THE JACIE ACCREDITATION PROCESS
Inspection to accreditation
Accreditation Process

- Invitation
- Inspection
- JACIE Accreditation Committee
- Evidence of corrections (EC)
- Accreditation

PRE-INSPECTION
- Pre-Inspection Documentation
- Teleconference

INSPECTION
- Inspection Report
- Summary Report and Checklist
- Assessment EC

POST-INSPECTION
- Inspector
- Center
- JACIE Office
Contents

1. Distribution of the standards
2. The inspection
3. The post-inspection procedure
4. Accreditation
Distribution of the standards
Distribution of the Standards

Part B/CM/C/D 4 QM excluding:
- Outcome analysis
- Tracking & traceability/labeling requirements
- Qualification
- Validation

Parts B/CM/C/D 5 Policies & Procedures

CLINICAL ADULT & PAED
- Part B
- Med-A
- Donors part B
- Part CM

COLLECTION
- Part C
- Donors part C
- Collection labels
- Part CM

PROCESSING
- Part D
- Processing labels
- Shipping labels
The inspection
Inspection agenda

1st Half Day – Day 1
  Opening meeting
  Review documentation

2nd Half Day – Day 1
  Tour of facilities
  Interviews key personnel each unit
  Observation of procedures

3rd Half Day – Day 2
  Continue tour, interviews and document review
  Exit Meeting with Programme Director
  Closing Meeting
Opening meeting

APPLICANT

Programme

TEAM LEADER

Roles & responsibilities

Inspectors

Scope

Agenda

Confidentiality
The on-site inspection

- Verification of the applicant’s completed checklist
- Examination of all aspects of the programme
The closing meeting

Inspection Team Meeting
Discuss & compare findings within team
Agree in grading

Exit Meeting with Programme Director
Brief on any sensitive / important issues
Private meeting

Closing Meeting
Inspectors present main findings
Congratulate on positive things
Inspection outcome will be made by JACIE Accreditation Committee

Q&A
The online post inspection survey

Applicants and inspectors feedback helps us to improve the accreditation process.
The post inspection procedure
Inspection report and Inspection checklist preparation

2 weeks

INSPECTORS

JACIE OFFICE

TEAM LEADER

Summary Report

Checklist
The inspection report path
Inspection Summary Report

Inspection Report and Recommendations to Applicant

Contents

Section A. General Information & Overview ................................................................. 1
Section B. Team Leader On-site Inspection Summary .............................................. 2
Section C: Observations ......................................................................................... 3
  Cellular Therapy Product Administration & Clinical Facilities ............................ 3
  HPC, Marrow Collection .................................................................................. 4
  HPC, Apheresis Collection ............................................................................. 5
  Cellular Therapy Product Processing .................................................................. 6
  CM7, C7 & D7 Labels (Cell Collection & Cell Processing) .................................. 7
  Quality Management ....................................................................................... 8
Section D: Accreditation Committee Summary ...................................................... 9

Note: The applicant should also refer to the Inspection Checklist for specific deficiencies where these have been observed during the inspection.
### Part C: Apheresis

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Standard</th>
<th>Applicant's assessment</th>
<th>Source of evidence and explanatory text</th>
<th>Inspector's Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.07.01</td>
<td>ISBT 128 CODING AND LABELING</td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
</tr>
<tr>
<td>C.07.01.01</td>
<td>Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.</td>
<td>Compliant</td>
<td></td>
<td>Compliant</td>
</tr>
<tr>
<td>C.07.01.02</td>
<td>If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.</td>
<td>Partially compliant</td>
<td>Implementing SEC</td>
<td>Partially compliant</td>
</tr>
</tbody>
</table>

Labeling operations shall be conducted in a manner...
Evidence of corrections
Accreditation Process

- Invitation
- Inspection
- JACIE Accreditation Committee
- Evidence of corrections (EC)
- Accreditation

PRE-INSPECTION
- Pre-Inspection Documentation
- Inspector

INSPECTION
- Teleconference
- Inspection Report
- JACIE Center
- Summary Report and Checklist
- Assessment EC

POST-INSPECTION
- YOU ARE HERE NOW
- JACIE Office
Evidence of corrections

JAC ASSESSMENT OF THE INSPECTION REPORT

All standards compliant

Minor deficiencies

Major deficiencies

NO CORRECTIONS

CORRECTIONS

CORRECTIONS + RE-INSPECTION

ACCREDITATION
• 99,99% of inspections reveal deficiencies

• In very rare occasions a re-inspection is required

• Around 8% of standards present non/partial compliances
Evidence of corrections

**APPLICANT PROVIDE**
- Checklist
- Supporting documentation

**INSPECTORS ASSESSMENT**
(same inspection team)
- All standards are compliant
- Further evidence of corrections needed
- Re-visit if:
  - Extensive QMS failures
  - New facility
Accreditation
Accreditation Awarded

ACCREDITED BY:
JACIE
Joint Accreditation Committee
ISCT | EBMT

✓ Inspectors confirm all points are resolved
✓ JACIE Accreditation Committee do not have further comments
✓ Applicants receive Certificate and letter of accreditation
✓ Listing at JACIE’s web site
Accreditation conditions

Accreditation awarded for 4 years

- If a centre takes more than 9 months to resolve the deficiencies, JACIE may award the accreditation from the date of the inspection

Annual report

- Summary of activity and changes

Interim Audit (50% centres)

- End of year 2 of Accreditation: focused QM review, based on standards, may result in on-site visit
Inspector’s time and timing

- Pre-Audit documentation: 11.5 hours
- Inspection: 1.5 days
- Teleconference: 0.5-1 hour
- Interim audit
- Diary
- Evidence of corrections
- Inspection report
- Annual reports

JAICE Inspector time
Accreditation Process

PRE-INSPECTION
- Invitation
- Pre-Inspection Documentation
- Inspector

INSPECTION
- Inspection
- Teleconference
- Inspection Report
- Center

POST-INSPECTION
- JACIE Accreditation Committee
- Summary Report and Checklist
- Assessment EC
- Evidence of corrections (EC)
- Accreditation
- JACIE Office

YOU ARE HERE NOW
Questions?