WMDA Certification Scheme			
Document type	Policy	Approved by	CEO WMDA
Document reference	ACC_7110_CS	Approval date	8/13/2025
Version	9	Approval status	approved
Pillar / Scope	P4/ Certification body	Status	Public

WMDA CERTIFICATION SCHEME FOR SERVICES INVOLVED IN COORDINATING THE PROVISION OF HAEMATOPOIETIC CELLULAR PRODUCTS WHILE PROTECTING THE CELL DONORS

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1. WMDA

WMDA, a legally identifiable entity, is a voluntary international association of organisations and individuals with a shared purpose. That purpose is reflected in the organisation's statements:

WMDA's vision: We strive for a world where access to life-saving cellular therapies for all patients is assured and donors' rights and safety are protected.

WMDA's mission: We work with our members to ensure reliable provision of life-saving cells while promoting patient and donor care and safety.

The WMDA community includes healthcare professionals with an interest in donor and patient care; most are employees of donor registries or cord blood banks.

2. Development and Management of the WMDA Certification Scheme

2.1 WMDA Certification Scheme Ownership

WMDA developed and owns the WMDA Certification Scheme and the WMDA Standards; both have been copyrighted. WMDA Standards and the Certification Scheme with copyright notices can be found on the WMDA public website: https://wmda.info/ensuring-quality/.

WMDA has the authority to establish, change and manage both the WMDA Standards and the WMDA Certification Scheme. Evidence to support this includes:

First descriptions of WMDA Standards and Certification Scheme published in scientific journals:

- Bone marrow transplants using volunteer donors--recommendations and requirements for a standardized practice throughout the world. The Executive Committee of the World Marrow Donor Association. Bone Marrow Transplant. 1992 Sep;10(3):287-91. PMID: 1422482
- Goldman JM. A special report: bone marrow transplants using volunteer donors--recommendations and requirements for a standardized practice throughout the world--1994 update. The WMDA Executive Committee. Blood. 1994 Nov 1;84(9):2833-9. PMID: 7949160.
- Hurley, C., Raffoux, C. on behalf of the World Marrow Donor Association. World Marrow Donor Association: international standards for unrelated hematopoietic stem cell donor registries. Bone Marrow Transplant 34, 103–110 (2004). https://doi.org/10.1038/sj.bmt.1704542
- Hurley CK, Foeken L, Horowitz M, Lindberg B, McGregor M, Sacchi N; WMDA Accreditation and Regulatory Committees. Standards, regulations and accreditation for registries involved in the worldwide exchange of hematopoietic stem cell donors and products. Bone Marrow Transplant. 2010 May;45(5):819-24. doi: 10.1038/bmt.2010.8. Epub 2010 Feb 22. PMID: 20173794

Current WMDA committees and staff form the Certification Body (CB) and can change and manage the Scheme. The Certification Body includes:

- Standards Committee
- Certification Steering Committee

- Certification Committee
- Membership Board including Leadership of WMDA Pillar 4, Ensuring Quality
- Management Board
- WMDA office staff supporting Pillar 4, Ensuring Quality

Authority, duties and responsibilities of these committees, boards and staff members of WMDA is documented in their respective job descriptions and the WMDA Operational Manual.

Development of the WMDA Standards and WMDA Certification Scheme continues to be overseen by individuals with the appropriate competence, participating in the committees listed above. Those individuals are members of the WMDA association who are or have been employed by donor registries and cord blood banks.

2.2 Stakeholders Engagement and Market Support

Only WMDA provides certification of organisations that provide haematopoietic cellular products from volunteers unrelated to patients. Cellular products, when imported into a country different from the country of the donor source, are subject to national or regional regulations. Other stakeholders include unrelated donor registries and cord blood banks, and other organisations in the field.

Every year, WMDA surveys the activities of registries and umbilical cord blood banks world-wide to create its Global Trends report. Today (January 1, 2025), the percentage of donors and cord blood units listed by 39 WMDA certified organisations is 90.6% of the total number of donors and cord blood units in the global database (almost 45 million). In 2023, there were 25,839 blood stem cell products collected from individuals unrelated to the patients receiving the grafts. About half of the products (47%) were shipped internationally; the remaining were provided to patients within the country of the registry.

