

THE JACIE ACCREDITATION PROCESS

Inspection to accreditation

Accreditation Process



Contents

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

Distribution of the standards

Distribution of the Standards

QM



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



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

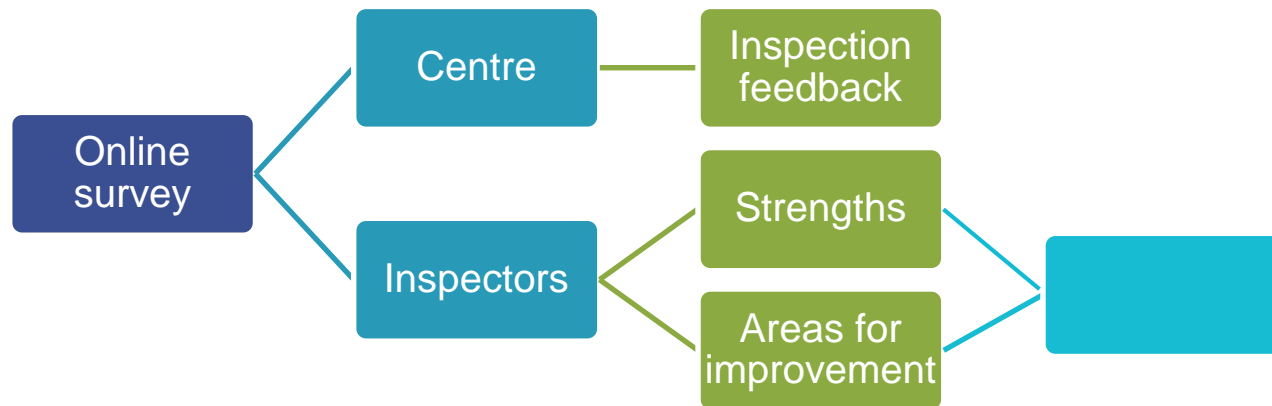
Brief on any sensitive / important issues
Private meeting

Closing Meeting

Inspectors present main findings
Congratulate on positive things
Inspection outcome will be made by JACIE Accreditation
Committee
Q&A

