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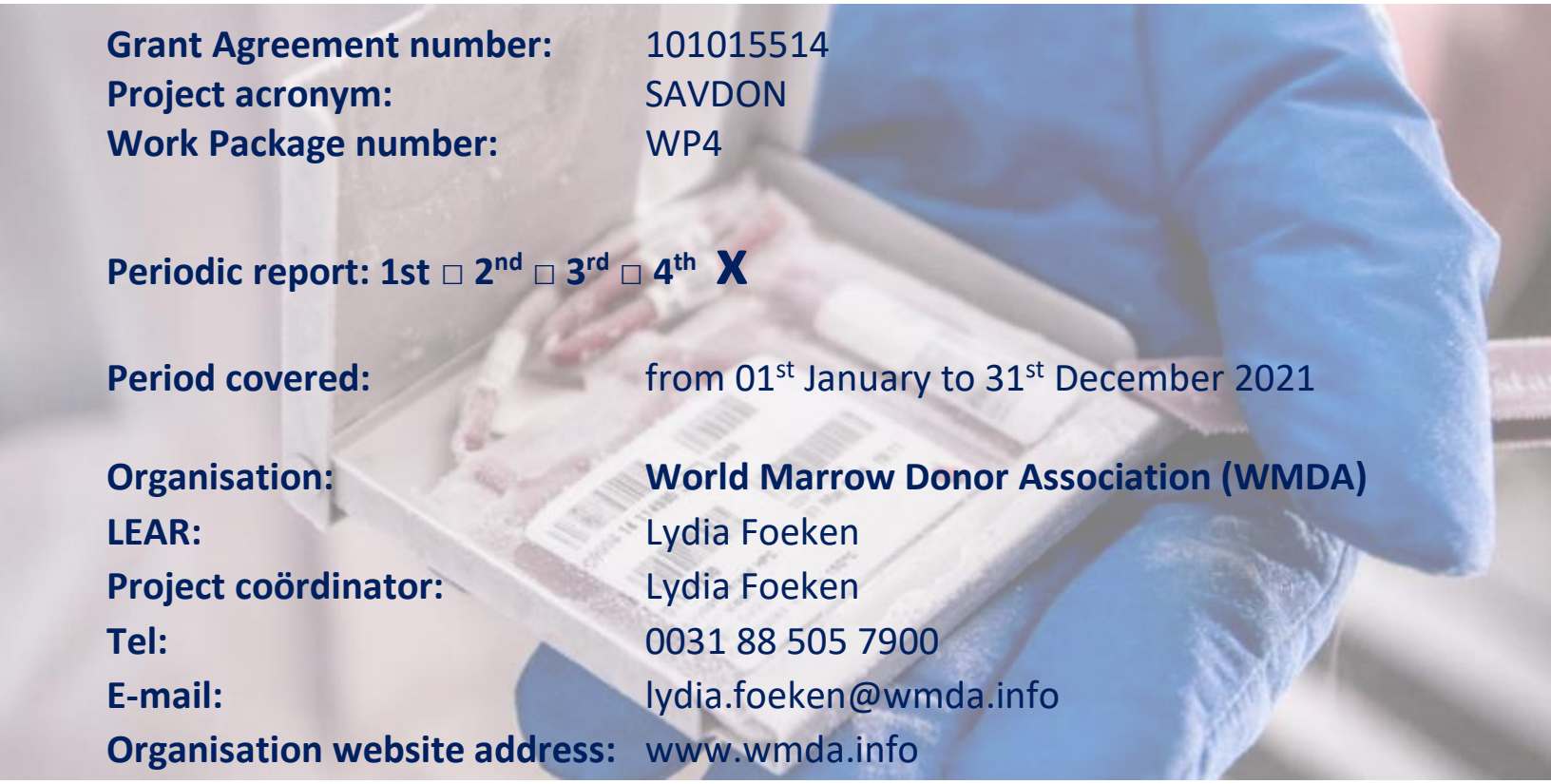
D4.3 Audit report on if it is feasible that WMDA will apply for ISO Certification



Grant Agreement number: 101015514
Project acronym: SAVDON
Work Package number: WP4

Periodic report: 1st □ 2nd □ 3rd □ 4th X

Period covered: from 01st January to 31st December 2021

Organisation: **World Marrow Donor Association (WMDA)**
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Description:

Contents

I. WMDA Accreditation Programme: to Standardize practice Worldwide.

Between 1988 and 1994, WMDA was founded with the goal to Standardize Practice Worldwide. In 1994, WMDA stablished the first recommendations and requirements for a standardized practice throughout the world for bone marrow transplants. These recommendations and requirements were the seed of WMDA Accreditation Programme.

WMDA Accreditation Programme accredited first registries in 2004:

- Registre France Greffe de Moelle, France
- Welsh Bone Marrow Donor Registry, Wales

Registries Qualified/Accredited Today list **90% of donors and cord blood units**

Australia	Greece-Hellenic CBB	Spain
Austria	Ireland	Switzerland
Belgium	Israel-Ezer Mizion	Sweden
Brazil	Israel Hadassah	Taiwan-Tzu
Canada-Hema Quebec Canada-One Match	India	Thailand
Canada-One Match	Italy	UK-Bristol
Chile	Japan	UK-Nolan
China	Netherlands	UK-Wales
Cyprus	New Zealand	UK-DKMS
Czech-SCR Czech National	Norway	USA-Be The Match
Denmark- East	Poland	USA-Gift of Life
Denmark - West	Russia-HPC	
France	Saudi Arabia	
Finland	Singapore	
Germany	South Africa	

WMDA Accreditation Programme is accepted by **National Authorities** like:

- Italy: National Competent Authorities for Donation and Transplant - CNT, CNS
- Switzerland: Federal Office of Public Health
- The Netherlands: Inspectie Gezondheidszorg (IGZ)
- Singapore
- Israel
- Denmark
- Czech Republic
- United Kingdom
- EU tissue directive

The WMDA Standards has been crosschecked with the EU Directives for Tissues and Cells and the European General Data Protection Legislation (GDPR) to ensure compliancy with the EU legislation. An increasing number of countries have implemented the WMDA accreditation as a way to ensure that hematopoietic stem cells that are imported to their country are compliant with the regulation.

WMDA strives that an increasing EU Member States accept WMDA accreditation as an import requirement for their country. Therefore, the WMDA has start up the process to professionalise its accreditation programme and to make it compliant with ISO-17065.

II. ISO Accreditation

www.iso.org

ISO, the **International Organization for Standardization**, has developed different international standards required by business, governments and society to **build trust** in products and services.

ISO standards are widely respected and accepted by public and private sectors internationally.

ISO has today 165 members (there is one member per country) and has developed 23.512 Standards covering almost all aspects of technology and manufacturing.

Its **Committee on Conformity Assessment (CASCO)** covers topics such as the operating of **certification bodies**, testing laboratories, marks of conformity, accreditation and mutual recognition of conformity assessment results.

III. Identification of the applicable ISO Standards.

WMDA is a **Certification Body** which has developed a **Certification Scheme**

For the development of the Certification Scheme

> WMDA must comply with ISO 17067- *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

For Certifying products, processes and services

> WMDA must comply with ISO 17065 - *Conformity assessment — Requirements for bodies certifying products, processes and services*

IV. Previous steps in the project

This section lists previous steps made in 2020 as part of the feasibility analysis for the implementation of the ISO 17065 for WMDA Accreditation Programme. After a positive conclusion, WMDA has started the development and implementation of the project in 2021. The information about the work done in 2021 can be found in Section VI. New steps in the project.

IV.I Gap analysis

To study the feasibility of ISO Accreditation, WMDA has performed a GAP Analysis between ISO 17065 and WMDA Accreditation Programme:

ISO/IEC 17065: 2012 (used Spanish version): Conformity assessment, requirements for bodies certifying products, processes, services

This gap analysis was prepared based on **ISO/IEC 17065: 2012 Conformity assessment, requirements for bodies certifying products, processes, services**

