

**Virginia Division of Consolidated Laboratory Services  
Virginia Environmental Laboratory Accreditation Program**

**FREQUENTLY ASKED QUESTIONS**

**Revised 1VAC30-45, Regulation for the Certification of  
Non-Commercial Environmental Laboratories  
Effective September 1, 2016**

On June 27, 2016, the revised 1VAC30-45 was published in the *Virginia Register of Regulations*, with an effective date of September 1, 2016. The following information has been provided by the Virginia Environmental Laboratory Accreditation Program (VELAP) to highlight the key changes of the revised regulation.

***Where can I get a copy of the revised 1VAC30-45?***

Information about the changes made to 1VAC30-45 are described in the Final Regulation Agency Background Document available from Virginia Regulatory Town Hall:

[http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\57\3726\7448\AgencyStatement\\_DGS\\_7448\\_v1.pdf](http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\57\3726\7448\AgencyStatement_DGS_7448_v1.pdf).

The following link to the online publication in the *Virginia Register of Regulations*, <http://register.dls.virginia.gov/vol32/iss22/v32i22.pdf>, includes the sections of the regulation changed by the revisions.

A full, revised copy of 1VAC30-45 will be available on or after September 1, 2016, on the VELAP web page, [www.dgs.virginia.gov/dcls](http://www.dgs.virginia.gov/dcls), under the Regulations header.

***What are the key changes in the revised 1VAC30-45?***

- **Administrative changes** impacting the length of the certification period and billing cycle, and adjusting fees for certification.
- **Assessment scheduling changes** allowing on-site visits on a 3-year cycle except when a laboratory's performance triggers the on-site assessment to remain on a 2-year cycle.
- **Proficiency Testing (PT) changes** reducing the number of PTs per year, requiring responses to VELAP following a failed PT study, and strengthening the requirement for accurate reporting of PT results.

***How do the changes to the lengths of the certification period and billing cycle affect my laboratory? How do the changes to fees affect my laboratory?***

The regulation changes the certification period and the billing cycle to a one-year period.

In order to be compliant with the regulation, VELAP will revise and re-issue any current certificates which reflect an expiration date greater than 1 year from September 1, 2016. For example, a certificate previously issued with a two-year expiration date of June 14, 2018 will be re-issued with a revised one-year expiration date of June 14, 2017.

The revised regulation updates the fee tables at 1VAC30-45-130.

See 1VAC30-45-70 K 4; 1VAC30-45-130.

**What are the changes to the on-site assessment scheduling? When will these schedule changes affect my laboratory?**

The revised regulation at 1VAC30-45-300A directs the on-site reassessment of certified laboratories on a schedule of “at least once every three years starting from the date of the previous assessment plus or minus six months”. The revision to the regulation further states six reasons which may cause the laboratory to be reassessed on a two year cycle:

1. *“When a laboratory has received “not acceptable” PT results.*
2. *When a laboratory’s corrective action presented to VELAP for “not acceptable” PT [Proficiency Testing] studies does not identify and correct the root cause of the PT study failure.*
3. *When DCLS has suspended certification for a laboratory in full or in part.*
4. *When on-site observations include non-conformances previously identified at an on-site assessment, indicating the corrective action was not implemented or not maintained.*
5. *When on-site observations include failure to qualify non-conforming data to the data user.*
6. *When on-site observations indicate the laboratory’s failure to monitor and maintain regulatory conformance in documentation, traceability, or quality control requirements such that data generated by the laboratory are of questionable quality or defensibility.”*

VELAP will phase-in the transition of laboratories to the new three-year assessment scheduling over the course of the next assessment cycle in an effort to utilize VELAP’s resources in the most efficient manner. The initial scheduling of laboratories will be dependent on VELAP’s available resources and scheduling needs until all laboratories can be evaluated against and transitioned to the new criteria.

**Can you explain the regulation’s changes to PT frequency? When can my laboratory change to the new PT schedule?**

The revised regulation changes the PT participation requirement to one acceptable PT study each calendar year. The regulation further specifies that the laboratory shall complete its PT studies by September 30 of each calendar year.

For 2016: If a laboratory has completed one PT for each applicable Field of Certification in 2016 (close date January 1, 2016 or later) with a passing score, it has met the requirements for 2016.

For 2017 and beyond: A Chapter 45 laboratory will need to assure that VELAP has results of a passing study submitted directly to DCLS before September 30. All laboratories are encouraged to complete studies with sufficient time prior to the September 30 cutoff to address any failed PT studies as required by the regulation and participate successfully in an additional PT study, if required, prior to September 30.

See 1VAC30-45-520 B.

**What are the changes in the revised regulation regarding failed PT studies?**

The procedure and requirements for “not acceptable” PT study results are specifically described in the regulation at 1VAC30-45-520 C. Refer to the regulation for the responsibilities of the laboratory when a failure occurs.

One important change, as described in the on-site assessment section of the regulation (1VAC30-45-300, described above), is that the regulation requires VELAP to take into account the laboratory's effective handling of corrective action for failed PT studies when scheduling the laboratory's next on-site assessment. Specifically, the regulation requires a corrective action presented to VELAP for "not acceptable" PT studies to identify and correct the root cause of the PT study failure. In keeping with the revised regulation, VELAP will request and review a copy of the laboratory's corrective action report for any failed PT study.

The regulation (1VAC30-45-520 C) also explains the consequences of a second consecutive failed study.

Laboratories are responsible for full review of the PT requirements of 1VAC30-45 and continual compliance. These requirements are in sections 500, 510, and 520 of the revised regulation. PT studies directly impact both the laboratory's on-site assessment scheduling and the laboratory's continued certification status.

*See 1VAC30-45-500, -510, and -520; 1VAC30-45-300 A 3.*

***What is the change to the regulation regarding accurate reporting of PTs?***

1VAC30-45-520 B 7 states that DCLS shall consider a laboratory's PT result not acceptable when the laboratory "makes any reporting error or omission that results in a nonspecific match" between the reported result and the laboratory's Field of Certification. This revision to the regulation requires VELAP to consider a result to be a failed study when the laboratory makes a reporting error regarding the method by which the testing was done. Most laboratories routinely report all PTs accurately with regard to their Fields of Certification. However, the revised regulation will have immediate impact on laboratories that make method-related reporting errors in their PT reports.

***How can my laboratory assure its compliance with all aspects of the revised regulation?***

VELAP encourages all laboratories to review the regulation in full, in addition to carefully reviewing the sections of the regulation described in this document.

Revised on-site assessment checklists for 1VAC30-45 will be available on the VELAP web page on or after September 1, 2016. Each laboratory is encouraged to use these checklists to conduct a thorough internal audit of its quality system to verify compliance with the revised regulation.