सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

NATIONAL QUALITY ASSURANCE STANDARDS

COMPREHENSIVE LACTATION MANAGEMENT CENTRE

2021

Ministry of Health and Family Welfare,
Government of India

National Quality Assurance Standards

for Comprehensive Lactation Management Centre

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Chapter 1

Introduction to CLMC & Quality Assurance

Comprehensive Lactation Management Centre

Background

Breastfeeding is the optimum exclusive nutritional choice for the neonates and infants. Breast milk provides long term benefits to babies as it promotes normal growth, increases immunity, reduces risk of illness, enhances IQ and also promotes optimal brain development in early life. Despite of knowing the benefits of breastfeeding compliance early and exclusive breastfeeding for first 6 months is dismal. Globally, only 40% of the children are exclusively breastfed at the age of 0-6 months, as per World Health Organization; however, 54.9% of children are breastfed in India as per NFHS -4 data.

In India, many children remain deprived of adequate breastfeeding, due to maternal mortality (46% maternal death on day of delivery), premature births (3.3 million), low birth weight and other medical conditions. Keeping in the view, the benefits of Breastfeeding and considering it as is the cost effective strategy for improving child survival and reducing the childhood diseases; it becomes furthermore important that maximum babies may have access to the human breast milk. To ensure the endeavour, Ministry of Health and Family Welfare, Government of India has taken many steps and one of the steps undertaken is to setup Human Milk Banks in high caseload secondary and tertiary care public healthcare facilities. The objective of initiatives is to protect, promote and support breastfeeding, to promote early initiation and exclusive feeding of human milk among sick and vulnerable newborns admitted in SNCUs/NICU and to save babies from the adverse events of formula feed. The foremost endeavour of the healthcare facility is to conserve the natural act of breastfeeding. If mother's own milk is insufficient, unavailable for the sick hospitalized newborn or any unavoidable reason, Donor Human Milk (DHM) is the next best alternative.

Human milk banks in India also known as Comprehensive Lactation Management Centres (CLMC) and Lactation Management Unit (LMU), depending on the level of health facilities where it has been established. Type of centre and its functions are given in Table-1. All the lactating mothers admitted or visiting in the healthcare facilities are encouraged to donate her excess milk as voluntary services without compromising her own baby's' satiety.

Milk banks collect and store the donated pre-term and term human breast milk after pasteurization and the milk and provide free of cost to admitted neonates those are sick, premature, low birth weight, mal absorption, feeding intolerance and other medical conditions. Process flow of comprehensive lactation management centre is given as Annexure – I

Table: 1 Representing the type and scope of services

Type of Centre	Location	Type of Milk	Function
Comprehensive Lactation Management Centre (CLMC)	Medical College with NICU/ Large District Hospitals	DHM & MoM	Milk Donation, counseling, screening, processing, storage and dispensing of DHM
Lactation Management Centre (LMC)	District hospitals/ Large Sub District Hospitals with SNCU	MoM	Expression of MoM, storage and dispensing
Lactation Support Unit (LSU)	All delivery points	MoM	Skilled lactation support and counseling

By virtue of the complexity of the existing system, rapidly evolving social, economic and technological environment, it is important to ensure that service delivered in human milk banks are safe, reliable, free of cost and maintains nutritive quality of the product. In order to ascertain the structured operationalization in the human milk Banks, Quality standards were defined in **"National Guidelines for Lactation Management Centers in Public Health Facilities".**

Under the ambit of Ministry of Health & family welfare, 'National Quality Assurance Standards for Public Health facilities' are already implemented across States/ UTs'. These standards ascertain the delivery of Quality of Care in primary and secondary healthcare facilities as well as in programs viz. District Hospitals, Community Health Centres, Primary Healthcare Centre (urban & rural) and Quality Assurance Standards for AEFI Surveillance programme respectively. Leading a way forward, quality assessment tool for milk banks has been developed.

NQAS for CLMC would be measuring Quality of services as well as functionality of its processes as per defined quality standards. It would be the first step in assessing the existing system and moving towards dwelling a Quality Management System in human milk banks.

It's not about donation of breast milk; it's all about saving and nurturing a life.

Scope

- National Quality Assurance Standards defined in this guideline are applicable to the Comprehensive Lactation Management Centres with core functions aligned to screening, donation, storage, processing, and distribution of Donated Human Milk & Mothers Own Milk.
- The guidelines are applicable to the CLMC or milk banks attached to NICU/ SNCU.
- Scope of standards are not applicable to Lactation management units (LMUs) or lactation management centre (LMCs), for these facilities please refer Breastfeeding guidelines or NQAS tool for breastfeeding initiative.

Objective

1. To protect, promote, and support breastfeeding for all new-born delivered in public healthcare facilities.
2. To enhance early initiation and exclusive feeding of human milk practices among sick and vulnerable newborns admitted in SNCUs/NICU.
3. To reduce the use of formula feed and save babies from its adverse effects.
4. To ensure the safety and sustainability in human milk bank processes viz. collection, storage, pasteurization etc.

Chapter 2

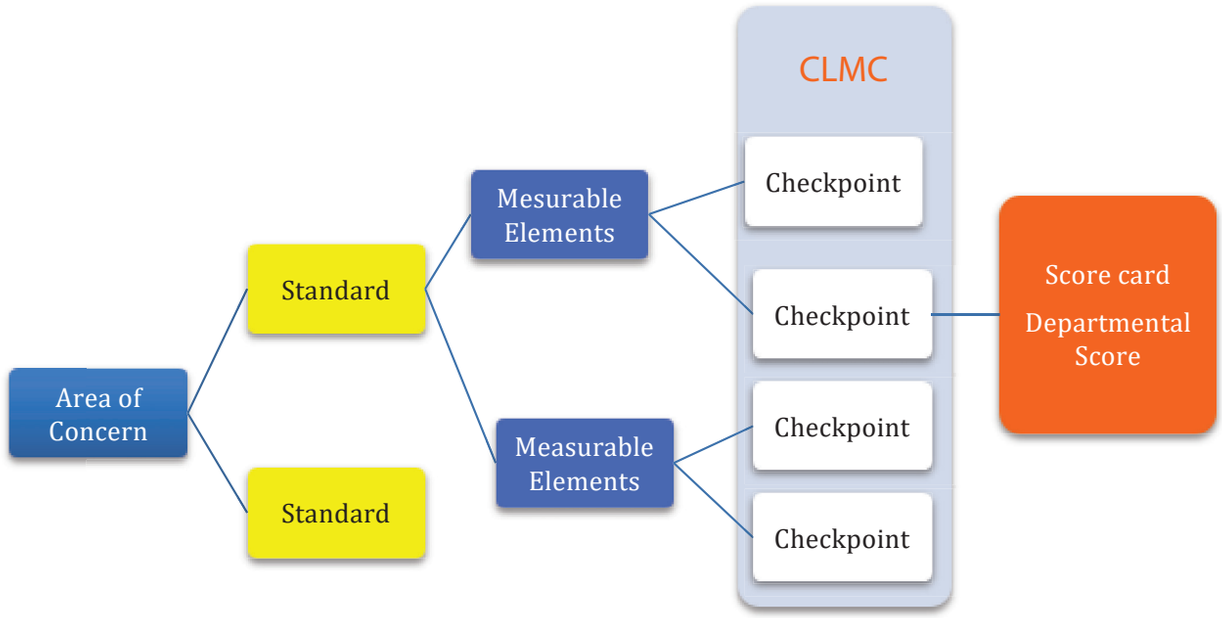
A. Quality Assurance Standards for CLMC

National Quality Assurance Standards for CLMC

National Quality Assurance Standards (NQAS) for Comprehensive Lactation Management Centre (CLMC) are laid down on the structure, process and outcome approach. Standards are organized around eight area of concern namely Service Provision, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management and Outcome. National Quality Assurance Programme has established organizational framework at all levels i.e. National, State, District and Facility level in all states and UTs. The program revolves around ensuring compliance against defined standards, proactively finding the gaps, prioritising, and traversing the gaps using continual and sustainable improvement approaches for specified processes.

There are thirty (30) standards, ninety (90) measurable elements and approx. three hundred & fifty (350) checkpoints in the assessment tool to ensure quality of care in milk bank as well as its concerned departments viz. postnatal wards, SNCUs, KMCs, mother & babies OPD etc. Each standard has assigned measurable element (ME), which are further linked to checkpoints. Each checkpoint has means of verification or tracers that ascertain the compliance towards the meeting the intent of standard and measurable elements.

Figure: 1 Functional Relationship between the components of Quality Measurement System



Intent of Area of Concern and Standards

Eight Area of Concern (08) and thirty (30) Standards those relates to the Quality Assessment of the CLMC department are enumerated below:

Area of Concern A – Service Provision

This area of concern relates to 'Availability' of committed services. It implies that the milk bank provides services as per their scope of services delivery. It needs to be understood that mere availability of human resources (who are capable of delivering the committed services), infrastructure, equipment, etc. does not necessarily ensure functionality of the services. Availability of functional services means services are available to end users means there are mothers available to donate milk voluntarily, there is adequate, safe, pasteurized donated milk available for ready to use as well as there are practices followed to provide human milk to sick and vulnerable newborn. Compliance to these standards and measurable elements should be checked, preferably by observing delivery of the services, review of records for utilization of services, and interviewing whether services were provided or not.

Standard A1 Services for promotion and adherence to early and exclusive breastfeeding are provided as per prevalent guidelines	Early initiation of breast feeding within one hour of birth is one the crucial component for the neonate care. This standard relates to promotion and implementation of early initiation & exclusive breast-feeding practices in healthcare facility. Assessment includes compliance to IYCF practices at facility level (early initiation of breast feeding, immediately after birth, preferably within one-hour, exclusive breast feeding for initial 180 days of life, timely introduction of complimentary foods and continued breast feeding up to two years)
Standard A2 Services for collection, processing, storage and dispensing of Donor Human Milk are available	This standard ensures the availability of the services of Screening, Donation, Processing, Storing and Pasteurization of the donated human milk and providing it to the neonates' as per defined criteria.

Area of Concern B – Patient Rights

This area of concern pertains to accessibility, affordability and quality of service delivery to the Users. Mere availability of services at a health facility does not necessarily meet the need of community, unless the available services are accessible to the users, and are provided with dignity and confidentiality. Access includes physical access as well as financial access. Area of concern Patients' rights also include that health services give due consideration to patients' social, cultural and religious preferences by delivering the services.

Standard B1 There are no Physical, Informational or Financial barriers in availing the services.	The standard & its measurable elements assess the accessibility to the milk bank without any physical barrier viz. ramp, wheelchair, proximity with other departments etc. One of the key points is user friendly signages, it needs to be bilingual for ease of understanding. The standard also evaluate services delivered are voluntary as well as no money or charges are taken for providing DHM.
Standard B2 Services are provided in dignified manner ensuring privacy & confidentiality as well as respecting societal and cultural preferences	The standard measures compliance to provide visual and verbal privacy to donor mother. It also ensures information and records pertaining to the donor mother and recipient are protected. The standard also ensures informed consent is taken from donor and recipient as well as mothers are sensitized for exclusive breastfeeding, personal hygiene etc. through appropriate IEC/ BCC.

Area of Concern C – Inputs

This area of concern predominantly covers the structural part of the facility. Standards given in inputs area of concern take cognizance of the Infrastructure, Drugs and Human Resource. However, focus of the standards has been in ensuring compliance to minimum level of inputs, which are required for ensuring delivery of committed level of the services.

Standard C1 Comprehensive Lactation Management Centre has adequate infrastructure and optimal layout for providing the mandated services.	This standard ensures availability of adequate infrastructure, in terms of space, patient amenities, layout, circulation area, linkage of CLMC with SNCU/ NICU. This also deals whether demarcated areas are in alignment to the department functions, adequate service counters as per the load available. Assessors are expected to assess the infrastructure requirements based on the workload.
Standard C2 Physical and fire safety measures have been implemented	This standard ensures floors are non-slippery, seismic safety and electrical safety is maintained in milk bank. Safety measures related to breast pumps and earthing audits are done at defined intervals. Standards also ensures compliance to fire safety as per prevalent norms.
Standard C3 Adequate qualified and trained staff for rendering the mandated services are available	This standard ensures adequate, qualified, and skilled staff is available as per workload. It also evaluates the criteria for competence assessment and based on it, staff training needs are assessed and acted upon.
Standard C4 Equipment and consumables for collection, processing and storage of Human milk are available as per defined norm and case load	This standard is concerned with the availability of necessary equipment and instruments for the collection, processing for pasteurization, and storage of DHM in the department. The standard also looks at the availability of required furniture & fixture in operational condition within the facility.

Area of Concern D – Support Services

Support services are the backbone of health care facilities. The area of concern includes system in place to ensure equipment maintenance, calibration, inventory management, security, facility management, water supply, power backup and comfortable environment for safe and improved functions. Area of concern also ensures compliance to prevalent legal and regulatory requirements.

