	SOP Evaluation Activities			
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WORLD MARROW DONOR ASSOCIATION

SOP: EVALUATION ACTIVITIES

CHANGE RECORDS

Version	Date	Change Type	Change Description
1	2021-12-07	Document creation	Subdivided up Accreditation Policy and Procedure Manual into separate policies and procedures
2	2022-12-06	No change in the document Moved to P4 Document Centre	Previous version of the document: 1 Previous reference: ACC-7400-SOP Approved by: ASC Approval date: 20211207 From now on, version control will be managed by SharePoint.
3	2023-07-13	Revision	Removed overlap with SOP on addressing CAPAs arising during evaluation; changing requirements for timing of response to RFI

1. INTRODUCTION

1.1 PURPOSE AND SCOPE

The World Marrow Donor Association (WMDA) has developed standards, a certification scheme, and a certification process for registries involved in the international exchange of blood stem cell products. This document describes the evaluation activities that occur once an application is accepted. It also covers a surveillance that takes place midway through the four-year cycle.

This document covers the following sections:

1. Introduction
2. Evaluation - Variation in activities
3. Evaluation - Desk audit
4. Evaluation - Request for more information (RFI)
5. Evaluation - On-site (or remote) audit
6. Evaluation report

7. Accreditation Committee - Review and certification decision
8. Mid-cycle surveillance during each four-year cycle
9. Review of a complaint or appeal related to application or mid-cycle surveillance

1.2 PARTY RESPONSIBLE FOR THIS DOCUMENT

The Accreditation Steering Committee (ASC) 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 extent of the policy itself.

Reference No.	Title
ACC_4400_P	Policy: Certification Body Application Requirements and Levels
https://wmda.info/wp-content/uploads/2021/01/WMDA-2020-Standards_AM1_Jan2021-1.pdf	WMDA International Standards for Haematopoietic Stem Cell Donor Registries
ACC_7400_01_M	How to Perform an On-Line Review in Share
ACC_7401_01_WI	Definitions of Scoring System for Nonconformities
ACC_7400_01_WI	Audit Review Plan
ACC_7401_01_F	WMDA Registry Benchmark L1/L2 Report
ACC_7401_02_F	WMDA Registry Full Compliance Report
ACC_7401_03_F	Review of Mid-Cycle Surveillance
ACC-7110-F	Standards, Services, Levels

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

Reference No.	Title
ACC_7200_SOP	SOP: Application and Application Review
https://share.wmda.info/x/uoptFQ	Template: Share Application
ACC_7130_SOP	SOP: Complaints and Appeals
ACC_7200_SOP	SOP: Corrective and Preventative Actions
ACC_6001_M	Reviewer Training and Continuing Education Manual
ACC_7500_SOP	SOP: Accreditation Committee
ACC-7400-13-F	Remote Audit Risk Assessment
https://share.wmda.info/x/eBXtFQ	Crosswalks of standards with other organisations

1.4 ABBREVIATIONS AND DEFINITIONS

- Accreditation / accredited, Full compliance with WMDA Standards
- Certification / certified, Benchmark L1 status
- Qualification / qualified, Benchmark L2 status

- ASC, Accreditation Steering Committee
- Benchmarked standards, a subset of WMDA Standards that represent the most critical standards for the activities of an applicant.
- Client or Applicant or Registry, Organisation responsible for coordination of the search for hematopoietic 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.
- Desk audit, assessment of documents that demonstrate compliance
- Evaluator or reviewer, individual selected to evaluate an application or mid-cycle surveillance
- LOI, letter of intent
- On-site or remote audit, audit where the evaluators are either on-site at the applicant's place of business or directly contacting the applicant through video conferencing and donor files are examined
- RFI, Request For Information
- Share, on-line collaboration platform
- SOP, standard operating procedure
- WMDA, World Marrow Donor Association

2. EVALUATION - VARIATION IN ACTIVITIES

2.1 Levels of certification program. Before the evaluation starts, the application needs to be approved according to the specifications in **SOP: Application and Application Review**. The evaluation activities differ as shown in Figure 1 and Table 1.

