

Virtual Inspection Guidelines for Applicants

GENERAL ASPECTS:

1. FACT virtual inspections will be conducted for renewal accreditation. The virtual inspection will mimic the actual on-site inspection to the extent possible. Processes for scheduling, choice of dates, inspection team selection will remain unchanged.
2. In general, the inspections will be scheduled in the applicant's time zone.
3. The inspection will be conducted via a series of Zoom meetings. The meetings will be set up in advance by the FACT Office with appropriate settings.
4. The full program inspection is expected to require most of two days. If personnel limitations necessitate (e.g., one quality manager for two areas), the areas may be inspected on sequential days rather than on the same day. Opening and closing meetings will be adjusted accordingly.
5. Resources required at the applicant program for virtual inspection
 - a. Private quiet room with reliable internet access for each facility that is part of inspection (clinical, apheresis, processing); i.e., one private room per inspector.
 - b. A quiet space with computer and internet access for each person who calls into the Zoom meeting. Camera and microphone are required for those actively participating in the inspection.
 - c. Computer with camera and audio and at least one cell phone with camera per facility. See page 5 for examples of cell phone stands that may be useful. Many varieties available.
 - d. Document camera is optional.
 - i. For information about document cameras, see <http://bestreviews.com/best-document-cameras>. Various models are available and reasonably priced. Many come with built-in software and can be connected to the computer via USB port. Examples shown – page 5.
 - ii. The document camera will be most useful for the Processing Facility inspection due to the likelihood that many documents to be reviewed [such as a product processing record] may be maintained as paper records.
 - iii. A single document camera could be shared as needed by the various areas throughout the days of the inspection.
 - e. Headphones with microphone are optional but may be desirable to minimize background noise at the program.
 - f. Three – four persons per inspector
 - i. Quality Manager, Director, other subject matter expert.
 - ii. Applicant coordinator to facilitate technical logistics. This person will be the designated as CO-HOST of the Zoom meeting and will be expected to facilitate navigation, allowing others to join the meeting, screen sharing, use of cell phone camera and document camera, and submission of additional requested documents to the FACT Portal.
 - iii. Someone to gather requested items, scan documents, etc.
 - iv. A designated back-up for the Co-Host.

PRIOR TO THE INSPECTION:

1. New documents may be required prior to virtual inspection.
 - a. Respond to RFIs entered by your coordinator.
 - b. Submit all other new documents and any that have been updated since original submission to the VIRTUAL INSPECTION TAB in the portal.
 - c. Identify each document by Standard number.
2. Protected Health Information (PHI) may be viewed but not retained by the inspection team. DO NOT SUBMIT documents containing PHI in advance or to the FACT Accreditation Portal.
3. Documents to be available must be immediately available. These are the same documents that an applicant would prepare and collect for an in-person on-site inspection. Refer to HCT Document Submission Requirements: <http://www.factwebsite.org/CTDocumentSubmissionRequirements7-0/>.

- a. Organize all documents according to Standard number. The Self-Assessment Tool is useful to record where evidence for each Standard can be located.
 - b. “Binders” can be organized in folders as scanned .pdf files or using electronic tools such as One Note or other software programs.
 - c. For information on the use of One Note, see the FACT webinar “*Using an electronic Platform for Accreditation Preparation and Continuous Readiness*” presented 26 June 2019 and available at <http://www.factweb.org/forms/store/ProductFormPublic/using-an-electronic-platform-for-accreditation-preparation-and-continuous-readiness-webinar>.
4. Inspectors will choose specific documents and records to review. Applicant will be informed on the morning of the inspection and throughout the inspection days as appropriate.
 5. Applicants should be prepared to show evidence by using one or more of the following methods:
 - a. Share screen for showing videos, and documents maintained electronically, such as virtual tours, meeting minutes, SOPs, validation reports, audit summaries. The inspector can “request Remote Control” to have control to scroll through shared documents.
 - b. Scan and share screen in Zoom.
 - c. For documents maintained in hard copy only, show via camera (cell phone) or document camera. Document camera will be easier for large documents with significant amount of text.
 - d. Documents such as SOPs could be uploaded into the FACT Portal (VIRTUAL INSPECTION TAB) during the inspection. The inspector could view the documents there or print and review.
 - e. Within *Chat* there is an option to upload documents to view by all or selected individuals.
 6. Recordings of a virtual tour of the area and of a mock procedure will be shown during the first section of the inspection for each area. Refer to the Virtual Facility Tour Requirements: <http://www.factwebsite.org/VirtualFacilityTourRequirements/>.
 - a. Tour can be narrated and should be produced with minimal background noise.
 - b. Care should be taken to not include patients or visitors in the video unless these persons have consented to photography.
 - c. There may still be a need to revisit spaces for specific questions.
 7. FACT staff will meet with representatives of the applicant program prior to the inspection to train personnel in technical aspects of Zoom necessary for the days of the inspection. Example: demonstrate alarms in processing facility using cell phone camera.
 8. Zoom meeting will be “active” (can be used) from the day before the scheduled inspection until after the exit interview. Applicants can sign in to test the technical capabilities of the meeting platform prior to the inspection.
 9. Applicants can also practice Zoom itself using any Zoom account. FACT coordinators will be available prior to the inspection to answer questions.