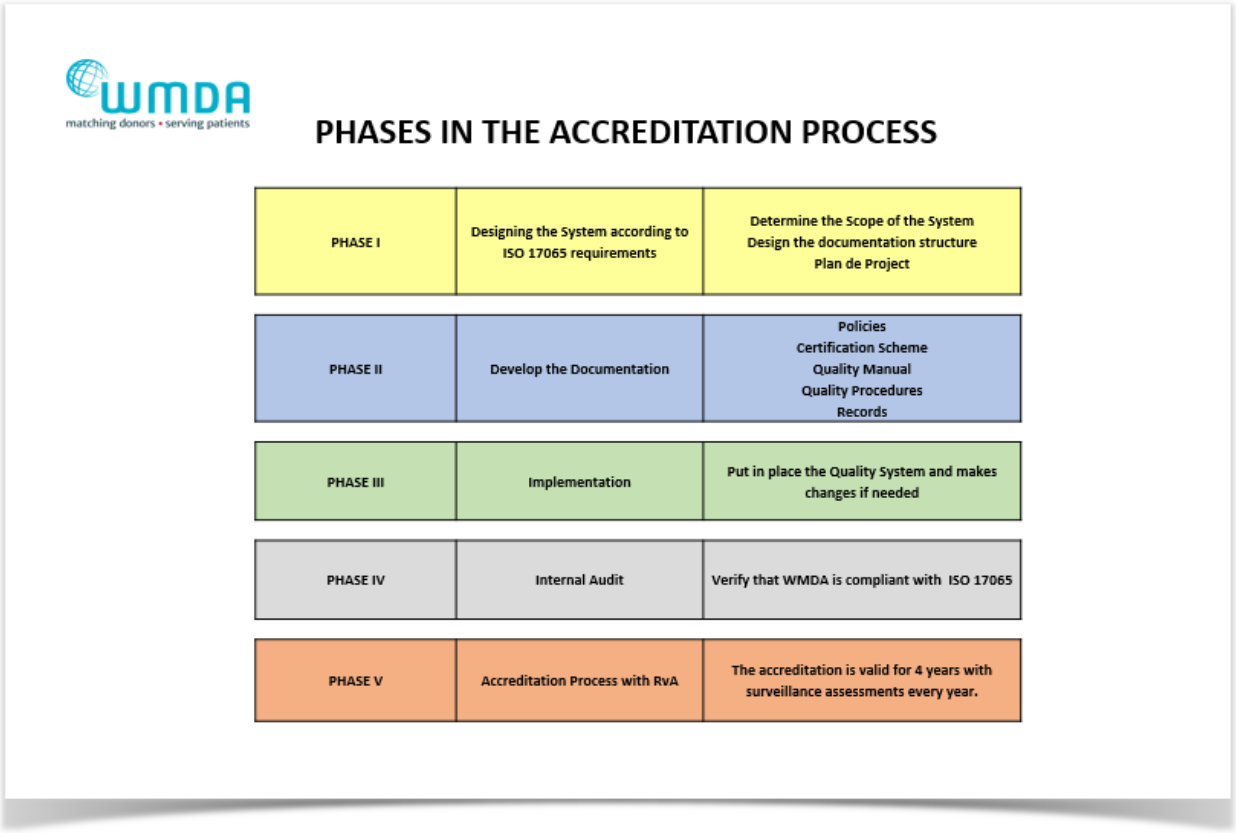
- Focuses on WMDA Accreditation Programme, not individual registry
- 17065 document includes coverage of other conformity assessment docs: ISO 17000 (vocabulary), 17020 requirements for operation of bodies performing inspections, 17021 performing audit and inspection of management systems, 17025 competence of testing and calibration laboratories. Note that 17065 requires standards in other specific other ISO documents to be met
- Overlap with 17021 noted; 17021 more detailed in some topics having more standards but doesn't cover actual evaluation process

	17065 General Topic	Specifics	To Do	17021 Overlap
4	GENERAL REQUIREMENTS			
4.1	Legal and contractual matters			
4.1.1	Legal entity			Yes
4.1.2	Certification agreement with client	Legally enforceable, Covers responsibilities, lists client requirements—use in advertisement, communicating changes, allowing evaluation/audit, records complaints	Certification agreement with all the requirements of 4.1.2.2 Certification Agreement Between WMDA and Client-ns rev 02132019.docx	Yes
4.1.3	Use of license, certificates and marks of conformity (Ownership of marks/certificates)	Signs of qualification/accreditation under control of WMDA	Doc for the use of the license, certificates or mark. https://share.wmda.info/display/BCAS/ISO+Regulations Check Guides in Share and https://share.wmda.info/display/BCAS/PoliciesProceduresAccreditation	
4.2	Management of impartiality			
	Impartiality in evaluation	~10 standards , ISO 17021	Doc showing how impartiality is granted and risk analysis on an ongoing process. (There is a risk analysis for the Qualification & Accreditation process that contains information about impartiality, check	Yes

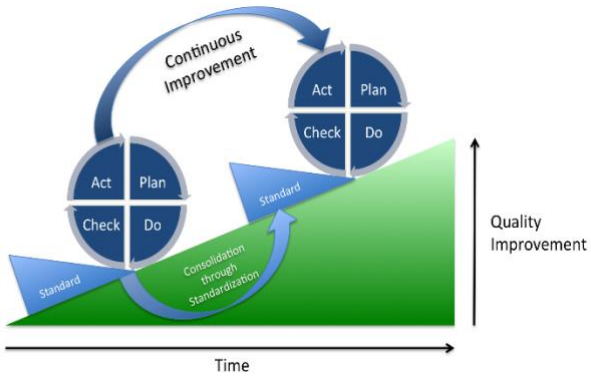
Figure 1- View of GAP analysis between ISO 17065 and WMDA Accreditation Programme

IV.II. Definition of the phases in the project

WMDA has identified the following phases in the project:



This project has been designed to follow a continuos improvement cycle or **plan-do-check-act (PDCA) cycle**:



- **Plan:** Plan de change.
- **Do:** Perform
- **Check:** Monitor
- **Act:** Improve

IV.III Completion of Phase I – Designing the system according to ISO 17065 requirements

i. Determination of the scope of the system

WMDA Accreditation Programme scope is the following:

Activities or services of coordination of the search for haematopoietic progenitor cells from donors (including cord blood) unrelated to the potential recipient in another country provided by Registries.

This activities or service includes the following

- Recruiting Donors
- Recruiting Cord Blood Units
- Identify potential donors/cord blood units
- Facilitate selected donor and/or umbilical cord blood donor education, consent, further testing, and medical evaluation; coordination with transplant centre activities regarding the patient
- Facilitate collection, labelling and shipment of viable hematopoietic stem or other cells to transplant centre of patient
- Support and care for the volunteer donor post-donation for issues related to the donation

ii. Organizing Policies and Procedures for ISO

WMDA has documented Policies and Procedures that covers all activities in the WMDA Accreditation process but should be modified according to ISO requirements.

According to the new proposed structure, WMDA will review, adapt and include all information needed to comply with ISO requirements.

Structure for the documentation (ISO 17067 + ISO 17065)

		Registries	Reviewers	BCAS + WMDA Pillar 4 office	ISO 17065	ISO 17067
1. Planning	1.1 Objectives		x	x		6.3.9
	1.2 Risks			x	4.2	6.3.10
	1.3 Planning of changes			x		6.6.2, 6.6.3
2. General	Legal entity	x	x	x	4.1.1	6.3.3
	2.1 Certification agreement	x	x	x	4.1.2	6.5.1 l)
	2.2 Use of license, certificate and marks of conformity	x	x	x	4.1.3	6.5.1 j), 6.5.1 k), 6.5.6, 6.5.12
	2.3 Impartiality Policy	x	x	x	4.2, 6.1	
	2.4 Financing and liability	x	x	x	4.3	6.3.11, 6.3.12
	2.5 Establishing certification Scheme: Develop, maintenance and improvement of the Scheme	x	x	x	6.2	6.3.1, 6.3.4, 6.3.5, 6.3.6, 6.3.7, 6.3,6.4, 6.5.1c),6.5.1d), 6.5.1e). 5.6.1 g), 6.5.7, 6.5.8, 6.6.2, 6.6.3
	2.6 Non-discriminatory conditions	x	x	x		
	2.7 Information confidentiality	x	x	x	4.5	6.3.9
	2.8 Publicly available information	x	x	x	4.6	6.5.1 u)
Structural requirements	Organizational chart		x	x	5.1	6.3.6
	Duties and responsibilities		x	x	5.1	6.3.6
Resources requirement	Competence of personnel		x	x	6.1 , 6.2	6.3.8, 6.5.1 l)
Process requirement	Certification workflows	x	x	x		
	WMDA Standards and guidance	x	x	x		6,5,1 a), b)
	Recognizing other certificates (NetCord/FACT)	x	x	x		6.5.3
	Certification Policy	x	x	x	4.4, 7	6.5.1 m), 6.5.1 n), 6.5.1 o), 6.5.1 p)
	Complaints and Appeals Policy	x	x	x		6.5.5
	Tariff	x		x		
	SOP Certification		x	x		6.5.1 h), 6.5.1 i), 6.5.2, 6.5.7
Management system	Document control			x	8	6.5.1 v), 6.6, 6.7
	Record control			x	8	6.5.1 v), 6.6, 6.7
	Non- conformity			x	8	6.6.1, 6.5.8
	Corrective actions			x	8	6.6.1
	Improvement			x	8	6.6.1
	Internal audit			x	8	6.6.1
	Feedback of interested parties			x	8	6.6.1
	Mechanism for safeguarding impartiality			x	5.2	6.6.1
	Management reviews			x	8	6.6.1
	Analysis and evaluation (KPI's CAB processes)			x	8	6.6.1

Figure 2 –Structure for the WMDA documentation to comply with ISO 17067 and ISO 1765. The figure also shows the visibility of this documentation for stakeholders in the WMDA Accreditation Programme.

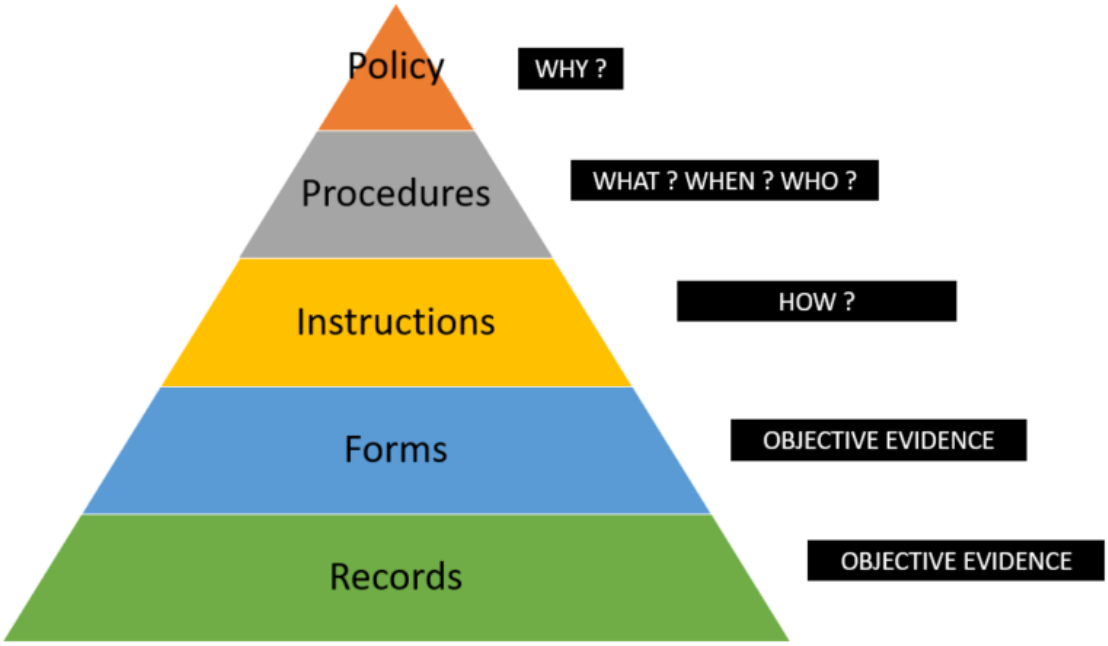
iii. Project plan

According to the gaps we identified, the structure of the documentation and the resources in the Accreditation Programme, WMDA prepared a project plan for the ISO Accreditation in 2021.

