

The Art of Performing Inspections

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Inspection Challenges

- So much to do, so little time
 - Numerous standards
 - Voluminous documentation
 - Typically one day

How to Rise to the Challenge

- Use the Compliance Application to your advantage, not to your detriment
 - Inspectors do not have to go sequentially through the questions
- Plan, plan, plan!
 - Organize your inspection day in advance, both with your team and for your own portion
- Get creative
 - Many different methods for verifying compliance
 - Use what works for you, so long as the focus remains on the Standards

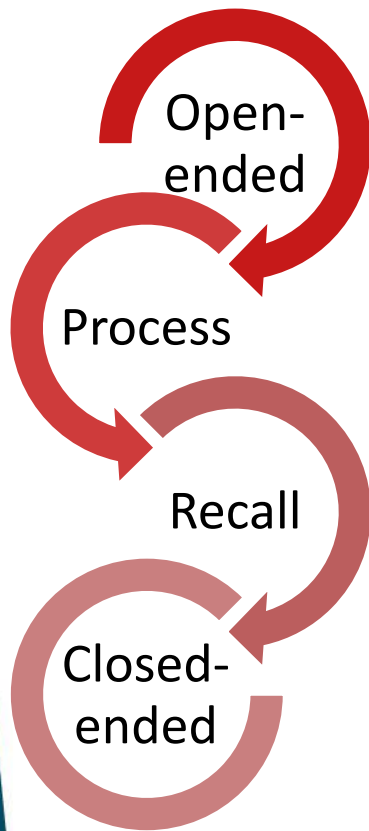
Interviewing: Closed versus Open Ended Questions

Type of Question	Definition	Pros	Cons	Example
Closed-ended	Can be answered with one-word or one-phrase answers	<ul style="list-style-type: none">• Very specific and directed• Require little time	<ul style="list-style-type: none">• Limits the amount of information received	Do you have an SOP for urgent medical need?
Open-ended	Require longer answers; infinite possible answers	<ul style="list-style-type: none">• Allows the interviewee to provide explanations• May provide evidence of compliance with multiple standards	<ul style="list-style-type: none">• Answers may not address the real issue at hand	What is your process for urgent medical need?

Interviewing: Recall versus Process Questions

Type of Question	Definition	Pros	Cons	Example
Recall	Requests recitation of specific information	<ul style="list-style-type: none">• Provides information to specifically address an issue• Confirms presence of something	<ul style="list-style-type: none">• Does not assess understanding of a process	Who approves urgent medical need?
Process	Requires critical thinking	<ul style="list-style-type: none">• Demonstrates training and implementation of processes	<ul style="list-style-type: none">• May require additional time or questions	What would you do if a donor does not meet FDA eligibility requirements?

Interviewing: Funneling



What is your process for urgent medical need?

What would you do if a donor does not meet donor eligibility requirements?

Who approves urgent medical need?

Do you have an SOP for urgent medical need?

Interviewing: Types of Questions to Avoid

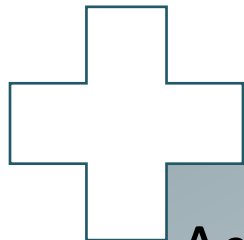
Type of Question	Definition	Cons	Example
Leading	Suggests an answer the interviewee may or may not have thought of	<ul style="list-style-type: none">• May result in an answer that is not completely true• Prevents interviewee from demonstrating knowledge	Do you obtain recipient informed consent as part of your urgent medical need process?
Loaded	Implies something about the interviewee using emotionally charged language	<ul style="list-style-type: none">• Intimidates interviewee• May result in untruthful answer	Would you delay collection from an ineligible donor for the urgent medical need process?

Observations

- Standards compliance is all about the implementation
- Use a “show me” mentality
 - Demonstrates that programs do what they say they do
 - Verifies knowledge of personnel (i.e., adequate training)



Observations: Advantages and Disadvantages



Advantages	Disadvantages
<ul style="list-style-type: none">• Processes become easier to visualize• Compliance can be verified for multiple standards	<ul style="list-style-type: none">• Require adequate time• Depends on applicant: scheduled activities, preparedness for mock activities, etc.

