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## DEPARTMENT OF VETERANS AFFAIRS

### Initial Research on the Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan

**ACTION:** Notice.

**SUMMARY:** This notice announces the preliminary plans of the Department of Veterans Affairs (VA) to conduct a longitudinal cohort study of adverse health effects related to military deployment to Iraq and Afghanistan, to include potential exposure to airborne hazards and burn pits, and to take related actions to promote the effective monitoring and assessment of deployment-related exposures and potential health effects of deployments. The planned actions are based in part on VA's review of the analysis and recommendations in an October 31, 2011, report of the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) concerning the potential long-term health consequences of exposure to burn pits in Iraq and Afghanistan.

**FOR FURTHER INFORMATION CONTACT:** Dr. Paul Ciminera, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 461-1020. (This is not a toll-free number.)

#### **SUPPLEMENTARY INFORMATION:**

On October 31, 2011, at VA's request, IOM issued a study titled, "Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan" (IOM report). The IOM reviewed a wide range of data sources including peer-reviewed literature on the subject of respiratory exposures in general, information on types of materials and

quantities burned during burn pit use in Iraq and Afghanistan, and analyses of ambient air sampling collected by the Department of Defense (DoD). IOM concluded that there was limited but suggestive evidence of an association between exposure to combustion products and reduced pulmonary function, but inadequate or insufficient evidence of an association between exposure to combustion products and cancer, respiratory diseases, circulatory diseases, neurologic diseases, and adverse reproductive and developmental outcomes in the populations studied. After careful review of the IOM report, the Secretary has directed the Veterans Health Administration to conduct a long-term prospective study on all adverse health effects potentially related to military deployment to Iraq and Afghanistan, to include health effects potentially related to exposure to airborne hazards and burn pits. In addition, the Secretary has requested participation by DoD in VA's proposed study, joint participation in long-term cohort studies for every future major deployment, priority staffing in support of the VA/DoD Environmental Exposure Data Transfer Agreement (DTA), and continued collaboration on a Joint VA/DoD Action Plan to address clinical and research issues associated with deployment. Additional efforts include inviting DoD to support a joint VA/DoD post-deployment health annual symposium to disseminate lessons learned to health care teams (and other stakeholders) and bring key subject matter and policy experts together to guide joint strategic research plans on post-deployment health related issues. VA intends, in conjunction with DoD, to establish clinical evaluation protocols for exposure to burn pit emissions and other airborne pollutants encountered by servicemembers deployed to Iraq and Afghanistan, and conduct research on the long-term health effects of exposure to burn pits.

Background. This IOM report was not required by law. It was requested by VA in response to increasing concerns about the long-term health of U.S. servicemembers who served in Iraq or Afghanistan who may have been exposed to potentially hazardous materials from open burn pits, which were commonly used for waste disposal. Specifically, VA asked IOM to examine potential exposures and long-term health risks arising from exposure to smoke created from open pit burning of solid waste and other materials in Iraq and Afghanistan. Using the Joint Base Balad (JBB) burn pit as an example, IOM was asked to evaluate the long-term health risks based on a review of a wide range of sources such as epidemiologic studies conducted either by or under the auspices of VA or DoD; other available epidemiologic literature on populations exposed to similar hazards; as well as relevant environmental studies, relevant toxicologic studies, veteran-specific clinical/pathologic studies, and the effects related to short-term peak exposures, as well as chronic exposures. In addition, IOM was asked to make recommendations for epidemiologic research initiatives for VA and DoD to further study potential long-term health effects.

IOM first assessed the types and quantities of materials burned during the time of pit use and analyzed air monitoring data collected at JBB during 2007 and 2009. It then examined anticipated health effects from exposure to air pollutants found at JBB and studies of health effects in similar populations with similar exposures, grading the quality of those studies as key or supportive. IOM then performed a synthesis of key information on potential long-term health effects in military personnel potentially exposed to burn pits and developed design elements and feasibility considerations for an epidemiologic study.

IOM concluded that there is limited but suggestive evidence of an association between exposure to combustion products and reduced pulmonary function in the populations studied. Pulmonary function tests are frequently used to diagnose respiratory disease, and changes can be observed in the absence of clinical symptoms or disease. However, this IOM finding focused on pulmonary function, not respiratory disease, and noted that further studies, including longitudinal studies, are required. The studies conducted to this point have been limited in scope and duration, and many focus on non-veterans in other (not completely similar) settings, including firefighters, residents living near incinerators, and incinerator workers.

IOM also concluded that there is inadequate or insufficient evidence of an association between exposure to combustion products and cancer, respiratory diseases, circulatory diseases, neurologic diseases, and adverse reproductive and developmental outcomes in the populations studied.

