Example Generic Laboratory Audit Checklist

(This checklist is supplemented by additional checklists that are specific to each type of analysis)

Laboratory Name	Date of Evaluation	Name and Affiliation of Evaluator(s)

Personnel		
Role	**Name**	**Comments**
Project Manager (responsible for overall technical effort) Normal qualifications: Masters degree or equivalent Required Experience: *(Insert specific project requirement, if any.)*		
Quality Assurance Officer (responsible for QA of technical effort) Normal qualifications: Masters degree or equivalent Required Experience: *(Insert specific project requirement, if any.)*		
Data Reporting/Delivery Officer (responsible for organization and delivery of data) Normal qualifications: B.S. or equivalent Required Experience: *(Insert specific project requirement, if any.)*		

Item to be Evaluated	Yes	No	NA	Comments
Part 1: Organization, Management & Personnel				
Is a laboratory organization chart or other information available listing staff organization and responsibilities? Does it identify the QA Officer and all the relationships between QA Officer, technical operations and support staff?				
If the laboratory is part of a larger organization, are there any organizational arrangements that could cause a conflict of interest?				
Does the laboratory have a Health and Safety program in place for all employees?				
Does laboratory have policies or procedures to ensure client confidentiality and proprietary rights including procedures for protecting the electronic storage and transmission of results?				
Do the laboratory managerial and technical personnel have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system, procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures?				
Are the education and technical background of all personnel documented?				
Does QA Officer have authority to “stop work” and initiate action to prevent or minimize quality system variances?				
Is there a formal QA manual in place and does the QA Officer maintain the current quality manual?				

Item to be Evaluated	Yes	No	NA	Comments
Does the QA Officer (and/or his/her designees) notify laboratory management of deficiencies in the quality system and monitor corrective action?				
Does the quality manual define the roles and responsibilities of technical management and the quality manager?				
Was the QA Officer available during the audit?				
Part 2: Physical Facilities				
Is the laboratory maintained in a clean and organized manner?				
Are laboratory coats, goggles and gloves worn in the laboratory?				
Are eye wash system, chemical shower, fire blanket, fire extinguishers, acid/base spill supplies easily accessible?				
Does laboratory have a sample receipt area that is an adequate, contamination-free, well ventilated work space provided with chemical resistant bench to for receipt and safe handling of samples?				
Does laboratory have a designated storage area that contains sufficient refrigerator space to maintain unused sample volume for 90 days after submission of a complete data package. Note: Samples, extracts, and standards shall each be stored separately.				
Are hoods equipped with charcoal and HEPA filters?				
Does laboratory contain a designated area for standards preparation that consists of a glove box, designated hood, or isolated area?				
Does laboratory have a Data Handling and Packaging area that provides adequate work space to compile, package and ship analytical data and other deliverables as required?				
Is there effective separation between neighboring areas in which there are incompatible activities?				
Are the solvent storage cabinets vented or located in such a way as to prevent possible laboratory contamination?				
Is access to and use of areas affecting the quality of the environmental tests controlled?				
Part 3: General Laboratory Equipment				
Does the quality system documentation include or reference a list of all major equipment? Is all major equipment uniquely identified?				
Are maintenance logs kept for lab equipment/instrumentation?				
Are manufacturer's maintenance manuals available?				
Does the laboratory have a list of preventative maintenance procedures and schedules?				
Is service for replacement parts for equipment readily available?				
Are contingencies adequate in case of major breakdown?				
Does the lab own, or have access to, an NIST-traceable factory certified thermometer?				
Is a copy of factory certificate for the thermometer available for inspection?				

