

The JACIE Accreditation Process

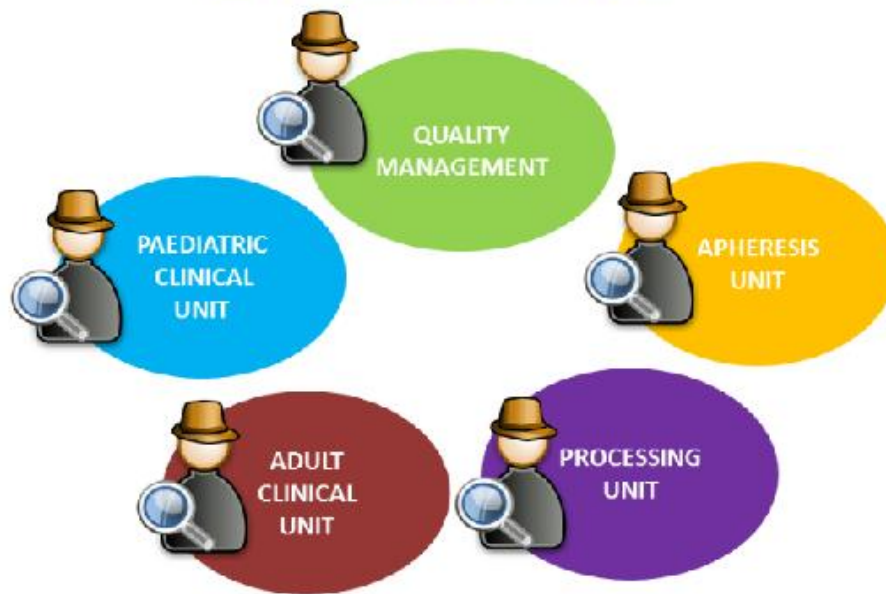
JACIE Office,
Barcelona, Spain



Accreditation Process



Current Inspection Team



Quality Management Inspectors



CURRENT INSPECTOR POOL (June 2016) = 32

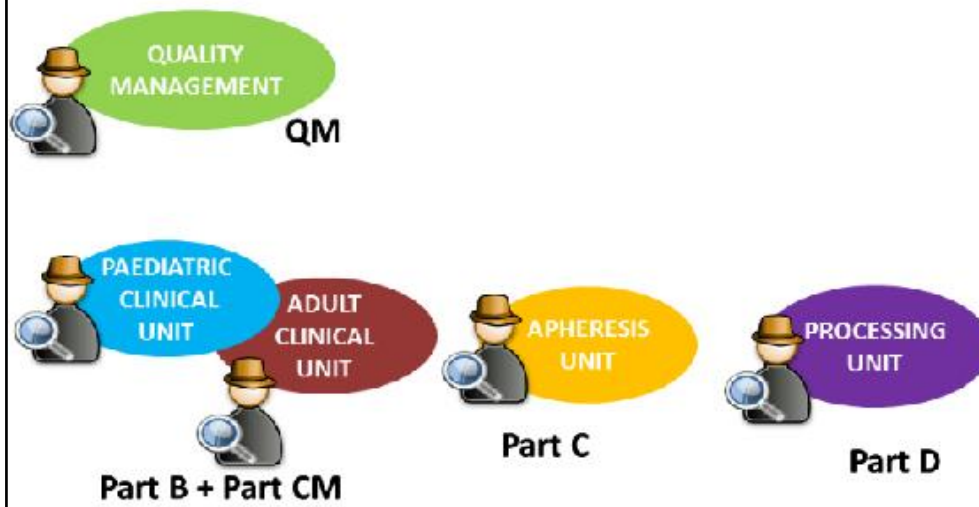
July 2016

ESTIMATED INSPECTOR POOL (December 2016) = estimated 60

QMI

Belgium, Czech Republic,
Denmark, France, Germany,
Greece, Ireland, Italy,
Nigeria, Saudi Arabia, Spain,
Sweden, Switzerland, Turkey,
UK

