100 $\mu g/m^3$, as OSHA has done, is plainly unjustified.

OSHA also rejects the ACC's characterization of its renal disease risk estimates as "rank speculation," with the Agency contending that its findings have been grounded in the "best available evidence." *Id*. at 16,343 (JA0059). This is indefensible in light of the great weight of contrary evidence that was brought to OSHA's attention and to which it has offered little or no meaningful response.

II. OSHA'S FINDING THAT THE RULE IS FEASIBLE IN THE FOUNDRY, HYDRAULIC FRACTURING, AND CONSTRUCTION INDUSTRIES IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.

Under Section 6(b)(5) of the OSH Act, health standards promulgated by the Agency must be "feasible." 29 U.S.C. § 655(b)(5). "Feasibility" sets a critical boundary to OSHA's rulemaking authority. It reflects Congress's judgment that

OSHA's authority in the realm of safety and health is not limitless, and the Agency must consider the ability of industry to comply with the requirements of new health standards and the related costs. *See* Remarks of Senator Javits, S. Rep. No. 91-1282 (noting that the Secretary, in setting standards, shall not require "absolute health and safety in all cases, regardless of feasibility."). This Circuit has interpreted the feasibility requirement to have two equally important components: technological feasibility and economic feasibility. *Nat'l Mar. Safety Ass'n v. OSHA*, 649 F.3d 743, 752-53 (D.C. Cir. 2011).

To establish technological feasibility, 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 standard] in most of its operations." *Am. Iron & Steel Inst. v. OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) ("*Lead II*"). OSHA must demonstrate this without regard to the use of respirators. *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1269-70 (D.C. Cir. 1980) ("*Lead I*"). OSHA standards will not pass a pre-enforcement challenge if substantial use of respiratory protection is necessary to protect employees. *See Pub. Citizen Health Research Grp. v. U.S. Dep't of Labor*, 557 F.3d 165, 179-80 (3d Cir. 2009).

A standard is economically feasible if it does not "threaten" the existence of, or cause massive economic dislocations within, a particular industry or alter the competitive structure of that industry. *See Lead I*, 647 F.2d at 1265. While a

reviewing court will not dictate a particular form of assessment, the "agency must of course provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry." *Id.* at 1266. OSHA has historically found a standard to be economically feasible if its costs do not exceed 10 percent of profits or 1 percent of revenues for affected industries. 81 Fed. Reg. at 16,533 (JA0249).

In addition, OSHA must make a finding of feasibility on an industry-by-industry basis. *Lead I*, 647 F.2d at 1277. Broad generalizations and unfounded assumptions that do not reflect reality will not satisfy OSHA's statutory responsibilities. *See W. Va. v. EPA*, 362 F.3d 861, 866-67 (D.C. Cir. 2004) ("[M]odel assumptions must have a 'rational relationship' to the real world")(internal citations omitted).

For the foundry, hydraulic fracturing, and construction industries, OSHA's conclusion that the Rule is technologically and economically feasible is not supported by substantial evidence in the rulemaking record. In addition, throughout its analyses, the Agency ignores the best available evidence in the record regarding the infeasibility of the Rule.

A. OSHA Failed To Demonstrate The Rule Is Technologically Feasible In The Foundry And Hydraulic Fracturing Industries.

1. OSHA's Finding Of Technological Feasibility In The Foundry Industry Is Not Supported By Substantial Evidence.

One of the most profoundly impacted industries by the final Rule is the foundry industry. "Foundries melt and cast metal in molds to produce precisely formed metal castings, which workers then trim and clean to create finished products." Doc.ID.4247, p. IV-225 (JA6130). At a basic level, the mold making process using sand involves three steps: preparing a mold using sand; melting and poring molten metal into the mold; and cleaning the cooled metal to remove the extraneous mold material. *Id.* at IV-228 (JA6133). The foundry industry uses 3 million tons of silica sand a year. Doc.ID.2379, p.37 (JA4037).

OSHA's finding of technological feasibility in the foundry industry is fundamentally flawed and ignores critical evidence of exposure variability and the *actual experience* of foundries that have attempted to comply with the previous PEL of 100 µg/m^3 in the context of OSHA enforcement actions, but have failed to reach that level.

a) *OSHA ignored dispositive evidence of exposure variability in foundry operations.*

There are unique challenges with controlling a substance as ubiquitous as crystalline silica on affected worksites. *See* Doc.ID.3578, pp.1035-36 (JA4434-JA4435); Doc.ID.2379, App.3, pp.2-5 (JA4075-JA4078). Foundry operations are

particularly susceptible to significant and unpredictable swings in exposure to silica. Doc.ID.3584, pp.2633-34 (JA4724-JA4725). Most foundries, and virtually all small foundries, are not devoted to producing a single cast item. Foundries are continually manufacturing new products and casts of different sizes, shapes, configurations, and materials. As one foundry owner/operator stated:

> Foundries vary in facility size from less than 1000 square meters to more than a million. We vary in number of employees, from less than five to more than a thousand. We vary in production rate, from making one casting a week to thousands of castings a day. And we vary in the size of castings we make, from less than a pound, to over [a] hundred tons.

Id. And even OSHA conceded:

> The volume, size, and type of castings produced vary widely from one foundry to another, ranging from a few large specialized castings to thousands of small castings per shift. Depending on the size of the foundry, operators might be responsible for a single task or several tasks.

Doc.ID.4247, p. IV-228 (JA6133).

As a result of the dynamic and ever-changing foundry work environment, there is significant variability in crystalline silica exposures. The best evidence of this variability in the foundry industry was a study performed by the American Foundry Society and submitted to the rulemaking record, "Critique of the Interpretation of Foundry Silica Sampling Results Used by OSHA as Support of Feasibility of Foundries Meeting a Reduced Silica Exposure Limit." Doc.ID.2379, App. 4 (JA4117-JA4144) (the "AFS Study"). This study applied a NIOSH strategy

for assessing the variability seen in repetitive sampling to determine the statistical confidence of reaching a reduced PEL for silica in a foundry environment. *Id.* at 1 (JA4118).

The study authors applied the NIOSH statistical approach to data provided by seven ferrous foundries and one non-ferrous foundry. The authors concluded:

> All of the repetitive silica exposure measurement sets, whether for individual workers or for groups of workers in specific job categories, evidenced ranges of variability which extended both below and above the proposed 50 µg/m^3 OSHA PEL.
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> * * *
>
> The 84% confidence level that silica exposures for workers or groups of workers would be below 50 µg/m^3 was also evaluated …. None of the individual workers and only one of the job categories, automatic mold machine operators, resulted in an 84% confidence limit that exposures would be below 50 µg/m^3. The calculated 84% confidence level for the individual worker exposures ranged from 69 to 125 µg/m^3 and for the job categories ranged from 35 to 220 µg/m^3.

Id. at 5 (JA4122).

The 84% confidence level corresponds to one geometric standard deviation ("GSD") above the geometric mean ("GM"). For the foundry job categories, the GSD ranged from 1.8 to 3.5 with an average of 2.5. *Id.* at Figure 4 (JA4143). Thus, for an 84% confidence of compliance the GM level must be one GSD (2.5 times) lower than the PEL. *Id.* Put simply, the study demonstrated that for a foundry employer to meet a PEL of 50 µg/m^3 with even 84% confidence, *the employer would need to attain a level of 20* µg/m^3. Doc.ID.2379 (JA4117-JA4144). For 95%

confidence, the level of compliance must be two GSDs below the PEL. *Id.* In the foundry industry, OSHA has not come close to making a finding that such levels are achievable.

In fact, OSHA specifically analyzed the extent to which a 25 µg/m^3 PEL could be met in General Industry operations and concluded that it was not achievable:

> For most of the industries and application groups included in this analysis, a review of the sampling data indicates that an alternative PEL of 25 µg/m^3 *cannot be achieved with engineering and work practice controls*. OSHA finds that engineering and work practice controls will not be able to consistently reduce and maintain exposures to an alternative PEL of 25 µg/m^3 in the sectors that use large quantities of silica containing material, *including foundries (ferrous, nonferrous, and non-sandcasting)*, concrete products, and hydraulic fracturing, or have high energy operations, such as jackhammering and crushing machines.

81 Fed. Reg. at 16,461 (emphases added) (JA0177). This is, in a word, – and by OSHA's own admission – dispositive of the technological feasibility issue for foundries. For all foundry operations, OSHA concluded that a PEL lower than 50 µg/m^3 could not be met on a consistent basis. *Id.* at 16,461-62 (JA0177-JA0178).

The importance of exposure variability for employers is significant. In the course of an OSHA inspection, a compliance officer will go to a worksite to conduct sampling. If the exposures for that particular day are above the PEL, due to exposure variability outside of the control of the employer, a citation will issue. The PEL is an upper limit, not a mean or average level that would allow 50% of exposures to

exceed the PEL as long as the other 50% were low enough to offset the exposures above the PEL.

In the final Rule, OSHA essentially ignores this evidence. Nowhere in the preamble to the Rule does OSHA at all address the AFS study.[42] Instead, OSHA devotes a mere three paragraphs in the *Federal Register* for generally addressing the issue of exposure variability. *Id*. at 16,460 (JA0176). This response does not come close to meeting the Agency's legal obligations. No rejoinder in a reply brief will cure this critical omission.

Instead, OSHA cites to studies of variability in "construction" (not foundries), but even those studies do not at all address the extensive exposure variability issues in the construction industry.

OSHA further attempts to discount the importance of exposure variability by citing to testimony that the variability can be reduced by the implementation of controls and improved work practices. *Id.* The notion that lower exposure levels are associated with reduced variability, however, is refuted by the AFS study which found that the three highest levels of variability were associated with mean exposures of 28, 33 and 45 $\mu g/m^3$. Doc.ID.2379, App. 4 at Fig. 4 (JA4143). Even

[42] A review of the preamble to the final Rule found only a reference to the AFS study in the discussion of exposure variability and *cost* issues, not technological feasibility. 81 Fed. Reg. at 16,475 (JA0191). Even so, that discussion simply alluded to the presence of the study but never specifically discussed it. *Id.*

OSHA recognizes the challenges that exposure variability presents in discussing evidence from the foundry industry in its own FEA. *See, e.g.*, Doc.ID.4247, p. IV-244 (JA6149) ("Four full-shift PBZ respirable quartz exposure results for shakeout operators at another foundry evaluated by NIOSH ranged from 37 to 214 µg/m^3, again indicating the potential for variability in respirable quartz exposures for a single job category at a single facility.").

Finally, OSHA cites its "enforcement discretion" to address exposure variability. "[I]n situations where exposure measurements made by OSHA indicate that exposures are above the PEL, and that result is clearly inconsistent with an employer's own exposure assessment, OSHA will use its enforcement discretion to determine an appropriate response." 81 Fed. Reg. at 16,460 (JA0176). Whatever this hypothetical "appropriate response" might be, this is an *insufficient response* to a significant issue of whether the PEL can be met in most operations most of the time. To the extent OSHA is suggesting that it could implement an enforcement policy that allows for certain re-sampling or other allowances during enforcement, OSHA has not done so. The Court must analyze the Rule as it is written, and should not rely on the Agency's representations of "enforcement discretion" to justify a statutory requirement of health standards rulemaking.[43]

[43] OSHA attempts to rely on *Building and Construction Trades Department, AFL-CIO v. Brock*, 838 F.2d 1258 (D.C. Cir. 1988) ("*Asbestos II*"), in support of its ability to evade its legal obligations through an unannounced enforcement policy. In that

b) *OSHA ignored the best available evidence of technological infeasibility in foundry operations.*

OSHA's attempt to meet its burden of proving technological feasibility is further deficient because OSHA essentially ignores the best available evidence in the record that the Rule is infeasible: evidence that numerous foundries' attempts to comply with the *previous* OSHA PEL of 100 µg/m^3 were unsuccessful.

In these situations, foundry employers agreed to "abate" violations of OSHA's previous silica standard by applying the hierarchy of controls (engineering and work practice controls first, followed by respiratory protection), precisely what OSHA would require in an action to enforce the new Rule. They were required to submit abatement documentation, and failure to do so could result in daily citations for "failure to abate" under the OSH Act. 29 U.S.C. § 666(d). Given the circumstances and the threat of additional enforcement, the employers in these cases would have expended all available resources to ensure that their operations were below the PEL.

The employers were unable to consistently do so. *See, e.g.*, Doc.ID.2379, App.2, p.3, (JA4052) ("Contrary to OSHA's assertion, AFS has learned that this foundry … has not been able to achieve compliance without respiratory protection."); p.6 (JA4055) ("[S]ampling showing a reduction of exposure levels

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case, however, the evidence of exposure variability was not at all as significant as the evidence presented in this rulemaking record. *Id.* at 1268. Furthermore, OSHA had more clearly articulated its enforcement position in the preamble to the Rule. *Id.* Even so, reliance on vague enforcement discretion cannot excuse OSHA from complying with the OSH Act's mandate that OSHA consider the best available evidence of feasibility.

was followed by sampling that indicated exposures above the current PEL"); and p.10 (JA4059) ("[D]ocket reference shows sampling data for other operations (cleaning and finishing) which exceed the current PEL").[44]

Recognizing the importance of this evidence, OSHA attempts to undermine it by stating that settlement agreements must be understood in "context" and that they "are an effort by OSHA to achieve the safest working conditions for the employees in the facility as a whole and take into account many other factors, not the least of which is achieving exposure reductions expeditiously by avoiding protracted legal proceedings." Doc.ID.4247, p. IV-269 (JA6174). OSHA here misses the point. The reasons that an employer would settle a case are irrelevant to their compliance obligations after settlement has occurred. The fact is that in these settlements employers were required to achieve the PEL and were in many instances unable to do so.

Instead of looking at the actual abatement experience of foundry employers, OSHA cherry-picks data that it finds useful to demonstrate feasibility. None of this other evidence, however, supports a finding of feasibility throughout the entire foundry industry. As an initial matter, in an industry as diverse as the foundry

[44] In one instance in the record, after investing in numerous control measures to reduce exposures to the previous PEL of 100 µg/m^3, the Area Director overseeing the abatement efforts by the foundry cautioned that the very sample results OSHA cited in the PEA to prove feasibility did not even demonstrate the ability to consistently comply with the previous PEL, noting in a letter that "[i]t is reasonable to expect that on any particular day an overexposure to silica could occur." Doc.ID.2379, p.17 (JA4017).

industry, it is wrong to apply the results of one study or one test to all of the industry and conclude that the same approach that might have worked (barely) in one foundry would work in another foundry. As Petitioner AFS stated:

> No two foundries are alike. Foundries differ in facility size from less than 1000 square feet to over several million, in number of employees from fewer than 5 to 1000, in production rate from less than one casting per week to tens of thousands per day, and in size of casting from a few ounces to over 100 tons.

Doc.ID.2379, App.3, p.1 (JA4074). In addition, the Agency *itself* recognized that no two foundries are alike in its overall design of the Rule. In deciding *not* to adopt a specification approach to the Rule in General Industry, such as it did for the construction industry, the Agency stated:

> Unlike for construction tasks, the rulemaking record does not provide sufficient information for OSHA to account for the wide variety of potential tasks across the range of manufacturing and other general industry work. In manufacturing industries such as foundries and pottery production, local exhaust specifications must be custom designed for each establishment considering its manufacturing processes, equipment, and layout.

