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Standard Guide for Establishing and Maintaining a Quality Assurance Program for Analytical Laboratories Within the Nuclear Industry[1]

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1. Scope

1.1 This guide covers the establishment and maintenance of a quality assurance (QA) program for analytical laboratories within the nuclear industry. References to key elements of ~~ASME NQA-1~~ASME NQA-1 and ~~ISO 9001~~ISO/IEC 17025 provide guidance to the functional aspects of analytical laboratory operations. 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:

	~~Section~~
~~Organization~~	~~5~~
~~Quality Assurance Program~~	~~6~~
~~Training and Qualification~~	~~7~~
~~Procedures~~	~~8~~
~~Laboratory Records~~	~~9~~
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~~Control of Procurement~~	~~11~~
~~Control of Measuring Equipment and Materials~~	~~12~~
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	Section
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Management of Customer Requests and Commitments to Customers	11
Control of Procurement	12
Control of Measuring Equipment and Materials	13
Control of Measurements	14
Control of Nonconforming Work	15
Candidate Actions	16
Preventative Actions	17

1.3 Collection of samples and associated sampling procedures are outside the scope of this guide. The user may refer to sampling practices developed by Subcommittee C26.02.

[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, Statistical Applications, and Reference Materials.

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1.4 Nuclear laboratories are required to handle a variety of hazardous materials, including but not limited to radioactive samples and materials. The need for proper handling of these materials is discussed in 13.2.4. While this guide focuses on the nuclear laboratory QA program, proper handling of nuclear materials is essential for proper function of the QA program.

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]

C859 Terminology Relating to Nuclear Materials
C1068 Guide for Qualification of Measurement Methods by a Laboratory Within the Nuclear Industry
C1108 Test Method for Plutonium by Controlled-Potential Coulometry
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
D4840 Guide for Sample Chain-of-Custody Procedures
E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
E178 Practice for Dealing With Outlying Observations
E542 Practice for Calibration of Laboratory Volumetric Apparatus
E617 Specification for Laboratory Weights and Precision Mass Standards
E694 Specification for Laboratory Glass Volumetric Apparatus
E1578 Guide for Laboratory Informatics

2.2 ~~*Other*~~*ISO Standards:*[3]

ISO 9000 Quality Management Systems—Fundamentals and Vocabulary
ISO 9001 Quality Management Systems—Requirements
ISO 1042 Laboratory Glassware—One-Mark Volumetric Flasks
~~ISO/IEC 17020 General Criteria for the Operation of Various Types of Bodies Performing Inspection~~
ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
~~ANSI N15.41 Derivation of Measurement Control Programs—General Principles~~
~~ANSI N15.51 Measurement Control Program—Nuclear Materials Analytical Chemistry Laboratory~~
~~JCGM 20:2008 International Vocabulary of Metrology—Basic and General Concepts and Associated Terms (VIM)~~
~~ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications~~[3]

2.3 *ANSI Standards:*[4]

ANSI N15.41 Derivation of Measurement Control Programs—General Principles
ANSI N15.51 Measurement Control Program—Nuclear Materials Analytical Chemistry Laboratory

2.4 *BIPM Standards:*[5]

JCGM 100:2008 Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement
JCGM 200:2008 International Vocabulary of Metrology—Basic and General Concepts and Associated Terms

2.5 *ASME Standard:*[6]

ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications

3. Terminology

~~3.1 For definitions of pertinent terms not listed here, see Terminology C859.~~

[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 International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

[6] Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, ~~Three~~Two Park Ave., New York, NY ~~10016-5990.~~10016-5990, http://www.asme.org.

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

[5] Available from Bureau International des Ponds et Mesures (BIPM), www.bipm.org .

3.1 ~~*Definitions of Terms Specific to This Standard:*~~*Definitions:*

3.1.1 For definitions of pertinent terms not listed here, see Terminology C859.

3.1.2 *assessment, n*—an all-inclusive term that may include review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

ASME NQA-1

3.1.3 *audit, n*—a planned and documented activity performed to determine, based on objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation (adapted from ASME NQA-1).

3.1.3.1 *Discussion*—
An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

ASME NQA-1

3.1.4 *calibration, n*—the set of operations that establishes, under specified conditions, a metrologically traceable relationship between a value measured or indicated by an instrument or system to a corresponding known value, typically derived from appropriate reference standards or established physical constants.

3.1.4.1 *Discussion*—
The calibration relationship can be expressed by a statement, function, diagram or table.

3.1.4.2 *Discussion*—
Test Method C1108 is an example of calibration using established physical constants.

