

Index

A

Acceptability criteria, 125
 Acceptance sampling, 93
 Accreditation. *See* Laboratory accreditation
 Accuracy, defined, 118
 ACS. *See* American Chemical Society
 ACS reagent grade water, 86
 Action limits, 40
 Aflatoxins, sampling food products, 98
 Agricultural food products
 aflatoxin sampling, 98
 sampling plans, 95–96
 Agriculture and Agri-food Canada, 154
 Air conditioning systems, 65
 A2LA. *See* American Association for Laboratory Accreditation
 ALACC. *See* Analytical Laboratory Accreditation Criteria Committee
 ALAWG. *See* Analytical Laboratory Accreditation Working Group
 American Association for Laboratory Accreditation, 110, 151–152, 155–156
 American Chemical Society
 Committee on Analytical Reagents, 81
 Committee on Chemical Safety, 67
 reagent grade water, 86
 training courses, 55
 American National Standards Institute, 153, 155
 American Public Health Association, 86
 American Society for Quality, 40
 American Society for Quality Control, 155
 American Society for Testing and Materials, 86, 153
 Analysts. *See* Bench analysts
 Analytical control charts. *See* Control charts
 Analytical Laboratory Accreditation Criteria Committee, 156
 Analytical Laboratory Accreditation Working Group, 156
 Analytical methods. *See* Methods
 Analytical standards, 84
 Analyzed reagents, 81
 Animals, special facilities for, 65
 ANSI. *See* American National Standards Institute

AOAC INTERNATIONAL

Analytical Laboratory Accreditation Criteria Committee, 156
Bacteriological Analytical Manual, 86–87
 collaborative studies, 120
 Committee on Chemical Safety, 67
 Laboratory Proficiency Testing Program, 138
 Official Methods, 113
 proficiency testing, 132
 sources for certified reference materials, 84
 training courses, 55
 volumetric glassware specifications, 87
 APHA. *See* American Public Health Association
 Appraisal costs, 7
 Archiving records, 107
 Arithmetic means
 defined, 31
 normal distribution and, 33
 ASQ. *See* American Society for Quality
 ASQC. *See* American Society for Quality Control
 Assigned values, 135–136
 ASTM. *See* American Society for Testing and Materials
 ASTM water grades, 86
 Atomic Energy Control Board Regulatory Document, 64
 Attribute sampling, 93
 Audits
 audit plans, 145
 audit units, 143–144
 checklists, 146
 external, 25, 141
 horizontal audits, 143
 internal, 10, 25–26, 141
 performance audits, 141–142
 recommendations, 148
 reports, 147
 selection of auditors, 144
 site visits, 146–147
 system audits, 142–143
 training for auditors, 144
 vertical audits, 143
 Australia, accreditation program, 5, 153–154
 Automated data tracking systems, 108–110

