#### INSTALLATION RESTORATION PROGRAM



NAVAL SUPPORT FACILITY INDIAN HEAD 3838 STRAUSS AVENUE INDIAN HEAD, MARYLAND 20640-5133



#### **RESTORATION ADVISORY BOARD (RAB) MEETING MINUTES**

Date of Meeting: April 16, 2015, 6:00 pm

#### **RAB Member Attendees:**

Mr. Joseph Rail (N) \* Ms. Robert Thomson (F) Mr. Curtis Detore (S)

#### Additional Attendees:

CAPT Mary Feinberg (N) Mr. Travis Wray Mr. Jeffrey Bossart (N) Mr. William Potter (N) Mr. Daniel Bragunier (N) Mr. Nicholas Carros (C)

#### **RAB** Members Not in Attendance:

Mr. Mark Williams (L) Mr. Fred Pinkney (F)

\* Co-chair

- C= Community
- F= Federal Official
- K= Contractor
- L= Local Official
- N= Navy Official
- R= Newspaper Reporter
- S= State Official

#### **Topics Discussed:**

1. Arrival/Welcome

Mr. Joseph Rail of the Naval Facilities Engineering Command, Washington (NAVFAC Washington) began the meeting by conducting introductions and welcoming everyone to the Indian Head Senior Center. Copies of RAB presentations and the agenda were offered to anyone in attendance. Mr. Rail then presented the meeting agenda, which is included in Attachment A.

2. RAB Presentations

Ms. Tara Carlson (C) Mr. Jim Long (C) Mr. Brandon Pavlin (C) Ms. Paula Gilbertson (N) Ms. Jeron Hayes (N)

Mr. Elmer Biles (C) Ms. Karen Wiggen (L) Presentations and updates were given by Mr. Rail of NAVFAC Washington. Mr. Rail presented a CERCLA overview, funding & appropriation process, and a risk assessment overview. Copies of all presentations are included in Attachment D.

#### 3. Comments, Questions and Answers

Numerous comments were made and questions asked during the meeting. These comments, questions and answers are provided in Attachment B. Additional correspondence concerning the Installation Restoration Program (IRP) or the Munitions Response Program (MRP) at the facility can be directed to:

Public Affairs Officer Naval Support Facility South Potomac Attn: Public Affairs Officer, Code 00P 6509 Sampson Rd. Dahlgren, VA 22448-5108 PHONE: (540) 284-0129 FAX: (540) 653-4269 Email: jeron.hayes@navy.mil

#### 4. Meeting Adjourn

Mr. Rail presented the tentative agenda for the next RAB meeting, which is scheduled for October 22, 2015. A copy of the draft agenda is included in Attachment C. Mr. Rail then concluded the meeting at 8:00 pm and thanked everyone in attendance.

#### NAVAL SUPPORT FACILITY INDIAN HEAD INSTALLATION RESTORATION (IR) PROGRAM RESTORATION ADVISORY BOARD (RAB) MEETING AGENDA

April 16, 2015

- 6:00 6:05 pmARRIVAL/WELCOME<br/>Mr. Joseph Rail<br/>Naval Facilities Engineering Command, Washington (NAVFACWASH)<br/>Remedial Project Manager6:05 6:20 pmCERCLA OVERVIEW<br/>Mr. Joseph Rail6:20 6:40 pmFUNDING & APPROPRIATION PROCESS<br/>Mr. Joseph Rail6:40 7:00 pmRISK ASSESSMENT OVERVIEW<br/>Mr. Joseph Rail
- 7:00 pm ADJOURN

Attachment A

#### INSTALLATION RESTORATION PROGRAM



NAVAL SUPPORT FACILITY INDIAN HEAD 3838 STRAUSS AVENUE INDIAN HEAD, MARYLAND 20640-5133



#### RESTORATION ADVISORY BOARD (RAB) MEETING COMMENTS, QUESTIONS AND ANSWERS April 16, 2015

#### Arrival/Welcome

No questions were asked nor comments made during this topic.

