HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Completion of the Hospital Blood Bank Annual Report
(Completion due 1 March annually)

IA-G0019-6
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1 SCOPE

This guide is issued by the Health Products Regulatory Authority (HPRA) to provide guidance on ~~completion of~~how to complete the hospital blood bank annual report (HBBAR).

2 INTRODUCTION

Regulation 12 of ~~Statutory Instrument~~S.I. 360 of 2005, European Communities (Quality and Safety of Human Blood and Blood Components) Regulations requires that all hospital blood banks submit an annual report to the HPRA, including a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the requirements of these Regulations and providing details of the systems which it has in place to ensure such compliance.

What is the definition of a hospital blood bank?

A hospital blood bank is defined as a unit within a hospital which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, and includes hospital-based transfusion services.

What is the definition of a facility?

A facility is defined as a hospital, ~~a~~ clinic, ~~a~~ manufacturer or ~~a~~ biomedical research institution to which blood or blood components may be delivered. This includes hospital wards, hospices or care homes, etc., which receive blood components from a hospital blood bank for transfusion purposes (but do not perform compatibility tests on site).

Facilities may perform key tasks which are covered by the scope of the blood legislation. These are:

1 The storage of blood components on site prior to transfusion (short term only~~)~~).
2 The control of monitoring, maintenance and calibration of any controlled temperature storage equipment on site, e.g. blood fridge/freezer.

Who needs to complete an annual report?

Hospital blood banks

- All hospital blood banks are required to complete all sections (1-8) of the hospital blood bank annual report.

- If the hospital blood bank is currently not accredited to the ISO 15189 standard, then all sections of Appendix 1 should also be completed and submitted to the HPRA with the hospital blood bank annual report.

- All relevant sections should be completed, typed or in block capitals legibly using black ink.

- If particular sections/questions are not applicable, then enter 'Not applicable' ~~should be entered~~ in that section/question along with a brief explanation as to why that section/question is not applicable.

From where can annual report forms be obtained?

The 'Hospital Blood Bank Annual Report' form is available on the HPRA website at www.hpra.ie. If you have any problems downloading this document, you may request one via ~~e-mail at~~email from hbbar@hpra.ie.

Submission of hospital blood bank annual reports

Completed and signed annual reports (and Appendix 1 where relevant) should be submitted to the HPRA ~~in hard copy or scanned document by e-mail~~via email to hbbar@hpra.ie by 1 March annually. ~~Relevant~~

Reports can also be submitted in hard copy. The relevant addresses are included on the annual report forms.

~~*NB*~~*Note: Each annual report submitted to the HPRA must contain appropriate signatures in sections 7 and 8* ~~*and therefore unsigned*~~*. Unsigned Word documents are not acceptable.*

Fees

Annually, a flat rate administrative fee will be charged to all hospital blood banks for submission of the hospital blood bank annual report. The fee code for this charge is 330.

Please see the 'Publications and Forms' section of www.hpra.ie ~~-~~for further information on the payment of fees.

Alternatively, please provide a purchase order number and contact details for invoicing in section 9 of the hospital blood bank annual report and the Accounts section of the HPRA will follow up accordingly.

Any questions?

~~There are some~~See section 3 of this document for brief guidance notes on the completion of the annual report ~~below~~. If you have any other queries, please ~~e-mail~~email hbbar@hpra.ie.

What does the HPRA do with the information provided in the annual report?

The HPRA will assess the level of compliance with the requirements of S.I. 360 of 2005. Further information may be requested to help formulate an accurate assessment of compliance status. If there is uncertainty relating to the level of compliance or the accreditation status of the hospital blood bank to the ISO 15189 standard, the HPRA may undertake an inspection of the hospital blood bank.

3 NOTES ON THE COMPLETION OF THE HOSPITAL BLOOD BANK ANNUAL REPORT AND APPENDIX 1

The hospital blood bank annual report has been amended into a separate form and appendix. Instructions on the completion of these sections, depending on the circumstances of the hospital blood bank and the activities performed on site, have been described above. The following provides guidance notes on the details that are required for each section:

Section 1 – Details

- Section 1.3
  Enter 24-hour contact phone number/s for the blood transfusion laboratory if available. These may be required during the investigation of serious adverse events or serious adverse reactions and in the event of a large-scale recall.

- Section 1.4
  Enter the name and contact details of an appropriate person, e.g. Chief Medical Scientist in Transfusion or Laboratory Manager. This person should be familiar with the day-to-day running of the hospital blood bank and the provision of transfusion services. This person should complete the hospital blood bank annual report, sign the completion of annual report section (section 7) and be available to clarify information required by the HPRA in relation to the annual report.

