33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	205
Committee:	MMSR

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

C. Proposed Solution

Changes to be made on page(s): 23,29 PMO, 82 MMSR of the (X - one of the following):

X	2009 PMO		2009 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

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SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank or from a properly installed and operated in-line-sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.
It shall be the responsibility of the industry plant sampler to collect a representative sample of milk from each milk tank truck or from a properly installed and operated aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck.

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4)

separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

~~3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from milk plants offering such products for sale, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.~~

~~4.~~3. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized (including Aseptically Processed and Ultra-Pasteurized) milk and milk products required sampling and testing is to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products with no validated and accepted methods are not required to be tested.

Page 29 PMO Table 1

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10ºC (50ºF) or less within four (4) h or less, of the commencement of the first milk and to 7°C (45ºF) or less within two (2) h after the completion of milking. Provided, tha blend temperature after the first milking subsequent milkings does not exceed 10ºC (5(**NOTE:** Milk sample submitted for testing co and maintained at 0ºC (32ºF) to 4.4ºC (4(where sample temperature is >4.4ºC (40ºF), ≤7.0ºC (45ºF) and less than three (3) hours a collection has not increased in temperature.
	Bacterial Limits.....	Individual producer milk not to exceed 100 per mL prior to commingling with other prod milk. Not to exceed 300,000 per mL as commin milk prior to pasteurization. **NOTE:** Tested in conjunction with the residue/inhibitory substance test.
	Drugs.....……	No positive results on drug residue detec methods as referenced in Section 6 - Labora Techniques.
	Somatic Cell Count*...	Individual producer milk not to exceed 750 per mL.

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS ~~AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS~~	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat. **NOTE:** Milk sample submitted for testing cooled and maintained at 0ºC (32ºF) to 4.4ºC (40ºF), where sample temperature is >4.4ºC (40ºF), but ≤7.0ºC (45ºF) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**…..	Not to exceed 20,000 per mL, or gm.*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform ****.	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase**** ≟.	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs**.....…..	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature……	Cooled to 7ºC (45ºF) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform……	Not to exceed 10 per gram. *Provided,* that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" ULTRA-PASTEURIZED MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat.
	Bacterial Limits**…..	Not to exceed 20,000 per mL, or gm.***
	Coliform**** •.....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Phosphatase**** ≟..	Phosphatase testing of Ultra-Pasteurized milks is not required.
	Drugs**.....…..	There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products
GRADE "A" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113. 3(e)(1)******
	Drugs**.....	There are no validated and accepted drug residue tests for Aseptically Processed Milk and Milk Products.

GRADE "A" NONFAT DRY MILK	Butterfat…… Moisture…… Titratable Acidity…….. Solubility Index…… Bacterial Estimate……. Coliform……... Scorched Particles disc B……	No More Than: 1.25% 4.00% 0.15% 1.25mL. 30,000 per gram 10 per gram 15.0 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature…….	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature……..	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit……..	Not to exceed 10 per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit……..	Not to exceed 10 per gram.

* Goat Milk 1,500,000/mL

** Not applicable to acidified or cultured products, eggnog and flavored (non-chocolate) milk and milk products.

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*)

~~**** Not applicable to bulk shipped heat-treated milk products~~.

****~~*~~ Not applicable to ~~bulk shipped heat-treated milk products;~~ UP products that have been thermally processed at or above 138°C (280°F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.

****~~**~~ 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY".

Page 82 MMSR

1. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO,* Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the plant, shall be collected, prior to pasteurization, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

b. During any consecutive six (6) months, at least four (4) samples of each milk product processed, as defined

in Sections 1 and 6 of the *Grade "A" PMO* shall be collected in four (4) separate months, except when three
(3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.
However, if the production of any Grade "A" condensed or dry milk product, as defined in the *Grade "A" PMO*,
is not on a yearly basis, at least five (5) samples shall be taken within a continuous production period.
~~c. During any consecutive six (6) months, at least four (4) samples of heat-treated products shall be collected in~~
~~at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates~~
~~separated by at least twenty (20) days.~~
~~d~~ c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase,
and cooling temperature) in an official or officially designated laboratory.
d. Assays of Vitamin A, D, and/or A and D fortified milk and milk products made at least annually in an
IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed
and records are available. Each fortified product is evaluated separately.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	208
Committee:	Hauling/Lab

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

C. Proposed Solution

Changes to be made on page(s): Table of contents "X", 24, 26, 130, 132, 134, of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

2009 PMO
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APPENDIX B. MILK SAMPLING, HAULING, AND RANSPORTATION……~~130~~

I. MILK SAMPLING AND HAULING PROCEDURES……...~~130~~
II. REQUIREMENTS FOR USING AN APPROVED IN-LINE SAMPLER…..~~134~~
III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS……...~~134~~
IV. **REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR ~~OBTAINING~~ FARM BULK MILK ~~TANK~~ TANKS AND SILOS ~~UNIVERSAL SAMPLES~~**……..~~135~~
V. MILK TANK TRUCK PERMITTING AND INSPECTION……....~~136~~
…..

2009 PMO
SECTION 6, PAGES 22, 24 AND 26

Page 22:

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank **and/or silo** or from a properly installed and operated in-line-sampler **or aseptic sampler**, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to **transferring or as** transferring milk **utilizing an aseptic sampler** from a farm bulk tank **or silo**, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

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……
Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers~~,~~ and **approved** aseptic samplers for milk tank trucks~~, alternative aseptic sampler~~ **or** for farm bulk **milk** ~~tank(s)~~ **tanks and silos**, ~~universal samples~~ and required laboratory examinations shall be in substantial compliance with the most current edition of the ~~PMO~~ *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures*. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM).

Page 26:

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers~~,~~ and **approved** aseptic samplers for milk tank trucks~~, alternative aseptic~~ **or for** farm bulk **milk** ~~tank~~ **tanks and silos**, ~~sampler for taking universal sample(s)~~, and **the** holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the ~~NCIMS/~~FDA 2400 Series ~~Laboratory~~ Forms, *SMEDP* and *OMA*. The procedures shall be those specified therein for:
…

2009 PMO
APPENDIX B, PAGES 130, 132, 134 AND 135

Page 130:

Training: To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler~~,~~ and **approved** aseptic samplers for milk tank trucks ~~and alternative aseptic~~ **or for** farm bulk **milk** ~~tank~~ **tanks and silos** ~~sampler~~, all bulk milk hauler/samplers and industry plant samplers must be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet **the** requirements can conduct this training. If the Regulatory Agency does not conduct the training, the training must be approved by or conducted under the supervision of the Regulatory Agency. …

Page 132:

2. **Equipment Requirements:**

~~Item~~ c. Sample dipper or other **approved aseptic** sampling devices ~~such as an alternative aseptic farm bulk tank sampler,~~ of sanitary design and material approved by the Regulatory Agency; clean and in good repair. ….

5. **Universal Sampling System:** When bulk milk hauler/samplers collect raw milk samples, the "universal sampling system" shall be employed, whereby samples are collected every time milk is picked up at the farm. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler. The use of the "universal sample" puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:

a. Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.

b. The milk must be agitated a sufficient time to obtain a homogeneous blend. Follow the State and/or manufacturer's guidelines **or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device**.

c. While the ~~tank~~ **farm bulk milk tank or silo** is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milk house aseptically. Remove the cap from the ~~tank~~ **farm bulk milk tank or silo** outlet valve and examine **the outlet valve** for milk deposits or foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

d. The sample may only be collected after the milk has been properly agitated **or when using an approved aseptic sampling device, follow the**

specified protocol and SOP for that device. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

e. Collect a representative sample or samples from the **farm** bulk **milk** tank **or silo by using a sample dipper or other approved aseptic sampling device. Refer to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B of this *Ordinance* for the specific protocol for the use of approved aseptic sampling devices.** When transferring milk from the sampling equipment, caution should be used to assure that ~~no~~ milk is **not** spilled back into the ~~tank~~ **farm bulk milk tank or silo**. Do not fill the sampling container more than ¾ full. Close the cover on the sample container.

f. The sample dipper shall be rinsed free of milk and placed in its carrying container.

g. Close the cover or lid of the **farm** bulk **milk** tank.

h. The sample must be identified with the producer's number at the point of collection.

i. A temperature control sample must be taken at the first stop of each load. This sample must be labeled with collection time (optionally, in military time (24 hour clock)), date, temperature and producer and bulk milk hauler/sampler identification.

j. Place the sample or samples immediately into the sample storage case.

~~Add a new 5.1. or, collect the universal farm tank sample(s) using the Approved Alternative Aseptic Farm Bulk Tank Sampling System. Refer to the requirements for using this system in item IV on page 134.~~

Page 134:

IV. REQUIREMENTS FOR USING AN APPROVED ~~ALTERNATIVE FARM BULK TANK SAMPLER~~ ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND SILOS

A protocol specific to each milk producer in which the milk producer, who transports milk only from his/her own dairy farm, or bulk milk hauler/~~sampler~~ samplers ~~utiliese~~ utilize an approved ~~alternative~~ aseptic ~~farm bulk tank sampling system~~

sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and ~~the~~ FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.

a. The aseptic sampler fitting must be installed according to the ~~manufacture's~~ manufacturer's recommendations and in a manner that is compatible with its intended use and does not create a dead end.

b. The aseptic sampler septum must be installed according to the manufacturer's instructions.

c. Transfer of milk is achieved using a Standard Operating Procedure (SOP) specific to the aseptic sampler.

2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.

3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the ~~sample collection device~~ aseptic sampling device as well as collect, identify, handle and store the milk sample.

Page 135:

~~IV.~~ V. MILK TANK TRUCK PERMITTING AND INSPECTION

2009 PMO
APPENDIX M-REPORTS AND RECORDS, PAGE 337

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS, the following changes to FORM FDA 2399a-BULK MILK HAULER/SAMPLER EVALUATION REPORT shall be made:

BULK TANK SAMPLING PROCEDURES

10. Sample Transfer Instrument …

c. Or an approved in-line sampler……□

d. Or an approved aseptic sampler …..□

~~d.~~**e.** Or a sanitized sampling cock …….□

……..

FORM FDA 2399b (~~10/08~~ 10/12) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

~~Milk Sample Collection Evaluation Form 2399 (10/06)~~

~~Item 9. Raw milk for pasteurization- milk trucks and plant storage tanks. (Refer to Item 8 for applicable procedures)……~~

~~b. Collect sample in a sanitary manner from tank opening (manhole)~~

~~new c. Collect sample from farm bulk tank using an approved aseptic sampler~~

~~Re-number the rest of the number 9 as appropriate.~~

~~Old item i, re-numbered item j~~

~~Sampler-dipper, washed and sanitized after each use and replaced in sanitizing solution~~

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **BULK MILK HAULER/SAMPLER EVALUATION REPORT**	BULK MILK HAULER/SAMPLER PERMIT NO.	TANKER PERMIT NO.
	BULK MILK HAULER/SAMPLER	DAILY PICKUP NO.