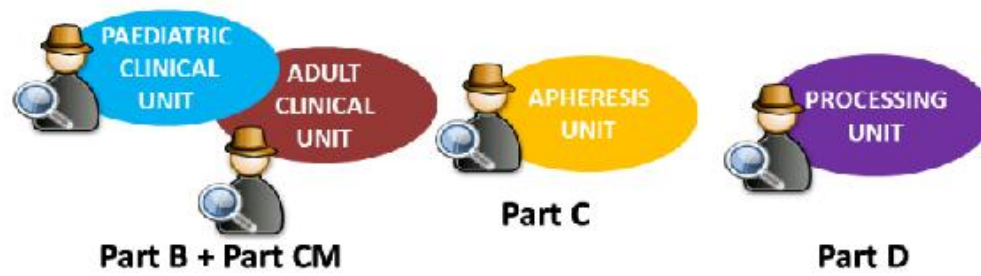
Distribution of Standards to be Inspected



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Inspection timetable

- Usually 1.5 days
- Proposal made by Team Leader
- Reviewed by the centre who can insist on reasonable changes if necessary



Sample timetable

1st Half-day Period

Inspectors' arrival to lim site, introduction & presentation of overall clinical programme by Programme Director
MEDA/B data audit and initial review of documentation

Quality Manual & SOPs and documentation

2nd Half-day Period

Tour around facilities demonstrating links between facilities

Interviews:

Clinical

Programme Director

A transplant physician

The quality manager

Senior Nurse

Nurse responsible for training

BMT and nurses

Pharmacist

Cell Collection

Collection facility director

Collection facility medical director

Potentially any staff involved in collection of cells

Laboratory

Laboratory Director

Laboratory Medical Director

Laboratory Processing Lead

Laboratory Quality Manager

Laboratory Trainee(s) (as appropriate)

3rd Half-day Period

Continues tour around facilities

Interviews and review of

remaining documentation

Exit Meeting with Programme

Director

Closing Meeting

FACE



Inspection

- Thorough examination of all aspects of the programme.
- Verification of the applicant's completed checklist



At the end of the inspection

- The exit interview
 - Inspector will discuss any sensitive issues with facility head and/or **Programme Director** in private **BEFORE** exit interview
 - The inspectors discuss their visit and inform the Programme Director and staff of what they found
 - Inspectors **do not** comment on possible outcome

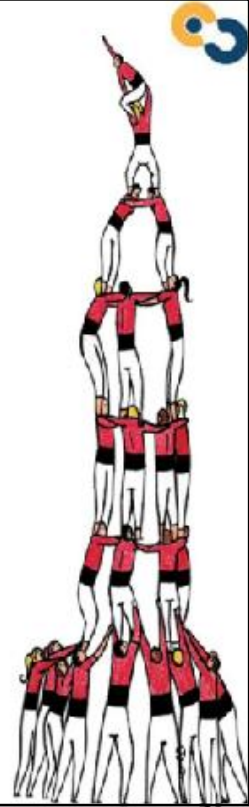


The Inspector

- Inspectors return Completed Inspection Checklist, any notes and documents to the Team Leader (TL) or directly to JACIE Office



