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Standard Guide for Qualification of Laboratory Analysts for the Analysis of Nuclear Fuel Cycle Materials[1]

This standard is issued under the fixed designation C1297; 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 covers the qualification of analysts to perform chemical analysis or physical measurements of nuclear fuel cycle materials. The guidance is general in that it is applicable to all analytical methods, but must be applied method by method. Also, the guidance is general in that it may be applied to initial qualification or requalification.

1.2 The guidance is provided in the following sections:

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Qualification Considerations	4
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1.3 This standard does not apply to maintaining qualification during routine use of a method. Maintaining qualification is included in Guide C1210.

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

C1068 Guide for Qualification of Measurement Methods by a Laboratory 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 the Nuclear Industry

C1215 Guide for Preparing and Interpreting Precision and Bias Statements in Test Method Standards Used in the Nuclear Industry

2.2 *ISO Standard:*

ISO Guide 30 Terms and Definitions Used in Connection with Reference Materials[3]

3. Significance and Use

3.1 This is one of a series of guides designed to provide guidance for implementing activities that meet the requirements of a sound laboratory quality assurance program. The first of these, Guide C1009, is an umbrella guide that provides general criteria for ensuring the quality of analytical laboratory data. Other guides provide expanded criteria in various areas affecting quality, producing a comprehensive set of criteria for controlling data quality. The approach to ensuring the quality of analytical measurements described in these guides is depicted in Fig. 1.

3.2 The training and qualification of analysts is one of the elements of laboratory quality assurance presented in Guide C1009, which provides some general criteria regarding qualification. This guide expands on those criteria to provide more comprehensive guidance for qualifying analysts. As indicated in Guide C1009, the qualification process can vary in approach; this guide provides one such approach.

3.3 This guide describes an approach to analyst qualification that is designed to be used in conjunction with a rigorous program for the qualification and control of the analytical measurement system. This requires an existing data base which defines the characteristics (precision and bias) of the system in routine use. The initial development of this data base is described in Guide C1068. The process described here is intended only to qualify analysts when such a data base exists and the method is in control.

3.4 The qualification activities described in this guide assume that the analyst is already proficient in general laboratory

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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.

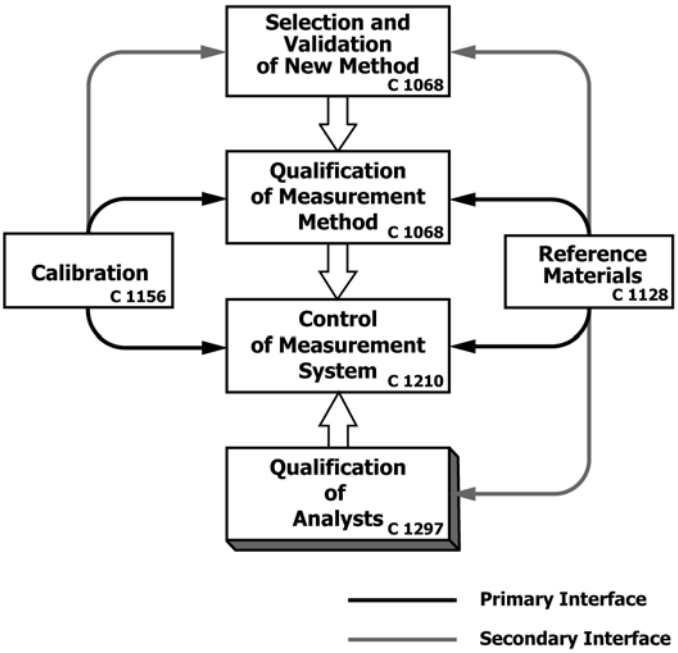

FIG. 1 Quality Assurance of Analytical Laboratory Data

operations. The training or other activities that developed this proficiency are not covered in this guide.

3.5 This guide describes a basic approach and principles for the qualification of laboratory analysts. Users are cautioned to ensure that the qualification program implemented meets the needs and requirements of their laboratory.

4. Qualification Considerations

4.1 When a qualification program is being established, consideration should be given to analyst selection criteria, the training program, and practical demonstration. The criteria that govern when qualification is achieved should be documented along with methods for determining the knowledge and skill of the analyst.

4.1.1 Analyst selection should be based on established criteria that are related to the complexity of the method that analysts are expected to perform. Criteria should include the minimum education required, any prerequisite training, and the overall experience required. The selection criteria should be defined and documented.

4.1.2 The method-specific analyst training program should be an established program with a prescribed training procedure. Some mechanism such as an oral or written test should be used to allow an analyst to demonstrate knowledge and understanding of the chemical, physical, instrumental, and mathematical concepts used to execute the method. It is advisable to monitor progress during training to ensure that the analyst has a reasonable chance of passing the qualification test.

4.1.3 The practical demonstration of the analyst's ability to generate results with the analytical method should be compared to established criteria. The comparison criteria should be defined and documented.

NOTE 1—The qualification of analysts, like many other laboratory processes, has the potential for undetected errors. There are two types of errors that occur. One is to fail an individual who should have been determined to be qualified. The other error is to pass an individual who should not have been determined to be qualified. The potential for these errors to occur and the potential consequences to the laboratory should be carefully considered when determining the laboratory's qualification methodology. A statistical approach includes choosing the significance level at which the determination of qualification will be made. This produces a quantitative value of the two possible risks. This is described further in Appendix X1.

5. Demonstration Process

5.1 The suggested approach to practical demonstration for analyst qualification that is described in the remainder of this guide involves a comparison of the performance of the analyst with the performance of all qualified analysts on a particular analytical method. The performance is measured by the analysis of reference materials (see ISO Guide 30) and comparison of the results to the data base for the analytical method. This approach requires a data base that describes method performance. The comparison described in this guide is statistical in nature and therefore statisticians should be involved early on in the process of defining qualification. Other types of comparisons may serve to qualify equally well; however, such comparisons are not addressed in this guide. If used, they should be defined and documented.

5.2 The data base for a given analytical method is generated by all qualified analysts who run reference material samples on an established schedule or frequency. The data base is used to establish the bias and precision of the method as routinely used in the laboratory. The data base is established through a measurement control program as presented in Guide C1210. For a new method, a data base should be established according to Guide C1068 and the analyst should be qualified against that data base.

5.3 If changes in a method occur or changes in the execution of a method occur that render the existing data base representation of the method questionable, the qualification of analysts should be suspended until the data base is verified or a new data base is generated. When a new data base is generated, the old data base should be archived (retained for future reference) as a part of the documentation of the laboratory quality assurance program.

5.4 A predetermined number of reference material samples should be selected for the analyst after training has been completed. The analyst should analyze the samples over several days, and not in a single session, to simulate more realistically the conditions under which the data base was established.

5.5 Since the samples may be at different concentration levels, the analyst's demonstration results are normalized using established parameters from the existing data base for each control standard. The normalized data are used to test for conformity to the data base. Statistical tests for the statistical distribution (normality) as well as precision and bias are suggested in Section 6. These terms are described in Guide C1215.

5.6 If the results of all three tests are satisfactory, the analyst is qualified on that method. If the analyst does not qualify,