



**REPORT TO CONGRESS
ON
EXPOSURE REGISTRY FEASIBILITY STUDY**

**Pursuant to House Report 111-491,
to Accompany H.R. 5136, the
National Defense Authorization Act for Fiscal Year 2011,**

May 2011

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**Department of Defense
Report to Congress**

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Background

House Report 111-491, to accompany H.R. 5136, the National Defense Authorization Act for Fiscal Year 2011, established a special interest item under Title VII—Health Care Provision, entitled, “Exposure Registry Feasibility Study,” which requested the Secretary of Defense to, “provide a report on the feasibility of establishing an active registry for each incidence of exposure of occupational and environmental chemical hazards, to include waste disposal, during conflicts, to monitor possible health risks and provide necessary treatment to those exposed,” to the congressional defense committees by March 31, 2011. “The report should discuss processes in which Service members exposed to toxic chemicals could be included on the registry and procedures to provide medical examinations to Service members who are eligible to be included on the registry” and “should also seek to leverage existing medical surveillance systems.” An interim report was submitted on March 7, 2011, indicating the Department of Defense (DoD) would provide the final report by May 31, 2011.

Feasibility of Establishing an Active Registry for Each Incidence of Exposure

DoD believes it is, indeed, feasible, despite some difficulties, to establish active exposure registries, but only for discrete and “known” exposure incidents in which it is known or believed to be extremely likely that all or most of the individuals involved in the incident were exposed above a health threshold. As will be discussed, adequate and accurate exposure documentation is often not available. In such cases, DoD establishes registries that are better termed registries of “possibly exposed” personnel. Most recently, DoD has accomplished this as part of a joint DoD-Department of Veterans Affairs (VA) Special Medical Surveillance Program recently established to evaluate health outcomes from possible sodium dichromate exposures at the Qarmat Ali Industrial Water Treatment Plant, near Basra, Iraq in 2003.

DoD previously described difficulties in establishing registries of chemical exposure to Congress in Section 7 of DoD’s April 28, 2010, report to Congress (RTC) entitled “The Use of Open-Air Burn Pits by the United States Armed Forces,” pursuant to section 317(b) of the National Defense Authorization Act for Fiscal Year 2010, Public Law 111-84. DoD was directed to “provide an assessment of the ability of existing medical surveillance programs to identify and track exposures to toxic substances that result from open-air burn pits, including recommendations for such changes to such programs as would be required to more accurately identify and track such exposures.” In that report, DoD stated that “while our current environmental health surveillance systems are much improved, there are limitations. The once-daily personnel location data is often not specific enough to definitively establish exact

location(s) of personnel at any given time during a 24-hour period. As a result, this data provides limited assistance in determining potential exposure concentrations or durations of exposure.”

These limitations hinder DoD’s ability to accurately determine or even reasonably estimate the “dose” (i.e., exposure) for individuals, or groups of individuals, who have been exposed. This impacts DoD’s ability to create active, effective, and accurate chemical exposure registries. To determine or assign a dose or exposure, which is critical in assessing the likelihood of any health impacts, one needs to know the amount (levels or concentrations) of the chemicals to which the person was exposed, along with the duration (time) of the exposure (concentration x time = dose). During conflicts it is extremely difficult to determine these exposure parameters, and without accurate estimation of dose, it is very difficult to make any prediction of health risk.

The number of individuals DoD deploys during military conflicts who are trained to assess chemical exposures is usually not sufficient to effectively gather information on the full range of chemical exposures (concentration) for all Service members deployed in support of military operations during conflicts. It is generally not possible to get enough Force Health Protectors into theater to match up and assess chemical exposures to all of our expeditionary and mobile operational forces. Second, DoD lacks sufficient theater-wide chemical detection systems and personal chemical dosimeters to provide a materiel solution to fill this personnel void. DoD cannot procure these technologies because they have not yet been fully developed and fielded.

In addition to difficulties in accurately determining the chemical concentration of potential exposures, it is often just as difficult to determine the proper duration or time of exposure. In relation to exposure events that take place over multiple days, weeks, or months, DoD often has to rely on the once-daily location data required by Department of Defense Instruction (DoDI) 6490.03, “Deployment Health,” August 11, 2006, <http://www.dtic.mil/whs/directives/corres/html/649003.htm>, to develop an estimate of a Service members exposure time. The assumption is that the longer the period of assignment to the location of possible exposure, the greater the duration of the exposure. Given the nature of military operations during conflict, this assumption may not be accurate for many of the Service members who are identified as possibly exposed, particularly as it relates to point source exposures (e.g., burn pits). Further complicating DoD’s ability to define “time” or “duration” of exposure, once-daily location data is generally only recorded for Service members who are assigned to base camps, so there is limited information to document changes in location for Service members outside base camp boundaries.

