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Designation: E 1488 – 02ϵ1

An American National Standard

Standard Guide for Statistical Procedures to Use in Developing and Applying Test Methods[1]

This standard is issued under the fixed designation E 1488; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

ϵ[1] NOTE—The introduction was deleted editorially in March 2003.

1. Scope

1.1 This guide identifies statistical procedures for use in developing new test methods or revising or evaluating existing test methods, or both.

1.2 This guide also cites statistical procedures especially useful in the application of test methods.

2. Referenced Documents

2.1 *ASTM Standards:*

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications[2]

E 105 Practice for Probability Sampling of Materials[2]

E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process[2]

E 141 Practice for Acceptance of Evidence Based on the Results of Probability Sampling[2]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[2]

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]

E 1301 Guide for Proficiency Testing by Interlaboratory Comparisons[2]

E 1325 Terminology Relating to Design of Experiments[2]

E 1402 Terminology Relating to Sampling[2]

2.2 *ISO Standards:*

ISO 5725 Accuracy (Trueness and Precision) of Measurement Methods and Results[3]

ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories[3]

ISO Guide to the Expression of Uncertainty in Measurement[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *statistical procedures*, *n*—the organized techniques and methods used to collect, analyze, and interpret data.

3.1.1.1 *Discussion*—Statistical procedures include the sampling considerations or the experiment design for the collection of data, or both, and the numerical and graphical approaches to summarize and analyze the collected data.

3.2 For all other formal definitions of statistical terms, see Terminology E 456.

4. Significance and Use

4.1 All ASTM test methods are required to include statements on precision and bias.[4]

4.2 Since ASTM began to require all test methods to have precision and bias statements that are based on interlaboratory test methods, there has been increased concern regarding what statistical experiments and procedures to use during the development of the test methods. Although there exists a wide range of statistical procedures, there is a small group of generally accepted techniques that are very beneficial to follow. This document is designed to provide a brief overview of these procedures and to suggest an appropriate sequence of carrying out these procedures.

4.3 Statistical procedures often result in interpretations that are not absolutes. Sometimes the information obtained may be inadequate or incomplete, which may lead to additional questions and the need for further experimentation. Information outside the data is also important in establishing standards and in the interpretation of numerical results.

[1] This guide 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.

Current edition approved Oct. 10, 2002. Published December 2002. Originally published as E 1488 – 92. Last previous edition E 1488 – 96.

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

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[4] See the Form and Style Manual for ASTM Standards that specifies, when possible, precision statements shall be estimated based on the results of an interlaboratory test program.

