



# Processing and Quality Assurance



# Processing and Quality Assurance

- Introduction
- Quality Assurance Workshop
  - Calibration
  - Equipment Maintenance
  - Cleaning, Sanitation and Chemical Testing
- Q&A
- Everyone will receive a certificate of completion!

# Thawing

- Approved HMBANA and FDA Thawing Methods
  - In a refrigerator
    - Final thaw can take place outside of refrigerator , but temperatures must be monitored and cannot exceed 45°F or 7.2°C.
    - Canada applies the 2 hour rule without concern for specific temperature.
  - Water bath
    - Lids of containers are kept above water line
    - Water temperature must be kept at 21°C or below (Food Code 3-501.13)

# Thawing

- Documentation of time and temperature during processing.
- Suggestion- Monitor with infrared temp guns if final thaw is being done outside of the refrigerator.
- FYI- The FDA allows up to 4 hours without temperature control, but it must have an initial temperature of 5°C or below when removed from cold holding for the purpose of “working with product.”

**RECORD TIME AND TEMP**





# Thawing in Stainless Steel to Minimize Milk Loss

1. Donors are left to thaw on color coded trays separated by donor.
2. Allow bags of milk to minimally thaw
  - Milk is still frozen but is soft enough to remove from bags
3. Use sanitized scissors to cut the top of the bags.
4. Pour milk in stainless steel containers.
5. Cover and label containers of milk. Each container must be labeled with donor number, date, and staff members initials.
6. Place containers in the refrigerator to gradually thaw overnight.
7. Dry and wet clean cutting table between each donor. Finish by sanitizing cutting table with proper sanitizing agent.

This process results in minimal to no loss of milk from leaky containers.

# Thawing (Donor Isolation on Trays)



# Equipment (Stainless Steel)



- Stainless steel containers are more expensive than plastic. But stainless steel equipment is more durable and has a lower risk of biofilm adhesion from spore-forming bacteria.
- Stainless steel holds cold temperature of milk better than plastic containers.
- Stainless steel increased our dishwasher cycle runs per day. Have to account for temperature increases and water consumption.
- <http://www.webstaurantstore.com/>

# Pooling and Aliquoting

## HMBANA

- Milk should be maintained at 45°F or 7.2°C inside or outside refrigerator.
- Canada has a 2 hour rule.

## FDA

- Allows up to 4 hours without temperature control, but must have an initial temperature of 5°C or below when removed from cold holding.
- Documentation of time and temperature during processing.





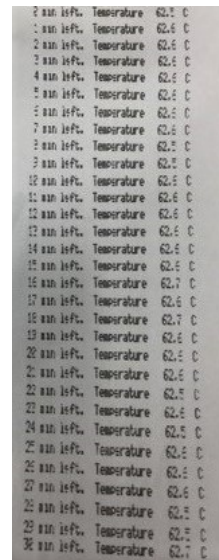
# Pasteurization

## Monitoring Time and Temperature

Understand the difference between constant monitoring and monitoring by exception.

### Constant Monitoring

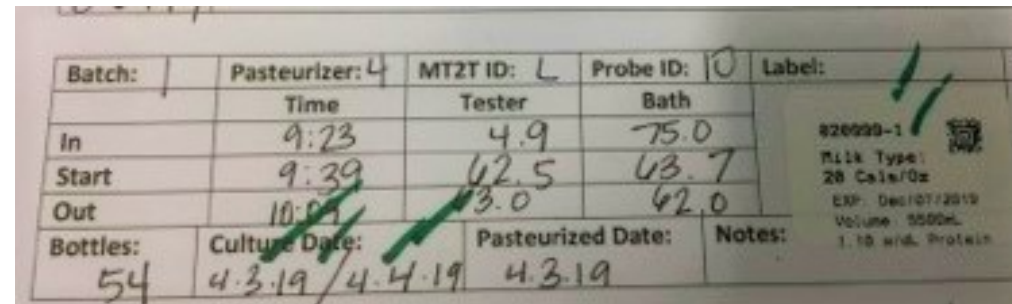
- Data Logger with printout of continuous data points
- Automatic pasteurizers with print out



A vertical printout showing a continuous stream of data points. Each line contains a time stamp (e.g., 1 min left), a label (Temperature), and a value (e.g., 62.1 C). The values are consistently around 62.1 to 62.7 C.

### Exception Monitoring

- Still Continuous
- Manual temperature and time recording



A handwritten record of pasteurization parameters on a form. The form includes fields for Batch, Pasteurizer, MT2T ID, Probe ID, Label, Time, Tester, Bath, In, Start, Out, Bottles, Culture Date, Pasteurized Date, and Notes. The values are handwritten and some are checked with green marks.

