BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings during an Infectious Disease Outbreak/Pandemic

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces this request for information regarding the deployment and use of elastomeric half-mask respirators in healthcare settings and emergency medical services (EMS) organizations during the COVID-19 crisis.

DATES: Comments must be received [**INSERT DATE** 30 days **AFTER PUBLICATION DATE IN THE FEDERAL REGISTER**].

ADDRESSES: Responses should be submitted to Dr. Lee Greenawald, NIOSH, 626 Cochrans Mill Road, Building 141, Pittsburgh, PA, 15236, or ppeconcerns@cdc.gov

FOR FURTHER INFORMATION CONTACT: Lee Greenawald, NIOSH, 626 Cochrans Mill Road, Building 141, Pittsburgh, PA, 15236; phone: (412) 386-6465 (not a toll-free number, email: ppeconcerns@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Informational submissions in response to this request for information (RFI) are due no later than [**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. Please limit informational submissions for each of the two sections to five pages or less (for a total of 10 pages or less).

NIOSH will not respond to individual informational submissions or publish publicly a compendium of responses. An informational submission in response to this RFI does not create any commitment on or behalf of CDC or HHS to develop or pursue the program or ideas discussed.

Respondents are requested to provide the following information at the start of their informational submission in response to this RFI:

- Company / institution name;
- Company / institution contact;
- Contact's address, phone number, and e-mail address.

Please provide any additional relevant background information about yourself or your organization but note that submissions will not be redacted.

Introduction

An elastomeric half-mask respirator (EHMR) is a non-powered air-purifying respirator that has a tight-fitting facepiece that covers the nose and mouth. The facepieces are made of synthetic or natural rubber material permitting repeated cleaning, disinfection, storage, and reuse. EHMRs use replaceable filters or cartridges, and they provide at least the same level of protection as single-use N95 filtering facepiece respirators (FFRs). As outlined in the Code of Federal Regulations[1],all EHMR models used in U.S. workplaces must be evaluated and approved by NIOSH's National Personal Protective Technology Laboratory (NPPTL). In 2018, NIOSH/NPPTL sponsored a National Academies of Sciences, Engineering, and Medicine Consensus Study Report[2] that discussed the feasibility of reusable respirator use (including EHMRs) for routine and surge situations in U.S. healthcare organizations. The National Academies' report also recommended various EHMR-related research activities related to cleaning/disinfection, fit testing, cost/market

[1] 42 CFR Part 84 – Approval of Respiratory Protective Devices. https://ecfr.io/Title-42/Part-84

2 https://www.nap.edu/catalog/25275/reusable-elastomeric-respirators-in-health-care-considerations-for-routine-and

analyses for EHMRs introduced to healthcare, and healthcare user acceptability considerations.

Although EHMRs have been used routinely in healthcare settings, they are not considered medical devices pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and thus are not typically authorized for use as U.S. Food and Drug Administration (FDA)-approved medical devices. However, in response to the COVID-19 crisis, FDA has issued an emergency use authorization (EUA) authorizing the "emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act," including EHMRs.[3] The Strategic National Stockpile (SNS) plans to purchase EHMRs to be deployed to and used by healthcare organizations in order to diversify the respiratory protection options available to healthcare workers and emergency responders during the COVID-19 crisis.

NIOSH anticipates that the widespread use of EHMRs will ease the demand for single-use N95 FFRs in healthcare settings experiencing high numbers of COVID-19 patients. In media reports about the COVID-19 crisis, medical professionals have noted that the use of EHMRs has been

[3] 85 FR 17335 (March 27, 2020).

critical to the response, especially during shortages of N95 FFRs. Wearers note that EHMRs are comfortable to wear, and that given their low cost, ease of use, and ability to be cleaned and decontaminated, hospitals have found these devices to be valuable in keeping workers safe.[4]

In order to gather more information from EHMR users in healthcare and emergency response settings, NIOSH is seeking input on two related endeavors: a deployment of EHMRs across the nation from the SNS, and future NIOSH EHMR demonstration projects. NIOSH's specific information needs are described below.

Defining a national strategy to inform the purchase, deployment, and use of reusable EHMRs in healthcare settings during an infectious disease outbreak/pandemic.

NIOSH seeks information and ideas that may be used by the SNS to conduct a program to solicit and obtain a diverse group of healthcare organizations to participate in a deployment of EHMRs across the nation.

