2014 PROCESSING PLANT SUPERINTENDENT UPDATES

Chris Hylkema
NYS Dept. of Agriculture & Markets
Division of Milk Control

- PMO App N Change
- Water Protection
- New Product Make Processes
- Product Cooling Exceptions
- Spargers
- Equipment Applications

PMO - Appendix N change

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

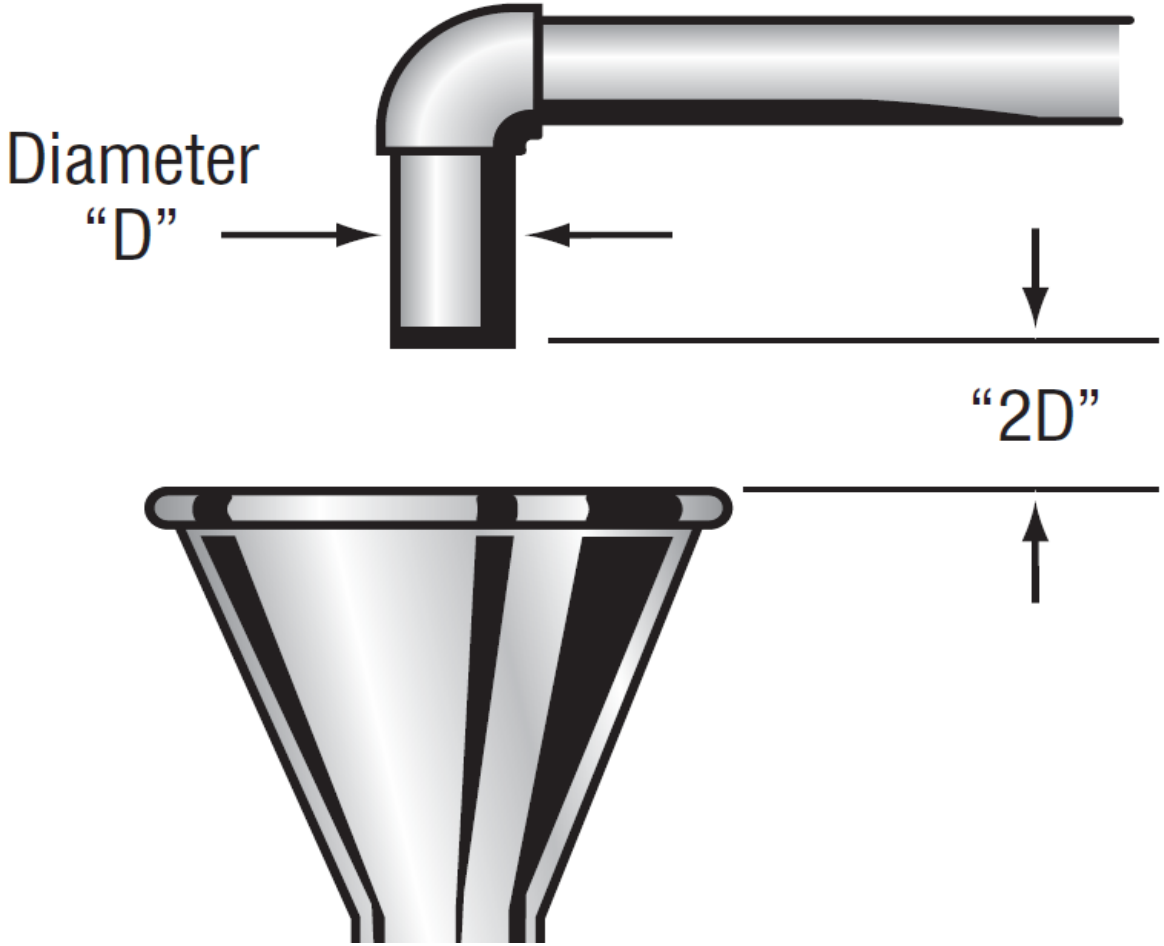
Industry shall screen all bulk milk pickup tankers **and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues**.

Water Protection

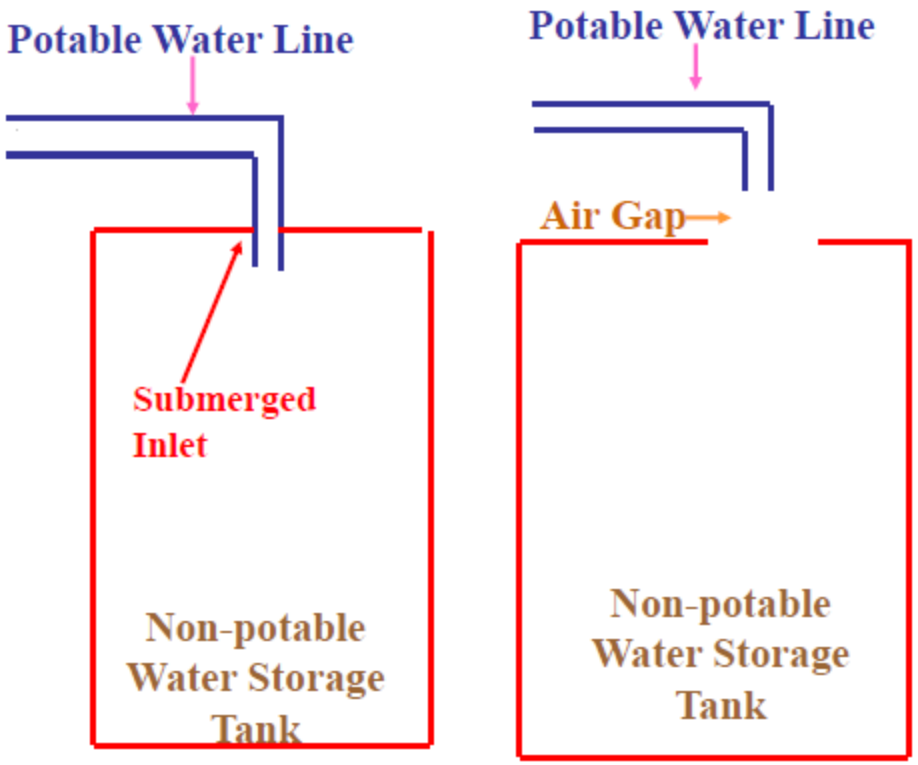
There is **no cross-connection between the safe water supply and any unsafe** or questionable **water supply**, **or** any **source of pollution** through which the safe water supply might become contaminated. A **connection between the water supply piping and a make-up tank**, such as for cooling or condensing, unless **protected by an air gap or effective backflow preventer,** constitutes a violation of this requirement.

