

Airborne Hazards And Open Burn Pit Registry Self-Assessment Questionnaire

Web-Accessible: VA Form 10-10066

OMB 2900-XXXX

A. JUSTIFICATION

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

Public Law 112-260 Section 201, enacted by President Obama on 10 January 2013, requires VA to establish and maintain an “Open Burn Pit Registry” no later than one year from enactment. 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”.

VA plans to conduct field trials with a limited number of Veterans. By conducting field trials before the registry becomes open to all Veterans, VA can better ensure that all aspects of the registry are functional. At this time, VA requests approval to set up the registry and administer the baseline questionnaire. Any follow-up work involving other information collections (e.g., follow-up self-assessments) will be the subject of future requests for approval.

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 will be used to provide outreach and quality health services to Airborne Hazards and Open Burn Pit Registry participants, and if the data quality permit, contribute to VA’s ability to understand the potential health effects of the exposure to “fumes caused by open burn pits” and other airborne hazards of deployment such as particulate matter (PM). Because of self-selection bias, the registry is unlikely, to provide “reliable” data generalizable to the population of all eligible individuals. As such, the intent of the registry is not to make generalizations or reliable estimates, but rather to help inform health care decisions and guide future research.

Participant health concerns, demographics, deployment information, environmental monitoring data, self-reported exposures, health status, and health care utilization will be monitored over time through routine and ad hoc analysis to improve health care programs and develop hypotheses as to the health effects of exposures.

VA researchers may access the identifiable data in a secure environment, and may merge it with other data sets in IRB approved research studies to test hypothesis or solicit participation in research studies (which may require approval under the Paperwork Reduction Act). Data may be used to target outreach to Veterans with specific exposures or health status of concern. Registry data will be maintained in accordance with federal privacy and information security standards. Participant questionnaires will be administered via World Wide Web. Data elements for the first component of the study 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 PRA clearance would be required for such collections.

The data collected via participant questionnaires will be analyzed in concert with data available from VA patient health records and Department of Defense (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, PRA 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 will be completed using an internet information technology solution to improve 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.

There are no existing registries that will satisfy the legislative mandate of Pub Law 112-260 section 201.

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

No 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 is required to establish the registry by 10 January 2014 per Public Law 112-260.

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 notice of Proposed Information Collection Activity was published in the Federal Register Wednesday, June 5, 2013 (Volume 78, Number 108, Page 33894 - 33895).

VHA has received over 274 public responses to this notice in Regulations.gov. The VHA PRA liaison has fielded an additional 80 public responses, by email and telephone calls. The comments can be reviewed by following the link provided.

<http://www.regulations.gov/#!searchResults:rpp=25;po=0;s=Open%252BBurn%252BPit%252BRegistry%252BAirborne%252BHazard%252BSelf-Assessment%252BQuestionnaire;ns=true>

VA would like to thank all those who participated in its recent solicitation for comments on the Airborne Hazards and Open Burn Pit Registry Questionnaire. In total, over 325 comments were received and, in general, commenters supported VA's effort to document the activities that may be associated with environmental exposures and the health concerns of veterans who deployed during their military service. Many comments provided personal accounts of deployed experiences and how this impacted the Veteran. VA examined all of the feedback it received through this solicitation—whether it was a personal account, a comment on questionnaire methodology, or a question about the registry. Feedback helped VA to understand Veterans' concerns about potential exposure to airborne hazards.

VA received comments on the draft questionnaire's wording and answer choices and suggestions for additional questions. Many of these suggestions were integrated into VA's revision of the questionnaire. For example, VA added questions on fibromyalgia, irritable bowel syndrome, constrictive bronchiolitis, pulmonary fibrosis, immune and neurological disorders, sewage treatment ponds, and modified exposure questions to enable more detail to the duration of exposures. Among commenter's, there was disagreement over the time burden that the questionnaire should pose to Veterans. One commenter suggested the burden be "10 to 15 minutes," while others suggested VA asks very detailed questions or make the questionnaire mandatory.

Many commenters questioned the rationale of including sections detailing Veteran residential history, hobbies, and occupational history. Others indicated that VA included these sections to allow it to blame health outcomes on non-deployment exposures. Questions on residential history, hobbies, and occupational history were included in the questionnaire to help gauge non-deployment exposure levels. Such exposures may help the VA determine whether these exposures interact with one another to affect the likelihood of a health outcome. VA has added the response, "I do not wish to answer this question" throughout the self-assessment questionnaire to enable veterans to "opt-out" of certain questions. It should be noted that the registry is best suited to identify possible associations between potential exposures and adverse health outcomes. The voluntary nature of registry participation restricts the ability of data generated from the registry to be generalized to the entire deployed population. VA is proposing

research studies to investigate the health effects of airborne hazards and deployment on a population basis which may provide additional information. Finally, it should be noted that under current VA authority, the presence of additional risk factors, such as environmental exposures, does not prevent service connection for diseases incurred or aggravated during military service.