81 Fed. Reg. at 16,704 (JA0420). Thus, for the foundry industry, proving technological feasibility in most of the operations most of the time is particularly difficult. As explained above, OSHA has come nowhere near meeting this burden.

This is further demonstrated by the wholly unpersuasive data upon which OSHA relies. Petitioner AFS reviewed OSHA's documentation for all ten foundry job categories and found not a single one to be supported by OSHA's references.

The detailed analysis of flaws in the case studies used by OSHA was submitted as Appendix 2 to AFS's comments. Doc.ID.2379 (JA4050-JA4073). OSHA continues to rely on this information, which simply does not demonstrate feasibility in vastly different foundry operations. For example:

- **For sand system operators**, OSHA relies essentially on one NIOSH study of the effectiveness of automation and enclosure to reach a PEL of 50 µg/m^3. That study, however, involved extensive automation that could not be replicated at other foundries and, even so, demonstrated that close to 20 percent of the samples generated actually *exceeded* the PEL. Doc.ID.4247, p. IV-261 (JA6166). OSHA dismisses, without any analysis, comments to the record about the unique nature of this one foundry and how it is not representative of the effectiveness of controls for sand system operators, simply noting that NIOSH makes "no mention" of it. Doc.ID.4247, pp. IV-261-62 (JA6166-JA6167). It stands to reason that a foundry making the same part over and over again is in a better position to take advantage of automation than a foundry that makes multiple different parts, requiring unique patterns, etc. OSHA cannot apply the results of this one study across the entire foundry industry.

- **For finishers**, another key foundry operation, OSHA relies largely on evidence from *non-foundry* operations. OSHA points to the effectiveness of local exhaust ventilation from *construction* operations and the use of wet methods from

the *stone cutting* industry to demonstrate feasibility. Doc.ID.4247, pp. IV-285-286, 289 (JA6190-JA6191, JA6194). At the same time, OSHA ignores evidence of infeasibility when OSHA's control methods are used. Doc.ID.4247, pp. IV-286-88 (JA6191-JA6193). For example, the record includes an inspection report for a Wisconsin foundry that involved the implementation of engineering controls to reach the previous PEL for cleaning and finishing operators. Doc.ID.0268 (JA1676-JA1689). Despite OSHA's assertion that the foundry in question reached levels below the PEL, information in the record showed that the foundry was unable to meet the prior PEL without respiratory protection. Doc.ID.2379, App.2, p.3, (JA4052).[45]

Briefly stated, OSHA's assertion of technological feasibility in the foundry industry is not based on substantial evidence in the record, ignores the best available evidence of the difficulties of compliance with the previous PEL (let alone the new PEL of 50 µg/m^3), and wholly fails to meet OSHA's burden of proof.

2. Substantial Evidence Does Not Support A Finding Of Technological Feasibility In Hydraulic Fracturing Operations.

Based on little to no data and evidence in the rulemaking record, OSHA also determined that a PEL of 50 µg/m^3 can be met in most operations most of the time in the hydraulic fracturing industry. The hydraulic fracturing industry, like the

[45] In addition, Petitioner AFS's review of the record showed no data in the record actually supporting the levels that OSHA said were achieved at the Wisconsin foundry.

foundry industry, is one of the most significantly impacted by the Rule. In hydraulic fracturing, companies pump hydraulic fracturing fluid into a well bore under high pressure to fracture a shale or rock formation. This allows "gas and oil trapped in the formation to flow into the well." Doc.ID.4247, p. IV-628 (JA6306). The fracturing fluid is comprised of a base fluid and a proppant and, typically, the proppant used is silica sand. *Id.*

OSHA's recognition of the extent of silica use in hydraulic fracturing came late in OSHA's development of the Rule. When OSHA performed the Small Business Regulatory Enforcement and Fairness Act ("SBREFA") analysis for the Rule, hydraulic fracturing was *not* considered, even though the Agency recognizes that hydraulic fracturing has been in existence for approximately 60 years. Doc.ID.4247, p. IV-628 (JA6306).[46]

Despite this, hydraulic fracturing was covered in the proposed rule and in this final Rule. Based on sampling data and NIOSH site visits, OSHA developed an exposure profile of hydraulic fracturing operations that included 114 samples, with

[46] Several commenters to the rulemaking record objected to including hydraulic fracturing in the proposed rule due to the Agency's failure to examine the industry as part of the SBREFA process. Doc.ID.2301 (JA2775-JA2964); Doc.ID.4194 (JA5326-JA5360). In addition, many other commenters generally objected that the SBREFA process held for the standard took place over a decade before the proposed rule was issued. Doc.ID.2380 (JA4145-JA4215); Doc.ID.4194 (JA5326-JA5360). Given the length of time between the SBREFA panel and the issuance of the proposal, the information gathered by OSHA during that process was of little or no value. Petitioners repeat those objections regarding the SBREFA panel process here.

79% of them above 50 µg/m^3. Doc.ID.4247, p. IV-632 (JA6310). OSHA concluded that "baseline operating conditions involve very high exposures with few engineering controls in place." Doc.ID.4247, p. IV-633 (JA6311). OSHA identified three job categories within hydraulic fracturing with silica exposure (fracturing sand workers, ancillary support workers, and remote/intermittent workers) and all three had significant exposures above the previous PEL of 100 µg/m^3. Doc.ID.4247, p. IV-641 (JA6319).

There was significant evidence and comment submitted to the record regarding the capability of the hydraulic fracturing industry to achieve the PEL of 50 µg/m^3 in most operations most of the time. Overwhelmingly, the data and testimony indicated that a PEL of 50 µg/m^3 could not be reliably reached. Specifically, OSHA examined information presented in the record on the following control methods that could be used (potentially) to control exposure to the new PEL for affected workers: local exhaust ventilation at release points of the process; a baghouse passive dust collection system that fits over individual thief hatches; a containment system that replaces a pneumatic loading process; caps on fill ports; partial enclosures on conveyors and transfer points; the use of operator booths; dust suppressants for proppants; dust suppressants for general work areas; work practices and administrative controls; and substitution. Doc.ID.4247, pp. IV-642-65 (JA6320-JA6323).

Despite a review of all of these control methods, there is no evidence that controls implemented specifically in hydraulic fracturing can reduce exposures to below 50 µg/m^3. First, OSHA admits that the record contains no individual personal breathing zone sample results associated with controls. 81 Fed. Reg. at 16,455 (JA0171). Second, the evidence showed only one commercially available local exhaust ventilation method that claimed to reach below a PEL of 50 µg/m^3 and there were just a handful of samples that the manufacturer reported actually confirmed this. *Id.* at 16,455-456 (JA0171-JA0172). Every other control method either lacked data suggesting application could reduce exposures to below 50 µg/m^3 or the method had never been specifically applied to hydraulic fracturing. *Id.*

Faced with no evidence of consistent ability to reach the new PEL, OSHA retreats to its position that the OSH Act does not require an actual finding that controls exist to meet the PEL, but the Agency is permitted to be "technology forcing." 81 Fed. Reg. at 16,456 (JA0172). OSHA states that it is not bound "to the technological status quo and can impose a standard where only the most technologically advanced companies can achieve the PEL even if it is only some of the operations some of the time." *Id.* (citing *Lead I*, 647 F.2d 1189).

In this instance, OSHA provided the industry five years to come into compliance, a time period the Agency contends is sufficient. *Id.* OSHA states "that these technologies will enable the industry to comply within five years" and that

these technologies "have been developed and tested, and that have demonstrated that the PEL is obtainable." *Id.* But that is untrue. The evidence overwhelmingly has shown that the PEL is not obtainable and may not ever be obtainable, due to the unique aspects of the process. These are not technologies that are on the "horizon" as OSHA states; they have been developed and have been shown not to meet the PEL of 50 µg/m^3. Indeed, in the preamble to the final Rule, OSHA suggests that in five years technology will advance to the point that the *preceding* PEL of 100 µg/m3 will be able to be met in most operations most of the time. 81 Fed. Reg. at 16,456-57 (JA0172-JA0173).

As with the foundry industry, OSHA has failed to show that it is technologically feasible to comply with the Rule in the hydraulic fracturing industry. These two industries cannot meet the PEL in most operations most of the time.

B. OSHA's Finding Of Economic Feasibility In The Foundry And Hydraulic Fracturing Industries Is Not Supported By Substantial Evidence.

In addition to failing to demonstrate that a PEL of 50 µg/m^3 is capable of being met in the foundry and hydraulic fracturing industries, OSHA has failed to make such a finding for the companion economic feasibility requirement. As with technological feasibility, a close review of the information, assumptions, and methodology that the Agency uses shows that OSHA's economic feasibility

determination is not supported by substantial evidence and is at odds with the best available evidence of the true impacts of the Rule in the record.

As stated above, OSHA has historically considered a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits or one percent of revenues. *Id*. at 16,533 (JA0249). That calculation must be based on substantial evidence, and while the Agency is not required to estimate costs, profits, revenues, and impacts with scientific certainty, it must make realistic assumptions and employ reasonable methodologies – i.e., use the best available evidence – in estimating the impact of the Rule on affected establishments. *See Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998) ("An agency's use of a model is arbitrary if that model 'bears no rational relationship to the reality it purports to represent.'") (quoting *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1005 (D.C. Cir. 1997)).

In concluding that the Rule is economically feasible for the foundry and hydraulic fracturing industries, OSHA developed estimates of the costs of the Rule and compared those costs against estimated industry revenues and profits. For the foundry industry, OSHA's calculations show that cost as a percentage of profits is higher than for many other industry groups. For example, OSHA calculated that the Rule will result in costs equal to 5.62% of profits and 0.25% of revenue for Steel Foundries (except Investment) and 4.96% of profits and 0.22% of revenue for Iron

Foundries. 81 Fed. Reg. at 16,538 (JA0254). The percentage of profits are even higher for small and very small employers: 6.38% for small Iron Foundries, 10.03% for very small Iron Foundries, 6.97% for small Steel Foundries (except Investment), and 12.27% for very small Steel Foundries (except Investment). *Id*. at 16,555, 16,564 (JA0271, JA0280).

OSHA's calculations for hydraulic fracturing are also striking. Overall, costs as a percentage of profits are almost 8% for hydraulic fracturing while costs as a percentage of revenue are 0.56%. 81 Fed. Reg. at 16,536 (JA0252). For small and very small hydraulic fracturing employers, the Rule is infeasible: costs as a percentage of profits are more than 18% for small employers and 29% for very small employers. *Id*. at 16,553, 16,562 (JA0269, JA0278). Thus, despite greatly underestimating costs and overestimating revenues and profits, OSHA's own calculations demonstrate that the Rule approaches, and in some instances surpasses, the thresholds denoting infeasibility for both the foundry and hydraulic fracturing industries.

And yet, OSHA's own cost estimates, as with technological feasibility, do not come close to representing the real world of compliance. A real analysis of the costs of compliance for both industries, compared to revenues and profits, demonstrates convincingly that the Rule is economically infeasible in both.

1. OSHA's Underlying Analysis For The Foundry Industry Is Flawed And Significantly Understates Costs.

With respect to the Agency's assessment of the foundry industry (and for most of General Industry also), OSHA's analysis suffers from two fundamentally incorrect assumptions that cause the Agency to significantly underestimate the costs of the Rule. The first is OSHA's adoption of an artificial "per worker" assessment of costs, as opposed to one that realistically assesses costs to establishments affected by the Rule. The second is OSHA's assumption that 50 percent of the costs of controls to be undertaken by employers to reach the PEL would be spent coming into compliance with the previous 100 ug/m^3 PEL and 50 percent of the costs would be undertaken in getting from the previous PEL to the new PEL.

A realistic analysis of the costs for the foundry industry, based on the best available evidence and using real-world assumptions, was submitted to the record by URS Corporation and Environomics. Doc.ID.2307, Att.8b (JA3603-JA3633). That analysis shows that full compliance with the Rule in all of General Industry would cost an estimated $6.1 billion, which is significantly higher than OSHA's estimate. Doc.ID.4209, pp.102-110 (JA5526-JA5534); 81 Fed. Reg. at 16,528 (JA0244). URS's estimate, when applied to industry profit estimates, showed that the costs of the Rule to the foundry industry exceed OSHA's 10% profit threshold, demonstrating the Rule is economically *infeasible* in this industry. Doc.ID.4209, pp.118-121 (JA5542-JA5545).

a) *OSHA's methodology for control costs does not constitute the best available evidence.*

The most significant driver of costs to employers with the Rule relates to the installation of engineering controls to address silica overexposures. Under OSHA's hierarchy of controls, employers are expected to institute engineering controls to reduce exposures to the PEL, before relying on respiratory protection. 81 Fed. Reg. at 16,293 (JA0009).

In the final Rule, OSHA adopted a "per-worker" model to estimate the cost of General Industry employers to install engineering controls. *Id*. at 16,469 (JA0185). Under this model, OSHA tied the costs of controls to the number of workers exposed to silica above the PEL in various jobs in the affected industry sectors. *Id.*

OSHA used essentially the same approach to calculating control costs in the proposed rule. Several commenters objected as the assumption has the effect of significantly underestimating the costs of the Rule. *See, e.g.*, Doc.ID.4035, p.6 (JA5263). In essence, it inappropriately focuses simply on the number of over-exposed employees, instead of ascertaining the need for controls based on the numbers of facilities that may need to implement controls to reduce exposures for the overexposed employees at the facilities. Employers make decisions as to whether controls are needed on a facility by facility basis. In a broad-based critique of OSHA's analysis, URS Corporation cogently stated:

> By focusing on the number of overexposed workers instead of on the facilities and the areas within the facilities that would need controls, OSHA's approach fails to recognize the realities of how industry works in the real world. As an example, for an iron foundry sand mixer operator, OSHA's model assumes that a local exhaust ventilation (LEV) control package with 1,050 cubic feet per minute (cfm) on a single mixer would be sufficient to cover four overexposed sand-mixer operators, two for each shift. However, our consultations with industry representatives indicated that each foundry sand-mixer operator usually operates multiple sand-mixers, not just one for every two workers as OSHA assumes. Sand mixing was not often performed on the second shift, but each mixer would still require separate LEV controls whether or not each sand mix operator on each shift was measured as being over the 50 µg/m^3 level. Therefore, OSHA's assumption that a single control was sufficient for four workers (two simultaneously for each shift), and that each of those workers was among those measured as overexposed, dramatically underestimated the number of controls and the LEV required for sand mixers.

Doc.ID.2307, Att.8b, pp.4-5 (JA3606-JA3607).

The costs of controls and their implementation are not driven simply by the total numbers of overexposed employees in each industry, as OSHA's cost model would have it. An employer who has to implement an engineering control to reduce exposures to workers in a particular job category will need to do so whether there are multiple employees in that job category or whether there is only one employee in that job category. Tying the costs of controls solely to the number of overexposed workers is not reflective of reality. The preferred way to estimate costs for installing controls would be to do so by *establishment*, as that would actually reflect the costs that an employer would invest in installing new engineering controls.

