LDEQ ANSWERS TO PROPOSERS QUESTIONS
RFP No. 3000002163
"Laboratory Auditing"

LDEQ's answers to the following questions are intended to provide information to potential proposer's questions to RFP No. **3000002163**.

Questions and answers that may potentially result in the disclosure of information from proposals of competing bidders will not be published.

Question 1: Louisiana does not have a requirement for a Certificate of Authority. Will the Department be willing to waive this requirement?

> **LDEQ's Answer: According to R.S. 12:301, a Certificate of Authority is required for all out-of-state corporations or associations. Due to this Statute, the Department cannot waive this requirement.**

Question 2: Section 2.5 regarding Certified Small Businesses, will any points be allocated for the use of small businesses from other states? If yes, will you accept their own state certification that they are veteran or small business (e.g. example Texas has a similar program)?

> **LDEQ's answer: This program is for Louisiana based companies only. For additional information regarding this program, please go to http://www.doa.louisiana.gov/osp/se/secv.htm and http://www.doa.louisiana.gov/osp/se/lavetcv.htm.**

Question 3: Is there a specified percentage of work that is to be contracted to the LA Veteran/Small Business in order to qualify for the allocated points?

> **LDEQ's answer: There is no specified percentage; however, the Department will allocate points *proportionally* based on the three criteria in RFP Section 2.5 (i.e., number, experience/qualifications, and anticipated earnings to accrue to the certified entrepreneurship). For example, to allocate points for percentage of work to certified subcontractors (i.e., anticipated earnings), the Department will consider a range of partial points, such as:**
>
> - **less than 5%**
> - **6-10%**
> - **Etc.**

Question 4: According to the Louisiana website small businesses or veteran businesses must be domiciled in Louisiana and must have their principle business office in Louisiana. Does this mean that nationally certified woman-owned small businesses in HUB zones (WBENC) will not be given any of the points?

LDEQ's answer: That is correct.

Question 5: Appendix C – Sample Contract, section 26 – Insurance. For subcontractors/sole proprietors or one person LLC's, can any of the insurance requirements be waived?

LDEQ's answer: Of the three (3) insurance coverage requirements in Appendix C, Sample Consulting Services Contract, Article No. 26, Contractor's Insurance, Item (a) Minimum Scope and Limits of Insurance, Workers Compensation is the *only* requirement that could potentially be waived. The remaining coverage requirements – Commercial General Liability and Automobile Liability – may not be waived. The Contractor may elect not to provide Workers Compensation coverage, as indicated in Contract, Article No. 26, Contractor's Insurance, Item (h) Worker's Compensation Indemnity. In such cases, election to not provide Worker's Compensation shall be provided in writing to the Department.

Question 6: Can any of the insurance requirements minimum levels of coverage be lowered?

LDEQ's answer: The levels of coverage provided in the RFP are those recommended by Louisiana Office of Risk Management. Due to the hazards inherent in analytical laboratories, the coverage limits shall not be lowered.

Question 7: Can the automobile insurance requirement be removed if there are no company owned vehicles? None of this work requires we drive on LDEQ property or drive LDEQ vehicles

LDEQ's answer: Contractor Automobile insurance coverage is required when Contractors travel on behalf of the Department on business as defined in the contract, regardless of whether or not Department property or Department vehicles are involved.

Question 8: Section 26.c.2 – Workers Compensation & Employers Liability Coverage. In order to waive all rights of subrogation we would be required to purchase additional insurance; can those costs be passed along to LDEQ? If not, can this clause be removed?

> **LDEQ's answer: Payment to the Contractor, by the Audited Laboratories, shall be limited to the pay items in Attachment 2, Schedule of Prices. Proposers may elect at their discretion, to include costs described in Question No. 8 in their unit rates, per the unit rate footnote in Attachment 2 Schedule of Prices, which indicates that "Unit Rates...shall include...all indirect costs." No payments shall be made by the Department under this contract. See also Question No. 5.**

Question 9: Please clarify the format for the deliverables. Section 3.0 of the SOW does not clearly define the required format; however Section 6.1 of the SOW states that, "All deliverables, which include the audit report, audit checklists, and itemized invoice shall be presented to the Department in both one hard copy and an electronic version." It will be a more costly venture to provide a hard copy of deliverables, when an electronic version can be transmitted by email. This clarification will assist us in making a more competitive offer of services.

> **LDEQ's answer: The format for the deliverables, referenced in the LELAP quality system documents, are attached (Q&A Attachments 1-7). The documents must be submitted as both hard copy and electronic copies.**

Assessment Report

for

[LAB NAME]
[ADDRESS]
[CITY, STATE ZIP]

Designated Representative: <*Name of Lab Representative*>

Performed:
[DATE]

SUBMITTED TO:
[ADMINISTRATOR]

Louisiana Department of Environmental Quality
Office of Environmental Services
Public Participation and Permit Support Division
Notifications and Accreditations Section
Louisiana Environmental Laboratory Accreditation Program
P. O. Box 4313
Baton Rouge, LA 70821-4313

Submitted by: [Lead Assessor name] _____

[Other Assessor(s) name(s)]: _____

Reviewed by: _____

[name and address of contract assessor organization]

ASSESSMENT REPORT

Scope

<*Laboratory Name*> has been granted accreditation by the Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) for <*general description of scope*>.

The Assessor must include introductory information regarding the assessment such as date, scope of the accreditation, purpose of the assessment and any other information that the Assessor deems appropriate. Must identify the lead assessor and any other assessor present during the assessment.

Materials Selected for Review

This report and the attached tables represent the conditions observed in the facility at the time of the assessment. Table 1 represents the Standard Operating Procedures that were reviewed as part of this assessment. Conditions identified in the course of the assessment that fail to satisfy the requirements of LAC 33, Part I, Subpart 3 are described in the attached List of Findings. An electronic copy of the List of Findings, in MS Word format, is included on the enclosed CD-R, to be used by the laboratory to prepare their corrective action response.

Data Package Review

A list of the data packages that were reviewed during the assessment is shown in Table 2. Electronic copies of the data packages and other materials reviewed are included as attachments on the enclosed CD-R.

Observations

Please include information on size of laboratory and number of employees. This section to be used for information that, in accordance with the judgment of the assessor, is necessary to provide a more accurate picture of the laboratory and/or its operations.

Table 1 Materials Selected for Review		
Parameter	**Reference Method**	**Standard Operating Procedure**

Table 2 Review of Data Packages and Other Materials	
Parameter	**Data Package Identifier (Sample #'s)**

Attachments

The enclosed CD-R contains electronic copies of the attachments listed below.

Attachment 1. *list item*

Attachment 2. *list item*

Attachment 3. .....

etc

<The list of Attachments shall include the following: pre-assessment checklist; list of methods and/or scope of accreditation; attendance at initial and final briefings; SOPs reviewed during the assessment; completed quality system checklists; and other documents as appropriate.

