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Standard Guide for ASTM Standard Specification Quality Statements[1]

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1. Scope

1.1 This guide is intended as a reference to assist ASTM technical committees and subcommittees addressing quality statements in product specifications under their jurisdiction.

1.2 It is recognized that quality provisions are not required in every standard specification. Lack of a quality provision does not indicate a deficiency in the standard.

1.3 This guide addresses the following areas and provides a check list of factors to be considered for each topic: calibration and measurement; inspection and testing; handling, storage, preservation, and shipping; nonconforming materials; and documentation.

1.4 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems 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. Table 1*

2. Referenced Documents

2.1 *ASTM Standards:*

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

2.2 *ANSI/ASQC Standard:*

M-1 Calibration Systems[3]

2.3 *Military Standards:*

MIL-I-45208 Inspection Systems Requirements[4]

MIL-Q-9858 Quality Program Requirements[4]

MIL-Q-21549 Product Quality Program Requirements for Fleet Missile Weapon Systems Contractors[4]

MIL-STD-45662 Calibration System Requirements[4]

Military Handbook 52A (Interpretation of MIL-STD-45662)[4]

3. Terminology

3.1 *Definitions*—Refer to Terminology E 456 for definition of terms other than those listed in 3.2 which are used in this standard guide.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *calibration*—comparison of a measurement standard or instrument of known bias with another standard or instrument to detect, report, and/or minimize by adjustment any unacceptably large bias of the item being compared.

3.2.2 *traceability (calibration sense)*—the ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain of comparisons (see MIL-STD 45662).

3.2.3 *raw material*—any material intended to undergo change when introduced into the process.

3.2.4 *component*—any material that is incorporated into the final product without undergoing any significant change in the manufacturing process.

NOTE 1—Components, (for example, electrical cables, plastic connectors), generally require control measures equivalent to those needed for the final product.

3.2.5 *nonconformance*—deviation of a material to some degree from one or more of the technical requirements of a standard.

NOTE 2—Conformance or nonconformance is an either/or determination, without regard to the degree to which a product may deviate from specified limits. An individual item may be nonconforming, and must be treated as such, even if it comes from a lot which meets an agreed sampling plan acceptance limit.

3.2.6 *fitness for use*—suitability of a product for its intended use.

NOTE 3—Fitness for use is a somewhat subjective concept in which degree of deviation from optimum becomes important, and may not relate directly to conformance or nonconformance.

4. Significance and Use

4.1 In view of the great diversity of ASTM specifications, it is not feasible to recommend a single set of suitable quality statements, nor even to develop a small number of statements with rules for selection. Each committee or subcommittee must consider the need for quality statements for its specifications.

[1] This guide is under the jurisdiction of ASTM Committee E-11 on Quality and Statistics in ASTM Standards and is the direct responsibility of Subcommittee E11.10 on Quality Document Preparation.

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

[3] Available from Society for Quality Control, 310 W. Wisconsin Ave., Milwaukee, WI 53203.

[4] Available from Naval Publications and Forms Center, 5801 Tabor Ave., Philadelphia, PA 19120.

TABLE 1 Checklist to Determine the Consistency of Any ASTM Standard With E-46 Guidelines and ASTM Form and Style Manual (Blue Book)

Note—This checklist is based on the "Standard Guide for ASTM Standard Specification Quality Statements" developed by ASTM Committee E-46. It is intended to be used by ASTM Technical Committees and Subcommittees in addressing quality statements in product specifications under their jurisdiction. This guide calls attention to issues that should be considered when developing specification quality statements. Reviewers of ASTM standard specifications may use this checklist to identify whether quality statements have been considered and whether their use agrees with the principles of this guide.

Instructions—Each item of the checklist requires one of four responses. Place one checkmark after each item under the appropriate column.

(1) Not applicable;
(2) Not addressed, but should be;
(3) Addressed, but review is recommended; or
(4) Adequately addressed.