The best evidence of the true costs of the Rule was submitted by URS Corporation and Environomics. Doc.ID.2307, Att. 8b & 9 (JA3603-JA3633, JA3637-JA3662). They created a control cost model that "takes into account the different sizes of facilities in order to more realistically approximate the number of engineering control bundles and the resulting expected cost to general industry." Doc.ID.2307, Att. 8b, p.7 (JA3609).

> For each job category with silica exposures within each industry, URS created three statistical binomial distributions of overexposed workers, one for each of the three facility sizes, using OSHA's estimate of the percentage of over-exposed workers for that job. The result was a binomial distribution curve indicating the percentage of overexposed workers for each job category for each size-specific "model facility."

Id.

OSHA rejected this alternative model in the final Rule, clinging to the per-worker model instead. OSHA suggested that its approach was a more accurate reflection of estimated control costs because overexposures are not random across facilities. 81 Fed. Reg. at 16,470 (JA0186).

OSHA's critique of the URS model is wrong and misses the point of the analysis. Through this model URS is not suggesting that overexposures are necessarily random throughout facilities. However, by assigning groups of overexposed workers statistically throughout establishments in an industry, URS's estimate is more closely akin to the costs of an "establishment" (i.e., a realistic cost assessment of what employers will actually do to achieve compliance).

OSHA has some discretion to adopt models for its feasibility analysis and there is some deference afforded to it in doing so. That discretion is not unbounded, however, and must be grounded in a realistic view of the costs to implement a rule. Here, OSHA's model is completely unrealistic in assigning costs and should not be considered as the best available evidence of the costs to comply with the standard.[47]

b) *OSHA's assumption regarding apportionment of incremental costs does not consider the best available evidence.*

The second major flawed assumption in the final economic analysis relates to OSHA's apportionment of costs between employers who are not in compliance with the previous PEL and those employers who are in compliance with the previous PEL but will need to expend additional money to meet the new PEL. In the final Rule, OSHA assumes that for those employers that have exposures above 100 µg/m^3 (1) 50% of the costs to achieve compliance with the new PEL will involve reaching the previous PEL of 100 µg/m^3, and (2) 50% of the costs to achieve the new PEL will be borne to get from the previous PEL of 100 µg/m^3 to 50 µg/m^3. 81 Fed. Reg. at 16,473 (JA0189).

[47] In the final Rule, OSHA made a small adjustment in its per-worker model to reduce the number of overexposed workers in small entities affected by the Rule. *Id.* This does not address the underlying issue of OSHA's flawed methodology of tying the cost of implementing controls to workers affected, rather than to establishments.

While this assumption may make OSHA's job of calculating costs "easier," it is not supported by the record. In fact, substantial evidence was submitted to the record stating that the costs to get into compliance with the new, more stringent PEL is greater than the cost to get to a PEL of 100 µg/m^3. As explained by URS:

> OSHA assumes that the exact same type and size of control will have the same incremental effect in reducing silica concentrations, regardless of the level of silica exposures that need to be reduced. This is fundamentally inconsistent with industry's experience over the past 40 years. While 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.

Doc.ID.2307, Att.8b, p.11 (internal citation omitted) (JA3613). Instead of adopting a cost model to reflect the best available evidence of the cost to comply with the Rule, OSHA simply made another "assumption" that has the effect of underestimating industry costs.

c) *OSHA's control costs for the foundry industry ignore key costs identified in its technological feasibility analysis.*

Notwithstanding the flawed assumptions above, perhaps the largest issue in OSHA's economic analysis relates to which controls it *actually* costs in its assessment. OSHA states in the final Rule that in determining which controls to cost, it used those controls that it determined needed to be added based on the technological feasibility analysis. However, a close review of both assessments shows for the foundry industry that OSHA did not include in the cost analysis many

of the engineering controls and work practices that the Agency's technological feasibility analysis indicated employers would need to implement to comply with the Rule.

Throughout the foundry industry technological feasibility analysis, OSHA cites to control measures that may need to be implemented to adequately control exposures to below the new PEL of 50 µg/m^3. Doc.ID.4247, pp. IV-256-302 (JA6161-JA6207). For example, for pouring operators in ferrous foundries, OSHA cites to four different "additional controls" that may be needed to get below the PEL: controlling adjacent sources of silica, use of operator booths, physical isolation of the process; or controlling airflow through ventilation modifications. Doc.ID.4247, pp. IV-270-71 (JA6175-JA6176). In the economic analysis of the cost of implementing controls to reach compliance for pouring operators, however, OSHA only calculates a cost for *two* of the possible controls: controlling adjacent sources of silica and the use of operator booths. Doc.ID.4247, p. V-A-54 (JA6871).[48]

[48] Other controls for foundry jobs that are referenced in the technological feasibility section of the analysis but are not costed in the economic feasibility assessment, include: (1) molders – enclosing a sand chute, adding a water spray to a sand feed belt, adding LEV to the return sand belt and bucket elevator; (2) knockout operators – 50,000 cfm canopy hood exhaust system, a 10,000 cfm make-up air system, baffle plates and side shields, and a new vibrator to the monorail conveyor carrying castings; and (3) abrasive blasting operators – a new abrasive blasting machine with LEV, enclosed and exhausted sand conveyors, and adding an enclosure and LEV to the shakeout exit. Doc.ID.4247, pp. IV-263-266, IV-275-282, V-A-52-55 (JA6168-JA6171, JA6180-JA6187, JA6869-JA6872).

In addition, looking at the entire "Iron Foundries" industry, the following controls are not costed at all by the Agency:

Iron Foundries	Substitute silica-free materials Non-silica cores and core coatings Minimize dust generated by sand contamination of scrap Physical isolation of pouring area Modify ventilation system to reduce airflow from other areas into the pouring area Reduce residual sand on castings Automate knockout process Process automation Wet methods Pre-cleaning with automated equipment Use low silica refractory Use of precast refractories and automated equipment for powdered refractory materials

Id. at V-A-52-57 (JA6869-JA6874).

One of the most significant costs that OSHA does not consider in its economic analysis is the use of substitutes for silica. OSHA notes throughout the technological feasibility analysis that one method to come into compliance with the PEL is through the use of substitution. In assessing whether to include any costs for substitution, however, OSHA declined to include any costs because it determined that "in most situations, substitution is not the least costly method of achieving the proposed or new PEL." 81 Fed. Reg. at 16,476 (JA0192).

OSHA's rationale for not including costs for substitution is wholly insufficient. The Rule requires that an employer implement the hierarchy of controls in attempting to meet the PEL. *See id.* at 16,863 (JA0579). Substitution is a part of

the hierarchy of controls, as OSHA recognizes. *Id*. at 16,293 (JA0009). And, in an enforcement action brought against an employer, OSHA would certainly expect an employer to consider substitution as a means of abatement.

OSHA's "theory" for not including a cost for substitution is an economic one. OSHA is correct that an employer may attempt to avoid using a substitute to control silica exposure if use of the substitute is more expensive than other potential control options. But, complying with the Rule within the confines of OSHA's hierarchy of controls is not based on economic theory, but the realities of having to implement engineering controls, including potentially substitution, as a result of Agency enforcement.

OSHA's failure to cost any substitution in the Rule is not supported by substantial evidence in the record and is a major omission. The rulemaking record showed that for the foundry industry the cost for substitution would exceed 2 billion annually. Doc.ID.2379, Att.B, p.6 (JA4006).

d) *Numerous cost inputs adopted by the Agency do not reflect the best available evidence.*

Yet another significant flaw in OSHA's economic analysis as it relates to the foundry industry is the inputs the Agency uses to calculate total costs to employers. In a sense, these inputs are the building blocks for the economic analysis. OSHA must realistically estimate what employers will need to spend to get into full

compliance and these determinations must be based on the best available evidence in the record. In several instances, OSHA has failed to do this.

The best available evidence of the cost of installing a control or taking other action required in the Rule is *the actual experience of employers that have installed* the control or taken the action. Petitioner AFS provided OSHA data on the cost of a variety of inputs gleaned from members that have specifically examined and installed the same controls that OSHA is requiring all employers to implement. Doc.ID. 2379, App. 3 (JA4074-4116). In many instances the costs that were actually incurred to upgrade facilities to reach compliance were far in excess of OSHA's estimates. For example, in the PEA OSHA estimated the annual cost of compliance for ventilation was $5.33 per CFM. Based on evidence from foundry ventilation managers who have actually had to install and maintain ventilation systems, the annual cost per CFM is closer to $20 for exhaust alone and another $6-10 for makeup air critical to achieving the PEL.[49] *Id*. at 9 (JA4082).

In another example, foundry members that had used and installed vacuum systems for molders presented evidence that OSHA's costs for vacuums to protect

[49] OSHA ultimately adjusted its estimate of the cost of CFM from the PEA to the FEA. 81 Fed. Reg. at 16,480 (JA0196). But even that estimate does not fully consider the actual experience of foundries that have attempted to reduce silica exposures in their work environments.

workers in that job were significantly understated (from OSHA's estimate of approximately $3,500 to real world purchases of up to $55,000). *Id.* at 12 (JA4085).

Petitioner AFS provided detailed cost estimates for foundries with supporting documentation. *Id.* OSHA largely ignored this evidence, often in favor of unsupported opinion from its contractor ERG. For example, AFS provided a detailed quotation from a professional cleaning services company for a thorough dust cleaning. The quotation was for more than $23,000 for a 20,000 sq. ft. area, a cost of more than $1 per sq. ft. *Id.* at pp. 13, 29 (JA4086, JA4102). OSHA ignored this evidence in favor of a conversation that its contractor ERG had with a cleaning service. The discussion that ERG had does not appear to relate to deep cleaning, but rather to a routine superficial housekeeping service (every 2 to 3 weeks). Even OSHA did not find that $0.01 to $0.02 per sq. ft. figure credible, using a series of "assumptions" to inflate it to an estimate of $0.15 per sq.ft. Doc.ID. 4247, p. V-41 (JA6727). OSHA then applied yet another assumption and annualized the cost to $0.02 per sq.ft. *Id.* at V-A-57 (JA6874).

In the final Rule, OSHA nibbles around the edges of its initial cost figures, raising some marginally in the FEA and making no adjustments to others. Either way, OSHA ignores the best available evidence of the compliance costs in the record, those costs that reflect the actual expenditures of employers implementing controls to reduce silica exposures. Taken as a whole, the real costs of compliance

– as reflected in the URS and Environomics estimate – demonstrates the rule is infeasible in the foundry industry.

2. OSHA's Assessment Of Feasibility For The Hydraulic Fracturing Industry Is Similarly Flawed.

In addition, OSHA's analysis of the economic feasibility of the Rule on the hydraulic fracturing industry is similarly not grounded in the real world. In particular, *none of the potential controls that the Agency considered in its cost analysis for hydraulic fracturing have been demonstrated to meet the final PEL,* as described fully above. As a result, OSHA costs a series of measures in the hydraulic fracturing industry to calculate the economic impacts of the Rule on that industry and those costs bear no relationship to the actual potential costs that the industry will need to incur to reach compliance, if employers can reach compliance at all.

Thus, in the final economic analysis, OSHA includes costs for dust booths for certain employees potentially exposed to silica, the implementation of water misting, and certain costs associated with controlling dust generated from traffic. *See* 81 Fed. Reg. at 16,483-84 (JA0199-JA0200). This does not come close to matching the controls discussed in the technological feasibility analysis as potentially being needed to meet the PEL. *See id.* at 16,456 (JA0172) (discussing dust system by KSW Environmental, the NIOSH baghouse method, shipping container by Sandbox Logistics, etc.).

The greatly understated costs to the industry were then compared with industry revenues and profits, which also do not reflect the real world. According to OSHA, revenue data from the Census Bureau's Statistics of U.S. Businesses were not sufficiently precise to isolate the hydraulic fracturing industry, so OSHA based revenues for hydraulic fracturing establishments on "estimated utilization rates and per stage revenues" in order to determine that the cost to profit and cost to revenue percentages were below OSHA's ten percent threshold. *Id*. at 16,549 (JA0265). These estimates are based on revenue data from 2012 supplemented with data from 2013 and early 2014. *Id.* In 2012, the price per barrel of oil fluctuated between $90 and $100 per barrel. The price of oil dropped in late 2014 and 2015, when it fluctuated between $45 and $60 per barrel. *Id.* This significant drop in revenue is not captured by OSHA's estimate.

Further, as OSHA noted, the recent drop in oil prices has caused a series of bankruptcies and closures across the oil industry, with a 50% reduction in the number of rigs. *Id.* Despite these very real changes to the hydraulic fracturing industry, OSHA asserts that oil prices are expected to increase in future years, although the "crude oil price forecast remains subject to significant uncertainties" and "could continue to experience periods of heightened volatility." *Id*. at 16,550 (JA0266). Nevertheless, OSHA asserts that the Rule will not have a significant impact on the hydraulic fracturing industry because advancements in technology and

application of new efficient drilling methods *may* increase production and lower costs. *Id.* OSHA concludes its unconvincing analysis by asserting that the cost of the Rule is a minor issue in comparison to changing energy prices.

As described above, OSHA's own low estimates of costs have a significant impact on the hydraulic fracturing industry, exceeding OSHA's threshold levels for feasibility for a large segment of the industry. A true accounting of the costs of the Rule – to the extent the costs can even be quantified – would exceed the threshold for the entire industry.

C. OSHA Failed To Demonstrate The Rule Is Technologically Feasible In Construction.

The construction industry is also significantly impacted by the Rule. Although the compliance challenges faced by these employers are different than those in the foundry and hydraulic fracturing industries, they are equally significant.

OSHA acknowledges the unique aspects of construction through the inclusion of Table 1. However, OSHA misses the mark with the substance of the Table. Further, as set forth below, OSHA's reliance on Table 1 to avoid legitimate issues of feasibility is wrong. As with the industries discussed above, OSHA's technological and economic feasibility finding is not based on substantial evidence in the rulemaking record, and OSHA ignores the best available evidence in reaching its conclusion of feasibility. OSHA uses faulty assumptions throughout the analysis to underestimate exposures and overestimate the effectiveness of controls. Even

with these assumptions, the Rule on its face is not technologically feasible, as evidenced by the significant use of respiratory protection that will be required for employers throughout the construction industry once the standard takes effect. OSHA also adopts a series of assumptions related to the costs of compliance that are not reflective of the best available evidence in the record and significantly understate the true impacts of the Rule.

1. OSHA Ignored the Best Available Evidence Regarding Exposure Variability in Construction.

Several commenters to the rulemaking record stated that exposure to crystalline silica is highly variable in the construction environment and, thus, the Agency must demonstrate that employers can reach a level significantly below 50 $\mu g/m^3$ in order to reliably ensure compliance with the PEL. Doc.ID.4247, p. IV-9 (JA6044). The best evidence of this *in construction* is in the testimony of NIOSH:

> [A construction employer would need to get at] or below the action level depending on how variable my environment is …. If I'm very well controlled and tight, and I've got data that shows that I'm always 70 percent of the occupational exposure limit, and I know that it doesn't vary much at all, I could operate there, but if it's bouncing around a good bit, I want to be sure that 95 percent of my measurements come in under the limit.

