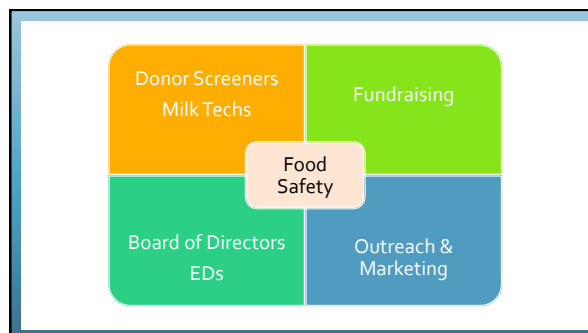



Food Safety and Milk Banking

Amy Vickers, MSN, RN, IBCLC
 Shaina Starks-Solis, PCOI
 Summer Kelly, MS, RN, IBCLC
 Jose Zepeda, PCOI



Food Safety Modernization ACT (FSMA)






Everything about Aly's life was a gift to us. We cherished every minute with her.

She came into this world as an unexpected gift to our family.

After taking only a few bites, I noticed the burger wasn't cooked all the way through...

God Danced the Day You Were Born



Each year in the US:*

48 million cases of foodborne illness

128,000 hospitalizations

3,000 deaths

*(CDC, 2018)

<https://stopfoodborneillness.org>

1985 Salmonella

- 16,000 sick (estimated 200,000 total cases)
- 2 confirmed deaths (12 additional suspected deaths)
- Valve used in unpasteurized and pasteurized lines
- Class action lawsuit- Jewel took too long to report & correct
- State public health director fired



1993 E. Coli 0157:H7

- 600 sick
- 170 hospitalized
- 4 deaths
- \$50 Million Settlements
- Federal government raised temperature from 140 to 155



E. coli 0157:H7 kills more than one victim each day.

WHO IS NEXT?



Janis Sowerby, Mother of Scott Hinkley Died age 3, E. coli 0157:H7

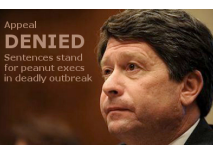
"Those of us who have fought so hard are tired. We have suffered so much... But we are dedicated to this cause and will continue to fight for as long as it takes to get new reforms to protect the American consumers. Why does the American Meat Institute continue to fight the necessary changes that must take place to protect us? How many more will be murdered? How dare you say that testing meat would only confuse the consumer and make them more lax on cooking it properly?"

<https://www.citizen.org/article/5-reasons-not-co-sponsor-s-746-thompson-levin-regulatory-roadblock-bill>

2009 Salmonella



- 700 sick (estimated 22,000)
- 9 deaths
- Most extensive recall in history: 3,900 products
- Affected budget brand peanut butter
- 71 criminal charges
 - CEO- 28 year prison sentence
 - Peanut Broker- 20 years
 - QA Manager- 5 years
 - Plant Manager- 3 years
 - Plant Manager- 3 years

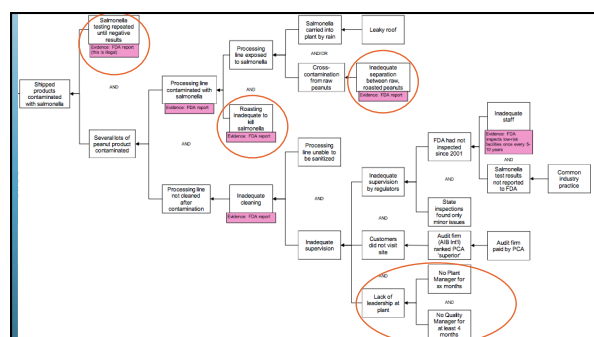
Peanut Corporation of America

- Filthy conditions
 - Rats, mice, birds
 - Rust, holes in ceilings and walls
- Staff
 - Lack of training, low pay, used temp workers
 - High turnover
- FDA registration
 - Failure to register Texas plant
- Lab testing
 - Dispensed product before results were available
 - Dispensed product that tested POSITIVE for salmonella
 - Shipped without re-testing
 - Re-tested until negative results achieved
 - Created FALSE COAs



"Just ship it."

"They [peanuts] need to be air hoisted off because they're covered in dust and rat crap."



