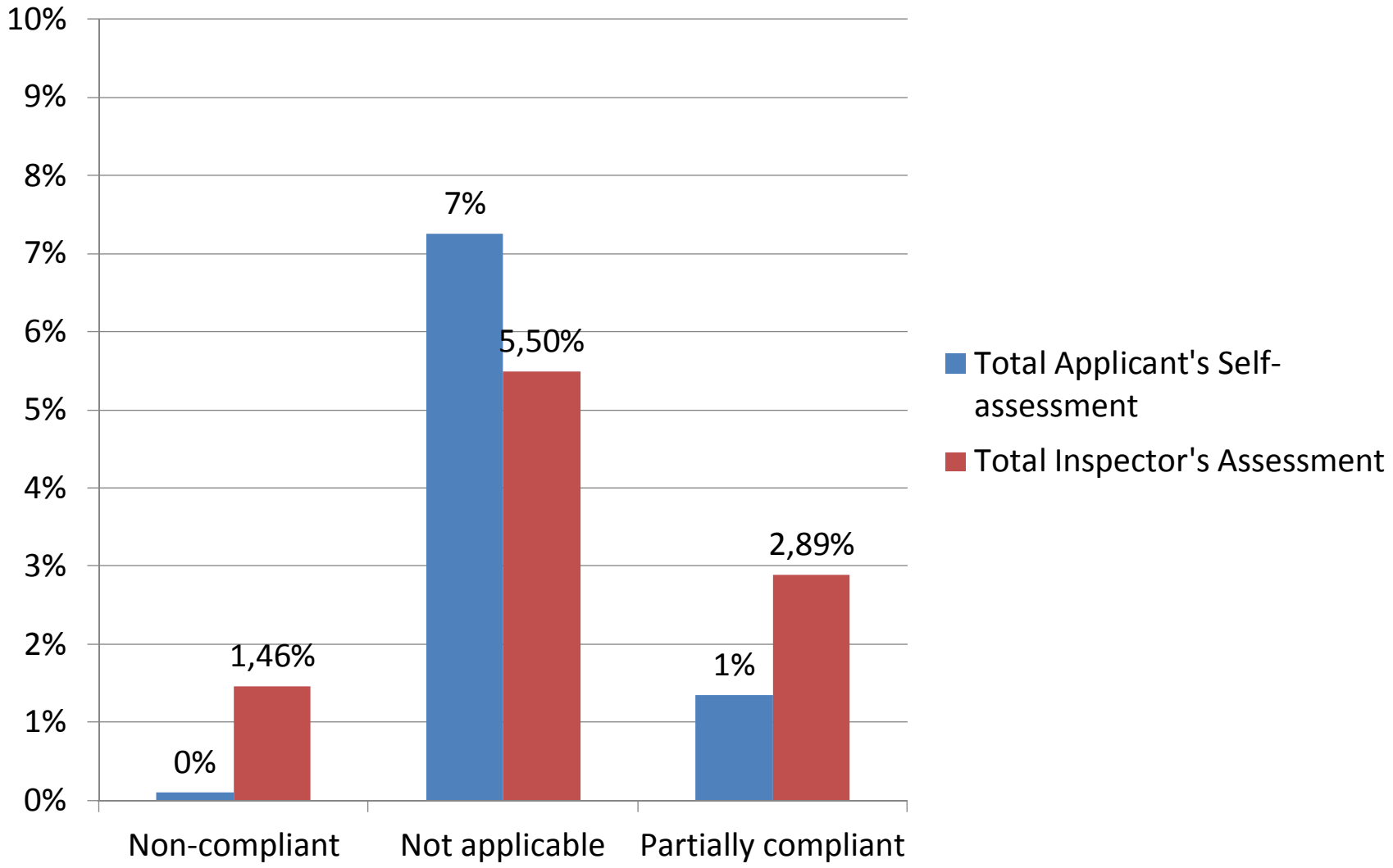
Common deficiencies

5th edition

Deficiencies cited by JACIE Inspectors

• Reports reviewed	75 (69% of all issued Summary Reports under the 5th edition)
• Total number of citations	1650
• Non-cited standards	444 Standards (40%)


