# Contents

## Part 1: Quality in Healthcare

1. Quality
   - Dimensions of Quality in Healthcare 4
   - Evolution of The Concept of Quality 5
   - The National Committee for Quality Assurance (NCQA), USA 12
   - Healthcare Effectiveness Data and Information Set (HEDIS) 12
   - Present International Scenario 13
   - International Society for Quality in Healthcare (ISQua)
   - Accrediting the Accreditors 15
   - Indian Scenario 16
     - CRISIL Rating of Hospitals/Nursing Homes 18
   - Cost of Quality : Economic Feasibility 19

## Part 2: Improvement of Quality of Services in Hospitals

2. How to Improve the Quality of Services in Hospitals
   - Essentials of Quality Improvement in Healthcare Services 23
   - Improvement of Quality in Healthcare: Different Approaches 25
     - Total Quality Management (TQM) 25
     - Lean Thinking (Lean Manufacturing) 25
     - Six Sigma 27
     - Lean Sigma 29
     - Kaizen 32
   - Quality Circles 33
     - ISO Certification 34
     - Accreditation of Hospitals 34
     - Important Considerations 35
   - Implementation of Quality Management Program in an Organization 36

## Part 3: Certification/Accreditation of Hospitals

3. ISO Certification
   - Benefits of ISO Certification 43
   - Structure of ISO 9001:2000 Standards 45
   - Quality Manual 46
     - Purpose 47
4. NABH ACCREDITATION
   - Composition of NABH  51
   - The Organogram of NABH  52
   - Objectives of Accreditation  52
   - Benefits of Accreditation  53
   - Activities/Achievements of NABH  53
   - NABH International (NABHI)  54
   - NABH Accreditation Standards for Hospitals  55
   - Accreditation of Dental Healthcare Service Providers (DHSP)  56
   - Accreditation of Blood Bank and Transfusion Services  56
   - Accreditation of Primary Health Centers and Community Health Centers  57
   - Accreditation of Small Healthcare Organizations  57
   - Medical Imaging Services  57
   - Medical Laboratory Program  58
   - Oral Substitution Therapy (OST) Center Accreditation  59
   - Accreditation of Wellness Centers  59
   - Accreditation of AYUSH Hospitals  60
   - Accreditation of Allopathic Clinics  60
   - Accreditation Standards  61
   - Accreditation Program and Patients’ Safety  62
   - NABH Accreditation Program for Hospitals  62
   - Hospital and SHCO Accreditation Time Line  65

5. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO)  66
   - Periodic Performance Review (PPR)  66
   - Tracer Methodology  66
   - Priority Focus Process (PFP)  67
   - Unannounced Survey  67
   - Extension Survey  67
   - Validation Survey  68
   - At Risk of Denial for Accreditation Policy  68

   JCAHO Patient Safety Goals  69
   - Submitting Alternative Approaches  69
   - Surveying and Scoring the NPSGs  69

