

ANSI/ASQC Q2-1991

AMERICAN NATIONAL STANDARD

Quality Management and Quality System Elements for Laboratories—Guidelines



AMERICAN SOCIETY FOR QUALITY CONTROL
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Abstract

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Foreword

Various professional and governmental, national and international bodies have developed lists of basic elements of quality control systems. The task force has analyzed the specific content of a considerable number of these documents.

This standard is drawn largely, by intent, from ANSI/ASQC Q94-1987, *Quality Management and Quality System Elements—Guidelines*, where that material was relevant to laboratory operations. However, a large number of suggestions and recommendations from reviewers of earlier drafts have also been incorporated. The result is a “balanced” document, outlining in sufficient detail, and with sufficient clarity, all basic elements that should be considered but not necessarily adopted in the quality system of a laboratory.

There is no question that as this standard is applied, modifications and additions will become apparent. Knowing this, the task force solicits specific comments that will aid in this standard’s improvement.

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ANSI/ASQC Q2-1991

Contents

ANSI/ASQC Q2-1991, Quality Management and Quality System Elements for Laboratories—Guidelines

1.0 Introduction	1
2.0 Scope and Field of Application	2
3.0 References	2
4.0 Definitions	3
5.0 Management Responsibility	4
6.0 Quality System Principles	5
7.0 Quality in Procurement	8
8.0 Laboratory Operations Quality Assurance	8
9.0 Control of Measuring and Test Equipment	10
10.0 Data Validation	11
11.0 Environmental Controls	11
12.0 Technical Complaints	11
13.0 Subcontracting	12
14.0 Personnel	12
15.0 Use of Statistical Methods	13
16.0 Nonconformity	13
17.0 Corrective Action	13
18.0 Auditing the Quality System	14
19.0 Economics—Quality-Related Cost Considerations	14
Appendix A: Sampling and Other Statistical Methods	16

QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS FOR LABORATORIES — GUIDELINES

1.0 INTRODUCTION

1.1 General: A primary concern of any analytical or testing laboratory must be the quality of its services. In order to be successful a laboratory must offer services that:

- a) Meet a well-defined need, use, or purpose.
- b) Satisfy customers' expectations.
- c) Use or comply with applicable standards, specifications, and test or analytical methods.
- d) Comply with statutory (and other) requirements of society (see 4.6).
- e) Are available at competitive prices.
- f) Are provided at a cost which will yield a profit, or is economically sound.

1.2 Organizational Goals: In order to meet its objectives, the laboratory should organize itself in such a way that the technical, administrative, and human factors affecting the quality of its services will be under control. All such control should be oriented towards the reduction, elimination, and most importantly, prevention of quality deficiencies.

A quality management system should be developed and implemented for the purpose of accomplishing the objectives set out in a laboratory's quality policies.

Each element (or requirement) in a quality system will vary in importance from one type of activity or service to another and from one test or analytical method to another.

In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality system be appropriate to the type of activity or service and type of test or analytical methods being offered.

1.3 Meeting Laboratory/Customer Needs: A quality management system has two interrelated aspects:

1.3.1 The Laboratory's Needs and Interests:

For the laboratory, there is a business need to attain and to maintain the desired quality of its services at an optimum cost; the fulfillment of this quality aspect is related to the planned and efficient utilization of the technological, human, and material resources available to the laboratory.

1.3.2 The Customer's Needs and Expectations:

For the customer there is a need for confidence in the ability of the laboratory to deliver the desired quality of its services as well as the consistent maintenance of that quality.

Each of the previous aspects of a quality system (see 1.1) requires the generation and communication of objective evidence in the form of information and data concerning the quality of the system and the quality of the laboratory's reported results.

1.4 Risks, Costs, and Benefits:

1.4.1 General: Risk, cost, and benefit considerations have great importance for both laboratory and customer. These considerations are inherent aspects of most products and services. The possible effects and ramifications of these considerations are given in 1.4.2 to 1.4.4.

1.4.2 Risk Considerations:

1.4.2.1 For the Laboratory: Consideration has to be given to risks related to deficient analytical or testing services as these lead to loss of image or reputation, loss of market, complaints, claims, liability, and waste of human and financial resources.

1.4.2.2 For the Customer: Consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with services, incorrect decisions, availability, marketing claims, and loss of confidence.

