Virtual Inspection Guidelines for Applicants

GENERAL ASPECTS:

1. FACT virtual inspections will be conducted for renewal accreditation. The virtual inspection will mimic the in-person on-site inspection to the extent possible. Processes for scheduling, choice of dates, inspection team selection will remain unchanged.

2. All documents related to virtual inspections can be found in FACT’s Virtual Inspection Resource Center at: http://www.factwebsite.org/VirtualInspections/.

3. In general, the inspections will be scheduled in the applicant's time zone.

4. The virtual 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.

5. 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.

6. The Inspection Team Leader and Program Director will work together to establish the agenda. Interviews with personnel will be scheduled for discrete times on the agenda. The FACT Accreditation Coordinator will provide assistance as needed.

7. 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.
      i. It is recommended that each person participate in the inspection at a separate computer to facilitate efficient responses.
      ii. Having the applicant team together in one conference room is acceptable if audio is clear enough; however, it is easiest if participants are in separate rooms or adequately socially distanced to avoid the need for masks that may interfere with clear communication.
   c. Computer with camera and audio and at least one cell phone with camera per facility. See page 8 for examples of cell phone stands that may be useful. Many varieties available.
   d. Document camera is recommended but is not required.
      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 are shown on page 8.
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 of the program throughout the days of the inspection.

iv. It is best to use desktop software with the document camera. This can be done by sharing screen and sharing the software. This gives greater functionality to the camera. The camera can be shared by using it as the camera for a Zoom participant, but this should not be done by the person who is the content expert and who is actively speaking with the inspector as it precludes the inspector from seeing the person with whom they are speaking.

e. Headphones with a 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. Another designated person to gather requested items, scan documents, etc.
   iv. A designated back-up for the Co-Host.

PRIOR TO THE INSPECTION:

1. Respond to RFIs entered by your coordinator.
   a. Submit new documents in response to the RFIs.
   b. Notify your coordinator if there are any documents that need to be updated that did not have an RFI.

2. New documents are required prior to virtual inspection.
   a. All policies and SOPs referenced in the Quality Management Plan must be submitted.
   b. The most recent Annual Report on the effectiveness of the Quality Management Plan must be submitted.
   c. Submit all new documents to the VIRTUAL INSPECTION TAB in the portal.
   d. Identify each document by Standard number.

3. 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.

4. 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.
5. The following documents should be immediately available on the days of the inspection:
   a. Quality management documents, including meeting minutes, audits, adverse reaction reports, occurrence reports, corrective and preventive actions and effectiveness. Include evidence of quality improvement actions taken.
   b. SOPs for the clinical, collection, and cell processing areas, as applicable.
   c. Recipient and donor medical records and product collection or processing records that demonstrate examples of compliance with standards related to management of deviation, products with positive microbial contamination ineligible donors, or adverse reactions.
   d. Clinical outcomes requirements as requested by the Clinical Outcomes Committee, as applicable.
   e. Data Audit requirements as requested by the FACT-CIBMTR Data Audit Committee, as applicable.
   f. Documentation of physician and staff training and continued competency.
   g. Contracts with external facilities including biennial review.
   h. Documentation of proficiency testing.
   i. Validation and qualification studies performed.
   j. IRB approval documentation, if applicable.
   k. Validation of electronic record systems if the system is within the control of the facility requesting accreditation and is considered to be a critical electronic record system.
   l. Updated licenses of contracts that expired between application submission and the date of the inspection.

6. Organization of documents is key to a successful virtual inspection. Use of an electronic software such as OneNote has been shown to be extremely helpful in preparing for and participating in a virtual inspection. In OneNote, SOPs, policies, and other supporting documents and examples are linked directly to the specific FACT Standard and checklist question, making demonstration of compliance efficient and clear. OneNote can also be used to maintain readiness during the accreditation cycle.
   b. FACT has provided a OneNote template for the 7th Edition FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. This template can be found in the Virtual Inspection Resource Center on FACT’s website.

7. 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.

