Standards for Haematopoietic Progenitor Cell Collection, Processing & Transplantation

The Joint Accreditation Committee of ISCT-EBMT

Second Edition
June 2003

Adapted
January 2005

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NOTICE

These Standards are designed to provide minimum guidelines for facilities and individuals performing haematopoietic cell transplantation and therapy or providing support services for such procedures. These Standards are not intended to include all procedures and practices that a facility or individual should implement if the standard of practice in the community or national and/or European Union regulations and directives establish additional requirements. Each facility and individual should analyse their practices and procedures to determine whether additional standards apply. The Joint Accreditation Committee of ISCT and EBMT disclaims any responsibility for setting maximum standards and expressly does not represent or warrant that compliance with the Standards is an exclusive means of complying with the standard of care in the industry or community.

Supported by the European Commission under the Public Health Programme (2003-2008)

Contents

Introduction

The major objective of these Standards for Haematopoietic Progenitor Cell Collection, Processing and Transplantation is to promote quality medical and laboratory practice in haematopoietic progenitor cell transplantation. These Standards apply to haematopoietic progenitor cells isolated from bone marrow or peripheral blood and to all phases of collection, processing, and administration of these cells. This includes, but is not limited to, a variety of manipulations including removal or enrichment of various cell populations, expansion of haematopoietic cell populations, cryopreservation and infusion. For the purposes of these Standards, the following definitions apply. Haematopoietic progenitor cells include primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified, regardless of tissue source. Haematopoietic progenitor cells also include therapeutic cells as defined in this section. Haematopoietic progenitor cell therapy refers to the infusion of haematopoietic products with the intent of providing effector cells in the treatment of disease or support of other therapy.

In association with FACT (Foundation for the Accreditation of Haematopoietic Cell Therapy), additional JACIE publications will address the medical and laboratory practice of new developments in cellular therapies such as genetic modification of haematopoietic and non-haematopoietic tissues intended to permanently or transiently engraft in the recipient and/or be used in the treatment of disease.

These Standards also apply to the transplantation of umbilical cord blood cells under the clinical standards for transplantation of allogeneic or autologous haematopoietic progenitor cells, as appropriate. The collection, processing and banking of cord blood cells are accredited by NETCORD[1]. These Standards also do not address the collection, processing or administration of erythrocytes, mature granulocytes, platelets, plasma or plasma-derived products intended for transfusion support.

Every effort has been made in these Standards to incorporate sound recommendations fostering quality medical and laboratory practice in haematopoietic progenitor cell therapy. However, no Standards can guarantee the successful outcome of such therapies. JACIE Standards are minimal performance guidelines that may be exceeded as deemed appropriate by the responsible personnel in individual facilities. Clinical Programme Directors, Collection Facility and Laboratory Directors/Medical Directors assume responsibility for adopting JACIE Standards as appropriate to the facility, and for setting more rigorous internal requirements where appropriate. Attempts have been made to conform these Standards to existing European clinical practices; however, regulations are changed often and compliance with these Standards does not guarantee compliance with all regulations. In all cases, personnel must follow all applicable national and/or European Union regulations and directives. These Standards will be reviewed and revised as appropriate based on developments in the field.

The current JACIE Standards for Haematopoietic Progenitor Cell Collection, Processing and Transplantation were developed after a review of the first edition of FACT Standards by the FACT Standards Committee. These draft Standards were submitted for comment from the public and from the membership of the parent organisations, International Society for Cellular Therapy (ISCT) and the American Society of Blood and Marrow Transplantation (ASBMT) with additional input from JACIE. Following a review of comments and legal review, this second edition was adopted by the FACT Board of Directors and subsequently by JACIE.

[1] NETCORD Cord Blood accreditation is determined by evaluation of written information provided by the applicant facility and by on-site inspection. All inspections are conducted by persons qualified by training and experience in haematopoietic progenitor cell therapy and cord blood banking, who have attended cord blood bank inspector training, and who have a working knowledge of the NETCORD Standards and of their application in the various cord blood banking activities. NETCORD Standards for Cord Blood do not cover the clinical transplantation of cord blood cells. Further information on NETCORD accreditation is available at www.netcord.org.

The second edition of the JACIE Standards differs from the first in several ways. Section A now contains only terminology, definitions and abbreviations. Product names have been changed to be consistent with the International Council for Commonality in Blood Banking Automation (ICCBBA) nomenclature, in an effort to facilitate international cooperation and bar coding in the future. There are no specific standards in this section. The requirements for Policies and Procedures, Validation and Qualification, Quality Management and Safety previously found in section A have been customised and placed in the specific Clinical, Collection and/or Laboratory sections as appropriate.

In the Clinical Section B, data management standards now include the specific items required on the MED A forms of the European Group for Blood and Marrow Transplantation (EBMT) (available from the EBMT web site www.ebmt.org under 'Registry'). This does not mandate reporting to the EBMT. Specific standards have been added for Paediatric transplantation. Standards for haematopoietic progenitor cell donor evaluation and selection have been moved to the Clinical Section; and the therapy administration standards have been expanded.

In the Collection Section C, responsibilities for donor evaluation have been clarified. In the laboratory Section D, labelling standards have been consolidated into a single table; and packaging and transportation standards have been clarified.

Finally, the individual items in each section have been reorganised as applicable in a parallel fashion to facilitate ease of locating information. In addition, a comparison with the First Edition of JACIE Standards is provided in Appendix I.

The Second Edition of the JACIE Standards was effective June 1, 2003. The wording of the Standards has been adapted to European terminology in this version (January 2005) but the requirements of the Standards have not been altered in relation to the Standards document of June 2003. Guidance and interpretation of the Standards is provided in the JACIE Accreditation Manual version 2, January 2005.

JACIE ACCREDITATION

The basis for JACIE Accreditation is documented compliance with the current edition of these Standards. Accreditation is determined by evaluation of the written information provided by the applicant facility and by on-site inspection. All inspections are conducted by persons qualified by training and experience in haematopoietic cell therapy, who have attended inspector training and who have a working knowledge of JACIE Standards and of their application to various aspects of the haematopoietic progenitor cell facility.

Facilities performing haematopoietic progenitor cell collection, processing, storage and/or transplantation may apply for voluntary accreditation by JACIE as follows:

1) A clinical haematopoietic progenitor cell transplantation programme may apply for accreditation alone or in conjunction with the collection facility and/or the cell processing laboratory with which it is associated. All facilities applying together should submit pre-inspection data together. If applying separately, a clinical transplant programme must use a collection facility and a processing laboratory that meet JACIE Standards and have a clearly defined contractual or reporting relationship.

2) A haematopoietic progenitor cell collection facility or service (peripheral blood or bone marrow) may apply for accreditation as an integral part of a clinical transplant programme, as a local or regional collection service providing haematopoietic progenitor cell collection services for one or more clinical transplant programmes, or in conjunction with a cell processing laboratory if the services of haematopoietic progenitor cell collection and processing/storage are functionally linked. An accredited haematopoietic progenitor cell collection facility may provide services for clinical transplant programmes that are or are not JACIE accredited, but must use a processing laboratory that meets JACIE Standards.

3) A haematopoietic progenitor cell processing laboratory may apply for accreditation as an integral part of a clinical transplant programme, as part of a collection service or facility, or as an independent laboratory that processes and stores haematopoietic progenitor cell products for clinical programme(s) or collection facilities. A JACIE-accredited laboratory may provide services for clinical transplant programmes and/or collection services that are or are not JACIE-accredited.

Accreditation of the clinical haematopoietic progenitor cell transplantation programme may be for allogeneic transplantation, autologous transplantation or both. The accreditation may cover haematopoietic progenitor cells derived from bone marrow and/or peripheral blood.

Accredited facilities will be re-inspected every three years or in response to complaints or information that a facility may be non-compliant with the Standards, or as determined by the JACIE Board. Accreditation may be suspended or terminated if a facility fails to comply with the Standards.

PART A: TERMINOLOGY, ABBREVIATIONS AND DEFINITIONS

A1.000 Terminology

A2.000 Abbreviations

A3.000 Definitions

PART A: Terminology, Abbreviations and Definitions

A1.000 Terminology

For the purposes of these Standards, the term *must* means that the Standard is to be complied with at all times. The term *should* indicates an activity that is recommended or advised, but for which there may be effective alternatives.

A2.000 Abbreviations

The following abbreviations cover terms used in these Standards.

Abbreviations

ABO	Human erythrocyte antigens, A, B, O.
Ag	Antigen.
Anti-	Antibody to the antigen designated.
C	Centigrade.
CMV	Cytomegalovirus).
DNA	Deoxyribonucleic acid.
EBMT	European Group for Blood and Marrow Transplantation
EFI	European Federation for Immunogenetics
FACT	Foundation for the Accreditation of Cellular Therapy
GVHD	Graft versus host disease.
HLA	Human Leukocyte Antigen.
HBc	Hepatitis B core.
HBsAg	Hepatitis B surface antigen.
HCV	Hepatitis C virus.
HIV	Human immunodeficiency virus.
HPC	Haematopoietic progenitor cells.
HTLV	Human T-lymphotropic virus.
IRB	Institutional Review Board.
JACIE	Joint Accreditation Committee of ISCT and EBMT.
MED A	Minimum Essential Data-A form
REC	Research Ethics Committee
Rh	Human erythrocytes antigen, Rhesus.
SOP(s)	Standard Operating Procedure(s)

A3.000 Definitions

Allogeneic refers to cells obtained from a donor and intended for infusion into a genetically distinct recipient.

Autologous refers to cells obtained from a patient and intended for infusion into that patient.

Cellular therapy refers to the infusion of products with the intent of providing effector cells in the treatment of disease or support of other therapy.

Clinical Transplantation Programme (Programme) consists of an integrated medical team housed in geographically contiguous or proximate space with a single Programme Director, common staff, training programmes, protocols, and quality assessment systems. The Programme must use haematopoietic cell collection and processing facilities that meet JACIE Standards. Clinical programmes that include non-contiguous institutions in the same metropolitan area must

demonstrate common protocols, staff training procedures, quality assessment systems, review of clinical results, and evidence of regular interaction. Several clinical sites, particularly with different Directors, or outside a single metropolitan area, joining together for the purpose of meeting criteria to qualify as a Programme, do not fulfil the intent of these Standards. In contrast, collection facilities and/or processing laboratories serving one or more clinical programmes are acceptable.

Collection includes any procedure for harvesting cells regardless of technique or source.

Competency is the adequate ability to perform a specific procedure according to direction.

Cord blood refers to haematopoietic progenitor cells collected from placental and umbilical cord blood vessels after the umbilical cord is clamped and/or severed.

Cord Blood Bank is a facility in which haematopoietic progenitor cells collected from the placental and umbilical cord blood vessels are processed, cryopreserved, and/or stored.

Director: For the purposes of these Standards includes individuals with the following qualifications:

Programme Director is the physician responsible for all administrative and medical operations of the clinical transplantation programme, including compliance with these Standards. The Programme Director must be appropriately licensed to practice medicine in the country where the Programme is located and have specialist registration / completed higher specialist training in one or more of the following specialties: Haematology, Medical Oncology, Immunology, or Paediatric Haematology/Oncology. Those physicians who completed their medical training prior to the introduction of national higher specialist training schemes in one of the required specialties may serve as Programme Director if they have documented experience and published contributions in the field of haematopoietic progenitor cell transplantation extending over ten years. The Programme Director should participate regularly in educational activities related to the field of haematopoietic stem cell transplantation.

Collection Facility Director is an individual with a relevant degree, qualified by postgraduate training or experience for the scope of activities carried out in the collection facility. The Collection Facility Director is responsible for all technical procedures and administrative operations of the collection facility. The Collection Facility Director should participate regularly in educational activities related to the field of haematopoietic cell collection and/or transplantation. The Collection Facility Director may also serve as the Collection facility Medical Director if appropriately qualified.

Collection Facility Medical Director is a physician appropriately licensed to practice medicine in the country where the Programme is located. This individual is directly responsible for the pre-collection evaluation of the donor, final approval of the prospective donor for the collection procedure, conduct of the collection procedure, care of any complications arising from collection and compliance of the collection facility with these Standards. The Collection Facility Medical Director should participate regularly in educational activities related to the field of haematopoietic cell collection and/or transplantation.

Laboratory Director is an individual with a relevant degree, and qualified by training or experience for the scope of activities carried out in the cell processing facility. The

Laboratory Director is responsible for all procedures and administrative operations of the cell processing facility, including compliance with these Standards. The Laboratory Director should participate regularly in educational activities related to the field of haematopoietic cell processing and/or transplantation. The Laboratory Director may also serve as the Laboratory Medical Director if appropriately qualified.

