AML-BB

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

This document has been compiled by the HPRA (formerly IMB) / INAB Expert Group on Blood and Blood Components and should be used in conjunction with the ISO 15189 Standard.

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1. Foreword

The European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 Statutory Instrument (SI) No. 360 of 2005 became effective for the purposes of regulation on 8 November 2005.

These Regulations implement the requirements of the EU Directives and S.I. as listed in section 9 References of this document. They apply to **blood establishments** and to **hospital blood banks** as defined in Directive 2002/98/EC.

The Health Products Regulatory Authority (HPRA) (formerly **Irish Medicines Board (IMB))** has been designated as the competent authority for the purposes of these Regulations.

INAB is the body responsible for assessing the competence of hospital blood banks to comply with Articles 14 and 15 of EU Directive 2002/98/EC, (S.I. 360/2005 and S.I. 547/2006), on behalf of the HPRA.

All Hospital blood banks are required to:

- Comply with the requirements laid down in National and European Legislation;
- Submit an annual report to the HPRA by 1st March after the end of the reporting year as per Regulation 12 of S.I. 360 of 2005;
- Operate to International Standard ISO 15189 ("*Medical laboratories – Particular requirements for quality and competence"*).

As per Regulation 16 of SI 360 of 2005, the HPRA may inspect hospital blood banks with a view to ensuring that –

a) hospital blood banks and persons responsible for the management of hospital blood banks comply with the requirements of these Regulations
b) problems relating to compliance with those requirements are identified, and
c) The hospital blood banks operate to International Standard ISO 15189 ("*Medical laboratories – Particular requirements for quality and competence"*)

<u>Background to AML-BB Document</u>

A Steering Committee was established to assist the Department of Health & Children (DoH&C) to implement Directive 2002/98/EC on 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.

The Steering Committee agreed that ISO 15189 would be the quality system required for hospital based blood banks and this was specified in SI 360 of 2005. The Irish National Accreditation Board (INAB) is responsible for accrediting medical testing laboratories to the international standard ISO 15189.

However, ISO 15189 does not fully meet the requirements of the Blood Directives in the areas of Traceability and Haemovigilance.

Consequently, an Expert Group on Blood and Blood Components was established to:

- assist the DoH&C, the HPRA and INAB in the effective interpretation and implementation of ISO 15189 in blood banks;
- identify areas where additional guidelines are required and
- advise and make recommendations to the DoH&C/HPRA and INAB on specific technical issues which are not already addressed in ISO 15189

The aim of this group was to specify the minimum requirements that need to be in place to ensure that hospital based blood banks comply with the requirements of Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of Directive 2002/98/EC (See Annex I for Text of Articles 14 & 15).

The group consisted of nominated experts from stakeholder associations and included representatives from the HPRA, the Irish National Accreditation Board (INAB), the Irish Blood Transfusion Service (IBTS), the National Haemovigilance Office (NHO), the Irish Haemovigilance Association (IHA), the Irish Haematology Society (IHS), the Academy of Medical Laboratory Science (AMLS) and the Faculty of Pathology, RCSI. The meetings of this group were co-chaired by the HPRA and INAB.

The specified minimum requirements for Article 14 and Article 15 of Directive 2002/98/EC as outlined in this document are intended to assist INAB Assessors during the assessment of hospital blood banks to ISO 15189 Accreditation. They may also be used by HPRA Inspectors during the inspections of hospital blood banks in the circumstances defined above.

2. Scope

This document sets out the minimum requirements that must be in place in a hospital blood bank to support Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of Directive 2002/98/EC within the ISO 15189 quality system.

Activities performed by staff in the hospital blood bank, in relation to the Falsified Medicines Directive Safety Features for medicinal products are outside the scope of the AML-BB guidance and ISO 15189 accreditation audit and process.

3. Definitions as defined in Directive 2002/98/EC

'Blood' shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing;

'Blood component' shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

A **'blood establishment'** is any structure or body involved in any aspect of the collection, testing, processing, storage and distribution of blood and blood components.