Standard D1 Maintenance and Upkeep processes are effectively implemented.	This standard ensures the equipment in milk bank are covered under maintenance programme and there is system at place for break down maintenance of all equipment including critical equipment, viz deep freezer etc. It also includes system for calibration of all the measuring equipment viz. PH meter, Data logger, Thermometer, Binocular Microscope, Autoclave etc. It also covers general cleanliness of department along with regular cleaning, inspection and troubleshooting of equipment used in milk bank viz. bio safety cabinet etc.
Standard D2 Procedures established for estimating the demand of donor human milk and maintaining the buffer stock to avoid stock out	This standard details about the indenting and inventory management techniques followed for storage and dispensing of the DH viz. 'First in and first out', methods, minimum stock maintenance etc. It also ensures maintenance of practices for storing of pre & post pasteurized DHM.
Standard D3 Safe and comfortable environment is provided to donors and as well as to the staff of lactation management centre	The Standard ensures that secure and conducive environment is provided to donor as well to the service providers which includes maintenance of Illumination level in working areas, temperature control, 24 *7 power, and water supply etc.
Standard D4 Compliance to applicable statutory and legal requirements are ensured.	This standard is concerned with compliance to statutory and regulatory requirements. It includes availability of requisite licenses, updated copies of applicable act and rules and adherence to legal requirement applicable to milk bank.

Area of Concern E – Clinical Services

Quality in healthcare has two broad components that is technical quality and service quality. Technical quality concerns the service provider as it has direct influence on outcome or result of services delivered while service quality is concerned to user as it has influence to customer satisfaction. The Standards under this area of concern describes about the technical component of milk bank that includes screening of donors, methodology followed for milk collection, pasteurization, storage, maintenance of temperature and dispensing of donated human milk and mother's own milk. Assessors are supposed to observe the complete process of DHM collection, storage, pre pasteurization, pasteurization, and post pasteurization.

Standard E1 Procedures established as per guidelines for recruitment of Donors	This standard is concerned about defining criteria for potential donor selection, their screening and selection of donation as well as temporary disqualification of existing donors.
Standard E2 Procedures established as per guidelines for screening of Donors	This standard elaborates the specific criteria for donor's selection by examination, laboratory investigations etc. Assessors need to check whether staff is adhering to the defined criteria.
Standard E3 Implementation of optimal and scientific milk collection processes are ensured as per guidelines	This standard relates to the assessment of the processes for counselling, preparedness of the donor and milk bank prior human milk donation. It also covers teaching and assisting mothers for milk expression by using electric breast pump or manual process. It also includes checkpoints pertaining to provide sterile labeled containers for collection of milk.
Standard E4 Labelling and pre-pasteurization storage of collected milk is done as per established protocols	This standard ensures defined protocols for labelling and storage of the Mothers own milk (MOM) and Donated Human Milk (DHM) is followed. It also ensures pre pasteurized milk (both DHM & MOM) is stored at recommended temperature and used within defined time duration.
Standard E5 Pooling and Aliquoting of milk are done as per established protocols	This standard ensures adherence to the processes of pooling and aliquoting of raw donated milk as per the guidelines. It also ensures samples of pre pasteurized milk is collected for lab investigation. Assessor are supposed to observe the process of DHM collection, storage, pre pasteurization, pasteurization and post pasteurization.

Standard E6 Pasteurization of Donor Human Milk is done as per protocol.	This standard ensures adherence to the milk pasteurization techniques i.e Low temperature, long time and High temperature, short time method compliance. It also covers post pasteurization assessment protocols are abide to prevent any contamination and mixing of pasteurized milk.
Standard E7 Post Pasteurization testing of milk is done as per established protocol	This standard ensures compliance to testing of Post pasteurized milk, time bound receipt of microbiological report & staff awareness about interpretation of culture report.
Standard E8 Storage of pasteurized donor human milk is done as per established protocols.	This standard advocates and adheres to the storage of pasteurized milk that includes labelling of expiry dates on the bottles, separate storage of milk bottle of those post pasteurized culture report are awaited, maintenance of temperature of the milk bottles while transportation in wards & critical areas etc.
Standard E9 Established procedures for Intramural issue of Donor Human Milk	This standard ensures dispensing of the DHM through doctor's valid prescription. It also covers adherence to standardized process of thawing of pasteurized milk before issuing for the use.
Standard E10 Optimal feeding practices are ensured in attached NICU/SNCU	This standard covers adherence to early initiation of the breast feeding preferably within one hour of birth, exclusive breast feeding for at least six months is promoted & supported in all the concerned departments, It also ensures all sick and vulnerable babies are provided with only human milk and breast feeding substitutes are not advocated at all.

Area of Concern F – Infection Control

Infection prevention and control is one of the most critical area in milk bank as it is concerned to provide safe, hygienic and decontaminated milk to needy sick babies. So, area of concern infection control not only covers the adherence of practices among milk bank staff but also among mothers visiting the milk bank for donation. Area of concern also persists on compliance with hand-hygiene, antisepsis, personal protection, processing of equipment, environment control, Biomedical Waste Management etc. practices

Standard F1 Hand Hygiene and personal protection ensured during handling of Human Milk.	This standard verifies the availability of hand hygiene and personal protective equipment. It also ensures adherence to hand hygiene practices among staff as well as mothers visiting milk bank for donation. Standard ensures training is provided to mothers on hand hygiene practices and maintenance of personal hygiene.
Standard F2 Sterility of processing and storage equipment are ensured	This standard is concerned with adequate decontamination, cleaning, disinfection and sterilization of equipment, instruments including utensils used for milk expression, storage and pasteurization. It also ensures cleanliness and hygiene in all process areas i.e. area where milk is pasteurized and stored
Standard F3 Microbiological testing data are analysed for improving the infection control practices	This standard ensures system for microbiological surveillance, its reporting as well as analysis of results. It also includes regular monitoring of infection control practices, medical check up of staff working in milk bank.

Area of Concern G – Quality Management

Quality management requires a set of interrelated activities that assure quality of services according to set standards and strives to improve upon it through a systematic planning, implementation, checking and acting upon the compliances. The standards in this area of concern are the opportunities for improvement to enhance quality of services and customer satisfaction. These standards are in synchronization with facility-based quality improvement programme and HACCP protocols.

Standard G1 Quality Policy and objectives have been defined and communicated to staff and users	This standard is concerned with constituting a Quality circle at CLMC. It also ensures Quality circles has defined their objectives and meeting frequently to review the progress. The standard is also concerned with having a measurement system for patient donor and recipient feedback. Assessors should review the records to ascertain that feedback is taken at prescribed intervals and actions are taken on lowest performing factors.
Standard G2 Hazard Analysis and Critical Control Point (HACCP) practices have been implemented as per guidelines	This standard ensures identification of hazards related to milk bank processes by defined checklist, training of staff on hazard identification and development of actions plan to mitigate the hazards based on severity.
Standard G3 Lactation management centre has documented and implemented Standard Operating Procedures	This standard is concerned with availability of adequate and updated Standard operating procedures and work instructions with the respective process owners.
Standard G4 Periodic review and Quality Improvement Processes are implemented	This standard is related to the conduct of periodic internal assessments and undertake corrective and preventive action for traversing the gaps. It also includes use of Quality methods and tools for process improvement and sustainability.

Area of Concern H – Outcome

Measurement of the quality is critical to improvement of processes and outcomes. This area of concern has standard to measure the Key Performance Indicators and to understand the utilization of departmental services for undertaking improvements.

Standard H1 Key performance indicators (KPI) are measured	This standard is related to measurement of certain critical to quality indicators under three broad heads that is productivity, efficiency & safety as well as service quality. Data captured under these indicators provide overall depiction about overall functioning of milk bank and its service quality. These indicators are used as key data elements for improvement in milk bank. Assessors are expected to review these indicators and also ensure few indicators are linked with overall objectives of milk bank and certain steps are taken for continual improvement.
Standard H2 Lactation Management Centre strive to improve KPI and meet established benchmarks	This standard focuses on using the outcome data (collected & collated in Standard Hi) for the trend analysis. Based on the findings of the analysis, facilities are expected to undertake RCA, prioritization, and action planning. The assessors are expected to review the methodology followed and improvement in the outcome indicators. The benchmarks may be defined by the state/district in a later stage to ensure quality improvement as a continuous journey in CLMCs.

B. Measurable Elements

Area of Concern -A Service Provision	
Standard A1	**Services for promotion and adherence to early and exclusive breastfeeding are provided as per prevalent guidelines**
ME A1.1	Facility provides Infant & young child feeding (IYCF) services
ME A1.2	Facility provides mandated new born & Infant health services
ME A1.3	Services are available for the time period as mandated
Standard A2	**Services for collection, processing, storage and dispensing of Donor Human Milk are available**
ME A2.1	Facility provides services for screening & collection of donor human milk
ME A2.2	Facility provides services for processing & testing of donor human milk
ME A2.3	Facility provides services for storage and dispensing of donor human milk
Area of Concern -B Patient Rights	
Standard B1	**There are no Physical, Informational or Financial barriers in availing the services.**
ME B1.1	The facility has user friendly and uniform signage system
ME B1.2	Access to facility is provided without any physical barrier & friendly to people with disability
ME B1.3	The facility provides cashless services to neonates and infants as per norms
Standard B2	**Services are provided in dignified manner ensuring privacy & confidentiality as well as respecting societal and cultural preferences**
ME B2.1	The facility ensures privacy & confidentiality of donor & recipient
ME B2.2	There is establish procedure for taking consent from donor and recipient
ME B2.3	Mother's and donors are sensitized and educated through appropriate IEC/ BCC Approaches
Area of Concern- C Inputs	
Standard C1	**Comprehensive Lactation Management centre has adequate infrastructure and optimal layout for providing the mandated services.**

ME C1.1	Department has adequate work space and layout is demarcated as per function
ME C1.2	Service counters and donors' amenities are available as per load
ME C1.3	The department is planned to ensure structure commensurate with function of the hospital & essential requirements are met
Standard C2	**Physical and fire safety measures have been implemented**
ME C2.1	The facility ensures the seismic and physical safety of infrastructure where services are provided
ME C2.2	The facility ensures safety of electrical establishment
ME C2.3	The facility ensures adequate fire safety measures as per requirement
Standard C3	**Adequate qualified and trained staff for rendering the mandated services are available**
ME C3.1	The facility has adequate staff available and deployed for stipulated functions
ME C3.2	The staff has been provided with required training/ skill set
ME C3.3	Competency assessment of staff is done as per predefined criteria at least once in a year
Standard C4	**Equipment and consumables for collection, processing and storage of Human milk are available as per defined norm and case load**
ME C4.1	Availability of functional equipment for collection and processing of Human milk
ME C4.2	Availability of functional equipment for storage
ME C4.3	Availability of equipment for support services
Area of Concern D- Support Services	
Standard D1	**Maintenance and Upkeep processes are effectively implemented.**
ME D1.1	The facility has established system for maintenance & calibration of critical equipment
ME D1.2	Operating & maintenance instructions are available with the user of equipment
ME D1.3	The facility has established system for maintenance & upkeep of CLMC

Standard D2	**Procedures established for estimating the demand of donor human milk and maintaining the buffer stock to avoid stock out**
ME D2.1	There is established procedure for forecasting and intending the requirement of the milk
ME D2.2	The facility has established procedure for inventory management of donor or mothers' milk
ME D2.3	There is process for storage of expressed milk at controlled temperature during pre pasteurization, transportation and post pasteurization period
Standard D3	**Safe and comfortable environment is provided to donors and as well as to the staff of lactation management centre**
ME D3.1	The facility ensures safe, secure and comfortable environment for mothers' and donors
ME D3.2	The facility provides adequate illumination at all working sites of lactation management centre
ME D3.3	The facility has arrangement for potable water and power back up in lactation management centre
Standard D4	**Compliance to applicable statutory and legal requirements are ensured.**
ME D4.1	The facility has requisite licences and Certificates for its operations
ME D4.2	Updated copies of relevant laws, regulations and Govt. orders are available
ME D4.3	The facility ensures relevant processes are in compliance with statutory requirements
Area of Concern E- Clinical Services	
Standard E1	**Procedures established as per guidelines for recruitment of Donors**
ME E1.1	The facility has defined and implemented Criteria for potential donor selection
ME E1.2	The facility has defined & implemented procedure for donors selection
ME E1.3	The facility has defined & implemented criteria for temporary disqualification
Standard E2	**Procedures established as per guidelines for screening of Donors**
ME E2.1	The facility has defined & implemented criteria for donor registration & consent
ME E2.2	The facility has defined & implemented criteria for screening through blood tests
ME E2.3	The facility has defined & implemented criteria for exclusion of donors

Standard E3	**Implementation of optimal and scientific milk collection processes are ensured as per guidelines**
ME E3.1	The facility has defined & implemented process for donor counselling
ME E3.2	The facility has defined & implemented process for preparatory activities
ME E3.3	The facility has defined & implemented process for expression of breast milk (Manual & electric breast pump)
Standard E4	**Labelling and pre-pasteurization storage of collected milk is done as per established protocols**
ME E 4.1	The facility has established procedure for labelling of bottles used for storage of milk
ME E 4.2	The facility has established procedure for pre pasteurization storage of milk
ME E 4.3	The facility has established procedure for thawing of frozen raw donor human milk
Standard E5	**Pooling and Aliquoting of milk is done as per established protocols**
ME E5.1	The facility has established procedure for pooling of raw donor human milk
ME E5.2	The facility has established procedure for aliquoting donor human milk
ME E5.3	The facility has established procedure for pre pasteurization testing of pooled milk
Standard E6	**Pasteurization of Donor Human Milk is done as per protocol.**
ME E6.1	Facility has defined and implemented standardised pasteurization methods
ME E6.2	Facility has defined and implemented standardized choice of pasteurization
ME E6.3	Facility has defined & implemented standardized post pasteurization processing
Standard E7	**Post Pasteurization testing of milk is done as per established protocol**
ME E7.1	Facility has adequate arrangement for testing of pasteurized donor human milk
ME E7.2	The Facility has defined & implemented process for testing of DHM
ME E7.3	The facility has standardized guideline for interpretation of tests results

