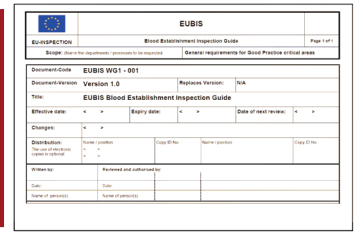
EuBIS

European Blood Inspection System

Co-funded by the EC – GA No. 2006202

Common European Standards and Criteria for the Inspection of Blood Establishments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Scope: (Due to the departments / processes to be inspected) | General requirements for Good Practice critical areas

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Audit / Inspection – Training Guide

including Preparatory Documents

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The guide gives valuable information and guidance on common criteria and standards for the inspection of blood establishments based on the requirements set-out in the blood legislation of the European Commission.

Further information on this manual including updated versions, national training courses or seminars organised by the project participants is available from the project Website of **EuBIS (European blood inspection system)** (www.eubis-europe.eu).

EuBIS
European Blood Inspection System
Co-funded by the EC – GA No. 2006202

Supported by the European Blood Alliance (EBA)

EBA European Blood Alliance

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The editors and project participants assume no responsibility for the use to which this manual is made.

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IBTS – Ireland	Irish Blood Transfusion Service
IHT – Poland	Instytut Hematologii I Transfuzjologii *(Institute of Haematology and Blood Transfusion)*
IMB – Ireland	Irish Medicines Board - Blood & Tissue Section
JAZM – Slovenia	Javna agencija RS za zdravila in medicinske pripomočke *(Agency for medicinal products and medical devices)*

MSC – Spain	DG Salud Pública. Ministerio de Sanidad y Consumo (Madrid) represented by Centro Vasco de Transfusion (San Sebastian)
MSP – Romania	Ministerul Sanatatii Publice (*Ministry of Public Health*)
MOH – Cyprus	Υπουργείο Υγείας της Κυπριακής Δημοκρατίας - Ιατρικές Υπηρεσίες κσι Υπηρεσίες Δημόσιας Υγείας *(Ministry of Health of the Republic of Cyprus - Medical and Public Health Services)*
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NBT – Bulgaria	НАЦИОНАЛЕН ЦЕНТЪР ПО ХЕМАТОЛОГИЯ И ТРАНСФУЗИОЛОГИЯ *(National Centre of Hematology and Transfusiology)*
PEI – Germany	Paul-Ehrlich-Institut *(Federal Government Institution)*
RPDA – Germany	Regierungspräsidium Darmstadt *(State Governmental Institution)*
SAM - Estonia	State Agency of Medicines, Department of Biologicals
Sanquin – The Netherlands	Stiching Sanquin Bloedvoorziening (*Sanquin Blood Supply Foundation*)
SUKL – Czech Republic	Vedoucí oddělení klinických praxí a dohledu nad zpracováním biologických materiálů. Státní ústav pro kontrolu léčiv *(State Institute for Drug Control)*
TILAK – Austria	Zentralinstitut für Bluttransfusion und Immunologische Abteilung, Universitätsklinikum
ZRS – Slovenia	Zavod Republike Slovenije za transfuzijsko medicino *(Blood Transfusion Centre of Slovenia)*

Supported by the European Blood Alliance (EBA)

COOPERATIVE WORKING PARTNERSHIPS

CoE – EDQM	Council of Europe - Blood Transfusion & Organ Transplantation activities. European Directorate for the Quality of Medicines and Health Care (EDQM – CD-P-TS), Strasbourg, France
EBA	European Blood Alliance (Executive office in Amsterdam*),* The Netherlands
JACIE	JACIE Accreditation Office - EBMT Secretariat, Spain
KMF	Koch-Metschnikow Forum (KMF), МЄЧНИКОВ-КОХ-ФОРУМ (МКФ).an initiative of the Petersburg Dialogue. (Germany and Russia)
WHO	World Health Organisation (WHO) Regional Office for Europe (Copenhagen), Denmark
DOMAINE Project	DOMAINE Project, Nijmegen and Amsterdam, The Netherlands
EUSTITE Project	EUSTITE – Project, Italy
Optimal Blood Use Project	EU Optimal Use of Blood Project, United Kingdom

AFFILIATED PARTNERS FOR THE INSPECTION SURVEY

AFSSAPS - France	Agence française de sécurité sanitaire des produits de santé (France)
FAGG - Belgium	Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium)
ASST - Portugal	Autoridade para os Serviços de Sangue e da Transplantação, (Portugal)
BDA - Bulgaria	Bulgarian Drug Agency (Bulgaria)
DMA - Denmark	Danish Medicines Agency (Denmark)
ITM – Rep. Macedonia	Institute of Transfusion Medicine (Republic of Macedonia)
MoH - Latvia	Ministry of Health, Health Statistics and Medical Technologies State Agency (Latvia)
MoH - Liechtenstein	Amt für Gesundheit (Health Ministry) (Liechtenstein)
SIDC - Slovakia	State Institute for Drug Control (SIDC), Bratislava (Slovakia)
Socialstyrelsen - Sweden	The National Board of Health and Welfare, Socialstyrelsen (Sweden)
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Uni-Graz - Austria	Universitätsklinik für Blutgruppenserologie und Transfusionsmedizin (Austria)

Abbreviations

BE	Blood Establishment
CA	Competent Authority
CAPA	Corrective and Preventive Action
CoE	Council of Europe
EDQM	European Directorate for the Quality of Medicines and Health Care of the Council of Europe
EMEA	European Medicines Agency
EQSTB	European Quality System for Tissue Banking
EU	European Union
EuBIS	European Blood Inspection System
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ISO	International Standards Organisation
IT	Information Technology
ID	Identification
PIC/S	Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme
QA	Quality Assurance
RP	Responsible Person
SAE	Serious Adverse Event
SMF	Site Master File
SOP	Standard Operating Procedure
SPC	Statistical Process Control
WG	Working Group

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1 Introduction

Aim and scope

This training Guide aims to assist blood establishments (BE) in setting-up an inspection process. It is complementary to the EuBIS Manual on '*Common European Standards and Criteria for the Inspection of Blood Establishments*'. The training guide can be also used, if wished by competent authorities as a reference to assist the implementation process of regulatory inspections as required by the EU blood legislation.

It comprises inspection criteria that cover the regulatory standards applicable within the European Union (EU) and based on its blood Directives. The criteria set out in the Guide, however, are not exhaustive and authorities and blood establishments may wish to supplement this material with additional requirements.

It is anticipated that this training material will prove useful for trainees involved in regulatory and self-inspections. The EuBIS project clearly recognises that additional inspection standards are used throughout Europe. These standards reflect in part legal requirements defined by individual EU Member States. In particular, good manufacturing practice (GMP) standards are the basis for inspections carried out by competent authorities as well as blood establishments. The training guide, therefore, provides clear references to relevant GMP standards and refers to other commonly applied standards and guidelines within the EU, such as the

- PIC/S guideline
- CoE (EDQM) guide

The EuBIS project also acknowledges that ISO standards are used increasingly by blood establishments and hospitals for their diagnostic activities and to augment GMP and good clinical practice guidelines.

Development of an audit / inspection guide.

This Guide summarises the major processes that are to be audited or inspected as a part of a quality management system. In preparing the Guide, the processes were divided into four sections based on the activities that were assigned to each of the EuBIS project's Working Groups (WG):

WG 1: Quality management system evaluation
WG 2: Donor recruitment and blood collection
WG 3: Processing and testing
WG 4: Blood component issuing, storage and logistics

Blood establishments should develop their own self-inspection documentation based on these criteria and relevant national standards. They should be in a format that will allow the documentation of findings on and classification of any associated non-compliances. From practical experience, most participating blood establishments are of the view that the use of 'formatted' checklists should be limited to key / major points and controls within the processes. A very detailed audit check-list detracts from the auditing of processes 'in-action' as well as following the 'audit-trail'.

The training material, therefore, is presented in this Guide as examples of how to set-up formatted audit guides for the major processes. These examples were developed by the EuBIS Working Groups.

2 General Information (How to use this training guide)

The training concept is based on the EuBIS manual entitled 'Standardised European processes and criteria for the inspection and self-inspection of blood establishments'. It comprises an inspection guide with detailed audit criteria (Chapter 3) and examples of the documents required to complete an audit / inspection (preparatory documents - listed in Annex I). The inspection guide has been developed by the Project participants assisted by the Manual drafting team and working groups (WGs).

2.1 The Inspection training guide

The training material presented in **Chapter 3** covers requirements applicable to blood establishments in the inspection process. Chapter 3 of the Inspection training guide is structured in the same order as the requirements set out in the Annex to Directive 2005/62/EC (Section 3.2 – 3.9). In addition, it includes requirements in section 3.10 on Traceability and notification of serious adverse reactions and events (following Directive 2005/61/EC) and on Information technology (IT) in section 3.11.

Each section contains a description of the inspection criterion and example evidence that should be obtained during the inspection to demonstrate compliance. Each inspection criterion is identified by an individual number (criterion No.), a reference to the applicable standard(s) and identifies the sub-process or control point.

The information in Chapter 3 is presented in the following tabular form.

Column 1	*Criterion number and primary reference to EU Directives*
Column 2	*Sub-process / control point (the manufacturing process step to which the audit criterion applies)*
Column 3	*Cross reference source*
Column 4	*Inspection criterion description*
Column 5	*Example evidence*

The inspection criteria listed can be used to assist the inspector in preparing the inspection record. For the less-experienced inspector, it may be suitable to transfer these directly to the self-inspection record (with any additional criteria identified). Depending on experience, others may prefer to only record the clause and a short description of the area inspected.

2.2 Preparatory Documents (Annex I)

This documentation identifies the **audit / inspection-trail** (e.g. area inspected) and findings. If applicable, non-conformances need to be summarised in an **inspection report**.

A survey of the EuBIS project's participants indicated that the following minimum requirements of the above documentation system should be covered

General document control requirements (SOP):

- Title and scope
- Document code
- Document version
- Effective date
- Expiry and review date
- Changes to current version
- Distribution details (name/position; copy ID No.),
- Author and reviewer (name, signature and date)
- Objective (e.g. self-inspection guidance based on relevant EU legislation and guidelines)
- Area of application (e.g. quality management system covering inspection and self-inspections)

Specific requirements for a self-inspection record / audit trail

- Date of audit
- Audit reference
- Organisation / Department (the area to be inspected, e.g. production department)
- Scope / Processes covered (during the self-inspection, e.g. blood separation)
- Auditor (Role), e.g. lead auditor, expert (in cases of peer-audits)
- Auditor name and signature
- Attendance list (representing auditees) for the opening and closing meetings with the role(s), name(s) and signature(s). The roles should include the names of key staff involved (e.g. audit guide, department managers, etc.)

- The clause[1] and/or area or a description of the inspection criterion.
  - Example of a clause / Area:
    Clause and Area: 2002/98/EC, 1.5 and Article 10, 2005/62/EC, Annex 2.1, 2.2. and GMP 2.1 and 2.2. Area: Personnel in General
  - Example of a description of an inspection criterion:
    Sufficient qualified personnel to carry out all the tasks, which are the responsibility of the manufacturer.
    Individual responsibilities are clearly understood by the individuals and recorded.
    Roles and responsibilities are defined within the organisation.
- Criterion number
- Audit findings and supporting evidence
- Outcome conclusion(s) of the inspection criterion assessed and if applicable a non-conformance reference (NCR) and severity classification. The severity classification should use the following: critical, major, other (other serious deviations) – see EuBIS manual.

[1] Clause: The standard and relevant section (e.g. GMP, chapter 4 documentation. 4.3 document approval) used for the self-inspection

Specific requirements for a self-inspection summary report

- **Part A - General observations, acknowledgements and remarks (including improvements)**

  The auditor should include in this section the overall impression of the inspection and especially any good practices or improvements observed during the inspection.

  This part is an opportunity to acknowledge personnel who were especially helpful and supportive. (e.g. the audit guides). It should be used to motivate the auditees in continuing to follow the quality policy, develop the quality system and improve quality overall.

  In some cases this may be challenging in others not. At least a statement like '*Progress is being made; however, there is still a lot to be achieved*' may assist the auditor in opening the mind of the auditees.

- **Part B - Description of non-compliances including classification and corrective and preventive action (CAPA)**
  - To be completed by the closing meeting
    - Non-compliance number
    - Description of the non-compliance including the severity / classification and clause
  - To be completed by the quality manager following the audit
    - Corrective action to be taken
    - Identity of person taking corrective action and target date
    - Confirmation of completion of corrective action (name, date and signature)

Examples of these documents are given in Annex I. The document lay-out is based on the common EU standard-operating-procedure document-control requirements defined by the Project group. The templates can be modified and / or adapted by those institutions needing to implement a self-inspection system or to improve their quality management system following EU legal requirements.

NOTICE:

All documents of the EuBIS inspection guide including updates and amendments can be downloaded from the following website: **www.eubis-europe.eu**

3 Inspection Guide

3.1 Licensing requirements

	Blood Establishment Inspection Guide	EuBIS

Scope:	Licensing requirements

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LR 001 2002/98/EC Article 5 – Licensing and authorisation Article 11. Quality system for blood	Licensing requirements	GMP Annex 14 PIC/S Chap. 2	The Blood Establishment has submitted the information listed in Annex I (2002/98/EC) to the Competent Authority. The Competent Authority has verified that the blood establishment complies with the requirements of Directive 2002/98/EC and indicated which activities it may undertake and which conditions apply.	• Manufacturers license and whole sale distribution license as appropriate to the activity profile assigned by the Competent Authority • N.B. For those blood establishments that follow the requirements defined by 2001/83/EC, individual product licenses are required.

