Hospital Blood Bank Annual Report

*(Please complete all relevant sections in this form, typed or in block capitals legibly using black ink.)*

### To be completed by all hospital blood banks

|  |  |
| --- | --- |
| Annual report year: |  |

Section 1 - Details

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| --- | --- |
| **1.1 Hospital name:** |  |
| **1.2 Full address:** |  |
| **1.3 Laboratory 24 hour contact phone number(s):** |  |
| **1.4 Contact name:**  **(include job title)** |  |
| Telephone no: |  |
| Fax no: |  |
| Email: |  |
| **1.5 Haemovigilance Officer:**  **(Or equivalent)** |  |
| Telephone no: |  |
| Fax no: |  |
| Email: |  |
| **1.6 Name(s) of supplying blood establishment(s) / hospital blood bank(s):** |  |

Section 2 – Activities undertaken

|  |  |  |
| --- | --- | --- |
| **2.1 List of activities undertaken** | **Yes √** | **No √** |
| Collection of whole blood (including autologous) |  |  |
| Apheresis collection  (of any blood component) |  |  |
| Storage of blood and blood components |  |  |
| Rerouting of blood/blood components to other hospital(s) |  |  |
| Distribution and/or transport of blood and blood components to another hospital blood bank/facility (other than through rerouting) |  |  |
| Testing (including all pre-transfusion testing) |  |  |
| Electronic issue of blood components |  |  |
| Irradiation of blood and blood components |  |  |
| Washing of blood and blood components |  |  |
| Pooling of components (e.g. cryoprecipitate) |  |  |
| Thawing of frozen components (e.g. cryoprecipitate/plasma) |  |  |
| Transfusion of blood and blood components |  |  |
| Other (please specify): |  |  |

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| --- | --- |
| **2.2 Blood transfusion laboratory activity in the year ending 31 December** | |
| Please indicate the number of ‘group and save samples’ processed: |  |
| Please indicate the number of ‘crossmatch’ samples processed: |  |
| Please indicate the number of ‘antibody identifications’ performed: |  |

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| **2.3 Details of blood component usage in the year ending 31 December** | | | | | | | |
| Component | Received | Issued | Transfused | | Discarded | Expired | Returned |
| Units | Recipients |
| Red cells (excluding paedipacks) |  |  |  |  |  |  |  |
| Paedipacks |  |  |  |  |  |  |  |
| Platelets |  |  |  |  |  |  |  |
| Plasma (fresh frozen plasma) |  |  |  |  |  |  |  |
| Plasma (solvent detergent plasma) |  |  |  |  |  |  |  |
| Other (e.g. cryoprecipitate, cryo-depleted plasma)  Please specify: |  |  |  |  |  |  |  |

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| --- | --- |
| **2.4 Rerouting** *(Please copy and insert this section for additional hospitals/components as required.)* | |
| Name of hospital supplied |  |
| Type of component supplied |  |
| Number of units supplied |  |

Section 3 – Activities undertaken for facilities

*(Please copy and insert this section for additional sites as required.)*

|  |  |  |  |
| --- | --- | --- | --- |
| **3.1 Name of facility:** | |  |  |
| **3.2 Are blood and blood components stored at these sites?** | Yes  No | | |
| **3.3 What other services does the hospital blood bank provide to this site(s)?** *(Please tick)* | | | |
| Patient ABO / Rh group / antibody screen / antibody identification |  | | |
| Crossmatching |  | | |
| Reporting SAR/Es |  | | |
| Maintenance and calibration of storage units |  | | |
| Maintenance of traceability records |  | | |
| Other (please specify) |  | | |
| Is there a service level agreement in place to describe the responsibility for these functions? | Yes  No | | |
| **3.4 Please indicate the number and type of blood components distributed to this facility:** | | | |
| Red cells (excluding paedipacks) |  | | |
| Paedipacks |  | | |
| Platelets |  | | |
| Plasma (fresh frozen plasma) |  | | |
| Plasma (solvent detergent plasma) |  | | |
| Other (e.g. cryoprecipitate, cryo-depleted plasma)  Please specify: |  | | |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **3.5 Details of blood component usage in the year ending 31 December for facility supplied (*if applicable*).**  *(Please copy and insert this section for additional sites as required.)*  **Name of facility supplied:** | | | | | | | |
| Component | Received | Issued | Transfused | | Discarded | Expired | Returned |
| Units | Recipients |
| Red cells (excluding paedipacks) |  |  |  |  |  |  |  |
| Paedipacks |  |  |  |  |  |  |  |
| Platelets |  |  |  |  |  |  |  |
| Plasma (fresh frozen plasma) |  |  |  |  |  |  |  |
| Plasma (solvent detergent plasma) |  |  |  |  |  |  |  |
| Other (please specify): |  |  |  |  |  |  |  |

Section 4A – Changes since previous submission of HBBAR

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| --- | --- | --- |
| **4.1 Have you previously submitted a HBBAR?** | Yes **√** | No **√** |
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| **4.2 If Yes, provide details of any significant changes in personnel, processes, facilities, equipment or workload since the previous HBBAR submission:** | | |
|  | | |

Section 4B – Planned future changes

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| **4.3 Provide details of any planned significant changes in personnel, processes, facilities, equipment or workload proposed for implementation in the next reporting year (to 31 December):** | |
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Section 5 – Status of ISO 15189 accreditation