Standard E8	**Storage of pasteurized donor human milk is done as per established protocols.**
ME E8.1	Facility has defined and implemented process for storage of pasteurized milk
ME E 8.2	Facility follows standardized temperature control & duration for storage of pasteurized milk in CLMC
ME E8.3	Facility adhere to standardized practices during storage & issuing of donor human milk
Standard E9	**Established procedures for Intramural issue of Donor Human Milk**
ME E9.1	Facility has established criteria to issue donor human milk
ME E9.2	Facility has established criteria for intramural transportation of donor human milk
ME E9.3	Facility follows standardized process for thawing of pasteurized milk before issuing it for use
Standard E10	**Optimal feeding practices are ensured in attached NICU/SNCU**
ME E10.1	The facility ensures optimal breast feeding practices for new born as per guidelines
ME E10.2	The facility ensures optimal breast feeding practices for sick new born & infant as per guidelines
ME E10.3	The facility has defined guiding principles for using donor human milk
Area of Concern F- Infection Control	
Standard F1	**Hand Hygiene and personal protection ensured during handling of Human Milk.**
ME F1.1	Facility has defined and implemented procedure for hand hygiene practices
ME F1.2	Facility has adequate personal protective equipment as per requirement
ME F1.3	Facility adhere to hand hygiene & standard personal protection practices
Standard F2	**Sterility of processing and storage equipment are ensured**
ME F2.1	The facility ensures standard practices for cleaning of equipment & procedure areas
ME F2.2	The facility ensures standard practices for high level disinfection and sterilization of equipment
ME F2.3	Facility ensures environmental control of CLMC for infection prevention

Standard F3	**Microbiological testing data are analysed for improving the infection control practices**
ME F3.1	The facility has provision of culture surveillance of CLMC
ME F3.2	There is established procedure for regular monitoring of infection control practices
ME F3.3	There is provision of periodic medical check-up and immunization of staff
Area of Concern G- Quality Management System	
Standard G1	**Quality Policy and objectives have been defined and communicated to staff and users**
ME G1.1	Facility has established quality framework for quality improvement
ME G1.2	Facility has established system for donor and client satisfaction survey at periodic intervals
ME G1.3	The facility has defined quality policy and objectives in congruency with organizations Mission & vision
Standard G2	**Hazard Analysis and Critical Control Point (HACCP) practices have been implemented as per guidelines**
ME G2.1	The facility has defined the framework of the CLMC based on the seven principles of HACCP
ME G2.2	HACCP assessment criteria and checklist for assessment have been defined and communicated to relevant stakeholders
ME G2.3	Identified hazards are analysed, evaluated, rated and treated based on severity
Standard G3	**Lactation management centre has documented and implemented Standard Operating Procedures**
ME G3.1	Standard operating procedures are available and it adequately describes processed and procedures
ME G3.2	Staff is trained and aware of procedures written in SOP
ME G3.3	Donor, procedural and administrative records are maintained.

Standard G4	**Periodic review and Quality Improvement Processes are implemented**
ME G4.1	The facility conducts periodic internal assessments
ME G4.2	The facility uses methods for quality improvement in services
ME G4.3	The facility uses tools for quality improvement in services
Area of Concern H- Outcomes	
Standard H1	**Key performance indicators (KPI) are measured**
ME H1.1	The facility measures productivity indicators on monthly basis
ME H1.2	The facility measures efficiency and safety indicators on monthly basis
ME H1.3	The facility measures Service Quality indicators
Standard H2	**Lactation management Centre strive to improve KPI and meet established benchmarks.**
ME H2.1	The facility endeavours to improve its productivity indicators to meet benchmarks
ME H2.2	The facility endeavours to improve its efficiency & safety indicators to meet benchmarks
ME H2.3	The facility endeavours to improve its service Quality indicators to meet benchmarks

Chapter 3

Preparing CLMC for Assessment

Assessment Protocol

Assessments need to be conducted based on the adherence to general principles which are prerequisites to achieve the objectives of the assessment. Following are the key principles of the assessments:-

1. Integrity
2. Fair presentation
3. Confidentiality
4. Independence
5. Evidence based approach

I. Planning for assessment

Baseline/Internal assessment – Baseline assessment would be done by Quality Circle/by facility quality team. A nodal person preferably CLMC manager can be designated as a coordinator for quality activities. The first assessment is considered as a baseline, subsequent assessment would be done at defined interval. District Quality Assurance Units can also help to conduct the internal/baseline assessment. Internal assessment is a continuous process so milk bank have to prepare a quarterly or earlier assessment schedule based on the gaps and causes of concern.

State assessment – Once milk bank start achieving 70% or more scores under internal assessment it can request State Quality Assurance Unit for state level assessment. SQAU can include empanelled state quality assessor for conducting state assessment.

National assessment for certification – All facilities achieving 70% or more scores in state assessment are eligible for National assessment. National assessment would be done by the deputed empanelled assessors by the Ministry of Health and family Welfare.

II. Constitution of Assessment teams:

Assessment team should be constituted based on scope of assessment. During internal assessment there should be at least one person from clinical domain preferably paediatrician/ trained MO. Apart from clinical domain expert, staff nurse trained in IYCF/MAA and Quality/hospital manager can support the internal

assessment. Facility can invite quality consultant from DQAU and district program officer for assessment.

State Assessment would be undertaken by at least two members that is quality consultant SQAU/ state empanelled assessor, domain expert /State program officer.

National Assessment would be undertaken by at least two members, at least one person from clinical domain preferably paediatrician/ trained MO. However, both the assessor should be empanelled NQAS external assessor.

III. Audit Man- days for National Assessment:

Two assessors for one working day.

IV. Preparing the assessment schedule:

The assessment schedule is a micro plan for assessment. It consists of details regarding levels of assessment, dates, timings, etc. The Assessment schedule should be prepared and shared beforehand.

V. Performing assessment

Designated team leader of the assessment team should ensure that assessment schedule has been communicated. Team leader should assign the area of responsibility to each team member, according to the schedule and competency of the members. A short opening meeting with the assessee should be conducted for introduction, aims & objective of the assessment and role clarity. The available records and documents such as Screening forms, Registers, microbiology reports etc. should be reviewed.

VI. Communication during assessment

Behaviour and communication of the assessors should be polite and empathetic. Assessment should be a fact-finding exercise and not a fault-finding exercise. All type of conflict should be avoided.

National Quality Assurance Standards						
Comprehensive Lactation Management Centre						
Reference No.	**ME Statement**	**Checkpoint**	**Assessment Method**	**Means of Verification**	**Compliance**	**Remarks**
Area of Concern - A Service Provision						
Standard A1	**Services for promotion and adherence to early and exclusive breastfeeding are provided as per prevalent guidelines**					
ME A1.1	Facility provides infant & young child feeding (IYCF) Services	Counselling and support services to initiate breastfeeding within one hour of birth	PI/RR	Brest examination & Counselling service during ANCs visits, Timely initiation of breast feed in Labour room, M-OT & Maternity ward / Post-op ward		
		Repeated counselling for exclusive breastfeeding for the first six month	RR/PI	Review feeding practices, counselling and support to mother and family members in post natal ward, Well baby clinic / immunization session / Paediatric OPD		
		Repeated counselling for initiation of appropriate complementary feeding form the age of 6 months	RR/SI	Review feeding practices, counselling and support to feeding options in Well baby clinic / immunization session / Paediatric OPD Availability of IEC material & education films, models, in the language undertood by the large section of population, for initiation of complimentary feeding from the age of six months		
		Counselling for continued		Review feeding practices, counselling and		

a, b, c, d, e, f, g, h, i, j

VII. Using the checklist for assessment

The checklist is the main tool for assessment. Assessors should familiarize themselves with the checklist beforehand. Layout of the checklists is given below:

(a) Title of the checklist denotes the name of Healthcare facility for which checklist is intended.

(b) The horizontal bar in grey colour contains the name of the Area of concern for which the underlying standards belong.

(c) Yellow horizontal bar contains the statement of standard which is being measured.

(d) Extreme left column of the checklist in blue colour contains the reference number of Standard and Measurable elements. The reference number helps in the identification and traceability of a standard.

(e) Second column contains text of the measurable element for the respective standard.

(f) The column next to measurable elements on right side has checkpoints for measuring compliance to respective measurable element and the standard.

(g) Next right to checkpoint column is the assessment method column. This denotes the 'HOW' to gather the information.

(h) Column next to assessment method contains means of verification. It denotes what to see in a particular Checkpoint. it may be list of equipment or procedures to be observed, or example questions which may be asked to the interviewee or some benchmark, which could be used for comparison, or reference to some other guideline or legal document. it may be left blank as checkpoint may be self-explanatory.

(i) Next right to means of verification column, a blank column is available where finding of assessment in terms of Full Compliance (2 marks), Partial Compliance (1 marks) and non-Compliance (0 marks) should be written.

(j) Next right to compliance column, a remark section is given. It needs to be filled by assessor whenever partial or non-compliance is given.

The assessor should read checklist beforehand and try to gather evidence and information to assess the compliance to the requirement of the measurable elements generally.

Information can be gathered by four methods:

- Observation (OB)
- Record Review (RR)
- Staff Interview (SI)
- Patient Interview (PI)

Scoring by using the checklists

After assessing the department, scores would be assigned against each checkpoint, in the compliance cell. The score obtained after filling the checklist will be in percentage. Three types of score cards would be generated by conducting assessment – Overall departmental score, Area of concern wise score and standard wise score. These scorecards will provide the holistic view of quality of service delivery in the department.

Rules of scoring

- 2 for full compliance
- 1 for partial compliance
- 0 for non-compliance

Calculation of percentage is as follows:

$$\frac{\text{Score obtained X 100}}{\text{No. of ME in checklist X 2}}$$

Scores can be calculated manually, or scores can be entered into the excel sheet given to get scores and dash boards.

VIII. <u>Assessment Conclusion</u> –

After gathering information and evidence for measurable elements, an assessor is expected to decide the level of compliance (full compliance, partial compliance, or non-compliance) for each of the Measurable elements.

External certification of CLMC would be taken up by the Government of India, empanelled national external assessors. National Certificate would be awarded based on following criteria

Criteria for National Level Certification:

I. Criterion 1 - Aggregate score of the department 70%

II. Criterion 2 - Segregated score in each Area of Concern (Service Provision, Patients' Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management, Outcome Indicator) 70%

III. Criterion 3 – Score of Standard A2, Standard B1, Standard D4 and Standard G2 is ≥70% in each applicable department.

- Standard A2 States **"Services for collection, processing, storage, and dispensing of DHM are available"**.
- Standard B1 states that **"There are no Physical, Informational or Financial barriers in availing the services".**
- Standard D4 states **"Compliance to applicable statutory and legal requirements are ensured"**

- Standard G2 states **"Hazard Analysis and Critical Control Point (HACCP) practices have been implemented as per guidelines".**

IV. Criterion 4 - Individual Standard wise score 50%

V. Criterion 5 - Patient Satisfaction Score of 70% in the preceding Quarter or more (Satisfied & Highly Satisfied on Mera-Aspataal) or Score of 3.5 on Likert Scale

Award of Certification –

a) Certification – If facility meets all the above-mentioned criteria. Certification is valid for a period of three years, subject to validation of compliance to the QA Standards by the SQAC team every year for subsequent two years. In the third year, the facility would undergo re-certification assessment by the National Assessors after successful completion of two surveillance audits by the SQAC.

b) Deferred Certification – The certification may be deferred until follow-up assessment if department overall score is 70% or less in external assessment and does not meet any of the criteria mentioned above. The department can reapply for certification within one year.

