Fighting counterfeit respirators
Interview between
Underwriters Laboratories' Monica Mena
& NIOSH NPPTL's Maryann D'Alessandro

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The National Personal Protective Technology Laboratory (NPPTL) is the home of the NIOSH respirator approval program. Maryann D'Alessandro explains how users can identify counterfeit respirators.



Monica Mena Underwriters Laboratories Director of Educational Programs

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Director of the National Personal Protective
Technology Laboratory (NPPTL)

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Monica Mena: Hello everyone, my name is Monica Mena and I'm Director of Anti-Counterfeiting Education for Underwriters Laboratories, a 128-year-old non-profit whose mission is to make the world a safer place. As part of our consumer anti-counterfeiting campaign, Be Safe Buy Real, I'm joined today by Maryann D'Alessandro. Hi Maryann!

Maryann D'Alessandro: Hi Monica!

Monica Mena: Thanks for finding time to talk to us today. Can you start by telling us about your role and title within the CDC and how that fits into the agency at large?

Maryann D'Alessandro: Sure thank you Monica, and thank you for the opportunity to the talk today. I am the director of the National

Personal Protective Technology Laboratory also known as **NPPTL**. NPPTL is a division of the National Institute for Occupational Safety & Health, or **NIOSH**. And NIOSH is the federal agency responsible for conducting personal protective equpipment commonly known as **PPE**, research and making recommendations for the prevention of work realted injury and illness. At NPPTL we conduct research on PPE such as respirators, protective clothing, gloves, and other types of PPE.

Respiratory protection is a corner stone of our work and we are the home of the NIOSH respirator approval program which is responsible for testing and approving respirators used in U.S. occupational settings. It is our job in NPPTL to ensure that all respirators used in a workplace meet our rigid quality and performance standards.

How users can identify a NIOSH-approved
N95 Filtering Facepiece Respirator

Manufacturers name,
logo or registered trademark

NIOSH in block letters
or NIOSH logo

TC-Approval Number
(TC-84A-XXXX)

Lot Number and
(TC-84A-XXXXX)

Filter Designation
(example, N95, N99, N100, R95, P95, P99, P100)

Monica Mena: Can you give a quick overview of what it means when a respirator is NIOSH approved?

Maryann D'Alessandro: The NPPTL (National Personal Protective Technology Laboratory) Respirator Approval Program is responsible for testing and approving respirators used in U.S. occupational settings. To be NIOSH approved, respirators must meet or exceed all of the approval requirements identified in our regulation, 42 Code of Federal Regulations Part 84. This regulation ensures respirators meet the minimum construction and respiratory protection performance requirements. The approval process includes a laboratory evaluation of the respirator model and a thorough evaluation of the manufacturer's quality control plan. Once approved, NIOSH performs routine audit testing of approved respirator samples to ensure the respirator continues to achieve the expected level of performance. NIOSH also conducts routine audits of the manufacturing plants to ensure the quality of the manufacturing process. These NIOSH quality checks provide respirator users confidence that NIOSH-approved respirators will provide the expected level of protection.

Monica Mena: What are counterfeit respirators and why are they a problem?

Maryann D'Alessandro: We at NIOSH use two terms to refer to products that wrongly use or misrepresent the NIOSH approval—counterfeit and misrepresentation. Counterfeit respirators refer to products trying to copy an actual NIOSH-approved model. They have not undergone NIOSH testing and evaluation but were manufactured to mimic a NIOSH approved respirator. Misrepresentation, on the other hand, of the NIOSH approval occurs when any respirator product is falsely marketed and sold as being NIOSH approved. Neither counterfeit nor misrepresented products are NIOSH approved because they have not been

evaluated according to NIOSH's strict requirements. This means that they may not provide the appropriate level of respiratory protection.

Monica Mena: How can users identify a NIOSH-approved respirator?

Maryann D'Alessandro: The markings on the respirator and the NIOSH approval label are key to helping you identify a NIOSH-approved respirator. All NIOSH-approved respirators will have a testing and certification approval number. For a filtering facepiece respirator, like an N95, this would look like TC 84A followed by four numerical digits. The NIOSH approval label, which is found on or within the respirator packaging includes the TC approval number. You can verify that the respirator you have is valid by checking the NIOSH Certified Equipment List or CEL. This is the official listing of all NIOSH-approved respirators, and this is the first place you should go to help identify if a respirator is NIOSH approved. It is important to verify that the information on your respirator matches the model name and NIOSH approval number that is listed in the CEL.

