INSTRUCTIONS

This checklist must be completed by the team leader or a team member who is qualified and trained to be a team leader. It is used to evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program, including the laboratory's quality management system (QMS). It is also used to identify major or systemic deficiencies detected during the inspection that reflect lack of director oversight in areas such as QC, QM, proficiency testing, employee qualifications and records, competence and training, and the maintenance of a safe work environment.

If major or systemic deficiencies are identified during the inspection, cite the related requirement from this checklist as a deficiency and elaborate on the findings in the Inspector's Summary Report, Part A (ISR-A).

The following activities provide the information needed to complete the requirements in this checklist:

- ***Interview the laboratory director, supervisory personnel and other laboratory personnel as appropriate***
- ***Observe the operation of the laboratory***
- ***Review the laboratory organizational chart, quality management system (QMS) document and records, committee minutes, and other relevant documents for appropriate director involvement***
- ***Interview the hospital administrator, or an executive from the organization if the laboratory is an independent organization***
- ***Interview the chief of the medical staff or a representative (for laboratories associated with a medical staff)***
- ***Discuss deficiencies with members of the inspection team to assess their extent and determine if they directly affect patient safety, or are pervasive in the laboratory, which may warrant a deficiency in the Director Oversight Responsibilities section of this checklist.***

Interviews with the laboratory director, hospital or organization administrator, and representative of the medical staff are essential parts of the inspection. If for any reason one of these interviews was not performed, discuss the circumstances in the Inspector's Summation Report.

Meeting with the Laboratory Director

Purpose: *To help determine if the laboratory director has sufficient responsibility and authority for operation of the laboratory. Allow a minimum of 15-20 minutes for the meeting.*

The interview is an opportunity to:

- *Evaluate the director's activities as listed in the Standards for Laboratory Accreditation*
- *Review any problems that the inspection experience might serve to resolve (eg, space problems, staffing shortages)*
- *Determine whether the laboratory director also functions as a technical supervisor, clinical consultant, general supervisor, or testing personnel.*

Meeting with the Organization/Hospital Administrator/Chief Executive Officer (CEO)

For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Allow at least 15-20 minutes for the meeting. Avoid scheduling the meeting early in the inspection to have a sense of the laboratory's operations first. For independent laboratories, meet with an executive from the laboratory organization.

Purpose: *To extend the College's appreciation for participating in the accreditation program, to record an evaluation of the laboratory from the administration's viewpoint, and help assess the director's involvement in the administration of the laboratory.*

Points to communicate during the interview are:
- *The goals of the CAP Laboratory Accreditation Program: education and laboratory improvement; establishing best practices in laboratory medicine, based on input from national experts*
- *The inspection process: two-year accreditation cycle; use of active laboratorians as inspectors; educational value to inspector and inspected laboratory*
- *The role of proficiency testing in the program*
- *The role of the laboratory director and responsibility for the overall operation of the laboratory, under the requirements of the CAP 's accreditation programs.*

The interview is an opportunity to:
- *Ascertain the administration's perception of the laboratory service*
- *Discuss administration's view of the laboratory director's role in ensuring high quality laboratory services to fulfill the needs of the institution's patients and clinicians*
- *Determine if the institution gives the director the authority to fulfill the director's responsibilities under CAP*
- *Address the effectiveness of the working relationship among the laboratory, its director and administration*
- *Identify any areas of conflict.*

Discuss all laboratories being inspected. Do not discuss any financial and/or contractual arrangements.

When speaking with the hospital administrator, ask if the laboratory service level is appropriate to the needs of the institution. Ask how the pathologists participate in hospital-wide committees, how effective they are in working with the medical and administrative staffs, and whether they meet the expectations of the administration.

Record key findings from this interview in Part A of the Inspector's Summation Report.

Meeting with a Representative of the Medical Staff

For laboratories associated with organized medical staff, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer, or a physician who uses the laboratory's services frequently).

Allow for a 15-20 minute discussion, and come prepared with a general understanding of the laboratory's operations beforehand.

Purpose: *To determine whether the director and the laboratory staff have established an effective working relationship with the medical staff and are effectively supporting patient care.*

The interview is an opportunity to:
- *Evaluate how effectively the scope, quality, and timeliness of laboratory services meet the patient care needs of the hospital*
- *Assess the contribution of the pathologist and laboratory staff to teaching conferences and meetings*
- *Determine the cooperation of medical staff and pathologist in problem resolution*
- *Judge the medical community's perception of the effectiveness of the laboratory director and other pathologists, and determine if the laboratory director has sufficient authority to fulfill the needs of the medical staff and patients.*

When meeting with the chief or other active member of the medical staff, ask questions about the scope, quality and timeliness of laboratory services. The team leader should ask the medical staff representative for input on pathologist participation in medical staff committees, participation in institutional QMS and patient safety activities, and participation in teaching conferences. Include all laboratories being inspected, including special function and satellite laboratories.

The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Pre-Summation Conference

Prior to the summation conference, allow 30-60 minutes to meet privately as a group with the inspection team members to discuss and record inspection findings. The goal of the meeting is to ensure that both verbal and written inspection reports are complete and consistent. During the meeting:

- *Resolve team members' questions*
- *Ensure consistency in recording similar findings (eg, deficiency versus recommendation)*
- *Identify serious deficiencies that may jeopardize patient care and systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections*
- *Review the Part A Questions in the Inspector's Summation Report.*

If serious deficiencies or systemic issues are identified or any question from Part A is answered "NO," cite the appropriate checklist requirements relating to the issue and the DRA Checklist requirement for the laboratory director responsibility.

Common examples include:

Issue Observed	***Related DRA Requirement***
Lack of laboratory director involvement	*DRA.10435*
QMS not properly implemented	*DRA.10440*
Lack of thoroughness of the self-inspection and/or inadequate or untimely correction of deficiencies noted during the self-inspection process	*DRA.10445*
Inconsistent quality control/lack of corrective action	*DRA.10460*
Improper handling of proficiency testing materials/lack of follow-up for unacceptable results	*DRA.10460*
Lack of validation/verification records for new tests or instruments	*DRA.10475*
Insufficient numbers of personnel or incomplete records for personnel qualifications and/or training	*DRA.11300*
Unsafe laboratory practices compromise the safety of personnel	*DRA.11400*
Incomplete records for delegation of duties or duties not effectively carried out by designee(s) (eg, competency assessments not performed as required by designee) or delegation of functions to individuals who lack the necessary qualifications	*DRA.11425*

Summation Conference

Citations in this checklist are optional for discussion at the summation conference to which laboratory staff, hospital administration, and others may be invited. The team leader may instead choose to discuss them with the laboratory director in a private summation meeting.

DEFINITION OF TERMS

Addendum - Information appended to a final report with no changes to the original test result(s); original report is intact and unchanged, the addendum is added as an attachment or supplement to the original report.

Alternative performance assessment - A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization.

Amended/amendment - Any change in a previously issued anatomic pathology or cytopathology report intended to correct an inaccuracy, including changes in the diagnosis, narrative text, clinical history, pre- and post-operative diagnoses, patient identification, or other content.