6TH EDITION OF FACT-JACIE STANDARDS
A QUICK SUMMARY

BHS JACIE Day, 6 March 2015

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CONTENTS

- Review process
- Sources of information
- Selection of main changes and developments
- Questions

Cellular Therapy Standards Committee
6th Edition Development Process

INCLUSIVE AND COLLABORATIVE

Standards Committee
4 Subcommittees
12 Countries Represented
46 Members

Reviews
Public Comments
Legal Consultation
FACT and JACIE Board Approval

In-Person Steering Committee Meetings
London Kick-off Meeting in June 2013
Grapevine Draft Review in February 2014

INTENSIVE

Duration of Commitment
1 Year
3 Months
26 Days
= 483 Days

Number of Teleconferences
15 Steering
31 Clinical
21 Collection
23 Processing
= 90 Meetings

Volunteer Hours
Based on Quorum
117 Meeting Hours/Member
= 922 Hours

Intangibles: Editing Standards, Drafting Guidance, Reviewing Meeting Materials, Researching Topics, and In-house Staff Support

SUMMARY DOCUMENT

- On web site
- Check the exact differences between each standard.
- Yellow indicates a change
- The change in text is underlined.
- Available from JACIE web site

6th Edition FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration Summary of Changes

This document summarizes the changes made to the 6th edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*. This summary does not list all changes made to the Standards; refer to the final Cellular Therapy Standards and the accompanying Accreditation Manual for all requirements. These documents will be published on March 1, 2015 and become effective on June 1, 2015.

Changes made to the 6th edition Cellular Therapy Standards and/or its accompanying Accreditation Manual include:

Global Changes

1. Revised Title
   a. FACT-JACIE Standards are now called *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, also referred to as the Hematopoietic Cell Therapy Standards.
   b. The purpose is to define the scope of these requirements due to an increasing number of accredited facilities that support non-hematopoietic cellular therapies and because FACT now has a separate set of Standards for those services (the Common Standards for Cellular Therapies). The scope of the Hematopoietic Cell Therapy Standards includes:
      i. Collection, processing, and administration of hematopoietic progenitor cells (HPCs), whether minimally or more than minimally manipulated, for hematopoietic indications.
      ii. Collection, processing, and administration of cellular therapy products for donor lymphocyte infusion (DLI).
   c. Facilities pursuing accreditation for hematopoietic services in addition to collection and processing for other clinical specialties (e.g., immunology, cardiology, neurology, etc.) may consult the Hematopoietic Cellular Therapy Standards as a single reference point.
   d. Clinical Programs for other specialties may only share an accreditation with a hematopoietic progenitor cell (HPC) transplant program if the same physician group serves the same patient population (for example, if an immunology program works with the transplant program to administer CAR-T cells). If a different patient population is served, the program likely will not be able to share an accreditation because of differing directorship and protocols. In these cases,

White = no change
Yellow = change (changed text underlined)

DRAFT - NOT FOR DISTRIBUTION

Note that the reference number may also have change

5 ref	5 standard	6 ref	6 standard	Change from 5th ed. Category
B3.1.3	The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations.	B3.1.3	The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations.	No change from 5th ed.
B3.1.4	The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of patients and donors, cell collection, and processing, whether internal or contracted services.	B3.1.4	The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of patients and donors, and cell collection and processing, whether internal or contracted services.	Reworded - no signif. change from 5th ed.

SCOPE

6TH EDITION

- INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

5TH EDITION

- INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

Clinical	Collection Marrow	Collection Apheresis	Processing
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Marrow Collection Facility	C2 Apheresis Collection Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	CM4 Quality Management	C4 Quality Management	D4 Quality Management
B5 Policies and Procedures	CM5 Policies and Procedures	C5 Policies and Procedures	D5 Policies and Procedures
B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management	CM6 Allogeneic and Autologous Donor Evaluation and Management	C6 Allogeneic and Autologous Donor Evaluation and Management	D6 Equipment, Supplies, and Reagents
B7 Recipient Care	CM7 Coding and Labeling of Cellular Therapy Products	C7 Coding and Labeling of Cellular Therapy Products	D7 Coding and Labeling of Cellular Therapy Products
B8 Clinical Research	CM8 Process Controls	C8 Process Controls	D8 Process Controls
B9 Data Management	CM9 Cellular Therapy Product Storage	C9 Cellular Therapy Product Storage	D9 Cellular Therapy Product Storage
	CM10 Cellular Therapy Product Transportation and Shipping	C10 Cellular Therapy Product Transportation and Shipping	D10 Cellular Therapy Product Transportation and Shipping
			D11 Distribution and Receipt
			D12 Disposal
B10 Records	CM11 Records	C11 Records	D13 Records
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	

TENETS OR FUNDAMENTAL PRINCIPLES

Basic tenets for compliance with these Standards include, but are not limited to:

- A.2.1 Where applicable laws and regulations include more stringent requirements than these Standards, those laws and regulations supersede the Standards. Conversely, when these Standards are more stringent than applicable laws and regulations, the Standards must be followed.

