CSI Process Engineering Memo

Legal Pasteurization Systems

What is pasteurization anyway?

Pasteurizing, in reference to milk and milk products, is a heat-treatment designed to kill pathogens that cause disease, which may be present in raw milk. It is important to understand that pasteurized products are not completely free of pathogens, but are generally considered safer to consume.

By definition: Pasteurization shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to a specified temperature and held continuously at or above that temperature for at least the corresponding specified time.

If I do not remember anything else about pasteurization...

Our typical customer who produces milk or milk products will use an HTST system. HTST stands for High Temperature / Short Time. The acronym HTST helps recall the two keys of pasteurization.

- High Temperature: 161°F (72°C)
- Short Time: at least 15 Seconds

Because the goal is to render the milk safe for consumption without curdling it or altering the flavor profile too much, it is important to note that these metrics are CRITICAL.

Is 161°F and 15 seconds the only acceptable combination?

The short answer is no. The following table can be used:

Temperature	Time	
*145°F (63°C)	30 minutes	
*161°F (72°C)	15 seconds	(Most Common)
191°F (89°C)	1 second	
194°F (90°C)	0.5 seconds	
201°F (94°C)	0.1 seconds	
204°F (96°C)	.05 seconds	
212°F (100°C)	.01 seconds	

*If the fat content of the milk product is 10% or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C).

What about pressure differential; is that important?

Differences between raw and pasteurized product may seem minimal, but according to regulatory officials, pressure differential is the difference between good and evil. The importance of maintaining a pressure differential cannot be overstated so that raw milk never leaks into pasteurized milk.

The key idea about pressure differential:

> Raw product shall always be processed at a lower pressure than pasteurized product when their flows are separated by only one surface.

This idea stands to reason. If a leak were to occur, you would want pasteurized milk to be forced into the raw stream instead of a situation where raw milk bypassed a processing step, contaminating an entire production run.

This is particularly important where regeneration heat exchangers are being used, due to the fact that pasteurized milk product is used to pre-heat raw product. These flows are separated by only a thin sheet of stainless steel.

Major components of HTST systems

- **Balance / Constant-level supply tank**
  Raw product from truck unloading stations as well as recirculated milk or milk product may be present here.

  While CSI does not fabricate tanks, we know many tank fabricators.

- **Regen / Regeneration / Heat exchange**
  Raw product is warmed through the use of plate and frame heat exchange technology. Basically you have cold raw product on one side and hot pasteurized product on the other.

  CSI has access to plate and frame heat exchangers through Alfa Laval, APV, and others.

- **Positive displacement timing pump**
  The timing pump, often called PD Pump, is responsible for maintaining the appropriate flow rate and delivery of raw products to the remainder of the HTST system.

  The PD pump settings are verified by the inspector and are “locked out” which helps prevent operators from changing set points and inadvertently producing illegal milk or milk products.

PD pumps are available from Alfa Laval and Waukesha, among others.

- **Primary heating / Heat exchange**
  Raw product is pumped through heat exchange equipment where hot water or steam is used as the heating media to raise the product to the appropriate temperature.

  Commonly, plate and frame heat exchangers are used here. CSI has access to these through Alfa Laval, APV, and others.

- **Homogenizer**
  Using high pressure, mechanical means, or a combination of the two, product is pressed through small holes. This process forces fats to break apart. Modern homogenization techniques can reduce the size of fat molecules by a factor of nearly 500.

  CSI would like more opportunities to sell homogenizers. We have options like GEA Niro, APV, and Gaulin.

- **Hold tube**
  The product, having been raised to the appropriate temperature, is held for the appropriate time (See Chart above). The velocity through the hold tube is determined by a number of factors including: timing pump, diameter and length of hold tube, and surface friction.

  CSI is an industry leader in the design and manufacture of hold tubes. We can engineer, design, and build a hold tube to accommodate nearly any application.

- **DRT / Indicating thermometer**
  The DRT, or digital reference thermometer, is positioned after the hold tube. Product passes the sensing bulbs of the thermometer which verifies whether or not the product has been held at the appropriate temperature through the hold tube.

  CSI primarily uses Anderson Instruments' products like the FD "DART" or other dual element temperature probes. Many options exist, but verify they are PMO compliant.

