Respiratory Protection

Disposable and Reusable Respirators and their approvals systems

A **respirator** is a device designed to protect the wearer from inhaling harmful dusts, fumes, vapors, or gases. Respirators come in a wide range of types and sizes used by the military, private industry, and the public. Respirators range from cheaper, single-use, disposable respirators to reusable models with replaceable cartridges.

There are two main categories: the *air-purifying respirator*, which forces contaminated air through a filtering element, and the *air-supplied respirator*, in which an alternate supply of fresh air is delivered. Within each category, different techniques are employed to reduce or eliminate noxious airborne contents.

Early development of respirators

The history of protective respiratory equipment can be traced back as far as the 16th century, when a finely woven cloth dipped in water was used to protect sailors from a toxic weapon made of powder. Practically all the early respirators consisted of a bag placed completely over the head, fastened around the throat with windows through which the wearer could see. Some were rubber, some were made of rubberized fabric, and still others of impregnated fabric, but in most cases a tank of compressed air or a reservoir of air under slight pressure was carried by the wearer to supply the necessary breathing air. In some devices certain means were provided for the adsorption of carbon dioxide in exhaled air and the re-breathing of the same air many times; in other cases valves were provided for exhalation of used air.

The first US patent for an air purifying respirator was granted to Lewis P. Haslett in 1848 for his 'Haslett's Lung Protector,' which filtered dust from the air using one-way clapper valves and a filter made of moistened wool or a similar porous substance. Following Haslett, a long string of patents were issued for air purifying devices, including patents for the use of cotton fibers as a filtering medium, for charcoal and lime absorption of poisonous vapors, and for improvements on the eyepiece and eyepiece assembly.

Inventors were also developing air purifying devices in Europe and were investigating the power of charcoal, in its various forms, to capture and hold large volumes of gas. They put their science to work in building one of the first respirators able to remove toxic gases from the air, paving the way for activated charcoal to become the most widely used filter for respirators.

Modern respirator technology

All respirators have some type of facepiece held to the wearer's head with straps, a cloth harness, or some other method. The facepiece of the respirator covers either the entire face or the bottom half of the face including the nose and mouth. Half-face respirators can only be worn in environments where the contaminants are not toxic to the eyes or facial area. For example, someone who is painting an object with spray paint could wear a half-face respirator, but someone who works with chlorine gas would have to wear a full-face respirator. Facepieces come in many different styles and sizes, to accommodate all types of face shapes, and there are many books and references available for determining which kind of hazard requires what type of respirator.

Air-purifying respirators

Protective filter mask worn by NYPD officer

Air-purifying respirators are used against particulates (such as smoke or fumes), gases, and vapors that are at atmospheric concentrations less than immediately dangerous to life and health. The air-purifying respirator class includes:

- negative-pressure respirators, using mechanical filters and chemical media
- positive-pressure units such as powered air-purifying respirators (PAPRs)
- Escape Only respirators or hoods such as Air-Purifying Escape Respirators (APER) for use by the general public for chemical, biological, radiological, and nuclear (CBRN) terrorism incidents.

Full hood, half- or full-facepiece designs of this type are marketed in many varieties depending on the hazard of concern. They use a filter which acts passively on air inhaled by the wearer. Some common examples of this type of respirator are single-use escape hoods and filter masks. The latter are typically simple, light, single-piece, half-face masks and employ the first three mechanical mechanisms in the list below to remove particulates from the air stream. The most common of these is the disposable white N95 variety. The entire unit is discarded after some extended period or a single use, depending on the contaminant. Filter masks also come in replaceable-cartridge, multiple-use models. Typically one or two cartridges attach securely to a mask which has built into it a corresponding number of valves for inhalation and one for exhalation.

The American National Standard for Air-Purifying Respiratory Protective Smoke Escape Devices was established to define both test criteria and approval methods for fire/smoke escape hoods. ANSI/ISEA 110 provides design guidance to Respiratory Protective Smoke Escape Devices (RPED) manufacturers in the form of a detailed set of performance requirements and testing procedures. Key sections of the standard cover certification, labeling, design, performance, conditioning and testing requirements.

