Designation: C1068 – 21

Standard Guide for Qualification of Measurement Methods by a Laboratory Within the Nuclear Industry[1]

This standard is issued under the fixed designation C1068; 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.

1. Scope

1.1 This guide provides guidance for selecting, validating, and qualifying measurement methods when qualification is required for a specific program. The recommended practices presented in this guide provide a major part of a quality assurance program for the laboratory data (see Fig. 1). Qualification helps to assure that the data produced will meet established requirements.

1.2 The activities intended to assure the quality of analytical laboratory measurement data are diagrammed in Fig. 1. Discussion and guidance related to some of these activities appear in the following sections:

	Section
Selection of Measurement Methods	5
Validation of Measurement Methods	6
Qualification of Measurement Methods	7
Control	8
Personnel Qualification	9

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

C859 Terminology Relating to Nuclear Materials

C1009 Guide for Establishing and Maintaining a Quality Assurance Program for Analytical Laboratories Within the Nuclear Industry

C1128 Guide for Preparation of Working Reference Materials for Use in Analysis of Nuclear Fuel Cycle Materials

C1156 Guide for Establishing Calibration for a Measurement Method Used to Analyze Nuclear Fuel Cycle Materials

C1210 Guide for Establishing a Measurement System Quality Control Program for Analytical Chemistry Laboratories Within Nuclear Industry

C1297 Guide for Qualification of Laboratory Analysts for the Analysis of Nuclear Fuel Cycle Materials

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E2554 Practice for Estimating and Monitoring the Uncertainty of Test Results of a Test Method Using Control Chart Techniques

E2655 Guide for Reporting Uncertainty of Test Results and Use of the Term Measurement Uncertainty in ASTM Test Methods

2.2 *ISO Standards:*[3]

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.3 *Other Standards:*

ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications[4]

IEEE/ASTM SI 10 American National Standard for Metric Practice[5]

JCGM 100 Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (GUM)[6]

JCGM 200 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)[6]

[1] This guide is under the jurisdiction of ASTM Committee C26 on Nuclear Fuel Cycle and is the direct responsibility of Subcommittee C26.08 on Quality Assurance, Statistical Applications, and Reference Materials.

Current edition approved Oct. 1, 2021. Published October 2021. Originally approved in 1986. Last previous edition approved in 2015 as C1068 – 15. DOI: 10.1520/C1068-21.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Two Park Ave., New York, NY 10016-5990, http://www.asme.org.

[5] Available from Institute of Electrical and Electronics Engineers, Inc. (IEEE), 445 Hoes Ln., Piscataway, NJ 08854-4141, http://www.ieee.org.

