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|  | SOP Complaints and Appeals | | | |
| | Document type | Operating procedure | Approved by | CEO WMDA |
| | Document reference | ACC_7130_SOP | Approval date | 7/7/2025 |
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| | Pillar / Scope | P4/ Certification body | Status | Confidential |

WMDA

SOP: COMPLAINTS, CONCERNS, AND APPEALS RELATED TO CERTIFICATION PROGRAMME

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 |
| 3 | 2024-11-23 | Terminology | Replacement of term Accreditation by Certification |
| 4 | 2025-02-04 | Update to clarify handling of complaints from 3 rd parties | Update to clarify handling of complaints from 3 rd parties |

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1. INTRODUCTION

1.1 PURPOSE AND SCOPE

This document describes how complaints, concerns 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 complaint / concern regarding certification process
4. Review of a registry following a complaint by a third party
5. Review of an assessment following a failure to comply with requirements for compliance
6. Appeals and complaints regarding assessment of compliance
7. Request to modify the content of a certification report

1.2 PARTY RESPONSIBLE FOR THIS DOCUMENT

The WMDA Certification Steering Committee (CSC) 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.


| Identifier | Title |
|-----------------|---|
| FNDN_110_01_F | Impartiality/Conflict of Interest/Confidentiality Statement |
| ACC_7402_SOP | SOP: Handling of Corrective and Preventative Action Plan Required by Major or Critical Finding During an Evaluation |
| ACC_4400_P | Policy: Certification Body Application Requirements and Levels |
| ACC_4120_F | Agreement for WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification |
| 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.

| Identifier | Title |
|----------------------|---|
| ACC_SOP_7500 | SOP: Certification Committee |
| ACC_6001_01_F_JD_CSC | Job Description: Certification Steering Committee Member |
| FNDN_4200_P | Policy: Management and Mechanisms for Safeguarding Impartiality, Confidentiality, and Diversity |

1.4 ABBREVIATIONS AND DEFINITIONS

- Full Standards, previously termed accreditation / accredited

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- Benchmark L1 status, previously termed certification / certified
- Benchmark L2 status, previously termed qualification / qualified
- Client or Applicant or 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 unrelated donor registries.
- 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, previously termed the World Marrow Donor Association

2. **DOCUMENTATION**

- Complaints and concerns by any person, registry, or organisation are directed to WMDA office.
- The WMDA office will acknowledge receipt.
- The office component within the Certification Body will record and track complaints, concerns, noncompliance with requirements, and appeals and the actions taken to resolve them.
- The WMDA office will forward any complaint, concern, or appeal that impacts the certification process or certification status to the Certification Steering Committee.

3. **REVIEW OF COMPLAINT / CONCERN REGARDING CERTIFICATION PROCESS**


- 3.1 If the issue involves the certification process and is not related to the approval of certification or the certification report, the Certification Steering Committee will determine whether the complaint is minor (e.g., problem with Share application form) or major (e.g., potential deviation from policies and procedures of the certification process).
 - 3.1.1 Minor complaints will be dealt with by the relevant entity but will be logged.
 - 3.1.2 Major complaints regarding activities of the certification program will be targeted for an immediate investigation of the complaint.
- 3.2 The Certification Steering Committee will identify one or more individuals to investigate each specific complaint or concern. Depending on the situation, the investigators may need to sign an impartiality, conflict of interest, confidentiality form ([FNDN_110_01_F Impartiality/Conflict of Interest/Confidentiality Statement](#)).
- 3.3 Investigators will obtain copies of pertinent documents and other information related to the complaint or concern.
- 3.4 The investigation team will prepare a corrective and preventative action report. This report may require additional reviewer training.
- 3.5 The Certification Steering Committee will determine if the report is acceptable. It will determine if the Management Board needs to be notified. The report and any relevant documents-will be retained.

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3.6 The WMDA office will send the results of the investigation and any decisions to the complainant.