Air Gap

- An approved **air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle**. The distance of the air gap is to be **measured from the bottom of the potable inlet supply pipe or faucet to the top of the effective overflow**, i.e., flood level rim or internal overflow, of the vessel. In no case, may the effective air gap be less than 2.54 centimeter (1 inch).

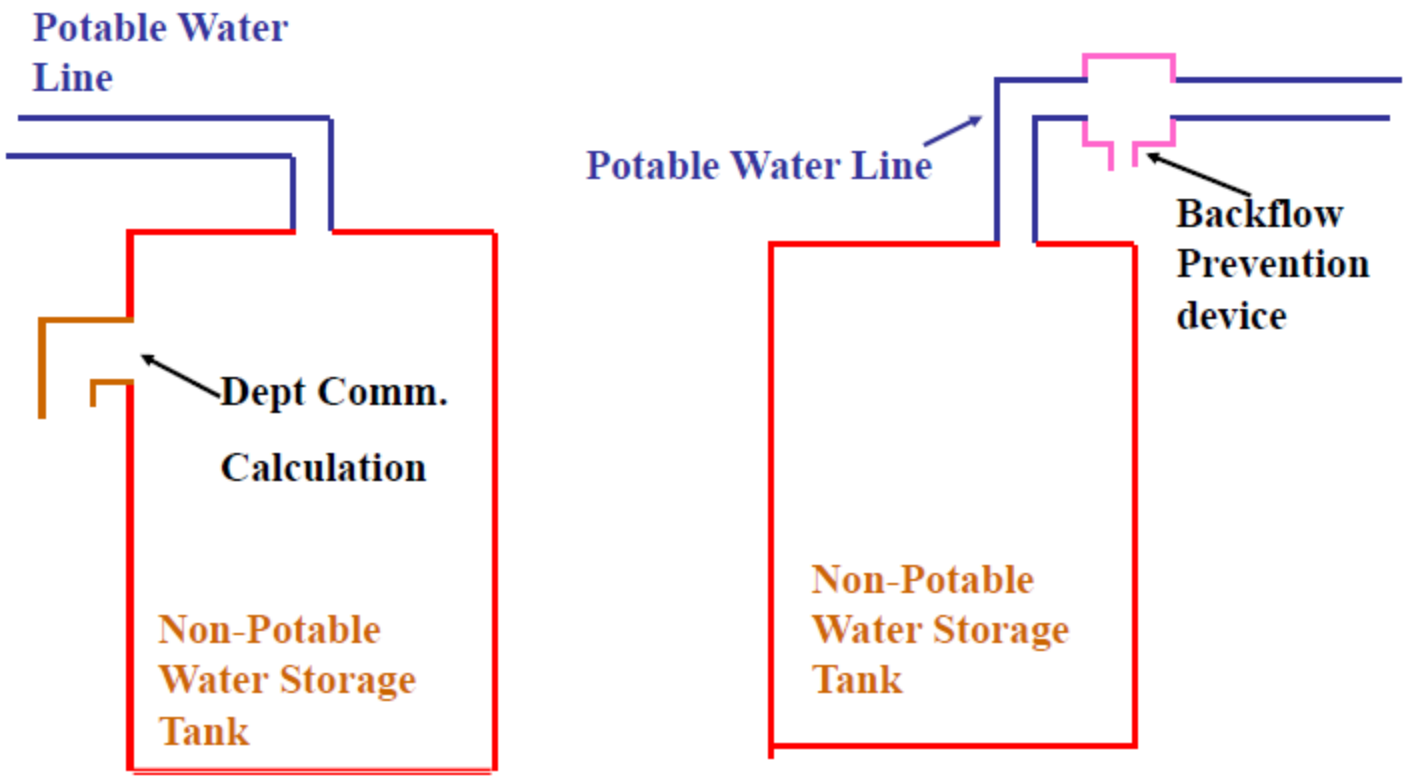

Diameter
"D"
"2D"

Air Gap



Note: The air gap space must be at least twice the diameter of the water line

Air Gap (cont.)


Potable Water Line
Dept Comm. Calculation
Non-Potable Water Storage Tank
Potable Water Line
Backflow Prevention device
Non-Potable Water Storage Tank

