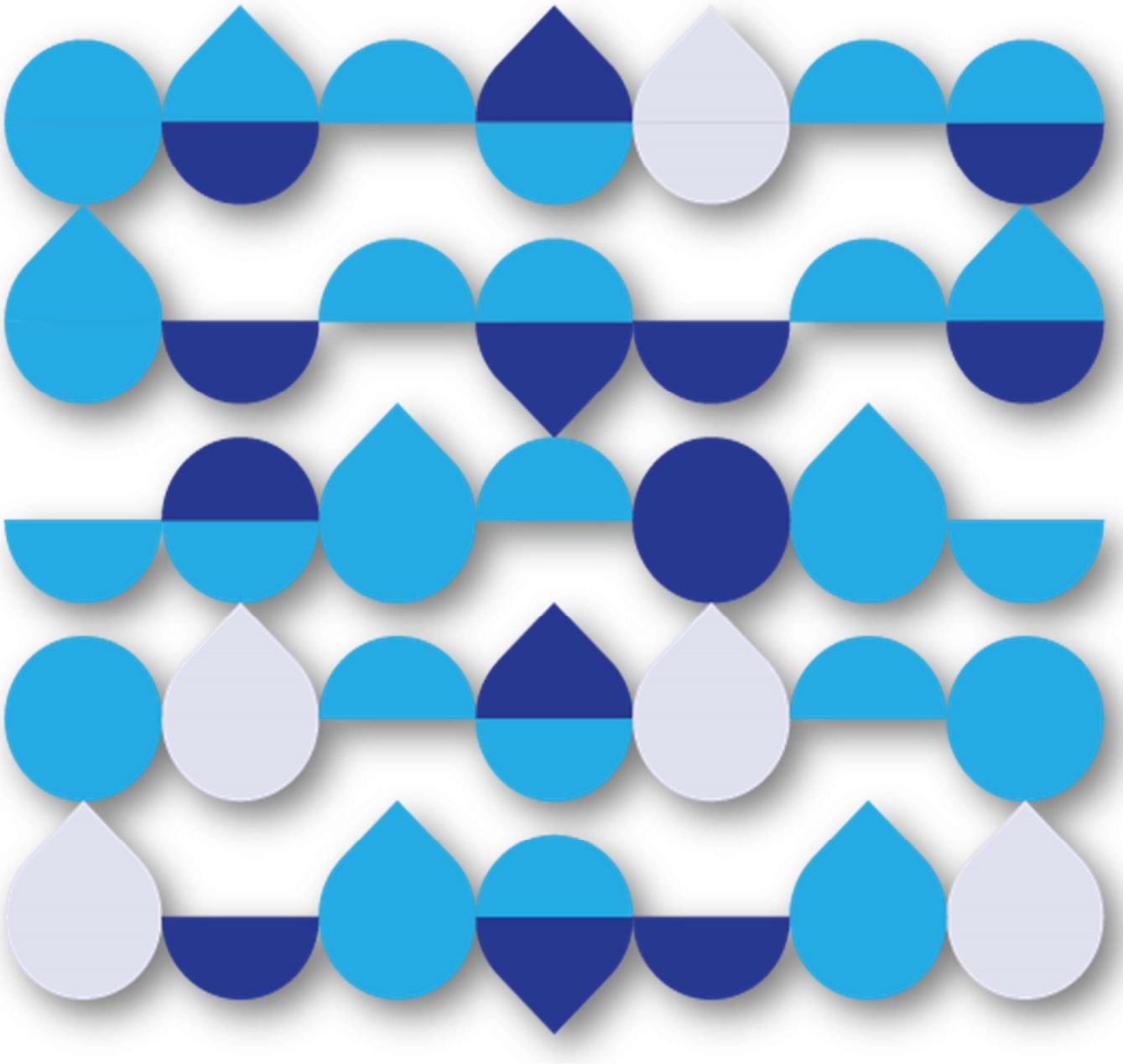
OPERATIONAL GUIDELINES FOR MILK BANKS IN AUSTRALIA AND NEW ZEALAND



CONTENT

FOREWORD

Mother's own milk and Human Milk Banks

Breastmilk provides all the energy and nutrients that an infant needs for the first months of life.[1][2][3] However, there may be scenarios where breastfeeding from the own mother's milk may be inhibited, delayed or curtailed. [4]

Donor human milk is the preferred alternative. [5][6][7]This is particularly true for very low weight preterm neonates, where current evidence identifies benefits from supplementation with donor human milk including: improved gut growth and maturation, decreased risk of necrotising enterocolitis (NEC) and late onset of sepsis, improved neurodevelopmental outcomes, and improved visual development. Moreover, preterm infants fed with milk formula (rather than donor human milk), while experiencing faster rates in growth, present a near-double risk of developing NEC. [8]

There are microbiological and chemical risks in donor human milk inherent to its human origin or introduced at the time of collection, storage or processing that may cause harm to the often highly vulnerable recipient population. Less explored, is the loss of nutritional and bioactive components as a result of handling, different pathogen reduction or elimination methods, further processing and prolonged storage conditions.

To minimise such hazards, Human Milk Banks have adopted principles in safety and quality management from work in similar fields, for example human tissue banking and the food industry [10][11][12], translated into specific human milk banking operational guidelines. [5][13][14][15][16][17]

The Operational Guidelines for Human Milk Banks in Australia and New Zealand

In 2020, the Australian Health Minister's Advisory Council (AHMAC) Clinical Principal Committee (CPC) Human Milk Regulation Working Group identified benefit in the development of the bi-nationally consistent Operational Guidelines for Human Milk Banks in Australia and New Zealand (the Guidelines) for the collection, processing and distribution of human donor milk.

In the context of the Guidelines, Human Milk Banks are defined as organisations established for the purpose of enrolling and collecting excess breastmilk from non-remunerated donors and the processing, testing, storing and distribution of safe and suitable human milk to recipients that are not the donor's own infants, to meet their specific needs for optimal health. Activities are subject to local and national legislation, and applicable regulations.

The Guidelines apply to human milk banks operating or being established in Australia and New Zealand. Embedded in its principles is the continued championing of breastfeeding, the respect to cultural diversity, the acknowledgement of the generosity of donors for their altruistic milk donation and of the intrinsic value that must be assigned to the human origin of the donated milk.
Human Milk Banks in Australia and New Zealand must comply with all applicable industry standards and regulations and corresponding national and state legislation. The Guidelines are intended to support that compliance and harmonise practice. [18][19][20]

The Guidelines are not directed to the collection, storage and handling of breastmilk for a mother's own infant. They also do not apply to informal breastmilk sharing in the community.

The Guidelines may be useful in providing medical practitioners, midwives/nurses, and allied health professionals, as well as government and regulatory enforcement agencies and auditors, with an improved understanding of the processes and challenges faced by Human Milk Banks seeking to provide optimal services.

Scope

The Guidelines outline the principles for processing donated human milk in a manner to reduce or eliminate pathogens whilst retaining the nutritional characteristics to the greatest extent possible. This includes Donor Human Milk (DHM) distributed in frozen or liquid form.

The scope extends to products derived from DHM with the purpose to change the original nutritional and bioactive composition or concentration of the milk. These products are collectively addressed in the Guidelines as Human Milk Derived Products (HMDP) and include, as an example, freeze-dried HMDP for reconstitution.

Structure and content

The Guidelines are structured around the key steps in human milk banking from donor enrolment, collection, processing to distribution and do not challenge the variable legislative and regulatory definition of donated and processed human milk in Australian jurisdictions or in New Zealand - whether 'food' or 'human tissue'. However, where relevant, this was considered in informing guidance.

Safety and quality are upfront as DHM and HMDP are dispensed mostly to vulnerable recipients and influential to their growth and wellbeing. Quality and safety can be assured by guidance which describes in detail, and from a practical point of view, key operational elements, management of risk and control of outcomes in the collection, processing and distribution of DHM and HMDP.

The Guidelines deliver current and referenced guidance, compiled from sector relevant international guidelines, key national and international peer-reviewed publications, current national milk banking practices identified through consultation with stakeholders, and comply with regulations and standards where applicable. They should enable, at a minimum:

- Awareness and consideration to identified ethical and cultural values and expectations of the community at large, including safeguarding breastfeeding;
- Provision of service and product outcomes compliant with national and jurisdictional legislation, applicable standards, and policy;
- Harmonised practice in donor identification and screening processes;
- Establishment of principles for good practices in milk banking;
- Implementation of a risk management system and product safety controls;
- Uniform criteria for assessment of operational performance and assurance of product safety and quality;
- Auditable and evidence-based pathways for the introduction of new pathogen reduction or elimination processing technologies; and
- Verified capacity for the traceability of DHM and HMDP from donors to recipients.

In the context of the Guidelines, the efficiency and outcomes of Holder Pasteurisation (HoP) have been used as minimum safety thresholds for donor selection and pre- and post-processing levels of contaminants in DHM and HMDP, where the impact on milk nutritional components and bioactivity is indirectly addressed. Albeit the acknowledged limitations of HoP, the consideration is supported by the widespread use and the published peer-reviewed evidence on: the efficiency in pathogen reduction or elimination, the compromise in nutritional value and bioactivity, and the clinical utility. [21][22][23][24][25][26][27][28][29]

However, in recognition of human milk banking as an evolving field of activity, other pathogen reduction or elimination alternatives, and additional processing, have been considered. [30]

Overall, the Operational Guidelines for Milk Banks in Australia and New Zealand recommend that any alternative method to HoP for pathogen reduction or elimination continues to abide by the principle of highest possible efficiency in pathogen reduction or elimination paired to the lowest possible impact on the nutritional value and bioactivity of the resulting product.

The writing of the Guidelines focussed on promoting 'best practice' in a milk bank service, where cost-impact considerations are not addressed and have not influenced the guidance provided.

Review process

This document reflects the best practice for Milk Banks in Australia and New Zealand at the time of its publication. However, Human Milk Banking is an evolving field constantly impacted by the introduction of innovative technology and expanded clinical utilisation. The status assigned to some of the recommended practices will benefit from future research and published evidence, with benchmarking of product outcomes updated accordingly.

An assessment on the implementation of the Guidelines should be undertaken 12 months from the date of first publication for updates and to address detected gaps. This initial evaluation should be followed by biennial reviews to ensure guidance remains current and in step with developments in the field.

I. GENERAL CONSIDERATIONS

1. Principles

1.1. Ethical principles

1.1.1. The ethical principles of Respect, Beneficence and Justice underpin Human Milk Banking practice in Australia and New Zealand. [1][2]

(a) Respect addresses:
   i. The ethical obligation to ensure that donors are treated as inherently valuable, and never as mere 'providers' of breast milk;
   ii. The autonomy of lactating women to make an informed choice about milk donation (i.e. donor consent);
   iii. The autonomy of parents or legal guardians to authorise use of human donor milk as nutritional support for their infant (i.e. recipient consent); and
   iv. The individual's right to privacy and confidentiality.

(b) Beneficence refers to:
   i. Enabling access to a valuable resource to benefit potential recipients; and
   ii. If harm (or risk) is unavoidable, that it is proportionate to the expected benefits of the access to DHM or HMDP.

(c) Justice implies:
   i. Managing scarce resources efficiently and effectively in ways that optimise use and avoid waste;
   ii. Access to donated human milk is fair and determined solely by need, utility and capacity of supply;
   iii. Policies and decision-making processes are public and transparent; and
   iv. Decisions rest on principles and evidence that are agreed upon by stakeholders, revised from time to time to ensure best and innovative practice.

1.2. Remuneration and human milk donation

1.2.1. Donating milk is an altruistic gesture whereby the desire to benefit the community is honoured. [2][3][4][5][6][7]

(a) Human milk is donated freely and not to the detriment of the lactating women or their infants.
(b) Milk expression is not elicited or continued for the sole purpose of donation (except in the case of a bereaved mother).
(c) Donors are not paid and there are no financial incentives or other value exchanged in association with the donation.

2. Mother's own milk and milk donation

2.1. A mother's own milk is recognised as best form of early nutrition. [1][2][3][4]

(a) The HMB collaborates, where possible, with relevant government, non-government and public health organisations in the promotion and protection of breastfeeding and the access to a mother's own milk. [5][6][7]

2.2. Potential donors meet the breastfeeding needs of their infant(s) before excess milk donation is considered. [8][9]

3. Service delivery and governance

3.1. Scope of service

3.1.1. The Human Milk Bank (HMB) is established in a hospital/ health service provider or is a stand-alone unit to:

(a) Collaborate with government and community stakeholders in the support of breastfeeding. (as in 2.1.)
(b) Raise, when appropriate, the opportunity of donation of excess milk.
(c) Inform, enrol, obtain informed consent and screen potential donors.
(d) Facilitate the donation and collection of donated human milk.
(e) Process, store and distribute DHM and HDMP in accordance with relevant jurisdictional and national legislation.
(f) Engage in DHM and/or HMDP product development, process validations, and collaboration in academic research programs.

3.2. Service provision

3.2.1 The HMB plans own supply capability of DHM and HMDP against the estimated demand and authorised supply in the jurisdiction(s) that it provides services to.

(a) Demand is established by trend analysis and consultations with serviced hospitals and other relevant stakeholders.
(b) Sufficiency informs fluctuations in donor enrolment efforts, so as to minimise waste.
    - There is a plan which includes consideration of any legislative or insurance requirements for alternate resourcing in an emergency scenario such as interstate acquisition and/or importation (e.g. in a pandemic severely impacting on donation rates):
    - The plan, in compliance with jurisdictional regulatory requirements, is agreed between the HMB, jurisdictional authorities and hospital units;
    - The feasibility of proposed alternative source(s) are reconfirmed at set intervals; and
    - The minimum safety and quality standards are upheld.
(c) The HMB has a plan to handle internal emergencies (e.g. power outage, equipment breakdown, staff shortages).

3.2.2. DHM and/or HMDP is distributed to a hospital milk dispensing unit and/or to the parent or the legal representative of a prescribed infant out of the hospital setting.

3.3. Operational model

3.3.1. The HMB(s) operational models include:

Centralised model:
The HMB is directly responsible for all activities: enrolling, consenting, screening, training and supporting donors, milk collection, processing, storage, safety and quality control, and distribution. Often, this is a facility within a hospital, catering mainly to the hospital-affiliated NICU.

De-centralised model:
There is a "hub and spoke" arrangement, where multiple affiliated collection centres located in hospitals or in the community, enrol, consent, train and support donors, and

temporarily store donated milk, in compliance with the HMB protocols. The HMB is responsible for all screening and final donor acceptance. Collected milk is transferred to the HMB's processing hub to be tested, processed and stored until distribution.

(a) Cultural sensitivities (e.g. return of the milk to the community of origin) and geographical distances are considered when establishing the model.
(b) Milk donation (and expression) takes place at hospitals, at HMB affiliated collection centres and at the donor home.
(c) Distribution is to receiving organisations (e.g. hospitals) for temporary storage under controlled conditions until further dispensing to in-patients and prescribed recipients.

3.3.2. HMB has administrative responsibilities over affiliated enrolling, collecting, processing and storing facilities.

(a) Affiliated enrolling, collecting, processing and storing facilities (including intermediate storage before distribution) operate under the administrative responsibility of the HMB and comply with regulatory standards and the relevant laws in the jurisdiction, or jurisdictions, they operate in and provide services to.
(b) There are service agreements for the provision of DHM and HMDP including the commitment of the receiving party to safeguard the safety of DHM and HMDP and ensure their traceability: (as in 11.2.1.)
    i. Mutually agreed protocols are in place for handling, storage and traceability.

3.4. Governance

3.4.1. The HMB is approved to operate. (1)(2)(3)

(a) The HMB holds an operational licence or authorisation issued by the appropriate enforcement agency.
(b) The enforcement agency is notified of the name and address of the responsible institution, the name of the responsible person, the nature of the business and scope of services, and the location of all premises of the HMB within the jurisdiction of the enforcement agency before the start of operations.
(c) The enforcement agency approves the operation of the HMB within its jurisdiction.
(d) The HMB may be questioned in the above matters by the enforcement authority.
(e) The HMB notifies the enforcement authority of any changes.

3.4.2. An individual is assigned as technically responsible for all the activities carried in the HMB. (2)

(a) There is a designated person to take over responsibility in the absence of the Responsible Person.

3.4.3. There is an organisational chart describing staff positions, authority assigned and reporting lines.

(a) The chart is populated and updated as required to maintain currency.
(b) There is a designated person to take over responsibility in the absence of a line manager.

3.4.4. Individuals in key roles have relevant qualifications and practical experience at management level. (1)(4)(5)

(a) There is a documented qualification assessment process.
(b) Responsibilities and authority are clearly addressed in the job description.

3.4.5. The processing responsibility and management of quality and safety roles are assigned to different individuals to ensure effective and reliable evaluation of processes. [4][5]

3.4.6. There is an internal advisory body to the HMB. [3][5]

(a) This Advisory Committee is established as part of the governance structure of the HMB to provide insight, advice and support to the HMB management.
(b) The membership includes a mix of individuals with diverse expertise, such as: quality, microbiology or infectious diseases specialists, clinical end-users (e.g. neonatologists), other relevant clinical and allied health specialties (lactation specialists), institutional representatives (e.g. Hospital NICU) and community representatives.
(c) The Committee meets at regular intervals and members are also available to counsel the HMB management on emerging strategic, clinical and technical matters.
(d) Advice is provided on (but not limited to):
    i. Scope of activity and business plan;
    ii. Distribution issues - available supply and jurisdictional policy;
    iii. Considerations on distribution for exceptional or new indications;
    iv. Review of HMB performance including discards, complaints, reported adverse events and recalls;
    v. Emerging and re-emerging infectious risks;
    vi. Product innovation;
    vii. Continuation or renewal of service agreements;
    viii. Appropriate provenance arrangements in undersupply or emergency situations; and
    ix. Release of unprocessed human donated milk, DHM or HMDP for approved research projects.

