Airborne Hazards and Open Burn Pit Registry
Self-Assessment Questionnaire

Web-Accessible: VA Form 10-10066

OMB 2900-0800

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

1.1 Public Law 112-260 Section 201, enacted by President Obama on 10 January 2013, required Department of Veterans Affairs (VA) to establish and maintain an "Airborne Hazards and Open Burn Pit Registry (AHOBPR)" no later than one year from enactment. VA launched the AHOBPR in June 2014. There is no sunset date identified in the law. The Secretary of Veterans Affairs may "include any information in such registry that the Secretary of Veterans Affairs determines necessary to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits." Currently, VA plans to operate the AHOBPR indefinitely, and we request approval to continue administering the questionnaire.

1.2 Qarmat Ali: This program is a new request for a follow-up information collection for a subset of Veterans impacted by a specific airborne hazard. In the spring and summer of 2003, approximately 700 U.S. Servicemembers may have been impacted by a specific airborne hazard while serving at a water injection plant in Qarmat Ali (QA), Iraq. The Department of Defense (DoD) was unable to determine specific exposure levels near the water treatment facility. In 2010, in response to DoD's notification, the VA offered no-cost medical evaluations and encouraged the cohort to enroll in a new Qarmat Ali medical surveillance program within the Gulf War Registry. The QA cohort is also eligible to participate in the AHOBPR program due to their deployment to Iraq. As part of the planned 5-year periodic medical follow-up and surveillance program, self-reported information will be collected through the AHOBPR as outlined above. Additional information on the Qarmat Ali water treatment facility can be found at the following link at: https://phc.amedd.army.mil/PHC%20Resource%20Library/QarmatAliWTPChromiumAssessmentMay2010.pdf.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

Information collected is voluntary and is used to provide outreach and quality health services to AHOBPR participants. Collected data contributes to VA's ability to understand the potential health effects of the exposure to burn pit emissions and other airborne hazards during deployment, such as particulate matter (PM).

Because of self-selection bias, the registry is unlikely to provide data generalizable to the entire eligible population. This point was emphasized in a recent report on the first year of operation, completed by National Academies of Sciences, Engineering and Medicine (NAM).

Participant health concerns, demographics, deployment information, environmental monitoring data, self-reported exposures, health status, and health care utilization are monitored, over time, through

routine and ad hoc analysis. The process helps to improve health care services and to generate hypotheses concerning exposure health effects.

VA researchers may access the identifiable data in a secure environment and may merge it with other data sets in Institutional Review Board (IRB) approved research studies to test hypotheses or solicit participation in research studies (which may require approval under the Paperwork Reduction Act). Data are used for targeted outreach to Veterans with specific exposures or health statuses of concern. Registry data are maintained in accordance with federal privacy and information security standards. Participant questionnaires are administered securely via the World Wide Web. Data elements include individual health concerns, demographic, self-reported exposures, communication preference, and health status. Subsequent studies may include measures of environmental exposure, and questions about health care. Additional clearance would be required for such collections.

The data collected via participant questionnaires are analyzed in concert with data available from VA patient health records and DoD personnel and other administrative records. If VA actively recruits participants to engage in follow-up clinical evaluation, medical diagnosis, medical procedures or other ancillary health care, VA understands that participants need to be informed that the information collected during these procedures will be used in the aforementioned study, and that, depending on the study design, specific clearance may be necessary.

Individuals eligible for the registry include members of the Armed Forces who may have been exposed to burn pit emissions or other potential airborne environmental hazards while deployed to the Southwest Asia theater of operations (Iraq, Kuwait, Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, Gulf of Aden, Gulf of Oman, waters of the Persian Gulf, the Arabian Sea, and the Red Sea) on or after August 2, 1990 (as defined in 38 CFR 3.317(e)(2)), or Afghanistan or Djibouti, Africa on or after September 11, 2001.

3. **Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.**

   Self-assessment questionnaires are completed using an internet information technology. Internet access has improved Veteran access by removing the requirement to travel to VA facilities to complete the questionnaire.

4. **Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

   At the time of the AHOBPR launch, there were no existing registries to satisfy the legislative mandate outlined in Pub Law 112-260 section 201. The AHOBPR continues to grow at a rapid pace and provides a model for future data collection requirements.

5. **If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.**

   Because this registry applies to individuals, small businesses or other small entities are impacted by the information collection.

