Generic Clearance for CDC/NIOSH/NPPTL

Assessing Respirator Perceptions, Experiences, and Maintenance

OMB Control Number: 0920-XXXX Expiration Date: XX-XX-XXXX

Supporting Statement A

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a new generic umbrella package for a period of three years under the project titled, "Assessing Respirator Perceptions, Experiences, and Maintenance." This study is being conducted by the National Institute for Occupational Safety and Health (NIOSH). NIOSH, under OSH Act of 1977 (29 USC 669 Section 20(a)(1)) (Attachment A), has the responsibility to conduct research related to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

Further, the National Personal Protective Technology Laboratory (NPPTL) a division of NIOSH, operates within the CDC. NPPTL was established in 2001, at the request of Congress, with the mission of preventing disease, injury, and death for the millions of individuals who rely on personal protective technology (PPT) to protect them on the job. The development of NPPTL filled a need for improved personal protective equipment (PPE) and focused research into PPT. Many of these projects provide the basis for the recommendations and guidelines that NIOSH provides.

According to data from the BLS, from 2011 to 2019 an estimated 52,910 workers experienced injuries or illnesses requiring days away from work and 423 fatal injuries due to inhalation of harmful substances. This results in significant cost to workers, their families, employers, and the U.S. economy. In 2001, NIOSH partnered with BLS to conduct the first voluntary Survey of Respirator Use and Practices. This survey revealed important insights into respiratory use and hazards in the U.S. Using data collected from 40,002 U.S. establishments, the 2001 survey estimated that approximately 281,776 establishments required 3,303,414 U.S. workers to rely on respirators for protection from injuries and illnesses due to respiratory hazards (BLS and NIOSH, 2003). Based on the number of workers who are required to use respiratory protection and the number of inhalation hazards they can help prevent, a mechanism to assess the perceptions and uses around new types of respiratory protection is critical.

A cornerstone of NPPTL is its respirator approval program (NIOSH 42 CFR Part 84) which tests and certifies respirators that provide a specific level of protection for users. Requests for manufacturer evaluation and approval are continuous, with new respirators routinely entering the market and made available. These activities certify respirators that are often assessed in NPPTL research projects. According to NIOSH's Certified Equipment List (CEL), for Schedule 84A – approvals for air purifying particulate filter respirators – over 8,000 approvals are documented for common types of respiratory protection such as N95 filtering facepiece respirators (FFRs), elastomeric half mask respirators (EHMRs), and full face respirators. These ~8,000 approvals only represent one schedule category. Additional respirator approvals exist for self-contained breathing apparatuses, gas masks, supplied-air respirators, and particulate respirators.

Regardless of the respirator and the protection level it offers, NIOSH research about the design, comfort, user experience, and organizational integration of the respiratory protection into their respiratory protection program (RPP) or another similar framework, remain consistent. This consistency further justifies the need for a generic IC that facilitates the collection of similar data on different respirator types across industries. The information collected from human subjects about their use of respirators is generally consistent across NPPTL studies, with only the use conditions changing (e.g., respirator type or management implementation practices related to

cleaning/decontamination, fit testing, and training). Data collection may focus on respirator types ubiquitous to the industry being studied, new to the industry being studied, or novel to any industry.

In addition to the respiratory protection device being provided to workers, federal regulations exist regarding the use of respirators in the workplace (Occupational Safety and Health Standards, 29 CFR 1910.134). The Occupational Safety and Health Administration (OSHA) requires employers whose hazard management includes the required or voluntary use of respirators to have an RPP, which has specified components. Therefore, this generic IC will not only collect information from individuals related to the perceptions and maintenance of respirator use but also the components of their RPPs. The ability to conduct research in this area is imperative as exposure risks can change instantly during public health emergencies (e.g., SARS-CoV-2) and some RPPs may not be comprehensive enough to include the types of respiratory protection needed. In these cases, having standardized measures and frameworks for evaluating respirator use in the context of an RPP or another program is important (Yarbrough et al., 2016).

This data collection activity benefits the Federal Government by providing NIOSH with data to determine how to best manage and improve the maintenance of respirators within a variety of organizational settings. These data also will be used to enhance respiratory protection programs and to gain feedback about different respirators being used by workers.

Data collection for this project is authorized under the OSH Act of 1977 (29 USC 669 Section 20(a)(1)) (Attachment A).