Doc.ID.3579, p. 189 (JA4476). In the final Rule, OSHA ignores NIOSH's comments. Instead, OSHA cites industry concerns about exposure variability generally and, after admitting "that differences in exposure can occur due to workplace variables that are not under the direct control of the employer (e.g.,

fluctuations in environmental conditions or air movement)," disputes that this variability is unpredictable. Doc.ID.4247, pp. IV-9-10 (JA6044-JA6045).

With respect to construction, OSHA relies on four studies to support its position that variability is not unpredictable but rather is "observable" and "controlled." Doc.ID.4247, p. IV-10 (JA6045). OSHA states that these studies used "multivariate statistical models to identify factors associated with increased exposure to silica during various construction activities." *Id.* A close review of the studies, however, shows the opposite.

Three of the studies are inapplicable to routine construction operations. "Application of Mixed-effects Models for Exposure Assessment" describes the application of mixed-effect exposure models to an industry-wide survey of the *rubber manufacturing industry* and *pig farmers'* exposure to endotoxins in The Netherlands. Doc.ID.3998, Att.5h (JA5210-JA5218). Another study cited, "Determinants of Respirable Silica Exposure in Stone Countertop Fabrication" examines factors for silica exposure in a segment of industry – countertop fabrication – that does not include the range of exposure variables that are present in the construction environment. Doc.ID.3956 (JA7915-JA7938). Yet a third study, "Determinants of Respirable Crystalline Silica Exposure Among Stoneworkers Involved in Stone Restoration Work," also looked principally at stationary stone cutting worksites with limited exposure variability. Doc.ID.3608 (JA7861-JA7874).

None of the worksites evaluated are at all representative of the range of construction operations covered by the Rule.

Only one study even attempted to gather data from a broad range of construction activities, "Silica Exposure During Construction Activities: Statistical Modeling of Task-Based Measurements from the Literature." Doc.ID.3803 (JA7875-JA7886). This study, however, simply identifies the types of variables that could impact exposures on a construction worksite. Many would not be controllable by an employer at all. For example, the study states that construction work outdoors with wind might reduce exposures to silica. It states that the "combination of outdoors without wind was associated with a 38-fold increase in exposure levels." *Id.* at 438 (JA7881). This makes the point that NIOSH made and that OSHA ignored. Just looking at wind alone, a construction employer working outside on any given day could experience significant exposure variability based solely on how much wind is present. Unfortunately, construction employers *cannot* control wind. As the study's authors note at the beginning of the article:

> The evaluation of exposure to RCS in the construction industry remains challenging due to the important variability in exposure determinants such as tasks, materials, and worksite characteristics, among others. Construction sites involve a variety of constantly changing operations and specialized workers, and the duration of exposure within a work shift can vary depending on the activities performed. Many studies have sampled a limited number of workers and have cautioned against generalizing their results to the entire industry.

Id. at 433 (JA7876) (internal citations omitted).

OSHA then relies on testimony from representatives of labor unions suggesting that most exposures are predictable and controllable. Doc.ID.4247, p. IV-10 (JA6045). These statements do not constitute the best available evidence. They cite to no data and OSHA does not explain why this "evidence" is more persuasive than the testimony of numerous rulemaking participants that cited exposure variability as a significant issue in meeting a PEL of 50 µg/m^3. *See* Post-hearing Comments of the Construction Industry Safety Coalition. Doc.ID.4217, pp. 11-12 (JA5610-JA5611).[50]

Rather than adjusting the PEL to one that is feasible given the variability of exposure, OSHA has clung to the proposed level of 50 µg/m^3 and indicated that any variability could be addressed through the adoption of an enforcement policy that would allow "for a possible re-inspection." Doc.ID. 4247, p. IV-11 (JA6046). Putting aside the fact that OSHA has not actually developed an enforcement policy for re-inspection as explained above, on its face this makes no sense in the construction environment. Any re-inspection of a construction worksite after the

[50] OSHA actually *emphasizes* the unpredictability of exposure conditions in construction when it serves OSHA's purposes to do so. For example, in the preamble to the Rule, OSHA cites to the difficulty of estimating labor productivity effects in construction, given the job-and site-specific factors that influence silica dust exposures: "Potential exposures vary widely with hard-to-predict characteristics of some specific work tasks (e.g., characteristics of materials being drilled), environmental factors (e.g., wet or dry conditions, soil conditions, wind conditions), work locations (e.g., varying dust control and dust cleanup requirements for inside or outside jobs), and other factors." 81 Fed. Reg. at 16,495 (JA0211).

sampling results came back would likely never be able to occur, as the job might be completed, the task completed, or the exposures could be completely different. As the Vice President of the American Industrial Hygiene Association stated, "the reality is that potential worker exposures on a construction site are constantly changing. By the time samples are collected and analyzed, tasks may have been completed and workers have disbursed to other jobs." Doc.ID.3578, p.1038 (JA4435b). OSHA's "fix" for the issue of exposure variability is no fix at all.

As with the foundry industry discussed above, OSHA has made no finding that a PEL below 50 µg/m^3 can be met in the construction tasks analyzed by the Agency. *See* 81 Fed. Reg at 16,461 (JA0177). In plain terms, according to NIOSH, to ensure compliance a construction employer must attain an exposure level to silica far below the final PEL. OSHA has not shown that can be done and, in fact, it cannot be done.

2. OSHA's Assumption of No Exposure For Non Full-Shift Samples Is Not Based on the Best Available Evidence.

In the final Rule, OSHA contends that it gathered 881 samples in construction of silica exposure in making its determination that a PEL of 50 µg/m^3 is technologically feasible. The samples collected vary widely in the amount of time that sampling actually occurred during an employee's work shift. A "full shift" sample would be one where sampling was performed for at least eight hours or 480 minutes. Of the samples collected and considered for the FEA, the duration of the

sampling ranged from 120 minutes to over 360 minutes. Doc.ID.4247, p. IV-42 (JA6077). For almost 60 percent of the samples included in the analysis, the sampling duration was under 360 minutes, i.e., under six hours. 81 Fed. Reg at 16,435 (JA0151).

Despite the fact that most of the data did not include full shift sampling, OSHA determined to include all of these samples in its analysis. In doing so, OSHA made a "general" assumption that "the sampled period in construction encompassed all of the worker's silica exposure. Thus, in calculating the 8-hour TWAs for construction tasks, OSHA assumed zero exposure to respirable crystalline silica for the unsampled portion of the shift." Doc.ID.4247, pp. IV-39-40 (JA6074-JA6075).

Because OSHA's PEL is set as a TWA, the duration of exposure to respirable crystalline silica is important in determining overall compliance. For example, cutting silica-containing block for two hours of a shift, followed by no other silica exposure will result in a lower TWA exposure level than performing that same silica generating task for eight hours. An employer, however, would need to be under the PEL if an employee were cutting for just two hours or cutting for eight hours.

When judging whether a PEL of 50 µg/m^3 can feasibly be reached with the use of engineering controls, OSHA must assume that at least some employees will be exposed to a silica generating task for a full shift. Indeed, OSHA has designed the standard to account for this in its Table 1, which bifurcates exposures to below

four hours or below eight hours. 81 Fed. Reg. at 16,877 (JA0593). In the course of an OSHA inspection, the compliance officer will simply measure the amount of silica exposed during the shift. The employer would not get the benefit of assuming that the employee was actually not exposed to silica during a period of time during the shift. Instead, the burden shifts to the employer to demonstrate the use of engineering controls is infeasible, even though OSHA may not have ever based its initial feasibility finding on exposures occurring for an entire shift.

In support of this assumption, OSHA cites to just three studies, two by Flanagan *et al.* and one by Susi *et al.* *Id*. at 16,460 (JA0176). None of these studies in fact support OSHA applying the assumption virtually across the board in all of construction.

In Flanagan *et al.* 2003, the authors looked at only eight construction tasks in analyzing silica exposures and the effectiveness of control measures. Doc.ID.0676, p. 322 (JA7469). The authors state that sampling occurred for the "entire activity period a worker was engaged in the target task." *Id.* at 320 (JA7467). The purpose of the study was not to make conclusions of the extent to which employees perform a silica producing task over the course of a shift, but the authors did note that the sample duration averaged 202 minutes. *Id.* at 321 (JA7468). The study authors observed that: "For some activities the dust-generating task tended to be continuous, whereas for others dusty tasks were more intermittent." *Id.* at 322 (JA7469). The

authors also conceded that if a job "required continuous cutting or mixing, exposures could be considerably higher than suggested by the activity concentration." *Id.* at 325 (JA7472). This study, rather than supporting OSHA's position, shows that a general assumption that employees are not exposed to silica for the unsampled portion of a shift should not be universally applied to all construction tasks.

Flanagan *et al.* 2006 actually contradicts OSHA's assumption. In that study, the authors collected and analyzed 1,374 samples collected from thirteen different organizations. Doc.ID. 0677, p. 145 (JA7477). Again, the purpose of the study was not to assess the duration of exposure to a silica-producing task but to characterize exposure and the effectiveness of engineering controls and respiratory protection. As with the 2003 study, the range of sample time varied greatly, from six minutes to 601 minutes. *Id.* at 146 (JA7478). Of relevance to the issue of OSHA's assumption, the authors only made conclusions about compliance with an exposure limit for "full shift" samples: "Only long-term or 'full shift' samples were analyzed for comparison with a full-shift exposure limit." *Id.* at 151 (JA7483). To emphasize, the authors only analyzed *full shift sampling* for comparison with an exposure limit. This is precisely *not* what OSHA did in its technological feasibility analysis.

Finally, OSHA relies on a one-page submission from the Building and Construction Trades Department ("BCTD") of the AFL-CIO, which purports to apply a task-based exposure assessment model for metal fumes to six masonry job

sites. Doc.ID.4073, Att.3a (JA5290-JA5295). For the only 12 "full shift" samples analyzed, exposures ranged from 163-390 minutes according to the document submitted. *Id.* Based on this data, the BCTD concludes that, "it's unlikely that workers, even in highly exposed occupations in the masonry field, perform silica generating tasks for 8 hours straight." *Id.*

Even if the BCTD's interpretation of the data were correct, it is wrong to extrapolate 12 samples of four masonry tasks to silica exposure throughout the entire construction industry. By OSHA's own admission, there are at least 18 separate construction tasks/jobs that generate significant silica exposure. Analysis of 4 masonry tasks does not support applying a general assumption of no exposure for non-full-shift samples across all of construction. Moreover, this data itself shows that many masonry task exposures extend well into the shift of a masonry worker.

It is also alarming that of the 881 samples OSHA examined to demonstrate technological feasibility across all of construction, only 37 constitute full shift samples demonstrating conditions after the implementation of controls (i.e., non-baseline conditions). Doc.ID.4248, Exhibit 19 (JA6926-JA6968). This does not constitute substantial evidence that a PEL of 50 µg/m^3 can be met in most operations most of the time.[51]

[51] OSHA further contradicts itself by stating in the preamble to the Rule that it anticipates that after the Rule goes into effect, silica generating work will become

3. Substantial Evidence in the Record Fails to Show that a PEL of 50 µg/m^3 is Capable of Being Met.

a) *Table 1 shows that a PEL of 50 µg/m^3 cannot be met in most operations most of the time.*

In the final Rule, OSHA ties its technological feasibility analysis to Table 1. 81 Fed. Reg. at 16,458 (JA0174) ("OSHA finds the operations listed in Table 1 to be technologically feasible for the vast majority of employers who will be following the table. Where available evidence indicates that exposures will remain above this level after implementation of dust controls … Table 1 requires that respiratory protection be used."). OSHA claims that virtually all construction employers will be able to use Table 1 to achieve compliance, with the exception of abrasive blasting, drywall finishing, and underground construction. *Id.* OSHA asserts that for those construction tasks on Table 1 where no respiratory protection is required, the tasks would be at or below 50 µg/m^3 most of the time. *Id.*

Assuming OSHA's analysis contained in Table 1 is correct – which is not the case as set forth below – it does *not* show that the standard is technologically feasible. Of the 31 tasks – and locations for those tasks – analyzed on Table 1, one-third of them require some form of respiratory protection when the task is performed for just over four hours. *Id.* at 16,877-79 (JA0593-JA0595). And as stated above,

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further specialized, thus leading to certain groups of workers spending even *more* of their shifts performing silica generating tasks. 81 Fed. Reg. at 16,527 (JA0243).

this does not include abrasive blasting, which OSHA concedes will require the use of respiratory protection in many instances. *Id.* at 16,458 (JA0174).

In the final Rule, OSHA converts the extent of respirator use to full time equivalent employees ("FTEs") within all affected construction industries and estimates that approximately 25,000 FTEs will be required to use respiratory protection as a result of the Rule, costing construction employers $22 million dollars annually. But when costing the number of construction employees that may need to be provided medical surveillance under the Rule because they have to wear respirators for at least 30 days per year, OSHA assumes approximately 300,000 construction employees will need to wear respirators. *Id*. at 16,625 (JA0341). This required usage is significant and it completely undercuts OSHA's claim of technological feasibility.

In OSHA's recently promulgated hexavalent chromium rule, the Agency concluded based on that record that the extent of respirator use in industries affected by the rule at a proposed PEL of 1 µg/m^3 prevented the Agency from finding that PEL feasible. In briefing before the Third Circuit Court of Appeals, the Agency stated that "the test for feasibility in a particular 'operation' is whether the PEL can be met with engineering and work practice controls, and only 'isolated' respirator use." *Pub. Citizen Health Research Grp. v. OSHA*, Docket Nos. 06-1818 and 06-2604, Final Brief for Respondents, p. 45 (3d Cir. Dec. 14, 2007) (JA7262). OSHA

went on to state that it was justified in suggesting that requiring one-third of workers in a certain group to wear respirators was more than "isolated." *Id.*

Given the method that OSHA adopted to assess respirators required by this Rule, it is difficult to compare its findings here with its findings in the hexavalent chromium rule. However, it is clear from Table 1 that approximately one-third of all tasks in construction will require respirator use whenever they are performed for more than four hours, and for six tasks, respirator use will be required *all* of the time, whenever any of these tasks are performed. It is hard to understand how this required use of respirators for so many common construction tasks constitutes "isolated" respirator use.

OSHA appears to treat the extent of respirator use as a metric to be cited at its convenience or whim, rather than as a true indicator of whether it is actually feasible to meet a PEL in most operations most of the time. In fact, in this Rule, OSHA changes the standard for feasibility and respirator use, from "isolated" in the hexavalent chromium rule, to not "excessive" in the Silica Rule. 81 Fed. Reg. at 16,462 (JA0178). The Agency seemingly has unbridled discretion to choose what amount of respirator usage is significant enough to impact feasibility based on nothing more than its interpretation of whether the use is "isolated."