2.2.1 Regulators

WMDA Certification has been accepted by some countries as meeting the requirements of national or regional regulators for the import of blood cellular products into their country. WMDA is mentioned in documentation supporting legislation in the European Union.

2.2.2 Registries and umbilical cord blood banks

As of January 2025, WMDA has certified 39 organisations internationally.

2.2.3 Other organisations in the field

Besides the market support by organisations (i.e., registries and cord blood banks) that provide haematopoietic cellular products from volunteers unrelated to patients, other stakeholders with an interest in the quality and standards of practice include entities that support the clinical medicine component of haematopoietic cellular product treatment as listed below:

- **WBMT, Worldwide Network for Blood & Marrow Transplantation**, a nongovernmental organisation in official relations with the World Health Organization (WHO). WMDA was a founding member of WBMT. WBMT promotes excellence in stem cell transplantation, stem cell donation, cellular therapy and accreditation as well as access to stem cell transplantation worldwide through collaboration of existing international societies using coordination, communication and advocacy
- **EBMT,** an association of healthcare professionals, involved in clinical haematopoietic cell transplantation and cellular therapy. JACIE is a committee of EBMT.
    - JACIE, Europe's only official certification body in the field of haematopoietic cell transplantation and cellular therapy. It promotes high-quality patient care and medical and laboratory practice through a profession-led, voluntary certification scheme.
- **ASTCT,** American Society for Transplantation and Cellular Therapy, an international professional membership association of more than 3,900 physicians, investigators and other healthcare professionals from more than 50 countries. ASTCT founded FACT to support clinical accreditation of cellular therapy.
    - FACT, non-profit corporation co-founded by the International Society for Cell and Gene Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy, establishing standards for high quality medical and laboratory practice in cellular therapies.
- **NetCord-FACT, NetCord**, the virtual office of NetCord has been merged into the WMDA, the certification activities were transferred to FACT, that is responsible for the development of international standards for cord blood collection, banking, and release for treatment.

2.3 Scheme Management

2.3.1 WMDA Scheme documentation

The Scheme documentation includes the following:

- Certification Scheme (this document)
- WMDA International Standards for Haematopoietic Stem Cell Donor Registries
- Letter of intent
- Certification Agreement
- Policy for the use of WMDA Certification marks
- Standard operating procedure: Complaints and appeals
- Certificate template
- Definition of scoring system for non-conformities
- Handling of CAPA from major or critical findings
- Certification Scheme evaluation method justification matrix

Documentation describing compliance with ISO/IEC 17065 as listed in T-033 specifying the rules and operating procedures and responsibilities for governance of the Scheme can be found in section C.

2.3.2 Subcontracting of the administration of the Scheme

WMDA does not subcontract any part of the administration of the Scheme.

2.3.3 Fraudulent claim of certification

Conditions for the use of certification marks are defined in a policy, linked to the Certification Agreement. Compliance with the Certification Agreement is checked during the mid-cycle surveillance process or the first time Full Standards is applied for. The use of certificates and certification marks must meet the requirements established in the WMDA Certification Agreement detailed in the policy for the use of certification marks. Fraudulent claims of certification will be investigated. WMDA may send warning notifications, open corrective actions, withdraw certification and/or start legal actions.

2.3.4 Complaints and appeals process

WMDA has a process to receive, evaluate, and address complaints or appeals related to WMDA Certification. The Certification Steering Committee is responsible for undertaking the management of complaints and appeals.

3. Content of WMDA Certification Scheme

3.1 Scope and Purpose of the WMDA Scheme

The scheme provides certification of the services involved in coordinating the provision of haematopoietic cellular products suitable for patient treatment in a timely manner while protecting the rights, health and well-being of the cell donors.

