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October 30, 2025

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October 21, 2025

Submitted via Regulations.gov Docket No. OSHA-2025-0024

Subject: Proposed Amendments to the Asbestos Standard (29 CFR 1910.1001)

Dear Assistant Secretary Keeling:

The <u>Asbestos Disease Awareness Organization</u> (ADAO) strongly opposes OSHA's proposed revisions to the <u>Asbestos Standard</u>, first issued in 1971. For nearly a century, asbestos has been recognized as a known human carcinogen, responsible for an estimated <u>40,000 preventable</u> <u>deaths each year in the United States</u> from mesothelioma, lung cancer, and other asbestos-related diseases. There is no safe level of exposure, a fact affirmed by decades of scientific and medical research.

Rolling back worker protections for a lethal substance is scientifically indefensible and contrary to OSHA's statutory mission to ensure safe and healthful working conditions. The proposed rule would remove clear, enforceable language defining when respiratory protection is required and replace it with vague employer discretion. This change would erode long-standing safeguards, increase confusion, and heighten the risk of preventable disease.

The current Asbestos Standard was built on sound science and medical evidence showing that only strict exposure limits, comprehensive training, and unambiguous respiratory protection requirements can prevent disease. Weakening these provisions in the name of "compliance flexibility" contradicts both the scientific record and the legal precedent that standards must be based on feasible measures necessary to protect worker health.

Asbestos should be prohibited entirely in the United States. Until that occurs, OSHA must maintain and strengthen, not dilute them. ADAO urges OSHA to withdraw this proposed rule and reaffirm its commitment to evidence-based, worker-protective regulation.

Respectfully submitted,

Lord Renni

Linda Reinstein

President and Co-Founder

Asbestos Disease Awareness Organization (ADAO)

Linda Reinstein, President and Cofounder, Asbestos Disease Awareness Organization (ADAO)



October 30, 2025

Mr. David Keeling Assistant Secretary of Labor Occupational Safety and Health Administration U.S. Department of Labor 200 Constitution Ave, NW Washington, DC 20210 Submitted via Regulations.gov

SUBJECT: Asbestos Standard 29 CFR 1910.1001 Proposed rule (90 *Federal Register* 28295-28302) Docket No. OSHA-2025-0024

Dear Assistant Secretary Keeling:

On behalf of the Occupational Health and Safety Section of the American Public Health Association (APHA), a diverse community of public health professionals that champion the health of all people and communities, we write to provide comments on the proposed rule on Asbestos.

We acknowledge the need to streamline standards and coordinate elements from the more updated Respiratory Protection Program Standard (29 CFR 1910.134) with older chemical-specific health standards that include provisions for respiratory protection. In this regard, it is reasonable to cross reference applicable elements of 1910.134 in the chemical-specific health standards. However, given the comprehensive nature of the Asbestos Standard, employers benefit from some redundancy to decrease confusion, increase compliance and provide better protections to their workers. We are concerned that the changes being proposed would not meet these objectives.

Exposure to asbestos causes mesothelioma, and cancer of lung, larynx and ovary, as well as asbestosis, pleural plaques; and is strongly associated with cancer of the pharynx, stomach, and colorectum. OSHA adopted the health standard on asbestos based on substantial evidence that work-related exposure to it is associated with material impairment of health or functional capacity. The proposed changes will diminish the health and safety protections currently afforded to workers. Given OSHA's history of *advancing* protections for workers, we are disappointed that resources are being used to degrade this standard, rather than developing standards that address hazards for which there are no OSHA standards (e.g., workplace violence, hazardous drugs in healthcare settings).

We are also concerned that the Administration's mass layoffs at the National Institute of Occupational Safety and Health (NIOSH) means that this proposed rule, and the 15 other chemical-specific proposed rules, were not written in consultation with NIOSH. Congress established NIOSH to conduct research to inform the development of new and improved OSHA standards and provide education and guidance to workers, employers and professionals. It is essential and we urge that any changes proposed to the respiratory protection provisions of the Asbestos Standard be developed in coordination with NIOSH.