V. New steps in the project

b) Phase II – Develop a system for document control

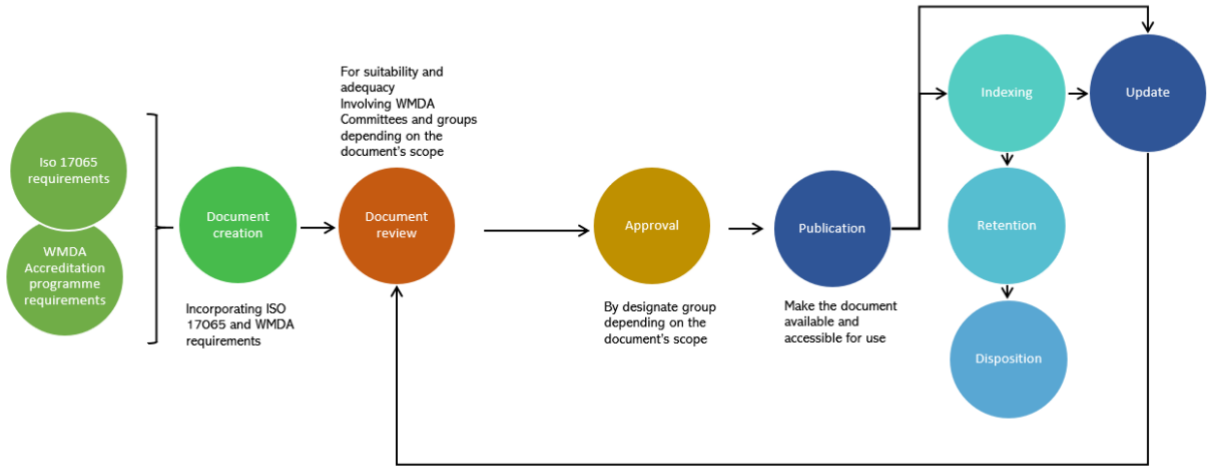
WMDA have used ISO 9001:2015 structure and requirements to do the document control for all documented information of the WMDA Accreditation Process.



The ISO 9001:2015 requirements for document control are as follows:

- Approve documents
- Review, update, and submit documents for re-approval
- Identify changes
- Make documents available
- Ensure documents are legible and identifiable
- Identify and control external documents
- Keep obsolete documents out of circulation
- Identify obsolete documents as necessary if retained
- Identifying records
- Storing records
- Protecting records (including keeping them identifiable and legible)
- Retrieving records
- Retaining records
- Disposing of records

Document control workflow



Document creation: Documents have been created by the people who has the knowledge in the specific area of the Accreditation Programme and in the ISO 17065 Standard, being most of them drafted by the Chair of the Accreditation Steering Committee together with WMDA CEO and WMDA Quality and Accreditation Coordinator.

Document review: After drafting the document, it is shared with the Committee/group that is involved in the processes covered by the document (Policy/Standard Operation Procedures/Work Instruction). During this phase, the Committee/group will review the document and provide any comments/request for changes they might consider necessary.

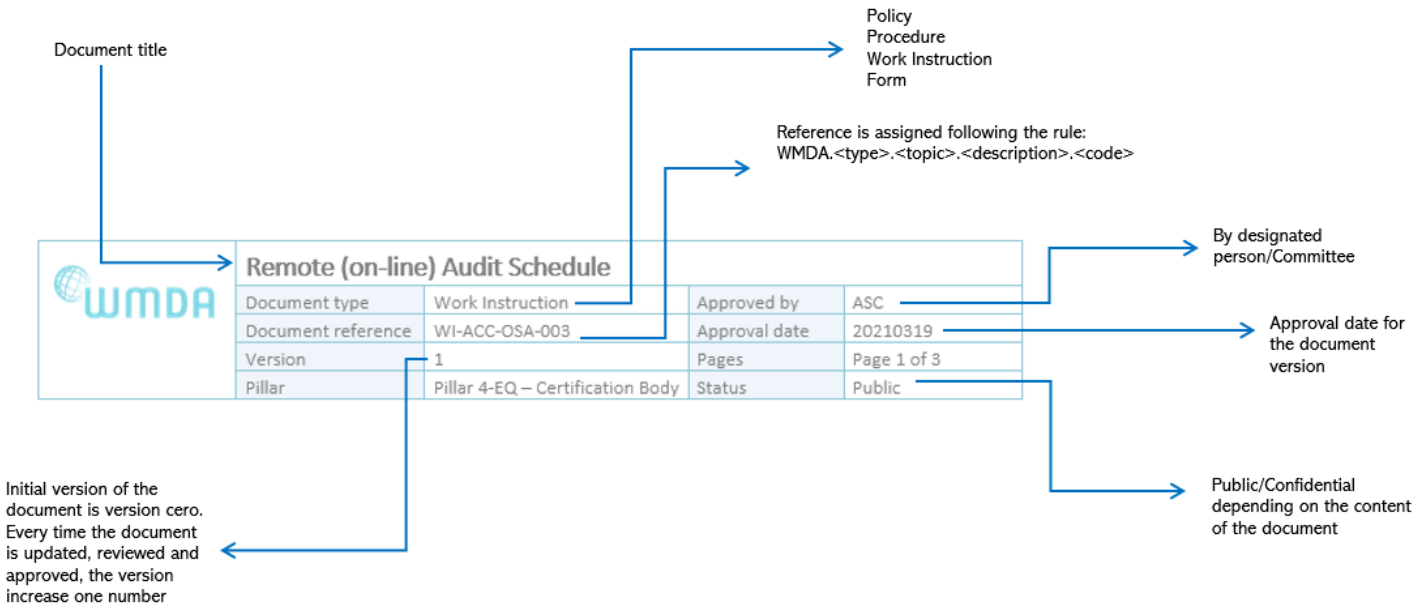
Document approval: WMDA Board has delegated in the Accreditation Steering Committee the approval of all operational Policies, SOPs and work instructions. WMDA Board must approve the following documents that cover key processes:

- Manual of operations
- Certification Scheme
- Nomination Committee SOP
- Finance Committee SOP
- Impartiality, confidentiality, and diversity Policy
- Risk identification, assessment and management and strategic planning.

Publication: Once the documents are approved, they are made available for the relevant parties at the appropriate point of use. This is done through WMDA Share platform.

Only current version of each document is available in the points of use. After and authorized change, the documents are readily updated.

To comply with the ISO requirements, all documents have a header with specific information to identify the document, the version and the responsibility and date approval.



c) Phase II – Develop the documentation

The following documents have been developed to comply with ISO 17065 requirements.

Reference	Name
N.A.	WMDA 2020 Standards AM1: January 2021
N.A.	WMDA Guidance to 2020 Standards
M-CB-001	WMDA CB ISO General Requirements Manual
M-CB-002	WMDA CB ISO Structural Resource Process Requirements Manual
N.A.	Bylwas_Z1-1 Statuten.pdf
M-FNDN-1100	WMDA Operational Manual
F-FNDN-1101	Impartiality, Conflict of Interest and Confidentiality form
F-FNDN-1102	WDMA Board rules - kit.docx
SOP-FNDN-2000	Nomination Committee
F-FNDN-110-01	Impartiality and COI form
SOP-ACC-4000	Systematic Revision Process for WMDA Standards
SOP-ACC-4100	Use of certification marks
N.A.	accreditation_logo.jpg
N.A.	accreditation_logo.pdf

Reference	Name
N.A.	qualified_logo.pdf
SOP-ACC-4200	Management and mechanisms for safeguarding impartiality, confidentiality, and diversity
F-ACC-4201	Impartiality Report to Board
F-ACC-401-1	ACCR-CONFLICT OF INTEREST for reviewers Rev2.docx
SOP-ACC-4300	Risk Identification, Assessment and Management and Strategic Planning
F-ACC-4301	Form - risk identification, assessment, and Management
F-ACC-4302	Form- Strategic planning
SOP-ACC-CP-501	Competence of personnel involved in Accreditation Program
F-ACC-CP-501-02	Job descriptions Accreditation Steering Committee
F-ACC-CP-501-02	Job description Nomination Committee
F-ACC-CP-501-02	Job description Pillar Board Committee
F-ACC-CP-501-02	Job description Standards Committee
F-ACC-CP-501-02	Job description Working Group
F-ACC-CP-501-02	Job description Impartiality Officer
F-ACC-CP-501-02	Job description- Trainee L1
F-ACC-CP-501-02	Job description - Desk trainee L2
F-ACC-CP-501-02	Job description - Inspection trainee L3
F-ACC-CP-501-02	Job description - Expert L4
F-ACC-CP-501-02	Job description - Team Leader L5
F-ACC-CP-501-02	Job description – Accreditation Committee
SOP-ACC-RTM-6001	Reviewers Training Manual
N.A.	Training Certificates
F-ACC-RTM-601-1	Trainee evaluation form
F-ACC-RTM-601-2	Expert evaluation form
F-ACC-RTM-601-3	Annual Training Plan
F-ACC-RTM-601-4	Evaluator’s summary report
F-ACC-RTM-601-5	Survey of educational needs of WMDA reviewers
SOP-ACC-7100	Certification Body application requirements and levels
SOP-ACC-7200	Application and application review
F-ACC-7201	Online profile
F-ACC-7202	Letter of Intent Certification/Qualification
F-ACC-7203	Letter of Intent Accreditation
F-ACC-7204	Certification Agreement Between WMDA Client
F-ACC-7205	Share application
WI-ACC-7200/1	Work Instruction Letter of Intent
SOP-ACC-7400	Evaluation activities
WI-ACC-604-01	Scoring System NC
F-ACC-602-01	Report Certification Qualification
F-ACC-602-02	Report (Re)Accreditation
F-ACC-602-03	Interim report for (Re)Accreditation