ASSE 1012 BACKFLOW PREVENTER WITH INTERMEDIATE VENT

MANF.	MODEL NO.
WATTS	9-D
WILKENS	750
FEBCO	815
CONBRACO	40-400 & 4J-400
CASH-ACME	BFP
DANFOSS	8200

ASSE 1013 REDUCED PRESSURE PRINCIPLE BACKFLOW PREVENTER

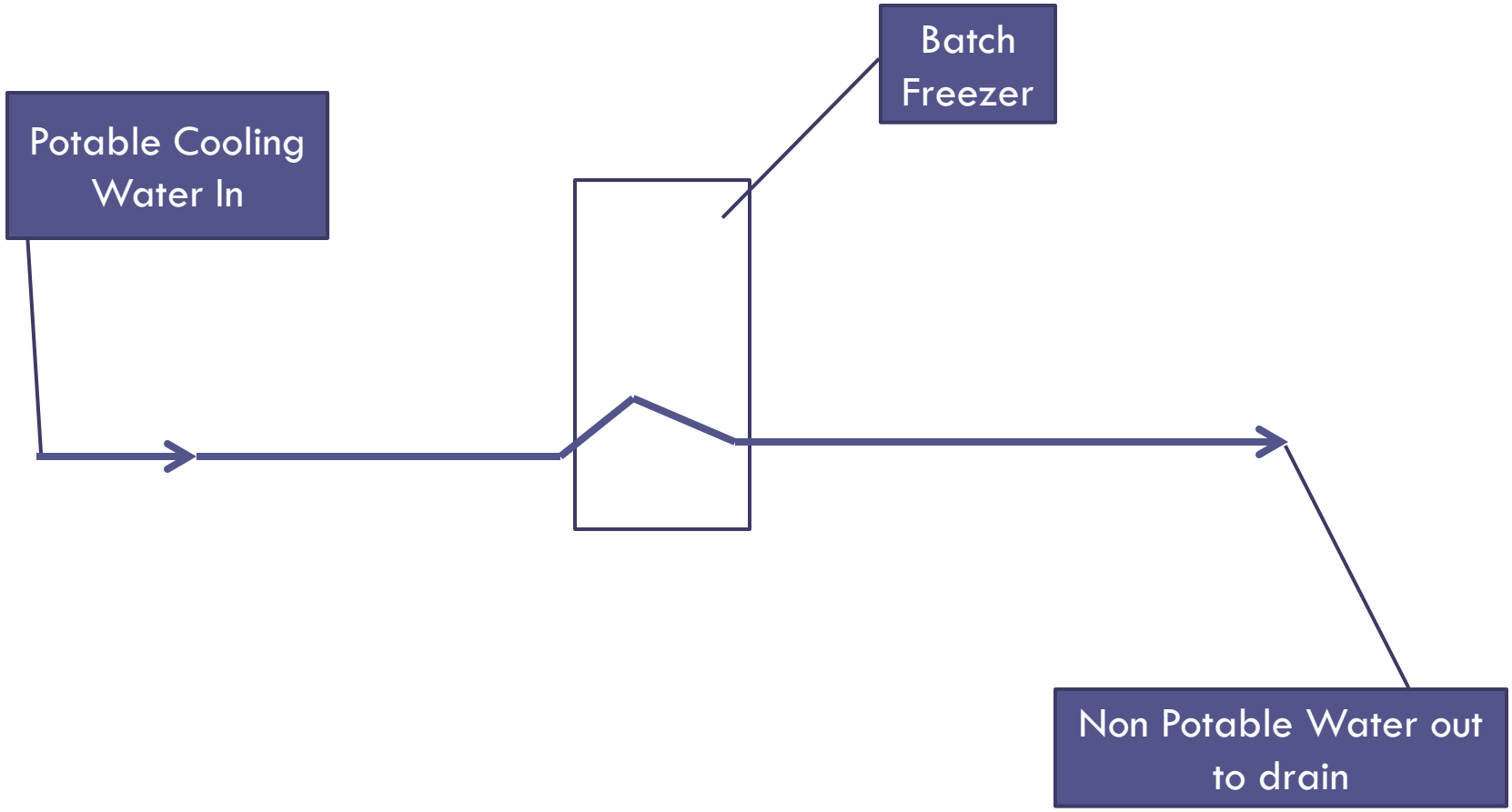
MANF.	MODEL NO.
WATTS	009, 909, 995, N995, Z995
WILKENS	375, 975, 975XL, 975BMS/MS, 975XLBMS/MS
FEBCO	860,880, 880V, 825, 825YA, 820
CONBRACO	40-200, 40-200U, 40-200Z, 4S RP
FLOMATIC	RPZE, RPZ IIE

ASSE 1001 PIPE APPLIED ATMOSPHERIC VACUUM BREAKER

MANF.	MODEL NO.
WATTS	288A
WILKENS	35
FEBCO	710 & 715
CONBRACO	38-100 & 38-200
CASH-ACME	V-101

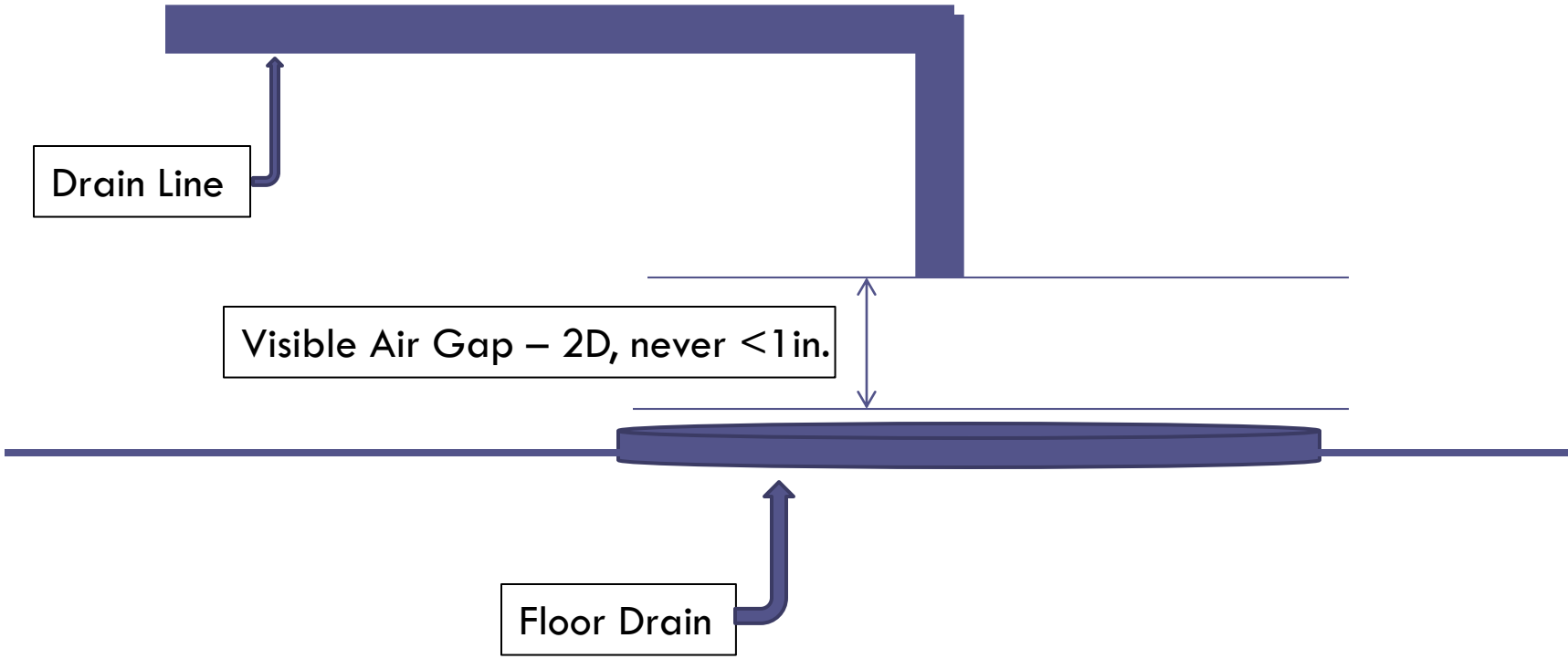
ASSE 1011 HOSE CONNECTION VACUUM BREAKER