For attachments that are not scanned onto the CD-R, paper copies must be attached after the List of Findings. Paper copies are NOT required for attachments that have been scanned onto the CD-R enclosed with the assessment report.>

LIST OF FINDINGS

Attached is a list of the findings that were identified during the on-site assessment and the review of the laboratory's documents and records. Each numbered item identifies a specific finding and references the LAC/NELAC citations that establish the requirement that was not met.

The laboratory must submit a corrective action plan (CAP) that addresses each of the cited findings, using the electronic copy of the List of Findings included with this Assessment Report. The laboratory response must be concrete, detailed, and specific, and must describe how the corrective action will be implemented and incorporated into the laboratory's quality system documentation. Where changes to procedures are appropriate, the submitted CAP shall include the location and summary of the change and provisions for training and follow up to ensure effectiveness of the change. Your response must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action. Enter your corrective action response to each finding in the appropriate spaces provided on the CD-R. An example is provided below, in which the sections to be completed by the laboratory are indicated by italics.

A paper copy and an electronic copy (in MS Word format) of the completed CAP must be submitted to LELAP within 30 days of the date of receipt of this report. All corrective actions must be completed satisfactorily within six months of the date of receipt.

Example of How to Submit your CAP Response with the Proposed/Completed Corrective Actions

Finding # XX

<Description of Finding cited by LELAP>

Regulation or Standard that establishes the Quality System Requirement:
LAC 33:I § <For LELAP use only>
NELAC: <For LELAP use only>

Description of Laboratory Corrective Action: *Provide a detailed narrative discussion of your proposed corrective action here.*

Laboratory Proposed Completion Date: *Insert date here*
Responsible Party: *Insert name of responsible party here*

LELAP Response to Proposed Corrective Action: <For LELAP use only>

Additional LELAP Comments (if necessary): <For LELAP use only>

Finding # 1

<Finding>

Regulation or Standard that establishes the Quality System Requirement:
LAC 33:I § 5301.C.7, 5301.C.8,
NELAC: 5.4.3.1

Description of Laboratory Corrective Action:

Laboratory Proposed Completion Date:
Responsible Party:

LELAP Response to Proposed Corrective Action:

Additional LELAP Comments (if necessary):

*<**Instructions to Assessor on List of Findings**: An electronic copy of the List of Findings with the instructions from the previous page is to be included on CD-R **as a separate document**, in MS Word format. The electronic copy of the List of Findings is to be used by the laboratory for their corrective action response, and will be the same as the List of Findings that is included as part of the assessment report. **The List of Findings for the CAP response will be the ONLY document using MS Word format to be provided on the CD.** All other electronic documents on the CD will be in PDF or other non-editable electronic format. An electronic copy of the final assessment report will also be provide, but in PDF format so it can not be edited. The PDF copy of the assessment report will include a scanned copy of the signed cover page.*

Multi-part findings must be done using standard outline numbering sequence. This is illustrated per the example below.

Finding #1
A. Secondary Level
B. Secondary Level
i. Tertiary Level
ii. Tertiary Level
Finding #2
A. Secondary Level
...etc....

LDEQ/LELAP

Review of

Lab Name: _____

Address: _____

City: _____ , ***ST:*** ___ ***zipcode:*** _____

Begin: _____ – ***end dates:*** _____

On the above date, *Ms./Dr./Mr. assessor's names* _____ _____representative(s) of the Louisiana Department of Environmental Quality (LDEQ), Louisiana Environmental Laboratory Accreditation Program (LELAP), performed an assessment of the above-named laboratory. In attendance were facility representative(s) for _____. See the meeting attendance form for the list of assessors and facility representative(s). The preliminary findings of the assessment are listed in the table below. Observations are listed after the end of the table. This list does not preclude the possibility that other findings may be discovered during the review of material for the preparation of the assessment report. A copy of the preliminary findings was submitted to the facility representative(s) along with the checklist(s).

Do not submit a corrective action plan for this document; the corrective action plan must be submitted for the assessment report which will be submitted within 30 days by the lead assessor.

No.	Checklist Item No.	[Finding or Observation]	[NELAC or LAC] Citation
1.			For national standard, list section, for LAC, use "LAC 33:I.xxxx.y.z, aaaa.b.c", etc.
2.			

No.	Checklist Item No.	[Finding or Observation]	[NELAC or LAC] Citation
3.			
4.			

Observations:

-
-

Name of Assessor(s): _____ Date: _____

_____ Date: _____

Name of Facility Representative(s): _____ Date: _____

_____ Date: _____

(NOTE: SIGNATURE DOES NOT NECESSARILY INDICATE AGREEMENT WITH ASSESSOR'S PRELIMINARY FINDINGS)

NOTE: The Information contained in this document reflects only the preliminary observations of the assessor(s). It should not be interpreted as a final determination by the Department of Environmental Quality or any of its officers or personnel as to any matter, including, but not limited to, a determination of compliance or lack thereof by the facility with any requirements of statutes regulations or permits.

CERTIFIED MAIL# xxxx xxxx xxxx xxxx
Return receipt requested

Month Day, Year

AI #aaaaaa **LELAP Lab ID #bbbbbb**

Prefix First Name Last Name
Name of Facility
Street Address
City, State Abbreviation Zip Code

RE: Corrective Action Plan Response

Dear Prefix Last Name:

The Louisiana Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) staff has reviewed your response to the quality system findings of your laboratory. The laboratory assessment was conducted by Assessor Name of Contractor Name on Month Day(s), Year. The formal assessment report was issued on Month Day, Year. The comments submitted in the enclosed attachment address the corrective action plan (CAP) that was received by the Program on Month Day, Year.

The review is summarized in the table below. You will note that x of y proposed corrective actions are approved. The remaining actions are not approved because they are incomplete or do not satisfactorily address all of the issues raised in the finding. Approved actions are noted with a date given for approval.

Finding Number	Response	Date Approved
1.	Proposed Corrective Action Incomplete. The corrective action plan does not include provisions for training the appropriate staff on the updated QSM and evaluation of the effectiveness of the training. Complete date is not within 6 months of receipt of AR.	
2.	Proposed Corrective Action Approved	month/day/ year
3.	Proposed Corrective Action Incomplete. The corrective action plan does not include provisions for training the appropriate staff on the updated QSM and the procedure to maintain/obtain current certifications of subcontractors and follow-up monitoring to ensure that the subcontractor certifications are updated annually.	

