
Contents

Preface xiii

About the Author xv

Chapter 1 Introduction 1

1.1 Need for Reliability Technology, Human Error Studies, and Quality in Health Care 1

1.2 History..... 1

1.2.1 Reliability Technology 1

1.2.2 Human Error 2

1.2.3 Quality..... 2

1.3 Facts and Figures 2

1.4 Terms and Definitions 4

1.5 Useful Information on Reliability Technology, Human Error, and Quality in Health Care 5

1.5.1 Journals 5

1.5.2 Books..... 6

1.5.3 Conference Proceedings..... 6

1.5.4 Organizations 7

1.6 Problems..... 7

References..... 8

Chapter 2 Basic Mathematical Concepts 11

2.1 Introduction..... 11

2.2 Range, Arithmetic Mean, and Standard Deviation..... 11

2.2.1 Range..... 11

2.2.2 Arithmetic Mean 12

2.2.3 Standard Deviation..... 12

2.3 Boolean Algebra Laws and Probability Properties..... 13

2.4 Basic Probability-Related Definitions..... 16

2.4.1 Probability Density Function 16

2.4.2 Cumulative Distribution Function..... 17

2.4.3 Expected Value..... 17

2.4.4 Variance..... 18

2.5 Probability Distributions..... 18

2.5.1 Exponential Distribution 18

2.5.2 Weibull Distribution 19

2.5.3 Normal Distribution 20

2.5.4 General Distribution..... 21

2.6	Laplace Transform Definition, Common Laplace Transforms, Final-Value Theorem, and Laplace Transforms' Application in Solving First-Order Differential Equations.....	21
2.6.1	Laplace Transform: Final-Value Theorem	22
2.6.2	Laplace Transforms' Application in Solving First-Order Differential Equations	23
2.7	Problems.....	24
	References	25

Chapter 3 Introduction to Reliability Technology, Human Error, and Quality..... 27

3.1	Introduction.....	27
3.2	Bathtub Hazard Rate Curve	27
3.3	Commonly Used Formulas in Reliability Analysis	28
3.3.1	General Formula for Reliability	29
3.3.2	General Formula for Hazard Rate.....	29
3.3.3	General Formula for Mean Time to Failure.....	30
3.4	Reliability Configurations.....	31
3.4.1	Series Configuration.....	31
3.4.2	Parallel Configuration	33
3.4.3	m -out-of- K Configuration.....	35
3.4.4	Standby System	37
3.5	Reliability Analysis Methods.....	38
3.5.1	Markov Method.....	38
3.5.2	Failure Modes and Effect Analysis	40
3.5.3	Fault Tree Analysis.....	41
3.6	Human Error Facts, Figures, and Causes.....	44
3.7	Human Error Classifications	44
3.8	Human Error Analysis Methods	45
3.8.1	Root Cause Analysis	45
3.8.2	Man-Machine Systems Analysis	46
3.9	Human Error Data Sources.....	46
3.10	Factors Affecting Product Quality and Services	47
3.11	Quality Assurance System Tasks.....	47
3.12	Total Quality Management versus Traditional Quality Assurance	47
3.13	TQM Elements and Obstacles to TQM Implementation	48
3.14	Problems.....	49
	References	50