Laboratory Medical Director is a physician appropriately licensed to practice medicine in the country where the Programme is located with postgraduate training in haematopoietic cell processing and/or transplantation. This individual is directly responsible for the medical aspects of the processing procedures. The Medical Director should participate regularly in educational activities related to the field of haematopoietic cell processing and/or transplantation. The Medical Director may also serve as the Laboratory Director if appropriately qualified.

Expansion refers to growth of one or more cell populations in an in vitro culture system.

Gene insertion refers to the introduction of one or more exogenous genes into one or more cell populations.

Haematopoietic progenitor cells include primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified, regardless of tissue source.
For the purposes of these Standards, haematopoietic progenitor cells also include therapeutic cells as defined in this section.

Haematopoietic progenitor cell therapy refers to the infusion of haematopoietic cell products with the intent of providing effector functions in the treatment of disease or support of other therapy.

Human tissue refers to cells obtained from any living or cadaveric human donor or organ.

Labelling process includes steps taken to identify the original haematopoietic progenitor cell collection, any products, and any product modifications; to complete the required reviews; and to attach the appropriate labels.

Manipulation refers to an ex vivo procedure(s) that functionally or genetically alters cell populations.

Manufacturing includes, but is not limited to, any or all steps in the recovery, processing, storage, labelling, packaging, or distribution of any human cellular or tissue-based product, and the screening and testing of a cell or tissue donor.

Manipulated cell products refers to cell products that have been functionally or genetically altered ex vivo, including ex vivo expanded cells.

Minimally manipulated cell products refers to cell products that have not been subjected to an ex vivo procedure that functionally or genetically alters specific nucleated cell populations.

Mid-Level Practitioners are non-Consultant/Senior Physician staff who provide primary clinical patient care and include both Advanced Nursing Practitioners (e.g. Nurse Practitioners, Specialist

Nurses, Physician Assistants) and medical staff in training (e.g. registrars, fellows, interns and equivalent staff.)

Potency is the therapeutic activity of a product as indicated by appropriate laboratory tests or adequately developed and controlled clinical data.

Processing includes all aspects of manipulation, labelling, and infusion of products, regardless of source.

Products

The proper name of each product is as follows:

Haematopoietic Progenitor Cells, Apheresis (HPC-A) - haematopoietic progenitor cells collected from the peripheral blood of a donor using an apheresis technique.

Haematopoietic Progenitor Cells, Marrow (HPC-M) - haematopoietic progenitor cells aspirated from the iliac crests, sternum or other bones of a human donor.

Haematopoietic Progenitor Cells, Cord Blood (HPC-C)

Therapeutic Cells (TC) - cell products harvested or manufactured for the purpose of providing therapeutic benefit.

Therapeutic Cells, T- cells (TC-T)
Therapeutic Cells, Dendritic (TC-D)
Therapeutic Cells, Natural Killer (TC-NK)
Therapeutic Cells, Cytotoxic Lymphocyte (TC-CTL)
Therapeutic Cells, other (such as tumour-derived cells) (TC-other)

Product modifications

Plasma Reduced - cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation using devices, supplies, and techniques validated for the procedure(s).

RBC Reduced - cells remaining after depletion of mature erythrocytes by sedimentation, centrifugation, or lysis using devices, supplies, and techniques validated for the procedure(s).

B-Cell-Depleted - cells processed by negative selection for B lymphocytes.

T-Cell-Depleted - cells processed by negative selection for T lymphocytes.

Buffy Coat Enriched - cells remaining after depletion of mature erythrocytes and plasma by sedimentation or centrifugation using devices, supplies, and techniques validated for the procedure(s). Mononuclear cell (MNC) preparations made without density gradient medium are included in this category.

Light Density Enriched - cells remaining after depletion of mature erythrocytes, polymorphonuclear leukocytes and plasma by techniques using defined density gradient medium and devices or reagents validated for the separation of cells based on density.

Other Target Cell Depletion or Enrichment:

CD34-Enriched – cells processed by positive selection for CD34-antigen bearing cells.

Ex Vivo Expanded – cells that have been cultured in vitro for the purpose of producing and/or enriching for a specific functional subset.

Tumour Cell Depletion – cells processed by negative selection for tumour cells.

Cryopreserved - cells frozen using devices, supplies, and techniques validated to maintain viability.

Gene-Manipulated – cells that have been processed to alter their own genes or introduce new genetic material.

Proficiency test refers to an evaluation of the ability to perform laboratory procedures within acceptable limits of accuracy, through the analysis of unknown specimens distributed at periodic intervals by a source outside the facility performing the proficiency test.

Purity refers to relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product.

Quality refers to conformance of a product or process with pre-established specifications or standards.

Quality assurance describes the actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product are working as expected individually and collectively.

Quality assessment describes the actions, planned and performed, to evaluate all systems and elements that influence the quality of the product or service.

Quality control refers to a product of a quality programme that includes the activities and controls used to determine the accuracy and reliability of the establishment's personnel, equipment, reagents, and operations in the manufacturing of haematopoietic progenitor cell products, including testing and product release.

Quality improvement describes the actions planned and performed to develop a system to review and improve the quality of a product or process.

Quality management refers to an integrated programme of quality assessment, assurance, control and improvement.

Safety refers to relative freedom from harmful effects to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

Standard Operating Procedures Manual refers to a compilation of written detailed instructions required to perform procedures.

Standards refers to the current edition of the *Standards for Haematopoietic Progenitor Cell Collection, Processing & Transplantation* published by JACIE.

Syngeneic refers to cells collected from the patient's genetically identical twin.

Time of collection refers to the end of the haematopoietic cell collection procedure.

Transplantation refers to the infusion of autologous, syngeneic or allogeneic haematopoietic progenitor cells with the intent of providing transient or permanent engraftment in support of therapy of disease.

Unmanipulated haematopoietic progenitor cells refers to haematopoietic progenitor cells as obtained at the time of collection and not subjected to any form of manipulation.

Validation refers to establishment of documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. A process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use.

PART B: Clinical Programme Standards

PART B: Clinical Programme Standards

B1.000 General

B1.100 Definition of a Clinical Transplantation Programme

The Clinical Transplantation Programme consists of an integrated medical team housed in geographically contiguous or proximate space with a single Programme Director and common staff training programmes, protocols, and quality management systems. The Programme must use haematopoietic cell collection and processing facilities that meet JACIE Standards with respect to their interactions with that clinical programme. Programmes that include non-contiguous institutions in the same metropolitan area must demonstrate common protocols, staff training procedures, quality management systems, and review of clinical results and evidence of regular interaction. Several clinical sites, particularly with different Directors, or outside a single metropolitan area, joining together for the purpose of meeting criteria to qualify as a Programme do not fulfil the intent of these Standards.

B1.200 The clinical programme must abide by all applicable national and/or European Union regulations and directives.

B1.300 Programme Size

B1.310 A minimum of 10 new patients must have been transplanted during the twelve-month period immediately preceding the application for Programme accreditation and annually thereafter.

B1.320 If the Programme requests accreditation for both allogeneic and autologous transplantation, a minimum of 20 new patients, including at least 10 new allogeneic patients and at least 5 new autologous patients must have been transplanted during the twelve-month period immediately preceding the application for Programme accreditation and annually thereafter.

B1.330 If accreditation for only one type of transplant (allogeneic or autologous) is being requested, 10 new recipients of transplants of that type must have been treated during the twelve-month period immediately preceding the application for Programme accreditation and annually thereafter.

B1.340 For combined adult and paediatric programmes, a minimum of four new adult patients and four new paediatric patients must have been transplanted during the twelve-month period immediately preceding the application for each type of transplant (allogeneic or autologous) for which accreditation is requested and annually thereafter.

B1.350 For programmes utilising more than one clinical site for transplantation, a minimum of four new patients must have been transplanted per site during the twelve-month period immediately preceding the application for accreditation and annually thereafter.

B2.000 Clinical Unit

B2.100 The Programme must have:

B2.110 A designated inpatient unit that minimises airborne microbial contamination.

B2.120 A designated area for outpatient care that reasonably protects the patient from transmission of infectious agents and can provide, as necessary, appropriate patient isolation, administration of intravenous fluids, medications, and/or blood products.

B2.130 Provisions for prompt evaluation and treatment by a transplant consultant/senior physician available on a 24-hour basis.

B2.140 Nurses experienced in the care of transplant patients.

B2.150 A nurse/patient ratio satisfactory to cover the severity of the patients' clinical status.

B2.160 A Collection Facility and a Haematopoietic Progenitor Cell Processing Facility that meet these Standards with respect to their interaction with that clinical programme.

B2.170 A transfusion service providing 24-hour availability of CMV appropriate and irradiated blood products needed for the care of transplant patients.

B2.180 A pharmacy providing 24-hour availability of medications needed for the care of transplant patients.

B2.181 If clinical research is performed, the pharmacy must have a mechanism for tracking, inventory, and secured storage of investigational drugs.

B2.190 Programmes performing allogeneic haematopoietic cell transplants must also use HLA testing laboratories accredited by the European Federation for Immunogenetics (EFI), with the capability of carrying out DNA-based HLA-typing.

B2.200 Safety Requirements

B2.210 The Programme must be operated in a manner to minimise risks to the health and safety of employees, donors, volunteers, and patients. Suitable quarters, environment, and equipment must be available to maintain safe operations.

B2.220 There must be procedures for biological, chemical, and radiation safety, as appropriate, and a system for monitoring training and compliance.

B2.230 Haematopoietic progenitor cells must be handled and discarded with precautions that recognise the potential for exposure to infectious agents.

B3.000 Personnel

B3.100 Transplant Team

A dedicated transplant team including a Programme Director and at least one other physician trained or experienced in haematopoietic progenitor cell therapy must have been in place for at least one year prior to being eligible for accreditation.

B3.110 Centres performing paediatric transplants must have a transplant team trained in the management of paediatric patients.

B3.120 For programmes performing paediatric transplantation, there must be at least one consultant/senior physician who has specialist registration / completed higher specialist training in Paediatric Haematology/Oncology or Paediatric Immunology

B3.130 For programmes performing adult transplantation, there must be at least one consultant/senior physician who has specialist registration / completed higher specialist training in Haematology, Medical Oncology or Immunology

B3.140 The Programme must have access to a team of licensed physicians who are trained and competent in bone marrow harvesting.

B3.200 Programme director

B3.210 The Programme Director must be appropriately licensed to practice medicine in the country where the Programme is located and have specialist registration / completed higher specialist training in one or more of the following specialties: Haematology, Medical Oncology, Immunology, or Paediatric Haematology/Oncology. Physicians who completed medical training prior to the introduction of national higher specialist training schemes may serve as Programme Director if they have documented experience and published contributions in the field of haematopoietic progenitor cell transplantation extending over ten years.

B3.220 The Programme Director must have at least one year of specific clinical training in haematopoietic progenitor cell transplantation as defined in B3.400, or two years experience as a consultant/senior physician responsible for the clinical management of haematopoietic progenitor cell transplant patients in the inpatient and outpatient settings. The Programme Director must have written confirmation of his/her training or experience from the Director of the programme, department, or institution in which that training or experience was obtained. The Programme Director should participate regularly in educational activities related to the field of haematopoietic stem cell transplantation.

B3.230 The Programme Director is responsible for the administrative and clinical operations including compliance with these Standards. The Programme Director must have oversight of all elements of the Programme including the selection of patients and donors, collection of cells, and processing of cells whether internal or contracted services.

B3.231 The Programme Director must be responsible for the quality management of the entire Programme.

B3.232 The Programme Director must be responsible for the policies and procedures for donor evaluation, selection, and pre- and post- donation care and compliance with these Standards as listed in Section B6.000.

B3.240 The Programme Director must have oversight of the medical care provided by the Programme including medical care provided by the physicians on the transplant team. The Programme Director is responsible for verifying the knowledge and skills of the physicians of the transplant team. Management of the Clinical Unit may be delegated to a Medical Director who fulfils the requirements in B3.300.

B3.300 Other Consultant/Senior Physicians

B3.310 Transplant Programme consultant/senior physicians must be appropriately licensed to practice medicine in the country where the Programme is located and should have specialist registration / completed higher specialist training in one of the specialties listed in B3.210.

B3.320 Transplant Programme consultant/senior physicians should have specific clinical training in haematopoietic progenitor cell transplant medicine as defined in B3.400, and should participate regularly in educational activities related to the field of haematopoietic stem cell transplantation.

