Part 2 – Technical Presentation

Risk Assessment Process

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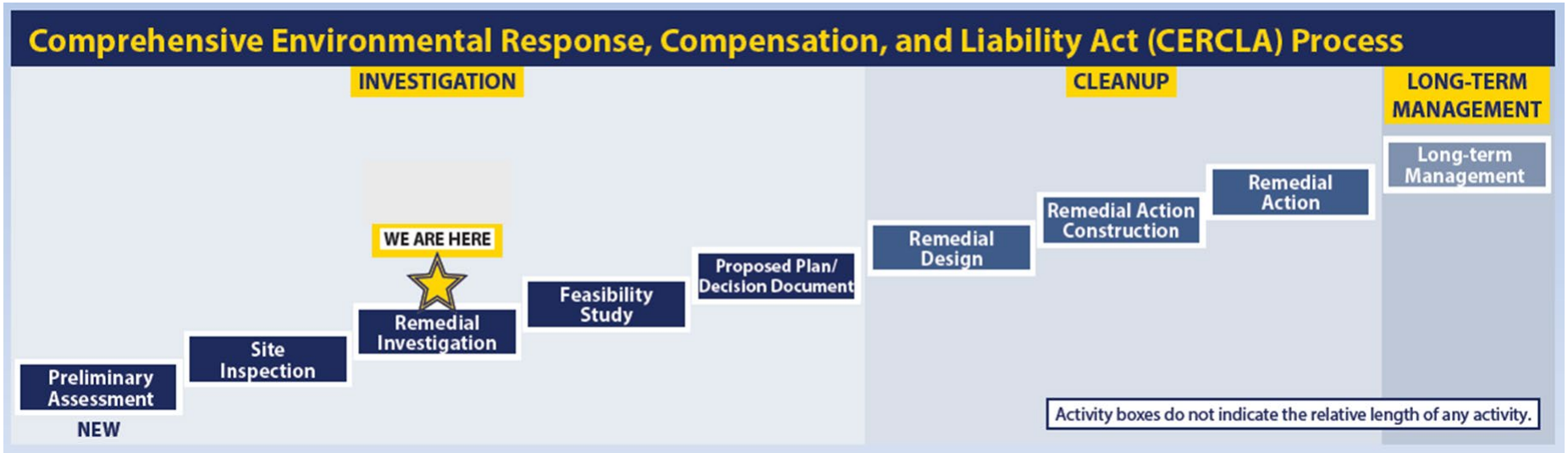
Overview of Regulatory Process