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| As per Regulation 16 paragraph 5(c) of Statutory Instrument 360 of 2005, European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005, all hospital blood banks are required to be accredited to International Standard – ISO 15189 – Medical Laboratories – Requirements for Quality and Competence. | | |
| **5.1 Is the hospital blood bank currently accredited to the ISO 15189 standard?** | Yes **√** | No √ |
|  |  |
| **5.2 If the answer to 5.1 is ‘Yes’, complete sections 5.2.1 – 5.2.4** | | |
| 5.2.1 Provide the date that accreditation was granted: |  | |
| 5.2.2 Provide the date of the last audit: |  | |
| 5.2.3 Provide the due date for the next audit: |  | |
| 5.2.4 Provide a summary of the scope of the accreditation: | | |
| 5.3 If the hospital blood bank is currently accredited to the ISO 15189 standard, but accreditation was suspended within the reportable 12 months, please provide details of the reason for suspension and the corrective actions implemented. | | |
| **N.B. If the hospital blood bank is currently accredited to the ISO 15189 standard the ‘Hospital blood bank annual report appendix 1’ form is not required to be completed.** | | |

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| **5.3 If the answer to 5.1 is ‘No’, complete sections 5.3.1 – 5.3.4 (where relevant)** | |
| 5.3.1 Please indicate the current status of accreditation: | **√** |
| In process:  (See 5.3.4 below) |  |
| Voluntarily suspended: |  |
| Suspended: |  |
| Terminated: |  |
| 5.3.2 Provide explanation as to why hospital blood bank is currently not accredited to the ISO 15189 standard and the expected timeframe for re-certification: | |
| 5.3.3 Indicate the corrective actions that are being undertaken to re-obtain accreditation to the ISO 15189 standard: | |
| **N.B. If the hospital blood bank is currently not accredited to the ISO 15189 standard then ‘Hospital blood bank annual report appendix 1’ form is required to be completed and submitted to the HPRA with this form.** | |

Section 5 – Status of ISO 15189 accreditation continued

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| 5.3.4 **In process applicants only:**  Has the hospital blood bank applied for ISO 15189 accreditation?  If Yes, provide the date of application: | Yes **√** | No **√** |
|  |  |
|  | |
| Has the hospital blood bank undergone an ISO 15189 pre-assessment?  If Yes, provide the date of the pre-assessment: | Yes **√** | No **√** |
|  |  |
|  | |
| Has the hospital blood bank undergone an ISO 15189 final assessment?  If Yes, provide the date of the final assessment: | Yes **√** | No **√** |
|  |  |
|  | |
| Has the hospital blood bank received a positive recommendation following an ISO 15189 final assessment?  If Yes, please indicate when it is anticipated that accreditation will be granted: | Yes **√** | No **√** |
|  |  |
|  | |
| If the hospital blood bank requires a further visit following an ISO 15189 final assessment, provide the date that the further visit will be performed (if known): |  | |
| **N.B. If the hospital blood banks application for ISO 15189 is currently ‘in process’ then ‘Hospital blood bank annual report appendix 1’ form is required to be completed and submitted to the HPRA with this form.** | | |

Section 6 – Additional information

6.1 Traceability

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| --- | --- | --- |
| 6.1.1 Please provide the traceability success rate for HBB: | | |
| The year ending 31 December : |  | |
| Is the hospital blood bank currently using the ISBT labelling system for blood and blood components? | Yes **√**: | No **√**: |
|  |  |
| 6.1.2 Please provide the traceability success rate for each facility supplied: *(Please copy and insert this section for additional sites as required.)*  Name of facility: | | |
| The year ending 31 December : |  | |
| Is the facility currently using the ISBT labelling system for blood and blood components? | Yes **√**: | No **√**: |
|  |  |

6.2 Reporting of serious adverse reactions and events

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| --- | --- | --- |
| 6.2.1 Please indicate the number of serious adverse reaction (SAR) and serious adverse event  (SAE) reports investigated and submitted to the National Haemovigilance Office (NHO) for  the year ending 31 December. | | |
|  | **Investigated within the hospital:** | **Reported to the NHO:** |
| **Number of SARs:** |  |  |
| **Number of SAEs:** |  |  |

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| --- | --- | --- |
| 6.2.2 Please indicate the number of serious adverse reaction (SAR) and serious adverse event  (SAE) reports investigated and submitted to the National Haemovigilance Office (NHO) for  the year ending 31 December which were reported to the HBB from each facility supplied.  *(Please copy and insert this section for additional sites as required.)* | | |
| **Name of facility:** | **Investigated within the hospital:** | **Reported to the NHO:** |
| **Number of SARs:** |  |  |
| **Number of SAEs:** |  |  |

Section 7 – Completion of hospital blood bank annual report

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| To the best of my knowledge and belief the details provided in the information given above are correct and complete.  Signed: \_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_     \_\_\_\_\_\_\_\_\_\_\_\_  Name: \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Position: \_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_  (To be signed by the person who has completed the annual report) |

Section 8 - Declaration

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| \_\_\_     \_\_\_\_\_\_\_\_\_\_ hospital blood bank **has/has not** in place appropriate systems to ensure compliance with the requirements of Statutory Instrument 360 of 2005 for the year ending 31 December. (Please circle as appropriate.)  Signed: \_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_     \_\_\_\_\_\_\_\_\_\_\_\_ \_  Name: \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Position: \_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_  (To be signed by the person responsible for the management of the hospital blood bank - Chief Executive Officer or General Manager of the hospital) |
| Additional information *(Please insert headings.)* |
|  |

Section 9 – Fees

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| Fee Code: 330 | *Please note a flat rate administrative fee will be charged to all hospital blood banks for submission of this form – please see guidance document for further information.* |
| Purchase order number:  (if required) |  |
| Invoice to:  (Provide relevant contact details) |  |

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| Please complete and return annually by **1 March** to:  Hospital Blood Bank Annual Report,  Compliance Department,  Health Products Regulatory Authority  Kevin O’Malley House  Earlsfort Centre  Earlsfort Terrace  Dublin 2  D02 XP77  Tel: + 353 1 676 4971  Fax: + 353 1 676 7836  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>’ |