

NAVY AND MARINE CORPS PUBLIC HEALTH CENTER

ENVIRONMENTAL PROGRAMS DEPARTMENT



What You Don't Know About Your Human Health Risk Assessment *Could* Hurt You (...and Your Site Decisions)

David F. McConaughy

7 May 2009

“Protecting Health and the Environment”

Report Documentation Page

Form Approved
OMB No. 0704-0188

Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

1. REPORT DATE 07 MAY 2009		2. REPORT TYPE		3. DATES COVERED 00-00-2009 to 00-00-2009	
4. TITLE AND SUBTITLE What You Don't Know About Your Human Health Risk Assessment Could Hurt You (...and Your Site Decisions)				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Navy and Marine Corps Public Health Center, 620 John Paul Jones Circle, Suite 1100, Portsmouth, VA, 23708				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES Presented at the NDIA Environment, Energy Security & Sustainability (E2S2) Symposium & Exhibition held 4-7 May 2009 in Denver, CO.					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 21	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

Presentation Overview

- What is Human Health Risk Assessment (HHRA)?
- Risk Assessment vs. Risk Management
- Effective Use of HHRA
 - Data Evaluation
 - Exposure Assessment
 - Toxicity Assessment
 - Risk Characterization
- Navy and Marine Corps HHRA Support



What is HHRA?

- Read all about it!
 - Review key guidance documents
 - Navy guidance and policy
 - <http://www-nehc.med.navy.mil/hhra/process/index.htm>
 - <http://www-nehc.med.navy.mil/hhra/guidancedocuments/policy/pdf/hrapolicy.pdf>
 - EPA's —Risk Assessment for Superfund" series
 - <http://www.epa.gov/oswer/riskassessment/ragsa/index.htm>
 - CECOS course on —Human Health Risk Assessment"
 - <https://www.netc.navy.mil/centers/csfe/cecos/>
 - Call me...I can talk about this for hours!



Why Bother with HHRA?

- Key component of CERCLA investigations
- Goals of Superfund HHRAs:
 - Provide an analysis of baseline risks
 - Determine need for remedial action
 - Determine levels of chemicals that can remain on site and still be protective
 - Compare health impacts of various remedial alternatives
 - Consistent process for evaluating and documenting possible health effects

**Ignorance
ISN'T
Bliss**



Risk Assessment vs. Risk Management

- Risk Assessment
 - Performed by risk assessor
 - Input from other technical areas
 - Based on best-available science
 - Integrated throughout entire investigation
 - Scoping, PA, SI, RI, FS, etc.
 - Formal analysis and written report/documentation
- Risk Management
 - Performed by RPM, regulators, etc.
 - Input from risk assessor
 - Based on stakeholder comfort levels with risk, uncertainty, etc.
 - At the end of each stage of the investigation
 - Usually informal; not always documented

Risk Assessment vs. Risk Management



No...not this either!

Effective Use of HHRA: Data Analysis

- Does the sampling strategy support the HHRA?
 - Sampling supports other aspects of the site investigation (e.g., ecological risk assessment, nature and extents, remedial design, etc.), which may have different needs than the HHRA
 - Lateral and vertical extent given the exposure areas and receptors
 - Sample collection techniques
 - Analytical methods and detection limits
 - Combining datasets (temporally and spatially)
 - Upfront and continual involvement of risk assessor

Does the sampling strategy support the HHRA? (con't)

- Why this matters
 - The data is the foundation for the entire HHRA! If the data isn't appropriate for the HHRA, run into the “garbage in—garbage out” phenomenon!
- Prevention
 - Upfront and continual involvement of risk assessor

Effective Use of HHRA: Data Analysis

- How are background conditions being assessed?
 - Baseline HHRA evaluates incremental risks from exposure to site-related contamination
 - Comparison of site conditions to background
 - Navy Policy on the Use of Background Chemical Levels (2004)
 - http://web.ead.anl.gov/ecorisk/policy/pdf/Final_Navy_Background_Policy.pdf
 - Upfront and continual involvement of risk assessor, chemist, geologist, statistician, etc. (in other words, whatever it takes!)

