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COLA Technical Bulletin

2023-2: Personnel, Maintenance and Verification of Performance

COLA periodically reviews the criteria for accreditation and makes changes or additions for several reasons:

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

The 2023 COLA Accreditation Manual will be published in February 2023. This edition includes the revision of criteria in the personnel (**PER**), maintenance (**MA**) and performance specifications (**VER**) sections, to guide COLA laboratories in best practices.

The purpose of this Technical Bulletin is to provide advance notice of these changes. See additional 2023 Technical Bulletins for information on other criteria changes and additions.

Revisions to COLA Criteria

Significant changes or clarifications to existing COLA criteria are underlined below.

PER 5 R

Does your director or Technical Supervisor/Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?

This is not simply a review of the individual's initiative, interpersonal relationships, and work ethic although these are important attributes. The focus of this process is the individual's ability to perform assigned tasks according to defined processes and procedures to assure accurate and reliable laboratory results. The review must address the competency of each individual to fulfill the duties and responsibilities of their position including assessment of actual test performance and interpretation of results.

All testing personnel are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance. Assessments should occur semi-annually for the first year and annually thereafter for all testing personnel, supervisors, technical consultants, and clinical consultants.

Competency assessments must also be performed with all method and instrument changes.

MA 7 -13 R

Are temperatures recorded each day of testing and corrective action taken and documented when out of range?

Each day of testing temperatures should be recorded. When the temperature is outside of the established range, corrective action should be taken to ensure the integrity of the reagents, specimens, instruments and kits. Temperature problems can adversely affect patient results. Always document the actions taken whenever a temperature problem is detected.

If an electronic temperature monitoring system is used, the personnel responsible for performing corrective action when

there are unacceptable temperatures must have immediate access to the temperature monitoring system to view current temperatures. Additionally, the electronic temperature monitoring system must be checked each day to confirm that the system is functioning properly.

Note: This grouping of criteria (**MA 7-13**) includes temperature recording for refrigerators, freezers, room temperature areas, incubators, water baths, dry baths and any other temperature-sensitive equipment. The new language concerning electronic temperature monitoring systems applies to the entire grouping of criteria.

Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: (VER 1-4)

VER 1 R

Accuracy?

When the real value of the substance tested is obtained.

Samples used to verify accuracy of qualitative tests must include both positive and negative samples.

VER 2 R

Precision?

When the results are reproducible upon repetitive testing.

Precision studies must encompass day-to-day, run-to-run, within-run precision and must include at least two levels for quantitative tests. For non-automated tests, involve various testing personnel who routinely run the tests.

Prior to patient testing, have each of the following performance specifications been established and documented for each non-waived test or method: (VER 5 – 11)

Note: **VER 5-11** apply to FDA-approved but modified, non-FDA approved, or in-house developed test systems.

VER 5 R

Accuracy?

The real value of the substance tested is obtained. Samples used to establish accuracy of qualitative tests must include both positive and negative samples.

VER 6 R

Precision?

When the results are reproducible upon repetitive testing.

Precision studies must encompass day-to-day, run-to-run, within-run precision, and must include at least two levels for quantitative tests. For non-automated tests, involve various testing personnel who routinely run the tests.