



AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

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Amanda Wood Laihow
Acting Assistant Secretary
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

RE: Docket No. OSHA–2025–0006: Amending the Medical Evaluation Requirements in the Respiratory Protection Standard for Certain Types of Respirators

Dear Acting Assistant Secretary Laihow:

The American College of Occupational and Environmental Medicine (ACOEM) welcomes the opportunity to respond to a request from the Occupational Safety and Health Administration (OSHA) for information and comment on the proposed change in the requirement in 29 CFR 1910.134 for the medical evaluation of workers provided filtering face mask respirators (FFRs) or loose-fitting powered air purifying respirators (PAPRs). ACOEM is the premier national medical society representing over 3,000 occupational medicine physicians and other health care professionals devoted to promoting optimal health and safety of workers, workplaces, and environments.

ACOEM is dedicated to improving the respiratory protection and well-being of workers through science and the sharing of our members' knowledge, while minimizing both employer and worker burden. Performing medical evaluations for respirator use is a key competency and activity of our members. Our members have decades of experience performing these medical assessments, including for workers using FFRs and PAPRs. In addition to clinical experience, several of our members (quoted in the CFR) research the impact of respirators on physical and psychological functioning. ACOEM members have published research studies as well as a widely used *Guide to the Medical Evaluation for Respirator Use*, the second edition of which is forthcoming in the very near future.⁽¹⁻³⁾

The introduction to the proposed rule change includes the following key points that OSHA considers as evidence for this change. Below, we offer comment on key points justifying the

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weakening of worker protection associated with the NPRM, then make recommendations for improving workplace respirator use and medical assessment.

I. Comments on Key Points Justifying Weakening Protection Associated with the Proposed Removal of Medical Evaluation Requirements for Respirator Use

- 1) There is a lack of large-scale epidemiologic studies about adverse effects associated with the use of FFRs or PAPRs.
 - a) We concur with the statement that there is a lack of studies exploring the adverse effects of FFRs or PAPRs and have called for these studies to inform practice.^(2, 4) But we believe that significant changes to medical practice should be guided by the presence (not the absence) of published evidence since eliminating or relaxing occupational health and safety precautions while awaiting large-scale epidemiologic data on adverse outcomes may lead to preventable harm.
- 2) Many workers wear FFRs and PAPRs without the benefit of a medical evaluation, which is mandated under the OSHA Respiratory Protection Standard, 29 CFR 1910.134. OSHA is not aware of adverse effects associated with this violation of 1910.134.
 - a) Citations for violation of 1910.134 have consistently been one of the top 10 reasons for OSHA citations.
 - b) These citations commonly point out not only failure to perform a medical evaluation, but also other deficiencies in respiratory protection. We are deeply concerned that eliminating aspects of the medical evaluation rule may create a broader failure of respiratory protection.
 - c) The large number of employers cited for violations of the respiratory protection rule suggests that workers of these employers are less likely to report adverse effects due to poor training, failure to comply with correct respirator use, or pressure not to report.
 - d) The fact that some workers use respirators without first undergoing medical evaluations should raise concerns regarding a lack of enforcement as opposed to encouraging deregulation, given that OSHA's mandate is intended to be preventive and not reactive.
- 3) A dramatic increase in the number of people not covered by the OSHA rule has used FFRs for protection against SARS-CoV-2 and wildfire smoke. OSHA is not aware of adverse effects associated with the absence of a medical evaluation for respirator use.
 - a) The widespread, unregulated use of FFRs by the general public during the COVID-19 pandemic and wildfire emergencies does not provide a scientifically valid basis for eliminating protections for occupational users. The public media have been replete with photos and accounts of people wearing respirators on their chins, inside out, or upside down.
 - b) Laboratory and some, but not all, worker studies revealed the effectiveness of N95s in reducing transmission of COVID-19. As a result, public messaging was mixed about their value. It is quite possible that anyone experiencing adverse effects stopped wearing a respirator or reverted to the use of a less effective face mask. We are not aware of a large-scale epidemiologic study investigating adverse effects associated with lay use.

However, substantial anecdotal evidence indicated that many people in the community found FFRs too uncomfortable to wear.

