

Corrective Action Tailored Oversight

Tailored Oversight



Today We Are Going To Discuss

- Goals of Oversight
- Difference Between Oversight and Tailored Oversight
- Tools of Oversight
- Sources of Error and Other Drivers of Oversight Needs
- General Tailoring Factors and Strategies

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Oversight

*The management of all activities
related to the Corrective Action
process*

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Taken from: Corrective Action Oversight EPA/ 9902.7, January, 1992



Implicit Goals

- To limit the regulatory agency's uncertainty regarding how the site has arrived at its conclusions
- To provide the regulatory agency with its own quality control on data collection and interpretation

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Appropriate oversight will leave measurement error and the natural variability of the release and the affected environment as the only uncertainties affecting the data carried into decision making regarding the risks posed by the site and what actions should be taken to control those risks.

- In other words, we will not be faced with significant doubts regarding why and how the site collected data or how they have interpreted that data.
- Instructor Notes: Stop here to discuss whether meeting these goals requires engaging in the same set of activities at each site.



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- Site-specific program based on facility-specific conditions and capabilities

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Review of Available Oversight Tools

1. Observation
2. Interview
3. Audits/Inspections
4. Split Samples and Parallel Samples

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Oversight tools can be employed through the use of EPA staff, Contractors, or other stakeholders (e.g state environmental agencies). Available tools include:

- Observation: As simple as it sounds. Be at the RFI, CMS, or CMI activities and watch how they are executed.
- Interview: Question the personnel directly involved in the task of interest to gauge their level of familiarity with relevant SOPs or other standards of practice and their general level of experience and expertise at the task.
- Audits/Inspections: This involves using senior, more experienced personnel who have performed a detailed review of the project specific work plan and QAPP and, using the same techniques as tools 1 and 2, conduct a more thorough review of the tasks of interest. An audit is typically conducted after the fact and rely more heavily on the written documentation. Major problems caught through this technique may require re-opening earlier project stages.
- Split samples and parallel samples: Split samples are samples collected by one party and then divided and analyzed under the control of two or more different parties. Parallel samples are samples that come from a single sample location but are collected and analyzed by different parties. Both create independent data, but it can be difficult to determine if differences between data sets come from natural site heterogeneity or sample/analytical error.



Review of Available Oversight Tools

5. Review
6. Re-interpretation
7. Analytical QA/QC Techniques (blanks, duplicates, spikes, etc.)
8. Self-implemented Administrative Controls (e.g., certifications, sign-offs, custody chains)

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- Review: Activities such as performing data validation, checking self-consistency of data sets, sample calculations, checking applicability of any calculations or manipulations performed with the data manipulations, and evaluating the logic of arguments made with the data, verify that the data is of the quality that it is asserted to be, that information derived from the data is also representative of conditions at the site and that any conclusion on the nature, extent and significance of releases at the site flow logically from the available data.
 - Re-interpretation: This requires senior personnel taking the same raw data used by the facility and seeing if alternative interpretations fit the available data.
 - Analytical QC tools (standards, blanks, duplicates, spikes, etc.): There are an array of tools available to assure the integrity, accuracy, and precision of samples. These are not implemented by EPA directly but provide us necessary evidence that the facility has met the data quality objectives for each of their activities. These tools are well discussed in numerous EPA guidance documents.
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- Self-implemented administrative controls: Requirements such as Certifications and Sign-offs are an indirect oversight tool. They provide a sense of our presence to upper management of the facility undergoing Corrective Action



Factors To Consider for Selecting Strategy

- Facility and Consultant Expertise
- Facility and Consultant Performance History
- Facility Financial Assurance
- Administrative Controls Available
- Data Quality Objectives
- Uncertainty of Sampling, Analytical, and Interpretation Techniques
- Stakeholder Concerns