Finding Number	Response	Date Approved
4.	Proposed Corrective Action Incomplete. The corrective action plan refers to Section 8.3.8 but does not specify the document. The corrective action plan does not address the finding that the laboratory has no records that it ever validated and checked the software currently in use to ensure that it is appropriate for its intended use. The corrective action plan does not include provisions for training the affected personnel and follow-up audits to evaluate effectiveness of the training.	
5.	Proposed Corrective Action Plan Incomplete. Please specifically identify the new SOPs addressing "manual calculations including integrations," and include the concise SOP language addressing the finding. The corrective action plan must include training of affected personnel on the updated QSM and new SOPs and follow-up audits to evaluate effectiveness of the training.	
6.	Proposed Corrective Action Plan Incomplete. The proposed corrective action plan does not include a provision for follow-up monitoring to ensure that the error correction training was effective.	

You must submit a revised CAP to LELAP and to Name of Contractor (at the address provided by the assessor) to address the items that were not approved, within thirty days of your receipt of this notice. Your revised plan must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action. The revision to the original plan must be clearly identified as such in the original document submitted to the Program so that the complete plan is located in one document.

LELAP requires that an attestation of compliance be completed prior to our final approval of these actions. LELAP approval of proposed corrective actions does not absolve the laboratory of the responsibility to correct any existing findings (conditions that fail to satisfy the requirements of the Louisiana Administrative Code, Title 33, Part I, Subpart 3), including findings that may not have been identified during the audit process or the review of corrective action documents.

The Louisiana Administrative Code, §5107.B requires that all corrective actions must be completed and approved by LELAP no later than six months after your receipt of the assessment report. Since the AR was received at your facility on Month Day, Year, the proposed corrective action completion date must be no later than Month Day, Year. Requests for extension of deadlines must be submitted in writing, and must include a reasonable justification as to why an extension ought to be granted. Address all correspondence to the Office of Environmental Services, Louisiana Environmental Laboratory Accreditation Program, P.O. Box 4313, Baton Rouge, Louisiana, 70821-4313; Attention: Name of LELAP Supervisor.

To meet the submittal deadline, you may send electronic copies by e-mail to Email address of LELAP Supervisor with a copy to Name of Contractor and Email address of LELAP assessor. Electronic copies are to be submitted in addition to the official copy mailed to LELAP in Baton Rouge.

If you have any questions, please contact Name of LELAP assessor at (area code) phone number.

Sincerely,

Name of LELAP Supervisor, Supervisor
Louisiana Environmental Laboratory Accreditation Program

Upper case initials of LELAP Supervisor: Lower case initials of LELAP assessor: Lower case initials of Contract assessor' representative

Enclosure

Template for LELAP Response to Corrective Action Plans All Approved

CERTIFIED MAIL# xxxx xxxx xxxx xxxx
Return receipt requested

Month day, year

AI # xxxxx **LELAP Lab ID #xxxxx**

Laboratory representative name
Laboratory
Address
city, state zip

RE: Corrective Action Plan Response

Dear Laboratory representative name:

The Louisiana Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) has reviewed your response to the quality system assessment findings of your laboratory. The onsite assessment was performed on month day, year. The formal assessment report was issued on month day, year. The corrective action plan (CAP) was received by the Program on month day, year.

Our review indicates that your CAP satisfactorily addresses the findings. The review is summarized in the table below, along with the date when each proposed corrective action was approved.

Finding Number	Response	Date Approved
1	Proposed Corrective Action Approved. (Include entire response here, excluding "Additional LELAP Comments".)	xx/xx/xxxx
2	Proposed Corrective Action Approved.	xx/xx/xxxx
3	Proposed Corrective Action Approved.	xx/xx/xxxx
4	Proposed Corrective Action Approved.	xx/xx/xxxx
5	Proposed Corrective Action Approved.	xx/xx/xxxx
6	Proposed Corrective Action Approved.	xx/xx/xxxx
7	Proposed Corrective Action Approved.	xx/xx/xxxx
8	Proposed Corrective Action Approved.	xx/xx/xxxx

LELAP requires that an attestation of compliance be completed prior to our final approval of these actions. Please sign and date the enclosed Attestation of Compliance form and return it to LELAP within ten (10) days of receipt of this notice.

Address all correspondence to the Office of Environmental Services, Louisiana Environmental Laboratory Accreditation Program, PO Box 4313, Baton Rouge, Louisiana, 70821-4313, Attention: LELAP Supervisor's Name.

If you have any questions, please contact Assessor name at (vvv) www-xxxx.

Sincerely,

Name, Supervisor
Louisiana Environmental Laboratory Accreditation Program

Supervisor's initial/ Assessor's initial (lower case)

Enclosure

Compliance Commitment Certification

I,_____, Environmental Scientist of the Louisiana Environmental Laboratory Accreditation Program and Assessor/Auditor of said program, do hereby certify the following:

1) I meet the education and training required by The NELAC Institute standard,

2) I shall commit myself to comply with the rules defined by the program,

3.a) I have not worked for, am not working for, do not foresee working for the laboratory(ies) assigned to me in the past three years, now, or in the future;

3.b) I have not been contracted by, am not currently contracted by, do not foresee being contracted by the laboratory(ies) assigned to me in the past three years, now, or in the future;

3.c) I have not been affiliated with, am not currently affiliated with, and do not foresee affiliation with the laboratory(ies) assigned to me in the past three years, now, or in the future, and

4) I shall not disclose confidential information about the laboratory assigned to me outside the program without the written consent of the laboratory, except where the law requires such information to be disclosed without such consent.

Signed this _____ in the City of
[list city], [list parish or county],
State of [list state]

_____
(Auditor/Assessor)
Louisiana Environmental Laboratory Accreditation Program

Louisiana Environmental Laboratory Accreditation Program

Assessment Checklist for State-Accredited Facilities Rev. 2

Special Instructions

This checklist must be completed by laboratory personnel. Each question must be responded to. LELAP requires that each "Laboratory Quality System Reference" be filled in with the citation to the specific section of the quality assurance manual or appropriate SOP.

Review of

Name of facility_____

Physical address (where assessment was conducted)_____

City_____

State_____ **Zip**_____

Date of Assessment:_____

On the above date, (print name(s)_____,

_____

representative(s) of the Louisiana Department of Environmental Quality (LDEQ), Louisiana Environmental Laboratory Accreditation Program (LELAP), performed an assessment of the above-named laboratory. The preliminary findings/observations (circle one) of the assessment are identified in the checklist below. This list does not preclude the possibility that other findings may be discovered during the review of material for the preparation of the assessment report.

Do not submit a corrective action plan for this document; the corrective action plan must be submitted for the assessment report which will be submitted within 60 days for the LAC assessment by the lead assessor.