Furthermore, for many of the operations in Table 1 where OSHA is claiming feasibility, the engineering controls cannot be used. For five of the first six tasks on

Table 1 (stationary masonry saws, handheld power saws (any blade diameter), walk-behind saws, drivable saws, and rig-mounted core saws or drills) the only engineering control method permitted is the use of wet methods. *Id*. at 16,877 (JA0593). OSHA's approach in the final Rule is that for these six tasks, it is feasible to meet a PEL of 50 µg/m^3 in some of the tasks *when using wet methods* and only wet methods. Even if that were true – and for two of the six tasks respiratory protection is required even with the wet methods – it does not address at all whether a PEL of 50 µg/m^3 can be met with these tasks when it is infeasible to introduce water to the work environment.

The record is replete with information and testimony when wet methods cannot be used to control exposure to respirable crystalline silica: (1) for work inside buildings when water would damage the interior of the buildings; (2) for work when the construction material and aggregate would be adversely impacted by the introduction of water; (3) when environmental conditions, such as cold temperatures, prevent the introduction of water to the silica generating task; (4) when water is unavailable at the job site, such that it cannot be introduced to the equipment at the flow rate dictated by the manufacturer; and (5) when introducing water would create greater hazards for employees, such as using them on top of roofs cutting roof tiles. *See, e.g.*, Doc.ID.2319 (JA3663-JA3677); Doc.ID.4217 (JA5599-JA5717). In these situations, the fact that OSHA has not included a dust collection system as an

alternative in Table 1 shows that reaching a PEL of 50 µg/m^3 cannot be met in many instances where the use of water is not an option.

OSHA suggests in the preamble to the Rule that the extent to which the PEL can be met in most operations most of the time may be of diminished importance given Table 1. In particular, OSHA assumes that virtually all employers will utilize Table 1 for compliance. 81 Fed. Reg. at 16,514 (JA0230). Table 1 does not absolve OSHA of its statutory burden to show that the PEL can be met in most operations most of the time, which it has failed to do within the multitude of silica-generating tasks performed in construction. In addition, the rulemaking record is replete with instances where Table 1 cannot be followed and an employer will need to follow the alternative, traditional approach to controlling silica exposures to below 50 µg/m^3. *See id*. at 16,718, 16,720, 16,730, 16,732, 16,735, and 16,749 (JA0434, JA0436, JA0446, JA0448, JA0451, JA0465).

b) *The data supporting a finding of technological feasibility for certain tasks does not constitute substantial evidence.*

As stated above, of the 12 application groups, OSHA concedes that it is infeasible in three of them to reach the PEL of 50 µg/m^3 (abrasive blasting, concrete dowel drilling, and tuckpointing). 81 Fed. Reg. at 16,459 (JA0175). In many of the individual application groups assessed by OSHA in the technological feasibility analysis, the evidence also does not support a showing of feasibility.

- **Hole Drillers Using Handheld or Stand-Mounted Drills.** OSHA concluded that it is technologically feasible for hole drillers using handheld or stand-mounted drills to meet the PEL of 50 µg/m^3. Doc.ID.4247, p. IV-757 (JA6435). The "substantial evidence" supporting this finding consisted of just 21 samples, only two of which appear to constitute a full-shift of exposure performing the task. *Id.* at IV-738 (JA6416). Despite making an assertion that drilling "might be done continuously during the work shift" by employees, OSHA assumed no exposure to crystalline silica for the unsampled duration of the shift. *Id.* at IV-736, 742 (JA6414, JA6420). Even so, OSHA still concluded that approximately half of exposures in baseline conditions would result in exposures over the PEL. The mean exposure for all samples for hole drillers was over the PEL. *Id.* at IV-744 (JA6422).

OSHA concludes that employers can get below the PEL of 50 µg/m^3 on a consistent basis through the use of local exhaust ventilation. *Id.* at IV-745 (JA6423). The basis for this is two studies that examined the effectiveness of controls in *controlled, laboratory* conditions. Doc.ID.4247, pp. IV-745-750 (JA6423-JA6428). One of the studies (Shepard *et al.* (2009)) asserts that "dust collection cowls connected to portable vacuums reduced silica exposures by 91 to 98 percent." *Id.* at IV-745 (JA6423). That statistic is meaningless, however, as it is not representative of *real* construction conditions. In the same section, OSHA even references an area sample reading of 2,150 µg/m^3 for locations where an outdoor handheld drill

operator was working alongside another worker performing silica-generating tasks. *Id.* at IV-742 (JA6420).

This does not constitute substantial evidence that a PEL of 50 µg/m^3 can be met in the vast range of hole drilling operations across the country.

- **Jackhammers and Other Powered Handheld Chipping Tools.** OSHA concludes that it is technologically feasible to reach a PEL of 50 µg/m^3 when performing jackhammering or using other powered handheld chipping tools. Doc.ID.4247, p. IV-774 (JA6452). It does so, despite the fact that Table 1 requires supplemental respirator use in all instances where the task is performed indoors with controls and whenever the task is performed for over four hours outdoors with controls. 81 Fed. Reg. at 16,877-78 (JA0593-JA0594). On its face, this shows that the PEL cannot be met in most operations most of the time. Indeed, in almost all instances it cannot be reached with engineering controls alone.

OSHA's position appears to be that most jackhammering is performed outdoors and for less than 4 hours. Doc.ID.4247, p. IV-774 (JA6452). But there is no real evidence of that. In fact, OSHA states in the FEA that "[w]orkers can use chipping breaking and impact drilling equipment for short periods of time of two or three hours *or for as long as seven hours based on a review of selected OSHA inspection reports*." *Id*. at IV-760 (JA6438) (emphasis added).

- **Masonry Cutters Using Stationary Saws.** OSHA also finds that the PEL of 50 µg/m^3 can be met for masonry cutters using stationary saws. The only engineering control that OSHA identifies as meeting the PEL is the use of an integrated water delivery system. *Id*. at IV-857 (JA6535). OSHA concludes that a PEL of 50 µg/m^3 can be met in most operations most of the time because it assumes that construction employers can use wet methods most of the time. The evidence does not support such a general assumption, however.

In fact, OSHA cites to testimony from labor unions regarding the feasibility of reaching the PEL, but that testimony only shows that wet methods *cannot* always be used. The BCTD suggested that it is quite common for contractors to have to utilize other control measures when using stationary masonry saws: "It is common for workers' assignments, and tools and control strategies they utilize, to vary. For example, an employer on one project could assign a worker to use a stationary masonry saw equipped with a water attachment to cut products containing silica, and on another project that same worker could be assigned to use a handheld masonry saw with a vacuum attachment to perform the same task." Doc.ID.4247, p. IV-848 (JA6526).

Even if some evidence supported the fact that using a stationary masonry saw with an integrated water delivery system may meet a PEL of 50 µg/m^3 most of the time – which Petitioners do not concede – substantial evidence does *not* support the

fact that the use of a stationary masonry saw in the variety of exposure conditions can meet a PEL of 50 µg/m^3 in most operations most of the time.

- **Mobile Crushing Machine Operators and Tenders.** OSHA's conclusion that mobile crushing machine operators and tenders can meet the PEL of 50 µg/m^3 is not supported by substantial evidence in the record or the best available evidence.

OSHA's finding of technological feasibility is based on a stunningly low eight samples. Doc.ID.4247, p. IV-957 (JA6635). These eight samples are supposed to represent the range of exposures and baseline conditions for operators and tenders working with and on mobile crushing machines. There is evidence in the rulemaking record that there are approximately 10,000 crushing machines across the country. Doc.ID.0203, p. 2 (JA1662). On its face, data from eight samples does not constitute substantial evidence showing *anything* related to the feasibility of reaching a PEL of 50 µg/m^3. In addition, OSHA finds that it is technologically feasible for tenders to meet the PEL of 50 µg/m^3 even though OSHA states it "has no exposure measurements from a worker strictly tending crushing machines in construction" and was thus unable to create an exposure profile for the job. Doc.ID.4247, p. IV-953 (JA6631). "No evidence" does not equal "substantial evidence."

The best available evidence of feasibility with respect to this work is a site visit conducted by OSHA's contractor ERG, where workers operating a mobile crushing machine were sampled and their work activities and controls were

analyzed. OSHA's contractor was on site for the duration of the shift, took detailed notes of exposures, environmental conditions, use of controls, and tasks performed. *Id.* The following description summarizes the conditions and the controls utilized:

> Multiple water spray nozzles were located at the crusher hopper, the post-crusher conveyor, the sizing screens exit point, and each major transfer point, including the point where crushed material eventually fell to a pile on the ground. The crusher operator controlled the nozzles from a panel in the control booth. The number of nozzles in action varied according to site conditions; at the time of the visit, only the water spray at the jaw crusher hopper was used since the material being crushed was wet from thawing ice. . . . Water sprayers were checked frequently and replaced if they became clogged, dripped, or squirted water, rather than producing a mist spray.

Doc.ID.4247, p. IV-959 (JA6637).

In addition, the crusher was equipped with a seven-month old operator booth. Doc.ID.0203, p. 12 (JA1672). The windows of the booth were rubber mounted and sealed with silicone. *Id.* at 13 (JA1673). It contained an air conditioning unit that recirculated air at 300 cfm and used two washable filters with dust spot efficiencies of less than 20 percent for particles 15 µm or less. *Id.*

Despite these extensive control measures and the fact that the site visit was performed in the winter such that the material crushed "was already damp," OSHA found that the crusher operator who spent at least half of his time within the operator booth was exposed above the PEL. Doc.ID.0203, p. 8 (JA1668). The best available evidence of the ability of a crusher to reach a PEL of 50 µg/m^3 in almost ideal conditions demonstrated that it could *not* be done.

In the FEA, OSHA attempts to address this evidence by suggesting that had the water hose used provided a finer mist or if certain water sprays had been used, "then this operator's exposure level would have been below 50 µg/m^3 on this sampling date." Doc.ID.4247, p. IV-960 (JA6638). OSHA cites to no evidence for this, nor is there evidence in the record to prove this. OSHA is simply speculating. Substantial evidence does not support a finding of technological feasibility for this task, nor does the best available evidence in the record.

Unfortunately, in its zeal to lower the PEL to a level that it hopes construction employers can meet, OSHA has set a PEL in construction that cannot be met in most operations most of the time. Substantial evidence does not support the finding and OSHA's own heavy reliance on respirator usage in the standard is the best indicator that it cannot feasibly be met.

D. Substantial Evidence Does Not Support OSHA's Finding that the Rule is Economically Feasible.

OSHA estimates that the annual cost to comply with the standard in the construction industry is $658,971,248. 81 Fed. Reg. at 16,468 (JA0184). Based on this estimate, OSHA concludes that the Rule is economically feasible for the entire construction industry. OSHA reaches its estimate of costs – and conclusion of feasibility – based on flawed assumptions and ignoring the best available evidence of costs and economic impacts.

1. OSHA's Estimates on their Face are Unsupportable.

In its economic analysis OSHA makes a series of assumptions that are unsupported by the record. Collectively, these assumptions result in costs attributed to the construction industry that are dramatically below the true costs of compliance. In no instance is that as evident as in the costs of compliance with the construction standard per affected establishment. The table below reproduces the annualized costs per establishment in some of the construction industries impacted by the Rule:

Industry	Annualized Cost per Affected Establishment
Electric Utilities	$360
Residential Building Construction	$364
Land Subdivision	$912
Building Equipment Contractors	$421
Building Finishing Contractors	$716

Id. at 16,573 (JA0289).

These estimated costs make no sense in the real world of construction. Take, for example, a residential home builder who is constructing multiple homes and home developments throughout the course of a year. Potential silica generating tasks involve cutting block and brick; cutting tile and granite; grinding and tuckpointing (particularly for remodeling jobs); cutting roof tiles; drilling holes into walls for piping and conduit; and so on. Under the Rule, that builder will have to implement controls, work practices, and respiratory protection under Table 1 (or the alternative exposure control methods), develop a written exposure control plan, and take a

myriad of other actions to ensure compliance. Under OSHA's estimate, an employer will be able to do all of those tasks on an annual basis for just over $350.

OSHA makes its feasibility finding, however, based on this unrealistically low cost. The Agency compares these costs to profits and revenues for these establishments. Given how low the estimated annualized costs actually are, it is not surprising that OSHA concludes that the Rule will not threaten the construction industry.

2. Critical OSHA Assumptions are Not Supported By Substantial Evidence in the Record.

a) *Substantial evidence does not support OSHA's assumption that there are 150 "Construction Working Days" a Year.*

For purposes of the FEA, OSHA assumes that engineering controls and other tasks only occur in construction for 150 days a year. *Id*. at 16,494 (JA0210). In support of this assumption, OSHA cites to "comments" from "industry representatives" during the 2003 SBAR Panel Process. The comments specifically referenced in the preamble to the Rule are from an organization referred to as "The Reform OSHA Coalition." Doc.ID.0968 (JA1932-JA1961). A review of this document found no mention of the number of days per year that construction tasks occurred. The document provided no independent evidence. This cannot be considered the best available evidence of the frequency of the performance of silica-generating construction tasks that serves as the basis for OSHA's economic analysis.

OSHA uses this assumption throughout the analysis, however. It does so for purposes of control costs and rental costs, for respiratory protection costs, and for the written exposure control plan provisions. 81 Fed. Reg. at 16,494 (JA0210); Doc.ID.4247, p. V-334 n.69, V-390 (JA6794, JA6844). The number of "working" days in a year in construction is greater than 150 and, thus, OSHA's assumption significantly underestimates costs. *See, e.g.*, Doc.ID.2322, Att.G, p.30 (JA3712); Doc.ID.4217, p.41 (JA5703).

b) *OSHA ignored substantial evidence in the rulemaking record in not costing virtually any use of the alternative exposure control methods.*

In the Final Economic Analysis, and throughout the preamble to the Rule, OSHA assumes that virtually all employers will follow Table 1:

> Changes from the proposed to the final rule have resulted in a significant reduction in OSHA's estimate of the annual number of samples taken by construction employers. For the final rule, employers following Table 1 are not required to engage in initial or subsequent exposure monitoring for those construction workers engaged in tasks on Table 1. Therefore, OSHA only estimated scheduled semi-annual exposure monitoring (for expected exposures at or above the action level but at or below the PEL) and scheduled quarterly exposure monitoring costs (for expected exposures above the PEL) and scheduled for those operations are not listed on Table 1. In addition, OSHA estimated that some small fraction of employers – 1 percent – will choose to conduct initial sampling to investigate the possibility that exposures are so low (below the action level) that Table 1 need not be followed.

81 Fed. Reg. at 16,514 (JA0230). Thus, OSHA's cost analysis only includes costs (1) for following Table 1, (2) for compliance with the PEL, including sampling, for

abrasive blasting operations and tunnel boring operations, and (3) for that "small percentage" of employers that might sample initially to determine if certain low exposure activities are under the action level. *Id.*

By making this assumption, OSHA significantly understates the costs of the Rule and ignores substantial evidence in the record that employers will not be able to follow Table 1 in all of the operations all of the time. As stated above, throughout the technological feasibility analysis, OSHA repeatedly states that there will be times where an employer cannot follow Table 1 and will have to at that point follow the alternative exposure control methods. However, in the economic feasibility analysis OSHA ignores this extensive evidence, instead clinging to the concept that the only reason an employer would choose to conduct exposure monitoring is to demonstrate a task is not covered by the Rule: "For establishments who would be performing tasks on Table 1 but not using Table 1, OSHA expects that the reason would likely be the availability of objective data (e.g., provided by professional trade or industry associations) showing that the exposures are below the threshold for engineering controls (or exposure monitoring) requirements to apply." Doc.ID.4247, p. V-345 (JA6250). In suggesting that the Rule is technologically feasible, the Agency is quick to note that employers are always free to deviate from Table 1. However, in suggesting that the Rule is economically feasible, OSHA ignores that same evidence.