We are deeply concerned that the overarching premise of this proposed rule leaves decisions on appropriately-protective respirators almost entirely up to employers. This proposed rule places a significant burden on employers, who often lack resources to understand exposures, their health effects, and appropriate respiratory protection. These proposed changes will cost employers time and money as they undertake the task of determining when respirators should be provided. Most importantly, these proposed changes will place workers at risk for adverse health impacts — impacts that are preventable with the appropriate use of respirators. Another critical factor that must be considered in making any changes to the respiratory protection provisions is the increase in average temperatures which are affecting workers in most, if not all, industries. Increased heat exposure increases the physiologic burden of work activities with and without the use of respirators.

We disagree with OSHA's underlying assertion that eliminating regulatory text about respiratory protection requirements will reduce the regulatory burden on employers. The provisions of the Asbestos Standard were written carefully and crafted to ensure clarity to employers. The changes being proposed will create confusion and uncertainty, and will increase the workload for employers while simultaneously decreasing protections for workers.

The proposed rule refers to Executive Order 14192 (2025 January 31), "Unleashing Prosperity Through Deregulation" as rationale for this proposed rule. It indicates that federal regulations... "are often difficult for the average person or business to understand...increasing compliance costs and the risk of costs of non-compliance." We argue that the regulatory text and therefore protections that OSHA is proposing to eliminate or replace with vague phrases and less detailed information specific to asbestos will perpetuate and even increase the issues the Administration claims it wants to address.

We provide below our comments on specific topics addressed in the proposed rule. We use the relevant sections in OSHA's general industry standards (29 CFR 1910) to explain our point. However, our comments apply to all comparable provisions in the OSHA standards applicable to shipyards (29 CFR 1915), marine terminals (29 CFR 1917), longshoring (29 CFR 1918), construction (29 CFR 1926) and agriculture (29 CFR 1928).

## Required Use of Respirators

We oppose the proposal to delete provisions of the Asbestos Standard which stipulate the circumstances in which employers must provide respiratory protection. Stating the basic requirements in the health standard makes the information more accessible for employers. If adopted, the proposed change would fail to provide adequate information to employers and workers and create insufficient compliance and protection due to uncertainty. In our experience, responsible employers want to know what is specifically necessary to provide a safe workplace.

The Asbestos Standard stipulates in 1910.1001(g)(i) through (iv) the four circumstances in which respiratory protection must be used. One circumstance, for example, is when "Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee

<sup>&</sup>lt;sup>1</sup> Executive Order 14192 (2025 January 31). Unleashing prosperity through deregulation. 90 *Federal Register* 9065. <a href="https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation">https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation</a>

exposure to or below the TWA and/or excursion limit.."<sup>2</sup> These four provisions give employers and workers the precise information they need to know about when respiratory protection is required, thereby removing any guesswork to determine when it must be used.

We disagree with OSHA's determination that Sections 1910.1001(g)(i) through (iv) "unnecessarily duplicate" the general provisions of 1910.134(a) and its proposal to eliminate it. The only comparable statement in 1910.134(a) is:

"Respirators must be used when the employer determines that it is necessary to protect the health of an employee."

This replacement sentence is in no way equivalent to 1910.1001(g)(i) through (iv). The proposed change incorrectly presumes that all employers have the expertise to make this determination or have the resources to obtain it. If adopted, this change would substantially undermine occupational health protections, making U.S. jobs less safe than they have been for decades. It would give employers complete discretion over whether to provide respiratory protection according to their own degree of knowledge or desire. We disagree with OSHA's assertion that the changes proposed to the Asbestos Standard will "be providing equivalent worker protection" than the current standard.<sup>4</sup>

To summarize, the text in 1910.1001(g)(i) through (iv) is concise and gives clear direction to both employers and workers. Deleting these provisions will create confusion and compliance uncertainty for employers, workers, and the agency itself. We strongly oppose this proposed change because it will increase the likelihood that workers will be overexposed to asbestos. OSHA's pursuit of "compliance flexibility" must not be at the expense of workers' health and safety.

# Filtering Facepiece Respirators

We oppose the proposed change to delete the prohibition on filtering facepiece respirators. OSHA speculates that this provision of the Asbestos Standard "may be based on outdated technology and certification data." We recommend that OSHA review closely the comments submitted by Mark Nicas, PhD, MPH, CIH which were submitted to the docket for this rulemaking. Dr. Nicas is one of the foremost experts on respirators. He provides substantial evidence which demonstrates why the prohibition on filtering facepiece respirators should remain in the standard. Doing otherwise would diminish worker protection. Moreover, a change of this magnitude must be made in close coordination with NIOSH, in particular, to rely on the nationally and internationally recognized expertise of its National Personal Protective Technology Laboratory.

