Clarifications to ITRC 2012 ISM-1 Guidance

October 27, 2020

Please Read

A revised and updated ITRC guidance (ISM-2) has been developed which builds on the 2012 version to reflect advancements in technology and to share case studies that provide insight into potential applications, benefits, and challenges of the approach. The ISM-2 Update Team also determined that clarification of incorrect, unclear, or inconsistent information in ISM-1 was also necessary and crafted a clarification statement**.** Despite these clarifications to ISM-1, it still provides useful information for those interested in learning about ISM and a good starting point which is built upon further, and updated, in ISM-2.

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1. **Decision and decision unit scale.** Sections 4.4.4 and 7.2.7 describe the situation where an "oversized decision unit", a decision unit larger than the scale of decision making, has been designated. The guidance suggests multiplying the incremental sample results from such oversized decision units by the number of increments in the sample as a very conservative approach to compensate for a decision unit too large to support the intended decision. However, the approach does not produce reliable or technically defensible results and should not be presented as a viable option to correct for a sampling design inappropriate to support the intended decision. Decision units should be designed at a scale appropriate to support the decision to be made.

2. **Use of M-3 Simulations.** Appendix A.5 presents the M-3 computer simulations which have been reexamined by statisticians who agree the conceptual approach upon which the simulation is based can bias the outcome of comparisons between data from simulated ISM samples and the simulated "true mean". The simulation should be disregarded.

3. **Use of replicate samples.** Sections 2, 3 and 7 (2.3.2, 2.5.6, 2.6, Table 3-1, 7.1, 7.2.1) include discussions related to the use of replicate ISM samples, and whether using the result from a single incremental sample can be acceptable as the basis for decision making. Some inconsistency is found between these sections. All ISM-2 update team members agree that the use of replicates produces a more complete data set and supports more defensible decisions, but the need and number of replicate samples necessary to meet data quality objectives and quality control requirements are project-specific decisions. Many federal, state and local agencies require replicates as part of sampling plans, but not all regulatory agencies require replicates under all

circumstances. ITRC does not make policy for regulatory agencies and thus is not in a position to mandate the use of replicates.

4. **Extrapolating variance.** Some inconsistencies are found between Sections 4.4.2 and 5.3.5 in discussing the possibility of extrapolating variance (precision estimates of relative standard deviation (RSD)/ coefficient of variation (CV)) from one decision unit having replicate incremental samples to another having only a single incremental sample. Although replicates to determine variance in all DUs are preferred, the variance (RSD or CV) across multiple DUs can be assumed to be equal based on qualitative information. This is an assumption that should not be made without an understanding that the uncertainty in the precision of estimates of the means based on single samples from each DU is unknown. The project team must decide whether an extrapolation sufficiently manages uncertainty for the decision to be made. Some regulatory agencies may not allow this type of extrapolation and replicates in all DUs may be necessary when a precision estimate is needed for each DU.

5. **Sampling produces approximations, rather than true population statistics.** An ISM sample provides an approximation of the true population mean of a DU. The uncertainty in the approximation is best determined through the use of replicates within the DU. However, as discussed above in points 3 and 4, DU specific replicates might not always be necessary to support the decisions to be made.

6. **Locating elevated concentration areas.** Discussions and use of the term “hot spots” in ISM-1 are inconsistent and some statements suggest they need to be identified regardless of whether they are large enough to affect decision outcomes. Use of the vague term “hot spot” should be avoided to the extent possible. When necessary for decision making, areas of elevated concentration large enough to be of possible concern can be can be located by using appropriately sized and located Decision Units/Sampling Units. There is no expectation that ISM can identify specific areas of elevated concentration smaller than the SU. Existing DUs/SUs can be subdivided and resampled if more detailed spatial resolution is needed. Several subsections of chapter 3 in the updated guidance (ISM-2, in preparation) discuss geometry and location of decision units based on site characteristics and project goals.

7. **Use of sampling units.** The term Sampling Unit (SU) was not always clearly used or options for use presented in ISM-1. The SU is the volume of soil represented by a single incremental sample. It defines the spatial resolution (the scale) of the data. In contrast, the term decision unit (DU) defines the scale at which decisions will be made. A DU may consist of one or more smaller SUs within a DU. The use of multiple SUs within a DU provides information on the spatial distribution of analytes within the DU, and results from multiple SUs can be combined to produce weighted means for larger DUs to satisfy multiple project decisions (see Section 3.1.4.1). The project team must determine the most appropriate sampling design based on the conceptual site model and project decisions that need to be supported.

8. **Sampling for bioavailability.** ISM samples can be used to estimate bioavailability provided the specific ISM sample processing options are chosen to reflect the appropriate receptors and exposure pathways. Once the analytical subsample is produced, the appropriate bioavailability test should be applied. EPA Methods 3050, 3540, 3545, 3546 and 3550 are generally not considered bioavailability sample preparation methods.

9. **Comparing discrete and ISM data.** Sections 3, 3.1.4.1 and 4.4.3.2 discuss sampling plans that include both ISM and discrete samples. Both sample collection techniques have been successfully used as part of an overall sampling plan. For example, discrete samples analyzed by field XRF have been used to help determine the locations of ISM decision units. Although there are statistical methods for comparing the means of discrete and ISM data sets, this should only be done with sufficient knowledge of the data sets and statistical theory. Discrete data and ISM data are not equivalent and should not be combined into a single data set. Sampling plans using both types of sampling should define how each type of data is to be used and their associated limitations.

10. **Consistent use of terms.** Some terms in ISM-1 had slightly different meanings as used in different sections of the document. The glossary and usage in ISM-2 will be updated for consistency to reflect the current communication practice within the environmental community using ISM.