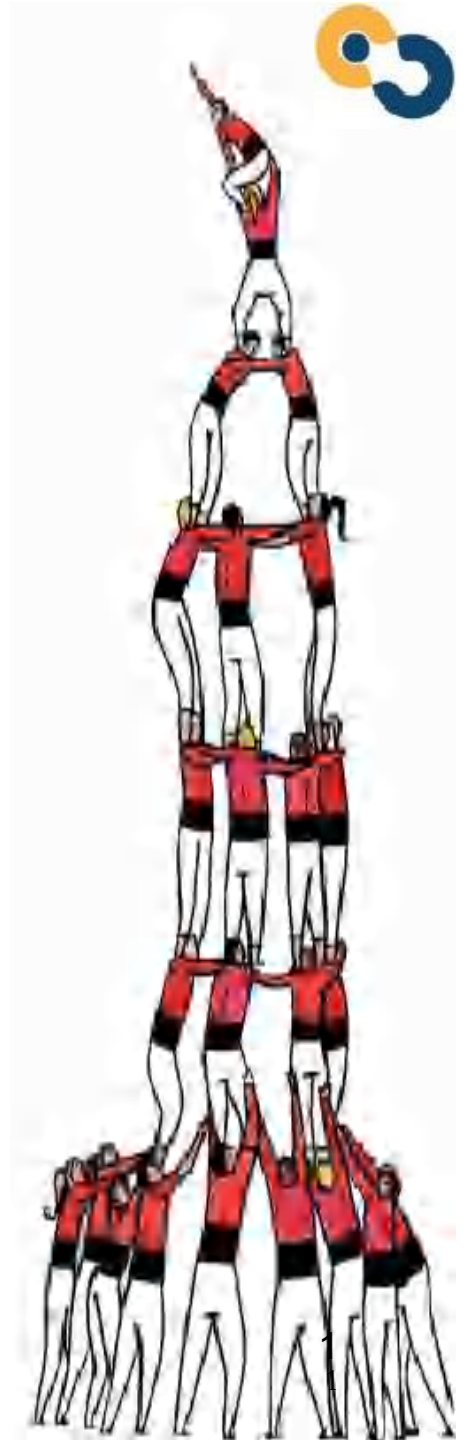


# The JACIE Accreditation Process

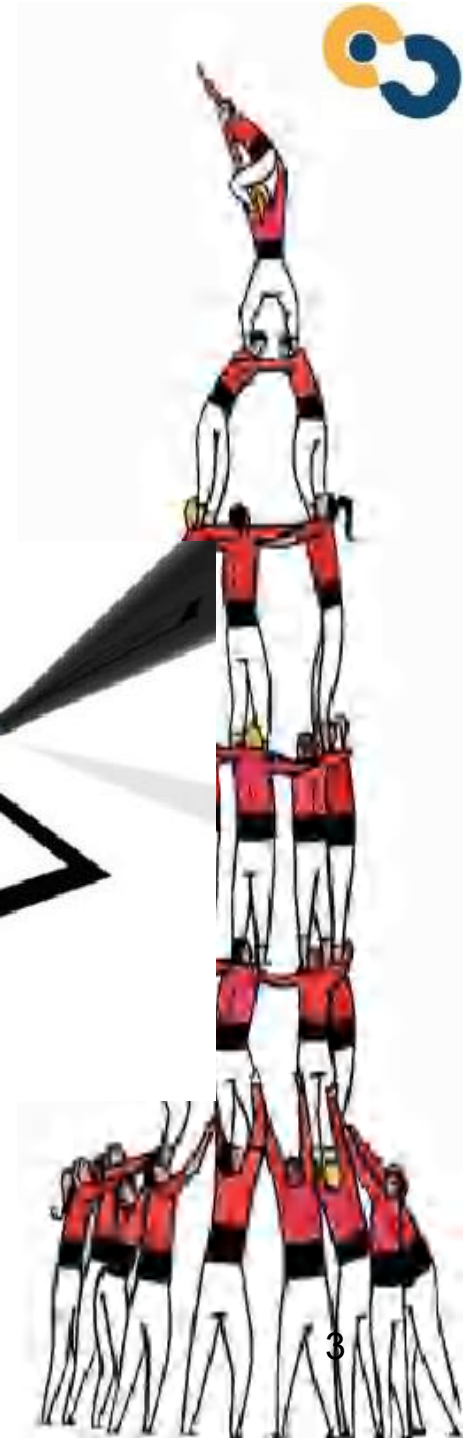
JACIE Office,  
Barcelona, Spain



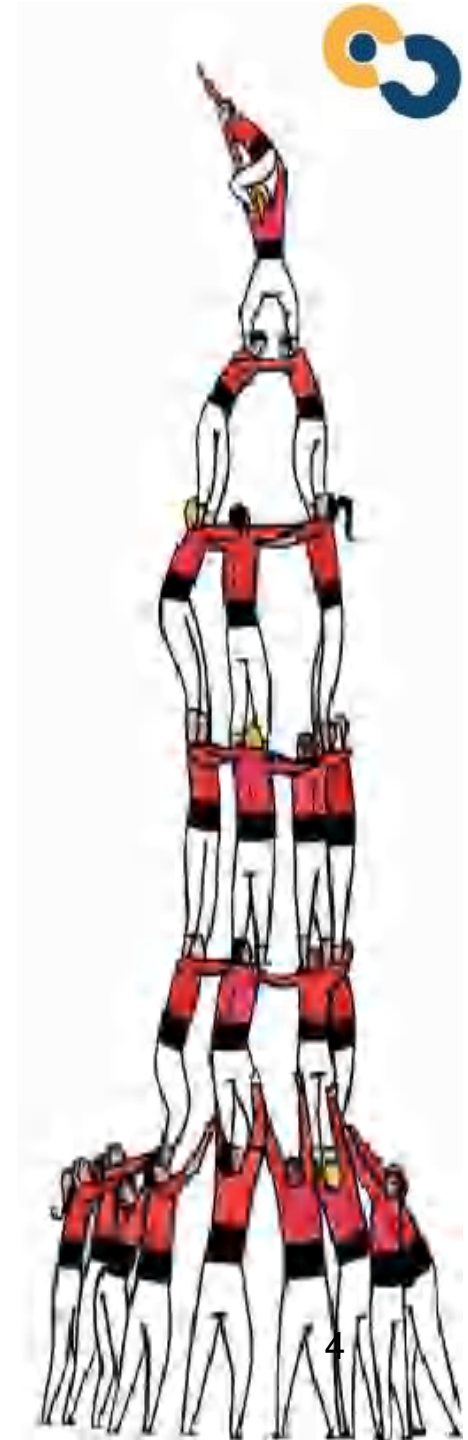


# Contents

- Phases
- Preparation by the centre
- Application
- Inspection Checklist
- Pre-inspection documentation
- Inspection