'Hospital blood bank' is a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities.

'Haemovigilance' shall mean a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

'Traceability' means 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;

'Serious adverse event' shall mean 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;

'Serious adverse reaction' shall mean 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

'Reporting establishment' means the blood establishment, the hospital blood bank or facilities where the transfusion takes place that reports serious adverse reactions and/or serious adverse events to the competent authority;

'Recipient' means someone who has been transfused with blood or blood components;

'Issue' means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;

'Imputability' means the likelihood that a serious adverse reaction in a recipient is attributed to the blood, blood component transfused, or that a serious adverse reaction in a donor can be attributed to the donation process;

'Facilities' means hospitals, clinics, manufacturers, and biomedical research institutions to which blood or blood components may be delivered.

4. ISO 15189 requirements that apply to traceability and notification of serious adverse reactions and events

The traceability functions within a hospital laboratory are subject to all of the requirements of ISO 15189. For each clause of ISO 15189, consideration shall be given and documented as to how the haemovigilance and traceability function comply with each of the requirements. This shall be documented in the quality system of the laboratory.

5. Traceability Requirements

Traceability

'***Traceability***' as defined in Directive 2005/61/EC is the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination.

Blood banks shall ensure the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system.

Blood banks shall ensure that they have a system in place to uniquely identify the facility(s) to which a given blood component has been delivered (if applicable).

Blood banks shall have a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment.

Verification Procedure

Hospital blood banks shall have in place a procedure to verify that each unit has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

Traceability Records

The following data set (as per Annex I of Directive 2005/61/EC) must be retained for at least 30 years in an appropriate and readable storage medium in order to ensure traceability:

- 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 (if relevant)

Requirements

In conjunction with the general ISO 15189 clauses that apply to traceability, the hospital/blood bank/facility should meet the requirements specified in 5.1 and 5.2 of this document.

5.1. Standard Operating Procedures (SOPs) Required to Establish Traceability

This list represents the minimum set of SOPs that should be in place within a hospital blood bank to ensure an appropriate system has been established to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded, distributed to another hospital/facility or returned to the distributing blood establishment.

Standard Operating Procedure	Available Yes/No	Adequacy/Comments
1. Ordering blood/components from supplying blood establishment/hospital(s) – in routine / emergency situations		
2. Transport of blood/components from the supplying blood establishment or other hospital(s) (This is relevant if the hospital is responsible for the transport of the blood/components from the supplying blood establishment/hospital(s))		
3. Receipt of blood/components from supplying blood establishment or other hospital(s)		
4. Stock entry SOP (for hospital with/without a laboratory)		
5. Storage of blood / components (stock)		
6. Dealing with requesting or ordering of blood/components by clinical area (routine/emergency)		
7. Selection of blood/components for compatibility testing		
8. Acceptance of compatibility and issuing or allocation of compatible blood/components		
9. Labelling of blood/components		
10. Storage of blood/components (Issued)		
11. Issue of blood/components to clinical area (i.e. removal of blood/components from laboratory e.g. collection or sign-out of blood/components by non-laboratory staff or sign-out/delivery of blood/ components to clinical areas by laboratory staff)		
12. Transport of blood/components within hospital (routine)		
13. Transport of blood/components within hospital (emergency)		
14. Blood/components administration		

Standard Operating Procedure	Available Yes/No	Adequacy/Comments
(See also under Haemovigilance section)		
15. Return of blood/components to laboratory and to inventory (stock)		
16. Quarantine of blood/components in laboratory		
17. Disposal of expired or unsuitable units (e.g. units out of controlled storage)		
18. Return of units to supplying blood establishment / hospital(s) (if relevant)		
19. Traceability SOP for clinical area (To cover how and when to record fate of unit and return information to sending laboratory)		
20. Traceability SOP for hospital blood bank (To cover how to record final fate of transfused and not transfused units)		
21. Sending blood/components with patient to another hospital		
22. Traceability SOP for blood/components transferred with patient to another hospital		
23. Product recall from the supplier of blood and blood components.		