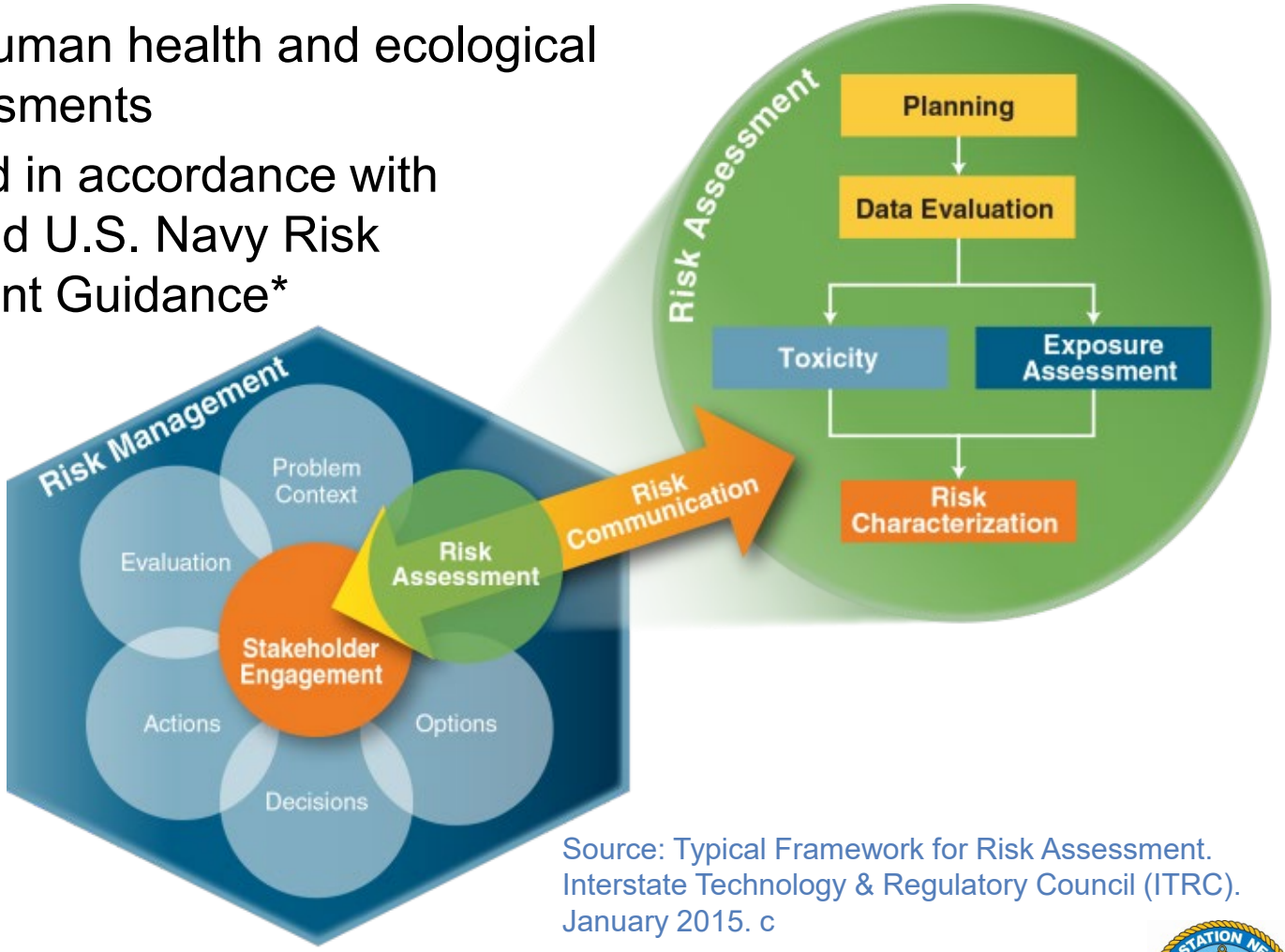


- **Remedial Investigation (RI) phase includes risk assessments**
  - – Unacceptable risk ⇒ Feasibility Study
  - – Acceptable risk ⇒ Proposed Plan/ Decision Document to support No Further Action

Risk Assessment Framework

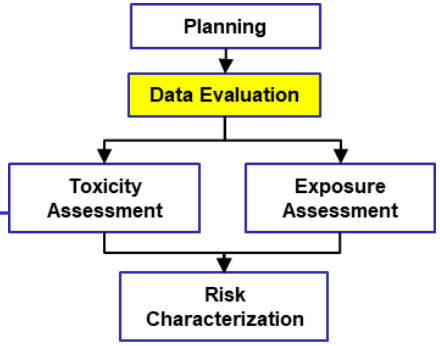
- Perform human health and ecological risk assessments
- Conducted in accordance with USEPA and U.S. Navy Risk Assessment Guidance*

*References and links provided at the end of this presentation



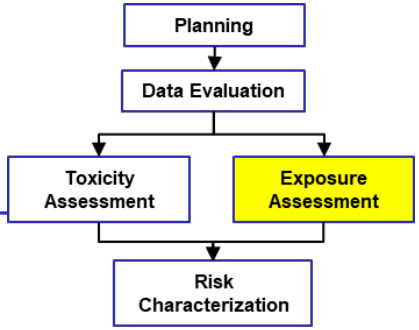
Source: Typical Framework for Risk Assessment. Interstate Technology & Regulatory Council (ITRC). January 2015. c