3.1.4.3 *Discussion*—
Additional details on calibration requirements for measurement methods used for the nuclear fuel cycle can be found in Guide C1156.

3.1.5 *condition adverse to quality, n*—an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. ~~**ASME NQA-1**~~ **ASME NQA-1**

3.1.6 *confidentiality, n*—management of information in a manner that prevents unauthorized disclosure of information obtained from a customer or from laboratory analysis or other activities.

3.1.6.1 *Discussion*—
In this context, “unauthorized” represents disclosure without prior approval of the customer, but does not include disclosures that may be required by law or regulation.

3.1.7 *custody, n*—physical possession or ~~control. A~~control; a sample is under custody if it is in possession or under control so as to prevent tampering or alteration of its characteristics. ~~**D4840**~~ **D4840**

3.1.8 ~~*customer,*~~*impartiality, n*~~—the entity requesting analytical services from the laboratory.~~presence of objectivity.

~~3.2.3.1 *Discussion*—~~
~~A customer may be a person or an organization, and may be internal to the organization of which the laboratory is a part, or may be an external entity.~~

ISO/IEC 17025

3.1.8.1 *Discussion*—
Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory.

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

3.1.10 *laboratory quality assurance, n*—all those planned and systematic actions necessary to provide adequate confidence in each analytical result reported by a laboratory (adapted from ~~ASME NQA-1).~~ ASME NQA-1).

3.1.11 *management system, n*—set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives. **ISO 9000**

3.1.12 *measurement method, n*—technique for determination of the presence, or quantity, or both, of one or more analytes in a sample.

3.1.12.1 *Discussion*—
A measurement method may utilize chemical reactions (such as titrations), instrumentation (such as a spectrometer), or both. Any sample preparation required prior to the analysis is part of the measurement method.

3.1.13 *metrological traceability, n*—property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.
JCGM 200:2008

3.1.14 *primary measurement standard, n*—measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention. ~~(VIM)~~ **JCGM 200:2008**

3.1.15 ~~*result,quality n—assurance program—a qualitative or quantitative description of a property obtained from an analysis and reported to a customer.*~~ that portion of a management system focused on the degree to which the characteristics of a product or service meets specified requirements

3.1.15.1 *Discussion*—
The quality assurance program is also known as a quality management system (see ISO 9000 and related documents).

3.1.16 *sample, n*—a portion of a process or product matrix that is collected and used to determine the characteristics of that matrix (adapted from Guide D4840).

3.1.17 *sample chain-of-custody, n*—the process whereby a sample is maintained under physical possession or control during its entire life cycle, that is, from collection to disposal. **D4840**

3.1.18 *significant condition adverse to quality*—a condition (see ~~3.2.1~~3.2.3) that, if uncorrected, could have a serious effect on safety or operability. **ASME NQA-1**

~~3.2.11 *traveler, n—a laboratory record used to transmit information and data through the laboratory during processing.*~~

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *customer, n*—the entity requesting analytical services from the laboratory.

3.2.1.1 *Discussion*—
A customer may be a person or an organization, and may be internal to the organization of which the laboratory is a part, or may be an external entity.

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

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

3.2.3.1 *Discussion*—
Other names for this record, such as task sheet, may be used in some laboratories.

4. Significance and Use

4.1 The mission of an analytical laboratory is to provide quality analyses on nuclear fuel cycle materials. An analytical 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 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. A documented QA program is also necessary for those laboratory operations required to comply with ~~ASME NQA-1~~ASME NQA-1 or ~~ISO/IEC 17025,~~ ISO/IEC 17025, or the requirements of many accreditation bodies. Even when not mandated, laboratory

QA programs should be established as a sound and scientific technical practice. This guide provides guidance for establishing and maintaining a QA program to control those analytical operations vital to ensuring the quality of chemical analyses.

4.3 Quality assurance programs are designed and implemented by organizations to assure that the quality requirements for a process, product or service will be fulfilled. The quality system is complementary to ~~specific technical requirements.~~ technical requirements that may be specific to a process or analytical method. 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 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~~ this 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 completely and adequately considers and includes all elements listed in Sections 5 – ~~14~~17 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 administrative controls should be defined. This is particularly true for laboratories having multiple functional groups.

