Information Collection Request for
"Noise Exposures and Hearing Loss in the Oil and Gas Extraction Industry"

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April 2023

Part A: Justification

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Attachments

- **Goals of the project:** The primary goal of this project is to generate knowledge about noise and ear-damaging (ototoxic) chemical exposures and hearing loss experienced by United States onshore oil and gas extraction (OGE) industry workers and noise controls and hearing protection activities in the industry.

- **Intended use of the resulting data:** These data will be used to understand noise exposures, ototoxic chemical exposures, self-reported hearing loss, and hearing loss prevention practices in the OGE industry. Subsequently, the data and analysis will be used to create evidence-based interventions and recommendations, which will be communicated to the spectrum of OGE industry stakeholders.

- **Methods to be used to collect data:** Questionnaire and audiometric testing

- **The specific subpopulation to be studied:** The respondent universe of interest for the proposed study includes all adults (18 years and older) employed in the U.S. onshore oil and gas extraction (OGE) industry at increased risk of hearing loss from noise or ototoxicant exposure.

- **How data will be analyzed:** Researchers will conduct a risk characterization and assessment of noise and ototoxic chemical exposures for workers who drill, complete, and service wells in the OGE industry. This includes a focus on collecting full-shift personal exposure data using direct-reading noise dosimeters placed on workers to evaluate the exposures associated with specific job activities across full work shifts. Audiometric test results will be analyzed collectively to look at broad patterns related to hearing loss across the industry documented by these tests.

1. Circumstances Making the Collection of Information Necessary

This study fulfills the responsibilities the National Institute for Occupational Safety and Health (NIOSH) was tasked with in P.L. 91-596 Section 20 (Attachment A), namely conducting research on occupational safety and health problems and preventing them. This is a new Information Collection Request (ICR) from NIOSH, which is within the Centers for Disease Control and Prevention (CDC); NIOSH is seeking 36-month approval from OMB. The 60-day Federal Register Notice for this ICR is included as Attachment B. The proposed study will investigate the problem of noise exposure, ototoxic chemical exposures, and noise-induced hearing loss and related health impacts among land-based oil and gas extraction (OGE) workers. OGE comprises upstream, midstream, and downstream segments. In 2017, 428,000 were employed directly in the OGE industry and were supported by employees in the transportation, construction, and other sectors. It is already known that the OGE workers experience significant burden of injury and workplace exposures. During 2008–2017, OGE employees experienced a fatality rate that was more than six times the rate of all United States (US) workers [NIOSH 2018a].

Noise-induced hearing loss is caused by damage to nerve cells of the inner ear and, unlike some conductive hearing disorders, can't be treated medically [Berger et al., 2003]. In most cases, this hearing loss happens slowly and occurs without notice; it is often severe enough to permanently affect a person's ability to hear and understand speech. Although hearing ability declines for most with age, noise exposure produces more hearing loss than that resulting from aging alone. In fact, the average otherwise healthy person will have essentially normal hearing through their working life (at least up to age 60) if their unprotected ears are not exposed to high noise levels [AAA 2003]. Hearing loss is the 3rd most common chronic physical condition among US adults and 24% of the hearing difficulty in U.S. workers is caused by occupational exposures [NIOSH 2019a]. A history of occupational noise exposure is also associated with a significantly elevated risk of both hypertension and elevated cholesterol [Kerns et al., 2018]. Additionally, hearing loss can be associated with difficulty in communicating; feeling socially isolated, stressed, and fatigued; depression; cognitive decline; dementia; falls; increased hospitalizations and health care costs; and mortality [Themann and Masterson 2019]. The economic burden of occupational hearing loss in this and other industries can be difficult to assess and estimates of workers compensation costs, likely the most common metric of the economic impact of occupational hearing loss, are scarce [Themann and Masterson 2019]. However, it is recognized that costs include those associated with lost productivity, absenteeism, reduced earnings, lost tax revenues, welfare payments, special education and vocational rehabilitation programs, and health care [Themann and Masterson 2019]. Neitzel et al. have estimated the cost of hearing loss on productivity in the United States to be nearly $615 billion; if the total number of individuals with hearing loss was reduced by 20% (i.e., the portion of hearing loss resulting from excessive noise exposure), employment and wage increases would result in increased earnings of $122 billion [Neitzel et al., 2017].

