Evaluation of Milk Laboratories

2011 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 evaluations 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 current in use edition of the Grade 'A' Pasteurized Milk Ordinance (PMO).

The information in this booklet was revised by the Food and Drug Administration Laboratory Proficiency Evaluation Team (FDA/LPET) in conjunction with the NCIMS and its Laboratory Committee. The basic responsibility for preparation of this revision was assumed by the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, HFH-450, 6502 South Archer Road, Bedford Park, IL 60501, USA (Telephone (708) 728-4114; Fax (708) 728-4179), hereafter referred to as FDA/LPET.

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EVALUATION OF MILK LABORATORIES
2011 Revision

INTRODUCTION

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

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

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

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

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

Certified Industry Supervisor (CIS): An industry supervisor who is evaluated and listed by a State LEO as certified to conduct drug residue screening tests at industry drug residue screening

sites for PMO, Appendix N regulatory actions (confirmation of tankers, producer trace back and/or permit actions).

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

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

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

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

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

1. FDA accreditation of state central milk laboratories and certification of analysts is based on (a) satisfactory triennial on-site evaluations 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 certification of State LEOs who (1) accredit local laboratories and certify analysts and CIS based on (a) satisfactory biennial on-site evaluations of laboratory facilities, equipment, records and analyses and (b) satisfactory annual proficiency testing which meets established national standards and (2) approve IS and IA (who only screen for drugs) based on (a) 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 IA they supervise, (b) verification that each IS and IA has demonstrated proficiency in performing drug residue analysis at least biennially. Verification of proficiency may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

SECTION 1: LABORATORY EVALUATION PROGRAMS

An evaluation of a milk laboratory must include an on-site visit to 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-2400 Series Forms). The Federal or State LEO shall determine if the laboratory facilities, equipment, records and techniques of analysts are in compliance with the FDA-2400 Series Forms.

A copy of the "Grade 'A' Milk Laboratory Evaluation Request and Agreement Form" (see page 20) must be signed by a representative of the facility prior to the initiation of the survey. This document must be maintained on file by the Federal or State LEO.

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

Survey reports of on–site evaluations of Official Milk Laboratories and CISs shall be sent within 60 days of the initial, biennial/triennial anniversary or supplemental date of the laboratory evaluation to the Official Milk Laboratory/CIS, the appropriate Food and Drug Administration Regional Office and the FDA/LPET. Reports can be submitted by traditional fashion (mail, common courier) or electronically. Reports to the Official Milk Laboratories /CIS must include the narrative report and may include copies of the completed FDA-2400 Series Forms. Reports to FDA Regional Office and FDA/LPET shall be sent electronically and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

Survey reports of on-site evaluations of screening sites shall be sent to the facility within 60 days of the initial, biennial anniversary, or supplemental date of the laboratory evaluation.

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

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

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

2. Evaluations of milk laboratories within a state shall be scheduled and performed by their biennial expiration date. Milk laboratories within a state shall submit requests, in writing, for on-site evaluation of new analyst(s) performance of techniques, new methods and/or new

facilities to the State LEO. The State LEO shall schedule a mutually agreeable date within 30 days of the receipt of the request for an evaluation.

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

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

5. Analysts meet the performance levels of the proficiency testing program (SECTION 2). The State LEO may issue a certificate of approval to each laboratory analyst who meets the stated criteria in numbers 3 and 4 above. The certificate, if issued, shall indicate the specific laboratory procedure(s) for which he or she is certified or approved.

6. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2).

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 approved to conduct official examinations only if criteria 3 and 4 are met. When such analysts successfully complete the next official proficiency tests administered by the State 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 approval to conduct official examinations shall be withdrawn.

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

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

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

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

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

ACCREDITATION/APPROVAL OF MILK LABORATORIES

Accreditation or approval of milk laboratories by Federal or State milk laboratory control agencies shall be based on meeting the following requirements:

1. The laboratory facilities, equipment, procedures and records must meet the requirements stated on the appropriate FDA-2400 Series Forms and for CIS, appropriate Appendix N 2400 Series Forms, as determined by an on-site evaluation.

2. All official examinations required by the PMO must only be performed by certified analysts or CIS.

3. Vitamin testing laboratories have submitted satisfactory quality control information, use methods acceptable to the FDA or other official methodologies which give statistically equivalent results to the FDA methods, have one or more certified analysts who have satisfactorily participated in the vitamin split sample program and have met performance levels of the proficiency testing program (SECTION 2).

The State 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 2 years unless revoked.

When an accredited laboratory changes location or undergoes substantial remodeling, an evaluation of the new laboratory or screening facility is required within 3 months. No evaluation of personnel or procedures is required at this time.

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

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

the Federal or State LEO shall immediately notify the milk laboratory involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For FDA/LPET notification, changes in accreditation shall be indicated on the appropriate, completed FDA summary template and shall be submitted electronically.

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

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

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

APPROVAL OF INDUSTRY ANALYSTS/INDUSTRY SUPERVISORS

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

1. The laboratory facilities, equipment, procedures and records meet the requirements stated on the approved 2400 Series Forms associated with the Appendix N program.

2. All screening tests required by the PMO, Appendix N must only be performed by approved IS, IA or by a certified entity.

3. Analyst performance is in compliance with procedures required by the approved FDA-2400 Series Forms associated with the Appendix N program.

4. The analyst meets the performance levels of the proficiency testing program (the examination of milk split samples).

5. Approval of IS and IA require verification of proficiency in performing drug residue analyses at least biennially, through on site performance evaluation and/or analysis of split samples, or another proficiency determination that the State LEO and the FDA/LPET agree is appropriate. (PMO, Appendix N)

6. The IS has attended and received training by the State LEO. This training must be documented.

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

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

Fully approved analysts failing to meet the established applicable criteria of laboratory performance during an on-site laboratory evaluation or analysis of split samples will 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 laboratory evaluation or analysis of split samples will have their provisionally approved status revoked.