<sup>&</sup>lt;sup>2</sup> 29 CFR 1910.1001(g)(1)(i)-(iv) reads: "... For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:(i) Periods necessary to install or implement feasible engineering and work-practice controls, (ii) Work operations, such as maintenance and repair activities, for which engineering and work-practice controls are not feasible, (iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA and/or excursion limit, and (iv) Emergencies."

<sup>&</sup>lt;sup>3</sup> 90 Federal Register 28297 (July 1, 2025).

<sup>&</sup>lt;sup>4</sup> 90 Federal Register 28296 (July 1, 2025).

<sup>&</sup>lt;sup>5</sup> 90 Federal Register 28295 (July 1, 2025).

## **Employee Requests for Respirators**

OSHA is "considering" removing requirements in (g)(2)(ii) of the general industry Asbestos Standard, and comparable provisions of the shipyard employment and construction Asbestos Standards to provide an employee with a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when the employee chooses to use a PAPR. OSHA indicates that removing this provision "would not compromise reduce worker safety and health." We disagree and strongly encourage OSHA not to remove this section.

Workers have rightly so become more empowered to request PAPRs when they are potentially exposed to hazardous substances, because these devices are much more comfortable to wear for extended periods of time. As OSHA acknowledges, increased worker comfort increases worker compliance for the use of respiratory protection. In addition, PAPRs provide air movement inside the respirator, which is a huge benefit for heat stress prevention. Employee respirator preference can also accommodate religious and other personal preferences, which further increase worker compliance with respirator use.

OSHA's motivation for the proposed change is to reduce employer compliance burdens. Accomplishing this objective must not be at the expense of worker protection or promoting options which are less comfortable for a worker and thus affect workers' use of respirators. In addition, while acknowledging there may be more up-to-date technology, such changes are not necessarily equally protective.

# **Employee Training**

The Asbestos standard includes requirements for "Employee information and training." There is one required topic related to respiratory protection, specifically the "purpose, proper use, and limitation of respirators..." (1910.1001(j)(7)(iii)(F). However, OSHA's Respiratory Protection Standard at 1910.134(k) includes requirements for additional training topics. Rather than deleting 1910.1001(j)(7)(iii)(F), as OSHA has proposed, we recommend that this provision be amended to refer employers to 1910.134(k). This change would help to ensure that all the required topics are covered in employee training, and it would be consistent with a goal of the proposed rule to "simplify compliance for employers."

## Recommendations from the Advisory Committee on Construction Safety and Health

OSHA indicated in the proposed rule that it intends to present the proposed rule to the Advisory Committee on Construction Safety and Health (ACCSH) to allow that expert panel to provide recommendations on it. OSHA also indicates that the ACCSH's recommendations would be available in the rulemaking docket to allow for public comment on them. We note, however, that when this proposed rule was published on July 1, 2025, all 12 of the ACCSH positions were vacant. As of October 30, 2025 all of these vacancies remain.

OSHA should continue the process of selecting and appointing representatives to ACCSH. Both the ACCSH's feedback and stakeholders' responses to it would be informative in determining

<sup>&</sup>lt;sup>6</sup> 90 Federal Register 28298 (July 1, 2025)

<sup>&</sup>lt;sup>7</sup> 90 Federal Register 28297 (July 1, 2025).

whether this rulemaking is consistent with OSHA's ultimate mission "to assure safe and healthful working conditions."

#### Conclusion

We urge OSHA to study the comments submitted by Dr. Mark Nicas and Dr. Roy T. McCay in which they challenge OSHA's assertions that the proposed changes will not diminish occupational health. In particular, both renowned experts on respirators address the topics of filtering facepiece and half face elastomeric devices, Assigned Protection Factors, and HEPA filters. Each provides evidence which illustrate why the changes being proposed to the Asbestos Standard should be rejected. Moreover, their comments demonstrate why close coordination with NIOSH is essential to OSHA rulemaking, especially proposal addressing toxic substances.

Asbestos should be banned in the United States, which would put in place an essential protection for workers and communities alike. We are concerned that OSHA's proposed rollback of requirements to protect workers from asbestos exposure, comes at a time when the Environmental Protection Agency is slow walking consideration of protections for workers who are exposed to legacy uses of asbestos.