B3.400 Physician Training For Transplant Programme Directors and Consultant/Senior Physicians

B3.410 Method of Training

B3.411 Adequate specific clinical training in haematopoietic progenitor cell transplant medicine is defined as a minimum of one year's experience in the management of transplant patients in both the inpatient and outpatient settings.

B3.412 Clinical training and competency must include the management of:

a) Autologous transplant patients for physicians in Programmes requesting JACIE accreditation for autologous transplantation.

b) Allogeneic transplant patients for physicians in Programmes requesting JACIE accreditation for allogeneic transplantation.

c) Both autologous and allogeneic transplant patients for physicians in Programmes requesting JACIE accreditation for autologous and allogeneic transplantation.

B3.413 Programmes transplanting paediatric patients must have physicians experienced in treating paediatric patients.

B3.420 Cognitive Skills

B3.421 Specific training and competency in each of the following areas required for physicians in Programmes requesting JACIE accreditation for autologous and/or allogeneic transplantation must include:

a) Indications for haematopoietic progenitor cell transplantation.

b) Selection of appropriate patients and preparative high dose therapy regimens.

c) Pre-transplant patient evaluation, including assessment of appropriate patient eligibility and haematopoietic progenitor cell adequacy with respect to collection.

d) Administration of high-dose therapy.

e) Administration of growth factors for haematopoietic progenitor cell mobilisation and for post-transplant haematopoietic cell reconstitution.

f) Management of neutropenic fever.

g) Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation.

h) Diagnosis and management of fungal disease.

i) Diagnosis and management of veno-occlusive disease of the liver.

j) Management of thrombocytopenia and bleeding.

k) Management of hemorrhagic cystitis.

l) Management of nausea and vomiting.

m) Management of pain.

n) Management of terminal care patients.

o) Documentation and reporting for patients on investigational protocols.

p) Diagnosis and management of haematopoietic progenitor cell graft failure.

B3.422 Specific clinical training and competency in each of the following additional areas required for physicians in Programmes requesting JACIE accreditation for allogeneic haematopoietic cell transplantation must include:

a) Identification and selection of haematopoietic progenitor cell source, including use of donor registries.

b) Methodology and implications of human leukocyte antigen (HLA-typing.

c) Management of patients receiving ABO incompatible haematopoietic progenitor cell products.

d) Diagnosis and management of cytomegalovirus (CMV) infection and disease.

e) Diagnosis and management of other viral infections in immunocompromised hosts.

f) Diagnosis and management of acute and chronic graft versus host disease (GVHD).

g) Diagnosis and management of post-transplant immunodeficiencies.

h) Evaluation of chimerism.

B3.430 Procedural Skills

B3.431 The haematopoietic progenitor cell transplant physician must be proficient in the following procedure:

a) Haematopoietic progenitor cell product infusion.

B3.432 The haematopoietic progenitor cell transplant physician must be knowledgeable in the following procedures:

a) Haematopoietic progenitor cell processing.

b) Haematopoietic progenitor cell cryopreservation.

c) Bone marrow harvest procedures.

d) Apheresis procedures.

B3.500 Mid-Level Practitioners (see section *A3.000 Definitions*)

B3.510 Mid-level practitioners must be appropriately licensed to practice medicine in the country where the Programme is located.

B3.520 Mid-level practitioners must be trained and competent specifically in the transplant-related cognitive and procedural skills that they routinely practice. These skills include but may not be limited to those listed in B3.420 and B3.430. Mid-level practitioners should participate regularly in educational activities related to the field of haematopoietic stem cell transplantation.

B3.600 Consultant/Senior Physicians in other specialities

B3.610 The Transplant Programme must have access to appropriately qualified consultant/senior physicians in other specialities who are capable of assisting in the management of patients requiring medical care, including but not limited to:

surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious disease, cardiology, pathology, psychiatry and,, if radiation therapy is administered, radiation oncology with experience in large-field (e.g. total body or total lymphoid) irradiation treatment protocols.

B3.620 Programmes treating paediatric patients must have consultant/senior physicians in other specialities, as defined in B3.610, qualified to manage paediatric patients.

B3.700 Nurses

B3.710 Programmes must have nurses and nurse supervisors formally trained and experienced in the management of patients receiving haematopoietic progenitor cell transplants.

B3.720 Programmes treating paediatric patients must have nurses formally trained and experienced in the management of paediatric patients.

B3.730 Training must include haematology/oncology patient care; administration of high-dose therapy, growth factors, and immunosuppressive medications; management of infectious complications associated with compromised host defence mechanisms; administration of blood products; and an appropriate degree of intensive medical/paediatric nursing care.

B3.740 There must be written policies for all relevant nursing procedures, including infection prevention and control, administration of the preparative regimen, transplantation of haematopoietic progenitor cells, use of immunosuppressive agents, and blood product transfusion.

B3.800 Other Staff

The Programme must have appropriate staff available to maintain support services, as follows:

B3.810 One or more designated staff to assist in the provision of appropriate pre-transplant patient evaluation, treatment and post-transplant follow-up and care.

B3.820 Pharmacy staff knowledgeable in the use and monitoring of pharmaceuticals used by the Transplant Programme.

B3.830 Dietary staff capable of providing dietary consultation regarding the nutritional needs of the transplant recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.

B3.840 Social Services staff.

B3.850 Physical Therapy staff.

B3.860 Data Management staff sufficient to comply with Section B9.000.

B4.000 Quality Management

B4.100 The Programme must have a written Quality Management Plan that describes, at a minimum, the methods for oversight of patient care (including detection of errors, accidents and adverse reactions, significant outcome parameters, the means for review of aggregate data on a regular basis (audits), and requirements for meetings, review, documentation, corrective actions and reporting.

B4.110 The Programme Director is responsible for the Quality Management Plan as it pertains to the clinical programme. The performance of this activity may be delegated to an individual within the Programme with sufficient expertise.

B4.200 Audits

B4.210 The Programme must develop and identify performance measures and must establish processes for collection and analysis of data related to performance.

B4.220 The results of such performance audits must be used to identify improvement opportunities and strategies to achieve improvement. Audit results and improvement strategies must be reviewed with documentation in accordance with the quality management plan.

B4.300 Errors, Accidents and Adverse Reactions

B4.310 The Programme must have a system for detecting, evaluating, documenting and reporting errors, accidents, suspected adverse reactions and biological product deviations. Corrective actions must be documented and reviewed by the Programme Director.

B4.320 All suspected adverse reactions must be evaluated promptly according to Standard Operating Procedures and reviewed by the Programme Director.

B4.330 Documentation of adverse reactions in the Programme must comply with institutional requirements and applicable national and/or European Union regulations and directives.

B4.340 Where applicable, the event must also be reported to the appropriate regulatory agency and, as indicated, to the appropriate collection facility and/or processing laboratory.

B5.000 Policies and Procedures

B5.100 The Programme must have written policies and procedures addressing all appropriate aspects of the operation including, but not limited to, donor and patient evaluation, selection and treatment; consent; emergency and safety procedures; donor and patient confidentiality; quality management and improvement; errors, accidents and adverse reactions; biological product deviations; corrective actions; personnel training; competency assessment; outcome analysis; audits; facility maintenance and monitoring; disposal of medical and biohazard waste; and disaster response.

B5.200 The Programme must maintain a detailed Standard Operating Procedures (SOPs) Manual.

B5.210 The SOPs Manual must include:

B5.211 A procedure for preparing, implementing and reviewing all procedures.

B5.212 A standardised format for procedures, including worksheets, reports and forms.

B5.213 A system of numbering and/or titling of individual procedures.

B5.220 Procedures must be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure must include:

B5.221 A clearly written description of the purpose.

B5.222 A clear description of equipment and supplies used.

B5.223 The objectives of the procedure, and acceptable end-points and the range of expected results where applicable.

B5.224 A reference section listing appropriate literature.

B5.225 Documented approval of procedure and each procedural modification by the Programme Director or designee prior to implementation and annually thereafter.

B5.226 Examples of correctly completed orders, worksheets, reports, labels and forms, where applicable.

B5.300 Copies of the SOPs Manual must be available in the immediate area to the facility staff at all times.

B5.400 All personnel in the facility must follow the SOPs detailed in the manual.

B5.500 New and revised policies and procedures must be reviewed by the staff prior to implementation. This review and associated training must be documented.

B5.600 Archived procedures and their historical sequence must be maintained indefinitely, including the inclusive dates of use.

B5.700 Deviations from SOPs must be documented and approved, if appropriate, by the Programme Director or designee.

B5.800 SOPs for all procedures must comply with these Standards.

B6.000 Donor Evaluation, Selection and Management

B6.100 There must be donor evaluation procedures in place to protect the safety of the haematopoietic progenitor cell donor and recipient. Both the potentials for disease transmission from the donor to the recipient and the risks to the donor from the collection procedure must be assessed. Donor evaluation and selection test results must be documented.

B6.110 There must be written criteria for donor evaluation and selection.

B6.120 Any abnormal findings must be reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.

B6.130 The use of a donor not meeting the criteria must require documentation of the rationale for his/her selection by the transplant physician and the informed consent of the donor and the recipient.

B6.131 Procedures must be in place to ensure both confidentiality of donor and patient health information.

B6.140 Issues of donor health that pertain to the safety of the collection procedure must be communicated in writing to the collection facility staff.

B6.150 Prospective donors must be evaluated by medical history, physical examination and laboratory testing for the risks of the collection procedure including the possible need for central venous access and/or mobilisation therapy for collection of blood cells and anaesthesia for collection of marrow. This evaluation must be documented.

B6.160 The medical history must include at least the following:

B6.161 Vaccination history.

B6.162 Travel history.

B6.163 Blood transfusion history

B6.164 Questions to identify persons at high risk for significant transmissible infections.

B6.170 Within 30 days prior to collection, each donor must be tested for evidence of infection by the following communicable disease agents:

B6.171 Human immunodeficiency virus, type 1

B6.172 Human immunodeficiency virus, type 2

B6.173 Hepatitis B virus

B6.174 Hepatitis C virus

B6.175 Human T-lymphotropic virus, type I

B6.176 Human T-lymphotropic virus, type II

B6.177 Treponema pallidum (syphilis)

B6.178 Cytomegalovirus) (unless previously documented to be positive)

B6.200 Allogeneic Donors

B6.210 A transplant physician must document in the recipient's medical record the prospective donor's suitability before the recipient's high dose therapy is initiated.

B6.220 Laboratory tests required for donor selection must be performed by a laboratory accredited or licensed in accordance with applicable national and/or European Union regulations and directives and must include at least the following:

:

B6.221 HLA-A, B, DR typing by an EFI-accredited laboratory.

B6.222 ABO group and Rh type and appropriate red cell compatibility with the recipient.

B6.223 Pregnancy assessment for all female donors of childbearing potential.

B6.300 Autologous Donors

B6.310 Laboratory tests required for donor selection must be performed by a laboratory accredited or licensed in accordance with applicable national and/or European Union regulations and directives and must include at least the following:

B6.311 ABO group and Rh type.

B6.312 Pregnancy assessment for all female donors of childbearing potential.

B6.400 Donor Consents

B6.410 Allogeneic Donors

B6.411 Informed consent from the donor must be obtained and documented by a licensed physician or other health care provider familiar with the collection procedure before the high dose therapy of the recipient is initiated.

B6.412 The procedure must be explained in terms the donor can understand, and must include information about the significant risks and benefits of the procedure and tests performed to protect the health of the donor and recipient and the rights of the donor to review the results of such tests.

B6.413 The donor must have an opportunity to ask questions and the right to refuse to donate.

B6.414 In the case of a minor donor, informed consent must be obtained from the donor's parents or legal guardian in accord with applicable law and must be documented.

B6.415 If the donor's name is to be added to a haematopoietic progenitor cell donor registry, specific informed consent and authorisation to release the donor's health information as appropriate must be obtained and documented in advance.

B6.420 Autologous Donors

B6.421 Informed consent from the patient must be obtained and documented by a licensed physician or other health care provider familiar with the collection procedure.

B6.422 The procedure must be explained in terms the patient can understand, and must include information about the significant risks and benefits of the procedure and tests performed to protect the health of the patient and the rights of the patient to review the results of such tests.

B6.423 The patient must have an opportunity to ask questions and the right to refuse to donate.

B6.424 In the case of a minor patient, informed consent must be obtained from the patient's parents or legal guardian in accord with applicable law and must be documented.