As with the General Industry standard, correcting only one of OSHA's flawed assumptions or methodological choices in the FEA would not necessarily result in a conclusion that the standard is not economically feasible in construction. The combination of the multiple flawed assumptions, data gaps, and poor methodological choices, however, *does have that effect*. Adjusting OSHA's analysis from the proposed rule to reflect real assumptions and real construction working conditions, the Construction Industry Safety Coalition concluded that direct compliance costs for the construction industry would exceed $3.8 billion dollars annually, which is nearly eight times larger than the estimate promoted by OSHA. The combination of these direct compliance costs and additional costs likely passed through to the construction industry in the form of increased costs for construction materials produced by regulated General Industries would exceed OSHA's 10% of profits threshold in 8 of the 10 construction sectors. Doc.ID.4217, pp. 27-30 (JA5626-JA5629).

OSHA's Rule is not feasible in the construction industry.

III. KEY "ANCILLARY PROVISIONS" IN THE RULE ARE NOT REASONABLY NECESSARY AND APPROPRIATE.

The final Rule also includes numerous ancillary provisions in addition to the PEL, such as requirements to conduct exposure monitoring, provide respiratory protection and a respiratory protection program, develop a written exposure control plan, and provide medical surveillance to certain employees. 81 Fed. Reg. at 16,862-

64 (JA0578-0580). OSHA has included similar ancillary provisions in previous health standards. *Id*. at 16,293 (JA0009). While reviewing courts have upheld the authority of the Agency to require employers to take ancillary measures to protect employees, that authority is not unbounded. Ancillary provisions required under a health standard must be reasonably necessary and appropriate to effectuate the purposes of the standard and, must also be based on substantial evidence in the rulemaking record. *Asbestos II*, 838 F.2d at 1274. OSHA is not permitted to simply make-up provisions that it believes will help reduce risk, without substantiating its reasons for doing so.

In addition, OSHA's authority to promulgate ancillary provisions is constrained by its past practice. Significant departures from past Agency practice must be explained and justified. *See UAW v. Pendergrass*, 878 F.2d 389, 400 (D.C. Cir. 1989). In two instances, the ancillary provisions in the standard fail to meet even this deferential test.

A. OSHA's Deviation from Past Practice Regarding Medical Surveillance is Not Justified.

The Silica Rule requires that employers "make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica at or above the action level for 30 or more days per year." 81 Fed. Reg. at 16,864, 16,880 (JA0580, JA0596). Breaking with prior OSHA precedent, the Rule denies employers crucial

information about the employee's workplace exposure to respirable crystalline silica. Pursuant to the Rule, a physician or other licensed health care professional ("PLHCP") is required to provide a written opinion to the employer, but that opinion can contain only (1) the date of the examination, (2) a statement that the exam met the requirements of the Rule, and (3) any recommended limitations on the employee's use of respirators. *Id*. at 16,881 (JA0597). The Rule does *not* allow employers to receive key information about the employee's recommended limitations on exposure to respirable silica *unless* the employee provides written authorization. *Id.* This denial runs directly counter to the primary purposes of medical surveillance: allowing employers to understand the effects that hazards in the work environment are having on the health of their employees and to make necessary changes to the worksite.

Traditionally, OSHA offered two primary justifications for medical surveillance and medical removal provisions: protection and prevention. OSHA claims that the PEL may not always be low enough to fully protect employee health due to technological and economic feasibility; thus, additional measures are needed to further protect employees. Secondly, OSHA recognizes that providing employers with information about employees' health effects permits the employer to make adjustments to the work environment in order to prevent further adverse health effects. In its rule on "Occupational Exposure to Hexavalent Chromium," OSHA specifically stated,

> The purpose of requiring the PLHCP to supply a written opinion to the employer is 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. If OSHA were to deny this information to the employer, as requested by the UAW, this would diminish one of the main benefits of the medical surveillance requirements of this standard.

71 Fed. Reg. 10,100, 10,365 (Feb. 28, 2006) (JA7027). *See also Lead I*, 647 F.2d at 1237 (1980); *Indus. Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 485 (1974) ("*Asbestos I*") ("The Secretary reasoned that the salutary purposes of this provision could not be fulfilled if employers were denied access to the medical records.").

Medical surveillance under the Rule deviates from past OSHA practice and fails to effectuate the purpose of the OSH Act. The Rule deprives employers of critical information that could be useful in adjusting or implementing new controls in the work environment. It also puts employers in the position of, potentially, continuing to expose employees to silica after they are showing signs of silica-related health effects. Although employees can elect to provide additional information to their employer under the Rule, there is no evidence to suggest that affected employees will agree to provide this information to their employer.

The purpose of medical surveillance is not to mandate that employers pay for ongoing medical diagnosis and treatment with no nexus to the workplace. In fact, Section 4(b)(4) of the OSH Act prohibits OSHA from infringing on state workers

compensation systems.[52] OSHA's medical surveillance provisions have withstood previous challenges based upon Section 4(b)(4) precisely because the employer is informed of the medical conditions of the employees as it relates to worksite exposure. Without a nexus with the worksite, medical surveillance requirements are not reasonably necessary and appropriate.

B. OSHA's Limitation on Dry Sweeping and the Use of Compressed Air is Overly Broad and Not Supported by Substantial Evidence.

The Silica Rule essentially prohibits dry sweeping and the use of compressed air as housekeeping measures across all affected industries.[53] While not a complete prohibition on these practices, the Rule restricts their use to situations where "wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible." 81 Fed. Reg. at 16,864, 16,880 (JA0580, JA0596).

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[52] "Nothing in this Act shall be construed to supersede or in any manner affect any workmen's compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment." 29 U.S.C. § 653(b)(4).

[53] The Rule states, "[t]he employer shall not allow dry sweeping or dry brushing where such activity could contribute to employee exposure to respirable crystalline silica unless wet sweeping, HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure are not feasible." 81 Fed. Reg. at 16,864, 16,880 (JA0562, JA0596).

The proposed rule also contained restrictions on these housekeeping practices. 78 Fed. Reg. at 56,489, 56,499 (JA0823, JA0833). However, the proposal required HEPA-filtered vacuuming or wet methods only when accumulated silica dust "could, if disturbed, contribute to employee exposure to respirable crystalline silica *that exceeds the PEL*." *Id.* (emphasis added). The final Rule contains no such qualification.

There was significant testimony in the rulemaking record regarding this prohibition, and numerous industry stakeholders argued that the prohibition was impracticable, burdensome, and unnecessary. For example, wet methods are explosion hazards in foundries and steel-making facilities, impracticable in concrete and brick plants where the water and dust would react and harden, and a safety hazard outdoors in freezing weather and in residential construction where water could lead to development of mold and structural problems. 81 Fed. Reg. at 16,795 (JA0511). HEPA-filtered vacuums and wet methods are also impracticable for cleaning tight spaces and hard-to-reach crevices that can only be cleaned with compressed air. *Id.*

In response to these comments, OSHA attempted to adjust the language to account for the practical implications of the proposal. The Rule itself, however, does not accomplish this goal. The Rule does not define what is feasible in any particular situation. Further, it shifts the burden to the employer who will then have to

convince a compliance officer in an individual enforcement action that using a wet method or vacuum system "would not be effective, would cause damage, or would create a hazard in the workplace." *Id*. at 16,796 (JA0512).

At a basic level, the provision as drafted is not reasonably necessary to protect against a health risk associated with silica. While OSHA claims evidence of poor housekeeping as a contributor to silica exposure above the PEL in some workplaces, that does not justify the broad prohibition adopted here. Indeed, the Rule by its own terms prohibits even very sporadic dry sweeping of worksites with low exposure as that "could contribute to employee exposure." *Id*. Such a broad prohibition is not supported by the record and not justified to effectuate the purposes of the Rule.

IV. OSHA'S RULEMAKING PROCEDURES VIOLATED SECTION 6 OF THE OSH ACT AND SECTION 553 OF THE ADMINISTRATIVE PROCEDURE ACT.

A. OSHA Deprived the Public of Notice and an Opportunity to Comment on Significant Exposure Data that OSHA Relied on in the Final Rule.

The OSH Act and the APA govern the process for promulgating occupational safety and health standards. Both the OSH Act and the APA require the Secretary to publish proposed rules and provide interested persons an opportunity to submit written data and comments. 29 U.S.C. § 655(b)(2); 5 U.S.C. § 553. In order to allow for meaningful comment, the Secretary must fully disclose the underlying data and reasoning. As this Court has explained:

> In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. *An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary*.

Conn. Light & Power Co. v. Nuclear Regulatory Com., 673 F.2d 525, 530-31 (D.C. Cir. 1982) (emphasis added); *see also Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007); *Home Box Office, Inc. v. Fed. Commc'ns Comm'n*, 567 F.2d 9, 36 (D.C. Cir. 1977); *Ohio Valley Envtl. Coal. v. U.S. Army Corps of Eng'rs*, 674 F. Supp. 2d 783, 802 (S.D. W. Va. 2009).

Here, OSHA based its preliminary exposure profile principally on OSHA and NIOSH inspection reports and ERG and OSHA site visits. Doc.ID.4247, p. III-90 (JA6000). This data was disclosed as part of OSHA's PEA, and interested parties had an opportunity to respond to and comment on the data and provide the Agency data to contradict that put forward by the Agency. *Id*. After the initial comment and hearing period, an Administrative Law Judge provided additional time for interested parties to submit data and post-hearing comments. At the very end of the data-submission period, OSHA submitted data from the OSHA Information System ("OIS") to the docket. Doc.ID.3958 (JA4954-JA5205) ("Sampling Scan Chart"). This data was ultimately used as a basis for OSHA's feasibility findings in the FEA.

81 Fed. Reg. at 16,434 (JA0150). *See also* Doc.ID.4247, p. IV-4 (JA6039) ("The exposure profiles presented in the PEA were updated for the Final Economic Analysis (FEA) using exposure measurements from the OSHA Information System (OIS) that were taken during compliance inspections conducted between 2011 and 2014.").

The OIS data did not merely serve as a supplement or addition to the PEA data. Of the 3,364 samples cited in the FEA, 699 – approximately 21% – are from OIS. 81 Fed. Reg. at 16,434 (JA0150). Further, for 10 general industry job/tasks and 2 construction job/tasks, the OIS data comprises *all* of the samples evaluated.[54] For an additional 15 general industry job/tasks and 4 construction job/tasks, OIS data comprises more than 50% of the sampling data.[55]

OSHA's failure to disclose the OIS data until the end of the data-submission period denied Petitioners the ability to meaningfully comment. "An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir. 1982). OSHA has committed that error here.

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[54] Examples include 09_Cleaning/Finishing Operator and 11_Maintenance Operator (Foundries-Captive) and 03_Operator/Helper – Small Driven Milling Machine (less than half lane) (Millers Using Portable or Mobile Machines). *See* Doc.ID.4248, Exhibit 19 ("Master List"), pp. 8 and 39 (JA6932, JA6933, JA6959).

[55] *See, e.g.*, Doc.ID.4248, Exhibit 19, pp. 4-6 and 35 (JA6930-JA6931, JA6956) (Cut Stone 02_Fabricator; Jackhammers 04_Indoor with water applied).

B. OSHA Deprived the Public a Meaningful Opportunity to Comment on and Examine Information Supplied by Its Contractor Eastern Research Group.

In this rulemaking, OSHA relied heavily on its contractor ERG to gather technical and economic information to support the Agency's rulemaking effort and to draft portions of the underlying FEA. OSHA has relied on consultants in past rulemakings and this Court has upheld this practice. *Lead I*, 647 F.2d at 1217.

Unlike in past rulemakings, however, in this Rule ERG served as not simply a "gatherer" of information and data, but the *source* of the data in several instances, with no or little cited support. Thus, in the FEA OSHA often cites "communications" or "interviews" conducted by ERG as a basis for its opinions.[56] For example, OSHA admitted it had no specific sampling data in its feasibility analysis for engineered cut stone, and, in the absence of data:

> OSHA relied on . . . descriptive information on engineered stone manufacturing and then extrapolated exposure information from analogous operations to estimate exposures for plant production workers. The descriptive information [relied upon] includes personal communications in 2008 between the OSHA contractor Eastern Research Group (ERG) and an individual familiar with a domestic engineered stone manufacturing facility.

[56] Doc.ID.4247, p. III-90 (JA6000) (stating that OSHA based exposure profiles in part on "[u]npublished information (*e.g.,* unpublished data and research obtained through personal communications, meetings, and presentations)").

Doc.ID.4247, p. IV-214 (JA6119).[57] OSHA also relied on additional information about the same facility obtained from "interview[s] of an individual involved in an OSHA compliance inspection" for which there was no data available. *Id.* The source data OSHA cites for these interviews does not include the names of the individuals interviewed, the individuals' qualifications, or the name of the facility. *See* Doc.ID.0650, 0816, 0817 (JA1764-JA1766, JA1769-JA1770, JA1771-JA1773). Furthermore, OSHA acknowledges that one of these interviewees expressly contradicted him- or her- self by first stating that the facility in question was free of visible dust and employees with silica exposure were limited but then later stating that the facility had many overexposures to silica, there were "many engineering controls to reduce exposure and respirator use was required in certain areas of the facility." Doc.ID.4247, p. IV-216 (JA6121).

In addition, OSHA often inexplicably cites an "estimate" by ERG when data is lacking. For example, OSHA states that "[s]tudies of the effectiveness of available dust collection systems have not addressed performance issues, but ERG judged that

[57] *See also, e.g.*, Doc.ID.4247, p. III-23 (JA5989) ("[A]lthough no reliable figures were identified, OSHA, based on ERG's interviews with industry representatives, estimated that there were approximately 150 of [these very small hydraulic fracturing firms]."); *id.* at IV-362 (JA6267) ("Based on an interview (conducted by OSHA contractor ERG) with a fiberglass manufacturer, OSHA concludes that the nature of the operations in mineral wool manufacturing is sufficiently similar to the glass industry as a whole to rely on the baseline conditions and exposure profile laid out in the PEA (Doc.ID.0699).").

their use does not affect drilling productivity." Doc.ID.4247, p. V-251 (JA6752). OSHA provided no scientific basis or reasonable justification for ERG's opinion. *See, e.g.*, *id.* at V-284 (JA6763) ("OSHA used ERG's estimate of 75 percent for operating engineers and 50 percent for excavating and loading machine and dragline operators in this category to estimate the number of heavy equipment operators performing silica-generating activities.").

