4.25.2023 Laboratory Quality Improvement Ideas from CAP Inspections Q&A Responses

Question: Does the CAP have approved document templates for labs?
Answer: The CAP does offer examples and templates through the CAP website and covers a variety of topics such as policies, procedures, and forms that are available to accredited laboratories.

You can find the example templates for labs on the CAP website under the "Accreditation" tab. Here's the step-by-step guide to find them:

1. Go to the CAP website at www.cap.org.
2. Click on the "Accreditation" tab in the top menu.
3. Select "Laboratory Accreditation" from the dropdown menu.
4. Click on the "Laboratory Accreditation Manuals & Checklists" button.
5. Scroll down to the "Document Templates" section and click on the "View Document Templates" button.
6. You'll be redirected to the Document Templates page where you can find templates for policies, procedures, forms, and other documents.

Note that these document templates are only available to laboratories enrolled in the CAP accreditation program.

Question: How should we evaluate a PT program when peer participant is less than 10?
Answer: Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, or all methods, or all participant statistics if provided. Perform and document the corrective action of any unacceptable results. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested or evaluated to the same level and extent that would have been.

Question: How do we bring back a test into the activity menu when we have received cease testing?
Answer: To bring a test back into the activity menu after receiving a cease testing notice, laboratories should contact the CAP Proficiency Testing Compliance department for guidance on the appropriate steps to take.

Question: Can we keep all test procedures up to date/or annual review in electronic files instead of paper?
Answer: Yes, laboratories can keep test procedures up to date and perform annual review in electronic files instead of paper as long as they comply with the CAP's record-keeping requirements.

The record-keeping requirements for test procedures, as outlined by the CAP (College of American Pathologists) accreditation program, include:

1. Written procedures that include the test's purpose, methodology, performance specifications, and quality control procedures.
2. A documented review and approval process for test procedures, including any changes or updates.
3. Documentation of the date when the test procedure was last reviewed and revised, along with the name and initials of the person who performed the review and revision.
4. An electronic or paper record of each test result that includes the patient's name or identifier, the date the test was performed, the name of the test, and the result of the test.
5. A record of corrective actions taken when test results do not meet performance specifications or quality control requirements.
6. Documentation of any equipment or reagent problems that affect test results, along with corrective actions taken to address these issues.

It's important to note that laboratories must keep records of test procedures for a minimum of two years after the discontinuation of the procedure, or longer if required by state or federal regulations. Additionally, laboratories should ensure that their record-keeping practices comply with all applicable laws and regulations.

Question: When a laboratory doesn't use certain equipment for a period of time because of lack of samples, what should they write on the maintenance sheet if we are not doing the daily maintenance?

Answer: Laboratories should document the reason for not performing daily maintenance on the maintenance sheet and follow the manufacturer's instructions for the appropriate maintenance schedule. COM.40805 may also apply if testing is taken out of production for a period of time. Please contact CAP Accreditation for specific guidance.

Question: How many samples can be used for instrument-to-instrument comparison?

Answer: The number of samples used for instrument-to-instrument comparison will depend on the test and the equipment being evaluated. The laboratory director must define the appropriate number of samples to use.

Question: Could you provide CAP-recommended references to be used in building a more comprehensive CAP-approved quality manual?

Answer: The College of American Pathologists (CAP) offers a comprehensive list of resources and references for laboratories to build a CAP-approved quality manual on their website. Here are the steps to find them:

1. Go to the CAP website at www.cap.org.
2. Click on the "Accreditation" tab in the top menu.
3. Select "Laboratory Accreditation" from the dropdown menu.
4. Click on the "Laboratory Accreditation Manuals & Checklists" button.

5. Scroll down to the "Quality Management Resources" section and click on the "View Quality Management Resources" button.
6. You'll be redirected to the Quality Management Resources page where you can find a comprehensive list of references and resources for building a CAP-approved quality manual, including:
    - CAP Accreditation Checklists
    - Quality Management Tools and Templates
    - CAP Education and Training
    - Quality Management Publications
    - Quality Management Links

The list includes a wide range of resources, such as guidelines, checklists, templates, and other tools that can help laboratories develop and maintain a comprehensive quality management system.

Question: Please provide examples of ways to track competency assessment on staff who work multiple departments, with training completed at different times.

Answer: To track competency assessment on staff who work in multiple departments, laboratories can use a variety of methods, such as job-specific checklists, cross-training records, and competency assessment logs. The CAP also offers a comprehensive Competency Assessment program that can electronically monitor due dates for competency assessments across the laboratory. For more information on this program, please contact competency@cap.org.

Question: What Microbiology EQA does CAP offer?

Answer: You can find information about the College of American Pathologists (CAP) Microbiology External Quality Assessment (EQA) program on the CAP website. Here are the steps to find it:

1. Go to the CAP website at www.cap.org.
2. Click on the "Accreditation" tab in the top menu.
3. Select "Proficiency Testing" from the dropdown menu.
4. Click on the "Microbiology" button.
5. You will be redirected to the Microbiology EQA page, where you can find information about the CAP's Microbiology EQA program, including:
    - Program overview
    - Enrollment information
    - Shipping schedules
    - FAQs
    - Contact information for technical support

The Microbiology EQA program is designed to help laboratories assess their performance and ensure accuracy in their microbiology testing. The program includes a range of samples, such as culture plates, specimens, and unknowns, which are shipped to participating laboratories on a regular basis. Participating

laboratories are evaluated based on their ability to accurately identify and report the results of these samples.

Question: Does the CAP have a checklist of required documents to keep?
Answer: Record and material retention requirements can be found in the General Checklist under GEN.20377 as well as the discipline specific checklist.

Question: Can Interlaboratory comparison satisfy the requirement for Instrument and Method performance semiannual check?
Answer: COM.04250 requires laboratories to compare instruments or test methods within their own laboratory, which is per CAP number. Interlaboratory comparisons (between different CAP numbers) would be at the discretion of the laboratory director but would not be required by the CAP.