



cap

Patient Safety  
Compliance  
Consistency  
Confidence  
Accuracy  
Quality

# CAP Accreditation Checklists

[cap.org/accreditation](http://cap.org/accreditation)

# Evidence of Compliance Expanded

Evidence of Compliance provides guidance to an inspector on how to assess whether the laboratory is in compliance with a requirement. Specific examples of acceptable documentation, including policies, procedures, reports, records, etc, help laboratories maintain accreditation and offer a consistent understanding of requirements leading to an efficient onsite inspection. In addition, inspectors can benefit from Evidence of Compliance statements when identification of a subject of interest requires a "drill down" technique to ensure an accurate assessment of compliance. This process also provides consistency and offers confidence to laboratories performing self audits and inspections. New for 2012, the CAP has expanded Evidence of Compliance in the Team Leader Assessment of Director and Quality Checklist.

## Roadmap



**R**ead/review documents that must be looked at during the inspection.



**O**bserve laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures.



**A**sk open-ended, probing questions that start with phrases such as "Show me how...", or "Tell me about...", or "What would you do if...". Ask follow-up questions for clarification.



**D**iscover/follow a specimen from collection to reporting to cover multiple checklist requirements simultaneously. Choose a representative specimen and track the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories. Examples of discovery opportunities are described throughout the checklist.

Note that all four ROAD elements are not always applicable.

## Get Involved

Share your suggestions and help initiative enhancements.  
Email us at [checklistcomments@cap.org](mailto:checklistcomments@cap.org).

## Questions

Contact us at **800-323-4040** or **847-832-7000** option 1 (international customers); or email us at [accred@cap.org](mailto:accred@cap.org).



As laboratory medicine advances, the CAP accreditation checklists guide laboratories to achieve continuous compliance and deliver the highest standard of patient care. The key 2012 checklist enhancements include fewer questions, less redundancy, more examples of acceptable documentation, and additions to emerging areas of pathology.

Participating laboratories and inspectors will experience the benefit of easy-to-use accreditation requirements, which saves time while maintaining the gold standard in laboratory quality. The CAP checklists continue to evolve and offer the most comprehensive, flexible, and customized inspection tool in the industry.



# Summary of Enhancements

Preparing for CAP accreditation is now easier and quicker than ever before.

## Integration of New Technologies

- To advance standardized practice in genomic testing, the CAP has introduced a new section to the Molecular Pathology Checklist to address next-generation sequencing (whole-genome sequencing). As a result this checklist has been reorganized and slightly renumbered to facilitate a more logical and efficient flow.
- The Clinical Biochemical Genetics Checklist was added in 2011 for laboratories providing clinical biochemical genetic testing for the diagnosis and management of patients with inborn errors metabolism (IEMs).

## Globalization of Checklist Language

- To accommodate international markets, checklists are now customized to exclude requirements only applicable or required by US agencies. This new change will make compliance easier regardless of laboratory size while facilitating standardization across global laboratories for international reference laboratories and academic medical centers.

## Further Elimination of Redundancy

- To minimize preparation time, requirements no longer relevant, duplicative, or rarely cited were eliminated without measurable effect on the CAP's decision to accredit the laboratory.

## A Customized Laboratory General Checklist

- To tailor your Laboratory General Checklist specific to your laboratory, simply update your laboratory general activity menu/scope of services and experience a shorter Laboratory General Checklist for your next onsite or self inspection.

## Generalized Requirements

- The requirements have become agency "neutral." Reference to outside agencies has become more generalized (eg, a requirement about the Health Information Portability and Accountability Act [HIPAA] requiring protection of patients' health care information would have been renamed to a requirement about patient confidentiality).

## Annotate your Checklists in MS Excel

- Did you know you can download your checklists in Excel to make laboratory preparation more efficient? Introduced in 2011, you can simply download to Excel through e-LAB Solutions™. Annotate and index your laboratory's policies, procedures, and records. Improve your document control and enjoy the efficiencies gained on your inspection day!

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## New Services

### CAP Accreditation for Biorepositories

The Biorepository Accreditation Checklist includes requirements to drive biospecimen quality and promote standardization. The CAP Biorepository Accreditation Program provides confidence to biorepositories to deliver high-quality biospecimens needed to support research and personalized medicine and to improve patient outcomes. This program is tailored to biorepositories storing tissue for nontransplant-related research.

