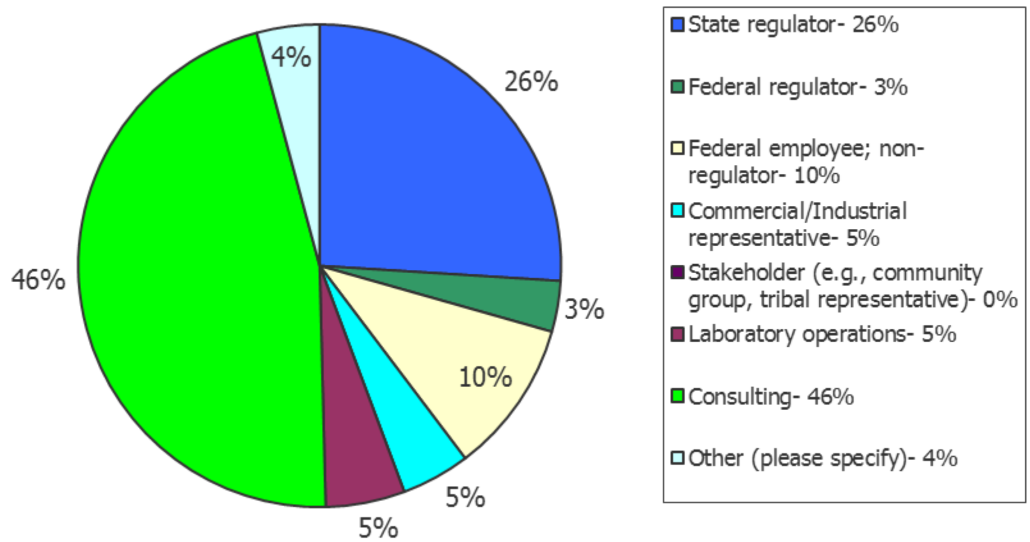
8. REGULATORY CONCERNS WITH ISM

8.1 Introduction

In August and September 2009, ITRC's ISM Team developed and conducted a survey designed to collect data on incremental sampling practices from regulators, consultants, commercial laboratory personnel, and project managers. The purpose of the survey was to gain an understanding of how incremental sampling is being used, how widespread is its use, what problems have been encountered, and the current level of understanding of ISM among the respondents. Nearly three-fourths of the respondents were either state regulators or consultants (see Figure 8-1).

Figure 8-1. Distribution of survey respondents (n = 263).



Specific focus areas covered by the survey included regulatory challenges to using ISM, comparison of ISM to discrete sampling techniques, and the type of projects/ programs for which ISM is used. Appendix B presents the results of the survey. A subsequent survey is planned to learn of advances made during the course of this ITRC effort.

8.2 Perception Issues

Few regulators and consultants had heard of ISM, and even fewer indicated they had appreciable experience with ISM. Based on the survey results, respondents' experience with and knowledge of the limitations of composite sampling appear to have colored their acceptance of ISM.

> Survey respondents indicated that the primary difficulties with ISM are delineation of hot spots, regulatory acceptance, inability to collect ISM VOC samples, delineating the extent of the release, and determining the size and shape of the DU.

To be able to address regulator and consultant perceptions of ISM, the ITRC Team asked a number of questions to rate ISM utility and the difficulty of its application.

The results indicated that as a whole, inability of ISM to delineate hot spots was the top difficulty in applying ISM, followed by lack of regulatory acceptance, problems with collecting VOC samples using ISM, inability of ISM to delineate the extent of contamination, and lack of knowledge on how to determine the size and shape of the DU. Regulators saw regulatory issues as the top difficulty in applying ISM. Nonregulators (consultants and laboratories) saw the inability of ISM to delineate hot spots as the top difficulty.

Respondents with lower and higher experience and knowledge perceived ISM differently. Individuals who rated their experience "high" indicated delineation of hot spots as the top problem but at less than half the frequency of less experienced individuals. Those with minimal experience responded that regulatory issues and acceptance as the top difficulty in applying ISM. Respondents also listed limited training and understanding, failure to properly apply systematic planning, application of ISM data, and dealing with VOCs as other major difficulties in applying ISM. It is interesting to note that the main issues are not technical in nature but are related to the application of ISM.

The survey asked respondents whether they had any personal opinion about ISM. For regulators and nonregulators, about one-third had evaluated ISM but used it only rarely. The personal opinions indicated caution regarding the use of ISM. The opinions ranged from questions about cost-effectiveness (laboratory preparation, smaller sites, etc.), applications such as VOC sampling and analysis, applicability to COCs other than explosive compounds, site-screening, and sediment sampling. The responses suggest that the reluctance to use ISM stems from a lack of experience.

8.3 Regulatory Challenges for ISM

When asked during the 2009 survey, 40% of regulator and 20% of the nonregulator respondents agreed there are specific applications for which ISM would not be endorsed. Both groups agreed that the least likely application to be endorsed for ISM is to identify areas of high concentration (i.e., hot spots).

Several states have regulations and guidance that specifically address hot spots. These states include Massachusetts and Oregon. See Table 3-2 of the *Use of Risk Assessment in Management of Contaminated Sites* (ITRC 2008) for more details.

Seventy-eight regulator respondents representing 25 states felt that ISM is discouraged (56%) or even expressly prohibited (3%). Three percent of respondents indicated ISM is recommended in their states (38% responded "other" or no comment).

Some states have statutory/rule prohibitions on compositing, while five states have policy/guidance restrictions on specific applications of compositing.

Only a few states (Alaska and Hawaii) generally accept the use of incremental sampling. Several states indicated that they are debating the widespread use of ISM, and Washington is updating its regulations to include ISM. Table 8-1 lists states that provided links to documents restricting or prohibiting ISM/compositing.

Table 8-1. List of states with specific restrictions on compositing[a]

State	Reason for Restriction	Link
Iowa	Discrete and maximum concentrations required	www.iowadnr.gov/land/ust/techindex.html
Florida	Some action levels based on acute exposure; compositing not allowed; if using 95% UCL, must use discrete samples; maximum may not exceed three times action level for many sites; leaching not to exceed action levels	www.dep.state.fl.us/waste/categories/wc/pages/ProgramTechnicalSupport.htm
Michigan	Composites of samples are not accepted without prior DEQ approval	www.michigan.gov/documents/deq/deq-erd-stats-s3tm_250015_7.pdf
Wisconsin	Sampling average by permission only	http://dnr.wi.gov/org/aw/rr/technical/results.pdf
New Jersey	Discrete required and composite prohibited	www.state.nj.us/dep/srp/regs/techrule N.J.A.C. 7:26E-3.4(c), N.J.A.C. 7:26E-3.6(a)5

[a] This information was true at the time of the survey 2009. Please contact the appropriate state to see whether this information is still current.

Language in applicable statutes or rules may specify delineation of the horizontal and vertical extent of contamination in a way that requires consideration of point concentrations rather than area averages. This would include, for example, situations in which the boundary of the contaminated area is defined through comparison of concentrations at various locations with not-to-exceed values (e.g., risk-based preliminary remediation goals or background levels).

8.4 State of Knowledge, Experience, and Training

One segment of the survey was designed to assess the current state of knowledge among the regulator and nonregulator communities and to gain a feel for respondents' level of experience and training with ISM sampling.

Responses to series of survey questions were used to gauge respondents' level of knowledge and acceptance of ISM. Responses were tabulated and scored, and statistical comparisons were made between groups of respondents. The analysis of the survey results shows that nonregulators were generally stronger proponents of ISM than the other respondent groups. Analysis of the data geographically also shows a stronger level of understanding and support for ISM within USEPA Regions 6, 9, and 10 as compared with other USEPA Regions.

> The survey results indicated that USEPA Regions 6, 9, and 10 generally understand and support ISM more than other EPA regions.

