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Standard Practice for Use of the Terms Precision and Bias in ASTM Test Methods[1]

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1. Scope

1.1 The purpose of this practice is to present concepts necessary to the understanding of the terms "precision" and "bias" as used in quantitative test methods. This practice also describes methods of expressing precision and bias and, in a final section, gives examples of how statements on precision and bias may be written for ASTM test methods.

NOTE 1—The term "accuracy", used in earlier editions of Practice E 177, embraces both precision and bias (see Section 20 and Note 4).

1.2 Informal descriptions of the concepts are introduced in the text as the concepts are developed, and appear in the following sections:

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 limitations prior to use.*

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2. Referenced Documents

2.1 *ASTM Standards:*

E 178 Practice for Dealing with Outlying Observations[2]

E 456 Terminology Relating to Quality and Statistics[2]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[2]

E 1169 Guide for Conducting Ruggedness Tests[2]

2.2 *ANSI/ASQC Standard:*

A1-1978 Definitions, Symbols, Formulas and Tables for Control Charts[3]

2.3 *Other Documents:*

TAPPI Collaborative Reference Program, Reports 25 through 51, Aug. 1973 through Jan. 1978[4]

[1] This practice is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.20 on Test Method Evaluation and Quality Control.

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[2] *Annual Book of ASTM Standards*, Vol 14.02.

[3] Available from American Society for Quality Control, 230 West Wells St., Milwaukee, WI 53203.

[4] Available from the Technical Association of the Pulp and Paper Industry, Technology Park/Atlanta, P.O. Box 105113, Atlanta, GA 30348.

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ASQC Glossary and Tables for Statistical Quality Control[3]

3. Terminology

3.1 The terminology defined in Terminology E 456 applies in all areas affected by this practice, except where modified by this practice.

3.2 This practice is specifically concerned with the development of statements on precision and bias for inclusion as descriptors of the performance of a test method. This application requires refinement of the Terminology E 456 definitions, as discussed herein.

3.3 The informal descriptions of concepts developed in this practice have been collected in Appendix X1, and have been arranged alphabetically for easy reference.

4. Significance and Use

4.1 Part A of the "Blue Book," *Form and Style for ASTM Standards*, requires that all test methods include statements of precision and bias. This practice discusses these two concepts and provides guidance for their use in statements about test methods.

4.2 *Precision*—A statement of precision allows potential users of a test method to assess in general terms the test method's usefulness with respect to variability in proposed applications. A statement on precision is not intended to contain values that can be exactly duplicated in every user's laboratory. Instead, the statement provides guidelines as to the kind of variability that can be expected between test results when the method is used in one or more reasonably competent laboratories. For a discussion of precision, see Section 18.

4.3 *Bias*—A statement on bias furnishes guidelines on the relationship between a set of typical test results produced by the test method under specific test conditions and a related set of accepted reference values (see Section 19).

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GENERAL CONCEPTS

5. Test Method

5.1 Section 2 of the ASTM Regulations describes a *test method* as "a definitive procedure for the identification, measurement, and evaluation of one or more qualities, characteristics, or properties of a material, product, system or service that produces a test result."

5.2 In this practice only quantitative test methods that produce numerical results are considered. Also, the word "material" is used to mean material, product, system or service; the word "property" is used herein to mean that a quantitative test result can be obtained that describes a characteristic or a quality, or some other aspect of the material; and "test method" refers to both the document and the procedure described therein for obtaining a quantitative test result for one property. For a discussion of test result, see Section 9.

5.3 During its development, a test method should be subjected to a screening procedure and ruggedness test in order to establish the proper degree of control over factors that may affect the test results (see Guide E 1169).

NOTE 2—A screening procedure or ruggedness test is a procedure for investigation of the effects of variations in environmental and other pertinent factors on the test results obtained from a test in order to determine how control of such factors should be specified in the written description of the method. For example, temperature of the laboratory or of a heating device used in the test may have a significant effect in some cases and less in others. In a screening procedure, deliberate variations in temperature would be introduced to establish the limits of significant effect, **(1, 2, 3)**.[5]

5.4 A well-written test method specifies control over such factors as the test equipment, the test environment, the qualifications of the operator (explicitly or implicitly), the preparation of test specimens, and the operating procedure for using the equipment in the test environment to measure some property of the test specimens. The test method will also specify the number of test specimens required and how measurements on them are to be combined to provide a test result (Section 9), and might also reference a sampling procedure appropriate for the intended use of the method.

