

Memorandum

To: Certified Laboratories under Ohio's Voluntary Action Program

From: Amy Yersavich, Manager, DERR/SABR and Darlene Stanley, CL Coordinator DERR/SABR

Date: April 20, 2011

Re: **Affidavit guidance – *certified data v. non-certified data***

Ohio EPA has received inquiries regarding when a certified laboratory (CL) can attest that data is "certified data" under Ohio's Voluntary Action Program (VAP), created under Ohio Revised Code (ORC) chapter 3746 and Ohio Administrative Code (OAC) chapter 3745-300. This guidance answers that question and related questions.

1. Under what circumstances may a CL conclude that its data is VAP certified data?

Answer: The CL can produce, and attest via affidavit, that data is VAP certified data *only when the analyses are performed within its current certification*. The VAP CL rule, OAC 3745-300-04(A)(1) (3/1/09 version) gives this overarching requirement, which consists of two main conditions.

Both conditions must have occurred for the CL to generate certified data:

- a. The CL held a valid certificate for the analytes, the parameter groups and the methods used at the time it performed the analyses.
- b. The CL performed the analyses in a manner consistent with its standard operating procedures (SOP) and quality assurance program plan (QAPP) as pre-approved by Ohio EPA.

Under these conditions, a CL produces and can attest to the data as certified data. See OAC 3745-300-04(A)(2).

Data that is not certified data: A CL would not produce certified data whenever the analyses do not fall under its current VAP certification. For example:

Example A: The CL performed analyses for Cyanide using method 9010A. The VAP certificate held by the CL at the time the analyses were performed listed Cyanide by method 335.2(CLP-M), only. As such, any data generated using the method 9010A is not considered certified data.

Example B: The CL received a request for analyses of an analyte that is not encompassed by the VAP's program authority, such as methane, fungal molds or high level radioactive waste (i.e., materials not within the definitions of "hazardous substances" or "release" under ORC 3746.01.) In such a case, the data generated could not be certified as VAP data.

Example C: The CL held VAP certification for Semi-Volatile Organics by method 8270C. The CL performed analyses for Polynuclear Aromatic Hydrocarbons (PAH) using selected ion monitoring (SIM) by method 8270C. However the CL's Ohio EPA-approved SOP did not include the option of using SIM. As such, any data generated using SIM is not considered certified data.

Note: A request to modify SOP or QAPP protocol would first require Ohio EPA's approval to be considered part of the CL's certification. See OAC 3745-300-04(Q).

Should any portion of a data set not qualify as certified data, the CL's affidavit needs to identify the portion consisting of non-certified data - see Question 2, below.

2. How should a CL disclose the non-certified data that is part of a larger reported data set containing certified data?

Whenever CL personnel will attest to certified data, the affidavit should describe which data from the reported data set equals a "non-certified" data. VAP's *Affidavit of VAP Certified Laboratory* dated April 2011, contains newly added prompts which CL personnel may find helpful to distinguish between certified and non-certified data. Please refer to the attached *Certified Lab Affidavit* template which the program recommends you follow.

Non-certified data, as discussed under question 1, would include data generated outside of the limits of the CL's current VAP certification, such as:

- Analyses involving an analyte, a parameter group or a method that is not listed on the CL's current certificate.
- A deviation from the laboratory's protocol in its Ohio EPA-approved SOP or QAPP, i.e., that authorized by the CL's current certification.

Not accounting for non-certified data under the CL affidavit could amount to incorrectly labeling all reported data as a certified data.

Note: OAC 3745-300-04(H)(2) directs a CL to disclose to the client requestor when the CL does not hold current VAP certification for a requested analyte, parameter group or method before proceeding with the analyses. If the client had still requested the analyses, the rule directs the CL to identify, within the analytical report, the results for which the CL cannot provide certified data. Even with a disclosure in the analytical report, any CL affidavit issued for the reported mixed data should separately call-out the non-certified data from the certified data to prevent a false affidavit, or false reporting in violation of OAC 3745-300-04(H)(9).

3. How does a CL prepare its VAP affidavit to disclose the reported data which is non-certified data?

The attached *Certified Lab Affidavit* template allows CL personnel to distinguish between certified and non-certified data in their VAP affidavits.

4. If the CL's client loses its original CL-issued affidavit, can CL personnel who were not on staff at the time of the original reporting sign a second affidavit that attests to, and forwards, a true and accurate copy of its original affidavit? Does the CL have other options?

Yes to both questions. The CL's client should have the CL's (original) affidavit, which attests to the analyses as VAP certified data, to use the certified data in support of a voluntary action. Certified data supports volunteer and CP determinations that the property complies with its applicable standards, see OAC 3745-300-07(F), 3745-300-13(E)(9) and (18). To this end, the client that misplaced the affidavit it had received from the CL will want to contact the CL to arrange for a replacement affidavit, i.e., that attests to the certified data.

However, in cases when no CL personnel are available who could currently renew the rule required affidavit statements, new CL personnel can sign a separate "authentic copy" affidavit. That is, one that attests to the authenticity of the original affidavit, assuming that the CL has retained an original of its earlier issued CL affidavit or a true and accurate copy of its earlier issued CL affidavit.

The CL should also consider whether reliable supporting documentation (such as raw data) exists from which CL personnel may conclude that the data may support the issuance of a replacement affidavit to re-attest to data as certified data. If a CL decides that it has no reliable information from which to re-attest to any data as certified, the client has the option to arrange to perform new confirmatory sampling to seek new certified data, consistent with OAC 3745-300-07(E)(1)(d).

5. What should a CL do if it discovers that an original affidavit attesting to data as certified data cannot be found?

It is possible for the circumstances to occur that may prevent a CL from attesting to data as VAP certified data, such as:

- When no original, nor true and accurate copy, of a previously issued CL affidavit is available from which the CL may authenticate the previous affidavit, i.e., under a separate affidavit (as noted in question 4. above).
- When CL's authorized personnel concludes that the stored (raw or final) data from the original analysis may not or does not support a finding by the CL today that the results are certified data.

The CL should report these circumstances to the client or party that requested the replacement affidavit.

In such an unusual case, the client may want to pursue the option to arrange for further field sampling so that new certified data, consistent with OAC 3745-300-07(E)(1)(d), may be obtained in support of the voluntary action project.

Further questions: If you have questions related to this guidance, please contact Darlene Stanley, at darlene.stanley@epa.state.oh.us or 614-644-3748.