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
	Program Requirements					
1	Is the laboratory legally identifiable and does it have a permanent business address and telephone number?	§4703.A				
2	Does the laboratory have the staff and resources sufficient to satisfactorily accomplish those analyses/tests for which accreditation is requested?	§4703.A				
3	Has the laboratory submitted a complete application package and paid all applicable fees?	§4703.B				
4	Are all of the laboratory facilities covered under the scope of accreditation located on the same or adjoining grounds?	§4703.C				
5	Has the laboratory designated an appropriate official (laboratory representative) to represent it in all matters related to attaining and maintaining environmental laboratory accreditation?	§4703.D				
6	Is the laboratory representative a person in a position of authority to ensure that the laboratory complies with the criteria and conditions for accreditation and does the representative have the authority to bind the company in a legal manner?	§4703.D				
7	Does the laboratory have copies of the relevant test method documentation and the requisite equipment for the methods available at the laboratory?	§4705.A				
8	Does the laboratory participate in department-approved proficiency testing programs relevant to its scope of accreditation, to provide suitable evidence of laboratory proficiency?	§4711.A; §4711.C				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
9	In cases where the department has determined that an appropriate proficiency test is not accessible or readily available for a particular type of analysis, has the laboratory submitted an "analytical data package" that includes all relevant analytical methodology, technical information, and quality assurance results for the requested method?	§4711.A; §4711.B				
10	Does the laboratory participate in two proficiency test studies per year for each field of testing, at intervals of approximately six months?	§4711.D				
11	Has the laboratory satisfactorily completed two proficiency test studies offered for each test category accredited within the most recent three proficiency test studies attempted?	§4711.E				
12	Has the laboratory authorized the proficiency test provider to release the results of all proficiency evaluation (PE) tests to LELAP at the same time that they are submitted to the laboratory?	§4711.F				
13	Has the laboratory performed corrective actions for all proficiency evaluation test results that are "unacceptable" for a specific analyte, including investigating and identifying likely causes for these results, resolving any problems, reporting such activity to LELAP, and submitting the corrective action proficiency sample test results?	§4711.F				
	Organization and Personnel Requirements					
14	Does the laboratory have the managerial staff with the authority and resources needed to discharge their duties?	§4901.A				
15	Is the technical director or his/her designated representative a full-time member of the laboratory staff with the authority to exercise the day-to-day supervision of the laboratory policies and procedures?	§4901.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
16	Does the laboratory specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of calibrations and tests?	§4901.A				
17	Does the documentation include a clear description of the lines of responsibility in the laboratory?	§4901.A.1				
18	Does the documentation include a description of personnel proportioned such that adequate supervision is ensured? Does the documentation include an organizational chart? (Recommended)	§4901.A.2				
19	Does the documentation include job descriptions for all positions?	§4901.A.3				
20	Does the laboratory technical director have a bachelor's degree in science or at least four years' equivalent experience in a related field?	§4901.B.1				
21	Does the laboratory technical director have at least two years' experience in the area of environmental analysis?	§4901.B.2				
22	Does the quality assurance manager have at least a bachelor's degree in science or four years' equivalent experience in a related field?	§4901.C.1				
23	Does the quality assurance manager have at least two years' environmental laboratory experience?	§4901.C.2				
24	Does the quality assurance manager have direct access to the highest level of management for decisions regarding laboratory quality assurance policy and resources, and independent authority regarding quality assurance oversight and implementation of the quality assurance program? **Note:** This organizational position must not report through the technical management of the laboratory.	§4901.C.3				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
25	Does the quality assurance manager have the opportunity and freedom to evaluate data objectively without influence from technical or financial management?	§4901.C.3				
26	Does the quality assurance manager have a general knowledge of all analytical methods that are performed by the laboratory?	§4901.C.4				
27	**NOTE:** In smaller laboratories (staff less than 10 total employees), the quality assurance manager's responsibilities may be performed by an upper level technical or operational manager of the facility. Academic and experience requirements apply.	§4901.C.5				
28	Do laboratory supervisors have at least a bachelor's degree or four years' experience in a related field?	§4901.D.1				
29	Do laboratory supervisors have at least one year of experience in the area to be supervised, preferably with a minimum of six months' supervisory experience?	§4901.D.2				
30	If the supervisor is a supervisor of a radiochemistry laboratory, does the individual have at least four years' experience in the field/area of radiochemistry or additional college-level training in related field? **Note:** Each year of additional college may substitute for one year of experience, up to a maximum of two years.	§4901.D.3				
31	1. Do the instrument operators have at least a high school diploma or equivalent? 2. Have instrument operators satisfactorily completed a short course or structured in-house equivalent on the operation of the instrument (by equipment manufacturer, professional organization, university, or other qualified training facility)?	§4901.E.1				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
32	Do instrument operators have at least six months' experience in the operation of the instrument with documentation that acceptable results are achieved by the operator?	§4901.E.2				
33	Do chemistry analysts have at least a high school diploma or equivalent, plus proper training in a methods training course or by a qualified analyst?	§4901.F.1.a				
34	Do chemistry analysts have at least six months' experience with the analysis procedure(s), with documentation that acceptable results are achieved by the analyst?	§4901.F.1.b				
35	1. Do microbiology analysts have at least a bachelor's degree in science or four years' experience in a related field? 2. Do microbiology analysts have training in water analyses for total coliform and fecal material and at least a high school diploma or the equivalent? Have they satisfactorily completed a short course or structured in-house equivalent on the proper techniques of analysis?	§4901.F.2.a				
36	Do microbiology analysts have at least six months' experience in microbiological analysis and techniques?	§4901.F.2.b				
37	Do radiochemistry analysts have at least a high school diploma or equivalent, plus specialized training in standards and sample preparation, instrument calibration, calculations, and data handling?	§4901.F.3.a				
38	Do radiochemistry analysts have at least six months of on-the-job training? **Note:** An analyst may assist in routine sample preparation and radioanalytical procedures provided that the work is supervised and validated by a qualified analyst and/or laboratory supervisor.	§4901.F.3.b				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
39	Do biomonitoring analysts have at least a high school diploma, or the equivalent, and documented training by a qualified analyst, with EPA video training tapes having been utilized where available?	§4901.F.4.a				
40	Do biomonitoring analysts have at least six months of on-the-job training with documentation of acceptable results from standard reference toxicant tests performed by the analyst?	§4901.F.4.b				
41	Does the laboratory maintain information on the relevant qualifications, training, and experience of all members of the technical staff?	§4901.G				
42	Does the laboratory provide additional training as needed in order to keep personnel current with new procedures, changes in existing procedures, and/or equipment changes or improvements?	§4901.H				
	Environment					
43	Are the following materials available for review at the laboratory: quality assurance plan; approved methodology manual(s); quality assurance data; and proficiency test data?	§5101.C				
44	Are the laboratory conditions in which the tests are undertaken such as to not invalidate the test results or adversely affect the required accuracy of measurement?	§5104~~3~~.A				
45	Does the laboratory have the necessary equipment, adequate storage facilities, procedures to preserve the identity, concentration and stability of samples, and energy sources needed for proper testing?	§5104~~3~~.A				
46	Is the laboratory equipped with devices to monitor essential environmental conditions?	§5103.A				
47	Does the laboratory have adequate workspace, ventilation, light, and access to stable power sources?	§5103.A.1				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
