

34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 101

Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal updates the Somatic Cell Count regulatory threshold for bovines to reflect advances in on-farm practices and commercial standards for milk marketed by U.S. dairy producers.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Changes in on-farm practices and the application of commercial standards at the farm level have resulted in a large and continuing decline in average Somatic Cell Count (SCC) levels in the United States. The average U.S. dairy producer bulk tank SCC has decreased from 596,000 per mL in 1984<sup>1</sup>, to 298,000 per mL in 2001<sup>2</sup>, to 206,000 per mL in 2011<sup>3</sup>. The bulk tank SCC of nearly ninety-three percent of milk marketed in 2011<sup>4</sup> was below 400,000 per mL.

On October 26, 2010, delegates to the National Milk Producers Federation (NMPF) Annual Meeting passed a resolution to support lowering the SCC regulatory threshold through the Grade "A" Pasteurized Milk Ordinance at the National Conference on Interstate Milk Shipments.

<sup>1</sup> Jones, G. M. 1986. *Journal of Dairy Science*. 69: 1699-1707.

<sup>2</sup> USDA. June 2007. *Determining U.S. Milk Quality Using Bulk Tank Somatic Cell Counts, 2006*

<sup>3</sup> USDA. September 2012. *Determining U.S. Milk Quality Using Bulk Tank Somatic Cell Counts, 2011*

<sup>4</sup> *Ibid.*

**C. Proposed Solution**

Changes to be made on page(s):		XVI, 29-30, 203, 357-358	of the (X - one of the following):
<u>X</u>	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

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***Make the following change to the 2011 PMO.***

Strike out text to be deleted and underlined text to be added.

**2011 PMO  
TABLES, PAGE XVI**

....

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examination  
(Effective January 1, 2014).....

Table 12A. Example of Enforcement Procedures for Raw Milk Laboratory Examination  
(Effective January 1, 2015).....

Table 13. Sieve Sizes and Designations.....

....

**2011 PMO  
SECTION 7-TABLE 1, PAGES 29-30**

....

Somatic Cell Count\*... Individual producer milk not to exceed ~~750,000 per mL~~ 600,000 per mL  
(effective January 1, 2014); and 400,000 per mL (effective January 1, 2015).

....

....

\* Goat Milk 1,500,000/mL; 750,000/mL for Sheep, Water Buffalo, and Hooved Mammals except Cattle.

....

**2011 PMO  
APPENDIX E, PAGE 203**

**Table 12. Example of Enforcement Procedures for Raw Milk Laboratory  
Examinations for Cattle (Effective January 1, 2014)**

<b>Date</b>	<b>Confirmed Somatic Cell Counts per mL</b>	<b>Enforcement Action as Applied to a Standard of <del>750,000</del> 600,000 per MI</b>
<del>7/10/2011</del> <u>7/10/2014</u>	500,000 <del>400,000</del>	No Action Required
<del>8/15/2011</del> <u>8/15/2014</u>	<del>600,000</del> <u>500,000</u>	No Action Required
<del>10/1/2011</del> <u>10/1/2014</u>	<del>800,000</del> <u>700,000</u>	Violative; No Action Required
<del>11/7/2011</del> <u>11/7/2014</u>	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
<del>11/14/2011</del> <u>11/14/2014</u>	1,200,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as <u>a</u> Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this <i>Ordinance</i> . Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i> . (Refer to Section 3.)
<del>11/18/2011</del> <u>11/18/2014</u>	<del>700,000</del> <u>550,000</u>	Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule as cited under <del>11/14/2011</del> <u>11/14/2014</u> .
<del>11/20/2011</del> <u>11/20/2014</u>	800,000	Violative; No Action Required <b>NOTE:</b> Samples collected prior to <del>11/18/2011</del> <u>11/18/2014</u> are not used for subsequent somatic cell count enforcement purposes.
<del>11/24/2011</del> <u>11/24/2014</u>	<del>700,000</del> <u>550,000</u>	No Action Required
<del>11/29/2011</del> <u>11/29/2014</u>	550,000	No Action Required
<del>12/3/2011</del> <u>12/3/2014</u>	400,000	Permit Fully Reinstated

**Table 12A. Example of Enforcement Procedures for Raw Milk Laboratory Examinations for Cattle (Effective January 1, 2015)**

<u>Date</u>	<u>Confirmed Somatic Cell Counts per mL</u>	<u>Enforcement Action as Applied to a Standard of 400,000 per MI</u>
<u>7/10/2015</u>	<u>300,000</u>	<u>No Action Required</u>
<u>8/15/2015</u>	<u>400,000</u>	<u>No Action Required</u>
<u>10/1/2015</u>	<u>600,000</u>	<u>Violative; No Action Required</u>
<u>11/7/2015</u>	<u>900,000</u>	<u>Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.</u>
<u>11/14/2015</u>	<u>1,200,000</u>	<u>Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as a Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this Ordinance. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this Ordinance. (Refer to Section 3.)</u>
<u>11/18/2015</u>	<u>450,000</u>	<u>Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule as cited under 11/14/2014.</u>
<u>11/20/2015</u>	<u>800,000</u>	<u>Violative; No Action Required NOTE: Samples collected prior to 11/18/2015 are not used for subsequent somatic cell count enforcement purposes.</u>
<u>11/24/2015</u>	<u>450,000</u>	<u>No Action Required</u>
<u>11/29/2015</u>	<u>450,000</u>	<u>No Action Required</u>
<u>12/3/2015</u>	<u>400,000</u>	<u>Permit Fully Reinstated</u>

*NOTE: Authorize FDA editorial license to delete the Table(s) cited above in future revisions of the PMO when they have reached their expiration date and the next lower SCC level has reached it's effective date.*

**2011 PMO  
APPENDIX P, PAGES 357-358**

**MINIMUM ONE (1) YEAR INSPECTION INTERVAL (ONE (1) INSPECTION EACH TWELVE (12) MONTHS):**

All criteria below must have been met for the previous twelve (12) months:

1. No more than one (1) sample with a Standard Plate Count (SPC) >25,000, but less than 100,000;
2. All Somatic Cell Count (SCC) samples  $\leq$  ~~500,000~~ 400,000 (effective January 1, 2014);
- .....

**NOTE:** Farms in this category who are re-categorized to a six (6) month inspection interval for a single violation of one (1) milk quality parameter (SCC  $\geq$  ~~500,000~~ or cooling temperature violation) may be re-categorized to the one (1) year inspection interval if all ten (10) criteria listed above are met for the next six (6) months.

**MINIMUM SIX (6) MONTH INSPECTION INTERVAL (ONE (1) INSPECTION EACH SIX (6) MONTHS):**

All criteria below must have been met for the previous twelve (12) months:

1. May have more than one (1) sample with SPC >25,000;
2. May have one (1) or more SCC sample  $>$  ~~500,000~~ 400,000 (effective January 1, 2014);
- .....

34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 102  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

Lower the PMO somatic cell count requirement from 750,000 per mL to 400,000 per mL.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Lowering the somatic cell count to 400,000 per/mL will improve raw milk quality, improve milk consumed by the public, and assure that dairy producers implement modern dairy management techniques to improve animal health to meet the regulatory standard for somatic cell count.

**C. Proposed Solution**

Changes to be made on page(s):	29, 203	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws



		three (3) days.
<u>11/14/2011</u> <u>11/14/2015</u>	<u>1,200,000</u> <u>500,000</u>	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: 1. Suspend producer permit; or 2. Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or 3. Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold or offered for sale as Grade "A" product. Except that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided: If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this <i>Ordinance</i> . Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this <i>Ordinance</i> . (Refer to Section 3.)
<u>11/18/2011</u> <u>11/18/2015</u>	<u>700,000</u> <u>390,000</u>	Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule as cited under 11/14/2011.
<u>11/20/2011</u> <u>11/20/2015</u>	<u>800,000</u>	Violative; No Action Required <b>NOTE:</b> Samples collected prior to 11/18/2011 are not used for subsequent somatic cell count enforcement purposes.
<u>11/24/2011</u> <u>11/24/2015</u>	<u>700,000</u> <u>360,000</u>	No Action Required
<u>11/29/2011</u> <u>11/29/2015</u>	<u>550,000</u> <u>240,000</u>	No Action Required
<u>12/3/2011</u> <u>12/3/2015</u>	<u>400,000</u> <u>200,000</u>	Permit Fully Reinstated

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 103  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To recognize somatic cell count (SCC) limit for cow (Bovine) milk of 400,000/ml.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The NCIMS has previously voted on several proposals to reduce the somatic cell count to 400,000/ml. The NCIMS reduced the SCC several years prior to 750,000/ml with accepted data that the level was not a health problem for the consuming public and for animal health.

The request to reduce cow milk SCC from 750,000 SCC to 400,000 SCC is being motivated by the European Union and other dairy importing countries demanding US milk products be processed using cow milk of 400,000 SCC/ml or less. For one year, the milk cooperatives, milk brokers, milk product marketers, and maybe USDA, have been notified of individual milk producers exceeding 400,000 SCC from an official sample or an averaging of samples in one month. Depending upon the buyer, various derogations and mathematical formulations can be implemented to allow >400,000 SCC/ml milk to be utilized or to have it diverted to non-export product use.

The fifth paragraph of the Preface in the *Grade A Pasteurized Milk Ordinance, 2011 Edition* states, "The *Grade "A" PMO* is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the Public Health Agencies, the

milk industry, and many others as the national standard for milk sanitation. The *Grade “A” PMO* adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either Regulatory Agencies or the dairy industry. It represents a “grass-roots” consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation.”

The fourth paragraph under Section 3 of the Introduction in the *Grade A Pasteurized Milk Ordinance, 2011 Edition* states, “The model *Ordinance* discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high quality milk from other milksheds. (Refer to Section 11.) On repeated requests from the Association of State and Territorial Health Officers and the NCIMS, the USPHS/FDA is actively cooperating in the voluntary program for the Certification of Interstate Milk Shippers. Such a program would be impossible without widespread agreement on uniform standards, such as those of this recommended *Ordinance*.”

The first paragraph of the Preface of the *Methods of Making Sanitation Ratings of Milk Shippers, 2011 Revision* states, “The objective of a rating is to provide an assessment of State and Local sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the *Grade “A” Pasteurized Milk Ordinance (Grade “A” PMO)* and Related Documents as listed in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipment (Procedures)*. Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance with public health standards as expressed in the *Grade “A” PMO*. Rating results are further utilized as a means of uniform education and interpretation, in addition to providing a basis for the acceptance/rejection of shippers by Regulatory Officials beyond the limits of routine inspection. Rating results are intended to establish uniform reciprocity between States to prevent unnecessary restrictions of the interstate flow of milk and milk products, yet assure public health protection.”

The third paragraph of Preface of *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2011 Edition* states, “The procedures accepted by the first Conference in 1950 have been used to advantage by many States in developing sound, and more uniform, milk sanitation programs. They have also led to the development of a greater degree of reciprocity between States on acceptance of inspection and laboratory results. These procedures have also been used by many States as a basis of programs for the supervision and certification of interstate milk sources.”

All fifty states have adopted the *PMO* or portions thereof, the *Procedures* document and the *Methods of Making State Ratings* to allow the shipment of milk or milk products between states and territories. The milk and milk products of the United States are recognized as the safest in the world. It has been brought to the attention of the NCIMS that the EU and other countries are only willing to accept US milk and milk products that meet their standard of <400,000 SCC/ml. As stated above in the three documents, they all refer to sanitation

regulations of milk and milk products of high sanitary quality in interstate and intrastate commerce.

The 400,000 SCC/ml limit for raw milk has not been established as a human/animal health risk. The health/milk regulatory divisions of the states should not be enforcing a sanitary standard that has not been established. The rules of the 2011 PMO, MMSR and Procedures allow the acceptance of listed milk suppliers and processors between states and IMS listed foreign entities. Subjecting states to enforce a non-established health standard is unwarranted.

A solution needs to be an alert/notify milk marketing agencies, individuals, or federal departments when monthly official raw samples exceed 400,000 SCC/ml.

**C. Proposed Solution**

Changes to be made on page(s):	<u>29 and 30</u>	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

Page 29, top half of page: Somatic Cell Count \* & \*\*\*\*\*  
Page 30, bottom text: \*\*\*\*\* Official sample results of bovine milk with SCC >400,000/ml must be sent to producer's cooperative or buyer.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 104  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To provide consistent and uniform wording and sanitary and sampling requirements for hauled water for use in milk plants as is currently required for use on dairy farms.

**B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission**

Item 7p-Water Supply of the PMO does not provide sanitary and sampling requirements for hauled water for use in milk plants. A milk plant has been identified that utilizes hauled water for milk plant operations. This Proposal adds the same wording and sanitary and sampling requirements as are currently cited in Item 8r-Water Supply of the PMO for use on dairy farms to Item 7p for use in milk plants. This Proposal provides consistency and uniformity related to the sanitary and sampling requirements of the PMO in relationship to the use of hauled water in milk plants and on dairy farms.

**C. Proposed Solution**

Changes to be made on page(s):	43, 61 and 62	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:***

Strike through text to be deleted and underline text to be added.

**ITEM 8r. WATER SUPPLY**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

*Page 43:*

6. All containers and tanks used in the transportation of water are ~~sealed and~~ protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material; provided with a dust and rainproof cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (Refer to Appendix D.) ...

*Page 61:*

**ITEM 7p. WATER SUPPLY**

**ADMINISTRATIVE PROCEDURES<sup>8</sup>**

This Item is deemed to be satisfied when:

4. All containers and tanks used in the transportation of water are protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the milk plant. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the milk plant, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the milk plant shall be constructed of impervious material; provided with a dust and rainproof cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (Refer to Appendix D.)

*Renumber remaining ADMINISTRATIVE PROCEDURES accordingly.*

*Page 62:*

78. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each six (6) months thereafter; and when any repair or alteration of the water supply system has been made. Provided, that when water is hauled to the milk plant, such water shall be sampled for bacteriological examination at the point of use and submitted to an official laboratory at least four (4) times in separate months during any consecutive six (6) months. Samples shall be taken by the Regulatory Agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this ~~Section~~ Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

*Renumber remaining ADMINISTRATIVE PROCEDURES accordingly.*

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# 34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 105  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

## A. Summary of Proposal

The PMO states that “Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance”. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices should be used as guidance for milk plant and dairy farm regulators. This will provide greater uniformity in determining compliance of all equipment with PMO Items 9r and 11p. Also, 3-A Accepted Practices and the organizational references cited in the “NOTE” have been updated to the current stakeholder names.

## B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

All equipment installed in Grade “A” dairy farms and milk plants shall comply with the construction and design criteria of the PMO. However, the wording of the equipment construction requirements in Item 9r and 11p of the PMO is somewhat vague whereas the 3-A Sanitary Standards and Accepted Practices provide additional detail to supplement the PMO and therefore should be used by milk regulatory agencies as guidance in determining PMO compliance of equipment not displaying the 3-A Symbol. The PMO references 3-A Sanitary Standards and Accepted Practices in the following sections:

Item 9r and 11p: “**NOTE:** Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance.”

Item 9r: “13. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the “3-A Sanitary Standards for Multiple-Use Plastic Materials Used as product Contact Surfaces for Dairy Equipment, Number 20-##”

Item 9r: “14. AMIs shall comply with all applicable Grade “A” PMO requirements and/or 3-A standards.”

Appendix B: V. The milk tank truck and all appurtenances shall meet applicable requirements of Section 7, Item 10p-Sanitary Piping and Item 11p-Construction and Repair of Containers and Equipment, of this *Ordinance*. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this *Ordinance*.”

Appendix F: III. “**NOTE:** For additional details refer to 3-A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products, Serial 26-##.”

Appendix H: II. “**NOTE:** For additional details, refer to 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product-Contact Surfaces 604-## and 3-A Accepted Practices for Spray Drying Systems 607-##.”

Appendix H: IV. “Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk or milk products; and the location of this seat to conform to the 3-A Sanitary Standard for a wall-type fitting or other equivalent sanitary fitting.”

<b>C. Proposed Solution</b>	
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Changes to be made on page(s):	45 and 67	of the (X - one of the following):
<input checked="" type="checkbox"/>	2011 PMO	2011 EML
<input type="checkbox"/>	2011 MMSR	2400 Forms
<input type="checkbox"/>	2011 Procedures	2011 Constitution and Bylaws

**NOTE:** ~~3-A Sanitary Standards and Accepted Practices for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Team, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services. developed by 3-A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA, Agricultural Marketing Service, Dairy Programs, the PHS/FDA, Center for Food Safety and Applied Nutrition, Milk Safety Team, academic representatives and others.~~

Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices should be used by milk regulatory agencies as guidance in determining compliance with this Section.

34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 106

Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal addresses concerns cited in Appendix Q-Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization, Ultra-pasteurization or Aseptic Processing and Packaging, Item 14r-Protection from Contamination of the PMO. It is related to the requirement of a fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, reference in Item 15p(B) of the PMO, to prevent cross contamination and adding the applicable requirements from Item 15p(B) into Item 14r for their use on Grade “A” dairy farms. It also provided editorial updates to Appendix Q of the PMO based on FDA’s evaluation of Automatic Milking Installations (AMIs).

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

With the onset of AMIs and the increased use of technologies on Grade “A” dairy farms, it has become apparent that it is appropriate to include applicable requirements only previously referred to for Grade “A” milk plants related to fail-safe valve systems used to prevent cross contamination into the PMO requirements for Grade “A” dairy farms. This Proposal would eliminate the reference in Appendix Q of the PMO to a milk plant requirement (Item 15p(B)) when it addresses the use of fail-safe valve systems to prevent cross contamination on Grade “A” dairy farms. It would incorporate applicable requirements contained within Item 15p(B) (1.)(a) and (b) 1-7 into Item 14r(2.) of the PMO. This Proposal addresses the requirements for the use of these fail-safe valve systems and at the same time assuring that the same or equivalent protection for contamination issues presented on Grade “A” dairy farms are maintained by the use of appropriate fail-safe valve systems.

**C. Proposed Solution**

Changes to be made on page(s): 49, 77, 78, 360 & 361 of the (X - one of the following):

<input checked="" type="checkbox"/>	2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2011 PMO.***

~~Strike through~~ text to be deleted and underline text to be added.

*Page 49:*

**ITEM 14r. PROTECTION FROM CONTAMINATION**

Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, containers, utensils and equipment. ~~No milk~~ Milk shall not be strained, poured, transferred or stored unless it is properly protected from contamination.

After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent the contamination of any milk product-contact surface.

Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and ~~no~~ any substance capable of contaminating the milk shall not be transported with the milk.

**PUBLIC HEALTH REASON**

Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort ~~should~~ shall be made to provide adequate protection for the milk at all times. This ~~should~~ shall include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air that is used for the agitation or movement of milk or is directed at a milk product-contact surface ~~should~~ shall be such that it will not contaminate the milk.

The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.

To protect milk during transportation, delivery vehicles ~~must~~ shall be properly constructed and operated.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when: ...

2. During ~~processing~~ milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk ~~and milk products~~, shall be effectively separated from tanks and/or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

a. Physically disconnecting all connection points between tanks and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk; or

b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or the following exception:

If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines.)

(2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices.)

(3) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that shall prevent the contamination of milk with cleaning and/or sanitizing solutions. Automatic fail-safe systems shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (6) below.

(4) The system shall not have any manual overrides.

(5) Controls for the fail-safe system are secured as directed by the Regulatory Agency in order to prevent unauthorized changes.

(6) The vent is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent may be cleaned while milk is present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve shall incorporate the following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets;

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times;

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a proximity switch that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure shall be immediately de-energized; and

iv) The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls.

(7) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised. ...

**ITEM 15p. PROTECTION FROM CONTAMINATION ...**

Page 77:

**15p.(B)**

1. During processing, pipelines and equipment used to contain or conduct milk and/or milk products shall be effectively separated from tanks and/or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

a. Physically disconnecting all connection points between tanks and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk and/or milk products; or

b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or one (1) of the following exceptions:

i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and/or sanitizing solution lines); or

ii) In low pressure, gravity drain applications, i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning and/or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats ~~need~~ are not required to be position detectable. In order to accept this variation, the valve(s) ~~must~~ shall fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk and/or milk product, cleaning solutions, and/or sanitizing solutions into this valve arrangement. ...

Page 78:

(3) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that ~~will~~ shall prevent the contamination of milk and/or milk product with cleaning and/or sanitizing solutions. Automatic fail-safe systems ~~will~~ shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (6) below. ...

(6) The vent is not cleaned until milk and/or milk products have been removed or isolated, except in the case of a properly designed and operated single-bodied double

seat valve, in which case, the vent may be cleaned while milk and/or milk products are present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve ~~will~~ shall incorporate the following:

- i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets; ~~and~~
- ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times; ~~and~~
- iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a proximity switch that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure ~~will~~ shall be immediately de-energized; and
- iv) The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls. ...

*Page 360:*

#### **APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING ...**

This Appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered to be in compliance with the *Grade "A" PMO*. It is formatted to follow the Items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING. Both requirements and recommendations are ~~discussed~~ provided.

#### **ITEM 1r. ABNORMAL MILK**

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank basis and ~~should be no~~ shall not be any different for a herd using AMI technology.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) are identified through an appropriate identification system so that their milk ~~will~~ shall be automatically excluded from the milk offered for sale, provided that the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized.

#### **ITEM 2r. MILKING BARN, STABLE OR PARLOR - CONSTRUCTION**

The AMI milker box shall be treated the same as any other milking parlor. The goal is a clean

environment in which to milk animals. All ventilation air ~~must~~ shall come from outside the cattle housing area. ~~It is recommended that the~~ The AMI shall be located to provide a clean access for all personnel. ...

#### **ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION**

AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc.

*Page 361:*

#### **ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE**

AMIs shall have positive air ventilation systems in operation whenever the milking system is cleaning being washed and/or sanitizing. The air for this ventilation system ~~must~~ shall come from outside the cattle housing area and ~~should~~ shall be as clean and dry as practical. This positive air ventilation system ~~may~~ shall also ~~need to~~ run during milking if needed to minimize ~~odor~~ odors, moisture and/or for pest control.

#### **ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS**

AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES #4:** “Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.” Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this ~~approval~~ FDA acceptance, including a detailed description of the ~~approved~~ accepted equivalent procedure. Each dairy producer shall keep a copy ~~on file~~ of the accepted teat prep protocol along with the appropriate AMI manufacturer’s teat prep protocol verification procedures on file at the dairy farm.

#### **ITEM 14r. PROTECTION FROM CONTAMINATION**

The teat cups (inflations) of the milking cluster ~~need to~~ shall be adequately shielded during the ~~udder teat~~ teat prepping system process to assure that contaminants ~~may~~ shall not enter through the teat ~~cup~~ cups and get into the milk.

AMIs are designed to automatically shift from ~~milk to wash~~ milking to washing/sanitizing positions; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item 14r, shall be located as needed to prevent cross contamination. Separation shall be provided between; milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale.

Each dairy producer shall keep a copy of the AMI manufacturer’s testing verification procedures for the fail-safe valve systems on file at the dairy farm.

AMIs, which have a pipe wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving system arrangement that provides for an air break equal to the diameter of the wash line.

**ITEM 18r. RAW MILK COOLING**

For AMIs, the raw milk for pasteurization shall be cooled to 10°C (50°F) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7°C (45°F). The milk in the farm bulk milk storage tank temperature should ~~shall~~ not exceed 7°C (45°F) after that ~~point~~ time. ~~Bulk Farm bulk~~ milk tank recording thermometers are recommended if not already required by this Ordinance.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 107  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal incorporates M-I-12-11 “Additional Information Related To The Storage Of Drugs Under Item 15r Of The Grade “A” Pasteurized Milk Ordinance (PMO)” into the Grade “A” PMO. M-I-12-11 specifically address the definition of lactating and dry cow specific to the grade “A” PMO.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The Food and Drug Administration’s (FDA) Center for Veterinary Medicine (CVM) issued the “CVM Update” entitled “FDA Clarifies use of the Term, ‘Non-lactating Dairy Cattle’” on February 21, 2012 to address different residue safety requirements for pre-market approval of animal drugs

The purpose of the drug labeling and storage requirements of Item 15r of the PMO is to ensure that dairy producers are aware of the labeling directions on the drugs they are using to treat their dairy animals. Dairy producers are reminded to read labels and understand how to properly use and administer animal drugs. When dairy producers have questions regarding the appropriate use of an animal drug, they should consult their veterinarian. The use of drugs in a class of dairy animals, for which they are not approved, outside of an appropriate extra-label use under the supervision of a veterinarian, may lead to residues in meat and/or milk.

This proposal clarifies that the storage space allocated to drugs for non-lactating dairy cattle includes drugs for the treatment of dry dairy cows which is in the interest of public health by minimizing potential for residues in the milk supply.

**C. Proposed Solution**

Changes to be made on page(s):		50	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

***Make the following change to the 2011 PMO.***

~~Strike out~~ text to be deleted and underlined text to be added.

**ITEM 15r. DRUG AND CHEMICAL CONTROL**

Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers. Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination. Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used.

For the purpose of this item, drugs intended for use in dairy calves, dairy heifers, dairy bulls and dry dairy cows shall be segregated from drugs for cows that are currently being milked. This required storage system shall also be followed for drugs intended for use in goats, sheep and other dairy animals.

The only drugs that should be stored with the “Lactating Drugs” are drugs that are specifically indicated on the drug label or on a veterinarian’s label for extra-label drug use to be used in specific class/species of lactating dairy animals. For the purpose of complying with this item “lactating dairy animals” means those dairy animals that are currently producing milk.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 108  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This proposal would allow for approved hand-drying devices as an acceptable alternative to individual sanitary towels at hand-washing facilities on dairy farms, identical to what is currently allowed for hand-washing facilities in milk processing plants.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The PMO states that adequate hand-washing facilities are essential to personal cleanliness and reduce the likelihood of contamination of milk and milk products. This basic public health principle applies throughout the production and handling of milk from the farm to the final product. Item 8p of the PMO describes proper hand-washing facilities in milk plants as including, among other things, individual sanitary towels or other approved hand-drying devices. However, current requirements for hand-washing facilities on dairy farms under Item 16r only allow for individual sanitary towels. Hand-drying devices are not only accepted in milk plants, they are widely recognized in the environmental and public health regulatory communities as an appropriate means of equipping hand-washing stations in food facilities or other locations where hand cleanliness is important. This proposal would amend Item 16r to allow dairy farms to also utilize approved drying devices at hand-washing facilities as an acceptable alternative to individual sanitary towels.

**C. Proposed Solution**

Changes to be made on page(s):		51 and 52	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

**ITEM 16r. PERSONNEL - HANDWASHING FACILITIES**

Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels or other approved hand-drying devices, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when:

1. Handwashing facilities are located convenient to the milkhouse, milking barn, stable, parlor and flush toilet.
2. Handwashing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels or other approved hand-drying devices and a lavatory fixture. Utensil wash and rinse vats shall not be considered as handwashing facilities.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 109  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal provides consistent and uniform wording and sanitary requirements for recirculated cooling water systems, including systems using a freezing point depressant, for use in milk plants and on dairy farms.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Item 18r-Raw Milk Cooling of the PMO does not provide sanitary requirements for recirculated cooling water systems, including systems using a freezing point depressant, for use on dairy farms as is required in Item 17p-Cooling of Milk and Milk Products for use in milk plants. This Proposal adds similar wording and sanitary requirements for recirculated cooling water systems, including systems using a freezing point depressant, as are currently cited in Item 17p-Cooling of Milk and Milk Products of the PMO for use in milk plants to Item 18r-Raw Milk Cooling for use on dairy farms. This Proposal provides consistency and uniformity related to the sanitary requirements of the PMO in relationship to the use of recirculated cooling water systems, including systems using a freezing point depressant, in milk plants and on dairy farms.

**C. Proposed Solution**

Changes to be made on page(s): 53 and 109 of the (X - one of the following):

<input checked="" type="checkbox"/>	2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:***

~~Strike through~~ text to be deleted and underline text to be added.

**ITEM 18r. RAW MILK COOLING**

*Page 53:*

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when: ...

2. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken under the direction of the Regulatory Agency and examination shall be conducted in a laboratory acceptable to the Regulatory Agency. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either U.S. Pharmacopeia (USP) Grade, Food Grade or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

**ITEM 17p. COOLING OF MILK AND MILK PRODUCTS**

**ADMINISTRATIVE PROCEDURES**

This Item is deemed to be satisfied when: ...

*Page 109:*

11. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall

comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either U.S. Pharmacopeia (USP) Grade, Food Grade or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 110  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To allow the cleaning of milk cans and portable storage bins, that do not leave the milk plant, in the same room where pasteurizing, processing, reconstitution, cooling, condensing, drying and packaging of milk and milk products occur.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Item 5p. *Separate Rooms* in Section 7 of the 2011 PMO requires that milk cans, portable storage bins, bottles and cases and milk tank trucks be cleaned in a separate room apart from other milk plant operations. This standard protects public health and prevents potential contamination based on the operational premise that these containers leave the plant and are returned, potentially contaminated, for cleaning. Bringing containers that have left the plant and returning them to areas for cleaning which are also being used for pasteurizing, processing, reconstituting, cooling, condensing, drying and packaging is inherently risk-prone. However in some cases, limited use of milk cans and portable storage bins occurs solely within the milk plant. In these instances, the milk cans and portable storage bins present no greater contamination risk than other product pipes and containers that are commonly cleaned properly in the same room where these other milk production activities occur.

This section is intended to prevent contamination from being introduced into a milk plant when items are returned for cleaning. However this risk is mitigated when items such as milk cans and portable storage bins do not leave the premises and are used solely for milk production operations inside the plant.

**C. Proposed Solution**

Changes to be made on page(s):           p.59           of the (X - one of the following):

<u>  X  </u>	<u>  2011 PMO  </u>	<u>          </u>	<u>  2011 EML  </u>
<u>          </u>	<u>  2011 MMSR  </u>	<u>          </u>	<u>  2400 Forms  </u>
<u>          </u>	<u>  2011 Procedures  </u>	<u>          </u>	<u>  2011 Constitution and Bylaws  </u>

***MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:***

Modify the 2011 PMO, p.58, Section 7, item 5p., sub-item 1., as follows:

This Item is deemed to be satisfied when:

1. Pasteurizing, processing, reconstitution, cooling, condensing, drying and packaging of milk and milk products are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, portable storage bins, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks, provided that these rooms may be separated by solid partitioning doors that are kept closed. Provided further, that cooling, plate or tubular, may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where milk tank trucks are unloaded and/or cleaned and sanitized. For the purposes of this section, only milk cans and portable storage bins that leave and are returned to the milk plant are required to be cleaned in a separate room.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 111  
Committee: Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To extend the cleaning frequency for silo's used for lactose reduced milk and milk products to 96 hours instead of 72 hours.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Some lactose reduced milk and milk products need to set in silo for approximately 72 hours for the enzyme activity to reach completion. This does not include the 6 to 8 hour filling or the 6 to 8 hour emptying time required on larger silos. When the filling time, set time, and emptying time are added together it takes close to 90 hours in most cases from beginning to end of a production run of this type of milk product. This overage of time from the 72 hour standard for raw milk silos causes every lactose reduced silo to go through the extended run proposal process. As with any 72 hour silo, the regulatory agency can evaluate this new time frame on the lactose reduced silos and cite deficiencies and seek corrective action if necessary without going through the extended run approval process.

**C. Proposed Solution**

Changes to be made on page(s):		67 & 68	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Modify the 2011 PMO, page 67, Standards for Grade “A” Raw Milk for Pasteurization, Item 12p., Administrative Procedures, #1

1. All multi-use containers and utensils are thoroughly cleaned after each use and all equipment is thoroughly cleaned at least once each day, unless the Regulatory Agency has reviewed and accepted information, in consultation with FDA, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one (1) day or seventy-two (72) hours in the case of storage tanks, or ninety-six (96) hours in the case of lactose reduction conversion storage tanks, or forty-four (44) hours in the case of evaporators, which are continuously operated.