MANF.	MODEL NO.
WATTS	8, 8A, 8AC, 8B, 8BC, 8C, NF8, NF8C, 8P, 8FR
WILKENS	BFP-8 & BFP-8F
CONBRACO	38-304, 38P, 38-400, 38-404
CASH-ACME	V-3, V-4, VB-222
FABCO	731 series
DANFOSS	HB8


Batch Freezer
Potable Cooling Water In
Non Potable Water out to drain

Water Cooled Batch Freezers

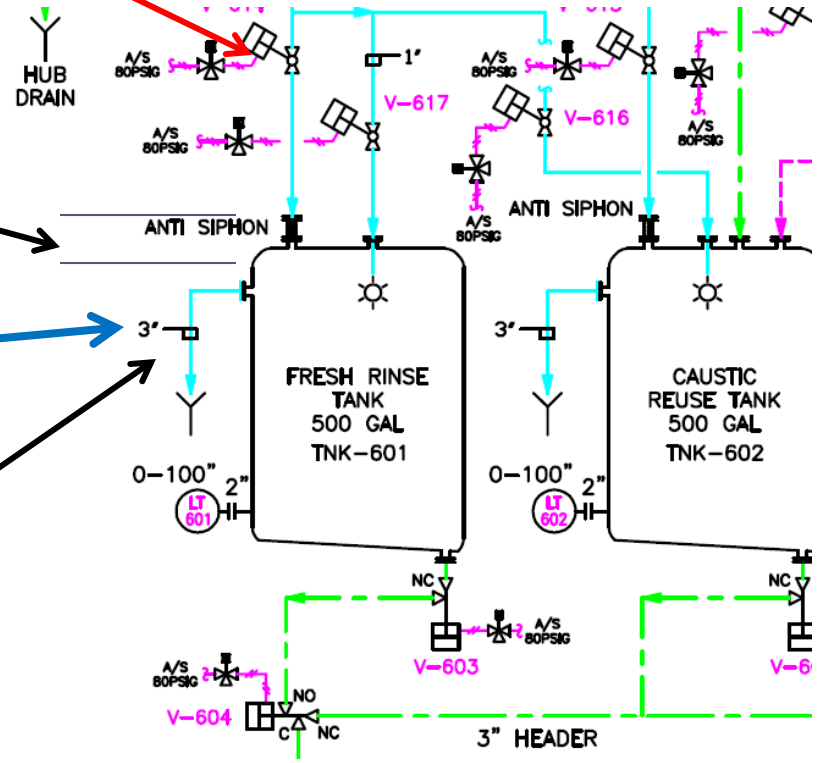
- The outlet to drain MUST be air gapped at the drain – DO NOT plumb directly into drain

