Regulatory Acceptance

ISM is a sampling methodology that, when appropriately applied, will improve decision-making with less time and money, while providing representative, reproducible, and defensible data. ISM is a valuable methodology for consultants, regulators, and environmental professionals working on contaminated sites and can be used with most chemicals/contaminants and for many applications, including risk assessment, investigation, and confirmation sampling. Over the past decade, ISM has been more widely used and has been growing in acceptance, as shown in 2019 survey results. However, there are still regulatory barriers to overcome.

The following subsections present the state of practice for ISM by documenting its use since 2009 as well as practical guidance for working with or within a regulatory agency to gain consensus for using ISM in investigations, risk assessments, and confirmation sampling.

7.1 Comparison of Survey Results from 2009 to 2019

To determine the growth and acceptance of ISM use, ITRC surveyed states, territories, and consultants in 2009 and then again in 2019 to collect data on the current state of practice. A comparison of survey results shows there is increasing demand for ISM guidance and training across the U.S.

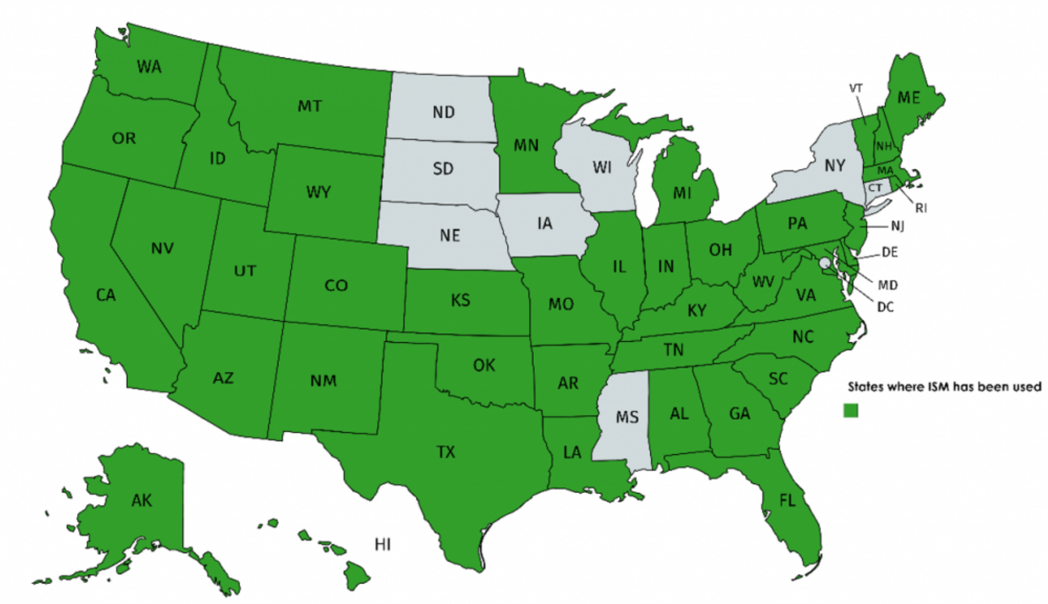

Figure 7-1. States where ISM has been used. Eighty-four percent of state respondents said “yes” when asked if they had used the methodology.
Source: ISM Update Team Survey, March 2019.

7.1.1 Demand for ISM guidance and training

There has been steady interest in incremental sampling use since ITRC published the 2012 ISM guidance document, as shown by the number of technical regulatory guidance document webpage views and the continued demand for internet-based training (IBT) (see Figure 7-2). ISM IBT began in 2012 and based on all subsequent annual IBT offerings, participation numbers and demand across the environmental and regulatory community remain high.