Little is known of the burden of hearing loss and disorders in this worker population in the U.S. Reasons may include a dearth of noise-related published studies for this industry. In one recent epidemiological study, NIOSH authors stated that "no known studies have measured the prevalence of hearing loss within OGE" [Lawson et al., 2019]. There is some evidence that the burden of hearing loss is high in the OGE sector. In one published study, the prevalence of hearing loss in the U.S. OGE sector from 2006–2015 was estimated to be 14.4% (and 27% when support activities were excluded), with prevalence at 16% among all industries [Lawson et al., 2019]. Unfortunately, the authors noted that "some subsectors, particularly in OGE, could not be examined due to low sample size" [Lawson et al., 2019].

Further research and knowledge on this topic may be hindered because of OGE industry exemptions from aspects of the federal Occupational Safety and Health Administration OSHA noise exposure standards. Employers engaged in oil and gas well drilling and servicing operations are exempt from typical requirements for hearing conservation programs, monitoring, audiometric testing programs, (i) hearing protectors, and training programs [OSHA 2008]. Some work has been done in Canada on the topic of hearing loss among OGE workers. WorkSafeBC has published data on the burden that Canadian oil and gas workers experience in that province related to noise and hearing loss. In a 2018 WorkSafeBC bulletin, the agency notes that their noise measurements and hearing test results show that almost all oil and gas workers are exposed to hazardous noise levels and that workers in the oil and gas drilling sector have some of the highest hearing loss rates of any industry [WorkSafeBC 2018a]. They also recently released information that showed that the percentage of workers who showed signs of hearing loss rose to 45% by 2017 [WorkSafeBC 2018b]. Because OGE operations in Canada differ little from those in the United States, the exposure risks and burdens are expected to be similar but should be confirmed with research.

To prevent hearing loss in this sector, it is important to understand exposures to noise and co-exposures that can contribute to hearing loss.

The proposed data collection will provide an initial step toward achieving a prioritized activity goals identified by the National Occupational Research Agenda (NORA) for workers in the Oil and Gas sector, specifically addressing goals related to hearing loss. NORA is a partnership program designed to stimulate innovative research and improve workplace practices. Unveiled in 1996, NORA has become a research framework for NIOSH and the nation. Diverse parties (industry, academia, government, insurance, etc.) collaborate to identify the most critical issues in workplace safety and health. The goals of the NORA Oil and Gas sector addressed by this project are as follows:

Activity Goal 2.6.1 (Basic/Etiologic Research): Conduct basic/etiologic research to better understand sources of noise exposure in oil and gas extraction worksites.

Activity Goal 2.6.2 (Intervention Research): Conduct studies to develop and assess the effectiveness of interventions to prevent noise overexposure among oil and gas extraction workers.

Activity Goal 2.6.3 (Translation Research): Conduct translation research to understand barriers and aids to effective use of PPE to prevent hearing loss among oil and gas extraction workers.

Activity Goal 2.6.4 (Surveillance Research): Conduct surveillance research to better understand the burden of hearing loss and sources of noise in the oil and gas extraction sector.

Ultimately, this study will contribute to the understanding the burden of noise and ear-damaging chemical exposures and hearing loss and contributing factors among OGE workers; this understanding will allow for more effective prevention of disabling occupational injuries and illness.

1.1 Privacy Impact Assessment (PIA)

NIOSH proposes a one-time information collection using a questionnaire (Attachment C). The questionnaire is based on validated questions, including from the National Health and Nutrition Examination Survey (NHANES) and the National Health Interview Survey (NHIS). The questionnaire administration will be overseen by trained NIOSH staff onsite at well sites, temporary lodging facilities set up for OGE workers, contractor meeting site, and OGE training facilities. Each participant will complete the questionnaire individually or with the assistance of a NIOSH investigator directly into an electronic tablet or by paper and pencil. Responses will be transmitted into an encrypted CDC-owned laptop computer and deleted from the tablet. All data collected will be maintained according to CDC record retention schedule and data security policies. Existing PIAs are in place for Research Electronic Data Capture (REDCap) to be used for this proposed data collection and for the NIOSH Edge computing platform (NECP) environment for storing, managing, and processing the data.