II. GOOD PRACTICES IN THE HUMAN MILK BANK

4. General principles

4.1. Managing safety and quality

4.1.1. The HMB implements and maintains a safety and quality management system to ensure produced DHM and HMDP are safe, that applied processes induce minimal or acceptable levels of change in donated milk nutritional and bioactive components, and that outcomes are compliant with regulatory requirements and legislation. [1][2][3][4][5][6][7]

(a) The safety and quality policy is understood, implemented and maintained at all levels of the HMB.
(b) The safety and quality management system is reviewed by HMB management annually, including the embedded risk management program (e.g. Hazard Analysis and Critical Control Point - HACCP) to ensure relevance and to identify any necessary improvements relating to suitability, adequacy and effectiveness of adopted procedures and controls.
(c) The pro-active management of quality and safety ensures that human donor milk is sourced and processed appropriately, and that outcomes are consistent with these Guidelines, and compliant with all applicable industry standards and regulations.
(d) Adherence to requirements is verified by the relevant jurisdictional quality and safety enforcement agency.

4.1.2. The safety and quality management system addresses all steps of milk banking from donor identification and enrolment, milk collection, transportation, processing, storage, to distribution (including traceability capacity and follow-up on adverse outcomes). [2][3][4][5][6][7]

(a) The scope of the safety and quality management plan includes:
    i. Risk identification and management;
    ii. Record-keeping and documentation;
    iii. Personnel – training and competence;
    iv. Premises, equipment and materials;
    v. Management of outsourced activities and provision of service;
    vi. Processing safety and quality controls;
    vii. Quarantine and release;
    viii. Validations and verifications;
    ix. Management of complaints, product and process non-conformances, adverse events and reactions;
    x. Investigations (including traceability) and reporting of deviations;
    xi. Product recall;
    xii. Internal and external auditing; and
    xiii. Continuous improvement.

4.2. Process controls

4.2.1. The HMB has written operational procedures to sample, test, and document that materials used meet required specifications and applied processes deliver outcomes compliant with regulations and these Guidelines. [2][3][4]

4.2.2. Controls encompass premise(s), maintenance, pest control and sanitation. [2][3][4]

4.3. Risk management

4.3.1. All steps in Human Milk Banking - from donor enrolment to distribution and dispensing (where related to product safety or quality) are subjected to a comprehensive risk assessment to identify potential microbiological, chemical and physical hazards. [1][2][8]

(a) The approach to risk assessment is systematic and documented in a safety program (such as the HACCP) and reviewed annually, or when there is a change in critical equipment or process.
(b) The process includes an estimation of the severity of all identified potential hazards, an assessment of the probability that the hazard will result in harm, and the proposed mitigating measures and corrective actions:
    i. Probability is based on evidence and experience whenever possible.
(c) The level of control measures within the safety and quality system is related to the degree and severity of associated risks.

4.3.2. Mitigating measures for identified risks are implemented and outcomes recorded. [2][8]

(a) The safety and quality program delineates the methods for monitoring outcomes and corrective action(s) for each identified hazard:
    i. Corrective action(s) should consider both product and process.
(b) The program also assigns appropriate corrective action(s) when a hazard is not under control and to prevent recurrences.
(c) Records demonstrating that hazards are controlled, or mitigated to acceptable levels, are kept by the HMB.
(d) The risk-based assessment is reviewed whenever a critical process is changed and within an interval that ensures its adequacy.

4.3.3. Traceability of DHM or HMDP is from donor to recipient, and backwards. [2][(9)][10][11][12][13][14]

(a) Product traceability is an important risk mitigating measure in the event of product failure leading to withdrawal or recall.
(b) The responsibility of each stakeholder for ensuring traceability is clearly stated in the service provision agreements. (as in 11.2.1.)
(c) There is effective identification of DHM or HMDP at all stages during its life span allowing for the linkage of recipients to the received DHM or HMDP.
(d) Traceability capacity extends to all materials and equipment that come in contact with the DHM or HMDP during their processing and storage.

4.4. Monitoring performance

4.4.1. Internal audits are part of a verification program ensuring that the safety and quality program is delivering the desired outcomes. [2][3][4][5]

(a) The HMB self-audits annually and verifies that the documented safety and quality plan is consistent and being followed.
(b) There is impartiality and auditors do not audit their own work.

(c) The audit program is documented and includes review of:
    i. The safety and quality management system;
    ii. Review of monitoring records, including product test results;
    iii. Non-conformances, including complaints and corrective actions;
    iv. Equipment performance;
    v. Staff training and competency;
    vi. Documentation;
    vii. Facility maintenance;
    viii. Service agreements.
(d) Observations, proposals for corrective measures and subsequent actions are recorded.

4.4.2. External audits are required in legislation. [2][3][4][5][9][10]

(a) External audits are conducted by an authorised independent certified auditor.
(b) The frequency is decided by legislative instrument, the regulatory agency, or a food safety auditor, in accordance with the state or territory Act, and informed by the risk assigned to the HMB and previous non-conformances in preceding audits.
(c) The safety program and records, as well as reports of audits made in the past four (4) years, are available upon request.
(d) Any findings during audits are appropriately documented by the auditor and discussed with staff, including a management representative, at the close-out of the meeting.
(e) The HMB closes out any non-conformances in a timely manner and within a time frame acceptable to auditor and HMB.

5. Documents

5.1. General considerations

5.1.1. Documentation describes and records all activities undertaken by the HMB. [1][2][3][4][5]

(a) Documented procedures provide instructions on how to conduct standardised work.
(b) Records accurately document activities, parameters measured and results, and corrective actions where applicable:
    i. They should be signed by the person undertaking the activity and by a supervisor.
(c) Records demonstrate that the products specific safety and quality requirements are met as set in regulatory standards or legislation and according to the HMB safety and quality program.

5.1.2. Access to documentation is controlled. [2][3]

(a) Documents and records are stored in secure areas, with controlled access.
(b) Personnel have access only to those categories of data, documents and records for which they are authorised, and for justified reasons.
(c) Donor privacy and legislative provisions on data protection are adhered to.

5.1.3. Procedures and records have unambiguous content. [2][3]

(a) Procedures and instructions are written using clear language and have unambiguous content.
(b) Written documentation reduces the risk of misinterpretation and error inherent in verbal or casually written communication:
    i. Where verbal communication is necessary for critical information exchange, audio recordings are useful.

(c) Records are legible and entries are indelible, dated and signed physically or electronically.
(d) Accuracy of critical entries, such as serology results, is checked by two individuals.
(e) Any alteration in a paper record is made using indelible ink, dated and signed:
    i. Alterations do not obscure an original entry.
(f) Alterations in electronic records are captured by the electronic data management system.
(g) Reproduced documents (copies) of master documents are clear, legible and void of errors introduced during the reproduction process.

5.1.4. Documents are approved, reviewed and updated at intervals. (2)(3)

(a) Documents are created, approved and signed by authorised persons as per the HMB organisational chart and corresponding responsibilities in their job description. (as in 6.1.1.)
(b) Documents are reviewed by authorised persons, at the appropriate intervals to assure currency and effectiveness.

5.1.5. Documents are version-controlled and the use of obsolete documents is prevented. (2)3)

(a) Established procedures ensure that documents are authorised and copies are controlled by a distribution list.
(b) Each version of a document is uniquely identified.
(c) As updated versions supersede older ones, obsolete documents are removed from all points of issue, and of utilisation, to prevent further use.
(d) Obsolete documents are archived but remain available in compliance with jurisdiction specific Records Acts and Privacy Information Acts and relevant human tissue or food regulatory requirements.

5.1.6. Documentation is retained to enable traceability. (2)(4)

(a) Documents and records are retained for the amount of time stipulated in jurisdiction specific Records Acts and Privacy Information acts:
    i. Where required, the HMB keeps a log of eventually destroyed Donor Files.
(b) Documents and records are stored at secured premises under conditions that safeguard integrity.
(c) Documentation is readily accessible and enables full traceability of distributed DHM and HMDP from the donor to the recipient, and backwards.

5.2. Electronic data

5.2.1. Data captured electronically is subject to similar requirements. (as in 5.1.) (2)(3)(9)

(a) Recording, storing and retrieving data in paper format or in electronic format have similar requirements.
(b) The development and implementation of a computerised recording system follows a documented pathway and each implemented step proven to achieve its written objective.
(c) When a computer system replaces a manual operation, records demonstrate that the two systems have operated in parallel and have been found equivalent, before the computer system replaces the manual operation.
(d) Any changes in the computer system are made in accordance with a documented change control procedure. (as in 5.4.)
(e) The product release process, when carried out using a computerised system, requires a validated electronic identification of the person doing the procedure.

5.2.2. Entries and amendments to entries are controlled. (2)(3)

(a) Only authorised persons are able to enter or amend data in the computer and access is restricted by a secure identifier (e.g. password, biometric system).
(b) The computer system creates an audit trail for any changes or deletion of electronic data. The trail record includes time, date, nature and author of each change.
(c) Records maintained in a computer are regularly and progressively backed-up, and the back-up is retained in a location remote from the active file.

5.3. Standard Operating Procedures Manual

5.3.1. The HMB maintains an updated Standard Operating Procedures Manual. (2)(6)

(a) All HMB procedures, underpinned by good practices principles and applicable standards are collated as individual Standard Operating Procedures (SOPs) and related instructions and record forms, into the Milk Bank Standard Operating Procedures Manual (SOP Manual), including:
    i. Organisational structure and safety and quality system; (as in 4.1.)
    ii. Internal (self-assessment) and external audits; (as in 4.4.)
    iii. Staff training and competency assessment; (as in 6.1 and 6.2.)
    iv. Cleaning and maintenance of the facility; (as in 7.1.)
    v. Equipment maintenance and calibration; (as in 8.1)
    vi. Donor enrolment, consent and screening; (as in 12.; 13. and 14.)
    vii. Milk expression, storage and transport to HMB; (as in 18.; 19. and 20.)
    viii. Milk receipt and quarantine; (as in 21.; 22. and 23.)
    ix. Processing (e.g. pasteurisation including in process controls and assessment of outcomes; additional processing; nutritional analysis); (as in 24.; 25.; 26.; 27. and 28.)
    x. Storage; (as in 27.2.4 and 29.1.)
    xi. Release and discard criteria; (as in 29.2)
    xii. Distribution; (as in 30.) and
    xiii. Complaints, incident reporting, product withdrawal and recall. (as in 34.)
(b) The content is available to milk bank personnel, at all times.
(c) The SOP Manual, instructions and record forms are reviewed annually to ensure accuracy and any required updating:
    i. The updated version is approved by the HMB responsible person.
(d) Specific SOPs and record forms may be updated at more frequent intervals in reflection to changes in procedures and related instructions as they are approved and implemented. (as in 5.4.2.)

5.4. Change Control

5.4.1. Changes to donated milk acceptance criteria, premises, equipment, processes, personnel and any item that may affect the quality or safety of DHM or HMDP, require assessment of risk before being implemented. (2)(3)(7)

(a) A system is in place to evaluate the impact of the changes proposed in the donor screening criteria and donated milk acceptance criteria, collection, processing, storage, distribution and safety and quality controls of DHM and HMDP.
(b) The evaluation includes the need to revalidate processes and equipment, and associated training requirements.
(c) Written procedures are in place to describe the actions to be taken.
(d) The proposed changes are authorised by the individual responsible for safety and quality management or an appropriate delegate.

5.4.2. Changes are addressed in updated SOPs, instructions and record forms.

(a) Staff are updated on changes impacting their work and are re-trained where required:
    i. There is signature validation by staff acknowledging they have read and understood the changes.
(b) Outdated SOP versions are removed from circulation and substituted by current ones.
(c) Effected changes in SOPs are captured in the annual SOP Manual review.

5.5. Records

5.5.1. Donor Files compile the life cycle of DHM or a HMDP. [2][6][7]

(a) A Donor File incorporates:
    i. Donation Records; (as in 5.5.2.)
    ii. Processing Records (including in-process controls and testing); (as in 5.5.3) and
    iii. Distribution Records. (as in 5.5.4.)
(b) The Donor File components, relevant equipment and facility records and any registered non-compliances and mitigating actions, are reviewed by authorised person(s) as part of the standard procedure to release a batch of DHM or HMDP for use. (as in 29.2)

5.5.2. Donation Records include details that confirm donor enrolment and milk donation are compliant to the required safety and quality guidance. [2][6][7][8]

(a) The HMB assigns a Donor Unique Identifier to each donor during the current lactation period to allow traceability from donors to DHM and HMDP (and to recipients), and backwards.
(a) Donation Records include:
    i. Donor identification details and contact address;
    ii. Informed consent for donation and intended uses; (as in 13.2.)
    iii. Initial suitability assessment (medico- social questionnaire and blood screening results); (as in 15.1.)
    iv. On-going suitability assessment (medico-social updates and blood re-testing, where applicable); (as in 16. and 14.3.2.)and
    v. Details of donated milk:
        - Date of expression;
        - Date of deposit at the HMB; and
        - Relevant issues (if any) during collection, storage (e.g.at the home) and/or transport (to the HMB).

5.5.3. Processing Records document all steps converting donated milk into DHM or HMDP. [2][3][4][6]

(a) DHM or HMDP Processing Records include:
    ii. Identification of the donated milk containers used to form each processing batch; (as in 9.3.3.; 9.3.4. and in 26.1.4)
    iii. Processing batch volume and number of resulting containers;
    iv. Details of pathogen reduction or elimination process (e.g. pasteurisation); (as in 26.1.3.)
    v. Pre and post-processing microbiological assessment; (as in 25.3.2 ; 26.2.4. and 27.2.2)
    vi. Processing controls and risk management; (as in 26. and 27.)
    vii. Details of additional processing steps, if any (e.g. freeze-drying); (as in 27.2.)
    viii. Final product nutritional and bioactive assessment when required (and osmolality if applicable); (as in 28.1.)
    ix. The process to release DHM or HMDP for distribution or discard; (as in 29.) and

x. Storage conditions and expiry dates. (as in 29.3)

(b) The HMB assigns an identifier number or code to each batch of processed milk that is traceable to the donor. (as in 9.3.4.)

(c) The HMB assigns a unique identifier number or code to every DHM or HMDP container at distribution so that it is traceable to the processing batch, and to the donor. (as in 9.3.5)

5.5.4. Distribution Records document distribution and enable follow-up of outcomes. (3)(6)

(a) Distribution records include:
   i. Distributed product details (e.g. DHM or HMDP unique product identifiers)and date of despatch);
   ii. Receiving organisation(s) or recipient(s) legal representative contact:
      - Information on recipients at the receiving organisation(s) is available upon request for the purpose of traceability, as per the agreement to supply; (as in 11.2.1.) and
   iii. Record of complaints, withdrawal and/or product recall.

5.5.5. Discard Records document disposal of non-compliant donated milk and processed non-compliant DHM and HMDP.

(a) Records document discard of unprocessed donated milk, DHM and HMDP:
   i. At collection (e.g. where collection is at hospitals or collection centres);
   ii. Pre and post-processing;
   iii. Upon reaching the expiry date;
   iv. At arrival to the dispensing unit or end-user (e.g. product non-conformance); and
   v. At the dispensing unit (as in the event of product recall).

(b) Recorded information captures unique product identifiers, circumstances, authorising person, date and volumes.

5.5.6. Safety and Quality Assurance Records reflect the effective management of risk. (1)(3)

(a) Records document that risk mitigating measures and corrective actions are in place and are effective.

(b) The Records include, where applicable:
   i. Premise cleaning and maintenance;
   ii. Environmental and pest controls;
   iii. Calibration records;
   iv. Testing (platforms with specificity, sensitivity and acceptance thresholds);
   v. Equipment performance and maintenance; (as in 8.1.1.)
   vi. Process validation and verification;
   vii. Process monitoring;
   viii. Personnel training and competency; and
   ix. Audits – outcomes and responses.

(c) The Records are reviewed as part of internal and external audits and in the investigation of product non-conformances or adverse events.

6. Personnel and training

6.1. General considerations

6.1.1. Sufficient and competent personnel carry out tasks in accordance with SOPs. (1)(2)(4)(5)

(a) All personnel have clearly documented and up-to-date job descriptions, outlined in an organisational chart.
(b) Responsibilities are clear, documented, and critical tasks authorised (e.g. product release):
    i. There are no gaps or unexplained overlaps.
(c) There is a registry of staff signatures and the registry is kept up to date.
(d) Staff members have the necessary knowledge and technical skills to perform assigned tasks in accordance with SOPs:
    i. Qualifications, previous professional experience and specific training are considered.

6.1.2. Personnel withdraw from work when unwell. [1][2][5]

(a) Staff understand the responsibilities about their health and risk impacting the safety and quality of DHM or HMDP.
(b) Staff do not engage in milk collection or processing if suffering from an illness that may affect the safety and/or quality of the donated milk or resulting product.

6.2. Training and competency

6.2.1. Relevant training is provided by the HMB to staff or qualified professionals acting on behalf of the HMB (e.g. lactation specialist).

(a) Training raises the awareness of cultural diversity and values and informs on the most appropriate and respectful conduct. [10]
(b) The elements of training include:
    i. Promotion of milk donation;
    ii. Donor enrolment (including provision of consent);
    iii. Screening of donors (including medico-social questionnaire); and
    iv. Milk expression (in the hospital, collection centre or at the home). [3][4]
(c) The procedure(s), documentation and rationale behind practice are understood by the trainee.

6.2.2. Documented training is provided to all staff members whose activities directly affect the DHM and HMDP safety and quality. [1][2][3][4][5][6][7][10]

(a) There is a record of qualifications for each staff member.
(b) Training allows staff to understand the technical processes relevant to their jobs and how these activities are conducted using best practices, and in accordance with the provisions of the Australia New Zealand Food Standards Code and/or other regulatory instruments.
(c) Training elements include:
    i. Overview of breastfeeding and the role of a Human Milk Bank;
    ii. Ethical principles and awareness to cultural sensitivities among the community of donors and recipients;
    iii. Legal and regulatory aspects including food handling principles (where applicable);
    iv. How the HMB is organised, staff roles and responsibilities;
    v. Safety and quality principles; (as in 4.3.)
    vi. Overview of processes undertaken: handling, processing and distribution;
    vii. Relevant technical processes; and
    viii. Personal hygiene and protection.
(d) Records document that staff are assessed and deemed competent for unsupervised work.
(e) Personnel signs documents only when competent and authorised to do so.
(f) Changes in procedures and equipment, and/or interruption in continuous work (e.g. long term service leave) may require re-training and renewed competence assessment.

