Evaluation of Milk Laboratories

2019 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 in state and local milk laboratories doing official analysis. In 1977, the Food and Drug Administration (FDA) and 46 States had programs for measuring analyst performance in official and officially designated milk laboratories, by on-site surveys of techniques and proficiency testing. Today all 50 States, Puerto Rico and the Virgin Islands participate in the National Conference on Interstate Milk Shipments (NCIMS) Milk Laboratory Program. These evaluations have resulted in greater uniformity, accuracy and precision of microbiological and chemical analysis.

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" Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the FDA Laboratory Proficiency Evaluation Team (LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the FDA, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, HFS-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) 924-0614; Fax (708) 924-0690), hereafter referred to as the FDA/LPET.

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ABBREVIATIONS AND ACRONYMS

* (Repeat Violation as Used on Evaluation Reports)
°C (Degrees Celsius)

AOAC (Association of Official Analytical Chemists)
ASTM (American Society of Testing and Materials)

BCC (Bentley BactoCount IBC)
BCMC (Bentley BactoCount IBCm)
BIO (BactoCount/BactoScan Industry Operator)
BSC (Foss BactoScan™ FC Count)

C (Conditional Certification as Used on Evaluation Reports)
CFSAN (Center for Food Safety and Applied Nutrition)
CIS (Certified Industry Supervisor)
cm (Centimeter)

DMSCC (Direct Microscopic Somatic Cell Count)

EML (*Evaluation of Milk Laboratories*)
EPA (Environmental Protection Agency)
EPC (Electronic Phosphatase Count)
ESCC (Electronic Somatic Cell Count)

FDA (Food and Drug Administration)
FDA/NCIMS 2400 Forms (Official Milk Laboratory Evaluation Forms)
ft (Foot/Feet)
ft-candles (Foot Candles)

HVD (Homogenized Vitamin D Milk)

IBC (Individual Bacteria Count)
IBCm (Individual Bacteria Count manual)
IA (Industry Analyst)
IMS (Interstate Milk Shipper)
IS (Industry Supervisor)
ISO (International Standards Organization)

LEO (Laboratory Evaluation Officer)
LPET (Laboratory Proficiency and Evaluation Team)

MRT (Maximum Registering Thermometer)
mU (milliUnits)

N (Number of Results per Test or Not Certification as Used on Evaluation Reports)
NA (Not Applicable)
NCIMS (National Conference on Interstate Milk Shipments)

O (Unused Laboratory Procedures or Equipment as Used on Evaluation Reports)
P (Provisional Certification as Used on Evaluation Report)
PAC (3M™ Petrifilm™ Aerobic Count)
PLC (Plate Loop Count)
PMO (*Pasteurized Milk Ordinance*)
PPAC (Charm® Peel Plate® Aerobic Count)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)
PT (Proficiency Testing)

QA (Quality Assurance)
QC (Quality Control)

RAC (3M™ Petrifilm™ Rapid Aerobic Count)
REV (Revision)

SPC (Standard Plate Count)
SPLC (Spiral Plate Count)

TAC (bioMerieux TEMPO® Aerobic Count)
TC (Temperature Control)

U (Undetermined as Used on Evaluation Reports)

X (Deviated Item or Full Certification as Used on Evaluation Reports)

EVALUATION OF MILK LABORATORIES
2019 Revision

INTRODUCTION

Official accreditation of milk laboratories and Certified Industry Supervisors (CIS) facilities requires that FDA/LPET or appropriate 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" 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 shall be an approved official or officially designated milk laboratory under the administrative control of a federal, state or local Regulatory 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 performance evaluations by analysis of split samples or by other means as noted in SECTION 2.

Laboratory Evaluation Officers (LEOs) certified by the FDA/LPET shall use the appropriate FDA/NCIMS 2400 Forms when evaluating official laboratories, officially designated laboratories, CISs, ISs and IAs. The FDA/LPET laboratory evaluation officer (FDA/LPET LEOs) shall use the appropriate FDA/NCIMS 2400 Forms when evaluating State Central Milk Laboratories and LEOs. Appropriate FDA/NCIMS 2400 Forms are those forms that have been approved by the NCIMS Laboratory Committee working cooperatively with the 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.

FDA laboratory accreditation procedures provide a 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 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 LEOs who:

    a. Accredit local laboratories and certify analysts and CIS based on:

1. Satisfactory biennial on-site 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 LEO and FDA/LPET agree is appropriate. (*Grade "A" PMO*, Appendix N).

SECTION 1: DEFINITIONS

1. **BACTOCOUNT/BACTOSCAN INDUSTRY OPERATOR (BIO):** A person who operates a Bentley BactoCount IBC, Bentley BactoCount IBCm or Foss BactoScan™ FC under the supervision of a certified BactoCount/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 (TPCs) 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, or fermented high acid shelf stable processing and packaging; and bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers 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 2: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory shall include an on-site 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 Forms). The FDA/LPET or LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA/NCIMS 2400 Forms.

