4717.8050 DEFINITIONS.

Subpart 1. **Scope.** For the purposes of parts 4717.8000 to 4717.8600, the terms in this part have the meanings given them.

Subp. 2. **Acute health risk value or acute HRV.** "Acute health risk value" or "acute HRV" means the concentration of a chemical or defined mixture of chemicals in ambient air, at or below which the chemical or defined mixture of chemicals is unlikely to cause an adverse health effect to the general public when exposure occurs over a prescribed time. For implementation purposes, acute HRVs are compared to one-hour averaged concentrations of chemicals or defined mixtures of chemicals in air. An acute HRV is expressed in units of micrograms of the chemical or defined mixture of chemicals per cubic meter of air ($\mu g/m^3$).

Subp. 3. **Additional lifetime risk.** "Additional lifetime risk" means the probability that daily exposure to a carcinogen over a lifetime may induce cancer. The Minnesota Department of Health uses an additional lifetime risk of 1E-5 (1 in 100,000) to set carcinogen exposure guidelines.

Subp. 4. **Benchmark concentration or BMC.** "Benchmark concentration" or "BMC" means the statistical lower limit on the concentration of the chemical or defined mixture of chemicals that produces a predetermined change in response rate of an adverse effect (called a benchmark response or BMR) compared to background. The change in response rate over background of the BMR is usually in the range of five to ten percent. The benchmark concentration may be used instead of the NOAEL for noncancer endpoints and is expressed in units of milligrams of chemical or defined mixture of chemicals per cubic meter of air (mg/m^3).

Subp. 5. **Benchmark dose or BMD.** "Benchmark dose" or "BMD" means the the statistical lower limit on the dose of the chemical or defined mixture of chemicals that produces a predetermined change in response rate of an adverse effect (called a benchmark response or BMR) compared to background. The change in response rate over background of the BMR is usually in the range of five to ten percent. The benchmark dose may be used instead of the NOAEL for noncancer endpoints and is expressed in units of milligrams of chemical or defined mixture of chemicals per kilogram of body weight per day (mg/kg-day).

Subp. 6. **Carcinogen.** "Carcinogen" means a chemical or defined mixture of chemicals:

A. listed as a human carcinogen or a probable human carcinogen according to "EPA Classification System for Categorizing Weight of Evidence for Carcinogenicity from Human and Animal Studies," The Risk Assessment Guidelines of 1986, United States Environmental Protection Agency, Office of Health and Environmental Assessment (August 1987). The classification system is incorporated by reference, is available through the Minitex interlibrary loan system, and is not subject to frequent change;

B. listed as "carcinogenic to humans" or "likely to be carcinogenic to humans" according to Proposed Guidelines for Carcinogen Risk Assessment, United States Environmental Protection Agency, Office of Research and Development (July 1999). The guidelines are incorporated by reference, are available through the Minitex interlibrary loan system, and are not subject to frequent change; or

C. listed as a substance known to be a human carcinogen or reasonably anticipated to be a human carcinogen in the Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, National Toxicology Program. The report is incorporated by reference and is subject to frequent change. The report is available on the Internet at http://ntp-server.niehs.nih.gov/newhomeroc/aboutroc.html.

Subp. 7. **Chemical abstracts service registry number or CAS RN.** "Chemical abstracts service registry number" or "CAS RN" means the number assigned to a chemical by the Chemical Abstracts Service, a division of the American Chemical Society, 2540 Olentangy River Road, Box 3012, Columbus, Ohio 43210. The chemical abstracts service registry numbers are published in Chemical Abstracts Service Registry Handbook - Number Section, American Chemical Society (1965). The handbook is incorporated by reference, is available through the Minitex interlibrary loan system, and is subject to annual change.

Subp. 8. **Chronic health risk value or chronic HRV.** "Chronic health risk value" or "chronic HRV" means the concentration of a chemical or defined mixture of chemicals in ambient air, at or below which the chemical or defined mixture of chemicals is unlikely to cause an adverse health effect to the general public when exposure occurs daily throughout a person's lifetime. For implementation purposes, chronic HRVs are compared to an annual average concentration of a chemical or defined mixture of chemicals in air. A chronic HRV is expressed in units of micrograms of the chemical or defined mixture of chemicals per cubic meter of air ($\mu g/m^3$).

