

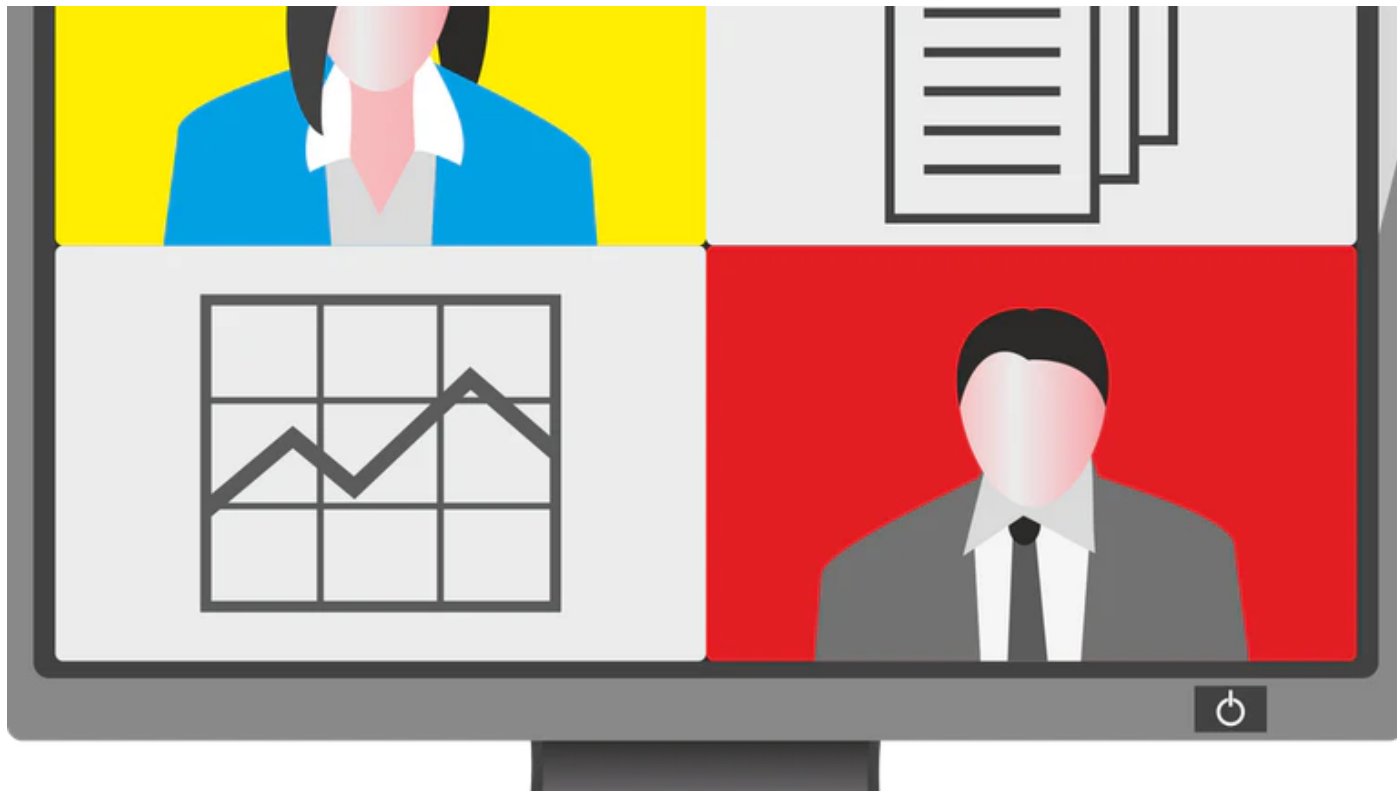


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The reality of virtual laboratory surveys

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In a world full of “virtual” everything (virtual work environment, virtual tour, and virtual happy hour) it is no surprise that virtual laboratory surveys have become a reality. According to the Cambridge Dictionary, the word “virtual” means “almost a particular thing or quality.”¹ It is also no wonder that when a laboratory is selected to participate in a virtual survey, anxiety levels can run higher than usual. We have to ask ourselves the question “how is this going to work?” To answer that question, this article discusses the virtual survey process, which typically includes three phases.

Documentation Review

There is no escaping the fact that documents are going to need to be reviewed – lots of documents. A standard letter sent to a laboratory from an accreditation organization discloses the list of documents to be submitted. Labs can submit their documents in a number of ways: fax, email or by upload. If a laboratory uses a quality management platform to house procedures, quality control data, personnel training and competency records, etc., sharing this information over a connected session with the surveyor is an ideal situation to perform the documentation review portion of the virtual survey.

Some examples of the documents that will be requested: a copy of the CLIA certificate, personnel qualification documents and associated training and competency records, instrument maintenance logs, quality control data and quality assessment reviews. As the documents come in, they are reviewed for acceptability. A surveyor may request additional documentation to ensure the laboratory is maintaining compliance with all standards. Once all of the documents have been submitted and reviewed, the laboratory will proceed to the next stage of the virtual survey process – the scheduled video conference.