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" (see page 26) shall be signed by a representative of the facility prior to the initiation of the survey. This document shall be maintained on file by the FDA/LPET or LEO.

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

Reports of on-site surveys of Official Milk Laboratories and CIS facilities shall be sent within sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory survey to the Official Milk Laboratory/CIS facility, the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. Reports to the Official Milk Laboratories/CIS facilities shall include the narrative report and may include copies of the completed FDA/NCIMS 2400 Forms. Reports to the appropriate FDA Milk Specialist shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 49-50).

Reports of on-site 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 survey.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

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

1. Evaluations of State Central Milk Laboratories shall be scheduled and performed by their triennial expiration date. The on-site survey may be conducted up to 60 days prior to the triennial expiration date. State central milk laboratories shall submit requests, in writing, for on-site survey of new analyst(s) performance of techniques, new methods and/or new facilities to the FDA/LPET. The FDA/LPET LEO shall schedule a mutually agreeable date within thirty (30) days of the request for an evaluation. If the FDA/LPET LEO is unable to travel to the state central milk laboratory requesting the analyst evaluation within 90 days, the state central laboratory may request that FDA/LPET allow an LEO from that state to perform the evaluation and based on this evaluation grant conditional certification of the analyst. If the requesting

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 FDA/LPET LEO as described below.

2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. The on-site survey may be conducted up to 60 days prior to the biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site survey of new analyst(s) performance of techniques, new methods and/or new facilities to the LEO. The 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 Forms, as determined by an on-site survey.

4. Analyst performance is in compliance during an on-site evaluation, with procedures required by the FDA/NCIMS 2400 Forms and the *Grade "A" PMO.*

5. Analysts meet the performance levels of the proficiency testing (PT) program (SECTION 3). The 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 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 test administered by 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 surveys, conditional certification or approval status 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 survey shall have their conditionally certified or approved status revoked.

Certified analysts and CISs 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 or failure to meet established satisfactory performance criteria shall result in the certified analyst(s) or CIS(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 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 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 Regulatory Agency, the Rating Agency, the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the 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 the FDA/LPET or Milk Laboratory Control Agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records shall meet the requirements stated on the appropriate FDA/NCIMS 2400 Forms and for CISs, appropriate Appendix N 2400 Forms, as determined by an on-site survey.

2. All official examinations required by the *Grade "A" PMO* 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 3).

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, survey of the new laboratory or screening facility is required within ninety (90) days. 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 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 demonstrating that critical equipment is functional.

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager shall notify the FDA/LPET or 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 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 FDA/LPET or LEO shall immediately notify the milk laboratory involved, the Milk Control Agency, the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides 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 completed FDA summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the LEO in writing. Upon receipt of the written request, the LEO shall immediately notify the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides 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 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 Milk Specialist responsible for the state in which the laboratory/facility resides 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 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 shall be sent to the LEO. Withdrawal of accreditation 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 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 Forms associated with the *Grade "A" PMO,* Appendix N program.
2. All screening tests required by the *Grade "A" PMO,* Appendix N 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 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 proficiency that the LEO and the FDA/LPET agree is appropriate. (*Grade "A" PMO,* Appendix N)

6. The IS has attended and received training by an LEO. This training shall be documented.

The IS shall report to the LEO the result of all competency evaluations performed by IAs. The name of each IS and IA (as well as their training and approval status) shall be maintained by the LEO and updated as replacement, additions and/or removals occur. The LEO shall verify (document) that each IS has established a program that ensures the proficiency of the IAs they supervise. The 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 or by other means of determining proficiency that the LEO and the FDA/LPET agree is appropriate.

When a new analyst is assigned to an approved laboratory, conditional approval status shall be provided to the new analyst upon satisfactory demonstration of competency to the IS. Full approval status 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 or analysis of split samples 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 or analysis of split samples 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 or analysis of split samples shall have their provisionally approved status revoked.

Failure by the ISs or the IAs to demonstrate adequate proficiency to the LEO shall lead to their removal from the 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 or otherwise demonstrating proficiency to the LEO. Analysts not on the 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 LEO shall immediately notify the screening facility involved, the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA Milk Specialist responsible for the state in which the facility resides 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 completed FDA summary template and shall be submitted by email.

Screening facilities requesting withdrawal of approval shall notify the LEO in writing. Upon receipt of the written request, the LEO shall immediately notify the Milk Control Agency, the respective Regulatory/Rating Agency, other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides 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 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 shall be sent to the 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 BENTLEY BACTOCOUNT IBC, BENTLEY BACTOCOUNT IBCm and FOSS BACTOSCAN™ FC INDUSTRY OPERATORS

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

1. The industry operator shall complete the BIO operating protocols, training and oversight specified in the training procedure document.

2. The laboratory shall maintain one (1) certified BactoCount/BactoScan analyst (see current FDA/NCIMS 2400 Form) for training and ongoing oversight of the BIO(s).