Figure 1. Evaluation activities vs certification scheme

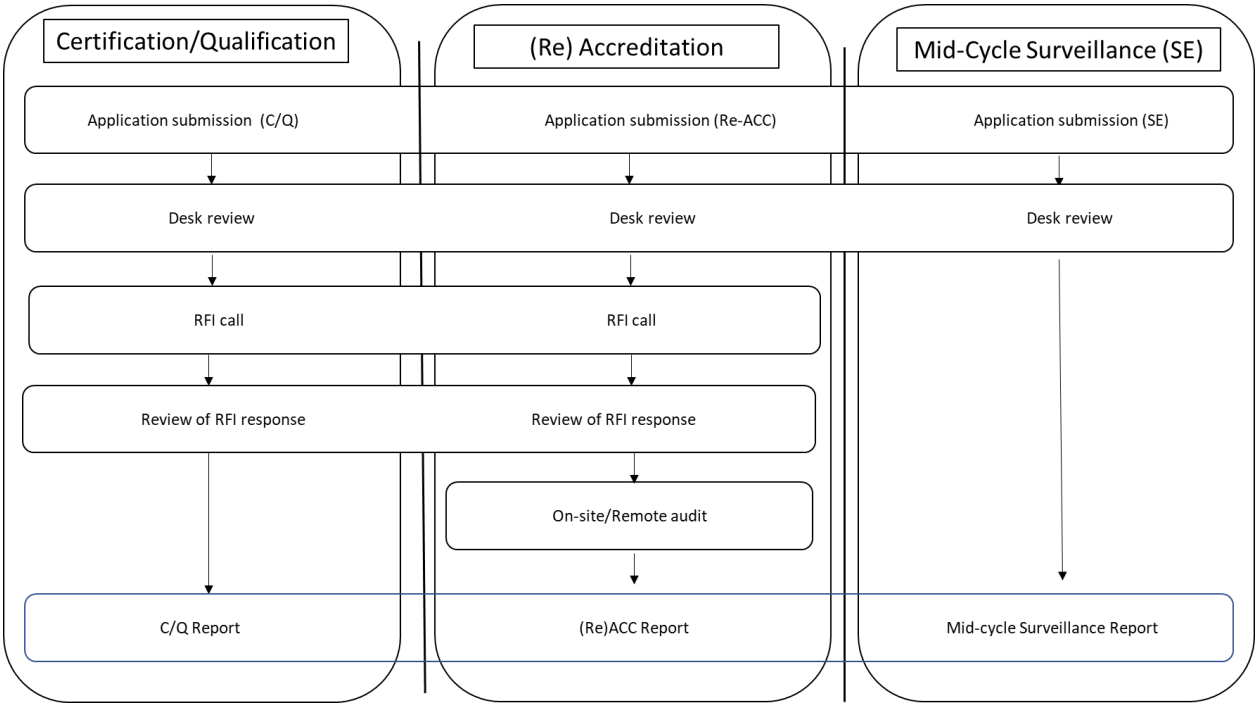

Table 1. Evaluation activities

Evaluation activity	Benchmark L1/L2 (previously known as certification/qualification)	Full Compliance previously known as (Re)-accreditation	Mid-cycle Surveillance
	Review letter of intent Preliminary assessment	Review letter of intent	
Desk review	Compliance of written policies/procedures with WMDA benchmarked Standards; Audit of records; Evaluation team: 2 experienced reviewers + optional trainee Time: 6 weeks	Compliance with all required WMDA Standards; Evaluation team: 2 experienced reviewers + optional trainee Time: 6 weeks	Compliance for specific areas (see section 9); Evaluation team: 1 experienced reviewer or L3 trainee Time: 4 weeks
RFI[1] call	Evaluation team + ASC representative	Evaluation team + ASC representative	N.A.[2]

Review of RFI responses	Evaluation team + ASC representative if discussion is required	Evaluation team + ASC representative if discussion is required	N.A.
On-site/remote audit	N.A.	Review of records, interviews, observation; Evaluation team: 2 experienced reviewers + optional trainee (if L3)	N.A.
Report	Evaluation team + ASC rep	Evaluation team + ASC rep	Evaluation team + ASC rep

[1] RFI, Request for (more) Information
[2]N.A., not applicable; ASC, Accreditation Steering Committee

2.2 Stem cell source and transplant centre affiliation variation

Applicants may apply for one or more of the following sets of services:

- Receive requests for searches; maintain searchable database
- Adult volunteer donors as a source of stem cells
- Umbilical cord blood units as a source of stem cells
- Support for search requests from affiliated transplant centres

2.3 Certification scheme

Depending on the client's letter of intent, evaluations will focus on subsets of the **WMDA International Standards for Haematopoietic Stem Cell Donor Registries** applicable to the chosen stem cell source, receipt of requests for searches, and whether the applicant supports international searches for affiliated transplant centres (see **Standards, Services, Levels**).

2.4 Certification by other organisations

If an applicant is certified by an international organisation with standards that meet or exceed a subset of WMDA Standards, the activities of evaluation will be more limited.

2.4.1 The applicant must provide a copy of its current certification document from an organisation recognized by WMDA as providing certification for standards that overlap WMDA Standards.

2.2.4.1 The WMDA Standards Committee is responsible for providing a list of the WMDA Standards that have already been evaluated by that alternative organisation (**SOP: Systematic Revision Process for WMDA Standards**). The list is posted in Share.

