**Hospital Blood Bank Annual Report Appendix 1**

If the hospital blood bank is currently accredited to ISO 15189, there is no requirement to complete this Appendix.

*If the hospital blood bank is currently not accredited to ISO 15189, all sections of this Appendix must be completed and submitted with the hospital blood bank annual report. Please complete all relevant sections in this form, typed or in block capitals legibly using black ink.*

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| Annual report year: |  |

Section 1 - Personnel

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| **1.1** How many personnel are involved in providing the blood transfusion service in the hospital blood bank?  Include personnel involved in blood transfusion, haemovigilance and traceability.  Please provide numbers in terms of whole time equivalents (WTEs). |
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| **1.2** How are personnel trained to perform procedures relevant to the hospital blood bank? |
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| **1.3** How is the competency of personnel assessed for procedures relevant to the hospital blood bank? (This should not be limited to testing procedures). |
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Section 1 – Personnel - Continued

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| **1.4** Is training in best practice and the requirements of the relevant Directives provided to all relevant personnel? Please give details (according to job function).  (Including those personnel involved in haemovigilance and traceability and in the delivery of blood and blood components within the hospital.) |
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| **1.5** Please list the type of personnel used for the distribution of blood components to clinical areas (e.g. porter, health care assistant, nurse etc.) |
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| **1.6** Who is responsible for the training of these personnel? |
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| **1.7** What percentage of these staff have been trained and assessed as competent in this task? |
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| **1.8** How are untrained personnel prevented from collecting and distributing blood components? |
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Section 2 - Work Contracted to Third Parties

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| **2.1** Do you contract any compatibility testing or antibody identification to outside laboratories? | Yes **√** | No **√** |
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| **2.2** If Yes, provide the name and address of the laboratory (s): | | |
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| **2.3** If Yes, indicate if a service level agreement / relevant policy / procedure is in place with this laboratory: | | |
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Section 3 - Quality System

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| **3.1** Who is responsible for the quality system in the hospital blood bank?  (Please give name and job title) |
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| **3.2** Are all documents relevant to the hospital blood bank managed through a document control system? Briefly describe this system. |
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| **3.3** How many deviations/non-conformances and complaints were recorded and investigated in the hospital blood bank during the year concerned? |
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Section 3 - Quality System - Continued

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| **3.4** Briefly describe how the corrective and preventative actions (CAPA) relating to the deviations/non-conformances and complaints are managed. |
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| **3.5** How many internal audits/self inspections were performed in the hospital blood bank during the year concerned? |
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| **3.6** Briefly describe the procedure for managing changes to personnel, processes, equipment, and facilities in the hospital blood bank. |
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*Note: Please provide reference numbers for procedures. There is no requirement to submit actual procedures with this report.*

Section 4 – Equipment

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| **4.1** Is there a current asset register of equipment available for the hospital blood bank? |
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| **4.2** Is there a maintenance schedule in place for equipment in use in the hospital blood bank? |
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| **4.3** Is there a cleaning schedule in place for equipment in use in the hospital blood bank? |
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| **4.4** Who is responsible for ensuring that equipment is maintained and calibrated (if required)? |
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| **4.5** Are maintenance and calibration reports reviewed for acceptability? Who is responsible for this task? |
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| **4.6** What is the current status with respect to the qualification (validation) of new and existing equipment in the hospital blood bank? |
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Section 5 - Traceability

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| **5.1** Briefly describe the system in place for verifying and recording that each unit of blood or blood component issued for transfusion has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.  (Indicate if verification system is paper based or electronic.) |
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| **5.2** Are issued components which have not been returned to the laboratory ‘autofated’ as transfused if positive verification cannot be determined? |
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| **5.3** Please indicate the actions taken where positive verification of final fate cannot be determined: |
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| **5.4** If traceability is not confirmed as 100%, please describe the corrective actions in place to ensure compliance: |
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| **5.5** What system is in place to ensure that traceability records will be retained for 30 years as required? |
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Section 6 - Reporting of Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs)

