

# THE JACIE ACCREDITATION PROCESS

JACIE Office,  
Barcelona, Spain

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# Phases



# Process

Decision to work according to the  
Standards



# Process

Preparations, working with quality

Decision to work according to the  
Standards

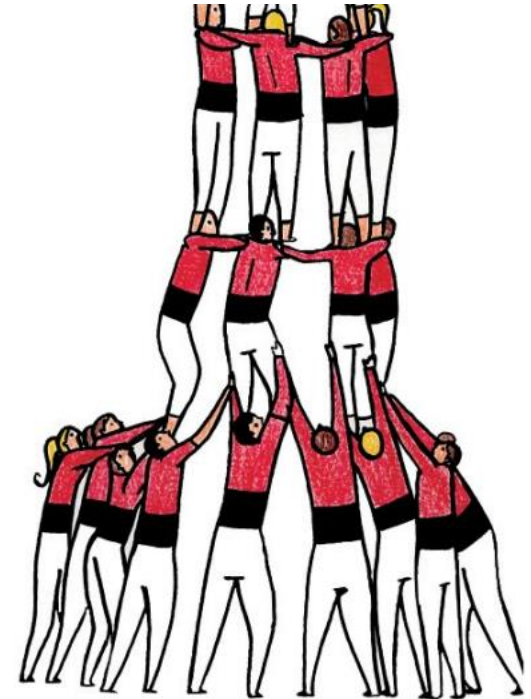


# Process

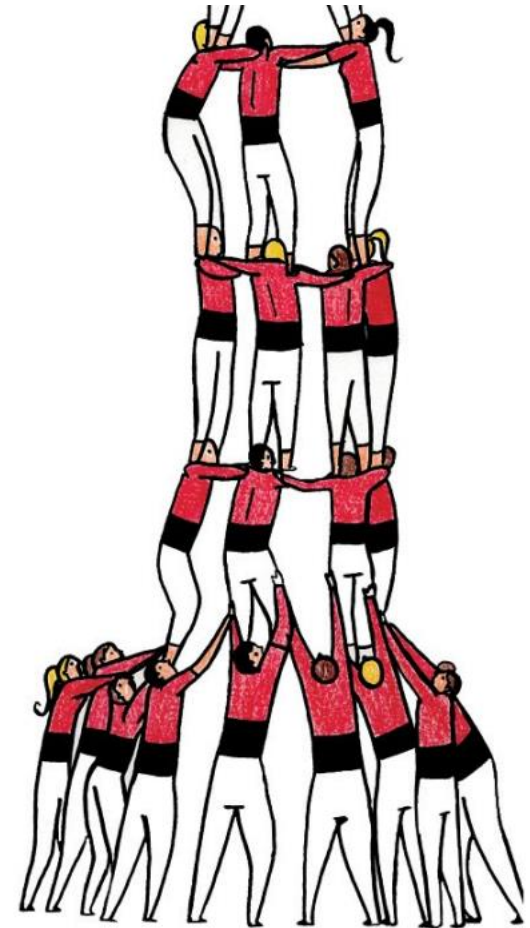
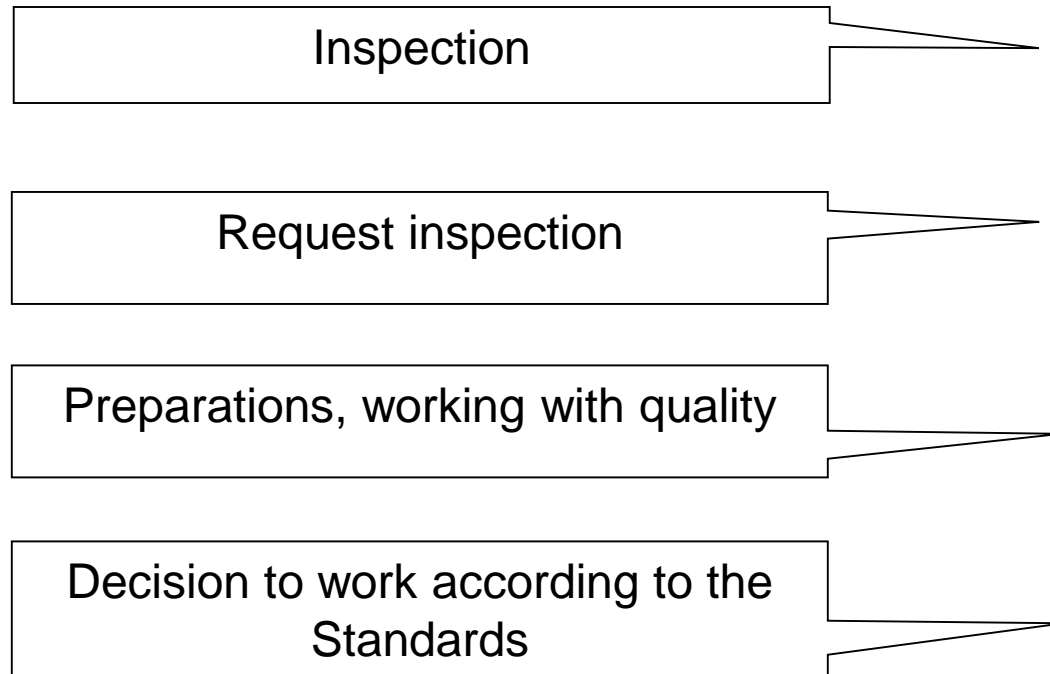
Request inspection