ADDRESS OF BULK MILK HAULER/SAMPLER	NAME AND ADDRESS OF INSPECTION LOCATION
OWNER	NAME AND ADDRESS OF RECEIVING PLANT
ADDRESS OF OWNER	

An evaluation of your sampling procedures showed violations existing in the Items checked below. You are further notified that this evaluation report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

HAULER SANITATION PROCEDURES

1. Pickup practices conducted to preclude contamination of milk contact surfaces ☐
2. Hands clean and dry, no infections ☐
3. Clean outer clothing, no use of tobacco ☐
4. Hose port used, tank lids closed during completion of pickup ☐
5. Hose properly capped between milk pickup operations, hose cap protected during milk pickup ☐
6. Hose disconnected before tank rinsed ☐
7. Observations made for sediment/abnormalities ☐
8. Sample collected from each producer's bulk tank picked up ☐

BULK TANK SAMPLING PROCEDURES

9. Thermometer – Approved Type ☐
   a. Accuracy – Checked against standard thermometer every 6 months – accuracy (+) (-) 1 division ☐
   b. Date checked and checker's initials attached to case ☐
10. Sample Transfer Instrument
    a. Clean, sanitized or sterilized and of proper construction and repair ☐
    b. Sterile needle for aseptically dispensing a milk sample from the bulk tank sample septum into a sample container (i.e., vial) ☐
    c. Or an approved in-line sampler ☐
    d. Or an approved aseptic sampler ☐
    e. Or a sanitized sampling cock ☐
11. Sampling Instrument Container
    a. Proper design, construction and repair for storing sample dipper in sanitizer ☐
    b. Applicable test kit for checking strength of sanitizer (200 ppm chlorine or equivalent) ☐
12. Sample Containers
    a. Clean, properly sanitized or sterilized ☐
    b. Adequate supply, properly stored or handled ☐
13. Sample Storage Case
    a. Rigid construction, suitable design to maintain samples at 0°C - 4.4°C (32°F - 40°F), protected from contamination ☐
    b. Ample space for refrigerant, racks provided as necessary ☐
14. Sample Collection – Precautions and Procedures
    a. Sampling instrument and container(s) properly carried into and aseptically handled in milkhouse ☐
    b. Bulk tank milk outlet valve sanitized before connecting transfer hose ☐
    c. Smell milk through tank port hole ☐
    d. Observe milk in a quiescent state with lid wide open and lights on when necessary ☐
    e. Test thermometer sanitized (1 min. contact time) ☐
    f. Non-acceptable milk rejected ☐
    g. Dry measuring stick with single-service paper towel ☐
    h. Measure milk only when quiescent ☐
    i. Do not contaminate milk during the measuring process ☐
    j. Agitate milk before sampling at least 5 min. or longer as may be required by tank specifications, or follow approved aseptic sampling device protocol and SOP ☐
    k. Do not open bulk tank valve until milk is measured and sampled ☐
    l. Temperature of milk, time, date of pickup and bulk milk hauler/sampler name and license or permit no. recorded on each farm weight ticket ☐
    m. Tank thermometer accuracy
       1. Tank thermometer accuracy checked monthly and recorded when used as test thermometer ☐
       2. Accuracy of required recording thermometer checked monthly against standardized thermometer and recorded ☐
    n. Temperature control sample provided at first sampling location for each rack of samples ☐
    o. Temperature control sample properly labeled with time, date, temperature, producer ID and bulk milk hauler/sampler identification ☐
    p. Sample containers legibly identified at collection points ☐
    q. Sample dipper rinsed at least two times in the milk before transferring sample ☐
    r. Dipper should be extended 6-8 inches into the milk to obtain representative sample ☐
    s. Sample cock properly sanitized and flushed prior to sampling ☐
    t. Septum surface properly sanitized and single service sterile needle used (Follow approved aseptic sampling device SOP for sample transfer) ☐
    u. Do not hold sample container over the milk when transferring sample into the container ☐
    v. Fill sample container no more than ¾ full ☐
    w. Rinse sample dipper in safe tap water, return to storage container, open tank valve, start milk transfer pump ☐
    x. Immediately place milk sample in the sample case ☐
15. Sample Collection – Storage and Transportation
    a. Sample storage – refrigerant maintained no higher than milk level in sample containers – maintain sample temperature 0ºC – 4.4ºC (32ºF- 40ºF), do not bury tops of containers in ice, protect from contamination ☐
    b. Deliver samples to laboratory promptly ☐
    c. Samples and sample data – submitted to laboratory – if by common carrier, use tamper proof shipping case with top labeled "This Side Up". ☐

REMARKS *(If additional space is required, please place information on the back of this Form or on a separate page.)*

DATE	SANITARIAN	AGENCY

NOTE: *An M-I shall be developed and issued addressing the Standard Operating Procedure (SOP) for this approved aseptic sampler for farm bulk milk tanks and silos.*

SOP for QMI
Alternative Aseptic Bulk Tank Sampling System

General Requirements:

1) The farm bulk tank(s) must have a working agitator equipped with a timer. This timer must make the bulk tank agitator run the minimum amount of time the bulk tank manufacture specifies.
2) There is no need to run the bulk tank agitator before pumping all the milk from the bulk tank using this QMI system onto the bulk milk transport tanker.
3) If the bulk tank will only be a partial pick-up, run the agitator before pumping milk from the bulk tank onto the bulk milk transport tanker as per manufacturer's specifications. Then run the QMI sampling system as normal.
4) The person(s) performing the following steps shall possess a valid bulk tank milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty four (24) months by the State Milk Regulatory Agency

Device Requirements:

1) The QMI supplied septum sampling device can be attached to the outlet valve of the farm bulk tank so it can be cleaned-in-place (CIP) when the farm bulk tank is washed or alternatively can be removed after each use to hand clean and sanitize before the next usage.
2) Use only QMI sterile septum inserts; hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten..
3) The protective cover for the septum shall be in place at all times when the septum is not in use.
4) Wash and sanitize hands before performing the following steps.
5) When ready to pump out the milk, remove the septum protective cover.
6) Sanitize the QMI sample septum protective white cover before inserting the sampling needle. For the perimeter needle channels, slant the needle toward the center, following the angle of the channel. Be careful not to bend the lumen tip of the needle.
7) SEPTUM REPLACEMENT PROCEDURE.
   a) There are seven (7) sampling ports in each QMI septum. Use a new sampling port each time a farm bulk tank is pumped out. Replace the septum when all seven (7) sampling ports have been used.
   b) Use each QMI septum insert sampling port ONLY ONCE! "Pierced sampling ports can be easily seen. Once pierced, a port may not be used again.
   c) When all 7 QMI septum insert sampling ports are used, remove the nut that holds the QMI septum in place and remove the used QMI septum insert and discard.
   d) CLEAN and SANITIZE the QMI septum insert holder area and install a new QMI septum insert, replace the nut, hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but

~~do not over-tighten. The protective cover should be kept over the QMI septum insert at all times when not in use.~~

8) ~~Use only QMI supplied sterile sample collection bags designed to work with this system.~~

9) ~~Use only the peristaltic pump recommended by QMI.~~

10) ~~Volume of the milk sample obtained can be no more than approximately three quarters (¾) of the volume of the QMI sample collection bag used. Pump speed (RPM) for pump type and size of QMI aseptic sampling bag used determined and recorded.~~

11) ~~The QMI sample collection bag must be placed in a portable hand carry type cooler during pumping out the milk from the bulk tank to maintain the temperature of the sample to no more than the allowable temperature in the PMO.~~

~~Sampling Procedures:~~

1) ~~The person(s) performing the following steps shall possess a valid bulk tank milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.~~

2) ~~The person(s) performing the following steps shall wash their hands before carrying out those steps.~~

3) ~~If QMI sampling septum device is not attached to the bulk tank outlet valve and has not been CIP cleaned and sanitized with the bulk tank wash, hand WASH and SANITIZE the bulk tank outlet valve and QMI sampling septum device. (See **Device Requirements item 1).** Use a spray bottle with approved sanitizer to best sanitize the outlet valve on the bulk tank~~

4) ~~Attach the QMI sampling septum device to the bulk tank.~~

5) ~~Remove the protective cover cap from the QMI sampler~~

6) ~~Sanitize the white covering area over the QMI sampling septum.~~

7) ~~Position the QMI peristaltic pump close enough to the bulk tank outlet valve so the QMI sampling bag can be hooked up with the needle going into an unused port on the QMI septum and the QMI sample collection bag in the portable hand carry type cooler.~~

8) ~~On the QMI peristaltic pump open the sampling head by lifting up on the lip on the upper part of the pump head. Operator's manual has pictures of this step.~~

9) ~~Take out a QMI sampling bag and locate the fatter section of the tubing. Place this fatter tubing section in the space created after opening the pump head lid and close the pump head lid when the tubing is positioned straight over the rollers in the pump head.~~

10) ~~Take the cover off the needle attached to the one end of the QMI sample collection bag tubing and locating an unused sampling port, there are 7 on each QMI septum insert and push the needle completely into the septum. For the perimeter needle channels, slant the needle toward the center following the angle of the channel. Be careful not to bend the lumen tip of the needle.~~

11) ~~Use each QMI septum insert sampling port ONLY ONCE! Pierced septum insert sampling ports can be easily seen. Once pierced, a port MAY NOT be used again. See **Septum Replacement Procedure in Device Requirements item 7.**~~

12) ~~When all 7 QMI septum insert sampling ports have been used, remove the nut that holds the QMI septum in place and remove the used QMI septum insert and discard. See **Septum Replacement procedure in Device Requirements item 7.**~~

13) CLEAN and SANITIZE the QMI septum insert holder area and install a new QMI septum insert, replace the nut, hand tighten the nut and then use a wrench to give it an additional 1/8th turn, but do not over-tighten. The protective cover should be kept over the QMI septum insert at all times when not in use.

14) Open the bulk tank outlet valve, press the start button on the control pad of the peristaltic pump and turn on the pump.

15) Make sure the RPM's of the pump display match what has been determined to meet the requirements in item 10 under Device Requirements.

16) If milk is not flowing toward the pump and sampling bag press the clockwise-counterclockwise arrows on the pump display until the milk starts flowing toward the bag.

17) Place and maintain the QMI sample collection bag in the cooler during sampling so the temperature of the sample is maintained at or below PMO temperature requirements. See **Device Requirements item 11.**

18) When the bulk tank has been emptied or collection of partial pickup completed turn off the pump and remove the needle from the QMI septum. Replace the needle cover.

19) Lift the pump head lid to open it up to allow removal of the sample tubing. The reverse process as was used in step 9. Tie a knot in the QMI sample collection bag tubing close to where the tubing is attached to the bag.

20) Take the sample bag and invert with constant uninterrupted inversions 25 times. This agitates the QMI sample collection bag so that a representative sample can be taken from the milk collected in the bag:

21) Sanitize (using an approved sanitizer) a cutting device and cut the tubing from the QMI sample bag just above where the tubing attaches to the bag. Tip the bag and allow some milk to flow before positioning a properly identified sample vial (use the same identification as would be used for a conventional dip sample) into the milk stream to fill the sample vial ¾ full. (Note: QMI sample collection bags are to be used only ONCE).

22) Immediately transfer the sample vial(s), to the bulk milk pick-up tankers sample storage cooler to maintain proper temperature. A temperature control (TC) sample will also need to be taken at the first stop on the bulk milk pick-up tankers route.

23) Handle the sample(s) from this point the same as a conventionally obtained universal dip sample.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	209
Committee:	Appendix N

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

C. Proposed Solution

Changes to be made on page(s): 25 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following change to the 2009 PMO.

~~Strike out~~ text to be deleted and <u>underlined</u> text to be added.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

Page 25
The determination of a problem is to be based upon:
1. Sample survey results;
2. USDA tissue residue data from cull ~~and veal~~ dairy animals;
3. Animal drug disappearance and sales data;
4. State feed back; and
5. Other relevant information.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	210
Committee:	Hauling

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

C. Proposed Solution

Changes to be made on page(s): 135 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Change the following sentence by striking the words “near the outlet valve” and adding the words “on the front left side of the tanker bulkhead”

The affixed label shall be located near the outlet valve or on the front left side of the **milk tank truck** bulkhead.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	212
Committee:	Scientific

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

C. Proposed Solution

Changes to be made on page(s): Pages 202 and 210 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Modify the 2009 PMO, page 202, Appendix F. Sanitization, Section I. Methods of Sanitization, Chemical.~~

~~Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in 21 CFR 178.1010 and shall be used in accordance with label directions, or equipment manufacturer instructions if produced onsite in accordance with Section III below.~~

~~Modify the 2009 PMO, Appendix F. Sanitization to include a new Section III starting on page 210.~~

~~III. ACCEPTED CRITERIA FOR THE ONSITE PRODUCTION AND SANITIZATION USE OF HYPOCHLOROUS ACID~~

~~BACKGROUND~~

~~Hypochlorous acid is already approved, at concentrations not to exceed 200 ppm, for use as an ingredient in an antimicrobial pesticide formulation that may be applied to dairy processing equipment, and food-processing equipment and utensils (Title 40: Protection of Environment; Part 180: Tolerances and Exemptions for Pesticide Chemical Residues in Food; Subpart D: Exemptions From Tolerances).~~

Hypochlorous acid can be generated by the electrolysis of a dilute NaCl (brine) solution passing through an electrolytic cell consisting of anode and cathode chambers separated by a membrane. The cell allows for the migration and separation of ions through the membrane. During this process, two separate streams of activated water are produced: hypochlorous acid (HOCl) on the anode side of the cell and sodium hydroxide (NaOH) on the cathode side.

The current EPA process for registering a chemical solution as an effective sanitizer does not address those solutions that are produced and used onsite. As a result, very specific production and efficacy criteria have been defined below under which hypochlorous acid is considered to be effective for the sanitization of milk containers, utensils and equipment.