Failure by the IS or the IA to demonstrate adequate proficiency to the State LEO shall lead to their removal from the State LEO list of IS/IA. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the State LEO. Analysts not on the State LEO list of Approved IS/IA are not approved to test bulk milk in the Appendix N program.

When a screening facility loses its approval because of lack of approved IS or IA, or for some other reason, the State LEO shall immediately notify the screening facility involved, the state milk regulatory agency, the state milk sanitation rating agency, any out-of-state milk regulatory agencies where known customers are located, the appropriate FDA Regional Office and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the appropriate, completed FDA summary template and shall be submitted by email.

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

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

APPROVAL OF BACTOSCAN INDUSTRY OPERATORS

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

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

2. The laboratory must maintain one certified BactoScan analyst (see current FDA 2400 series form) for training and ongoing oversight of the BIO.

3. Refer to the BIO approved training procedures at the end of the BactoScan FDA 2400 series form.

4. The BIO meets the performance levels of the proficiency testing program (the examination of milk split samples)

5. Records are to be maintained for BIO oversight.

NOTE: A BIO can analyze samples for regulatory compliance.

SECTION 2: PROFICIENCY TESTING PROGRAMS

SPLIT SAMPLES - MICROBIOLOGY

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

State milk laboratory control agencies having less than 10 analysts (total) in their milk laboratory program are to develop joint state proficiency testing programs with other states which 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 will be made by a determination that the State LEO and the FDA/LPET agree is appropriate.

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

1. When an analyst examines both raw milk for pasteurization and pasteurized milk and milk products, a minimum of twenty-two (22) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests, categories, types and recommended duplicates of milk products are shown in Table 1, page 27.

2. When an analyst examines only raw milk for pasteurization, a minimum of fourteen (14) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

3. When an analyst examines only pasteurized milk and milk products, a minimum of sixteen (16) samples shall be examined by the analyst using those procedures for which the analyst has been approved unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

4. When a CIS examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kit(s) for which that CIS is certified or approved, or for which the CIS is seeking certification. In general, the milk samples shall consist of the members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect as well as milk samples containing no animal drug residues. The CIS may misidentify one of the samples and maintain and/or gain certification. If more than one sample is misidentified, the CIS falls one level of certification. If this occurs twice consecutively, the CIS is no longer certified or approved (rules for Recertification of laboratories apply).

5. When an IS or an IA examines bulk milk tanker milk or its equivalent for Appendix N purposes, a minimum of eight (8) samples shall be analyzed utilizing the test kits for which that IS or IA is approved or for which the IS or IA is seeking approval. In general, the milk samples shall consist of members of beta-lactam family, at the safe/tolerance levels, which the test kits are designed to detect as well as milk samples containing no animal drug residues. The IS or IA may misidentify one of the samples and maintain and/or gain approval. If more than one sample is misidentified, the IS or IA falls one level of approval. If this occurs twice consecutively, the IS or IA is no longer approved. Re-instatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the State LEO.

6. Each analyst certified to perform visual drug residue tests will participate in annual proficiency tests to demonstrate 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 must be correct. If eight (8) samples are used, an analyst/CIS may miss one (1) and still pass the proficiency test.

7. An acceptable annual proficiency testing program for the BactoScan FC (all NCIMS approved models), shall meet the following applicable criteria.

   (a) The BactoScan FC (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC and for which the analyst or BIO has been certified/approved, respectively.
   (b) Split samples (minimum of 14) shall be made up using BactoScan FC Blank solution and BactoScan FC Bacteria Control Samples.
   (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1, page 27.

SPLIT SAMPLE ANALYSIS

The Standard Plate Count (SPC), Petrifilm Aerobic Count (PAC), Plate Loop Count (PLC), BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count (DMSCC), Electronic Somatic Cell Count (ESCC), Electronic Phosphatase Count and Vitamin A and D_3 result of each certified analyst shall fall within the limits shown in Table 2, page 28.

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

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

2. Calculate the logarithmic mean for the Standard Plate Count, Petrifilm Aerobic Count, Plate Loop Count, BactoScan FC Count (BSC), Spiral Plate Count Method (SPLC), Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase

Count and Vitamin A and D_3 results of each test sample; using a table of common logarithms, list the logarithms of all analyst counts for a given sample. Calculate the mean of the logarithms for the sample.

3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each analyst's result the limit (sample mean ± L_1). Results falling outside the limit are classified as outliers and are unacceptable. Note by sample and test, the analysts who have results outside of the limits.

4. Determine for each sample for each test whether there are analyst results outside of the Rejection Limit (L_2). Remove unacceptable analyst result and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each analyst's result the limit (sample mean ± L_2). Results falling outside the limit are classified as "out of limits" and are unacceptable. Note by sample and test, the analysts who have results outside of these limits.

5. Using Table 3, page 26, list all analysts who have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.

6. Analysts certified for vitamin analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28.

7. An acceptable annual proficiency testing program for the BactoScan FC Count (all NCIMS approved models), shall meet the following applicable criteria.

   (a) The BactoScan FC Count (all NCIMS approved models) shall be used to examine a minimum of fourteen (14) samples and be operated by a certified analyst or an approved BIO using the procedures approved to operate the BactoScan FC Count and for which the analyst or BIO has been certified/approved, respectively.
   (b) Split samples (minimum of 14) shall be made up using BactoScan FC Blank solution and BactoScan FC Count Bacteria Control Samples.
   (c) Value ranges (count ranges) and dilutions shall be made to achieve the levels as set by the FDA. Recommended duplicates of samples are shown in Table 1 page 27.

