

Bulk Milk Hauler/Sampler Study Materials

Arizona Department of Agriculture

* Includes materials from the *Pasteurized Milk Ordinance* and the *USDA Farm Bulk Milk Haulers Manual*



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

ADDRESS OF BULK MILK HAULER / SAMPLER OWNER ADDRESS OF OWNER	NAME AND ADDRESS OF INSPECTION LOCATION NAME AND ADDRESS OF RECEIVING PLANT
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An evaluation of your sampling procedures showed violations existing in the Items checked below. You are further notified that this evaluation report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

HAULER SANITATION PROCEDURES

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

BULK TANK SAMPLING PROCEDURES

- 9. Thermometer – Approved Type
 - a. Accuracy – Checked against standard thermometer every 6 months – accuracy (+)(-) 1 division
 - b. Date checked and checker's initials attached to case
- 10. Sample Transfer Instrument
 - a. Clean, sanitized or sterilized and of proper construction and repair
 - b. Sterile needle for aseptically dispensing a milk sample from the bulk tank sample septum into a sample container (i.e., vial)
 - c. Or an approved in-line sampler
 - d. Or an approved aseptic sampler
 - e. Or a sanitized sampling cock
- 11. Sampling Instrument Container
 - a. Proper design, construction and repair for storing sample dipper in sanitizer
 - b. Applicable test kit for checking strength of sanitizer (200 ppm chlorine or equivalent)
- 12. Sample Containers
 - a. Clean, properly sanitized or sterilized.....
 - b. Adequate supply, properly stored or handled
- 13. Sample Storage Case
 - a. Rigid construction, suitable design to maintain samples at 0°C - 4.4°C (32°F - 40°F), protected from contamination
 - b. Ample space for refrigerant, racks provided as necessary
- 14. Sample Collection – Precautions and Procedures
 - a. Sampling instrument and container(s) properly carried into and aseptically handled in milkhouse
 - b. Bulk tank milk outlet valve sanitized before connecting transfer hose
 - c. Smell milk through tank port hole
 - d. Observe milk in a quiescent state with lid wide open and lights on when necessary

- e. Test thermometer sanitized (1 min. contact time)
- f. Non-acceptable milk rejected
- g. Dry measuring stick with single-service paper towel
- h. Measure milk only when quiescent
- i. Do not contaminate milk during the measuring process
- j. Agitate milk before sampling at least 5 min. or longer as may be required by tank specifications
- k. Do not open bulk tank valve until milk is measured and sampled
- l. Temperature of milk, time, date of pickup and bulk milk hauler/ sampler name and license or permit no. recorded on each farm weight ticket
- m. Tank thermometer accuracy
 - 1. Tank thermometer accuracy checked monthly and recorded when used as test thermometer
 - 2. Accuracy of required recording thermometer checked monthly against standardized thermometer and recorded
- n. Temperature control sample provided at first sampling location for each rack of samples
- o. Temperature control sample properly labeled with time, date, temperature, producer ID and bulk milk hauler/sampler identification
- p. Sample containers legibly identified at collection points
- q. Sample dipper rinsed at least two times in the milk before transferring sample
- r. Dipper should be extended 6-8 inches into the milk to obtain a representative sample
- s. Sample cock properly sanitized and flushed prior to sampling
- t. Septum surface properly sanitized and single service sterile needle used
- u. Do not hold sample container over the milk when transferring sample into the container
- v. Fill sample container no more than ¾ full
- w. Rinse sample dipper in safe tap water, return to storage container, open tank valve, start milk transfer pump
- x. Immediately place milk sample in the sample case
- 15. Sample Collection – Storage and Transportation
 - a. Sample storage – refrigerant maintained no higher than milk level in sample containers – maintain sample temperature – 0°C - 4.4°C (32°F - 40°F), do not bury tops of containers in ice, protect against contamination
 - b. Deliver samples to laboratory promptly
 - c. Samples and sample data – submitted to laboratory – if by common carrier, use tamper proof shipping case with top labeled "This Side Up"

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

DATE	SANITARIAN	AGENCY
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APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Milk sampling, hauling, and transport are integral parts of a modern dairy industry. Hauling, sampling and transport can be categorized into three (3) separate functions: Dairy or Industry Plant Samplers, Bulk Milk Hauling and Sampling and Milk Transport from one (1) milk handling facility to another.