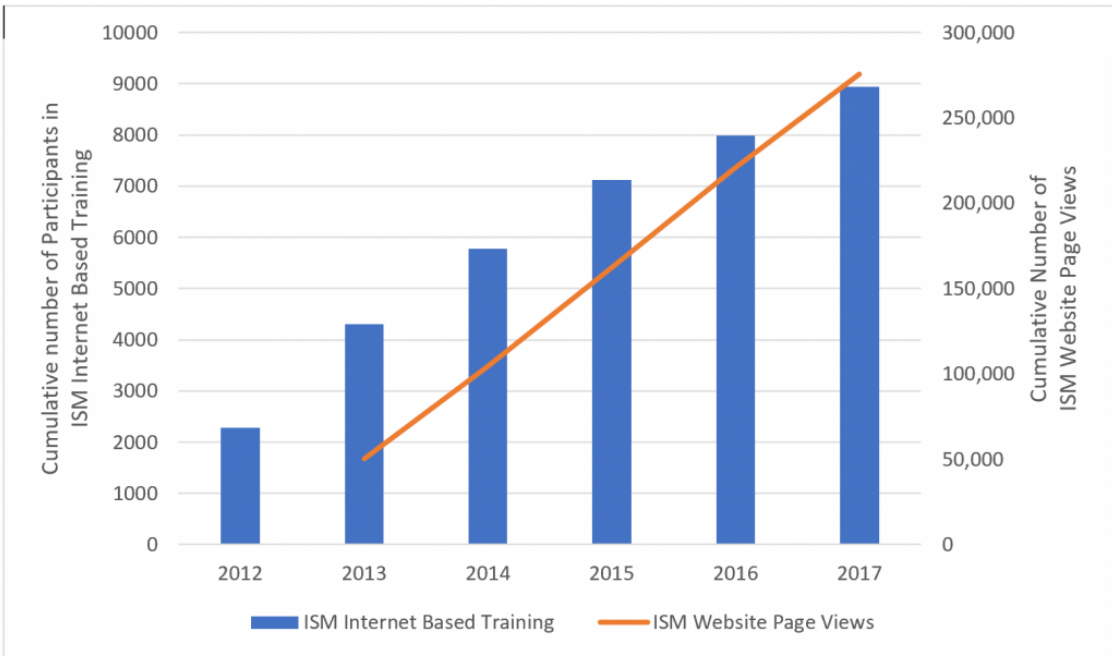

Figure 7-2. Participants in ISM training 2012-17 and ISM website statistics 2013-17.
Source: ITRC, 2019.

As mentioned, the 2012 ISM guidance is one of the most viewed documents on the ITRC webpage and has been downloaded in part or full 3,300 times in its first seven years (Figure 7-2), making it one of the top three ITRC documents downloaded in the last four years and the most downloaded document in 2017.

7.1.2 Regulatory use and acceptance of ISM

The primary respondents of the 2019 survey were state regulators and consultants, but federal regulators, state regulators, and consultants are also common users of the 2012 ISM guidance document and IBT (Figure 7-3).

