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Standard Guide for Establishing a Measurement System Quality Control Program for Analytical Chemistry Laboratories Within the Nuclear Industry[1]

This standard is issued under the fixed designation C1210; 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 standard provides guidance for establishing and maintaining a measurement system quality control program. Guidance is provided for general program considerations, preparation of quality control samples, analysis of quality control samples, quality control data analysis, analyst qualification, measurement system calibration, measurement method qualification, and measurement system maintenance.

1.2 This guidance is provided in the following sections:

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2. Referenced Documents

2.1 *ASTM Standards:*[2]

ASTM C1210-12 https://standards.iteh.ai/catalog/standards/sist/45a97e35-8e4b-4994-b1df-5d7d1f1a7e8a/astm-c1210-12

C859 Terminology Relating to Nuclear Materials

C1009 Guide for Establishing a Quality Assurance Program for Analytical Chemistry 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

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

2.2 *ANSI Standards:*[3]

ANSI/ASQ B1 Guide for Quality Control Charts

ANSI/ASQ B2 Control Chart Method of Analyzing Data

ANSI/ASQ B3 Control Chart Method of Controlling Quality During Production

3. Terminology

3.1 For definitions of terms used in this guide, see Terminology C859.

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[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 Applications.~~

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Current edition approved June 1, 2012. Published July 2012. Originally approved in 1991. Last previous edition approved in 2006 as C1210 – 06. DOI: 10.1520/C1210-12.

[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.

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4. Significance and Use

~~3.1A~~4.1 A laboratory quality assurance program is an essential program for laboratories within the nuclear industry. Guide C1009 provides guidance for establishing a quality assurance program for an analytical laboratory within the nuclear industry. The basic elements of a laboratory quality assurance program are organization, quality assurance program, training and qualification, procedures, laboratory records, control of records, control of procurement, control of measuring equipment and materials, control of measurements, and deficiencies and corrective actions. This guide deals with the control of measurements aspect of the laboratory quality assurance program. Fig. 1 shows the relationship of measurement control with other essential aspects of a laboratory quality assurance program.

~~3.2The~~4.2 The fundamental purposes of a measurement control program are to provide the *with use* assurance (real-time control) that a measurement system is performing satisfactorily and to provide the data necessary to quantify measurement system performance. The *with use* assurance is usually provided through the satisfactory analysis of quality control samples (reference value either known or unknown to the analyst). The data necessary to quantify measurement system performance is usually provided through the analysis of quality control samples or the duplicate analysis of process samples, or both. In addition to the analyses of quality control samples, the laboratory quality control program should address (*1*) the preparation and verification of standards and reagents, (*2*) data analysis procedures and documentation, (*3*) calibration and calibration procedures, (*4*) measurement method qualification, (*5*) analyst qualification, and (*6*) other general program considerations. Other elements of laboratory quality assurance also impact the laboratory quality control program. These elements or requirements include (*1*) chemical analysis procedures and procedure control, (*2*) records storage and retrieval requirements, (*3*) internal audit requirements, (*4*) organizational considerations, and (*5*) training/qualification requirements. To the extent possible, this standard will deal primarily with quality control requirements rather than overall quality assurance requirements.

~~3~~4.3 Although the Standard Guide uses suggestive rather than prescriptive language (for example, "should" as opposed to "shall"), the elements being addressed should not be interpreted as optional. An effective and comprehensive laboratory quality control program should, at minimum, completely and adequately consider and include all elements listed in Section 1 and in the corresponding referenced sections of this guide.

~~4.~~5. General Quality Control Program Considerations

~~4.1The~~5.1 The quality control activities described in this guide are intended for a quality control function which is internal to an analytical chemistry laboratory. The quality control program should have an administrator or manager working in concert with laboratory managers to produce cost effective measurements of demonstrated quality. The program manager should have the authority based on quality control sample performance to disqualify analysts or measurement systems, or to request or require additional quality control sample analyses. It is desirable for the quality control program to have periodic internal assessments. These assessments should involve laboratory managers, the quality control manager, and laboratory customers. The quality control program should be audited for procedure compliance at periodic intervals by the quality assurance organization.

~~4.2The~~5.2 The analytical laboratories quality control program should be described in laboratory procedures and all measurement system quality control activities should be documented. The retention period for the documentation should be

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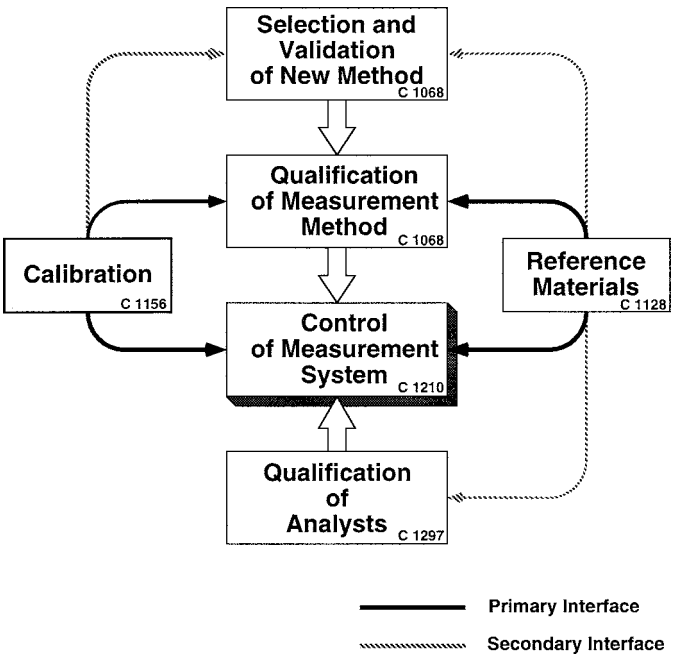