CRITERIA

The following is a list of criteria that is required to accept hypochlorous acid, that was produced onsite, as an effective sanitizer of milk containers, utensils and equipment.

1. An acceptable hypochlorous acid solution is one that meets DIS/TSS-4 Jan 30, 1979 Efficacy Data Requirements, Sanitizing rinses (for previously cleaned food-contact surfaces). The applicable test requirements and performance standards are:
   a. Test requirement. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.
   b. Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.

   The manufacturer of the production machine is required to keep on file all related testing results and must make the information available to regulatory agencies upon their request.

2. The manufacturer of the machine used to produce an acceptable hypochlorous acid solution must obtain an EPA establishment number for the machine and must comply with all related machine labeling and reporting requirements.

3. The manufacturer of the machine shall provide instructions on the production and use of the acceptable hypochlorous acid solution as an effective sanitizer without post-rinse. In addition, the manufacturer shall specify: 1) the minimum acceptable Free Available Chlorine (FAC) level of the hypochlorous acid solution to be used with the maximum not to exceed 200ppm, 2) the acceptable pH range of the hypochlorous solution to be used, and 3) the maximum amount of residual NaCl in the hypochlorous solution to be used measured in terms of microsiemens. Onsite testing of the FAC level is recommended on a regular basis to ensure compliance.

4. The machine used to produce an acceptable hypochlorous acid solution must possess the capability to measure and record on a real time basis the following production parameters, and automatically stop production and trigger an alarm when operating outside of the application specifications.
   a. Softened water flow into the electrolytic cell

~~b. Brine solution flow into the electrolytic cell~~
~~c. Voltage and amperage across the electrolytic cell~~

~~5. The machine used to produce an acceptable hypochlorous acid solution must possess the capability to measure and record on a real-time basis the ORP, pH and microsiemens of the generated hypochlorous acid, and automatically stop production and trigger an alarm when operating outside of the application specifications.~~

~~6. The machine used to produce an acceptable hypochlorous acid solution shall be designed with an automatic, self-cleaning capability such that the electrolytic cell and the integrated water softener are cleaned on a regular frequency and in a consistent manner to ensure that they operate within their application specifications.~~

~~7. The machine shall be constructed of materials that do not impart toxic materials into the acceptable hypochlorous acid solution either as a result of the presence of toxic constituents in the materials of construction, or as a result of physical or chemical changes that may occur during the electrolysis process.~~

~~8. All records shall be accessible to the Regulatory Agency for inspection. Electronically generated records, if used, shall meet the criteria specified in Appendix H., V.~~

2009 PMO

TABLE OF CONTENTS, PAGE xi

SECTION 7, ITEM 11r, PAGE 46

ITEM 11r. UTENSILS AND EQUIPMENT – SANITIZATION ADMINISTRATIVE PROCEDURES

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in ~~21 CFR 178.1010~~ 40 CFR 180.940 and shall be used in accordance with label directions, or the electro-chemical activation (ECA) device

manufacturer's instructions if produced onsite in accordance with Appendix F. Section II. (Refer to Appendix F. for further discussion of approved sanitizing procedures.)

APPENDIX F.SANITIZATION, PAGE 202

I. METHODS OF SANITIZATION

CHEMICAL

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in either in ~~21 CFR 178.1010~~ 40 CFR 180.940 and shall be used in accordance with label directions, or ECA device manufacturer's instructions if produced onsite in accordance with Section II below.

II. CRITERIA FOR THE ONSITE PRODUCTION AND USE OF ELECTRO-CHEMICAL ACTIVATION (ECA) GENERATED HYPOCHLOROUS ACID FOR THE SANITIZATION OF MULTI-USE CONTAINERS, UTENSILS, AND EQUIPMENT

The following is a list of criteria that are required for on-site generation of ECA generated hypochlorous acid that was produced onsite and used as a sanitizer for the sanitization of multi-use containers, utensils and equipment.

1. The ECA device manufacturer shall be registered with the EPA as a pesticidal device establishment pursuant to 40 CFR 152.500 and shall comply with the labeling requirements outlined in 40 CFR 156.10.

2. The minimum dilution percentage of the sanitizer shall be 50 parts per million (ppm) free available chlorine (FAC) with a minimum contact time of 30 seconds pursuant to the efficacy requirements for EPA DIS/TSS 4 Sanitizer rinses, for previously cleaned milk-contact surfaces, and less than 200 ppm FAC. The sanitizer produced shall meet the data requirements of 40 CFR Part 158 Data Requirements for Registration, Pesticide Assessment Guidelines – Subdivision G, 91-2(f), and its test documents shall be pursuant to Good Laboratory practices (GLP's).

3. The salt used to generate the sanitizer shall be of food-grade quality rated at a minimum of 99.6% purity, and potable water shall be used to ensure quality and consistency of the sanitizer generated.

4. The ECA device and its solution concentrate storage containers shall be constructed of materials that do not impart toxic materials into the sanitizing solution either as a result of the presence of toxic constituents in the materials of construction or as a result of physical or chemical changes that may occur during the ECA process.

5. The ECA solution concentrate storage containers shall be labeled with the following:

a. Contents;
b. EPA Establishment Number for the ECA device manufacturer;

c. Dilution percentage instructions for use and storage conditions, including the shelf-life;
d. A list of its active and inert ingredients; and
e. Other required standard safety data disclosures, formerly referred to as Material Safety Data Sheet (MSDS).

6. The ECA device used to produce the hypochlorous sanitizer shall control and record the parameters to ensure that the ECA device is operating within its design limits and provides an effective real time notification or alarm and will shut down when it falls out of the required range as recommended by the ECA device manufacturer.

7. Standard measurement methods such as FAC titration or chlorine test strips shall be used to verify that the concentration of the ready to use sanitizer being applied is in a range between 50 ppm and 200 ppm. Measurement equipment shall be checked, calibrated and measurements recorded. All records shall be accessible to the Regulatory Agency for inspection. Electronically generated records for FAC concentrations, if used, shall meet the criteria specified in Appendix H Section V.

III. EVAPORATING, DRYING AND DRY PRODUCT EQUIPMENT CLEANING

APPENDIX L, PAGE 336

APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT* AND THE *FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT*

40 CFR Part 141- NATIONAL PRIMARY DRINKING WATER REGULATIONS
40 CFR 152.500 Requirements for Devices
40 CFR 156.10 Labeling Requirements for Devices and their Products
40 CFR 158 Data Requirements for Registration, Pesticide Assessment Guidelines
40 CFR 180.940 Tolerance Exemptions for Active and Inert Ingredients for use in Antimicrobial Formulations, Food-Contact Surface Sanitizing Solutions

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	214
Committee:	

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

C. Proposed Solution

Changes to be made on page(s): 46, 202 and 336 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and <u>underline</u> text to be added.

2009 PMO
SECTION 7, PAGE 46

11r. UTENSILS AND EQUIPMENT – SANITIZATION

ADMINISTRATIVE PROCEDURES

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in ~~21 CFR 178.1010~~ <u>40 CFR 180.940</u> and shall be used in accordance with label directions. (Refer to Appendix F. for further discussion of approved sanitizing procedures.)

2009 PMO
APPENDIX F, PAGE 202

I. METHODS OF SANITIZATION

CHEMICAL

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in ~~21 CFR 178.1010~~ 40 CFR 180.940 and shall be used in accordance with label directions.

2009 PMO
APPENDIX L, PAGE 336

APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT*

40 CFR PART 141 – NATIONAL PRIMARY DRINKING WATER REGULATIONS
40 CFR 180.940 – Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (~~F~~food contact surface sanitizing solutions)

FFD&CA, as amended, Sec. 402. [342] Adulterated Food and Sec. 403. [343] Misbranded Food

2009 PMO
APPENDIX J, PAGES 319-321

D. FABRICATION PLANT STANDARDS

17. WAXES, ADHESIVES, SEALANTS, COATINGS AND INKS

...

c. Waxes, adhesives, sealants, coatings and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surface shall comply with the requirements of 21 CFR Parts ~~175~~ 174-178. ….

19. WRAPPING AND SHIPPING

…

e. All packaging materials that contact the product-contact surface of the container or closure shall comply with the requirements of 21 CFR Parts ~~175~~ 174-178 and the bacteriological standards of Section C of these Standards, but the materials do not have to be manufactured at a listed single-service plant. Some outer packaging material such as corrugated cardboard boxes used for the packaging of milk carton flats, are exempt from this bacteriological standard. The edges of these flats are subject to heat during the forming and sealing of the container.

20. IDENTIFICATION AND RECORDS

…

e. The fabricating plant shall have on file information from suppliers of raw material, waxes, adhesives, sealants, coatings and inks indicating that the material complies with the requirements of 21 CFR Parts ~~175~~ 174-178.

f. The fabricating plant shall have on file information from the suppliers of packaging materials specified in these Standards indicating that the material complies with the requirements of 21 CFR Parts ~~175~~ 174-178 and the bacteriological standards of Section C. of these Standards. There are no specifications for sampling frequency. The Regulatory Agency may choose to collect samples of packaging materials to determine compliance with bacteriological standards of this Section. ….

…

…
21 CFR 173.310 Boiler Water Additives
21 CFR 174 - INDIRECT FOOD ADDITIVES: GENERAL
21 CFR PART 175 - INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS…

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	215
Committee:	Lab

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

C. Proposed Solution

Changes to be made on page(s): 211 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER - BACTERIOLOGICAL

Reference: Section 7, Items 8r, 18r, 7p and 17p.
Application: To private water supplies, used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and to recirculated cooling water, used in milk plants, receiving stations and dairy farms.
Frequency: Initially; after repair, modification or disinfection of the private water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and thereafter; semiannually for all milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities water supplies and at least every three (3) years on dairy farms. Recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually.
Criteria: A Most Probable Number (MPN) of coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 mL are tested using the Multiple Tube Fermentation (MTF) technique, or one of the Chromogenic Substrate ~~techniques~~ multiple tube procedures; a direct count of less than 1 per 100 mL using the Membrane Filter (MF) technique; or a presence/absence (P/A) determination indicating less than 1 per 100 mL when one vessel containing 100 mL ~~are~~ is tested using the MTF technique or one of the Chromogenic Substrate ~~techniques~~ procedures. The Chromogenic ~~s~~Substrate ~~techniques~~ procedures are not acceptable for recirculated cooling water. Any

sample producing a bacteriological result of Too Numerous To Count (TNTC)~~, greater than 200 total bacteria colonies per 100 mL,~~ or Confluent Growth (CG)~~, bacterial growth covering the entire filtration area or a portion thereof and colonies are not discrete~~ **by the MF technique**; or turbidity in a presumptive test with no gas production and ~~without~~ with no gas production in confirmation (optional test) by the MTF technique (both MPN and P/A format) shall be considered invalid and shall have a Heterotrophic Plate Count (HPC)~~,~~ from the same sample or subsequent resample~~,~~ of less than 500 **colony forming units (CFU) per mL** in order to be deemed satisfactory. Findings by HPC shall be reported as Positive or Not-Found.

Apparatus, Methods and Procedure: Tests performed shall conform with the current edition of *SMEWW* or with FDA approved, EPA promulgated methods for the examination of water and waste water or the applicable FDA 2400 Series Forms.

Corrective Action: When the laboratory report on the sample is unsatisfactory, the water supply in question shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	216
Committee:	MMSR

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

C. Proposed Solution

Changes to be made on page(s): 30, 31, 48, 51, 52, 54, 56, 76, 77 and 82-84 of the (X - one of the following):

	2009 PMO		2009 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and <u>underline</u> text to be added.

*Make the following changes to the **2009 MMSR**.*

G. EXAMPLES OF RATING, NCIMS HACCP LISTING FORMS

4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4)……..

5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5)…….

***Note:** Update the FORMs cited above as indicated below:*

Page 30:

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
DAIRY FARM ENFORCEMENT
PROCEDURES
(Refer to PART I, Item 10 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) on page 9 of this Proposal.

NOTE: Also make these same changes on Pages 51, 54 and 56 of the 2009 MMSR.

Page 31:

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

For the Calculation of
MILK PLANT ENFORCEMENT
PROCEDURES
(Refer to PART II, Item 9 on PAGE 2 of this Form)

1 Category I-Permit Issuance ~~(PI)~~
2 Category II-Permit Suspension ~~(PS)~~
3 Category III-Permit Revocation ~~(PR)~~
4 Category IV-Permit Reinstatement ~~(PRI)~~
5 Category V-Hearing/Court Action ~~(H/CA)~~

FORM FDA 2359j (~~10/09~~ 10/12) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

Refer to the actual FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) on page 10 of this Proposal.

