



Advance Document Review for CAP Accreditation Inspections

Information for Inspectors & Laboratories

The College of American Pathologists (CAP) modified the inspection process and now provides options for advance document review prior to the inspection.

The CAP recognizes that not all laboratories will be able to accommodate document sharing prior to the inspection, and in this case the inspection team will need to review the documents during the virtual or in-person inspection.

The process is as follows:

- The laboratory will select the preferred document review option (options detailed below) through Organization Profile.
 - The selection triggers an email notification of the laboratory's preferred document review option to the inspection Team Leader who receives the notice four months prior to the inspection due date.
 - Regardless of the option selected, as stated in the CAP Accreditation Program Policy Manual 2.05, documentation is confidential and should be utilized solely for inspection purposes.
 - *Note: If you have any questions or need further assistance selecting the preferred document review option in Organization Profile please contact us at accred@cap.org.*

The document review options include:

- **Option 1: Share documents during your inspection.**
 - No advance document review. All documents will be reviewed during the in-person or virtual inspection.
 - For virtual inspections, document review may occur by screenshare, webcam, and/or email.
 - See Additional Documentation and Inspection Summation Report sections below.
- **Option 2: Provide the inspection team with guest access to your document management system (DMS) to share documents in advance of your inspection.**
 - The inspection team will provide the laboratory with a complete list of inspectors participating in advance document review.
 - The laboratory will provide all inspectors with guest access to the DMS in advance of the inspection.
 - The inspectors may request instructions for use of the DMS from the laboratory.
 - Inspectors and laboratory staff are encouraged to utilize the Inspection Planning and Tracking Tool to help determine which documents will be shared in advance. The inspectors may use this tool to make notes on findings from advance document review.
 - The inspector(s) may request documentation not available in the DMS during the inspection or, if agreed to by both parties, prior to the inspection.
 - *Recommended processes:*
 - The Team Leader should carefully evaluate the team composition and amount of time required for the inspection after completing the advance document review to identify reductions in the number of team members and/or inspection duration.
 - The same or different inspectors that will participate in the in-person or virtual inspection may perform advance document review. The Team Leader should ensure that information is communicated between inspectors, if applicable.



COLLEGE of AMERICAN PATHOLOGISTS

Laboratory Quality Solutions

- The inspection team will notify the laboratory staff of any noted deficiencies from the advance document review and then document on the appropriate inspector summation report (ISR) pages.
- The inspection team will complete the inspection within two weeks of completing the advance document review.
- See Additional Documentation and Inspection Summation Report sections below.
- **Option 3: Upload documents in Organization Profile to share with inspection team in advance of your inspection.**
 - CAP leadership identified documents for advance document review for the laboratory to upload using Organization Profile. These include:
 - Delegation of Responsibility
 - Quality Management Plan
 - Individualized quality control plans (IQCP)
 - Method/Test/Instrument Validation
 - Laboratory Developed Test (LDT)
 - The CAP will activate document upload functionality at the start of the application or reapplication process, and it remains available until four months prior to the anniversary date. Upon request, the CAP can accommodate requests for access outside of this window.
 - The Team Leader will have access to the uploaded documents two weeks prior to the scheduled inspection date. Documents are accessible by:
 - Navigating to the “Inspection Packet” page for the Team Leader on cap.org.
 - Clicking the link on the email sent to the Team Leader two weeks prior to the schedule date.
 - Team Leader providing team members access to documents using the “Share” functionality on the Inspection Packet page.
 - See *Recommended Processes* in option 2.
 - See Additional Documentation and Inspection Summation Report sections below.

Additional Documentation

- During the inspection or, if agreed to by both parties, prior to the inspection, inspectors will request additional documentation other than those listed above in Organizational Profile to ensure compliance with applicable requirements.
 - *Note: If the laboratory chooses to share more documentation, they may request a link to a CAP SharePoint folder by contacting the Inspection Assignment Specialist at accred@cap.org.*

Inspection Summation Report

- The team may allow correction of identified deficiencies any time within the two-week advance document review window, and through the inspection by marking those deficiencies as “corrected on site” on the Inspection Summation Report (ISR) and making a brief note as to the corrective actions taken (eg, Policy “123” updated).
- Complete the inspection paperwork, including having all inspectors (including document reviewers) sign the ISR pages for the areas they inspected, within the two-week advance review window. The team should provide a copy of the completed ISR with the laboratory director and return all ISR pages to the CAP office at the end of the inspection.
- The 30-day deficiency response period begins with the completion of the inspection.

Anytime you have questions or concerns, please call the CAP office at 1-800-323-4040, extension 6065, and a technical specialist will help you. International customers can email accred@cap.org or call +1-847-832-7000, option 1