

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 231

Committee: Lab

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

A. Summary of Proposal

This Proposal is to revise the 2011 Evaluation of Milk Laboratories (EML) to include changes passed at the 2013 NCIMS Conference and add other edits.

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

This proposal updates the 2011 EML with required changes approved at the 2013 NCIMS Conference and adds other edits deemed necessary for uniformity of text throughout and as well as other edits to clarify the current wording or improve clarity of laboratory program requirements.

C. Proposed Solution

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

<u> </u> 2013 PMO	<u> X </u> 2011 EML
<u> </u> 2013 MMSR	<u> </u> 2400 Forms
<u> </u> 2013 Procedures	<u> </u> 2013 Constitution and Bylaws

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

See attached document. The narrative report examples and FDA/LPET Summary Template are complete replacements. Original text for the narrative report examples and FDA/LPET Summary Template of the 2011 EML are NOT included.

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Evaluation of Milk Laboratories

~~2011~~ 2015 Revision

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
and the
National Conference on Interstate Milk Shipments

PREFACE

In 1941 the United States Public Health Service began evaluations of the facilities, procedures and techniques of analysts laboratories doing official and Drug Administration programs for measuring official and officially by on-site evaluations proficiency testing. Rico and the Virgin National Conference on (NCIMS) Milk evaluations have resulted in greater uniformity, accuracy and precision of microbiological and chemical analysis.



in state and local milk analysis. In 1977, the Food (FDA) and 46 States had analyst performance in designated milk laboratories, surveys of techniques and Today all 50 States, Puerto Islands participate in the Interstate Milk Shipments Laboratory Program. These

The material in this publication provides the procedures for the evaluation of milk laboratories required to meet the sanitation standards of the current in use edition of the Grade 'A' "A" Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the ~~Food and Drug Administration~~ FDA Laboratory Proficiency Evaluation Team (~~FDA~~/LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the ~~Food and Drug Administration~~ FDA, Center for Food Safety and Applied Nutrition, Office of

Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, ~~HPH-450~~ HFS-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) ~~728-4114~~ 924-0614; Fax (708) ~~728-4179~~ 924-0690), hereafter referred to as the FDA/LPET.

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EVALUATION OF MILK LABORATORIES 2015 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (CIS) facilities requires that FDA/LPET ~~or the appropriate Federal or State~~ Milk Laboratory Control Agency conduct an on-site survey to determine satisfactory performance of analysis in milk laboratories and performance of analysis by CIS in facilities where the examinations, required by the *Grade 'A' "A" Pasteurized Milk Ordinance* (PMO), are performed. In addition, satisfactory performance in the analysis of annual proficiency test samples must be demonstrated. An accredited milk laboratory ~~may~~ shall be an approved official or officially designated milk laboratory under the administrative control of a federal, state or local Regulatory authority Agency. Approval of Industry Supervisors (IS) and Industry Analysts (IAs) requires verification of proficiency in performing drug residue analysis at least biennially, through laboratory evaluations ~~and/or on-site performance evaluations~~ and/or by analysis of split samples or by other means as noted in SECTION ~~1~~ below 2.

~~The State Laboratory Evaluation Officer (State-LEOs)~~ certified by the FDA/LPET ~~will~~ shall use the appropriate FDA/NCIMS 2400 Series Forms when evaluating official laboratories, officially designated laboratories, CISs, ISs and IAs. ~~The Federal FDA/LPET laboratory evaluation officer (Federal FDA/LPET LEOs)~~ will shall use the appropriate FDA/NCIMS 2400 Series Forms when evaluating State Central Milk Laboratories and ~~State~~ LEOs. Appropriate FDA/NCIMS 2400 Series Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the ~~Food and Drug Administration (FDA)~~ FDA/LPET and the NCIMS Executive Board, and are effective ninety (90) days after Executive Board approval. Approved forms shall be issued within ninety (90) days of NCIMS Executive Board approval. If the FDA/LPET 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 ninety (90) days after NCIMS Executive Board approval.

~~Official Laboratory: An official laboratory is a biological, chemical or physical laboratory which is under direct supervision of the state or a local regulatory agency.~~

~~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.~~

~~Officially Designated Laboratory: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of Grade 'A' raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues.~~

~~Certified Industry Supervisor (CIS): An industry supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for PMO, Appendix N regulatory actions (confirmation of tankers, producer trace back and/or permit actions).~~

~~Industry Supervisors (IS): An individual trained by the State LEO who is responsible for the supervision and training of industry analysts who test milk tank trucks for Appendix N drug residue requirements.~~

~~Industry Analyst (IA): A person under the supervision of the CIS or IS who is assigned to conduct screening of milk tank trucks for Appendix N drug residue requirements.~~

~~BactoScan Industry Operator (BIO): A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.~~

~~Food and Drug Administration (FDA) laboratory accreditation procedures provide a national base for the uniform collection and examination of milk, in compliance with the sanitation standards of the Grade "A" PMO.~~

Uniform accreditation of milk laboratories is maintained by the following two functions:

1. FDA accreditation of state central milk laboratories and certification of analysts is based on:
 - a. Satisfactory triennial on-site evaluations surveys of laboratory facilities, equipment, records, and analyst performance of techniques, and
 - b. Satisfactory annual proficiency testing (the examination of split milk samples) to continuously appraise analyst performance.
2. FDA/LPET certification of ~~State~~ LEOs who:
 - a. Accredit local laboratories and certify analysts and CIS based on:
 1. Satisfactory biennial on-site evaluations surveys of laboratory facilities, equipment, records and analyses and
 2. Satisfactory annual proficiency testing which meets established national standards.
 - b. Approve ISs and IAs (who only screen for drugs) based on:
 1. Verification that each IS has been trained (by conducting required workshops for all industry supervisors) and has established a program that ensures the proficiency of the IAs they supervise and
 2. Verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the ~~State~~ LEO and the FDA/LPET agree is appropriate. (Grade "A" PMO, Appendix N).

SECTION 1: DEFINITIONS

1. **BACTOSCAN INDUSTRY OPERATOR (BIO):** A person who operates a BactoScan FC under the supervision of a certified BactoScan analyst and analyzes samples for regulatory compliance.
2. **CERTIFIED INDUSTRY SUPERVISOR (CIS):** An industry supervisor who is evaluated and listed by an LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for Grade “A” PMO, and Appendix N regulatory actions (confirmation of milk tank trucks, producer trace back and/or permit actions).
3. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the FDA/LPET, using the *Evaluation of Milk Laboratories* (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and who has a valid certificate of qualification.
4. **FOOD AND DRUG ADMINISTRATION/LABORATORY PROFICIENCY EVALUATION TEAM LABORATORY EVALUATION OFFICER (FDA/LPET):** An FDA employee that has been internally standardized to evaluate State Central Milk Laboratories for the purpose of accreditation to conduct official NCIMS milk testing. They are standardized to evaluate and certify milk Laboratory Evaluation Officers (LEOs) working for a Regulatory Agency or Milk Laboratory Control Agency for the purpose of accrediting other official and officially designated laboratories participating in the NCIMS Grade “A” Milk Safety Program.
5. **INDUSTRY ANALYST (IA):** A person under the supervision of a CIS or IS who is assigned to conduct screening of milk tank trucks for *Grade “A” PMO*, Appendix N drug residue requirements.
6. **INDUSTRY SUPERVISOR (IS):** An individual trained by an LEO who is responsible for the supervision and training of IAs who screen milk tank trucks for *Grade “A” PMO*, Appendix N drug residue requirements.
7. **INTERNATIONAL CERTIFICATION PROGRAM (ICP):** The NCIMS voluntary program designed to utilize Third Party Certifiers (TCPs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Programs for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

8. **MILK LABORATORY CONTROL AGENCY:** A governmental or other Regulatory Agency body which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *EML* and is responsible for the enforcement of such ordinance, rule or regulation in substantial compliance with the Grade “A” Milk Safety Program for a listed milk laboratory. The Milk Laboratory Control Agency has authority, recognized by the NCIMS, to oversee and control the activities of milk laboratories and/or personnel involved with official NCIMS Grade “A” milk testing. The term, “Milk Laboratory Control Agency”, whenever it appears in the *EML* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited in this *EML*.
9. **OFFICIAL LABORATORY:** A biological, chemical or physical laboratory which is under the direct supervision of the Regulatory Agency or Milk Laboratory Control Agency.
10. **OFFICIALLY DESIGNATED LABORATORY:** A commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade “A” raw milk for pasteurization ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues.
11. **RATING AGENCY:** A State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade “A” PMO* and are conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion in the *IMS List*. The certifications are based on compliance with the requirements of the *Grade “A” PMO* and are conducted in accordance with the procedures set forth in the *MMSR*. The definition of a Rating Agency also includes a TPC that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS member states that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.
12. **REGULATORY AGENCY:** An agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade “A” PMO* and is responsible for the enforcement of such ordinance, rule or regulation, which is in substantial compliance with the *Grade “A” PMO* for a listed interstate milk shipper and milk laboratory. The “Regulatory Agency”, whenever it appears in the *EML* shall also

mean the appropriated TPC having jurisdiction and control over the matters cited within this *EML*.

13. **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, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, pasteurized milk and milk products, and dairy waters, as necessary.

14. **THIRD PARTY CERTIFIER (TPC):** Non-governmental individual(s) or organization authorized under the NCIMS voluntary ICP that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade “A” PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary ICP. The TPC provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary ICP, a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the TPC.

SECTION 12: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory ~~must~~ shall include an on-site ~~visit to~~ survey of the laboratory, a review of the records, including training records of IAs, records of split sample performance, facilities, equipment, materials and procedures. The evaluation shall be made using the most recent approved Official Milk Laboratory Evaluation Forms (FDA/NCIMS 2400 ~~Series~~ Forms). The ~~Federal~~ FDA/LPET or ~~State~~ LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA/NCIMS 2400 ~~Series~~ Forms.

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" (see page 24) ~~must~~ shall be signed by a representative of the facility prior to the initiation of the survey. This document ~~must~~ shall be maintained on file by the ~~Federal~~ FDA/LPET or ~~State~~ LEO.

A set of completed evaluation forms may accompany the narrative report ~~which~~ that describes the degree of suitability of the laboratory facilities, equipment, records, the analysts' ~~procedures~~ technique, 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~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA/NCIMS 2400 ~~Series~~ Forms.

~~Survey-r~~ Reports of on-site ~~evaluations~~ surveys of Official Milk Laboratories and CISs facilities shall be sent within sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS facility, the appropriate ~~Food and Drug Administration~~ FDA 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 facilities ~~must~~ shall include the narrative report and may include copies of the completed FDA/NCIMS 2400 ~~Series~~ Forms. Reports to the appropriate FDA Regional Office ~~and FDA/LPET~~ shall be sent electronically and shall include the narrative report only. ~~and appropriate,~~ Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).

~~Survey-r~~ Reports of on-site ~~evaluations~~ surveys of screening sites shall be sent to the facility within sixty (60) days of the initial, biennial anniversary, or supplemental date of the laboratory ~~evaluation~~ survey.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the ~~Federal~~ FDA/LPET or ~~State~~ LEO shall be based on the following criteria:

1. Evaluations of 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~~ survey of new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. The ~~Federal~~ FDA/LPET LEO shall schedule a mutually agreeable date within thirty (30) days of the request for an evaluation.
2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in

writing, for on-site ~~evaluation~~ survey of new analyst(s) performance of techniques, new methods and/or new facilities to the ~~State~~ LEO. The ~~State~~ LEO shall schedule a mutually agreeable date within thirty (30) days of the receipt of the request for an evaluation.

3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA/NCIMS 2400 ~~Series~~ Forms, as determined by an on-site ~~evaluation~~ survey.
4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA/NCIMS 2400 ~~Series~~ Forms and the Grade "A" PMO.
5. Analysts meet the performance levels of the proficiency testing program (SECTION 2 3). The ~~State~~ LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved.
6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2 3).

Analysts seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification, may be certified or approved to conduct official examinations only if criteria 3 and 4 above are met. When such analysts successfully complete the next official proficiency tests administered by ~~the State an~~ LEO, a certificate of approval may be issued to such analyst. If such analyst does not successfully meet the performance levels of the proficiency testing program, the certification or approval to conduct official examinations shall be withdrawn.

When a new analyst is assigned to an accredited laboratory between on-site ~~evaluations~~ surveys, conditional certification or approval status ~~will~~ shall be provided to the new analyst upon satisfactory completion of criteria 4 or 5 above. Full certification will follow after acceptable completion of both criteria 4 and 5. Conditionally certified or approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory ~~evaluation~~ survey ~~will~~ shall have their conditionally certified or approved status revoked.

~~The Certified analysts and CISs and certified analysts must~~ shall participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedures for which they are certified. Failure without cause to participate in the annual split samples ~~evaluation~~ or failure to meet established satisfactory performance criteria ~~will~~ shall result in the certified analyst(s) or CIS(s) or certified analyst(s) having their certification status downgraded from full to provisional. Failure of a provisionally certified analyst or CIS to participate in the examination of or to meet established satisfactory performance levels on the next set of split samples ~~will~~ shall result in withdrawal of their certification.

A CIS or certified analyst that loses their certification for one or more tests cannot examine official samples using a test for which their certification was withdrawn. Recertification procedures are shown in "SECTION 2 3: PROFICIENCY TESTING PROGRAMS".

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.

Upon notice of revocation, the certificate, if issued, shall be returned to the issuing State LEO within ninety (90) days.

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by ~~Federal~~ the FDA/LPET or ~~State~~ Milk Laboratory Control Agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records ~~must~~ shall meet the requirements stated on the appropriate FDA/NCIMS 2400 Series Forms and for CISs, appropriate Appendix N 2400 Series Forms, as determined by an on-site ~~evaluation~~ survey.
2. All official examinations required by the Grade "A" PMO ~~must~~ shall only be performed by certified analysts or CISs.
3. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION ~~2~~ 3).

~~The State~~ An LEO may issue a certificate of accreditation or approval to each official, commercial, and industry laboratory meeting criteria 1 and 2 above. The certificate shall be valid for two (2) years unless revoked.

When an accredited laboratory changes location or undergoes substantial remodeling, an ~~evaluation~~ survey of the new laboratory or screening facility is required within ~~3 months~~ ninety (90) days. ~~No evaluation~~ A survey of personnel or procedures is not required at this time.

For initial accreditation, milk laboratories shall have a minimum of fifteen (15) days of required records available at the time of the on-site ~~evaluation~~ survey. The laboratory has records to show that all necessary quality control requirements have been performed and are satisfactory, and that there are fifteen (15) days of records to ~~demonstrate~~ demonstrating that critical equipment is functional.

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager ~~must~~ shall notify the ~~Federal~~ FDA/LPET or ~~State~~ LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's/facility's accreditation. For example, a laboratory having only one certified analyst or CIS ~~will~~ shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories/facilities. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts or CISs, or for some other reason, the ~~Federal~~ FDA/LPET or

State LEO shall immediately notify the milk laboratory involved, the ~~state Milk regulatory Control Agency~~, the respective state milk sanitation Regulatory/Rating Agency, any ~~out-of-state milk other Regulatory/Rating Agencies that oversees locations~~ where known customers of that laboratory 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 any 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 respective state milk sanitation Regulatory/Rating Agency, any ~~out-of-state milk other Regulatory/Rating Agencies that oversees locations~~ where known customers of that laboratory 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 ninety (90) days. For FDA/LPET notification, changes in accreditation shall be indicated on the ~~appropriate~~, completed FDA summary template and shall be submitted electronically.

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 five (5) working days of FDA/LPET's receipt of the written request.

Additionally, the laboratory/CIS facility shall notify its customers in writing, that it has withdrawn or ~~been decertified~~ has had its accreditation withdrawn and shall not represent itself as an official laboratory or officially designated laboratory, for those decertified or unapproved procedures under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the State LEO. ~~Decertification~~ Withdrawal of accreditation ~~will~~ shall remain in effect until measures are taken by the laboratory/CIS facility to attain compliance and another on-site survey is completed successfully.

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

Approval of Industry Supervisors (ISs) and Industry Analysts (IAs) by ~~the State~~ LEOs shall be based on meeting all of the following requirements:

1. The laboratory facilities, equipment, procedures and records meet the requirements stated on the approved FDA/NCIMS 2400 Series Forms associated with the Grade "A" PMO, Appendix N program.
2. All screening tests required by the Grade "A" PMO, Appendix N ~~must~~ shall only be performed by approved ISs, IAs or by a certified entity.
3. Analyst performance is in compliance with procedures required by the approved FDA/NCIMS 2400 Series Forms associated with the Grade "A" PMO, Appendix N program.
4. The analyst meets the performance levels of the proficiency testing program (the examination of milk split samples).

5. Approval of ISs and IAs require verification of proficiency in performing drug residue analyses at least biennially, through an on-site survey performance evaluation and/or analysis of split samples, or by other means of determining another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (*Grade "A" PMO*, Appendix N)
6. The IS has attended and received training by ~~the State~~ an LEO. This training ~~must~~ shall be documented.

The IS shall report to the State LEO the result of all competency evaluations performed by IAs. The name of each IS and IA (as well as their training and ~~evaluation~~ approval status) shall be maintained by the State LEO and updated as replacement, additions and/or removals occur. The State LEO shall verify (document) that each IS has established a program that ensures the proficiency of the IAs they supervise. The State LEO shall also verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site survey performance evaluation or by ~~another other means of determining proficiency determination~~ that the State LEO and the FDA/LPET agree is appropriate.

When a new analyst is assigned to an approved laboratory, conditional approval status ~~will~~ shall be provided to the new analyst upon satisfactory demonstration of competency to the IS. Full approval status ~~will~~ shall follow after verification of proficiency (see criteria #5, above). Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site survey laboratory evaluation or analysis of split samples ~~will~~ shall have their conditionally approved status revoked.

Fully approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site survey laboratory evaluation or analysis of split samples ~~will~~ shall have their fully approved status downgraded to "provisional". Provisionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site survey laboratory evaluation or analysis of split samples ~~will~~ shall have their provisionally approved status revoked.

Failure by the ISs or the IAs to demonstrate adequate proficiency to the State LEO shall lead to their removal from the State LEO List of Approved ISs/IAs. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site survey evaluation or otherwise demonstrating proficiency to the State LEO. Analysts not on the State LEO List of Approved ISs/IAs are not approved to test raw, commingled, bulk milk in the *Grade "A" PMO*, Appendix N program.

When a screening facility loses its approval because of the lack of approved ISs or IAs, or for some other reason, the State LEO shall immediately notify the screening facility involved, the respective state milk sanitation Regulatory/Rating Agency, any out-of-state milk other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory 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 Control Agency, the respective state milk sanitation Regulatory/Rating Agency, any ~~out-of-state-milk~~ other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory 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.

Additionally, the screening facility shall notify its customers in writing that it has been withdrawn or has lost its approval and shall not represent itself as an approved screening facility under the agreements of the NCIMS. A copy of the generic notification ~~must~~ shall be sent to the ~~State~~ LEO. Loss of approval will remain in effect until measures are taken by the screening facility to attain compliance and another on-site survey is completed successfully.

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

Approval of BactoScan Industry Operators (BIO) shall be based on meeting the following requirements:

1. The industry operator ~~must~~ shall complete the BIO operating protocols, training and oversight specified in the training procedure document.
2. The laboratory ~~must~~ shall maintain one (1) certified BactoScan analyst (see current FDA/NCIMS 2400 Series Form) for training and ongoing oversight of the BIO(s).
3. Refer to the Foss BactoScan FC BIO Companion Protocol approved training procedures at the end of the BactoScan FDA 2400 series form.
4. The BIO(s) meets the performance levels of the proficiency testing program (the examination of milk split samples)
5. Records are to be maintained for BIO(s) oversight.

