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| 2024 Blood Compliance Report and Declaration Guidance Notes for Hospital Blood Banks |

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10. **Introduction**

The purpose of this document is to provide guidance for Hospital Blood Banks and Blood Facilities in the requirements for providing declarations of compliance and compliance reports to ensure compliance with the UK Blood Safety and Quality Regulations (SI 2005/50 as amended).

1. **General**
   1. Hospital Blood Bank (HBB)
      1. An HBB is a unit within a hospital which:

* stores and distributes blood
* performs compatibility tests on blood and blood components exclusively for use in hospital facilities, including hospital-based transfusion activities.
  + 1. HBBs must:
* Submit an annual compliance report (Blood Compliance Report) and pay a compliance fee
* Pay a haemovigilance fee

*Transfusion laboratory sites which are named on a* *Blood Establishment Authorisation (BEA) to perform blood collection, processing or donor testing are not required to submit a BCR.*

* 1. Blood Facility
     1. A blood facility is a site that receives blood from a hospital blood bank for transfusion purposes but does not perform compatibility tests.

*A ward within the same hospital site as a hospital blood bank is not considered to be a separate facility.*

* + 1. Facilities may perform three key tasks which are covered by the scope of a blood compliance report (BCR). These are:
* The control of monitoring, maintenance and calibration of any controlled temperature storage equipment on site.
* Reporting of serious adverse events and reactions to SABRE
* Maintenance of traceability records

***A ‘Facility’ should have a Service Level Agreement (or similar document) in place if the supplying Hospital Blood Bank is responsible for any of these functions.***

Where HBBs supply blood components to other sites within the same Trust, shared quality systems and standard operating procedures may be relied on in lieu of an agreement to ensure compliance with the BSQRs.

1. **Completing and submitting a Blood Compliance Report (BCR)**
   1. The deadline for submission of the BCR is **30th April 2024**.
   2. The [hospital blood bank declaration](https://www.gov.uk/government/publications/blood-facility-compliance-report-template) form should accompany the BCR.
   3. Please complete one Compliance Report for each Transfusion Laboratory (including satellite laboratories operated under the same management structure as any main laboratory).
   4. The 2024 Hospital Blood Bank Compliance Report must be completed electronically and submitted as a Microsoft Excel file (.xls) when completed (see section 6 of this guidance note for file download and saving instructions).
   5. Follow instructions and look for menu arrows indicating menu-selected responses. Most other boxes will require text or numbers. An error message will appear when a text answer is given where a numerical response is required.
   6. The compliance report is password protected to prevent changes made to the questions. It is not designed to be printed and completed manually. It is possible to use the Print Screen function to print a section of the BCR template as required, e.g. to use as a guide when collating the relevant information to complete the form electronically. However, care must be taken as it is not possible to determine from the appearance of a printed copy whether a question requires a menu-selected response or a free-text response.
   7. Answers to questions should be based upon the systems currently in place at the time of report completion.
   8. Some questions in the compliance report are ‘nested’, i.e. the requirement to answer a specific question may be dependent upon the answer provided to previous questions.
   9. **The accuracy of information provided in the Compliance Report responses will be verified during site inspections. This may include ‘control’ inspections of sites that appear compliant on the basis of the information supplied to validate the assessment process.**
2. **Downloading and saving the BCR**
   1. Downloading and saving the compliance report form

The form should be downloaded from the GOV.UK ‘Medicines, medical devices and blood regulation and safety’

<https://www.gov.uk/government/publications/blood-bank-compliance-report-template>

and saved on the local IT system. This will allow the report to be completed in more than one work session if required and enable the file to be periodically saved while answering questions. The form is not designed to be completed ‘on-line’ in one session, and there is no facility to save a partially completed file on the MHRA’s website.

* 1. There are two options for saving the completed form.
     1. Click ‘Save’ to update the compliance report contents without changing the file name.
     2. Click ‘Save As’ to save the file with a new file name.
        1. If you are using Microsoft Excel version 2003 or lower, the file will be automatically saved as an acceptable Excel workbook format.
        2. If you are using a version of Microsoft Excel higher than the original Excel 2003 file (i.e. Excel 2007 or higher) please ensure that the file type is listed as Excel 2003 workbook format (or Excel 97-2003 workbook format).