5.2. Assessor checklists

Please note that if blood is transferred between hospitals on a routine basis a contract detailing responsibilities in relation to same is required. If the hospitals are within the same legal entity (i.e. network) a policy document may be sufficient.

If blood is transferred on an emergency basis only a policy document is sufficient.

Please see section 8 on information on service level agreements (SLAs).

This checklist is intended to assist INAB assessors (& HPRA Inspectors when required) to track the receipt of blood and components from the supplying Blood Establishment or other Hospital Blood Banks or sharing hospitals. It will serve as an input to the MF116 form and/or annex completed at each on site assessment.

5.2.1 Receipt of Blood and Components from Supplying Blood Establishment/Hospital(s)	**Available Yes/No**	**Adequacy/Comments**
Is the transfer of blood on a routine or emergency basis?		
Are the requirements detailed in an appropriate SOP/policy document/contract/service level agreement?		
Is the transport container validated? Is the validation adequate? (Relevant if the hospital is responsible for the transport of the blood/components)		

Is the correct temperature control measure (e.g. ice pack/cooling pack) used? Has the method been validated? Is the validation adequate? (Relevant if the hospital is responsible for the transport of the blood/components)		

5.2.1 Receipt of Blood and Components from Supplying Blood Establishment/Hospital(s)	**Available Yes/No**	**Adequacy/Comments**
How is the security of the container maintained?		
Is the delivery received by authorised personnel?		
Is the signature/date/time recorded on the delivery docket?		
What are the acceptance criteria for blood and blood components that arrive at the hospital/blood bank/facility? How are acceptance criteria recorded? Do they include: ➢ Visual check on units received ➢ Delivery docket ➢ Date ➢ Time ➢ Receiving signature ➢ Is the correct temperature control measure used ➢ Has security of container been maintained ➢ Is there a tamperproof seal? ➢ Has blood/component been received within recommended maximum transport time (i.e. according to validated transport method) ➢ Is there reconciliation with order?		

5.2.1 Receipt of Blood and Components from Supplying Blood Establishment/Hospital(s)	**Available Yes/No**	**Adequacy/Comments**
How is stock placed in inventory : Is the following recorded? ➢ Blood component supplier identification ➢ Product code/product description ➢ Lot number of blood component if relevant ➢ Blood unit identification ➢ Blood group ➢ Expiry date ➢ Special requirements e.g. CMV negative, irradiated, antigen typing etc. ➢ Type of component e.g. red blood cell/platelet etc. ➢ Additional info if appropriate — blood reserved for particular patient		
Are the blood/blood components stored in the appropriate locations/designated areas? Are the following requirements in place? ➢ Appropriate temp ➢ Expiry date order ➢ ABO RHD group ➢ Monitoring by chart recorders for temp or by electronic system		

5.2.2 Transport of Blood and Components between Hospital Blood Banks and/or Facilities	**Available Yes/No**	**Adequacy/Comments**
Is the transfer of blood on a routine or emergency basis?		

Are the requirements detailed in an appropriate SOP/policy document/contract/service level agreement?		
Who is responsible for organising and transporting blood/ blood components?		
Is the transport container validated? Is the validation adequate?		
How is the security of the container maintained?		
Is the correct temperature control measure (e.g. ice pack/cooling pack) used? Has the method been validated? Is the validation adequate?		
Is the receiving hospital/laboratory contacted prior to the delivery of the blood/blood component (and patient if applicable)?		
Received by authorised personnel?		
Signature/date/time on delivery docket?		
Was the component received within recommended maximum transport time? (i.e. according to validated transport method)		
How is the fate of all matched units to be documented and returned to the sending hospital?		