(g) Ongoing training is available to complement capabilities and when competency reassessment is required (e.g. casual work, redeployment or return from long-service leave).
(h) The HMB extends training to hospital staff on DHM and HMDP handling, where required.

6.2.3. Personnel working in areas where contamination is a hazard are given specific training. [1][2][3][4][5][6][7][8][10]

(a) Operators and supervisors receive appropriate training in hygienic product handling and aseptic technique.
(b) Maintaining personnel cleanliness includes but is not limited to:
    i. Maintaining personal hygiene;
    ii. Wearing outer garments, caps, beard covers (if required), protective eye wear masks and disposable gloves whenever milk is poured, sampled or aliquoted:
        - Gloves are changed, at a minimum, between different donor milk processing batches; and
        - Donning and doffing is done in dedicated area(s).
    iii. Washing and sanitising hands in dedicated facilities (i.e. not used to wash equipment) whenever the milk handling area is vacated, or if it becomes soiled or clearly contaminated;
    iv. Washing hands using running warm water, effective soap or disinfectant and drying with disposable towels;
    v. Removing all jewellery or other objects that may fall into milk equipment or containers; and
    vi. Not eating food, chewing gum, smoking or drinking in the milk handling area.

7. Premises

7.1. General design and maintenance

7.1.1. Dedicated premises are designed, constructed, adapted, maintained and suitable for the intended purpose. [1][2][3][4][5][6][7]

(a) The dedicated premises may be stand alone, or co-located within a larger organisation (e.g. a milk collection unit sited within a Hospital NICU).
(b) Premises are access controlled:
    i. Visitors or untrained individuals entering the facility should be appropriately briefed, attired and accompanied by an authorised person; [4][6]
    ii. Contractors are appropriately dressed and accompanied at all times before site-induction is completed; and
    iii. Visitors, maintenance personnel and sub-contractors are checked in and out.
(c) The layout, design and demarcated working zones favour controlled workflows and reduce the risk of errors and contamination (particulate and microbial) during milk handling.
(d) Supporting areas and amenities may be shared with other organisational sectors (e.g. storage of single use materials, sterilisation in central CSSD).
(e) Premises are periodically evaluated to verify they operate in an efficient and safe manner.

7.1.2. The layout and finishes allow for effective cleaning and maintenance of sanitary operations and minimise contamination, and cross-contamination. [1][2][3][4][5][6][7]

(a) Equipment and fixtures are designed and placed in a manner to facilitate cleaning and sanitation.

(b) There are separated sinks for the washing and cleaning of containers, instruments and any critical materials.
(c) Floors, walls, surfaces and fixtures are easily cleaned and sanitised.
(d) There are written cleaning protocols describing methods and frequency of cleaning:
    i. Protocols include policies for the supply of all cleaning and disinfectant products.
(e) Premises are cleaned according to a schedule and in a procedure validated to achieve the required level of cleanliness:
    i. All cleaning procedures are recorded; and
    ii. An environmental monitoring program (for total viable count or specific pathogens) is maintained to verify the effectiveness of the cleaning and sanitation process of critical surfaces.

7.1.3. The HMB has an adequate supply of potable water. (1)(2)(3)(5)

(a) Water systems are sanitised according to written procedures.
(b) The quality of the water is monitored to ensure that it meets the specifications for the intended purpose.
(c) Automatic equipment using water to sanitise utensils or other equipment only operates for the purpose of sanitation using (potable) water at a temperature that will sanitise utensils or equipment.

7.1.4. Lighting, temperature, humidity, air quality and ventilation are adequate. (1)(2)(3)(4)(7)

(a) Ambient temperature delivers comfort levels to staff and protects equipment from overheating.
(b) There is an emergency (back-up) electrical power supply for critical equipment (as in 8.2.) during outages.
(c) Where specific temperature conditions are required, including during donated milk, DHM or HMDP transport, the environment is controlled.
(d) Air conditioners have filters and are maintained as per the manufacturer's instructions.

7.1.5. Dedicated hand-washing facilities are provided close to where the handling, collection, testing and processing of DHM or HMDP takes place. (1)(2)(3)(5)(4)

(a) Lavatory fixtures (sinks) are of a size that allows easy and effective hand washing, with hot/cold or warm running water, soap or detergent, and drying with disposable towels.
(b) Dedicated hand washing facilities are easily accessed and located near working areas and immediately adjacent to the toilets or toilet cubicles.

7.1.6. Change rooms and toilets are available to staff. (1)(2)(5)

(a) There is adequate storage for clothing and personal items that can be a source of contamination.
(b) Toilet facilities do not open directly to any room in which human milk is being handled or processed.
(c) Change rooms and toilet facilities can be shared with other areas of the organisation.

7.1.7. There are practicable measures to prevent and eradicate pests. (1)(2)(3)(4)

(a) There is a documented program to prevent pests from entering the premises and to eradicate and prevent the harbourage of pests.
(b) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of milk, milk contact surfaces and milk packaging materials.

7.1.8. There is appropriate disposal of waste and waste water. [1][2]

(a) Premises have facilities for the temporary and enclosed, storage of regular waste and biological waste, and allow for effective and safe disposal.
(b) Sewage and waste water are effectively disposed of, with no likelihood of the sewage or waste water polluting the water supply or contaminating products.

7.2. Donor enrolment and milk expression facilities

7.2.1. Facilities enable donor interviews in a conducive and culturally sensitive environment. [3][4]

7.2.2. Areas provided for milk expression (as in hospitals and affiliated collection centres) are culturally sensitive and allow for donor privacy, comfort and the recommended hygienic measures. [3][4]

(a) The milk is expressed in a dedicated space in the ward or a room in the hospital (e.g. close to Neonatal Unit or NICU).
(b) There are dedicated areas in a collection centre to provide for donor privacy and comfort.

7.3. Processing facilities

7.3.1. Access is limited to authorised and trained personnel. (as in 6.2.2 and 6.2.3.) [3][4][5]

7.3.1. There are dedicated rooms or areas for the receiving and handling of milk. [5]

7.3.2. Appropriate conditions are defined, implemented and monitored where the environmental conditions (temperature, humidity, air quality) can have an adverse effect on product safety and quality. [3][4][5]

(a) Environment is controlled to minimise the risk of microbiological and particulate contamination during open processing steps.
(b) Aseptic technique is used.
(c) Microbial environmental monitoring and testing is scheduled at standard intervals to ensure trends and deviations are captured, or as needed.

7.3.3. A separate room or area is provided for cleaning of equipment and containers. [5]

(a) When a separate room or area is not available, cleaning takes place only after milk decanting and/or aliquoting is completed.

7.4. Storage facilities at the HMB and affiliated collection centres

7.4.1. Access to storage facilities is secured to ensure that quarantined or released products are not tampered with, or removed by an unauthorised person. [3][4][5]

7.4.2. There is dedicated and exclusive equipment (freezers, refrigerators and chilling equipment) for the storage of human milk.

(a) Access to stored donated milk is controlled.

(b) The temperature of the freezers in hospitals and affiliated collection centres is monitored. (as in 8.2.3.)

Note: storage of donated milk at the home is addressed in 19.2.

7.4.3. Materials are stored appropriately and protected from contamination. (1)(2)(3)

(a) Materials are stored where there is no likelihood of items becoming exposed to contaminated human milk or other contaminants.
(b) Storage areas provide adequate space, suitable lighting and are arranged and equipped to allow for the dry, clean, and orderly placement of stored materials under the required monitored conditions of temperature, light and humidity:
    i. Boxes, containers and/or transport shippers are stored off the floor (e.g. on pallets or casters); and
    ii. Floors in storage areas are accessible for regular cleaning.
(b) Materials are segregated until approved for use.

7.4.4. Sanitisers and cleaning products are properly identified, stored in dedicated containers and kept apart from processing areas.

7.5. Distribution areas

7.5.1. If despatch is in a different location from the main HMB storage area, there is the provision of appropriate temporary storage conditions while awaiting transport. (3)

8. Equipment

8.1. General requirements and maintenance

8.1.1. Fixtures, fittings and equipment are appropriate for safety and quality controlled production. (1)(2)(3)(4)(5)(6)(9)

(a) The equipment used is appropriate for human milk processing, pathogen reduction or elimination and storage, and used only for human milk banking purposes:
    i. Performance of new equipment is pilot and full-scale tested, in accordance to the HMB operational realities (e.g. 'routine' processing batch volumes).
(b) The design, construction and use of equipment do not result in the adulteration of milk with lubricants, fuel, metal fragments, contaminated water or any other contaminants.
(c) The equipment is designed, qualified and validated (and re-validated), calibrated and maintained (including effective cleaning) to suit its intended purpose and to minimise hazards to donors, recipients, operators and the human milk.
(d) Equipment that may affect temperature or contamination levels has sensors and alarms so that the required and constant conditions are monitored and maintained.
(e) Apparent deviations on the performance of equipment are investigated and documented promptly, triggering corrective and preventive actions.
(f) Critical equipment (as in 8.2.) is uniquely identified; the equipment used (including storage) is traceable in all records related to the DHM or HMDP processing.
(g) The records of each critical equipment performance and maintenance are collated in a HMB Equipment Performance and Maintenance Register, to include:
    i. Maintenance records;
    ii. Equipment performance validation and re-validations; and
    iii. Performance controls, apparent deviations, investigations and corrective actions.

8.1.2. There is a contingency plan in the event of an electrical breakdown or mechanical failure precluding the use of equipment. [3][9]

8.1.3. Equipment manuals and utilisation instructions are available to staff at all times. [3][4][5]

(a) Periodic reviews ensure that the documentation is complete, current and accurate.

8.1.4. Measuring, weighing and recording equipment is calibrated and checked at defined intervals, by appropriate methods. [3][4][6]

(a) All equipment with a critical measuring, weighing and recording function is monitored and calibrated according to a planned schedule.
(b) Records of calibration and re-calibration are kept in an Equipment Performance and Maintenance Register.
(c) A report is provided if calibration is performed by a contracted third party.
(d) A risk assessment procedure is launched if the calibration activities provide evidence that DHM or HMDP was released for use when critical measurement equipment was not measuring accurately or precisely:
    i. Decision is made on appropriate corrective or preventive actions to be taken.

8.1.5. Preventative maintenance is carried out on premises and equipment. [1][2][3][6][7][8][9]

(a) Preventative maintenance is carried out on premises, facilities and fittings.
(b) Equipment maintenance and monitoring is carried out according to a manufacturer's recommendations and a HMB schedule.
(c) Outcomes are documented in the Equipment Performance and Maintenance Register.
(d) Apparent deviations in equipment performance are investigated, documented and corrective action(s) undertaken, where needed.
(e) Defective equipment is removed from the HMB area; if not possible, the equipment is labelled as defective.

8.1.6. Equipment cleaning and sanitation is carried out according to a schedule and documented in the equipment register. [1][2][3][5][7][9]

(a) Equipment that is in direct contact with the milk (including breast pumps) is designed, constructed and finished so that it can be sanitised.
(b) Where the removal of traces of surface contaminants or products is important to minimise risk, cleaning methods are validated.
(c) Chemicals and agents used in cleaning are appropriate for use on food contact surfaces.

8.2. Critical equipment

8.2.1. Biosafety cabinets or isolators: [3][4][10]

(a) Biosafety cabinets Class II or isolators provide for a controlled environment to mitigate air-borne milk contamination and protect staff during open processing steps (e.g. pouring, sampling and aliquoting):
    i. A particle-controlled background for the biosafety cabinet may not be required when open handling steps are to be followed by a terminal pathogen reduction or elimination step (e.g. aliquoting milk into distribution containers, pre-pasteurisation);
    ii. The effectiveness of the biosafety cabinet is protected by its location in a secluded area, enclosure or room, good practices from trained operators,

limited movement of people in the background and other preventative measures against disruption of cabinet's air flows; and

iii. The cabinet and isolators surfaces are clean and sanitised to the appropriate standard.

(b) The suitability of the processing environment is verified by a documented monitoring program, and as deemed appropriate (e.g. qualification of the equipment and cleaning protocols; during or after batch procedure; following maintenance and exchange of HEPA filter) using:

i. Contact plates or 100% surface swabs; and/or
ii. In-process open air culture plates; and/or
iii. Air particle count (e.g. following HEPA filter changes).

(c) Records of the environmental monitoring, maintenance schedule and outcomes are recorded in the Equipment Performance and Maintenance Register.

8.2.2. Milk pathogen reduction or elimination equipment: [4][5][7][9][11]

(a) The equipment (e.g. pasteuriser and/or other validated equipment) is compatible with human milk processing.
(b) Surfaces in contact with milk are made of non-toxic (food-grade) materials, are corrosion-resistant and withstand the cleaning compounds and sanitising agents.
(c) Seams on milk contact surfaces are smoothly bonded or maintained to minimise the opportunity for growth of micro-organisms.
(d) The use of the equipment is in accordance with the manufacturer's instructions and equipment qualification.
(e) Following the initial performance qualification, re-qualification of the equipment is repeated every twelve (12) months and after any major repair or change in equipment location.
(f) Equipment performance (i.e. temperature cycle) is monitored at every treatment cycle during the heating, holding and cooling, as recorded by:

i. In-built equipment temperature controls; and
ii. Calibrated data loggers inserted in proxy container(s) placed in the processing chamber, at the point recommended by the manufacturer or as per in-house mapping.

(g) A difference of temperature measured in the equipment and in the proxy bottle above or below 0.5°C requires re-calibration of the equipment.
(h) Other in process controls are in place (e.g. chamber pressures) where applicable.
(i) The equipment is maintained as per manufacturer's guidelines including re-calibration following a set number of runs (based on risk assessment), or at six (6) months interval (as a minimum), or following maintenance.
(j) Calibration of temperature probes, thermometers and temperature cycle data loggers, equipment maintenance and deviations are recorded in the Equipment Performance and Maintenance Register.

8.2.3. Refrigerators and freezers: [1][3][4][5][9]

(a) Where possible, separate equipment is used for storage of unprocessed donor milk, of processed DHM or HMDP not yet released for distribution or under investigation (*quarantine status*), and of DHM or HMDP released for distribution *(released status*).

i. The equipment is identified accordingly to highlight the different stages of processing and/or status (quarantine/release) of DHM or HMDP to avoid human error;
ii. When not possible or unavoidable (e.g. equipment break-down), donated milk and DHM or HMDP in quarantine status, and released DHM or HMDP are stored in a single refrigerator or freezer, but in clearly different, and identified, sections; and
iii. Rejected (and returned) products are segregated in dedicated discard refrigerators and freezers before discard, as soon as possible.

(b) Temperature points are set for refrigerators and freezers:
   i. Refrigeration storage temperature is at or below +5°C;
   ii. Freezing storage temperature is at or below -18°C;
   iii. Time limited fluctuations in temperature (e.g. door opening) may be acceptable if conditions do not adversely impact on the safety or quality of unprocessed milk and milk products; and
   iv. Milk is monitored to remain hard frozen when stored at the home. (as in 19.2.)

(c) Refrigerators, thawing cabinets and freezers in the HMB, hospitals and affiliated collection centres are qualified, and temperatures measured and recorded.
   i. A minimum of two (2) calibrated thermometers or temperature data loggers, placed in the mapped 'colder' and the 'hotter' spots is recommended;
   ii. Temperatures are checked at set intervals (e.g. once per shift) or preferably continuously recorded in a paper or electronic chart; and
   iii. The equipment temperature monitoring system or the temperature monitoring devices are connected to alarms that sound locally and remotely (e.g. linked to a management alarm system) and are attended at all times.

(d) Freezers and refrigerators are connected to the electrical emergency power circuits or generator.

(e) Equipment is qualified, and maintained as per manufacturer's instructions:
   i. Qualifications, maintenance and deviations in performance are registered in an Equipment Performance and Maintenance Record.

(f) Milk cross-contamination is minimised by the adopted equipment cleaning and sanitising protocols, hygienic handling of milk containers, physical distancing between different donor batches (where applicable), and use of secondary bags or boxes to contain drips and spills.

(g) Milk is protected from the damaging effects of prolonged light exposure by opaque doors.

8.2.4. Temperature measuring devices: (1)(5)

(a) Temperature measuring devices are calibrated and can accurately measure the temperature to +/- 1°C.

(b) Thermometers and temperature data loggers are calibrated at appropriate intervals as per manufacturer instructions, frequency of use, or if dropped, damaged or due to any question regarding accuracy (e.g. readings off by more than +/- 1°C).

(c) Calibration is performed by an accredited service provider (e.g. NATA certified), or as 'in-house' calibration using the ice-point method or the boiling point method, depending on the type of thermometer and its use:
   i. The procedure requires a reference thermometer, calibrated by an accredited service provider.

9. Materials

9.1. General considerations

9.1.1. Materials (single or multi-use) that may impact on milk safety upon contact are made of food-grade plastic or stainless steel.

(a) These include (non-exclusive list):
   i. Jugs for decanting;
   ii. Pooling containers;
   iii. Sieves and filters;
   iv. Mixers; and
   v. Containers and bottles.

9.1.2. All materials which may affect the product safety and quality are controlled and meet defined specifications. (3)(4)(9)

(a) Critical materials are obtained from suppliers that have been evaluated and approved by the HMB or delegate (e.g. Hospital Purchase Department) to ensure their ability to supply materials that meet requirements.
(b) There is a record of purchase and the receipt of critical material by the HMB, including:
    i. Description;
    ii. Date of receipt;
    iii. Quantity; and
    iv. Supplier and as applicable, lot or batch number, or a unique material identifier number.
(c) Incoming materials are quarantined and assessed to ensure they meet approved HMB specifications before being released for use:
    i. The status - cleared for use, or not - is clearly identified by the HMB on the external packaging.
(d) Critical materials are stored under appropriate conditions.

