TABLE OF CONTENTS

Preface v

Introduction vii

1. ORGANIZATION **1**

1.0 Organization 1
1.1 Executive Management 1
1.2 Quality Plan 5
1.3 Policies, Processes, and Procedures 6
1.4 Disaster Preparedness 6
1.5 Communication of Concerns 6

2. RESOURCES **7**

2.0 Resources 7
2.1 Human Resources 7

3. EQUIPMENT **9**

3.0 Equipment 9
3.1 Information Systems 9
3.2 Equipment Controlled by Other Departments 10

4. SUPPLIER AND CUSTOMER ISSUES **11**

4.0 Supplier and Customer Issues 11
4.1 Supplier Qualification 11
4.2 Agreements 11

5. PROCESS CONTROL 12

5.0 Process Control 12
5.1 General Elements 12
5.2 Phlebotomy 13
5.3 Consents, Approvals, and Notifications 13
5.4 Transfusion Orders 14
5.5 Pre- and Posttransfusion Patient Care 14
5.6 Preoperative or Preintervention Patient Care 15
5.7 Methods for Patient Blood Management During Surgery and Invasive Procedures 16
5.8 Postoperative or Postintervention Patient Care 16
5.9 Patients Who Do Not Require Invasive Procedures 16
5.10 Massive Blood Loss and Emergent Care 17
5.11 Performance Indicators 17

6. DOCUMENTS AND RECORDS 18

6.0 Documents and Records 18
6.1 Documents 18
6.2 Records 19
6.3 Policies, Processes, and Procedures Controlled by Other Departments 20
6.2A Retention of Records 22

7. DEVIATIONS, NONCONFORMANCES, AND ADVERSE EVENTS 24

7.0 Deviations, Nonconformances, and Adverse Events . . . 24
7.1 Nonconformances 24

8. ASSESSMENTS: INTERNAL AND EXTERNAL 26

8.0 Assessments: Internal and External 26
8.1 Review Process 26

8.2 Management of Assessment Results 26
8.3 Reporting 26
8.4 Quality Monitoring 27

9. PROCESS IMPROVEMENT THROUGH CORRECTIVE AND PREVENTIVE ACTION 28

9.0 Process Improvement Through Corrective and Preventive Action 28
9.1 Data Collection 28
9.2 Corrective Action 28
9.3 Preventive Action 29

10. FACILITIES AND SAFETY 30

10.0 Facilities and Safety 30

GLOSSARY 31

"CROSSWALK" BETWEEN THE 1st AND 2nd EDITIONS OF *PBM STANDARDS FOR PATIENT BLOOD MANAGEMENT PROGRAM*. 37

INDEX 41