



CAP 15189 Accreditation Program Readiness Checklist

The timeline for the initial accreditation cycle varies depending on the laboratory's readiness, resources, and level of commitment. Use this checklist to ensure that you are fully prepared to submit your application.

ACTIVITY	COMPLETE (Y/N)
Achieve accreditation from the CAP Laboratory Accreditation Program	
Purchase and review the ISO 15189 standard*	
Review the 15189 Walkthrough and QMS Implementation Roadmap QMED courses in e-LAB Solutions Suite	
Use the Root Cause Analysis toolkit in e-LAB Solutions Suite as needed	
Purchase and complete these QMED courses:*	
<ul style="list-style-type: none"> • Internal Auditing • Quality Manual Development 	
Establish budget. Contact the CAP for a fee estimate.	
Secure management support	
Gather the following items to be submitted with your application:**	
<ul style="list-style-type: none"> • Quality manual (see ISO 15189 clause 4.2.2.2 for details on quality manual requirements) • Updated organization chart with key personnel • Credentials (CVs) of key personnel (medical and administrative directors and quality manager—however named) 	
Procedures for:	
<ul style="list-style-type: none"> • Internal audits (clause 4.14) • Management review (clause 4.15) • Document control (clause 4.3) • Management of occurrences <ul style="list-style-type: none"> ◦ Resolution of complaints (clause 4.8) ◦ Identification and control of nonconformities (clause 4.9) ◦ Corrective and preventive actions (clauses 4.10 and 4.11) 	
If available at time of application:	
<ul style="list-style-type: none"> • Internal audit records and summary (required prior to scheduling the accreditation assessment) • Management review records and summary (required prior to scheduling the accreditation assessment) • Process map/flow charts (not procedures) for: <ul style="list-style-type: none"> ◦ Pre-examination process ◦ Examination process ◦ Post-examination process • Records and analysis of quality indicators (if separate from the management review) 	
Schedule an onboarding call with the CAP to discuss the accreditation process, fee estimate, and online application process. Email cap15189@cap.org	
Request access to online application and pay application fee	

Questions?

Contact us at cap15189@cap.org or call 800-323-4040 or 847-832-7000.

* Visit cap.org and search "CAP 15189 program" for links to the ISO 15189 standard and the QMED courses.

**The items you provide do not have to be perfect; they will not be used to make any pass/fail decisions. If you do not have a requested item, it is acceptable to state that the item does not yet exist in your system.