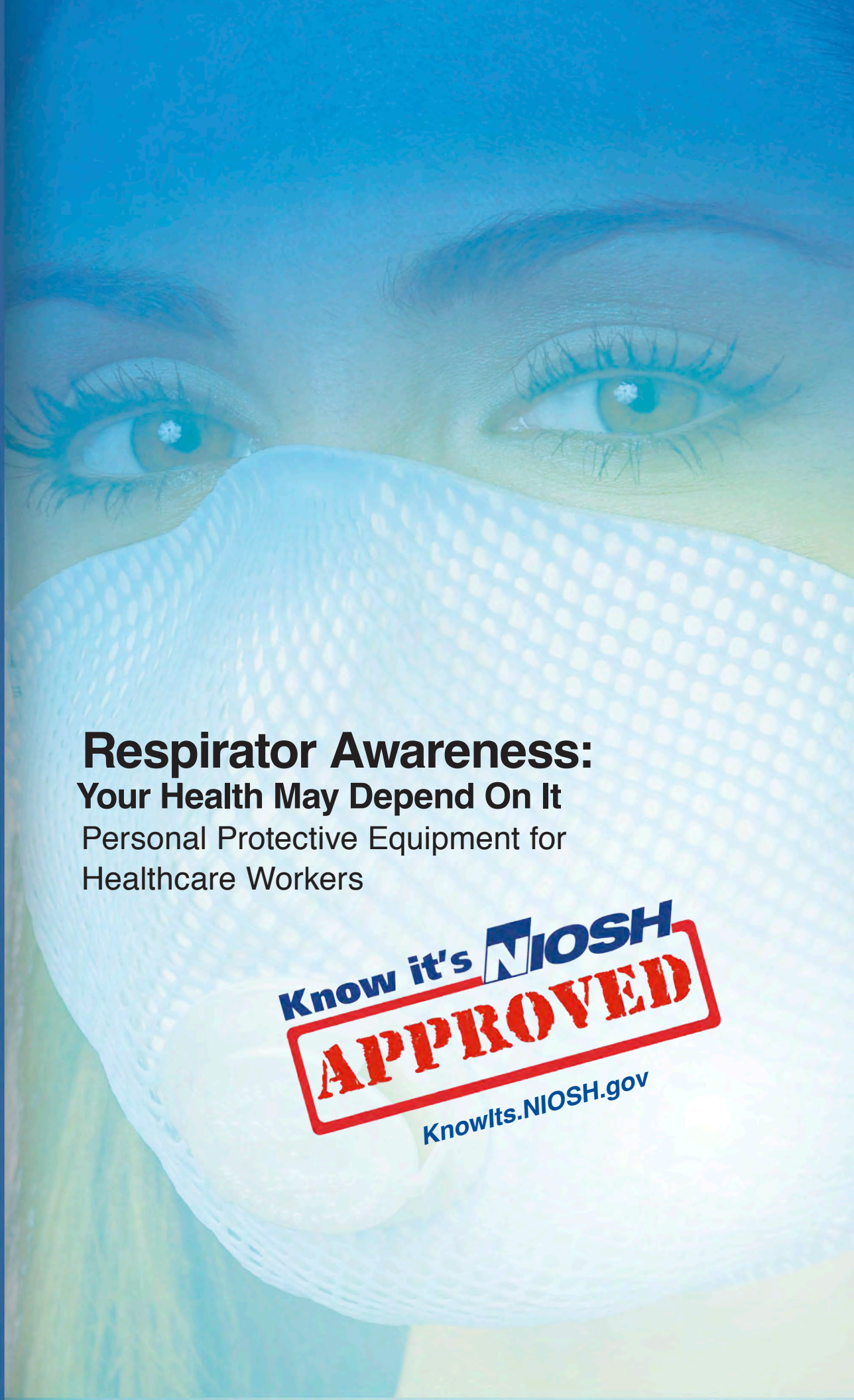


Respirator Awareness:

Your Health May Depend On It

Personal Protective Equipment for Healthcare Workers

Clearing the Air About Respirators

Photo courtesy of Moldex

Photo: Thinkstock Images

Photo courtesy of Moldex

One of the occupational hazards in the healthcare setting is the airborne transmission of certain infectious diseases.[1] The potential of exposure is not limited to physicians, nurses, and support personnel in direct patient care. It extends to those delivering food, cleaning patient rooms, and performing maintenance. Anyone working in areas with patients infected with airborne-transmissible diseases is potentially at risk.