Questionnaire data to be collected include:

- Demographic data
- Medical information
- Employment information
- Noise and chemical exposure information
- Smoking history

In addition to the collection of information in the questionnaire, the study includes personal exposure sampling (noise and ototoxic chemicals such as hexane, toluene, p-xylene, ethylbenzene, and lead) as well as audiometric testing. Participation is voluntary. The audiometric testing and personal air sampling will be conducted at separate times.

A recruitment letter will be sent to companies to solicit participation in the study (Attachment D). Workers will receive a study recruitment fact sheet that includes purpose of the study, how to participate, risks and benefits of participation, and the contact information for the primary investigator (Attachment E). To participate in the questionnaire, personal exposure sampling, and audiometric testing, each employee will be required to review and sign an informed consent document with the assistance of NIOSH representative (Attachment F). Participants undergoing audiometric testing will be administered the Audiometry Data Capture Form (Attachment G). NIOSH staff will keep track of the air, noise, and surface sampling information using log sheets (Attachment H). Participants who request personal air sampling results will receive letters with their personal air sampling results in a timely manner (Attachment I). Participants will receive letters with their personal audiogram results (Attachment J).

This project does not involve any data collection, web-based or otherwise, with content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The information collected in this study will be used to prevent occupational hearing loss among OGE workers by generating understanding about noise and chemical exposures, and hearing loss experienced by workers in this industry. This study has three aims: collecting noise and ear-damaging (ototoxic) chemical exposure measurements; evaluating exposure controls; and collecting self-reported information on hearing loss, job activities, perceived noise and chemical exposures, and other work-related characteristics. These data will be used to identify over exposures to noise and ototoxic toxic chemicals, identify factors or work characteristics that contribute to noise exposure or hearing loss in OGE. The

analysis will be used to identify how exposures can be reduced and the burden of hearing loss and related health effects minimized for OGE workers.

3. Use of Improved Information Technology and Burden Reduction

Participating OGE employees will be offered to fill out a questionnaire (Attachment C) via touchscreen electronic tablet using REDcap, on hardcopy, or the worker can choose to be verbally interviewed in a private location. The touchscreen electronic tablet is the preferred approach as it will ensure accurate data collection and reduces burden to follow paper-based skip patterns. Estimated time for questionnaire completion is approximately 17 minutes per participant. For workers who choose to be verbally interviewed, their responses will be entered directly into the tablets during the interview by the research staff. Data from each tablet will be downloaded to a secure CDC-owned laptop at the end of each day. All electronic data will be erased from the tablet using necessary software. Tablets will be password protected and kept in the possession of staff and in a locked box between questionnaire administration periods. Each questionnaire will have a unique identifier but no personally identifiable information. Capturing data on tablets reduces the burden of post hoc data entry, as data will have already been captured in an electronic format.

Some participants will be offered participation in audiometry, which requires an Audiometry Data Capture Form (Attachment G). This form will be given in hardcopy to participants to facilitate onsite implementation of audiograms and secure collection of personal identifiable information.

4. Efforts to Identify Duplication and Use of Similar Information

The NIOSH OGE program has assessed a variety of exposures in the onshore OGE industry in the US. These exposures included respirable crystalline silica, hydrocarbon gases and vapors, and diesel particulate matter. The program has yet to study noise exposure in the industry. NIOSH researchers have conducted comprehensive searches to identify available literature regarding hearing loss information and occupational noise and ototoxic chemical exposure for onshore oil and gas industry workers. The information that would be collected by this study is not available for US OGE workers neither within nor external to NIOSH, based on literature reviews and from information provided by sector and occupational health and safety experts. NIOSH is positioned to conduct this study in the OGE industry due to its history and established relationships within the sector.