DoD often defaults to performing ambient environmental monitoring for a broad range of chemicals and then translates that data into estimates of individual and population-level doses or exposures by taking the highest measured concentration, assuming an exposure duration of 24 hours a day, 7 days a week, for up to 1 year, and then assigning the resulting exposure estimate to all Service members possibly exposed. The process inherently introduces a great degree of imprecision into these dose estimates and leads to risk estimates that err on the conservative side for many of the possibly exposed Service members.

The issues described above lead to three additional points of discussion. First, given the limited number of individuals deployed to evaluate chemical hazards in comparison to the total deployed force and the lack of technology to more accurately determine and assign exposures to Service members during conflicts, DoD believes additional research and development into biomarkers of exposure and individual chemical dosimeters is critical to accurately measure chemical exposure. DoD is currently engaged in research efforts in these areas.

Second, given DoD's stated difficulties in establishing accurate "registries of exposure" to chemicals during conflicts, especially involving large numbers of individuals over geographically dispersed areas, DoD has instead constructed registries of individuals who have been possibly exposed. These registries can be used in a similar fashion as a true exposure registry to target individuals for health risk communication, medical care, and/or medical surveillance. Such a registry is currently being used to identify Service members and DoD civilian employees for participation in the joint DoD-VA Qarmat Ali Special Medical Surveillance Program to assess possible sodium dichromate exposures in Iraq in 2003. One is also being developed in support of Operation Tomodachi in order to identify all DoD-affiliated individuals (Service members and their family members, DoD civil servants, DoD-employed foreign nationals, etc.) possibly exposed to radiation and other health hazards in the aftermath of the Japan earthquake, tsunami, and damage to the Fukushima nuclear power plant reactors.

Third, DoD believes it is inappropriate to establish active exposure registries for every exposure incident, because unless an exposure threshold is set to include only those above a health threshold, the number of such incidents is virtually unlimited. Additionally, DoD maintains that establishing registries of chemical exposures is only advantageous and warranted for those exposures of sufficient magnitude to have the potential to cause latent, chronic illness.

Processes by which Service Members Exposed to Toxic Chemicals Could be Included in the Registry

DoD's processes and decisions to include Service members exposed to toxic chemicals on an exposure registry would be based upon direct measurement of the dose or exposure each individual received and the ensuing assessment of the health risk that level of exposure presented. However, as DoD has pointed out, assessing chemical exposures during conflicts is an inherently imprecise process which often results in assigning conservative dose estimates to the Service members possibly exposed. This means that the doses assigned are likely higher for most, if not all of the individuals than would have been measured directly. In turn, these conservative dose estimates drive conservative health risk estimates.

There are primarily two ways DoD includes Service members exposed to toxic chemicals in an exposure registry. The first involves assigning an actual or estimated exposure or dose to a Service member or group of Service members (population) based on an actual or estimated concentration and duration of the exposure (as outlined in the first section) and then assessing the health risk of these actual or possible exposures. If the resulting health risk assessment indicates an elevated long-term health risk based upon the procedures contained in DoDI 6490.03, DoDI 6055.05, "Occupational and Environmental Health", Chairman's Memorandum 0028-07,

“Procedures for Deployment Health Surveillance,” and Service-level instructions, then all Service members to whom the health risk applies would be included in the registry.

The second way in which Service members would be included on a chemical exposure registry is by virtue of any post-exposure medical encounters resulting in exposure-related diagnoses or findings. Both DoDI 6490.03 and DoDI 6055.05 require medical record entries for confirmed exposures and for Service members who experience acute illness or who are clinically evaluated for exposures. Medical record entries are to identify the chemical to which the Service member was exposed (if known) along with any associated signs, symptoms and treatments. Given that the vast majority of these medical record entries are now done electronically, even in deployed locations, these medical encounter-based chemical exposure registries would most often be virtual and contained within DoD’s electronic health record (EHR). Additionally, all exposures deemed immediately hazardous to life or health or that may significantly increase long-term health risks (e.g., cancer) are required to be reported through command channels, providing another means by which Service members exposed to toxic chemicals could be included in the registry.

DoDI 6490.03 also requires rosters of possibly exposed individuals be created for all exposure incidents. These incident-based rosters are archived at the U.S. Army Public Health Command for future use and reference, as needed.

