

# Donor Apheresis Collection Personnel Staff Requirements and Challenges

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## DISCLAIMER

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- Employee of NeoStem, Inc.

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## OBJECTIVES

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- List staffing requirements at donor centers
- Identify staffing challenges at donor centers
- Discuss how to manage staffing challenges at donor centers
- List staffing requirements with contracted apheresis personnel
- Identify staffing challenges with contracted apheresis personnel
- Discuss how to manage staffing challenges with contracted apheresis personnel



# Managers

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- Organize people to accomplish goals
- Assign tasks to staff who can do them best
- Create an environment for human performance
- Recruiting, selecting, career building, compensating, training = developing job holders to meet the goals of the organization



# Regulatory Guidelines

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- FDA – Code of Federal Regulations
- AABB Standards
  - Blood Banks and Transfusion Services
  - Standards for Cellular therapy Product Services
- Department of Health – by State
- FACT – Foundation for the Accreditation of Cellular Therapy



# 21 CFR 600.10

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- Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application of the pertinent provisions of this subchapter to their respective functions. Personnel shall include such professionally trained persons as are necessary to insure the competent performance of all manufacturing processes.



# 21 CFR 1271.170

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- You must have personnel sufficient to ensure compliance with the requirements of this parts.
- You must have personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions. Personnel must perform only those activities for which they are qualified and authorized.
- You must train all personnel, and retrain as necessary, to preform their assigned responsibilities adequately.



# AABB - BB

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- 2.1 The blood bank or transfusion service shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualified for each job position.



# AABB - BB

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- 2.1.1 Qualification – Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training and /or experience.



# Staffing Requirements

- What's your staff:donor ratio?
- Whole blood
- Platelets – which instrument?
- Automated donors
- Influencing factors
  - Staff level of competency
  - Donor's venous access
  - Weather
  - Donor events
  - Recruiting events



# Managers

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- Complex decision-making
- Problem solving
  - Track/trend to solve repeatable problems
- Administration
  - SOPs
- Human resource management
  - Interpersonal relationship
  - Teamwork



# AABB - BB

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- 2.1.2 The blood bank or transfusion service shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.



# AABB - BB

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- 2.1.3 Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.



# AABB - BB

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- 2.1.4.1 For those authorized to perform or review critical tasks, records of names, signatures, initials, or identification codes and inclusive dates of employment shall be maintained.



# Collection Center Staff

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- Amount of collection centers you are over seeing
- Level of staffing competency
  - Whole blood
  - Platelets
  - Therapeutic apheresis (Deanna)
- Union employees



