

REVIEW DRAFT

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Please provide comments by Friday April 24, 2009 to

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NOTE TO REVIEWERS – MassDEP had been asked a simple question: “How many significant figures are appropriate for a Method 1 and Method 3 risk assessment?” There is no simple answer. After preparing a preliminary draft (September, 2008) and discussing the issue with interested parties, the Department recognizes that the “significant figures” question is tied to a broader question of how the precision of measured and observed values are handled in regulations and how the language of the MCP itself has shaped (or distorted) the discussion. The multitude of approaches to determining the significance of figures, the variety of rounding rules, and the strategies to balance loss of information with simplicity and clarity all complicate what appears – on the surface – to be a simple question.

The discussions following the September, 2008 draft have helped the Department identify the broader issues – issues that will take longer to resolve than answering the initial (seemingly simple) question about significant figures. This discussion presents several short-term options for addressing the significant figures question, given the current language of the regulations. It is also the first step for potential MCP revisions to resolve the larger issues.

In the long-term, MassDEP believes that the MCP should specify the rounding method (Absolute or Rounding) used to calculate EPCs and risk estimates used in MCP Risk Characterizations, as discussed in ASTM E29-06b. To the extent that the MCP itself creates a non-conservative bias, the Department should also reassess the rounding rules used in the development of the Method 1 standards and the language associated with the comparison of EPCs and risk estimates to the MCP standards and risk limits.

The Department solicits your input at the upcoming Advisory Committee meeting (Thursday, March 26, 2009 @ 9:30 am, MassDEP Boston Office) and/or through written comments by Friday, April 24, 2009.

Expressing the Precision of Exposure Point Concentrations and Risk Estimates in MCP Risk Characterizations

1.0 Introduction

This update provides guidance on expressing the level of precision in calculated values, such as Exposure Point Concentrations (EPCs) and risk estimates used in MCP risk characterizations.

MassDEP is recommending a short-term and long-term approach for addressing the question of expressing precision in MCP EPCs and risk estimates. While the original question posed to the Department was specific to the appropriate number of significant figures, the underlying problem is more complex.

The structure of MassDEP's the Waste Site Cleanup program calls for clear and consistent risk management criteria. Ambiguity in regulations and guidance creates uncertainty among LSPs, PRPs and DEP staff about both the appropriate number of significant figures that should be reported in a result and the rounding rules that should be applied.

This issue has generally been couched in terms of “significant figures,” to the extent that the precision of calculations has been addressed at all. The Department has published general guidance¹ on the topic of significant figures and rounding, and in the absence of more specific guidance, practices have been limited to identifying the appropriate number of significant figures.

The number of figures presented in a measured or observed value indicates the precision inherent in the value and, conversely, the associated error range. The use of significant figures is a crude means of expressing both the nominal value and the precision in a single value. The error range around a value can also be expressed with error bars, or explicitly denoting the error as +/- a certain amount. Further, the distribution of potential values within (and beyond) the error range can be expressed with a probability function.

Since measurements, such as groundwater concentrations, have limited precision, any calculations using these values – such as to generate EPCs or risk estimates – will also have limited precision. When using significant figures to convey precision, the use of too many figures in a calculation implies a greater level of precision (“superfluous precision”) than may be justified by the input data. Using too few figures may reduce the accuracy of the result (“roundoff error”). The explicit use of error bars minimizes such ambiguities.

¹ Guidance for Disposal Site Risk Characterization (Policy #WSC/ORS-95-141), Section 2.5

The approach to expressing the precision of an EPC or risk estimate must take into account technical, regulatory and policy considerations within the context of the MCP.

2.0 Technical, Regulatory and Policy Considerations

2.1 MCP Language and Implications

This guidance considers the implications of the language and intent of several sections of the MCP that may be, in some instances, internally inconsistent².

- First, the MCP Method 1 Standards were rounded, either up or down using standard procedures, to one digit³. While the rounding considered the uncertainty inherent in the calculation of the standards, MassDEP did not consider the implications of rounding on how the standards would be used.
- Second, the MCP quantitatively defines the concept of “No Significant Risk” to mean no exposures “*greater than*” the applicable standard (Method 1, 310 CMR 40.0973(7)) or risk limit (Method 3, 310 CMR 40.0993(7)).
- Third, the MCP requires (at 310 CMR 40.0926(3)) that in estimating the Exposure Point Concentration (“EPC”), the objective shall be to identify a conservative estimate of the average concentration contacted by a receptor at the Exposure Point over the period of exposure. This is consistent with other MCP regulatory imperatives to take a conservative, health-protective approach to site assessment and risk assessment.

The standard approach to rounding when using the significant figures approach to expressing precision, combined with the first two MCP items bulleted above, can produce a *non-conservative* result that is contrary to bullet three. While the process of rounding is assumed to be inherently unbiased, the regulations, as written, create a non-conservative bias. In fact rounding to a specific number of significant figures can only decrease apparent risk and eliminate the need for remediation – you can never “round up” into a need for remediation.

