3M Health Care

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Subject: **Request for Public Comments on the "Draft Guidance for Industry and FDA Staff. Surgical Masks – Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA" dated May 15, 2003 [Docket number 03D-0137]**

As a manufacturer of surgical masks and respirators, 3M would like to comment on the recently published draft guidance document on surgical masks [docket number 03D-0137]. Please consider our comments, and feel free to contact us if discussion is required at the above address.

Section 1

Lines 17-20; We agree that this document should guide industry in preparing premarket notification submissions for surgical masks. However, we believe that the current 21 CFR 878.4040 definition does not accurately represent the scope of the document. According to that definition, "Surgical masks" are those devices that are worn by operating room personnel during surgical procedures..." This definition does not consider intended uses outside of the operating room arena (i.e. isolation, dental, or procedures). We recommend that the guidance document clearly inform the reader that these other intended uses are included in the FDA's interpretation of the 21 CFR definition for surgical masks.

3M believes a better surgical mask definition would be defined as "devices worn by ***health care professionals*** during ***medical procedures*** to protect both the patient and the ***health care worker*** from the transfer of microorganisms, body fluids, and particulate matter generated during possible splash and splatter."

In addition, surgical masks should be differentiated from respirators such that surgical masks provide barrier protection to help prevent microorganisms and body fluids from reaching the patient and wearer. Whereas, National Institute for Occupational Safety and

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Health (NIOSH)-approved particulate respirators are intended to provide respiratory protection to the wearer by filtering particles and also providing a barrier while forming a seal to the face.

Section 4

Line 133;
Respirators should be referred to as "NIOSH-approved Particulate Respirators" instead of "N95 Respirator". There are 9 classes of NIOSH-approved particulate respirators and respirators from any of these classes could also be cleared as a surgical mask.

Line 139-141; The OSHA Respiratory Protection Standard requires that all devices used to provide respiratory protection be certified by NIOSH. Therefore, any workplace that uses a device for worker respiratory protection that is not approved by NIOSH is in violation of OSHA regulations. Any surgical mask wishing to claim respiratory protection to the wearer ***must be*** approved by NIOSH as a respirator.

Section 6

Line 195; The identified risk "Inadequate bacterial filtration efficiency" should be changed to read "Inadequate barrier for bacteria." Bacterial filtration efficiency (BFE) is a test to determine if the risk has been mitigated. BFE is not the risk.

The identified risk "Inadequate respiratory protection for wearer" should be added to the table. The recommended mitigation measure for this risk is "NIOSH approval"

Section 7:

Line 217; The device should be allowed to claim fluid resistance if the device passes ASTM F 1862-00a at any of the three levels (80, 120 or 160 mm Hg).

Section 8

Lines 222-230; Although not referenced in the Draft document, we assume that the FEP test that FDA is referring to is ASTM F 2100-02 (Standard Specifications for Performance of Materials Used in Medical Face Masks), which cites a "Sub-micron particulate filtration efficiency at 0.1 micron" of ≥ 98% and refers to ASTM F 1215-89 (Standard Test Method for Determining the Initial Efficiency of a Flatsheet Filter Medium in an Airflow Using Latex Spheres) for the test method.

It is misleading to refer to the filtration efficiency in a surgical mask without also taking into consideration its ability to provide a good seal around the wearer's face. Particles and air will take the path of least resistance and pass through the gaps between the mask and the face instead of through the filter media. We urge the FDA to consider removing the "Filter Efficiency Performance" (FEP) test for surgical masks *unless the mask is clearly labeled that it does not provide respiratory protection.* We realize that the

industry uses this test to differentiate between similar masks, but it can be misleading to users without this statement. If there exists a hazard for which respiratory protection is required, then the mask used must also pass the 42 CFR 84 test requirements and carry NIOSH approval. The most important reason for requiring this statement is that without it there is a potential to increase the risks to health that the FDA is trying to minimize. The existence of the FEP claim alone creates confusion in the user community, where it can be interpreted as an *alternative* product to the NIOSH approved particulate respirator. Uninformed users may easily misinterpret statements about 0.1 μm filtration efficiency as evidence that the surgical mask provides respiratory protection without this statement.

If the FDA continues to recommend the FEP test as a measure of risk mitigation, we advocate that the reference to "unneutralized" particles (line 228) be changed to "neutralized" particles to maintain consistency with ASTM F 1215-89. ASTM F 1215-89 recommends the use of neutralized particles. In addition, we urge the FDA to recommend a flow rate for the FEP test. This would allow a consumer to compare FEP results between masks, something that is not possible without a specified flow rate.