48	Does the laboratory have exhaust hoods for proper elimination of volatile materials?	§5103.A.2				
49	Does the laboratory have contamination-free work areas as necessary?	§5103.A.3				
50	Does the laboratory have chemical and sample handling areas that provide safe working areas and that prevent cross contamination of samples?	§5103.A.4				
51	Does the laboratory have adequate storage facilities for samples, extracts, reagents, solvents, reference materials, and standards to preserve their identity, concentration, purity, and stability?	§5103.A.5				
52	Does the laboratory have adequate procedures and facilities in place for collection, storage, and disposal of wastes, including expired chemicals, reagents, solutions, standards, and other material with a limited shelf life?	§5103.A.6				
53	Does the laboratory have adequate procedures and facilities for handling materials that may transmit infectious agents and radioactive materials, where relevant?	§5103.A.7				
54	Does the laboratory have appropriate storage for volatile, corrosive, or explosive chemicals and flammable solvents?	§5103.A.8				
55	Does the laboratory have adequate separation of activities to ensure that no activity has an adverse effect on analyses?	§5103.A.9				
56	Does the laboratory have separate culturing and testing facilities for biomonitoring laboratories?	§5103.A.10				
57	Does the laboratory have counting rooms that are physically separate from other activities in radiological laboratories?	§5103.A.11				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
58	Is access to and use of test areas regulated in a manner appropriate to their designated purpose, and entry by persons external to the laboratory controlled?	§5103.B				
59	Are adequate measures taken to ensure cleanliness in the testing area?	§5103.C				
	Test Methods and Procedures					
60	Does the testing laboratory have adequately documented instructions on the use and operation of all relevant equipment, on the handling and preparation of test items, where applicable, and on standard testing techniques, where the absence of such instructions could jeopardize the efficiency of the testing process?	§5105.A				
61	Are all instructions, standards, manuals, and reference data relevant to the work of the testing laboratory maintained up-to-date and readily available to the staff?	§5105.A				
62	Does the testing laboratory use department-approved methodologies that are available to the staff performing the tests?	§5105.B				
63	Has the testing laboratory implemented the written standard operating procedures (SOPs) that are available to the staff and inspector?	§5105.D				
64	Does the testing laboratory have an acceptable and written quality assurance program plan that is implemented by the staff and readily available to the inspector?	§5105.E				
65	Has the laboratory implemented satisfactory corrective action for all deficiencies or deviations identified in the previous on-site assessment?	§5107.B				
66	Does the laboratory strictly follow all safety practices that are included in or required by any approved method?	§5111.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
	Quality System Requirements					
67	Does the laboratory maintain its Quality Assurance/Quality Control (QA/QC) program using appropriate document control practices?	§5301.A				
68	Have the quality assurance manual, analytical methods, and administrative procedures necessary to meet requirements of these regulations been reviewed for accuracy and approved for release by the appropriate personnel, distributed, and controlled to ensure the use of the current approved version?	§5301.A				
69	Does the laboratory have documented quality control procedures in use for each analytical procedure?	§5301.A.1				
70	Does the laboratory comply with all quality control procedures required by applicable federal, state, or public health agencies when performing analyses?	§5301.A.2				
71	Does the laboratory have procedures to be followed for feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur?	§5301.A.3				
72	Does the laboratory operate an internal quality assurance program appropriate to the type, range, and volume of work performed?	§5301.B				
73	Has the laboratory management designated a person/persons having responsibility for quality assurance within the laboratory and having direct access to top management? (Quality Assurance Manager)	§5301.B				
74	Has the quality assurance program been documented in a quality assurance manual that is available for use by the laboratory staff?	§5301.C				
75	Is the quality assurance manual maintained by the Quality Assurance Manager?	§5301.C				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
76	Does the quality assurance manual contain information regarding the structure of the laboratory (organizational charts and generic position descriptions) including relationship between management, technical operations, support services, and quality systems?	§5301.C.1				
77	Does the quality assurance manual contain information regarding the operational and functional duties and services pertaining to quality assurance, so that each person concerned knows the extent and the limits of his/her responsibility?	§5301.C.2				
78	Does the quality assurance manual contain information regarding general quality assurance procedures?	§5301.C.3				
79	Does the quality assurance manual contain information regarding procedures for feedback and corrective action whenever testing discrepancies are detected?	§5301.C.4				
80	Does the quality assurance manual contain information regarding chain of custody procedures?	§5301.C.5				
81	Does the quality assurance manual contain information regarding a quality policy statement, including objectives and commitments, by management?	§5301.C.6				
82	Does the quality assurance manual contain information regarding procedures for the control and maintenance of documents, including document control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting?	§5301.C.7				
83	Does the quality assurance manual contain information regarding the laboratory's procedures for achieving traceability of measurements to NIST reference materials or other traceable commercial vendors?	§5301.C.8				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
84	Does the quality assurance manual contain information regarding the laboratory's scope of tests?	§5301.C.9				
85	Does the quality assurance manual contain information regarding procedures for handling submitted samples?	§5301.C.10				
86	Does the quality assurance manual contain information regarding major equipment, as well as the facilities and services used by the laboratory?	§5301.C.11				
87	Does the quality assurance manual contain information regarding procedures for calibration, verification, and maintenance of equipment?	§5301.C.12				
88	Does the quality assurance manual contain information regarding verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes?	§5301.C.13				
89	Does the quality assurance manual contain information regarding the laboratory management arrangements for departures from documented policies and procedures or from standard specifications?	§5301.C.14				
90	Does the quality assurance manual contain information regarding policy and procedures for the resolution of complaints received from clients or other parties, including a requirement that records of all complaint and subsequent actions must be maintained?	§5301.C.15				
91	Does the quality assurance manual contain information regarding procedures for protecting confidentiality and proprietary rights?	§5301.C.16				
92	Does the quality assurance manual contain information regarding procedures for audit and review?	§5301.C.17				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
93	Does the quality assurance manual contain information regarding identification of the laboratory's approved signatories?	§5301.C.18				
94	Does the title page of the quality assurance manual have the signed and dated concurrence (with appropriate titles) of all responsible parties, including the quality assurance officer(s), technical director, and the laboratory manager?	§5301.C.18				
95	Does the quality assurance manual contain information regarding processes/procedures for educating and training personnel in their ethical and legal responsibilities, including potential punishment and penalties for improper, unethical, or illegal actions?	§5301.C.19				
96	Does the quality assurance manual contain information regarding processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training?	§5301.C.20				
97	Does the quality assurance manual contain information regarding procedures for reporting analytical results?	§5301.C.21				
98	Does the quality assurance manual include a table of contents and applicable lists of references, glossaries, and appendices?	§5301.C.22				
99	Does the laboratory have documentation that the quality assurance system has been reviewed annually by management to ensure its continued effectiveness?	§5301.D; §5315.A				
100	Is there documentation that the laboratory has conducted annual internal audits to verify the compliance with the laboratory's quality system?	§5301.E; §5315.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
101	Is the quality assurance officer responsible for planning and organizing internal audits? Personnel shall not audit their own activities.	§5301.E				
102	Does the laboratory have a manual of standard operating procedures (SOPs) available to the analyst and the inspector? **Note:** SOPs may be included as a part or section of the laboratory's quality assurance manual.	§5301.F				