Reference	Name
F-ACC-602-04	Report (Re)Accreditation COVID
F-ACC-602-05	Report (Re) Accreditation remote audit
F-ACC-603-01	Mid-cycle surveillance Review form
WI-ACC-OSA-001	Audit General Plan
WI-ACC-OSA-002	Guidance for audit checklist
WI-ACC-OSA-003	Remote audit Schedule
WI-ACC-OSA-004	Pre-planning meeting for Remote audit
F-ACC-OSA-001	Audit Checklist Registry
F-ACC-OSA-002	Audit Checklist Search
F-ACC-OSA-003	Audit Checklist Verification Typing
F-ACC-OSA-004	Audit Checklist Cord Blood
F-ACC-OSA-005	Audit Checklist Work-up Collection
F-ACC-OSA-006	Audit Checklist Donor Follow-up
F-ACC-OSA-007	Audit Checklist Quality Management System
F-ACC-OSA-008	Audit Documents Available
F-ACC-OSA-009	Checklist intro-closing meeting onsite-remote audit
SOP-ACC-7500	SOP-Accreditation Committee
SOP-ACC-7600	SOP- Certification documentation
N.A.	Certification/Qualification Certificate
N.A.	Accreditation Certificate
SOP-ACC-7130	SOP-Complaints and Appeals
F-ACC-7131	Complaints and appeals form
SOP-ACC-8000	Control of documents and records
N.A.	Microsoft SharePoint
SOP-ACC-8100	Management Review
F-ACC-8101	Management Review Report
SOP-ACC-8200	Internal audits
F-ACC-8201	Annual Audit Program
F-ACC-8202	Audit Plan
F-ACC-8203	Internal Audit Report
F-ACC-8204	Audit Checklist
SOP-ACC-8300	Corrective and preventive actions.
F-ACC-83001	Nonconformity, C&P Actions form

d) Phase III – Implementation

All certified management systems are based on evidence of fulfilment of the requirement. In this phase WMDA will put in place all the processes documented in the previous phase. That way, WMDA will have the objective evidence needed to demonstrate compliance with ISO 17065 to Dutch Council for Accreditation, Raad voor Accreditatie.

New structures have been created to keep the records that show evidence of the implementation of policies and Standard Operating Procedures.

Figure 1 –Structure to archive records. This specific example provides the structure to keep records showing compliance with the WMDA Certification/Qualification or Accreditation Processes.

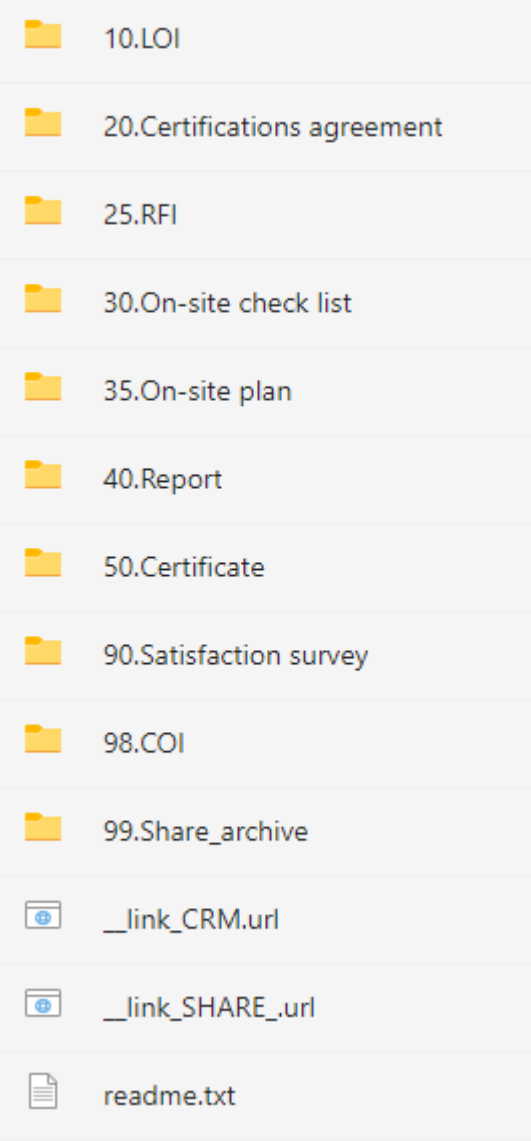


Figure on the left shows the structure designed to archive records that demonstrate compliance with ISO 17065 and WMDA Certification requirements.

Example: SOP-ACC-7200 Application and application review requires that all organizations applying for WMDA Certification/Qualification or Accreditation need to send a Letter of Intent (LOI) with specific information about their organization. After that, a Certification Agreement is signed between WMDA and the client. Both documents will be store in WMDA SharePoint to be able to demonstrate compliance during the internal and external audits.

To improve the efficiency and for traceability purposes, links to WMDA CRM database and WMDA Share (Confluence) have been also added.

e) Phase IV – Internal Audit

Aim of Internal Audits:

Verify that WMDA fulfils the requirements of ISO 17065 and that the management system is effectively implemented and maintained.

According to ISO 17065, one complete internal audit needs to be done at least every 12 months.

Three months before the end of the year, the Accreditation Steering Committee prepares the audit program for next year.

In the future, the audit strategy will take into account the risk assessment, changes affecting organization, and the results of previous audits. As this is the first internal audit, the findings from previous audits have not been an input to prepare the audit program. It has been decided to perform a whole audit of all requirements of ISO 17065.

This internal first audit has been focused on checking that all requirements of ISO 17065 have been covered in the policies, standard operating procedures and other documents included in the management systems and to give an overview of the state of the implementation of new requirements.

An audit checklist has been created to perform the Internal Audit. The Internal Audit Report can be found in Annex IV Internal Audit Report.

WMDA has demonstrated adherence to most requirements of ISO 17065 Conformity Assessment – Requirements for bodies certifying products, processes, and services. A total of 17 findings and/or suggested improvements were identified.

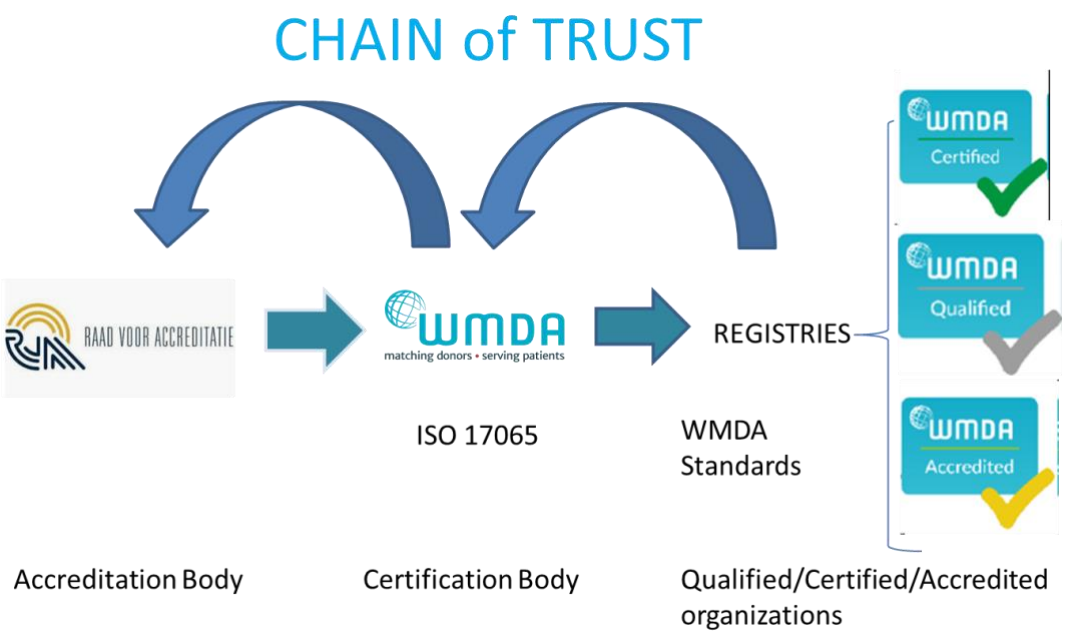
Next steps will be to prepare a Corrective Action Plan with the findings identified in the Internal Audit to address them.

It is also recommended to wait until the implementation of the management system can provide a sufficient amount of objective evidence (records) before applying to the ISO 17065 with the Dutch Accreditation Council.

f) Phase V – Accreditation process with Raad voor Accreditatie (Dutch Accreditation Body)

Most countries have a national accreditation body. Because WMDA is registered as a legal entity in The Netherlands, WMDA will need to follow the Accreditation process with the Dutch Accreditation Body. It is called “Raad voor Accreditatie” abbreviated as RvA.

That way, WMDA grants Certification/Qualification or Accreditation to registries that demonstrate compliance with WMDA Standards and Dutch Accreditation Body will grant Accreditation to WMDA when WMDA is compliant with ISO 17065.



The Accreditation process with Raad voor Accreditatie has 4 steps:

1) In the first step WMDA must send an Application containing the scope of accreditation, WMDA Standards, policies and procedures.
2) Then there is a Preliminary Assessment where RvA informs WMDA whether or not we are ready to undergo the assessment.

   If WMDA is not ready, Raad voor Accreditatie provides a report with non-conformities that WMDA will need to address

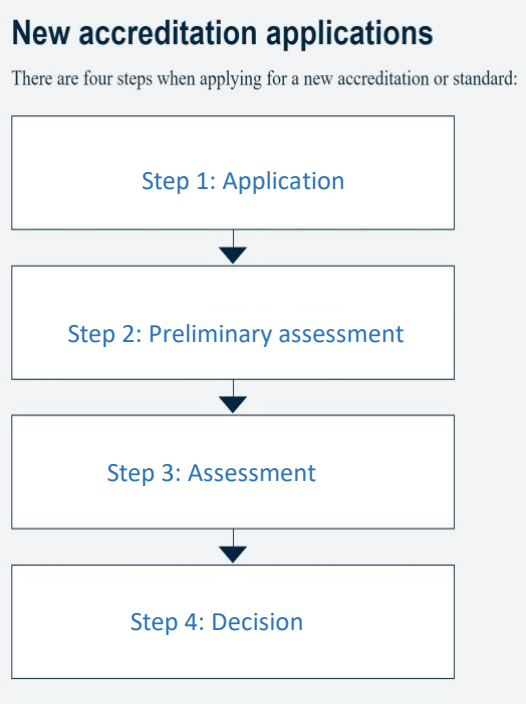
   and if ready, then next steps are:

3) Audit
4) Final decision

If final decision is positive WMDA will obtain the accreditation and it will be valid for 4 years,

During those 4 years we will have to undergo a number of surveillance audits.

Accreditation process with RvA



DUTCH ACCREDITATION COUNCIL

Before sending the application to Dutch Accreditation Council, WMDA needs to address the findings form the Internal Audit and prepare the Management Review.

Annex I - Example of Standard Operating Procedure

WMDA	WMDA SOP: Evaluation Activities			
	Document type	Standard Operating Procedure	Approved by	ASC
	Document reference	PC-ACC-7200	Approval date	20210710
	Version	0	Pages	Page 1 of 11
	Pillar	Pillar 4-EQ – Certification Body	Status	Public

WORLD MARROW DONOR ASSOCIATION

SOP: EVALUATION ACTIVITIES

Written by	Responsibility
[redacted]	Author
Verified by	
[redacted]	ASC member responsible for reviews
[redacted]	Quality and Accreditation Coordinator
[redacted]	WMDA Executive Director
Approved by	
[redacted]	WMDA Executive Director

CHANGE RECORDS

Version	Date	Change Type	Change Description
0	2021-07-10	Document creation	

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. Evaluation of corrective action preventive action plan (CAPA) - Mechanism to address nonconformities that must be addressed earlier than the next scheduled surveillance
9. Mid-cycle surveillance during each four year cycle

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.

Identifier	Title
F-FNDN-1101	Impartiality, conflict of interest and confidentiality form
SOP-ACC-RTM-6001	Reviewer Training and Continuing Education Manual
M-ACC-RTM-601/6	Manual: How to perform a document review in WMDA Share
F-ACC-602-1	Report Certification/Qualification
F-ACC-602-02	Report (Re)Accreditation
F-ACC-603-01	Form: Midcycle Surveillance
SOP-ACC-7200	SOP: Application and application review
SOP-ACC-7100	Policy: Certification body application requirements and levels
SOP-ACC-4100	Policy: Use of WMDA Certificates and marks of conformity
F-ACC-CP-501-02	WMDA Accreditation Team Leader Reviewer L5 Job description

F-ACC-CP-501-02	WMDA Accreditation Expert Reviewer L4 job description
F-ACC-CP-501-02	WMDA Accreditation Inspection Trainee Reviewer L3
F-ACC-CP-501-02	WMDA Accreditation Desk Trainee Reviewer L2 job description
F-ACC-CP-501-02	WMDA Accreditation Trainee Reviewer L1 Job description
N.A.	Template: Share Application
SOP-ACC-7130	SOP: Complaints and appeals
SOP-ACC-4300	SOP: Risk identification, assessment and management and strategic planning

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

Identifier	Title
SOP-ACC-7500	SOP: Accreditation Committee
N.A.	Crosswalks of standards with other organizations share page
N.A.	WMDA International Standards Haematopoietic Stem Cell Donor Registries

1.4 ABBREVIATIONS

- 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, 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.
- 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-ACC-7200 Application and application review.** The evaluation activities differ for Certification/Qualification, (Re)Accreditation and Mid-cycle surveillance as shown in Figure 1 and Table 1.

Figure 1. Evaluation activities vs Certification processes

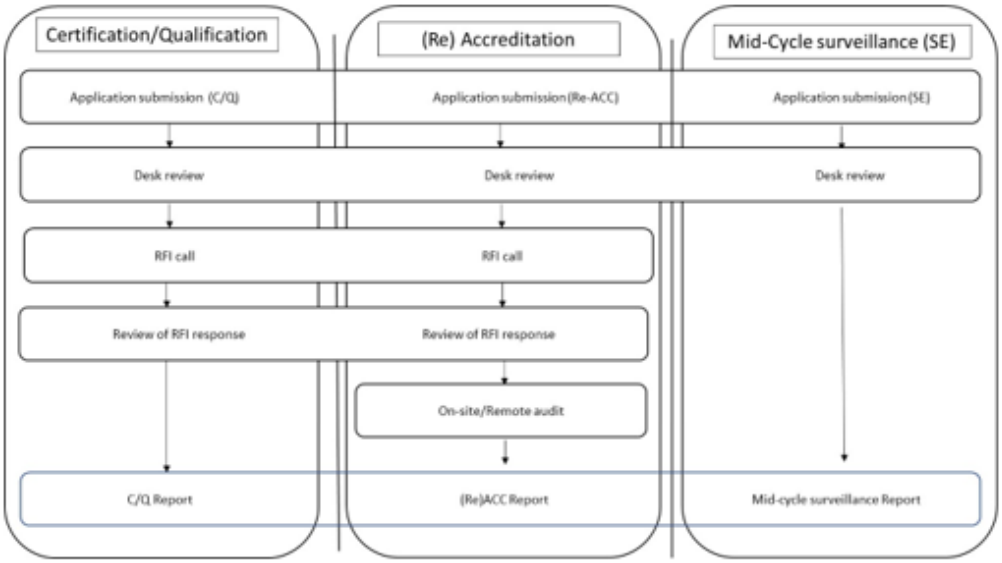


Table 1. Evaluation activities

Evaluation activity	Certification/Qualification	(Re)-Accreditation	Mid-cycle Surveillance
Desk review	Compliance with WMDA benchmarked Standards; Review Team: 2 experienced reviewers + optional trainee Time: 6 weeks	Compliance with all WMDA Standards; Review Team: 2 experienced reviewers + optional trainee Time: 6 weeks	Compliance for specific areas (see section 5); Review Team: 1 experienced reviewer or L3 trainee Time: 4 weeks
RFI call	Review Team + ASC representative	Review Team + ASC representative	N.A.
Review of RFI responses	Review Team + ASC representative if discussion is required	Review Team + ASC representative if discussion is required	N.A.
On-site/remote audit	N.A.	Review Team: 2 experienced reviewers + optional trainee (if L3)	N.A.
Report	Review Team + ASC	Review Team + ASC	Review Team + ASC

2.2 Certification by other organizations

If an applicant is accredited for international exchange of hematopoietic stem cells by an international organisation with standards that meet or exceed WMDA Standards, the activities of evaluation will be more limited.

2.2.1 The applicant must provide a copy of its current certification document from an organization recognized by WMDA as providing certification to standards that overlap WMDA Standards.

2.2.1.1 The WMDA Standards Committee is responsible for providing a list of the WMDA standards that have already been evaluated by that alternative organization (**SOP-ACC-4000 Systematic Revision Process for WMDA Standards**). The list is posted in Share.

2.2.2 The applicant is not required to demonstrate compliance with the identified overlapping standards but is required to respond to the remaining standards. If the registry will used the

certificate from the other organization to demonstrate compliance for the overlapping standards.

2.2.3 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.

3. EVALUATION - DESK AUDIT

This evaluation step is applicable for Certification / Qualification/ (Re)Accreditations and Mid-cycle surveillance (see Figure 1 and Table 1).

3.1 Once the application template is completed by the applicant (**Template: Share Application**), the office provides access to the on-line application to the evaluation team.

3.2 Each evaluator is required to independently assess the application and enter any comments/questions in the Share site (**M-ACC-RTM-601/6 Manual: How to perform a document review in WMDA Share**).

3.3 Evaluations are based on compliance with **WMDA International Standards 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.

3.2.1 Evaluations of Certification or Qualification applications are based on a subset of WMDA Standards designated as "benchmarked." If the registry also includes documentation for non-benchmarked standards, these will also be evaluated; however, the decision is based only on benchmarked standards.

3.2.2 Evaluation of Accreditation applications are based on all WMDA Standards.

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

4. EVALUATION - REQUEST FOR MORE INFORMATION (RFI)

This evaluation step is application for Certification / Qualification / (Re)Accreditations. It is not applicable for 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 teleconference 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 Qualification or Certification is given a maximum of three (3) months to respond to the request for more information. An applicant seeking Accreditation is given a maximum of 1.5 months to respond to the request for more information. Exceptions 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 in the on-site/remote audit (if applicable).

5. EVALUATION - ON-SITE/REMOTE AUDIT

This evaluation step is applicable for (Re)Accreditation. It is not applicable for Certification / Qualification 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 accreditation (**SOP-ACC-8200 Internal Audits**). The Accreditation Steering Committee representative together with the office will determine if the audit will be remote or on-site with on-site audits being preferred. 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.

