

LABORATORY AUDIT SERVICES

Project Highlights:

- Multi-national Project
- Qualification of Laboratories for Multi-national Corporation
- Design of four step qualification process:
- Pre-selection
- Paper Audit
- Physical Audit
- Action Items
- Data Traceability
- Check for Analytical Consistency between Analyses

LABORATORY APPROVAL PROGRAM

International Analytical Group, Inc. (IAG) was contracted by a multi-national corporation with operations in Latin America and the Caribbean to design a Laboratory Approval Program to determine which local laboratories could provide quality environmental services for the specific needs of the corporation.

Given the vast area of operations and to minimize time and money expenditures, IAG divided the qualification process into four steps: pre-selection, paper audit, physical audit and action items. The pre-selection process involved research with local personnel, environmental consultants, universities, etc. on local environmental laboratories that could potentially provide services to the corporation. Once the potential laboratories were selected, IAG sent the selected laboratories a questionnaire it designed to determine if the

laboratories had the qualifications to merit a physical audit. The questionnaire covered areas such as: infrastructure, analytical and safety equipment, technical personnel, certifications and/or accreditations, and safety culture. The physical audit verified equipment and physical plant layout, personnel qualifications, laboratory quality systems and standard operating procedures, safety equipment and practices, local and/or international certifications, sample handling procedures, etc. In addition, during the physical audit, several samples were picked at random and traced "from cradle to grave", as a way of tracing the actual operating procedures and analysis of the data. Based on the results of the physical audit, IAG either recommended approval of the laboratory or provided a list of corrective actions for the laboratories to meet in a des-



ignated time frame. Approval depended on implementation of the corrective actions. The Corporation's project manager gave the final approval.

DATA REVIEW, VALIDATION AND CHECK FOR ANALYTICAL CONSISTENCY

IAG reviewed a completed laboratory report that had all the analyses of interest to the Corporation. The analytical data was reviewed with regards to accuracy and compliance with pertinent Quality Assurance/Quality Control (QA/QC) parameters, the analytical records were checked for the particular

samples reported, the chain of custody records were reviewed, holding times were verified, the raw data for the analyses was reviewed. The data from the different analyses was compared to data from related analyses to ensure consistency between the analyses. In addition, IAG reviewed the laboratory's

records to verify the "traceability" of the reported results.