1 VAC 30 CHAPTER 45

Summary of regulatory citations for Most Frequent Inspection Findings

for Inspections Conducted Between 03/01/2015 and 03/01/2018

This list may be a helpful tool for internal auditing, in conjunction with full checklists used to assess compliance with 1VAC30-45.

This list does not provide a full quality system internal audit.

	Checklist Group(s)	Reference	Text
1	SOP	730 D 2	Test methods. The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample handling, transport and storage, preparation and analysis). The method and procedures shall be consistent with the accuracy required and with any standard specifications relevant to the calibrations or tests concerned.
2	SOP / Quality Manual	730 C 2	Laboratory method manuals: Each test method shall include or reference where applicable: ___Identification of the test method; ___Applicable matrix or matrices; ___Method detection limit; ___Scope and application, including components to be analyzed; ___Summary of the test method; ___Definitions; ___Interferences; ___Safety; ___Equipment and supplies; ___Reagents and standards; ___Sample collection, preservation, shipment and storage; ___Quality control; ___Calibration and standardization; ___Procedure; ___Calculations; ___Method performance; ___Pollution prevention; ___Data assessment and acceptance criteria for quality control measures; ___Corrective actions for out-of-control data; ___Contingencies for handling out-of-control or unacceptable data; ___Waste management; ___References; and, ___Any tables, diagrams, flowcharts and validation data.

	SOP / Quality Manual	610 C13	The elements of a quality manual shall include but not be limited to: A list of all technology/methods under which the laboratory performs its certified testing.
	SOP / Quality Manual	730 B 2	The SOPs shall be organized. Each SOP shall clearly indicate the effective date of the document, the revision number and the signature or signatures of the responsible laboratory manager or managers.
	SOP / Quality Manual	610 D 2	The quality assurance manual shall be reviewed and approved by the quality assurance officer, the laboratory manager, and the responsible official at least annually.
	SOP / Quality Manual	610 A 3	The quality manual and any related documents shall be communicated to, understood by, available to, and implemented by all laboratory personnel.
3	Reporting/Reports / Subcontracting	860 B	Laboratory reports. Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable certification number.
		680 C	The laboratory shall retain records demonstrating that subcontracting requirements have been met.
4	Records / Traceability	640 A	The laboratory shall have a recordkeeping system that allows historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample shall be readily understood through the documentation. This shall include inter-laboratory transfers of samples or extracts or both.
		850 1	Sample tracking. The laboratory shall have a documented system for uniquely identifying the items to be tested to ensure that there can be no confusion regarding the identity of such items at any time.
		640 G	Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to recordkeeping errors shall be made by one line marked through the error. The individual making the correction shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.
		660 D 3	Administrative records: The laboratory shall maintain the following administrative records: A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.
5	Demonstration Of Capability	730 F 4	Procedure for Demonstration of Capability. Using all of the results, calculate the mean recovery in the appropriate reporting units (such as g/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest.

	Demonstration Of Capability	730 F 5	Procedure for Demonstration of Capability. Compare the information from section 1VAC30-45-730 F 4 to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.
	Demonstration Of Capability	730 G	Documentation of demonstration of capability: The laboratory shall document each demonstration of capability so that the following information shall be readily available for each employee: __ 1. Analyst or analysts involved in preparation and analysis. __ 2. Matrix. __ 3. Analytes, class of analytes, measured parameters, or organisms. __ 4. Identification of methods performed. __ 5. Identifiation of laboratory-specific SOP used for analysis, including revision number. __ 6. Date or dates of analysis. __ 7. All raw data necessary to reconstruct and validate the analyses. __ 8. Data evaluation required by 1VAC30-45-730 F.
6	Support Equipment	740 D 1 E	Calibration - Support Equipment. Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.
		798 B 3 A-C	Volumetric equipment: Volumetric equipment shall be calibrated as follows: ___ Equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly. ___ Equipment such as filter funnels, bottles, non-class A glassware, and other marked containers shall be calibrated once per lot prior to first use. ___ The volume of the disposable volumetric equipment such as sample bottles and disposable pipettes shall be checked once per lot.

		740 D 1 D	Calibration - Support Equipment. On each day the equipment is used, balances, ovens, refrigerators, freezers, and water baths shall be checked in the expected use range, with NIST traceable references where available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.
		740 D 1 B	Calibration - Support Equipment. All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used. If not, the laboratory shall either (i) remove the equipment from service until repaired or (ii) maintain records of established correction factors to correct all measurements.
7	Internal Audits	670 A 1	The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management.
8	Management Review	670 B 1	The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness, and to introduce necessary changes or improvements in the quality system and laboratory operations.
9	Reagents & Media	796 F	Documentation for media purchased pre-prepared, ready-to-use shall include: ___ Manufacturer ___ Lot number ___ Type and amount of media received ___ Date of receipt ___ Expiration date of the media ___ pH of the media
	Reagents & Media	773 B 2	Chemical testing: quality of standards and reagents. Water. The quality of water sources shall be monitored and documented and shall meet method specified requirements.
10	Proficiency Testing	510 B	When analyzing a PT sample, the laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

	Proficiency Testing	520 C 1	When a laboratory receives a PT study result of "not acceptable,", the laboratory shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request.