NUSTL
NATIONAL URBAN SECURITY TECHNOLOGY LABORATORY

SAVER TechNote

August 2021

PARTICULATE RESPIRATORY PROTECTION

Particulate respirators worn over the nose and mouth protect the wearer from inhaling hazardous particulate matter such as dusts and airborne biohazards. The level of protection depends upon filtration effectiveness and the tightness of the seal around the edges of the mask when it is worn. The National Institute for Occupational Safety and Health (NIOSH) tests and certifies particulate air purifying respirator products that exceed the minimum 95% level of filtration. Respirators required in the workplace are regulated by the Occupational Safety and Health Administration (OSHA). The devices covered here fall under AEL numbers 01AR-06-DISP and 01AR-06-REUS.

Overview

Respirable hazards include airborne particulate solids such as pollutants from fires and liquid aerosol droplets that may transmit bacteria and viruses. The inhalation of both solid and liquid airborne hazards can be reduced by a filter material which mechanically blocks the particulates but allows air to pass through when the wearer inhales. Gaseous hazards require different respiratory protection using specific vapor filters (or a supply of clean air) and are not covered here.

Disposable Filtering Facepiece Respirators (FFRs)/Courtesy CDC

Disposable particulate respirators, also known as filtering facepiece respirators (FFRs), are comprised of a filtering medium worn over the nose and mouth and are designed to be discarded when soiled. FFRs are available in different formats, one style being a molded cup with elastic straps and a metal strip to conform to the shape of the wearer's nasal bridge. Some have a one-way exhalation valve to reduce breathing resistance. The level of protection depends on both the filter material and the tightness of the face seal to minimize inhalation of unfiltered air through the edges.

Reusable Elastomeric Half Facepiece Respirator/Courtesy CDC

Reusable particulate respirators, also known as elastomeric facepiece respirators, have a facepiece designed to be cleaned and reused, with filters that are discarded and replaced [1]. A rubber or silicone surface seals the edges onto the face, using either a half facepiece design, which fits over the nose, mouth and under the chin, or a full facepiece design, which also covers the eyes. The choice of filter defines the level of protection. These devices are available with and without a one-way exhalation valve and come in various shapes and styles.

Both FFRs and elastomeric facepiece respirators are "passive" or "negative pressure" devices, meaning the wearer draws in breath through the filter. The filter may consist of a mat of fine nonwoven fibers. The diameter of the fibers, the space between them, and the thickness of the mat affect filter efficiency and breathing resistance. In some filters, the fibers have an electrostatic charge that enhances particle collection without increasing breathing resistance.

The U.S. Department of Homeland Security (DHS) established the System Assessment and Validation for Emergency Responders (SAVER) program to help emergency responders improve their procurement decisions.

Located within the Science and Technology Directorate, the National Urban Security Technology Laboratory (NUSTL) manages the SAVER program and conducts objective operational assessments of commercial equipment and systems relevant to the emergency responder community.

The SAVER program gathers and reports information about equipment that falls within the categories listed in the DHS Authorized Equipment List (AEL).

SAVER publications focus on answering two main questions: "What equipment is available?" and "How does it perform?"

SAVER knowledge products are created for the nation's first responders and made available to help them make operational and procurement decisions.

To explore the full reports library and to learn more, visit SAVER online at www.dhs.gov/science-and-technology/SAVER.

For additional information on the SAVER program, email NUSTL at NUSTL@hq.dhs.gov.

Homeland Security
Science and Technology

Federal Standards and Certification

The NIOSH voluntary testing and certification program uses an alpha-numeric scale to rate filter efficiency and resistance to industrial oils (which may reduce electrostatic charge). Filter performance is tested using an aerosol of sodium chloride solution or oil consisting of the most penetrating particle size range for most filter materials. The percentage of particles that are blocked is measured [2].

Filters that block 95% of the test aerosol are rated "95." Those collecting 99% and 99.7% are rated "99" and "100." A preceding letter "N," "R," or "P" indicates oil-resistance as "none," "moderate," or "strong." FFRs made of NIOSH-certified material are labelled with their specific rating (e.g. N95) and may be marketed as "NIOSH-approved." NIOSH-approved filters for elastomeric respirators use the same designations. NIOSH websites [3] [4] list the approved products.

NIOSH does not test the effectiveness of an FFR's face seal. Seal design varies among products and each user must adjust the fit to their individual face. The Occupational Safety and Health Administration (OSHA) requires medical clearance, respirator training, and regular fit testing for each wearer [5].

Surgical N95/
Courtesy CDC

"Surgical N95 respirators" are a subset of N95 FFRs cleared by the Food and Drug Administration (FDA) for medical use. In addition to filter efficiency, they conform to FDA medical device standards for biocompatibility, flammability, and fluid resistance. Approved surgical N95s are listed on a NIOSH website [6]

Other Designations

OSHA uses numerical "assigned protection factors" (APFs) to guide selection of respiratory protection equipment for workplace atmospheres that are not immediately dangerous to life or health. A higher APF indicates a relatively higher level of protection. Both an FFR and an elastomeric half-mask respirator have an APF of ten; an elastomeric full-face respirator, an APF of 50.

Other countries have their own performance test standards and compliance designations for particulate filtering facepiece respirators. Their standards may use slightly different parameters than those applied in the U.S., for example in the flow rates of the challenge aerosol. A U.S. manufacturer of N95 masks has published a comparison of some key similarities in performance standards from different countries [7]. It states that the following respirator designations can reasonably be considered similar to NIOSH N95 for filtering non-oil-based particles: Europe FFP2, China KN95, Australia AS/NZ P2, Korea 1st Class, and Japan DS2. During the COVID-19 pandemic, the FDA issued emergency use authorization (EUA) for FFRs designed using foreign standards. Some OSHA requirements for FFRs were also waived to facilitate widespread use of respiratory protection. As access to NIOSH-approved FFRs increased nationwide, the FDA revoked EUAs for non-NIOSH-approved disposable respirators, effective July 6, 2021 [8].

References

[1] National Personal Protective Technology Laboratory (NPPTL), CDC. "Elastomeric Half Mask Respirator Resources," July 14, 2021. www.cdc.gov/niosh/npptl/respirators/elastomeric/default.html

[2] "Code of Federal Regulations. Title 42 Part 84, (42CFR84), Approval of Respiratory Protective Devices." ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-G/part-84

[3] NPPTL, CDC. "NIOSH-approved particulate filtering facepiece respirators," April 9, 2020. www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

[4] NPPTL, CDC, "NIOSH Certified Equipment List," April 4, 2020. www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html

[5] Occupational Safety And Health Administration, US Dept of Labor. "1910.134(f) Respiratory Protection, Fit Testing," www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

[6] NPPTL, CDC, "Respirator Trusted-Source Information: Surgical 95 Protection," July 14, 2021. www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html

[7] 3M Technical Bulletin. "Comparison of FFP2, KN95, N95 and Other Filtering Facepiece Respirator Classes." Feb 2021 R6. multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf

[8] US Food and Drug Administration (FDA), "FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic," June 30, 2021. www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic