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ANSI/ASQC Q2-1991

# AMERICAN NATIONAL STANDARD

## *Quality Management and Quality System Elements for Laboratories—Guidelines*

**AMERICAN SOCIETY FOR QUALITY CONTROL**
**310 West Wisconsin Avenue**
**Milwaukee, Wisconsin 53203**

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*Sponsor: 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.

Task force members serving as writers and editors of this standard were:

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# 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