Reference 8

Expert Meeting on Radiological Protection for Decontamination and Related Works
Reference Material

Industrial dust masks, medical masks and general-use masks in Japan

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Industrial dust masks

Industrial dust masks in Japan are certified for their types pursuant to the notification of the Ministry of Health, Labour and Welfare, "Standards for Dust Masks", and have a certification mark attached on them. These are specified in the provision in the Industrial Safety and Health Act.

The masks are made to collect air-borne fine particulates. It has been demonstrated that they filter out particles ranging from nanoparticles (approx. 0.01μm and larger) to particles with diameters at the upper limit of respirable suspended particles (RSPs). For the filter efficiency test, either salt particles with a median diameter of 0.06-0.1 μm or a mist of dispersed oil particles (DOPs) with a median diameter of 0.150-0.25 μm are used.

The masks are either full-faced or half-faced designs and made of silicon rubber with replaceable filters attached, or charged processing disposable masks made of nonwoven cloth. Masks without certification cannot be called industrial dust masks, even though they are similar to those certified in terms of their configuration. Such masks are called dust masks or clean masks and available at DIY or hardware shops for use by the general public.

Medical masks (surgical masks)

Medical masks are worn to prevent infection and infiltration by air-borne droplets of body fluids. The particle sizes to be removed with these masks range from about 0.05 μm to as large as a few tens of μm; but are generally understood to remove particles larger than 5 μm. Because of the large size of these particles, their residence time in air is short and after dispersal they are considered to drop to the ground within a few meters. When a single infectious virus exists as particulates in the air (for example, the SARS virus of ≤0.1 μm size), medical masks are not sufficient for protection and industrial dust masks of at least N95 or DS2 class are used.

In the US, medical masks for infectious aerosols are classified as surgical masks and they need to be registered with the FDA (US Food and Drug Administration). These masks have the FDA

registration numbers indicated on them.

- FDA: Surgical Masks-Premarket Notification, 510 (k)

Mask manufacturers submit their products together with the results of the performance test of the products conducted according to the specified standards to the FDA for registration. N95 masks that have been certified by the National Institute of Occupational Safety and Health (NIOSH) for use as a disposable industrial dust mask also have to be re-registered by the FDA when these masks are used as surgical masks, despite the performance of the masks having been guaranteed. In this case, no performance test data needs to be attached to the application.

In US in the past, there were standards for the design of the surgical masks. However, they do not exist any longer. The FDA will judge the acceptability by comparing the current products with those in the past. In general, the face area covered by the latest masks has been extended. Some of the available products are shown below.




The performance test methods for surgical masks specified by the FDA are specified in the American Society for Testing and Materials (ASTM) as shown below:

- ASTM F 2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus
- ASTM F 2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F 1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F 2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks

In Japan there are no particular provisions concerning surgical masks with respect to the designation or performance.

The Japan Hygiene Products Industry Association (JHPIA) is an organization of manufacturers of masks used by the general public in daily life. They voluntarily control the labels of their masks to avoid exaggerated expression of their performance based on the instruction from the Consumer Affairs Agency. Within the Association, there are no regulations for the performance testing of masks.

The only performance test applied for surgical masks is JIS T 8062: 2010.

- JIS T 8062: 2010 Clothing for protection against infectious agents - Face masks – Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

This standard does not address the shapes or structures of masks, it only considers the performances of filter materials. This JIS standard is non-obligatory and voluntary. Some of the unwoven masks marketed for flu viruses have an indication of their performance being tested by ASTM2101 after the Japanese mask manufacturers voluntarily requested a US test organization confirm the performance. Even in this case, the test is conducted only for filter materials and does not include the standards for any shapes of masks.

Types and names of masks for flu viruses and others recommended by the Japanese government

During a relatively recent epidemic of infectious respiratory disease (i.e. a new strain of influenza) that required government intervention, the government issued guidelines in which it provided an instruction below for the use of masks.

For a new strain of influenza (Swine flu) in 2007:

- Guidelines for measures to prevent infection at medical facilities
  - ✓ Health professionals in contact with patients and staff who handle patients' waste shall wear surgical masks
  - ✓ Those staff members who enter patients' rooms controlled under a negative pressure shall wear N95 masks
  - ✓ Patients leaving their rooms shall wear surgical masks
- Guidelines for measures to protect from a new strain influenza taken by individuals, at homes or in communities
  - ✓ People who are coughing and/or sneezing shall proactively wear masks to avoid the dispersal of airborne droplets. Masks shall be nonwoven types.

As stated above, staff members are instructed to wear surgical masks at medical facilities. However, there are neither performance standards nor any registration system for either surgical masks or nonwoven masks. Therefore it is difficult to determine which products fall under the category of

surgical masks.

The JHPIA classifies general-purpose or home-use masks into gauze types and nonwoven types. The JHPIA calls masks used for medical purposes surgical masks. Since there are no legal standards or certification systems for these masks, the JHPIA has established a product labeling standard on a voluntary basis.