Subp. 9. **Cumulative health risk value or cumulative HRV.** "Cumulative health risk value" or "cumulative HRV" is a HRV calculated by summing the hazard quotients of chemicals sharing a common endpoint. A hazard quotient for a particular chemical is calculated by dividing the measured or modeled ambient air concentrations for a chemical by the HRV for that chemical. The equation used to calculate a cumulative HRV or hazard index for noncarcinogenic effects of chemicals is found in part 4717.8600. The equation used to calculate a cumulative HRV or cancer index for carcinogens is found in part 4717.8550.

Subp. 10. **Cumulative multimedia health risk value or cumulative MHRV.** "Cumulative multimedia health risk value" or "cumulative MHRV" is a MHRV calculated by summing the hazard quotients of chemicals sharing a common endpoint. A hazard

quotient for a particular chemical is calculated by dividing the measured or modeled ambient air concentrations for a chemical by the MHRV for that chemical. The equation used to calculate a cumulative MHRV or hazard index for noncarcinogenic effects of chemicals is found in part 4717.8600. The equation used to calculate a cumulative MHRV or cancer index for carcinogens is found in part 4717.8550.

Subp. 11. **Defined mixture of chemicals.** "Defined mixture of chemicals" means a mixture of chemical compounds where the toxicity of that mixture of chemical compounds is quantified as a group, rather than individually, in an analytical procedure. Defined mixtures of chemicals include, but are not limited to, coke oven emissions, diesel particulate, and nickel refinery dust.

Subp. 12. **Endpoint of concern or endpoint.** "Endpoint of concern" or "endpoint" means an observable and measurable adverse biological event used as a scientifically defensible index of an effect of a low dose chemical exposure. The designation of an endpoint of concern does not exclude other possible observable and measurable biological events.

Subp. 13. **Extrarespiratory effect.** "Extrarespiratory effect" means a toxic effect produced at a site other than the respiratory system following inhalation of a chemical.

Subp. 14. **Extrarespiratory regional dose deposition or RDD_{ER}.** "Extrarespiratory regional dose deposition" or "RDD_{ER}" is the estimated amount of inhaled chemical or defined mixture of chemicals that is transported to nonrespiratory tract tissues after absorption of the chemical has occurred. The default normalizing factor for extrarespiratory effects is body weight. Until clearance and distribution parameters can be incorporated, it is assumed that 100 percent of a deposited dose to the entire respiratory system is available for uptake by the systemic circulation.

Subp. 15. **Extrarespiratory regional dose deposition ratio or $RDDR_{ER}$.** "Extrarespiratory regional dose deposition ratio" or "$RDDR_{ER}$" means the ratio of the extrarespiratory regional dose deposition calculated for an experimental animal to the calculated extrarespiratory regional dose deposition in a human.

Subp. 16. **$(H_{b/g})_A$.** "$(H_{b/g})_A$" means the blood to gas (air) partition coefficient of a chemical in an experimental animal.

Subp. 17. **$(H_{b/g})_H$.** "$(H_{b/g})_H$" means the blood to gas (air) partition coefficient of a chemical in a human.

Subp. 18. **Health effects assessment summary tables or HEAST.** "Health effects assessment summary tables" or "HEAST" means the health effects assessment summary tables prepared by the United States Environmental Protection Agency, Office of Research and Development (1991). The tables are incorporated by reference, are available through the Minitex interlibrary loan system, and are subject to quarter-annual changes.

Subp. 19. **Health risk value or HRV.** "Health risk value" or "HRV" means the concentration of a chemical or defined mixture of chemicals in ambient air, at or below which the chemical or defined mixture of chemicals is unlikely to cause an adverse health effect to the general public. The HRV is expressed in units of micrograms of the chemical or defined mixture of chemicals per cubic meter of air ($\mu g/m^3$).

Subp. 20. **Human equivalent concentration or HEC.** "Human equivalent concentration" or "HEC" means the concentration of inhalation exposure for humans of an agent that is believed to induce the same magnitude of a toxic effect as associated with the experimental animal species exposure concentration. HEC derivation may incorporate toxicokinetic information on the particular agent, if available, or use a default procedure, such as assuming that daily oral doses experienced for a lifetime are proportional to body weight raised to the 0.75 power.

Subp. 21. **Integrated risk information system or IRIS.** "Integrated risk information system" or "IRIS" means the United States Environmental Protection Agency's electronic database for toxicologic information on chemicals. The IRIS is updated monthly and is available on the Internet at the Web site of the United States Environmental Protection Agency (www.epa.gov/iris/). The database is incorporated by reference and is subject to frequent change.