Modify the 2011 PMO, page 68, Standards for Grade “A” Raw Milk for Pasteurization, Item 12p., Administrative Procedures, #1

1. continued  
 Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours or ninety-six (96) hours in the case of lactose reduced milk storage tanks. Records must be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours or ninety-six (96) hours in the case of lactose reduced storage tanks.

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---

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 112  
Committee: SSCC

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To reduce the frequency of sampling and testing of single service containers in the PMO.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Single service containers are produced in such a manner that it is not possible for bacteria (including coliforms) to survive the production process. From the period of June 1, 2010 through December 31, 2010 there were 1,469 samples collected in a state which included single service containers, closures and paper. During that time 1,469 SPC and 1,468 coliform tests were performed. There were no violative counts for coliform. Of the 45 violative counts for the SPC test none counted against the facility as the containers were sampled in groups and the average count was not in violation.

Therefore we are expending time and effort collecting samples and doing testing that produces few violations when that time and effort could be better spent elsewhere.

**C. Proposed Solution**

Changes to be made on page(s):		Pages 71&318	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Page 71

**Item 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT**

Administrative Procedures 6.  
 c. When single-service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J. and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional testing. If there is reason to believe that containers do not conform to the bacteriological standards, additional testing may be required. If containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J., from each manufacturing line, as defined in Appendix J., in at least ~~four (4)~~ two (2) separate months, except when ~~three (3) months~~ show a one (1) month containing ~~two (2) sampling dates~~ separated by at least twenty (20) days, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under Appendix J.

Page 318

**C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES**

1. Paper stock shall meet the bacteriological standard of not more than two hundred fifty (250) colonies per gram as determined by the disintegration test. The paper stock supplier shall certify that their paper stock was manufactured in compliance with this Standard. This applies only to the paper stock prior to lamination.
2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per 8 square inches (1 per square centimeter) of product-contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.
3. During any consecutive six (6) months, at least four (4) sample sets shall be collected in at least ~~four (4)~~ two (2) separate months, except when ~~three (3) months~~ show a one (1) month containing ~~two (2) sampling dates~~ separated by at least twenty (20) days, and analyzed at an Official, Commercial or Industry Laboratory approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under these Standards. (Refer to Item 12p of this *Ordinance* for sampling of containers and closures in milk plants.)

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 113  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal adds an option to Item 15p (A)-Protection from Contamination, Administrative Procedures 19 of the PMO to allow for other combinations of valve(s) that supply equivalent protection to the sanitary check valve protection currently required in the PMO.

**B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission**

By allowing other equivalent valve arrangements in place of a sanitary check valve, this proposed change would allow plants more flexibility for installing alternative combinations of valves, but ensure that these combinations still provide equivalent protection as to what is currently required in the PMO.

**C. Proposed Solution**

Changes to be made on page(s):	<u>76-77</u>	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

**MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:**

~~Strike through~~ text to be deleted and underline text to be added.

**ITEM 15p. PROTECTION FOM CONTAMINATION**

**ADMINSTRATIVE PROCEDURES**

This Item is deemed to be satisfied when: ...

*Page 76:*

19. Water piping and raw milk and milk product lines and vessels may be separated by one (1) fail-safe valve that upon loss of air or power shall move to a position that will close or block the water lines from milk or milk product lines or vessels. Water piping conducting water, which has undergone an equivalent process to pasteurization as described in Item 15p.(B)2. and pasteurized milk and milk product lines or vessels may also be separated by one (1) fail-safe valve. In addition, a sanitary check-valve or a sanitary valve arrangement(s) that is equally effective shall be located between the fail-safe valve and the milk product line(s) and/or vessel(s). Sanitary piping shall be used downstream from the sanitary check-valve single-bodied double seat valve, that are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. Provisions shall be made for cleaning this sanitary piping.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 114  
Committee: None

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This proposal would clarify that the PMO does not require that pasteurized water be used in the load out lines for bulk tanker shipments of dairy products shipped for further processing.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

When bulk Grade “A” milk and milk products are transported for further processing, these dairy products will be fully pasteurized prior to leaving the next facility, and prior to be made available for sale to the public. This is required by Item 16p. and Item 18p. of the administrative procedures, number 1, pg. 111 of the Pasteurized Milk Ordinance.

Since the dairy products will be pasteurized after passing through load out lines, then there is no negative effect on public health of using potable water in the load out lines. Additionally, the potable water used in the load out lines is required to meet the microbiological criteria and testing requirements of the PMO.

**C. Proposed Solution**

Changes to be made on page(s):		79 and 85	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Make the following edit on page 79 to read:  
 2. Except as permitted in Item 16p, there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized nondairy products not completely separated from pasteurized milk and milk products, shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in Definition HH. Water used to flush load out lines for Grade “A” milk and milk products leading to bulk tankers must meet potable water requirements, but is not required to be pasteurized.]

Change p.85 administrative procedures; #5 to read:  
 5. Potable water may be used to flush load out lines of Grade “A” milk and milk products into bulk tankers as all ~~All condensed~~ Grade “A” milk and milk products transported to a milk plant for ~~drying~~ further processing shall be re-pasteurized at the milk plant where it ~~is dried~~ undergoes final processing.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 115

Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

Eliminate the need for testing the flow rate alarms on HHST pasteurizers where the holding tube is grossly oversized due to being sized for ultra-pasteurization processing. The test procedures for high flow alarm settings and flow rate accuracy are some of the more time consuming tests done on pasteurizers. Eliminating these tests for systems that definitely do not have the capability to exceed the safe flow rate of the holding tube will help maximize the efficiency of the regulatory agency inspection and reduce the amount of time a plant will need to be out of production to perform regulatory testing.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

HHST systems operating at temperatures over 94°C (201°F) require a holding time of only 0.01 seconds to achieve legal pasteurization. A system designed to produce ultra-pasteurized milk products will have a holding time of 2 seconds, 200 times what is required to produce safe pasteurized product, and be operating in excess of 138°C (280°F). In order for the flow rate to exceed the capability of the holding tube, the flow rate would have to increase to over 200 times the rated capacity of the pasteurizer. This is a practical impossibility. Therefore, there is no need to actually establish the flow rate of the system or the settings of the high/low flow alarms by the regulatory tests.

**C. Proposed Solution**

Changes to be made on page(s):	100, 296	of the (X - one of the following):
X	2011 PMO	2011 EML
	2011 MMSR	2400 Forms
	2011 Procedures	2011 Constitution and Bylaws

Page 100

c. **Continuous-Flow Pasteurization Systems with Magnetic Flow Meter Based Timing Systems:** Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in Subitem a. above, except (3), (4), (5), (6), and (7), and in addition, shall include the following:

- (1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
- (2) A continuous record of the flow rate.

**Note:** Recording of the flow alarm set point and flow signal alarm status is not required in the case of HHST pasteurization systems utilizing temperatures and holding times to meet the UP definition of this Ordinance.

Page 296

**TEST 11.**

**CONTINUOUS-FLOW HOLDING TUBES - HOLDING TIME**

**Reference:** Item 16p.(B) and (D)

Continuous-flow holding tubes shall be tested for holding times by one (1) of the following applicable Tests, except that in the case of HHST pasteurization systems utilizing temperatures and holding times to meet the UP definition of this Ordinance, Tests 11.2B, 11.2C, 11.2F, 11.3, 11.4 are not required to be performed:

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# 34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	116
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

## A. Summary of Proposal

This Proposal provides editorial consistency and a technical update of Section 7. Standards for Grade “A” Milk and Milk Products, Item 16p.(D), 2. Equipment Tests and Examinations and Appendix I. Pasteurization Equipment and Controls of the PMO.

This Proposal does not add any new Tests to Appendix I, but provides consistency of language between all of the Tests where appropriate. It also eliminates unwarranted requirements and provides needed flexibility in identified Test procedures.

## B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The intent of the proposed editorial clarifications in this Proposal is to make it easier to understand and/or more convenient to perform the required tests.

## C. Proposed Solution

Changes to be made on page(s):	101, 102 and 277-315	of the (X - one of the following):
X	2011 PMO	2011 EML
	2011 MMSR	2400 Forms
	2011 Procedures	2011 Constitution and Bylaws

**MAKE THE FOLLOWING CHANGES TO THE 2011 PMO.**

Strike through text to be deleted and underline text to be added.

**SECTION 7. STANDARDS FOR GRADE “A” MILK AND MILK PRODUCTS**

**STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS**

**ITEM 16p.(D) PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS**

*Page 101:*

**2. EQUIPMENT TESTS AND EXAMINATIONS:**

The Regulatory Agency shall perform the indicated ~~tests~~ Tests on the following instruments and devices ~~identified in Table 4~~ initially ~~on~~ upon installation; ~~and~~ at least once each three (3) months thereafter, including the remaining days of the month in which the equipment ~~tests~~ Tests are due; ~~and~~ whenever any alteration or replacement is made which may affect the proper operation of the instrument or device; or whenever a regulatory seal has been broken. Provided, that the pasteurization holding time ~~tests~~ Tests shall be conducted at least ~~every~~ once each six (6) months thereafter, including the remaining days of the month in which the equipment ~~check~~ Test is due.

On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met:

a. The individual applying the seal(s) ~~is~~ shall be employed by the milk plant in which the ~~seal~~ seal(s) was removed; ...

d. The individual ~~is~~ shall be in possession of authorization from the Regulatory Agency to perform these pasteurization equipment tests;

e. The individual ~~will~~ shall immediately notify the Regulatory Agency of the time of the shutdown that would necessitate the breaking and removal of the regulatory seal(s). Permission to test and ~~seal~~ reseal the equipment ~~must~~ shall be obtained for each specific incident. The individual ~~will~~ shall also notify the Regulatory Agency of the identity of the pasteurization equipment controls affected, the cause, if known, of the pasteurization equipment failure, the repairs made and the results of the pasteurization equipment testing. Test results for the Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.) The individual ~~will~~ shall provide to the Regulatory Agency the identity and volume of milk and/or milk products processed during the period that the temporary seals were seal(s) was applied ~~to the Regulatory Agency~~;

f. If regulatory ~~tests~~ pasteurization equipment testing reveals that the pasteurization equipment or controls are not in compliance with the provisions of this *Ordinance*, all milk and/or milk products that were processed during ~~that~~ this period may be recalled by the Regulatory Agency;

g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible ~~State~~ Regulatory Agency, of each participating non-U.S. country or political

subdivision thereof, ~~will~~ shall remove the temporary seal(s), retest the pasteurization equipment and apply the regulatory seal(s) within ten (10) working days of the notification by ~~industry~~ the milk plant; and

h. ~~No~~ Grade “A” milk and/or milk products ~~will~~ shall not be processed after ten (10) working days of the notification by the milk plant without the affected pasteurization equipment being tested and sealed by the Regulatory Agency or a properly trained regulatory official, commissioned by the responsible State Regulatory Agency, of each participating non-U.S. country or political subdivision thereof.

*Page 102:*

In the case of milk plants with HACCP Plans regulated under the NCIMS voluntary HACCP Program, pasteurization equipment may be tested and sealed by industry personnel acceptable to the Regulatory Agency, if the following conditions are met:

a. Test results for the Pasteurization Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.)

b. Industry personnel conducting the Pasteurization Equipment Testing ~~must~~ shall be adequately trained and ~~must~~ shall be able to demonstrate an acceptable understanding and ability to conduct these pasteurization equipment tests to the Regulatory Agency.

(1) Industry ~~must~~ shall physically demonstrate to the Regulatory Agency that they understand and can perform the required pasteurization equipment tests according to the requirements of this *Ordinance*.

(2) The Regulatory Agency shall accept a field practical exercise, a written exam, formal classroom training, on-the-job training or any combination of these except that, if industry personnel do not physically demonstrate the appropriate capability to perform the pasteurization equipment tests to the satisfaction of the Regulatory Agency, they are not acceptable for conducting such pasteurization equipment tests.

(3) Continued training such as, but not limited to, on-the-job training with supervision or an acceptable pasteurizer training course ~~should~~ shall be completed before they reapply for pasteurizer equipment testing approval.

c. Pasteurization Equipment Tests shall be conducted at a frequency not less than the requirements of this *Ordinance*. Industry shall have responsibility for the performance of all required pasteurization equipment tests. At least each six (6) months the Regulatory Agency shall physically supervise these pasteurization equipment tests. Regulatory supervised pasteurization equipment tests shall include the semi-annual HTST and HHST pasteurization equipment tests, if applicable. These six (6) month pasteurization equipment tests ~~should~~ shall be performed at a time that is mutually convenient to all parties. Because these pasteurization equipment tests are required to support a CCP, the industry is responsible for conducting these pasteurization equipment tests even in the absence of the regulatory official.

d. Upon initial installation or extensive modification of any pasteurization equipment, pasteurization equipment tests shall be physically supervised or conducted by the Regulatory Agency.

e. Sealing guidance for pasteurization equipment by industry is as follows:

(1) All pasteurization equipment that is required to be sealed within this *Ordinance* shall also be sealed under the HACCP System. The sealing shall be done by a trained, qualified individual who is acceptable to the milk plant and the Regulatory Agency; and

(2) The Regulatory Agency may verify any pasteurization equipment sealing and evaluate (accept or reject) the skills and knowledge of the individual performing the sealing.

f. During an audit, the auditor may conduct any or all of the Pasteurization Equipment Tests. The auditor ~~should~~ shall, through a combination of the physical examination of the pasteurization equipment and a records review, satisfy themselves that the pasteurization equipment is properly installed and operated.

## **APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS**

### **I. TESTING APPARATUS SPECIFICATIONS**

#### **TEST THERMOMETER ...**

*Pages 277-315:*

#### **TIME MEASURING DEVICE**

An Accurate Time Measuring Device may include but is not limited to a stopwatch, digital watch, conductivity device timer and any other device which keeps time accurately.

#### **STOPWATCH**

**Type:** Open face, indicating fractional seconds.

**Accuracy:** Accurate to 0.2 of a second.

**Hands:** Sweep hand, if applicable, one complete turn every sixty (60) seconds or less.

**Scale:** Divisions of not over 0.2 of a second.

**Crown:** Depression of crown or push button starts, stops and resets to zero.

### **II. TEST PROCEDURES**

Equipment and field Pasteurization equipment Tests to listed and referenced below shall be performed by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, as cited in Item 16p.(D); or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, as cited in Item 16p.(D) are listed and suitably referenced below. The results of the Tests shall be recorded on suitable appropriate forms and filed, as the Regulatory Agency shall direct. (Refer to Appendix M.) Regulatory seals shall be installed where required at the commissioning of a new pasteurization system. If the public health control(s) is within a computer system used to manage the functions of the public health control device(s) that operate the pasteurization system, the computer shall be in compliance with Appendix H. VI before the access to the computer program is sealed. Whenever a regulatory seal has been broken, the pasteurization equipment shall be re-sealed after the appropriate testing has been conducted by the Regulatory Agency or qualified industry personnel in compliance with Item 16p.D and are found to be in compliance with the applicable Test procedure(s).

**NOTE:** If the pasteurization system fails one (1) or more of the required Tests, the

pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

If it is required to break a regulatory seal to conduct any of the following Tests, it shall be replaced by the Regulatory Agency or HACCP qualified personnel acceptable to the Regulatory Agency, after testing has been completed and compliance has been verified.

**NOTE:** For various pieces of equipment approved for pasteurization systems, Testing Procedures which have been reviewed specifically for that equipment are included within the FDA accepted operations manual for the equipment and/or within the Memorandum of Milk Ordinance Equipment Compliance (M-b) issued upon FDA's review and acceptance of the equipment. These Testing Procedures shall be used.

## **TEST 1.**

### **INDICATING THERMOMETERS - TEMPERATURE ACCURACY**

**Reference:** Item 16p.(A), (B) and (D)

**Application:** To all indicating thermometers, including airspace thermometers, if applicable, used for the measurement of milk and/or milk product temperature during pasteurization and/or ultra-pasteurization, including airspace thermometers. Do not run this Test if the liquid column has been split or the capillary tube is broken.

**Frequency:** Upon installation; at least once each three (3) months thereafter; whenever the thermometer has been repaired and/or replaced; or whenever the regulatory seal on a digital sensor sensing element or a digital control box has been broken.

**Criteria:** Within  $\pm 0.25^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{F}$ ) for pasteurization and ultra-pasteurization indicating thermometers and  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ) for airspace thermometers, in a specified scale range. Provided, that on a batch ~~pasteurizers~~ pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ), the indicating thermometers thermometer shall be accurate to within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ).

**Apparatus:**

1. Test thermometer meeting the specifications cited in Section I of this Appendix;
2. Water, oil or other suitable media bath and agitator; and
3. Suitable means of heating the media bath.

**Method:** Both the indicating and/or airspace thermometer, if applicable, and test thermometers thermometer shall be exposed to water, oil or other suitable media of a uniform temperature. The ~~Indicating~~ indicating thermometer and/or airspace thermometer, if applicable, reading is compared to the reading of the test thermometer.

**Procedure:**

1. Prepare a ~~quantity of water, oil or other suitable media in a bath,~~ by raising the temperature of the media to within  $2^{\circ}\text{C}$  ( $3^{\circ}\text{F}$ ) of the appropriate lowest sealed cut-out pasteurization or ultra-pasteurization temperature, or minimum legal indicating or airspace temperature for batch pasteurization.
2. Stabilize the media bath temperature and agitate rapidly.
3. Continue agitation and insert the indicating and/or airspace thermometer, if applicable, and test thermometers thermometer to the indicated immersion point.

4. Compare ~~both~~ the thermometer readings at ~~the~~ a temperature within the test range.
  5. Repeat the comparison of the thermometer readings.
  6. If the results of this Test are outside the **Criteria** noted above, the indicating thermometer or airspace thermometer, if applicable, shall be adjusted by milk plant personnel to agree with the test thermometer, retest and record the action taken on the appropriate Form.
  - ~~67.~~ When compliance is achieved and/or verified, ~~Reeord~~ record the thermometer readings, from both comparisons and record the thermometer identification or location on the appropriate Form.
  - ~~78.~~ Install **Re-seal** seals as appropriate on the sensors sensing elements and control boxes of the digital thermometers.
- Corrective Action:** ~~Do not run the Test if the mercury column has been split or capillary tube is broken. The thermometer should be returned to the factory for repair. When the indicating thermometer differs from the test thermometer by more than 0.25°C (0.5°F) and the airspace thermometer by more than 0.5°C (1°F), the indicating thermometer should be adjusted to agree with the test thermometer. Retest the thermometer after adjustment. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.~~

## TEST 2.

### TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - TEMPERATURE ACCURACY

**Reference:** Item 16p.(A), (B) and (D)

**Application:** To all ~~mercury-actuated~~ temperature recording and recorder-controller thermometers ~~controllers~~ used to record milk and/or milk product temperatures during pasteurization and/or ultra-pasteurization except those which are electronic or computer controlled.

**Frequency:** Upon installation; at least once each three (3) months thereafter; ~~whenever the recording pen arm setting requires frequent adjustment;~~ when the sensing element has been repaired and/or replaced; or ~~when~~ whenever a the regulatory seal has been broken.

**Criteria:** Within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ), in a specified scale range as described in **Procedure 1** below. Provided, that on a batch ~~pasteurizers~~ pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ), the temperature recording ~~thermometers~~ thermometer shall be accurate to within  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ), between  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ) and  $77^{\circ}\text{C}$  ( $170^{\circ}\text{F}$ ).

**Apparatus:**

1. The indicating thermometer, which was previously tested against a known accurate test thermometer;
2. Water, oil or other suitable media bath and agitator;
3. Suitable means of heating the media bath; and
4. Ice.

**NOTE:** When this Test is performed on ~~mercury-actuated~~ temperature recorder-controllers

used with HHST pasteurization systems that operate at or above the boiling point of water, an oil or other suitable media bath shall be substituted for the processing (operating) temperature water mentioned in **Procedures** 1, 4, 5, 6, and 7 as well as the boiling water mentioned in **Procedures** 2, 3 and 5. The temperature of the oil bath that is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

**Method:** The testing of a ~~mercury-actuated~~ temperature recording or recorder-controller thermometer for temperature accuracy involves the determination of whether or not the temperature pen-arm will return to within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ); or  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) as provided for in the **Criteria** above, of its previous setting, after exposure to high heat and melting ice.

**Procedure:**

1. Heat a media bath to a constant temperature, utilizing one (1) of the following temperatures:

- a. Lowest sealed cut-out pasteurization temperature; or
- b. Minimum legal indicating or airspace pasteurization temperature for batch pasteurization.

Provided, that on a batch pasteurizer used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ), this test shall be conducted with a media bath temperature above  $71^{\circ}\text{C}$  ( $160^{\circ}\text{F}$ ) and below  $77^{\circ}\text{C}$  ( $170^{\circ}\text{F}$ ).

Immerse the temperature recording or recorder-controller thermometer sensing element into the media bath. After a stabilization period of five (5) minutes, Adjust if necessary, adjust the temperature recording or recorder-controller thermometer pen to read exactly as the previously tested indicating thermometer, in the temperature range for the process being used, after a stabilization period of five (5) minutes, at a constant temperature. The media bath shall be rapidly agitated throughout the this stabilization period.

2. Prepare a second media bath by heating the media bath to the boiling point of water, or in the case of HHST pasteurization systems, to a temperature above the normal operating range but below the highest temperature division on the chart, and maintain temperature. Prepare a third ~~container~~ media bath with melting ice and water. Place all media baths within working distance of the temperature recording or recorder-controller thermometer temperature-sensing element(s).

3. Immerse the temperature recording or recorder-controller thermometer sensing element into the ~~boiling water, or in the case of HHST pasteurization systems into the~~ hot media bath described as prepared in Procedure 2, above, for not less than five (5) minutes.

4. Remove the temperature recording or recorder-controller thermometer sensing element from the ~~boiling water or other hot~~ media bath and immerse it in the media bath as prepared in Procedure 1 above, at a temperature within the temperature range for the process being used. Allow a five (5) minute stabilization period for both the indicating and temperature recording or recorder-controller thermometers. Compare the readings of the indicating and temperature recording or recorder-controller thermometers. The temperature recording or recorder-controller thermometer reading ~~should~~ shall be within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ) or  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) as provided for in the **Criteria** above, of the indicating thermometer reading.

5. Remove the temperature recording or recorder-controller thermometer sensing element from the media bath in the temperature range for the process being used, and immerse it in the melting ice and water bath for not less than five (5) minutes.

6. Remove the temperature recording or recorder-controller thermometer sensing element from the ice and water bath and immerse it in the a media bath as prepared in Procedure 1, above, at a temperature, range for the process being used. Allow a five (5) minute stabilization

period for both the indicating and temperature recording or recorder-controller thermometers. Compare the readings of the indicating and temperature recording or recorder-controller thermometers. The temperature recording or recorder-controller thermometer reading ~~should~~ shall be within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ), or  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) as provided for in the Criteria above, of the indicating thermometer reading.

7. When compliance is achieved and/or verified, Re-seal re-seal the regulatory controls thermometer sensing elements and recorder-controller as necessary and record the indicating and temperature recording thermometer or recorder-controller thermometer readings obtained from Procedures 1, 4, and 6 above on the appropriate Form.

**Corrective Action:** If the temperature recording or recorder-controller thermometer pen does not return to  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ); or  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) as provided ~~above, of indicating thermometer reading at in Procedures 4 and 6 above,~~ the temperature recording or recorder-controller thermometer shall be repaired or replaced by milk plant personnel as necessary. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### TEST 3.

#### TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - TIME ACCURACY

**Reference:** Item 16p.(A), (B) and (D)

**Application:** To all temperature recording and recorder-controller thermometers used to record the time of pasteurization and/or ultra-pasteurization.

**Frequency:** Upon installation; at least once each three (3) months thereafter; whenever the temperature recorder-controller thermometer or programmable recording thermometer has been repaired and/or replaced; or whenever the regulatory seal of on a programmable temperature recorder-controller thermometer or programmable recording thermometer or sensing element has been broken.

**Criteria:** The recorded time of pasteurization or ultra-pasteurization shall not exceed the true elapsed time.

**Apparatus:** An accurate time measuring device.

1. ~~A watch, graduated at intervals not to exceed one (1) minute, and accurate to within five (5) minutes in twenty-four (24) hours; and~~

2. ~~A pair of dividers or any other suitable device for measuring short distances.~~

**Method:** A Comparison comparison of the recorded time over a period of not less than thirty (30) minutes with a watch of known accuracy an accurate time measuring device. For recorders utilizing electric clocks, check the cycle on the faceplate of the clock with a known cycle and observe that the clock is in operating condition.

**Procedure:**

1. Determine if the recording chart is appropriate for the temperature recording or recorder-controller thermometer. Insure that the recording chart pen is aligned with the time arc of the recording chart at both the center and the outside edge.

2. Inscribe a reference mark at the pen point on the recording chart and record the time.

3. At the end of thirty (30) minutes ~~by utilizing the watch~~ an accurate time measuring device, inscribe a second reference mark at the pen point position on the recording chart.
4. Determine the distance between the two (2) reference marks and compare the distance with the time-scale divisions on the recording chart at the same temperature.
5. ~~For electric clocks, remove the faceplate and compare the cycle specification on the faceplate with the current cycle utilized.~~
6. Re-seal the regulatory controls sensing elements and recorder-controller as necessary; enter the findings results on the recording chart and initial the recording chart; and record the results beginning and ending times on the appropriate Form.

**Corrective Action:** If the recorded time is incorrect, the ~~clock~~ temperature recording or recorder-controller thermometer device ~~should~~ shall be adjusted or repaired by milk plant personnel. If the pasteurization or ultra-pasteurization system fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

#### TEST 4.

### TEMPERATURE RECORDING AND RECORDER-CONTROLLER THERMOMETERS - ~~CHECK~~ CHECKED AGAINST INDICATING THERMOMETERS THERMOMETER

**Reference:** Item 16p.(A), (B) and (D)

**Application:** To all temperature recording and recorder-controller thermometers used to record milk and/or milk product temperatures during pasteurization or ultra-pasteurization, and for batch pasteurizer digital combination airspace/recording thermometers with a continuous recording of the airspace temperature and where the airspace temperature is read and recorded on the recording chart only at the start of the pasteurization or ultra-pasteurization holding period.

**Frequency:** Upon installation; ~~and~~ at least once each three (3) months thereafter ~~by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(D)2;~~ whenever the temperature recording or recorder-controller thermometer has been repaired and/or replaced; whenever the regulatory seal is has been broken; and daily; and immediately after a recording chart has been changed by the a milk plant plant's HTST and/or HHST pasteurization system operator ~~personnel for the HTST and HHST pasteurization systems.~~

**Criteria:** The temperature recording thermometer and recorder-controller thermometer shall not read higher than the indicating or airspace thermometer, which were previously tested against a known accurate test thermometer.

**Apparatus:** No supplementary materials required.

**Method:** This Test requires only that the reading of the temperature recording thermometer, recorder-controller thermometer or airspace recording thermometer be compared with the indicating thermometer at a time when both are exposed to a stabilized temperature at or above the minimum legal pasteurization temperature.

**Procedure:**

1. ~~While~~ When the indicating and temperature recording or recorder-controller thermometer

~~temperatures~~ temperature readings are stabilized at or above the minimum legal pasteurization temperature, read the indicating thermometer.

2. For batch pasteurizers, ~~while~~ when the airspace indicating and recording ~~temperatures~~ temperature readings are stabilized at or above the minimum legal pasteurization temperature, read the airspace thermometer.

3. Immediately ~~record~~ enter the results; the time at which this comparison was made; and identify on initial the recording ~~thermometer~~ chart, ~~the observed indicating and/or airspace thermometer temperature reading and the time at which this comparison was made.~~ This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other methods method acceptable to the Regulatory Agency.

4. Record the observed indicating and temperature recording thermometer or recorder-controller thermometer readings on the appropriate Form.

~~**NOTE:** This Test shall be performed while the pasteurization operating temperatures are within the accurate range for the specific thermometers and charts used.~~

**Corrective Action:** If the ~~mercury-actuated~~ temperature recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by ~~the milk plant operator~~ personnel to agree with the indicating thermometer.

~~If the digital recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the recording temperature should be adjusted to agree with the indicating thermometer. Retest the thermometer after adjustment. If after adjustment the temperature recording thermometer or recorder-controller thermometer fails this Test, the pasteurization or ultra-pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.~~

## TEST 5.

### FDD - PROPER ASSEMBLY AND FUNCTION

**Reference:** Item 16p.(B) and (D)

**Application:** ~~Parts 1 5.1 to 4 5.4 and 6 5.6 to 8 5.8 below~~ apply to all FDDs used with continuous-flow ~~pasteurizers~~ pasteurization systems. ~~Parts 5 5.5 and 9 5.9 below~~ apply only to FDDs used with HTST ~~pasteurizers~~ pasteurization systems.

**Frequency:** Upon installation; at least once each three (3) months thereafter; whenever the FDD has been repaired and/or replaced; or when whenever a the regulatory seal(s) has been broken.

**Criteria:** The FDD shall function ~~correctly~~ as required in all operating situations and shall de-energize the timing pump and all other flow-promoting devices capable of causing flow through the FDD, in the event of a FDD malfunction or incorrect assembly when the FDD is incorrectly assembled.

#### 5.1 LEAKAGE PAST THE VALVE SEAT(S)

**Apparatus:** Suitable tools for the disassembly of the FDD and ~~the~~ any connected sanitary piping.

**Method:** Observe the valve seat(s) ~~of the FDD~~ for leakage.

**Procedure:**

1. With the pasteurization system operating on water, place the FDD in the diverted-flow position.

2a. For single stem FDDs, disconnect the forward-flow sanitary piping and observe the valve seat for leakage. Check the leak escape ports to see if they are open; or

3b. For dual stem FDDs, observe the leak-detect line discharge or sight glass for leakage.

2. Record the results of the Test on the appropriate Form.

**Corrective Action:** If leakage is ~~noted~~ observed, the FDD must be dismantled and defective gaskets replaced or other suitable repairs shall be made to the FDD by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 5.2 OPERATION OF THE VALVE STEM(S)

**Apparatus:** Suitable tools for tightening the packing nut on the valve stem(s) of a single stem FDD.

**Method:** Observe the ~~FDD~~ valve stem(s) for ease of movement.

**Procedure:**

1. For single stem FDDs, ~~When a stem packing nut is used,~~ tighten the valve stem packing nut ~~it~~ as much as possible. Operate the pasteurization system at maximum ~~normal~~ operating pressure and place the FDD in both forward and diverted-flow several times. The valve stem shall move freely in both forward and diverted-flow positions when the stem-packing nut is fully tightened. Note the freedom of action of the valve stem.

2. For dual stem FDDs, operate the pasteurization system at maximum operating pressure and place the FDD in both forward and diverted-flow several times. The valve stems shall move freely in both forward and diverted-flow positions. Note the freedom of action of the valve stems.

3. Record the results of the Test on the appropriate Form.

**Corrective Action:** If the valve stem(s) action is sluggish, suitable adjustment or repair shall be made by milk plant personnel. ~~The stem shall move freely in all positions, when the stem-packing nut is fully tightened.~~ If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 5.3 DEVICE ASSEMBLY - SINGLE STEM ~~DEVICE~~ FDD

**Apparatus:** ~~Sanitary fitting wrench~~ Suitable tools for the disassembly of the FDD and the any

connected sanitary piping.

**Method:** When the FDD is improperly assembled and in diverted-flow, (below the cut-out temperature), observe the function of the timing pump and all other flow-promoting devices capable of causing flow through the FDD.

**Procedure:**

1. With the pasteurization system in operation, in "Process" mode, and below the cut-in temperature, unscrew by one-half (1/2) turn, the 13H hex nut that holds the top of the valve to the valve body. This ~~should~~ shall de-energize the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD. In addition, separators and/or downstream vacuum sources shall be effectively valved-out of the pasteurization system. This Test shall be conducted without any sanitary piping connected to the forward-flow port of the FDD. (This allows for the movement of the top of the valve when the hex nut is loosened.) Re-tighten the 13H hex nut.

2. With the pasteurization system in operation, in "Process" mode, and below the cut-in temperature, remove the connecting key, which is located at the base of the valve stem. The timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, ~~should~~ shall be de-energized. In addition, separators and/or downstream vacuum sources shall be effectively valved-out of the pasteurization system.

