



BILLING C

This document is scheduled to be published in the Federal Register on 07/19/2021 and available online at [federalregister.gov/d/2021-15228](https://www.federalregister.gov/d/2021-15228), and on [govinfo.gov](https://www.govinfo.gov)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21GO; Docket No. CDC-2021-0068]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Evaluating the use of EHMRs in health settings to improve organizational implementation and worker adoption during and after the COVID-19 pandemic. NIOSH proposes using surveys and interviews to understand how elastomeric half mask respirators (EHMRs) are being perceived and used by healthcare and first responder settings during the COVID-19 pandemic.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2021-0068 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Evaluating the use of EHMRs in health settings to improve organizational implementation and worker adoption during and after the COVID-19 pandemic - New - National Institute of Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC/NIOSH is requesting approval of a new data collection for a period of two years under the project titled "Evaluating the use of EHMRs in health settings to improve organizational implementation and worker adoption during and after the COVID-19 pandemic." The data collection activities were initiated under the Public Health Emergency PRA waiver. NIOSH has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems. Additionally, OSHA's Emergency Temporary Standard (ETS) for COVID-19 in Healthcare released in June 2021 (29 CFR 1910, Subpart U) is facilitating the need for this work. Finally, during the nationwide shortage of filtering facepiece respirators (FFRs), the Food and Drug Administration (FDA) issued an emergency use authorization (EUA), allowing the use of all NIOSH-approved respiratory protective devices in healthcare settings during the pandemic - of which elastomeric half mask respirators (EHMRs) were included (85 FR 17335, March 27, 2020). This EUA was provided for alternative FFR use in healthcare settings to prevent wearer (i.e., worker) exposure to

airborne particulates because of the COVID-19 pandemic and the life-threatening illness it can cause (FDA, 2020).

Currently, organizations are being confronted with the use of new respiratory protection and questions on how to best support its implementation during the pandemic. To that end, the purpose of this demonstration research study is to assess the integration of EHMRs in various healthcare and first responder settings and subsequently update and enhance EHMR best practices and implementation guidelines to encourage adoption and consequently, reduce PPE supply shortages during the current and future pandemics.

This project is supported through a NIOSH Federal Register Notice (FRN) that posted in September 2020, titled, "A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings During an Infectious Disease Outbreak/Pandemic." - Vol. 85, No. 178. The announcement requested information regarding the deployment and use of EHMRs in healthcare settings and first responder organizations during the COVID-19 crisis.

This proposed study involves conducting surveys and interviews. Individual workers who receive EHMRs from their organization will have the option to voluntarily participate in a pre-/post-survey. Voluntary data collection at the organizational level with members of management will occur using an interview format that follows a semi-structured approach to capture information throughout the duration of NIOSH's research

study. Individual workers (via surveys) and organization management (via interviews) will participate in data collection activities over a period of approximately 4-9 months to assess perceptions, knowledge, attitudes, and experiences using EHMRs as well as best practices for adoption and implementation of EHMRs at their organizations. Individuals who are asked to respond are those who notified NIOSH of their interest of participating in the study. Respondents are expected to include a variety of job types including industrial hygienists, occupational health professionals, infection control professionals, physicians, nurse practitioners, nurses, infection preventionists, fire department chiefs, battalion chiefs, sheriffs, shift supervisors, firefighters, police officers, and paramedics.

A multi-site approach is necessary to answer and further validate findings related to the study objectives. By conducting several studies at healthcare and first responder locations, NIOSH researchers can make the case for research progression, which enhances the reliability and validity of any revised guidance.

NIOSH requests approval for a total of 42,877 estimated burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Organizational manager/POC	Informed Consent	150	3	5/60	38
	Time 1 Interview	150	1	45/60	113
	Time 2 Interview	150	1	45/60	113
	Time 3 Interview	150	1	45/60	113
Individual Healthcare/First Responder	Informed Consent	51,000	2	5/60	8,500
	Baseline Survey	51,000	1	20/60	17,000
	Follow-up Survey	51,000	1	20/60	17,000
Total					42,877

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2021-15228 Filed: 7/16/2021 8:45 am; Publication Date: 7/19/2021]