10%
9%
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7%
6%
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4%
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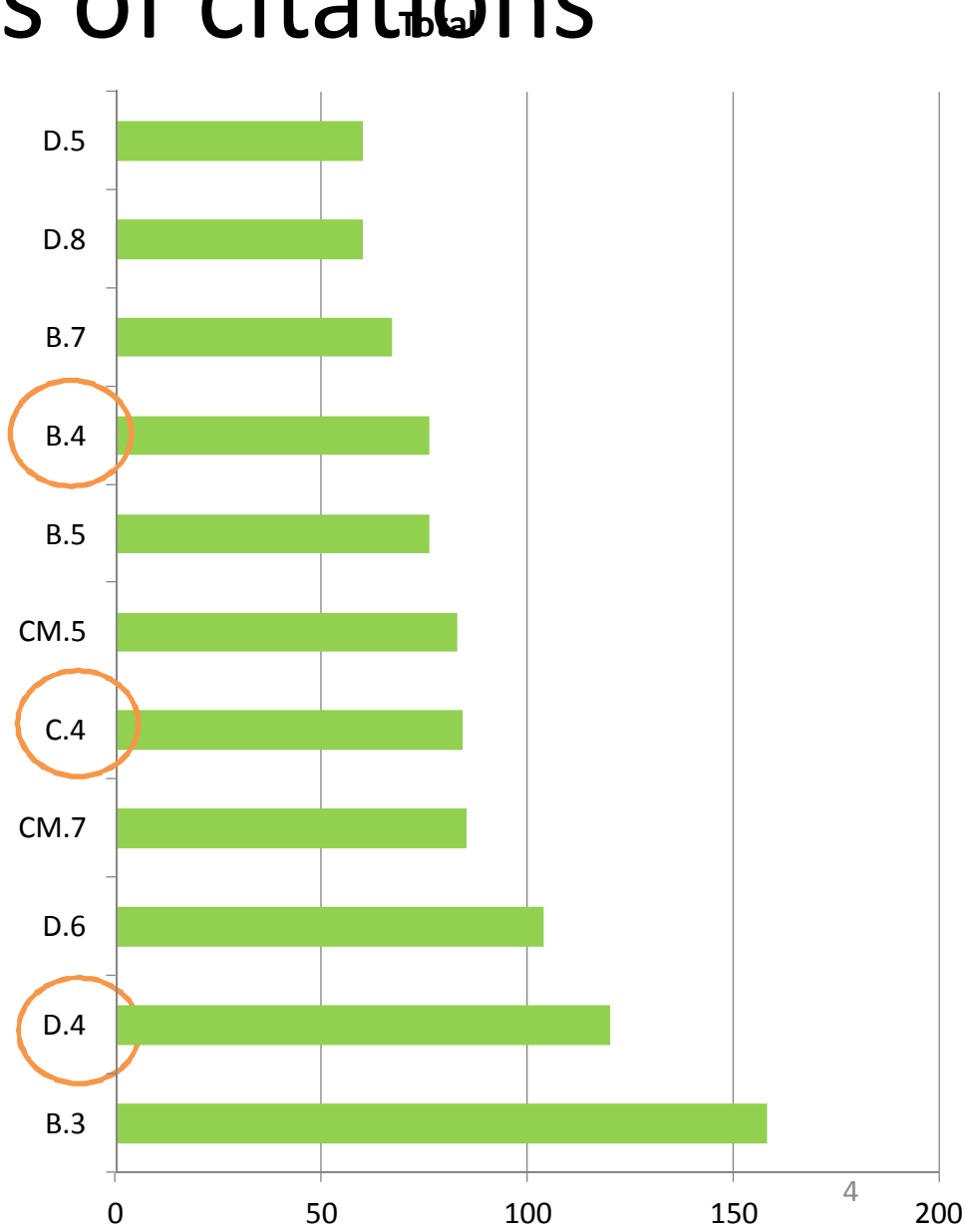
1%
0%
7%
5,50%
2,89%
1,46%
1%
0%
Non-compliant
Not applicable
Partially compliant
Total Applicant's Self-assessment
Total Inspector's Assessment

Top-10 areas of citations

- Based on 75 reports
- 5th ed. Standards
- Non- & Partial compliances
- Count only - no weighting given



Sections by Part

Part B

	Findings	%
B.3	158	37,00%
B.5	76	17,80%
B.4	76	17,80%
B.7	67	15,69%
B.8	19	4,45%
B.1	12	2,81%
B.10	9	2,11%
B.2	8	1,87%
B.6	2	0,47%
B.9	0	0,00%
Total general	427	100,00%

Part C

	Findings	%
C.4	84	35,90%
C.2	34	14,53%
C.8	26	11,11%
C.11	23	9,83%
C.7	15	6,41%
C.1	15	6,41%
C.3	12	5,13%
C.5	11	4,70%
C.6	7	2,99%
C.10	6	2,56%
C.9	1	0,43%
C.12	0	0,00%
Total general	234	100,00%

