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StandardGuide for Establishing a Quality Assurance Program for Analytical Chemistry Laboratories Within the Nuclear Industry[1]

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1. Scope

1.1 This guide covers the establishment of a quality assurance (QA) program for analytical chemistry laboratories within the nuclear industry. Reference to key elements of ANSI/ISO/ASQC Q9001, Quality Systems, provides guidance to the functional aspects of analytical laboratory operation. When implemented as recommended, the practices presented in this guide will provide a comprehensive QA program for the laboratory. The practices are grouped by functions, which constitute the basic elements of a laboratory QA program.

1.2 The essential, basic elements of a laboratory QA program appear in the following order:

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Organization	5
Quality Assurance Program	6
Training and Qualification	7
Procedures	8
Laboratory Records	9
Control of Records	10
Control of Procurement	11
Control of Measuring Equipment and Materials	12
Control of Measurements	13
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2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

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

D1193 Specification for Reagent Water

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E542 Practice for Calibration of Laboratory Volumetric Apparatus

E617 Specification for Laboratory Weights and Precision Mass Standards

E694 Specification for Laboratory Glass Volumetric Apparatus

2.2 *ANSI Standard:*

ANSI/ISO/ASQC Q9001 Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing[3]

2.3 *NIST Standard:*

NIST IR74-461 The Calibration of Small Volumetric Laboratory Glassware (1974)[4]

2.4 *ASME Standard:*

ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications[5]

3. Terminology

3.1 *Definitions:*

3.1.1 *laboratory quality assurance, n*—all those planned and systematic actions necessary to provide adequate confidence in each analytical result reported by a laboratory.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *chain of custody, n*—a procedure that documents continuous sample control and security.

3.2.2 *custody, n*—physical possession of a sample by a 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.

[4] Available from National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 3460, Gaithersburg, MD 20899-3460.

[5] Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Three Park Ave., New York, NY 10016-5990.

3.2.3 *laboratory, n*—an organization established to provide analyses of materials.

3.2.4 *out-of-control, adj*—failing to meet preselected performance criteria.

3.2.5 *requester, n*—the person or organization requesting analyses.

3.2.6 *result, n*—a qualitative or quantitative description of a property obtained from an analysis and reported to a requester.

3.2.7 *traveler, n*—a laboratory record used to transmit information and data through the laboratory.

4. Significance and Use

4.1 The mission of an analytical chemistry laboratory is to provide quality analyses on nuclear fuel cycle materials. An analytical chemistry laboratory QA program is comprised of planned and systematic actions needed to provide confidence that this mission is conducted in an acceptable and consistent manner.

4.2 The analytical chemistry laboratories involved in the analysis of nuclear fuel cycle materials are required to implement a documented QA program. Regulatory agencies may mandate some form of control requirements for all or a part of a laboratory's operation. When not mandated, laboratory QA programs should be established as a sound and scientific technical practice. This guide provides guidance for establishing a QA program to control those analytical chemistry operations vital to ensuring the quality of chemical analyses.

4.3 Quality assurance programs are designed to meet the needs of the organization. The quality system is complementary to specific technical requirements. Each laboratory should identify applicable program requirements and use standards to implement a quality program that meets the appropriate requirement. This guide may be used to develop and implement an analytical chemistry laboratory QA program. Other useful implementation standards and documents are listed in Section 2 and Appendix X1.

4.4 The guides for QA in the analytical laboratory within the nuclear fuel cycle have been written to provide guidance for each of the major activities in the laboratory and are displayed in Fig. 1. The applicable standard for each subject is noted in the following sections.

4.5 Although the Standard Guide describes "Recommended Practices" and "Recommendations" and 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 assurance / 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.