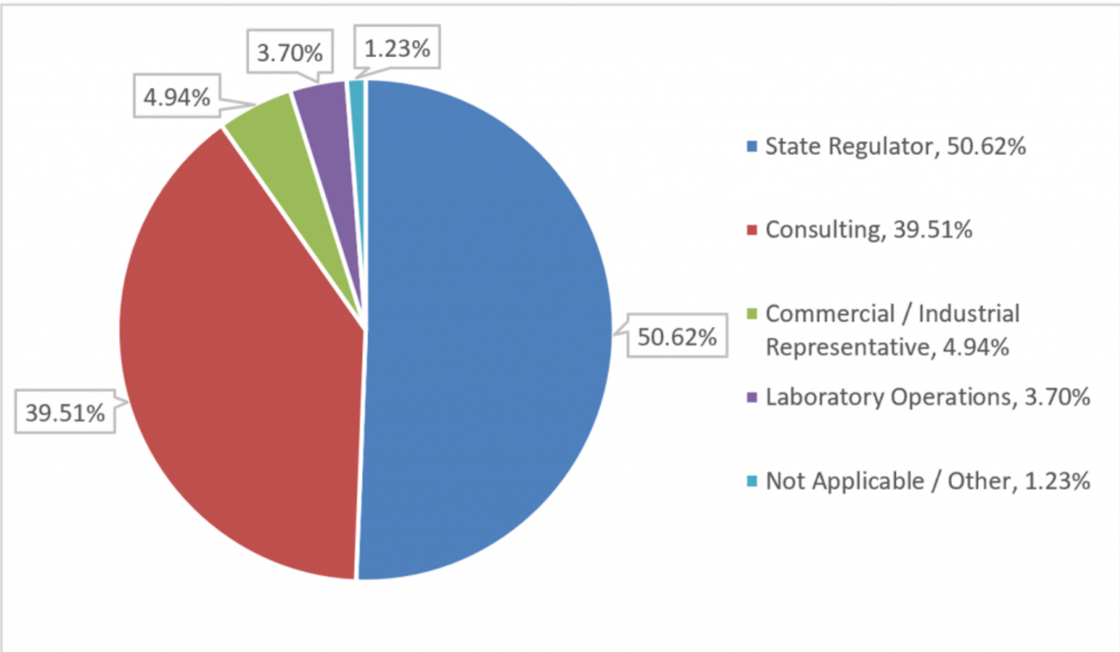

Figure 7-3. Primary job function of 2019 survey respondents.
Source: ISM Update Team Survey, March 2019.

Nearly 87% of survey respondents have used the 2012 ISM guidance to develop or review an incremental sampling WP, and almost 86% of survey respondents indicated that an updated ISM guidance for soils would be valuable to their organization. More people than ever know about ISM, which has helped increase its acceptance by regulators to correct common misconceptions about the applicability of ISM across the country. While federal regulators were not surveyed, they serve as members of ITRC and regularly use ISM sampling. Many federal agencies have their own guidance and many more state agencies have developed guidance since 2009.

7.2 Current State of Practice

Based on recent survey results, ISM is gaining acceptance across the country in both privately funded cleanups as well as state and federal projects. The legal community is also beginning to recognize the power of representative and reproducible sampling strategies in their cases.

ITRC, USEPA, and several states' guidance documents, coupled with online and classroom trainings, are supporting the expansion of ISM knowledge and practice.

Guidance from several federal agencies has existed for many years. However, some states have supplemental guidance or independent regulations on ISM in lieu of federal regulations as noted below:

- Alaska Department of Environmental Conservation. 2019. "Field Sampling Guidance" (Conservation 2019).
- California Department of Toxic Substances Control. 2019. "Guidance for Screening Level Human Health Risk Assessments." Human Health Risk Assessment Note Number 4 (DTSC 2019).
- (DTSC 2018).
- (HDOH 2017b).

- Idaho Department of Environmental Quality. 2015. "Pile Sampling White Paper" (IDEQ 2015).
- Maine Department of Environmental Protection. 2015. "Standard Operating Procedure." SOP No. RWM-DR-015 (MEDEP 2015).
- Michigan Department of Environmental Quality. 2018. "Incremental Sampling Methodology and Applications." RRD-Resource Materials (MDEQ 2018).
- Ohio Environmental Protection Agency. 2016. "Incremental Sampling for Soils and Sediments." FSOP 2.1.3 (OEPA 2016).
- Washington Department of Ecology. 2019. "Sediment Cleanup User's Manual." Publication No. 12-09-057 (WDOE 2019).

In addition to ITRC IBT, there are also several commercial or private training courses available for interested parties.

7.2.1 Current use of ISM

ISM is most frequently used for surface soil, but it is also commonly used for subsurface soil, stockpiles, and sediment sampling. It is used with increasing frequency for defining the nature and extent of contamination, including brownfield redevelopment projects needed to define large areas (Figure 7-4).

