

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-06-6

May 15, 2006

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Application and Standard Operating Procedures (SOPs) For The Installation And Use Of Approved In-Line Samplers (ISO-LOK, Anderson Instruments and QMI) For The Collection Of Dairy Farm Samples From Direct Load Tankers As Required In Section 6 of the Grade "A" PMO

Proposals 237 (ISO-LOK) and 240 (QMI) passed at the 2003 National Conference on Interstate Milk Shipments (NCIMS) and Proposal 233 (Anderson Instruments) passed at the 2005 NCIMS, provided for the use of approved in-line samplers for the collection of dairy farm samples from direct load tankers as required in Section 6-The Examination of Milk and Milk Products and as referenced in Appendix B-Milk Sampling, Hauling and Transportation of the Grade "A" PMO. Additionally these Proposals contained the following information that was not specifically cited to be included in any related NCIMS document:

- The sampling device operation shall be overseen on the farm by a bulk milk hauler/sampler permitted by the State.
- The FDA requests a third party validation study to be performed on the sampling devices (ISO-LOK) currently in use in New York State.
- The in-line samplers will be considered validated for use for collecting regulatory samples on the passage of this proposal in the State of New York and until the validation study is evaluated by the FDA.

At the May 13, 2005, NCIMS Executive Board Meeting, FDA's Laboratory Quality Assurance Team (LQAT) reported the following: "FDA has received data and a SOP from the State of New York, which contained application forms on the ISO-LOK In-Line Sampler. The data for the SPC, ESCC and inhibitors, as submitted, was found to be acceptable based on the criteria established by the NCIMS Laboratory Committee for alternate methods. This completes the Third Party Verification for this Sampler. The SOP and application forms contained within the SOP were reviewed and found to be acceptable. The sampler is recommended by FDA to the NCIMS Laboratory Committee as approved. Future users of the ISO-LOK Sampler will have to make application and

follow the approved SOP prior to use as agreed to by the NCIMS Laboratory Committee in its consideration of the ISO-LOK Sampler at the previous conference.”

Proposal 233 passed at the 2005 NCIMS Conference made the following changes (underlined) to Section 6 of the PMO: “It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank or from a properly installed and operated in-line-sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a farm bulk tank, 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 also made the following addition to APPENDIX B:

II. REQUIREMENTS FOR USING AN APPROVED IN-LINE SAMPLER

A protocol specific to each milk producer who direct loads milk tank trucks (through bypassing 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.

Based on the above cited “Requirements for Using an Approved In-Line Sampler” and the SOP accepted by FDA and the NCIMS Laboratory Committee for the ISO-LOK In-Line Sampler the other two approved in-line samplers mentioned above (Anderson Instruments and QMI), in conjunction with the State Regulatory Agencies sponsoring the study, were responsible to submit data and a written SOP, which contains an application form, to LQAT for review and NCIMS Laboratory Committee acceptance. The data for the SPC, ESCC and inhibitors, as submitted for both samplers (Anderson and QMI), were found to be acceptable based on the criteria established by the NCIMS Laboratory Committee for alternate methods. This completes the initial submission by Anderson Instruments and the Third Party Verification for the QMI In-Line Sampler. The SOPs and application forms contained within the SOPs were reviewed and found to be

acceptable. These samplers are recommended by FDA to the NCIMS Laboratory Committee as approved and have been accepted by the NCIMS Laboratory Committee. Future users of the ISO-LOK, Anderson Instruments and/or QMI In-Line Sampler(s) will have to make application and follow the applicable approved SOP prior to use as agreed to by the NCIMS Laboratory Committee.

Included in this document are the SOPs and application forms for all three approved in-line samplers (ISO-LOK, Anderson Instruments and QMI). Also, included is an "Application to Install or Modify a Milk System" form for use in obtaining permission from the State Milk Regulatory Agency to install or modify a milking system for the installation of an approved in-line sampler.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

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Larry Maturin, PhD, Chief
Laboratory Quality Assurance Team

CAPT Robert F. Hennes, RS, MPH, Chief
Milk Safety Team

SOP for the ISO-LOK In-Line Sampler

General Requirements:

- 1) The application to install the in-line sampler should be filed with the operation installing the in-line sampler, the State Milk Regulatory Agency, the person responsible for the operation's regulatory oversight and the in-line sampler installer. (Refer to the application form)
- 2) If the application form is not available, fill out the information requested in the attached Form A.

Device Requirements:

- 1) The ISO-LOK device is to be installed in an appropriate location in the milk line to ensure accurate sampling and proper cleaning. (The installation must meet the approval of the State Milk Regulatory Agency and the equipment manufacturer.)
- 2) The ISO-LOK sampler shall be installed in a refrigerator that must maintain an internal temperature of 32°-40°F (0°-4.4°C) if the ISO-LOK sampler is using the optional attachment that allows a sample collection bottle to be attached directly on the sampler and the sample goes directly from the sampler into the attached sample collection bottle. (The sample bottle and refrigerator installation must meet the approval of the State Milk Regulatory Agency.)
- 3) If the ISO-LOK sampler is using the attachment that allows for an approved milk tube to be attached to the milk sample outlet, then the container used for the collection of the milk sample shall be in a refrigerator that must maintain an internal temperature of 32°-40°F (0°-4.4°C). The sample tubing length shall be no longer than necessary. (The sample tubing and refrigerator installation must meet the approval of the State Milk Regulatory Agency.)
- 4) The ISO-LOK sampler may be cleaned-in-place (CIP) and sanitized, if not manually cleaned and sanitized, after each milking cycle. The sample bottle attachment area of the sampler shall be manually cleaned and sanitized after each milking cycle.
- 5) The ISO-LOK sampler shall be disassembled, inspected, manually cleaned and sanitized monthly, and the O-rings checked and replaced, if needed, every month.
NOTE: If a positive antibiotic result is obtained, the sampler shall be disassembled and manually cleaned and sanitized prior to the next milking.
- 6) The sample collection container, if not single use, shall be hand washed and sanitized after each use and meet the PMO requirements and have the State Milk Regulatory Agency approval.
NOTE: If a positive antibiotic result is obtained, the multi-use sample collection container must be discarded and replaced.
- 7) The size of the milk sample is to be determined in cooperation with the State Milk Regulatory Agency to ensure that the sample collection container size is adequate, so overflow does not occur and adequate air space is allowed for the proper agitation of the sample.

Refrigerator Requirements:

- 1) The sample collection refrigerator must be of an appropriate size to hold the sample container and the ISO-LOK sampler, if applicable.
- 2) The sample collection refrigerator shall be able to maintain the sample between 32°-40°F (0°-4.4°C).
- 3) Calibrated thermometer(s) must be used to track the refrigerator temperature.
 - a. The thermometer(s) shall be of the digital or liquid filled in-glass type, checked and tagged annually by an NCIMS certified facility.
 - b. The thermometer(s) shall have a minimum scale of 1°C or 2°F.
 - c. The sample collection and sample storage refrigerator's temperatures shall be recorded AM-PM, from the thermometers located on the top and bottom shelves, where applicable. Check the temperature just prior to the collection of the sample (s) to assure the temperature is within the Regulatory compliance range of 32°-40°F (0°-4.4°C). Alternatively, a PMO acceptable temperature-recording device may be used if accepted by the State Milk Regulatory Agency.
 - d. The refrigerator temperature records shall be retained for six (6) months.
 - e. The annual NCIMS thermometer(s) accuracy check shall be retained for two (2) years.
- 4) The refrigerator shall only be used to collect and store milk samples. No food, beverage, antibiotics, chemicals, drugs or any other items not related to the samples or sampling procedures, shall be stored in the refrigerator.
- 5) The refrigerator shall be maintained in good working condition, be in good repair and clean both inside and outside at all times.

Collecting the Milk Sample:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before handling the equipment used to collect the milk sample.
- 3) At the start of milking and at the start of filling an empty direct load tanker, make sure the sample bottle or sample collection container is cleaned, sanitized, dry and properly positioned to collect the sample. Check the refrigerator temperature prior to starting the sample collection. Corrective action(s) shall be taken if there is a temperature problem. Document all corrective action(s) taken and retain on file for six (6) months.
- 4) At the end of each milking cycle, remove the sample bottle from the ISO-LOK sampler or the sampling tube from the sample container.
- 5) Immediately cap the milk sample bottle or container using the approved storage cap and store the sample bottle or container in the approved sample refrigerator.
- 6) Prepare the ISO-LOK sampler for CIP cleaning and sanitization, if not hand cleaning and sanitizing the sampler. The sampler must be cleaned and sanitized after each milking cycle.
- 7) The ISO-LOK sampler and milk sampling tube, if one is used, shall be hand-cleaned and sanitized before the start of the next milking cycle.

- 8) At the start of the next milking make sure the sample collection bottle or sample collection container and milk sampling tube, if one is used, is properly positioned to collect the milk sample.
- 9) Repeat steps 2, 3, 4, 5, 6, 7 and 8 until the tanker is full.

Taking the Representative Sample and Sample Handling:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before carrying out those steps.
- 3) Remove the sample container, which is no more than $\frac{3}{4}$ full, from the refrigerator. Check and record the temperature(s) in the refrigerator. It must be 32°–40°F (0°–4.4°C).
- 4) Agitate the sample container sufficiently to obtain a representative sample by shaking the sample container twenty-five (25) times in seven (7) seconds with a one (1)-foot arc of movement, or alternatively, agitate the sample container by rapidly inverting the sample container completely, twenty-five (25) times.
- 5) This vigorous shaking, if done correctly, may create undesirable foam. It may be appropriate to wait for nearly three (3) minutes to allow the foam to disperse and then without contamination, transfer a portion of the sample contents using aseptic techniques, into smaller, properly identified sterile sample vials, filling each only $\frac{3}{4}$ full. The transfer of sample contents shall be done within three (3) minutes of agitation on a well-lighted, clean work surface in the milkhouse, or other suitable location approved by the State Milk Regulatory Agency. A temperature control (TC) sample must also be taken.
- 6) The milk sample and TC sample containers and the weigh slip shall be identified with the following information:
 - a. Producer identification or number;
 - b. Date of sampling;
 - c. Temperature of sample (Using the temperature of the TC sample);
 - d. Time of sampling;
 - e. Initials of the person taking the sample shall be recorded on the milk sample and TC sample; and
 - f. Name and license or permit number of the person taking the sample shall be recorded on the weigh slip.
- 7) A TC sample shall be taken with each milk sample and be identified with TC or by some other manner approved by the State Milk Regulatory Agency.
- 8) Store the samples in the sample collection refrigerator or another State Milk Regulatory Agency approved storage location until the tanker leaves the dairy farm. The samples shall accompany the loaded tanker to the milk plant, receiving station or transfer stations receiving the milk.
- 9) Duplicate samples may be taken for pick-up and testing by the producer's milk handling company or State Milk Regulatory Agency.

