US ERA ARCHIVE DOCUMENT



## **Objectives**

#### Participants will:

- Become familiar with the new El guidance via discussions, scenarios, and regional experiences
- Use the new EI guidance on real-world case study



## Current Human Exposures Under Control El

#### Key components:

- Intended to be realistic, risk-based evaluation
- Based on actual, "current" land use, not hypothetical or future land uses
- Looks at complete exposure pathways resulting in human exposure to levels of contaminants giving rise to unacceptable risk
- No ecological risk evaluated (eco-risk El possible in future)

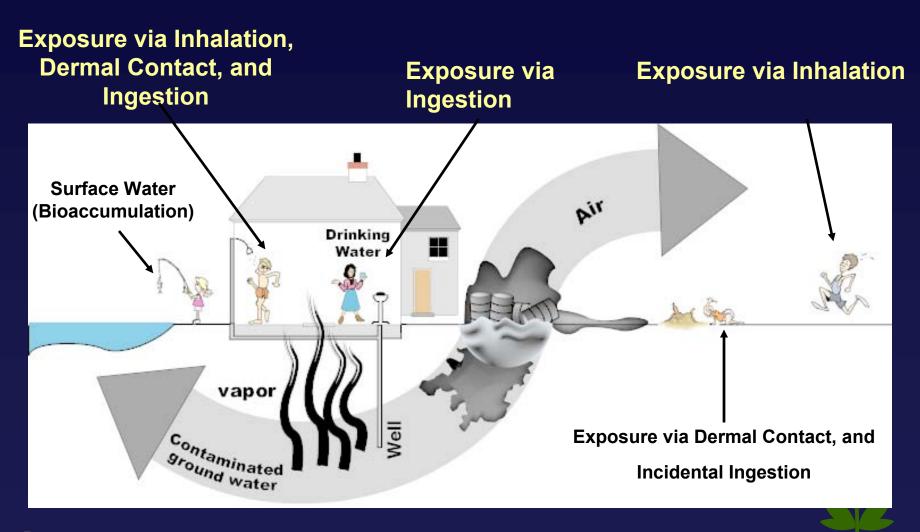


# Current Human Exposures Under Control El (Cont.)

#### Key components (continued):

- All media need to be considered (soil, sediment, water, air).
- A number of potential exposure pathways need to be considered if realistic (e.g., actual groundwater use to be considered).
- A number of potential exposure scenarios need to be considered if realistic (consistent with current actual land use).

### Some Principal Pathways to be Considered for "Current Human Exposures Under Control"



## Human Exposures El Evaluation and Documentation Guidance

Tiered five-step screening process:

- has all relevant data been evaluated?
- any media contaminated above appropriate risk-based levels ("contamination")?
- are there complete pathways between humans and "contamination"?
- are exposures expected to be significant?
- have exposures been demonstrated (e.g., quantitatively) to be acceptable?



# Exposure Controls for Human Exposures El

The objective is to reduce 1) concentrations, or 2) exposures (e.g., cut the pathways):

- It is not necessary to investigate all areas if there are exposure controls in place that adequately limit, control, or prevent exposures to the concentrations likely or possibly present
- Optional pathway evaluation worksheet and example controls (early draft available)



## Current Human Exposures Under Control El

#### Risk:

- Is the probability of an undesirable effect
- For environmental risk, it is the product of contaminant concentrations and exposures (i.e., = Conc. x Exposure) [& Toxicity]
- Can be reduced by controlling either concentrations or exposures
- Acceptability is a societal value judgment
  - Voluntary Involuntary
  - Benefits No benefits
  - Well-known Not familiar
  - Warnings No warnings



## Current Human Exposures Under Control El

#### Summary and key communication points:

- Three possible answers ("YE," "NO," & "IN")
- "YE"(s)\* exposures are "Under Control"
- A "NO" answer means that Current Human Exposures are Not Under Control
  - we are aware that unacceptable human exposures are currently occurring
  - these conditions should be addressed as soon as possible
- "IN"sufficient data to make a determination



## In-depth Review of HUMAN EI

- Current Human Exposures Under Control
- RCRIS code CA725
- Background/Cover memo
- Flowchart
- Questions slightly abbreviated in slides
- Response criteria abbreviated in notes
- Full text in 2/5/99 Guidance



Has <u>all</u> available relevant/significant information on known and reasonably suspected releases

- subject to RCRA Corrective Action (e.g., SWMU, RU, AOC)
- been considered in this EI determination?

A "no brainer" gentle reminder



Are <u>media</u> (groundwater, soil, surface water, sediments, or air)

- known or reasonably suspected to be "contaminated"?
- above appropriately protective risk-based "levels" (applicable promulgated standards, as well as other appropriate standards, guidelines, or criteria)?
- from releases subject to RCRA Corrective Action (from SWMUs, RUs, or AOCs)?

Are there "complete pathways" between "contamination" ("Above Levels of Concern" ALC) and human receptors \*

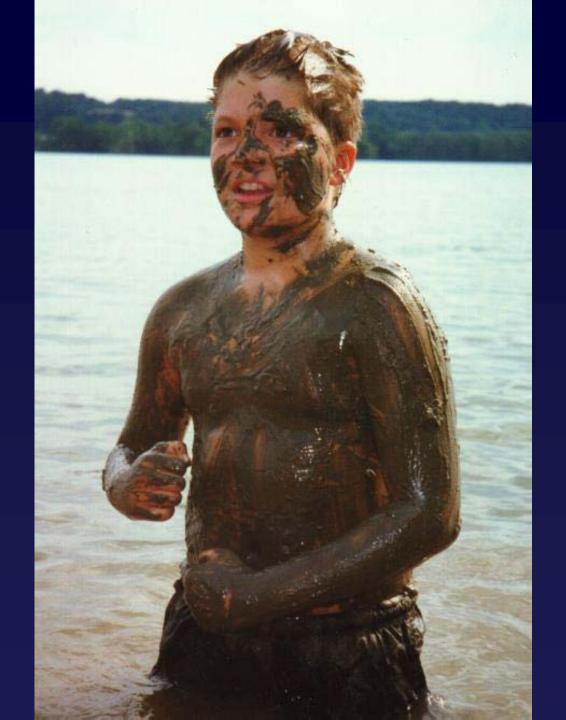
- such that exposures can be reasonably expected?
- under the current land- and groundwater-use conditions?



Can the exposures reasonably be expected to be significant, i.e., magnitude (intensity, frequency and/or duration)?

- An opportunity to use professional qualitative judgment and not require a Quantitative Risk Assessment for every complete pathway
- Most difficult portion of Human El
- If there is any question consult a Risk Assessment specialist







## **HUMAN EI - Question 4 (Cont.)**

#### Suggested:

- Semi-quantitative tool for assessing combination of concentrations and exposure magnitudes
- See-Saw Analogy
  - As concentrations go up (above "levels"),
    exposures had better go down (<< in "levels")</li>



- Have the "significant" exposures (identified in Question 4) been shown to be within acceptable limits (i.e., is there a Quantitative Risk Assessment (QRA) demonstrating their acceptability)?
- What exposure limitations/controls are assumed in the QRA?
- What confidence is there in these, and what notification procedures for changes?



- Check the appropriate RCRIS status codes for Human Exposures EI event code CA 725,
- Obtain supervisor (or appropriate manager) signature and date on the EI determination
- Attach
  - appropriate supporting documentation
  - a map of the facility.