1.4.3. Cost Considerations:

1.4.3.1. For the Laboratory: Consideration has to be given to costs due to marketing and operating inefficiencies, lost or damaged samples, duplicate analyses or retesting, or recalibration of instruments.

1.4.3.2. For the Customer: Consideration has to be given to cost of liability, cost of the analytical or testing service, and the potential costs resulting from poor decisions based on poor results received.

1.4.4 Benefit Considerations:

1.4.4.1 For the Laboratory: Consideration has to be given to

ANSI/ASQC Standard Q2-1991

increased profitability, reputation, and market share, either directly to the laboratory or indirectly to its parent organization.

1.4.4.2 For the Customer: Consideration has to be given to reduced costs, increased satisfaction, and increased confidence in the laboratory.

1.4.5 Conclusion: An effective quality management system should be designed to satisfy customer needs and expectations while protecting the laboratory's interests. A well-structured quality system is a valuable management resource in the optimization and control of data quality in relation to risk, cost, and benefit considerations.

2.0 SCOPE AND FIELD OF APPLICATION

This standard describes a basic set of elements by which laboratory quality management systems can be developed and implemented.

It is intended as a guideline and model for a quality system operating within an overall testing or analytical laboratory system, excluding laboratories devoted only to research. As such, it attempts to encompass quality provisions at all stages and levels of a sample's total life cycle, from collection or selection through its receipt, identification, analysis or testing and reporting of results, and retention or disposal. It is not limited to the specific assignment of a quality control department.

The selection of appropriate elements contained in this standard and the extent to which these elements are adopted and applied by a laboratory depend upon such factors as: market served, nature of services, methods, and consumer needs.

This standard is particularly relevant to laboratories performing chemical analyses and environmental testing and calibration, where statistical control methods have been effectively integrated into the analytical or testing process. Although such elements may not be appropriate for all other fields of testing, the concept of statistical control is applicable to many of these fields.

The very existence of this standard can incorrectly imply that one basic quality system will suffice in a given laboratory, indeed in any situation.

Experience shows that the order of presentation (format) of subjects described here may vary from one laboratory to another depending upon factors such as regulatory requirements; the needs, customer, and field of competence of the laboratory; practices in the various methodologies used in the laboratory; and the needs of the laboratory's customers.

It may be impractical for all subjects identified in these guidelines to be contained within a single document. It is therefore acceptable to produce separate documents. However, all these documents should be cross-referenced to a single document, generally called Quality Manual, which specifies their location and updating and control procedures.

These guidelines supplement and expand upon the items relating to a quality system identified in ANSI/ASQC Q94-1987.

NOTES:

1. This standard is not intended to be used as a checklist for compliance with a set of requirements.
2. The American Society for Quality Control is in the process of developing a separate standard on the subject of service.
3. The American Society for Quality Control is also in the process of developing a new standard for quality control systems in the research and development laboratory.
4. An effective quality system should readily adapt to changes brought about by new methods, new technology, and changing personnel. As a guideline, the standard should be used to structure quality control programs, or to evaluate systems, but should not be permitted to stagnate a quality system so that it ceases to meet the laboratory requirements when new measuring, operating, or quality control tools are developed. As changes come about, the quality system should be updated and documented in an appropriate quality manual.

3.0 REFERENCES

- a) ASTM STD E105 *Standard Recommended Practice for Probability Sampling of Materials*
- b) ASTM STD E122 *Standard Recommended Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process*
- c) ASTM STD E141 *Standard Recommended Practice for Acceptance of Evidence Based on the Results of Probability Sampling*
- d) ASTM STD E177 *Standard Practice for the Use of the Terms Precision and Bias in ASTM Test Methods*
- e) ASTM STD E178 *Standard Practice for Dealing with Outlying Observations*
- f) ASTM STD E994 *Standard Guide for Laboratory Accreditation Systems*
- g) ANSI Z1.9-1980, (MIL-STD-414-1957) *Sampling Procedures and Tables for Inspection by Variables for Percent Non-conforming*
- h) ANSI Z1.4-1981, (MIL-STD-105D-1973) *Sampling Procedures and Tables for Inspection by Attributes*
- i) ANSI/ASQC Standards B1-1985 and B2-1985, (ANSI