Preparations, working with quality

Decision to work according to the  
Standards

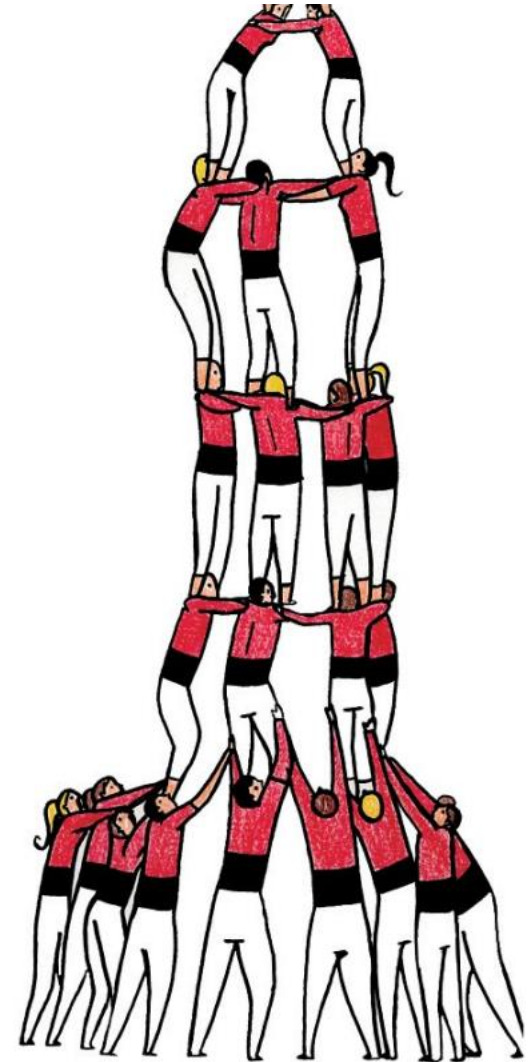
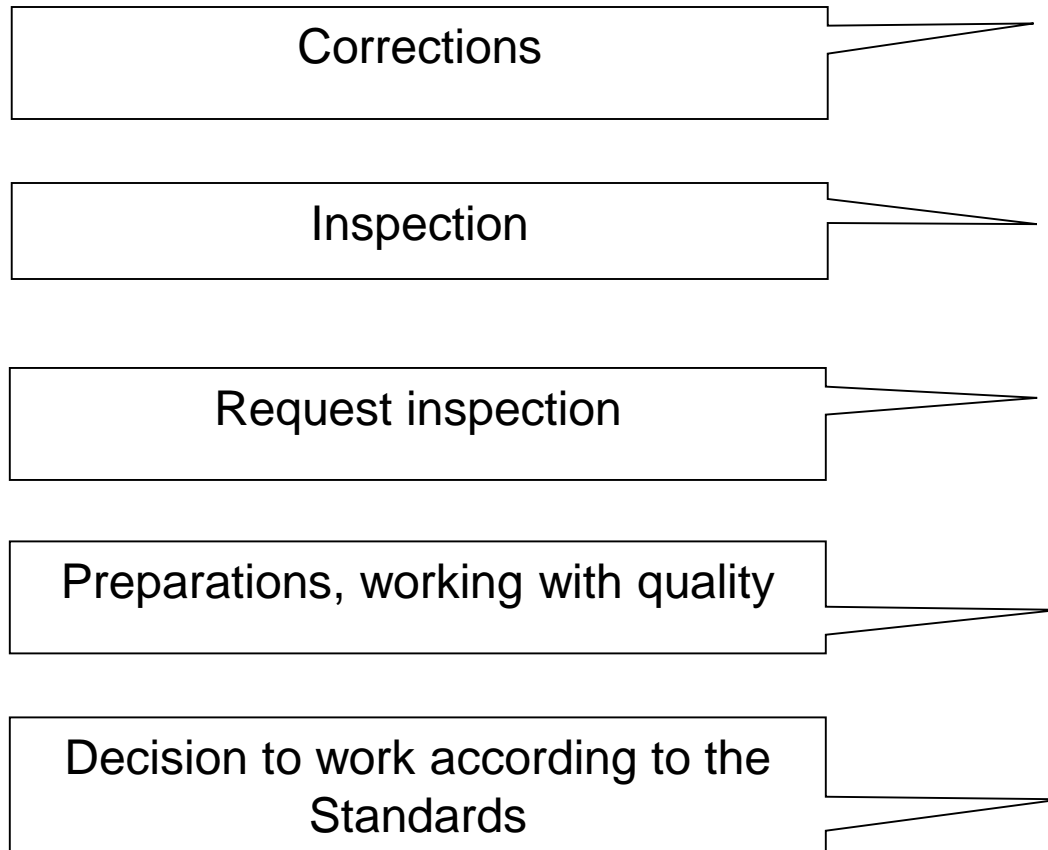