3. Attempt to restart ~~the timing pump and~~ each flow-promoting device capable of causing flow through the FDD. None of these flow-promoting devices ~~should~~ shall start or operate. Separators and/or downstream vacuum sources shall remain effectively valved-out of the pasteurization system

4. Record the results of the Test on the appropriate Form.

**Corrective Action:** If any flow-promoting device fails to respond as indicated above, an immediate check of the device FDD assembly and wiring is required by milk plant personnel to locate and correct the cause of the failure. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

#### 5.4 DEVICE ASSEMBLY - DUAL STEM ~~DEVICE~~ FDD

**NOTE:** The Test procedure presented in this Section is typical of Tests accepted by FDA for various specific types of FDDs. Testing details, which may vary, are provided in individual FDD operator's manuals that have been reviewed by FDA and are specified by part number in FDA's Coded Memoranda (M-b's). In each of these ~~FDA~~ M-b accepted Test methods, if the words "metering pump" or "timing pump" are used they shall be understood to mean "timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD".

**Apparatus:** ~~None~~ No supplementary materials required.

**Method:** Observe the function of the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD when the FDD is improperly assembled.

**Procedure:**

1. With the FDD in diverted-flow, caused by temperature, and the FDD is properly

assembled, move the FDD to the forward-flow position by moving the switch to the “Inspect” mode and disconnect the valve stem from the actuator of the valve being tested.

2. Move the FDD to the diverted-flow position by moving the switch to the “Product” mode and turn on the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD. The timing pump and all other flow-promoting devices ~~must~~ shall be de-energized and ~~must~~ shall not run. If any ~~pump~~ flow-promoting device, which is capable of causing flow through the FDD, starts momentarily and then stops running, it may indicate the improper wiring of the one (1) second time delay as allowed for in 16p(B)2.b.(10). In addition, ~~Separators~~ separators and/or downstream vacuum sources ~~must be~~ shall remain effectively valved-out of the pasteurization system. Move the switch to the “Inspect” mode and properly Reassemble reassemble the FDD by moving it to the forward flow position and reconnecting the stem to the actuator. Start the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, to determine if the FDD has been properly reassembled.

3. Repeat ~~the this procedure~~ **Procedure** for the other actuator.

5. Record the results of the Test on the appropriate Form.

**Corrective Action:** If any of the flow-promoting devices, which are capable of causing flow through the FDD, fail to respond as indicated, an immediate check of the FDD assembly and wiring is required shall be conducted by milk plant personnel to locate and correct the cause problem. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 5.5 MANUAL DIVERSION

(Booster pump installed in the HTST system)

**Apparatus:** ~~None~~ No supplementary materials required.

**Method:** Observe that the appropriate responses in Procedures 1 and 2, as required below, have occurred the response of the system to during the activation and deactivation of manual diversion.

**Procedure:**

1. With the HTST pasteurization system in operation and the FDD in the forward-flow position, ~~press~~ activate the manual diversion divert control button. This should:

- a. ~~Cause the~~ The FDD to shall assume the divert diverted-flow position;
- b. ~~De-energize the booster pump;~~ Any flow-promoting device downstream from the FDD, which is capable of causing flow through the FDD, shall be de-energized; and
- c. Any separator and/or downstream vacuum sources source downstream from the FDD must shall be effectively valved out; and.
- d. ~~The pressure differential between raw and pasteurized milk or milk product in the regenerator should be maintained.~~

2. ~~Operate the HTST system in forward flow and activate the manual divert button until the raw pressure reaches zero (0) psi. Deactivate the manual divert button and observe the raw milk or milk product and pasteurized milk or milk product pressures. The pressure differential between raw and pasteurized milk or milk product in the regenerator should be maintained.~~

If a booster pump is installed in the HTST pasteurization system and the pasteurization system

is in operation with the FDD in the forward-flow position:

a. Activate the manual divert control. The booster pump shall be de-energized. The required minimum pressure differential of at least 6.9 kPa (1 psi) between raw milk and/or milk product and pasteurized milk and/or milk product in the regenerator shall be maintained.

b. After the raw pressure reaches zero (0) psi, deactivate the manual divert control and observe that the required minimum pressure differential of at least 6.9 kPa (1 psi) between raw milk and/or milk product and pasteurized milk and/or milk product in the regenerator has been maintained.

3. ~~Re-seal the regulatory controls as necessary.~~ Record the results of the Test on the appropriate Form.

**Corrective Action:** If the above described required actions do not occur, or the ~~necessary~~ required pressure differential between raw and pasteurized milk and/or milk product is not maintained, ~~the assembly and wiring of the HTST pasteurization system must shall~~ be immediately reviewed and evaluated by milk plant personnel and the indicated deficiencies corrected or proper adjustments made. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 5.6 RESPONSE TIME

### Apparatus:

1. Water, oil or other suitable media bath and agitator;
2. Suitable means of heating the media bath; and
3. ~~Stopwatch~~ An accurate time measuring device.

**Method:** Determine that the elapsed time does not exceed one (1) second between the instant of the activation of the FDD control mechanism at cut-out temperature<sub>2</sub> on declining temperature<sub>2</sub>, and the instant the FDD takes the fully diverted-flow position.

### Procedure:

1. With the water, oil or suitable media bath at a temperature above cut-out temperature, allow the water, oil or other suitable media to cool gradually. The moment the cut-out mechanism is activated, start the ~~watch~~ accurate time measuring device. The moment the FDD takes the fully-diverted position, stop the ~~watch~~ accurate time measuring device.
2. ~~Re-seal the regulatory controls as necessary and record~~ Record the results of the Test on the appropriate Form.

**Corrective Action:** If the response time exceeds one (1) second, immediate ~~corrective~~ action must shall be taken by milk plant personnel to correct this FDD deficiency. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 5.7 TIME DELAY INTERLOCK WITH TIMING PUMP AND OTHER FLOW

## PROMOTING DEVICES

**Application:** To all dual stem FDDs with a manual forward-flow control switch.

**Apparatus:** ~~None~~ No supplementary materials required.

**Method:** Determine that the ~~device~~ FDD does not assume a manually induced forward-flow position, while the timing pump or any other flow-promoting device, which is capable of causing flow through the FDD, is operating.

**Procedure:** With the pasteurization system operating in forward-flow, move the control switch to the "Inspect" position and observe that the following events automatically occur in sequence:

1. The FDD immediately moves to the diverted-flow position and the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, are de-energized, or in the case of separators and/or downstream vacuum sources, are effectively valved-out of the pasteurization system.

2. The FDD remains in the diverted-flow position ~~while~~ until the timing pump and all other flow-promoting devices, which are capable of causing flow through the FDD, ~~are running down~~ have completely stopped running or in the case of a separator and/or downstream vacuum sources, are effectively valving ~~valving~~ valved out of the pasteurization system.

3. ~~Then~~ The ~~the~~ FDD may assume the forward-flow position ~~only after the timing pump stops turning, and all other flow-promoting devices, which are capable of causing flow through the FDD have also stopped, or in the case of separators or downstream vacuum sources, have been effectively valved out of the system.~~

4. ~~Repeat the above procedure by moving the control switch to the "Cleaned in Place" (CIP) position.~~

5 4. Record the ~~Test~~ results of the Test on the appropriate Form and seal the control enclosure.

**Corrective Action:** If the above sequence of events do not occur, either a timer adjustment or wiring change is required to be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **5.8 CIP TIME DELAY RELAY**

**Application:** To all continuous-flow ~~pasteurizer~~ pasteurization systems in which it is desired to run ~~the timing pump and/or other~~ any flow-promoting devices during the CIP cycle ~~without the controls required during product processing.~~

**Criteria:** When the mode switch on the FDD is moved from "Process" to "CIP", the FDD shall move immediately to the ~~diverted~~ diverted-flow position. It shall remain in the ~~diverted~~ diverted-flow position for at least ten (10) minutes, with all public health controls required in the "Process" mode functioning, before starting its normal cycling in the "CIP" mode. In HTST pasteurization systems, the booster pump shall be de-energized, and separators and/or downstream vacuum sources, shall be effectively valved-out of the pasteurization system during the required ten (10) minute time delay.

**Apparatus:** ~~Stopwatch~~ An accurate time measuring device.

**Method:** Determine that the set point on the "CIP" time delay relay is equal to or greater than

the required ten (10) minutes by observing the time when the FDD moves to the forward-flow position or is again capable of moving to the forward-flow position.

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system in forward-flow, with the mode switch on the FDD controls in the “Process” position, using water above the minimum legal pasteurization temperature. For magnetic flow meter based timing systems, operate the system, at a flow-rate below the ~~Flow Alarm~~ flow alarm set point and above the low-flow or Loss of Signal Alarm ~~loss-of-signal alarm~~ set point.

**NOTE:** The appropriate temperature sensing elements may be placed in a water, ~~or~~ oil or other suitable media bath to simulate the normal pasteurization temperature ~~of~~ within the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature.

2. Move the mode switch on the FDD control to the “CIP” position. The FDD ~~should~~ shall move immediately to the ~~diverted~~ diverted-flow position. Start the ~~stopwatch~~ accurate time measuring device when the FDD moves to the ~~diverted~~ diverted-flow position. ~~Check~~ Confirm that all public health controls required in diverted flow in the “Process” mode are functioning ~~controls that are required to be in operation when the system is in the “Process” mode and in diverted-flow.~~ For example, in HTST systems, the booster pump must stop running. Separators located between regenerator sections or on the pasteurized side of the system must be effectively valved out and stuffer pumps for such separators must be de-energized. Any downstream vacuum source must be effectively valved out.

3. Stop the ~~stopwatch~~ accurate time measuring device when the ~~CIP timer times out~~ FDD moves to the forward-flow position or is again capable of moving to the forward-flow position. ~~On most systems this is when the FDD moves to the forward position for its initial cycle in the “CIP” mode.~~ At this time, the pasteurization system may be operated without the FDD controls normally required during the “Process” mode during product processing. ~~For example, the booster pump may start at this time.~~

4. Record the results of the Test on the appropriate Form.

5. ~~Install and seal~~ Re-seal the regulatory enclosure over the time delay ~~relay~~.

**Corrective Action:** If the FDD does not remain in the ~~diverted~~ diverted-flow position for at least the required ten (10) minutes after the FDD mode switch is moved from “Process” to “CIP”, increase the set point on the time delay ~~relay~~ and repeat this Test ~~procedure~~ Procedure. All public health controls required when the pasteurization system is in “Process” mode and in diverted-flow ~~must~~ shall be functional during ~~these~~ this required ten (10) minutes. ~~If any of the public health controls are not functional during these ten (10) minutes, adjustments or repairs are needed. In HTST systems, if the booster pump runs at any time during the ten (10) minute delay, the booster pump wiring is in need of repair. If the above does not occur, either a timer adjustment or wiring change is required to be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.~~

## 5.9 LEAK-DETECT VALVE FLUSH - TIME DELAY

**Application:** ~~The minimum one (1) second delay applies to~~ To HTST continuous-flow pasteurizers pasteurization systems in which the space between the divert and leak-detect valve valves is not self-draining when the FDD is in the diverted-flow position.

~~The maximum of five (5) seconds for this delay is not applicable if:~~

- ~~1. The minimum acceptable holding time in diverted-flow can be achieved without the use of a restriction in the divert line; or~~
- ~~2. The timing system is magnetic flow meter based.~~

**Criteria:** The space between the divert and leak-detect valve valves will shall be flushed for at least one (1) second and not more than five (5) seconds after the divert valve moves to the forward-flow position and before the leak-detect valve moves to the forward ~~forward~~ forward-flow position.

The maximum of five (5) seconds delay is not applicable if:

1. The minimum acceptable pasteurization holding time in diverted-flow can be achieved without the use of any restriction in the divert line; or
2. The timing system is magnetic flow meter based.

**Apparatus:** ~~Stop watch~~ An accurate time measuring device.

**Method:** Observe the movement of the divert and leak-detect valves to the forward-flow position and measure the time interval between the movement of the two (2) valves.

**Procedure:**

1. Move the FDD from the diverted-flow position to the forward-flow position either by:
  - a. Raising the temperature above the cut-in set point; or

**NOTE:** The appropriate temperature sensing elements may be placed in a water, oil or other suitable media bath to simulate the normal pasteurization temperature within the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature.

- b. Operating the HTST ~~pasteurizer~~ pasteurization system above the cut-in temperature in manual divert mode and then ~~releasing~~ deactivate the manual divert control.
2. When the divert valve begins to move to the forward-flow position, start the ~~watch~~ accurate time measuring device.
3. When the ~~detect~~ leak-detect valve begins to move to the forward-flow position, stop the ~~watch~~ accurate time measuring device.
4. Record the elapsed time on the appropriate Form.
5. If the elapsed time is at or above one (1) second and at or below five (5) seconds, except as noted in the exceptions in the **Criteria** above, seal the time delay as required.

**Corrective Action:** If the elapsed time is less than one (1) second or greater than five (5) seconds, except as noted in the exceptions in the **Criteria** above, appropriate changes to the pasteurization system or pasteurization system's FDD controls ~~must~~ shall be made by milk plant personnel. If after adjustment and/or repair the FDD fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 6.

## **BATCH (VAT) PASTEURIZER LEAK-PROTECTOR OUTLET VALVE**

**Reference:** Item 16p.(A) and (D)

**Application:** To all batch (vat) ~~pasteurizer~~ pasteurizers that have an outlet valves valve.

**Frequency:** Upon installation; and at least once each three (3) months thereafter.

**Criteria:** No leakage of ~~milk or milk product~~ past the outlet valve seat in any the closed position.

**Apparatus:** No supplementary materials required.

**Method:** By observing whether or not leakage past the outlet valve seat occurs when pressure is exerted against the upstream face of the outlet valve.

**Procedure:**

1. Utilizing milk, ~~or~~ milk products or water, fill the batch (vat) pasteurizer to the normal operation level ~~so that pressure is exerted against the closed outlet valve.~~

**NOTE:** ~~Care must be taken to avoid contamination of the outlet valve.~~

2. Observe the outlet valve in the closed position and determine whether or not ~~any~~ milk, ~~or~~ milk product or water is leaking past the outlet valve seat into the valve outlet.

3. ~~Turn the outlet valve to the just-closed position, and examine for any leakage into the valve outlet.~~ Record the results of the Test on the appropriate Form.

4. ~~Record the identity of the outlet valve and findings for the office record.~~

**Corrective Action:** If leakage past the outlet valve seat ~~should occur~~ occurs in any the closed position, the outlet valve plug ~~should~~ shall be ~~re-ground, gaskets replaced, repaired~~ or any other necessary steps shall be taken to prevent leakage replaced by milk plant personnel. If the outlet valve fails this Test, the batch (vat) pasteurizer shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## **TEST 7.**

### **INDICATING THERMOMETERS LOCATED ON WITHIN HTST PASTEURIZATION SYSTEMS PIPELINES - THERMOMETRIC RESPONSE**

**Reference:** Item 16p.(B) and (D)

**Application:** To all ~~continuous-flow pasteurizers~~ HTST pasteurization systems, except for those in which the FDD is located downstream of the pasteurized regenerator section(s) and/or the final cooler section.

**Frequency:** Upon installation; once each three (3) months thereafter; whenever the indicating thermometer has been repaired and/or replaced; and or whenever the regulatory seal on a digital thermometer sensing element or digital control box has been broken.

**Criteria:** Four (4) seconds or less ~~under specified conditions.~~

**Apparatus:**

1. ~~Stopwatch~~ Accurate time measuring device;

2. The indicating thermometer, which was previously tested against a known accurate test thermometer;

3. Water, oil or other suitable media bath and agitator; ~~and~~

4. Suitable means of heating the water media bath; and
5. Ice and water media bath

**Method:** ~~By~~ The measuring of the time required for the reading of the indicating thermometer being tested to increase 7°C (12°F) through a specified temperature range. This temperature range must shall include the minimum legal pasteurization temperature temperature(s). ~~The temperature used in the water bath will depend upon the scale range of the thermometer to be tested.~~ If there are multiple cut-in temperatures and one (1) or more are separated by more than 7°C (12°F), this Test shall also be conducted for any cut-in temperature(s) not included within the initial 7°C (12°F) range as addressed in Procedure 1 below.

**Procedure:**

1. Immerse the indicating thermometer in the water media bath, which has been heated to a temperature at least 11°C (19°F) higher than the minimum scale reading on the indicating thermometer. The media bath temperature should shall be 4°C (7°F) higher than the ~~maximum required~~ highest pasteurization temperature set point (cut-in temperature) for which the indicating thermometer is being used.
2. Immerse the indicating thermometer in ~~a bucket of an ice cold~~ an ice cold and water media bath for several seconds to cool it.

**NOTE:** Continuous agitation of the ~~water baths~~ heated media bath during the performance of **Procedures** 3, 4 and 5 is required. The elapsed time between the end of **Procedure** 1 and the beginning of **Procedure** 3 ~~should~~ shall not exceed fifteen (15) seconds, unless a constant temperature media bath is used to prevent the ~~hot water~~ heated media bath from cooling significantly.

3. Insert the indicating thermometer into a ~~the hot water~~ heated media bath to the proper indicating thermometer bulb immersion depth.
4. Start the ~~stopwatch~~ accurate time measuring device when the indicating thermometer reads 11°C (19°F) below the heated media bath temperature.
5. Stop the ~~stopwatch~~ accurate time measuring device when the indicating thermometer reads 4°C (7°F) below the heated media bath temperature.
6. Record the ~~thermometric response time for the office record~~ results of the Test on the appropriate Form.

**For Example:** For a an indicating thermometer used at pasteurization temperature set points of 71.7°C (161°F) and 74.4°C (166°F), a water media bath at a temperature of 78.3°C (173°F) could be used. ~~40.6°C 11°C (19°F) lower than a 78.3°C (173°F) water media bath would be 67.8°C (154°F); 3.9°C 4°C (7°F) lower than a 78.3°C (173°F) water media bath would be 74.4°C (166°F).~~ Hence, after immersing the indicating thermometer that has been previously cooled in the ice and water media bath, ~~in~~ into the 78.3°C (173°F) bath, the ~~stopwatch~~ accurate time measuring device is started when the thermometer reads 67.8°C (154°F) and the accurate time measuring device is stopped when it reads 74.3°C (166°F).

**NOTE:** The ~~Test~~ Example included the pasteurization temperature set points of 71.7°C (161°F) and 74.4°C (166°F). If the pasteurization temperature set points had been 71.7°C (161°F) and 79.4°C (175°F), it would not have been possible to include both set points within a ~~6.7°C 7°C (12°F) span~~. With these set points of 71.7°C (161°F) and 79.4°C (175°F) the Test would have to be ~~done~~ conducted separately for each set point.

**Corrective Action:** If the response time exceeds four (4) seconds, the indicating thermometer should shall be repaired or replaced or returned for repair by milk plant personnel. If the thermometer fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 8.

### TEMPERATURE RECORDER/CONTROLLER RECORDER-CONTROLLER THERMOMETERS - THERMOMETRIC RESPONSE

**Reference:** Item 16p.(B) and (D)

**Application:** To all HTST continuous-flow pasteurizers pasteurization systems, except for those in which the FDD is located at the end of the cooler downstream of the pasteurized regenerator section(s) and/or the final cooler section.

**Frequency:** Upon installation; and at least once each three (3) months thereafter; whenever the temperature recorder-controller thermometer has been repaired and/or replaced; or whenever the regulatory seal has been broken.

**Criteria:** Five (5) seconds, under specified conditions or less.

**Apparatus:**

1. ~~Stopwatch~~ Accurate time measuring device;
2. The indicating thermometer, which was previously tested against a known accurate test thermometer;
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the water media bath.

**Method:** Measure the time interval between the instant when the temperature recording recorder-controller thermometer reads 7°C (12°F) below the cut-in temperature and the moment of cut-in by the temperature recorder/controller recorder-controller. This time interval measurement is made when the temperature recorder-controller sensing element is immersed in a rapidly agitated water media bath maintained at 4°C (7°F) above the cut-in temperature.

**Procedure:**

1. Check and, if necessary, adjust the pen-arm setting of the recording temperature recorder-controller thermometer in the proper reference to agree with read the same as the indicating thermometer reading at the pasteurization temperature.
2. Determine the cut-in temperature of the recorder/controller, either while in normal operation or by using a water bath. (Refer to Test 10.)
3. ~~Remove the~~ Allow the temperature recorder-controller sensing element and allow it to cool to room temperature.
4. Heat the water media bath to 4°C (7°F) above the cut-in temperature, while continuously vigorously agitating the media bath to insure a uniform temperature.
5. Immerse the temperature recorder/controller recorder-controller sensing element bulb in the media bath. Continue agitation during Procedures 6 5 and 7 6 below.
6. Start the stopwatch accurate time measuring device when the temperature recording recorder-controller thermometer reaches a temperature of 7°C (12°F) below the cut-in temperature.

~~76. Stop the stopwatch accurate time measuring device when the temperature recorder/controller recorder-controller cuts in.~~

~~87. Re-seal the regulatory controls as necessary and record the thermometric response time for office record. Record the results of the Test on the appropriate Form.~~

8. Repeat **Procedures 1 through 7** for each temperature cut-in set point.

**Corrective Action:** If the response time exceeds five (5) seconds, the temperature recorder/controller recorder-controller ~~should~~ shall be repaired or replaced by milk plant personnel. If the temperature recorder-controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 9.

### REGENERATOR PRESSURE CONTROLS

**Reference:** Item 16p.(C) and (D)

#### 9.1 PRESSURE SWITCHES

~~Used to control the operation of the booster pump.~~

**Application:** To all pressure switches controlling the operation of a booster pump on HTST ~~pasteurizer~~ pasteurization systems employing regenerators with a regenerator section(s).

**Frequency:** Upon installation; at least once each three (3) months thereafter; ~~after~~ whenever there is any change in ~~to~~ the booster pump or the pressure switch circuit; ~~and/or~~ or whenever the ~~pressure switch~~ regulatory seal is ~~is~~ has been broken.

**Criteria:** The booster pump shall not operate unless there is at least a 6.9 kPa (1 ~~pound~~ psi) pressure differential on the pasteurized milk and/or milk product side of the regenerator section.

**Apparatus:**

1. ~~A~~ Sanitary sanitary pressure gauge; ~~and~~

2. ~~pneumatic~~ Pneumatic testing device, for checking and adjusting the pressure switch settings; ~~and~~

**NOTE:** A simple pneumatic testing device may be made from a ~~discarded 50 millimeters (2 inches) 7BX~~ sanitary tee; with a cap on one outlet of the tee that is two (2) additional 13H nuts, one (1) of which is provided with a 16A cap, drilled and tapped and fitted in sequence from the cap with an air bleeder valve, an air pressure reducing valve (suggested range 0-60 psi) and a quick disconnect fitting for attaching a pneumatic device to a milk plant air line. for a 13 millimeters (0.5 of an inch) galvanized iron nipple for the air connection. A hose connection is made to a compressed air source in the milk plant by means of a snap-on fitting. The air pressure can be controlled by pressure reducing valve (range 0-60 psi) followed by a 13 millimeters (0.5 of an inch) globe type bleeder valve connected into the side outlet of a 13 millimeters (0.5 of an inch) tee installed between the pressure reducing valve and the testing device. The pressure switch to be tested is disconnected from the pasteurizer and connected to another of the outlets of the sanitary tee, and the pressure gauge is connected to the third outlet

~~of the sanitary tee. By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the testing device may be regulated slowly and precisely. In operating the device, care should be taken to avoid exposing the pressure switch and the sanitary pressure gauge to excessive pressure that may cause damage. This may be done by first closing off the air pressure regulating valve and opening fully the bleeder valve; these may then be manipulated slowly to bring the air pressure in the testing device within the desired range.~~

3. A test light of proper voltage ~~should be~~ placed in-series with the pressure switch contact and in parallel with the electrical load, booster pump starter, ~~so the actuation point may be readily determined.~~

**Method:** Check and make the adjustment of the pressure switch to prevent the operation of the booster pump, unless the pressure of the pasteurized milk and/or milk product side of the regenerator section is greater by at least 6.9 kPa (1 psi) than any pressure that may be generated by the booster pump on the raw side.

**Procedure:**

1. Determine the maximum pressure of the booster pump.
  - a. Install the sanitary pressure gauge in a tee at the discharge of the booster pump;
  - b. Operate the ~~pasteurizer~~ pasteurization system with on water; with the FDD in forward-flow; the timing pump operating at the minimum speed possible; and the booster pump operating at its ~~rated~~ maximum speed. If a separator and/or vacuum equipment is located between the raw outlet ~~from~~ of the regenerator section and the timing pump, ~~it the separator and/or vacuum equipment should shall be bypassed~~ effectively valved out of the pasteurization system while this determination is made.
  - c. ~~Note~~ Determine the maximum pressure indicated by the pressure gauge under these conditions.
2. Check and set the pressure switch.
  - a. ~~Install a sanitary pressure gauge of known accuracy on the pneumatic testing device to which the pressure switch sensing element should also be connected. Disconnect the pressure switch to be tested from the pasteurization system and connect it to one (1) of the outlets of the pneumatic testing device sanitary tee.~~
  - b. Connect the sanitary pressure gauge to the third outlet of the sanitary tee.
  - c. Close the air pressure regulating valve and fully open the air bleeder valve. Slowly manipulate these valves to bring the air pressure in the pneumatic testing device within the desired range.

**NOTE:** By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the pneumatic testing device may be regulated slowly and precisely. When operating the pneumatic testing device, care shall be taken to avoid exposing the pressure switch and the sanitary pressure gauge to excessive pressure that might cause damage to the pressure switch.

- ~~bd.~~ Remove the regulatory seal and cover to expose the adjustment mechanism on the pressure switch.
- ~~ee.~~ Operate the pneumatic testing device and determine the pressure gauge reading at the ~~cut in~~ booster pump start point ~~of~~ on the pressure switch, which will light the test ~~lamp~~ light. If the pressure switch is short circuited, the ~~lamp~~ test light will be ~~lighted~~ lit before the air pressure is applied.

~~df.~~ The ~~cut-in~~ booster pump start point ~~should~~ shall be adjusted, if necessary, so as to occur at a pressure gauge reading at least 6.9 kPa (1 psi) greater than the maximum booster pump operating pressure, as determined under ~~Section~~ Step 1 of this ~~procedure~~ Procedure. ~~Where~~ If an adjustment is necessary, refer to the manufacturer's instructions for the adjusting procedures. After adjustment, recheck the ~~actuation~~ booster pump start point and ~~readjust~~ if necessary.

eg. Replace the cover, seal the pressure switch and ~~restore~~ put the pressure switch sensing element ~~back to~~ at its original location.

3. Identify the motor, casing and impeller of the booster pump.

~~4.~~ Record the maximum booster pump pressure developed and, the pressure switch setting and the identity of the motor, casing and impeller of the booster pump for the office record on the appropriate Form.

**Action:** If the pressure switch fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 9.2 DIFFERENTIAL PRESSURE CONTROLLER

**Application:** Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps ~~on~~ within HTST pasteurization systems or used to control the operation of FDDs on HHST and HTST pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section.

Test 9.2.2 applies only to HTST pasteurization systems with the FDD located immediately following the holding tube.

Test 9.2.3 applies to the testing of ~~continuous-flow~~ continuous-flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD.

**Frequency:** Upon installation; at least once each three (3) months thereafter; ~~and~~ whenever the differential pressure controller is adjusted or repaired; or whenever the regulatory seal has been broken.

**Criteria:** The booster pump shall not operate, or the ~~pasteurizer~~ pasteurization system shall not operate in forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the milk and/or milk product pressure in the raw side of the regenerator section(s). When the differential pressure controller is used to control the FDD on HHST pasteurization systems, and improper pressure occurs in the regenerator section(s), the FDD shall move to the diverted-flow position and remain in diverted-flow until the proper pressures are re-established in the regenerator section(s) and all milk and/or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required minimum legal pasteurization temperature, continuously and simultaneously for at least the required time.

**Apparatus:**

1. A sanitary pressure gauge; ~~and~~ a
2. ~~pneumatic~~ Pneumatic testing device, described in Test 9.1 PRESSURE SWITCHES can be used for checking and adjusting the differential pressure switch setting. (Refer to Test 9.1.);
3. Water, oil or other suitable media bath and agitator;
4. Suitable means of heating the media bath. (Refer to Test 9.2.2); and

5. Test light. (Refer to Test 9.2.3)

**Method:** The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the pressure in the raw side of the regenerator section(s).

### **9.2.1 CALIBRATION OF THE DIFFERENTIAL PRESSURE CONTROLLER PROBES SENSING ELEMENTS**

**Procedure:**

1. Loosen the ~~process sanitary pipeline connection~~ connections at to both differential pressure controller pressure sensors sensing elements and wait for any liquid to drain through the loose sanitary pipeline connections. Both pointers, or digital displays, ~~should~~ shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s), or the digital display(s), to read 0 kPa (0 psi).
2. Remove both differential pressure controller sensors sensing elements from the ~~processor pasteurization system~~ and mount them ~~in~~ on a testing tee, which is connected either at the discharge of the booster pump; or ~~connected to~~ at the pneumatic testing device. Note the separation between the two (2) pointers or digital displays. ~~The~~ A change in elevations elevation of the differential pressure controller sensors sensing elements ~~will~~ may ~~cause~~ have caused some change in the ~~zero~~ 0 kPa (0 psi) readings. Turn on the booster pump switch and ~~depress~~ activate the test ~~push-button~~ switch/button to operate the booster pump; ~~or~~ If ~~if~~ the pneumatic testing device is used in lieu of the booster pump, adjust the air pressure to the normal operating pressure of the booster pump. Note that the ~~pointer~~ pointers, or digital display reading separation is within 6.9 kPa (1 psi) of that observed before the pressure was applied. ~~If not, the instrument requires adjustment or returned for repair.~~
3. Record the results of the Test results for the office record on the appropriate Form.

**Action:** If the differential pressure controller fails to respond as indicated above, an immediate check of the differential pressure controller is required by milk plant personnel to correct the cause of the failure. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **9.2.2 HTST - INTERWIRING OF THE ~~PRESSURE~~ DIFFERENTIAL PRESSURE CONTROLLER WITH THE BOOSTER PUMP**

**Method:** Determine if the booster pump stops running when the pressure differential is not properly maintained in the regenerator section(s).

**Procedure:**

1. Connect the pasteurized regenerator section differential pressure controller sensor sensing element to a testing tee with the other end of the testing tee capped.

**NOTE:** If there is water in the HTST pasteurization system, ensure that the recorder/controller recorder-controller probe sensing element and the pasteurized regenerator section differential

pressure controller sensor sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller probe sensing element in a hot water media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump shall start running.
5. Decrease the air supply to the testing tee until the pasteurized milk and/or milk product differential pressure controller sensor sensing element pressure is less than 14 kPa (2 psi) greater than ~~of~~ the pressure on the raw milk and/or milk product side differential pressure controller sensor sensing element. The booster pump ~~should~~ shall have stopped ~~stop~~ running. Ensure that the FDD remains in the forward-flow position and the timing pump continues to operate.
6. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test results for the office record on the appropriate Form.

**Corrective Action:** If the booster pump fails to stop running when the pressure differential is not maintained, ~~have the milk plant maintenance personnel shall~~ determine and correct the ~~cause problem~~. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **9.2.3 INTERWIRING OF THE PRESSURE DIFFERENTIAL PRESSURE CONTROLLER WITH THE FDD IN AN HHST CONTINUOUS FLOW CONTINUOUS-FLOW PASTEURIZATION SYSTEM**

#### **Application:**

~~1. To all differential pressure controllers used to control the operation of FDDs on HHST continuous flow continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or final cooler section, and~~

~~2. To all differential pressure controllers used to control the operation of FDDs, milk or milk product divert systems, milk or milk product divert valve(s).~~

**Apparatus:** ~~A sanitary pressure gauge and pneumatic testing device, described in PRESSURE SWITCHES can be used for checking and adjusting the differential pressure switch setting. (Refer to Test 9.1.)~~

**Method:** The differential pressure ~~switch~~ controller is checked and adjusted to prevent forward-flow, unless the milk and/or milk product pressure in the pasteurized side of the regenerator section(s) is at least 6.9 kPa (1 psi) greater than the pressure in the raw milk and/or milk product side of the regenerator section(s). In the case of milk and/or milk product-to-water-to-milk or milk product regenerators, protected on the pasteurized side of the regenerator section(s), the "water side" of the regenerator section(s) shall be considered to be the "raw product side" for purposes of this Test.