9.1.3. Non-compliant critical materials are discarded or returned to the supplier. [3]

9.1.4. Materials Records are maintained for traceability and to prevent use of materials after their expiry date. [4]

9.2. Milk containers

9.2.1. Milk is collected in containers or bottles that can be hermetically closed, and withstand the handling and storage under the required conditions. [1][2][3][4][5][6][9][10][11][12][13][15]

(a) Single use and sterile containers are recommended, in particular in the hospital setting.
(b) Plastic containers or bottles are food-grade plastic (BPA-free):
    i. Containers made of glass are not used due to risk of breakage;
    ii. Storage in stainless steel containers is avoided;
    iii. Containers are filled to less than full capacity to avoid breaks or cracks as a result of content expansion during freezing; and
    iv. Caps are airtight and provide for hermetic closure and protection of content.
(c) Using plastic bags that are not fit for the purpose of collecting milk (e.g. Zip-lock bags) is not advisable due to the risk of packaging micro and macro fractures:
    i. If bags are used, a secondary bag is recommended.
(d) Re-utilisation of containers or bottles for milk collection may be acceptable but requires cleaning and disinfection that ensures complete removal of any biological or chemical residues.

9.2.2. Milk is processed and distributed in food-grade plastic containers that can withstand the processing (including the pathogen reduction or elimination step) and storage under the required conditions. [3][4][5]

(a) The use of sterile, single use, containers is recommended.
(b) Choice of container volume is informed by:
    i. The type and capacity of the pasteuriser or equipment processing chamber;
    ii. The most efficient use of available milk to minimise discard while generating products of uniform volume; and
    iii. The preferred container volume at the recipient's end (if any).
(c) Containers are hermetically closed with leak proof caps and wadding or seals before pasteurisation.

i. Unless container closure is water tight (e.g. seals) or equipment performance addresses the issue of water seepage into the containers (e.g. during cooling), container closures should remain above water level to prevent contamination;
ii. Containers are filled up with a standard volume of milk, validated to ensure desired temperatures are evenly attained and/or maintained across the processing batch; and
iii. Space is allowed for eventual hot air expansion (during heat pathogen reduction or elimination process) and /or milk expansion (during freezing).

(d) Glass containers are avoided due to risk of breakage.
(e) DHM or HMDP distribution containers are hermetically closed and have tamper evident seals or labels:
    i. Containers safeguard the decontaminated status of the milk and product characteristics during the ascribed shelf life.

9.3. Labels

9.3.1. Donor milk containers should be identified with indelible markings or labels at all stages of handling and processing. (1)(2)(3)(4)(5)(6)(7)(8)

(a) Traceability is possible as the HMB identifies DHM or HMDP in a way that it is uniquely linked to the donor at every stage of the product lifecycle.

9.3.2. Labels remain adherent and inscriptions withstand all processes and environments the containers are exposed to, throughout the product life cycle. (3)(4)

(a) The writing on labels is water and heat-resistant.
(b) The labels are written in the English language, in legible character.
(c) Volume is described in metric units (e.g. gr, mL, L).
(d) The assigned Donor Unique Identifier is reflected on all labels for the purpose of traceability donor-recipient and backwards:
    i. Proprietary markings, numbers, codes or coding/labelling systems can be used as long as DHM or HMDP traceability to donor, and backwards, is demonstrated.
(e) Barcoding provides for an accurate and rapid link to critical information, eliminating manual transcription errors.

9.3.3. Milk collection labels allow traceability from collection milk container to donor. (3)(4)(6)(16)

(a) Information includes:
    i. Donor Unique Identifier (as in 5.5.2.) - if already assigned and/or in pre-printed labels by the HMB with a place to record the date of expression (when available); or
    ii. Name of donor and date of birth; or
    iii. The name of the neonate and date of birth, and hospital record number (e.g. if donation occurs in the hospital and this is the identifier used);
    iv. Date of expression; and
    v. Identification of collection facility (hospital or collection centre), where applicable.

9.3.4. Intermediate milk processing labels (or markings on containers) retain traceability from containers to donor. (3)(4)(5)(6)

9.3.5. Final distribution labels retain traceability from DHM or HMDP containers to donor. (3)(4)(5)(6)(14)

(a) Information on DHM or HMDP labels includes:
   i. The product name (e.g. Pasteurised Donor Human Milk; Freeze-dried Donor Human Milk);
   ii. The unique product identification (e.g. an alphanumeric number) that allows traceability from the distribution container of DHM or HMDP backwards to the donor;
   iii. Volume in the container (in metric units);
   iv. Sterile content (if applicable);
   v. Storage conditions (e.g. frozen until use; use within 24 hours of thawing);
   vi. Expiry date ("use by" information); and
   vii. Name and contact details of the supplying HMB.

9.3.6. Additional information is provided with the DHM or HMDP as accompanying documentation. (3)

(a) The information includes:
   i. Alternative pathogen reduction or elimination method used (e.g. other than HoP) and/or additional processing (e.g. freeze drying);
   ii. Information on protein, fat and caloric content (if available);
   iii. Handling recommendations (e.g. thawing and use within 24 hours; instructions for reconstitution);
   iv. Discard instructions of unused containers upon expiry; and
   v. 24/7 contact details to address complaints and report an adverse reaction or event.

9.3.7. Printed labels to be used in final containers of DHM or HMDP are version-controlled and in secured storage accessible only to authorised personnel. (3)

9.3.8. Additional external packaging materials withstand predicted product handling and storage conditions during the ascribed shelf life. (4)

10. Validations and verifications

10.1. Principles

10.1.1. Validations and/or verifications demonstrate that critical procedures and equipment deliver continued desired outcomes. (1)(2)

(a) The risk assessment (e.g. HACCP) identifies which equipment or processes are critical and need to be validated or verified, including:
   i. The equipment used in processing (e.g. pasteuriser), storage, testing and distribution (e.g. shippers or insulated transport containers and temperature loggers), and any equipment and software used to manage their operation and data storage;
   ii. Materials and reagents used which come into contact with human milk;
   iii. Labels, labelling equipment and tracking software;
   iv. Written procedures used by operational staff to instruct their work;
   v. Processing steps from collection to distribution where there is a risk of a detrimental effect on the safety and quality characteristics of DHM or HMDP if not performed correctly and consistently;
   vi. Analytical test methods used to assess and confirm the safety of milk donors, and the safety and quality of DHM or HMDP (e.g. sampling volumes and method, bioburden testing platforms); and
   vii. Other auxiliary processes (e.g. environmental cleaning and sanitation processes).

10.1.2. Validation planning and execution requires technical expertise.

(a) The validation process requires expertise in the processes to be executed and all items and equipment used, as well as knowledge of any applicable regulatory or technical standards or new research by those involved.
(b) Where necessary, published validation guidelines are used as references and/or external experts are mobilised.

10.1.3. The identified components within the HACCP (or equivalent risk management plan) requiring validation are recorded in a Validation Master Plan. [1][2]

(a) The Validation Master Plan consolidates the HMB risk-based approach as far as the validation of its premises, processes, equipment, safety and quality controls and staff performance.
(b) The Plan also outlines circumstances under which re-validation and verification of processed are undertaken.

10.1.4. The reproducibility of outcomes under worst case scenarios is explored in the validation plan design. [1][2]

(a) Both the normal variation of possible conditions and the more extreme 'worst-case scenarios' are included in the validation plan design:
    i. The 'worst case scenario' approach is emphasised when processes being validated relate to removing undesirable substances or potential pathogenic microorganisms.
(b) Procedures are repeated consecutively (usually for three (3) times) to demonstrate that desired outcomes are consistently achieved and confirm specified parameters can be reproducibly met.
(c) Review of documented outcomes during the validation procedure demonstrates that established safety (and quality where applicable) control end-points are consistently reached and accurately recorded.

10.2. Validation of critical equipment

10.2.1. Equipment validations are based on manufacturer's instructions, use and performance, and risk-assessment. [1][2][3]

(a) There is a procedure addressing the design (DQ), installation (IQ), operational qualification (OQ) and performance qualification (PQ) of critical equipment.
(b) Equipment is validated by the manufacturers or appropriately trained and qualified personnel using provided instructions.
(c) Pending assigned risk, specific equipment requirements and use, a re-validation plan ('how, when and by whom') is established.
(d) Variations in performance that do not comply with set safety and quality (where applicable) end-points require risk analysis and may trigger intermediate re-validations.
(e) Equipment already in use, which has been moved to another location, taken out of service, modified or undergone major repairs is re-validated before re-entry into service.

10.3. Retrospective validation or verification of an established critical process

10.3.1. Long established practices rely on ongoing safety and quality controls and past performance audits may be used to support the validation plan. [1][2]

(a) Where an established process uses a method supported by robust published evidence (e.g. HoP) and the process has been in use at the HMB for a substantial period of time,

deploying the same equipment, reagents and materials, and testing (where applicable), the retrospective data can be used to substantiate the validation process.

10.3.2. Re-validations are considered when elements of on-going manufacturing processes may affect the safety, quality or reproducibility in routine processing. [1][2][3]

(a) The need to re-validate an established process, or a step in an established process, is based on detected potential hazards and risk analysis.
(b) Trigger factors may include changes in donor cohort and milk handling, in premises critical equipment, in critical materials, in testing platforms or in testing protocols.
(c) Established practices require re-validation as part of recurring product non-compliance or as part of the investigation of an adverse event.

10.4. Validation of a new critical process or technology

10.4.1. The validation plan is developed based on the identified risk(s) to be managed and regulatory compliance requirements. [1][2][4]

(a) Before the introduction of a new critical process in the HMB, a hazard analysis exercise defines the elements requiring validation to include:
    i. Operating procedure or method;
    ii. Critical materials;
    iii. Equipment;
    iv. Sampling, testing and quality controls; and
    v. Staff training and competency.
(b) Validation studies deploy good processing practices and are conducted in accordance with defined procedures, in qualified equipment and by trained operators:
    i. The validation takes place within the operational reality of the HMB (e.g. donor cohort and batch volumes), using dedicated and fit for purpose equipment;
    ii. Pilot and full load runs are implemented in accordance with the set parameters by the HMB;
    iii. In process and post-processing controls are introduced and monitored; and
    iv. Results and conclusions are recorded.

10.4.2. Products developed using new processes or technologies are not released for distribution until validations are completed and approved. [1][2]

(a) Internal audits review validations and confirm the results are reproducible, and outcomes deliver a product compliant with the required safety and desired quality parameters (as set by the HMB).
(b) Regulatory authorities review process in external audits.
(c) DHM or HMDP are not released for distribution before approval and authorisation is received from jurisdictional regulatory authorities.

11. Contracts and Service Agreements

11.1. Contracts of services supplied to the HMB

11.1.1. Contracts with contractors and suppliers of services are in place. [1][2]

(a) Terms of contract include the specifications and requirements of the service to be provided to the HMB.

(b) The roles and responsibilities of all parties to fulfil the requirements in the service provided (e.g. cold chain maintenance during transport by the contracted courier) are clearly stated.
(c) Terms allow for on-site audits of contracted third parties to confirm their compliance with expectations.
(d) Written agreements are in place for:
    i. Testing laboratories;
    ii. Milk collection centres;
    iii. Transport companies (e.g. couriers);
    iv. Suppliers of critical equipment, consumables and reagents, cleaning products and PPE;
    v. Sterilisation services;
    vi. Suppliers of information technology;
    vii. Maintenance services; and
    viii. Contractors (e.g. auditors, product developers).
(e) The contract acceptor does not subcontract any work without written authorisation from the HMB.
(f) Contracts are dated, reviewed and renewed on a regular basis.

11.1.2. Contracts with couriers or transport services include measures to safeguard donated milk, DHM and/or HMDP. [1][2]

(a) The HMB provides clear instructions on the requirements to protect the integrity of milk containers and maintenance of required temperatures (e.g. to avoid thawing of DHM during transport).
(b) Containers are identified and the inventory in the transport load is recorded.
(c) Vehicles are clean and appropriate for the transport of perishable goods.
(d) Use of secure (tamper proof), clean and insulated transport containers (e.g. shippers, thermal bags, coolers) is recommended.
    i. The maintenance of the desired temperature in the transport containers is validated (as in 10.1.) and/or the cold-chain temperatures are controlled with data-loggers; or
    ii. Donated milk is maintained hard frozen using dry ice or frozen cool packs:
        - The use of wet ice is avoided.
(e) Hygiene principles apply to transport containers, which are cleaned and disinfected between transported batches.
    i. To contain cross-contamination in the event of unprocessed donated milk spillage:
        - Donated milk containers from different donors are transported in different transport coolers or shippers; or
        - Donated milk containers from different donors in a single transport cooler or shipper are packed into separate and identified plastic bags.

11.2. Agreements for supply of DHM and HMDP

11.2.1. Agreements for the provision of processed human milk are in place.

(b) Written agreements are in place for:
    i. Distribution to receiving organisation(s) for the use by prescribed infant(s);
    ii. Distribution of a consignment of products to a receiving organisation; and
    iii. Distribution of a product directly to a parent or legal guardian of a prescribed recipient.
(c) The roles and responsibilities of all parties in maintaining quality and safety requirements throughout the DHM and HMDP shelf life are clearly stated. This includes:
    i. The enactment of mutually agreed DHM and HMDP handling protocols and storage conditions;

ii. The responsibility of the receiving organisation to obtain consent and dispense DHM and HMDP only to consented recipients; and
iii. The responsibility of the receiving organisation to record dispensing details so as to enable traceability of dispensed products to all recipients and backwards (i.e. from recipients to dispensed DHM and HMDP):
    - This information is available to the HMB upon request, in a recall event.

(c) The agreement content may include:
i. The purpose of the agreement or contract.
ii. Terms:
    - Commencement and termination schedule;
    - Conditions for termination of the agreement; and
    - Terms for variations, renewal and extension.
iii. Transfer of donated milk or DHM and HMDP:
    - Service to be performed;
    - Schedule of transfer;
    - Distribution priorities or limitations (if any);
    - The possibility of fluctuations in supply and alternative source(s);
    - Ability for both organisations to inspect each other (where applicable); and
    - The hospital NICU, parent or guardian responsibilities in regards to the obtaining recipient's legal representative consent, the storage, dispensing (to the recipient level to ensure traceability requirements) and records of DHM and HMDP handling.
iv. Warranties and disclosures:
    - Compliance to regulatory requirements;
    - Donor and recipient consent;
    - Mutual liabilities; and
    - Donor protection around confidentiality and donor liabilities.

III. DONOR ENROLMENT

12. Enrolling donors

12.1. Donation awareness

12.1.1. Awareness campaigns about milk donation are underpinned by the safeguarding of breastfeeding, the altruistic and volunteer values of donation and the benefits of access to DHM or HMDP. [1][2][3][4][5][6][7][8][11][12][13][15][16]

(a) Donation campaigns meet the jurisdictional advertising requirements as regulated by the relevant Act.
(b) Milk donation opportunities are promoted in diverse media in a culturally sensitive manner and using appropriate language.
(c) Campaigns consider the circumstances and cultural intrinsic value assigned to breastfeeding in the community.

12.1.2. Milk donation is an option offered to women with established lactation. [9][10][11][12][13][14]

(a) Donors are enrolled at different stages of lactation, but milk donation is not considered earlier than four (4) weeks post birth and/or until lactation is well established, and meets the nutritional needs of their infants.
(b) While preference is given to a donor breastfeeding a less than six (6) months old infant, excess milk donations can be accepted from women breastfeeding an infant up to twelve (12) months of age.
(c) Potential donors whose infants are in-patients, self-identify to the health carers in the hospital or directly to the HMB.
(d) Alternatively, women breastfeeding in the community wishing to donate excess milk may contact the HMB.
(e) Bereaved mothers are offered the option to donate if this provides them with a positive outcome and there are no clinical contra-indications:
    i. The recommendation in (a) does not apply.

13. Consenting donors

13.1. Process outline

13.1.1. Donor privacy and confidentiality of information are upheld at all times. [1][5]

(a) The potential donor is interviewed in an environment that warrants privacy and confidentiality, including during telephone or video conferencing (e.g. telehealth).
(b) Access to personal details and collated social, and medical information, is secured and limited to authorised personnel.
(c) The anonymity between donor and recipient(s) is protected.

13.1.2. The potential donor is legally competent. [1][4]

13.1.3. Communication with potential donors is clear and sensitive. [4][6][7][8][9]

(a) Consent Interviews are carried out by trained HMB staff or health professionals (e.g. hospital lactation nurses) acting on behalf of the HMB. (as in 6.2.1.)
(b) Cultural values, beliefs and personal circumstances are explored and respected.
(c) The information is clearly provided in a culturally sensitive way, avoiding technical terms and in the preferred language of the donor:
    i. Suitable interpreters are available when needed.

13.2. Consent

13.2.1. Consent is informed. (1)(2)(3)(5)

(a) Detailed information is provided in clear language about how donations may be used, including:
    i. That once donated, milk is not returned to the donor;
    ii. Clinical uses;
    iii. To be commercialised by the HMB or by a contracted distributor (where applicable and if allowed under jurisdiction-specific legislation);
    iv. Possible discard and implications (or lack of) for breastfeeding own infant; (as in 13.2.5.) and
    vi. Use of discarded milk in HMB internal product development, process validations and/or external research projects approved by Human Research Ethics Committees.

13.2.2. The potential donor is informed that she will be required to undergo a medico-social screening, including serology testing. (2)(3)(4)

(a) Information discloses the need for access, and continued access while donating, to accurate medico-social information.
(b) Potential donors are instructed that changes in provided medico-social information at enrolment are to be updated as they occur, or at every ensuing donated milk deposit.
(c) Information discloses the need and reasons for mandatory serology tests at the initial donation point before donated milk can be accepted, and re-testing at set intervals (if applicable).
(d) The process of communication of results, potential impact on donation or on breastfeeding, and follow-up in case of a positive result are discussed and counselling provided:
    i. The donor is informed that the HMB, complying with specific jurisdictional requirements, is legally obliged to inform (some or all) confirmed positive results to the health authority.

13.2.3. The potential donor is made aware that consent for donation can be withdrawn and milk donation ceased at any point.

(a) The self-determination of the donor and her right to refuse to donate are respected.

13.2.4. The potential donor is informed that she will not be held liable to any adverse events or reactions detected in recipients.