Post-inspection



Accreditation Process

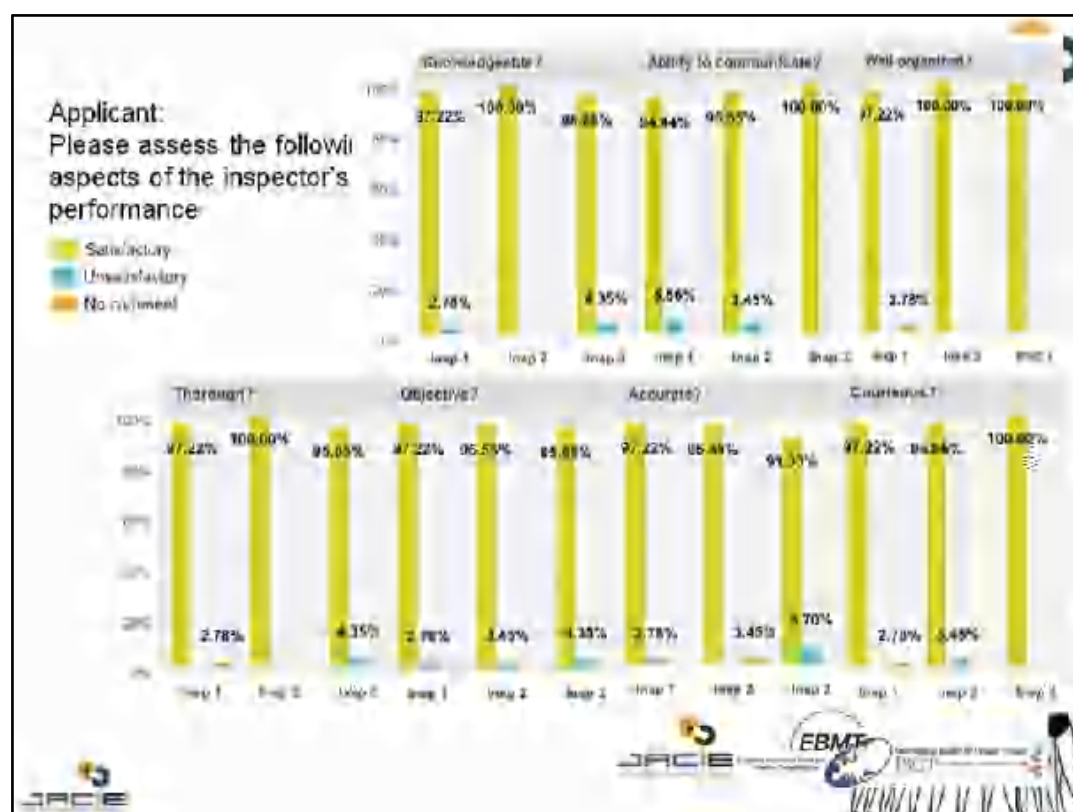


The Applicant

- Complete and return the Onsite Evaluation form for JACIE Office
 - Opportunity to raise concerns (or give praise!) about anything involving the on-site inspection



[illegible]



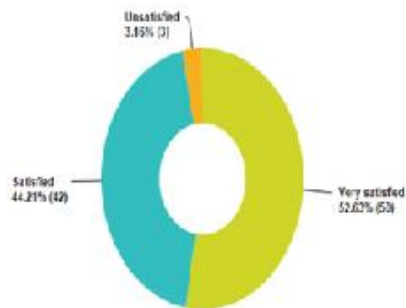
JACIE Survey - 2015



INSPECTOR'S SATISFACTION

Overall, how satisfied are you with the onsite inspection process (preparation phase and onsite inspection)?