2.4.2 If the registry will use the certificate from the other organisation to demonstrate compliance for the overlapping WMDA Standards, the applicant is not required to demonstrate compliance with the identified overlapping standards but is required to respond to the remaining WMDA Standards and to inform WMDA about non-compliance identified by the other certification body and currently active.

2.4.3 The evaluation procedure will be performed as indicated in Evaluation - desk audit; Evaluation - Request for more information, and Evaluation - On-site/remote audit as required according to this procedure.

2.4.4 Loss of certification from the other international organization is considered a major change. This includes the situation where one of several cord blood banks loses FACT/NetCord or AABB certification. In this case, the registry will be asked to complete section 4 (cord blood) of the standards if they have not already done so.

3. EVALUATION - DESK AUDIT

This evaluation step is applicable for all types of submissions (see Figure 1 and Table 1). (**How to Perform a Document Review in WMDA Share**).

3.3 Evaluations are based on compliance with **WMDA International Standards for Haematopoietic Stem Cell Donor Registries** aided by the guidance associated with each standard. The WMDA Standards are associated with a series of services that are evaluated by the evaluation team (**Standards, Services, Levels**).

3.2.1 Evaluations of Benchmark Level 1 or Level 2 applications are based on a subset of WMDA Standards designated as "benchmarked." Registry's written policies and procedures and records are evaluated for compliance with WMDA Standards. If the registry also includes documentation for non-benchmarked standards, these will also be evaluated; however, the decision to approve Benchmark Level 1 or Level 2 is based only on benchmarked standards.

3.2.2 Evaluations of Full Compliance applications are based on all required WMDA Standards.

3.2.3 Evaluation of a Mid-cycle Surveillance submission is focused on only specific requirements (See Section 9).

3.4 Assessment of services by evaluators, experienced in the services evaluated, through a desk audit includes:

- Review of documents, such as policies, procedures, forms, instructions, service level agreements, and certificates / licenses
  - A valid certificate is sufficient to satisfy some standards
- Analyses based on key performance indicators
- Review of records--files of donor / recipient activities (only for Benchmark applications)
- Review of websites

4. EVALUATION - REQUEST FOR MORE INFORMATION (RFI)

This evaluation step is part of the application for submissions. It is not applicable to mid-cycle surveillance (see Figure 1 and Table 1).

4.1 Evaluator comments are consolidated by the team leader and discussed by the team via a videoconference within 1.5 months of receiving the application. If the information provided is deemed

as inadequate to document compliance with a WMDA Standard, a request for additional information is sent to the applicant.

4.2 An applicant seeking compliance for the first time is given a maximum of two (2) months to respond to the request for more information. An applicant seeking Full Compliance is given a maximum of 1.5 months to respond to the request for more information. Exceptions regarding timing can be granted by the Accreditation Steering Committee.

4.3 If the first RFI does not provide all the information the evaluation team needs for the assessment, they can decide to request more information in another RFI round or during the on-site/remote audit (if applicable).

5. EVALUATION - ON-SITE/REMOTE AUDIT

This evaluation step is applicable for Full Compliance. It is not applicable for Benchmark Level 1/Level 2 and Mid-cycle Surveillance (see Figure 1 and Table 1).

5.1 The WMDA will conduct an on-site or remote audit when the client applies for and when it renews Full Compliance (**ROA General Audit Plan**).

5.2 The Accreditation Steering Committee representative together with the WMDA office will determine if the audit will be remote or on-site based on a risk assessment **(Remote Audit Risk Assessment)**. The on-site or remote audit will take place after the initial review of submitted documentation (i.e., after the desk audit) and after the request for more information is sent to the applicant.

5.3 Assessment of services by evaluators through an on-site or remote audit includes:

- Interviews with employees
- Observations of activities and the surrounding work environment and conditions;
- Review of records, such as audit reports, agendas, files of donor / recipient activities; verify the existence and completeness of documents; verify the usage of documents/forms/procedures and adherence to policies

6. EVALUATION REPORT

This evaluation step is applicable for all submissions (see Figure 1 and Table 1).

6.1 For applications, following the receipt of additional information and/or the on-site (or remote) audit (if applicable), the evaluators complete their independent review.

6.2 Evaluator comments are consolidated by the team leader and discussed by the team (if needed) within one (1) month of the receipt of addition information or the on-site/remote audit.

6.3 The identification of nonconformities by evaluators must be accompanied by documentation proving that the applicant did not meet a WMDA Standard or its activities do not reflect best practice (e.g., the specific details of files examined). Scores indicating the severity of the nonconformity are listed in **WI Scoring System**. Suggestions for improvement are included.