8. Applicants should be prepared to show evidence by using one or more of the following methods:
   a. Share screen for showing the tour videos, and documents maintained electronically, such as meeting minutes, SOPs, validation reports, audit summaries. The inspector can “request Remote Control” to have control to scroll through shared documents.
b. Scan documents 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.

9. Be prepared to demonstrate tracking and tracing of products and processes from donor identification through product collection, processing, storage, and administration.

10. 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 Facility Virtual Tour Requirements: http://www.factwebsite.org/VirtualFacilityTourRequirements/. An example virtual tour is also provided in the Virtual Inspection Resource Center.
   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.

11. 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.

12. 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.

13. 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 and Closing meeting will occur.
   a. Each inspector will have a separate Zoom 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.
   b. The inspection team will also have a separate “closed” meeting for times needed to meet without disruption.

2. There will be an agenda that includes the Zoom links for each area, identification of the inspector for that area, 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. Clinical Program Medical Director
   b. Attending Physician
   c. Nursing – inpatient, outpatient, ambulatory
   d. Advanced Practice Provider
   e. ICU Nurse / Physician
   f. ER Nurse / Physician
   g. Pharmacist
   h. Data Manager
   i. Radiation Oncology
   j. Clinical Research Coordinator
   k. Marrow Collection Medical Director
   l. OR Nurse, as applicable
   m. Apheresis Collection Staff
   n. Cell Processing Staff
   o. 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. The applicant is responsible for creating the first draft of the agenda. Personnel limitations (such as one Quality Manager covering multiple areas), staffing times for interviews, and other considerations should be included in this agenda and noted for the inspection team.
   a. The program will create the first draft of the agenda and send it to the Team Leader, with any notifications regarding time restrictions or reviewing a common QMP together with more than one inspector.
   b. The Team Leader will distribute the agenda to the inspection team and receive feedback from the team. If any changes are made, the Team Leader will send the agenda back to the program for approval.
   c. If no changes are made and the agenda is approved by the inspection team, the Team Leader will send the agenda to the Manager of Accreditation Services.
   d. The Manager of Accreditation Services will add all Zoom links for the inspection, and send the final agenda to the inspection team and to the program.

2. If more than one area (for example, both the adult and pediatric clinical programs, or clinical, apheresis, cell processing) uses the same Quality Management Plan, the applicant program should consider jointly reviewing the Quality Management section with all relevant inspectors. This should be built into the agenda when it is created and shared with the inspection team prior to the inspection.
3. 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 in the program, and your role in the inspection.
   b. Inspectors introduce themselves.
   c. Inspectors review some house keeping guidelines for the inspection.
      i. Role of host and co-host
      ii. Keep yourself on mute when not speaking, etc.
   d. Applicant will present overview of the program using power point and shared screen.
   e. Review the agenda for the inspection, confirm that it is still appropriate.
   f. Inspectors will present list of specific documents they want prepared for each area – which recipient/donor medical records, product collection or processing procedure records, minutes, training records, etc. Alternatively, this could be deferred to each individual group meeting.

4. 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

5. Lunch break – take an actual break; then inspectors meet in closed meeting Zoom 5.

6. Resume inspections in afternoon in separate (Zoom 2-4) meetings.

7. 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.

8. Inspectors have a closed meeting at end of day.

9. Inspectors and applicant facility personnel meet after the inspection team meeting to discuss plans for Day 2.

10. DAY 2:
    a. Begin with joint meeting in Zoom 1 to review plan for the day, estimate time for exit interview. Exit interview time may be retained if desired.
    b. Divide group into respective areas.
    c. One hour before exit interview, inspectors have closed meeting to prepare for EXIT Interview.
    d. EXIT INTERVIEW: Zoom 1 – all call in at designated time.

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.
   - Chat function will be enabled.
   - 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. You can join the Zoom meeting with more than one device.

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 FACT 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 their 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 required for participants, but optional for attendees only listening to and viewing the meeting.
Examples of Document Camera

Examples of Cell Phone Stands