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Understanding Filtering Facepiece Respirators

How to ensure adequate protection.

Respirators substantially lower the risk of breathing dangerous substances, such as viruses, bacteria, and air pollutants. The most commonly used respirators in health care settings are disposable N95 filtering facepiece respirators (FFRs),[1] which filter out at least 95% of very small (0.3-micron) particles.[2] In the United States, the Occupational Safety and Health Administration (OSHA) mandates that employer-provided respirators must be approved by the National Institute for Occupational Safety and Health (NIOSH) in order to ensure that these devices sufficiently protect the wearer.[3]

NIOSH approves respirators in accordance with the Code of Federal Regulations Title 42, Part 84 (42 CFR 84), evaluating both the respirator and the manufacturing process by which it is produced.[4] Respirators submitted for approval are examined for quality, inspected for defects, and tested. Only those that meet the minimum 42 CFR 84 requirements are eligible for approval. NIOSH also conducts site visits to evaluate the manufacturer's quality control processes.

Workplace use of non-NIOSH-approved respirators. Early in the COVID-19 pandemic, shortages of NIOSH-approved N95 respirators created a need for alternatives to protect workers. In response, as a crisis capacity strategy to optimize the supply of personal protective equipment in U.S. health care settings, the Centers for Disease Control and Prevention recommended the use of non-NIOSH-approved respirators that claimed to meet international standards similar to those met by N95 respirators.[5] Following suit, the Food and Drug Administration (FDA) issued a March 2020 emergency use authorization (EUA)—later revoked in July 2021—allowing such respirators to be used by U.S. health care workers.[6, 7] Additionally, OSHA issued temporary enforcement guidance permitting the use of these respirators in U.S. workplaces.[8]

These actions led to an influx of respirator products to the United States claiming to conform to international respirator standards. The FDA-authorized respirators included those claiming to meet the standards of seven countries or jurisdictions: Australia, Brazil, China, the European Union, Japan, South Korea, and Mexico.[8] While these products have similar performance requirements as NIOSH-approved N95 respirators,[9] NIOSH has not approved them, and has no knowledge of their quality and performance over time.

NIOSH testing. In April 2020, to ensure U.S. workers were being adequately protected, NIOSH began assessments of the filtration efficiency of products claiming to meet the seven international respirator standards.[10] The results of these assessments informed subsequent revisions to the FDA's list of non-NIOSH-approved respirators granted EUA.[6, 10]

Nearly 66% of the respirators assessed claimed to meet Chinese standard GB2626-2006.[10] The next highest percentage (17%) claimed to meet both GB2626-2006 and the European EN149-2001 standard. Eight percent claimed to meet EN149-2001 only.

For each test assessment, NIOSH evaluated a minimum of 10 respirators.[10] Of the 356 tests (257 different manufacturers and 279 different models) completed between April 10, 2020, and August 17, 2020[10]:

- 124 (35%) found that all units had a filtration efficiency below 95%
- 93 (26%) found that some units had a filtration efficiency above 95% while others had a filtration efficiency below 95%
- 139 (39%) found that all units had a filtration efficiency above 95%

Although the respirators tested claimed to meet filtration efficiency standards similar to the 95% filtration efficiency required for NIOSH-approved N95s,[9] the NIOSH analysis suggests that many respirators claiming to meet international standards provide substandard protection.[10] The lack of consistency and filtration efficiency among the international respirators compared with NIOSH-approved N95s was of concern as international respirators were being used to combat N95 respirator shortages in the United States.

