



ACCREDITATION MANUAL – Standards for Amniotic Membrane

(Chapter G)

EUROPEAN GROUP FOR ACCREDITATION AND
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS



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INTRODUCTION

EGALiTE is a voluntary accreditation programme endorsed by the leading European Scientific Societies [European Eye Bank Association (EEBA), European Association of Tissue and Cell Banks (EATCB), and European Society for Blood and Marrow Transplantation (EBMT), and European Blood Alliance (EBA)].

The EGALiTE Standards are designed to provide guidelines for organisations, programmes, facilities, and individuals involved in activities pertaining to Substances of Human Origin (SoHO) - or providing support services for such activities – and who wish to apply for the European/EGALiTE Accreditation Program.

These Standards are designed by experts in the SoHO field for facilities wishing to demonstrate their commitment to quality medical care and best laboratory practice through an EGALiTE accreditation.

EGALiTE Standards are intended to apply to all actions performed by SoHO Entities in the preparation of SoHO, which include donor recruitment, selection, evaluation, testing, and SoHO collection, sampling, quality control, processing, preservation, storage, release and distribution for clinical application. The standards applicable to hematopoietic progenitor cells (HPC) activities are defined by FACT-JACIE (Foundation for the Accreditation of Cellular Therapy and Joint Accreditation Committee of the International Society for Cell and Gene Therapy and the European Society for Blood and Marrow Transplantation (EBMT))^{*} and the World Marrow Donor Association (WMDA)[†], and are not included in this guide.

The EGALiTE Standards were defined taking into account on the good practices defined by:

- European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) Guide to the quality and safety of tissues and cells for human application¹;
- EDQM Guide to the preparation, use and quality assurance of Blood Components²
- FACT-JACIE³;
- WMDA Standards⁴
- EuroGTP I and EuroGTP II⁵
- And other guidelines, namely related with the Good Manufacturing Practices (GMP)⁶ and quality management.

^{*} The scope of the FACT-JACIE Standards includes:

- HPCs defined as self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluripotent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).
- Nucleated cells or mononuclear cells from any hematopoietic tissue source (marrow, peripheral blood, umbilical cord, and placental blood) collected for therapeutic use other than as HPCs.
- Immune effector cells (IECs), defined as cells, in vitro modified or not, that have differentiated into a form capable of modulating or effecting a specific immune response.
- Genetically modified cells, defined as cells that have been modified by replacing a disease-causing gene with a health copy of the gene, inactivating a disease-causing gene that is not functioning properly, or introducing a new or modified gene into the body to help treat a disease.
- Clinical administration of the cellular therapy products derived from umbilical cord.

[†] WMDA standards cover all aspects of blood stem cell registry operations

These Standards are not intended to establish absolute best practice or include all procedures and practices that an organisation, programme, facility, or individual should implement if the standard of practice in the community or applicable governmental laws or regulations have determined additional requirements. Each organisation, programme, facility, and individual should analyse its practices and procedures to ascertain whether additional standards apply. In addition, compliance with these Standards is not an exclusive means of complying with the required standards of care as dictated by local, national, or international laws or regulations.

Compliance with the Standards does not guarantee compliance with Applicable Law. Governmental regulations must also be followed. It is the responsibility of the individual facility to determine which laws and regulations are applicable. In some cases, regulations of governmental authorities outside of the jurisdiction of the Donation Centre may apply; for example, when a facility is sending or receiving SoHO from outside of its immediate jurisdiction.

Compliance with other organisations' standards or governmental regulations does not ensure that the Standards have been met. Governmental regulations supersede any organisation's standards if those regulations set a higher standard or are inconsistent with a specific standard. However, if a standard is more rigorous than a governmental regulation, that standard must be followed.

Disclaimer

EGALiTE expressly disclaims any responsibility for setting maximum standards and additionally expressly disclaims any responsibility, liability, or duty to member programmes, directors, staff, or programme donors or patients for any such liability arising out of injury or loss to any person by the failure of member programmes, directors, or staff to adhere to the Standards or related guidance.