1. **How to complete the BCR**

*Note the BCR has been changed but the section / question numbers have not. You will note that some sections are not available, for example Sections K and V or some question numbers, e.g. questions C 3.1 to 3.5, do not appear.*

**There are no new questions for 2024**

The regulatory references for each BCR section can be found in Annex 1

* 1. Section A
     1. Questions A1– A11: Hospital name and address

Ensure that the appropriate fields are completed with the name of the hospital and the name of the Trust / healthcare provider that is responsible for the site where the HBB is located. Where the HBB is managed by e.g. a pathology partnership this should be listed in A9. Please provide a PO number where one is required by your Trust.

* + 1. Questions A12 – A16: number of blood components issues each year.

Each blood component should be counted as ‘issued’ each time it is identified for a specific patient. For example, if a unit of cross-matched red cells are unused and subsequently re-issued for another patient, this should count as 2 issues. This information is used as part of the BCR assessment process to obtain an indication of transfusion laboratory workload.

*Please note that this information differs from that required as part of the SABRE annual report, where each individual blood component is counted as a single unit, irrespective of the number of ‘issue and return’ cycles.*

* 1. Section C
     1. Question C3.6 - How many significant changes have you had in TOTAL?

A significant change is one that may affect the quality, traceability, availability or effect of components or the safety of components or patients.

Multiple changes to a single system (e.g. two upgrades to an analyser during the year) should be counted as two changes for the purposes of question C3.6.

* 1. Section E
     1. Question E6 – Resource planning

The Good Practice Guide requires the organisation to have adequately trained personnel to carry out transfusion related activities and to maintain the Quality Management System. There should be a documented justification of the resourcing of the HBB including laboratory equipment such as analysers.

* + 1. Question E7.4 – Staffing issues

Only a numerical answer is accepted. Please do not enter No or Yes.

If there is no impact, please enter “0”.

If there is impact due to on-going staff issues, please enter the level of understaffing (average during the reporting year) as a decimal fraction (i.e. if 20% understaffing, enter 0.20).

* 1. Section F
     1. Question F5 – Training for laboratory staff

This question has been changed and clarified; it is asking whether all staff performing tasks unsupervised have documented training in place. This includes staff that may work out of hours alone and locums and would require competence in key quality systems such as incident reporting as well as pre-transfusion tests.

* 1. Section G
     1. Question G1.7 – Senior management oversight

An answer of “Yes” to this question should only be used where there is documented review of the QMS, at for example meetings attended by senior management, and where there are issues such as overdue CAPA, audits, change controls discussed that there are documented actions supported by senior management.

* 1. Section H
     1. Question H3 (NEW) – trending of incidents

Incidents should be analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventative action.

* + 1. Question H4 – Potential for harm

The risk assessment applied to incidents should look at the ‘potential for harm for this type of incident’ and not the ‘actual harm caused by the incident under investigation’ alone.

* + 1. Question H5 – Timescale

Note this timescale is for investigation of the incident and does not include CAPA.

* + 1. Question H5.2 – Open investigations

This is a snapshot of the number of investigations that remained open on 1st December 2023 therefore please include all investigations that remained open and were overdue by more than a month on 1st December. You do not need to include for example an investigation that was overdue by two months but was closed in Oct 2023.

* + 1. Question H10 (NEW)

Personnel must be trained appropriately for their specific tasks and this includes quality related tasks.

* 1. Section I
     1. Question I1.4 – Effectiveness of recall

The effectiveness of the arrangements for recalls should be regularly evaluated. This question is asking whether your evaluation considers all forms of recall including internal recalls in your schedule of evaluation. If you have had several external recalls, then these may be reviewed but internal recall may need to be carried out via a ‘mock’ recall. Consideration should be given to different scenarios in internal recall such as analyser test card failure.

