



**RISK MANAGEMENT  
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*Health & Environmental Services*



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30<sup>th</sup> September 2014  
RMI Project 2014-190-00

Ms. Cheryl A. Chase, P.E.  
CT DEEP  
79 Elm Street  
Hartford, CT 06106-5127

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**Subject:** Public Comments: Connecticut Risk-Based Decision Making – *Final Report*  
Connecticut Department of Energy & Environmental Protection  
Report Prepared by Charter Oak & CDM Smith, 29<sup>th</sup> August 2014

**Dear:** Ms. Chase

This letter is in response to your request for Public Comments made at the Public Meeting to present the subject report on the 10<sup>th</sup> September 2104 at the CT DEEP Phoenix Auditorium, Hartford, Connecticut (CT).

RMI has been very interested in the development of the subject report funded by DECD, since we were the first MA Risk Assessors in CT to conduct and have approved by CTDEP (*at the time*) Alternative Criteria derived using an EPA/RAGs Risk Assessment for Human Health & the Environment under the direction of Mathew E. Hackman, P.E. CHMM, LEP, LSP for VPH and EPH fractions from a No. 4 Fuel Oil Release.

RMI was also part of a team that bid on this project and had proposed a very similar approach to that taken by Charter Oak & CDM Smith to address CT DEEP's Work Outline for Scope, Task 1 and 2, plus specific areas to be addressed under these Tasks.

Accordingly, we are not surprised by the contents of the Final Report and its Recommendations.

Namely:

**First** - We totally agree with placement of HHRA, HHRM, ERA and ERM under the CT DEEP umbrella to facilitate coordination of their respective roles and obligations, especially as they relate to the Risk Assessment & Risk Management components of the "CT Chemically Contaminated Sites Cleanup Program."

From RMI's past project experience, the existing structure/responsibilities did not readily facilitate the development of Alternative Pollutant Criteria, the review process and ultimately site closure.

We still have clients with a number of open sites at this time awaiting comments or acceptability even after 2-5 years in the “pipeline.” In some cases, comments came back asking us to use “proposed” CT DEEP Revised Guidance Documents, which were never enacted by the Legislature, and have since been withdrawn from CT DEEP’s website.

**Second** – This recommendation is laudable with a view to potentially reducing cleanup costs and expediting site closures. However, from RMI’s past experience with large and/or private sector stakeholders, in some cases our Risk Assessors have been pressured by these individuals to propose non-standard solutions that we do not truly consider fully protective of Human Health, Public Welfare and the Environment. In those situations, we have declined the Risk Assessment commissions!

**Third** – We totally agree with this recommendation, since we have encountered both mathematical errors and/or inconsistencies in exposure assumptions used in the algorithms to develop alternative criteria published in the RSRs, even those included in the amended June 27, 2013. Section 1. Sections 22a-133k-1 to 22a-133k-3, inclusive, of the Regulations of Connecticut State Agencies. Official corrections to the algorithms used to develop the current Volatilization Criteria for Soil and Groundwater have not been officially acknowledged or published to our knowledge. Although the exposure assumptions for Residential Default Volatilization Criteria were corrected in an Internal Draft Memorandum for revisions to the RSRs and their derivations in a 2008 Internal Memorandum, but not identified as such, and since withdrawn from CT DEEP’s website.

In 1996, RMI reported errors to the Department of Environmental Protection, Bureau of Water Management in the algorithms and Correction Factors used to calculate the Residential Default DEC and GWPC and other values. However, this was not acknowledged until November 18, 2002 in a CTDEP Internal Memorandum dated November 18, 2002!

Issues such as those described above would hopefully be readily addressed in the future using the recommended centralized, electronically documented information on assumptions, models, exceptions and other aspects of default criteria. Needless to say, this recommendation should also mitigate time wasted as Risk Assessors in attempting to develop Alternative Criteria (*using current CT DEEP incorrect RSR algorithms*) that cannot be charged to clients.

**Fourth** – We agree with these comments and recommendations and understand that a colleague of ours, Bonnie Potocki from EcoSolutions Inc. is expected to comment on these separately in more detail.