5. Impact on Small Businesses or Other Small Entities

Businesses in the OGE industry will be asked to participate regardless of their size. Some of these entities which would grant permission to evaluate their workers may be small businesses. The duration of the questionnaire and participation in exposure assessment is not expected to impact the participating businesses. The number of questions on the questionnaire have been held to the minimum to meet study aims. They include only what are considered essential topics and the length of the survey was kept as short as possible. Survey questions that are not applicable to the respondent are skipped. Participation in the survey is voluntary and conducted at a time convenient for the participant as well as the business, which would allow the worker time to complete the questionnaire.

Exposure monitoring for noise and chemicals for workers is not expected to negatively impact business operations. Additionally, there may be benefits for participating companies. The information provided

back to participating companies is valuable information that can be used to maintain or improve a healthy and safe workplace and reduce the impact of work-related injury and illness.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection from each participant. Less frequent would not allow the information to be captured. If this data collection does not take place, industry leaders and federal programs will not be able to make evidence-based decisions regarding the safety and health concerns of upstream oil and gas industry workers as it pertains to noise and ototoxic chemical exposure and hearing loss prevention. Additionally, this data collection will inform NIOSH's research agenda by aiding in prioritization of research activities and resources. There are no legal or technical obstacles to reduce the burden as this is a one-time data collection.

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

This information will be collected in accordance with the regulations outlined in 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on Friday, May 12, 2023, Vol. 88, No. 30750 pages 30750-30751. (Attachment B).

   CDC did not receive public comments related to this notice.

B. We consulted with several experts on the topic of ototoxicity and surveys related to noise and chemical exposure, and hearing loss, within and external to CDC. There were no issues with data collection tools, methods, or frequency that were unable to be resolved through this consultation.

Dr. Lisa L. Hunter, PhD, FAAA. She is the Scientific Director of Research at Cincinnati Children's Hospital and has expertise in ototoxic medications. She was consulted in 2022. Phone number: (513) 803-0532; E-mail address: lisa.hunter@cchmc.org

Dr. Emily Mosites, PhD. She is an epidemiologist and senior advisor in CDC's Division of Developmental and Intellectual Disabilities. She provided a data collection tool and related information that had been used to collect data on use of ototoxic medications during her graduate work. She was consulted in 2021. Phone number: (907) 346-0570; E-mail address: lwx@cdc.gov

The following consultants provide ongoing feedback on the data collection tools and methods with the latest consultation in 2022.

Dr. Thais Morata, PhD. She is a senior research audiologist with the NIOSH Division of Field Studies and Engineering and a co-coordinator for the NIOSH Hearing Loss Prevention Cross-Sector Program. She has expertise in otoxicity and reviewed and assisted in the development of data collection methods and tools for this project. Phone number: (513) 533-8487; E-mail address: tcm2@cdc.gov.

Ms. Christa Themann, MA, CCC-A. She is a Research Audiologist with the NIOSH Division of Field Studies and Engineering. She has expertise in hearing loss surveillance and provided consultation during questionnaire development. Phone number: (513) 533-8485; E-mail address: clt6@cdc.gov.

Dr. Elizabeth Masterson, PhD, CPH, COHC. She is an epidemiologist in the NIOSH Division of Field Studies and Engineering and a co-coordinator for the NIOSH Hearing Loss Prevention Cross-Sector Program with expertise in hearing loss epidemiology with NIOSH. She provided expertise during questionnaire development. Phone number: (513) 841-4291; E-mail address: efm3@cdc.gov.

CAPT Chucri (Chuck) Kardous, MS, PE is a research engineer with the NIOSH Division of Field Studies and Engineering and is an expert in the collection of noise exposure measurements. Phone number: (513) 533-8146; E-mail address: cyk5@cdc.gov.

Eric Esswein, MSPH, CIH is an industrial hygienist contracted by the NIOSH Western States Division. He reviewed the data collection instrument and provided expertise on OGE operations. Phone number: 303-236-5946; E-mail address: eje1@cdc.gov.

Barbara Alexander, PhD, PE, CIH is a senior service fellow with the NIOSH Division of Field Studies and Engineering. She reviewed the data collection instrument and provided expertise on OGE operations. Phone number: 513-841-4581; E-mail address: vot3@cdc.gov.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not be paid or compensated by NIOSH to complete the information collection instruments.

