

|                                                                                   |                                        |                        |                 |           |
|-----------------------------------------------------------------------------------|----------------------------------------|------------------------|-----------------|-----------|
|  | CB_Application Requirements and Levels |                        |                 |           |
|                                                                                   | Document type                          | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                     | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                         | P4/ Certification body | Status          | Public    |

## 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                                                                                                  |
| 5       | 2025-04-03 | Addition          | Added more details on requirements to be eligible to submit an application.                                                                       |
| 6       | 2025-07-10 | Addition          | Added reference to WMDA Certification Scheme and removed Table 1                                                                                  |
| 7       | 2025-08-25 | Revision          | Updated definition of Benchmark Standard<br>Updated terminology (evaluators instead of reviewers)<br>Updated signature of Certification Agreement |

|                                                                                   |                                               |                        |                 |           |
|-----------------------------------------------------------------------------------|-----------------------------------------------|------------------------|-----------------|-----------|
|  | <b>CB_Application Requirements and Levels</b> |                        |                 |           |
|                                                                                   | Document type                                 | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                            | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                       | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                                | P4/ Certification body | Status          | Public    |

## 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 programme
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                                                                      |
|-----------------------------------------|----------------------------------------------------------------------------|
| <a href="#">Ensuring Quality   WMDA</a> | WMDA International Standards for Haematopoietic Stem Cell Donor Registries |
| ACC_7200_01_F_LOI                       | Letter of Intent to Submit an Application for WMDA Certification           |
| ACC_7700_SOP                            | SOP: Certification Documentation                                           |
| ACC_7110_SC                             | WMDA Certification Scheme                                                  |

|                                                                                   |                                               |                        |                 |           |
|-----------------------------------------------------------------------------------|-----------------------------------------------|------------------------|-----------------|-----------|
|  | <b>CB_Application Requirements and Levels</b> |                        |                 |           |
|                                                                                   | Document type                                 | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                            | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                       | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                                | P4/ Certification body | Status          | Public    |

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_4131_P     | Policy: Use of WMDA Certification Marks                                       |
| ACC_7130_SOP   | SOP: Complaints, Concerns, And Appeals Related to Certification Programme     |

#### 1.4 ABBREVIATIONS

- CSC, Certification Steering Committee
- Benchmarked standards, a subset of the WMDA Standards that are considered as the basis for the evaluation of Benchmark L1 or Benchmark L2 status. Benchmark L2 is considered a first step to Full Standards status. The benchmarked standards are critical for registry quality and provide a reasonable and practical first step for a registry undergoing its first compliance assessment (Benchmark L2) and / or a registry with very low activity (Benchmark L1).
- Donor centre, An organisation responsible for donor recruitment, consenting, testing, management and the collection of donor personal, genetic, and medical data
- 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. It can also include a donor centre that is affiliated with an uncertified registry.
- Evaluators, qualified individuals who assess compliance with WMDA Standards

|                                                                                   |                                               |                        |                 |           |
|-----------------------------------------------------------------------------------|-----------------------------------------------|------------------------|-----------------|-----------|
|  | <b>CB_Application Requirements and Levels</b> |                        |                 |           |
|                                                                                   | Document type                                 | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                            | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                       | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                                | P4/ Certification body | Status          | Public    |

- 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)

## 2. REQUIREMENTS TO SUBMIT AN APPLICATION, NONDISCRIMINATORY CONDITIONS

### 2.1 REQUIREMENTS

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.

The minimum requirements to submit an application listed in the letter of intent state: 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 haematopoietic stem cells (HSC) and other cellular products for an unrelated potential recipient; and (3) providing HSC; is eligible for WMDA Benchmark Level 1/2 as a first step, followed by WMDA Full Standards compliance as a second step.

### 2.2 SCOPE OF THE APPLICATION

All applications will be evaluated based on the purpose of WMDA Certification and a subset 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](#)).

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 subservices 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.

|                                                                                   |                                               |                        |                 |           |
|-----------------------------------------------------------------------------------|-----------------------------------------------|------------------------|-----------------|-----------|
|  | <b>CB_Application Requirements and Levels</b> |                        |                 |           |
|                                                                                   | Document type                                 | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                            | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                       | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                                | P4/ Certification body | Status          | Public    |

- 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.
  - Once the registry has become approved for both volunteer donors and cord blood units at the Full Standards level, 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).

### 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 Programme meet the basic requirements for a scope of operation that allows sufficient activity for evaluation by the WMDA evaluators. 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

|                                                                                   |                                               |                        |                 |           |
|-----------------------------------------------------------------------------------|-----------------------------------------------|------------------------|-----------------|-----------|
|  | <b>CB_Application Requirements and Levels</b> |                        |                 |           |
|                                                                                   | Document type                                 | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                            | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                       | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                                | P4/ Certification body | Status          | Public    |

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 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). The certification documentation will only be issued after the Certification Agreement has been completed/signed.

## 5. MID-CYCLE SURVEILLANCE

Surveillance includes an external assessment 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 (i.e., noncompliances)/suggested improvements) noted in the last external evaluation team report
- Implementation of new/revised WMDA Standards
- Update of previously submitted certifications from other certification bodies provided for Standard 1.02
- Compliance with Certification Agreement

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:

|                                                                                   |                                        |                        |                 |           |
|-----------------------------------------------------------------------------------|----------------------------------------|------------------------|-----------------|-----------|
|  | CB_Application Requirements and Levels |                        |                 |           |
|                                                                                   | Document type                          | Policy                 | Approved by     | CEO WMDA  |
|                                                                                   | Document reference                     | ACC_4400_P             | Approval date   | 8/31/2026 |
|                                                                                   | Version                                | 7                      | Approval status | approved  |
|                                                                                   | Pillar / Scope                         | P4/ Certification body | Status          | Public    |

- 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\\_4131\\_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](#)). 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](#).