DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) Announcement Opportunity for Businesses To Partner With National Institute for Occupational Safety and Health (NIOSH) on a Research Project To Evaluate the Reusability of Disposable Filtering Facepiece Respirators (FFR) Used for Protection Against Infectious Aerosols

Summary: The National Personal Protective Technology Laboratory (NPPTL), NIOSH, is conducting research to determine the reusability of filtering facepiece respirators (FFR) exposed to infectious aerosols. One aim of this research is to address whether NIOSH-certified FFR are suitable for reuse after decontamination. NIOSH proposes to study the effects of decontaminating a diverse array of FFR including NIOSH-certified N95, P100, and N95 filtering facepiece respirator/surgical mask. This project will also study the survivability of a simulant influenza virus on FFR. NIOSH plans to include in the research study some of the respirator models that have been stockpiled by the U.S. government to be used in the event of an influenza pandemic. NIOSH also plans to include models that have head straps versus those that do not have head straps, as well as models with and without exhalation valves.

Through this announcement, NIOSH is seeking to identify FFR products or prototypes that possess anti-viral or other novel technologies that disinfect or sterilize infectious aerosols (e.g., viruses) as part of their materials of construction. Program funding constraints may limit the number of candidate respirators that may be included in the research program. NIOSH will give consideration to the incorporation of novel anti-viral technologies into this research study using the following hierarchy for selection of candidate FFR products and prototypes: (1) The FFR proposed for consideration in this study are commercially available and are currently certified to meeting 42 CFR part 84 requirements, (2) the FFR proposed for consideration is in the process of being certified by NIOSH to meet 42 CFR part 84 requirements, (3) the FFR proposed for consideration are either a prototype or a commercially available product that has not been submitted to NIOSH for certification and the manufacturer submitting the letter of interest has received NIOSH certification for other respiratory protection products, and (4) the FFR prototype contains a unique technology for disinfecting or sterilizing infectious aerosol particles trapped on the exterior surface of the FFR and complements the diversity of technologies already considered in the research design. Candidate companies will be evaluated based on their capability to achieve the identified criteria in sufficient quantities for testing. Candidates selected could be requested to enter into a Cooperative Research and Development Agreement (CRADA). This announcement does not obligate NIOSH to enter into a contractual agreement with any respondents. NIOSH reserves the right to establish a partnership based on scientific analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.

Dates: Submit letters of interest within 30 days after the date of publication of this notice in the Federal Register.

Addresses: Interested manufacturers should submit a letter of interest with information about their capabilities to: NIOSH, National Personal Protection Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Attn: Jonathan Szalajda, Pittsburgh, PA 15236, E-mail address: szf1@cdc.gov.

Supplementary Information: CDC recommends the use of disposable N95, N99, or N100 filtering facepiece particulate respirators (FFR) as the minimum level of respiratory protection against transmission of influenza virus. During a respirator shortage, it is important to consider whether a previously worn FFR can be used again. Reuse guidelines in the NIOSH Guide to the Selection and Use of Particulate Respirators Certified under 42 CFR 84 recommend reuse based on loading of the filter and functioning of the respirator. Hospital settings tend to have relatively low concentrations of particulates, but the potential for infectious agents exists. Thus, reuse is more dependent upon infection control procedures than on respirator loading considerations. Respirators exposed to viruses are considered to be potentially harmful because of the possibility for the respirator to act as a fomite and the potential for the viral particle to become dislodged during a sneeze/cough or from rough handling. Thus, respirators worn in the presence of a potentially infected patient or co-worker should be disposed of as infectious waste, and touching of the outside of the respirator should be avoided.

In January, 2006, the Department of Health and Human Services asked the Institute of Medicine (IOM) to convene a committee to conduct an assessment of measures that can be taken that would permit the reuse of disposable N95 particulate filtering respirators in healthcare settings and to report the status of current knowledge about the need and development of reusable N95 respirators for healthcare providers and the general public. Some of the key recommendations from that study were that research studies should be conducted to (1) understand the efficacy of simple decontamination methods that could be used without negative effects on respirator integrity; and (2) understand the risks associated with handling a respirator that has been used for protection against a viral threat (e.g., study the likelihood that the exterior surface of the respirator might harbor pathogenic microorganisms and thus serve as a fomite).

This research project addresses the major research gaps related to the reusability of filtering facepiece respirators (FFR) during an influenza pandemic. NIOSH/NPPTL plans to conduct a variety of tasks in this research project, including: (1) Determining the effect of decontamination on FFR filtration.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Portfolio on the Division of Human Development and Disability

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Portfolio on the Division of Human Development and Disability.

Times and Dates:
6 p.m.–8 p.m., October 22, 2006 (Closed).
8 a.m.–5 p.m., October 23, 2006 (Closed).
8 a.m.–3 p.m., October 24, 2006 (Closed).

Place: National Center on Birth Defects and Developmental Disabilities, CDC, 12 Executive Park Drive, Atlanta, Georgia 30329, Telephone Number 404.498.3013.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

SUMMARY: Section 103(d) of the Americans with Disabilities Act of 1990, Public Law 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The Centers for Disease Control and Prevention (CDC) published a final list on August 16, 1991 (56 FR 40897) and updates on September 8, 1992 (57 FR 40917); January 13, 1994 (59 FR 4918); August 15, 1996 (61 FR 42426); September 22, 1997 (62 FR 49518–9); September 15, 1998 (63 FR 49359), September 21, 1999 (64 FR 51127); September 27, 2000 (65 FR 58088), September 10, 2001 (66 FR 47030), and September 27, 2002 (67 FR 61109). The final list has been reviewed in light of new information and has been revised as set forth below.

EFFECTIVE DATE: September 26, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Donald Sharp, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G–24, Atlanta, Georgia 30333 Telephone: (404) 639–2213

SUPPLEMENTARY INFORMATION: Section 103(d) of the Americans with Disabilities Act of 1990, 42 U.S.C. 12113(d), requires the Secretary of Health and Human Services to:
1. Review all infectious and communicable diseases which may be transmitted through handling the food supply;
2. Publish a list of infectious and communicable diseases which are transmitted through handling the food supply;
3. Publish the methods by which such diseases are transmitted; and,
4. Widely disseminate such information regarding the list of diseases and their modes of transmissibility to the general public. Additionally, the list is to be updated annually. Since the last publication of the list on October 4, 2004 (67 FR 61109), new information has been reviewed and added. Norwalk and norwalk-like viruses, previously listed in Part I, are now identified as noroviruses so as to conform with current scientific nomenclature. Sapoviruses have been added to Part II.

I. Pathogens Often Transmitted by Food

The contamination of raw ingredients from infected food-producing animals and cross-contamination during processing are more prevalent causes of foodborne disease than is contamination of foods by persons with infectious or contagious diseases. However, some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: Diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. The failure of hand-holders to wash hands (in situations such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage, for example), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors.

Matters To Be Discussed: The meeting will include expert review of science and programs of the Disability and Health Team.

Contact Person for More Information: Esther Sumartojo, Associate Director for Science, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE, Mailstop E–87, Atlanta, GA 30333, Telephone Number 404.498.3072.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 18, 2006.

Alvin Hall,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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