B7.000 Therapy Administration

B7.100 There must be a written policy to ensure that the preparative regimen is administered safely.

B7.110 The treatment orders must include the patient height and weight, specific dates, daily doses (if appropriate) and route of each agent. Pre-printed orders should be used for protocols and standardised regimens.

B7.120 The pharmacist preparing the chemotherapy must verify the doses against the protocol or standardised regimen listed on the orders.

B7.130 Prior to administration of chemotherapy, two persons qualified to administer chemotherapy must verify 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.

B7.200 There must be a written policy to ensure safe administration of haematopoietic cell products.

B7.210 Two qualified persons must verify the identity of the recipient and the product prior to the infusion of the product.

B7.220 There must be documentation in the patient's medical record of the unit identifier for all infused products.

B8.000 Clinical Research

B8.100 If required by applicable regulations, Programmes must have formal review of investigational treatment protocols and patient consent forms by a mechanism that is approved by the applicable national and/or European Union regulations and directives.

B8.200 Documentation for all research protocols performed by the Programme, including all audits, documentation of Institutional Review Board or Research Ethics Committee approval where appropriate, correspondence with regulatory agencies, and any adverse outcomes, must be maintained in accordance with institutional policies and applicable national and/or European Union regulations and directives.

B8.300 For clinical research, informed consent must be obtained from each research subject, or his/her legally authorised representative, in language he or she can understand and under circumstances that minimise the possibility of coercion or undue influence. The research subject must be given the opportunity to ask questions and to have these answered to his/her satisfaction, and to withdraw from the research without prejudice. Informed consent for a research subject must contain at least the following elements and comply with applicable national and/or European Union regulations and directives:

B8.310 An explanation of the research purposes, a description of the procedures to be followed and the identification of experimental procedures.

B8.320 The expected duration of the subject's participation.

B8.330 A description of the reasonably expected risks, discomforts, benefits to the subject or others, and alternative procedures.

B8.340 A statement of the extent to which confidentiality will be maintained.

B8.350 An explanation of the extent of compensation for injury.

B8.400 There must be a mechanism in place to ensure as appropriate, the financial disclosure of any issues that may represent a conflict of interest in clinical research.

B9.000 Data Management

B9.100 The Programme must keep complete and accurate patient records.

B9.200 The Programme must collect all the data contained in the Minimum Essential Data Forms of the EBMT.

B9.300 Each transplant programme must use its data to periodically audit patient outcomes.

B10.000 Records

B10.100 Clinical Unit Records

Records related to quality control, personnel training or competency, facility maintenance, facility management, or other general facility issues must be retained for 10 years by the clinical transplant programme, although not all need be immediately available.

B10.200 Patient Care Records

Patient care records including consents must be maintained in a confidential manner as required by applicable national and/or European Union regulations and directives.

B10.300 Research Records

Research records must be maintained in a confidential manner as required by applicable national and/or European Union regulations and directives.

B10.400 Records In Case Of Divided Responsibility

B10.410 If two or more facilities participate in the collection, processing or transplantation of the product, the records of each facility must show plainly the extent of its responsibility.

B10.420 The Programme must furnish to other facilities involved in the collection or processing of the product, transplant outcome data in so far as they concern the safety, purity and potency of the product involved.

PART C: Haematopoietic Progenitor Cell and Therapeutic Cell Collection Standards

PART C: Haematopoietic Progenitor Cell and Therapeutic Cell Collection Standards

C1.000 General

C1.100 These Standards apply to marrow and peripheral blood progenitor cells and therapeutic cells collection activities.

C1.200 The Collection Facility must abide by all applicable national and/or European Union regulations and directives.

C2.000 Haematopoietic Progenitor Cell Collection and Therapeutic Cell Collection Facility

C2.100 There must be adequate and confidential space for donor examination and evaluation.

C2.200 There must be emergency medical care available for the donor, including:

C2.210 A transfusion facility or blood bank providing 24-hour blood product support including irradiated blood products and products suitable for CMV-negative recipients.

C2.220 An intensive care unit and emergency services.

C2.300 There must be a designated area for appropriate preparation and storage of the reagents and equipment needed and for the performance of the collection procedure.

C2.400 Procedures that will require general or regional anaesthesia must be performed by a licensed, appropriately qualified anaesthetist.

C2.500 Central venous catheters must be placed by a licensed physician qualified to perform the procedure.

C2.510 Adequacy of line placement must be documented.

C2.600 Haematopoietic growth factor administration must be under the supervision of a physician experienced in the management of persons receiving these agents.

C2.700 Safety

C2.710 Each collection facility must be operated in a manner to minimise risks to the health and safety of employees, donors, volunteers, and patients. Suitable quarters, environment, and equipment must be available to maintain safe operations.

C2.720 There must be procedures for biological, chemical, and radiation safety, as appropriate, and a system for monitoring training and compliance.

C2.730 Haematopoietic progenitor cell collections must be handled and discarded with precautions that recognise the potential for transmission of infectious agents.

C3.000 Personnel

C3.100 There must be a Collection Facility Director who is an individual with a relevant medical or scientific degree, qualified by postgraduate training or experience for the scope of activities carried out in the collection facility. The Collection Facility Director is responsible for all technical procedures and administrative operations of the collection facility. The Collection Facility Director should participate regularly in educational activities related to the field of haematopoietic cell collection and/or transplantation. The Collection Facility Director may also serve as the Collection Facility Medical Director if appropriately qualified.

C3.110 The Collection Facility Director must have at least one year's experience in the collection procedure, and must have performed or supervised at least 10 collection procedures of each type (marrow and/or peripheral blood haematopoietic progenitor cells) for which the collection facility is requesting accreditation.

C3.200 There must be a Collection Facility Medical Director who is a licensed physician with postgraduate training in haematopoietic cell collection and/or transplantation. This individual is directly responsible for the medical care of patients undergoing the collection procedure. The Medical Director should participate regularly in educational activities related to the field of haematopoietic cell collection and/or transplantation. The Medical Director may also serve as the Collection Facility Director if appropriately qualified.

C3.210 The Collection Facility Medical Director or designee is responsible for the pre-collection evaluation of the prospective donor at the time of donation, performance of the collection procedure and supervision of assistants for the procedure, care of any complications resulting from the collection procedure, and compliance with these Standards.

C3.220 The Collection Facility Medical Director must have at least one year's experience in the collection procedure, and must have performed or supervised at least 10 collection procedures of each type (marrow and/or peripheral blood haematopoietic progenitor cells) for which the collection facility is requesting accreditation.

C3.300 There must be adequate numbers of trained support personnel available at the facility where the collection is performed.

C3.310 The training, continued education and continued competency for the performance of operations must be documented.

C4.000 Quality Management

C4.100 The Collection Facility must have a written Quality Management Plan that describes, at a minimum, the methods for oversight of donor care (including detection of errors, accidents and adverse reactions), significant outcome parameters, the means for review of aggregate data on a regular basis (audits), validation of significant processes of the

collection programme and requirements for meetings, review, documentation, corrective actions and reporting.

C4.110 The Collection Facility Director is responsible for the Quality Management Plan as it pertains to the Collection Facility.

C4.120 The Collection Facility must establish and maintain a programme of quality management, under the supervision of a designated person. The individual must review and approve policies and procedures that document compliance with regulatory requirements and standards, and the performance of quality audits.

C4.130 Protocols must be developed, implemented, and documented for the validation or qualification of significant products of facilities, processes, equipment, reagents, labels, containers, packaging materials, and computer systems. Determination of which elements are to be validated or qualified must be made by the Collection Facility Director.

C4.140 Evaluation of validation studies and audits must be reviewed with documentation of approval by the appropriate individual from the quality management programme.

C4.200 Laboratory Testing

C4.210 Tests required by these Standards must be performed in a laboratory accredited or licensed in accordance with applicable national and/or European Union regulations and directives.

C4.300 Supplies and Reagents

C4.310 Reagents used in collection of products must be of appropriate grade for the intended use and must be sterile.

C4.320 Procedures for production of in-house reagents must be validated.

C4.330 Each supply and reagent used in the collection of the product must be examined visually for damage or evidence of contamination as it comes into inventory. Such examination must include inspection for breakage of seals, abnormal colour and expiration date.

C4.340 All supplies and reagents used in the collection of products must be stored in a safe, sanitary, and orderly manner.

C4.350 Lot numbers and expiration dates of reagents and disposables must be recorded.

C4.400 Equipment

C4.410 Equipment used in the collection of products must be maintained in a clean and orderly manner and located so as to facilitate cleaning, calibration and maintenance.

C4.420 The equipment must be observed, standardised and calibrated on a regularly scheduled basis as described in the SOPs Manual and according to the manufacturer's recommendations.

C4.500 Review of Collection Records

C4.510 Records pertinent to the product collected must be regularly reviewed by the Collection Facility Director or designee.

C4.520 A thorough investigation, including resolution and outcome of any adverse event or the failure of a product to meet any of its specifications must be made and documented.

C4.600 Errors, Accidents and Adverse Reactions

C4.610 Each Collection Facility must have a system for detecting, evaluating, documenting and reporting errors, accidents, suspected adverse reactions, biological product deviations and complaints. Corrective actions must be documented and reviewed by the Collection Facility Director.

C4.620 All suspected clinical adverse reactions to the collection of cells must be evaluated promptly according to SOPs, and reviewed by the Collection Facility Medical Director.

C4.630 A written evaluation of reported adverse reactions to the collection of cells must be included as part of the haematopoietic progenitor cell collection record and made available to the donor's physician.

C4.640 Where applicable, the event must also be reported to the appropriate regulatory agency, clinical programme and cell processing laboratory as appropriate.

C4.700 Outcome Analysis

C4.710 Documentation and review of product quality must be part of the ongoing quality programme.

C4.720 There must be ongoing review of the products collected.

C4.730 All suspected adverse reactions to the collection of a product must be evaluated promptly and reviewed by the Collection Facility Medical Director.

C4.740 Documentation and review of time to engraftment after haematopoietic progenitor cell infusion must be part of the on-going quality management programme.

C5.000 Policies and Procedures

C5.100 The collection programme must have written policies and procedures addressing all aspects of the operation including, but not limited to, screening, consent, collection, treatment, emergency and safety procedures, donor and patient confidentiality, quality management and improvement, errors, accidents and adverse reactions, biological product deviations, corrective actions, personnel training, competency assessment, outcome analysis, audits, labelling, storage, transportation, expiration dates, release and

exceptional release, disposal of medical and biohazard waste, equipment and supplies, maintenance and monitoring, cleaning and sanitation procedures, and a disaster plan.

C5.200 The collection programme must maintain a detailed Standard Operating Procedures (SOPs) Manual.

C5.210 The SOPs Manual must include:

C5.211 A procedure for preparing, implementing and reviewing all procedures.

C5.212 A standardised format for procedures, including worksheets, reports and forms.

C5.213 A system of numbering and/or titling of individual procedures.

C5.220 Procedures must be sufficiently detailed and unambiguous to allow qualified technical staff to follow and complete the procedures successfully. Each individual procedure requires:

C5.221 A clearly written description of the purpose.

C5.222 A clear description of equipment and supplies used.

C5.223 The objectives of the procedure, and acceptable end-points and the range of expected results where applicable.

C5.224 A reference section listing appropriate literature.

C5.225 Documented approval of procedure and each procedural modification by the Collection Facility Director or designee prior to implementation and annually thereafter.

C5.226 Examples of correctly completed orders, worksheets, reports, labels and forms, where applicable.

C5.300 Copies of the SOPs Manual must be available in the immediate area to the facility staff at all times.

C5.400 All personnel in the facility must follow the SOPs detailed in the manual.

C5.500 New and revised policies and procedures must be reviewed by the staff prior to implementation. This review and associated training must be documented.

C5.600 Archived procedures and their historical sequence must be maintained indefinitely, including the inclusive dates of use.

C5.700 Deviations from SOPs must be documented and approved, if appropriate, by the Collection Facility Director or designee.

C5.800 SOPs for all procedures must comply with these Standards.

C6.000 Donor Evaluation and Management

C6.100 In the case of more than one collection from the same donor, the tests in B6.170 as appropriate must have been performed within 30 days prior to each collection.

C6.200 There must be written documentation of an interim assessment of donor suitability for the collection procedure by a qualified person immediately prior to each collection procedure.

C6.300 For donors of peripheral blood products, a complete blood count, including platelet count, must be performed within 72 hours prior to the first collection and within 24 hours before each subsequent apheresis.