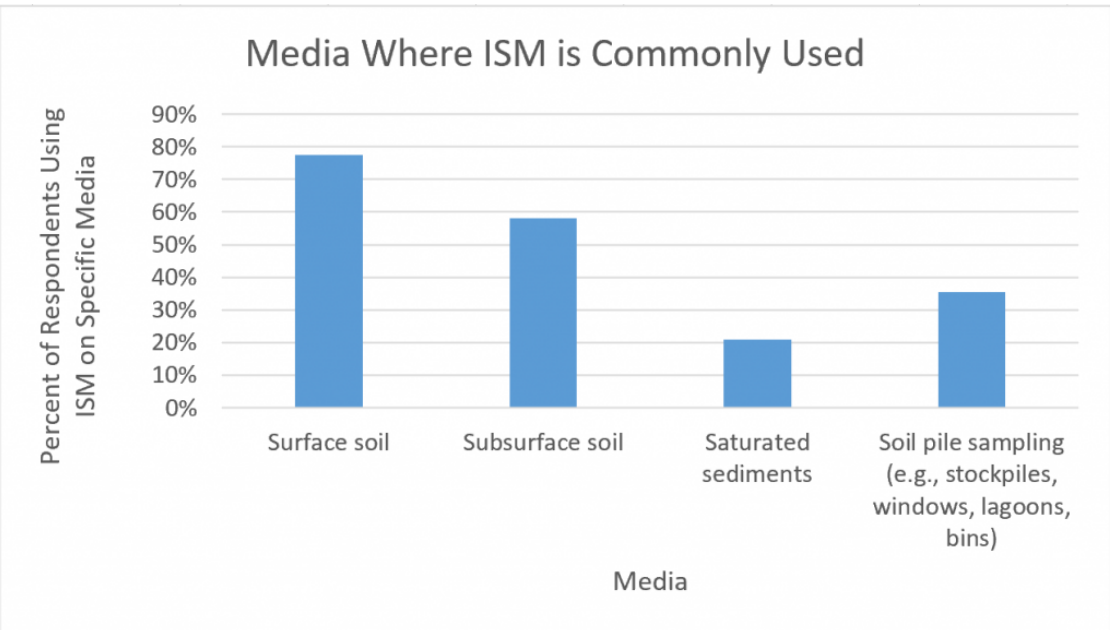

Figure 7-4. Media where ISM is commonly used.
Source: ISM Update Team Survey, March 2019.

ISM is also being used for many COCs, including metals, SVOCs, PCBs, TPHs, VOCs, and PFAS compounds as shown in Figure

7-5. Sections 3, 4, and 5 have further discussion on using ISM for VOCs and PFAS.

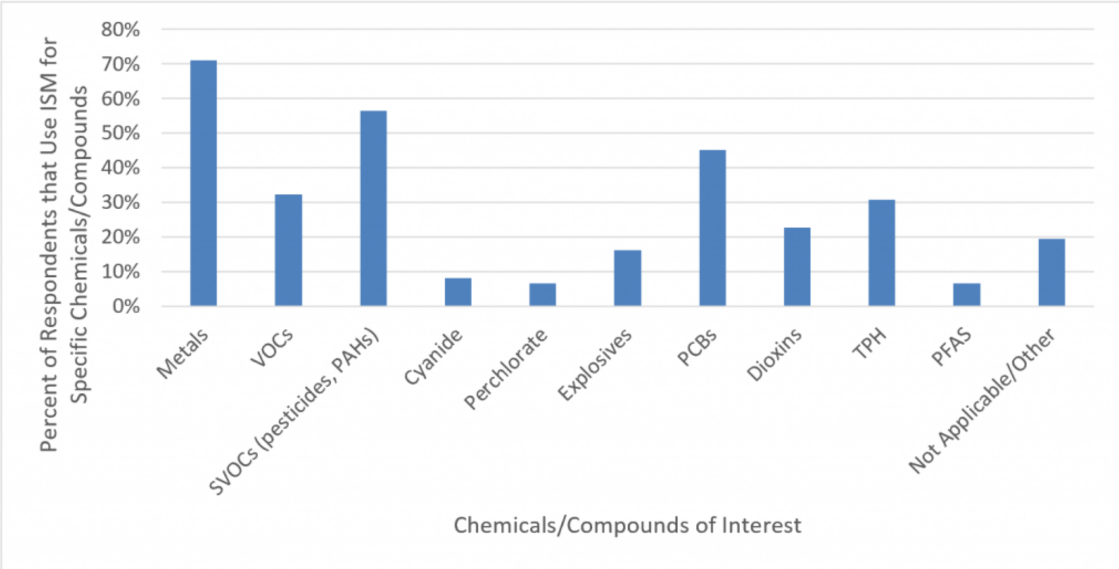

Figure 7-5. ISM's use for chemicals/compounds of interest.
Source: ISM Update Team Survey, March 2019.