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- The facility and/or their contractors demonstrated level of expertise in dealing with questions of the complexity posed by a given site will guide what level of agency oversight is required and indicate in what areas of the RFI/CMS/CMI process it is most needed (i.e field sampling, sample analysis, data interpretation, plan formulation, or project management).
- Separate from the question of level of expertise is the quality of work performed by the facility and/or consultant.
- If the financing of the Corrective Action Process is not secure this may enhance our need to insure that work is performed correctly on the first attempt.
- The mechanism we have in place to drive Corrective Action (e.g. permit, order, self-directed) and our ability to revisit decisions in the future (audit programs) may govern the form and level of oversight we need at this time.
- The quality objective defined for the task will influence the level of oversight required for the task.
- Innovative techniques, established techniques that are known to be error prone, or techniques whose limit of resolution is close to project action levels, will generally warrant a higher level of oversight.
- Oversight level can also be adjusted to meet the comfort level of other stakeholders involved in the process. This presumes efforts to convey the basis of our assessment of oversight needs have left a reasonable, but unresolvable, difference of opinion.



The SYSTEM functions as if it believes that...

Methods = Data = Decisions

Screening Methods → Screening Data → Uncertain Decisions

"Definitive" Methods → "Definitive" Data → Certain Decisions

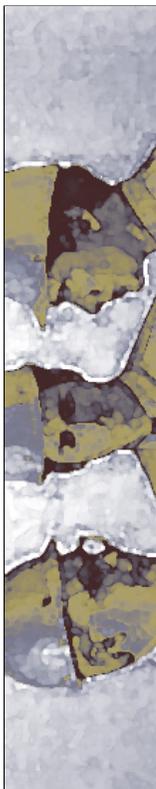
Fail to Distinguish: Analytical Methods from Data from Decisions

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For example, Data Quality Objectives Process for Superfund: Interim Final Guidance (Sept. 1993), page 42: "Screening data are generated by rapid, less precise methods of analysis with less rigorous sample preparation."

Page 43: "Definitive data are generated using rigorous analytical methods, such as approved EPA reference methods. Data are analyte-specific, with confirmation of analyte identity and concentration. Methods produce tangible raw data (e.g., chromatograms, spectra, digital values) in the form of paper printouts or computer-generated electronic files. Data may be generated at the site or at an off-site location, as long as the QA/QC requirements are satisfied. For the data to be definitive, either analytical or total measurement error must be determined."



Reality: Data used for Project Decision Making is Generated on Samples

Perfect Analytical Chemistry + **Non-Representative Sample**

↓

“BAD” DATA

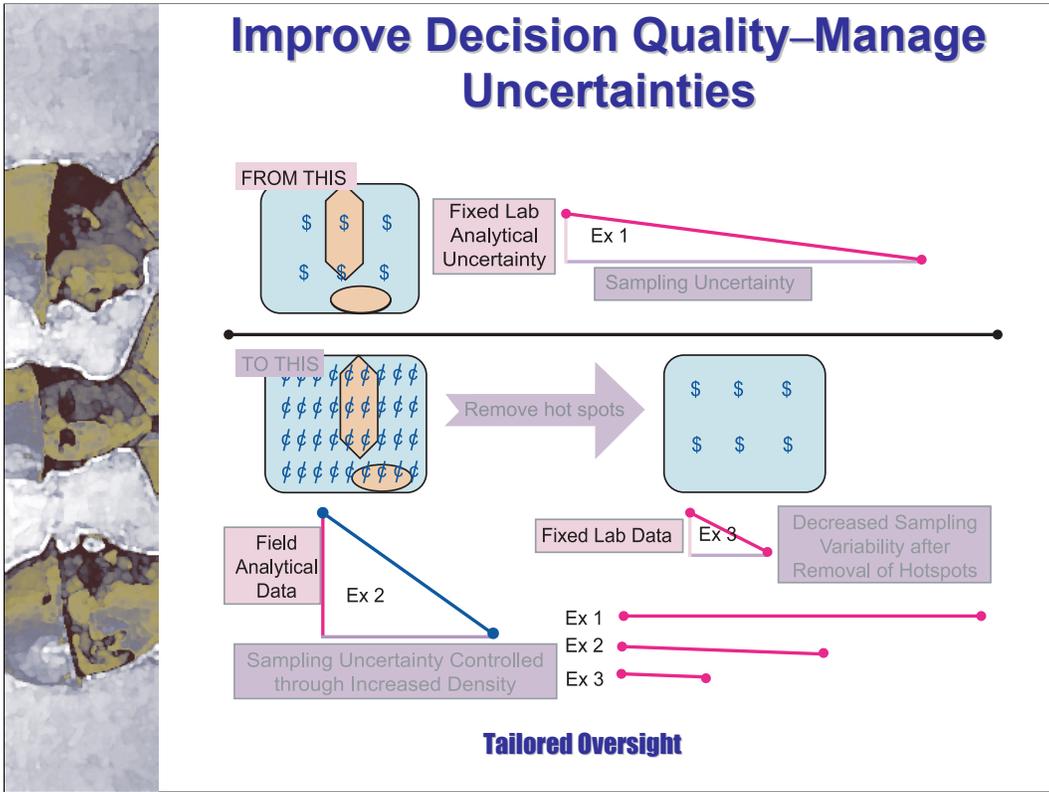
**Distinguish:
Analytical Quality from Data Quality**