#### **Procedure:**

1. Wire the test ~~lamp~~ light in series with the signal from the ~~pressure~~ differential pressure ~~switch~~ controller to the FDD.

2. Calibrate the ~~pressure~~ differential pressure ~~switch~~ controller and ~~probes~~ sensing elements. (Use Test 9.2.1.)
3. Adjust the pressure on the ~~differential~~ pressure ~~switch~~ controller ~~sensors~~ sensing elements to their normal operating pressures, with the pasteurized milk and/or milk product pressure at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure.
  - a. The test ~~lamp~~ ~~light should~~ shall be lit. If not, increase the pasteurized milk and/or milk product pressure, or lower the raw milk and/or milk product pressure, until the test light is lit.
  - b. Gradually lower the pasteurized ~~side~~ milk and/or milk product pressure, or raise the raw milk and/or milk product pressure until the test light turns off.
  - c. The test light ~~should~~ shall turn off when the pasteurized milk and/or milk product pressure is at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure.
  - d. Note the ~~differential~~ pressure differential at the point the test light turns off.
  - e. Gradually raise the pasteurized milk and/or milk product pressure, or lower the raw milk and/or milk product pressure, until the test light turns on.
  - f. The test light ~~should~~ shall not turn on until the pasteurized milk and/or milk product pressure is at least 14 kPa (2 psi) higher than the raw milk and/or milk product pressure. Note the ~~differential~~ pressure differential at the point the test light turns off.

**NOTE:** This Test may be completed using a pneumatic testing device capable of producing ~~differential pressures~~ pressure differentials on the ~~probes~~ sensing elements. ~~This device should be capable of being operated, and be operated, in a manner so as to duplicate~~ duplicating the conditions described above.

4. ~~Seal the instrument and record~~ Record the results of the Test results for the office record on the appropriate Forms.

**Action:** If the differential pressure controller fails to respond as indicated above, an immediate check of the differential pressure controller is required by milk plant personnel to locate and correct the problem. If after adjustment and/or repair the differential pressure controller fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **9.3 ADDITIONAL HTST PASTEURIZATION SYSTEM TESTS FOR BOOSTER PUMPS - INTERWIRING**

**Application:** To all booster pumps used for HTST pasteurization systems where the FDD is located immediately after downstream of the holding tube, ~~except for those systems which are magnetic flow meter based timing systems~~, that Test 9.3.2 is not required to be performed on magnetic flow meter based timing systems.

**Frequency:** Upon installation; at least once each three (3) months thereafter; whenever there is any change to the booster pump or the booster pump interwiring; or when the regulatory seal has been broken.

**Criteria:** The booster pump shall be wired so it cannot operate if the FDD is in the ~~diverted~~ diverted-flow position or if the timing pump is not in operation.

**Apparatus:**

1. A sanitary pressure gauge; and
2. pneumatic Pneumatic testing device, as described in Test 9.1 Pressure Switches PRESSURE SWITCHES, can be used for checking and adjusting the differential pressure controller setting. (Refer to Test 9.1);
3. Water, oil or other suitable media bath and agitator; and
4. Suitable means of heating the water media bath.

**9.3.1 BOOSTER PUMPS -INTERWIRED WITH FDD**

**Method:** Determine if the booster pump stops running by dropping the temperature and causing the FDD to divert.

**Procedure:**

1. Connect the pasteurized regenerator section(s) differential pressure controller sensor sensing element to a testing tee with the other end of the testing tee capped.

**NOTE:** If there is water in the HTST pasteurization system, ensure that the ~~recorder/controller~~ recorder-controller probe sensing element and the pasteurized regenerator section (s) differential pressure controller sensor sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller probe sensing element in a hot water media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump shall start running.
5. Remove the ~~recorder/controller~~ recorder-controller probe sensing element from the hot water media bath.
6. When the FDD moves to the diverted-flow position, the booster pump ~~must~~ shall stop running. Ensure that the pressure differential remains ~~adequate~~ greater than or equal to 6.9 kPa (1 psi) and the other flow-promoting devices, which are capable of causing flow through the FDD, in the timing pump system continues continue to operate.
7. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test results for the office record on the appropriate Form.

**Corrective Action:** If the booster pump fails to stop running when the FDD is in the diverted-flow position, ~~have the milk plant maintenance personnel check the wiring~~ shall determine and correct the cause. If after adjustment and/or repair the booster pump fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

**9.3.2 BOOSTER PUMPS - INTERWIRED WITH THE TIMING PUMP**

**Method:** Determine if the booster pump stops running when the timing pump is ~~off~~ not running.

**Procedure:**

1. Connect the pasteurized regenerator section(s) differential pressure controller sensor sensing element to a testing tee with the other end of the testing tee capped.

**NOTE:** If there is water in the HTST pasteurization system, ensure that the ~~recorder/controller~~ recorder-controller probe sensing element and the pasteurized regenerator section(s) differential pressure controller sensor sensing element ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the ~~recorder/controller~~ recorder-controller probe sensing element in a hot water media bath, which is above the cut-in temperature.
4. ~~Turn up~~ Increase the air supply on the testing tee to provide an adequate pressure differential to start the booster pump. The booster pump ~~should~~ shall start running.
5. Turn off the timing pump. The booster pump ~~must~~ shall stop running. Ensure that the pressure differential remains adequate and the FDD remains in the forward-flow position.
6. ~~Reseal the regulatory controls as necessary and record~~ Record the results of the Test results for the office record on the appropriate Form.

**Corrective Action:** If the booster pump fails to stop running when the timing pump ~~has been turned off~~ is not running, ~~have the milk plant maintenance personnel~~ shall determine and correct the cause. If after adjustment and/or repair the booster pump fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 10.

### MILK OR MILK PRODUCT FLOW CONTROLS AND THE MILK OR MILK PRODUCT TEMPERATURE AT CUT-IN AND CUT-OUT

**References:** Item 16p.(B) and (D)

**Frequency:** Milk and/or milk product flow controls shall be tested for the milk and/or milk product temperature at cut-in and cut-out by one (1) of the following applicable Tests at the frequency prescribed:

**Apparatus:**

1. Water, oil or other suitable media bath and agitator;
2. Suitable means of heating the media bath; and
3. Test light for Tests 10.2 and 10.3.

#### 10.1 HTST PASTEURIZERS PASTEURIZATION SYSTEMS

**Application:** To All all ~~recorder/controllers~~ recorder-controllers used in connection with HTST ~~pasteurizers~~ pasteurization systems, except those in which the FDD is located downstream from ~~at the end of the~~ pasteurized regenerator section(s) and/or final cooler section.

**Frequency:** Upon installation; at least once each three (3) months thereafter ~~by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory~~

~~Agency, qualified under Item 16p(D)2; daily by the milk plant operator; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; or when whenever a the regulatory seal has been broken; and daily by a milk plant's pasteurization system operator.~~

~~Criteria:~~ Forward-flow cannot be achieved until at least the minimum legal pasteurization temperature has been reached. Flow shall be diverted before the temperature drops below the minimum legal pasteurization temperature.

~~Apparatus: No supplemental materials needed.~~

**Method:** By observing the actual temperature of the indicating thermometer at the instant forward-flow starts (cut-in) and forward-flow stops (cut-out).

**Procedure:**

**1. Cut-in temperature:**

a. While milk, milk product or water is completely flooding the sensing ~~element~~ elements of the ~~recorder/controller~~ recorder-controller and the indicating thermometer, which was previously tested against a known accurate test thermometer, increase the heat gradually so as to raise the temperature of the milk, milk product or water at a rate not exceeding to exceed 0.5°C (1°F) every per thirty (30) seconds. If a water, oil or other suitable media bath is used in place of milk, milk product or water flowing through the pasteurization system, the water, oil or other suitable media bath shall be adequately and continuously agitated during this Test.

b. Observe the indicating thermometer reading at the moment forward-flow starts begins, i.e., the FDD moves. Observe that the recorder-controller frequency event pen reading is synchronized with the recording pen on the same reference arc as on the recording chart.

c. Immediately Record record and identify on the recording chart, the observed indicating thermometer temperature reading at cut-in on the recording thermometer chart and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the Regulatory Agency. The Regulatory Agency shall record Test findings.

**2. Cut-out temperature:**

a. After the cut-in temperature has been determined, and while the milk, milk product or water is above the cut-in temperature, allow the milk, milk product or water to cool slowly at a rate not exceeding to exceed 0.5°C (1°F) per thirty (30) seconds. If a water, oil or other suitable media bath is used in place of milk, milk product or water flowing through the pasteurization system, the water, oil or other suitable media bath shall be adequately and continuously agitated during this Test. Observe the indicating thermometer reading at the instant forward flow stops.

b. Observe the indicating thermometer reading at the moment flow is diverted. Observe that the recorder-controller event pen reading is synchronized with the recording pen on the same reference arc as on the recording chart.

~~bc. Re-seal the regulatory controls as necessary and~~ Immediately record and identify on the recording chart, the observed indicating thermometer temperature reading at cut-out on the recording thermometer chart and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the Regulatory Agency.

**3. Record the results of both the cut-in and cut-out Tests on the appropriate Form.**

**Corrective Action:** Should If the cut-in and/or cut-out reading indicating thermometer reading be is below the minimum legal pasteurization temperature, the cut-in and and/or cut-out setting(s) mechanism and/or the differential temperature mechanism should shall be ad-

justed by milk plant personnel to obtain proper cut in and cut out temperatures by repeated Tests. When compliance is achieved, seal the recorder/controller mechanism. If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## **10.2 PASTEURIZERS PASTEURIZATION SYSTEMS USING INDIRECT HEATING**

**Application:** To All all HHST and HTST continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section using indirect heating.

**Frequency:** Upon installation; at least once every three (3) months thereafter; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; and or whenever the ~~thermal controller~~ recorder-controller thermometer regulatory seal is has been broken.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the minimum legal pasteurization temperature has been achieved in the holding tube and at the FDD. The milk and/or milk product flow shall be diverted at a temperature lower than before the temperature falls below the chosen minimum legal pasteurization standard temperature in the holding tube.

**Apparatus:** No supplemental materials needed.

**Method:** The cut-in and cut-out temperatures as read from the indicating thermometer located within the pasteurization system are determined by observing using a the actual temperature in the constant temperature media bath at which and the two (2) sensing elements from the holding tube and the FDD. signal forward-flow (cut-in) and diverted-flow (cut-out).

### **Procedure:**

#### **1. Cut-in temperature:**

a. Wire the test lamp light in series with the control contacts of the holding tube recorder-controller sensing element. Immerse this the recorder-controller and holding tube indicating sensing element elements in the constant temperature media bath. Raise the media bath temperature at a rate not exceeding to exceed 0.5°C (1°F) every per thirty (30) seconds. Observe the temperature reading on the indicating thermometer when the test light comes on, which is at the cut-in temperature. Record the temperature for the office record.

b. Record the observed indicating thermometer cut-in reading on the appropriate Form.

#### **2. Cut-out temperature:**

a. After the cut-in temperature has been determined and while the media bath is above the cut-in temperature, allow the media bath to cool slowly at a rate not exceeding to exceed 0.5°C (1°F) per thirty (30) seconds. Observe the temperature reading on the ~~thermal limit-controller~~ recorder-controller when the test lamp light goes out, which is the cut-out temperature. Determine that the cut-out temperature, on the ~~thermal limit-controller~~ recorder-controller is equivalent to or greater than the chosen minimum legal pasteurization standard temperature. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.

b. Record the observed indicating thermometer cut-out reading on the appropriate Form.

3. Repeat the procedure for the FDD sensing element. Rewire the test light in series with the control contacts for the FDD sensing element. ~~When proper cut-out temperature has been verified for both sensing elements, seal the thermal limit controller system.~~

**Action:** Whenever adjustment is necessary, refer to the manufacturer's instructions. Retest the cut-in and cut-out temperatures after any adjustment, repair, replacement or whenever the regulatory seal has been broken. If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **10.3 PASTEURIZERS PASTEURIZATION SYSTEMS USING DIRECT HEATING**

**Application:** ~~To All~~ all HHST and HTST continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section using indirect heating.

**Frequency:** Upon installation; at least once every three (3) months thereafter; whenever the recorder-controller and/or recorder-controller thermometer has been repaired and/or replaced; and or whenever the ~~thermal limit controller~~ recorder-controller thermometer regulatory seal is has been broken.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the minimum legal pasteurization temperature has been achieved in the holding tube, at the vacuum chamber and at the FDD. The milk and/or milk product flow shall be diverted at a temperature lower than before the temperature falls below the chosen minimum legal pasteurization standard temperature in the holding tube.

**Apparatus:** ~~No supplemental materials needed.~~

**Method:** The cut-in and cut-out temperatures as read from the indicating thermometer located within the pasteurization system are determined by observing using a the actual temperature in the constant temperature media bath at which each of and the three (3) sensing elements from the holding tube, vacuum chamber and the FDD signals forward flow (cut in) and diverted-flow (cut-out).

**Procedure:**

1. **Cut-in temperature:**

a. Wire the test ~~lamp~~ light in series with the control contacts of the holding tube recorder-controller sensing element. Immerse this the recorder-controller and holding tube indicating sensing element elements in the constant temperature media bath. Raise the media bath temperature at a rate not exceeding to exceed 0.5°C (1°F) every per thirty (30) seconds. Observe the temperature reading on the ~~thermal limit controller~~ indicating thermometer when the test ~~lamp~~ lights light comes on, which is the cut-in temperature. Record the temperature for the office record.

b. Record the observed indicating thermometer cut-in reading on the appropriate Form.

2. **Cut-out temperature:**

a. After the cut-in temperature has been determined and while the media bath is above the cut-in temperature, allow the media bath to cool slowly at a rate not exceeding to exceed 0.5°C (1°F) per thirty (30) seconds. Observe the temperature reading on the ~~thermal limit controller~~ recorder-controller when the test ~~lamp~~ light goes out, which is the cut-out

temperature. Determine that the cut-out temperature, on the ~~thermal limit controller recorder-controller~~ is equivalent to or greater than the ~~chosen~~ minimum legal pasteurization standard temperature. ~~Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.~~

b. Record the observed indicating thermometer cut-out reading on the appropriate Form.

3. Repeat the procedure for the other two (2) sensing elements, ~~i.e., from the vacuum chamber and the FDD~~. Rewire the test ~~lamp~~ light in series with the control contacts ~~from~~ for each sensing element, respectively. ~~When proper cut-out temperatures have been verified for all three (3) sensing elements, seal the thermal limit controller system.~~

**Action:** Whenever adjustment is necessary, refer to the manufacturer's instructions. Retest the cut-in and cut-out temperatures after any adjustment, repair, replacement or whenever the regulatory seal has been broken. If after adjustment the cut-in and/or cut-out temperature(s) fail this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 11.

### **CONTINUOUS-FLOW PASTEURIZATION SYSTEM HOLDING TUBES – PASTEURIZATION HOLDING TIME**

(Continuous-flow pasteurization system holding tubes shall be tested for pasteurization holding times by one (1) of the following applicable Tests.)

**Reference:** Item 16p.(B) and (D)

~~Continuous-flow holding tubes shall be tested for holding times by one (1) of the following applicable Tests:~~

#### **11.1 HTST PASTEURIZERS PASTEURIZATION SYSTEMS**

(Except for magnetic flow meter based timing systems)

**Application:** To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems employing a pasteurization holding time of fifteen (15) seconds or longer, except for magnetic flow meter based timing systems.

**Frequency:** Upon installation; ~~semi-annually~~ at least once every six (6) months thereafter; ~~whenever the seal on the speed setting is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, such as the replacement of the timing pump, motor, belt, drive or driven pulleys, or a decrease in the number of HTST pasteurization system heat-exchange plates or the capacity of the holding tube; ~~or~~ whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.

**Criteria:** Every particle of milk and/or milk product shall be held for at least ~~fifteen (15) seconds~~ a minimum legal pasteurization holding time of fifteen (15) seconds or twenty-five (25) seconds, respectively in both the ~~forward~~ forward-flow and diverted-flow positions.

**Apparatus:**

1. ~~An Electrical~~ electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with standard electrodes;
2. Table salt (sodium chloride) or other appropriate conductive solution;
3. A suitable apparatus for injecting the salt solution or other appropriate conductive solution (50 ml syringe) into the holding tube; and
4. An accurate timing time measuring device.

**Method:** The pasteurization holding time is determined by timing the interval for an ~~added~~ injected trace substance, such as sodium chloride, to pass through the entire length of the legal holding tube. Although the time interval of the fastest particle of milk and/or milk product is desired, ~~the~~ this conductivity Test is ~~made performed with using~~ water. The results ~~found with~~ obtained when using water are converted to the milk and/or milk product flow pasteurization holding time, ~~by using either the volume or weight~~ formulation, as shown below, since a timing pump may not deliver the same amount of milk and/or milk product as it does water.

**Procedure:**

1. ~~Examine the entire~~ Operate the pasteurization system on water, to insure that with all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding equipment is ~~devices so~~ adjusted or bypassed as to provide the minimum amount of resistance to the flow through the pasteurization system. There shall not be ~~no~~ any leakage on the suction side of the timing pump.
  - a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.
  - b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.
  - c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

**NOTE:** For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. ~~Adjust the variable speed pump to its maximum capacity, preferably with a new belt and full size impellers. Check the homogenizer for seals, and/or gears or pulley identification. Check the AC variable speed timing pump control box for seals. For systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry pump must be energized and running at its maximum speed and the slurry supply tank must be completely filled with water.~~
32. ~~Install one (1) electrode at the inlet to~~ beginning of the legal holding tube and the other electrode ~~in~~ at the end of the legal holding tube outlet.
43. ~~Operate the pasteurizer~~ pasteurization system, using water at or above the minimum legal pasteurization temperature, with the FDD in the forward-flow position.
54. Quickly inject a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube inlet.
65. ~~The timer~~ accurate time measuring device should shall start when it detects a change in conductivity ~~and~~ at the beginning of the legal holding tube.
76. ~~The timer~~ accurate time measuring device should shall stop when it detects a change in conductivity ~~and~~ at the end of the legal holding tube.
8. ~~Record the results.~~

~~97.~~ Repeat ~~the~~ this Test six (6) or more times, until six (6) ~~successive~~ consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in forward-flow. ~~When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side. Repeat this Test. Should consistent readings not be obtained, use the fastest time as the holding time for water.~~

**NOTE:** When consistent Test readings cannot be obtained, purge the pasteurization system, check the Testing instruments and connections and check for any air leakage on the suction side of the timing pump. Repeat **Procedure 7**. When consistent readings cannot be obtained after repeating **Procedure 7**, use the fastest time obtained from any of these Tests as the pasteurization holding time for water in forward-flow.

8. Record all of the pasteurization holding time results for water in forward-flow as conducted in **Procedure 7** above and the average of these six (6) Tests on the appropriate Form.

~~109.~~ Repeat **Procedures 4 3** through **9 7** above for the pasteurization holding time ~~on~~ for water in diverted-flow.

~~For all gear driven timing pumps complete **Procedures 11, 12 and 13**. For those homogenizers used as timing pumps, when the measured holding time for water is less than 120% of the legal holding time, complete **Procedures 11, 12 and 13**. For those homogenizers used as timing pumps, when the measured holding time for water is 120% or more of the legal holding time, **Procedure 11** is optional and **Procedure 12 and 13** are not required.~~

10. Record all of the pasteurization holding time results for water in diverted-flow as conducted in **Procedure 9** above on the appropriate Form.

11. Complete a., b. or c. below as appropriate:

a. For all gear driven timing pumps complete **Procedures 12 through 16** below.

b. For those homogenizers used as timing pumps, when the measured pasteurization holding time for water is less than 120% of the minimum legal pasteurization holding time, complete **Procedures 12 through 16** below.

c. For those homogenizers used as timing pumps, when the measured pasteurization holding time for water is 120% or more of the minimum legal pasteurization holding time, **Procedure 12** is optional and **Procedure 13 through 16** below are not required.

~~112.~~ With the timing pump at the same speed and all other equipment flow-promoting devices, which are capable of causing flow through the FDD, and flow-impeding devices adjusted as cited in **Procedure 1**, determine the time it takes to fill the filling of a 38 liter (10 gallon) can with a measured weight or volume of water, using the pasteurization system discharge outlet with the same head pressure as in normal is normally used during the operation of the pasteurization system. Average the time filling times of for several trials (minimum of three (3)). Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10 gallon) can, it is suggested, that a calibrated tank of considerable size be used.

**NOTE:** Since flow rates of a large capacity unit makes it very difficult to determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is recommended that a calibrated tank of considerable size be used. It is also acceptable to use any other means to determine a measured weight or volume of water.

13. Record all of the can fill time results and the average time it takes to fill a 38 liter (10 gallon) can or other means as described in the NOTE above with a measured weight or volume of water for Procedure 12 above on the appropriate Form.

~~14.~~ Repeat **Procedure 12** above using milk.

15. Record the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for Procedure 14 above on the appropriate Form.

~~16.~~ Compute the pasteurization holding time for milk from one (1) of the following formulas, either by volume or by weight. Compute separately for forward-flow and diverted-flow. ~~Re-seal the regulatory controls as necessary.~~

### **BY VOLUME:**

The adjusted pasteurization holding time for milk is equal to: ~~the~~

The pasteurization holding time for water; times the quotient of the time it takes to deliver a volume of milk; divided by the time it takes to deliver the same volume of water.

$$T_m = T_w(V_m/V_w)$$

Where:  $T_m$  = Adjusted product pasteurization holding time for milk.

$T_w$  = Pasteurization Holding holding time for water, the salt (sodium chloride or other appropriate conductive solution) ~~Test test results.~~

$V_m$  = Time, usually in seconds, that it takes to pump a known volume of milk.

$V_w$  = Time, usually in seconds, that it takes to pump a the same volume of water.

~~$V_m$  = Time, usually in seconds, that it takes to pump the same volume of milk.~~

### **BY WEIGHT (Using specific gravity):**

The adjusted pasteurization holding time for milk is equal to:

~~the~~ The specific gravity of milk; times the pasteurization holding time for water; times the quotient of the time it takes to deliver a measured weight of milk; divided by the time it takes to deliver the same weight of water.

$$T_m = 1.032 \times T_w(W_m/W_w)$$

Where:  $T_m$  = Adjusted product pasteurization holding time for milk.

1.032 = The specific gravity of milk

**NOTE:** If another milk product is used, use the appropriate specific gravity.

~~$T_m$  = Adjusted product holding time for milk.~~

$T_w$  = Pasteurization-Holding holding time for water, the salt (sodium chloride or other appropriate conductive solution) ~~Test test results.~~

$W_m$  = Time, usually in seconds, that it takes to pump a measured weight of milk.

$W_w$  = Time, usually in seconds, that it takes to pump the same measured weight of water.

~~17.~~ Record the computed adjusted pasteurization holding time for forward-flow and divert-flow for milk, using either the formula for volume or weight as identified in Procedure 16

above, ~~results for the office record~~ on the appropriate Form.

**Corrective Action:** When the computed adjusted pasteurization holding time for milk is less than ~~that required the minimum legal pasteurization holding time~~, either in forward-flow or diverted-flow, the speed of the timing pump shall be reduced or an adjustment shall be made in to the length or diameter of the holding tube and ~~the timing~~ Test 11.1 shall be repeated until a satisfactory pasteurization holding time is achieved. ~~Should~~ If an orifice (restrictor) be used is required to be installed in the FDD divert line to correct comply with the minimum legal pasteurization the holding time in diverted-flow, there ~~should~~ shall not be ~~no~~ any excessive pressure exerted on the underside of the valve seat of the FDD. ~~Governors~~ Variable speed drives shall be sealed on for motors on timing pumps that do not provide a constant speed as provided for in Item 16p(B)5.b 16p(B)2.f.(2). If after adjustment the pasteurization holding time fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

#### **11.2A CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEMS SYSTEM CONTINUOUS-FLOW - PASTEURIZATION HOLDING TIME**

**Application:** To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems with a magnetic flow meter based timing system, used in lieu of a timing pump.

**Frequency:** Upon installation; semiannually at least once every six (6) months thereafter; whenever a seal on the flow alarm is broken; whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of holding tube; or whenever a check of the capacity indicates a speed up; or whenever the regulatory seal on the flow alarm has been broken.

**Criteria:** Every particle of milk and/or milk product shall be held for at least a minimum legal pasteurization holding time of fifteen (15) seconds or twenty-five (25) seconds, respectively in both the forward forward-flow and diverted-flow positions.

**Apparatus:**

1. An Electrical electrical conductivity measuring device, which is capable of detecting a change in conductivity, and is equipped with standard electrodes;
2. Table salt (sodium chloride) or other appropriate conductive solution;
3. A suitable apparatus for injecting the salt solution or other appropriate conductive solution (50 ml syringe) into the holding tube; and
4. An accurate timing time measuring device;
5. Water, oil or other suitable media bath and agitator; and
6. Suitable means of heating the media bath.

**Method:** The pasteurization holding time is determined by timing the interval for an added injected trace substance, such as sodium chloride, to pass through the entire length of the legal holding tube.

**Procedure:**

Utilize either **TEST OPTION I** or **TEST OPTION II**.

## TEST OPTION I:

1. Adjust the set point on the high flow alarm above the estimated acceptable flow rate or bypass the high flow alarm.
2. Adjust the set point on the flow ~~recorder/controller~~ recorder-controller to a flow rate estimated to yield an acceptable pasteurization holding time.
3. Install one (1) electrode at the ~~inlet to~~ beginning of the legal holding tube and the other electrode at the end of the legal holding tube ~~outlet~~.
4. Operate the ~~pasteurizer~~ pasteurization system, using water, at or above the minimum legal pasteurization temperature, with the FDD in the forward-flow position.

**NOTE:** The appropriate temperature sensing elements may be placed in a water, ~~or~~ oil or other suitable media bath to simulate the ~~normal~~ minimum legal pasteurization temperature ~~of in~~ the holding tube as an alternative method to the heating of the water in the pasteurization system above the minimum legal pasteurization temperature.

5. Quickly inject ~~the a~~ a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube ~~inlet~~.
6. The ~~timer~~ accurate time measuring device ~~should~~ shall start when it detects a change in conductivity at the beginning of the legal holding tube.
7. The ~~timer~~ accurate time measuring device ~~should~~ shall stop when it detects a change in conductivity at the end of the legal holding tube.
8. ~~Record the results.~~
9. Repeat ~~the this~~ Test six (6) or more times, until six (6) ~~successive~~ consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in forward-flow. ~~When consistent readings cannot be obtained, purge the equipment, check the instruments and connections; and check for air leakage on the suction side of the pump, located at the constant level tank. Repeat this Test. If six (6) consecutive readings Tests cannot be achieved within 0.5 seconds of each other, the pasteurizing system is in need of repair refer to the Action below.~~
9. Record all of the pasteurization holding time results for water in forward-flow as conducted in Procedure 8 above and the average of these six (6) Tests on the appropriate Form.
10. This procedure is not a required Test; it is at the option of the Regulatory Agency. With the flow ~~recorder/controller~~ rate recorder-controller at the same set point as in **Procedure 2**, determine the time the it takes to filling of fill a 38 liter (10 gallon) can with a measured weight or volume of water using the pasteurization system discharge outlet, with the same head pressure as ~~in normal~~ is normally used during the operation of the pasteurization system. Average the time of several trials (minimum of three (3)). Since ~~the~~ flow rates of ~~the a~~ large capacity units unit make makes it very difficult to ~~check by filling~~ determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is suggested that a calibrated tank of considerable size be used. ~~This procedure is not a required Test; it is at the option of the Regulatory Agency.~~ It is also acceptable to use any other means to determine a measured weight or volume of water.
11. ~~Re-seal the regulatory controls as necessary and record this result for the office record. If the Regulatory Agency chooses to conduct Procedure 10 above, record all of the can fill time results and the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for Procedure 10 above on the appropriate Form.~~

## TEST OPTION II:

1. Install one (1) electrode at the ~~inlet to~~ beginning of the legal holding tube and the other electrode at the end of the legal holding tube ~~outlet~~.
  2. Operate the ~~pasteurizer~~ pasteurization system; using water; with the FDD in the ~~diverted flow~~ divert-flow position at a flow rate just above the high flow alarm set point.
  3. Quickly inject ~~the~~ a saturated sodium chloride or other appropriate conductive solution into the inlet at the beginning of the legal holding tube ~~inlet~~.
  4. The ~~timer~~ accurate time measuring device ~~should~~ shall start when it detects a change in conductivity at the beginning of the legal holding tube.
  5. The ~~timer~~ accurate time measuring device ~~should~~ shall stop when it detects a change in conductivity at the end of the legal holding tube.
  6. ~~Record the results.~~
  7. Repeat ~~the this test~~ Test six (6) or more times, until six (6) successive consecutive results are within 0.5 seconds of each other. The average of these six (6) Tests is the pasteurization holding time for water in diverted-flow. ~~When consistent readings cannot be obtained, purge the equipment, check the instruments and connections; and check for air leakage on the suction side of the pump, located at the constant level tank. Repeat this Test. If six (6) consecutive readings Tests cannot be achieved within 0.5 seconds of each other, the pasteurizing system is in need of repair refer to the Action below.~~
  7. Record all of the pasteurization holding time results for water in diverted-flow as conducted in Procedure 6 above and the average of these six (6) Tests on the appropriate Form.
  8. If the ~~required~~ minimum legal pasteurization holding time is achieved in diverted-flow ~~with this~~ when conducting TEST OPTION II, all flows through the pasteurization system below the high flow alarm set point will meet the required minimum legal pasteurization holding time in forward-flow. Proceed to ~~Procedure~~ Procedure 10 below.
  9. If the Test results, when conducting TEST OPTION II, are not all above the required minimum legal pasteurization holding time in diverted-flow, **TEST OPTION I** ~~must~~ shall be conducted.
  10. This procedure is not a required Test; it is at the option of the Regulatory Agency. With the flow recorder/controller rate recorder-controller at the same set point as in Procedure 2, determine the time the it takes to filling of fill a 38 liter (10 gallon) can with a measured weight or volume of water using the pasteurization system discharge outlet, with the same head pressure as in normal is normally used during the operation of the pasteurization system. Average the time of several trials (minimum of three (3)). Since the flow rates of the a large capacity units unit make makes it very difficult to check by filling determine the time it takes to fill a 38 liter (10 gallon) can with a measured weight or volume of water, it is suggested that a calibrated tank of considerable size be used. This procedure is not a required Test; it is at the option of the Regulatory Agency. It is also acceptable to use any other means to determine a measured weight or volume of water.
  11. Record this result for the office record.
- If the Regulatory Agency chooses to conduct Procedure 10 above, record all of the can fill time results and the average time it takes to fill a 38 liter (10 gallon) can or other means used with a measured weight or volume of milk for Procedure 10 above on the appropriate Form.

**Corrective Action:** When the computed pasteurization holding time for milk is less than ~~that~~ required the minimum legal pasteurization holding time in diverted-flow, the set point on the flow ~~rate recorder/controller~~ recorder-controller shall be decreased, or an adjustment shall be

made in the length or diameter of the legal holding tube by milk plant personnel to correct the pasteurization holding time, and the timing Test TEST OPTION I shall be repeated until a satisfactory pasteurization holding time is achieved. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.2B CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND HIGH FLOW ALARM**

**Application:** To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace, in lieu of a timing pump.~~

**Frequency:** Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; whenever a seal on the flow alarm is broken; whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; or whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the high flow alarm has been broken.