Subp. 22. **Lowest observed adverse effect level or LOAEL.** "Lowest observed adverse effect level" or "LOAEL" means the lowest exposure dose or concentration of a chemical or defined mixture of chemicals at which adverse effects have been observed in test animals or human test subjects and where the adverse effects are statistically different from background or a control group. The LOAEL is expressed in units of either milligrams of a chemical or defined mixture of chemicals per cubic meter of air (mg/m^3) for inhalation exposures or units of milligrams of a chemical or defined mixture of chemicals per kilogram of body weight per day (mg/kg-day) for multimedia exposures.

Subp. 23. **Lowest observed adverse effect level adjusted or $LOAEL_{[ADJ]}$.** "Lowest observed adverse effect level adjusted" or "$LOAEL_{[ADJ]}$" means the lowest observed adverse effect level for a chemical or defined mixture of chemicals adjusted to a specific period of time. For the chronic HRVs, the concentration in the scientific study is adjusted to a 24-hour per day, seven-day per week exposure period. For acute HRVs, the adjustment may include either a time adjustment to a one-hour exposure period or an adjustment for concentration as indicated in part 4717.8500, subparts 3, 4, and 5.

Subp. 24. **$\mu g/m^3$.** "$\mu g/m^3$" means micrograms per cubic meter.

Subp. 25. **mg/m^3.** "mg/m^3" means milligrams per cubic meter.

Subp. 26. **Modifying factor.** "Modifying factor" means a factor used in the derivation of a reference dose or reference concentration. The magnitude of the modifying factor

reflects the scientific uncertainties of the study and database not explicitly treated with standard uncertainty factors (e.g., the completeness of the overall database). A modifying factor is greater than zero and less than or equal to ten, and the default value for the modifying factor is one.

Subp. 27. **Multimedia health risk value or MHRV.** "Multimedia health risk value" or "MHRV" means the total daily dose of a chemical or defined mixture of chemicals that results from an emission to ambient air, at or below which is unlikely to cause an adverse health effect to the general public over a lifetime exposure. Total daily dose is the sum of the exposure doses calculated from applicable inhalation or noninhalation exposure pathways. The MHRV is expressed in units of micrograms of the chemical or defined mixture of chemicals per kilogram of body weight per day (µg/kg-day).

Subp. 28. **No observed adverse effect level or NOAEL.** "No observed adverse effect level" or "NOAEL" means the highest exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control. Some effects may be produced at this level, but they are not considered adverse or precursors to adverse effects. The NOAEL is expressed in units of milligrams of chemical or defined mixture of chemicals per cubic meter of air (mg/m^3) or milligrams of chemical or defined mixture of chemicals per kilogram of body weight per day (mg/kg-day).

Subp. 29. **No observed adverse effect level adjusted or $NOAEL_{[ADJ]}$.** "No observed adverse effect level adjusted" or "$NOAEL_{[ADJ]}$" means the no observed adverse effect level for a chemical or defined mixture of chemicals adjusted to a specific period of time. For the chronic HRVs, the concentration is adjusted to a 24-hour per day, seven-day per week exposure period. For acute HRVs, the adjustment may include either a time adjustment to the scientific study data to a one-hour exposure period or an adjustment for concentration as indicated in part 4717.8500, subparts 3 and 4.

Subp. 30. **Potency slope or slope factor.** "Potency slope" or "slope factor" means an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime exposure to a chemical or defined mixture of chemicals. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than one in 100. This number is derived from a mathematical extrapolation model that uses toxicologic data specific to each carcinogen. The potency slope for a carcinogen by ingestion is expressed in units of the inverse of milligrams of the chemical or defined mixture of chemicals per kilogram of body weight per day $(mg/kg\text{-}day)^{-1}$.

Subp. 31. **Reference concentration or RfC.** "Reference concentration" or "RfC" means an estimate, with uncertainty spanning perhaps an order of magnitude, of a

continuous inhalation exposure to the human population, including sensitive subgroups, that is likely to be without an appreciable risk or deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations on the scientific data available. The RfC is expressed in units of milligrams of the chemical or defined mixture of chemicals per cubic meter of air (mg/m^3).

Subp. 32. **Reference dose or RfD.** "Reference dose" or "RfD" means an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population, including sensitive subgroups, that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the scientific data available. The RfD is expressed in units of milligrams of the chemical or defined mixture of chemicals per kilogram of body weight per day (mg/kg-day).

Subp. 33. **Reference exposure level or REL.** "Reference exposure level" or "REL" means the concentration level of a chemical or defined mixture of chemicals at or below which no adverse health effects are anticipated for a specified exposure duration. Reference exposure levels have been derived by the California Environmental Protection Agency, the Office of Environmental Health Hazard Assessment, under the Air Toxics "Hot Spots" Information and Assessment Act of 1987. The exposure levels are available on the Internet at the Web site of the Office of Environmental Health Hazard Assessment (www.oehha.org/air/acute_rels/acuterel.html).