The 2009 survey data indicate that while there is a basic level of understanding of ISM, the level of actual experience with ISM is fairly low. Sixty percent of respondents rated their understanding of ISM concepts as moderate or very good, while nearly 70% rated their level of experience as modest to none.

8.4.1 How ISM Is Being Conducted

ISM sampling has been used nearly twice as frequently on sites with commercial/industrial land use as compared with residential land use. When queried about the programs in which ISM sampling was most often conducted, survey respondents identified CERCLA and state-lead cleanup sites most frequently, followed by RCRA and petroleum sites (see Figure 8-2).

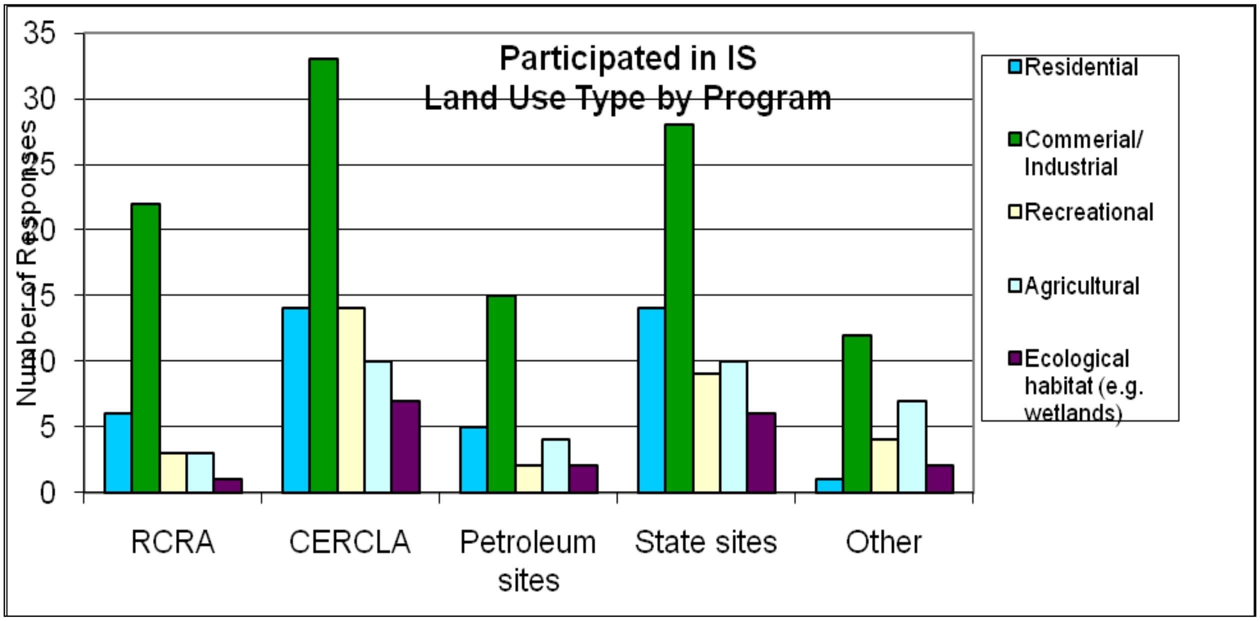


Figure 8-2. Survey response of ISM sampling in land use type by program.

According to the survey responses, ISM is being used primarily during screening investigations or to obtain data for meeting regulatory or cleanup criteria (see Figure 8-3) and primarily on surface soils (see Figure 8-4). Fewer than half of the respondents indicated they had used ISM for subsurface soil sampling. Very few respondents cited use of ISM for other matrices, such as sediment, soil gas, and water.

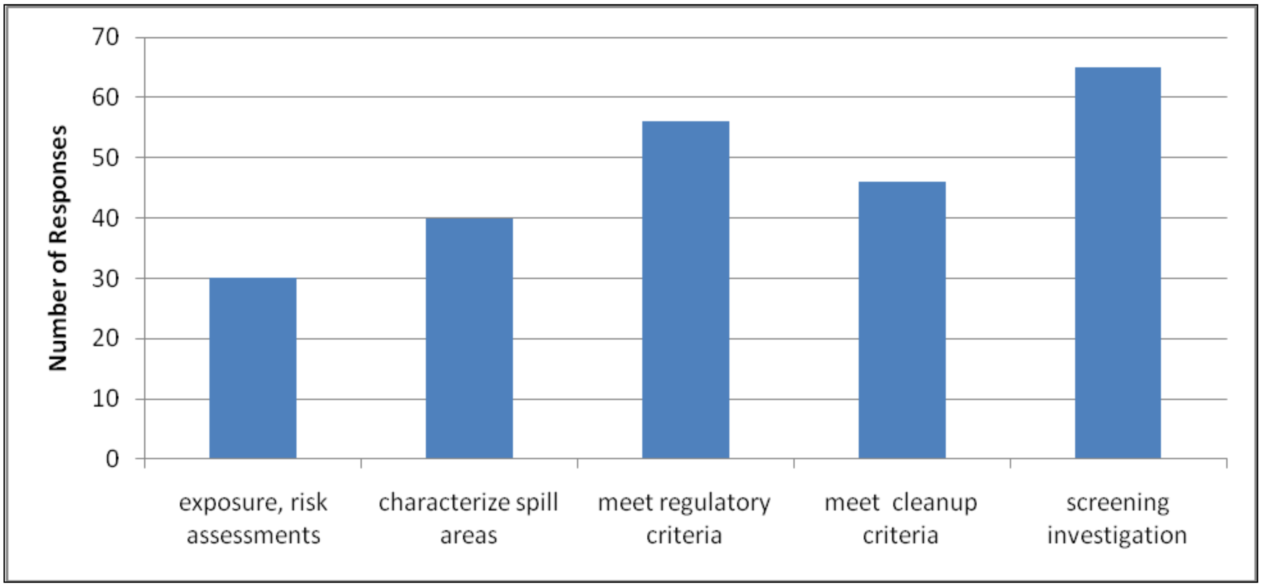


Figure 8-3. Survey responses identifying the objectives of ISM sampling.

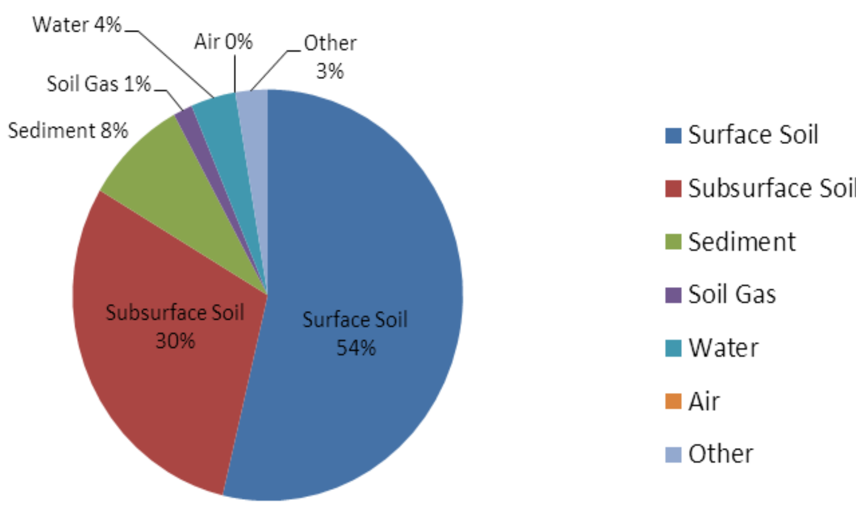


Figure 8-4. Survey responses of the ISM media applications.

ISM has been used primarily to assess heavy metals and explosive residues. Other contaminants cited less frequently include VOC and SVOCs, PCBs, and total petroleum hydrocarbons (TPH).