Section 9

Lines 248, 249; The reference to "N95" should be removed and replaced by "NIOSH-approved particulate"

Section 11

Lines 288-290; Any surgical mask wishing to claim respiratory protection for the wearer must be approved by NIOSH as a respirator. The reference to "N95" should be removed and replaced by "NIOSH-approved particulate"

Lines 290-291: The Introduction of this document (lines 17-20) clearly states that this guidance is for devices intended to be used by operating room personnel during surgical procedures. 3M believe the FDA should expand this definition to clearly include other intended uses such as the dental, procedure and isolation uses. The scope as it is stated masks worn in an operating room does not include these other indications.

Appendix II

Lines 315: The reference to "N95" should be removed and replaced by "NIOSH-approved particulate." Microns should be changed to percentage.

Line 317: The reference to "N95" should be removed and replaced by "NIOSH-approved particulate "

Additional Comments

1. Respiratory protection is recommended to help reduce exposures to biological agents in healthcare settings. For airborne contaminants, including biological agents, that can cause disease through the airborne route, it has been widely recognized that use of NIOSH-approved particulate respirators are necessary to provide respiratory protection to the wearer.[1] For example, the Centers for Disease Control and Prevention (CDC) has recognized that NIOSH-approved particulate respirators are necessary for those situations in which respiratory protection for the wearer is needed, including exposures to *Mycobacterium tuberculosis*[2,3], *Bacillus anthracis*[4] and the virus that causes Severe Acute Respiratory Syndrome[5].

As an example, regarding *M.tuberculosis* the CDC states[1]

"The first step in preventing the spread of TB is to quickly identify, isolate and properly treat contagious patients. Nearly all TB patients under proper treatment will become "non-contagious," that is, he or she will not be able to transmit the disease to others. Other steps to reduce the spread of the disease include ventilation to remove the bacteria from the air you breathe, and ultraviolet lights that kill the bacteria...

When you are in close contact with a contagious TB patient, none of these steps will completely protect you, and respirators are needed."

[1]Occupational Safety and Health Administration. 1910.134 Respiratory protection. 29 CFR Ch. XVII (7–1–99 Edition)

[2]"Protect Yourself Against Tuberculosis -- A Respiratory Protection Guide for Health Care Workers" **(DHHS (NIOSH) Publication No. 96-102, National Institute for Occupational Safety and Health Publications Dissemination, Cincinnati, OH)**

[3]CDC Publication MMWR Oct. 28, 1994/Vol. 43/No. RR-13. *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities.*

[4]CDC Interim* Recommendations for Protecting Workers from Exposure to *Bacillus anthracis* in Work Sites Where Mail Is Handled or Processed (*Updated from CDC Health Advisory 45 issued 10/24/01) October 31, 2001, http://www.bt.cdc.gov/DocumentsApp/Anthrax/10312001/han51.asp).

[5]Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS, May 6, 2003, http://www.cdc.gov/ncidod/sars/respirators.htm)

2. Respiratory protection will not be provided without a good fit and high filtration efficiency. When respiratory hazards in the workplace cannot be controlled by engineering controls (i.e. ventilation), the Occupational Safety and Health Administration (OSHA) requires the use of respirators approved by the National Institute for

Occupational Safety Health (NIOSH)[1]. NIOSH evaluates the filtration performance of the respirator as part of the certification under 42 CFR Part 84.

OSHA regulates proper use of the respirator. Proper use encompasses proper selection, medical evaluation, training and fit testing within a respiratory protection program as specified by OSHA's Respiratory Protection Standard, 1910.134. Under OHSA 1910.134, the user is required to do a fit test before they wear a respirator for the first time. They are also required to do a user seal check (i.e. fit check) every time they put the respirator on. If they notice any leakage around the edges of the respirator, they cannot enter the contaminated area. Filtering facepiece respirators must fit tightly to the face to form a seal with the user's skin. In addition, male users must be clean-shaven (within 24 hours) so that the skin is smooth and a seal can be formed. NIOSH-certified filtering facepiece respirators cannot be loose-fitting or the wearer will not be able to pass a fit test or do a user seal check. Gaps between the edge of the respirator and the user's face increases the air and particles that enter into the breathing zone of the user. A good seal, and therefore a good fit, is essential to providing proper respiratory protection. Any device, such as a surgical mask, that has gaps between the mask and the face may not form a tight seal to the face, will not provide adequate respiratory protection or a reduction in exposure, even if the filter media has a very high efficiency.