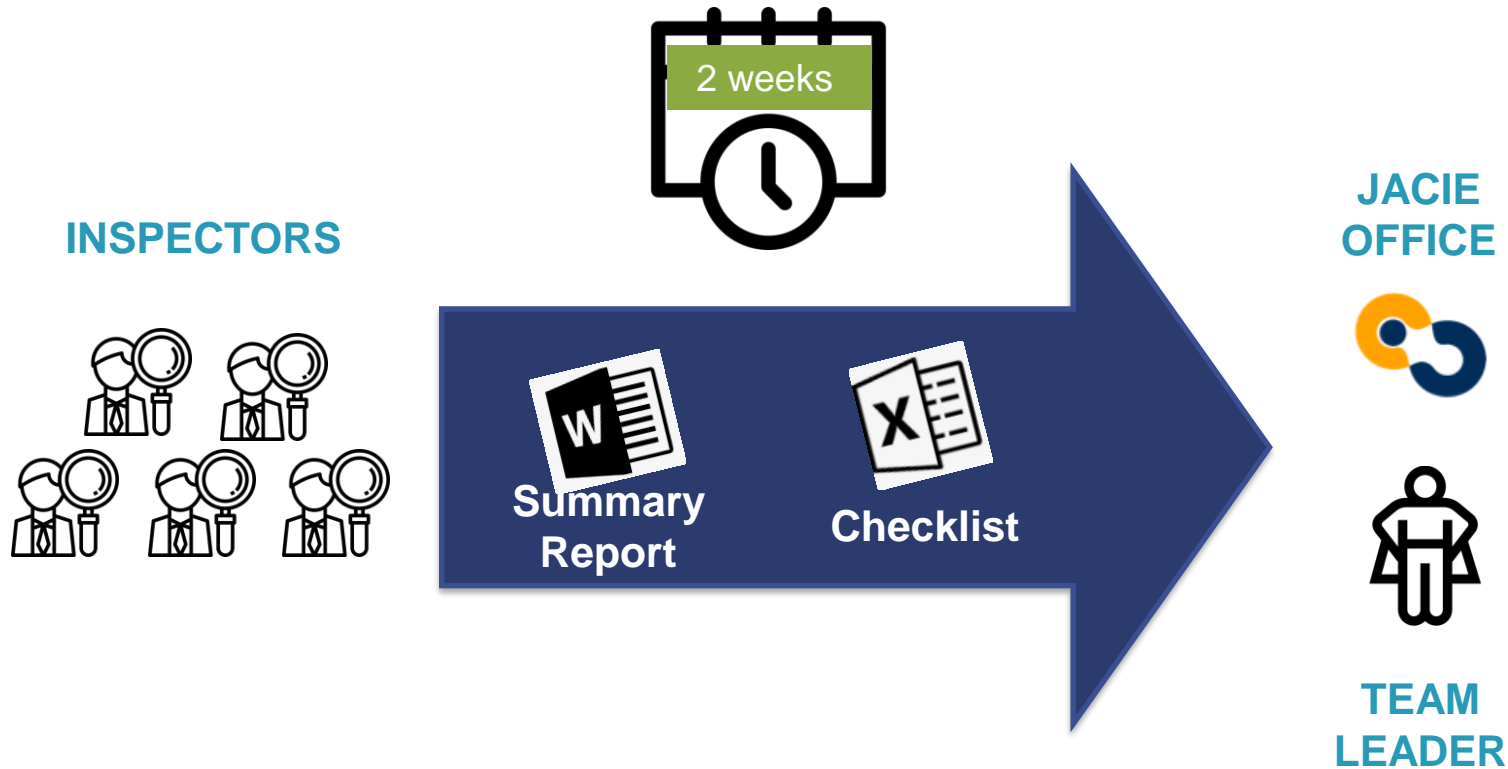
The online post inspection survey

Applicants and inspectors feedback helps us to improve the accreditation process.