Automated methods, 113

B

Bacteriological Analytical Manual, 86–87

Bacteriological ware, cleaning, drying, and sterilizing, 88

BAM. *See Bacteriological Analytical Manual*

BCS. *See British Calibration Service*

Bench analysts

performance audits, 141–142

responsibilities of, 50–51, 124–125

Benefit evaluations, 6–7

Bias control charts, 42

Blind samples, 134–135

British Calibration Service, 5

Bulk sampling, 93

C

CAEAL. *See Canadian Association for Environmental Analytical Laboratories*

Canada, accreditation programs, 154

Canadian Association for Environmental Analytical Laboratories, 154, 156

Canadian Atomic Energy Control Board Regulatory Document, 64

Canadian Food Inspection Agency, 154

Canadian Society of Forensic Science, 156

Cardiopulmonary resuscitation, 70

Career development training, 54–55

CEN. *See Committee for Standardization*

Central limit theorem, 35

Central tendency, measures of, 30–31

Certification

chemists, 157–158

laboratories, 150

Certified Reference Materials, 25, 83–84

CFIA. *See Canadian Food Inspection Agency*

Chain-of-custody, 8

Check sample analysis reviews, 142

Check samples. *See Proficiency testing*

Chemical Hygiene Officers, 67

Chemical Hygiene Plans, 67, 69

Chemicals

analyzed reagents, 81

commercial grade, 82

practical grade, 82

primary standards, 81

purified, 82

purity, 82

reference standards, 82–85

standardized solutions, 85

technical grade, 82

USP reference standards, 82

Chemists, certification, registration, or licensing of, 157–158

CITAC Guide, 121

Class A commercial glassware, 87

Classroom training, 55

CLP. *See Contract Laboratory Program*

Code of Federal Regulations, occupational exposure to hazardous chemicals regulation, 69

Codex Alimentarius, 120

Coefficient of variation, 32

Collaborative studies, 120–121

College training courses, 55

COMAR. *See International Database of Certified Reference Materials*

Commercial grade chemicals, 82

Commercial laboratories, mission of, 49

Commission on Physicochemical Measurements and Standards, 84

Committee for Standardization, 113

Committees

quality assurance, 12

safety, 67

Composite laboratory samples, 96–97

Computers

automated data tracking systems, 108–110

laboratory requirements, 66

sample accountability systems, 100

sample records, 105

security, 24

Confidence intervals, 36

Confirmatory methods, 113

Contamination

control of, 65

laboratory maintenance and, 22

Contract Laboratory Program, 152

Control charts

based on range, 42–43

bias control charts, 42

construction of, 40–42

control limits, 40

cumulative sum charting, 44

duplicate analyses, 42

function of, 12, 29, 39

interpretation guidelines, 43

plotting values of blank determinations, 42

precision control charts, 41–42

spiking recovery tests, 42

standard solutions, 41–42

types of, 41–42

Control limits, 40

“Controlled” manuals, 20, 23

Correction costs, 7

Correction factors, 123–124
 Corrective Actions, 10, 25–26
 Cost analysis techniques, 7
 Cost considerations, 6–7
 Council Committee on Reference Materials, 83
 CPR. *See* Cardiopulmonary resuscitation
 CRMs. *See* Certified Reference Materials
 Cross contamination, laboratory maintenance
 and, 22
 CSFS. *See* Canadian Society of Forensic Science
 Culture media, 86–87
 Cumulative sum charts, 44

D

Data. *See also* Records; Statistical applications
 automated tracking systems, 108–110
 types of, 30
 Data Quality Objectives, 93
 Data transfer, 24
 Definitions of terms, 2
 Degrees of freedom, 35–36
 Determinate errors, defined, 117
 Determinative methods, 113
 Diagnostic activities, 25–26
 Directors. *See* Laboratory directors
 Discipline-focused accreditation programs, 151
 Dispersion, measures of, 31–32
 Distilled water, 85–86
 Dixon Test, 38
 DNA analysis, 65
 Documentation. *See* Records
 Double blind samples, 134–135
 DQOs. *See* Data Quality Objectives

E

EA. *See* European Cooperation for Accreditation
 Earthquakes, 70
 Eco-Management and Audit Scheme Regulation, 62
 Electrical systems, 64–65
 Electromagnetic noise, 63–64
 Electronic signatures, 110
 EMAS. *See* Eco-Management and Audit Scheme Regulation
 Emergency response plans, 70
 Empirical methods, 113
 Employees. *See* Personnel
 Employment values, 53
 Environmental laboratories, accreditation programs, 152