6. EVALUATION REPORT

This evaluation step is applicable for Certification / Qualification/ (Re)Accreditations and Mid-cycle surveillance (see Figure 1 and Table 1).

6.1 For Certification / Qualification/ (Re)Accreditations, 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 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-ACC-604-01 Scoring System for Nonconformities.**

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 (**F-ACC-602-1 Report Certification/Qualification or F-ACC-602-02 Report (Re)Accreditation**).

7. ACCREDITATION COMMITTEE - REVIEW AND CERTIFICATION DECISION

The consensus report from the evaluation team is provided to the Accreditation Committee for review and the decision regarding certification (**SOP-ACC-7500 SOP-Accreditation Committee**).

8. EVALUATION OF CORRECTIVE ACTION PREVENTIVE ACTION PLAN (CAPA) - MECHANISM TO ADDRESS NONCONFORMITIES THAT MUST BE ADDRESSED EARLIER THAN THE NEXT SCHEDULED SURVEILLANCE

Depending on the categorization of the findings in the evaluator's report, the applicant organization might be required to present a Corrective Action Plan. This will occur in the cases of nonconformities categorized as "major" or "critical" (**WI-ACC-604-01 Scoring System for Nonconformities)**. In that case, an evaluation of the plan and subsequent action by the applicant to address the nonconformities will be performed as follows:

8.1 Evaluation team leader will be sent the proposed corrective action plan to determine if the plan is sufficient to address the nonconformity. If the plan is not sufficient, the applicant will be notified and asked to modify the plan.

8.2 Office monitors that the response to Corrective Action Plan is received in the WMDA office by due date.

8.3 The response and other applicant materials will be sent by Office to the evaluation team leader to evaluate whether the noncompliance has been addressed. Other team member may be designated to review response in team leader's absence.

8.4 If response is not satisfactory, discussion with other members of evaluation team will be held. The team's evaluation of the response is submitted to Accreditation Committee within 2 weeks of receipt.

- 8.4.1 Major issue: If action plan and evidence are appropriate, Accreditation Committee is notified and provided an amended evaluation report. A critical issue will be raised if a major issue has not been corrected in the agreed time period.
- **8.4.2** Critical issue: The result of the evaluation, documented in an amended evaluation report, is provided to the Accreditation Committee to vote on the certification decision as stated in **SOP-ACC-7500 SOP-Accreditation Committee**

8.5 In the next scheduled surveillance, evaluators must check to determine if all the nonconformities have been addressed.

9. 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. Assessment covers the following areas:

- 9.1.1. Changes to the applicant not previously reported to the WMDA that may affect WMDA Certification / Qualification / (Re)Accreditation (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

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 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-ACC-7500 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 for Certification, Qualification, or Accreditation or a decision related to mid-cycle surveillance, the subsequent evaluation will focus only on those standards in question (**SOP-ACC-7130 SOP-Complaints and Appeals**).

7. PLANNING AND EVALUATION

7.1 Evaluators will receive input into their performance as described in the Reviewers Training Manual (**SOP-ACC-RTM-6001 Reviewer Training and Continuing Education Manual**).

7.2 Evaluators will be able to assist with planning and evaluation through surveys and planning sessions (**SOP-ACC-4300 Risk identification, assessment and management and strategic planning**).

Figure 2 – Evaluation and evaluation review process

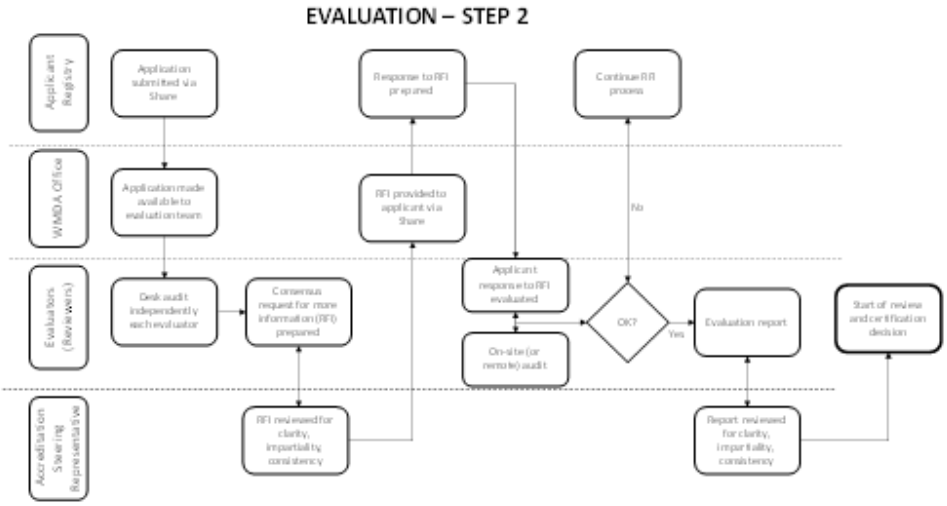
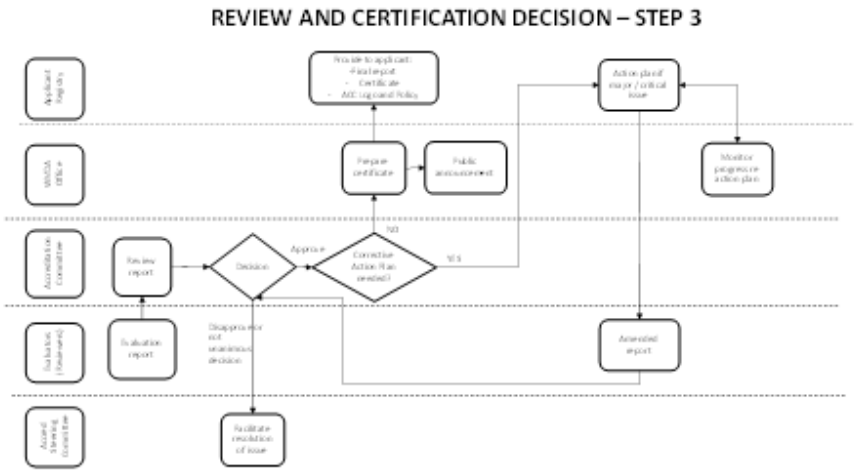


Figure 3. Review and certification decision



Annex II – Example of Form

	(Re) Accreditation Report			
	Document type	Form-Written Report	Approved by	ASC
	Document reference	F-ACC-602-02	Approval date	20210721
	Version	2	Pages	Page 1 of 6
	Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

WMDA REGISTRY ACCREDITATION REPORT
(including <Site Visit/Remote Audit>)

Name of the registry/ION:
Representative of the registry:
Date of initial qualification: **<yyyy-mm-dd>**
Date of initial accreditation[1]: **<yyyy-mm-dd>**
Date of last reaccreditation[2]: **<yyyy-mm-dd>**
Version of WMDA Standard used:

History of review:

- **WACC:**
- Application received WMDA office:
- Additional information requested by reviewers:
- Additional information received by WMDA office:
- Date of <on-site visit/remote audit>:
- Final report sent to WMDA office:
- Date of Accreditation Committee approval:

Review team: <Reviewer name>, <Reviewer name>, <Reviewer name (trainee) if applicable>

<Re>-accreditation review process:

The purpose of the review was to determine <registry name>'s compliance with the WMDA standards.

<Due to <provide reason>, a remote audit was performed instead of an on-site visit.>

Prior to the <on-site visit/remote audit>, the review team assessed information and supporting documents submitted with the registry's application. A series of checklists were used during the <on-site visit/remote audit> to assess operational compliance in the following areas:

- General registry facilities
- Searches
- Donor verification typing
- Cord blood
- Donor work-up/collection
- Donor follow-up
- Quality management

[1] If applicable (only for accredited registries)
[2] If applicable (only for re-accredited registries)

The checklists completed by the review team include the identifiers of the assessed files and names of staff members interviewed. Information from the checklists is maintained by the WMDA office and is available upon request.

The findings and suggested improvements contained in this report are based on both the application review and the <on-site/remote> audit. Findings are classified based on criticality[i] as Critical Issue, Major Issue, or Observation of Concern. Findings in these categories require action by the registry. Suggested improvements are optional recommendations the registry is encouraged to consider.

Brief overview of the <registry name>:

<Brief description of the registry including general structure, number of partners (DCs, CC, CBB, TCs, labs etc, including those in another country if applicable), local regulatory oversight, number of donor/CBBs listed and number of transplants facilitated in the past year>

Executive summary:

<Brief summary of general impression, commendable practices, and any areas of weaknesses/concern (see examples below); may also include feedback on the on-site/remote audit (staff professional, knowledgeable, accommodating etc), quality of the application, etc>

<Examples: The registry has a well-developed quality plan with defined SOPs addressing quality systems. These SOPs were well implemented and integrated into processes and daily operations. There appears to be a good understanding of the WMDA standards.>
<Progress has been made at the registry in implementation and understanding of WMDA Standards. In particular, there appears to be greater oversight by the Quality Unit. It was also noted that there was a great improvement in the topics covered and format of SOPs. However, there are still significant gaps in the SOPs. And it must be noted that there are repeat findings which indicate that certain corrective actions defined in the response to the last audit were apparently not effective.>

The registry has demonstrated adherence to <all, most> WMDA Standards. <The following findings and /or suggested improvements were identified>:

- Critical issues: <number of critical issues>
- Major issues: <number of major issues>
- Observations of Concern: <number of observations of concern>
- Suggested improvements: <number of suggested improvements>

The review team recommends that the <registry name/ION> is granted WMDA <re->accreditation for <adult volunteer donors and/or cord blood units>, <based on compliance with all WMDA Standards OR pending resolution of and/or acceptable action plan to address the critical/major issues identified below>.