3. Refer to the Bentley BactoCount IBC, Bentley BactoCount IBCm or Foss BactoScan™ FC BIO Companion Protocol approved training procedures at the end of the BactoCount IBC, BactoCount IBCm and BactoScan™ FC FDA/NCIMS 2400 Forms.

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 3: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES - MICROBIOLOGY

The FDA/LPET shall split samples annually with all FDA/LPET certified analysts of each Milk Laboratory Control Agency accredited Central Milk Laboratory. Milk Laboratory Control Agencies shall split samples at least annually with all certified analysts of each official, officially designated accredited milk laboratory, and all CISs. Milk Laboratory Control Agencies shall verify that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially through laboratory evaluation and/or annual performance evaluation, or by other means of determining proficiency that the LEO and the FDA/LPET agree is appropriate.

Milk Laboratory Control Agencies having less than ten (10) analysts (total) in their milk laboratory program are to develop joint proficiency testing programs with other Milk Laboratory Control Agencies that can meet the criteria for certification of analysts and accreditation of laboratories. In cases where a minimum number of analysts ($\geq$ 10) are not available, evaluation of proficiency shall be made by a determination that the 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 33.

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 33.

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 33.

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 for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the target testing or tolerance levels, which the test kit(s) is designed to detect as well as milk samples 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 is

reduced one (1) level of certification. If this occurs twice consecutively, the CIS is not certified (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 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 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 survey or otherwise demonstrating proficiency to the LEO.

6. Each analyst certified to perform visual drug residue tests 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, Ceftiofur, and Cephapirin) using blind samples with duplicate negatives. A minimum of six (6) samples may be used. However, with six (6) samples ALL results 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 BactoCount IBC, BactoCount IBCm and BactoScan™ FC (all NCIMS approved models), shall meet the following applicable criteria.

   (a) The BactoCount IBC, BactoCount IBCm and 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 33.

SPLIT SAMPLE ANALYSIS
(Proficiency Testing Studies)

Evaluation criteria of split sample results vary on the type of data such as qualitative (Found or Not Found) or quantitative data. The Standard Plate Count (SPC), 3M™ Petrifilm™ Aerobic Count (PAC), 3M™ Petrifilm™ Rapid Aerobic Count (RAC), Charm® Peel Plate® AC (PPAC), Plate Loop Count (PLC), Bentley BactoCount IBC Count (BCC), Bentley BactoCount IBCm

Count (BCMC), Foss BactoScan™ FC Count (BSC), bioMerieux TEMPO® Aerobic Count (TAC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count, and Vitamins A and D_3 results are quantitatively reported. The quantitative results of each certified analyst shall meet acceptance criteria determined by protocols based on International Standards Organization (ISO) 17043, ISO 13528 and/or the International Harmonized for the Proficiency Testing of Analytical Chemistry Laboratories. Generally, various international standards and guidelines do not address comparison of qualitative proficiency testing studies.

Determination of Assigned Value and Standard Deviation and Evaluation of Analysts Reporting Quantitative Data:

1. The robust mean (x_{pt}) and standard deviation of the PT (σ_{pt}) are calculated according to Algorithm A and xpt is used as the assigned value for quantitative data. At least 80% of participants must submit quantitative results in order for the statistical calculations for x_{pt} and σ_{pt} to be executed. If this criterion is not met, those quantitative results will not be scored.

2. Algorithm A according to ISO 13528:2015 is used to calculate x_{pt} (x* = robust average) and σ_{pt} (s* = robust standard deviation). Other options for calculating mean and standard deviation are outlined in ISO 13528:2015. Calculations for microbiological testing are typically carried out on data that have been log transformed. Calculations for chemical testing are typically carried out on data that have undergone no transformation. Along with x_{pt} and σ_{pt}, values for standard uncertainty (u(xpt)) divided by σpt are calculated to ensure use of z-scores is appropriate. When $u(x_{pt})/ \sigma_{pt}$ t ≤ 0.3, the uncertainty of the assigned value may be considered to be negligible. If $u(x_{pt})/ \sigma_{pt} > 0.3$, either z' scores will be calculated ($zi' = (xi - x_{pt}) / (\sqrt{\sigma_{pt}}\ 2 + u2(x_{pt}))$ to take into account uncertainty of the assigned value or participants will be informed that uncertainty of the assigned value is not negligible and impact on scoring will be addressed.

3. Performance Evaluation for Quantitative Data

    a. The z-score value summarizes how many standard deviations from the mean the reported value is located. This is known as standardizing; thus, analysts receive standard z-scores. The formula for z-score calculation is as follows: $zi = (xi - x_{pt})/ \sigma_{pt}$ (where xi is the reported value, x_{pt} is the PT mean/assigned value, and σpt is the standard deviation for the PT, also referred to as target s.d.) (ISO 13528:2015). Data with a normal distribution have 95 % of values within 2 σ of the mean and 99.7 % of values within 3 σ (ISO 22117). According to ISO guidelines, results with a z-score greater than $\left|2\right|$ are considered questionable because only 5% of correct measurements are expected to be that different from the assigned value. Results with a z-score greater than $\left|3\right|$ are considered unsatisfactory because only 0.3 % of correct measurements are expected to be that different from the assigned value (see ISO/IEC 17043:2010, B.4).