Assessment Tool

National Quality Assurance Standards					
Comprehensive Lactation Management Centre					
Reference No.	**ME Statement**	**Checkpoint**	**Assessment Method**	**Means of Verification**	**Compli-ance**
Area of Concern - A Service Provision					
Standard A1	**Services for promotion and adherence to early and exclusive breastfeeding are provided as per prevalent guidelines**				
ME A1.1	Facility provides Infant & young child feeding (IYCF) services	Counselling and support services to initiate breastfeeding within one hour of birth	PI/OB	Breast examination & Counselling service during ANCs visits: Skin to skin contact, timely initiation of breast feed in Labour room, M-OT& Maternity ward/ Post -op ward	
		Repeated counselling for exclusive breastfeeding for the first six months	RR/ PI	Review feeding practices, Counselling and Support to mother and family members in post-natal ward, Well baby clinic / immunization session/ Paediatric OPD	
		Repeated counselling for initiation of appropriate complementary feeding from the age of 6 months	RR/PI	Review feeding practices, Counselling and Support on feeding options in Well baby clinic / immunization session/Paediatric OPD Availability of IEC Material & education films, models, in the language understood by the large section of population, for initiation of complimentary feeding from the age of six months	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Counselling for continued breastfeeding for two years and beyond	RR/PI	Review feeding practices, Counselling and Support on feeding options in Well baby clinic / immunization session/Paediatric OPD	
ME A1.2	Facility provides mandated new born & Infant health services	Availability of Mother's own milk (MOM) for new born and infant as first and foremost choice	RR/ OB	Check provision in SNCU/ NICU, Post Natal ward/ KMC Ward	
		Availability of Donor Human Milk (DHM) for Sick new born and infant	RR/OB	Functional linkage with SNCU/ NICU, Post Natal ward/ KMC Ward	
		Availability of DHM services for newborn	RR/SI		
ME A1.3	Services are available for the time period as mandated	CLMC services are functional as per state norms	SI/ RR	Minimum 8 hrs per day	
		Provision of providing DHM to newborn and infants 24*7	SI/ RR	(1) Check functional linkage with SNCU/ NICU (2) Check advance estimation for DHM is taken from concerned departments (3) As per estimation pasteurized deep freeze DHM is kept in dedicated refrigerator in milk bank/ NICU/SNCU for gradually thawing	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check DHM is available in concerned departments during holidays/ long weekends	PI/RR	As per estimation pasteurized deep freeze DHM is kept in dedicated refrigerator in milk bank/ NICU/SNCU for gradually thawing	
Standard A2	**Services for collection, processing, storage and dispensing of Donor Human Milk are available**				
ME A2.1	Facility provides services for screening & collection of donor human milk	Availability of Screening services for donor mother in CLMC	RR/ SI	Availability of Services for Donor Registration, Blood Test (Side Lab/ linkage with certified lab) and physical examination	
		Availability of Collection Services for donor in CLMC	OB/ RR	(1) Check support for milk expression using manual or breast pump methods are available (2) Check labelling of bottles used for milk collection	
ME A2.2	Facility provides services for processing & testing of donor human milk	Availability of Processing Services in CLMC	OB/ RR	Pre and Post pasteurization services	
		Availability/ Linkage with microbiological laboratory with CLMC	OB/ RR	Services for culture and other procedures to test the milk for ensuring safety of processed milk through side lab. / Linkage with outside lab.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME A2.3	Facility provides services for storage and dispensing of donor human milk	Availability of Storage Services for DHM	OB/ RR	Deep Freezer and Refrigerator	
		Availability of Dispensing services	OB/ RR		
Area of Concern -B Patient Rights					
Standard B1	**There are no Physical, Informational or Financial barriers in availing the services.**				
ME B1.1	The facility has user friendly and uniform signage system	Directional and Departmental Signages for CLMC are displayed	OB	Direction (from main gate), name of the department and restricted area signages	
		Internal section & restricted area signages are displayed	OB	Registration, Collection, Processing and dispensing	
		Check signage are in a language, easily understood by the visitors	OB/PI	Signages are user friendly, pictorial, and in uniform colour	
		Check the adherence to restricted access in DHM storage area	OB	Restricted Signage and only authorized person has access to DHM Storage area	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME B1.2	Access to facility is provided without any physical barrier & friendly to people with disability	Availability of Wheel chair and ramp with railing/ lift for easy access to milk expression area or milk bank	OB	Ramp have a slope that is conducive for use (gradient not to be steeper than 1:12, Width 120 cm, Ramps are provided with slip resistant)	
		Availability of disabled friendly toilet in/ proximity to toilet	OB	Check for grab bars, emergency pull string, wheelchair friendly door	
		Crowd management is orderly & respectful	OB	Both within and outside the CLMC	
ME B1.3	The facility provides cashless services to neonates and infants as per norms	DHM is provided free of cost	PI/SI	Check with recipient parents if they have paid for DHM	
		No incentives are provided to donor mother	PI	Milk Donation should be voluntary	
Standard B2	**Services are provided in dignified manner ensuring privacy & confidentiality as well as respecting societal and cultural preferences**				
Standard B2.1	The facility ensures privacy & confidentiality of donor & recipient	Screen/ curtains are provided	OB	(Expression room, physical examination area) secondary curtain/ screen is available to create a visual barrier and protect privacy of a mother	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Curtains at windows and doors of the expression room	OB		
		No male member is allowed in the milk expression room	OB/ PI		
		Only on duty staff is allowed in milk expression area when it is occupied	OB/ PI		
		Special front open Breastfeeding/ nursing gowns are provided	OB/ RR		
		Visual privacy is maintained between the donor mothers	OB	Screens are available	
		Confidentiality of the donor and recipient is maintained	OB/ RR/ SI	Records are kept in secure place beyond access of general public	
		Confidentiality of the results of screening is maintained	SI/OB/ RR		
Standard B2.2	There is established procedure for taking consent from donor and recipient	Procedure is established to take written informed consent from the donors	RR/ PI	Consent form is available in local language and is explained to mother/ father/dually authorized representative	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Procedure is established to take written informed consent from the recipients	PI/ RR	Consent form is available in local language and is explained to mother/ father/dually authorized representative Check few filled in formats and verify with issue register	
Standard B2.3	Mother's and donors are sensitized and educated through appropriate IEC/BCC Approaches	Appropriate IEC/ BCC activities are conducted to promote IYCF practices	OB/ SI/ PI	IEC Material & education films/ models in the language understood by the large section of population on promotion of early initiation of breast feeding and complementary feeding	
		Appropriate IEC/ BCC activities are conducted to promote benefits of Breastfeeding	OB	IEC and counselling on Kangaroo Mother Care, advantages of early breastfeeding, benefits of milk donation, disadvantage of formula feed	
		Appropriate IEC/ BCC activities are conducted for Health Promotion	OB	IEC and counselling for Intake of Nutritious food, personal hygiene, avoidance of tobacco and alcohol, Hand Hygiene, post-natal advice (danger signs of neonate and infants), warning signs of cancer	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Area of Concern- C Inputs					
Standard C1	**Comprehensive Lactation Management centre has adequate infrastructure and optimal layout for providing the mandated services.**				
ME C1.1	Department has adequate work space and layout is demarcated as per func-tion	Adequate Space as per the scope of service	OB		
		Demarcated reception cum administrative area	OB	Reception at entrance and serve purpose of enrolment, initial screening and dispensing of DHM	
		Dedicated Counselling Area	OB	Facilitate registration and support one to one or group counselling	
		Demarcated Milk Expression and Collection Room	OB		
		Dedicated Milk Processing Area/ Room	OB	Glass doors, exhaust fan, Split AC	
		Area for the microbiological laboratory	OB	Glass door, exhaust fan, Window AC Give full compliance if microbiological tests are conducted within hospital or linked with outside lab.	
		Dedicated Milk Storage Area/ Room	OB	Split AC	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Dedicated Cleaning/ Autoclaving Area & sluice room	OB	Glass/ Swing door, Exhaust fan, Water reservoir with both in and outlets	
		Separate Changing Room, Shower Room and toilets for mothers	OB	(1) Shoe rack, locker, shower with hot and cold water/ bucket with mug, exhaust fan, plain soap. ensure toilet is not within shower room. (2) Check toilet should not open directly into any room in which milk or milk products are processed. Toilets, changing rooms and shower rooms must have tight fitting, self-closing doors.	
ME C1.2	Service counters and donors' amenities are available as per load	Availability of Milk Expression Station as per the load	OB	Adequate number of milk stations are available as per load with provision of privacy	
		Adequate chairs for donor mothers & baby cots/ space to keep their baby safe & comfortable	OB	Check suitable arrangement are made to keep babies within visible reach of donor mothers	
		Adequate amenities for mothers & attendants in waiting area	OB	Adequate sitting arrangement and availability of drinking water & toilets in vicinity	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compliance
ME C1.3	The department is planned to ensure structure commensurate with function of the hospital & essential requirements are met	CLMC maintains linear fashion in coherence with its processes	OB	(Registration, Screening of Donor, Shower Room and Changing Room, Milk Expression cum Collection Room Pooling Area, Testing Room, Storage Room and Dispensing Area)	
		Check location of storage and pasteurization area is away from general walkways	OB		
		CLMC is in proximity to MCH Wing/ NICU/ SNCU	OB		
Standard C2	**Physical and fire safety measures are implemented**				
ME C2.1	The facility ensures the seismic and physical safety of infrastructure where services are provided	Non-structural components are properly secured	OB	Check for fixtures and furniture like cupboards, cabinets, and heavy equipment, hanging objects are properly fastened and secured	
		Floors of the CLMC are non-slippery and even	OB		
		CLMC building is well maintained	OB	No major cracks and chipped plaster on ceiling, walls & floors of the building	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME C2.2	The facility ensures safety of electrical establishment	No temporary connections and loosely hanging wires	OB		
		CLMC has earthing system available	SI/RR	(1) Heavy equipment have earthing & fuse, (2) Earth resistance should be measured twice in a year and logged (3) CLMC has mechanism for periodical check / test of all electrical installation	
		Safety measures are undertaken to use electrical breast pump	SI/RR	For electrical protection replaceable fuses or reset table over current breakers	
		No extension board/ multioutlet converter are used with heavy equipment	OB	Switch are marked 5amp and15 amp for clear identification and correct use	
ME C2.3	The facility ensures adequate fire safety measures as per requirement	CLMC has fire exit to permit safe exit	OB	Check the fire exits are clearly visible in dark and exit routes are clearly marked & obstruction free, Check the evacuation plan. Give non-compliance if main exit door is labelled & is used as fire exit	
		CLMC has installed fire extinguisher as per requirement	OB/RR	Check Class ABC type & CO2 type fire extinguisher are available, Check the expiry date and due date for next refilling is displayed. Check for fire safety alarm	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check for staff trained for operating fire extinguisher	SI/RR	Ask to demonstrate, Staff is aware of PASS (Pull the pin, Aim at the base of fire, Sway from side to side), RACE (Rescue, Alarm, Confine, Extinguish)	
Standard C3	**Adequate qualified and trained staff for rendering the mandated services are available**				
ME C3.1	The facility has adequate staff available and deployed for stipulated functions	Availability of neonatologist/ paediatrician	SI/ RR	Two (One designated and other additional charge)	
		Availability of Microbiologist	SI/ RR	Part Time i.e., 2 hrs / day, Periodic visit of microbiologist	
		Availability of CLMC Manager	SI/ RR	One	
		Availability of Lactation Support Staff	SI/ RR	Only Females, 3 in number/as per case load	
		Availability of CLMC Technician	SI/ RR	One	
		Availability of Hygiene Helper	SI/ RR	Hospital deputes at least 1 hygiene helper for each shift	
ME C3.2	The staff has been provided with required training/ skill set	Training of Lactation Support Staff	SI/ RR	IYCF training, Collection, Storage, thawing, record keeping of DHM training, Infection Control, HACCP, F-IMNCI, Quality Training, BLS	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Training of CLMC Technician	OB/ SI	Milk Processing for Pasteurization, testing, Storage and Record keeping, HACCP, Quality Training	
		Training of CLMC Manager	OB/ SI	HACCP, Training on Use of quality Tools and Methods, Infection Control	
		Training of Microbiologist	OB/ SI	Infection Control, Quality management, HACCP, BLS	
		Training of Neonatologist/ Paediatrician	OB/ SI	HACCP, F-IMNCI, Biomedical Waste Management & Infection control and hand hygiene, Quality Management, BLS	
		Training of Hygiene Helper	OB/ SI	Cleaning Protocols, BMW, Infection Control Practices	
ME C3.3	Competency assessment of staff is done as per pre-defined cri-teria at least once in a year	Check parameters for assessing skills and proficiency of clinical& para clinical staff has been defined	SI/RR	Check objective checklist has been prepared for assessing competence of doctors staff based on job description defined for each cadre of staff.	
		Check for competence assessment is done at least once in a year	SI/RR	Check for records of competence assessment including filled checklist, scoring and grading. Verify with staff for actual competence assessment is done	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard C4	**Equipment and consumables for collection, processing and storage of Human milk are available as per defined norm and case load**				
ME C4.1	Availability of functional equipment for collection and processing of Human milk	Availability of equipment for milk expression	OB/ SI	Electric breast pump with isolated motor	
		Adequate availability of containers and consumables for milk collection	OB/ SI	Separate Sterile bottles with cap for collection, Sterile tubing of breast pump. Separate container for colostrum, Pre-term and mature milk)	
		Availability of equipment for Milk Processing	OB/ SI		
		Availability of equipment and instrument for testing of DHM	OB/ SI/ RR	Level II Bio Safety Cabinet, Microscope with oil emulsion lens, Hot air circulating oven, PH meter, Lab Incubator, Bunsen Burner,	
		Availability of Consumables for testing of DHM	OB/ SI/ RR	Petri dishes, pipets with pipet aids, dilution blanks, reagents	
ME C4.2	Availability of functional equipment for storage	Dedicated Cold Storage equipment as per requirement	OB/ SI	At least 2 Deep Freezer and Refrigerator with thermometer or temperature sensitive alarm	
		Check Stabilizer for all critical equipment	OB/SI		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Availability of equipment & consumables at Autoclaving room	OB/ SI	2 bay scrub station, Dishwasher/ Washer, Kitchen basket, Thermal Disinfector, Table top autoclave machine, heat sealer machine with cutter, Neutralizer, Detergent (adequate quantity)	
ME C4.3	Availability of equipment for support services	Availability of functional equipment at Reception Area/ Counter	OB/ SI	Intercom, Cupboards for Records, Computer with Printer	
		Availability of functional equipment at Counselling Room	OB/ SI	Audio Visual Aids (TV, Video System, Mike), Mannequins	