# Phases



# Process

Decision to work according to the Standards



# Process

Preparations, working with quality

Decision to work according to the  
Standards

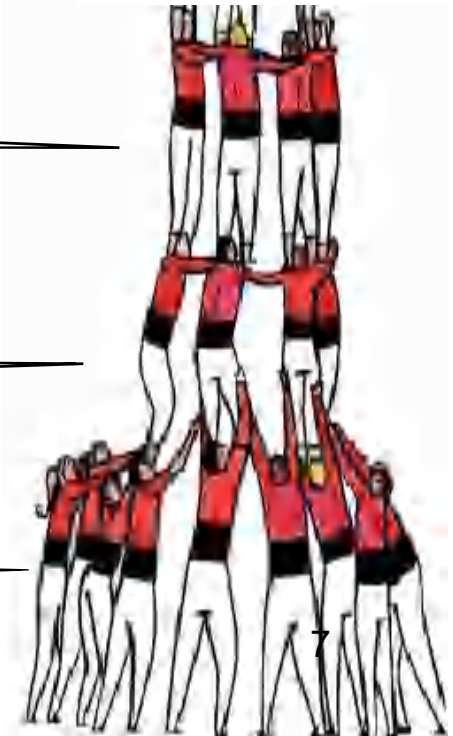


# Process

Request inspection

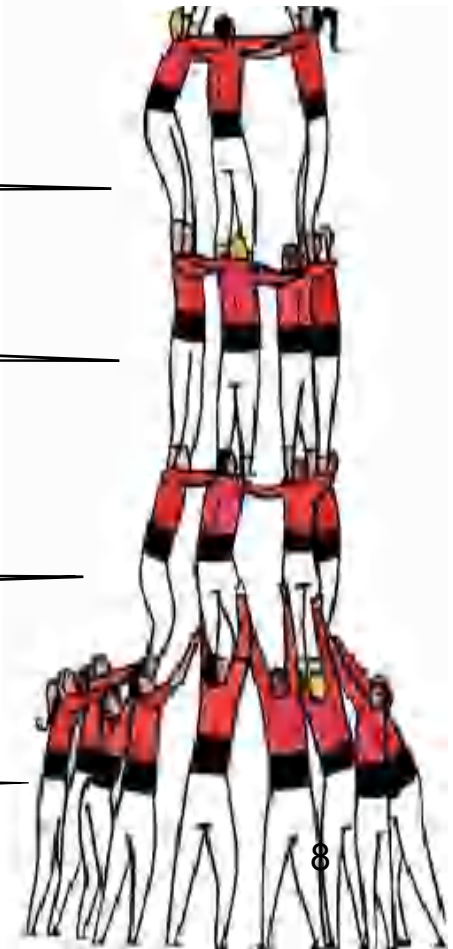
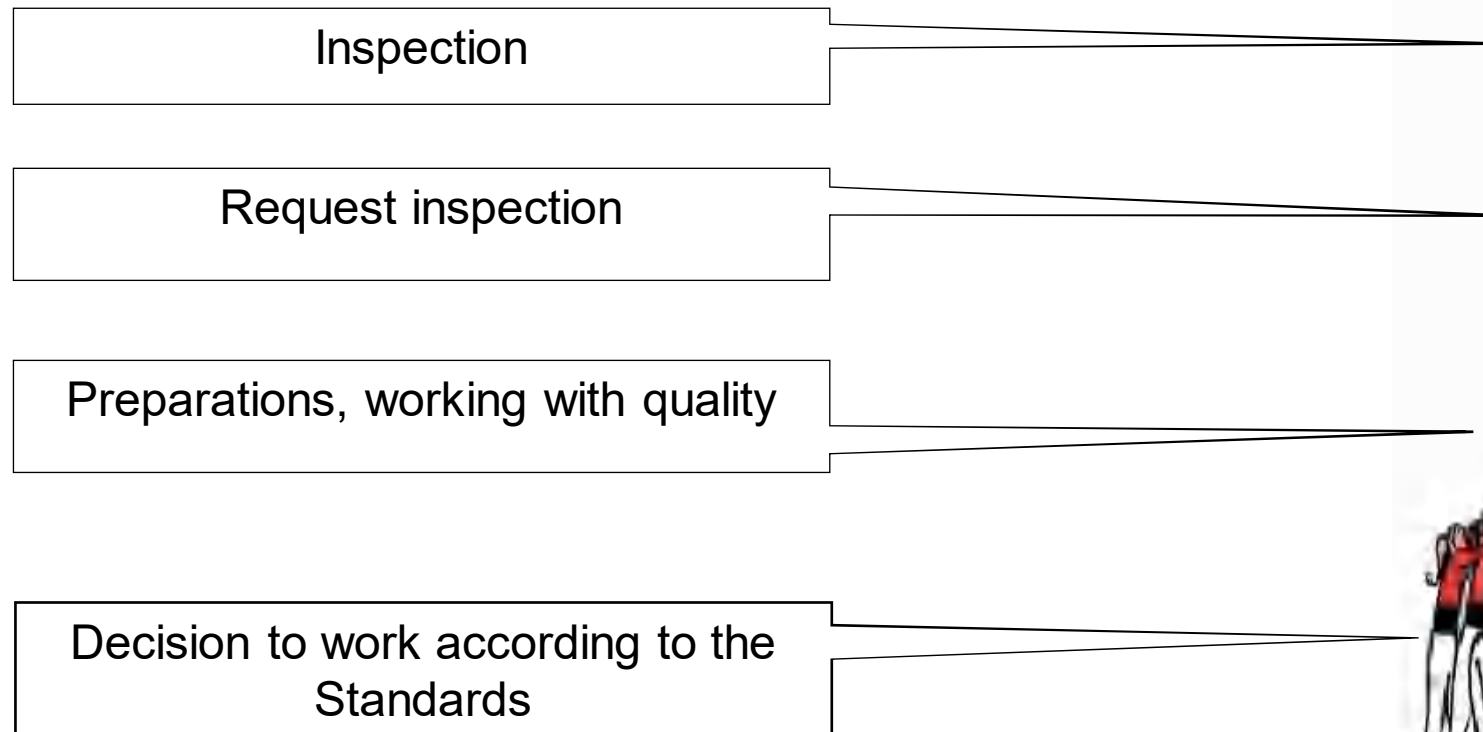
Preparations, working with quality

