

# Index

- 3.4 DPMO, 93
- 5 Whys, 91
- 5S, 104
- 80/20 rule, 87
  
- Acceptance sampling, 118, 121
- Accommodating, 64
- Accreditation audit, 7, 9
- Accreditation bodies (AB), 9
- Action effectiveness, 53
- Active listening, 66
- Adjourning, 69
- ANAB, 9
- Analyze phase, 94
- Anderson-Darling, 113
- ANSI National Accreditation Board (ANAB), 9
- ANSI/ASQ Z1.4, 118
- ANSI/ASQ Z1.9, 118
- Appraisal cost, 84
- AQL, 118
- ASQ Code of ethics, 19, 20
- ASQ CQA Exam, 2
- Assertiveness, 63
- Assignable causes, 112
- Attention to detail, 59
- Attribute sampling, 118
- Audit accommodations, 33
- Audit agenda, 41
- Audit authority, 25
- Audit benefits, 82
- Audit budgeting, 72
- Audit checklists, 35
- Audit client, 17, 54
- Audit closure, 57
- Audit communication, 38, 39, 41, 46, 65
- Audit completion, 57
- Audit conclusions, 46, 49
- Audit confidence, 22
- Audit conflict, 62
- Audit consistency, 35
- Audit constraints, 28
- Audit costs, 72
- Audit coverage, 13
- Audit credibility, 22
- Audit criteria, 3, 10, 15, 26, 31, 38
- Audit criteria standards, 16
- Audit data collection, 42
- Audit definition, 3
- Audit documentation, 34
- Audit duration, 27
- Audit evidence, 43, 44, 49
- Audit execution, 28
- Audit file, 51
- Audit findings, 45, 47, 48, 50
- Audit follow-up, 46, 57
- Audit function, 71
- Audit guides, 40
- Audit independence, 71
- Audit interruptions, 62
- Audit interviews, 28, 42, 66
- Audit leadership, 60, 67, 69
- Audit liaison, 40
- Audit logistics, 28, 33, 61
- Audit methods, 30, 34
- Audit metrics, 74
- Audit objectives, 26, 38
- Audit objectivity, 68
- Audit observations, 43
- Audit observers, 40
- Audit opening meeting, 41
- Audit participants, 17, 18
- Audit plan, 38

- Audit plan adjustment, 39
- Audit planning, 13, 27, 31, 38
- Audit policies, 75
- Audit preparation, 33
- Audit process, 11
- Audit program evaluation, 74
- Audit program management, 75
- Audit program manager, 54
- Audit program objectives, 74
- Audit purpose, 7, 8, 10, 12, 26
- Audit records, 57
- Audit report, 48
- Audit report approval, 51
- Audit report distribution, 51
- Audit report elements, 49
- Audit report quality, 50
- Audit reporting, 11, 47, 65
- Audit resource allocation, 39
- Audit resource management, 61, 72
- Audit resources, 27
- Audit results, 78, 80
- Audit roles, 18
- Audit scheduling, 75
- Audit scope, 13, 26, 27, 38
- Audit strategies, 37
- Audit team, 27
- Audit team coaching, 68
- Audit team coordination, 61
- Audit team management, 60
- Audit team member, 18
- Audit team roles, 67
- Audit team selection, 30
- Audit teamwork, 59
- Audit techniques, 36
- Audit time management, 39, 61
- Audit types, 4, 5, 26
- Auditee, 17
- Auditee delaying tactics, 62
- Auditee liability, 21
- Auditee responsibilities, 40
- Auditing as a management tool, 82
- Auditing fundamentals, 3
- Auditing principles, 23
- Auditing strategies, 36
- Auditing tools, 34
- Auditor, 17
- Auditor characteristics, 59
- Auditor competence, 29, 73
- Auditor independence, 22, 29
- Auditor liability, 21
- Auditor misconduct, 20
- Auditor objectivity, 22
- Auditor qualifications, 22, 29
- Auditor selection, 29
- Auditor training, 73
- Auditor-auditee relationship, 6
- Avoiding, 64
- Backward tracing, 36
- Benefits of audits, 14
- Best practices, 78
- British Standards Institution (BSI), 9
- Bureau Veritas, 9
- Business continuity planning, 79
- Business processes, 83
- CAPA, 52
- CAPA audit, 8
- CAPA closure, 57
- CAPA escalation, 56
- CAPA follow-up, 56
- CAPA process, 53
- CAPA review, 54
- CAPA verification, 55
- Carelessness, 21
- Cause and effect diagram, 88
- Certification audit, 9
- Certification bodies (CB), 9
- Certified Quality Auditor, 2
- Change control, 122
- Change request, 122
- Check sheets, 89
- Closed questions, 66
- Closing meeting, 46
- Closing meeting agenda, 47
- Cluster sampling, 119
- Collaborating, 64
- Combined audit, 5, 30
- Common audit elements, 10
- Common cause variation, 112
- Competing, 64
- Compliance audit, 7, 12