Environmental Protection Agency, 152, 157
 EPA. *See* Environmental Protection Agency
 Equipment. *See also* Supplies
 calibration, 12, 21–22
 installation, 76–77
 interval establishment for service tasks, 78–79
 inventories, 21, 77–78
 list of instruments, 161–162
 location in laboratories, 63
 maintenance records and documentation, 80
 maintenance training, 79
 noise interference, 63–64
 operating the maintenance system, 79
 performance checks, 161–171
 performance parameters, 78
 personnel assignments, 79
 preventive maintenance, 9, 12, 21–22, 77–81
 purchase, 75–76
 recommendations, 88–89
 safety equipment, 68–69
 selection, 75–76
 service tasks, 78
 servicing, 76–77
 special maintenance instructions, 79
 training in use and operation of, 80–81
 verification of preventive maintenance tasks, 80–81
 vibration interference, 63–64
 Errors, defined, 117
 EURACHEM, 121, 123, 137, 157
 European Committee for Standardization, 113
 European Cooperation for Accreditation, 156–157
 European Proficiency Testing Schemes, 137
 Evacuations, 70
 Explosion hazards, 65, 68
 External audits, 25, 141
 External quality assessment. *See* Proficiency testing

F

F-test, 37
 FAPAS. *See* Food Analysis Performance Assessment Scheme
 FDA. *See* Food and Drug Administration
 Federal Food, Drug and Cosmetic Act, 156
 Fire fighting, 70
 Fire hazards, 65, 68
 First Aid, 70
 Fisher, Sir Ronald, 37
 Fitness for purpose, 119

Food Analysis Performance Assessment Scheme, 132
 Food and Drug Administration, 86–87, 156–157
 Food products
 accreditation of testing laboratories, 156
 aflatoxin sampling, 98
 sampling, 98
 sampling plans, 95–96
 three-class sampling plan, 94–95
 Fume hoods, 64
 Furniture, laboratory, 65

G

GALP. *See* Good Automated Laboratory Practices
 Gaussian curves, 33
 Glassware
 bacteriological ware, 88
 cleaning, 87–88
 volumetric, 87
 GLPs. *See* Good Laboratory Practices
 Good Automated Laboratory Practices, 24
 Good Laboratory Practices, 156–157
 Government laboratories, mission of, 49
 Group leaders, responsibilities of, 48
 Grubbs Test, 38

H

Hazardous chemicals, defined, 69
 Hazardous materials, safe handling of, 69
 Health hazard, defined, 69
 Heating systems, 65
 Hoods. *See* Fume hoods
 Horizontal audits, 143
 Horwitz curve, 119–120

I

ILAC. *See* International Laboratory Accreditation Cooperation
 In-house methods, 113
 Indeterminate errors, defined, 117
 Individual instruction programs, 55
 Industrial laboratories, mission of, 49
 Instrument performance checks, 161–171
 Instrument vendor training courses, 55
 Instruments. *See* Equipment
 Interlaboratory testing
 overview, 9–10
 proficiency testing, 134
 sample analysis reviews, 142

Internal audits, 10, 25–26, 141
 International Database of Certified Reference Materials, 83
 International Laboratory Accreditation Cooperation, 5, 18, 132, 155
 International Organization for Standardization, 5, 83, 95, 104, 123, 132
 International Union of Pure and Applied Chemistry, 84, 132
 Interval data, 30
 Intralaboratory testing
 overview, 9–10
 proficiency testing, 138–139
 sample analysis reviews, 142
 Inventories, 21, 77–78
 Ion exchange water systems, 86
 ISO. *See* International Organization for Standardization
 ISO 43, 138
 ISO 9000, 149–150
 ISO 14000, 62
 ISO 17025, 5, 50–51, 55, 62, 104, 121, 141, 149–153
 ISO 9000 series, 5, 25
 ISO Guides, 5, 83
 ISO quality assurance protocols, 175–176
 IUPAC. *See* International Union of Pure and Applied Chemistry