Data Evaluation

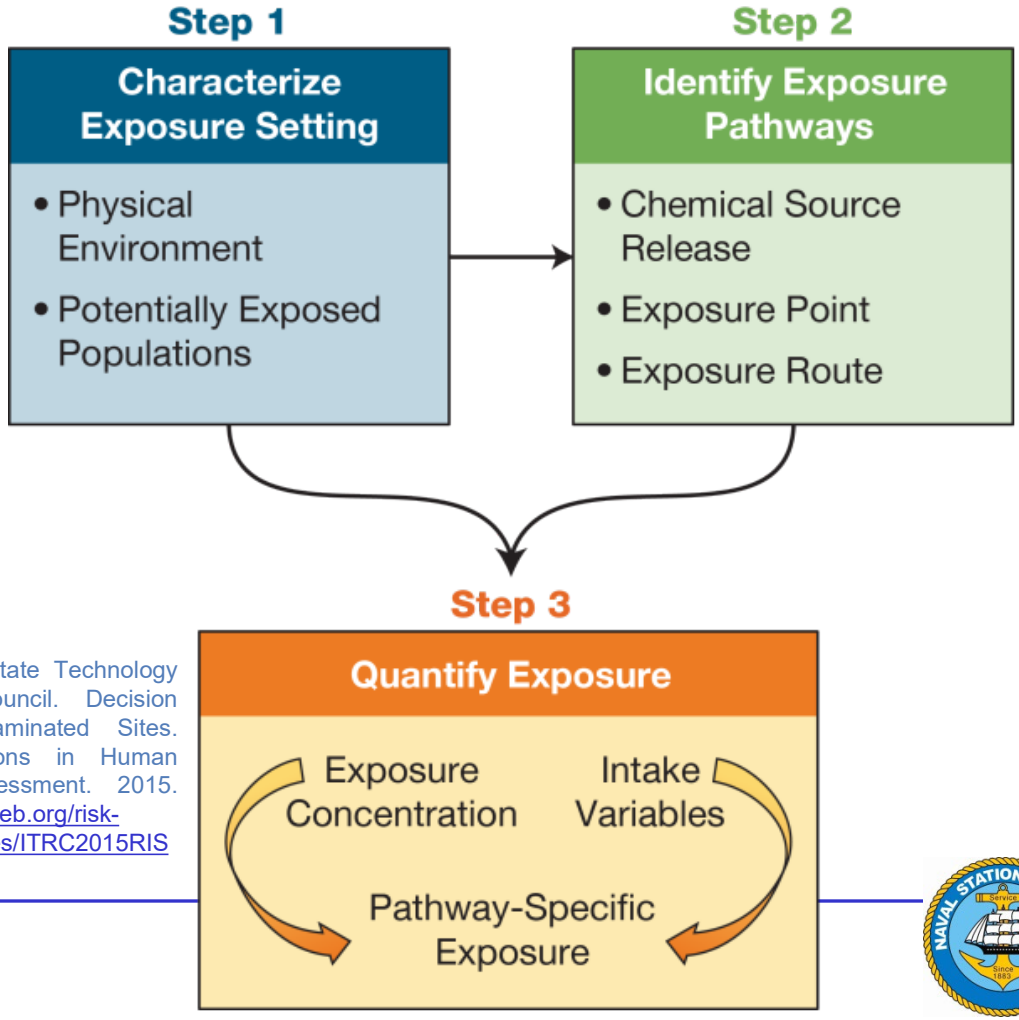


- Risk assessments are performed after the Remedial Investigation (RI) field work is complete and the nature and extent is defined
- Compile dataset for use in the risk assessments
  - Samples of environmental media (i.e., soil, groundwater, etc.) may be grouped by depth interval or area
- Select chemicals of potential concern (COPCs) / chemicals of potential ecological concern (COPECs)
  - Site-related chemicals
  - Detected at concentrations > screening levels and background levels
  - Further evaluated in the risk assessments

Exposure Assessment

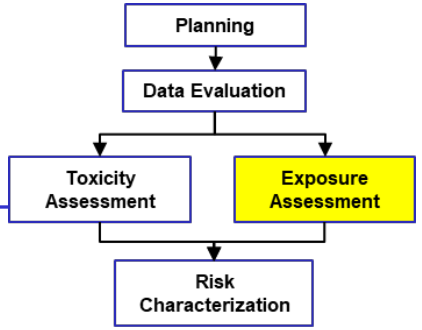


- Identify how humans and ecological receptors may contact COPCs/COPECs, and quantify the exposure



Source: The Interstate Technology & Regulatory Council. Decision Making at Contaminated Sites. Issues and Options in Human Health Risk Assessment. 2015. https://projects.itrcweb.org/risk-3/Content/Resources/ITRC2015RISK-3.pdf

Human Health Conceptual Site Model (CSM)



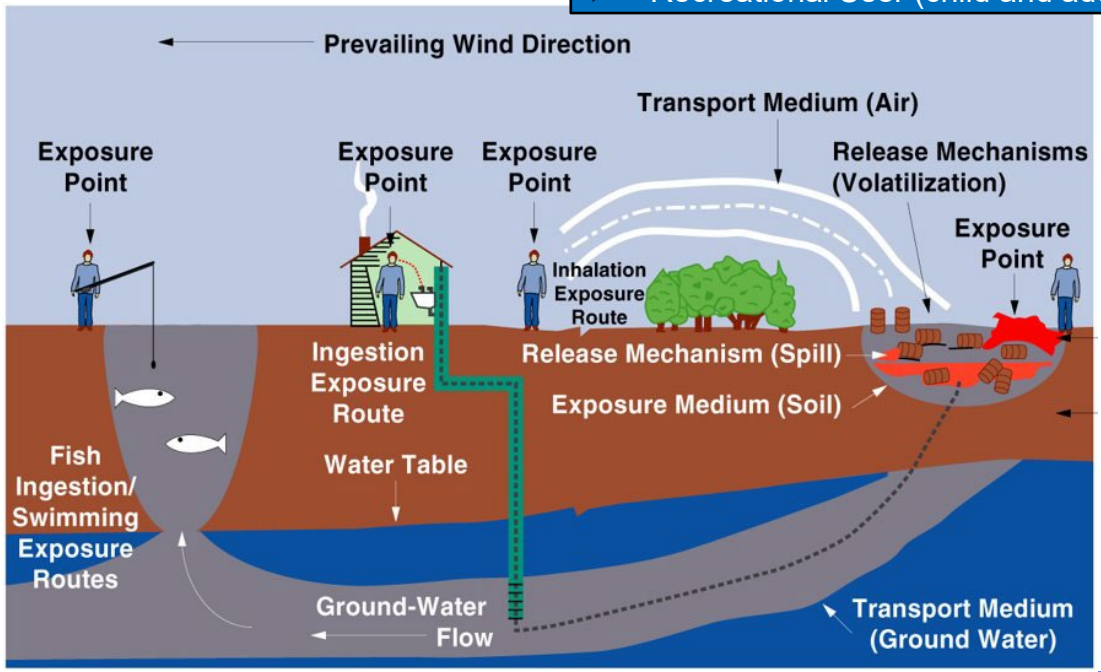
- Receptors and exposure pathways selected based on current and potential future land use
- Reasonable maximum exposure (RME) scenarios evaluated

