



# THE JACIE ACCREDITATION PROCESS

JACIE Office,  
Barcelona, Spain

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  - Inspection Team
  - Preparation
  - Travel and Hotel





# Phases



# Process

Decision to work according to the Standards



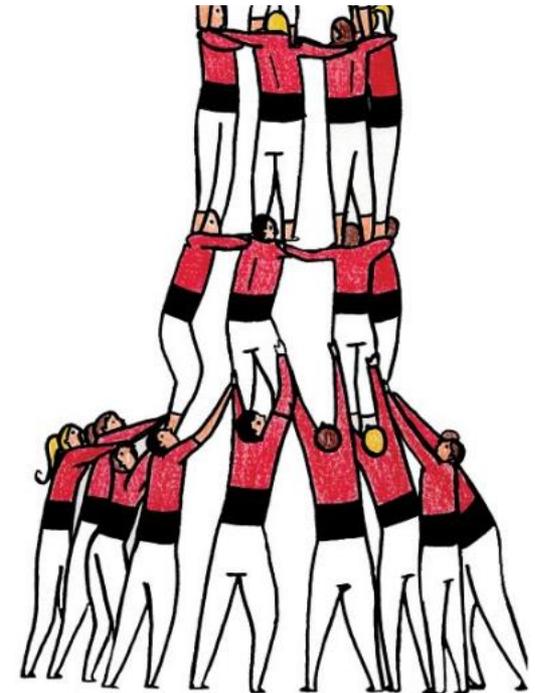
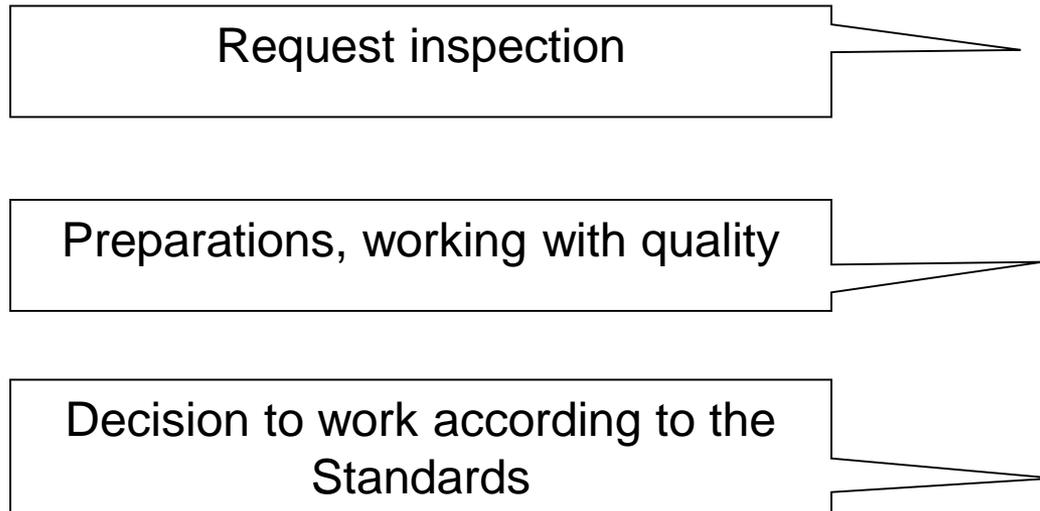
# Process

Preparations, working with quality

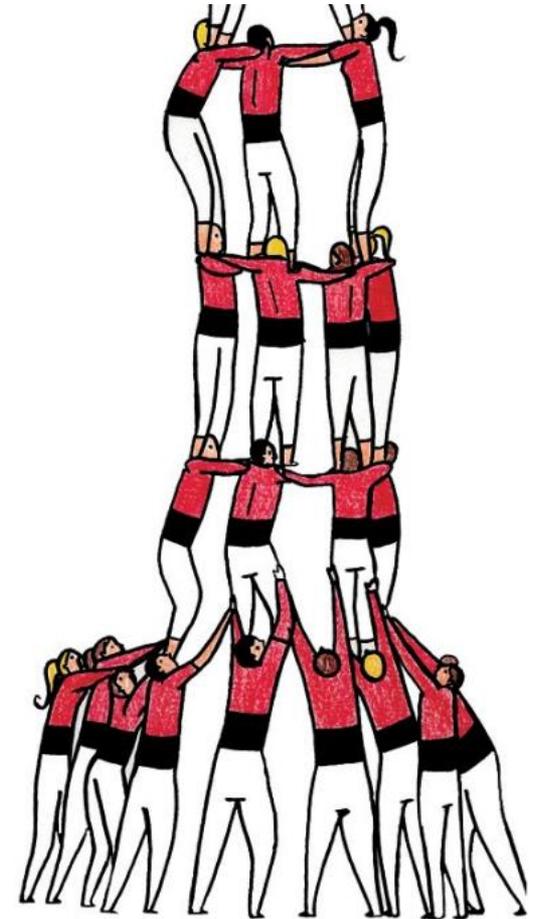
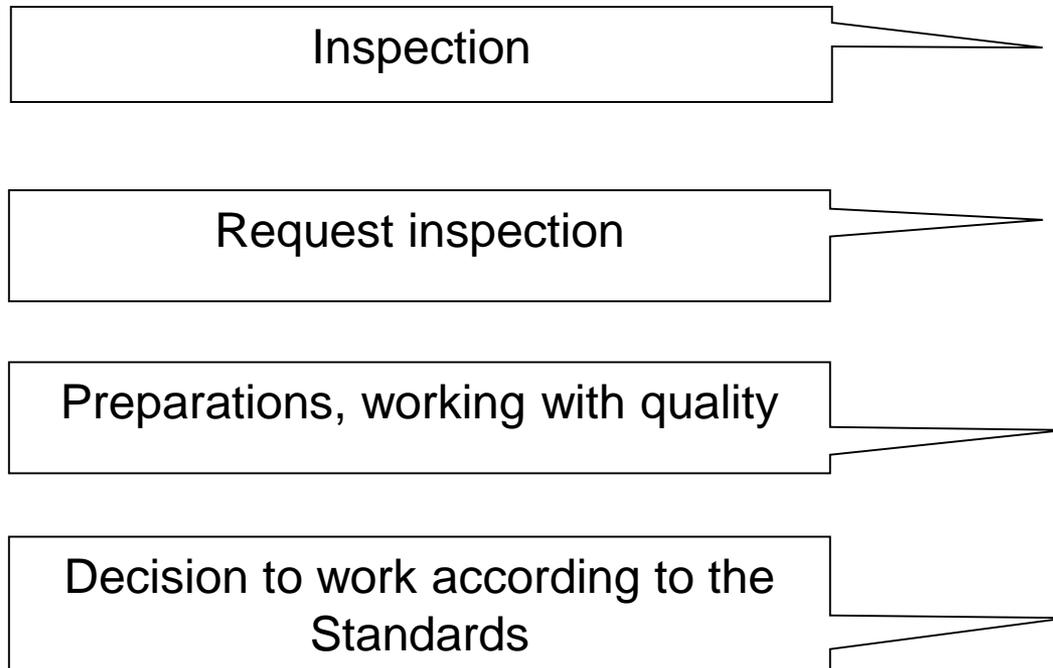
Decision to work according to the Standards



