

173-55-040 Initial Accreditation Application

Are existing labs considered applying for initial accreditation or accreditation renewal?

173-55-050 Accreditation Renewal Application

- (3) A laboratory must submit a renewal application to the department 30 days before their accreditation expires.
 - 30 days does not seem a sufficient amount of time to request and perform an audit, allowing for response time for audit deficiency findings. Currently we have 90 days to complete an audit.

173-55-060 Review and Approval of Accreditation Application

(1) (c) the applicant laboratory has paid the application fee.

AND:

173-55-180 Fee structure

- (d) The department and an individual laboratory may establish a payment schedule requiring periodic installments of the annual fee.
 - These 2 statements seem to contradict each other, can we receive accreditation and be on a payment plan for the annual fees.

173-55-070 Quality Assurance Manual

- . Guidelines for contents of the QA manual are in the procedural manual.
 - When will the procedural manual be available?

173-55-075 Standard Operating Procedures

- (2) The laboratory must submit a revised SOP whenever the laboratory makes updates to an SOP.
- Can you outline what changes constitute the need to submission?
- (3) Guidelines for contents of a standard operating procedure are in the procedural manual.
- This will be our 3rd SOP format change in 3 years.

173-55-090 Proficiency Testing

(1) To receive initial accreditation laboratories must analyze a minimum of two PT samples per applicable parameter for which the laboratory is seeking accreditation.

- (a) After an accredited laboratory submits two acceptable PT sample results and no unacceptable results in an accreditation year, the laboratory is required to submit only one acceptable PT sample result in subsequent accreditation years.
- (b) If a laboratory has an unacceptable PT result when they are only required to analyze one, the lab must have an acceptable result prior to their next renewal and must return to a biannual PT schedule for the following year.
 - Although this appears to be a decrease in PTs per year, because of the per matrix requirement, it is actually an increase in PTs per year from what we currently are required, adding a significant cost to labs. The cost of cannabis PTs are much higher than environmental PTs.
- (2) For full accreditation, proficiency tests for potency, pesticides, and residual solvents must be in cannabis material containing concentrations of cannabinoids representative of products available to consumers.
 - Since actual in-matrix PT samples are not available, what is the per matrix requirement for PTS? (is it just one PT per relevant test?)
 - When do the per matrix PT rules go into effect?

173-55-180 Fee structure

- (1) Fees in this chapter are in U.S. dollars and are established to cover costs of administering the cannabis accreditation program.
- (2) Effective July 1, 2025, the yearly accreditation fee for a cannabis laboratory is determined using Equation
- 1. Equation 1 Fee = 0.5*(C/N)
 - We are currently paying approx. \$8k for in-person audits, and \$2k for off-site audits. The
 proposed fee structure is a cost burden that will inevitably force some labs to close their doors.
 It is not competitive with our current audit pricing, or the environmental lab audit pricing
 performed by the DOE.