NEW YORK STATE | Agriculture and Markets

Division of Milk Control

INSTRUCTIONS FOR MAKING AN APPLICATION FOR THE INSTALLATION OR MODIFICATION OF MILK HANDLING EQUIPMENT, CONSTRUCTION OR RENOVATION OF A PROCESS FACILITY, OR THE INSTALLATION OR MODIFICATION OF A CONTINUOUS FLOW PASTEURIZER.

2021 Revision

Instructions for Making an Application for the Installation or Modification of Milk Handling Equipment, Construction or Renovation of a Process Facility, or the Installation or Modification of a Continuous Flow Pasteurizer.

Requirement for Submitting Applications Prior to Starting an Installation

Per the requirements of 1 NYCRR Part 2 Regulations, §2.64 EQUIPMENT INSTALLER PERMIT and the Pasteurized Milk Ordinance (PMO), SECTION 12. PLANS FOR CONSTRUCTION AND RECONSTRUCTION, applications and supporting documentation must be submitted and fully approved by this Department prior to starting the installation or modification of milk or milk product processing equipment or any construction, reconstruction or extensive renovation of a milk or milk product processing facility. These documents may be found on our website (https://agriculture.ny.gov/

All installations and equipment shall meet all applicable requirements of 1 NYCRR PART 2 REQUIREMENTS FOR THE PRODUCTION, PROCESSING, MANUFACTURING AND DISTRIBUTION OF MILK AND MILK PRODUCTS and the most current version of the Pasteurized Milk Ordinance (PMO).

If you have any questions regarding the submission of an application, please contact the Division of Milk Control's Dairy Equipment Specialist, (518) 457-1772.

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

Applications are in electronically fillable PDF format and may be digitally signed. For installation of milk and milk product handling equipment, including vat pasteurizers, and new processing facility or processing facility expansions, please use form DMC-1505. For installation or modification of continuous flow pasteurization systems (HTST and HHST), please use form DMC-1512. Forms and related documents may be found at https://agriculture.ny.gov/dairy/milk-processing-equipment.

Submit, by email, applications and supporting documentation to the Dairy Products Specialist II (Regional Supervisor) and the Dairy

Products Specialist I assigned to your facility. If application is for a new facility, then please submit to the DPS II for the inspectional region that your facility is located in. Inspection regions and a staff map can be found at: (https://agriculture.ny.gov/dairy/milk-inspections). Please be sure that all documents are submitted as attachments and are Word or PDF document format. Please consider using a file naming scheme that will allow for identification of your project.

It is preferred that all applications and supporting documentation be submitted by email, however, if necessary, they may also be submitted as hard copies. When submitting hard copies please submit two complete copies to the DPS II Regional Supervisor. Mailing addresses can be obtained by contacting the regional supervisor or our central office at (518)457-1772. Please note, it is not necessary to submit information by both email and hard copy unless specifically requested by this Department.

Applications and supporting documentation must be submitted no less than 60 days prior to the anticipated start date of installation. An exception from this timeframe requirement may be acceptable in the case of a documented emergency. Any exception given will only apply to modifications and all related information outlined below would need to be received in a timely manner.

Plans for new processing facilities and major expansion projects must be submitted far in advance of the start of the project to provide adequate time for proper review.

When planning to purchase milk and milk product handling equipment, either new or previously used, it is suggested that conditions for final payment be based on final inspection for regulatory compliance. This is particularly important when purchasing equipment from non-domestic suppliers.

If necessary, previously used equipment must be brought into compliance with the most current sanitary design requirements.

The following documentation must be submitted with the application:

Please note that applications for all installation types must be accompanied by a process narrative and a project schedule. Information required to be submitted in addition to the process narrative and schedule is listed below and will be necessary when applicable. A

checklist is included at the end of this document to provide further guidance on what may be expected to be included within a process narrative and overall plan submission. This list is guidance and is not all inclusive.

Process Narrative

A process narrative is a written description detailing the scope of a project and will also include details of the manufacturing process. The process narrative should include, but is not limited to, project start date, product type, product process description, equipment to be installed including the intended method of cleaning (mechanical or manual)and material specifications for the floors, walls and ceilings of processing and storage areas. Specifics related to equipment and materials of construction may be listed within other documents such as equipment lists and process and instrumentation drawings.

The product process description should indicate the steps of the process starting with raw ingredient receipt and ending with finished product distribution. Product process details should include, but are not limited to, aspects such as raw ingredient receiving procedures including antibiotic testing requirements, pasteurization requirements, processing temperatures, incubation times and finished product storage requirements for all product types intended to be processed. The product process description may be presented in flow diagram format.