ANALYST PERFORMANCE LEVEL

Analysts certified to perform the examinations required by the "Grade 'A' PMO" shall meet the following performance levels on an annual basis.

1. Analysts certified to perform the Standard Plate Count, Petrifilm Aerobic Count, Plate Loop Count, BactoScan FC, Spiral Plate Count Method, Direct Microscopic Somatic Cell Count, Electronic Somatic Cell Count, Electronic Phosphatase Count and Vitamin A and D_3 analysis, and BIOs approved to operate a BactoScan FC shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

2. Analysts certified to perform inhibitor tests shall detect samples that contain beta-lactam or other animal drug residues detectable by the appropriate official test for the drug and product. If using drug other than beta-lactam, samples must be spiked in duplicate. See Table 3, page 28.

3. Analysts certified to perform phosphatase tests shall detect samples that contain residual phosphatase detectable by appropriate official test methods. Analysts certified for Electronic Phosphatase Count methods shall detect samples that contain between 100 and 2,500 mU (the majority of values at the action level of 350 mU) within the specified limits in Table 2, page 28.

4. Analysts certified for the coliform procedure shall qualitatively detect and verify coliform organisms in samples containing at least five (5) but not greater than ten (10) coliform organisms per milliliter or gram of product. See Table 3, page 28.

5. Certified Industry Supervisors certified to perform Appendix N test(s) for beta-lactam drugs shall detect members of the beta-lactam family, at the safe/tolerance levels, which the test kit(s) is designed to detect. See Table 3, page 28.

Fully certified analysts not meeting the described performance levels shall be provisionally certified for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally certified analysts can regain full certification status by meeting satisfactory performance levels on the next set of split samples. If a provisionally certified analyst does not meet satisfactory performance levels on the next set of split samples, certification to perform the specific test(s) will be withdrawn. An analyst who has lost certification may be required to participate in a training program acceptable to the milk laboratory certifying authority before requesting recertification. Recertification after training shall be based on the analyst meeting the certification criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS. A certified analyst may only become conditionally approved again by the route by which he/she lost certification, i.e. if the analyst lost certification due to failure on milk split samples then he/she can only become conditionally certified by passing the next set of milk split samples. If the analyst failed an on-site evaluation that leads to his/her loss of certification then he/she must pass the next on-site certification to become conditionally certified.

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

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

SPLIT SAMPLES – CHEMISTRY

VITAMINS

The Vitamin Proficiency Test Program is operated by the FDA/LPET. In order to be accredited and be listed, laboratories must have analysts who have satisfactorily participated in at least two consecutive split sample analyses and must 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 Vitamin Proficiency Testing Program involves the analysis of sets of four samples sent to participating laboratories every four (4) months, i.e., three times a year with a total of twelve (12) samples. Certification status is based in part on the ability of analysts to analyze samples and have their results fall within limits (L_1=0.300 and L_2=0.200, based on the statistical parameters set at the 1995 NCIMS Conference in St. Louis, MO). Conditional certification is granted to an analyst (not to a laboratory) when the analyst has satisfactorily analyzed two sets of samples (eight (8) samples in two consecutive shipments). Analysts may have one (1) unsatisfactory result, i.e., miss (out of limits) one 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 year period (twelve (12) consecutive samples analyzed).

Once fully certified, analysts maintain certification by satisfactorily analyzing all three (3) sets of split samples each year. During the course of the year full certification is maintained if no more than two samples (of 12) are missed. Failure without cause to analyze all twelve (12) samples during the course of the year will result in the down grading 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 samples (of 12) then that analyst will be down graded to provisional certification. Full certification will be regained if that analyst misses no more than one sample of the next eight (8) that he/she analyzes. Provisionally or conditionally certified analysts that miss more than one (1) sample in the next eight samples analyzed after receiving the respective status will have certification/approval removed.

Once certification/approval is removed an analyst may only regain conditional certification by satisfactory performance on the next eight samples, i.e., miss no more than one (1) sample. Full certification requires that the analyst meet the criteria described above.

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

Re-entry of laboratories that have voluntarily withdrawn or laboratories that have had their accreditation removed is subject to meeting all requirements needed from a new laboratory, including all quality control (QC) information. It is the responsibility of the laboratory to inform the FDA/LPET when a certified analyst is no longer employed at that laboratory. A laboratory

that loses all of their certified analysts is no longer accredited to do official work and must seek new laboratory entry prior to resuming official analysis.

An acceptable annual proficiency testing program shall consist of the analyst examining pasteurized milk and milk products for Vitamins A and D_3, a minimum of four (4) samples three (3) times a year for a total of twelve (12) samples annually using the methods developed by the FDA, or methods that give statistically equivalent results to the FDA methods, for which the analyst has been approved, unless excused for due cause. The laboratory tests and recommended duplicates of samples are shown in Table 1, page 27.

WATER MICROBIOLOGY

Laboratories using EPA or State administrated programs for water analysis are not required to meet the intentions of this Section. State administered programs include central, official, officially designated and other water testing laboratories sanctioned by the state and participation in a split sample program is voluntary.

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

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

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

SPLIT SAMPLE ANALYSIS

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

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

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

2. Calculate the logarithmic mean for the multiple tube fermentation, membrane filtration and heterotrophic plate count for each test sample; using a table of common logarithms, list the logarithms of all counts for a given sample. Calculate the mean of the logarithms for the sample.