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This is an oversimplified model because reality is much more complicated. For example, you can have perfectly accurate analyses, but if the sample itself was not representative of the feature under investigation, the outcome is BAD data. It is “bad data” because data generated on non-representative samples can be misleading (i.e., leading to erroneous conclusions).

The issue of sampling representativeness, and the challenges posed by heterogeneous environmental media have been discussed for years in many different forums. Analytical scientists understand this concept very well. But it is not understood by many others in the environmental field, including policy-makers, program managers, and project managers.

Unfortunately, by focusing so much energy on prescriptive analytical methods, there is the widespread misconception that “highly accurate analyses automatically produce accurate data.” In addition, the terminology we have developed over the years has become ingrained with unspoken assumptions that reinforce this misconception.



In contrast to the way definitive methods are conventionally used (upper panel), field analytical methods can be used to increase the sampling density, which permits rigorous management of sampling uncertainty (middle panel). Reliable site decisions can then be made (such as whether to rigorously delineate and remove hotspots of contamination). If needed to meet regulatory requirements for final site closure, follow-on analysis of samples can be performed by definitive, analyte-specific methods. The selection of samples for final closure decisions builds on the previous characterization decisions or cleanup actions to markedly decrease sampling variability in the data set used to support site closure or decisions about regulatory compliance.



The Point?

- Analytical error has received scrutiny through the legal process and appropriate error controls have become institutionalized
- The uncontrolled errors occur in:
 - Where the samples are collected
 - How the samples are collected
 - Interpretations of the meaning of the data

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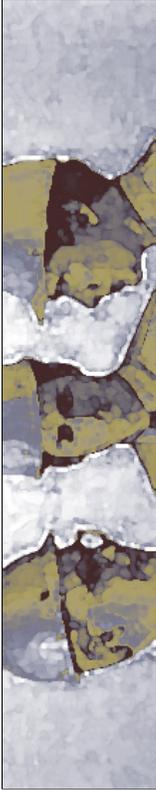


Three Basic Strategies for Tailoring Oversight

- Strategy A: Highly randomized oversight of a low to moderate percentage of CA activities
- Strategy B: Targeted oversight of low to moderate percentage of CA activities
- Strategy C: Oversight of a high percentage of CA activities

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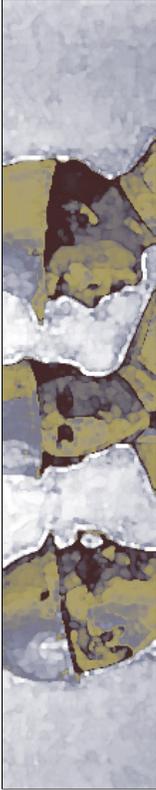


Strategy A: Highly Randomized Oversight of a Low to Moderate Percentage of Activities

- Check on unanticipated sources of error
- Useful for sites with:
 - Demonstrated expertise and good performance history
 - “Lower threshold” data quality needs
 - Proven, reliable data collection and interpretation techniques

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Strategy B: Targeted Oversight of Low to Moderate Percentage of Activities