Determination of Assigned Value and Evaluation of Analysts reporting Qualitative Data:

1. Assigned values are determined by one of the following (ISO 13528:2015 11.3.1): participant consensus, expert laboratory results and/or performance criterion based on expert judgement

a. Participant Consensus: The consensus value for qualitative PT studies conducted by the FDA Moffett Campus PT Laboratory is defined as 80% agreement of responses (per sample) (ISO 17043:2010 B.2.4). Consensus for a particular sample must be at least 80% for accurate scoring of results (42 CFR §493.911(c).1). The assigned value is determined using the consensus results of participants and the results of expert lab(s). In those PT samples where consensus among participant results is less than 80%, participant performance will not be evaluated. These guidelines accommodate for situations in which an analyte was spiked, but recovery is fractional among participants possibly due to differences in methodology, inhomogeneity, instability, etc.

b. Expert Laboratory Results: The results from PT provider laboratory may be considered in absence of equivalent to those of an expert, or reference, laboratory. Results from three separate sets of analyses will be considered during the determination of assigned values for qualitative PTs: Bulk scale trials, Pre-shipment analytical tests and Post-shipment analytical tests

c. Performance Criterion based on Expert Judgement: It is preferred that expert judgement comes from a panel or advisory group of qualified experts. In some cases, a single expert may be designated to determine the assigned value. Significant disagreement among a group of qualified experts for a PT sample must be noted, and if agreement cannot be reached, the PT sample will not be used to evaluate participant performance.

Evaluation of Analysts:

The evaluation of participant performance in qualitative PT studies is often dependent on the nature of the PT study report and the objective of the study. Therefore, the objective of the PT study and method for determining assigned value will be documented in the PT Planning prior to final shipment of PT samples. Proper planning will ensure the evaluation criteria for the PT scheme meets the objectives of the PT scheme. The origin or source of the final PT samples will also be documented in the PT Planning for traceability.

The interpretation of analyst results is as follows:

a. No color = Analysts/labs with z-score where $|z| \leq 2$ is acceptable and indicates that the performance of the analyst or laboratory is satisfactory.

b. Yellow = Analysts/labs with z-scores $2 < |z| < 3$ are given a “warning signal” (ISO 13528)

c. Red = Analysts/labs with z-scores $|z| \geq 3$ are given an “action signal” (ISO 13528)

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

1. A minimum of ten (10) results per sample per test for statistical analysis is recommended.

2. An acceptable annual proficiency testing program for the BCC, BCMC and BSC (all NCIMS approved models), shall meet the following applicable criteria.

   (a) BCC, BCMC and 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 Bentley BactoCount IBC, Bentley BactoCount IBCm or Foss 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 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 33.

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 SPC, PAC, RAC, PPAC, PLC, BCC, BCMC, BSC, TAC, SPLC, DMSCC and ESCC analysis, and approved BIOs shall meet the acceptance and performance levels shown in Table 2, page 34.

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 shall be spiked in duplicate. See Table 2, page 34.

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).

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 2, page 34.

5. 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 target testing level or tolerance, which the test kit(s) is designed to detect. See Table 2, page 34.

6. Analysts certified to perform vitamins A and D_3 tests shall detect samples that contain vitamins A and D_3 and shall meet the acceptance and performance levels shown in Table 2, page 34.

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) shall be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the Milk Laboratory Control Agency before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION 2: LABORATORY EVALUATION PROGRAMS. A formerly certified analyst who has lost certification may only become 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 the analyst can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site survey that leads to his/her loss of certification, then the analyst must pass the next on-site certification to become conditionally certified.

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 Milk Specialist responsible for the state in which the laboratory/facility resides, and the FDA/LPET.

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The *Grade "A" PMO* Vitamin PT Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories shall have analysts who have satisfactorily participated in at least two (2) consecutive split sample analyses and 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 PT Program involves the analysis of six (6) to eight (8) samples sent to participating laboratories every six (6) months, i.e., two (2) times a year with a 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 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.

Once fully certified, analysts maintain certification by satisfactorily analyzing both sets of split samples each year. During the course of the year full certification is maintained if not more than two (2) samples are missed. Failure without cause to analyze all samples during the course of the year 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 then that analyst shall be downgraded to provisional certification. Full certification 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 set of samples analyzed after receiving the respective status shall have certification removed.

Once certification is removed an analyst may only regain conditional certification by satisfactory performance on the next set of samples, i.e., miss not more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

For split sample purposes each analyst 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 not employed at that laboratory. A laboratory that loses all of their certified analysts is no longer accredited to do official work and shall seek new laboratory entry prior to resuming official analysis.

An acceptable annual PT program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D_3, a minimum of six (6) samples 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 33.

