COLLEGE of AMERICAN PATHOLOGISTS

Master

# Chemistry and Toxicology Checklist

CAP Accreditation Program

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## ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

## CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

## SUMMARY OF CHECKLIST EDITION CHANGES
## Chemistry and Toxicology Checklist
## 12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged**:**
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

*NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.*

**Previously Cited Checklist Requirements**

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

| Requirement | Effective Date |
|---|---|
| CHM.12925 | 12/26/2024 |
| CHM.15225 | 12/26/2024 |
| CHM.18610 | 08/24/2023 |
| CHM.18620 | 08/24/2023 |
| CHM.18640 | 08/24/2023 |
| CHM.31150 | 12/26/2024 |

REVISED Checklist Requirements

| Requirement | Effective Date |
|---|---|
| CHM.13550 | 08/24/2023 |
| CHM.13600 | 08/24/2023 |
| CHM.18600 | 08/24/2023 |
| CHM.18700 | 08/24/2023 |
| CHM.18825 | 08/24/2023 |
| CHM.18850 | 08/24/2023 |
| CHM.29100 | 08/24/2023 |
| CHM.30150 | 08/24/2023 |
| CHM.30700 | 08/24/2023 |
| CHM.30800 | 08/24/2023 |
| CHM.31950 | 12/26/2024 |
| CHM.32300 | 12/26/2024 |
| CHM.32800 | 12/26/2024 |
| CHM.33900 | 12/26/2024 |

DELETED/MOVED/MERGED Checklist Requirements

| Requirement | Effective Date |
|---|---|
| CHM.18800 | 08/23/2023 |
| CHM.31100 | 12/25/2024 |
| CHM.31200 | 12/25/2024 |
| CHM.31300 | 12/25/2024 |
| CHM.31400 | 12/25/2024 |
| CHM.31500 | 12/25/2024 |
| CHM.31550 | 12/25/2024 |
| CHM.31600 | 12/25/2024 |
| CHM.31650 | 12/25/2024 |
| CHM.31700 | 12/25/2024 |
| CHM.32100 | 12/25/2024 |

# INTRODUCTION

*This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a chemistry laboratory section or department.*

*Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.*


*Policy/Procedure icon - The placement of this 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.*

***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).*

# CHEMISTRY & TOXICOLOGY GENERAL ISSUES

## PROFICIENCY TESTING

### Inspector Instructions:


- Records of hemoglobin A1C accuracy-based proficiency testing results evaluation, as applicable

***NEW** 12/26/2024*

**CHM.12925 Hemoglobin A1C Testing** **Phase I**

**For laboratories that use accuracy-based proficiency testing (PT) for hemoglobin A1C, the laboratory evaluates its results based on acceptable performance criteria of +/- 6% from the target value, with appropriate corrective action taken for each unacceptable result.**

*NOTE: The CAP recommends use of accuracy-based PT products, when possible, to evaluate the accuracy of hemoglobin A1C results. Due to limitations in product stability, this may not be available for laboratories outside of the US.*

*The Centers for Medicare and Medicaid Services (CMS) have established acceptable performance criteria for hemoglobin A1C as a regulated analyte at +/- 8% from the target value. The CAP and all CAP-accepted PT providers must use the +/- 8% criteria in the formal grading of the PT for reporting non-waived results to the CMS. For laboratories participating in the CAP's accuracy-based PT program for hemoglobin A1C, the CAP will also evaluate their results against the target value using +/- 6% performance criteria. This is provided in the participant evaluation*