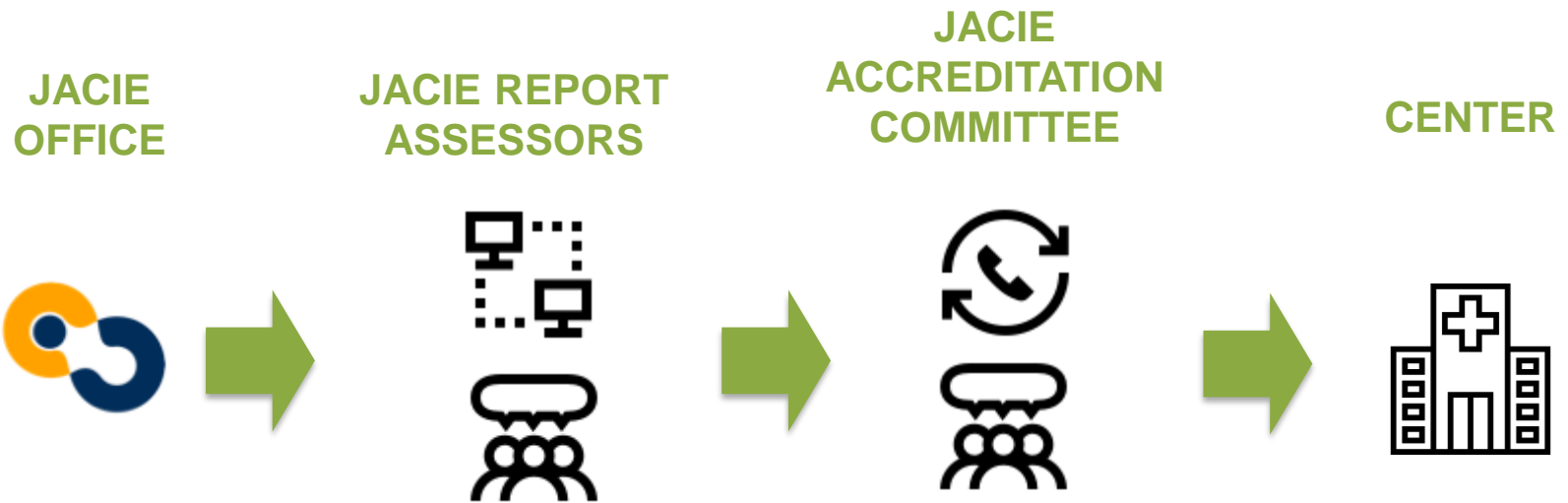


The post inspection procedure

Inspection report and Inspection checklist preparation



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

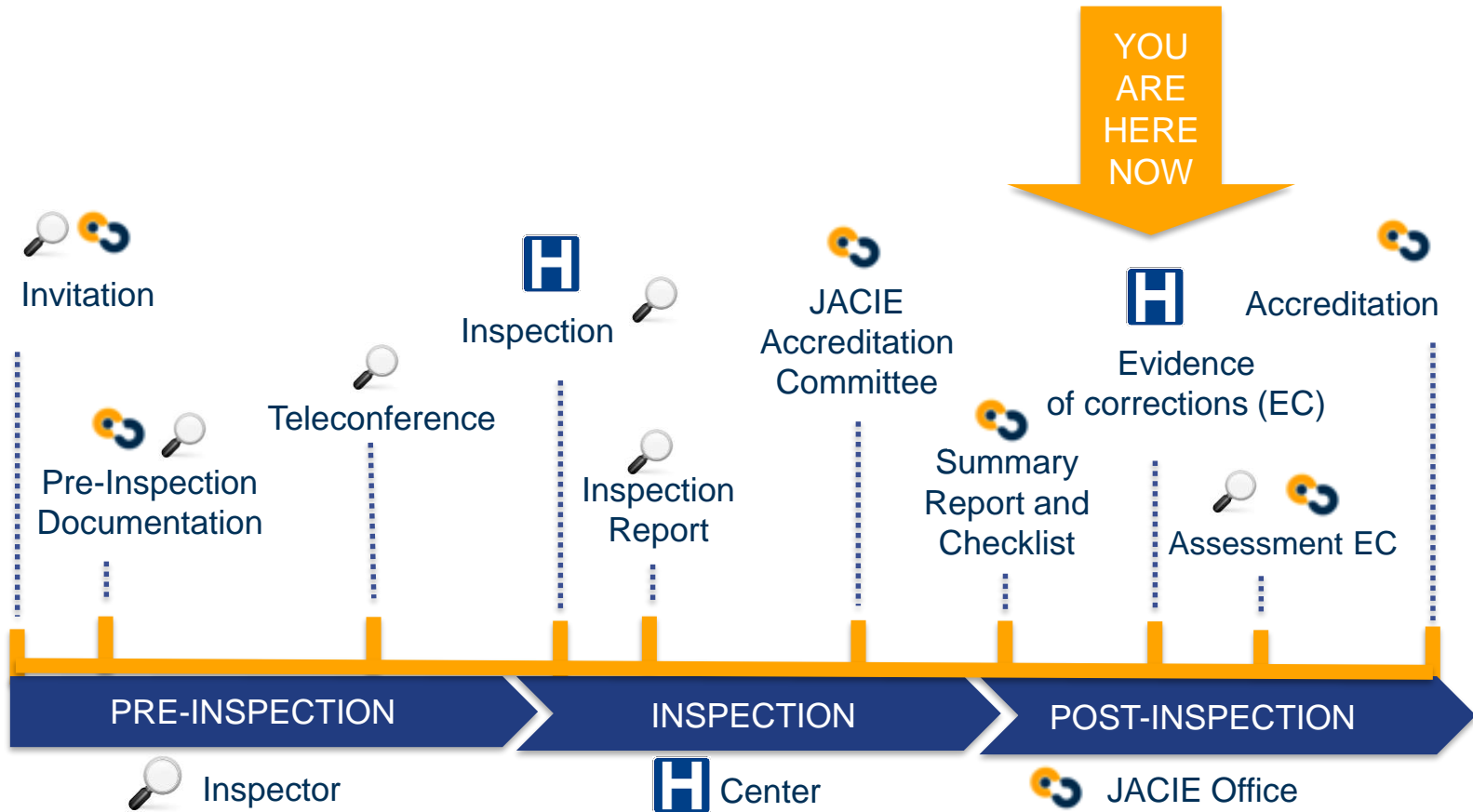
Note: The applicant should also refer to the Inspection Checklist for specific deficiencies where these have been observed during the inspection.