J

Job Descriptions, 20–21, 52

L

Laboratories. *See also* Equipment; Laboratory accreditation; Supplies
 air conditioning requirements, 65
 codes and standards, 66, 68
 communication requirements, 63
 computer requirements, 66
 defined, 69
 design, 10, 61–73, 68
 electrical systems, 64–65
 emergency control procedures, 70
 equipment location, 63
 expansion of, 63
 explosion hazards, 65, 68
 fire hazards, 65, 68
 fume hoods, 64
 furniture, 65
 hazardous materials, 69
 heating requirements, 65
 internal traffic patterns, 63

- inventories, 32
 - lighting requirements, 65
 - location of, 63
 - mechanical systems, 64–65
 - mission of, 49
 - noise, 63–64
 - office design, 66
 - personnel considerations, 62
 - purpose of, 62
 - Quality Manual description, 20
 - radioactive materials, 64
 - receiving docks, 64
 - recommendations, 72–73
 - requirements for physical components, 22
 - safe operating practices for personnel, 70–72
 - safety, 67–69
 - safety cabinets, 64
 - security, 22, 110
 - special facilities, 65
 - special rooms, 66
 - storage facilities, 64
 - telephone systems, 66
 - training visits, 55
 - ventilation requirements, 65
 - vibration, 63–64
 - walls, ceilings, and floors, 65
 - workloads, 63
 - Laboratory accreditation
 - approaches to, 151–152
 - assessment procedures, 154
 - chemist certification, registration, or licensing, 157–158
 - costs of, 151–152
 - defined, 2, 149
 - discipline-focused programs, 151
 - Good Laboratory Practices, 156–157
 - international accreditation criteria, 155–156
 - International Laboratory Accreditation Cooperation, 155
 - ISO 9000 standards, 149–150
 - ISO 17025 standards, 149–153
 - national programs, 152–155
 - objectives of systems, 150–151
 - personnel files and, 58–59
 - product-focused programs, 151
 - recommendations, 158
 - Laboratory directors
 - hazardous chemicals handling procedures, 69
 - laboratory design responsibilities, 62
 - responsibilities of, 48–49
 - Laboratory information management systems, 108
 - Laboratory managers. *See* Managers
 - Laboratory of the Government Chemist, 137
 - Laboratory Proficiency Testing Program, 138
 - Laboratory Quality Assurance Manual*, 161
 - Laboratory supervisors, responsibilities of, 49–50
 - Laboratory ware, cleaning, 87–88
 - Leadership values, 53
 - Lecture training, 55
 - Legal samples, documentation for, 110
 - LGC. *See* Laboratory of the Government Chemist
 - Licensing, of chemists, 157–158
 - Lighting systems, 65
 - LIMS. *See* Laboratory information management systems
 - Location parameters, 30–31
 - Lots
 - defined, 94
 - true value of, 91
 - variability of, 91
- ## M
- Management
 - policy statements, 5–6
 - responsibilities in planning a quality system, 4
 - reviews, 142
 - values, 53
 - Management Representatives, 19
 - Managers, responsibilities of, 47–48
 - Manuals. *See* Quality Assurance Manuals
 - Material Safety Data Sheet, 69
 - Matrix effects, 125
 - MDL. *See* Minimum Detection Limits
 - Means
 - central limit theorem, 35
 - comparison of, 36–37
 - confidence intervals, 36
 - defined, 31
 - normal distribution and, 33
 - standard error, 34–35
 - Measurement uncertainty, 123–124
 - Measures of central tendency, 30–31
 - Measures of dispersion, 31–32
 - Mechanical systems, 64–65
 - Media. *See* Culture media
 - Median, 31
 - Method Authorization Forms, 124
 - Methods
 - acceptability criteria, 125
 - accuracy, 117–118
 - analysts' roles, 124–125
 - classification of, 113
 - collaborative studies, 120–121