- **Flow diversion devices**
  A flow diversion setup uses two normally closed divert seat valves, like Alfa Laval series 762. When appropriate conditions are not met, both valves remain in the closed position which sends raw product back to the balance tank. If the temperature of the product

has been verified as appropriate, the first and second valves are diverted allowing product to pass.

The second valve serves as a fail-safe for when the first valve has a leaking seal. With both valves in the closed position raw product flowing through the second valve would be returned to the balance tank via a leak detect line. A common feature of the leak detect line is a sight glass, where operators can see raw product flowing.
**Product in the leak detect line means a leak at the primary valve.

Both valves are required to have an open yoke, or open area between the valve and actuator for leak detection. Alfa Laval provides flow diversion setups that include two seat valves and can include a control panel if needed. Series 762-227 or similar

- **Regen / Regeneration**
  Pasteurized product is passed through a plate and frame heat exchanger where heat is exchanged, through stainless steel plates, with raw product. Higher pressure should always be maintained on the pasteurized product side.

  See Regen / Regeneration / Heat exchange above.

- **Cooling heat exchange**
  A plate and frame heat exchanger uses coolant opposite pasteurized product to reduce the temperature, ultimately reaching 40°F (4.4°C) or below.

  Note: The Heating, Regen, and Cooling heat exchangers are often combined in one plate and frame heat exchanger with multiple sections.

  As noted before, Alfa Laval and APV are common plate and frame manufacturers.

- **Recorder/controller**
  Generally a chart recorder that is designed to record data and provide a measure of control based on time and temperature set points. One of the primary functions of the recorder is to provide proof, which cannot be tampered with, that the product produced is safe for distribution.

  Recorded data should indicate that appropriate pasteurization temperatures were reached. Anderson Instruments provides the AV-9900 or similar as recording/control equipment.

What do inspectors look for when approving pasteurization systems?

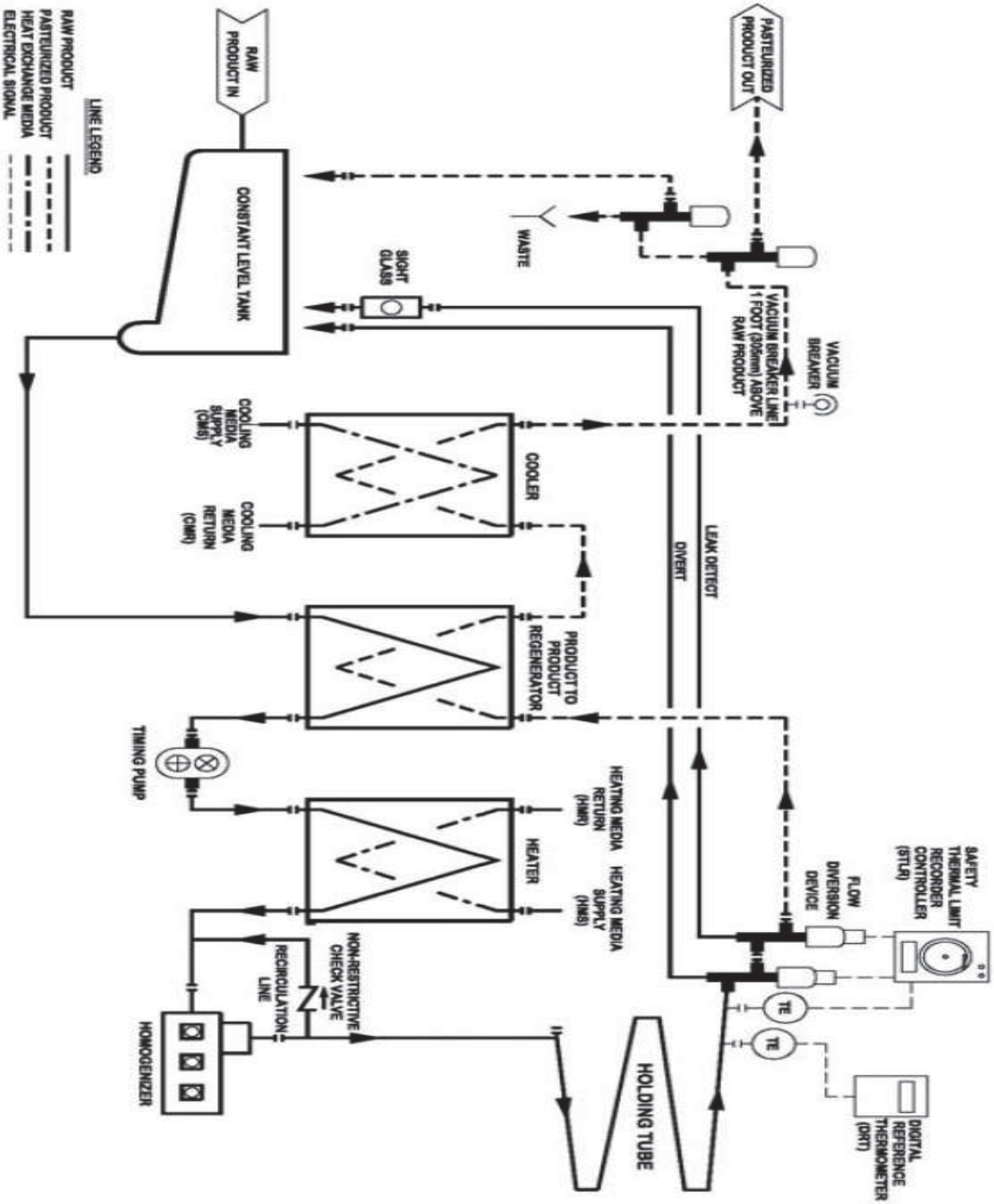
- Pasteurizing, processing, cooling and packaging of milk and milk products should take place in a room separate from cleaning and sanitizing facilities for milk tank trucks, and other areas in which raw milk and raw milk utensils are handled.