ANSI/ISEA 110 was prepared by members of the ISEA RPED Group, in consultation with testing laboratories and was reviewed by a consensus panel representing users, health and safety professionals and government representatives.

ANSI/ISEA Standard 110 contains general requirements for certification – including ISO registration for the manufacturer, independent process and quality control audits and follow-up inspection programs – and a comprehensive schedule of performance requirements and associated test methods.

The U.S. Consumer Product Safety Commission is using ANSI/ISEA 110 as the benchmark in their testing of fire escape masks, stating on their website, “Emergency escape masks have the potential to reduce consumer-related deaths and injuries by assisting in egress from fires, provided they perform effectively and reliably."

The Safety Equipment Institute (SEI) is a private, non-profit organization that administers a non-governmental, third-party certification program and tests and certifies a broad range of safety and protective products used occupationally and recreationally. SEI certification programs are voluntary and available to any manufacturer of safety and protective equipment seeking to have product models certified by SEI.

Mechanical filter respirators

Mechanical filter respirators retain particulate matter when contaminated air is passed through the filter material. This was the method used by early inventors such as Haslett and Tyndall. Wool is still used today as a filter, along with other substances such as plastic, glass, cellulose, and combinations of two or more of these materials. Since the filters cannot be cleaned and reused and therefore have a limited lifespan, cost and disposability are key factors. Single-use, disposable as well as replaceable cartridge models are common.

Filtering half mask with exhalation valve (class: FFP3)

Mechanical filters remove contaminants from air in the following ways:

1. by particles which are following a line of flow in the airstream coming within one radius of a fiber and adhering to it, called *interception*;
2. by larger particles unable to follow the curving contours of the airstream being forced to embed in one of the fibers directly, called *impaction*; this increases with diminishing fiber separation and higher air flow velocity
3. by an enhancing mechanism called *diffusion*, which is a result of the collision with gas molecules by the smallest particles, especially those below 100 nm in diameter, which are thereby impeded and delayed in their path through the filter; this effect is similar to Brownian motion and increases the probability that particles will be stopped by either of the two mechanisms above; it becomes dominant at lower air flow velocities
4. by using certain resins, waxes, and plastics as coatings on the filter material to attract particles with an electrostatic charge that holds them on the surface of the filter material;
5. by using gravity and allowing particles to settle into the filter material (this effect is typically negligible); and
6. by using the particles themselves, after the filter has been used, to act as a filter medium for other particles.

Considering only particulates carried on an air stream and a fiber mesh filter, diffusion predominates below the 0.1 µm diameter particle size. Impaction and interception predominate above 0.4 µm. In between, near the 0.3 µm most penetrating particle size (MPPS), diffusion and interception predominate.

For maximum efficiency of particle removal and to decrease resistance to airflow through the filter, particulate filters are designed to keep the velocity of air passing through the filter medium as low as possible. This is achieved by manipulating the slope and shape of the filter to provide larger surface area.

A substantial advance in mechanical filter technology was the HEPA filter. A HEPA filter can remove as much as 99.97% of all airborne particulates with aerodynamic diameter of 0.3 micrometres or greater.

United States NIOSH standards define the following categories of particulate filters:

Oil resistance	**Rating**	**Description**
Not oil resistant	N95	Filters at least 95% of airborne particles
	N99	Filters at least 99% of airborne particles
	N100	Filters at least 99.97% of airborne particles
Oil Resistant	R95	Filters at least 95% of airborne particles
	R99*	Filters at least 99% of airborne particles
	R100*	Filters at least 99.97% of airborne particles
Oil Proof	P95	Filters at least 95% of airborne particles
	P99	Filters at least 99% of airborne particles
	P100	Filters at least 99.97% of airborne particles
*No NIOSH approvals are held by this type of disposable particulate respirator.		