NOTE: A BIO can analyze samples for regulatory compliance.

SECTION 2 3: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES - MICROBIOLOGY

The ~~Food and Drug Administration~~ FDA/LPET shall split samples annually with all ~~federally~~ FDA/LPET certified analysts of each ~~State/Territory (hereafter noted as State)~~ Milk Laboratory Control Agency ~~central~~ accredited Central Milk Laboratory. State Milk Laboratory Control Agencies shall split samples at least annually with all ~~state~~ certified analysts of each official, officially designated accredited milk laboratory, and all CISs. State Milk Laboratory Control Agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through ~~on-site performance~~ laboratory evaluation and/or analysis of split samples annual performance evaluation, or ~~another~~ by other means of determining proficiency determination that the State LEO and the FDA/LPET agree is appropriate.

State Milk Laboratory Control Agencies s having less than ten (10) analysts (total) in their milk laboratory program are to develop joint state proficiency testing programs with other states Milk Laboratory Control Agencies ~~which that~~ can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts (≥ 10) are not available, evaluation of proficiency ~~will~~ shall be made by a determination that the State LEO and the FDA/LPET agree is appropriate.

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When an analyst examines both raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, and pasteurized milk and milk products, a minimum of twenty-two (22) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates of milk products are shown in Table 1, page ~~27~~ 31.
2. When an analyst examines only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, a minimum of fourteen (14) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page ~~27~~ 31.
3. When an analyst examines only pasteurized milk and milk products, a minimum of sixteen (16) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page ~~27~~ 31.
4. When a CIS examines commingled raw bulk milk tanker milk or its equivalent for Grade "A" PMO, Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified ~~or approved~~, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The CIS may misidentify

one (1) of the samples and maintain and/or gain certification. If more than one (1) sample is misidentified, the CIS falls is reduced one (1) level of certification. If this occurs twice consecutively, the CIS is ~~no longer~~ not certified or approved (rules for recertification of analysts and accreditation of laboratories apply).

5. When an IS or an IA examines commingled raw bulk milk tanker milk or its equivalent for Grade "A" PMO, Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples ~~containing no~~ that do not contain animal drug residues. The IS or IA may misidentify one (1) of the samples and maintain and/or gain approval. If more than one (1) sample is misidentified, the IS or IA falls one level of approval. If this occurs twice consecutively, the IS or IA is ~~no longer~~ not approved. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site ~~evaluation~~ survey or otherwise demonstrating proficiency to the ~~State~~-LEO.
6. Each analyst certified to perform visual drug residue tests ~~will~~ shall participate in annual proficiency tests to demonstrate their ability to detect the beta-lactams at safe/tolerance level per kit label claim (Penicillin G, Cloxacillin, Cefotiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results ~~must~~ shall be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test.
7. An acceptable annual proficiency testing program for the BactoScan FC (all NCIMS approved models), shall meet the following applicable criteria.
 - (a) The BactoScan FC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC and for which the analyst or BIO has been certified/approved, respectively.
 - (b) Split samples (minimum of fourteen (14)) shall be made up using BactoScan FC Blank solution and BactoScan FC Bacteria Control Samples.
 - (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1, page ~~27~~ 31.

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), and Electronic Phosphatase Count ~~and Vitamin A and D₃~~ result of each certified analyst shall fall within the limits shown in Table 2, page ~~27~~ 32. The vitamin A and D₃ results of each analyst shall be calculated by z-scores, which are based on ISO Standards, and are calculated for individual set of split samples.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.
2. ~~Calculate~~ Determine the logarithmic ~~mean~~ of each test sample for the ~~Standard Plate Count, SPC~~ Petrifilm Aerobic Count PAC, Plate Loop Count PLC, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count DMSCC, Electronic Somatic Cell Count ESCC, and Electronic Phosphatase Count ~~and Vitamin A and D₃ results of each test sample;~~ using a table of common logarithms; and list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for ~~the~~ each sample.
3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each analyst's result the limit (sample mean $\pm L_1$). Results falling outside the limit are classified as outliers and are unacceptable. Note, by sample and test, the analysts who have results outside of the limits.
4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L_2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean $\pm L_2$). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note, by sample and test, the analysts who have results outside of these limits.
5. Using Table 3, page ~~26~~ 32, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.
6. Analysts certified for vitamin analysis shall meet the acceptance ~~limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28~~ criteria using z-scores.
7. An acceptable annual proficiency testing program for the ~~BactoScan FC Count~~ BSC (all NCIMS approved models), shall meet the following applicable criteria.
 - (a) ~~BactoScan FC Count~~ BSC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC Count and for which the analyst or BIO has been certified/approved, respectively.
 - (b) Split samples (minimum of fourteen (14)) shall be made up using BactoScan FC Blank solution and ~~BactoScan FC Count~~ BSC Bacteria Control Samples.
 - (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1 page ~~27~~ 31.
8. The annual proficiency testing (PT) program for vitamins A and D₃ shall be based on z-scores following ISO Standards. Data shall be converted to log base 10 values and a consensus mean determined. Based on the data for each PT, standard deviations shall be determined. Acceptable results shall be within plus or minus two (2) standard deviations.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the ~~“Grade ‘A’ PMO”~~ Grade “A” PMO shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the ~~Standard Plate Count, SPC~~ Petrifilm Aerobic Count PAC, Plate Loop Count PLC, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count DMSCC, Electronic Somatic Cell Count ESCC, and Electronic Phosphatase Count and ~~Vitamin A and D₃~~ analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page ~~28~~ 32.
2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using drug other than beta-lactam, samples ~~must~~ shall be spiked in duplicate. See Table 3, page ~~28~~ 32.
3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) within the specified limits in Table 2, page ~~28~~ 32.
4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table 3, page ~~28~~ 32.
5. ~~Certified Industry Supervisors~~ CISs certified to perform Grade “A” PMO, Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page ~~28~~ 32.
6. Analysts certified to perform vitamins A and D₃ tests shall detect samples that contain vitamins A and D₃ and shall meet the acceptance limits and performance levels for the calculated z-scores, which are based on ISO Standards. Acceptable results shall be within plus or minus two (2) standard deviations.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) ~~will~~ shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the Milk Laboratory certifying authority Control Agency before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION ~~4~~ 2: LABORATORY EVALUATION PROGRAMS. A formerly certified analyst who has lost certification may only become ~~conditionally approved~~ certified again by the route

by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then ~~he/she~~ the analyst can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site ~~evaluation~~ survey that leads to his/her loss of certification then ~~he/she~~ the analyst must pass the next on-site certification to become conditionally certified.

~~BactoScan Industry Operators~~ BIOs performance levels shall follow the performance procedures indicated above for fully certified analysts.

Copies of the proficiency testing report, including tabulation of analyst results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate FDA Regional Office, and the FDA/LPET.

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Grade "A" PMO Vitamin Proficiency Test PT Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories ~~must~~ shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and ~~must~~ shall have submitted satisfactory method validation and quality control/quality assurance (QC/QA) information. Participation in proficiency testing alone does not satisfy the criteria for analyst certification and laboratory accreditation.

The Grade "A" PMO Vitamin Proficiency Test PT Program involves the analysis of ~~sets of four~~ six (6) to eight (8) samples sent to participating laboratories every ~~four (4)~~ six (6) months, i.e., ~~three~~ two (2) times a year with a ~~total~~ minimum of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits, ($L_1=0.300$ and $L_2=0.200$, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO) which are evaluated using z-scores that are based on ISO Standards and calculated for each set of split samples. Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two (2) sets of samples (eight (8) samples in two (2) consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one (1) sample, and still be considered as having satisfactory performance. After analyzing the next consecutive set of samples the analyst is considered fully certified if no more than 2 samples have been missed over the course of a one (1) year period (~~twelve (12) consecutive samples analyzed~~).

Once fully certified, analysts maintain certification by satisfactorily analyzing ~~all three (3)~~ both sets of split samples each year. During the course of the year full certification is maintained if ~~no~~ not more than two (2) samples (~~of 12~~) are missed. Failure without cause to analyze all ~~twelve (12)~~ twelve (12) samples during the course of the year ~~will~~ shall result in the downgrading of an analyst's status. It is imperative that laboratory schedules be set up to allow for the analysis of these samples. If a fully certified analyst misses more than two (2) samples (~~of 12~~) then that analyst ~~will~~ shall be downgraded to provisional certification. Full certification ~~will~~ shall be regained if that analyst misses no more than one sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next

~~eight set of~~ samples analyzed after receiving the respective status ~~will~~ shall have certification/~~approval~~ removed.

Once certification/~~approval~~ is removed an analyst may only regain conditional certification by satisfactory performance on the next ~~eight set of~~ samples, i.e., miss ~~no~~ not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst ~~must~~ shall independently analyze the samples. Routine analysis may be performed by multiple analysts working together or by partitioning duties. Certified analysts are responsible for conducting official analysis. Non certified analysts may assist in analysis but may not solely perform official analyses or report official results.

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed is subject to meeting all requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is ~~no longer~~ not employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and ~~must~~ shall seek new laboratory entry prior to resuming official analysis.

An acceptable annual ~~proficiency testing~~ PT program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D₃, a minimum of ~~four (4)~~ six (6) samples ~~three (3)~~ two (2) times a year for a total of twelve (12) samples annually using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, for which the analyst has been approved, unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page ~~27~~ 32.

WATER MICROBIOLOGY

Laboratories using Environmental Protection Agency (EPA) or ~~State~~ other officially administrated programs for water analysis are not required to meet the intentions of this Section. ~~State administered programs~~ Programs administered by Milk Laboratory Control Agencies include central, official, officially designated and other water testing laboratories sanctioned by the ~~state~~ Milk Laboratory Control Agencies and participation in a this split sample program is voluntary.

Each accredited State central accredited milk laboratory, and all State, official, officially designated accredited milk laboratories not participating in an EPA or ~~State~~ other officially administered program for water analysis ~~shall~~ should participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is ~~certified~~ accredited. The ~~proficiency testing~~ PT samples are to be provided by ~~State~~ Milk Laboratory Control Agencies ~~programs~~ or through private providers.

An acceptable annual proficiency testing program shall meet the following applicable criteria:

1. When a laboratory examines dairy water for the presence of coliforms, a minimum of eight (8) samples shall be examined by the laboratory using those procedures for which the laboratory has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates are shown in Table 1, page ~~27~~ 31.

SPLIT SAMPLE ANALYSIS

The multiple tube fermentation (Lauryl Tryptose Broth or Chromogenic substrate), membrane filtration and heterotrophic plate count result of each laboratory shall fall within the limits shown in Table 2, page ~~28~~ 32.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.
2. ~~Calculate~~ Determine the logarithmic ~~mean~~ for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.
3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each laboratory's result the limit (sample mean $\pm L_1$). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have results outside of the limits.)
4. Determine for each sample for each test whether there are laboratory results outside of the Rejection Limit (L_2). Remove unacceptable laboratory results and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each laboratory's result the limit (sample mean $\pm L_2$). Results falling outside the limit are classified as "out of limits" and are unacceptable. (Note by sample and test, the laboratories that have results outside of these limits.)
5. Using Table 3, page ~~26~~ 32, list all laboratories that have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.
6. Laboratories accredited for dairy water analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page ~~28~~ 32.

LABORATORY PERFORMANCE LEVEL

Laboratories accredited to perform the examinations of dairy water for coliforms required by the PMO shall meet the following performance levels on an annual basis.

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page ~~28~~ 32.
2. Laboratories accredited for presence-absence procedures shall qualitatively detect and verify coliform organisms in samples containing coliform organisms.

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which ~~they~~ it exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) ~~will~~ shall be withdrawn. A laboratory that has lost its accreditation ~~must~~ shall participate in a training program acceptable to the Milk Laboratory certifying authority Control Agency before requesting reaccreditation. Reaccreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 4.2: LABORATORY EVALUATION PROGRAMS.

Copies of the ~~proficiency testing~~ PT report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate ~~Food and Drug Administration~~ FDA Regional Office, and the FDA/LPET.

SECTION 3 4: CERTIFICATION OF MILK LABORATORY CONTROL AGENCY LABORATORY EVALUATION OFFICERS

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

1. The individual ~~must~~ shall be a State government an employee of a Regulatory or Milk Laboratory Control Agency and demonstrate competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods and/or Grade "A" PMO, Appendix N procedures as stated on the FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/LPET on ~~an~~ the initial check ~~laboratory~~ on-site survey(s). The ~~Federal LEO~~ FDA/LPET shall accompany the State LEO to not more than two (2) laboratories/facilities during ~~an~~ the initial check survey(s) for initial certification purposes. Initial check on-site survey(s) (for certification) should not be conducted at sites that have been evaluated within the past ninety (90) days. The individual check surveys of an initial LEO evaluation must be official, but may be conducted as (1) biennial (all inclusive) or (2) supplemental (where the number of participating analysts may be reduced and the time span of records may be reduce, but all applicable record types must be reviewed) to facilitate the timely survey of the laboratory or Appendix N facility.
2. The individual ~~must~~ shall submit an acceptable written report(s) of the milk laboratory initial check on-site survey(s) to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate FDA Regional Office ~~and FDA/LPET~~ shall be sent electronically and shall include the narrative report only. ~~and appropriate, Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).~~
3. The individual ~~must~~ shall 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~~ the individual ~~must~~ shall attend FDA Course #374 "Laboratory Examination of Dairy Products" conducted by the FDA/LPET 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.

Laboratory evaluations conducted by conditionally ~~approved~~ certified State LEOs ~~will~~ shall be considered official.

Conditional certification of a State new LEO can occur following the initial check on-site survey(s) described in items 1 and 2 above. Full certification ~~will~~ shall be granted after the State LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified State LEO to attend the next scheduled Workshop, unless excused with cause by the FDA/LPET, will require that the State LEO must restart the process. The State LEO candidate would then be required to participate in another check on-site survey(s) with a representative of the FDA/LPET, and then attend the next scheduled Milk Laboratory Evaluation Officers Workshop.

Recertification of ~~the State~~ an LEO will occur triennially, and ~~will~~ shall be based on satisfactorily meeting the following criteria:

1. The individual ~~must~~ shall be a ~~State government~~ an employee of a Regulatory or Milk Laboratory Control Agency and demonstrate continued competence in evaluating milk testing laboratories and analysts' performance of milk laboratory test methods and/or Grade "A" PMO, Appendix N procedures as stated on the FDA/NCIMS 2400 Series Forms when accompanied by a representative of the FDA/LPET on a check ~~laboratory~~ on-site survey(s). The ~~Federal LEO~~ FDA/LPET shall accompany the ~~State~~ LEO to not more than two (2) laboratories/facilities during a check on-site survey(s) for recertification purposes. The individual check surveys of a continuing LEO evaluation may be conducted as (1) biennial (all inclusive), (2) supplemental (where the number of participating analysts may be reduced and the time span of records may be reduce, but all applicable record types must be reviewed) to facilitate the timely survey of the laboratory or Appendix N facility, or (3) unofficial (where the same criteria for a biennial or supplemental may apply) to facilitate a timely survey and/or avoid assessment of a fee to the laboratory or Appendix N facility.
2. The individual ~~must~~ shall submit an acceptable written report(s) of the milk laboratory check on-site survey(s) to the FDA/LPET within sixty (60) days of the evaluation survey(s). Reports to the appropriate FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report only. and appropriate, Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA summary template only (see pages 47 – 48).
3. The individual ~~must~~ shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular biennial on-site surveys must shall be performed within the month of their anniversary date).
4. The individual ~~must~~ shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the ~~state milk sanitation Regulatory and/or Rating Agency~~ and the FDA/LPET.
5. The individual has met the responsibilities for the training of ~~Industry Supervisors~~ ISs.
6. The individual ~~must~~ shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.
7. The individual ~~must~~ shall not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds an FDA Regional Milk Seminar, then ~~State~~ LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year the ~~State~~ LEO may opt to attend that regional milk seminar in lieu of attending the seminar held in their region and still meet the requirement.

Once an individual has become a ~~State~~ an LEO and is therefore considered fully certified, if ~~he/she~~ the individual fails to submit acceptable written reports of milk laboratory evaluations on-site surveys within sixty (60) days to the FDA/LPET or fails to comply with item 2 above for recertification (or continued certification), the ~~State~~ LEO ~~will~~ shall have their certification status downgraded from full to provisional. In addition, an action plan ~~will~~ shall be established that is

mutually agreeable to the FDA/LPET and the ~~state~~ Milk Laboratory Control Agency. The ~~State~~ LEO ~~would have to~~ shall 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~~ certified ~~State~~ LEOs ~~will~~ shall be considered official.

Should a provisionally certified ~~State~~ LEO meet the criteria specified by their action plan and EML, SECTION ~~3~~ 4, their certification ~~status will~~ shall be returned to full certification once they have successfully undergone their next check ~~evaluation~~ on-site survey(s) with the FDA/LPET.

Should a provisionally certified ~~State~~ LEO fail to meet the criteria specified in EML, SECTION ~~3~~ 4 and/or follow the action plan, then their certification ~~would~~ shall be revoked.

The procedures for revocation ~~must~~ shall follow SECTION V. QUALIFICATIONS AND CERTIFICATIONS, Part H. of the *Procedures* Document.

~~State~~ LEOs who lose certification cannot be re-certified for a period of sixty (60) days from the date of the loss of their certification. Recertification ~~will~~ shall require meeting the requirements for initial certification.

SECTION 4 5: EQUIPMENT AND APPARATUS OF AID TO MILK LABORATORY EVALUATION OFFICERS

While conducting laboratory ~~evaluations~~ on-site surveys, the ~~Federal~~ FDA/LPET or ~~State~~ LEO may find it extremely useful to have in ~~his/her~~ their possession different types of equipment which ~~will~~ shall enable them to examine the apparatus in use and judge the proficiency of laboratory procedures in use for the examination of milk products. Some ~~evaluation officers~~ LEOs currently use a large percentage of the equipment and apparatus listed below. Equipment should be maintained in proper working conditions to assure accuracy.

1. Brom thymol blue solution.
2. Chlorine test kit (chloramine or free chlorine).
3. Conductivity meter.
4. Anemometer.
5. Level (or cross test level).
6. Light meter (in foot-candles).
7. Maximum registering thermometer (MRT) for autoclaves.
8. Reference books (e.g., AOAC Official Methods of Analysis, Standard Methods for the Examination of Water and Wastewater).
9. Ruler, pocket - metric.
10. Special measuring flask (calibrated at 97-99-101-ml).
11. Taper gauge or drill bits for PLC loops.
12. Thermometer(s).
13. Weights - accurate (S/S1 or ASTM 1, 2 or 3).

SECTION 5 6: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a ~~Federal~~ FDA/LPET or ~~State~~ LEO should be systematic. These guidelines are recommended to enable complete evaluation of the laboratory facilities, equipment and records and of analyst technique.

Upon initial evaluation and/or renewal, the laboratory, ~~must~~ shall make application for an evaluation upon a form provided by the ~~Federal~~ FDA/LPET or ~~State~~ LEO. The application ~~will~~ shall include the statement:

“I AGREE TO THE PROVISIONS OF THE NCIMS AND THE PROCEDURES FOR THE EVALUATION OF MILK LABORATORIES.”