10) Fill out a chain-of-custody (COC) sheet if you place the samples into a refrigerator for storage until the samples leave the dairy farm with the loaded tanker or are collected by the producer's milk handling company or State Milk Regulatory Agency.

METHODS AND MEANS TO DETERMINE WEIGHT

The method and means that will be used to determine the weight of milk on the milk tank truck will be specific to each installation. Each individual installation protocol, which is acceptable to the State Milk Regulatory Agency, shall include a description of the method and means used to make this determination.

FORM A
Application to Install an ISO-LOK In-Line Sampler

General Requirements:

Producer Name: _____, Date: _____
Producer Address: _____, State and Zip: _____
Producer Phone/Fax/E-mail: _____
Producer's Regulatory License or Permit Number: _____
Purchaser of Milk: _____
Producer's Regulatory Inspector: _____
Pounds of Milk/Day Direct Loaded: _____
Sampling Rate: _____ ml or oz./ _____ lbs. or gals. (Based on milk flow rate)
Flow Rate: _____ lbs. or gals./min. or hour.
Sample End Volume Desired: _____ (mls, ozs. or gals.)
Sample Container of Approved Material: Yes _____ No _____
Sample Container of Approved Design: Yes _____ No _____
Material Type: _____
Sample Container Size: _____ (mls, ozs. or gals.)
In-Line Sampler SOP for the Appropriate Sampler on File: Yes _____ No _____
Appropriate Sampler SOP Being Followed: Yes _____ No _____
Number of Milkings to Fill the Tanker: _____

Sampler System Design:

(Meets State Milk Regulatory Agency and PMO Requirements)

Sampler Location: _____
Sample Collection Location: _____
Refrigerator: Type _____, Make _____, Size (cu. ft.) _____
Refrigerator-Adequate Size to Maintain Sample(s) at Correct Temperature: Yes ___ No ___
Refrigerator, monitoring, upkeep and operation must follow the latest version of the NCIMS 2400 Cultural Procedures Form. (Refrigeration Section attached to this SOP)
Records shall be retained for six (6) months.

System Operation:

Person(s) Operating the System Trained: Yes _____ No _____
Person(s) Operating the System, Training Dates on File: Yes _____ No _____
Person(s) Operating the System, Certification #'s on File: Yes _____ No _____
Person(s) who Performed the Training: _____
SOP for the In-Line Sampler Being Used on File and Being Followed: Yes ___ No ___
Cleaning/Sanitizing of the Sampler Approved by the Regulatory Agency: Yes ___ No ___
Cleaning/Sanitizing Protocol Posted and Followed: Yes _____ No _____
All materials; approval for the installation plans; approval of the installation; and all other relevant areas relating to the equipment construction of the in-line sampler and its usage must meet the requirements of Item 9r-Utensils and Equipment Construction of the most recent edition of the PMO.

Methods and Means to Determine Weight:

Protocol Acceptable to State Milk Regulatory Agency: Yes _____ No _____

5/2006 Revision

SOP for the QMI In-Line Sampler

General Requirements:

- 1) The application to install the in-line sampler should be filed with the operation installing the in-line sampler, the State Milk Regulatory Agency, the person responsible for the operation's regulatory oversight and the in-line sampler installer. (Refer to the application form)
- 2) If the application form is not available, fill out the information requested in the attached Form A.

Device Requirements:

- 1) The QMI device is to be installed in an appropriate location in the milk line to ensure accurate sampling and proper cleaning. (The installation must meet the approval of the State Milk Regulatory Agency and the equipment manufacturer.)
- 2) Use only QMI sterile septum inserts; make sure the nut holding the insert in place is tight.
- 3) The protective septum cover shall be in place at all times when the septum is not in use.
- 4) If the QMI sampler is being installed in a refrigerator, that refrigerator must maintain an internal temperature of 32°-40°F (0°-4.4°C). (The sample collection bag or bottle and refrigerator installation shall meet the approval of the State Milk Regulatory Agency.)
- 5) If the QMI sampler is not installed in a refrigerator, then the container used for the collection of the milk sample shall be in a refrigerator that must maintain an internal temperature of 32°-40°F (0°-4.4°C). Sample tubing length shall be no longer than necessary. (The sample tubing and refrigerator installation must meet the approval of the State Milk Regulatory Agency.)
- 6) The sample collection container, if using a reusable container, shall be hand washed and sanitized after each use and meet the PMO requirements and have State Milk Regulatory Agency approval.

NOTE: If a positive antibiotic result is obtained, the reusable sample collection container must be discarded and replaced.

- 7) There are seven (7) sampling ports in each QMI septum. Use a new sampling port each time loading a new tanker. Replace the septum when all seven (7) sampling ports have been used.

NOTE: If a positive antibiotic result is obtained, manually clean, sanitize and replace the septum prior to the next milking.

- 8) Single-service use containers must only be used for collecting the sample from one (1) tanker. The container is discarded after the official sample is taken.
- 9) The sampling apparatus (needle and tubing) and sample collection bag can be purchased assembled or assembled on-site using good sanitary practices. The sampling apparatus can be used to collect the sample from one (1) tanker only. After the tanker is full the sampling apparatus must be discarded.

