



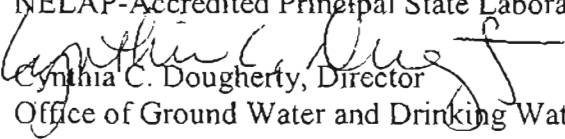
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 29 2009

OFFICE OF
WATER

MEMORANDUM

SUBJECT: Clarification of Regional Office Responsibilities Related to Oversight of
NELAP-Recognized State Drinking Water Laboratory Programs and
NELAP-Accredited Principal State Laboratories

FROM: 
Cynthia C. Dougherty, Director
Office of Ground Water and Drinking Water

TO: Regional Science and Technology Directors
Regional Certification Authorities
Regional Drinking Water Branch Chiefs

The Office of Ground Water and Drinking Water (OGWDW) has been asked to clarify roles and responsibilities for EPA's Regional Offices, vis-à-vis those of the National Environmental Laboratory Accreditation Program (NELAP) in oversight and decision-making associated with state Accreditation Bodies (ABs) and NELAP-accredited state laboratories (i.e., "principal state laboratories" [PSLs]). Clarification of roles and responsibilities is particularly important as we work together to ensure that primacy conditions are being met, and as we collectively seek to maximize drinking water laboratory integrity and minimize vulnerabilities, per the recommendations from the Office of Inspector General's 2006 review of drinking water laboratories.

EPA oversight of state drinking water programs and PSLs is fundamentally a primacy responsibility that is carried out by the Regions, as described in Attachment 1. OGWDW anticipates that Regions will typically use the NELAP-led evaluations of the state (AB) programs and the NELAP audits of PSLs to support the Region's determination that the state is meeting its "primacy" requirements. Accordingly, OGWDW values Regional participation in the NELAP evaluations of the state programs and encourages continued participation; OGWDW similarly encourages Regions to participate in NELAP audits of PSLs seeking to attain or renew NELAP accreditation. However, we note that Regions may choose to independently review the drinking water portion of a NELAP state program, or may choose to independently audit the PSL for a NELAP state, just as they would for a non-NELAP state.

Ongoing Regional participation in the NELAP process (evaluation of ABs, audits of PSLs) promotes quality and consistency, and allows for efficient use of limited resources. Such collaboration results in better communication between EPA and NELAP and helps

minimize the potential for disputes. Nonetheless, we recognize that there may be times when a Region and NELAP will have different opinions regarding the acceptability of a state program or PSL. In such cases, we encourage the Region to work directly with the particular AB and, as appropriate, the NELAP Board to resolve the differences. OGWDW is also available to work with you, especially if you need input regarding program requirements or policy matters or you are not able to resolve differences through the other channels. *Ultimately, the primacy decisions regarding the acceptability of the state program and the PSL rest with the Region.*

OGWDW appreciates the input from the Regional Science and Technology (RS&T) Directors, Regional certification programs, and representatives of NELAP and The NELAC Institute (TNI), among others, towards our development of this memo and its attachments. Should you have any further questions regarding the subject, please contact Greg Carroll of OGWDW's Technical Support Center at 513-569-7948 or carroll.gregory@epa.gov.

Attachment 1: *“Respective EPA/NELAP Roles Associated with NELAP-Recognized Accreditation Bodies/Programs and NELAP-Accredited State Drinking Water Laboratories”*

Attachment 2: *“OGWDW Clarification Regarding Principal State Laboratory Definition/ Oversight”*

cc (w/ attachments):

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Attachment 1

Respective EPA/NELAP Roles Associated with NELAP-Recognized Accreditation Bodies/Programs and NELAP-Accredited State Drinking Water Laboratories

Issue: For State¹ Drinking Water accreditation programs and for Principal State DW Labs (PSLs) being recognized/accredited by the National Environmental Laboratory Accreditation Program (NELAP), there are really two sets of decisions being made: one regarding NELAP accreditation status (i.e., Should the State be recognized to serve as a NELAP Accreditation Body [AB]? Should the PSL be NELAP-accredited?) and the other regarding SDWA primacy conditions (i.e., Are the conditions of 142.10(b) being met?). The former is a NELAP decision; the latter is an EPA decision. Respective roles are described further below.