5.2.3 Collection/Delivery of Blood to Clinical Area	**Available Yes/No**	**Adequacy/Comments**
Is there an SOP detailing the collection/delivery of blood to clinical area?		
Unit collected from issue fridge/issue area/issuing establishment by: ➢ porter ➢ nurse ➢ doctor/medical student ➢ other		
Is there a blood request form/collection docket?		
Is the transport container suitable?		
Is the delivery docket checked by collector with suitable unit?		
How is the security of internal transport boxes maintained?		
Is the correct temperature control measure used? Has the transport container/method been validated? Is the validation adequate? (Relevant if the units are stored in this container e.g. during surgery or at the clinical area prior to transfusion)		

5.2.3 Collection/Delivery of Blood to Clinical Area	**Available Yes/No**	**Adequacy/Comments**
What method is used to record collection details? Is the blood unit/blood component signed out of issue fridge/issue area by collector manually or electronically – date, time, signature?		
Is the blood unit/blood component checked with cross-match/issue form or chart copy?		
Is the blood unit/blood component delivered to ward in appropriate container with cross-match/issue form or chart copy if appropriate?		
Is the blood unit/blood component delivered within specified time? (How is this recorded?)		

Is the blood unit/blood component delivered to specified person? (How is this recorded?)		

5.2.4 Fate of blood and blood components: (Hospital Blood Bank)	**Available Yes/No**	**Adequacy/Comments**
Is there an SOP on fating/traceability in hospital blood bank?		
How are fate details received from the clinical area? ➢ Manual/paper based? ➢ Electronic/computerised?		
How are fate details in the laboratory recorded? ➢ Manual/paper based? ➢ Electronic/computerised?		
What is the mechanism of recording fate? ➢ Are fate details recorded in a laboratory computer manually e.g. typing or bar code scan? ➢ Are fate details recorded in a laboratory computer electronically e.g. direct transfer from ward?		
How are units which are not transfused and returned to the establishment dealt with?		
Is there a reconciliation of stock received and fate?		
Are the following details stored (for 30 years) for blood and blood components **transfused:** ➢ Blood component supplier identification ➢ Blood/component identification ➢ Transfused recipient identification ➢ Date of transfusion ➢ Lot number/product code (type of component)		
Are the following details stored (for 30 years) for blood and blood components **not transfused:** ➢ Blood component supplier identification ➢ Blood/component identification ➢ Confirmation of fate and method of disposal ➢ Date of disposition ➢ Lot number/product code (type of component)		

5.2.5 Fate of blood and blood components: (Clinical Level)	**Available Yes/No**	**Adequacy/Comments**
How are details of the transfusion returned to the hospital blood bank / supplying blood establishment/supplying hospital blood bank?		
What method of fating details (donation verification) is performed? Manual/paper based? Electronic/computerised?		
Are the following fate details returned to the hospital blood bank/supplying blood establishment/supplying hospital blood bank: ➢ Transfused recipient identification		

➢ Transfused blood and blood/component identification ➢ Date of transfusion ➢ Blood/component description ➢ Identity of person witnessing transfusion ➢ Occurrence of SAE/SAR (if one occurred)		
How are used transfusion packs disposed of? Is the disposal of used packs described in an SOP? Who is responsible for the disposal of used blood packs? Does the SOP referred to comply with the guidelines from the Department of Health (April 2004) for disposal of clinical waste?		
If there is no hospital blood bank/laboratory on site: Are the following details stored (for 30 years) for blood and blood components transfused: ➢ Blood and blood component supplier identification ➢ Blood/component identification ➢ Transfused recipient identification ➢ Date of transfusion ➢ Lot number/product code (type of component)		

5.2.5 Fate of blood and blood components: (Clinical Level)	**Available Yes/No**	**Adequacy/Comments**
If there is no hospital blood bank/laboratory on site: Are the following details stored (for 30 years) for blood and blood components **not transfused:** ➢ Blood and blood component supplier identification ➢ Blood/component identification ➢ Confirmation of subsequent disposition ➢ Date of disposition ➢ Lot number/product code (type of component)		

6. Haemovigilance Requirements

'Haemovigilance' as defined in EU Directive 2002/98/EC is a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow-up of donors.

