Counterfeit Respirators: Misrepresentation of NIOSH Approval

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ESIS Health, Safety, and Environmental

Overview

Counterfeit respirators are products that are falsely marked or labeled and sold as being National Institute for Occupational Safety and Health (NIOSH) approved. These counterfeit products may not be capable of providing appropriate respiratory protection. As NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval, they are posted on the NIOSH website to alert users, purchasers, and manufacturers:

www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

Background

NIOSH, part of the Centers for Disease Control (CDC), is the research agency for the Occupational Safety and Health Administration (OSHA). NIOSH is the body that approves respirators. Filtering facepiece respirators (FFRs) are divided into classes based on their filtration capabilities. “N95 respirator” designation describes the class of respirators/filters which use N95 filters to remove particles from the air. The NIOSH respirator approval regulation defines the term N95 to refer to a filter class that, during NIOSH testing, removes at least 95% of airborne particles during “worst case” testing using a “most-penetrating” sized particle. Filters meeting this criteria are given a 95 rating. Many filtering facepiece respirators are constructed of a N95 class filter material, and those meeting this filtration performance are often referred to simply as N95 respirators.[1]

How to Identify a NIOSH-Approved Respirator

NIOSH-approved respirators have an approval label on or within the packaging of the respirator (on the box itself and/or within the users’ instructions). Also, an abbreviated approval is on the FFR itself. The approval number can be verified on the NIOSH Certified Equipment List[2] or the NIOSH Trusted Source[3] page to determine if the respirator has been approved by NIOSH. NIOSH-approved FFRs will always have one the following designations:

- N95 – filters at least 95% of airborne particles, not resistant to oil
- N99 – filters at least 99% of airborne particles, not resistant to oil
- N100 – filters at least 99.97% of airborne particles, not resistant to oil
- R95 – filters at least 95% of airborne particles, somewhat resistant to oil
- R99 – filters at least 99% of airborne particles, somewhat resistant to oil
- R100 – filters at least 99.97% of airborne particles, somewhat resistant to oil
- P95 – filters at least 95% of airborne particles, strongly resistant to oil
- P99 – filters at least 99% of airborne particles, strongly resistant to oil
- P100 – filters at least 99.97% of airborne particles, strongly resistant to oil

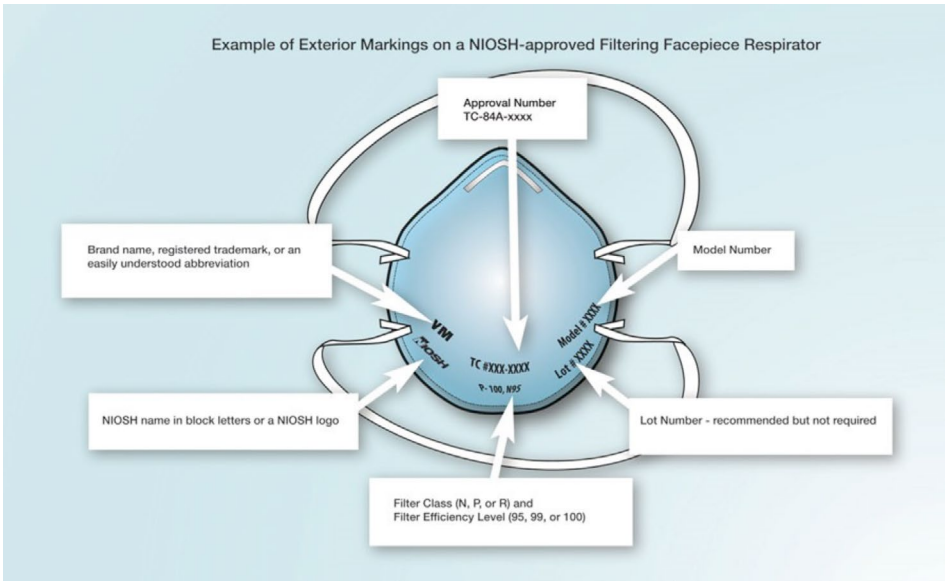
Signs that a respirator may be counterfeit:

- No markings at all on the filtering facepiece respirator
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings, or NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)
- Claims for the of approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands

On the NIOSH website (www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html), there are photographs of several counterfeit respirators that NIOSH has discovered. Figure 1 below illustrates two counterfeit respirators and a counterfeit certificate of conformity:

Figure 1

Figure 2
Example of Exterior Markings on a NIOSH-Approved Filtering Facepiece Respirator[4]



Additional Tips to Identify Counterfeit Respirators[5]

Before buying large quantities of respirators from third party marketplaces or unfamiliar websites, look for the following possible warning signs:

Third-Party Marketplaces

- If a listing claims to be "legitimate" and "genuine," it likely is not.
- Examine transactions history of and feedback about the seller, if possible.
  - On auction sites or third-party distribution networks you can often find a link to the seller of the item and their past sales. This is where buyers have the option to leave feedback regarding the experience with the seller (e.g., if the buyer received the item as advertised, if they received it in reasonable amount of time, and if the buyer was unhappy with the product). Many reviewers will report if a product didn't work or if it was cheap in construction.
- Are there fluctuations in the items or types of items traded over time?
  - Is the seller marketing the same products over time, or are they primarily selling trendy items? Legitimate businesses and distributors typically sell what they know and remain consistent in what they stock and sell over time. A buyer should be able to discover this by looking into a businesses' other products. Buyers should also be able to gain insight to sellers by reading reviews available on many large online marketing platforms.
- Are there price deviations and fluctuations that differ significantly from another sellers' pricing (i.e., does it appear to be "too good to be true")?
- Look at the quantity a buyer has in stock.
  - During a time of shortage, advertising "unlimited stock" could be an indication that the respirator is not approved.
- Does the seller break marketplace policy and hide their contact information within images to circumvent the normal communications channel or process for the site?
  - Typical third-party marketplaces require interactions between seller and buyer to occur within an on-site messaging system. Sellers should not try to circumvent this system to display personal contact information.

On Websites – Look at the Big Picture

- Is the primary contact email address connected to the website, or is it a free email account?
  - Using a free email service (e.g., Gmail, Yahoo Mail) may suggest the seller is not committed to the domain
- Look for bad grammar, typos, and other errors.
- Check the website for signs the company is not legitimate
  - Inconsistent use of names/logos throughout the site
  - Site has incomplete content/uses "dummy" or placeholder text
  - Blank pages
  - A nonsense privacy policy page and/or broken links.
  - Domain squatting type activity (misspell the domain name of a reputable site)

Emergency Use Authorization

On June 6, 2020, the U.S. Food and Drug Administration (FDA) reissued its Emergency Use Authorization (EUA) for non-NIOSH approved ***disposable*** filtering facepiece respirators (FFR). Concern has been raised that certain FFRs from China and other countries may not provide consistent and adequate respiratory protection to health care personnel if they are exposed to COVID-19. This concern is based on additional filtration performance testing conducted by the NIOSH National Personal Protective Technology Laboratory (NPPTL). Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that these respirators should not be decontaminated for reuse by health care personnel. In accordance with that understanding, the FDA has revised and reissued the May 7, 2020, EUA. The FDA took this public health action primarily because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95 percent in testing conducted by NIOSH.

On June 6, 2020, the FDA further revised this Authorization. Respirators that have a failing grade as indicated by NIOSH testing are not approved as respirators under the EUA. However, they may be re-labeled as face masks and authorized as face masks for use as source control if certain criteria are met under the Face Mask Umbrella EUA.

Table 1 below lists products manufactured in other countries that meet the FDA EUA criteria:

Table 1.
Disposable FFRs that Have Been Designed, Evaluated, and Validated to Meet a Given Performance Standard and Have Corresponding Acceptable Product Classifications[6]

Jurisdiction	Performance Standard	Acceptable Product Classification	Standards / Guidance Documents	Protection Factor >10
Australia	AS/NZS 1716:2012	P_3, P2	AS/NZS 1715:2009	Yes
Brazil	ABNT/NBR 13698:2011	FFP_3, FFP2	Fundacentro CDU 614.894	Yes
Europe	EN149-2001	FFP_3, FFP2	EN 529:2005	Yes
Japan	JMHLW-2000	DS/DL_3 DS/DL2	JIS T8150 2006	Yes
Korea	KMOEL-2017-64	Special 1st	KOSHA Guide H-82-2015	Yes
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, N95, P95, R95	NOM-116	Yes

NOTE: Canada is not listed because it allows self-declaration to NIOSH or equivalent standards.