#### CERCLA Overview

- Question: Is money required to be available for the remedy selected in a Record of Decision (ROD?)
- Answer: Yes, once a ROD is signed, the Navy has a set amount of time to begin a remedial action and must be prepared to fund that action.
- Question: Does the amount of money that's available determine which remedy is selected in a ROD?
- Answer: No, several criteria are evaluated to choose the best remedy for a site. Factors may include: protection of human health and the environment, reduction of contamination, cost, and compliance with applicable rules and regulations.
- Question: How is it determined which remedy is selected?
- Answer: Alternatives are evaluated based on the factors described in the previous question.
- Question: When is public review required in the process and are all alternatives shown to the public?
- Answer: A public meeting is held to present the Proposed Plan and solicit comment. All alternatives are presented in the Proposed Plan and one is selected as the preferred alternative.

Attachment B

- Question: Are all steps mandatory, including the Engineering Evaluation/Cost Analysis (EE/CA), under the CERCLA process?
- Answer: Once a Remedial Investigation is started, all steps are mandatory and a ROD will be required to implement a remedial action. If an EE/CA is used, a site can be addressed under an Action Memorandum and Interim Remedial Action (IRA), in which case, a ROD would not be required.

- Question: If the cost of a remedy is higher than available funds, what happens?
- Answer: In this case, the remedial action would need to be delayed until funds are available. If it was a high risk site and a ROD was signed, it's possible that the cleanup would get funding and other sites would have to be delayed.
- Question: How many sites have funds budgeted out to 30 years for long-term monitoring?
- Answer: Indian Head currently has approximately 7 IR sites with 30 years of long-term monitoring budgeted.
- Question: Is 2021 a realistic goal to have all site cleanups completed?
- Answer: Yes, as of FY15, 2021 remains a realistic goal. However, as new sites and new areas of contamination are identified, the goal of 2021 is likely to slip.
- Question: Does the fact that Indian Head is a Superfund site affect its consideration to be on the BRAC list?
- Answer: Yes, Indian Head's listing as a Superfund site is one factor to consider, along with many others, concerning the BRAC list.
- Question: Are sites being delayed due to lack of funding?
- Answer: Yes, sites are ranked as high, medium, or low and are funded accordingly based on available funds. Annual budgets vary from year to year, and inevitably, some sites will experience delays in funding.

#### Attachment B

#### Risk Assessment Overview

Question: What is the meaning of "prescribed site scenario?"

- Answer: This phrase was developed by the Environmental Protection Agency to characterize the potential harm of known contaminants in a hypothetical situation.
- Question: Were landfills on the base legal dumping sites?
- Answer: No, landfills are considered "unregulated dump sites" according to the Maryland Department of Environment.
- Question: Concerning assessment of risk, what does "Not a bright line" mean?
- Answer: This phrase basically means that risk assessment is a conservative estimation and not an exact science.
- Question: Are risk assessments completed during Tier 1, 2, and 3?
- Answer: Yes. Tier I is a basic screening, Tier 2 is a baseline risk assessment, and Tier 3 is the evaluation of remedial alternatives.

Attachment B

#### NAVAL SUPPORT FACILITY INDIAN HEAD INSTALLATION RESTORATION (IR) PROGRAM RESTORATION ADVISORY BOARD (RAB) DRAFT MEETING AGENDA

October 22, 2015

6:00 - 6:05 pm **ARRIVAL/WELCOME** Mr. Joseph Rail Naval Facilities Engineering Command, Washington (NAVFACWASH) Remedial Project Manager 6:05 – 6:20 pm UXO 4-BASIC IED AREA, UXO 5-ADVANCED IED AREA, UXO 12-TORPEDO BURIAL SITE, & UXO 21-TEST AREA 1 STUMP NECK MRP REMEDIAL INVESTIGATION UPDATES Mr. Joseph Rail **UXO 9-SINGLE-BASE PROPELLANT GRAIN SPILL AREA RI/FS** 6:20 – 6:30 pm UPDATE Mr. Joseph Rail 6:30 – 6:45 pm SWMU 14-PHOTOGRAPHIC LAB SEPTIC TANK SYSTEM PILOT STUDY UPDATE Ms. Allison Cantu SITE 38-RUM POINT LANDFILL REMEDIAL ACTION UPDATE 6:45 – 7:00 pm Mr. Joseph Rail 7:00 – 7:10 pm SITE 43-TOLUENE DISPOSAL AREA FEASIBILITY STUDY Mr. Joseph Rail 7:10 – 7:20 pm SITE 47-MERCURIC NITRATE DISPOSAL AREA POST-INJECTION MONITORING UPDATE Ms. Allison Cantu 7:20 – 7:30 pm SITE 57-BUILDING 292 TCE CONTAMINATION FIELDWORK UPDATE Ms. Allison Cantu 7:30 – 7:45 pm SITE 66-TURKEY RUN DISPOSAL AREA BASELINE ECOLOGICAL RISK ASSESSMENT Ms. Allison Cantu 7:45 – 8:00 pm SITE 70-GROUNDWATER CONTAMINATION ALONG WATER WORKS WAY RI UPDATE Ms. Allison Cantu 8:00 pm **ADJOURN** 