Consumer evaluation of respirators. Per the FDA's revocation of its March 2020 EUA,

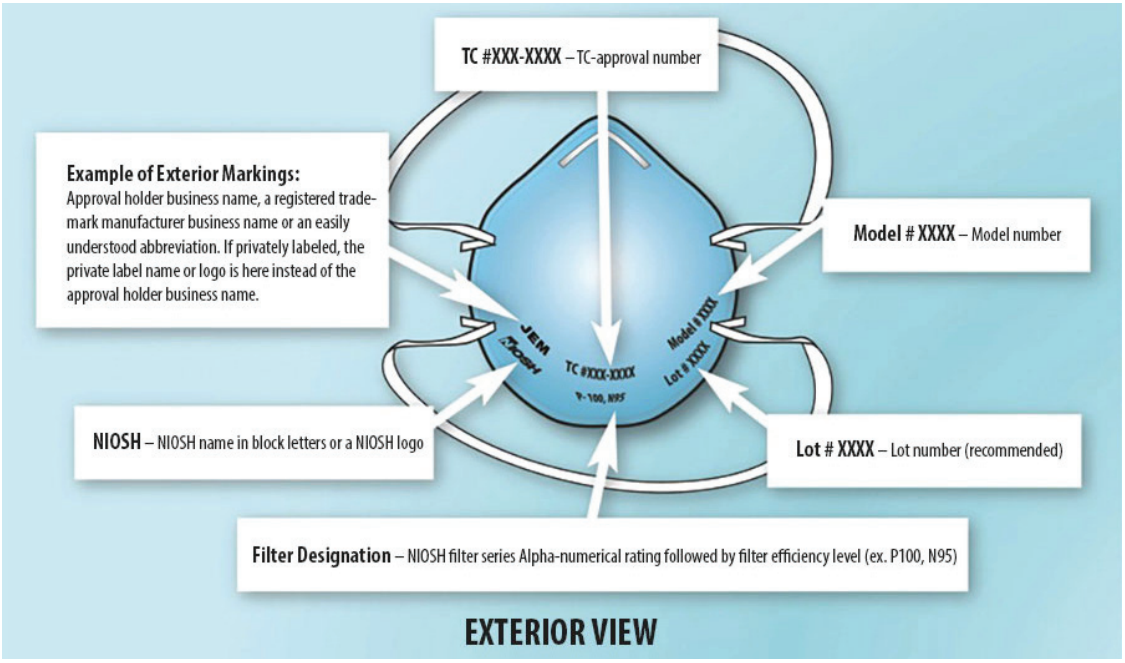

Figure 1. The correct approval markings on a NIOSH-approved filtering facepiece respirator. Image courtesy of the Centers for Disease Control and Prevention.

non-NIOSH-approved respirators are no longer authorized for use by health care workers.[7] However, it is still important for users to be able to determine whether a respiratory protection device provides adequate protection. NIOSH publicly released a list of the international non-NIOSH-approved products assessed and their filtration efficiencies to help users and purchasers determine if their respiratory protection device conforms to the expected standards (see www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html).[11] This list also identifies whether the device was included in the 2020 FDA EUA.

OSHA requires tight-fitting respirators to be fit tested.[3] A respirator's effectiveness is highly dependent on proper fit and use. Fit testing confirms that a tight seal forms on the user's face, ensuring the user receives the expected level of protection. However, international respiratory protection devices typically have ear loop designs, which may limit the user's ability to achieve a tight fit. For this reason, NIOSH-approved N95 respirators typically have head straps. To confirm that an adequate seal has been achieved, a user seal check should be performed each time a respirator is worn.[12]

Another important step in determining whether a respirator will provide adequate protection is verifying that it is not counterfeit. NIOSH urges consumers to contact manufacturers directly if they have questions about product authenticity.

In addition, some respirators may be advertised as having NIOSH approval, but are not actually approved as such. All NIOSH-approved FFRs are required to have approval markings (see Figure 1).[13] These should specify the NIOSH name or logo and the protection level—N95, for example. Additionally, they should be marked with a NIOSH approval number (such as TC-84A-XXXX). FFRs without the required markings are not NIOSH approved and may be counterfeit.

The NIOSH Respiratory Protection Information Trusted Source website (www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html) provides resources to check whether a respirator is NIOSH approved and to find information on products that have been identified as counterfeit or misrepresented.[14] ▼

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