   JCI Accreditation Program  70

6. IDEAL APPROACH TO QUALITY  73

   Part 4: Quality Management at Departmental Level

7. PATIENT FRIENDLY HOSPITAL  77
   - The Simple Test  82
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. FRONT OFFICE</td>
<td>83</td>
</tr>
<tr>
<td>Functions of Various Sections</td>
<td></td>
</tr>
<tr>
<td>Quality Assurance of Front Office</td>
<td>85</td>
</tr>
<tr>
<td>9. OUTPATIENT DEPARTMENT</td>
<td>89</td>
</tr>
<tr>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>10. EMERGENCY SERVICE</td>
<td>95</td>
</tr>
<tr>
<td>Quality Assurance of Accident and Emergency Services</td>
<td>96</td>
</tr>
<tr>
<td>11. DEPARTMENT OF DENTAL SURGERY</td>
<td>102</td>
</tr>
<tr>
<td>Services Provided by Dental Surgery Department</td>
<td>102</td>
</tr>
<tr>
<td>Quality of Dental Service</td>
<td>102</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>103</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>104</td>
</tr>
<tr>
<td>Indicators for Evaluation of Quality of Services</td>
<td>106</td>
</tr>
<tr>
<td>12. PATHOLOGY DEPARTMENT</td>
<td>107</td>
</tr>
<tr>
<td>Quality Assurance of Pathology Department</td>
<td>107</td>
</tr>
<tr>
<td>The Internal Quality Control Mechanism</td>
<td>108</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>110</td>
</tr>
<tr>
<td>External Quality Assurance</td>
<td>112</td>
</tr>
<tr>
<td>Criteria for Evaluation of Quality in Laboratory Services</td>
<td>112</td>
</tr>
<tr>
<td>13. RADIOLOGY DEPARTMENT</td>
<td>114</td>
</tr>
<tr>
<td>Quality Assurance of Radiology Services</td>
<td>115</td>
</tr>
<tr>
<td>Structure Elements Important from Quality Point of View</td>
<td>116</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>118</td>
</tr>
<tr>
<td>Radiation Safety Measures</td>
<td>120</td>
</tr>
<tr>
<td>Indicators for Evaluation of Quality of Services</td>
<td>121</td>
</tr>
<tr>
<td>14. OPERATION THEATER (OT) DEPARTMENT</td>
<td>123</td>
</tr>
<tr>
<td>Quality of Services of OT Department</td>
<td>124</td>
</tr>
<tr>
<td>Quality Aspects of Structure</td>
<td>124</td>
</tr>
<tr>
<td>Quality Control of Process</td>
<td>126</td>
</tr>
<tr>
<td>15. BLOOD BANK</td>
<td>132</td>
</tr>
<tr>
<td>What Does Quality Mean in Blood Bank Service?</td>
<td>133</td>
</tr>
<tr>
<td>Quality of Outcome</td>
<td>133</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>133</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>134</td>
</tr>
<tr>
<td>NABH Standards for Blood Transfusion Services</td>
<td>136</td>
</tr>
<tr>
<td>Quality Control Criteria for Transfusion Services</td>
<td>136</td>
</tr>
<tr>
<td>16. PHYSIOTHERAPY AND REHABILITATION DEPARTMENT</td>
<td>138</td>
</tr>
<tr>
<td>Quality Assurance of Physiotherapy and Rehabilitation Service</td>
<td>139</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>139</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>140</td>
</tr>
<tr>
<td>Criteria for Evaluation of Quality of Services</td>
<td>141</td>
</tr>
<tr>
<td>17. MATERNITY SERVICES</td>
<td>142</td>
</tr>
<tr>
<td>Functions of Maternity Service</td>
<td>143</td>
</tr>
</tbody>
</table>
Quality Management in Hospitals

Program of Quality Assurance 144
Quality of Structure 144
Quality of Process 145
Indicators for Quality of Services 146

18. INPATIENT AREAS (WARD UNIT) 148
Definition 148
Important Aspects of Ward Management 148
Important Quality Parameters 149
Infrastructure 149
Quality of Process 150
Criteria for Evaluation of Quality of Services in the Wards 152

19. INTENSIVE CARE UNIT (ICU) 154
Definition 154
Role 154
Functions 154
Quality Management of Intensive Care Service 155
Quality of Structure 156
Quality of Process 157
Indicators for Evaluation of Quality of Services 159

20. NEONATAL INTENSIVE CARE UNIT 160
Quality of Neonatal Intensive Care Service 161
Quality of Outcome 161
Quality of Structure 161
Quality of Process 162
Indicators for Quality Evaluation 164

21. DIALYSIS SERVICE 165
Quality of Outcome of Dialysis Services 165
Quality of Structure 166
Quality of Process 167
Indicators for Quality of Services 168

22. PHARMACY SERVICE 169
Role and Functions of Pharmacy Service 169
Quality Management in Pharmacy Service 170
Quality of Structure 170
Quality of Process 171
Evaluation of Quality of Services 173
Criteria for Quality Evaluation 174

