



Section 1), these reasons must be documented in the QC section of the test method. See 1.5 and Explanation 1 in [Appendix X1](#).

5. Significance and Use

5.1 In order to be certain that the end user of analytical results obtained from using an ASTM Committee D19 test method can be confident that the values have been obtained through a competent application of the test method, a demonstration of the proficiency of the analytical system must be performed. Appropriate proficiency is demonstrated by achievement of performance criteria derived from results of the test method collaborative study. The QC measures specified in this practice must be included in each ASTM test method, as applicable, to ensure the quality of measurements.

5.2 In order for users of D19 test methods to achieve consistently valid results, a minimum level of QC must be performed. This minimum level of QC is stipulated in this practice and by the task groups developing D19 test methods. If the specific requirements outlined in this practice are not applicable to the test method, alternative QC must be defined in the test method.

6. Requirements for QC Specifications in Test Methods

6.1 Every test method must have a quality control (QC) section. Listed below are requirements applicable to nearly all chemical test methods and that must be followed to ensure that the test method is in control and to validate the accuracy of data generated for a specific matrix.

6.1.1 The measures that must be specified in the QC section of test methods and the reasons for these measures are as follows:

6.1.1.1 Calibration and calibration verification are necessary to ensure that the analytical system is properly calibrated during the period that the analysis is performed.

6.1.1.2 An initial demonstration of laboratory capability is necessary to prevent errors as a result of unfamiliarity with the test.

6.1.1.3 Analysis of a blank with each batch may indicate that analytes in a test sample are the result of contamination.

6.1.1.4 An LCS is run with each batch to determine that the measurement system is in control at the time samples are being analyzed.

6.1.1.5 An MS (recovery check) provides information on the bias of the test method in a specific matrix.

6.1.1.6 A duplicate analysis (Dup) or duplicate of the MS (matrix spike duplicate; MSD) indicates the repeatability of the method for a specific matrix.

6.1.1.7 An IRM is analyzed periodically to validate the accuracy of the test system and standards used for calibration.

6.1.2 In addition to the QC measures required above, each test method should contain a detection limit and a quantitation limit so that there is an indication of the lowest level at which the substance(s) determined by the test method can be detected and measured.

6.1.3 Statistical tests should be done at a significance level of $\alpha \leq 0.01$, that is, $\geq 99\%$ confidence level. If other levels are specified, the reason for deviation should be delineated in the test method.

6.1.4 The operational principles and characteristics of detectors used for radioactivity measurements are somewhat different from those of instruments used for measurements of chemical and physical properties. Therefore, authors of ASTM test methods for radioactivity measurements should provide specific guidance within each test method, practice, or guide relative to applicable QC program requirements. Guidance on the preparation and use of instrument tolerance and control charts can be found in Practices [D3648](#), Guide [D3856](#), and ASTM MNL 7.⁴

6.2 *Calibration and Calibration Verification*—For test methods requiring calibration of instrumentation, an appropriate number of calibration standards must be analyzed during day that an analysis is performed to confirm that the instrument is properly set up and required sensitivity is being obtained. The actual number of standards required will depend on the requirements of the test method. For tests run infrequently, analysis of a single calibration standard to verify an existing calibration curve may suffice. For tests run frequently, it may be necessary to intersperse verification standards with test samples. Under these circumstances, it is recommended that a different standard concentration be used each time calibration is verified. Raw data (absorbance, intensity, etc.) should be compared to data generated in the past under the same conditions and should fall within three standard deviations of the mean value found in the past based on the pooled single operator precision. Alternatively, data should be compared to the calibration limits stated in the test method or should be developed from collaborative study data. Refer to Guide [D3856](#) and Practices [D3648](#) for further information on calibration checks.

6.2.1 For titrimetric test methods, titrants must be standardized on a scheduled basis against a standard solution of known concentration in duplicate or triplicate. The average normality/molarity is then used for calculation. The frequency of standardization is left to the judgment of the writer of the test method and should be based on the stability of the titrant.

6.2.2 An alternate calibration procedure, such as an internal standard, external standard, or single-point calibration procedure, must be specified in the test method.

6.2.3 The test method must establish the frequency of calibration and calibration verification.

6.3 *Initial Demonstration of Laboratory Capability*—A test must be included in the test method to confirm that the laboratory is capable of running the test method and generating acceptable data. This test of laboratory capability will vary depending on the test method. Whenever appropriate, a precision and bias (as recovery) test is performed. For most test methods this can be done by analyzing at least seven replicates of a standard solution prepared from a reference material containing the analyte at one of the concentration levels used in the collaborative study. The matrix and chemistry of the solution should be such that, when spiked, results statistically equivalent to results produced in the collaborative study should be produced. Each of the replicates should be presented to the

⁴ ASTM Manual on Presentation of Data and Control Chart Analysis, ASTM MNL 7.

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