Any serious adverse events (accidents and errors) 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 serious adverse reactions observed during or after transfusion which may be attributed to the quality and safety of blood and blood components shall be notified to the National Haemovigilance Office.

These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in 2005/61/EC.

Facilities where transfusions take place shall ensure there are procedures in place to:

- Retain the record of transfusions and to notify blood establishments 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.

- Retain the record of any serious adverse events which may affect the quality or safety of blood and blood components.
- Communicate to the National Haemovigilance Office as soon as known all relevant information about serious adverse reactions and events.
- Notify the National Haemovigilance Office of any case of transmission of infectious agents by blood and blood components as soon as known.

Please see Section 7 for definitions of Serious Adverse Reactions and Events.

In conjunction with the general ISO 15189 clauses that apply to haemovigilance, the hospital/blood bank/facility should meet the requirements specified in 6.1 and 6.2 of this document.

6.1. Standard Operating Procedures (SOPs) Required for a Haemovigilance function in a Hospital Blood Bank

This list represents the minimum set of SOPs that should be in place within a hospital blood bank to ensure an appropriate haemovigilance system is in operation within a hospital/blood bank/facility.

Standard Operating Procedure	**Available Yes/No**	**Adequacy/Comments**
1. Patient information leaflet		
2. Prescription of blood/blood components		
3. Patient identification		
4. Pre-transfusion sampling Refer to ISO 15189:2022 [7.2 Pre-examination processes]		
5. Requesting blood/blood components including completion of request form for blood/blood components		
6. Blood administration		
7. Care and monitoring of transfusion recipient		
8. Serious adverse reactions (clinical areas) – mandatory reporting (including rapid alert procedure)		
9. Serious adverse events (clinical areas) – mandatory reporting (including rapid alert procedure)		
10. Haemovigilance management of serious adverse reactions (including reporting to the NHO)		
11. Haemovigilance management of serious adverse events (including reporting to the NHO)		

6.2. Assessor checklist

This checklist may be used by INAB assessors (& HPRA Inspectors when required) to ensure that an appropriate haemovigilance function is in place in a hospital blood bank/facility where transfusion takes place. It will serve as an input the MF116 form completed at each on site assessment.

6.2.1 Provision of Patient Information	**Available Yes/No**	**Adequacy/Comments**
How is information provided to the patient? ➢ Is there an information leaflet? ➢ Is the leaflet suitable for all patients? e.g. children, day ward patients, chronically ill patients? ➢ Is adequate advice on reactions to blood transfusions provided? ➢ Are information leaflets document controlled? ➢ Are translations of the transfusion information leaflets available?		

6.2.2 Prescription of blood/blood components	**Available Yes/No**	**Adequacy/Comments**
➢ Is there a dedicated blood transfusion prescription & administration record form? Please provide a completed example ➢ Does it include patient details, components details? ➢ Does it include a space for special requirements? ➢ Does the record form state what components are to be prescribed? ➢ Does the record form / relevant SOP state who can prescribe blood? Is the prescriber recorded? ➢ Does the record form require a signature and/or block capitals? ➢ How is the prescription cancelled? ➢ How many units/episodes does the prescription cover? How many days does the prescription last?		

6.2.3 Patient Identification	Available Yes/No	Adequacy/Comments
➢ What patients does the SOP cover: Conscious patients Unconscious patients Emergency-major incident patients Theatre Day case patients Children/neonates (where applicable)? ➢ Who is responsible for applying the ID band Administration staff Clinical staff ➢ What is required for positive patient identification for all of above? Verbal identification ID band ➢ Does the SOP state which 3 identifiers are required for positive patient identification? ➢ Who is responsible for replacing the wristband?		

