Planning the Inspection

Helen Heslop, MD
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
<table>
<thead>
<tr>
<th>Standard</th>
<th>Question</th>
<th>Answer(s)</th>
<th>Refinement(s)</th>
<th>Applicant Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA.8.2.3</td>
<td>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?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>CA.8.3.2</td>
<td>Are the results of audits used to recognize problems, detect trends, identify opportunities, implement preventive actions?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>CA.8.3.3</td>
<td>Are audits include documentation of proper device eligibility determinations prior to start of collection procedures?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>CA.8.3.4</td>
<td>Are audits include documentation that essential facilities performing critical contracted services have met the requirements of the written agreements?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>CA.9.1.1</td>
<td>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?</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>CA.9.1.2</td>
<td>Does the Quality Management Plan include or summarize and reference, policies and procedures for errors, accidents, adverse events, biological product deviations, and complaints?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>CA.10.1.1</td>
<td>Does the Quality Management Plan include or summarize and reference, policies and procedures for investigations?</td>
<td>Yes, No</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

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**Notes:**
- [Checklist details and comments]
Preparing the Checklist
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
**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!](#)

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Thank You