



**Billing Code 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Partnership Opportunity to Develop New Designs of Powered Air-Purifying Respirators for Healthcare Workers**

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

**ACTION:** Notice

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), announces the opportunity for inventors, researchers, and/or respirator manufacturers to participate, through a collaborative agreement, in a project titled "New Generation Powered Air-Purifying Respirators," to develop new designs of powered air-purifying respirators (PAPRs) for healthcare workers.

**DATES:** Interested parties must submit a letter of intent, electronically or written, by **[INSERT DATE 30 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**FOR FURTHER INFORMATION and to SUBMIT A LETTER OF INTENT**

**CONTACT:** Dr. Ziqing Zhuang, NIOSH National Personal Protective Technology Laboratory, 626 Cochran's Mill Road,

Pittsburgh, PA 15236, 412-386-4055 (not a toll-free number), zaz3@cdc.gov

Letters of intent should be sent electronically to Dr. Zhuang at the email address listed.

**SUPPLEMENTARY INFORMATION:**

*Additional Information:* The National Institute for Occupational Safety and Health (NIOSH) is seeking to identify inventors, researchers, and/or respirator manufacturers with the respirator design and manufacturing capabilities to construct a new respirator prototype, based on the characteristics included in this notice.

This research endeavor grew from recommendations issued by the National Academies, Institute of Medicine's (now known as the National Academy of Medicine) 2008 report, "*Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers;*" [2011](#) report, "*Respiratory Diseases: Personal Protective Equipment for Healthcare Workers: Update 2010;*" and 2015 report, "*The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary.*" These reports outline the next steps toward better respiratory protection for healthcare workers.

This project aims to create and develop new concepts in PAPR design targeted for healthcare workers using a government-private partnership development model.

During the first phase of the project, a team of researchers from NIOSH's National Personal Protective Technology Laboratory will develop a set of consensus recommendations for this project, that, if implemented, are expected to improve the function and utility of respiratory protective devices used by healthcare workers. The consensus recommendations for respirator design will be comprised of desirable characteristics of the PAPR and respiratory protection programs, which fall into one of four actionable categories:

- Respirators should perform their intended functions effectively and safely.
- Respirators should support, not interfere with, healthcare worker activities.
- Respirators should be comfortable and tolerable.
- Respirators should support healthcare system policies and practices.

The following presents the plan for this phase of the study:

- The consensus recommendations developed by the National Personal Protective Technology Laboratory will be shared during partnership meetings.
- The candidate organizations will then use the guidance to build the respirator prototype(s).
- NIOSH researchers will evaluate, to the extent possible, the respirator prototype(s), to determine whether the respirator(s) under evaluation meets or exceeds the performance requirements identified in the consensus recommendations.
- NIOSH researchers will seek the collective expertise of related stakeholders regarding optimal product development.
- NIOSH researchers will pursue, to the extent possible, field evaluation of resulting respirator prototype(s), including feedback from healthcare workers.

Collaborative efforts may be made via a Cooperative Research and Development Agreement (CRADA) under the authority of the Federal Technology Transfer Act, 15 U.S.C. 3710a, or another appropriate agreement. No federal funds will be provided under this project.

NIOSH may select one or more partnering candidates with respirator design and commercial manufacturing capabilities using the following criteria:

- The candidate organization has adequate and sustained resources and/or funding, as appropriate, to develop a new PAPR prototype(s) or modify existing PAPR models.
- The candidate organization has scientific advisors and staff with a demonstrated record of new product development and knowledge to construct the desired new respirator prototype(s) within 24 months of the effective date of the CRADA or other appropriate agreement.
- The candidate organization is capable of providing up to five units of the prototype for laboratory and limited field-testing.  
Note: preference is for substantial U.S. manufacture of resultant product.
- A candidate organization who has prior experience with respiratory protection products is preferred, but this experience is not required.
- A candidate organization who has the capacity to transform a proof-of-concept prototype into a

commercially viable model is preferred, but such capacity is not required.

Candidate organizations will be evaluated against the selection criteria above, which indicate an organization's capability to incorporate the consensus recommendations, when they are developed, into the prototype(s). The partnership also requires the candidate organization to a) abide by HHS policies regarding testing in human subjects, as applicable, and b) support the advancement of scientific research, as evidenced by a written agreement to publish jointly research results in a prompt manner.

This announcement does not obligate HHS, CDC, or NIOSH to enter into a contractual or collaborative agreement with any respondents.

*Background:* The 2003 severe acute respiratory syndrome (SARS), 2009 H1N1 influenza, and 2014 Ebola outbreaks highlighted the ongoing need for effective respiratory protective devices for healthcare workers. Powered air-purifying respirators are an important type of respiratory protection to defend against high-level respiratory hazards and infectious body fluids. Challenges that have limited widespread utilization of PAPRs in healthcare settings remain.

PAPRs were originally developed to protect industrial workers (primarily in mining) for a typical 8-hour work shift. Changes in PAPR design can be made to better meet the needs in the healthcare environment. Compared to industrial settings, ambient particulate and toxic gas/vapor levels in typical U.S. healthcare environments are lower. As a result, the silica dust test, which was designed for a mining or other dusty environment, may not apply to healthcare settings. Additionally, because the typical work rates of healthcare workers are significantly lower than those of industrial workers, a lower PAPR air flow rate may be justified to provide a sufficient level of protection.

Potential issues related to the protection, performance, and usability of PAPRs include particle leakage during strenuous activity, noise, overall bulkiness, visual impairment, interference with tasks, and issues related to decontamination, among other problems associated with their use.

Beginning in 2006, NIOSH requested the Institute of Medicine (now the National Academy of Medicine) review, and a follow-up review, of personal protective equipment (PPE) with the explicit purpose of recommending how to best protect healthcare workers during an influenza pandemic

(IOM, 2007, 2011). In the reports, "*Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*" and "*Respiratory Diseases: Personal Protective Equipment for Healthcare Workers: Update 2010*", the Institute of Medicine noted a lack of evidence behind respirator protective measures, including minimal attention placed on the development of equipment meeting the unique needs of the healthcare workforce. The Institute of Medicine recommended revisiting elemental aspects of respirator design and development, including distinct attention to respirators tailored to the jobs performed by healthcare workers, and pursuing an evidence-based approach for equipment design to the extent possible.

In 2014, at NIOSH's request, the Institute of Medicine convened a workshop, titled, "*The Use and Effectiveness of Powered Air-Purifying Respirators in Health Care*", to help prioritize and accelerate NIOSH activities to update certification requirements for PAPRs. The proceedings of the workshop are available on the IOM website (linked above).

Some of the research over the past 10 years at NIOSH's National Personal Protective Technology Laboratory has focused on breathing patterns of healthcare workers, barriers and usability of PAPRs in healthcare settings, and



development of new testing methods for evaluating protective performance. The National Personal Protective Technology Laboratory previously developed a set of consensus recommendations, under the *Better Respiratory Equipment using Advanced Technologies for Healthcare Employees* project (Project BREATHE), to improve respiratory protective equipment used by healthcare workers. These earlier consensus recommendations will be modified as NIOSH develops the consensus recommendations for the project New Generation PAPRs.

This project seeks to improve respirator tolerability, comfort, and other functional characteristics, while maintaining a level of protection equivalent to or greater than current standards. The design changes contemplated in this project could increase compliance with respiratory protection guidelines and standards among healthcare workers.

**John J. Howard, MD**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention*

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