Hawaii, California, and Alaska together account for more than 40% of all ISM sampling activity.

Although survey data show ISM has been conducted in 36 states, over half of the ISM sampling activity has been conducted in a relatively small number of states, with Hawaii, California, and Alaska together accounting for over 40% of all ISM sampling activity (see Figure 8-5). The survey found that about half of the ISM sampling projects have been conducted on commercial/industrial land use types (see Figure 8-6).

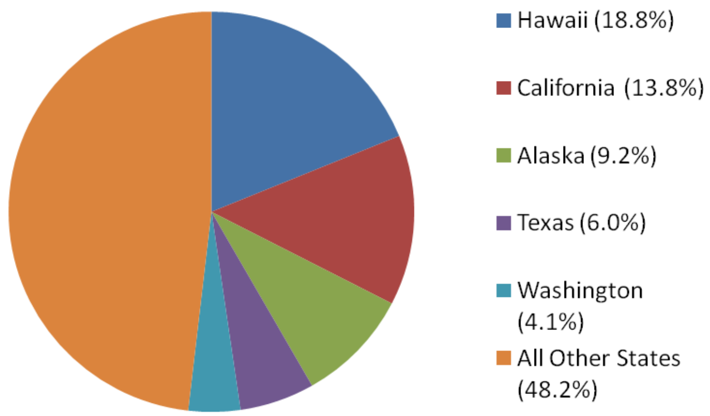


Figure 8-5. Survey responses of states where the organization has participated in ISM.

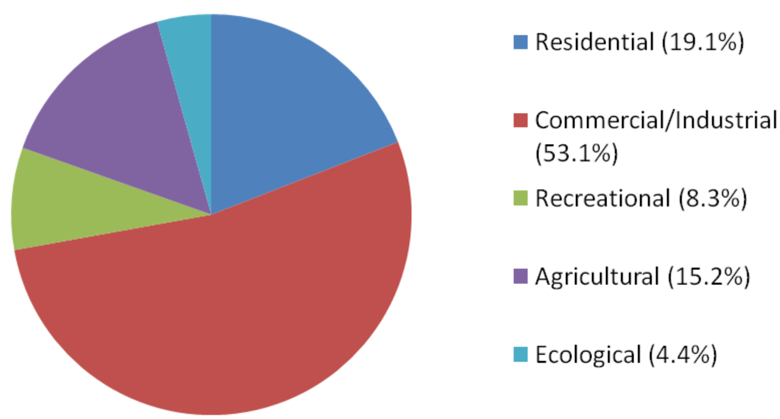


Figure 8-6. Survey responses of ISM sampling participation per land use type.

8.4.2 Written Guidance

There is relatively little written guidance available on the use of ISM for environmental contaminants. Most survey respondents cited one of three primary written sources:

Hawaii Department of Health. 2008b. *Technical Guidance Manual*, in preparation. Office of Hazard Evaluation and Emergency Response. www.hawaiidoh.org.

Alaska Department of Environmental Conservation. 2009. *Draft Guidance on MULTI INCREMENT Soil Sampling*. Division of Spill Preventions and Response, Contaminated Sites Program. www.itrcweb.org/ism-1/references/multi_increment.pdf.

U.S. Environmental Protection Agency. 2006c. "Method 8330B: Nitroaromatics, Nitramines, Nitrate Esters by High-Performance Liquid Chromatography (HPLC)," Appendix A. "Collecting and Processing of Representative Samples for Energetic Residues in Solid Matrices from Military Training Ranges." www.itrcweb.org/ism-1/references/8330b.pdf.

The following are other guidance documents cited by survey respondents which address the use of ISM:

USACE *Protocols for Collection of Surface Soil Samples at Military Training and Testing Ranges for the Characterization of Energetic Munitions Constituents* (Hewitt et al. 2007)
USEPA *Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples* (Gerlach and Nocerino 2003)

8.4.3 Misconceptions

With proper identification of sampling goals and use of the systematic planning process, an ISM sampling design can be created to identify specific areas of high contaminant concentration within an area of interest (DU) (see Figure 8-7). However, a significant percentage of survey respondents either felt that ISM cannot accomplish this goal or were undecided. This opinion was particularly pronounced in responses by regulators relative to nonregulator respondents.

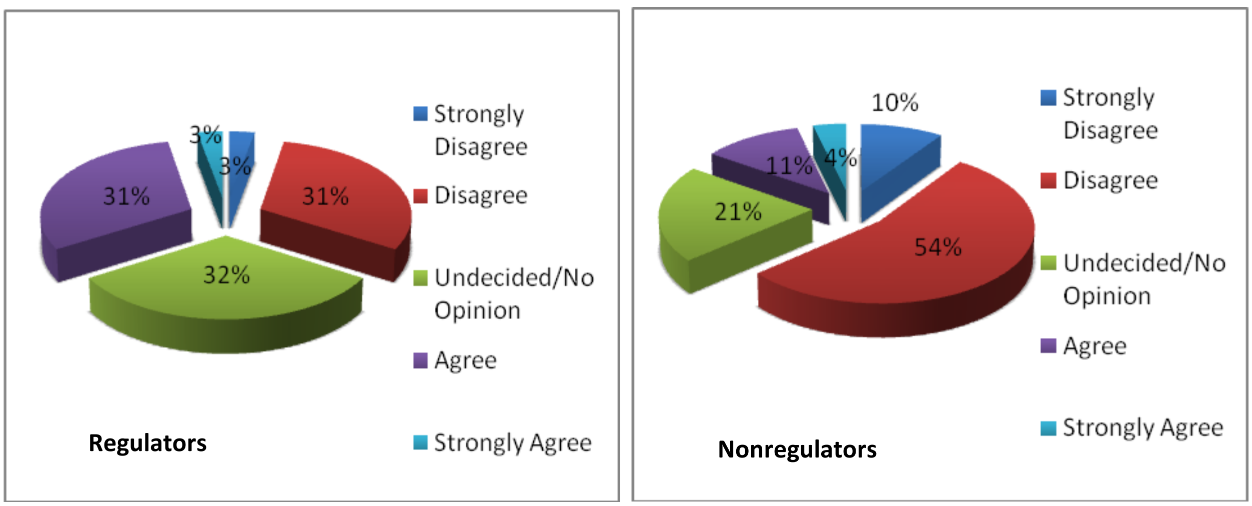
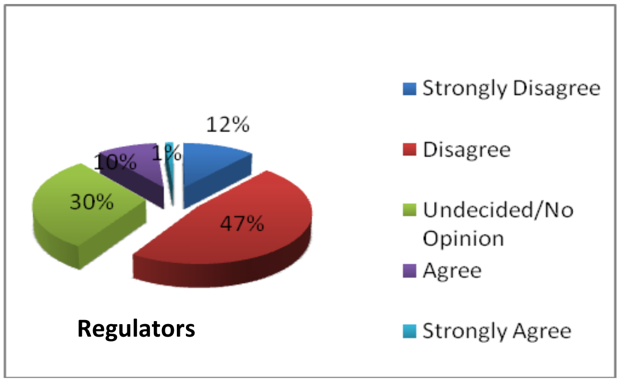


Figure 8-7. Survey responses for the statement "ISM is ineffective because it cannot identify specific areas of high concentration."

As described in Section 4.3, an ISM sampling plan can be designed to collect information about contaminant distribution variability and provide input for conventional risk assessment calculations. About 30% of regulators and 46% of nonregulators are undecided whether this is the case (Figure 8-8).

As stated in Section 2, the contaminant concentration reported by the lab is a ratio of the mass of contaminant measured to the total mass of the analytical subsample. Approximately 47% of respondents disagree that contaminant concentrations are related to the amount of the soil sample (see Figure 8-9).