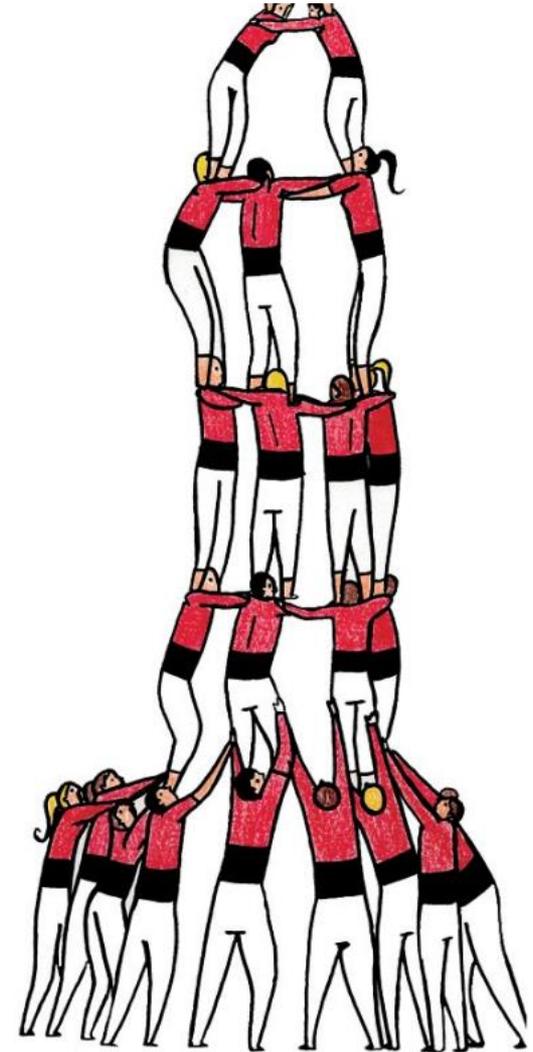
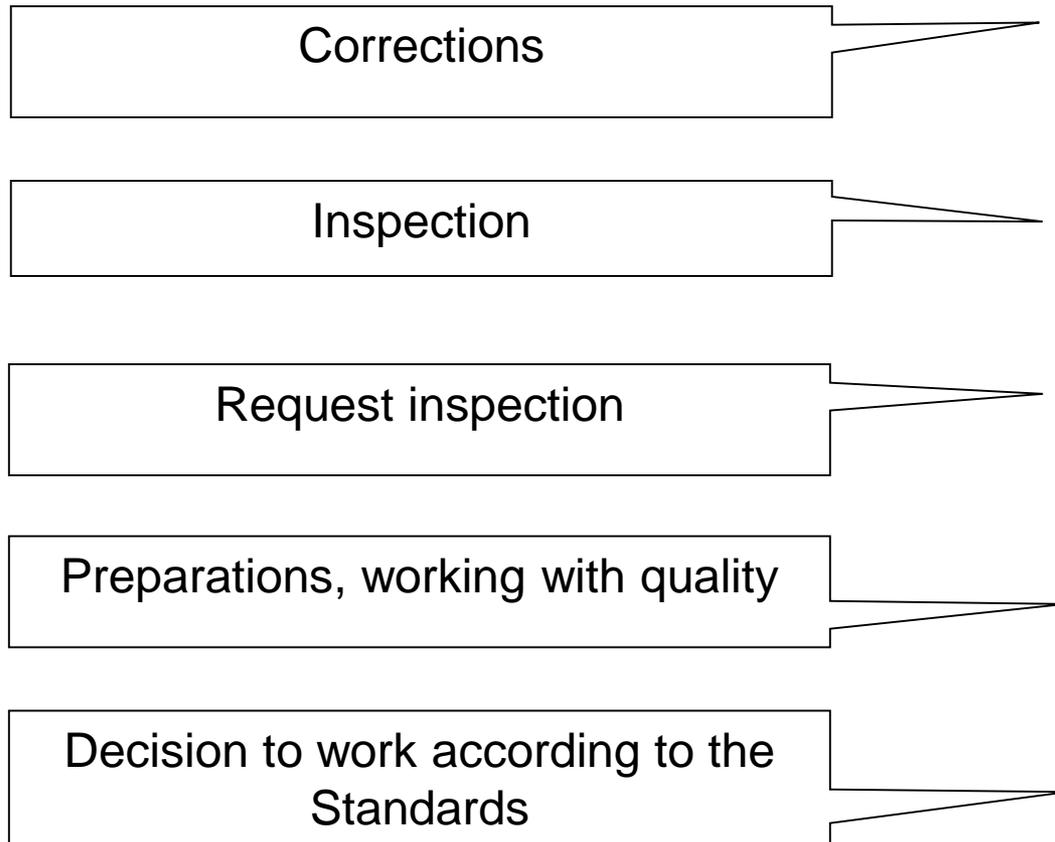
# Process