common mistakes, 126–127
 consumer requirements, 114
 control, 124
 correction factors, 123–124
 evaluation of, 9
 factors affecting analytical results, 125–127
 figures of merit, 114, 116
 Horwitz curve, 119–120
 inclusion in manual, 22–23
 matrix effects, 125
 measurement uncertainty, 123–124
 non-matrix effects, 125
 non-routine methods, 121
 non-standard methods, 23
 operations, 114
 performance attributes, 121–122
 precision, 117–120
 recommendations, 127
 results validation, 122
 ruggedness testing, 122–123
 selection, 9, 114–116
 technical mistakes, 126
 validation, 13, 116–118
 validation parameters, 121–122
 Methods Manuals, 18, 22–23
 Microbiological testing
 special facilities for agents, 65
 three-class sampling plan, 94–95
 Millipore/Milli-Q water systems, 86
 Minimum Detection Limits, 24–25
 Minimum Reportable Limits, 95
 Mode, 31
 Modified methods, 113
 MRLs. *See* Minimum Reportable Limits
 MSDS. *See* Material Safety Data Sheet
 Multiple unit laboratory sampling, 96
 $\mu(\text{mu})$, 34

N

NACLA. *See* National Cooperation for Laboratory Accreditation
 NAMAS. *See* National Measurement Accreditation System
 NATA. *See* National Association of Testing Authorities
 NATA News, 137
 National Academy of Sciences, 69
 National accreditation programs, 152–155
 National Association of Testing Authorities, 5, 153–154
 National Cooperation for Laboratory Accreditation, 152

National Environmental Laboratory Accreditation Conference, 152
 National Institute for Standards and Technology, 83, 87, 152
 National Measurement Accreditation System, 153
 National Research Council, 69
 National Voluntary Laboratory Accreditation Program, 138, 151–152
 NBL Certified Reference Materials, 83
 “NBS Standard Reference Materials Catalog,” 83
 NELAC. *See* National Environmental Laboratory Accreditation Conference
 New Brunswick Laboratory, 83
 NIST. *See* National Institute for Standards and Technology
 Noise interference, 63–64
 Nominal data, 30
 Non-matrix effects, 125
 Non-probability sampling, 93
 Non-routine methods, 121
 Non-standard methods, 23
 Non-supervisory staff, responsibilities of, 50–51
 Normal distribution, 33
 Notebooks
 laboratory, 104–105, 107
 reviews, 141–142
 Nuclear reference materials, 83
 Null-hypothesis formulation, 36
 NVLAP. *See* National Voluntary Laboratory Accreditation Program

O

OC curves. *See* Operating characteristic curves
 Occupational Safety and Health Administration, 67, 69
 OECD. *See* Organization for Economic Cooperation and Development
 Office design, 66
 Official Methods, 3, 113, 120
Official Methods of Analysis, 67, 84, 87, 113
 On-site analyst work reviews, 142
 On-the-job training, 54–55, 144
 Operating characteristic curves, 93–94
 Operating personnel, responsibilities in planning a quality system, 4–5
 Operations, 12–13
 Oral reviews, 142
 Ordinal data, 30
 Organization for Economic Cooperation and Development, 157

Organizations, list of, 173–174
 Orientation programs, 53–55
 OSHA. *See* Occupational Safety and Health Administration
 Outliers, 38

P

PALCAN. *See* Program for Accreditation of Laboratories Canada
 Parameters, 34
 Pareto analysis, 7
 Peer Verified Methods, 120
 Performance appraisals, 56–57
 Performance audits, 141–142
 Performance checks, 161–171. *See also* Proficiency testing
 Performance of methods, 121–122
 Performance Tested Methods, 120
 Personal Protective Equipment, 22, 68–69
 Personal Quality Assurance Profiles, 58
 Personnel
 chemist certification, registration, or licensing, 157–158
 employee motivation, 47–48
 employees' responsibilities, 47–48
 Job Descriptions, 20–21, 52
 laboratory director's responsibilities, 48–49
 laboratory supervisor's responsibilities, 49–50
 management's responsibilities, 47–48
 non-supervisory staff's responsibilities, 50–51
 operating personnel's responsibilities in planning a quality system, 4–5
 orientation, 53–55
 performance appraisals, 56–57
 personnel files, 58–59
 position qualifications and descriptions, 52
 pre-employment interviews, 52–53
 qualifications, 20–21
 Quality Assurance Officer's responsibilities, 51–52, 143
 recommendations, 59
 safe operating practices, 70–72
 self-evaluation, 57–58
 training, 11, 53–55
 Pest Management Regulatory Agency, 156
Pharmacopeial Forum, 84
 Policy statements, 5–6
 Pooled standard deviations, 35–36
 Populations, defined, 34
 Position qualifications, 52
 PPE. *See* Personal Protective Equipment

