Checklist for ASVCP Quality Assurance Guideline Section 2, Total Quality Management System (TQMS) (v.3, 2019)

The purpose of these checklists is to facilitate guideline implementation/practical application and may be further detailed in laboratory-specific standard operating procedures (SOPs). The numbers in the first column correspond to the section numbers in the guideline.

Guideline Recommendation	Compliant?	Additional Comment(s) by Auditor
2.1 Quality Goals for accuracy/effectiveness of lab function that will meet the requirements of users, are defined (pre-determined prior to test evaluation) for the preanalytical, analytical, and postanalytical phases. Goals are evaluated and refined on a pre-determined schedule.	☐ Yes ☐ No	
2.2.1 Size dependent, the lab has a dedicated quality manager or management team as a complete or partial job description. This person(s) has outlined duties and appropriate training to successfully execute the lab's Total Quality Management System (TQMS).	☐ Yes ☐ No	
2.2.2 There is a written quality policy/manual that specifies a commitment to continuous quality improvement and outlines the tenets of lab organization, lab function, and the TQMS. The document is available to all workers, updated as needed, and incorporated into personnel training.	☐ Yes ☐ No	
2.2.3 Annual management reviews of the TQMS are scheduled, and results are shared with laboratory personnel. Time frames for implementation and evaluation of any changes are established.	☐ Yes ☐ No	
2.3, Appendix 1 The laboratory has a catalogue of easily-accessible standard operating	☐ Yes ☐ No	

procedures (SOPs) for all laboratory processes and procedures.		
2.3, Appendix 1 Laboratory personnel are required to read/sign off on all SOPs pertaining to their job duties, with scheduled document re-review (mandatory upon any SOP update) and formal demonstration of SOP knowledge.	☐ Yes ☐ No	
2.3 All laboratory SOPs are updated upon any procedure/method/instrumentation changes and otherwise reviewed every 1-2 years for accuracy and completeness.	☐ Yes ☐ No	
2.4 Routine quality control procedures are established for all instruments/methods (see section 4 for more detailed guidelines). Identified non-conformities initiate corrective/preventive actions, and clients are contacted as necessary if non-conformities have impacted patient results.	☐ Yes ☐ No	
2.5, 2.6 Periodic internal and external audits/assessments are scheduled, to include enrollment in an external quality assurance (EQA)/proficiency testing (PT) program.	☐ Yes ☐ No	
2.1, 2.4, 2.6, Tables 1,2 Key quality/performance indicators are established for preanalytical, analytical, and postanalytical phases, with regular calculation of the percentage of errors/non-conformities that are compared against predetermined goals.	☐ Yes ☐ No	
2.6 Quality improvement suggestion forms are readily available for all personnel.	☐ Yes ☐ No	
2.2, 2.6 Preventive/corrective actions to eliminate/minimize detected sources of error are implemented continually as necessary and	☐ Yes ☐ No	

evaluated for effectiveness on a determined schedule. Design and implementation of these actions are made by defined personnel.		
2.2.3, 2.6.1 Feedback surveys are provided to lab personnel and users/clients, and results are shared with laboratory staff and evaluated at management reviews.	☐ Yes ☐ No	