- 10) Needle size(s) is to be determined by the State Milk Regulatory Agency, Sampler Installer and the user of the sampler. The needle size needs to be determined to meet the sampling rate and sample end volume stated on the Application Form.
- 11) The size of the milk sample is to be determined in cooperation with the State Milk Regulatory Agency to ensure that the sample collection container size is adequate so overflow does not occur and adequate air space is allowed for the proper agitation of the sample.

Refrigerator Requirements:

- 1) The sample collection refrigerator must be of an appropriate size to hold the sample container and the QMI sampler, if applicable.
- 2) The sample collection refrigerator shall be able to maintain the sample between 32°-40°F (0°-4.4°C).
- 3) Calibrated thermometer(s) must be used to track the refrigerator temperature.
 - a. The thermometer(s) shall be of the digital or liquid filled in-glass type, checked and tagged annually by an NCIMS certified facility.
 - b. The thermometer(s) shall have a minimum scale of 1°C or 2°F.
 - c. The sample collection and sample storage refrigerator's temperatures shall be recorded AM-PM, from the thermometers located on the top and bottom shelves, where applicable. Check the temperature just prior to the collection of the sample(s) to assure the temperature is within the Regulatory compliance range of 32°-40°F (0°-4.4°C). Alternatively, a PMO acceptable temperature recording device may be used if accepted by the State Milk Regulatory Agency
 - d. The refrigerator temperature records shall be retained for six (6) months.
 - e. The annual NCIMS thermometer(s) accuracy check shall be retained for two (2) years.
- 4) The refrigerator shall only be used to collect and store milk samples. No food, beverage, antibiotics, chemicals, drugs or any other items not related to the samples or sampling procedures, shall be stored in the refrigerator.
- 5) The refrigerator shall be maintained in good working condition, be in good repair and clean both inside and outside at all times.

Collecting the Milk Sample:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before handling the equipment used to collect the milk sample.
- 3) At the start of milking and at the start of filling an empty direct load tanker, make sure the sample bottle or sample collection container is cleaned, sanitized, dry and properly positioned to collect the sample. (Single service collection bags are sterile already and do not need to be washed and sanitized.) Check the refrigerator temperature prior to starting the sample collection. Corrective action(s) shall be taken if there is a temperature problem. Document all corrective action(s) taken and retain on file for six (6) months.

- 4) At the start of milking, remove the protective cover from the QMI septum and using alcohol or a sanitizer properly sanitize the white cover over the septum surface.
- 5) There are seven (7) sampling ports in each QMI septum. Use a new sampling port each time you start loading a new tanker. Replace the septum when all seven (7) sampling ports have been used.
 - a. When subsequent milkings are going into the same tanker you can reuse the original sampling port that was initially used to begin sampling the tanker.
- 6) To begin the sampling of an empty tanker; insert the needle into an unused port of the QMI insert.
- 7) When not using pre-assembled sample collection bags remove the protective cover from the needle on the discharge side of the sampling tubing and insert the tubing into the sample collection container after first using alcohol or a sanitizer to sanitize the port.
- 8) Regulate the flow of milk into the sample container, at the predetermined rate developed and agreed to by the State Milk Regulatory Agency.
- 9) Place the sample collection bag or container into the refrigerator, if the unit is not already installed in a refrigerator, and close the door. Suggest initial monitoring to ensure the system is operating properly.
- 10) At the end of each milking cycle, remove the needle from the QMI septum.
- 11) If the tanker is not full and will require subsequent milkings to fill, replace the needle's protective cover, which has been stored in the refrigerator, over the needle.
- 12) Place the tubing and covered needle into the refrigerator.
- 13) Place the protective cover over the QMI septum.
- 14) At the start of the next milking, if continuing to fill the same tanker, repeat steps 4, 5, 8, 9, 10, 11, 12 and 13 until the tanker is full.
- 15) When the tanker is full, remove the needles from the QMI septum and the sample collection container.
- 16) Immediately cap the milk sample bottle or container using the approved storage cap and store in the approved sample refrigerator.
- 17) The QMI device can be CIPed. However, when replacing the septum after all seven (7) sampling ports have been used, the opening that the septum sets in must be hand cleaned.

Taking the Representative Sample and Sample Handling:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before carrying out those steps.
- 3) Remove the sample container, which is no more than $\frac{3}{4}$ full, from the refrigerator. Check and record the temperature(s) in the refrigerator. It must be 32°–40°F (0°–4.4°C).
- 4) Agitate the sample container sufficiently to obtain a representative sample by shaking the sample container twenty-five (25) times in seven (7) seconds with a one