7.2.2 Types of sites and uses of ISM

ISM can be used on residential, commercial/industrial, recreational, agricultural, and ecological sites. As such, ISM is most appropriate to make risk-based decisions on any volume of soil or surface area where a reproducible mean concentration is needed. Survey respondents indicated that they most commonly use ISM sampling in order by popularity to:

- determine if a DU met a regulatory cleanup criteria/cleanup level
- compare site data to published screening levels
- compare site data to site-specific human risk-based cleanup criteria
- compare site data to background concentrations
- determine baseline site screening levels
- determine if a remedial action met the site cleanup criteria (Figure 7-6)

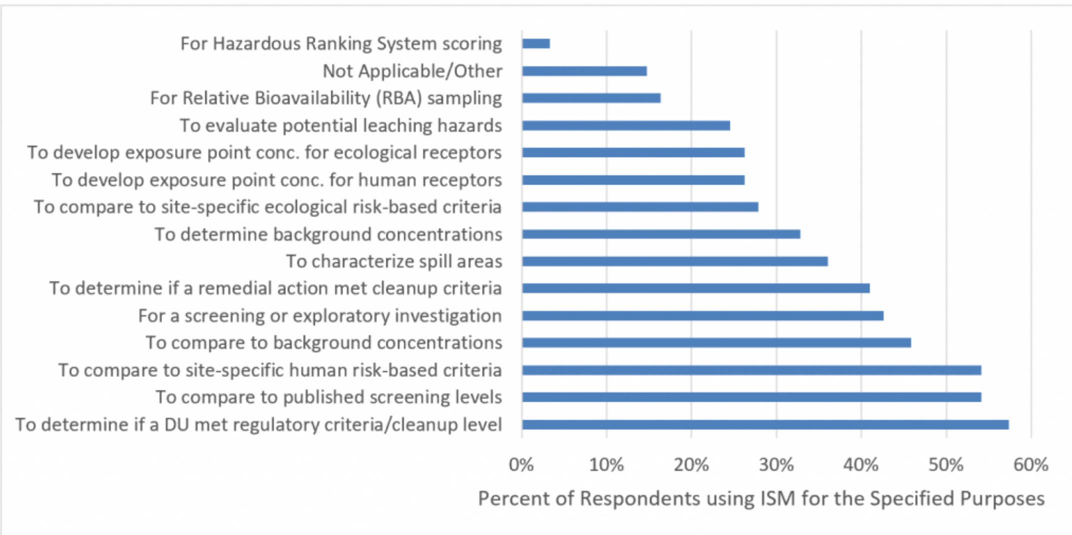

Figure 7-6. Current uses of ISM.
Source: ISM Update Team Survey, March 2019.

7.3 Factors Affecting Regulatory Acceptability

Regulatory acceptance for ISM use is primarily focused around certain concerns for accurate characterization of the nature and extent of contamination. There appears to be four common misconceptions:

- ISM cannot find areas of elevated concentrations.
- ISM will miss the maximum concentration.
- ISM 95% UCLs are unreliable.
- ISM cannot evaluate acute hazards.

Soil heterogeneities lead to increased data variability at spatial scales for which sample collection and analysis are performed (inches and grams), but we make decisions on spatial scales of cubic yards, acres, and tons.

Finally, there are barriers to ISM use related to programmatic or administrative requirements, including provisions for specific types of discrete samples, prohibitions on the use of any compositing techniques, or a lack of laboratory certifications or available facilities. Where there are statutory requirements that are incompatible with ISM, advocates need to work with state agencies over time to influence the development of updated regulations. In cases where the prohibitions are guidance (not regulation) or related to other programs at the agency, ISM practitioners may be able to advocate for ISM application.