Part CM

	Findings	%
CM.7	85	26,81%
CM.5	83	26,18%
CM.8	51	16,09%
CM.3	39	12,30%
CM.1	24	7,57%
CM.2	16	5,05%
CM.10	10	3,15%
CM.6	4	1,26%
CM.9	4	1,26%
CM.4	1	0,32%
CM.11	0	0,00%
CM.12	0	0,00%
Total general	317	100,00%

Part D

	Findings	%
D.4	120	21,20%
D.6	104	18,37%
D.5	60	10,60%
D.8	60	10,60%
D.10	55	9,72%
D.12	52	9,19%
D.7	36	6,36%
D.2	30	5,30%
D.9	23	4,06%
D.11	13	2,30%
D.3	11	1,94%
D.1	2	0,35%
Total general	566	100,00%

Part (Varios elementos)

	Findings	%
B/CM/C06.04.02	5	9,80%
B/CM/C06.04.01	5	9,80%
B/CM/C06.03.08	5	9,80%
B/CM/C06.02.05	5	9,80%
B/C06.03.02.02	4	7,84%
B/C06.04.06.04	4	7,84%
B/CM/C06.03.02	4	7,84%
B/C06.03.02.01	4	7,84%
B/CM/C06.02.04.01	3	5,88%
B/C/CM/C06.04.14	3	5,88%
B/C06.04.04.01	3	5,88%
B/CM/C06.03.09	3	5,88%
B/CM/C06.03.10	3	5,88%
Total general	51	100,00%

Ref	Standard	Non-compliant	Partially Compliant	Total
D10.04.03.02	The shipping facility shall maintain a record of the temperature over the period of travel.	2	6	8
D04.14.01	Critical procedures to be validated or verified shall include at least the following processing techniques, cryopreservation procedures, labeling, storage, and distribution.	2	5	7
C11.06.06.02	A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.	2	5	7
C04.03.02.03	Initial training.	3	5	8
CM03.01.02.02	Performance of the collection procedure.	2	6	8
C04.08.03.01	Documentation of proper donor eligibility determination prior to start of collection procedure.	3	6	9
C11.04	Records to allow tracking and tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after final distribution of the product, or as required by applicable laws and regulations. These records shall include at a minimum: product identity, unique numeric or alphanumeric identifier, and collection date and time; and donor and recipient identification as far as known.	6	3	9
B07.03	There shall be a policy addressing safe administration of extracorporeal photopheresis (ECP).	0	7	7
C04.05.01.04	Forms.	4	3	7
C08.05	There shall be written documentation of an interim assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.	1	6	7
C04.05.08	A system for the retraction of obsolete documents to prevent unintended use.	1	6	7

Clinical Standards	Findings	Requirements
B03.04.04.07	8	Diagnosis and management of acute and chronic graft versus host disease.
B05.01.05	8	Administration of the preparative regimen.
B10.03	7	Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.
B05.01.10	7	Emergency and disaster plan, including the Clinical Program response.
B07.02.01.04	6	Prior to administration of chemotherapy, two (2) persons qualified to administer chemotherapy shall verify and document the drug and dose in the bag or pill against the orders and the protocol, and the identity of the patient to receive the chemotherapy.
B07.02.01.03	6	The pharmacist preparing the chemotherapy shall verify and document the doses against the protocol or standardized regimen listed on the orders.
B05.03	6	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:
B03.04.03.04	6	Donor and recipient informed consent.
B07.02.02.06	5	A final report of the details of the radiation therapy administered shall be documented in the patient medical record.
B03.09.01.06	5	Data Management staff sufficient to comply with B09.
B07.02.01.02	5	Preprinted orders or electronic equivalents shall be used for protocols and standardized regimens. These orders shall be verified and documented by an attending physician.
B03.06.04	5	There shall be written policies for all relevant nursing procedures, including but not limited to:
B05.01.04	5	Infection prevention and control.
B03.07.01	5	The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of patients requiring medical care, including but not limited to:
B03.03.03	5	For Clinical Programs performing adult transplantation, there shall be at least one attending physician who has achieved specialist certification in Hematology, Medical Oncology, or Immunology. An attending physician may also serve as the Clinical Program Director, if appropriately credentialed.
B03.09.01.05	5	Physical Therapy staff.