Decision to work according to the Standards





# Process





# Process

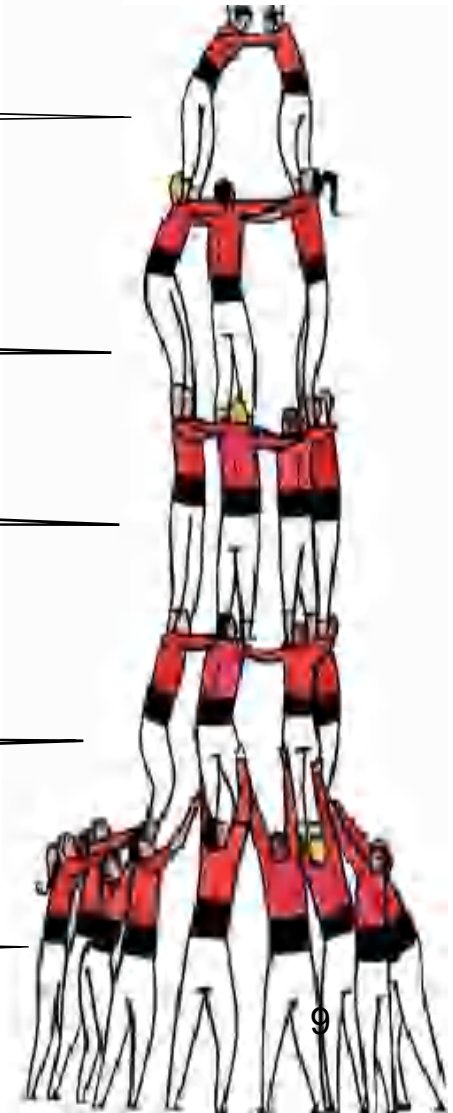
Corrections

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards





Accreditation

ess

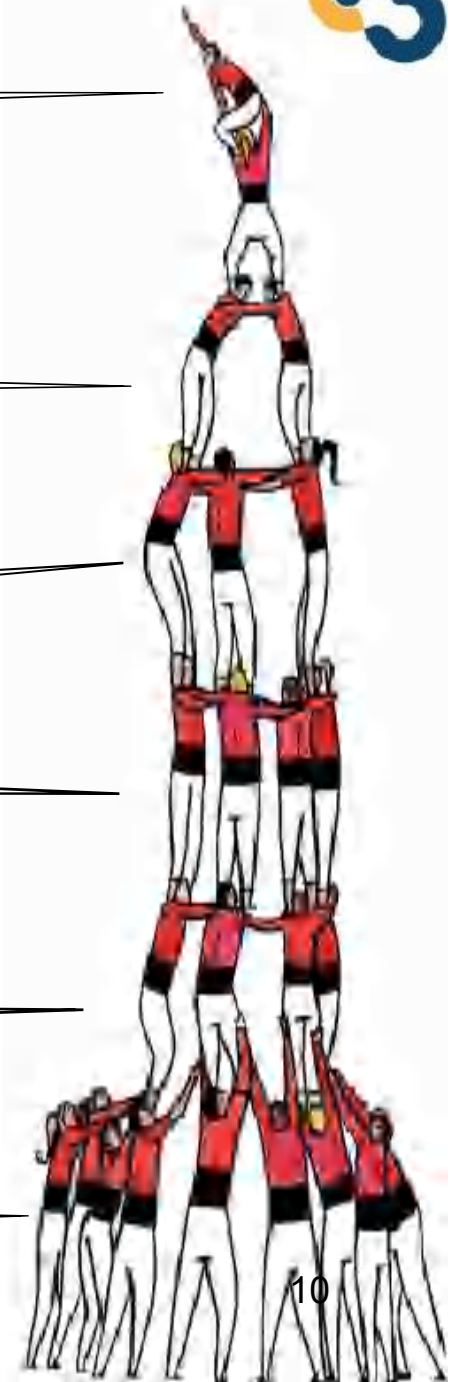
Corrections

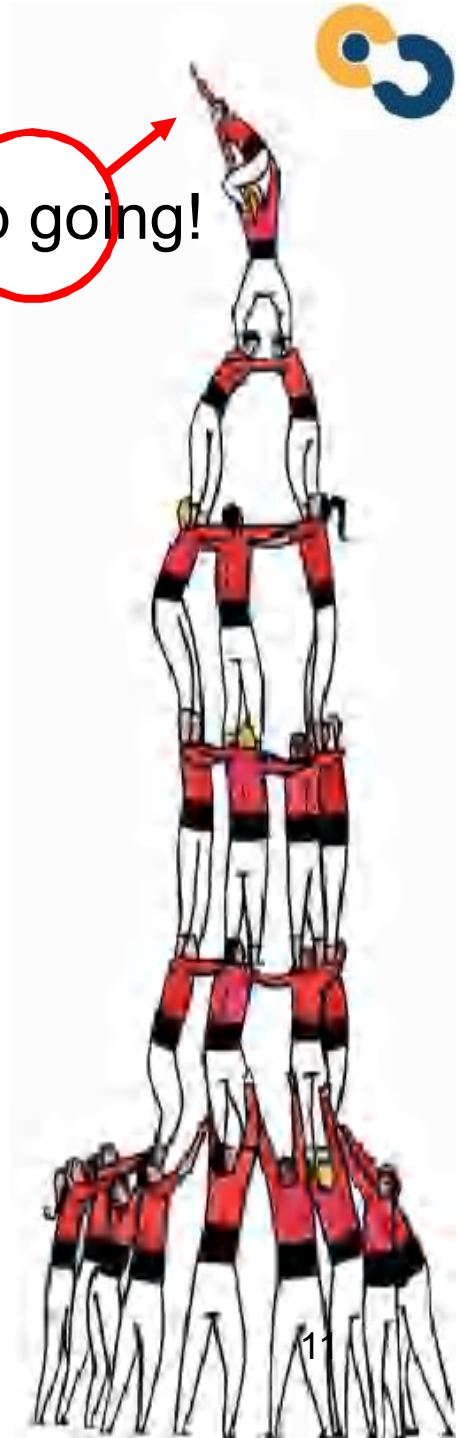
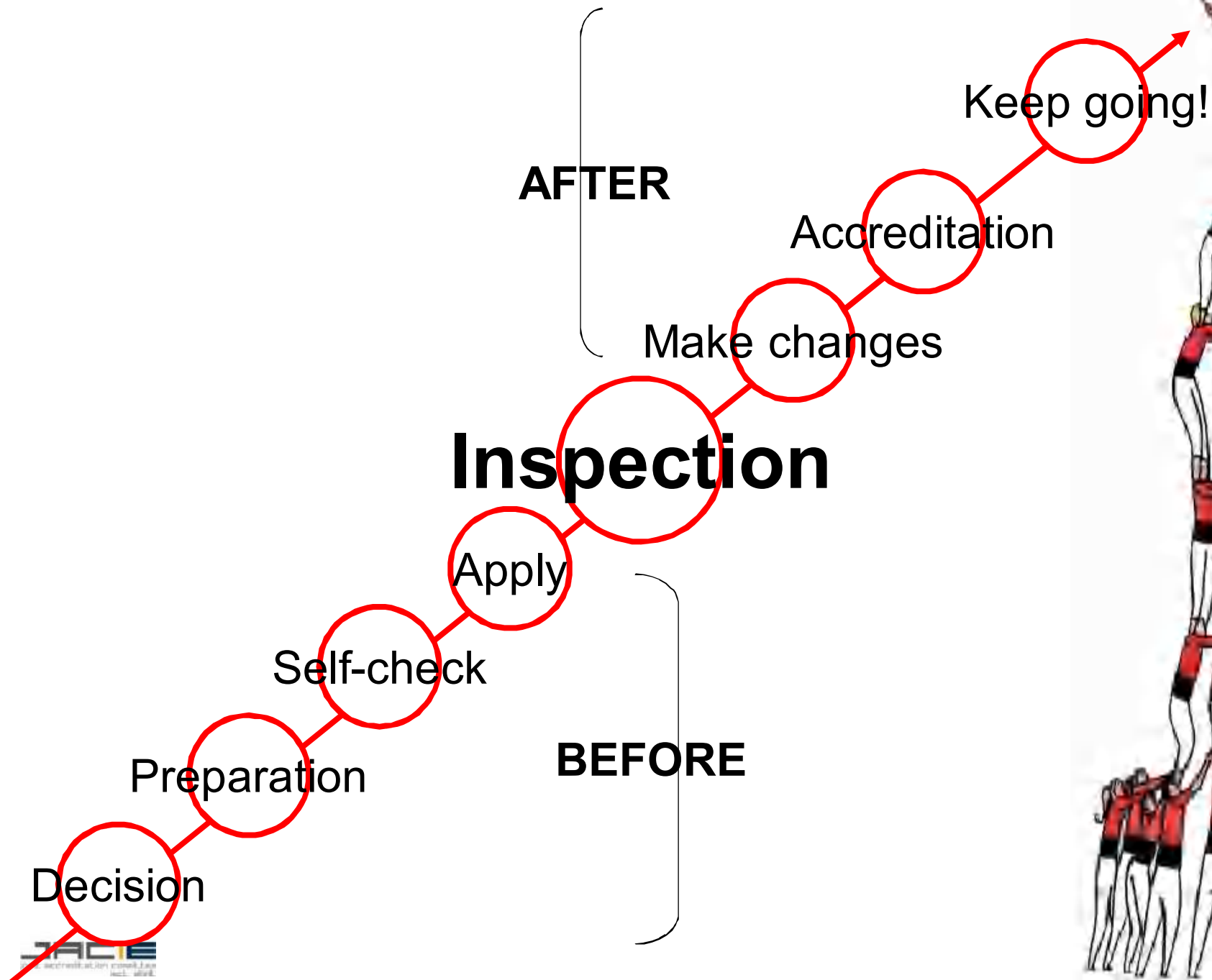
Inspection