- A2.2 Applicant organizations are responsible for providing verifiable documentation of evidence of compliance with these Standards.

- A2.3 Standards related to services not provided by the applicant do not apply to the applicant organization. The burden to demonstrate that a requirement is not applicable rests with the applicant organization.

OUTCOME ANALYSIS

- (B4.7, C4.7, D4.7)
- Outcome analysis must include evaluation of individual cellular therapy product data and aggregate data for each type of cellular therapy product and/or recipient type.
- Clinical Programs must compare one-year survival to national or international outcome data, and should achieve survival rates within expected ranges.

LABELING

- The sixth edition requires that organizations be actively implementing ISBT 128 coding and labeling technologies.
  - The 5th edition required organizations to have a plan for ISBT 128 coding and labeling technology implementation. "Actively implementing" could be demonstrated by registration with ICCBBA, identification or creation of appropriate product codes, label designs, label validation, and/or use of scanned information.
- Barcoding - verification now may be conducted by two qualified people or by one qualified person using a validated process.
- (CM7, C7, D7, APPENDIX II, APPENDIX III)

ISBT 128
ICCBBA is a nongovernmental organization in official relations with the World Health Organization

CONTINUING EDUCATION

- 10 hours per annum
- Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.
- Affects key personnel (directors, attending physicians, quality managers, and designated pharmacists)

ACCREDITATION OF TECHNIQUES USED FOR CHIMERISM TESTING

- Requires accreditation of the *techniques* used in chimerism.
- EFI and other organizations provide external laboratory accreditation and quality assurance in chimerism testing.
- Rationale
  - Clinical decisions regarding the pace of withdrawal of post-transplant immunosuppression and/or subsequent administration of donor lymphocytes based on chimerism results may have potentially life-threatening consequences with respect to GVHD, relapse risk, or graft failure.
  - Chimerism testing may be performed with a variety of methods and interlaboratory variability may be significant.
- (B2.12)

CLINICAL PROGRAM PERSONNEL (B3)

- **Pharmacists (B3.8)**
  - Pharmacist requirements relate to those who perform services for the transplant program.
  - Pharmacists must be licensed to practice and limited to a scope of practice within the parameters of their training and licensure.
  - Training : overview of hematology/oncology patient care, therapeutic drug monitoring, monitoring for and recognizing drug/drug and drug/food interactions and making necessary modifications, and recognition of medications that require adjustment for organ dysfunction.
  - Pharmacists should be involved in the development of guidelines or SOPs related to pharmaceutical management of transplant recipients.
  - Designated transplant pharmacists (i.e., those who have a leadership role or routine involvement in the care of transplant recipients) must meet continuing education requirements.

CLINICAL PROGRAM PERSONNEL (B3)

New sections were added to B3 Personnel to include all key providers in a Clinical Program.

- Physicians-in-Training (B3.4)
- Mid-level practitioners are now referred to as **Advanced Practice Providers/Professionals**, or APPs. (B3.5)
- Consulting specialists must now also include
  - Ophthalmology
  - obstetrics/gynecology
  - dermatology. (B3.9)

BACKUP COVERAGE OF STAFF (CM3.3.2, C3.4.1, D3.4.1)

- Facilities were often found to have minimal staff that was only sufficient should no staff members be absent.
- To provide sufficient coverage should staff members become unavailable, facilities must have a minimum of one designated trained individual with an identified trained backup.

DONORS

DONOR ADVOCATE

- A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.