OSHA's reliance on ERG is beyond significant and the record lacks transparency of the bases for many of the opinions and views of the contractor. The maze that is the FEA, created in large part by ERG and its behind-the-scenes data gathering, makes the underlying analyses virtually impossible to dissect. More importantly, OSHA never made ERG available at the informal public hearing to address its work, explain its estimates, or be subject to cross-examination and questioning by stakeholders. This Court has admonished federal agencies for playing "hunt the peanut" with the public, "hiding or disguising the information that it employs." *Conn. Light & Power Co.*, 673 F.2d at 530-31. For OSHA, ERG served as one big peanut, largely hidden from stakeholders, but relied upon almost entirely for substantial portions of OSHA's feasibility assessment. This, too, constitutes significant procedural error by the Agency.

V. OSHA'S REFUSAL TO EXCLUDE THE BRICK INDUSTRY FROM REGULATION UNDER THE RULE IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE AND IS OTHERWISE CONTRARY TO LAW.

It is well-settled that OSHA has the authority to exclude an industry from a regulation, and, more generally, to modify specific standards according to the unique problems of specific industries, or even specific functions within those industries. Indeed, OSHA is *required* to do so where it is able to differentiate between affected industries. *See Asbestos I,* 499 F.2d at 480 n.31; *Nat'l Grain & Feed Ass'n v. OSHA*, 866 F.2d 717, 727 (5th Cir. 1988) (noting OSHA required to differentiate between grain mills and grain elevators in imposing standard governing grain dust levels because a "myriad of ingredients" rendered grain dust less flammable in mills than elevators); *Am. Dental Ass'n v. Martin*, 984 F.2d 823, 827-28 (7th Cir. 1993) (stating OSHA cannot impose onerous requirements on industry that does not pose substantial hazards to health or safety to workers merely because agency has decided to regulate larger industry sector).

The brickmaking industry sought to be excluded from the proposed rule (such that the then-current PEL would continue to apply) on the grounds that there is no substantial evidence that its workers are exposed to significant risk from respirable crystalline silica at a PEL of 100 $\mu g/m^3$. As OSHA acknowledges, surface impurities on crystalline silica alter its toxicity. *See, e.g.*, 81 Fed. Reg. at 16,376 (JA0092). Studies submitted by the brick industry show that the toxic effects of quartz are

"greatly reduced" in the aluminum-rich clays used for brickmaking,[58] because the aluminum coats the surface of the quartz particles in the clay and renders them less toxic.[59] For instance, in a study of more than 1900 workers from 18 brick plants in England and Scotland (Love *et al.*, 1999), brick and tile workers had much a lower prevalence of abnormal findings on x-rays than the other groups in those plants (surface mine workers, workers quarrying hard rock). Moreover, a group of postal and telecommunication researchers, used as a control population for the studies, actually had a *higher* prevalence of abnormal x-rays. Thus, the findings for brick and clay workers were determined to be within "what could be considered as background for a normal population not exposed to dust." *See* Glenn Report at 50-51 (JA3900-JA3901).

[58] Clay minerals used in brickmaking are complex mixtures with usually a large component of specific clay minerals, such as bentonite, kaolinite, or illite. Silica, alumina, lime, iron oxide and magnesia are generally found in brick clays, with alumina comprising 20-30% of that composition by weight. *See* R. Glenn, "Health Effects of Crystalline Silica in the Clay Brick Industry," January 27, 2014, p. 29 ("Glenn Report"), Doc.ID.2343, Attach. 2 (JA3879).

[59] *See* Glenn Report, discussing *in vitro* and *in vivo* animal experimental studies, as well as epidemiological studies dating back to 1939 and as recently as 2006, that "consistently show that the toxic effects and fibrogenicity of quartz are greatly reduced when exposures occur in the presence of aluminum-rich clays." *Id* at 2 (JA3852). Brick industry-specific studies showed that rates of silicosis were historically low in the structural clay brick industry despite exposure to silica in amounts that exceed the 100 $\mu g/m^3$ PEL.

A. OSHA Has Not Established That A Substantial Risk of Material Harm Exists for Brick Industry Workers at Either the New PEL or the Former PEL.

For its part, OSHA acknowledges that the risk of silicosis among brick workers appears to be lower than in other industries, and also concedes that "occlusion [of silica particles] may weaken the carcinogenicity of silica in the brick clay industry." 81 Fed. Reg. at 16,378 (JA0094). Nonetheless, OSHA refused to exclude the brick industry, arguing that the lower risk of silicosis in the brick industry is still significant (*i.e.*, greater than a lifetime risk of 1 in 1000 workers developing silicosis), and speculating – albeit without any quantification – that the risk of silicosis "is likely to still be significant" in that industry. *Id.* It rejected the Love study because it allegedly did not meet "the same standards as those studies used by OSHA in its quantitative risk assessment," and therefore did not constitute the best available evidence of risk. *Id.*

In drawing these conclusions, OSHA has not met its burden of showing a significant risk of material health impairment to brick workers at the former PEL of 100 $\mu g/m^3$. First, OSHA did not itself investigate the brick industry specifically or conduct any sort of analysis addressing the effects of reduced silica toxicity in the clays used to make bricks. Rather, OSHA's risk assessments for silicosis and NMRD morbidity and mortality are based on studies of workers in other industries. For example, for silicosis morbidity, the data OSHA considered most reliable came

from five studies involving gold miners, coal miners, tin miners, tungsten miners and other non-brick workers. *See* 81 Fed. Reg. at 16,320 (JA0036). For silicosis and NMRD mortality, OSHA relied on an analysis of diatomaceous earth workers and a pooled analysis of silicosis mortality data from epidemiological studies, none of which involved the brick industry and none of which discussed the mitigating factors relevant to the brick industry. *See id*. at 16,303 (JA0019); *see also* "Occupational Exposure to Respirable Crystalline Silica – Review of Health Effects Literature and Preliminary Quantitative Risk Analysis," Doc.ID.1711, p.293, Table II-3 (JA2371). No matter how credible and reliable in other contexts, it follows necessarily that data can never constitute the "best available evidence" when it is not derived from a study of the industry that OSHA seeks to regulate nor in any way applicable or relevant to that industry, particularly when there is available data about that industry. *Tex. Indep. Ginners Ass'n. v. Marshall*, 630 F.2d 398, 407 (5th Cir. 1980).

Further, OSHA's contention that there are excessive risks of silicosis in the brick industry (defined as the occurrence of a disease worker process in more than one in 1,000 workers) rings hollow in light of the fact that OSHA simply does not know the actual risk to brick workers, because OSHA failed itself to investigate the brick industry specifically. Studies submitted into the record showed low to no evidence of silicosis or increased respiratory disease, even with exposures that

greatly exceeded the former PEL.[60] OSHA acknowledged that conditions in the brick industry will result in lower exposure to silica, and therefore are far less likely to result in disease processes, but nevertheless swept brick workers into its overall risk estimates, without making any actual attempt separately to quantify those risks. 81 Fed. Reg. at 16,378 (JA0094). For instance, OSHA declined to develop a quantitative risk assessment based on the Love study, which would have given it the specific information it lacked about the brick industry. *Id*. Instead, it concluded, without any supporting data, that the Love study demonstrated a significant risk for brick workers (i.e., a lifetime risk of 1 in 1,000). OSHA has the burden of showing that the new standard will confer a significant benefit on brick industry workers, and in its refusal to pursue information that is highly relevant to that determination, did not meet that burden.

OSHA's rejection of the brick industry studies presented in the Glenn report is particularly problematic in light of its refusal to accept similar criticisms of studies on which it *did* choose to rely. For example, OSHA chose to reject a study by Vacek,

[60] *See* Glenn Report (JA3847-JA3953), reviewing studies, including one by Love *et al.* of more than 1900 brick workers from 18 brick plants in England and Scotland, two NIOSH studies of silicosis in the North Carolina brick industry (NIOSH, 1978 and 1980) (JA3869, JA3870, JA3888, JA3896-JA3899), and many others. Particularly notable were early studies of exposure conditions in the brick industry in the late 1930s through the early 1950s, which revealed concentrations well above accepted levels for the period, and represented conditions that would have been expected to result in silicosis cases of epidemic proportions – but did not.

et al. (2011) on lung cancer mortality, in favor of a less comprehensive study by Attfield and Costello (2004). As detailed above, the latter included fewer workers, had a shorter follow-up period, and had less complete work histories than the Vacek study. *See*, *e.g.*, 81 Fed. Reg. at 16,386 (JA0082); Health Effects Review, Doc.ID.1711, p. 371 (JA2449). Elsewhere, OSHA responds to the substantial evidence of a sharp decline in silicosis morbidity and mortality by contending that silicosis is underreported as a cause of death, even though it concedes "there is little empirical evidence describing the extent to which [it] is underreported." 81 Fed. Reg. at 16,329 (JA0045). OSHA rests this conclusion largely on a single study (Goodwin, *et al.* (2003), Doc.ID.1030, (JA7519-JA7526)), and brushes off scholarly criticism of the faulty methodology of that study, which produced unreliable estimates. *See* 81 Fed. Reg. at 16,329 (JA0045); *see also* Report of Patrick Hessel, PhD, Doc.ID.2332, p. 2 (JA3799).

Finally, serving to underscore that OSHA acted arbitrarily and capriciously in failing to exclude the brick industry from regulation is that it granted an exclusion to the sorptive minerals industry, whose situation, in every practical respect, is indistinguishable from that of the brick industry. 81 Fed. Reg. at 16,376-380 (JA0092-JA0096). OSHA fails to show that there is any rational distinction to be made between the data submitted by the two industries and, indeed, no such showing is possible.

Like the clays and shales used for brickmaking, the bentonite clays used by the sorptive minerals industry also reduce the toxicity of crystalline silica, and, as did the brick industry, the Sorptive Minerals Institute (SMI) argued that the risk associated with exposure to silica in sorptive clays is lower than the silica risks associated with other materials. *Id.* SMI submitted several studies in support of this proposition, as did the brick industry, and OSHA also questioned the strength of those studies.

For instance, OSHA labelled "of little value" a study of clay workers in Georgia which showed a "significant deficit" of NMRD and no clear excess of lung cancer mortality among those workers, noting that the workers in that study were exposed to very low airborne levels of silica. *Id.* It pointed out that a World Health Organization (WHO) study submitted by SMI did not in fact establish that sorptive clay workers were free from silica exposure risk. To the contrary, the WHO study cited reports of cases of silicosis among bentonite-exposed workers. *Id.* OSHA concluded that this study was "unsuitable for evaluating risks in the range of the former and final rule PELs," in part because of the limited exposure data offered in the studies. *Id.* Based on animal studies, OSHA concluded only that "silica in bentonite clay is of lower toxicological potency than that found in other sectors" because of its surface occlusions, *id.*, just as it did with respect to brick clays.

Yet OSHA reached a different result for sorptive clays: it excluded the industry from the new regulation on the grounds that it could not quantify the lifetime risk of exposure to quartz in sorptive clays. In contrast to its treatment of the brick industry, OSHA did not speculate that the unquantifiable risk was unacceptable. OSHA's disparate treatment of two essentially identical situations reflects arbitrary reasoning on its part.

OSHA errs when it ignores data as it relates to specific industries, and when, having ignored that data, goes on to impose onerous requirements on an industry that does not pose substantial hazards to the safety or health of its workers, merely because the industry is part of some larger sector that the agency has decided to regulate. *Lead I*, 647 F.2d at 1301 (feasibility is to be tested industry-by-industry); *Martin*, 984 F.2d at 827-28. Because OSHA's disparate treatment of the brick and sorptive minerals industries is not supported by record evidence, much less "substantial evidence," it has exceeded the scope of its regulatory authority under OSH Act § 3(8), which authorizes it to impose permanent safety and health standards only where they are "reasonably necessary or appropriate" to provide safe or healthful places of employment. If the sorptive mineral industry does not require such regulation, neither does the brick industry.

B. An OSHA Standard Cannot Be "Reasonably Necessary or Appropriate Under Section 8(3) of the Act Where the Cost of Compliance is High and the Standard Does Not In Any Way Eliminate or Lessen a Significant Risk."

Members of the brick industry testified forcefully and repeatedly throughout the administrative proceedings that the costs imposed by the rule would be both staggering and out of proportion to the costs imposed on other industries. The Final QRA confirms this: the brick and structural clay manufacturing industry would incur total annualized costs of $7.8 million, and annualized costs per affected establishment of $38,422 – costs per establishment exceeded by only one other industry sector, and overwhelmingly more than in industries with the lowest cost impacts (for instance, $49 for dental offices, $107 for paint and coating manufacturers). *See* 81 Fed. Reg. at 16,535, Table VII-18 (JA0251-JA0260). Between 2005 and 2012, brick industry production dropped from 9.7 billion units to 3.4 billion units, which translates into a 59% reduction in profit. Doc.ID.3586, Testimony of Ray Leonhard, President and CEO, Brick Industry Association, pp. 3325-3333 (JA4823-JA4831).

Although OSHA is not required to explicitly balance the costs and benefits of a new rule, it cannot adopt a standard that imposes very large costs on an industry without producing any quantifiable health benefit. *See, Ala. Power Co. v. OSHA*, 89 F.3d 740, 746 (11th Cir. 1996) (benefit must bear reasonable relationship to costs imposed). It is not the brick industry's job to show that there is no benefit to the

rule and the costs are too high; rather, OSHA has the burden of showing that there *is* a benefit derived from the new standard. Yet here, those burdens have been reversed. OSHA has not shown by substantial evidence that reducing the PEL will benefit brick industry workers, while the brick industry has shown the opposite: that this rule provides *no* benefits to its workers, who are not exposed to material health risks due to silica exposure. OSHA thus is imposing debilitating capital expenditures on the brick industry for no material change in the health of its workers. For these reasons, as well, OSHA should exclude the brick manufacturing industry from the silica rule and continue to apply the prior standard. *See, United Steelworkers of Am., AFL-CIO-CIC v. Auchter*, 763 F.2d 728, 738-39 (3d Cir. 1985) (Section 6(g) of OSH Act authorizes agency to target particular industries to address their "unique problems").

CONCLUSION

For the foregoing reasons, the petitions should be granted and the new Rule vacated.

Respectfully submitted,

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Dated: March 23, 2017

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

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March 23, 2017

/s/ Bradford T. Hammock
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United States Court of Appeals
for the District of Columbia Circuit

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by JACKSON LEWIS P.C., counsel for Petitioners. I am an employee of Counsel Press.

On **March 23, 2017**, Counsel for Petitioners has authorized me to electronically file the foregoing **Joint Opening Brief of Industry Petitioners** with the Clerk of Court using the CM/ECF System, which will serve, via e-mail notice of such filing, to any of the following counsel registered as CM/ECF users:

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Eight paper copies will be filed with the Court within the time allowed by rule. All counsel for Amicus Curiae appearing at the time of this filing will also be serve via CM/ECF notice.

March 23, 2017

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ADDENDUM

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§655. Standards

(a) Promulgation by Secretary of national consensus standards and established Federal standards; time for promulgation; conflicting standards

Without regard to chapter 5 of title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

(b) Procedure for promulgation, modification, or revocation of standards

The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this chapter, the Secretary may request the recommendations of an advisory committee appointed under section 656 of this title. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health and Human Services, together with all pertinent factual information developed by the Secretary or the Secretary of Health and Human Services, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefor and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

ADD1

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall 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 dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and

specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health and Human Services certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health and Human Services designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health and Human Services, such examinations may be furnished at the expense of the Secretary of Health and Human Services. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health and Human Services, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.