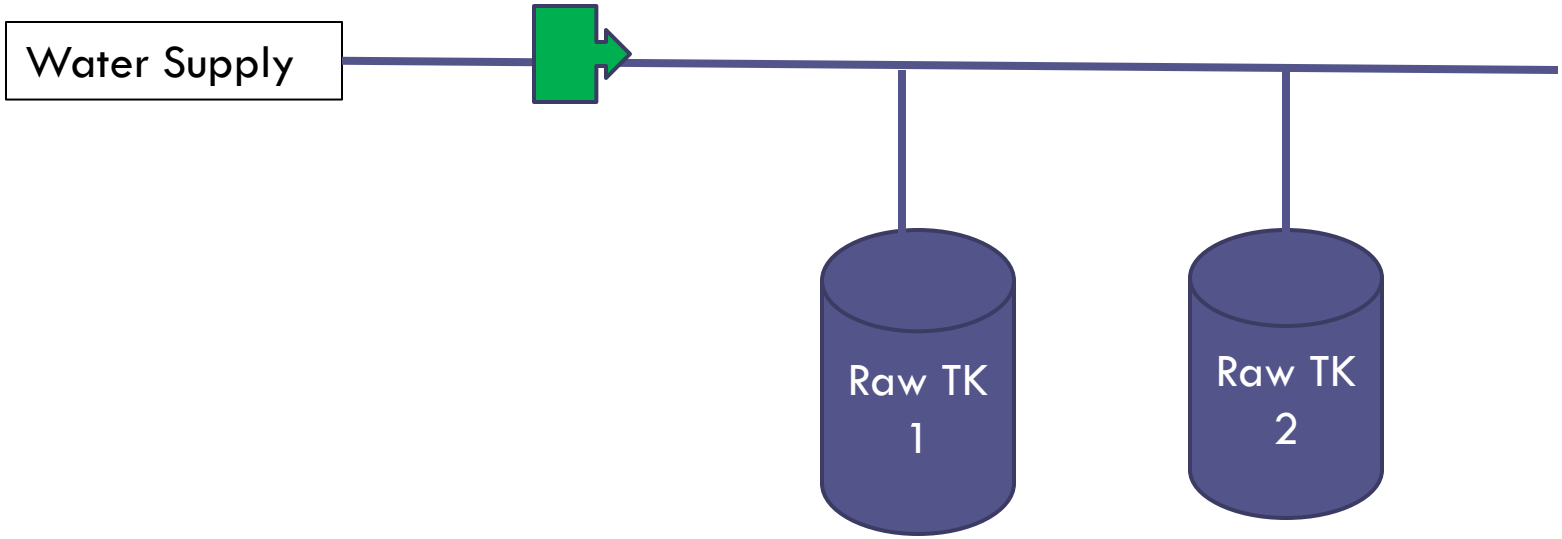


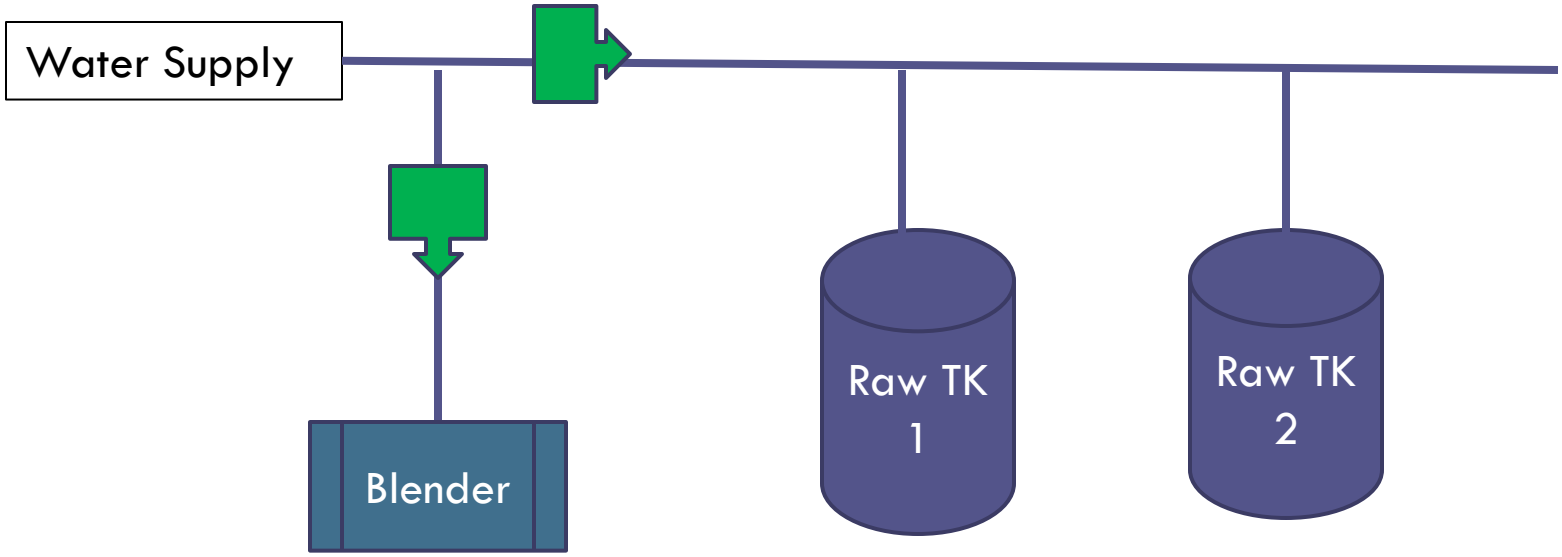
What if this feed line is 2" OD – is this set up OK?

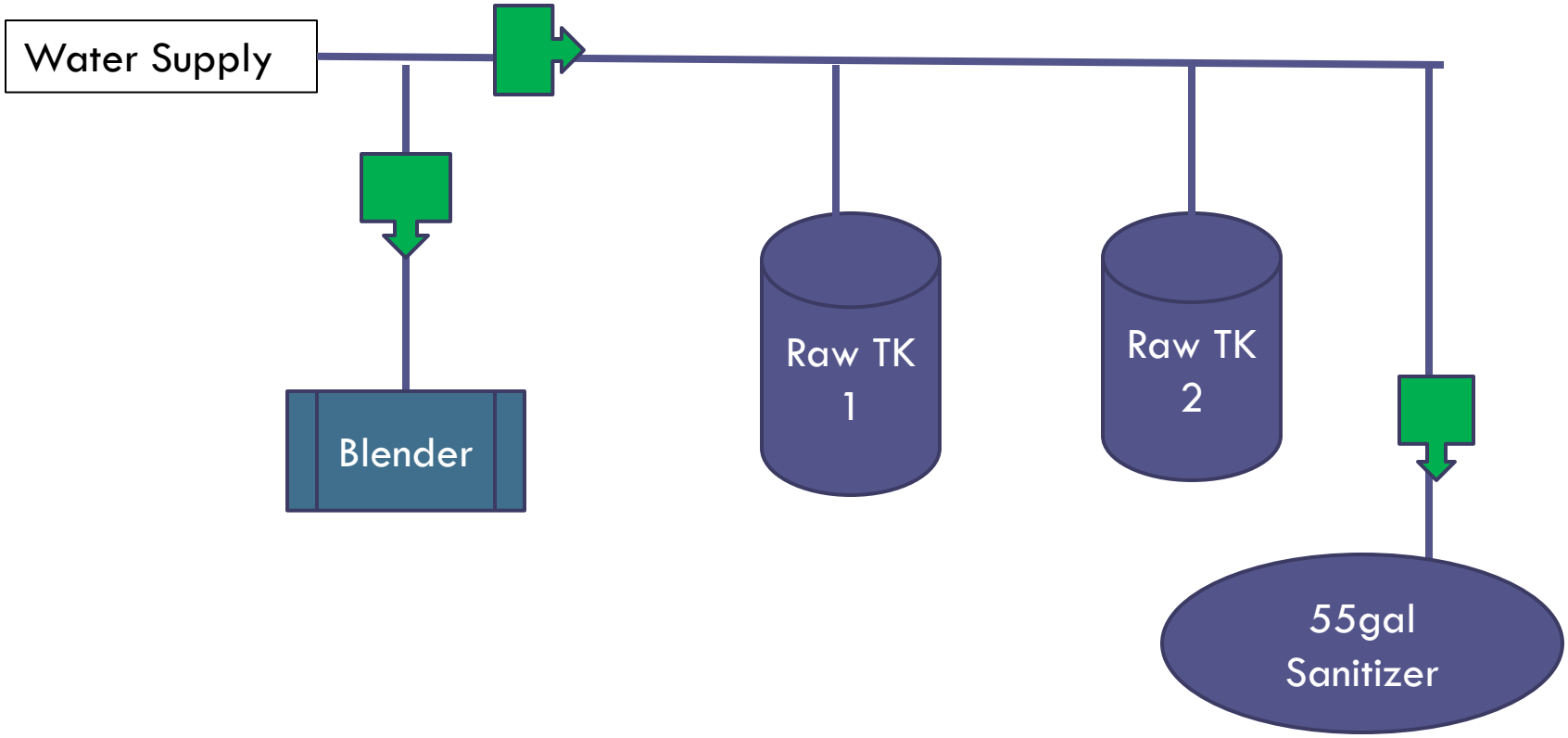
The air gap from the termination of the inlet to the top of the external overflow must be 2xD of the feed line or larger

