Annex to AF-1-D for Blood Banks for compliance with Article 14 & Article 15 of EU Directive 2002/98/EC

AF-1-D-BB

(A) Instructions

This annex to application form AF-1-D should be completed by the applicant Blood Bank and submitted with all relevant documentation to:

The INAB Executive, Metropolitan Building, James Joyce Street, Dublin 1.

(B) Information

Please submit the following information:-

1) An Organisation Chart which clearly outlines reporting relationships and interactions between Blood Bank and Haemovigilance and Traceability Functions within the Organisation.

2) A list of Liaison Personnel for Haemovigilance and Traceability
Please provide details of technical qualifications and experience.

3) A chart of the relationship between Blood Bank, blood establishment(s) and other recipient organisations (e.g. other blood banks, hospices, nursing homes etc.)
Where the Blood Bank receives and/or provides blood and/or blood products to external organisations please confirm if contract is in place for each location, and provide brief summary of traceability and haemovigilance arrangements in place in each external location.

4) A process flow diagram(s) describing the physical flow of blood and blood components from receipt to transfusion at the clinical area. (Include all satellite storage locations)

5) A list of blood and blood component fridges and freezers and confirmation of storage conditions, validation of temperatures and details of continuous monitoring systems in place.

6) Schematic diagram of Traceability and Verification System. This should include the processes of receipt, issue, transfusion, destruction or wastage and the return of blood from the clinical area.
Please detail applicable record(s) at each stage.

7) The schedule of Blood Transfusion Committee meetings (and other meetings if relevant).

8) **A Log of notifications to The National Haemovigilance Office regarding serious adverse reactions and events over the last 12 months.**

9) **Please submit a summary report of blood usage for the last 12 months. This should include the number of units cross-matched, issued, transfused, wasted / destroyed and returned to supplier.**
Please supply this information for all locations (see Q3).

10) **The schedule of Blood Bank Audits of Haemovigilance and Traceability Functions.**
Please supply this information for all locations (see Q3).

11) **Full list of SOPs for Haemovigilance and Traceability**
Include a cross reference to list of SOPs in AML-BB.

12) **Full list of tests undertaken in blood bank; please identify those tests proposed for scope of accreditation.**
e.g. ABO and Rh testing, Antibody screen, antibody Identification, phenotyping, DAT, Cross-match.