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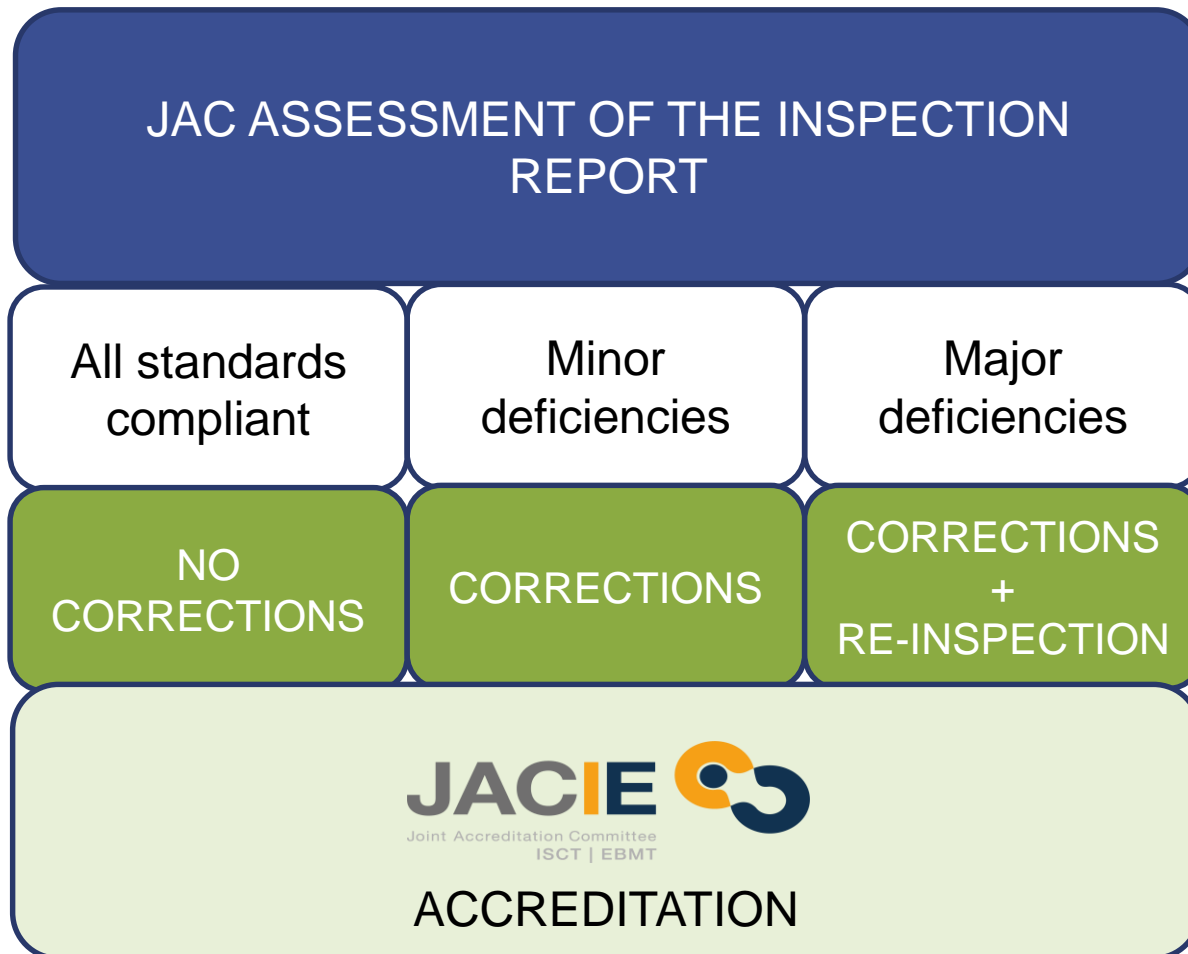
72						
A	B	D	E	F		
Part C: Apheresis				Inspector: All items compliant?		
				No		
Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's (support your additional info)	
C.07.01	ISBT 128 CODING AND LABELING	BLANK CELL	BLANK CELL	BLANK CELL		
C.07.01.01	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.	Compliant		Compliant		
C.07.01.02	If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.	Partially compliant	Implementing SEC	Partially compliant	The Collection Facility implemented only the	
RECORDED WITH C.07.02 SCREENCAST	LABELING OPERATIONS Labeling operations shall be conducted in a manner	BLANK CELL	BLANK CELL	BLANK CELL		