	1	2	3	4
1. Calibration and Measurement Precision and Bias				
(a) Limits of acceptable error quantified.	—	—	—	—
(b) Recommendations to minimize bias relative to national measurement standards ("traceability to NBS") identified.	—	—	—	—
(c) Recommendations for particular instruments, standards reference materials, calibration methods, calibration points, or other factors identified.	—	—	—	—
(e) Comprehensive measurement quality assurance program specified.	—	—	—	—
2. Inspection and Testing				
(a) Characteristics to be inspected or tested identified.	—	—	—	—
(b) Method of sampling defined.	—	—	—	—
(c) Special inspection, preparation, and test procedures addressed.	—	—	—	—
(d) Environmental requirements for inspection and testing addressed.	—	—	—	—
(e) Equipment identified by type.	—	—	—	—
(f) Required precision and calibration, personnel certification requirements identified.	—	—	—	—
3. Handling				
(a) Measures to maintain quality and condition of products addressed.	—	—	—	—
(b) Measures to prevent mixups addressed.	—	—	—	—
4. Storage and Preservation				
(a) Specification or control of environmental conditions addressed.	—	—	—	—
(b) Protective measures to maintain quality and conditions of materials in storage addressed.	—	—	—	—
(c) If quality or fitness for use of product deteriorates over time, control measures addressed.	—	—	—	—
(d) Measures to prevent mixups addressed.	—	—	—	—
5. Shipping				
(a) Protective measures to maintain quality and condition in shipment addressed.	—	—	—	—
(b) Regulatory requirements pertaining to markings on packaging and information on shipping documents addressed.	—	—	—	—
(c) Inclusion of technical documents or instructions with shipments is appropriate and measures to ensure their inclusion addressed.	—	—	—	—
(d) Measures to prevent mixups addressed.	—	—	—	—
6. Nonconforming Materials				
(a) Aspects of a standard where nonconformance of the material would be most serious identified.	—	—	—	—
(b) Requirements for marking, segregating, or otherwise identifying nonconforming materials to prevent inadvertent use addressed.	—	—	—	—
(c) Formal material review procedures to provide for disposition of nonconforming materials, notification to users, and traceability of nonconforming items addressed.	—	—	—	—
(d) Requirements to investigate for assignable causes and institute corrective actions addressed.	—	—	—	—
7. Documentation				
(a) Documenting quality of supplies and/or raw materials addressed.	—	—	—	—
(b) In-process quality testing, and documentation of such testing addressed.	—	—	—	—
(c) Documentation of final product testing addressed.	—	—	—	—
(d) Documentation of product quality to be provided to the user addressed.	—	—	—	—
(e) Audit of the vendor's facilities by the buyer or other interested party be required or encouraged addressed.	—	—	—	—

This guide is intended to simplify the process by calling attention to the considerations that should enter into development of specification quality statements.

5. Nonconforming Materials

5.1 *Check List for Nonconforming Materials*:

5.1.1 Identify the aspects of a standard where nonconformance of the material would be most serious.

5.1.2 Consider requirements for marking, segregating, or otherwise identifying nonconforming materials to prevent inadvertent use.

5.1.3 Consider need for formal material review procedures to provide for disposition of nonconforming materials, notification to users, and traceability of nonconforming items, and

5.1.4 Consider need for requirements to investigate for assignable causes and institute corrective actions.

5.2 *Discussions*:

5.2.1 *Importance of Conformance*—Ideally, all products conform to all aspects of the standards to which they are manufactured. However, in all standards, some characteristics are more important than others to final service. Identification of the most important characteristics by the standards-writing committees helps to focus manufacturing and inspection attention where it is most needed, and helps guide material review and user decisions regarding possible fitness for use when nonconformances are found. It is particularly important to identify latent or hidden characteristics of importance, as nonconformances in such characteristics may not be readily

apparent to the user. For standards covering products with a multiplicity of uses, the standard should require users to make those determinations.

5.2.2 *Identification of Nonconforming Materials*—When materials are found to be nonconforming, they must be positively identified as such to prevent inadvertent shipments or use while final disposition is being determined. This can be a very difficult task for some continuous processes. Identification of nonconforming materials can take many forms, including but not limited to physical segregation, marking of the material, and identification of the nonconformance by means of documents. If a committee wishes to establish a particular means of identifying nonconforming material or to emphasize the need for some positive identification scheme, the standard should so state. A specification statement regarding identification of nonconformance may be particularly important for products manufactured by continuous processes.

