

**WORLD MARROW DONOR ASSOCIATION
WMDA
INTERNATIONAL STANDARDS
UNRELATED HEMATOPOIETIC STEM CELL DONOR REGISTRIES**

AMENDMENT 1: January 2021

Page 10, Standard 1.01

Replace standard **1.01** with the following:

An organisation responsible for all of the following: (1) maintaining a searchable donor file of at least 500 adult volunteer donors and/or at least 100 umbilical cord blood units; (2) coordinating the search of this file for a source of hematopoietic stem cells (HSC) for an unrelated potential recipient; and (3) providing HSC; is eligible for WMDA certification or WMDA qualification as a first step, followed by WMDA accreditation as a second step.

Justification of change: Removing requirement to be a WMDA member in order to apply for certification/qualification but retaining the requirements to be a registry. This will allow any applicant to apply and meets ISO 17065 requirements for non-discriminatory conditions.

Page 25, Standard 9.03

Replace standard **9.03** with the following:

Serious Adverse Events and Reactions affecting donors undergoing collection of HSC and/or cellular product, occurring both in the long term and/or the short term as a consequence of the donation, must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Events and Reactions must be submitted to the WMDA S(P)EAR Committee.

Justification of change: Addition of the term "Events"