In preparation for an on-site survey ~~the laboratory evaluation~~, normally the laboratory director or supervisor should be notified in advance to insure the presence of analysts and the availability of samples for laboratory examination. In arranging for an initial ~~evaluation~~ on-site survey, laboratory officials should be told that all tests ~~must~~ shall be set up and that during the ~~evaluation~~ on-site survey the work of all analysts, who may perform any official methods ~~must~~ shall be observed. If laboratory ~~evaluations~~ on-site surveys are conducted on days when procedures, e.g. the SPC, are not normally performed, advance arrangements should be made to have samples on hand in order to observe the SPC procedure and the laboratory personnel should be requested to save countable plates from the previous day. Where the latter is not feasible, previously prepared and incubated plates may be brought to the laboratory by the ~~Federal~~ FDA/LPET or ~~State~~ LEO to permit observations of counting procedures.

On the designated ~~laboratory evaluation~~ day of the on-site survey, delay arrival at the laboratory/facility until 10 - 15 minutes after the opening of the laboratory, to allow all personnel to start their day's activities normally. A visit to the laboratory director and/or supervisor's office should be made prior to entering the laboratory. At this time the purpose of the ~~evaluation~~ on-site survey should be reviewed, and arrangements made to discuss the completed laboratory ~~evaluation~~ on-site survey informally with the laboratory director and/or supervisors on completion of the ~~evaluation~~ on-site survey. Assure that the “~~Grade ‘A’~~ Grade “A” PMO Milk Laboratory Evaluation Request and Agreement Form” has been signed by a representative of the facility.

After entering the laboratory, the ~~Federal~~ FDA/LPET or ~~State~~ LEO should note the names of all analysts in laboratory as/or after they are introduced and record the procedures performed by each analyst.

Before beginning the survey, the ~~Federal~~ FDA/LPET or ~~State~~ LEO should discuss the “ground rules” for the survey. Rules should be established for ~~procedural evaluations~~ the observation of the analysts’ technique (e.g. whether an analysts can restart a procedure if ~~the~~ analysts notices that ~~he/she~~ they have ~~make~~ made an error, how many times may ~~an~~ analysts restart, etc.).

During an ~~evaluation~~ on-site survey of a large laboratory, various analysts may be performing different examinations, which may make a comprehensive ~~evaluation~~ survey difficult, particularly since all analysts are to be observed for each bacteriological and chemical procedure

for which certification is requested. It is recommended that the ~~office~~ FDA/LPET or LEO establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms will be used at separate times, it is advisable to note observed items of the various procedures on the ~~left-hand~~ margins of the evaluation FDA/NCIMS 2400 Series Forms. By frequent referral to the noted items, the ~~Federal~~ FDA/LPET or State LEO ~~will~~ shall be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

While observations of procedures are being made and the evaluation forms completed, certain precautions should be taken by the ~~Federal~~ FDA/LPET or State LEO:

1. Do not ask leading questions, e.g., do not ask analysts if plating media and dilution blanks are autoclaved at $120\pm 1^{\circ}\text{C}$ for 15 minutes; simply ask how media and water blanks are autoclaved;
2. Try to keep the ~~evaluation~~ on-site survey on an informal basis and to minimize nervousness on the part of analysts, e.g., do not over emphasize the evaluation of procedures by unusually close physical observation; and
3. Stay alert during the observation of procedures so as to avoid necessary requests to repeat a technique overlooked during a procedure.

During the laboratory ~~evaluation~~ on-site survey it is probable that some items pertinent to receiving samples ~~will~~ may not be observed. However, the ~~Federal~~ FDA/LPET or State LEO should determine from consultation with the laboratory supervisor the procedures used in receiving samples from the sample collectors:

1. Do the samples arrive at the laboratory as specified in the appropriate FDA/NCIMS 2400 Series Forms?
2. Are the samples suitably identified as to date, temperature and time of pickup, identification of sampler (e.g. name or initials) and sample identification or this information is readily available?
3. Is an extra sample or pilot container of appropriate size provided as a temperature control (TC)?
4. Are the raw milk sample containers no more than three-quarters (3/4) full?
5. Are samples ever rejected because they are outside of the acceptable temperature range at the time of pick-up from a sample storage depot or arrival at the laboratory, are samples ever rejected because they are too full or not properly identified?
6. How many hours pass (from initial time of collection of samples) before samples are plated?

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on the validity of results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed ~~evaluation form~~ FDA/NCIMS 2400 Series Forms and each major deviation should be discussed by the officer with interested staff. At that time comments should be invited from the staff concerning the evaluation. The ~~Federal~~ FDA/LPET or ~~State~~ LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

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

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

SECTION 6 7: LABORATORY EVALUATION REPORTS

EVALUATION FORMS

FDA/NCIMS 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. Forms pertaining to procedures not used should not be returned with the report.

Copies of the completed evaluation survey forms may be prepared for the laboratory evaluated. The ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~must~~ shall maintain a complete copy of the survey on-site report, including forms. The laboratory/facility and ~~Federal~~ FDA/LPET or ~~State~~ LEO ~~must~~ shall maintain, at minimum, copies of the last two (2) biennial/triennial surveys, subject to verification by the ~~State~~ LEO and the FDA/LPET. In marking the official copies of the completed survey evaluation forms, leave items in compliance blank. When ~~typing~~ preparing copies for transmittal to others, do not include check marks in the margins ~~which~~ that were made at the time of the actual on-site survey for the convenience of the evaluating ~~official~~ FDA/LPET or LEO.

NARRATIVE REPORT

The set of completed survey evaluation forms for the laboratory may accompany the narrative report, which states the conclusions of the ~~Federal~~ FDA/LPET or ~~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~~ shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA/NCIMS 2400 Series Forms. Each form used shall have the revision date noted in the report. Additional narrative reports, without FDA/NCIMS 2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory survey. The copy of the narrative report submitted by email to FDA/LPET ~~must~~ shall be accompanied by the ~~appropriate~~, completed FDA summary template, both attached to the same email. The ~~State~~ LEO ~~must~~ shall receive verification of receipt by return email and ~~must~~ shall maintain a copy of the verification in their records. The narrative report ~~must~~ shall identify the laboratory, give the laboratory number, show the date of the on-site survey, ~~who made~~ name of the LEO that conducted the survey, list the prior status, list the date of the last on-site survey, indicate the present status, what recommendations were made to correct any deviations, what test(s) were approved, and ~~who was certified to do them~~ necessary changes to the IMS List.

Formats suitable for narrative reports appear on pages ~~29—36~~ 33 - 46.

If choosing the option to send the narrative only via electronic submission, it ~~will~~ shall be necessary to summarize what each item is. Grouped under the title of each method observed (e.g., Standard Plate Count), list each major and/or minor deviation or omission numbered identically with the item number on the evaluation form and the corrective action necessary for compliance with standard procedures or good laboratory practices.

A paragraph headed "Remarks" or "Recommendations" may be included if the ~~officer~~ FDA/LPET or LEO wishes to comment on an item, e.g., one which could be improved by a

change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report.

After "Personnel and Procedures Certified" list the full name of all laboratory personnel qualified to make each individual test for which certification or approval is given. Include information on the analysts' last split sample performance. Also include a statement requiring participation in the Proficiency Testing Program to maintain certification (e.g., "To maintain certification, analysts ~~must~~ shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted").

Demonstrated proficiency or outstanding ability of individuals for one or more procedures which deserve special commendation may be given after the side heading "Commendations". If no commendation is warranted, delete this side heading from the narrative report. Such commendations should be used for outstanding performance.

Under "Conclusion" give a descriptive statement of the degree of acceptability or rejection of the procedures used by the laboratory, including recommendations for approval or rejection of the results of the laboratory. Some typical conclusions are given in the following text, and except in special circumstances, one of the conclusions listed ~~must~~ shall be used to indicate whether the results are (or are not) acceptable to ~~State authorities~~ Milk Laboratory Control Agency for use in rating milk for interstate shipment, where this is the purpose of the evaluation.

CONCLUSIONS

1. This laboratory is accredited/approved as the procedures, records, facilities and equipment in use at the time of the survey were in compliance with the requirements of the *Grade "A" PMO*.

Explanation: Unqualified acceptance of the laboratory.

2. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey were in substantial compliance with the requirements of the *Grade "A" PMO* the analyst/facility/equipment/records deviations noted must be corrected. This laboratory is accredited/approved for thirty (30) – sixty (60) days pending correction of the deviations and receipt of a letter by the ~~evaluation officer~~ FDA/LPET or LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval ~~will~~ shall be given.

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

3. Although the procedures, records, facilities and/or equipment in use at the time of the ~~evaluation~~ on-site survey did not substantially comply with the requirements of the *Grade "A" PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for () days pending correction of the deviations. Corrections ~~must~~ shall be made and detailed in writing to the ~~evaluation officer~~ FDA/LPET or LEO during this period. A new survey ~~will~~ shall be scheduled upon receipt of the letter to assure full compliance.

Explanation: A qualified acceptance where procedural or technical errors or facilities which could have an effect on analytical results are noted but which are readily correctable by the analysts or management. Depending on the judgment of the FDA/LPET or LEO, a period of no more than sixty (60) days usually is given to make the required adjustments before another survey is made or specified criteria are met, record, new equipment, etc. (some things may not require a return visit) to fully accredit (or approve) the laboratory/facility.

4. This laboratory is not accredited/approved as the procedures, records, facilities and/or equipment in use at the time of the survey did not comply with the requirements of the Grade "A" PMO".

Explanation: Severe deficiencies in facilities, records, staff and/or procedural techniques exist which would result in unacceptable results. A new on-site survey shall be made when the ~~Federal~~ FDA/LPET or State LEO has reason to believe that a rating would result in an acceptable rating. A new on-site survey would not be required for certified milk laboratories, CIS facility or screening facilities if the withdrawal was for facility deficiencies only. The laboratory, CIS facility or screening facility would be required to submit pictures, invoices, etc. to show compliance with the facility requirements noted in the last on-site ~~evaluation~~ survey.

FDA SUMMARY TEMPLATES

The narrative report sent to FDA/LPET ~~must~~ shall 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~~ shall be used. There ~~are two~~ is one (1) FDA summary templates: ~~one~~ for full service laboratories and ~~one for~~ Grade "A" PMO, Appendix N screening ~~Only~~ facilities (CISs and ISs). 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~~ shall also be used for the notification of changes in accreditation and certification status, and ~~must~~ shall be submitted by email to the FDA/LPET.

Directions for completing the FDA summary template, authored by FDA/LPET, ~~will~~ shall 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 ~~37-40~~ 47 - 48.

REFERENCES

1. Copies of the FDA/NCIMS 2400 Series Forms can be obtained from ~~Federal~~ FDA/LPET or State LEOs.

A list of ~~Federal~~ FDA/LPET or State LEOs can be found at the website:
~~<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm>~~

<http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2007965.htm>

Once at that website:

For FDA/LPET LEOs click on the link “FDA CFSAN Personnel” and scroll down to the Laboratory Proficiency and Evaluation Team.

For State LEOs click on the link “State Grade “A” Milk Regulatory, Rating and Laboratory Personnel” and then click on ~~your~~ the State. The table is organized by listing Regulatory personnel first, then Rating personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for ~~your~~ State’s LEOs.

For TPC LEOs, click on the link “International Certification Program Third Party Certifiers”. The table is organized by individual TPCs, listing Regulatory personnel first, then Rating Personnel, and finally Laboratory personnel. Scroll down to the laboratory section to find the contact information for TCP LEOs.

TABLE 1: SPLIT SAMPLE COMPOSITION

<u>PRODUCTS</u>	<u>NUMBER OF SAMPLES</u>	<u>DUPLICATES</u>	<u>ANALYSIS</u>	<u>NUMBER OF PRODUCT SAMPLES ANALYZED</u>
HVD, or 2%, or Skim	3	1	Plate Count /Coliforms	3
			Phosphatase	1
			Vitamins	3 <u>1-8</u>
Cream, heavy	2	1	Plate Count /Coliforms	2
			Phosphatase	2
			Vitamins	2 <u>1-8</u>
Cream, light	2 ^a	0 or 1	Plate Count /Coliforms	1
			Phosphatase	2 ^b
			Vitamins	1 <u>1-8</u>
Chocolate	2	1	Plate Count /Coliforms	2
			Phosphatase	1
			Vitamins	2 <u>1-8</u>
Raw	6	3	Plate Count	6
Raw	8	4	Inhibitors	8
			Somatic Cells	8
			Added Water ^c	8
Dairy Water	8	4	Coliforms	8
			Heterotrophic Plate Count	8
Milk Totals	23 ^a	10 or 11	Plate Count	14
			Coliforms	8
			Phosphatase	6
			Vitamins	8 <u>12-16</u>
			Inhibitors	8
			Somatic Cells	8
			Added Water ^c	8
Dairy Water Total	8	4	Coliforms	8
			Heterotrophic Plate Count	8

a - One of these samples serves as the temperature control (TC).

b - These two (2) samples are tested for both residual and reactivated phosphatase

c - This analysis is optional.

TABLE 2: STATISTICAL LIMITS

<u>TEST</u>	<u>REJECTION LIMIT 1</u> <u>(L₁)*</u>	<u>REJECTION LIMIT 2</u> <u>(L₂)*</u>
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins	0.300 **	0.200 **
Electronic Phosphatase Count	0.300	0.200
Dairy water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.

** Limits for vitamin test results shall be based on z-scores. Acceptable results shall be within plus or minus two (2) standard deviations.

TABLE 3: MAXIMUM NUMBER OF UNACCEPTABLE RESULTS

<u>NUMBER OF RESULTS PER TEST</u> <u>(N)</u>	<u>MAXIMUM NUMBER OF</u> <u>UNACCEPTABLE RESULTS PER</u> <u>TEST FOR APPROVAL</u>
5 – 10	1
11 – 20	2
21 – 30	3

EXAMPLE NARRATIVE REPORT #1

Report of a Biennial Evaluation of
{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # {SSXXX}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28

Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 5, 9C13, 9D3, 12, 16, 20 22, 24, 28

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

Changes to IMS List: Drop procedure 9C14, add procedure 16, New expiration date.

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

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

{Cite procedure title and revision date for each FDA/NCIMS 2400 Form used to conduct the survey followed by any applicable deviations, notes or relevant remarks/comments}

{Item} {First statement should be a concise descriptive representation of the observed issue with specific example(s) of occurrence(s) in one or two sentences} {Second statement should specifically describe what, how and/or when the lab is to remedy the issue} {The third statement should specifically describe what is to be submitted by the lab along with the written response (copies of new or revised records, service manifest, new purchase shipping manifest, certificate of authenticity, etc.) to the LEO as verification that appropriate corrective action was taken, when applicable}.

Cultural Procedures – General Requirements (rev. 2/10 mm/yy)

- 2e During the review of the autoclave records it was observed that there were several data points written over. Analysts are to use proper protocol for correcting mistakes: cross out the error with a single line, initial and write the correct information next to it. The date discovered/corrected should also be documented as a good laboratory practice. Lab is to send copies of the autoclave records from the time of the survey that demonstrates proper corrective action being taken.
- 3a Note: The graduations on the lower end of the NIST thermometer are so worn that it is difficult to read. If the graduations cannot be restored, it is suggested that a new thermometer be purchased. Optionally, the lab may use the new electronic/digital NIST traceable temperature measuring device (with access to certificate of accuracy and annual ice point check records) that is available for use in the rest of the laboratory.
- 3c3 Although the accuracy check was documented, no tag was found on the freezer thermometer. Tag the thermometer with the following information: identification or serial number (SN) / location, date of check, temperature checked and the correction factor. Send a copy of the new tag.
- 5b Over the past four months at least 50% of the days observed in the temperature monitoring records showed that the freezer was consistently greater than the acceptable temperature range with no corrective action documented. This is a serious violation and no reagents or controls may be kept in this freezer until it is proven that the freezer holds the temperature within the acceptable temperature range (<-15.0 °C). If this freezer cannot maintain the proper temperature, then a new freezer will need to be purchased. Send copies of the repaired or new freezer temperature monitoring records for the next 4 months from the date of the survey.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

13i There were no accuracy-checked thermometers for the spore incubation units used for the autoclave performance check. There must be a way to check the appropriate temperature range for the test. Lab must obtain/purchase thermometers dedicated for these units. Send a copy of the shipping manifest (if newly purchased), the accuracy check records and the temperature monitoring records for the following two months.

Petrifilm Aerobic and Coliform Counts (5 & 20, rev. 4/13 mm/yy)

No deviations were observed.

Comment: The analysts showed marked improvement over the last biennial on-site survey.

Pasteurized Milk Containers (22, rev. 1/13 mm/yy)

10b2 One analyst held the bottle against the container while adding the rinse solution. Use aseptic technique while adding the rinse solution to the container, and do not touch the bottle while pouring the rinse solution to the container.

Appendix N – General Requirements (rev. 2/10 mm/yy)

1-8 See Cultural Procedures, items 1-32 (as applicable).

9 See Cultural Procedures, item 33 (as applicable).

10a Note: Suitability on new purchased lot of test kits should be conducted in a timely manner that allows enough time to replace the new lot of test kits upon failure and prior to running out of previous lot in use.

12 The lab records showed that a new bulk milk tanker sample was collected without a documented explanation to perform confirmation testing of a presumptive positive load. A resample may only be collected at the discretion of the State regulatory agency and with appropriate justification and documentation.

14 See Cultural Procedures, item 34 (as applicable).

15 See Cultural Procedures, items 35 (as applicable).

Delvotest P 5 Pack (9D3, rev. 12/11 mm/yy)

No deviations were observed.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

Charm SL Beta-Lactam Test (IMS# 9C13 rev. 12/11 mm/vy)

4c1 Commingled raw milk was being collected from a raw milk silo for preparation of the Negative and subsequent Positive Controls without prior testing for the presence of drug residues. Silo milk must be shown to test negative using the test kit of use prior to preparing the controls for use or storage (previously tested negative). Send copy of records demonstrating that previously tested negative raw milk is used to prepare the Negative and Positive Controls.

Direct Microscopic Somatic Cell Count (12, rev. 2/10 mm/vy)

21e When preparing the milk smears, one analyst held the metal (positive displacement) syringe above the slide and dripped the milk sample test portion. Holding the syringe almost vertically and the syringe tip contacting the slide near the center of the delineated area for the milk smear gently depress the plunger to slowly expel the milk. Maintaining the plunger fully depressed, remove the tip from the milk and touch off to a dry spot.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 03/11 mm/vy)

No deviations were observed.

Dairy Waters using Multiple Tube Fermentation (MTF) Technique by Most Probable Number (MPN), Heterotrophic Plate Count (HPC) and Idexx Colilert-24 by Presence-Absence (24, rev. 1/09 mm/vy)

No deviations were observed.

Alkaline Phosphatase Test – Advanced Instruments Fluorophos (28, rev. 6/05 mm/vy)

15g2b The A/D value for substrate/buffer stability as part of the Daily Performance Check was missing on several days of official sample testing records reviewed during the survey period. 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 documented with both the old and new values recorded.

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									ON-SITE Last 2	SPLITS Last 2
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F			F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F			F	F	F	F	m/yy	m/yy
Analyst 5*	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified

P = Provisionally Certified

C = Conditionally Certified

N = Not Certified

* = Analyst excused – on medical leave.

To maintain certification, analysts shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted shall be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, full accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #2

Report of a Supplemental {used for interim accreditation of new analyst(s), new procedure(s), check surveys or walk-through} Evaluation of

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # {SSXXX}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 5, 9C13, 9C14, 9D3, 12, 20, 22, 24, 28

Prior Laboratory Status: Fully Accredited

Evaluated Procedure: 12 and 16

Participating Analysts: Analyst 3 and Analyst 4

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

Changes to IMS List: None.

