# HANDBOOK OF QUALITY ASSURANCE FOR THE ANALYTICAL CHEMISTRY LABORATORY

SECOND EDITION

James P. Dux

VAN NOSTRAND REINHOLD New York

# Contents

Chapter 1.  Quality, Quality Control, and Quality Assuran	ce
Quality 3 Quality Control 5 Quality Assurance 6 Quality Assurance and Laboratory Management 8	
Chapter 2. Error and Elementary Statistics 11	

Preface xi

Error 11 Statistics

# **Chapter 3.**Statistical Quality Control Techniques

31

47

Control Charting 31 Blind Samples 42 Performance Evaluation Samples 44

Documentation for Quality Assurance

# Chapter 4. Sampling and Quality Assurance

Sampling Plans 48

# Chapter 5. Analytical Methods 59

56

Sources of Analytical Methods 60 Evaluation of Analytical Methods 62 Writing Analytical Methods 71 Authorization of Analytical Methods 75

## Chapter 6.

Quality Assurance and Instruments, Equipment and Materials 79

Instruments and Equipment 79
Materials 90

95

# **Chapter 7.**Documentation for Quality Assurance

General Principles 96 Data Acquisition 97 Analytical Methods 101 Sampling and Sample Handling 102 Instrument Calibration and Maintenance 107 Reagents and Reagent Solutions 108 Personnel Training Records 110 Analytical Reports Filing Quality Assurance Documentation 114

## Chapter 8.

#### Organizing for Quality Assurance 117

Management Commitment 117
The Quality Assurance Officer 118
Responsibility for Quality Assurance 123
Motivating Personnel for Quality Assurance 126

## Chapter 9.

#### Establishing a Quality Assurance Program 129

Defining the Quality Assurance Program	129
The Written Program 131	
Standard Operating Procedures 131	
Consolidating the Program 136	
Monitoring and Evaluating the Program	137
Writing the Quality Assurance Manual	140

# Chapter 10.

Quality Assurance Auditing 145

Internal Audits 146 External Audits 148

### Chapter 11.

Laboratory Facilities and Quality Assurance

155

General Requirements 155
Sample-Handling Facilities 157
Glassware-Cleaning Facilities 159
Archives 160

## Chapter 12.

Computers and Quality Assurance 161

Laboratory Information Management System 162 Laboratory Robotics 172

## Chapter 13.

Mandated Quality Assurance Programs and Laboratory Accreditation 175

The Good Laboratory Practices 176
Other Mandated Quality Assurance Programs 179
Laboratory Accreditation 181

Appendix 191

Additional Readings 195

Index 000