In summary, the changes proposed to this health standard will not maintain the protections currently provided to workers. Responsible employers want clear language from OSHA on what they must do to comply with OSHA regulations in order to protect the health and safety of their employees. We concur with the comments submitted by the Occupational Safety and Health State Plan Association (OSHSPA) that including "prescriptive respiratory protection requirements [in each standard] provide better guidance to employers," and agree with OSHSPA's position that this proposed rule "...is a move in the wrong direction." In addition, specificity in the Asbestos Standard is important to workers who want to easily understand what preventive measures their employers are obligated to have in place. We are deeply concerned that the proposed changes will increase work-related morbidity and mortality from exposure to asbestos. The Administration's pursuit of deregulation must not be at the expense of U.S. workers' health and livelihood.

Sincerely,

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<sup>&</sup>lt;sup>8</sup> Occupational Safety and Health Act of 1970, Public Law 91-956.

# Occupational Safety and Health Administration, U.S. Department of Labor Docket No. OSHA-2025-0024 Proposed Rules on Workplace Asbestos 29 CFR Parts 1910, 1915, 1917, 1918, 1926 Federal Register, Volume 90, No. 124, July 1, 2025

#### **Comments**

Mark Nicas, PhD, MPH, CIH Emeritus Adjunct Professor School of Public Health University of California, Berkeley email: mnicas@berkeley.edu

Regarding the general industry asbestos standard, 29 CFR 19010.1001, OSHA has proposed eliminating the requirement that any air-purifying respirator used against asbestos be equipped with HEPA filter media, and proposed permitting the use of filtering facepiece respirators. Both changes would "decrease worker safety" as OSHA put it, that is, increase the health risk to those working with asbestos-containing materials. I explain why below. The only sensible change to harmonize the standard's language with the 1995 NIOSH respirator approval regulations would be to simply specify the use of "high efficiency filter media that meet the HEPA, N100 or P100 approval test criteria in 42 CFR Part 84." The only justified action at this time regarding the prohibition of filtering facepiece respirators is to leave it alone.

## **Eliminating the HEPA Filter Requirement**

OSHA begins its justification by stating: "That requirement [for HEPA filters] was included because HEPA filters were originally part of NIOSH's certification standards for respirators under 30 CFR part 11." That statement is incorrect in two ways. First, the term high efficiency or HEPA is absent from the 30 CFR Part 11 regulations in effect from 1972-1995. However, submicron DOP particle testing was required for radionuclide filters, so the latter filters were the same as HEPA filters. More importantly, 30 CFR Part 11 per se did not require using high efficiency filters against asbestos. In its 1986 preamble to 1910.1001, OSHA alluded to such a requirement by citing paragraphs 11.130(a) and (c) of 30 CFR Part 11 [page 22695, FR Volume 51, No. 19, June 20,1986]. However, those paragraphs simply stated that respirators with dust or mist filters intended for particulate contaminants with a PEL not less than .05 mg/m<sup>3</sup> were covered by the approval regulations. For asbestos more specifically, paragraphs 11.130(f) and (h) pertained to, respectively, respirators with replaceable filters and to single-use respirators designed for use against asbestos-containing dusts or mists. According to Table 10 of 11.130, these latter respirators were not subject to the submicron particle DOP test, which is to say, they did not need to be high efficiency. OSHA's 1986 preamble failed to identify those 30 CFR Part 11 paragraphs.

In the preamble, OSHA went on to say that: (i) no filter other than a high efficiency filter was allowed by NIOSH if the particulate contaminant had a PEL less than .05 mg/m³, and (ii) 0.2 f/cc was equal to .006 mg/m³. I beg to differ with item (ii), because there are laboratory test data

from the early 1970s showing that 0.2 f/cc of chrysotile fibers > 5 µm long is approximately equivalent to 0.1 mg/m<sup>3</sup>. Moreover, NIOSH never revoked its certification of respirators with replaceable filters and of single-use respirators that had been approved for use against asbestos under 30 CFR Part 11, so there was a glaring inconsistency between what NIOSH actually allowed and what OSHA claimed NIOSH allowed.