European standard EN 143 defines the following classes of particle filters that can be attached to a face mask:

Class	**Filter penetration limit (at 95 L/min air flow)**
P1	Filters at least 80% of airborne particles
P2	Filters at least 94% of airborne particles
P3	Filters at least 99.95% of airborne particles

European standard EN 149 defines the following classes of “filtering half masks” (also called “filtering face pieces”), that is respirators that are entirely or substantially constructed of filtering material:

Class	Filter penetration limit (at 95 L/min air flow)	Inward leakage
FFP1	Filters at least 80% of airborne particles	<22%
FFP2	Filters at least 94% of airborne particles	<8%
FFP3	Filters at least 99% of airborne particles	<2%

Both European standards test filter penetration with both dry sodium chloride and paraffin oil aerosols, after storing the filters at 70 °C and −30 °C for 24 h each. The standards also include tests on mechanical strength, breathing resistance and clogging. EN 149 also tests the inward leakage between the mask and face (ten human subjects perform five exercises each and for eight of these individuals the average measured inward leakage listed above must not be exceeded).

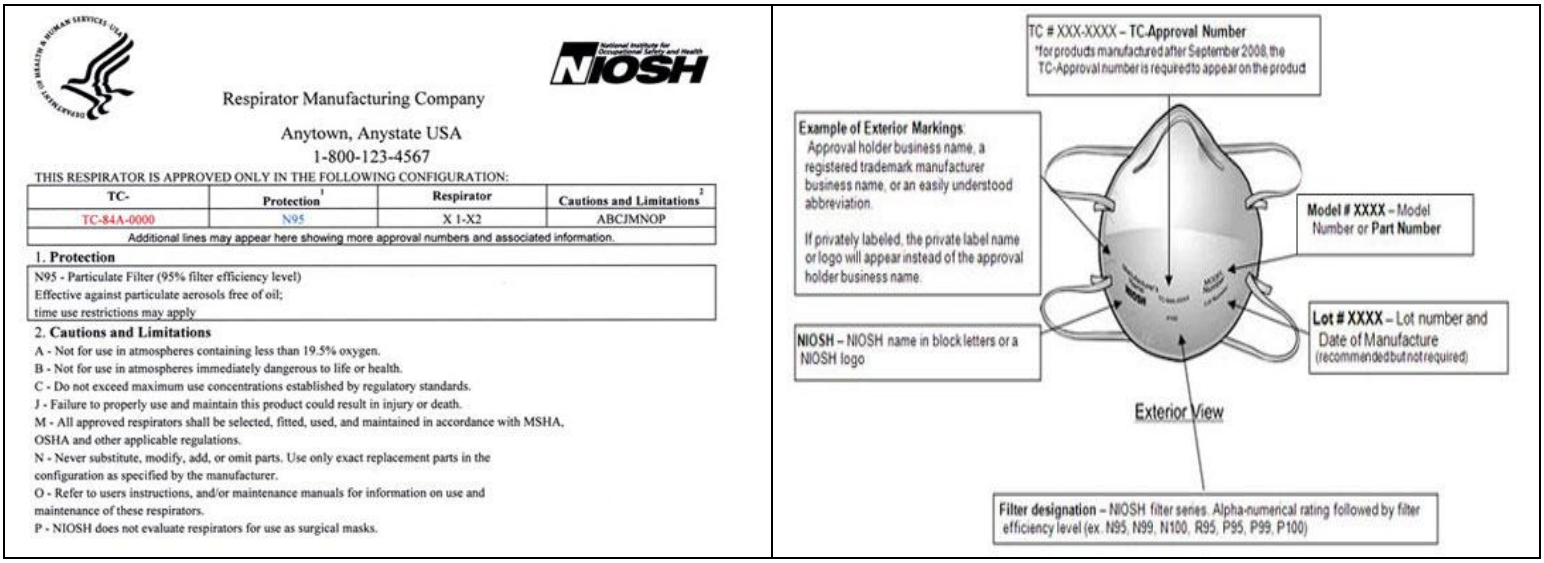
Markings and Approval Labels

When it comes to knowing if your respirator has a NIOSH approval, the label is important.