- (1)-foot arc of movement, or alternatively, agitate the sample container by rapidly inverting the sample container completely, twenty-five (25) times.
- 5) This vigorous shaking, if done correctly may create undesirable foam. It may be appropriate to wait for nearly three (3) minutes to allow the foam to disperse and then without contamination, transfer a portion of the sample contents, using aseptic techniques, into smaller, properly identified sterile sample vials, filling each only $\frac{3}{4}$ full. The transfer of sample contents shall be done within three (3) minutes of agitation on a well-lighted, clean work surface in the milkhouse, or other suitable location approved by the State Milk Regulatory Agency. A temperature control (TC) sample must also be taken.
 - 6) The milk sample and TC sample containers and the weigh slip shall be identified with the following information:
 - a. Producer identification or number;
 - b. Date of sampling;
 - c. Temperature of sample (Using the temperature of the TC sample);
 - d. Time of sampling;
 - e. Initials of the person taking the sample shall be recorded on the milk sample and TC sample; and
 - f. Name and license or permit number of the person taking the sample shall be recorded on the weigh slip.
 - 7) A TC sample shall be taken with each milk sample and be identified with TC or by some other manner approved by the State Milk Regulatory Agency.
 - 8) Store the samples in the sample collection refrigerator or another State Milk Regulatory Agency approved storage location until the tanker leaves the dairy farm. The samples shall accompany the loaded tanker to the milk plant, receiving station or transfer station receiving the milk.
 - 9) Duplicate samples may be taken for pick-up and testing by the producer's milk handling company or State Milk Regulatory Agency.
 - 10) Fill out a chain-of-custody (COC) sheet if you place the samples into a refrigerator for storage until samples leave the dairy farm with the loaded tanker or collected by the producer's milk handling company or State Milk Regulatory Agency.

METHODS AND MEANS TO DETERMINE WEIGHT

The method and means that will be used to determine the weight of milk on the milk tank truck will be specific to each installation. Each individual installation protocol, which is acceptable to the State Milk Regulatory Agency, shall include a description of the method and means used to make this determination.

FORM A
Application to Install a QMI In-Line Sampler

General Requirements:

Producer Name: _____, Date: _____
Producer Address: _____, State and Zip: _____
Producer Phone/Fax/E-mail: _____
Producer's Regulatory License or Permit Number: _____
Purchaser of Milk: _____
Producer's Regulatory Inspector: _____
Pounds of Milk/Day Direct Loaded: _____
Sampling Rate: _____ ml or oz./ _____ lbs. or gals. (Based on milk flow rate)
Flow Rate _____ lbs. or gals/min. or hour.
Sample End Volume Desired _____ (mls or ozs. or gals.)
Needle Size QMI Side ___ Gauge, Needle Size Sample Container Side ___ Gauge (if used)
Sample Container of Approved Material: Yes _____ No _____
Sample Container of Approved Design: Yes _____ No _____
Material Type: _____
Sample Container Size: _____ (mls or ozs. or gals.)
In-Line Sampler SOP for the Appropriate Sampler on File: Yes _____ No _____
Appropriate Sampler SOP Being Followed: Yes _____ No _____
Number of Milkings to Fill the Tanker _____

Sampler System Design:

(Meets State Milk Regulatory Agency and PMO Requirements)

Sampler Location: _____
Sample Collection Location: _____
Refrigerator: Type _____, Make _____, Size (cu. ft.) _____
Refrigerator-Adequate Size to Maintain Sample(s) at Correct Temperature: Yes ___ No ___
Refrigerator, monitoring, upkeep and operation must follow the latest version of the NCIMS 2400 Cultural Procedures Form. (Refrigeration section attached to this SOP)
Records shall be retained for six (6) months.

System Operation:

Person(s) Operating the System Trained: Yes _____ No _____
Person(s) Operating the System Training Dates on File: Yes _____ No _____
Person(s) Operating the System Certification #'s on File: Yes _____ No _____
Person(s) who Performed the Training: _____
SOP for the In-Line Sampler Being Used on File and Being Followed: Yes ___ No ___
Cleaning/Sanitizing of the Sampler Approved by the Regulatory Agency: Yes ___ No ___
Cleaning/Sanitizing Protocol Posted and Followed: Yes _____ No _____
All materials, approval for the installation plans, approval of the installation and all other relevant areas relating to the equipment construction of the in-line sampler and its usage must meet the requirements of Item 9r-Utensils and Equipment Construction of the most recent edition of the PMO.

Methods and Means to Determine Weight:

Protocol Acceptable to State Milk Regulatory Agency: Yes _____ No _____

5/2006 Revision

SOP for the ANDERSON INSTRUMENTS In-Line Sampler

General Requirements:

- 1) The application to install the in-line sampler should be filed with the operation installing the in-line sampler, the State Milk Regulatory Agency, the person responsible for the operation's regulatory oversight and the in-line sampler installer. (Refer to the application form)
- 2) If the application is not available, fill out the information requested in the attached Form A.

Device Requirements:

- 1) The Anderson Instruments device is to be installed in an appropriate location in the milk line to ensure accurate sampling and proper cleaning. (The installation must meet the approval of the State Milk Regulatory Agency and the equipment manufacturer.)
- 2) The Anderson Instruments sampler shall be installed in a refrigerator that must maintain an internal temperature of 32°-40°F (0°-4.4°C). (The refrigerator installation must meet the approval of the State Milk Regulatory Agency.)
- 3) The Anderson Instruments sampler may be cleaned-in-place (CIP) and sanitized, if not manually cleaned, after each milking cycle. The sample bottle attachment area of the sampler shall be manually cleaned and sanitized after each milking cycle.
NOTE: For the CIP cleaning of the sampler itself, make sure that the vacuum line and the two air lines are properly attached to the sampler. The lack of vacuum does not allow the diaphragm to pulse properly in conjunction with the use of applied air pressure.
- 4) The Anderson Instruments sampler shall be disassembled, inspected, manually cleaned and sanitized, and the diaphragm changed every month.
NOTE: If a positive antibiotic result is obtained, the sampler shall be disassembled, manually cleaned and sanitized prior to the next milking.
- 5) The sample collection container shall be of single-service use, unless the State Milk Regulatory Agency approves an appropriate method for the cleaning and sanitizing of the sample container.
NOTE: If a positive antibiotic is obtained, the multi-use sample collection container must be discarded and replaced.
- 6) The size of the milk sample is to be determined in cooperation with the State Milk Regulatory Agency to ensure that the sample collection container size is adequate so overflow does not occur and adequate airspace is allowed for the proper agitation.
- 7) Because the CIP cycle can warm the refrigerator above the proper sample storage temperature of 32°-40°F (0°-4.4°C), a method approved by the State Milk Regulatory Agency to properly refrigerate the samples or a second refrigerator must be provided for sample storage.