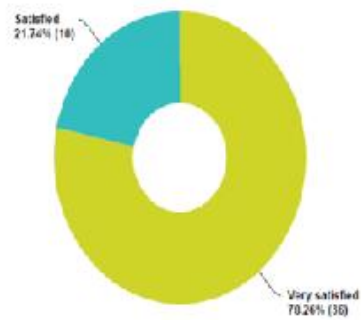
Answered: 16 Skipped: 0



CENTER'S SATISFACTION

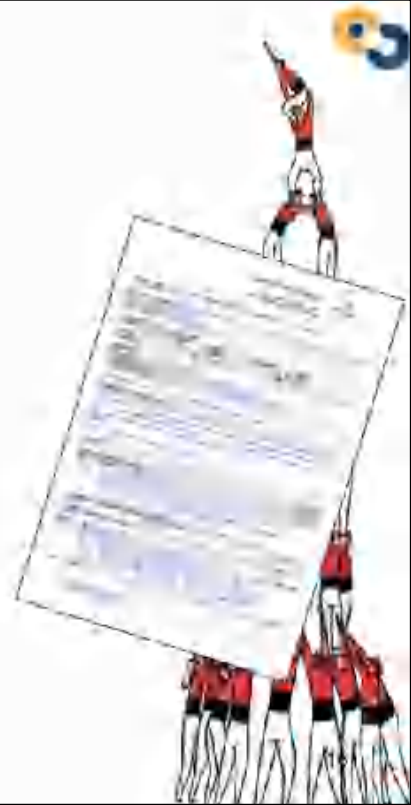
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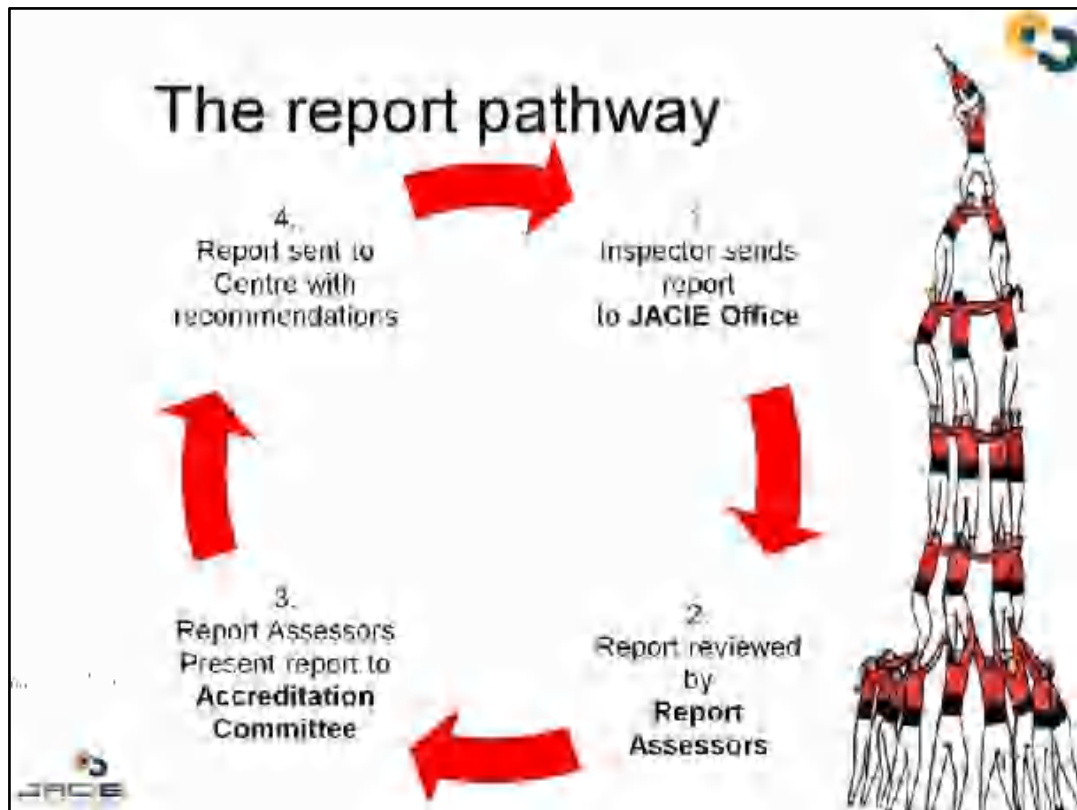
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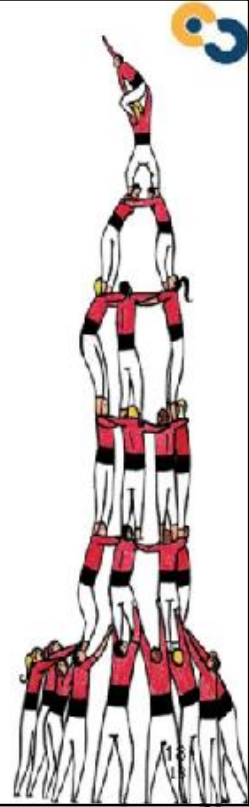
Report

- Fundamental part of the Accreditation Process
- All decisions are made based on the report.
- Based on completed Inspection Checklist





Accreditation Committee



Accreditation Committee

- Discusses each individual report and make recommendations
- Source of expert opinion



- Monthly teleconference



Accreditation Committee

Chair: Maria Vittoria Gazzola (Italy)

Clinical

John Snowden (UK)

Rafael Duarte (Spain)

Hellmut Ottinger (Germany)

Paediatric

Christiane Vermylen (Belgium)

Justyna Kanold (France)

Collection

Kim Orchard (UK)

Kristina Hölzig (Germany)

Processing

Dominique Latinne (Belgium)

Monique Grommé (The Netherlands)

Maria Vittoria Gazzola (Italy)





Corrections

"Well, nobody's perfect":

Osgood Fielding III
Some Like It Hot (1959)

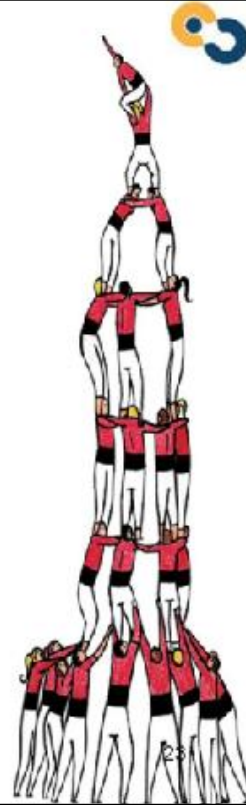


Corrections

- "99.99%" of inspections reveal deficiencies
- Great variety in seriousness of deficiencies
 - Vary from missing references in SOPs to dangerous storage areas
- Most cases, evidence of corrections is submitted electronically and reviewed by inspectors