		Availability of equipment at Sluice Room	OB/ SI	2 bucket trolley, Mop wringer with liquid detergent, soap and phenyl, Janitor Trolley, Window wiper, laundry trolley, Rubber gloves and gum boots etc.	
		Availability of equipment for transportation	OB/ SI	Ice box with cold gel pack	
Area of Concern D- Support Services					
Standard D1	**Maintenance and Upkeep processes are effectively implemented.**				
ME D1.1	The facility has established system for maintenance & calibration of critical equipment	All equipment including IT are covered under AMC including preventive maintenance	RR/SI	Contact details of the agencies responsible for maintenance are communicated to the staff	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		There is system of timely corrective break down maintenance	RR/SI	All equipment including IT, there is a system to maintain records of down time of equipment, Check the log book.	
		Regular cleaning and maintenance of bio safety cabinets/ laminar flow	RR/SI	As per manufacturer's instructions for air flow, pressure gradient and HEPA filter efficiency.	
		All the monitoring equipment and pasteuriser are calibrated	OB/ SI	PH meter, Data logger, Thermometer, Binocular Microscope, Autoclave, including storage and processing equipment, records of calibrated equipment are maintained	
		Operator is skilled for periodic cleaning, inspection and troubleshooting of equipment	SI/ RR		
		Functional, operational & integrity of laminar air flow cabinet & pasteuriser is checked regularly	SI/ OB	At the time of installation and thereafter regularly as per manufacturer instruction and annual certificate is issued	
ME D1.2	Operating & maintenance instructions are available with the user of equipment	Operating Instructions for critical equipment are available at the point of use	OB/ RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Operator is skilled for operating the milk bank equipment	OB/RR		
ME D1.3	The facility has established system for maintenance & upkeep of CLMC	Walls are well plastered and painted	OB	Floors, ceiling and walls are smooth and easy to clean, no seepage. Department is painted in uniform colour	
		Window Panes, Doors and other fixtures are intact	OB		
		No condemn/ junk material is lying in the department	OB		
		Use of Three bucket system for cleaning	SI/OB	Check if cleaning staff uses three bucket system for cleaning. One bucket for cleaning solution, second for plain water and third one for wringing the mop. Ask the cleaning staff about the process	
		Use unidirectional method and outward mopping	SI/OB	Ask cleaning staff to demonstrate how they apply mop on floors. It should be in one direction without returning to the starting point. The mop should move from inner area to outer area of the room.	
		No use of brooms in any area of the CLMC	SI/OB	Check if brooms are stored in patient care areas. Ask cleaning staff if they are using brooms for sweeping.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Use of separate mops for milk processing area and general procedure areas	SI/OB	(1) Check if cleaning staff is using same mop for outer general areas, milk processing and milk storage areas. (2) The mops should not be shared between milk processing and general area. (3) The clothes used for cleaning procedure surfaces should not be used for mopping the floors.	
		Disinfection and washing of mops after every cleaning cycle	SI/OB	Check if cleaning staff disinfect, clean and dry the mop before using it for next cleaning cycle.	
		Use of Housekeeping Checklist in procedure Areas	OB/RR	(1) Check that Housekeeping Checklist is displayed. (2) Check Housekeeping records whether checklist has been daily updated for at least last one month. (3) Check a person is designated for monitoring of Housekeeping Activities	
		No dirt/ grease/ stains and cobwebs/ bird nest/ vegetations/ dust	OB/SI	Check cleaning of the corridors, walls, roof and circulation area	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Shower and Toilets are clean	OB	No clogged/ overflowing drain in the department. There is no foul smell in toilets	
		No animals/ rodents/ birds/ flies in the department	OB	Use of fly swats/ flaps for flies, Pest, rodent and termite Control Measures are taken	
Standard D2	**Procedures established for estimating the demand of donor human milk and maintaining the buffer stock to avoid stock out**				
ME D2.1	There is estab-lished proce-dure for fore-casting and intending the requirement of the milk	There is established system of timely indenting of Milk from CLMC	SI/RR	Requisition is placed in advance	
		Mechanism for daily calculation of milk requirement by users for indenting is established	SI/RR	Daily requirement of each baby is calculated based on the Neonate / infant disease condition, weight and as per prescription.	
		There is established system for keeping pasteurized DHM in refrigerator beforehand (i.e., well in advance)	SI/RR	Thawing of milk require 24 hrs as per requirement	
ME D2.2	The facility has established procedure for inventory management of donor or mothers' milk	Physical Verification of stock is done on periodic interval	SI/RR	Stock level are updated as and when transaction take place	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		First Expiry and First Out system is followed	SI/RR	First batch going inside the deep freezer should be the first batch coming out	
		Established system to define Minimum Stock level	SI/RR	Check how Buffer stock is maintained	
		Check Staff is aware of notification plan in case of inability to dispense milk	SI/ RR	In case of stock out or natural/ manmade calamity	
ME D2.3	There is pro-cess for stor-age of ex-pressed milk at controlled tempera-ture during pre-pasteuri-zation, trans-portation and post pasteuri-zation period	Temperature is maintained during Pre-Pasteurization	RR/ OB/ SI	Refrigerator 4°C, Deep freezer (-) 20°C.	
		Temperature is maintained during transportation	OB/ SI	Ice box with cold gel pack	
		Temperature is maintained during post pasteurization	RR/ OB/ SI	(1) Deep freezer (-) 20 degree C. (2) Cooled, heat processed milk can be stored sealed for up to 72 hours at 4°C for dispensing without freezing once bacteriological culture procedures and standards are met. Milk can then be frozen for later use if not needed immediately.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check deep freezer have functional temperature monitoring devices	OB	Monitoring devices are temperature sensitive having functional audible and visual alarm	
		Check refrigerator have functional temperature monitoring devices	OB	Monitoring devices are temperature sensitive having functional audible and visual alarm. Check refrigerator is defrosted at defined intervals	
		There is system in place to maintain temperature chart of refrigerator & deep freezer	OB/RR	Daily log is maintained at least twice /day	
		Staff is aware of hold over time of cold storage equipment	SI/RR	In case of electricity fluctuation & if temp cannot be maintained for 24 hrs - Discard DHM	
		Staff is aware of protocols in case electricity fluctuations are reported	SI/RR	If temperature cannot be maintained for 24 hrs - Discard the milk	
		No Deep freezer and refrigerator are without dedicated power back up	OB/SI		
Standard D3	**Safe and comfortable environment is provided to donors and as well as to the staff of lactation management centre**				
ME D3.1	The facility ensures safe, secure and comfortable environment for mothers' and donors	Temperature control and ventilation in CLMC	PI/OB	Air conditioners/Fans/ Heating/Exhaust/ Ventilators as per environmental condition and requirement	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check availability of functional air conditioner in milk expression area	PI/OB	As per environmental condition	
		Ask mothers & female staff whether they feel secured and comfortable at milk bank	SI		
		Music System is installed in Milk Expression area	OB/ PI		
ME D3.2	The facility provides adequate illumination at all working sites of lactation management centre	Adequate illumination in Processing Area	OB	Check milk processing area have Illumination Level of -300 Lux	
		Adequate illumination in Ancillary Area	OB	Toilets, Circulation, waiting area, reception etc. area have Illumination Level of -150 Lux	
ME D3.3	The facility has arrangement for potable water and power back up in lactation management centre	Availability of 24X7 running and potable water	OB/ SI	Check CLMC has dedicated water tank with adequate storage as per the requirement.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check chemical and biological testing of water is done at defined intervals	SI/RR	Chemical and Biological testing of water is done at least quarterly. Hospital Water testing report is also acceptable if samples of water have been taken from CLMC for testing.	
		Availability of 24*7 power back up	OB/ SI		
Standard D4	**Compliance to applicable statutory and legal requirements are ensured.**				
ME D4.1	The facility has requisite licences and certificates for its operations	Availability of valid No objection Certificate from fire safety authority	RR	Standalone building - Separate Fire NOC or Fire NoC for main hospital is also acceptable if CLMC building is a part of approved hospital fire plan	
		Availability of authorization for generation of Bio Medical waste	RR	Main hospital's authorization for handling BMW is also acceptable if collection, transportation & disposal is done by main centre or If CLMC is standalone building- Separate authorization for BMW	
		Availability of licence for operating lift	RR	Give full compliance if CLMC is at ground floor	
ME D4.2	Updated copies of relevant laws, regulations and Govt. orders are available	IMS Act 1992 and its subsequent amendments	RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Code of Medical ethics 2002 and its subsequent amendments	RR		
ME D4.3	The facility ensures relevant processes are in compliance with statutory requirements	No information, counselling and educational material is provided to mothers and families on Formula Feed	PI/ SI		
		No display of poster/ placards/ pamphlets/ logos at the health facility/ CLMC for the promotion of Formula feed	PI/ SI		
		Check staff can explain at least 3 components of IMS Act	SI	(1) Prohibition from any kind of promotion and advertisement of infant milk substitutes, (2) Prohibition of providing free samples and gifts to pregnant women or mother, (3) Prohibit donation of free or subsided free samples, (4) Prohibit any contact of manufacturer or distributor with staff	
		Check milk substitute manufacturing and marketing companies are not sponsoring hospital activities	SI/PI	(1) Workshops/Seminars/ CMEs/research etc. (2) Funding, gifts to the staff (3) Gift hampers to mothers	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Area of Concern E- Clinical Services					
Standard E1	**Procedures established as per guidelines for recruitment of Donors**				
ME E1.1	The facility has defined and implemented criteria for potential donor selection	CLMC has established criteria to identify potential donor	SI/RR	Potential donors could be Mothers': (1) whose babies are sick and not in a position to be fed/ taking minimal enteral feed, (2) mother with good milk output, (3) mothers who have congested breast and need to express milk.	
		CLMC has identified areas/ sites where they promote the importance of breastfeeding and get potential donors	SI/OB	SNCU/ NICUs, postnatal and KMC wards, well baby follow up clinics, paediatric wards, immunization sessions and lactating women in staff	
ME E1.2	The facility has defined & implemented procedure for donors selection	CLMC has established criteria for Donor selection	SI/RR	Lactating women having good health condition & willing to donate her surplus expressed milk at health facility.	
		No incentives/ special allowance is given to donor	SI/PI	Practice is completely voluntary	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME E1.3	The facility has defined & implemented criteria for temporary disqualification	CLMC has established criteria for temporary disqualify the selected donor visiting CLMC regularly	SI/RR	Suffering from acute infection, or reactivation of illness, cough for more than 2 weeks, mastitis or fungal infection, active herpes or chicken pox infection, received vaccination for rubella, measles, mumps within last 1 month & varicella vaccination in last 3 months, one month restriction for more with rubella or chicken pox in house hold	
		Donors are instructed to report illness in household for evaluation of communicable diseases and contamination of milk	PI/RR	Check with donor if she is aware about reporting of recent illness	
		Check staff is aware of illness where deferral period is not required	SI/RR	Illness or exposure not related to milk safety viz. Common cold, conjunctivitis, seasonal flu as long as medication are not needed	
		Check temporary disqualified/ disqualified donors are referred for further diagnosis & management	SI/RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E2	**Procedures established as per guidelines for screening of Donors**				
ME E2.1	The facility has defined & implement-ed criteria for donor registra-tion & consent	Unique identification number is given to each donor	RR	Registration number should be linked to hospital registration and donor card is issued to each donor	
		Donor's demographic details are recorded	RR	Donors' demographic details like donor's name, age, address, age of her child.	
		Standardised donor registration form is available	RR/SI	Form explicitly mentions about inclusion & exclusion criteria. Form is available bi lingual	
		Establish system to carry out Physical examination of breast at time of registration	SI/OB/RR	Check for presence of skin or breast lesions etc	
		Informed written consent is taken from all donors	RR	Check few consent forms	
ME E2.2	The facility has defined & implement-ed criteria for screening through blood tests	Mandatory screening of blood tests is done	RR/SI	Either HIV, Hep B, VDRL, any other highly contagious prevalent disease viz COVID -19 etc. or antenatal serology reports done within 6 month is available	
		Staff is aware of conditions when blood test can be exempted	SI/RR	Antenatal serology test conducted by certified lab within 6 months, negative test results do not require confirmatory testing	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME E2.3	The facility has defined & implemented criteria for exclusion of donors	Donor exclusion criteria is established & follow it	SI/RR	Blood transfusion, organ/ tissue transplant, tattoo/ ear/body piercing within past 12 months, use of alcohol, tobacco, usual/ occasional smoker. Chronic infection (HIV, TB, Hepatitis), history of hepatitis or treatment of any type of cancer within last 3 yrs., partner suffering from HIV, hepatitis, venereal disease in past 12 months	
		Staff is aware of medications allowed to prospective donor while donating milk	SI/RR	Vitamin, insulin, thyroid replacement hormones, hydrocortisone, inhaler for Asthma, eye drops, nasal spray, topical medication, OCP immunoglobulin (tetanus, rabies), Antacids, Calcium, magnesium, cynethicon, non-sedating Anti histamines	
		Check Staff is aware of medications contraindicated to prospective donor	SI/RR	Contraindicated medicine -- immunosuppressive drugs, Anti-Cancer/ cytotoxic drugs, radioactive compound, palliative care drugs, lithium, gold salt, iodine, retinoids, Amiodarone, Androgren, chloramphenicol, Estrogens, Iodine, Ergotamine etc.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E3	**Implementation of optimal and scientific milk collection processes are ensured as per guidelines**				
ME E3.1	The facility has defined & implemented process for donor counselling	Check education and sensitization of donor mother is done by lactation counsellor	OB/SI/RR	(1) Personal hygiene, hand washing, method & collection techniques, cleaning of breast pump & tubing. (2) Sensitization of donor mothers about activities/ diseases that may put her in risk of transmitting blood borne diseases	
		Check instructions are given both written and verbally	OB/PI	Information given in local language. Check availability of IEC material	
ME E3.2	The facility has defined & implemented process for preparatory activities	Step by step process of milk expression & collection are explained and followed	OB/SI	Shower followed by consumable food/ hot drink followed by expression of milk	
		Pre labelled sterile container is given to collect the milk	OB/RR/SI	Label should be waterproof and able to with stand high/low temperature	
