How do I request a change in Scope of Certification or Accreditation for my laboratory?

Once a laboratory has applied and satisfied the application requirements, a change in Scope is requested as follows:

- The owner of the laboratory or his/her designee supplies a written request, clearly stating the desired matrix, method, and analyte combination(s) desired using the Form # 6972, Change in Scope Form. The form is available from the VELAP web page at www.dgs.virginia.gov/dcls.
- The laboratory with certification under 1VAC30-45 or with primary accreditation under 1VAC30-46 supplies:
  - Demonstration of Capability (DOC) documentation supporting the request(s), to include the DOC certification statement, final results, and statistical evaluation where applicable. Refer to 1VAC30-45-730 E or 2009 TNI V1M4 1.6, V1M5 1.6, and/or other applicable section(s) for DOC requirements.
  - Proficiency Testing Results:
    - For Chapter 45 Labs: One successful proficiency test (PT) per field of certification, where applicable, occurring within 12 months of the request.
    - For Chapter 46 Labs: Two successful proficiency tests (PTs) per field of accreditation, where applicable, occurring within 18 months of the request with the most recent study within 6 months of the application and at least 15 days between analysis dates of subsequent studies.
  - The laboratory’s Standard Operating Procedure.
- The laboratory with secondary accreditation under 1VAC30-46 supplies:
  - A current copy of the laboratory’s primary certificate with Scope of accreditation (if not previously on file with VELAP).

Please explain how and when fees are calculated and invoiced.
Fees for changes to the Scope of Certification/Accreditation (hereafter, “Scope”) cover the labor and expenses to process requests for changes in Scope. The labor to process a change in Scope will vary depending on the complexity of the request, the lab’s current Scope, and whether or not a site visit is required.

Note: The regulation provides a 90-day period for a change in Scope to be processed. When the following conditions are met, VELAP processes the change in Scope in conjunction with the biennial renewal without billing the laboratory separately for the change in Scope:

- the request is submitted 90 days prior to the application biennial renewal;
- the change in Scope request does not require data review or a site visit;
- the laboratory is not requesting the change in Scope to be completed prior to the scheduled certificate issue date;
- the labor to process the request does not exceed the amount of labor [3 hours staff labor] covered by the standard change in Scope base fee.

The laboratory will be invoiced upon completion of the processing. An updated Scope of Certification or Scope of Accreditation will be issued after payment for the request is received.

The laboratory should refer to the regulation (1VAC30-45-130 or 1VAC30-46-150) in advance of submitting the request for change in Scope to calculate or estimate associated regulatory fees associated with the change in Scope.

DCLS will charge the base fee plus applicable additional fees as described below.

FEE SCHEDULE:

A. BASE FEE: The base fee will be charged for any request for an additional Field of Certification

PROCESSING REQUIRES:

- Fields of Certification (FOCs) reviewed and updated into the VELAP database;
- Proficiency Test data entered into the database;
- Invoice generated;
- Response letter generated and sent with invoice;
- Record of request and all related correspondences recorded in files and database;
- Paid invoice received, logged into database, documented in files; and
- Amended Certificate and Scope of Certification/Accreditation generated, reviewed by management, and sent in duplicate (Technical Manager / Responsible Official) with cover letter, by mail and e-mail.

Base Fee: $150
B. ADDITIONAL FEES: SOP/Data Review Fee
SOP/Data Review Fees are charged for additional time spent in excess of the time covered by the initial base fee; e.g. multiple method additions, SOP and/or data review, logging proficiency study information, etc. Laboratories will be invoiced for additional data review at the rate of $50 per hour.

C. ADDITIONAL FEES: Regulatory Fees
See 1VAC30-45-130 B or 1VAC30-46-150 B for regulatory fee information. Changes to Scope may require payment for a new test category, or may affect the regulatory base fee and/or test category fee due to a change in the number of methods or matrices requested.

D. ADDITIONAL FEES: On-Site Visit Expenses
VELAP management will decide whether an additional site visit is necessary. Site visit expenses vary per lab location and complexity of review. Site visit expenses are calculated separately from other fees upon completion of the site visit and may include some or all of the following charge categories:
- Travel Time
- On-Site Time
- Transportation Fees (mileage, gas, rental car, airline, parking, tolls, cab)
- Per Diem
- Hotel
- Office Time (writing findings report, corrective action follow-up)

What is the regulatory basis for charging fees for changes to a Scope of certification or accreditation?
Changes to the Scope of Certification or Scope of Accreditation can be made according to 1VAC30-45-90 B or 1VAC30-46-90 B. Fees will be charged for these changes per 1VAC30-45-130 F and 1VAC30-46-150 F, as the certification program must be self-funded. The basis for fee calculations can be found in 1VAC30-45-130 G and I, and 1VAC30-46-150 F and H.