**Criteria:** ~~When~~ Whenever the high flow rate equals or exceeds the value at which the pasteurization holding time was measured, the high flow alarm shall cause the FDD to assume the diverted diverted-flow position, even though the temperature of the milk and/or milk product in the holding tube is above the minimum legal pasteurization temperature.

**Apparatus:** ~~None.~~ No supplementary materials required.

**Method:** The high flow alarm set point must shall be set so that flow is diverted when the flow rate equals or exceeds the value at which the pasteurization holding time was measured or calculated. (Refer to ~~Procedure 3 or 4 of this Test.~~)

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow, at a flow rate below the high flow alarm set point; using water above the pasteurization temperature.

**NOTE:** The appropriate temperature sensing elements may be placed in a water, or oil or other suitable media bath to simulate the normal processing pasteurization temperature within of the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature. Observation and recording of this temperature should be done as described in ~~Procedures 3 and 4 below.~~

2. Slowly raise the flow rate of the pasteurization system until the frequency pen on the flow recorder/controller indicates that flow has been diverted following occur:
- a. The frequency pen(s) on the STLR and the flow rate recorder-controller(s) indicate that the FDD is in the diverted-flow position.
  - b. Observe that the FDD moved to the diverted-flow position.

**NOTE:** ~~When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.~~

3. ~~Observe that the FDD moved to the diverted position, while the temperature requirements are satisfied. Record the rate of flow where the FDD moved to the diverted position~~
4. ~~Re-seal the regulatory controls as necessary. Record the rate of flow; the set point of the high flow alarm at the occurrence of flow diversion; and the temperature on the STLR recording device during the flow alarm divert; at the occurrence of flow-diversion for this Test the official record on the appropriate Form.~~

**Corrective Action:** ~~If the FDD does not move to the diverted diverted-flow position, when the frequency pen of the recorder/controller flow rate recorder-controller indicates a diversion flow-diversion, milk plant personnel shall make a modification or repair of the control wiring to the FDD or the STLR recorder-controller is as required. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.~~

### **11.2C CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND LOW FLOW/LOSS-OF-SIGNAL ALARM**

**Application:** To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace, in lieu of~~ a timing pump.

**Frequency:** Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; whenever a seal on the flow alarm is broken; or whenever any alteration is made affecting the holding time flow rate in the holding tube; or whenever the regulatory seal on the low flow/loss-of-signal flow alarm has been broken.

**Criteria:** Forward-flow occurs only when flow rates are above the ~~loss-of-signal~~ low flow/loss-of-signal alarm set point.

**Apparatus:** ~~None.~~ No supplementary materials required.

**Method:** By observing the actions of the frequency pens pen on the ~~recorder/controller~~ flow rate recorder-controller and the position of the FDD.

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system, using water, in forward-flow, at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point; using water.
2. Disrupt the power to the magnetic flow meter to activate the loss-of-signal alarm or decrease the flow through the flow meter to a flow rate below the low flow/loss-of-signal alarm set point. Observe that the FDD assumes the diverted-flow position and both that the safety thermal limit recorder/controller frequency pen pen(s) on the STLR and the flow rate recorder-controller(s) frequency pen assume assumed the diverted-flow position.
3. ~~Re-seal the regulatory controls as necessary and record the results for the office record. Record the results of this Test and the low flow/loss-of-signal alarm set point, if applicable on the appropriate Form.~~

**Corrective Action:** If the ~~valve~~ FDD does not divert or the frequency pens do not move assume the diverted-flow position, milk plant personnel shall make an adjustment of to the low flow/loss-of-signal alarm or a modification or repair of the control wiring to the FDD, the

STLR or flow rate recorder-controller is as required. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.2D CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND FLOW RATE CUT-IN AND CUT-OUT**

**Application:** To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace, in lieu of~~ a timing pump.

**Frequency:** Upon installation; ~~semiannually at least once every six (6) months thereafter; whenever a seal on the flow alarm is broken; whenever~~ any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; or whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the high flow and/or low flow/loss-of-signal alarm(s) has been broken.

**Criteria:** Forward-flow occurs only when flow rates are below the high flow alarm set point and above the low flow/loss-of-signal alarm set point.

**Apparatus:** ~~None.~~ No supplementary materials required.

**Method:** By observing the ~~recorder/controller~~ flow rate recorder-controller's readings along with the action of the frequency pen on the ~~recorder/controller~~ flow rate recorder-controller and the position of the FDD.

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow; at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point, ~~using water above the pasteurization temperature.~~
2. Using the flow rate ~~recorder/controller~~ recorder-controller, slowly increase the flow rate slowly until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates a ~~flow diversion~~ flow-diversion, because the high flow cut-out alarm set point had been exceeded. The FDD ~~will~~ shall also assume the ~~diverted~~ diverted-flow position. Observe the flow rate reading of flow rate from the flow rate ~~recorder/controller~~ recorder-controller at the instant ~~flow~~ forward-flow cut-out occurs, as indicated by the flow rate recorder-controller's frequency pen.
3. With the ~~pasteurizer~~ pasteurization system operating on water, above the minimum legal pasteurization temperature; and with the FDD ~~in the diverted~~ diverted-flow position ~~because of excessive~~ due to exceeding the high flow rate alarm set point, slowly decrease the flow rate until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates the start of a the FDD's forward-flow movement, which indicates the flow rate cut-in point. Because of the time delay ~~relay~~ described in Test ~~11-2~~ 11.2E, the FDD will not move immediately to the forward-flow position. Observe the flow rate reading from the flow rate recorder/controller at the instant flow rate cut-in occurs, as indicated by the flow rate recorder-controller's frequency pen.
4. ~~Re-seal the regulatory controls as necessary and record the results for the office record.~~ Record the flow rate cut-in and cut-out results of this Test on the appropriate Form.

**Corrective Action:** If the flow rate cut-in or cut-out point point(s) occurs at a flow rate equal to or greater than the value at which the pasteurization holding time was measured, milk plant personnel shall adjust the high flow alarm to a lower set point, and repeat the this Test shall be repeated. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.2E CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HOLDING TUBES AND TIME DELAY RELAY**

**Application:** To all HTST ~~pasteurizers~~ continuous-flow pasteurization systems with a FDD located at the end of the holding tube that use a magnetic flow meter based timing system ~~to replace, in lieu of~~ a timing pump.

**Frequency:** Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; whenever the seal on the flow alarm is broken; whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; or whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the flow alarm has been broken.

**Criteria:** Following the determination of the flow rate cut-in, as described in Test 11.2D, forward-flow shall not occur until all milk and/or milk product in the holding tube has been held at or above the minimum legal pasteurization temperature for at least the minimum legal pasteurization holding time.

**Apparatus:** ~~Stopwatch~~ An accurate time measuring device.

**Method:** Set the time delay equal to or greater than the minimum legal pasteurization holding time.

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow; at a flow rate below the high flow alarm set point and above the low flow/loss-of-signal alarm set point, ~~using water above the pasteurization temperature.~~
2. Using the flow rate ~~recorder/controller~~ recorder-controller, slowly increase the flow rate slowly until the frequency pen on the flow rate ~~recorder/controller~~ recorder-controller indicates a ~~diversion~~ flow-diversion movement and the FDD moves to the ~~diverted~~ diverted-flow position. There shall not be ~~no~~ any time delay between the movements of the flow rate recorder-controller's frequency pen and the FDD.
3. With the ~~pasteurizer~~ pasteurization system operating on water, above the minimum legal pasteurization temperature; and with the FDD in the ~~diverted~~ diverted-flow position, ~~because of excessive~~ due to exceeding the high flow rate alarm set point, slowly decrease the flow rate.
4. Start the ~~stopwatch~~ accurate device the instant the flow rate recorder-controller's frequency pen ~~on the flow recorder/controller~~ indicates ~~the start of a forward-flow movement~~ flow rate cut-in.
5. Stop the ~~stopwatch~~ accurate time measuring device the instant the FDD starts to move to the forward-flow position.
6. Record the results of this Test on the appropriate for the office record Form.

7. ~~Install and seal the enclosure over the time delay relay.~~

**Corrective Action:** If the time delay is less than the minimum pasteurization holding time, milk plant personnel shall increase the time setting on the time delay and repeat Test 11.2E shall be repeated. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.2F CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEM - HIGH FLOW ALARM RESPONSE TIME**

**Application:** To all continuous-flow pasteurization systems using a magnetic flow meter based timing system ~~to replace,~~ in lieu of a timing pump.

**Frequency:** Upon installation; ~~semiannually~~ at least once every six (6) months thereafter; whenever the seal on the flow alarm is broken; whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow or the capacity of the holding tube; or whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the flow alarm has been broken.

**Criteria:** When the flow rate equals or exceeds the value at which the pasteurization holding time was measured, the high flow alarm shall cause the FDD to assume the diverted diverted-flow position within one (1) second.

**Apparatus:** ~~Stopwatch~~ An accurate time measuring device.

**Method:** Rapidly increase the flow rate to exceed the high flow alarm and verify that the FDD ~~shifts~~ moves to the ~~diverted~~ diverted-flow position within one (1) second.

**Procedure:**

1. Operate the ~~pasteurizer~~ pasteurization system, using water above the minimum legal pasteurization temperature, in forward-flow, at a flow rate 25% below the high flow alarm set point as determined in Test 11.2B (Procedure 2).

2. ~~Mark~~ Identify the high flow alarm set point on the flow rate recorder recorder-controller chart with the high flow alarm set point. This may be accomplished by inscribing a line intersecting the recorded flow arc at the pen location or any other method acceptable to the Regulatory Agency.

**NOTE:** The appropriate temperature sensing elements may be placed in a water, or oil or other suitable media bath to simulate the normal processing pasteurization temperature within of the holding tube as an alternative to heating the water in the pasteurization system above the minimum legal pasteurization temperature. The Observation observation and recording of this the temperature high flow alarm response time should shall be done conducted as described in Procedures Procedures 3 and 4 through 6 below.

3. Increase the pasteurization system flow rate as rapidly as practical to a point above the high flow alarm set point.

**NOTE:** When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.

4. Start the ~~stopwatch~~ accurate time measuring device when the flow rate ~~recorder~~ recorder-controller's recording pen exceeds the high flow alarm set point.
5. Stop the ~~stopwatch~~ accurate time measuring device when the FDD has moved to the ~~diverted~~ diverted-flow position.
6. Record the ~~elapsed~~ high flow alarm response time on the appropriate Form for the office record.

**Corrective Action:** If the response time exceeds one (1) second, immediate ~~corrective~~ action must shall be taken by milk plant personnel to correct this FDD deficiency. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.3 CALCULATED HOLD PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING INDIRECT HEATING**

**Application:** To all HHST ~~pasteurizers~~ pasteurization systems using indirect heating.

**Frequency:** ~~When installed~~ Upon installation; semiannually at least once every six (6) months thereafter; ~~whenever the seal on the speed setting is broken;~~ whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, i.e., such as the replacement of the timing pump, motor, belt, driver drive or driven pulley, decrease in the number of HHST pasteurization system heat-exchange plates, or the capacity of the holding tube; and whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.

**Criteria:** Every particle of milk and/or milk product shall be held for the applicable minimum pasteurization holding time in both the ~~forward~~ forward-flow and diverted-flow positions.

**Apparatus:** No supplemental materials ~~needed~~ required.

**Method:** ~~For this Test, Fully~~ fully developed laminar flow is assumed and the required holding tube length is shall be calculated from an experimental determination of the pumping rate. An experimental determination of the pumping rate is ~~required; this is~~ can be accomplished by determining the time required for the ~~pasteurizer~~ pasteurization system to fill a vessel of a known volume; converting these data by division to obtain the flow rate in gallons per second; and then multiplying this value, by the proper value referenced in Table 14 to determine the required holding tube length. ~~Holding tube lengths for HHST pasteurizers with indirect heating for a pumping rate of 1 gallon/second are:~~

<b>Table 14. Holding Tube Length - HHST Pasteurizers <u>Pasteurization System- Indirect Heating</u> - at a Pumping Rate of 1 gallon/second</b>			
<b>Tubing Size (inches)</b>			
<u>Pasteurization Holding Time (sec.)</u>	2	2-1/2	3
<b>Holding Tube Length (inches)</b>			
1.0	168.0	105.0	71.4
0.5	84.0	52.4	35.7
0.1	16.8	10.5	7.14

0.05	8.4	5.24	3.57
0.01	1.68	1.05	.714

**Procedure:**

1. ~~Examine the entire~~ Operate the pasteurization system on water, in forward-flow, with to ensure that all flow-promoting equipment is devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding equipment is so devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system. Remove in-line filters; make sure the booster pump is operating; and that vacuum equipment in the system is operating at the maximum vacuum. Also, before the Tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system, about fifteen (15) minutes, and tighten the pipe connections on the suction side of the timing pump, tight enough to exclude the entrance of air. With the pasteurizer operating on water, adjust the timing pump to its maximum capacity, preferably with a new belt and full-size impellers.

There shall not be any leakage on the suction side of the timing pump.

- a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.
- b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.
- c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

**NOTE:** For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required to deliver a known volume of water at the discharge outlet of the pasteurizer pasteurization system in forward flow. Repeat the Test determine that until the measurements are consistent.
3. Repeat **Procedures** 1 and 2 in diverted-flow by collecting the effluent water at the pasteurization system's diverted-flow discharge of the divert line.
4. Select the ~~greatest~~ highest flow rate, the shortest delivery time for the known volume; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 14 to determine the required holding tube length for the pasteurization system.
5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. ~~Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration for the office record. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall be protected against heat loss by material that is impervious to water.~~

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the

direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water.

6. ~~Re-seal the regulatory controls as necessary.~~ When the actual holding tube length is equivalent to or greater than the calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipe, the holding tube configuration and the results on the appropriate Form. If the actual holding tube length is not equivalent or greater than the calculated minimum holding tube length, refer to the **Action** noted below.

**Alternate Procedure for Measuring the Flow Rate:** ~~For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient. The following alternate Test procedure may be used. Remove the divert line from the constant-level tank and turn off the milk or milk product pump feeding the constant level tank. Suspend a sanitary dipstick in the constant-level tank and operate the pasteurizer pasteurization system at its maximum flow capacity. Record the time that is required for the water level in the constant-level tank to move drop between two (2) identified graduations on the dipstick. The volume of water is calculated from the dimensions of the constant-level tank and the drop in water level. The Flow flow rate is determined as follows:~~

1. Divide the volume of water, in gallons, removed from the constant-level tank by the time, in seconds, required to remove # the volume of water.
2. Then use this flow rate to calculate the required holding tube length as provided in Procedures 3 and 4 above. Table 14 to calculate the required holding tube length.

**Alternate Procedures for the Determination of the Holding Tube Length for Non-Standard Pipe Size:** The holding tube length may be accurately calculated from the following equation:

$$L = 588 Qt/D^2$$

- Where: L = Holding tube length (inches)  
 Q = Pumping rate (gallons per second)  
 t = ~~Pasteurization~~ Holding holding time standard (seconds)  
 D = Internal diameter of the holding tube (inches)

~~Table 15 provides internal pipe diameters for piping in HHST holding tubes with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches.~~

**NOTE:** Table 15 provides the internal pipe diameters for piping in a HHST pasteurization system's holding tube with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches. Internal diameters, for pasteurization system's holding tubes designed for high pressure and for holding tubes with external piping sizes not listed in Table 15, ~~must~~ shall be individually determined and the minimum holding tube length calculated using the above formula.

<b>Table 15. Dimension for Standard Stainless Steel Sanitary Tubing<sup>1</sup></b>	
<b>Nominal External Diameter<sup>2</sup></b>	<b>Internal Diameter<sup>2</sup></b>

2.0	1.870
2.5	2.370
3.0	2.870
4.0	3.834

<sup>1</sup> Abstracted from Table 6.1 “Pipe and Heat Exchanger Tube Dimensions”, Fundamentals of Food Process Engineering, 1979, R. T. Toledo, AVI Press

<sup>2</sup> Measurements are in inches.

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. ~~The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.~~ Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration results on the appropriate Form.

**Corrective Action:** If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing pump system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat this the Test Procedure Procedure previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

#### **11.4 CALCULATED HOLD PASTEURIZATION HOLDING TIME FOR HHST PASTEURIZATION SYSTEMS USING DIRECT HEATING**

**Application:** To all HHST ~~pasteurizers~~ pasteurization systems using direct ~~contact~~ heating.

**Frequency:** ~~When installed~~ Upon installation; semiannually at least once every six (6) months thereafter; whenever the seal on the speed setting is broken; whenever any alteration is made affecting the pasteurization holding time, the velocity of the flow, i.e., such as replacement of the timing pump, motor, belt, driver drive or driven pulley, or a decrease in number of heat-exchange plates; or the capacity of the holding tube; and whenever a check of the capacity of the holding tube indicates a speedup; or whenever the regulatory seal on the timing pump speed setting has been broken.

**Criteria:** Every particle of milk and/or milk product shall be held for the appropriate minimum pasteurization holding time in both the forward forward-flow and diverted-flow positions.

**Apparatus:** No supplemental materials ~~needed~~ required.

**Method:** For this Test, Fully fully developed laminar flow and a temperature increase by the steam injection of 67°C (120°F) are assumed; and the processor chooses the temperature-time standard and the required holding tube length is calculated from an experimental determination of the pumping rate.

**Procedure:**

1. ~~Examine the entire~~ Operate the pasteurization system on water, in forward-flow, with to

~~ensure that all flow-promoting equipment is devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding equipment is so devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system. Remove in-line filters; make sure the booster pump is operating; and that vacuum equipment in the system is operating at the maximum vacuum. Also, before the Tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system, about fifteen (15) minutes, and tighten the pipe connections on the suction side of the timing pump, tight enough to exclude the entrance of air. With the pasteurizer operating on water, adjust the timing pump to its maximum capacity, preferably with a new belt and full-size impellers.~~

There shall not be any leakage on the suction side of the timing pump.

- a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.
- b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.
- c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).
- d. When vacuum equipment is present, operate the vacuum equipment at maximum vacuum rate.

**NOTE:** For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required to deliver a known volume of water at the discharge outlet of the ~~pasteurizer~~ pasteurization system ~~in forward flow.~~ Repeat the Test ~~to determine that until~~ the measurements are consistent.
3. Repeat **Procedures** 1 and 2 in diverted-flow by collecting the ~~effluent~~ water at the pasteurization system's diverted-flow discharge of the divert line.
4. Select the ~~greatest~~ highest flow rate, the shortest delivery time for the known volume; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 16 to determine the required holding tube length for the pasteurization system. ~~Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are:~~

<b>Table 16. Holding Tube Length, HHST Pasteurizers <del>Pasteurizer</del> Pasteurization System, Direct Heating - at a Pumping Rate of 1 gallon/second</b>			
<b>Tubing Size (inches)</b>			
<u>Pasteurization Holding time Time (sec.)</u>	2	2-1/2	3
	Holding tube length (inches)		

1	188.0	118.0	80.0
0.5	94.0	59.0	40.0
0.1	18.8	11.8	8.0
0.05	9.40	5.90	4.0
0.01	1.88	1.18	0.8

5. The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. ~~If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 of an inch) per foot. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall also be protected against heat loss by material that is impervious to water.~~

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. If the indicating temperature sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall be protected against heat loss by a material that is impervious to water.

6. ~~Re-seal the regulatory controls as necessary. When the actual holding tube length is equivalent to or greater than the calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipe, the holding tube configuration and the results on the appropriate Form. If the actual holding tube length is not equivalent or greater than the calculated minimum holding tube length, refer to the **Action** noted below.~~

**Alternate Procedure for Measuring the Flow Rate:** ~~For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient. The following alternate Test procedure may be used. Remove the divert line from the constant-level tank and turn off the milk or milk product pump feeding the constant level tank. Suspend a sanitary dipstick in the constant-level tank and operate the pasteurizer pasteurization system at its maximum flow capacity. Record the time that is required for the water level in the constant-level tank to ~~move~~ drop between two (2) identified graduations on the dipstick. The volume of water is calculated from the dimensions of the constant-level tank and the drop in water level. The Flow flow rate is determined as follows:~~

1. Divide the volume of water, in gallons, removed from the constant-level tank by the time, in seconds, required to remove ~~it~~ the volume of water.
2. Then use this flow rate to calculate the required holding tube length as provided in Procedures 3 and 4 above. ~~Table 16 to calculate the required holding tube length.~~

**Alternate Procedures for the Determination of the Holding Tube Length for Non-Standard Pipe Size:** The holding tube length may also be accurately calculated from the following equation:

$$L = (588 Qt \times 1.12)/D^2$$

Where: L = Holding tube length (inches)  
Q = Pumping rate (gallons per second)  
t = Pasteurization Holding holding time standard (seconds)  
1.12 = 12% expansion for steam  
D = Internal diameter of the holding tube (inches)-  
1.12 = 12% expansion for steam

Table 15 provides internal pipe diameters for piping in a ~~HHST~~ holding tubes with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches.

**NOTE:** Table 15 provides the internal pipe diameters for piping in a HHST pasteurization system's holding tube with nominal external diameters of 2.0, 2.5, 3.0 and 4.0 inches. Internal diameters, for pasteurization system's holding tubes designed for high pressure and for holding tubes with external piping sizes not listed in Table 15, ~~must~~ shall be individually determined and the minimum holding tube length calculated using the above formula.

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. ~~The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.~~ Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration results on the appropriate Form.

**Corrective Action:** If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing pump system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat the Procedure Test Procedure previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

### **11.5 HHST PASTEURIZATION SYSTEMS HOLDING TIME—USING DIRECT STEAM INFUSERS INFUSION HEATING WITH A STEAM PRESSURE RELIEF POP-OFF VALVE AND A VACUUM CHAMBER ORIFICE USED IN PLACE OF A TIMING PUMP**

**Application:** To all HHST ~~pasteurizers~~ pasteurization systems using direct steam infusion heating and using a steam pressure relief pop-off valve and a vacuum chamber orifice in place of a timing pump.

**Frequency:** Upon installation; at least once every each three (3) months thereafter; whenever the steam infusion shell or feed line, pressure relief pop-off valve or vacuum chamber orifice has been repaired or replaced; or when a whenever the regulatory seal has been broken.

**Criteria:** Every particle of milk and/or milk product shall be held for the applicable minimum pasteurization holding time in both the forward forward-flow and diverted-flow positions.

**Apparatus:** No supplemental materials ~~needed~~ required.

**Method:**

1. The steam ~~infuser~~ infusion shell or feed line shall be equipped with a pressure relief pop-off valve. This pressure relief pop-off valve shall be located and sized so that the total pressure inside the steam infuser infusion shell or feed line can never exceed the set point on this pressure relief pop-off valve.
2. An orifice or restriction, which is permanently installed in a noticeable fitting, shall be placed in the holding tube just prior to the vacuum chamber. The opening in the orifice or restriction, shall be sized to ensure a minimum milk and/or milk product residence pasteurization holding time at least as long as that specified in the chosen HHST pasteurization standard.
3. The size of the opening in the orifice or restriction and the setting of the pressure relief valve shall be determined by trial and error. Once an appropriate maximum flow rate has been determined and a ~~legal~~ minimum legal pasteurization holding time has been calculated, both the ~~restriction or orifice or restriction~~ and the steam pressure setting on the pressure relief pop-off valve shall be sealed by the Regulatory Agency so that neither can be changed or altered.
4. ~~The Regulatory Agency shall keep records of the orifice or restriction size. They shall also keep records of the location, size, setting and manufacturer of the pressure relief valve.~~

**Procedure:**

1. Operate the pasteurization system on water, in forward-flow, with to ensure that all flow-promoting equipment is devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding equipment is so devices adjusted or bypassed to provide the minimum amount of resistance to the flow through the pasteurization system.

There shall not be any leakage on the suction side of the timing pump.

- a. For a variable speed timing pump adjust the timing pump to its maximum capacity, preferably with a new belt and full size impellers.
- b. For a homogenizer used as the timing pump, check the homogenizer for its regulatory seal(s), and gears or pulley identification.
- c. For AC variable speed timing pump, check the timing pump's control box for its regulatory seal(s).

**NOTE:** For pasteurization systems that employ a liquid ingredient injection (slurry) system as described in Appendix H., the slurry injection pump shall be energized and running at its maximum speed and the slurry supply tank shall be completely filled with water.

2. The steam pressure in the steam infuser infusion shell or feed line shall be raised to a level just below the pressure relief pop-off point ~~on~~ of the pressure relief pop-off valve.
3. Any back-pressure valves or other variable restrictions in the holding tube shall be ~~normally~~ placed into the fully open position.
4. All air bleeds to the vacuum chamber shall be closed so that the vacuum chamber will be operating under maximum vacuum.
5. ~~Before the Tests are begun, operate~~ Operate the pasteurizer pasteurization system at its maximum flow for a sufficient time approximately fifteen (15) minutes to purge the air from the pasteurization system, about fifteen (15) minutes, and tighten the pipe connections to exclude the entrance of air.
6. ~~Determine that no flow exists in the diverted line, and measure~~ Measure the time required

to deliver a known volume of water at the discharge outlet of the ~~pasteurizer~~ pasteurization system in forward flow. Repeat the Test until the measurements are consistent.

~~7. Repeat the Test to determine that the measurements are consistent.~~

~~87.~~ Repeat **Procedures** 1 through 5 in diverted-flow by collecting the effluent water at the pasteurization system's diverted-flow discharge of the divert line.

~~98.~~ Select the greatest highest flow rate, the shortest delivery time for the known volume; and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect the known volume. Multiply this value with the appropriate value referenced in Table 16 to determine the required holding tube length for the pasteurization system.

~~10.~~ Multiply this value, gallons per second, with the appropriate value in Table 16 to determine the required holding tube length.

~~11.~~ Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are specified in Table 16.

~~129.~~ The holding tube may include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

~~13.~~ Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 of an inch) per foot.

**NOTE:** The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters (0.25 of an inch) per foot. ~~14.~~ If the indicating temperature sensor sensing element is located at the beginning of the holding tube, the entire length of the holding tube shall also be protected against heat loss by a material that is impervious to water.

~~1510.~~ If the actual holding tube length is equivalent to or greater than the required calculated minimum holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration and results for the office record on the appropriate Form.

~~16.~~ Re-seal the regulatory controls as necessary.

**Corrective Action:** If the length of the holding tube is shorter than the calculated required minimum length, reseal the timing pump system at a slower maximum speed, based on new calculations with this slower maximum speed, or have milk plant personnel lengthen the holding tube, or both, and repeat the Test Procedure previously used. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 12.

### THERMAL-LIMIT-CONTROLLER FOR CONTROL - SEQUENCE LOGIC

**References:** Items 16p.(B) and (D)

Thermal-limit-controllers used with ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section shall be tested by one (1) of the following applicable Tests at the frequency prescribed:

## 12.1 PASTEURIZATION - INDIRECT HEATING

**Application:** To all ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section and using indirect heating.

**Frequency:** Upon installation; at least once every each three (3) months thereafter; whenever the thermal-limit-controller has been repaired or replaced; or ~~when~~ whenever the a regulatory seal has been broken.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow until the milk and/or milk ~~product~~ product-contact surfaces downstream from the holding tube have been sanitized. Upon start-up, milk and/or milk product-contact surfaces shall be exposed to fluid at the applicable required pasteurization temperature for at least the applicable required pasteurization or sterilization time. If any public health control causes the FDD to assume the diverted-flow position due to incorrect temperature, pressure or flow, forward-flow shall not be re-achieved until the milk and/or milk product-contact surfaces downstream from the holding tube have been re-sanitized or re-sterilized as appropriate.

**Apparatus:** A constant temperature bath of water, ~~or oil,~~ or other suitable media and the test ~~lamp~~ light from the pneumatic testing device described in Test 9.1 may be used to check the control-sequence logic of the thermal-limit-controller.

**Method:** The control-sequence logic of the thermal-limit-controller is determined by monitoring the electric signal from the thermal-limit-controller during a series of immersions and removals of the two (2) sensing elements, located at the FDD and in the holding tube, from a media bath heated above the cut-in temperature.

### **Procedure:**

1. Heat the ~~water or oil~~ media bath to a constant temperature, a few degrees above the cut-in temperature ~~on~~ of the thermal-limit-controller. Wire the test ~~lamp~~ light in series with the signal from the thermal-limit-controller to the FDD.

**NOTE:** Some processors may have time delays built into their control logic in excess of that required for public health reasons. If so equipped, by-pass these ~~timers~~ time delays or account for their effect in delaying forward-flow.

2. Immerse the sensing element ~~of~~ from the FDD ~~in~~ into the media bath, which is above the cut-in temperature. The test ~~lamp~~ light ~~should~~ shall remain ~~unlighted~~ unlit, i.e., indicating diverted-flow. Leave ~~the~~ this sensing element in the media bath.

3. Immerse the sensing element from the holding tube ~~in~~ into the media bath. The test ~~lamp~~ light ~~should~~ shall light up, i.e., indicating forward-flow after a minimum time delay of one (1) second for continuous-flow pasteurization systems.

4. Remove the sensing element ~~of~~ from the FDD from the media bath. The test ~~lamp~~ light ~~should~~ shall remain lighted lit, i.e., indicating forward-flow.

5. Remove the ~~holding-tube~~ sensing element from the holding tube from the media bath. The test ~~lamp~~ light ~~should~~ shall turn off immediately, i.e., indicating diverted-flow.

6. Re-immerses the sensing element ~~of from~~ the holding tube ~~in~~ into the media bath. The test ~~lamp light should~~ shall remain ~~unlighted~~ unlit, i.e., indicating diverted-flow.

7. ~~Re-seal the regulatory controls as necessary. Record the results of the Test on the appropriate Form.~~

**Corrective Action:** If the control-sequence logic of the thermal-limit-controller does not follow these **Procedures**, the instrument shall be reconfigured to conform to this logic. If after reconfiguration, the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## 12.2 PASTEURIZATION - DIRECT HEATING

**Application:** To all ~~HHST~~ HTST and ~~HTST~~ HHST pasteurization systems that have the FDD located downstream ~~from~~ of the pasteurized regenerator section(s) and/or cooler section and using direct ~~contact~~ heating.

**Frequency:** Upon installation; at least once every each three (3) months thereafter; whenever the thermal-limit-controller has been repaired or replaced; or ~~when~~ whenever the a regulatory seal has been broken.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow until the milk and/or milk product-product-contact surfaces downstream from the holding tube have been sanitized. Upon start-up, milk and/or milk product-contact surfaces shall be exposed to fluid at the applicable required pasteurization temperature for at least the applicable required pasteurization or sterilization time. If the milk and/or milk product temperature falls below the applicable pasteurization standard in the holding tube, forward-flow shall not be re-achieved until the milk and/or milk product-contact surfaces downstream from the holding tube have been re-sanitized or re-sterilized as appropriate.

**Apparatus:** A constant temperature bath of water, ~~or~~ oil, or other suitable media and the test ~~lamp light~~ from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal-limit-controller.

**Method:** The control-sequence logic of the thermal-limit-controller is determined by monitoring the electric signal from the thermal-limit-controller during a series of immersions and removals of the three (3) sensing elements, located at the FDD, vacuum chamber and in the holding tube, from a media bath heated above the cut-in temperature.

### **Procedure:**

1. Heat a ~~water or oil~~ media bath to a constant temperature, a few degrees above the cut-in temperature on the thermal-limit-controller. Wire the test ~~lamp light~~ in series with the signal from the thermal- limit-controller to the FDD.

**NOTE:** Some processors have time delays built into their control logic, in excess of that required for public health reasons. If so equipped, bypass these ~~timers~~ time delays or account for their effect in delaying forward-flow. Before performing this Test, make sure the pressure switches, which ~~must~~ shall be closed to achieve forward-flow, have also been bypassed.

2. Immerse the sensing element from the FDD ~~in~~ into the media bath ~~that,~~ which is above the cut-in temperature. The test ~~lamp light should~~ shall remain ~~unlighted~~ unlit, i.e., indicating

diverted-flow. Remove this sensing element from the media bath.

3. Immerse the sensing element, ~~in~~ into the media bath. The test ~~lamp light should~~ shall remain ~~unlighted~~ unlit, i.e., indicating diverted-flow. Remove ~~the~~ this sensing element from the media bath.