The primary reason OSHA required HEPA filters in 1910.1001 in 1986 is that it knew they were more efficient at removing asbestos fibers than non-high efficiency filters. In the preamble, OSHA cited data from a Los Alamos Scientific Laboratory study in which five different NIOSH-approved filters were tested against chrysotile fibers > 5 µm long. I believe these were the same data later published in 1988 by Ortiz et al., "Penetration of Respirator Filters by an Asbestos Aerosol," American Industrial Hygiene Association Journal, Volume 49, pages 451-460. According to the preamble: "Only one model (the high efficiency filter) functioned consistently well under all experimental conditions ..."

A minor comment is that in the July 1,2025, Federal Register announcement, OSHA claimed "the HEPA filter requirement is not part of the revised 42 CFR Part 84 because additional types of filters have been certified for protection from particulates and can be used with powered and non-powered air-purifying respirators." However, current 42 CFR Part 84 regulations use the high efficiency or HEPA term with respect to PAPR filters, as in PAPR Class HE, per paragraph 84.170. Paragraph 84.175 requires a PAPR Class HE filter to be at least 99.97% efficient against submicron DOP particles. Curiously, paragraph 84.179 permits the same PAPR Class HE filter to be only 99% efficient against a silica dust aerosol which, of course, is entirely inconsistent.

The main justification OSHA now uses for not requiring high efficiency filters against asbestos is that "all particulate filters certified under 42 CFR Part 84, including HEPA filters, are efficient in preventing the penetration of submicron-sized particles ..." Yes, one might say they are all efficient, but they clearly are <u>not equally efficient</u>.

To my knowledge, there has been no direct comparative testing of N or P 95, 99, and 100 filter media efficiency versus the same asbestos test aerosol. Given OSHA's vague claim that all these filters are equally efficient against asbestos, OSHA might want to fund such testing to support its view. Such new testing would be welcome. However, there are data from circa 1995 which show that a HEPA filter (equivalent to the P100) was at least 50-fold more efficient than a fumegrade filter against asbestos fibers with lengths < 5 µm [Cheng, et al, (2006): "Evaluation of Respirator Filters for Asbestos Fibers," Journal of Occupational and Environmental Hygiene, Volume 3, pages 26-35]. When tested against chrysotile fibers, a dust/fume/mist-grade filter allowed 0.5% penetration while a HEPA filter allowed < .01% penetration. I recognize dust/fume/mist is a filter classification no longer used, but I imagine such a filter would pass the current N95 efficiency test against submicron NaCl particles, although not the N100 or P100 efficiency test. According to the Pb fume filter test described in 30 CFR Part 11, paragraphs 11.140-6(a)-(f), a fume grade filter had to be at least 99% efficient against freshly-generated Pb oxide fume. Fume particle sizes are submicron.

I also recognize that OSHA regulates only asbestos fibers longer than 5  $\mu$ m, but to ignore the shorter fibers is simply putting one's head in the sand. These are not inert particles. The 2011

NIOSH Current Intelligence Bulletin 62 *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* [DHHS (NIOSH) Publication No. 2011–159, page 59] reported the following: "TEM analysis of sampled [asbestos] fibers found all size-specific categories (35 categories were assigned, based on combinations of fiber width and length) to be highly statistically significant predictors of lung cancer and asbestosis [Stayner et al. 2007]. The smallest fiber size—specific category was thinner than 0.25 µm and < 1.5 µm long." The Stayner reference is: "An Epidemiologic Study of the Role of Chrysotile Asbestos Fiber Dimensions in Determining Respiratory Disease Risk in Exposed Workers," Occupational and Environmental Medicine, Volume 65, pages 613–619. The adopted phase contrast microscopy rule of counting only fibers longer than 5 µm was never meant to demarcate "safe" vs "unsafe" asbestos fibers. It was meant to increase the reliability of fiber counting. The 1976 NIOSH *Revised Recommended Standard for Asbestos* [DHEW (NIOSH) Publication No. 77-169] stated: "This technique, by which only fibers longer than 5 µm are counted, is recognized as only an index of total fiber exposure and does not imply that shorter fibers do not pose a health hazard."

Two other reasons that all asbestos fibers should be considered are that: (i) shorter and/or thinner fibers have a greater tendency overall to penetrate a respirator filter, and (ii) airborne asbestos fibers emitted due to insulation work are predominantly less than 5  $\mu$ m long. With regard to item (i), I have two unpublished laboratory reports (a 1971 study from McGill University and a 1978 study from the UK Institute of Occupational Medicine) that I suspect OSHA has possessed for decades. Both show that as asbestos fiber length decreases, penetration through a non-high-efficiency filter increases. I quote a conclusion from one of the reports: "These results indicate that respirators preferentially filter the longer fibres and that the % penetration of ALL fibers will be greater than that measured for those fibres 5  $\mu$ m in length or longer" [emphasis in the original report].