While the EGALiTE Accreditation Programme encourages the sharing of best practices and recommendations, it does not assume the role of a regulatory body or authority. The EGALiTE Accreditation Programme involves a peer review process designed to assess and evaluate the compliance of SoHO organisations with standards and criteria established in the present document, where experts in the field conduct assessments based on predetermined criteria. The peer review process is conducted with the utmost independence and impartiality to ensure a fair and unbiased evaluation, and the compliance with the best practices.

The EGALiTE Accreditation Programme is not responsible for informing National Competent Authorities of any non-compliance identified during the peer review process, including major non-compliances.

Participants voluntarily engage in this process to demonstrate their commitment to quality and best practices, and organisations participate in the EGALiTE Accreditation Programme voluntarily, acknowledging that the outcomes of the process are not intended for regulatory purposes.

ABBREVIATIONS[‡]

ADM	Acellular dermal matrix (ADM)
AM	Amniotic Membrane
aW	available water
CAPA	Corrective and Preventive Actions
CFU	Colony-forming units
CMV	Cytomegalovirus
CV	Cardiovascular
DALK	Deep anterior lamellar keratoplasty
DCD	Deceased donors after circulatory death
DMEK	Descemet membrane endothelial keratoplasty
DMSO	Dimethyl sulphoxide
DSAEK	Descemet stripping automated endothelial keratoplasty
EATCB	European Association of Tissue and Cell Banks
EBA	European Blood Alliance
EBMT	European Society for Blood and Marrow Transplantation
EBV	Epstein–Barr virus
ECDC	European Centre for Disease Prevention and Control
EDQM Blood	Guide to the preparation, use and quality assurance of Blood Components (20 th Edition)
EDQM Guides	<i>Guide to the quality and safety of tissues and cells for human application</i> and <i>Guide to the preparation, use and quality assurance of Blood Components</i>
EDQM Tissue and Cells	Guide to the quality and safety of tissues and cells for human application (5 th Edition)
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEBA	European Eye Bank Association
EK	Endothelial keratoplasty
EM	Electron microscopy
EU	European Union
EuroGTP II	Good Practices for demonstrating safety and quality through recipient follow-up - Good Practices for evaluating quality, safety and efficacy of novel tissue and cellular therapies and products (EU Project 709567)
FMEA	Failure mode and effects analysis
FMECA	Failure mode, effects and criticality analysis
FMT	faecal microbiota transplantation
FTSG	Full-thickness skin graft

[‡] For practical reasons, the present list includes the abbreviations and acronyms utilized in other chapters of the EGALiTE Standards.

GAPP JA	Facilitating the Authorisation of Preparation Process for blood, tissues and cells, Joint Action
GMP	Good Manufacturing Practice
HACCP	Hazard analysis and critical control points
HM	Human Milk
HMB	human milk bank
HoP	Holder pasteurisation
HV	Heart valve
IDM	infectious disease marker
JACIE	Joint Accreditation Committee of the ISCT (International Society for Cellular Therapy) and the EBMT
MiRCA	Microbiological Risk of Contamination Assessment tool for tissues and cells
MSK	Musculoskeletal Tissues
ORHA	Organisations for Human Application
PK	Penetrating keratoplasty
PPA	Preparation Process Authorisation
PQR	Product Quality Review
PRF	Platelet-Rich fibrin
PRP	Platelet-Rich Plasma
QM	Quality Manager
rCDI	<i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> infection
RP	Responsible Person
SARE	Serious Adverse Reaction and Event
SED	Serum Eye Drops
SMF	Site Master File
SoHO	Substances of Human Origin
SOP	Standard Operating Procedure
TED	Tissue Establishment Dossier
TGOT	Technical Guidelines for Ocular Tissue
TNC	Total nucleated cell
UCB	Umbilical Cord Blood
URS	User-requirement specifications
VMP	Validation Master Plan
WMDA	World Marrow Donor Association

DEFINITIONS[§]

Audit	means a systematic and independent examination to determine whether activities and the related results of such activities comply with legislation and planned arrangements and whether such arrangements are applied effectively and are suitable to achieve the objectives ⁷
Collection	means a process by which SoHO are obtained from a person, including any preparatory steps, such as hormone treatment, needed to facilitate the process at, or under the supervision of, a SoHO entity ⁷
Donation Centre	A SoHO Entity that carries out one or more of the activities: SoHO donor history review and eligibility assessment; SoHO testing of donors for eligibility or matching purposes; collection of SoHO from donors or patients.
Donor recruitment	means any activity aimed at informing persons about activities related to SoHO donation or at encouraging them to donate SoHO ⁷
Must (or shall)	Indicates an absolute requirement. Compliance with the statement is mandatory, and failure to meet this requirement is considered a violation of the standard.
Processing	All operations involved in the preparation, manipulation, preservation, storage and packaging of SoHO intended for human application. ¹ means any operation involved in the handling of SoHO, including, but not limited to, washing, shaping, separation, decontamination, sterilisation, preservation and packaging, except for the preparatory handling of SoHO for immediate human application during a surgical intervention, without the SoHO being removed from the surgical field before they are applied ⁷ .
Qualification	According to European Union Good Manufacturing Practice (EU GMP) ^{6,8} , the action of proving that any equipment works correctly and actually leads to the expected results. More generally, qualification is applied to the inputs to a process, i.e. equipment, facilities, materials and software (and their suppliers), as well as to operators and the relevant written procedures ¹
Quality Management System	The organisational structure, with defined responsibilities, procedures, processes and resources, for implementing quality management, including all activities that contribute to quality, directly or indirectly ¹
Risk assessment	Identification of potential hazards with an estimation of the likelihood that they will cause harm and of the severity of the harm should it occur ¹ .

^{§ §} For practical reasons, the present list includes the definitions referred in other chapters of the EGALiTE Standards.

Should	Indicates a recommendation. While it is not mandatory, adherence to this statement is strongly advised to ensure the best outcomes. Non-compliance is not a violation of the standard but may affect the overall effectiveness or quality of the implementation.
SoHO Entity	Means an organisation legally established in the Union that carries out one or more of the SoHO activities that have a direct impact on the quality, safety or effectiveness of SoHO, as follows: (i) SoHO donor registration; (ii) SoHO donor history review and medical examination; (iii) testing of SoHO donors or of persons from whom SoHO are collected; (iv) collection; (v) processing; (vi) quality control; (vii) storage; (viii) release; (ix) distribution; (x) import; (xi) export; (xii) human application; (xiii) clinical-outcome registration. ⁷
SoHO establishment	means a SoHO entity that carries out any of the following SoHO activities: (a) both processing and storage; (b) release; (c) import; (d) export. ⁷
SoHO preparation	means a type of SoHO that: (a) has been subjected to processing and, where relevant, one or more other SoHO activities referred to in Article 2(1), point (c) of the EU SoHO Regulation; (b) has a specific clinical indication; and (c) is intended for human application to a SoHO recipient or is intended for distribution. ⁷
SoHO Regulation	Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024, on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.
Substance of Human Origin (SoHO)	means any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance ⁷
Validation	Documented evidence giving a high degree of assurance that a specific process or system, including pieces of equipment or the environmental conditions, will perform consistently to deliver a product meeting its pre-determined specifications and quality attributes, based on intended use (EU Directive 2006/86/EC⁹)¹. or Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled (ISO9000:2015¹⁰)¹
Verification	Preferred term for the validation or qualification of IT systems/software. Or, Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO9000:2015 ¹⁰) ¹

