
Document Control

1. PURPOSE

This procedure describes the processes to ensure that controlled documents of the Haemopoietic Stem Cell Transplant (HSCT) Programme are authorised, uniquely identified, distributed, reviewed and archived in a controlled manner.

2. SCOPE

This procedure applies to all controlled documentation within the HSCT Programme Quality System and all associated trained staff. External documentation is managed by the respective supplier, but classified according to this procedure. The Cell Therapy and Flow Cytometry Laboratory manage their document control according to the Royal Children's Hospital Laboratory Services Quality System.

3. RESPONSIBILITY

All staff are responsible to follow procedures to maintain the integrity of the controlled document system.

It is the responsibility of the Document Author to;

- Ensure that the details within the document are correct and the document is formatted and compliant according to QS-P-001, Preparing Quality System Documentation.
- Initiate an accompanying Document Flyer, QS-F-002.

It is the responsibility of the Document Reviewer (or Reviewing Committee(s)) to;

- Review the draft document for accuracy, clarity and where applicable, compliance with the respective standard / guideline the document is addressing.
- In conjunction with the author, undertake responsibility for the document.

It is the responsibility of the Document Authoriser to;

- Take overall management of the document including final approval for submission of the document for Document Control and distribution.
- Complete record of the document process on the Document Flyer, QS-F-002, and forward the document (electronically) and Flyer to the Quality Manager or designee.

It is the responsibility of the Quality Manager (QM) or designee to;

- Respond with an acknowledgement email, confirming that documents have been received.
- Ensure the document is controlled utilising a paper base system and Qpulse Quality Management System Software.
- Ensure that information in the Document Master List (excel spreadsheet / module on Qpulse) is accurate and completed in a timely manner.
- Ensure that superseded or obsolete versions are removed (both hard and electronic copies) so only current versions are in circulation.
- Maintain (inclusive of generating) both hard and electronic PDF copies of all current versions of controlled documentation.
- Initiate annual controlled document review.
- Ensure implementation, maintenance and compliance to this procedure and in conjunction with Preparing Quality System Documentation procedure (QS-P-001).

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4. DEFINITIONS

Controlled Documentation – Documents which describe how to perform or record organisational and technical processes. This includes Policies, Procedures, Forms, Agreements and Contracts generated by the HSCT Programme or may refer to;

- documents from other Departments within the RCH organisation and
- external documents such as company procedures and equipment manuals.

Controlled documents are identifiable and traceable by a unique document control and version number. The printed version (hard copy) is a Controlled Document **ONLY** if printed on controlled stationery (red stripe in margin) (*see note on forms for exceptions 5.1.6*).

Electronic versions of controlled documents are available for viewing in PDF format on the Children's Cancer Centre (CCC) Department Intranet listing.

Master List – The Master List of the controlled documents is maintained in a paper base and QPulse systems by the QM or designee. The Master List is divided into respective sections (Clinical, Apheresis, Cell Therapy and Flow Laboratory and Quality System / Occupational Health and Safety) pertaining to the HSCT Programme. Each section Master List must include;

- document title,
- unique document number,
- version number,
- date of issue and
- distribution list.

(see note on Cell Therapy and Flow Cytometry Laboratory for exceptions)

Active Documents – These are the current version of the controlled document which is operational. Controlled copies are managed by the QM or designee and are available as;

- hard copies printed on controlled stationery generated by the QM and
- electronic PDF's which are accessible to all staff via the intranet.

Inactive Documents – Any document which has been superseded by the next version.

Obsolete Documents – Any document (inclusive of all versions) which is no longer required (e.g.; procedure no longer performed). These documents are no longer required on the Master List and are accessible electronically for a minimum of 10 years following withdrawal.

Controlled Stationery – Stationery designated for printing controlled documents.

QPulse – Quality Management System Software, used by the QM or designee.

5. EQUIPMENT AND SUPPLIES

QPulse Quality Management System Software

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6. PROCEDURE

6.1 Overview

6.1.1 This procedure should be read in conjunction with QS-P-001 Preparing Quality System Documentation. Refer to QPulse Document Control Users Guide, issued by Royal Children's Hospital Laboratory Services for additional software instructions.

6.1.2 Once the document (new or amended version) with the accompanying Document Flyer is received by the QM or designee, an acknowledgement email is sent to the authoriser, confirming that documents have been received.

6.1.3 The QM or designee ensures that all documents are uniquely numbered and that details are entered and maintained by a paperbase and on the QPulse systems. The Document Master List is also updated by the QM or designee. The accompanying Document Flyer is filed.

6.1.4 The QM or designee maintains the Document Master List, updating distribution location(s) of both 'hard copies' - generated controlled documents and 'electronic copies' - PDF format.

6.1.5 Internally generated controlled documents are printed on controlled stationery - red stripe located in the margin. When this stationery is used, details are recorded in Controlled Document Stationery Register, QS-F-003. The QM or designee is responsible for printing and distribution of all current document versions and also retrieval of all superseded copies according to the Distribution List in the Master List.

6.1.6 The QM or designee is also responsible for maintaining valid electronic versions of all current controlled documentation. Electronic versions accessible in PDF format are located via;

Royal Children's Hospital Intranet-RCH Departments-Children's Cancer Centre-For Health Professionals-HSCT Programme Controlled Documents.

http://www.rch.org.au/ccp/prof.cfm?doc_id=11332

6.1.7 Documents **NOT** printed on 'red stripe' paper are not considered Controlled Documents- these include photocopies, PDF hard copies and documents sent electronically via email. It is the responsibility of all staff to maintain the integrity of the controlled document system by **NOT** referring to 'stored copies of procedures and policies' as they may not be the current version.