Evidence of corrections

Accreditation Process



Evidence of corrections



- 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



- ✓ 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

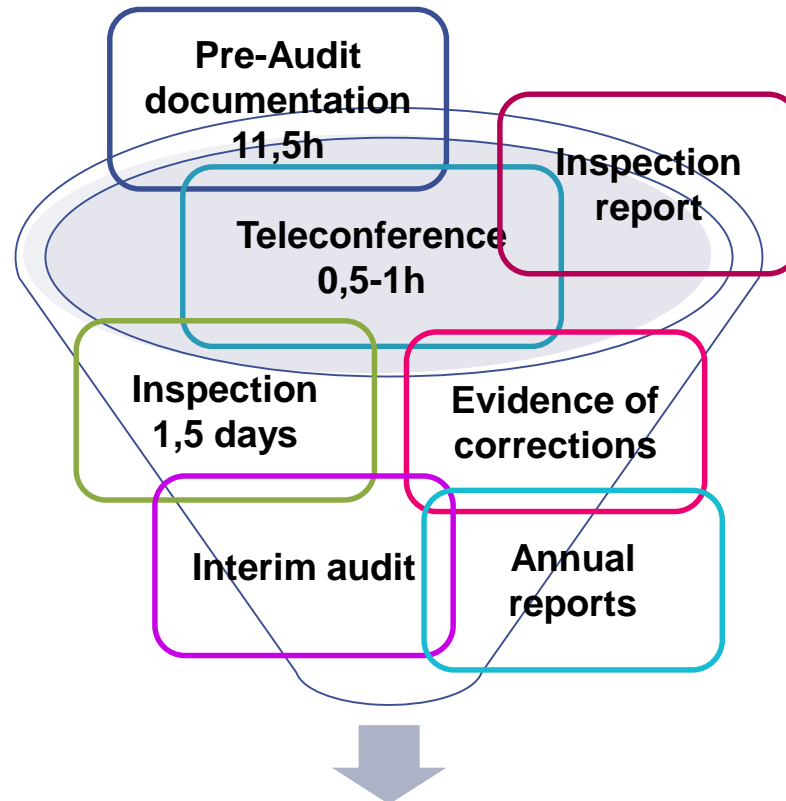
Annual report

- Summary of activity and changes

Interim Audit (50% centres)