Request inspection

Preparations, working with quality

Decision to work according to the  
Standards





# Preparation by the centre



- Create a Quality Management Group

- Write QM, SOPs Instructions



- Establish Indicators



- Perform Audits

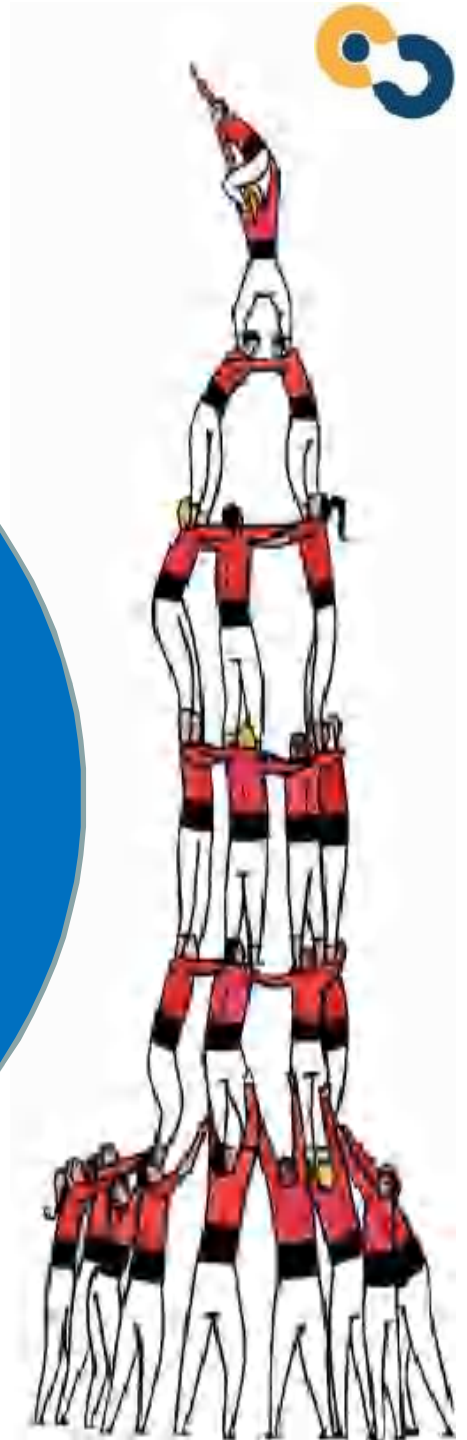
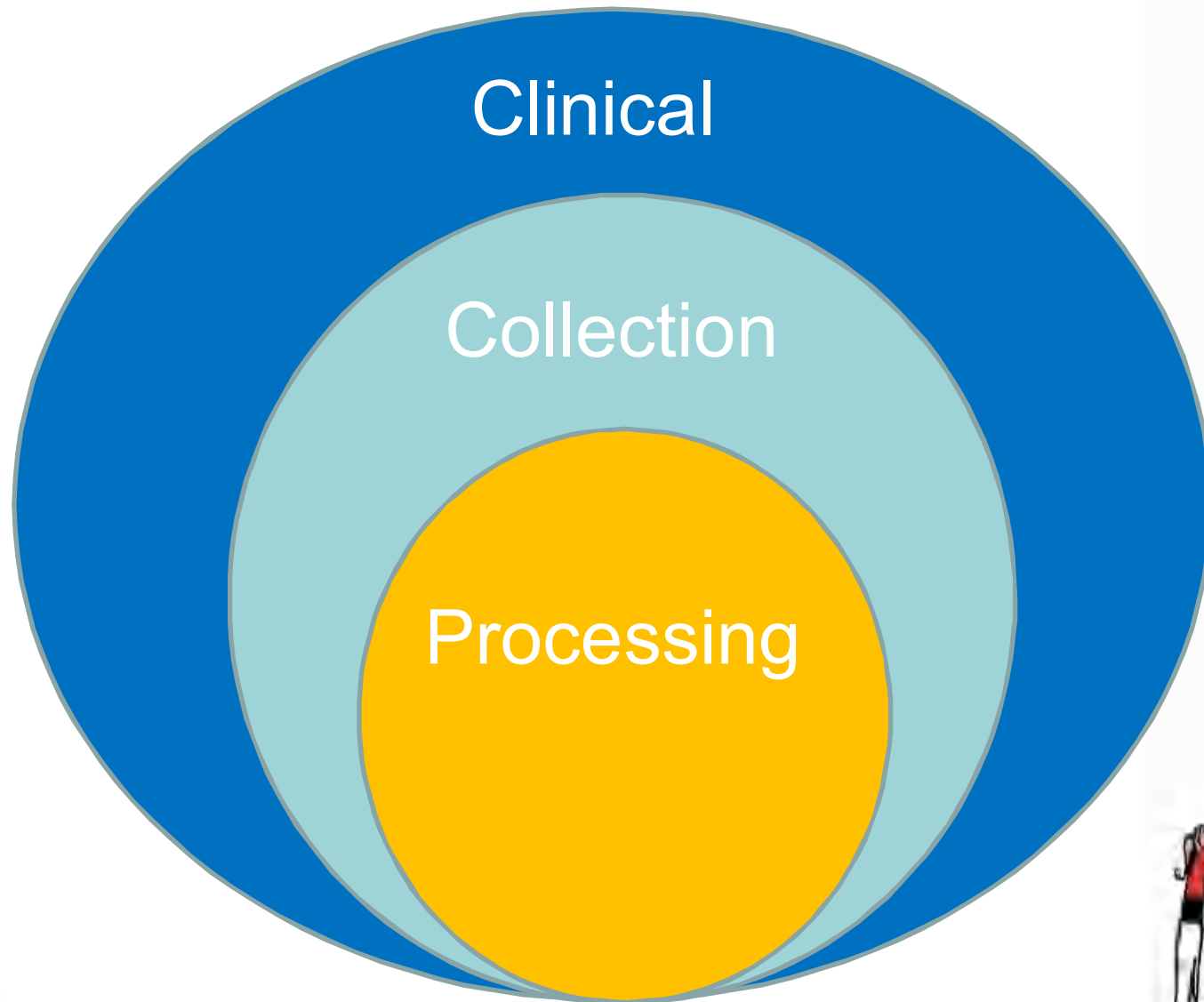


