

COLA Technical Bulletin

2022-1: Criteria Updates

COLA periodically reviews the criteria for accreditation, and makes changes or additions to the criteria and/or accreditation process for several reasons:

- To clarify language, so that the intent of the criterion is clear
- To incorporate new information, which may be in response to changes in technology or regulatory emphasis

This Technical Bulletin serves to notify our customers about the following upcoming changes and additions to the Accreditation Manual.

NEW CRITERION

PER 7 R: Do all testing personnel have training documented when initially hired and for each new test system introduced after initial training?

All testing personnel must have training performed when initially hired that includes pre-analytic, analytic and post-analytic aspects for all testing the individual will be responsible for performing.

While any designated individual can perform training for new testing personnel, the Laboratory Director or Technical Supervisor/Technical Consultant is responsible for signing the training documentation, indicating the new testing personnel received the necessary training and is competent to perform testing.

REVISED CRITERIA

Significant changes or clarifications are underlined below.

PST 26 R: Are pathology reports, including macroscopic examination of gross tissue, all types of histopathology, oral pathology, and cytology reports, paper or electronic, maintained, stored and preserved for at least 10 years?

This requirement only pertains to laboratories that process cytology and pathology requests and reports through the laboratory. Pathology reports must include any applicable macroscopic examinations (see HIS 89). Be aware that state regulations may mandate longer retention.

REVISED CRITERIA (CONTINUED)

TS 69: Does documentation verify that the unit was maintained at the proper temperature at all times?

Blood leaving the laboratory's controlled storage must be maintained at 1-6° C at all times.

Assessing a unit for acceptability for reissue cannot be based alone on the unit being returned to the laboratory within a predetermined timeframe.

Reason for the change: The previous version of TS 69 asked “Does documentation verify that the unit was maintained at the proper temperature at all times *or returned to the lab within 30 minutes?*” We have removed the reference to the “30-minute rule” in order to align with the FDA regulations under [21 CFR 640.2 \(c\): Reissue of blood](#). Any units that leave controlled temperature storage in the laboratory must be maintained at 1-6° C at all times in order to be accepted back into the laboratory for reissue.