With regard to item (ii), testing by Mt. Sinai investigators circa 1971 showed that for cutting calcium silicate block insulation, about 96% of the asbestos fibers had lengths  $< 5 \mu m$ , and for removing pipe insulation, about 94% of the asbestos fibers had lengths  $< 5 \mu m$  [WJ Nicholson, et al., "Direct and Indirect Occupational Exposure to Insulation Dusts in United States Shipyards," in *Safety and Health in Shipbuilding and Ship Repairing*, International Labour Office, Geneva, 1972]. In a 1985 workplace protection factor study conducted by DuPont Company of workers who wore a variety of respirators while removing pipe insulation and ceiling fire-proofing, TEM was used to characterize the distributions of airborne asbestos fiber lengths and diameters. It was reported that the count median fiber length was 2.5  $\mu$ m with a GSD = 2.2; these parameters correspond to about 80% of the fibers having lengths  $< 5 \mu$ m.

OSHA ends its HEPA filter discussion as follows: "In fact, OSHA has issued other substance-specific regulations since the revised Respiratory Protection standard and NIOSH's revised certification requirements were issued and has not incorporated a requirement for HEPA filters in similar respirator provisions in those rules." Beyond the hexavalent chromium and respirable crystalline silica standards, I do not see to what other substance-specific standards this statement applies. As to those two standards, I view OSHA's failure to require high efficiency filters to be short-sighted. For carcinogenic substances, the goal should be to keep exposures as low as reasonably achievable, and it is certainly feasible to require N100 or P100 filters against both

CrVI and respirable crystalline silica. Stainless steel welding creates submicron particles containing CrVI, and grinding/polishing on artificial stone creates submicron particles containing crystalline silica. Why use N95 or P95 filters that might permit penetration of several percentages of these submicron particles when one can as easily use N100 or P100 filters that permit no more than .03% penetration? Supporting a new mistake by citing similar past mistakes is not really a justification.

# **Allowing Filtering Facepiece Respirators (FFRs)**

In justifying this proposed change, OSHA says the prohibition on FFRs "may be based on outdated technology and certification data and that the use of filtering facepieces would therefore not reduce worker safety and health." This is a non-explanation explanation, and leaves the reader to guess what OSHA is saying. My guess is that OSHA believes approved FFRs currently on the market "may" provide a superior facial fit compared to FFRs in use circa 1986. Rather than speculate that the fit of current FFRs "may" be better than the fit of FFRs from the 1980s, OSHA should present workplace protection factor (WPF) or simulated WPF (SWPF) data that demonstrates this circumstance. I don't think such comparative data exist, although I could be wrong. In 1986, OSHA believed that FFRs did not provide reliable protection against asbestos (it also cited six commenters asserting inadequate protection), and at the time it had in its possession the DuPont study in which both FFRs and elastomeric respirators were evaluated against asbestos. Absent the comparative data to which I alluded, there is no sound justification for removing the prohibition for wearing FFRs against asbestos.

I do know of WPF data post-1986 that suggest FFRs provide an adequate facial fit, along with data that they do not. In particular, there are two studies from the early 2000s that showed N95 FFRs approved at the time did not meet OSHA's criterion for an APF = 10. OSHA was aware of these data when it promulgated the APF standard in 2006, but seems to have wished the bothersome data away. One study from 2002 involved 14 welders who each wore three models of approved N95 FFRs [DH Han, "Correlations between Workplace Protection Factors and Fit Factors for Filtering Facepieces in the Welding Workplace," Industrial Health, Volume 40, pages 328-334]. Because 32/42 QNFT fit factors conducted on these subjects (prior to the WPF measurements) were < 100, OSHA ignored the 10 WPF values associated with FFs > 100. When the 10 perfectly fine WPF values [9.5, 13.8, 14.4, 18.8, 24.3, 50.6, 60.3, 65.5, 78.3, 132.9] are analyzed, one finds their GM = 33.5 and GSD = 2.43, and the parametric estimate of the 5<sup>th</sup> percentile WPF is 7.8. Although OSHA rejected the entire study, it noted "the study results confirmed that when a worker's filtering facepiece respirator is fit tested properly, it is capable of achieving a protection factor of at least 10." However, the WPF value of 9.5 is not "at least 10," and if by "a protection factor" OSHA actually meant "an APF," the 5<sup>th</sup> percentile WPF of 7.8 estimated from the sample data is not "at least 10." Which is to say, the data contradicted the meaning that OSHA attributed to them.

