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The Impact of Short-Term PCE/TCE Exposure Guidelines on Intermittent & Chronic Exposures at VI Sites

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Why Do We Need NC RA Guidance

- PCE/TCE RfC drives clean-ups in 10^{-5} States or when trying to close above 10^{-6}
- EPA 2015 VI Guidance is rigorous and most sites are not screened out
- There is (unanticipated) widespread intermittent and (in some instances) continuous indoor air exposure in schools, residences, commercial land use
- Changing regulatory screening levels create real world implications

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Exposure is often above the RfC

- Risk Managers are generally not able to understand or communicate the non-cancer risk of exposure above the RfC to the public or other concerned parties.
  - Information provided to public is generally, long on effects literature and short on risk understanding

- Risk managers are not able to determine when there is a science or health-based need to take immediate action.
  - Even more complex when intermittent exposures are above the RfC
- Amid the confusion, there is substantial opportunity for over-reaction on the part of the public and legal liability to the responsible party

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How did this happen?

- Risk managers do not commonly make decisions based on Non-Cancer risk
- Most assume it is a bright line, if this is communicated to the public they also assume anything above the RfC creates a toxic effect
- The “bright line” understanding is out of date and not consistent with the science
- The IRIS, EPA, ATSDR and common definition of RfC infers a range for NC.

RfC Defined

An estimate (with *uncertainty spanning perhaps an order of magnitude*) of a *continuous* inhalation exposure of a chemical to the human population through inhalation (including sensitive subpopulations), that is likely to be without risk of deleterious noncancer effects *during a lifetime*.

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Uncertainty fleshed out

- What does this mean in practical application and how should risk managers apply this meaning
- In practical application the result of uncertainty is a margin of safety
- A margin of safety is created because every time there is a gap in the science understanding a mathematical safety factor or uncertainty factor is applied in order to insure safety.
- Successive uncertainty factors compound and often create a wide margin of safety

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Applied Science Slide

- What is needed is "applied science" information that is not given by EPA or ATSDR on:
  - ATSDR draft toxicity profiles
  - Some indication of risk above the RfC
  - A science based immediate action level
  - Some guidance on exposure period of sampling

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ARA Recommended Approach

- The Alliance for Risk Assessment has addressed these issues for TCE using current science and EPA guidance.
  - Allows an understanding of risk above the RfC
  - A science based understanding of a ceiling action level which in application can be treated as an immediate action level
  - Better understanding of sampling needs for comparison

ARA Range

- NC has a range - floor, intermediate, & ceiling:
  - Floor: this level signals a concentration below which risk managers do not commonly take action
  - Intermediate: this level helps to guide understanding of risk above the RfC, aid in remedial levels and acceptable long term exposure levels
  - Ceiling: this level signals a concentration above which risk managers almost always take action

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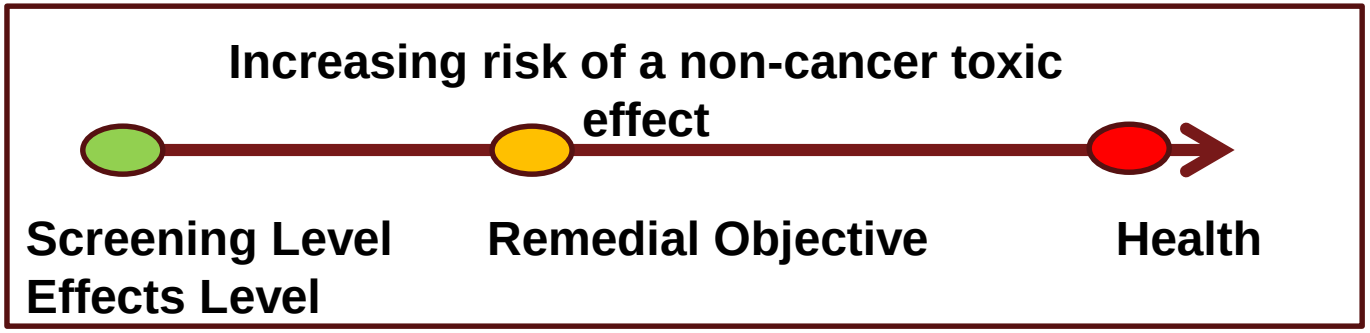