C7.000 Haematopoietic Progenitor Cell and Therapeutic Cell Collection

C7.100 Collection of haematopoietic progenitor cells and therapeutic cells must be performed according to written procedures in the facility's SOPs manual.

C7.200 Before collection of marrow or peripheral blood progenitor cells is undertaken, there must be a written order for the collection from a physician regarding timing and procedural details of collection and goals of collection.

C7.300 Methods for collection must employ aseptic technique and must use procedures validated to result in acceptable progenitor cell viability and recovery.

C7.400 The collected cells must be packaged in a closed sterile container and labelled.

C7.410 For marrow and peripheral blood cells, the haematopoietic progenitor cells must be packaged in transfer packs approved for human cells.

C7.420 Marrow cells must be filtered to remove particulate material prior to final packaging, distribution or transplantation using sterile filters that are non-reactive with blood.

C7.500 Procedures for transportation of the collected product must be designed to protect the integrity of the product being shipped and the health and safety of facility personnel. Frozen or non-frozen products that leave the facility or are transported on public roads must be shipped in an outer shipping container.

C7.510 The primary product container must be placed in a secondary container and sealed to prevent leakage.

C7.520 The outer shipping container should be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

C7.530 The product must be shipped to the processing laboratory at a temperature defined in the Standard Operating Procedure Manual.

C8.000 Labels

C8.100 Labelling Operations

C8.110 Labelling operations must be conducted in a manner adequate to prevent mislabelling of products.

C8.120 The labelling operation must include the following quality management elements:

C8.121 Container labels must be held upon receipt from the manufacturer pending review and proofing against a copy approved by the Collection Facility Director or designee to ensure accuracy regarding identity, content, and conformity.

C8.122 Stocks of unused labels representing different products must be stored in an orderly manner to prevent errors. Stocks of obsolete labels must be destroyed.

C8.123 A system of checks in labelling procedures must be used to prevent errors in translating information to container labels.

C8.124 All labelling must be clear and legible and printed using moisture-proof ink.

C8.130 Labels must be affixed or attached firmly to the container.

C8.140 The proper name and significant modification(s) must be noted on the label.

C8.150 Products that are subsequently re-packaged into new containers must be labelled with new labels as appropriate. Records to allow tracking of products including collection or processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product identity, donor and recipient information on the original container must be maintained.

C8.160 When the label has been affixed to the container, a sufficient area of the container must remain uncovered to permit inspection of the contents.

C8.170 The product label must be complete. 'Not applicable' (NA) may be used when appropriate.

C8.180 Labelling requirements, if any, required by applicable national and/or European Union regulations and directives must be observed.

C8.200 Product Identification

C8.210 Each product must be assigned a unique numeric or alphanumeric identifier by which it will be possible to relate any product to its donor, the donor's medical record, and to all records describing the handling and final disposition of the product. If a single product is divided in multiple containers, there must be a system of identifying each container.

C8.220 Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the product. Supplementary identifiers must not obscure the original identifier. The facility associated with each identifier must be designated.

C8.221 Products shipped by registries may obscure the donor name and collection facility identifiers to maintain confidentiality as long as there is sufficient documentation to allow tracking to the original donor.

C8.230 Products must be identified according to the proper name of the product as defined in A3.000, including the appropriate modifiers.

C8.300 Label Content

C8.310 Partial Label

C8.311 If the container is capable of bearing only a partial label, the container must show as a minimum the unique identifier of the product, proper name of the product as well as the name and identifier of the intended recipient, if known.

C8.312 Additional information, as required in Section D8.300, must be provided with the product when the product is distributed.

C8.320 Labelling At the End of Collection

C8.321 Labelling at the end of collection must occur before the container is removed from the proximity of the donor.

C8.322 At the end of collection in the operating room or apheresis unit, the label on the primary container must bear the information in the Table D8.310.

C8.330 Biohazard Label

C8.331 A biohazard label must be applied to each product prior to release from the Collection Facility if any test shows evidence of infection due to communicable disease agent(s) as designated in B6.171 – B6.177.

C8.332 A biohazard label must be applied to each product if testing was not performed or final results are not available.

C9.000 Records

C9.100 Collection Facility Records

Records related to quality control, personnel training or competency, facility maintenance, facility management, or other general facility issues must be retained for 10 years by the collection facility, although not all need be immediately available.

C9.200 Patient Care Records

Patient care records including consents must be maintained in a confidential manner as required by applicable national and/or European Union regulations and directives.

C9.300 Research Records

Research records must be maintained in a confidential manner as required by applicable national and/or European Union regulations and directives.

C9.400 Records In Case Of Divided Responsibility

C9.410 If two or more facilities participate in the collection, processing or transplantation of the product, the records of each facility must show plainly the extent of its responsibility.

C9.420 The Collection Facility must furnish to the facility of final disposition a copy of all records relating to the collection and processing procedures performed in so far as they concern the safety, purity and potency of the product involved.

PART D: Haematopoietic Progenitor Cell and Therapeutic Cell Processing Standards

PART D: Haematopoietic Progenitor Cell and Therapeutic Cell Processing Standards

D1.000 General

D1.100 These Standards apply to the processing of marrow and/or peripheral blood cells by the collection facility and/or laboratory.

D1.200 The Processing Facility must abide by all applicable national and/or European Union regulations and directives.

D2.000 Laboratory Facilities

D2.100 The facility responsible for processing haematopoietic progenitor cells must be of adequate space and design for the intended procedures.

D2.200 The operation of the facility must be divided into defined areas of adequate size for each operation to prevent improper labelling and/or contamination of the product.

D2.300 The facility must be operated in a manner to minimise risks to the health and safety of employees, patients, donors and visitors.

D2.310 The facility must have written policies and procedures for infection control, biosafety, chemical and radiological safety, emergency response to worksite accidents, and waste disposal.

D2.311 Instructions for action in case of exposure to communicable disease, or to chemical, biologic and radiological hazards must be included in the safety manual.

D2.320 Decontamination and disposal techniques for medical waste must be described. Human tissue must be disposed of in such a manner as to minimise any hazard to facility personnel or the environment in accordance with applicable national and/or European Union regulations and directives.

D2.330 Eating, drinking, smoking, the application of cosmetics or the insertion or removal of contact lenses must not be permitted in work areas.

D2.340 Gloves and protective clothing must be worn while handling human tissue specimens. Such protective clothing must not be worn outside the work area.

D2.400 There must be adequate equipment for the procedures performed at the facility.

D2.500 The facility must be maintained in a clean and orderly manner as established in Standard Operating Procedures.

D2.600 The facility must be secure to prevent the admittance of unauthorised personnel.

D3.000 Personnel

D3.100 There must be a Laboratory Director who is an individual with a medical degree or doctoral degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the cell processing facility. The Laboratory Director is responsible for all procedures and administrative operations of the processing facility, including compliance with these Standards. The Laboratory Director should participate regularly in educational activities related to the field of haematopoietic cell processing and/or transplantation. The Laboratory Director may also serve as the Laboratory Medical Director if appropriately qualified.

D3.200 There must be a Medical Director who is a licensed physician with postgraduate training in haematopoietic cell processing and/or transplantation. This individual is directly responsible for the medical aspects of the processing procedures. The Medical Director should participate regularly in educational activities related to the field of haematopoietic cell processing and/or transplantation. The Medical Director may also serve as the Laboratory Director if appropriately qualified.

D3.300 There must be a Laboratory Quality Management Supervisor designated by the Laboratory Director to establish and maintain systems to review, modify as necessary, and approve all procedures intended to monitor compliance with these Standards and/or the performance of the facility. The Laboratory Quality Management Supervisor should participate regularly in educational activities related to the field of haematopoietic cell processing, transplantation and quality management.

D3.400 The Cell Processing Laboratory must have adequate staff whose training, continuing education, and continued competency for the performance of all operations must be documented.

D4.000 Quality Management

D4.100 The Cell Processing Laboratory must establish and maintain a programme of quality management as it pertains to the laboratory, under the supervision of a designated person. The individual must review and approve policies and procedures that document compliance with regulatory requirements and standards, and the performance of quality audits.

D4.110 Protocols must be developed, implemented and documented for the validation or qualification of significant procedures of facilities, processes, equipment, reagents, labels, containers, packaging materials, and computer systems. Determination of which elements are to be validated or qualified must be made by the Laboratory Director.

D4.120 Evaluation of validation studies and audits must be reviewed with documentation of approval by the appropriate individual from the quality management programme.

D4.130 Outcome Analysis

Documentation and review of time to engraftment after haematopoietic progenitor cell infusion must be part of the on-going quality management programme.

D4.200 Testing Of Products

D4.210 The Laboratory Director must prescribe tests and procedures for measuring, assaying, or monitoring properties of the cell products essential to the evaluation of their safety and usefulness. Results of all such tests and procedures must become part of the permanent record of the product processed.

D4.220 There must be documentation of on-going proficiency testing for tests performed within the cell processing laboratory as designated by the Laboratory Director.

D4.230 Tests required by these Standards, not performed by the haematopoietic progenitor cell collection or laboratory facility, must be performed in a laboratory accredited or licensed in accordance with applicable national and/or European Union regulations and directives.

D4.240 A nucleated cell count must be performed for any product after collection and as specified in Standard Operating Procedures.

D4.250 The processing facility must monitor and document microbial contamination of haematopoietic progenitor cells after processing and as specified in Standard Operating Procedures.

D4.251 The results of microbial cultures must be reviewed by the Laboratory Director or designee in a timely manner.

D4.252 The recipient's transplant physician must be notified in a timely manner of any positive microbial cultures.

D4.260 A test for the ABO group and Rh type must be performed on each product or on blood obtained from the donor at collection. If there are previous records, there must be a comparison of ABO group and Rh type with the last available record. Any discrepancies must be resolved and documented prior to issue of the product.

D4.261 A test for red cell compatibility must be performed if indicated.

D4.270 For products undergoing manipulation that alters the final cell population, a relevant and validated assay, where available, should be employed for evaluation of the target cell population before and after the processing procedure(s).

D4.300 Supplies and Reagents

D4.310 Protocols must be developed, implemented, and documented for the validation or qualification of significant products of facilities, processes, equipment, reagents, labels, containers, packaging materials, and computer systems. Determination of which elements are to be validated or qualified must be made by the Laboratory Director.

D4.320 Reagents used in processing and preservation of products must be of appropriate grade for the intended use and must be sterile.

D4.330 Procedures for production of in-house reagents must be validated.

D4.340 Each supply and reagent used in the processing and infusion of the product must be examined visually for damage or evidence of contamination as it comes into inventory. Such examination must include inspection for breakage of seals, abnormal colour and expiration date.

D4.350 All supplies and reagents used in the processing, testing, freezing, storage, and transplantation of products must be stored in a safe, sanitary, and orderly manner.

D4.360 All supplies and reagents coming into contact with products during processing, storage, and transplantation must be sterile.

D4.370 Supplies and reagents should be used in a manner consistent with instructions provided by the manufacturer.

D4.400 Equipment

D4.410 Equipment used in the processing, testing, freezing, storage, transportation, and transplantation of products must be maintained in a clean and orderly manner and located so as to facilitate cleaning, calibration and maintenance.

D4.420 The equipment must be observed, standardised and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and according to the manufacturer's recommendations.

D4.430 Sterilisation equipment must be designed, maintained and used to ensure the destruction of contaminating microorganisms.

D4.440 Refrigerators and freezers used for the storage of specimens, haematopoietic progenitor cell products, blood products, human tissues, or reagents must not be used for any other purpose.

D4.500 Review of Processing Records

D4.510 Records pertinent to the product must be regularly reviewed by the Laboratory Director or designee.

D4.520 The review may be performed at appropriate periods during or after product processing, testing, freezing, and storing.

D4.530 A thorough investigation, including resolution and outcome of any unexplained discrepancy or the failure of a product to meet any of its specifications must be made and documented.

D4.600 Errors, Accidents and Adverse Reactions

D4.610 Each cell processing facility must have a system for detecting, evaluating, documenting and reporting errors, accidents, suspected adverse reactions, biological product deviations and complaints. Corrective actions must be documented and reviewed by the Laboratory Director.

D4.620 All suspected clinical adverse reactions must be evaluated promptly according to Standard Operating Procedures, and reviewed by the Laboratory Medical Director.

D4.630 A written evaluation of reported adverse reactions must be included as part of the processing record and made available to the patient's physician.

D4.640 Where applicable, the event must also be reported to the clinical programme, the collection facility and appropriate regulatory agency.