There is no clear consensus among respondents about whether ISM is more expensive than discrete sampling (see Figure 8-10). Refer to Section 8.5.3 for additional discussion of this topic.



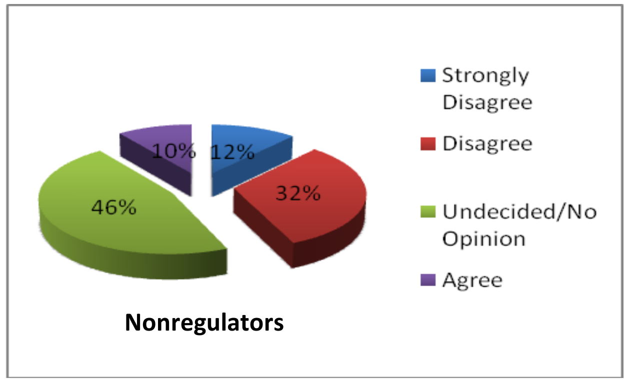


Figure 8-8. Survey responses for the statement "incremental sampling cannot be used for risk assessment because it does not address variability."

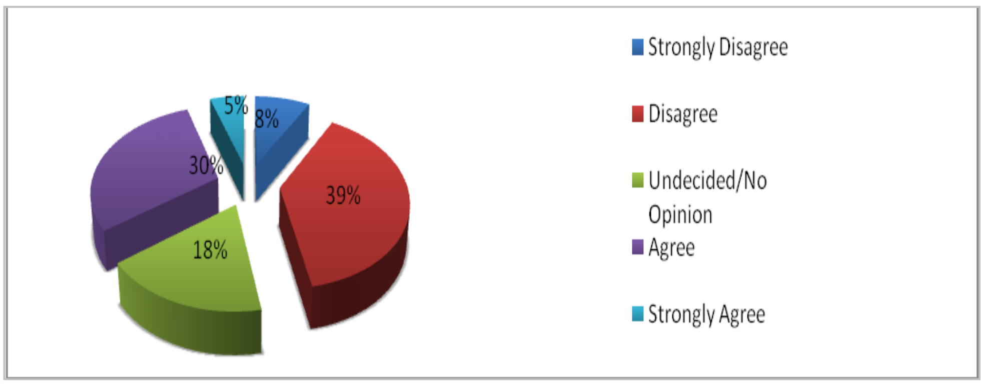


Figure 8-9. Survey responses for the statement "contaminant concentration depends on the amount of soil sample."

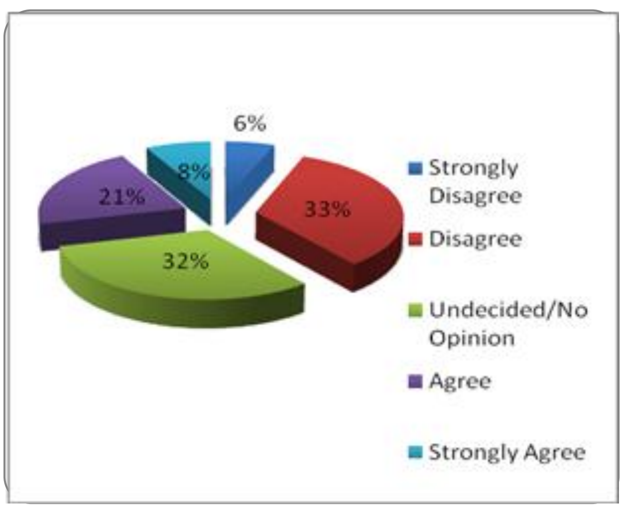


Figure 8-10. Survey responses for the statement "ISM is generally more expensive than conventional discrete sampling."

Although an important element of ISM is sample processing procedures that are typically employed prior to sample analysis, there appears to be a significant level of misunderstanding regarding this issue. Over half of regulator survey respondents were either undecided or disagreed that these additional measures are commonly needed (see Figure 8-11).

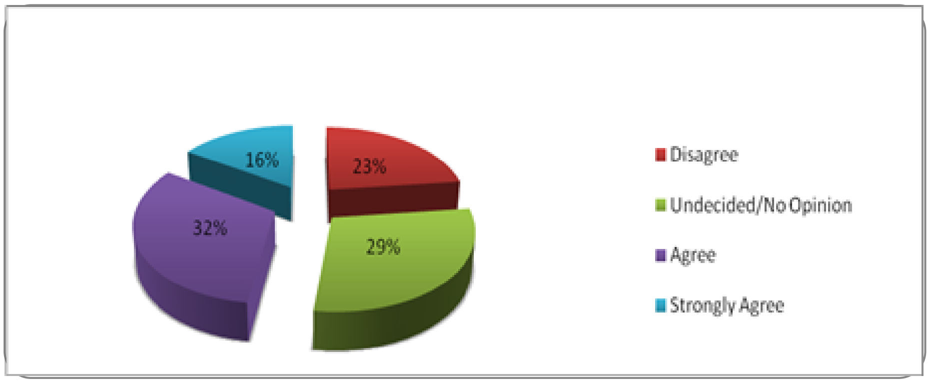


Figure 8-11. Survey responses for the statement "Incremental samples commonly require additional laboratory sample preparation."

8.4.4 Limitations

When asked to identify the most significant challenges to broader implementation of ISM, survey respondents identified delineation of local areas of high concentration as the top difficulty, with the lack of regulatory acceptance at or near the top. In fact, regulators identified regulatory acceptance as the most important challenge, followed by collecting ISM samples for VOC analysis and determining the DU. By contrast, nonregulator respondents identified delineation of hot spots as the top difficulty, followed by regulatory acceptance and delineation of the extent of contamination.

Other limitations identified by respondents include a general lack of training/knowledge of ISM concepts and techniques in both the regulatory and consulting communities, difficulties in using ISM techniques on projects involving collection of subsurface samples, and comparing ISM data sets with historic discrete sampling results.

8.5 Implementation Issues

This section identifies potential obstacles to implementing ISM, particularly those identified in the survey, and provides recommendations to assist project teams in addressing the challenges. For purposes of this section, the project team includes the project manager, geologist, engineer, toxicologist, laboratory personnel, and in some cases, interested public stakeholders, consultants, and one or more regulatory agencies. The project team personnel are determined in the DQO process and by other project considerations.

8.5.1 Systematic Planning

Any type of sampling design (ISM or discrete) should be based on a systematic planning approach to ensure that there are clear objectives and that the data obtained are of sufficient quality to make an environmental decision (see Section 3). Good systematic planning involves a series of well-thought-out steps, but often projects omit this process entirely or miss one or more key elements. The project team needs to continually review and understand the key elements listed below and apply a systematic approach to site investigation to bring the site to completion.

Develop the CSM.
Identify the COPCs.
Identify data info needs. (What is the reason for the sampling, and what is the function of the data?)
Determine the need to find hot spots. Agree on concentration and size of hot spot (i.e., volume).
Define the DU.
Develop decision statements.
Develop and implement SAP.
Ensure data quality.
Control decision error using defensible decision rules.
Conduct data assessment and identify environmental hazards.
Reevaluate the CSM.

Lack of a clear and concise CSM at the start of a project can lead to confusion and disagreements throughout the planning, implementation, and data assessment phases. The primary objective of most site investigations is to determine the presence or absence of potential environmental hazards associated with environmental contamination. Sampling objectives tie directly to development of the DU and the CSM.

The project team needs to discuss all the systematic planning elements. Experience has shown that some elements are more difficult to develop and agree to than others. Some of the common ISM systematic planning challenges are discussed in the following subsections.

8.5.1.1 CSM

Challenge: Developing a CSM acceptable to the entire planning team.

