Question ID	Question	App Standards

Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 01 General Information

001	Laboratory Name:	*OAC 252:301-1*
002	Address:	
003	Phone/Fax Number:	
004	Date:	
005	Primary POC:	
006	Email/Website:	
007	*Applicable to laboratories, which have performed previous work.	
008	Recommended Action	
009	Laboratory Name	
010	Address	
011	Phone Number	
012	Date	
013	Principal Analytical Specializations:	
014	Persons Contacted	
015	Name	
016	Title	
017	Evaluation Team	
018	Name	
019	Company	
020	Title	
021	Name(s) of employee interviewed:	
022	Position/Title:	
023	Years of experience:	
024	Analyses performed:	
025	Comments:	

SubHeader : 02 Specific Project Issues

001	PROJECT NUMBER	
002	DESCRIPTION	
003	LABORATORY RESPONSE/	
004	CORRECTIVE ACTION	

SubHeader : 03 QA/QC Manual - Review Prior to Lab Audit

001	Does the Quality Assurance (QA) Manual contain the 16 elements required by the U.S. Environmental Protection Agency (USEPA)?	*OAC 252:301-9-2*
001.01	Title Page/Introduction	*OAC 252:301-9-2*
001.02	Table of Contents	*OAC 252:301-9-2*
001.03	Lab Description	*OAC 252:301-9-3*
001.04	Lab Organization	*OAC 252:301-9-3*
001.05	QA Objectives for Data Measurement	*OAC 252:301-9-3*
001.06	Sampling Procedures	*OAC 252:301-9*
001.07	Sample and Document Custody Procedures	
001.08	Calibration Procedures and Frequency	*OAC 252:301-9-5*
001.09	Analytical Procedures	*OAC 252:301-9-6*

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Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 03 QA/QC Manual - Review Prior to Lab Audit

001.10	Data Reduction, Validation and Reporting	*OAC 252:301-9-5*
001.11	Internal Quality Control (QC) Checks	*OAC 252:301-9-4*
001.12	Performance and System Audits	*OAC 252:301-9-4*
001.13	Preventive Maintenance	*OAC 252:301-9-4*
001.14	Data Measurement Assessment Procedures	*OAC 252:301-9-4*
001.15	Corrective Action	*OAC 252:301-9-4*
001.16	QA Reports to Management	*OAC 252:301-9-4*
002	Does the manual discuss facilities and equipment?	*OAC 252:301-9-6*

SubHeader : 04 Organization & Personnel

001	Does the laboratory have an organization chart?	*OAC 252:301-9-3*
002	Is there a clear description of the lines of responsibility and authority in the laboratory?	*OAC 252:301-9-3*
003	Is a Laboratory Manager identified?	*OAC 252:301-9-3*
03.1	Name	
004	Is a QA Officer/Coordinator identified?	
04.1	Name	
005	Is the position of QA Officer sufficiently independent of cost and schedule considerations?	*OAC 252:301-9-3*
006	Does the QA Officer have the proper authority to stop work if the data do not meet QC criteria?	*OAC 252:301-9-3*
007	Are QA duties clearly outlined and defined?	*OAC 252:301-9-3*
008	Is a Project Manager for this client/project identified?	*OAC 252:301-9-3*
08.1	Name	
009	Is the position of Project Manager clearly defined?	*OAC 252:301-9-3*
010	Will the Project Manager have the authority to utilize the laboratory resources to the fullest?	*OAC 252:301-9-3*
011	Does the Project Manager have a mechanism to assure meeting turnaround time (TAT) objectives on projects?	
012	Is evidence available to verify the qualifications and training of all laboratory personnel?	*OAC 252:301-9-3*
013	Does the training include a course in ethics?	*OAC 252:301-9-3*
13.1	The evidence must be on file which demonstrates that each employee has read, acknowledged, and understood their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical, or illegal actions.	*OAC 252:301-9-3*
014	Does the lab promote technical growth of the staff through outside training?	*OAC 252:301-9-3*
015	Attach list of facilities and equipment or reference SOQ	*OAC 252:301-9-4*