3.2 General principles – Quality system and quality assurance

	Blood Establishment Inspection Guide	EuBIS
Scope:	**General principles – Quality system and quality assurance**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: **2005/62/EC – Introduction and general principles**			
	Quality System (2005/62/EC), Annex 1.1 – quality system			
QS 001 2002/98/EC. Article 11 2005/62/EC, Annex 1.1	Quality system for blood	GMP, Chap.1.1 PIC/S Chap. 5 EDQM(CoE), Principles Chap. 1 Standards Chap. 1	There is a documented Quality System with stated policy(ies), procedures and work instructions. The Quality System references relevant standards, guidelines and other external documents. There are documented reviews of the Quality System by Senior Management, with evidence of action taken.	• Quality Manual • Site-Master-File • Quality system documents • Quality policies and procedures • Quality review(s) (e.g. Minutes of quality review meetings)

	Blood Establishment Inspection Guide	EuBIS

Scope:	General principles – Quality system and quality assurance	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
QS 002 2005/62/EC Annex 1.2	Quality assurance	GMP, Chap. 1.2 PIC/S, Chap. 5.4 EDQM (CoE) Principles Chap. 1 Standards Chap. 1	A quality assurance (QA) function is established that is managerially independent of 'production'. The QA function is involved in all quality related matters and reviews and approves all quality related documents. All procedures, premises, and equipment having an influence on the quality and safety of blood and blood components are validated prior to introduction and re-validated at regular intervals determined as a result of these activities.	• Organisation chart (Organogram) including QA • Job description including QA personnel • Validation / Re-validation reports • Document approvals (formal)

	Blood Establishment Inspection Guide	EuBIS
Scope:	**General principles – Quality system and quality assurance**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
QS 003 2005/62/EC Annex 1.2 2005/62/EC, Annex 5	Quality control specifications	GMP, Chap. 1.2 4.1, 4.10, 4.11, 4.12, 4.13 EDQM (CoE) Standards Chap. 5	Minimum specifications are defined for all blood components and other materials including storage requirements. Results of testing against these specifications are collected and reviewed by quality assurance to ensure that any appropriate corrective action is taken. Relevant quality control data is documented.	• Written specifications • Quality control data • Product conformance reviews • Corrective action reports
QS 004 2005/62/EC Annex 1.1, Para. 2 Contract management Annex 8.0	Contract-management Suppliers	EDQM (CoE) Standards Chap. 1	Reagents and materials are from approved suppliers and conform to written specifications. Critical materials are released by a person qualified to perform this task. Where relevant, materials, reagents and equipment meet the requirements of Directive 93/42/EEC for medical devices and Directive 98/79/ECfor *in vitro* diagnostic medical devices.	• List of approved suppliers • Certificates of conformity • Supplier audit reports • Audit scheme of suppliers

3.2 Personnel and organisation

	Blood Establishment Inspection Guide	EuBIS

Scope:	Personnel and organisation			
Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Personnel and organisation			
PO 001 2005/62/EC Annex 2.0 2002/98/EC, Article 10	Personnel - General	GMP Chap. 2 GMP Annex 16 EDQM (CoE), Principles Chap. 1 Standards Chap. 1 PIC/S – Chap. 6	There are sufficient qualified personnel to carry out all tasks which are the responsibility of the blood establishment. Individual responsibilities are clearly understood by individuals and recorded. Roles and responsibilities (including delegated) are defined within the organisation. Staff have appropriate access to their line management and are adequately supervised in accordance with the criticality of task(s) being performed and their level of training / competency	• List of established posts and their occupancy. • Sample check of qualifications • Organisation charts • Evidence of awareness of department structure • Job descriptions • Proof of qualifications and identity. • Process performance indicators for product quality (e.g. qualification and number of staff is sufficient to ensure

	Blood Establishment Inspection Guide	EuBIS

Scope:	Personnel and organisation	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
				product quality) • Observation
PO 002 2005/62/EC Annex 2.3, 2.4	Personnel – Training	GMP, Chap. 2 (2.8-2.12) PIC/S, Chap. 6.4.- 6.6 EDQM (CoE), Principles Chap. 1 Standards Chap. 1	Staff has appropriate qualifications. Staff receives documented training and competency assessments.	• Training records that include induction, GMP, quality system / policy, SOPs. • Continual training needs identified and followed-up (e.g. annual review of competence / personal development plans)

	Blood Establishment Inspection Guide	EuBIS

Scope:	Personnel and organisation	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
PO 003 2005/62/EC Annex 2.5	Personnel – Personal Hygiene	GMP 2.16, 2.17, 2.19 PIC/S Chap. 6.7	Written safety and hygiene instructions are in place. Protective garments are worn, appropriate to the operations carried out. Eating, drinking, chewing and smoking are prohibited in production, testing and storage areas. Personnel receive appropriate instruction in personal hygiene. All personnel must use hand washing facilities. Hand wrist watches, jewellery or other related items must not be worn.	• Hygiene policy (plan) • Cleaning policy (plan) • Safety and hygiene instructions written into SOPs • Direct observation of staff. • Training records

3.3 Premises

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – General requirements**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 3 - Premises			
PR 001 2005/62/EC Annex 3.1	Premises – General requirements	GMP Chap. 3 (3.1 - 3.5) GMP Annex 14 Annex 15 PIC/S, Chap. 7 (7.1-7.3) EDQM (CoE), Principles Chap. 1 Standards Chap. 1	Premises and equipment are located, designed, constructed, adapted, validated and maintained to suit the operations carried out. Layout and design minimises the risk of errors and permits effective cleaning and maintenance in order to avoid cross-contamination, build up of dust or dirt and, in general, any adverse effect on the quality of products. Waste is disposed correctly / promptly. Separate areas for blood collection, production and testing / quality control. Dedicated, secure IT and long-term archiving areas with appropriate environmental control	• Validation/qualification records • Layout / adequacy of space, cleanliness / environmental control (e.g. room plan) • Environmental procedures / monitoring records • Temperature records • Process performance indicators

	Blood Establishment Inspection Guide	EuBIS

Scope:	Premises – General requirements	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PR 002 2005/62/EC Annex 3.1	Cleanliness and Maintenance	GMP 3.1, 3.2, 3.19	Premises are maintained and cleaned to the standard required. Regular building inspections are carried out. A safe working environment is maintained.	• Observation of cleanliness / condition of premises • Cleaning records • Training records • Maintenance records • Risk assessments carried out to determine cleaning / maintenance requirements • Building inspection reports • Incident / accident records • Corrective action plans

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – General requirements**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PR 003 2005/62/EC Annex 3.5	Storage areas	GMP 3.18, 3.19, 3.20, 3.21, 3.22, 3.23, 3.24, 3.25 EDQM (CoE) Principles Chap. 1,4 Standards Chap. 4	Storage areas provide for secure and segregated storage of blood, blood components and other materials. There are separate areas for non-conforming and rejected materials and for autologous donations.	• Observation that these requirements have been implemented in all processing, testing and storage areas • Temperature monitoring records
PR 004 2005/62/EC 3.4	Building security	GMP 3.4, 3.5 EDQM (CoE) Standards Chap. 1	Design of the building and security measures prevent unauthorised entry. There is no ingress of insects or animals (Pest control).	• Secure exterior access • Internal restrictions on movement • Condition of building fabric

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – General requirements**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PR 005 GMP 3.2	Maintenance and Cleaning Policy	GMP 3.2	A system is in place for maintenance and repairs of building fabric and plant and conforms to current legislation and guidance.	A documented policy for building surveillance including • Regular audits of rooms and technical facilities • Accessibility to legislation and guidance
PR 006 Refer to local guidelines	Blood Spillage		There is a procedure in event of blood spillage or contamination.	• SOP referring to local guidelines • Cleaning / hygiene plan
PR 007 GMP 6.7, Annex 1	Environmental monitoring of blood component production facilities	GMP Annex 1 (1.1, 1.2, 1.3, 1.4, 1.5, 1.6). PIC/S 11.6, 11.7, 13.8, 13.9	Clean areas are identified and classified according to air cleanliness level for blood components produced. There are documented procedures for environmental monitoring including: Methods, growth media and incubation periods, location, sampling interval and	• SOPs / training records • Sampling map / plans • Environmental monitoring reports • Records of test method, growth medium, batch No. and

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – General requirements**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		EDQM (CoE) Principles, Standards Chap. 4	timings, analysis, action limits and reporting of all results, escalation of repeat and significant failures, further investigation of repeat and significant failures (e.g. identification of micro-organism), and use of controls. Results of environmental monitoring are trended to highlight developing 'out-of-control' situations. Batches of growth media are validated before use.	expiry date, date and location of test, person(s) who set up, read and reported tests, control results, trends, and certificates of conformance.

3.3.1 Blood donor and collection area

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Blood donor and collection area**	

Criterion-No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 3.2 Blood donor area – Annex 3.3 Blood collection area			
PR 008	Off-site blood collection	PIC/S 7.15, 7.18 EDQM (CoE) Standards Chap. 3	Session venues are of sufficient size and design and are adequately cleaned and maintained. Venues are assessed before each use to ensure that facilities and services (lighting, heating, hand washing and ventilation) are adequate.	• Non-slip washable floor material • No inaccessible areas • Air condition ventilation, if possible, or • Records of daily maximum /minimum temperature and humidity

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Blood donor and collection area**	

Criterion-No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PR 09 2005/62/EC Annex 3.2	Blood donor area assessment	GMP Annex 14 PIC/S Section 7.6 / Mobile sites 7.15-7.18 EDQM (CoE) Principles Chap. 1,3 Standards Chap. 1,3	An area for confidential personal interviews is provided to assess an individual's eligibility to donate. This area is separated from all processing areas.	• Floor plan • Observation
PR 010 2005/62/EC Annex Chap. 3.3	Blood collection area	GMP Annex 14 PIC/S Section 7.6 and Mobile sites 7.15-7.18 EDQM (CoE), Principles Chap. 1,3 Standards Chap. 1,3	Blood collection conducted in an area for safe blood withdrawal, appropriately equipped for initial treatment of donors experiencing adverse reactions / injuries from events associated with blood donation,/ organised to ensure safety of donors, staff, general public and to avoid errors in collection procedures.	• Location / maintenance records of first-aid equipment • Separated, non-crossing paths for donors / whole blood. • Separate refreshment and meeting areas • Observation

3.3.2 Blood testing and processing areas

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Blood donor testing and processing area**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 3.4 Blood donor testing and processing area			
PR 011 2005/62/EC Annex 3.4 (also 3.1)	Blood testing and processing	GMP Annex 14 PIC/S 7.4.-7.7 EDQM (CoE) Principles Chap. 1 Standards Chap. 1	There is a dedicated laboratory area for testing that is separate from the blood donor and blood component processing area with access restricted to authorised personnel.	• Observation • Map / Floor plan

3.3.3 Storage area including blood

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Storage area including blood**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 3.5 Storage area including blood			
PR 012 2005/62/EC Annex 3.5	Storage area	GMP Annex 14 Chap. 3 (3.18-3.25) PIC/S, Chap. 7.8-7.10 EDQM (CoE), Principles Chap. 1 Standards Chap. 1,4	Storage areas are constructed of adequate capacity, cleaned and maintained to provide for properly secure and segregated storage of different categories of blood and blood components and materials including quarantine and released materials and units of blood or blood components collected under special criteria (e.g. autologous donation). A clear separation exists between products for issue and returned products Storage areas are designed and laid out to facilitate storage operations and	• Separated rooms or clear indication of separated storage (e.g. label or segregation in separated cages) • Quarantined / segregated storage available. • Visual inspection of storage areas • Temperature monitoring records • Secure disposals • Access control to

	Blood Establishment Inspection Guide	EuBIS

Scope:	Premises – Storage area including blood	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
			prevent mix-ups.	sensitive or restricted areas • Pest control measures • Cleaning records • Authorisation records for area
PR 013 2005/62/EC, Annex 3.5, Para. 2	Power supply		Provisions are in place in the event of equipment or power failure in the main storage facility.	• Back-up generator (regularly tested) • Check-up polices • Emergency procedures

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Storage area including blood**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PR 014 2005/62/EC Annex 3.5	Materials storage	GMP, Annex 14 Chap. 3.19 PIC/S 7.13 EDQM (CoE), Principles Chap. 1,4 Standards Chap. 4	The temperature and humidity in storage areas for critical materials, blood and blood components is appropriately controlled, monitored and checked to demonstrate compliance with specifications and equal distribution throughout the storage facility. The checks are recorded. Stock is managed on a 'first in first out' basis when possible.	• Storage conditions - separation of released / not released material • Shelving • Security • Appropriate segregation
PR 015 Ref. GMP and manufacturers instructions for use.	Storage area conditions	GMP 3.19 + 5.7 PIC/S, 7.14 EDQM (CoE), Principles Chap. 1,4 Standards Chap. 1,4	There is an alarm system in place. Regular checks of the alarm system are performed and recorded. There is a written procedure describing the actions to be taken in response to alarms.	• Record of alarm checks • Records on temperature deviations and actions taken • SOPs / training records

	Blood Establishment Inspection Guide	EuBIS

Scope:	Premises – Storage area including blood	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
			All materials, products and reagents are stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation.	• Check the Manufacturers instructions for use (storage conditions)

3.3.4 Waste disposal area

	Blood Establishment Inspection Guide	EuBIS

Scope:	Premises – Waste disposal area	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
	Process(es) covered: 2005/62/EC – Annex 3.6 Waste disposal area			
PR 016 2005/62/EC Annex 3.6	Waste disposal area		An area is designated for safe disposal of waste and disposable items used during the collection, testing, and processing and for rejected blood or blood components.	• Observations • Design qualification records • Needle (sharps) disposal system • Floor plan showing dedicated area
PR 017 2005/62/EC Annex 3.6	Biohazard products	GMP 5.61	There is a documented procedure for retrieval of biohazard components. An audit trail is maintained from the identification of biohazard components through to final disposal. Biohazard material is stored in dedicated secure storage. There is an inventory of biohazard packs	• SOPs / training records • Audit trail • Records of treatment and disposal