While the CEL is the "official" listing of the NIOSH-approved respirators, if you are looking for a particular filtering facepiece respirator, we also provide approved table <u>listings of NIOSH-Approved Particulate Filtering Facepiece Respirators on our website</u>. Our website also has an <u>infographic that identifies all</u> the required markings you should be looking for on the respirator.





Our Respiratory Protection Information Trusted Source webpage provides a variety of resources, not only to help identify NIOSH-approved respirators, but also information on the use of NIOSH-approved respirators and commonly asked questions and answers, which makes it a great resource to check out.

Monica Mena: What are some signs that a respirator may be counterfeit?

Maryann D'Alessandro: There are a few key signs that can indicate a N95 respirator is counterfeit. One sign is that the respirator does not include all the required label markings on the facepiece or straps such as the approval number, part number, or manufacturer name. Other signs include the incorrect spelling of NIOSH, any decorative fabric or other decorative add-ons such as sequins or claims of approval for children. It is important to note that at this time, NIOSH does not approve any type of respiratory protective device specifically for children. Also, most NIOSH-approved respirators will have two headband straps, at this time NIOSH has not approved respirators that use ear loops that do not use an approved fastener to connect the loops behind the head.

We have a <u>Counterfeit Respirator and Misrepresentation of the NIOSH Approval webpage</u> where we describe the signs users should look for to spot counterfeit respirators. We also provide possible warning signs to be aware of before purchasing a respirator from a third-party marketplace or unfamiliar website.

Monica Mena: What happens when NIOSH becomes aware of a counterfeit respirator? Is there an investigation conducted and if so, what federal agency conducts the investigation?

Maryann D'Alessandro: When a NIOSH-approved counterfeit respirator is identified, we work with the actual approval holder meaning the respirator manufacturer to validate the counterfeit claim. Once the claim is verified, we post information on our Counterfeit Respirators/Misrepresentation of NIOSH Approval webpage to alert users, purchasers, and manufacturers. This is the best place to check if a product has been identified as being a counterfeit.

During the pandemic, other federal agencies have performed investigations regarding counterfeit products. Some of these agencies include the FBI, the FDA, the Federal Trade Commission, the Department of Justice, and the Department of Homeland Security.

Monica Mena: If someone suspects they have a counterfeit respirator, can they report it to NIOSH? If so, how?

Maryann D'Alessandro: Before reporting a counterfeit respirator to NIOSH, you should first verify the identified respirator is counterfeit or misrepresenting a NIOSH approval by looking up the TC approval number on our Certified Equipment List and verifying the required approval markings. Then check our Counterfeit Respirators/Misrepresentation of NIOSH Approval webpage to see if the information is already listed. If it is not listed, you should send an email to PPEConcerns@cdc.gov with details about the respirator. If possible, include photos of the respirator itself and package with your submission.

Monica Mena: What measures has NIOSH taken to combat counterfeit respirators?

Key signs that indicate a N95 respirator may be counterfeit



^{*} NIOSH does not approve any type of respiratory protection for children.





Maryann D'Alessandro: Protecting the NIOSH brand is a high priority for us. We successfully recorded the NIOSH stylized logo with and without text, as well as the certification marks N95, N99, N100, P95, P100, and the term "NIOSH APPROVED" with the U.S. Patent and Trademark Office (USPTO) as federal registrations. We now own the logo and certification marks and control who can use them. Any misuse of these marks is a direct violation of applicable trademark laws and NIOSH may pursue action as necessary. A few more of our certification marks are still pending federal registrations with the USPTO. The enforcement of the marks continues to evolve, and ongoing efforts are underway to continue mitigating fraudulent claims.

Monica Mena: Thank you so much Maryann, this has been very enlightening and helpful! Keep up your great work!

Maryann D'Alessandro: Thank you so much Monica, it's been a pleasure working with UL on this effort and we look forward to further exchange in the future.

Monica Mena: And to everyone out there watching, please remember to be safe and buy real. Thank you!

Learn more about how to avoid buying counterfeit goods at

BeSafeBuyReal.ul.org