10. Assurance of Confidentiality Provided to Respondents

Privacy Act Review

ISSO determined in conjunction with the CDC Privacy Office that Privacy Act is not applicable. The collection does not contain PII. Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP) include the in-place technical, physical, or administrative controls (safeguards). Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP) System Security Plan (SSP) defines the process for handling security incidents. The system's team and the Cybersecurity Program Office (CSPO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer (ISSO), CDC helpdesk, or to the CDC Security Incident Response Team (CSIRT). The CDC CSPO reports to the HHS Computer Security Incident Response Center (CSIRC), which reports incidents to US-CERT as appropriate.

Consent of Participants

To participate in the questionnaire, personal exposure sampling, and audiometric testing, each eligible worker will be required to review and sign an informed consent document (Attachment F – Informed Consent Form). This document provides information about the study, their participation, risks and benefits of participation, and procedures for keeping personal information confidential. The consent document is written at a reading level that is expected to be understood by the large majority of OGE workers. The Informed Consent Form asks for the minimal amount of personally identifiable information to be able to fulfill the responsibilities of the project officer. The document will contain the participant's name and signature, at minimum.

If the participant will undergo personal exposure monitoring or audiometry, they can elect to receive those results. To facilitate that, the participant is asked to provide their contact information (mailing address, e-mail address, and phone number) so their personal results can be returned to them. The participant can elect not to provide contact information.

The completed consent documents will be maintained in locked containers at the point of collection and will be handled by NIOSH staff or contractor. The completed forms will be maintained in locked cabinets and in secure NIOSH facilities while they need to be maintained under the CDC record retention schedule.

Data Access Control

Study participants will be given unique identification numbers assigned by the NIOSH project officer which will be used to manage their data. The consent will contain the name and date of birth, and a study identification (ID) number. The results contact form will also contain contact information in addition to their name, date of birth, and study ID (i.e., mailing address, phone, and email). Documents associated with each participant (personal air sampling forms, audiogram results, questionnaire) will contain a study ID number to be able to link all components of the participant's contributions to the study without using PII. This study ID number will be the only link to the data collected and will be used to link data collected by the questionnaire (including medical information). Date of birth is being collected to be able to be used with name to verify the study ID and confirm consent for an individual who participates in components of the study at different points in time. Questionnaire data will be collected using REDCap software on secure CDC-owned electronic tablets. Data from each tablet will be downloaded to a secure CDC-owned laptop at the end of each day. All electronic data will be erased from the tablet using necessary software. Tablets will be password protected and kept in the possession of staff and in a locked box between survey administration periods. Each questionnaire will include the unique identifier but no personal identification information such as name or contact information but will include medical information.

The study ID numbers will also be used for the industrial hygiene exposure assessment and audiometry testing. Samples collected from these aspects of the study will be labeled with the unique study ID number; therefore, contracted labs will analyze de-identified samples and will not receive any PII. In the field, hard copy informed consent forms will be kept in a lockbox and returned to the NIOSH office on the same day as collection. When the lockboxes cannot be returned to the NIOSH office on the same day as collection, the lockboxes will be kept (1) with the NIOSH project officers or (2) in a locked, private, and secure location. The consent forms linking names and addresses to code numbers will be stored in a locked file at the NIOSH office accessible only to NIOSH personnel. We will leverage NECP/Virtual Volumes to store the data (including the link between the participant's name and study ID number) and possibly the Virtual Analytical Workspace, if available.

CDC will treat data and gathered information in a secure manner and will not disclose, unless otherwise compelled by law.

All data for this study is collected under the system of record notice (SORN) CDC Privacy Act System Notice 09-20-0147 and will be maintained in accordance with the Federal Privacy Act of 1974. Additionally, this research is covered by a Certificate of Confidentiality (CoC) from the Centers for Disease Control and Prevention. Consistent with Section 301(d) of the Public Health Service Act, a

Certificate of Confidentiality (CoC) applies to this research because this research is funded, conducted, or supported by CDC and the research involves Human Subjects as defined by 45 CFR Part 46. Individually identifiable (including coded) information will be obtained or used for research purposes. The research involves information about an individual for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive "identifiable, sensitive Information" as defined by subsection 301(d) of the Public Health Service Act shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. CDC will ensure the following:

1) that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and
2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act.

Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens. All research subjects will be informed of the protections and the limits to protections provided by this Certificate through the informed consent process. All study staff who obtain consent from study subjects will be trained on how the Certificate protects the information collected and the limitations of the Certificate's protections.

Public health partners may assist in data collection during site visits at the worksite in question as well as data analysis; however, CDC/NIOSH will own and maintain the data.

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

Institutional Review Board (IRB) Approval

The project has been determined to be research involving human subjects. The NIOSH Institutional Review Board has reviewed and approved the proposed study (Attachment K – IRB approval letter).

Justification for Sensitive Questions

The proposed questionnaire contains questions that may be sensitive in nature, including race and ethnicity and use of certain medications. Some individuals may consider a question about self-evaluation of hearing ability to be sensitive as well. The potentially sensitive questions on race and ethnicity are needed to accurately describe the demographics of the workforce population in the study and to identify potential increases in exposure or risk to minority populations. Information on use of medications will be collected to evaluate results for potential ototoxic effects from medication use.

The questionnaire asks for a self-evaluation of hearing ability; this question will be used as a surrogate for hearing loss. Collecting this information is important to accomplish the aim of assessing the relationship between exposures and protective factors to hearing loss. A small subset of participants will undergo audiometric testing to evaluate their hearing by an audiometry professional, so most hearing loss data will be obtained using the questionnaire thereby justifying the inclusion of this potentially sensitive question. Answering any question on the questionnaire is voluntary and participants may choose to not answer any question they find too sensitive by selecting "Prefer not to answer."

Social security numbers will not be collected.

The potentially sensitive questions about race, ethnicity, medication use, and hearing ability asked in the questionnaire are in Table A11.1.

Table A11.1 Potentially Sensitive Questions in Questionnaire

Question	**Answer**
What race or races do you consider yourself to be? (Select all that apply)	American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White Prefer not to answer
Do you consider yourself to be Hispanic or Latino?	Yes No Prefer not to answer
Have you ever taken "mycin" antibiotics (such as streptomycin, gentamycin, or neomycin) for 2 weeks or longer?	Yes No Prefer not to answer Don't know
Have you ever taken any Chemotherapy drugs (such as cisplatin or carboplatin) for 2 weeks or	Yes No

longer?	Prefer not to answer Don’t know
Have you ever taken water loss medicines, also called diuretics (such as Edecrin [ethacrynic acid] or Lasix [furosemide]) for 1 month or longer?	Yes No Prefer not to answer Don’t know
Have you ever taken any Antimalarial drugs (such as quinine, chloroquine, or hydroxychloroquine) for 1 month or longer?	Yes No Prefer not to answer Don’t know
Have you ever taken aspirin for 1 month or longer?	Yes No Prefer not to answer Don’t know
Which statement best describes your hearing (without a hearing aid or other listening devices)?	Excellent Good A little trouble Moderate hearing trouble A lot of trouble Deaf Prefer not to answer Don’t know

All questionnaire response data will be treated in a secure manner, leveraging the NECP/Virtual Volumes, and possibly the Virtual Analytical Workspace, if available, and will not be disclosed, unless compelled under law. Aggregation of responses will ensure participants will not be identifiable.

12. Estimates of Annualized Burden Hours and Costs

The burden hour estimates are presented in Table A12.1. We estimate a total response burden of 106 hours. A target of 500 respondents will read and complete a questionnaire (Attachment C) as well as an informed consent form (Attachment F). A hundred workers will undergo audiometry (Attachment G).

Table A12.1 Estimated Annualized Time Burden to Respondents

Type of Respondents	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden (in hours)**

Oil and Gas Workers	Noise and Hearing Questionnaire	167	1	17/60	47
	Informed Consent	167	1	15/60	42
	Audiometry Testing	33	1	30/60	17
Total					106

To estimate cost burden to respondent, we used the estimated time burden from Table A12.1 and hourly wage using hourly rate data from the Bureau of Labor Statistics. These estimates are in Table A12.2.