		Do's and do not's are displayed & explained	OB/ PI	Don't discard foremilk, practice simultaneous expression of both breasts, passively collected milk/drip milk not used for donation, home collection is not permissible, No sharing of breast pumps, funnel and milk containers	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME E3.3	The facility has defined & implemented process for expression of breast milk (Manual & electric breast pump)	Mother is explained about methods of breast milk expression	SI/PI/OB	(1) By hand expression (manual) (2) Using electric breast pump	
		Techniques of expression of milk is displayed & taught	OB	Both Manual and using breast pump	
		Special instruction to use electric breast pump is displayed & followed	OB/SI	Switch off the pump before removing funnel from breast, it should not be painful, stop pumping after 20-40 min or when milk stops flowing, double pumping reduce time for expression	
		Mother is assisted to express and collect the milk by lactation counsellor / trained staff	SI/PI/OB	Special attention is given if mother is donating for first time	
		Step by step process for expression of milk are followed as per guidance	OB/RR	In both cases Manual and using breast pump	
		Number of times or minutes per day women can express milk is defined and there is a mechanism in place to check it	PI/RR	Minimum 8 times/day or 100 min in 24 hours till baby start breastfeed.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E4	**Labelling and pre-pasteurization storage of collected milk is done as per established protocols**				
ME E 4.1	The facility has established procedure for labelling of bottles used for storage of milk	All the bottles used for donation of human milk are labelled	OB/SI	Name of CLMC, unique ID no, date of donation, age of child, time of collection, container no., site of collection, date of freezing, pasteurization, testing and expiry	
		All the bottles used for storage of mother's own milk (MOM) are labelled	OB/SI	Name of CLMC, Unique ID no, Age of child, date & time of collection, site of collection, date of freezing, and expiry	
		No mixing of milk donated by same mother at different times	OB/RR/SI	Check milk donated collected in different containers & it is labelled with same ID, different time & date	
		CLMC has system in place for logging of DHM	RR/OB	Logging of donated milk including its volume estimation is done	
		Check the donated milk bottle for any contamination at collection counter	OB/SI	Staff observe the bottle for foreign matter, any contamination including broken storage container while receiving the DHM	
ME E 4.2	The facility has established procedure for pre pasteurization storage of milk	Recommended temperature and duration is maintained for storage of Mother's own milk	OB/RR/SI	(1) Temp. of +2 to +4 ^{0}C if used within 24 hrs. (both full or not full bottle). (2) Mother's own milk which is not expected to be fed within 24 hours should be immediately transferred to a separate deep freezer (–) 20˚C	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Recommended Temperature and duration is maintained for storage of donor human milk	OB/RR/SI	Deep freezer at -20^{0}C (both full or not full bottle). DHM should not to be stored more than 3 months before pasteurization	
		Check there is no mixing of Pre and Post Pasteurized Milk (DHM)	OB/SI	Ensure separate deep freezer installed in processing and storage room	
		Check separate compartment in freezer and refrigerator for storage of pre term and mature milk	OB/SI/RR	Compartments are labelled/ mistake proofing methods are followed row avoid mixing in compartments	
		Protocols for storage of pre pasteurized milk are displayed and practiced	RR/SI	Instruction for Temperature and duration maintenance for storage of Mother's own milk & donors human milk is displayed & followed No shifting of containers, protocols for thawing of frozen milk etc are in place	
ME E 4.3	The facility has established procedure for thawing of frozen raw donor human milk	Thawing protocols are established as per standard guidelines	RR/SI/OB	Shift frozen DHM to refrigerator overnight & allow to thaw slowly at 4^{0}C	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Thawing protocols for emergency required are established	RR/SI	Thawing can be done in a wide container of warm water (not exceed 37 ^{0}C) ensuring that water does not touch the lid of container and it does not fall over/ Milk warmer with specific temperature can be used	
		Date and time of thawing is accurately maintained	RR	Check the records	
		Protocols of after thawing is followed	SI/ OB	Outside of the container of DHM should be dried and clean with paper towel. Gently agitate in order to uniformly distribute constituents like protein, water, fat etc	
		Staff is aware of **DON'TS** of thawing	SI	1) Thawing should not be done at room temp. (2) Thawing should never be done in microwave or below radiant warmer/ boiling water (3) No mixing of raw and frozen milk of same mother (4) Thawed milk should never be freezed again (5) Raw thawed DHM should never be frozen without pasteurization	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E5	**Pooling and Aliquoting of milk is done as per established protocols**				
ME E5.1	The facility has established procedure for pooling of raw donor human milk	Pooling of raw milk is done as per standard guidelines	RR/OB	Sterilized conical flask is to be used for pooling of DHM from 3 mothers. Stir the flask with sterile stirrer and swirled for homogeneity	
		One batch is constituted from pooled raw milk of 3 mothers	RR/SI/OB	Preferably 3 mothers. It may be 3-5 mothers in case donor volume is small	
		Unique identification number is given to each batch	RR/SI/OB	An alphanumeric code containing 8 letters linked with registration no. of all donors in pool	
		Pooling of raw DHM is done in clean & hygienic environment	OB	Preferably on steel slab under laminar air flow system	
		Visual screening on surface of each container is undertaken during pooling	SI/OB	(1) Use of fine sieve for segregation of physical contaminants. (2) Check for any hair/ skin cell on surface of containers.	
		No pooling of pre term and term milk	SI/RR		
ME E5.2	The facility has established procedure for aliquoting donor human milk	Aliquoting of pooled milk is done as per standard protocols	RR/SI	Predetermined amount as per bottle size aliquoted in clean container under laminar flow	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Adequate air space is left in container	OB/SI	(1) Allow to expand during freezing (2) Check milk bottles is distorted or chipped	
		Containers are sealed tightly with sterile cap	OB/SI	Electronic sealing is used.	
		Serial number is allocated to each bottle	OB	Check all bottles are allocated with serial number	
		Different type of milk is pooled and labelled separately	OB/RR	Pre term and mature milk	
ME E5.3	The facility has established procedure for pre pasteurization testing of pooled milk	Sample is taken for pre pasteurization microbiological testing	RR/OB	1-2 ml sample of pooled raw DHM is collected in sterile bottle/test tube	
		Sample collected for Pre pasteurization is marked	RR/SI/OB	Sample is marked with **P** with its serial number	
		Check milk bank follow precise & accurate pre pasteurization testing procedures	SI/RR	Check staff is aware of bile broth testing for confirmation of coliforms	
		The result of pre pasteurized raw milk is analysed	RR/SI	Raw DHM is tested for Staphylococcus aureus colony count	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check the Action taken report for last 3-6 months	RR/SI	(1) Discard milk if colony count is more than 10^4 CFU for Staphylococcus aureus, other microbes are accepted. (2) Check the record of the discarded milk	
Standard E6	**Pasteurization of Donor Human Milk is done as per protocol.**				
ME E6.1	Facility has defined and implemented standardized pasteurization methods	Staff is aware of importance of pasteurization	SI	It retains milk's beneficial components and prevent lipid peroxidation and inactivates and kills pathogenic bacteria	
		Check the frequency of pasteurization in CLMC	SI/RR	Preferably each day or depend upon quantity of milk collected.	
		Staff has in depth knowledge of different method of pasteurization/heat treating human milk	SI/RR	Low temperature, long time (LTLT) High temperature, short time (HTST). (LTLT is recommended for CLMC, also known as holder pasteurization)	
ME E6.2	Facility has defined and implemented standardized choice of pasteurization	Staff is aware of temperature and duration maintained for holder pasteurization	OB/RR	Heat DHM to 62.5^0C (+/- 0.5 ^{0}C) and holding this temperature for 30 min. Rapidly reduce the temp. i.e., 25 ^{0}C attained within 10 min. Final temp. 4^0C attained prior to transfer it to freezer	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check visual output of temperature & time is displayed in fully automated / Semi automated pasteurization	OB/RR	Check Data Logger for temperature	
		Check data records of pasteurization are available in CLMC	RR		
		Staff is aware of manual method (heating processing followed by chilling)	SI/RR		
ME E6.3	Facility has defined & implemented standardized post pasteurization processing	Post pasteurization process is established	RR/SI	Randomly choose aliquot of processed milk and send it to culture test	
		Labelling of aliquot taken for culture is done as per guidelines	OB/SI	Labelled with **S**	
		Check there is no mixing of pasteurized DHM awaiting for culture report with culture negative pasteurized DHM	BO/SI	Check availability of 2 freezer to store negative culture processed milk & DHM whose report is awaited	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E7	**Post Pasteurization testing of milk is done as per established protocol**				
ME E7.1	Facility has adequate arrangement for testing of pasteurized donor human milk	Check availability of lab support for microbiological testing	SI/RR	Side Lab./ Linkage with in house or outsourced certified microbiological laboratory with CLMC	
		Check frequency of microbiological testing of stored pasteurised DHM is defined and followed	RR/SI	Either at least once a month or every 10 cycles of pasteurization - Which ever come first	
		Check mechanism in place to conduct the test on adhoc basis	RR/SI	Whenever new staff, equipment and process is introduced	
		Check action taken report for the cases when any growth reported	RR/SI	Discard the entire batch	
ME E7.2	The Facility has defined & implemented process for testing of DHM	Check Microbiological testing of pasteurized DHM is done after each pasteurization cycle	RR/SI	Check total number of pasteurized cycles are matching with total number of microbiological reports received	
		Check plates and tubes culture medica are labelled before sample testing	SI/OB		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check methods used for testing of pasteurized DHM	RR/SI	Testing is done using serial dilution followed by Spread plate or pour plate method	
		Check staff is aware of interpretation of test result	RR/SI	Both pre-pasteurized and pasteurized milk	
		Staff is aware of do's & don't to be followed in microbiological lab.	SI/OB	(1) General safety measures for microbiological lab should be followed (2) Nutritional Assessment of DHM is not recommended (3) post-pasteurisation milk sample is taken from test bottle identified per batch.	
ME E7.3	The facility has standardized guideline for interpretation of tests results	Result of testing of pasteurized milk is co-related as per standard guidelines	RR/SI	Discard the milk if total viable microbial count of 10 CFU/ml or more	
		Check the report of microbiological surveillance for completeness and appropriateness	RR	Check report clearly defines method used for testing and its interpretation	
		Check records of action taken if report is positive	RR	In case the milk sample tests positive as per norms, the batch of bottles from which this sample is collected should be discarded and proper documentation should be maintained along with back tracking of mothers.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E8	**Storage of pasteurized donor human milk is done as per established protocols.**				
ME E8.1	Facility has defined and implemented process for storage of pasteurized milk	Sealed Pasteurized milk is stored as per standard protocols	RR/SI		
		Check Expiry date is labelled on each bottle	OB/RR/SI	Not more than 6 months from date of expression of milk	
		No expired milk is found in CLMC	OB		
		Check the pasteurised milk whose report is awaited, is stored separately in deep freezer	OB/SI	Check the deep freezer is locked and avoid accidental usage of milk	
ME E 8.2	Facility follows standardized temperature control & duration for storage of pasteurized milk in CLMC	Sealed Pasteurized milk is stored at standard temperature and duration in refrigerator & deep freezer	OB/SI/RR	At 4^0C for 24 hrs At -20 degree C for 6 months (from date of expression of milk)	
		Precautions are taken while storing DHM	OB/SI	Should be stored towards back of freezer, as temp. mostly remain constant	
ME E8.3	Facility adheres to standardized practices during storage & issuing of donor human milk	CLMC has defined protocols to issue the stored DHM	RR/SI	(1) Issued by Physician prescription only. (2) Copy of prescription is maintained in CLMC (3) Check FEFO is followed for dispensing	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Check lid of pasteurized DHM bottle is not opened in CLMC	SI/OB	It should not be opened till milk is dispensed	
		Pasteurized milk is not issued by transferring it in another container	OB/SI		
Standard E9	**Established procedures for Intramural issue of Donor Human Milk**				
ME E9.1	Facility has established criteria to issue donor human milk	No milk is dispensed without Physicians' prescription	RR/OB/SI	Check duly signed requisition form from NICU/SNCU etc	
		Recipient 's parents consent is taken to issue DHM	RR/PI	Verify filled recipient consent form and with issue register	
		CLMC has established criteria for selecting the new born for DHM	RR/SI	Premature& LBW baby, sick preterm new born, Severe IUGR, new born not having access to mothers' milk, physical absence of mother, lactation failure, multiple birth etc.	
		Check recipient receives DHM as per their need and indications	RR/SI	Pre term baby receive processed DHM of pre term donor	
		There is no discrimination on the basis of social and economic status of the patients	PI/SI/OB		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME E9.2	Facility has established criteria for intramural transportation of donor human milk	Check the protocols for intramural transport of DHM is defined and followed	RR/SI	Designated hospital staff to transport DHM to departments, fixed time to supply the DHM as per request, staff awareness about temperature maintenance protocols	
		There is established process to issue and transport DHM for first time	SI/PI	(1) Recipient consent form (2) Issue and transport of DHM for first time (3) Check who is authorized to take DHM from CLMC to SNCU/NICU	
		Temperature is maintained while transferring milk from CLMC to NICU/SNCU or any other place	SI/RR	Check the availability and use of cold gel packs while transportation	
		No milk is dispensed to parents/ guardians	PI/OB	Milk is handed over to designated Staff. Check parents are not transporting DHM from CLMC to SNCU/NICU	
ME E9.3	Facility follows standardized process for thawing of pasteurized milk before issuing it for use	Thawing of pasteurized milk is done as per standard guidelines	RR/SI	Transfer the DHM from Deep freezer to refrigerator to thaw at 4^0C	
		Staff is aware of time period for which DHM can be refrigerated for thawing	SI/RR	Maximum time period of 24 hours	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		CLMC issue instructions to use the DHM in NICU/ SNCU	SI/RR	Do not re freeze thawed pasteurized milk, use thawed pasteurized within 24 hours or discard. Once removed from refrigerator use within 4 hours or discard. Bring the DHM to room temperature. Not to keep thawed milk under radiant warmer	
		Time of opening of the DHM bottle is recorded	OB/SI/RR	There is a system in place to ensure the opening and consumption of its milk within 2 - 4 hrs	
		Check no left-over milk is further used	OB/ SI	Verify the time mentioned on the bottle and give non-compliance if it is used beyond 4 hours	
		Check information regarding opening of milk bottle, its consumption, left over and discarded milk is given by SNCU/NICU	RR/SI	Information is sent back to CLMC regularly in standardized format	