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Premises – Waste disposal area**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			held in storage. Biohazard donations are inactivated before disposal	
PR 018 2005/62/EC, Annex 3.6	Clinical waste	Ref. local legislation	Clinical waste is transported, handled and disposed of safely and in compliance with statutory requirements.	• Colour coded containers • Observation

3.4 Equipment and materials

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 4. Equipment and materials			
EM 001 2005/62/EC Annex 4	Equipment and materials	GMP 3.34 to 3.36, 3.38 to 3.40, 3.44 Annex 15 PIC/S. Chap 8.1 EDQM(CoE) Principles Chap. 1,3,4 Standards Chap. 1,3	Equipment is suitable for its intended use.	• Validation records • Observation • Logbooks • Labels for its specific purpose • Labels indicating expiry-date

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 002 2005/62/EC Annex 4	Maintenance & Calibration	GMP 3.41, 4.28 PIC/S Chap. 8.2 to 8.4 EDQM(CoE) Principles Chap. 1 Standards Chap. 1	Critical equipment is maintained and calibrated including centrifuges, sterile connecting devices, plasma separation equipment, blast freezers, irradiators, cell washers, storage refrigerators and freezers, vacuum packing equipment, balances, temperature monitoring systems, air handling systems, laminar flow cabinets, autoclaves, heat sealers and illuminators.	• Records of cleaning, maintenance and calibration (e.g. log books) • 'in calibration' stickers • SOPs / training records • Used by dedicated personnel with appropriate training

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 003 Ref. GMP	Blood irradiation	GMP Annex 12 PIC/S 11.10, 11.11 EDQM (CoE) Principles Chap. 4 Standards Chap. 4	Blood irradiators are correctly used and maintained in accordance with European and national regulations. • Irradiators are regularly dose mapped. • There is an adjustment of the irradiation period based on decay calculations. • A back-up timer is present • There is a uniform exposure to the radiation field e.g. turntable rotation • Indicator labels are used with each product • Indicator labels are correctly stored • Absorbed dose is between 25 - 40 Gy.	• Maintenance records • Dose mapping records • Decay calculations records • Timers calibration records • Indicator labels • Dedicated, access controlled location • Emergency plans in accordance with national legislation.

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 004 2005/62/EC Annex 4.3	Specifications	GMP 5.26	There are documented specifications (performance standards) for critical items, such as: • analytical equipment, measuring equipment, e.g. balances, blood mixers and balances • temperature controlled equipment, e.g. blood banks	• Documented definition of critical items • Documented specifications for critical items
EM 005 2005/62/EC Annex 4.3	Incoming goods inspection / Receipt of materials	GMP 5.27 4.19 to 4.21	There are documented procedures for the receipt of purchased materials including inspection of packaging for • Good condition • Reconciliation of materials received against purchase order	• SOPs / training records • Purchasing / inspection records • Appearance of the products

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 006 2005/62/EC Annex 5.1	Quarantine, testing and release of materials	GMP 3.21, 4.11, 5.2, 5.5 EDQM (CoE) Principles Chap. 1, Standards Chap. 1	There are documented procedures for the quarantine, testing and release of materials that have an effect on product quality or safety.	• Specifications for material testing • Acceptance criteria and release • SOPs / training records • Labelling and segregation of quarantined materials • Electronic segregation of quarantined materials to prevent issue • Certificates of analysis / conformance

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Equipment and materials**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 007 GMP 3.23, 5.61	Recall, return or disposal of materials	PIC/S Chap. 15 EDQM(CoE) Principles Chap. 1 Standards Chap. 1	There are documented procedures for the recall, return or disposal of rejected, defective, obsolete or surplus materials.	• SOPs / training records • Segregation and labelling of returned / recalled materials • Electronic segregation of recalled materials to prevent issue • Recalled material records • Goods returned notes

3.5 Documentation

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Documentation and document control**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: **2005/62/EC – Annex 5 Documentation**			
DO 001 2005/62/EC Annex 5 2002/98/EC Article 12, 13, 14.	Management of records (that affect the quality of products)	GMP Chap 4 (4.7, 4.8, 4.9) Chap 6 Annex 11 PIC/S Chap. 9 EDQM (CoE) Principles Chap. 1,3 Standards Chap. 1	Records are maintained, are legible and permanent. Corrections are correctly handled, e.g. hand written corrections must be signed. A documentation control system is in place to ensure up-to-date procedures, specifications and records. This comprises documented procedures for: • Design • Preparation • Review • Approval • Distribution • Archive • Retention of documents	• SOPs / training records • Quality records - corrections and alterations correctly handled • Correcting fluid (Tippex) not used • Observation • Signatures and dates • List of initials / signatures

	Blood Establishment Inspection Guide	EuBIS

Scope:	Documentation and document control	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
DO 002 Ref. GMP 5.2, 5.15, 5.22, 5.23	Control of Processes	EDQM (CoE) Principles Chap. 1, Standards Chap. 1	All processes are adequately documented. Operators follow the procedures as documented. All significant changes are validated, authorised and adequate training performed for staff members. Document archiving follows relevant standards	• Existence of documented policies / procedures • Physical observation of operators performing procedures • Review of documents (to ensure up-to-date) • SOP / training records • Document archive system

3.5 Blood collection, testing and processing

3.5.1 Donor eligibility

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.1 Donor eligibility			
DE 001 2002/98/EC Article 20	Receipt of starting materials	EDQM (CoE), Principles Chap. 2 Standards Chap. 2	Blood donations that are received for processing are from voluntary and 'non-remunerated' (unpaid) donors. The BE decides the final acceptance or deferral of a prospective donor (the BE is ultimately responsible for the quality and safety of blood and blood components collected and therefore must be entitled to decide on the final acceptance or deferral of a prospective donor, considering that right of blood recipients to the protection of their health and the resulting obligation to minimise the risk of transmission of	• Blood collection policy • Inspection of blood collection process

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			infectious diseases override any other consideration including an individual's willingness to donate blood).	
DE 002 2002/98/EC Article 16 and 17 2004/33/EC, Annex II (information provided and obtained)	Donor information provided	GMP Annex 14 PIC/S 10 EDQM (CoE), Principles Chap. 2 Standards Chap. 2	All prospective donors of blood or blood components are provided with the information referred to in Article 29(b) (2002/98/EC). Donors are advised before donation of requirements for blood donors and are informed of common risks and discomforts associated with donating. Each donor is notified that his/her donation is tested for presence of infectious disease markers and informed of factors that may increase the risk to the recipient of donated blood. An informed consent form is given to each donor and is signed by the donor prior to collection.	• Check information material provided for donors (e.g. flyer) against Directive • Informed consent form completed with signature • Donor questionnaire completed

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
DE 003 2002/98/EC Article 16 and 17 2004/33/EC, Annex II (information provided and obtained)	Donor interview	GMP Annex 14 PIC/S 10 EDQM(CoE), Principles Chap. 2 Standards Chap. 2	Relevant information is obtained from all donors willing to donate blood or blood components (Article 29(b)). This comprises the following • identification, • health history, • signature of the donor There is unique personal data, (without any risk of mistaken identity) to identify the donor, as well as their contact details.	• Donor registration record with evidence of name, date of birth and permanent address • Review donor interview procedure in the absence of the donor • Donor selection records are signed by authorised interviewer • Identification of donor recorded and linked to the donation record.
DE 004 Ref. PIC/S		PICS/10.6 EDQM (CoE) Principles Chap. 2, Standards Chap. 2	Donor identification, donor selection interview and donor assessment take place immediately before each donation	• Observation

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
DE 005 2002/98/EC, Article 16 - 18, 2005/62/EC, Annex 6.1	Donor information for registration and eligibility	GMP, Annex 14 PIC/S, 10 EDQM (CoE), Principles Chap. 2 Standards Chap. 2	A system is in place to document donor history and information data. Donor history from previous donor records is taken into account for donor registry	• Data system using donor records • Check for donor information (donor history) • Up-to-date information available
DE 006 2005/62/EC, Annex 6.1	New donor registration (first time donors)	EDQM (CoE) Principles Chap. 2 Standards Chap. 2	There are documented procedures for registration of new donors. Staff members have access to and are trained in the required registration procedure. There is a reconciliation of donor registration forms (signed by the donor) against records of attendance (e.g. on the session computer).	• SOPs / training records • Observation, • Procedures for manual intake

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
DE 007 2005/62/EC, Annex 6.1 2004/33/EC, Annex II and Annex III	Donor registration (Automated and manual data upload)	EDQM (CoE) Principles Chap. 2, Standards Chap. 2	There are documented procedures for • automated and manual upload of data • actions to be taken for withdrawn or deferred donors • investigation of missing session records Staff are trained in and have access to required registration data bases. Staff are trained in latest requirements for donor selection criteria.	• SOPs / training records • Observation
DE 008 2002/98/EC, Article 19 2004/33/EC, Annex III		PIC/S 10.4 EDQM (CoE) Principles Chap. 2, Standards Chap. 2	Donors are chosen by using documented selection criteria. Only volunteer donors who are in good health are accepted. The donor's haemoglobin is checked against established acceptance criteria for males and females before each donation using a validated, quality controlled procedure.	• SOP / training records for donor selection criteria • Observation • Donor questionnaire • Validation records • Quality control / assessment records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
DE 009 2005/62/EC, Annex 6.1	Information exchange	EDQM (CoE) Principles Chap. 2, Standards Chap. 2	There are documented procedures for the handling of donor information in all formats including • Information that affects the quality of the product • Referral of medical queries to medically qualified staff • Handling of inconsistencies and errors • Handling of complaints •	• SOPs / training records • Observation • Recall of a donor
DE 010 PIC/S 10.8	Apheresis	EDQM (CoE) Principles Chap. 2,3 Standards Chap. 2,3	The criteria for apheresis donors meet at least the general acceptance criteria for blood donation, unless otherwise specified (nationally).	• Relevant specifications • SOPs / training records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Donor eligibility**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
DE 011 Ref. PIC/S	Whole blood collection (general)	PIC/S 10.2 EDQM (CoE) Principles Chap. 3, Standards Chap. 3	Detailed records are kept for each important activity associated with donation. The record should record any • unsuccessful donation • rejection of a donor • adverse reactions • donor complaints or • unexpected events.	• All records of date and donation number entered and maintained in an electronic format • All adverse reactions with action taken recorded • Full details of incidents, adverse effects and donor complaints and staff action recorded

3.5.2 Collection of blood and blood components

	Blood Establishment Inspection Guide	EuBIS

Scope:	Collection of blood and blood components			
Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.2 Collection of blood and blood components			
CO 001 2005/62/EC Annex 6.2 Para. 1		GMP, Annex 14 PIC/S 10 EDQM(CoE), Principles Chap. 3 Standards Chap. 3	The blood collection procedure is designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established. • A system of donation numbers is used to uniquely identify each donation, the samples collected during donation and to link the donation / samples to the donor's record. • The identity of the donor is re-checked against documentation at the bedside. • The donation number is traceable to all records linked to a donation to allow	• Label on blood bag can be traced back to donor and respective records. • Record of an unsuccessful donation

	Blood Establishment Inspection Guide	EuBIS

Scope:	Collection of blood and blood components	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
			identification of each important step associated with each donation. • All donations are recorded; reason for any unsuccessful donations are also recorded.	
CO 002 ref. GMP	Disinfection of venapuncture site	GMP Annex 14 EDQM (CoE) Standards Chap. 3	The procedure used to disinfect the venapuncture site is clearly defined and shown to be effective. Strict adherence to the documented procedure is maintained.	• SOPs / training records • Disinfectant validation • Bacteriological monitoring. • Observation of process of cleaning and disinfection
CO 003 2005/62/EC Annex 6.2, Para. 4		EDQM(CoE) Principles Chap. 3 Standards Chap. 3	Laboratory samples are taken at the time of donation and appropriately stored prior to testing	• Observation • Labelling of test samples

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Collection of blood and blood components**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
CO 004 2005/62/EC Annex 6.2		GMP Annex 14 PIC/S, Chap. 10 EDQM(CoE), Principles Chap. 3 Standards Chap. 3	Sterile blood bag systems are used for collection of blood and preparation of blood components. Bags are CE marked (or approved by the Competent Authority). Blood bags are used in accordance with the manufacturer's instructions and are inspected for damage and deterioration before use. The batch number(s) are recorded. The blood pack is mixed continuously during the donation and blood flow and donation time are monitored	• Certificate of analysis for each batch • Records of any checks carried out upon receipt. • Instructions for use • SOPs / training records.
CO 005 2005/61/EC Article 2	Receipt of starting materials	GMP Annex 14 EDQM (CoE) Principles Chap. 3,	All donations are identified by a unique donation number (attached to all blood bags within the blood pack assembly). An independent check is made to ensure that donation numbers used on the blood	• Observation

	Blood Establishment Inspection Guide	EuBIS

Scope:	Collection of blood and blood components	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
		Standards Chap. 3	pack, samples and documentation are identical.	
CO 006 Ref. GMP	Receipt of starting materials	GMP 5.3 to 5.5, EDQM (CoE) Principles Chap. 3, Standards Chap. 3	Received donations and samples are reconciled against records of blood collection.	• Completed session delivery notes
CO 007 2005/62/EC, Annex 6.2, Para. 6	Storage of collected blood	EDQM (CoE) Principles Chap. 3 Standards Chap. 3	After collection, the blood donations are handled, stored and transported securely and at the correct temperature. Storage and transport is in accordance with the intended further processing of the donations (e.g. to prepare platelet concentrate) in order to maintain their quality for further processing and use by the patient.	• SOPs / training records • Observation • Temperature records throughout the supply chain • Storage / transport container validation records