Recommendation: Making decisions based on a poor CSM can lead to incorrect environmental decisions. Whenever practical, conduct face-to-face planning meetings and use site maps and figures to aid in developing the CSM. The planning team should visit the site prior to or as part of planning meeting(s) to aid in developing the CSM. Revise and update the CSM, if appropriate, with new information. Indicate whether the new information supports the existing CSM.

8.5.1.2 Sampling objectives and developing the decision unit

Challenge: Some project stakeholders are concerned about identifying potential hot spots.

Recommendation: Because the size of the DU sets the scale of the resolution of the investigation, it is critical to ask and resolve the following questions before dividing an area under investigation into DUs:

What is the overall objective(s)?
What is the amount of soil to be concerned about?

Do acute hazards need to be addressed?

With discrete sample data, assertions about hot spots are typically made after looking at the results of the investigation. Claiming that a single discrete soil sample result represents a meaningful volume of highly contaminated soil is rarely defensible and more importantly often not practical. A hot spot identified by an individual discrete soil sample within a DU may simply denote the degree of heterogeneity of contaminant concentrations within the DU. It is sometimes assumed that a sample or samples from a data set which contain the highest contaminant concentrations represent the highest concentrations actually present at a site, when in fact, due to short-scale heterogeneity, an area only an inch away may contain higher concentrations. An extremely large number of samples is required to estimate and delineate with any degree of certainty relatively small areas with the highest concentrations that might be present at a site. Estimating the actual true maximum contaminant concentrations in soil is therefore often an impractical endeavor.

ISM cannot identify hot spots smaller than the DU.

ISM replicates provide a measure of variability in estimates of the mean concentration in the DU but do not provide information about the spatial distribution. To characterize spatial variability, either the scale of the DU or the scale of the areas sampled within the DU need to be adjusted. DUs can vary greatly in size from very small (e.g., much less than ¼ acre such as a sandbox) to very large (e.g., hundreds of acres). During systematic planning, options for either combining or splitting DUs may be considered to address multiple objectives. It is possible that prior site knowledge can be used to refine the sampling plan to account for potential source areas as separate DUs, but there must be high confidence that this information is accurate. If a DU is subdivided to evaluate smaller volumes of soil, it is likely that additional ISM samples will need to be collected before decisions can be made at the scale of the smaller DU. For example, a large DU may be subdivided into four areas with ISM samples collected from each subarea. The data would support calculations of an area weighted mean concentration and 95% UCL for the large DU, as well as preliminary estimates of means within each subarea. Additional ISM samples could then be collected to reduce uncertainty and delineate areas of elevated mean concentrations at the smaller scales. More detail on combining and splitting DUs and calculating area weighted means can be found in Sections 4.4.1 and 3.4.

As a general rule, misunderstandings about potential hot spots can be avoided with proper DU scaling during systematic planning and by keeping the investigation and evaluation focused on the DU identified, not to the scale of an individual sample.

Challenge: Some project stakeholders are concerned that potential areas of higher concentration within a DU (i.e., hot spots) will be diluted out when combined through ISM with increments of soil from less-contaminated portions of the DU.

Recommendation: Even the best systematic planning and underlying CSM could result in a sampling design that fails to identify small areas of extreme high and low concentrations within the DU in the proper proportion compared to the total mass of the soil. This reality contributes to a concern about dilution of hot spots. There are at least two issues with the issue of hot-spot dilution:

There are two concerns regarding hot spots: sampling density and defining the DU. ISM effectively addresses compliance when action levels are based on the mean concentration within a DU. Concerns related to spatial resolution can be addressed only by changing the scale

- Sampling density. If the small area(s) within a DU with extremely high concentrations are not represented by a sample in the proper proportions (compared to the total mass of soil in the DU), the estimate of the sample mean can be highly variable. Unless the ISM sampling process is repeated many times (replicates), there remains a concern about the performance of any one sampling event. Specifically, if the difference between the estimate of the mean and the true population is large, there is a greater chance of reaching the wrong conclusion regarding compliance with an action level (see performance metrics, Section 4). For this reason, it is very important to consider collection of replicates to ensure that the small areas of high concentration are collected in the proper proportion relative to the total mass.
- Defining the DU. Different sampling designs provide different information concerning the location, spatial extent, and magnitude of subareas of high concentrations. Uncertainty regarding the toxicological significance of acute exposures leads to uncertainty in the definition of a hot spot. This uncertainty creates a challenge for any sampling design—without a clear definition of what constitutes a hot spot, it is difficult to delineate a DU and develop a sampling design that provides information to adequately address hot spots. For this reason, the definition of hot spot and size of the DU must be agreed on by the team during the systematic design phase.

The chance that any single sampling event will include subareas of high and low concentrations in the proper proportion is directly related to the number of samples collected within a DU. An advantage of ISM over other sampling designs is that it accommodates large sample sizes (i.e., large number of increments as well as multiple replicates). For this reason, while any individual sample collected in a hot spot is diluted within the larger group of samples, we are more likely to achieve an estimate of the mean that is representative of the true mean within the DU. This advantage of ISM addresses the first concern (compliance with action levels) but not the second concern (spatial resolution). If the DQO includes the identification and delineation of small areas of elevated concentrations, ISM sampling can address this objective only by changing the scale of the DU (i.e., DU must be the same size as the hot spot of concern).

Challenge: Developing the correct DU.

Recommendation: The DU is properly sized when knowledge about spatial variability/spatial patterns of contaminant concentrations within the DU are no longer of interest. Section 3.3 provides information to consider when developing the DU(s). Keep in mind that a site may be subdivided into multiple DUs to accomplish investigation objectives. Consider how DU sample results will be used. If the objective is to assess potential exposure concentrations over a ¼-acre residential lot, then the DU is ¼ acre, and subdivision into smaller DUs is not necessary. If the objective is to investigate and locate areas of potentially higher contaminant concentration within the site as a whole (e.g., source areas or separate exposure areas), using multiple smaller DUs is appropriate.

Although DUs are ideally sized no larger than the volume of soil in which the average concentration is sufficient to make a decision, there may be situations where DUs cannot be sized small enough for practical reasons. For example, the Florida Department of Environmental Protection has criteria for some contaminants in soil for protection from acute exposure. These criteria are based on a scenario in which a small child ingests, on a single occasion, a handful (10 g) of soil. For this scenario, the DU should be an area approximately the size of child's hand. Obviously, it would be impractical to divide a site into DUs of this size, and use of a larger DU encompassing thousands of these exposure areas would raise legitimate questions of whether acute toxicity potential can be evaluated. This is a problem with the use of discrete data as well, but with discrete data, some information on variability of concentrations within an area is obtained with which to estimate what the concentration in the most contaminated exposure area might be. For sites in Florida in which acute exposure and toxicity are a concern, the regulatory acceptance issue is whether to allow use of a method such as ISM that appears incapable of providing reasonable assurance that acute-toxicity based criteria have been met. A similar issue may apply to ecological risk assessments, where the area of exposure for some species of interest is smaller than can be accommodated by an affordable number of DUs. Again, discrete sampling has its own set of problems dealing with this issue, but a sufficient number of samples can provide information on variability of concentrations over space from which predictions regarding worst-case exposure areas can be made.

A refinement of initial DUs flagged for remediation may be useful to better isolate areas of high contamination and optimize resources available for cleanup. See Section 3 for a thorough discussion on this topic.

8.5.2 Lab Availability

Application of ISM to environmental site assessment has primarily occurred in the last few years. Thus, only a few technically advanced commercial laboratories have developed ISM sample processing and handling capabilities, primarily in support of federal agencies such as USACE and USEPA or state agencies such as HDOH and ADEC. As of the survey date in 2009, laboratories providing support work for military sites or sites in Hawaii or Alaska were the most likely to have experience supporting the advanced processes used for incremental samples.