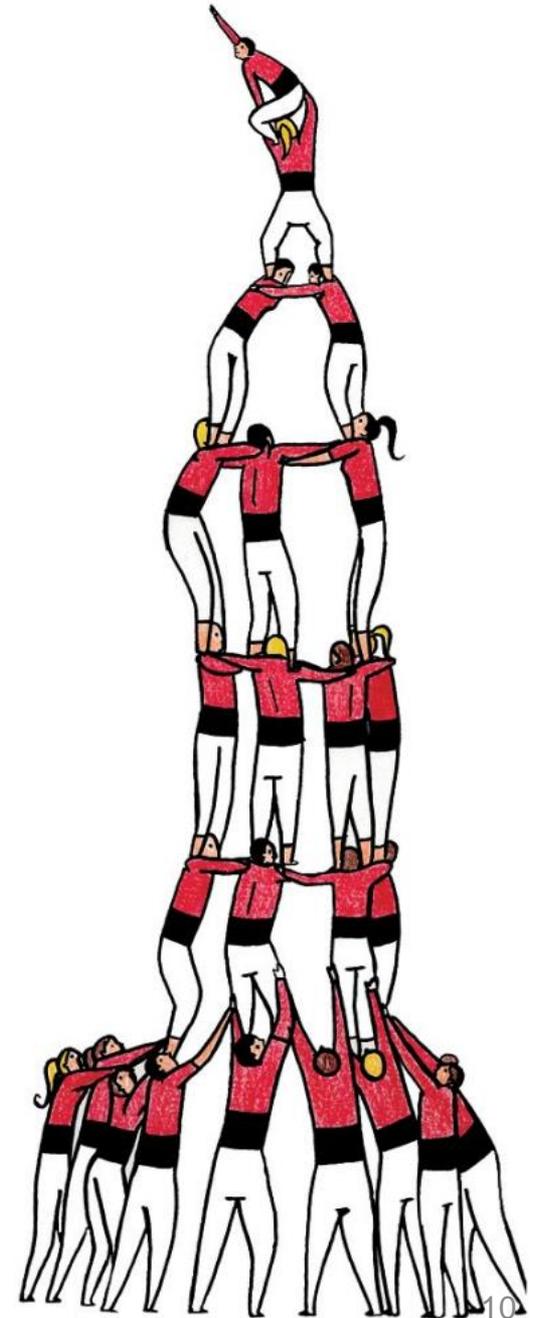
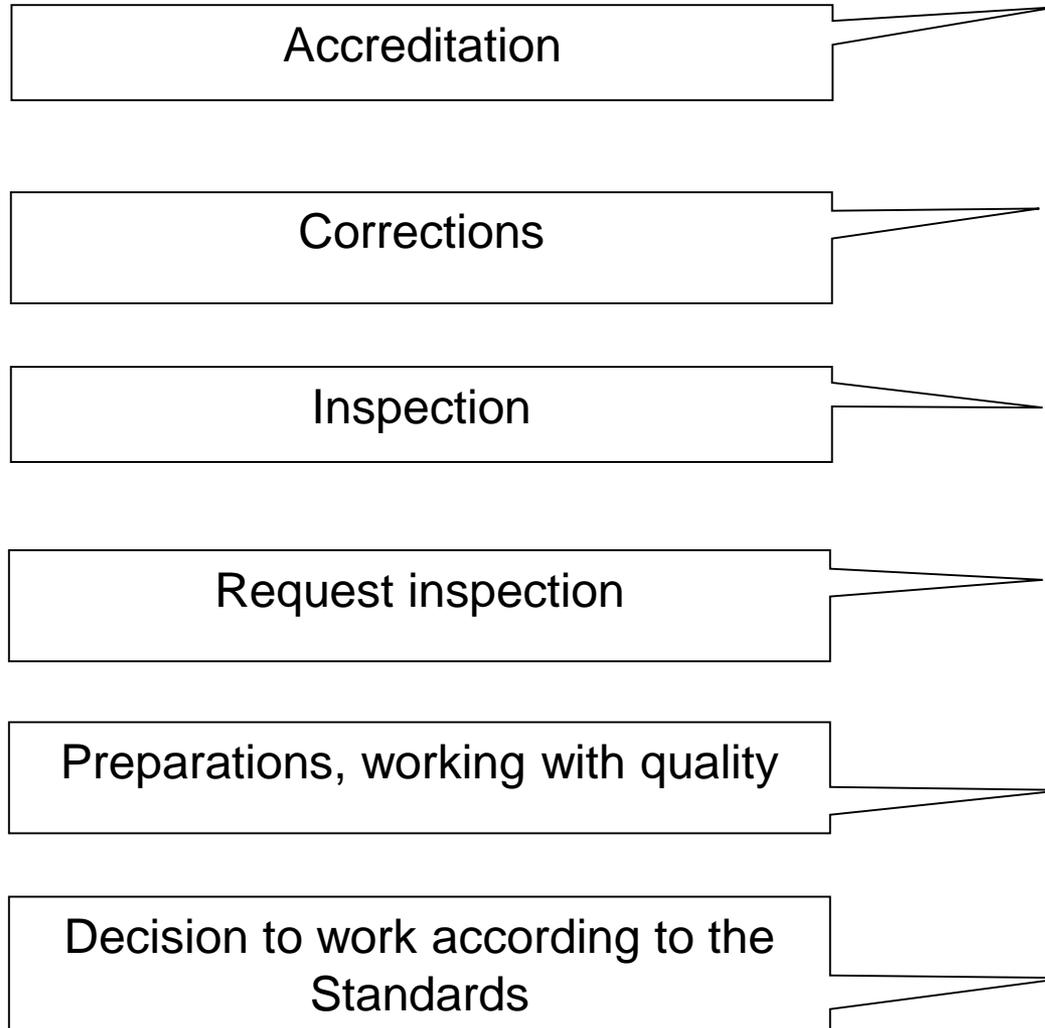
# Process