Bone Marrow Transplantation (2014), 1–4

www.nature.com/bmt

ORIGINAL ARTICLE

The impact of improved JACIE standards on the care of related BM and PBSC donors

C Anthias[1,2], ME Ethell[3], MN Potter[3], A Madrigal[1,2] and BE Shaw[1,2,3]

Discrepancies exist between the care of unrelated donors (UDs) and related donors (RDs), particularly regarding medical suitability criteria, consenting procedures and donor follow-up. Changes to the most recent JACIE standards have addressed these issues. We studied 208 RDs who underwent PBSC or BM donation in a single centre during 2004–2013 to determine the impact of regulatory changes on donor care, and assessed the safety and efficacy of stem cell donation in donors not meeting UD medical suitability criteria. We observed significant improvements in donor consenting procedures ($P=0.003$) and donor follow-up ($P=0.007$) after stipulations in these areas were introduced. We saw a higher incidence of serious adverse events (SAEs) in RDs not meeting UD suitability criteria ($P=0.018$), and a higher incidence of SAEs in donors $\geqslant 60$ years ($P=0.020$). Haematopoietic progenitor cell donation is less safe in RDs who do not meet UD criteria for medical suitability. Although changes to JACIE standards have improved practice, development of specific medical suitability for RDs and guidelines around 'grey areas' where risks to a donor are unclear or theoretical, will be important in improving RD safety and standardising practice.

Bone Marrow Transplantation advance online publication, 10 November 2014; doi:10.1038/bmt.2014.260

PREGNANCY TEST

- A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

DONOR SELECTION, EVALUATION, & MANAGEMENT

- The Clinical Program must have written criteria for selection of allogeneic donors who are
  - elderly **NEW**
  - minors.
- Informed consent and donor evaluation now must be obtained by a health care professional who is not the primary health care professional overseeing care of the recipient.
  - This was only a recommendation in the 5th edition.
- The informed consent process must inform the donor of the policy for cellular therapy product discard or disposal.

DONOR SELECTION, EVALUATION, & MANAGEMENT

- Written order from a physician specifying the timing and goals of collection and processing is now also included in the clinical standards.
- Clinical Programs must have a policy for anti-HLA antibody testing for mismatched donors and recipients.
- Records required for donor eligibility determination must be in English or translated into English when crossing international borders.
- Standards throughout the document explicitly reference requirements for incomplete donor eligibility determination in addition to ineligible donors.

NEW REQUIRED ANALYSES

- Clinical Programs:
  - Acute GVHD grade within one hundred (100) days after transplantation.
  - Chronic GVHD grade within one (1) year after transplantation.
  - Central venous catheter infection.
- Apheresis Collection and Processing Facilities:
  - Time to engraftment measured by ANC and platelet count.

STABILITY PROGRAMME

- D9.2.2 There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, minimally annually.

Bone Marrow Transplantation (2013) **48,** 32–35; doi:10.1038/bmt.2012.97; published online 4 June 2012

Stem Cell Procurement

Relative recovery of haematopoietic stem cell products after cryogenic storage of up to 19 years

L J Fernyhough[1,2,3], V A Buchan[2], L T McArthur[2] and B D Hock[3]

Cytotherapy

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Effects of long-term cryopreservation on peripheral blood progenitor cells

November 2012, Vol. 14, No. 10 , Pages 1228-1234 (doi:10.3109/14653249.2012.706707)

Gregory S. Vosganian, Jill Waalen, Kevin Kim, Sejal Jhatakia, Ethan Schram, Tracey Lee, Dan Riddell, and James R. Mason

HTML

Sign up for eAlerts

STABILITY PROGRAMME

- There were many questions surrounding how stability studies must be performed and how they could be applied to early phase cellular therapy products.
- The Standards Committee felt that this requirement is appropriate, but added guidance that includes examples of how to perform stability studies and clarification that stability studies can be in development for early phase products that do not yet have a definitive potency marker.

QUALITY MANAGENT

NEW CLINICAL SOPS

- Donor screening, testing, eligibility determination, selection, and management
- Management of donors who require central venous access
- Administration of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell or plasma reduction
- Duration and conditions of cellular therapy product storage and indications for disposal
- Hygiene and use of personal protective equipment

NOW INCLUDED IN PART C

- SOP for Administration of blood products.
- All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- Review and approval of the validation plan, results, and conclusion by the Facility Director or designee and the Quality Manager or designee.
- The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

AUDITS

- Most required audits must now be performed annually.
  - Audits do not need to have the same objective every year.
  - Different points of processes can be audited.

MANAGE ERRORS ETC.

- Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.
- Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.
- Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products.

RECIPIENT CARE (B7)

- Previously titled, "Therapy Administration," but now contains all requirements related to the care of the transplant recipient.
- Recipient informed consent must be obtained and documented by a licensed health care professional familiar with the proposed therapy, and this process must provide information regarding the risks and benefits.
- Records must be made concurrently with each step of recipient care in such a way that all steps may be accurately traced, and must identify the person immediately responsible for each significant step (including dates and times).
- Specific references to "chemotherapy" were replaced with references to the "preparative regimen" to encompass all regimens.