- Document Training



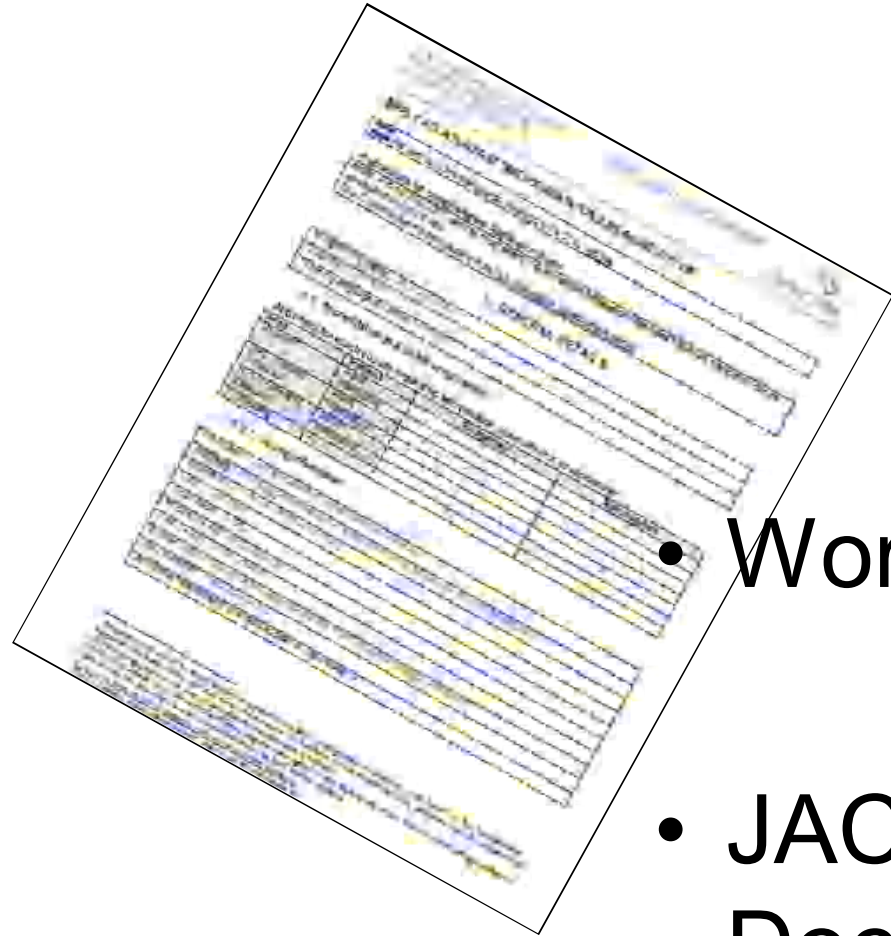
Remember to provide evidence

# Accreditation

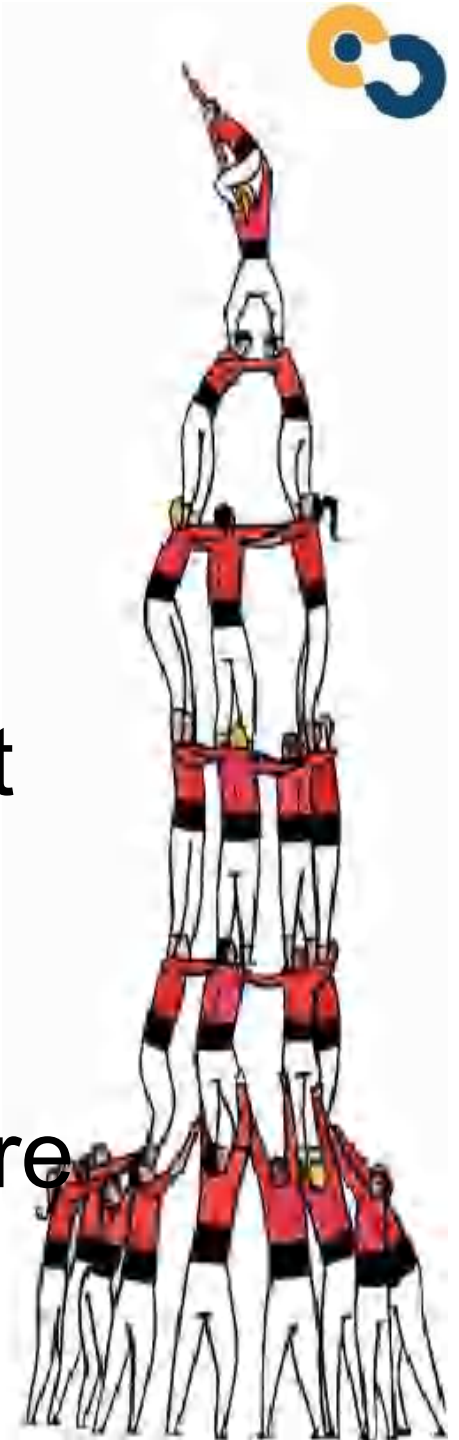


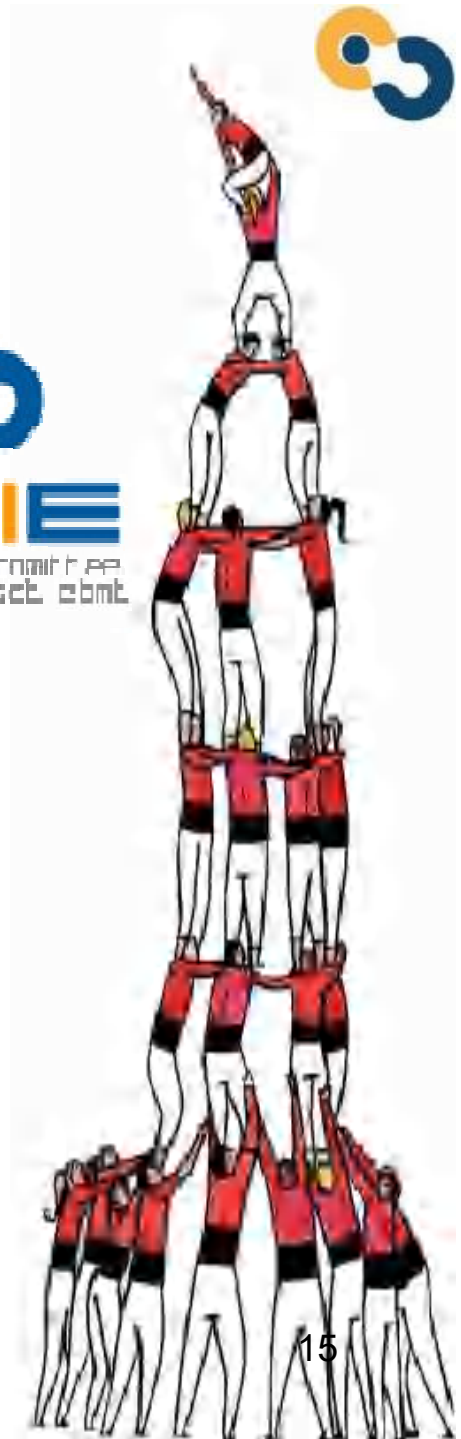
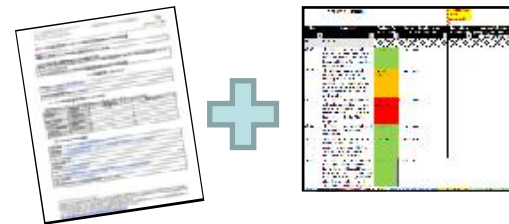