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

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Cultural Procedures – General Requirements (rev. 2/10 mm/yy)

- 3 The thermometer used in the water bath dedicated for the Electronic Somatic Cell Count procedure was not labeled. Records for this thermometer's accuracy check were current. The thermometer label was replaced during the survey. No further corrective action is required.
- 20 See ESCC item 4a below.

Direct Microscopic Somatic Cell Count (12, rev. 2/10 mm/yy)

- 25i Monthly comparison counts were not being evaluated properly. When 3 or more analysts are participating, the RpSm method of evaluation must be used (see PAC item 17a1). Submit copies of the monthly comparison counts from the date of this on-site survey showing the use of the RpSm method of evaluation.

No technique deviations were observed.

Electronic Somatic Cell Count – Bentley 150 (16, rev. 03/11 mm/yy)

- 4a The water in the ESCC water bath was not circulating. Lab must repair or replace the circulating water pump before the water bath can be used to warm the ESCC samples immediately prior to analysis. Submit itemized service receipt or shipping manifest along with written response.

No technique deviations were observed.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES CERTIFIED:

Analyst	Procedures (IMS Codes)									ON-SITE Last 2	SPLITS Last 2
	5	9C13	9D3	12	16	20	22	24	28		
Analyst 1	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 2	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 3	F	F	F	C	C*	F	F	F	F	m/yy, m/yy	m/yy, m/yy
Analyst 4	F	F	F	C	C*	F	F	F	F	m/yy	m/yy
Analyst 5	F	F	F	F	F	F	F	F	F	m/yy, m/yy	m/yy, m/yy

F = Fully Certified

P = Provisionally Certified

C = Conditionally Certified

N = Not Certified

E = Analyst excused – on medical leave.

* Conditional certification status was granted at the end of the on-site survey because the comparison study was submitted on {Month Day, Year} and found to be satisfactory as of {Month Day, Year}, and are on file.

To maintain certification, analysts shall successfully participate in the Annual Proficiency Testing Program for all procedures for which certification has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*, the analyst/facility deviations noted shall be corrected. This laboratory is accredited, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, full accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #3

Report of a Supplemental Evaluation of
an Appendix N Bulk Milk Tanker ~~Screening~~ CIS Facility at
{Laboratory Name}

{Address of Physical Location}
{City, State & Zip Code}

IMS LAB # *{SS6xx}*

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO} Laboratory Evaluation Officer
State Department of *{Health or Agriculture}*
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: *{Month Day(s), Year}*

Prior Procedures (IMS Code): 9C14

Prior Laboratory Status: Fully Accredited

Evaluated Procedures: 9C15

Participating Analysts: Analyst 1 and Analyst 2

Present Laboratory Status: Fully Accredited, pending receipt of a satisfactory written response to the cited deviations on or before *{Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}*.

Changes to IMS List: Drop procedure 9C14 and add procedure 9C15.

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

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the *Grade "A" Pasteurized Milk Ordinance*. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms, laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 2/10 mm/yy)

1c During survey of analyst technique, the previously dedicated wall light was not used. The lighting measured 14-24 foot candles in the testing area, which was below the requirement of > 50 foot-candles at the working surface. The testing area had 83-105 foot candles when the wall light was utilized. Whenever testing is being conducted the wall light must be utilized.

3c3a The tags for those temperature measuring devices in the media preparation area did not include correction factors. These tags are to include the correction factor determine at the temperature of use. Send copies of the revised tags.

Charm 3 SL3 Beta-Lactam Test (9C15, rev. 11/12 mm/yy)

5b1 Two analysts shook samples 25 times, but always took greater than 7 sec. Analysts are to shake raw milk samples 25 times in 7 sec with 1 ft. movement.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES CERTIFIED:

<u>Analyst</u>	<u>Procedures (IMS Codes)</u>								<u>ON-SITE</u>	<u>SPLITS</u>
	<u>9C¹⁴</u>	<u>9C¹⁵</u>							<u>Last 2</u>	<u>Last 2</u>
<u>Analyst 1 CIS</u>	<u>N¹</u>	<u>C</u>							<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 2 CIS</u>	<u>N¹</u>	<u>C</u>							<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 3 IA</u>	<u>NA²</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 4 IA</u>	<u>NA²</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>

F = Fully Certified

FA = Fully Approved

P = Provisionally Certified

PA = Provisionally Approved

C = Conditionally Certified

CA = Conditionally Approved

N = Not Certified

NA = Not Approved

1 Laboratory accreditation, and as a consequence analyst certification has been removed due to voluntary withdraw during this on-site survey for the indicated procedure.

2 Approval status was removed due to analyst no longer employed.

To maintain approve status, analysts shall successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted shall be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, fully accreditation status shall be granted.

EXAMPLE NARRATIVE REPORT #4

Report of a Biennial Evaluation of
an Appendix N Bulk Milk Tanker Screening Only Facility at

{Laboratory Name}
{Address of Physical Location}
{City, State & Zip Code}
IMS LAB # {SS999-yyyy}

On

{Date of Survey (Month Day(s), Year)}

By

{Name of LEO}
Laboratory Evaluation Officer
State Department of {Health or Agriculture}
{Physical / Mailing Address}
{City, State & Zip Code}

Date of Last Evaluation: {Month Day(s), Year}

Prior Procedures (IMS Code): 9I1

Prior Laboratory Status: Fully Approved

Evaluated Procedures: 9I1

Present Laboratory Status: Fully Approved, pending receipt of a satisfactory written response to the cited deviations on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}.

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

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade "A" Pasteurized Milk Ordinance. If FDA/NCIMS 2400 Forms accompany the narrative report, deviated items are marked with an "X"; undetermined items because of local conditions at the time of the evaluation are marked "U"; on the accompanying evaluation forms. laboratory procedures and/or equipment not used are marked "O"; optional procedural techniques and/or equipment not applicable to designated laboratory procedures are marked "NA"; repeat deviations from the previous on-site survey are marked with an asterisk "*"; and supplementary information or suggested good laboratory practices not specifically listed in the FDA/NCIMS 2400 Forms or considered stand-alone deviations but are intended to improve laboratory function are designated by "Note" and do not require a written response.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 2/10 mm/yy)

1c Note: During the survey of analyst technique, the lighting in the immediate testing area measured 20-25 foot candles. Additional lighting should be added to the testing area, increasing the lighting to be >50 foot-candles. Whenever testing is being conducted the additional lighting should be utilized.

3 Digital thermometer placed in well of heat block fit loosely. Probe/sensor of digital/electronic temperature measuring device must have proper diameter to fit snugly into heat block or it must be placed in tube with water and placed in test well.

Idexx New Snap Beta-Lactam Test (9I1, rev. 7/12 mm/yy)

6c The sample and control tubes were not labeled during observation of the analysts' testing technique. All tubes and devices must be properly labeled for testing regardless of how many samples are being tested.

{Laboratory Name}

{City, State & Evaluation Date} Page # of 5

PERSONNEL & PROCEDURES APPROVED:

<u>Analyst</u>	<u>Procedures (IMS Codes)</u>								<u>ON-SITE</u>	<u>SPLITS</u>
	<u>9I</u>								<u>Last 2</u>	<u>Last 2</u>
<u>Analyst 1</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 2</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 3</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy, m/yy</u>
<u>Analyst 4</u>	<u>FA</u>								<u>m/yy, m/yy</u>	<u>m/yy,m/yy</u>

FA = Fully Approved

PA = Provisionally Approved

CA = Conditionally Approved

NA = Not Approved

To maintain approve status, analysts shall successfully participate in annual milk split sample performance evaluation provided by the Industry Supervisor or a State Laboratory Evaluation Officer for all procedures for which approval has been granted.

CONCLUSION:

Although the procedures, records and/or equipment in use at the time of the evaluation were in substantial compliance with the requirements of the Grade "A" Pasteurized Milk Ordinance, the analyst/facility deviations noted shall be corrected. This laboratory is approved, pending correction of the deviations and receipt of a letter detailing the corrections made. Upon receipt of a satisfactory written response and other appropriate documentation detailing the corrective actions taken on or before {Month Day(s), Year - specified date usually sixty (60) days from expected receipt of the narrative report}, fully approved status shall be granted.

FDA SUMMARY TEMPLATE

LEOReports Template v2013b.xlsm

LPET Summary Template v2013b
 [Subtitle]
[CAUTION: Do not fill with drop-downs, please do not use "Cut-N-Paste"]

REMINDER: Report Type not entered.

Report Type

Lab Type

IMS No.

Lab States

Send to FDA

Evaluation Date
 Month Year

Expiration Date
 Month Year

REMINDER: Report Type not entered.

LEO Initials

Lab Name

Address-1 / Postal Box #

Address-2

City / Town

Province **State** **ZIP / Postal Code**

REMINDER: Report Type not entered.

Country/Country Code

[Title]
 [Please fill in by row, L-R]

0

	1	2	3	4	5	6	7
Plate Count	<input type="text"/>						
Drug Residue	<input type="text"/>						
Drug Residue	<input type="text"/>						
Somatic Cell Count	<input type="text"/>						
PMO, Dairy Waterz, Alkaline Phosphatase, etc	<input type="text"/>						
IMS Order for Other1, Other2, Other3	<input type="text"/>						

[Click Below for Description of Procedures]

LPET Summary Template v2013b

Summary Procedures

Fig. 1: Summary sheet, FDA/LPET Summary Template v2013b.xls

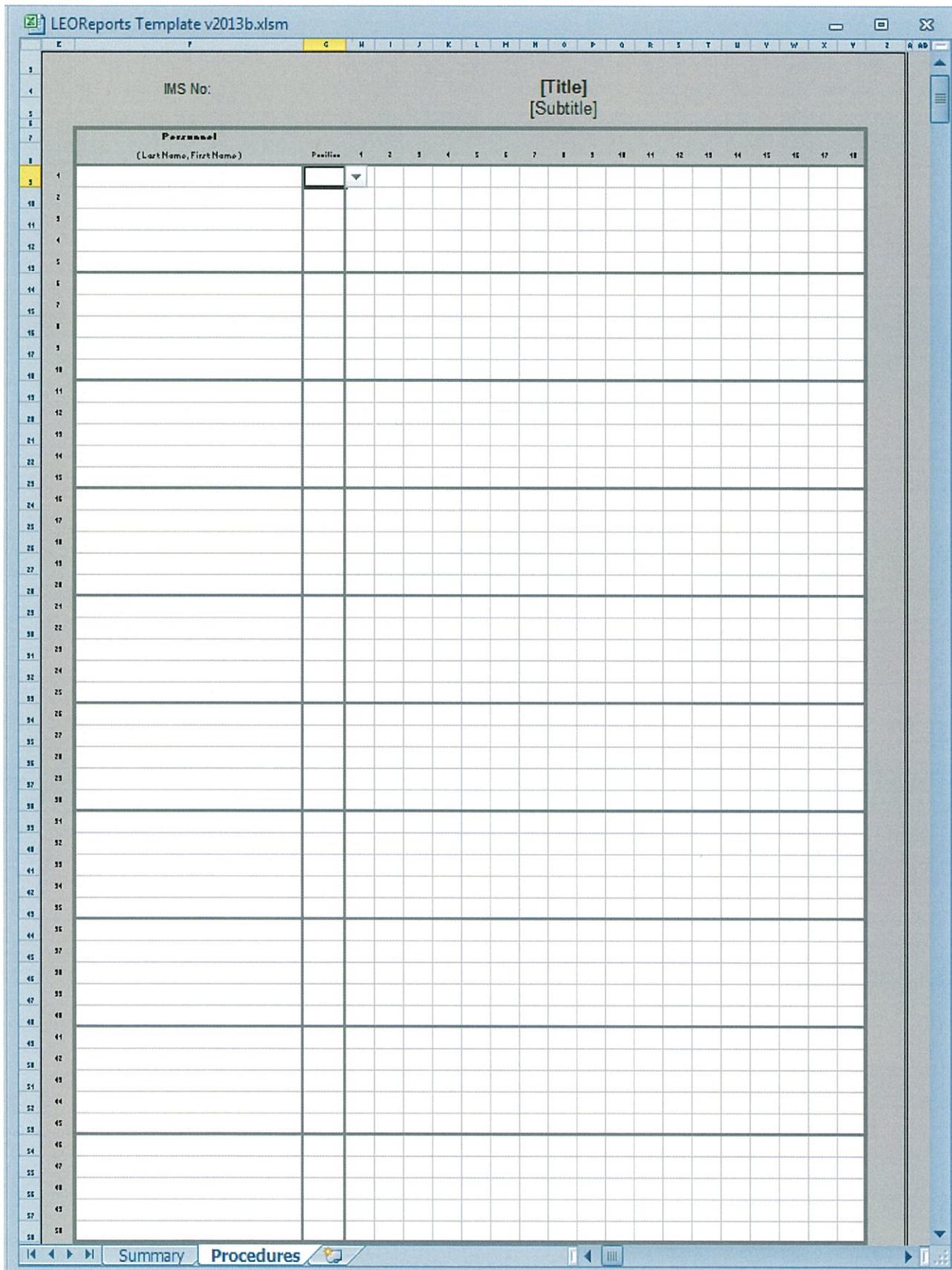


Fig. 2: Procedures sheet, FDA/LPET Summary Template

35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 232

Committee: Lab

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

A. Summary of Proposal

Update the Evaluation of Milk Laboratories (EML) (2011 Revision) document to allow FDA certified State LEOs to evaluate and conditionally certify new analysts at the state central milk laboratories.

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

Many state central milk laboratories experience critical testing capacity issues due to loss of FDA NCIMS certified analysts. The FDA document "[Evaluation of Milk Laboratories](#)" (EML) 2011 revision describes the analyst's certification process for state central milk laboratories to follow when analysts are added outside of the annual proficiency testing cycle. This document states that the "Federal LEO shall schedule a mutually agreeable date within 30 days of the request for an evaluation" to conditionally certify analysts. However, due to FDA resource limitations, conditional certification of state central milk laboratory analysts is often delayed to a degree which makes it difficult to meet essential program demands for laboratory testing support. The EML 2011 revision provides for conditional certification of state central milk analysts annually through the dairy proficiency testing program. Full certification occurs every three years during the triennial on-site assessment of state central milk laboratories.

A survey of state central milk laboratories was conducted by the Association of Public Health Laboratories (APHL). This survey was requested by APHL member laboratories with state central milk laboratories. Survey findings will be provided to FDA and the Laboratory committee meeting scheduled for Friday April 24th and Saturday April 25th at the National Conference on Interstate Milk Shippers 2015 conference.

C. Proposed Solution

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

- | | | |
|---------------------------------|-----------------|------------------------------|
| <u> </u> 2013 PMO | <u> X </u> | 2011 EML |
| <u> </u> 2013 MMSR | <u> </u> | 2400 Forms |
| <u> </u> 2013 Procedures | <u> </u> | 2013 Constitution and Bylaws |

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the federal or State LEO shall be based on the following criteria:

1. State central milk laboratories' evaluation 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 Federal LEO shall schedule a mutually agreeable date within 30 days of the request for evaluation. If the Federal LEO is unable to travel to the state central milk laboratory requesting the analyst evaluation in a reasonable timeframe a State LEO from that state may perform the evaluation and based on this evaluation grant conditional certification of the analyst. If the requesting state's LEO is directly affiliated with the laboratory (as determined by FDA/LPET) another State's LEO may be used for the evaluation and conditional certification of the analyst. Full certification of state central milk laboratories analyst(s) shall remain with the Federal LEO as described below.
2. Evaluation of milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site evaluation of new analysts(s) performance of techniques, new methods and/or new facilities to the State LEO. The State LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation.
3. The laboratory facilities, equipment and records shall meet the requirements stated on the FDA-2400 Series Forms and the PMO.
4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA-2400 Series Forms and the PMO.
5. Analysts meet the performance levels of proficiency testing program (SECTION 2). The State LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for with he or she is certified or approved.
6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give

statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2).

Analyst seeking certification or approval who are employed in laboratories not previously approved, or laboratories that have lost accreditation or approval and are seeking Recertification may be approved to conduct official examination only if criteria 3 and 4 are met. When such analysts successfully complete the next official proficiency tests administered by the State LEO, certificate of approval may be issued to such analysts. If such analyst does not successfully meet the performance levels of the proficiency testing program, the approval to conduct official examinations shall be withdrawn.

When a new analyst is assigned to an accredited laboratory between on-site evaluation condition approval status will be provided to the new analyst upon satisfactory completion of criteria 4 or : Full certification will follow after acceptable completion of both criteria 4 and 5. Conditionally approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site evaluation will have their conditionally approved status revoked.

The CIS and certified analysts must participate, at least annually, in proficiency testing (the examination of milk split samples) for those specific procedure for which they are certified. Failure without cause to participate in annual split sample evaluation or failure to meet established satisfactory performance criteria will result in the CIS or certified analyst(s) having their certification status downgraded from full to provisional. Failure of provisionally certified analysts or CIS to participate in the examination of or to meet the established satisfactory performance levels on the next set of split samples will result in withdrawal of certification.

A CIS or certified analyst that loses certification for one or more tests cannot examine official samples using a test for which certification was withdrawn. Recertification procedure are shown "SECTION 2: PROFICIENCY TESTING PROGRAM".

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 the certification shall be indicated on the appropriate completed FDA summary template and shall be submitted electronically.

Upon notice of evocation, the certificate, if issued shall be returned to the issuing State LEO within 90 days.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 233

Committee: Lab

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

A. Summary of Proposal

Add PeelPlate methods to the EML as techniques for evaluating aerobic bacteria and coliform counts.

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

PeelPlate-AC, aerobic count, PeelPlate-EC, total coliform count, and PeelPlate-EC-HVS, high volume coliform counts, are new methods that have been evaluated in dairy products following FDA/NCIMS protocol. A 2400 form is in preparation for these methods and these methods should be included into the appropriate performance sections of the EML.

C. Proposed Solution

Changes to be made on page(s): 10, 11 of the (X - one of the following):

- 2013 PMO 2011 EML
- 2013 MMSR 2400 Forms
- 2013 Procedures 2013 Constitution and Bylaws

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), PeelPlate-AC (PPAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count and Vitamin A and D3 result of each certified analyst shall fall within the limits shown in Table 2, page 28.

The steps for statistical analysis of split sample results are as follows:

1. A minimum of ten (10) results per sample per test is required for statistical analysis.
2. Calculate the logarithmic mean for the Standard Plate Count, Petrifilm Aerobic Count, Peel Plate-AC aerobic count, Plate Loop Count, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase

p. 11

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the “Grade ‘A’ PMO” shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the Standard Plate Count, Petrifilm Aerobic Count, PeelPlate-AC aerobic count, Plate Loop Count, BactoScan FC, Spiral Plate Count Method, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase Count and Vitamin A and D3 analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 234

Committee: Lab

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

A. Summary of Proposal

We propose that established, fully certified LEOs be allowed to be certified for a period of 5 years instead of the present 3 years. We also would like to change the on-site check evaluation to a mock survey situation that could be set up as part of the FD373 course.

Presently fully certified LEOs are required to participate in the FD373 course every 3 years but *only for the last 3 days* of the course and are required to demonstrate competence on a check laboratory survey also every 3 years.

What is being suggested is that fully certified LEOs be allowed to have a mock survey at the time of the FD373 course where specific deviations could be set up, each LEO would also be required to write a report to be submitted before the end of the course. This would allow for a controlled setting to evaluate all LEOs on a level playing field (e.g. all established LEOs should be seeing the same deviations and marking them in the same manner) and could also be a training tool for new or conditional LEOs at the same time.