RECIPIENT CARE (B7)

- Barcoding : The verification now may be conducted by two qualified people or by one qualified person using a validated process.
- The recipient's medical record of the administered cellular therapy product must include the product's unique identifier, initiation and completion times of administration, and any adverse events related to administration.
- Standard of care has evolved in the assessment of recipients for evidence of acute and chronic GVHD, need for vaccinations, and post-transplant late effects.
  - Allogeneic recipients must be assessed regularly for evidence of acute and chronic GVHD using an established staging and grading system.
  - There must be policies and procedures in place for allogeneic recipient post-transplant vaccination schedules and indications.

MINIMUM NUMBER OF MARROW COLLECTION PROCEDURES (CM1.5)

- The minimum number remains at a minimum average of one (1) collection procedure per year within the accreditation cycle.
- This requirement applies to a single team of collectors and support staff. When different teams are used at different sites, the minimum number of procedures must be performed at each of those sites.
- The guidance also emphasizes that marrow collectors with little experience must be supervised appropriately to build and maintain competency.

APHERESIS EQUIPMENT (C8.3)

- Must be inspected for cleanliness prior to each use and verified daily to be in compliance with the maintenance schedule prior to use.
- Calibration must be performed according to a traceable standard and, when out of calibration, there must be a defined process for action for cellular therapy products collected since the last calibration.

OTHER MARROW AND APHERESIS COLLECTION FACILITY CHANGES

- Marrow and Apheresis Collection Facility records must identify the person immediately responsible for each significant step (including dates and times). (CM8.15.1, C8.16.1)
- Marrow Collection Facilities must also control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products. (CM9.1)
  - Cellular therapy products are always undergoing some process, and temporary holding until they are picked up by another facility is considered storage.
- Cellular therapy products must be transported or shipped to the Processing Facility in a validated container. (CM10.3, C10.3)

OTHER MARROW AND APHERESIS COLLECTION FACILITY CHANGES

- Apheresis collection performed in outpatient units must be in a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination. (C2.1.2)
- Apheresis Collection Facility Directors and Medical Directors must have performed or supervised a minimum of 5- previously 4- collection procedures in the 12 months preceding initial accreditation and a minimum average of 5 collection procedures per year within the accreditation cycle. (C3.1.4, C3.2.4)
- Extracorporeal photopheresis (ECP) requirements are now also included in the apheresis section

PROCESSING FACILITY STANDARDS (PART D)

- Part D was reorganized to separate the Process Controls section into more manageable sections of like requirements.
- New sections:
  - *Equipment, Supplies, and Reagents*
  - *Cellular Therapy Product Transportation and Shipping*
  - *Distribution and Receipt*.

OTHER PROCESSING FACILITY CHANGES

- Processing Facility Directors and Medical Directors - minimum of two years of postgraduate training and practical and relevant experience for the scope of activities carried out in the facility.
  - Some regions of the world may have degrees that are equivalent to the doctoral degree. If a Processing Facility Director has such a degree, significant and compelling information regarding the degree requirements must be submitted to demonstrate equivalency. (D3.1.1, D3.2.1).
- Policies and procedures on the management of cellular therapy products with positive microbial culture results must also address the identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum. (D4.9.4)

OTHER PROCESSING FACILITY CHANGES

- Records of identification codes of personnel with methods to link the name and/or signature to the identification codes is no longer required because of improvements in recordkeeping.
- Alarm systems shall have audible and visible signals or other effective notification methods.

LABELS

CELLULAR THERAPY PRODUCT LABELING

6th edition

5th edition

6th	6th	6th	6th	6th	5th	5th	5th	5th	5th
Element	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration	Element	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration
Unique numeric or alphanumeric identifier	AF	AF	AF	AF	Unique numeric or alphanumeric identifier	AF	AF	AF	AF
Proper name of product	AF	AF	AF	AF	Proper name of product	AF	AF	AF	AF
Product attributes			AC	AC	Product modifiers	AF		AF	AF
					Product attributes (manipulations)			AC	AC
Recipient name and/or identifier		AT	AT	AT	Recipient name and identifier (if applicable)	AF	AT	AT	AT
Identity and address of collection facility or donor registry		AT	AC	AC	Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC	Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT	Approximate volume		AT	AT	AT
Name and quantity of anticoagulant and other additives		AC	AC	AC	Name and volume or concentration of anticoagulant and other additives		AT	AT	AT

