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| Virtual Inspection Checklist for Applicants |

Complete all RFIs entered in the portal to update any certificates, licenses, continuing education, and policies/procedures that may have changed.

When requested, provide potential inspection dates to FACT’s Business Manager. Plan for the inspection to last 2 days. If additional consideration needs to be given because of number of sites, or a shared Quality Manager, let the Business Manager know at this time.

Review the following documents located on the Virtual Inspection page of the FACT website:

* + [*Virtual Inspection Guidelines for Applicants*](https://fact.policytech.com/docview/?docid=486&public=true)
  + [*FACT Virtual Inspection Agenda Example*](https://www.factglobal.org/education-and-resources/general/virtual-inspection-resource-center/)
  + [*Facility Virtual Tour Requirements*](https://www.factglobal.org/education-and-resources/general/virtual-inspection-resource-center/)
  + [*Zoom How-To Guide for Virtual Inspections: Applicants*](https://fact.policytech.com/docview/?docid=279&public=true)
  + [OneNote Self-Assessment Tool. HCT Standards. Seventh Edition](https://www.factglobal.org/education-and-resources/general/virtual-inspection-resource-center/)
  + [Virtual Tour Example](https://www.factglobal.org/education-and-resources/general/virtual-inspection-resource-center/)
  + [Timeline for Virtual Inspections](https://fact.policytech.com/docview/?docid=270&public=true)

Determine how you plan to share documentation. There are four ways to share documentation of compliance electronically:

* + Sharing the screen of a computer – this works best for any documents or records that are saved electronically or can easily be scanned.
  + Using a document camera – this works best for any documents or records that are saved on paper or cannot be easily scanned, such as a processing record or cleaning logs.
  + Using the camera on a cell phone – this works best for showing small things that you cannot scan, like equipment tags, or initials on a form or log.
  + Submitting documents to your document library in the FACT Accreditation Portal under the Virtual Inspection tab – this works best for electronic or scanned documents but must not contain any PHI.

Organize your documentation electronically. This can be done in the following ways:

* + Using folders on a desktop and naming items by Standard so you can easily find and open the correct document.
  + Utilizing OneNote to track documents and link to their locations. 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:

<https://www.fact.maxx.matrixdev.net/forms/store/ProductFormPublic/using-an-electronic-platform-for-accreditation-preparation-and-continuous-readiness-webinar>

* 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*](https://www.factglobal.org/education-and-resources/general/virtual-inspection-resource-center/) on the FACT website.
  + Using the printed completed checklist from the portal and putting in locations or links into Excel.
  + Using other software in use in your Program.

Identify the staff members who will participate in the inspection. This will require three to four persons per inspector:

* + Quality Manager, Director, other subject matter experts.
  + 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.
  + Additional designated person to gather requested items, scan documents, etc.
  + A designated back-up for the Co-Host.

Identify the additional staff members who may be interviewed during the inspection.

Prepare an agenda to give to the inspectors. This should take into consideration any resource (person or equipment) sharing, and timing at your organization for staff interviews. The agenda must be sent to the Team Leader at least 2 weeks prior to the inspection. The list of participants and interviewees must be provided to the inspection team and updated to include any changes the day of the inspection.

Identify the equipment each person will use to participate in the inspection. Each participant must have a working camera and microphone. If you will be sharing documentation by document camera or cell phone, identify those items and be prepared to use them.

Identify the space that each person will use to participate in the inspection. This includes the identified staff for each inspector and anyone who will be interviewed. Spaces must be quiet and private for the main participants, and quiet and private enough to prevent distractions for those being interviewed.

Set-up and record the required virtual tours. There should be a separate video tour for each area included in the inspection scope. The video tours will be shared with the inspectors during the virtual inspection.

* + The tours should be narrated and produced with minimal background noise. If there is a question related to audio quality, the audio should be turned off, and the video narrated for the inspectors at the time of the virtual inspection.
  + Care should be taken to not include patients or visitors in the video unless these persons have consented to photography.
  + Each tour video can be one continuous video, or multiple smaller videos labeled by the area they demonstrate.

Schedule a training session with your coordinator approximately one month prior to the inspection. Be prepared to have all staff involved with running the Zoom application and their back-ups involved.

After training with your coordinator has been completed, practice how you will demonstrate documentation. If you have any questions or if further training is needed, contact your coordinator.

Prepare the introductory meeting using PowerPoint. Inspectors and Program personnel will introduce themselves and be expected to have their cameras on with their names displayed correctly. Each participant should give a short description of himself/herself, the role in the applicant program and for the day of the inspection.

The day before the inspection, double check that Zoom has been updated to the most current version. Verify the connectivity and functionality of equipment.