4. Immerse the two (2) sensing elements ~~located at~~ from the vacuum chamber and the FDD, into the media bath. The test ~~lamp light should~~ shall remain ~~unlighted~~ unlit, i.e., indicating diverted-flow. Leave ~~the~~ these two (2) sensing elements in the media bath.

5. Immerse the third sensing element ~~located at~~ from the holding tube, into the media bath. The test ~~lamp light should~~ shall light up, i.e., indicating forward-flow, after a minimum time delay of one (1) second for continuous-flow pasteurization systems.

6. Remove the ~~FDD~~ sensing element from the FDD from the media bath. The test ~~lamp light should~~ shall remain lighted lit, i.e., indicating forward-flow.

7. Remove the ~~vacuum chamber~~ sensing element from the vacuum chamber from the media bath. The test ~~lamp light should~~ shall remain lighted lit, i.e., indicating forward-flow.

8. Remove the remaining, ~~holding tube~~, sensing element from the holding tube from the media bath. The test ~~lamp light should~~ shall immediately turn off, i.e., indicating diverted-flow, immediately.

9. Re-immerses the ~~holding tube~~ sensing element from the holding tube into the media bath. The test ~~lamp light should~~ shall remain ~~unlighted~~ unlit, i.e., indicating diverted-flow.

10. ~~Re-seal the regulatory controls as necessary.~~ Record the results of the Test on the appropriate Form.

**Corrective Action:** If the control-sequence logic of the thermal-limit-controller does not follow these **Procedures**, the instrument shall be reconfigured to conform to this logic. If after reconfiguration the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 13.

### SETTING OF CONTROL SWITCHES FOR MILK AND/OR MILK PRODUCT PRESSURE IN THE HOLDING TUBE

**Reference:** Item 16p.(B) and (D)

**Application:** To all HHST pasteurization systems, which are capable of operating with milk and/or milk product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube.

**Frequency:** Upon installation; at least once every each three (3) months thereafter; whenever the pressure switch has been repaired or replaced; whenever the pressure switch regulatory seal is broken; and or whenever the operating temperature is changed.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the milk and/or milk product.

**Apparatus:** A The sanitary pressure gauge and a the pneumatic testing device described in Test 9.1 can be used for checking and adjusting the pressure switch setting.

**Method:** The pressure switch is checked and adjusted so as to prevent forward-flow unless

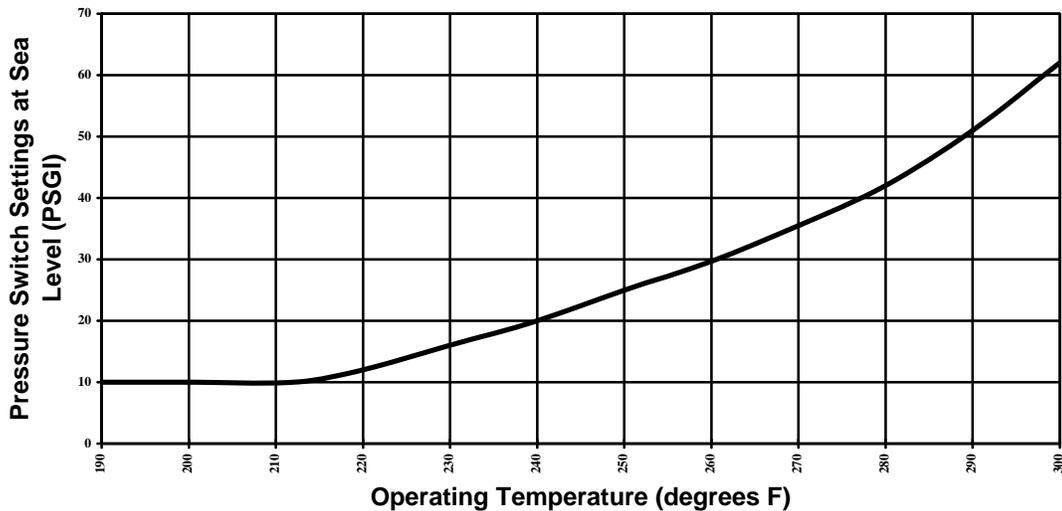
the milk and/or milk product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the milk and/or milk product.

**Procedure:**

1. ~~From~~ Using Figure 57 determine the pressure switch setting necessary for the operating temperature being used in the pasteurization system, do not use the diversion temperature; ~~being used in the process~~. Install the sanitary pressure gauge, ~~of known accuracy~~, and the pressure switch sensing element on the pneumatic testing device.
2. Remove the regulatory seal and cover to expose the adjustment mechanism on the pressure switch. Place the test ~~lamp~~ light in series with the pressure switch contacts or use some other method to monitor the cut-in signal.
3. Apply air pressure to the pressure switch sensing element and determine the pressure gauge reading at the cut-in point of the pressure switch, which ~~should~~ shall turn on the test ~~lamp~~ light. If the pressure switch is short circuited, the ~~lamp~~ light will ~~be lit~~ light up before the air pressure is applied.
4. Determine that the cut-in pressure on the pressure switch is equivalent to or greater than the required pressure from Figure 57. If adjustment is necessary, refer to the manufacturer's instructions.
5. After the necessary adjustment is made, repeat the Test.
6. ~~When the results are satisfactory, seal the pressure switch setting and record the results for the office record.~~ Record the results of the Test on the appropriate Form.

**Action:** If forward-flow is achieved with less than 69 kPa (10 psi) above the boiling point of the milk and/or milk product in the holding tube, adjust the pressure setting and retest. If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

For each HHST ~~pasteurizer~~ pasteurization system temperature, the milk and/or milk product pressure switch setting is as follows:



## Figure 57. Pressure Switch Setting

This pressure switch setting shall be adjusted upward by the difference between the routine local ~~normal~~ atmospheric pressure and the atmospheric pressure at sea level.

### TEST 14.

#### **SETTING OF THE CONTROL FOR THE DIFFERENTIAL PRESSURE SWITCHES CONTROLLER FOR DIFFERENTIAL PRESSURE ACROSS THE STEAM INJECTOR**

**Reference:** Item 16p.(B) and (D)

**Application:** To all HTST and HHST continuous-flow pasteurization systems using direct steam injection heating.

**Frequency:** : Upon installation; at least once every each three (3) months thereafter; whenever the differential pressure controller has been repaired or replaced; and or whenever the differential pressure ~~controller~~ controller's regulatory seal is broken.

**Criteria:** The ~~pasteurizer~~ pasteurization system shall not operate in forward-flow unless the milk and/or milk product pressure drop across the steam injector is at least 69 kPa (10 psi).

**Apparatus:** A The sanitary pressure gauge and a the pneumatic testing device described in Test 9.1 can be used for checking and adjusting the differential pressure controller.

**Method:** Adjust the differential pressure switch controller to prevent forward-flow, unless the pressure differential ~~pressure~~ across the steam injector is at least 69 kPa (10 psi).

#### **Procedure:**

##### **1. Calibration of the Steam Injector Differential Pressure Controller ~~Probes~~ Sensing Elements:**

a. Loosen the connection at both pressure ~~sensors~~ sensing elements and allow for any liquid to drain through the loose connections. While the sensing elements are still in their original positions. ~~Both both~~ pointers; or the digital ~~displays~~ display(s), shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s); or the digital display(s), to read 0 kPa (0 psi).

b. Remove both ~~sensors~~ sensing elements and ~~mount~~ install them ~~in~~ onto a tee; or connect them to a the pneumatic testing device. Record any difference ~~in~~ from the zero (0 kPa (0 psi)) readings in Procedure 1.a. that may have occurred ~~because of this change in elevation~~ when installing the sensors sensing elements onto the tee. Attach the tee and both ~~sensors~~ sensing elements to a the pneumatic testing device described in Test 9.1 and adjust the air pressure to the ~~normal~~ operating pressure used at the steam injector. Make sure that the ~~pointer~~ pointer(s) or digital ~~display~~ display(s) reading separation is within 6.9 kPa (1 psi) of that observed before the pressure was applied. If not, the ~~instrument~~ differential pressure controller requires adjustment or repair.

c. ~~When the results are satisfactory, record the Test results for the office record and proceed as directed below.~~

##### **2. Setting of the Steam Injector Differential Pressure Controller Switch:**

a. Disconnect the sanitary pressure sensing element that is ~~normally~~ located after the steam injector from the pneumatic testing device and cap the ~~resulting~~ opening. Leave the pressure sensing element, which is installed prior to the steam ~~injection~~ injector, on the pneumatic testing device.

b. Leave the other pressure sensing element open to the atmosphere, but at the same

- height as the pressure sensing element connected to the pneumatic testing device.
- c. Wire the test ~~lamp~~ light in series with the differential pressure controller microswitch or use the method provided by the instrument manufacturer to monitor the cut-in signal.
  - d. Apply air pressure to the pressure sensing element and determine, from the test ~~lamp~~ light, the pressure gauge reading at the cut-in point of the differential pressure ~~switch~~ controller.
  - e. The differential pressure cut-in on the differential pressure controller shall be at least 69 kPa (10 psi). If adjustment is necessary, refer to the manufacturer's instructions.
  - f. After adjustment, repeat ~~the~~ this Test.
  - ~~g. When the results are satisfactory, seal the instrument and record the results for the office record.~~

3. Record the results of the Test on the appropriate Form.

**Action:** If after adjustment the pasteurization system fails this Test, the pasteurization system shall not be allowed to operate until the cause of this failure has been corrected and compliance has been verified by the Regulatory Agency; or in the case of HACCP listed milk plants, qualified industry personnel, acceptable to the Regulatory Agency, in compliance with Item 16p.D; or on an emergency basis, an industry temporary testing and sealing program, authorized by the Regulatory Agency, in compliance with Item 16p.D.

## TEST 15.

### ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

**Application:** To all electronic control devices used to assure compliance with public health safeguards on HTST and HHST continuous-flow pasteurization equipment that are installed in milk plants.

**Frequency:** Upon installation; ~~any alteration of the electronic control devices; at least once every~~ each three (3) months thereafter; whenever any alteration of the electronic control devices occur; and or whenever the type or wattage of the hand-held communication device(s) used in that milk plant is changed. Once a hand-held communication device has been shown to cause a given electronic control device to react adversely, the electronic control device ~~must~~ shall be repaired and re-tested using the same type hand-held communication device. (Refer to the **NOTE:** below.) If any electronic control device is altered or there is a change in the hand-held communication device(s) used, the electronic control device(s) ~~would be required to~~ shall be tested.

**Criteria:** The use of hand-held communication devices shall not have any adverse effect on the electronic control device's public health safeguards.

**Apparatus:** One (1) hand-held communication device representing each make and model used in the milk plant. The hand-held communication device ~~device(s)~~ must shall be operating at maximum output and be fully charged.

**Method:** By observing the actual effect of the hand-held communication device on an electronic control device, it can be determined if that hand-held communication device can be used near that equipment without compromising any of the electronic control device's public health ~~safeguard~~ safeguards.

**Procedure:**

1. Position the hand-held communication device 30.5 centimeters (12 inches) in front of the electronic control device where the public health safeguard(s) resides.

# 34th NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	117
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

## A. Summary of Proposal

This Proposal provides updated and simplified criteria/requirements for the use of pressure relief valves within HTST pasteurization systems. The simplified criteria/requirements do not change what is currently required but only provide a more easily understandable statement of these criteria/requirements.

## B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

By making these criteria/requirements easier to understand, hopefully it will increase the likelihood of industry providing and Regulatory Agency's accepting compliant pressure relief valves within HTST pasteurization systems.

## C. Proposed Solution

Changes to be made on page(s):	<u>222, 223, 296, and 299</u>	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/> 2011 EML	
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/> 2400 Forms	
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/> 2011 Constitution and Bylaws	

**MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:**

Strike through text to be deleted and underline text to be added.

Page 222:

**PRESSURE RELIEF VALVES LOCATED WITHIN DOWNSTREAM FROM THE HOLDING TUBE WITHIN HTST PASTEURIZATION SYSTEMS**

~~Between the Timing Pump and the Beginning of the Holding Tube:~~ Placement of a pressure relief valve between the timing pump and the beginning of the holding tube is acceptable provided it meets either OPTION I or II below:

Page 223:

**OPTION I:**

- ~~a. Provisions are made for the cleaning of the valve vent and any return piping to the constant level tank whenever the system is cleaned.~~
- ~~b. The pasteurizer shall not be timed if the valve is leaking. Leakage may be determined by observation at the pressure relief valve vent opening to the floor or at the opening of the return piping from the pressure relief valve vent into the constant level tank.~~
- ~~c. The system is designed and operated so that loss of pressure from the pasteurized side of the regenerator cannot occur if the system flow promoting devices stop while the FDD is in the forward flow position. A system not protected against this potential pressure loss is considered a violation of Item 16p(C) of this Ordinance.~~

~~**OPTION II.** The pressure relief valve is spring loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator if the system flow promoting devices stop while the FDD is in the forward flow position. This is considered a violation of Item 16p(C) of this Ordinance. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant level tank and shall be provided with a properly located and installed sight glass.~~

~~2. **Downstream from the Holding Tube:** The pressures in the pasteurized side of the regenerator ~~must~~ shall be protected from falling within 6.9 kPa (1 psi) of the pressures in the raw side of the regenerator at all times, including during shut down. A pressure relief valve and line on the pasteurized side of the FDD ~~can~~ will meet this criterion if:~~

- ~~a. After the relief valve and before the entrance to the pasteurized side of a regenerator, all milk or milk product rises at least 30.5 centimeters (12 inches) higher than the highest raw milk or milk product in the system, and is open to the atmosphere at that point; or~~
- ~~b. After exiting the pasteurized regenerator, and before the pressure relief valve, all milk or milk product must rise at least 30.5 centimeters (12 inches) higher than the highest raw milk or milk product in the system, and be open to the atmosphere at that point; or~~

e. ~~The pressure relief valve is spring loaded and plumbed so that it cannot be opened or forced open in any mode, “Product”, “CIP” or “Inspect”, without the assistance of pressure from the liquid flowing through the system. the pressure relief valve is fail-safe. In this case, a~~ A leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator during a shut down and is considered a violation of Item 16p(C) of this *Ordinance*. Any leakage from this pressure relief valve ~~must~~ shall be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

Page 296:

## TEST 11.

### CONTINUOUS-FLOW HOLDING TUBES – HOLDING TIME ...

#### 11.1 HTST PASTEURIZERS PASTEURIZATION SYSTEMS ...

Page 297:

#### **Procedure:**

1. ~~Examine the entire~~ Operate the pasteurization system on water to insure that with all flow-promoting ~~equipment is~~ devices, which are capable of causing flow through the FDD, operating at their maximum capacity and all flow-impeding ~~equipment is~~ so devices adjusted or bypassed ~~as~~ to provide the minimum amount of resistance to the flow through the pasteurization system. There shall not be ~~no~~ any leakage on the suction side of the timing pump.

NOTE: In pasteurization systems equipped with a pressure relief valve located between the timing pump and the beginning of the holding tube, this Test shall not be performed if the pressure relief valve is observed to be leaking. ...

Page 299

#### 11.2A CONTINUOUS-FLOW PASTEURIZATION SYSTEMS UTILIZING A MAGNETIC FLOW METER BASED TIMING SYSTEMS SYSTEM CONTINUOUS FLOW – PASTEURIZATION HOLDING TIME ...

#### **Procedure:**

Utilize either **TEST OPTION I** or TEST OPTION II.

NOTE: In pasteurization systems equipped with a pressure relief valve located between the timing pump and the beginning of the holding tube, this Test shall not be performed if the pressure relief valve is observed to be leaking. ...

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 118  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

Allow magnetic flow meters to be installed according to manufacturer's recommended installation instructions.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The current requirement of installing 10 diameters of straight pipe before and after magnetic flow meters is not necessary with the design of modern flow meters, and, in some cases, causes difficulties in the arrangement of components within a piping system. Manufacturers of approved magnetic flow meters have established recommended installation conditions, including inlet and outlet piping, that assure the accuracy of their flow meters. These recommendations should be sufficient to assure the accuracy of product flow through the holding tube.

**C. Proposed Solution**

Changes to be made on page(s): 227 of the (X - one of the following):

X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

Page 227

7. The magnetic flow meter shall be piped in such a manner that ~~at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the magnetic flow meter, before any elbow or change of direction takes place~~ conforms to the manufacturer's recommendations, including minimum distances of straight pipe at the inlet and outlet of the magnetic flow meter. Except that other piping configurations upstream and downstream of the magnetic flow meter may also be used if they have been reviewed and found acceptable to FDA and the Regulatory Agency.

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34th NATIONAL CONFERENCE ON  
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Proposal #: 119  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

This Proposal addresses changes to Figures 37, 39, 41 and 42 of the PMO to rectify errors identified in the existing HTST and HHST Pasteurization System Figures. This Proposal is limited to correcting those errors and does not create any additional requirements for continuous flow HTST or HHST pasteurization systems.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

Figures 37, 39, 41 and 42 currently include technical inaccuracies that may lead to confusion for individuals that utilize the Figures when evaluating HTST and HHST pasteurization systems for compliance with Item 16p-Pasteurization and Aseptic Processing and Packaging of the PMO.

By correcting and eliminating these errors and potential sources of confusion it will assist individuals during their evaluation of HTST and HHST pasteurization systems. The corrections to the Figures include: Figure 37 now includes a relocated stuffing pump, Figure 39 includes a valve identified as a Vacuum Stop Valve and adds a foot note “\* Or Other Effective Means of Preventing a Negative Pressure as Required by Section 7, Item 16p.(C), Administrative Procedures #9 of this *Ordinance*”, Figure 41 relocates the ratio controller sensor and Figure 42 deletes the differential pressure controller around the infusion chamber.

**C. Proposed Solution**

Changes to be made on page(s):		<u>232, 233 and 234</u>	of the (X - one of the following):	
<u>X</u>	2011 PMO			2011 EML
	2011 MMSR			2400 Forms
	2011 Procedures			2011 Constitution and Bylaws

***MAKE THE FOLLOWING CHANGES TO THE 2011 PMO:***

*Replace Figures 37, 39, 41 and 42 with the following revised Figures 37, 39, 41 and 42.*

***NOTE: In order to facilitate explanation of the areas of revision, a "Revision Cloud" is shown surrounding the area of the modification within each Figure. These revision clouds will be deleted in the final version for publication into the PMO.***

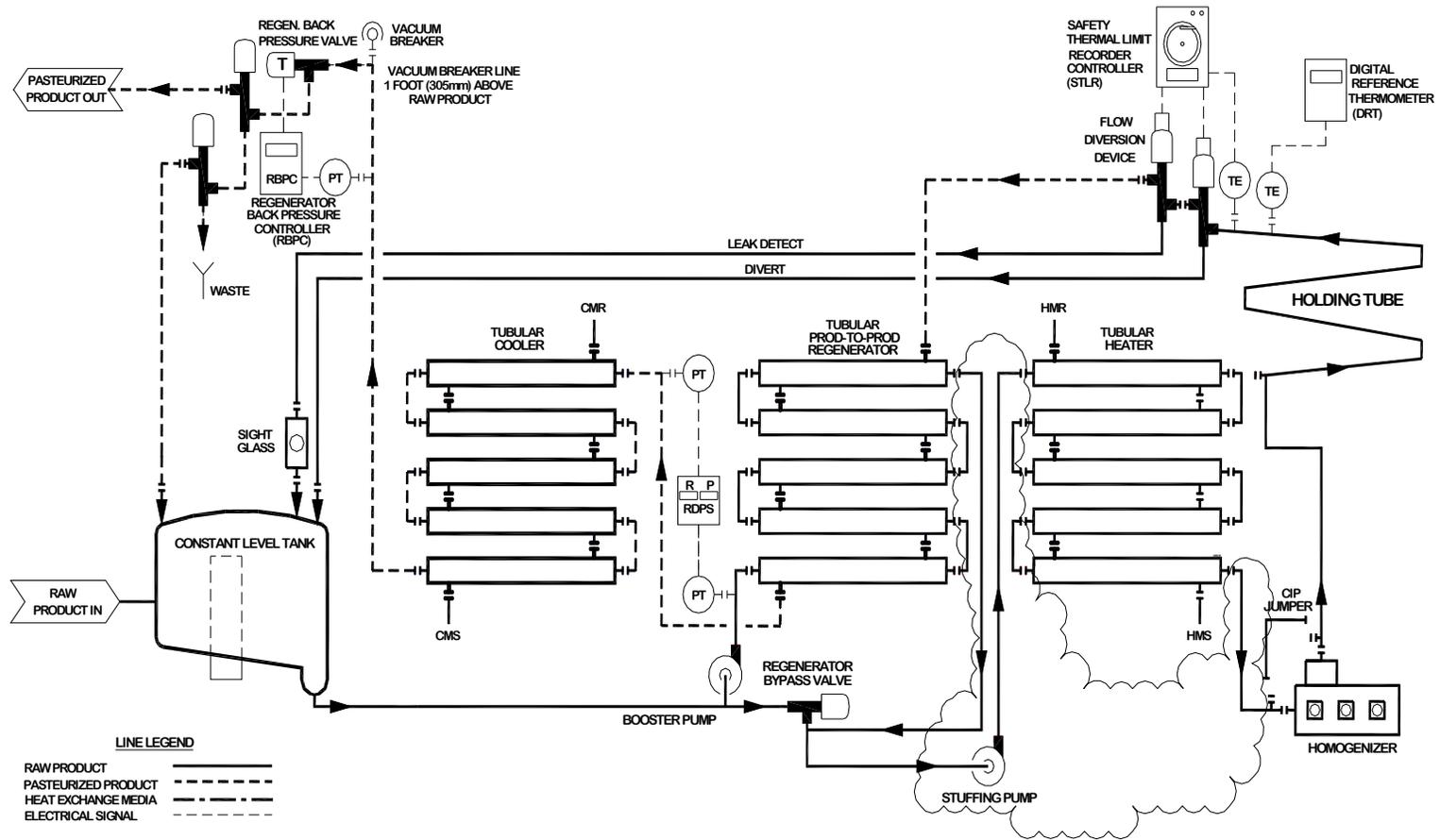
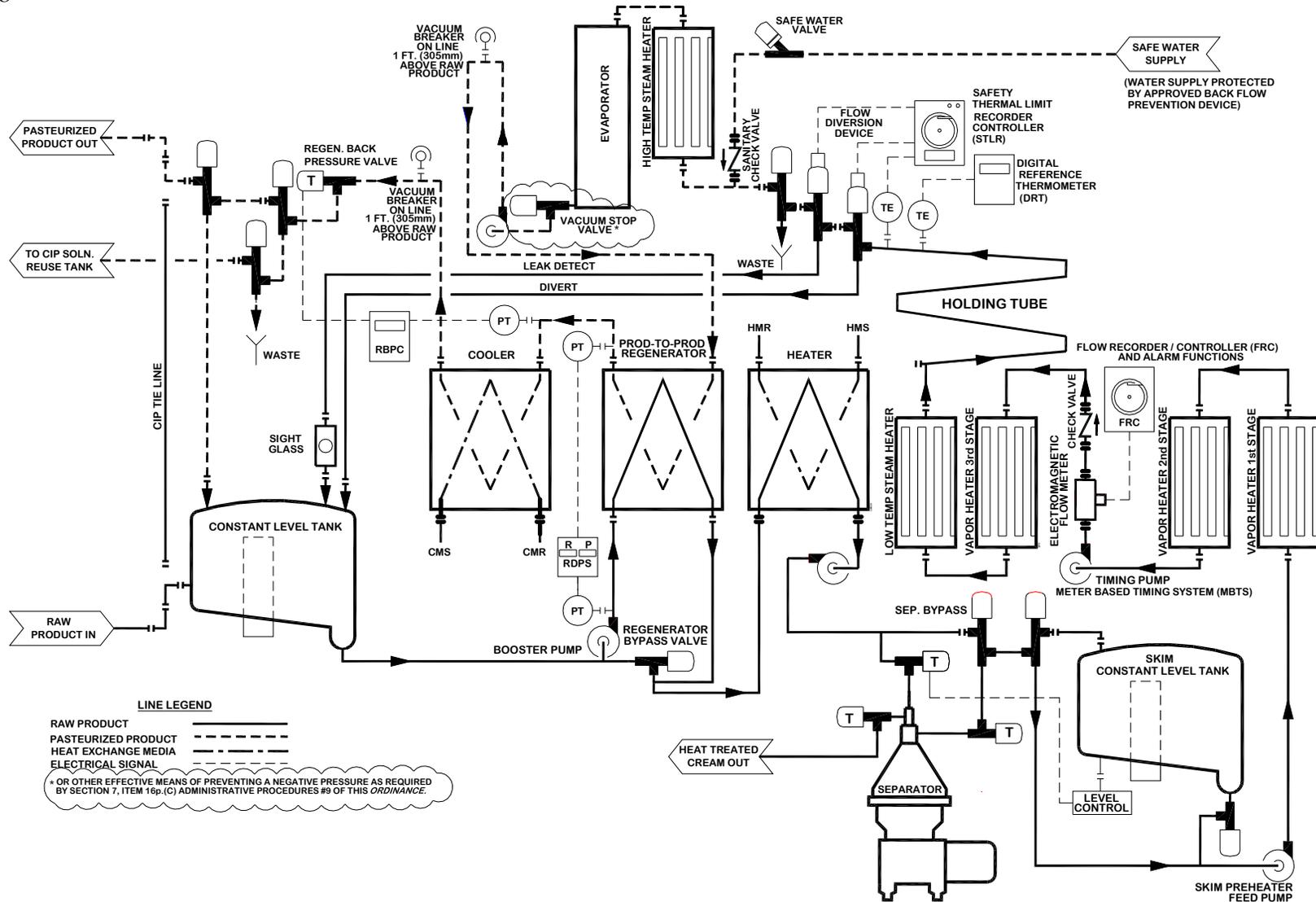
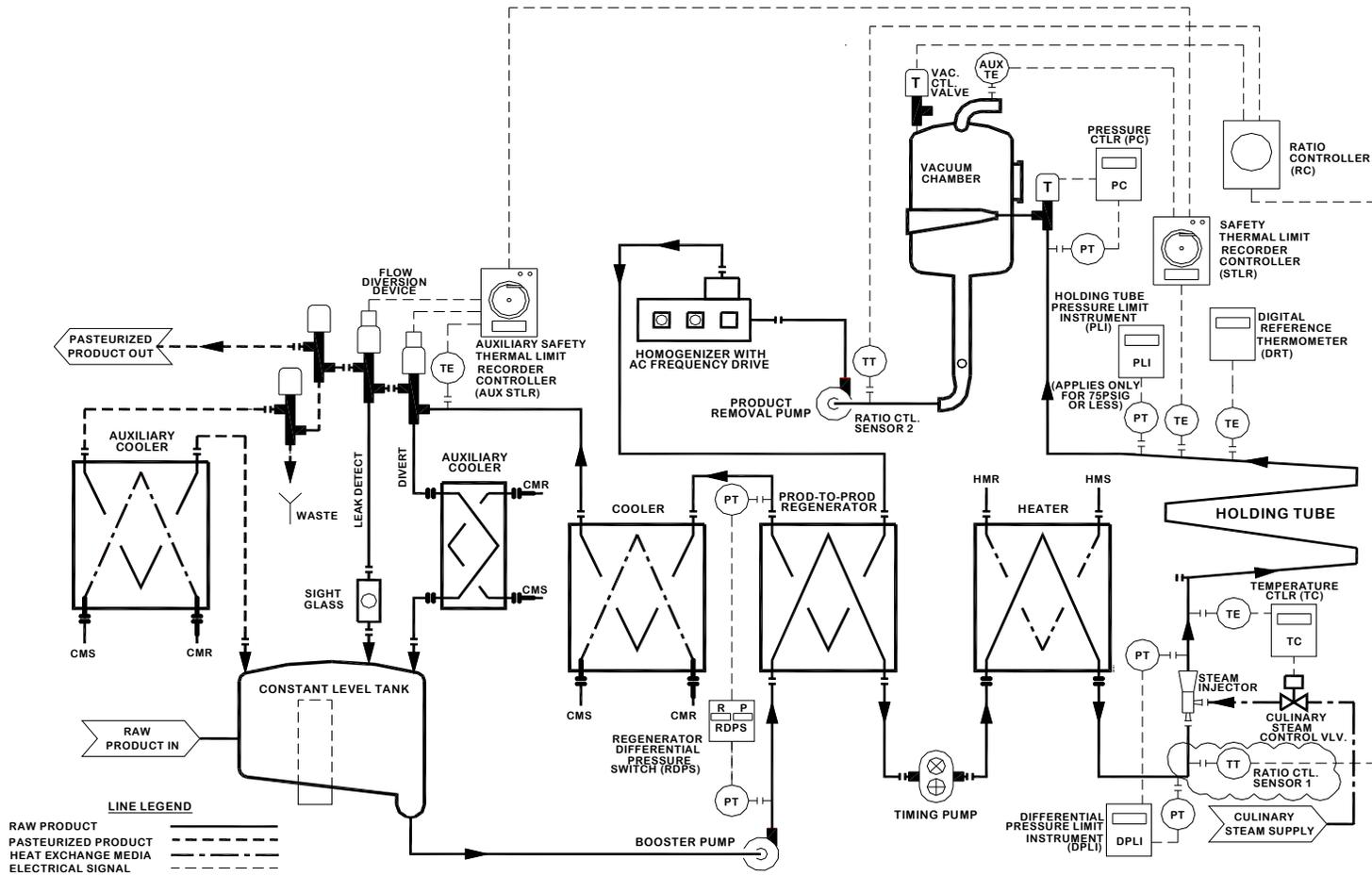


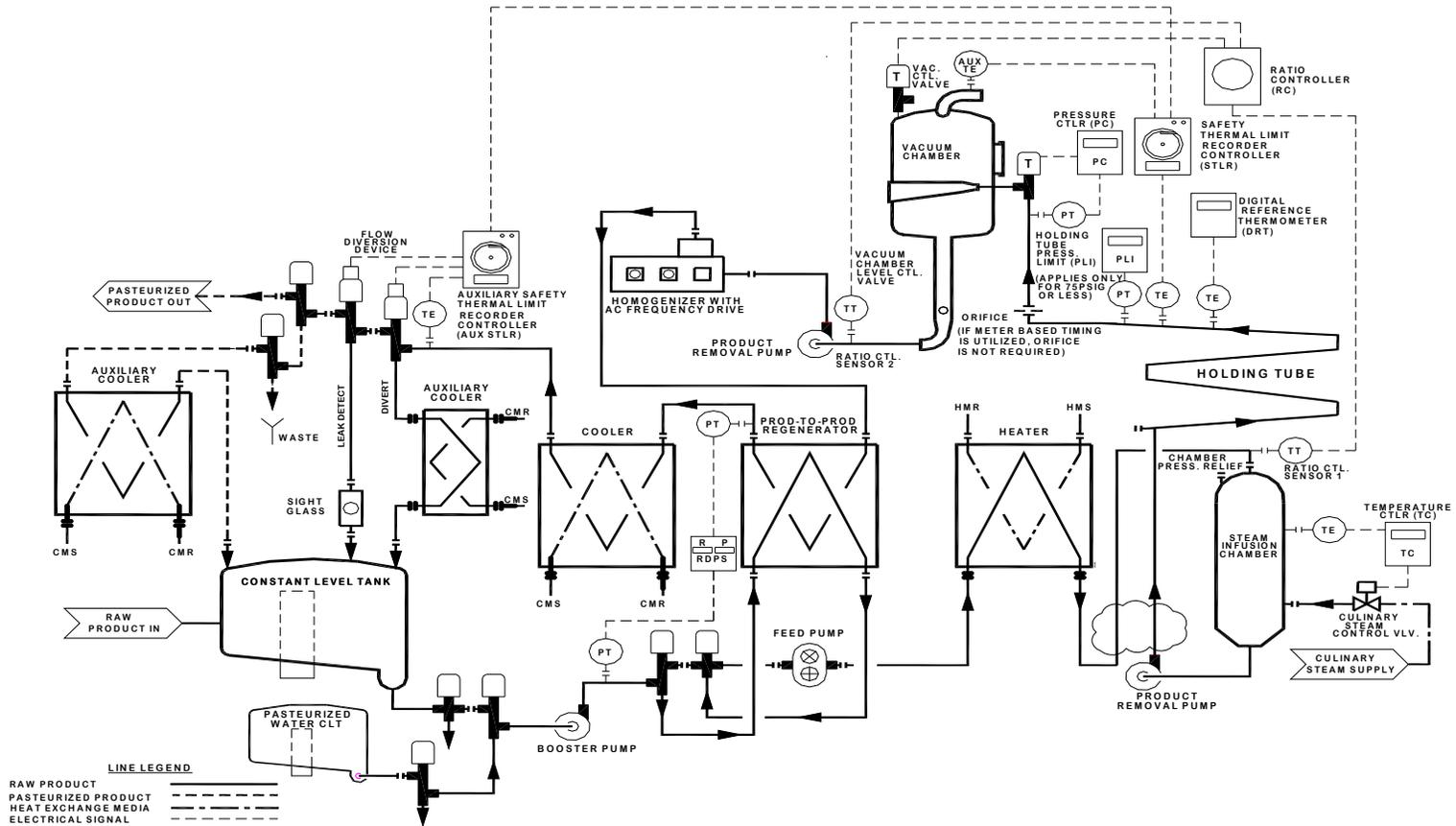
Figure 37. HTST Pasteurizer Utilizing Tubular Type Heat Exchangers and A Homogenizer as the Timing Pump



**Figure 39. HTST Pasteurizer with a Regenerator, Separator, Skim Surge Tank and a Meter Based Timing System Located Upstream from an Evaporator**



**Figure 41. HHST Pasteurizer Utilizing Steam Injection Heating, Vacuum Flash Cooling and a Flow-Diversion Device Located Downstream of the Cooler Section**



**Figure 42. HHST Pasteurizer Utilizing Direct Culinary Steam Infusion and Vacuum Flash Cooling with a Homogenizer Located Downstream**

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2. Place the hand-held communication device in the “send” mode for five (5) seconds and observe the effect on the electronic control device’s public health safeguard(s). There ~~should~~ shall not be any adverse effect with the electronic control device. An adverse effect is any change that may adversely affect an electronic control device’s public health safeguard(s).
3. If applicable, repeat the Test with the operator access door open
4. Repeat the above Test for each hand-held communication device identified ~~in the~~ under Apparatus Section.
5. Repeat the above Test for each electronic control device used to regulate a pasteurization system’s public health safeguard(s).
6. Record the make and model of each hand-held communication device tested and the Test results on the appropriate Form.