FDA Requirements

(Code of Federal Regulation) CFR 21

Food Modernization Safety Act

Good Manufacturing Practices

Food Safety Plan

FSMA regulations mandate a shift from a reactive to preventative approach with a heavy emphasis on documentation

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CFR Title 21

- CFR Title 21– Food and Drug Administration Department of Health and Human Services – Subchapter B – Food for Human Consumption



"Looks like you're on top of the new regulations."

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FSMA

- FSMA - Food Safety Modernization Act- two parts of compliance to FSMA
 - Compliance with Good Manufacturing Practices- detailed in Policies and Procedures or SOPs. Documentation of evidence that procedures are followed and staff is trained.



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FMSA

2. FOOD SAFETY PLAN

A set of written documents that is based on food safety principles. It is developed by a team of staff and is specific to the location. The team must include a PCQI.

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PCQI – Preventative Controls Qualified Individual

Definition - A qualified individual who has successfully completed training in the development and application of risk-based preventative controls, at least equivalent to that received under standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.



Food Safety Plan

Key Components

Assemble an FSP Team

- Conduct a Risk-Based Hazard Analysis
- Establish Preventative Controls
- Oversight and Management
 - Monitoring
 - Corrective actions
 - Verification
 - Documentation



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Assemble an FSP Team

- PCQI
- Executive Director
- Operations Director
- Lab Supervisor
- "Person In Charge" of Donor Screening

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Responsibilities of FSP Team



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Hazard Analysis

- Hazard – Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
- Identify foreseeable hazards in your milk bank's operations.
 - B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens
 - C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives
 - P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health
- Completed by a PCQI – Certified milk bank staff member or qualified consultant.

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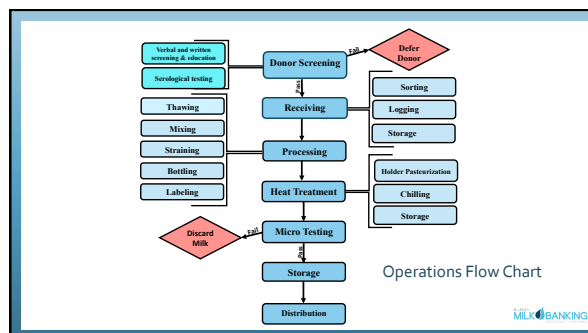
Hazard Analysis

First Step

Develop a flow chart of operations and identify critical control points (CCPs).

CCP - A point, step or procedure in processing at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard risk to an acceptable limit.

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Hazard Analysis

Examine each step of the process to determine if this step is a CCP.

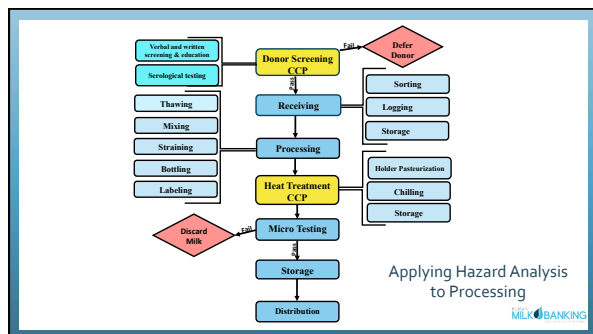
Hazard Analysis					
(1) Processing Step	(2) Identify potential safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require preventative controls?	(4) Justify your decision for column 3	(5) What preventative control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventative control applied at this step?
		Yes	No		Yes
Receiving Milk	Biological - Pathogens are introduced through damaged containers or cross contamination.	X		Milk containers are visually inspected and damaged containers are discarded. CDMPs minimize cross contamination.	

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Hazard Analysis

Hazard Analysis					
(1) Processing Step	(2) Identify potential safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require preventative control?	(4) Justify your decision for column 3	(5) What preventative control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventative control applied at this step?
		Yes	No		Yes
Donor Screening	Communicable diseases may be transmitted via human milk.	X		HIV, hepatitis B, hepatitis C, syphilis, and HTLV may be transmitted via human milk. Serological screening is performed on each donor at a certified laboratory for HIV, HTLV, hepatitis B, hepatitis C and Syphilis. Pasteurization destroys many viral contaminants (subsequent step).	X

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Preventive Controls

- Process controls: During operations
 - Donor screening
 - Pasteurization
- Food allergen controls: N/A
 - HMBANA milk banks do not offer dairy free milk
 - Milk banks may offer dairy restricted milk that may contain dairy
 - All donor milk products may contain dairy, including dairy restricted
 - There is currently no test to assure that milk does not contain dairy allergen
 - "Dairy free" label introduces significant risk (regulatory, legal, financial)

<https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm584807.pdf>



Process Preventative Controls

Process Step	Holder Pasteurization
Hazard	Bacteria are present in human milk. Viruses may be present in human milk.
Preventative Steps	Holder pasteurization kills heat-sensitive bacteria and viruses.
Critical Limits	Temperature: 62.0°C Time: 30 minutes

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Critical Limit is a Preventive Control

Parameters and limits associated with the control of a hazard.