How are background conditions being assessed? (con't)

- Why this matters
 - If background isn't separate, the cleanup goals may be below background conditions!
- Prevention
 - Upfront and continual involvement of risk assessor, chemist, geologist, statistician, etc. (in other words, whatever it takes!)

Effective Use of HHRA: Exposure Assessment

- Is residential land use reasonably expected at the site?
 - Conservative exposure scenario
 - Navy policy
 - —Do not evaluate unrealistic exposure scenarios that are not likely to take place at the site.”
 - EPA guidance
 - HHRA and FS should focus on the development of practicable and cost-effective remedial alternatives, leading to site activities that are consistent with the reasonably-anticipated future land use.

Is residential land use reasonably expected at the site? (con't)

- Why this matters
 - This assumption could lead to overly conservative and costly remedial goals
- Prevention
 - Support your risk assessor by doing homework about local land use
 - Initiate this dialog early and often with regulators

Effective Use of HHRA: Exposure Assessment

- Does the HHRA evaluate both the reasonable maximum exposure (RME) and central tendency exposure (CTE) scenarios?
 - Consistent with Navy policy and EPA guidance
 - RME is conservative and thus generally considered protective

Does the HHRA evaluate both RME and CTE scenarios? (con't)

- Why this matters
 - HHRA is not an “exact” science and thus a single number (hazard index or cancer risk) for a single exposure scenario does not necessarily result in practicable, cost-effective site decisions
- Prevention
 - Discuss both scenarios and how they will be used in decision making with regulators

Effective Use of HHRA: Toxicity Assessment

- Are cleanup decisions being made for chemicals that have Tier 3 toxicity values?
 - EPA hierarchy of sources for toxicity values and Tier 3 is appropriate, but has the lowest confidence
 - Tier 3 sources are more uncertain
 - Subject to more frequent update (read: CHANGE)
 - Many Tier 3 sources, so possibly many Tier 3 toxicity values (and thus opinions on those values)

Are cleanup decisions being made for chemicals that have Tier 3 toxicity values?

- Why this matters
 - Any remedial decisions made on chemicals with Tier 3 toxicity values may be subject to dispute/change more often than other sources
- Prevention
 - Educate regulators
 - May want to accept a higher —“acceptable risk” level based on uncertainty surrounding the toxicity value

Effective Use of HHRA: Risk Characterization

- Have the risk managers considered the uncertainty assessment or are they just focused on the numerical output?
 - The risk characterization *–serves as the bridge between risk assessment and risk management and is therefore a key step in the ultimate site decision-making process”* (EPA, 1989).

Effective Use of HHRA: Risk Characterization

- Numerical outputs are not the only (or most important) part of the risk characterization
 - Quantitative estimates of risk (i.e., calculation of incremental lifetime cancer risks and hazard indices [HIs] for non-carcinogens),
 - Qualitative descriptors of risk
 - Uncertainty assessment, and
 - Summary of the risk characterization results.
- Numerical outputs are conditional estimates based on many assumptions

Navy and Marine Corps HHRA Support

- Navy and Marine Corps Public Health Center
 - HHRA professionals available for FREE consultation or review of RI-related documents
 - Technical review is advantageous because NMCPHC offers an unbiased set of eyes that may identify issues with the HHRA such as:
 - Development of appropriate DQOs;
 - Identification of COPCs;
 - Identification of data gaps;
 - Use of appropriate analytical method/detection limit;
 - Appropriate handling of analytical results near the limits of detection;
 - Identification and use of appropriate toxicity values;
 - Evaluation of appropriate potentially complete exposure pathways; and
 - Clarification of risk characterization to facilitate decision-making.

For Additional Information

Jennifer Corack

Phone: 757-953-0950

E-mail: jennifer.corack@med.navy.mil

David McConaughy

Phone: 757-953-0942

Email: david.mcconaughey@med.navy.mil

Questions?