5.5 It is necessary that the writers of the test method provide instructions or requirements for every known outside influence.

6. Measurement Terminology

6.1 The following terms have been used to describe both the measurement process and the partial or complete result of the process: measurement, observation, observed value, test, test determination, test result, and others. These terms have often been used loosely and interchangeably.

6.2 For clarity, it is necessary to select certain of these terms for specific use. However, the word "measurement" will be used in a generic sense to cover observation (or observed value), test determination and test result. The use of the word "test" by itself is discouraged.

6.3 A quantitative test method may have three distinct stages: (*1*) the direct measurement or observation of dimensions or properties; (*2*) the arithmetical combination of the observed values to obtain a single determination; and (*3*) the arithmetical combination of a number of determinations to obtain the test result of the test method. These three stages are explained and illustrated in Sections 7-9.

7. Observation

7.1 For the purposes of this practice, *observation* or *observed value* should be interpreted as the most elemental single reading or corrected reading obtained in the process of making a measurement. This statement is a narrower interpretation than is given in Terminology E 456 in that the latter applies to nonquantitative as well as quantitative test methods.

7.2 An observation may involve a direct reading (for example, a zero-adjusted micrometer reading of the thickness of a test strip at one position along the strip) or it may require the interpolation of the reading from a calibration curve.

8. Test Determination

8.1 For a quantitative test method, a *test determination* may be described as (*1*) the process of calculating from one or more observations a property of a single test specimen, or as (*2*) the

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.

value obtained from the process. Thus, the test determination may summarize or combine one or more observations.

8.2 *Examples*:

8.2.1 The measurement of the density of a test specimen may involve the separate observation of the mass and the volume of the specimen and the calculation of the ratio mass/volume. The density calculated from the ratio of one pair of mass and volume observations made on one specimen is a test determination.

8.2.2 The determination of the thickness of a test specimen strip may involve averaging micrometer caliper observations taken at several points along the strip.

9. Test Result

9.1 A *test result* is the value obtained by carrying out the complete protocol of the test method once, being either a single test determination or a specified combination of a number of test determinations.

9.2 In general, a test method describes not only the manner in which each test determination is to be made, but also the number of test determinations to be made and how these are to be combined to provide the test result.

9.3 *Examples*:

9.3.1 The test method on density might require that the mass and volume observations of a specimen be combined to give a test determination of density (8.2.1) and the test determination of each of five specimens be averaged to give a test result.

9.3.2 The test method for paper thickness may require that the determination of strip thickness in 8.2.2 be made on ten strips and that the ten test determinations be averaged to give the test result.

9.3.3 The test method for a tensile strength test of paper may specify that a tensile strength determination be performed on each of ten specimens and that the ten tensile test determinations be averaged to get the test result.

9.3.4 In chemical analyses a variety of situations may occur. Thus, in some cases, the method may call for the preparation of a single solution from a test unit, and measurement on three aliquots (specimens) of the solution made up to a specified volume. The average of the three analytical determinations would then be called the test result. In other cases of chemical analysis, the method may call for two individual test determinations, each one made on a different specimen with recalibration of the measuring instrument for each of the two determinations. The average of the two determinations would then be the test result.

9.3.5 In rubber testing, the method may describe not only the shape of the test specimen to be taken from a sheet of rubber, but also the preparation of the sheet, including compounding and curing. For example, one rubber test method specifies that four sheets be individually compounded and cured and three specimens tested from each sheet. The test result is then defined as the average of the four medians, each median being the middle determination, in the order of magnitude, of the three values obtained from a sheet.

9.3.6 Some test methods, such as those for analytical chemistry, involve calibration with known standard substances. The originally collected test determinations may be subjected to complex computational and statistical treatment prior to being converted into a test result. Such treatment might include separation of the analytical response for the substance of interest from the chromatographic absorption data, elimination or other treatment of outliers (see Practice E 178) in the data for the known standard substances, and preparation of a calibration curve to determine the test result.

