Impact Assessment and Management of Naphthalene-Related Risks

11881-436

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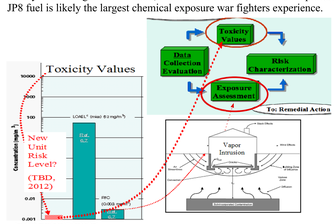
Abstract: The Department of Defense's (DOD's) Chemical and Materials Risk Management (CMRM) Directorate is using a scan-watch-action process to identify, rank and manage risks associated with emerging contaminants. Naphthalene is characterized as a likely human carcinogen by the National Toxicology Program (NTP) and in the Environmental Protection Agency's (EPA's) most recent draft health risk assessment. Thus, naphthalene-related environmental health regulations are evolving. The potential impacts have been assessed, using multi-criteria decision analysis, for five of the DOD's functional areas. One of the areas of concern is exposure to naphthalene among fuel handlers. To determine whether these exposures present unacceptable risk, the Army Research Office awarded a Small Business Innovative Research (SBIR) Project for the development of a miniature real-time naphthalene sensor. The National Institute of Occupational Safety and Health's (NIOSH's) Biomonitoring Research Team and investigators from the Army Research Institute for Environmental Medicine, University California-Davis, Temple University, and the Army Corps of Engineers are collaborating on related projects. The research will validate the prototype sensor as a dosimeter by defining correlations between measured exposures and biomarkers of exposures to-be-collected from military fuel handlers. To date, naphthalene specificity with sensitivity of 0.5 mg/m^3 has been demonstrated and definition of the firmware chemometrics is underway. Implementation of the human subjects research protocol is pending institutional review boards' (IRBs') approval.

Introduction: The NTP conducted a series of rodent exposure studies between 1985 and 2002. In 2005, the EPA published a draft risk assessment that characterized naphthalene as a likely human carcinogen based on results from these and other rodent studies. The DOD CMRM Directorate subsequently assessed the potential impacts to five DOD functional areas and implemented risk management options that included funding projects that will develop and validate a naphthalene dosimeter. In addition to the DOD, the Army, National Institute of Environmental Health Sciences (NIEHS), National Science Foundation (NSF) and NIOSH are each funding components of the research. Collaborating scientists are from the Army Corps of Engineers, Army Research Office, Army Research Institute of Environmental Medicine, CDC Foundation, NIOSH, University of California-Davis and Temple University. Several other Defense organizations are represented on an interagency advisory committee.

Potential impact to DOD's occupational health programs:
Naphthalenes are 1-3 % of jet fuels and DOD's annual consumption is approximately 5 billion gallons. In 2002, the National Research Council reported that JP8 fuel is likely the largest chemical exposure war fighters experience.



Potential impacts to DOD's environmental restoration programs:
If the EPA's draft risk assessment is finalized as written, a cancer potency value will be developed for the first time. New screening values for the evaluation of the vapor intrusion pathway will also be developed. The additional risk assessments may increase the cost to complete remediation and old sites may need to be reassessed. The EPA's health risk assessment is to be finalized in 2012.

The Naphthalene Dosimeter Advisory Group

Janis Hulla, PhD, DABT (Chair)
Senior Toxicologist, Sacramento District
U.S. Army Corps of Engineers

Micheline Strand, PhD (Co-Chair) Life Sciences Division Chief, Armv Research Office	LtCol. Jonathan Thomas, (Co-Chair) USAF, BSC, PhD, PE, CIH Assistant for Safety, Health & Fire Office of the Deputy Under Sec. Def. (I&E)
David R. Mattie, PhD, DABT Research Toxicologist Air Force Research Lab- RHPB	CDR Gail D. Chapman, Ph.D., MBA Navy Liaison, Military Infectious Disease Research Prog. Army Medical Research & Materiel Com.
John Snawder, PhD, DABT Biomonitoring Team Leader NIOSH	Susan P. Proctor, DSc Research Epidemiologist Army Research Inst. of Enviro. Medicine
Katharine Kurtz, Toxicologist Navy & Marine Corps Public Health Center	John P. Hinz, Toxicologist Air Force School of Aerospace Medicine Health Risk Assessment Support, Brooks
Charles A. Kubrock, CIH Lab Director Navy & Marine Corps Public Health Center	John Cambre Field Industrial Hygienist Army Cent Health Promo. Prev. Medicine
Alan R. Buckpitt, Ph.D.* Professor Department of Molecular Biosciences University of California- Davis	Rominder Suri, Ph.D., P.E.* Associate Professor Civil and Environmental Engineering Temple University

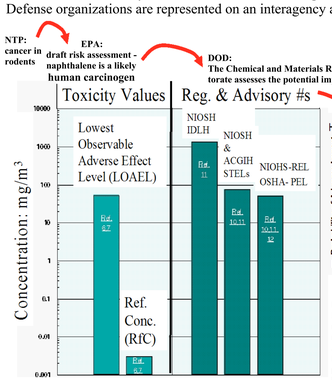
* Participate in the Naphthalene Dosimeter Advisory Group as Independent Advisors

An advisory group was chartered in 2008 in the Office of the Deputy Under Secretary of Defense for Installations and Environment. The Group will guide the development of the dosimeter and ensure best return on the agencies' investments.

