The following changes were made to the A3 Definitions:

**Re: A.3 Analyte** - used in relation to Proficiency Testing refers to all Class I or Class II locus tests for a single sample for any method or combination of methods or any level of resolution that is reported and graded separately. A method is graded separately if it serves as a “stand-alone test” for the analyte.

**Calibration verification**: A process of confirming that the current calibration settings remain valid.

**Qualitative test**: An assay that detects the presence or absence of a specific analyte, but does not determine the specific amount of the analyte.

**Semi-Quantitative test**: An assay that does not measure the precise amount of a substance, but provides an estimate of how much of a detected substance is present. Results for semi-quantitative tests may be expressed in units, median fluorescence intensity (MFI), titers, etc.

**Re: A.3 Semi-Quantitative test** - Even though a semi-quantitative test provides a numerical result, the number must not be interpreted as a quantitative measurement.

**Quantitative test**: An assay that measures the amount of an analyte in a specimen and reports the results in units traceable to a recognized standard.

**Qualitative method**: An assay that detects the presence or absence of a specific analyte, but does not determine the specific concentration of the analyte.

**Quantitative method**: An assay that measures the amount of an analyte in a specimen and reports the results in units traceable to a recognized standard.

**Reportable range**: The span of test result values over which the laboratory can establish and verify the accuracy of the instrument or test system.
Re: C.2.1 - Note: For any CMS Regulated Analyte, e.g., serologic ABO/RhD Typing, CLIA-certified laboratories must have a mechanism for reporting each PT survey’s results to CMS at the time the results are available. ABO/RhD by DNA methods may be performed to predict the ABO/RhD phenotype. The use of molecular DNA based screening assays is not acceptable for ABO and RhD assignment for the purposes of transfusion or transplantation. Laboratories performing molecular ABO/RhD genotyping must participate in PT (e.g. shared samples with another laboratory or in-house comparisons) with satisfactory performance of at least 80% concordance. 100% concordance is required for serological ABO/RhD testing.

D.2.9.2.5.1 Procedures, including appropriate diluent, for performing dilutions on samples with results falling above the reportable range.

D.4.1.5.2.1.3 Reportable range of test results for a quantitative test system or values for a qualitative or semi-quantitative test system.

D.4.1.8.3 Controls as Calibration Materials: Controls provided by manufacturers in a test kit are considered to be calibration materials if they are used to calculate the cutoff value of a test or a patient test result.

D.4.1.8.4 Testing of Additional External Controls: If the manufacturer’s instructions include a formula which uses the positive and/or negative controls included in the kit to determine the cutoff value of a test or a patient test result, additional external positive and/or negative controls must also be tested.

D.4.1.8.6.2.2 For each qualitative and semi-quantitative procedure, include a negative and positive control material.

D.5.3.3.1.4 In the case of cord blood units, ensure verification typing is performed prior to shipment verify the HLA assignment using a sample obtained from a contiguous segment or from the unit itself.

Re: 5.3.3.1.4 - It is recommended that the laboratory serving the HCT program perform an additional verification typing on the shipped unit to verify the correct unit was received.