FIG. 1 Quality Assurance of Analytical Laboratory Data

described in laboratory procedures and consistent with other laboratory storage requirements and any applicable contractual or regulatory requirements.

45.3 External quality control program assessment should be conducted by an outside organization or agency at a frequency dictated by company or facility policy, contract, or other applicable regulations or requirements. When possible, laboratory and quality control management should involve laboratory measurement systems in external exchange programs, such as: interlaboratory exchange programs, sample exchange programs, sample or standard round robins, and referee analyses programs. The programs provide some degree of external verification or validation of the measurement system quality control program that is desirable.

5.6. Quality Control Samples

56.1 Quality control samples (knowns, unknowns, blinds, blanks, etc.) are used to verify and monitor measurement system performance. Quality control samples should be prepared or purchased over the measurement range of interest and have an impurity content and matrix composition that approximates the process samples, unless the measurement method has been shown to be free from sample matrix effects. Quality control sample preparation procedures, specific requirements (purity of source materials and solvents; storage requirement; shelf life; etc.), and the preparation should be documented. Quality control samples may be prepared from the following: Certified Reference Materials (CRMs), Working Reference Materials (WRMs), other reference materials, pure elements or compounds with vendor supplied assay, reagent grade (or better) chemicals with assay, and process materials. Guidance on the preparation of WRMs for use in the analysis of nuclear fuel cycle materials is provided in Guide C1128.

5.2When6.2 When quality control samples are prepared, the preparation procedure and data (mass, volume, etc.) should be documented. Further, appropriate measurements should be performed to verify the prepared value.

5.3The6.3 The quality control samples should be characterized to establish their reference values when prepared from materials with uncertain assays, or from process material, or when a smaller uncertainties are required on the samples than can be obtained from the source materials. A record of the preparation procedure and data should be maintained. The characterization method or procedure, complete with calibration data and the characterization analysis results, should be referenced or included in the preparation data.

5.4All6.4 All quality control samples should be labeled with (*1*) the concentration, activity, abundance, etc. of the species of interest, (*2*) solvent if other than water, (*3*) matrix, (*4*) date prepared, (*5*) identification of preparer, and (*6*) storage requirements or limitations. Alternately, QC samples should be coded in such a manner as to uniquely identify this same information.

5.5All6.5 All incoming chemicals and RMs should be labeled with a shelf life, acceptance date, or expiration date, if applicable.

6.7. Analysis of Quality Control Samples

6.1The7.1 The analysis of data from quality control samples provides a demonstration of measurement system performance and provides the information necessary to quantify that performance over the portion of the system covered by the quality control samples. The reference value of the quality control samples may be either known or unknown to the analyst.

6.1.1The7.1.1 The analysis of known quality control samples can provide a satisfactory bench demonstration of whether a system is in- or out-of-control without the need for a computer based quality control program. In general, the data resulting from the analysis of known quality control samples is not recommended for quantifying measurement system performance.

6.1.2In7.1.2 In general, the analysis of unknown quality control samples provides the data necessary to quantify measurement system performance. The data resulting from the analysis of unknown quality control samples may also be used to provide the *with use* assurance of method performance, but some form of computer based system would be required in order to provide the real-time, at-bench determination of system performance. The use of unknown quality control samples for both functions can significantly increase the amount of data available to model measurement systems.

6.2The7.2 The frequency of analysis of quality control samples should be determined and described in laboratory procedures. The frequency should be a function of the stability of the measurement system.

67.3 Quality control samples should be subjected to the same analysis conditions as the actual samples. The condition should be the same over the entire analysis sequence from sample aliquoting and preparation to data reduction.

67.3.1 When quality control samples are not subjected to a portion of the sample analysis sequence, sufficient documentation should exist to demonstrate that the portion of the system that is not covered does not contribute significantly to the measurement system bias and precision. The liability that exists for not covering the entire sequence should be understood and documented.

67.3.2 Even though sample aliquoting by mass or by volume may be included in the analysis of quality control samples, this function is so fundamental and common to nearly all measurement systems that laboratories should maintain calibration and quality control programs on balances and, if applicable, on volume aliquoting and measuring devices. Balance and volume aliquoting devices should be treated as measurement systems or methods and should have calibration and quality control programs that satisfy the information contained in this guide.

6.4The7.4 The analysis of quality control samples should be documented. The documentation should include, but not necessarily be limited to, date and time of analysis, measurement system identification, analyst identification, quality control sample reference value or code, analysis results, analysis raw data, and whether the analysis passed or failed system performance criteria.

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