

Commonwealth of Virginia  
Department of General Services  
Division of Consolidated Laboratory Services  
Richmond, Virginia

**Ch 45 Quality Manual Completeness Checklist for Renewal Applicants**

<b>Laboratory Name:</b>	<b>VELAP ID:</b>
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**1 VAC 30-45**

*Please indicate by section number and/or page number, where the following elements are found in the Laboratory Quality Manual*

1 VAC 30-45-610 A. The laboratory shall document its quality system in a quality manual. The quality manual shall reflect all quality assurance and quality control practices and programs used by the laboratory. The required elements of the quality system may be described in more than one document. The elements of a quality manual shall include but not be limited to:

Mandatory Quality Elements	Laboratory Reference	INTERNAL USE ONLY			
		Document Compliant			Comments and Corrective Actions
		Y	N	N/A	
1 VAC 30-45-610 B 1-6. Title page, including: document title; the name, address (if different from lab), and telephone number of the responsible official, laboratory manager, and QA officer; laboratory facility(ies) covered by the quality manual; signed and dated concurrence, with appropriate titles, of responsible official, lab manager, and QA officer, & effective date		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 B 7. Table of contents and applicable lists of references, glossaries, and appendices		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 B 8. Quality policy statement, including objectives of the quality system and commitment to ethical laboratory practices and to upholding the requirements of Chapter 45		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 1. Organization & management structure, its place in any parent organization and relevant organizational charts		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 2. Job descriptions of key staff and reference to job descriptions of other staff		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 3. Processes or procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 4. Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities & resources before commencing such work		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 5. Procedures to ensure that all records required by Chapter 45 are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all SOPs, manuals, or documents clearly indicate the time period during which the procedure or document was in force		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Mandatory Quality Elements	Laboratory Reference	INTERNAL USE ONLY			
		Document Compliant			Comments and Corrective Actions
		Y	N	N/A	
1 VAC 30-45-610 C 6. Procedures for dealing with complaints		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 7. Procedures for audits & data review		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 8. Verification practices that may include inter-laboratory comparisons, proficiency testing, use of reference materials & internal QC schemes		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 9. Procedures to be followed for feedback & corrective action whenever testing discrepancies are detected, or departures from documented policies & procedures occur		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 10. Laboratory management arrangements for permitting departures from documented policies and procedures		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 11. Major equipment and reference measurement standards used as well as the physical facility & environment used in conducting tests		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 12. Procedures for calibration, verification and maintenance of equipment		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 13. List of all technology/methods under which the laboratory performs its certified testing		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 14. Procedures for achieving traceability of measurements, including standards		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 15. Procedures for receiving, handling, storing, and disposing of submitted samples		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 16. Procedures for reporting analytical results		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1 VAC 30-45-610 C 17 Policy addressing the use of unique electronic signatures, where applicable		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
DCLS Assessor Review (Initials/Date):					

Return completed checklist to DCLS (Richmond, VA) with Quality Manual