[6] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

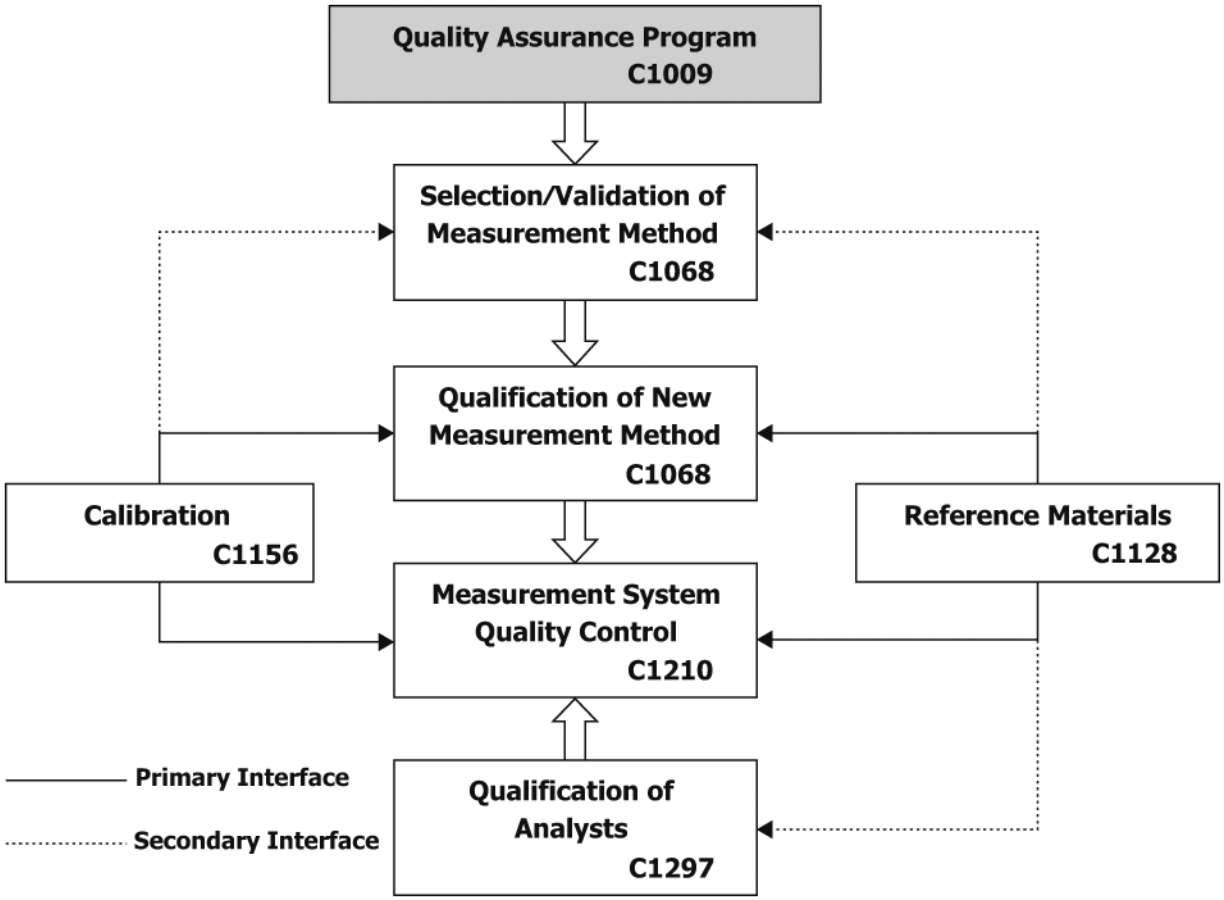

FIG. 1 Quality Assurance of Analytical Laboratory Data

3. Terminology

3.1 Except as otherwise defined herein, definitions of terms are as given in Terminology C859.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *fitness for purpose, n*—degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose (**1**).[7]

3.2.2 *qualification*—a formal process to provide a desired level of confidence that measurement methods used will produce data suitable for their intended use. The methods must meet established criteria prior to use and must be used under conditions established for qualifications.

3.2.3 *representative sample, n*—a sample resulting from a sampling plan that can be expected to adequately reflect the properties of interest of the parent population (**1**).

3.2.4 *validation, n*—a verification that a measurement method fulfills specified requirements that are adequate for an intended use (adapted from JCGM 200).

3.2.5 *verification, n*—provision of objective evidence that a given measurement method fulfills specified requirements (adapted from JCGM 200 by changing "item" to "measurement method").

3.2.5.1 *Discussion*—Examples of verification include but are not limited to: (*a*) confirmation that performance properties or legal requirements of a measuring system are achieved; (*b*) confirmation that a target measurement uncertainty can be met.

4. Significance and Use

4.1 Because of concerns for safety and the protection of nuclear materials from theft, stringent specifications are placed on chemical processes and the chemical and physical properties of nuclear materials. Strict requirements for the control and accountability of nuclear materials are imposed on the users of those materials. Therefore, when analyses are made by a laboratory to support a project such as the fabrication of nuclear fuel materials, various performance requirements may be imposed on the laboratory. One such requirement is often the use of qualified methods. Their use gives greater assurance that the data produced will be satisfactory for the intended use of those data. A qualified method will help assure that the data produced will be comparable to data produced by the same qualified method in other laboratories.

4.2 This guide provides guidance for qualifying measurement methods and for maintaining qualification. Even though all practices would be used for most qualification programs, there may be situations in which only a selected portion would be required. Care should be taken, however, that the effectiveness of qualification is not reduced when applying these

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