Diameter of overflow must be 2xD of the feed line or larger




Water Supply
Raw TK 1
Raw TK 2


Water Supply
Blender
Raw TK 1
Raw TK 2


Water Supply
Blender
Raw TK 1
Raw TK 2
55gal Sanitizer

Anti Siphon Devices


Anti Siphon Inlet on CIP Tank

Anti Siphon Inlets

- Installed to **allow air to enter the tank** during an overflow situation
- **NOT backflow prevention** – NOT a substitute for a PROPER AIR GAP or BACKFLOW PREVENTION DEVICE
- **Evaluate your water systems** – make corrections
- Evaluate size of overflows when purchasing new equipment

New Products

- Need to make sure you are submitting make processes for new / novel products
- We need to identify pathogen risks
  - Process and handling temperatures
  - pH, water activity
  - Need to understand the barriers to prevent pathogens
    - *Clostridium botulinum*
  - May request process authority review

Pasteurized Milk Ordinance (PMO) Item 17p. Cooling of Milk and Milk Products

Product Cooling Exceptions M-I-13-4

PMO ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured;
2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
4. **All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;**
5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;

6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

a. Filled at 63□C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or

b. Filled at 69□C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and

c. The additional applicable critical factors*, as cited below, shall also be utilized for either hot fill temperature to determine the acceptability of filling at these temperatures, or

d. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, or

e. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13°C (55°F) or less*; and

7. All condensed whey and whey products shall be cooled during the crystallization process to

10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and

emptying time, unless filling occurs above 57oC (135oF), in which case, the seventy-two (72) hour time period begins when cooling is started.

All pasteurized milk and milk products, **except the following**, **shall be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed:**

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;

3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C **(45°F) or less within ninety-six (96) hours of filling**;**

4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**;

5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

a. Filled at 63□C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15□C (59□F) or less within ten (10) hours of filling**, and cooled to 7□C (45□F) or less within twenty-four (24) hours of filling**, or

b. Filled at 69□C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15□C (59□F) or less within ten (10) hours of filling**, and cooled to 7□C (45□F) or less within twenty-four (24) hours of filling**, or

c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7□C (45□F) or less within seventy-two (72) hours of filling**, or

d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7□C (45□F) or less within seventy-two (72) hours of filling**.

* Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, ***shall be monitored and documented by the processing facility for verification by the Regulatory Agency***. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Cooling temperatures monitored at the ***slowest cooling portion***, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-13-4

May 20, 2013

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Clarification of a Milk Plant's and a Regulatory Agency's PMO Requirements Related to the Temperature Exceptions Cited in Item 17p-Cooling of Milk and Milk Products and the Sampling Requirements of These Specifically Identified Milk and Milk Products in Item 17p as Addressed in Section 6-The Examination of Milk and Milk Products of the *Grade "A" Pasteurized Milk Ordinance* (PMO)

Item 17p-Cooling of Milk and Milk Products of the PMO provides for cooling temperature exceptions for pasteurized milk and milk products from the PMO requirement of having to be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing, for specifically identified milk and/or milk products. It also provides for cooling temperature exceptions for pasteurized milk and/or milk products from the PMO requirement of having to be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed for specifically identified milk and/or milk products.

Following is a series of questions and answers related to the cooling temperature exceptions for specifically identified milk and milk products as cited in Item 17p of the PMO:

Spargers

I'm working on it

Need help / input

New Applications for Equipment Installation and HTST Installation

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE & MARKETS
10 B AIRLINE DRIVE
ALBANY, NEW YORK 12235
www.agriculture.ny.gov

Division of Milk Control
Casey M. McCue – Director
518-457-1772
Fax 518-485-8750

Instructions for Making an Application to Install / Modify Dairy Processing Equipment

Completely & legibly fill in the application (Form DMC-1505 (Rev 9/2013). Please note: For the installation or modification of a pasteurization system you must submit form DMC 1512 (Rev. 9/2013).

Submit hard copies of this application and required information as follows: one copy to the DPS 1 assigned to your facility, one copy to the Regional Supervisor, and one copy to the Division of Milk Control's Dairy Equipment Specialist. Mailing addresses can be obtained by contacting the regional supervisor or our central office at (518)457 -1772. Most often, the scope of a project is planned well in advance of the creation of engineered plans. It is advisable that a process narrative along with a draft layout of the plant and project be sent via email prior to finalizing plans in an effort to expedite the review and approval process. Electronic versions of finalized plans and information may also be submitted ahead of hard copies to expedite review. When submitting plans and information by email, be sure attachments are PDF or Word documents.