I. MILK SAMPLING AND HAULING PROCEDURES

The dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. These persons are employees of the Regulatory Agency and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official. These individuals are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

The bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk receiver, the operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies. Section 3 of this *Ordinance* requires that Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once each two (2) year period using FORM FDA 2399a-BULK MILK HAULER/SAMPLER REPORT. (Refer to Appendix M.)

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Appendix N. These industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once each two (2) year period by a SSO or a properly delegated Sampling Surveillance Regulatory Official. These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M.)

The milk tank truck driver is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

The criteria for permitting these individuals should embrace at least the following:

TRAINING: To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler and approved aseptic samplers for

milk tank trucks or for farm bulk milk tanks and/or silos, all bulk milk hauler/samplers and industry plant samplers must be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet the requirements can conduct this training. If the Regulatory Agency does not conduct the training, the training must be approved by or conducted under the supervision of the Regulatory Agency. Training also frequently takes the form of classroom sessions in which the trainer describes pickup practices, demonstrates sampling and care of samples and affords the candidate the opportunity for guided practice in these techniques. Basic considerations of sanitation and personal cleanliness, which are important to the protection of milk quality, are discussed here. Officials administering weights and measures may participate in these programs and provide instruction in the measuring of milk and the keeping of required records.

An examination, approved by the Regulatory Agency, shall be administered at the conclusion of this program. Candidates failing the exam, a score of less than seventy percent (70%), shall be denied permits or licenses until indicated deficiencies are corrected. The examination should be adequate enough to determine if a bulk milk hauler/sampler is competent. The exam shall be composed of a minimum of twenty (20) total questions broken down into the following areas:

1. Six (6) questions relating to sanitation and personal cleanliness;
2. Six (6) questions relating to sampling and weighing procedures;
3. Four (4) questions relating to equipment, including proper use, care, cleaning, etc.; and
4. Four (4) questions relating to proper record keeping requirements.

Regularly scheduled refresher short courses by the regulatory agents and officials administering weights and measures would assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler. Appropriate training should also be provided to industry plant samplers with regularly scheduled refresher short courses.

QUALIFICATIONS:

1. **Experience:** Experience may include a required period of observation during which the candidate accompanies a bulk milk hauler/sampler in the performance of their duties.
2. **Personal References:** Permit applications should be supported by suitable references testifying to the character and integrity of the candidate.

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: The routine inspection of bulk milk hauling/sampling procedures provides the Regulatory Agency with an opportunity to check both the condition of the bulk milk hauler/sampler's equipment and the degree of conformance with required practices.

The bulk milk hauler/sampler's technique is best determined when the regulatory agent is able to observe the bulk milk hauler/sampler at one (1) or more farms. Each bulk milk hauler/sampler must be inspected by the Regulatory Agency prior to the issuance of a permit and at least once every twenty-four (24) months thereafter as referenced in Section 5 of this *Ordinance*. The bulk milk hauler/sampler must hold a valid permit prior to the collection of official samples. States may use inspections from any Regulatory Agency as a means of maintaining record requirements and enforcement.

The procedures for sampling and the care of samples should be in compliance with the current edition of *SMEDP*.

Specific Items to be evaluated in determining compliance include:

1. **Personal Appearance:** Bulk milk hauler/samplers shall practice good hygiene; shall maintain a neat and clean appearance; and not use tobacco in the milkhouse.
2. **Equipment Requirements:**
 - a. Sample rack and compartment to hold all samples collected.
 - b. Refrigerant to hold temperature of milk samples between 0°C- 4.4°C (32°F- 40°F).
 - c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
 - d. Single use sample containers; properly stored.
 - e. Calibrated pocket thermometer; certified for accuracy every six (6) months; accuracy \pm 1°C (2°F).
 - f. Approved sanitizing agent and sample dipper container.
 - g. Watch for timing milk agitation.
 - h. Applicable sanitizer test kit.
3. **Milk Quality Checks:**
 - a. Examine the milk by sight and smell for any off odor or any other abnormalities that would class the milk as not being acceptable. Reject if necessary.
 - b. Wash hands thoroughly and dry with a clean single-service towel or acceptable air dryer immediately prior to measuring and/or sampling the milk.
 - c. Record milk temperature, collection time (optionally, in military time (24 hour clock)), date of pick-up and bulk milk hauler/sampler's name and license or permit number on the farm weight ticket; monthly the hauler/sampler shall check the accuracy of the thermometer on each bulk tank and record results when used as a test thermometer. Accuracy of required recording thermometers shall be checked monthly against a standardized thermometer and recorded. Pocket thermometer must be sanitized before use.
4. **Milk Measurements:**
 - a. The measurement of the milk shall be taken before agitation. If the agitator is running upon arrival at the milkhouse, the measurement can be taken only after the surface of the milk has been quiescent.
 - b. Carefully insert the measuring rod, after it has been wiped dry with a single-service towel, into the tank. Repeat this procedure until two (2) identical measurements are taken. Record measurements on the farm weight ticket.
 - c. Do not contaminate the milk during measurement.
5. **Universal Sampling System:** When bulk milk hauler/samplers collect raw milk samples, the "universal sampling system" shall be employed, whereby samples are collected every time milk is picked up at the farm. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler. The use of the "universal sample" puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:
 - a. Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.
 - b. The milk must be agitated a sufficient time to obtain a homogeneous blend. Follow the State and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device.

- c. While the farm bulk milk tank and/or silo is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the farm bulk milk tank and/or silo outlet valve and examine for milk deposits or foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage.
 - d. The sample may only be collected after the milk has been properly agitated or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.
 - e. Collect a representative sample or samples from the farm bulk milk tank and/or silo by using a sample dipper or other approved aseptic sampling device. Refer to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B. of this *Ordinance* for the specific protocol for the use of approved aseptic sampling devices. When transferring milk from the sampling equipment, caution should be used to assure that milk is not spilled back into the farm bulk milk tank and/or silo. Do not fill the sampling container more than $\frac{3}{4}$ full. Close the cover on the sample container.
 - f. The sample dipper shall be rinsed free of milk and placed in its carrying container.
 - g. Close the cover or lid of the farm bulk milk tank.
 - h. The sample must be identified with the producer's number at the point of collection.
 - i. A temperature control sample must be taken at the first stop of each load. This sample must be labeled with collection time (optionally, in military time (24 hour clock)), date, temperature and producer and bulk milk hauler/sampler identification.
 - j. Place the sample or samples immediately into the sample storage case.
6. **Pump Out Procedures:**
- a. Once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk is below the level that will cause over-agitation.
 - b. When the milk has been removed from the tank, disconnect the hose from the outlet valve and cap the hose.
 - c. Observe the inside surfaces of the bulk tank for foreign matter or extraneous material and record any objectionable observations on the farm weight ticket.
 - d. With the outlet valve open, thoroughly rinse the entire inside surface of the tank with warm water.
7. **Sampling Responsibilities:**
- a. All sample containers and single-service sampling tubes used for sampling shall comply with all the requirements that are in the current edition of *SMEDP*. Samples shall be cooled to and held between 0°C (32°F) and 4.4°C (40°F) during transit to the laboratory.
 - b. Means shall be provided to properly protect the samples in the sample case. Keep refrigerant at an acceptable level.
 - c. Racks must be provided so that the samples are properly cooled in an ice bath.
 - d. Adequate insulation of the sample container box or ice chest shall be provided to maintain the proper temperature of the samples throughout the year.

The SSO conducts periodic evaluations of sampling procedures. This program will promote uniformity and compliance of sample collection procedures.