Attachment C

**Attachment D- RAB Presentations** 



### NAVAL SUPPORT FACILITY, INDIAN HEAD



# Installation Restoration Program Framework: Introduction to CERCLA

Joseph Rail NAVFAC Washington

April 16, 2015

1





- CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980
  - AKA "Superfund," this federal law regulates environmental investigation and cleanup of sites contaminated by past disposal practices and that are identified as possibly posing a risk to human health or the environment





### CERCLA:

- Established requirements concerning closed and abandoned hazardous waste sites
- Provided for liability of persons responsible for releases of hazardous wastes at these sites
- Established a trust fund to provide for cleanup when no responsible party could be identified





### CERCLA:

- Was amended by SARA (the Superfund Amendments and Reauthorization Act) in October 1986
- Enabled the revision of the NCP (National Oil and Hazardous Substances Pollution Contingency Plan), the federal regulation that guides determination of sites to be corrected under CERCLA





- CERCLA is implemented at Department of Defense facilities through the Installation Restoration (IR) Program
  - Implemented at DoD facilities, both active and closed
  - Identifies, evaluates, and addresses sites contaminated by past activities
- CERCLA authorizes two kinds of response actions:
  - Short-term removal actions, where actions may be taken to address releases/threatened releases requiring prompt response
  - Long-term remedial response actions that permanently and significantly reduce the dangers associated with releases/threatened releases of hazardous substances that are serious but not life threatening







6





- Preliminary Assessment (PA)
  - First step performed before either a remedial or a removal action begins
  - Limited-scope investigation designed to identify sites posing a potential risk to human health or the environment
  - Includes collecting and reviewing all available records and information (may include interviews with former workers, archival research, etc.)
  - Usually does not include sampling or fieldwork





- Site Inspection (SI)
  - If PA finds that a site could pose a threat to human health or the environment, a site inspection is conducted
  - Includes on-site surveys to evaluate the source and nature of hazardous substances present – sampling of surface water, groundwater, soil, and/or sediment
  - If no harmful contamination found, Navy and agencies decide no further action needed
  - If harmful contamination found, further action is recommended





- Remedial Action Process
  - If PA/SI finds harmful contamination but no immediate threat to human health or the environment, the remedial action process is followed





- Remedial Investigation (RI)
  - RI builds on the SI and involves further fieldwork (groundwater, soil, etc.)
  - Sampling and analysis plan (Work Plan) is prepared and approved by Navy and agencies before fieldwork begins
  - Each sample taken is analyzed for specified contaminants agreed upon in the plan
  - Potential risk to human health or the environment determined





- Remedial Investigation (cont.)
  - Results of the RI determine whether a site is a candidate for no further action or further action
  - If further action is required, the RI information is used to conduct a feasibility study





- Feasibility Study (FS)
  - Follows the RI and looks at possible cleanup alternatives to address the contamination
  - Evaluates the feasibility or suitability of each alternative to address the contamination using various factors
- Remedial Action Plan/Proposed Plan
  - Results from the FS are used to develop a plan for remedy (remedial action plan or proposed plan)
  - Plan recommends a preferred cleanup remedy based on alternatives evaluated in the FS and that meets required criteria
  - Formal public review comment period and meeting are provided for the draft plan





- Record of Decision (ROD)
  - Once comments on the draft proposed plan are resolved, the selected remedy is documented in the ROD
  - ROD includes attachment with responses to comments ("responsiveness summary")





- Remedial Design and Remedial Action
  - Cleanup remedy is designed and implemented
  - Site can be closed out if the remedy successfully and permanently reduces risk to human health or the environment to acceptable levels
  - Long-term monitoring may be carried out to assure that the remedy continues to be effective
- Removal Action Process
  - If PA/SI finds harmful contamination with immediate threat to human health and the environment, the removal action process is followed
  - More streamlined than the remedial action process