		Staff is aware of emergency thawing protocols	SI/RR	In paucity of time DHM is thawed in a container of warm water (temp not exceeding more than $+37^0$ C) and adequate precautions are taken (Water should not touch lid, once DHM come to chilled liquid form, bottle should be dried and stored are $+4^0$C)	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard E10	**Optimal feeding practices are ensured in attached NICU/SNCU**				
ME E10.1	The facility ensures optimal breast-feeding practices for new born as per guidelines	Facility ensures promotion for breast feeding and provide correct information on breast feeding practices during ANC/ PNC visits	OB/RR	Check & discuss with mother on breastfeeding pattern, emphasising on exclusive and demand feeding. Demonstrate the proper positioning and attachment of baby	
		Facility promotes breast crawl to initiate breast feeding	PI/RR/ OB	in Labour room/OT	
		Facility ensures initiation of breast feeding with in 1 hour	PI/RR/OB	Check data entry for early initiation of breastfeeding	
		HIV positive mothers are counselled on options of baby feeding during antenatal & birthing time	SI/RR		
		Check mothers are providing exclusive breast milk at least six months	PI	Check mother's knowledge regarding importance of breast feeding	
		Check mothers are aware of complimentary feeding after six months	PI	Check mother's knowledge regarding importance of complimentary	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME E10.2	The facility ensures optimal breast-feeding practices for sick new born & infant as per guidelines	Counselling and supporting mother for alternate method of feeding in case of pre term /low birth/ baby unable to suck the breast	SI/PI/RR	Expressed milk is given by spoon or cup or fed by gastric tube in adequate amounts according to age.	
		Baby's intake is monitored and ensure adequate amount as per age and disease condition is provided	SI/RR	Frequent feeding at least 8 times per day including night feeding. Check monitoring checklist of feeding for LBW newborn	
ME E10.3	The facility has defined guiding principles for using donor human milk	Staff is aware of WHO's best feeding practices for new born	SI	Sequence from best to worse: Mothers' own breast milk (fresh)> Donated fresh preterm milk> Donated fresh term milk> Pasteurized donated breast milk> Preterm formula> Ordinary formula (worst)	
		CLMC staff strictly follow human milk donation process & consumption principles as per guidelines	SI/RR	Mother donate milk after providing to her own baby. Informed consent is taken from both donor & recipients' parents. DHM cannot be used for any commercial purpose	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Area of Concern F- Infection Control					
Standard F1	**Hand Hygiene and personal protection ensured during handling of Human Milk.**				
ME F1.1	Facility has defined and implemented procedure for hand hygiene practices	Availability of hand washing facility at Point of Use	OB	Handwashing facility is available separately for every area/room	
		Availability of elbow operated taps, running water & wide and deep sink	OB		
		Availability of antiseptic soap with soap dish/ liquid antiseptic with dispenser	OB/PI	Check for availability/ Ask staff if the supply is adequate and uninterrupted	
		Availability of alcohol-based sanitizer	OB/SI		
		Hand washing sink is wide and deep enough to prevent splashing and retention of water	OB		
		Display of Hand washing instruction at Point of Use for staff and mothers	OB		
		Mothers are explained for personal hygiene	SI/PI	Mothers are trained for hand washing, bathing with soap and water, wearing clean gown before milk expression.	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME F1.2	Facility has adequate personal protective equipment as per requirement	Availability of autoclaved/ disposable gowns, headcap, slippers and masks for mothers	PI/OB		
		Availability of lab aprons/coats, Mask (3 layered), head cap for staff	SI/OB		
		Dedicated Slippers for staff	OB/SI		
		Gloves are available at point of use for staff	OB/SI	Both clean and sterile	
		Adequate supply of PPE	RR		
ME F1.3	Facility adheres to hand hygiene & standard personal protection practices	Staff adheres to 6 steps of Hand washing	OB/SI	Ask to demonstrate	
		Staff is aware of when to wash hands	OB/SI	5 moments	
		Staff adheres to usage of PPE as per the requirement	OB/SI	Hair and beard are covered	
		No reuse of disposable gloves, masks, caps and aprons.	OB		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Compliance to correct method of wearing and removing the gloves	OB/SI	Ask to demonstrate	
		Staff adheres to personal hygiene practices	OB/ SI	(1) No Eating, chewing, smoking, spitting and nose blowing in milk bank (2) Avoid wearing loose jewellery, glass items, false nails etc. in milk bank (3) Ensure nails are clean & trimmed and no scratching of body parts & hair during process	
		CLMC support and encourage their staff not to work when they are sick	RR/SI	(1) CLMC has defined protocols and staff adhere to protocols. (2) Disease conditions: Scabies, eczema, fever, cold, diarrhoea, URI etc.	
		Mothers adhere to Six steps handwashing practices	OB/ SI	Mothers- wash hands with soap and water, lather hands for 15-20 sec especially nails and air dry the hands.	
		Mothers adhere to personal hygiene practices	OB/ SI	(1) No Eating, chewing, smoking, spitting and nose blowing in milk bank (2) Avoid wearing loose jewellery, glass items, false nails etc. in milk bank (3) Ensure nails are clean & trimmed and no scratching of body parts & hair during process	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard F2	**Sterility of processing and storage equipment are ensured**				
ME F2.1	The facility ensures standard practices for cleaning of equipment & procedure areas	Cleaning of breast pump tubing's and accessories as per the protocol	OB/SI	• Soak all separate parts in warm soap water for 5 minutes. • Clean with soft brush. • Rinse all separate parts with clear water. • Allow all parts to air dry in a clean area. • Store dry parts when not in use.	
		Decontamination of Procedure surfaces is done as per protocol	OB/ SI	All surfaces of pooling and pasteurising area are cleaned with surface disinfectant before and after every use.	
		Decontamination of Procedure surfaces of laminar flow cabinet is done as per protocol	OB/ SI	As per manufacturer's instructions	
		Decontamination of Procedure surfaces of bio safety cabinet is done as per protocol	OB/ SI	As per manufacturer's instructions	
ME F2.2	The facility ensures standard practices for high level disinfection and sterilization of equipment	Sanitise the breast pump/ lactation set as per the protocol	OB/SI		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		CLMC sterilizes/ autoclave the equipment as per the protocol	SI/ RR	(1) Check availability and usage of washer/ thermal disinfect or hot air oven and table top autoclave machines as per manufacturer's guidelines. (2) Check bottle, cap, containers used for milk collection, sieve etc. are sterilized before use	
ME F2.3	Facility ensures environmental control of CLMC for infection prevention	No Criss cross movement of donors, recipients and staff	OB		
		Adequate ventilation and air quality is maintained to prevent air contamination	OB	Laminar flow is maintained in milk processing and microbiological lab	
		Floors are cleaned daily with phenyl/ soap and water/ any appropriate disinfectant	SI/RR	Dry mopping is not to be done. Door handles, switches etc. to be cleaned daily with surface disinfectant	
		Floors are washed as per the requirement on the fixed day	SI/RR	Fixed day washing is done	
		Walls are cleaned at least twice a week with standard disinfectant	SI/RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Lockers and drawers to be cleaned twice a week.	SI/RR		
		CLMC has availability of colour coded bins and liners at point of waste generation	OB/ SI	Dustbins to be washed daily with soap and water & liner to be changed daily.	
		Segregation of different category of waste is done as per latest recommended guidelines	OB/ SI		
		Display of work instructions for segregation and handling of Biomedical waste	OB/ SI		
		Check no waste is stored inside CLMC	OB/ SI	Transported to hospital main collection room	
		There is no mixing of general waste with Biomedical waste	OB/ SI		
		There is a defined protocol to dispose off the discarded milk	OB/ SI	Treated as liquid waste management protocol	
		Facility has milk spill management protocol	RR/SI/OB	Immediately clean with Soap and water	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard F3	**Microbiological testing data are analysed for improving the infection control practices**				
ME F3.1	The facility has provision of culture surveillance of CLMC	Periodic microbiological surveillance is done	RR/SI	Periodic collection of water, air and surface swabs for bacterial culture	
		Defined format for requisition and reporting of surveillance report	RR/ SI		
		Result of culture is analysed and appropriate actions are taken	RR/SI	Check report and action taken reports	
ME F3.2	There is established procedure for regular monitoring of infection control practices	Regular monitoring of infection control practices	SI/RR	Hand washing and infection control audits done at periodic intervals	
		Reports of culture surveillance are collated and analysed	RR	If found positive appropriate actions are taken	
ME F3.3	There is provision of periodic medical check-up and immunization of staff	Periodic medical check-ups of the staff	SI/RR		
		There is procedure for immunization of the staff	SI/RR	Hepatitis B, Tetanus Toxoid etc	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Area of Concern G- Quality Management System					
Standard G1	**Quality Policy and objectives have been defined and communicated to staff and users**				
ME G1.1	Facility has established quality framework for quality improvement	CLMC has constituted a Quality Circle	RR/SI	Check for the order. QC members are aware of their respective roles and responsibilities	
		There is a designated person for coordinating overall quality activities at CLMC	RR/SI	CLMC manager	
		Quality circle meets monthly and review the quality activities	RR/SI	Check for the Minutes of meetings of past three months' meetings. Follow up actions from previous meetings are reviewed	
		Minutes of Meetings are recorded	RR/SI	Check action taken on last MoM, Monthly indicators, results of donor and recipient satisfaction survey, results of periodic internal audits, results of microbiological surveillance and HACCP practices	
ME G1.2	Facility has established system for donor and client satisfaction survey at periodic intervals	Donor Satisfaction survey is done at defined interval	RR	The Donor satisfaction survey form is available in local language	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Recipient Satisfaction survey is done at defined interval	RR	The Recipient satisfaction survey form is available in local language	
		There is a designated person for conducting, analysing and presenting the surveys 'results	RR	Low performing attributes are identified and Root cause analysis of the attributes is done	
		CLMC prepares action plan for lowest performing attributes	RR	Check for both surveys	
ME G1.3	The facility has defined quality policy and objectives in congruency with organizations Mission & Vision	CLMC has defined their Quality policy	RR	Must be in alignment with organisation's Vision and Mission	
		Quality policy is duly signed by competent authority and displayed at strategic points	RR	Quality policy is in local language	
		Quality objectives for CLMC have been defined & reviewed at periodic intervals	RR	Specific, Measurable, Attributable, Realistic and Time bound	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
Standard G2	**Hazard Analysis and Critical Control Point (HACCP) practices have been implemented as per guidelines**				
ME G2.1	The facility has defined the framework of the CLMC based on the seven princi-ples of HACCP	The facility has identified and evaluated the hazards	SI/ RR	Transmission of infection, non-maintenance of temperature while storing, pasteurizing and dispensing	
		The facility has determined the Critical Control Points (CCP)/Good Manufacturing practices (GMP)	SI/ RR	Well defined donor selection criteria, ensuring pasteurization and refrigeration temperature	
		The facility has determined the Critical Control limits for each CCP	SI/ RR	temperature limits	
		The facility has defined the monitoring system for each CCP	SI/ RR	Microbiological surveillance	
		The facility has established corrective action	SI/ RR		
		The facility has established Verification Procedures	SI/ RR		
		The facility has established the process for necessary Documentation and Record Keeping	SI/ RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME G2.2	HACCP as-sessment criteria and checklist for assessment have been defined and communicat-ed to relevant stakeholders	Based on the principles facility has developed their internal assessment checklist considering CCP and GMP	SI/ RR		
		The Checklist have been communicated to the relevant stakeholders	SI/ RR		
		The stakeholders have been trained to perform activities	SI/ RR		
ME G2.3	Identified hazards are analysed, evaluated, rated and treated based on severity	Hazards are identified and analysed	SI/ RR	List of Hazards are available	
		Hazards are evaluated and prioritized	SI/ RR	Severity of hazards are defined and recorded	
		Actions are taken based on severity	SI/ RR		
Standard G3	**Lactation management centre has documented and implemented Standard Operating Procedures**				
ME G3.1	Standard operating procedures are available and it adequately describes processes and procedures	Standard operating procedure for CLMC has been prepared and approved	RR	SOP include description of all quality related activities	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Current version of SOP is available with process owner	OB/SI		
		CLMC has documented the process of donor selection and enrolment	RR	Check SOP for donor selection and enrolment	
		CLMC has documented procedure of Milk collection and pooling	RR	Check SOP for Milk collection and pooling	
		CLMC has documented procedure of Milk processing	RR	Check SOP for Milk processing	
		CLMC has documented procedure of Milk dispensing	RR	Check it covers written policy on how to dispense the milk on priority basis	
		CLMC has documented procedure for infection control practices	RR	Check the SOP for Infection prevention	
		CLMC has established process to take donor and recipient feedback	RR/PI	Check who is responsible for taking feedback, data analysis and action taken processes are defined	
		The facility has documented and established Policy for Promotion and Practice of Breastfeeding	RR/PI	Check policy is displayed	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		CLMC has documented policy on maintaining privacy of donors and recipients	RR/PI	Check policy on maintaining privacy of donors and recipients	
		CLMC has documented and established system for tracking DHM from donor to recipient	RR	Check SOP for tracking DHM from donor to recipient	
		CLMC has documented procedure for cleaning & maintenance of Laminar flow / Bio safety cabinets	RR	Check SOP for trouble shooting, maintenance, routine & deep cleaning of laminar flow & Bio safety cabinets	
ME G3.2	Staff is trained and aware of procedures written in SOP	Check staff is aware of relevant part of SOPs	RR/SI	E.g., donor selection, Milk processing, breast milk promotion, infection prevention etc.	
		Check staff is following the processes as it is documented in SOPs	RR/SI	e.g., recipient satisfaction, DHM processing technique,	
		Work instructions are displayed at each point	RR	Expression room, collection area, processing area, lab. dispensing area, autoclaving area etc	
ME G3.3	Donor, procedural and administrative records are maintained.	Milk Refrigeration records are maintained	RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Milk Pooling records are maintained	RR		
		Milk Pasteurising records are maintained	RR		
		Milk Dispensing records are maintained	RR		
		Deep freezer records are maintained	RR	1. Raw milk/Report awaited/ post pasteurization 2. PT/mature milk 3. Expiry date etc. 4. Date and time of movement of milk	
		Daily feeding records are maintained	RR		
		Discard Registers are maintained	RR		
		Culture Report registers are maintained	RR		
		Preventive management register is maintained	RR		
		CLMC has system for storage, retaining, retrieval of records	RR		
Standard G4	**Periodic review and Quality Improvement Processes are implemented**				
ME G4.1	The facility conducts periodic internal assessments	Internal assessment is done at periodic interval	SI/RR	Check internal audit plan is available	