9.4 Precision statements for ASTM test methods are applicable to comparisons between test results, not test determinations nor observations, unless specifically and clearly indicated otherwise (see Section 18).

SOURCES OF VARIABILITY

10. Experimental Realization of a Test Method

10.1 A realization of a test method refers to an actual application of the test method to produce a test result as specified by the test method. The realization involves an *interpretation* of the written document by a *specific test operator*, who uses a *specific unit and version of the specified test apparatus*, in the *particular environment* of his testing laboratory, to evaluate a *specified number of test specimens* of the material to be tested. Another realization of the test method may involve a change in one or more of the above emphasized experimental factors. The test result obtained by another realization of the test method will usually differ from the test result obtained from the first realization. Even when none of the experimental factors is intentionally changed, small changes usually occur. The outcome of these changes may be seen as variability among the test results.

10.2 Each of the above experimental factors and all others, known and unknown, that can change the realization of a test method, are potential sources of variability in test results. Some of the more common factors are discussed in Sections 11-15.

11. Operator

11.1 *Clarity of Test Method*—Every effort must be made in preparing an ASTM standard test method to eliminate the possibility of serious differences in interpretation. One way to check clarity is to observe, without comment, a competent laboratory technician, not previously familiar with the method, apply the draft test method. If the technician has any difficulty, the draft most likely needs revision.

11.2 *Completeness of Test Method*—It is necessary that technicians, who are generally familiar with the test method or similar methods, not read anything into the instructions that is not explicitly stated therein. Therefore, to ensure minimum variability due to interpretation, procedural requirements must be complete.

11.2.1 If requirements are not explicitly stated in the test method (see 5.5), they must be included in the instructions for the interlaboratory study (see Practice E 691).

11.3 *Differences in Operator Technique*—Even when operators have been trained by the same teacher or supervisor to give practically identical interpretations to the various steps of the test method, different operators (or even the same operator at different times) may still differ in such things as dexterity, reaction time, color sensitivity, interpolation in scale reading, and so forth. Unavoidable operator differences are thus one source of variability between test results. The test method

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should be designed and described to minimize the effects of these operator sources of variability.

12. Apparatus

12.1 *Tolerances*—In order to avoid prohibitive costs, only necessary and reasonable manufacturing and maintenance tolerances can be specified. The variations allowed by these reasonable specification tolerances can be one source of variability between test results from different sets of test equipment.

12.2 *Calibration*—One of the variables associated with the equipment is its state of calibration, including traceability to national standards. The test method must provide guidance on the frequency of verification and of partial or complete recalibration; that is, for each test determination, each test result, once a day, week, etc, or as required in specified situations.

13. Environment

13.1 The properties of many materials are sensitive to temperature, humidity, atmospheric pressure, atmospheric contaminants, and other environmental factors. The test method usually specifies the standard environmental conditions for testing. However, since these factors cannot be controlled perfectly within and between laboratories, a test method must be able to cope with a reasonable amount of variability that inevitably occurs even though measurement and adjustment for the environmental variation have been used to obtain control (see 17.2). Thus, the method must be both robust to the differences between laboratories and require a sufficient number of test determinations to minimize the effect of within-laboratory variability.

14. Sample (Test Specimens)

14.1 A lot (or shipment) of material must be sampled. Since it is unlikely that the material is perfectly uniform, sampling variability is another source of variability among test results. In some applications, useful interpretation of test results may require the measurement of the sampling error. In interlaboratory evaluation of test methods to determine testing variability, special attention is required in the selection of the material sample (see 18.4 and Practice E 691) in order to obtain test specimens that are as similar as possible. A small residual amount of material variability is almost always an inseparable component of any estimate of testing variability.

15. Time

15.1 Each of the above sources of variability (operator performance, equipment, environment, test specimens) may change with time; for example, during a period when two or more test results are obtained. The longer the period, the less likely changes in these sources will remain random (that is, the more likely systematic effects will enter), thereby increasing the net change and the observed differences in test results. These differences will also depend on the degree of control exercised within the laboratory over the sources of variability. In conducting an interlaboratory evaluation of a test method, the time span over which the measurements are made should be kept as short as reasonably possible (see Sections 23 and 24).