# Process





# Process



# Process

Accreditation

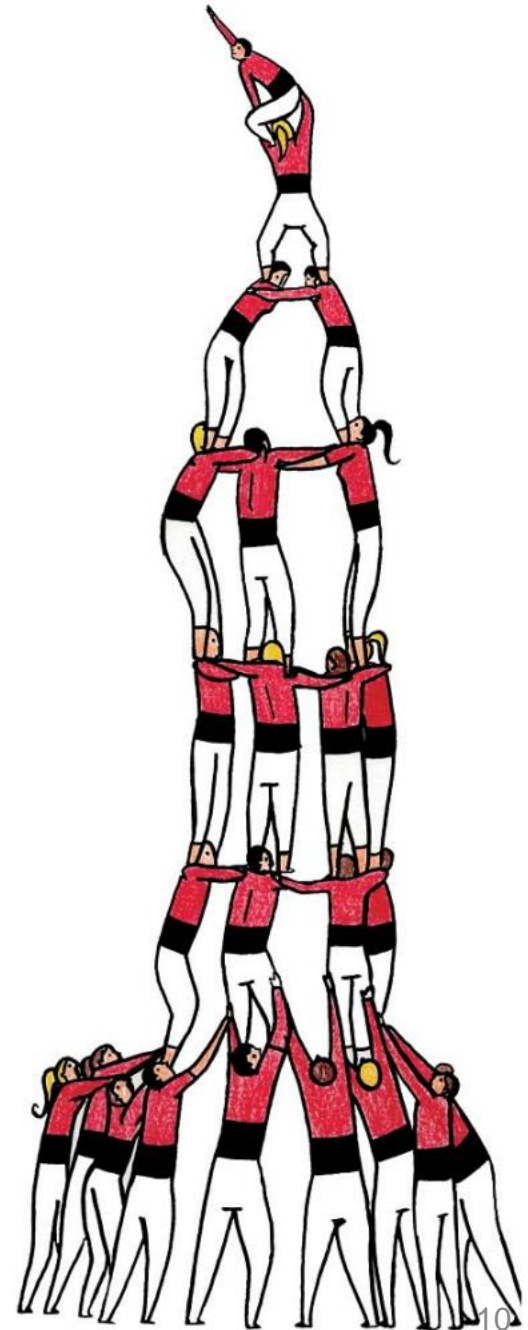
Corrections

Inspection

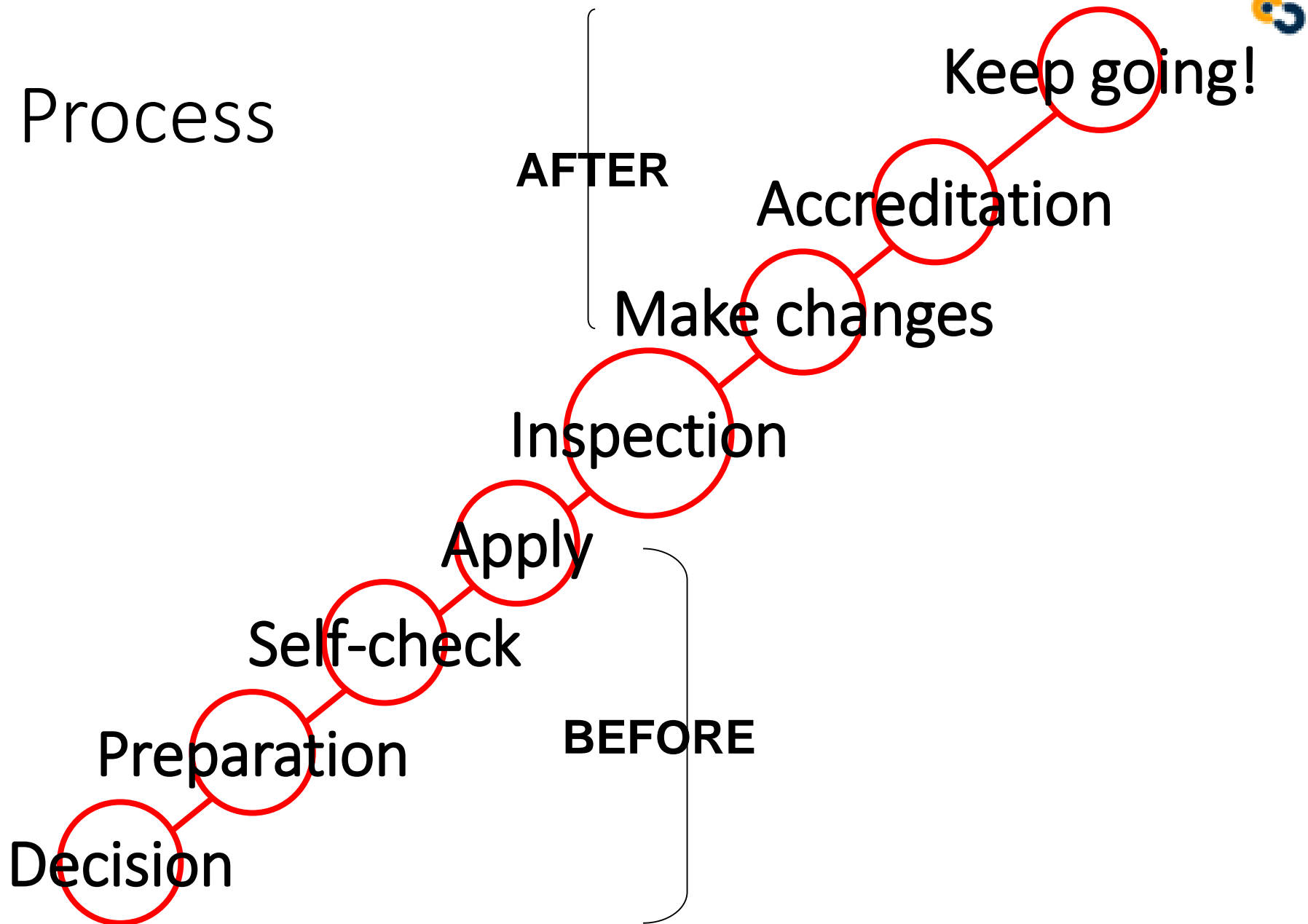
Request inspection

Preparations, working with quality

Decision to work according to the  
Standards



# Process



# Preparation by the Centre

# Preparation by the centre



**QM Group**



**QM, SOPs**



**Indicators**



**Audits**



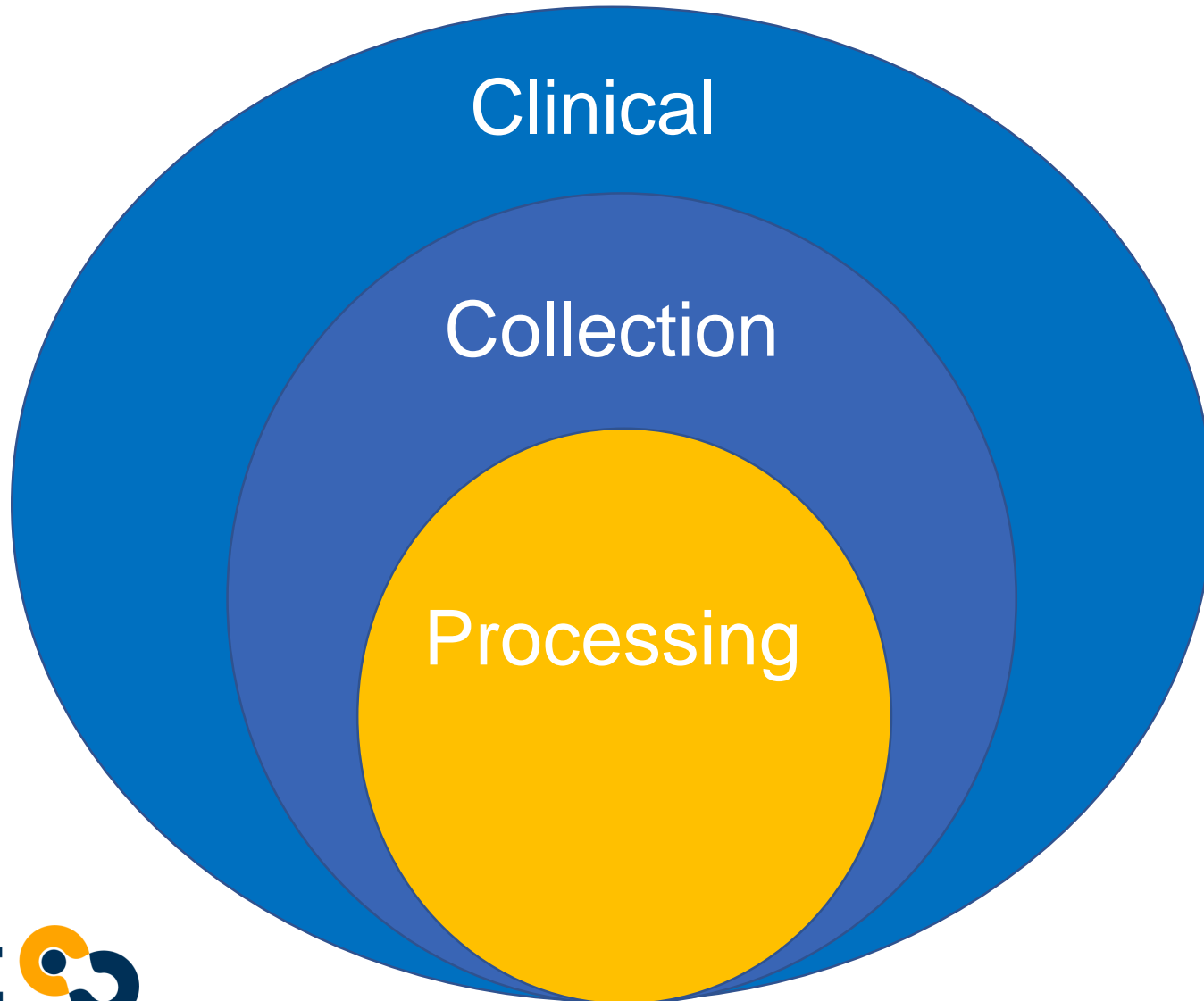
**Training**



**Remember to provide  
evidence**

# Application

# Accreditation



# Application Form

File: Application form ver 3.3 (inception)  
File created: 06/12/2012 13:30  
Effective from: 12/12/2012 9:10

**APPLICATION FOR FIR ST-TIME ACCREDITATION & RE-ACCREDITATION**

For centres in The Netherlands, please go to the [COCL website](http://www.jace.org.uk/document-centre)

Application for Accreditation

**JACE**

Instructions for completing the Application Form  
Note: From 28/12/2017, centres must submit the completed Inspection Checklist before an application can be assessed and approved.  
The Checklist can be downloaded from <http://www.jace.org.uk/document-centre>

Programme name: LABOURING

Country: INDONESIA

Working language of centre: Indonesian

**1. GENERAL DETAILS**

1.1 Accreditation goal (delete as appropriate):

Activity(s) for which you are requesting accreditation (mark with an 'X' as appropriate):

Area	Patient	Autologous