Typical human receptors:

- Resident (child and adult)
- Commercial/Industrial Workers (office worker, groundskeeper, etc.)
- Construction/Utility Worker
- Trespasser (adolescent)
- Recreational User (child and adult)

Exposure pathways:

- Ingestion
- Incidental Ingestion
- Dermal Contact
- Inhalation



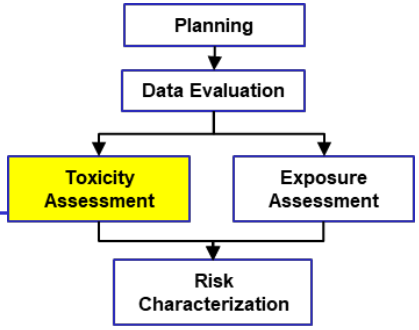
Exposure media:

- Soil (surface, subsurface)
- Groundwater
- Outdoor air (fugitive dust, volatiles)
- Indoor air
- Sediment
- Surface Water
- Fish/shellfish tissue

NAVFAC Naval Facilities Engineering Command Atlantic Division

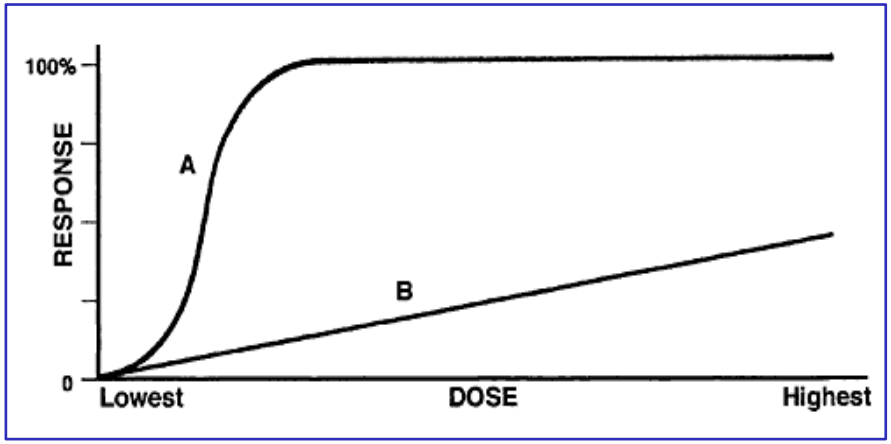
NAVAL STATION NEWPORT

HHRA - Toxicity Assessment

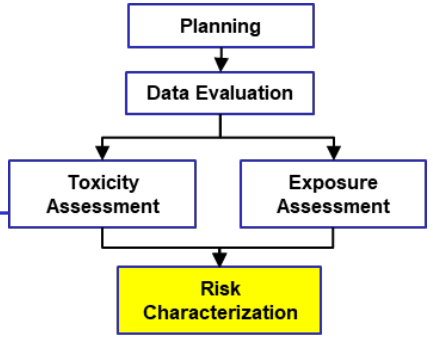


- Hazard Identification
  - Determine whether exposure to a chemical can cause an adverse human health effect (e.g., cancer, noncancer [liver disease])
- Dose-Response
  - Quantify relationship between exposure to a chemical and likelihood/magnitude of an adverse effect
- Published toxicity values from USEPA-recommended hierarchy of sources

Additional information can be found at: https://www.epa.gov/risk/conducting-human-health-risk-assessment#tab-3