Wearing appropriate respiratory protection when necessary is a vital line of defense. In healthcare, the N95 filtering facepiece respirator is the most commonly used.

Employers and employees need to follow safety and health standards established by the Occupational Safety and Health Administration (OSHA), the Joint Commission, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid, and other organizations.

It is important for you to be aware of the following considerations with respiratory protection products:

- Follow the guidance of your organization's respiratory protection program, including medical clearance
- Be sure you are using a NIOSH-approved respirator
- Get fit-tested on an annual basis
- Know how to don and doff the specific brand and model of respirator you are using
- Know how to use the respirator safely and effectively

1. HICPAC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

Respiratory Protective Devices

N95 filtering facepiece respirators are an important part of infection control in a healthcare setting.

Unlike surgical masks, respirators are specifically designed to provide respiratory protection by forming a tight seal against the wearer's skin and efficiently filtering out airborne particles including pathogens. The N95 designation indicates that the respirator filters at least 95% of airborne particles.

Personnel must use respirators in conjunction with the OSHA 1910.134 comprehensive respiratory protection program standards. Employers are required to develop and implement a written respiratory protection program with procedures specific to the workplace, and to provide qualified training in those procedures. The complete OSHA 1910.134 standard can be found at http://www.osha.gov (search standard 1910.134).

FILTERING FACEPIECE RESPIRATORS

In most instances in healthcare settings, a NIOSH-approved N95 filtering facepiece respirator is used to protect wearers from airborne particles, including pathogens. Please note N95s do not provide protection against gases, vapors, or sprays, and may provide little protection against direct liquid splashes.

Photo courtesy of 3M

N95 Filtering Facepiece Respirator - Tight-fitting. Tested and approved by NIOSH.

SURGICAL MASKS ARE NOT RESPIRATORY PROTECTION

A surgical mask can help block large particle droplets, splashes, sprays or splatter that may contain germs, viruses, and bacteria from reaching the nose and mouth. However, surgical masks are primarily intended to protect the patient from the healthcare worker by reducing exposure of saliva and respiratory secretions to the patient. They do not form a tight seal against the skin or filter very small airborne pathogens, such as those involved in airborne disease transmission.

Photo: iStockphoto

Surgical Mask - Loose fit creates gaps where particles can enter. Cleared by the FDA.

SURGICAL N95 RESPIRATORS

A surgical N95 respirator provides the respiratory protection of an N95 respirator and the splash and spray protection of a surgical mask. These products are approved by NIOSH as N95 respirators and cleared by the Food and Drug Administration (FDA) as medical devices.

Photo courtesy of Moldex

Surgical N95 Filtering Facepiece Respirator - Tight-fitting and fluid-resistant. Tested and approved by NIOSH, cleared by the FDA.

NIOSH-Approved – Your Health May Depend on It

What Does it Mean to be NIOSH-Approved?

All respirators used in healthcare settings must be approved by NIOSH and are thoroughly evaluated and tested by NIOSH to meet strict federal safety requirements. To receive NIOSH approval, respirators must adhere to established standards of quality and performance. Only then will NIOSH authorize a respirator manufacturer to use the NIOSH name in block letters or a NIOSH logo on the product. Manufacturers must have and maintain an established quality program that ensures that their products meet the NIOSH requirements.