II. REQUIREMENTS FOR USING AN APPROVED IN-LINE SAMPLER

A protocol specific to each milk producer who direct loads milk tank trucks (through by-passing the use of farm bulk milk tanks or silos) while utilizing an approved in-line sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk buyer, the milk producer and FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
2. A description of the means used to refrigerate the sample collection device and milk sample collection container throughout the milk sample collection period.
3. A means to monitor the sampler device temperature and milk sample temperature, and the milk temperature.
4. A description of how and when the sampler is to be cleaned and sanitized, if not of a single use design.
5. A listing of the licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the sample collection device as well as to collect, identify, handle and store the milk sample.
6. A description of the method and means that will be used to determine weight of the milk on the milk tank truck.

III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS

A protocol specific to each milk plant in which industry plant samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk plant and FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
 - a. The aseptic sampler fitting must be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
 - b. The aseptic sampler septum must be installed according to the manufacturer's instructions.
 - c. Transfer of milk is achieved using a Standard Operating Procedure (SOP) specific to the aseptic sampler.
 - d. An appropriate device, i.e., a syringe, must be used to transfer the milk.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the industry plant samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampler as well as to collect, identify, handle and store the milk sample.

IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND/OR SILOS

A protocol specific to each milk producer in which the milk producer, who transports milk only from his/her own dairy farm, or bulk milk hauler/samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. As a minimum, the protocol should include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
 - a. The aseptic sampler fitting must be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use and does not create a dead end.
 - b. The aseptic sampler septum must be installed according to the manufacturer's instructions.
 - c. Transfer of milk is achieved using a Standard Operating Procedure (SOP) specific to the aseptic sampler.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampling device as well as collect, identify, handle and store the milk sample.

V. MILK TANK TRUCK PERMITTING AND INSPECTION

Milk tank trucks shall be evaluated annually using the requirements established in Sections 3 and 5 of this *Ordinance* using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M.)

PERMITTING: Each milk tank truck shall bear a permit for the purpose of transporting milk and milk products. (Refer to Section 3 of this *Ordinance*.) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and State issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed each year pending satisfactory completion of an inspection as outlined in the following **INSPECTION** Section.

RECIPROCITY: Each permit shall be recognized by other Regulatory Agencies under the reciprocal agreements of the NCIMS and supporting documents of this *Ordinance*. A milk tank truck need only bear one (1) permit from an appropriate Regulatory Agency. A milk tank truck may be inspected at any time when deemed appropriate by the Regulatory Agency. Absent proof of a current permit and current inspection, when the milk tank truck is inspected by a Regulatory Agency other than the permitting agency, an inspection fee may be charged to the owner of the milk tank truck. This is necessary to allow a milk tank truck to pickup and deliver in several jurisdictions without the need for more than one (1) permit. A Regulatory Agency may have the option of inspecting any milk tank truck at any time when milk and milk products are transported in or out of a particular jurisdiction. It is the responsibility of the milk tank truck owner or

operator to maintain a current proof of inspection to avoid a re-inspection fee. Disputes concerning reciprocal agreements on milk tank truck inspection between Regulatory Agencies may be tendered to the Chair of the NCIMS or the Chair's designee for resolution.

INSPECTION: Each milk tank truck shall be inspected at least once each year by a Regulatory Agency. (Refer to Section 5 of this *Ordinance*.) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead.

When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of annual inspection as required in the **PERMITTING** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.

MILK TANK TRUCK STANDARDS: All Items of FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT fall into the categories of "Compliance", "Non-Compliance" or "Not Applicable" (NA) as determined during the inspection. The following Items relate to FORM FDA 2399b: (Refer to Appendix M.)

1. **Samples and Sampling Equipment:** (When provided)
 - a. Sample containers shall be stored to preclude contamination.
 - b. The sample box shall be in good repair and kept clean.
 - c. Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected.
 - d. The sample transfer instrument container is provided and adequate means for maintaining sanitizer solutions is on hand.
 - e. The samples are properly stored to preclude contamination.
 - f. The sample storage compartment shall be clean.
 - g. Samples are maintained at an acceptable temperature 0°C-4.4°C (32°F-40°F) and a temperature control sample is provided.
 - h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.
2. **Product Temperature 7°C (45°F) or Less:**
 - a. The product temperature must meet all the requirements of Section 7, Items 18r and 17p-Cooling of Milk, of this *Ordinance*.