Identifying approved respirators is not too difficult if you know what to look for. **All NIOSH-approved respirators have an approval number.** With few exceptions the NIOSH approval number is not on the respirator itself, but on a separate NIOSH approval label which is found on or within the packaging. An example of this type of NIOSH label is shown in Figure 1. The approval number is shown in red, and the protection is shown in blue, N95 on this example. The NIOSH approval number and approval label are your keys to identifying NIOSH-approved respirators. Respirator approvals are occasionally revoked. If this should happen, NIOSH sends a User Notice to all NIOSH NPPTL listserv subscribers and removes the approval number from NIOSH listings of approved respirators. However, inventories of the revoked respirators still may be available for purchase or consumers may have them on hand from an earlier purchase. You may readily verify that respirator approvals are valid by checking the information links on the NIOSH Trusted-Source page or in the NIOSH Certified Equipment List (CEL). Users are encouraged to self-subscribe to the NIOSH listserv service to receive User Notice email notifications concerning the status of respirator approvals and other relevant information.

Both an approval label and user instructions are supplied with all NIOSH-approved respirators. These documents, a single copy of which may accompany either a large or small package of respirators, should not be discarded before all of the respirators are used or discarded. In addition to the approval number, the NIOSH approval label contains contact information for the respirator manufacturer/supplier, cautions, and limitations for use, and directions for proper use. It is very important to read and follow all of the manufacturer’s instructions for the particular respirator that you are using.

With regard to the approval number not appearing on the respirator, one important exception to note would be some filtering face piece respirators. Figure 2 below shows typical markings on approved filtering face piece respirators. The markings shown in red are present on all NIOSH-approved filtering face piece respirators, although they may appear either on the face, on the exhalation valve (if one exists) or on the head straps. The markings shown in black may or may not be on the respirator at all. The model or part number marked on the respirator will also appear on the approval label.



Respirator Manufacturing Company

Anytown, Anystate USA

1-800-123-4567

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection[1]	Respirator	Cautions and Limitations[2]
TC-84A-0000	N95	X 1-X2	ABCJMNOP

Additional lines may appear here showing more approval numbers and associated information.

1. **Protection**

N95 - Particulate Filter (95% filter efficiency level)
Effective against particulate aerosols free of oil;
time use restrictions may apply

2. **Cautions and Limitations**

A - Not for use in atmospheres containing less than 19.5% oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.

TC # XXX-XXXX – TC-Approval Number
*for products manufactured after September 2008, the TC-Approval number is required to appear on the product

Example of Exterior Markings:
Approval holder business name, a registered trademark manufacturer business name, or an easily understood abbreviation.

If privately labeled, the private label name or logo will appear instead of the approval holder business name.

Model # XXXX – Model Number or Part Number

NIOSH – NIOSH name in block letters or a NIOSH logo

Lot # XXXX – Lot number and Date of Manufacture (recommended but not required)

Exterior View

Filter designation – NIOSH filter series. Alpha-numerical rating followed by filter efficiency level (ex. N95, N99, N100, R95, P95, P99, P100)

Figure 1 - Example of NIOSH approval label.	Figure 2 - Example of typical markings on approved filtering face-piece respirators.

What is the meaning of a CE mark on Personal Protective Equipment?

The European Directive 89/686/EEC lays down the requirements for CE marking of personal protective equipment (PPE).
CE marking can, in simple terms, be described as a passport or 'license to sell' allowing free movement of goods within the internal market of the European Community.
It simplifies the task of market surveillance but also informs all market operators (consumers, manufacturers, tradesmen) that the product meets the essential requirements relating to safety, public health, consumer protection and other specific aspects of community interest laid down in the directives.
Amendments of Dir 89/686/EEC:

1. 93/68/EEC - CE not EC in text
2. 93/95/EEC - Products covered
3. 96/58/EEC - CE mark changes

When will PPE need a CE mark?