6.2.4 Pre-Transfusion Sampling	Available Yes/No	Adequacy/Comments
➢ Who is responsible for sampling? ➢ Does the SOP include procedural requirements for patient ID, taking sample, and labelling sample? ➢ Does the SOP include procedural requirements for sample taking in an emergency? ➢ What are the procedures to be followed if an adverse event /near miss/non-compliance is discovered? **Please refer also to Section 7.2 Pre-Examination Processes of ISO 15189:2022.**		

6.2.5 Completion of Request form for Blood /Blood Components	Available Yes/No	Adequacy/Comments
➢ Who is responsible for completing request form? ➢ Is the request form adequately filled out? ➢ What are the minimum requirements to be included e.g. Patient identification details, Transfusion details, details of reason for transfusion, Obstetric history, transfusion history (where applicable). ➢ See copy of request form ➢ Storage of request forms		

6.2.6 Request for Blood/Blood Components	Available Yes/No	Adequacy/Comments
➢ Who is responsible for requesting blood? ➢ What procedures are to be followed both in the clinical area and in the laboratory, when requesting blood to include routine, on-call, and emergency and telephone requests? ➢ Does the collector bring details of the patient to the hospital blood bank e.g. patient name, hospital number, ward etc.?		

6.2.7 Blood Administration to the Patient	Available Yes/No	Adequacy/Comments
Is there a SOP for blood administration? Does this SOP: ➢ Cover transfusion in different situations e.g. routine, emergency, major disaster plan? ➢ State who can prescribe blood? ➢ State who can administer a transfusion? ➢ Require pre transfusion observations and recording of same if appropriate? ➢ Request visual checks on the blood? ➢ Request identification checks? e.g. Patient identification (Cross reference haemovigilance SOP on patient Identification), Product identification, Compatibility label. ➢ Request a verbal identification check? ➢ State the person responsible for the above checks?		

➢ State how to record the transfusion in patients chart? ➢ State what to do if a non-conformance/serious adverse event/serious adverse reaction occurs?		

6.2.8 Care and monitoring of the transfusion recipient	**Available Yes/No**	**Adequacy/Comments**
➢ What observations must be carried out and how often? ➢ Where are the observations recorded?		

6.2.9 Serious Adverse Reactions (Clinical Areas) - Mandatory reporting	**Available Yes/No**	**Adequacy/Comments**
➢ What procedures must be followed in the event of a suspected transfusion reaction? ➢ Which severe reactions are collected? ➢ How are these collected/documented? ➢ Are forms available for review? ➢ How are they reported to the haemovigilance officer/laboratory/NHO? ➢ How are records of reactions stored? For how long? ➢ What investigations are carried out in the event of a reaction? ➢ Does SOP define procedure for rapid alert/notification situation? ➢ Does SOP define systems for sending report to patient's clinician?		

6.2.10 Serious Adverse Events (Clinical area) - Mandatory reporting	Available Yes/No	Adequacy/Comments
➢ What procedures must be followed in the event of a serious adverse reaction? ➢ Which serious events are collected? ➢ How are these collected/documented? ➢ Are forms available for review? ➢ How are they reported to the haemovigilance officer/laboratory/NHO? ➢ Does SOP define procedure for rapid alert/notification situation? ➢ How are records of events stored? ➢ For how long? ➢ Is root cause analysis carried out where appropriate?		

6.2.11 Haemovigilance Management of Serious Adverse Reactions	Available Yes/No	Adequacy / Comments
➢ From which sources is information on serious adverse reactions retrieved? ➢ How are reports managed? ➢ How are reports closed off? ➢ How are reports sent to NHO, fed back to patient charts, fed back to patient physician? ➢ Is there appropriate management review of serious adverse reactions e.g. hospital transfusion committee, risk management etc.		

6.2.12 Haemovigilance Management of Serious Adverse Events	Available Yes/No	Adequacy/Comments
➢ How are events from laboratory/transport/clinical area/storage etc. notified to Haemovigilance? ➢ From which sources is full information on serious adverse events retrieved? ➢ How are reports managed? ➢ Is root cause analysis carried out where appropriate? ➢ How are reports closed off? ➢ How are reports sent to NHO, fed back to patient charts, fed back to patient physician? ➢ Is there appropriate management review of serious adverse reactions e.g. hospital transfusion committee, risk management etc.		