One common thread in the comments was the expression of concerns, questions, and comments on registry eligibility. Some commenters wanted to expand eligibility to current active duty Servicemembers or to deployed civilian employees. The VA is currently working with the DoD to extend eligibility to active duty military members, and although VA cannot extend eligibility to civilians, it encourages exposed civilians to contact their former employers with their concerns. Some commenters were concerned that veterans would have to prove individual exposure in order to be found eligible for the registry, which they said was not feasible. Eligibility will be determined via existing DoD electronic deployment records and does not involve individual exposure. The largest area of eligibility comments centered on geographic and temporal (timeframe) eligibility. Public Law 112-260 requires that VA establish an open burn pit registry for members of the Armed Forces who deployed as part of a contingency operation to Iraq or Afghanistan on or after September 11, 2001. At this time, VA intends to extend eligibility in the Airborne Hazards and Open Burn Pit Registry to deployments on or after September 11, 2001, to the Persian Gulf region and Djibouti, or during the first Persian Gulf War. The larger numbers of Veterans in this expanded eligibility criteria will improve VA's ability to analyze Veteran outcomes, especially for rare outcomes from potential exposures in this geographic region. Some commenters asked that other contingency operations such as Somalia and Vietnam be included in the registry. Including other contingency operations would significantly increase the length of the questionnaire because of the need to ascertain exposures unique to these other regions (e.g. Vietnam and Somalia). (Note: See supporting Federal Register Notice (FRN) to be posted when the registry is established announcing the expansion of eligibility to include the Persian Gulf region and Djibouti.)

VA would also like to let commenters and all others know that Veterans who participate in the registry do not need to enroll in the VA health care system, although we encourage them to do so. Also, registry participation will not impact individual Veteran eligibility for VA benefits or health care services. VA believes that its current eligibility criteria will be sufficient to meet the goals of the registry program, as the registry is primarily a public health initiative aimed at facilitating outreach and health care, monitoring the health care needs and concerns of Veterans, developing possible reasons for any possible associations between potential exposures and the development of adverse health effects, and to aid in recruiting veterans to participate in future research.

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 which 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 FRNs. Interagency coordination of the VA response to open burn pit and other airborne health hazards included a VA sponsored study by the Institute of Medicine (IOM) released in October of 2011, a DoD sponsored study by the National Research Council in 2009 of the DoD Enhanced Particulate Matter Study, and frequent collaboration with the National Institute of Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), and academic institutions. Veteran Service Organizations (VSO) were invited to provide opening remarks during an Airborne Hazard Symposium in August 2012 and attend a follow-on symposium in August 2013. Veterans Health Administration (VHA) has briefed Veteran Service Organizations twice during an established quarterly VHA-VSO meeting.

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.

Information on these forms will become part of a system of records which 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 at <http://www.gpoaccess.gov/privacyact/index.html>

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 will not be collected. Collected data will be secured in accordance with the VHA Systems of Record Notices. Refer to 173VA005OP2 VA Mobile Application Environment (MAE) –VA, 172VA10P2 VHA Corporate Data Warehouse-VA, and 24VA10P2 Patient Medical Record –VA). The benefits of responding to the web survey is that this information will help VA answer important questions about the health effects of airborne hazard exposures and provide 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:

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

Follow-up questionnaires, should they be required, will be requested in a future PRA renewal. VA cannot estimate the burden at this time.

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 of OMB 83-I.

This request covers only one form.

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.

VA does not require any additional recordkeeping. The cost to the respondents for completing these forms is \$766,659 (\$23 per hour x 33,333 burden hours).

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 is 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.

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 will be required 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) within the Office of Public Health (OPH).

Table: Cost Estimate

FY	Analysis, Reporting, and Staff Education	IT Development	Veteran Outreach	Total
2013	\$100,000	\$2,000,000	\$70,000	2,170,000

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.

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 will produce descriptive statistics for registry participants and will periodically provide outreach to participants as required by Pub. L. 112-260. Process metrics will be reported twice per year or quarterly. Outcome analysis is planned to occur annually. Public law does not specify an end date for this collection.