3.5.3 Laboratory testing

	Blood Establishment Inspection Guide	EuBIS

Scope:	Laboratory testing			
Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered:: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.3 Laboratory testing			
LT 001 2002/98/EC Article 21, Annex IV	Strategy	GMP, Annex 14 Chap. 6 PIC/S 14 EDQM (CoE) Principles Chap. 8, 9 Standards Chap. 8,9	Donated blood is grouped and screened for mandatory infectious markers.	• Records of ABO, RhD, HBsAg, Anti-HCV and Anti-HIV 1+2 testing; plus records of other tests that are required locally. Check up-to-date test requirements against tests carried out. [N.B. Requirements may change over period this Manual is use]. • Records of irregular red cell antibody screening • Quality control records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LT 002 2005/62/EC, Annex 6.3., Para. 6	First time donor or regular donor testing	EDQM (CoE) Standards Chap. 8 PIC/S 14.07, 14.08	Blood group serology testing includes procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).	• Observation • SOP / training records
LT 003 Directive 2005/62/EC Annex 6.3	Sample receipt, reconciliation and storage	GMP 4.23, 6.11, 6.13, 6.14 PIC/S 7.13, 7.14 EDQM (CoE) Principles Chap. 8,9, Standards Chap. 8,9	There are procedures for sample reception, checking, storage and management of sample archive. Samples have a unique barcode identifier. SOPs include sample reconciliation against session documentation to verify that all samples have been received for testing. Samples are checked for their suitability for testing (label integrity, deterioration, haemolysis, icterus, lipaemia). Unsuitable samples are segregated and	• SOP / training records • Sample receipts and testing criteria • Storage and archiving conditions (refrigerator/freezers) • Records • Observation • Transfer documents • Traceability of labels

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			excluded. Samples are appropriately stored before testing in accordance with assay instructions for use.	
LT 004 Directive 2005/62/EC Annex 6.3	Control of Processes	GMP 5.2, 5.15, 5.22, 5.23, PIC/S 5.8 EDQM (CoE) Principles Chap. 1,8,9 Standards Chap. 1,8,9	Critical processes are adequately documented. Operators follow the procedures as documented. Critical assays are from approved suppliers (CE marked IVDs) and fit for their intended purpose. Assays are validated in conjunction with test equipment before use. Sample dispensers and sample processor/readers have been set up and validated for new assays according to written procedures/protocols. Assays are used in accordance with each manufacturer's instructions.	• SOP / training records • CE Marking for assays and equipment • Validation records for critical processes, equipment and assays. • Physical observation of operators performing procedures. • Review of documents

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LT 005 Directive 2005/62/EC Annex 6.3	Reagents	GMP 6.19, 6.20, 6.21 PIC/S 14.6 EDQM (CoE) Principles Chap. 1,8,9 Standards Chap. 1,8,9	New deliveries of assays and reagents are tested before placing into routine use. Reagents are prepared and stored in accordance with each manufacturer's instructions. Reagents have expiry dates on containers and these dates are not exceeded. Locally prepared reagents (e.g. saline and deionised water) are subject to quality control.	• SOP / training records • Records of the preparation of reagents covering for example: ·batch number, preparation date, ·expiry date, dilution factors, ·completion signature. • Reagent validation / quality control records • Version controlled instructions for use • Direct observation
LT 006 Directive 2005/62/EC Annex 6.3	Equipment calibration	GMP 4.26 PIC/S 8.4 EDQM (CoE) Principles Chap. 1,	Requirements for internal and external calibration are defined, with frequencies. Requirements for internal calibration for each instrument have been defined according to the manufacturer's	• SOP / training records • Calibration records

	Blood Establishment Inspection Guide	EuBIS

Scope:	Laboratory testing	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		Standards Chap. 1	recommendations. Records of calibration are up-to-date and complete.	
LT 007 Directive 2005/62/EC 6.3	Automated blood grouping machines	GMP 4.26, 4.27 EDQM (CoE) Principles Chap. 8	Procedures are documented. Validated profiles are used. Profiles have been defined and documented for machines used for secondary testing Back-up and secondary grouping instruments have been validated	• SOP / training records • Materials and equipment, taking into account manufacturer's instructions. • Documented profiles

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LT 008 Directive 2005/62/EC 6.3	Sample handling and pipetting	GMP 4.15, 4.22, 4.26 PIC/S 10.12, 14.3, 14.4, 14.5, 14.12) EDQM (CoE) Principles Chap. 8, 9, Standards Chap. 8,9	Automated sample handler programs have been validated. Documented procedures covering the use of the sample handlers including sample racking, sample registration, handling of consumables, wash solution, sample tips, selection and placement of appropriate kit and external quality control samples, identification of test plate or other reaction vessels, procedure when a sample or plate barcode cannot be read, procedure for 'missed samples' and error messages. Shutdown and cleaning procedure. Permissible delay between sample addition to test plates and transfer to the automated processor defined are documented or controlled by the instrument.	• SOP / training records • Validation records, including installation qualification • Records of testing • Observation • Process routing instructions

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LT 009 Directive 2005/62/EC 6.3	Assay processing	GMP 4.27, 4.28, 6.7 PIC/S 14.4 EDQM (CoE) Principles Chap. 8,9, Standards Chap. 8,9	Settings for the automated processor / readers have been validated for each assay. SOPs are used for the operation of automated processor/readers for tasks including: the loading and checking of reagents and wash solutions; checking of incubator temperatures; validation of assays runs and release of results; handling of aborted and invalid test runs; and shutdown and cleaning.	• SOP / training records • Validation records • Records of testing • Observation
LT 010 Directive 2005/62/EC 6.3	Manually processed assays	GMP 4.1, 4.8, 6.6, 6.7, 6.15 PIC/S 14.4	Manually completed assays are processed in accordance with the manufacturer's instructions. Procedures for carrying out assays manually are in place. These include: the requirement for staff that undertake the tasks to be of sufficient seniority and properly trained; segregation of manual	• SOP / training records • Records of plates processed covering – who performed each assay stage – incubation start / finish times for each stage so that correct incubation

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		EDQM (CoE) Principles Chap. 8,9, Standards Chap. 8,9	tests to prevent mix-ups; the required equipment is checked before use; there are step-by-step instructions for reagent preparation, addition, incubation etc.; and a requirement is in place to cross-check the addition of the correct reagent to each well and all the equipment involved. Full records kept of each assay processed.	period can be verified – identity of equipment used for each stage – checks on equipment (e.g. incubator temperature).
LT 011 Ref. PIC/S	Part used microbiology plates	PIC/S 14.4	Documented procedure for the use of microplate assays when one or more strips have been removed from the array of test wells. The use of blank wells for part plates is controlled. Their preparation has been validated.	• SOP / training records • Validation records

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Scope:	Laboratory testing	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
LT 012 Directive 2005/62/EC 6.3	Results handling	GMP 6.9, 6.16 PIC/S 9.4, 11.19, 11.20, 14.7, 14.8, 14.18 EDQM (CoE) Principles Chap. 8,9 Standards Chap. 8 ,9	For blood grouping, documented procedures are in place dealing with: the review of printouts including checking proportion of ABO and Rh blood groups (sense check), unresolved results, monitoring of trends in unresolved groups, handling of indeterminate blood group results, and investigation of results which do not agree with historic results or where duplicate tests do not agree. For microbiology, results are validated by visual checking when appropriate (to check for false negative results).	• SOP / training records • Validation reports • Records of testing • Observation
LT 013 Directive 2005/62/EC 6.3 and Annex 4	Microbiology results reporting (infectious diseases)	GMP Annex 11 PIC/S 14.11	The current version of data reduction software used to interpret assays and report to the mainframe has been validated with each assay. Download validation criteria have been	• SOP / training records • Validation reports • Records of testing • Observation

	Blood Establishment Inspection Guide	EuBIS

Scope:	Laboratory testing	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
		EDQM (CoE) Principles Chap. 9 Standards Chap. 9	defined and implemented. There is an SOP for the use of download software. Access to software is controlled.	
LT 014 Directive 2005/62/EC Annex 6.3	Assay quality control	PIC/S 14.14 EDQM (CoE) Principles Chap. 8,9 Standards Chap. 8,9	Kit manufacturer's assay quality control criteria are applied and the assay test run is automatically rejected where these are not satisfied. An external 'go/no go' control is set up on each plate or test run and the assay results are automatically rejected where this is negative. Quality control results are analysed for trends.	• SOP / training records • Validation records • Records of testing

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Laboratory testing**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LT 015 Directive 2005/62/EC Annex 6.3	Repeat and confirmatory testing	PIC/S 14.13 EDQM (CoE) Principles Chap. 9 Standards Chap. 9	There is a documented "Repeat and Confirmatory Testing" procedure including: Segregating and checking samples for repeat testing; repeat testing initial reactivity; recording results of repeat testing; referral of samples to a reference laboratory; acting on reference laboratory results; follow-up of delayed results. Reference tests have been validated.	• SOP / training records • Validation records • Records of testing • Reference test results
LT 016 Directive 2005/62/EC Annex 6.3	Archive samples	PIC/S 14.15 EDQM (CoE) Principles Chap. 3 Standards Chap. 3	There is a documented archiving policy and procedure defining volume, retention time, temperature, storage, handling of plates, identification, retrieval of samples and final disposal of samples	• SOP / training records • Records • Observation

	Blood Establishment Inspection Guide	EuBIS

Scope:	Laboratory testing	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
LT 017 Directive 2005/62/EC Annex 6.3 Para. 5	Quality assessment within participating laboratories	PIC/S 14.9 EDQM (CoE) Principles Chap. 8,9 Standards Chap. 8,9	There is participation in suitable external quality assessment schemes (proficiency testing) The results are reviewed and action taken.	• External Proficiency Testing schemes reports [e.g. National External Quality Assessment Scheme (EQAS), INSTAND (‘Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V’] • Corrective action reports

3.5.4 Processing and validation

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Processing and validation**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.4 Processing and validation			
PV 001 2005/62/EC Annex 6.4	Production procedures	GMP Annex 1 Annex 15 GMP 5 (5.2, 5.21, 5.22. 5.23, 5.24) PIC/S 8, 11 EDQM (CoE) Principles Chap. 4 Standards Chap. 4	There are documented procedures for all parts of the process including primary processing and secondary processing (e.g. irradiation and the use of sterile connection).	• SOP / training records • Leading production structure (plasma or platelet driven production department) • Equipment validation; Log files; labels; routings • Absences of crossing lines • Limits with respect to conditions during processing (time; temperature; humidity)

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Processing and validation**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
PV 002 2005/62/EC Annex 6.4	Process control	GMP 5.8, 5.38, 5.50, 5.54, 6.3, 6.4, 6.18	Factors that influence the performance of processes are identified and monitored. e.g. processing and storage environment, equipment, staff, intermediate products (e.g. buffy coat)	• SOP / training records • Records e.g. Blast freezers. • Trend analysis • Records of corrective action
PV 003 GMP 5.38	Visual inspection	EDQM (CoE) Principles Chap. 3, Standards Chap. 3	The integrity, labelling and content of blood bags are visually examined by agreed criteria	SOP / training records for handling of leakage or failure in labelling. Visual standards (colour comparators) for • haemolysis, lipaemic or icteric plasma • red-cell contaminated platelets
PV 004 2002/98/EC Article 29(f)	Quality monitoring of blood components	GMP Chap. 6 (6.4,6.7, 6.9, 6.10 to 6.13, 6.15 to 6.21) PIC/S 13	Blood components are monitored for conformance to EU specifications. Validated and documented procedures for blood component Quality Monitoring are in place. These include: sampling	• Blood component specifications • Validation reports • SOPs / training records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Processing and validation**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
2004/33/EC Article 6 Annex V.		(13.1, 13.4 to 13.7) EDQM (CoE), Principles Chap. 4,5 Standards Chap. 4,5	plans; taking samples; use of controls; use of statistical process control (SPC); and reporting of 'out of control' events. Results of 'Product Testing' are monitored to ensure compliance with the EU Directive and EDQM (CoE) guidelines.	• Sampling plans • Results records • Records of results • Corrective action reports
PV 005 Ref. GMP Annex 12	Secondary processing (Irradiation)	GMP Annex 12 (12-9, 12-10, 12-11, 12-17, 11-29, 11-31, 12-42, 12-44) PIC/S 11.00, 11.11 EDQM (CoE) Principles Chap. 4,6 Standards	There is a specification for irradiated components including any change to shelf life. Records of irradiation are kept; 'irradiation' (gamma sensitive) labels are used to monitor the dose of each 'irradiation' load; and labels are stored at the correct temperature. There is a validated and documented procedure that indicates the maximum number of units that can be placed in each load. The irradiator is validated.	• Documented specification. Component Irradiation records showing the number of units irradiated and for each unit: • component type • dose given • date, time and operator • Documented procedure. • Irradiation records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Processing and validation**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		Chap. 4	The irradiation chamber is 'dose mapped' at intervals not exceeding 12 months. Checks are performed on the timer. Decay rates been calculated and times adjusted to give the required dose.	• SOPs / training records • Dose mapping records • Validation records • Procedure for recalculating dose time • Product labelling
PV 006 EDQM (CoE) Ch 95.3, Ch 19	Other secondary processing including leucocyte filtration, pooling, neonatal split products	EDQM (CoE) Principles Chap. 4 Standards Chap. 4,5	Secondary processes are validated to produce sterile blood components that meet their specification. Critical equipment such as sterile tune welders are validated, calibrated, cleaned and maintained. Secondary processing takes place within a suitable environment	• Production records • SOPs / training records • Validation records • Product labelling • Floor plan • Observation