There are four possible subservices within the scope of the scheme:

- Receive requests for searches; maintain searchable database
- Coordinate provision of adult volunteer donors as a source of stem cells
- Coordinate provision of umbilical cord blood units as a source of stem cells
- Provide support for search requests from registry's transplant centres

All of the subservices are critical components of the purpose of the scheme

Product / product group	**Certification scheme**	**Standard / normative document**
Services involved in coordinating the provision of haematopoietic cellular products suitable for patient treatment in a timely manner while protecting the rights, health and well-being of the cell donors	WMDA Certification Scheme, levels: - Benchmark L1 - Benchmark L2 - Full Standards Possible sub-services: • Receive requests for searches; maintain searchable database • Coordinate provision of adult volunteer donors as a source of stem cells • Coordinate provision of umbilical cord blood units as a source of stem cells • Provide support for search requests from registry's transplant centres Initial certification: • Desk review (inspection of documents) • Audit (on-site or remote, Full Standards only) Mid-cycle surveillance • Desk review (inspection of documents)	WMDA International Standards for Haematopoietic Stem Cell Donor Registries

3.2 Requirements Against Which the Services Are Certified

WMDA International Standards for Haematopoietic Stem Cell Donor Registries (copyright ©2023 by the World Marrow Donor Association (WMDA)). These standards focus on the services involved in coordinating the provision of haematopoietic cellular products suitable for patient treatment in a timely manner while protecting the rights, health and well-being of the cell donors.

WMDA developed and owns the WMDA Certification Scheme and the WMDA Standards. WMDA has the authority to establish, change and manage the scheme.

3.3 Disclaimer About Compliance with Regulations

The WMDA International Standards do not set forth all that may be required to conform to governmental regulations or the standards prevailing in the local legal environment. Each service provider must determine and follow applicable laws, regulations, practices and procedures that apply in their local legal and regulatory environment. The WMDA disclaims all representations or warranties, expressed or implied, that compliance with the WMDA Standards will fulfil the requirements of all applicable governmental laws and regulations or the standard of care prevailing in the local legal and regulatory environment.

3.4 Other Requirements to be Met by the Service Provider

Letter of Intent requirements to submit an application, access WMDA Certification and to determine the type of application:

- An organisation responsible for all of the following: (1) maintaining a file of at least 500 adult volunteer donors and/or at least 100 umbilical cord blood units; (2) enabling the availability of the donor/cord blood unit file for unrelated donor search; and (3) coordinating the testing of the potential volunteer (or maternal and infant) donor and the provision or procurement of haematopoietic stem cells and other cellular products from donors (including cord blood) unrelated to the potential recipient is eligible for WMDA Benchmark Level 1 or Benchmark Level 2 as a first step, followed by WMDA Full Standards compliance as a second step.
- Achieving and retaining minimum levels of activity are needed to demonstrate compliance with the three certification levels. Benchmark L1 (low activity; initial application), Benchmark L2 (sufficient activity; initial application), Full Standards (sufficient activity; second and subsequent application)
    - Note: In order to have a sufficient activity to demonstrate compliance with the WMDA Standards, a minimum of six (6) donations within the last three years with two of the six for international patients is required to be eligible for WMDA Certification for volunteer donors as a stem cell source. The remaining four donations may be for national patients. A similar level of activity is required for cord

blood shipments. If the minimum activity is not reached by the registry, the registry can apply for WMDA Benchmark Level 1 certification.

- Note: Full Standards status is attainable for organisations that have maintained Benchmark L2 status for 2-4 years. Full Standards status involves a comprehensive evaluation of all WMDA Standards.

A Certification Agreement is required to be signed by the service provider and WMDA prior to awarding first and subsequent WMDA Certification to the provider. This agreement covers the 4-year cycle.