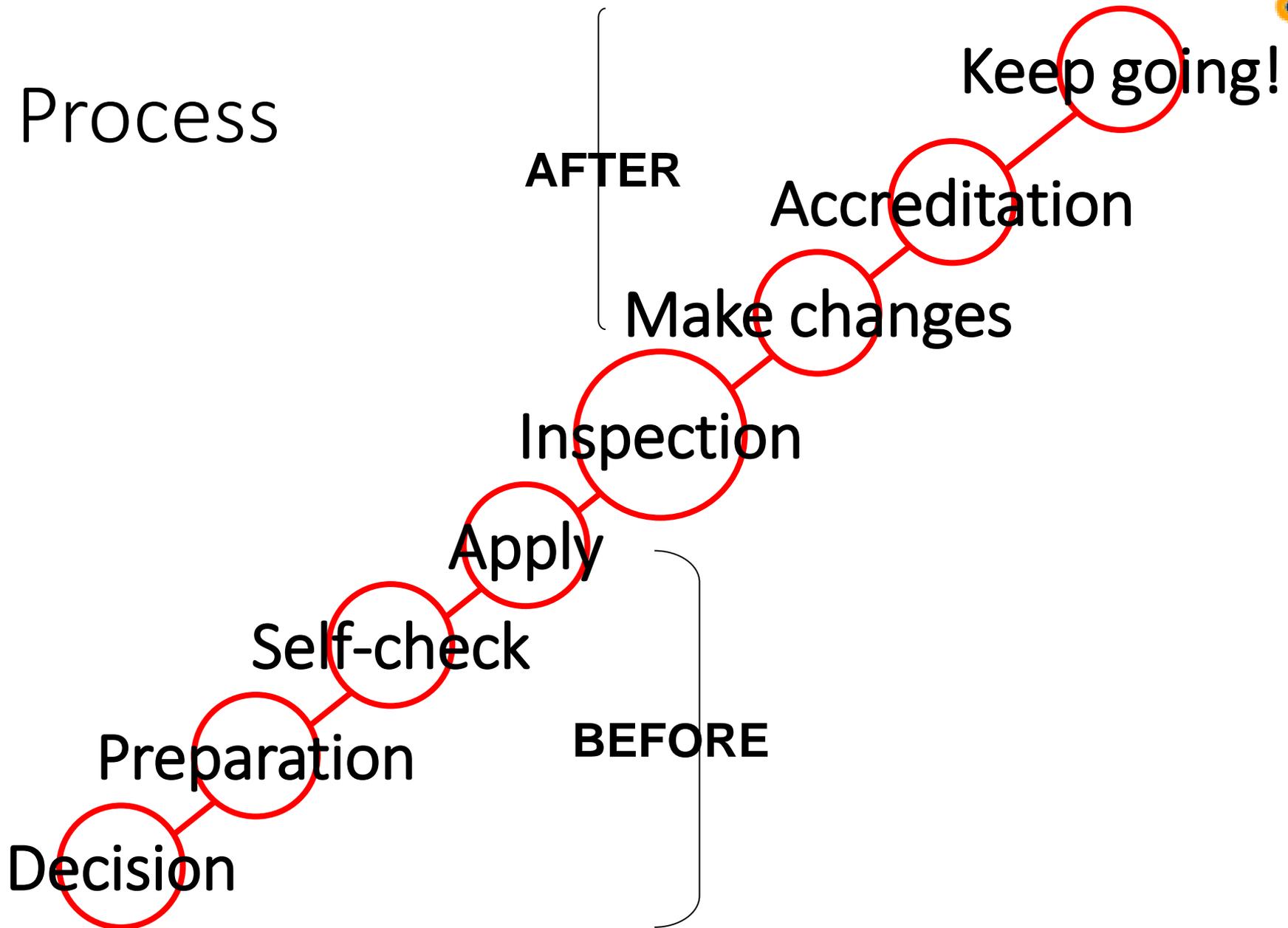
# Process



# Process



# Process





# Preparation by the Centre

# Preparation by the centre



**QM Group**



**QM, SOPs**



**Indicators**



**Audits**



**Training**



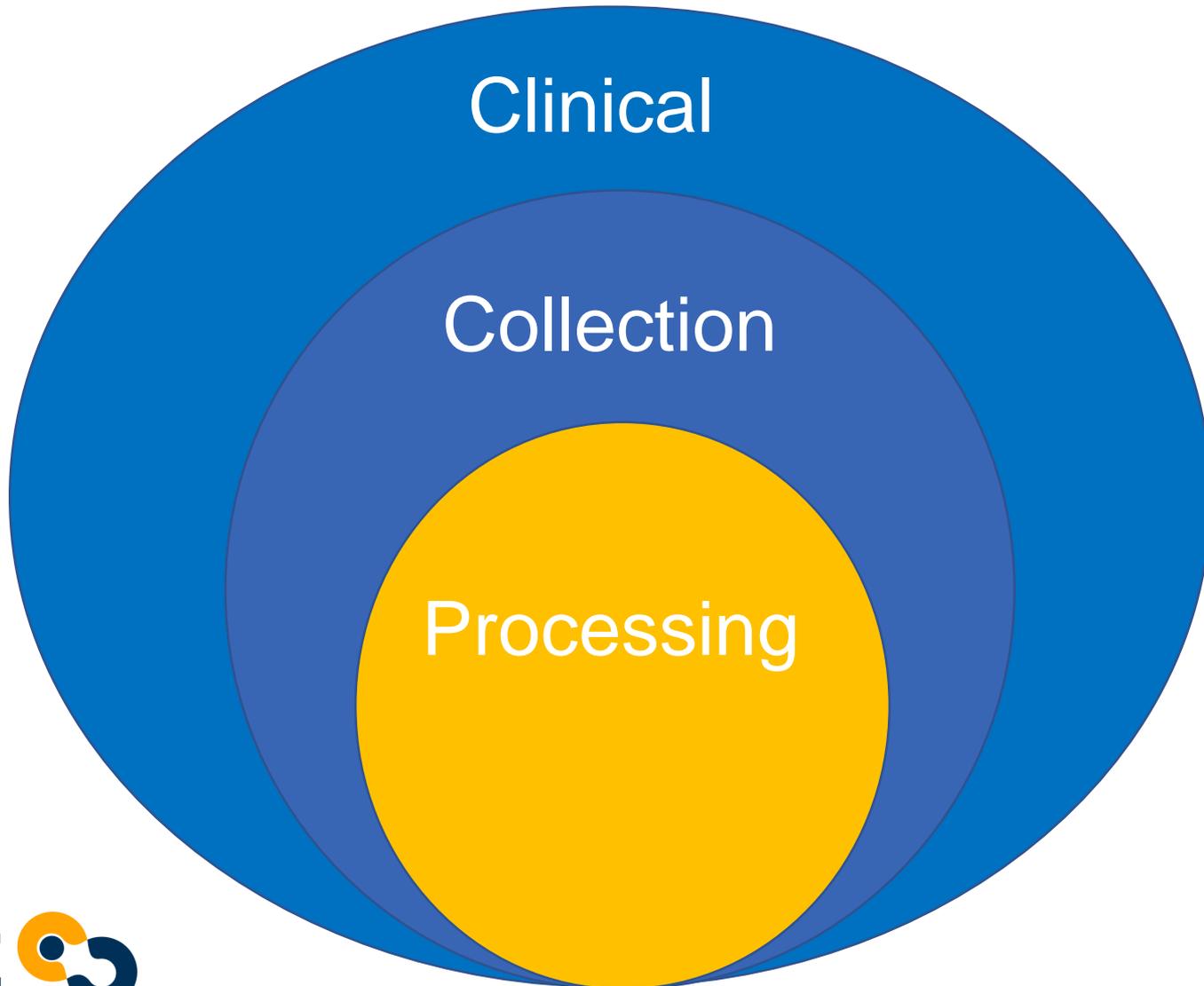
Remember to provide  
evidence



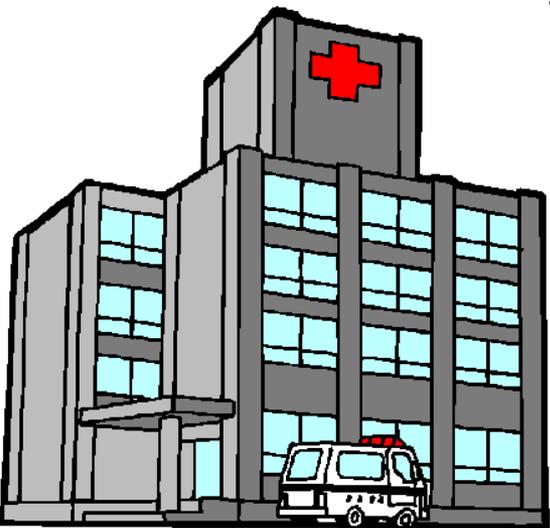
# Application



# Accreditation







Part B: Clinical						
Ref.	Standard	Applicant's Assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (Insert your answers in yellow otherwise delete)	
031.01	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	
031.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director's housed in a defined location.	Compliant	No evidence			
031.01.01	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			
031.02	The Clinical Program shall use the collection and reporting facilities that meet FACT-JACIE Standards as required in their interactions with the Clinical Program.	Compliant	No evidence			
031.03	The Clinical Program shall abide by all applicable laws and regulations.	Compliant	No evidence			
031.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authority for the activities.	Compliant	No evidence			
031.04	The Clinical Program shall have a designated transplant team. The designated transplant team shall include a Clinical Program Director, a Quality Manager, and a representative of an additional referring transplant physician.	Compliant	No evidence			





