

Standard Guide for Quality Control and Quality Assurance Procedures for Aromatic Hydrocarbons and Related Materials¹

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1. Scope

1.1 This guide contains non-mandatory Quality Assurance/ Quality Control (QA/QC) activities that may be referenced in standards maintained by ASTM Committee D16 on Aromatic Hydrocarbons and Related Materials.

1.2 This guide does not purport to address all of the issues that may be pertinent to an active QA/QC process.

1.3 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.

2. Referenced Documents

2.1 ASTM Standards:

- D 4790 Terminology of Aromatic Hydrocarbons and Related Chemicals $^{2}\,$
- E 177 Practice for the Use of the Terms Precision and Bias in ASTM Test Methods³
- E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method³

2.2 ASTM Document:

MNL7 Manual on Presentation of Data Control Chart Analysis, 6th Edition, Section 3: Control Charts for Individuals⁴

2.3 Other Documents:

Western Electric Company, Inc., Statistical Quality Control Handbook (1982)⁵

Juran's Quality Control Handbook, Fourth Edition (1988)⁶

3. Terminology

3.1 Definitions:

3.1.1 precision-the degree of agreement of repeated mea-

² Annual Book of ASTM Standards, Vol 06.04.

³ Annual Book of ASTM Standards, Vol 14.02.

surement of the same property, expressed in terms of dispersion of test results about an arithmetical mean result obtained by repetitive testing of a homogeneous sample under specified conditions. The precision of a test method is expressed quantitatively as a standard deviation computed from the results of a series of controlled determinations. **D 4790**

3.1.2 quality assurance—the general activity of providing evidence needed to establish confidence that the quality function is being effectively performed; may include quality planning, quality control, quality improvement, quality audit, and reliability. **Juran's Quality Control Handbook** 3.1.3 quality control—the specific tools, skills, or techniques through which the quality function is carried out, can be part of a control process, for example, product inspection. **Juran's Quality Control Handbook**

4. Summary of Guide

4.1 This guide contains non-mandatory information to be considered for reference in all ASTM Committee D16 standards on aromatic hydrocarbons and related materials. This information is provided as a QA/QC system guide for D16 standard users who do not have an active QA/QC process in their laboratory.

5. Significance and Use

5.1 Quality Control and Quality Assurance practices are important for the optimum operation of testing laboratories using D16 methods for aromatic hydrocarbons and related materials. Quality procedure guidelines, like those described in this document or other suitably correct QA/QC-related reference, can be useful to optimally perform these methods.

6. Quality Procedure Guidelines

6.1 *Statistical Control*—To establish the statistical control status of the testing process since the last valid calibration, quality control (QC) samples should be regularly tested as if they were routine samples. Results should be recorded and immediately analyzed by control charts, as described in MNL7, or other statistically equivalent techniques. Any out-of-control data should provide an immediate trigger for an investigation of root cause(s) that might require corrective action.

6.2 Selection of the QC Sample—Choose an ample quantity of a homogeneous material that is representative of the

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⁴ Available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

⁵ Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

⁶ Available from McGraw-Hill Inc, St. Louis, MO.

sample(s) routinely being tested with the testing process, and capable of being stored without degradation over the intended period of use. Carefully consider the matrix, interfering species, and analyte concentration/value. Primary standard materials may be used to characterize the precision and bias of the method, as described in Practice E 177.

6.3 *Control Charting*—Use any valid statistical charting technique for variables (for example, individuals/range, CUSUM, subgroups, moving averages, etc., as described in MNL7) where appropriate.

6.4 *QC Material Statistics*—Obtain a minimum of 16 data points (24 is better) when a new QC material is started or an existing QC material requires replacement (for example, due to contamination or depleted supply), to establish a statisticallyacceptable mean, and upper and lower control limits. Fewer data points will produce less acceptable control determinations, and are acceptable only if absolutely necessary. QC material testing precision should be compared periodically with ASTM method precision (as developed using Practice E 691) where possible. If the QC test precision is considerably worse than the ASTM method precision, continuous improvement activity should be initiated to improve the QC test precision.

6.5 Out-of-Control Data Points-Any QC sample data

point outside the upper or lower control limits, or that violates any other valid statistical rule being used in the facility (for example, Western Electric SQC Handbook), should be considered out-of-control. Such a result should trigger an investigation to determine the root cause, and the implementation of appropriate corrective action(s).

6.6 *Frequency of QC Sample Testing*—For routine testing (for example, plant quality control), QC testing frequency is dependent on the criticality of the parameter being measured, the demonstrated stability of the testing process, and customer requirements. Generally, QC samples should be analyzed at a defined frequency with samples. Additional QC sample testing is also recommended after a change is made relating to the method (for example, replenishment of reagents, change of analyst, maintenance of instrument, etc.). For non-routine testing (for example, R&D process development), the analyst should determine an appropriate QC testing frequency to meaningfully monitor test performance.

7. Keywords

7.1 aromatic hydrocarbons; quality; quality assurance; quality control

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