Scheduled Video Conference

The next phase of the virtual survey is the video conference. This is a scheduled event that takes place at a date and time mutually agreed upon by the laboratory and the surveyor. The only equipment required is a laptop or tablet computer (preferred) with a camera. Equipment mobility is preferred because the surveyor will want you to “virtually” take them around the laboratory.

There are numerous online meeting platforms that can be used to facilitate the video conference portion of the virtual survey. Microsoft Teams is a good choice, as it does not require that the laboratory download any software in order to meet with the organizer of the meeting.

What kind of opportunities does the video conference afford the lab and the surveyor? First, the surveyor has the ability to speak to any of the laboratory staff. If, for example, the surveyor wants to speak to the laboratory director about delegated responsibilities and then ask the testing personnel to explain how they handle critical results, this can all be easily accomplished.

The camera, too, has many uses. The laboratory personnel can take the surveyor around and let them see testing being performed; the surveyor can take a look inside of a lab's storage refrigerator and check the expiration dates on your reagents (you can actually read

them); and the surveyor can check specimen labeling by having personnel hold some specimens up to the camera.

Of no less importance, the video conference provides a lab and a surveyor with a stage for the exchange of information. Questions can be asked and answered, explanations can be provided, and any loose ends from the documentation review portion of the virtual survey can be tied up. This is the laboratory's opportunity to engage with the surveyor in a one-on-one situation.

A survey summation will take place at the end of the video conference. Any citations noted from the documentation review and the video conference will also be confirmed at this time. The lab is then ready to proceed to the final stage of the virtual survey – the brief on-site visit.

On-site visit to confirm lab operations

If the geographical area where the laboratory is located is deemed safe (in respect to whatever it was that created the need to perform surveys virtually), the surveyor will schedule a brief on-site visit with the laboratory within approximately four months of the video conference.

The purpose of the brief on-site visit is to confirm laboratory operations. Laboratories should be prepared to report any significant changes in laboratory operations to the surveyor (e.g. change in laboratory director, change in test menu, and change in annual test volume). The surveyor will perform a walk-through of the laboratory. For all intents and purposes, the survey was complete at the end of the video conference. However, the surveyor can utilize the on-site visit to follow up on any serious or significant issues noted from the documentation review or video conference stages of the virtual survey.

Good candidates for a virtual survey

Not every laboratory is going to be an ideal candidate for a virtual survey. The single most important factor is the size of the laboratory. If a laboratory has an extensive test menu, performs more than 100,000 tests annually, or performs full transfusion services, mass spectrometry or molecular testing, it is not an ideal candidate for virtual survey. The sheer amount of documentation that would need to be submitted for review would be substantial. These types of laboratories are much better targeted for on-site surveys. Applicant laboratories are also not good candidates for virtual survey. It is very important that applicant laboratories get started on the right foot, and an on-site visit is a great way to establish this relationship.

Preparing for a virtual survey

When preparing for a virtual survey, the laboratory should designate a point person for the duration of the virtual survey. This will help with organization and efficient use of time by not having to bring in a new person at each stage of the survey and get them up to speed on the status of the process.

Laboratories should always be in a state of survey readiness. Laboratories should perform a self-assessment of their laboratory and correct any non-compliances prior to the virtual survey.

Laboratories will have 21 days in which to submit the required documentation for the documentation review stage of the virtual survey. It would be wise to prepare for how this will be accomplished. Are you going to fax your documents in? Do you have extra manpower appointed to that task? If your plan is to upload documents, do you have access to a scanner? Perhaps your laboratory can share your documents online with the surveyor via quality management software. If so, you need to make the surveyor aware of this capability and get the logistics of the online meeting worked out beforehand.

Other steps to prepare for the virtual survey involve equipment. In addition, does the laboratory have the necessary equipment for the video conference? Do you have a mobile computer device with a camera? If not, you should arrange to borrow this equipment. Accreditation organizations may allow a lab to borrow this equipment for the virtual survey. Make an effort to schedule the video conference on a date and time when the largest number of laboratory staff will be available. It is important that the laboratory director be available, perhaps the technical consultant, and certainly some testing personnel.

Again, a brief on-site visit will take place approximately four months after the video conference. Treat this visit like a regular on-site survey. This means a lab may want to tidy up the facility and be prepared for a walk-through. Labs also should be sure to report any significant changes in operations to the surveyor.

Value of a virtual survey

Accreditation organizations are collecting data on the virtual process, and time will tell us if the virtual surveys are effective. In the face of a pandemic, performing a virtual survey is better than the alternative, which is to do nothing. Accreditation organizations need to be able to assess laboratory quality and compliance as best we can in these circumstances. At this time, the virtual survey is the best alternative we have to a traditional on-site process.

References

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