Clinical	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RPC: marrow	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Collection	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Proc: Apheresis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Collection	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Processing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

1.2 Invoicing information

Institution: Clinic Hospital Universitas Sebelas Maret

Address: Jl. Sekeloa Utara No. 100-101, Surakarta 57126

City: Surakarta

Post-code: 57126

Phone: (+62) 271 250 2500

Fax: (+62) 271 250 2500

E-mail: info@clinic-hospital-sebelas-maret.co.id

VAT number: PT-0000000000

Any other references that should appear on the invoice: -

Programme name should be used to describe an application including (1) multiple sites or institutions e.g. the Central City-B&M Transplantation Programme that name will be used in all correspondence. The coordinator will list the individual site institutions within the programme / IF (2) where the appropriate is for a multi-centre application. (3) the name of the programme and the name of the institution. (4) the name of the institution. (5) the name of the institution. (6) the name of the institution. (7) the name of the institution. (8) the name of the institution. (9) the name of the institution. (10) the name of the institution. (11) the name of the institution. (12) the name of the institution. (13) the name of the institution. (14) the name of the institution. (15) the name of the institution. (16) the name of the institution. (17) the name of the institution. (18) the name of the institution. (19) the name of the institution. (20) the name of the institution. 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- Word Document
- <http://www.ebmt.org/jacie-accreditation-pre-inspection-process>






**Part B: Clinical**

Ref.	Standard	Applicant's Response	Source of evidence and explanatory text	Applicant's Assessment	Inspector's Comments (Insert your answers on additional documents)
B31.01	GENERAL				
B31.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director's involvement in a defined function.	Compliant	No evidence		
B31.01	The Clinical Program shall demonstrate consistent staff training protocols, procedures, quality management systems, clinical outcome analysis, and regular education among all clinical staff.	Partially compliant	No evidence		
B31.02	The Clinical Program shall use real collection and processing facilities that meet FACT-JCCE standards with respect to their interactions with the Clinical Program.	Compliant	No evidence		
B31.03	The Clinical Program shall adhere to all applicable laws and regulations.	Compliant	No evidence		
B31.03	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authority for the activities.	Compliant	No evidence		
B31.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a representative of the additional attending transplant physician.	Compliant	No evidence		



**JACIE**   
 Joint Accreditation Committee  
 ISCT | EBMT



# Inspection Checklist

## Part B: Clinical

Inspector: All items compliant?