HHRA - Risk Characterization

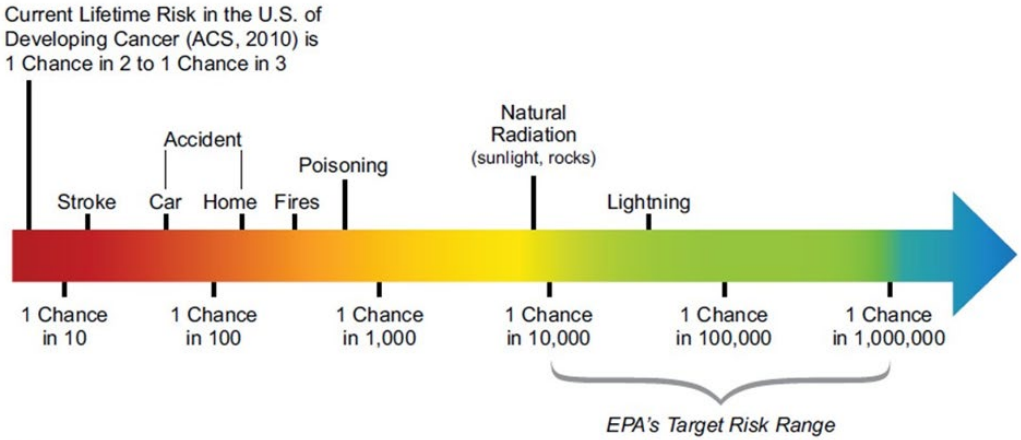


- Combines the results of the exposure assessment and toxicity assessment to provide a quantitative estimate of risk

- **Cancer**
  - Probability of cancer over a lifetime over and above background cancer incidence
  - Compared to USEPA's risk range of 1 in a million (10^{-6}) to 1 in ten thousand (10^{-4})

- **Noncancer**
  - Expressed as a "Hazard"
  - Compared to USEPA's HI of 1

Range of Lifetime Risk of Fatality Compared with EPA's Target Risk Range



Sources

- *Adapted from U.S. EPA 450/3-90-022, Mar. 1991, http://www.epa.gov/air/oaqps/air_risc/3_90_022.html (1996)*
- *American Chemical Society. 2010. Cancer Facts and Figures 2010 http://www.cancer.org/acs/groups/content/@nho/documents/document/acspc-024113.pdf*

ERA Overview

- **Screening Level ERA (SLERA) (Steps 1 and 2 EPA; Tier 1 Navy)**
  - Screening-level assessment to identify whether further evaluation is required
  - Identify potential habitats and ecological receptors
  - Compare available data to conservative ecological screening values
  - Can chemicals or receptors be eliminated from further evaluation?

Some or all receptors and chemicals can exit the ERA process at this point

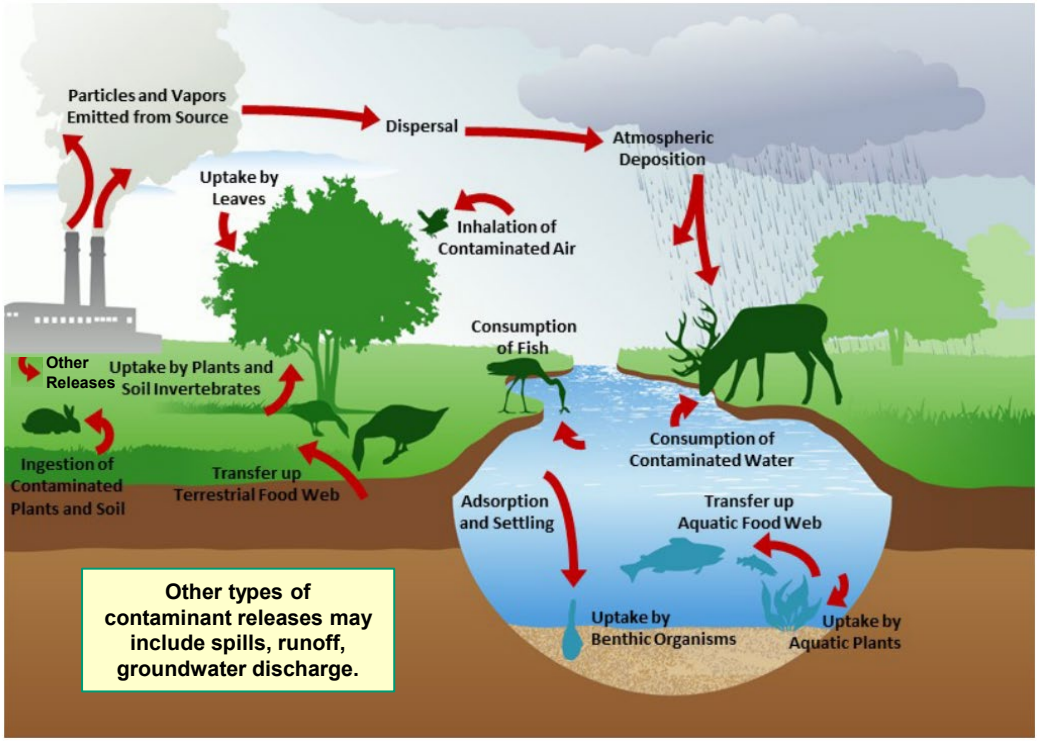
- **Baseline ERA (Steps 3 through 8 EPA; Tier 2 Navy)**
  - More site-specific approach using more realistic assumptions
  - Reduces uncertainty using more site-specific data (e.g., toxicity testing, tissue, community assessments)
  - Considers background concentrations
  - Provides a more site-specific basis for remedial action, if warranted