2. Purpose and Use of Information Collection

NIOSH has a need to collect data to evaluate the use of approved respiratory protective devices under 42 CFR 84 CFR to pinpoint areas where improvements in respirators and complementary RPPs are necessary. Further, recent assessments conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM), have recommended that NIOSH continue to engage in research that informs respiratory protection for workers both with and without RPPs to enhance the understanding of respirator use in the U.S. (2022). To fulfill this recommendation, an integrated research effort is needed to fill in the gaps around respirator use and maintenance as well as organizational programs that reduce barriers surrounding these topics. Similar data collection activities occur across NPPTL research projects to understand barriers to respirator use and integration as well as the development of programs and best practices in the workplace.

In addition, the U.S. economy has seen significant changes in recent years, necessitating additional research studies around respirator use and practices. For example, in 2017, the healthcare and social assistance industry sector employed more U.S. workers than the manufacturing sector (Thompson, 2018). This is in stark contrast to 2000, where there were 7 million more workers in the manufacturing sector and 2.4 million more in the retail sector than in healthcare (Thompson, 2018). An increase in alternative or non-traditional work arrangements such as the increase of gig employees, traveling nurses, and contractor work is also raising challenges in the management of respiratory protection for workers. Finally, the employment of young adults or children in industries such as agriculture and those who work for family businesses who have fewer employees, also creates a new space where the use and oversight of respiratory protection has not received enough attention (OSHA, 2014; NASEM, 2022). Overall, the combination of these major shifts in the U.S.

economy represents the potential for a drastic change in how respirators are used and managed in the workplace.

This package will allow for the emergence of patterns in respiratory protection use, as well as health and safety programs including practices and directives that are missing in RPPs. This includes workplaces whose use of an RPP framework is not under OSHA for enforcement purposes so it can include workers in nontraditional work arrangements such as contractors. None of the studies proposed under the auspices of this generic IC intend to produce results that can be generalized beyond the scope of each study. The objective of this request is to enable NIOSH to engage in information collection activities that are focused on assessment and will result in the development of interventions, new or improved respirator designs and adoption of respiratory protection/best practices, and concept development and/or product development and testing and decrease burden to the public. Outcomes will inform new content for improved respirator training, management, and use. The types of information collection activities included in this generic package include qualitative interviewing or focus groups for exploratory and formative research purposes, perception and knowledge-based surveys, qualitative fit testing, and physiological monitoring while wearing a respirator.

The information collected for each project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. Individual projects will not collect sensitive personally identifiable information (PII) but will likely collect derived PII (e.g., job, age). If a project under this generic IC is going to collect any form of PII, it will be kept in a separate location and accessible only to the project-specific research staff. This information will be destroyed when the project has ended. Under no circumstances will an individual be identified using a combination of variables such as gender, race, birth date, and/or other descriptors.

3. Use of Improved Information Technology and Burden Reduction

All data collected will require respondents to answer questions during a survey, interview, focus group, or laboratory monitoring that may be completed in-person, over the phone, or electronically. To reduce burden to the respondents and comply with the Government Paperwork Elimination Act, Public Law 105-277, title XVII, signed into law on October 21, 1998, data collection will occur electronically when possible. In situations where an electronic survey can be used, projects will use this mechanism to reduce burden because this approach ensures data quality but decreases respondent burden with built-in skip logic. Most often electronic platforms such as CDC's Research Electronic Data Capture (REDCap), an approved IT platform, will be used.

Where possible, qualitative data collection can occur over the phone using a secure government license such as Teams or Zoom. The use of data collection using virtual platforms reduces burden on the respondent in multiple ways. For instance, by not traveling to the site or organization, employers do not have to provide CDC NIOSH employees with site-specific health or safety training or review emergency evacuation procedures. Additionally, electronic participations allow respondents more flexibility in their schedule, and, if time is limited at least some information can be collected. These calls may or may not be recorded, depending on the individual project.

Though electronic technologies will be used by many of the individual projects in this data collection, the nature of some proposed activities requires direct interaction between respondents

and project staff, especially in the case of in-depth focus groups and psychological observation and monitoring.

4. Efforts to Identify Duplication and Use of Similar Information

As the nation's respirator approver for all workplaces (42 CFR Part 84), NPPTL conducts respiratory protection research to examine exposures to inhalation hazards, dermal hazards, and any other hazardous environmental threats within an occupational setting. The agency collaborates with other federal agencies, academic institutions, and contracting mechanisms to advance its mission in PPT. Additionally, NIOSH is the lead agency on objectives within the National Strategy for a Resilient Public Health Supply Chain that aim to coordinate PPE activities across agencies to 1) launch a new public health supplies innovation center and 2) launch a new product standardization task force. These extensive collaborations serve as mechanisms to ensure research efforts are necessary and filling a critical gap in respiratory protection research, design, and implementation. For example, NPPTL established a Memorandum of Understanding with the Food and Drug Administration (FDA) and holds bi-weekly meetings to ensure research and development efforts around respirators are not only warranted but coordinated. Similar meetings occur with OSHA on a regular basis.