13.2.5. Consent is documented.

(a) The Consent document, written in clear language, is dated and signed by the potential donor:
    i. Electronic signature is accepted where legally possible.

(b) The donor consents for the provision of past and continued personal medico-social details, serology testing (as in 14.2. and 14.3.) and for the collection, processing, storage and distribution or discard of donated milk, as deemed appropriate by the HMB.
(c) There is specific consent for:
    i. Use of discarded milk in research projects approved by a Human Research Ethics Committee; and/or
    ii. Use of discarded milk in HMB internal product development and/or process validations; and/or
    iii. Donated milk to be commercialised by the HMB or by a contracted distributor (where applicable and if allowed under jurisdiction-specific legislation).
(d) A copy of the signed consent is kept in the HMB Donor File.

14. Screening potential donors

14.1. Process outline

14.1.1. The donor screening process ensures that donated human milk provenance is appropriate for later processing and use. (1)(2)(3)

(a) The voluntary consent for screening is confirmed.
(b) There is a documented procedure defining the assessment requirements including an acceptable timeframe for the assessment.
(c) There is a procedure to obtain information on medical conditions and social behaviours that includes, at a minimum:
    i. Medico-social questionnaire and interview; and
    ii. Blood serology and NAT testing.

14.2. Medico-social questionnaire and interview

14.2.1. The medico-social questionnaire content and interview explore medical and lifestyle risk factors. (1)(2)(3)

(a) The interview is conducted by a HMB trained professional (as in 6.2.1) that understands the rationale for the questions being asked and the HMB deferral criteria. (as in 15.1.1.)
(b) The medico-social questionnaire is written and administered using clear language avoiding technical terms where possible:
    i. Suitable interpreters are available, if required.
(c) The content of the medico-social questionnaire is reviewed at regular intervals and updated to reflect emerging and re-emerging diseases and risks.
(d) Where further information is deemed necessary to establish suitability, the potential donor is invited to pursue it (e.g. GP, neonatal clinic) or where possible, authorise the HMB to do so on their behalf.

14.2.2. The medico-social interview takes place prior to the first milk deposit. (2)(4)(5)

(a) The medico-social interview takes place at a mutually acceptable time and location.
(b) The arrangements and interviews are underpinned by privacy and confidentiality.
(c) Face to face or telehealth interactions are preferred.
(d) Donor identity is confirmed at the time of the first milk deposit.

14.3. Serology and Nucleic Acid Amplification Technique (NAT) testing

14.3.1. Infectious disease blood screening is performed as close as possible to the first milk expression for donation. (1)(3)(4)(5)(6)

(a) Donors are reminded that serology and NAT testing is mandatory and specific consent is confirmed.
(b) Antenatal serology and/or NAT tests results are not suitable.

14.3.2. The serology and NAT testing regimen reflects current HMB policy and regulatory requirements regarding transmission of infectious diseases. (1)(2)(3)(4)(6)(7)(8)(9)

(a) The recommended testing regimen includes testing for:
    i. Human Immunodeficiency viruses (HIV type 1 and type 2 antibodies and RNA);
    ii. Hepatitis B viruses (surface antigen and DNA);
    iii. Hepatitis C virus (antibody and RNA);
    iv. Human T–Lymphotropic viruses types 1 and 2 (HTLV 1 and 2 antibodies); and
    v. Syphilis (antibodies).
(b) Other tests may be conducted pending provenance, recipient needs and processing pathogen reduction or elimination efficiencies (e.g. Cytomegalovirus - CMV).
(c) Consideration for re-testing of on-going donors at set intervals (e.g. every three (3) months) as a precautionary measure to capture an emerging disease, or if relevant donor medico-social circumstances change, is recommended.
(d) Efficacy and currency of the HMB testing regimen is reviewed:
    i. As the donor cohort changes (e.g. new catchment area);
    ii. Where a relevant emerging or re-emerging infectious disease is detected in the community and more specifically, in the potential or on-going donor cohort;
    iii. As part of the process validation during the implementation of a new processing method or step or equipment;
    iv. Where there are changes in testing assays; and
    v. Where there are changes in the regulatory testing requirements.

14.3.3. The serology and NAT testing is conducted in an accredited testing laboratory and results are managed accordingly. (1)(2)(3)

(a) The testing facility performs screening tests using documented procedures, qualified equipment and validated methodology (including acceptance criteria for individual tests):
    i. Aliquots of tested material are stored as per regulatory requirements.
(b) Test results are communicated clearly between the testing laboratory and the HMB, and appropriate interpretive comments are provided:
    i. Written results follow the verbal communication between the laboratory and the HMB.
(c) Manual and electronic result entries in HMB Donor Records or results registries are confirmed by two staff members.
(d) The HMB has a protocol to manage screening blood results to include:
    i. Interpretation of received screening test results;
    ii. Requisition of confirmatory testing (where applicable);
    iii. Decision-making algorithm for the deferral of a potential donor (and previously expressed milk) based on screening results and/or confirmatory testing;
    iv. Disclosure of results and referral of potential donor for further clinical follow-up and care (where applicable); (as in 15.1.3.)
    v. Provision of support related to continuation or interruption of breastfeeding; and
    vi. Notification of state and territory relevant health authority of positive confirmatory results (where applicable).

15. Donor acceptance or deferral

15.1. Process of ascertaining suitability

15.1.1. There is a documented procedure describing the donor eligibility assessment process. [1][2][3][4][6][7][9][10]

(a) Eligibility, and continued eligibility, is based on the premise that:
   i. There is voluntary, informed and signed consent; (as in 13.2.5.)
   ii. Donation will not be detrimental for the donor wellbeing;
   iii. The lactating woman has sufficient milk to provide adequate nutrition to her infant;
   iv. The risk of a medical condition, social behaviour, or exposure to toxic elements affecting the safety or quality of the donated milk is non-existent, minimal or can be mitigated; and
   v. Changes in medico-social conditions are informed by the donor and may require reassessment regarding eligibility.

(b) The HMB has a Donor Eligibility Resource that establishes donor permanent or temporary deferral criteria.
   i. The Donor Eligibility Resource addresses the wellbeing of the donor, her infant and of household contacts to mitigate the risk of potential contaminants affecting the quality and safety of donated milk; and
   ii. This includes assessing:
      - Infectious diseases - acute and chronic;
      - Acute and chronic medical conditions;
      - Medication;
      - Vaccinations; and
      - Social risk (e.g. behaviour, diet, over the counter medication, workplace exposure to toxic substances, etc.).

(c) The Donor Eligibility Resource is updated at intervals to reflect changes in risk (e.g. emerging and re-emerging disease transmission):
   i. Donor eligibility is reassessed against revised or new medico-social criteria prior to processing of any collected donor milk, or release of DHM or HMDP.

15.1.2. Medico social information is reviewed against established suitability criteria.[1][2]

(a) Qualified, trained and competent HMB delegate(s) (as in 6.1.1. and 6.2.2.) establish the eligibility, or the temporary or the permanent deferral status of potential donors.
(b) Suitability is assessed against the established HMB criteria based on information collated from the medico-social questionnaire interview responses, complementary medico-social information and the results of screening (immunoassays and NAT testing).
(c) There is an established consultation pathway with expert members of the HMB Advisory Committee and/or with external subject matter experts to support the HMB delegate(s) in their decision making process.
(d) As a precautionary measure, irrespective of negative blood screening results, a donor is deferred if her lifestyle or medical risks suggest that she could harbour harmful substances in her milk.

15.1.3. Support and reassurance is given to a potential donor if she, or her milk, is found not to be eligible. [4][5]

(a) Medico-social findings leading to deferrals (including confirmed serology) are communicated to potential donors, in a face to face or telehealth scheduled appointment:
   i. By HMB qualified staff; or

ii. By the clinician caring for the mother or infant, if the donation occurred in a hospital; or
iii. By the donor's GP or referred infectious disease specialist.

(b) The donor understands the reasons for deferral (temporary or permanent) and is reassured that her milk, but for specific circumstances, remains the best nutritional source for her own infant.
(c) If there is a medical contra-indication for continuing breastfeeding, or concerns on the welfare of own infant, the donor receives adequate explanation, support and the instructions on how to receive further counsel from appropriate health professionals.
(d) The donor is referred for further clinical follow-up and care where applicable.

15.1.4. Any milk donated by a donor found not to be eligible is segregated, excluded from processing and disposed of. [5]

(a) Reflective of donor consent, discarded donated milk is used in HMB quality controls and validations, or released for use in an approved research project. (as in 13.2.5.)

15.1.5. The HMB determines individual circumstances under which milk expressed before a donor becomes eligible is accepted. [1][8]

(a) The medico-social interview ensures that relevant information during the milk collection period is captured and acceptance criteria are met.
(b) Accumulated milk expressed before confirmation of donor eligibility is accepted if it was appropriately collected, identified and stored in accordance to HMB requirements.
(c) Donated milk is not processed until donor suitability is confirmed.

16. Continued donor eligibility

16.1. Assessment

16.1.1. Donors are informed of the importance of updating changes in their general health, social behaviour and in the household. [1][2][3]

(a) Donors are asked about their general health, of their partners, and of household members, including the breastfed infant at each milk deposit.
(b) Donors are also asked about lifestyle changes at each milk deposit.
(c) Donors are reminded to advise the HMB on relevant post donation illness.

16.1.2. The HMB authorised delegate (as in 6.1.1. and 6.2.2.) reviews the recorded changes in medico-social circumstances against the established HMB acceptance criteria and determines whether a temporary or permanent deferral is warranted. [1][2][3][4][5][6][7][8]

(a) The assigning of a permanent or temporary deferral (including duration) varies according to circumstances and medical considerations (as established in the HMB Donor Eligibility Resource).
(b) The review also considers acceptance or discard criteria for expressed milk during or preceding the assessed event.
(c) The donor is assured that the reasons for temporary or permanent deferral as a donor do not necessarily impact on the quality of her milk or on her capacity to breastfeed:
i. The donor receives adequate explanations and is referred for follow-up with appropriate health professionals (if necessary).

IV. MILK DONATION

17. General considerations

17.1. Donation opportunities

17.1.1. The HMB enables donation in the hospital, at affiliated collection centres and at the donor home. [5][6]

17.1.2. There are documented procedures and records for all processes related to milk donation. [1][2]

(a) Irrespective of provenance, there is a formal and documented process to inform, enrol, consent, and assess donor suitability. (as in 12.; 13. and 14.)
(b) There is a documented process to educate donors about hygiene, expression technique and storage requirements of milk expressed for donation. (as in 17.3.)
(c) There are documented processes for the transport of donated milk from collection sites or the home to the HMB. (as in 20.)
(d) There are documented procedures related to the receipt of donated milk at the HMB. (as in 22. and 23.)
(e) Operational efficiencies may establish a minimum volume for each deposit or collected batch of donated milk.

17.2. Donor support on lactation

17.2.1. Ongoing support is provided to all active donors, according to their individual needs. [2][3]

(a) Support is provided by the HMB trained staff or lactation specialists face to face, via teleconferences or by telephone, at a mutually agreed time, and where needed and possible.
(b) This includes:
    i. Dietary requirements;
    ii. Maintaining lactation;
    iii. Instructions on acute illness, medication, smoking, alcohol intake, or of other substances, and potential impact on breastfeeding and milk donation; and
    iv. Self-care and emotional support.
(c) Provision of support is extended to deferred donors, where possible.

17.3. Good hygiene practices

17.3.1. Training in good hygiene practices is provided to all new donors. [2][4][7]

(a) The importance of strict hygiene at all times is emphasised.
(b) Training is provided by competent staff, familiar with the HMB protocols on expression, storage and transport of donated milk.
(c) The training is preferably face to face or via video-conferencing, at a mutually suitable time.
(d) Verbal information is supplemented with written instructions and infographics.

17.3.2. Training elements include:

(a) Overall personal hygiene, including local breast and nipple hygiene and skin care, avoiding the use of skin products on breast surfaces that are unsuitable for ingestion or may contaminate the milk.
(b) Hand hygiene immediately before expressing or handling milk containers, including washing with soap or antiseptic solution and water, and drying with a clean cloth or disposable paper towels.
(c) Prevention of foreign body contamination, including the possible use of protective gown and hair protection.
(d) Handling of milk containers to avoid contamination of inner surfaces and lids.

17.3.3. Complementary training and support is provided to donors who repeatedly donate milk that does not meet microbiology requirements or other testing criteria. [2][3][9]

17.4. Milk expression and collection

17.4.1. Hand and manual or electrical pump expressed milk is accepted. [2][3][4][7][8][9]

(a) Milk collected via drip collection ('drip milk') is not considered suitable for donation.
(b) The first volume of expressed milk can be included.
(c) Pumps and tubing (and cups, when not single-use) are cleaned and sanitised as per HMB protocols or manufacturer's instructions.
(d) Sharing of milk pumps is avoided.

18. Expressing milk in the hospital and affiliated collection centres

18.1. General considerations

18.1.1. There are dedicated spaces for milk expression. (as in 7.2.2) [1][2]

18.1.2. In the context of milk donation, staff in the affiliated hospitals and collection centres follow protocols established in consultation with the HMB. [3][4][6][7]

(a) Where needed, the HMB provides guidance and training to staff in hospitals or in affiliated collection centres that are involved in the collection, identification and storage of donated milk until the transfer to the HMB.
(b) Staff provide donors the necessary training in hygienic practices and provide support towards effective lactation. (as in 17.2 and 17.3.)
(c) Milk is collected in containers provided or approved by the HMB: (as in 9.2.)
    i. Use of a fresh container per expression is recommended (as "top up" of partially filled containers may increase contamination rates through recurrent container handling and unwarranted temperature variations); and
    ii. Containers are not filled to the maximum capacity before freezing.

18.1.3. Collected donated milk is transferred as soon as possible to an access controlled area (e.g. Milk Room), for immediate identification. (as in 9.3.3) [2][5]

18.1.4. Collection details are transcribed into a Log Book. [2][3]

(a) Confidential and access restricted donation records are maintained at each facility, and include:
    i. Donor details;

ii. Expression dates (and the number of donated milk containers/date), including the name of the staff member accepting and logging in the milk donation; and
iii. Any additional information that may affect the safety or quality of the donated milk (e.g. donor unwell, container failure, deviations in storage temperatures).

(b) Collection records are made available, upon request, to the HMB.

18.2. Temporary storage in the hospital or in the collection centre

18.2.1. The identified donated milk container is immediately frozen in a dedicated, access controlled and temperature monitored freezer. (3)(4)(7)

(a) Milk is stored frozen at or below –18°C. (as in 8.2.3)
(b) If an emergency situation requires temporary storage under refrigeration (e.g. freezer break-down and an alternative freezer is not available) milk is stored in a temperature monitored refrigerator (at or below+5°C). (as in 8.2.3)
i. The refrigerator is dedicated to the storage of human milk, is locked and/or placed in an access secured area; and
ii. Chilled milk is transferred from refrigerator to freezer within twenty four (24) hours.

19. Expressing milk in the home

19.1. General considerations

19.1.1. Donors follow HMB instructions for good hygiene and procedures related to milk expression and storage in the home. (1)(2)(3)(4)(6)(7)

(a) Donors will receive appropriate training and additional written instructions on the HMB recommended personal hygiene practices (as in 17.3.), milk expression principles (as in 17.4.), the importance of hygienic handling of containers, their identification and the cleaning and disinfection of pumps (if used) in the home.
(b) Expressed milk is collected in containers provided by the HMB at the time of enrolment or only in approved containers: (as in 9.2.1.)
i. Containers are not filled to their maximum capacity (due to content expansion on freezing); and
ii. A different container is used at each expression event as "top up" is not recommended.
(c) The donor identifies the container immediately after the milk is collected with indelible markings or using the HMB pre-printed labels, when available, including:
i. Donor name and date of birth; and
ii. Date of milk expression.
(d) The expressed milk is not heat treated in any way (including warming, scalding, boiling, or thawing after freezing).
(e) Donors are reminded to update the HMB regarding changes in medico-social status and lifestyle as often as needed to ensure continued suitability:
i. The donor is asked to retain a notebook at the home and enter any issues arising while donating: during expression (e.g. pump failure); handling of containers (e.g. leaks), storage (important temperature variation; partial defrost) or medico social and lifestyle changes (e.g. nipple discharge, medication); and
ii. The collated information is shared with the HMB at the time of donated milk batch deposit:
- The HMB has a form or standard questionnaire to record medico-social changes in ongoing donors, at the time of donated milk deposits.

19.2. Temporary storage in the home

19.2.1. Identified containers with expressed milk are frozen as soon as possible.[1][2][3][4][5]

(a) Milk containers are placed into larger containers or bags to minimise risk of contamination from other foods.
(b) If access to the freezer is not possible due to an emergency or unpredicted situation (e.g. lack of storage capacity), freshly filled containers can be placed at the back of a shelf of the refrigerator, for not more than 24 hours:
    i. The HMB is contacted for further instructions.

19.2.2. Storage temperatures are monitored. [1][3][5]

(a) Donor monitors that milk remains hard frozen.
(b) Brief fluctuations in temperature secondary to opening the doors or self-defrosting are acceptable as long as the milk remains hard frozen.
(c) Any concerns with the storage temperatures or milk condition are discussed with the HMB or collection centre staff.
(d) An emergency plan for power failure in the home is discussed.
(e) Once frozen, milk is not to be refrozen in the event of partial thawing.
    i. Contacting the HMB or collection centre staff is recommended before discard.

20. Transferring donated milk to the Milk Bank

20.1. General considerations

20.1.1. Donated milk is transferred to the HMB as soon as the collected donated milk reaches an agreed volume. [1][2][3][5]

(a) Irrespective of volume, the donated milk batch is transferred to the HMB within 10 weeks from the earliest date in any container within the specific donated milk batch.
(b) If further donation is deferred, the already expressed donated milk is transferred as soon as possible to the HMB.
(c) Transfer is organised by the donor or by the HMB, using private transport, HMB vehicles or contracted couriers: (as in 11.1.2)
    i. Milk is collected from the hospital, collection centres or from the donor home at mutually agreed intervals and times, informed by the volumes and time since milk expression.
    ii. Donors may deposit donated milk at the HMB or at the affiliated collection centre following HMB instructions:
        - Milk is transferred from the home in clean, insulated transport containers (e.g. thermal bags, coolers);
        - The milk is maintained hard frozen using frozen cool packs; and
        - The use of wet ice is avoided.
(d) Deposits arriving at the HMB are checked against transport inventory and identification details entered into the respective donor Donation Records. (as in 5.5.2.)