5.2.3 *Material Review Procedures*—Nonconforming material is nearly always reviewed for final disposition, whether the review is formal or informal. Possible dispositions include scrap, reworking to specification, assignment to less-demanding applications, or use as is. This last disposition, to use nonconforming material for its originally intended purpose, requires considerable care and thought. Such dispositions can only be based on fitness for use. Often the disposition is based on the fact that the nonconformance will no longer exist by the point of end use, as with off-dimension in a metal mill product to be eliminated by machining or other processing. At other times a nonconforming product may be used when it is determined that the nonconformance does not make the product unfit for use. It is essential that the user take part in any decision to use nonconforming material, especially when the nonconformance will still exist in the finished product. Certification of material accepted on this basis must indicate the nonconformance. Products not conforming to standards should not be supplied without approval of the purchaser.

5.2.3.1 An ASTM committee may wish to consider specifying a particular procedure for reviewing nonconforming materials. A traceability system for such materials and even for presumed-satisfactory products, so that problems arising from nonconformances may be more easily tracked, may also be recommended in a standard.

5.2.4 *Corrective Action*—It is simply good quality assurance and quality control practice to attempt to identify an assignable cause for any significant recurring nonconformance, and then to take corrective action to eliminate this assignable cause. It is only in this manner that high quality levels can be attained and maintained economically.

5.2.4.1 Normally identification and correction of nonconformance causes is purely a management function, and not a concern of a standards-writing committee. However, a high level of nonconformances due to failure to take corrective action can affect the user, due to nonconforming materials escaping detection (no inspection is actually 100 % reliable), delivery schedule slippage, or economic pressures. Therefore, for sensitive products or applications, a committee may consider requiring at least the existence of a corrective action system, though it is preferable not to specify details. Provisions for corrective action are a part of many military standards (see 2.3) and voluntary standards for supply of materials to be used in the nuclear power industry.

6. Calibration and Measurement Precision and Bias

6.1 Check list for calibration and measurement precision and bias:

6.1.1 Identify the most important measurements (with respect to control and assurance of quality).

6.1.2 Determine limits of acceptable measurement error in light of product tolerances, and specify maximum acceptable measurement uncertainty for the measurement uncertainty can be shown to be negligibly small compared to the tolerance being assessed, it should not be neglected in setting acceptance limits. That is, the tolerance band should be narrowed by the uncertainty. For example, if an ASTM standard specification calls for a dimension that is 20 cm ± 0.1 cm, items falling in the range 19.9 cm to 20.1 cm would be accepted as being within specification if the measurement uncertainty were negligibly small. If the uncertainty of measurement were estimated to be 0.05 cm, the range of acceptable dimensions should be shrunk to 19.95 cm to 20.05 cm to allow for the measurement uncertainty.

6.1.3 Identify the most likely sources of bias and imprecision in the measurement process and consider providing guidelines on how to minimize these sources of error.

6.1.4 Consistent with the desired uncertainty limits, recommend calibration procedures where it is appropriate to do so and specify how traceability to national standards is to be realized (if applicable).

6.1.5 Identify particularly important measurements for which special measurement assurance procedures might be specified and consider specifying suitable procedures.

6.2 *Discussion*:

6.2.1 *Defining Measurement Uncertainty for Important Measurements*—Measurements important with respect to control and assurance of quality should be flagged during the standards development process. Some variation in product parameters is inevitable, so upper limits of permissible variation (product tolerances) are established. It must be recognized that, in the general case, the measurement system used to quantify these parameters will also have some imprecision and bias, and limits to this variability and bias must also be established. Measurement errors generally consist of a random error component (imprecision) and a systematic error component (bias). The uncertainty of a measurement is the best estimate of the upper bounds to a suitable combination of these two error sources. (See Practice E 177, the Appendix to ANSI/ASQC M-1, and Ref (**1**)[5] for a more comprehensive treatment of this topic.)

6.2.1.1 Measurement uncertainty should be small compared to the tolerances in the product parameters being assessed for compliance with the specification. For example, a frequently-used rule of thumb is to limit measurement uncertainty to no more than 10 % of the tolerance of the parameter being

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