- Removal Action Process (cont.)
  - Removal action process involves specific technologies to reduce the risk to human health & the environment
  - Removal action process combines investigation and cleanup phases, resulting in faster cleanup
  - Removal action can also be one component of a long-term solution and may be undertaken at any time during the remedial action process





- Removal Site Evaluation
  - Depending on the results of the site inspection, a removal site evaluation may be conducted
  - Further evaluates site conditions and determines the need for next step
- Engineering Evaluation/Cost Analysis (EE/CA)
  - Determines the best way to clean up a site to protect human health or the environment
  - Evaluates remedies, their effectiveness, and their respective costs
  - Public review & comment period held
  - Responsiveness summary prepared





- Action Memorandum
  - The Action Memorandum documents the selected action (remedy) put forth in the engineering evaluation/cost analysis
- Removal Action/Post-Removal Action
  - Selected cleanup remedy is implemented during the removal action
  - Following cleanup, the site is evaluated for possible remaining risk to human health or the environment
  - The site can be closed out if the remedy successfully reduced potential risk to acceptable levels
  - In this case the removal action is the final action for the site and the site cleanup is documented in the ROD







*18* 





# Questions???





### NAVAL SUPPORT FACILITY, INDIAN HEAD



# **Environmental Restoration Navy (ER,N) Funding and Appropriation Process**

Joseph Rail NAVFAC Washington

April 16, 2015

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### CERCLA PROCESS

- Preliminary Assessment (PA)
- Site Investigation (SI)
- Remedial Investigation/ Feasibility Study (RI/FS)
- Remedial Design/Remedial Action (RD/RA)
- Record of Decision (ROD) and Site Closure
  - At the completion of the PA, the Remedial Project Manager (RPM) projects the outyear funding requirements for each phase of investigation or remediation
  - These requirements are not static, as site conditions can change during the investigation process





### NAVFAC FUNDING PROCESS

- 1998 National Defense Appropriations Act established military component Environmental Restoration accounts
- Navy's account is called ER,N (Environmental Restoration, Navy)
- Congress funds each service's program based on identified needs and priorities
- Funding can only be obligated for response actions under the jurisdiction of the Secretary of Defense
- NAVFAC is the command that manages the ER,N account





### NAVFAC FUNDING PROCESS, cont.

- NAVFAC distributes funds based on program priorities
- The RPMs administer the program for their installations
- The RPMs develop the plan to close out sites in a timely and cost-effective manner, and identify all program requirements for each budget submittal to obtain required funding
- NAVFAC has established semi-annual budget updates using a programmatic budgeting tool called NORM ("normalization of data")
- *RPMs provide updates in NORM -- they are then consolidated, reviewed, and validated at NAVFAC HQ*
- Each budget submit, RPMs update Cost-to-Complete (CTC) for each site using best available data and cost-estimating tools





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	10 M Remedial Design (Phase 3)	0				Т	\$214,423								
	11 S PHASE 4 RA	0	03/01/2016	180	08/28/2016	-	\$2,235,550		\$2,235,550.00 awds		F1			_	
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	13 M Construction Project Management (P	0				T	\$141,318							_	
	14 M Enhanced Bioremediation (Phase 4)						\$2,087,686							-	
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	22 Award	0	10/15/2023	365	10/14/2024		\$150,000	24						-	
	23 Award	0	10/15/2020	365	10/15/2021	A	\$200,000	21						-	
	24 Award	0	10/15/2024	365	10/15/2025	A	\$698.085	25	LTO costs through 20					-	
	25 M User Defined Cost Model (Phase 6)	-				T	\$179.400		Revised UDCM wit					-	
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	27 Award	0	04/01/2021	365	04/01/2022	A	\$28,850	21	5-Year Review					-	
	28 Award	0	04/01/2025	10950	03/25/2055	Α	\$121,700	25	5-Year Review (throu					-	
	29 M _PL_Operations-Maintenance Proje	0				Т	\$124,093							1	
	30 M _PL_Organic Compounds (GW/Liqui	0				Т	\$16,074							-	
	31 M _PL_Organic Compounds (Air/Gas)	0				Т	\$17,378							-	
	32 M In Situ Chemical Oxidation (ISCO) - A					Т	\$1,390,540							1	
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#### NAVFAC FUNDING PROCESS, cont.

