Case Study-Specific Charge Questions
Methods for Deriving Inhalation Effect Levels for Comparison to Health-Protective Values

Please comment on proposed procedures used to develop effect levels, not TCEQ procedures established under agency guidance to calculate health-protective reference values (shown in tables primarily for comparison to effects levels).

1. When both concentration and duration play a role in toxicity, and only a subacute or subchronic animal study is used for developing an effect level, how should the corresponding human exposure duration be determined (e.g., 90-day mouse exposure = x-day human exposure, proportion of lifespan, etc.)?

2. The main purpose of determining effect levels is to provide perspective on the health-protective reference value (e.g., RfC, Rev) and useful information to risk managers and risk assessors conducting health effects reviews of data when an exceedance of a health-protective value is observed. Instead of providing a single effect level value, please comment on the utility of providing "effect level intervals" (e.g., when using animal data and information on interspecies sensitivity is lacking, providing the air concentration interval corresponding to the lowest exposure at which increased risk was observed as well as a 10^{-3} excess risk level for cancer effect levels).

3. Please comment on the usefulness of providing information on effect levels or effect level intervals to understand potential health effects when health-protective reference values are exceeded.

4. The procedures for developing effect levels that are predictive do not include the application of uncertainty factors (UFs) because when UFs are applied, it often produces an unknown effect on the probability of the response observed at the POD. For example, if a UF of 10 is applied for intrahuman variability and true (but unknown) human variability for the chemical and endpoint is only around 3, the excess UF may result in a value that actually represents a NOAEL instead of an effects level. TCEQ's goal is to estimate human effects levels with as high of a degree of confidence as possible that effects would indeed occur in some individuals, as opposed to speculating about how low an effects level could be in the absence of dose-response data in sensitive subpopulations. Comment on the "meaning" or definition of an effect level if central tendency values of the distribution of UF_H and UF_A are applied to effect levels.