- Check on specific, sensitive questions
- Useful for sites with:
 - Demonstrated expertise and good performance history
 - Specific questions with “high threshold,” rigorous data quality needs
 - Specific, difficult to execute data collection and interpretation techniques
 - Third parties sensitive to specific questions

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Strategy C: Oversight of a High Percentage of Activities

- Check on anticipated error
- Useful for sites with:
 - No established track record on performance or expertise
 - Financial/administrative need to get things right the first time
 - Difficult data collection (e.g., sensitive techniques, complex site, subjective interpretative techniques)
 - Third parties sensitive to many questions

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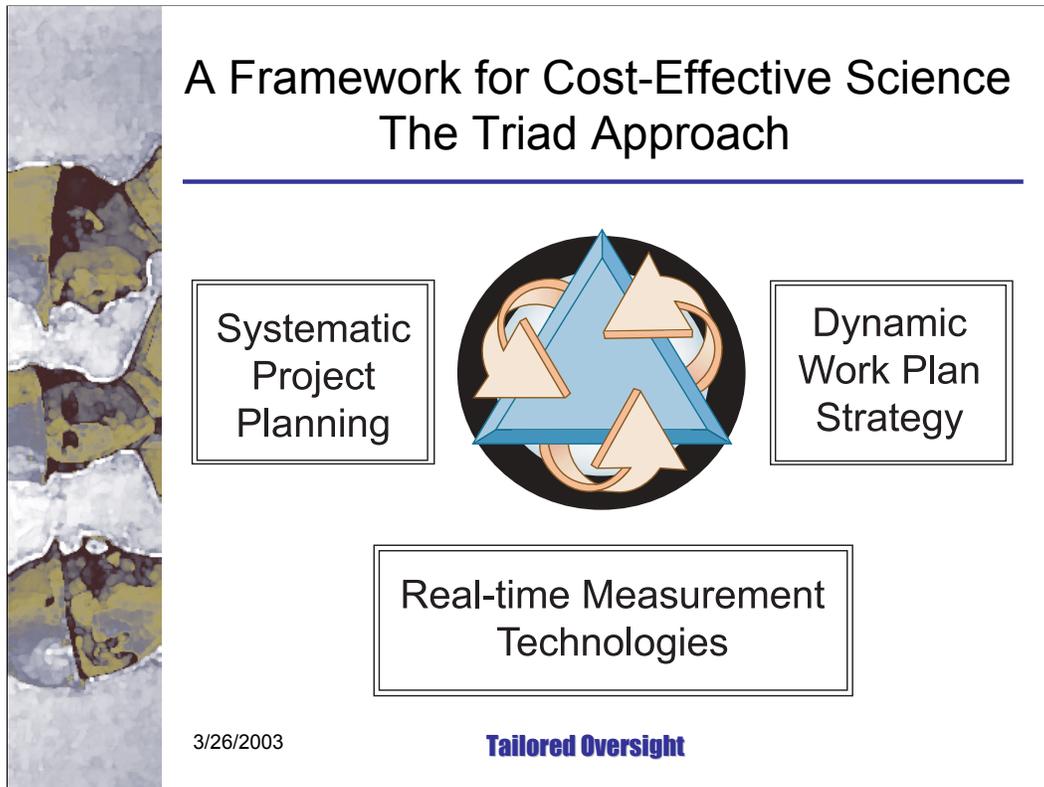
A Fourth Strategy:

- Move out of oversight and into partnership—use the Triad Approach

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Note: This and the next slide are borrowed from the TIO presentation on the Triad Approach.