ISM sample processing techniques are so new that many have not been fully documented in laboratory SOPs. Laboratory support for USEPA SW-846 Method 8330B (explosives) is probably the best-documented ISM method. Certification and reference material are available for this method. There are currently no other USEPA-approved ISM methods for other contaminants; thus, the laboratory processes have been developed on a case-by-case basis. Technical conversations between the laboratory and project chemists and other data users early on during the systematic planning process are strongly recommended to ensure that the appropriate support processes are selected to meet the DQOs. Support processes can vary greatly from one laboratory to the next for parameters other than explosives. Guidance about the strengths and limitations of the various options within the laboratory is discussed in Section 6.

It is expected that as use of ISM increases, more laboratories will gain experience, and finding laboratories familiar with the necessary procedures for handling ISM samples will no longer be an issue.

8.5.3 Costs

A cost comparison of ISM to discrete sampling approaches is difficult. Cost-effective sampling is important, but it is more critical that the sampling approach(es) meet the sampling objectives.

The cost of collecting and processing an individual ISM sample is nearly always more than that for a single discrete sample. In general, the number of analytical samples to be analyzed for ISM is less than for discrete samples, so ISM analytical cost may be lower. However, costs differences are based on various issues, including specific analytical costs (e.g., metal vs. dioxin), availability and quality of screening technologies, and ease of collecting samples. Costs should be evaluated on a case-by-case basis.

It is also important to remember that ISM generally yields more precise and unbiased estimates of the mean (for example, three 30-increment ISM samples as compared to three discrete samples). This difference is important because, from a decision-making standpoint, investigations based on limited discrete sample data are in many cases more likely to result in a decision error. In those instances where an ISM investigation costs more than discrete sample investigation, the cost-benefit ratio might still favor the ISM investigation because it may result in fewer decision errors.

When ISM and discrete sampling costs are similar, variability in the ISM data can be significantly less. This decreased data variability might allow for less uncertainty in decision making, especially when estimates of the mean are close to an action level. Ultimately, making a correct decision at a site reduces overall project costs by eliminating costly and unnecessary remediation of DUs incorrectly identified as dirty or dealing with the consequences of mistakenly walking away from a DU that is actually contaminated.

Although the survey did not query the question of cost vs. benefit, this section discusses general costs for ISM. It should be noted that the Florida field study presented in Appendix C did not have a detailed cost-benefit analysis as a project objective, and for this reason costs analysis for the Florida field study are not presented.

Challenge: How do costs for ISM compare to discrete sampling approaches?

Recommendation: The recommendations below discuss four areas of cost differences between ISM and discrete sampling approaches: systematic planning, sampling plan review, field costs, and laboratory costs.

Systematic Planning. Systematic planning, including the designation of DUs and associated decision statements that guide evaluation of the data collected, while being key components of ISM investigations, are not unique to ISM. ISM requires the up-front consideration of DUs and associated decision statements. Although this should be done prior any project involving soil sample collection, traditionally, systematic planning is often omitted completely or only partially conducted prior to many site investigations. This omission often results in multiple sample collection events purely for site characterization purposes, followed by the designation of what are essentially DUs using already-collected data on which final decision making is based. This process often leads to the need for additional site investigations to fill data gaps or, especially at small sites with limited budgets, final decisions based on low-quality data that may or may not reflect the actual risks posed by contamination at the site.

Very little data exist on how much systematic planning for ISM costs vs. more traditional discrete sample approaches. The reason is likely that the ISM approach is new and that conditions vary so greatly from site to site. Systematic planning costs should be roughly equivalent regardless of the sampling design. Developing DUs, discussing hot spots, including additional staff to participate in planning meetings, and stakeholder agreement may increase front-end costs but can significantly reduce costs and the need for lengthy discussions following completion of the field investigation. The intent of systematic planning is to minimize the need for remobilization to collect additional data or situations where parties disagree on the size of a hot spot. Eliminating both would result in lower overall costs in the project life cycle.

<u>Sampling Plan Review</u>. A common concern of both regulators and the regulated community is ISM sampling plan review. For regulators not trained in ISM investigation approaches, the sampling plan review can be labor-intensive. Many regulators stated that they currently do not have time to review standard sampling plans and reports, let alone a more labor-intensive ISM plan. For consultants, the time required for regulatory approval of ISM projects from agencies that lack adequate training and guidance documents also increases costs to their clients and at least perceived risk of rejection. Many consultants find it much easier to submit standard sampling plans and assessment/remediation reports to regulators in an attempt to get a quicker turnaround time for their clients even if they know that this approach will ultimately result in a more drawn out and costly investigation over the life of the project. While this statement may be true currently, the publication of this ISM document and subsequent training should allow practitioners to develop ISM work plans with less risk of rejection and regulators to review sampling plans more quickly.

<u>Field Costs</u>. Many factors can affect the cost for ISM field sampling. Only limited data on ISM sampling costs were available at the time this ITRC document was developed. All of the costs are highly dependent on DQOs. The discussion of costs presented below is only for surface soil sampling. Generally, field costs for ISM and the equivalent number of discrete samples (e.g., three ISM or 30 discrete samples) are approximately equivalent. Cost considerations include the number of increments in an ISM sample, replicate collection, and field processing.

Based on experience reported by the State of Hawaii, the average time needed to lay out up to a 1-acre DU in the field and collect a single 30–50 point ISM sample is approximately 45 minutes for a three-person field team (two to collect samples and one to manage samples, decontaminate, manage paperwork, etc.). For the same number of discrete sample or increment points (e.g., 30 points within a targeted area), the collection of a single ISM sample will be faster than the collection of 30 discrete samples due to the need to label, pack, and document a much larger number of the discrete samples. In cases where a relatively low number of discrete samples are required for characterization of a targeted area (e.g., 10 discrete samples), the field time required to collect the discrete samples is likely to be significantly shorter than the time required to collect and process an ISM sample, especially if replicate ISM samples are to be collected.

The real cost saving is in the analysis effort needed to produce equivalent precision, where, for example, instead of analyzing 30 discrete samples from a targeted area, the lab analyzes three ISM samples (one incremental sample and two replicates). An example presented at the 2010 Environment, Energy Security and Sustainability Conference (Penfold 2010), indicated that the total field and lab costs for one ISM sample and two replicates from a single DU was $3,150 vs. $6,975 for 30 discrete samples. The ISM samples contained 100 increments each. The total field and lab cost for 10 DUs was $20,700 for ISM vs. $62,725 for discrete samples. The samples were analyzed by USEPA SW-846 Method 8330B for explosives.

The 2009 Environmental Security Technology Certification Program (ESTCP) *Cost and Performance Report* (Hewitt et al. 2009) prepared for characterization of energetic residues provides an excellent discussion on the cost issues associated with ISM sampling for USEPA SW-846 Method 8330B. According to the report, extra costs could include ISM sample shipment and disposal (due to extra weight) as well as QA/QC costs associated with batch samples. In addition, the report noted that ISM was not projected to be cost-competitive on smaller scale due to the relative increased processing (e.g., sieving and handling) and analysis; however, the report concluded that there is a cost saving of 50%–80% using ISM (Hewitt et al. 2009).

Laboratory. ISM increases the amount of sample handling in the laboratory. There is a wide variety of ISM laboratory sample processing and subsampling options. The price of ISM processing depends on the specific options selected, the amount of soil to be processed, analytes of concern, and other general business concerns (e.g., number of samples, turnaround time). As of mid-2010, the additional cost of ISM sample processing ranged from $50–$250 for a 1 kg soil sample. Normal sample preparation and analysis charges depend on the contaminant(s) of interest and are not included in this price range estimate. Processing equipment blanks, LCSs, and MS/MSDs through the ISM laboratory steps is recommended, but the lack of readily available and suitable reference materials makes it challenging to estimate potential costs. Depending on QA/QC samples necessary to meet DQOs, per batch cost could increase significantly. Despite increased costs, the added value of processing known QA/QC samples may be worthwhile. Discuss batch QA/QC options with the laboratory during project planning to get specific cost estimates.