Item to be Evaluated	Yes	No	NA	Comments
Is a record of thermometer calibration maintained?				
Does each working thermometer have a unique identifying number?				
Are calibration of glass/mercury thermometers checked annually (dial thermometers quarterly) at the temperature used against a reference NIST-traceable thermometer or equivalent?				
Prior to use on each working day, are balances, ovens, refrigerators, freezers, and water baths checked in the expected use range, with NIST-traceable references where commercially available?				
Is the flow of the hoods periodically checked and permanently recorded?				
Are instruments, including GC/MS pumps, vented into hoods or control devices such as charcoal traps?				
Is an SOP available for glassware washing?				
Is there a separate designated area for cleaning glassware?				
Are adequate glassware cleaning procedures posted in that area?				
Is distilled or deionized water used for glassware final rinse?				
Are mechanical volumetric dispensing devices including burettes (except Class A glassware) checked for accuracy on at least a quarterly use basis?				
Is equipment that has been subjected to very high concentrations, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service?				
Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded, or otherwise identified to indicate the status of calibration including the date when last calibrated and the date or expiration criteria when recalibration is due?				
Part 4. Quality System Components				
4.1 Standard Operating Procedures (SOPs)				
Does the laboratory maintain SOPs for the following procedures: sample handling logistics, extractions, concentrations, digestions, analyses, standards preparation, instrument repair, automated and manual report generation?				
Does the laboratory maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods?				
Does each SOP clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority?				
Are all relevant SOPs present and current?				
Do the project personnel have SOPs for all of the required activities?				
Are SOP copies located within easy access of the appropriate work area?				
Is the responsibility for reviewing and updating SOPs assigned to the QA Officer? If NO, who has the responsibility?				

Item to be Evaluated	Yes	No	NA	Comments
4.2 Routine QC Requirements				
4.2.1 Initial Precision & Recovery (IPR)				
Are acceptable IPRs performed prior to sample analysis?				
Is the IPR requirement included in SOPs?				
Is an IPR repeated each time there is a change in instrument type, personnel, or method?				
4.2.2 Method Detection Limit Study (MDL)				
Are MDLs performed prior to sample analysis by that method?				
Are MDLs generated using the specifications in 40 CFR part 136, Appendix B, or as specified in the individual methods?				
Are MDLs updated annually?				
Is the MDL requirement included in SOPs?				
4.2.3 Initial Calibration				
Are initial calibrations required in SOPs for all colorimetric, spectrophotometric, potentiometric, coulometric, turbidimetric and instrumental analyses?				
Are the following specific calibration requirements included in the appropriate SOP: Equipment Identification, Calibration procedure (including all formulas and calculations), Acceptance criteria including accuracy and precision requirements, Corrective action for failed criteria, Calibration frequency, and List of required standards?				
Is initial instrument calibration used directly for quantitation; is continuing instrument calibration verification used to confirm the continued validity of the initial calibration?				
Are the details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria, and associated statistics included or referenced in the test method SOP?				
Are all initial instrument calibrations verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots?				
Are the criteria for the acceptance of an initial instrument calibration established, e.g., correlation coefficient or relative standard deviation?				
Are results outside the working range reported with defined qualifiers or flags, or explained in the case narrative?				
If the initial instrument calibration results are outside established acceptance criteria, are corrective actions performed and all associated samples reanalyzed? Or, if reanalysis of the samples is not possible, are data associated with an unacceptable initial instrument calibration reported with appropriate data qualifiers?				

Item to be Evaluated	Yes	No	NA	Comments
4.2.4 Initial Calibration Verification (ICV)				
Is ICV required for all calibrated instrumentation, including analytical balances used in gravimetric determinations?				
Is ICV concentration at approximately the mid-point of the calibration range?				
Are the ICV and CCV being performed at the appropriate frequency?				
4.2.5 Ongoing Precision and Recovery (OPR)				
Are OPR samples run at the frequency required by the method?				
Is an acceptable OPR associated with each sample examined?				
Does the laboratory maintain control charts of OPR results?				
4.2.6 Method Blank				
Are method blank acceptance criteria included in SOPs?				
Is an acceptable method blank associated with each sample at the required frequency? (One per preparation batch, not to exceed 20 samples, or with each instrument analyses, as described in SOPs)				
Is blank subtraction specifically prohibited?				
Is the method blank processed along with and under the same conditions as the associated samples including all steps of the analytical procedure?				
Are procedures in place to determine if a method blank is contaminated?				
Are any affected sample associated with a contaminated method blank reprocessed for analysis or the results reported with appropriate data qualifying codes?				
Does the method blank consist of a matrix that is similar to the associated samples known to be free of the analytes of interest?				
Is the source of blank contamination investigated and measures taken to minimize or eliminate the problem? Are the resulting corrective actions documented by QA Officer?				
4.2.7 Matrix Spike / Matrix Spike Recovery (MS/MSD)				
Are MS/MSD requirements included in SOPs?				
Does the laboratory have procedures in place for tracking, managing, and handling matrix-specific QC criteria, including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, and evaluating and reporting results based on performance of the QC samples?				
Are the results of the matrix spike compared to the acceptance criteria as published in the mandated test method?				
Where there are no established criteria for the matrix spike, does the laboratory determine internal criteria and document the method used to establish the limits?				
When matrix spike results are outside of established acceptance criteria, are corrective actions taken and documented? Or are the data reported with appropriate data qualifying codes?				
Are QC control charts maintained for MS/MSD analyses?				