End of Step 3a Refinement – Second exit point from ERA process

Remaining receptors and chemicals continue into the Baseline ERA

Ecological CSM

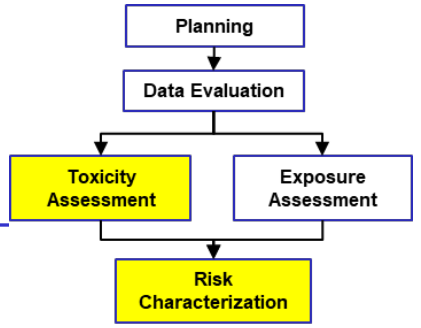
- **Understand site conditions and potential contaminant sources**
- **What are your potential exposure pathways?**
  - Potential for direct toxicity and food web exposures
- **What are your potential ecological receptors?**
  - Terrestrial receptors
  - Aquatic receptors
  - Any threatened or endangered species present?
- **Evaluate types and quality of habitats present**



Source: EPA EcoBox Tools by Exposure Pathways - Exposure Pathways In ERA | US EPA (modified)

Ecological CSM provides a road map to identify pathways that require assessment in the ERA

Screening Level ERA (Steps 1 & 2 EPA; Tier 1 Navy)



- **SLERA Toxicity Assessment**
  - Maximum detected concentrations compared to ecological screening values (ESVs) protective of relevant ecological receptors
  - Food web model for wildlife using maximum concentrations and estimated tissue concentrations

- **SLERA Risk Characterization**
  - Calculate Hazard Quotients

HQ ≤ 1 = acceptable risk; no further evaluation

HQ > 1 = potentially unacceptable risk; COPECs move to Step 3a

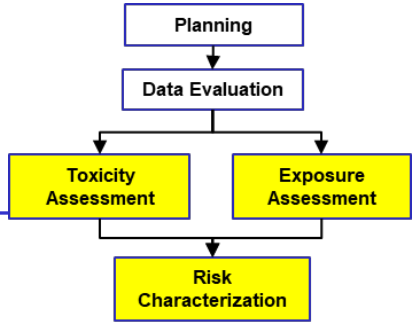
HQ = Maximum Detected Concentration / ESV

HQ = Maximum Dose / Dose-based ESV

COPEC = Chemical of Potential Ecological Concern (HQ > 1)

SLERA is a conservative evaluation intended to eliminate chemicals with no complete exposure pathways and chemicals present at "safe" concentrations

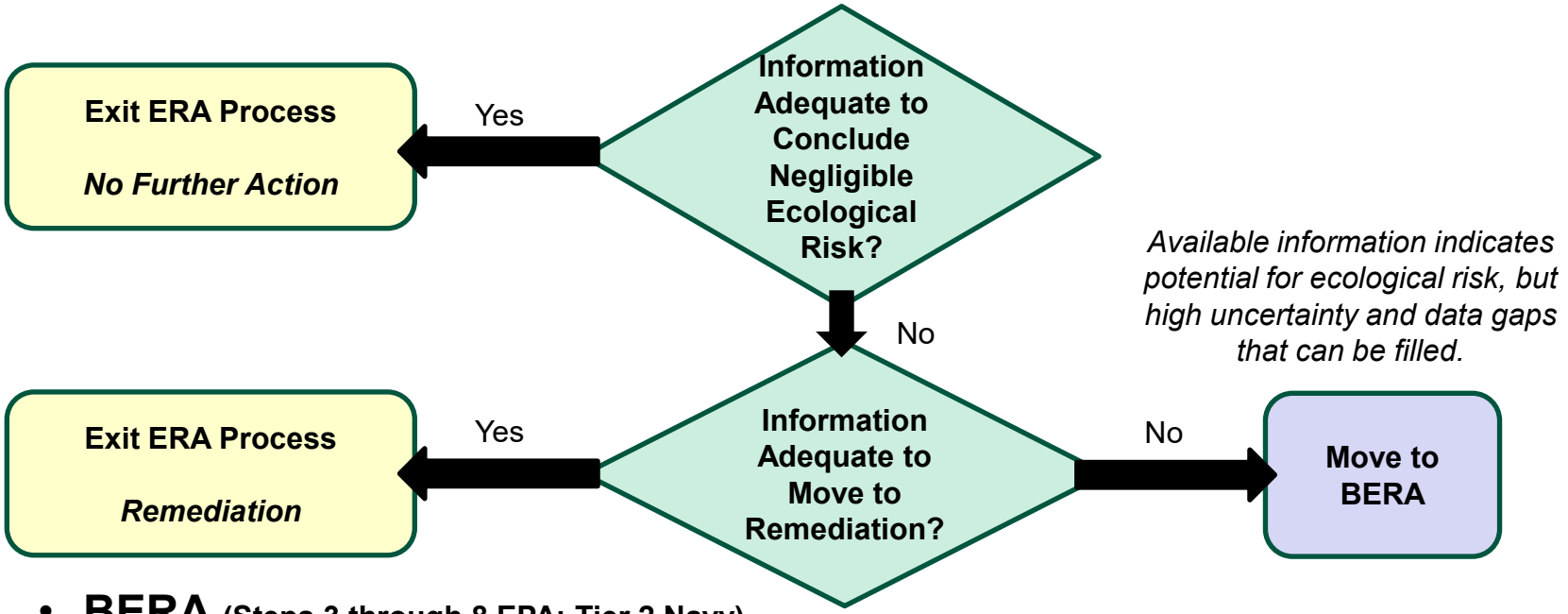
Step 3A SLERA Refinement (Step 3a EPA; Tier 2 Step 3a Navy)