Procedures to Provide Medical Examinations to Service Members Who are Eligible to be Included on the Registry

Just as DoD believes it is inappropriate to establish an active registry for chemical exposures in which there is minimal medical or scientific basis for expected long-term health risks, DoD also believes it is inappropriate to automatically provide or require medical examinations for all Service members who have been included on an exposure registry. There are multiple reasons for this. First, based on the conservative processes used by DoD to establish chemical exposure registries, many of the Service members included in the registries would likely not be expected to develop any lasting or long-term health conditions, thereby making routine examinations unnecessary, expensive, and potentially upsetting to them. Additionally, such exams run the risk of generating false positives, clinical tests that indicate a problem when there is actually no problem, which contribute to further angst and cost without benefit. Second, in an era of constrained resources and increasing costs to the Military Health System, requiring medical examinations without confirmed or exposures likely to have long-term health implications diverts valuable medical resources away from more urgent patient care. Third, for many possible exposures during conflict, there may be no appropriate medical exam or laboratory test that would provide any useful information regarding the Service members’ exposure or medically appropriate follow-on surveillance and/or treatment. It is DoD’s position that the decision to provide exposure-related medical surveillance examinations should be on an exposure-by-exposure basis, specific to the type and level of exposure, as is standard practice in the discipline of Occupational and Environmental Medicine. Such determinations are routinely made by credentialed medical providers in DoD’s in-garrison Occupational and Environmental Health and Deployment Health programs. Once these determinations are made, standard procedures for scheduling and completing medical examinations/evaluations would be followed.

Methodology to Leverage Existing Medical Surveillance Systems

DoD strongly believes that in order to efficiently and effectively construct exposure registries for personnel exposed to occupational and environmental chemical hazards during conflict, it is essential to leverage existing medical surveillance systems, such as the Defense Medical Surveillance System (DMSS), found at <http://afhsc.army.mil/dmss>, as well as DoD's EHR, using a business intelligence strategy that permits the mining of the appropriate data needed to create the required chemical exposure registries. In most cases, this strategy would look for diagnosis or procedure codes within DMSS or the EHR that indicate a chemical exposure is suspected or has been confirmed. This business intelligence strategy can also be adapted to look for diagnoses within targeted populations that are frequently associated with possible or suspected chemical/environmental exposures. Such a strategy was applied to assess the long-term health impacts from open burning operations in the U.S. Central Command Area of Operation by linking medical outcome data from DMSS with once-daily personnel location data to determine if people assigned to specific locations with active burn pits had increased prevalence or incidence of disease. Preliminary findings were presented in the May 2010 report, "Epidemiologic Studies of Health Outcomes Among Troops Deployed to Burn Pit Sites," jointly prepared by the Armed Forces Health Surveillance Center, the Deployment Health Research Center, and the U.S. Army Public Health Command (Provisional), and is available at: http://fhp.osd.mil/pdfs/100604_FINAL_Burn_Pit_Epi_Studies.pdf. No increased prevalence or incidence of disease has been shown to date.

While the leveraging of these medical surveillance and EHR systems proved useful in completing the above studies, DoD believes these systems alone are insufficient to establish accurate and useful chemical exposure registries. DoD believes the creation of accurate and effective exposure registries is predicated on the ability to produce Individual Longitudinal Exposure Records (ILERs) as envisioned in Presidential Review Directive 5, "A National Obligation: Planning for Health Preparedness for and Readjustment of the Military, Veterans, and Their Families after Future Deployments," August 1998. Conceptually, ILERs will combine data from multiple sources to provide a comprehensive record of all exposures or possible exposures that individual Service members experience during their military careers. For example, it is envisioned ILERs will use information from (1) self-reported exposure information from post-deployment health assessments and post-deployment health reassessments, (2) ambient (air, water, and soil) monitoring data for their deployment locations, (3) EHR entries for exposure-related diagnoses, treatments, or evaluations, (4) medical record entries of health outcomes, (5) biomonitoring data for exposure agents for which they may have been evaluated, (6) Service member location and exposure incident databases in which they are included, and (7) data from individual dosimeters that measured the concentration of chemicals (including chemical warfare agents/toxic industrial chemicals, and chemical, biological, radiological, or nuclear agents) to more accurately determine the extent of the various chemical exposures experienced by Service members over the course of their careers and the health risks resulting from those exposures. This capability would allow DoD to establish a virtually unlimited number of chemical exposure registries with relative ease based on the specific chemical of interest, time, symptoms, location, etc. These registries would then be available for multiple purposes including medical surveillance, medical diagnosis and treatment, and claims adjudication.

While significant investment is needed to achieve ILERs, DoD's ability to assess toxic chemical exposures during conflict and establish registries of exposure has never been greater, nor has DoD's determination to improve these capabilities, on behalf of all Service members who fight for our freedom, ever been stronger.