6. **Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

   VA was required to establish the registry by 10 January 2014, per Public Law 112-260. The registry began on 14 June 2014. At the current time, there is no legislation under consideration to end the registry.

7. **Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.**

   There are no such special circumstances.

8. **a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.**

   The 60-day notice of Proposed Agency Information Collection Activity was published in the Federal Register on May 6, 2019 (84 FR 19829-19830). We received no comments in response to this notice.

   The 30-day notice of Agency Information Collection Activity under OMB Review was published in the Federal Register on July 25, 2019 (84 FR 35930-35931). We have received no comments to date in response to this notice.

   b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances that preclude consultation every three years with representatives of those from whom information is to be obtained.

   Outside consultation is conducted with the public through the 60- and 30-day Federal Register notices.

9. **Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

   No payment or gift is provided to respondents.

10. Describe any assurance of privacy to the extent permitted by law provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Registry information and applicant completed questionnaires become part of a system of records that complies with the Privacy Act of 1974. This system is identified as "VA Mobile Application Environment (MAE)-VA" (173VA005OP2) as set forth in the Compilation of Privacy Act Issuances via online GPO access.

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Information regarding sexual behavior and attitudes, religious beliefs, or mental health issues are not collected. Collected data are secured in accordance with VHA Systems of Record Notices. Refer to 173VA005OP2 MAE) –VA, 172VA10P2 VHA Corporate Data Warehouse-VA, and 24VA10P2 Patient Medical Record –VA). The benefits of responding to the Web Survey includes helping VA to answer important questions concerning the health effects of airborne hazard exposures and providing an evidence base for policy recommendations and research.

12. Estimate of the hour burden of the collection of information:

a. The number of respondents, frequency of responses, annual hour burden, and explanation for each form is reported as follows:

<u>Airborne Hazards and Open Burn Pit Registry Questionnaire</u>:

Open Pit Burn Registry	No. of respondents	x No. of responses	Equals	x No. of minutes	Equals	÷ by 60 =	Number of Hours
VA Form 10-10066	50,000	1	50,000	40	2,000,000		33,333

<u>Subset of AHOBPR , Qarmat Ali Questionnaire</u>:

Qarmat Ali Cohort Questionnaire	No. of respondents	x No. of responses	Equals	x No. of minutes	Equals	÷ by 60 =	Number of Hours
Original VA Form Estimate	686	1	686	10	6860		114

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13.

See charts in subparagraph 12a above.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

VHA uses general wage data to estimate the respondents' costs associated with completing the information collection. In accordance with the Bureau of Labor Statistics (BLS) May 2018 Occupational Wage Code Median Hourly, the mean hourly wage is $24.98 based on the BLS wage code – "00-0000 All Occupations." This information was taken from the following website: https://www.bls.gov/oes/2018/may/oes_nat.htm.

Legally, respondents may not pay a person or business for assistance in completing the information collection, and a person or business may not accept payment for assisting a respondent in completing the information collection. Therefore, there are no expected overhead costs.

VHA estimates the total annualized cost to respondents to be $835,506.06 (33,447 total burden hours x $24.98 per hour). VA does not require any additional recordkeeping.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

a. There are no capital, start-up, operation or maintenance costs.
b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
c. There is no anticipated recordkeeping burden beyond that which is considered usual and customary.

14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

An IT development was used to support this assessment. Costs for similar Web solution and registry database project development, operations, and sustainment were used. Analysis of the data and staff education may require additional resources. VA Veteran outreach costs are based on current registry programs (e.g., Agent Orange, Gulf War, Ionizing Radiation) within the VHA Patient Care Services Office for Post Deployment Health Services.

Table: Annual Cost Estimate

Analysis, Reporting Staff Education Congress Mandated Reports	IT Development	IT Sustainment	Total
$350,000	$400,000	$350,000	$1,100,000

15. Explain the reason for any burden hour changes or adjustments reported in items 13 or 14 of the OMB form 83-1.

This is a new collection and all burden hours are considered a program increase. An additional cost burden of ten minutes, per respondent, is added for the approximately 686 veterans included in the Qarmat Ali Cohort. All registrants included with this subset cohort also are eligible for the AHOBPR.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

VA produces descriptive statistics for registry participants and periodically provides outreach to participants as required by Pub. L. 112-260. Outcome analysis and research are ongoing and published as completed. Public law does not specify an end date for this collection.