# Application Form



- Word Document
- JACIE Website/  
Document Centre

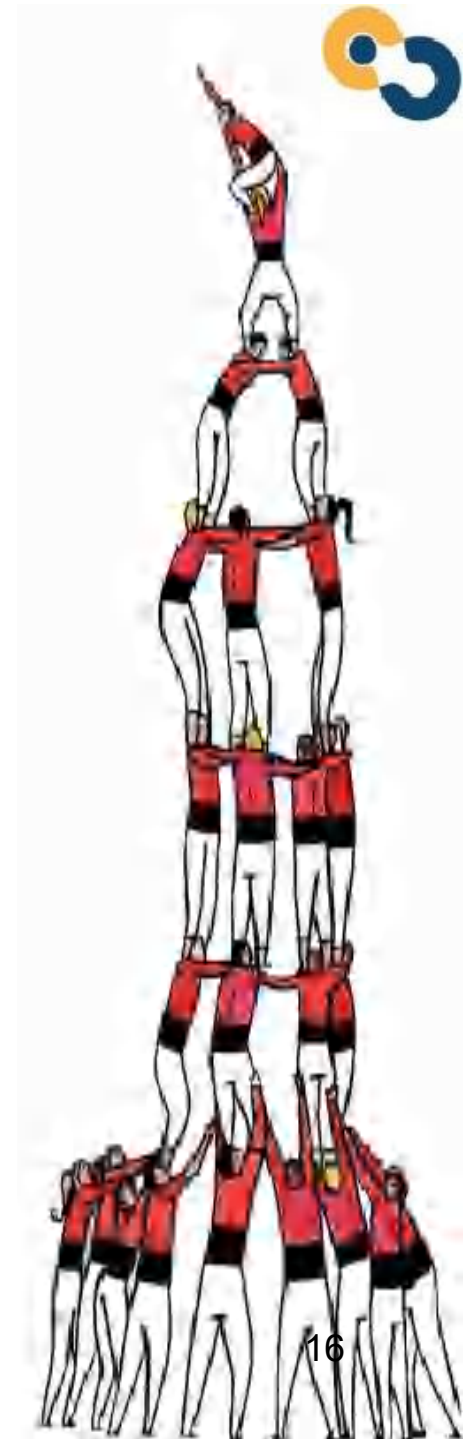






# Inspection Checklist

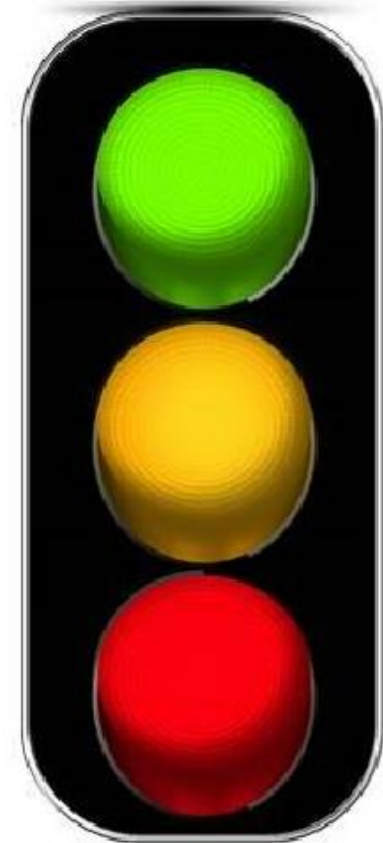
Part B: Clinical					
Item	Criteria	Applicable Exemption	Summative Evidence Link (mandatory for)	Inspection Assessment	Inspection Comments (summary of evidence link criteria and exemption)
1.1	1.1.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.2	1.2.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.3	1.3.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.4	1.4.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.5	1.5.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.6	1.6.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.7	1.7.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.8	1.8.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.9	1.9.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				
1.10	1.10.1 The clinical governance system is in place and is effective in ensuring the quality of care and the safety of patients.				



# Inspection Checklist

- Based on Traffic Light system

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





## Part B: Clinical

Inspector's  
Assessment  
Compliant  
No

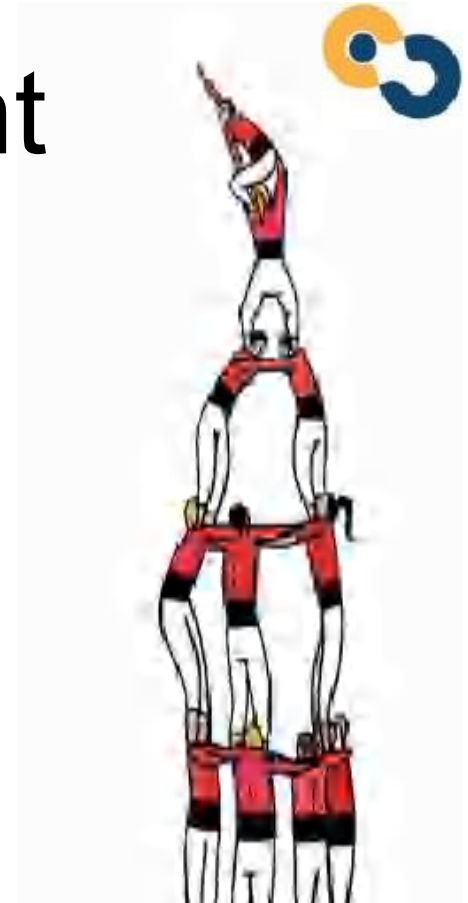
Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (support your answers with additional information)
B-01	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
B-01.01	The Clinical Program shall consist of an integrated medical team 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.	Partial compliance	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-01.02	The Clinical Program shall abide by all applicable laws and regulations.	Compliant	No evidence		
B-01.02.01	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's  
Comments



# Accreditation Agreement

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



# Submit documentation before inspection

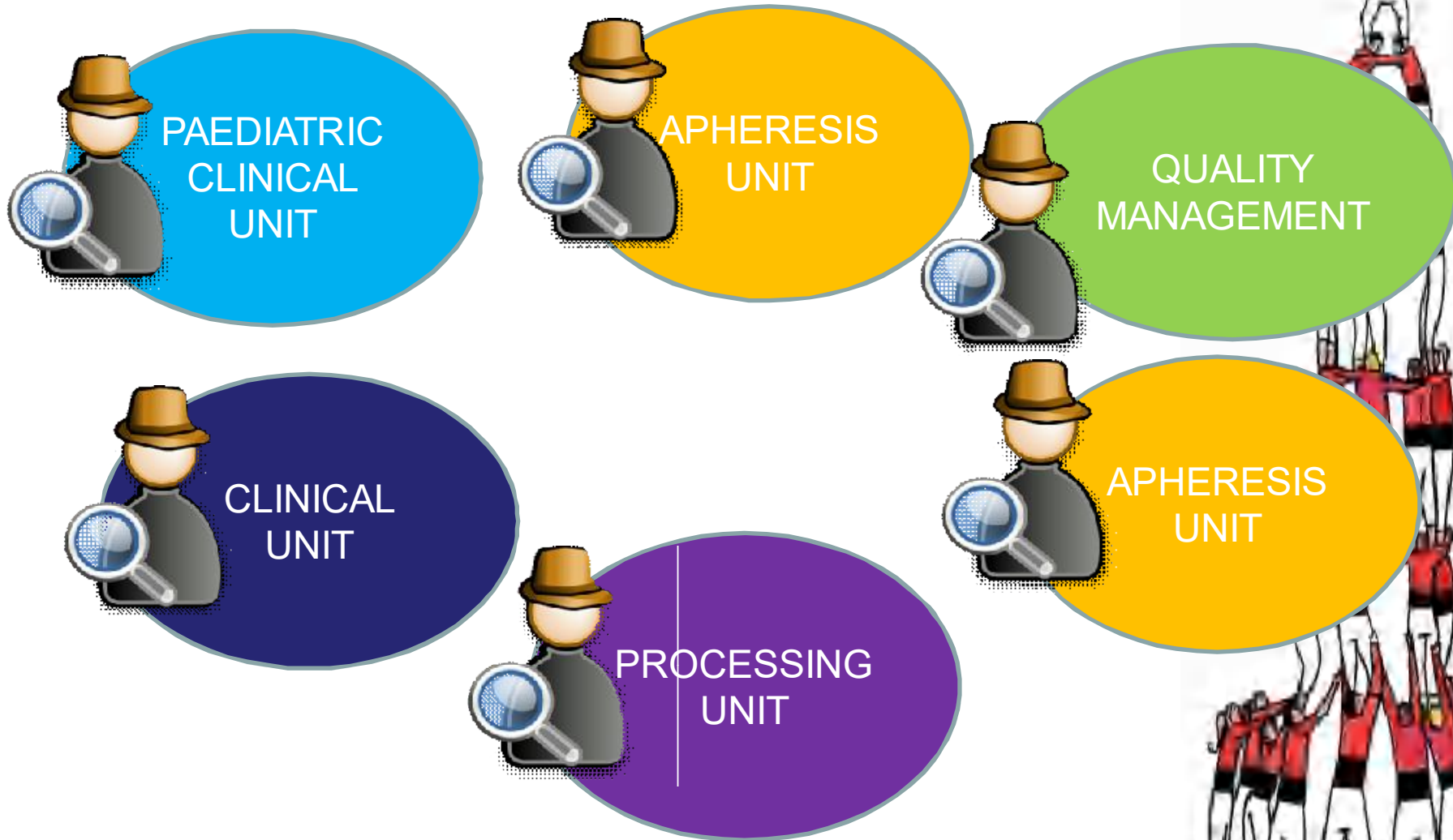
- 30 days to submit documentation
- Labels
- List of SOPs
- Donor / patient consent information
- Evidence of audits performed....