<Indicate the actions and timeline required by the registry to address critical or major issues (actions/timelines to be determined based on criticality), e.g., The registry shall provide an action plan detailing how they will address/rectify the following <specify issues> within <two weeks> of receiving this report. An accreditation certificate will be awarded if the plan of action is acceptable. The WMDA office will follow-up with the registry at <six months> of this report to monitor the progress towards these goals>.

<The registry is expected to address observations of concern as soon as possible; progress on these items will be assessed at the next surveillance. If not addressed, these will be considered Major Issues at the next re-accreditation assessment.>

Future timelines:

	yyyy-mm-dd
<Registry to provide action plan for Critical or Major Issue(s)> *(remove row if not applicable)>*	
WMDA office follow-up on progress for Critical or Major Issues(s) *(remove row if not applicable)>*	
Year 2: internal self-evaluation + accompanying documentation for review by the Accreditation Committee	
Letter of Intent for WMDA Accreditation	
6 months into 4th year: Submission of application package for WMDA Accreditation <Shortened application or full application with comprehensive documentation>	

Critical Issues <insert number found, entire section may be removed if none>:
The registry is not considered compliant, action is required as per the executive summary.

Standard (benchmarked are bold)	**Reviewer Findings**
<insert the standard # and text, bolded if benchmark; may list more than one if applicable>	**Finding:** <Description of the finding, indicate if observed in the application and/or during on-site audit. Be succinct and objective/factual as possible, do not include opinions or generalizations. For on-site finding, include the checklist and audited file identifier(s) if applicable> **Rationale:** <describe potential risks; cite supporting information if applicable, such reference to a part of the standard and/or guidance that the observation is not aligned to; reference applicable supporting documents (eg. WMDA publications, etc)> **Registry actions:** <General statement of the actions the registry needs to take (eg. assess root cause and implement

	measures to ensure the finding is prevented in future/to align to the standard); can include suggestions for the registry to consider/expectations for addressing/rectifying the issue, but do not prescribe what the regsitry must do>
<insert additional rows as needed>	

Major Issues <insert number found, entire section may be removed if none>
The registry is not considered compliant, action is required as per the executive summary.

Standard (benchmarked are bold)	**Reviewer Findings**
<insert the standard # and text, bolded if benchmark; may list more than one if applicable>	**Finding:** <Description of the finding, indicate if observed in the application and/or during on-site audit. Be succinct and objective/factual as possible, do not include opinions or generalizations. For on-site finding, include the checklist and audited file identifier(s) if applicable> **Rationale:** <describe potential risks; cite supporting information if applicable, such reference to a part of the standard and/or guidance that the observation is not aligned to; reference applicable supporting documents (eg. WMDA publications, etc)> **Registry actions:** <General statement of the actions the registry needs to take (eg. assess root cause and implement measures to ensure the finding is prevented in future/to align to the standard); can include suggestions for the registry to consider/expectations for addressing/rectifying the issue, but do not prescribe what the regsitry must do>
<insert additional rows as needed>	

Observations of Concern <insert number found, entire section may be removed if none>
The registry is considered compliant, but action is required to address the concerns identified. If not addressed, these will be considered Major Issues at the next re-accreditation assessment.

Standard (benchmarked are bold)	**Reviewer Findings**
<insert the standard # and text, bolded if benchmark; may list more than one if applicable>	**Finding:** <Description of the finding, indicate if observed in the application and/or during on-site audit. Be succinct and objective/factual as possible, do not include opinions or generalizations. For on-site finding, include the checklist and audited file identifier(s) if applicable> **Rationale:** <describe potential risks; cite supporting information if applicable, such reference to a part of the standard and/or guidance that the observation is not aligned to; reference applicable supporting documents (eg. WMDA publications, etc)> **Registry actions:** <General statement of the actions the registry needs to take (eg. assess root cause and implement measures to ensure the finding is prevented in future/to align to the standard); can include suggestions for the registry to consider/expectations for addressing/rectifying the issue, but do not prescribe what the regsitry must do>
<insert additional rows as needed>	

Suggested Improvements <insert number found, entire section may be removed if none>
The registry is considered compliant; the registry is encouraged to consider the following recommendations.

Standard (benchmarked are bold)	**Reviewer suggested improvements**
<insert the standard # and text, bolded if benchmark; may list more than one if applicable>	**Finding:** <Description of the weakness identified, indicate if observed in the application and/or during on-site audit. Be succinct and objective/factual as possible, do not include opinions or generalizations. For on-site finding, include the audited file identifier(s) if applicable> **Rationale:** <cite supporting information if applicable, such reference to a particular part of the standard and/or guidance that the observation is not aligned to; reference applicable supporting documents (eg. WMDA publications, etc)>

	Recommendation: <suggestions for the registry to consider, but do not prescribe what the registry must do>
<insert additional rows as needed>	

[i] See WI-ACC-604-01 Scoring System for Nonconformities

Annex III – Example of distribution of documents through WMDA Share

Reviewers document centre

Created by Matilde Lartategui, last modified on Sep 23, 2021

Conflict of Interest form (COI)

- COI

Audit checklists and other documents

- Audit_Review Plan
- Guidance for Audit checklist
- Remote (on-line) Audit Schedule
- Pre-planning meeting for remote audit

- Checklist intro-closing meeting audit
- Checklist_Registry
- Checklist_Search
- Checklist_Donor verification typing
- Checklist_Cord blood
- Checklist_Work-up/collection
- Checklist_Donor follow-up
- Checlklist_Quality management

- Form - files available at registry for audit

Written report:

- Written Report for Certification/Qualification Template
- Written Report for (Re)Accreditation Template
- **NEW!!** Interim Written Report for (Re)Accreditation Template

(Only for on-going accreditations during COVID-19 Pandemic)

Internal Self-Evaluation form

- Self Evaluation Review Form

Scoring System for nonconformities

- Scoring system for nonconformities

	ISO 17065 Audit Checklist			
	Document type	Form-Audit checklist	Approved by	ASC
	Document	F-ACC-8204	Approval date	20210706
	Version	0	Pages	Page 37 of 59
	Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
4	**GENERAL REQUIREMENTS**			
4.1	**Legal and contractual matters**			
4.1.1	Legal entity	Is the certification body a legal entity, or a defined part of a legal entity, that can be held legally responsible for all its certification activities?	**Docs showing compliance:** WMDA Bylaws WMDA Manual of Operations **Comments:** The association is established under the laws of the Netherlands **World Marrow Donor Association**, having its registered office at Schipholweg 57, 1st floor, unit 2, 2316 ZL Leiden, The Netherlands, registered at the	None

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
			Dutch Chamber of Commerce with number 40448326. Bylaws The Certification Body is defined in the Manual of Operations. WMDA Manual of Operations	
4.1.2	Certification agreement with client	Does the certification body have a legally enforceable agreement with each client for the provision of certification activities in accordance with the relevant requirements of ISO 17065?	**Docs showing compliance:** Certification Agreement between WMDA and Clients **Comments:** Legally enforceable, covers responsibilities of WMDA CAB and its clients including all requirements of ISO 17065. General information about Certification Agreement can be found in:	Finding 1

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
			WMDA Manual CB ISO General Requirements, section 3 SOP-Application review, section 7 Certification Agreement must be signed for each Certification/Qualification or Accreditation cycle (4-year cycle). When a new cycle starts, a new Certification Agreement is signed.	
4.1.3	Use of license, certificates, and marks of conformity	Does the CB have rules governing certification marks that it authorizes certified clients to use? Do these rules ensure, among other things, traceability back to the certification body? Is there any ambiguity, in the mark or accompanying text, as to what has been certified (scope of the	**Docs showing compliance:** SOP-ACC-4100 Use of certification marks **Comments:** Doc for the use of the license, certificates, or mark.	Finding 2 Finding 3

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		Certification) and which level of Certification has been granted?		
4.2	**Management of impartiality**			
	Impartiality in evaluation	Is the CB responsible for the impartiality of its conformity assessment activities? Does the certification body allow commercial, financial or other pressures to compromise impartiality or ensure that conformity assessment activities are undertaken impartially?	**Docs showing compliance:** SOP-ACC-4200 Management and mechanisms for safeguarding impartiality, confidentiality, and diversity. **Comments:** A **risk analysis** has been performed and last update was in July 2021. Board and Committee members sign annually the Confidentiality & Conflict of Interest & Impartiality form.	Finding 4
		Does the CB have a policy demonstrating that it understands the importance of impartiality in carrying out its management system certification activities and managing conflicts of interest thus ensuring the objectivity of its management system certification activities?		

