
HUMAN EI

Objectives

Participants will:

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

Current Human Exposures Under Control EI

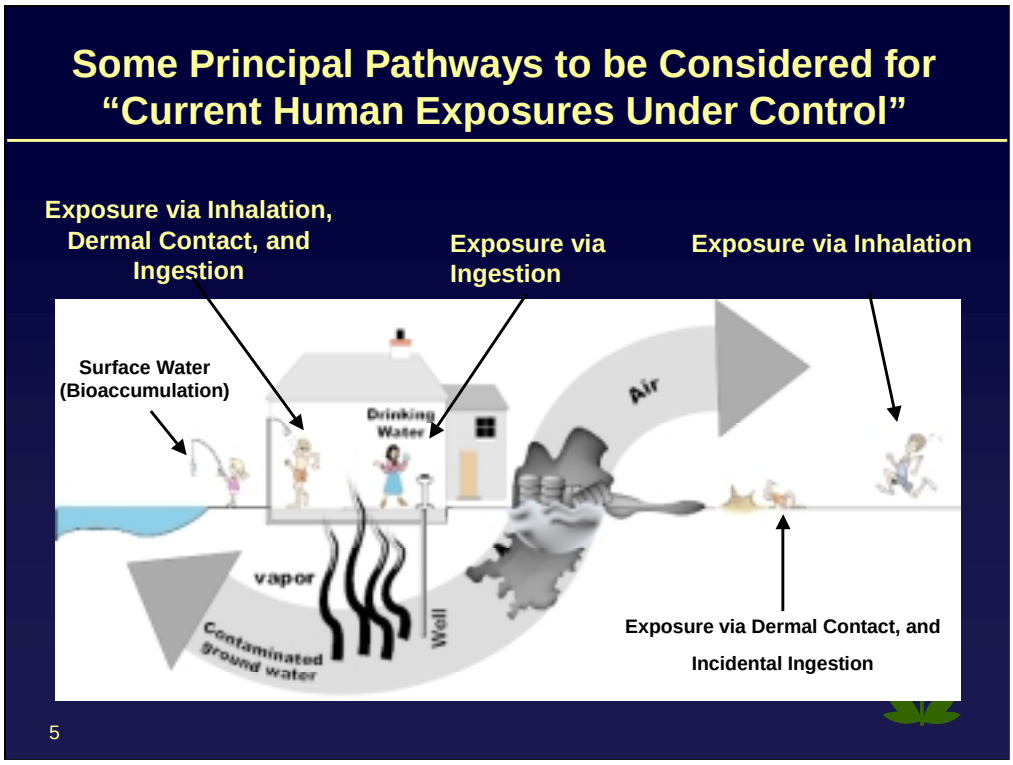
Key components:

- 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 EI possible in future)

Current Human Exposures Under Control EI (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).



Summary Exposure Pathway Evaluation Table (CA725 Question 3, Page 3)

Potential[**ly Applicable**] Human Receptors (Under Current Conditions)

"Contaminated" Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food3
Groundwater	___	___	___	___			___
Air (indoors)	___	___	___				
Soil (surface, e.g., <2 ft)	___	___	___	___	___	___	___
Surface Water	___	___			___	___	___
Sediment	___	___			___	___	___
Soil (subsurface e.g., >2 ft)				___			___
Air (outdoors)	___	___	___	___	___		

Human Exposures EI 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?

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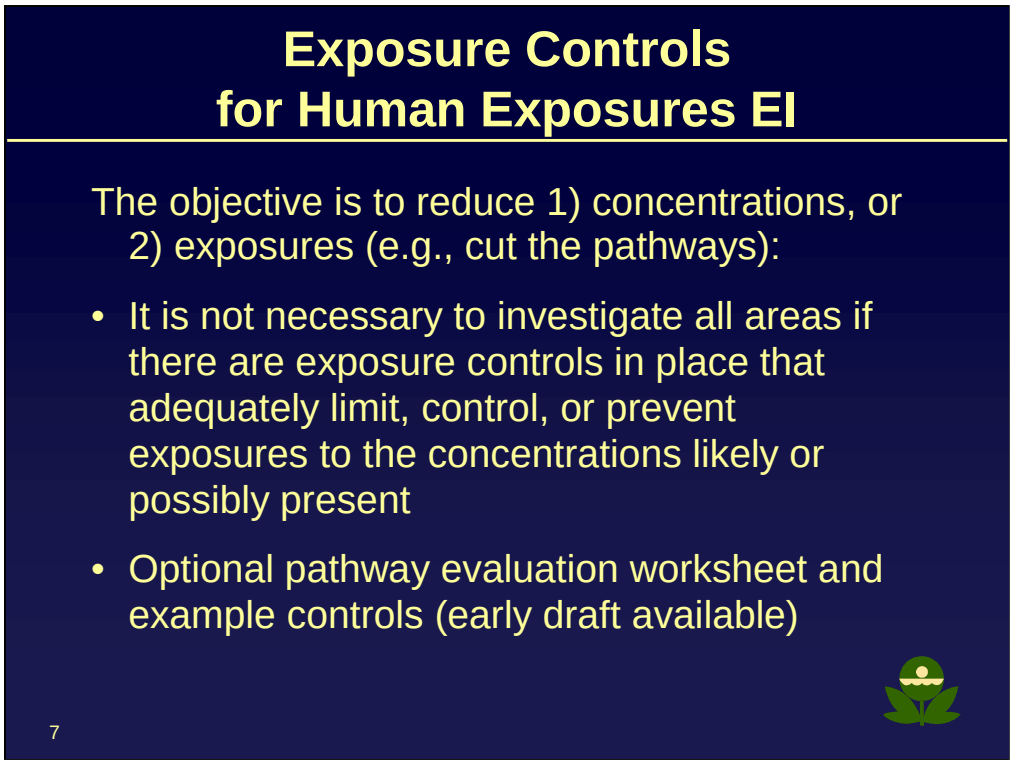
Notes:

This slide presents an easy-to-read introduction to the EI guidance questions.