- **First step in the Baseline ERA (BERA)**
  - Focus on COPECs and receptors with HQs >1 in SLERA
  - Re-evaluate exposure and toxicity using more realistic assumptions
  - Site concentrations reflective of average exposure not maximum (95% upper confidence limit [UCL])
  - ESVs adjusted to site conditions (total organic carbon) and receptors present on-site

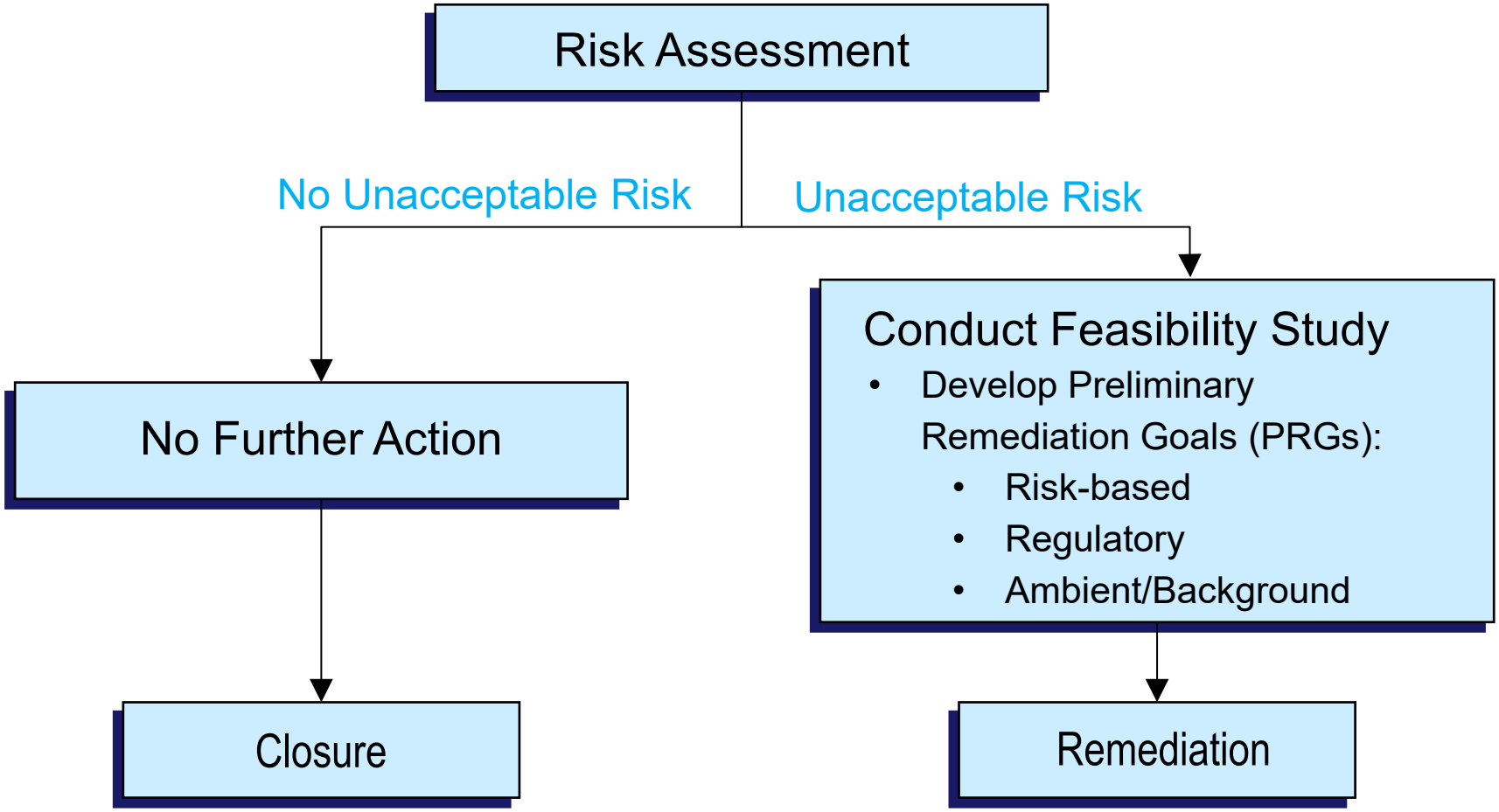
Step 3a SLERA Refinement
Site concentrations = Lower of maximum and 95% UCL
ESVs = No observed adverse effect levels and lowest observed adverse effect levels
Food web model = Assume wildlife forage outside site; consider migration
Other considerations = frequency of detection, background analysis, habitat quality assessment