### New CAP Accreditation Manager™

Through a partnership with SoftTech Health, the CAP introduces CAP Accreditation Manager, new software that streamlines accreditation, document control, and the regulatory compliance processes in the laboratory. This advanced, time-saving laboratory software tool provides a better way to efficiently manage laboratory resources that maintain accreditation and allows laboratories to create and manage CAP accreditation custom checklists.

### All Common Checklist

The All Common Checklist, created in 2011 to standardize and streamline the accreditation process, has been expanded for 2012. Applicable questions with regard to quality management, reagents, collection manuals, instrument evaluations, and review of unusual laboratory reports have been moved from individual discipline specific checklists to the All Common Checklist. This checklist remains a consolidated set of requirements that are similar or identical across multiple disciplines. Featuring a reduction in the number of requirements, laboratories will experience a decrease in preparation time and response to deficiencies that may exist in multiple sections.

The inspector's findings, referred to as the Inspector's Summation Report (ISR), will continue to be left with a laboratory after inspection. Deficiencies cited in the All Common Checklist will be recorded in reference to the discipline where the deficiency occurred. For example, a deficiency cited from the All Common Checklist used to inspect hematology, will be listed on the hematology deficiency page.

### Reorganization Benefits Include:

- A reduction in laboratory preparation time in meeting document control guidelines
- An overall reduction in the number of requirements and possible citations per section
- Less time needed to respond to similar deficiencies within the different disciplines in the same section unit/department

► Figure 1

Laboratory section units that previously had one discipline-specific checklist per section unit/department will now receive two checklists per section unit/department:

1. The All Common Checklist
2. The discipline-specific checklist (ie, Chemistry, Hematology, and/or Anatomic Pathology checklists)

Figure 1

Customized Laboratory General Checklist		
Team Leader Checklist		
<b>Laboratory Department Section Unit 1 Chemistry</b>	<b>Laboratory Department Section Unit 2 Hematology</b>	<b>Laboratory Department Section Unit 3 Anatomic Pathology</b>
<b>NEW! All Common Checklist</b> (requirements about proficiency testing, procedure manual, results reporting, method performance specifications, and reference intervals)	<b>NEW! All Common Checklist</b> (requirements about proficiency testing, procedure manual, results reporting, method performance specifications, and reference intervals)	<b>NEW! All Common Checklist</b> (requirements about proficiency testing, procedure manual, results reporting, method performance specifications, and reference intervals)
<b>Chemistry Checklist</b> (chemistry-specific requirements only)	<b>Hematology Checklist</b> (hematology-specific requirements only)	<b>Anatomic Pathology Checklist</b> (anatomic pathology-specific requirements only)

► Figure 2

In section units/departments with multiple discipline-specific checklists per section unit/department (eg, both Chemistry and Hematology Checklists in one core laboratory), common requirements will be grouped together in the All Common Checklist. The result is a net reduction in checklist requirements, since the requirements that formerly were duplicated in the Chemistry and Hematology Checklists have been deleted and replaced by the All Common Checklist.

Figure 2

Customized Laboratory General Checklist		
Team Leader Checklist		
<b>Laboratory Department Section Unit 1 Core Laboratory</b>		<b>Laboratory Department Section Unit 3 Anatomic Pathology</b>
<b>NEW! All Common Checklist</b> (requirements about proficiency testing, procedure manual, results reporting, method performance specifications, and reference intervals)		<b>NEW! All Common Checklist</b> (requirements about proficiency testing, procedure manual, results reporting, method performance specifications, and reference intervals)
<b>Chemistry Checklist</b> (chemistry-specific requirements only)	<b>Hematology Checklist</b> (hematology-specific requirements only)	<b>Anatomic Pathology Checklist</b> (anatomic pathology-specific requirements only)



## Let them know you've earned the mark.

The CAP Certification Mark recognizes laboratory organizations for achieving CAP accreditation, shared among more than 7,000 laboratories worldwide. The mark is a way to display to peers, patients, and the public that you've attained CAP accreditation through the most respected and recognized laboratory accreditation program in the world.

The CAP is pleased to recognize each of the laboratories making the commitment to quality and patient safety.

To access and download the CAP Certification Mark, please log in to your e-LAB Solutions™ account, or contact the CAP Customer Contact Center.

### **College of American Pathologists**

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