The second study from 2005 involved subjects wearing two models of approved N95 FFRs in agricultural environments [SA Lee, et al., "Respiratory Protection Provided by N95 Filtering Facepiece Respirators against Airborne Dust and Microorganisms in Agricultural Farms," Journal of Occupational and Environmental Hygiene, Volume 2, pages 577-585]. An optical particle counter was used to measure count concentrations of all airborne particles, and dust

collected on filters was assayed for culturable fungi and bacteria. According to the paper's Figure 1, more than 5% of the WPFs for total particle size fractions less than 5  $\mu$ m were less than 10, and more than 5% of the WPFs for culturable fungi and culturable bacteria were less than 10. According to the paper's Appendix I, for 2/6 subjects, the typical WPF was less than 10 against total particles in the 0.7-2  $\mu$ m size range. A major conclusion of the authors was that WPFs decreased as contaminant particle sizes decreased. OSHA rejected the study by stating "it is not clear whether the WPF differences are valid or simply the result of using different measurement methods." The study's authors did not share OSHA's confusion, and collection of particles (in this case viable fungi and bacteria) on filters with subsequent laboratory assay is entirely analogous with collecting metal particles or asbestos fibers on a filter with subsequent laboratory assay. I note that OSHA judged the DuPont study WPF data to be valid even though the study had the anomalous finding that the WPFs for an SCBA were lower than numerous WPFs reported for FFRs.

Because it is not feasible to directly test current FFRs versus FFRs manufactured 40 years ago, a logical new study would be to look at WPFs or SWPFs achieved by the same subjects who each wore currently marketed FFRs, elastomeric halfmask respirators, and full-facepiece respirators against the same test agent. A SWPF study mimicking asbestos removal work would be logistically far easier than a WPF study, and by a SWPF study I do not mean a QNFT study. One wants wearers to perform body movements that more realistically stress the facepiece fit. Ensuring humid conditions would be important, because asbestos abatement work in indoor enclosures use wetting agents to suppress fiber emission. There are many experimental details to consider, but my aim here is not to offer a SWPF study protocol. Rather, my aim is to call for data that compare, in a standardized fashion, the efficacy of current FFRs, elastomeric halfmask respirators, and full-facepiece respirators. Those are data that would address the most relevant question – do current FFRs provide a facial fit equivalent to elastomeric facepieces?

It is fair to ask why such a study is necessary given that in 2006 OSHA gave both FFRs and elastomeric halfmasks the same APF. The simple answer is that OSHA's 2006 APF analysis of the WPF data was fundamentally flawed, so say the least. OSHA took WPF data from 16 studies that were <u>not</u> corrected for particle deposition in the respiratory tract (when the need for such correction had been recognized since the 1970s), took WPF data that were <u>unbalanced</u> within a study (some subjects contributed more WPF values than did other subjects) and <u>unbalanced</u> between studies (some studies contributed many more WPF values than did other studies), effectively <u>double-counted</u> WPFs in four of the studies, <u>ignored</u> the two N95 FFR studies it found inconvenient, <u>ignored</u> the within-subject/between-subject variability in WPFs it knew was inherent in a study, aggregated all the data, and produced an aggregate 5<sup>th</sup> percentile WPF estimate. And at the end of that process, OSHA never defined in exact statistical terms what meaning it gave to the aggregate 5<sup>th</sup> percentile WPF estimate with regard to different respirator wearers. For example, was it the 5<sup>th</sup> percentile value for 100% of wearers, for 95% of wearers, for 95% of wearers, for 95% of wearers, that it was the 5<sup>th</sup> percentile value for 100% of wearers.