Observation - Assess the Facility

- Clean, orderly, secure
- Appropriate signage
- Adequate, designated space and equipment
 - Is there space to get around patients or equipment?
 - Is there storage space for supplies, reagents, and records?
 - Look at lighting, temperature, access to sinks, etc.
 - What does the staff think about the space?
- Stocked with in-date supplies, reagents, labels
- Safety and access to other services
- Confidentiality and privacy

Observations: Mock Procedures

- Real-time observation may not be possible
 - No scheduled collections on day of inspection
 - Applicant institutions' policies restricting observation of patients
- Inspectors should request mock procedures
 - Reminding applicants prior to inspection is a good idea

Observation - Observe Compliance with SOPs

- Where is the SOP Manual?
 - Copies of SOPs relevant to processes being performed must be readily available
 - Ask staff to locate SOP manual
 - Works for paper or electronic SOPs

Observation Examples: Processes to Observe

- Donor evaluation
 - Confirm designated space for donor evaluation is confidential.
 - Determine who conducts donor screening and informed consent.
 - Observe actual or mock donor screening and informed consent processes.
 - Do they include all required elements?
 - Is the donor given an opportunity to ask questions and to refuse to donate?

Observation Examples: Processes to Observe

BONE MARROW COLLECTION

- Assess facility design and space similar to inpatient unit.
- Confirm compliance with SOP standards by asking:
 - Where are the relevant SOPs?
 - How is personnel trained on new and revised SOPs?
 - Do personnel follow the procedures?
 - Product labeling, storage and distribution

APHERESIS

- Ensure the appropriate process controls take place and that personnel follow the SOP for the collection procedure.
- Look at how the product is stored before it is transferred to another facility
- Concurrent completion of worksheets.
- Adequate labeling operations
- Product storage and distribution

Observation Examples: Processes to Observe

- Processing
 - Validated and aseptic techniques
 - Concurrent completion of worksheets
 - Adequate labeling operations

Observation Examples: Processes to Observe

Cryopreservation

- Concurrent completion of worksheets
- Process for preparing, freezing and storing reference samples
- Adequate labeling operations – double verification
- Inventory management

Observation Examples: Processes to Observe

Observe Cellular Therapy Product Administration

- Do personnel follow SOPs for safe administration of cell therapy products, pre-medication?
- Confirm process for variable amounts of product volume, RBCs, cryoprotectants, and other additives.
- Is bedside emergency equipment and medication available.
- Observe process for product and recipient verification.

Observation Examples: Processes to Observe

- Storage Facilities
- Chain of custody documentation
- Cellular product storage area: product segregation, alarm, back-up, inventory mgt.

Observation Examples: Labels and Containers

- Labels on actual products
 - Content
 - Warning labels
 - Affixed versus attached versus accompanying
- Storage, transport and shipping containers



<https://www.labrepco.com/store/categories/view/id/44/title>



<https://www.iccbbba.org/subject-area/cellular-therapy>



<https://static.fishersci.com>

Review of Documentation of Compliance

Document Review and Interviews

Document Review

- Assess compliance with the Standards over time
- Review established policies and procedures
- Historical behavior predicts future performance

Document Review: Looking for Clues

- Documents reveal many things, such as:
 - Establishment of processes
 - Actual performance of processes
 - Timeframes in which tasks were completed
 - Approvals
 - Reporting

Document Review: Tracer Methodology

- Method used by Joint Commission (https://www.jointcommission.org/facts_about_the_tracer_methodology/)
- Trace entire history in a patient or product record and evaluate:
 - Donor selection, evaluation, and management
 - Collection procedures
 - Distribution from collection to processing
 - Processing procedures, including preparation for administration
 - Storage procedures
 - Chain of custody; distribution for administration
 - Administration
- Include exceptional cases, such as ineligible donors, nonconforming products, patients with adverse events, etc.