Table A12.2 Estimated Annualized Cost Burden to Respondents

Type of Respondents	**Form Name**	**Total Burden (in hours)**	**Hourly wage rate***	**Total respondent cost**
Oil and Gas Workers	Noise and Hearing Questionnaire	47	$22.60	$1062
	Informed Consent	42	$22.60	$949
	Audiometry Testing	17	$22.60	$384
Total				$2395

*Hourly rate based on “Construction and extraction occupations” median weekly pay for 2021 found at Median weekly earnings of full-time wage and salary workers by detailed occupation and sex (bls.gov)

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

The estimated annualized cost to the government is $397,206 for the four years of the project. The breakdown by cost type is outlined in Table A14.1. The estimated costs will cover the following:

- Government personnel time (pro-rated using percentage of time dedicated to the project);
- Equipment for exposure assessment;
- Media and supplies for sample collection;
- Personal protective equipment for project staff;
- Contracts for staff, translation, and sample analytical service;
- Travel for partner development, field evaluations, field questionnaire delivery, audiometry, and dissemination of findings.

Table A14.1 Annualized costs to the government incurred by this project

Item	**Annualized Cost**
NIOSH Personnel	$147,206
Supplies	$5,000

Equipment	$12,5000
Contracts for staff, sample analysis, and translation	$167,500
Travel	$65,000
Total	*$397,206*

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Once approved by OMB, oil and gas extraction companies and workers will be recruited for participation in this project using the recruitment letter and fact sheet (Attachments D and E). The tentative project time schedule is in Table A16.1. Data collection will start between 3 and 6 months after approval, depending on company operations and NIOSH staff schedule availability. Exposure results will be returned to participants on a rolling basis after data collection as results are returned from the analytical laboratory to the project officers. Aggregate data will be compiled and returned to the participating companies. Timely return of these results is a priority so they can be acted upon to reduce noise and chemical exposures in the event exposures are high relative to occupational exposure limits. Then, data analysis will begin on the data collected using the questionnaire and during exposure monitoring and audiometric testing. Descriptive statistics on questionnaire, sampling, and audiometry data will be calculated to demonstrate the prevalence of hearing loss among this worker population, exposure to ototoxic chemicals, availability and use of exposure controls, among other variables. For exposure data, the geometric mean, geometric standard deviation, maximum and minimum concentration (milligrams/cubic meter of air) for the exposure of concern will be calculated for each group of workers. Exposure measurements will be compared to available regulatory, recommended, and consensus occupational exposure limits (OELs) and that information will be shared with the participant if they elect as such.

For analysis of questionnaire data, descriptive statistics will be used to determine the means, standard deviations, percentages, and frequencies of variables. Using data from questions sourced from NHANES and NHIS, the proportion of participants reporting hearing loss, noise exposures at work and outside of work, and other variables will be compared between OGE workers and what was reported in the general population.

Univariate and multivariate regression techniques will be used to examine predictors of hearing loss and over exposure to noise and chemicals. Predictors may include both work related factors (noise exposure on the job, ototoxic chemical exposure, noise exposure controls in place) and non-work-related factors (use of ototoxic medication, non-work-related noise and chemical exposure, tobacco use).

The results of the study will be disseminated in the scientific literature and published in trade journals. Partners and companies that are active participants in the field portion of this study will be encouraged to disseminate the findings to stakeholders. Through the end of the OMB approval period, the results will be disseminated. They will be used to identify & prioritize worker exposures, identify sources of occupational hearing loss, provide information about noise and chemical exposure controls, and develop education and awareness programs for workers and employers in the OGE industry and workers sectors that support OGE activities.

Table A16.1 Tentative Projected Schedule by Quarter

Activity	Months after OMB approval											
	0-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36
Recruitment												
Data collection												
Report exposure results to individuals												
Data analysis												
Aggregate data reporting to company												
Develop communication products on study results, including scientific journal articles												
Presentations at scientific meetings												

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

Display of OMB Expiration Date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions.

19. References

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