20.2. Transport conditions

20.2.1. Contracted courier and transport services use appropriate vehicles and transport containers. (as in 11.1.2) [4][5][6][7][8]

20.2.2. Milk is transferred from the home to the HMB in clean, insulated transport containers (e.g. thermal bags, coolers). [7][8]

(a) The milk is maintained hard frozen using frozen cool packs, as instructed by the HMB.
(b) The use of wet ice is avoided.

V. PROCESSING

21. General considerations

21.1. Documented procedures and records

21.1.1. There are documented SOPs that define materials, equipment, processes and process controls used in the processing of DHM and HMDP. (as in 5.1.; 5.3. and 5.5.)

21.2. Staff

21.2.1. Staff are trained and competent to undertake assigned tasks as per HMB protocols. (as in 6.1.and 6.2.)

21.3. Premises and equipment

21.3.1. Access controlled premises are dedicated to the processing activity, designed and maintained accordingly. (as in 7.1. and 7.3.)

21.3.2. Potential contamination of donated milk, DHM and HMDP is curtailed by controlling staff flows, the presence of minimal staff numbers required, and appropriate personal hygiene and product protection measures (e.g. working in a laminar flow cabinet during decanting and aliquoting).

21.3.3. Dedicated equipment is used, maintained and cleaned according to documented procedures. (as in 8.1.and 8.2.)

22. Receiving donated milk at the Milk Bank

22.1. Receipt

22.1.1. The deposited containers are identified with the HMB assigned Donor Unique Identifier that maintains traceability to the donor. (1)(2)

(a) Information on deposited container labels is complemented with the HMB assigned Donor Unique Identifier and with a deposit batch identifier (if applicable).
(b) The number of deposited milk containers and respective volumes, date of expression, and assigned batch identification are registered in the respective donor Donation Records.
(c) Where milk was expressed prior to screening and acceptance of a donor, the milk is segregated and identified as not to be used until the donor is approved:
    i. The HMB will reconcile the donated milk with a now eligible donor and re-label the container(s) with the assigned Donor Unique Identifier.

22.1.2. Received containers are segregated in a holding quarantine freezer until donated milk compliance with HMB criteria is confirmed.

23. Accepting or rejecting donated milk

23.1. Evaluation process

23.1.1. There is a SOP describing the verification of consent and donor suitability, examination of deposited milk container(s), acceptance and quarantine storage before further processing, or rejection and segregated storage for disposal.

23.1.2. Consent and donor suitability is confirmed.

(a) There is a copy of the written consent in the Donor File confirming donor authorisation for the HMB to further process, store and distribute the donated milk. (as in 13.2.)
(b) Donor suitability (or on-going suitability) is confirmed, including:
    i. Favourable medico-social and serology/NAT testing outcomes at enrolment; (as in 14.1)
    ii. Favourable results in repeat serology re-testing (if applicable); (as in 14.3.2.) and
    iii. Consideration whether any updated medico-social and lifestyle information requires temporary or permanent deferral of donation. (as in 16.1.1)

23.1.3. Containers with donated milk are correctly identified and intact. [1][4][5][6][7]

(a) Containers are compliant to HMB requirements. (as in 9.2.1.)
(b) Label information includes the required information. (as in 9.3.3.)
(c) Containers are clean, have no cracks or detected leaks.
(d) Caps are tightly fit and have not been tampered with.

23.1.4. Content is compliant to temperature requirements and no abnormalities are detected at visual inspection. [2]

(a) The milk arrives at the HMB hard frozen:
    i. There is no account of issues during the storage in the hospital, collection centre or home before the delivery to the HMB.
(b) Gross contaminants are not detected.
(c) Abnormal colour requiring further investigation is not noted.

23.2. Accepted or rejected status

23.2.1. An authorised and competent person (as in 6.1.1. and 6.2.2.) reviews the inspection process, considers the compliance status, and accepts or rejects donated milk. [1][8]

(a) The decision to reject a donation batch, or a number of containers in a deposit of donated milk, is informed by the HMB established donor eligibility criteria, medico-social updates, and the findings at inspection upon donated milk receipt.
(b) Advice from senior line managers and specialists is sought when required. (as in 3.4.5.)

23.2.2. In the event that a non-compliance is detected, the donor is informed.

(a) Provision of options for increased emotional, lactation and technical support is considered by the HMB. (as in 15.1.3.)
(b) Causes and timeframes for temporary or permanent deferrals are discussed with donors. (as in 16.1.2.)

23.3. Storage or discard of donated milk

23.3.1. Accepted donated milk containers are identified and stored under controlled quarantine conditions. [2][3][5][6][7][8][10]

(a) Containers with donated milk accepted for further processing are identified accordingly.
(b) Containers are stored frozen in dedicated pre-processing quarantine freezers, under monitored conditions.
(c) Frozen donated milk is further processed within three (3) months of the date of expression or is discarded.

23.3.2. Rejected donated milk containers are segregated immediately. [1][7][8][9]

(a) Rejected containers are identified as such and segregated for discard.
(b) Pending donor consent and risk assessment, consideration is given to the future use of the rejected donated milk in internal validation processes or the distribution to ethically approved research projects. (as in 13.2.5.)
(c) Rejected donated milk containers are discarded as per HMB protocols:
    i. Containers to be used in internal validation processes or distributed for research are segregated in a dedicated, access controlled freezer located in a separate area in the HMB.

23.3.3. Accept or reject status is registered in the donor respective Donation Records.

(a) The rejection is registered in the HMB Discard Records. (as in 5.5.5.)
(b) The reason(s) for rejection and disposal (discard or other use) are registered.

24. Thawing donated milk

24.1. Process

24.1.1. Complete thawing under controlled temperatures at or below +5°C, is recommended. [1][2][3][4][5][6][7][8][9][10]

(a) The time required for complete thawing of a batch of approved containers at or below +5°C is validated.
(b) Rapid thawing at +37°C using orbital shakers, food grade thawing cabinets or water bath require a validated process and temperature monitoring to assure the milk temperature remains at or below +5°C while thawing.
(c) Seepage of water into containers or bags is prevented when a water bath is used.
(d) Microwave use is not recommended.

24.2. Temporary storage post thawing

24.2.1. Thawed milk is refrigerated and processed within 24 hours. [1][2][3][5][6][8]

(a) Once thawed, the unprocessed milk is maintained at or below +5°C in the assigned refrigerator for the temporary storage of unprocessed donated milk until further processing.
(b) Thawed milk is not refrozen.
(c) Thawed milk is discarded if not further processed (e.g. pasteurised) within 24 hours since thawing is complete:
    i. The storage of thawed milk at or below +5°C beyond 24hours requires the HMB to validate that microbial load and detected endotoxin levels remain within safe levels.

25. Pooling and aliquoting donated milk

25.1. Handling conditions

25.1.1. Milk is decanted and aliquoted in an environment that protects the milk from direct exposure to sunlight, heat, microbial, chemical and physical contamination. [1][2][3][4][5]

(a) Decanting and aliquoting take place within a biosafety cabinet Class II or in an isolator. (as in 8.2.1.)
(b) The milk temperature is maintained at or below+5°C by limiting time out of refrigeration during decanting, sampling and aliquoting.
(c) Trained and competent staff use aseptic technique while handling the milk. (as in 6.2.3.)
(d) The processing area and contact surfaces are cleaned and sanitised with food approved sanitisers between the handling of different donor milk batches: (as in 7.1.2. and 8.1.6.)
    i. Monitoring confirms adequacy of environment cleaning and sanitation.

25.2. Pooling considerations and process

25.2.1. Pooling donated milk from a single donor is recommended. [6][7][8][9]

(a) Different donor milk batches are not decanted, aliquoted or sampled within the same environment (e.g. biosafety cabinet or isolator), at the same time. (except as in 25.2.2.)

25.2.2. Pooling milk from multiple donors should be justified by improved quality, and safety issues addressed in the risk management plan. [4][5][6][12]

(a) Perceived risks are mitigated by:
    i. Limiting the number of donors per multiple-donor milk pools to no more than six (6) individual donors;
    ii. Increased scrutiny in the medico-social donor eligibility investigation – at enrolment and on-going - using updated infectious diseases prevalence and surveillance tools;
    iii. Repeat blood screening tests (at 3 months minimum interval) for on-going donors;
    iv. Use of validated protocols for representative sampling and microbiology testing in the pre and post-processing pathogen load calculation, including consideration for dilution and accurate sampling technique;
    v. Implementation of effective handling and pathogen reduction or elimination in-process controls;
    vi. Verification that the pathogen reduction or elimination process delivers, at a minimum, the agreed efficiency in reduction or elimination of pathogenic microorganisms and virus; (as in 26.1.1) and
    vii. Efficient multiple donor pool product traceability (i.e. all DHM or HMDP units from recipients to all donors in the original pool, and backwards), as demonstrated in 'mock' product recalls.

(b) Additional risk mitigating measures may include (collectively or not):
    i. A precautionary approach to serology screening results;
    ii. Certification of pre-processing milk purity;
    iii. Acceptance of lower thresholds or no growth for specific microbial cohorts (e.g. for spore forming and/or toxin producing bacteria) in pre-processed milk;
    iv. Sterility as a requirement in originated DHM and/or HMDP;
    v. Evaluation of post-processing milk toxin levels;

vi. Undertaking work in environmentally controlled conditions (e.g. classified rooms).

25.3. Pathogen assessment in donated milk pools

25.3.1. Representative samples are taken from each milk pool for assessment. [2][3][5][6][7][8]

(a) Testing is undertaken by an accredited laboratory (e.g. a NATA (Australia) or ANZ (New Zealand) accredited food testing laboratory).
(b) Sampling is undertaken using the recommended procedure of the accredited microbiological testing laboratory, established in collaboration with the HMB.
(c) The number of containers sampled, and the volume in each sample, provide for the appropriate representation of the milk pool.
(d) Re-evaluation of testing protocols is triggered by changes in collection, pooling regimen (single or multiple donors), equipment, or process.

25.3.2. There are pathogen acceptance criteria for unprocessed milk. [3][5][6][7][8]

(a) The unprocessed milk batch is **accepted** for processing if microorganism growth is:

- ≤ 10^4 cfu/ml *Staphylococcus aureus*
- ≤ 10^4 cfu/ml Enterobacteriacea
- ≤ 10^5 cfu/ml total viable organisms

(b) The HMB pathogen acceptance criteria in unprocessed milk reflect assessed risk and consider the efficacy of the ensuing pathogen reduction or elimination process:
   i. The HMB may expand the cohort of tested microbes and their specific exclusion criteria; and
   ii. The HMB may use stricter cut-off levels (e.g. no detection of heat-stable endotoxin producing bacteria) based on the efficiency of the ensuing pathogen reduction or elimination process and vulnerability of the targeted recipient population.
(c) Non-compliant unprocessed milk pools or specific containers are disposed of and this is entered in the HMB Discard Records (as in 5.5.5.) and the respective donor Donation Records.

25.3.3. Communication with testing laboratory is clear and collaborative. [2][6]

(a) Results are clearly communicated and recorded.
(b) Verbally communicated results are followed by written documentation and manual entries in the processing batch records are checked by two staff members.
(c) Instances of significant and unusual contamination are investigated.
(d) The HMB and the testing laboratory establish the need for further specialised testing.
(e) Recurrent deviations trigger risk assessment and a review of donor milk expression technique, storage and transport conditions, milk handling and testing protocols.

25.4. Aliquoting donated milk pools

25.4.1. Pooled milk is aliquoted into fit for purpose containers. (as in 9.2.2) [4][5][7]

(a) Containers are uniquely identified. (as in 9.3.4.) [2][7]
(b) Aliquoted unprocessed milk is refrigerated (at or below+5°C) until further processing. (as in 24.2.1.)

25.5. Records of pooling and aliquoting donated milk

25.5.1. The identification of the donor(s) included in the pool and the number of resulting aliquots are recorded in the Processing Records. (as in 5.5.3.) [2][7]

(a) The information includes:
  i. identification of donated milk containers mixed to form the pre-processed milk pool:
    - The earliest date of milk expressed in the pool is to be used as one of the parameters to establish DHM batch shelf life. (as in 29.)
  ii. The total pool volume, and the volume and number of generated pre-processed aliquots; and
  iii. Testing and results.

26. Pathogen reduction or elimination process and controls

26.1. Principles

26.1.1. The HMB uses a validated pathogen reduction or elimination process, as in: [1][2][3][4][5][6][7][8][9]

(a) Holder Pasteurisation (HoP) by which the milk or milk product is:
  i. Rapidly heated to a temperature of not less than +62.5 °C; and
  ii. Retained at that stable temperature for not less than thirty (30) minutes; and
  iii. Cooled from +62.5°C to +21°C within the maximum interval of two (2) hours, and from +21°C to +5°C, in the next four (4) hours or faster.

(b) Other heat treatment method using any other time and temperature combination validated to have **equal or greater** lethal effect on virus and bacterial contaminants – including spore forming - as in HoP. (note consideration to changes in milk quality as in 26.1.2. and 28.1.3.)

(c) Other process of pathogen elimination or reduction using technology that provides an **equal or greater** lethal effect on virus and bacterial contaminants - including spore forming, as in HoP. (note consideration to changes in milk quality in 26.1.2. and 28.1.3.)

(e) A less efficient pathogen reduction or elimination process **may** be tolerated if:
  i. Justified by strong evidenced benefits to nutritional quality and/or bio-activity; **and**
  ii. The increased risk is efficiently mitigated by:
    - Effective donor exclusion criteria based on incidence and prevalence of viral diseases and targeted additional screening (e.g. CMV);
    - Lower or nil levels of endotoxin producing pathogens in pre-processed donated milk;
    - Sterility levels required post treatment.

26.1.2. The pathogen reduction or elimination process safeguards the nutritional and bio-active characteristics of human donor milk to the greatest extent possible. [1][12][13][14][15]

(a) The dyad maximal efficiency in bioburden reduction and minimal alteration of the milk characteristics underpins the adopted method.

(b) The process should trigger **equal (or lesser)** changes in macro and micro nutrients and bioactive components as those following HoP.

26.1.3. The pathogen reduction or elimination process, the controls and expected outcomes are documented in a SOP. (1)(3)(6)

(a) The implementation of any pathogen reduction or elimination process requires a hazard analysis, identification of critical points, controls, and proposed mitigating measures.
(b) The SOP is validated by the HMB to demonstrate repeatability of predicted outcomes (as in 10.4.), and will describe:
    i. Set performance parameters for the equipment (e.g. min-max cycle temperatures, number and duration of cycles, applied chamber pressures, etc.);
    ii. In-process controls (e.g. equipment in-built monitoring; sensors in proxy containers); and
    iii. Post process safety and quality controls including frequency of testing, sampling criteria, and method of analysis.
(c) The equipment used is:
    i. Dedicated and fit for the processing of human milk; and
    ii. Pilot and full-scale tested within the HMB operational realities (e.g. milk volumes).
(d) The ability of the proposed pathogen reduction or elimination process to achieve the minimal required safety standards and the desired milk quality is audited by the enforcement agency before the resulting DHM is authorised to be distributed.

26.1.4. Milk containers that are processed together, configure a pathogen reduction or elimination processing batch. (3)(4)(5)(6)(7)(8)(9)(10)

(a) In-process controls are confirmed to have been compliant during the completed run.
(b) Resulting DHM containers will be identified in a manner to allow their traceability to the processing batch, and to the milk donor(s).
(c) Cooled containers are transferred to identifiable post pathogen reduction or elimination quarantine storage freezers until release for distribution (or additional processing, when applicable).
(d) Containers from non-compliant cycles are discarded.
(e) Process reviews and mitigating measures are implemented where appropriate.

26.1.5. Aliquoting or re-aliquoting of content following the pathogen reduction or elimination requires work in a controlled environment and aseptic handling to prevent re-contamination.

(a) Aseptic technique is used.
(b) The work environment has a controlled quality of air (e.g. biosafety cabinet or isolator)(as in 8.2.1.), with a controlled background.
(c) There are in-process controls to monitor the hazard of re-contamination (e.g. open culture plates).
(d) There is representational sampling and bioburden testing to confirm release criteria is maintained. (as in 26.2.)
(e) The resulting containers are labelled to retain traceability to the processing batch (and the donor(s)), and the re-aliquoting step recorded in the Processing Records. (as in 5.5.3.)

26.2. Pathogen assessment post-reduction or elimination process

26.2.1. Testing for residual pathogens at the completion of each pathogen reduction or elimination cycle, or following re-aliquoting (where pertinent), is recommended. (3)(4)(5)(6)(8)(10)

(a) Testing protocol sensitivity and specificity is developed and validated by the accredited laboratory where testing is performed (e.g. NATA accredited food safety testing laboratory).
(b) Testing sensitivity and specificity is re-evaluated at agreed time intervals and following an adverse event.
(c) Testing protocol review is triggered by changes in equipment, or pathogen reduction or elimination process (pasteurisation or other).

26.2.2. The sampling method, number and volume of samples provide appropriate representation of the pooled milk in each processing batch.

(a) Representative samples are :
    i. Taken from each 'single donor' pool or from each 'multiple donor pool' within the processing batch; and
    ii. Chosen containers represent the 'worst case scenario' in the equipment vault or chamber (e.g. mapped colder point in the pasteuriser chamber).
(b) Sample numbers and volume/sample is established in collaboration with the testing laboratory.
(c) Samples are labelled with details linking to the respective originating container(s).
(d) Any container opened for sampling is discarded.

26.2.3. Communication with testing laboratory is clear and collaborative. [9]

(a) Results are clearly communicated and recorded.
(b) Verbally communicated results are followed by written documentation and manual result entries in the Processing Records are checked by two staff members.