D5.000 Policies and Procedures

D5.100 The Cell Processing Facility must have written policies and procedures addressing all appropriate aspects of the operation including processing; emergency and safety procedures; donor and patient confidentiality; quality management and improvement; errors, accidents and adverse reactions, biological product deviations; corrective actions; personnel training; competency assessment; outcome analysis; audits; labelling; storage, including alternative storage if the primary storage device fails; transportation; expiration dates; release and exceptional release; disposal of medical and biohazard waste; equipment and supplies; maintenance and monitoring; cleaning and sanitation procedures; and a disaster plan.

D5.200 The Cell Processing Laboratory must maintain a detailed Standard Operating Procedures (SOPs) Manual.

D5.210 The SOPs Manual must include:

D5.211 A procedure for preparing, implementing and reviewing all procedures.

D5.212 A standardised format for procedures, including worksheets, reports and forms.

D5.213 A system of numbering and/or titling of individual procedures.

D5.220 Procedures must be sufficiently detailed and unambiguous to allow qualified technical staff to follow and complete the procedures successfully. Each individual procedure requires:

D5.221 A clearly written description of the purpose.

D5.222 A clear description of equipment and supplies used.

D5.223 The objectives of the procedure, and acceptable end-points and the range of expected results where applicable.

D5.224 A reference section listing appropriate literature.

D5.225 Documented approval of procedure and each procedural modification by the Laboratory Director or Medical Director as appropriate prior to implementation and annually thereafter, including the associated validation studies.

D5.226 Examples of correctly completed orders, worksheets, reports, labels and forms, where applicable.

D5.300 Copies of the SOPs Manual must be available in the immediate area to the facility staff at all times.

D5.400 All personnel in the facility must follow the SOPs detailed in the manual.

D5.500 New and revised policies and procedures must be reviewed by the staff prior to implementation. This review and associated training must be documented.

D5.600 Archived procedures and their historical sequence must be maintained indefinitely, including the inclusive dates of use.

D5.700 Deviations from SOPs must be documented and approved, if appropriate, by the Laboratory Director or designee.

D5.800 SOPs for all procedures must comply with these Standards.

D6.000 Haematopoietic Progenitor Cell and Therapeutic Cell Processing

D6.100 Laboratory control procedures must include:

D6.110 The establishment of validated and appropriate assays, standards and test procedures for the evaluation of products.

D6.120 Provisions for monitoring the reliability, accuracy, precision and performance of laboratory test procedures and instruments.

D6.130 Identification and handling of all test samples so that they are accurately related to the corresponding product being tested, or to its donor, or to the corresponding recipient, where applicable.

D6.200 Cell Processing

D6.210 There must be a written request from the recipient's physician before processing is initiated.

D6.220 Processing of haematopoietic progenitor cells must be performed according to protocols defined in the facility's SOPs.

D6.230 Methods for processing must employ aseptic technique and be validated to result in acceptable haematopoietic progenitor cell viability and recovery.

D6.240 The objectives and acceptable end-points for each procedure must be specified.

D6.250 Worksheets must be maintained for all procedures.

D6.251 The individual responsible for each significant step of processing must be documented.

D6.252 Lot numbers and expiration dates of reagents and disposables and a record of key equipment used in processing must be documented.

D6.260 The Laboratory Director or designee must review the processing record for every product.

D6.261 The appropriate transplant physician must be notified when the clinically relevant processing end-points are not met.

D6.262 Notification and appropriate remedial actions, if taken, must be documented in the processing record.

D6.270 Processing using more than minimal manipulation must only be performed with Institutional Review Board or Research Ethics Committee approval where appropriate and with the written informed consent of the recipient of the product, or in compliance with applicable national and/or European Union regulations and directives.

D6.280 There must be a policy and procedure to cover the processing of ABO incompatible products.

D7.000 Cryopreservation

D7.100 Samples

D7.110 Sample aliquots of the product, cryopreserved and stored under the same conditions as the product, should be available for testing as necessary.

D7.200 Procedures

D7.210 Cryopreservation procedures must be included in the cell processing facility's SOPs and must describe:

D7.211 The name and freezing criteria of the haematopoietic progenitor cell product or aliquot.

D7.212 The cryoprotectant solution and its final concentration.

D7.213 Cryopreservation container.

D7.214 Acceptable range of product volume for reproducible cryopreservation.

D7.215 Acceptable range of nucleated cell concentration of the final product after cryopreservation.

D7.216 Cooling rate.

D7.217 Product temperature at endpoint of controlled cooling.

D7.218 Acceptable temperature range for storage.

D7.300 Cooling Rate:

D7.310 The cryopreservation procedure must be validated.

D7.320 The cooling rate achieved must be recorded if a rate-controlling device is used.

D8.000 Labels

D8.100 Labelling Operations

D8.110 Labelling operations must be conducted in a manner adequate to prevent mislabelling of products.

D8.120 The labelling operation must include the following quality management elements:

D8.121 Container labels must be held upon receipt from the manufacturer pending review and proofing against a copy approved by the Laboratory Director or designee to ensure accuracy regarding identity, content, and conformity.

D8.122 Stocks of unused labels representing different products must be stored in an orderly manner to prevent errors. Stocks of obsolete labels must be destroyed.

D8.123 A system of checks in labelling procedures must be used to prevent errors in translating information to container labels.

D8.124 All labelling must be clear and legible and printed using moisture-proof ink.

D8.130 Labels must be affixed or attached firmly to the container.

D8.140 The proper name and significant product modification(s) must be noted on the label.

D8.150 Products that are subsequently re-packaged into new containers must be labelled with new labels as appropriate. Records to allow tracking of products including collection or processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product identity, donor and recipient information on the original container must be maintained.

D8.160 When the label has been affixed to the container, a sufficient area of the container must remain uncovered to permit inspection of the contents.

D8.170 The product label must be complete. ‘Not applicable’ (NA) may be used when appropriate.

D8.180 Labelling requirements, if any, required by applicable national and/or European Union regulations and directives must be observed.

D8.200 Product Identification

D8.210 Each product. must be assigned a unique numeric or alphanumeric identifier by which it will be possible to relate any product to its donor, the donor's medical record, and to all records describing the handling and final disposition of the product. If a single product is stored in multiple containers, there must be a system of identifying each container.

D8.220 Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the product. Supplementary identifiers must not obscure the original identifier. The facility associated with each identifier must be designated.

D8.221 Products shipped by registries may obscure the donor name and collection facility identifiers to maintain confidentiality as long as there is sufficient documentation to allow tracking to the original donor.

D8.230 Products must be identified according to the proper name of the product as defined in A3.000, including the appropriate modifiers.

D8.231 Significant modifications made to the product subsequent to collection and prior to cryopreservation must be noted.

D8.300 Label Content

D8.310 Each label must include at least the elements detailed in the following table:

Element	Partial label	Label at completion of collection	Label during processing	Label at completion of processing	Label at distribution	Inner & outer shipping container label
Unique identifier of product.	X	X	X	X	X	
Proper name of product	X	X	X	X	X	
Recipient name and identifier	X (If applicable)	X (If applicable)	X (If applicable)	X (If applicable)	X	
Date, time collection ends and (if applicable) time zone		X		X	X	
Approximate volume		X		X	X	
Name and volume or concentration of anticoagulant and other additives		X		X	X	
Donor identifier and (if applicable) name		X		X	X	
Identity and address of collection facility or donor registry		X		X	X	
Recommended storage temperature		X		X	X	
Biohazard Label		X (if applicable)		X (if applicable)	X (if applicable)	X (if applicable)
Identity and address of processing facility				X	X	
ABO and Rh of donor				X	X	
RBC compatibility testing results					X (if applicable)	
Statement "Properly Identify Intended Recipient and Product"				X	X	
Statement "Warning: This Product May Transmit Infectious Agents"				X	X	
Expiration Date				X (if applicable)	X (if applicable)	
Expiration Time				X (if applicable)	X (if applicable)	
Statement "For Autologous Use Only" *OR* Statement "For Use By Intended Recipient Only"				X (if applicable) X (if for allogeneic recipient)	X (if applicable) X (if for allogeneic recipient)	
Statement “Do Not Irradiate”				X	X	
Statement "Not for Infusion" including reason				X (if applicable)	X (if applicable)	
Name and street address of receiving institution						X
Name and phone number of contact person at receiving institution						X
Statement "Medical Specimen"						X
Statement "Do Not X-Ray"						X
Name, street address and phone number of shipping facility						X

D8.320 Partial Label

D8.321 If the container is capable of bearing only a partial label, the container must show as a minimum the unique identifier of the product, proper name of the product as well as the name and identifier of the intended recipient, if known.

D8.322 Additional information, as required in Section D8.300, must be provided with the product when the product is distributed.

D8.330 Biohazard Label

D8.331 A biohazard label must be applied to each product if any test shows evidence of infection due to communicable disease agent(s) as designated in B6.171 – B6.177.

D8.332 A biohazard label must be applied to each product if testing was not performed or final results are not available.

D8.340 Label during Processing

D8.341 Any container used during processing must contain at a minimum the information required in the Table D8.310.

D8.350 Labelling at Completion of Processing

D8.351 At the end of processing, the label on the product container must bear the information in the Table D8.310.

D8.360 Labelling Prior To Distribution

D8.361 At the time of distribution the name and unique patient identifier of the intended recipient must be attached to the product container if this information is not already on the primary container label.

D9.000 Issue of Products Prior to Distribution

D9.100 Inspection of Products Prior To Distribution

D9.110 Each product issued for infusion must be inspected by two trained personnel immediately before release to verify appropriate labelling and integrity of the product container.

D9.120 The Laboratory Director or designee must give specific authorisation for use when the container is compromised and/or recipient information is not verified.

D9.200 Return of Products from Issue

D9.210 Products accepted for return must meet the following conditions:

D9.211 The integrity of the primary container has not been compromised subsequent to issue from the laboratory.

D9.212 The product has been maintained subsequent to issue at the specified temperature range during storage and transportation.

D9.220 If the conditions in Sections D9.211 and D9.212 have not been met, the Laboratory Director or designee must give specific authorisation to accept the products for return.

D9.230 The Laboratory Director or designee must consult with the patient's transplant physician regarding reissue or discard of the returned product.

D9.240 Documentation of the events requiring return, the results of inspection upon return, and subsequent action taken to ensure product safety and viability must be maintained in the laboratory record.

D9.300 Instructions for Administration

D9.310 For each type of product, the laboratory must maintain a current document containing the following as appropriate:

D9.311 The use of the haematopoietic progenitor cell product, indications, contraindications, side effects and hazards, dosage and administration recommendations.

D9.320 The instructions for administration must be available to the clinical staff caring for the recipient.

D9.400 Infusion Forms

D9.410 The laboratory must provide a written form to be completed for products issued containing at a minimum the name and unique identifier of the intended recipient, the proper product name and product identifier, and the initials of the medical staff receiving the product.

D10.000 Conditions for Storage

D10.100 Storage Duration

D10.110 Facilities storing haematopoietic progenitor cell products must establish policies for the duration and conditions of storage and indications for discard. Patients, donors, and associated transplant centres should be informed about these policies before haematopoietic progenitor cell collection.

D10.200 Temperature

D10.210 Storage temperatures must be defined in the SOPs Manual.

D10.220 Haematopoietic progenitor cells stored in a liquid state must be maintained within a specific temperature range and for a period of time specified in a Standard Operating Procedure.

D10.230 Cryopreserved products must be stored within a temperature range appropriate for the cell product and cryoprotectant solution used and as defined in the SOPs.

D10.300 Product Safety

D10.310 Materials that may adversely affect haematopoietic progenitor cell products must not be stored in the same refrigerators or freezers.

D10.320 For products immersed in liquid nitrogen, procedures to minimise the risk of microbial cross-contamination of products must be employed.

D10.400 Monitoring

D10.410 Refrigerators and freezers for product storage must have a system to monitor the temperature continuously and to record the temperature at least every 4 hours.

D10.411 For products fully immersed in liquid nitrogen continuous temperature monitoring is not required.

D10.420 There must be a mechanism to ensure that levels of liquid nitrogen in liquid nitrogen freezers are maintained.

D10.500 Alarm Systems

D10.510 Storage devices for products or reagents for product processing must have alarm systems that are continuously active.

D10.520 Alarm systems must have audible signals.

D10.530 If laboratory personnel are not always present in the immediate area of the storage device, a remote alarm device must be available at a location staffed 24 hours a day.

D10.540 Alarms must be set to activate at temperatures or an unsafe level of liquid nitrogen to allow time to salvage products.