WATER MICROBIOLOGY

Laboratories using Environmental Protection Agency (EPA) or other officially administrated programs for water analysis are not required to meet the intentions of this Section. Programs administered by Milk Laboratory Control Agencies include central, official, officially designated and other water testing laboratories sanctioned by the Milk Laboratory Control Agencies and participation in 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 other officially administered program for water analysis should participate annually in a microbiological proficiency testing program for each water analysis methodology for which the laboratory is accredited. The PT samples are to be provided by Milk Laboratory Control Agencies 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 total coliforms and *E coli*, 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 33.

SPLIT SAMPLE ANALYSIS

The Multiple Tube Fermentation (Lauryl Tryptose Broth), Enzyme Substrate, Membrane Filtration and Heterotrophic Plate Count result of each laboratory shall meet the criteria specified for microbiological split samples on pages 13 – 17.

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

1. A minimum of ten (10) results per sample per test for statistical analysis is recommended.

2. Using Table 2, page 34, indicate all analysts who have more than the maximum number of sample results per test classified as unacceptable.

3. Laboratories accredited for dairy water analysis shall meet the acceptance and performance levels shown in Table 2, page 34.

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 and performance levels shown in Table 2, page 34.

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 it exceeds 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) shall be withdrawn. A laboratory that has lost its accreditation shall participate in a training program acceptable to the Milk Laboratory Control Agency before requesting reaccreditation. Reaccreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 2: LABORATORY EVALUATION PROGRAMS.

Copies of the 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 FDA Milk Specialist responsible for the state in which the laboratory/facility resides, and the FDA/LPET.

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

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

1. The individual shall be 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 Forms when accompanied by a representative of the FDA/LPET on the initial check on-site survey(s). The FDA/LPET shall accompany the LEO to not more than two (2) laboratories/facilities during 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 reduced, but all applicable record types must be reviewed) to facilitate the timely survey of the laboratory or Appendix N facility.

2. The individual 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 Milk Specialist responsible for the state in which the laboratory/facility resides shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 49 - 50).

3. The individual shall attend the Milk Laboratory Evaluation Officers Workshop (FDA Course #373) conducted by the FDA/LPET. If the individual does not have experience in the examination of dairy products, the individual shall attend Course 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 certified LEOs shall be considered official.

Conditional certification of a new LEO can occur following the initial check on-site survey(s) described in items 1 and 2 above. Full certification shall be granted after the LEO attends the next scheduled Milk Laboratory Evaluation Officers Workshop. Failure of a conditionally certified LEO to attend the next scheduled Workshop, unless excused with cause by the FDA/LPET, will require that the LEO restart the process. The 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 an LEO will occur triennially, and shall be based on satisfactorily meeting the following criteria:

1. The individual shall be 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 Forms when accompanied by a representative of the FDA/LPET on a check on-site survey(s). The FDA/LPET shall accompany the 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 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 survey(s). Reports to the appropriate FDA Milk Specialist responsible for the state in which the laboratory/facility resides shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 49 - 50).

3. The individual shall have all laboratory evaluations, proficiency test examinations, and reports current (in particular biennial on-site surveys shall be performed within the month of their anniversary date).

4. The individual shall have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the Regulatory and/or Rating Agency and the FDA/LPET.

5. The individual has met the responsibilities for the training of ISs.

6. The individual shall attend the Milk Laboratory Evaluation Officers Workshop once every three (3) years.

7. The individual shall not fail, without cause, to attend an FDA Milk Seminar once within their three (3) year certification period.

Once an individual has become an LEO and is therefore considered fully certified, if the individual fails to submit acceptable written reports of milk laboratory 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 LEO shall have their certification status downgraded from full to provisional. In addition, an action plan shall be established that is mutually agreeable to the FDA/LPET and the Milk Laboratory Control Agency. The LEO 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 certified LEOs shall be considered official.

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

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

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

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 shall require meeting the requirements for initial certification.

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

While conducting laboratory on-site surveys, the FDA/LPET or LEO may find it extremely useful to have in their possession different types of equipment which 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 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 6: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

The evaluations of laboratories by a FDA/LPET or 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, shall make application for an evaluation upon a form provided by the FDA/LPET or LEO. The application 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 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 on-site survey, laboratory officials should be told that all tests shall be set up and that during the on-site survey the work of all analysts, who may perform any official methods shall be observed. If laboratory 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 FDA/LPET or LEO to permit observations of counting procedures.

On the designated 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 on-site survey should be reviewed, and arrangements made to discuss the completed laboratory on-site survey informally with the laboratory director and/or supervisors on completion of the on-site survey. Assure that the "*Grade "A" PMO* Milk Laboratory Evaluation Request and Agreement Form" has been signed by a representative of the facility.

After entering the laboratory, the FDA/LPET or 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 FDA/LPET or LEO should discuss the "ground rules" for the survey. Rules should be established for the observation of the analysts' technique (e.g. whether an analyst can restart a procedure if the analyst notices that they have made an error, how many times may analysts restart, etc.).