INDEX/STANDARDS STRUCTURE

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	C. PROCESSING, STORAGE AND RELEASE OF SoHO		I. CARDIOVASCULAR
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	D. DISTRIBUTION		K. UMBILICAL CORD BLOOD
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	E. REGISTRIES AND VIGILANCE		M. HUMAN MILK
			N. BLOOD COMPONENTS FOR TOPICAL USE OR INJECTION
			O. INTESTINAL MICROBIOTA

PART G.1.: AMNIOTIC MEMBRANE

Donor Evaluation

STANDARD:

G.1.001 Placenta/fetal membranes must be collected only from living donors, after a full-term pregnancy

Evidence:

SOP on procurement of placenta/ fetal membranes

STANDARD:

G.1.002 In addition to the general exclusion criteria, the following specific conditions exclude placenta/fetal membranes donation:

- a. significant local bacterial, viral, parasitic or mycotic infection of the genital tract, especially amniotic infection syndrome;*
- b. (known) malformation of the unborn/newborn;*
- c. premature rupturing of membranes;*
- d. endometritis;*
- e. meconium ileus;*
- f. vaginal delivery or emergency caesarean delivery, if a terminal sterilisation is not performed.*

Explanation:

Other diseases of the female genital tract or other diseases of the donor or unborn child that present a risk to the recipient include may also be considered exclusion criteria for Amniotic Membrane (AM) donation.

Evidence:

SOP defining exclusion criteria.

Collection

STANDARD:

G.1.003 Donor placenta/fetal membranes must be procured by clinical staff at obstetrics units after delivery.

Evidence:

SOP on procurement of placenta/ fetal membranes

STANDARD:

G.1.004 Staff undertaking procurement must be dressed appropriately for the procedure to minimise the risk of contamination of the procured tissue and any hazard to themselves.

Evidence:

SOP on procurement of placenta/ fetal membranes

STANDARD:

G.1.005 The storage and transport time of procured placenta/fetal membranes must be kept as short as possible (the recommended maximum time is 24 h) and a temperature of +2-8 °C must not be exceeded. If AM is processed within less than 2 h after the delivery, the placenta/fetal membranes may be transported at room temperature

Explanation:

Placenta/fetal membranes must be stored at appropriate temperatures to maintain the structural and biological properties of AM.

Evidence:

SOP on procurement of placenta/fetal membranes and any validation reports required for alternative procedures defined.

STANDARD:

G.1.006 Procured placenta/fetal membranes must be placed in a sterile, pre-labelled container. If the transport exceeds 2 h an appropriate transport medium (or decontamination solution) should be used.

Explanation:

SoHO Establishments should validate the composition of the transport medium and determine if antibiotics are required.

Evidence:

SOP(s) and validation reports.

STANDARD:

G.1.007 The sterile packaging should be placed inside an adequate outside container to be transported to the SoHO Establishment.

Evidence:

SOP on procurement of placenta/ fetal membranes.

STANDARD:

G.1.008 The temperature during transport to the SoHO Establishment must be maintained.

Explanation:

Temperature stability should be guaranteed by the container, conditions of transport used and for the time interval before processing. A temperature-recording unit (data logger) should be enclosed in the container to record temperature at ≤ 30 -minute intervals unless the transport system has been previously validated to maintain the temperature within the required limits for the required transport time.

Evidence:

SOP on procurement of placenta/ fetal membranes and validation reports.

Processing, preservation and storage

STANDARD:

G.1.009 For Placenta/fetal membranes procured during vaginal delivery, different sterilisation procedures must be applied during processing

Evidence:

Associated SOPs

Example(s):

Sterilisation by gamma irradiation.

STANDARD:

G.1.010 Processing must be carried out within 24 h after procurement

Evidence:

SOP and associated registries.

STANDARD:

G.1.011 The amnion must be rinsed several times in sterile saline until blood residues are removed completely.

Evidence:

Associated SOPs.