The ISM approach might not be the most cost-effective option when low-cost field screening tests provide acceptable accuracy and sensitivity (such as XRF for selected metals) and can be used inexpensively on large numbers of discrete samples.

Challenge: Are there cases where ISM is not cost-effective or when is ISM most cost-effective?

Recommendation: Costs need to be evaluated on a site-by-site basis as DQOs and other site-specific factors make it very difficult to predict which sample method will be the most cost-effective. The following issues related to costs should be considered:

- What are individual analyte costs?
- Are there field analytical methods that can be used for specific contaminants?

> Cost considerations for ISM include individual analyte costs, availability of field analytical methods, type of sample processing necessary (drying, particle size reduction, sieving, subsampling), difficulty in sieving, whether the lab has an ISM SOP, shipping and disposal costs associated with larger ISM sample mass, and need for

- What type of sample processing has to be done (drying, particle size reduction, sieving, subsampling)?
- If sieving in the field, does the soil contain clay, roots, or very wet soil? These will likely increase overall field processing time and increase costs.
- Will the laboratory charge be based on how difficult is it to sieve the soil (clay, roots, very wet)?
- Does the lab have an ISM SOP, and if not, will it charge to develop one?
- What are the costs for extra QC samples (i.e., batch samples) often needed with ISM?
- Are there added costs for shipping and disposing the large volumes of soil collected with ISM?

Note, however, that cost should not be the most important issue. The priority should be whether the sampling design meets the sampling objectives.

8.5.4 Challenges in Developing and Using ISM Data

Regulatory agencies are most accustomed to working with discrete sample data sets, with a variety of concentration measurements from within an area of interest. It is not surprising that some regulatory criteria are written specifically to deal with these data sets, specifying decisions to be made based upon data parameters readily obtained (e.g., mean, maximum concentration observed). ISM data, while providing in most cases a better estimate of the mean, cannot provide all of the parameters that may be called for in some regulations (e.g., maximum concentration observed, upper percentile concentrations observed). This shortcoming can constitute a regulatory barrier to acceptance, as noted in some of the sections below. Other sections address other practical problems associated with the nature of ISM and discrete data that may limit regulatory acceptance of ISM.

8.5.4.1 Validation of statistical analysis within ISM

A rigorous statistical analysis regarding the extent to which various ISM sampling strategies provide accurate estimates of the average has not yet been published. Information from simulation studies can be used to address this issue, and results from efforts conducted during development of this document are described in Section 4 and Appendix A. However, it is reasonable to state that this is not a "mature" area of study, meaning that the strengths and limitations of ISM from a statistical standpoint are only just now being rigorously explored. Given that the statistical foundation of ISM is critical to understanding its reliability in providing estimates of the mean for site evaluation, regulatory agencies may be reluctant to embrace ISM until more thorough statistical evaluation has been conducted and formal guidance that addresses these issues is available.

8.5.4.2 Meeting regulatory requirements for average and maximum concentration estimates

EPCs that present a spatial average are often required to be the upper 95% confidence limit (95% UCL) on the mean. If only a single ISM sample is taken from a DU, a UCL on the mean cannot be calculated to satisfy regulatory requirements. In this situation, a sampling strategy involving replicate measurements is required. (See Section 4 for a discussion of calculation of 95% UCL values from ISM data.) Also, some programs that accept an expression of the mean for risk and cleanup evaluation also specify an upper percentile or a maximum concentration that can remain on site. For example, some states currently require for most sites that if the 95% UCL is below the soil criterion, contamination is still not within acceptable limits unless the maximum concentration is at or below three times the criterion. Because ISM provides no direct indication of the maximum concentration, its ability to demonstrate compliance with this regulatory requirement is questionable. Approaches to estimate maximum concentrations within a DU using ISM data are discussed in Section 4 and might be useful to address this issue but have not been widely used.

8.5.4.3 Decision unit versus exposure unit

Some DUs selected for a project may not match the definition of an exposure unit, for example, when DUs are designed solely for comparisons with cleanup values to reach “remediate/don’t remediate” decisions for specific plots. Another situation is when there are different exposure units over the same area for different receptors but only one set of DUs for a site. Depending on how DUs are defined, it is possible to have a DU that is larger or smaller than an exposure unit. There are no statistical procedures in place to estimate an EPC when the DU is larger than the exposure unit, although some possibilities for estimating high end concentrations are discussed in Section 3.5. Similarly, when an exposure unit is composed of more than one DU, unless replicate ISM are available for each, there is no established method to combine results from the DUs to produce a robust, demonstrably conservative EPC. Limitations of methods in situations where the DUs do not match the exposure units may be a significant obstacle to the use of ISM data in risk assessment. Methods for overcoming these limitations are discussed in Section 4.2.

8.5.4.4 Comparison of discrete samples and ISM samples

Many sites have historical discrete sampling data, and some have concurrent discrete sampling data taken in response to specific needs or regulatory requirements. Qualitative comparisons can be very instructive, but quantitative comparison of discrete and ISM data should be done only with caution. Comparison of ISM samples to discrete samples is discussed in Section 4.4.3.2. Key issues that should be considered whenever comparing ISM and discrete samples are sampling design, sample collection method, similar soil conditions, similar sample processing and analysis, and data quality being understood and appropriate for intended use.

8.5.4.5 Comparison of ISM means and “not to exceed” basis regulation

Regulatory requirements in some situations compel evaluation of concentrations within an area on a “not-to-exceed” basis. This may include screening levels, action levels, or leachability values, depending on the state. In this situation, derivation of a mean concentration by ISM alone does not satisfy the requirement. The development of statistical approaches that use ISM data in some form to estimate variability across the sampled area could overcome this challenge and allow ISM to be used in these circumstances, as discussed in Section 4.

Under some state regulations, leachability-based cleanup goals may be considered to be not-to-exceed values for any single, discrete sample collected within the targeted volume of soil. In this situation, ISM samples would not allow a direct comparison to cleanup objectives; however, it is important to consider that the cleanup goals need to consider not only the concentration but the mass of the contamination. ISM data can provide an estimate of the mass of the contaminant within the DU. This allows for better comparison to the cleanup goals. As an update to the survey, some states are moving in the direction of emphasizing mass of contamination over leachability goals by establishing a minimum volume of soil and contaminant concentrations that need to be considered for potential leaching hazard.

8.5.4.6 Decisions based on a single ISM

This limitation applies specifically to an approach where only one ISM sample is taken per DU. Because a 95% UCL cannot be calculated from a single ISM result, this approach is precluded when a 95% UCL is required by regulation. It may also not be accepted because of the inherent uncertainty associated with using a single, unreplicated estimate of the mean and the potential to underestimate the actual mean.

8.5.4.7 Background/geochemical limitations

Comparison of site data with background data may be necessary to establish the extent to which chemicals present are naturally occurring. As discussed in Section 4.4.3.3, the two key challenges for ISM are the likelihood of detecting differences in the populations that exist (ISM background data to ISM site data) and the inability to evaluate upper tails of the background to site underlying distributions. In addition, decision errors may be affected if the background samples are collected with different sampling designs from the site samples, including different number of increments/replicates, different sample masses, sampling protocols, depth intervals, and sampling patterns. Therefore, the results of hypothesis tests applied to ISM data sets should be interpreted with caution until these limitations can be more thoroughly studied. Even if formal statistical tests are not used, simple graphical analysis (e.g., plots grouping ISM results by study area) may be informative as a semiquantitative method for comparing background and site distributions.