23. MEDICAL RECORDS DEPARTMENT 175
Role and Importance of Medical Records 175
Functions of Medical Records Department 176
Quality Assurance of Medical Records 176
What does Quality of Medical Records mean to all these Clients? 177
What all is Required to Satisfy all the Clients? 178
<table>
<thead>
<tr>
<th>24. CENTRAL STERILE SUPPLY DEPARTMENT (CSSD)</th>
<th>185</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>185</td>
</tr>
<tr>
<td>Functions of CSSD</td>
<td>185</td>
</tr>
<tr>
<td>Quality Management of Services in CSSD</td>
<td>185</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>186</td>
</tr>
<tr>
<td>Quality of Processes Used in CSSD</td>
<td>187</td>
</tr>
<tr>
<td>Indicators for Evaluation of Quality of Services</td>
<td>189</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>25. DIETARY SERVICE</th>
<th>190</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functions of Dietary Services</td>
<td>190</td>
</tr>
<tr>
<td>Improvement of Quality of Dietary Services</td>
<td>190</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>191</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>192</td>
</tr>
<tr>
<td>Criteria for Evaluation of Quality</td>
<td>195</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>26. LAUNDRY SERVICE</th>
<th>196</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Outcome</td>
<td>196</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>197</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>198</td>
</tr>
<tr>
<td>Criteria for Evaluation of Quality of Services</td>
<td>199</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>27. HOUSEKEEPING SERVICE</th>
<th>201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities</td>
<td>201</td>
</tr>
<tr>
<td>Quality Assurance of Housekeeping Service</td>
<td>201</td>
</tr>
<tr>
<td>Structure</td>
<td>202</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>203</td>
</tr>
<tr>
<td>Indicators for Quality of Services</td>
<td>204</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>28. HOSPITAL ENGINEERING SERVICES</th>
<th>206</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functions of the Engineering Services</td>
<td>207</td>
</tr>
<tr>
<td>Assurance of Quality of Engineering Services</td>
<td>208</td>
</tr>
<tr>
<td>Quality of Structure</td>
<td>209</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>210</td>
</tr>
<tr>
<td>Indicators for Evaluation of Quality of Services</td>
<td>212</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>29. CENTRALIZED GAS AND VACUUM SUPPLY SERVICE</th>
<th>214</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functions</td>
<td>214</td>
</tr>
<tr>
<td>Quality of Services</td>
<td>214</td>
</tr>
<tr>
<td>Outcome of Service</td>
<td>214</td>
</tr>
<tr>
<td>Structure</td>
<td>215</td>
</tr>
<tr>
<td>Quality of Process</td>
<td>217</td>
</tr>
<tr>
<td>Indicators for Evaluation of Quality of Services</td>
<td>219</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>30. HOSPITAL INFORMATION SYSTEM (HIS)</th>
<th>220</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functions of HIS</td>
<td>221</td>
</tr>
</tbody>
</table>
Quality Management in Hospitals

Quality Assurance of Hospital Information System 221
Quality of Structure 221
Quality of Process 223
Indicators for Quality of Hospital Information System 226

31. SECURITY SERVICE 227
Quality of Outcome 227
Quality of Structure 228
Quality of Process 229
Indicators for Quality of Security Services 230

32. FIRE SAFETY SERVICE 232
Common Causes of Fire in the Hospitals 233
Areas More Prone to Fire 233
Quality of Fire Safety Services 233
Expectations of the Clients and the Regulatory Authorities 233
Quality of Structure 234
Manpower 234
Quality of Process Used 235
Indicators for Quality of Fire Safety Services 237

33. ACCOUNTS DEPARTMENT 239
Functions of the Accounts Department 239
Quality of Outcome of Accounts Department 241
Quality of Structure 241
Quality of Process 242
Quality Indicators for Evaluation of Performance 243

34. MARKETING AND PUBLIC RELATIONS 244
Public Relations Service 244
Functions of the Department 245
Essentials for High Quality Public Relations 245
Quality of Process 246
Indicators for a Successful Public Relations Program 247
Marketing Department 247
Functions 247
Essentials for Quality of Marketing Services 249
Quality of Marketing Process 249
Indicators for Quality of Marketing Program 250