An application and plans must be submitted and fully approved by this Department prior to starting any installation. In most cases, applications should be submitted no less than 60 days prior to the anticipated date of installation. A variance from this timeframe requirement can be given in the case of a documented emergency. A variance will only apply to modifications and all related information outlined below would need to be received in a timely manner. **Please note:** Plans for new processing facilities and major expansion projects must be submitted far in advance of the start of the project in order to provide for proper review. Please contact the Division Dairy Equipment Specialist for guidance (contact information below).

Required information that must accompany the application:

1. **Process Narrative**
   A process narrative detailing the scope of the project including, but not limited to, the start date, product type, the type of equipment to be installed, the flow of product within the system, unique instrumentation and other detailed aspects of the process as applicable. Some detailed aspects could include process temperatures, flow rates, storage times, etc.
2. **Plans**
   Detailed plans of the process flow including both product and CIP. Process and Instrumentation drawings (P&ID) and other types of flow diagrams must be color coded to differentiate between product, CIP, water and others. These drawings must also be coded for direction of flow with arrows. Process modifications must show differentiation between the modifications that are new and those that are not changing. Please include a symbol key with all types of drawings. In addition to process flow drawings, a plant layout drawing must also be submitted showing location of equipment in relation to drains, distances to walls and other equipment.
3. **List of Equipment**
   Include a list of equipment and appurtenances to be installed with applicable documentation specifying material type and finish, including gaskets, o-rings, valve seats, etc. Also include any certifications that will aid in approval (ex. 3-A certifications, compliance with CFR, FDA issued equipment M-b). Be sure that the information submitted is specific to the model of equipment you are installing. Please do not submit brochures listing specifications for several different models. This information may be included within the process narrative. Please note that equipment is not required to be 3-A certified to be acceptable, however, the 3-A standards may be employed as reference during the evaluation of equipment.
4. **Installer Information**
   Include a list of installers / fabricators and contact information. Any outfit performing sanitary welding of stainless steel in a dairy operation must be registered with this Department (application available on web site).

PLEASE NOTE: Applications will not be reviewed without the aforementioned information.

All installations and equipment shall meet all applicable requirements.

References for review of equipment and installations:

- **Pasteurized Milk Ordinance (PMO) – most current version, available on NYS Dept. of Agriculture & Markets web site**
- **1 NYCRR Part 2 – available on web site**
- **3A Sanitary Standards and Accepted Practices (available at 3-A.org)**
- **Milk & Milk Product Equipment: A Guideline for Evaluating Construction – available on web site**

If you have any questions regarding the submission of an application please contact:

Chris Hylkema
DPS 2 – Dairy Equipment Specialist
NYS Dept. of Agriculture & Markets
Division of Milk Control & Dairy Services
(716) 725-5080
Christopher.hylkema@agriculture.ny.gov

DMC - 1505 (Rev. 9/2013)

	State of New York Department of Agriculture & Markets Division of Milk Control & Dairy Services 10 B Airline Dr. Albany, NY 12235	**APPLICATION TO INSTALL / MODIFY DAIRY PROCESSING EQUIPMENT**

Pursuant to Part 2 of 1 NYCRR §2.64 paragraph (b), I hereby make application to install or modify dairy processing equipment at the facility listed below.

Plant Name & Number	
Address (incl. County) & Phone #	
PPS Name & Contact (incl. email address)	
Project Title	
Approximate Start Date	Approximate Welding Date
Plant Representative, Signature & Date	

FOR OFFICE USE ONLY

Project Tracking #: _____

DATE RECEIVED: _____

- ☐ Received Process Narrative
- ☐ Received Flow Diagram / Layout
- ☐ Received Equipment List
- ☐ Received Installer Information

PLAN APPROVAL

Dairy Products Specialist, Signature & Date

INSTALLATION APPROVAL

Dairy Products Specialist, Signature & Date

THIS APPLICATION, WHEN PROPERLY FILLED OUT BY THE REGULATORY AGENCY, SERVES AS THE OFFICIAL APPROVAL. PLEASE MAINTAIN A COPY OF THIS APPLICATION ON FILE FOR REVIEW BY OTHER INSPECTION AGENCIES.

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE & MARKETS
10 B AIRLINE DRIVE
ALBANY, NEW YORK 12235
www.agriculture.ny.gov

Division of Milk Control
Cassy M. McCue – Director
518-457-1772
Fax 518-485-8730

Instructions for Making an Application to Install / Modify a High Temperature Short Time (HTST) or Higher Heat Shorter Time (HHST) Pasteurization System

Completely & legibly fill in the application (Form DMC-1512 (Rev 9/2013). Please note: For the installation or modification of other dairy process equipment you must submit form DMC - 1505 (Rev.9/2013).

Submit hard copies of this application and required information as follows: one copy to the DPS 1 assigned to your facility, one copy to the Regional Supervisor, and one copy to the Division of Milk Control's Dairy Equipment Specialist. Mailing addresses can be obtained by contacting the regional supervisor or our central office at (518)457 -1772. Most often, the scope of a project is planned well in advance of the creation of engineered plans. It is advisable that a process narrative along with a draft layout of the plant and project be sent via email prior to finalizing plans in an effort to expedite the review and approval process. Electronic versions of finalized plans and information may also be submitted ahead of hard copies to expedite review. When submitting plans and information by email, be sure attachments are PDF or Word documents.

An application and plans must be submitted and fully approved by this Department prior to starting any installation. In most cases, applications should be submitted no less than 60 days prior to the anticipated date of installation. A variance from this timeframe requirement can be given in the case of a documented emergency. A variance will only apply to modifications and all related information outlined below would need to be received in a timely manner. Please contact the Division Dairy Equipment Specialist for guidance (contact information below).