3.5.5 Labelling

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Labelling**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered :: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.5 Labelling			
LB 001 2002/98/EC Article 14, Annex III 2005/61/EC 2005/62/EC Annex 6.5	Blood component labelling, and the labelling of sample tubes	GMP 5.45, 5.52 PIC/S 10.23 11.12-11.15 EDQM (CoE) Principles Chap. 3,4 Standards Chap. 3,5	Blood components are labelled in conformance with the EU Directive. This should include the requirements for labelling and traceability referred to in Article 14 of Directive 2002/98/EC and Commission Directive 2005/61/EC. Labelling is performed in an environment and in a way that minimises the risk of mix ups and errors Labels have been validated at appropriate temperatures and storage times to ensure they do not detach, fade or fragment.	• Official name of component • Volume, weight or cell count • Unique donation identifier • Name of producing establishment • ABO and RhD group • Date or time of expiry • Temperature of storage • Name, composition and volume of anticoagulant and/or

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Scope:	**Labelling**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
				additive solution. • Observation • SOPs / training records • Unique donation – test sample identifier • Visual inspection of stored tubes at relevant temperatures (e.g. freezer or refrigerator) • In case of Barcode, label read-out • Reading test of 'hand-written' labels

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Labelling**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
LB 002 Medical Devices Directives 98/79/EC	Blood collection systems	EDQM (CoE) Principles Chap. 3 Standards Chap. 3,5 EN/ISO 3826 Parts 1 to 3.	The manufacturer's base label on all blood bags conforms to EN/ISO 3826 parts 1 to 3.	Labels contain • eye-readable information: • manufacturer's name and address, • name of blood bag and/or name of blood bag plastic material, • name, composition and volume of anticoagulant or additive solution, • product catalogue number and lot number • Expiry date

3.5.6 Release of blood and blood components

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Release of blood components**	

Criterion No. and Primary Ref. (EU Dir.).	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 6 Blood collection, testing and processing – Annex 6.6 Release of blood component			
RB 001 2002/98/EC Article 9	Product release of blood components into stocks for issue	2005/62/EC Annex 6.6 GMP Ch 2 EDQM (CoE) Principles Chap. 4 Standards Chap. 4 PIC/S 11:1.6-2.3	Each blood component (allogeneic, concessionary and autologous) is formally released (electronically or paper-based) by the responsible person or his/her nominee. There are documents demonstrating that before a blood component is released all collection, medical and tests records are checked to ensure they meet acceptance criteria.	• SOPs / training records • Records of product release • Job descriptions
RB 002 Ref local guidelines	Product release for non-clinical use		Release of components for non-clinical issue (e.g. for reagent purposes) must be performed by a nominated person.	• SOPs / training records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Release of blood components**	

Criterion No. and Primary Ref. (EU Dir.).	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
				• Job descriptions • Records of donations used as reagents and controls
RB 003 2004/33/EC Annex V	Product release		Specifications exist for the release of blood components. These are defined and approved by the responsible persons after validation. Blood component quality monitoring is covered in the Processing and Validation section (3.5.4). For some products these tests form a part of the product release procedure and results must be demonstrated to be within specification before release. Records shall demonstrate that all test results meet acceptance criteria SOPs are in place describing these activities.	• Approved specifications • Job descriptions • SOPs / training records • Quality monitoring records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Release of blood components**	

Criterion No. and Primary Ref. (EU Dir.).	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
RB 004 2005/62/EC Annex	Biohazard products	EDQM (CoE) Standards Chap. 9	There are documented procedures for the handling of biohazard donations and blood components. In case of a confirmed positive infectious test result, all components from that donation and from previous donations from that donor are identified and appropriately segregated / labelled for disposal (The donor's record is updated immediately).	• SOPs / training records • Records of disposal • Observation

3.6 Storage and distribution

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 7 Storage and distribution			
SD 01 2002/98/EC Article 22, 29(e) 2004/33/EC Article 5 Annex IV 2005/62/EC Annex 7	General principles of blood and blood component, storage, distribution and transport	PIC/S 7.13, 7.14, 10.24, 11.3 - 11.5, 12.1, 12.2 GMP Chap. 5 (5.58, 5.61-5.65) GDP Good distribution practises EDQM (CoE)	Storage, transport and distribution of blood and blood components at all stages of transfusion chain are under conditions that maintain product efficacy and safety All storage, distribution and transportation actions are defined by written procedures and specifications. Procedures for storage, distribution and transportation are validated, to ensure blood and blood component quality during entire storage and transportation	• SOPs / training records • Specifications of storage and transport conditions • Validation of storage conditions • Validation of transportation system • Lighting, temperature and humidity appropriate for materials stored • Area clean, tidy and

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		Principles Chap. 1,3,4 Standards Chap. 4,5	period and to exclude mix-ups of blood components.	free from sources of contamination • Pest control programme • Segregation of materials • Facilities for storage of hazardous materials
SD 02 Ref. PIC/S	Security, location of blood storage facilities	PIC/S 12.5, 12.6	Only authorised persons have access to storage areas. Storage areas are located near to an entrance or exist to limit the number of personnel entering work areas.	• Access control system and records • Floor plans • Observation • Temperature logging • Records of temperature registration and alarming systems

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SD 03 2004/33/EC Article 5 Annex IV 2005/62/EC Annex 7.5	Temperature and other storage requirements	EDQM (CoE) Principles Chap. 4 Standards Chap. 4	Storage of blood and blood components during processing, storage and dispatch conforms to specified temperature according to the regulatory requirements:- **Red cell** components and whole blood: +2 to +6°C Platelets and granulocytes: +20 to +24°C **Platelets** must be mixed during storage and storage bags placed singly (non-overlapping) to allow maximum ventilation and pH contingency. **Frozen products** (fresh frozen plasma, cryoprecipitate and cryoprecipitate depleted plasma) are stored at temperatures suitable for the shelf life of the products.	• Storage specifications • Validation records • SOPs / training records • Storage records • Observation
SD 04 Ref. PIC/S	Temperature / humidity control	PIC/S 7.13	Temperature and humidity (where appropriate) in storage areas for materials, blood and blood components	• Temperature and humidity specifications

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			are controlled appropriately , monitored and checked to demonstrate conformance to specifications. Temperature and humidity are within specification throughout the storage facility. Temperature and humidity are continuously monitored and recorded. Storage areas are temperature alarmed. Upper and lower alarm limits are set at the appropriate levels. Alarms are regularly tested. Out-of-specification events are recorded and investigated and appropriate remedial taken for adversely affected components.	• Validation records • SOPs / training records • Temperature and humidity checks • Observation of storage areas. • Records of alarm tests • Quality Incident reports

	Blood Establishment Inspection Guide	EuBIS

Scope:	Cold chain (storage and distribution)	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SD 05 Ref. GMP	Storage capacity	GMP 3.18	Storage areas of sufficient capacity for orderly storage of materials, and to prevent mix-ups.	• Orderly storage of materials • Segregation of materials
SD 06 2005/65/EC Annex 7	Stock organisation	GMP 5.7	Appropriate records of inventory and distribution shall be kept. There are procedures for the control of stock levels, stock rotation, batch control and stock taking.	• List of stock levels for critical materials • Evidence of stock control (e.g. first in first out, expiry dates, batch control) • Evidence of batch control for critical materials • Inventory reports / stock control records • Reconciliation of book and actual stock

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SD 07 2004/33/EC Annex IV 2005/62/EC Annex 7.3	Autologous transfusion	PIC/S 12.4 EDQM (CoE) Principles Chap. 7 Standards Chap. 7	Autologous blood and blood components collected for specific purposes are stored separately.	• SOPs / training records • Observation
SD 08 2005/61/EC	General principles of traceability	EDQM (CoE) Principles Chap. 1 Standards Chap. 1	Full traceability of blood, blood components and materials is maintained	• Traceability testing • Stock / non-stock requisitions • Delivery notes • Goods incoming inspection • Blood bank information system • Traveller records • Picking slips and Shipping Notes

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
				• Stock Transfer Records Contingency in the event of the 'Blood bank Information System' failure
SD 09 2004/33/EC Annex IV	General principles of transporting blood and components	PIC/S 12.10, 12.11 EDQM (CoE) Principles Chap. 4 Standards Chap. 4,5	Validation data to demonstrate that the method of transport maintains the blood within the specified temperature range throughout the period of transportation. Packaging is of a sturdy, well insulated and easily cleaned construction so as to resist damage and to maintain acceptable storage conditions for blood and blood components during transportation. Containers are regularly cleaned. Transportation and storage conditions for	• Validation of transport conditions • SOPs / training records • Agreement between establishment and facility receiving the blood / components specifying responsibilities and conditions • Transport records • Cleaning records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			blood components, packaging format and responsibilities of persons involved are in accordance with procedures agreed between the sites in question (donor site to BE or BE to hospital) If storage or transportation are sub-contracted, their requirements should be defined in a specific written contract.	• Blood spillage SOP
SD 10 PICS 11.3, 11.4	Transporting blood from donor sessions	EDQM (CoE) Standards Chap. 3	Blood from donor sessions is transported to the processing site under temperature and time conditions appropriate for the component that will be prepared.	• Transportation specifications • Validation records • Transport records • Observation
SD 11 GMP 5.24	Refrigerated Vehicles		Refrigerated vehicles are validated, cleaned and maintained to ensure that materials / components are transported within the required temperature specifications.	• Specifications for refrigerated vehicles • Validation records for refrigerated vehicle • Maintenance records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
				for refrigeration units • Temperature monitoring records • Cleaning records • Environmental monitoring records
SD 12 Local policies and procedures	Order taking from the hospital		Order taking is in accordance with documented procedures. Orders are confirmed in writing Particular delivery requirements such as time, CMV negativity and for irradiated products are documented There are documented procedures for • emergency deliveries • receiving and processing orders for cross-matched blood	• SOPs / training records • Ordering records • Customer complaint records • Observation

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SD 13 2005/62/EC Annex 7, 9.1	Issue	Good Pharma. Distribution Practice 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	There are safe and secure systems for issuing blood components. Blood issues are reconciled against the order. Issuing is performed according to documented procedure. There is a documented procedure for the issue of blood components when the computer is out of use. Computer records are updated when the main system becomes available. There is a documented procedure for the issue of autologous donations. There is an SOP for 'concessionary issue' (deviations from specification). Concessionary issues are medically approved for a named patient. A signed acceptance of risk is obtained from the receiving consultant.	• SOPs / training records • Records of blood issue • CAPA records • Customer complaint records • Observation • Signed informed consent examples

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Scope:	Cold chain (storage and distribution)	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SD 14 2005/62/EC Annex 7.6	Return of blood	EDQM (CoE) Standards Chap. 4 PIC/S 12.12	Return of blood / blood components into inventory for subsequent reissue is only accepted when all of the quality requirements / procedures laid down by the blood establishment to ensure blood component integrity are fulfilled. If blood components are returned, the following steps taken: – procedure for maintenance of cold chain and return of a blood component is specified within a contract between the hospital and blood establishment – each consignment of returned blood component(s) lists the returned products and is accompanied by a signed and dated statement that the agreed storage conditions have been met and that products have been inspected before return;	• SOPs / training records • Physical observation • Contract • Records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Cold chain (storage and distribution)**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			at least one sealed segment of integral donor tubing remains attached to the container.	
SD 15 Ref. Good Pharma. Distribution	Major Incidents and disasters	Good Pharma. Distribution Practice 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	There are documented procedures for handling the blood establishment's response to a hospital 'Major Incident'. There are emergency planning / disaster recovery procedures concerning blood establishment premises, facilities and personnel. Where appropriate, emergency procedures are interfaced with those of other health and emergency service contingency arrangements.	• Major incident and emergency planning documentation • Records of training and awareness

3.7 Contract management

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Contract management**	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 8 Contract management			
CM 01 2005/62/EC Annex 8	Third party agreements	EDQM (CoE), Standards Chap. 1 GMP 7.1, 7.2 7.10 – 7.15	Written contracts are in place for work carried out by Third Parties clearly defining: • The Sellers roles and responsibilities (e.g. batch release by Qualified Person) • Standards to be achieved, (product and service related e.g. acceptable down-time) • Maintenance / repair arrangements. • Service continuity / disaster recovery arrangements • Compensation and liabilities in the	• Records of relevant contracts including responsibilities • Supplier audit reports • Reports from the Contractor e.g. quality control data • Policies and SOPs for development and implementation of contracts with third parties whose services impact the product (blood component).

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Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			event of defective product or failures of service provision. The Seller notifies the BE in writing of proposed variations which are agreed before proceeding. The contracting process includes: Checks prior to awarding the contract to help ensure that the Seller meets the establishment's needs (e.g. through supplier audit or questionnaire); Appropriate checks on received goods to confirm they meet specifications; The requirement for manufacturers to provide a certificate of conformance / analysis for critical material; Appropriate checks to ensure that goods continue to meet specification during use	• Certificate of analysis provided by manufacturer to the blood establishment should be available

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			especially those with limited shelf life; Regular contact with Seller of critical good or services to help understand and resolve problems. The contract stipulates the frequency with which a supplier carries out re-validation (processes, materials, equipment). The interval is based on risk.	
CM 02 Ref. GMP	Defects /recall/ non-compliance	GMP 7.13	Manufacturing, analytical and distribution records, and reference samples are kept by Seller, or available to, the blood establishment in case of complaint / recall.	• Manufacturing, analytical and distribution records, and reference samples. • Sellers SOP on the defect/recall procedure.

