

ANSI/ASQ Z1.13-1999

# AMERICAN NATIONAL STANDARD

## *Quality Guidelines for Research*

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Approved as an American National Standard by:

**ANSI Accredited Standards Committee Z1 on Quality Assurance  
American Society for Quality, Secretariat**

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An American National Standard Approved on February 20, 1998

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# Foreword

The purpose of this document is to provide guidance for the development and implementation of a quality management system to scientists and managers involved in basic and applied research. Historically, quality management system guidance for researchers has been limited or nonexistent. This document will provide the scientists and technical managers with information that has been difficult to locate. Documents that have been written in the past on quality systems for research have been written more with an intent of adapting hardware and compliance-oriented quality assurance regulations to basic and applied research. The guidance in those documents has been too cumbersome or not applicable to the work of the researcher. The guidance in this document is concise and uses familiar scientific and technical terminology in order to translate quality management concepts into a document that is usable by the scientist and technical manager.

# Introduction

This document is intended to provide guidelines for the development of quality management systems at basic and applied research laboratories. It is written primarily for scientists and technical managers and purposely uses scientific and technical terminology in an attempt to translate the concepts of quality management into language that is more familiar to scientists and technical personnel.

It is intended that this document will normally be adopted in its present form, but on occasion it may need to be tailored for specific types of research activities or because of contractual requirements.

## 1 SCOPE AND FIELD OF APPLICATION

### 1.1 Scope

This document can be used in the development of a quality system for basic and applied research. That is where the output is knowledge, information, data, or proof-of-concept, but not product or service design or development. This includes fields like the biological, physical, and applied sciences, which use methods such as field investigation, laboratory experimentation, computer modeling, and theory formulation.

While this document presents an overall quality system for all aspects of research institution activities, it attempts to focus the application of quality systems on the main output of research institutions—the research results.

### 1.2 Field of application

This document can be used as a quality system model in situations where

—The development of a quality system for a basic and applied research environment is desired.

—A baseline is required for evaluating a laboratory's organizational capabilities for managing and performing basic and applied research.

## 2 REFERENCES

ANSI/ISO/ASQC A8402-1994, "Quality Systems Terminology."

ANSI/ISO/ASQC Q9004-1-1994, "Quality Management and Quality System Elements—Guidelines."

DOE Standard DOE-ER-STD-6001-92, "Implementation Guide for Quality Assurance Programs for Basic and Applied Research," U.S. Department of Energy, Washington, D.C., June 1992.

## 3 DEFINITIONS

### 3.1 External customer

An organization or person outside the research institution organizational structure who funds the research activities and for whom the outcome and associated peripherals of that research are provided. As defined below, stakeholders are not external customers.

### 3.2 Internal customer

An organization or person inside the research institution organizational structure that is provided a product or service from some other organization or person in the laboratory.

### 3.3 Principal investigator

An individual who has primary responsibility for performing or overseeing the research. In some instances, the principal investigator is also referred to as the project manager for the research project.

### 3.4 Peer review

One of the primary mechanisms for assuring quality in science. Within a scientific community, peers are defined as those persons who constitute the competent professional group whose role it is to define what quality research results are within that particular discipline. Technical peers are individuals who typically meet all of the following criteria

—They have an equal or greater level of academic education in the same technical discipline in which the work is performed or in a closely related field, or have equivalent work experience and technical activity in a related discipline.

—They have demonstrated evidence of proposing and solving engineering, experimental, or theoretical problems that are recognized as valid by that community of technical peers.

—They have contributed to the body of knowledge within a technical discipline such as publishing research results in the proceedings of scientific meetings or in professional journals.

### 3.5 Research plan

A document that describes the management systems used for the planning, performing, documenting, assessing, and transferring of research results in basic and applied research institutions. While this document uses the words *research plan*, it may also be referred to as a research proposal or an experimental proposal.

### 3.6 Stakeholder

An organization or person with an interest or share in the research performed at the laboratory and with something to lose or gain depending on the quality of the research. Stakeholders might include a scientific