Documentation in the  
language of the Centre



# Inspection 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 JACIE website

- Centre & Inspector shall inform of potential conflicts of interest



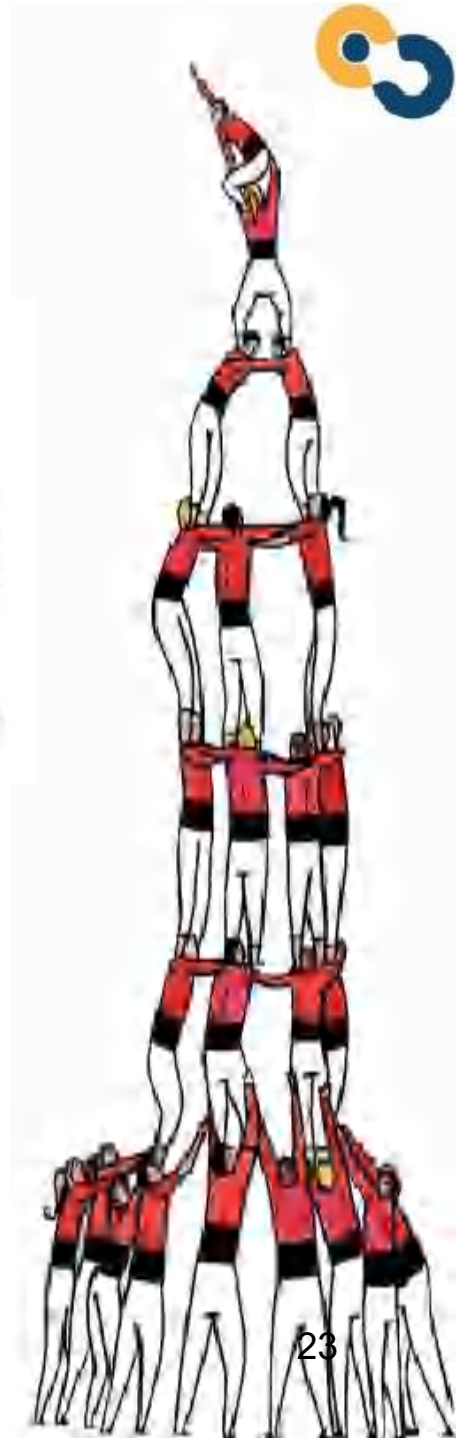


# Inspection Team

- 1 team leader

In addition, possible inclusion of:

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



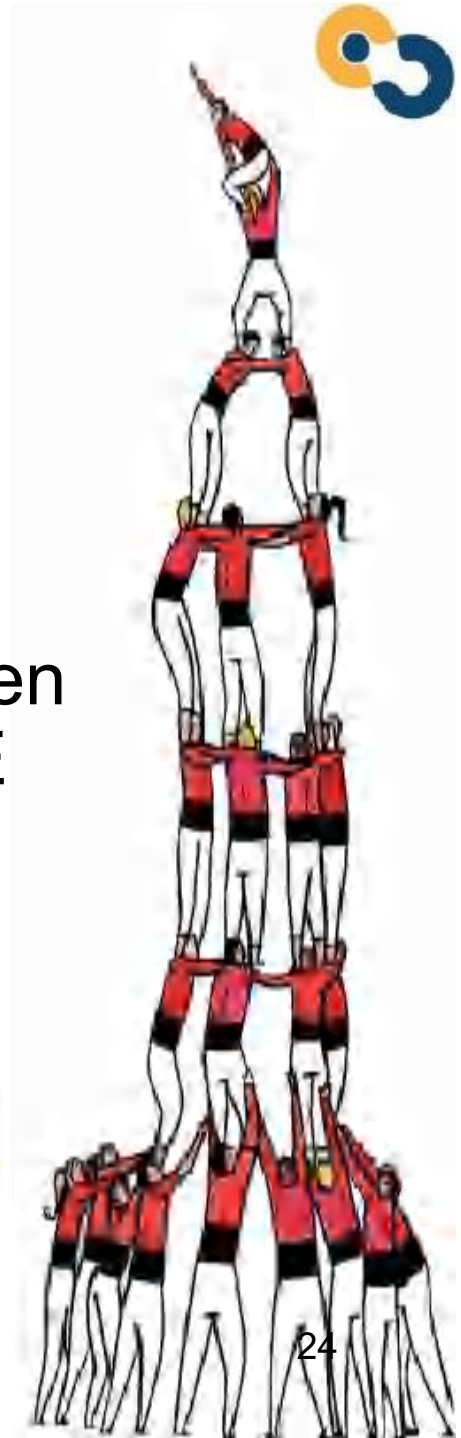
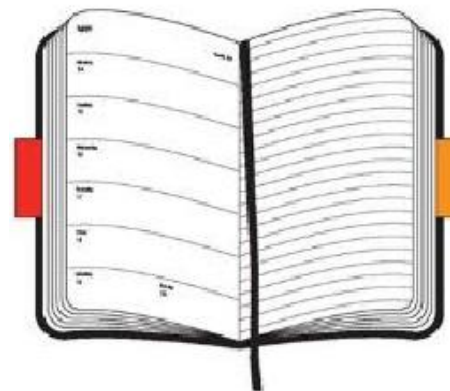
# Team Leader