Item to be Evaluated	Yes	No	NA	Comments
4.3 Standard Traceability				
Does documentation exist for standards preparation that uniquely identifies the reagents/solvents used and the method of preparation, date of preparation and identification of standard preparer, and concentrations of all solutions used?				
Are spiking solutions checked for stability?				
Are standards stored under appropriate conditions (i.e., refrigerated)?				
Are standards being replaced at proper intervals?				
Are reagent grade or higher purity chemicals used to prepare standards?				
Are analytical reagents dated upon receipt?				
4.4 Training				
Is there a training protocol for new employees?				
Are employee training records available and up to date?				
Do training records adequately document that technicians/analysts have successfully completed all training requirements?				
Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?				
Does laboratory management maintain documentation on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities?				
Does laboratory management provide for and document training courses or workshops on specific equipment, analytical techniques, or laboratory procedures?				
4.5 Performance Testing (PT) Samples				
Does the laboratory participate in or perform regularly scheduled PT sample analysis? If so, what PT providers are used? (List all)				
Has the laboratory NOT achieved an acceptable score for any PT in the past 3 years? If so, list analytes/methods. If so, is their documentation of successful analysis of a remedial PT sample?				
Are all PT samples handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples using the same staff, methods, procedures, equipment, and facilities?				
4.6 Internal Audits				
Does the laboratory periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system?				
Is it the responsibility of the QA Officer to plan and organize audits as required and requested by management?				
Is there a permanent audit record detailing each audit performed, results, corrective actions taken, and followup verification that the problem has been solved?				

Item to be Evaluated	Yes	No	NA	Comments
4.7 Corrective Action & Exception Procedures				
Does the quality manual and related quality documentation include or reference procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur?				
Do these corrective action procedures include the following: 1. Identify the individual(s) responsible for assessing which QC data type? 2. Identify individual(s) responsible for initiating and/or recommending corrective actions? 3. Define how the analyst shall treat a data set if the associated QC measurement are unacceptable? 4. Specify how out-of-control situations & subsequent corrective actions are to be documented? 5. Specify procedures for management & the QA officer to review corrective action reports?				
Do the policy and procedures for nonconforming work ensure that corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work?				
Do the policy and procedures for nonconforming work ensure that where the data quality is or may be impacted, the client is notified and the work may be recalled?				
Does the laboratory document and implement any required changes resulting from corrective action investigations?				
Does the laboratory monitor the results to ensure that the corrective actions taken are effective?				
Does laboratory management provide a mechanism for confidential reporting of data integrity issues in their laboratory? Does the mechanism include a trigger for further actions?				
4.8 Documentation				
Are permanently bound notebooks with preprinted, consecutively numbered pages being used? Is the type of work and appropriate time period clearly displayed on the notebook?				
Are entries in logbooks signed, dated, and legible?				
Has the analyst avoided obliterating entries and the use of a pencil? Are changes to logbooks dated and initialed by the person who made the change?				
Are inserts (i.e., chromatograms, computer printouts, etc.) permanently affixed to the notebook and signed across the insert edge and page?				
Has the supervisor of the individual maintaining the notebook personally examined and reviewed the notebook periodically, and signed his/her name and date therein?				
Are there specific paper or electronic formats for recording bench data?				

