
Table of Contents

| | |
|-----------------------------------------------|-----------|
| Preface | v |
| Introduction | ix |
| QSE 1 – Organization | 1 |
| 1. Organization | 3 |
| 1.0 Organization | 3 |
| 1.1 Executive Management | 3 |
| 1.2 Quality System | 5 |
| 1.3 Policies, Processes, and Procedures | 5 |
| 1.4 Risk Assessment | 6 |
| 1.5 Operational Continuity | 6 |
| 1.6 Emergency Preparedness | 6 |
| 1.7 Communication of Concerns | 6 |
| 1.8 Customer Focus | 7 |
| QSE 2 – Resources | 8 |
| 2. Resources | 9 |
| 2.0 Resources | 9 |
| 2.1 Human Resources | 9 |
| 2.2 Inventory Resources | 10 |
| 2.3 Educational Resources | 11 |
| 2.2A Inventory Resources | 12 |
| 2.2B Additional Inventory Resources | 14 |

Table of Contents

- QSE 3 – Equipment 18**
- 3. Equipment 20**
 - 3.0 Equipment 20
 - 3.1 Equipment Specifications 20
 - 3.2 Qualification of Equipment 20
 - 3.3 Use of Equipment 20
 - 3.4 Unique Identification of Equipment 20
 - 3.5 Equipment Monitoring and Maintenance 21
 - 3.6 Equipment Traceability 23
 - 3.7 Information Systems 23
 - 3.8 Storage Devices for Blood, Blood Components,
and Reagents 25
 - 3.9 Liquid Nitrogen Storage and Alarms 25
 - 3.10 Alarm Systems 25
- QSE 4 – Suppliers and Customers 27**
- 4. Suppliers and Customers 29**
 - 4.0 Suppliers and Customers 29
 - 4.1 Supplier Qualification 29
 - 4.2 Agreements 30
 - 4.3 Incoming Receipt, Inspection, and Testing 30
 - 4.4 Customers 30
- QSE 5 – Process Control 32**
- 5. Process Control 34**
 - 5.0 Process Control 34
 - 5.1 General Elements 34
 - 5.2 American Rare Donor Program 41
 - 5.3 Serologic Investigation 42
 - 5.4 Molecular Tests 45

| | | |
|----------------------------------------------------------------------|-----------------------------------------------------|-----------|
| 5.5 | Results and Reports | 45 |
| 5.5.1A | Requirements for Investigation Reports | 46 |
| QSE 6 – Documents and Records | | 49 |
| 6. Documents and Records | | 51 |
| 6.0 | Documents and Records | 51 |
| 6.1 | Document Control | 51 |
| 6.2 | Record Control | 53 |
| 6.2.9A | Retention of Records | 58 |
| QSE 7 – Deviations, Nonconformances, and Adverse Events | | 64 |
| 7. Deviations, Nonconformances, and Adverse Events | | 66 |
| 7.0 | Deviations, Nonconformances, and Adverse Events ... | 66 |
| 7.1 | Deviations | 66 |
| 7.2 | Nonconformances | 66 |
| 7.3 | Adverse Events | 67 |
| QSE 8 – Assessments: Internal and External 69 | | |
| 8. Internal and External Assessments | | 71 |
| 8.0 | Internal and External Assessments | 71 |
| 8.1 | Internal Assessments | 71 |
| 8.2 | External Assessments | 71 |
| 8.3 | Management of Assessment Results | 71 |
| 8.4 | Quality Monitoring | 71 |
| QSE 9 – Process Improvement | | 73 |
| 9. Process Improvement | | 75 |
| 9.0 | Process Improvement | 75 |

Table of Contents

9.1 Corrective Action 75

9.2 Preventive Action 75

9.3 Performance Improvement 76

QSE 10 – Facilities and Safety 77

10. Facilities and Safety 78

10.0 Facilities and Safety 78

10.1 Safe Environment 78

10.2 Biological, Chemical, and Radiation Safety 78

10.3 Handling and Discarding of Products 78

10.4 Environmental Monitoring 78

Glossary 81

**“CROSSWALK” BETWEEN THE 12TH AND 13TH EDITIONS
OF *STANDARDS FOR IMMUNOHEMATOLOGY REFERENCE
LABORATORIES*. 91**

INDEX 97