Collection Standards	Findings	Requirements
C01.04	9	For initial accreditation, the Apheresis Collection Facility, including an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, and at least one staff member, shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding accreditation.
C02.06	7	There shall be access to autologous and/or CMV-appropriate and irradiated blood products.
C04.02.02.03	6	The Apheresis Collection Facility Director or designee shall report on quality management activities, at a minimum, quarterly.
C02.02	5	The Apheresis Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.
C04.03.02.01	5	Initial qualifications.
C04.05.01.05	5	Labels.
C01.04.01	5	A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) months preceding accreditation.
C02.03.01	4	When using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled where appropriate for temperature, humidity, ventilation, air quality, and surface contaminates.
C03.02.03.01	4	The Apheresis Collection Facility Medical Director shall have performed or supervised a minimum of four (4) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of four (4) cellular therapy product apheresis collection procedures per year within the accreditation cycle.
C04.05.01	4	Listing of all active critical documents that shall adhere to the document control system requirements. Controlled documents shall include at a minimum:
C04.01	4	The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan.
C02.03	4	Critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection shall be identified, controlled, monitored, and recorded to demonstrate ongoing compliance.
C03.02.03	4	The Apheresis Collection Facility Medical Director shall have at least one year experience in cellular therapy product collection procedures.

Processing Standards	Findings	Requirements
D07.01.01	13	Cellular therapy products shall be identified according to the proper name of the product, including appropriate modifiers and attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.
D04.06.01	9	Agreements shall include the responsibility of the facility performing any step in processing, testing, or storage to comply with applicable laws and regulations and these Standards.
D04.14	8	The Quality Management Plan shall include, or summarize and reference, policies and procedures for validation and/or verification of critical procedures.
D11.01.01	7	A pre-collection written agreement between the storage facility and the designated recipient or the donor, as appropriate, defining the length of storage and the circumstances for disposal of cellular therapy products.
D04.05.09	6	A system for record creation, assembly, review, storage, archival, and retrieval.
D06.16	6	Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution of each cellular therapy product in such a way that all steps may be accurately traced.
D04.08.02	6	The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, and implement corrective actions when necessary.
D05.01.09	6	Product storage to include alternative storage if the primary storage device fails.
D09.06.05	5	Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products.
D08.01.01.01	5	Records shall demonstrate trackability from the donor to the recipient and traceability from the recipient to the donor.
D02.02	5	Critical facility parameters that may affect cellular therapy product processing, storage, or distribution shall be controlled, monitored, and recorded to demonstrate ongoing compliance.
D04.07	5	The Quality Management Plan shall include, or summarize and reference, policies and procedures for documentation and review of cellular therapy product efficacy, and/or outcome analysis, as appropriate, including at least
D08.01.02	5	Each cellular therapy product shall meet pre-determined release criteria prior to distribution from the Processing Facility. The release criteria shall include donor eligibility determination for allogeneic products.

Donor Standards	Findings	Requirements
B/CM/C06.04.02	5	A red cell antibody screen shall be performed on allogeneic recipients.
B/CM/C06.04.01	5	Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
B/CM/C06.03.08	5	Issues of donor health that pertain to the safety of the collection procedure shall be communicated in writing to the Collection Facility staff.
B/CM/C06.02.05	5	In the case of a minor donor, informed consent shall be obtained from the donor's parent or legal guardian in accordance with applicable laws and regulations and shall be documented.
B/C06.03.02.02	4	Mobilization therapy for collection of HPC, Apheresis.
B/C06.04.06.04	4	Trypanosoma cruzi (Chagas' Disease).
B/CM/C06.03.02	4	The risks of donation shall be evaluated and documented, including:
B/C06.03.02.01	4	Possible need for central venous access.
B/CM/C06.02.04.01	3	Informed consent from the allogeneic donor should be obtained by a licensed health care professional other than the intended recipient's primary transplant physician.
B/C/CM/C06.04.14	3	Allogeneic donor eligibility and suitability shall be communicated in writing to the Collection and Processing Facilities.
B/C06.04.04.01	3	Vaccination history.
B/CM/C06.03.09	3	There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.
B/CM/C06.03.10	3	A red cell antibody screen shall be performed on allogeneic recipients

B6 Donors - Problems

- Lack of written donor information

  e.g. collection procedures and risks of G-CSF, central lines
- Missing/inconsistent donor info e.g. travel, transfusion, immunisation histories
- Lack of clear selection criteria
- No clear 'final authorisation'
- Not relaying donor info to collection facility
- No record in patient record of donor suitability e.g. HLA, CMV, ABO

SOLUTIONS

- **Clear, comprehensive and unambiguous policies and procedures**
- **Checklists**
- **Final approval documents**