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Person is designated for coordinating periodic internal assessment	SI/RR		
		CLMC has documented system for internal and external Quality assurance of tests	SI/ RR	In case of linkage, check lab is certified and following internal and external QA check for Outsourced tests	
		Non-Compliance is enumerated and recorded	RR	Action plan is prepared	
		Corrective and preventive action taken	RR/SI	Records of internal assessment are maintained	
ME G4.2	The facility uses methods for quality improvement in services	PDCA	SI / RR		
		5S	SI / RR		
		Mistake Proofing	SI / RR		
		Advance Quality improvement methods are used	SI/RR	Six sigma, lean.	
ME G4.3	The facility uses tools for quality improvement in services	7 Quality tools	SI / RR	As required	
		Process mapping is done for critical processes	SI/RR	Check process map for identification of value & non value adding activities	

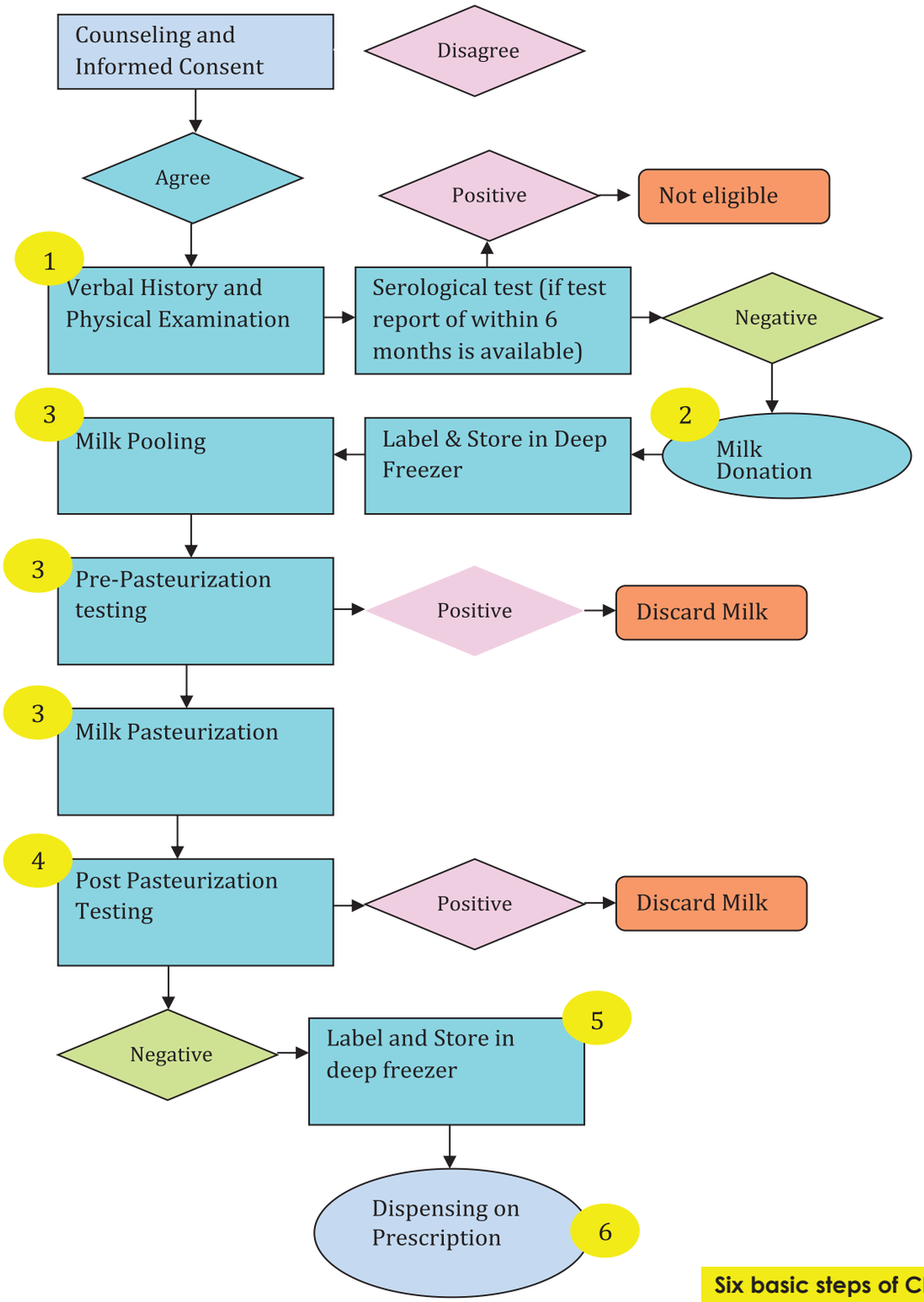
Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Actions are taken to improve the process mapping	SI / RR	Processes are rearranged as per requirement and followed	
Area of Concern H- Outcomes					
Standard H1	**Key performance indicators (KPI) are measured**				
ME H1.1	The facility measures productivity indicators on monthly basis	Percentage of newborn receiving breastfeeding with in 1 hour after birth	RR	Inclusion- babies born inside the facility	
		Percentage of admitted babies who received Mother's milk only	RR	Exclude babies from denominator where NPO or Parenteral nutrition is recommended. Denominator - all admitted Babies less than 6 months	
		Percentage of admitted sick babies who received DHM	RR	Exclude new-borns from denominator where NPO or Parenteral nutrition is recommended Includes all admission in NICU/ SNCU	
		Number of mothers who were counselled for breast milk donation	RR	In SNCU/ NICU, Well baby clinic, Postpartum ward, Post-surgical ward, Paediatric ward, KMC ward & MNCU	
ME H1.2	The facility measures efficiency and safety indicators on monthly basis	Downtime of critical equipment	RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
		Percentage of pre-pasteurization unfit batch	RR		
		Percentage of Post-pasteurisation unfit batch	RR		
		Percentage of donated milk discarded	RR		
		Percentage of Prescriptions where DHM is provided by CLMC	RR		
ME H1.3	The facility measures Service Quality indicators	Donor Satisfaction Score	RR		
		Recipient Satisfaction Score	RR		
		Staff Satisfaction Score	RR		
Standard H2	**Lactation management Centre strive to improve KPI and meet established benchmarks.**				
ME H2.1	The facility endeavours to improve its productivity indicators to meet benchmarks	Facility do the trend analysis, find out the non performing indicator , take up the root cause analysis and strive to improve them using PDCA	RR		

Reference No.	ME Statement	Checkpoint	Assessment Method	Means of Verification	Compli-ance
ME H2.2	The facility endeavours to improve its efficiency & safety indicators to meet benchmark	Facility do the trend analysis, find out the non performing indicator, take up the root cause analysis and strive to improve them using PDCA	RR		
ME H2.3	The facility endeavours to improve its service Quality indicators to meet benchmarks	Facility do the trend analysis, find out the non performing indicator , take up the root cause analysis and strive to improve them using PDCA	RR		
		Staff Satisfaction Score	RR		

Annexure-1

Process Flow Chart of CLMC for Donor Milk Utilization (Heterologous)



Six basic steps of CLMC

List of Abbreviations

HTST	High Temperature, short time
AEFI	Adverse Event Following Immunization
ANC	Ante Natal Care
BCC	Behaviour Change Communication
BLS	Basic Life Support
BMW	Bio Medical Waste
CCP	Critical Control Points
CFU	Colony Forming Unit
CLMC	Comprehensive Lactation Management Centre
CQSC	Central Quality Supervcisory Committee
DHM	Donor Human Milk
DQAU	District Quality Assurance Unit
FEFO	First Expiry First Out
F-IMNCI	Facility based Integrated Management of Neonatal and Childhood Illness
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
Hep B	Hepatitis B virus
HIV	Human immunodeficiency virus
HTST	High temperature, short time
IEC	Information, Education and Communication
IMS act	Infant Milk Substitutes, Feeding Bottles, and Infant Foods Act
IQ	Intelligence Quotient
IT	Information Technology
IYCF	Infant and Young Child Feeding

KMC	Kangaroo Mother Care
KPI	Key Performance Indicators
LMC	Lactation Management Centre
LSU	Lactation Support Unit
LTLT	Low Temperature, Long Time
MAA	Mother's Absolute Affection
MO	Medical Officer
MoM	Mother's Own Milk
NICU	Neonatal Intensive Care Unit
NQAS	National Quality Assurance Standards
OB	Observation
OPD	Outpatient Department
PASS	Pull the pin, Aim at the base of fire, Sway from side to side
PI	Patient Interview
RACE	Rescue, Alarm, Confine, Extinguish
RR	Record Review
SI	Staff Interview
SNCU	Special Newborn Care Units
SOP	Standard operating procedure
SQAU	State Quality Assurance Unit
TB	Tuberculosis
URI	Upper Respiratory Infection
VDRL	Venereal Disease Research Laboratory test

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