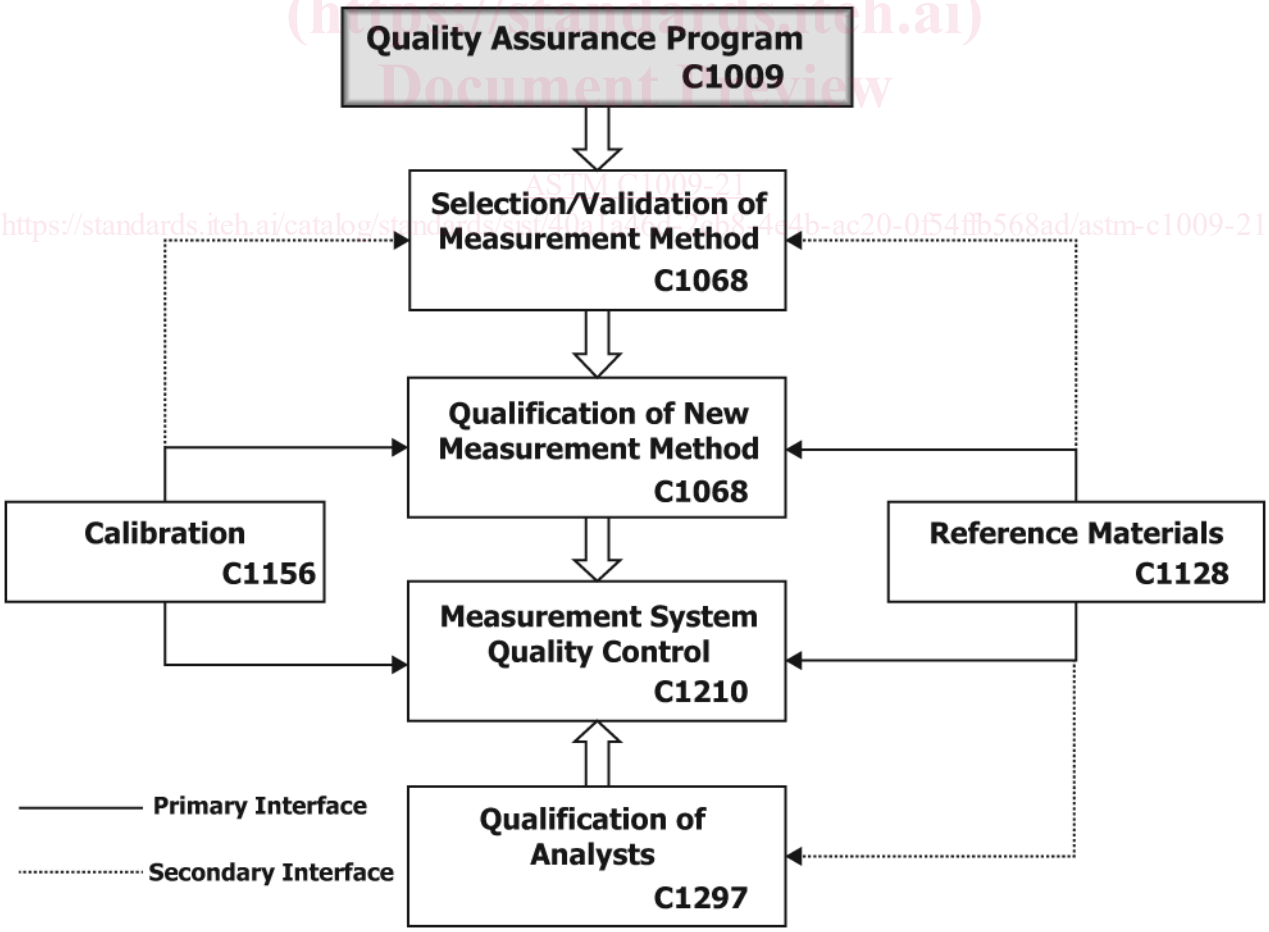

FIG. 1 ~~Quality Assurance~~Essential Elements of Analytical Laboratory ~~Data~~Quality Assurance System

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 small laboratories, defining an internal structure may not be necessary.

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:* ~~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.~~

5.2.3.1 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.

5.2.3.2 Personnel should have the authority and resources needed to perform their assigned duties.

5.2.3.3 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. This includes communications related to the effectiveness of the laboratory's management system.

6. Quality Assurance Program

6.1 *~~Summary~~—Description:* ~~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. This document should be reviewed on an established frequency and updated as necessary.~~

6.1.1 QA becomes a formal, visible program for a laboratory when documentation that *(1)* prescribes the QA requirements applicable to operation of the laboratory, and *(2)* describes how those requirements are implemented, is prepared and approved. This documentation becomes a key component of the overall management system for the laboratory and is controlled as part of the management system.