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
CM 03 Ref. GMP	Buyer's responsibilities	GMP 7.3-7.5	Performs regular visits / audits of the Seller. Provides all information necessary to carry out the contracted operations correctly in accordance with requirements. Ensures awareness of problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products Ensures that all processed products and materials delivered to him by the Seller comply with their specifications or that the products have been released by a Qualified Person. Retains ultimate responsibility for the final blood component.(this does not mean	• Written contract and associated correspondence • Quality control data • Audit reports • Reports of contract review

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			that the contract giver will not recover compensation from the Seller if the Seller is shown to be at fault)	
CM 04 Ref. GMP	Sellers responsibilities	GMP 7.6 – 7.9	Has adequate premises and equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Buyer. Ensures that all products or materials are suitable for their intended purpose. Does not pass any work to a Sub Contractor without the Buyers prior evaluation and approval of the arrangements. Ensures that for any arrangement with a Sub-Contractor that manufacturing and analytical information is made available in the same way as between the original	• Qualifications and experience of service provider • Details of contactors premises / facilities • Quality control data • Clear indications of any other subcontracted third party by the contract acceptor • Supplier audit reports

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			Buyer and Seller. The Seller refrains from any activity that may adversely affect the quality of the product manufactured and/or analysed for the Buyer. That in the event of termination of activities for whatever reason, archived samples (required fro future investigations/incidents) are transferred to other licensed Sellers or to the buyer.	
CM 05 Ref. PIC/S	Third-party transportation	PIC/S 12.11	The transportation and storage conditions for blood components, the packaging format and the responsibilities of the persons involved should be in accordance with procedures agreed between the Buyer and Seller.	• Validation data of transport conditions • Presence of contract and instructions

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
Notes on contractual arrangements with rare blood groups registries and policies for importing rare blood				
Note 1	**Rare blood groups registries**	isbt-web.org IBGRF	**This topic is not covered by the EU legislation.** General consensus is, that blood components used to treat patient immunized against common antigens are special cases dealt with on a 'named patient basis' .	Further information on the handling and application of rare blood group components can be obtained from **ISBT Working Party on Rare Blood Donors www.isbt-web.org** or the **International Blood Group Reference Laboratory (IBGRF) in Bristol, UK**
Note 2		White Paper: Updated report of the working party on the use of	Information would be also available from the following Oral Presentation given by Sandra Nance during the Meeting of the German Society for Blood Transfusion 2008	**Sandra Nance | Sr Director, IRL, Biomedical Services**

	Blood Establishment Inspection Guide	EuBIS

Scope:	Contract management	

N.B. The terms 'contract acceptor' and 'contract giver' have been replaced by 'buyer' and 'seller' for simplicity

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
		rare blood for non-members and physicians (2004) isbt-web.org	Using the link: http://www.uni-ulm.de/%7Ewflegel/RARE/ISBT_RareDonors_2008-09-08_08-56-AM.htm	**American Red Cross** 700 Spring Garden Street Philadelphia PA 19123 (215) 451-4362 (p) | (215) 687-8831 (c) (215) 451-2538 (f) | snance@usa.redcross.org
Note 3		ISBT working Party Report 2004 isbt-web.org	**Policies for importing rare blood**	
Note 4		ISBT working Party • Transfusion Today [2]	**Flow-Chart for requesting rare blood**	

[2] ISBT Working Party on rare Donors, Transfusion Today, Issue 71, 2007, page 15-16.

3.8 Non-conformance

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Non-conformance**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
	Process(es) covered: 2005/62/EC – Annex 9 Non-conformance			
	9.1. Deviations			
NC 01 2005/62/EC, Annex 9.1	Concessions, process deviations and product non-conformances	GMP 5.15, 5.61, 5.62, 5.64 EDQM (CoE) Standards Chap. 1	There are documented procedures for: • Clinical concessions (Donations directed to a named patient) • Process deviations • Product non-conformances	• Observation • SOPs / training records • Records
	9.2 Complaints			
NC 02 2005/62/EC, Annex 9.2	Customer and donor complaints	GMP 8 (8.1 - 8.7) , Risk Management 18, 19 PIC/S 15 EDQM (CoE) Standards Chap. 1	There are documented procedures for recording, investigating and resolving: • Customer complaints • Donor complaints	• Observation • SOPs / training records • Records • Annual statistics

	Blood Establishment Inspection Guide	EuBIS

Scope:	Non-conformance	

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
	9.3 Recall			
NC 03 2005/62/EC, Annex 9.3	Recall and disposal Notification to Competent Authority	GMP 3.23, 5.61 PIC/S 15	There are effective procedures for the recall, return and disposal of rejected, defective, obsolete and surplus materials. The recall procedure includes a description of the responsibilities and actions to be taken. This includes notification to the Competent Authority.	• Segregation and labelling of returned / recalled materials • Recalled material records • Goods return notes • Notification notes • SOP / training records
NC 04 2005/62/EC Annex 9.3, Para. 3	Trace-back (look-back) procedure	GMP 8 PIC/S 15 EDQM (CoE) Principles Chap. 1, Standards Chap. 9	Actions identified following an adverse event/transfusion reaction and/or product recall are taken within pre-defined time limits and trace all relevant blood components. (N.B. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as	• SOP (trace back) / training records(action plan) • Action plan • Records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Non-conformance**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			to notify hospitals and recipients of components collected from the same donor in the event that they might have been put at risk).	
	9.4 Corrective and preventive actions (CAPA)			
NC 05 2005/62/EC, Annex 9.4 Para. 1	Non-conforming product	GMP 5.61 – 5.65 PIC/S 5.5, 5.6 EDQM (CoE) Principles Chap. 1 Standards Chap. 1	There is an audit trail from identification of non conforming product through to final discard or use. (including labelling, segregation and quarantine)	• SOP / training records • Physical observation of quarantine area • Biohazard discard list • Discard records

	Blood Establishment Inspection Guide	EuBIS

Scope:	Non-conformance	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
EM 05 2005/62/EC, Annex 9.4 Para. 3	Events Management / CAPA	GMP 5.15 EDQM (CoE) Standards Chap. 1	All errors and accidents shall be documented and investigated in order to identify corrective and preventive action. There are documented procedures for the following events: • Quality incidents / CAPA • Serious adverse events of donation* • Patient adverse events* Corrective/preventive action is timely and appropriate Events have been closed out in a timely fashion * refer also to Chapter 3.12 of this guide	• SOP / training records) • Adverse vent records • Root cause analysis records • Records of event escalation / referral • Event trends analysis • Organisation wide leaning from events

3.9 Self-Inspection, audits and improvements

	Blood Establishment Inspection Guide	EuBIS

Scope:	Self-Inspection, audits and improvements	

Criterion No. and Primary Ref. (EU Dir.).	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
	Process(es) covered: 2005/62/EC – Annex 10 Self-Inspection, audits and improvements			
SE 01 GMP 9	Audit	GMP 9.3, Annex 20 (risk management EDQM (CoE) Standards Chap. 1	Internal and external audits are properly responded to, followed-up and closed in a timely manner.	• Corrective action plans. • Evidence of follow up through to closure
SE 02 2002/98/EC, Article11 2005/62/EC, Annex 10.1	Areas covered and timing of the internal audit programme	PIC/S 5.9-5.10 EDQM (CoE) Standards Chap. 1	Self-inspection or audit systems are in place for all parts of the operations to verify compliance with the standards set out in this Annex. They are carried out regularly (2005/62/EC, Annex 10.1). An audit programme is planned, taking into consideration the areas to be audited, importance of the processes (i.e.	• Audit plan (includes all relevant areas/departments) • Audit guides / check-lists (includes relevant criteria) • SOPs / training records • Audit reports

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Self-Inspection, audits and improvements**	

Criterion No. and Primary Ref. (EU Dir.).	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			associated risks) and, the results of previous audits. Self-inspection comprises all parts of the operations is performed regularly to a plan and documented.	• CAPA reports • Records of audit closure / time-scales • Trends of audit nonconformities
SE 03 2005/62/EC, Annex 10.1	Auditor qualification	PIC/S 5.9 EDQM (CoE) Standards Chap. 1	Self-inspection carried out by trained / competent persons managerially independent of area / department being audited. A training programme is in place for lead auditors / auditors which is periodically reviewed for effectiveness. Trainee auditors are supervised. Self–inspections performed under responsibility of quality assurance unit.	• Training programme • Auditor qualifications • Auditor training records • Job descriptions (to show independence):

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Self-Inspection, audits and improvements**	

Criterion No. and Primary Ref. (EU Dir.).	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
SE 04 2005/62/EC, Annex 10.2	Follow up of deviations / Improvements	PIC/S 5.10 EDQM (CoE) Principles Chap. 1, Standards Chap. 1	All results are documented and appropriate corrective / preventive actions are taken in a timely and effective manner All audit results documented and reported to management. Appropriate corrective actions are taken Management responsible for area being audited ensures that actions taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include verification of actions taken and reporting of verification results. Corrective actions documented / completed in timely / effective manner.	• Audit reports • Evidence of systematic failure across the organisation • CAPA reports • Audit closure reports • Evidence of repeat non-conformities

3.10 Traceability and notification of serious adverse reactions and events

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	Sub-process/ control point	Cross-Ref. source	Inspection criterion description	Example evidence
	Process(es) covered: 2005/61/EC – Traceability and notification of SAR and SAE			
TR 01 Directive 2002/98/EC Article 14	Traceability	IMB / INAB guide[3] EDQM (CoE) Standards Chap. 1 PIC/S 9.3	A system for identification of each blood donation and its components exists enabling full traceability from the donor to the transfused recipient.	• Quality management system • Quality policy

[3] Minimum requirements for blood banks compliance with Article14 (Traceability) and Article 5 (Notification of serious adverse reactions and events) of EU Directive 2002/98/EC. Reference document compiled by the IMB/INAB expert group on blood and blood components (National guideline from Ireland to be used in conjunction with the ISO 15189 standard

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 02 Directive 2005/61/EC, Article 1	Blood establishment and Hospital interaction	GMP 5.3, GMP 5.27 EDQM (CoE) Principles Chap. 1, Standards Chap. 1	SOPs are in place to trace each blood donation and its components from the donor to its final destination (whether this is a recipient, a manufacturer of medicinal products or disposal). This SOP must also allow traceability from the final destination to the donor. This process covers responsibility of the 'blood establishment' and the 'hospital blood bank' (including the hospital and treatment facilities). For blood establishments that provide a blood banking service for their hospitals, when issuing blood/components for transfusion an SOP is provided to verify that each unit issued has been transfused to the intended recipient of or, if not transfused, to verify its subsequent disposal.	• SOPs (including emergency situations) / training records • Contract and Annexes

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 03 2002/98/EC Article 14, Para. 3 2005/61/EC, Article 4 and Annex I	Record of data on traceability	IMB/INAB guide EDQM (CoE) Principles Chap. 2,3 Standards Chap. 1,5	Data is kept for at least 30 years This comprise the following data set: • Blood establishment identification • Blood donor identification • Blood unit identification • Individual blood component identification • Date of collection (year/month/day) • Facilities to which blood units or blood components are distributed, or subsequent disposition • Blood component supplier identification • Issued blood component identification • Transfused recipient identification • For units not transfused, confirmation of subsequent disposition/date of transfusion/disposition (Year/month/day) • Lot number of component *N.B. Some blood establishments only have records up to point of delivery to hospitals they support.*	Records of ordering, transportation and receipt of blood, including emergency situations, records of storage of blood (pre and post issue), labelling and validation, issuing blood components to hospitals, transportation to hospitals, delivery to wards, blood component administration, return of blood to blood bank inventory, quarantine, disposal of empty transfusion packs.

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 04 Directive 2005/61/EC	Traceability	GMP 5.3, GMP 5.27, Annex 17.17 EDQM (CoE) Principles Chap. 1, Standards Chap. 1	Procedures in place for the traceability of goods from receipt to issue. Sufficient and adequate records shall be maintained of all materials received and dispatched.	• Stock / non-stock requisitions • Delivery notes
TR 05 2002/98/EC, Article 14 and 15	Notification of serious adverse reactions (SAR) and events (SAE) to the blood establishment	EDQM (CoE) Principles Chap. 11 Standards Chap. 11	Procedures between the blood establishment and those facilities where transfusion occurs are in place to retain the record of transfusions and to notify the blood establishment without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components.	SAR and/or SAE record form

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 06 Ref. GMP	Audit Trail for Collection and Delivery	GMP 4.8, 4.25	Procedures are in place to ensure an effective audit trail for all blood and critical items collected and delivered. Records are completed fully and accurately and returned to the appropriate department.	• Inter Centre Transfer Record • Session delivery note • Hospital delivery note • Sample reception records
TR 07 2002/98/EC, Article 15, Para. 1	Withdraw from distribution	EDQM (CoE) Principles Chap. 1, 11, Standards Chap. 1, 11	Procedure to accurately, efficiently and verifiably withdraw from distribution blood or blood components associated with the notification referring to any serious adverse events (SAE) or serious adverse reaction (SAR).	• SOPs / training records • Record on withdraw (if available)

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 08 2002/98/EC Article 15 2005/61/EC, Annex I-III	Notification of SAR and SAE	EDQM (CoE) Principles Chap. 11 Standards Chap. 11	Notification to the competent authority has to be given in all cases of SAE related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any SAR observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components.	Notification of SAE form containing a rapid and confirmatory format • Reporting establishment • Report identification • Reporting date (year/month/day) • Date of SAE (year/month/day) • Root cause analysis (confirmatory) • Corrective measures taken (confirmatory)
TR 09 2005/61/EC, Article 5 and Annex II – Part A and B	Notification of SAR including imputability levels	EDQM (CoE) Principles Chap. 1, 11, Standards Chap. 1, 11	Procedures in place to ensure that blood establishment communicates to the Competent Authority as soon as known all relevant information about SAR of imputability level 2 or 3.	Notification of SAR form to allow rapid action and confirmation • Reporting establishment • Report identification

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
				• Reporting date (year/month/day) • Date of SAR and transfusion (year/month/day) • Age / sex of recipient • Blood/component causing SAR • Type of SAR • Imputability level (NA, 0-3) • Change of type of SAR (confirmatory) • Clinical outcome (if known)