**Fifth** – Again, RMI fully supports this recommendation for the use of site-specific Risk assessments where RSR Default Criteria may be inappropriate. As mentioned earlier, we successfully conducted a site-specific Risk Assessment (*in accordance with EPA/RAGs Risk Assessment Guidance per CT RSRs*) that was equivalent to the MCP Method 3 Risk Characterization for Human Health, Safety, Public and the Environment, in order to develop Alternative Criteria for VPH/EPH fractions detected in a No. 4. Fuel Oil Release. Both the Risk Assessment and derived Alternative Criteria were approved and accepted by CTDEP at the time.

However, we caution against the development and use by CT of the equivalent of a MassDEP Method 3 Shortform Risk Characterization for Human Health, which has been problematic when used by LSPs here in MA and by LSP/LEP's (CT), being nicknamed the "Plug & Chug" approach to Human Health Risk Assessments. Primarily, because of overly conservative default or non-compliant EPA Exposure Assumptions for receptor age-groups, out-of date Toxicity Values for the Chemical Contaminants listed, and incorrect algorithms and Plant Uptake Factors (PUFs) for the Residential "Homegrown Fruits & Vegetables Exposure Scenario; the latter give rise to incorrect Excess Lifetime Cancer Risks (ELCRs) and Non-Cancer Hazard Indices (HIs). Example: MA MCP Lead Soil Standard S-1/GW-1 at 200 mg/Kg yields an  $HI_c = 10$  and an  $HI_{sc} = 20$ ; MA MCP Arsenic Soil Standard S-1/GW-1 at 20 mg/Kg yields an  $ELCR = 3 \times 10^{-4}$ ;  $HI_c = 2$  and an  $HI_{sc} = 3$ ). To MassDEP's credit, use of the latter exposure scenario is no longer considered acceptable. Instead, MassDEP has been and continues to develop "Best Practices" Guidance for mitigating potential exposures to residual chemical contaminants in site soils, especially in the root zones of fruits, vegetables and other cultivated produce destined for human consumption, primarily in the residential setting, but also for use in public cultivated allotments, etc. However, as a precaution RMI still uses an MCP Method 3 Risk Characterization for Human Health for direct and indirect soil exposures to the chemicals in question via the oral, dermal and inhalation exposure routes in tandem with MassDEP's current Best Current Management Practices.

It should be noted MassDEP now recommends/advises that use of the MA Shortform by LSPs is undertaken using a qualified Risk Assessor. A number of LSPs who haven't heeded MassDEP's advice have received Notices of Non-Compliance (*NONs*) because of failure to also address risk of harm to Safety, Public Welfare & the Environment per the requirements of 310 CMR 40.0990 for an MCP Method 3 Risk Characterization!

Accordingly, RMI would discourage development of such a "Shortform" for Human Health Risk Assessments Exposures as part of an option for site-specific Risk Assessments in CT. Period.

**Sixth** – RMI again agrees with the recommendation of using an Individual Chemical-Specific Cancer Risk Limit of  $1 \times 10^{-5}$  and a Total Site Cancer Risk of  $1 \times 10^{-4}$  under certain circumstances, based on the: size of the impacted population; nature of risk (*theoretical or actuarial*) and the size and type of uncertainties. Use of inflexible "bright lines" has always been problematic in Risk Assessments for Hazardous Chemicals and Radionuclides because of the potentially high uncertainty associated with the fixed values under widely varying site conditions.

As noted in the subject Final Report (*Table 6-2, page 6-25*), the respective Risk Limits in CT and MA are  $1 \times 10^{-6}$  and  $1 \times 10^{-5}$  versus EPA's current Total Site Acceptable Cancer Risk Limit Range for the Reasonably Maximally Exposed Individual (*RMEI*) of  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$  (NCP Preliminary Remediation Goals that represent an upper-bound lifetime cancer risk to an individual – (*see 40 CFR § 300.430(e)(2)(I)(A)(1)*))

In fact, it should also be noted that over the years, acceptable Lifetime Exposure Cancer Risk Limits have changed (e.g., EPA OSWER's RAGs Volume 1, Human Health Evaluation Manual (Part A – 1989 Interim Final), where NCP Site Remediation Goals for Cumulative Cancer Risks ranged from  $1 \times 10^{-4}$  to  $1 \times 10^{-7}$ , in part to address the uncertainty of the derivation of Class A, B1 and B2 Carcinogens' Oral Slope Factors (OSFs) (*from Low Dose Linear Extrapolation*

*Models*) to current use of Multistage models (*with linear extrapolation from the point of departure (BMDL10)*), followed by route-to-route extrapolation to the oral route and interspecies extrapolation using the PBPK model of Chiu and Ginsberg (2011) to reduce uncertainties in the OSFs (*e.g., see Tetrachloroethylene – IRIS 2014*). Even the derivation of Inhalation Unit Risk Factors (*URs*) have changed, using Multistage models with linear extrapolation from the point of departure (*BMCL10*), followed by extrapolation to humans using the PBPK model of Chiu and Ginsberg (2011) (*e.g., see Tetrachloroethylene – IRIS 2014*).