Due to budget constraints, more and more often new LEOs are not being hired until the previous LEO has been gone for several months so there is no carryover of knowledge or training from someone who knows the job intimately. During this mock lab evaluation LPET could pair a new LEO with a fully certified LEO who has practical knowledge for hands-on training. The new LEO would not gain certification from this exercise but will be able to perform better at the time of their check evaluation.

We do want to stress this option would not be available for new LEOs or LEOs that are on provisional status. Only LEOs that are in good standing with LPET and that have met all their obligations for the past 5 years would be eligible for the mock survey evaluation certification. This also doesn't remove the requirement that LEOs attend an annual regional meeting so that LPET would still have opportunities to interact on a regular basis.

The EPA Laboratory program has employed a method similar to this for certification purposes successfully for many years.

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

Both State and FDA-LPET are restricted on their travel budgets. Travel funds are tight everywhere and this proposal would address some of those concerns while still allowing oversight without impacting public health.

C. Proposed Solution

Changes to be made on page(s): 16, 17 of the (X - one of the following):

- | | | |
|---------------------------------|-------------------|------------------------------|
| <u> </u> 2013 PMO | <u> </u> X | 2011 EML |
| <u> </u> 2013 MMSR | <u> </u> | 2400 Forms |
| <u> </u> 2013 Procedures | <u> </u> | 2013 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 “Laboratory Examination of Dairy Products” prior to or within the year of attending the Milk Laboratory Evaluation Officers Workshop.
4. During the FD373 course the mock laboratory evaluation will be used as training. Each new LEO candidate will accompany and observe an established LEO.

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

Recertification of the State LEO will occur ~~triennially~~ every 5 years, and will be based on satisfactorily meeting the following criteria:

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 ~~when accompanied by a representative of the FDA/LPET~~ on a check laboratory survey or at the mock laboratory evaluation during the FD373 course. The Federal LEO shall accompany the State LEO to not more than two laboratories/facilities during a check survey for recertification purposes. Optionally a certified State LEO may maintain their certification by participating satisfactorily in the FD373 course mock laboratory survey.
2. The individual must submit an acceptable written report of the milk laboratory check

survey 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 37 – 40). When the option of participating in the FD373 mock survey is used then all required reports must be submitted before the end of the course.

3. The individual must have all laboratory evaluations, proficiency test examinations, and reports current (in particular biennial surveys must be performed within the month of their anniversary date).
4. The individual must have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the state milk sanitation rating agency and the FDA/LPET.
5. The individual has met the responsibilities for the training of Industry Supervisors.
6. The individual must attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.
7. The individual must not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then State LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year the State LEO may opt to attend that seminar in lieu of attending the seminar held in their region and still meet the requirement.
8. If an LEO is not in good standing, has not met the standards in items 3 through 7 listed above, the FD373 mock laboratory evaluation option is not available for their continuing certification.

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 235
Committee: Lab - 2400

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

A. Summary of Proposal

Omit the requirement for DMSCC certification as a co-requisite for ESCC certification in laboratories that purchase certified somatic cell standards for instrument calibration and verification.

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

As volumes increase throughout the dairy industry, the majority of somatic cell testing is performed electronically. ESCC certification requires that analysts also be certified in DMSCC. This requirement is now out dated as laboratories are purchasing certified standards for calibration and verification of their instruments. Requiring DMSCC as a co-requisite is no longer necessary. This proposal eliminates the DMSCC requirement for analysts being certified in ESCC methods for laboratories purchasing certified somatic cell standards.

C. Proposed Solution

Changes to be made on page(s): ESC 2400 Forms of the (X - one of the following):

- | | |
|---------------------------------|--|
| <u> </u> 2013 PMO | <u> </u> 2011 EML |
| <u> </u> 2013 MMSR | <u> X </u> 2400 Forms |
| <u> </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

2. Comparative Test with DMSCC (co-requisite for certification, unless certified somatic cell standards are being purchased)

- a. Analyst(s) certified for DMSCC
- b. Each analyst seeking certification for the ESCC test shall perform the comparative test
 - 1. Test 4 samples (100K-200K, 300K-500K, 600K-800K and 900K-1.2M) in triplicate for both DMSCC (three separate smears each) and ESCC
 - 2. Results must be evaluated by State/Federal LEO and shown to be acceptable prior to official use of test in laboratory
 - 3. Copy of comparison and results in QC record (or easily accessible on file in the laboratory); kept for as long as analyst is certified

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 236
Committee: Lab - 2400

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

A. Summary of Proposal

Increase the required autoclave temperature for media sterilization by moist heat by 1°C from 120±1°C to 121±1°C.

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

The 2400 form for Cultural Procedures – General Requirements states that autoclave temperature for media is required to be 120±1°C for 15 minutes although section 27 also states that media should be prepared following manufacturer’s instructions unless otherwise stated. The Pasteurized Milk Ordinance states to follow Standard Methods for the Examination of Dairy Products (SMEDP). SMEDP, AOAC Official Methods, and numerous BD media source instructions (Standard Methods Agar, BGGBB, LST, etc.) suggest autoclaving at a temperature of 121±1°C.

This modification allows laboratories to follow manufacturer’s instructions for preparation of media without deviation.

C. Proposed Solution

Changes to be made on page(s): 8 of Cultural Proc – Gen Req _____ of the (X - one of the following):

_____ 2013 PMO _____ 2011 EML
_____ 2013 MMSR X _____ 2400 Forms

14. Sterilization by Moist Heat

- a. Autoclave media at $120\pm 1^{\circ}\text{C}$ $121\pm 1^{\circ}\text{C}$
 1. Dilution buffer blanks for 15 min (30 min optional)
 2. Media for 15 min (sugar broths as per manufacturer instructions)
- b. Autoclave media within 1 hour of preparation
- c. Autoclave dilution buffer on same day prepared
- d. Loosen stoppers or caps slightly to permit passage of steam and air
- e. All air expelled from autoclave before pressure allowed to rise
- f. Autoclave will reach $120\pm 1^{\circ}\text{C}$ $121\pm 1^{\circ}\text{C}$ within 15 min (5 min pref) of starting air-exhaust

Name: Caly Zmijewski

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 237
Committee: Lab - 2400

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

A. Summary of Proposal

Update 2400 Pasteurized Milk Containers, Closures and Packaging with new bacterial methods.

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

Bacterial methods approved for use in the PMO need to also be demonstrated to meet the sanitary container testing requirements of Appendix J. New bacterial methods, PeelPlate-AC aerobic count and PeelPlate-EC-HVS high sensitivity coliform count, were evaluated using nutrient broth rinse of gallon containers. The methods were found equivalent to other approved NCIMS methods in the study below. The acceptable method should be included into the 2400 form so that it is an option for testing dairy containers.

Aerobic Count and Coliform/E. coli Method Comparison in pasteurized milk closed cap containers

Purpose:
The goal of this study is to compare the Charm PeelPlate™-EC-HVS (total coliform) and PeelPlate-AC (aerobic count) methods to the NCIMS/FDA reference methods Violet Red Bile Agar (VRB) pour plate for coliform and Standard Plate Count (SPC) pour plate for aerobic count, and the NCIMS/FDA alternative method 3M Petrifilm™ Coliform and Aerobic Count Plate for the enumeration of total coliform and aerobic bacteria in pasteurized milk closed cap containers.

Materials and Methods:
Thirty (30) new one gallon milk were tested in accordance with NCIMS/ FDA form 2400i

Pasteurized Milk Containers using the rinse method. The containers were divided into six (6) groups of five (5) containers each. All groups had 100 ml of nutrient broth added to each container and were closed in a sanitary manner. One of the groups was nested as supplied from the container manufacture, each of the five (5) other groups were inoculated with *P. aeruginosa* and either *K. pneumonia* and/or *E. coli* at various levels. After agitation, each container was plated for both aerobic count and total coliform on each of the three (3) test systems (Charm Peel Plate, 3M Petrifilm and pour plate). Plates and films were then incubated at 32±2° C for 24±2 hours for coliform and 48±3 hours for aerobic plate count. Ten percent (10%) of the colonies on each VRB plate was then confirmed using Brilliant Green Bile Broth 2%.

Results:

Milk Regulatory Consultants performed the experimental design and work. Log mean values were calculated for each spike level.

Aerobic Count: Paired analysis¹ between Peel Plate-AC and SPC was performed for each lab at each spike level and log mean difference, standard deviations and upper and lower confidence levels (UCL and LCL) are reported in Table 1. For comparison purposes the alternative reference method compared to the reference method is reported in Table 2. The mean log values are shown graphically for each method in Figure 1.

Table 1: Aerobic count of 5 inoculated levels of bacteria into closed cap containers as determined by PeelPlate-AC and Standard Plate Count(SPC)

Cont. level	Peel Plate AC Method			SPC Method			Mean diff. ^d	95% CI ^e		r ^{2h}
	Mean ^a	s _r ^b	RSD _r ^c	Mean	s _r	RSD _r		LCL ^f	UCL ^g	
1	1.48	0.068	4.6	1.35	0.11	8.3	0.13	-0.232	-0.0347	0.907
2	1.73	0.054	3.1	1.73	0.065	3.7	0.002	-0.0657	0.0608	
3	1.82	0.039	2.2	1.79	0.055	3.1	0.027	-0.0698	0.0146	
4	1.89	0.042	2.2	1.95	0.077	4.0	-0.061	0.0139	0.1071	
5	1.95	0.069	3.5	2.01	0.035	1.7	-0.049	-0.0126	0.1095	

^aMean of 5 replicate portions, plated in duplicate, after logarithmic transformation: Log₁₀[CFU/g + (0.1)f].

^bRepeatability standard deviation.

^cRelative standard deviation for repeatability.

^dMean difference between the candidate and reference methods.

^eConfidence interval.

^f95% Lower confidence limit for difference of means.

^g95% Upper confidence limit for difference of means.

^hSquare of correlation coefficient.

Table 2: Aerobic count of 5 inoculated levels of bacteria into closed cap containers as determined by 3M-PAC and Standard Plate Count(SPC)

Cont. level	3M PAC Method			SPC Method			Mean diff. ^d	95% CI ^e		r ^{2h}
	Mean ^a	s _r ^b	RSD _r ^c	Mean	s _r	RSD _r		LCL ^f	UCL ^g	
1	1.46	0.119	8	1.35	0.111	8	0.112	-0.249	0.025	0.932
2	1.84	0.039	2.1	1.73	0.065	3.7	0.108	-0.160	-0.057	
3	1.92	0.044	2.3	1.79	0.055	3.1	0.133	-0.177	-0.089	
4	2.03	0.058	2.9	1.95	0.077	4.0	0.084	-0.142	-0.027	
5	2.09	0.065	3.1	2.01	0.035	1.7	0.090	-0.124	-0.057	

Coliform Count: Paired analysis¹ between Peel Plate-EC-HVS and VRB was performed for each lab at each spike level and log mean difference, standard deviations and upper and lower confidence levels (UCL and LCL) are reported in Table 3. For comparison purposes the alternative reference method compared to the reference method is reported in Table 4. The mean log values are shown graphically for each method in Figure 2.

Table 3: Coliform count of 5 inoculated levels of bacteria into closed cap containers as determined by PeelPlate-EC-HVS and VRBA agar

Cont. level	Peel Plate EC-HVS Method			VRB Method			Mean diff. ^d	95% CI ^e		r ^{2h}
	Mean ^a	s _r ^b	RSD _r ^c	Mean	s _r	RSD _r		LCL ^f	UCL ^g	
1	0.81	0.156	19.3	0.546	0.29	52.6	0.263	-0.473	-0.054	0.9598
2	1.64	0.063	3.9	1.500	0.32	21.3	0.140	-0.386	0.105	
3	1.53	0.078	5.1	1.524	0.09	6.0	0.001	-0.074	0.072	
4	1.79	0.050	2.8	1.769	0.08	4.4	0.025	-0.088	0.038	
5	1.91	0.049	2.5	1.931	0.04	2.1	-0.019	-0.035	0.074	

Table 4: Coliform count of 5 inoculated levels of bacteria into closed cap containers as determined by 3M Coliform and VRBA agar

Cont. level	3M Coliform Method			VRB Method			Mean diff. ^d	95% CI ^e		r ^{2h}
	Mean ^a	s _r ^b	RSD _r ^c	Mean	s _r	RSD _r		LCL ^f	UCL ^g	
1	0.71	0.223	32	0.55	0.287	53	0.160	-0.433	0.113	0.848 2
2	1.68	0.066	3.9	1.50	0.319	21.3	0.183	-0.442	0.076	
3	1.60	0.044	2.8	1.52	0.091	6.0	0.076	-0.146	-0.006	
4	1.88	0.080	4.3	1.77	0.078	4.4	0.111	-0.214	-0.009	
5	1.98	0.047	2.4	1.93	0.041	2.1	0.049	-0.099	0.002	

Discussion:

The Peel Plate-AC analysis presented in Table 1 indicate that mean log differences at all concentrations are within 0.2 log, well within the AOAC definition of significance, confidence values < +/-0.5log. Standard deviations of log means of PP-AC are consistent with the standard deviations of SPC. In comparison the alternative reference method also consistently met these specifications in all five concentrations.

The Peel Plate-EC-HVS analysis presented in Table 3 indicate that mean log differences at all concentrations are within 0.2 log well within the AOAC definition of significance, confidence

values $< \pm 0.5 \log$. Standard deviations of log means of PP-EC-HVS are consistent with the standard deviations of VRB. In comparison the alternative reference method also consistently met these specifications in all five concentrations.

Figure 1 is a graph of log means of all laboratory data comparing the log means of PeelPlate-AC (\square) and 3M-PAC (\circ) to SPC. Linear regression analysis of the data show Peel Plate had a $R^2=0.91$ and 3M-PAC of $R^2=0.93$ indicating equivalent laboratory reproducibility with the PeelPlate-AC method in comparison to the alternative reference method. In addition the slope and y intercept of the PeelPlate-AC regression are consistent with the reference methods.

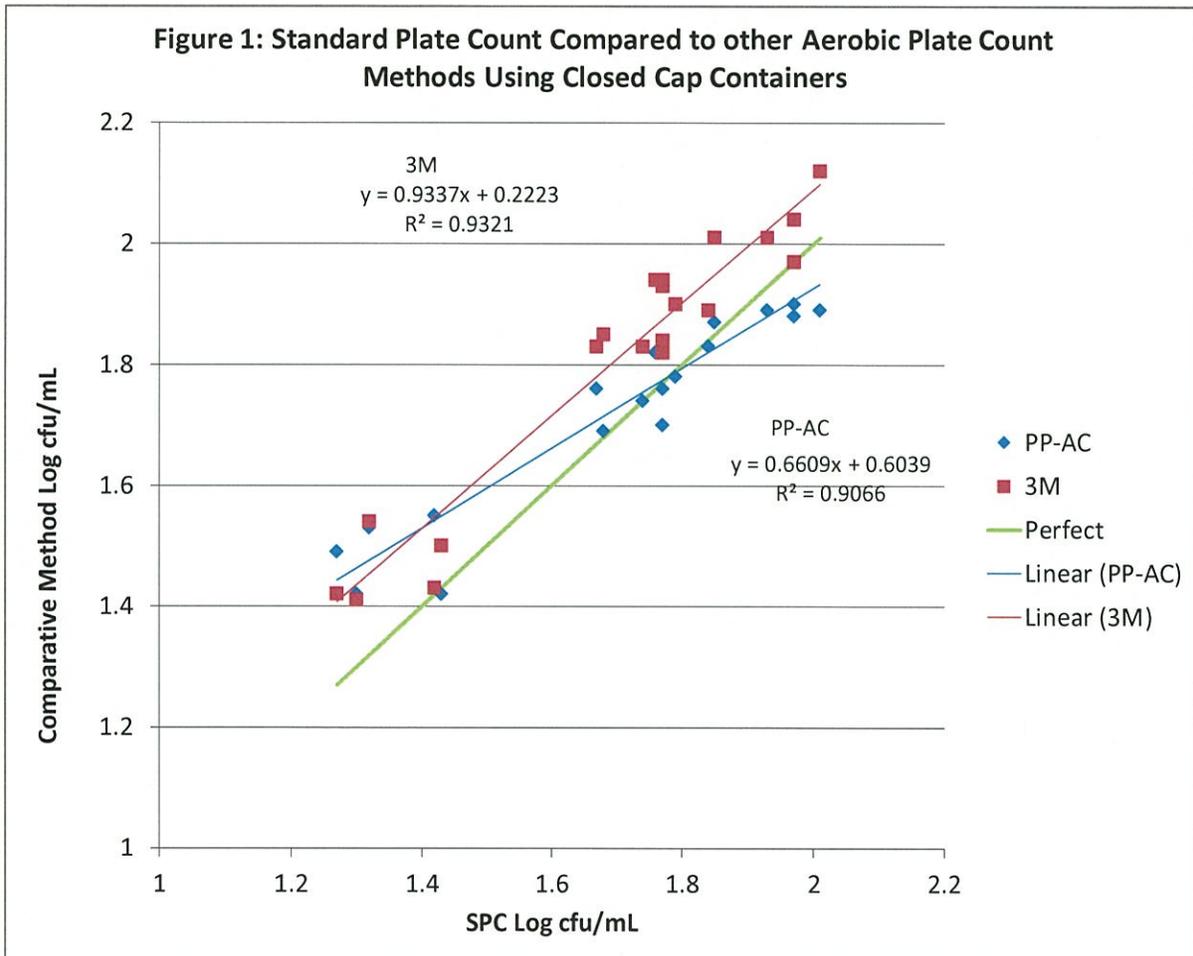


Figure 2 is a graph of log means of all laboratory data comparing the log means of PeelPlate-EC-HVS (\square) and 3M-PCC (\circ) to VRB. Linear regression analysis of the data show Peel Plate had a $R^2=0.96$ and 3M-PCC of $R^2=0.85$ indicating equivalent or better laboratory reproducibility with the Peel Plate method in comparison to the alternative reference method. In addition the slope and y intercept of the PeelPlate-EC regression are consistent with the reference methods.