35. NURSING SERVICE 252
Role 252
Quality of Process 254
Documentation of Nursing Care 256
Criteria for Evaluation of Quality of Service 257

36. HUMAN RESOURCE DEPARTMENT (HRD) 259
Role of HRD 259
Activities 259
Assurance of Quality of Services 261
Quality of Structure 261
Quality of Process 262
Indicators for Evaluation of Quality of Performance 265

37. MORTUARY SERVICE 266
Functions of Mortuary Service 266
Quality of Structure 267
Quality of Process 268
Indicators for Quality Evaluation of Mortuary Service 269

38. OUTREACH SERVICES 270
Purpose of Outreach Services 270
What does Quality of Outreach Services mean? 271
Quality of Structure 271
Quality of Process 272
Indicators for Evaluation of Quality 273

Part 5: Important Programs for Hospitalwide Improvement of Services

39. STATUTORY COMPLIANCE IN HOSPITALS 277
System of Ensuring Statutory Compliance 278
Structural Requirements 278
Process Requirements for Statutory Compliance 278
Indicators for Evaluation of Statutory Compliance 282

40. PATIENT SAFETY MANAGEMENT PROGRAM (PSMP) 284
Essentials of Patient Safety Management Program (PSMP) 285
Identification of Risk Factors 286
Infrastructural Risk Factors 286
Quality of Process 288
Implementation of PSMP 290
Criteria for Evaluation of Effectiveness of Patient Safety Program 291
Pre-requisites for a Successful Program 292
Management of Sentinel/Adverse/Near-Miss Events (Annexures 9, 10) 293

41. DISASTER MANAGEMENT PROGRAM IN A HOSPITAL 297
Peculiarities/Problems of a Disaster Situation 298
Expectations from a Hospital in a Disaster Situation 298
Quality of Structure 299
Quality of Plan/Process of Disaster Management 299
Evaluation of Quality of Disaster Management System 301

42. INFECTION CONTROL PROGRAM 303
Aims and Objectives of Infection Control Program 303
Quality Requirements of a Successful Infection Control Program 304
Quality of Structure 304
Quality Management in Hospitals

Quality of Process 305
Criteria for Evaluation of Quality of Infection Control Program 308

43. BIOMEDICAL WASTE MANAGEMENT PROGRAM 310
Objectives of BM Waste Management Program 311
Quality of Infrastructure Available 312
Quality of Process Used for Implementation of Program 313
Indicators for Quality Evaluation 314

44. EQUIPMENT MANAGEMENT PROGRAM 316
Purpose 316
Activities of the Equipment Management Program 317
Quality of Outcome Expected from the Program 317
Essentials for a Successful Program 318
Quality of Process Utilized 318
Indicators for Quality of Equipment Management Program 320

45. TRAINING PROGRAM IN A HOSPITAL 322
Purpose of a Training Program 322
Quality of Outcome of a Training Program 323
Quality of Structure 323
Quality of Process 324
Indicators for Quality of Training Program 325

46. PATIENTS’ INFORMATION AND EDUCATION PROGRAM 326
Patient Information System 326
Prerequisites for a High Quality Patient Information Program 327
Process of Implementation of the Program 327
Indicators of an Effective Patient Information System 328

47. RIGHTS AND RESPONSIBILITIES OF PATIENTS 329
Indian Scenario 330
Responsibilities 334

Part 6: Evaluation of Performance

48. APPROACHES TO EVALUATION OF THE SUCCESS OF QMS 339

49. EVALUATION THROUGH STATISTICAL APPROACH 341
Prerequisites for Evaluation 341
Criteria and Standards for Evaluation 342
Comparison of Pre- and Post-Implementation Data and Assessment of Improvement 344
Failure Analysis 344

50. EVALUATION THROUGH MEDICAL AUDIT 346
Objectives 346
Functions 346
Requirements of a High Quality Medical Audit 347
Process of Medical Audit 347
Indicators of Effectiveness of the Program 350

