
	SOP Complaints and Appeals			
	Document type	Operating procedure	Approved by	CEO WMDA
	Document reference	ACC_7130_SOP	Approval date	10/25/2023
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	Pillar / Scope	P4 / Certification body	Status	Public

WORLD MARROW DONOR ASSOCIATION
SOP: COMPLAINTS AND APPEALS RELATED TO CERTIFICATION PROGRAM

CHANGE RECORDS

Version	Date	Change Type	Change Description
0	2021-07-10	Document creation	Subdivided up Accreditation Policy and Procedure Manual into separate policies and procedures
1	2023-03-20	Addition	Clarified whether audit will be conducted; added process for complaint to be noted by future review team From now on, version control will be managed by SharePoint.
2	2023-09-20	Revision	Revised how complaints/appeals are received; broadened description of how complaints are handled; added section on how requests to change certification reports are handled

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1. INTRODUCTION

1.1. PURPOSE AND SCOPE

This document describes how complaints and appeals are received, evaluated and decisions made. The primary focus of the document is how issues impacting the certification activities are handled.

This document covers the following sections:

1. Introduction
2. Documentation
3. Review of a registry following a complaint by a third party
4. Review of an assessment following a failure to comply with requirements for compliance
5. Appeals and complaints regarding assessment

1.2. PARTY RESPONSIBLE FOR THIS DOCUMENT

The WMDA 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
FNDN-110-01-F	Impartiality/Conflict of Interest/Confidentiality Statement
ACC-7200-SOP	SOP: Corrective and Preventative Actions
ACC-4400-P	Policy: Certification Body Application Requirements and Levels
ACC_4120_F	Agreement for WMDA Certification / Qualification / Accreditation
ACC-7401-04-WI	Evaluation of Compliance with Certification Agreement

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

Reference No.	Title
ACC-SOP-7500	SOP: Accreditation Committee
ACC_6001_01_F_JD	Job Description: WMDA Accreditation Steering Committee Member
FNDN_4200_P	Policy: Management and Mechanisms for Safeguarding Impartiality, Confidentiality, and Diversity

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1.4. ABBREVIATIONS AND DEFINITIONS

Accreditation / accredited, Full compliance with WMDA Standards

Certification / certified, Benchmark L1 status

Qualification / qualified, Benchmark L2 status

Client or Applicant or Registry, Organization 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.

Corrective and preventative actions (also known as CAPA), this covers background, investigations, findings, root cause analysis, and actions taken and to be taken to address a nonconformity and prevent its future occurrence

Share, on-line collaboration platform


WMDA, World Marrow Donor Association

2. DOCUMENTATION

The office component within the Certification Body will record and track complaints, noncompliance with requirements, and appeals and the actions taken to resolve them.

3. ACTIONS TAKEN FOLLOWING A COMPLAINT


- 3.1. Complaints by any person, registry, or organization are directed to WMDA office.
- 3.2. If the complaint concerns the certification program, the Pillar 4 coordinator will acknowledge receipt of the complaint and will log the complaint. They will determine whether the complaint is minor (e.g., problem with Share application form) or major (e.g., complaint that a certified registry does not follow a WMDA Standard).
 - 3.2.1. Minor complaints will be dealt with by the relevant entity but will be logged.
 - 3.2.2. Major complaints regarding activities of the certification program will be sent to the Accreditation Steering Committee for an immediate investigation of the complaint.
- 3.3. The Accreditation Steering Committee will identify one or more individuals to investigate each specific complaint. Depending on the situation, the investigators may need to sign an impartiality, conflict of interest, confidentiality form ([Impartiality/Conflict of Interest/Confidentiality Statement](#)).

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- 3.4. Investigators will obtain copies of pertinent documents and other information related to the complaint and, if relevant, where a registry may be noncompliant with specific WMDA Standards.
- 3.5. The investigation team prepares a corrective and preventative action report.
- 3.6. The Accreditation Steering Committee will determine if the report is acceptable. It will determine if the WMDA Board needs to be notified. The report and any relevant documents-will be retained.
- 3.7. The WMDA office will send the results of the investigation and any decisions to the complainant and to the client identified in the complaint.