General Items to Review

- Verify compliance with all standards
- SOPs / Policies / Labels:
 - Present; required elements in format; consistent
 - Complete, unambiguous; reasonable; adequate
 - Versioned, current, approved
- Understand document management system
 - Good documentation practices
 - Archival of obsolete documents; preserve integrity
 - Numbering, titling, versions
 - Electronic records: retrieve readily; true copies

Available Documents: Quality Management Records

- Quality Management Records
 - Audits: schedule, examples (good and bad)
 - Validations, qualifications
 - Adequacy of design (number of replicates, extreme conditions, correct elements, conclusions)
 - Occurrences (errors, accidents, deviations, adverse events)
 - Detect/document/investigate/CAPA/effectiveness check
 - Appropriate review from Quality Unit and Directors
 - Personnel:
 - Position description, training, competency, continuing ed
 - Training records (eg: newest; oldest; specific product)

Document Review: Quality Management

- For each required element of Quality Management, look for:
 - Inclusion in the QM Plan (in detail or summarized with a reference to the details)
 - Policies and procedures
 - Records of completed activities (worksheets, forms, clinical notes, etc.)

Available Documents

- Outcome analysis
 - Individual Units –immediate engraftment and/or efficacy
 - Aggregate Data – consistent, safe, and efficacious products
- SOP Manual /SOP on SOPs
- Written agreements (reviewed, approved)
- Facility documents (cleaning, monitoring)

Document Review Example: Audits

- Documents should include:
 - Inclusion in the QM Plan
 - A policy and/or procedure about how to perform audits
 - A schedule of audits, including those required by the Standards
 - Audit records that include all required steps (data collection, evaluation, corrective actions and follow-up when necessary etc.)

Record Review: Personnel

- Directors / Medical Directors
 - Review in advance
 - Medical license / relevant degree
 - Review organizational chart and/or job description
 - Continuing education – past accreditation cycle
 - On site
 - Evidence of directors' involvement in activities
 - Signed approval or review of SOPs, worksheets, collection records
 - Participation in programmatic QM meetings (minutes)
 - Review of audit results, involvement with corrective / preventive action and follow-up
 - Product review prior to listing, prior to distribution
 - Validation / qualification studies

Donor Records

- Review donor records:
 - Informed consent to donate (and review consent process)
 - Medical history requirements
 - Documented laboratory tests
 - Compare test dates to the collection dates
 - Eligibility determination