The requirements for the service provider include:

- Reviewing application training materials three months prior to submission of the application
- Paying fees for certification
- Making all necessary arrangements for the conduct of evaluations
- Responding to a major or critical concern raised in an evaluation with the time limit set
- Providing information of major changes that might impact certification status
- Submitting a mid-cycle surveillance and applications for renewal of certification in a timely fashion
- Using the certificate and marks of conformity appropriately
- Complying with the latest active version of the WMDA Standards once certified
- Remaining in compliance with local laws, rules and regulations that may relate to the WMDA Standards
- Having a standard operating procedure focused on preparing future applications
- Identifying a staff member to serve as a WMDA evaluator unless excused by the Certification Steering Committee

3.5 Requirement for Certification Body

The WMDA is the scheme owner and is responsible for assessing compliance with the WMDA Standards. The WMDA Certification Body is working towards accreditation based on ISO/IEC 17065.

3.6 Resources Required for the Operation of the Scheme

The WMDA Certification Body consists of the following groups with responsibilities listed (Table 1). Membership in these groups does not overlap.

Table 1. Composition of the WMDA Certification Body

Group	Responsibility
Membership Board	Approves new or revised WMDA Standards from a membership perspective; approves appointment of members to Certification Body Committees

Management Board	Approves new or revised WMDA Standards from an operational perspective; Oversees day to day activities and provides financial and resource oversight of the certification activities; signs certification certificates
Impartiality Officers	Oversee impartiality of certification decisions
Office staff for Pillar4	Coordinates day to day certification activities; performs initial review of letter of intent and application
Certification Steering Committee	Develops, oversees, approves and trains evaluators; implements and coordinates the WMDA Certification Programme
Certification Committee	Reviews evaluation reports and makes decisions on certification applications and mid-cycle surveillances. Each of the major focus areas of WMDA (Pillars) is represented by 1-2 WMDA members.
Standards Committee	Develops, reviews and revises the WMDA Standards. Each Pillar is represented with 1-2 members.

Evaluators are initially selected for training by the Certification Steering Committee based on their experience in the area of registry / cord blood bank coordination of the provision of haematopoietic cellular products from donors unrelated to the recipient and/or experience in some aspect of registry operations with focused experience or training in quality management or preparation of a registry certification package. Once selected, evaluators are required to undergo training and are authorized to perform assessments in a stepwise manner. Annually, evaluators are required to obtain a specific number of credits for participating in certification training activities. An annual training plan and an online educational platform are in place. Competence of evaluators is evaluated on an ongoing basis.

Members of WMDA who are employed by, or consultants of unrelated donor registries and cord blood banks form the various committees of the Certification Body and provide their knowledge in the services offered by applicants. Competence requirements for these personnel in the Certification Body have been established in written job descriptions and an annual Certification Body training plan.

A Certification Steering Committee representative oversees all the assessments for consistency and impartiality. A separate committee, the Certification Committee, makes the final determination of compliance and formally awards WMDA Certification.

Impartiality Officers evaluate impartiality of certification decisions on an annual basis and report to the Management Board. Impartiality is managed through a risk assessment and measures to mitigate the risks are embedded in the certification process.

An annual report by the Certification Steering Committee evaluates the resources and is reviewed and approved by the WMDA Management Board.

No subcontractors are used.

3.7 Access to the Scheme

A description of the WMDA Scheme is publicly available on the WMDA website. Detailed information for members of the Certification Body and applicants is available through WMDA Share (online collaboration tool).

3.8 Content, Conditions and Responsibility for Publication of a Directory of Certified Services by the Certification Body / Scheme Owner

A directory of certified organisations is publicly available on the WMDA website.

3.9 The Need for Legally Enforceable Arrangements Between the Certification Body and the Service Providers

Liability clauses have been included in the Certification Agreement.

3.10 General Conditions for Granting, Maintaining, Continuing, Extending, Reducing, Suspending and Withdrawing Certification

Granting and maintaining. Conditions for granting and maintaining WMDA Certification are described above. Certification must be renewed every four years. Failure to comply with requirements may lead to a change in certification status.

Expand or reduce scope. Requests to expand the scope of certification (e.g., add cord blood when currently certified for adult donors) will only be evaluated and approved at the time of application (i.e., at the start of a 4-year cycle). Requests to reduce the scope of certification (e.g., discontinue cord blood as a donor source) may be requested during the 4-year cycle. WMDA will provide a new certificate and mark of conformity at that time.