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| **6.1** Who is responsible for the reporting of SAEs and SARs to the National Haemovigilance Office? |
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| **6.2** Describe the system in place for the reporting of SAEs and SARs to the National Haemovigilance Office. |
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Section 7 - Recall

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| **7.1** Briefly describe the procedure in place for the recall of blood and blood components: |
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| **7.2** Does this procedure extend to or include the internal recall of blood and blood components? (Initiated locally within the hospital) Provide brief details. |
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Section 8 - Storage of Blood and Blood Components

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| **8.1** Does storage of blood and blood components occur at the hospital blood bank/facility? | Yes **√**: | No **√**: |
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| **8.2** Provide brief details of the system in place for the receipt and storage of blood and blood components into the hospital blood bank. | | |
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| **8.3** Provide brief details of the procedure in place for the return/acceptance of blood into the hospital blood bank following delivery to the clinical area or from another facility. | | |
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| **8.4** Have storage units, utilised for the storage of blood and blood components, been temperature mapped? (Please provide the date that temperature mapping was performed.) | | |
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| **8.5** Are storage units, utilised for the storage of blood and blood components, continuously temperature monitored? (Please provide details of the temperature monitoring system in place.) | | |
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| **8.6** How often is maintenance and calibration performed on storage units that are utilised for the storage of blood and blood components? | | |
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Section 8 - Storage of blood and blood components continued

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| **8.7** Are storage units utilised at satellite locations within the hospital for the storage of blood and blood components? | Yes **√**: | No **√**: |
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| 8.7.1 If Yes, who is responsible for ensuring that these satellite storage units are appropriately maintained, calibrated, continuously monitored and mapped? | | |
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| 8.7.2 If Yes, please provide brief details regarding the maintenance, calibration, continuous monitoring and mapping of these satellite storage units. | | |
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Section 9 – Distribution of blood and blood components

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| **9.1** To whom does your hospital blood bank distribute blood and/or blood components? (Provide a list with the names and addresses of any other hospitals, hospices, community hospitals etc.) | | | | |
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| **9.2** Are blood and blood components stored at these sites? | Yes **√**: | | No **√**: | |
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| **9.3** What other services does the hospital blood bank provide to this site/these sites?  (Please tick.) | | | | |
| Patient ABO / Rh Group / Antibody Screen / Antibody Identification | | | |  |
| Crossmatching | | | |  |
| Maintenance and calibration and storage units | | | |  |
| SAR / SAE reporting to the National Haemovigilance Office | | | |  |
| Traceability | | | |  |
| Other (Please specify) | | | |  |
| **9.4** Is this site(s) in the same legal entity (e.g. network) as the supplying hospital blood bank? | | Yes **√**: | | No **√**: |
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| **9.5** If Yes, is there an appropriate policy or procedure in place describing responsibilities in relation to the above activities including distribution? (Provide brief details.) | | | | |
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| **9.6** If No, is there an appropriate service level agreement(s) in place with the site(s) in question? (Provide brief details.) | | | | |
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Section 9 – Distribution of blood and blood components - Continued

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| **9.7** Provide brief details as to how the integrity of blood and blood components is maintained during transport, delivery and distribution. |
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| **9.8** Provide brief details relating to the validation of the methods utilised during transport, delivery and distribution. |
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| Additional Information *(Please insert headings.)* |
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| Please complete and return by **1 March** annually to:  Hospital Blood Bank Annual Report  Compliance Department,  Health Products Regulatory Authority  Kevin O’Malley House,  Earlsfort Centre,  Earlsfort Terrace,  Dublin 2.  Alternatively the completed form may be scanned and emailed to [hbbar@hpra.ie](mailto:hbbar@hpra.ie)  With a heading of ‘Hospital Blood Bank Annual Report – <Insert Hospital Name>’ |