6.1.2 QA documentation should be reviewed on an established frequency and updated as necessary.

6.2 *Recommendations:*

6.2.1 *Quality Assurance Program ~~Description—~~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.~~

6.2.1.1 Once QA requirements have been selected and existing laboratory practices evaluated with respect to those requirements, documentation (for example, procedures) should be written and approved by laboratory management to describe how those QA requirements are implemented in laboratory operations.

6.2.1.2 QA program documentation should include, at a minimum, the elements described in Sections 5 – 17 of this guide. Requirements for impartiality and confidentiality should also be addressed.

6.2.1.3 The QA program documentation, either added to existing laboratory documents or assembled into a separate laboratory QA manual, define the laboratory QA program.

6.2.1.4 The documentation should be reviewed on a pre-determined schedule and updated as needed.

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. Corrective and preventive ~~actions~~ actions, as well as risks and opportunities for improvement, should be identified, evaluated, and resolved as described in ~~Section~~Sections ~~14~~16 and 17. 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—~~Assessment:* ~~All levels of management should critically assess work under their cognizance and determine whether they are meeting established quality objectives.~~

(1) On an ongoing basis, all levels of management should critically assess work under their cognizance and determine whether they are meeting established quality objectives.

(2) On a periodic basis, management should perform a documented review of all elements of the QA program, identifying deficiencies and opportunities for improvement. ISO/IEC 17025 describes components that should be included.

6.2.3.2 *Internal Audit*—On a periodic basis, audits of the management system should be performed by qualified personnel within, or on behalf of, the laboratory. ISO/IEC 17025 describes expectations for internal audits.

6.2.3.3 *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. Conflicts of interest should be avoided to the extent possible, and should be disclosed where they cannot be avoided.

6.2.3.4 *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*—Information obtained through QA program implementation, assessments, periodic reviews, corrective and preventive actions should be used to continuously improve the effectiveness of the program. Feedback from the laboratory's customers should be obtained on a periodic basis and used to improve QA program effectiveness (see Section 17).

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 customer'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,~~samples or should be working under the direct supervision of a qualified analyst.

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—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).~~

7.2.2.1 Personnel involved with method development and oversight, performance of measurements, and troubleshooting and maintenance of laboratory equipment, should be qualified, in accordance with procedures approved by laboratory management, for the tasks that they perform.

7.2.2.2 Qualification should be based on requirements established for each method. As with training, management is responsible for the qualification process, which can range from a simple statement of qualification based on of education, experience, and job knowledge to a formal system requiring passing tests and routinely demonstrating proficiency in required job skills. For analysts, Guide C1297 provides guidance on qualification (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 Procedures should be developed to provide direction to those performing work, provide information for training personnel, and (as applicable) contain criteria for determining whether the prescribed activity has been completed satisfactorily. Procedures ensure that work is conducted in a planned, systematic, and controlled manner.

8.1.2 Procedures are needed for the performance of analyses, other technical work within the laboratory, and for QA and other programmatic requirements.

8.1.3 Procedures should be well-written, complete and correct.

8.1.4 ~~Analyses should be conducted in a planned, systematic, and controlled manner. Any~~ Procedures are particularly important for analyses since any unauthorized change in the actions or their specified sequence may produce incorrect results. ~~Documented~~ The technical basis for 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.~~ documented either in the procedure or in associated documentation. Qualification of a procedure (method) may be required. Guide C1068 provides guidance on the qualification of measurement methods (see Fig. 1).

8.1.5 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.

8.1.6 Measures should also be established for the preparation and control of instructions or procedures for special or ~~one-analytical~~oneanalytical processes.

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, terms and definitions, 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 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. 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. Any 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,~~ workplace, the changes should be documented at the time in a prescribed ~~manner,~~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.

8.2.3 *Periodic Review*—Procedures should be reviewed on an established frequency to ensure that they remain effective for their intended use. Changes identified by the periodic review, if any, should be carried out in a timely manner.

9. Laboratory Records

9.1 *Summary:*

9.1.1 Records are used to document the work performed in the ~~laboratory~~laboratory; provide traceability of analytical results; establish control of ~~samples,~~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 ~~customer;~~customer, *(2)* provide sample ~~identification;~~identification, *(3)* transmit information and data through the ~~laboratory;~~laboratory, *(4)* provide a record of data and ~~information;~~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. ~~the~~the recommended practices that follow. These functions are typically managed electronically through a

laboratory information management system ~~(LIMS), with hard copy records~~ (LIMS). Records generated from the ~~LIMS and~~ LIMS, whether electronic or hard copy, are controlled as described in Section 10. Additional guidance on the use of a LIMS is found in Guide E1578.