SubHeader : 05 Sample Receipt, Log-in, Storage & Disposal

001	Is a Sample Custodian identified?	
001.1	Name	
002	Are written Standard Operating Procedures (SOPs) developed for receipt, log-in, storage, and disposal of samples?	*OAC 252:301-9-31*
003	Are the appropriate portions of the SOPs available to the laboratory staff?	*OAC 252:301-9-31*
004	Does the staff understand the importance of sample receiving and log-in?	*OAC 252:301-9-56*
005	Are bottles used for sample collection precleaned and documented as cleaned?	*OAC 252:301-9-35*

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Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 05 Sample Receipt, Log-in, Storage & Disposal

006	Are the sample shipping containers opened in a manner, which prevents possible laboratory and sample contamination?	*OAC 252:301-9-54*
007	Are samples verified for integrity, proper preservation, and temperature upon receipt? How is this documented?	*OAC 252:301-9-54*
008	Are records available to confirm notification to the client when samples are received broken, warm, with insufficient volume, or with custody seals removed?	*OAC 252:301-9-54*
009	Is there a written sample acceptance policy that outlines the circumstances under which samples will be accepted or rejected?	*OAC 252:301-9-54*
010	Are the sample receipt, log-in, storage, and disposal logbooks and forms completed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-54*
011	Is there evidence of a secondary review of all documents and logbooks by someone other than the person generating the documents?	
012	When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered?	
013	Are all changes to records signed or initialed by the person making the correction?	
014	Are adequate facilities provided for storage of samples (including cold storage and long term storage)?	*OAC 252:301-5-3*
015	Is the temperature of the cold storage units recorded in a logbook?	*OAC 252:301-9-54*
016	Are temperature excursions noted and appropriate corrective actions taken when required?	*OAC 252:301-9-54*
017	Are corrective action SOPs posted on the cold storage units?	*OAC 252:301-9-54*
018	Is the mercury thermometer checked annually against NIST traceable thermometer at two separate temperatures?	*OAC 252:301-9-54*
019	Are samples checked out of the storage areas by the analysts with proper chain-of-custody?	
020	Are samples for volatile organics testing stored in a refrigerator of sufficient size and reserved for exclusive use for volatile organic analysis (VOA) samples?	*OAC 252:301-5-3*
021	Are chemical waste disposal procedures in place?	*OAC 252:301-5-3*
022	Are sample disposal records kept on file?	*OAC 252:301-5-3*
023	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-31*
024	Are facilities sufficient to provide security and chain-of-custody records?	

SubHeader : 06 Sample Preparation (Organics)

001	Are written SOPs developed for preparation of samples?	*OAC 252:301-9-31*
002	Are the appropriate portions of the SOPs available to the laboratory staff?	*OAC 252:301-9-31*
003	Is the laboratory maintained in a clean and organized manner?	*OAC 252:301-5-3*
004	Does the laboratory appear to have adequate workspace?	*OAC 252:301-5-3*
005	Does the laboratory appear to have adequate lighting, heating, cooling, and ventilation?	*OAC 252:301-5-3*
006	Are contamination-free work areas provided for trace level analytical work?	*OAC 252:301-5-3*
007	Are exhaust hoods provided to allow contamination-free work with volatile materials?	*OAC 252:301-5-3*
008	Is the flow of the hoods periodically checked and recorded in a logbook?	*OAC 252:301-5-3*
009	Can it be documented that organic-free water is available and used for the preparations of standards and blanks, where applicable?	*OAC 252:301-5-3*
010	Are the analytical balances located away from drafts and areas subject to rapid temperature change?	*OAC 252:301-9-54*

Oklahoma Checklist (OK)