- Section 1.5
  Enter the name and contact detail for the Haemovigilance Officer(s) or equivalent within the hospital. One or more names may be entered here.

- Section 1.6
  Provide the name of the blood establishments or hospital blood banks which supply blood components to your hospital blood bank. This may be a blood establishment or another hospital with which you share blood components or have a service level agreement or contract or policy with for the supply of blood and blood components. If the supplying blood establishment is the Irish Blood Transfusion Service, please indicate if it is the National Blood Centre or the Munster Regional Transfusion Centre.

Section 2 – Activities undertaken

- Section 2.1
  Tick 'yes' or 'no' beside each activity specified in this section. It is likely that most hospital blood banks will be involved in the storage of blood and blood components, the distribution and/or transport of blood and blood components and the testing (including all pre-transfusion testing) of all blood and blood components.

- Section 2.2
  Provide the number of 'group and save samples' processed, the number of 'crossmatch' samples processed and the number of 'antibody identifications' performed by the blood transfusion laboratory annually beginning 1 January and ending 31 December.

- Section 2.3
  Give details regarding blood usage annually beginning 1 January and ending 31 December. Please note the terms used in this section should be interpreted as follows:
  Received = Number of units received from supplying blood establishment/hospital blood bank
  Issued = Number of units issued for transfusion
  Transfused = Number of units transfused and the number of recipients transfused
  Discarded = Number of units to include both laboratory and clinical discards
  Expired = Number of units which expired in the hospital blood bank without being transfused
  Returned = Number of units returned to the supplying blood establishment (in date~~) /~~)/re-routed to the supplying hospital blood bank for subsequent use~~.~~

- Section 2.4
  Provide details regarding the type and number of blood/blood components supplied to any other hospital(s) through rerouting schemes annually beginning 1 January and ending 31 December.

Section 3 – Activities undertaken for facilities

This information relates to activities undertaken by the hospital blood bank on behalf of a facility.

- Section 3.5
  Give details regarding blood usage annually beginning 1 January and ending 31 December. Please note the terms used in this section should be interpreted as follows:
  Received = Number of units received by facility from supplying blood establishment/ hospital blood bank
  Issued = Number of units issued for transfusion
  Transfused = Number of units transfused and the number of recipients transfused

Discarded = Number of units to include both laboratory and clinical discards
Expired = Number of units which expired in the facility without being transfused
Returned = Number of units returned to the supplying blood establishment (in date~~) /~~)/re-routed to the supplying hospital blood bank for subsequent use~~.~~

Section 4A – Changes since previous submission of hospital blood bank annual report

- Section 4.1
  Tick 'yes' or 'no'.

- Section 4.2
  If an annual report was submitted by the hospital blood bank for the previous year, provide details of any significant changes in personnel, processes, facilities, equipment or workload since the previous submission. This may include, for example, a move to a new facility, an upgrade of an existing laboratory, a move to automated grouping, implementation of electronic crossmatching, purchase of new fridges or freezers for the storage of blood and blood components, etc.

Section 4B – Planned future changes

- Section 4.3
  Provide details of any planned significant changes in personnel, processes, facilities, equipment or workload since the previous submission. This may include, for example, a move to a new facility, an upgrade of an existing laboratory, a move to automated grouping, implementation of electronic crossmatching, purchase of new fridges or freezers for the storage of blood and blood components, etc.

Section 5 – Status of ISO 15189 accreditation

- Section 5.1–5.3
  Provide details regarding the status of ISO 15189 accreditation at the hospital blood bank. Note that these details will be cross checked with the Irish National Accreditation Board. Please follow the relevant instructions in this section for the completion of ~~Annex~~Appendix 1.

Section 6 – Additional information

- Section 6.1
  This section requests specific information relating to the traceability success rates for the hospital blood bank and each facility supplied.

- Section 6.2
  This section requests specific information relating to the numbers of serious adverse reactions (SARs) and serious adverse events (SAEs) investigated within the hospital and reported to the National Haemovigilance Office (NHO). ~~Also include the~~The number of SARs and SAEs reported to the NHO which were reported to the hospital blood bank from each facility supplied must also be included.

Section 7 – Completion of annual report

This section should be signed by the person who has completed the annual report.