Also, in 2005, NPPTL requested that the National Academies of Sciences, Engineering, and Medicine (NASEM) form a standing Committee on Personal Protective Equipment (COPPE) for Workplace Safety and Health. The committee provides a forum for discussion of scientific and technical issues relevant to the development, deployment, and use of PPE, standards, and related systems to ensure workplace safety and health. The COPPE coordinates and meets with NPPTL multiple times per year to become informed of existing conditions and emerging issues related to respirators, to discuss studies around respiratory protection. This generic package will allow such recommendations to be coordinated and addressed holistically and systematically across industry sectors and respiratory hazards.

5. Impact on Small Businesses or Other Small Entities

Some surveillance or research activities involve data collection from small business (e.g., medical offices) or small governmental entities; therefore, methods and instrument development activities may also be conducted with these groups. If such activities are conducted, these businesses will be approached in the same manner as the individuals we normally recruit, we will ask the organization to identify the appropriate staff members with whom to conduct the activities. In some studies, no small businesses will be involved in the data collection activities. The methods used to minimize burden on small businesses or other small entities will be explained in each study submitted under this generic.

6. Consequences of Collecting the Information Less Frequently

As more occupational sectors continue to implement new types of respirators, hire new workers, and implement updates to their RPPs, it is critical that research be conducted to assess and update best practices. If this research is not conducted, assessments and subsequent recommendations

about how to safely integrate new types of respirators will not be disseminated to industry personnel.

As an example, although N95 filtering facepiece respirators (FFRs) have been traditionally used in healthcare, there has been a surge in interest in reusable respirators such as elastomeric half mask respirators (EHMRs) and powered air purifying respirators (PAPRs). When there was a shortage in traditionally used N95 FFRs, healthcare organizations were confronted with first, the use of unfamiliar types of respiratory protection and second, questions in how to best support its implementation during the COVID-19 pandemic. This information collection would support and be able to address problems like this in a timely manner. Similarly, as temporary rules (e.g., 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 (85 FR 17335, March 27, 2020), NIOSH needs to be poised to respond to the massive ebbs and flows of interest in some of these types of respiratory protection.

Because this generic clearance covers a wide range of studies, each individual project submitted under this generic IC will clearly define the specific data collection methods and procedures. Individual data collections will be time-limited and generally conducted only once, except in the cases of the pilot testing of interventions where respondents may have to be approached several times on the same or similar topic under evaluation. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The Federal Register notice was published for this collection on May 6, 2022, Vol. 87, No. 88, pg. 27152-27154. (See **Attachment 2**) No substantive public comments were received.

No other public contacts and opportunities for public comments were received.

Representatives from CDC NIOSH were engaged to develop this request. The names and representatives are available upon request.

9. Explanation of Any Payment or Gift to Respondents

A review of survey methodologists and practitioners in October, 1992, The “Symposium on Providing Incentives to Survey Respondents,” sponsored jointly by OMB and the Council of Professional Associations on Federal Statistics (COPAFS), considered a number of incentive-related issues, including the impacts on response rates, biases, and incentive types, recommended OMB “seriously consider the use of incentives” for surveys that target difficult-to-engage respondent populations, surveys that are long or time consuming, surveys with items that are potentially sensitive or require detailed record keeping, surveys for which relatives serve as gatekeepers to respondent access, and surveys that are part of longitudinal panels.”

In many cases incentives will not be necessary, but when they are, incentives will not exceed $40 per hour for such intensive interviews like focus groups and cognitive interviews unless compelling evidence shows that recruitment is very difficult for a particular subgroup.