STATISTICAL CONCEPTS

16. Accepted Reference Value

16.1 A measurement process is generated by the application of a test method. Variability can be introduced unintentionally into the measurement process through the impact of many sources, such as heterogeneity of the material, state of maintenance and calibration of equipment, and environmental fluctuations (Sections 10-15). The variability may include systematic as well as random components. The systematic components may be evaluated (Section 19) if an accepted reference value is available. An *accepted reference value*, according to Terminology E 456, is a value that serves as an agreed-upon reference for comparison. It may be:

(*1*) a theoretical or established value based on scientific principles;

(*2*) an assigned value based on experimental work of some national or international organization such as the U.S. National Institute of Standards and Technology;

(*3*) a consensus value based on collaborative experimental work under the auspices of a scientific or engineering group; or

(*4*) for a specific application, an agreed upon value obtained using an accepted reference method.

16.2 When the accepted reference value is the theoretical value, it is sometimes referred to as the "true" value, but this usage is not recommended.

17. Statistical Control

17.1 A process is in a *state of statistical control* if the variations between the observed test results from it can be attributed to a constant system of chance causes. This is a modification of the definition of a "a state of statistical control" given in ANSI/ASQC Standard A 1-1978 (or the 1983 ASQC Glossary and Tables for Statistical Quality Control) by using the term "test results" in place of "sampling results". By "chance causes" is meant unknown factors, generally numerous and individually of small magnitude, that contribute to variation, but that are not readily detectable or identifiable.

17.2 The measurement process is in a state of statistical control when the test results obtained vary in a predictable manner, showing no unassignable trends, cycles, abrupt changes, excess scatter, or other unpredictable variations as determined by application of appropriate statistical methods. The ensurance of a state of statistical control is not a simple matter **(4)**, but may be helped by the use of control charts (see Part 3, STP 15D) **(5, 6)**.

17.2.1 If the set of test results to be considered in terms of statistical control is obtained in different laboratories, it may be possible to view the laboratories as a "sample" of all qualified laboratories that are likely to use the given test method, or as a set comprising a special category of such laboratories, and that the differences between the laboratories represent random variability. "Qualified" may mean, for example, laboratories that have used this test method for a year or more.

17.3 The presence of outliers (Practice E 178) may be evidence of a lack of statistical control in the production process or in the measurement process. It is quite proper to discard outliers for which a physical explanation is known.

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Discarding outliers in the measurement process on the basis of statistical evidence alone may yield biased results since one can truly measure the value of the property of interest only if the measurement process is in control. The presence of one or more outliers may indicate a weakness in the test method or its documentation.

17.4 The discussion in succeeding sections assumes that the measurement process is in a state of statistical control for some specified set of conditions. If measurements are all to be made in a given laboratory, for example, any systematic deviation from the expected value pertinent to that laboratory will show up as a bias for measurements made under the prescribed conditions (see Section 19).

18. Precision

18.1 The *precision* of a measurement process, and hence the stated precision of the test method from which the process is generated, is a generic concept related to the closeness of agreement between test results obtained under prescribed like conditions from the measurement process being evaluated. The measurement process must be in a state of statistical control; else the precision of the process has no meaning. The greater the dispersion or scatter of the test results, the poorer the precision. (It is assumed that the least count of the scale of the test apparatus is not so poor as to result in absolute agreement among observations and hence among test results.) Measures of dispersion, usually used in statements about precision, are, in fact, direct measures of imprecision. Although it may be stated quantitatively as the reciprocal of the standard deviation, precision is usually expressed as the standard deviation or some multiple of the standard deviation (see Section 27).

18.2 A measurement process may be described as precise when its test results are in a state of statistical control and their dispersion is small enough to meet the requirements of the testing situations in which the measurement process will be applied. The test results of two different processes expressed in the same units may be statistically compared as to precision, so that one process may be described as more (or less) precise than the other.