CRITICAL LIMIT (CL)

- Is the criterion that specifies safe product from unsafe product.
- Is the maximum or minimum value that must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the identified hazard.

OPERATING LIMIT (OL)

- A criterion that is more strict than the critical limits.
- Operators use operating limits to reduce the possibility of a deviation.

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Preventive Controls:

Parameters and limits (critical and operating limits) associated with the control of a hazard.

Examples of Parameters that May Be Critical Limits

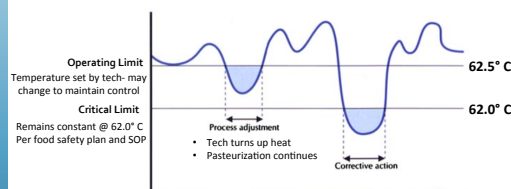
- Temperature
- pH
- Moisture level
- Line Speed
- Time
- Flow rate
- Water activity
- Salt concentration
- Physical dimensions
- Weight
- Viscosity

These parameters are:

- in place and operational
- measurable
- observable

Must record and verify!

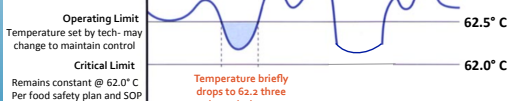
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CORRECTIVE ACTION

- Discard batch and record date of disposition
- Re-work (re-pasteurization) must follow strict SOP
- Re-categorize as research and record segregation

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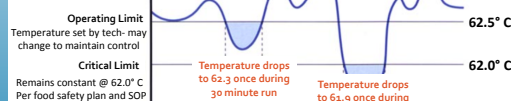


CASE ONE: Automatic pasteurizer record review

SOP/FSP:

- Achieve initial temp of 62.5
- Critical Limit 62.0 for 30 min
- Brief fluctuation to 61.5 acceptable if critical limit achieved

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CASE TWO: Automatic pasteurizer record review

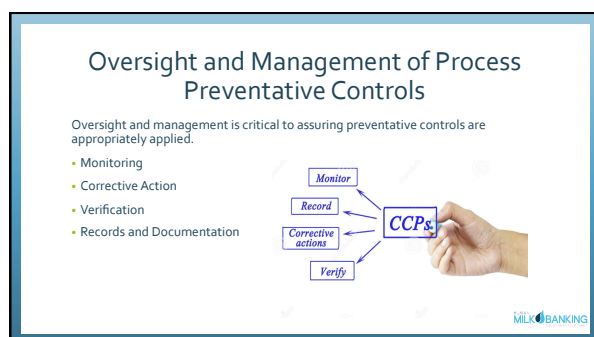
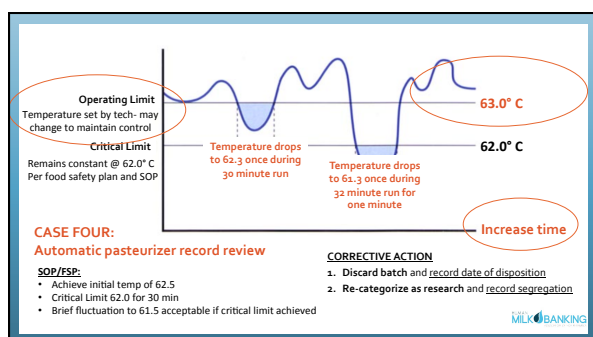
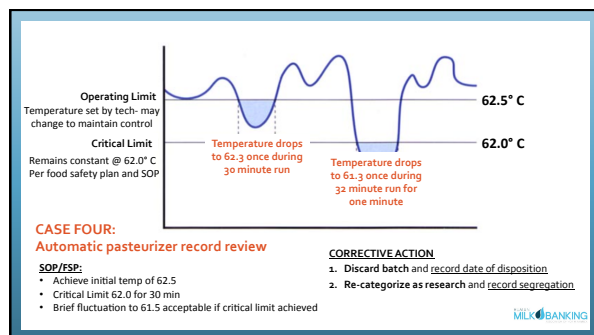
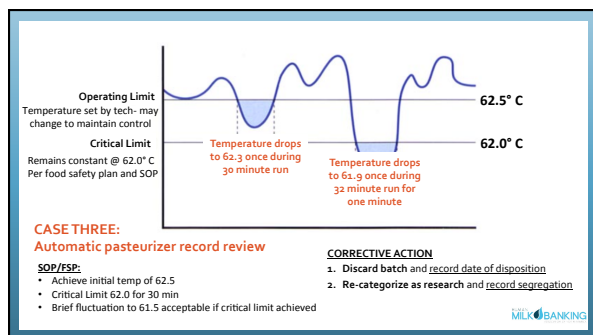
SOP/FSP:

- Achieve initial temp of 62.5
- Critical Limit 62.0 for 30 min
- Brief fluctuation to 61.5 acceptable if critical limit achieved

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CORRECTIVE ACTION

- Discard batch and record date of disposition
- Re-categorize as research and record segregation



Oversight and Management of Process Preventative Controls

Monitoring

- Define how each CCP is monitored at your facility.

- What to monitor.
- How to monitor.
- Frequency of monitoring.
 - Continuous monitoring - datalogger
 - Non-continuous monitoring – monitoring by exception
- Who will monitor.

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Oversight and Management of Process Preventative Controls

Verification and Validation

- Verification** – Review of processes to ensure they are being properly carried out.
 - Regular review of food safety plan
 - Review of records and documentation
 - Visual inspections
 - Environmental monitoring
- Validation** – Proof of accuracy using scientific principles.
 - Thermometer and equipment validation
 - Microbial testing

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Oversight and Management of Process Preventative Controls

Corrective Action

- Action that must take place if there is a deviation from a critical limit.
 - EXAMPLE: time and temperature requirements of pasteurization were not met.
- Corrective action plan should be written (SOPs).
- Develop corrective action form and document any corrective actions taken.
 - Date and time of incident
 - Evaluation of the incident
 - Action taken

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Oversight and Management of Process Preventative Controls

Records

- Establish record keeping for each CCP
- Document everything!
 - Monitoring records
 - Verification and validation records
 - Corrective actions

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Oversight and Management of Preventative Controls

Example

Process Step	Holder Pasteurization
Hazard	Bacteria and viruses are present in human milk.
Preventative Steps	Holder pasteurization kills heat-sensitive bacteria and viruses.
Critical Limits	Temperature: 62.5°C with brief fluctuations between 62°C and 63°C Time: 30 minutes
Monitoring	What: Control bottle is monitored with a calibrated thermometer. Milk is pasteurized for 30 minutes. Pasteurization begins when milk reaches 62.5°C. Control bottle must maintain temperatures between 62°C and 63°C for 30 minutes. How: Frequency: Each batch is pasteurized. Who:
Verification and Validation	Time: Temperature: Microbiological testing
Corrective Action	Temperature: Control bottle must reach 62.5°C and maintain temperature for 30 minutes. Brief fluctuations between 62°C and 63°C are acceptable. If batch does not meet time and temperature parameters... What is your policy for corrective action? If batch fails microbiological testing, milk is discarded.
Records	Complete this section

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Sanitation Preventative Controls

These are steps taken to prevent cross-contamination from staff and environment.

- Cleaning and sanitization procedures
- Zoning
- Pest management

You must have written procedures that are followed and documented.

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Cleaning and Sanitation Procedures

- Detailed procedure for each activity (example: handwashing,) item (example: flasks, trays, freezers or pasteurizer) or area (example: lab floor).
- Includes a monitoring plan and documentation.

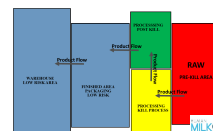
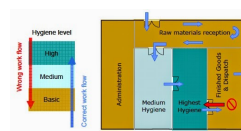


Area	Frequency	Method	Responsible	Verified
Lab Floor	Before/After Shift	Disinfectant	Lab Tech	Supervisor
Freezer	Weekly	Thaw, Clean, Disinfect	Lab Tech	Supervisor
Flasks/Trays	After Use	Wash, Rinse, Sterilize	Lab Tech	Supervisor
Pasteurizer	After Each Batch	Follow SOP	Lab Tech	Supervisor

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Zoning

- A zoning (segregation) plan is implemented when areas are identified for potential cross contamination.
- Determined during Hazard Analysis
- Optimally, the facility is designed and constructed to separate areas where milk could be contaminated.
- Physically Identified zones.



