What You Don’t Know About Your Human Health Risk Assessment Could Hurt You (…and Your Site Decisions)

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“Protecting Health and the Environment”
# What You Don’t Know About Your Human Health Risk Assessment Could Hurt You (...and Your Site Decisions)

**Abstract**

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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
    • EPA’s — Risk Assessment for Superfund” series
      – 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
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)
  – 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

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Questions?