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Standard Practice for Certificates of Reference Materials for Water Analysis[1]

This standard is issued under the fixed designation D6362; 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 practice covers the information that must be provided on certificates of analysis of reference materials designated to support ASTM methods. It provides end users of these materials with a defined set of data that is required to be on a certificate of analysis and provides information to assist the end user in evaluating the independence of the material. Similarly, it provides the suppliers of reference materials with a consistent format for the presentation of certification data.

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

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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1129 Terminology Relating to Water

E826 Practice for Testing Homogeneity of a Metal Lot or Batch in Solid Form by Spark Atomic Emission Spectrometry

2.2 *ISO Standards*[3]

ISO Guide 30 Terms and definitions used in connection with reference materials

ISO Guide 31 Contents of certificates of reference materials

ISO Guide 35 Certification of reference materials—General and statistical principles

ISO/REMCO N280

3. Terminology

3.1 *Definitions*—For definitions of terms used in this practice, refer to Terminology D1129 and ISO Guide 30

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *prepared value, n*—the best estimate of the concentration of a given analyte based upon the purity of raw materials and the method of preparation of the material.

4. Significance and Use

4.1 This practice is designed to assist suppliers and users of reference materials by identifying the information necessary on the certificate of analysis of materials designated for use in ASTM test methods. This practice is specifically designed to ensure that materials suitable for use as either calibration or quality control standards are available. This practice does not define a specific certification protocol, but rather provides guidance in the development of adequate data to support the use of the material as either a calibration or quality control standard. Suppliers are referred to ISO Guide 35 for guidelines on acceptable certification protocols. End users are referred to ISO Guide 31 for a more complete description of the elements of typical certificates of analysis.

5. Certificate of Analysis

5.1 The certificate of analysis is a summary of the analysis performed to support the designated use of the material. As a summary, the certificate must be brief, but it must provide sufficient information to allow the potential user of the material to assess the suitability of the material for his intended use. Therefore, reference material suppliers are encouraged to supply method information and analytical data in a summary that clearly and unambiguously allows the user to make an informed decision about the suitability of the material. The use of terms as defined by ISO or ASTM is required.

5.2 The certificate of analysis must be supported by a certification report for the material. The certification report must contain the details of the analyses performed to develop the certified values reported on the certificate of analysis. It must contain the method(s) used for analysis, details of the method of preparation, if appropriate, including gravimetric

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[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.

data, supporting instrumental data, and the results of supporting statistical analysis reported on the certificate of analysis. The certification report must be provided to the end user of the material if requested.

6. Certificate Headings

6.1 The following sections detail the headings to be used on the certificate of analysis. ASTM methods require the use of a diverse set of reference materials. Therefore, it is expected that all headings will not be appropriate for all materials. However, exceptions should be avoided in order to insure sufficient information for evaluation of materials. Therefore, each of the following sections is designated as either mandatory or optional based upon ensuring a minimum data set. Appendix X1 contains examples of typical certificates of analysis designed to meet these requirements.

6.1.1 *Name and Address of Certifying Organization (Mandatory)*—This is the name and address of the organization that accepts responsibility for the information on the certificate. Organizations that provided analytical data or prepared the material may be provided elsewhere on the certificate.

6.1.2 *Material Identification (Mandatory)*—This section must identify the material by name, as labeled, and must include a lot or batch number that can be used to uniquely identify the material.

6.1.3 *Supplier of the Reference Material (Optional)*—If the supplier of the reference material is different from the certifying organization then this section should contain the name and address of the supplier of the material.

6.1.4 *Preparer of the Material (Optional)*—If the material was not prepared by the supplier or the certifying organization, then this section should include the name and address of the preparer of the material.

6.1.5 *Source of the Material (Mandatory)*—For a solution standard, or a matrix material, this section must identify the source of the raw materials or the source of the matrix material, used in the preparation of the material. The supplier may identify the source of the material as proprietary. If the source of the material is declared to be proprietary then the supplier must provide contact information on the certificate in order to assist end users.

6.1.6 *Description and Intended Use of the Material (Optional)*—Most reference materials are designed to be used for a specific purpose. This section should designate the intended use of the material. It should also contain a sufficiently detailed description of the material to allow the user to estimate its usability in their application.

> This material is designed to be used in D XXXX as a calibration standard. The material was prepared in Type I water to contain 1 mg/ml of the certified components.

6.1.7 *Stability, Transportation, and Storage Conditions (Mandatory)*—Any known temperature, storage, or transportation factors that could influence the stability of the material must be identified. It is required that the supplier identify proper storage and handling conditions that are necessary to insure usability for the expected life of the material. Similarly, the supplier should identify the period of time for which they will assume responsibility for the validity of the certified values.

6.1.8 *Instructions for Use (Mandatory)*—If the material requires special handling, dilution, drying, or any other specific manipulation in order to achieve the certified values, these procedures must be clearly identified in this section.

6.1.9 *Method of Preparation (Optional)*—If the method of preparation gives the user an idea of the care taken by the supplier, significant details of the preparation procedure may be included in this section.

6.1.10 *State of Homogeneity (Mandatory)*—As it relates to the certification of reference materials, homogeneity refers to the analysis and demonstration of uniformity of final packaged units. Every certificate must contain a homogeneity statement. This section must include the sampling, analytical method(s), and procedure used to evaluate the homogeneity of the material. Appendix X2 provides a suggested procedure for homogeneity testing and references to alternative internationally accepted homogeneity testing procedures. If the homogeneity of the material has not been determined, then this must be stated on the certificate.

6.1.11 *Certified Property Values and Their Associated Uncertainties (Mandatory)*—The information in this section should be given in tabular form with appropriate subsection headings. The minimum information to be provided includes the property, the certified value of the property, the associated uncertainty, and the method of analysis. Since the certificate is a synopsis of the certification report, suppliers are encouraged to identify the method of analysis by appropriate standard method number. Modifications or exceptions to the given method may be annotated in another section of the certificate. Likewise, if the values certified are dependent upon certain conditions, for example temperature, these can be identified in footnotes to the table. Values for properties that are not certified should be included in a separate table.

NOTE 1—Several different procedures can be used to certify reference materials. These depend upon the nature of the material to be certified and the technical capability of the supplier and certifying body. The three most common procedures for certification are detailed in Section 7. The procedure used to certify property values must be provided under the heading of statistical estimators and uncertainty referenced below.

6.1.12 *Uncertified Properties (Optional)*—Many times properties of the material are known but without sufficient accuracy or precision to support certification. These values may be reported by the supplier in this section to assist the user in the selection of appropriate materials.

6.1.13 *Values Obtained by Individual Laboratories or Methods (Optional)*—Many times materials are certified based upon interlaboratory studies or by using several different methods of analysis. In these cases, this section can be used to report individual data by laboratory or method where appropriate. If the supporting data are too voluminous to report in this section, a reference to the certification report may be made here to identify the source and availability of supporting data.

6.1.14 *Statistical Estimator and Uncertainty (Mandatory)*—The meaning and nature of the certified values must be given, that is, the statistical estimator must be named. Where the estimator cannot be named then the mathematical expression used in calculation must be presented.