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Zoning Considerations

- Cross contamination of raw milk across batches.
- Contamination of clean supplies with milk.
- Segregating clean and dirty utensils.
- Avoid contamination of packaging materials and outside of bottles.

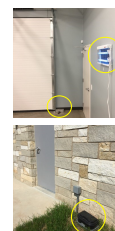


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Pest Management

REMEMBER: FSMA regulations mandate a shift from a reactive to preventative approach with a heavy emphasis on documentation.

- A pest management program should mirror this preventative nature of FSMA.
- Must be a targeted plan to not only deal with pests, but to prevent them and minimize their impact before they become a problem.
- The Preventative Controls for Human Food Regulation within FSMA requires that food plants have a written preventative pest management plan that includes monitoring.



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DOCUMENT

- *Identify Hazards
- *Develop Controls for Prevention
- *Write a Plan

- *Implement and Monitor
- *Corrective Action
- *Verify and Validate

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Staff Training

Person in Charge - Chapter 2 of FDA Food Code 2017.

- A Person in Charge is present during all hours of operation.
- Certified Food Safety Manager – Needs to be an accredited program by the Conference for Food Protection.
- Oversees that employees are performing in compliance with HMBANA guidelines and cGMPs.
- Responsible for oversight and management of FSP.
- Determines exclusions for symptomatic food employees.



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Summary of Requirements for Symptomatic Food Employees

Symptoms	Exclusion or Restriction	Removing Symptomatic Food Employees from Exclusion or Restriction	Regulatory authority Approval Needed to Return to Work?
Vomiting	Excluded	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation. Exceptions: If diagnosed with Norovirus, Shingella spp., STEC, HAV, or typhoid fever.	No, if not diagnosed.
Diarrhea	Excluded	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation. Exceptions: If diagnosed with Norovirus, Shingella spp., STEC, HAV, or typhoid fever.	No, if not diagnosed.
Jaundice	Excluded if the onset occurred within the last seven days.	When approval is obtained from a regulatory authority. Food employee has been jaundiced for more than 7 calendar days.	Yes

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Hepatitis A

Symptoms

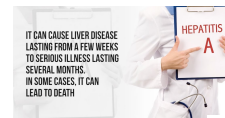
- Fatigue.
- Sudden nausea and vomiting.
- Abdominal pain or discomfort.
- Clay-colored bowel movements.
- Loss of appetite.
- Low-grade fever.
- Dark urine.
- Joint pain.

Outbreaks

- HEP A cases are down in the U.S., but there is still an occasional outbreak.
- Multistate frozen strawberry outbreak 2016

Cause of Foodborne Outbreaks

- Hepatitis A infection, caused by hepatitis A virus (HAV), is the leading cause of human viral hepatitis throughout the world and is mainly propagated via the fecal-oral route.



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Noroviruses

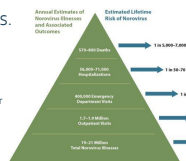
- Highly Contagious
- Leading cause of acute gastroenteritis in the U.S.
 - Bacillus

Symptoms

- Vomiting
- Diarrhea
- Nausea
- Stomach Pain

How to Prevent Norovirus

- Wash hands often
- Stay home when sick and for two days after symptoms stop
- Avoid preparing food for others when sick and for two days after symptoms stop



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Staff Training

Employees

- Food handler's licenses –Lab techs
- cGMP onsite training by certified individual
- Health and hygiene training



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GOOD MANUFACTURING PRACTICES AND MILK BANKING PART 117.10 PERSONNEL: HEALTH AND HYGIENE ONSITE JOB TRAINING

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- Creating a safe, healthy, and working environment
- Developing a culture of safety, health, and hygiene
- Ensuring that all personnel are trained and certified
- Ensuring that all personnel are trained and certified
- Ensuring that all personnel are trained and certified

Section 117.10A

- All personnel shall wear clean, appropriate clothing to prevent contamination of the food. Food contact surfaces in food packaging materials.

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Staff Training

Frequency

- Onboarding
- Annual HMBANA technical training check list
- Food Safety and Recall
- Ongoing – Should be a part of the culture. We should continuously be looking at quality and improving operations.
 - Emails
 - Employee Meetings
 - Presentations
- DOCUMENT ALL TRAINING!