Refrigerator Requirements:

- 1) The sample collection refrigerator must be of an appropriate size to hold the sample container and the Anderson Instruments sampler.
- 2) The sample collection refrigerator shall be able to maintain the sample between 32°-40°F (0°-4.4°C).
- 3) Calibrated thermometer(s) must be used to track the refrigerator temperature.
 - a. The thermometer(s) shall be of the digital or liquid filled in-glass type, checked and tagged annually by an NCIMS certified facility.
 - b. The thermometer(s) shall have a minimum scale of 1°C or 2°F.
 - c. The sample collection and sample storage refrigerator's temperatures shall be recorded AM-PM, from the thermometers located on the top and bottom shelves, where applicable. Check the temperature just prior to the collection of the sample to assure the temperature is in the Regulatory compliance range of 32°-40°F (0°-4.4°C). Alternatively, a PMO acceptable temperature-recording device may be used if accepted by the State Milk Regulatory Agency.
 - d. The refrigerator temperature records shall be retained for six (6) months.
 - e. The annual NCIMS thermometer(s) accuracy check shall be retained for two (2) years.
- 4) The sample collection and sample storage refrigerators shall only be used to collect and store milk samples. No food, beverage, antibiotics, chemicals, drugs or any other items not related to the samples or sampling procedures, shall be stored in the refrigerator.
- 5) The refrigerators shall be maintained in good working condition, be in good repair and clean both inside and outside at all times.

Collecting the Milk Sample:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before handling the equipment used to collect the milk sample.
- 3) At the start of milking and at the start of filling an empty direct load tanker, make sure the sample bottle is cleaned, sanitized and properly positioned to collect the sample. Check the refrigerator temperature prior to starting the sample collection. Corrective action(s) shall be taken if there is a temperature problem. Document all corrective action(s) taken and retain on file for six (6) months.
- 4) At the end of each milking cycle, remove the sample bottle from the Anderson Instruments sampler.
- 5) Immediately cap the milk sample bottle using the approved storage cap and store the sample container in the approved sample refrigerator.
- 6) Prepare the Anderson Instruments sampler for CIP cleaning and sanitization, if not hand cleaning the sampler. The sampler must be cleaned and sanitized after each milking cycle.
- 7) The sample bottle attachment area of the Anderson Instruments sampler shall be manually cleaned and sanitized before the start of the next milking cycle.

- 8) At the start of the next milking make sure the sample collection bottle is properly positioned to collect the milk sample.
- 9) Repeat steps 2, 3, 4, 5, 6, 7 and 8 until the tanker is full.

Taking the Representative Sample and Sample Handling:

- 1) The person(s) performing the following steps shall possess a valid bulk milk hauler/sampler license/permit issued by the State Milk Regulatory Agency and their sampling and sub-sampling techniques shall be evaluated at least once every twenty-four (24) months by the State Milk Regulatory Agency.
- 2) The person(s) performing the following steps shall wash their hands before carrying out those steps.
- 3) Remove the sample container, which is not more than $\frac{3}{4}$ full, from the sampler in the sample collection refrigerator. Check and record the temperature(s) in the refrigerator. It must be 32°-40°F (0°-4.4°C).
- 4) Agitate the sample container sufficiently to obtain a representative sample by shaking the sample container twenty-five (25) times in seven (7) seconds with a one (1)-foot arc of movement, or alternatively, agitate the sample container by rapidly inverting the sample container completely, twenty-five (25) times.
- 5) This vigorous shaking, if done correctly may create undesirable foam. It may be appropriate to wait for nearly three (3) minutes to allow the foam to disperse and then without contamination, transfer a portion of the sample contents, using aseptic techniques, into smaller, properly identified sterile vials, filling each only $\frac{3}{4}$ full. The sub-sampling shall be done within three (3) minutes of agitation on a well-lighted, clean work surface in the milkhouse, or other suitable location approved by the State Milk Regulatory Agency. A temperature control (TC) sample must also be taken.
- 6) The milk sample and TC sample containers and the weigh slip shall be identified with the following information:
 - a. Producer identification or number;
 - b. Date of sampling;
 - c. Temperature of sample (Using the temperature of the TC sample);
 - d. Time of sampling;
 - e. Initials of the person taking the sample shall be recorded on the milk sample and TC sample; and
 - f. Name and license or permit number of the person taking the sample shall be recorded on the weight slip.
- 7) A TC sample shall be taken with each milk sample and be identified with TC or by some other manner approved by the State Milk Regulatory Agency.
- 8) Store the samples in the sample storage refrigerator or another State Milk Regulatory Agency approved storage location until the tanker leaves the dairy farm. The samples shall accompany the loaded tanker to the milk plant, receiving station or transfer station receiving the milk.
- 9) Duplicate samples may be taken for pick-up and testing by the producer's milk handling company or State Milk Regulatory Agency.
- 10) Fill out the chain-of-custody (COC) sheet if you place the samples into a refrigerator for storage until samples leave the dairy farm with the loaded tanker or are collected by the producer's milk handling company or State Milk Regulatory Agency.