STANDARD:

G.1.012 When AM is decontaminated by soaking in antibiotic/antimycotic solution, the incubation temperature and the composition of decontamination cocktails must be defined, after validation, by each SoHO Establishment.

Evidence:

Validation Report

STANDARD:

G.1.013 When applicable (i.e. does not apply to AM suspension or extract) AM must be spread on a suitable carrier membrane (e.g. nitrocellulose), or fine mesh gauze for easier handling and if it needs to be cut into multiple pieces.

Explanation:

Depending on the intended clinical use, both sides of amnion (epithelial and stromal) can be placed directly on the selected carrier.

Evidence:

Associated SOP(s) and validation reports

STANDARD:

G.1.014 The processing and storage of AM must be performed according the methods and technical criteria defined in the 5th edition of the EDQM Tissue and Cells Guide

Explanation:

The technical requirements associated with the storage and processing of different preparations of AM are defined in the 5th edition of the EDQM Tissue and Cells Guide.

Evidence:

Associated SOPs

Example(s):

Follow the 5th edition of the EDQM Guide to see the examples of the storage and transport requirements for each preparation type of AM:

Heat-dried amniotic membrane

The processed AM is dried overnight in an oven at $+40 \pm 2$ °C, then packed and sterilised. Storage should be stored according to the stability studies

Air-dried amniotic membrane

The processed AM is air-dried overnight in a laminar-flow hood. It can then be packed and sterilised. Air-dried irradiated AM grafts should be stored according to the stability studies

Lyophilised (freeze-dried) amniotic membrane

The processed AM is rapidly frozen at -50 °C to -80 °C. Then it is vacuum-dried using a freeze-drying device. Water from the tissue is extracted through sublimation until a final water content of 5-10 % is obtained. Following packaging, AM grafts may be sterilised by irradiation even if alterations to AM were demonstrated. The AM, and the product can be stored at room temperature for a long period of time without deterioration. The expiration time should be validated due to different packaging system and residual water.

Glycerolised amniotic membrane

Typically, 85 % (v/v) glycerol is used to preserved AM, which can then be stored at $+2-8$ °C for up to two years, although it does lose some of its biological properties.

AM intended to be glycerolised may be decontaminated by soaking in antimicrobial solution or sterilised by irradiation.

Amniotic drops/suspension

AM should be sliced into small pieces through pulverisation, micronisation or morselisation. The small pieces obtained should be immersed in a suitable certified liquid for the clinical application or freeze dried. Biochemical properties should be assessed during validation.

Amniotic membrane extract

The steps are: washing isolated human AM, slicing into small pieces, and submerging in liquid nitrogen. The mixture is homogenised and centrifuged, and then the supernatant is collected. Biochemical properties should be assessed during validation.

STANDARD:

G.1.015 Consistent with the defined preservation method, AM grafts may be decontaminated or sterilized by irradiation.

Explanation:

AM intended to be cryoprotected may be decontaminated by soaking in antibiotic/antimycotic solution. Sterilisation methods should be validated for the initial estimated level of bioburden. Sterilization is to be applied only when the cell viability of the AM is not to be maintained, the processed AM can be deep frozen without addition of a cryoprotective agent or controlled-rate freezing.

STANDARD:

G.1.016 AM grafts must be packaged in sterile containers

Evidence:

Associated SOP(s).

STANDARD:

G.1.017 Maximum storage must be defined based on the AM specifications and validated based on stability studies

Explanation:

Maximum storage time depends on the preservation method.

Evidence:

SOP(s) and validation reports.

Example(s):

Follow the 5th edition of the EDQM Guide to see the examples of the storage times and associated requirements for each preparation type of AM:

Cryoprotected amniotic membrane (i.e. AM in the presence of cryoprotectants) can be preserved in culture medium containing glycerol or dimethyl sulfoxide (DMSO). Most SoHO Establishments consider the maximum storage time at – 80 °C to range between 1 and 2 years.