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Calibrations and Maintenance

HMBANA Guidelines Equipment Maintenance Frequency

- Storage and processing equipment - every 6 months
- Refrigerators
- Freezers
- Ice Machines
- Pasteurizers
- Dishwashers

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Calibrations and Maintenance

- **Calibration** – is the act of comparing a device under test (DUT) of an unknown value with a reference standard of a known value. A person typically performs a **calibration** to determine the error or verify the accuracy of the DUT's unknown value.
- Only refers to measuring devices.

Source
<https://us.flukecal.com/literature/about-calibration>



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Calibrations and Maintenance

- **HMBANA Guidelines Equipment Calibration Frequency**
- Temperature measuring devices (thermometers) – NIST certified (or similar agency), or calibrated quarterly by the milk bank using an NIST-certified reference thermometer. Thermometers are also calibrated when dropped, damaged, or anytime accuracy is in question.
- Minimum Standards
 - Validate and calibrate as needed.
 - Thermometers
 - Scales – 6 months
 - Dispensers
- Must keep records of calibrations.

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Calibrations and Maintenance

Thermometers Used in Pasteurization and Milk Cooling Process

- 2 Point Calibration – hot and cold
- Manual pasteurizers that require a control bottle.
- Hot Point Calibration
 1. Submerge DUT and reference thermometer in water at 65.4°C.
 2. Allow to stabilize.
 3. Compare reading of the DUT to reference thermometer reading.
 4. Adjust thermometer to reference thermometer reading according to manufacturer's instructions and/or service, or replace thermometers that cannot be calibrated.
 5. Document calibration results.
- Cold Point Calibration
 1. Submerge DUT and reference thermometer in a container of ice water at 0°C.
 2. Allow to stabilize.
 3. Compare reading of the DUT to reference thermometer reading.
 4. Adjust thermometer to reference thermometer reading according to manufacturer's instructions and/or service, or replace thermometers that cannot be calibrated.
 5. Document calibration results.

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Hot Point



Cold Point



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Calibrations and Maintenance

Thermometers Used in Freezers and Refrigerators

- Minimum of two calibrated thermometers.
- One point calibration
- Cold Point Calibration: -20°C
 1. Place reference thermometer in freezer or refrigerator with DUT.
 2. Allow it to stabilize.
 3. Compare reading of the DUT to reference thermometer reading.
 4. Document calibration results.

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Calibrations and Maintenance

Accuracy Requirements – Pasteurization

- Food temperature measuring devices dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^\circ\text{C}$ in the intended range of use.
 - Food temperature measuring devices scaled in Fahrenheit shall be accurate to $\pm 2^\circ\text{F}$ in the intended range of use.
- FDA Food Code 2017 4-203.11

Accuracy Requirements – Freezers and Refrigerators

- Thermometers that are dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1.5^\circ\text{C}$ in the intended range of use.
 - Devices that are scaled only in Fahrenheit shall be accurate to $\pm 3^\circ\text{C}$ in the intended range of use.
- FDA Food Code 2017 4-203.12

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Calibrations and Maintenance

Example Calibration Log

Thermometer ID	Thermometer Reading	Reference Thermometer Reading	Corrective Action	Date	Staff Member Performing Calibration
Thermometer A	64.7°C	65.0°C	N/A	3/10/2019	Shaina Starks
Thermometer B	63.8°C	65.0°C	Send thermometer back to manufacturer for calibration	3/10/2019	Shaina Starks

*Create a calibration/maintenance calendar

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Equipment Maintenance

- Basic Freezer Components
- General Freezer Maintenance
- Detecting Common Issues

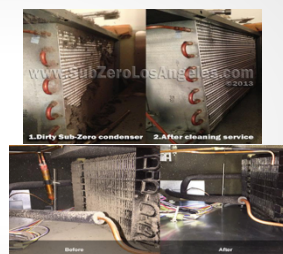
Main Equipment Components

- **Compressor**- Turns low pressure gas into high pressure gas.
- **Condenser**- Condenses gas into a liquid state.

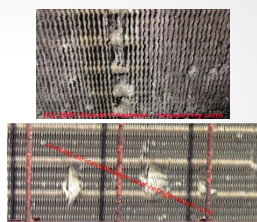


Equipment Maintenance

- It's important to record freezer temperatures daily.
- Brush the aluminum condenser fins with a brush and vacuum remaining dust.
- Clean compressor with cloth to ensure it's not leaking Freon
- Check door gaskets for any excessive wear and tear.