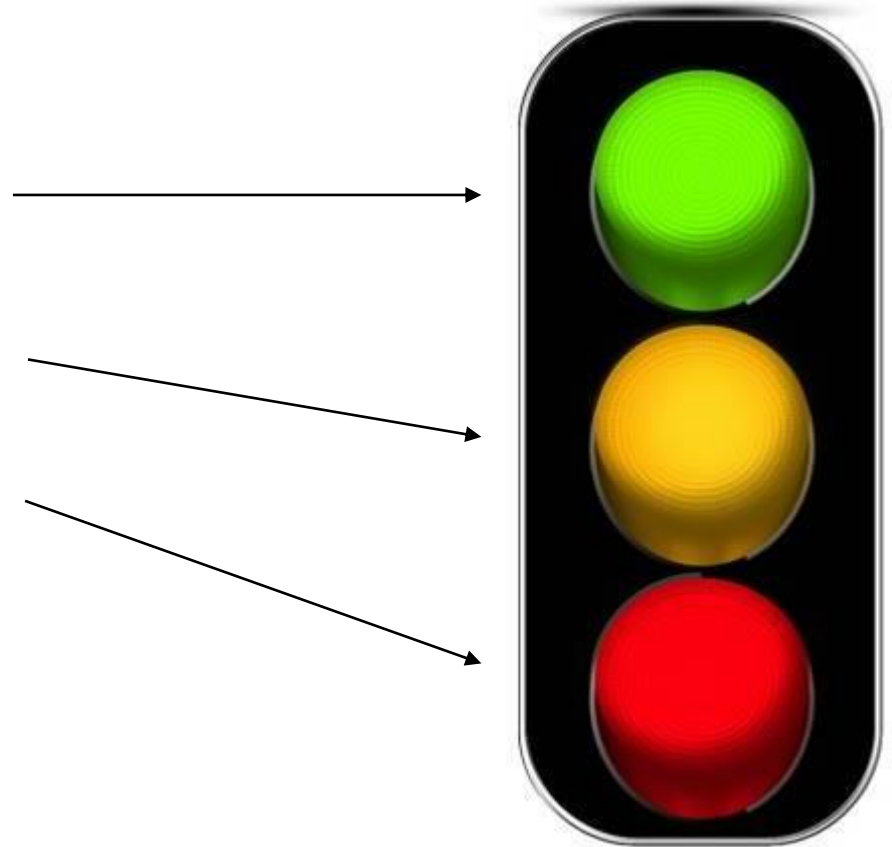
No

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (support your answers with additional information)
B.01	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	Compliant	No evidence		
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	Partially compliant	No evidence		
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	Non-compliant	No evidence		
B.01.03	The Clinical Program shall abide by all applicable laws and regulations.	Compliant	No evidence		
B.01.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities	Compliant	No evidence		
B.01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team	Compliant	No evidence		

# Inspection Checklist


- Based on Traffic Light system

- Compliant
- Partially Compliant
- Non-compliant
- Not Applicable (N/A)



# Inspection Checklist

0.01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team	Compliant	No evidence		
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Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text
B.01	GENERAL	BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	Compliant	No evidence
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	Partially compliant	No evidence
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program	Non-compliant	No evidence

# Inspection Checklist

Inspectors Assessments

Inspectors comments

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (support your answers with additional information)
B.01	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	Compliant	No evidence		
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	Partially compliant	No evidence		
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	Non-compliant	No evidence		

# Application Approval

- Quotation
- **2 Weeks** to submit the JACIE Accreditation Agreement Signed



# Pre-Inspection Documentation



# Pre-Inspection Documentation

- 30 days to submit documentation
- Labels
- List of SOPs
- Donor / patient consent information
- Evidence of audits performed....

