



Designation: D6808 – 02 (Reapproved 2018)^{ε1}

Standard Practice for Competency Requirements of Reference Material Producers for Water Analysis¹

This standard is issued under the fixed designation D6808; 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.

^{ε1} NOTE—The Keywords section was added editorially in August 2018.

1. Scope

1.1 This practice establishes the general requirements with which a reference materials (RM) producer has to demonstrate that it operates, if it is to be recognized as competent to produce RMs used for water analysis.

1.2 This practice establishes the quality system requirements in accordance with which waters RMs shall be produced. It is intended to be used as part of a RM producer's general quality assurance (QA) procedures. RM producers shall define their scope in terms of the application, the measurement methods used in the homogeneity, stability, and characterization studies.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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.*

1.5 *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

D1129 Terminology Relating to Water

¹ This practice is under the jurisdiction of ASTM Committee D19 on Water and is the direct responsibility of Subcommittee D19.02 on Quality Systems, Specification, and Statistics.

Current edition approved Aug. 1, 2018. Published September 2018. Originally approved in 2002. Last previous edition approved in 2012 as D6808 – 02 (2012). DOI: 10.1520/D6808-02R18E01.

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.

D6362 Practice for Certificates of Reference Materials for Water Analysis

2.2 ISO Documents:³

ISO/IEC 17025:1999 General Requirements for the Competence of Calibration and Testing Laboratories

ISO 8402:1994 Quality Management and Quality Assurance—Vocabulary

ISO 10012-1:1992 Quality Assurance Requirements for Measuring Equipment—Part 1: Metrological Confirmation Systems for Measuring Equipment

ISO/IEC Guide 2:1996 Standardization and Related Activities—General Vocabulary

ISO Guide 30:1992 Terms and Definitions used in Connection with Reference Materials

ISO Guide 31:2000 Contents of Certificates and Labels of Reference Materials

ISO/IEC Guide 32:1997 Calibration in Analytical Chemistry and Use of Certified Reference Materials

ISO Guide 34:2000 General Requirements for the Competency of Reference Material Producers

ISO Guide 35:1989 Certification of Reference Materials—General and Statistical Principles

ISO 3534 Series: 1993 Statistics—Vocabulary and Symbols
VIM: 1993 International Vocabulary of Basic and General Terms in Metrology (issued by ISO, IEC, BIPM, IFCC, IUPAC, IUPAP and OIML)

ISO Guide to the Expression of Uncertainty in Measurement: 1995 (issued by ISO, IEC, BIPM, IFCC, IUPAC, IUPAP and OIML)

3. Terminology

3.1 Definitions:

3.1.1 For the purposes of this practice, the definitions given in Terminology **D1129**, ISO/IEC Guide 2, ISO/IEC 17025, ISO Guide 30, ISO 8402, ISO 3534, VIM, and the following definitions apply.

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

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *collaborator, n*—technically competent body (organization or firm, public or private) that undertakes aspects of the manufacture, or characterization, of the (certified) RM on behalf of the RM producer, either on a contractual (as a sub-contractor) or voluntary basis.

3.2.2 *reference material producer, n*—technically competent body (organization or firm, public or private) that is fully responsible for assigning the certified or other property values of the RMs it produces and supplies, which have been produced in accordance with ISO Guide 35, Practice D6362, and ISO Guide 31.

4. Significance and Use

4.1 This practice is for the use by RM producers in the development and implementation of their quality system and by those concerned with assessing the competence of RM producers. It should be recognized that a RM needs to be characterized mainly to the level of accuracy required for its intended purpose (that is, appropriate measurement uncertainty). The RM producer shall describe the procedure for establishing the quality of materials as a component of the quality system.

4.2 This practice is for the use of RM users in the establishment if a RM producer has a quality system adequate to produce high quality RMs. It can be used by users to determine if the scientific and technical competence of a RMs producer is adequate to ensure the quality of RMs. This practice is consistent with the requirements for RM producers established in ISO Guide 34.

4.3 This practice does not specify specific protocols for the contents of RMs certificates of analysis, for calibration in analytical chemistry and use of certified RMs and for certification of RMs. For this information, users are referred to Practice D6362, ISO Guide 32, and ISO Guide 35.

5. Organization and Management Requirements

5.1 Quality System Requirements:

5.1.1 The RM producer shall establish, implement, and maintain a quality system appropriate to the scope of its activities including the type, range, and magnitude of the RM production it undertakes.

5.1.2 Quality Policy:

5.1.2.1 The RM producer shall define and document its policy, objectives, and commitment to ensuring and maintaining the quality of all aspects of RM production, including material quality (that is, homogeneity and stability), characterization (that is, equipment calibration and measurement method validation), assignment of property values (that is, use of appropriate statistical procedures), and material handling, storage, and transport procedures.

5.1.2.2 The quality policy shall, when appropriate, include use of interlaboratory characterization studies employing laboratories that are active and competent in the respective field of measurement in this context. The policy shall include a commitment to interact with the appropriate sectors of the measurement community in order to prevent working in isolation. The policy shall also include a commitment to

produce RMs which conform to the definitions given in ISO Guide 30, characterized according to the requirements of ISO Guide 35, and whose property values are assessed using accepted statistical techniques. The policy shall, where appropriate, include a commitment to comply with Practice D6362 for the contents of RM certificates and supply of associated information for users. It is important that the policy also specifies the intended use of the RMs in order to ensure that the RM producer fully advises the user which types of application the materials may be used.

5.1.3 Quality System:

5.1.3.1 The RM producer shall establish, implement, and maintain a documented quality system appropriate to the type, range, and volume of RM production it undertakes. The RM producer shall document all of its policies, systems, programs, procedures, instructions, findings, etc., to the extent necessary to enable the producer to assure the quality of the RMs produced. Documentation used in this quality system shall be communicated to, understood by, available to and implemented by all personnel concerned. In particular, the producer shall have a quality system that covers the following:

- (1) Arrangements for ensuring the suitable choice (for example, particle size range, concentration range, etc.) of the candidate RMs;
- (2) Preparation procedures;
- (3) Achievement of the required degree of homogeneity of the RM;
- (4) Assessment of the stability of the RM; including on-going assessment of stability where necessary;
- (5) Procedures for undertaking characterization;
- (6) Practical realization of traceability to national or international standards of measurement;
- (7) Assignment of property values, including preparation of certificates or statements in accordance with Practice D6362 when appropriate;
- (8) Arrangements for ensuring adequate storage facilities;
- (9) Arrangements for suitable identification, labeling and packaging facilities, packing and delivery procedures, and customer service; and
- (10) Compliance with ISO Guides 30, 34, and 35, and Practice D6362.

It is encouraged that the documented quality system specify which activities are undertaken by the RM producer and, where relevant, which activities are undertaken by collaborators and shall include policies and procedures used by the producer to ensure that all activities conducted by collaborators comply with the relevant clauses of this practice.

5.1.3.2 The documented quality system shall define the roles and responsibilities of the technical manager (however named) and quality manager including their responsibilities for ensuring compliance with this practice.

5.2 Organization and Management:

5.2.1 The RM producer, or the organization of which it is part, shall be legally identifiable.

5.2.2 The RM producer shall be organized and shall operate in such a way that it meets all the applicable requirements of this practice whether carrying out work in its permanent facilities or at sites (including associated temporary or mobile