Practical grade chemicals, 82
 Pre-employment interviews, 52–53
 Precision
 defined, 118
 factors affecting, 119–120
 Precision control charts, 41–42
 Prevention costs, 7
 Primary standards, 81
 Probability sampling, 93
 Product-focused accreditation programs, 151
 Proficiency samples, 13
 Proficiency testing
 assigned value, 135–136
 blind samples, 134–135
 double blind samples, 134–135
 instrument performance checks, 161–171
 interlaboratory test programs, 134
 intralaboratory testing, 138–139
 program format, 132–133
 programs, 25, 137–138
 purpose of, 131–132
 recommendations, 139
 referee laboratories, 136
 sample analysis, 135
 statistical assessment of test results, 136–137
 z-scores, 136–137
 Program for Accreditation of Laboratories Canada, 154
 Programmed instruction courses, 55
 Protective equipment, 22, 68–69
 Proximate methods, 113
Prudent Practices for Disposal of Chemicals from Laboratories, 69
Prudent Practices for Handling Hazardous Chemicals in Laboratories, 69
 Purified chemicals, 82
 Purified water, 85–86

Q

Qualitative appraisals, 142–143
 Quality assurance
 basic premises of, 14
 chain-of-custody requirements, 8
 committees, 12
 components of, 2–3
 control of samples and records, 8
 corrective actions, 10
 cost-versus-benefits analysis, 6–7
 defined, 2
 documentation requirements, 13
 elements of, 5–11
 employee training, 11, 53–55
 equipment maintenance, 9

- establishing, 3–5
 - format of the quality assurance plan, 6
 - internal audits, 10
 - intra- and interlaboratory testing, 9–10
 - laboratory design, 10
 - management's policy statements, 5–6
 - manuals, 17–28
 - methods evaluation, 9
 - methods selection, 9
 - objectives of, 2, 11–12
 - operations, 12–13
 - overview, 1–14
 - personnel practices, 6
 - planning work activities, 8
 - procurement practices, 8
 - program objectives, 6
 - quality improvement, 11
 - quality system review, 10
 - recommendations, 14–15
 - reference standards, 9
 - statistical considerations, 10
 - structure of, 3–4
- Quality Assurance Manuals**
- audits, 25–26
 - “controlled” manuals, 20, 23
 - Corrective Actions, 25–26
 - defined, 17
 - description of, 19–20
 - diagnostic activities, 25–26
 - elements of, 17–18
 - equipment calibration and maintenance, 21–22
 - ILAC model, 18–26
 - laboratory description, 20
 - laboratory environment, 22
 - personnel, 20–21
 - Quality Policy statements, 19
 - recommendations, 27–28
 - records maintenance, 26
 - revision of, 23
 - sample management, 23–24
 - Standard Operating Procedures, 26–27
 - subcontracting, 26
 - table of contents, 19
 - test methods and procedures, 22–23
 - test reports, 24–25
 - verification of results, 24
- Quality Assurance Officers, responsibilities of, 51–52, 143**
- Quality Assurance Training Profiles, 57–58**
- Quality Assurance Units, 51–52**
- Quality control, defined, 2**
- Quality Managers, responsibilities of, 51–52**
- Quality Manuals. *See* Quality Assurance Manuals**
- Quality Policy statements, 19**
- Quality Statements, 5–6**
- Quality system, defined, 2**
- Quality system registration, 149–150**
- Quality system review, 10**
- Quantitative appraisals, 141–142**
- Quantitative methods, 113**