METHODS AND MEANS TO DETERMINE WEIGHT

The method and means that will be used to determine the weight of milk on the milk tank truck will be specific to each installation. Each individual installation protocol, which is acceptable to the State Milk Regulatory Agency, shall include a description of the method and means used to make this determination.

FORM A

Application to Install an ANDERSON INSTRUMENTS In-Line Sampler

General Requirements:

Producer Name: _____, Date: _____
Producer Address: _____, State and Zip: _____
Producer Phone/Fax/E-mail: _____
Producer's Regulatory License or Permit Number: _____
Purchaser of Milk: _____
Producer's Regulatory Inspector: _____
Pounds of Milk/Day Direct Loaded: _____
Sampling Rate: _____ ml or oz./ _____ lbs. or gals. (Based on milk flow rate)
Flow Rate: _____ lbs. or gals./min. or hour.
Sample End Volume Desired _____ (mls or ozs. or gals.)
Sample Container of Approved Material: Yes _____ No _____
Sample Container of Approved Design: Yes _____ No _____
Material Type: _____
Sample Container Size: _____ (mls or ozs. or gals.)
In-Line Sampler SOP, for Appropriate Sampler on File: Yes _____ No _____
Appropriate Sampler SOP Being Followed: Yes _____ No _____
Number of Milkings to Fill Tanker: _____

Sampler System Design:

(Meets State Milk Regulatory Agency and PMO requirements)

Sampler Location: _____
Sample Collection Location: _____
Refrigerator: Type _____, Make _____, Size (cu. ft.) _____
Refrigerator-Adequate Size to Maintain Sample(s) at Correct Temperature: Yes ___ No ___
Refrigerator, monitoring, upkeep and operation must follow the latest version of the NCIMS 2400 Cultural Procedures Form. (Refrigeration section attached to this SOP)
Records shall be retained for six (6) months.

System Operation:

Person(s) Operating the System Trained: Yes _____ No _____
Person(s) Operating the System, Training Dates on File: Yes _____ No _____
Person(s) Operating the System, Certification #'s on File: Yes _____ No _____
Person(s) who Performed the Training: _____
SOP for the In-Line Sampler Being Used on File and Being Followed: Yes ___ No ___
Cleaning/Sanitizing of the Sampler Approved by the Regulatory Agency: Yes ___ No ___
Cleaning/Sanitizing Protocol Posted and Followed: Yes _____ No _____
All materials; approval for the installation plans; approval of the installation; and all other relevant areas relating to the equipment construction of the in-line sampler and its usage must meet the requirements of Item 9r-Utensils and Equipment Construction of the most recent edition of the PMO.

Methods and Means to Determine Weight:

Protocol Acceptable to State Milk Regulatory Agency: Yes _____ No _____

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APPLICATION TO INSTALL OR MODIFY A MILKING SYSTEM

Producer Name: _____ Date: _____

Producer Address: _____ State and Zip Code: _____

Producer Phone/Fax/E-Mail: _____

Producer's Regulatory License or Permit Number: _____

Purchaser of Milk: _____ Producer's Farm Inspector: _____

I HEREBY MAKE APPLICATION FOR PERMISSION TO INSTALL OR MODIFY A MILKING SYSTEM. THIS EQUIPMENT WILL CONFORM TO OR EXCEED 3-A ACCEPTED PRACTICES FOR THE DESIGN, FABRICATION, AND INSTALLATION OF MILKING AND MILK HANDLING EQUIPMENT.

I. INSTRUCTIONS:

- A. All blanks that apply to this installation must be completed.
- B. This application must be accompanied by a detailed legible drawing for the following areas. Circle the areas that are relevant to this application.
 - 1. High Point
 - 2. Direction of Milk Flow
 - 3. Receiver(s) or Transfer Stations
 - 4. Air Injector(s)
 - 5. Inspection point(s)
 - 6. Wash Vat(s)
 - 7. Milk Cooling and Holding Tank(s)
 - 8. Milk Pre-cooler(s)
 - 9. Milk Chiller(s)
 - 10. In-Line Milk Sampler(s)

II. FABRICATION OF MILKING SYSTEM:

A. Milk Line:

- 1. Material(s): _____
- 2. Diameter (in.): _____
- 3. Length (ft.): _____
- 4. Welded: _____
- 5. Gasketed: _____
- 6. Number of slopes: _____
- 7. Slope (in./10 ft.): _____
- 8. High line: _____
- 9. Maximum height from floor (in.): _____
- 10. Low line: _____

B. Receiver:

- 1. Number of inlets: _____
- 2. Size of milk inlet(s) (in.): _____
- 3. Size of vacuum inlet (in.): _____
- 4. Sanitary Trap: Yes _____ No _____