Required information that must accompany the application:

1. **Process Narrative**
   A process narrative detailing the main legal aspects of the unit including, but not limited to, products, process temperatures, hold times, cut in and cut out temperatures, etc. Also detail of the flow of product within the system, any unique instrumentation and other detailed aspects of the process as applicable.

2. **Plans**
   Detailed plans of the process flow including both product and CIP. Process and Instrumentation drawings (P&ID) and other types of flow diagrams must be color coded to differentiate between product, CIP, water and others. These drawings must also be coded for direction of flow with arrows. Process modifications must show differentiation between the modifications that are new and those that are not changing. Please include a symbol key with all types of drawings. In addition to process flow drawings, a plant layout drawing must also be submitted showing location of the unit in relation to drains, distances to walls and other equipment.

3. **Equipment Documentation**
   Include documentation that will aid in approval (ex. 3A certifications, compliance with CFR, FDA issued equipment M-b; Example: Tuchenhagen Flow Diversion Device Type XKR and XWR has been issued equipment M-b-358 by FDA. You would include this document.) This information may be included within the process narrative. Also, include any documentation for critical components of the system not specifically listed on the DMC 1512.

4. **Programmable Logic Controller (PLC)**
   Include a copy of the ladder logic for the dairy legal PLC, if applicable, that will be used to manage the functions of the public health control devices that will operate the pasteurization system. The PLC must meet the applicable requirements of Appendix H of the most current Pasteurized Milk Ordinance (PMO). Please also include contact information for the creator of the logic program. *The ladder logic, if not fully complete at time of application, must be submitted and reviewed prior to initial testing of the unit by the Dairy Products Specialist.*

5. **Testing Standard Operating Procedure (SOP)**
   Submit a copy of the SOP outlining the applicable testing requirements as per Appendix I of the most current PMO specific to the unit being installed. *The SOP must be submitted prior to initial testing of the unit by the Dairy Products Specialist if not complete at time of application.*

6. **Installer Information**
   Include a list of installers / fabricators and contact information. Any outfit performing sanitary welding of stainless steel in a dairy operation must be registered with this Department (application is available on web site).

7. **Higher Heat Shorter Time (HHST) Units**
   When submitting information for HHST units please include all hold tube calculations (long and short tubes as applicable) including maximum flow rates and type of heat application (direct or indirect, steam infusion or injection). Also include documentation (make, model) for all vessels in the system including, but not limited to, steam infuser vessels and vacuum chambers and documentation for pressure differential switches used to monitor pressure across injectors, in hold tubes and product to product regenerators. This information may be included in the process narrative.

PLEASE NOTE: Except where noted above, applications will not be reviewed without the aforementioned information.

If you have any questions regarding the submission of an application please contact:

Chris Hylkema
DPS 2 – Dairy Equipment Specialist
NYS Dept. of Agriculture & Markets
Division of Milk Control & Dairy Services
(716) 725-5080
Christopher.hylkema@agriculture.ny.gov

DMC 1512 (Rev. 9/2013)

State of New York
Department of Agriculture & Markets
Division of Milk Control & Dairy Services
10 B Airline Dr.
Albany, NY 12235

APPLICATION TO INSTALL / MODIFY A HIGH TEMPERATURE SHORT TIME (HTST) or HIGHER HEAT SHORTER TIME (HHST) PASTEURIZATION SYSTEM

Pursuant to Part 2 of 1 NYCRR §2.64 paragraph (b), I hereby make application to install or modify dairy processing equipment at the facility listed below.

Plant Name & Number
Address (Incl. County) & Phone #
PPS Name & Contact

Install or Remodel	HTST or HHST	Capacity (lbs. per hour)	Approximate Date of Installation

Principal Equipment

Timing Pump (Make)	Model	Drive / AC Controller
Flow Diversion Device (Make)	Model	
Recorder Controller (Make)	Model	
Programmable Logic Controller (PLC) - (Make)	Model	
Regenerator Booster Pump (Make)	Model	Drive / AC Controller
Regenerator Differential Pressure Switch (Make)	Model	

Plate Heat Exchanger

Make	Model

List Each Section of the Plate Heat exchanger, Media (steam, glycol, etc.) & Number of plates

Section, Media	No. Plates	Section, Media	No. Plates	Section, Media	No. Plates	Other
Section, Media	No. Plates	Section, Media	No. Plates	Section, Media	No. Plates	

Holding Tube	Diameter	Length in Inches	Capacity (cu. in.)	Expected Hold Time (Incl. flow rate)

Meter Based Timing System

Magnetic Flow Meter (Make)	Model
Flow Promoting Device (Make)	Model
Flow Recorder (Make)	Model

DMC 1512 (Rev. 9/2013)

Additional Equipment

Homogenizer (Make)	Model	Drive / AC Controller
Homogenizer Stuffing Pump (Make)	Model	Drive / AC Controller
Separator (Make)	Model	Drive / AC Controller
Separator Stuffing Pump (Make)	Model	Drive / AC Controller
Vacuum Breaker (Make)	Model	

Additional Comments

Plant Representative, Signature and Date

FOR OFFICE USE ONLY

DATE RECEIVED:		Project Tracking #:	
Floor space and facilities found adequate by DPS review		Received Process Narrative with Equipment List	
		Received Flow Diagram / Layout	
DPS Initials:	Date:	Received PLC Ladder Logic & Wiring Diagram	
		Received Installer Information	
		Received Testing SOP	

PLAN APPROVAL

Dairy Products Specialist, Signature & Date

INSTALLATION APPROVAL

Dairy Products Specialist, Signature & Date

THIS APPLICATION, WHEN PROPERLY FILLED OUT BY THE REGULATORY AGENCY, SERVES AS THE OFFICIAL APPROVAL. PLEASE MAINTAIN A COPY OF THIS APPLICATION ON FILE FOR REVIEW BY OTHER INSPECTION AGENCIES.

http://www.agriculture.ny.gov/index.html

Christopher.hylkema@agriculture.ny.gov