Project Schedule

To facilitate timely evaluations of the project, submit a tentative schedule indicating the expected timeline for each phase of a project. Include items such as, but not limited to, placement of floor drains, start dates for welding of sanitary piping and arrival of milk or milk product handling equipment.

Plan Drawings - Facility Layout

A facility layout drawing must indicate placement of product handling and cleaning equipment within the facility. The layout must indicate the distance relation of such equipment to drains, walls, other equipment, and operator thoroughfares. In addition to product handling and cleaning equipment placement, all plant layout drawings should depict the entire facility layout and must include, at minimum, locations of floor drains, bathrooms, employee welfare areas, handwash stations, and ventilation equipment. The materials of finish for the floors, walls and ceilings of processing areas may be indicated on the facility layout drawings.

Plan Drawings - Process and Instrumentation Drawing
Submit detailed plans of the process flow including product and cleaning solution flow (CIP). The format of these drawings may be a Process and Instrumentation Drawing (P&ID) or equivalent.

Plan drawings, both layout and process, are not required to be done by an engineer and / or architect to be acceptable for review. However, they must be drawn to scale and a symbol key must be submitted with all types of drawings.

P&ID and other types of flow diagrams must be color coded to indicate product, CIP, water, and other processes. The drawings must indicate, with arrows, directional flow of all processes.

Process modification drawings must differentiate between modifications that are new and those that are not changing.

All uses of processing water must be indicated on the P&ID or equivalent drawings. Any components necessary for protection of the facility water supply must be identified, i.e. backflow prevention devices.

Equipment Information
Include a list of equipment and appurtenances to be installed with applicable documentation indicating how the equipment is to be cleaned, i.e. Clean in Place (CIP) or manually cleaned.

Include documentation specifying material type and surface finish for all milk and milk product contact surfaces.

Include schematics or diagrams of equipment showing the product contact surfaces and how the equipment is accessible for cleaning and inspection. Photographs may be acceptable when submitted with detailed explanation.

Equipment that has been manufactured in conformity with 3-A Sanitary Standards and Practices or has an FDA issued M-b document, complies with the sanitary design and construction standards of the PMO, NYSCRR Part 2 and 21 CFR 117. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by representatives of this Department as reference during the evaluation of equipment.

Please note: For new equipment displaying a current 3-A symbol, it is not necessary to submit fabrication specifications as requested above

for that piece of equipment. This would also include equipment with an FDA issued M-b certificate. Please include the applicable 3-A certificate or FDA issued M-b with submittal.

When submitting information for equipment to be installed, be sure that the information is specific to the model of equipment intended for installation. Do not submit brochures or marketing materials for equipment that lists information, model options and specifications for several different models.

For the installation of sanitary piping, a weld evaluation protocol must be developed by the plant in conjunction with the piping installer and found to be acceptable by the Division of Milk Control.

Installer Information

Include a list and contact information for the installation companies performing the sanitary welding for a project. Any outfit performing sanitary welding of milk and milk product handling equipment in a dairy operation must be registered with this Department using form DMC-1573 Dairy Equipment Installer Registration.

Vat Pasteurizers

Application for vat pasteurizer installation should be made with the form DMC 1505.

In addition to the above required information please also include information for make and size of vat, specifications for the temperature recording system, specifications for the air space heater and specifications for the leak detect valve.

Include within the process narrative a list of the products intended to be processed including the intended processing temperatures and holding times.

It is suggested that a standard operating procedure (SOP) for testing the vat pasteurization unit be developed per Appendix I of the most current version of the PMO. Submit a copy of the SOP outlining the applicable testing requirements and procedures specific to the unit being installed.

Vat pasteurizers must be inspected and tested by representatives of the Division of Milk Control according to the applicable tests of Appendix I of the PMO prior to use.

Supplemental Information for Continuous Flow Pasteurization Systems (HTST and HHST)

Please submit the required application DMC-1512 and applicable documentation for the information requested above. In addition, please also provide the following for HTST and HHST installations:
Include within the process narrative a list of the products intended to be processed including the intended processing temperatures and holding times.

Public Health Control Programmable Logic Controller (PLC)and Wiring Diagram
Include a copy of the ladder logic for the dairy legal PLC, when applicable, that will be used to manage the functions of the public health control devices operating the pasteurization system. The PLC must meet the applicable requirements of Appendix H of the most current Pasteurized Milk Ordinance (PMO).