2-3 ug/m^3

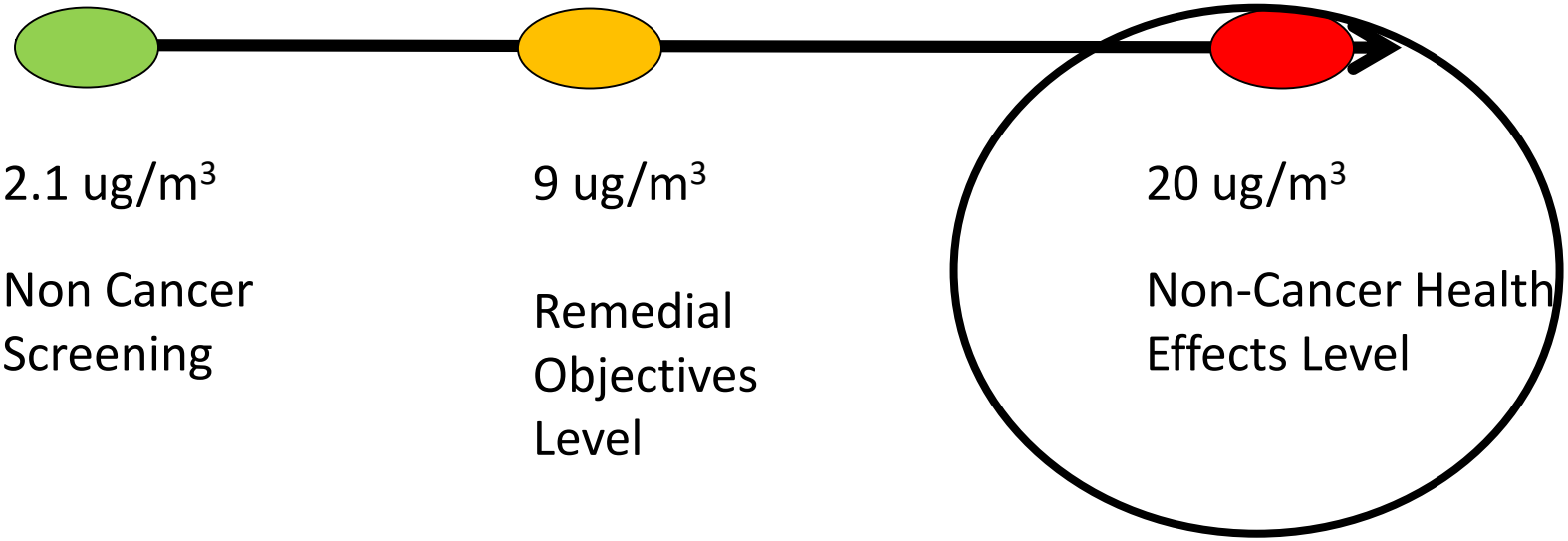
20 ug/m^3

Establishing an Intermediate Value

- Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC)
- Size of the total uncertainty factor (safety factors) as a crude measure of the overall uncertainty (margin of safety) in the database
- Confidence in the choices of critical effect; and
- Confidence in the Point of Departure from the animal or human exposure study

TCE

- **Non-cancer range**



PCE

- **Non-cancer PCE Floor and Ceiling Level**

42 ug/m^3

Non Cancer Screening

130 ug/m^3

Non-Cancer Health Effects Level

Non-Cancer TCE and PCE Action Levels

	Level Below Which Action is Generally not Taken	Immediate Action Assessment	Interpreting the Risk above the RfC but below the Immediate Action Level for Continuous Exposure
TCE	2.1 ug/m^3 (for all intents and purposes the RfC)	20 ug/m^3 assessed as a 24 hour continuous or intermittent average. Actions to reduce exposure within 96 hours.	Less than 9 ug/m^3 of the 3 - 20 ug/m^3 range can be interpreted as presenting low risk of a toxic effect from exposure.
PCE	42 ug/m^3 (for all intents and purposes the RfC)	130 ug/m^3 assessed as a seven day average continuous or intermittent average. Actions to reduce exposure within 96 hours.	Not enough information to establish an intermediate value. Recommend that the ARA undertake this assessment.

Intermittent Exposures

- Screening comparisons are made using intake at the RfC concentration over time under residential low activity exposures as the screening level
- This is compared to actual time, activity and exposure levels in the exposure setting
- This method is used in order to unequivocally demonstrate non-cancer risk is negligible
- Methods are fully detailed in the paper (available upon request)

Next Steps

- HSIA funded study
- ATSDR completes TCE/PCE Toxicity Profiles
- US EPA issues supplemental guidance as alluded to in Fall 2014 and June 2015
- Open a dialogue on applied science guidance using ARA NC Range as interim approach

Questions or Comments

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