- Usually Clinician

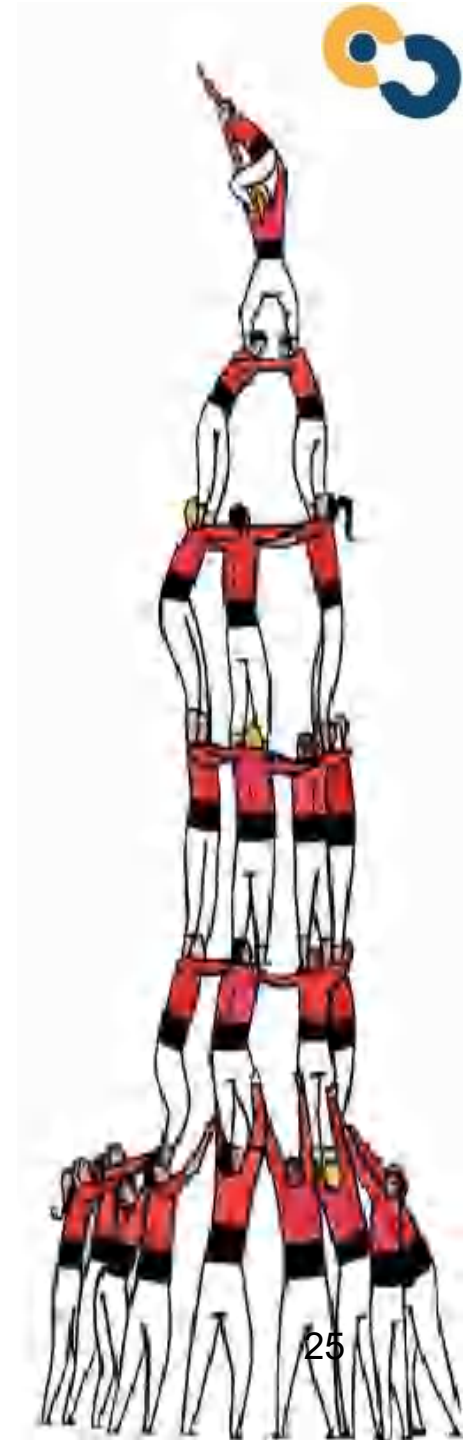


- Point of contact between Team, Centre and JACIE Office

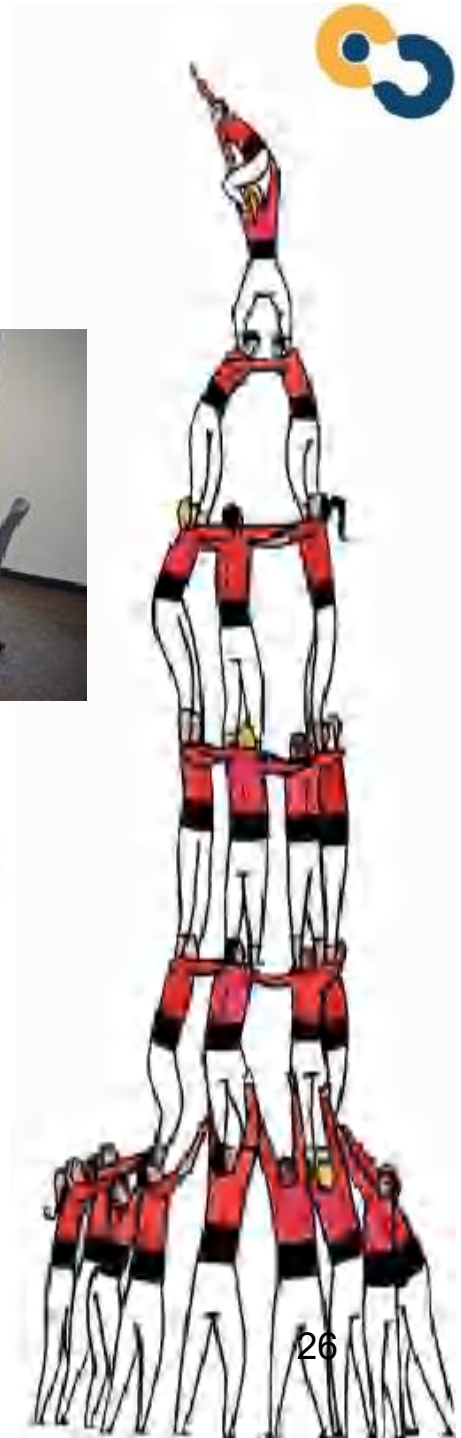
- Arranges timetable with programme director



# Inspection: Preparation



# Applicant: Preparation





# Inspector: Preparation



Part B: Clinical

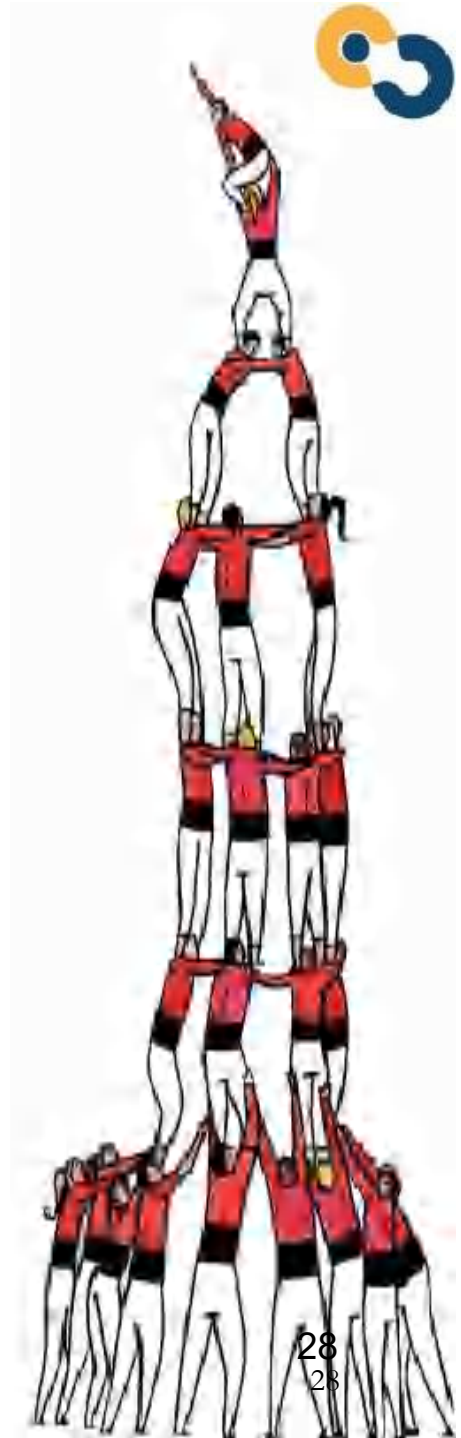
Item	Criteria	Approach	Quality of evidence and impact of key findings	Recommendations	Notes on performance
1.1	1.1.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1
1.1.2	1.1.2.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.2.1	1.1.2.1	1.1.2.1	1.1.2.1
1.1.3	1.1.3.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.3.1	1.1.3.1	1.1.3.1	1.1.3.1
1.1.4	1.1.4.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.4.1	1.1.4.1	1.1.4.1	1.1.4.1
1.1.5	1.1.5.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.5.1	1.1.5.1	1.1.5.1	1.1.5.1
1.1.6	1.1.6.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.6.1	1.1.6.1	1.1.6.1	1.1.6.1
1.1.7	1.1.7.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.7.1	1.1.7.1	1.1.7.1	1.1.7.1
1.1.8	1.1.8.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.8.1	1.1.8.1	1.1.8.1	1.1.8.1
1.1.9	1.1.9.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.9.1	1.1.9.1	1.1.9.1	1.1.9.1
1.1.10	1.1.10.1 The Clinical Practice should have a clear vision and mission statement that includes the purpose of the practice and the values that underpin its work.	1.1.10.1	1.1.10.1	1.1.10.1	1.1.10.1



# 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





# Time-Line



Application



Approval  
Quotation  
JACIE

Agreement

~1/2  
weeks



JACIE  
Agreement  
Signed



Invitation

2  
weeks

1 month



Pre-audit  
documentation  
Submission

~6  
months



Teleconference

Inspection





- Thank you for listening
- Any questions?