NOTE: Also make these same changes on Pages 48 and 52 of the 2009 MMSR.

APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS

PART I. DAIRY FARMS

Pages 76-77:

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken

as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF DAIRY FARMS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTY). The BTU will be prorated by enforcement action(s) in compliance per farm. Five (5) Categories (a-e) will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%) compliance. The Categories are as follows:

a. Category I: Permit Issuance ~~(PI)~~;
b. Category II: Permit Suspension ~~(PS)~~;
c. Category III: Permit Revocation ~~(PR)~~;
d. Category IV: Permit Reinstatement ~~(PRI)~~; and
e. Category V: Hearing/Court Action ~~(H/CA)~~.

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. **NOTE:** Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI*)~~
b. Permit issuance based on compliance. ~~(PI*)~~

Category II: Permit Suspension

~~c~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS*)~~
~~d~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS*)~~

c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". ~~(PS*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided ….."

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR*)~~
~~f. Hearings provided for as required. (H*)~~

Category IV: Permit Reinstatement

~~g.~~ Reinstatement procedures followed. ~~(PRI*)~~

NOTE: *Grade "A" PMO*, Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements."

~~h. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A". (PS*)~~

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk produced during suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A". ~~(PS*)~~
b. When two (2) out of the last four (4) samples exceed the standards, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS*)~~
c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:

1.) Section 3 for serious health hazard; or
2.) Section 6 for:
   i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
   ii. "Four (4) in six (6) months" positive antibiotic (not of Appendix N. origin); or
   iii. If pesticide contaminated milk is not withheld from sale. ~~(PS*)~~

Category IV: Permit Reinstatement

~~d~~a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard. ~~(PRI*)~~
~~e~~b. "Reinstating accelerated sample(s)" for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period. ~~(PRI*)~~

For Example: FORM FDA 2359j-PART I, Item 10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section G, #4 for an example of the Form.): …..

PART II. MILK PLANTS

Pages 82-84:

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3 - PERMITS, Section 5 - INSPECTION OF MILK PLANTS, Section 6 - EXAMINATION OF MILK AND MILK PRODUCTS and Section 16 - PENALTIES). Prorate by enforcement action(s) in compliance. **NOTE:** A milk plant will be prorated by enforcement action(s) in compliance. Five (5) Categories will be utilized for determining compliance with this Item and each will possess a value of twenty percent (20%) compliance. The Categories are as follows:

a. Category I: Permit Issuance ~~(PI)~~;
b. Category II: Permit Suspension ~~(PS)~~;
c. Category III: Permit Revocation ~~(PR)~~;
d. Category IV: Permit Reinstatement ~~(PRI)~~; and
e. Category V: Hearing/Court Action ~~(H/CA~~).

The Categories relate to the following Sanitation Requirements and Product Compliance~~, which are identified with an *~~. Compliance will be prorated based on **full** compliance with each of the five (5) Categories. **NOTE:** Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section G, #5 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

a. Inspected prior to the issuance of a permit. ~~(PI)*~~
b. Permit issuance based on compliance. ~~(PI)*~~

Category II: Permit Suspension

~~c.~~a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required. ~~(PS)*~~
~~d.~~b. Permit suspension upon violation of:

1.) Section 3 for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
2.) Section 5 for sanitation and/or uncorrected critical processing elements; or
3.) Section 5 for consecutive violation(s) of the same requirements of Section 7. ~~(PS)*~~

c. Milk products processed during suspension or while a monetary penalty is imposed for

repeated inspection violations is not eligible for sale as Grade "A". ~~(PS)*~~

NOTE: *Grade "A" PMO,* Section 3 states: "The Regulatory Agency may forego suspension of the permit, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk or milk product in violation is not sold or offered for sale as a Grade "A" milk or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided ….."

Category III: Permit Revocation

~~e.~~ Action to revoke a permit taken upon multiple suspensions. ~~(PR)*~~

Category IV: Permit Reinstatement

~~f. Hearings provided for as required. (H/CA)*~~
~~g.~~ Reinstatement procedures followed. ~~(PRI)*~~

NOTE: *Grade "A" PMO,* Section 3 states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

~~h. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations are not eligible for sale as Grade "A". (PS)*~~

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and milk products produced during suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A". ~~(PS)*~~
~~b. All product violations followed promptly by an inspection to determine the cause(s). (PRI)*~~
~~c.~~b. When two (2) out of the last four (4) samples exceed the limits, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days. ~~(PS)*~~
~~d.~~c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended. ~~(PS)*~~
~~e. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues). (PRI)*~~
~~f. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform~~

~~counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period. (PRI)*~~

~~g.~~d. Violation of Vitamin Fortification Levels (Refer to M-I-92-13): Determine the cause and re-sample or withhold product from the market. ~~(PS)*~~

~~h.~~e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization it shall be corrected before further sale of milk is allowed. ~~(PS)*~~

~~i.~~f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of milk is allowed. ~~(PS)*~~

~~j.~~g. Permit suspension upon violation of:

1.) Section 3 for serious health hazard; or

2.) Section 6 for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld. ~~(PS)*~~

h. All permits suspended as required by the *Grade "A" PMO*.

Category IV: Permit Reinstatement

a. All product violations followed promptly by an inspection to determine the cause(s).

b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues).

c. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.

d. All permits reinstated as required by the *Grade "A" PMO*.

~~k. All permit issuance, suspension, revocation, etc., as required by the *Grade "A" PMO*.~~

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
BTU NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES

(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of DAIRY FARM RECORDS

(Refer to PART I, ITEM 11 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection Records				25	
3	Category III-Laboratory Records				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

MILK SANITATION RATING REPORT

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
PLANT NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES

(Refer to PART II, ITEM 9 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance ~~(PI)~~				20	
2	Category II-Permit Suspension ~~(PS)~~				20	
3	Category III-Permit Revocation ~~(PR)~~				20	
4	Category IV-Permit Reinstatement ~~(PRI)~~				20	
5	Category V-Hearing/Court Action ~~(H/CA)~~				20	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of MILK PLANT RECORDS

(Refer to PART II, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Records				25	
2	Category II-Inspection/Equipment Records				25	
3	Category III-Laboratory Records (Also Containers/Vitamin Volume Control)				25	
4	Category IV-Plan Review File (Within Rating Period)				25	
					100	

TOTAL CREDIT ➡

TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	217
Committee:	MMSR/HACCP

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

C. Proposed Solution

Changes to be made on page(s): 39 and 65 of the (X – one of the following):

	2009 PMO		2007 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2007 Constitution and Bylaws

Modify Section 11 of ~~the~~ **FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/10)** as follows:

Pages 39 and 65:

Section 11 **HACCP SYSTEM TRAINING** (Individuals trained according to Appendix K or alternatively, have equivalent job experience.)

~~A. Employees trained in monitoring operations.~~
~~B. HACCP Plan reassessment performed by trained individual.~~
~~C. Records review performed by trained individual.~~
~~D. Employees trained in PP operations.~~

A. PPs developed by trained personnel.
B. Hazard Analysis developed by trained personnel.
C. HACCP Plan developed by trained personnel.
D. HACCP Plan validation, modification or reassessment performed by trained personnel.
E. HACCP Plan records review performed by trained individual
F. Employees trained in monitoring operations.
G. Employees trained in PP operation**S**

…

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	218
Committee:	MMSR/HACCP

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

C. Proposed Solution

Changes to be made on page(s): 41, 67 of the (X – one of the following):

	2009 PMO		2007 EML
X	2009 MMSR		2400 Forms
	2009 Procedures		2007 Constitution and Bylaws

Modify the **NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (Form FDA 2359n)** Item #2 as follows:

2. Milk plant, receiving station or transfer station audited by a **HACCP** trained State Regulatory auditor ~~the Regulatory Agency~~ at the minimum required frequency, and follow-ups conducted as required.

…

FORM FDA 2359n (10/12)

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	219
Committee:	Appendix N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X block vote 2400 form
FINAL ACTION			X

C. Proposed Solution

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

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Approve the Charm Beta lactam and Flunixin Test for screening under Appendix N and Section 6 of the PMO, develop a 2400 Series Form and add the test method to M-a-85-Beta lactam Test Methods For Use Under Appendix N And Section 6 Of The Grade "A" Pasteurized Milk Ordinance (PMO). Also, revise M-I-96-10 accordingly.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	222
Committee:	Lab

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

C. Proposed Solution

Changes to be made on page(s): Look at all NCIMS related documents of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR	X	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

The NCIMS Laboratory Committee is directed to develop a review/study committee, with the direction to report back to the 2013 NCIMS Conference, to review all uses and intended uses of references to the SMEPD as they are used in the PMO and related documents. Identify areas of duplication and where specific conference actions have eliminated the need to reference the SMEDP. The review committee is also charged to identify areas where, if any, the SMEDP reference needs to remain and recommend the specific targeted areas in SMEDP for intended conference use.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	224
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

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

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Revise 2400 form Appendix N Bulk Milk Tanker Screening for Neogen BetaStar US to reflect specific changes to the new BetaStar Plus test, which has met the requirements of FDA/AOAC validation. The BetaStar Plus test will replace the BetaStar US test upon final FDA approval and the form must be revised to meet the new requirements.

Additional changes in formatting by the NCIMS Laboratory Committee to conform with new format for 2400 forms.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	225
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 2400 (Rev. 1-09): 15-20 of the (X - one of the following):

	2007 PMO		2005 EML
	2007 MMSR	X	2400 Forms
	2007 Procedures		2007 Constitution and Bylaws

Add to page 15 "27. Media":

c. Easygel Aerobic Plate Count, Pectin Gel Method
1. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____

Re-letter c. – r., currently in Form 2400

Add to page 20 "29.Prepared Media Storage":

e. Easygel Aerobic Plate Count plate storage
1. Store at room temperature.
2. Use before expiration date on package.
3. Store Easygel pretreated petri dishes at room temperature. Reseal unused dishes in bag.

Re-letter e. – f., currently in Form 2400

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	226
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 4 & 5 of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR	X	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Starting at item 6q

q. At the end of incubation, visually inspect the control and test spot. The test is invalid and the same sample should be retested with a new SNAP device if:

1. The control spot fails to develop color.
2. Blue streaking occurs in the background or the background is the same color as the sample or control spots.
3. The sample or control spots are not uniform in color or exhibit poor spot quality.

. ~~Read~~ Insert only valid tests into the reader **IMMEDIATELY (no longer than 30 seconds) ~~after final incubation)~~** after completion of incubation. ~~with IDEXX Reader for SNAP devices~~

s. Use the stylus to tap OK

7. Interpretation with Idexx Reader for SNAP Devices

~~a. The control spot is on the top and the test spot on the bottom of the Results Window (Correct orientation is with activator button to right and sample well to left)~~

~~b. Negative result:~~

~~1. If test spot is darker than or equal to the control spot, sample is **Negative (NF)**~~
~~c. Positive result:~~
~~1. If test spot is lighter than control spot, sample is **Initial Positive**~~
~~d~~.
a. IDEXX Reader for SNAP devices automatically prints results as **Positive** ~~(initial)~~ or **Negative (NF)**

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	227
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

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

____	2009 PMO	____	2009 EML
____	2009 MMSR	____ All Appendix N	2400 Forms
____	2009 Procedures	____	2009 Constitution and Bylaws

The NCIMS Laboratory Committee shall clarify the intent, use in the App N 2400 forms and give guidance on enforcement of the phrase “Previously negative tested raw milk” that is currently used in the forms. The Laboratory Committee shall clarify the intended use and interpretation by stating the intent and interpretation on all the appropriate 2400 forms. Also review this phrase in the context of how it shall be used in the requirement for “Daily performance checks” of the testing equipment and test as stated on the appropriate 2400 forms.

This hopefully will clarify the intent of this phrase and correct the inconsistent usage by industry and interpretation on enforcement currently happening in the program.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	228
Committee:	Lab -2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 1,2 of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR	X	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Appendix N Bulk Milk Tanker Screening Test Form General Requirements

3.a2 and 3.b3 Graduation/recording interval not greater than ~~1.0C~~ 0.5C [~~NCIMS CETIFIED LABORATORIES and CETIFIED INDUSTRY SUPERVISORS, 0.5~~]

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	229
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): Charm SL, SL6 and Charm 3 SL3 2400 of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR	X	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	230
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 1, 2, 6 of the (X - one of the following):

____	2009 PMO	____	2009 EML
____	2009 MMSR	X App N GR	2400 Forms
____	2009 Procedures	____	2009 Constitution and Bylaws

Appendix N Bulk Milk Tanker Screening Test Form
General Requirements

(Unless otherwise stated all tolerances ±5%)

Items 1.-2.