The conceptual framework to modernize site cleanup: Triad Approach

The 3 Legs of the Triad Approach:

Systematic Project Planning

- Take the time to clarify project-specific and decision-specific issues with all stakeholders
- Articulate clear project goals and the decisions (and the tolerable uncertainties) that must be made to bring the project to a satisfactory resolution
- Evaluate potential causes for making decision errors; identify uncertainties
- Develop strategies to manage uncertainties so that decision errors can be avoided
 - Chart best course to reach project goals using conceptual site models (CSMs) that help identify information gaps (i.e., uncertainties) and clarify goals
 - Use multi-disciplinary technical team for project planning and implementation

Dynamic Work Plan Strategy

- Real-time, decision-making in the field by experienced technical personnel allows for a seamless flow of site activities = fewer mobilizations
- Regulator-approved decision trees guide data gathering to support rapidly and efficiently evolving the CSM to maturity

Real-time (or near real-time) Data Availability

- Generally will mean on-site analyses
- Support implementation of dynamic work plans
- Permit management of sampling uncertainty
- Method/technology selection and QC design based on integrating the intended data uses with available technologies that can meet the turn-around time and “field-friendliness” needed to support the dynamic work plan.
- Mix-and-match analytical techniques according to specific needs (e.g., field and traditional lab methods; direct push in situ detections and an on-site lab; etc.)

Improving the cost-effectiveness of hazardous waste site characterization and monitoring” Available at <http://clu.in.org/tiopersp/>

The Triad approach is a work strategy framework for economically managing project decision uncertainties by drawing on the technical knowledge and experience gained over the past 20-30 years of hazardous site cleanup. The Triad approach proactively exploits new characterization and treatment tools, using work strategies developed by innovative and successful site professionals.



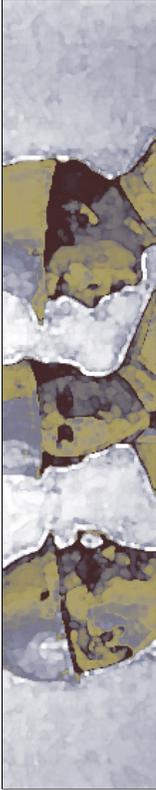
Tailored Oversight Exercise

- Task: Plan oversight activities for 4 sites for one year
- Four site descriptions follow

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Instructor Notes: This is designed as a small group exercise though the group is taking on the role of being one person, the regulatory agency project manager. The task is to plan oversight activities for four sites for the coming fiscal year. The exercise is conducted in two rounds. In the first round sites Triple A Acrylics & Cambridge Gear Works are close enough for day trips but Barnum Switches & Dontno require overnight travel. The group has \$140,000 in contract support to spread across the sites.

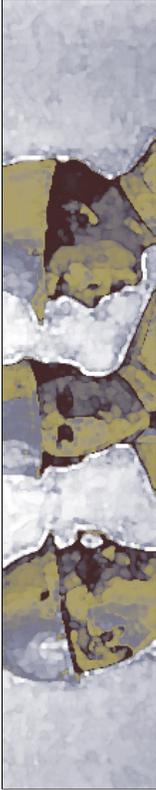


Site: Triple A Acrylics

- Removing PAH contaminated soil using immuno-assay test kits to guide limits of excavation with a low density of confirmation samples analyzed by a lab.
- Site successfully used this approach with one other area.
- Company has good track record on compliance with 3008 (h) order and a consulting firm of generally good reputation doing clean-up work.

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Site: Barnum Switches

- Conducting ongoing monitoring in their network of 15 wells.
- Lab that analyzed samples for last 2 years has been indicted for misreporting holding times.
- Barnum changed back to lab previously used but members of the public have expressed concern on reliability of data that has been generated for the site.

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Site: Cambridge Gear Works

- New site for you that has just submitted phase I of ecological risk assessment which awaits review.
- Site conducting further efforts at some stations based on their interpretation of phase I data.
- An at-risk fast track approach implemented by previous project manager.
- Have not yet established working relationship with site but previous project manager says “easy to work with” and their consulting firm is “top-notch.”

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Site: Dontno

- Have worked with site for many years to get approvable work plan in place.
- Facility did not “get it” as to what was required of them.
- This year will begin implementing work plan and will pull one UST with previous contamination associated with it.

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Additional Resources

- Corrective Action Oversight, USEPA/OSWER EPA/9902.7 January 1992.
- RCRA Corrective Action Plan, USEPA/OSWER EPA/520-R-94-004 May 1994
- Triad Approach: www.clu-in.org/triad/
- Contact: Ernest Waterman, EPA R1, waterman.ernest@epa.gov 617/918-1369

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