Header : 31.0 ***Laboratory Systems Audit Summary***

SubHeader : 06 ***Sample Preparation (Organics)***

011	Have the balances been calibrated and checked within one year by a certified technician?	*OAC 252:301-9-54*
012	Are the analytical balances checked daily with the appropriate class S weights and the results recorded?	*OAC 252:301-9-54*
013	Have the class S weights been calibrated within five years and are they traceable to NIST?	*OAC 252:301-9-54*
014	Are the solvent storage cabinets vented or located in such a way as to prevent possible laboratory contamination?	*OAC 252:301-5-3*
015	Are reagent grade or higher purity chemicals used to prepare standards?	*OAC 252:301-5-3*
016	Are analytical reagents dated upon receipt?	*OAC 252:301-5-3*
017	Are reagent inventories maintained on a first-in, first-out basis?	*OAC 252:301-5-3*
018	Does the lab secure lots of solvents such as methylene chloride, hexane, etc. from the vendor once they have passed QC checks?	*OAC 252:301-5-3*
019	Is the purity of the analytical reagents verified before use?	*OAC 252:301-5-3*
020	Can the laboratory document the traceability, purity, and procedure for the preparation of standards?	*OAC 252:301-5-3*
021	Are fresh analytical standards prepared at a frequency consistent with the lab SOPs?	*OAC 252:301-9-32*
022	Are spiking standards preparation and tracking logbooks maintained?	*OAC 252:301-9-32*
023	Are reference standards properly labeled with concentrations, date of preparation, the identity of the person preparing the standard, and expiration date of the standard?	*OAC 252:301-5-3*
024	Are purchased standards documented with manufacturer, lot number, date of receipt, concentrations (if applicable), and expiration date of the standard?	*OAC 252:301-5-3*
025	Are the sample preparation procedures performed and documented in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-32*
026	Do the analysts record bench data in a neat and accurate manner?	*OAC 252:301-9-54*
027	When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered?	*OAC 252:301-5-3*
028	Are all changes to records signed or initialed by the person making the correction?	
029	Is there evidence of a secondary review of all documents and logbooks by someone other than the person generating the documents?	
030	Are out of criteria QC events documented and followed up with corrective action?	
031	Are soils subsampled in a manner, which obtains a homogenous and consistent sample aliquot?	*OAC 252:301-9-32*
032	Do all staff follow the same procedure for soil subsampling?	*OAC 252:301-9-32*
033	Is the lab knowledgeable in clean-up procedures such as GPC, alumina, Florisil, or silica gel?	
034	Are the temperatures of the storage refrigerators/freezers recorded daily?	*OAC 252:301-9-54*
035	Are temperature excursions noted and the appropriate corrective actions taken when required?	*OAC 252:301-9-54*
036	Are corrective action SOPs posted on the cold storage units?	*OAC 252:301-9-54*
037	Are standards stored separately from sample extracts?	*OAC 252:301-5-3*
038	Are volatile and semivolatile solutions properly segregated?	*OAC 252:301-5-3*
039	Are the SOPs for glassware posted at the cleaning stations?	*OAC 252:301-9-32*
040	Do deviations from analytical methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?	*OAC 252:301-9-4*

SubHeader : 07 ***Sample Preparation (Inorganics)***

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Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 07 Sample Preparation (Inorganics)

001	Are written SOPs developed for preparation of samples?	*OAC 252:301-9-32*
002	Are the appropriate portions of the SOPs available to the laboratory staff?	*OAC 252:301-9-32*
003	Is the laboratory maintained in a clean and organized manner?	*OAC 252:301-5-3*
004	Does the laboratory appear to have adequate workspace?	*OAC 252:301-5-3*
005	Does the laboratory appear to have adequate lighting, heating, cooling, and ventilation?	*OAC 252:301-5-3*
006	Are contamination-free work areas provided for trace level analytical work?	*OAC 252:301-5-3*
007	Is the flow of the hoods periodically checked and recorded in a logbook?	*OAC 252:301-5-3*
008	Can it be documented that analyte-free water is available and used for the preparations of standards and blanks?	*OAC 252:301-5-3*
009	Is the conductivity of the analyte-free water checked and documented in a logbook?	*OAC 252:301-5-3*
010	Are the analytical balances located away from drafts and areas subject to rapid temperature change?	*OAC 252:301-9-54*
011	Have the balances been calibrated and checked within one year by a certified technician?	*OAC 252:301-9-54*
012	Are the analytical balances checked daily with the appropriate class S weights and the results recorded?	*OAC 252:301-9-54*
013	Have the class S weights been calibrated within five years and are they traceable to NIST?	*OAC 252:301-9-54*
014	Are the chemical storage cabinets vented or located in such a way as to prevent possible laboratory contamination?	*OAC 252:301-5-3*
015	Are reagent grade or higher purity chemicals used to prepare standards?	*OAC 252:301-5-3*
016	Are analytical reagents dated upon receipt?	*OAC 252:301-5-3*
017	Are reagent inventories maintained on a first-in, first-out basis?	*OAC 252:301-5-3*
018	Is the purity of the analytical reagents verified before use?	*OAC 252:301-9*
019	Are spiking standards preparation and tracking logbooks maintained?	*OAC 252:301-9-33*
020	Can the laboratory document the traceability, purity, and procedure for the preparation of standards?	*OAC 252:301-5-3*
021	Are fresh analytical standards prepared at a frequency consistent with the laboratory SOPs?	*OAC 252:301-9-32*
022	Are reference standards properly labeled with concentrations, date of preparation, expiration date, and the identity of the person preparing the standard and/or is a traceable reference code number used?	
023	Are purchased standards documented with manufacturer, lot number, date of receipt, concentrations (if applicable), and expiration date of the standard?	
024	Do the analysts record bench data in a neat and accurate manner?	
025	Is there evidence of a secondary review of all documents and logbooks by someone other than the person generating the documents?	
026	When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered?	
027	Are all changes to records signed or initialed by the person making the correction?	
028	Are soils subsampled in a manner, which obtains a homogenous and consistent sample aliquot?	
029	Do all staff follow the same procedure for soil subsampling?	*OAC 252:301-9*
030	Are the temperatures of the storage refrigerators/freezers recorded daily?	*OAC 252:301-9-54*
031	Are temperature excursions noted and the appropriate corrective actions taken when required?	*OAC 252:301-9-54*
032	Are corrective action SOPs posted on the cold storage units?	*OAC 252:301-9-33*
033	Are standards stored separately from sample digestates?	*OAC 252:301-5-3*

Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 07 Sample Preparation (Inorganics)

034	Are the SOPs for glassware posted at the cleaning stations?	
035	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-31*
036	Do deviations from analytical methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?	*OAC 252:301-9-4*

SubHeader : 08 Data Management

001	Are written SOPs developed for data management?	*OAC 252:301-9-32*
002	Are the appropriate portions of the SOPs available to the laboratory staff?	*OAC 252:301-9-31*
003	Are the hard copy final reports and electronic deliverables being inspected by an internal QC process, where applicable?	*OAC 252:301-9-4*
004	Are raw data deliverables checked in the review process for completeness and accuracy?	*OAC 252:301-9-4*
005	Are resubmitted deliverables reinspected?	*OAC 252:301-9-4*
006	Are data deliverables and final reports archived and stored in a secured area?	*OAC 252:301-9-3*
007	Are all records necessary for the historical reconstruction of the data retained by the laboratory?	*OAC 252:301-9-51*
008	Is there a system in place that provides for retrievability and traceability of the data deliverables and reports?	*OAC 252:301-9-51*
009	Is access to the archived information documented by an access log?	*OAC 252:301-9-51*
010	What is the length of storage for archived data/reports (records retention policy)?	*OAC 252:301-9-51*
011	What is the actual retention of data versus the record retention policy?	*OAC 252:301-9-51*
012	What is the procedure and frequency of purging of “old” data? (client notification, documentation, note last few events)	*OAC 252:301-9-51*
013	Are records archived electronically? (magnetic or optical)	*OAC 252:301-9-51*
014	Does the laboratory audit the stored data for quality? (corrupted data)	*OAC 252:301-9-51*
015	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-31*

SubHeader : 09 Project Management

001	Are written SOPs developed for project management?	*OAC 252:301-9-31*
002	Is the position of Project Manager clearly defined? (See also III, 9)	*OAC 252:301-9-3*
003	Will the Project Manager have the authority to utilize the laboratory resources to the fullest? (See also III, 10)	*OAC 252:301-9-3*
004	Does the Project Manager have a mechanism to assure meeting turnaround time (TAT) objectives on projects? (See also III, 11)	*OAC 252:301-9-3*
005	How are project specifics communicated to laboratory personnel?	*OAC 252:301-9-3*
006	How are sample or analytical problems communicated to the client?	*OAC 252:301-9-3*
007	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-32*

SubHeader : 10 Laboratory Information Management System (LIMS)

001	Are written SOPs developed for data management?	*OAC 252:301-9-32*
002	Are users manuals and operations/systems manuals available?	*OAC 252:301-9-33*
003	Are the appropriate portions of the SOPs available to the laboratory staff?	*OAC 252:301-9-31*

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Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 10 Laboratory Information Management System (LIMS)