During an on-site survey of a large laboratory, various analysts may be performing different examinations, which may make a comprehensive 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 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 margins of the FDA/NCIMS 2400 Forms. By frequent referral to the noted items, the FDA/LPET or LEO 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 FDA/LPET or LEO:

1. Do not ask leading questions, e.g., do not ask analysts if plating media and dilution blanks are autoclaved at 120±1°C for 15 minutes; simply ask how media and water blanks are autoclaved;

2. Try to keep the 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, on-site survey, it is probable that some items pertinent to receiving samples may not be observed. However, the FDA/LPET or 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 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 FDA/NCIMS 2400 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 FDA/LPET or 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 FDA/LPET or 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) shall be evaluated by the FDA/LPET or 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 FDA/LPET or LEO shall serve notice that the laboratory shall not be accredited or shall have its accreditation withdrawn until such time as the laboratory agrees to abide by the voluntary accreditation program. The laboratory may make reapplication by completing the application form and stipulating that future interference or refusals shall result in non-accreditation or removal of accreditation for thirty (30) days. Or, if at any time before or during any on-site survey the FDA/LPET or LEO feels their safety is in jeopardy or determines extensive non-compliance, they may terminate the survey. The FDA/LPET or LEO shall indicate to the laboratory management the reason why the survey was terminated and shall indicate what steps must be taken before a resurvey 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 noncompliance issues have been addressed.

SECTION 7: LABORATORY EVALUATION REPORTS

EVALUATION FORMS

FDA/NCIMS 2400 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 forms may be prepared for the laboratory evaluated. The FDA/LPET or LEO shall maintain a complete copy of the survey on-site report, including forms. The laboratory/facility and FDA/LPET or LEO shall maintain, at minimum, copies of the last two (2) biennial/triennial surveys, subject to verification by the LEO and the FDA/LPET. In marking the official copies of the completed evaluation forms, leave items in compliance blank. When preparing copies for transmittal to others, do not include check marks in the margins that were made at the time of the actual on-site survey for the convenience of the evaluating FDA/LPET or LEO.

NARRATIVE REPORT

The set of completed evaluation forms for the laboratory may accompany the narrative report, which states the conclusions of the FDA/LPET or 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 shall be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA/NCIMS 2400 Forms. Each form used shall have the revision date noted in the report. Additional narrative reports, without FDA/NCIMS 2400 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 shall be accompanied by the completed FDA summary template, both attached to the same email. The LEO shall receive verification of receipt by return email and shall maintain a copy of the verification in their records. The narrative report shall identify the laboratory, give the laboratory number, show the date of the on-site survey, 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 necessary changes to the *IMS List*.

Formats suitable for narrative reports appear on pages 35 - 48.

If choosing the option to send the narrative only via electronic submission, it 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 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 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 shall be used to indicate whether the results are (or are not) acceptable to 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 on-site 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 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 FDA/LPET or LEO detailing the corrections made. Upon receipt of such letter, full accreditation/approval shall be given.

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

3. Although the procedures, records, facilities and/or equipment in use at the time of the 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 shall be

made and detailed in writing to the FDA/LPET or LEO during this period. A new survey 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 on-site 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 FDA/LPET or 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 survey.

FDA SUMMARY TEMPLATE

The narrative report sent to FDA/LPET 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 along with other useful information to be used by FDA/LPET. Only the current revision of the FDA Summary Template, authored by FDA/LPET, shall be used. There is one (1) FDA Summary Template for full service laboratories and *Grade "A" PMO*, Appendix N screening 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 LEO.

The appropriate FDA Summary Template form shall also be used for the notification of changes in accreditation and certification status and shall be submitted by email to the FDA/LPET.

Directions for completing the FDA Summary Template, authored by FDA/LPET, 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 49 - 50.

REFERENCES

1. Copies of the FDA/NCIMS 2400 Forms can be obtained from FDA/LPET, LEOs or NCIMS website.

   http://ncims.org/

   A list of FDA/LPET or LEOs can be found at the website:

   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 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 State 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: RECOMMENDED SPLIT SAMPLE COMPOSTION

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

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

EXAMPLE NARRATIVE REPORTS

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.

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. 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 ºC). 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.

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. mm/yy)

No deviations were observed.

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

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

No deviations were observed.

Charm SL Beta-Lactam Test (9C13 rev. mm/yy)

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. mm/yy)

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. mm/yy)

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. mm/yy)

No deviations were observed.

Alkaline Phosphatase Test – Advanced Instruments Fluorophos (28, rev. mm/yy)

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**	**SPLITS**
	5	9C13	9D3	12	16	20	22	24	28	**Last 2**	**Last 2**
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 on-site survey 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. 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. 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. 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 on-site survey 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 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.