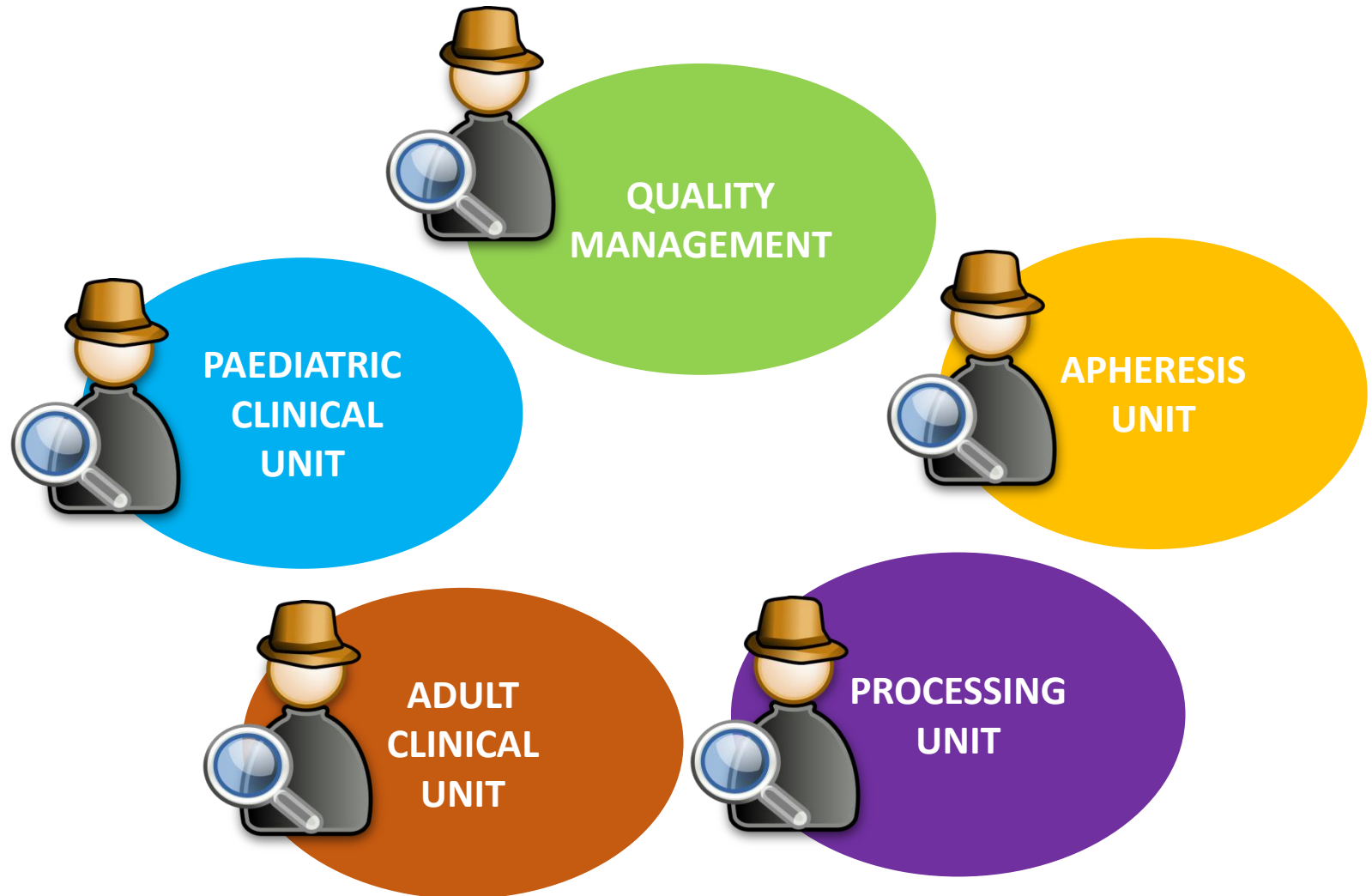


Documentation in the  
language of the Centre

# Inspection:

## *Inspection Team*

# Inspection Team



# Inspection Team



- Language of the centre
  - Language facilitator can be added to the team
- 
- Centre is invited to look at the JACIE list of inspectors, public in EBMT website
  - Centre & Inspector shall inform of potential conflicts of interest

# Inspection Team

- 1 team leader

In addition, possible inclusion of:

- Observer e.g. JACIE National Representative, regulatory agency
- Trainee

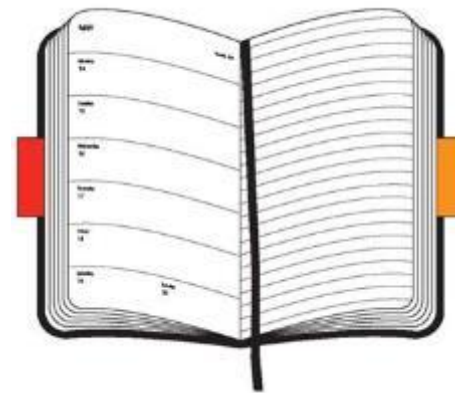


# Team Leader

- Usually Clinician



- Point of contact between Team, Centre and JACIE Office



- Arranges timetable with programme director

# Inspection:

## *Preparation*

# Applicant: Preparation





# Inspector: Preparation



Part B: Clinical

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (Support your answer with additional information)
B-1	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
B 01 01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	Compliant	No evidence		
B 01 01 01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	Partially compliant	No evidence		
B 01 02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACE Standards with respect to their interactions with the Clinical Program.	Non-compliant	No evidence		
B 01 03	The Clinical Program shall abide by all applicable laws and regulations.	Compliant	No evidence		
B 01 03 01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities.	Compliant	No evidence		
B 01 04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team	Compliant	No evidence		

Inspector: All items compliant?