004	Are data and file access user identifications password protected in the lab computer system?	*OAC 252:301-9-51*
005	Are records stored on personal computers backed up?	*OAC 252:301-9-51*
006	Are records stored electronically on tape or disk?	*OAC 252:301-9-51*
007	Are data (instrument and reports) downloaded and stored electronically on disk or tapes at an acceptable frequency?	*OAC 252:301-9-51*
008	Is the record keeping of the archived data up to date?	*OAC 252:301-9-51*
009	Are computer tapes and disks archived and stored in a secured area?	*OAC 252:301-9-51*
010	What is the length of storage for archived data?	*OAC 252:301-9-51*
011	Does the laboratory audit the stored data for quality? (corrupted data)	*OAC 252:301-9-51*
012	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	*OAC 252:301-9-33*

SubHeader : 11 QA/QC

001	Are QA duties clearly outlined and defined?	*OAC 252:301-9-3*
002	Is the position of QA Officer sufficiently independent of cost and schedule considerations?	*OAC 252:301-9-3*
003	Does the QA Officer have the proper authority to stop work if the data do not meet QC criteria?	*OAC 252:301-9-3*
004	Does the QA Officer perform annual internal audits that address all elements of the quality system, including testing and calibration?	*OAC 252:301-9-3*
005	Is documentation of previous internal and external audits kept on file?	*OAC 252:301-9-32*
006	Is laboratory management notified of deficiencies and are corrective actions monitored?	*OAC 252:301-9-32*
007	Is there evidence that the laboratory has corrected all past deficiencies identified in previous audits? (See attachment A)	*OAC 252:301-9-32*
008	Are control limits updated annually, at a minimum, for accuracy and precision criteria such as matrix spike recoveries and surrogate recoveries?	*OAC 252:301-9-56*
009	Is a corrective action plan actively used to identify and correct out of control events?	
010	Does the QA officer spot check final reports and data deliverable packages at an acceptable frequency?	
011	Are procedures and documentation performed in a manner consistent with the laboratory SOPs?	
012	Is there a procedure to ensure that invalid or obsolete documents are promptly removed from use or assured against unintended use?	*OAC 252:301-9-4*
013	Are SOPs uniquely identified?	
014	Does the identification include the date of issue, revision, page numbering, review and approval?	*OAC 252:301-9-32*
015	Are SOPs no longer in use archived for reference?	*OAC 252:301-9-4*
016	Is there a record management system for control of laboratory notebooks, instrument logbooks, and standards logbooks?	*OAC 252:301-9-4*
017	Does the laboratory have a policy and procedure for the resolution of complaints from clients?	
018	Are the records of complaints and corrective actions archived?	
019	Does the laboratory notify clients promptly, in writing, of any event that casts doubt on the validity of the results?	

SubHeader : 12 Safety / Facilities

Question ID	Question	App Standards

Oklahoma Checklist (OK)

Header : 31.0 Laboratory Systems Audit Summary

SubHeader : 12	Safety / Facilities	
001	Are safety meetings held with all personnel?	
002	Are safety inspections performed annually?	
003	Does the lab have adequate safety devices such as eye wash stations, spill control stations, showers, first-aid stations, etc.?	
004	Are these safety devices checked routinely to ensure that they are still working properly?	
005	Are volatile or corrosive chemicals and flammable solvents stored in accordance with Occupational Health and Safety Administration (OSHA) regulations?	
006	Are appropriate occupational safety and health laws posted and observed?	*OAC 252:301-5-3*
007	Is the laboratory secure from unauthorized personnel?	
008	Are chemical waste disposal policies and procedures well defined and followed by lab personnel?	

SubHeader : 13	Audit Summary	
001	Do the responses to the evaluator indicate that laboratory supervisory and staff personnel are aware of QA/QC and its application to specific projects?	
002	Do laboratory personnel place positive emphasis on QA/QC?	
003	Have responses with respect to QA/QC aspects of the project been open and direct?	

SubHeader : 14	Attachment A. Past Audit Findings	
001	(Fill in recommendations prior to audit.) Applicable to laboratories, which have performed previous	
002	Have corrective actions recommended during previous evaluations been implemented?	
003	What are they	

SubHeader : 15	Additional Comments, Observations, or Problems	
001		