26.2.4. The residual pathogen acceptance criteria are: [1][2][4][5][6][7][8][9][10][11]

- total viable count of ≤ 1 cfu/ml
- *Listeria monocytogenes* and *Salmonella spp*. not detected in 25 g

(a) The HMB may expand the cohort of tested microbes and specific exclusion criteria.
(b) The HMB may use stricter cut-off levels (e.g. sterility) based on the vulnerability of its targeted recipient population.
(c) Instances of significant and unusual type or level of contamination are investigated.
(d) Communication with the laboratory establishes need for further testing and identification.
(e) Recurrent deviations trigger risk assessment and review of milk expression, milk handling and testing protocols.

26.2.5. Non-compliant containers or processed batches are segregated and discarded.

26.3. Pathogen reduction or elimination process records

26.3.1. Equipment performance data (e.g. pasteurisation cycle temperature controls) are recorded as part of the processing batch details.

(a) Equipment performance as per set parameters (e.g. temperature) is monitored during each pathogen reduction or elimination procedure: (as in 8.2.2.)
    i. In-built equipment sensors and/or sensors inserted in proxy containers are used.
(b) Deviations in process are risk assessed, addressed where required, and measures recorded.

26.3.2. Identification details of resulting DHM containers and respective volumes from the processing batch are registered in the respective donor(s) Processing Records.

(a) DHM containers are identified with the processing batch identification number and the individual container identification (e.g. DHM unit number).
(b) The identification on the DHM containers allows traceability to the pathogen reduction or elimination processing batch, and to the individual donor(s) within.
(c) Discard of non-compliant container or batches, is recorded.

26.3.3. Testing samples, tests performed and results are recorded as part of the processing batch details, in the donor(s) Processing Records.

27. Additional processing into Human Milk Derived Product (HMDP)

27.1. General considerations

27.1.1. Processing in addition to the pathogen reduction or elimination treatment is implemented, with the purpose of changing the original nutritional and bioactive composition, or concentration, of the human milk. [1][2][3][4][5][6][7][8][9]

(a) In the context of the Guidelines, the generated products are addressed as HMDP and include: freeze dried milk in powder form for reconstitution w/w; human milk derived fortifier in liquid form or powder form; high fat (cream) or low fat human milk.
(b) Additional processing may include, but is not limited to:
    i. Freeze drying; or
    ii. Freeze drying and deliberate alteration of nutrients; or
    iii. 'In house' addition of freeze dried human milk to DHM; or
    iv. Alteration of fat content (e.g. homogenisation; ultrafiltration); or
    v. Addition of constituents (e.g. nutrients, emulsifiers, etc.)
(c) The additional processing step may precede or follow the reduction or elimination process, where:
    i. Freeze-drying is not considered a pathogen reduction or elimination method.

27.1.2. The additional processing protocols are described in SOPs integrated into the safety and quality management program. [1][3]

(a) The implementation of any additional processing requires a risk analysis, identification of critical points, controls, and proposed mitigating measures.
(b) The resulting HMDP:
    i. Retains, at a minimum, the equivalent pathogen release criteria to DHM (as in 26.2.4).
    ii. Has the suitable nutritional and bioactive composition for the intended use (e.g. fortification) and the recipient cohort (e.g. preterm or term infant feeding).
    iii. Has the appropriate physical characteristics (e.g. final water activity; osmolality upon reconstitution) as targeted by the HMB.
    iv. Added nutrients or additives (e.g. emulsifier) are food-grade and levels are within safe concentrations for the targeted recipients.

27.2. Requirements

27.2.1. Additional processing takes place within a suitable environment, using fit-for purpose equipment, by competent staff, following the validated SOP.

27.2.2. Quality and safety compliance requirements are established in process validations and verified at set intervals. [5][9][10][11][2][13][14]

(a) The compliance to maximum pathogen contamination and nutrient and bioactivity composition is verified by:
    i. In-process controls of equipment performance (e.g. freeze-drying cycle time, temperature and vacuum pressure);
    ii. Testing or confirming:
        - Residual pathogen numbers (if any);
        - Level of endotoxins or other potential toxic substances where milk original concentration occurs);
        - Required physicochemical characteristics (e.g. final water activity, osmolality, etc.); and
        - The concentration of nutritional and bioactive components. (as in 28.1.3.)

(b) Testing for residual pathogens is recommended at the completion of every processing batch of a HMDP.
    i. Albeit recommended sterility, the accepted microbial load in reconstituted product is, at a maximum:

- total viable count of ≤ 1 cfu/ml
- L. monocytogenes and Salmonella sp. not detected in 25 g

(c) The HMB may expand the cohort of tested microbes and their specific exclusion criteria.
(d) Determination of endotoxin levels (in particular where additional processing induces concentration) at the completion of every processing batch of a HMDP is recommended.
(d) Verification of relevant physicochemical characteristics (e.g. final water activity) is recommended at the completion of every processing batch of a HMDP.
(e) Analysis of the nutritional and bioactive components is recommended as part of the process validation and at established intervals. (as in 28.)

27.2.3. Sampling, frequency of sampling and testing method to ascertain compliance to safety and quality of the HMDP is established by the HMB. [1][3][4][5][6][7][8][9][10][11][12][13][14]

(a) The sampling method, number and volume of samples provide the appropriate representation of the resulting, additionally processed, product batch.
(b) Testing protocols are developed in collaboration with - and validated by - the accredited laboratories where testing is performed.
(c) Confirmation or review of protocols is triggered by:
    i. Relevant changes in donor cohort;
    ii. Changes in equipment; and
    iii. Significant deviations in results.
(d) Any container opened for sampling is discarded.

27.2.4. Storage conditions and product shelf life are established by the HMB. [3][4][5][8]

(a) The HMB validates the product stability of the HMDP at the proposed storage conditions and duration (e.g. vacuum packaged freeze dried milk, at < +5°C, for six (6) months).

(b) Packaging is demonstrated to protect the product integrity (e.g. vacuum maintenance, sterility), allowing for storage and handling throughout the predicted product shelf life:
    i. Nutritional value and bioactivity are maintained during product shelf life.
(c) Container identification allows traceability from product to donor(s) and backwards. (as in 9.3.5.).
(d) Accessory information on handling and dispensing (e.g. reconstitution instructions) and contact details of the HMB are provided. (as in 9.3.6.)

27.2.5. Once implemented, additional processing and expected outcomes are audited and approved by the jurisdictional enforcement agency **before** the HMDP distribution is authorised.

27.2.6. Records of additional processing, controls and outcomes are registered in the Processing Records. (as in 5.5.3.) [1]

28. Nutritional and bioactivity analysis

28.1. Principles

28.1.1 The highest level of safety, paired to the lowest possible compromise in product nutritional and bioactivity suitability, is recommended. [1][2][3][4][5][6][7]

(a) Criteria for suitability are established against the needs of the targeted recipient cohort (e.g. preterm infants; term infants) and product utilisation.

28.1.2. Where HoP has been adopted as the pathogen reduction or elimination method, and been in use for a substantial period of time, using the same equipment and processing controls, the following is recommended:

(a) Retrospective HMB past data (if available), utilisation outcomes and published work is used to support claims on the current nutrient and bioactivity suitability:
    i. Where possible, it is recommended the HMB establishes a base-line of current 'in-house' outcomes. (as in 28.1.3.)
(b) Implement repeat pre and post pasteurisation comparative nutrient and bioactivity analysis, at a set interval (e.g. following a number of batches; once every twelve (12) months as part of internal audits), to confirm there are no significant deviations from predicted outcomes:
    i. The interval considers changes in donor cohort, and/or processed volumes, and/or equipment.
(b) If consistent batch variation is predicted and risk assessed as important to the outcomes of further DHM or HMDP utilisation, the nutritional and bioactivity analysis (as in 28.1.3.(b)) is performed at the end of every processing batch:
    i. At a minimum the results will include protein, carbohydrate and total fat content, osmolality and energy calculation.
(c) Results are recorded in the respective processing batch records:
    i. Review of results is included in the Product Release SOP; and
    ii. Deviations in predicted or desired product outcomes are addressed in non-conformance audits.

28.1.3. Where an alternative pathogen reduction or elimination method and/or an additional processing step are implemented, the impact on nutritional and bioactive components is evaluated by the HMB as part of the initial process validation.

(a) A comparative pre and post-processing nutritional and bioactivity analysis, is performed with the acceptable variation established as part of the initial process validation (as in 28.2.1.);

(b) The assessment of the following nutrient and bioactive panel is recommended:
    i. Macronutrients: total protein; total lipids; carbohydrates (e.g. lactose) and total energy content; and
    ii. Micronutrients: Calcium, Potassium, Sodium, Phosphate, Magnesium, Copper, Zinc, Iodine, Selenium; Vitamins - A, B2, B3, B6, B7, B12, C and E; and
    iii. Bioactive components: Lysosyme, Lactoferrin, BSSL and IGA; and
    iv. Alternative or additional testing profile as justified by the HMB.
(c) Where relevant, suitable product osmolality is confirmed (e.g. freeze dried milk upon reconstitution).
(d) Results are recorded in the respective process validation records.

28.1.4. Ongoing verification of outcomes is recommended.

(a) Provided the donor cohort remains comparable (e.g. gestational age and lactation time post-partum), and the same equipment and processing parameters are used, the nutritional and bioactive component analysis is repeated after a set number of processing batches and/or as part of a scheduled verification of initial findings.
(b) If consistent batch variation is predicted and risk assessed as important to the outcomes of DHM or HMDP utilisation, the analysis of nutritional and bioactivity is performed at the end of every processing batch:
    i. At a minimum the results will include protein, carbohydrate and total fat content, osmolality and energy calculation.
(c) Results are recorded in the respective Processing Records:
    i. Review of results is included in the Product Release process; and
    ii. Deviations in predicted or desired product outcomes are addressed in non-conformances audits.

28.2. Requirements

28.2.1. There is a documented product acceptance threshold.

(a) Published outcomes of HoP are set as the minimal benchmark for acceptable post-processing values. [8][9][10][11][12][13][14][15][16][17]
(b) Detected variation in values agree with published data (where available) for similar processing. [18][19][20][21][22][23][24][25]
(c) Deviations are to be technically justified against claimed benefits to the potential recipient cohort.

28.2.2. There is a documented testing protocol.

(a) Where the tests are performed by an accredited facility, there is a service agreement.
(b) The HMB and the testing facility establish, in collaboration, the appropriate testing panel, sampling volumes, need for preservatives and the transport conditions.
(c) Alternatively, the HMB establishes an 'in-house capability':
    i. Testing instruments are appropriate for human milk platforms; and
    ii. Testing instrument use and maintenance follows manufacturer's instructions.

29. Post-processing quarantine, release process and pre-distribution storage

29.1. Post-processing quarantine

29.1.1. DHM and HMDPs are stored in quarantine *status* until compliance is verified. [1][2][4][5][6][7][8][10][11][12][13][14][15]

(a) Storage is in dedicated, monitored, access controlled post-processing quarantine freezers. (as in 8.2.3.)

(b) DHM is stored frozen at or below -18°C for no longer than six (6) months following the earliest date the milk within the processing batch was expressed, or no longer than three (3) months from the date of pasteurisation or alternative pathogen reduction or elimination process.
(c) Freeze dried product is stored under refrigeration or ambient temperature, as established during the process validation at the HMB.

29.2. Release process

29.2.1. There are designated and competent staff, to ascertain the continued donor(s) eligibility, the processing, storage records and associated safety (and quality, where pertinent) controls. (3)(5)(10)

29.2.2. There is a documented SOP to assess compliance and to release DHM and HMDPs for supply. (3)(5)(10)

29.2.3. All records in the Donor(s) File(s) related to the DHM and HMDPs processing are reviewed.

(a) The records will include:
    i. Donation records; (as in 5.5.2.)
    ii. Processing Records; (as in 5.5.3.).
    iii. Pre and post-processing storage; and (as in 5.5.3)
    iv. Critical equipment performance (and failures). (as in 5.5.5.)
(b) The SOP may consider intermediate compliance approvals at the end of a critical step in the production line before progression to the next (e.g. confirmation of donor eligibility at enrolment and on-going eligibility; processing batch compliance).
(c) The review confirms DHM and the HMDP is compliant to the HMB established safety criteria and quality outcomes (where suitability of nutritional and bioactive composition, and concentration, is addressed).
(d) Outcomes of the review are recorded in the Donor File:
    i. Containers of DHM and HMDP compliant and approved for supply containers are identified as "released" and included in the HMB inventory for supply; and
    ii. Failed DHM and HMDP containers are identified as "reject", segregated and disposed of following discard SOP, or used in internal product development / validations and research. (as in 13.2.5)

29.3. Pre-distribution storage

29.3.1. Released DHM and HMDPs are transferred to dedicated storage for released products and maintained under appropriate conditions until distribution. (1)(2)(4)(5)(6)(7)(8)(10)(11)(12)(13)(14)

(a) Released DHM is maintained frozen at or below -18°C.
(b) The freezers are identified as 'DHM released' and monitored. (as in 8.2.3.)
(c) Physical segregation of quarantine freezer(s) and released DHM freezer(s) is recommended.
(d) Freeze-dried milk is kept at the temperature required for product stability, as validated by the HMB, in access controlled storage.

29.3.2. Final DHM or HMDP packaging is appropriate to withstand handling and the storage conditions during ascribed shelf life. [1][2][3][4]

(a) DHM and HMDP identification in distribution label provides information enabling traceability from DHM or HMDP to donor(s). (as in 9.3.5.)
(b) Written additional information (e.g. on product, product handling and storage, and addressing contacts for complaints or adverse events) may be included at the time of distribution. (as in 9.3.6.)

29.3.3. Expiry dates relate to the type of processing, the packaging material and impact of storage conditions onto the safety and quality of stored DHM or HMDP. [1][2][4][5][7]

(a) DHM is discarded at three (3) months past the date of the pathogen reduction or elimination process (i.e. six (6) months following the earliest date the milk within the processing batch was expressed).
(b) HMDP is discarded at the validated time-frame as determined by the HMB (e.g. based on residual water activity levels, on packaging integrity and on vacuum maintenance within container, where applicable).
(c) Products that reach end of shelf life are segregated and discarded as soon as possible.
(d) Discarded products are registered in the Discard Register and in the Donor File, and removed from the HMB supply inventory.
(e) As part of best inventory management strategy, DHM or HMDPs containers that are closer to expiry date are distributed first.

VI. DISTRIBUTION

30. Providing DHM and HMDP

30.1. Agreements for provision of service

30.1.1. There is a service agreement between the HMB and the receiving organisation the DHM is provided to. (as in 11.2.1)

30.1.2. The receiving organisation maintains a dispensing facility that complies with safe DHM and HMDP handling, storage and aliquoting.

(a) There is a dedicated area for the receipt, storage and dispensing of DHM and HMDP.
(b) There are dedicated, monitored and alarmed refrigerators and/or freezers for storage:
    i. Equipment is locked or is in an access controlled area.
(c) There is controlled access to storage at room temperature (e.g. between +20°C to +25°C, at mid-range humidity levels).
(d) Staff are trained and competent in handling DHM and/or HMDP.
(e) Records are secure and register the receipt conditions as the DHM and HMDP arrives from the HMB, the storage, the dispensing and the utilisation records.

30.2. Recipient consent

30.2.1. There is a written informed consent signed by the parent or legal representative of the infant for the feeding of DHM and/or HMDP. [1][2][3][4][5][6][7][8][10][11]

(a) The consent is obtained by the health practitioner (e.g. GP prescribing use, NICU consultant).
(b) The consenting process considers beliefs and cultural values influencing the acceptability of anonymised donor human milk.
(c) The information is provided:
    i. Verbally and in writing using non-technical terms;
    ii. In the language preferred by the parent or guardian; and
    iii. An interpreter is involved when required.
(d) The information includes:
    i. Proposed administration of DHM and HMDP;
    ii. Expected benefits; and
    iii. Possible reactions (e.g. allergens) and biological risk (linked to human origin).

30.2.2. A copy of the consent from the infant legal representative is provided to the HMB upon request. [9]

31. Delivery of DHM and/or HMDP

31.1. Delivery of DHM or HMDP to an infant outside a hospital setting

31.1.1. A parent or legally authorised representative 'picking-up' or receiving DHM or HMDP from the HMB is provided with verbal and in-writing instructions.[1][2][3][3][4][5][6]

(a) The parent or representative provides appropriate identification and a copy of the informed consent for use.

(b) The HMB provides instructions on the requirements to protect the integrity of milk containers and maintenance of required temperatures during transport (e.g. to avoid thawing of DHM) and dispensing:
    i. The instructions are provided in clear terms, in a culturally appropriate way, using in the preferred language of the parent or guardian language, and/or the services of an interpreter; and
    ii. Dispensing instructions include:
        - Hygienic handling and storage conditions at the home;
        - Thawing DHM;
        - Reconstitution (if applicable) and aliquoting of the DHM or HMDP as prescribed by the neonate's health carer; and
        - Discard of expired containers. (as in 9.3.6.)

31.2. Delivery of DHM or HMDP to a receiving organisation

31.2.1. The HMB delivers consignments to the dispensing facility at the receiving organisation (e.g. Hospital Milk Room), at agreed inventory levels, dates or time intervals. (as in 11.2.)

31.2.2. There is a documented procedure that assures safe transport and inventory traceability. (2)(3)

31.2.3. Processed milk is transported in a HMB transport vehicle or by a contracted courier. (as in 11.1.2.)

(a) Product integrity is safeguarded and temperatures are maintained within acceptable ranges for DHM and/or HMDP, as determined by the HMB.
(b) Containers are identified and the inventory in the transport load is recorded.

32. Receiving and storing DHM and HMDP in the receiving organisation

32.1. Receipt

32.1.1. The Hospital receiving a consignment of DHM or HMDP maintains a dispensing facility that complies with the HMB requirements. (1)(2)(3)(4)

(a) There is a dedicated area for the receipt, storage and dispensing of DHM and HMDP (e.g. NICU Milk Room).
(b) Sufficient, trained and competent staff are available to meet the handling and dispensing protocols.
(c) There is a Human Milk Log Book to register the receipt, acceptance (or disposal) of DHM and/or HMDP.

