Planning the Inspection

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Why is it important to be prepared?

Pre-inspection logistics

Pre-Inspection Logistics

- Arrange Travel
  - Make arrangements as early as possible
  - FACT provides travel booking instructions
  - *Do not book your departure flight before 7 pm on the final day of the inspection!
- Reserve hotel rooms
  - Stay-overs are billable once report is completed
  - Private meeting rooms
- Review Pre-inspection submissions
  - Ensure complete submission of required documentation
  - Assess appropriateness of documentation
- Ask questions
  - Your Accreditation Coordinator is available to answer any questions throughout the process

Initial Communication Among Team Members

- Plan a team conference call
  - FACT can assist if necessary
  - This ideally takes place a month prior to the inspection date
- Create a plan to maximize inspection time
- Discuss issues found during documentation review
- Reminder that all Requests for Information (RFI) must be submitted 3 weeks before inspection

Team Leader Responsibilities

- Two weeks before an inspection, the Team Leader must:
  - Contact the Program Director and review the inspection agenda
  - Confirm a meeting location for the initial interview
  - Inquire about internet access on-site for each inspector
  - Contact all team members and schedule a pre-inspection team meeting *important*

Communication with the Program Director

- Be sure the team leader contacts the Program Director and the inspection coordinator from the organization
- Provide the Program Director with the agenda for the day
- Be positive and friendly, show excitement for the inspection

Setting the Inspection Agenda

- Incorporate feedback from inspection team and Program Director
- Distribute to inspection team and Program Director and program contact person
- Confirm all areas are included
- Account for time required to get to different locations
- See example in handouts

In-Person Meeting Before Inspection

- Review agenda
- Initial interview expectations
- Be sure all team members have a solid understanding of how the organization has been established and functions
- Review and organize pre-inspection materials
- Schedule the inspection activities
- Final questions

Inspecting Multiple Sites

- Coordinate efforts
- Communicate findings
- Cross-check rather than repeat

Documentation review

Major Goals of Pre-Inspection Review

- Familiarize inspector with organization
- Allow verification of compliance for some Standards beforehand
- There is a lot that must be covered on site
  - Take advantage of the opportunity for a head start
- Additional information can be requested prior to the inspection

Importance of Pre-Inspection Review

- Inspectors become familiar with the organization
  - Get a feel for the quality of the organization in advance
- Optimizes utilization of time and the quality of the inspection on inspection day
- The inspector and program will not feel rushed during the actual inspection
  - Reduces anxiety and stress on the inspector and thus the program

Importance of Pre-inspection Review

- Advance review facilitates detection and potential correction/clarification of issues such as:
  - Incomplete documentation
  - Misunderstanding of Standards
  - Unclear structure and/or services of program
- Documentation can therefore be corrected/clarified prior to inspection
  - Organizations can thus avoid unnecessary citations
- Clarifies perceptions and expectations among the FACT Accreditation Coordinators, the inspection team, and the organization being inspected

Pre-Inspection Review

- Review application materials promptly
- Review inspection report from previous inspection
  - If possible, check for compliance in document submitted as well as on-site