103	Does the laboratory have clearly defined, written SOPs or an equivalent that at addressing the following required elements? a. identification of the test method b. applicable matrix or matrices c. detection limit d. scope and application, including components to be analyzed e. summary of test method f. definitions g. safety h. equipment and supplies i. reagents and standards j. sample collection, preservation, storage, handling, and chain of custody k. quality control l. calibration m. procedure n. calculations o. method performance p. pollution prevention q. data assessment and acceptance criteria for quality control measures r. corrective actions for out-of-control or unacceptable data s. contingencies for handling out-of-control or unacceptable data t. waste management u. references v. any tables, diagrams, flowcharts, and validation data	§5301.F.1.a -v				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
104	Does the laboratory have clearly defined, written procedures for procurement and inventory procedures?	§5301.F.2				
105	Does the laboratory have clearly defined, written procedures for preventive maintenance?	§5301.F.3				
106	Does the laboratory have clearly defined, written procedures for recordkeeping and record storage (archives)?	§5301.F.4				
107	Does the laboratory have clearly defined, written procedures for data reduction, validation, and reporting?	§5301.F.5				
108	Does the laboratory have clearly defined, written procedures for correcting erroneous reports?	§5301.F.6				
109	Does the laboratory have clearly defined, written procedures for management of laboratory wastes and hazardous materials?	§5301.F.7				
110	Does the laboratory have clearly defined, written procedures for handling complaints registered against the laboratory's testing procedures, reporting procedures, and/or other general operating procedures?	§5301.F.8				
111	Have the written quality assurance/quality control procedures been implemented?	§5301.G				
112	Does the laboratory employ adequate quality controls to monitor tests such as blanks, spikes, or reference toxicants?	§5301.H.1.a				
113	Does the laboratory employ adequate tests to define the variability and/or reproducibility of the laboratory results such as duplicates?	§5301.H.1.b				
114	Does the laboratory employ measures to ensure the accuracy of the test data, including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures?	§5301.H.1.c				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
115	Does the laboratory employ measures to evaluate test performance, such as method detection limits, or range of applicability such as linearity?	§5301.H.1.d				
116	Does the laboratory employ selection of appropriate formulae to reduce raw data to final results such as linear regression, internal standards, or statistical packages?	§5301.H.1.e				
117	Does the laboratory employ measures to ensure selection and use of reagents and standards of appropriate quality?	§5301.H.1.f				
118	Does the laboratory employ measures to ensure constant and consistent test conditions (both instrumental and environmental) where required by the method?	§5301.H.1.g				
119	Are all quality control measures assessed and evaluated on an ongoing basis, and are quality control acceptance limits used to determine the validity of the data?	§5301.H.2				
120	Are acceptance/rejection criteria updated at a frequency established by the test method or by the department's standards?	§5301.H.2				
121	Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists?	§5301.H.3				
122	Are the method-specified and/or method-recommended quality control protocols followed?	§5301.H.4				
123	Are the essential quality control standards described in §5301.H used if no protocols are written into the method or if the method protocols are less stringent?	§5301.H.4				
	Equipment and Supplies					
124	Does the laboratory have access to all items of equipment required for correct performance of the analytical procedures for which it is accredited?	§5303.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
125	Does the laboratory have documentation that all equipment has been properly maintained?	§5303.B				
126	Is defective equipment removed from service and labeled until it has been repaired and shown to function satisfactorily?	§5303.C				
127	Have records been maintained for each item of equipment and for all reference materials significant to the tests performed?	§5303.D				
128	Have maintenance logbook(s) and/or an electronic maintenance database with scheduled backups been maintained for all major equipment?	§5303.D				
129	Do the equipment maintenance logs include the following required elements? 1. the name of the item of equipment 2. the manufacturer's name, type identification, and serial number 3. the date received and the date placed in service 4. the condition of equipment when placed in service (new, used, or reconditioned) 5. the current location 6. the location of manufacturer's instruction manual (if available) 7. the details of maintenance, including history of any damage, malfunction, modification, or repair.	§5303.D.1-7				
130	Are calibration records maintained for all measuring equipment?	§5303.E				
131	Are records maintained for acquisition of all equipment, reagents, and support services utilized by the laboratory in the generation of analytical data?	§5303.F				
132	Are reagent requirements specified by the accredited individual procedures being satisfied?	§5303.G.1.a				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
133	Are stock and working standard solutions checked regularly for signs of decomposition and expiration?	§5303.G.1.b				
134	Are all solutions labeled with identification of the compound, concentration, date prepared, analyst who prepared solution, and expiration date?	§5303.G.1.c				
135	Are all purchased chemicals, solutions, and standards labeled with dates of receipt, the dates of expiration on the container, and the date when the container is opened?	§5303.G.1.d				
136	When reagents are removed from a container, does the laboratory use the reagent entirely or discard the unused portion? Note: Unused portions of a reagent may not be returned to the original container	§5303.G.1.e				
137	Are all compressed gases of commercial grade, unless individual procedures specify other requirements?	§5303.G.1.f				
138	Is all glassware cleaned and maintained properly as required by the test methodology?	§5303.G.2				
139	Where temperature measurements are required, does the laboratory have access to a NIST (National Institute of Standards and Technology) traceable thermometer?	§5303.G.3.a				
140	Has the calibration of working thermometers been checked at least annually against a NIST-traceable certified thermometer, and the results recorded and documented per thermometer?	§5303.G.3.b				
141	Has the calibration of dial-type thermometers been checked at least quarterly against a NIST traceable thermometer and results recorded per thermometer?	§5303.G.3.c				
142	Have all thermometers been labeled when calibrated and the correction factor recorded?	§5303.G.3.d				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
143	Does the laboratory have records showing daily (or before each use) functional/calibration checks for analytical balances and monthly functional/calibration checks for pan balances?	§5303.H.1.a				
144	Does the laboratory use at least two ranges when calibrating analytical balances and pan balances with a minimum class S or S-1 reference weights or equivalent?	§5303.H.1.a				
145	Have the reference weights used for balance calibration checks been recertified every two years?	§5303.H.1.a				
146	Have all balances been calibrated and serviced at a minimum of once per year, and has the service date been recorded on the balance?	§5303.H.1.b				
147	Are balances only used with suitable support?	§5303.H.1.c				
148	For pH measurements, does the laboratory use a pH meter with appropriate electrode with scale graduations at least 0.1 pH units (calibrated to ± 0.1 pH units for each use period) with temperature correction?	§5303.H.2.a				
149	For pH measurements, does the laboratory use either a thermometer or a temperature sensor for automatic temperature compensation?	§5303.H.2.b				
150	For pH measurements, have records been maintained indicating calibration daily or before each use, whichever is less frequent?	§5303.H.2.c				
151	For pH measurements, are aliquots of standard pH 4 and pH 7 or pH 7 and pH 10 used only once?	§5303.H.2.d				
152	For conductivity measurements, is a conductivity meter and probe of sufficient sensitivity used?	§5303.H.3.a				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
153	For conductivity measurements, have records been kept to show a daily or before each use calibration check, whichever is less frequent? **Note:** Calibration shall be within the range of interest using standard solutions.	§5303.H.3.b				
154	For conductivity measurements, have records been kept showing that the cell constant has been determined annually?	§5303.H.3.c				
155	Does each refrigerator have a thermometer immersed in liquid to the appropriate immersion line?	§5303.H.4.a				
156	Are refrigerator thermometers graduated in increments no larger than 1°C?	§5303.H.4.b				
157	Have temperatures for each refrigerator been recorded for each day in use for laboratory activities?	§5303.H.4.c				
158	Are samples stored in separate refrigerators from all standards where a potential for cross-contamination exists?	§5303.H.4.d				
159	Have refrigerator temperatures been maintained between 1°C and 6°C (inclusive), and have freezer temperature been maintained below 0°C?	§5303.H.4.e				