Condenser Fins



Signs of Trouble

- It's important to notice any significant changes in the temperature logs.
- Major increases or decreases in temperature are signs that the equipment is struggling. Make sure staff isn't recording temperature during preset defrost cycles.
- Other major signs to look for are frozen coils, moisture build up around the door, and water build up in drain pan over days.



Frozen Coils



Calibration vs Maintenance

- Calibration refers to calibrating devices that measure. Devices that measure temperature, volume, time, etc.
- Examples of measuring devices are: thermometers, data logger, scale, and milk dispenser.
- Maintenance on equipment is upkeep cleaning/inspection to ensure the equipment is not under-performing.
- Maintenance on equipment should be every 6 months with record keeping of maintenance performed. If there is not any record of maintenance performed then it did not happen.



Recall

- Action taken by an establishment to remove an adulterated, misbranded, or violative product from the market.
- Recall Plan is REQUIRED for any food that has a hazard requiring preventative control.
- Must:
 - Be written
 - Be tested
 - Describe steps
 - Define roles and responsibilities
 - Detail communication

Source: <https://www.fda.gov/food/food-safety/modernizing-regulatory-processes>

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Recall

- **Class I recall:** reasonable probability that the use of or exposure will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall:** not likely to cause adverse health consequences.

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Recall

- **Market Withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.
- **Stock Recovery:** Self removal of a product that has not left the control of the milk bank.

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Recall

A RECALL is required for any product in which a hazard requiring preventative controls has been identified.

HMBANA Requirements

- A system for tracking donor milk to donor is in place.
- Individual milk banks are responsible for ensuring they are compliant with state, federal, and provincial requirements for operation.
- Perform mock recall – Must be carried out the first year of operation and every two years after that in under 6 hours.
- Report recall verbally and in writing to chairperson of the Guidelines Committee and president of HMBANA.

FDA Requirements

- Visit FDA website for requirements and guidance documents.
- Know your District Recall Coordinator contact.



Recall

FDA Resources

- **Guidance for Industry: Product Recalls, Including Removals and Corrections**
<https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>
- **FDA District Recall Coordinators**
A current list of FDA recall coordinators can be found on FDA's website at:
<http://www.fda.gov/Safety/Recall/IndustryGuidance/ucm129334.htm>



Recall Plan

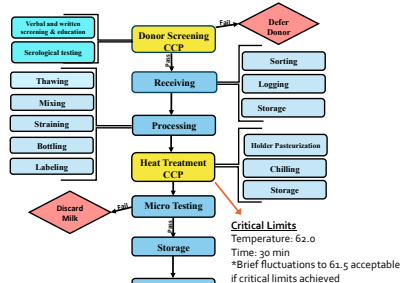
Suggested Components of a Recall Plan

- Form a recall team including necessary milk bank staff, medical advisory board members, and any other applicable individuals.
- Develop recall SOP with step by step instructions on how to carry out a recall at your facility. Should include- notification of recipients, notification of the public, disposing of product.
- Complete a root cause analysis.
- Develop documents and templates used to carry out recall.
- Inform and train staff on how to handle a product recall.
- Develop media management plan and messaging.



Prepare for FDA inspection & HMBANA accreditation

- Print copy of FDA registration or renewal and identify due date for next registration
- Identify PCQI and research PCQI training options (if PCQI hasn't received formal training)
- Identify Food Safety Manager and research training courses for state certification
- Assemble food safety plan team
- Print current FSP and place in binder that is available to staff
- Update FSP as needed
 - Specific to your milk bank
 - Update processing flow chart
 - Create hazard analysis
 - Identify preventive controls, critical limits, corrective actions
 - Update and sign annually



Prepare for FDA inspection & HMBANA accreditation

- Create/update staff training binder
- Food handling training
- GMPs, employee illness, sanitation
- Add certificates from HMBANA symposium!
- Update pasteurization SOP with critical limit and corrective action
- Create/update sanitation SOPs (SSOPs): Sanitation, pest control, dish machine...
- Update calibration/maintenance SOPs
 - Quarterly calibration
 - Freezer maintenance/inspection every 6 months
- Maintain calibration and maintenance records
- Update recall SOP and conduct mock recall every two years
- Create mock FDA audit