Suspending or withdrawing certification. Complaints and concerns by any person or organisation are directed to the WMDA office. The WMDA office will acknowledge receipt of the complaint or concern. The office will record and track complaints and concerns and noncompliance with requirements and the actions taken to resolve them. They will determine whether the issue is minor (e.g., problem with Share application form) or major (e.g., appeal of a certification decision or

complaint that a certified registry does not follow a WMDA Standard). Minor issues usually are dealt with by the office.

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 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. If impacted by a complaint, the registry under investigation will be notified in writing. The Certification Steering Committee will identify one or more evaluators to investigate each specific complaint or concern. If noncompliance with WMDA Standards is in question, the assessment will focus only on those WMDA Standards which are in dispute. Evaluations may include a short notice audit of the registry. For complaints that impact a registry's compliance with WMDA Standards, the evaluators' report will be provided to the members of the Certification Committee. The Certification 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 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.

3.11 Records of Complaints to the Service Providers

The Certification Agreement states that the client will keep a record of all complaints made known to it relating to compliance with WMDA Certification requirements, take appropriate action to address the complaints and document the actions taken. Records of these complaints shall be available to the WMDA on request, including to evaluators during any audit. Client's complaints records and responses are reviewed during the on-site/remote audit. This information is part of the Quality Management checklist used during the audit.

3.12 Reference to the Scheme by Clients

The Certification Agreement states that: Registry will not make misleading or unauthorized claims about (the scope of) its Benchmark L1 / Benchmark L2 / Full Standards certification. Registry will not use its Benchmark L1 / Benchmark L2 / Full Standards certification to bring the WMDA into disrepute. If Registry provides copies of its certificate to others, the certificate shall be reproduced in its entirety.

3.13 Retention of Records by Certification Body / Scheme Owner

WMDA will maintain data acquired throughout and relevant to the application and renewal process for two (2) completed application cycles with a minimum of eight (8) years based on its document retention policy and/or as long as legal obligations apply. Applicants will receive a notification of deletion of provided data / information.

3.14 Review of Scheme Operation and Changes in Specified Requirements

The Certification Steering Committee is tasked with oversight of the operation of the scheme. It receives input from the number of certifications granted, issues during the certification process, resources, complaints and appeals, results of internal audits, improvement actions, surveys of applicants, surveys of evaluators about training programmes, performance of evaluators and risk management.

The Certification Steering Committee is responsible for the oversight of any changes to rules, procedures and management of the scheme. Changes are documented in the Scheme policies, standard operating procedures and other documents. Changes affecting applicants and certified organisations are communicated through the WMDA newsletter (*Stem Cell Matters*) and the WMDA website.

The Standards Committee is responsible for updating the standards as practice changes. WMDA members are able to request changes at any time through the collaboration platform, WMDA Share. The membership and stakeholders are asked to comment on all changes to the Standards before a new version is finalised and published. There is a defined transition period to implement a new version of the WMDA Standards. For new/revised standards, clients are usually given six months to incorporate the changes and changes are reviewed during the next application or mid-cycle surveillance. If, for any reason, the defined transition period needs to be altered, new timelines will be defined and communicated.

3.15 Transitional Arrangements for New or Revised Schemes

If a major change in the Scheme will take place in the future, a specific plan will be developed in consultation with the clients and the transition period determined based on the impact of the change. In general, changes to the Scheme are expected to be minor, for examples, the addition of new or revised WMDA Standards or minor revision in the criteria for submitting an application. These changes will likely be approved by the WMDA Membership Board after publication of the upcoming changes and consideration of the comments from the WMDA membership. For new/revised standards, clients are usually given six months to incorporate the changes and changes are reviewed during the next application or mid-cycle surveillance.