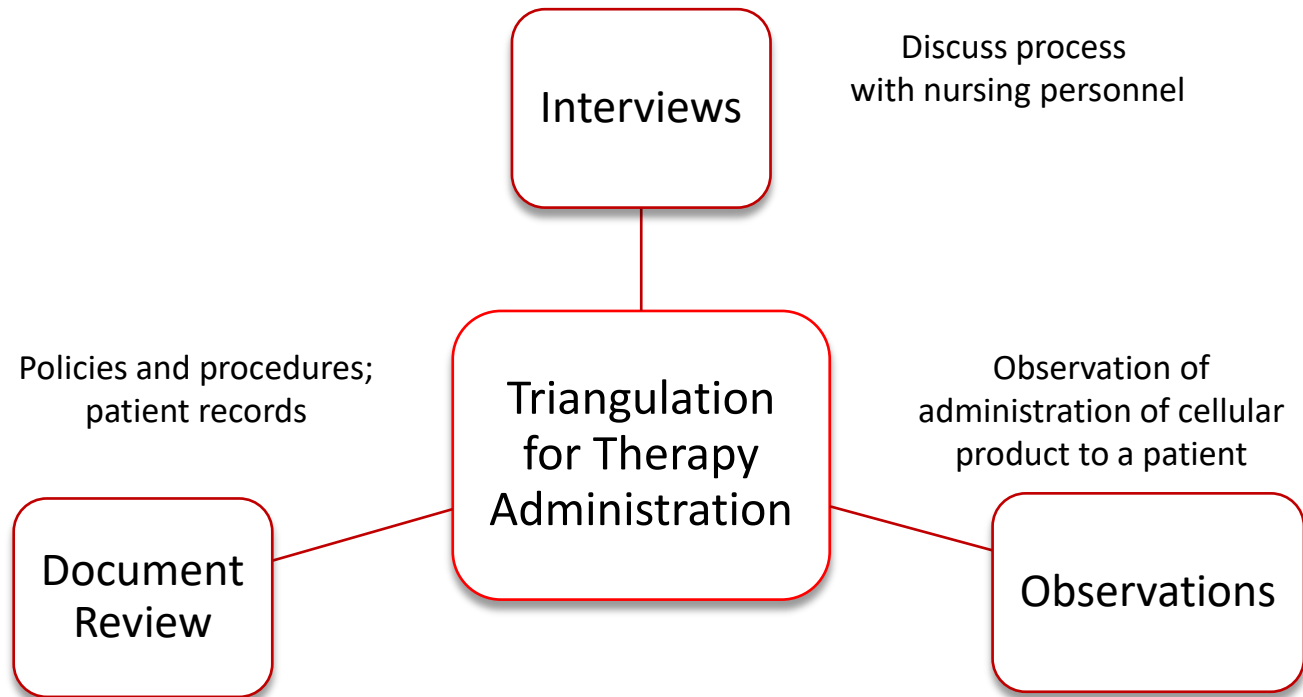
Transport Records

- Trace the product from collection to laboratory to clinical unit (level of detail depends on whether product is from third-party manufacturer, if it is received directly by the Clinical Program, etc.)
- Shipping list identifying each product and piece of documentation
- Records documenting
 - Entity responsible for distributing the unit
 - Date / time of packaging
 - Date / time package left facility
 - Identity of courier and tracking information
 - Date / time of receipt
 - Maintenance of temperature within specified range

Triangulating

- Combine findings from interviews, observations, and document reviews
- Different angles of review provide a complete picture of an applicant's compliance

Triangulating: Cellular Therapy Administration Example



Did You See Anything Particularly Amazing?



- FACT would like to share commendable practices with accredited programs
- As the eyes and ears of FACT, inspectors are the ones who see great ideas
- When you see something impressive:
 - Ask the program if you can share it with FACT, and document
 - Notify the FACT office of commendable practice

Case Study - 1

An inspector interviews a nurse on the clinical unit about what to do when a cellular therapy recipient needs intensive care. She says she reports at shift change when she feels a recipient needs to be transferred to the ICU. The inspector visits the ICU and asks a nurse how the unit protects recipients from infection. He said, “we treat all our patients similarly.” The inspector probed further, asking the nurse about training he has had regarding cellular therapy patients. The nurse stated he had no specific training. Later, during document review, the inspector finds an SOP on ICU transfers that requires prompt notification of the attending physician when the patient presents certain symptoms.

How many deficiencies are present?

Case Study - 1

How many deficiencies are present? **THREE**

1. Nurse does not follow SOPs regarding promptly notifying attending physicians of needed ICU transfers
2. No provision on ICU to treat neutropenic patients
3. ICU nurse was not trained on pertinent cell therapy-related SOPs

Case Study - 2

A collection inspector is ready to tour the facility. The facility's contact person tells the inspector to let herself into the procedure room. The inspector asks a staff member to retrieve a specific SOP, and staff member knew exactly where to find it and gave it to the inspector. She asks the staff member to demonstrate the process outlined in the SOP. The staff member yawns while completing the process, stating that this is his sixth straight 12-hour shift at work because two people had recently resigned.

How many deficiencies are present?

Case Study - 2

How many deficiencies are present? **TWO**

1. The facility was not secure
2. Most likely inadequate number of staff to do the work.

Case Study - 3

The recipient's physician obtains donor informed consent verbally, and documents this with a clinic note that says, "donor gives consent after discussion of donation process."

How many deficiencies are present?

Case Study - 3

How many deficiencies are present? **TWO or THREE**

1. Standard B6.2.6.1 requires that informed consent from the allogeneic donor be obtained by a licensed health care professional who is NOT the primary health care professional overseeing care of the recipient.
2. Details of the informed consent discussion are not documented in clinic note, therefore –
3. It is unclear if all the required elements of informed consent are included or if the donor was able to ask questions and have those questions answered

Thank You