R

- R-charts, 42–43
- RAB. *See* Registration Accreditation Board
- Radioactive materials, 64
- Random errors, defined, 117–118
- Range**
 - control charts based on, 42–43
 - defined, 32
- Ranked data, 30
- Rapid methods, 113
- Ratio data, 30
- Rational methods, 113
- Raw data, 30
- Receiving docks, 64
- Records. *See also* Quality Assurance Manuals**
 - archiving, 107
 - audit reports, 147
 - automated data tracking systems, 108–110
 - computerized, 105
 - control, 8
 - electronic, 110
 - maintenance of, 26, 106–107
 - notebooks, 104–105, 107
 - purpose of, 103–104
 - recommendations, 110–111
 - requirements, 13
 - responsibility for, 104
 - retention of, 100, 107
 - revision of, 23
 - technical records, 103
 - test reports, 105–106
 - types of, 103–104
 - worksheets, 105, 107
- Referee laboratories, 136
- Reference Materials, 25, 83–84
- Reference methods, 113
- Reference samples, 13
- Reference standards, 9, 82–85
- Registration**
 - chemists, 157–158
 - laboratories, 150
- Registration Accreditation Board, 144, 155
- Regression lines, 38–39

Relative standard deviation, 32
 REMCO. *See* Council Committee on Reference Materials
 Repeatability, 118
 Reporting Limits, determining, 25
 Reports. *See* Test reports
 Reproducibility, 118–119
 Reverse osmosis water systems, 86
 RMs. *See* Reference Materials
 Round robin testing. *See* Proficiency testing
 Ruggedness testing, 122–123

S

Safety

chemical laboratories, 67
 codes and standards, 66, 68
 emergency control procedures, 70
 in facility design, 68
 hazardous materials, 69
 manuals, 18
 publications, 67
 safe operating practices for personnel, 70–72
 safety committees, 67
 safety equipment, 68–69

Safety Manuals, 18

Samples

accountability systems, 99–100
 composite laboratory samples, 96–97
 control of, 8
 custodians, 24
 defined, 34
 dry, 97
 food samples, 98
 grinding, 98
 liquids, 97
 management of, 23–24
 moisture loss or gain, 98
 multiple unit laboratory sampling, 96
 preparation for analysis, 97–99
 proficiency testing samples, 133, 135
 retention of, 100, 107
 sample variance, 32
 security, 110
 trace metals analysis, 98
 true value of lots, 91
 variability of lots, 91

Sampling

collection of samples, 91–92
 compositing, 96–97
 International Organization for Standardization sampling plan format, 95–96
 recommendations, 100–101
 retention of samples and records, 100

sample accountability, 99–100
 sample preparation for analysis, 97–99
 sample selection methods, 92–93
 sampling plans, 92–96
 statistical approaches, 92
 subsampling for analysis, 96–97

SCC. *See* Standards Council of Canada

Science managers, responsibilities of, 49–50

Screening methods, 3, 113

Security

computer systems, 24
 for laboratories, 22
 for records, 110
 sample storage, 24

Self-evaluation checklists, 57–58

Shewhart, W.A., 29

Shewhart control charts, 40–41

σ (sigma), 34

Significance testing, 36

Site visits, 146–147

SOPs. *See* Standard Operating Procedures

Sorted data, 30

Special laboratory facilities, 65

Spike recovery tests, 42

SRMs. *See* Standard Reference Materials

Staff. *See* Personnel

Standard analytical methods, 3

Standard deviations

defined, 32
 estimated from a pair of results, 35
 estimated from duplicate measurements, 35
F-test, 37
 normal distribution and, 33
 pooling estimates, 35–36
 probability of occurrence between specified intervals, 34

