



Topic: CAP Virtual Inspections: Two Laboratories' Shared Perspectives

Date: January 13, 2021

Subject: Questions and Answers

Use of SharePoint

- 1. If a laboratory has a document management system such as MediaLab or other cloud-based service, are they required to use the SharePoint site?**

No, the laboratory is welcome to allow temporary access of their document control system to the inspection team leader and members rather than use the CAP's SharePoint site.

- 2. When will the laboratory receive the SharePoint link?**

Once the inspection has been confirmed as either a virtual or hybrid inspection, and the SharePoint folders are created, the link will be sent.

- 3. How much time does the laboratory have to upload documents into SharePoint?**

The amount of time that the laboratory will have to upload documents into the SharePoint site is typically about two weeks. However, this can vary somewhat depending on individual circumstances.

- 4. Would you recommend uploading all documents in advance or only the requested documents?**

It is recommended to upload all documents that you believe to be most useful to the inspection team to be able to determine compliance with CAP accreditation requirements. The requested documents are a minimum of information to assess compliance. Your inspection team may request additional documents.

- 5. What if your laboratory does not allow the use of SharePoint?**

There are other solutions for sharing your documents with the inspection team. If you have a document control software solution or other mechanisms to share documents, discuss this with your inspection team leader.

- 6. Many of our documents are paper based including the monthly LJ chart. What is the best strategy to upload all personnel, LJ chart, and other documents?**

If possible, discuss with your team leader about the minimum documents to share with the team to enable the team to complete an inspection. The inspection team leader may request certain months as an example to demonstrate compliance.

- 7. Our signed laboratory procedures are paper based. Do we need to scan the signed copy to upload or could we share the unsigned word document?**

Depending on the preference of the team leader, you could scan a sampling of signed copy documents and be ready to share additional samples if requested. Otherwise, it is permissible to share the word documents which may be more efficient for you to do.



8. For a system inspection, will each laboratory have its own SharePoint site, or will it be shared?

There will be both a system wide link as well as individual links for each laboratory to be inspected.

Inspection Planning and Document Tracking tool

1. Where is the tool located?

The tool, created to be used by both the inspector and laboratory, is included in the laboratory's folder on the CAP SharePoint site. The inspection team leader and inspection contact will receive a link to the SharePoint site once the laboratory has finished uploading their documents.

Email discussing the details of a hybrid or virtual inspection will also include a link to the tool.

2. When will the tool be available for the laboratory and the inspection team?

The tool will be first included in an email from the Inspection Assignment Specialist when a virtual or hybrid inspection is agreed upon by both parties. It will also be available in the main SharePoint folder for the inspection. The laboratory will have the SharePoint link first, in order to upload their documents. When the documents are ready for the inspection team to view, the SharePoint link will be shared with them.

3. Does the tool include an example inspection schedule for each laboratory?

The tool includes a generic example of a multi-day inspection. Not all inspections will require multiple days, and the inspection team leader, in consultation with the laboratory director, will determine the final inspection schedule for each inspection. CAP Assignments staff are available to help answer questions and provide guidance if needed.

Hybrid and Virtual inspections

1. Are the hybrid and virtual inspections announced or unannounced?

Currently, the inspection team leaders for all inspections discuss the optimal dates for the inspection to occur with the laboratory director prior to setting the inspection date.

2. Who or what determines whether the inspection will use the hybrid or virtual model? How do we find out which model will be used?

This will be a decision reached between the laboratory director and the inspection team leader, with input from CAP if necessary. The driving factor for virtual inspections will be the laboratory's ability to support livestreaming video and provide adequate evidence of compliance with accreditation requirements electronically. If both of these elements are not possible, then a virtual inspection is not possible. If the laboratory has some evidence of compliance available electronically, then we encourage the hybrid inspection model.

3. Our inspection window opens later in 2021. Should we plan for a virtual inspection?



At this point, we are not able to pinpoint an exact date when we will move away from virtual inspections and resume our traditional on-site inspections more fully. Our best advice at this point is to be prepared for a virtual inspection in 2021. As the situation changes, we will provide further updates to help you understand the current environment and expectations.

4. Can a laboratory decline to be inspected virtually?

If the laboratory is unable to facilitate a virtual inspection, meaning that they lack sufficient evidence of compliance with accreditation requirements in electronic format, and/or are unable to support livestreaming video in their laboratory, then we will not be able to perform a virtual inspection for these sites. When it is possible to support a virtual inspection, but there is a preference for non-virtual options, we will work with the laboratory and inspection teams to come to an acceptable inspection approach. However, if there are significant restrictions that make an in-person inspection impractical, a virtual inspection may be necessary despite a preference otherwise.

5. Has anyone done a virtual system inspection?

We have completed several hybrid system inspections but have not completed a fully virtual system inspection as of February 9, 2021.

6. Are AABB coordinated inspections available with the hybrid and virtual model?

Yes, AABB coordinated inspections are possible at this time with either model. However, the goal is to get all sections of the laboratory inspected and accredited as soon as possible near the inspection due date.

7. Will the hybrid and virtual inspection models continue after the public health emergency is lifted?

It is important to note that the current hybrid and virtual CAP inspections are intended to be temporary solutions during the public health emergency. However, it is likely that some components of the remote document review and virtual assessments will continue post pandemic but will likely vary somewhat in future models.

Follow-up onsite inspections:

1. Is an onsite inspection required after a virtual inspection? If yes, what is the timing to complete the onsite inspection?

CMS requires an onsite inspection for CLIA-certified laboratories. During the public health emergency, when it is not possible for an inspection team to come onsite, the CAP may conduct a virtual inspection followed by an on-site visit four to six months after, or once it is safe to do so, fulfilling CLIA's on-site inspection requirement. The on-site inspection is not meant to be another full inspection and will focus on direct observation of testing procedures that are unable to be accomplished virtually.

2. How do we choose who conducts the onsite inspection?

The CAP headquarters will work with CAP staff and previously assigned inspection teams to conduct the onsite component in the most efficacious way.

3. If we are a non-CLIA laboratory, do we still need an onsite inspection?



Laboratories not subject to the US CLIA regulations will not have a mandatory on-site inspection, unless it is determined that the virtual inspection could not adequately determine a laboratory's compliance with CAP accreditation.

Inspection Timing

- 1. Our inspection is overdue. When should we expect to be inspected? Is there anything we need to do?**

The CAP is working with inspection teams to find the best match available to get your laboratory inspected. The CAP is also prioritizing overdue inspections based upon accreditation status, i.e., initial laboratories, sanctioned laboratories, and then by anniversary date.

Inspector Training

- 1. Is the Inspection Team Leader and Inspection Team Member training still required in addition to the “Performing Virtual Inspections: Being the CAP’s “Eyes and Ears” from Home training course?**

Yes, inspectors need to be trained. The “Performing Virtual Inspections: Being the CAP’s “Eyes and Ears” from home is a short, less than 30 minutes, training course designed to supplement the inspection team leader and team member training. It was designed specially for inspectors performing their first hybrid or virtual inspection.