As previously noted, IOM relied on peer reviewed studies of surrogate patient populations (firefighters and incinerator workers) because there were limited studies, long or short term, of servicemembers exposed to burn pits or similar contaminants while in an operational area. VA believes such studies would be helpful in properly assessing affected veterans for compensation purposes as well as for medical evaluation, treatment and follow up. The following precursor actions will facilitate such future studies:

(1) Development of a standardized post-deployment evaluation protocol. VA and DoD believe that the post-deployment evaluation of servicemembers and veterans

with respiratory complaints should be standardized across the Departments. VA recognizes that burn pits may not be the main cause of any long-term health effects related to deployment to Iraq and Afghanistan. Military operations in these areas also expose servicemembers to other air pollutants, predominately particulate matter (PM), which might be associated with long-term health effects, particularly in highly exposed or susceptible populations. Developing a standardized screening and diagnostic evaluation protocol will facilitate appropriate assessment and medical care as needed. VA intends to work jointly with DoD to develop expert consensus on these evaluation protocols.

(2) Development of validated exposure assessment instruments. VA will continue to work in a supporting role with DoD to attempt to develop exposure assessment instruments for use in both research and clinical evaluation. This will aid in identifying any health outcomes potentially associated with burn pit emissions by identifying sources of exposure as well as the chemicals associated with burning waste and other pollution sources. Accurate assessment of exposure potential requires identifying possible toxicants, detailed deployment information, duration of deployment, job duties, and in the case of burn pits, the distance from the burn pit and whether the individual lived and worked upwind or downwind from the burn pit. VA relies on DoD to provide these confirmatory data, and is actively pursuing a Data Transfer Agreement (DTA) to include more specific data elements.

(3) Supporting an integrated DoD/VA clinical informatics system. VA recognizes that assessment of health outcomes is best done collaboratively using the clinical informatics systems of DoD and VA. An integrated VA-DoD electronic medical

record is the optimal solution. The issue of integration is being addressed through several ongoing initiatives. The VA-DoD Deployment Health Work Group is sponsoring a DTA that will enable DoD exposure data to be transferred to VA. In addition, VA plans to link outcome data with self-reported questionnaire data from DoD's Millennium Cohort Study (MCS), which includes a large veteran population that deployed in support of current operations in Iraq and Afghanistan. VA is working to embed personnel in the MCS office to conduct joint research and provide VA medical record reviews of conditions self-reported from veterans participating in the MCS.

To address the need for further study of the long-term health effects of exposure to airborne hazards (such as pollution and burn pit emissions) in Iraq and Afghanistan, VA intends to take the following steps:

Design appropriate studies. The long-term health effects related to exposure to burn pit emissions should be assessed. Early markers of respiratory disease, via measurable changes in the respiratory system, should be examined through a research-based physical examination component of a broader research program. As a first step, VA intends to develop research goals and objectives, structures, and establish essential study design features. Existing research studies, such as the Million Veteran Program, the Cooperative Studies Program, the Gulf War Veteran studies, the MCS, and the National Health Study for a New Generation of U.S. Veterans, will be evaluated to determine whether any of these can be used to support burn pit exposure studies, or whether modifications to these studies may be necessary to meet the overall goals of a research plan. In 2005, DoD formed the Joint Particulate Matter Work Group to investigate the composition of PM across USCENTCOM. The Pulmonary Working

Group was established in 2010 to investigate reports of specific respiratory conditions found in returning veterans. VA and DoD continue to collaborate and support ongoing activities that may be leveraged in the study of long-term health effects related to exposure to airborne hazards such as burn pit emissions.

Establish an independent oversight mechanism. VA intends to establish an independent oversight committee to provide guidance and to review specific research objectives, study designs, research and evaluation protocols, and results from burn pit emissions research. VA has established independent advisory bodies that could potentially provide the required level of external oversight. These bodies include standing review committees that provide peer review for VA researchers. The committees should include external subject matter experts recruited from academia, internal VA experts, and experts from other government agencies, and should be modeled after the National Institutes of Health's Center for Scientific Review.

Conduct a cohort study. VA intends to work jointly with DoD to develop and conduct a cohort study of veterans and servicemembers to assess potential long-term effects related to burn pit emissions in the context of other ambient exposures. This will likely involve a population-based prospective study that includes baseline and repeated clinical examinations with sufficient follow up to address the potential long-term health effects of deployment to Iraq and Afghanistan as well as potential burn pit exposure.

#### Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal

Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on December 26, 2012, for publication.

Dated: January 29, 2013

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William F. Russo, Deputy Director,  
Office of Regulation Policy and Management  
Office of the General Counsel,  
Department of Veterans Affairs.

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