
	CB_Application Requirements and Levels			
	Document type	Policy	Approved by	CEO WMDA
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WMDA

POLICY: CERTIFICATION BODY APPLICATION REQUIREMENTS AND LEVELS

CHANGE RECORDS

Version	Date	Change Type	Change Description
1	2021-07-10	Document creation	Subdivided up Accreditation Policy and Procedure Manual into separate policies and procedures
2	2023-04-05	Revision	Changed terms for status, added donor centres
3	2024-09-17	Terminology	Replacement of term Accreditation by Certification
4	2025-02-04	Revision	Added reference to inspections during assessment

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1. INTRODUCTION

1.1 PURPOSE AND SCOPE

The WMDA has developed standards, a certification scheme, and a certification process for registries involved in the international exchange of blood stem cells. This document describes the policy regarding the criteria to submit an application for certification or to renew certification status over time.

This document covers the following sections:

1. Introduction
2. Requirements to submit an application, non-discriminatory conditions
3. Levels of certification program
4. Certification agreement
5. Mid-cycle surveillance Certification requirements
7. Notification of status
8. Termination, reduction, suspension, or withdrawal of certification


1.2 PARTY RESPONSIBLE FOR THIS DOCUMENT

The WMDA Certification Steering Committee develops and reviews this document.

1.3 APPLICABLE AND REFERENCE DOCUMENTS

Here below are listed the documents needed to understand the information provided by this policy and intended to be an extension of the policy itself.

Identifier	Title
https://share.wmda.info/display/EnsuringQuality/WMDA+Standards	WMDA International Standards for Haematopoietic Stem Cell Donor Registries
ACC_7200_01_F_LOI	Letter of Intent to Submit an Application for WMDA Benchmark L1/L2 or Full Standards Certification
ACC_7700_SOP	SOP: Certification Documentation


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The following documents, although not a part of this policy / procedure, amplify or clarify its contents.

Identifier	Title
ACC_4120_F	Agreement for WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification
ACC_7400_SOP	SOP: Evaluation Activities
ACC_7100_SOP	SOP: Systematic Revision Process for WMDA Standards
ACC_7500_SOP	SOP: Certification Committee
ACC_7401_01_WI	WMDA Definitions of Scoring System for Nonconformities
ACC_4130_P	Policy: Use of WMDA Certification Marks
ACC_7130_SOP	SOP: Complaints and Appeals Related to Certification Program

1.4 ABBREVIATIONS

- CSC, Certification Steering Committee
- Benchmarked standards, a subset of WMDA Standards that represent the most critical standards for the activities of a registry or donor centre.
- Donor centre, An organisation responsible for donor recruitment, consenting, testing, management and the collection of donor personal, genetic, and medical data
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- HSC, haematopoietic stem cells
- ICCBBA, International Council for Commonality in Blood Banking Automation, Inc.
- Registry, Organisation responsible for coordination of the search for haematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient, for the collection and transport of the donation, and for the care of the donor. It includes both unrelated donor registries and umbilical cord blood banks acting as a registry.
- Reviewers/evaluators, qualified individuals who assess compliance with WMDA Standards
- Searchable donor file, a database which lists donors (anonymously) and key characteristics important in donor selection for a specific patient.
- Share, on-line collaboration platform
- WMDA (previously World Marrow Donor Association)

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2. REQUIREMENTS TO SUBMIT AN APPLICATION, NONDISCRIMINATORY CONDITIONS

2.1 WMDA STANDARD 1.01 ([WMDA International Standards for Haematopoietic Stem Cell Donor Registries](#))

WMDA Certification Body policies and procedures do not impede or inhibit access by applicants whose activities fall within the scope of its operations. Access is not conditional on the size of the client when the searchable donor / cord blood unit file size is met. It is not conditional on membership in WMDA and is not conditional on the number of certifications already issued.

This WMDA Standard 1.01 sets out the minimum requirements to submit an application.

2.2 SCOPE OF THE APPLICATION

All applications will be evaluated based on a set of services linked to a normative standard, WMDA International Standards for Haematopoietic Stem Cell Donor Registries ([WMDA International Standards for Haematopoietic Stem Cell Donor Registries; Letter of Intent to Submit an Application for WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification](#)).