Item to be Evaluated	Yes	No	NA	Comments
4.9 Data Review Procedures				
Do supervisory personnel review the data and QC results?				
Does the quality manual and related quality documentation include or reference procedures for data audits and data review?				
4.10 Manual Integration Documentation				
Does the laboratory have established SOPs addressing manual calculations including manual integrations?				
Part 5 Sample Management				
5.1 Receipt				
Are there written SOPs for the receipt of samples? If yes, where are the SOPs readily available?				
Has a sample custodian been designated?				
Is there adequate work space for receipt and handling of samples?				
Are samples subject to a chain of custody? Are the chain-of-custody procedures documented?				
Are samples assigned a unique identifier by the laboratory?				
Does the laboratory have criteria for sample acceptance and corrective action procedures?				
Does sample custodian check that shipping information is complete, including the time and date of sample receipt, sample condition, and noting any discrepancies between samples on the traffic report and samples received?				
Are sample temperatures and preservation checked upon receipt?				
Are the samples logged into a LIMS?				
Are clients notified of any discrepancies?				
Are the sample shipping containers opened in a manner that prevents possible laboratory and sample contamination?				
5.2 Storage				
Is sample storage documented and inventoried?				
Are refrigerator/freezer temperature excursions noted and appropriate actions taken?				
Are the sample receipt/storage and temperature logbooks completed in a manner consistent with the laboratory's SOP?				
Are sample receipt/storage areas secure (in accordance with the laboratory's SOP)?				
Are there separate storage areas designated for each analysis (i.e., volatile samples stored in different refrigerator)?				
Are samples stored away from all standards, reagents, food and other potentially contaminating sources?				

Item to be Evaluated	Yes	No	NA	Comments
5.3 Disposal				
Does the laboratory have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products?				
Part 6: Document Control/Data Management				
6.1 Communication				
Does laboratory notify the client of problems with documentation and/or condition of samples upon receipt?				
Does laboratory provide timely notification to the client(within 48 hours while samples are still within extraction/analysis holding times) of problems with extraction or analysis?				
6.2 Data Acquisition				
Are sufficient raw data records retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration.				
Are batch and lot numbers of reagents used in the analysis of the sample recorded with the associated raw data?				
Are calculations of final concentrations and recoveries complete and correct and reproducible?				
Do values recorded on the data sheets match the reported values? What procedures are in place to assure this?				
6.3 Data Reduction and Reports				
Can data be tracked from the point of generation to the final result?				
Are data that are manually entered into the computer checked by a second person?				
Do the project files identify the specific pieces of instrumentation that were used?				
Are data periodically confirmed by independent (i.e., manual) reduction?				
Is there a project/run tracking/filing system in place?				
In the event that special circumstances preclude meeting one or more method criteria, is there a well defined management system for describing and explaining noncompliance in the report narrative?				
Is all information relating to analytical equipment used, analytical methods, sample receiving and sample preparation included in the final data package?				
Are raw data records retained to document support equipment performance?				
6.4 Data Storage				
How long does the laboratory retain hard copy and/or electronic records of sample analyses?				
Are there written instructions for data storage and retrieval?				
Are hardcopy records well organized, complete, and easily accessible?				
Are data (electronic and hard copy) archived in a retrievable fashion?				

Item to be Evaluated	Yes	No	NA	Comments
Does the laboratory have procedures to protect and backup records stored electronically and to prevent unauthorized access to or amendment of records stored electronically?				
Are any changes to posted data traceable and include the name of the person making the change and the reason fo the change? Are the original data still available?				
6.5 Electronic Data				
If data is stored electronically, does the laboratory have an SOP for checking the accuracy of data entry, storage, retrieval into an electronic system?				
If data are stored electronically, are redundant backup copies made and stored offsite?				
If there is an electronic copy of the manually corrected data, are the electronic data also changed?				
What procedure is in place for documenting that hard copy lab reports are identical to electronic reports?				