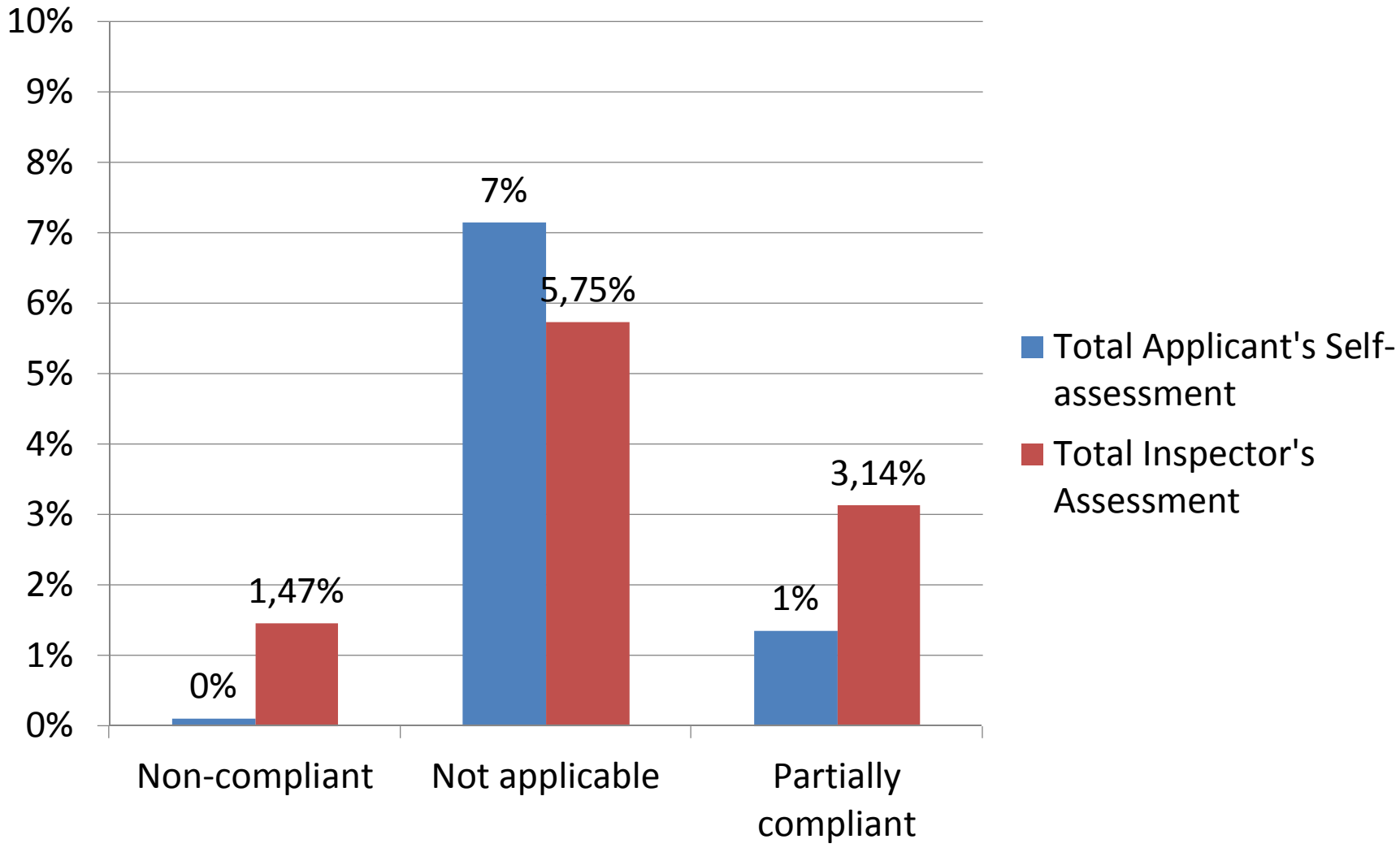
Common deficiencies

5th edition

Deficiencies cited by JACIE Inspectors

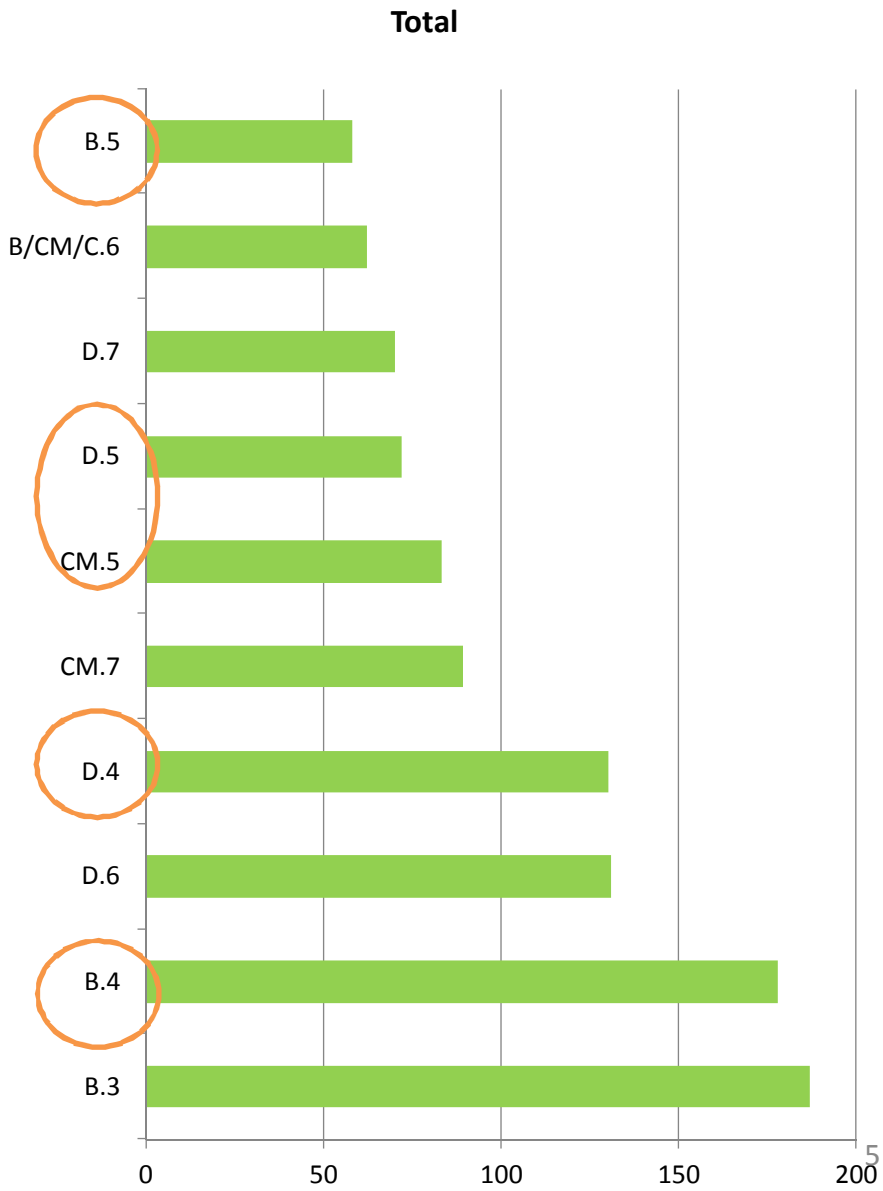
• Reports reviewed	83 (68% of all issued Summary Reports under the 5th edition)
• Total number of citations	1806
• Non-cited standards	434 Standards (38%)


10%
9%
8%
7%
6%
5%
4%
3%
2%
1%
0%
0%
1,47%
7%
5,75%
1%
3,14%
Non-compliant
Not applicable
Partially compliant
Total Applicant's Self-assessment
Total Inspector's Assessment

Stds with citations	Stds with 0 citations
710	434
62%	38%

Top-10 areas of citations

- Based on 68% (83) of all issued summary reports
- 5th ed. Standards
- Non- & Partial compliances
- Count only - no weighting given



Countries where reports issued

- Belgium
- Finland
- France
- Germany
- Hungary
- Ireland
- Israel
- Italy
- Netherlands
- Portugal
- Saudi Arabia
- Singapore
- South Africa
- Spain
- Switzerland
- United Kingdom

Parts B & C

Part	B	
	Findings	%
B.3	187	34,50%
B.4	178	32,84%
B.5	58	10,70%
B.7	52	9,59%
B.2	32	5,90%
B.1	14	2,58%
B.8	12	2,21%
B.10	5	0,92%
B.6	4	0,74%
B.9	0	0,00%

Part	C	
	Findings	%
C.4	55	17,63%
C.5	42	13,46%
C.11	42	13,46%
C.7	37	11,86%
C.8	34	10,90%
C.3	31	9,94%
C.1	25	8,01%
C.2	25	8,01%
C.9	9	2,88%
C.10	6	1,92%
C.6	6	1,92%
C.12	0	0,00%