Prolonged storage up to 5 years has been used after storage at –140 °C.

Deep frozen AM (with or without cryoprotectant) should be stored at < – 60 °C.

The shelf life ranges between 1 and 2 years and should be justified according to the storage temperature conditions that could impact on the critical properties of the graft.

Cryopreserved AM derivatives are stored in liquid or vapour phase of nitrogen at temperatures below – 140 °C. Distribution should be in dry ice (solid carbon dioxide) or in a liquid nitrogen dry-shipper.

Deep frozen AM derivatives (with or without cryoprotectant) should be stored at < – 60 °C and transported at a similar temperature as was used during storage. Transport temperatures of cryoprotected products above – 60 °C must be avoided to ensure the stability of the product and maximum safety for the recipient. The shelf life ranges between 1 and 2 years and should be validated according to the storage temperature conditions that could impact on the critical properties of the graft.

Lyophilised/freeze-dried AM can be stored and transported at room temperature (15-25 °C). Freezing and high temperatures (> 30 °C) should be avoided. The shelf life should be validated to allow for used packaging system and residual water.

Lyophilised/freeze-dried AM derivatives can be stored and transported at room temperature (15-25 °C). Freezing and high temperatures (> 30 °C) should be avoided. The shelf life should be justified according to the known range of ambient variables that could affect the critical properties of the graft

STANDARD:

G.1.018 Cryopreservation must be performed using a controlled-rate freezing procedure

Explanation:

Following packaging, AM grafts are stored at –80 °C or in liquid or vapour phase of nitrogen at temperatures below –140 °C (cryopreserved) but, in the case of cryopreservation, only after being previously submitted to a controlled-rate freezing procedure.

Evidence:

Associated SOPs.

STANDARD:

G.1.019 Reliable macroscopic examination of the donor fetal membranes must be undertaken to exclude visible pathological changes and ensure structural integrity of the tissue

Evidence:

Associated SOPs.

STANDARD:

G.1.020 Samples for detecting aerobic and anaerobic bacteria and fungi must be obtained from the transport/storage medium or from the initial washings of the AM, and from pieces of the tissue obtained both before and after antibiotic decontamination step.

Explanation:

These approaches cover the minimum standards to control microbiological safety.

Deviations from such standards should be justified, and the suitability of the intended test method must be demonstrated. Factors such as samples containing antibiotics or very small sample amounts may affect the sensitivity of tests leading, in the worst case, to false-negative results. Where samples taken before antibiotic/antimycotic decontamination yield microorganisms that are considered pathogenic and highly virulent, the tissue cannot be approved for clinical use.

Tissue showing heavy or confluent bioburden growth should also be rejected.

Evidence:

Associated SOPs.

STANDARD:

G.1.021 After decontamination, tissue is not deemed suitable for transplantation if the samples taken for microbiological testing show signs of any microbial growth.

Evidence:

Associated SOPs.

Distribution

STANDARD:

G.1.022 AM should be transported at a similar temperature as was used during storage, according validated systems and procedures.

Explanation:

For cryopreserved AM, distribution should be in dry ice (solid carbon dioxide) or in a liquid nitrogen dry-shipper or alternative validated systems.

Transport temperatures of cryoprotected or deep-frozen AM above –60 °C must be avoided, to ensure the stability of the product and maximum safety for the recipient

Evidence:

Associated SOPs.

Example(s):

Follow the 5th edition of the EDQM Guide to see the examples of the storage times and associated requirements for each preparation type of AM:

Transport temperatures of cryoprotected AM above – 60 °C must be avoided to ensure the stability of the product and maximum safety for the recipient.

The expiration date of AM stored in liquid nitrogen and shipped in dry ice must be shorter.

For frozen AM grafts, distribution should be in dry ice or alternative validated systems.

Heat-dried, air-dried and freeze-dried AMs can be distributed at room temperature.

Glycerolised AM should be transported at +2-8 °C.

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