3. Determine for each sample for each test whether there are results outside of the Rejection Limit (L_1). Rejection results are identified by applying to each laboratory's result the limit (sample mean ± L_1). Results falling outside the limit are classified as outliers and are unacceptable. (Note by sample and test, the laboratories that have results outside of the limits.)

4. Determine for each sample for each test whether there are laboratory results outside of the Rejection Limit (L_2). Remove unacceptable laboratory results and re-compute the mean of each sample if results have been rejected in accordance with 3 above. If there are none, use the same means calculated in 2 or 3 above. Rejection results are identified by applying to each laboratory's result the limit (sample mean ± L_2). Results falling outside the limit are classified as "out of limits" and are unacceptable. (Note by sample and test, the laboratories that have results outside of these limits.)

5. Using Table 3, page 26, list all laboratories that have more than the maximum number of sample results per test classified as unacceptable by either the L_1 or L_2 or both limits.

6. Laboratories accredited for dairy water analysis shall meet the acceptance limits (L_1 and L_2) and performance levels shown in Tables 2 and 3, page 28.

LABORATORY PERFORMANCE LEVEL

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

1. Laboratories accredited to perform the multiple tube fermentation, membrane filtration, heterotrophic plate count and chromogenic substrate analysis shall meet the acceptance limits and performance levels shown in Tables 2 and 3, page 28.

2. Laboratories accredited for presence-absence procedures shall qualitatively detect and verify coliform organisms in samples containing coliform organisms.

Fully accredited laboratories not meeting the described performance levels shall be provisionally accredited for the test procedure(s) in which they exceed the maximum number of unacceptable results on samples. Provisionally accredited laboratories can regain full accreditation status by meeting satisfactory performance levels on the next set of split samples. If a provisionally accredited laboratory does not meet satisfactory performance levels on the next set of split samples, accreditation to perform the specific test(s) will be withdrawn. A laboratory that has lost accreditation must participate in a training program acceptable to the milk laboratory certifying authority before requesting reaccreditation. Re-accreditation after training shall be based on the laboratory meeting the accreditation criteria described in SECTION 1: LABORATORY EVALUATION PROGRAMS.

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

SECTION 3: CERTIFICATION OF LABORATORY EVALUATION OFFICERS

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

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

2. The individual must submit an acceptable written report of the milk laboratory initial check survey to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

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

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

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

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

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

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

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

2. The individual must submit an acceptable written report of the milk laboratory check survey to the FDA/LPET within 60 days of the evaluation. Reports to FDA Regional Office and FDA/LPET shall be sent by email and shall include the narrative report and appropriate, completed FDA summary template only (see page 37 – 40).

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

4. The individual must have prepared and transmitted, at least annually, a summary list of certified and approved analysts and procedures by laboratory to the state milk sanitation rating agency and the FDA/LPET.

5. The individual has met the responsibilities for the training of Industry Supervisors.

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

7. The individual must not fail, without cause, to attend an FDA Regional Milk Seminar. If a region holds a FDA Regional Milk Seminar, then State LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year the State LEO may opt to attend that seminar in lieu of attending the seminar held in their region and still meet the requirement.

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

Laboratory evaluations conducted by provisionally approved State LEOs will be considered official.

Should a provisionally certified State LEO meet the criteria specified by their action plan and EML, SECTION 3, their certification will be returned to full certification once they have successfully undergone their next check evaluation with the FDA/LPET.

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

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

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

SECTION 4: EQUIPMENT AND APPARATUS OF AID TO EVALUATION OFFICERS

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

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

SECTION 5: GUIDELINES FOR CONDUCTING LABORATORY EVALUATIONS

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

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

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

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

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

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

Before beginning the survey, the Federal or State LEO should discuss the "ground rules" for the survey. Rules should be established for procedural evaluations (e.g. whether an analyst can restart a procedure if the analyst notices that he/she make an error, how many times may an analyst restart...).

During an evaluation of a large laboratory, various analysts may be performing different examinations which may make a comprehensive evaluation 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 officer establish a schedule so as to be in a position to evaluate apparatus and procedures used in the laboratory without disrupting, as far as

possible, the routine examination of samples. Since it is expected that various portions of the evaluation forms will be used at separate times, it is advisable to note observed items of the various procedures on the left hand margins of the evaluation forms. By frequent referral to the noted items, the Federal or State LEO will be reminded to observe all laboratory procedures in use and avoid misuse of the phrase "undetermined" (U) when procedures were actually in use but were not observed.

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

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

2. Try to keep the evaluation on an informal basis and to minimize nervousness on the part of analysts, e.g., do not over emphasize the evaluation of procedures by unusually close physical observation; and

3. Stay alert during the observation of procedures so as to avoid necessary requests to repeat a technique overlooked during a procedure.

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

1. Do the samples arrive at the laboratory as specified in the appropriate FDA-2400 Series Forms?

2. Are the samples suitably identified as to date, temperature and time of pickup, identification of sampler (e.g. name or initials) and sample identification or this information is readily available?

3. Is an extra sample or pilot container of appropriate size provided as a temperature control (TC)?

4. Are the raw milk sample containers no more than three-quarters (3/4) full?

5. Are samples ever rejected because they are outside of the acceptable temperature range at the time of pick-up from a sample storage depot or arrival at the laboratory, are samples ever rejected because they are too full or not properly identified?

6. How many hours pass (from initial time of collection of samples) before samples are plated?

Deviations are to be discussed with the analysts at some time after it has been observed and properly recorded. This discussion should include the nature of the deviation, any effect on

validity of results, remedial action suggested and reasons justifying the change. All interested personnel should have an opportunity to look over the completed evaluation form and each major deviation should be discussed by the officer with interested staff. At that time comments should be invited from the staff concerning the evaluation. The Federal or State LEO should make suggestions concerning any needed improvement of laboratory techniques. Following the discussion of procedures and competence of analysts, past split sample results of the laboratory should be discussed, suggestions made for improvement, and/or commendations made for superior performance.