Testing for IDMs

- "Within 30 d prior to collection all HPC donors shall be tested for evidence of clinically relevant infection – HIV 1/2, HBV, HCV, HTLV 1/2*, syphilis

- Deficiencies – medical history doesn't include the correct questions
  - specific tests e.g. syphilis omitted
  - not repeated if SCT delayed

Corrective actions

- "corrective action shall be implemented as appropriate"
- Deficiencies recorded
  - lack of audit
  - audit not regular
  - critical endpoints not defined
  - not disseminated
- Adverse events and clinical incidents not reported/recorded; absence of corrective actions

Bone Marrow Collection

- May be ‘forgotten’ if very few harvests
- Very few procedures
- SOPs
- Staff competency and experience

Quality Management: Peripheral Blood

- Collection outcomes e.g. yields, engraftment and AE's not regularly reviewed by CF Director
- The QMP does not describe the validation of significant apheresis procedures
- The SOP does not give the range of expected outcomes/results

Donor Selection & Management

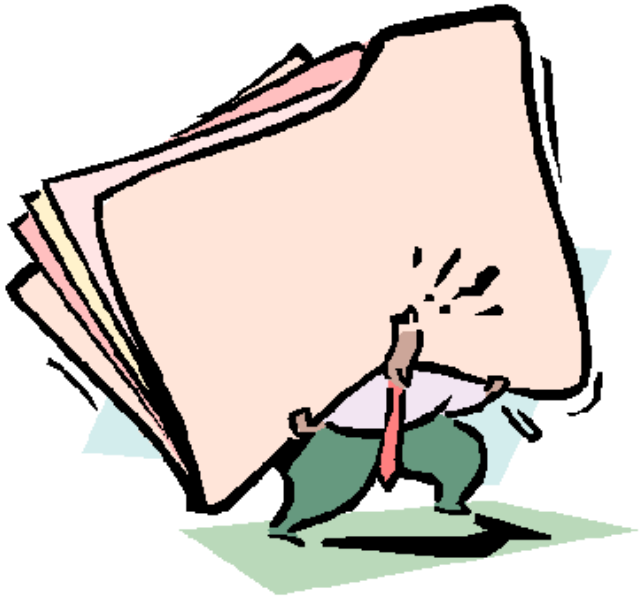
- No written orders for collection
- Absence of documented consent
- No arrangements for assessment of (interim) donor suitability
- No formal policy / SOP for assessment of venous line placement
- Assessment of venous line placement not documented in patient/donor record

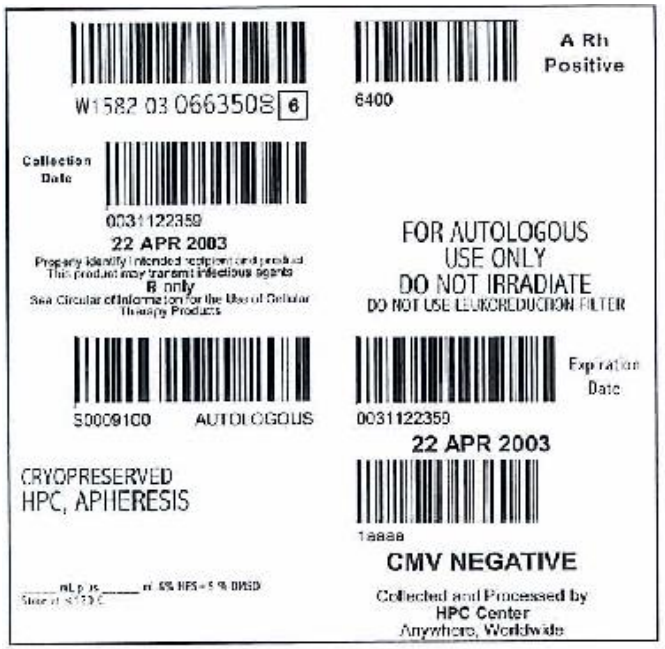
Processing Facility – Most Common and Important Deficiencies

- D5 Policies and procedures
- D7 Labels – information contained, usage

Policies and Procedures

- Document control system inadequate
- Specific policies missing e.g. storage, transportation
- Lack or approval or regular review
- Format incorrect, no range of expected results or acceptable endpoints
- No references given
- No examples of associated worksheets or forms
- No documented training to new/revised SOPs



LABELS

- Example labels not appended to SOP
- SOP to include Biohazard label
- Pre-printed / on-demand- labels
- Name + volume and/or additives not stated