3. Thermometers _____

a. National Institute of Standards and Testing (NIST) traceable thermometer or other temperature measuring device with certificate. _____

1. Must be checked annually at ice point (liquid-in-glass) _____

2. Must be re-calibrated according to manufacturer recommendation (electronic/digital) _____

~~1~~ 3. Reference temperature measuring device identity: _____

	Serial #	Date of Certificate	Ice Point Date (Liquid-in-glass)	
a:	_____	___/___/___	___/___/___	_____
b:	_____	___/___/___	___/___/___	_____

2. Graduation/recording interval not greater than 1.0C (liquid-in-glass). **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C]** Graduation/recording interval not greater than 0.1C (electronic/digital) _____

b. Range of test temperature measuring device appropriate for designated use _____

1. Mercury-in-glass, alcohol/spirit or electronic/digital thermometers in degrees centigrade _____

2. Plastic lamination recommended for mercury thermometers _____

3. Graduation/recording interval not greater than 1.0C (liquid-in-glass). **[NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C]** Graduation/recording interval not greater than 0.1C (electronic/digital) _____

c. Accuracy of all test temperature measuring devices checked before initial use and annually _____

1. Checked against NIST traceable thermometer to 0.1C _____

2. Accurate to ±1C when checked at temperature(s) of use _____

3. Results recorded/documented and individual devices tagged _____

a. Tag includes identification/location, date of check, temperature(s) checked and correction factor(s), as applicable _____

~~d. Temperature measuring devices are to be read to the nearest graduation/recording interval, optionally labs may interpolate between graduations~~ _____

ed. Temperature Monitoring Systems (wired/wireless) _____

1. The software must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency as stipulated for MIG or AIG thermometers. Optionally, set to register an alert/alarm when out of the acceptable temperature range _____

a. When temperature(s) are out of acceptable range for greater than two hours, event must be documented and corrective action taken as necessary. Records maintained _____

2. Optionally, a minimum two-day backup power source (battery/electrical) for the temperature monitoring system and/or all required sensors/probes, remote signal device and

monitor/controller may be employed in case of power failure _____

3. Temperature monitoring system records for each piece of equipment must be available/accessible for auditing as described in item 2c above _____

~~f~~e. Automatic temperature recording instruments, if used, compared weekly against an accurate thermometer, results recorded _____

~~g~~f. Temperature measuring device(s) calibrated at another location _____

1. Location calibrated: _____ _____

2. Calibrations current and acceptable _____

3. Copy of calibration record on-site _____

~~h~~g. Dial thermometers not used in the laboratory _____

Items 4.-8.

SAMPLES

9. Sample Requirements _____

a. Appendix N tanker sample(s) _____

1. Prevent contamination with disinfectants from hands or other sources _____

2. Ascertain temperature of bulk milk tanker, record maintained _____

3. Secure a representative sample for testing. Sample not over filled. If sample will not be tested without delay then a temperature control (TC) sample must be taken at the same time, transported, and maintained with the tanker sample(s) until it is tested _____

4. Transport sample(s) to the testing location promptly (preferably on ice if needed to maintain temperature) _____

5. Tanker sample(s) tested promptly upon arrival at the testing location _____

a. Determine sample temperature by inserting a pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control

b. Sample temperature must be 0.0-4.4C at testing _____

~~b~~c. Date, time and temperature of bulk milk tanker may be used for date, time and temperature as received and tested if sample testing begins without delay, record maintained _____

b. Appendix N Producer Trace Back Samples (Sample(s) not meeting the conditions outlined below may still be tested. The certified

laboratory or CIS will document the condition of the samples(s)) _____

1. Samples should be accompanied by a temperature control (TC). If no TC, aliquot sample(s) for testing and measure temperature using one of the producer samples _____

2. Sample(s) should not be leaking _____

3. Tops of samples should be protected from direct contact with ice _____

4. Unprotected samples should not be submerged in water and/or ice or slush _____

Items 10.-15.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	231
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 1-11 of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR	X 2400j	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

PHOSPHATASE TEST - FLUOROPHOS ALP TEST SYSTEM
[Unless otherwise stated all tolerances are ±5%]

SAMPLES

1. Laboratory Requirements (see CP, item 33 & 34) _____

APPARATUS

2. See CP, items 1-32 (as necessary) _____

3. Cuvette Heating Block _____

a. Thermostatically ~~\~~controlled at 38±1C _____

~~b. NIST-traceable thermometer, calibration checked as specified in CP item 3~~ _____

~~c.~~b. Temperature checked and recorded ~~daily~~ each day of use _____

4. Pipettors, fixed volume or electronic _____

a. 75 µL pipettor _____

b. 25 µL pipettor, for use with high\turbidity or high fat products (if needed) _____

c. Calibrated as specified in CP item 6e; records maintained _____

5. Reagent Dispenser _____

a. Fixed volume 2.0 mL, calibrated and checked _____

b. Optionally, use 2.0 mL fixed volume or electronic pipettor to dispense reagent _____

c. Calibrated as specified in CP item 6e; records maintained _____

6. Cuvettes _____

a. Disposable glass 12 x 75 mm, dirt and scratch free _____

7. Fluorometer

a. Air fan in the rear unobstructed _____

b. Vents in the bottom base plate are unobstructed _____

~~c. Sufficient paper is on the roll in the printer~~ _____

~~d.~~c. User's manual available _____

8. Water Bath, 34±1C and 63±1C, circulating (Confirmation procedures) _____

REAGENTS

9. Reagents, Handling and Storage _____

a. Test Reagent Set _____

1. Fluorophos substrate and Substrate buffer _____

2. Lot # _____ ~~Rcd date _____~~ Exp date _____ _____

b. Calibrator Set _____

1. Calibrators A, B and C _____

2. Lot # _____ ~~Rcd date _____~~ Exp date _____ _____

c. PhosphaCheck Pasteurization Controls Set _____

1. Positive and negative control _____

2. Lot # _____ ~~Rcd date _____~~ Exp date _____ _____

d. Daily Instrument Control

1. Lot # _____ ~~Rcd date _____~~ Exp date _____ _____

e. Reagents stored at 0-6C _____

~~f. Bottles labeled with receive and open dates _____~~

REAGENT PREPARATION

10. Working substrate _____

a. Prepare reagents as per manufacturer instructions, mix by inversion until fully dissolved _____

b. Date (mixture stable 60 days at 0-6C) _____

1. Bottle labeled with date prepared _____

2. Preparation date _____

c. Place cleaned, 2 mL reagent dispenser (item 5) on prepared reagent bottle, or cap if using 2 mL pipettor _____

INSTRUMENT AND REAGENT CHECKS

~~14.~~11. Check Procedures _____

a. Check calibration if readings are suspect (positive control value out of limits) _____

b. Press set-up button _____

c. Press left or right arrow key to get A/D option _____

d. Select A/D Mode _____

e. Zero Check _____

1. With no tube in the instrument, press "Start" key

and take a reading _____

2. A/D value _____ _____

3. The reading must not exceed 314. If the reading exceeds 314, an instrument problem is indicated, call for technical assistance _____

4. Record value ~~on printout and~~ <u>in</u> QC record _____

f. Calibrator C/Daily Instrument Control Check _____

1. Dispense 2.0 mL of Calibrator C (item 9b) or Daily Instrument Control (item 9d) into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed Calibrator C or Daily Instrument Control into the sample chamber and press "Start" key _____

a. The A/D value should be 602±15 (maximum allowable drift _____

b. A/D value _____ _____

c. Record Lot # and value ~~on printout and~~ <u>in</u> QC record _____

3. If the value does not fall within the acceptable range, then perform the following procedure (refer to manual, or contact manufacturer if unsure) _____

a. With Calibrator C or Daily Instrument Control in the sample chamber, adjust the R15 resistor until the A/D value reads 602±2 _____

b. Allow the instrument to equilibrate for 15 minutes, the A/D value should still read 602±2 _____

c. Record Lot # and value ~~on strip and~~ in QC record _____

~~4.~~ <u>d.</u> If the value does not fall within and stabilize at 602±2 seek technical assistance _____

~~5.~~ <u>e.</u> For older units requiring the instrument cover to be removed or if unsure seek technical assistance _____

g. Reconstituted Substrate/Buffer stability check _____

1. Dispense 2.0 mL of working substrate (item 10)

into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed working substrate into the sample chamber and press "Start" key _____

   a. The A/D value should be < 1,200 _____

   b. A/D value _____ _____

   c. Record Lot # and value ~~on printout and~~ <u>in</u> QC record _____

h. Reconstituted Substrate/Buffer contamination check _____

1. Dispense 2.0 mL of working substrate (item 10) into a 12x75 mm cuvette and allow to warm to 38±1C for 20 minutes _____

2. Place the cuvette with the warmed working substrate into the sample chamber _____

3. Initiate an ALP sample reading of the working substrate on an unused channel _____

4. The ALP value should be < 10 mU/L _____

   a. ALP value _____ _____

   b. Record Lot # <u>and value</u> ~~on printout and~~ <u>in</u> QC record _____

5. If the working substrate value does not fall within the acceptable range, do not use working substrate, re-check to verify, reconstitute a new set of reagents or seek technical assistance before testing samples _____

CALIBRATION
(Required at installation and after any instrument adjustments)

~~11.~~<u>12.</u> <u>Calibration</u> Procedure _____

a. Perform instrument and reagent checks (item ~~14~~ <u>11</u>) prior to proceeding _____

1. Readings from item ~~14~~ <u>11</u> are within specification, proceed with calibration _____

2. If readings not within specification, do not proceed with calibration, make appropriate adjustments or seek technical assistance and re-check _____

3. Record all values (initial and re-checks) ~~on tape and~~ in QC record _____

b. Check calibration ratio of Calibrators A, B and C, record Calibrator Lot # ~~on strip and~~ in QC record _____

1. Label two (2) tubes each for Calibrators A, B and C _____

2. Add 2 mL of each calibrator to the appropriately labeled tubes _____

3. Heat tubes for 20 minutes to 38±1C _____

4. Find an empty channel _____

a. Press the "Calib" key _____

b. Locate the channel to be used, using the "<" and ">" keys _____

c. Press the "Enter" key to select the channel _____

5. Place a tube of warmed Calibrator A (with no milk added) into the cuvette chamber, close the door and press the "Start" key _____

6. Continue as prompted until all six (6) tubes have been run _____

7. Calibration ratio should be 151±7 (when A/D mode check for Calibrator C/Daily Instrument Control is 602±6) _____

8. If ratio within specification continue, if not make adjustment and re-check calibration ratio _____

c. <u>Sample agitation</u>

<u>1.</u> Invert retail containers 25 times, each inversion a full cycle down and up _____

d. Remove test portions (avoiding foam) within 3 min of agitation _____

e. To each calibrator, add 75 µL (or 25 µL) of the well-mixed product being tested and immediately mix by vortexing _____

1. For positive displacement pipettor with reusable tip _____

~~1.~~a. Prior to pipetting sample, draw up MS water once and expel to waste _____

~~2.~~b. Dry exterior of piston and tip _____

~~3.~~c. Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____

~~4.~~d. Draw sample into pipettor~~, touch off to side of container~~ _____

~~5.~~e. Holding pipettor at 90^{o} to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____

~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____

~~b.~~g. If concave, re-sample _____

~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 12e1e) _____

2. For air displacement pipettor with new tip for each Sample _____

a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____

b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three

times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

f. Add products to calibrators one tube at a time just prior to being tested _____

g. ~~Mix by vortexing~~ Run test within 20 sec of adding sample to calibrator _____

h. Place cuvette in Fluorometer, close cuvette door _____

i. Press the "CALIB" key on the Fluorometer keypad and follow the prompts on the display panel _____

j. After each reading, remove cuvette and close door immediately _____

k. Record lot #'s of the calibrators used ~~on the tape printout and~~ in the QC record book _____

l. Instrument calibrated for each product type to be tested, some products with similar fat content may share same channel _____

m. Re-calibration required if: _____

1. Controls out of limits _____

2. Adjustments made to bring A-D mode checks (item ~~14~~ 11) into specification _____

3. Any significant instrument service if performed, ex. lamp or filter replaced _____

n. Instrument checks and calibrations within specification _____

CONTROLS

~~12.~~13. Negative Control _____

a. Use PhosphaCheck negative control from set in item 9c _____

b. Or, optionally heat a sample of product to 95±1C for 1 min with stirring (temperature control [TC] used) _____

