
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 Operational Continuity	7
1.6 Communication of Concerns	7
2. RESOURCES	8
2.0 Resources	8
2.1 Human Resources	8
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 14
 - 5.3 Consents, Approvals, and Notifications 14
 - 5.4 Transfusion Orders 15
 - 5.5 Pre- and Posttransfusion Patient Care 15
 - 5.6 Preoperative or Preintervention Patient Care 16
 - 5.7 Methods for PBM During Surgery and Invasive
Procedures 17
 - 5.8 Postoperative or Postintervention Patient Care 17
 - 5.9 Patients Who Do Not Require Invasive Procedures . . . 17
 - 5.10 Anemia Care Inpatients 18
 - 5.11 PBM for Obstetric Patients 18
 - 5.12 Massive Blood Loss and Emergent Care 18
 - 5.13 Reversal of Acquired Coagulopathy 19
 - 5.14 PBM for Pediatric Patients 19
 - 5.15 PBM for Outpatients 19
 - 5.16 High Blood Use Service Lines 19
 - 5.17 Performance Indicators 19

- 6. DOCUMENTS AND RECORDS 21**
 - 6.0 Documents and Records 21
 - 6.1 Documents 21
 - 6.2 Records 22
 - 6.3 Policies, Processes, and Procedures Controlled
by Other Departments 23
 - 6.2A Retention of Records 25

- 7. DEVIATIONS, NONCONFORMANCES, AND
ADVERSE EVENTS 28**
 - 7.0 Deviations, Nonconformances, and Adverse Events . . . 28
 - 7.1 Nonconformances 28

8.	ASSESSMENTS: INTERNAL AND EXTERNAL.	29
8.0	Assessments: Internal and External	29
8.1	Review Process	29
8.2	Management of Assessment Results.	29
8.3	Reporting.	29
8.4	Quality Monitoring	30
9.	PROCESS IMPROVEMENT THROUGH CORRECTIVE AND PREVENTIVE ACTION.	31
9.0	Process Improvement Through Corrective and Preventive Action	31
9.1	Data Collection	31
9.2	Corrective Action	31
9.3	Preventive Action	32
10.	FACILITIES AND SAFETY	33
10.0	Facilities and Safety	33
	GLOSSARY	35
	“CROSSWALK” BETWEEN THE 2nd AND 3rd EDITIONS OF PBM STANDARDS FOR PATIENT BLOOD MANAGEMENT PROGRAM.	41
	INDEX	45