Subject of Certification: Services	Certification Scheme	Standard / Normative Document
1) Receive requests for searches; maintain searchable database 2) Coordinate the provision of adult volunteer donors as a source of stem cells 3) Coordinate the provision of umbilical cord blood units as a source of stem cells 4) Provide support for search requests from registry's transplant centres	WMDA Certification Scheme ACC-7110-F-SSL WMDA Standards, Services, Levels Conformity assessment activities by expert evaluators: <ul style="list-style-type: none"> • Review of documented information, such as policies, procedures, forms, instructions, service level agreements, and certificates / licenses; • Analyses based on performance indicators; • Review of websites; • Interviews with employees; • Observations of activities • Inspection of services and outcome services and the surrounding work environment and conditions; 	WMDA International Standards for Haematopoietic Stem Cell Donor Registries


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Table 1. Overview of WMDA Certification Scheme		
Subject of Certification: Services	Certification Scheme	Standard / Normative Document
	<ul style="list-style-type: none"> Review of records, such as audit reports, agendas, files of donor / recipient activities 	


Applications seeking Benchmark L1 or L2 will be evaluated on the basis of a subset of WMDA Standards termed benchmarked standards. The designation of the benchmarked standards is overseen by the Standards Committee ([ACC_7100_SOP Systematic Revision Process for WMDA Standards](#)).

Applicants must maintain a searchable donor file of adult volunteer donors or umbilical cord blood units or both donor sources. Their application can cover only one or both donor sources. Additional alternatives are whether the registry requests international searches on behalf of its affiliated transplant centres or receives requests for searches and maintains a searchable database .

2.3 MINIMAL ACTIVITY REQUIREMENT

In order to have a sufficient activity to demonstrate compliance with the services evaluated under the scope of certification, applicants applying for certification must meet the following criteria:

- Minimum of six (6) donations within the last three (3) years with two (2) of the six (6) for international patients is required to be eligible for WMDA Benchmark L2 / Full Standards for volunteer donors as a stem cell source. The remaining four (4) donations may be for national patients.
- Minimum of six (6) cord blood unit shipments within the last three (3) years with two (2) of the six (6) for international patients is required to be eligible for WMDA Benchmark L2 / Full Standards for cord blood as a stem cell source. The remaining four (4) stem cell shipments may be for national patients.
 - This requirement only applies for the submission of a Benchmark L2 application. Once the registry has become approved for both volunteer donors and cord blood units, it no longer needs to meet the requirements for the number of cord blood shipments.
- If a registry applies for both stem cell sources but meets the required activity level for only one, it will receive approval for only the stem cell source that meets the activity level. A registry cannot simultaneously hold two certificates for stem cell sources, e.g., Benchmark L2 for adult volunteers and Benchmark L1 for umbilical cord blood. If a registry achieves an acceptable level of activity for the stem cell source not currently included, it can request an extension of the scope.
- If the minimum activity is not reached by the registry, the registry can apply for WMDA Benchmark L1 (instead of WMDA Benchmark L2 / Full Standards).

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3. LEVELS OF CERTIFICATION PROGRAM

A stepwise progress towards Full Standards has been developed, beginning first with Benchmark and then Full Standards, to help registries achieve compliance with the WMDA Standards. Furthermore, it is important that organisations applying to the WMDA Certification Program meet the basic requirements for a scope of operation that allows sufficient activity for evaluation by the WMDA reviewers. If the level of activity is not met, the registry may be awarded Benchmark L1. Donor Centre applications will only receive Benchmark L1 status.

3.1 BENCHMARK L1 (previously termed “CERTIFICATION”)

The applicant must comply with a subset of WMDA Standards designated as “benchmarked”. Benchmark L1 is awarded for four (4) years with a mid-cycle surveillance occurring at two (2) years. Benchmark L1 can be renewed indefinitely as long as the activity level remains below the minimum required. Once the level increases to meet the criteria listed in 2.3, the applicant must submit an application for Benchmark L2 and/or Full Standards.

Applications are accepted for Benchmark L1 from donor centres that are not within a WMDA Benchmark L1/L2 or Full Standards registry at the time of application. Evaluation will be based only on the relevant benchmarked standards and will result in WMDA Benchmark L1 status. Certification can be renewed every 4 years. Donor centres are not eligible for WMDA Benchmark L2 or Full Standards at this time. Once the affiliated registry becomes WMDA Benchmark L1 or L2, donor centre certification status will cease and the registry will become responsible for overseeing compliance of the donor centre with relevant WMDA standards.