7.3.1 ISM can find areas of elevated concentrations

- There is a common misconception that ISM cannot be used to define the nature and extent of contamination or find areas of elevated concentrations. This misconception is primarily based on historic composite sampling done inappropriately. ISM can in fact find areas of elevated concentrations when those areas' size and concentration are defined upfront, and the project teams focus on systematic planning, the DQO process, sample populations, and the delineation of DUs (Crumbling 2014, Hadley and Mueller 2012). To define the size and concentration of a significant small area of elevated contamination, an Excel spreadsheet tool can be used if the critical condition of a mature CSM is met. For an example and more details on this concept, see (Crumbling 2014). As presented in Section 3.1.5.2, statistically based sampling designs can be developed to determine whether localized areas of higher soil concentrations exist, even if the locations of such subareas within a larger site are unknown. The spacing of increments (and thus the number of increments needed to fill the DU's area) can be set to have a desired statistical probability of increments being collected from within an area of defined size for incorporation into the field sample. In this case, if the size of a potential subarea of elevated concentrations is specified, sampling can be conducted to determine whether one or more such areas exist within a DU with an objective degree of confidence and scientific defensibility. A free software program developed by PNNL called VSP is available to determine the increment spacing for the DU grid so as not to miss sampling from a significant small area of elevated concentrations within the DU. Additional information on VSP, as well as important assumptions and limitations for any statistical tools and those specific to VSP, are included in Section 3.1.5.2. Practitioners of ISM are cautioned, however, that typical SUs are going to be much smaller for these purposes, and there may be a need to assign more SUs, depending on the site. Therefore, costs should be carefully considered.
- The perception that ISM will obscure areas of elevated concentrations is untrue and has not been borne out in case studies. Properly planned and conducted ISM programs have been found to actually produce higher estimates of mean concentrations than traditional grab samples, in addition to producing a more representative estimate than a grab sample of the overall concentration in any collected sample (Brewer, Peard, and Heskett 2016).

7.3.2 ISM will not miss the maximum concentration

There is also a common misconception among the regulatory community that ISM will obscure, miss, or "dilute out" small areas with elevated concentrations. However, most regulatory decisions are based on the upper bound estimate of the mean concentrations of contaminants or 95% UCL, not the maximum soil concentration. In actuality, as discussed in Section 2.5.2, Section 2.5.3.2, Section 3.1, Section 3.2, and Section 8.3.2, because ISM has superior spatial coverage, there is a higher probability that the resulting DU mean will capture the effects of areas with higher concentrations. The dilution misconception is a question of scale and highly depends on sample support (volume of soil collected) both from the field and in the laboratory subsampling process. As discussed in Section 2, at the microscopic level, the maximum soil concentration for any chemical contaminant is always 100%, and the minimum is always 0%. The smaller the sample support, the less representative the sample it. Does that 1 g of soil running through the laboratory instrument truly represent the 3D volume of soil collected and awaiting a decision? Depending on the CSM and nature of the release, there is a high probability that a discrete dataset may not represent the true mean conditions in the field. In the end, both discrete and ISM samples (assuming the same sample preparation, subsampling, and analysis steps are utilized for both types of sampling) represent mean concentrations in each respective sample. Instead of just the 10-g discrete sample location, ISM sample results provide better estimates of the true population mean of the whole DU because of the increased spatial coverage, increased sample support, and rigorous sample processing (see Section 8.3.2). A spreadsheet tool for establishing the size and concentration of a significant small area of elevated contamination can be used if the critical condition of a mature CSM is met. A freeware software program called VSP is available to determine the increment spacing for the DU grid so as not to miss sampling from a significant small area of elevated concentrations within the DU. For more details on this concept and the tools available, see the White Paper (Crumbling 2014) and Section 3.1.5.2.

Concerns about exposure to higher concentration areas in a DU can often occur. Proper utilization of ISM is simply a matter of proper sample planning. For example, in an ecological risk assessment, a high-value receptor (an endangered species, fragile ecosystem, protected waters, and so on) may have a very small home range. This issue can be addressed in the DQO process (see Section 3.3).