Parts B/C/CM Donors

Part	**(Varios elementos)**	
	Findings	%
B/CM/C06.03.01.02	7	13,46%
B/C06.03.02.02	7	13,46%
B/CM/C06.03.08	6	11,54%
B/C06.04.03	5	9,62%
B/CM/C06.02.01.05	5	9,62%
B/C06.04.04.06	5	9,62%
B/CM/C06.02.07	5	9,62%
B/CM/C06.03.01.03	4	7,69%
B/CM/C06.03.01	4	7,69%
B/CM/C06.03.04	4	7,69%

Parts CM & D

Part	CM	
	Findings	%
CM.7	89	25,80%
CM.5	83	24,06%
CM.8	54	15,65%
CM.3	42	12,17%
CM.2	34	9,86%
CM.1	15	4,35%
CM.10	10	2,90%
CM.12	6	1,74%
CM.6	5	1,45%
CM.4	4	1,16%
CM.9	3	0,87%
CM.11	0	0,00%

Part	D	
	Findings	%
D.6	131	25,99%
D.4	130	25,79%
D.5	72	14,29%
D.7	70	13,89%
D.8	40	7,94%
D.2	36	7,14%
D.3	24	4,76%
D.9	1	0,20%
D.12	0	0,00%
D.11	0	0,00%
D.10	0	0,00%
D.1	0	0,00%

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

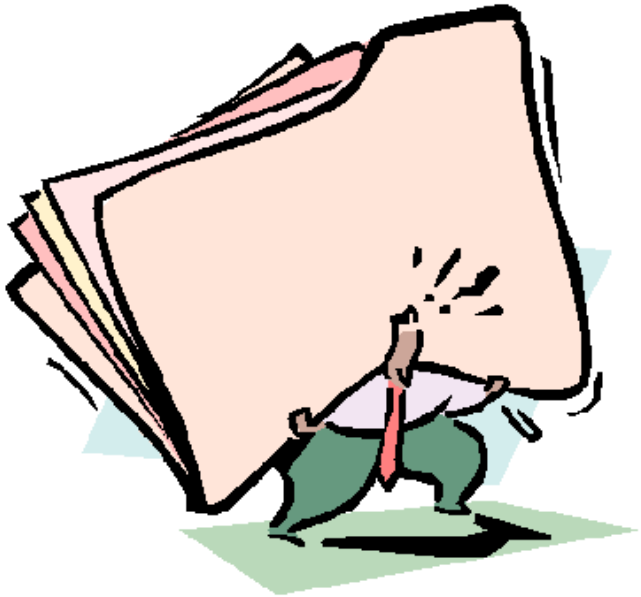
- No written orders for collection
- Absence of documented consent
- No arrangements for assessment of (interim) donor suitability
- No formal policy / SOP for assessment of venous line placement
- Assessment of venous line placement not documented in patient/donor record

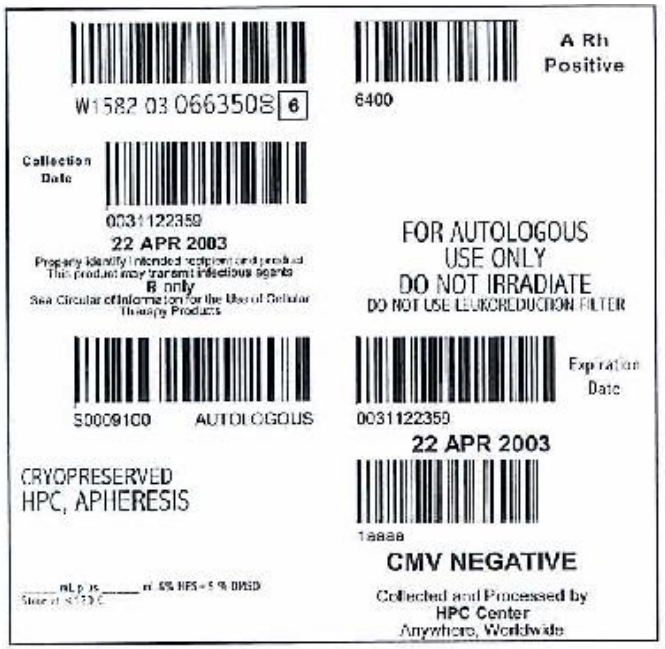
Processing Facility – Most Common and Important Deficiencies

- 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