  The key idea is separation:

  > The customers should have practices and procedures in place that quickly and easily identify those items used for raw products versus items which would be used for pasteurized products and that they remain separate at all times.

  Often customers will have color coding or some other easily identifiable procedure in place. It is important that the separation is evident.

- Single service items, such as some woven milk filter material, are to be replaced daily.
- Raw milk should be protected from outside contamination.
- Receiving hoses should be clean, protected and cleaned daily after the last truck of incoming raw milk or cream has been received.
- Raw tanks are to be cleaned and sanitized when empty and emptied at least every 72 hours.
- Tanks should be properly vented
- Product must be maintained at 45°F (7.2°C) or below prior to and after pasteurization.
- The piping diagram should be reviewed and compared to the actual plant layout and all potential cross-connections found should be followed-up. No cross-connections are allowed between raw and pasteurized product or between CIP and product.
- If a continuous process is used (HTST), a flow diagram showing each piece of equipment (i.e. pumps, valves, thermometers, etc.) and temperatures at each point of the process should be collected as an exhibit.
- Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.
- The term “automatic product flow controls” shall mean those safety devices which control the flow of milk or milk product in relation to the temperature of the milk or milk product or heating medium and/or pressure, vacuum or auxiliary equipment.



Source: Grade “A” Pasteurized Milk Ordinance

References:

1. Grade “A” Pasteurized Milk Ordinance, Recommendations of the United States Public Health Service/Food and Drug Administration (PMO). Current Revision
   http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipments NCIMSModelDocuments/UCM291757.pdf
2. 21 CFR Sections 1/10; 101; 108; 110; 113; 130; 131; 133; 173.310; and 178.1010
3. Grade “A” Condensed and Dry Milk Products and Condensed and Dry Whey (DMO). Current Revision
4. FDA Frozen Dessert Processing Guidelines. Current Edition
5. 3A Sanitary Standards for Dairy Equipment
6. PMO, Part 1, Definition S; Attachment 4 for acceptable pasteurization times and temperatures; and Attachment 1 for pasteurizer evaluation
7. 3-A Accepted Practices for the Sanitary Construction, Installation, testing and Operations of HTST Pasteurizers
8. CPG 7119.05, Imported Milk and Cream
9. CPG 7158.01, MOU with the National Conference on Interstate Milk Shipments Relating to Interstate Milk Shipments
10. Federal Import Milk Act Regulations, 21 CFR, Part 1210
11. NCIMS Memorandums to supplement the PMO and related documents
12. Regional/District Milk Specialists
13. Guide to Inspections of Dairy Product manufacturers
    http://www.fda.gov/iceci/inspections/inspectionguides/ucm074974.htm