Comparison of site ISM data to background discrete data using either hypothesis testing or upper tolerance limits is not recommended because the variance is represented differently in ISM and discrete sampling. Careless comparison of an ISM estimate of the mean to a discrete sample collected from soil representing background is likely to lead to decision errors in which one incorrectly concludes that the contaminant distribution on site is consistent with background conditions.

8.5.4.8 Extrapolation between and within DUs

In some situations, the area to be evaluated is larger than can be effectively sampled. This is typically the case for large tracts of land where available resources may preclude sampling each properly sized DU. One approach in this situation is to sample a portion of the area to be evaluated using ISM and extrapolate data to other, unsampled areas. This can take a number of forms, including (a) dividing the area into DUs, sampling some fraction of the DUs, and extrapolating the mean and/or variance of ISM data from sampled to unsampled DUs and (b) creating SUs within a DU that cover some but not all of the area. Results from the SUs are used to make a decision on the DU.

Justification for extrapolation from sampled to unsampled areas is usually based on a CSM that predicts a similar distribution of concentrations in both areas. Generally, this assumption is based solely on judgment and can be associated with considerable uncertainty. This issue is not unique to ISM and applies equally if extrapolation is considered using data from other sampling strategies such as composite and discrete. It is also important to note that ISM offers no special advantage in reducing this uncertainty. Regulatory acceptance of uncertainty associated with extrapolation can vary considerably, depending on the agency and sometimes site-specific circumstances such as the intended use of the property (e.g., agricultural vs. residential). Discussions within the ITRC ISM Team and feedback from states indicate that extrapolation will be accepted by some states, under some circumstances, but not by others.

8.5.5 Matrix and Parameter Issues

8.5.5.1 Laboratory experience

Based on the survey results, most laboratories' ISM experience has been with metals projects. Explosives and SVOC projects are next in frequency. PCBs and TPHs make up the third tier. A few laboratories have ISM experience with VOC and dioxins, and fewer still with perchlorate and cyanide. Parameter-specific certification of the ISM laboratory processes is generally not available due to a lack of reference methods. Section 6 provides specific guidance about appropriate laboratory processes for the various parameter groups. Some laboratories have experience with a wider range of contaminants, including metals, pesticides, dioxins, PCBs, SVOCs, VOCs, and petroleum, so it is important to ask laboratories how much experience they have for contaminant analytes required by the DQOs.

8.5.5.2 Sample processing

Two key issues are the applicability of air-drying and the use of particle size reduction to facilitate representative laboratory subsampling. These techniques generally work well for higher-boiling-point, thermally stable contaminants. The question of whether to grind samples prior to metals analysis should be carefully considered, since this can both improve reproducibility and release metals previously bound inside particles that were less environmentally accessible. The ISM principles have been applied to VOCs in a manner that does not require air-drying or additional air exposure. See Section 5 for field activities and Section 6 for the corresponding laboratory activities.

Meeting traditional holding times is more challenging when air-drying and particle size reduction techniques are used at the laboratory, due to the lengthened sample processing; however, data from USEPA SW-846 Method 8330B studies indicate that contaminant stability can be much longer in dried samples than is common in as-received moist samples. The Method 8830B process has been validated for energetic residues, but it should not be assumed to apply to all other contaminants or contaminant groups. See Section 6.2 for a detailed discussion of the strengths and limitations of the various ISM sample processing options.

Lab certification for ISM sample processing procedures may require certification by laboratory SOP except for USEPA SW-846 Method 8330B. This may be a significant limitation for certain regulatory entities. Please see Section 6.4 for more details.

Below is a list of recommendations for addressing matrix and parameter issues:

Minimize error by processing ISM samples in a controlled setting.
Do not use particle size reduction on ISM samples to be analyzed for organic contaminants other than energetics.
Request that the lab analyze a laboratory control sample at a minimum frequency of one per analytical batch of 20 ISM samples.
When analyzing ISM samples for SVOCs, confirm that drying is acceptable for the specific target compounds.

8.6 Summary

The survey identified several issues concerning the use of ISM, including how to successfully collect VOC samples with ISM, misconceptions about hot spot identification, how to use ISM data, how to apply ISM cost-effectively, and when ISM may not be the best choice. The ISM Team used the survey information to aid in developing this technical-regulatory guidance document. If the guidance document is successful, the perception of ISM will be improved, and regulatory challenges can be broken down, thus allowing ISM to be used more often and in an appropriate fashion. Table 8-2 provides a summary of the limitations and possible solutions for more widespread implementation of ISM.

Table 8-2. Limitations, solutions, and section references for using ISM

Limitations	Solutions	Section reference
Hot spots	Address during systematic planning with proper scaling, combining, or splitting DUs	Sections 3.5, 8.2, and 8.5
Vertical and horizontal DU delineation	Address during systematic planning with proper scaling or splitting DUs	Section 3.3
Acute exposure	Development of approaches for “decompositing” ISM data to estimate variability in concentrations within a DU	Section 3.1, 3.3, and 3.5
Background	Development of formalized guidance on statistical methods for comparison of site and background ISM data.	Sections 3.1, 3.2, 3.3, 4.4.3.3, 7.2.4, and 8.5.4.7
Leachability	ISM provides probability statement	Sections 3.1, 3.2, 3.3, 8.3, and 8.5
Compare with regulatory standards	Discuss with stakeholders during systematic planning	Sections 3.1, 7, and 8.5.4.5
ISM cost-effectiveness	Cost-effective when large DU, expensive analyte cost, remobilization is expensive	Section 8.5.3
Statistical challenges—compare ISM and discrete	Development of statistically sound methods for comparison of discrete and ISM data	Sections 4.4.3.2 and 8.5.4.4
Statistical challenges—95% UCL	Use Student’s-*t* or Chebyshev	Section 4 and Appendix A

Limitations	Solutions	Section reference
Statistical challenges—DUs that do not correspond to exposure units	Development of statistically based methods for combining and subdividing DUs	Sections 3.1, 3.3, 4, and 7
Grinding	Not recommended for organics other than energetics by USEPA SW-846 Method 8330B; recommended for nonvolatile metals; may not be appropriate for project-specific DQOs	Section 3.1 and 6.2
Lab-processing, equipment—sieving, grinding, drying	Close coordination with laboratory is essential throughout ISM; lab business decision to have specific equipment; may need to evaluate different grinding equipment based on method detection limit requirements; laboratory should be familiar with the project-specific ISM requirements and have the facilities (space) and equipment (air-drying racks, grinders, etc.) to meet project-specific DQOs	Section 6.2
Lab—lack of nationally recognized methods	USEPA/DOD methods development	Section 6.1
Field—shipping VOC container	Complete extraction in field and ship subaliquot to the lab; transport via lab pick-up or appropriate method for hazardous goods	Section 5.4.2
Lab—VOC elevated method detection limit	Analyze by USEPA SW-846 Method 8260C SIM; additionally, may be necessary to use low-level VOC discrete sampling and/or a combination of ISM and discrete	Section 6.3.2
Lab—certification	Check with the appropriate regulatory agency; some states have certification process for lab SOPs; continued research is necessary on possible effects of ISM sample preparation procedures on COPCs, especially organics; develop and implement lab certification for ISM, possibly through NELAP	Sections 6.4.1 and 8.5.5.2
DU size and shape	Establish based on site history during systematic planning; may require remobilization if concern over results at the end of sample collection	Sections 3.1, 3.2, and 3.3
Regulators reluctance to use ISM	Review ITRC document and attend ITRC training	All

Although this document attempts to cover all the relevant topics to ISM, there are several issues which were not addressed, including the following:

- consequences of sample grinding on assumptions made during ecological risk assessments
- use of ISM for sampling air, sediment, or other environmental media
- additional statistical simulation to evaluate:
  - combining DUs (Section 4)
  - comparing site to site DUs
  - comparing IS vs. discrete
  - comparing site vs. background
  - comparing oversized DUs
  - other types of sampling errors