	NELAP/TNI - Drinking Water	NELAP/TNI - Other (non Drinking water)
<u>State Accreditation Program</u>		
On-site (typically triennial) evaluation of State program ²	NELAP (and Region, as appropriate)	NELAP
Off-site, annual review of State DW program	Region	NA
Decision regarding <i>NELAP</i> recognition of State program as an Accreditation Body	NELAP	NELAP
<i>EPA</i> determination that the State program is meeting primacy conditions [142.10(b)(3)]	Region	NA
<u>Principal State Lab³</u>		
Audit/review of Principal State Lab	State ⁴ Accreditation Body [AB] (and Region, as appropriate)	State AB
Decision regarding <i>NELAP/TNI</i> accreditation of Principal State Laboratory	State AB	State AB
<i>EPA</i> determination that Principal State Laboratory is meeting primacy conditions [142.10(b)(4)]	Region	NA
<u>Commercial (non-PSL) Laboratory</u>		
Audit/review of commercial laboratory	State AB	State AB
Decision regarding accreditation of commercial laboratory	State AB ⁵	State AB

¹The term "State" is used for simplicity and refers, for purposes of these discussions, to Primacy Agencies

²Typically includes observation of the State during their review of a non-PSL lab(s)

³Includes commercial labs serving as the PSL under contract to the State

⁴ Potential for conflict of interest should be evaluated/addressed if the AB and PSL are with the same State, particularly if the Region is not involved in PSL audit/review

⁵ If the commercial laboratory is being accredited by other than its "parent" State/primacy agency, this presumes that the primacy agency has established an agreement whereby it will accept/recognize accreditation by a NELAP AB (e.g., a VT lab being accredited by FL). Commercial laboratories residing in a NELAP state are accredited by that State, per the TNI Standard.

Attachment 2

OGWDW Clarification Regarding Principal State Laboratory Definition/Oversight

What Constitutes A Principal State Laboratory (PSL)?

40 CFR 142.10(b)(4) requires that a primacy agency ensure the availability of certified laboratory facilities capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations. These laboratory facilities may be made available to the State by the operation of a State laboratory, by contracting with commercial laboratories (within or outside of the State), by making arrangements (e.g., a Memorandum of Understanding (MOU)) with another State, or by some combination of the above. These laboratories, collectively, represent the Principal State Laboratory (PSL) network.

Above and beyond meeting the minimum requirements of 40 CFR 142.10(b)(4) (i.e., having at least one laboratory available to analyze each regulated contaminant), States may have additional laboratory capacity available to them (e.g., multiple State/district laboratories, contracts with multiple commercial laboratories, MOUs with multiple States). Regions are not obligated to treat these additional supplemental/secondary laboratories as PSLs; therefore, these laboratories are not strictly subject to the PSL certification conditions described below. Regions may choose to implement additional measures for the oversight of such laboratories, particularly if the secondary laboratory routinely does work for the State (as opposed to a secondary laboratory that is available to the State for occasional or emergency use), and/or if there are conflict of interest issues associated with certification of those laboratories by the State.

How Does A Principal State Laboratory (PSL) Become Certified/Accredited?

40 CFR 142.10(b)(4) requires certification of PSLs by EPA; this authority has been delegated to Regional Certification Authorities but cannot be further delegated to the States or to other non-EPA parties. Regional certification of the PSL may be achieved by one of the following approaches:

1. A Region may certify the PSL directly, acting either on their own audit of the laboratory or on an audit performed by a third party expert (e.g., a contractor). Certification of a PSL by one Region (presumably their parent Region) may be accepted by other Regions that rely on that laboratory as a PSL.
2. A Region may use NELAP accreditation of a laboratory serving in a PSL capacity to support Regional recognition. If the NELAC AB (i.e. the State) has accredited a laboratory that ultimately serves as a PSL for the same State, the potential for conflict of interest should be considered and, as need be, addressed by the Region to ensure that the AB is independent of the PSL. The Region should document its recognition of the laboratory as a PSL by issuing a letter to the PSL.

3. A Region may use State certification of a laboratory serving in a PSL capacity to support Regional recognition. If a State has certified a laboratory that ultimately serves as a PSL for the same State, the potential for conflict of interest should be considered and, as need be, addressed by the Region to ensure that the State Certification Authority is independent of the PSL. The Region should document its recognition of the laboratory as a PSL by issuing a letter to the PSL.

Regions may apply additional conditions as they see fit (e.g., limiting their reliance on State certification of commercial laboratories to support Regional certification to States within their particular Region).

How Should a Mobile Laboratory Affiliated with a Principal State Laboratory (PSL) be Treated?

At the discretion of the Region, a mobile laboratory can be considered an extension of the “primary”/stationary Principal State Laboratory, particularly when the mobile laboratory is used on an interim, emergency, and/or transient basis. On this basis, the Region may extend their recognition/certification of the stationary PSL to the mobile laboratory if the mobile laboratory only performs analytical techniques for which the stationary laboratory is certified/accredited. If the mobile laboratory is operating as a stand-alone laboratory (such that media preparation, etc. are occurring in the mobile laboratory), particularly on an ongoing basis, OGWDW generally believes that an independent certification of the mobile laboratory is warranted (as opposed to extending the stationary laboratory certification to the mobile laboratory).