Provide the wiring diagram for the legal PLC showing the PLC inputs and the outputs to the devices that the PLC is controlling.

Please note that it is necessary to submit PLC logic and wiring diagrams for the control and function of the public health controls for the pasteurization system. It is not necessary to submit PLC logic for the main non-public health computer system.

The ladder logic, if not fully developed at time of application, must be submitted, and reviewed prior to initial testing of the unit by the Dairy Products Specialist.

Unit Inspection and Testing Standard Operating Procedure (SOP)
It is required that a SOP for testing the pasteurization unit be developed outlining the applicable tests per Appendix I of the PMO and the procedures for conducting those tests specific to the unit being installed.

The testing SOP,if not fully developed at time of application, must be submitted prior to initial testing of the unit by the Dairy Products Specialist.

Prior to final inspection and sealing of the public health controls by representatives of this department, the unit must be tested according to Appendix I of the PMO. This testing is to be conducted and documented by plant personnel in consultation with the installer, or

other entities as necessary, to verify operational aspects of the pasteurization unit indicating compliance with Appendix I.

Higher Heat Shorter Time (HHST) Units (direct or indirect heating)
When submitting information for HHST units 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 or an equipment list.

Supplemental Information for Single-bodied Double Seat Mixproof Valves

The installation and use of single-bodied double seat mixproof valves must meet all the applicable requirements of Item 15p(B) of the most current version of the PMO.

In addition to the above required documentation, please also provide the following for mixproof valve installations:

Identification of the valves that will be used to separate product and CIP. Typically, this is presented in a matrix format showing the valve identity and alarm conditions. Other formats are acceptable when the valves and alarm conditions are clearly identified.

Mixproof valves have four states, each with distinct feedback

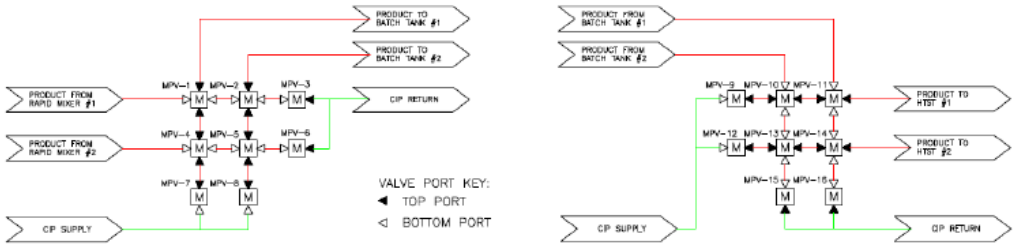
- All solenoids off
- Full Open
- Lower Seat Push
- Upper Seat Lift
- If the valve is not in one of the four states it requires maintenance

	Lower Seat Prox	Full Open Prox	Upper Seat Prox
All Solenoids Off	1	0	1
Full Open	0	1	0
Lower Seat	0	0	1
Upper Seat	1	0	0

A product / CIP matrix is developed and used to identify alarm conditions of those valves used to separate product from CIP solutions, and which will require testing for compliance with 15p(B) of the PMO. The alarms must immediately deenergize the CIP supply pump if active.

An example of a matrix identification is shown here:

Mixproof Valve Alarms



	CIP CIRCUITS					
	RAPID MIXER #1	RAPID MIXER #2	BATCH TANK #1	BATCH TANK #2	HTST #1	HTST #2
RAPID MIXER #1 TO BATCH TANK #1		MPV-4 US MPV-3 LS		MPV-2 LS MPV-7 US		
RAPID MIXER #1 TO BATCH TANK #2		MPV-5 US MPV-3 LS	MPV-1 US MPV-8 US			
RAPID MIXER #2 TO BATCH TANK #1	MPV-1 US MPV-6 LS			MPV-5 LS MPV-7 US		
RAPID MIXER #2 TO BATCH TANK #2	MPV-2 US MPV-6 LS		MPV-4 US MPV-8 US			
BATCH TANK #1 TO HTST #1				MPV-10 US MPV-16 LS		MPV-14 LS MPV-9 US
BATCH TANK #2 TO HTST #1			MPV-11 US MPV-15 LS			MPV-13 LS MPV-9 US
BATCH TANK #1 TO HTST #2				MPV-13 US MPV-16 LS	MPV-11 LS MPV-12 US	
BATCH TANK #2 TO HTST #2			MPV-14 US MPV-15 LS		MPV-10 LS MPV-12 US	

Documentation indicating the way the system programming will be protected against unauthorized changes and tampering. This will need to be reviewed with NYSAGM personnel for acceptance. It should be noted that simple password protection may not be considered sufficient. One example of an acceptable form of protection would be a password protected "add-on instruction" within the ladder logic programming for the valves that may only be accessed by the code developer using specific software.