* 1. Section J (NEW)

This section has been amended to contain questions to look at the timely reporting and investigation of serious adverse events (SAE) and serious adverse reactions (SAR).

* 1. Section L
     1. Question L1.6 – Open audit non-conformances

This is a snapshot of the number of audit non-conformances that remained open on 1st December 2023 therefore, please include all non-conformances that remained open and were overdue by more than a month on 1st December. You do not need to include for example a non-conformance that was overdue by two months but was closed in Oct 2023.

* 1. Section N
     1. Question N7.2 – Transport over 30 minutes

If you do not transport blood components to areas where the transportation area is over 30 minutes away, then answer ‘yes’ to this question as validation is only required where transportation takes more than 30 mins.

* + 1. Question N8.1.1

Changes to SOPs and records controlled within the document control system are acceptable. If this is the case answer ‘yes’ to this question.

* + 1. Question N8.1.3

Significant changes to the laboratory management structure should be handled through the change control system to ensure that the impact has been assessed appropriately. For example, the addition of new roles or the removal of roles or sharing of roles across sites or disciplines.

* 1. Section O
     1. Question O3

Only answer “Yes” to this question where a legacy system is routinely accessed as part of the laboratory procedure.

* 1. Section P
     1. Question P3.4.3

This question has been clarified to ensure that when there is an IQC failure the impact on all samples back to the last successful IQC run is considered. Procedures should clarify where it is acceptable to carry out a simple rerun of the IQC because the IQC failure was due to obvious reasons such as ‘short sample’.

* 1. Section R

If the Hospital Blood Bank supplies other sites with blood components (e.g. other local hospitals or Hospices), the details of these sites should be listed in Section R. Please provide full name and address for each facility. Ensure that an up to date contact email is included.

The compliance report template provides space for 10 external distribution sites; if more than 10 are supplied, additional sites can be reported including the same information using the 2024 Distribution sites addendum page (Microsoft Word document). This can be downloaded from the GOV.UK ‘Medicines, medical devices and blood regulation and safety’

<https://www.gov.uk/government/publications/blood-bank-compliance-report-template>

It is important that the first 10 sites supplied are completed on the Hospital Blood Bank Compliance Report (2024).

Blood facilities do not need to complete a compliance report or declaration for 2024 but must ensure that they have an agreement in place with the HBB that intends to supply them with blood components. The agreement should confirm the responsibility of the facility to comply with the BSQRs, with specific reference to storage (where relevant), traceability and reporting of serious adverse reactions and events.

* 1. Section T and U

Apart from Corrective Action Commitments and Proposed Corrective Actions, any clarifying remark can be documented in these sections. Individual non-compliance indicators, if accompanied by robust corrective action plan in Section U, may not in themselves result in a final decision of non-compliance.

* 1. Missing response alerts

A table at the end of the compliance report template will alert the user to any questions which have not been answered. The table will adapt to the responses provided and will only flag missing responses to valid questions. If an indicator appears please revisit the question highlighted.

1. **Checking the accuracy of answers**

Some numerical and menu-based responses automatically alert MHRA to risk indicators. It is therefore important that responses are accurate, as mistakes may lead to a laboratory being assigned a higher risk score. High risk scores may result in an inspection.

It is recommended that responses are checked for accuracy before submission to MHRA. In particular, compliance reports received in previous years have identified errors when reporting temperature alarm settings (e.g. maximum and minimum alarm settings for freezer alarms reported as ‘maximum temperature -45°C, minimum temperature -30°C’, when they should read as ‘maximum temperature -30°C, minimum temperature -45°C’).

1. **Completing the BCR declaration page**
   1. The declaration page is a separate document which can be downloaded from the GOV.UK.
   2. Signed declaration pages must be returned by email with the compliance report.
   3. If the Trust has more than 1 hospital blood bank, please scan only one declaration form for each hospital blood bank at a time as each one is saved with the BCR under the site number.
   4. The declaration must be printed and ‘wet’ signed before scanning. If document scanning equipment is not available to the transfusion laboratory, the declaration page may be returned as a hard copy to:

Blood Compliance Reports

MHRA

10 South Colonnade

Canary Wharf E14 4PU

London

* 1. The person responsible for signing the “Compliance Report completed by” section on the declaration form must ensure all the questions are completed on the BCR, and the completed answers are true and accurate.
  2. The report must be signed by the Chief Executive Officer (in the case of hospital blood bank located in a hospital managed by a health service body), or the Registered Person (in the case of an independent hospital).
  3. The content of the declaration should be read carefully by the CEO or Registered Person before signing.