3.16 Requirement for Other Conformity Assessment Bodies Involved in the Process

Currently, WMDA is accepting certificates according to the following worldwide recognized standards as proof of compliance with a subset of WMDA Standards:

- ISO 9001
- NetCord-FACT
- FACT-JACIE

Before accepting the certificates from other organisations, the WMDA Standards Committee reviews the proposed alternatives standards and designates which WMDA standards are covered. [Note: The NetCord-FACT and FACT-JACIE certificates are not issued until all deficiencies are addressed.] A

current NetCord-FACT certification will be accepted to cover Section 4 of the WMDA Standards (Umbilical cord blood and maternal donor recruitment, consenting, screening, testing and review/release of cord blood units); ISO 9001 for WMDA Standard 2.10 (quality management) and JACIE-FACT for a subset of standards related to collection of blood stem cells. NetCord-FACT and FACT-JACIE standards are accepted by international stakeholders including the European Union. During the WMDA evaluation process, the organisation applying for WMDA Certification, needs to provide current certificates of any other organisations used to show compliance with WMDA Standards. Any change in the certification status of those organisations must be reported to WMDA as a major change in timely fashion. In addition, NetCord-FACT informs WMDA of any withdrawn certificate and has a public website to check current certified organisations.

For related service activities not specifically covered by WMDA Standards such as genetic testing of blood group and infectious disease testing of volunteer donor and the clinical aspects of patient treatment and collection of haematopoietic cellular products, evaluators look for current licenses or certificates provided by governmental or standards organisations with expertise not covered by WMDA. The standards organisations (e.g., FACT-JACIE for clinical oversight and EFI/ASHI for blood group testing) are those considered competent and widely accepted by relevant stakeholders.

4. Selection Elements in the Scheme

4.1 Selection of Conformity Assessment Activities

Determination activities include the following (depending on the certification level sought, i.e. Benchmark L1, Benchmark L2 or Full Standards certification):

- Inspection
  - Desk review:
    - All levels of certification: Documents (e.g., policies, procedures, forms, service level agreements, websites, informational material, certificates, licenses, risk assessments, contingency arrangements, security and privacy procedures) are assessed by inspection to evaluate whether they comply with WMDA Standards. Analysis based on performance indicators is also evaluated.
    - Benchmark L1 and Benchmark L2 only: Two sets of clinical files of volunteers who have gone through the entire process (search, verification typing, workup, collection of blood stem cells, transport, follow-up post donation) are assessed to determine if the applicant is complying with a subset of WMDA Standards on a day to day basis. Cord blood unit files are similarly assessed. The files requested by evaluators are two of the most recent international donations (adult volunteer and / or cord blood unit provision).
- Auditing: Full Standards only; on-site or remote (video conference)
  - A risk assessment is used to determine if the service provider will undergo an on-site or remote audit. Full Standards service providers will all undergo an on-site audit for

their first Full Standards certification and likely every other certification period following that.

- Video conferencing was introduced during the SARS CoV 2 pandemic and has been used in cases of political unrest at the location of the applicant or the potential for bad weather (hurricane) at the site. Initially, WMDA performed pilot video conferencing audits and collected surveys from both evaluators and applicants on satisfaction. It also held a conference with participants to identify strengths and weaknesses needed to fine-tune the procedure. Today, video conferencing versus on-site for evaluation of a Full Standards application is determined by a risk-based assessment. The video conference uses the same checklists, reviews donor and quality management files, and interviews staff as an on-site audit does. It differs in that the tour of the applicant's office is performed by video or slides; the audit is spread out over several days; and the applicant is given early notice of the files to be audited only if it needs time to scan paper files into electronic format.

- Files to be audited are selected by evaluators at the time of the audit
- Files of activities are reviewed for compliance with a subset of WMDA Standards using a set of WMDA checklists to determine if the applicant is complying with WMDA Standards on a day to day basis including:
  - Quality management files (applicant audits of outsourced service providers, reports of serious events and reactions, agendas, training records, records granting access to confidential information)
  - Clinical files of adult volunteers who have gone through the entire process (search, verification typing, workup, collection of haematopoietic cellular products, transport, follow-up post donation). Similar audit of umbilical cord blood files if a service of the applicant.
- This is complemented by interviews with staff performing these activities assessing their competence and communication skills and by observation of activities and the surrounding work environment and conditions. The latter assesses the security, privacy and accessibility of donor and patient information.