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		In the event where any threats to impartiality are identified, does the certification body document and demonstrate how it eliminates such threats and document any residual risk Does the top management of the certification body review the residual risk to determine if the risk is within the level of acceptable risk?	Evaluators sign an Impartiality and Conflict of Interest form before participating in a Certification process. There is no evidence of consultancy of any part of WMDA to its clients.	
		Does the CB or any part of the same legal entity and any entity under the organizational control of the certification body offer or provide management system consultancy?		
4.3	**Liability and financing**			

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
	Liability and financing	Can the CB demonstrate that it has evaluated the risks arising from its certification activities? Does the CB have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates? Does the CB evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial, or other pressures do not compromise impartiality?	**Docs showing compliance:** Liability insurance Annual reports containing financial report. **Comments:** WMDA Certification program is a well stablished program that started in 2004. All Certified organizations pay an annual fee depending on the level of Certification. The evaluators are volunteers who work in the stem cell registries or cord blood banks and related organizations.	Finding 5
4.4.	**Non-discriminatory**			

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
4.4.	Non-discriminatory	Does the CB make its Certification services accessible to all applicants whose activities fall within the scope of its operations? Is access to the Certification process conditional to the size of the client or any membership?	**Docs showing compliance:** WMDA Standard 1.01 **Comments:** Standard 1.01 list the activities that an organization need to carry out to fall into the scope of operations. No other requirement is needed.	None
4.5	**Confidentiality**			
	Confidentiality	Is all other information, except for information that is made publicly accessible by the client, considered confidential?	**Docs showing compliance:** SOP-ACC-4200 Management and mechanisms for safeguarding	None

		Do personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, keep all information obtained or created during the performance of the certification body's activities confidential except as required by law?	impartiality, confidentiality, and diversity. **Comments:** Confidentiality agreements are signed by Committee members annually and before starting a Certification review.	
4.6	**Publicly available information**			

	Publicly available information	Does the certification body maintain (through publications, electronic media or other means), and make public, or available upon request, in all the geographical areas in which it operates, information about? a) Policies and procedures related to accreditation, b) sources of funding, c) rights and duties of applicants &clients and d) procedure for complaints and appeals	**Docs showing compliance:** SOP-ACC-7100 Certification Body application requirements and levels. WMDA Annual Report. Certification fees. SOP-ACC-7130 Complaints and appeals **Comments:** Information is available in WMDA Share	Finding 6 Finding 7
5	**STRUCTURAL REQUIREMENTS**			
5.1	**Organizational structure and top management**			

This audit report covers the following:	**Document review and assessment of files**		
ISO 17065 Requirements	**Questions to check requirement**	**Evidence and Comments**	**Findings**
Organizational structure and top management	Has the CB documented its organizational structure, duties, responsibilities and authorities of management and other personnel involved in certification and any committees? When the certification body is a defined part of a legal entity, does the structure include the line of authority and the relationship to other parts within the same legal entity?	**Docs showing compliance:** M-FNDN-1100 WMDA Operational Manual. Job descriptions SOP-FNDN-2000 Nomination Committee. **Comments:** The SOP show the organizational structure. All duties and responsibilities have been defined for the different roles involved in Certification activities. The appointment and terms of reference are managed according to SOP-FNDN-2000 Nomination Committee.	None

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		Are the certification activities structured and managed so as to safeguard impartiality? Does the certification body have formal rules for the appointment, terms of reference and operation of committees involved in the certification activities?		
5.2	**Mechanism to safeguard impartiality**			

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
	Mechanism to safeguard impartiality	Does the CB have a process for effective control of certification activities to check if impartiality is maintained?	**Docs showing compliance:** SOP-ACC-4200 Management and mechanism for safeguarding impartiality, confidentiality, and diversity **Comments:** The mechanism has been stablished and documented in the SOP.	Finding 8
6	**RESOURCE REQUIREMENTS**			
6.1	Certification body personnel	Has the CB sufficient number of personnel to cover its activities? Are personnel competent to perform jobs?	**Docs showing compliance:** M-CB-002 WMDA CB ISO Structural Resource Process Requirement Manual **Comments:** WMDA has a poll of more than 50 evaluators. It is constantly	None

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
			increasing the number of evaluators by training new people with the appropriate background.	
6.1.2	Management of competence for personnel involved in accreditation	Does the CB have a process for determining the competence criteria for personnel involved in the management and performance of audits and other certification activities?	**Docs showing compliance:** SOP-ACC-CP-501 Competence of personnel involved in Accreditation Program F-ACC-CP-501-02 Job descriptions SOP-ACC-RTM- Reviewers Training Manual F-ACC-RTM-6012/3 Evaluation forms. **Comments:** System for the Evaluation and Validation of competences has been stablished for personnel involved in certification activities.	Finding 9

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
6.1.3	Contract with personnel	Does the CB have a contract with personnel?	Document is signed with every personnel participating in the Certification process.	None
6.2	**RESOURCES FOR EVALUATION**			
6.2.1	Internal resources		WMDA uses internal resources for Certification processes.	None
7	**PROCESS REQUIREMENTS**			
7.1	Process requirements-general	The CB must have certification scheme and standards	WMDA has Standards, the current version is WMDA 2020 Standards AM1: January 2021, and the WMDA Guidance V4 July 27, 2021. There is and SOP to review WMDA Standards, SOP-ACC-4000 Systematic Revision Process for WMDA Standards.	Finding 10
7.2	Application	Does the CB have a process to gather all necessary information to complete the certification process?		Finding 11
7.3	Application review	Is any known difference in understanding resolved?		Finding 12
7.4	Evaluation	Does the CB have a plan for the evaluation activities?		

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		Does the CB have a process to grant that all the information to perform the evaluation is available? Does the CB inform the client about the nonconformities and any additional evaluation tasks to continue with the certification process?	SOP-ACC-7200 Application and application review contains information to evaluate and make a decision about applications to WMDA Certification Program. The SOP-ACC-7500 Accreditation Committee documents the steps to take the Certification decision. Certification decisions are registered in WMDA Share and an electronic voting tool is used. Once the process is completed, WMDA informs the client about the Certification decision an	
7.5	Review	Does the CB have a process to review all the information and results related to the evaluation? Is this review carried out by person(s) who have not been involved in the evaluation process?		
7.6	Certification decision	Is the CB responsible for its decisions relating Certification?		

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
7.7	Certification documentation	Does the CB provide the client with formal certification documentation that contains? a) Name and address of the CB b) Date the certification is granted c) Name and address of the client d) Scope of the certification	provides a Certificate, certification marks depending on the certification level. The publicly available information about the organization is updated. WMDA Certification program has stablish a 4-year cycle certification with mid-cycle surveillance in the second year. All changes in the Certification Scheme are communicated to clients using different media. All changes initiated by the client are registered in a form and go to	
7.8	Directory of certified products/services	Does the CB maintain information on certified organizations?		
7.9	Surveillance	Does the CB require surveillance to ensure ongoing validity of the demonstration of fulfilment of product requirements?		
7.10	Changes affecting certification	Does the CB communicate changes in requirements to all clients?		

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		Does the CB verify the implementation of the changes by its clients? Does the CB have a process to decide upon the appropriate action on changes affecting certification initiated by the client?	the Accreditation Steering Committee who decides on the appropriate action. WMDA has developed a structure to keep all the records related with the certification activities. The records are maintained during 2 certification cycles as the ISO 17065 requires. The SOP-ACC-7130 shows the process to receive, evaluate and make a decision on appeals. The	
7.11	Termination/suspension of certification	Does the CB have documented procedure(s) for suspension, withdrawal or reduction of the scope of certification?		
7.12	Records	Does the certification body maintain records on the audit and other certification activities for all clients, including all organizations that submitted applications, and all organizations audited, certified, or with certification suspended or withdrawn?		

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
7.13	Complaints and appeals	Does the CB have a documented process to receive, evaluate and make decisions on appeals? Does the CB ensure that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions?	process grants that this evaluation and the decisions are made by people not involved in the certification decision.	
8	**MANAGEMENT SYSTEM REQUIREMENTS**			
	Management system requirements	Does the certification body establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO17065? In addition to meeting the requirements of Clause 5 to 9, does the certification body implement a management system in	Develop according to the Option A or B. -Control of documents **Comments:** WMDA has a quality management system based on ISO 9001 for the following requirements:	

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		accordance with either: a) general management system requirements or b) Management system requirements in accordance with ISO 9001?	- Control of records - Management review - Internal audit - Non conformances - Corrective/Preventive Actions	
8.2	General management system documentation	Has the certification body's top management established and documented policies and objectives for its activities?	The SOP-ACC-8000 Control of documents are records covers the requirements of ISO 17065	
8.3	Control of documents	Has the CB established procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard? Do the procedures define the controls needed to: a) approve documents for adequacy prior to	The SOP-ACC-8000 Control of documents are records covers the requirements of ISO 17065	Finding 13

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		issue, b) review and update where necessary and reapprove documents, c) ensure that changes and the current revision status of documents are identified, d) ensure that relevant versions of applicable documents are available at points of use, e) ensure that documents remain legible and readily identifiable, f) ensure that documents of external origin are identified and their distribution controlled, and g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?		
8.4	Control of records	Has the CB established procedures to define the controls needed for the identification, storage, protection,	The SOP-ACC-8000 Control of documents are records covers the requirements of ISO 17065	Finding 14

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		retrieval, retention time and disposition of its records related to the fulfilment of this part of ISO 17065? Has the certification body established procedures for retaining records for a period consistent with its contractual and legal obligations? Is access to these records consistent with the confidentiality arrangements?	Records are kept for 2 certification cycles as per standard.	
8.5	Management review	Has the certification body's top management established procedures to review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the	SOP-ACC-8100 Management reviews covers all requirements in ISO 17065. The management review inputs include: a) Results of internal and external audits	Finding 15

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		fulfilment of this International Standard? Are these reviews conducted at least one a year?	b) Feedback from clients and interested parties c) Feedback from mechanisms for safeguarding impartiality d) Status of corrective and preventive actions e) Follow-up actions from previous management reviews, f) Fulfilment of objectives g) Changes that could affect management system h) Appeals and complains	
8.6	Internal audits	Has the certification body established procedures for internal audits to verify that it fulfils the requirements of this International Standard, and that the management system is effectively implemented and maintained?	SOP-ACC-8200 Internal audits fulfils the requirements in ISO 17065 including the need of an annual audit program, audit plan, competence requirements for the auditor and audit report.	Finding 16

This audit report covers the following:		**Document review and assessment of files**		
ISO 17065 Requirements		**Questions to check requirement**	**Evidence and Comments**	**Findings**
		any actions resulting from internal audits are taken in a timely and appropriate manner, and any opportunities for improvement are identified?		
8.7 &.8.8	Corrective actions / Preventative actions	Has the certification body established procedures for identification and management of nonconformities in its operations? Does the certification body also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence?	SOP-ACC-8300 Corrective and preventive actions fulfil the requirements of ISO 17065	Finding 17