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

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

SECTION 6: LABORATORY EVALUATION REPORTS

EVALUATION FORMS

FDA-2400 Series Forms shall be completely identified with the name of the laboratory, the laboratory number, its location, date and the name of the individual making the evaluation when the option to send them with the narrative report is used. Forms pertaining to procedures not used should not be returned with the report.

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

NARRATIVE REPORT

The set of completed survey forms for the laboratory may accompany the narrative report which states the conclusions of the Federal or State LEO as to whether or not the laboratory is doing acceptable work. If the completed evaluation forms do not accompany the narrative report, the report must be sufficiently detailed to allow readers to determine what is being cited without having to refer to the FDA-2400 Series Forms. Each form used shall have the revision date noted. Additional narrative reports, without FDA-2400 Series Forms, are to be sent to others that need to be informed as to the outcome of the laboratory survey. The copy of the narrative report submitted by email to FDA/LPET must be accompanied by the appropriate, completed FDA summary template, both attached to the same email. The State LEO must receive verification of receipt by return email and must maintain a copy of the verification in their records. The narrative report must identify the laboratory, give the laboratory number, show the date of the survey, who made the survey, list the prior status, list the date of the last on-site survey, indicate the present status, what recommendations were made to correct any deviations, what test(s) were approved, and who was certified to do them.

Formats suitable for narrative reports appear on pages 29 - 36.

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

A paragraph headed "Remarks" or "Recommendations" may be included if the officer wishes to comment on an item, e.g., one which could be improved by a change in procedure or by new equipment, or for any comment which is not appropriately covered in other Sections of the report.

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

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

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

CONCLUSIONS

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

   Explanation: Unqualified acceptance of the laboratory.

2. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation 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 30 - 60 days pending correction of the deviations and receipt of a letter by the evaluation officer detailing the corrections made. Upon receipt of such letter, full accreditation/approval will be given.

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

3. Although the procedures, records, facilities and/or equipment in use at the time of the evaluation did not substantially comply with the requirements of the *Grade 'A' PMO*, the analyst/facility/equipment/records deviations noted are readily correctable. This laboratory is accredited/approved for (___) days pending correction of the deviations. Corrections must be made and detailed in writing to the evaluation officer during this period. A new survey will 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 State LEO, a period of no more than 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.

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

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

FDA SUMMARY TEMPLATES

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

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

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

An example of a completed FDA summary template for each application appears on pages 37-40.

REFERENCES

1. Copies of the FDA-2400 Series Forms can be obtained from Federal or State LEO(s).

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

   Once at that website:

   For Federal LEOs click on the link FDA CFSAN Personnel and scroll down to the Laboratory Proficiency and Evaluation Team.

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

TABLE 1: SPLIT SAMPLE COMPOSITION

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

a - One of these samples serves as the temperature control (TC).
b - These two (2) samples are tested for both residual and reactivated phosphatase
c - This analysis is optional.

TABLE 2: STATISTICAL LIMITS

TEST	REJECTION LIMIT 1 (L_1)*	REJECTION LIMIT 2 (L_2)*
Plate Counts	0.268	0.179
Direct Somatic Cell Count	0.300	0.200
Electronic Somatic Cell Count	0.212	0.143
Vitamins	0.300	0.200
Electronic Phosphatase Count	0.300	0.200
Dairy water MPN	0.949	0.632
Heterotrophic Plate Count	0.300	0.200

* To be used with logarithmic mean.

TABLE 3: MAXIMUM 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 REPORT #1

Report of a Biennial On-Site Evaluation

of

City Health Department Milk Laboratory

Accredited Laboratory
NCIMS LAB #####

100 South Main Street
City, State 78000

On

March 1, 2010

By

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

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

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

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

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

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

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

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

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

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

2. Records

2e Corrections to all records follow appropriate requirements

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

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

Send copies of the March and April autoclave records.

3. Thermometers

3a NIST Thermometer

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

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

3c3 No tag was found on the freezer thermometer

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

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

Send a copy of the tag.

5. Freezer

5b Maintains -15C or below

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

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

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

13. Autoclave

13i Performance check

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

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

TECHNIQUES

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

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

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

10. Collection of Surface Rinse Samples

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

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

Use aseptic technique when adding the rinse solution.

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

No deviations noted.

DMSCC (IMS# 12 rev. 2/10)

21. Sample Measurement

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

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

Take the syringe and hold it vertically against the slide, depress the plunger slowly allowing the milk to be expelled. Then touch off to a dry spot.

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

No deviations noted.

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

15. Instrument and Reagent Checks

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

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

No deviations noted.

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

No deviations noted.

PERSONNEL & PROCEDURES OBSERVED

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

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

CONCLUSION

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

Sincerely,
LEO

EXAMPLE REPORT #2

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

Certified Laboratory
NCIMS Lab #####

Certified Industry Supervisor
CIS #####

Appendix N Screening Site

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

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

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

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

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

The following is a summary of the recent evaluation of your milk laboratory in accordance with the requirements of the Grade 'A' PMO. If forms accompany the narrative then deviated items are marked with an "X" on the evaluation forms. Items marked "U" are undetermined because of local conditions at the time of the evaluation. Laboratory procedures and/or equipment marked "O" are not used. Items marked "NA" are optional procedural techniques and/or equipment not applicable to designated laboratory procedures. Repeat deviations are marked by an asterisk "*". Noted items are not considered deviations. The phrase "Note" as used in these narrative reports is to suggest or remark upon items which would improve laboratory functions. These are usually considered to be good laboratory practices but are not listed in the FDA-2400 Series Forms and are not debitable items.