1. Cool rapidly to 0-4.4C in an ice bath _____

2. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at -15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

~~c. Add 2.0 mL of working substrate (Reagent C) to cuvettes and heat to 38±1C for 20 min (use within 4 hours)~~ _____

~~d. Add 75 µL of well mixed control to cuvette and immediately vortex~~ _____

~~e. Once control is added to reagent test within 20 sec~~ _____

~~f. Place the cuvette in the Fluorometer, close the cuvette door and press the "TEST" key on the keypad~~ _____

c. Test control as a sample (see item 15 b-k) _____

~~g.~~d. Value less than (<) 20 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

~~13.~~14. Positive Control _____

a. Use PhosphaCheck positive control from set in item 9c _____

b. Or, optionally to a portion of negative control (Item 13b), add ~~exactly~~ 0.1 mL of mixed-herd raw milk and bring up to ~~exactly~~ 100 mL with additional negative control ~~(as in item 12b)~~ _____

1. If desired, ~~distribute~~ aliquot 1 mL quantities ~~in small tubes,~~ within 24 hours, seal and freeze at -15C or colder in a non-frost-free freezer, or place in a Styrofoam container and place in the center of a frost-free freezer ~~for no more than~~ ,use within 2 months _____

c. Test ~~as in items 12 c-f~~ control as a sample (see item 15 b-k) _____

d. Value between 500±150 mU/L _____ _____

e. Record lot # or identity and value in QC record _____

TEST PROCEDURE

15. Test Procedure _____

a. Perform all instrument and reagent checks (item ~~14~~11), negative control test (item ~~12~~13) and positive control test (item ~~13~~14) prior to running analysis _____

b. Using reagent dispenser, fixed volume or electronic pipettor, dispense 2.0 mL of working substrate into labeled 12 x 75 mm glass cuvettes _____

1. Prime reagent dispenser (item 5) 3x prior to dispensing volumes to cuvettes to remove any bubbles from dispenser tubing _____

c. Warm substrate to 38±1C in the heating block for 20 min (use within 4 hours) _____

d. Sample agitation _____

1. Invert filled retail containers 25 times, each inversion a full cycle down and up _____

e. Remove test portions (avoiding foam) within 3 min of agitation _____

f. Press the "Test" key on the keypad _____

g. Select the product type channel and enter identification number _____

h. Dispense 75 µL (or 25 µL) of the well-mixed sample into the warmed substrate and immediately mix by vortexing _____

1. For positive displacement pipettor with reusable tip _____

~~1.~~a. Prior to pipetting sample, draw up MS water once and expel to waste _____

~~2.~~b. Dry exterior of piston and tip _____

~~3.~~c. Place tip of pipettor into sample (no more than 1 cm) and draw up and expel several times _____

~~4.~~d. Draw sample into pipettor~~, touch off to side of container~~ _____

~~5.~~e. Holding pipettor at 90° to lab bench and with tip down and at eye level, dry exterior of tip by quickly wiping from the pipettor over the tip _____

~~a.~~f. Carefully inspect the pipettor tip to insure sample volume is flush with the tip _____

~~b.~~g. If concave, re-sample _____

~~c.~~h. If convex, re-wipe as above to achieve a flush sample volume (see Item 15h1e) _____

2. For air displacement pipettor with new tip for each Sample _____

a. Depress plunger and place tip into sample (avoiding foam or bubbles) _____

b. Draw up test portion _____

c. Remove from sample, touch off to side of container _____

d. If excess product adheres to tip, wipe carefully without wicking sample _____

~~6.~~3. Dispel 75 µL (or 25 µL) of sample 1 cm below the surface of the calibrator (do not dispense down side of cuvette) _____

~~7.~~4. With tip still below surface depress plunger three times into calibrator to completely expel sample _____

~~8.~~5. With plunger still completely depressed, remove from tube _____

i. Add products to substrate one tube at a time just prior to being tested _____

~~9.~~j. Run test within 20 sec of adding sample to reagent _____

~~i.~~k. Place the cuvette in the Fluorometer, close the cuvette door, and press the "START" key on the keypad _____

~~j.~~l. Results will display in 3 min., save tape print-

out of results ~~in record book~~ and QC record _____

~~a.~~1. If a 25 µL sample volume was used multiply the displayed value by 3 _____

~~b.~~2. Record adjusted value on printout _____

~~k.~~m. Values of ≥ 350 mU/L or more of ALP activity are considered to contain approximately 0.1% (v/v) raw milk and must be confirmed _____

n. Record lot # of the substrate used in the QC record. _____

CONFIRMATION

16. Negative Control _____

a. Prepare separate negative control ~~for each product~~ from each suspect product _____

b. For preparation of control using the suspect product

1. Prepare by heating sample for at least 1 min after thermometer registers 95±1C, stirring or mixing as necessary (TC used) _____

~~c.~~2. Cool rapidly to 0-4.4C in an ice bath _____

~~d.~~c. This control must be less than 20 mU/L when tested _____

~~**17. Positive Control (See item 13)**~~

~~a. Must be prepared from suspect product~~

~~18.~~17. Microbial Phosphatase _____

a. To determine presence of microbial phosphatase, heat 1.0 mL of suspect milk at 63±1C for 30 min, stirring or mixing every 10 min (if fat content is >10%, heat at 66±1C) [TC used] _____

b. Cool rapidly to 0-4.4C in an ice bath _____

c. Test heated portion, unheated portion, and positive and negative controls _____

d. Interpretation _____

1. If heated and unheated portions have equal activity (within ±5%), the sample is regarded negative for residual phosphatase, the activity originally measured is microbial _____

2. If the heated portion has significantly reduced (>5%) or no activity, the sample contains milk phosphatase activity, either residual or reactivated _____

~~19.~~18. Reactivated Phosphatase _____

a. Magnesium acetate solution _____

1. Dissolve 35.4g of $Mg(C_2H_30_2)_2 \cdot 4H_20$ in 25 mL MS water warming slightly to aid solution.

2. Pour solution into 100 mL volumetric flask, rinse original container several times and add rinses to flask.

3. After cooling, make up to 100 mL (stable for 1 year at 0-4.4C) _____

b. Procedure _____

1. Place 10 mL of each milk or milk product sample to be tested in a boiling water bath and hold 1 min after temperature sample has reached 95±1C (TC used) _____

2. Cool samples rapidly to 0-4.4C in an ice bath _____

3. Place a 5 mL aliquot of sample (unheated) to be tested in a screw-cap test tube and add 0.1 mL MS water ("Blank" sample) _____

4. To a second 5 mL aliquot (unheated) in an identical tube, add 0.l mL Mg acetate solution ("Test" sample) _____

5. Cap tubes and incubate both aliquots for 1 hr at 34±1C _____

6. Remove samples from water bath and cool rapidly to 0-4.4C in an ice bath _____

7. Dilute 1 mL of sample containing magnesium (Test) with 5 mL (1:6 dilution) of corresponding boiled milk or milk product control (items 21b 1 & 2 above) _____

8. Test undiluted sample containing no magnesium (Blank) and diluted sample containing magnesium (Test) for phosphatase activity (as described in item 16) _____

c. Interpretation _____

1. If the diluted aliquot containing magnesium (Test) has equal (±5%) or greater phosphatase activity than the undiluted aliquot containing no magnesium (Blank), the sample is regarded negative for residual phosphatase, and the phosphatase originally measured is of **reactivated** origin _____

Diluted w/Mg (Test) ≥ Undiluted (Blank) = Reactivated

2. If the diluted aliquot (Test) contains less activity (< 5%) than the undiluted aliquot (Blank), the sample is considered positive for **residual phosphatase** _____

Diluted w/Mg (Test) < Undiluted (Blank) = Residual

3. A false-positive for residual phosphatase may also be obtained if a reactivatable sample has been allowed to stand at elevated temperatures (20C) for periods of 1 hr or more before testing (SPC <20,000/mL) _____

RECORDING AND REPORTING

~~20.~~19. Confirmatory Interpretation _____

a. Report as positive for residual phosphatase if microbial phosphatase, and reactivatable phosphatase are not present _____

b. ~~Report~~ Record all values in mU/L _____

c. Report as **Not Found** for residual phosphatase if: _____

l. If microbial phosphatase present _____

~~3.~~2. Or, if reactivatable phosphatase present _____

~~4.~~3. Or, if there is documentation that the product was treated such that reactivatable phosphatase may be present _____

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	232
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

Changes to be made on page(s): 1 of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR	X	2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Addition to Item 1 on the DMSCC form:

a. Un-preserved samples may be run up to 72 hours after initial collection.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	233
Committee:	Lab/Other Species - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

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

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Request a study, after study review refer to 2400 form committee.

~~Make changes to the Form FDA 2400n-1 Charm SL / SL6 / SL3 to reflect that frozen samples of sheep milk can be officially tested using the Charm SLBL method after properly thawing using the same instructions as given for control samples.~~

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	234
Committee:	Lab - 2400

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote	
FINAL ACTION		X	

C. Proposed Solution

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

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Cultural Procedures – General Requirements form –

Item 13. Autoclave

i. Performance checked with full load and results recorded ~~weekly~~ quarterly at a minimum (preferably once during each week of use) using spore (G. stearothermophilus) strips or suspensions, include positive control check, results maintained _____

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	235
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 3, 22, 27, 30 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Page 3, paragraph 3:

~~Sets~~ A set of completed evaluation forms ~~shall~~ may ~~be~~ ~~accompanied~~ **accompany** ~~by~~ **the** ~~a~~ narrative report which describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' procedures, and a statement as to whether the results of the analyst or CIS examinations are acceptable for use in rating milk for interstate shipments. The narrative report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms.

Page 3, paragraph 4:

Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories–/CIS must include the narrative report and may include copies of the completed FDA-2400 Series Forms ~~and a copy of the narrative~~ ~~report~~. Reports to FDA Regional Office and FDA/LPET should only include the narrative report.

Page 22, paragraph 1:

FDA-2400 Series Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation when the option to send them with the narrative report is used.

Page 22, paragraph 2:

Copies of the evaluation forms ~~are to~~ may be prepared for the laboratory evaluated.

Page 22, paragraph 3:

The set of completed evaluation forms for the laboratory ~~must~~ may be accompanied by ~~a~~ the narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted.

Page 22, paragraph 5:

~~A format~~ Formats suitable for narrative reports ~~appears~~ appear on pages 27 – 32.

Page 22, paragraph 6:

If choosing the option to send the narrative only via electronic submission, it will be necessary to summarize what each item is.

Pages 27 and 30:

If forms accompany the narrative report then, ~~Deviated~~ deviated items are marked with an "X" on the evaluation forms.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	236
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 3, 5, 6, 7, 16, 22, 24, new 33-xx of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

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

Make the following changes to the 2009 EML.

SECTION 1: LABORATORY EVALUATION PROGRAMS

Page 3:

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories/CIS must include copies of the completed FDA-2400 Series Forms and a copy of the narrative report. Reports to FDA Regional Office and FDA/LPET ~~should~~ shall be sent electronically and shall ~~only~~ include the narrative report and appropriate, completed FDA summary templates only (see page xx – xx). …

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Page 5:

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the milk regulatory agency, the state milk sanitation rating agency, the appropriate FDA Regional Office and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically. …

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Page 6:

Official examinations cannot be conducted at non-accredited laboratories. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts, or for some other reason, the Federal or State LEO shall immediately notify the milk laboratory involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be returned to the issuing State LEO within 90 days. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically. …

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Page 7:

When a screening facility loses its approval because of lack of approved IS or IA, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET,

by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

Screening facilities requesting withdrawal of approval shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall immediately notify the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email. …

SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS

Initial certification of State LEO shall be based on meeting the following criteria:

2. **The individual must submit an acceptable written report of the milk laboratory initial check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page xx – xx). …**

Laboratory evaluations conducted by conditionally approved State LEOs are official.