- CTC estimates include all anticipated costs through LTM required to close the site, including costs of complying with legal and regulatory requirements
- These estimates are based on actual requirements and not tied to availability of funds
- NAVFAC submits budget to Department of Navy (DON)
- DON submits annual budget to Office of Secretary of Defense (OSD)
- OSD reviews DON budget, sends to Congress





#### NAVFAC FUNDING PROCESS, cont.

- Congress passes Authorization and Appropriation Acts or continuing resolution, then the President signs
- Money is then distributed down through DoD to NAVFAC
- The process of money distribution does take time
- The Authorization and Appropriation Acts authorize the budget and then give the money to the agencies or they can pass Continuing Resolution, which allows the government to run (often on the prior year budget)
- Both Acts must be passed for money to be distributed
- During Continuing Resolution, NAVFAC may not get the full amount of funds budgeted for the year -- this delays the awarding of contracts





### NAVFAC FUNDING PROCESS, con't.

- NAVFAC has set controls for the amount of money requested in future years
- The amount in the control may not be the same as the actual requirements of the installations -- this is why funding/projects are pushed out
- There is a balancing act between amount of budget available and the requirements





#### FISCAL CALENDAR

- Federal Government Fiscal Year runs Oct 1 Sep 30
  - *ex*) *FY15* runs October 1, 2014 September 30, 2015
- State of Maryland Fiscal Year runs July 1 June 30
- Congress must pass funding by Sep 30 in order to ensure no disruption of budget within the government


# Funding and Appropriation Process



## **Example Funding by Site for FY15 - 25**

SITE_NAME	RIP	RC	RISK	СТС	DELTA	FY_2015	FY_2016	FY_2017	FY_2018	FY_2019	FY_2020	FY_2021	FY_2022	FY_2023	FY_2024	FY_2025
SITE 00001	09/30/2016	09/30/2016		422,216	(	422,216	0	0	0	C	C	0 0	0	0	0	0
SITE 00011	01/03/2012	05/30/2012		895,024	(	47,052	28,850	47,052	0	47,052	C	75,902	0	47,052	0	602,064
SITE 00012	01/31/2003	01/06/2004		959,946	(	0	130,560	0	0	C	94,560	36,000	0	94,560	0	604,266
SITE 00014	02/14/2013	06/16/2014		235,000	(	0	35,425	0	0	C	C	35,425	0	0	0	164,150
SITE 00017	11/28/2012	09/30/2021		700,616	(	262,183	28,850	0	0	C	C	291,033	0	0	0	118,550
SITE 00021	01/21/2013	02/26/2014		895,024	(	47,052	28,850	47,052	0	47,052	C	75,902	0	47,052	0	602,064
SITE 00028	11/03/2008	08/10/2009		75,909	(	0	52,534	0	0	C	C	23,375	0	0	0	0
SITE 00036	05/01/1983	06/16/2014		1,205,984	(	97,750	35,000	97,750	0	97,750	C	132,750	0	97,750	0	647,234
SITE 00038	06/12/2015	07/13/2015		1,639,768	(	0	128,850	0	100,000	C	100,000	28,850	100,000	0	100,000	1,082,068
SITE 00042	11/30/2006	12/20/2006		2,123,850	(	0	163,210	0	127,210	C	127,210	36,000	127,210	0	127,210	1,415,800
SITE 00043	09/15/2016	10/15/2025		4,099,626	(	210,730	2,476,147	0	0	C	C	228,850	0	250,000	150,000	783,899
SITE 00047	09/30/2013	04/25/2050		6,190,500	(	269,828	28,850	0	125,830	1,355,154	526,283	28,850	124,683	124,683	124,683	3,481,656
SITE 00057	08/30/2011	09/25/2049		3,545,150	(	0	237,046	0	208,196	C	208,196	28,850	208,196	0	0	2,654,666
SITE 00066	08/25/2018	02/12/2020		4,929,530	(	103,000	1,936,443	891,383	366,950	C	117,350	C	117,350	0	117,350	1,319,704
SITE 00067	09/01/2017	07/31/2020		2,065,360	(	153,297	75,001	1,158,673	105,000	573,389	C	) C	0	0	0	0
SITE 00069	01/15/2018	10/12/2027		2,103,424	(	240,188	127,402	782,492	163,002	C	C	150,000	0	150,000	150,000	340,340
SITE 00070	01/15/2019	10/12/2027		2,568,481	(	0	330,355	110,278	0	1,324,797	150,000	) C	150,000	0	0	503,051
SWMU 00014	12/01/2016	10/12/2027		2,061,966	(	0	941,723	192,672	0	C	C	178,850	0	150,000	0	598,721
Total						1853296	6785096	3327352	1196188	3445194	1323599	1350637	827439	961097	769243	14918233
Target						1,571,000	3,847,000	4,938,000	559,000	727,000	627,000	962,000	572,000	704,000	283,000	15,541,000
Delta						282,296	2,938,096	(1,610,648)	637,188	2,718,194	696,599	388,637	255,439	257,097	486,243	(622,767)