As an example, consider the effect of rounding on a calculated hazard index of 1.44:

- If two significant figures were used, the result would be rounded to 1.4, leading to the conclusion that the risk exceeds the MCP hazard index limit of 1.
- If one significant figure were used, the result would be rounded to 1, leading to a conclusion that the risk does not exceed the MCP hazard index limit of 1.

² Resolution of any such inconsistencies must be addressed through amendments to the regulations, not through policy. This guidance is intended to assist users comply with the MCP as it is currently written (as of March, 2009).

³ Many Method 1 groundwater standards were adopted directly from MMCLs and were not rounded. Some GW-1 standards are, therefore, expressed with two digits (e.g., the GW-1 standard for lead is 15 µg/L).

Note that the same rounding effect occurs when comparing site concentrations with values of 1.4, 14, 140 or 1400 to Method 1 Standards with values of 1, 10, 100, or 1000 respectively.

The implication of the MCP language described above does not change the need to correctly express the precision of the MCP risk calculations. It does underscore the importance of careful consideration of this issue, particularly when using the significant figures approach. The incorrect use of significant figures, including the use of over-simplified rounding rules, can have a disproportionate effect of the conclusions of the risk characterization.

2.2 *Regulatory Standards as Exact Values*

While the MCP standards are often (not always) expressed with a single digit, this does not determine or influence the number of significant figures that should be used in the calculation of EPC's or risk estimates. The MCP does not specifically address the question of significant figures.

As noted in ASTM's Standard Practice for Using Significant Digits in test data to Determine Conformance with Specifications (E29-06b), "*the unqualified statement of a numerical limit, such as [comparison to a standard or risk limit], cannot, in view of different established practices and customs, be regarded as carrying a definite operational meaning concerning the number of digits to be retained in an observed or calculated value for purposes of determining conformance with the [standard].*"

In other words, since there are so many different ways to approach the issue and the Department has not specifically addressed *how* significant figures should be used with the standards, nothing can or should be read into the presentation of the standards as one digit. The format of the standards themselves cannot be used to justify the use of a single significant figure in the calculation of EPC's or risk estimates. The promulgated standards, whether they are Method 1 soil and groundwater standards or the Method 3 Risk Limits, are considered absolute (exact) values similar to constants for the purposes of determining the appropriate number of significant figures.

2.3 *Absolute and Rounding Methods to Determine Compliance with a Standard*

The ASTM E29-06b standard practice describes two approaches that the Department can take to describe conformance with the MCP standards: the *Absolute Method* and the *Rounding Method*. Either approach can be applied, but the Method to be used must be specified to avoid confusion and ambiguity.

Absolute Method (ASTM E29-06b, Section 5.). The Absolute Method applies where it is the intent that all digits in an observed value or a calculated value are to be considered significant for purposes of determining compliance with a standard. Applied this way, the standards would be considered "absolute limits."

In the MCP context, an EPC or risk estimate would not be rounded, but would be compared directly with the standard.

Rounding Method (ASTM E29-06b, Section 6.) The Rounding Method applies where it is the intent that a limited number of digits in an observed value are to be considered significant for purposes of determining compliance with a standard. An observed or measured value would be rounded (using a specified process) to the nearest unit in the designated place of figures in the standard. In the MCP context, an EPC or risk estimate would be rounded to a specific percent error, number of significant figures or other appropriate expression.

In order to fully implement the ASTM Standard, MassDEP would need to specify whether the Absolute Method or the Rounding Method applies to the Method 1 standards, Method 2 standards and the Method 3 risk limits. If the Rounding Method is chosen, then the Department would need to specify the acceptable rounding process and final expression of the EPC and risk estimates.

As a regulatory agency, MassDEP needs to provide a “bright line” as to what meets the “No Significant Risk” standard and what requires further remediation.

2.4 Approaches to Rounding

ASTM (E29-06b, Section 7.1) notes that “*Any approach to retention of significant digits of necessity involves some loss of information; therefore, the level of rounding should be carefully selected considering both planned and potential uses for the data.*”

There are no absolute rules for retaining significant figures and rounding, and the available approaches range in complexity from simple to statistical. *Too few significant digits cause information to be lost and too many are considered bad style in numerical reporting — showing a lack of understanding of precision*⁴.” The standard rounding rules, such as those described in MassDEP risk assessment guidance (Section 2.5), are approximations of, and substitutes for, more complex analyses, such as the use of the standard deviation of the samples to determine the rounding interval.

An analysis of the standard rule⁵ used in calculations involving multiplication or division, such as in estimating risk or EPCs, suggests that the standard rule predicts 1 less significant digit than warranted 53.5% of the time. Conversely, the standard rules appear to predict too many significant figures less than 0.05% of the time.