# Inspection Checklist

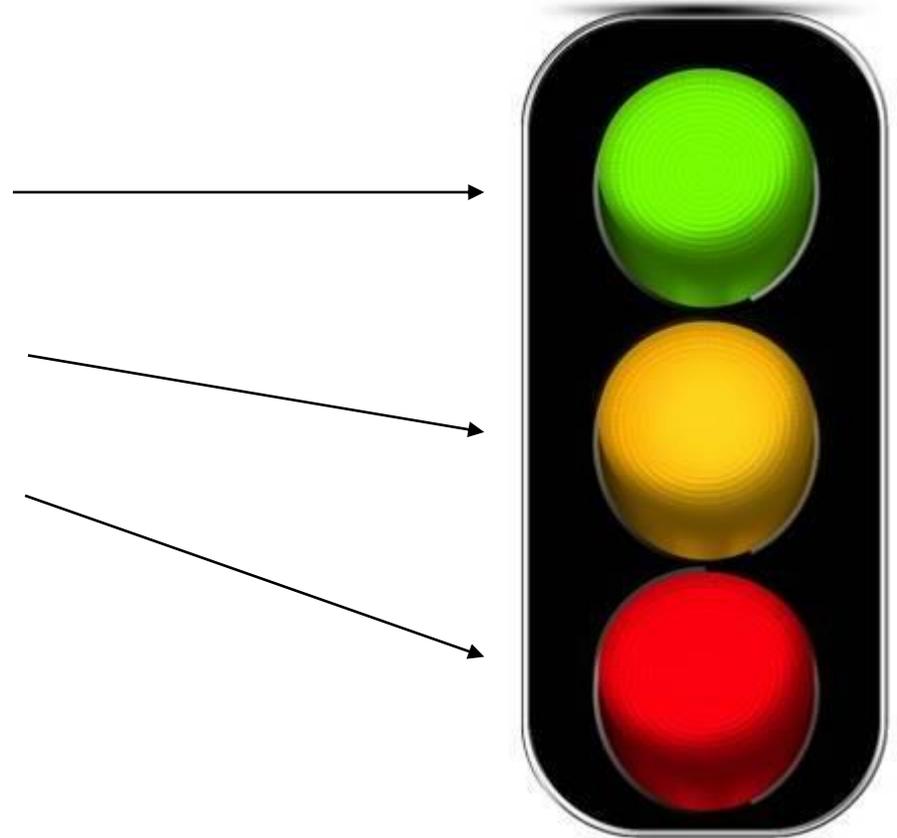
## Part B: Clinical

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

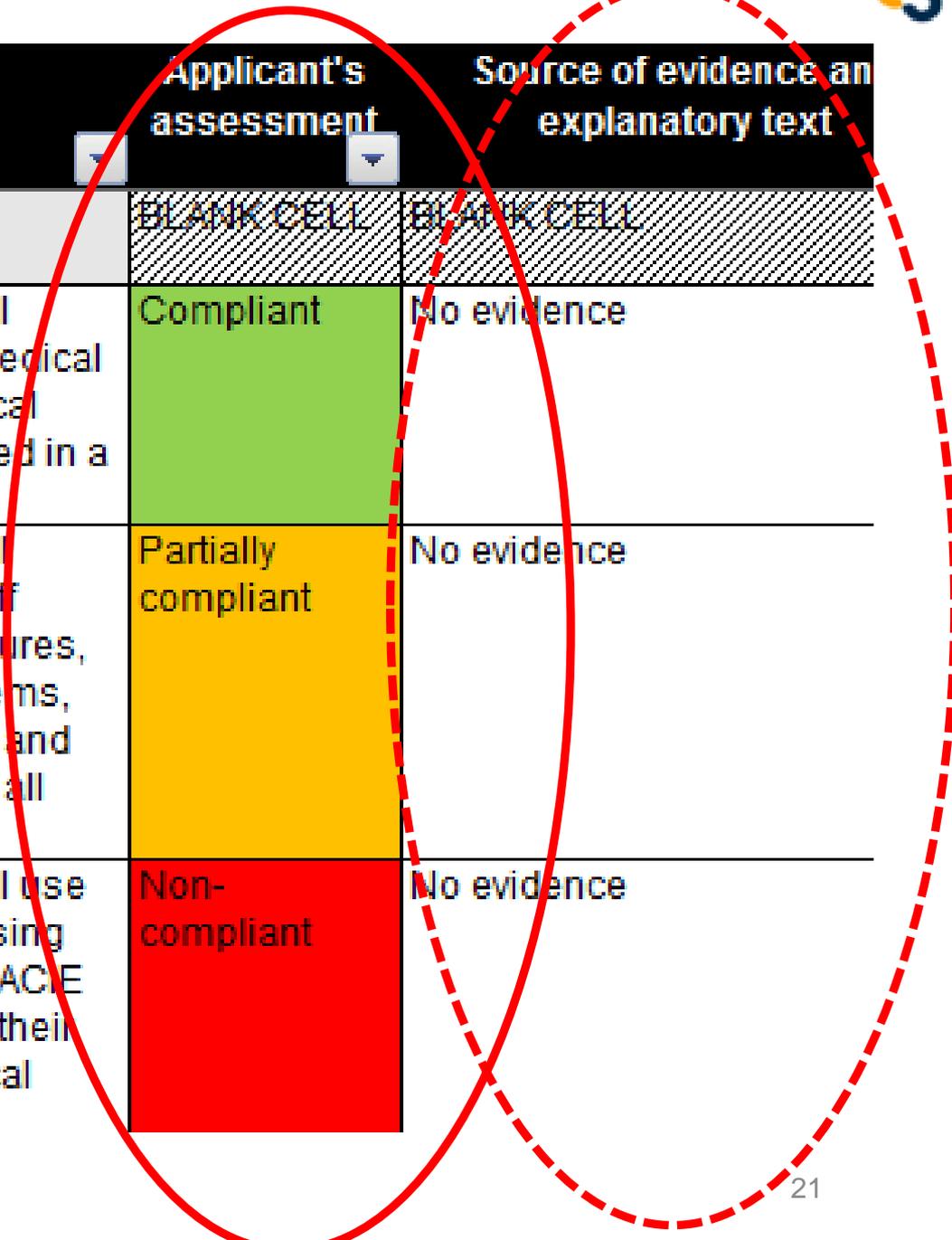
5.01.07	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team	Compliant	No evidence		
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Navigation bar: Snapshot | Dashboard | **Part B Clinical** | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Bone Marrow



Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text
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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



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# 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....