# **Funding and Appropriation Process**



# Questions???





**Risk Assessment Overview Environmental Restoration Program for Restoration Advisory Board** 

16 April 2015

Joseph Rail Environmental Restoration Remedial Project Manager NAVFAC Washington



#### Agenda

- •Overview
- Introduction
- Types of Risk Assessment
- Components of Determining Risk
  - -Conceptual Models and Collecting Data
  - -Evaluating Exposure
  - -Evaluating Toxicity
  - -Calculating Risk
- •Risk Numbers What do they mean?
- Risk Management Decisions
- Risk Uncertainty



**Does this number** Why are we even mean my family or I looking at risk? Shouldn't it just get What is Risk will get cancer or some other cleaned up? **Assessment?** disease? Do I need to What do all these understand numbers really complicated math? mean?



# A method for assessing the technical likelihood of undesirable effects from exposure to a stressor (e.g., released chemicals).







- Decisions under Navy Environmental Restoration Program follows CERCLA/Superfund Framework
- •Risk Assessment plays a key role in decision making process
- USEPA has defined how risk assessment is conducted

United States Environmental Protection Agency EPA/540/1-89/002

Introduction

Risk Assessment Guidance for Superfund (RAGS) Human Health Evaluation Manual



Risk assessment is protective

- -Methods are conservative, designed so that any actual risk, should it exist will be lower than that actually calculated
- •Estimates likelihood that exposure to chemicals from a particular site will result in an adverse health effect.
- Presents cancer risks and non-cancer hazard estimates.
- Provides information to help identify
  - -If and where a response is needed;
  - -Which site-related chemicals and media will need a response.



# What Risk Assessment Does and Does Not Do

#### <u>Does</u> . . .

- •Estimate cancer and noncancer risks for specific types of exposure.
- Indicate the populations we are concerned about and how they are exposed.
- Identify site-related contaminants that need to be addressed.

# Does not . . .

- •Determine if health effects occurred in the past or will occur in the future.
- •Determine if an observed condition in an individual or population is the result of exposure to site contaminants.
- •Evaluate a catastrophic exposure different than the prescribed site scenario.

Risk assessment is not a medical study, an exposure study, or a study of actual conditions – it is a hypothetical evaluation



•Two types:

- -Human health risk assessment
- -Ecological risk assessment
- Each type has different "tiers"
  - -Tier 1 Screening level
  - -Tier 2 Baseline risk assessment
  - -Tier 3 Calculating cleanup goals
- •Standards models (mathematical formulas) used in calculating risk were developed by USEPA
- Process of Calculating:
  - -Potential risk to human beings from developing cancer
  - -Potential for human beings to experience an adverse effect (e.g. liver damage)
  - Potential risk to ecological "receptors" to develop an adverse effect

Similar in some ways, different in others

# Relationship of the Tiered Approach to the CERCLA Remedial Process







#### •Several stages as part of the Installation Restoration Program

- Start with generic screening assessments and gradually move to more detailed assessments as data are collected
- •Site Inspection Tier I
  - Screening levels available from USEPA
  - -Limited exposure scenarios
- Remedial Investigation Tier II
  - Baseline risk assessment
  - Detailed breakdown and mathematical modeling of exposure based on potential pathways and exposure scenarios identified in the Conceptual Site Model.
- Feasibility Study through remedial action Tier III
  - Calculating of cleanup goals

# Tiered Risk Assessment Approach - Human Health Risk Assessment









- Develop Conceptual Site Model
- Collect Data to support/enhance understanding of model
  - -Data are collected for media within different pathways for exposure
  - -Data also are collected to evaluate background or ambient conditions
- •Check Conceptual Site Model based on data and refine as necessary





A description of the *known/expected* relationships between the contaminants and the receptors:

Environmental settingKnown or suspected contaminantsContaminant fate and transportExposure assumptionsPotential contaminant effects



#### **Example Conceptual Site Model**





#### • Evaluate Exposure – Step 2





#### • Evaluate Toxicity – Step 3

- -Toxicity factors are developed through scientific studies that evaluate effects of chemicals on people or animals.
- -Two types of health effects are considered
  - Cancer
  - Noncancer Effects (e.g., liver damage, hair loss, etc.)

