

UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

All checklist requirements contain a requirement number, subject header, phase, and a declarative statement. Some requirements also contain the following:

- Policy/Procedure Icon:
 - The placement of the icon next to a checklist requirement indicates that a **written policy or procedure is required to demonstrate compliance with the requirement.**
 - The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.
- NOTE:
 - Additional detail used to assist in interpreting the requirement. Information in the NOTE is considered integral to the requirement and must be complied with as part of the declarative statement itself, unless it is expressed as a recommendation or best practice.
- Evidence of Compliance (EOC):
 - A listing of suggested ways to demonstrate compliance with the requirement; some elements are required.

The Master version of the checklist also contains references and the inspector R.O.A.D. instructions (Read, Observe, Ask, Discover), which can provide valuable insight for the basis of requirements and on how compliance will be assessed.

INTRODUCTION

The Director Assessment Checklist, formerly known as the Team Leader Assessment of Director & Quality Checklist (TLC), emphasizes the role of the laboratory director and fulfillment of the laboratory director responsibilities. The checklist is used primarily by the team leader to perform a peer assessment of the laboratory director's role in ensuring laboratory quality.

When the term "laboratory director" is used, it refers to the individual who is listed on the laboratory's CAP and CLIA certificate (as applicable). Laboratory directors may delegate tasks to other qualified individuals, but the laboratory director retains full responsibility for such tasks. Delegation does not negate the need for laboratory director involvement in the laboratory.

When the term "patient" is used within a checklist, it may also refer to donors, clients, and study participants.



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Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).