Batch:	Pasteurizer: 4	MT2T ID: L	Probe ID: 10	Label:
	Time	Tester	Bath	
In	9:23	4.9	75.0	
Start	9:39	62.5	63.7	
Out	10:09	63.0	62.0	
Bottles: 54	Culture Date: 4.3.19 / 4.4.19	Pasteurized Date: 4.3.19	Notes:	

Additional information on the right side of the form includes: 826999-1, Milk Type: 28 Cals/0z, EXP. Dec 10/2019, Volume: 3500mL, 1.10 wtd. Protein.

# FDA Guidance on Monitoring



U.S. Department of Health and Human Services



**U.S. FOOD & DRUG  
ADMINISTRATION**

PART 117 -- CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart C--Hazard Analysis and Risk-Based Preventive Controls

Sec. 117.145 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system:

- (a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and
- (b) *Monitoring.* You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.
- (c) *Records.* (1) *Requirement to document monitoring.* You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with 117.155(a)(2) and records review in accordance with 117.165(a)(4)(i).
- (2) *Exception records.* (i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.
- (ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

# Chilling

## HMBANA

- Milk is rapidly cooled to 4°C or 39°F and then promptly frozen.
- Caps remain above water level to prevent contamination.
- Most milk banks use some form of ice bath or process with a pasteurizer that performs cooling process automatically.

## Ideas for Chilling with Ice Bath

- Shakers
- Pellet Ice
- Adding a spigot to ice bath so water can easily be removed and prevent bottles from floating and falling over as ice melts.

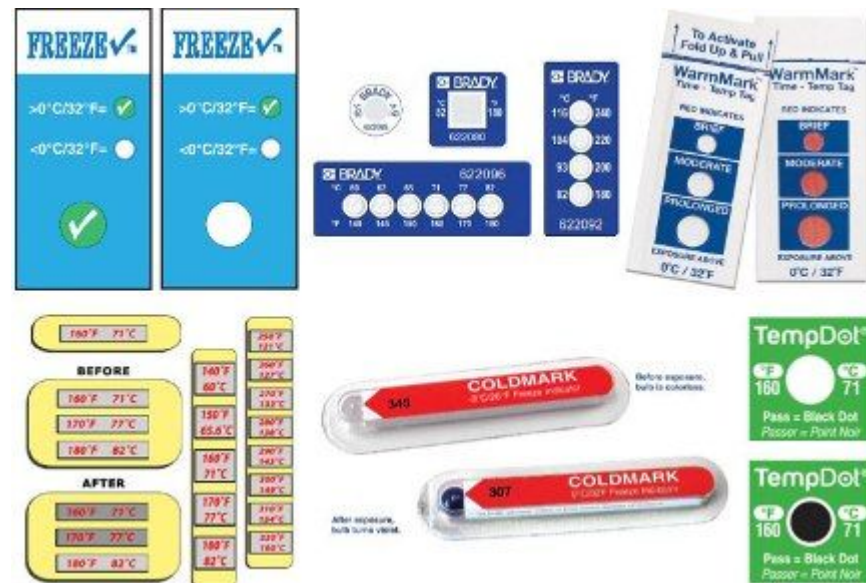
# Chilling





# Shipping

- Cold chain verification
  - Required by some hospital regulatory agencies.
  - Temperature indicator and documentation.



Indicator  
attached  
here

**Cold Chain Verification**  
Orders Shipped Via Overnight Carrier (FedEx)

Recipient Institution: \_\_\_\_\_

Order Date: \_\_\_\_\_

Order Number: \_\_\_\_\_

Milk is shipped in shipping coolers packed on dry ice.

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Departing the Mothers Milk Bank of North Texas  
When order is packed, the date, time and temperature is documented by MMBNT staff.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Temperature: \_\_\_\_\_ °C

Recorded by: \_\_\_\_\_

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**Instructions for Staff Member Unpacking Shipment**

- Staff member unpacking the box should immediately examine the WarmMark Monitoring device.
- Verify that the milk did not reach unacceptable temperatures during shipping.

If there is no red in the window under the words BRIEF, MODERATE, or PROLONGED then the inside of the shipping container did not reach unacceptable temperatures during shipping. If there is any red in the window under the words BRIEF, MODERATE, or PROLONGED, please contact MMBNT immediately.



No Red in Window



Red in Window

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**To be completed by staff unpacking shipment.**

Date: \_\_\_\_\_ Time: \_\_\_\_\_

\_\_\_\_ (check) The WarmMark indicated had no red in the indicator windows. (This indicates that the shipment stayed below the indicated temperature and remained in a frozen state during shipping.)

Recorded by: \_\_\_\_\_

This form is for your records. It is verification that this order of donor human milk remained in a frozen state during the delivery process.