Requirements in VHA Directive 1061 for Detection of *Legionella* in Environmental Samples

July 27, 2018

Purpose of this Document:
Questions have been raised regarding the requirements in VHA Directive 1061 for detection of *Legionella* in water samples, especially since new testing technologies are becoming available. This document provides a description of the policy requirements in the Directive for testing environmental samples for *Legionella*.

VHA Directive 1061 can be found at the following link:
https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3033

If you have any questions, please contact the National Infectious Diseases Service at Shantini.Gamage@va.gov.

VHA Policy for Environmental Detection of *Legionella*
NOTE: Underlines and footnotes are used in this policy excerpt to denote requirements that are further clarified in the next section of the document.

Per VHA Directive 1061, Appendix C, paragraph 2b(1):

> "Laboratories that process the water samples for *Legionella* must be certified by the Centers for Disease Control and Prevention (CDC) Environmental *Legionella* Isolation Techniques Evaluation (ELITE) program[1] or the Public Health England (PHE) *Legionella* External Quality Assessment (EQA) scheme as proficient at performing the culture[2] of *Legionella*[3] from environmental samples. Information about CDC ELITE certified laboratories can be found at https://wwwn.cdc.gov/elite/Public/MemberList.aspx. Laboratories must also be able to determine if the *Legionella* detected in environmental samples is the species *Legionella pneumophila* serogroup 1[4]. ***NOTE:*** *Per CDC guidance, rapid testing methods, such as polymerase chain reaction (PCR) and direct fluorescent antibody (DFA), are not recommended for the detection of* Legionella *in environmental water samples.* In addition to the requirement for current CDC ELITE or PHE *Legionella* EQA certification, consider using a laboratory that also has environmental microbiology accreditation by a recognized accrediting program."

Further Description of VHA Policy for Environmental Detection of *Legionella*
In the list of policy requirements below, the numbers correspond to the footnotes in the policy excerpt on Page 1.

1. Centers for Disease Control and Prevention (CDC) Environmental *Legionella* Isolation Techniques Evaluation (ELITE) program**.**
    - Laboratories that process VA facility environmental samples for *Legionella* detection must be certified by the CDC ELITE program or the PHE EQA scheme.
    - For a laboratory to have CDC ELITE certification, it must use a **traditional culture method** that will detect all species of *Legionella* (not just a subset of *Legionella* species).
        - "**Traditional culture method**" means a method that results in detection of bacterial colonies that are then verified to be *Legionella*.
        - The actual culture method used is not part of the certification process since different methods or variations can be used. So, for example, CDC does not require that laboratories use a specific ISO method to qualify for certification. Concomitantly, VHA Directive 1061 does not require a specific method be used as long as a culture method is used by a CDC ELITE (or PHE EQA) certified laboratory.

    - The CDC ELITE program does not provide certification to laboratories based on use of non-culture methods of *Legionella* detection (e.g. PCR) or culture methods that do not produce colonies (e.g. liquid-based culture methods that give a result without further analysis).

      NOTE: From the CDC ELITE website: "Beginning in November 2016, the Wisconsin State Laboratory of Hygiene (WSLH) began managing the production and distribution of testing samples as well as analysis of lab results. CDC's continued role will be to oversee the ELITE Program as a whole, provide customer support to members, and host the public, online members list."
        - With this partnership with WSLH, there are new services offered. Laboratories can use non-traditional methods (e.g. PCR or liquid-based culture methods) to test samples provided by the WSLH and receive a report with a score of their proficiency at identifying *Legionella*; however, these results are not used by CDC to then determine ELITE certification. Only results from traditional culture methods are reviewed by the CDC ELITE program for certification.
        - Even though VHA Directive 1061 does not explicitly indicate that a CDC ELITE-certified laboratory must use the same *Legionella* detection method for processing of VA facility samples that it used to receive the certification, this was the intent; it would be good practice to ensure that a method used on facility samples is the traditional culture method used to receive ELITE certification.

    - For more information on the CDC ELITE program, please see this link to Frequently Asked Questions: https://wwwn.cdc.gov/elite/Public/FAQ.aspx

2. Culture
   - VHA Directive 1061 requires that *Legionella* detection in environmental samples be accomplished using a culture methodology. While the policy does not specify what kinds of culture methods are acceptable, the requirements of the CDC ELITE program as stated above, or the PHE EQA scheme, apply since labs need to be certified by either of those entities.

   - Facilities may choose to use other methods in addition to culture by a CDC ELITE certified lab (e.g. use of PCR as an early screen for *Legionella*-negative samples). This is a local decision and not required by the Directive. *NOTE: If a facility chooses to use these additional methods, it would be prudent to use a laboratory that has demonstrated proficiency in the method(s) from the Wisconsin State Laboratory of Hygiene.*

3. *Legionella*
   - VHA Directive 1061 includes actions based on the type of *Legionella* detected (i.e. whether it was *L. pneumophila* or not). Furthermore, knowing if non-pneumophila species are present in the water is informative for guiding remediation actions, understanding patient risk, and informing the type of diagnostic tests to order. Therefore, the policy requires that water samples be processed for detection of any *Legionella* species (not just *L. pneumophila*).
     - *NOTE: If non-pneumophila* Legionella *are detected, the facility can determine if it wants to know the name of the species or if it just wants to know that the* Legionella *detected was non-pneumophila. The policy does not require speciation of* Legionella *that are not* L. pneumophila*.*

   - Methodologies that only detect certain species of *Legionella* are not, by themselves, sufficient for compliance with the Directive. Furthermore, labs that use methods that only detect certain species of *Legionella* by culture are not eligible for CDC ELITE certification.
     - Facilities may choose to use methods that detect only a subset of species in addition to culture of all *Legionella* by a CDC ELITE certified lab. This is a local decision and not required by the Directive.

4. *Legionella pneumophila* serogroup 1
   - If *L. pneumophila* is detected, the laboratory must provide information on whether it is serogroup 1 or not. This requirement is in place because *L. pneumophila* serogroup 1 is the most common type of *Legionella* that causes disease in the U.S. Specifically, all *L. pneumophila* serogroups cause about 90% of cases and *L. pneumophila* serogroup 1 causes about 80% of cases.

   - If the *L. pneumophila* is determined not to be serogroup 1, it is a local facility decision as to whether the laboratory should provide the serogroup type (e.g. *L. pneumophila* serogroup 6) or not (e.g. *L. pneumophila* 2-14, or *L. pneumophila* not serogroup 1).