3.2 BENCHMARK L2 (previously termed “QUALIFICATION”)


The applicant must comply with a subset of WMDA Standards designated as “benchmarked”. Benchmark L2 is awarded for four (4) years with a mid-cycle surveillance occurring at two (2) years. At the end of four years, the registry must apply for transition to Full Standards. If the evaluation of that application indicates that the registry is not yet prepared for Full Standards, Benchmark L2 may be renewed for another two years. Every two years subsequent to that renewal, the registry must submit an application based on all WMDA Standards for consideration. The registry has up to a total of eight (8) years to successfully reach Full Standards status.

3.3 FULL STANDARDS (previously termed “ACCREDITATION”)

The applying registry must hold WMDA Benchmark L2 status or be renewing their Full Standards status. The registry is required to meet all of the WMDA required standards. Full Standards is awarded for four (4) years and can be renewed. A mid-cycle surveillance occurs at two (2) years.

4. CERTIFICATION AGREEMENT

Once the applicant has indicated that it will submit an application, the applicant and WMDA will sign [Agreement for WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification](#). The WMDA Certification Agreement is a legally enforceable agreement for the provision of the Benchmark L1, Benchmark L2, or Full Standards activities. It contains the responsibilities of WMDA and the client (applicant). WMDA and the client will sign a

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certification agreement specific for each Benchmark L1, Benchmark L2, or Full Standards process. The certification documentation will only be issued after the Certification Agreement has been completed/signed.

5. MID-CYCLE SURVEILLANCE

Surveillance includes an external review of each Benchmark L1, Benchmark L2, or Full Standards organisation midway through each four-year cycle. The focus of the surveillance is to determine if the organisation is “on track” for its next application. Documentation is submitted through Share using a standard template and assessment covers the following areas:

- Changes to the organisation not previously reported to the WMDA that may affect WMDA Benchmark L1, Benchmark L2, or Full Standards status (WMDA Standard 1.05).
- Major changes as to how the organisation complies with WMDA Standards
- Weaknesses/suggested improvements noted in the last external review team report
- Implementation of new/revised WMDA Standards
- Update of previously submitted certifications from other certification bodies provided for Standard 1.02

Documentation is assessed by an evaluator ([ACC_7400_SOP Evaluation Activities](#)) and the decision to accept the mid-cycle surveillance is made by the Certification Committee ([ACC_7500_SOP Certification Committee](#)). Serious nonconformities will require further action ([ACC_7401_01_WI WMDA Definitions of Scoring System for Nonconformities](#)).


6. CERTIFICATION REQUIREMENTS

Requirements of the certification process include, but are not limited to:

- Completing a certification agreement once certification is approved ([ACC_4120_F Agreement for WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification](#))
- Paying fees for certification
- Providing information on major changes that might impact certification status
- Submitting the mid-cycle surveillance in a timely fashion
- Responding to a major or critical concern raised in an evaluation within the time limit set
- Using the certificate or marks of conformity appropriately ([ACC_4130_P Policy: Use of WMDA Certification Marks](#))

7. NOTIFICATION OF STATUS

A list of organisations with Benchmark L1, Benchmark L2, or Full Standards status will be reported at the WMDA general membership meeting and will be provided on the <https://wmda.info/> website. Organisations may list their WMDA Benchmark L1, Benchmark L2, or Full Standards status in their literature. The content of the certificate received by the organisation is described in [ACC_7700_-SOP Certification Documentation](#). Certified organisations may use the WMDA certification mark ([ACC_4130_P Policy: Use of WMDA Certification Marks](#)).

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Reports and web sites from other organisations may list WMDA certified organisations. Information on Benchmark L1, Benchmark L2, or Full Standards status may be provided to third party organisations by the WMDA office upon request.

8. TERMINATION, REDUCTION, SUSPENSION, OR WITHDRAWAL OF CERTIFICATION

When a nonconformity with the certification requirements is observed during the evaluation of an application or during a mid-cycle surveillance, several actions may be taken depending on the severity of the nonconformity. The process and actions are described in [ACC_7401_01_WI WMDA Definitions of Scoring System for Nonconformities](#).

When a nonconformity is identified through a complaint, the procedure to be followed is described in [ACC_7130_SOP Complaints and Appeals Related to Certification Program](#).