Standard error of the mean, defined, 34–35

Standard Operating Procedures

for equipment, 80
 examples, 26–27
 format, 27
 function of, 26
 manuals, 18
 staff responsibilities, 21

Standard Reference Materials, 83

Standard solutions, 85

Standards

analytical standards, 84
 reference standards, 9, 82–85
 Standards Council of Canada, 154
 Standards of performance, 52
 Statistical applications
 analytical control charting, 29
 comparison of means, 36–37

comparison of two standard deviations, 37
 confidence intervals, 36
 control charts, 39–43
 control limits, 40
 cumulative sum charting, 44
 curve line fitting, 38–39
 data transfer errors, 24
 data types, 30
 measures of central tendency, 30–31
 measures of dispersion, 31–32
 normal distribution, 33
 outliers, 38
 overview, 10
 presentation, 30
 proficiency testing, 136–137
 recommendations, 44
 sampling plans, 92
 standard deviation, 35
 statistical tables, 37–38
 uses of, 33–35
 Statistical control, 39
 Statistical samples, defined, 34
 Sterilizing glassware, 88
 Storage facilities, 64
 Straight lines, equation for, 39
 Student's *t* variate, 36
 Subcontracting, 26
 Subsampling, 96–97, 98
 Supervisors. *See* Laboratory supervisors
 Supervisory staff, responsibilities in planning a quality system, 4
 Supplies. *See also* Equipment
 bacteriological ware, cleaning, drying, and sterilizing, 88
 chemicals, 81–82
 cleaning glassware and laboratory ware, 87–88
 culture media, 86–87
 management of, 81
 purified water, 85–86
 recommendations, 88–89
 reference standards, 82–85
 standardized solutions, 85
 volumetric glassware, 87
 Survey sampling, 93
 System audits, 142–143
 Systematic errors, defined, 117

T

t-Test, 36–37
 Technical grade chemicals, 82
 Technical managers, responsibilities of, 48–50
 Technical records, defined, 103

Technicians, responsibilities of, 50–51
 Telephone systems, 66
 Test reports, 24–25, 105–106
 Testing programs. *See* Proficiency testing
 Three-class sampling plan, 94–95
 Toxic substances, special facilities for, 65
 Trace metals analysis, 98
 Training programs, 11, 53–55, 79–81, 144
 Trend analysis, 7, 12
 Trueness, defined, 118

U

UKAS, 153
 Uncertainty
 defined, 29
 of measurements, 123–124
 United Kingdom
 Food Analysis Performance Assessment Scheme, 132
 Laboratory of the Government Chemist, 137
 UKAS, 153
 United States Military Standards, 93
 United States Pharmacopeia, 82, 84, 86
 Universes, defined, 34
 University laboratories, mission of, 49
 University training courses, 55
 Upper Control/Warning Limits, 43
 U.S. Department of Commerce, 151
 U.S. Department of Energy, 83
 U.S. Environmental Protection Agency, 152, 157
 U.S. Food and Drug Administration, 156
 U.S. National Institute of Occupational Safety and Health, 115
 USP Reference Standards, 82, 84
 USP water grades, 86

V

Valid Analytical Measurement Bulletin, 137
 Validated methods, 3, 116–118
 VAM Bulletin, 137
 Variable sampling, 93
 Variance, 32
 Variance Ratio Tables, 37
 Ventilation systems, 65
 Vertical audits, 143
 Vibration interference, 63–64
 Volumetric glassware, 87

W

Warning limits, 40

-
- Water, purified, 85–86
Water systems, 64
WELAC. *See* Western Europe Laboratory Accreditation Conference
Western Europe Laboratory Accreditation Conference, 156
Workload management systems, 108
Workplace values, 53
Worksheets
 laboratory, 105, 107
 reviews, 141–142

Z

Z-scores, 136–137