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 10 2005/61/EC, Article 5 and Annex II – Part D	SAR – Annual summary report	EDQM (CoE) Principles Chap. 1, 11, Standards Chap. 1, 11	Regular annual reports on SAR with at least the following information • Reporting establishment • Reporting period (12 month) including number of units issued, number of recipients transfused, number of units transfused • Total number of confirmed SAR separated by type and imputability level	Annual report to Competent Authority

	Blood Establishment Inspection Guide	EuBIS

Scope:	Traceability and notification of serious adverse reactions and events

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
TR 11 2005/61/EC, Article 6 and Annex III – Part C	SAE - Annual summary report	EDQM (CoE) Principles Chap. 1, 11, Standards Chap. 1, 11	Regular annual reports on SAE with at least the following information: • Reporting establishment • Reporting period (12 month) • Total number of blood and bloodcomponents processes • Total number of SAE events related to blood components (subdivided into deviations in whole blood, apheresis collection, Testing of donations, processing, storage, distribution, materials, others (as specified).	Annual report to Competent Authority including a specification (explanation) on the deviation categorised as follows: • Product defect • Equipment failure • Human error • Other as specified

3.11 Information technology (IT)

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Information Technology**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
IT 001 GMP Annex 11	Critical systems / softw are	GMP 4.9, 6.16, GMP Annex 11-5, 11-9, 11-11 EDQM (CoE) Principles Chap. 1	Software and spreadsheets used for result calculations have been validated. Software and spreadsheets used for result calculations are protected against change by an unauthorised person.	• Validation reports for all systems in use • SOPs / training records • Records of results
IT 002 GMP Annex 11	Data control	GMP Annex 11-9 GMP4.9 EDQM (CoE) Principles Chap. 1	The manual entry of critical data, such as laboratory test results is independently verified by a second authorised person. Database amendments are checked by an authorised person before approval and reviewed for accuracy after completion.	• Observation of procedure • Audit trail (electronic and documented) • SOPs / training records • Database Amendment Records

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Information Technology**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
IT 003 GMP Annex 11	Access control	GMP Annex 11.8 EDQM (CoE) Principles Chap. 1	Access by staff and third parties, is limited to those who have a professional need and have been trained. There is authorised access (stratified) to carry out each of the following activities: Data entry, data amendment, reading and printing of data. Methods of preventing unauthorised access are in place, such as personal identity codes or passwords. These are changed on a regular basis. There are SOPs for: creating new accounts, amending existing accounts, suspending or deleting accounts.	• Observation of procedure • SOPs / training records • Records of access requests for a new user of the system (or part of the system). • Records of access removal for “leavers”

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Information Technology**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
IT 004 GMP Annex 11	Environment	GMP Annex 11.3, 11.7, 11.11, EDQM (CoE) Principles Chap. 1	The location of IT equipment complies with manufacturers instructions in respect of temperature and humidity and is properly protected against unauthorised access, fire, flood and other risks. It is also protected against unauthorised access (i.e. hacking) by a firewall or other software.	• Observation • Records of temperature, humidity
IT 005 GMP Annex 11	Software code and configuration	GMP Annex 11.7 EDQM (CoE) Principles Chap. 1	Changes to software code and configuration approved, controlled and validated with records of all these activities.	• SOP / training records • Validation and change control records.
IT 006 GMP Annex 11	Data backup and storage	GMP Annex 11-14 EDQM (CoE) Principles Chap. 1	Business critical data is backed-up. Back-up media (e.g. tapes) are used and stored in accordance with manufacturers instructions in respect of humidity / temperature.	• Observation • SOPs • Back-up records • Records of back-up trials or actual data restoration.

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Information Technology**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
			Backup media is stored securely against fire, theft and other risks. Backup media is stored separately (preferably on a separate site) from the devices being backed up so that risks are controlled whilst system recovery can take place within a acceptable period. The back-up procedure is tested periodically.	
IT 007 GMP Annex 11	Contingency planning / System Recovery	GMP Annex 11-15, 11-16 EDQM (CoE) Principles Chap. 1	A system recovery procedure (dependent upon criticality of system) is in place. The recovery procedure is tested periodically. Alternative procedures for the issue of blood products exist for the period the computer is 'down' (out of use). Computer records are updated when the main system becomes available.	• SOPs/training records • Records of recovery trials or actual recoveries

	Blood Establishment Inspection Guide	EuBIS
Scope:	**Information Technology**	

Criterion No. and Primary Ref. (EU Dir.)	**Sub-process/ control point**	**Cross-Ref. source**	**Inspection criterion description**	**Example evidence**
IT 008 GMP Annex 11	Problem resolution by Third Party	GMP Annex 11 - 18	There are documented procedures for problem resolution by Third Parties that include root cause analysis and implementing effective corrective action. Problems referred to Third Parties are monitored to resolution by the blood establishment and closure agreed between both parties.	• Contracts/service level agreements • SOPs/training records • Records of investigation and corrective action
IT 009 GMP Annex 11	Product release	GMP Annex 11 – 19 EDQM (CoE) Principles Chap. 1	Where release of blood components is carried out using a computerised system, role of authorised persons in releasing each component is clearly defined (see Release of Blood Components RB 001). Non conforming products are electronically blocked from issue.	• Observation • Job descriptions • SOP/training records • Access records • Audit trail

Annex I - Preparatory documents for the self-inspection process

Self-Inspection record / trail

	Quality Management System	**EuBIS**
EU-Inspection	**Self-Inspection Record / Audit Trail**	**Page 1 of 5**

Scope: (Name the departments / processes to be inspected			**> <**		
Document-Code	**EUBIS WG - 001**				
Document-Version	**Version 1.0**		**Replaces Version:**	**N/A**	
Title:	**EUBIS Blood Establishment Self-Inspection Record / Audit Trail**				
Effective date:	**< >**	**Expiry date:**	**< >**	**Date of next review:**	**< >**
Changes:	**< >**				

	Quality Management System	**EuBIS**
EU-Inspection	**Self-Inspection Record / Audit Trail**	**Page 1 of 5**
Scope: (Name the departments / processes to be inspected	> <	

Distribution: The use of electronic copies is optional	Name / position < >	Copy ID No.	Name / position	Copy ID No.

Written by:	**Reviewed and authorised by:**		
Date:	Date:		
Name of person(s)	Name of person(s)		

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Record / Audit Trail	Page 2 of 5
Scope: (Name the departments / processes to be inspected	> <	

1. Objective:

The objective of these preparatory documents is to provide a standardised self-inspection / audit trail record based on the relevant EU legislation and guidelines which form a part of the 'Inspection Framework' developed by EuBIS. This self-inspection / audit trail document aims to assist those that will have to implement a self-inspection / audit system for their blood establishment following the European blood legislation.

The template enables the auditor to record the audit scope and criteria to be assessed in advance of the audit. During the audit, the template enables details to be recorded on participants, the documentation of findings / outcomes and classification of any deviations or non-compliances observed.

2. Area of application: The document is part of the quality management system covering the inspection and self-inspection / audit of blood establishments (e.g. Processing and testing of blood donations and blood components).

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Record / Audit Trail	Page 3 of 5
Scope: (Name the departments / processes to be inspected		> <

Date of Audit:		**Audit-Reference:**	
Organisation / Department:	Blood Establishment in the European Union – - Department/Area of processing - Department/Area of testing		
Scope / Processes covered	e.g. **General requirements for processing and testing**		

Auditor (Role)	**Name:**	**Signature:**
e.g. Lead auditor		
e.g. Expert (Peer-Audit)		

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Record / Audit Trail	Page 4 of 5
Scope: (Name the departments / processes to be inspected		> <

Attendance List * (Department Representatives)		**Opening Meeting**	**Closing Meeting**
Role	**Name**	**Signature**	**Signature***
Audit-Guide * (the person from the organisation responsible for the coordination during the audit)			
Staff involved			
e.g. Institutional Director			
e.g. Department Manager			
e.g. Lead Technician			

* Attendance list: of participants: Complete list of all individuals present during the opening and closing meeting. Remark: Staff interviewed during the inspection are not required to sign. These individuals can be mentioned in the inspection (finding) report.

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Record / Audit Trail	Page 5 of 5
Scope: (Name the departments / processes to be inspected		> <

EuBIS	Record	Version: XYZ

Criterion No.	Inspection Criterion or Clause / Area examined	Findings / Evidence	Conclusion / NCR / Severity*
PO 001	**Example of an inspection criterion:** Sufficient qualified personnel to carry out all the tasks which are the responsibility of the manufacturer. Individual responsibilities are clearly understood by the individuals and recorded. Roles and responsibilities are defined within the organisation.		
PO 001	**Example of a Clause / Area** Clause: 2002/98/EC, Article 10, 2005/62/EC, Annex 2.0 and GMP Chap. 2., Annex 16 Area: Personnel in General		
Etc.			

NCR=Non-Compliance Reference (e.g. NCR 1); Severity = Classification of NCRs using following classification: critical, major, other (other significant) and observations – see EuBIS Manual (Inspection standards and criteria)

* Clause: The standard used for the self-inspection (e.g. GMP)

Self-Inspection Summary Report

	Quality Management System	EuBIS
EU-Inspection		Page 1 of 5
Scope: (Name the departments / processes to be inspected	> <	

Document-Code	**EUBIS WG - 001**				
Document-Version	**Version 1.0**		**Replaces Version:**		**N/A**
Title:	**EUBIS Blood Establishment Self-Inspection Report**				
Effective date:	**< >**	**Expiry date:**	**< >**	**Date of next review:**	**< >**
Changes:	**< >**				
Distribution: The use of electronic copies is optional	Name / position **< >**	Copy ID No.		Name / position	Copy ID No.

	Quality Management System	**EuBIS**
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Scope: (Name the departments / processes to be inspected	> <	

Written by:	**Reviewed and authorised by:**		
Date:	Date:		
Name of person(s)	Name of		

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Summary Report	Page 2 of 5
Scope: (Name the departments / processes to be inspected		> <

1. Objective:

To provide a standardised self-inspection summary report based on the relevant EU legislation and guidelines, which form part of the "Inspection Framework" developed by EuBIS (referring to Chapter 4 of the EuBIS Manual 'European inspection and self-inspection guide for blood establishments'). This self-inspection summary is to assist those that will have to implement a self-inspection / audit systems for their blood establishments following the European blood legislation.

The template enables the auditor to summarise the non-compliances, their severity and classification and to monitor the completion of corrective action. The summary report should be presented to the management of the unit being audited during the closing meeting. It subsequently enables the unit that has been audited to record and manage the corrective and preventive action agreed in response to the non-compliances.

2. Area of application:

The document is part of the quality management system covering the inspection and self-inspection / audit of blood establishments. (e.g. Scope: Processing and testing of blood donations and blood components)

	Quality Management System	EuBIS
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Scope: (Name the departments / processes to be inspected		> <

Date of Audit:		**Audit-Reference:**	e.g. Audit number
Organisation / Department:	Organisation/Department/Section/Activities audited		
Scope / processes covered	Scope of the audit (e.g. blood separation)		
Attendance list (Department Representatives)	Refer to the self-inspection record / audit trail		

Auditor (Role)	**Name:**	**Signature:**
e.g. Lead auditor *		
e.g. Expert (Peer-Audit)		

* In general the self-inspection report will be only signed by the lead-inspection on behalf of the inspection team.

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EU-Inspection	Self-Inspection Summary Report	Page 4 of 5
Scope: (Name the departments / processes to be inspected		> <

Part A - General Observations, Acknowledgements and Remarks (including improvements):

General Observations:
Acknowledgements and Remarks (including improvements):

	Quality Management System	EuBIS
EU-Inspection	Self-Inspection Summary Report	Page 5 of 5
Scope: (Name the departments / processes to be inspected		> <

Part B - Description of non-compliances including classification and CAPA:

No.	Description of non-compliances including classification (severity) and clause	Corrective action to be taken	Corrective and preventive action (CAPA) to be completed by: Dept/Person/Date	Corrective action			
				Taken	Not taken	Verified by	Date

Annex II – Documents cross-referenced

EU Legislation on blood and blood components

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal of the European Union L311, 28/11/2001, p.67.

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Official Journal of the European Union, L33, 8/02/2003, p.30.

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. Official Journal L159, 27.6.2003. p.46.

Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components. Official Journal of the European Union, L91, 30/03/2004, p.25.

Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. Official Journal of the European Union, L256, 1/10/2005, p.32.

Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments. Official Journal of the European Union, L256, 1/10/2005, p.41.

European standards for Good Manufacturing Practice (GMP)

EudraLex, The rules governing medicinal products in the European Union, Volume 4 – EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and veterinary Use, Chapter 1-9., European Commission, Enterprise and industry Directorate-General, 2005.

EudraLex, The rules governing medicinal products in the European Union, Annex 2 – Manufacture of biological medicinal products for human use, European Commission, Enterprise and industry Directorate-General, 2005.

EudraLex, The rules governing medicinal products in the European Union, Annex 14 – Manufacture of medicinal products derived from human blood or plasma, European Commission, Enterprise Directorate-General, Working Party on Control of Medicines and Inspections, 2000.

Council of Europe (CoE) – CD-P-TS (EDQM)

European Directorate for the Quality of Medicines & HealthCare (EDQM), European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), (Ed. Council of Europe). Guide to the preparation, use and quality assurance of blood components. 15th Edition, 2009.