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VA seeks to minimize the cost to itself of collecting, processing and using the information by not displaying the expiration date. VA seeks an exemption that waives the displaying of the expiration date on this VA Form. The VA Form may be reproduced by the respondents and VA field facilities from the internet and then stocked. If VA is required to display an expiration date, it would result in unnecessary waste of existing stock of the forms. Inclusion of the expiration date would place an unnecessary burden on the respondent (as they would find it necessary to obtain a newer version, while VA would have accepted the old one).

18. Explain each exception to the certification statement identified in Item 19, “Certification for Paperwork Reduction Act Submissions,” of OMB 83-I.

There are no exceptions.

The following exposures, outcomes and health care operation data variables are explored:

4.1 **Exposures of Interest**

a) Deployment anthropogenic PM, fumes, vapors and gases
   i) Deployment location
   ii) Reported exposures to open burn pits
   iii) Fuel vapors
   iv) Weapon combustion gases
   v) Oil well fires
   vi) Blasts (overpressure or gases)
   vii) Other occupations with possible exposures (pesticides, engine maintenance, construction)
b) Deployment natural/geologic PM
   i) Dust storms
   ii) Convoy operations
c) Places of residence as a proxy for general PM levels
d) Non-military occupational exposures
e) Tobacco exposure
f) Alcohol consumption

4.2 Outcomes of interest

a) Functional limitations
b) Employment status
c)Respiratory disease
   i) Asthma
   ii) Emphysema
   iii) Chronic bronchitis
   iv) Chronic obstructive pulmonary disease
   v) Constrictive bronchiolitis
   vi) Idiopathic pulmonary fibrosis
   vii) Sarcoidoisis
   viii) Other respiratory conditions
d) Cardiovascular disease
e) Hypertension
f) Coronary artery disease
g)Myocardial infarction
h) Congestive Heart Failure
i) Chest pain
j) Other cardiac conditions
k) All Cancers/leukemia's
l) Neurologic disease
   i) Renal disease and impairment
   ii) Overall health
   iii) Symptom history and current symptoms
   iv) Reported exposure mitigation

4.3 Health Care Operation Variables

a. Eligible for registry participation
b. Registry participation
c. Enrollment in VHA health care vs. non-enrolled
d. Beneficiary status (e.g. Active Duty, Retiree, Reserve and Guard, Service, separated from duty)
e. Reported health concerns
f. Reported health care utilization
g. Utilization of in-person VHA health evaluation

4.4 Methods

Frequencies and descriptive statistics for demographic characteristics including age, sex, race, ethnicity, branch of service, unit component, and rank are performed and stratified by self-reported exposure. Demographic and deployment data are available from existing VHA and DoD datasets that are merged with the unique participant identifier. (See attached table shells).

The prevalence of specific conditions and exposures that were measured using National Health Interview Survey questions cannot be compared to the United States (U.S.) population data, as we do not expect the registry to produce a generalizable sample.

4.5 Strengths

This registry has several strengths. It is the first U.S. Government airborne hazards registry to date. Analysis of the registry data benefits from linkages to data from various sources with multiple data points per participant (e.g. initial self-assessment, potential follow-up self-assessments, optional in-person medical evaluations, external data sources). Self-reported exposure data are collected years before chronic conditions develop, which could reduce recall bias. The registry includes Veterans and Active Duty Servicemembers, VA users and non-users, which could reduce selection bias and expedite data transfer for members separating from the military and transitioning to a Veteran

4.6 Limitations

The self-assessment is a cross-sectional study of self-reported exposures and outcomes. Cross-sectional studies are limited in their ability to study the timing of outcomes vs. exposures which inherently limits the ability to make causal associations. Two types are most common in the registry, recall bias and selection bias. The registry may not be representative of the entire deployed population because for selection bias. Recall of exposures may not be accurate given both the length of time from deployment to self-assessment and may be different between the Active Duty and Veteran groups given differences in cultural norms around reporting unpopular perceptions. In addition, respondents suffering from respiratory conditions (or other conditions that are thought to be a result of an airborne hazard) may recall differently than those who are not suffering from the outcomes of interest in an effort to find a reason for their illness. This can lead to differential misclassification of exposure and outcome.