The following exposures, outcomes and health care operation data variables will be explored (also refer to the proposed table shells):

4.1 Exposures of Interest

- a. Deployment anthropogenic particulate matter, 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 particulate matter
 - a. Dust storms
 - b. Convoy operations
- c. Places of residence as a proxy for general particulate matter 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
 - a. Asthma
 - b. Emphysema
 - c. Chronic bronchitis
 - d. Chronic obstructive pulmonary disease
 - e. Constrictive bronchiolitis
 - f. Idiopathic pulmonary fibrosis
 - g. Sarcoidosis
 - h. Other respiratory conditions
- d. Cardiovascular disease
 - a. Hypertension
 - b. Coronary artery disease
 - c. Myocardial infarction
 - d. Congestive Heart Failure
 - e. Chest pain
 - f. Other cardiac conditions
- e. All Cancers/leukemia's
- f. Neurologic disease
- g. Renal disease and impairment

- h. Overall health
- i. Symptom history and current symptoms
- j. 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 will be performed and stratified by self-reported exposure. Demographic and deployment data are available from existing VHA datasets that will be merged with the unique participant identifier. Frequencies of all exposures will be performed. Frequencies of all outcomes will be performed, and stratified by exposure (See attached table shells).

The prevalence of specific conditions and exposures that were measured using NHIS questions cannot be compared to the US 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 will likely have benefit 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 being collected years before chronic conditions would naturally develop, which could reduce recall bias. The registry will include Veterans and Active Duty Servicemembers, VA users and non-users, which could reduce selection bias.

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 of bias will likely exist in this registry, recall bias and selection bias. Recall of exposures may not be accurate given both a) 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, subjects taking the self-assessment that are 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.

Although individuals do not need to be enrolled in VA in order to take part in the registry, the majority of the communication used to advertise the registry will occur using VA information outlets (OPH website, VA Facebook/Twitter, clinicians, flyers in hospitals), so Veterans who are engaged with VA would be more likely to find out about the registry and subsequently participate leading to a possibly biased sample. Also, those with greater concern about the exposure, including those with chronic health problems, may be more likely to make the effort to participate in the self-assessment.

Proposed Table Shells

Table I: Demographics, Department of Veterans Affairs Open Burn Pit Registry Participants (N=)

Characteristic	N (%)
Birth Year	
Pre-1960	XX (XX%)
1960-1969	XX (XX%)
1970-1979	XX (XX%)
1970-1979	XX (XX%)
1980 or later	XX (XX%)
Sex	
Male	XX (XX%)
Female	XX (XX%)
Branch of Service	
Air Force	XX (XX%)
Army	XX (XX%)
Marine Corps	XX (XX%)
Navy	XX (XX%)
Coast Guard	XX (XX%)
Unit Component	
Active Duty	XX (XX%)
National Guard	XX (XX%)
Reserves	XX (XX%)
Rank	
Enlisted	XX (XX%)
Officer	XX (XX%)

Table 2: Health Care Operations Characteristics, Department of Veterans Affairs Open Burn Pit Registry Participants (N=)

Characteristic	N(%)
Eligible for participation	XX (XX%)
Enrolled in VHA Health care	XX (XX%)
Beneficiary Status (Veteran, Active Duty, Retiree)	XX (XX%)
Utilization of in-person health evaluation	XX (XX%)
Mean number of days between self-assessment and in-person evaluation	XX (SD)

Table 3: Frequencies of Self-Reported Exposures, Department of Veterans Affairs Open Burn Pit Registry Participants (N=)

Exposure	N(%)
Burn Pit Exposures	XX (XX%)
Engine Combustion Products	XX (XX%)
Fuel Vapors	XX (XX%)
Weapon Combustion Gases	XX (XX%)
Oil Well Fires	XX (XX%)
Particulate Matter	XX (XX%)

Table 4: Demographics by Self-Reported Exposure Status, Department of Veterans Affairs Open Burn Pit Registry Participants (N=)

Characteristic	Burn Pit Exposures	Engine Combustion Products	Fuel Vapors	Weapon Combustion Gases	Oil Well Fires	Particulate Matter
	N(%)	N(%)	N(%)	N(%)	N(%)	
Birth Year						
Pre-1960						
1960-1969						
1970-1979						
1970-1979						
1980 or later						
Sex						
Male						
Female						
Branch of Service						
Air Force						
Army						
Marine Corps						
Navy						
Unit Component						
Active Duty						
National Guard						
Reserves						
Rank						
Enlisted						
Officer						

Table 5: Self-Reported Outcomes and Exposures, Department of Veterans Affairs Open Burn Pit Registry Participants (N=)

	Burn Pit Exposures	Engine Combustion Products	Fuel Vapors	Weapon Combustion Gases	Oil Well Fires	Particulate Matter
	N(%)	N(%)	N(%)	N(%)	N(%)	
All Cancers						
Asthma						
Chest Pain						
Chronic Bronchitis						
COPD						
Congestive Heart Failure						
Constrictive Bronchiolitis						
Coronary Artery Disease						
Current Symptoms						
Emphysema						
Employment Status						
Functional Limitations						
Hypertension						
Idiopathic Pulmonary Fibrosis						
Myocardial infarction						
Neurologic Disease						
Other Cardiac Conditions						
Other Respiratory Conditions						
Overall Health						
Renal Disease and Impairment						
Sarcoidosis						

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 (since 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.