Non-NIOSH-approved disposable filtering facepiece respirators that meet the other eligibility criteria in the reissued Emergency Use Authorization remain authorized by the FDA for use during the COVID-19 pandemic and continue to be listed by FDA.

OSHA's Respiratory Protection Standard Compliance During the COVID-19 Pandemic

COVID-19 has resulted in reduced availability of respirators and fit-testing supplies. As a result, OSHA has released temporary enforcement guidance for the Respiratory Protection Standard, 29 CFR 1910.134. Specifically, the Standard includes enforcement discretion to permit the extended use and reuse of respirators, as well as the use of respirators that are beyond their manufacturer's recommended shelf-life. This guidance applies in all industries, including workplaces in which:

- Healthcare personnel (HCP) are exposed to patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other sources of SARS-CoV-2 (the virus that causes COVID-19).
- Protection of workers exposed to other respiratory hazards is impacted by the shortage resulting from the response to the COVID-19 pandemic. Such workplace respiratory hazards may be covered by one or more substance-specific health standards.

All employers whose employees are required to use respirators must continue to manage their respiratory protection programs. Where respirators are required, employers may consider alternative classes of respirators that provide equal or greater protection to N95s, such as NIOSH-approved, non-disposable, elastomeric respirators or powered, air purifying respirators (PAPR). Other filtering facepiece respirators, such as N99, N100, R95, R99, R100, P95, P99, and P100 are also permissible alternatives.[7]

Employers should understand that non-compliance still violates the Standard; however, these temporary enforcement guidance memos provide OSHA discretion, on a case by case basis during the COVID-19 pandemic only, to refrain from issuing citations to employers for violating certain provisions of the Standard. OSHA will look for and consider documentation and other available information showing that the employer took steps to protect workers, including:

- Utilized strategies to prioritize and conserve the use of N95 respirators according to CDC guidelines:
  - Considerations for release of stockpiled N95 respirators beyond the manufacturer-designated shelf life
  - Strategies for optimizing the supply of N95 respirators;
- Maintained a fully compliant Respiratory Protection Program in all other regards (written program, medical evaluation, respirator maintenance and care, employee training);
- Reassessed their engineering and administrative controls to identify and implement changes to decrease the need for N95 respirators without exposing employees to additional hazards;
- Monitored respirator supplies and made objectively reasonable efforts to obtain NIOSH-approved respirators; and, in healthcare settings, prioritized the best respiratory protection options available for use during high hazard aerosol-generating medical procedures;
- Explored options to obtain and use other types of respirators that offer equivalent or higher protection when N95 respirators were not available; and
- Monitored fit-testing supplies and made objectively reasonable efforts to obtain fit-testing supplies.[8]

Other Considerations – *Caveat Emptor*

Knowing that there is a shortage of respiratory protection (specifically N95 FFR) and that employers still rely on respiratory protection for protection from a variety of particulate matter, the ESIS Health Safety, and Environmental team recommends that employers be aware that counterfeit respirators are being offered for sale and use their best judgement to select respiratory protection based on the guidance above. For respiratory protection to adequately work, it must be adequately designed, fit tightly against the face forming a tight seal, and be in good condition. Adequate inspections and fit (verified through a properly conducted fit test) are keys to proper employee protection should an employer require respirator use. The employer is ultimately responsible for adequately protecting their workers.

The Latin phrase *caveat emptor* expresses the principle that the buyer alone is responsible for checking quality and suitability of goods before a purchase is made. Employers should take the time to vet products carefully. If the respirator is not NIOSH-approved and does not meet the FDA Emergency Use Authorization requirements, it may not adequately protect employees.

Contact Us

To learn more about our services please contact us.

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Footnotes

1. www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1quest1.html
2. www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
3. www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html
4. www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
5. www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html
6. www.fda.gov/media/136403/download
7. www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus
8. www.osha.gov/SLTC/respiratoryprotection/respiratory-protection-covid19-compliance.pdf

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