(c) Emergency temporary standards

(1) The Secretary shall provide, without regard to the requirements of chapter 5 of title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

(d) Variances from standards; procedure

Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order

if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Statement of reasons for Secretary's determinations; publication in Federal Register

Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this chapter, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Judicial review

Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) Priority for establishment of standards

In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health and Human Services regarding the need for mandatory standards in determining the priority for establishing such standards.

(Pub. L. 91–596, §6, Dec. 29, 1970, 84 Stat. 1593; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

References in Text

The effective date of this chapter, referred to in subsec. (a), is the effective date of Pub. L. 91–596, Dec. 29, 1970, 84 Stat. 1590, which is 120 days after Dec. 29, 1970, see section 34 of Pub. L. 91–596, set out as an Effective Date note under section 651 of this title.

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (b)(1), (6)(C), (7), and (g) pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

Termination of Advisory Committees

Advisory committees in existence on January 5, 1973, to terminate not later than the expiration of the 2-year period following January 5, 1973, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Prohibition on Exposure of Workers to Chemical or Other Hazards for Purpose of Conducting Experiments

Pub. L. 102–394, title I, §102, Oct. 6, 1992, 106 Stat. 1799, provided that: "None of the funds appropriated under this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used to grant variances, interim orders or letters of clarification to employers which will allow exposure of workers to chemicals or other workplace hazards in excess of existing Occupational Safety and Health Administration standards for the purpose of conducting experiments on workers' health or safety."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title I, §102, Nov. 26, 1991, 105 Stat. 1114.

Pub. L. 101–517, title I, §102, Nov. 5, 1990, 104 Stat. 2196.

Pub. L. 101–166, title I, §102, Nov. 21, 1989, 103 Stat. 1165.

Pub. L. 100–202, §101(h) [title I, §102], Dec. 22, 1987, 101 Stat. 1329–256, 1329–263.

Pub. L. 99–500, §101(i) [H.R. 5233, title I, §102], Oct. 18, 1986, 100 Stat. 1783–287, and Pub. L. 99–591, §101(i) [H.R. 5233, title I, §102], Oct. 30, 1986, 100 Stat. 3341–287.

Pub. L. 99–178, title I, §102, Dec. 12, 1985, 99 Stat. 1109.

Pub. L. 98–619, title I, §102, Nov. 8, 1984, 98 Stat. 3311.

Occupational Health Standard Concerning Exposure to Bloodborne Pathogens

Pub. L. 102–170, title I, §100, Nov. 26, 1991, 105 Stat. 1113, provided that:

"(a) Notwithstanding any other provision of law, on or before December 1, 1991, the Secretary of Labor, acting under the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.], shall promulgate a final occupational health standard concerning occupational exposure to bloodborne pathogens. The final standard shall be based on the proposed standard as published in the Federal Register on May 30, 1989 (54 FR 23042), concerning occupational exposures to the hepatitis B virus, the human immunodeficiency virus and other bloodborne pathogens.

"(b) In the event that the final standard referred to in subsection (a) is not promulgated by the date required under such subsection, the proposed standard on occupational exposure to bloodborne pathogens as published in the Federal Register on May 30, 1989 (54 FR 23042) shall become effective as if such proposed standard had been promulgated as a final standard by the Secretary of Labor, and remain in effect until the date on which such Secretary promulgates the final standard referred to in subsection (a).

"(c) Nothing in this Act [enacting section 962 of Title 30, Mineral Lands and Mining, amending section 290b of Title 42, The Public Health and Welfare, enacting provisions set out as notes under section 1070a of Title 20, Education and section 1383 of Title 42, and amending provisions set out as notes under section 1255a of Title 8, Aliens and Nationality, and section 1221–1 of Title 20] shall be construed to require the Secretary of Labor (acting through the Occupational Safety and Health Administration) to revise the employment accident reporting regulations published at 29 C.F.R. 1904.8."

Retention of Markings and Placards

Pub. L. 101–615, §29, Nov. 16, 1990, 104 Stat. 3277, provided that: "Not later than 18 months after the date of enactment of this Act [Nov. 16, 1990], the Secretary of Labor, in consultation with the Secretary of Transportation and the Secretary of the Treasury, shall issue under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) standards requiring any employer who receives a package, container, motor vehicle, rail freight car, aircraft, or vessel which contains a hazardous material and which is required to be marked, placarded, or labeled in accordance with regulations issued under the Hazardous Materials Transportation Act [former 49 U.S.C. 1801 et seq.] to retain the markings, placards, and labels, and any other information as may be required by such regulations on the package, container, motor vehicle, rail freight car, aircraft, or vessel, until the hazardous materials have been removed therefrom."

Chemical Process Safety Management

Pub. L. 101–549, title III, §304, Nov. 15, 1990, 104 Stat. 2576, provided that:

"(a) Chemical Process Safety Standard.—The Secretary of Labor shall act under the Occupational Safety and Health Act of 1970 (29 U.S.C. 653) [29 U.S.C. 651 et seq.] to prevent accidental releases of chemicals which could pose a threat to employees. Not later than 12 months after the date of enactment of the Clean Air Act Amendments of 1990 [Nov. 15, 1990], the Secretary of Labor, in coordination with the

Administrator of the Environmental Protection Agency, shall promulgate, pursuant to the Occupational Safety and Health Act, a chemical process safety standard designed to protect employees from hazards associated with accidental releases of highly hazardous chemicals in the workplace.

"(b) LIST OF HIGHLY HAZARDOUS CHEMICALS.—The Secretary shall include as part of such standard a list of highly hazardous chemicals, which include toxic, flammable, highly reactive and explosive substances. The list of such chemicals may include those chemicals listed by the Administrator under section 302 of the Emergency Planning and Community Right to Know Act of 1986 [42 U.S.C. 11002]. The Secretary may make additions to such list when a substance is found to pose a threat of serious injury or fatality in the event of an accidental release in the workplace.

"(c) ELEMENTS OF SAFETY STANDARD.—Such standard shall, at minimum, require employers to—

"(1) develop and maintain written safety information identifying workplace chemical and process hazards, equipment used in the processes, and technology used in the processes;

"(2) perform a workplace hazard assessment, including, as appropriate, identification of potential sources of accidental releases, an identification of any previous release within the facility which had a likely potential for catastrophic consequences in the workplace, estimation of workplace effects of a range of releases, estimation of the health and safety effects of such range on employees;

"(3) consult with employees and their representatives on the development and conduct of hazard assessments and the development of chemical accident prevention plans and provide access to these and other records required under the standard;

"(4) establish a system to respond to the workplace hazard assessment findings, which shall address prevention, mitigation, and emergency responses;

"(5) periodically review the workplace hazard assessment and response system;

"(6) develop and implement written operating procedures for the chemical process including procedures for each operating phase, operating limitations, and safety and health considerations;

"(7) provide written safety and operating information to employees and train employees in operating procedures, emphasizing hazards and safe practices;

"(8) ensure contractors and contract employees are provided appropriate information and training;

"(9) train and educate employees and contractors in emergency response in a manner as comprehensive and effective as that required by the regulation promulgated pursuant to section 126(d) of the Superfund Amendments and Reauthorization Act [of 1986] [Pub. L. 99–499, set out in a note below];

"(10) establish a quality assurance program to ensure that initial process related equipment, maintenance materials, and spare parts are fabricated and installed consistent with design specifications;

"(11) establish maintenance systems for critical process related equipment including written procedures, employee training, appropriate inspections, and testing of such equipment to ensure ongoing mechanical integrity;

"(12) conduct pre-start-up safety reviews of all newly installed or modified equipment;

"(13) establish and implement written procedures to manage change to process chemicals, technology, equipment and facilities; and

"(14) investigate every incident which results in or could have resulted in a major accident in the workplace, with any findings to be reviewed by operating personnel and modifications made if appropriate.

"(d) STATE AUTHORITY.—Nothing in this section may be construed to diminish the authority of the States and political subdivisions thereof as described in section 112(r)(11) of the Clean Air Act [42 U.S.C. 7412(r)(11)]."

WORKER PROTECTION STANDARDS

Pub. L. 99–499, title I, §126(a)–(f), Oct. 17, 1986, 100 Stat. 1690–1692, as amended by Pub. L. 100–202, §101(f) [title II, §201], Dec. 22, 1987, 101 Stat. 1329–187, 1329–198, provided:

"(a) PROMULGATION.—Within one year after the date of the enactment of this section [Oct. 17, 1986], the Secretary of Labor shall, pursuant to section 6 of the Occupational Safety and Health Act of 1970 [29 U.S.C. 655], promulgate standards for the health and safety protection of employees engaged in hazardous waste operations.

"(b) PROPOSED STANDARDS.—The Secretary of Labor shall issue proposed regulations on such standards which shall include, but need not be limited to, the following worker protection provisions:

"(1) SITE ANALYSIS.—Requirements for a formal hazard analysis of the site and development of a site specific plan for worker protection.

"(2) TRAINING.—Requirements for contractors to provide initial and routine training of workers before such workers are permitted to engage in hazardous waste operations which would expose them to toxic substances.

"(3) MEDICAL SURVEILLANCE.—A program of regular medical examination, monitoring, and surveillance of workers engaged in hazardous waste operations which would expose them to toxic substances.

"(4) PROTECTIVE EQUIPMENT.—Requirements for appropriate personal protective equipment, clothing, and respirators for work in hazardous waste operations.

"(5) ENGINEERING CONTROLS.—Requirements for engineering controls concerning the use of equipment and exposure of workers engaged in hazardous waste operations.

"(6) MAXIMUM EXPOSURE LIMITS.—Requirements for maximum exposure limitations for workers engaged in hazardous waste operations, including necessary monitoring and assessment procedures.

"(7) INFORMATIONAL PROGRAM.—A program to inform workers engaged in hazardous waste operations of the nature and degree of toxic exposure likely as a result of such hazardous waste operations.

"(8) HANDLING.—Requirements for the handling, transporting, labeling, and disposing of hazardous wastes.

"(9) NEW TECHNOLOGY PROGRAM.—A program for the introduction of new equipment or technologies that will maintain worker protections.

"(10) DECONTAMINATION PROCEDURES.—Procedures for decontamination.

"(11) EMERGENCY RESPONSE.—Requirements for emergency response and protection of workers engaged in hazardous waste operations.

"(c) FINAL REGULATIONS.—Final regulations under subsection (a) shall take effect one year after the date they are promulgated. In promulgating final regulations on standards under subsection (a), the Secretary of Labor shall include each of the provisions listed in paragraphs (1) through (11) of subsection (b) unless the Secretary determines that the evidence in the public record considered as a whole does not support inclusion of any such provision.

"(d) SPECIFIC TRAINING STANDARDS.—

"(1) OFFSITE INSTRUCTION; FIELD EXPERIENCE.—Standards promulgated under subsection (a) shall include training standards requiring that general site workers (such as equipment operators, general laborers, and other supervised personnel) engaged in hazardous substance removal or other activities which expose or potentially expose such workers to hazardous substances receive a minimum of 40 hours of initial instruction off the site, and a minimum of three days of actual field experience under the direct supervision of a trained, experienced supervisor, at the time of assignment. The requirements of the preceding sentence shall not apply to any general site worker who has received the equivalent of such training. Workers who may be exposed to unique or special hazards shall be provided additional training.

"(2) TRAINING OF SUPERVISORS.—Standards promulgated under subsection (a) shall include training standards requiring that onsite managers and supervisors directly responsible for the hazardous waste operations (such as foremen) receive the same training as general site workers set forth in paragraph (1) of this subsection and at least eight additional hours of specialized training on managing hazardous waste operations. The requirements of the preceding sentence shall not apply to any person who has received the equivalent of such training.

"(3) CERTIFICATION; ENFORCEMENT.—Such training standards shall contain provisions for certifying that general site workers, onsite managers, and supervisors have received the specified training and shall prohibit any individual who has not received the specified training from engaging in hazardous waste operations covered by the standard. The certification procedures shall be no less comprehensive than those adopted by the Environmental Protection Agency in its Model Accreditation Plan for Asbestos Abatement Training as required under the Asbestos Hazard Emergency Response Act of 1986 [Pub. L. 99–519, see Short Title of 1986 Amendment note, set out under section 2601 of Title 15, Commerce and Trade].

"(4) TRAINING OF EMERGENCY RESPONSE PERSONNEL.—Such training standards shall set forth requirements for the training of workers who are responsible for responding to hazardous emergency situations who may be exposed to toxic substances in carrying out their responsibilities.

"(e) INTERIM REGULATIONS.—The Secretary of Labor shall issue interim final regulations under this section within 60 days after the enactment of this section [Oct. 17, 1986] which shall provide no less protection under this section for workers employed by contractors and emergency response workers than the

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protections contained in the Environmental Protection Agency Manual (1981) 'Health and Safety Requirements for Employees Engaged in Field Activities' and existing standards under the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.] found in subpart C of part 1926 of title 29 of the Code of Federal Regulations. Such interim final regulations shall take effect upon issuance and shall apply until final regulations become effective under subsection (c).

"(f) COVERAGE OF CERTAIN STATE AND LOCAL EMPLOYEES.—Not later than 90 days after the promulgation of final regulations under subsection (a), the Administrator shall promulgate standards identical to those promulgated by the Secretary of Labor under subsection (a). Standards promulgated under this subsection shall apply to employees of State and local governments in each State which does not have in effect an approved State plan under section 18 of the Occupational Safety and Health Act of 1970 [29 U.S.C. 667] providing for standards for the health and safety protection of employees engaged in hazardous waste operations."

5 U.S.C.
United States Code, 2011 Edition
Title 5 - GOVERNMENT ORGANIZATION AND EMPLOYEES
PART I - THE AGENCIES GENERALLY
CHAPTER 5 - ADMINISTRATIVE PROCEDURE
SUBCHAPTER II - ADMINISTRATIVE PROCEDURE
Sec. 553 - Rule making
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§553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 383.)

HISTORICAL AND REVISION NOTES

Revised Statutes and

Derivation	*U.S. Code*	*Statutes at Large*
	5 U.S.C. 1003.	June 11, 1946, ch. 324, §4, 60 Stat. 238.

In subsection (a)(1), the words "or naval" are omitted as included in "military".

In subsection (b), the word "when" is substituted for "in any situation in which".

In subsection (c), the words "for oral presentation" are substituted for "to present the same orally in any manner". The words "sections 556 and 557 of this title apply instead of this subsection" are substituted for "the requirements of sections 1006 and 1007 of this title shall apply in place of the provisions of this subsection".

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 553 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2245 of Title 7, Agriculture.

EXECUTIVE ORDER NO. 12044

Ex. Ord. No. 12044, Mar. 23, 1978, 43 F.R. 12661, as amended by Ex. Ord. No. 12221, June 27, 1980, 45 F.R. 44249, which related to the improvement of Federal regulations, was revoked by Ex. Ord. No. 12291, Feb. 17, 1981, 46 F.R. 13193, formerly set out as a note under section 601 of this title.