C. Auxiliary Milking Equipment: Number Manufacturer and Model

- 1. Milk meter(s): _____
- 2. Milk weighing device(s): _____
- 3. Automatic take-offs: _____
- 4. End of milk indicators: _____
- 5. Milk filtration: _____
- 6. Transfer station: _____
- 7. Automatic back flush: _____
- 8. In-line milk sampler(s): _____
- 9. Other (specify): _____

D. Vacuum System:

- 1. Main airline: Material _____, Diameter (in.) _____, Length (ft.) _____
- 2. Pulsator airline: Material _____, Diameter (in.) _____, Length (ft.) _____
- 3. Automatic drains in pulsator airlines: Yes _____ No _____
- 4. Number of clusters: _____
- 5. Vacuum pump(s): Brand _____, Model(s) _____, hp _____
- 6. Total vacuum pump capacity: _____ CFM/ASME at 15 in. Hg.
- 7. Vacuum regulator: Brand _____, Model _____
- 8. Number of distribution tank(s): _____
- 9. Other (specify): _____

E. Milk Cooling and Storage System:

- 1. Pre-cooler: No. _____, Brand(s) _____, Type _____, Number _____
- 2. Type of coolant(s): _____
- 3. Milk cooling & holding tank: Brand _____, Model _____, Ser. # _____
Milk capacity _____, Cooling capacity (BTU/hr) _____
- 4. Chiller: Brand _____, Type _____, Model _____
- 5. Temperature Probe: Brand _____, Type _____, Serial # _____
Location(s) _____

F. In-Line Sampler(s):

- 1. General Requirements:
 - a. Pounds of milk/day direct loaded: _____
 - b. Number of milkings to fill the tanker: _____
 - c. Sampling rate: _____ ml or oz./ _____ lbs. or gals. based on flow rate,
Flow rate: _____ lbs or gals/ min. or hour.
 - d. Sample end volume desired _____ in mls or ozs. or gals.
 - e. Sample container of approved material: Yes _____ No _____
 - f. Sample container of approved design: Yes _____ No _____
 - g. Material Type: _____

- h. Sample container size: _____ in mls or ozs. or gals.
 - i. In-line sampler SOP on file and being followed: Yes _____ No _____
2. Sample system design (meets State Milk Regulatory Agency and PMO requirements)
- a. Sampler(s) location: _____
 - b. Sample collection location: _____
 - c. Refrigerator(s):
 - 1.) Sample collection: Type _____, size _____, cu.ft. _____
 - 2.) Sample storage: Type _____, size _____, cu.ft. _____
 - a. Refrigerator of adequate size to keep sample(s) cool: Yes ___ No ___
 - b. Thermometers calibrated and tagged: Yes _____ No _____
3. System Operation
- a. Persons operating the system trained: Yes _____ No _____
 - b. Persons operating the system training dates on file: Yes ___ No ___
 - c. Persons operating the system certification #'s on file: Yes ___ No ___
 - d. Person(s) who performed the training: _____
 - e. SOP for in-line sampler on file and being followed: Yes ___ No ___

G. Cleaning and Sanitizing System:

- 1. Automatic: _____, Manual _____
- 2. Automatic pre-rinse diverter valve: _____
- 3. Wash procedure:
 - a. Pre-rinse cycle: gals. _____, vol. _____, temp. _____, time _____
 - b. Wash cycle: gals. _____, vol. _____, temp. _____, time _____
 - c. Acid cycle: gals. _____, vol. _____, temp. _____, time _____
 - d. Sanitize cycle: gals. _____, vol. _____, temp. _____, time _____

H. Water Heating Equipment:

- 1. Type of heater: Electric ____, Gas ____, Propane ____, Other ____
- 2. Capacity of heater: _____ gals.
- 3. Recovery rate (gal/hr/100 deg. Rise): _____ gals.
- 4. Additional water heating: Type _____, gals. _____
- 5. Other, specify: _____

I. Manually Cleaned Components (Circle all that apply)

- 1. Diverter plug(s); Manual shut-off valve(s); Milk tank outlet valve(s)
- 2. In-line milk sampler; Farm tanker loading pump and or hose(s)
- 3. List other components in this system: _____

J. Physical Separation of Wash System (Lines) From:

- 1. Milking system during milking: Yes _____ No _____
- 2. Milk tank during CIP operation: Yes _____ No _____
- 3. In-line sampler during CIP operation: Yes _____ No _____

K. Initial Dynamic Test Performed:

Yes ___ No ___, Date: _____

A CLEANING PROGRAM, INCLUDING WATER HARDNESS, DETERGENT AND SANITIZER MUST BE POSTED IN THE MILK ROOM

The posted chart shall be up to date and legible. If procedures, chemicals used or any other changes to the system occur in any way, a new program must be posted.

III. METHODS AND MEANS TO DETERMINE WEIGHT:

The method and means that will be used to determine the weight of milk on the milk tank truck will be specific to each installation. Each individual installation protocol, which is acceptable to the State Milk Regulatory Agency, shall include a description of the method and means used to make this determination.

Owner or Authorized Representative: _____

Installer/Dealer: _____

Installer/Dealer Address: _____

Installer/Dealer Contact Numbers:

Phone _____

Cell Phone _____

Fax _____

E-mail _____

OFFICIAL ACTION

1. Plan Approval

Field Person: _____, Date _____

State Sanitarian _____, Date _____

2. Installation Approval:

State Sanitarian _____, Date _____

5/2006 Revision