2. The individual must submit an acceptable written report of the milk laboratory check evaluation to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page xx – xx). …

2009 EML
SECTION 6, PAGES 22 AND 24

SECTION 6: LABORATORY EVALUATION REPORTS

Page 22:

NARRATIVE REPORTS

The set of completed evaluation forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State LEO as to whether or not the laboratory is doing acceptable work. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory evaluation. The copy of the narrative report submitted by email to FDA/LPET must be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The LEO must receive verification of receipt by return email and must maintain a copy of the verification in their records. State LEOs may submit reports by email; however, they must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the evaluation, who made the evaluation, list the prior status, list the date of the last on-site evaluation, indicate the present status, what recommendations were made to correct any deviations, what test were approved, and who was certified to do them. …

Page 24:

…compliance with the facility requirements noted in the last on-site evaluation.

FDA SUMMARY TEMPLATES

The narrative report must be accompanied by the appropriate, completed FDA summary template for the laboratory, specifically representing the information required for verifying and updating the IMS List of accredited laboratories and CISs along with other useful information to be used by FDA/LPET. Only the current revision of the FDA summary templates, authored by FDA/LPET, may be used. There are two FDA summary templates: one for full service laboratories and one for Appendix N Screening Only facilities (CIS and IS). The information captured on the FDA summary template must match the information provided in the narrative report (i.e., IMS number, facility identification, accreditation and certification status, dates, procedures, conclusion, etc.). The information captured may also lend itself to analyst/laboratory tracking and filing by the State LEO.

The appropriate FDA summary template form must also be used for the notification of changes in accreditation and certification status, and must be submitted by email to FDA/LPET.

Directions for completing the FDA summary template, authored by LPET, will be updated with each revision of the FDA summary template, as necessary, and provided to the LEOs by email.

An example of a completed FDA summary template for each application appears on pages 33-xx.

REFERENCES

New Page 33-xx:

NOTE: At the end of the EML document, add an example of a completed FDA summary template for each application on pages 33-xx.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	237
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 28-32 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Strike the existing language and use the new examples.

~~EXAMPLE~~

~~Report of a Biennial On-Site Evaluation~~

~~of~~

~~Certified Industry Supervisor~~
~~Name~~
~~Plant Manager~~

~~Laboratory Name~~
~~Laboratory number: 00600~~
~~Laboratory Street Address~~
~~City, State 00000~~

~~On~~

~~Evaluation Date~~

~~By~~

~~LEO Name~~

Laboratory Evaluation Officer

Last Certified: Date

A copy of the “Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [List Procedures].

Present Laboratory Status: Fully certified for [List Procedures] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of [Date].

Other changes that need to be made to IMS list, etc: None or List Changes

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade ‘A’ PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.

Beta lactam Tests

DEVIATIONS AND CORRECTIONS

GENERAL REQUIREMENTS

3. Thermometers for use with Test Kits and Laboratory Equipment.

d. Calibrate your freezer thermometer against a traceable thermometer.

d2. Tag above calibrated thermometer with date, identification and correction (+0.0, if none) and record results.

6. Balance.

e. Note: Have your new balance calibrated annually by a qualified service representative.

TECHNIQUES

[Name Test]

No deviations were observed for the [Name Test].

[Name of Second Test]

15. Test Procedure.

p. Multiple tests were run at the same time. Start incubation timing immediately after the sample is added to the last test device. Analyst started timing too late.

CONCLUSIONS

[CIS Name] is certified as a Certified Industry Supervisor to perform the procedures as listed above pending correction of listed deviations and receipt of corrections in writing by the State LEO within sixty days of receipt of this evaluation. Contact me if there are questions.

Sincerely,

LEO Name
Laboratory Evaluation Officer

EXAMPLE REPORT

REPORT Of an On-Site Biennial/
Supplemental (analyst, procedure, walk-through)/
Unofficial

Certified Laboratory
NCIMS Lab ##

Certified Industry Supervisor
CIS ##

Appendix N Screening Site

NAME OF SITE
Address
Date of evaluation
By LEO's name

Previous Laboratory Status: Fully/provisionally/conditionally Certified until date
Previous Procedures: X, X, X

Present Laboratory Status: Fully/provisionally/conditionally Certified until date, pending acceptable response to this report
Procedures evaluated: X, X

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.

Other changes that need to be made to IMS list, etc: None

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time

of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. They will be marked as deviations if not corrected by the next evaluation.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES FOR CERTIFIED LAB/
GENERAL REQUIREMENTS FOR APP N

CERTIFIED LAB

3d1.In the media section, calibration of thermometers was done but the calibration temperature was not always at temperature of use. Refrigerator was calibrated at 5C vs. 0.0C and hot air oven was calibrated at 65C vs. 170C. Send new/proper calibrations with response.

3d2a. The tags did not include correction factors in media area. Send verification.

APPENDIX N LAB

1c. Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

ITEM METHOD

TESTS LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods

5b1/2.Proper mixing or shaking of samples, retail must have complete inversion top over bottom and raw is to be more vigorous than observed.

6d. Analysts are to avoid the foam of sample. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri

dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

3a1. Incubator level. Temperature checked daily (day of use), records maintained.

The temperature is not being recorded to the tenth of a degree. Please instruct analysts to record the strip incubator to the tenth of a degree.

10a. Reader tapes or computer printouts maintained for two years.

Please remember that the kit number is the lot number. Please Note: Post the analyst codes in each testing area (confirmation testing area and screening testing area). This will eliminate any confusion as to which code belongs to which analyst.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/PACCOLI/PCCPMC	D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]		
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

Certified Industry Analysts	2004 On-Site Evaluation TEST KIT	4/2004 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x

~~Name CIS 3 — No Longer Employed — x~~

~~Industry Analysts~~	~~2004 On-Site Evaluation TEST KIT~~	~~6/2004 Split Sample Survey TEST KIT~~
~~Name IA 1~~	~~x~~	~~x~~
~~Name IA 2~~	~~x~~	~~x~~

~~CONCLUSION~~

~~Use the proper conclusion found on pages 23 & 24.~~

New example reports for the EML.

EXAMPLE REPORT #1

Report of a Biennial On-Site Evaluation

of

City Health Department Milk Laboratory

Accredited Laboratory
NCIMS LAB #####

100 South Main Street
City, State 78000

On

March 1, 2010

By

LEO Name
Laboratory Evaluation Officer
State Department of [Health, Agriculture}
100 Healthy Way
City, State 78000

Last Full Evaluation Date: March 19, 2008
Next Evaluation Due By: March 31, 2012

A copy of the “Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file.

Previous Laboratory Status: Fully certified for [5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28]

Present Laboratory Status: Fully certified for [5, 9C13, 9D3, 12, 16, 20 22, 24, 28] pending receipt within 60 days of correction of deviations resulting from on - site evaluation of March 1, 2010.

Other changes that need to be made to IMS list, etc: Update Anniversary Date, drop procedure 9C14, add procedure 16.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or

procedures equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. ~~They will be marked as deviations if not corrected by the next evaluation.~~ The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

CULTURAL PROCEDURES - GENERAL REQUIREMENTS (rev. 2/10)

2. Records

2e Corrections to all records follow appropriate requirements

During the review of the autoclave records it was noticed that there were a number a items written over.

Analysts are to be reminded of the proper protocol for correcting mistakes. Cross out the error with one line, initial, date and write the correct information next to it.

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

#NOTE: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. It is suggested that a new thermometer be purchased.

The other option is to use the new NIST traceable unit that is available for use in the rest of the laboratory.

3c3 No tag was found on the freezer thermometer

Although the accuracy check was documented the unit was not tagged.

Tag the thermometer with the following: identification/location, date of check, temperature checked and the correction factor.

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

Over the past four months at least 50% of the days noted with the unit out of temperature range with no corrective action noted.

This is a serious violation and no controls or samples may be kept in the unit until it is proven that that the unit holds the proper temperature.

Send copies of the freezer temperature records for the next 4 months. If the unit cannot be maintained then a new one will need to be purchased.

13. Autoclave

13i Performance check

There were no thermometers for the incubation units for the spore check. There must be a way to check the appropriate temperature range for the test.

Please purchase thermometers for these units and send a copy of the purchase order, the temperature calibrations when received and the temperature records for the two months following.

TECHNIQUES

PETRIFILM AEROBIC AND COLIFORM COUNTS (IMS# 5,20 rev. 1/09)

No deviations noted. The analysts showed marked improvement over the last biennial on-site.

PASTEURIZED MILK CONTAINERS (IMS# 22 rev. 1/09)

10. Collection of Surface Rinse Samples

10b2 While adding the rinse solution to the container, do not touch the bottle of rinse solution to the container.

One analyst held the bottle against the container while adding the rinse solution.

Use aseptic technique when adding the rinse solution.

DELVOTEST P 5 PACK (IMS# 9D3 rev. 2/10)

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

21e Touch the slide with the tip and expel the test portion.

One analyst held the syringe above the slide and dripped the milk.

Take the syringe and hold it vertically against the slide, depress the plunger slowly

allowing the milk to be expelled. Then touch off to a dry spot.

ESCC – BENTLEY 150 (IMS# 16 rev. 10/07)

No deviations noted.

FLUOROPHOS ALP (IMS# 28 rev. 6/05)

15. Instrument and Reagent Checks
Page 4 / #####
3/1/2010

15g2b Reconstituted Substrate / Buffer Stability Check A/D Value Recorded
The A/D value for this check was missing on several days of testing records during the period evaluated. While this may be from having to reconstitute a new bottle of substrate because the A/D value was greater than 1200, the corrective action must be noted with both the old *AND* new values recorded.

DAIRY WATERS (IMS# 24 rev. 1/09)

No deviations noted.

CHARM SL BETA LACTAM (IMS# 9C13 rev. 1/10)

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

Analyst	5	9C13	9D3	12	16	20	22	24	28	ON-SITE Last 2	SPLITS Last 2
Analyst 1	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 2	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 3	X	X	X	X	X	X	X	X	X	3/10, 3/08	10/09, 10/08
Analyst 4	X	X	X	X		X	X	X	X	3/10	10/09
Analyst 5*	X	X	X	X	X	X	X	X	X	3/08, 3/06	10/09, 10/08

X = Fully Certified
* = Analyst excused – on medical leave.
5 = Petrifilm Aerobic Count
9C13 = Charm SL Beta Lactam
9D3 = Delvotest 5 Pack
12 = DMSCC
16 = ESCC (Bentley 150)
20 = Petrifilm Coliform Count
22 = Pasteurized Milk Containers
24 = Dairy Waters
28 = Advanced Fluorometer

CONCLUSION

Although the procedures, records, facilities and equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade 'A' PMO* the analyst, equipment and record deviations noted must be corrected. This laboratory is accredited until May 1, 2010 pending correction of the deviations and receipt of a letter by the evaluation

officer detailing the corrections made. Upon receipt of such letter, full accreditation will be given.

Sincerely,

LEO

EXAMPLE REPORT #2

REPORT Of an Biennial On-Site/
Supplemental (analyst, procedure, walk-through)/
Unofficial/Check

Certified Laboratory
NCIMS Lab #####

Certified Industry Supervisor
CIS #####

Appendix N Screening Site

NAME OF SITE
Address
Date of Evaluation
By LEO's name

Previous Laboratory Status: Fully/provisionally/conditionally Certified until [date]
Previous Procedures: X, X, X

Present Laboratory Status: Fully/provisionally/conditionally Certified until [date], pending acceptable response to this report
Procedures evaluated: X, X

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" is signed and is on file with LEO.

Other changes that need to be made to IMS list, etc: None or addition of analysts, change in procedures, etc.

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. Deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time

of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase “Note” as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM METHOD

CULTURAL PROCEDURES FOR CERTIFIED LAB [rev. 2/10] /
GENERAL REQUIREMENTS FOR APPENDIX N [rev. 2/10]

CERTIFIED LAB

3. Thermometers

3c2 All test temperature measuring devices are checked at temperature of use.
The thermometers in the media section were checked for accuracy but were not always done at the temperature of use as required. The hot air oven was checked at 65C vs. 170C.
Re-check the thermometer and send with the response.

3c3a Tags include correction factors on temperature measuring devices.
The tags did not include correction factors in media area.
Send copies of the tags.

APPENDIX N LAB

1c Adequate lighting, [NCIMS Certified Laboratories, and Certified Industry Supervisors >50 foot candles at the working surface (pref. 100)].

During the technique demonstration, the wall light was not used. The lighting measured 14-24 foot candles in the confirmation testing area. The confirmation testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

It was determined during the survey that the screening test area had 20-25 foot candles of light. Add additional lighting to the area to increase to >50 ft-candles and send verification.

ITEM METHOD

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

Standard Plate Count, Coliform, and Simplified Count Methods (IMS#2 rev. 1/09)

5. Sample Agitation

5b1 Shake samples raw samples 25 times in 7 sec with 1 ft movement
All analysts did not shake quickly enough. Raw samples need to be shaken more vigorously.