Subp. 34. **Regional deposited dose or RDD.** "Regional deposited dose" or "RDD" means the deposited dose of particles calculated for a respiratory tract region of interest as related to an observed toxicity. For respiratory effects of particles, the deposited dose is adjusted for ventilatory volumes and the surface area of the respiratory region affected and is expressed as milligrams per minute per square centimeter (mg/min-sq. cm). For extrarespiratory effects of particles, the deposited dose in the total respiratory system is adjusted for ventilatory volumes and body weight and is expressed as milligrams per minute per kilogram (mg/min-kg).

Subp. 35. **Regional deposited dose ratio or RDDR.** "Regional deposited dose ratio" or "RDDR" means the ratio of the regional deposited dose calculated for a given exposure in the animal species of interest (RDD_A) to the regional deposited dose of the same exposure in a human (RDD_H). This ratio is used to adjust the exposure effect level for interspecies dosimetric differences to derive a human equivalent concentration (HEC) for particles.

Subp. 36. **Regional gas dose or RGD.** "Regional gas dose" or "RGD" means the gas dose calculated for the respiratory system region of interest as related to the observed effect for respiratory effects. The deposited dose is adjusted for ventilatory volumes and

the surface area of the respiratory region affected. RGD is calculated per minute expressed as milligrams per minute per square centimeter (mg/min-sq. cm).

Subp. 37. **Regional gas dose ratio or RGDR.** "Regional gas dose ratio" or "RGDR" means the ratio of the regional gas dose calculated for a given exposure in the animal species of interest (RGD_A) to the regional gas dose of the same exposure in humans (RGD_H). This ratio is used to adjust the exposure effect level for interspecies dosimetric differences to derive a human equivalent concentration (HEC) for gases with respiratory effects.

Subp. 38. **Respiratory effect.** "Respiratory effect" means a toxic effect produced in the respiratory system. Respiratory effects are divided into the categories of upper respiratory effects and lower respiratory effects. Effects in the upper respiratory system consist of effects primarily in the extrathoracic (ET) region, consisting of the nose, mouth, nasopharynx, oropharynx, laryngopharynx, and larynx, and in the upper tracheobronchial (TB) region consisting of the trachea, bronchi, and bronchioles.

The lower respiratory system effects consist of effects primarily in the pulmonary (PU) region, consisting of the respiratory bronchioles, alveolar ducts, alveolar sacs, and alveoli, and effects in the lower tracheobronchial (TB) region, consisting of the trachea and bronchioles to the terminal bronchioles.

Subp. 39. **Respiratory system.** "Respiratory system" means the nose, mouth, nasopharynx, oropharynx, larynx, trachea, bronchi, bronchioles, and the alveolar ducts, alveolar sacs, and alveoli of the lung.

Subp. 40. **Statistical significance.** "Statistical significance" means the probability that a result is likely to be due to chance alone. By convention, a difference between two groups is usually considered statistically significant if chance could explain it only five percent of the time or less. Study design considerations may influence the *a priori* choice of a different statistical significance level.

Subp. 41. **Subchronic health risk value or subchronic HRV.** "Subchronic health risk value" or "subchronic HRV" means the concentration of a chemical or defined mixture of chemicals in ambient air at or below which the chemical or defined mixture of chemicals is unlikely to cause an adverse health effect to the general public when exposure occurs on a continuous basis over a less than lifetime exposure. For implementation purposes, subchronic HRVs are compared to a 13-week averaged concentration of a chemical or defined mixture of chemicals in ambient air. A subchronic HRV is expressed in units of micrograms of the chemical or defined mixture of chemicals per cubic meter of air ($\mu g/m^3$).

Subp. 42. **Uncertainty factor.** "Uncertainty factor" means the numerical factors used to account for the variation in sensitivity among members of the human population; the uncertainty in extrapolating laboratory animal data to humans; the uncertainty in extrapolating from data obtained in a study that involves less than lifetime exposure to

lifetime exposure; the uncertainty in using LOAEL data due to the absence of NOAEL data; and the inability of any single study to adequately address all possible adverse outcomes in humans.

Subp. 43. **Unit risk.** "Unit risk" means the upper bound excess cancer risk from a continuous lifetime exposure to a chemical or defined mixture of chemical concentration at one microgram per cubic meter (1 $\mu g/m^3$) in air.

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