Alternative approaches have been identified that add a significant digit to a calculation in order to minimize data lost through rounding, either under specific conditions, across the

⁴ *Reporting Test Results, Determining Significant Digits and Rounding Properly*
http://www.astm.org/SNEWS/SO_2008/datapoints_so08.html

⁵ “On the Standard Rounding Rule for Multiplication and Division” by Christopher Mulliss & Wei Lee, *Chinese Journal of Physics*, **36**(3), 479-487.
<http://www.angelfire.com/oh/cmulliss/rrmultdiv.pdf>

board or based on magnitude of the percent error. For example, ASTM (E29-06b, Section 7.6) suggests an addition digit be used when averaging “large” datasets⁶.

In short, there is no absolute “right” way to retain significant figures or round values. There are numerous alternative approaches designed to address the balance between data loss and misinterpretation of precision.

2.5 *Method 3 Risk Characterizations*

The appropriate number of significant figures for Method 3 risk estimates should consider the factors that enter into the risk calculations, including the uncertainty about the toxicity values and exposure factors. Many of the toxicity and exposure factors employed in risk calculations may be reasonably considered to include only one significant figure.

2.6 *Method 1 Risk Characterizations*

The precision of measured contaminant concentrations is the primary consideration in determining the appropriate number of significant figures for an Exposure Point Concentration.

Analytical results for environmental media are dependent on the specific analytical method and the precision attained for each analysis. Laboratories are generally reporting analytical data with at least two digits, although this practice may be as much by convention as resulting from an analysis of the measurement precision. MassDEP believes it is not appropriate to draw broad conclusions about the precision of an analytical method or any specific result without evaluating the QA/QC data. Case-by-case decisions about the precision of analytical results and appropriate number of significant figures may be impractical. Such an approach would necessitate additional efforts to evaluate QA/QC information, possibly reporting of additional material from laboratories, likely at additional cost. Laboratories do not follow one consistent practice when reporting results, and often do not report measured concentrations with the issue of significant figures foremost in mind. It is not the Department’s intent to create additional reporting requirements or modify laboratory operations to address this issue.

⁶ The definition of “large” is variable, dependent upon the lead digit of the standard deviation: the smaller the standard deviation, the smaller the data set need for an “additional” significant figure.

4.0 Conclusions

In the short-term, MassDEP recognizes that the regulations, as written, do not provide sufficient direction. In the absence of specific regulatory language, the Department will accept risk characterizations using either the Absolute or Rounding Methods for comparisons to standards or risk limits.

For risk characterizations using the Absolute Method, the calculated EPCs and risk estimates are compared to the promulgated standards and risk limits without rounding.

For risk characterizations using the Rounding Method, the documentation should specify which rounding rules were used. The appropriate number of significant figures should be identified considering the following guidance:

1. Presumptive Certainty

In all cases, the Department will accept Exposure Concentrations and risk estimates rounded to two or more digits. While the presentation of data with several digits may imply a level of precision inconsistent with the calculation inputs, the inconsistency is more philosophical than substantive. This approach is not inconsistent with the MCP charge to provide a conservative estimate of the potential exposures and risks at a site. LSPs and PRPs wishing to adopt a simple, clear approach may choose to round to two or more digits. A informal review of historic practice indicates that this approach is consistent with the majority of the risk characterizations submitted to MassDEP.

2. Rounding in Method 1 Risk Characterizations

The MCP contains requirements to conservatively calculate the EPC, including:

- The identification of “*a conservative estimate of the average concentration contacted by a receptor at the Exposure Point over the period of exposure*” (310 CMR 40.0926(3));
- The use of maximum of 95% UCL values when the data are “*likely to be insufficient for the simple arithmetic average to estimate the true value with reasonable confidence and there is a considerable probability of substantially underestimating the mean*” (310 CMR 40.026(3)(c)); and
- The development of an Exposure Point Concentration “*representative of the actual concentration of oil or hazardous materials at the Exposure Point, unmodified by other exposure assumptions*” (310 CMR 40.0973(4)(b)).

When a case-specific analysis of QA/QC data would otherwise determine that a single significant figure is appropriate, the regulatory mandate to conservatively calculate the EPC would provide two options:

1. Round up in all cases to provide an upper bound estimate of the EPC using one significant figure; or
2. Use two significant figures (see Option 1 – Presumptive Certainty).

3. Rounding in Method 3 Risk Characterizations

The appropriate number of significant figures for risk estimates calculated for a Method 3 Risk Characterization should be determined by the precision of the factors that go into the risk estimate, including the analytical data used to calculate the EPC (discussed above) and toxicity factors that are typically, although not universally, expressed as one significant figure. MassDEP expects that most Method 3 risk estimates should be expressed as one significant figure, based on the standard input parameters used in the calculations. However the Department recommends that the risk assessor review such inputs to confirm that the use of one significant figure is appropriate.