Review Applicant Documentation

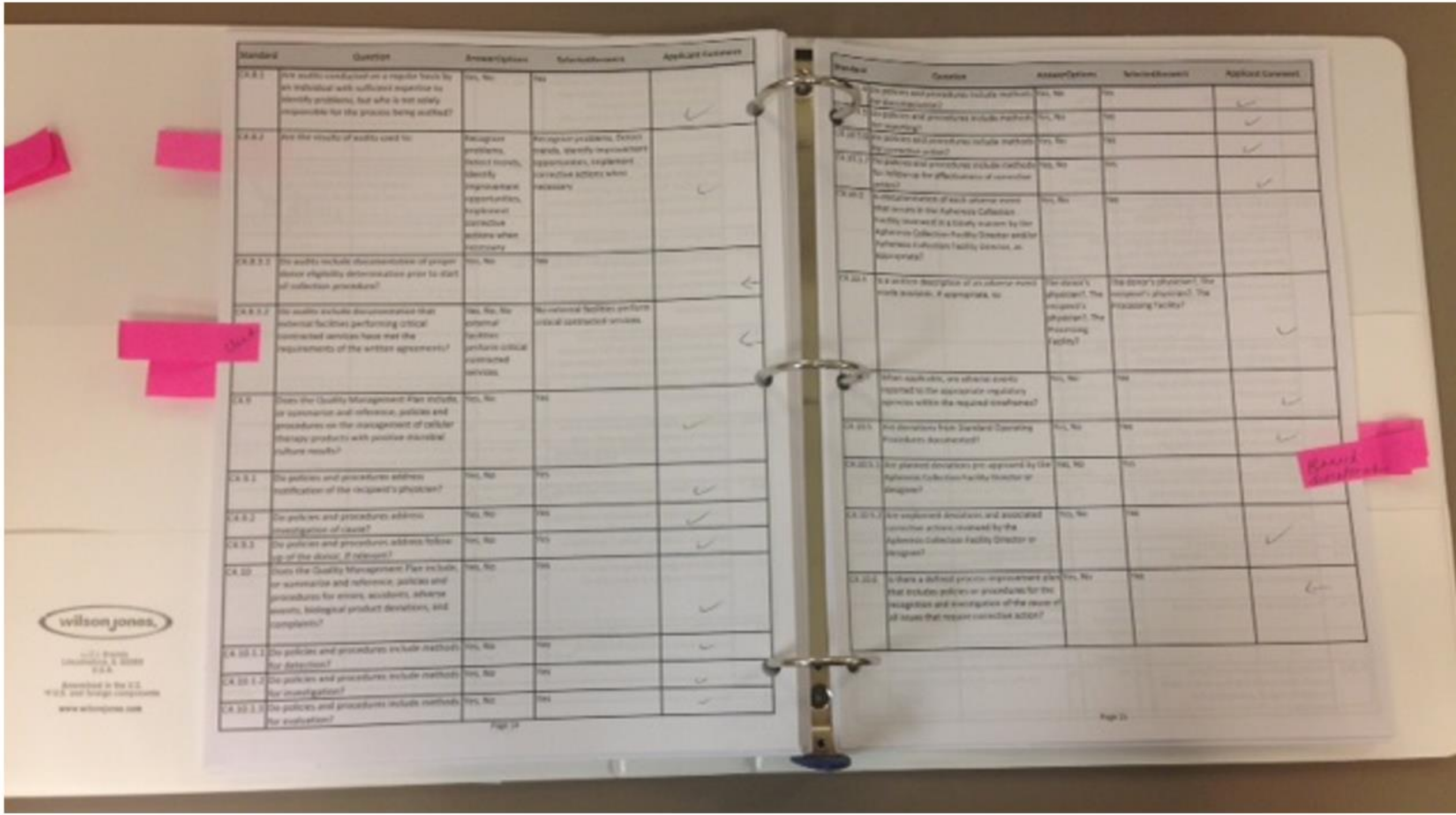
- Review documentation submitted by the applicant
  - Highlight missing documentation
  - Note questions for RFI (Request for Information) or for the on-site inspection
  - Perform a thorough pre-inspection review of documentation to ensure an efficient on-site inspection
  - In the applicant's compliance checklist, indicate compliance for standards that can be verified with pre-inspection submissions

What is Available to Inspectors Pre-Inspection?

- See the Hematopoietic Cellular Therapy Document Submission Requirements handout in your folder
  - Similar to what will be required for Immune Effector Cell inspections
- Documents that can:
  - Be verified in advance (i.e., credentials)
  - Demonstrate inspection readiness
  - Inform inspectors of the structure and processes of the program

Preparing the Checklist

- Use your checklist as a guide during your inspection
- Annotate it before arriving and mark any questions/clarifications/verifications that need answered during the inspection
- Double check where facilities have answered “Not applicable” to ensure it is accurate
- Color code any areas that need additional information
- Make notes on your checklist prior and during your inspection



Standard	Question	AnswerOptions	SelectedAnswer(s)	Applicant Comment
C4.8.1	Are audits conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited?	Yes, No	Yes	
C4.8.1.1	Are the results of audits used to:	Recognize problems, Detect trends, Identify improvement opportunities, Implement corrective actions when necessary	Recognize problems, Detect trends, Identify improvement opportunities, Implement corrective actions when necessary	
C4.8.3.1	Do audits include documentation of proper donor eligibility determination prior to start of collection procedure?	Yes, No	Yes	
C4.8.3.2	Do audits include documentation that external facilities performing critical contracted services have met the requirements of the written agreements?	Yes, No, No external facilities perform critical contracted services	No external facilities perform critical contracted services	
C4.9	Does the Quality Management Plan include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results?	Yes, No	Yes	
C4.9.1	Do policies and procedures address notification of the recipient's physician?	Yes, No	Yes	
C4.9.2	Do policies and procedures address investigation of cause?	Yes, No	Yes	
C4.9.3	Do policies and procedures address follow-up of the donor, if relevant?	Yes, No	Yes	
C4.10	Does the Quality Management Plan include, or summarize and reference, policies and procedures for errors, accidents, adverse events, biological product deviations, and complaints?	Yes, No	Yes	
C4.10.1.1	Do policies and procedures include methods for detection?	Yes, No	Yes	
C4.10.1.2	Do policies and procedures include methods for investigation?	Yes, No	Yes	
C4.10.1.3	Do policies and procedures include methods for evaluation?	Yes, No	Yes	