1. **Submitting the BCR and declaration**
   1. Email the BCR and declaration to [bcr@mhra.gov.uk](mailto:bcr@mhra.gov.uk).
   2. Send the forms individually i.e. one hospital BCR and declaration per email.
   3. Send with email subject heading ‘Full Hospital Name – BCR 2024’.
2. **Following submission**
   1. Following the BCR assessment, Hospital Blood Banks will be provided with a BCR Assessment Confirmation Letter to confirm that assessment has been completed, without indicating the outcome (i.e. inspection or no inspection).
   2. The level of compliance determined will be used to inform the inspection programme for 2024/2025
   3. The Hospital Blood Banks selected for inspection will be contacted by the inspectors to arrange a date.
   4. All inspections will be performed with a maximum of 7 days’ notice.

**ANNEX 1**

**Regulatory references for each BCR section:**

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| **BCR Section** | **Section Title** | **Reference** |
| A | General Information |  |
| B | Activities Undertaken |  |
| C | Previous Compliance Reports |  |
| D | MHRA Inspection History |  |
| E | Key Personnel | Directive 2005/62 Annex, para 2.1  CoE GPG 2  *If transfusion services at the site named in section A are provided by an external contractor, or another Hospital site, the contact details of the Service Provider should be listed in section E.* |
| F | Training | BSQR (SI 2005 No.50) Regulation 9 (1) a  Directive 2005/62 Annex, section 2  CoE GPG 2 |
| G | Quality Management System | BSQR (SI 2005 No.50) Regulation 9 (1) b  Directive 2005/62 Annex, section 1  CoE GPG 1 |
| H | Corrective and Preventative Action (CAPA) | BSQR (SI 2005 No.50) Regulation 9 (1) b  Directive 2005/62 Annex, para 1.2 .1 & section 9.4  CoE GPG 1.2, 9.1, 9.2 |
| I | Component recall | BSQR (SI 2005 No.50) Regulation 9 (1) g  Directive 2005/62 Annex, section 9.3  CoE GPG 1.2, 1.3, 9.3 |
| J | Reporting Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) | BSQR (SI 2005 No.50) Regulation 9 (1) f and Regulation 12B  Directive 2005/62 Annex, section 9.2 |
| L | Self Inspection (Internal Audit) | BSQR (SI 2005 No.50) Regulation 9 (1) b  Directive 2005/62 Annex, section 10  CoE GPG 10 |
| M | Equipment maintenance and calibration | BSQR (SI 2005 No.50) Regulation 9 (1) b  Directive 2005/62 Annex, para 4.1 and 4.2  CoE GPG 4.1 |

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| N | Qualification, Validation and change control | BSQR (SI 2005 No.50) Regulation 9 (1) c  Directive 2005/62 Annex, para 1.2.2, 4.1, 4.5, 6.3.1, 7.2  CoE GPG 4.3, 4.6 |
| O | Computerised systems and data management | Directive 2005/62 Annex, para 4.5  CoE GPG 4.2, 5.4 |
| P | Pre-transfusion testing | Directive 2005/62 Annex, para 4.3, 6.3 |
| Q | Description of systems in place for traceability of blood components | BSQR (SI 2005 No.50) Regulation 9 (1) e, i, j and 9 (2)  Directive 2005/61 |
| R | Distribution of blood components | BSQR (SI 2005 No.50) Regulation 9 (1) h  Directive 2005/62 Annex, section 7 |
| S | Work contracted to third parties | Directive 2005/62 Annex, section 8  CoE GPG 8 |
| T, U | Corrective Actions, Preventive Actions |  |