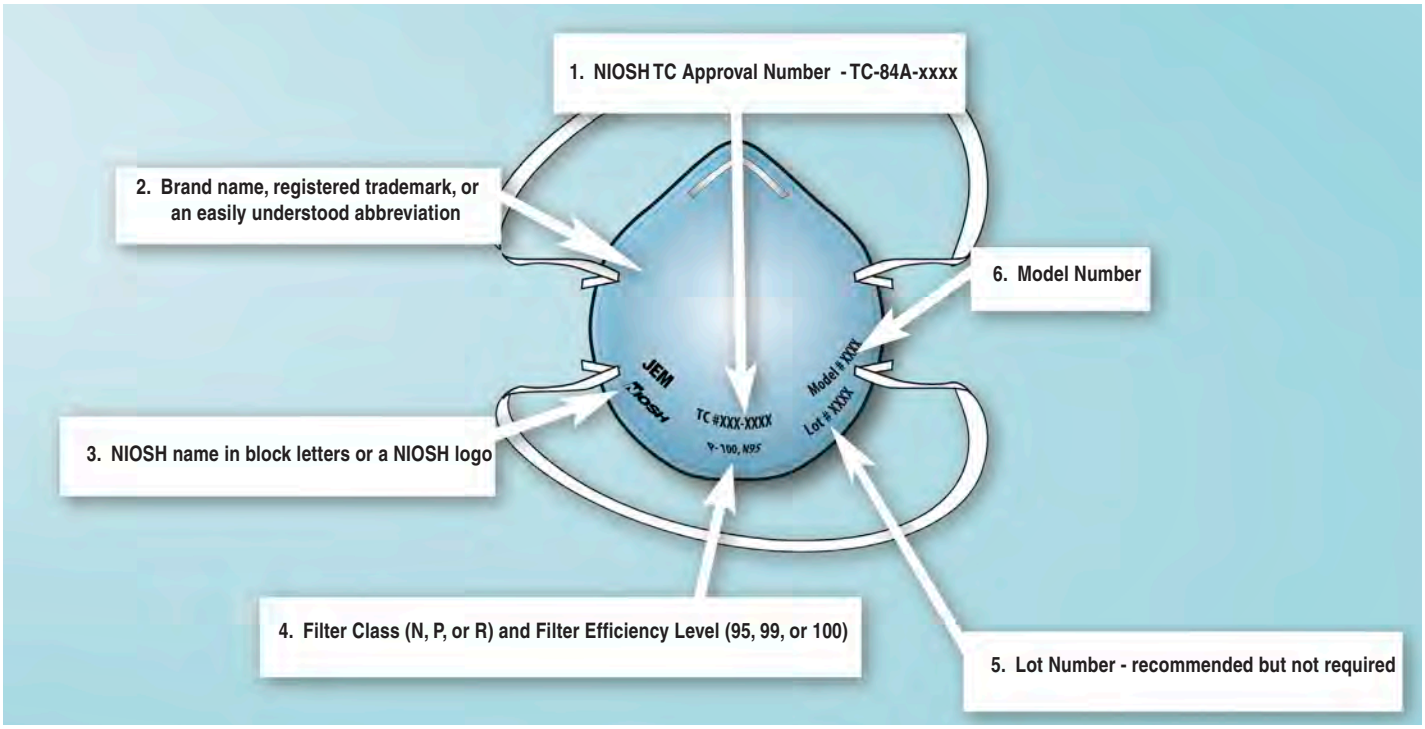
Markings on a NIOSH-approved filtering facepiece respirator may appear on the facepiece itself or on the straps and include the elements shown below. If a filtering facepiece respirator has approval markings but is not on the NIOSH table of approved filtering facepiece respirators, it is likely to be either a counterfeit product or a respirator that has had its certification revoked or rescinded by NIOSH. If there is no TC number on the respirator's packaging, the user instructions, or the product itself, it is not NIOSH-approved. If you are unsure of your respirator's approval status, you can call NIOSH at 412-386-4000.

NIOSH certification lab equipment

Example of Exterior Markings on a NIOSH-Approved Filtering Facepiece Respirator

1. NIOSH TC Approval Number - TC-84A-xxxx
2. Brand name, registered trademark, or an easily understood abbreviation
3. NIOSH name in block letters or a NIOSH logo
4. Filter Class (N, P, or R) and Filter Efficiency Level (95, 99, or 100)
5. Lot Number - recommended but not required
6. Model Number

Example of Exterior Markings on a NIOSH-Approved Filtering Facepiece Respirator



Appearances May Be Deceiving

Employers are required to provide NIOSH-approved respirators to personnel when respiratory protection is needed. Workers can assist their employers by verifying NIOSH markings. However, even when the appropriate markings appear to be present, there are additional issues that can compromise safety.