C. Proposed Solution

Changes to be made on page(s): In Pasteurized milk
containers 2400 form of the (X - one of the following):

- | | |
|-----------------------------------|--|
| <u> </u> 2013 PMO | <u> </u> 2011 EML |
| <u> </u> 2013 MMSR | <u> X </u> 2400 Forms |
| <u> </u> 2013 Procedures | <u> </u> 2013 Constitution and Bylaws |

PASTEURIZED MILK CONTAINERS, CLOSURES, AND PACKAGING [Unless otherwise stated all tolerances are $\pm 5\%$] **IMS #22**

1. Laboratory Requirements

- a. Record time and date when samples received
- b. Record time and date when samples examined

RINSE METHOD APPARATUS

2. See Cultural Procedures (CP) items 1-23

3. To Add Rinse Solution to Containers

- a. Sterile hypodermic syringes (capacity 20 or 100 mL) and needles
- b. Or, sterile pipets
- c. Or, sterile automatic syringe
- d. Or, sterile graduated cylinder
- e. Or, pre-dispensed dilution bottles or tubes with rinse solution (see CP item 29.f); volumes checked

MATERIALS

4. See CP items 24-32

5. Rinse Solutions

- a. Buffered Rinse Solution or Nutrient broth (see CP items 27.i-j) for Standard Plate Count (SPC) and Coliform Plate Count (CPC) agar based media

- b. Nutrient broth (see CP item 27.j) for 3M™ Petrifilm™ Aerobic Count (PAC), Coliform Count (PCC) and High Sensitivity Coliform Count (HSCC) plates, [Charm™ PeelPlate™ Aerobic Count \(PP-AC\)](#), [PeelPlate Coliform Count \(PP-EC\)](#) and [PeelPlate High Sensitivity Coliform Count \(PP-EC-HVS\)](#)

6. Ethyl Alcohol, 70%

7. Plastic Tape

PROCEDURE

8. Identify Plates (SPC item 5 or Petrifilm item 6 [or PeelPlate item 5](#))

9. Controls (See SPC item 6 or Petrifilm item 7 [or PeelPlate item 6](#)), in addition; _____

- a. Transfer 1 mL of rinse solution to SPC or PAC [or PP-AC](#) plate for sterility control

10. Rinse Solution Volumes for Collection of Surface Rinse Samples

- a. 100 mL (+/- 2mL) for gallons (3784 mL) or larger
- b. 50 mL (+/- 1mL) for ½ gallons (1892 mL)
- c. 20 mL (+/- 0.4mL) for 100 mL to ½ pints (236 mL), pints (473 mL), and quarts (946 mL)
- d. For containers <100 mL and closures use swab method, see items 18-32
- e. Irregular shaped containers of <100 mL, use rinse method in item 10.c. Equally distribute the 20 mL among multiple units with the amount per unit no more than 20% of the volume

11. Collection of Surface Rinse Samples

- a. Firm walled paper containers, sealed on line
 - 1. Swab top of containers with 70% alcohol at the site of injection
 - 2. Add required amount of rinse solution to each container by injection and seal puncture with plastic tape
 - 3. Vigorously shake container length-wise on flat sides (or quadrants of round containers) 10 times, holding container horizontally

4. Each shake a complete back and forth movement of approximately 20 cm
 5. Turn container 90° and repeat horizontal shaking treatment
 6. Turn container 90° twice more and repeat horizontal shaking
 7. Grasp container and swirl 20 times in a small flat circle while upright (top up)
 8. Invert (top down) and repeat swirling of container 20 times
 9. Stand upright and allow to drain for 1-3 min
- b. Plastic capped containers (submitted with caps)
1. Swab top of container with 70% alcohol when appropriate
 2. Add required amount of rinse solution by aseptically removing cap, pouring in solution without touching the top and replace cap
 3. Complete rinse procedure as described in 11.a.3-9 above
- c. Flexible-walled containers/bags
1. Add 100 mL aseptically by swabbing an area of tube adjacent to liner with 70% alcohol; introduce rinse by syringe and seal puncture with plastic tape
 2. Place container/bag on smooth, clean, firm horizontal surface as flat
as its construction permits
 3. With hands or roller, move rinse solution back and forth 10 times, contacting all surfaces completely
 4. Lift liner and hang with “fill tube” down to permit rinse solution to collect for 1-3 min
 5. Transfer rinse solution to sterile container by cutting “fill tube” with sterile scissors
- d. Irregular shaped containers of <100 mL
1. Swab top of container with 70% alcohol when appropriate e.g. at injection site
 2. Aseptically add required amount of rinse solution to each container,

seal with cap or appropriate sterile closure

3. Complete rinse procedure as described in 11.a.3-9 above
4. Transfer rinse solutions of the multiple containers in sequence by aseptically removing cap or sterile closure, pouring solution into a

12. Sample Measurements

- a. As described in SPC items 9 & 10 or Petrifilm items 10 & 11, [or PeelPlate items 9 & 10](#) except:
 1. For Residual Bacterial Count (RBC), pipet 2 mL portion in a single SPC plate or pipet two 1 mL portions on 2 PAC [or PP-AC](#) plates
 2. For Residual Coliform Count (RCC), pipet 10 mL of remaining rinse solution among 3 CPC plates, or pipet ten 1 mL portions of remaining rinse solution on 10 PCC [or PP-EC](#) plates or two 5 mL portions on 2 HSCC [or PP-EC-HVS](#) plates

13. Pouring Agar (See SPC item 13)

14. Incubating Plates (See SPC item 14 or Petrifilm item 13 [or PeelPlate item 12](#)) _____

15. Confirmation Test for CPC (See SPC item 17.c)

16. Counting and Recording Colonies (See SPC items 15-17 or Petrifilm items 14-16 [or PeelPlate items 13-15](#))

- a. Count obtained from RBC plate(s) recorded as colonies counted
- b. If no colonies on RBC plate(s), record as 0
- c. Count obtained from RCC plates recorded as colonies counted
- d. If no colonies on RCC plates, record as 0
- e. Values are recorded as number of colonies per container

REPORTS

17. Reporting Counts

- a. Report computed bacterial count as RBC/container
 1. Containers rinsed with 20 mL

- a. 2 mL plated for RBC, multiply colony count by 10
- 2. Containers rinsed with 50 mL
 - a. 2 mL plated for RBC, multiply colony count by 25
- 3. Containers rinsed with 100 mL
 - a. 2 mL plated for RBC, multiply colony count by 50
- b. Report computed coliform count as RCC/container
 - 1. Containers rinsed with 20 mL
 - a. 10 mL plated for RCC, multiply colony count by 2
 - 2. Containers rinsed with 50 mL
 - a. 10 mL plated for RCC, multiply colony count by 5
 - 3. Containers rinsed with 100 mL
 - a. 10 mL plated for RCC, multiply colony count by 10
- c. If no colonies appear on plate(s), report as less than n/container, substituting for n the number that would be reported if 1 colony had been counted from the volume of rinse solution plated and multiplied by appropriate factor

SWAB METHOD

APPARATUS

18. See CP items 1-23

19. Screw-capped Containers

- a. 7 to 10 cm long to contain:
 - 1. 5 mL rinse solution for non-soluble swabs (see item 5)
 - 2. 4.5 mL rinse solution for alginate swabs (see item 5, SPC & CPC only)
- b. Sterile

20. Swabs

- a. Cotton, non-absorbent (firmly twisted to about 5 mm diameter by 2 cm long over one end of applicator stick 12-15 cm long)

- b. Or, calcium alginate fibers (SPC & CPC only)
- c. Or, polyester or rayon fibers
- d. Commercial source, sterile, non-toxic in protected containers
 - 1. Supporting documentation from manufacturer
 - 2. Maintain records

MATERIALS

- 21. See Items 4 & 5
- 22. Sodium Hexa-metaphosphate Solution, 10% (if calcium alginate swabs used, SPC & CPC only), sterile
- 23. Shaking Machine, optional (See SPC item 8.c or PAC item 9.c)

PROCEDURE

- 24. Identify Plates (See SPC item 5 or Petrifilm item 6 [or PeelPlate item 5](#))
- 25. Controls (See SPC item 6 or Petrifilm item 7 [or PeelPlate item 6](#)), in addition; _____
 - a. Pipet 1 mL of rinse solution to SPC or PAC [or PP-AC](#) plate for sterility control _____
 - b. For calcium alginate swab, break off swab head in container with 4.5 mL rinse solution plus 0.5 mL Na Hexa-metaphosphate solution and continue as described in 27.a.1, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle
 - c. For all other fibers, break off swab head in container with 5 mL rinse solution and continue as described in item 27.a.2 & 27.b, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle
- 26. **Collection of Swab Samples from Product Contact Surfaces**
 - a. 250 sq. cm of product contact surface must be swabbed or five 50 sq. cm for a total of 250 sq. cm (calculate or use template – must be sterile if swab will be in contact with template)
 - b. Aseptically remove sterile swab from container

- c. Open vial of solution, wet swab and press out excess solution
- d. Holding swab at 30° angle to surface, rub over 50 sq. cm area three times, reversing direction between successive strokes
 - 1. For snap or screw cap closures, calculate number of closures required for product contact surface area of 50 sq. cm
 - 2. For cup shaped containers, determine 50 sq. cm for the product contact surface
- e. Rinse swab in solution and press out excess
- f. Swab four additional 50 sq. cm areas
- g. After fifth area has been swabbed, position swab head in vial and break stick, leaving swab head in vial

27. Sample Measurement

- a. As described in SPC items 9 & 10;
 - 1. For calcium alginate, add 0.5 mL of sterile Na Hexa-metaphosphate solution (see item 22) to 4.5 mL rinse solution in vial and shake until
 - 2. For all other fibers:
 - a. Shake swab container 50 times
 - b. Each shake a complete back and forth movement of approximately 15 cm
 - c. Strike palm of hand at end of each cycle
 - d. Complete shaking in approximately 10 sec
- b. As described in Petrifilm items 10 & 11 [or PeelPlate items 9 & 10](#);
 - 1. Shake swab container 50 times
 - 2. Each shake a complete back and forth movement of approximately 15 cm
 - 3. Strike palm of hand at end of each cycle
 - 4. Complete shaking in approximately 10 sec

- c. For RBC, pipet 1 mL portion to a single SPC or PAC [or PP-AC](#) plate
- d. For RCC, pipet 3 mL to a single CPC plate or three 1 mL portions on three PCC [or PP-EC](#) plates

28. Pouring Agar (See SPC item 13)

29. Incubation (See SPC item 14 or Petrifilm item 13 [or PeelPlate item 12](#))

30. Confirmation for CPC test (See SPC item 17.c)

**31. Counting and Recording Colonies
(See SPC items 15-17 or Petrifilm items 14-16 [or PeelPlate item 13-15](#))**

- a. Count obtained from RBC plates, record as colonies counted
- b. If no colonies on RBC plates, record as 0
- c. Count obtained from RCC plate(s) record as colonies counted
- d. If no colonies on RCC plate(s), record as 0

REPORTS

32. Reporting Counts

- a. Report the count in 31.a as the RBC/50 sq. cm
- b. If no colonies on RBC plate, report as < 1/50 sq. cm
- c. Report the count in 31.c as the RCC
- d. If no colonies on RCC plate(s), report as < 1

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 238
Committee: Lab - 2400

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

A. Summary of Proposal

Update 2400 Cultural Procedures-General Requirements with information about new approved simplified methods for bacteria testing.

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

When new bacterial methods are approved for NCIMS testing, the 2400 Form Cultural Procedures-General Requirements needs updating with lot, expiration and storage information. PeelPlate information has been submitted for approval in 2015 conference and this proposal makes necessary information changes to the general requirements form.

C. Proposed Solution

Changes to be made on page(s): 11, 17 and 18 of Cultural Procedures-GR of the (X - one of the following):

- | | |
|--|---|
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML |
| <input type="checkbox"/> 2013 MMSR | <input checked="" type="checkbox"/> 2400 Forms |
| <input type="checkbox"/> 2013 Procedures | <input type="checkbox"/> 2013 Constitution and Bylaws |

- a. Type: _____
- b. System used: _____
- c. Monthly testing criteria
 - 1. Standard plate count or Petrifilm Aerobic Count or PeelPlate Aerobic Count < 1,000 colonies/mL (< 10,000 colonies/mL if stored)

p. 17

27. Media

[Follow manufacturer's instructions unless otherwise stated]

- s. PeelPlate Aerobic Count (PPAC) Plate
 - 1. Lot #: _____ Exp. Date: _____
- t. PeelPlate Coliform Count (PPEC) Plate
 - 1. Lot #: _____ Exp. Date: _____
- u. PeelPlate Coliform Count High Volume (PPEC-HVS) Plate
 - 1. Lot #: _____ Exp. Date: _____

p. 18

29. Prepared Media Storage

- h. PeelPlate storage
 - 1. Refrigerate unopened packages of PeelPlate plates at or below 8°C; if frozen allow 30 min room temperature thaw time before opening packages
 - 2. Use before expiration date on package
 - 3. After opening, return unused plates to the foil pouch with desiccant indicator, Zip-seal open end shut
 - 4. Store opened (re-sealed) packages refrigerated at or below 8°C
 - 5. Check desiccant indicator of PeelPlate plates before use. Do not use if desiccant has turned white or pink. Do not use if plates are discolored, pink, yellow or brown. Use within product expiration date

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 239
Committee: Lab - 2400

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

A. Summary of Proposal

Approve a 2400 form for the new bacterial methods, PeelPlate-AC for aerobic bacterial count and PeelPlate-EC and PeelPlate-EC-HVS coliform count, for milk products. Update M-a-98-10 Table 3 with the new methods and the validated matrices.

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

New bacterial methods for aerobic bacterial count, PeelPlate-AC, and coliform count, PeelPlate-EC, and PeelPlate-EC-HVS, have been evaluated in raw and pasteurized milk and milk products. Collaborative study data summarized below were performed in pasteurized whole, skim and chocolate milk and cream. Data have been provided to FDA-LPET and the NCIMS Laboratory Committee. The data demonstrate comparable results to pour plate and film methods already NCIMS approved. A 2400 form needs to be approved for the methods use in Grade A dairy products. Additionally M-a-98-10 Table 3 needs to be updated to include the new tests and the matrices that that may be tested to comply with bacterial standards referenced in PMO.

Summary of collaborative laboratory results using aerobic and total coliform methods to test pasteurized dairy products.

Purpose: These studies compared new bacterial test methods for aerobic and total coliform to reference methods using pasteurized whole milk, skim milk, chocolate milk and cream

products.

Methods: Each study comprised 30 samples, 5 blank and 5 each of 5 different bacterial fortifications, prepared by Q-Laboratory, Cincinnati, OH. Samples were tested and sent to 4 additional testing laboratories to be tested in duplicate. There were 60 results per lab and 300 results per study. Four aerobic count studies, one for each study matrix, were performed comparing a new aerobic count method, PeelPlate-AC Aerobic Count (PP-AC), to the reference method Standard Plate Count Agar (SPC) and the alternative reference method AOAC 986.33 (3M-PAC, Petrifilm Aerobic Count). Three coliform count studies, one for each study matrix, were performed comparing the new coliform count method, PeelPlate-EC Coliform Count (PP-EC) to the reference method Violet Red Bile Agar (VRBA) and the alternative reference method AOAC 989.10 (3M-PCC, Petrifilm Coliform Count). One coliform study was performed using high sensitivity coliform tests for cream, PeelPlate-EC-HVS compared to AOAC 996.02 (3M high sensitivity coliform) and VRBA.

Data were collected and shared with FDA-LPET and the NCIMS laboratory committee.

Results: Each matrix concentration with 10 tests results by each method was analyzed in a sample-pair t-test. Log mean differences and their upper and lower 95% confidence intervals were determined. When those confidence intervals were less than 0.5 log different from reference methods the results were considered not-significantly different from reference method. Each study generated 25 calculations per method comparison (5 fortified levels at 5 laboratories) with the exception of two aerobic studies where one laboratory was not able to test the samples where only 20 calculations were performed. Log mean values are plotted versus reference method in Figures 1-8 for each method and matrix evaluated, \diamond PeelPlate and \square 3M alternate reference method. Exact reference method correlation is represented by the solid “perfect” line.

Discussion: PeelPlate methods were not significantly different from reference methods or alternative reference methods in most dairy matrices studied. In the skim milk aerobic count evaluation the PeelPlate-AC and 3M were not significantly different from each other but both methods recovered less than the SPC method presumably due to a matrix stress on the fortified bacteria. In whole milk coliform evaluation the 3M-PCC method did not correlate at all concentrations with the VRBA method while PeelPlate-EC correlated with VRBA. In skim milk coliform method evaluation the middle fortified level was lower with the PeelPlate-EC method, but this result was not reproduced in additional study indicating a sample preparation effect. In chocolate milk coliform evaluation the 3M method was significantly different and lower than PeelPlate and VBRA methods, presumably because additional dilution of neat milk is required for 24 hour growth on 3M. Overall the results support that PeelPlate method results are equivalent with other NCIMS 2400 form methods for testing these dairy products.

Aerobic Count Method Studies

Figure 1:

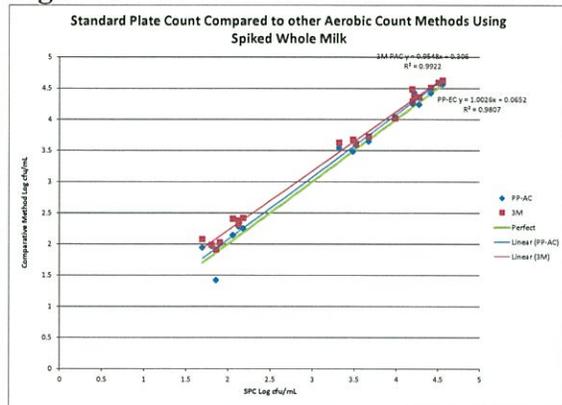


Figure 2:

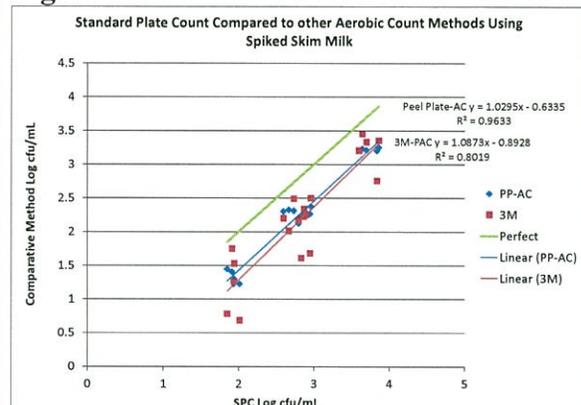


Figure 3:

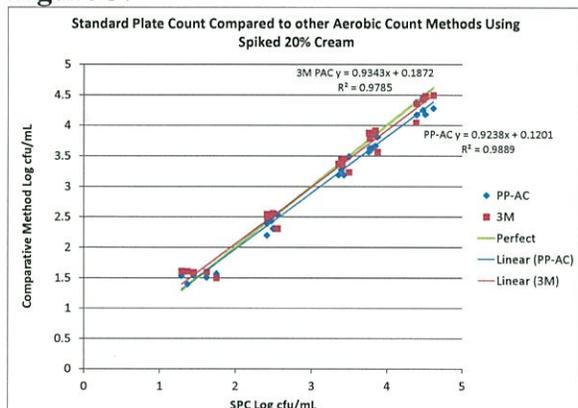
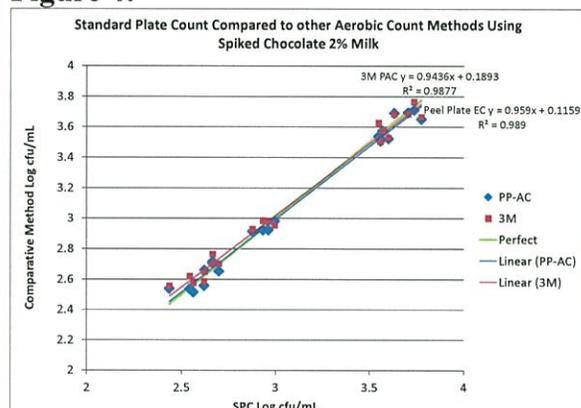


Figure 4:



Total Coliform Count Studies

Figure 5:

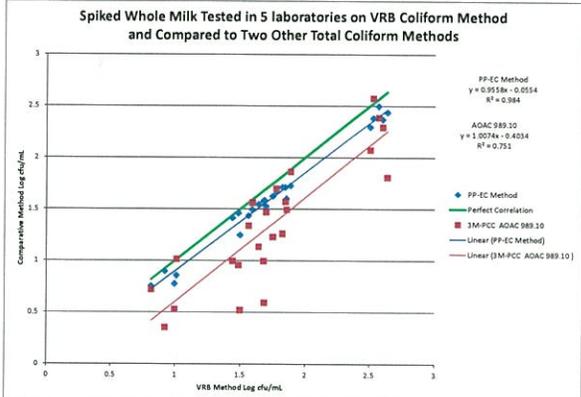


Figure 6:

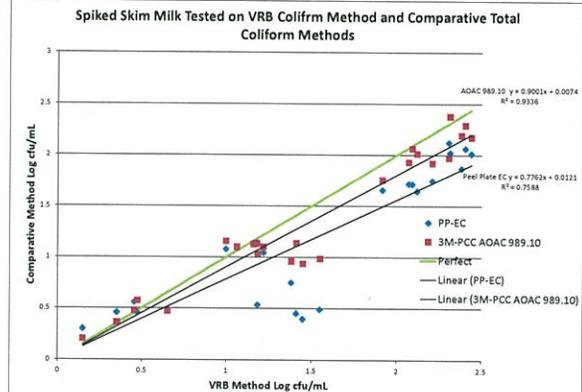


Figure 7:

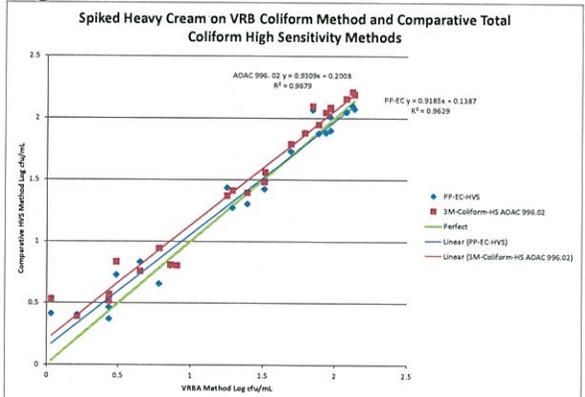
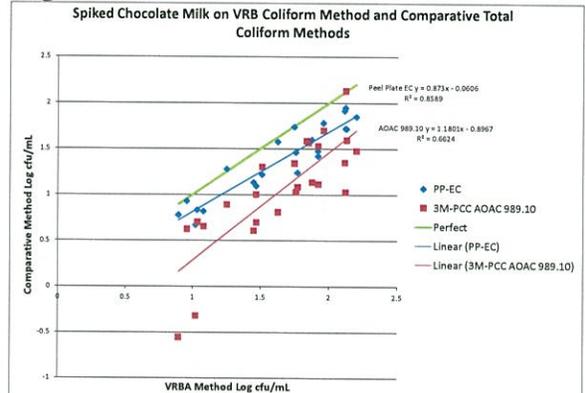


Figure 8:



C. Proposed Solution

Changes to be made on page(s):	New 2400 form		of the (X - one of the following):
	2013 PMO		2011 EML
	2013 MMSR	X	2400 Forms
	2013 Procedures		2013 Constitution and Bylaws

Approve a 2400 form (below) that has been supplied to laboratory committee for amendment and adoption.