4.2 Validation of the Methods Chosen for Conformity Assessment

Methods chosen for assessment (e.g., inspection, audit) were selected to provide a stepwise process and are based on methods in use by other standards organisations that certify/accredit aspects of the client's activities. The merits of each conformity assessment activity were evaluated based on: 1. Alignment with the purpose of certification and service(s) provided; 2. Ability to address a risk; 3. If considered a quality assurance measure; 4. Feasibility of performing the method of assessment; and 5. Market acceptance of the assessment.

4.3 Sampling of the Service Being Certified

The purpose of the inspection and audit of clinical files is to obtain a "snapshot" of whether the applicant is following their processes in a vertical audit. The recommended number of cases is based on guidelines from the Bristol NHS University Hospital. The clinical files assessed cover search of volunteer donor database, verification typing, workup, collection, transport of cells, and follow-up of a cell donor. A similar set of clinical files are assessed to cover all stages of identification and provision of umbilical cord blood units.

Desk review of clinical files (Benchmark L1, Benchmark L2)

Applicant must provide files from last two (2) adult volunteer donations collected and transported to a patient in another country. If there have not been two donations within the last two years, applicant must substitute donations collected for a patient in the country of the applicant. If the registry is also applying for cord blood, two (2) cord blood files must be submitted.

Audit (on site or remote, Full Standards only)

The evaluators will select files randomly to review from the list of recent files (last year or six months depending on the level of activity) provided by the registry. The list of files to be reviewed will be provided to the registry at the opening meeting for an on-site or remote audit. If the applicant has only paper files, the list of files to be reviewed will be provided to the registry in advance of a remote audit in order to give the registry time to scan the selected files for the video conference. The recommended number of files from each step in the process of donor selection is three. Additional files may be reviewed if questions arise in the audit or if the organisation of the applicant is complex.

5. Certification Process

5.1 Phases in the Certification Process

The assessment of conformity follows a defined step-wise process:

1. Application: Submission of a letter of intent (LOI) to submit an application by the client using a template
2. Application review: Review of LOI by WMDA office to determine that the applicant meets the application requirements (minimal size of donor/cord blood database, level of activity in supporting the provision of haematopoietic cellular products internationally)
3. Submission of documentation by the applicant demonstrating compliance with services based on WMDA Standards using an on-line template
4. Application (preliminary) review: Review of the submitted application by WMDA office to determine if the application is complete (e.g., responses included for all required standards, sufficient translation to English of documents, links to documents and websites accessible). Applications that are unable to be assessed due to lack of information are returned to the applicant with a request for further preparation.
5. Completion of a certification agreement by applicant and WMDA. Additional requirements for achieving and maintaining certification (e.g., paying annual fee, allowing for conduct of evaluation process, appropriate use of certification mark).

6. Assignment of 2-3 impartial evaluators. Evaluators are selected by the WMDA office staff overseeing the certification process together with a member of the Certification Steering Committee.
7. Evaluation by desk review by inspection (Benchmark Level 1, Benchmark Level 2, Full Standards) and on-site/remote audit (Full Standards). This is performed by impartial evaluators who have signed conflict of interest and confidentiality forms.
8. Request for more information. If the evaluators are unable to evaluate compliance in the desk review, the applicant is asked to clarify their responses. This clarification is then taken into consideration in evaluating compliance with the WMDA Standards.
9. Planning and preparation if there is to be an on-site or remote (video conference) audit component
10. Report by evaluators with recommendation and participation in discussion of application by the Certification Committee.
11. Review of report and certification recommendation by Certification Committee; decision regarding certification by Committee.
12. Office provides certificate and public announcement of positive outcome.
13. Surveillance at 2 years into the 4-year cycle. Renewal of certification every 4 years.

5.2 Information to be Provided by the Applicant for Certification

Applicants are requested to provide the information listed in the Letter of Intent in order to demonstrate eligibility to apply for certification.