32.1.2. Delivered DHM and HMDP are immediately unpacked and checked for appropriate identification, temperature conditions and container integrity. (2)(3)(4)

(a) DHM is hard frozen.
(b) HMDP is at the required transport temperature range (as established by the HMB).
(c) Packaging is intact:
    i. No damage to containers or leaks is detected;
    ii. Caps and/or external tamper proof seals have not been tampered with; and
    iii. Labels on the containers are adherent and intact.

(d) Identification numbers of each DHM and HMDP containers are checked against a despatch inventory provided by the HMB.
(e) Valid expiry dates are confirmed.
(f) Where the supply is directed to a single recipient, the details of the recipient are confirmed.

32.1.3. Non-compliant DHM or HMDP containers are rejected, segregated and discarded. [2][3][4]

(a) The HMB is contacted as soon as possible and the Milk Room is instructed to retain until further notice (e.g. to be collected for investigation) or to discard the non-compliant product(s).
(b) Discard follows hospital protocols.
(c) The reject status of the received container(s) is registered in the Human Milk Log Book.

32.1.4. The identification details of the accepted unit(s) are entered in a Human Milk Log Book. [3]

32.2. Pre-utilisation storage

32.2.1. The accepted containers of frozen DHM are transferred to a dedicated storage freezer. [1][3][4]

(a) The freezer is locked or in an access controlled area.
(b) Temperatures are monitored and recorded (at least once per shift). (as in 8.2.3.)
(c) The freezer is alarmed and connected to emergency power supply. (as in 8.2.3.)

32.2.2. The accepted containers of HMDPs are stored in access controlled areas following the HMB instructions. [2][3]

33. Dispensing DHM and HMDP

33.1. General considerations

33.1.1. Thawing, aliquoting and dispensing at the hospital safeguards the safety and quality of DHM and HMDPs.

(a) Handling follows the hospital protocols in conformity to instructions provided by the HMB.
(b) DHM and Human Milk Products are aliquoted in a dedicated area.
(c) Staff follow the written protocols and are competent to perform assigned tasks:
    i. Staff are trained, use PPE, comply with hygienic requirements and understand aseptic or clean technique principles;
    ii. Aseptic technique in the handling of DHM is recommended; and
    iii. Staff avoid temporarily caring for infants (e.g. nappy change) while aliquoting and/or dispensing DHM or HMDP, to avoid milk contamination.

33.2. Thawing

33.2.1. Container(s) with the calculated volume for the 12-24 hour interval prescribed for the recipient(s) are removed from freezing storage and thawed following established protocols.

(a) The removal of DHM or HMDP container for thawing is noted in the Human Milk Log Book alongside the respective container entry:
    i. Priority for thawing is 'first container in – first container out'.
(b) Thawing milk in a dedicated refrigerator overnight, at or below +5°C, is recommended.
(c) "Quick thawing" takes place by immersing frozen container in a milk warmer designed for human milk:
    i. The use of microwave is not recommended.

33.3. Aliquoting and dispensing

33.3.1. Completely thawed DHM is stored refrigerated and is further aliquoted, or discarded, within 24 hours. [1][2][3][4][5][6][7]

(a) Thawed DHM is not frozen again.
(b) Each container of DHM is aliquoted to be dispensed to the least possible number of recipients.
(c) Labelled aliquots are refrigerated (at or below+5°C) until use within twenty-four (24) hours from thawing.
(d) Unused refrigerated aliquots are discarded, as per hospital protocols.
(e) Aliquots left at room temperature beyond two (2) hours are discarded.

33.3.2. HMDP is reconstituted as per the HMB instructions.

(a) Each container of reconstituted HMDP is dispensed to the least possible number of recipients.

33.3.3. The supplementation of DHM or mother's own milk with HMDP follows instructions from prescribing clinicians. [10][11][12][13][14][15]

33.3.4. Intake of DHM and HMDP is recorded in the Human Milk Log Book. [6][7][8][9]

(a) There is in informed consent by the parent or legal representative of the recipient. (as in 30.2)
(b) The dispensing organisation undertakes responsibility to register the identity of recipients of DHM and HMDPs (for the purpose of traceability), to include:
    i. Infant hospital medical record number;
    ii. Date of birth;
    iii. Mother's name; and
    iv. Volume and date of dispensing.
(c) The entries enable traceability of dispensed DHM and HMDP recipient(s) and backwards, from recipient to the dispensed container(s).
(d) Records of utilisation are kept as part of the recipient medical file for the period prescribed in jurisdictional Health Records Acts and Privacy of information Acts.
(e) Details on recipients are available, upon request, to the HMB.

33.3.5. There is a documented procedure for discard of expired containers of DHM or HMDPs.

33.3.6. There is a documented procedure to inform the HMB of product non conformities and immediate contact in any adverse event. (as in 34)

34. Management of complaints, product non-compliance and adverse events

34.1. Complaints

34.1.1. All complaints are documented as received, carefully investigated and managed in a timely manner.

(a) Documented mechanism classifies and trends received complaints.
(b) Recurring service complaints trigger the review of pertinent related procedures, staff training and terms of service agreements.
(c) Complaints related to a non-compliant product or to an adverse event require immediate investigation, risk assessment and implementation of appropriate mitigating measures:
    i. There is a roster for 'out of hours' staff contacts and an HMB - 24/7- emergency contact phone number(s).

34.2. Product withdrawal

34.2.1. DHM or HMDP withdrawal is considered when a detected non-compliance is important but does not pose an imminent safety risk. [3]

(a) Non-compliances that have the potential to become a safety risk must be further investigated.
(b) Pending the outcomes of the investigation, the HMB instructs:
    i. An immediate halt to the dispensing of unused aliquots originated from a non-compliant DHM or HMDP container;
    ii. The segregation of all unused containers from the same processing batch (as instructed by the HMB), until further notice;
    iii. All DHM or HMDP from same processing batch, or processing batches from same donor(s) at the HMB to be put 'on hold' for despatch until further notice, as deemed appropriate; and
    iv. Segregation of same processing batch containers distributed to other organisations, as deemed appropriate.
(c) The withdrawal is informed to relevant government authorities if public notification is expected (e.g. media release).
(d) Product non-compliances are registered in the Donor File(s):
    i. Records include the root cause analysis and implemented corrective measures; and
    ii. Efficacy of implemented measures is confirmed in future internal audits.

34.3. Product recall

34.3.1. There is a HMB written procedure to recall non-compliant DHM or HMDP that pose a safety risk and/or to address an adverse event ascribed to the DHM or HMDP. [1][2][3][4][5][6]

(a) Initial investigations establish there is a safety risk and/or ascertain the DHM or HMDP is the possible or probable cause of an adverse event.
(b) The HMB recall SOP covers the procedures, records and staff responsibilities in place to recall the product.
(c) The investigative root cause effort is collaborative, and may involve the HMB staff, hospital Milk Room, staff, clinicians (hospital, community), subject matter experts as required, and the regulatory agency officer recall coordinator (as established in the HMB recall procedure).
(d) Actions include:

i. At the HMB: review of product donor suitability, product testing, processing, storage, in process safety controls and delivery.
ii. At the dispensing organisation or home: review of receipt, storage, aliquoting and dispensing (including the identification of all recipients of implicated container / batch of DHM and/or HMDP.

34.3.2. Dispensing organisations and parents (or legal representatives) are instructed to halt use and segregate or discard specific product containers in stock as soon as possible, as instructed by the HMB. (3))(4)

(a) The health of any recipient of non-compliant DHM or HMDP is monitored and attended to.
(b) Broader consequences beyond the affected infant are considered.

34.3.3. The HMB quarantines undistributed DHM and HMDP containers of same single donor or same multiple donor pool processing batches until further notice.

(a) Other processing batches from the same donor or donor pool are recalled as the root cause investigations so directs.
(b) Non-compliant recalled and undistributed DHM and/or HMDP are discarded as soon as possible following any additional inspection or testing as part of the investigation.

34.3.4. The HMB contacts the regulatory authority to report the product recall, shares the reason for recall and informs the response measure and mitigating measures to prevent recurrence of problem. (3)(4)

34.3.5. 'Mock Recall' exercises at set intervals verify the ability of HMB to recall products effectively. (1)(2)(5)

(a) Effective product recall target is the ability to identify all recipients (as recorded by the dispensing organisations or the HMB),to recall all unused products stored at the dispensing organisations, and to segregate all undistributed DHM or HMDP stored at the HMB from a defective batch, within six (6) hours.
(b) Mock recall exercises are conducted every two (2) years at a minimum.
(c) A true recall in any given year resets the calendar until a mock recall is needed.

ACRONYMS

CMV	Cytomegalovirus
CSSD	Central Sterilisation Services Department
DHM	Donor Human Milk
DNA	Deoxyribonucleic Acid
HACCP	Hazard Analysis and Critical Control Points
HIV	Human Immunodeficiency Virus
HMB	Human Milk Bank
HMDP	Human Derived Milk Product
HoP	Holder Pasteurisation
HPP	Hydrostatic Pressure Processing
HTLV	Human T-Lymphotropic Virus
HTST	High Temperature Short Time Pasteurisation
LTLT	Low Temperature Long Time Pasteurisation
NAT	Nucleic Acid Amplification Technique
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure
VLBW	Very Low Birth Weight
WHO	World Health Organization

DEFINITIONS

Adverse event	Unwanted or unexpected event following the administration of DHM or HMDP.
Aliquot	A fraction of the original volume (e.g. in a container).
Amenities	Facilities for common use (e.g. staff room, toilets, change rooms, etc.).
Authorised staff	Trained and competent staff member, who receives the authorisation to perform a critical task within specific role description (e.g. release of DHM for distribution; line manager 'signing-of' a pasteurisation batch).
Bioburden	Microbiological load on tested milk, materials or surfaces. In the context of the Guidelines, this may include: non- pathogenic (normal skin flora, natural milk microflora) and pathogenic bacteria (in particular spore forming), fungi and yeast.
Clean room	An enclosed area whereby filtration systems and cleanliness, and protocols minimise contamination from the controlled number of airborne and surface particles, gases or liquids, or static electricity.
Cold-chain	The maintenance of appropriate storage and transport conditions under which donated milk, DHM and HMDP are handled within the safe temperature range, appropriate to that product to guarantee the suitability for clinical use.
Collection centres	Collection centres are outreach facilities located in a hospital or in the community, affiliated to the HMB or holding an agreement with the HMB, where capacitated staff enrol, consent, train and support donors, and provide temporary storage of donated milk, in compliance to the HMB protocols. Collected milk is transferred to the HMB for processing. The HMB retains responsibility for donor screening and donor acceptance.
Competent staff	Staff member trained, assessed and deemed capable to perform an assigned task unsupervised, in accordance to HMB protocol.
Container	Vessels, bottles, bags or boxes to contain [the milk].
Contaminant	Biological or chemical agent, foreign matter or other substances that may compromise milk safety or suitability.
Contamination	The introduction or occurrence of a contaminant.
Critical equipment	Equipment that directly interferes with the quality or safety of the product (e.g. laminar flow cabinet; pasteuriser; freezer).
Critical materials	Supplies that directly interfere with the quality or safety of the human milk (e.g. milk containers).
Deferral	When milk donation is suspended temporarily or permanently.

Dispensing	The process of allocating DHM or HMDP to a recipient (e.g. neonate in the NICU).
Dispensing facility	The HMB or dispensing unit in a Hospital (e.g. Hospital Milk Room) supplying DHM to a recipient.
Distribution	The delivery of DHM from the Milk Bank to a hospital, a parent or guardian of a recipient, or approved researcher.
Donated milk	In the context of these Guidelines, refers to unprocessed human donor milk.
Donor	In the context of these Guidelines, refers to a legally responsible, lactating woman who volunteers and consents to altruistically donate her excess breastmilk, without detriment to the breastfeeding of her own infant.
Donor Human Milk	In the context of the Guidelines, Donor Human Milk (DHM) refers to donated human milk processed in a manner whereby the milk composition is only altered as minimally as possible while microbiological safety is achieved.
Donor Unique Identifier	Numeric or alpha-numeric sequence that provides unique identification to a donor. The Donor Unique Identifier, included in or referred to in the product label or code, warrants traceability from unprocessed milk donor to originated DHM and/or HDMP containers, and backwards.
Drip milk	Milk dripping passively from one breast while the newborn is fed at the other breast.
Emergency	Need is urgent.
Equipment	Machine, instrument, apparatus, appliance or utensils, other than single use items, used or intended to be used in connection to donor human milk handling and processing. Includes any equipment used to clean the premises, ascertain the environmental quality, and nutritional or bioactivity composition.
Excess milk	Residual milk after the breastfeeding needs of the own infant are satisfied.
Facilities	Spaces used to handle and store human milk. Used as a synonym to premises.
Food grade	Safe for human consumption or verified as safe to come into direct contact with food products.
Fortification	Supplementation to the mother's milk or DHM of additionally required nutrients and bioactive components.
Hard frozen	Frozen in solid form.
Hazard	Agent or event with the potential to cause deviation in required or expected safety and quality parameters.

Hazard Analysis and Critical Control Points	A system which identifies, evaluates, and controls hazards which are significant for the product safety.
Holder pasteurisation	Pasteurisation process that includes a heating phase to 62.5°C, a holding phase of 30 minutes at this temperature, and a cooling phase (within the parameters required in applicable standards).
Human Milk Bank	Organisations established for the purpose of enrolling and collecting excess breastmilk from non-remunerated donors and the processing, testing, storing and distribution of ethical, safe and suitable human milk to recipients that are not the donor's own infants, to meet their specific needs for optimal health.
Human Milk Derived Product	In the Guidelines, refers to a product derived from Donor Human Milk (DHM) as a consequence of an applied process beyond pasteurisation or equivalent treatment, with the purpose to change the original nutritional and bioactive composition or concentration of the milk.
Lactation period	The period of time when a woman is lactating, lasting from confinement to one year post-partum.
Materials	In the context of the Guidelines, single or multiple use supplies used in the processing and identification (e.g. containers, bottles, caps, labels). Interchangeable with *materiel.*
Medical practitioner	Person registered or licensed as a medical practitioner under legislation in Australia and New Zealand.
Milk Room	A unit located in a hospital to collect and store donated milk before the transfer to the HMB, and/or to receive DHM or HMDP for further aliquoting and dispensing to recipients.
Pasteurisation	Heat processing method resulting in the reduction or destruction of undesirable microbiological loads.
Permanent deferral	Milk donation is suspended or not accepted indefinitely. For example, if the donor has a blood borne infection, a chronic medical condition or is at ongoing risk of a blood-borne infection.
Prescribed	Use is recommended, in writing, by a qualified health care practitioner.
Pests	Include birds, rodents, insects and arachnids.
Premises	In this context, spaces used to interview donors, and express, collect, handle, process and store donated human milk. Used as a synonym to facilities.
Process controls	In HACCP referred as critical control points, such as time and temperature of pasteurisation, time and temperature of storage prior to pasteurisation, etc.
Processing	Refers to any activity related to the handling, preparation, manipulation, pathogen reduction or elimination process, sampling and testing, preservation for storage, storage, packaging and identification of processed human milk as DHM or HDMP.

Quality	In the context of the Guidelines, refers to the maintenance of the nutritional and bioactive characteristics of processed and stored DHM or HMDP as close as possible to unprocessed human milk.
Quarantine	Describes the status of unprocessed or processed human donor milk, isolated physically or by other effective means, while evaluation of data, process controls and outcomes is undertaken to inform compliance (or not) to requirements.
Recall	In the context of the Guidelines, is the action taken to remove from distribution and dispensing DHM or HMDP which is considered unsafe consequent to: testing indicating there may be a potential problem with a particular product or processing batch; received complaint or feedback; a non-compliance detected in a critical material notified by the supplier; information received from the jurisdictional authority.
Recipient	New born or infant fed with DHM or HMDP.
Receiving organisation	A Human Milk Bank or a Hospital based unit (e.g. NICU or hospital Milk Room) that receives, stores and dispenses DHM and HMDP.
Safety	In the context of the Guidelines, defined as the presence of acceptable levels (if any) of pathogens, detected chemicals(e.g. residues from cleaning and sanitising) and physical contaminants (e.g. a mother's hair)
Sanitation	A treatment involving a physical or, chemical process applied to equipment, surfaces or materials so that the number of microorganisms and viral load on the surface is reduced to a level that does not compromise the safety of the milk with which it may come into contact and does not permit the transmission of an infectious contaminant to it.
Standard Operating Procedure	The detailed set of instructions enabling staff to carry out a routine operation with the continued efficiency, quality of outputs and uniformity of performance, as established and required by the HMB.
Standard Operating Procedures Manual	Orderly collection of the HMB Standard Operating Procedures. May be inclusive of the instructions and protocols used and shared by the HMB with affiliated organisations.
Sterilisation	Process of elimination of all living organisms (including: microbes, microbial spores, yeast, fungi and virus). The method may eliminate prions.
Storage	Maintaining a substance, materials or product under appropriate controlled conditions.
Sufficiency	Demand is quenched by adequate supply.
Temporary deferral	Milk donation is suspended for part of the lactating period due to a short lived contra-indication. It is expected the donor will continue to donate pending resolution of the condition and re-assessment.
Terminal pathogen reduction on sterilisation	The product is in its final distribution packaging at the time of the pathogen reduction or elimination process.
Thawing	Process of converting [milk] from hard frozen to liquid.

'Top up" (of milk)	The addition of freshly expressed milk to a previously collected amount, into the same container.
Traceability	In the context of the Guidelines, the possibility to link the donor to any recipient of DHM or HMDP resulting from her donated milk, and backwards.
Undersupply	Shortage of DHM or HMDP.
Validation	The action of obtaining and evaluating scientific and technical evidence to demonstrate the validity or accuracy of a process or a control measure against predicted or desired outcomes.
Withdrawal	In the context of the Guidelines, is the action taken to remove DHM or HMDP from the supply chain where there is no safety risk or the safety risk has not yet been confirmed.

KEY REFERENCES

Foreword

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Section 21 – General considerations (processing)

Please refer to references in Sections: 5. , 6. , 7. and 8.

Section 22 – Receiving donated milk at the Milk Bank

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