ANSI/ASQC Standard Q2-1991

- Z1.1-1958 R-1975 and Z1.2-1958 R-1975) *Guide for Quality Control and Control Chart Method of Analyzing Data*
- j) ANSI/ASQC C1-1985, Corrected Edition (ANSI Z1.8-1971) *Specification of General Requirements for a Quality Program*
 - k) ANSI/ASQC Q1-1986, *Generic Guidelines for Auditing of Quality Systems*
 - l) ANSI/ASQC A3-1987, *Quality Systems Terminology*
 - m) ANSI/ASQC M1-1987, *American National Standard for Calibration Systems*
 - n) ANSI/ASQC Q90-1987, *Quality Management and Quality Assurance Standards — Guidelines for Selection and Use*
 - o) ANSI/ASQC Q94-1987, *Quality Management and Quality System Elements — Guidelines*
 - p) ANSI/ASQC Q4-19XX (DRAFT), *Quality Control of Measurements*
 - q) *Glossary and Tables for Statistical Quality Control* (ASQC 1983)
 - r) *Statistical Quality Control*, 4th Ed., Grant, E.L. and Leavenworth, R.S. (McGraw-Hill 1972)
 - s) ISO Guide 2-1983, *General Terms and Their Definitions, Concerning Standardization, Certification, and Testing Laboratory Accreditation*
 - t) ISO 8402-1986, *Quality—Vocabulary*
 - u) ISO 9000-1987, *Quality Management and Quality Assurance Standards — Guidelines for Selection and Use*
 - v) ISO/IEC Guide 49, *Guidelines for Development of a Quality Manual for a Testing Laboratory*
 - w) *Quality Control Handbook*, 3rd Ed., Juran, J.M. (McGraw-Hill 1974)
 - x) MIL-STD-1235, *Single and Multi-Level Continuous Sampling Procedures and Tables for Inspection by Attributes*
 - y) Ratliff, T.A., Kelley, W.D., and Bryant, J.M. NIOSH Technical Report No. 78 Industrial Hygiene Laboratory Quality Control Manual (Rev. 3, July 1979, Cincinnati, OH)

4.0 DEFINITIONS

For the purposes of this standard, the definitions given in ANSI/ASQC A3-1987 and the following definitions apply:

4.1 Accuracy:

- a) ANSI/ASQC A3-1987, "Degree of agreement of individual measurements with an accepted reference value."
- b) ASTM E177, "The degree of agreement of (such) measurements with an accepted reference level of the property of the material measured."
- c) ASTM E456, "The degree of agreement of individual or average measurements with an accepted reference value or measurement."

4.2 Corrective Action: "When failure occurs — the process of investigation, correction, and institution of preventive measures to preclude the recurrence of failure."

4.3 Customer: "Ultimate consumer, user, client, beneficiary, or second party."

4.4 Organization: "A company, corporation, firm, or enterprise whether incorporated or not, public or private."

4.5 Precision:

- a) ANSI/ASQC M1-1987, "The degree of agreement among independent measurements of a quality under specified conditions."
- b) ASTM E456, "Standard Terminology for Statistical Methods" Precision — the degree of mutual agreement among individual measurements. Relative to a method of test, precision is the degree of mutual agreement among individual measurements made under prescribed like conditions. The imprecision of measurement may be characterized as the standard deviation of errors of measurement.
- c) ASTM E177, "Standard Recommended Practice for Use of Terms Precision and Accuracy as Applied to Measurement of a Property of a Material." *Precision* of a measurement process refers to the degree of mutual agreement between individual measurements from the process.
- d) ASTM E691, "Standard Practice for Conducting an Inter-laboratory Test Program to Determine the Precision of Test Methods." Par. 3.4.2 Numerical measures of the variability between such test results provide inverse measures of the precision of the test method. Greater variability implies smaller (that is, poorer) precision and larger imprecision.

4.6 Quality Program: "Those elements, primary support and monitoring functions, which serve to implement the quality plan."

4.7 Requirements of Society: "Requirements including laws, statutes, rules and regulations, codes, environmental considerations, health and safety factors, and conservation of energy and materials."

4.8 Shelf Life: "That interval of elapsed time in which a product or sample continues to perform to specific parameters and/or undergoes no structural, physical, chemical, biological, or functional degradation or change."