18.3 The precision of the measurement process will depend on what sources (Sections 10-15) of variability are purposely included and may also depend on the test level (see Section 21). An estimate of precision can be made and interpreted only if the experimental situation (prescribed like conditions) under which the test results are obtained is carefully described. There is no such thing as *the* precision of a test method; a separate precision statement will apply to each combination of sources of variability. The precision of a particular individual test result depends on the prescribed conditions for which it is considered a random selection. For example, will it be compared with other results obtained within the laboratory or with results obtained in other laboratories? No valid inferences on the precision of a test method or a test result can be drawn from an individual test result.

18.4 In order to minimize the effect of material variability in evaluating the precision of a test method, it is desirable to select a relatively uniform material for each of several test levels (magnitudes) chosen for the property being tested (see Practice E 691 for further information).

19. Bias

19.1 The *bias* of a measurement process is a generic concept related to a consistent or systematic difference between a set of test results from the process and an accepted reference value of the property being measured. The measuring process must be in a state of statistical control; otherwise the bias of the process has no meaning. In determining the bias, the effect of the imprecision is averaged out by taking the average of a very large set of test results. This average minus the accepted reference value is an estimate of the bias of the process (test method). Therefore, when an accepted reference value is not available, the bias cannot be established.

19.2 The magnitude of the bias may depend on what sources of variability are included, and may also vary with the test level and the nature of the material (see Section 21).

19.3 When evaluating the bias of a test method, it is usually advisable to minimize the effect of the random component of the measurement error by using at each test level the average of many (30 or more) test results, measured independently, for each of several relatively uniform materials, the reference values for which have been established by one of the alternatives in 16.1 (see 23.3 and 25.3).

19.4 If the bias of a test method is known, an adjustment for the bias may be incorporated in the test method in the section on calculation or in a calibration curve and then the method would be without bias.

19.5 The concept of bias may also be used to describe the systematic difference between two operators, two test sites (see 23.3), two seasons of the year, two test methods, and so forth. Such bias is not a direct property of the test method, unless one of the test sites or test methods provides the accepted reference value. The effect of such bias may be reflected in the measured reproducibility of the test method.

20. Accuracy

20.1 Accuracy is a generic concept of exactness related to the closeness of agreement between the average of one or more test results and an accepted reference value. Unless otherwise qualified, the use of the word “accuracy” by itself is to be interpreted as the accuracy of a test result. The *accuracy of a test result* is the closeness of agreement between the test result and the accepted reference value. It depends on both the imprecision and the bias of the test method.

20.2 There are two schools of thought on defining the *accuracy of a measuring process* **(5, 7).** In either case, the measurement process must be in a state of statistical control, otherwise the accuracy of the process has no meaning:

20.2.1 The closeness of agreement between the accepted reference value and the average of a large set of test results obtained by repeated applications of the test method, preferably in many laboratories.

20.2.2 The closeness of agreement between the accepted reference value and the individual test results **(8, 9).**

20.3 In 20.2.1 the imprecision is largely eliminated by the use of a large number of measurements and the accuracy of the measuring process depends only on bias. In 20.2.2 the imprecision is not eliminated and the accuracy depends on both bias and imprecision. In order to avoid confusion resulting from use

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of the word "accuracy", only the terms precision and bias should be used as descriptors of ASTM test methods.

21. Variation of Precision and Bias with Material

21.1 A test method is intended to cover a class of materials. Any one material within the class differs from any other in the following two basic ways: the level of the property that is being measured; and the matrix of the material. The matrix is the totality of all properties, other than the level of the property to be measured, that can have an effect on the measured value. Thus the precision and the bias of the test method may be functions of the property level and of the material matrix.

21.2 In some cases, a test method may be intended to be applied to more than one class of materials. If so, it may be advisable to provide separate statements of precision for each class (see 31.3).

22. Variation of Precision and Bias with Sources of Variability

22.1 The precision and bias of test results obtained by repeated applications of a test method depend upon what combinations of the sources of variability (Sections 10-15) affect the variability of the test results. For example, test results obtained by all possible operators within one laboratory using one set of test apparatus would have a bias based in part on that laboratory's apparatus and environment and a precision that would depend in part on the quality of training and supervision of operators in that laboratory. Many combinations of sources of variability are possible. Some of the combinations used by ASTM committees are described in Sections 23-25.