6.2.13 Overall Management of Near Miss/Non-Compliance	Available Yes/No	Adequacy/Comments
➢ Does SOP cover the management of all near miss/non-compliance in blood bank/facility? ➢ How are relevant incidents communicated to Haemovigilance? ➢ Which sources are used to retrieve information on Near misses/non-compliances? ➢ How are reports managed? ➢ Is root cause analysis carried out where appropriate? ➢ How are these incidents closed off - sent to NHO, other relevant parties? ➢ Is there appropriate management review of these incidents e.g. Hospital Transfusion Committee, Risk Management etc. ➢ How are records of incidents stored? For how long?		

7. Definitions of Serious Adverse Reactions and Events

*Serious Adverse **Event**:*

Any untoward occurrence associated with the collecting, testing, processing, storage and distribution of blood and blood components that might lead to

- Death
- Life-threatening
- Disabling or incapacitating conditions for patients
- which results in, or prolongs, hospitalisation or morbidity

*Serious Adverse **Reaction***:

An unintended response in the patient associated with the collection or transfusion of blood and blood component that is

- Fatal
- Life-threatening
- Disabling or incapacitating conditions for patients
- which results in, or prolongs, hospitalisation or morbidity

All facilities should consult the NHO in relation to reportable serious adverse reactions and events. Definitions currently used by the NHO are contained in the current version of the NHO Handbook which is available on the NHO website at:
https://healthprofessionals.giveblood.ie/clinical-services/reporting-to-nho/

8. Service Level Agreements / Contracts

A service level agreement or contract is required for the routine transfer of blood and/or blood components between hospitals. If blood is transferred on an emergency basis only, a policy document is sufficient.

If a hospital is also providing haemovigilance and traceability (Hv &T) services to another site / legal entity, any SLA / contract shall define the responsibilities. It is necessary that the accredited entity (hospital blood bank) shall take full responsibility for the entire service (both haemovigilance and traceability) to the other site / legal entity in order for INAB to assess the implementation of the accredited entities haemovigilance and traceability systems in the other site. This arrangement does not confer accreditation on the other site(s).

If the accredited entity (hospital blood bank) has an SLA with another site that is a different legal entity and indicates that it does not have responsibility for all haemovigilance and traceability services, INAB cannot assess the haemovigilance and traceability being undertaken at the other site.

Note, INAB verification of the accredited entity's systems does not confer any accreditation status on the other site.

The agreement between the two sites shall clarify the responsibility for the following items:

- Service objectives;
- Storage of blood and blood components, please clearly specify which types of components are stored;
- Reporting SAR/SAEs including the clinical oversight responsibilities;
- Responsibility for internal auditing, recording nonconformities, and implementation of corrective actions on the site;

- Maintenance and calibration of storage units;
- Maintenance of traceability records;
- Training and monitoring of haemovigilance and traceability staff (i.e. haemovigilance officer(s) and deputies);
- Training of hospital staff in procedures required to support the Haemovigilance and Traceability systems
- Legal liability, insurance and indemnity

9. References

S.I. 360 of 2005 – European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005

S.I. 547 of 2006 – European Communities (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulation 2006

S.I. 562 of 2006 – European Communities (Quality System for Blood Establishments)

Directive 2002/98/EC – 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.

Directive 2004/33/EC – implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components.

Directive 2005/61/EC – implementing Directive 2002/98/EC as regards Traceability requirements and notification of serious adverse reactions and events.

Directive 2005/62/EC - implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments.

International Standard ISO 15189 – Medical Laboratories – Requirements for quality and competence.

10. Annex I

Article 14 **Traceability**

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa. To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a). With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

Article 15 **Notification of serious adverse events and reactions**

1. Member States shall ensure that:

   — any serious adverse events (accidents and errors) 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 serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority,

   — blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

2. These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in Article 29(i).