- c) During World War I and World War II, some governments distributed gas masks (full-face negative-pressure respirators) to large swaths of their populations. More recently, Israel effectively distributed and trained about 60% of their population for protection from terrorism.⁽⁵⁾ A retrospective study of “mask skills” 10 years after initial distribution found that respondents reported good adherence to respirator maintenance, filter replacement, and current knowledge and skills in their use.⁽⁶⁾ Although some small studies have examined the psychological and medical impact of civilian and military use of gas masks, to our knowledge, no large-scale epidemiological study has been conducted to investigate adverse health effects from this practice or the widespread use of FFRs by the public during the COVID-19 pandemic. This certainly does not mean these effects have not occurred. Some deaths have been reported in community settings, but mainly due to the use of the wrong type of respirator for the hazard.
- 4) The absence of adverse physiological effects while using FFRs or PAPRs, documented by large-scale epidemiologic studies, provides a scientific rationale to discontinue medical evaluations for FFRs and PAPRs. Scientific papers since 1998 have demonstrated that FFRs and PAPRs do not create significant physiologic loads. Available data on effects shows minimal impact on health.
 - a) We agree that evidence has accumulated that FFRs and PAPRs do not create a significant physiologic burden. However, we would broaden OSHA's interpretation of “health” to include dermatologic conditions and symptoms that drive intolerance, both dermatologic and non-dermatologic. Additionally, “worker and patient safety” can be compromised due to the lack of respirator use under conditions where respirators should be used, such as discomfort and conditions, such as dermatitis, which develop with respirator use.
 - i. Substantial field evidence demonstrates that FFRs are uncomfortable and are poorly tolerated by many workers, resulting in hazardous exposures. For example, Radinovich, in a trial of 8 different respirator ensembles including PAPRs and various N95 models, found that the majority of healthcare workers, citing a variety of symptoms, would not tolerate any of the styles for an 8-hour shift, even with breaks.⁽⁷⁾
 - ii. Symptoms impacting comfort without a specific medical diagnosis are likely to drive many workers to be intolerant to FFRs. Authorities have proposed many factors that can drive this intolerance, including underlying disease status, such as asthma or pre-existing dermatologic conditions.⁽⁸⁾ Table 2 in Harber and Beckett (2024) lists a wide array of comfort issues that impact respirator use. The use of FFRs and PAPRs decreases the field of vision and reduces the clarity of communication, creating safety hazards. Training is necessary to diminish the impact of these changes in communication, especially in health care settings.⁽⁹⁾
 - iii. In addition to discomfort, even short-duration use of FFRs commonly results in adverse dermatologic conditions that can drive non-compliance.⁽¹⁰⁾ A systematic review of healthcare workers using FFRs demonstrated an association with occupational dermatoses.⁽¹¹⁾ Another systematic review and meta-analysis

demonstrated adverse dermatologic effects as well as other symptoms that can drive FFR intolerance.⁽¹²⁾

- 5) Workers are able to respond quickly when symptoms arise. In the absence of an IDLH environment (where an FFR or PAPR would not be appropriate), workers will not suffer adverse effects from exposures if they remove their respirator.
 - a) The recommended use of an FFR or PAPR, based on a hazard evaluation, indicates their importance in respiratory protection. This protection may prevent some illnesses that occur after relatively long durations of potential exposure (e.g., chronic effects of wildfire smoke). In these cases, a brief lapse in respiratory protection by removal of the respirator will have a limited adverse impact. However, some workers (e.g., persons with asthma) and some use settings (e.g., exposure to mycobacteria aerosol in inpatient care) may suffer from significant effects even with brief exposures.
 - b) The most vulnerable workers, including those with significant pulmonary or cardiovascular disease, anxiety disorders, pregnancy, or immunosuppression, may face elevated risks even from brief or intermittent exposures. Relying on workers' symptom recognition and judgment in such scenarios transfers unacceptable risk from the employer to the individual.
- 6) Few workers are refused respirators.
 - a) As cited in the OSHA introduction, we agree that this is true. However, this analysis overlooks several factors inherent in a medical evaluation.
 - i. Although a small percentage of workers may be denied respirator use for medical reasons, a small percentage (2%) multiplied by MILLIONS of medical evaluations yields a LARGE number of denials. Granted, we do not know all the reasons for these denials. Large-scale research is needed to provide an evidence-based rationale for various aspects of the medical evaluation. The cost or burden of a medical evaluation is arguably negligible compared to the medical, legal, and ethical consequences of preventable harm. A low rate of exclusion underscores the importance of the medical evaluation rather than diminishing its value.
 - ii. A recent paper reviewed medical evaluations for respirator use that primarily included FFRs and PAPRs in medical centers and found that, consistent with other studies, few examiners declined all respirator use.⁽⁴⁾ However, in some cases, accommodations were medically recommended, primarily the use of a PAPR rather than an N95. At least some employers will rely on medical recommendations (rather than worker requests) to provide individuals with expensive PAPRs. Although often the appropriate accommodation for an FFR is a PAPR, other accommodations, such as duration of use or restriction from potential exposure to certain hazards, may be recommended. For example, an examiner could recommend that an immunocompromised individual wear an FFR, but should not work in an environment with certain infectious agents transmitted by the respiratory route.