THE INSPECTION

1. The Team Leader for the inspection will host the main Zoom meeting where the Introduction, private inspection team meetings (“lunch”), and Closing meeting will occur.
 - a. Each inspector will have a separate meeting for the area to be inspected. All meetings will be set up in advance by FACT Staff, who will not be present at the inspection but will be available for technical assistance throughout the inspection days.
2. There will be an agenda that includes the Zoom links for each part, identification of the inspector for that part, expected participants from the applicant facility, and cell phone contact information for each person. Refer to the FACT Virtual Inspection Agenda Example: <http://www.factwebsite.org/VirtualInspectionAgendas/>.
3. Interviews will be scheduled (and listed on agenda) for various people who may be interviewed during the tour. These people should call in to designated Zoom meeting from a quiet private place. (e.g., not the nurses’ station). These people should be prepared to show their environment (e.g., clinical unit, apheresis, ICU) or someone from the applicant team could go there to assist. This will include:

- a. Nursing – inpatient, outpatient, ambulatory
 - b. Advanced Practice Provider
 - c. Attending Physician
 - d. ICU Nurse / Physician
 - e. ER Nurse / Physician
 - f. Pharmacist
 - g. Data Manager
 - h. Apheresis Collection Staff
 - i. Processing Staff
 - j. Quality Managers, if not already part of team
4. The inspector will need a listing of the names of all persons interviewed. Provide the list and update with any changes that occurred on inspection day.

AGENDA – Refer to the FACT Virtual Inspection Agenda Example:

<http://www.factwebsite.org/VirtualInspectionAgendas/>.

1. Introductory Meeting – Zoom 1 - Attended by all inspectors, applicant facility personnel from clinical, apheresis, and processing facilities – about 30-45 min
 - a. Begin with Introductions:
 - i. Everyone introduces self; have camera on and name displayed correctly. It is possible to change the name if necessary. Include short description of yourself, your role for the day
 - b. Inspectors introduce themselves
 - c. Inspectors review some house keeping guidelines for the inspection
 - i. Role of host and co-host
 - ii. Applicants will let appropriate people into meeting from waiting room
 - iii. Keep yourself on mute when not speaking, etc.
 - d. Applicant will present overview of the program using power point and shared screen
 - e. Review schedule for the inspection, confirm it is still appropriate
 - f. Inspectors will present list of specific documents they will want prepared for each area – which medical records, procedure records, minutes, training records, etc. Alternatively, this could be deferred to each individual group meeting.
2. All persons leave this Zoom 1 meeting and go to assigned Zoom meeting to conduct inspections:
 - a. Clinical – “Zoom 2”
 - b. Apheresis – “Zoom 3”
 - c. Processing – “Zoom 4”
 - d. Additional meetings will be available if needed for larger programs
3. Lunch break – take an actual break; then inspectors meet in Zoom 1 for closed meetings
4. Resume inspections in afternoon in separate Zoom meetings
5. Designated individuals will call into assigned Zoom meeting for interview at designated times. Inspectors will document the name and job title for each person interviewed.
6. Inspectors meet in Zoom 1 at end of day
7. DAY 2:
 - a. Begin with joint meeting in Zoom 1 to review plan for the day, estimate time for exit interview
 - b. Divide group into respective areas
 - c. One hour before exit interview, inspectors meet in Zoom 1 to prepare
 - d. EXIT INTERVIEW: Zoom 1 – all call in at designated time

GENERAL ZOOM Guidelines [Refer also to Zoom How-To Guide for Virtual Inspections: Applicants: <http://www.factwebsite.org/ZoomHTGVirtualInspections-Applicants/>.]

1. Within a few days of the inspection, update to newest version of Zoom on all computers, cell phones, and tablets that will be used for the inspection.

2. Ensure each team (clinical, collection, cell processing) has at least one cell phone with Zoom capabilities.
3. Test technical capabilities in the rooms that will be used.
4. Retest connectivity and functionality the night before the inspection.
5. Do not use virtual backgrounds.
6. Zoom Meetings will have settings determined in advance by the FACT Office so that functionality will be ensured as described.
 1. Chat function will be enabled.
 2. Doorbell will not be active, but this function can be chosen by the applicant if desired.
7. You can only be in one Zoom Meeting at a time. Sign out of one before signing into another.
8. The inspector will be the HOST. The applicant coordinator will be designated as Co-Host.
9. As the HOST, the inspectors must sign into the Zoom account before entering the meeting. Everyone else can sign in by selecting the link in the agenda.
10. Waiting Room option will be available if applicant prefers. Default setting will not have a waiting room.
11. All participants have the ability to share screen.
12. Introduce everyone who is on the Zoom call. Inspectors will do likewise.
13. Do not share confidential information unless you know who can view it.
14. Do not share screen during the introductions so that everyone can be seen. Only share screen when there is actually a document to view.
15. Be sure that everyone who calls in has a quiet private location.
16. Camera and microphone are optional but preferred for attendees only listening to and viewing the meeting.

Examples of Document Camera



Examples of Cell Phone Stands