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 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. 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:

Analyst	Procedures (IMS Codes)									**ON-SITE Last 2**	**SPLITS Last 2**
	9C[14]	9C[15]									
Analyst 1 CIS	N[1]	C								m/yy, m/yy	m/yy, m/yy
Analyst 2 CIS	N[1]	C								m/yy, m/yy	m/yy, m/yy
Analyst 3 IA	NA[2]									m/yy, m/yy	m/yy, m/yy
Analyst 4 IA	NA[2]									m/yy, m/yy	m/yy, m/yy

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 on-site survey 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}

DEVIATIONS AND CORRECTIVE ACTIONS:

Item Method

Appendix N – General Requirements (rev. 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. 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.

PERSONNEL & PROCEDURES APPROVED:

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

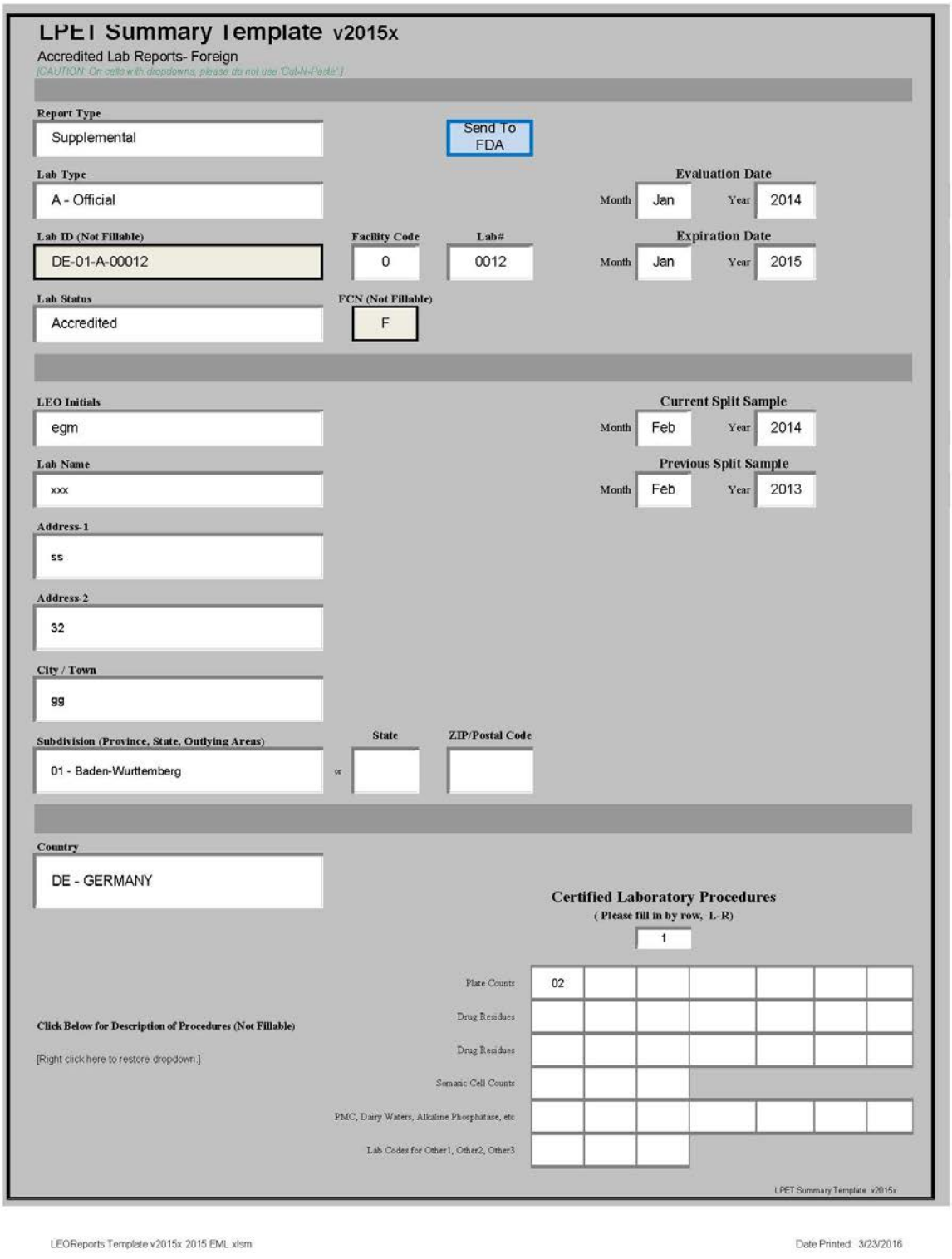
FA = Fully Approved
PA = Provisionally Approved
CA = Conditionally Approved
NA = Not Approved

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 on-site survey 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



LPET Summary Template v2015x

Accredited Lab Reports- Foreign

[CAUTION: On cells with dropdowns, please do not use 'Cut-N-Paste']