5. Organization

5.1 *Summary*—An organizational structure is the framework within which functional responsibilities, authorities, and interfaces are established. From a QA viewpoint, the subjects included as recommended practices in 5.2 are areas in which

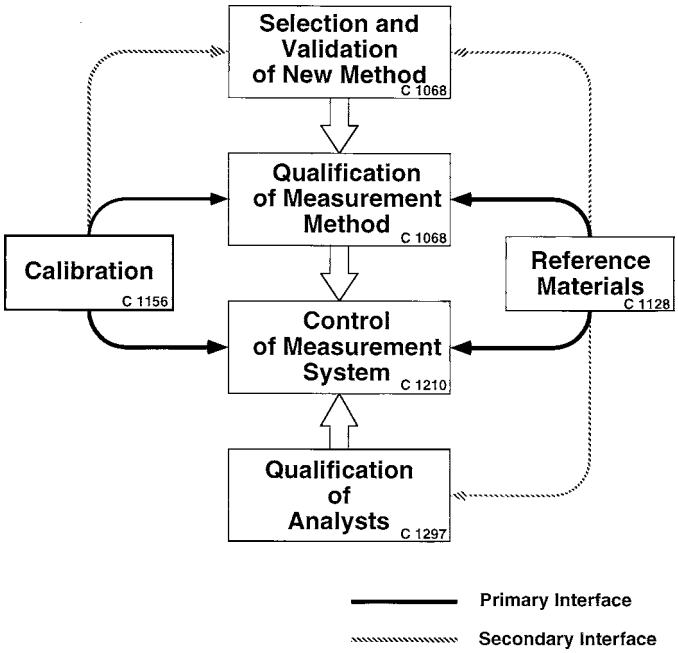

FIG. 1 Quality Assurance of Analytical Laboratory Data

administrative controls should be defined. This is particularly true for laboratories having multiple functional groups.

5.2 *Recommended Practices:*

5.2.1 *Organizational Structure*—Each laboratory should define its internal structure and its position within the larger structure when the laboratory exists within a larger organization. For a laboratory having only a few people, defining an internal structure may not be appropriate, but defining its position in a larger organization is relevant.

5.2.2 *Functional Responsibilities*—Functional responsibilities should be clearly established for job classifications and functional groups within a laboratory. Functional responsibility defines how work is accomplished in the laboratory in terms of who does it and where it is done. This helps to establish relationships and interfaces within the laboratory.

5.2.3 *Levels of Authority*—Authority to carry out work responsibilities, particularly those involving technical and operational decisions, should be clearly established. Authority includes decision making and approval of actions, extending from the working level up to the manager of the laboratory and beyond if the laboratory is a part of a larger organization. The actions requiring approval and the types of decisions permitted should be established for job classifications at each organizational level.

5.2.4 *Communications*—Methods of communication, both formal and informal, should be clearly established between working groups within a laboratory and, particularly, between the laboratory and outside organizations interacting with the laboratory.

6. Quality Assurance Program

6.1 *Summary*—QA becomes a formal, visible program for a laboratory when a document that *(1)* prescribes the QA

requirements applicable to operation of the laboratory and *(2)* describes how those requirements are implemented, is prepared and approved.

6.2 *Recommendations:*

6.2.1 *Quality Assurance Program Description*—Once QA requirements have been selected and existing laboratory practices evaluated with respect to those requirements, procedures should be written to describe how those QA requirements are implemented in laboratory operations. These QA procedures, either added to existing laboratory documents or assembled into a separate laboratory QA manual, define the laboratory QA program.

6.2.2 *Implementation*—Once the QA program documentation has been prepared, reviewed, and approved, new or modified practices should be implemented by training personnel in their use. In addition, personnel should receive an overview of the contents of the QA program and specific instruction in elements applicable to their responsibilities.

6.2.3 *Assessment Program*—There should be a procedure established whereby the adequacy of laboratory management and operations is assessed regularly. This procedure should ensure that problems and deficiencies are identified, documented, analyzed, resolved, and followed up. Assessment programs should consist of at least two components: management and independent assessment. Personnel performing assessments should be technically qualified and knowledgeable in the areas assessed.

