

KEY PERFORMANCE FACTORS for Laboratory Selection

HOW TO: Choose a Laboratory for the Analysis of Environmental Samples

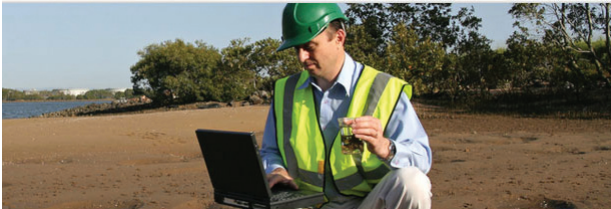
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Selecting qualified laboratories for environmental sample analysis can be a daunting and expensive process. The cost of poor selection can have broad impacts on analytical data and remedial costs if the selection process is conducted without regard to the key factors reflective of a solidly performing laboratory.

Commercial programs may offer shortcuts to improved laboratory selection at reduced costs using narrow, imprecise methodology and criteria that is subject to interpretation errors. Abbreviated approaches are contrary to the comprehensive national approach developed for the accreditation of environmental laboratories.

Laboratory services purchasers should always employ selection processes that incorporate key laboratory qualification elements. Typically, this process relies upon existing laboratory qualification information that is available from the laboratory without cost.

An effective laboratory selection process must be comprehensive, incorporating the following key elements. This approach assures that selection is based on essential laboratory performance factors instead of single factors which may be misrepresented or misinterpreted:



Identify Potential Candidates. Candidate laboratories that are capable of delivering the data and services needed by the purchaser are identified. These laboratories are typically identified based on size, reputation and geographical proximity to the buyer or buyer's project. Qualified consultants can contribute recommendations based on their experiences.

The entire laboratory qualification process can be managed internally or through an engineering or quality assurance consultant.

Pre-Qualification. Candidate laboratories should be asked to submit a qualifications package tailored to the buyer's needs. These qualifications are evaluated by individuals experienced in laboratory accreditation and operations.

- **ACCREDITATIONS.** A list of accreditations and accreditation venues should be provided. The buyer compares this information to his accreditation needs for the analysis being performed. An accreditation is the laboratory's license to report regulatory data and is granted on a method, matrix and analyte basis.
- **PRODUCTS.** Product listings, including all sample preparation and analysis methods, data delivery formats, including electronic products must be provided. Laboratory capability should be evaluated in relationship to project needs, validation needs or regulatory agency requirements.
- **CAPACITY.** Laboratory capacity data provides the buyer with a measure of a laboratory's size with quantitative information on their ability to deliver data for specific analyses. Turnaround information informs the buyer how quickly data is delivered. Assuring that a laboratory has sufficient capacity to perform the required analysis within a desirable turnaround period is essential to project success.
- **EXPERIENCE.** The laboratory's staff credentials and experience reflect broad, in-depth knowledge of environmental analytical chemistry and longevity with the organization. A relevant project experience summary to obtain a flavor for the types of projects the laboratory performs provides a perspective on their ability to perform to the buyers needs.
- **QUALITY SYSTEM.** All laboratories maintain a documented quality system manual, which they will provide to clients freely on request. The majority of laboratories have NELAC quality systems which are based on ISO/IEC Standard 17025. Descriptions of active quality system programs should be evaluated to determine if they reflect industry standard, regulatory and buyer expectations and that the system fosters an environment where data of known and documented quality is being produced.
- **STANDARD OPERATION PROCEDURES.** Standard operating procedures (SOPs) are required for all laboratory activities. Key process SOPs that are within the scope of analytical activities required for client projects can be requested and should be reviewed to assure that the laboratory's methods applications are compliant with the published method and laboratory activities conform to standard practices.
- **ACCREDITATION AUDIT.** Accredited laboratories receive a comprehensive on-site assessment from their Accrediting Body (AB - State). The laboratory will provide a copy of the latest laboratory audit performed by their primary AB. Laboratories are required to prepare corrective action responses to audit findings, which they will also provide. Audit findings can be evaluated to determine if they could jeopardize data or program execution.
- **STATISTICAL PERFORMANCE DATA.** Laboratories generate annual statistical data based on previous performance that defines the criteria which is used to assess method control. This data includes performance ranges for quality control parameters and method detection limits for every method. It can be obtained for methods of interest and reviewed to verify that the laboratory's method execution complies with expected performance requirements and method sensitivity is sufficient for buyer needs.
- **PERFORMANCE METRICS.** Performance metrics provide an overview of delivery timeliness, which can be essential to meeting regulatory reporting commitments or limiting downtime awaiting analytical data for remedial activities. Performance metrics can be extended to other performance areas including error rates and client complaints. Each provides specific information regarding laboratory performance and client satisfaction.