Report Type: Supplemental

Send To FDA

Lab Type: A - Official

Evaluation Date: Month Jan Year 2014

Lab ID (Not Fillable): DE-01-A-00012

Facility Code: 0

Lab#: 0012

Expiration Date: Month Jan Year 2015

Lab Status: Accredited

FCN (Not Fillable): F

LEO Initials: egm

Current Split Sample: Month Feb Year 2014

Lab Name: xxx

Previous Split Sample: Month Feb Year 2013

Address-1: ss

Address-2: 32

City / Town: gg

Subdivision (Province, State, Outlying Areas): 01 - Baden-Wurttemberg

or

State:

ZIP/Postal Code:

Country: DE - GERMANY

Certified Laboratory Procedures

(Please fill in by row, L-R)

1

Plate Counts	02						
Drug Residues							
Drug Residues							
Somatic Cell Counts							
PMC, Dairy Waters, Alkaline Phosphatase, etc							
Lab Codes for Other1, Other2, Other3							

Click Below for Description of Procedures (Not Fillable)

[Right click here to restore dropdown.]

LPET Summary Template v2015x

LEOReports Template v2015x 2015 EML.xlsm

Date Printed: 3/23/2016

Fig. 1: Summary sheet, FDA/LPET Summary Template (current in use version)

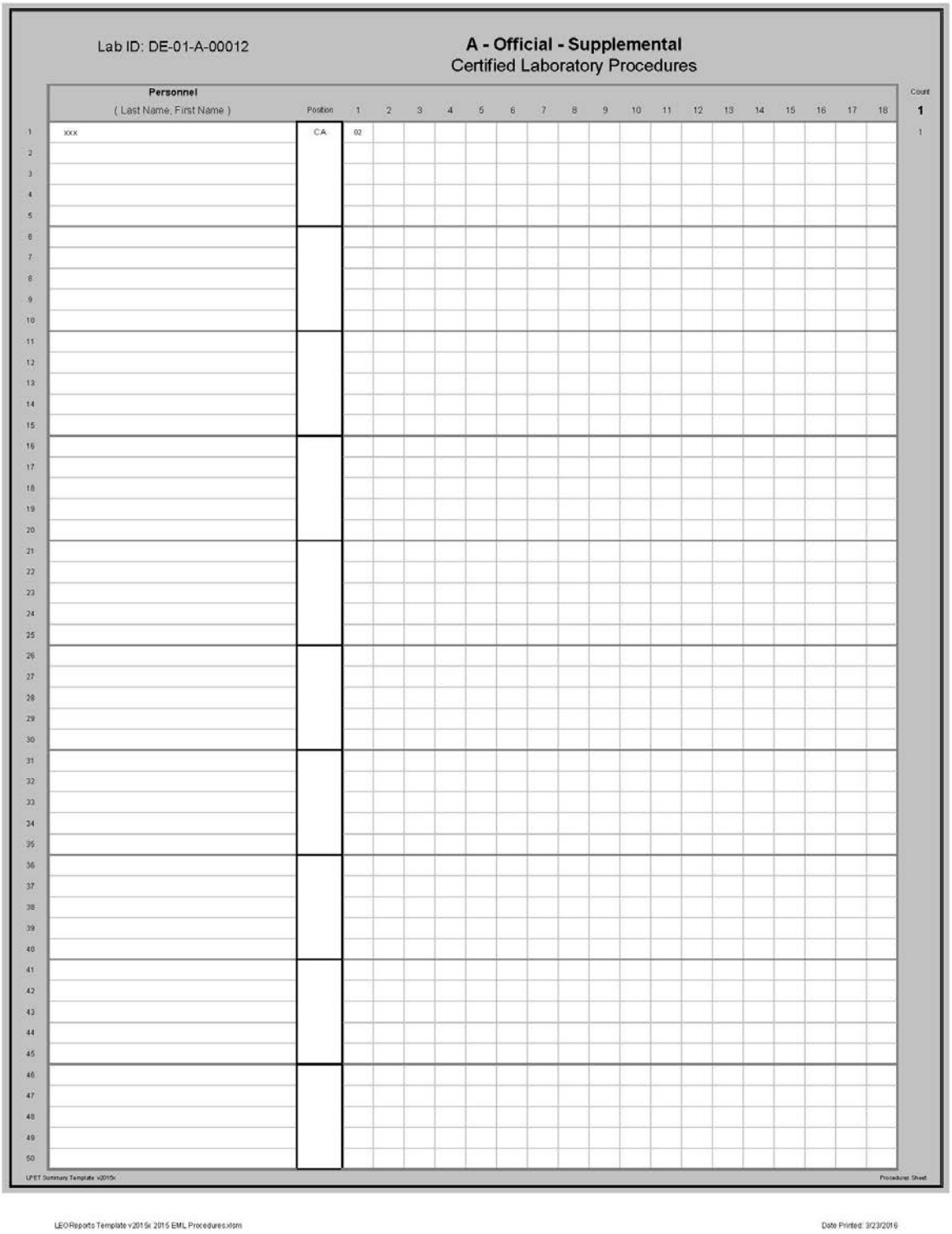


Fig. 2: Procedures sheet, FDA/LPET Summary Template (current in use version)