#### -Dose-response is estimated based on the toxicity values

- Toxicity values are based on the exposure route
- Ingestion, inhalation, dermal contact







#### •Calculating Risk – Step 4

- -Risk characterization ties everything together
- -Uncertainty assessment is vital to understanding how to use the risk "numbers"
- -Risk characterization typically includes
  - Reasonable maximum exposure (RME) risks/hazards, and
  - Central tendency exposure (CTE) risks/hazards
    - –NOTE: These are the same receptors and the same toxicity values, but some of the exposure assumptions are changed to provide a range of estimates

# Risk ≈ Exposure × Toxicity

#### Carcinogen versus Non-carcinogen



# •Carcinogen

- A stressor that upon exposure may induce some form of cancer
  - Skin cancer, lung cancer, etc.
  - Toxicity expressed as a *cancer slope factor* or *inhalation unit risk*

# Non-carcinogen

- A chemical that causes an effect other than cancer
  - Kidney failure, developmental problems, etc.
  - Toxicity expressed as a reference dose or reference concentration





#### U.S.EPA's Method to Estimate Cancer Toxicity





**CSF = Cancer Slope Factor** 



•Believed to act via a "threshold" mechanism of action. –There is a level of exposure (i.e., a threshold) below which there is no effect.







Background Constituents = Constituents whose presence can be attributed to *naturally occurring* or *anthropogenic* sources



#### Naturally Occurring

- Ambient concentrations of constituents present in the environment that have not been influenced by human activity
  - -Broad concentration ranges of metals in soil
  - -Significant geographic differences due to source rock and geochemical processes
  - Upper range of background metals can exceed risk levels

## Anthropogenic

- •Widely distributed chemicals present in the environment due to human activities, but are non-site sources
- •Can range from localized to ubiquitous
- •Attributed to past legal applications (e.g., lead in adjacent freeway soils)



•CERCLA <u>precludes</u> cleaning up to below background levels

- •EPA RAGS Part A:
  - -"Distinguish site-related contamination from naturally occurring or other non-site related levels of chemicals"
- Identify site-specific chemicals of potential concern (COPCs)
- •Differentiate between site-related and background levels of chemicals





# Risk = Dose x CSF

# Incremental risk expressed as a probability:

1/10	0.1	<b>10</b> <sup>-1</sup>
1/100	0.01	<b>10</b> <sup>-2</sup>
1/1,000	0.001	10 <sup>-3</sup>
1/10,000	0.0001	<b>10</b> <sup>-4</sup>
1/100,000	0.00001	<b>10</b> <sup>-5</sup>
1/1,000,000	0.000001	<b>10</b> <sup>-6</sup>

**CSF = Cancer Slope Factor** 



•Risk estimated as a Hazard Quotient:

*HQ* = *Dose* / *Reference Dose* 

•Reference Dose (RfD):

-the estimated daily dose to a human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

•When HQ < 1.0

-Estimated dose is less than the "safe" reference dose.

# •Hazard Index (HI)

-Sum of the HQs

-Site decisions should be based on target organ-specific HI

• For example, kidney failure and hair loss should NOT be summed!

Context – How Does Risk Assessment Results Compare with other Risks?



# •<u>Incremental</u> Cancer Decision points

- > 10<sup>-4</sup> (1 excess cancer lifetime cancer risk per 10,000 people)
  - Action generally taken
  - Not a bright line; based on site conditions
- Between 10<sup>-4</sup> to 10<sup>-6</sup>
  - Risk management range; action dependent upon many factors
- < 10<sup>-6</sup> (1 excess cancer lifetime cancer risk per 1,000,000 people)
  - Point of departure
  - Action not taken

# •Hazard Index/Quotient Decision Points

- > 1.0 Possible adverse effect for sensitive receptors
  - Possible action taken
  - Risk management decisions
- < 1.0 Exposure unlikely to cause adverse effect
  - Point of departure
  - Action not taken

Context – How Does Risk Assessment Results Compare with other Life Risks?



