



## Legionella Culture Analysis ELAP Certification Frequently Asked Questions June 1, 2016

**FAQ 1:** Why is ELAP offering certification for *Legionella* Culture Analysis beginning June 1, 2016?

**ANS 1:** ELAP is offering *Legionella* certification in response to the proposed permanent Protection Against Legionella regulation which will require all *Legionella* culture analyses to be performed by a laboratory that is approved to perform such analyses by the New York State Environmental Laboratory Approval Program (ELAP).

**FAQ 2:** Are the *Legionella* regulations in effect?

**ANS 2:** At this time (June 1, 2016), these are proposed regulations. The proposed permanent regulations are available for review and comment until June 6, 2016 and can be viewed at <http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac9558781006774852569bd00512fda/518310a14613699085257f9900656270?OpenDocument>.

**FAQ 3:** ELAP notified laboratories that certification for *Legionella* culture analysis will be offered in the category of Non-Potable water. The proposed regulation addresses Potable water systems in residential health care facilities and hospitals. Will ELAP be offering certification for *Legionella* culture analysis in the category of Potable water?

**ANS 3:** Yes. Application materials for certification for *Legionella* culture analysis in the categories of Potable water and Non-Potable water are available.

**FAQ 4:** What methods will laboratories be allowed to use for *Legionella* culture analysis in the categories of Non-Potable and Potable water?

**ANS 4:**

-Non-Potable water: Certification for *Legionella* culture analysis will be offered in the category of Non-Potable water using International Standard Method 11731 Water quality-detection and enumeration of Legionella (ISO 11731).

-Potable water: Certification for *Legionella* culture analysis will be offered in the category of Potable water using International Standard Method 11731 Water quality-detection and enumeration of Legionella (ISO 11731) or International Standard Method 11731-2 Water quality-detection and enumeration of Legionella Part 2: Direct membrane filtration method for waters with low bacterial counts (ISO 11731-2).

**FAQ 5:** Will New York State (NYS) be offering proficiency testing (PT) for *Legionella* culture analysis?

**ANS 5:** No.

**FAQ 6:** If NYS is not offering *Legionella* PTs, where can I obtain *Legionella* PT samples for Non-Potable and Potable water?

**ANS 6:** In the absence of a New York State PT, PT samples needs to be obtained from another organization accredited by a Proficiency Testing Provider Accreditor that meets the NELAC/TNI requirements, if there is a PT provider available.

-Non-Potable water: we are aware of one PT provider for *Legionella* that meets the NELAC/TNI requirements. This is Sigma-Aldrich RTC (phone: 307-742-5452). Our understanding is that they have a Quick turnaround PT available.

-Potable water: we are not aware of a PT provider for *Legionella* that meets the NELAC/TNI requirements for potable water. Therefore, laboratories seeking certification for *Legionella* culture analysis in the category of Potable water will not need to submit PT data. In the absence of a PT, an initial demonstration of capability will be required with the submission of the application for certification in the Potable water category.

**FAQ 7:** Will PTs performed as part of the CDC ELITE program be accepted to meet the ELAP PT requirement for Non-Potable water?

**ANS 7:** No. The CDC ELITE program PT does not meet the NELAC/TNI requirements.

**FAQ 8:** ELAP indicated that applicants for certification for *Legionella* culture analysis in the category of Non-Potable water must demonstrate passing scores in at least two (2) of three (3) consecutive proficiency tests performed at least fifteen (15) days apart. With having to perform these at least 15 days apart we will likely not have this finished before the June 29th deadline. Will laboratories need to participate in 2 successful PT's prior to June 29, 2016?

**ANS 8:** A laboratory should make every effort to submit documentation to demonstrate passing scores in at least two (2) of three (3) consecutive proficiency tests (PTs) performed at least fifteen (15) days apart. For purposes of compliance with the *Legionella* regulations, a laboratory that submits an application for certification for *Legionella* culture analysis in the category of Non-Potable water with documentation showing a passing score in one PT event will be granted interim approval provided that documentation is submitted that indicates steps have been taken to perform additional PT studies, including an expected date of completion. A laboratory that has been granted interim approval with one (1) passing PT event will be required to submit documentation to demonstrate passing scores in at least two (2) of three (3) consecutive proficiency tests performed at least fifteen (15) days apart by July 29, 2016.

**FAQ 9:** Will ELAP accreditation/requirements also cover *Legionella* PCR analysis?

**ANS 9:** No. ELAP is only certifying for *Legionella* culture analysis. Certification for PCR and other methods used for the identification and/or speciation of *Legionella* is not required.

**FAQ 10:** If our laboratory is recognized by another accrediting agency for *Legionella* testing, is ELAP certification still required?

**ANS 10:** Yes. At this time, ELAP is not recognizing other accrediting agencies.