6.4 A consensus report with a recommendation for approval/disapproval is prepared and reviewed by the Accreditation Steering Committee representative for clarity and consistency. The report will be

submitted to the Accreditation Committee (**WMDA Full Compliance Report**, **WMDA Benchmark L1/L2 Report**).

7. ACCREDITATION COMMITTEE - REVIEW AND CERTIFICATION DECISION

The consensus report from the evaluation team is provided to the Accreditation Committee for review and decision on compliance (**SOP: Accreditation Committee**).

8. MID-CYCLE SURVEILLANCE DURING EACH FOUR-YEAR CYCLE

9.1 The focus of the surveillance is to determine if the applicant is "on track" for its next application (**Mid-Cycle Surveillance Report**). Assessment covers the following areas:

9.1.1 Changes to the applicant not previously reported to the WMDA that may affect WMDA compliance status (WMDA Standard 1.05).

9.1.2 Major changes as to how the applicant complies with WMDA Standards

9.1.3 Weaknesses/suggested improvements noted in the last external evaluation team report

9.1.4 Implementation of new/revised WMDA Standards

9.1.5 Update of previously submitted certifications provided for Standard 1.02 (NetCord/FACT)

9.1.6 Noncompliance at the level of major or critical will be noted as described in **SOP: Handling Of Corrective and Preventative Action Plan Required By Major Or Critical Finding During an Evaluation**

9.2 The applicant will complete a template in Share covering the assessment areas listed above.

9.3 The surveillance will be performed by a single experienced L4 or L3 reviewer (Figure 1 and Table 1).

9.4 The evaluation report will be provided to the Accreditation Committee for review and a decision (**SOP: Accreditation Committee**).

10. REVIEW OF A COMPLAINT OR APPEAL RELATED TO APPLICATION OR MID-CYCLE SURVEILLANCE

If an applicant appeals a decision related to its application or a decision related to Mid-cycle Surveillance, the subsequent evaluation will focus only on those standards in question (**SOP: Complaints and Appeals**). Surveys completed by the applicant and evaluators post-decision will be used to determine the level of satisfaction with the certification scheme and its associated activities. Actions may be taken based on comments received (**SOP: Corrective and Preventative Actions**).

Figure 2 – Evaluation activities

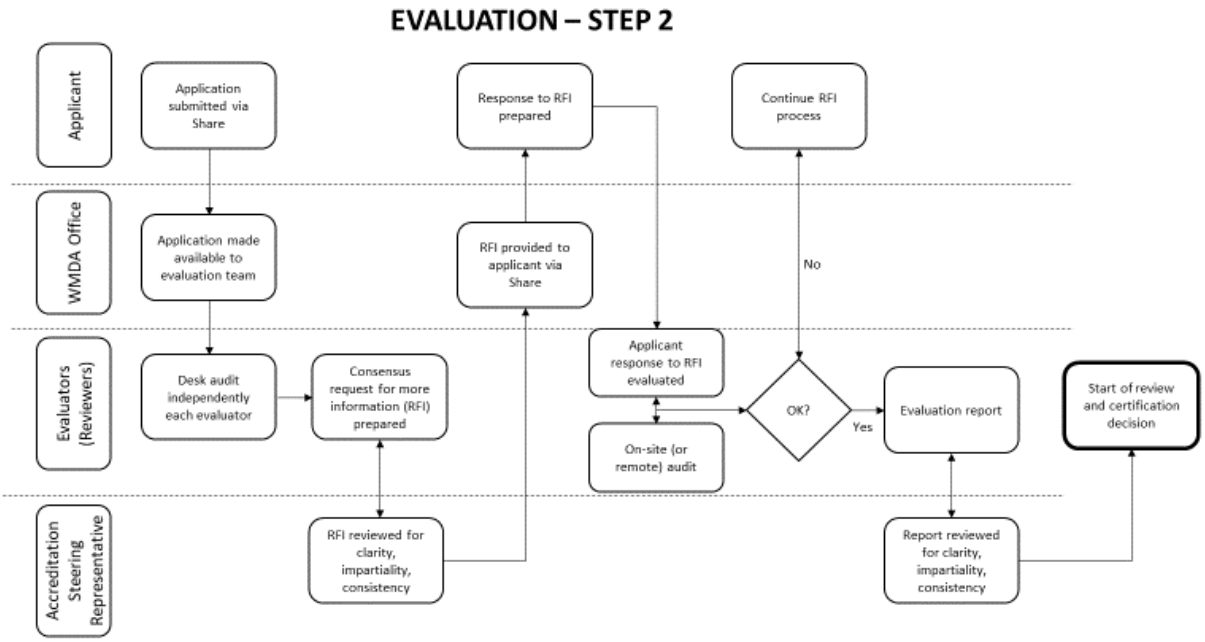

Figure 3. Review and certification decision

REVIEW AND CERTIFICATION DECISION – STEP 3