D10.550 There must be written instructions to be followed if the storage device fails. These instructions must be displayed in the immediate area containing the storage device.

D10.551 A procedure for notifying laboratory personnel must be placed at each remote alarm location and in the immediate area of the storage device.

D10.560 Alarm systems must be checked periodically for function.

D10.570 Additional storage devices of appropriate temperature must be available for product storage if the primary storage device fails.

D10.600 Security

D10.610 The storage device must be located in a secure area. Locking capability for the device or the storage location should be used when the area is unattended.

D10.700 Inventory Control

D10.710 An inventory control system to identify the location of each product and associated sample aliquots must be in use.

D10.720 The inventory control system records must include:

D10.721 Donor name or identifier

D10.722 Patient name or identifier (if known)

D10.723 Product unique identifier.

D10.724 Product or specimen proper name

D10.725 Date of collection

D10.726 Storage device identifier

D10.727 Location within the storage device

D10.728 Dates of issue

D10.729 Disposition

D11.000 Transportation

D11.100 Procedures for transportation of non-frozen and/or cryopreserved products must be designed to protect the integrity of the product being shipped and the health and safety of facility personnel.

D11.200 The primary product container for non-frozen products must be placed in a secondary plastic bag and sealed to prevent leakage.

D11.300 Frozen or non-frozen products that leave the facility or are transported on public roads must be shipped in an outer shipping container.

D11.310 The outer shipping container must be thermally insulated and must conform to the regulations regarding the mode of transport.

D11.320 The outer shipping container should be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

D11.330 The shipping container must be of appropriate design and construction for transportation of the cryogenic material used.

D11.340 Cryopreserved products with an indicated storage temperature below -80°C must be shipped in a liquid nitrogen "dry shipper" that contains adequate absorbed liquid nitrogen to maintain temperature at least 48 hours beyond the expected time of arrival at the receiving facility.

D11.350 During transport, the product temperature must be maintained at the storage temperature specified by the Processing Laboratory.

D11.360 The sending facility must include a temperature monitor in the shipper.

D11.370 Outer shipping container must be labelled as defined in D8.300.

D11.380 There must also be a label inside the shipping container that includes all the information required on the outer shipping container as defined in D8.300.

D11.390 The shipping container must be labelled in accordance with applicable regulations regarding the cryogenic material used and the transportation of biologic materials.

D11.400 The receiving facility must verify the presence of cryogenic material (absorbed liquid nitrogen or dry ice as applicable) in the shipper and the status of the temperature monitor must be recorded upon arrival.

D11.500 Method of Transport

D11.510 The transit time should be minimised.

D11.520 If the intended recipient has received high-dose therapy, the product must be hand-carried by a suitably informed courier in the passenger compartment.

D11.530 There must be plans for alternative transport in an emergency.

D11.540 The products should not be passed through X-Ray irradiation devices designed to detect metal objects. If inspection is necessary, the contents of the container must be inspected by hand.

D11.600 Transport Records

D11.610 Transport records must permit tracing of the product from one facility to another.

D11.620 Transport records must identify the date and time product is shipped and received.

D11.630 Transport records must identify the source facility, the receiving facility, and the personnel responsible for shipping and receiving the product.

D11.640 Transport records must document the identity of the courier and any delays or problems occurring during transportation of the product.

D12.000 Disposal

D12.100 There must be a written policy for disposal of haematopoietic progenitor cell products.

D12.200 There must be a written agreement between the patient or designated recipient and the storage facility defining the circumstances for disposal or transfer of cells.

D12.210 If the patient or designated recipient is still alive his/her written consent for disposal or transfer of the products must be obtained. If consent is denied the patient must be offered the opportunity to ship the product to another facility.

D12.300 There must be written documentation of patient death or no further need for the product before any product is discarded.

D12.400 The records for discarded products must indicate the product discarded, date of discard, and method of disposal.

D12.500 The Laboratory Medical Director of the processing facility, in consultation with the patient's transplant physician, must approve of product discard and method of disposal.

D12.600 The method of disposal and decontamination must meet applicable national and/or European Union regulations and directives for disposal of biohazardous materials.

D13.000 Records

D13.100 General Requirements

D13.110 All records and communications among the collection, processing and transplant facilities and their patients must be regarded as privileged and confidential. Safeguards to assure this confidentiality must be established and followed in compliance with applicable national and/or European Union regulations and directives.

D13.120 Records must be made concurrently with each step of the processing, testing, cryopreservation, storage, and infusion or disposal of each product in such a way that all steps may be accurately traced.

D13.130 Records must be legible and indelible, must identify the person immediately responsible for each significant step, and must include dates (and times where appropriate) of various steps and must show the test results as well as the interpretation of each result where appropriate.

D13.140 Records of each step must be as detailed as necessary for a clear understanding of each step by a person experienced in haematopoietic progenitor cell processing and transplantation, and must be available for inspection by authorised individuals.

D13.150 Appropriate records must be available from which to determine the lot numbers and manufacturer of supplies and reagents used for the processing of specific products.

D13.160 Records must be maintained in such a way as to assure their integrity and preservation.

D13.200 Records to be Maintained Indefinitely

Records related directly to the processing, testing, storage or release of haematopoietic progenitor cells must be maintained indefinitely.

D13.210 Processing records:

D13.211 Identity of any facility involved in the collection, processing, storage or transplantation of the product.

D13.212 Product processing, including lot numbers and expiration dates of reagents and disposables and a record of key equipment used in processing must be documented.

D13.213 Authorisation by the transplant physician for the processing of products.

D13.214 Results and interpretation of all tests and re-tests.

D13.215 Information on characterisation of materials and devices used in the manipulation of products including but not limited to antibodies, serum, cytokines, toxins, antibiotics, pharmacologic agents, other chemicals or solid supports. Records must include the manufacturer's name and lot numbers of all reagents used.

D13.216 Records of laboratory personnel involved in the labelling, processing, storage or distribution of the product, including their name, signature, initials, identification and inclusive dates of employment.

D13.217 Documentation of donor's infectious disease testing results.

D13.218 Signature of the Laboratory Medical Director authorising the release of products in cases where there is a nonconforming product.

D13.220 Storage and distribution records:

D13.221 Distribution or disposition, as appropriate, of products.

D13.222 Visual inspection of liquid products immediately before distribution.

D13.223 Product storage temperature, including initialled temperature recorder charts.

D13.224 Reissue, including records of proper temperature maintenance, documentation of events requiring return, results of inspection upon return and actions taken to insure product safety and viability prior to reissue.

D13.230 Compatibility test records:

D13.231 Results of all compatibility tests, including red cell compatibility testing of patient samples, antibody screening and identification as specified in the facility SOPs.

D13.240 Errors, accidents, adverse reactions and complaints:

D13.241 Records of errors, accidents and corrective action regarding processing, storage or infusion occurring within the facility.

D13.250 All superseded procedures and policies.

D13.300 Records to Be Maintained For 10 Years

Records related to quality control, personnel training or competency, equipment maintenance, sterilisation of supplies and reagents, disposition of rejected supplies and reagents, management, or other general facility issues must be retained for 10 years by the processing facility, although not all need be immediately available. If national and/or European Union regulations and directives require a longer retention period, records must be retained for the period required by such regulations and directives.

D13.310 Temperature charts and records for storage of reagents.

D13.320 Calibration and standardisation of equipment including initial installation.

D13.330 Performance checks of equipment and reagents.

D13.340 Periodic tests of capacity and integrity of shipping containers to maintain proper temperature in transit.

D13.350 Periodic check on aseptic technique and competency.

D13.360 Proficiency test results.

D13.370 Results of inspection and accreditation visits.

D13.380 General facility records.

D13.381 Sterilisation records of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.

D13.382 Technical personnel training, continuing education, and periodic competency testing

D13.383 Maintenance records for equipment including preventive maintenance and general physical plant.

D13.384 Documentation of acceptance for supplies and reagents, including name of manufacturer or supplier, lot numbers, date of receipt and expiration date as established in the facility SOPs.

D13.385 Disposition of rejected supplies and reagents used in the collection, processing, testing, freezing and storage of products.

D13.400 Electronic Records

An electronic record is any record or document consisting of any combination of text or graphics or other data that is created, stored, modified, or transmitted in digital form by a computer.

D13.410 If a computer record-keeping system is used, there must be a system to ensure the authenticity, integrity and confidentiality of all records.

D13.420 There must be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

D13.430 The facility must have an alternative system that ensures continuous operation in the event that computerised data are not available. The alternative system must be tested periodically.

D13.440 There must be established written procedures for record entry, verification and revision. A system must be established for display of data before final acceptance.

D13.441 The quality assurance system must include an assessment of computer functions to ensure that errors and problems are reported and resolved.

D13.450 There must be a system whereby access is limited to authorised individuals.

D13.460 There must be the ability to generate true copies of the records in both paper and computer form suitable for inspection and review.

D13.470 When a computer system is used, there must be validated procedures for and documentation of:

D13.471 Systems development, if carried out internally.

D13.472 Numerical designation of system versions if applicable.

D13.473 Prospective validation of system, including hardware, software, and database.

D13.474 Installation of the system.

D13.475 Training and continuing competency of personnel in systems use.

D13.476 Validation and monitoring of data integrity.

D13.477 Policies and procedures for system maintenance and operations. Documentation must be complete, in language understandable by users.

D13.480 All system modifications must be authorised, documented, and validated prior to implementation.

D13.490 The computer system must ensure that all donor, product and patient identifiers are unique.

D13.500 Records In Case Of Divided Responsibility

D13.510 If two or more facilities participate in the collection, processing or transplantation of the product the records of the Cell Processing Laboratory must show plainly the extent of its responsibility.

D13.520 The Cell Processing Laboratory must furnish to the facility of final disposition a copy of all records relating to the collection and processing procedures performed in so far as they concern the safety, purity and potency of the product involved.

Appendix 1: Comparison of the JACIE Standards, 1st Edition, 1998 to the JACIE Standards, 2nd Edition, 2003.

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
A1.000	A1.000
A1.100	A1.000
A1.200	A2.000/A3.000
A2.000	B5.000/C5.000/D5.000
A2.100	B5.100/C5.100/D5.100
A2.200	B5.200/C5.200/D5.200
A2.210	B5.210/C5.210/D5.210
A2.211	B5.211/C5.211/D5.211
A2.212	B5.212/C5.212/D5.212
A2.213	B5.213/C5.213/D5.213
A2.220	B5.220/C5.220/D5.220
A2.221	B5.221/C5.221/D5.221
A2.222	B5.222/C5.222/D5.222
A2.223	B5.223/C5.223/D5.223
A2.224	B5.224/C5.224/D5.224
A2.225	B5.225/C5.225/D5.225
A2.226	B5.226/C5.226/D5.226
A2.230	B5.800/C5.800/D5.800
A2.240	B5.700/C5.700/D5.700
A2.250	B5.300/C5.300/D5.300
A2.260	B5.400/C5.400/D5.400
A2.270	B5.500/C5.500/D5.500
A2.280	B5.600/C5.600/D5.600
A3.000	C4.130/D4.110
A3.100	C4.130/D4.110
A3.200	C4.140/D4.120
A4.000	B4.000/C4.000/D4.000
A4.100	B4.100/C4.100/D4.100
A4.200	B8.200
A4.300	B4.300/C4.600/D4.600
A4.310	B4.310/C4.610/D4.610
A4.320	B4.320/C4.620/D4.620
A4.330	B4.330/C4.630/D4.630
A4.340	B4.340/C4.640/D4.640
A5.000	B2.200/C2.700
A5.100	B2.210/C2.710/D2.300
A5.200	B2.220/C2.720/D2.310
A5.300	B2.230/C2.730/D2.320
B1.000	B1.100
B2.000	B1.300
B2.100	B1.310
B2.200	B1.320
B2.300	B1.330
B3.000	B8.100
B4.000	B9.000
B4.100	B9.100
B4.200	B9.200 (MED A forms)
B5.000	B4.000/B4.100
B6.000	B3.000
B6.100	B3.100
B6.200	B3.200
B6.210	B3.210
B6.220	B3.220
B6.230	B3.230
B6.240	B3.240
B6.300	B3.300