**For Example:** For the temperature set point, operate the pasteurization equipment on water in diverted-flow in the “Product” mode, at a steady temperature within 3°C (5°F) of the lowest cut-in temperature. In this example, an adverse effect is defined as the forward-flow movement of the FDD or any artificial increase in temperature.

**Corrective Action:** Have the milk plant check for shielding, grounding and other installation concerns with the electronic control device and retest. Until a solution, acceptable to the Regulatory Agency, can be found that does not adversely affect the electronic control device’s public health safeguard(s), the hand-held communication device cannot be used in the area of the electronic control device’s public health safeguard(s).

**NOTE:** Continuous “Hand-Held Communication Device Free” or “Radio Free” zones, etc., are not acceptable permanent solutions to hand-held communication devices which cause adverse affects to an electronic control device’s public health safeguards.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 120  
Committee: Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To approve the use of Beverage Grade, 0.2um Polyethersulfone, integrity testable, and validated membrane filtration for the creation of Pasteurized Equivalent Water in the Grade “A” Pasteurized milk Ordinance. This would replace or be used in addition to the existing information concerning Ultraviolet Light (UV) Disinfection Of Water now referenced.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The importance of the removal of viable and non-viable bacteria from water used in the production of PMO related products for direct consumption or those intermediates used for related purposes is critical to the stable formulation of those products. Validated process 0.2um microfiltration has long been a FDA approved method of bacterial removal from fluids used in critical processes where production operations must be monitored by both Plant QC and compendia inspectors. Sanitary Style microfiltration systems, properly sized and engineered, have become accepted insurance to operations to certify that physical controls are in place to deal with biological variations in water quality as well as seasonal changes to that water.

**IX. ACCEPTED PROCESS FOR THE CREATION OF PASTEURIZED  
EQUIVALENT WATER**

**ULTRAVIOLET LIGHT (UV) DISINFECTION OF WATER**

**BACKGROUND**

UV light between 2000-4000 Angstrom (200-400 nanometers) is well known for inactivating pathogenic microorganisms in water via several mechanisms, including the formation of DNA bonds (dimers) that inhibit reproduction and infectivity. Different microbes have different responses to specific wavelengths which also can account for differences in overall dose requirements. Some microbes can use their own enzymes and mechanisms, or take advantage of host cell enzymes to repair the damaged DNA, requiring higher doses of UV to cause irrevocable damage and effective pasteurization-level disinfection.

Three (3) critical factors determine a UV unit's ability to reliably achieve the necessary dose at any point in time: The transmissivity of the water to UV, the performance of the lamps, and the hydraulics and rate of the flow in the disinfection chamber. Color, turbidity, particles and organic impurities can interfere with the transmission of UV energy and lower the disinfection efficiency below levels required to insure destruction of pathogenic organisms. Similarly, lamps can age unevenly and water can foul the protective sleeves and prevent light from reaching some pathogens. Hydraulic patterns or flow that is too high or too low can cause uneven distribution of the dose and leave some areas without adequate disinfection.

Other important factors include the geometric configuration of the reactor, the power, wavelength and physical arrangement of the UV lamps, and the UV path length. Longer path lengths provide more opportunities for UV photon-microbe interaction and inactivation.

UV lamps treat water instantaneously while it is flowing through the disinfection chamber but do not provide residual bactericidal action. Using UV for pasteurized equivalent water is not a substitute for appropriate maintenance, periodic flushing and sanitizing of the water distribution system inside the plant.

## **CRITERIA**

The following is a list of criteria that is required to accept water treated with UV light to be considered equivalent to pasteurized water:

1. UV light shall be applied so that the entire volume of water receives at least the following dose when used as pasteurized water.
  - a. Low pressure UV at 2,537 Angstrom (254 nanometers) at 186,000 microwatt-seconds per square centimeter or a 4 log adenovirus equivalent.
  - b. Medium pressure UV at 120,00 microwatt-seconds per square centimeter or a 4 log adenovirus equivalent.
2. A flow or time delay mechanism shall be provided so that all water moving past the flow stop or divert valve receives the minimum dose required above.
3. The unit shall be designed to permit the frequent cleaning of the system without disassembly of the unit and shall be cleaned often enough to ensure that the system will provide the required dose at all times.
4. An automatic flow control valve, accurate within the expected pressure range, shall be installed to restrict flow to the maximum design flow of the treatment unit so that all particles receive the minimum dose listed above.
5. An accurately calibrated UV intensity sensor, properly filtered to restrict its sensitivity to the 2,500-2,800 Angstrom (250-280 nanometers) germicidal spectrum, shall measure the UV energy from the lamps.
6. There shall be one (1) sensor for each UV lamp.
7. The light shall adjust based on water quality measured with a real time ultraviolet transmissivity (UVT) analyzer to assure that the dose is always calculated accurately and

provided reliably.

8. A flow diversion valve or automatic shut-off valve shall be installed which will permit flow into the pasteurized product lines only when at least the required UV dosage is applied. When power is not being supplied to the unit, the valve should be in a closed (fail-safe) position which prevents the flow of water into the pasteurized product lines.

9. The materials of construction shall not impart toxic materials into the water either as a result of the presence of toxic constituents in materials of construction or as a result of physical or chemical changes resulting from exposure to UV energy.

10. The unit shall record the operating parameters (flow, UVT and dose) on a real time basis. These records shall be accessible to the Regulatory Agency for inspection. Electronically generated records, if used, shall meet the criteria specified in Appendix H., V.

**C. Proposed Solution**

Changes to be made on page(s):	<u>274-275</u>	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/> 2011 EML	
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/> 2400 Forms	
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/> 2011 Constitution and Bylaws	

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# PROPOSAL

## STATEMENT OF PROPOSAL

The purpose of this proposal is to suggest amending the existing "Grade A Pasteurized Milk Ordinance, 2011 Revision " APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES OTHER EQUIPMENT, Section IX. ACCEPTED PROCESS FOR THE CREATION OF PASTEURIZED EQUIVALENT WATER. This proposal will include reference to Validated Process Membrane Filtration Media and Sanitary Equipment manufactured by Shelco Filters of Middletown, CT, 06457. Specifically, Beverage Grade, 0.2um, Polyethersulfone, Pleated Membrane Filter Cartridges with 226, Double O-ring Locking End Caps, Fin Assembly and EPR O-Rings installed in 316L SS Sanitary Grade, Electropolished, 226 Filter Housings with Tri-Clamp "T" Style Inlet and Outlet Connections. Each Beverage Grade Shelco filter cartridge is produced with approximately 7.2 sq.ft. of pleated membrane area per 10" filter length and integrity tested by the factory before release. A certificate of that test is included with each filter by Lot Number for the end users records.

## INTENDED USE

Membrane filtration placed at the final point of use/discharge in a sanitary process water system provides a microbiological barrier to any viable or non-viable bacteria larger than the rated pore size of the membrane (common pathogens and water bacteria). That filtration allows the end user to satisfy compendia requirements and test membrane performance in-situ using FDA (CGMP) approved test methods that have been correlated by the manufacturer of the filter cartridge to microbiological challenges of bacteria ( $1 \times 10^7$  CFU per sq. cm . of filter area) selected and approved by FDA for that pore size. In the case of 0.2um, that test organism is *Brevundimonas diminuta*. In the case of a Beverage Grade membrane filter, test methods (Bubble Point and Pressure Hold Testing) will demonstrate via the manufacturers Validation Data the pass/fail criteria for microbiological challenge vs. these approved tests. Each end users batch /operation therefore may be backed by these tests as well as the required microbiological laboratory testing to certify that operation with the applicable batch records for QC acceptance and product release.

## Review of Equipment to Be Used In the Process

In a production environment, the membrane filter system must be placed as close as possible to the final point of use. That filter may be steamed in-situ or chemically sanitized with citric acid or other approved chemical agents as a method of initial set-up and microbiological control. It then may be flushed to remove any potential residuals before processing. A stainless steel sanitary filter housing, "T" style, with tri-clamp inlet and outlet is first installed. Note: This may be in either a fixed location or on a portable dolly that can be moved from one point of discharge to another. The size of this sanitary filter housing will be based on manufacturing flow rate requirements, plant water quality and water consumption levels during a given day's operation. (Assistance is available at no charge to assist with the

system sizing) into that sanitary filter housing Beverage Grade Polyethersulfone membrane filter(s) are installed and the system checked for integrity using an approved test method (Bubble Point or Pressure Hold Test). Following successful completion of the testing, the filter system can be operated. Please note that initially and with a clean filter cartridge in place, little or no flow resistance (delta P) will be observed on a pressure gauge mounted either on the top of the filter housing or placed immediately upstream of the filter system). Only after the filter begins to clog will this resistance to flow begin to be noticeable in a properly sized system.

Sanitary valves will be installed to control water flow into and from the sanitary filter housing allowing the end user to segregate the filter at any time during the production operation for flow control sanitizing and or in-situ testing.

Following a schedule, usually daily, the filter cartridge and system are backwashed with hot water for approximately 2-4 minutes. The filter is then submerged in a 1% solution of NaOH until needed again. Before use, the filter is flushed with water to remove any residual NaOH and integrity tested. The system now may be used for operations.

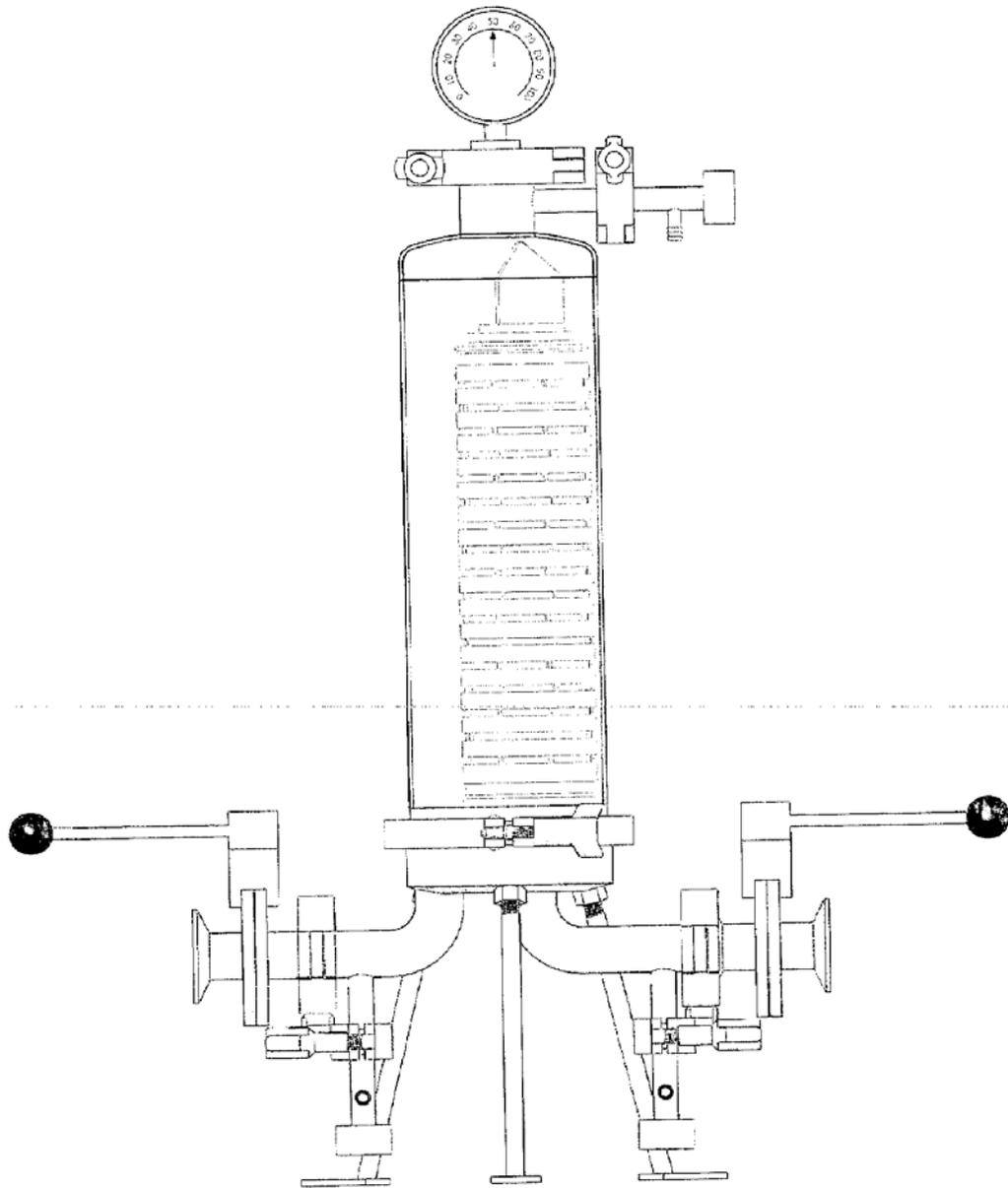
Enc. System Diagram

Shelco Filter Beverage Grade Validation Manual (0.22um Polyethersulfone Membrane)

SFH Series Specification Sheet, Shelco Filters

MAS-B Series Specification Sheet

Shelco Filters Operating Instructions, Test Procedures and Quality Certification



# MicroVantage Ultra Premium Filter Series

## MicroVantage™ MA Series - 0.2 - Beverage Grade Performance Qualification Guide



SAMPLE IDNTIFICATION: PES 0.2 MEMBRANE  
EFFECTIVE FILTRATION AREA: 6503 cm<sup>2</sup>  
SAMPLE IDENTIFICATION LOT #'s  
920841,925041,920741,920641,917581,924921,924941,928841,925141



## BACTERIAL RETENTION OF MEMBRANE FILTER CARTRIDGES UTILIZED FOR LIQUID FILTRATION

### INTRODUCTION:

This Report describes the results of testing under approved protocol for the evaluation of bacterial retention characteristics of membrane filters used to sterilize liquids. This method uses *Brevundimonas diminuta* as the challenge organism.

The test filter was challenged with a suspension of *Brevundimonas diminuta* prepared at a concentration  $\geq 1 \times 10^7$  colony forming units (CFU) per  $\text{cm}^2$  of effective filtration area (EFA). The sterility of the complete apparatus was tested before the challenge. The filter was challenged at a pressure of 35 psig. The effluent was collected and quantified on 0.45  $\mu\text{m}$  assay membranes. Integrity testing was performed before and after the bacterial challenge procedure.

### JUSTIFICATION:

This test method was designed to determine the bacterial retention characteristics of membrane filters used to sterilize liquids. The selection of *Brevundimonas diminuta* as the challenge organism is based on its historical acceptance within the industry. When grown under stress or starvation conditions, many *Brevundimonas diminuta* will pass through 0.45  $\mu\text{m}$  membranes, so *B. diminuta* represents a severe bacterial challenge to the filter. The organism's low pathogenicity also favors the use of *B. diminuta* in laboratory studies.

The test procedure complies in intent and content with the ASTM F838-05 "Determining bacterial retention of membrane filters utilized for liquid filtration" and the health industry manufacturers association (HIMA) test method "Microbiological evaluation of filter for sterilizing liquids". Challenge conditions include high pressure, high flow rates and high bacterial concentration per  $\text{cm}^2$  of effective filtration area. Growth parameters, temperatures and media were as detailed in the protocol as specified by ASTM and HIMA.



#### DIFFUSION TESTS:

A single membrane filter was placed into a sterile filter housing and steam sterilized by autoclaving. After sterilization the filter and apparatus returned to room temperature.

Diffusion testing was performed using DI H<sub>2</sub>O as the test liquid. The test apparatus is outlined in figure 1. The filter was securely installed in the apparatus and the pressure vessel was filled. The downstream valve was closed and the pressure regulator opened to begin flooding the filter housing with the test liquid. The air was vented from the apparatus using the valve on top of the housings to ensure that no air was trapped inside. The pressure was raised to 20 psig and the system was held at pressure for at least 5 minutes. The downstream valve was slowly opened to initiate the wetting procedure. The test liquid was allowed to run to waste. After the liquid flow stopped, the pressure in the pressure vessel was adjusted to 5 psig and increased in 2 psig increments up to the bubble point. The diffusion flow rate was determined using a mass flow meter attached to the downstream side of the filter housing.

#### MICROBIAL CHALLENGE:

After sterilization the filter and apparatus returned to room temperature, the filter was wet with DI H<sub>2</sub>O and the diffusion test was repeated as detailed above. After the diffusion test, the pressure vessel was filled with approximately 20 liters of purified water. The downstream valve was closed and the pressure regulator opened to begin flooding the housing with purified water. The air was vented from the apparatus using the valve on top of the housing to ensure that no air was trapped inside. The pressure was increased to 2 psig and the downstream valve was opened. The purified water ran through the system to clean the apparatus and filter off any residual isopropyl alcohol. After clearing the apparatus of residual alcohol, approximately one liter of purified water was added to the pressure vessel. This rinse fluid was collected in a sterile carboy and then quantified to verify the sterile condition of the complete apparatus. The rinse fluid was passed through 0.45µm assay membranes and plated onto SCDA. A portion of the rinse (~150mL) was spiked with a 0.1 mL aliquot of *B.dimimuta* to verify that no alcohol remained to inhibit growth. All plates were incubated at 30±2°C for 7 days. The sterile integrity of apparatus was not broken between the rinse step and the challenge. The spike plate indicated the purified water the system of residual alcohol.

Sufficient volume (approximately 8 liters) of the challenge suspension was added to the pressure vessel to meet the guideline of  $\geq 1 \times 10^7$  CFU/cm<sup>2</sup> of EFA. The upstream and downstream valves were closed and the pressure vessel pressurized to about 2 psig. The upstream valve was slowly opened to begin filling the housing with the *B.dimimuta* challenge. The air was vented as described previously.

The pressure was increased to 35 psig and the downstream valve opened to initiate filtration. The challenge flow rate was determined using volume of filtrate per time. The diffusion test was repeated as previously described. The filtrate was collected and secured as seen in figure 2.



Shelco Filters

### Bacterial Retention of Membrane Filter Cartridges Utilized for Liquid Filtration

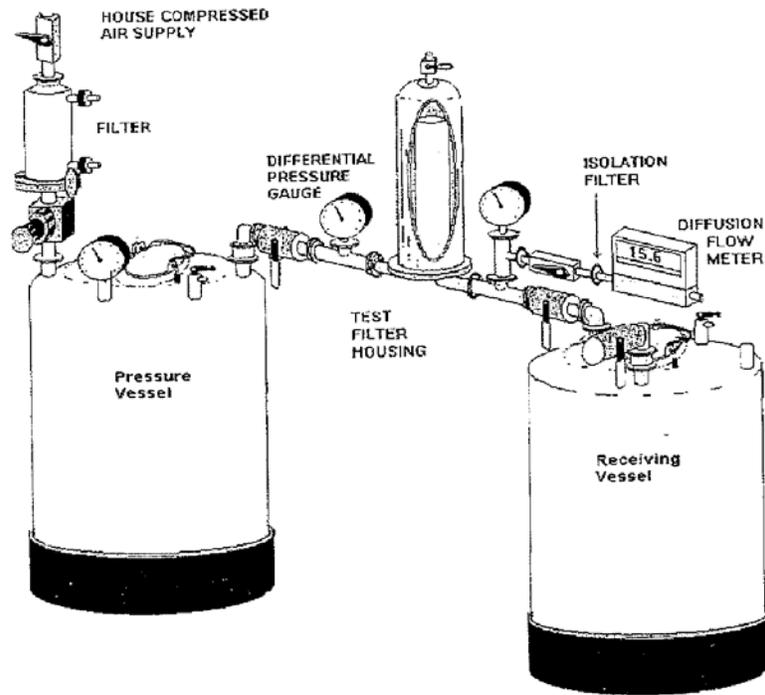


Figure 1. Test Apparatus



Shelco Filters

Bacterial Retention of Membrane Filter Cartridges Utilized for Liquid Filtration

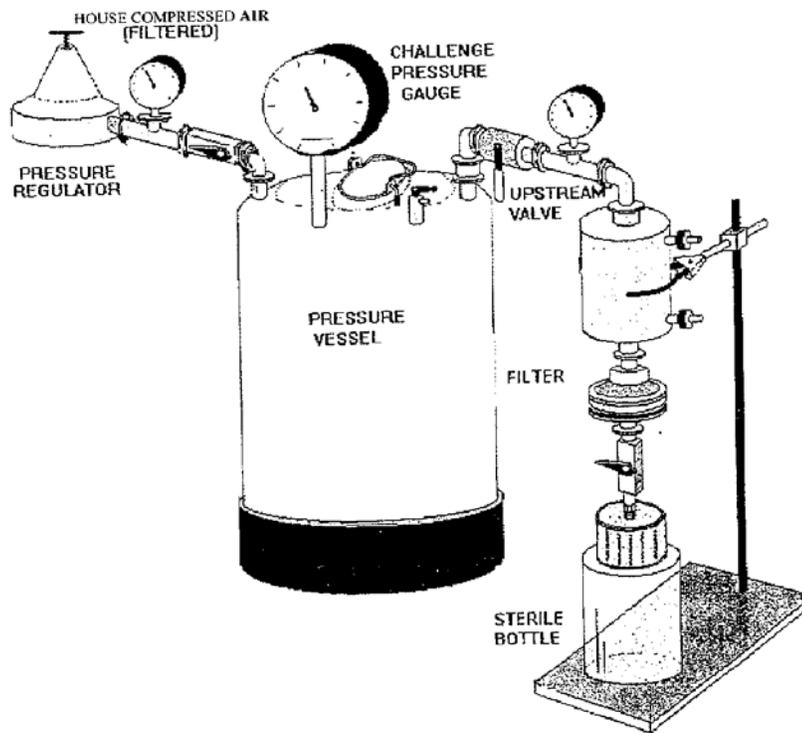


Figure 2. Positive Control Apparatus



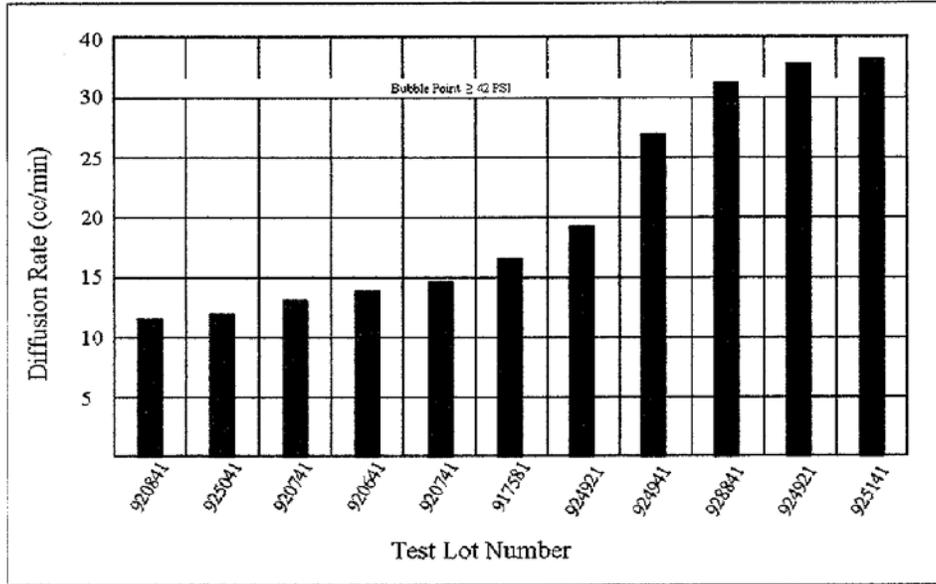
## RETENTION TEST DATA:

Filter Identification Lot#	Diffusion rate @ 35 psi	Challenge with: Brevundimonas diminuta ATCC 19146	LRV	Pass / Fail
HSPN - Negative	9	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	N/A
920841	11.5	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
925041	11.8	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
920741	12.6	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
920641	13.9	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
920741	14.4	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
917581	16.2	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
924921	19.3	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
924941	28.8	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
928841	31.3	10 <sup>7</sup> CFU per CM <sup>2</sup>	≥8.2 log reduction value	Pass
924921	34.6	10 <sup>7</sup> CFU per CM <sup>2</sup>	6.9 log reduction value	Fail
925141	35.2	10 <sup>7</sup> CFU per CM <sup>2</sup>	6.8 log reduction value	Fail
RB5N - Positive	36	10 <sup>7</sup> CFU per CM <sup>2</sup>	6.1 log reduction value	N/A /Fail

All filters which were tested that exhibited a diffusion rate less than or equal to 30 cc/min produced sterile filtrate. This is consistent with test data from many manufactures using the same PES membrane with similar filter area.

Note: The diffusion Bubble Point Test results are influenced by the nature of the wetting medium. The diffusion and bubble point values listed for the MAS-B grade cartridges wetted with water at 20 deg C. It should be noted, that a variation of the test conditions such as temperature, wetting liquid or type of gas may require a different integrity test method.





MAS-0.2 Beverage Grade cartridges have the following maximum allowable diffusion values at  $\leq 30$  cc/min at 35 psi. and a Bubble Point  $\geq 42$  psi at 20 °C water wetted membrane.