Decision-Making After SLERA and Step 3a



- **BERA (Steps 3 through 8 EPA; Tier 2 Navy)**
  - Develop BERA Work Plan and collect site-specific data to further assess risk
  - Measure chemical concentrations in tissue, conduct toxicity tests, perform focused species surveys (wildlife, fish, benthic invertebrates), compare to reference locations
  - Re-evaluate risks for COPECs and receptors retained after Step 3a in the USEPA and Navy approaches

Risk Assessment Conclusions and Next Steps



Risk Assessment Process Overview

Questions?

Key Guidance Documents

- USEPA Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual (Parts A, B, D, E, F) (1989, 1991, 2001, 2004, 2009). Available at: https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part
- USEPA Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. 1997. Available at: https://www.epa.gov/risk/ecological-risk-assessment-guidance-superfund-process-designing-and-conducting-ecological-risk
- USEPA Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. Office of Solid Waste and Emergency Response (OSWER) Directive 9355.0-30. 1991. Available at: https://www.epa.gov/sites/default/files/2015-11/documents/baseline.pdf.
- USEPA Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites. OSWER Directive 9285.6-10. 2002. Available at: https://www.epa.gov/sites/default/files/2015-11/documents/ucl.pdf
- USEPA. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. 2002. Available at: https://www.epa.gov/superfund/superfund-soil-screening-guidance#supplemental
- USEPA. Human Health Toxicity Values in Superfund Risk Assessments. OSWER Directive 9285.7-53. 2003. Available at: https://www.epa.gov/sites/default/files/2015-11/documents/hhmemo.pdf
- USEPA Exposure Factors Handbook. 2011 and updates. Available at: https://assessments.epa.gov/risk/document/&deid=236252
- USEPA Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors. OSWER Directive 9200.1120. 2014. Available at: https://www.epa.gov/sites/default/files/2015-11/documents/OSWER-Directive-9200-1-120-ExposureFactors.pdf
- Department of the Navy. Navy Policy for Conducting Human Health Risk Assessments Under the Environmental Restoration Program. 2001. Available at: https://exwc.navfac.navy.mil/Portals/88/Documents/EXWC/Restoration/er_pdfs/gpr/cno-ev-pol-hhra-20010212.pdf?ver=tnd0TfF2u3dlly_zNLyAAg%3d%3d&timestamp=1651084833730
- U.S. Navy Human Health Risk Assessment Guidance. 2008. Available at: https://exwc.navfac.navy.mil/Portals/88/Documents/EXWC/Restoration/er_pdfs/gpr/navy-ev-guid-hhra-2008012r.pdf?ver=B1cDBicHPl9leymMK64-Ug%3d%3d&timestamp=1651084771529
- Department of the Navy. Environmental Restoration Program Manual. 2018. Available at: don-ev-man-nerp-201801A.pdf
    - Chapter 8.3.3.1 covers HHRA
    - Chapter 8.3.3.2 covers ERA

Acronyms and Abbreviations

%	percent
BERA	Baseline Ecological Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	chemical of potential concern
COPEC	chemical of potential ecological concern
CSM	conceptual site model
ELCR	excess lifetime cancer risk
EPC	exposure point concentration
ERA	Ecological Risk Assessment
ESV	ecological screening value
FS	Feasibility Study
HHRA	Human Health Risk Assessment
HI	hazard index
HQ	hazard quotient
OSWER	Office of Solid Waste and Emergency Response
PRG	Preliminary Remediation Goal
RAGS	Risk Assessment Guidance for Superfund
RI	Remedial Investigation
RME	Reasonable Maximum Exposure
SLERA	Screening Level Ecological Risk Assessment
SRA	Screening Level Risk Assessment
UCL	upper confidence limit
U.S.	United States
USEPA	United States Environmental Protection Agency

Thank You