



CAP 15189SM Accreditation Fact Sheet Preparing for Initial Accreditation

Preparing your laboratory to become CAP 15189 accredited may require time and resources that go beyond the boundaries of the laboratory. The CAP has prepared this fact sheet to outline the steps that a laboratory should take in preparation for CAP 15189 accreditation.

1. Gain buy-in from key stakeholders, (eg, Senior Administrators, Vice President of Risk Management, Chief Medical Officer, Executive Officers, and Senior Managers outside the laboratory) in the organization that is seeking to become accredited.
2. Obtain and read an official copy of ISO 15189:2007 standards. A laboratory must purchase an official copy of the standards in order to become accredited. You may purchase the official standards from www.ISO.org or from www.ANSI.org.
3. Assign appropriate roles for conducting an internal audit.
 - Updated Organizational chart with key personnel (ISO Reference # 5.1.1)
 - i. The Laboratory Director (5.1.3)
 - ii. All Supervisors (5.15)
 - iii. All Internal Auditors (4.14.2)
 - The Quality Manager (4.1.5.i)
4. Apply for CAP 15189 accreditation with the CAP.
5. For those organizations that are not familiar with ISO, the CAP recommends the following optional services to help you prepare for your accreditation assessment:
 - **Gap assessment.** A Gap assessment is conducted more than 90 days in advance of an accreditation assessment and will be a detailed review to the standards to determine areas of strengths and weaknesses. No corrective action response to CAP is required from a Gap assessment.
 - **Pre-assessment.** A pre-assessment will be a dry-run assessment that is a high-level review for degree of conformity to the standards and will take place within 90 days of the accreditation assessment. We encourage you to send your documentation to us, prior to our visit, so we may conduct a desk assessment. This will allow our independent assessor to evaluate your written system against your working practices. No corrective action response to CAP is required from a pre-assessment.
6. Perform an internal audit to ISO 15189. Note that internal auditors may not audit their own work product.
 - Document the internal audit findings.
 - Perform root cause analysis and corrective actions where necessary.
 - Continue the auditing and corrective action process until all major non-conformances (systemic process issues) are corrected.
7. Document a description of participation in external quality assessment schemes/proficiency testing programs for all tests and evidence of participation over the preceding two years (5.6.4 and 5.6.5).
8. Update your Quality Manual, including Quality Policy and any supporting documentation for the Quality Manual (electronic is preferred) (4.2.4).
9. When the laboratory has corrected all non-conformances that were identified in the internal audit, then contact the CAP to schedule your accreditation assessment.

For additional information call 800-323-4040 option 1.