# TABLE OF CONTENTS

## PREFACE

vii

## INTRODUCTION

ix

## 1. ORGANIZATION

1. Organization

1.0 Organization

1.1 Executive Management

1.2 Quality System

1.3 Policies, Processes, and Procedures

1.4 Operational Continuity

1.5 Emergency Preparedness

1.6 Communication of Concerns

1.7 Customer Focus

## 2. RESOURCES

4

2.0 Resources

2.1 Human Resources

## 3. EQUIPMENT

5

3.0 Equipment

3.1 Selection of Equipment

3.2 Qualification of Equipment

3.3 Use of Equipment

3.4 Unique Identification of Equipment

3.5 Equipment Monitoring and Maintenance

3.6 Storage Devices for Blood, Blood Components, Reagents, Tissue, and Derivatives

3.7 Alarm Systems

3.8 Warming Devices for Blood and Blood Components

3.9 Information Systems

## 4. SUPPLIER AND CUSTOMER ISSUES

9

4.0 Supplier and Customer Issues

4.1 Supplier Qualification

4.2 Agreements

4.3 Incoming Receipt, Inspection, and Testing
5. **PROCESS CONTROL** ........................................... 11

5.0  *Process Control* ........................................... 11

5.1  General Elements ........................................... 11

**Collection and Production of Components**

5.2  Information, Consents, and Notifications .......... 16
5.3  Care of Donors ........................................... 18
5.4  Donor Qualification ....................................... 18
5.5  Additional Apheresis Donor Qualification
    Requirements ............................................. 21
5.6  Blood Collection .......................................... 24
5.7  Preparation and Processing of Components .......... 26
5.8  Testing of Donor Blood ................................. 33
5.9  Final Labeling ............................................ 37
5.10 Final Inspection ........................................... 38

**Transfusion-Service-Related Activities**

5.11 Samples and Requests .................................... 38
5.12 Serologic Confirmation of Donor Blood ABO/Rh
    (including autologous units) ............................ 39
5.13 Serologic Confirmation of Donor Blood Red Cell
    Antigens Other than ABO/Rh ........................... 39
5.14 Pretransfusion Testing of Patient Blood ............. 39
5.15 Selection of Compatible Blood and Blood
    Components for Transfusion ............................ 41
5.16 Crossmatch ................................................ 42
5.17 Special Considerations for Neonates ................ 43
5.18 Special Considerations for Intrauterine Transfusion . 44
5.19 Selection of Blood and Blood Components in
    Special Circumstances .................................. 44
5.20 Preparation of Tissue .................................... 46
5.21 Preparation of Derivatives ............................. 46
5.22 Final Inspection Before Issue .......................... 46
5.23 Issue of Blood and Blood Components ............... 46
5.24 Issue of Tissue and Derivatives ....................... 47
5.25 Discrepancy Resolution ................................. 47
5.26 Reissue of Blood, Blood Components, Tissue, and
    Derivatives .............................................. 47
5.27 Urgent Requirement for Blood and Blood
    Components .............................................. 47
5.28 Administration of Blood and Blood Components ...... 48
5.29 Medical Record Documentation ........................ 50