- Compromise, 64
- Computerized systems, 81
- Confidentiality, 19, 23, 47, 51
- Confidentiality agreements, 33
- Confidentiality breach, 20
- Configuration audit, 123
- Configuration identification, 123
- Configuration management, 123
- Conflict of interest, 19, 20
- Conflict Resolution, 64
- Conflict resolution, 62, 68
- Conflict styles, 63
- Consensus building, 68
- Consumer's risk, 121
- Continuing education, 73
- Continuous data, 110
- Continuous improvement, 82, 92, 95, 105
- Contracts, 15, 25
- Control charts, 90
- Control phase, 94
- COQ, 84
- Correction, 52
- Corrective action, 8, 47, 52
- Corrective action effectiveness, 14, 55
- Corrective action plan, 53
- Corrective action plan review, 54
- Corrective action process, 53
- Corrective action timeline, 50
- Correlation, 89
- Corroboration, 43, 44
- Cost of quality, 45, 84
- Cost reduction, 14
- Cp, 113–116
- Cpk, 113–116
- Cross-functional interfaces, 83
- Cultural awareness, 59
- Cultural diversity, 73
- Customer confidence, 14
- Customer satisfaction, 82
- Cybersecurity, 81
- Cycle time, 102
- Cycle time reduction, 102
- DAkkS, 9
- Data analysis, 117
- Data collection, 89
- Data distribution, 91
- Data gathering techniques, 11
- Data integrity, 81
- Data types, 110
- Data visualization, 111
- Defects per million opportunities (DPMO), 93
- Define phase, 94
- Deming cycle, 92
- Department audit, 5
- Descriptive statistics, 108
- Desk audit, 5
- Det Norske Veritas (DNV), 9
- Detection, 125, 127
- Deutsche Akkreditierungsstelle (DAkkS), 9
- Disagreements, 62
- Discovery audit, 36
- Discrete data, 110
- DMADV, 93
- DMAIC, 93, 94
- DNV, 9
- Document review, 43, 55
- Documented information, 32, 43
- Due professional care, 23
- Effective audit reports, 50
- Eight wastes, 101
- Electronic documented information, 81
- Electronic records, 81
- Element audit, 5
- Empathy, 63
- Environmental audits, 10
- EPA, 25
- Equitable treatment, 67
- Error proofing, 107
- Ethical principles, 19
- Ethical violations, 20
- Evidence-based approach, 23
- Executive summary, 50
- Exit meeting, 46
- External audit, 6, 12
- External audit authority, 25
- External audit program, 77
- External failure cost, 84

- External providers, 77
- Failure Mode and Effects Analysis (FMEA), 127
- Fair presentation, 23
- FDA, 25
- Final audit report, 51
- Financial audits, 10
- First-party audit, 6, 12
- Fishbone diagram, 88
- Fitness for use, 14, 124
- Flowchart, 88, 89
- Follow-up audit, 11, 55
- For-cause audit, 8
- Forming, 69
- Forms, 32
- Forward tracing, 36
- Fraud risk, 81
- Functional audit, 5
  
- Gap assessment, 31
- Generic audit training, 73
- Global recognition of certification, 9
- Graphs and charts, 65
- Guide, 18
  