These questions will be discussed in more depth in the next section of this presentation.

The full text of these questions is in the 2/5/99 guidance provided in the Handbook

These questions are summarized and their functional relationships are illustrated in the EI flowcharts.



1. Examples of Physical Controls

- Caps
- Fences/Walls
- Security Guards
- Vegetative Cover
- Natural Inaccessibility
- Remoteness/Unattractiveness
- Vapor Barriers/Ventilation Systems
- Permitted releases – NPDES, CAA, etc.

2. Examples of Institutional Controls – Do not need to be legally binding documents (sitting in courthouse), could be written commitments (e.g. on facility letterhead). "EFFECTIVE controls"

- Posted Signs
- Land-use Restrictions (e.g., zoning, deed, Responsible Party statements)
- Level of PPE (Personal Protection Equipment)
- Safety Training/Newsletters
- Activity Permits/Notifications (e.g., construction permits/notifications)
- Well Restrictions
- Media-use Restrictions
- Responsible Party statements of activity/use restrictions
- Testing/Monitoring (and restrictions if necessary)
- Consumption Restrictions
- Restrictions on Frequency of Exposures

Current Human Exposures Under Control EI

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

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Notes:

Risks* can be reduced by:

Reducing contaminant concentrations (cleanup, remediation, restoration, etc.)

or

Reducing exposures (effective controls on exposure intensity, frequency, or magnitude)

Obviously, reducing contaminant concentrations (and removing all hazards) is preferable (for many reasons); however, given the GPRA timeframe, exposure controls are likely to be more frequently used to meet "Under Control" goals.

Acceptable risk levels are typically identified in State or EPA guidance (e.g., lifetime cancer risks within 10-4 to 10-6 range and Hazard Indices of <1).

*(Incremental risks due to environmental hazards)

Current Human Exposures Under Control EI

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

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Notes:

There shouldn’t be many “NO” status codes (if we are protecting human health)

“NO” status codes shouldn’t exist for long (if we are addressing problems as soon as we are aware of them)

“YE”s status codes (exposures are “Under Control”) need to be carefully communicated for sites where “un-natural” (or natural) background hazards exist (i.e., from sources other than these facilities, and/or not reachable by RCRA)

It is important for us (regulators) to be careful in the communication of what "under control" means. "Under control" refers to a specific facility's releases and may not mean that there are not other unacceptable exposures (which are not the responsibility of the identified facility).

Additional guidance/methodologies for clearly and accurately communicating this issue will likely need to be developed in the future. (All we need is someone to do it.)

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

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Reference: "RCRA Corrective Action Environmental Indicator (EI) RCRIS code (CA725)," US EPA, Interim Final 2/5/99.

HUMAN EI - Question 1

Has all 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

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_____ If yes – check here and continue with Question 2.

_____ If no – re-evaluate existing data, or

_____ If data are not available skip to Question 6 and enter "IN" (more information needed) status code.

HUMAN EI - Question 2

Are media (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)?

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Notes:

Appropriately protective "levels" for the obvious land use (e.g., industrial) and for the aquifer-wide groundwater use.

This should not consider site-specific conditions that limit risks.

This is a straightforward hazard identification (potential risks under possible exposure scenarios).

Media listed in guidance.

Groundwater, air (indoors), surface soil (e.g., <2 ft), surface water/sediment, subsurface soil (e.g., >2 ft), Air (outdoors)

_____ If no (for all media) - skip to Question 6, and enter "YE," status code after providing or citing appropriate "levels," and referencing sufficient supporting documentation demonstrating that these "levels" are not exceeded.

_____ If yes (for any media) - continue after identifying key contaminants in each "contaminated" medium, citing appropriate "levels" (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

_____ If unknown (for any media) - skip to Question 6 and enter "IN" status code.

HUMAN EI - Question 3

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?

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Summary Exposure Pathway Evaluation Table (CA725 Question 3, Page 3)

Potential Human Receptors (Under Current Conditions)

“Contaminated" Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food3
Groundwater	___	___	___	___			___
Air (indoors)	___	___	___				
Soil (surface, e.g., <2 ft)	___	___	___	___	___	___	___
Surface Water	___	___			___	___	___
Sediment	___	___			___	___	___
Soil (subsurface e.g., >2 ft)				___			___
Air (outdoors)	___	___	___	___	___		

HUMAN EI - Question 4

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 EI
- If there is any question consult a Risk Assessment specialist

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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”)

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Notes:

The “levels” used are developed from assumed exposure magnitudes, including some rate of intake (intensity), frequency, and duration of exposures (typically lifetime or career).

If the concentration of contaminants where exposures occur are 10 times the acceptable “levels,” then the exposure magnitudes (intensity times the sum of lifetime or career frequency and durations) had better be less than 1/10 of that assumed in the derivation of the acceptable “levels” to retain the ‘acceptable” product (risk) of concentrations times exposures.

HUMAN EI - Question 5

- 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?

HUMAN EI - Question 6

- 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.