Reports and Records: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate or notified of satisfactory re-certification. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a ledger of the percentage agreement on individual items, shall be retained by the Regulatory Agency.
Revocation of Certification: The certification of an industry inspector may be revoked by the Regulatory Agency upon a finding that the inspector is:

1. Not in agreement with the Regulatory Agency at least eighty percent (80%) of the time on Items of sanitation in a field examination conducted as described in the **Field Procedure** outlined above; or
2. Not complying with the established administrative procedures of the Regulatory Agency for the program; or
3. Failing to carry out the provisions of this *Ordinance* in the course of the inspector's work.

INSPECTION/AUDIT REPORTS: A copy of the inspection/audit report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection/audit forms are identified in Appendix M.

NOTE: The option to use Certified Industry Inspection as cited in this Section, shall not be applicable to a TPC authorized under the ICP.

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

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

1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or
2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk

from a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. for processing at that location.

During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging, shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.
During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging,
During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products shall be exempt from the sampling and testing requirements of this Item.

NOTE: If the production of any Grade "A" condensed or dry milk product as defined in this *Ordinance* is not on a yearly basis, at least five (5) samples shall be taken within a continuous production period.

Samples of milk and/or milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer.
Samples of milk and/or milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and/or milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk and/or milk products are obtained.

NOTE: The sampling of milk and/or milk products from locations where milk and/or milk products are sold as cited above, shall not be applicable to a TPC authorized under the ICP.

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, aseptic processing and packaging, or retort processed after packaging. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.
All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

NOTE: When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts, somatic cell counts, coliform determinations or cooling temperatures.
Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.
Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and milk and/or milk products as defined in this *Ordinance* shall not be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.
Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.
Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (*SMEDP*) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of Association of*

Official Analytical Chemists (*AOAC) INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures*.

Each milk plant regulated under the NCIMS voluntary HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section 7 of this *Ordinance*. The Regulatory Agency shall monitor and verify that appropriate action(s) was taken by the milk plant.

Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing shall continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a potential problem is to be based on relevant scientific information.

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual.

In addition, all milk plants fortifying milk and/or milk products with vitamins shall keep volume control records. These volume control records shall cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of milk and/or milk products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (Refer to Appendix E. Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures.)

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

1. Bacterial count at 32ºC (89.6°F) (Standard Plate Count (SPC) or Petrifilm Aerobic Count (PAC) methods).
2. Alternate methods, for bacterial counts at 32°C (89.6°F), including the Plate Loop Count (PLC), Spiral Plate Count and the BactoScan FC for raw milk.
3. Coliform count at 32ºC (89.6°F) (Coliform Plate Count, Petrifilm Coliform Count (PCC) and/or High Sensitivity Coliform Count (HSCC) methods) for all milk and/or milk products.
4. A viable bacterial count of nonfat dry milk shall be made in accordance with the procedures in *SMEDP* for the SPC of Dry Milk, except agar plates shall be incubated for 72 hours.
5. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current safe or tolerance levels, shall be used for each Beta lactam drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam drug test kits available. (Refer to M-a-85, latest revision, for the approved drug tests and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved drug tests available.) Regulatory action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N.) A result shall be considered positive for Beta lactam if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV of Appendix N.
6. Screening and Confirmatory Methods for the Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.
When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy farm should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time.

a. Milk (Non-Goat): Any of the following confirmatory or screening test procedures shall be used: Single Strip Direct Microscopic Somatic Cell Count (DMSCC) or Electronic Somatic Cell Count (ESCC).

b. Goat Milk: DMSCC or ESCC may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,500,000/mL. Screening for official purposes shall be conducted by an analyst (s) certified for that procedure.

Only the Pyronine Y-Methyl Green stain or "New York modification" Single Strip DMSCC test procedures shall be used to confirm the level of somatic cells in goat milk by certified analysts.

c. Sheep Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results from the Single Strip DMSCC procedure exceed the 750,000/mL standard set forth in this *Ordinance*, the count shall have been derived from, or be confirmed by, the Pyronine Y Methyl-Green Stain or the "New York modification".

7. Electronic Phosphatase Tests: The phosphatase test is an index of the efficiency of the pasteurization process. In the event an accredited laboratory finds that a sample confirms positive for phosphatase, the pasteurization process shall be investigated and corrected. When a laboratory phosphatase test is confirmed positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7, Item 16p, the

Regulatory Agency should immediately conduct field phosphatase testing at the milk plant. (Refer to Appendix G.)
8. Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.
9. Any other tests, which have been approved by FDA to be equally accurate, precise and practical.
10. All standards used in the development and use of drug residue detection methods designed for *Grade "A" PMO* monitoring programs shall be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method shall define the standard to be used.
11. Procedural or reagent changes for official tests shall be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: *SMEDP* contains guidance for the sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. for a reference to drug residues in milk and/or milk products and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)
When samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging are taken at a milk plant prior to pasteurization, ultra-pasteurization, aseptic processing and/or retort processing, respectively, they shall be drawn following adequate agitation from randomly selected storage tanks/silos. All counts and temperatures shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used.

NOTE: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO*, Section 6 and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

All Grade "A" raw milk and/or milk products for pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging and all Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, or retort processed after packaged low-acid milk and/or milk products, shall be produced, processed**,** manufactured and pasteurized, ultra-pasteurized, aseptically processed and packaged, or retort processed after packaged to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.
No process or manipulation other than pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and/or milk products for the purpose of