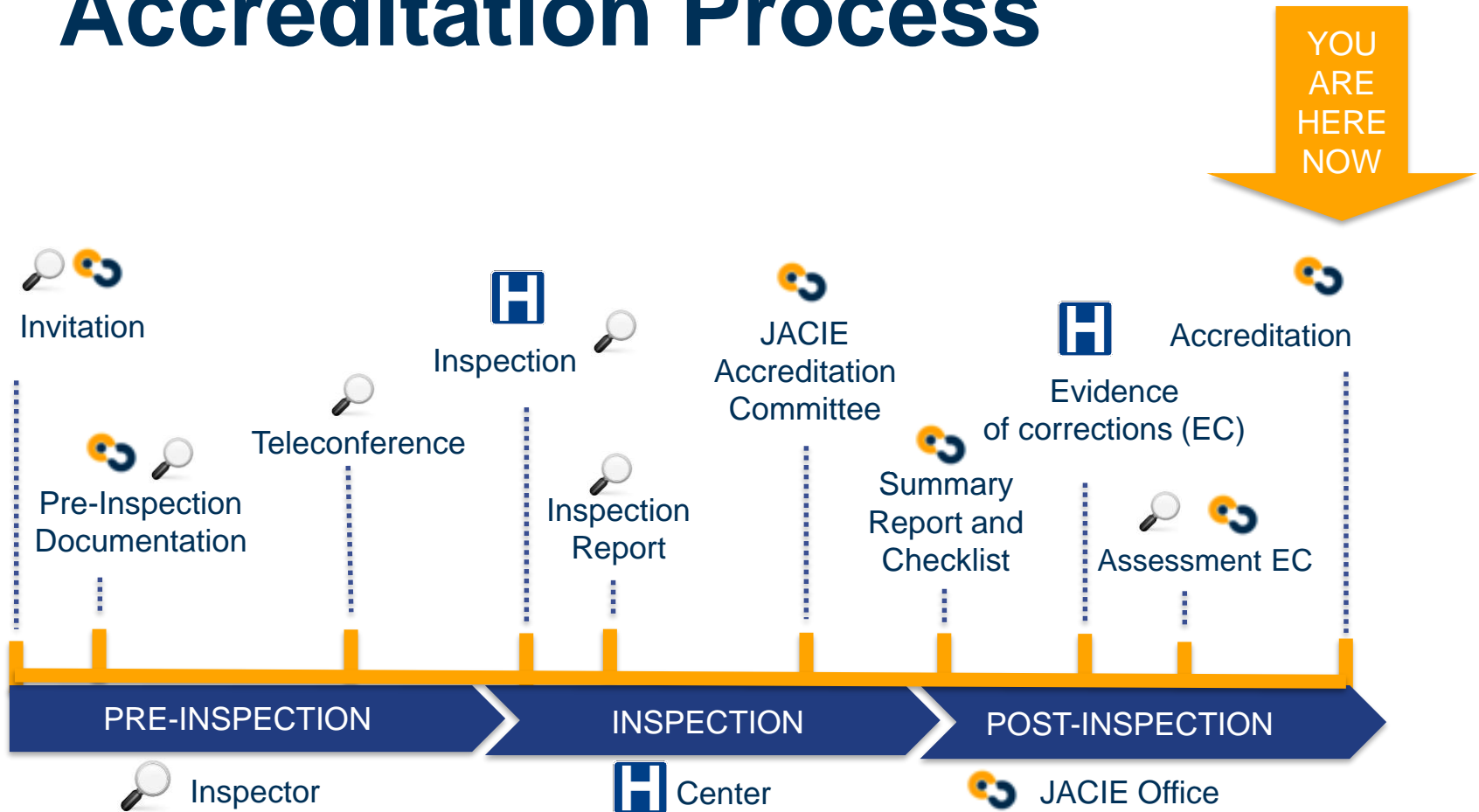
- End of year 2 of Accreditation: focused QM review, based on standards, may result in on-site visit

Inspector's time and timing



JACIE Inspector time

Accreditation Process



Questions?