PIC/S

Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme (PIC / PIC/S) PIC/S GMP Guide for blood establishments, PE-005-3, 25. September 2007

Annex III – Additional references and project related publications

Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC. Published by the Irish Medicines Board and the Irish National Accreditation Board. Edited by IMB/INAB Expert Group on Blood and Blood Components and should be used in conjunction with the ISO15189 Standard (available via the IMB homepage)

Guide of Recommendations for Tissue Banking. Edited by SANCO-EQSTB Project participants. Recommendations has been developed as a result of a European project entitled *European Quality System for Tissue Banking* (EQSTB) co-funded by DG Sanco. http://sanco-eqstb.hospitalclinic.org/sanco/index.html

These Guidelines have been produced as part of an EU funded project entitled 'European Union Standards and Training for the Inspection of Tissue Establishments' (see www.eustite.org)

Seidl C, Schellenberg E, Sobaga L, O'Connell M, van Kimpers P, McMillan Douglas A, Gorham M, Letowska M, de Wit J, Seifried E on behalf of the Project's participants. EU-Q-Blood-SOP: Development of European Quality Management in Transfusion Medicine. Transfusion Today 2006; 69:8-10.

Seifried E, Seidl C (ed.) European standard operating procedure (SOP) methodology reflecting European best practice within the area adressing the qualtiy and safety of blood. Manual, Edition 1.0, 2007 published by the EU-Blood-SOP project cofunded by the European Commission, DG Sanco, Public Health and Risk Assessment Directorate (available under www.equal-blood.eu or www.eubis-europe.eu).

Seidl C, O'Connell M, Delaney F, McMillan Douglas A, Gorham M, van Krimpen P, Letowska M, Sobaga L, de Wit J, Erhard Seifried E. European best practice in blood transfusion: Improvement of quality related processes in blood establishments. ISBT Science Series, Vox Sanguinis, Volume 2 (1), 2007; 143-9.

Seidl C, Cermakova Z, Costello P, Delanay F, McMillan Douglas A, Siegel W, Slopecki A, Sobaga L, De Wit J, Seifried E. Development of Pan-European Standards and criteria for the inspection of blood establishments (Eu-Blood-Inspection) – EuBIS. ISBT Congress Macao, Vox Sanguinis Vol 95(Supp 1): P525, 249, 2008.

Seidl C, Nightingale M, Brixner V, Müller-Kuller T, Costello P, van Galen JP, Sireis W, Sobaga L, deWit J, McMillan Douglas A, Delaney F, Siegel W, Cermakova Z, Seifried E. Blood transfusion in Europe: Differences and communalities leading to pan-European standards and criteria for the inspection of blood establishments. The EuBIS Project. Transfus Med Hemother, 2008

Annex IV – Terminology

Term	Definition	Source
Audit	Documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to written SOPs, standards, or government laws and regulations, conducted by professional peers, internal quality system auditors or certification body auditors.	Adapted from the Council of Europe Guide for Safety and Quality Assurance for Organs, Tissue and Cells for Transplantation, 3rd Edition, 2007
Audit, peer	A 'peer'-audit is carried out by auditors from different facilities within the same blood establishment. The 'peer'-audit will require a multi-centre structure of the same blood establishment that provides experts with equivalent skills and knowledge based at different locations. Alternatively, 'peer'-audits can be organised through the cooperation between national or regional blood services.	EuBIS
Audit programme	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.	Council of Europe: EDQM, Guide.

Audit- team	A team comprising several individuals that perform an audit. Very often an audit-team consists of two auditors. One auditor will inspect the quality system and in the case of Peer-audits' a technical specialist auditor may also be available.	EuBIS
Auditor, lead	The lead auditor is responsible for coordinating the activity of the audit-'team' and presenting the findings and outcomes of the self-inspection/audit. In smaller BE very often the audits are carried out by a single auditor.	EuBIS
Blood	Whole blood collected from a donor and processed either for transfusion or for further manufacturing	Directive 2002/98/EC
Blood component	A therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods	Directive 2002/98/EC
Blood establishment	Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks.	Directive 2002/98/EC
Calibration	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.	EudraLex

Clean Area	An area with defined environmental control of particulate and microbial contamination constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area. Note The different degrees of environmental control are defined in the Supplementary Guidelines for the Manufacture of sterile medicinal products.	EudraLex
Clean / contained area	An area constructed and operated in such a manner that will achieve the aims of both a clean area and a contained area at the same time.	EudraLex
Deficiencies, critical	Any deficiency in a process or a written procedure which directly affects the safety of the donor or patient. See also non-compliance	EMEA
Deficiencies, major	A serious inadequacy in a process or a written procedure but does not on its own affect the safety of the donor or patient. See also non-compliance	EMEA
Deficiencies, other significant	An inadequacy in a system or process or there is insufficient information to classify it as a major or critical. See also non-compliance	EMEA

Distribution	The act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.	Directive 2002/98/EC
Donation	Blood and blood components collected from an individual and intended for transfusion to another individual (allogeneic) or to the same (autologous).	EuBIS
Donor	A person in normal health with good medical history who voluntarily gives blood or plasma for therapeutic use.	Council Recommendation 98/463/EC
Donor, first time	Someone who has never donated either blood or plasma	Council of Europe: EDQM, Guide.
Donor, regular	Someone who routinely donates their blood or plasma (i.e. within the last two years), in accordance with minimum time intervals, in the same donation centre.	Council of Europe: EDQM, Guide. PIC/S GMP Guide

Donor, repeat	Someone who has donated before but not within the last two years in the same donation centre.	Council of Europe: EDQM, Guide. PIC/S GMP Guide
Expert	Individual with appropriate qualifications and experience to provide technical advice to a CA inspector	EUSTITE Guidelines
Familiarisation visit:	An activity, that includes a visit to a blood establishment in order for a candidate inspector to become familiar with its overall processes, functions and operations.	EuBIS
Good practice	All elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations	Directive 2005/62/EC
Good Manufacturing Practice	All elements in the established practice that will collectively lead to final products or services that consistently meet appropriate specifications and compliance with national and international regulations.	PIC/S GMP for blood establishments, PE 005-3, 25 September 2007
Inspection	Formal and objective control according to adopted standards to assess compliance with this Directive and other relevant legislation and to identify problems	Directive 2002/98/EC

Inspection, self- / Audit	An inspection conducted by representatives of the organisation itself. *Note:* There are several equivalent definitions for this term. The word self-inspection is very often used *inter alia* with the expression of an 'audit' or 'internal-audit'. A self-inspection should be conducted by trained and competent persons managerially independent of the department concerned.	EuBIS
Inspection / audit, external (regulatory)	An inspection carried out by the Competent Authority or accreditation body. Formal and objective control according to adopted standards to assess compliance with the European blood legislation and other relevant legislation and to identify problems. (This definition expands on the definitions given by the Directive 2002/98/EC and the CoE Guide).	EuBIS
Inspectorate training programme	An inspectorate training programme covers general topics essential for the inspector, including principles of inspection techniques as well as specific and on-going training.	EuBIS
Non-Compliance	Deficiency observed during an inspection. This term is used similar to the term non-conformance defined by EMEA	GMP
Critical non-compliance	*Any non-compliance in a process or a written procedure which directly affects the safety of the donor or patient.*	GMP
Major non-compliance	*A serious non-compliance in a process or a written procedure but does not on its own affect the safety of the donor or patient.*	GMP

Other significant non-compliance	*An non-compliance in a system or process or there is insufficient information to classify it as a major or critical.* *Note: There could be a combination of several "other" significant non-compliances, none of which on their own may be major or critical, but may together represent a major or critical non-compliance. These should be clearly explained and reported as such.*	GMP
Pathogen Reduction Technologies (PRT)	Procedures that alter pathogen surface structures and/or penetrate into pathogens irreversibly impeding proliferation of pathogens	Council of Europe: EDQM, Guide.
Processing	Any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component.	Directive 2005/62/EC
Qualification	As part of validation means the action of verifying that any personnel, premises, equipment or material works correctly and delivers expected results	Council of Europe: EDQM, Guide.
Quality system	The organisational structure, responsibilities, procedures, processes, and resources for implementing quality management.	Directive 2005/62/EC
Quarantine	The physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents.	Directive 2005/62/EC

Responsible person	A person responsible for - ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State, — providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures — the implementation of the requirements of [specified Articles] in the blood establishment.	Directive 2002/98/EC. Article 9
Risk assessment	Method to assess and characterise the critical parameters in the functionality of an equipment, system or process.	Council of Europe: EDQM, Guide.
Serious adverse event	Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.	Directive 2002/98/EC
Serious adverse reaction	An unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.	Directive 2002/98/EC

Specification	A description of the criteria that must be fulfilled in order to achieve the required quality standard.	2005/62/EC
Standard	The requirements that serve as the basis for comparison.	Directive 2005/62/EC
Standard operating procedures (SOP)	A document describing a regularly recurring operation that affects the quality of the process. Its purpose is to ensure that the operations are carried out correctly and in a consistent way.	EU-Blood-SOP Manual
Statistical process control	Method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.	Council of Europe: EDQM, Guide.
Third country	Any country that is not a Member State of the European Union.	European Commission www.ec.europa.eu
Third party (Subcontractor)	Any organisation that provides a service to a procurement organisation or a BE on the basis of a contract or written agreement. Includes donor or blood testing laboratories, contract sterilisers and user hospitals which store blood components pending human application.	European Quality System for Tissue Banking (EQSTB), Guide for auditing tissue establishments
Traceability	The ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa;	Directive 2005/61/EC

Validation	The establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled.	Directive 2005/62/EC
Validation Plan	A description of the validation activities, responsibilities and procedures. It describes specifically how a certain validation is to be done.	Council of Europe: EDQM, Guide.

Annex V – Project participants and collaborating institutions

Country	Participants		Working Group members
AT **AUSTRIA**	Zentralinstitut für Bluttransfusion und Immunologische Abteilung *(Central Institute for Blood Transfusion and Department of Immunology)* University Clinics Innsbruck Anichstrasse 35 A - 6020 INNSBRUCK		Prof. Dr. Harald Schennach Director
BE **BELGIQUE / BELGIË**	Het Belgische Rode Kruis Dienst voor het Bloed, Rode Krius-Vlaanderen Vieurgatsesteenweg 98 1050 BRUSSEL Mailing address: Motstraat 40, 2800 MECHELEN	Prof. Dr. Philippe Vandekerckhove CEO, Director	Jan Ceulemans QA Manager Dr. Matine Baeten, Medical Director
BG **BULGARIA**	НАЦИОНАЛЕН ЦЕНТЪР ПО ХЕМАТОЛОГИЯ И ТРАНСФУЗИОЛОГИЯ *National Center of Hematology and Transfusiology* Plovdivsko Pole Str. 6 1756 SOFIA	Prof. Andrey Andreev, MD, PhD, Director	Svetla Bakalova, MD, PhD Quality Assurance Department

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	Vedoucí oddělení klinických praxí a dohledu nad zpracováním biologických materiálů Státní ústav pro kontrolu léčiv (SUKL) *(State Institute for Drug Control*) Státní ústav pro kontrolu léčiv-State Šrobárova 48 CZ-10041 Praha 10		MUDr. Renata Zimová
CY **KYPROS**	Υπουργείο Υγείας της Κυπριακής Δημοκρατίας - Ιατρικές Υπηρεσίες κσι Υπηρεσίες Δημόσιας Υγείας (*Ministry of Health of the Republic of Cyprus - Medical and Public Health Services*) Medical Services and Public Health Services 10 Marcou Drakou, Pallouriotissa 1449 LEFKOSIA (Nicosia)	Dr. Stala Kioupi Dr. Androulla Agrotou, Acting Director	Zoe Sideras

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IE **IRELAND**	Irish Blood Transfusion Service National Blood Centre James´s Street IE - DUBLIN 8	Dr. William Murphy National Medical Director	Dr. Marie O`Connell Director of Quality

Country	Participants		Working Group members
	Irish Medicines Board Blood & Tissue Section Earlsfort Centre Earlsfort Terrace IE - DUBLIN 2I	Dr. Patrick Costello Blood & Tissues Manager, Compliance Department,	Dr. Grace Cunningham
IS **ICELAND**	Blóðbankinn, Landspítali (The Blood Bank, Landspítali University Hospital), Snorrabraut 60 IS-105 Reykjavík	Dr Sveinn Guðmundsson, MD. Director and CEO	Ína Björg Hjálmarsdóttir, Cand.Scient, Quality Manager
IT **ITALIA**	Centro Nazionale Sangue (CNS) (Italian National Blood Centre) Istituto Superiore di Sanità National Institute of Health Via Giano della Bella, 27 00162 Rome	Prof. Dr. Giuliano Grazzini General Director - CNS	Dr. Simonetta Pupella
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RO ROMANIA	Universitatea de Medicina si Farmacie "Victor Babes" Timisoara Physiology and Immunology Uta loan Colonel Martir No.2 300041 TIMISOARA	Prof. Dr. Virgil Paunescu Director	Dr. Carmen Tatu, Ph.D. Blood Transfusion Center Timisoara
	Ministerul Sanatatii Publice *(Ministry of Public Health)* 1-3 Cristian Popisteanu Street 010024 BUCHAREST		Dr. Antoaneta Dragoescu Dr. Gabriela Uifalean
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Annex VI – Associated or observing institutions and participants

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	Abteilung III/4 - Strategische Angelegenheiten, Blut, Gewebe und Transplantationswesen Bundesministerium für Gesundheit Radetzkystraße 2 1031 Wien	Min.-Rat Dr. Johann Kurz
BE **Belgique / België**	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten Eurostation - Bloc 2 Place Victor Horta 40 bte 40 Brussels	Walter Bontez
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Country	Collaborating Partners	Collaborating members
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FYROM **Macedonia**	Institute Of Transfusion Medicine Vodnjanska 17, Skopje Republic of Macedonia	Dr. Risto Dukovski Dr. Olga Todorovsca
LV **Latvia**	Health statistics and medical Technologies State Agency Duntes 12/22, Riga, LV-1005	Anita Daugavvanaga Head of the System of Standards for Biomedicine Health Statistics and Medical Technologies
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