- **PAST PROFICIENCY TEST (PT) SCORES.** Laboratories regularly perform comprehensive PT studies to maintain their accreditation. They frequently are requested to provide PT data reports to clients, which they do without cost. Each PT vendor employs a different format to report PT results. Although general information about a laboratory's performance can be obtained from PT scores, they are of limited value in demonstrating a lab's true performance in "real world" situations. The international community recommends that PT data not be used to rank laboratories in ISO/IEC Guide 43-1:1997 (E) 6.6.5 stating that "Reporting of performance by ranking laboratories in a table according to their performance is not recommended in proficiency testing."
- **CLIENT SERVICES SYSTEM.** The relationship between the buyer and the laboratory is critical to project management. Understanding the processes a laboratory uses to manage clients and their projects indicates how that client can be expected to be treated. The client services system should be clearly documented and reflect the level of communication the client expects from the laboratory.
- **REFERENCES.** Buyer assessments of laboratories provide valuable information on the laboratory's performance and relationships with clients even though the feedback may be biased by the laboratory's selection of the reference. Nonetheless, feedback on the attributes and shortcomings of a client's interaction with the laboratory may be obtained through brief interviews with the referenced individual.

analysis conducted by the laboratory is traceable and can be reconstructed upon challenge.

- **SAMPLE MANAGEMENT.** Proper sample handling upon laboratory receipt is essential to the production of valid environmental data. Sample management activities should be assessed to assure that incoming samples are properly documented on arrival, are checked for thermal and chemical preservation, maintained under custody, properly preserved until analyzed and disposed in accordance with Resource Conservation and Recovery Act requirements. Improper sample management practices may invalidate data and/or create waste disposal liabilities for the buyer.
- **ANALYTICAL COMPETENCY.** Assessing analytical competency through an evaluation of paper documents only provides limited information on the laboratory's application of a method. Assessments of individual methods of importance to the buyer can be evaluated through analyst interviews, designed to obtain information on sample handling at the bench, method application, data review, documentation and corrective action for quality control failures. Assessments include a review of relevant data packages to obtain a first hand view of the procedures, process and outcome of all data production activities.
- **HEALTH & SAFETY.** A strong health and safety program not only protects individual employees, but also protects the laboratory from liability associated with insufficient health and safety training. This philosophy can be extended to the buyer with a strong health and safety program insulating them from liability as well. It also reflects a higher level of operational discipline consistent with a well functioning quality assurance system.



Although there are strong economic incentives to employ qualification programs that rely on limited factors for the basis of laboratory selection, these types of processes are likely to result in the selection of unqualified organizations because they fail to consider essential information that contributes to the accreditation process. Accordingly, it is essential to rely on a laboratory selection process that is based on an accreditation system which is designed to foster the generation of environmental data of known and documented quality.

Site Visits. Sufficient information to qualify a laboratory can be obtained through a pre-qualification information package. However, it behooves buyers to conduct a formal laboratory site visit to verify operational functionality and the quality system described in the pre-qualification package. Site visits can be as brief or as comprehensive as the buyer desires and can also take the form of a qualification audit where the laboratory is evaluated to existing accreditation and performance standards.

- **QUALITY SYSTEM VERIFICATION.** Verify the functional elements of the quality system with the laboratory demonstrating through documentation or action that the system is in use or functional. Verifying documentation practices assures that all



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