The intent is for the SNS to provide participating organizations with a fixed quantity of the EHMR devices it purchases to use in their healthcare activities. Each participating organization will also receive the EHMR Best

[4] Hamby C. May 2020. They Evoke Darth Vader, but These Masks May Save your Doctor's Life. https://www.nytimes.com/2020/05/27/us/coronavirus-masks-elastomeric-respirators.html.

Practice Guidelines/Hospital Implementation Guide prepared by NIOSH. Each participating organization will provide NIOSH a detailed report of its experiences using the EHMRs, including user acceptability and feasibility of implementation. These reports will inform future updates to the Best Practice Guidelines/Hospital implementation Guide.

The types of potential participant organizations that will be sought include, but are not limited to, hospital systems, hospitals, hospital intensive care units (ICUs), hospital general wards, hospital emergency departments, outpatient care settings, nursing homes, dental organizations, and first responders, including, but not limited to, emergency medical services, police officers, and firefighters.

Please provide responses to one or both of the following:

1. Provide a Statement of Interest (SOI) to participate in the deployment of EHMRs across the nation:

    a. Describe the nature of the organization that desires to participate, including type, geographical location (including rural or urban), size (e.g., hospital beds, healthcare staff), and prior experience with the organizational use of

EHMRs. Although prior experience with EHMRs is not required, any EHMR experience can be specified, including manufacturers, model numbers, and quantity of devices used;

b. Describe the proposed approach regarding how the received EHMRs would be implemented into the organization (e.g., strategy for distribution to the appropriate staff and care settings); and

c. Describe the interested participant's commitment to developing a report based on the EHMR experiences of staff.

2. Provide information that will assist the SNS and NIOSH in the following:

a. Defining the strategic parameters of this distribution program; for example, considerations about fit testing, training, education, filter change-out schedule, cleaning/disinfection, storage considerations, and appropriate clinical care settings for EHMR use; and

b. The potential criteria to be used to determine how the purchased devices should be distributed; for example, the technical approach of the use of the EHMRs, and technical

qualifications of key staff who would lead the initiative.

Interest in participating and refining additional, future, EHMR demonstration projects

In addition to NIOSH's current EHMR research activities, NIOSH is considering conducting additional EHMR demonstration projects. These EHMR demonstration projects would consist of healthcare or EMS organizations using EHMRs in their respiratory protection programs and providing user acceptability feedback, such as on fit testing and disinfection protocols, among other implementation parameters. The full scope of these additional EHMR demonstration projects is still being defined. NIOSH seeks information on interest in participating as a future demonstration site to gauge interest in the nationwide implementation of using EHMRs in hospital and EMS settings to supplement current respiratory protection program activities, and to collect additional user input parameters not currently being collected in the current activities.

The types of potential participant organizations that will be sought include, but are not limited to, hospital systems, hospitals, hospital intensive care units (ICUs), hospital general wards, hospital emergency departments,

outpatient care settings, nursing homes, dental organizations, and first responders, including, but not limited to, EMS, police officers, and firefighters.

Please provide responses to one or both of the following:

1. Provide a Statement of Interest (SOI) describing interest in participating in future EHMR demonstration project activities. The SOI should describe the nature of the organization that desires to participate as a demonstration site, including type, geographical location (including rural or urban), size (e.g., hospital beds, healthcare staff), and prior organizational experience with the use of EHMRs. The SOI should also provide reasons for interest in participating as a demonstration site. Prior experience with the use of EHMRs will NOT be required to participate in the EHMR demonstration project activity. The description of an approach that has the potential to be effective for conducting a demonstration project will be required.

2. Provide information that will assist NIOSH in the refinement of the EHMR demonstration projects, including the following:

a. Defining the strategic parameters of this EHMR demonstration activity; for example, considerations of fit testing, training, education, filter change-out schedule, cleaning/disinfection, storage considerations, and appropriate clinical care settings for EHMR use; and

b. The potential criteria to be used to determine how the EHMR devices should be distributed to the demonstration sites; for example, the technical approach of the use of the EHMRs, and technical qualifications of key staff who would lead the initiative.

No SNS Applications will be accepted through this RFI: While the strategy for distribution of the purchased EHMRs is being developed, its details will only be finalized after consideration and analysis of the informational submissions in response to this RFI.

Disclaimer and Important Notes

This RFI is for planning purposes; it does not constitute a formal announcement for comprehensive applications. In accordance with Federal Acquisition Regulation 48 C.F.R. 15.201(e), responses to this RFI are not offers and cannot be accepted by the Government to form

a binding award. NIOSH will not provide reimbursement for costs incurred in responding to this RFI.

Dated: September 8, 2020.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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