

64801.00 Definitions

The definitions listed in 2016 TNI Standard - Revision 2.1, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, herein incorporated by reference, apply throughout this chapter. Definitions used differently or that do not exist in 2016 TNI Standard - Revision 2.1, Volume 1, are defined below.

(a)

"Acceptable Scores" means analytical results for a Proficiency Testing sample are within the specified acceptance criteria for that sample.

(b)

"Accreditation" means the recognition of a laboratory by ELAP to conduct analyses of environmental samples for Regulatory Purposes.

(c)

"Assessment Agency" means ELAP or any entity that is contracted by ELAP to conduct laboratory assessments for ELAP.

(d)

"CA-NV/AWWA" means California-Nevada Section of the American Water Works Association.

(e)

"Citation" means a monetary fine assessed to a laboratory due to non-compliance with a statute, regulation, or order issued or adopted pursuant to the

Environmental Laboratory Accreditation Act.

(f)

"Client" means the entity for which the laboratory is performing analyses for Regulatory Purposes.

(g)

"Complete Application Package" means an application package containing all the elements required in Section 64802.00.

(h)

"Corrective Action Plan" means the response to an onsite assessment report that contains a Root Cause Analysis of the finding(s) identified in the onsite assessment report, the corrective actions that will take place to address the findings, and the date by which the finding(s) will be corrected.

(i)

"CWEA" means California Water Environment Association.

(j)

"Days" means calendar days, unless otherwise stated.

(k)

"Denial" means a decision to reject an application for accreditation due to non-compliance with ELAP statutes and regulations.

(l)

"ELAP" means the California Environmental Laboratory Accreditation Program, a program within the State Water Resources Control Board.

(m)

"Field(s) of Accreditation" means the matrix, technology/method, and analyte combinations for which ELAP will offer accreditation, as defined in 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, herein incorporated by reference.

(n)

"Owner" means a public agency, or any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

(o)

"Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act on its behalf for purposes of complying with ELAP regulations or the statutes under which ELAP regulations are adopted.

(p)

"Primary Accreditation Body" means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, supporting documents, Proficiency Testing sample results, and conducting on-site assessments or reviewing on-site assessment reports.

(q)

"Quality Manager" means a member of the laboratory staff who is responsible for ensuring the management system related to quality is implemented and followed at all times. Where staffing is limited, the Technical Manager and Quality Manager may be the same person.

(r)

"Quality Manual" is defined in 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, herein incorporated by reference, and replaces the term Quality Assurance Manual.

(s)

"Regulatory Purposes" is defined in Health and Safety Code section 100825.

(t)

"Revocation" means the permanent loss of a certificate of accreditation due to non-compliance with ELAP statutes and regulations.

(u)

"Root Cause Analysis" means an investigation by the laboratory to determine the underlying cause(s) of a finding identified in an onsite assessment report or a non-compliance identified by the laboratory.

(v)

"Sophisticated Technology" means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding including gas chromatography/mass spectrometry (GC/MS), inductively coupled plasma spectrometry (ICP), inductively coupled plasma/mass spectrometry (ICP/MS), liquid chromatography/mass spectrometry (LC/MS), atomic absorption spectrophotometry (AA), gas chromatography (GC), alpha particle or gamma ray spectrophotometry, electron microscopy (EM), polarized light microscopy (PLM), high pressure performance liquid chromatography (HPLC), bioanalytical assays, and advanced molecular methods.

(w)

"State Regulatory Agencies" means those state agencies whose statute or regulations require it to use laboratories that have been accredited by ELAP.

(x)

"State Water Board" means the California State Water Resources Control Board, which includes ELAP.

(y)

"Suspension" means the total or partial removal of a laboratory's accreditation to allow the laboratory to correct findings that identified non-compliance with ELAP

statutes and regulations.

(z)

"Technical Manager" is described in 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, Section 4.1.7.2, herein incorporated by reference (with the exception of part [f]), and replaces the title of Laboratory Director.

(aa)

"TNI" means The NELAC Institute.

(bb)

"Trade Secret" means any information that meets the definition in Government Code section 6254.7(d).

(cc)

"Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Vehicle Code section 630.