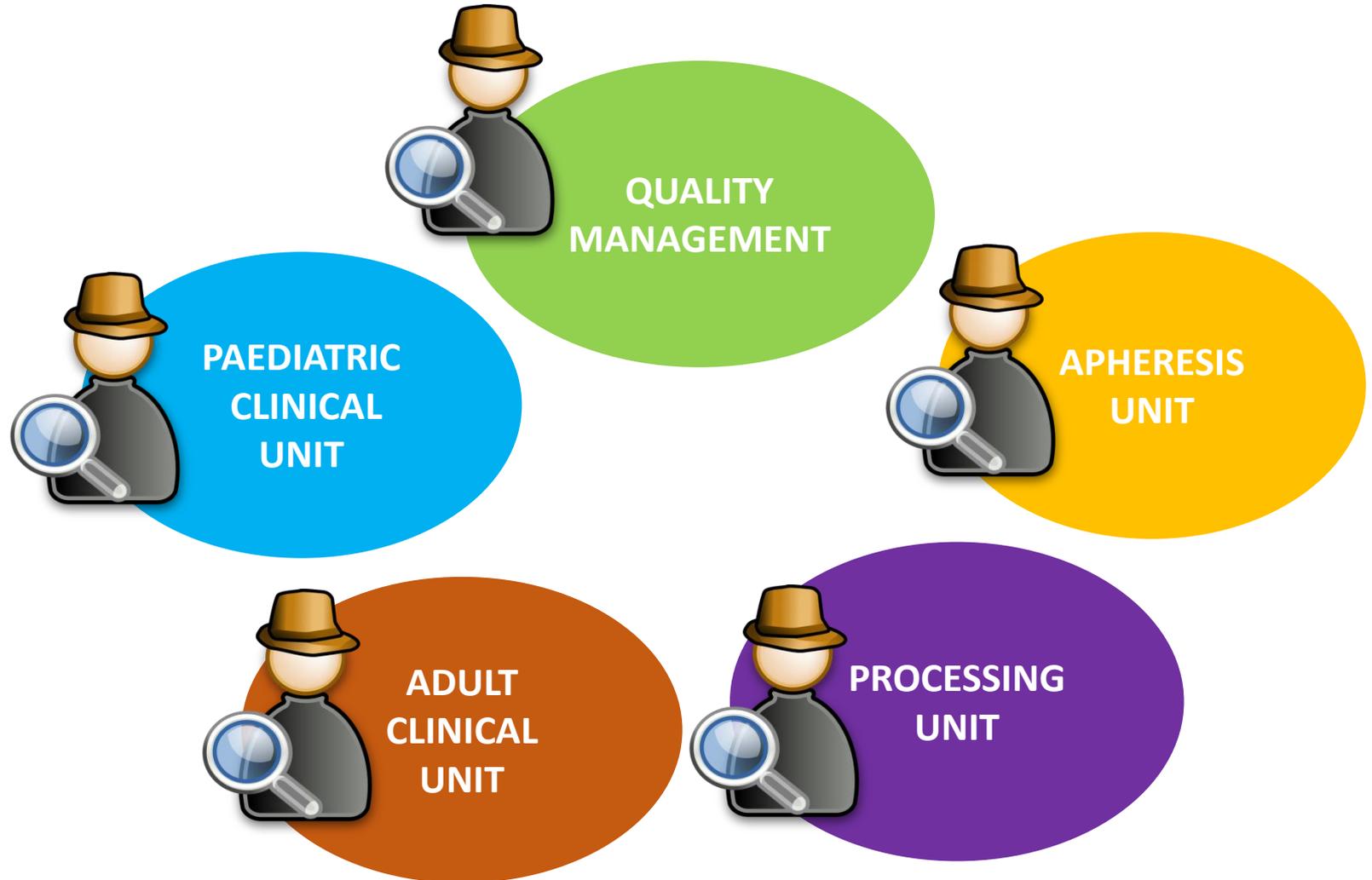
Documentation in the  
language of the Centre



# 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



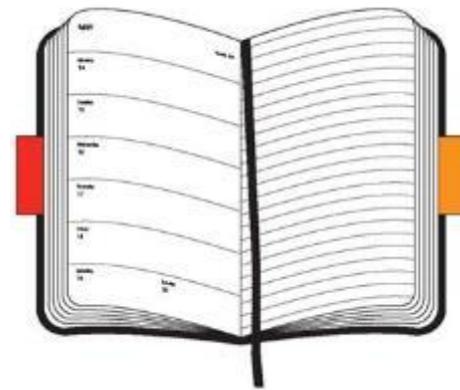
# Team Leader

- 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

Inspector: All items completed?

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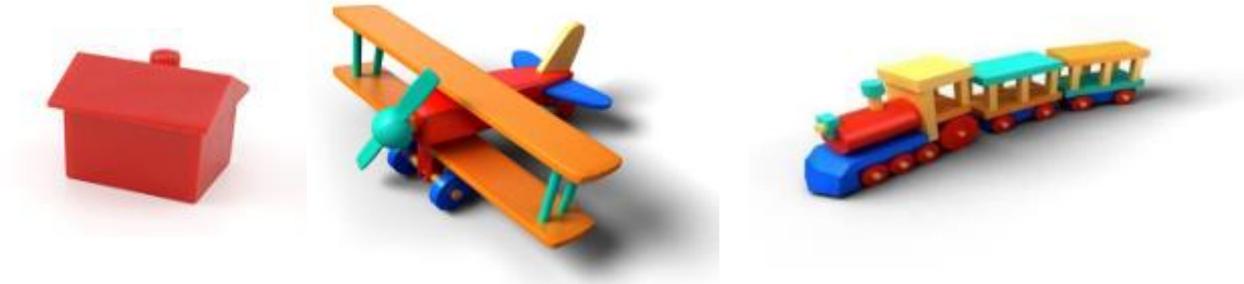