- b. Product that remains in external transfer systems that exceeds 7°C (45°F) is discarded. This includes pumps, hoses, air elimination equipment or metering systems.
3. **Equipment Construction, Cleaning, Sanitizing and Repair:** Items a. through l. on FORM FDA 2399b shall be evaluated according to the following criteria:
- a. Construction and Repair Requirements:
- (1) The milk tank truck and all appurtenances shall meet applicable requirements of Section 7, Item 10p-Sanitary Piping and Item 11p-Construction and Repair of Containers and Equipment, of this *Ordinance*. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this *Ordinance*.
 - (2) The interior of the milk tank trucks shall be constructed of smooth, non-absorbent, corrosion-resistant, non-toxic material; and it shall be maintained in good repair.
 - (3) The appurtenances of the milk tank truck includes aseptic samplers, if applicable, hoses, pumps and fittings, shall be constructed of smooth, non-toxic cleanable material; and shall be maintained in good repair. Where flexibility is required, the fluid transfer system shall be free draining and so supported to maintain uniform slope and alignment. They shall be easily disassembled and accessible for inspection.
 - (4) The cabinet portion(s) of the tank, used for the storage of appurtenances and sampling equipment, where applicable, shall be constructed to preclude contamination by dust, dirt; be clean; and in good repair.
 - (5) The milk tank truck dome lid assembly, vent and dust cover shall be designed to protect the tank and milk from contamination.
- b. Cleaning and Sanitizing Requirements:
- (1) The milk tank truck and all of its appurtenances shall be cleaned and sanitized in accordance with applicable requirements of Section 7, Item 12p-Cleaning and Sanitizing of Containers and Equipment, of this *Ordinance*.
 - (2) The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank must be re-sanitized.
 - (3) It is allowable to pickup multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each day's used.
4. **Exterior Condition of Tank:** The exterior of the milk tank truck is properly constructed and in good repair. Defects and damage that would adversely affect products contained in the milk tank truck are pointed out on FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT and corrective actions are prescribed. Cleanliness of the milk tank truck exterior is evaluated with consideration for existing weather and environmental conditions.
5. **Wash and Sanitize Record:**
- a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.
 - b. A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than fifteen (15) days.

- c. The following information shall be recorded on the cleaning and sanitization tag:
 - (1) Identification of the milk tank truck.
 - (2) Date and time (optionally, in military time (24 hour clock)) of day the milk tank truck was cleaned and sanitized.
 - (3) Location where the milk tank truck was cleaned and sanitized.
 - (4) Signature or initials of the person who cleaned and sanitized the milk tank truck.
- d. The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of the bulk milk hauler/sampler or the milk tank truck operator.
- e. State will submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS or other easily accessible web site.

6. Location of Last Cleaning/Sanitizing:

The location of the last cleaning and sanitizing shall be verified by the Regulatory Agency during any milk tank truck inspection and recorded on the Milk Tank Truck Inspection Form.

7. Labeling: The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk milk hauler/sampler. A milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station is required to be marked with the name and address of the milk plant or hauler and the milk tank truck shall be under a proper seal. All shipping documents must contain the following information as outlined in Section 4-Labeling, of this *Ordinance*:

- a. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS BTU identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;
- b. Permit identification of the hauler, if not an employee of the shipper;
- c. Point of origin of shipment;
- d. Milk tank truck identification number;
- e. Name of product;
- f. Weight of product;
- g. Temperature of product when loaded;
- h. Date of shipment;
- i. Name of supervising Regulatory Agency at the point of origin of shipment;
- j. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;
- k. Seal number on inlet, outlet, wash connections and vents; and
- l. Grade of product.

All information contained on the above described documents shall be verified by the Regulatory Agency and recorded on the appropriate inspection sheet for any bulk milk tank trucks under inspection.

8. Vehicle and Milk Tank Truck Properly Identified: It shall be the responsibility of the milk tank truck owner or operator to insure the proper and legible identification of the milk tank truck(s) in their possession.