COMBINATIONS OF SOURCES OF VARIABILITY (TYPES OF PRECISION AND BIAS)

23. Repeatability and Laboratory Bias

23.1 *Within-Laboratory Precision*—Information about a frequently used within-laboratory precision, sometimes called single-operator-day-apparatus precision, can be obtained from at least the three experimental situations described in 23.1.1-23.1.3, the last situation being most reliable; that is, the estimate of this precision is improved progressively by pooling additional information.

NOTE 3—If the test method requires a series of steps, the "single-operator-equipment" requirement means that for a particular step the same combination of operator and equipment is used for every test result and on every material. Thus one operator may prepare the test specimens, a second measure the dimensions and a third measure the breaking force. The "single-day" requirement means that the test results, at least for a particular material are obtained in the shortest practical period of time, whether this be a fraction of a day or several days.

23.1.1 *Precision From an Experiment Involving One Operator, Day and Apparatus*—A single, well-trained operator using one set of equipment obtains two or more test results in a short period of time during which neither the equipment nor the environment is likely to change appreciably. The variability is due primarily to small changes in equipment, calibration, reagents, environment, and operator's procedure, and possibly to some heterogeneity in the material tested. The last is kept small by use of test specimens from a reasonably uniform lot of material. The precision estimate for this operator, day, and equipment is determined from the variability of the test results. In this situation and the other experiments listed below, all potential sources of variability must be carefully controlled within the tolerances specified in the test method.

23.1.2 *Precision from Repeated Experiments Within a Laboratory*—In order to get an expression of precision that applies to any operator and day with a specific set of equipment at a given laboratory, the experiment of 23.1.1 must be repeated on different days by the same and different operators. Then the precision estimates, obtained as in 23.1.1, for each operator-day combination must be suitably combined or pooled to obtain an estimate of single-operator-day precision that applies to this laboratory and equipment. If the laboratory has several sets of equipment for this test method, the experiment may be enlarged to include tests on each set of equipment and the test results pooled in order to obtain an overall single-operator-day-equipment precision for that laboratory.

23.1.3 *Precision from Within-Laboratory Experiments in Several Laboratories*—In order to obtain an estimate of within-laboratory precision that is characteristic of the test method and may reasonably be applied to any laboratory, the whole within-laboratory experiment of 23.1.2 could be repeated in a number of laboratories. Alternatively, this desired broadly-applicable estimate may be obtained by pooling within-laboratory information from only one operator-day-equipment combination carried out in each of a number of laboratories. Although only one operator, one day, and one set of equipment are combined in each laboratory, the use of many laboratories, as in an interlaboratory study such as described in Practice E 691, provides an evaluation based on many operators, many days and many units of equipment. This abbreviated approach, only one operator-day-equipment combination in each laboratory, is based on the assumption that this estimate of within-laboratory precision does not change, or should not be expected to change, significantly from laboratory to laboratory. Consequently, this measure of precision can be treated as a characteristic of the test method. This pooled within-laboratory precision is called the **repeatability** of the test method.

23.2 *Repeatability Conditions*—While other conditions (Section 24) have sometimes been used for obtaining repeated test results in the determination of repeatability, the preferred conditions (illustrated above in 23.1-23.1.3) are those under which test results are obtained with the same test method in the same laboratory, by the same operator with the same equipment, in the shortest practical period of time, using test units or test specimens (see Practice E 691, 10.3) taken at random, from a single quantity of material that is as nearly homogeneous as possible. For meaning of "same operator, same equipment" and" shortest practical period of time," see Note 3 above.

23.3 *Repeatability*—The closeness of agreement between test results obtained under repeatability conditions.

23.4 *Bias of a Particular Laboratory*, relative to the other laboratories may be calculated by averaging test values obtained as described in 23.1.2 for that laboratory and comparing the result with the average of all test values obtained as described in 23.1.3. The *bias of the test method* may be calculated by comparing the latter average with the accepted

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