Canadian Blood Services

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Stem Cell Registry
Transplant Centre Reference Manual

Section 11 – Quality/Adverse Event Reporting

Effective Date:	2020-06-29

Approval Signatures	Date
Approved by Heidi Elmoazzen, Director, Stem Cells see attached email approval	
Approved by Manager, Quality Assurance	2020-04-03

Revision History

Version	Amdt.	Detail	Effective Date
1	0	CR #17603: New document created from UBMTC0101 as per corporate LINK project	2020-06-29

OVERVIEW

Canadian Blood Services Stem Cell Registry (stem cell registry) defines a "Quality Event" as any unplanned occurrence, problem or undesirable event, or incident that represents a departure from approved processes or procedures, specification or manufacturer's instructions or from what is required, expected or acceptable, from a product and/or transfusable & transplantation services standpoint."

A quality event occurring at or discovered by the transplant centre must be reported immediately to the stem cell registry.

The transplant centre will be responsible to investigate and report to the stem cell registry the root cause of any quality event that occurs in their facility and must identify and implement corrective action(s) to prevent a quality event from re-occurring in the future.

The transplant centre must report any errors, accidents, quality events, and adverse recipient events to Health Canada as per the **Safety of Human Cells, Tissues and Organs for Transplantation Regulations** and **Guidance Document for Source Establishments – Reporting Adverse Reactions to Human Cells, Tissues and Organs.** For further information, refer to: http://www.healthcanada.gc.ca.

The transplant centre must also inform the stem cell registry of any quality event which is thought to be associated with the product. The stem cell registry will report all serious defects in the stem cell product to the WMDA Serious Product Events and Adverse Events Registry (SPEAR). The SPEAR reporting criteria include, but are not limited to, any events that lead to one or more of the following outcomes in the recipient:

- Death
- Life-threatening disease
- Unexpected hospitalization or considerable prolongation of existing hospitalization
- Persistent or significant disability/incapacity.

The stem cell registry will notify the transplant centre immediately if a donor health issue is identified that may affect the well-being of the recipient.

ASSOCIATED DOCUMENTS:

None