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
B6.310	B3.310
B6.320	B3.320
B6.400	B3.400
B6.410	B3.410
B6.411	B3.411
B6.412	B3.412
B6.420	B3.420
B6.421	B3.421
B6.422	B3.422
B6.430	B3.430
B6.431 (a)	B3.432(c)
B6.431 (b)	B3.431(a)
B6.432	B3.432
B6.500	B3.600/B3.610
B6.600	B3.700
B6.610	B3.710
B6.620	B3.730
B6.700	B3.800
B6.710	B3.810
B6.720	B3.820
B6.730	B3.830
B6.740	B3.840
B6.750	B3.850
B6.760	B3.860
B7.000	B2.000
B7.100	B2.110
B7.200	B2.120
B7.300	B2.130
B7.400	B2.140
B7.500	B2.150
B7.600	B3.740
B8.000	B2.160/B2.170
B8.100	B2.160/B2.170
B8.110	B2.160
B8.120	B2.170
B8.200	B2.170/B2.190
B8.210	B2.170
B8.220	B2.190
C1.000	B6.000
C1.100	B6.100
C1.110	B6.120
C1.120	B6.130
C1.200	B6.200/B6.300
C1.210	B6.200
C1.211	B6.150/B6.210
C1.212	B6.160/B6.161
C1.213	B6.163
C1.214	B6.223
C1.215	B6.220
C1.215 (a)	B6.221
C1.215 (b)	B6.222
C1.215 (c)	B6.170-B6.178
C1.216	B6.164
C1.217	B6.210
C1.218	B6.170/C6.100
C1.220	B6.300

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
C1.221	B6.170-B6.178 B6.311/B6.312
C1.222	B6.170-B6.178
C1.223	B6.150/B6.210
C1.300	C6.000
C1.310	C6.000
C1.311	B6.150
C1.312	C6.200
C1.313	C6.300
C1.320	C6.000
C1.321	B6.150/B6.160/B6.161 B6.163/B6.164/B6.210 B6.220-B6.223/ B6.170-B6.178/C6.100
C1.322	B6.170-B6.178
C1.330	B6.300/B6.311/B6.312 B6.170-B6.178/C6.100
C1.400	NETCORD
C1.410	NETCORD
C1.411	NETCORD
C1.412	NETCORD
C1.413	NETCORD
C1.414	NETCORD
C1.415	NETCORD
C1.416	NETCORD
C1.420	NETCORD
C1.500	B6.400
C1.510	B6.400
C1.511	B6.411/B6.421
C1.512	B6.412/B6.422
C1.513	B6.413/B6.423
C1.514	B6.414/B6.424
C1.515	B6.415
C1.520	NETCORD
C1.521	NETCORD
C2.000	C2.000
C2.110	C3.100
C2.111	C3.110
C2.112	NETCORD
C2.120	C3.300
C2.130	C4.210
C2.140	C2.300
C2.150	C2.100
C2.160	C2.200
C2.200	C2.000
C2.210	C2.210
C2.220	C2.220
C2.230	C2.400
C2.300	C2.000
C2.310	C2.100/C2.210-C2.220 C2.300/C2.400/C3.100 C3.110/C3.300/C4.210
C2.320	C2.600
C2.330	C2.500
C2.400	NETCORD
C3.000	C7.100
C3.100	B6.100/B6.120/B6.130

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
C3.200	C5.000
C3.300	C7.200
C3.400	C7.300
C3.500	C4.310
C3.600	C4.350
C3.700	C7.400/C8.000/D8.300
C3.710	C7.410
C3.720	C7.420
C3.800	C4.600-C4.640
D1.000	D1.000
D1.100	D3.000
D1.110	D3.100
D1.120	D3.200
D1.130	D3.100/D3.400
D1.140	D3.400
D1.200	D2.000
D1.210	D2.100
D1.220	D2.400
D1.230	D2.500
D1.240	D2.600
D1.300	D5.000
D1.310	D3.300
D1.320	D5.200
D1.400	D2.300
D1.410	D2.300
D4.420	D2.310
D1.421	D2.311
D1.430	D2.320
D1.440	D2.330
D1.450	D4.440
D1.460	D2.340
D2.000	D6.000
D2.100	D6.000
D2.110	B6.000
D2.120	D6.210
D2.130	D6.220
D2.140	A3.000
D2.150	A3.000
D2.160	A3.000
D2.170	D6.270
D2.171	D6.270
D2.172	D6.270
D2.180	D6.230
D2.190	D6.250
D2.1100	D6.240
D2.1110	D6.260
D2.1111	D6.261
D2.1112	D6.262
D2.1120	D4.410
D2.1130	D6.252
D2.200	A3.000
D2.210	A3.000
D2.220	A3.000
D2.230	A3.000
D2.231	A3.000
D2.232	A3.000

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
D2.240	A3.000
D2.241	A3.000
D2.242	A3.000
D2.250	NETCORD
D2.251	NETCORD
D2.252	NETCORD
D2.260	A3.000
D2.300	A3.000
D2.310	A3.000
D2.320	A3.000
D2.330	A3.000
D2.331	A3.000
D2.332	A3.000
D2.333	A3.000
D2.334	A3.000
D3.000	D7.000
D3.100	D7.100/D7.110
D3.200	D7.210
D3.210	D7.211
D3.220	D7.212
D3.230	D7.215
D3.240	D7.216
D3.250	D7.217
D3.260	D7.218
D3.300	D7.300
D3.310	D7.310
D3.320	D7.320
D4.000	D4.000
D4.100	D4.200
D4.110	D4.210
D4.120	D4.230
D4.130	D4.240
D4.140	D4.250
D4.141	D4.251
D4.142	D4.252
D4.150	D4.260
D4.160	D4.130
D4.170	D4.270
D4.171	D4.270
D4.180	D6.280
D4.200	D4.210
D4.210	D4.210
D4.211	D4.210
D4.212	D4.310
D4.213	
D4.300	D4.300
D4.310	D4.310
D4.320	D4.350
D4.330	D4.360
D4.340	D4.320/D4.360
D4.350	
D4.351	
D4.360	D4.340
D4.370	
D4.380	D4.370

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
D4.400	D4.400
D4.410	D4.410
D4.420	D4.420
D4.430	D4.430
D4.500	D4.510/D4.520/D4.530
D5.000	C8.000/D8.000
D5.100	C8.100/C8.100
D5.110	C8.110/D8.110
D5.120	C8.120/D8.120
D5.121	C8.121/D8.121
D5.122	C8.122/D8.122
D5.123	C8.123/D8.123
D5.124	C8.124/D8.124
D5.130	C8.130/D8.130
D5.131	C8.150/D8.150
D5.140	C8.160/D8.160
D5.200	C8.200/D8.200
D5.210	C8.210/D8.210
D5.220	C8.220/D8.220
D5.300	C8.310/D8.320
D5.310	C8.311/D8.321
D5.320	C8.312/D8.322
D5.400	C8.320/D8.310
D5.410	C8.322/D8.310
D5.411	C8.322/D8.310
D5.412	C8.322/D8.230/ D8.310
05.413	C8.322/D8.310
D5.414	C8.322/D8.310
D5.415	C8.322/D8.310
D5.416	C8.322/D8.310
D5.417	C8.322/D8.310
D5.418	C8.322/D8.310
D5.500	D8.360
D5.510	D8.310/D8.361
D5.511	D8.310
D5.512	D8.310
D5.513	D8.310/D8.361
D5.514	D8.310/D8.361
D5.515	D8.330
D5.516	D8.330/D8.331/D8.310
D5.517	D8.310
D5.518	D8.230
D5.519	D8.310
D5.520	D8.310
D5.530	D8.310
D5.540	D8.310
D5.600	D8.310/D8.360
D5.610	D8.310
D5.620	D8.310/D11.380
D5.621	D8.310/D11.380
D5.622	D8.310/D11.380
D5.623	D8.310/D11.380
D5.624	D8.310/D11.380
D5.700	D8.310
D5.710	D8.310/D8.351

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
D5.711	D8.310
D5.712	D8.310
D5.713	D8.310
D5.720	D9.400
D5.800	D9.000
D5.810	
D5.811	D8.310
D5.812	D9.400
D5.820	D9.100
D5.830	D9.200
D5.831	D9.210
D5.831 (a)	D9.211
D5.831 (b)	D9.212
D5.832	D9.220
D5.833	D8.310/D9.100
D5.834	D9.240
D5.900	D9.300
D5.910	D9.310
D5.911	D9.311
D5.920	D9.320
D6.000	D10.000
D6.100	D10.100
D6.110	D10.110
D6.200	D10.200
D6.210	
D6.211	D10.220
D6.220	
D6.221	D10.230
D6.230	D10.210
D6.240	D10.320
D6.300	
D6.310	D10.310
D6.400	D10.400
D6.410	D10.410
D6.411	D10.411
D6.420	D10.420
D6.500	D10.500
D6.510	D10.510
D6.520	D10.520
D6.530	D10.530
D6.540	D10.540
D6.550	D10.550
D6.551	D10.551
D6.560	D10.560
D6.570	D10.570
D6.600	D10.600
D6.610	D10.610
D6.700	D10.700
D6.710	D10.710/D10.720
D7.000	D11.000
D7.100	
D7.110	D11.200
D7.120	
D7.121	D4.370
D7.122	

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
D7.123	D11.100/D11.200
D7.130	
D7.131	D11.200
D7.140	
D7.141	D11.310
D7.142	D11.320
D7.143	
D7.150	D8.310
D7.151	D8.310/D11.380
D7.152	D8.310/D11.370
D7.160	
D7.161	D11.350
D7.162	
D7.163	
D7.164	
D7.170	D11.500
D7.171	D11.510
D7.172	D11.520
D7.173	D11.530
D7.174	D11.540
D7.180	D11.600
D7.181	
D7.182	D11.630
D7.183	D11.640
D7.200	
D7.210	D11.340
D7.220	
D7.230	D11.360/D11.400
D7.240	D11.330
D7.241	D11.310
D7.250	D11.390
D7.300	D11.100
D8.000	
D8.100	D12.000
D8.110	D12.100
D8.120	D12.200
D8.130	D12.300
D8.140	D12.400
D8.150	D12.500
D8.151	D12.210
D8.160	D12.600
D9.000	D13.000
D9.100	D13.100
D9.110	D13.120
D9.120	D13.130
D9.130	D13.140
D9.140	D13.150
D9.150	D13.110
D9.160	D13.160
D9.200	D13.400
D9.210	D13.410
D9.220	D13.420
D9.230	D13.430
D9.240	D13.440
D9.241	D13.441

JACIE STANDARDS 1st Edition, 1998	JACIE STANDARDS 2nd Edition, 2003
D9.260	D13.460
D9.270	D13.470
D9.271	D13.471
D9.272	D13.472
D9.273	D13.473
D9.274	D13.474
D9.275	D13.475
D9.276	D13.476
D9.277	D13.477
D9.280	D13.480
D9.290	D13.490
D9.300	D13.000
D9.310	
D9.311	B10.200/C9.200
D9.312	D13.210
D9.312(a)	D13.212/D13.214
D9.312(b)	D13.216
D9.312(c)	D13.217
D9.313	D13.220
D9.313(a)	D13.221
D9.313(b)	D13.222
D9.313(c)	D13.223
D9.313(d)	D13.224
D9.314	D13.230
D9.314(a) (b)	D13.231
D9.315	
D9.315(a)	D13.320
D9.315(b)	D13.330
D9.315(c)	D 13.350
D9.315(d)	D13.340
D9.315(e)	D13.360
D9.315(f)	D13.370
D9.316	D13.100
D9.316(a)	D13.381
D9.316(b)	D13.216
D9.316(c)	D13.241
D9.316(d)	D13.383
D9.316(e)	D13.384
D9.316(f)	D13.385
D9.400	D13.240
D9.410	D13.241
D9.420	D4.640
D9.500	D13.000
D9.510	D13.200
D9.511	D13.221
D9.512	B10.200/C9.200/D13.217
D9.513	B10.200
D9.514	D13.211
D9.515	D13.213
D9.516	B10.200/C9.200/D13.212
D9.517	B10.100/C9.100/D13.216
D9.518	D13.215
D9.519	
D9.5110	D13.218
D9.5111	D13.240
D9.5112	D13.240
D9.5113	D13.250
D9.520	
D9.521	D13.310
D9.522	D13.300/D13.320/ D13.330/D13.340/ D13.350/D13.360/
D9.523	D13.382
D9.524	D13.383
D9.525	D13.381
D9.526	D13.385
D9.600	B10.400/C9.400/D13.500
D9.610	B10.410/C9.410/D13.510
D9.620	B10.420/C9.420/D13.520

Based on comparison prepared by FACT Technical Coordinators:
Sarah Litel-Smith, BSMT (ASCP)
Linda Cave, BSMT (ASCP)

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