Section 8 – Declaration

The declaration should be signed by the person responsible for the management of the hospital blood bank (Chief Executive Officer or General Manager of the hospital). If the person responsible for the management of the hospital blood bank declares that all appropriate systems are not in place, a proposed timetable for implementation of outstanding systems should be provided.

Note: annual reports cannot be accepted if they are not signed by the appropriate personnel.

APPENDIX 1

Section 1 – Personnel

- Section 1.1
  Provide the number of medical laboratory scientists, laboratory aides, haemovigilance officers or equivalent and other relevant personnel involved in providing the blood transfusion service in the hospital blood bank.

- Section 1.2
  Provide a brief overview of the training that personnel involved in providing the transfusion service undergo in all pertinent procedures prior to being allowed to carry out these procedures unsupervised.

- Section 1.3
  Give brief details of the competency assessment procedures in place. Please note that competency assessment should not be limited to testing procedures and should incorporate all critical procedures in the hospital blood bank.

- Section 1.4
  Provide a brief overview of the training in relation to best practice and the requirements of the Directives provided to relevant staff within the hospital blood bank according to job function, e.g. what type of training has been provided to a porter involved in the distribution or delivery of blood or blood components within the hospital.

- Section 1.5–1.8
  Provide details in relation to the personnel that are responsible for distributing blood and blood components from the blood transfusion service to the clinical areas.

Section 2 – Work contracted to third parties

- Provide the name and address of any outside testing laboratories used. Provide details regarding the type of testing performed and indicate if technical agreements or relevant policies or procedures are in place.

- A service level agreement is required if the outside laboratory is a separate legal entity, i.e. a private sector laboratory or a laboratory that is not within the same HSE network as the hospital blood bank to which it provides a service.

Section 3 – Quality system

- Sections 3.1–3.6 require information on the major aspects of a quality system that should be in place in a hospital blood bank. Where it is required, provide a brief overview of these aspects and provide a reference to the procedure in place for each aspect. Please note that

it is not required to submit actual procedures with this report. Unless specifically requested, submitted procedures will not be reviewed.

Section 4 – Equipment

- Sections 4.1–4.6 require information on the control and management of equipment in place in a hospital blood bank. It is required to provide a brief overview of the aspects covered in these sections and to provide a reference to the procedure in place for each aspect if relevant. Please note that it is not required to submit actual procedures with this report. Unless specifically requested, submitted procedures will not be reviewed.

Section 5 – Traceability

The aim of this section is to provide an overview of the traceability and verification system within the hospital blood bank. Specific details have been requested in relation to the positive verification of final disposition of all blood and blood components, autofating, the actions taken where positive verification of final fate cannot be determined, and the corrective actions to ensure compliance if traceability is not confirmed as 100%.

Section 6 – Reporting of serious adverse events (SAEs) and serious adverse reactions (SARs)

The aim of this section is to provide an overview of the system for reporting SARs and SAEs within the hospital blood bank.

Section 7 – Recall

- Section 7.1
  Provide brief details in relation to the procedure in place for the recall of blood and blood components.

- Section 7.2
  Please confirm if this procedure extends to or includes the internal recall of blood components, i.e. those initiated by locally within the hospital. Please provide brief details or an explanation where relevant.

Section 8 – Storage of blood and blood components

The aim of this section is to obtain an overview of the storage system for blood and blood components within the hospital.

- Section 8.2
  Provide details regarding the receipt and storage systems in place in the hospital blood bank for blood and blood components. Include number and type of storage units in use.

Indicate the temperatures that each type of blood component is stored at in the hospital blood bank.

- Section 8.7
  Provide details regarding the storage of blood and blood components in satellite storage units within the hospital.

Section 9 – Distribution of blood and blood components

The aim of this section is to obtain an overview of the distribution of blood and blood components which occur at the hospital.

- Section 9.1
  Provide the names and addresses of all other facilities supplied with blood from the site specified in this report. This should include all hospitals, hospital blood banks, hospices and community hospitals.

- Section 9.3
  Indicate the other services that the hospital blood bank provides to this site(s) by ticking the box associated with each service listed.

- Section 9.4–9.6
  Indicate if a service level agreement or relevant policy/procedure is in place regarding the distribution of blood and blood components and the provision of extra services as indicated in section 9.3 to the sites listed in section 9.1.

- A service level agreement is required if the supplied facility is a separate legal entity, i.e. a private hospital/facility or a hospital/facility that is not within the same HSE network as the supplying hospital blood bank.

- Section 9.7–9.8
  Provide details relating to the system/method that is used for the transport/delivery/ distribution of blood components. Also provide details relating to the validation of this system/method.