Misleading Advertising: Counterfeit NIOSH-Approved Respirators and False Claims

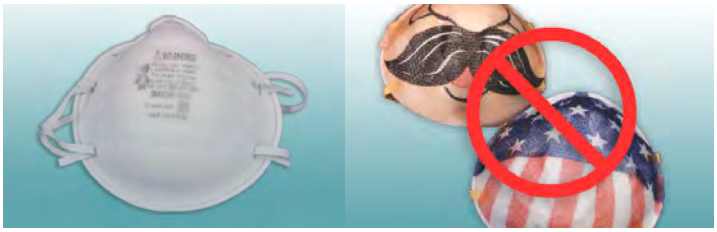
Counterfeit respirators bearing the NIOSH name or logo do appear in the marketplace. They are advertised as NIOSH-approved and often sold at low prices. The best defense is to verify the "TC" number on the NIOSH table of approved filtering facepieces http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part and if in doubt contact NIOSH at 412-386-4000.

Approved Respirators that have been Altered or Modified or had NIOSH-Approval Revoked

A NIOSH approval applies only to the respirator as it was tested and approved by NIOSH. Even the slightest modification to an approved respirator may affect its form, fit, or function and the protection it provides. Here are some ways respirators are altered, voiding NIOSH approval:

- A manufacturer or vendor makes a modification to a respirator, unaware of the impact of the changes or the need to obtain new testing and approval (e.g. a manufacturer may change the way the straps are attached to the facepiece)
- A third party, who is not authorized by NIOSH, makes changes to a NIOSH-approved respirator. This could also involve attempting to copy an approved product.
- Wearers themselves modify a respirator in some way in order to enhance comfort or appearance, compromising their own protection (e.g. decoration is applied to an approved respirator to make it a fashion statement)
- Respirators that were previously approved by NIOSH and had the approval revoked or rescinded are repackaged and sold under another brand

FALSE N95 CLAIM: *This product had no NIOSH marking, but is labeled N95. When tested, this product did not meet N95 filtration performance requirements.*



UNAUTHORIZED ALTERATION, BEFORE & AFTER: *An N95 respirator, covered with fabric and decorated with a colorful design – voiding the NIOSH certification and compromising user safety.*

How Does NIOSH Discover Counterfeit and Modified Respirators?

NIOSH is actively engaged in identifying counterfeit respirators, as well as approved respirators that have been modified in any manner. These safety-compromising products come to the attention of NIOSH in a variety of ways:

- Legitimate manufacturers report vendors marketing products that have been modified
- Legitimate manufacturers report knock-off copies of their products being produced
- Users make inquiries and reports
- Advertisements of altered respirators
- Advertisements of falsely-labeled or mislabeled products
- The NIOSH Approval Program conducts ongoing post-approval audits of certified products and authorized manufacturing sites

Your Respirator – Know It's NIOSH-Approved

Photo courtesy of Moldex

Photo courtesy of Moldex

At NIOSH, your health and safety is our first priority. Because your first line of defense is awareness, we've made sure that all the information you need is as close as your computer. Visit http://KnowIts.NIOSH.gov for access to information regarding respirators, their use, and the issues that affect your well-being and that of the patients under your care.

Additional NIOSH Resources

- User Alerts and Safety Bulletins regarding unauthorized products and products whose approval has been rescinded or revoked http://www.cdc.gov/niosh/npptl/usernotices/default.html
- Publications on various aspects of respirators, their use, and care http://www.cdc.gov/niosh/topics/respirators/
- NIOSH National Personal Protective Technology Laboratory 412-386-4000

Powerful Peace of Mind

With a few clicks of a mouse, you can verify if the respirator you depend on to protect you from airborne diseases has undergone the rigorous NIOSH certification process and is genuinely NIOSH-approved.

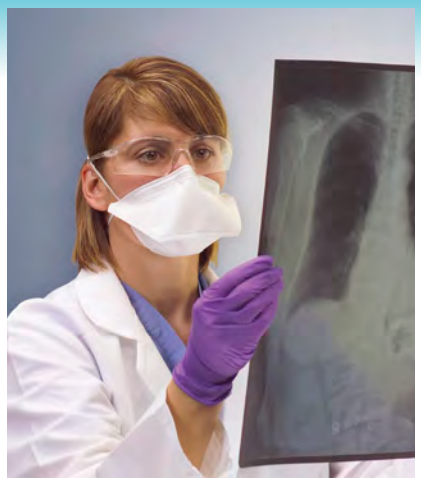


Photo courtesy of Sperian

Know it's NIOSH-Approved

and you can breathe easy!

Photo courtesy of Kimberly-Clark Healthcare

Know it's NIOSH APPROVED

KnowIts.NIOSH.gov

Photo courtesy of Sperian

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TTY 1-888-232-6348
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