Review of corrections and/or need for revisit



Review of corrections and/or revisit

- The same inspectors assess evidence of corrections
- In certain cases, a revisit to the site may be required.
 - extensive failures in the quality management system,
 - new construction since inspection



Accreditation

- Accreditation awarded when inspectors are satisfied that all points have been resolved + the JAC do not have further comments



- Certificate and letter issued to the centre



Accreditation

- Accreditation for 4 years from date of award
 - If a centre takes more than 9 months to resolve deficiencies, JACIE may award accreditation from date of inspection
- Annual report – short summary of activity and changes
- Interim review at end of year 2 of accreditation



Interim audit

- At end of year 2 of accreditation
- Documentation review will focus on how the quality management system is functioning
 - Evidence of audits
 - QM meetings
 - SOP review
 - Etc.
- Based on standards i.e. no new requirements
- May result in on-site visit



Fees - effective April 3rd 2016

Registration Fee (non-refundable):

€3,850 on application (*applicable to all applications, both first-time and reaccreditation, and non-refundable*)

Inspection Fees:

€2,310 charged per area to be inspected

Supplementary Fee

€1,100 per each additional site

Applications from centers whose staff members have participated in an inspection event(s) in the 4 years preceding submission of the new application will qualify for a discount of 10% per event up to a maximum of 20%.



Time

Pre-audit documentation: 11.5 hr

Teleconference: 0.5 - 1 hr

Inspection: 1.5 days (plus travel time)



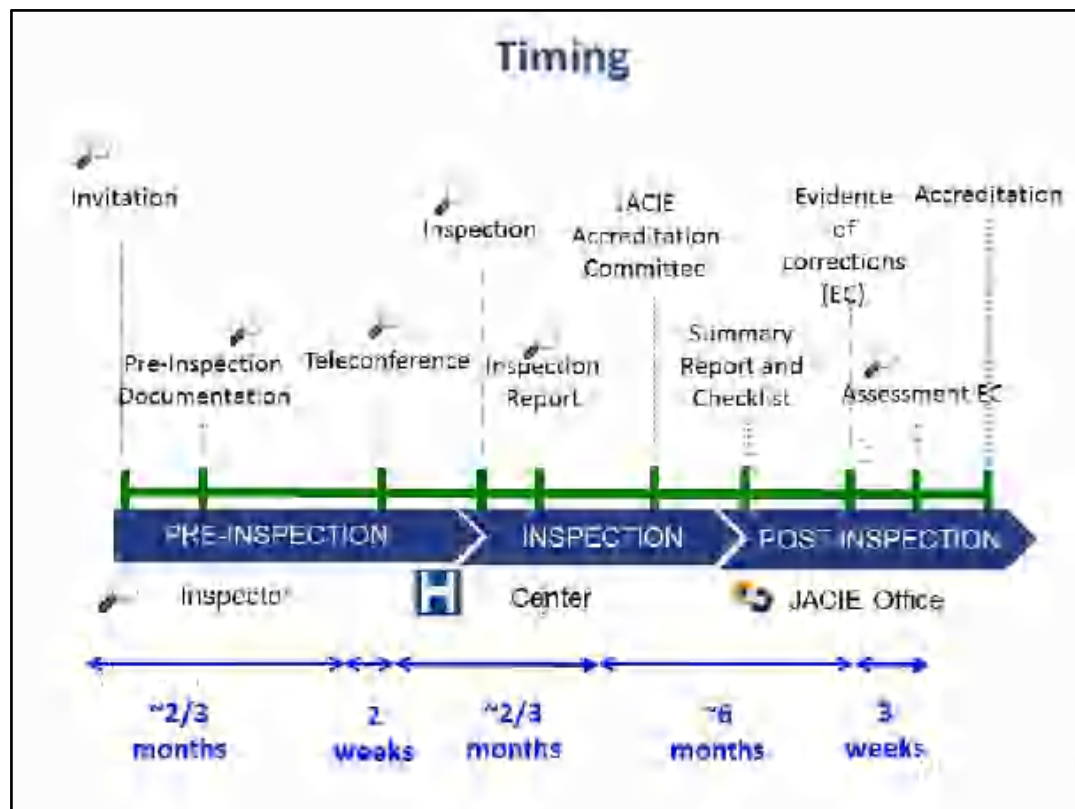
Inspection Report

Evidence of corrections

Interim Audit

JACIE Inspector





- Thank you for listening
- Any questions?