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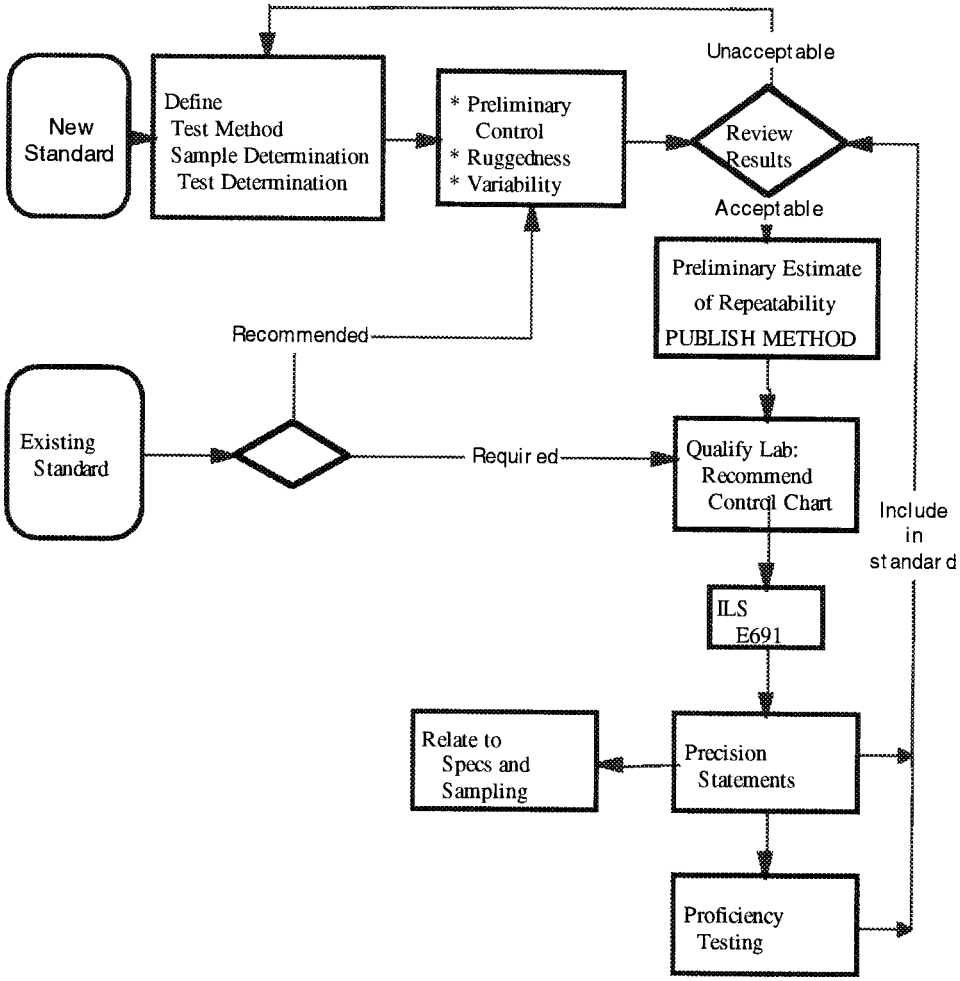

FIG. 1 Sequence of Steps

5. Summary of Guide

5.1 Outlined below is a suggested sequence of four phases useful in the development of a test method. A flowchart is provided in Fig. 1. Such a sequence of analyses may need to be modified in specific situations. The assistance of a qualified statistician is recommended at each review phase.

5.2 *Design Phase*:

5.2.1 This phase includes the formalization of the scope and the significance and use sections. It may include determining the purpose and describing a general approach to the test method but usually does not involve statistical studies.

5.3 *Development Phase*—

5.3.1 Studies may be conducted to evaluate the basic performance of the method. The draft test method is prepared and sampling requirements and the test result are clearly defined.

5.3.2 A flow chart is extremely valuable to identify the sequence of operations involved in a test method, for example, the sampling steps required to obtain the test specimens, definition of the test determination, how a test result is to be computed, and running the tests on the specimens.

5.4 Validation Phase

5.4.1 The test method is examined for such concerns as its stability, ruggedness, statistical control and the contributions to variability. The completion of this phase should result in preliminary estimates of precision and the identification and suggested ways to estimate potential contributors to uncertainty.

5.4.2 *Evaluation of Short Term Control of Test Method*—A test method must exhibit an ability to provide consistent results at least over short time periods. Preliminary studies or a pilot test should be conducted to evaluate the short term stability of the test method. A small series of repeated tests should be conducted.

5.4.3 *Analysis of Variability*—Statistically designed experiments conducted in one or two laboratories can be used to assess the relative magnitudes of different sources or potential contributors to variability of the test results. Such studies can provide estimates of intermediate measures of precision.

5.4.4 *Ruggedness Test*—A ruggedness test (see Guide E 1169) is a statistically designed experiment that helps identify problems in running the test method, clarifies errors, and points out possible environmental conditions, which may adversely affect the test method or point out need for tightening requirements. The ruggedness test can assist in locating ways of reducing variability in the test method.

5.4.5 *Preliminary Estimates of Precision*—From the various studies conducted in accordance with 5.4.2–5.4.4, preliminary

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