5b2 Invert filled retail container 25 times, each inversion a complete down and up motion
All analysts did not complete the inversions.

6d Avoid foam if possible when pipet is inserted into sample.
All analysts did not avoid the foam. The raw milk container may be tapped on the container on counter and tilted as to show clear spot on surface of milk. The pipet is not inserted more than 2.5 cm. Analysts may use the cap of retail containers or sterile Petri dish to adjust the pipet volume and not adjust pipet volume while pipet is still in liquid portion of sample.

APPENDIX N LAB

CHARM SL BETA LACTAM (IMS# 9C13 rev 2/10)

3a1 Incubator level. Temperature checked daily (day of use), records maintained.
The temperature is not being recorded to the tenth of a degree.
Please instruct analysts to record the strip incubator to the tenth of a degree.
Send copies of the temperature record for the next two months.

14d Reader tapes or computer printouts maintained for two years.
It would be best to keep the printouts with the daily sheets as it is more difficult to look through separate stacks to match.the tankers tested.

Comments/Recommendations: Optional Areas that may need to be addressed or LEO has some concern.

PERSONNEL AND PROCEDURES CERTIFIED

LEO IS TO LIST ALL THE PERSONNEL AND PROCEDURES THAT WERE EVALUATED AT THIS AUDIT. INCLUDE A LETTER (X, C, N, ETC) THAT DENOTES THE STATUS OF ANALYSTS (REFERENCED AS BELOW) ON THE EVALUATION AND SPLIT SAMPLES.

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

	SPC/P	ACCOLI/PC	CPMC	D3	I1	C[3,9,10,12]	DMSCC	PHOS[28]
Name Analyst 1	X/N	X/X	X	C	X	X	X	X
Name Analyst 2	X/P	X/X	X	X	X	X	X	X

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

Certified Industry Analysts	2010 On-Site Evaluation TEST KIT	4/2010 Split Sample Survey TEST KIT
Name CIS 1	x (CIS)	x
Name CIS 2	x (CIS)	x
Name CIS 3	No Longer Employed	x

Industry Analysts	2010 On-Site Evaluation TEST KIT	6/2010 Split Sample Survey TEST KIT
Name IA 1	x	x
Name IA 2	x	x

CONCLUSION

Use the proper conclusion found on pages 23 & 24.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	238
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 3 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

1. State central milk laboratories' evaluations shall be scheduled and performed by their triennial expiration date. State central milk laboratories shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. ~~The FDA/LPET shall schedule a mutually agreeable date or a date within 60 days of the request for an evaluation.~~ The Federal LEO shall schedule a mutually agreeable date within 30 days of the request for evaluation.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	241
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 3, 4, 16, 18, of the (X - one of the following):

	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Page 3:

The Federal or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms. ~~and where appropriate the latest edition of *Standard Methods for the Examination of Dairy Products*[1] (SMEDP).~~

Page 4:

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms~~, and where appropriate SMEDP,~~ as determined by an on-site evaluation.

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA-2400 Series Forms~~,~~ **and the PMO**~~, and where appropriate SMEDP~~.

Page 16:

1. The individual must be a State government employee and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms~~, and where appropriate, as described in SMEDP~~ when accompanied by a representative of the FDA/-LPET on a check laboratory evaluation.

Page 18:

8. Reference books ~~– other than SMEDP~~. (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater)

Page 24:

~~1. Available from the American Public Health Association, 800 I St., N.W., Washington, D.C. 20001-3710, USA.{http://www.apha.org}~~

~~2~~ 1. Copies of the FDA-2400 Series Forms can be downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	242
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 1, 2, 5, 16, 17, 18, 19, 20, 21, 22, of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Proposal 242 Revised Solution

Page 1:

The State Laboratory Evaluation ~~Office~~ Officer (State LEO) will use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. The Federal Laboratory Evaluation Officer (Federal LEO) will use the appropriate FDA-2400 Series Forms when evaluating State Central Milk Laboratories and State LEOs). Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the Food and Drug Administration (FDA) and the NCIMS executive board, and are effective 90 days after executive board approval.

State Central Milk Laboratory: A State owned and operated Official

Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary.

Page 2:

~~The Federal LEO will accompany the State LEO on no more than two check surveys for certification purposes.~~

Page 3, second paragraph:

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" (see page 19) must be signed by a representative of the facility prior to the initiation of the survey. This document must be maintained on file by the respective State~~/~~ or Federal LEO.

Page 5:

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager must notify the respective State~~/~~ or Federal LEO immediately.

Page 6:

Laboratories requesting withdrawal of accreditation shall notify the State LEO in writing. Upon receipt of the written request, the State LEO shall ….

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA Regional Office in writing within 5 working days of FDA/LPET's receipt of the written request.

Page 16:

SECTION 3: CERTIFICATION OF STATE LABORATORY EVALUATION OFFICERS

Initial certification of a State ~~or Federal~~ LEO shall be based on meeting the following criteria:

1. The individual must be a State ~~or Federal~~ government employee and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods or Appendix N procedures as stated on the FDA-2400 Series Forms, and where appropriate, as described in SMEDP when accompanied by a representative of the FDA/LPET on an initial check laboratory ~~evaluation~~ survey. The Federal LEO shall accompany the State LEO to not more than two laboratories/facilities during an initial check survey for initial certification purposes. Initial check evaluation surveys (for certification) should not be conducted at sites that have been evaluated within the past 90 days.

3. Add to end of paragraph:

If the individual does not have experience in the examination of dairy products, they must attend Course FD374 (formerly STT 300) "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

Laboratory evaluations conducted by conditionally approved State~~/Federal~~ LEOs ~~are~~ will be considered official.

Conditional certification of a State~~/Federal~~ LEO can occur following the initial check ~~evaluation~~ survey described above. Full certification will be granted after the State/Federal LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified State~~/Federal~~ LEO to attend the next scheduled

Workshop, unless excused with cause by FDA/LPET, will require that the State~~/Federal~~ LEO must restart the process. The State/~~Federal~~ LEO candidate would then be required to participate in another check ~~evaluation~~ survey with a representative of the FDA/LPET, and then attend the next scheduled Workshop.

Recertification of the State LEO will occur triennially, and will be based on satisfactory meeting the following criteria:

1. Add to end of paragraph:

   The Federal LEO shall accompany the State LEO to not more than two laboratories/facilities during a check survey for recertification purposes.

Page 17:

Once an individual has become a State~~/Federal~~ LEO and is therefore considered fully certified, ~~is~~ if he/she fails to submit acceptable written reports of milk laboratory evaluations within 60 days to the FDA/LPET or fails to comply with item 2 above for Recertification (or continued certification), the State~~/Federal~~ LEO will have their certification status downgraded from full to provisional. In addition, an action plan will be established that is mutually agreeable to the FDA/LPET and the State. The State~~/Federal~~ LEO would have to meet the action plan criteria in addition to continuing to meet all the criteria specified in items 1-7 above, to maintain provisional certification status.

Laboratory evaluations conducted by provisionally approved State~~/Federal~~ LEOs ~~are~~ will be considered official.

State~~/Federal~~ LEOs who lose certification cannot be re-certified for a period of 60 days from the date of loss of certification.

Page 18:

While conducting laboratory evaluations, the State≠ or Federal LEO may find it

Page 19:

1st P: The evaluations of laboratories by a State≠ or Federal LEO should be systematic.

2nd P: Upon initial evaluation and/or renewal, the laboratory, must make application for an evaluation provided by the State≠ or Federal LEO.

3rd P: Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the State≠ or Federal LEO to permit observations of counting procedures.

5th P: After entering the laboratory, the State≠ or Federal LEO should note the names of all analysts in the laboratory as/or after they are introduced and record procedures performed by each.

6th P: Before beginning the survey, the State≠ or Federal LEO should discuss the “ground rules” for the survey.

Page 20:

1st P: By frequent referral to the noted items, the State≠ or Federal LEO will be reminded to observe all laboratory procedures.

2nd P: While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the State≠ or Federal LEO:

6th P: However, the State≠ or Federal LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors.

Page 21:

1st P: The State~~/~~ or Federal LEO should make suggestions concerning any needed improvement of laboratory techniques.

2nd P: In addition to a regularly scheduled visit, some State~~/~~ or Federal LEOs find that an occasional unannounced visit to an accredited laboratory provides them with supporting information concerning laboratory practices. Information generated on all surveys (unannounced, scheduled, check surveys) must be evaluated by the State~~/~~ or Federal LEO and used to determine compliance ~~to~~ with the NCIMS Milk Laboratory Program.

3rd P: If at any time during any ~~evaluation~~ survey there is interference with or willful refusal to permit the ~~evaluation~~ survey, the State~~/~~ or Federal LEO will serve notice that the laboratory will not be certified or will be decertified until such time as the laboratory agrees to abide by the voluntary certification program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals will result in non-certification or decertification for thirty days (30). Or, if at any time before or during any ~~evaluation~~ survey the State~~/~~ or Federal LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the ~~evaluation~~ survey. The State~~/~~ or Federal LEO must indicate to the laboratory management why the ~~evaluation~~ survey was terminated and must indicate what steps must be taken before a ~~re-evaluation~~ resurvey will be scheduled. The laboratory may make reapplication by addressing the concerns that led to the termination of the ~~evaluation~~ survey and by completing the application form and stipulating that the safety concerns and/or non compliance issues have been addressed.

Page 22:

2nd P: The State~~/~~ or Federal LEO must maintain a complete copy of the

~~evaluation~~ survey report, including forms. The laboratory/facility and State~~/~~ or Federal LEO must maintain, at minimum, copies of the last two biennial/triennial ~~evaluations~~ surveys, subject to verification by the State LEO and the FDA/LPET.

3rd P: The set of completed ~~evaluation~~ survey forms for the laboratory must be accompanied by a narrative report giving the conclusions of the State~~/~~ or Federal LEO as to whether or not the laboratory is doing acceptable work.

Page 23:

Item 2: Explanation: A qualified acceptance where the State~~/~~ or Federal LEO believes that the deviations noted do not seriously affect the analytical results and that a letter explaining the corrective actions taken will be sufficient to ensure compliance.

Page 24:

Item 4: A new on-site ~~evaluation~~ survey shall be made when the State~~/~~ or Federal LEO has reason to believe that a rating would result in an acceptable rating.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	243
Committee:	Lab - EML

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

C. Proposed Solution

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

_____	2009 PMO	X	2009 EML
_____	2009 MMSR	_____	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

EML Introduction Page 1 Second Paragraph

The State Laboratory Evaluation Officer (State LEO) will use the appropriate FDA-2400 Series Forms when evaluating official laboratories, officially designated laboratories, CIS, IS and IA. Appropriate FDA-2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the FDA and the NCIMS executive board, and are effective 90 days after executive board approval. ~~FDA memoranda with the approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, the NCIMS Lab Committee shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.~~ **Approved forms shall be issued within 90 days of NCIMS Executive Board approval. If the FDA is unable to release the approved forms within the 90 day time frame, FDA LPET shall issue a draft version of the 2400 series forms 90 days after NCIMS Executive Board approval.**

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	246
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 16 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

3. The individual must attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET in conjunction with the Food and Drug Administration, State Training Team. If the individual does not have experience in the examination of dairy products, they must attend Course FD374 (formerly STT 300) "Laboratory Examination of Dairy Products" prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.

Note: It is recommended that the individual attend the Milk Laboratory Evaluation Officers Workshop prior to step 1 above.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	247
Committee:	Lab - EML

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

C. Proposed Solution

Changes to be made on page(s): 24 of the (X - one of the following):

	2009 PMO	X	2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

2. Copies of the FDA-2400 Series Forms can be ~~downloaded from {http://www.fda.gov/opacom/morechoices/fdaforms/default.html}~~ obtained from your federal or state LEO.

A list of federal or state LEO's can be found at the website: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm.

Once at that website:

For federal LEO's click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team

For state LEO's click on the link State Grade A Milk Regulatory, Rating and Laboratory Personnel and them click on your state. The table is organized Regulatory, Rating, then Laboratory. Scroll down to the laboratory section to find the contact information for your state's LEO(s).

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	248
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION		X block vote 2400 form	
FINAL ACTION		X	

C. Proposed Solution

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

_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	X	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

All sections listing control samples for instruments approved for testing somatic cells electronically for regulatory counts required under the PMO.