- Histogram, 91
- Horizontal audit, 37
- Hybrid audit, 5
  
- IAF, 9
- IAF Multilateral Recognition Arrangement (MLA), 9
- Improve phase, 94
- Improvement audit, 12
- Independence, 23
- Industry standards, 16
- Industry-specific training, 73
- Ineffective corrective action, 56
- Inference, 120
- Inherent risk, 126
- Integrated audit, 5
- Integrity, 19, 23
- Internal audit, 6, 12, 76
- Internal audit authority, 25
- Internal audit program, 75
- Internal failure cost, 84
- Internal QMS, 15
- International Accreditation Forum (IAF), 9
- Interpersonal skills, 59
- Interviewing, 42
- Interviewing techniques, 66
- Ishikawa diagram, 88
- ISO 10007, 123
- ISO 19011, 23, 79
- ISO 19011:2018, 78
- ISO 31000, 79, 125
- ISO 9000, 3
- ISO 9001, 25, 76, 77, 80, 122, 128
- ISO 9001 audits, 9
- ISO 9001 certification, 9
- ISO standards, 16
- Isolated problems, 111
- Issue, 126
  
- JAS-ANZ, 9
- Joint Accreditation System of Australia and New Zealand (JAS-ANZ), 9
- Joint audit, 5, 30
- Judgmental sampling, 119
  
- Kanban, 103
- Kolmogorov-Smirnov, 113
  
- Lead auditor, 18, 30, 54, 60
- Lead time, 102
- Lean, 95, 101, 105
- Lean improvement, 102
- Lean philosophy, 95
- Lean tools, 107
- Lean waste, 100
- Legal consequences of audits, 21
- Lessons learned, 51, 78
  
- Management audit, 5
- Management commitment, 71
- Management review, 80
- Management system standards, 16
- Mean, 108
- Measure phase, 94

- Measures of central tendency, 108
- Measures of dispersion, 109
- Median, 108
- Mode, 108
- Muda, 100, 101
- Multi-site operations, 83
- Multilateral Recognition Arrangement (MLA), 9
- Mura, 100
- Muri, 100
  
- Negative risk, 134
- Negligence, 21
- Negotiation skills, 60
- Non-assignable causes, 112
- Non-probability sampling, 119
- Non-value-added activities, 96, 101
- Non-verbal cues, 66
- Nonconformities, 45
- Normality Test, 113
- Norming, 69
  
- Objective evidence, 3, 15, 44, 45
- Observation, 36
- Observer, 18
- Occurrence, 125, 127
- On-site audit management, 39, 40, 61
- Open-ended questions, 66
- Opening meeting, 41
- Opportunities for improvement, 14, 49
- Opportunity, 126
- Opportunity management, 135
- Organizational metrics, 83
- Organizational reputation, 14
- Organizational risk management, 79
- OSHA, 25
- Outliers, 117
- Outsourced audits, 72
  
- Parameter, 120
- Pareto chart, 87
- PDCA, 92
- PDSA, 92
- Performing, 69
- Poka-Yoke, 107
- Policies, 15
  
- Population, 120
- Population variance, 109
- Positive risk, 135
- Post-audit activities, 28
- Pp, 113–116
- Ppk, 113–116
- Pre-audit information, 31
- Presentation techniques, 65
- Prevention cost, 84
- Preventive action, 8, 52, 107
- Preventive detection, 14
- Prior audits, 31
- Probability sampling, 119
- Probability-impact matrix, 133
- Problem prioritization, 87
- Problem solving, 91
- Problem-solving, 59
- Procedure effectiveness, 14
- Procedures, 15, 32
- Process audit, 4, 84
- Process capability, 113, 114, 116
- Process capability indices, 115
- Process centering, 116
- Process flow, 102
- Process interrelationships, 83
- Process mapping, 88
- Process performance, 116, 117
- Process performance indices, 115
- Process standardization, 105
- Process variation, 90, 111, 112, 114
- Producer's risk, 121
- Product audit, 4, 84
- Product conformity, 124
- Product traceability, 123
- Professional liability, 21
- Pull System, 103
  
- Qualitative data, 110
- Qualitative risk analysis, 132
- Quality audits, 4
- Quality management system audit, 76
- Quality management system review, 80
- Quality system documentation, 32
- Quality tools, 89, 91, 92
- Quantitative data, 110, 111
- Quantitative risk analysis, 132

