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	□ Yes □ No	
evaluation) for the preanalytical, analytical, and		
postanalytical phases. Goals are evaluated and		
refined on a pre-determined schedule.		
2.2.1 Size dependent, the lab has a dedicated		
quality manager or management team as a		
complete or partial job description. This	□ Yes □ No	
person(s) has outlined duties and appropriate		
training to successfully execute the lab's Total		
Quality Management System (TQMS).		
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.	☐ Yes ☐ No	
The document is available to all workers,		
updated as needed, and incorporated into		
personnel training.		
2.2.3 Annual management reviews of the		
TQMS are scheduled, and results are shared		
with laboratory personnel. Time frames for	☐ Yes ☐ No	
implementation and evaluation of any changes		
are established.		
2.3, Appendix 1 The laboratory has a catalogue	☐ Yes ☐ No	
of easily-accessible standard operating		

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-	☐ Yes ☐ No	
review (mandatory upon any SOP update) and		
formal demonstration of SOP knowledge.		
2.3 All laboratory SOPs are updated upon any		
procedure/method/instrumentation changes and	□ Yes □ No	
otherwise reviewed every 1-2 years for accuracy		
and completeness.		
2.4 Routine quality control procedures are		
established for all instruments/methods (see		
section 4 for more detailed guidelines).		
Identified non-conformities initiate	☐ Yes ☐ No	
corrective/preventive actions, and clients are		
contacted as necessary if non-conformities have		
impacted patient results.		
2.5, 2.6 Periodic internal and external		
audits/assessments are scheduled, to include	□ Yes □ No	
enrollment in an external quality assurance	2 . 66 2 . 146	
(EQA)/proficiency testing (PT) program.		
2.1, 2.4, 2.6, Tables 1,2 Key		
quality/performance indicators are established		
for preanalytical, analytical, and postanalytical	□ Yes □ No	
phases, with regular calculation of the	2 . 66 2 . 146	
percentage of errors/non-conformities that are		
compared against predetermined goals.		
2.6 Quality improvement suggestion forms are	☐ Yes ☐ No	
readily available for all personnel.		
2.2, 2.6 Preventive/corrective actions to		
eliminate/minimize detected sources of error are	☐ Yes ☐ No	
implemented continually as necessary and		

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	□ Yes □ No	
shared with laboratory staff and evaluated at		
management reviews.		