Chapter 4 Medical Device Safety and Quality Assurance 53

4.1	Introduction.....	53
4.2	Medical Device Safety versus Reliability and Types of Medical Device Safety	53

4.3 Medical Device-Related Safety Requirements and Safety in Device Life Cycle..... 54

4.4 Safety Analysis Tools for Medical Devices and Considerations for Selecting Safety Analysis Methods..... 56

4.4.1 Considerations for Selecting Safety Analysis Methods 59

4.5 Regulatory Compliance of Medical Device Quality Assurance and Program for Assuring Medical Device Design Quality 60

4.6 Methods for Medical Device Quality Assurance 64

4.6.1 Flowcharts 64

4.6.2 Check Sheets 64

4.6.3 Scatter Diagram..... 65

4.6.4 Histogram..... 65

4.6.5 Cause-and-Effect Diagram..... 65

4.6.6 Pareto Diagram 66

4.7 Problems..... 66

References 67

Chapter 5 Medical Device Software Quality Assurance and Risk Assessment 69

5.1 Introduction..... 69

5.2 Medical Device Software Failure Examples 69

5.3 Classifications of Medical Software 70

5.4 Framework for Defining Software Quality Assurance Programs in Medical Device Manufacturing Organizations 71

5.5 Software Design, Coding, and Testing 72

5.5.1 Software Design..... 72

5.5.2 Software Coding..... 74

5.5.3 Software Testing..... 74

5.6 Software Metrics..... 76

5.6.1 Metric I: McCabe’s Complexity 76

5.6.2 Metric II: Halstead Measures..... 77

5.7 Risk Management Definition and Program Steps..... 78

5.8 Factors in Medical Device Risk Assessment 79

5.8.1 Design and Manufacturing..... 79

5.8.2 Materials Toxicity and Degradation..... 80

5.8.3 Human Factors 80

5.8.4 Interaction with Other Devices 81

5.9 Integrating Risk Assessment into Medical Device Design Control 81

5.10 Medical Device Risk Assessment-Related Data..... 81

5.11 Problems..... 82

References 82

Chapter 6	Medical Device Maintenance and Sources for Obtaining Medical Device-Related Failure Data.....	85
6.1	Introduction.....	85
6.2	Medical Equipment Classifications.....	85
6.3	Medical Equipment Maintenance Indexes.....	86
6.3.1	Broad Indexes.....	86
6.3.2	Medical Equipment-Specific Indexes.....	87
6.4	Medical Equipment Computerized Maintenance Management Systems	89
6.5	Mathematical Models for Medical Equipment Maintenance	91
6.5.1	Model I.....	91
6.5.2	Model II.....	92
6.6	Medical Device-Related Failure Data Sources.....	93
6.7	Organizations for Obtaining Medical Device-Related Failure Data.....	94
6.8	Medical Device Failure-Related Data.....	95
6.9	Problems.....	96
	References.....	96
Chapter 7	Human Error in Health Care.....	99
7.1	Introduction.....	99
7.2	Human Error in Health Care-Related Facts, Figures, and Examples	99
7.3	Human Error in Medication.....	100
7.3.1	Types of Medication Errors.....	100
7.3.2	Common Reasons for Occurrence of Medication Errors.....	101
7.3.3	Useful General Guidelines to Reduce Occurrence of Medication Errors	101
7.4	Human Error in Anesthesia	102
7.4.1	Common Anesthesia Errors	103
7.4.2	Common Causes of Anesthesia Errors.....	103
7.4.3	Useful Methods to Prevent or Reduce Anesthetic Mishaps Due to Human Error	104
7.5	Human Error in Medical Devices.....	106
7.5.1	Medical Devices with High Incidence of Human Errors.....	106
7.5.2	Human Errors Causing User-Interface Design Problems	106
7.5.3	Medical Device-Associated Operator Errors.....	107
7.5.4	Human Error Analysis Methods for Medical Devices.....	107
7.6	Human Error in Miscellaneous Health Care Areas.....	108
7.6.1	Human Error in Emergency Medicine.....	108
7.6.2	Human Error in Intensive Care Units	109
7.7	Useful Guidelines to Prevent Occurrence of Human Error in Health Care	109
7.8	Problems.....	110
	References.....	111

Chapter 8	Health Care Human Error Reporting Systems and Models for Predicting Human Reliability and Error in Health Care	115
8.1	Introduction.....	115
8.2	Key Points Associated with Current Event Reporting Systems and Methods Practiced in Such Systems	115
8.3	Health Care Human Error Reporting Systems	116
8.4	Medical and General Human Error-Related Data	117
8.5	Model I: Human Reliability in Normal Work Environment.....	117
8.6	Model II: Human Reliability in Fluctuating Work Environment	120
8.7	Model III: Human Reliability with Critical and Non-Critical Human Errors in Normal Work Environment	124
8.8	Problems.....	126
	References.....	127
Chapter 9	Patient Safety.....	129
9.1	Introduction.....	129
9.2	Facts and Figures	129
9.3	Patient Safety Goals	130
9.4	Patient Safety Culture and Its Assessment.....	131
9.5	Patient Safety Program	132
9.6	Patient Safety Measure Selection and Patient Safety Measures and Analysis Methods.....	134
9.7	Patient Safety Organizations.....	136
9.8	Problems.....	136
	References.....	137
Chapter 10	Introduction to Quality in Health Care.....	141
10.1	Introduction.....	141
10.2	Reasons for Escalating Health Care Costs and Quality Dimensions of Today's Health Care Business.....	141
10.3	Health Care Quality Goals and Their Associated Strategies	143
10.4	Health Care and Industrial Quality Comparisons and Quality Improvement versus Quality Assurance in Health Care Institutions	144
10.5	Common Health Care Administrators' Appeals for Total Quality and Physicians' Reactions.....	145
10.6	Steps for Improving Quality in Health Care.....	145
10.7	Implementation of Six Sigma Methodology in Hospitals and Its Advantages and Implementation Barriers.....	147
10.8	Quality Indicators for Use in Hospital Departments	148
10.8.1	Department: Nursing, Acute Care.....	149
10.8.2	Department: Physiotherapy	149
10.8.3	Department: Social Work Services	149
10.8.4	Department: Pharmacy	149
10.8.5	Department: Food Services Excluding Therapeutic Nutrition.....	149

10.9 Problems..... 150

References..... 150

Chapter 11 Quality Methods for Use in Health Care 153

11.1 Introduction..... 153

11.2 Group Brainstorming..... 153

11.3 Cause-and-Effect Diagram 154

11.4 Quality Function Deployment..... 155

11.5 Process Flow Diagram..... 156

11.6 Affinity Diagram..... 156

11.7 Check Sheet..... 157

11.8 Force Field Analysis..... 157

11.9 Multivoting..... 158

11.10 Pareto Chart 159

11.11 Scatter Diagram 159

11.12 Control Chart 160

11.12.1 The C-Chart 160

11.13 Problems..... 162

References..... 163

Bibliography 165

Index..... 191