DEVIATIONS AND CORRECTIVE ACTIONS

ITEM **METHOD**

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

CERTIFIED LAB

3. Thermometers

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

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

APPENDIX N LAB

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

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

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

TESTS-LIST ALL TESTS OBSERVED and DEVIATIONS OF TECHNIQUES.

CERTIFIED LAB

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

5. Sample Agitation

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

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

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

APPENDIX N LAB

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

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

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

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

PERSONNEL AND PROCEDURES CERTIFIED

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

CERTIFIED LAB

PERSONNEL AND PROCEDURES CERTIFIED

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

[X denotes full certification in the indicated procedures pending acceptable performance in the annual proficiency testing program (split sample) for all procedures for which certification has been granted. P denotes provisional certification pending acceptable performance in the annual

proficiency testing program for all procedures for which certification has been granted. C denotes conditional certification pending acceptable performance in the annual proficiency testing program for all procedures for which certification has been granted. N denotes no certification status granted.].

APPENDIX N LAB

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

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

CONCLUSION

Use the proper conclusion found on pages 24 & 25.

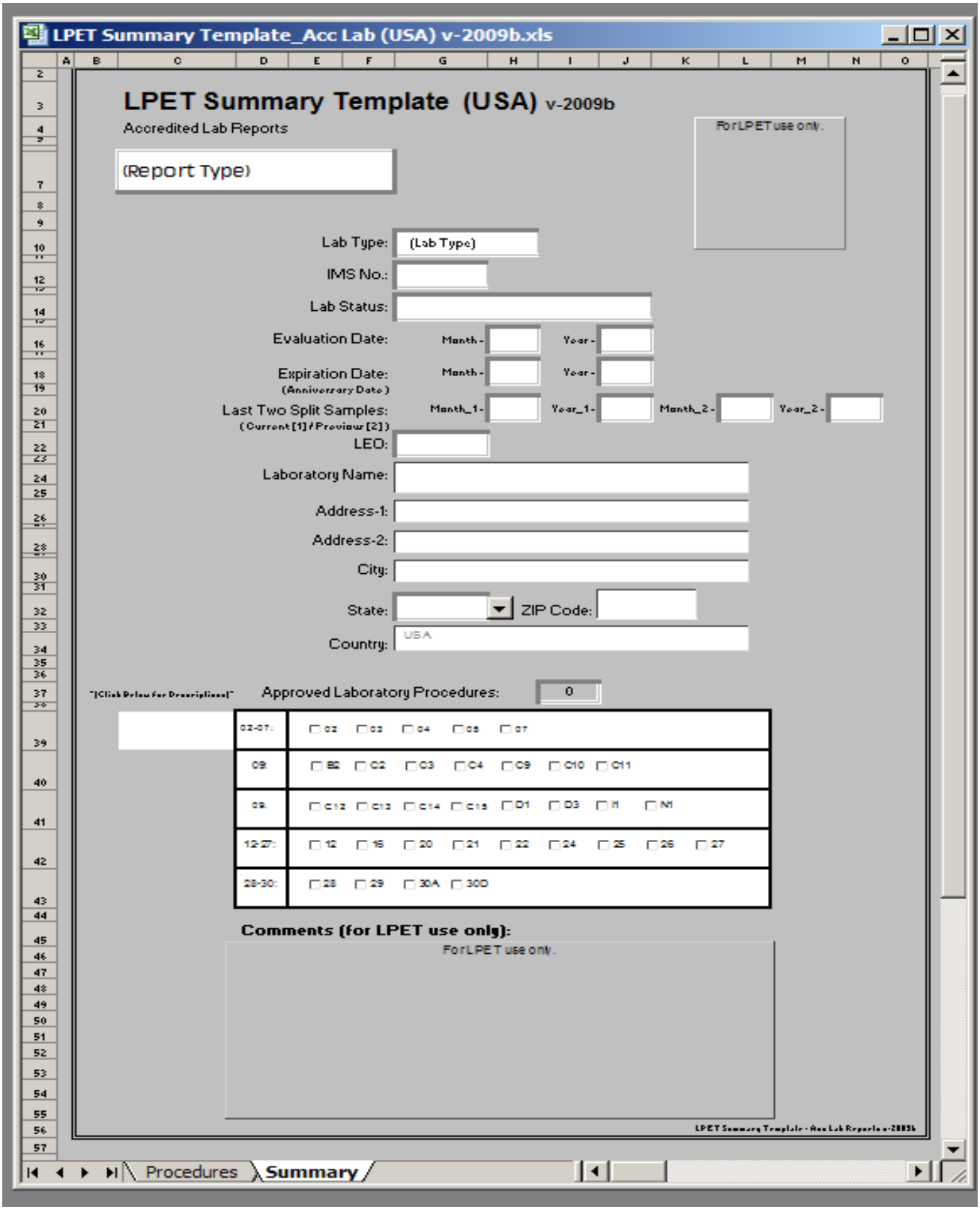

Figure 1: Summary sheet, LPET Summary Template_AccLab (USA) v-2009b.xls

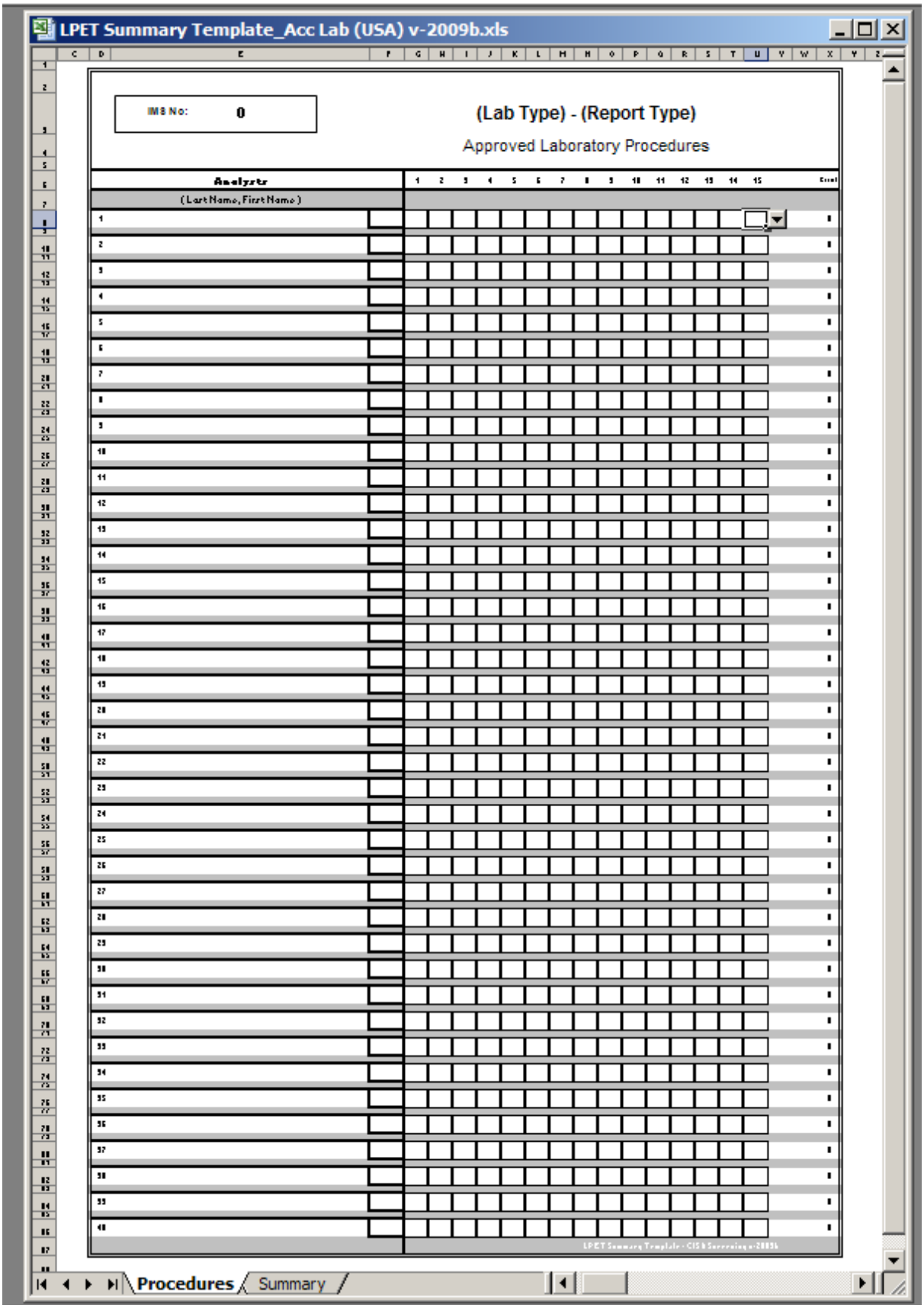

Figure 2: Procedures sheet, LPET Summary Template_AccLab (USA) v-2009b.xls

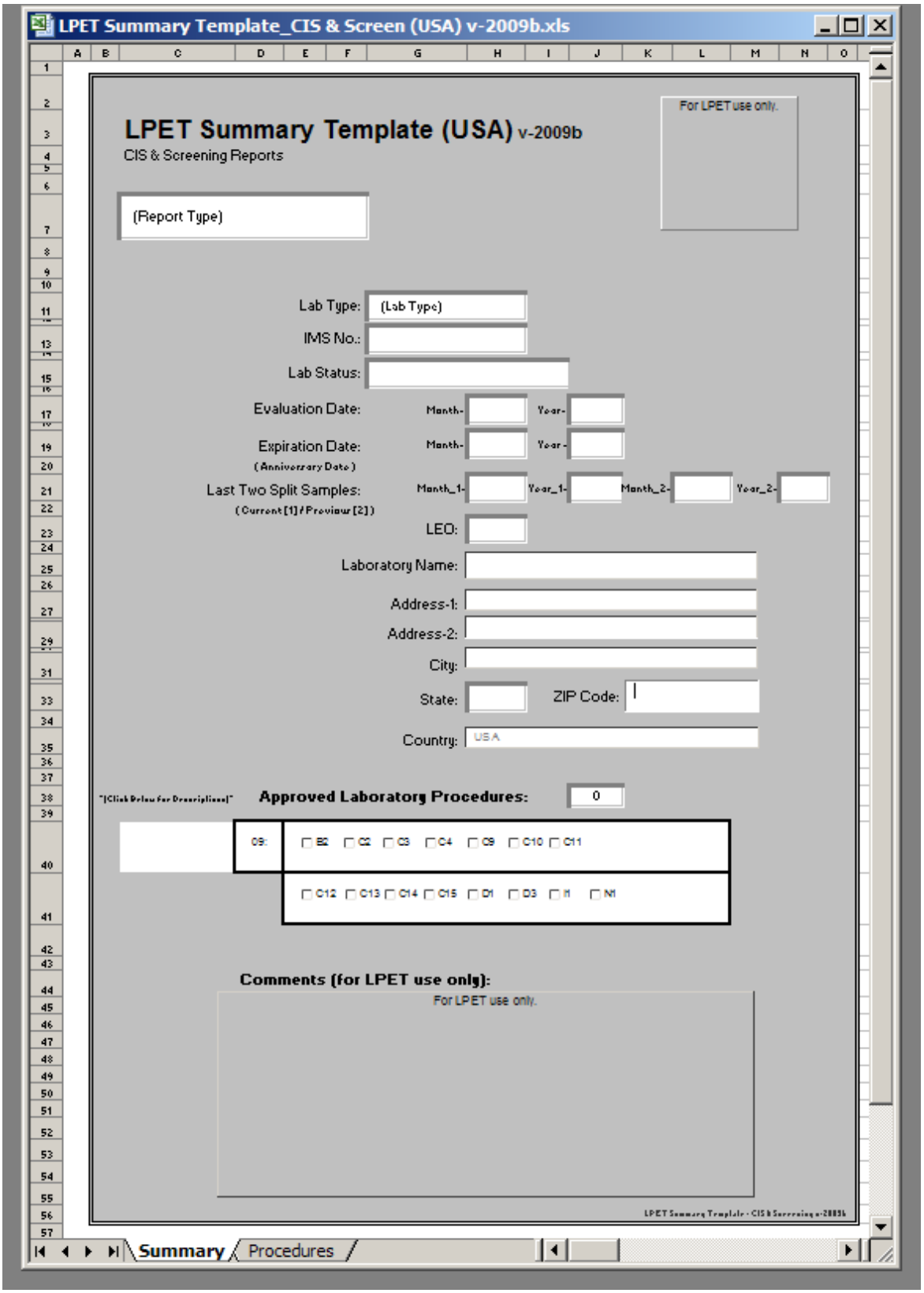

Figure 3: Summary sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls

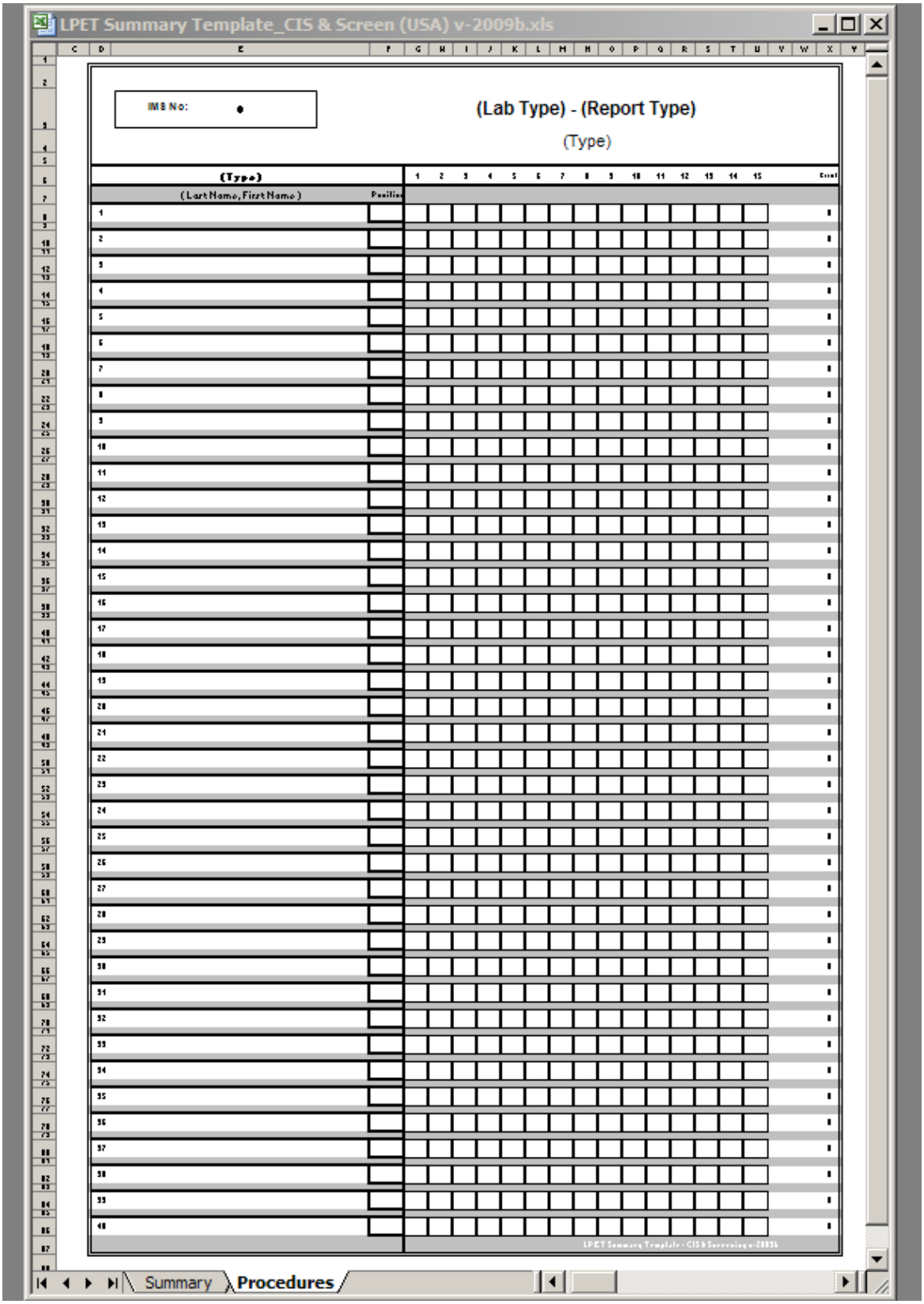

Figure 4: Procedures sheet, LPET Summary Template_CIS & Screen (USA) v-2009b.xls