After May 1st 2004 the CE mark will be compulsory for all PPE placed on the market.
All 3M products are already CE marked.
PPE without a CE mark already in use before this date can continue to be used.
When the product becomes worn out or broken and you need to buy new equipment, it must be CE marked.

Does the CE mark tell me anything about the performance of the PPE?

The technical performance of PPE is specified by European Norms, harmonized standards or in a technical file when harmonized standard does not exists.
Very often you will find reference to this European Norm as additional information on the product, the packaging or other documentation.
This information is important to better understand the different performance classes and/or types of the PPE in use

Is the CE mark a quality symbol?

No, all CE marked PPE has to be submitted to the appropriate conformity assessment evaluation procedures according to the directive.
Only in certain cases can the procedure for maintaining a CE mark to be considered equivalent to that required for the quality mark.

What certification procedures are in place for different types of PPE?

The directive 89/686/EEC divides all PPE into three different categories according to the degree of risk. The higher the risk the PPE needs to protect against, the more stringent the certification procedure.

Category I

- All PPE protecting against minimal risks, where the user himself/herself can assess the level of protection needed, or where the effects are gradual and can safely be identified by the user in good time. e.g. gardening gloves, sunglasses, garments and footwear designed for use in bad weather conditions.

Certification Process:
The manufacturer has to assemble the technical documentation so that this can, if necessary, be submitted to the competent authorities = self declaration by means of EC declaration of conformity.

Category I products would be marked as follows: CE

Category II

- Head, face, eye protectors, garments, shoes and gloves protecting against normal risks
- All hearing protectors

Certification Process:
The manufacturer submits a model for EC type-examination, whereby an approved inspection body (notified body) establishes and certifies that the PPE-model in question satisfies the relevant provisions of the directive.

Marking of Category II products: CE

Category III

All PPE intended to protect against mortal danger or against dangers which may seriously and irreversible damage health, or where the effects cannot be identified in sufficient time.
e.g. respirators, fall arrestors All other PPE protecting against:

- extreme heat (>100°C)
- extreme cold (< - 50°C)
- electrical risks
- chemical and ionising radiation

Certification Procedure:
On top of the type EC examination required for category II products, the manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and test ensures the homogeneity of the conformity of PPE with the type described in the EC type-approval.

This can be done in 2 ways:
1. EC quality control system for the final product: necessary checks shall be carried out by a notified body at random, normally at intervals of at least a year. Art. 11A
2. System for ensuring EC quality of production by means of monitoring: installation of a quality control system under supervision of a notified body Art. 11B

Marking of Category III products: e.g. CE 0086

0086 is the identification number of the notified body involved in the production control phase.

Are there any documents that support the CE marking of PPE in use?

Yes, 2 documents can be obtained from 3M on request in order to complete your files on PPE in use.

1. EC-type examination certificate drawn up by the inspection body reproducing the findings of the examination on 3M products.
2. Declaration of conformity in which 3M certifies that the PPE placed on the market is in conformity with the directive

Chemical cartridge respirators

Chemical cartridge respirators use a cartridge to remove gases, volatile organic compounds (VOCs), and other vapors from breathing air by adsorption, absorption, or chemisorptions. A typical organic vapor respirator cartridge is a metal or plastic case containing from 25 to 40 grams of sorption media such as activated charcoal or certain resins. The service life of the cartridge varies based, among other variables, on the carbon weight and molecular weight of the vapor and the cartridge media, the concentration of vapor in the atmosphere, the relative humidity of the atmosphere, and the breathing rate of the respirator wearer. When filter cartridges become saturated or particulate accumulation within them begins to restrict air flow, they must be changed.

IMPORTANT NOTE

Mixing of Face-piece and Cartridges of different approvals - Care should be taken NEVER to mix face-piece and cartridges of different approvals. This renders the entire respirator as unapproved since the approvals are given for every cartridge with a particular Face piece and is mentioned on the approval certificate. The user should always demand for the approval certificate copy if not provided along with the supply and should make it clear that the name of the Face piece and the respirator are mentioned on the same document.