A testing SOP must be developed and reviewed with NYSAGM personnel for use in verification of the valve alarm conditions required to deenergize the CIP supply pumps as identified in the product / CIP matrix.

Supplemental Information for Installation of Electronic Data Recording Systems

An electronic data recording system would be considered a system used to replace required paper chart recorders used for milk and milk product storage temperature recordings and cleaning systems.

All electronic data recording systems must meet the applicable requirements of Appendix H, V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING of the most current revision of the PMO.

Information to show compliance with this section must be submitted in a format explaining how the system complies with each of the 12 points of criteria listed in Appendix H of the PMO. Manufacturers of previously accepted systems will often have a "white paper" explaining how their system meets the PMO requirements.

References for review of equipment and installations:

1 NYCRR PART 2 REQUIREMENTS FOR THE PRODUCTION, PROCESSING, MANUFACTURING AND DISTRIBUTION OF MILK AND MILK PRODUCTS - available here or at agriculture.ny.gov

Pasteurized Milk Ordinance (PMO) - available here or at fda.gov

3A Sanitary Standards and Accepted Practices (available at https://www.3-a.org/)

Required materials and information for making an Application to Install or Modify Milk Handling Equipment

- ☐ **Process Narrative - detailed description of process and plans**
- ☐ **Project and Equipment Installation Schedule**
- ☐ **Plan Drawings**
  - ☐ **Facility Layout**
  - ☐ **Equipment and drain locations**
  - ☐ **Process Flow P&ID**
- ☐ **List of equipment to be installed (type, manufacturer, supporting documentation – 3A certification, FDA M-b)**
- ☐ **Sanitary Piping Weld Evaluation Protocol**
- ☐ **List of installers / fabricators and responsibilities**
- ☐ **Vat Pasteurizer Information**
  - ☐ **Size and Make of Vat**
  - ☐ **Temperature Recording System**
  - ☐ **Air Space Heating**
  - ☐ **Leak Detect Valve meets 3-A® Sanitary Standards for Inlet and Outlet Leak-Protector Plug-Type Valves for Milk and Milk Products, Number 56-**
  - ☐ **List of Products and respective processing temperatures and hold times**
- ☐ **Continuous Flow Pasteurization System**
  - ☐ **Application for HTST / HHST – DMC 1512**
  - ☐ **Full schematic of pasteurizer (including destination lines and return lines)**
  - ☐ **Ladder logic for HTST / HHST**
  - ☐ **Wiring diagram**
  - ☐ **Testing SOP**
  - ☐ **List of Products and respective processing temperatures and hold times**
- ☐ **Information for Mix Proof Valve Installation**
  - ☐ **Identification of Valves (matrix)**
  - ☐ **Protection of programming against unauthorized changes**
  - ☐ **Valve testing SOP**
- ☐ **Electronic Data Recording Systems**
  - ☐ **Information to verify compliance with Appendix H**
- ☐ **Material Schedule for Floors, walls, and ceilings**
- ☐ **Record Keeping**
  - ☐ **Paper charts including description of processes monitored**
  - ☐ **Electronic including description of processes monitored**

- **Water Supply**
  - **Municipal**
  - **Private (specify type)**
  - **Bacteria results in compliance**
- **Water Protection**
- **Cooling Media:**
  - **Glycol**
  - **Chilled / Sweetwater**
  - **Tower Water**
  - **Other (specify)**
  - **Sample ports installed**
- **Pasteurized Equivalent Water (study proposal submitted)**
- **Water for raw product flush**
- **Air under pressure for product contact**
  - **Filter specifications**
  - **Air blow assembly type and locations**
- **Boiler water**
  - **Description of intended uses (if for product contact)**
  - **Additives meet req. of CFR 21 Part 177 (signed letters on file)**
- **CIP Systems**
  - **Single use**
  - **Multiple use**
  - **Central system with day tanks**
  - **Other (specify)**
- **Appendix N Testing Lab**
  - **Lab layout submitted to Laboratory Evaluation Officer (LEO) for review**
- **License & Permit Applications (for new plants)**
  - **Milk Dealer**
  - **Wholesale Frozen Dessert**
  - **Part 2**
  - **Processing Plant Superintendent (PPS)**
  - **Interstate Milk Shippers (IMS) Certification Listing**