Should any current OSHA staff want to consider the flaws in the 2006 APF analysis, I refer them to my 2024 paper ["A Critique of OSHA's Halfmask Respirator Assigned Protection Factor," Annals of the New York Academy of Sciences, 1536:5-12]. By the way, if current OSHA staff

were to look more carefully than their predecessors did, they would see that in OSHA's final WPF database, 26 DuPont study WPFs for elastomeric halfmasks were attributed to FFRs, and 32 DuPont study WPFs for FFRs were attributed to elastomeric halfmasks. I have not tried to determine the manner or degree to which this mistake affected OSHA's comparison between FFRs and elastomeric halfmasks in Table III-4 of the APF standard preamble. One could determine the effect with certainty by correcting the misclassification and rerunning the statistical analysis. Given that OSHA surely has kept the database and all the computer codes, it is in a position to do just that.

A final consideration is that one cannot effectively fit check FFRs that do not have an exhalation valve, in which case one cannot reliably identify an inadequate fit when donning a valveless FFR. An undetected inadequate fit when donning a respirator against asbestos certainly increases asbestos exposure. I recognize that OSHA came to the opposite conclusion regarding fit checks for FFRs in its APF standard preamble. OSHA used the circular logic that because the WPF values for FFRs in the 16 studies had an aggregate 5<sup>th</sup> percentile greater than 10, the associated fit checks were adequate [page 51064, Federal Register, Volume 71, No. 164, August 24,2006]. I expect that had the WPFs been corrected for particle deposition in the respiratory tract, and had OSHA's statistical analysis not been so fundamentally flawed, the aggregate 5<sup>th</sup> percentile WPF for FFRs would have been less than 10.

A less subtle mistake was OSHA's non-critically accepting the fit check study identified as Exhibit 9-16-1-13. I assume this was exactly the same, or substantially similar to, Dr. Myers' 1995 published paper "Effectiveness of Fit Check Methods on Half Mask Respirators," Applied Occupational and Environmental Hygiene, Volume 10, pages 934-942. The paper summarized data that had been generated by internal 3M Company testing. Instead of using a QNFT FF  $\geq$  100 as the criterion for an adequate fit, Dr. Myers used a FF  $\geq$  10 as the adequate fit criterion. The latter criterion should have been a red flag, because in both the 1986 asbestos standard and the 1998 revised respiratory protection standard, OSHA used a pass criterion FF  $\geq$  100 for a halfmask respirator. Curiously, in the same year that the Myers paper appeared, a group of 3M researchers published a study to "validate" the 3M Bitrex QLFT for halfmask respirators [HE Mullins, at al., "Development of a New Qualitative Test for Fit Testing Respirators," American Industrial Hygiene Association Journal, Volume 56, pages 1068-1073, 1995]. The latter group used the same corn oil QNFT and a FF  $\geq$  100 as the criterion for an adequate fit.

A second red flag was that Dr. Myers reported 1.25% filter penetration by the corn oil test particles through the filter of a disposable dust/mist respirator in the study; this circumstance was, in part, used to justify the  $FF \ge 10$  pass criterion. However, a 1992 paper by 3M researchers [SG Iverson, et al., "Validation of a Quantitative Fit Test for Dust/Fume/Mist Respirators: Part I," Applied Occupational and Environmental Hygiene, Volume 7, pages 161-167, 1992] reported that the corn oil test particles showed only 0.1% penetration through a dust/mist filter. Further, if filter penetration had truly been 1.25%, the maximum measured FF would have been 80 (or 1/.0125). However, the Myers paper's Figure 1 showed that even after the measured FFs were reduced to account for respiratory tract deposition, most were greater than 80.

Based on using a FF  $\geq$  100 as the pass criterion for a QNFT, the positive pressure fit check recommended by the 3M Company for this disposable dust/mist respirator exhibited a substantial Beta error, as can also be seen from Figure 1. In this context, the Beta error is the probability that a wearer passes the fit check when the facial fit is inadequate. Even greater Beta errors (over 95%) subsequently were found in two studies with similar fit checks performed with different N95 FFRs: (i) Q Danyluk, et al., "Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?" Journal of Occupational and Environmental Hygiene, Volume 8, pages 267-270, 2011; and (ii) SC Lam, et al., "Evaluation of the User Seal Check on Gross Leakage Detection of 3 Different Designs of N95 Filtering Facepiece Respirators," American Journal of Infection Control, Volume 44, pages 579-586, 2016. Again, an undetected inadequate fit when donning a respirator against asbestos increases asbestos exposure.

To reiterate, the bottom line regarding FFRs and 29 CFR 1910.1001 is that OSHA has offered no justification for removing the prohibition for wearing FFRs against asbestos.