160	Have visual comparison devices been calibrated according to manufacturer's specifications and/or test methodologies?	§5303.H.5.a				
161	Have the calibration results for visual comparison devices been recorded and maintained?	§5303.H.5.b				
162	For ovens, incubators, or baths, is there documentation that the temperature has been adequately controlled?	§5303.H.6.a				
163	For ovens, incubators, or baths, have records been kept to show that temperature has been maintained (e.g., beginning and end of each use cycle or daily for extended drying periods)?	§5303.H.6.b				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
	Calibration					
164	Have measuring and testing equipment used by the testing laboratory been calibrated, where appropriate, before being put into service and thereafter according to an established program?	§5305.A				
165	Does the laboratory have an overall program of calibration of equipment designed and operated so as to ensure that measurements made in the testing laboratory are traceable (where the concept is applicable) to national standards of measurement and, where available, to international standards of measurement specified by the International Committee of Weights and Measures?	§5305.B				
166	Where the concept of traceability to national or international standards of measurement is not applicable, has the testing laboratory provided satisfactory evidence of correlation or accuracy of test results (e.g., by participation in a suitable program of interlaboratory comparisons)?	§5305.B				
167	Does the laboratory maintain a record of all calibration data including frequency, conditions, and standards used for all analytical methodology?	§5305.C				
168	Has the laboratory verified and documented all standards versus primary (reference) standards?	§5305.D				
	Test Methods and Procedures					
169	Does the laboratory have procedures for making and controlling revisions to in-house SOPs, using revised SOPs only after written authorization from the designated laboratory authority?	§5307.A				
170	Are all quality control procedures documented and available to the staff as required in LAC 33:I.5301.C?	§5307.B				
171	Are all manual calculation and data transfers subject to appropriate checks?	§5307.C				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
172	When manual calculations have been checked by a supervisor or another analyst, have the results been initialed and dated on the work sheet by the individual who verified the results?	§5307.C.1				
173	Where results are derived by electronic data processing techniques, is stability of the system such that the accuracy of the results is not affected?	§5307.C.2				
174	Does the laboratory have the ability to detect malfunctions in computer hardware during program execution and to take appropriate corrective action?	§5307.C.2				
175	Does the laboratory adhere to good automated laboratory practices (GALP)? (Recommended)	§5307.C.2				
176	Does the laboratory employ computer software that is appropriate for the intended use?	§5307.C.2.a				
177	Has the laboratory established and implemented procedures for the protection of the integrity of data?	§5307.C.2.b				
178	Do the laboratory procedures for protection of the integrity of data address the following required elements? i. integrity of data entry or capture; ii. data storage; iii. data transmission iv. data processing;	§5307.C.2.b .i-iv				
179	Have computer and automated equipment been provided with acceptable environmental operating conditions in order to maintain the operating integrity of the system?	§5307.C.2.c				
180	Have appropriate procedures been implemented in order to maintain the security of data, including prevention of unauthorized access to computer records and prevention of unauthorized amendments or changes to computer records?	§5307.C.2.d				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
181	Whenever samples are subcontracted to another environmental testing laboratory, does the original laboratory maintain a verifiable copy of results with a chain of custody?	§5307.D				
182	Does the laboratory ensure that any subcontracted laboratory used is properly accredited for the scope of testing performed?	§5307.D				
	Reports					
183	Do the laboratory's test reports accurately, clearly, and unambiguously present the test results and all other relevant information?	§5313.A				
184	Are the laboratory's test reports designed for the type of test/analysis reported, with standardized heading utilized whenever possible?	§5313.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
185	Does each test report include the following required information? 1. name and address of testing laboratory 2. title of report, unique identification of report (such as log number), identification of each page of the report by number, and total number of pages in the report 3. description and identification of the sample(s) 4. date of receipt of sample(s) and date(s) of performance of test, as appropriate 5. identification of the test method 6. any deviations, additions to, or exclusions from the test method and any other information relevant to a specific test 7. disclosure of any nonstandard test method utilized 8. measurements, examinations, and results, accompanied by appropriate quality assurance (QA) documents 9. a statement on measurement uncertainty (where relevant) 10. a signature and title of person(s) accepting technical responsibility for the test report and date of issue 11. if applicable, a statement that indicates that the results relate only to the items tested 12. if applicable, a statement that indicates that the report shall not be reproduced in full (or in part, if required) without the written approval of the customer	§5313.B.1-12				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
186	Are corrections or additions to a test report after issue made only by a further document that is suitably marked (e.g., "Supplement to test report log number ..." or as otherwise identified) and that meets the relevant requirements of §5313?	§5313.C				
187	In instances where the laboratory transmits a report via telephone, telex, facsimile (FAX), or any other means of electronic transmittal, does the laboratory have in place a written procedure that will provide protection and/or preservation of client confidentiality?	§5313.D				
	Records					
188	Does the laboratory maintain a record system that produces accurate, readily available records (including archived SOPs) that document all laboratory activities?	§5315.A				
189	Does the testing laboratory retain on record all original raw data and observations, calculations and derived data, calibration records, and the final test report in a manner in which the continuity and integrity of the analytical process is preserved?	§5315.A				
190	Does the laboratory retain all records for a minimum of 10 years or as required by regulatory or legal requirement?	§5315.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
191	Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of test data, does the laboratory ensure that the following requirements are met? 1. computer software has been documented and is adequate for use 2. procedures have been established and implemented to protect the integrity of data. Such procedures include, at a minimum, integrity of data entry or capture, data storage, data transmission, and data processing 3. computers and automated equipment are maintained to ensure proper functioning and retrieval of data 4. procedures have been developed and implemented to maintain security of data, including prevention of unauthorized access to, or unauthorized amendment of, computer records.	§5315.A.1-4				
192	Are all records and test reports held securely and in confidence to the client, unless otherwise required by law?	§5315.B				
193	Does the testing laboratory maintain a system that provides for retrievability of the chain of custody of the sample source, the analytical method, results (including calibration and instrument checks), the analyst performing the analysis, and the date?	§5315.C				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
194	If laboratory records indicate that incorrect or questionable data has been generated by defective or improperly operated equipment, erroneous data entry, or other such anomalies, and a report has been issued, does the laboratory immediately notify the client and issue a written, corrected or amended report to the client?	§5315.C				
195	Are current reference documents (e.g., EPA manuals, CFRs, Standard Methods) maintained and available to the staff?	§5315.D				
196	Are all entries to laboratory analytical records made in a legible, permanent fashion?	§5315.E				
197	Are any corrections to laboratory analytical record made without obliterating original entries, and initialed and dated?	§5315.E				
198	Has a permanent record of employees' signatures and initials been maintained?	§5315.F				
199	Has the laboratory maintained administrative records (e.g., training records) in a manner in which the continuity, integrity, and retrievability processes are preserved?	§5315.G				
	Unacceptable Samples					
200	Does the laboratory have a written procedure for handling of questionable samples in cases where a sample is received by the testing laboratory and it is apparent or suspected that the sample protocol has not been followed? **Note:** The laboratory may choose to notify the customer and either request another sample or, if the customer insists upon analysis of the sample, reserve the right to include a disclaimer in the final report identifying the sample anomaly. This disclaimer must be permanently attached to the final report.	§5501.A				