Tokens of appreciation may be offered in cash or kind for these activities for several reasons:

- Eligibility criteria for respondents are usually very specific. Some of these criteria are determined by the subject matter of the survey or intervention study (e.g., questions or interventions may be relevant only to people with certain health conditions). The more specific the subject matter, the more difficult it is to recruit eligible respondents; tokens of appreciation may help to attract them.
- Respondents may incur additional expenses such as leaving their jobs during business hours or making arrangements for childcare. This may be especially true of some key respondents who may be economically disadvantaged but would provide valuable information in the development of these projects.
- Some major metropolitan areas may be highly saturated with other research activities (e.g., academic research initiatives), which typically provide remuneration and may compete for respondents' time.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

Depending on the specifics of the individual data collection project, the Privacy Act may or may not apply to an information collection. Depending on the specifics of the individual investigation (i.e., data collection project), the Privacy Act may or may not apply to an information collection. The appropriate CDC NIOSH contacts are consulted for an official Privacy Act determination for each individual investigation.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

IRB requirements are investigation specific. Some investigations require IRB approval while others fall within the IRB exemption criteria (45 CFR Part 46.104) or are considered a non-research, public health surveillance activity (45 CFR Part 46.102(l)(2). For individual investigations, the appropriate CDC NIOSH contacts are consulted for an official research determination.

Projects that need IRB approval will be submitted with a copy of the approval document. If the study has been determined to be exempt from IRB, a copy of the exemption determination will be attached. If the appropriate CDC official has determined that the data/ information collection is not research involving human subjects, the information collection submitted under this generic clearance will state that IRB approval is not required.

Sensitive Questions

At times the diseases that will be covered by these information collections may involve non-compliant attitudes and practices that may be considered private. Race and ethnicity data, as well as diagnoses of medical conditions that may affect employability or insurability may also be viewed as sensitive or even threatening by a portion of respondents. The reasons for collection of sensitive information and their application for the improvement of CDC's prevention efforts for the specific

population sub-group will be addressed in specific requests. The procedures used to obtain consent and the content of the consent form will also be explained and justified.

12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 214,542 hours.

We anticipate approximately 6 information collections per year. These may include surveys, interviews, focus groups, or physiological monitoring in response to routine and emergency/extended use of respirators during different job activities.

Exhibit A.12. Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Informed consent	**110,000**	**1**	5/60	**9,167**
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Demographics standardized survey with decision logic allowing some questions to be omitted	**110,000**	**1**	15/60	**27,500**
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Qualitative fit testing survey measurements	**675**	**20**	15/60	**3,375**
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Perceptions-based survey instrument	**105,000**	**2**	15/60	**52,500**
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Knowledge-based survey instrument	**105,000**	**2**	30/60	**105,000**
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Interview/Focus group	**4,000**	**2**	1	**8,000**
Individuals who	Physiological	**1,000**	**1**	9	**9,000**

wear respirators in any occupational setting or oversee/advise on respirator use	Monitoring: Heart rate, blood pressure, blood oxygen saturation, breathing rate, etc.				
Total					**214,542**

Estimated Annualized Burden Costs

Collections by health jurisdictions are generally funded through cooperative grants and these will be noted in the specific collection requests. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics, May 2021 http://www.bls.gov/oes/current/oes_nat.htm.) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $25.00 per hour was used as an estimate of average hourly wage across the country.

Exhibit A.12.B. Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Data collection	214,542	$25.00	$5,363,550

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

NIOSH does not anticipate providing start up or other related costs to private entities.

14. Annualized Costs to the Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one NIOSH project officer (GS-12, 13, 14, or 15 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. The NIOSH project officer will provide remote and onsite technical assistance to the local areas implementing the data collection. Travel may be required to provide this technical assistance. In most cases, a NIOSH data manager's (typically equivalent to GS-9, 11 or 12) time will also be required. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request.

Expense Type	Expense Explanation	Annual Costs

		(dollars)
Direct Costs to the Federal Government		
	NIOSH Project Officer (GS-13/14, 0.5 FTE)	$40,641
	NIOSH Data Manager (GS-9/11, 0.5 FTE)	$13,450
	CDC NIOSH IT Security Compliance	$100,000
	NIOSH Travel (10 trips)	$20,000
	Subtotal, Direct costs	$174,091
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	$400,000
	TOTAL COST TO THE GOVERNMENT	**$574,091**

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases of individual interviews conducted during pilot testing of interventions where respondents may have to be approached several times on the same or similar topic under evaluation. No single data collection activity will take longer than 2 years to complete from inception of information collection to the first report of findings. Proposed timelines will be submitted for each individual data collection activity.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

29 C.F.R. § 1910.134. Final rule. Fed. Reg. 63:1152–1300 Respiratory Protection. See also Appendix A to § 1910.134 Fit Testing Procedures (Mandatory).

42 C.F.R. § 84.2 (2020) (“NPPTL administers the NIOSH conformity assessment program for respiratory protective devices, replacing the former Certification and Quality Assurance Branch”).

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