51. EVALUATION THROUGH NURSING AUDIT 351
Objectives of Nursing Audit 351
Essentials of a Successful Nursing Audit Program 352
Process of Implementation of Nursing Audit Program 352
Indicators of Quality of a Nursing Audit Program 354

52. EVALUATION THROUGH EQUIPMENT AUDIT 355
Benefits of Equipment Audit 355
Starting a System of Equipment Audit 355
Process of Equipment Audit 356
Indicators for Quality of Equipment Audit 357

53. EVALUATION THROUGH PATIENT SATISFACTION SURVEY 359
Resources Required 359
Process 359

Part 7: Annexures

ANNEXURE 1: ISQua ACCREDITED STANDARDS AND ORGANIZATIONS 367
Standards Accredited by ISQua 368

ANNEXURE 2: JCAHCO NATIONAL PATIENT SAFETY GOALS 373
National Patient Safety Goals, 2003 (Revised) 373
National Patient Safety Goals, 2004 374
National Patient Safety Goals, 2005 374
National Patient Safety Goals, 2006 375
National Patient Safety Goals, 2007 375
National Patient Safety Goals, 2008 375
National Patient Safety Goals, 2009 375
National Patient Safety Goals, 2010 (Effective July 1, 2010) 375
National Patient Safety Goals, 2012 376
National Patient Safety Goals, 2013 377

ANNEXURE 3: INITIAL ESTIMATE OF EXPENDITURE FOR TREATMENT 378

ANNEXURE 4: CRITICAL VALUES (GROSSLY ABNORMAL REPORTS) 379

ANNEXURE 5: MAINTENANCE OF RECORDS OF MONITORING/SURVEILLANCE OF STAFF FOR EXPOSURE TO RADIATION 381

ANNEXURE 6: PREVENTION OF WRONG PATIENT/WRONG SITE/WRONG SURGERY 382

ANNEXURE 7: FORMAT FOR INFORMED CONSENT 384

ANNEXURE 8: FORMAT FOR INFORMED REFUSAL OF CONSENT 386

ANNEXURE 9: SENTINEL/ADVERSE/NEAR-MISS EVENTS 387

ANNEXURE 10: FORMAT FOR REPORTING OF SENTINEL/ADVERSE/NEAR-MISS EVENTS 390

ANNEXURE 11: ADMISSION AND DISCHARGE POLICY FOR THE INTENSIVE CARE UNIT 392
ANNEXURE 12: PROTOCOL FOR PREVENTION OF ERRORS IN INVASIVE PROCEDURES  395
ANNEXURE 13: STATUTORY REQUIREMENTS APPLICABLE TO THE HOSPITALS/NURSING HOMES  397
ANNEXURE 14: LIST OF LICENSES/CERTIFICATIONS APPLICABLE TO THE HOSPITALS/NURSING HOMES  403
ANNEXURE 15: LIST OF REPORTS AND RETURNS TO BE SUBMITTED BY HOSPITALS  405
ANNEXURE 16: PROBLEM SOLVING BY ROOT CAUSE ANALYSIS TECHNIQUE  407
ANNEXURE 17: HOSPITAL ANTIBIOTIC POLICY  411
ANNEXURE 18: UNIVERSAL WORK PRECAUTIONS—NATIONAL GUIDELINES FOR CLINICAL MANAGEMENT OF HIV/AIDS BY NACO, GOVT. OF INDIA  415
ANNEXURE 19: EXTRAMURAL TRANSPORTATION OF BIOMEDICAL WASTE FROM ON-SITE STORAGE TO OFF-SITE DISPOSAL FACILITY  416
ANNEXURE 20: PROTOCOL FOR MANAGEMENT OF SPILLAGE OF CHEMICALS/POTENTIALLY INFECTED MATERIALS  418
ANNEXURE 21: CHARTER OF PATIENT’S RIGHTS AND RESPONSIBILITIES  420
ANNEXURE 22: PROFORMA FOR PATIENT SATISFACTION SURVEY (IPD)  422
ANNEXURE 23: PROFORMA FOR PATIENT SATISFACTION SURVEY (OPD)  424
REFERENCES  427
INDEX  431