9. Previous Inspection Sheet or Affixed Label Available: When a milk tank truck transports milk and milk products from one (1) regulatory jurisdiction to another it is not necessary to inspect each milk tank truck upon each arrival. Milk tank truck owners and operators shall carry proof of annual inspection from a recognized Regulatory Agency. A milk tank truck may be

inspected at any time or at the discretion of any Regulatory Agency responsible for the milk supply.

10. **Sample Chain-of-Custody:** When samples for official laboratory analysis are transported by any individual where the sample chain-of-custody must be established, the driver may be required to carry a valid permit or shall be evaluated biennially for the collection of samples for official laboratory analysis. The criteria from Section I-Evaluation of Bulk Milk Hauler/ Sampler Procedures, Item 7-Sampling Responsibilities of this Appendix will be used as the basis for the evaluation. As an alternative, a sample case sealed as required by the Regulatory Agency may be accepted.

The identity labeling requirement may be interpreted as permitting milk plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another milk plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging milk plant is identified by a proper code.

MISLEADING LABELS: The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. For dry milk products, the outer bag must be preprinted "Grade "A" before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade "AA" Pasteurized", "Selected Grade "A" Pasteurized", "Special Grade "A" Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products when properly enforced, will ensure that this grade of milk and milk products will be as safe as they can practically be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk or milk products are intended for consumption within ...of...¹ or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months.
2. Inspect each bulk milk hauler/sampler's, dairy plant sampler's and industry plant sampler's pickup and sampling procedures at least once every twenty-four (24) months.
3. Inspect each milk plant and receiving station at least once every three (3) months, provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. Provided further, that regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the State Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S.) The milk plant's APPS shall

be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K.
5. Inspect each dairy farm at least once every six (6) months.⁶

Should the violation of any requirement set forth in Section 7, or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6 and Appendix B, be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection/audit shall be used to determine compliance with the requirements of Section 7 or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6 and Appendix B. Any violation of the same requirement of Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B, on such second inspection/audit, shall call for permit suspension in accordance with Section 3 and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by the Regulatory Agency. Provided, that when the Regulatory Agency finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;
2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance*.

One (1) copy of the inspection/audit report shall be handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.

The Regulatory Agency shall also make such other inspections and investigations as are necessary for the enforcement of this *Ordinance*.

Every permit holder shall, upon the request of the Regulatory Agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or milk plant operator shall furnish the

Regulatory Agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance*, which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk products or results of inspections/audits or tests thereof, to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for all other milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twelve (12) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection each twenty-four (24) months; or one (1) producer, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, or milk tank truck cleaning facility inspection every six (6) months; or one (1) milk plant producing pasteurized, ultra-pasteurized, condensed or dried milk and milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.

For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.

Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement, which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent.

Additional Information for Hauler/Samplers.

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

When taking a sample from a milk storage tank or bulk milk tanker, to obtain a representative sample, the dipper should be extended 6-8 inches into the milk.

The sampling and collection of milk from a farm bulk tank, and the delivery of milk to a dairy plant, receiving station or transfer station shall only be done by a licensed bulk hauler. This includes the relief or part-time hauler.

ABNORMALITIES OF MILK: The following types of lacteal secretions are not suitable for sale for Grade "A" purposes:

A-1. **Abnormal Milk:** Milk that is visibly changed in color, odor and/or texture.

A-2. **Undesirable Milk:** Milk that, prior to the milking of the animal, is expected to be unsuitable for sale, such as milk containing colostrum.

A-3. **Contaminated Milk:** Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA).

The milk samplers' hands must be clean and dry immediately prior to taking the milk samples.

Care must be taken not to introduce water into the milk tanker. The hauler must exercise care and make sure the transfer hose is disconnected before the bulk tank is rinsed. Adding water to milk is also avoided by not using water to flush the remaining milk from the bulk storage tank into the tanker.

If a hose port is available, at the dairy farm, it must be used to pass the transfer hose from the milk room to the tanker. Open doors allow for insects, dust and other potential contaminants to enter the milk storage room.