Amend M-a-98-10 (or last revision) by adding the PeelPlate methods for dairy matrices and with dairy products as appropriate with FDA-LPET and AOAC-RI submitted matrix data.

**STANDARD PLATE AND COLIFORM COUNT
PEEL-PLATE™ AEROBIC, COLIFORM AND HIGH SENSITIVITY COLIFORM
METHODS
IMS #??**

[Unless otherwise stated all tolerances are ±5%]

SAMPLES

- 1. **Laboratory Sample Requirements (see CP items 33 & 34)
[For inhibitor testing requirements, refer to Section 6 of the PMO]**

MATERIALS AND APPARATUS

- 2. **Peel Plate Aerobic Count (PP-AC), Peel Plate Total Coliform (PP-EC, E.coli+Coliform) and Peel Plate Total Coliform High Volume Sensitivity (PP-EC-HVS,)** _____

PROCEDURE

- 3. **Work Area**
 - a. Level plating bench not in direct sunlight
 - b. Sanitize immediately before start of plating
- 4. **Selecting Dilutions**

- a. Aerobic Count, PP-AC
 1. Plate two decimal dilutions per sample
 2. Select dilutions that would be expected to yield one plate with 25-250 colonies _____
 - a. Raw milk is normally diluted to 1:100 and 1:1000
 - b. Finished products are normally diluted to 1:10 and 1:100
 3. PP-AC not performed on cultured or acidified products
- b. Total Coliform, PP-EC
 1. For pasteurized fluid milk samples (except chocolate), 1 mL direct and/or decimal dilutions, as appropriate
 2. For chocolate milk samples, distribute 2 mL of a 1:2 dilution among two (2) Peel Plate EC tests, 1 mL per plate
 3. For samples other than milk (item 12) distribute 10 mL of a 1:10 dilution among ten (10) Peel Plate EC tests, 1 mL per plate or use Peel Plate EC-HVS plates (see 4c below)
 4. For PP-EC performed on cultured product containing active Lactic Acid Bacteria (LAB), e.g. yogurt and cottage cheese, homogenize 1:10 dilution and centrifuge 1200g for 1 minute to settle solids. Distribute supernatant among ten (10) Peel Plate EC tests, 1 mL per plate or use Peel Plate EC-HVS plates (see 4c below)
- c. High Volume Sensitivity Coliform, Peel Plate EC-HVS
 1. At least a 1:10 minimum dilution required for: evaporated milk, sour cream, and sour cream based dips and eggnog (flavored milk optional)
 2. For cultured product containing active LAB, e.g. yogurt and cottage cheese, homogenize 1:10 dilution and centrifuge 1200g for 1 minute to settle solids.
 3. Test 10 mL of 1:10 dilution (5 mL on 2 plates)
- d. For acidified products, it is not necessary to adjust pH because of buffering capacity in the Peel Plate test. The pH range of the rehydrated test may be

checked with different acidified products using pH paper:

1. Peel Plate EC – pH range 6.6 to 7.2
2. Peel Plate HVS – pH range 6.5 to 7.5
3. Refer to manufacturer's instructions for list of low pH products that may require adjustment before plating

5. Identifying Peel Plate Tests

- a. Select number of samples in any series so that all will be plated within 20 min (pref ≤ 10) after diluting first sample
- b. Label each plate with sample or control identification and dilution
- c. Arrange plates in order before preparation of dilutions

CONTROLS

6. Controls (AM and PM)

- a. Check sterility of dilution blanks, Peel Plate-AC plates, and pipets/tips used for each group of samples
- b. Expose a rehydrated Peel Plate plate to air during plating for 15 min
 1. The air control plate must be the first plate set up immediately before samples are shaken and must be located such that it is in the area of the plating activity (not off to the side)
 - a. Inoculate the center of the PP-AC with 1 mL dilution buffer as described in items 9.i.1 or 10.i
 - b. Pull adhesive film off and save to side. Leave plate open, completely exposing rehydrated surface for 15 min; timer used
 - c. After 15 min, replace adhesive film back down as described in 9.i.2 and incubate as described in item 10.i.2
 2. After incubation, air plate(s) shall contain <10 colonies
 3. Take and record corrective actions for air control plate(s) with >10 colonies
 - a. Maintain records

- b. Include information on bench sheet, work sheet or report sheet(s)

DILUTING SAMPLES

7. Sample Agitation

- a. When appropriate, wipe top of unopened containers with sterile, ethyl alcohol-saturated cloth
- b. Before removal of any portion or sub-samples, thoroughly mix contents of each container
 - 1. Mix raw sample(s) by shaking 25 times in 7 sec with a 1 ft movement (containers approx $\frac{3}{4}$ full)
 - 2. Mix retail milk samples by inverting containers top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times
- c. Remove test portion within 3 min of sample agitation

8. Dilution Agitation

- a. Before removal of any portion, shake each dilution bottle 25 times in 7 sec with a 1 ft movement
- b. Remove test portion within 3 min of dilution agitation _____
- c. Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria

PLATING

9. Sample and Dilution Measurement, Pipets

- a. Use separate sterile pipets for the initial transfers from each container, adjust pipets in pipet container without touching the pipets
- b. Do not drag pipet tip over exposed exterior of pipets in pipet container
- c. Do not drag pipet across lip or neck of sample container or dilution blank
- d. Insert pipet not more than 2.5 cm (1") below sample surface or dilution surface (avoid foam and bubbles)
- e. Using pipet aid, draw test portion above pipet graduation mark and remove

pipet from liquid (mouth pipetting not permitted)

- f. Adjust test volume to mark with lower side of pipet:
 1. In contact with inside of sample container (above the sample surface)
 2. Or, in contact with inside of dilution blank neck or area above buffer on straight-walled container
 3. Ensure excess liquid does not adhere when pipet is removed from the sample container or dilution blank
- g. For dilutions, dispense test portion to dilution blank (with lower side of pipet in contact with neck of dilution blank, or area above buffer on straight-walled containers) with column drain of 2-4 sec
- h. Keeping plate flat on bench, peel back the top adhesive film (Peel Plate EC) or lift plate top (Peel Plate EC-HVS) to fully expose the test plate
- i. Deposit 1 mL (PP-AC/PP-EC), or 5 mL (Peel Plate EC-HVS) of sample or dilution keeping plate flat and pipet nearly vertical and in center of plate
 1. Release sample or dilution portion just above the center of the plate base with tip slightly above but not in contact with plate base plate with a column drain of 2-4 sec
 - a. Using pipet aid, blow out last drop of undiluted sample, away from main part of sample on plate
 - b. Gently touch off pipet to dry area
 2. PP-AC/PP-EC- Replace the adhesive film onto base preventing wrinkles.
Apply pressure around perimeter to seal
 3. Peel Plate HVS – Gently rotate plate to expose dry area to sample.
Replace the lid.
- j. Leave plates undisturbed for gel solidification:
 1. 10 seconds for PP-AC/PP-EC
 2. 1 min for PP-EC-HVS
- k. Discard pipets into disinfectant OR dispose into biohazard bags or containers to be sterilized, (using this method of disposal does not require placing into disinfectant first)

10. Sample & Dilution Measurements, Pipettors [for electronic pipettors, follow manufacturer instructions] Mechanical ____ Electronic ____

- a. Each day before use, vigorously depress plunger 10x to redistribute lubrication and assure smooth operation (mechanical pipettors)
- b. Before each use examine pipettor to assure that no liquid is expelled from the pipettor nose-cone (contaminated), if fouling is detected do not use until cleaned as per manufacturer recommendation
- c. Use separate sterile tip for the initial transfers from each container
- d. Depress plunger to first stop (mechanical pipettors)
- e. Do not drag tip/barrel across lip or neck of sample container or dilution blank, and do not allow pipettor barrel within sample container
- f. Insert tip approximately 0.5-1.0 mm below sample or dilution surface (avoid foam and bubbles)
- g. With plate flat and pipettor vertical, slowly and completely release plunger on mechanical pipettor; do not lay pipettor down once sample is drawn up, use vertical rack or charging stand if necessary
- h. Touch off lower side of tip:
 1. To inside of sample container above the sample surface, excess liquid not adhering to tip
 2. Or to the inside of dilution blank neck or area above buffer on straight-walled containers, excess liquid not adhering to tip
 - a. For dilutions, hold pipettor nearly vertical with lower side of tip touching neck of dilution blank (or area above buffer on straight-walled containers), dispense test portion to blank by slowly depressing plunger to stop (mechanical pipettor)
 3. For two (2) stop pipettors, depress plunger to second stop with tip remaining in contact with dilution blank
- i. Lift the top adhesive film, fully exposing medium circle and keep plate flat. Deposit 1 mL (PP-AC/PP-EC), or 5 mL (PP-EC-HVS) of sample or dilution keeping pipettor nearly vertical
 1. Release sample or dilution portion within 2-4 seconds onto the center or just above the center of the plate with tip slightly above but not in

- a. If pipettor has two (2) stops, depress plunger to second stop
 - b. Do not touch off pipettor tip(s) on plates
 - c. Optionally, deposit samples with pipettor capable of making a 1:10 dilution in the tip
2. PP-AC/PP-EC – Replace the adhesive film onto base preventing wrinkles.
Apply pressure around perimeter to seal
 3. PP-EC-HVS – Gently rotate plate to expose dry area to sample.
Replace the lid
- j. Allow sample to wick into test material
 1. 10 seconds for PP-AC/PP-EC
 2. 1 minute for PP-EC-HVS
 - k. Discard tips into disinfectant OR dispose into biohazard bags or containers to be sterilized (using this method of disposal does not require placing into disinfectant first)

11. Samples other than milk

- a. Weigh 11g aseptically into a 99mL dilution blank heated to 40-45°C

INCUBATION

12. Incubating Peel Plate Plates (see CP item 15)

- a. Stack plates in horizontal position, clear side up
 1. PP-AC/PP-EC – no more than 20 high
 2. PP-EC-HVS – no more than 10 high
- b. Incubate within 10 min
 1. PP-AC/PP-EC and PP-EC-HVS - 24±2 hours at 32±1°C

COUNTING COLONIES

13. Counting Aids (see CP item 17)

- a. Count colonies with aid of magnification under uniform and properly controlled artificial illumination

- b. Hand tally (see CP item 17)

14. Counting, Recording and Computing Aerobic Count, PP-AC

- a. After incubation count all colonies on selected plates
- b. Where impossible to count at once, store plates at 0.0-4.4°C for not longer than 24 hours (avoid as a routine practice)
- c. Record results of sterility and control tests
- d. Record dilutions used and number of colonies on each plate counted
- e. When possible, select spreader colony free plates with 25-250 colonies and count all red colonies
 - 1. Use higher magnification if necessary to distinguish colonies from foreign matter
 - 2. Examine edge of plates for colonies
 - 3. Count all colonies stained various shades of red, even those outside the circular indentation left by the spreader
- f. If consecutive plates yield 25-250 colonies, count all colonies on plates from both dilutions
- g. Spreader colonies or plates with gel liquefaction
 - 1. Count colonies on representative portion only when colonies are well distributed and area covered, repressed or liquefied colonies do not exceed 25% of plate
 - 2. Do not count if repressed growth area or gel liquefaction >25% of plate area
 - 3. When spreader colonies must be counted, count each as a single colony
 - 4. Count chains/spreader colonies from separate sources as separate colonies _____
 - 5. If 5% of plates are more than 25% liquefied or covered by spreader colonies, take immediate steps to eliminate and resolve problem
- h. If there is no plate yielding 25-250 colonies, use plate having nearest to 250 colonies

- i. If plates from all dilutions exceed 250 colonies, estimate
- j. If plates from all dilutions yield < 25 colonies each, record actual number in lowest dilution
- k. If all plates from a sample show no colonies, record count as 0
- l. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution

- 1. If consecutive dilutions yield 25-250 colonies, compute count using formula below

$$N = \Sigma C / [(1 \times n_1) + (0.1 \times n_2)]d$$

Where, N = number of colonies per milliliter or gram

ΣC = sum of all colonies on all plates counted

n1 = number of plates in lower dilution counted

n2 = number of plates in next highest dilution counted

d = dilution from which the first counts were obtained

Example: 1:100 = 244 colonies 1:1,000 = 28 colonies

$$N = (244 + 28) / [(1 \times 1) + (0.1 \times 1)]0.01$$

$$= 272 / [1.1]0.01$$

$$= 272 / 0.011$$

$$= 24,727 [25,000 \text{ (reported)}]$$

Note: In the NCIMS Program the denominator will always be 0.11 for 1:10 dilutions and 0.011 for 1:100 dilutions

15. Counting, Recording and Computing Total Coliform, PP-EC and PP-EC-HVS _____

- a. After incubation count all colonies on selected plates
- b. Where impossible to count at once, store plates at 0.0-4.4°C for not longer than 24 hours (avoid as a routine practice)
- c. Count all colonies regardless of color or size. Red colonies are coliform producing galactosidase while blue/purple and black colonies are coliform producing the enzymes galactosidase and glucuronidase. (No further confirmation is required)
- d. If no colonies appear on plate(s), record count as 0
- e. If there are 1-154 colonies on a plate, record number counted
- f. If >154 colonies develop on highest dilution plate, record number as >150

- g. When multiple plates of a dilution are used (items 4.a.2 and 4.a.3), sum counts of the plates
- h. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution

15. Identifying Counting Errors

- a. Perform monthly counting for PP-AC
 - 1. With 3 or more analysts, use the RpSm method (see current SMEDP); maintain records
 - 2. With two analysts, comparative counts agree within <10%; maintain records
 - 3. If only one analyst, replicate counts agree within 8% of one another; maintain records

REPORTING

16. Reporting (see CP item 34.b.2.d)

[When samples are demonstrated to contain inhibitors, no bacteria counts are reported; report as positive for inhibitors or growth inhibitors (GI)]

- a. Aerobic Count, PP-AC
 - 1. Report computed count as Peel Plate Aerobic Count/mL or /g (PP-AC/mL or PP-AC/g) when taken from plate(s) in the 25-250 range
 - 2. Report PP-AC plate counts of 0 to 24 as < 25 times the reciprocal of the dilution and report as Estimated PP-AC (EPP-AC)
 - 3. When colonies on PP-AC plates exceed 100/sq cm, compute count by multiplying 100 x dilution factor x 20 sq cm and report as > computed count Estimated (EPP-AC)
 - 4. If computed counts from PAC plates >250, report as Estimated PP-AC (EPP-AC)
 - 5. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPP-AC)
- b. Total Coliform, PP-EC
 - 1. Report count as Peel Plate Coliform/mL or /g (PP-EC/mL or PP-EC/g) when taken from plate(s) in the 1-154 range

- a. For chocolate milk run 1:2 dilutions in duplicate and sum results to get a sensitivity of 1 coliform/mL as required by the PMO (PP-EC/mL) _____
 2. If no colonies appear on coliform plates, report as < 1 times the reciprocal of the dilution and report as Estimated (EPP-EC)
 3. Counts from coliform plates > 154 are reported as > 150 Estimated Peel Plate Coliform Count (EPP-EC)
- b. High Sensitivity Total Coliform, PP-EC-HVS
 1. Run 1:10 dilutions in duplicate to get a sensitivity of 1 coliform/mL or g as required by the PMO (PP-EC-HVS)
 2. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPP-EC-HVS)
- c. Report only first two left-hand digits
 1. If the third digit is 5 round the second number using the following rules
 - a. When the second digit is odd round up (odd up, 135 to 140)
 - b. When the second digit is even round down (even down, 125 to 120)
- d. If all plates from a sample have excessive spreader colony growth or liquefiers, report as spreaders (SPR) or liquefiers (LIQ)
- e. If a laboratory accident renders a plate uncountable, report as laboratory accident (LA)

Example Revisions needed to be made in Table 3 of M-a-98-10 (or latest revision)

M-a-98-10 March 1, 2013

TABLE 3.

GRADE "A" MILK AND MILK PRODUCTS REQUIRED PMO LABORATORY TESTING BY MICROBIOLOGICAL OR CHEMICAL TEST METHOD

(This Table will be revised and reissued as new information becomes available.)

BACTERIAL COUNT METHODS - MICROBIOLOG	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST. WHITE MILK (ALL FAT LEVELS)	PAST. CHOCOLATE MILK (ALL FAT LEVELS)	PAST. STRAWBERRY MILK (OTHER FLAVORS- ALL FAT LEVELS)	PAST. LACTOSE REDUCED MILK AND LOW-SODIUM MILK	PAST./UP ½ & ½ AND CREAM (ALL FAT LEVELS)	ULTRA-PASTEURIZED MILK (UP) (ALL FAT LEVELS)
3M PETRIFILM AEROBIC COUNT* (PAC)	X	X	X	X	X	X	X	X	X	X	X
CHARM PEEL PLATE- AEROBIC COUNT (AC)	<u>X</u>	<u>X</u>	<u>X</u>			<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>
COLIFORM COUNT METHODS - MICROBIOLOG											
COLIFORM PLATE COUNT 21 (Violet Red Bile - Approved for All Products.						X	X	X	X	X	X
CHARM PEEL PLATE- TOTAL COLIFORM (EC)						<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>
CHARM PEEL PLATE- TOTAL COLIFORM HIGH SENSITIVITY (EC-HVS)						<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 240

Committee: Lab - 2400

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

A. Summary of Proposal

To expand training requirements and documentation for performance testing under Appendix N general Requirements section 10.