4. **REVIEW OF A CERTIFIED REGISTRY FOLLOWING A COMPLAINT BY A THIRD PARTY**

- 4.1 If it appears that there is serious non-compliance with a benchmarked standard identified by a 3rd party and the issue is not resolved in any other way, the WMDA office will forward the complaint to the Certification Steering Committee for investigation and resolution.
- 4.2 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 The Certification Steering Committee may alert the Management Board that it will request the Certification Committee to suspend the registry's certification until the investigation is complete. The community will be notified of any change in the registry status as appropriate.
- 4.4 The Certification Steering Committee will identify one or more individuals to investigate the complaint. Depending on the situation, the investigators may need to sign an impartiality, conflict of interest, confidentiality form (FNDN_110_01_F Impartiality/Conflict of Interest/Confidentiality Statement).
- 4.5 Investigators will obtain copies of pertinent documents and other information related to the complaint or concern. The assessment will focus only on those WMDA Standards which are in question. Evaluations may include a short notice audit of the registry.
- 4.6 The investigation team will prepare a corrective and preventative action report. The corrective and preventative action plan will include a score for the situation.
- 4.7 The report will be provided to the members of the Certification Committee for a decision. The expected vote may be (1) Complaint is not justified; (2) Complaint is justified with ranking of observation of concern / major / critical. The Certification Committee may also suspend / reduce / terminate the registry's certification. The Management Board will be notified of any alteration in the registry's certification status.
- 4.8 If the complaint is justified and relates to compliance with WMDA Standards, the response required of the client will be based on the ranking ([ACC_7402_SOP: Handling of Corrective and Preventative Action Plan Required by Major or Critical Finding During an Evaluation](#)).
- 4.9 If relevant, the corrective and preventative action plan will be provided to reviewers of the next application or mid-cycle surveillance. Reviewer notification will also be made when a 3rd party complaint has been addressed through a process outside of the Certification Steering Committee. Reviewers in these situations will receive a copy of the formal WMDA letter sent to the organisation that is the subject of the complaint and a description of any resolution.
- 4.10 The community will be notified of any change in a registry status. The way in which notification is performed will be determined by the Management 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 ([ACC_4400_P Policy: Certification Body Application Requirements and Levels](#); [ACC_4120_F Agreement for WMDA Benchmark L1 / Benchmark L2](#) / [Full Standards Certification](#)) 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 surveillance 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 Assessment of compliance with the Certification Agreement will be assessed at the time of the evaluation of the mid-cycle surveillance by the office.

5.3 If the registry is not in compliance with the Certification Agreement or other requirements, the Certification Steering Committee will notify the registry indicating the requirement ([ACC_7401_04_WI 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 WMDA office will document the lack of compliance.

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

5.5 Renewal of certification will occur upon the registry's acceptable response to the deficiency.

6. APPEALS AND COMPLAINTS REGARDING ASSESSMENT OF COMPLIANCE


6.1 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.

6.2 The WMDA office will acknowledge receipt of the appeal in writing. The WMDA office will track the appeal process.

6.3 The WMDA office will forward this request to the WMDA President, WMDA Management Board and the Certification Steering Committee.

6.4 The Certification Steering Committee will form a new evaluation team.

6.5 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

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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.

- 6.6 The evaluation team members have six weeks to submit a written report to the Certification Committee. A conference call may be used to discuss the issues.
- 6.7 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.
- 6.8 WMDA office will provide a copy of the evaluation summary to the members of the Certification Committee. From this point, the same process as followed for the initial review is followed, that is, the Certification Committee will vote.
- 6.9 The WMDA office will send the results of the Certification Committee's decision to the WMDA President and WMDA Management Board and to the applicant registry. If necessary, the documentation (certificate and certification mark) will be changed.
- 6.10 The decision regarding the registry's request to appeal the decision is final and may not be appealed again.
- 6.11 The initial review team will be notified of the decision and any changes in their assessment.

7. REQUEST TO MODIFY THE CONTENT OF A CERTIFICATION REPORT

- 7.1 Requests to modify the content of a certification report will be sent to the Certification Steering Committee to develop a plan for evaluating the request.
- 7.2 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 Certification Committee review and approval. Alternatively, the review team leader may decline to make any changes. In this case, the team leader will alert the Certification Committee to the request and the reasons for declining to make the change.
- 7.3 The final decision as to amend the report will be made by the Certification Committee.
- 7.4 If the request is for a major adjustment in the content, the Certification 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. The Certification Committee will be notified about the issue and report of the second review team since their decision regarding an amended report will be final.