The information to show compliance with the WMDA Standards is provided through an application template available in WMDA Share (an online collaboration platform). Applicants are requested to provide documents, such as policies, procedures, forms, instructions, service level agreements, and certificates / licenses and any other documented information that can be used to determine compliance with the specified requirements. Applicants for Benchmark status are also required to provide copies of two donor and/or cord blood unit records covering the entire process.

Applicants for Full Standards status must provide access to donor and/or cord blood unit records covering search through donor follow up as well as quality management documents during the on-site or remote (video conference) audit. A set of checklists are used to evaluate the records.

Benchmark applications are based on a subset of WMDA Standards called benchmarked standards. Full Standards applications are based on the complete set of WMDA Standards. The specific standards evaluated will depend on the subservices provided by the applicant.

5.3 Content of the Statement of Conformity

The certificate provided to the applicant will list the service and subservices to which it applies and the period for which the certificate is valid.

An example of the wording of a certificate for Full Standards will read:

WMDA certifies that {Registry/Cord Blood Bank/Donor Centre, Address}
Has been assessed based on the WMDA Certification Scheme for Services Involved in Coordinating the Provision of Haematopoietic Cellular Products Suitable for Patient Treatment in a Timely Manner While Protecting the Rights, Health and Well-Being of the Cell Donors and has been found to meet the Full Standards requirements of World Marrow Donor Association International Standards for Unrelated Haematopoietic Stem Cell Donor Registries Edition # 2024

For the following subservice(s) {*select subset that was evaluated*}:
{-Receive requests for searches; maintain searchable database}
{-Coordinate provision of adult volunteer donors as a source of stem cells}
{-Coordinate provision of umbilical cord blood units as a source of stem cells}
{-Provide support for search requests from registry's transplant centres}

Effective date: DD Month YYYY
Certificate expiration date: DD Month YYYY
Certificate number: WACC-XXXX/ZZZZ (ION NUMBER)
Signature of Management Board
Certification Body: WMDA, Schipholweg 55, 1st floor, 2316 ZL Leiden, The Netherlands

5.4 Use of Certificates and Marks of Conformity

If copied, certificates must be reproduced in their entirety.

WMDA is in the process of trademarking the marks of conformity with the European Union Intellectual Property Office. Once WMDA Certification is approved, the client may use the assigned mark of conformity on its documents and its web site. Newly assessed programs may begin using the mark as soon as the WMDA Certification Committee formally approves their status. The organisation can continue using the mark until their status changes. Upon removal or termination of compliance level, the organisation shall stop publishing and distributing documents or digital communication bearing the certification mark. The timing for complying with removal of mark will depend on the registry's ability to remove the mark which might vary from two weeks to remove it from electronic documentation to a maximum of six months to remove it from paper documents. The compliance level shall no longer be stated or suggested in any way.

5.5 How Results of Evaluation and Surveillance Are Reported and Used by the Certification Body / Scheme Owner

Evaluation and surveillance results are documented in a standardised report that contains, among other information, evaluators' recommendations regarding granting or continuing certification. The Certification Committee makes the final decision based on the information provided in the report. The report, once approved by the Certification Committee, is sent to the applicant.

5.6 How Nonconformities with Certification Requirements Are Addressed and Resolved

Non-conformities are listed and communicated through the evaluation and surveillance reports to the applicants. Categorisation of non-conformities is done according to a work instruction. Depending on the categorisation, applicants may need to provide a corrective and preventative action (CAPA) plan. The timing of the response is determined by the severity of the score; critical or major nonconformities require a faster response than observations of concern. Approval by the Certification Committee is held until critical findings are addressed. The status of findings is evaluated in the next assessment (i.e., surveillance or application for renewal of certification).

5.7 Surveillance Procedures

Mid-cycle surveillance occurs in year 2 of each 4-year cycle. The desk review of submitted documentation covers major changes that may impact certification, the status of findings from the last evaluation (if any), and compliance with new or revised WMDA Standards since the last application. A template in the Share collaboration platform is used to collect the necessary information. An experienced evaluator assesses the applicant's information, and the Certification Committee decides on whether the applicant's progress is acceptable.