No



# Inspection:

## *Travel and Hotel*

# Travel & Hotel



- Inspectors make travel arrangements with JACIE Travel Agency
  - No big payments in advance for the inspector
    - JACIE pays directly
  - *Per diem* allowance €80 / day

# Timeline

# Timeline



Application

JACIE

Pre-audit

Agreement  
Signed

documentation  
Submission

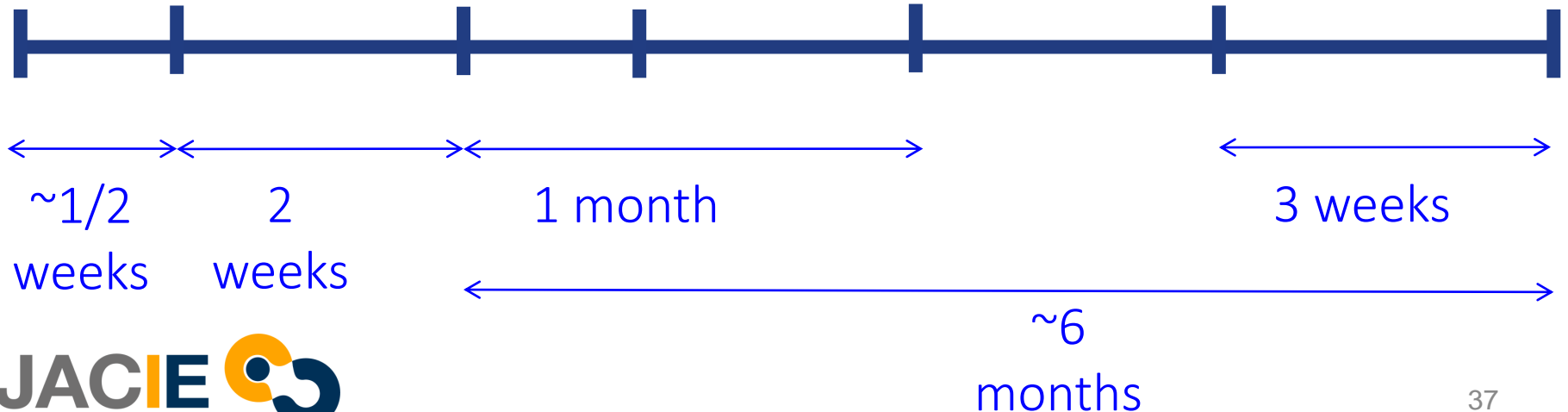
Quotation Approval  
JACIE

Agreement

Invitation

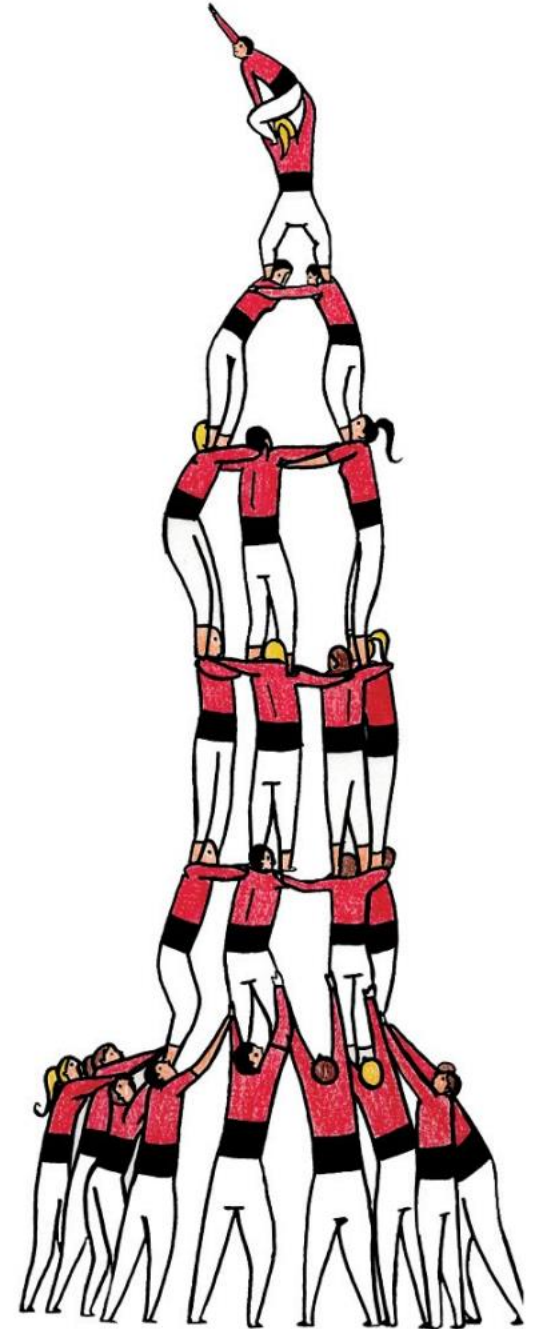
Teleconference

Inspection



# Summary

- Multiphases process, Team Work
  - Team Work
- Preparation by the centre,
  - Time
  - Quality
- Preparation by the Inspection Team
  - Coordination
  - Communication



- Thank you for listening
- Any questions?