II. ACOEM Recommendations

ACOEM recommends the following:

- 1) Increase the use of online and automated machine review of OSHA questionnaires which can substantially reduce the burden of medical evaluations for both employers and workers.
- 2) The recent short-term closure of the National Personal Protective Technology Laboratory (NPPTL) temporarily eliminated federal efforts to design more comfortable, more effective, and less restrictive respirators. Although funding was restored, the future of the NPPTL remains uncertain beyond the current fiscal year. The NPPTL has primary responsibility for assessing conformance of respirators to required standards. According to 42 CFR 84, NIOSH only approves respirators that meet its strict quality assurance and performance requirements as identified by the regulation. The work done by NPPTL personnel is essential to respiratory protection integrity, and funding of NPPTL should continue.
- 3) As noted, citations for failure to comply with 29 CFR 1910.134 have consistently been one of the top 10 reasons for citations. Many employers do not provide their workers with adequate respirator protection. Eliminating the medical evaluation requirement risks misinterpretation or potential further non-compliance with 1910.134 and should not be done.

Although we agree that modification of the current requirement and design for the medical evaluation for FFR and PAR use is warranted, we believe that simply deleting any requirement of medical assessment will put some workers at increased risk of adverse health effects. We strongly urge OSHA to consider the following:

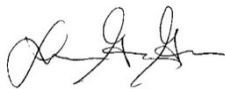
- 1) Modification of the requirement should consider evidence of occupational dermatoses and skin trauma, symptoms that drive intolerance, and that these symptoms are more frequent in individuals with some underlying conditions. The modification should also note the communication, sensory, and perceptual hazards associated with the current design of FFRs and PAPRs. The conditions of the work environment, intensity of effort, hazards, and need for other personal protective equipment (PPE) should also be factors to consider as reasons for a medical evaluation in targeted scenarios.
- 2) Large-scale epidemiologic studies should be conducted to inform best practices and the best approach to the medical evaluation process. Recent studies conducted by ACOEM members have recommended changes to the OSHA questionnaire and proposed study designs to inform the medical evaluation process better.^(2, 4)
- 3) Current clinical practice and the **limited** studies available indicate that some modification, but not elimination, of the medical evaluation for FFR and PAPR use may be justified. We strongly recommend that this modification be conducted with a panel of

experts in the field, representing researchers, clinicians, employers, workers, organized labor, and clinicians who perform these evaluations for different business sectors.

- 4) One example of a modification would be to require a medical evaluation for all workers required to wear an FFR or PAPR in the following circumstances: extended use, worn with other PPE, or in environments that may increase symptoms or result in serious consequences if the respirator is removed. Another approach could emphasize and expand the current OSHA expectation that respiratory problems noted during fit testing trigger a medical evaluation. (29 CFR 1910.134 Appendix A, Fit Testing Procedures (Mandatory)). In these situations, an abbreviated questionnaire and medical evaluation prompted by positive responses would be required at the time of initial and recurrent annual fit testing. The following is an example of questions that may trigger a medical evaluation:
 - a. Do you have a medical problem or symptoms that may limit your ability to use a respirator?
 - b. Have you been told by a health care professional, your supervisor, or the respirator program administrator that you should be medically evaluated?
 - c. Are you concerned that hazardous conditions (effort, temperature, humidity, other PPE, or clothing) will impair your ability to safely work and wear the prescribed respirator?
 - d. Have you previously had problems wearing an N95 or PAPR?
 - e. Do you want to talk to a health professional about your use of the respirator?
- 5) Employers should continue to be obligated to refer for medical evaluation for any of the current OSHA triggers under 1910.134(e)(7)(i-iv).
- 6) Given the appalling frequency of failure of employers to comply with 29 CFR 1910.134, Federal OSHA should conduct a National Emphasis Program to assess compliance with this Rule.
- 7) For a thorough review of OSHA's proposed changes in 29 CFR 1910.134, we request a public hearing.

If you have any questions or need additional information, please contact Julie Ording, MPH, ACOEM Director, Scientific Affairs at julie@acoem.org.

Sincerely,



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