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

Current wording in the FDA 2400 from Appendix N General Requirements form gives no detail or parameters on how rotational performance check is to be performed. It is suggested to revise this requirement to include an alternative monthly training to be performed by all approved/ certified analysts to maintain analyst proficiency with the performance testing required. A CIS or IS will observe each analyst perform the daily calibrator checks (if required for the assay) and the daily positive and negative controls. This monthly check would be performed and documented similar to the monthly comparison counts required in plating and DMSCC assays.

C. Proposed Solution

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

 2013 PMO 2011 EML
 2013 MMSR X 2400 Forms

Modify page 6 of the Appendix N General Requirements form

10. Performance Testing.....

d. If more than one analyst performs analysis, have a different analyst run performance ~~check~~ checks on a rotational basis

e. If rotation of analysts' duties is not feasible, then daily performance checks will be performed by each approved/certified analyst and observed by supervisor (IS or CIS) monthly.

1. Observation will include:

a. Set up of reader software (if applicable)

b. Instrument check with check devices/calibrators (if applicable)with valid results

c. Positive and negative control run with valid results

d. Training records maintained

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 241
Committee: Lab - 2400

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

A. Summary of Proposal

To allow the use of an alternative pre-incubation step to the Colilert-18 method.

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

The manufacturer's instructions for the Colilert-18 method for water testing allow the alternative use of a 44.5C water bath for warming the sample for 7-10 minutes. Currently this alternative method is not reflected in the FDA 2400 form Dairy Waters.

C. Proposed Solution

Changes to be made on page(s): 7 of the (X - one of the following):

- | | |
|--|---|
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML |
| <input type="checkbox"/> 2013 MMSR | <input checked="" type="checkbox"/> 2400 Forms |
| <input type="checkbox"/> 2013 Procedures | <input type="checkbox"/> 2013 Constitution and Bylaws |

Modify page 7 of the Dairy Water 2400 form

24. Materials

e. Water Bath, circulating, maintains $35\pm 0.5^{\circ}\text{C}$; records maintained during periods of use (required for Colilert-18)

f. Water bath, circulating, maintains $44.5\pm 0.5^{\circ}\text{C}$; records maintained during periods of use (optional for Colilert-18)

25. Procedure

a. Aseptically add pre-weighed substrate to 100 mL of the water sample

b. Optionally, add 100 mL of sample to the substrate in a sterile container provided by the manufacturer

c. Aseptically cap and mix thoroughly by inverting 25 times to dissolve reagent (does not completely dissolve)

d. For Colilert-18, thermally equilibrate test solution for 20 min in a $35\pm 0.5^{\circ}\text{C}$ circulating water bath or alternatively 7-10 minutes in a 44.5°C circulating water bath, and then continue incubation in water bath or dry incubator for a total of 18 hours (minimum), not to exceed 22 hours

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 242
Committee: Lab - 2400

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

A. Summary of Proposal

To clarify procedure for accuracy check of dairy pipettors in regards to matrix used.

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

Current wording in the 2400 forms does not state the matrix (milk vs water) required to perform the accuracy check of the pipettors. The only reference to a specific matrix in the current revisions is in the DMSCC form, which require the use of milk. Clarification is needed to avoid assumptions on the accuracy test procedure.

C. Proposed Solution

Changes to be made on page(s): 5-CP, 4-Apx N GR of the (X - one of the following):

- | | |
|--|---|
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML |
| <input type="checkbox"/> 2013 MMSR | <input checked="" type="checkbox"/> 2400 Forms |
| <input type="checkbox"/> 2013 Procedures | <input type="checkbox"/> 2013 Constitution and Bylaws |

Modify page 5 of FDA 2400 form Cultural Procedures

6. Pipets

e. Pipettors

4. Check accuracy ~~with ten (10) consecutive weighings~~ once every 6 months ~~(using separate tip for each weighing), average of all 10 weighings must be $\pm 5\%$ of specified delivery volume (by weight, or if ≥ 1.0 mL by volume using class A graduated cylinder);~~ maintain records

a. Ten (10) consecutive weighings on analytical balance using separate tip for each weighing

b. Optionally pipettors ≥ 1.0 mL ten measurements by volume using class A graduated cylinder

c. Use matrix specified by manufacturer

e. If using matrix other than water, pipettor labeled for '(matrix) use only'

f. Average of all 10 measurement must be $\pm 5\%$ of specified delivery volume

g. Records maintained

Modify page 4 of FDA 2400 form Appendix N General Requirements

7. Pipettors

f. Check accuracy ~~with ten (10) consecutive measurements, by weight or by volume (> 1.0 ml using a class A graduated cylinder), using separate tip for each measurement,~~ every 6 months

1. Ten (10) consecutive weighings on analytical balance using separate tip for each weighing

2. Optionally pipettors ≥ 1.0 mL ten measurements by volume using class A graduated cylinder

3. Use matrix specified by manufacturer

4. If using matrix other than water, pipettor labeled for '(matrix) use only'

5. Average of all 10 measurement must be $\pm 5\%$ of specified delivery volume

6. Records maintained

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 243
Committee: Lab - 2400

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

A. Summary of Proposal

To state the sample temperature and time requirements for raw milk in the Appendix N testing program, as well as wording to reflect single producer/ farm bulk tank sampling and testing.

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

Currently the allowable time and temperature ranges for milk samples are not stated in the Appendix N General form under Sample Requirements. These ranges were found in Section 9 of the Appendix N General form up to the 2/2005 revision but were removed with the 2/2010 revision. They are currently only found in the PMO. Having the time (>72 hours) and temperature (0.0-4.5C) requirements in the section 9 of the Appendix N General form would make for easier reference when performing the Appendix N testing.

The form as currently written only contain wording for bulk milk tankers arriving at a processing plant. This wording is not a good reflection of the procedure at the single farm processors sampling and testing out of their own farm bulk tank.

C. Proposed Solution

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

<u> </u> 2013 PMO	<u> </u> 2011 EML
<u> </u> 2013 MMSR	<u> X </u> 2400 Forms
<u> </u> 2013 Procedures	<u> </u> 2013 Constitution and Bylaws

Modify page 5 of the Appendix N General Requirements form

9. Sample Requirements.....

a. Appendix N Tanker/Bulk Milk tank samples(s)

2. Ascertain temperature of bulk milk tanker/tank; maintain records

3. Secure a representative sample for testing. If sample will not be tested without delay (within 3 minutes of sampling) then a temperature control (TC) sample must be taken at the same time, transported preferably on ice to maintain temperature, and maintained with the tanker/bulk tank sample(s) until it is tested

4. Tanker/bulk tank sample(s) tested promptly upon arrival at the testing location (date and time and temperature of samples as received and tested recorded)

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

b. Temperature of bulk milk tanker/tank may be used for temperature as received and tested if sample testing begins without delay (within 3 minutes of sampling)

c. Temperature of milk sample is to be 0.0 - 4.5°C (32.0-40.0°F) prior to testing. Do not test sample(s) if temperature is out of range.

1. Samples may be received up to 7.0°C if time of receipt is less than 3 hours from collection and receipt temperature does not exceed sampling temperature. Cool sample to 0.0-4.5°C before testing.

d. Testing of bulk tank (on-farm processors) samples is to begin, preferably immediately after sampling, but no longer than 24 hours after sampling and prior to processing of the bulk tank milk.

e. If test kit indicates a positive result, confirmation completed within 72 hours of initial collection

5. Do not accept samples that are over filled, more than ¾ full

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 244
Committee: Lab - 2400

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

A. Summary of Proposal

Eliminate the DMSCC certification prerequisite for an ESCC method when a laboratory is purchasing certified Somatic Cell Standards.

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

The majority of Section 6 samples being tested for somatic cells are done on electronic somatic cell counters (ESCC). A co-requisite for ESCC certification is that analyst(s) are certified for the DMSCC procedure. In many NCIMS Laboratories this co-requisite is out dated since "certified standards" are being purchased to calibrate the electronic counters and analyst proficiency in the DMSCC procedure is no longer necessary or pertinent. This proposal grants the option for laboratories, and or specific analysts, that purchase certified cell standards to bypass the DMSCC requirement.

C. Proposed Solution

Changes to be made on page(s): ESCC 2400 Forms-pg. 1 of the (X - one of the following):

- | | |
|--|---|
| <input type="checkbox"/> 2013 PMO | <input type="checkbox"/> 2011 EML |
| <input type="checkbox"/> 2013 MMSR | <input checked="" type="checkbox"/> 2400 Forms |
| <input type="checkbox"/> 2013 Procedures | <input type="checkbox"/> 2013 Constitution and Bylaws |

PRE-REQUISITE

2. Comparative Test with DMSCC (co-requisite for certification, unless certified somatic cell standards are being purchased)

- a. Analyst(s) certified for DMSCC
- b. Each analyst seeking certification for the ESCC test shall perform the comparative test
 1. Test 4 samples (100K-200K, 300K-500K, 600K-800K and 900K-1.2M) in triplicate for both DMSCC (three separate smears each) and ESCC
 2. Results must be evaluated by State/Federal LEO and shown to be acceptable prior to official use of test in laboratory
 3. Copy of comparison and results in QC record (or easily accessible on file in the laboratory); kept for as long as analyst is certified

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35th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 245
Committee: Lab - 2400

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

A. Summary of Proposal

To give the option of standardization temperatures on the immersion oil on the DMSCC Form.

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

It was noted by several individuals that the DMSCC 2400 form only states a standardization temperature of 20°C for the immersion oil. Upon investigation it was observed that most of the immersion oil available does a standardization at 23°C which appears to be the international standard. Only one company uses the 20°C and it would force the program to only allow this particular brand.

C. Proposed Solution

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

<input type="checkbox"/> 2013 PMO	<input type="checkbox"/> 2011 EML
<input type="checkbox"/> 2013 MMSR	<input checked="" type="checkbox"/> 2400 Forms
<input type="checkbox"/> 2013 Procedures	<input type="checkbox"/> 2013 Constitution and Bylaws

Update the following item to include 23°C.

Item 13.a.

a. Refractive index 1.51-1.52 at 20°C or 23°C.

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34th NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 246 (#231-2013)
Committee: 2400-Lab/
Scientific Advisory

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

A. Summary of Proposal

Extend the allowable time for the transportation of water samples from 30 hours to 48 hours for water samples tested in IMS listed laboratories.

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

Background and Current Standards

The current 30 hour limit for water samples to be tested after collection at times necessitates special trips for water samples to be specially delivered to the laboratory. Over the last several years we have extended the 36 hour time for milk samples to be in transit first to 48 hours and then to 60 hours at the 2009 NCIMS conference.

The Environmental Protection Agency (EPA) test procedures require that tests be started within 30 hours of sample collection. The EPA drinking water program has no mandatory cooling requirement but encourages water samples in transit to be stored at 10⁰ C or less. Safe sample standards are established as <1 coliform per 100 ml is satisfactory for drinking water purposes, ≥1 coliform per 100 ml is unsatisfactory for drinking water purposes. In the Final Revised Total Coliform Rule signed by the EPA Administrator on December 20, 2012 for publication in the Federal Register the standard for water sample storage during transportation was not changed.

The FDA Pasteurized Milk Ordinance (PMO) requirements are a little more stringent.

FDA form 2400m Dairy waters require that samples transported more than 6 hours to be stored at 0-4.4⁰ C with temperature control sample when going to a Grade “A” certified laboratory. When going to an EPA certified laboratory samples are not required to be refrigerated but are recommended to be refrigerated at 10⁰ C. Sample testing must still begin within 30 hours. Results standards are the same <1 coliform per 100 ml is satisfactory, ≥1 coliform per 100 ml is unsatisfactory.

Discussion

Five (5) independent studies cited in this proposal. These studies were directed mainly to justify the need to refrigerate samples to preserve the sample in a truly representative state. Data extracted from the studies also shows that not only does refrigeration preserve the sample but that preserved sample will be truly representative for a longer period of time than is currently accepted. The standard for drinking water accepted during the time period of the studies was a more lenient standard than used currently.

An in house study was also conducted to specifically examine the effects of time on refrigerated samples. This study used both seeded prepared samples and raw natural samples collected from various dairy water sources. The samples were held at 4.4⁰ C and tests were conducted at 0, 30, 48, 54, and 72 hour hold times. The in house study also indicated that the temperature preserved sample will be truly representative at 72 hours as well as at 0 hours or 30 hours. There was some variation in microbial counts over the testing period and some between laboratories. However, the variations were not statistically significant from 30 hours to 72 hours after sample collection. At no time did counts decrease to a point that would produce a false negative under current standards.

Data

Several scientific studies were reviewed to obtain data that relates to the effect of hold time on water samples. Generally the studies were done to show either the relationship of ambient temperatures and sample storage or to justify the refrigeration to preserve a sample. The data does support the hypothesis that hold time can be extended without adversely affecting the sample. All of the studies used MF and MPN analysis techniques except the in-house study which used several types of analysis.

Data found in 2 studies indicate that hold time of unrefrigerated samples up to 48 hours does not significantly change number of positive results.

In a study conducted by S.C. Hsu and T.J. Williams^b in 1981 over 4658 samples of municipal and private water were analyzed. Hold times were measured in days rather than hours at ambient temperatures. Study findings suggest that cyclical die-off and regrowth patterns may occur over periods of days for some members of the coliform group. The percentage of positive coliform test results did not exhibit regular increases

or decreases with increasing sample hold times.

Another study conducted by Jon H. Standridge and Joseph J. Delfino^c 1983. In this study 3154 samples of private and municipal water were analyzed after 24 hours and 48 hours hold time at ambient temperatures ($20 \pm 2^{\circ}$ C). Study findings indicate the total number of coliform-positive samples was unchanged by increasing storage time to 48 hours.

In 3 studies reviewed samples were held at two temperatures ambient temperature and 5° C. All of the studies had similar results.

A 1983 study conducted by A.E. McDaniel and R.H. Bordner^c 50L samples were collected weekly or bi-weekly for 15 weeks. Each sample was broken down into 7 subsamples, one subsample for chemical analysis and 6 for bacteriological analysis. Samples were held at 22° C and at 5° C and analyzed at 12 hours, 24 hours, and 48 hours. The results as seen in Fig. 4 of this study indicated that the unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

Another study conducted by A.E. McDaniels, et. al.^a had similar results. Over 512 samples were collected from a municipal water supply plus a 50-60 liter samples. Samples were inoculated with *E. cloacae* and *C. freundii*. Samples were stored at 5° C and at 22° C at 24 hours, 30 hours, and 48 hours. The results as seen in Fig. 4 of this study were similar to the 1983 study. The unrefrigerated samples lost significant numbers of bacteria but did not lose enough to produce negative results. The refrigerated samples did not lose significant numbers from 24 hours to 48 hours. In fact the refrigerated samples lost fewer numbers in 48 hours than the unrefrigerated samples did in 24 hours.

A third 1955 study by E. E. Geldreich^d was reviewed. Samples were taken in winter and summer, 3 each, from six sources farm wells, rivers and a lake for a total of 36 samples. Samples were held at 5° C, at room temperature (13° - 32° C) and at 35° C. Samples were analyzed at 24 hours, 48 hours, and 72 hours. Results varied in this study but comparing mean ratios as in Table 4 all samples showed significant loss in the first 24 hours, however, the refrigerated samples showed significantly less loss in 48 hours and 72 hours than did the unrefrigerated samples. The ratios still indicate that the loss still would not have produced a negative result under current standards.

The In house study was conducted in 2011. Samples were tested at 4 laboratories the MRC Laboratory, Oklahoma State Department of Agriculture Laboratory, Kansas State Board of Agriculture Laboratory, and the Arkansas Department of Health Laboratory.

A combination of prepared samples and natural samples were used in this study. Well water, chill water from a dairy plant and glycol from a dairy plant was collected to prepare samples to be shipped to the various laboratories. Samples were seeded with *E. coli*, and *K. pneumonia* to achieve a target count of approximately 30 CFU's/100ml. *Pseudomonas aeruginosa* was added to see if it had any effect on coliform survival. All samples were stored and shipped at temperatures between 0-4.4⁰ C. Samples were analyzed at 0 hours, 24 hours, 30 hours, 48 hours, 60 hours, 72 hours, and 96 hours.

Different analysis methods were used to compare results. Membrane filtration was used at 2 of the laboratories, Colilert was used at two laboratories, Colisure was used at one laboratory, and MPN was used in three laboratories

The results over all showed that the microbial loss over the analysis period was statistically insignificant. There were a few instances that numbers dropped slightly but not enough to produce a negative result. There was also some instances that a drop in numbers occurred at one analysis time but the count rebounded by the next analysis.

Data extracted from the various studies along with the in-house study would indicate that allowing and extended hold time of up to 60 hours would not have an adverse effect on the number of positive samples. Given current standards and current testing technology none of the data reviewed would indicate an adverse effect on positive samples if the samples were transported and/or held up to at least 48 hours. Some of the data actually indicates a 60 hour hold time is feasible without adverse effects since there appears to be some cyclical loss and growth even under refrigeration during the hold period. Protecting the public health is still served very well. If coliform is present in a sample it will still likely be present at some level above the standard

Conclusion

It is clear that the milk program will continue to use EPA certified laboratories and they will be allowed to accept samples up to 30 hours without refrigeration. As presented in the various papers samples that are refrigerate show less die off at 48 plus hours, possibly out to 72 hours, than those that are held 30 hours without refrigeration. This extended time, necessary for travel from point of collection to laboratory in many cases, would have little if any effect on the sample on samples currently tested under the dairy water program and these samples will continue to be more representative of the when they were collected verse the 30 hour unrefrigerated samples that we accept the results on that are tested in an EPA certified laboratory.

Literature Cited

- a. A.E. McDaniels, R.H. Bordner, P.S. Gartside, J.R Haines, K.P Brenner, C.C. Rankin, Holding Effects on Coliform Enumeration in Drinking Water Samples, Applied and Environmental Microbiology, Oct. 1985

- b. S.C. Hsu, T.J. Williams, Mich. Dept. of Public Health, Evaluation of Factors Affecting the Membrane Filter Technique for Testing Drinking Water, Applied and Environmental Microbiology, Aug. 1982
- c. A.E. McDaniel, R.H. Bordner, Effects of Holding Time and Temperature on Coliform Numbers in Drinking Water, Research and Technology, Journal AWWA, Sept. 1983
- d. E.E. Geldreich; P.W. Kabler, M.D., Ph.D. F.A.P.H.A.; H.L. Jeter; H.F. Clark, A Delayed Incubation Membrane Filter Test for Coliform Bacteria in Water, American Journal of Public Health, Nov. 1955
- e. J.H. Standridge, J.J. Delfino, Effect of Ambient Temperature Storage on Potable Water Coliform Population Estimations, Applied and Environmental Microbiology, Nov. 1983

C. Proposed Solution

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

Edit 2400m Dairy Waters as follows

1. Laboratory Requirements

- e. Transit time does not exceed ~~30~~ 48 hours
- f. Samples examined within ~~30~~ 48 hours of collection or within 2 hours of receipt (item 1d)

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