6.1.8 Because many forms are electronically generated, it is acceptable to print forms directly from the current form version PDF located on the intranet. To avoid the use of superseded versions, printed forms should be used as soon as possible and not stored indefinitely.

6.1.9 Kit inserts, discussion papers etc are designated as controlled documents, but these are referenced as attachments in their respective procedure. These attachments are not entered in the Document Master List, but are signed and dated by the respective Authoriser.

6.2 Document Numbering

6.2.1 Documents are uniquely identified alphanumerically using the following format: XX-Y-ZZZ where;

- XX = Section Abbreviation
- Y = Document Classification Code
- ZZZ = Document Number (i.e. document number 1 is numbered 001)

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HSCT Programme Section Abbreviations

| | |
|------|--|
| AP | Apheresis (Collection Facility – Ambulatory Care Centre) |
| CL | Clinical (Children's Cancer Centre) |
| CT | Processing Facility (Cell Therapy and Flow Cytometry Laboratory) |
| OH&S | Occupational Health and Safety |
| QS | Quality Systems |

HSCT Document Classification Codes

| | |
|---|------------------------|
| O | Policy |
| P | Procedure |
| F | Form |
| W | Work Instruction |
| E | External Document |
| A | Agreements & Contracts |

6.3 Document Authorisation

Authorisation is shown by inclusion of an electronic signature in the document footer. Refer to QS-P-001 Preparing Quality System Documentation for more detail.

6.4 Electronic Document Storage

All controlled documents on the excel and QPulse Master List are managed and stored in [\rchfs\ccc\bmt_fact](#) drive, in HSCT Controlled Document Folders according to the respective Section. It is recommended that these documents are password protected / read only to prevent unauthorised persons making changes to the electronic document. Access to the 'bmt_fact' is password restricted and managed by RCH Information Technology Department.

6.5 Document Copies

6.5.1 It is the responsibility of all staff to maintain the integrity of the controlled document system by **NOT** referring to 'stored copies of procedures and policies' as they may not be the current version.

NOTE Hard copy controlled documents are printed on 'Red Stripe' stationery and are managed by the QM or designee.

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6.5.2 Photocopies of controlled documentation are **NOT** recommended. To avoid circulation of superseded documents, all controlled documentation should be printed from document controlled electronic PDF's accessed on the intranet. The QM or designee is responsible for ensuring that **ALL** PDF's are the current versions.

6.5.3 To avoid completion of superseded versions of forms, printed PDF's should not be stored / filed.

6.6 Electronic Only Distribution

6.6.1 Some documents may only be issued 'electronic only', that is, there is no hard copy available. This is specified in the Distribution Lists in the Master List on excel and QPulse. These documents are accessible to staff on the intranet. These documents undergo review as per **ALL** controlled documentation.

6.7 Document Review.

Refer to QPulse Document Control Users Guide, issued by RCH Laboratory Services.

6.7.1 The QM or designee initiates the annual review process. The document to be reviewed and accompanying Document Flyer is sent electronically to the original author in the first instance, or the most appropriate staff member who is familiar with the respective process following procedure Preparing Quality System Documentation, QS-P-001. The reviewed document and completed Document Flyer is returned to the QM or designee.

6.7.2 If there are no amendments, the version number is not changed, hence the document does not need to be reprinted, nor does the PDF alter.

6.7.3 The document registration is updated in the paper base and QPulse systems, with a note 'reviewed-no changes' and the review date is updated for another 12 months.

6.7.4 When changes are made, the QM or designee completes the details in the Master List, updates the version number and the new version is issued immediately in accordance with the distribution list. The new version PDF is also issued according to the distribution list. All changes are recorded in the document history.

6.7.5 Hand-written minor amendments are permissible. All hand written amendments on the controlled document **MUST** be dated and signed by the author. If the amendment is considered major by the Manager of the section, the document is reviewed and submitted for document control.

6.8 Inactive or Obsolete Documents

5.8.1 The QM or designee informs the designated contact (on the distribution list) of the new version document. The old version is destroyed and replaced with the new version. All electronic copies of inactive (old versions) and obsolete documents are transferred to the inactive or obsolete register in the paper base and QPulse systems.

6.9 Computer Security

6.9.1 Before amendments are made to electronic versions of documents, a copy is made and stored for archival purposes.

6.9.2 Where possible documents are password protected / read only.

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6.9.3 All documents on the Master List are stored on '\\rchfs\ccc\bmt_fact', in HSCT Controlled Documents Folder according to the respective Section. Access to the '\\rchfs\ccc\bmt_fact' is password restricted, backed up regularly and managed by RCH Information Technology Department.

6.10 Tables of Contents

The Table of Contents at the front of each manual is NOT considered a controlled document it is the responsibility of the QM or designee to ensure it is current and correct.

7. ENDPOINT

Not applicable

8. ATTACHMENTS

QPulse Document Control Users Guide, issued by RCH Laboratory Services.

9. REFERENCES

9.1 Preparing Quality System Documentation. RCH CCC Haemopoietic Stem Cell Transplant Programme Quality Systems Manual. Doc. No. QS-P-001. Version: 001. 2008.

9.2 QPulse Document Control Users Guide. User Manual. Gael Quality Limited. 2000.

9.3 ISO9001:2000 Quality Management Systems – Requirements. 2000.

9.4 International Standards for Cellular Therapy Product Collection, Processing and Administration. FACT-JACIE. Fourth Edition. October 2008.