6.2.3.1 *Management Assessment*—All levels of management should critically assess work under their cognizance and determine whether they are meeting established quality objectives.

6.2.3.2 *Independent Assessment*—Independent assessments should be performed to focus on issues that affect the organization's performance. They should be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. Independent assessment personnel should have sufficient authority and organizational independence to carry out their responsibility. Independent assessment personnel may act as advisors to senior management to assess quality and process effectiveness.

6.2.3.3 *Reporting*—Assessment procedures should include provisions for reporting the results to those responsible for ensuring correction of the problems identified.

6.2.4 *Quality Improvement*—Processes to detect and prevent quality problems should be established and implemented. The processes should include identification of the causes of problems and work to prevent recurrence. Quality-related information should be reviewed and data analyzed to identify areas of needed improvement, according to the importance of the problem and the work affected.

7. Training and Qualification

7.1 *Summary:*

7.1.1 An important factor affecting all laboratory activities is the training and qualification of those doing the work, including chemists, technicians, clerical workers, and other support personnel. Training can vary from direct, on-the-job training by a more experienced person to a formal program involving both classroom and on-the-job training. The extent of training required depends on the complexity of the work, educational background, demonstrated level of competence, previous work experience, and the requester's requirements. Training should be ongoing and laboratory personnel should be encouraged to attend seminars, courses, and professional meetings as appropriate. Analysts should be qualified before beginning the analysis of samples.

7.1.2 Qualification includes not only specific training, but also the review and verification of applicable education and experience. All operations should be performed by adequately trained and qualified people. The requirements for qualification of each person performing analyses should be defined by management (see Fig. 1).

7.2 *Recommendations:*

7.2.1 *Training*—Providing training is a basic management responsibility. The need for training and the type of training used should be a management decision based on the factors mentioned previously. Management should establish a documented training system to ensure that persons are trained adequately and that they remain trained as changes in work practices occur. Such a program should be developed based on job requirements relating to skills, knowledge, and levels of competency required for adequate job performance. Quality assurance training should be included.

7.2.2 *Qualification*—Analysts should be qualified in accordance with qualification requirements established for each method. As with training, management is responsible for the qualification process, which can range from a simple practice of stating that an analyst is qualified by reason of education, experience, and job knowledge to a formal system requiring passing tests and routinely demonstrating proficiency in required job skills. Guide C1297 provides guidance on the qualification of analysts (see Fig. 1).

7.2.3 *Records*—Training and qualification records should be maintained to give visibility to the training program and to show the past and current qualification status of each person trained. The extent of the records required will depend on the scope of the qualification process.

7.2.3.1 The qualification record should identify the basis of the analyst's qualification, and those methods for which the analyst is qualified. Management should verify qualification before assigning work.

7.2.3.2 Qualification should be reviewed and updated, if required, on at least a yearly basis.

7.2.3.3 Training and qualification records are QA records, and they should be controlled as prescribed in Section 10.

8. Procedures

8.1 *Summary:*

8.1.1 Analyses should be conducted in a planned, systematic, and controlled manner. Any unauthorized change in the actions or their specified sequence may produce incorrect results. Documented procedures should be implemented to provide direction to those performing the work, provide information for training analysts, and describe the methods to be used and their technical basis. Procedures should be well-written, complete and correct, and should contain criteria

for determining whether the prescribed activity has been completed satisfactorily. Qualification of a procedure (method) may be required. Guide C1068 provides guidance on the qualification of measurement methods (see Fig. 1).

8.1.2 Measures for the preparation and control of procedures should be established to ensure their completeness and correctness prior to issuance, and as they are used over time.

8.2 *Recommendations:*

8.2.1 *Preparation*—A formal process for writing procedures helps to promote well-written, complete, and correct procedures. The following elements should be included in the preparation process:

8.2.1.1 *Format*—Before writing procedures, a format should be established that will help provide consistency across a series of procedures and completeness within each procedure; it will also help simplify the writing process. Formats generally contain such components as purpose or scope, applicability, references, and technical instructions. Technical instructions may include such components as a listing and description of equipment and materials required, applicable safety precautions, tolerances, step-by-step instructions for performing the work, calculations, and expected precision and bias. Instructions for calibration and control charting are sometimes included in the analysis procedures.