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. and custodial responsibilities. The number of record copies is determined by each laboratory. Electronic notebooks and similar files may be substituted for bound notebooks, provided the users do not have the ability to modify or delete the recorded information once it is entered and transmitted or electronically signed.~~ *Types of Records:*

9.1.2.1 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.

9.1.2.2 Laboratories may apply flexibility in how these practices are documented as long as the basic requirements are met. 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, if used, 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.

9.1.2.3 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.

9.1.2.4 The number of record copies is determined by each laboratory. Electronic notebooks and similar files may be substituted for bound notebooks, provided the users do not have the ability to modify or delete the recorded information once it is entered and transmitted or electronically signed.

9.1.2.5 Management of laboratory records should ensure appropriate confidentiality; that is, it should prevent unauthorized disclosure of data records and analytical reports.

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 customer, submittal date, analyses requested, sample identification, material type and special instructions, as applicable. Each sample submitted should be accompanied by a properly completed analysis request, although the same request may be used for more than one sample. The request should be reviewed by laboratory personnel to ensure that all requirements and other information are clearly understood. Any problems should be resolved with the customer.

NOTE 1—The analysis request may be submitted on chain-of-custody forms. See Guide D4840 for additional information.

9.2.1.2 *Distribution*—The original should be retained by the laboratory and a copy provided to the customer after being logged in. Documentation may be hard copy or electronic, based on established procedures.

9.2.2 *Sample Registration Log:*

9.2.2.1 *Use*—The sample registration log provides a means to register the sample and assign it a unique number for the laboratory's sample identification. For each sample it should identify the unique number, customer, analysis request number,

customer's sample identification, date received, analyses required, type of material, date completed, sample disposition and date. The log may be manual or within the LIMS.

9.2.2.2 *Distribution*—The log should be retained by the laboratory. Documentation may be hard copy or electronic, based on established procedures.

9.2.3 *Traveler:*

9.2.3.1 *Use*—The traveler transmits sample information to the analyst, initiates analyses, and provides sample identification throughout processing. The traveler may consist of one or more printed forms, or may be incorporated in the LIMS. It identifies the sample registration number, analysis request number, and sequence of operations to be performed, and should be signed and dated, or electronically authenticated, by the person performing each operation.

9.2.3.2 *Distribution*—The traveler should be retained by the laboratory. Documentation may be hard copy or electronic, based on established procedures.

9.2.4 *Data Record:*

9.2.4.1 *Use*—The data record contains all data generated during the analyses, and documents activities relating to measurement control including unusual or unexpected occurrences during analyses. The data record should maintain traceability between the original sample and the analytical report, and include the sample unique number, customer's sample identification, data obtained, identification of standards ~~used,~~ used (and, as applicable, information on their metrological traceability), analyst's signature, completion date, special observations (if any) and a summary of actions taken in connection with unusual occurrences.

9.2.4.2 *Distribution*—The data record should be retained by the laboratory.

9.2.5 *Analytical Report:*

9.2.5.1 *Use*—The analytical report transmits analytical results to the customer. For each sample it should include the ~~unique number, customer's sample identification, and analytical results with uncertainties.~~ elements identified in ISO/IEC 17025, except where there are valid reasons not to include one or more of those elements. If additional items are specified by the customer, these should also be included. The report should be reviewed for correctness and approved by an authorized person prior to issuance. The responsibility for reviewing, approving and issuing reports should be identified clearly.

9.2.5.2 *Distribution*—The original is sent to the customer and a copy is retained by the laboratory. Additional distribution may also be specified by the customer. Transmission of the report may be hard copy or electronic, based on established procedures.

10. Control of Records

10.1 *Summary:*

10.1.1 The use and control of records is a key in providing documentary evidence of the technical adequacy of practices. Records provide the direct evidence and support for the technical interpretations, judgments, and decisions regarding the quality of data generated in the laboratory. Records provide the historical evidence needed for future reviews and evaluations, particularly if regulatory or legal questions are raised concerning data generated in the laboratory. Therefore, the control of records should be an integral part of ongoing activities conducted in the laboratory.

10.1.2 An effective records management system should be established as part of the QA program, to ensure that ~~records, whether in hard copy or electronic form, are identifiable and~~ all records are identifiable, legible, protected, electronic records are backed-up and that all retained records are retrievable for the established retention time. Access to the records and their disposal should be consistent with the confidentiality commitments.

10.1.3 All records should be ~~in ink,~~ legible and neat, without erasures. Handwritten ~~changes or corrections~~ records should be made ~~with a single line through, and~~ in ink. Amendments should be tracked to previous versions or to original, signed or initialed and dated by the person making the change. The original information should be retained or remain visible after the change.

10.2 *Recommendations:*