[1]Occupational Safety and Health Administration. 1910.134 Respiratory protection. 29 CFR Ch. XVII (7–1–99 Edition)

3. Particles larger than 5 microns in diameter are considered airborne hazards : A potential source of confusion on the appropriate use of respirators and surgical masks is the Centers for Disease Control and Prevention's (CDC) "Guideline for Isolation Precautions in Hospitals" [1]. The Guideline distinguishes between airborne transmission of inhalable particles and droplet transmission of particles that are propelled through the air (e.g., by sneezing) and infect a person through contact with the conjunctivae, nasal mucosa, or mouth. The Guideline defines airborne particles as those 5 microns (μm) or smaller in size and droplets as those larger than 5 μm. The Guideline recommends the use of a respirator for protection against airborne particles whereas a mask is recommended for droplets.

The distinction between airborne and droplet transmission is important, because the routes of infection are quite different. However, it is not clear how CDC arrived at the definition of airborne and droplet particles, which appears without any reference, citation, or other supporting documentation. The CDC definition of airborne particles is contrary to that of the American Conference for Governmental Industrial Hygienists (ACGIH), which has defined "inhalable" particles (i.e., those that can enter and be deposited in the respiratory tract), as those less than 100 μm. The ACGIH definition[2] is based on an extensive review of research published in peer reviewed literature (see also Hinds[3] for a thorough review). Particles in the 100 μm size range are still small enough to be inhaled into the respiratory system. Commonly accepted industrial hygiene practice assumes that all particles of 100 μm and less are health hazards through the airborne route. Consequently, CDC's recommendation of a surgical mask for protection against particles

larger than 5 μm (rather than a tight-fitting respirator) poses the risk of infection for health care workers.

The paradigm of airborne transmission and droplet transmission of infectious agents remains valid; however, the assumption that particles greater than 5 mm in size cannot be transmitted through the airborne route has not been proven. Therefore, until there is a better understanding of the particle size of infectious agents, it would be more appropriate to recommend a respirator for all particles that are 100 μm or less. For particles larger than that size, a surgical mask may be adequate; for particles smaller than that size, a respirator should be used.

[1]Garner JS, et al., *Hospital Infection Control Practices Advisory Committee. Guideline for Isolation Precautions in Hospitals, Infect Control Hosp Epidemiol 1996;17:53-80, Am J Infect Control 1996;24:24-52, and* http://www.cdc.gov/ncidod/hip/isolat/isolat.htm

[2]2002 Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices. American Conference of Governmental Industrial Hygienists, Cincinnati, OH.

[3]Hinds, W.C. Aerosol Technology, 2nd Ed., J. Wiley & Sons, 1999, pp 233-259.

4. The Filter Efficiency Performance (FEP) test is not an appropriate or rigorous test of filtration efficiency: Although not referenced in the Draft document, we assume that the FEP test that FDA is referring to is ASTM F 2100-02 (Standard Specifications for Performance of Materials Used in Medical Face Masks), which cites a "Sub-micron particulate filtration efficiency at 0.1 micron" of ≥ 98% and refers to ASTM F 1215-89 (Standard Test Method for Determining the Initial Efficiency of a Flatsheet Filter Medium in an Airflow Using Latex Spheres) for the test method. However, ASTM F 1215-89 specifies testing with latex spheres ranging in size from 0.5 to 5.0 μm and air flow velocities between 1 and 25 cm/s. This test method can reasonably be extended to particles of 0.1 μm diameter by those practiced in the art; however, it does not provide any guidance on selecting a flow rate (velocity) for tests, nor does ASTM F 2100-02 specify a flow rate (velocity). The efficiency of a filter is highly dependent on the flow rate of the test, so without a flow rate specification test results can not be compared between filters. The lack of a flow rate standard makes the FEP test results much less meaningful, and the test would be strengthed immensely by the specification or recommendation of a flow rate.

If the FDA continues to recommend the FEP test as a measure of risk mitigation, we advocate that the reference to "unneutralized" particles (line 228) be changed to "neutralized" particles to maintain consistency with ASTM F 1215-89. ASTM F 1215-89 recommends the use of neutralized particles. Neutralization is important because the test aerosol is produced by atomization of water containing polystyrene latex (PSL) spheres. Atomization produces a cloud of water droplets, each of which contains a PSL sphere. The water evaporates, leaving just the solid particle. Electrolytic charging of the water droplet, which naturally occurs during the atomization process (see reference 1),

followed by evaporation of the water produces high charge levels on the PSL particles. The charge on the particles (which can be many times the natural charge level such a particle would attain) contributes significantly to their electrostatic capture on fibers in the mask, yielding a misleading measure of filtration performance. In this case, an unneutralized particle does not mimic the charge state of a naturally occurring particle. Therefore, the test method would be improved and more consistent with accepted filter testing practices if the FDA specifically recommended the use of neutralized particles.

Reference:

1. Hinds, W.C. Aerosol Technology, 2nd Ed., J. Wiley & Sons, 1999, pp 324, 434.