Modifers now “attributes”

Volume now “quantity”

CELLULAR THERAPY PRODUCT LABELING

6th edition					5th edition				
Donor identifier and (if applicable) name		AT	AT	AT	Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature range		AT	AT	AT	Recommended storage temperature range		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see CM7.4.2, C7.4.2, D7.4.2).		AT	AT	AT	Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4).		AT	AT	AT
As applicable:					If applicable:				
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT	Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT	Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT	Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT
Identity and address of processing and distribution facility(ies)			AC	AC	Identity and address of processing and distribution facility(ies)			AC	AC
Statement "Do Not Irradiate"			AT	AT	Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AC	AC	Expiration Date (if applicable)			AT	AT
Expiration Time (if applicable)			AC	AC	Expiration Time (if applicable)			AC	AT
ABO and Rh of donor (if applicable)			AC	AC	ABO and Rh of donor (if applicable)			AC	AC

CELLULAR THERAPY PRODUCT LABELING

RBC compatibility testing goes to “determination”

Filters goes from “should” to “shall”

6th edition					5th edition				
RBC compatibility determination (if applicable)				AC	RBC compatibility testing results (if applicable)				AC
					Statement "Properly Identify Intended Recipient and Product"				AT
Statement indicating that leukoreduction filters shall not be used.				AT	Statement indicating that leukoreduction filters should not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT	Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
					Statement “For Use By Intended Recipient Only" (if for allogeneic recipient)				AT
					Statement “For Nonclinical Use Only” (if applicable)				AT
Date of distribution				AC	Date of distribution				AC

CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING & TRANSPORT ON PUBLIC ROADS

Time and date separated into distinct items

6th edition					5th edition		
Element	Inner container document	Outer container label			Element	Inner container document	Outer container label
Date of distribution	AC	AC			Date of distribution and time, if appropriate	AC	AF
Time of distribution, if appropriate	AC	AC					

DEFINITIONS

- Some changes to the definitions so pay attention to this section

White = no change
Yellow = change (changed text underlined)

DRAFT - NOT FOR DISTRIBUTION

DEFINITIONS		CATEGORY
5th	6th	Change from 5th ed. Category
Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular therapy product container.	Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular	No change from 5th ed.
Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.	Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.	No change from 5th ed.
Advanced Practitioner: Advanced Practitioner of Nursing; includes certified nurse anesthetist, nurse practitioner, certified nurse midwife, and clinical nurse specialist.	Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners	Change from 5th ed.

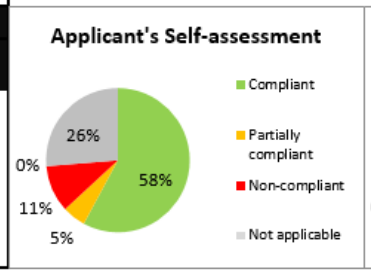
CHECKLIST

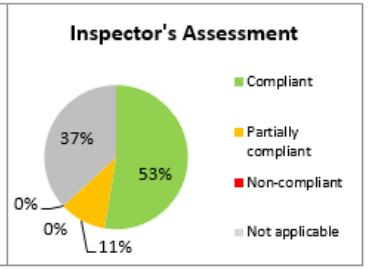
- Dashboard

Shipping labels

INNER & OUTER CONTAINER DOCUMENTS

Answers	Applicant's Self-assessment	%	Inspector's Assessment	%
Compliant	11	58%	10	53%
Partially compliant	1	5%	2	11%
Non-compliant	2	11%	0	0%
Not applicable	0	0%	0	0%
Uncompleted	5	26%	7	37%
TOTAL	19	100%	19	100%





- Labels

Back to checklist

PARTIAL LABELS

Inspector: All items compliant? Yes

Type of label	Standard	Cat.	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
Label at completion of collection	Unique numeric or alphanumeric identifier	AF	Compliant		Compliant	
Label at completion of collection	Proper name of product	AF	Compliant		Compliant	
Label at completion of collection	Recipient name and/or identifier	AT	Compliant		Compliant	
Label at completion of collection	Identity and address of collection facility or donor registry	AT	Compliant		Compliant	
Label at completion of collection	Date, time collection ends, and (if applicable) time zone	AT	Compliant		Compliant	
Label at completion of collection	Approximate volume	AT	Compliant		Compliant	
Label at completion of collection	Name and quantity of anticoagulant and other additives	AC	Compliant		Compliant	
Label at completion of collection	Donor identifier and (if applicable) name	AT	Compliant		Compliant	


That's all Folks!
Any Question ?