# Inspection:

## *Travel and Hotel*

# Travel & Hotel



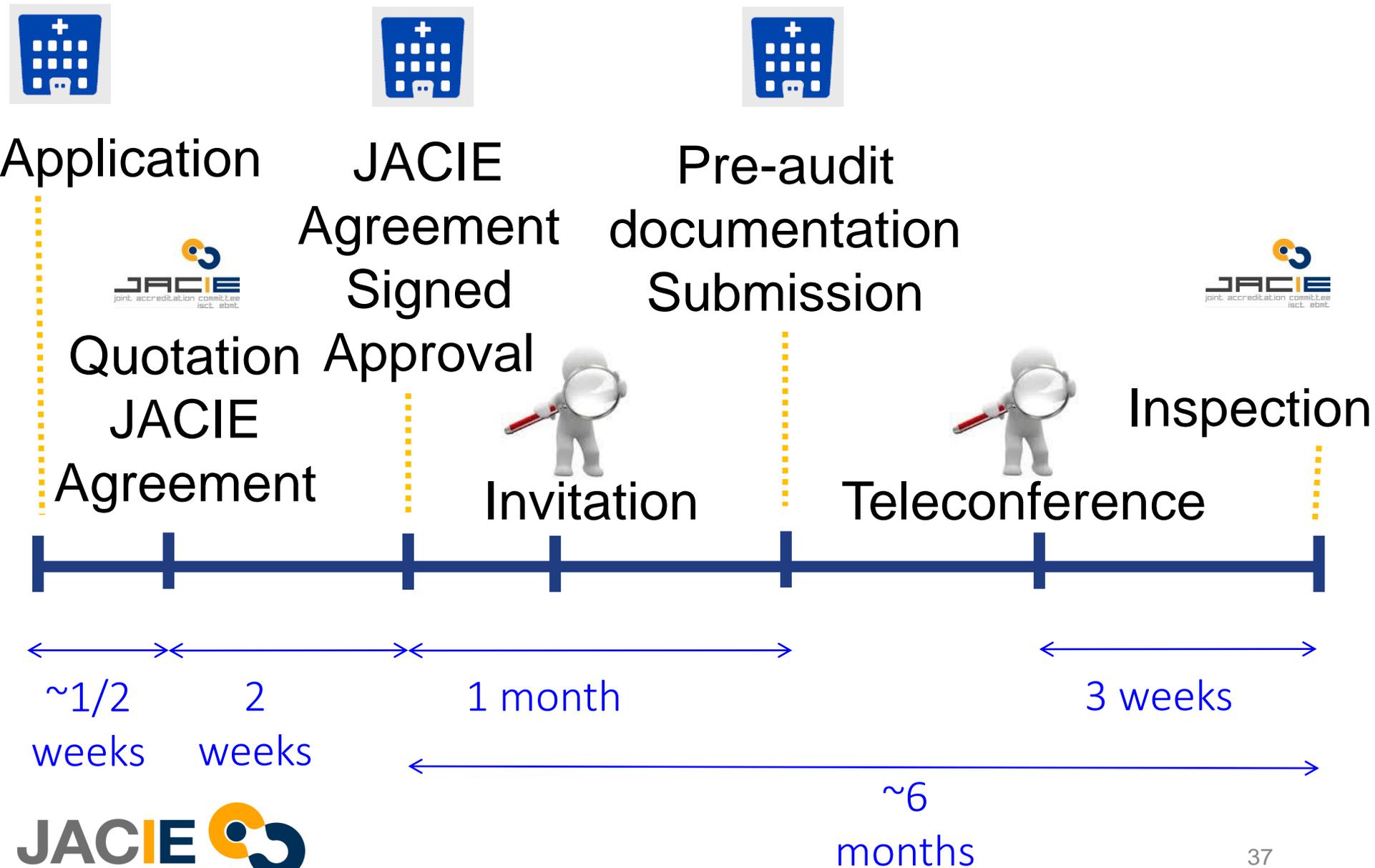
- Inspectors make travel arrangements with JACIE Travel Agency
  - No big payments in advance for the inspector
    - JACIE pays directly
  - *Per diem* allowance €80 / day



# Timeline

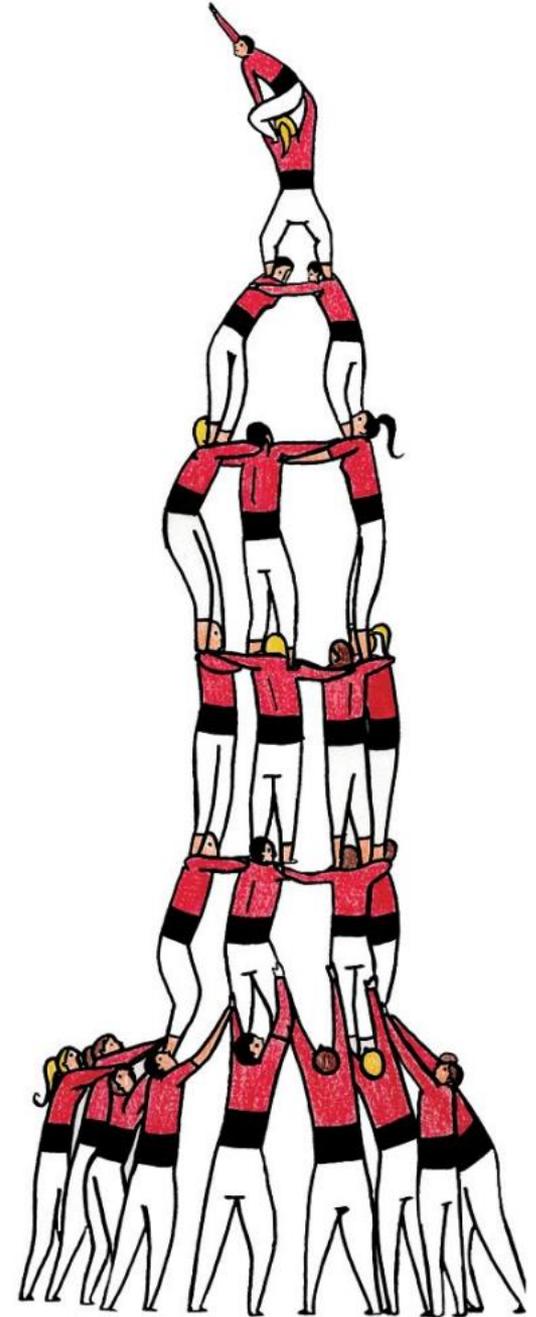


# Timeline



# 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?