•Lifetime risk of dying from the flu – 1 in 63 (1.6x10<sup>-2</sup>)<sup>b</sup>

 Lifetime risk from dying by lightning – 1 in 79,746 (1.3x10<sup>-5</sup>)<sup>b</sup>

•General population – lifetime risk of being diagnosed with cancer – all sites all races = 40.77% (i.e., 407,700 people in 1,000,000 or 4x10<sup>-1</sup>)<sup>a</sup> •Lifetime risk from dying in a car accident –

1 in 84 (1.2x 10<sup>-2</sup>)<sup>b</sup>

 Lifetime risk from dying from sun/heat exposure -1 in 13,729 (7.3x10<sup>-5</sup>)<sup>b</sup>

- •Lifetime risk of dying in a shark attack -
  - 1 in 3,748,067 (2.7x10<sup>-7</sup>)<sup>b</sup>
    - a National Cancer Institute, 2010.
    - b National Safety Council, 2003.



- •Often risk at site is between 10<sup>-4</sup> and 10<sup>-6</sup> or above HI = 1 and the team must make decisions regarding cleanup
- •Use nine criteria defined in CERCLA/NCP to help define the need for action and defining which action best address the problem
  - -1) Threshold Criteria Overall Protection of Human Health and Environment
  - -2) Threshold Criteria Compliance with Laws and Regulations
  - -3) Balancing Criteria Long Term Effectiveness and Permanence
  - -4) Balancing Criteria Reduction of Toxicity, Mobility or Volume
  - -5) Balancing Criteria Short Term Effectiveness
  - -6) Balancing Criteria Implementability
  - -7) Balancing Criteria Cost
  - -8) Modifying Criteria State Acceptance
  - -9) Modifying Criteria Community Acceptance



• Stakeholders review the different criteria and balance protection of human health and environment with other criteria:

- Cost to get to 85% contaminant reduction is \$1,000,000,
- Cost to get to 100% is \$10,000,000.
- Risk with 85% contaminant left would be reduced from 10<sup>-3</sup> to 10<sup>-5</sup>
- Future land use is for a public park
- Chances for exposure are low once contaminants reduced, and mobility of contaminants reduced to below concerns for groundwater or indoor air transport

#### Risk Management Decision

- Team makes decision additional 15% reduction in contaminant may not be an effective use of taxpayer funds
- Team decides to implement land use controls as part of remedy with less reduction to provide protectiveness that will prevent receptors from contacting the last 15% of contaminant left.



- Nothing is a perfect model uncertainty exists in our ability to model risk
- Uncertainty comes from variability
  - Natural inherent variability
  - Data limitations
  - Scientific limitations
- Uncertainty Examples
  - Data collection
  - Toxicity values
    - Extrapolation from animal studies to humans
    - Joint toxicity effects greater or less than additive
  - Exposure: Variations in actual exposure versus what is modeled
  - Risk Calculation
    - How closely does model really reflect how human body responds?





- •Risk assessment is a defined process to identify if and where action to clean up a site is necessary.
- •Tiers of Decision in CERCLA/NCP
  - -If incremental cancer risk is greater than 1 in 10,000 and hazard index above 1: remedial action likely
  - -If incremental cancer risk is between 1 in 10,000 and 1 in 1,000,000 and/or hazard index is above 1: risk management range, some action possible; situation dependent
  - -If incremental cancer risk is less than 1 in 1,000,000 and hazard index is less than 1: no action taken
- •Risk assessment occurs during main phases of the CERCLA process.
- •Risk assessment evaluates potential cancer risk and risk from other adverse effects over a lifetime of exposure.


- •Risk assessment involved evaluating data, exposure, and toxicity.
- Exposure values should be realistic but conservative.
- •Toxicity is based on laboratory animals and/or true human data.
- •There are inherent uncertainties with the risk estimations.
- •Risk management decisions are sometimes necessary to determine define the best course of action.
- •Risk assessment is not a medical study, an exposure study, or a study of actual conditions – it is a tool designed to give a reasonable but conservative assessment that can be used as a tool in decision making.



## **QUESTIONS?**