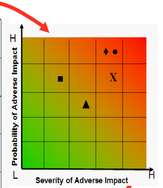
NTP: cancer in rodents

EPA: draft risk assessment - naphthalene is a likely human carcinogen

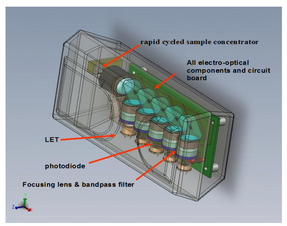
DOD: The Chemical and Materials Risk Management Directorate assesses the potential impact to 5 functional areas.



Source: www.epa.gov/ttn/atw/hlthef/naphthal.html

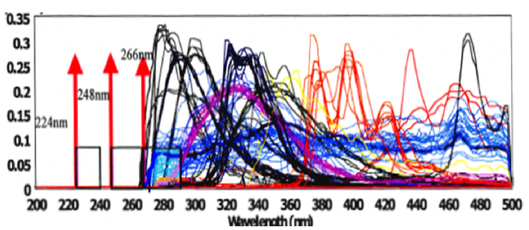


DOD: The Chemical and Materials Risk Management Directorate funds a more rigorous impact assessment and implements risk management actions. The Army Research Lab (ARL) funds phase II of the naphthalene dosimeter SBIR project. DOD funds the military fuel hander biomarker project.



Photon Systems' naphthalene dosimeter concept

Photon Systems' innovations include applying newly developed light emitting diodes (LEDs) to generate deep UV excitation of naphthalene's native fluorescence. This analytical approach offers the advantage of a favorable signal to noise ratio since there is little natural background fluorescence in this region of the spectrum as shown in the illustration below. Diodes being developed offer improved illumination of the target molecules.



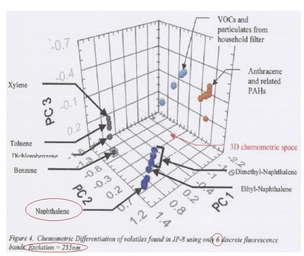


Figure 4. Chemometric Differentiation of volatiles found in JP-8 using only 6 discrete fluorescence bands. Excitation = 255nm

Up to six different diodes may be incorporate to ensure the naphthalene-specificity illustrated by this principal component analysis.

Conc. by prototype dosimeter

The performance of bench scale prototypes will be evaluated against GS/SM analyses of test atmospheres generated in an exposure chamber.

Biomarker study Phase I	Number of Bases	Number of Samples per Area	Number of Days	Number of Subjects at each base	Number of Areas per day	Number of exhaled samples per day	Number of urine voids per day	Under NIEHS-IRB approval- Number of Nasal samples	Total # Samples
Phase I									
Stationary Area Dosimeter Readings 1/day X 5 locations X 2 days	2	1	2	x	5	x	x	x	20
Conventional Stationary Area Air 1/day X 5 locations X 2 days	2	1	2	x	5	x	x	x	20
Dosimeter, Task specific 15 subjects X ~12 hours/day X 2 days	2	x	2	15	x	x	x	x	60
Conventional personal breathing zone 15 dosimeter subjects X 12 hours/day X 2 days	2	x	2	15	x	x	x	x	60
Task specific									

Phase II	Number of Bases	Number of Samplers per Areas	Number of Days	number of Subjects at each base	Number of Areas	Number of Exhaled Samples per Day	Number of urine voids per day	Number of Nasal samples	Total # Samples
Phase II									
Stationary Area air (conventional) 1/day X 15 locations X 4 days	2	1	4	x	5	x	x	x	40
Sationary Dosimeter in Area 1/day X 5 locations X 4 days	2	1	4	x	5	x	x	x	40
Dosimeter Wearing 15 dosimeter subjects over work shift 15 X 12 hours/day X 4 days	2	x	4	15	x	x	x	x	120
Conventional personal breathing zone work shift 15 dosimeter subjects X 12 hours/day X 4 days	2	x	4	15	x	x	x	x	120
exhaled breath up to 4 Samples/day X 15 Dosimeter Subjects	2	x	4	15	x	4	x	x	480
dermal 15 subjects x 2 (pre&post) samples/body location/2 locations X 4 days hand & back of neck (washing or 2x takes of tape strips)	2	2	4	15	2	x	x	x	480
urine- Morning Pre-shift, Post-shift, Bedtime, First Void in the morning 4 voids X 15 subjects X 4 days	2	x	4	15	x	x	4	x	480
Under NIEHS-IRB approval: nasal epithelial cells 15 dosimeter subjects X (pre & post)/day X 4 days P4502F13 mRNA expression and Protein, naphth adducts	3	x	4	15	x	x	x	2	360

