

NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration

SIGNIFICANT CHANGES FROM THIRD EDITION TO FOURTH EDITION

This document is intended to outline the significant changes made to the NetCord-FACT Cord Blood Standards during the fourth edition standards development process. The outline includes global changes and specific changes to the individual sections. These do not include every change made to the Standards. Refer to the *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration* to review all changes. The accompanying Accreditation Manual is available for further reference.

Global changes:

Title change: The title of the Standards was changed to reflect that all key components of cord blood (CB) unit manufacturing are included, which are donor management, collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution.

General reorganization: Emphasis was placed on organizing the Standards to match the logical flow of CB unit manufacturing. Most changes were to clarify the requirements and make the document easier for inspectors and cord blood banks (CBB) to understand. Redundancies were minimized and most cross-references were removed to prevent confusion and facilitate a streamlined inspection process. Specific examples include:

- Merged QM requirements into the Cord Blood Bank Operational section.
- Included requirements that apply to the entire CBB operation into the Cord Blood Bank Operations section and removed cross-references throughout the document.
- Organized the Cord Blood Selection and Release section by process rather than by type of CB unit.

Consistency and precision: Coordination with all subcommittees as well as other FACT documents promoted consistency and precise language throughout the Standards. The intent of these exercises was to clarify the intent of the Standards and increase efficiency in the inspection and accreditation process. Specific examples include:

- Expanded facility requirements to more clearly illustrate what is expected of CBBs.
- Analyzed often misunderstood or misinterpreted standards to determine the true intent and then drafted new language as appropriate.
- Integrated requirements throughout the document to prevent inconsistencies in practice and inspection (e.g., required testing).
- Specifically stated what is required before listing a CB unit and before releasing a CB unit.

Quality Management and Policies and Standard Operating Procedures: The QM and Standard Operating Procedures (SOP) requirements were combined into a single section to reduce

redundancies and clarify the role SOPs have in a QM program. Additional changes to the QM and SOP standards include:

- Ordered the QM standards from broad to specific to facilitate understanding.
- Moved operational quality control activities out of the QM section and into the applicable operational sections.
- Separated large sections into clearly defined substandards for clarity.

Registries: Steps CBBs need to take to ensure activities delegated to registries were included in these Standards to ensure listing, search, selection, reservation, and/or release of CB units meet the Standards when performed by a registry, such as:

- Added specific standards requiring CBBs using registries to clearly document the responsibilities of the registry, requiring the registry to comply with the Standards, and recommending that the registry be accredited by the WMDA.
- Included the process of reserving CB units, such as requiring policies and SOPs and notification of all registries when a CB unit is removed from inventory.

Designation of CB units: These Standards include more specific requirements for directed CB units and unrelated CB units collected at non-fixed sites, including:

- Clarified the intent of the interim standards (edition 3.1).
- Distinguished when differences are allowed between directed and unrelated CB units.
- Included standards specific to directed CB units.
- Added strict requirements for cases when CB units collected for directed use are subsequently released for unrelated use.

Communication between the CBB and Clinical Programs: Previous editions of the Standards included requirements for communication between the CBB and Clinical Programs, and the fourth edition expanded on those requirements. Particular attention was given to the information Clinical Programs need when searching for CB units from a registry, when requesting additional information, when selecting and reserving a CB unit, and when receiving a CB unit from the CBB.

Specific sectional changes:

Cord Blood Bank Operational Standards:

- Expanded document control to explicitly state what needs to be included in the system.
- Expanded labeling requirements based upon updated recommendations for labeling processes.
- Relocated accompanying documentation requirements into a new appendix.
- Reduced Documents and Records requirements to eliminate redundancy and inconsistency.

- Changed required leadership of collection sites from a CBB Collection Facility Medical Director to a CB Collection Site Director, which does not require a doctorate degree.

Cord Blood Donor Management and Collection Standards:

- Replaced the term “CB Collection Facility” with “CB Collection Site” to include collection at non-fixed sites.
- Clarified requirements for CB Collection Site communication with the CBB.
- Designated required elements of informed consent for before collection and before processing and storage.
- Removed the use of the term “active labor” and required informed consent to be obtained while the mother is able to concentrate on the information and is not distracted by aspects of labor.

Cord Blood Processing Standards:

- Clarified storage conditions requirements (including temperature, disposal, etc.).
- Defined requirements for HLA typing.
- Expanded facility requirements.
- Required non-CBB personnel to comply with the Standards as applicable to the quality of the CB unit (e.g., the use of shared equipment).
- Relaxed standards requiring completion of processing within a designated timeframe based upon evidence found in research studies.

Cord Blood Listing, Search, Selection, Reservation, Release, and Distribution Standards:

- Delineated information that must be reviewed prior to listing a CB unit and that must be provided to a Clinical Program upon selection.
- Clarified the intent of the outcome data collection requirements, which acknowledges the CBB’s dependency on Clinical Programs to obtain the information.