- Questioning techniques, 42
- Random sampling, 119
- Range, 109
- Re-audit, 56
- Record retention, 51
- Reduced rework, 14
- Registrar, 9
- Registration audit, 7
- Regulatory audits, 25
- Regulatory compliance, 14
- Reliability of evidence, 44
- Remote audit, 5, 55, 65
- Report development, 48
- Requirements, 15
- Residual risk, 126
- Resource availability, 67
- Respect and fairness, 19
- Responsibility, 19
- Right of access, 33
- Risk, 125
- Risk acceptance, 134, 135
- Risk analysis, 129, 132
- Risk appetite, 126
- Risk assessment, 48
- Risk audits, 136
- Risk avoidance, 134
- Risk control, 136
- Risk criteria, 130
- Risk documentation, 131
- Risk enhancement, 135
- Risk evaluation, 133
- Risk exploitation, 135
- Risk governance, 130
- Risk identification, 14, 129, 131
- Risk impact, 126, 132
- Risk likelihood, 126
- Risk Management, 127
- Risk management, 82, 125
- Risk Management Plan, 130
- Risk management process, 129
- Risk matrix, 133
- Risk mitigation, 134
- Risk monitoring, 129, 136
- Risk owner, 126
- Risk planning, 129, 130
- Risk priority number (RPN), 127
- Risk probability, 132
- Risk reduction, 74
- Risk register, 131
- Risk response, 129, 134, 135
- Risk sharing, 135
- Risk sources, 131
- Risk tolerance, 126
- Risk transfer, 134
- Risk-based approach, 23
- Risk-based audit, 8
- Risk-based auditing, 79
- Risk-based grading, 45
- Risk-based sampling, 119
- Risk-Based thinking, 125, 128
- Risk-based thinking, 52
- Roles and responsibilities, 17
- Root cause analysis, 53, 88, 91
- Root cause analysis tools, 56
- Safety and security, 33
- Safety audits, 10
- Sample, 120
- Sample variance, 109
- Sampling, 120
- Sampling methods, 119
- Sampling plans, 34
- Scatter diagram, 89
- Scope boundaries, 13
- Scoring checklists, 35
- Second-party audit, 6, 12
- Sector-specific standards, 16
- Senior management support, 71
- Service audit, 5
- Severity, 125, 127
- Severity classification, 48
- SGS, 9
- Shapiro-Wilk, 113
- Shewhart cycle, 92
- Sigma overall, 114, 115
- Sigma within, 114, 115
- Six sigma, 93, 94
- Six sigma belts, 93
- Société Générale de Surveillance (SGS),  
9
- SPC charts, 90

- Special cause variation, 112
- Specifications, 15
- Staffing, 72
- Standard deviation, 109
- Standard work, 105
- Statistic, 120
- Statistical process control, 90
- Storming, 69
- Strategic alignment, 74
- Stratified sampling, 119
- Strengths, 78
- Succession planning, 79
- Supplier audits, 77
- Supplier development, 77
- Supplier management, 82
- Supplier selection, 77
- Supplier surveillance, 77
- Surveillance audit, 7
- Sustainability audits, 10
- System audit, 4, 84
- Systemic problems, 111
- Systemic trends, 75
  
- Team building, 67
- Team development, 69
- Team facilitation, 68
- Technical expert, 18, 30
- Third-party audit, 6, 12
- Third-party certification, 9
- Thomas-Kilmann model, 63
- Time value of auditing, 72
- Tracing methods, 11
- Trends, 111
- TUV, 9
- Type I error, 121
- Type II error, 121
  
- UKAS, 9
- Unexpected risks, 136
- United Kingdom Accreditation Service  
(UKAS), 9
  
- Validation, 124
- Value added, 101
- Value stream, 95
- Value stream mapping, 96–98
  
- Value-added activities, 96
- Variable sampling, 118
- Variance, 109
- Variation, 117
- Verification, 44, 124
- Version control, 122
- Vertical audit, 37
- Visual control, 106
- Visual management, 103, 104, 106
- VSM, 96
  
- Waste reduction, 95, 100
- WECO rules, 90
- Work instructions, 32, 105
- Work-in-process, 103
- Workarounds, 136
- Workflow analysis, 88
- Working papers, 34, 35
- Workplace control, 106
- Workplace organization, 104