8.2.1.2 *Writing*—Procedure writers should be competent in technical writing skills, but need not be expert in the analytical methods involved. The writing style used should provide clear and concise instructions to avoid confusion and misunderstanding by the users.

8.2.1.3 *Editorial Review*—Someone other than the author should review procedures for conformity to format, consistency in terms and abbreviations, punctuation and spelling, and clarity. An editorial review will help in providing quality documents, which will help enhance the credibility of the laboratory issuing the procedures.

8.2.1.4 *Technical Review*—Procedures should be reviewed for technical adequacy. Such a review would normally be conducted by technically competent persons within the issuing laboratory having no direct responsibility for the procedures. Such a peer review could extend outside of the issuing laboratory to provide a more independent evaluation of technical adequacy.

8.2.1.5 *Approval*—Line management should approve each procedure prior to issuance, to certify that the procedure was prepared as prescribed by applicable requirements, and to signify management responsibility for its adequacy. Additional management or customer approvals may also be required.

8.2.2 *Control*—Control practices should be established to provide assurance that the adequacy and effectiveness of procedures is not affected adversely with time and use. This includes ensuring that procedures are applied correctly when used. The following actions should be included in the control process:

8.2.2.1 *Distribution*—A controlled distribution should be established to ensure that the correct procedures are available where needed, and that all copies are updated when revisions are made. Distribution can be controlled by numbering each copy and establishing a distribution list by number. The distribution list should include all recipients of controlled copies.

8.2.2.2 *Application*—Management should ensure that each procedure is being applied as intended.

8.2.2.3 *Changes*—Changes in procedures should be controlled to avoid changes that would cause errors in the analyses. All controlled copies of a procedure should be updated when a change is made and approved. Control practices may distinguish between major and minor changes, providing the differences are clearly defined. Where these practices allow minor changes to be made at the work place, the changes should be documented at the time in a prescribed manner, and incorporated in the next revision. Major changes should be reviewed and approved by the same functions that performed the original review and approval.

9. Laboratory Records

9.1 *Summary:*

9.1.1 Records used to document the work performed in the laboratory provide traceability of analytical results; establish control of samples, and identify how and by whom the work was done. To carry out those purposes, a laboratory record system should provide for five specific activities or functions as follows: *(1)* receive sample information from the requester; *(2)* provide sample identification; *(3)* transmit information and data through the laboratory; *(4)* provide a record of data and information; and *(5)* report results of analyses. Performing those functions usually involves the use of several forms that become laboratory records requiring control actions to prevent loss of data and information. These functions form the basis for the recommended practices that follow. If a computer is used to manage data and information, the five functions should be conducted through the computer program.

9.1.2 The recommended practices are described in the following terms: analysis request, log, traveler, data record, and analytical report. The purposes of each are given, along with recommended distribution and retention time. Purposes can be accomplished using an individual form for each practice or using a combined form that incorporates two or more practices. A combined form should permit all purposes of the individual forms to be fulfilled. The distribution and retention time of a combined form should be governed by the widest distribution and longest retention time represented by the individual forms. A bound laboratory notebook can be used instead of a form for several of the practices. A bound notebook is often used for the data record, for example, using a different notebook for each analytical method. Notebooks and accumulations of completed forms in loose-leaf notebooks and files should be controlled through distribution lists, retention times, and assigned preparation and custodial responsibilities. The number of record copies is determined by each laboratory.

9.2 *Recommendations:*

9.2.1 *Analysis Request:*

9.2.1.1 *Use*—The analysis request initiates work in the laboratory and provides sample information. It should identify the requester, submittal date, analyses requested, sample identification, material type and special instructions, as applicable.