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# An Update of the Proposed 6th Edition JACIE Cell Processing

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# Introduction

- Review process commenced mid June 2013
- Standards committee and 3 sub committees (clinical, collection and processing)
- Each sub committee has FACT and JACIE representatives

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# Introduction continued

- Teleconferences started end of summer 2013 (every 2 weeks) until mid December
- Standards committee met on 24th Feb
- New edition published April 2014 for public consultation

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# Processing committee

- 19 members from US and Europe representing FACT or JACIE
- Not everyone phoned in each time
- Each section had 2 reviewers
- Most people reviewed 2 or 3 sections

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# Public Comments

- Public consultation closed on 24th July 2014
- Weekly processing committee teleconferences started on 12th June to review the comments
- Finished 11th September
- 294 comments for processing standards reviewed

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# Next steps

- Reviewed comments reviewed/approved by the standards committee
- 6th edition published on 1st March 2015
- 01/03/15 final date for sending applications based on 5th edition
- 31/05/15 final date to submit the pre-audit documentation under the 5th edition

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# Standard D1.3 - General

- The PF  shall have a PF director, medical director, at least 1 **designated** staff member and **QM supervisor**
- The **team** shall have been in place for at least 12 months

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# Standard D2 – Processing Facility

- Sections moved to flow better

- Additional standard D2.1.2 Oxygen sensors shall be appropriately placed and utilised in areas where LN2 is present

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# Standard D2

- D2.2 Critical parameters that may affect processing storage or distribution including temperature and **humidity** shall be **assessed for risk** to product
- D2.2.1 Parameters identified to be a risk must be controlled, monitored and recorded

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# Standard D2

- D2.3 When using **procedures** that may result in contamination of cellular therapy products or **when performing more than minimal manipulation** critical environmental conditions shall be controlled, **monitored and recorded** where appropriate for air quality and surface contaminants

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# Standard D2

- D2.3.1 Surface microbial monitoring in areas where the cellular therapy product is handled shall be performed (moved)

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# Standard D2

- D2.4 The processing facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations

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# Standard D3 – Processing Facility Director

- D3.1.1 Minimum of 2 years training and/or experience
- D3.1.3 Minimum of 10 hours annually in educational activities related to cellular therapy product processing
- Present to board issue about qualifications

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# Standard D3 – Medical Director

- D3.2.1 Medical Director shall have a minimum of 2 years postgraduate training and practical and relevant experience
- D3.2.3 Minimum of 10 hours annually in educational activities related to cellular therapy product processing

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# Standard D3

- D3.4.1 Staff – shall include no less than one designated trained individual with an identified trained backup to maintain sufficient coverage

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# Standard D4 – Quality Management

- D4.6.3 QM plan shall include policies and procedures for review outcome analysis and cellular product efficacy to verify procedures
- D4.6.2 Individual cellular therapy data and aggregate data shall be evaluated
- D4.6.3 Time to engraftment - ANC and platelet count shall be analysed

# Standard D4

- D4.7.2 Follow up on effectiveness of actions from audits
- D4.9 Section on errors, adverse events, deviations etc reorganised with more detail and split into
- Detection
- Investigation
- Documentation
- Reporting
- Corrective and preventative action

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# Standard D4

- D4.12.4 New standard – Lot to lot DMSO comparison shall be done to include at least a post-thaw CD34 and TNC viability and recovery (if not approved for clinical use)
- D4.12.5 New standard – External facilities to which the processing facility distributes cellular therapy products shall be qualified for suitability (separate into 2 standards, review from FACT)
- D4.13 More detail/clarification on validation and what shall be included

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# Standard D5 – Policies and Procedures

- Not many comments
- (Red cell compatibility testing and) Processing of ABO incompatible products SOP

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# Standard D6 – Equipment, Supplies and Reagents

- New section
- Stock control/inventory control
- Track equipment/critical reagents used
- Cleaning/calibration
- Equipment failure
- Procedure to link reagents/supplies/equipment used in processing of each cellular therapy product

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# Standard D7 –Coding and Labelling

- D7.1.2 Processing facility shall be actively implementing ISBT128 coding and labelling technologies
- D7.2.7 The information entered on a container label shall be verified by 1 qualified staff member using a validated process to verify the information or 2 qualified staff members prior to distribution
- Added to guidance that validated process can be computer checks or barcodes. Also qualified person has received training and is experienced

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# Standard D8 – Process Controls

- D8.1.4.1 All products – TNC and viability
- HPC products – viable CD34
- T cell products – viable CD3

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# Standard D8

- D8.4.3 Cord  blood units that have not been red cell reduced shall be washed prior to administration
- D8.4.4 Cord blood units that have been red cell reduced shall be diluted or washed prior to administration
- Now same as clinical standards B7.4.3.1 and B7.4.3.2

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# Standard D8

- D8.10 There shall be documented notification to the recipients physician and MD when clinically relevant end points not met
- D8.12.2 Results for a red cell antibody screen on the recipient shall be available

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# Standard D9 – Cellular Therapy Product Storage

- D9.2.3 There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, minimally annually (new standard)
- Since the period of time products may be stored is unknown, stability testing of units and or samples from units of various storage duration should be tested each year for viability and potency. Can include TNC viable cell recovery, viable CD34, viable CD3

# Standard D9

- D9.3.4 For cryopreserved products received from an external facility, the PF shall assure availability of adequate storage space at the appropriate temperature
- D9.6.2 Alarm systems shall have audible and visible signals or other effective notification methods

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# Standard D10 – Cellular Therapy Product Transportation and Shipping

- Receipt removed from this section
- D10.5.2.1 The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products
- D10.5.3 The outer container shall be secured

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# Standard D11 – Distribution and Receipt

- D11.4.5 The receiving facility shall review and verify product specification provided by the manufacturer if applicable
- D11.4.7.1 For cellular therapy products received from external facility there shall be documented evidence of donor eligibility screening and testing

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# Standard D12 - Disposal

- D12.1.6 Processing facilities, in consultation with the clinical program, shall establish policies for the duration and conditions of storage and indications for disposal
- D12.1.6.1 Recipients, donors and clinical programs should be informed about policies for directed cellular therapy products before collection

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# Standard D13 -Records

- D13.2.6.9 There shall be validated procedures for system assignment of unique identifiers
- Explanation about shared responsibility expanded

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# Product labelling

- Product modifiers removed
- Name and quantity of anticoagulant and other additives (previously volume or concentration)
- Statement ‘Properly identify intended recipient and product’ removed

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# Product Labelling

- Statement ‘WARNING Leucoreduction filters shall not be used’
- Statement ‘For use by intended recipient only’ (if allogeneic) removed
- No change to whether AF, AT or AC

- Any Questions