COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Information for Optional Modified Inspection Process - Inspector & Laboratory Participants

Due to the COVID-19 global pandemic, the College of American Pathologists (CAP) is encouraging a modified inspection process to best address the current climate in health care and address safety concerns for all. All inspections during the pandemic will be scheduled ahead of time and the inspection date will be made known to the laboratory being inspected.

The CAP recommends that laboratories and inspectors participate in the review of some laboratory documentation prior to the on-site inspection during this time to facilitate the inspection. This will allow the inspection team to still perform a thorough review of the laboratory, potentially reducing the number of inspectors needed to complete the on-site portion of the inspection, and possibly decreasing the amount of time needed on-site. This will result in less exposure time for all.

There is no mandate that laboratories provide electronic documents ahead of time, nor are inspection teams required to review documents ahead of time. Documents can be made available through any mechanism the laboratory is most comfortable using. The laboratory director and the team leader should discuss how to best accomplish this, such as setting up a conference or video call between the laboratory staff and inspectors to review documents interactively, or providing requested documents via email or through a guest login to web-based systems. The CAP does recognize that not all laboratories will be able to accommodate this sharing of documents for a variety of reasons, and in these cases the documents will need to be reviewed by the inspection team during the on-site inspection. As stated in the CAP Accreditation Program Policy Manual 2.05, documentation is confidential and should be utilized solely for inspection purposes.

For those laboratories and inspection teams opting to perform a review of available documents prior to the on-site, please note the following recommended process:

- The laboratory will provide or make available electronic documents for review by the inspectors prior to the on-site inspection.
    - The team leader should carefully evaluate the team composition and amount of time required on site after completing the document review to identify possible reductions in the number of team members and time needed on site.
- The inspection team will document any noted deficiencies from the document review on the appropriate inspector summation report (ISR) pages.
- The inspection team will complete the on-site inspection within two weeks of completing the document review.
- Opening and summation conferences may be completed using video or conference calls at the laboratory director and team leader's discretion.

To ensure all inspection team members understand the expectations under this modified inspection process, the CAP asks that team leaders share the following information with all team members:

1. The date of the on-site inspection, the agreed upon documents the laboratory will share, and the timeframe and mechanism (video call, conference call, remote guest log in etc.) for the document review.
    a. The remote document review should be completed within 2 weeks prior to the planned on-site inspection date.
    b. If the laboratory director and team leader have agreed on an interactive document review including staff from the various laboratory departments, be sure all team members are provided with the details for joining these sessions.
        i. Be sure to clearly indicate any identified deficiencies to the laboratory staff during the document review.
2. The CAP recommends inspectors drive to the inspection location whenever possible.
3. Participate in any on-site temperature monitoring and truthfully answer any questions to ensure the health and safety of inspection participants when required by the facility.
    a. Any inspector experiencing any symptoms of SARS CoV-2 infection MUST NOT participate in any on-site inspection activities.
4. All inspectors participating in the on-site inspection are expected to comply with Centers for Disease Control and Prevention (CDC) guidelines for social distancing and any facility or local requirements vis-a-vis wearing facemasks and other required personal protective equipment (PPE).
5. All inspectors are prohibited from visiting any patient care areas or outpatient drawing/specimen collection stations. Instead, these areas will be assessed via a conference or video call with the relevant staff.
6. Any persons unable or unwilling to meet these requirements in items 3 – 5 may participate in the document review but may not participate in the on-site inspection.
7. You may allow correction of identified deficiencies any time within the two-week document review window, and through the on-site 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).
8. Complete the inspection paperwork, including having all inspectors (including document reviewers) sign the ISR pages for the areas they inspected, within the 2-week inspection window and return all the pages of the ISR together to the CAP office. A copy of the completed ISR should be left with the laboratory director at the end of the on-site inspection.

To ensure all accredited laboratories understand the expectations under this modified inspection process, the CAP asks that all laboratory directors share the following information with their leadership team:

1. The date of the on-site inspection, the agreed-upon documents the laboratory will share ahead of time, and the timeframe and mechanism (video call, conference call, remote guest log in etc.) for the document review.
    a) If the laboratory director and team leader have agreed on an interactive document review including staff from the various laboratory departments, be sure laboratory staff are provided with the details for joining these sessions.

2. During the two weeks prior to the on-site inspection date, provide electronic documents or access to electronic documents for the team's review.
    a) Consider using guest logins to web-based document management applications or the use of video conferencing technologies if possible. (The CAP office will not have access to the documents that you review with your inspectors.)
3. Provide appropriate PPE for inspectors who complete the on-site portion of the inspection (disposable laboratory coats, gloves, and facemasks).
4. Participate in the on-site inspection on the scheduled inspection day.
5. Assist with setting up conference or video calls for interviews with hospital administration and medical staff with the team leader, and appropriate representatives for the assessment of point of care testing, blood administration staff, phlebotomy staff, etc
6. Secure a room that allows for social distancing or facilitate a video or virtual summation conference at the end of the on-site inspection if needed.
7. The 30-day deficiency response period begins with the completion of the on-site 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.