SHELCO FILTERS  
100 BRADLEY STREET  
MIDDLETOWN, CT 06457  
WWW.SHELCO.COM

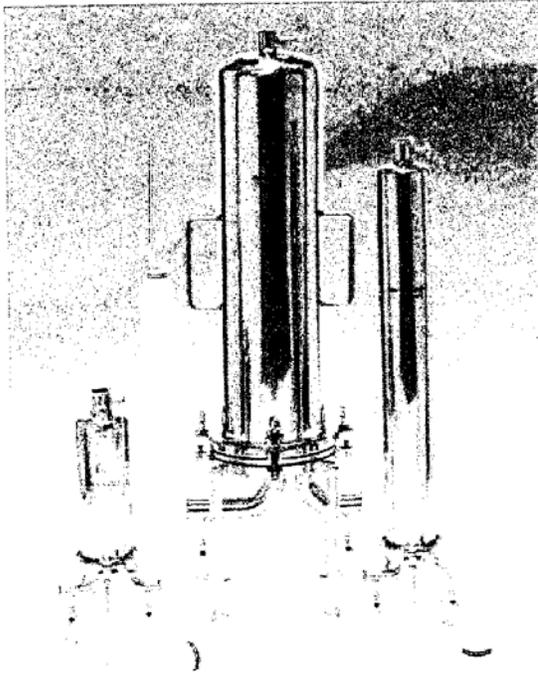




## MicroVantage™ SFH Series

Sanitary Filter Housings

## MicroVantage Ultra Premium Filter Series



- Designed for critical applications requiring high purity and durability
- All wetted parts are 316L Stainless Steel electro-polished with standard 25RA internal finish and 32RA external finish.
- In-line single cartridge design
  - Tri-clamp closure for easy cartridge change-outs
  - Ideal for vent applications
- T-style housing design
  - Available for 1 through 21 cartridges
  - Tri-clamp closure for single cartridge housing
  - Swing bolt closures for rugged design and secure sealing
  - Removable bottom seal plate allows ease of cleaning
- Available with 226 or 222 style cartridge connectors
- 1 1/2" TC Gauge Port and 1/2" TC vent and drains are standard
- Optional Sanitary Twist Valve is available for easy sampling of process fluid

### Applications

Ultrapure Water	Food & Beverage
Fine Chemicals	Wine/Beer
Electronics	Vent
Pharmaceuticals	DI Water

### Specifications

*Maximum Operating Pressure*  
150 psig (10.3 bar) @ 225° F (107° C)

*Inlet and Outlet Connections*  
Inlet/Outlet: Tri- Clamp  
Drain Ports: 1/2" Tri-Clamp  
Gauge Port with Vent: 1 1/2" Tri-Clamp with  
1/2" Tri-Clamp

*Materials of Construction*  
Head and Shell: 316L Stainless Steel  
Connections: 316L Stainless Steel  
Closure: 316L Stainless Steel  
Mounting Legs: 316L Stainless Steel

### Gaskets

Silicone  
*Optional: EPR, Viton, Teflon, Teflon Encapsulated  
Silicone and Teflon Encapsulated Viton*

### Finish

Internal surfaces: 25RA Electro-polished  
External surfaces: 32RA Electro-polished

### Cartridge Type

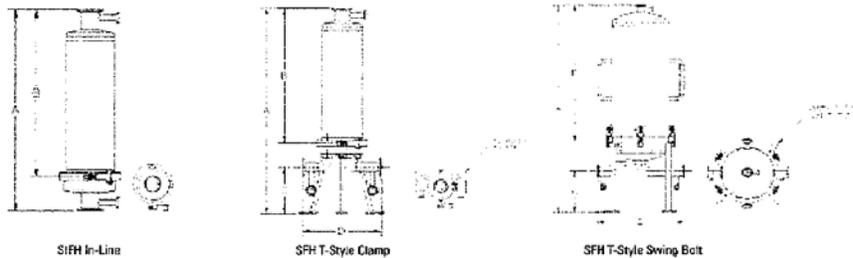
222 or 226 cartridges (maximum 2 3/4" OD)

### Custom Options

Sanitary Twist Valve's for vent and drains  
*See Ordering Guide for complete listing*

Model	Length (in)	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6	Port 7	Port 8	Port 9	Port 10
1SIFH5	1 (5")	1.5" TC	1/2" TC	-	-	2.34"	17.7/16" (44.3 cm)	7" (17.8 cm)	-	-	-
1SIFH1	1 (10")	1.5" TC	1/2" TC	-	-	2.34"	21.7/16" (54.5 cm)	11" (27.9 cm)	-	-	-
1SIFH2	1 (20")	1.5" TC	1/2" TC	-	-	2.34"	31.1/4" (79.4 cm)	20.7/8" (53.0 cm)	-	-	-
1SIFH3	1 (30")	1.5" TC	1/2" TC	-	-	2.34"	41.1/8" (104.5 cm)	30.3/4" (78.1 cm)	-	-	-
1SIFH4	1 (40")	1.5" TC	1/2" TC	-	-	2.34"	50.15/16" (128.4 cm)	40.9/16" (103.0 cm)	-	-	-
1SPH5	1 (5")	1" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	17.1/2" (44.5 cm)	10.7/32" (26.0 cm)	4.3/4" (12.1 cm)	7.7/8" (20.0 cm)	8.21/32" (22.0 cm)
1SPH1	1 (10")	1" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	21.1/2" (54.6 cm)	14.7/32" (36.1 cm)	4.3/4" (12.1 cm)	7.7/8" (20.0 cm)	8.21/32" (22.0 cm)
1SPH2	1 (20")	1" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	31.1/2" (80.0 cm)	24.7/32" (61.5 cm)	4.3/4" (12.1 cm)	7.7/8" (20.0 cm)	8.21/32" (22.0 cm)
1SPH3	1 (30")	1" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	41.1/2" (105.4 cm)	34.7/32" (86.9 cm)	4.3/4" (12.1 cm)	7.7/8" (20.0 cm)	8.21/32" (22.0 cm)
1SPH4	1 (40")	1" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	51.1/2" (130.8 cm)	44.7/32" (112.3 cm)	4.3/4" (12.1 cm)	7.7/8" (20.0 cm)	8.21/32" (22.0 cm)
3SPH2	3 (20")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	39.1/2" (100.3 cm)	25.5/8" (65.1 cm)	7.3/8" (18.7 cm)	13.3/8" (34.3 cm)	14.7/16" (38.6 cm)
3SPH3	3 (30")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	49.5/8" (125.4 cm)	31.1/2" (80.0 cm)	7.3/8" (18.7 cm)	13.3/8" (34.3 cm)	14.7/16" (38.6 cm)
3SPH4	3 (40")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	59.3/16" (150.3 cm)	41.3/8" (105.1 cm)	7.3/8" (18.7 cm)	13.3/8" (34.3 cm)	14.7/16" (38.6 cm)
5SPH3	5 (30")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	50.7/16" (128.1 cm)	31.1/2" (80.0 cm)	7.7/8" (20.0 cm)	15.3/4" (40.0 cm)	16.13/16" (42.7 cm)
5SPH4	5 (40")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	60.1/4" (153.0 cm)	41.5/16" (104.9 cm)	7.7/8" (20.0 cm)	15.3/4" (40.0 cm)	16.13/16" (42.7 cm)
7SPH3	7 (30")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	50.3/4" (128.9 cm)	31.1/2" (80.0 cm)	7.7/8" (20.0 cm)	16.9/16" (42.1 cm)	17.3/4" (45.1 cm)
7SPH4	7 (40")	2" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	60.3/16" (153.8 cm)	41.5/16" (104.9 cm)	7.7/8" (20.0 cm)	16.9/16" (42.1 cm)	17.3/4" (45.1 cm)
12SPH3	12 (30")	3" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	49.5/16" (125.2 cm)	34.11/16" (88.1 cm)	6.1/16" (15.4 cm)	18.1/2" (47.0 cm)	18.7/16" (49.3 cm)
12SPH4	12 (40")	3" TC	1/2" TC	1.5" TC / 1/2" TC	-	2.34"	59.5/16" (150.8 cm)	44.11/16" (113.5 cm)	6.1/16" (15.4 cm)	18.1/2" (47.0 cm)	19.7/16" (49.3 cm)

Dimensions



Ordering Guide (Example: 7SPH3-SS226-2TC25-1-1-8)

Model	Length	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6	Port 7	Port 8	Port 9	Port 10
1SIFH	5 = 5" 1 = 10" 2 = 20" 3 = 30" 4 = 40"	C = Tri-Clamp	222 = 222 Style Cartridge 226 = 226 Style Cartridge	1.5TC = 1.5" TC	25	N = None 1 = 1/2" TC ferrule with solid end caps and 1 1/2" TC gauge port	N = None 1 = 1/2" TC ferrules with solid end caps 2 = 1/2" TC ferrules with sanitary twist valves	S = Silicone (standard) E = EPDM V = Viton TS = Teflon Encapsulated Silicone TV = Teflon Encapsulated Viton			
1SPH 3SPH 5SPH 7SPH 12SPH 21SPH	5 = 5" 1 = 10" 2 = 20" 3 = 30" 4 = 40"	C = Tri-Clamp ** SB = Swing Bolt	222 = 222 Style Cartridge 226 = 226 Style Cartridge	1TC = 1" TC + 2TC = 2" TC + 3TC = 3" TC + 4TC = 4" TC +	25	2 = 1/2" TC ferrules with sanitary twist valve 1 1/2" TC gauge port					

\* 5" length available in 1SIFH and 1SPH models. \*\* Tri-clamp closure and 1" TC connections only available on 1SPH models.  
 + Standard connection sizes are: 2" TC for 3SPH, 5SPH and 7SPH models. 3" TC for 12SPH models and 4" TC for 21SPH models. ++ Contact factory for alternate finishes.

Customization

Housings may be customized to meet your precise requirements. Contact Shelco's technical support staff or your distributor for more information.



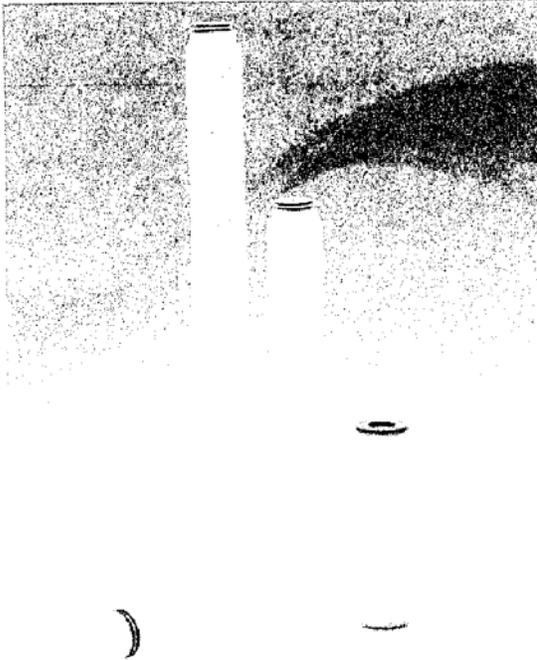
**Shelco Filters**  
 100 Bradley Street  
 Middletown, CT 06457 USA  
 Tel: 800-543-5843 / Fax: 860-854-6120 / E-mail: info@shelco.com

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## MicroVantage™ MAS-B Series

Beverage Grade Polyethersulfone Membrane Filter Cartridges

## MicroVantage Ultra Premium Filter Series



- Absolute retention ratings from 0.1 to 1.2 microns
- 7.2 square feet (0.67 m<sup>2</sup>) of media surface area per ten inch length for optimal performance
- Fully integrity tested to ensure reliable performance in critical applications
- 100% flushed with 18 megohm DI water for low extractables
- Rigid, molded cage protects pleated media and strengthens structural stability
- Manufactured in a Class 10,000 Clean Room environment for high purity
- Complies with Food & Drug Administration's CFR criteria for food & beverage contact
- Meets USP Class VI Biological Test for plastics
- Available in standard lengths and end cap configurations to fit most filter housings
- Produced up to 40 inches in length (10 inch modules)

### Applications

Food & Beverage	Wine
Malt Beverages	Bottled Water
Beer	Process Water
RO Pre/Post Filtration	Water & Wastewater

### Specifications & Operating Parameters

**Flow Sizes** 0.1, 0.2, 0.45, 0.65, 0.8, 1.0, 1.2 microns absolute retention

**Maximum Operating Temperature** 176°F (80°C)

**Nominal Lengths** 9.75" (24.7 cm), 10" (25.4 cm), 20" (50.8 cm), 30" (76.2 cm), 40" (101.6 cm)

**Recommended Change-out Differential Pressure** 35 psid (2.4 bar)

**Outside Diameter** 2.67" (6.78 cm)

**Maximum Differential (Collapse) Pressure** 75 psid @ 70°F (5.2 bar @ 21°C), 40 psid @ 176°F (2.8 bar @ 80°C)

**Inside Diameter** 1.0" (2.54 cm)

**Media Surface Area** 7.2 sq.ft. (0.67 m<sup>2</sup>) per 10 inches filter length

### Sanitization and Sterilization

Hot water at 175°F (80°C) at 5 psid for 30 minutes  
In-line steam at 257°F (125°C) @ 1 psid (0.7 bar) for 30 minutes  
Autoclavable at 257°F (125°C) for 30 minutes

### Gaskets/O-rings

Silicone, Buna N, EPR, Viton, Teflon Encapsulated Viton (O-rings only)

### Materials of Construction

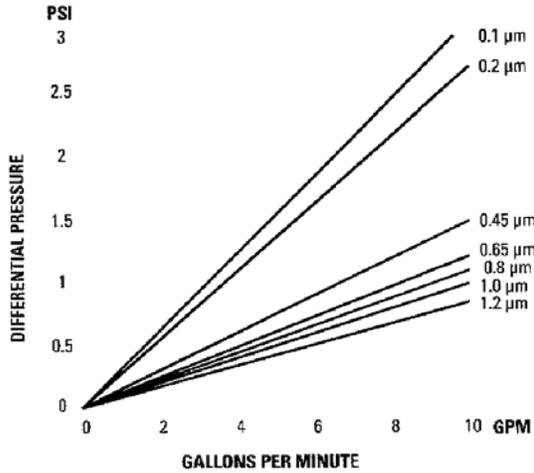
Filter Media:	Polyethersulfone
Outer Cage	Polypropylene
Inner Core:	Polypropylene
End caps:	Polypropylene

### FDA and USP Compliance

All filters are manufactured of virgin polypropylene materials with no additives or other manufacturing agents. All polypropylene materials comply with the requirements of Food and Drug Administration Title 21 of The Code of Federal Regulations 174.5, 177.1520 and 177.1630. All components meet current USP Class VI biological tests for plastics

[www.shelco.com](http://www.shelco.com)

*Flow vs. Pressure Drop*



*Integrity Testing*

0.1 µm	≤30cc/min@48psi
0.2 µm	≤30cc/min@35psi
0.45 µm	≤30cc/min@20psi
0.65 µm	≤30cc/min@15psi
0.8 µm	≤30cc/min@12psi
1.0 µm	≤30cc/min@8psi
1.2 µm	≤30cc/min@7psi
<b>Per 10" length water wetted membrane</b>	

This chart represents the typical water flow per 10" cartridge length. Cartridges are tested in water at ambient temperature. Data may be extrapolated for multiple lengths, but as flow rate increases, ΔP of the housing becomes more apparent.

*Ordering Guide (Example: MAS9.2-1804S-5)*

MAS	0.2	-	10	S4	S	-	B
MAS	0.1	9.75"	S1 = DOE	B = Buna N	B = Beverage	HT = High Temperature*	
	0.2	10"	S3 = 222 w/ Fin End	E = EPDM			
	0.45	19.75"	S4 = 222 w/ Flat End	S = Silicone			
	0.65	20"	S5 = 225 w/ Fin End	V = Viton			
	0.8	29.25"	S6 = 225 w/ Flat End	T = Teflon encapsulated Viton (O-ring only)			
	1.0	30"	S7 = Internal O-ring with Recessed Plug				
	1.2	40"	S9 = Internal O-ring on both ends				

\* High Temperature construction (cage, core, end caps): Maximum Temperature 200°F (93.3°C) - Available only in 222 or 225 with Fin or Flat end caps.

*Filter Housing*

Shelco manufactures a full line of filter housings. From our rugged single cartridge housings to our heavy duty multi-cartridge housings. Shelco is the perfect choice for your filtration solutions.



**Shelco Filters**  
 100 Bradley Street  
 Middletown, CT 06457 USA  
 Tel: 800-543-5843 / Fax: 860-854-6120 / E-mail: info@shelco.com

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**INSTALLATION**

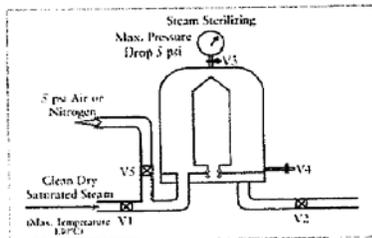
1. Remove the bagged filter from the filter cartridge box. Verify that the part number is correct and record the cartridge lot number if necessary.
2. Carefully open the filter cartridge bag. If the filter is a single open end style, cut the bag at the open end.
3. Do not completely remove the filter cartridge from the bag, but use the bag as a handling device to reduce the possibility of contamination.
4. Install the filter cartridge into the housing. If the cartridge has o-rings, the o-rings should be pre-wetted with a suitable fluid. CAUTION: Do not overtighten compression plate as this may damage filter and void warranty.

**SANITIZATION/ STERILIZATION**

Shelco MICROVANTAGE filters may be sterilized or sanitized by a variety of methods. Due to varying system designs and requirements, users should validate their procedure in order to demonstrate its efficacy.

**In Line Steaming**

- 1.) With the filters installed, close the downstream and gas valves on the housing (V2) and (V5) and open the vent (V3) and drain valve (V4).
- 2.) Introduce clean, dry, saturated steam into the upstream side of the filter assembly by opening valve (V1). The maximum temperature of the steam must not exceed 275°F (135°C).
- 3.) When steam issues from the vent and drain, slowly close the vent (V3) and the drain (V4) until they are only slightly open.
- 4.) Slowly open the downstream valve (V2) to allow steam to pass through the filter. The differential pressure must not exceed 5 psi (0.34 bar) to avoid damage to the filter cartridge.
- 5.) Continue the flow of steam for the prescribed length of time (typically at least 20 minutes after the filter assembly has reached the desired temperature).
- 6.) Shut off the steam and close the vent (V3) and the drain (V4) and downstream valve (V2).
- 7.) Allow the filter to cool while maintaining a positive pressure of gas at 5 psig (0.34 bar) on the upstream side by introducing regulated air or nitrogen.

**Hot Water Sanitization**

- 1.) With the cartridges installed, fill the upstream side of the housing with cold water and ensure that all the air has been vented from the housing.
- 2.) Flow clean, hot water (maximum 180°F/82°C filtered to at least 1 micron nominal) through the filter with a maximum differential pressure of 5 psi (0.34 bar).
- 3.) Flow the hot water for at least 30 minutes or for a period of time in which sanitization efficacy has been documented.

- 4.) Stop the flow of hot water. Flow cold water through the filter at low differential pressures to cool the filter to operating temperature.

**Autoclaving**

Shelco MICROVANTAGE filters are compatible with all autoclave cycles up to a temperature of 275°F (135°C).

**Chemical Sterilization**

Shelco MICROVANTAGE filters may be sterilized/sanitized by many of the commonly used chemicals (Refer to Cleaning and sanitizing instructions). It is recommended that compatibility testing be conducted prior to using any specific chemical. For any chemical cleaning regimen, it is important to flush the filter completely to remove any chemical residue.

**INTEGRITY TESTING**

Shelco MICROVANTAGE cartridges may be integrity tested by diffusion test or bubble point methods. In general, due to the large surface area, the diffusion test will yield more accurate results. In these circumstances, the bubble point test may show a "false failure" due to the rate of diffusion. If a bubble point test is performed and a failure is recorded, the results should be confirmed by diffusion testing. If the diffusion testing is satisfactory, then the filter can be considered integral.

**Cartridge Wetting**

Place the cartridge into the housing and flow filtered water or the selected test fluid through the housing at 2 liters per minute for 10 minutes. Start closing down stream housing valve to reduce water flow and increase inlet pressure. Bring the inlet pressure up to 15-20 psi by lowering the outlet flow. Be sure to vent the housing of air during this process or incomplete cartridge wetting may occur.

**Diffusion Testing**

- 1.) Complete cartridge wetting procedure outlined above.
- 2.) With the filter completely wetted, close off water flow and apply 5 psid (0.34 bar) of compressed air to the upstream side of the filter. Allow any water in the housing to pass through the filter and drain on the downstream side of the housing.
- 3.) Slowly increase the pressure to the value shown in Table 1, "Diffusion Pressure" and allow the system to stabilize for two minutes. The pressure ramp should not exceed 10 psid (0.7 bar) per minute.
- 4.) Measure the diffusive air flow through the filter system and compare this value with the maximum values in Table 1 for the pore size being tested. If the diffusive flow is equal to or less than the published value, the system is integral. If the value exceeds the maximum, then:
  - a. Check the pressure gauges for accuracy
  - b. Re-wet the cartridge and repeat the diffusion test from Step 1.

**Bubble Point Testing**

- 1.) Follow Steps 1 through 3 for Diffusion testing, stated above.
- 2.) Increase the pressure to the value shown in Table 1, "Bubble Point". The pressure ramp should not exceed 10 psid (0.7 bar) per minute.
- 3.) Observe the outlet and note the rate of bubbling. Note the pressure at which there is a marked increase in the rate of bubbling. This is the bubble point of the filter.
- 4.) If the pressure noted in Step 3 is equal to or above the bubble point value shown in Table 1, then the filter is integral. If the filter fails the test, verify the results by conducting Diffusion Testing

**Integrity Test Parameters for MICROVANTAGE MAS-B Grade Filters**

Pore Size	Diffusion Pressure	Max. Diffusion Flow / 10" Cartridge	Bubble Point (psig)
0.1	48 psig	≤ 30 cc/min	≥ 58 psig
0.2	35 psig	≤ 30 cc/min	≥ 42 psig
0.45	20 psig	≤ 30 cc/min	≥ 24 psig
0.65	15 psig	≤ 30 cc/min	≥ 18 psig
0.8	12 psig	≤ 30 cc/min	≥ 15 psig
1.0	8 psig	≤ 30 cc/min	≥ 10 psig
1.2	7 psig	≤ 30 cc/min	≥ 8 psig

Per 10" Length Water Wetted Membrane

**Microbiological Performance**

The retention of the filter can be expressed as Log Reduction Value (LRV)

Pore Size	<i>Acetobacterium Laidlawii</i>	<i>Brevundimonas diminuta</i>	<i>Serratia Marcescens</i>	<i>Lactobacillus Lindneri</i>
0.1	≥ 7	≥ 10		
0.2		≥ 7		
0.45			≥ 7	
0.65				≥ 7

MAS-B cartridges are well-suited for the removal of contaminants, microbes and spoilage organisms. For each rated pore size of MAS-B filters, the LRVs for appropriate challenge organisms are more than sufficient to reduce bioburdens to acceptable levels.

**MicroVantage  
Ultra Premium Filter Series**

**MicroVantage PES Membrane Filter Series  
B (Beverage) Grade**

**Certification of Quality Assurance**

**Materials of Construction**

Filtration Media: Polyethersulfone  
Support layers: Polypropylene  
Structural Supports: Virgin Polypropylene

**Operational Limits**

Maximum Forward Differential: 75 psid @ 70°F  
40 psid @ 176°F  
Max. Sustained Operating Temp.: 176°F

**USP Biosafety**

MICROVANTAGE cartridges are non-toxic and meet the requirements of the current USP Plastic Class VI Testing.

**Shelf Life**

2 years from ship date providing filters are stored unopened in a dry and ambient environment. Ideal temperature is 25°C.

**Integrity Testing / Characteristics**

The universal assemblies utilized to construct the B-Grade cartridges are individually tested utilizing the forward flow test specified in this document. Each assembly is high flow flushed with Pre-polished .03 micron 18 megohm high purity DI water.

**Quality Assurance**

The MICROVANTAGE filter cartridges are manufactured using Good Manufacturing Practices under a quality system that has been certified to meet ISO 9001 standards. Each MICROVANTAGE filter is assigned a lot code to ensure traceability of data and materials

**Operating Instruction, Test  
Procedures and Quality  
Certification**



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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 121  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To exempt HTST gear driven positive displacement timing pumps with greater than 120% of the legal holding time from the 2011 PMO Equipment Test 11.1, Procedures 11, 12, & 13. This is the water and milk drawdown conversion procedures.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The 2011 PMO, Appendix I, Pasteurization Equipment and Controls – Tests Section under Test 11.1, HTST Pasteurizers, page 297, & 298, require that gear driven timing pumps complete Procedure 11, 12, & 13. This is the drawdown test comparison between water and milk used in conjunction with the salt tests done in both forward and divert flow to determine milk holding time in holding tube.

Homogenizers operating at greater than 120% of the legal holding time are exempt from Procedures 11, 12, 13. These homogenizers operate at higher pressure than gear driven timing devices, yet are allowed to be exempt. Why would a lower speed and lower pressure gear driven pump operating at greater than 120% of legal holding time not be exempt also?

The 2011 PMO, Standards for Grade “A” Pasteurized Milk, Item 16p(B) HTST Pasteurization, letter (f) 2, page 94, allows for the motor to be connected to a timing pump by means of a drive shaft, gears, pulleys, or a variable speed drive in such a manner that the holding time cannot be shortened without detection by the regulatory agency. This can be accomplished with the use of seals after being tested by the regulatory agency.

**C. Proposed Solution**

Changes to be made on page(s):		297, 298	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

2011 PMO, page 297

10. Repeat Procedures 4 through 9 for the holding time on water in diverted-flow. ~~For all gear driven timing pumps complete Procedure 11, 12, and 13.~~ For those homogenizers used as timing pumps, when the measured holding time for water is less than 120% of the legal holding time complete Procedures 11, 12 and 13. For those homogenizers or gear driven pumps used as timing

2011 PMO, page 298

pumps, when the measured holding time for water is 120% or more of the legal holding time, Procedure 11 is optional and 12 and 13 are not required.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 122  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To exempt HHST Pasteurization systems with the Flow Diversion Device (FDD) at the end of the regenerator/cooling section, and utilizing a sequence logic computer program, from the hold tube calculation in diverted flow. The 2011 PMO, Appendix I, Test 11.3 Calculated Hold For Indirect Heating, page(s) 304, 305 & 306 now requires calculation in both forward and divert flow for all HHST systems.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

HHST pasteurizers with the FDD at the end of the regenerator/cooling section and utilizing a sequence logic computer program will go into a controlled cool down/shutdown program sequence if there is any compromise of pasteurization pressure, time, or temperature. The FDD will not move back into forward flow. The system will completely shut down and require a wash and sterilization cycle sequence before the flow diversion valves will move forward again.

With a HTST, where the FDD can move from forward flow to divert flow and back to forward flow, the above mentioned type of HHST system application cannot. This makes the hold tube divert flow calculation irrelevant.

On the HHST with FDD at end of regenerator/cooling section, with computer controlled sequence logic, the holding tube calculation in forward flow is the true measure of how long milk is the holding tube and the required length of holding tube.

Using the draw down method on pasteurizers has shown that the holding tube length calculation in both forward flow and divert flow to be approximately the same based on the fact that the FDD is all the way at the end of the system and not at the end of the holding tube.

The testing of this type of HHST system running at 100 gallons per minute, with a 5 to 10 minute time frame to reach maximum speed results in 600 gallons of water being ran out onto the floor being wasted in diverted flow.

**C. Proposed Solution**

Changes to be made on page(s): 304 of the (X - one of the following):

<input checked="" type="checkbox"/>	2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

2011 PMO, Appendix I, Test 11.4 Calculated Hold for Direct Heating, page 306

Criteria: Every particle of milk or milk product shall be held for the minimum holding time in both forward and diverted-flow positions.

NOTE: HHST Pasteurizers with the FDD located at the end of the regenerator / cooling section and utilizing a sequence logic computer program shall be exempt from direct heating hold tube calculation in diverted flow.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 123  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To exempt HHST Pasteurization systems with the Flow Diversion Device (FDD) at the end of the regenerator/cooling section, and utilizing a sequence logic computer program, from the hold tube calculation in diverted flow. The 2011 PMO, Appendix I, Test 11.4 Calculated Hold For Direct Heating, page(s) 306, 307 & 308 now requires calculation in both forward and divert flow for all HHST systems.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

HHST pasteurizers with the FDD at the end of the regenerator/cooling section and utilizing a sequence logic computer program will go into a controlled cool down/shutdown program sequence if there is any compromise of pasteurization pressure, time, or temperature. The FDD will not move back into forward flow. The system will completely shut down and require a wash and sterilization cycle sequence before the flow diversion valves will move forward again.

With a HTST, where the FDD can move from forward flow to divert flow and back to forward flow, the above mentioned type of HHST system application cannot. This makes the hold tube divert flow calculation irrelevant.

On the HHST with FDD at end of regenerator/cooling section, with computer controlled sequence logic, the holding tube calculation in forward flow is the true measure of how long milk is the holding tube and the required length of holding tube.

Using the draw down method on pasteurizers has shown that the holding tube length calculation in both forward flow and divert flow to be approximately the same based on the fact that the FDD is all the way at the end of the system and not at the end of the holding tube.

The testing of this type of HHST system running at 100 gallons per minute, with a 5 to 10 minute time frame to reach maximum speed results in 600 gallons of water being ran out onto the floor being wasted in diverted flow.

**C. Proposed Solution**

Changes to be made on page(s): 306 of the (X - one of the following):

<input checked="" type="checkbox"/>	2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/>	2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

2011 PMO, Appendix I, Test 11.4 Calculated Hold for Direct Heating, page 306

Criteria: Every particle of milk or milk product shall be held for the minimum holding time in both forward and diverted-flow positions.

NOTE: HHST Pasteurizers with the FDD located at the end of the regenerator / cooling section and utilizing a sequence logic computer program shall be exempt from direct heating hold tube calculation in diverted flow.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 124  
Committee: SSCC

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

For manufacturers of single-service containers as outlined in Appendix J:  
Acknowledge the annual certification to a GFSI recognized standard as equivalent to a PMO-IMS inspection by extending the interval between IMS inspections to 24 months and IMS listing validity time for food packaging manufacturers fulfilling these requirements from 12 months to 24 months.

**B. Reason for the Submission and  
Public Health Significance and/or Rationale Supporting the Submission**

The rationale behind the proposal is that many food packaging suppliers have made a lot of efforts in achieving a 3<sup>rd</sup> party annual certification that meets the globally recognized requirements set out by the Global Food Safety Initiative (GFSI). A certification to a GFSI recognized standard, e.g. SQF ed 7 or BRC/Iop ver 4, will guarantee that the food packaging manufacturer has an extensive Pre Requisite Program in place covering the requirements listed in the PMO-IMS Appendix J, section D “Fabrication plant standards” and more. The GFSI recognized standards does also require a HACCP based system to be in place in addition to the Pre Requisite programs. This is well in line with the preventive intentions of the Food Safety Modernization Act.

**C. Proposed Solution**

Changes to be made on page(s):		325	of the (X - one of the following):	
X	2011 PMO		2011 EML	
	2011 MMSR		2400 Forms	
	2011 Procedures		2011 Constitution and Bylaws	

**E. CRITERIA FOR LISTING CERTIFIED SINGLE-SERVICE MANUFACTURERS IN THE IMS LIST**

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating and listing single-service manufacturing plants. Rating and/or Regulatory Agencies may choose from the following list of criteria for listing certified single-service manufacturers:

...<point 1, 2 and 3 to be kept as is>

4. Single-service manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months.

5. Single-service manufacturers that operate as a separate entity and have a 3<sup>rd</sup> party audited management system that is certified to a standard recognized by the Global Food Safety Initiative ( e.g SQF-edition 7 or BRC/Iop-version4) may be optionally listed for twenty-four (24) months.

~~5. 6.~~ Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest survey date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest survey date. In the case of a one (1) year certification with the earliest survey date of 6/15/2011, the expiration date would be 6/14/2012.

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34th NATIONAL CONFERENCE ON  
INTERSTATE MILK SHIPMENTS

Proposal #: 125  
Committee: Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

**A. Summary of Proposal**

To pulse a CIP blocking valve seat in a block-bleed-block valve arrangement separating milk and cleaning/sanitizing solution for on-farm raw milk collection and storage in Automatic Milking Installations (AMI).

**B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission**

The AMI block-bleed-block valve arrangement, required to separate milk for sale from cleaning/sanitizing solution or from milk with abnormalities, can have one valve seat and/or a portion of the bleed vent open to atmosphere between the blocking valve seats which are not exposed to cleaning/sanitizing solution at every cleaning routine.

In a typical AMI operation, for cleaning/sanitizing solution to come into contact with the CIP blocking valve seat and/or the bleed vent open to atmosphere between the blocking valve seats, this compromises the block-bleed-block valve arrangement.

**C. Proposed Solution**

Changes to be made on page(s):	361	of the (X - one of the following):
<input checked="" type="checkbox"/> 2011 PMO	<input type="checkbox"/>	2011 EML
<input type="checkbox"/> 2011 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/> 2011 Procedures	<input type="checkbox"/>	2011 Constitution and Bylaws

Modify the 2011 PMO, page 361, Appendix Q, Item 14r., Protection From Contamination

The teat cups of the milking cluster need to be adequately shielded during the udder prepping process to assure that contaminants may not enter through the teat cup and get into the milk. AMIs are designed to automatically shift from milk to wash; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and sanitizing solutions. A fail-safe valve system ~~providing protection equivalent to an inter-wired block and bleed, as referenced in Item 15p.(B)~~, shall be located as needed to prevent cross contamination. Separation shall be provided between, milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale. This can be accomplished by separation of all connection points between such circuits by at least two (2) automatically controlled valves, or valve seats in the case of single-bodied double seat valves, with a drainable opening to the atmosphere between, if:

1. The opening to the atmosphere (vent) is equal to the largest pipeline feeding the valves.
2. These valves, or valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position.
3. These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that will prevent contamination of milk intended for sale with cleaning/sanitizing solutions, or milk with abnormalities. Automatic fail-safe systems will be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position, and the vent for the cavity between opened, before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (6) below.
4. The system shall not have manual override capability, except for testing and inspection with no potential for adulteration.
5. Controls for the automated fail-safe system are tested as directed by the Regulatory Agency in order to verify/validate protection.
6. The valve vent cavity is not cleaned until downstream milk intended for sale has been removed or isolated, except in the case of a properly designed and operated system, in which case this drainable opening to the atmosphere may be cleaned while milk intended for sale is isolated by one (1) of the blocking valves, or valve seats in the case of single-bodied double seat valves. A properly designed and operated system shall incorporate the following:
  - a. During CIP, a seat-lift operation of the cleaning/sanitizing solution blocking valve seat may be used for cleaning the valve vent cavity, provided there shall not be pressurization of cleaning solutions on the exterior of the valve seat isolating milk intended for sale that can equal or exceed the pressure of the milk being isolated, and
  - b. During CIP, with a seat-lift operation for cleaning the valve vent cavity, the position detection of the seat isolating milk intended for sale from the valve vent cavity, and the position detection of the vent open to the atmosphere, shall be monitored and interlocked with the pump or source of liquid pressure, such that if it is determined they are not properly positioned, the pump or source of liquid pressure will be immediately de-energized.
7. Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

AMIs, which have a pipe into the wash vat that is continuously connected to the system, shall have a valving system that provides for an air break equal to the diameter of the wash line.

Name: **Engineering Committee:** Gary Steingraber-BouMatic, Russ Kolstad-DeLaval,  
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**C. Proposed Solution**

Changes to be made on page(s):		297, 298	of the (X - one of the following):
X	2011 PMO		2011 EML
	2011 MMSR		2400 Forms
	2011 Procedures		2011 Constitution and Bylaws

2011 PMO, page 297

10. Repeat Procedures 4 through 9 for the holding time on water in diverted-flow. ~~For all gear driven timing pumps complete Procedure 11, 12, and 13.~~ For those homogenizers used as timing pumps, when the measured holding time for water is less than 120% of the legal holding time complete Procedures 11, 12 and 13. For those homogenizers or gear driven pumps used as timing

2011 PMO, page 298

pumps, when the measured holding time for water is 120% or more of the legal holding time, Procedure 11 is optional and 12 and 13 are not required.

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