# Staff

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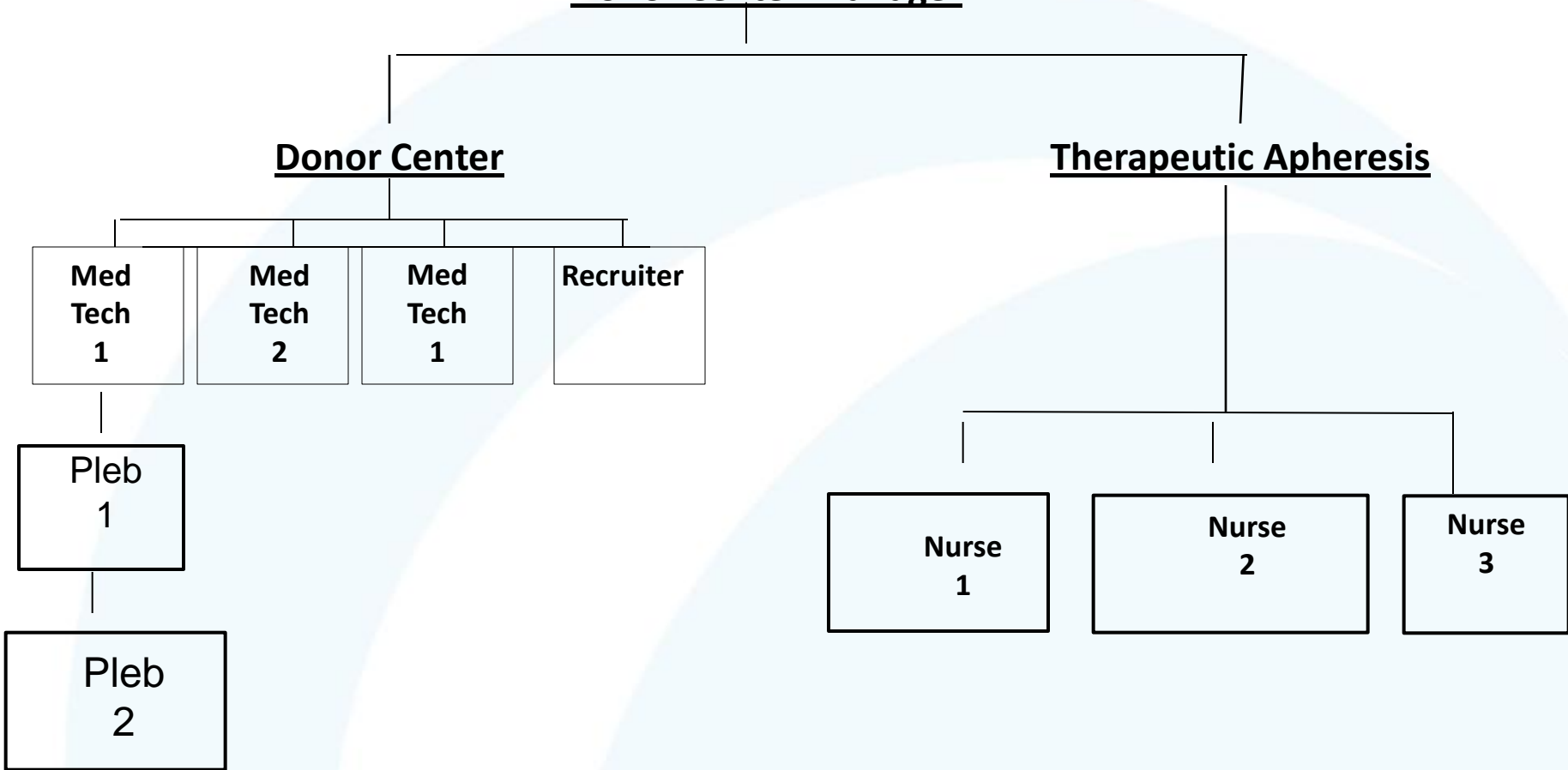
- Physician overseeing procedure should know apheresis, apheresis adverse events and how to treat them
- Qualified staff operating the instrument
  - Registered Nurse
  - Medical technologist
  - Trained phlebotomist



Donor Center Manager

Donor Center

Therapeutic Apheresis



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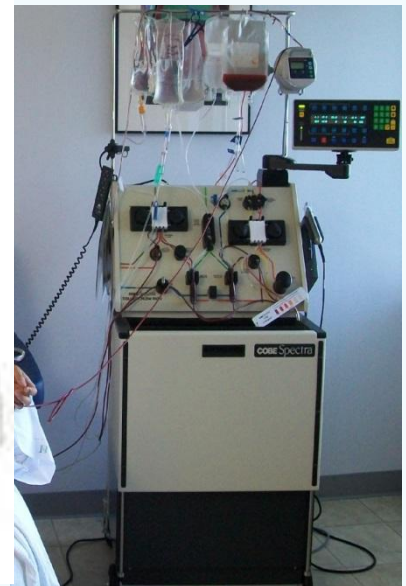
# Instruments

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- Best instrument to meet your organizational goals
- Cost
- Training requirements
- Validation of instrument



# Instruments



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# Best instrument?

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- What are you using it for – maximize outcomes
- Today vs. future
- FDA approval
- Cost vs. Budget
  - Purchase
  - Lease
  - Kit requirements
- SOPs
- Validation
- Training
  - Experts in each center and shift
  - Documents for inspections



# Goals – donor center

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- Number of collections/day with least cost and minimum waste
  - Platelets
  - Plasma
  - RBCs
- Number of staff to achieve this goals
- Schedule
- Budget



# Donor Eligibility

- TTD testing
- CBC – meet collection criteria
  - Plts  $\geq$  110,000
  - Hct  $\geq$ 38%
- Donor History Questionnaire (DHQ)
  - CDC website
  - FDA requirements
  - Medications



# Contracted Apheresis Staff

- Contract
- SOPs – which are you following?
- Education
  - Copy at your site of apheresis staff training docs
  - Requirements
- cGMP training
- TTD testing – who to complete and when
  - Results shared
- Mobilization



# Outsourced Apheresis Staff



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# Managing Long Distance



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# Recruiters/Call Center



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# Management

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- Art or Science of achieving goals through people
- Ensure greater productivity
- Continuous improvement



# Budget

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- Expenses
  - Staff hours/overtime
  - Supplies
  - Instrument maintenance
- Income – billing
  - CPT codes (billing code)
  - ICD-9-CM codes (Diagnosis/Procedure)



# Your Concerns/Issues

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# Thank you!



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