4. COMPLAINTS THAT IMPACT CERTIFICATION

- 4.1. Based on the severity of the complaint and whether it appears that compliance with one or more WMDA Standards is in question or with the certification process, the Accreditation Steering Committee may alert the Board that it will request the Accreditation Committee to suspend registry’s certification until the investigation is complete. The community will be notified of any change in the registry status. The way in which notification is performed will be determined by the Board on a case-by-case basis.
- 4.2. If impacted by a complaint, the registry under investigation will be notified in writing at the beginning of the investigation. Usually, the registry will be notified first by email and, if no response, second by written letter sent by express courier, and third by personal contact and/or letter.
- 4.3. If noncompliance with WMDA Standards is in question, the assessment will focus only on those WMDA Standards which are in dispute.
- 4.4. Evaluations may include a short notice audit of the registry
- 4.5. For complaints that impact a registry’s compliance with WMDA Standards, WMDA office will provide a copy of the corrective and preventative action plan , which will also provide a score for the situation, to the members of the Accreditation Committee. The Accreditation Committee will review the assessment and will vote. The expected vote may be (1) Complaint is not justified; (2) Complaint is justified with ranking of observation of concern / major / critical. The Accreditation Committee may also suspend / reduce / terminate the registry’s certification. The Board will be notified of any alteration in the registry’s certification status.
- 4.6. If the complaint is justified and relates to compliance with WMDA Standards, the response required of the client will be based on the ranking (**SOP: Corrective and Preventative Actions**).
- 4.7. If relevant, the corrective and preventative action plan will be provided to reviewers of the next application or mid-cycle surveillance.
- 4.8. The community will be notified of any change in a registry status. The way in which notification is performed will be determined by the Board on a case-by-case basis.

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5. REVIEW OF ASSESSMENT FOLLOWING A FAILURE TO COMPLY WITH REQUIREMENTS FOR COMPLIANCE.

5.1. Requirements of the certification process ([Policy: Certification Body Application Requirements And Levels, Agreement for WMDA Certification/Qualification/Accreditation](#)) include, but are not limited to:


- Completing a certification agreement at the time of an application
- Paying fees for certification
- Providing information on major changes that might impact certification status
- Submitting the mid-cycle evaluation at the required time
- Responding to a major or critical concern raised in an evaluation within the time limit set
- Using the certificate or marks of conformity appropriately

5.2. Accreditation Steering Committee will notify the registry indicating the requirement ([Evaluation of Compliance with Certification Agreement](#)), requesting an explanation of the failure to respond, and providing a timeline for response. Usually, the registry will be notified first by email and, if no response, second by written letter sent by express courier, and third by personal contact and/or letter.

5.3. The office will document the lack of compliance.

5.4. If required, Accreditation Steering Committee will notify the Board that it will request the Accreditation Committee to either suspend or withdraw compliance to WMDA Standards. The applicant registry will be notified in writing and their status changed on the WMDA website.

5.5. Renewal of their compliance will occur upon the registry’s acceptable response to the deficiency.

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6. APPEALS AND COMPLAINTS REGARDING ASSESSMENT

6.1. Appeal of a certification decision

- 6.1.1 An applicant registry may request that a decision be appealed by submitting a written request to the WMDA office within three (3) months of receiving notification of the WMDA decision. This request must include a justification for reversing the decision.
- 6.1.2 The WMDA office will acknowledge receipt of the appeal in writing. The WMDA office will track the appeal process.
- 6.1.3 The WMDA office will forward this request to the WMDA President, executive director and the Accreditation Steering Committee.
- 6.1.4 The Accreditation Steering Committee will form a new evaluation team.
- 6.1.5 Evaluators will receive copies of pertinent documents including the final report, the registry's reply, and all parts of the application for which the registry was rated as noncompliant with WMDA Standards. Evaluations may include a short notice audit of the registry. The appeal process will focus only on those WMDA Standards for which the applicant was judged as noncompliant, and which are in dispute. The purpose of the review will be to ascertain whether compliance with the standards was evaluated correctly in the original assessment.
- 6.1.6 The evaluation team members have six weeks to submit a written report to the Accreditation Committee. A conference call may be used to discuss the issues.
- 6.1.7 The evaluators of an appeal may recommend that the initial decision stand, may recommend modification of the initial decision, or may overturn the original decision.
- 6.1.8 WMDA office will provide a copy of the evaluation summary to the members of the Accreditation Committee. From this point, the same process as followed for the initial review is followed, that is, the Accreditation Committee will vote.
- 6.1.9 The office will send the results of the Accreditation Committee's decision to the WMDA President and to the applicant registry.
- 6.1.10 The decision regarding the registry's request to appeal the decision is final and may not be appealed again.
- 6.1.11 The initial review team will be notified of the decision and any changes in their assessment.

6.2. Request to modify the content of a certification report

- 6.2.1 Requests to modify the content of a certification report will be sent to the Accreditation Steering Committee to develop a plan for evaluating the request.
- 6.2.2 If the request is for minor adjustments, the request will be sent to the registry's review team leader for consideration. The review team leader may incorporate the changes or otherwise modify the wording and submit a revised report for Accreditation Committee review and approval. Alternatively, the review team leader may decline to make any changes. In this case,

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the team leader will alert the Accreditation Committee to the request and the reasons for declining to make the change. The final decision as to amend the report will be made by the Accreditation Committee.

- 6.2.3 If the request is for a major adjustment in the content, the Accreditation Steering Committee will ask the original review team for their input and/or appoint a new team to assess the issue in dispute as described in section 6.1. The Accreditation Committee will be notified about the issue and report of the second review team since their decision regarding an amended report will be final.