Item	Requirement	LAC Reference	LELAP Use Only	LELAP Use Only	Quality System Reference	Comment
			Present	Absent/ Further Review		
	Display of Accreditation Certificate					
201	Is the current accreditation certificate displayed at all times in a location visible to the public in the laboratory?	§5701.A				
202	Does the laboratory accurately represent its accreditation status in laboratory reports, catalogs, advertising, business solicitations, or proposals?	§5701.C				
	Changes in Laboratory Operation					
203	Has the laboratory reported any changes in laboratory name, ownership, location, personnel, facilities, methodology, or any factors significantly affecting the performance of analyses for which the laboratory was originally accredited, within 30 days of occurrence?	§5707				

Name of Assessor(s): _____ Date: _____

_____ Date: _____

Name of Facility Representative(s): _____ Date: _____

_____ Date: _____

ID #	Major Topic	Topic	Subject	Category	Citation	Does the laboratory comply with this section?	Yes	No	N/A
1	Quality Systems Summary				V1M2 1	***Summary of Quality System Requirements - Checklist responses will determine whether or not these have been met. You may use any of these items for assessment if you want.***			
2	Quality Systems Summary	Introduction			V1M2 1	**INTRODUCTION, SCOPE AND APPLICABILITY**			
3	Quality Systems Summary	Introduction			V1M2 1.1	Introduction			
4	Quality Systems Summary	Introduction	General		V1M2 1.1	Each laboratory shall have a quality system. The laboratory's quality system is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements such as:			
5	Quality Systems Summary	Introduction	General	Quality System Components	V1M2 1.1 a)	policies and objectives,			
6	Quality Systems Summary	Introduction	General	Quality System Components	V1M2 1.1 b)	procedures and practices,			
7	Quality Systems Summary	Introduction	General	Quality System Components	V1M2 1.1 c)	organizational authority,			
8	Quality Systems Summary	Introduction	General	Quality System Components	V1M2 1.1 d)	responsibilities, and			
9	Quality Systems Summary	Introduction	General	Quality System Components	V1M2 1.1 e)	performance measures.			
10	Quality Systems Summary	Introduction	General	Use and Documentation	V1M2 1.1	The quality system provides the framework for planning, implementing, assessing, and improving work performed by an organization so as to provide the client with data of known and documented quality, sufficient to evaluate the usability of the data to the clients needs. The quality system shall be documented in the laboratory's quality manual and related quality documentation, and shall be referenced in the quality manual.			
11	Quality Systems Summary		General	Requirement and Purpose	V1M2 1.1	This Standard contains detailed quality system requirements for consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies. Each laboratory seeking accreditation under this Standard shall ensure that they are implementing their quality system and that all Quality Control procedures specified in this module are being followed. The Quality Assurance policies, which establish quality control procedures, are applicable to environmental laboratories regardless of size and complexity.			
12	Quality Systems Summary	Introduction	General		V1M2 1.1	This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services.			
13	Quality Systems Summary	Introduction	General	Requirement and Purpose	V1M2 1.1	All items identified in this document shall be available for an on-site assessment.			
14	Quality Systems Summary	Scope			V1M2 1.2	Scope			
15	Quality Systems Summary	Scope			V1M2 1.2	The requirements in this document give the basis for a laboratory's quality system in order to carry out environmental tests. It covers testing performed using reference methods, non-reference methods, and laboratory-developed methods. This document contains the essential elements required to establish a quality system that produces data of known and documented quality, and demonstrates proficiency through the use of proficiency testing and employee training.			
16	Quality Systems Summary	Scope			V1M2 1.2	The general requirements of this document apply to all organizations performing environmental tests, regardless of the number of personnel or the degree of environmental testing activities. When the use of the data requires compliance with the Standards, these Standards shall be followed.			

ID #	Major Topic	Topic	Subject	Category	Citation	Does the laboratory comply with this section?	Yes	No	N/A
17	Quality Systems Summary	Scope			V1M2 1.2	This document is for use by laboratories, clients, regulatory authorities, and accreditation bodies to ensure the laboratory has appropriate management and technical quality systems to perform environmental testing. This document specifies technical, managerial, and documentation requirements needed for assessment by organizations or accreditation bodies to grant approval.			
18	Quality Systems Summary	Scope			V1M2 1.2	This document provides the requirements needed for laboratory accreditation. If the requirements of this document are met, the laboratory operates a quality system in conformance with the applicable clauses of ISO/IEC 17025:2005(E).			
19	Definitions	Definitions			V1M2 3	***Make sure you understand all these terms as they relate to the assessment.***			
20	Definitions	Definitions			V1M2 3	**TERMS AND DEFINITIONS**			