However, even with a reduction of this form of uncertainty in the derivation of OSFs and URs for Human Health Risk Assessments, use of more recent toxicity studies by EPA (*and approved by the National Academy of Sciences- NAS*) to derive IRIS Toxicity Factors have resulted in values that are more conservative (*e.g., see Trichloroethylene – IRIS 2014*), such that use of the current IRIS TCE Chronic Inhalation Exposure Reference Concentration (RfC) value of 2 µg/m<sup>3</sup> (*micrograms per cubic meter*)<sup>1</sup> for Risk Assessments evaluating short-term Indoor Air Inhalation exposures (*Imminent Hazards*) to TCE vapors has become problematic, yielding an Hazard Index (*HI*) = Unity or a value of 1 (*one*), especially for women in their first eight weeks of pregnancy or involving women of child-bearing age.

In this situation, maybe Risk Assessors should consider Non-Cancer Risk Limits of HI= 2 to 10 to address this site-specific receptor uncertainty.

Another area of uncertainty evolving for Individual and/or Totals Site ELCRs concerns EPA's list of "Emerging Chemical Contaminants" in Drinking Water, where certain chemicals are being added as the result of improvements in Laboratory Analytical Sample Extraction methodology and a consequent drop in a chemical's Laboratory Reporting Limit. An example we have encountered here in MA is 1,4-Dioxane, where the RL has dropped from 200 to 0.02 µg/L (*micrograms per liter*) over time and the chemical is now being detected in municipal water and private drinking water supplies. In addition, the revised IRIS UR for Drinking Water for 1,4-Dioxane addition has dropped 10-fold, resulting in the derivation and drop in a revised MA Office of Drinking Water Guideline (*ORSGL*) Action Level from 3 to 0.3 µg/L for 1,4-Dioxane very close to the RL of 0.02 µg/L and potentially within a Laboratory Reporting Error of up to ±10 % (*percent*). Hence, use of an Individual Cancer Risk Limit of 1 x 10<sup>-5</sup> to address this uncertainty may well be appropriate for CT's consideration.

One minor point, noted both by Risk Management Incorporated (RMI) and the LSPA (*Licensed Site Professionals Association*) Risk Assessors and the board itself, is MassDEP's incorrect calculation of the revised ORSGL value of 0.3 µg/L. The correctly calculated and rounded value is 0.45 µg/L. MassDEP was notified of this by the LSPA Board and a change requested to the 2014 MCP Revisions in April. However, MassDEP has not recognized the corrected value to date. Hence, this form of Uncertainty should be recognized by states, including CT that adopt rounded rather than raw EPA IRIS UR or RfD Toxicity Values in their derivation of Action Levels etc.!

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<sup>1</sup> RfC value of 2 µg/m<sup>3</sup> based on short-term exposure fetal development and immunological system effects (*see TCE – IRIS 2014*)

Depending on the State, the latter should not be an issue, since Site-Specific Risk Assessments such as the MCP Method 3 Risk Characterization used in MA, prohibit the use of Primary MCP Soil and Groundwater Standards for comparison to Chemical Exposure Point Concentrations (EPCs), but allow comparison of MCP-compliant EPCs to other Applicable, Suitable or Analogous Standards, but rendering invalid the use of any secondary MCP/MassDEP derived Action Levels or Guideline Values. Something that should be considered in the event CT DEEP adopts the use of Site-Specific Risk Assessments for Human Health, Ecology, Environment, Public Welfare and Safety.

Thank you for providing us with an opportunity and invitation to submit public comments on the issues and recommendations presented in the subject “*Connecticut Risk-Based Decision Making – Final Report dated 29<sup>th</sup> August, 2014.*”

Sincerely yours,

**Risk Management Incorporated**  
*Health & Environmental Services*



Peter W. Woodman, Ph.D.  
President, CEO & Co-Founder

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