Standard	Question	AnswerOptions	SelectedAnswer(s)	Applicant Comment
C4.10.1.4	Do policies and procedures include methods for determination?	Yes, No	Yes	
C4.10.1.5	Do policies and procedures include methods for monitoring?	Yes, No	Yes	
C4.10.1.6	Do policies and procedures include methods for corrective action?	Yes, No	Yes	
C4.10.1.7	Do policies and procedures include methods for follow-up for effectiveness of corrective actions?	Yes, No	Yes	
C4.10.2	Is initial/subsequent of each adverse event that occurs at the Apheresis Collection Facility reviewed in a timely manner by the Apheresis Collection Facility Director and/or Apheresis Collection Facility Director, as appropriate?	Yes, No	Yes	
C4.10.3	Is a written description of an adverse event made available, if appropriate, to:	The donor's physician?, The recipient's physician?, The processing Facility?	The donor's physician?, The recipient's physician?, The processing Facility?	
C4.10.4	When applicable, are adverse events reported to the appropriate regulatory agencies within the required timeframes?	Yes, No	Yes	
C4.10.5	Are deviations from Standard Operating Procedures documented?	Yes, No	Yes	
C4.10.5.1	Are planned deviations pre-approved by the Apheresis Collection Facility Director or designee?	Yes, No	Yes	
C4.10.5.2	Are unplanned deviations and associated corrective actions reviewed by the Apheresis Collection Facility Director or designee?	Yes, No	Yes	
C4.10.6	Is there a defined process improvement plan that includes policies or procedures for the recognition and investigation of the cause of all issues that require corrective action?	Yes, No	Yes	

Preparing the Checklist

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

What to look for…

- Quality Plan
- Organizational Chart
- Labels
- Audits
- Validations
- Policies and Procedures

Quality Plan

- Coordinator will verify all areas are included; if not, will send an RFI
- Inspector evaluates adequacy of the plan
  - How does the collection facility interact with other associated facilities?
  - How does the quality plan support operations?
  - Is key performance data adequately assessed?
    - Documentation and review of outcome analysis and product efficacy
    - Handling of errors, accidents, BPDs, serious AEs, complaints
  - Personnel education, experience, training requirements
  - A system documenting training, performance review, continuing education, and continuous competency
  - A system for document control and management (development, approval, implementation, review, revision, archive)

Organizational Chart

- Does the facility appear to have the appropriate FACT Requirements?
  - Referenced or included in the Quality Management Plan
  - Key personnel
  - Functions
  - Interactions to implement QM activities
  - Reporting structure
  - Functions
    - Clinical
    - Collection
    - Processing

Labels (Collection and Processing Only)

- Coordinators will review labels submitted in advance but inspectors should also review for the necessary elements
- Familiarizing with the labels beforehand makes the on-site duties quicker and easier
- Inspectors must verify:
  - Labels provided are actually in use
  - Labeling operations meet the Standards
  - Labeling operations follow SOPs

Audits

- Is there a schedule/timetable available?
- Are audits performed at least annually as required?
- Are required audits performed?
- Onsite documentation must demonstrate use of audit detect trends and implement corrective actions.
- Programs commonly need reminding to have audits available for review.

Policies and Procedures

- Are they approved before the effective date?
  - Are personnel trained/signed-off before they use SOP?
- Do they follow a standardized format?
- Is there version control?
- Are directions clear and complete for the process performed?
- Are procedures validated before implementation?
- On-site, verify procedures are followed.

Actual Tips from Current Inspectors

- “Check and make sure licenses are not out of date since initial submission (some rely on the FACT office for this).”

- “Check consents to see how much of Section C6.2 was addressed in the consent form. (e.g.: opportunity to ask questions, donor has right to refuse donation, allogeneic donor shall be informed of the potential consequences to recipient of refusal to donate).”

Actual Tips from Current Inspectors

- “Review CME to ensure there are enough BMT- related hours.”
  - But CME need NOT be “certified.”
- “Sketch a crosswalk between standards and SOPs, particularly the quality plan as it pertains to each section of the program.”
- “If there are major issues call your FACT coordinator to discuss them before the inspection.”

Inspection Must Haves

- Applicable Standards or Accreditation Manual
  - Available electronically but you may wish to reference them when offline.
  - Acceptable to save them on personal electronic devices for easy searching.
- Print checklist exported from Excel
- Print or save key documents in the event the Internet is not functioning
  - *Upon finalization of the program's accreditation outcome, destroy all inspection documentation, including files saved on your computer.

Review FACT Resources

- Review the Standards
  - Especially changes from previous edition
  - Must be confident of your understanding of each standard
  - Direct any questions to your Accreditation Coordinator
- Review FACT Accreditation Portal
  - Online guides and recordings will be available upon launch of new system
  - Must be confident in using portal before inspection
  - Direct any questions to your Accreditation Coordinator or FACT IT Business Analyst, Alisa Forsythe
- Review Inspector Resources
  - A number of helpful inspection resources are available and now linked to all emails you receive pertaining to the inspection

Inspect

FACT INSPECTOR AREA

Inspector Tools

The following tools are provided for use by FACT Inspectors to aid in preparing, organizing, and conducting an on-site inspection.

- Performing a FACT Inspection
- Participating in a Training Inspection
- Inspector Handbook
- Sample Inspection Agenda:
  - Cellular Therapy
  - Cord Blood

- Inspector Reimbursement Form
- FACT Inspector Insights Submission - Share your Experience!

www.factwebsite.org/factweb > Inspector Area

Thank You