Naph. mg/m^3 Conventional

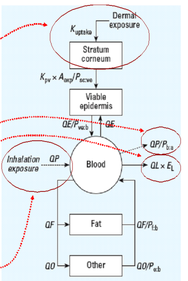
Naph. mg/m^3 Prototype

biomarkers

Naph. mg/m^3 (Prototype)

10/10-10/12: The goals of the biomarker validation study are; a) field validate the prototype dosimeter and b) define the relationships between concentration of exposure biomarkers and concurrently collected dosimeter-measured exposures. Exposures measured by the prototype dosimeter will be compared to concurrent exposures measured by conventional pump-trap-purge technology.

Making it a *Dosimeter*



From: Env Health Perspect, Vol 115, No 6, June 2007, PBPK Modeling Dimensions: Contributions of Dermal and Inhalation Exposure Components to End Exhaled Breath Concentrations of Naphthalene, Kim, et al.

Dermal, Exhaled Air & Urine Metabolite/Adduct analytical data will inform the PBPK & BBDR Models.

Prototype Dosimeter Data

Conclusions: This poster outlines naphthalene risk management actions that integrate five multi-disciplinary research projects with funding from five federal agencies. The research will generate a real-time, data-logging naphthalene sensor and independently validate its performance. The dosimeter will provide new protection for industrial site workers, military fuel handlers and civilian transportation workers. The data generated will extend what is known about naphthalene's mode of action and fill the single most important data gap in the naphthalene health risk assessment. The governance efficiency to be captured is improved health protection at lower cost.

Capabilities measured by Temple University

Capabilities measured by Photon Systems

9/09: The Naphthalene Dosimeter Advisory Group proposes independent validation of the dosimeter's performance. The National Science Foundation will provide about $70K to Temple University investigators to do the evaluations.

8/09: Ancillary NIOSH/NORA proposal submitted. Goals are: a) extend the dosimeter's detection capability to include other polycyclic aromatic hydrocarbons, b) biomonitor transportation industry workers and c) develop clinical sampling capability. NIOSH funding awarded 11/09 for a 3-year project. Total values about $850K.

4/08: The Naphthalene Dosimeter Advisory Group proposes an interagency project to validate the dosimeter with biomakers collected from military fuel handlers. The CMRM Directorate competes the proposal. It's funded 12/08.

2/10-10/10: Advisory Group reviews the protocol for NIOSH's and Army's institutional review board submission and approval.

2/10-09/12: The Naphthalene Dosimeter Advisory Group anticipates providing the CMRM Directorate with progress reports, future work statements, budgets and justifications. Continued funding of the dosimeter biomarker validation study is to be determined through a competitive process.

University of California-Davis investigator's NIEHS-funded research renewal application is submitted 9/09. Goals include collection of nasal epithelium from military fuel handlers for analyses of biomarkers of exposure and disease progression. Work to be conducted under NIEHS IRB approval.

Actions taken by the Army Research Office and Naphthalene Dosimeter Advisory Group:

8/06: The Army Research Office proposed the dosimeter concept to the SBIR Program.

6/07: The SBIR project is solicited

12/07: Two SBIR Phase I Awards, $100K/6mo, each

9-11/08: SBIR projects are evaluated for Phase II award

12/08: Photon Systems Awarded Phase II project

4-8/09: Phase II project, interim funding at $125K/4mo

9/09: Phase II project funded at full rate, $750K/2yr

Action taken by the DOD Chemical & Materials Risk Management Directorate:

9/06-09/07: Noblis, the Corps of Engineers and others take part in the Directorates's first Phase I Impact Assessment. It's on naphthalene.

12/07: The CMRM Directorate forms the Naphthalene Dosimeter Advisory Group.

4/08-11/09: CTC conducts the Directorates's Phase II Impact Assessment

12/08-2/09: The Naphthalene Dosimeter Advisory Group proposes the biomarker validation study and DOD funds year 1 at $110K. The fuel handlers study protocol is developed by these authors for research to be conducted under a NIOSH IRB approval.

The CMRM Directorate will continue to monitor to ensure that the naphthalene risk management actions are sufficient. The Directorate will continue to act as the contract officer's representative for the dosimeter validation study.

2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012