COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION

POLICY ON AN INTERIM RISK EVALUATION AND MANAGEMENT APPROACH FOR PCE

August 17, 2006

The Hazardous Materials and Waste Management Division ("the Division") is issuing this interim policy to provide guidance on managing the risks associated with tetrachloroethylene (PCE). The Division does not intend to propose any change to the Maximum Contaminant Level (MCL) used for setting standards for drinking water supplies.

Background

The Environmental Protection Agency (EPA) is currently evaluating the toxic potential of PCE, including its carcinogenicity, and therefore no relevant cancer toxicity values are available. This evaluation has been ongoing for some time and it is not known when EPA will post a new value in the USEPA Integrated Risk Information System (IRIS) or what it will be. PCE is a contaminant at numerous sites in Colorado, especially dry-cleaning facilities; therefore it is appropriate that the Division provide the public and the regulated community guidance on PCE risk evaluation and remediation using the most current toxicological data. The primary pathway for potential human exposure at these sites is through inhalation of contaminated indoor air. The approach described below will be used until EPA makes a final determination in IRIS or until additional information causes a reassessment by the Division. In either of those cases, the Division will use the Department's August 20, 2004 "Policy on Use of Human Health Toxicity Values in Environmental Risk Assessment and Remediation Management" to determine which value to use.

Generally, in the absence of relevant inhalation cancer toxicity value in IRIS, a provisional value from EPA's National Center for Environmental Assessment, Superfund Technical Support Center (NCEA/STSC) is used. The EPA issued an Office of Solid Waste and Emergency Response (OSWER) Directive on June 12, 2003 (OSWER No. 9285.7-75) concerning PCE. This directive, formulated in consultation with the STSC, states "In the absence of relevant values in the US Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) or a value from EPA's National Center for Environmental Assessment/Superfund Technical Health Risk Support Center (STSC), which are the first two tiers of human health toxicity values in the EPA Superfund hierarchy, we would support consideration of the Cal EPA inhalation unit risk value..."[1]. Based on the Department's August 20, 2004 policy, the appropriate categorization of the PCE inhalation cancer slope factor is Tier III.

Therefore, until EPA's review process is complete and consistent with the Department's August 20, 2004 policy, the Department's Environmental Toxicology Program recommends: a) basing interim decisions for PCE on EPA's June 2003 OSWER Directive which supports the use of the

[1] This value was obtained from Cal EPA Office of Environmental Health Hazard Assessment (OEHHA), 2002 Technical Support Document, for describing available cancer potency factors.

Cal EPA PCE inhalation cancer slope factor of $2x10^{-2}$ per mg/kg/day[2], and b) applying the age-adjusted child correction factor[2]. This change results in lowering the $1x10^{-6}$ cancer risk-based value from 4.3 µg/m^3 to 0.31 µg/m^3.

Interim value range

While EPA continues its assessment of PCE carcinogenicity, the Division will use the Cal EPA inhalation slope factor for PCE for screening purposes. This will allow Division staff to make protective risk management decisions on a site-specific basis using the most current thinking on the risk posed by PCE.

Risk management

The cancer risk-based value (0.31 µg/m3) based on EPA's 2003 OSWER Directive is below concentrations that have been observed as background levels at Colorado PCE-impacted remediation sites and in at least some Northern Front Range and Grand Junction ambient air, and is below typical commercially available analytical reporting limits. In light of these factors, the Division will apply the following PCE risk management framework[3]:

- Measured indoor air concentrations of greater than 31.0 µg/m^3 would trigger the need for action to mitigate human exposure. This is the 10^{-4} (1 excess cancer in 10,000) level.

- Measured indoor air concentrations between 15.5 µg/m^3 and 31.0 µg/m^3 (corresponding to $5x10^{-5}$ and $1x10^{-4}$ risk, respectively) would trigger the need for further study to determine whether or not the situation warrants action to mitigate exposures. Lines of evidence will be examined to determine whether the observed concentrations are derived from a subsurface source (ground water or soil) or background. If the lines of evidence indicate a subsurface source, the Division would require remedial actions to mitigate exposure.

- Provided the soil contamination and/or groundwater plume is being mitigated through treatment or monitored natural attenuation, measured concentrations of less than 15.5 ug/m^3 would not require continued monitoring of indoor air quality at the location, unless determined appropriate due to special circumstances, such as sensitive populations like those found at day care centers, schools and medical facilities.

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[2] The age adjusted child concentration factor is based on EPA Region 3 methodology. For more details, please refer to EPA Region 3 website: http://www.epa.gov/reg3hwmd/risk/human/info/tech.htm.

[3] This recommendation follows the general framework of the Department's 2004 trichloroethylene (TCE) interim policy. However, the policy presented here is based primarily upon PCE background contributions in indoor and ambient air and analytical reporting limit constraints. TCE differs from PCE in that there is no formal EPA headquarters' TCE toxicity policy available. Therefore, the TCE policy was based upon the uncertainty surrounding the EPA proposed draft cancer slope factor range and background contributions.

- In the event a facility seeks a "No Further Action" (NFA) determination during this interim period, measured PCE concentrations in indoor air must either be below background or 0.31 $\mu g/m^3$, whichever is higher. The Division will determine where in that range an NFA determination is appropriate based on site-specific information. An NFA assumes that remedial action to address indoor air is not necessary.

The 31.0 $\mu g/m^3$ and 15.5 $\mu g/m^3$ trigger levels were calculated using exposure assumptions based on a residential exposure scenario. Parties conducting indoor air investigations have the option of calculating equally protective values for individuals in other exposure settings (e.g., industrial and commercial) based on current land use. These alternate values would be calculated using the new interim toxicity value, the $5x10^{-5}$ to $1x10^{-4}$ risk levels and the appropriate exposure/intake parameters approved by the Division.

It is important to emphasize the utilization of these levels is an interim decision until EPA completes its health assessment of PCE, and does not set a precedent for other chemicals or remedial actions now or in the future.