7.3.3 ISM 95% UCLs are reliable

A common misconception that affects ISM use acceptance is related to generating statistical estimates of EPCs. Some regulators or stakeholders may believe that a single set of three replicate samples cannot be used to calculate a 95% UCL, but, in fact, ISM is a strongly controlled sampling regime that produces highly reliable 95% UCL estimates (see Section 3.2.4) and can be used for risk assessment or, as appropriate, comparison to regulatory values. This is in contrast to many discrete sampling methods, where statistical evaluations cannot be completed, are ignored, or show poor reliability. The use of a simple RSD analysis rule set ahead of time in the DQO process can reduce disagreement(s) and statistical uncertainties.

7.3.4 ISM can evaluate acute hazards

Although ISM is typically used to evaluate chronic risk, it has also been used to identify acute hazard source soils that the limited spatial coverage of discrete sampling had missed (Walsh et al. 1997). In “Composite Sampling of Sediments Contaminated with White Phosphorus,” by M.E. Walsh et al., CRREL Report 97-30. ISM was used to identify portions of a study area that would have likely resulted in acute ecological risk.

7.3.5 Regulatory guidance limitations

As mentioned earlier, there are barriers to ISM use related to programmatic or administrative requirements and/or guidance. These include provisions for specific types of discrete samples, prohibitions on the use of any compositing techniques, or a lack of laboratory certifications or available facilities.

In several known instances, ISM data are not allowed by rule and/or statute, but there may also be instances where the state/territory regulatory officials do not approve a sampling plan that uses ISM for other reasons. For example, 40 CFR § 268.40 requires that “no portion of the waste may exceed the applicable treatment standard, otherwise, there is evidence that the standard is not met,” where a portion is considered to be a discrete sample. For this reason, ISM cannot be used in RCRA hazardous waste disposal decisions. Moreover, many state petroleum leaking underground storage tank (LUST) programs specify discrete sampling and will not accept ISM samples.

Where there are statutory requirements that are incompatible with ISM, advocates need to work with state agencies over time to influence the development of updated regulations. In cases where the prohibitions are guidance (not regulation) or related to other programs at the agency, ISM practitioners may be able to advocate for ISM application.

7.4 Benefits to Foster Regulatory Acceptance of ISM

Incremental sampling is a powerful tool for making sound decisions about soil contamination. Optimal decisions need to be based on data that are representative, reproducible, and defensible. Soil heterogeneity creates challenges for interpreting analytical data from discrete sampling, but these challenges can be diminished by using ISM, which provides a representative sample and an average concentration over a defined soil mass (or DU), making the ISM data reproducible and defensible.

Regulators want data to answer these common questions:

- What volume of soil in the field was the sample(s) intended to represent?
- Were the samples collected in such a way so that there is a good chance they actually do represent field volume?
- What evidence is there that the representativeness goal was achieved?
- Was the sample analyzed in a way that its representativeness was maintained (meaning, was subsampling variability controlled)?

  - Does the QC data support the initial CSM and sampling design?
    - Good replication implies “yes” and increases confidence that data results represent the DU.
    - If replication is poor, the QC process may help identify if more increments are needed to manage heterogeneity, or if sieving or grinding need to be considered in consultation with the laboratory. ISM provides advantages over discrete sampling, for example, when there is not a reason to bias a sample toward a specific known release area. DUs help avoid the problems associated with typical composite sampling. ISM is appropriate any time you need to determine a mean concentration of a volume of soil. The DQO process helps answer two key questions: (1) why sample, and (2) what the result represents. It also provides reproducibility of samples upfront versus after getting the results, which is key to scientifically sound and defensible decisions.

Soil heterogeneities lead to increased data variability at spatial scales for which sample collection and analysis are performed (inches and grams), but we make decisions on spatial scales of cubic yards, acres, and tons. ISM gives representative, reproducible, defensible data at a lower cost than traditional samples with less contention after getting the results, which leads to better decision-making.

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