

Bulk Tank - With or Without Agitation SOP



1. Purpose:

The purpose of this standard operating procedure is to describe the process of collecting a sample while unloading the contents of a bulk tank or silo directly onto a milk tanker truck used for transport. The key advantage to this process is that it allows a representative sample to be collected via a peristaltic pump and bag, **with or without** the need for agitating the tank prior to loading. The time savings to the hauler or a transport company, coupled with the removal of errors in sampling because of inadequate agitation, is paramount to the industry as a whole.

2. Scope:

These guidelines and SOP apply to the QualiTru Sampling System application used to obtain the NCIMS required sample for milk directly loaded onto a milk tanker truck. The NCIMS approved this sampling method with the issuance of FDA MI-12-4 released February 7, 2012.

For further questions, please contact QualiTru.

3. Responsibility:

- a. Senior management is responsible for annual procedural review, training, oversight and standards compliance.
- b. Quality assurance is responsible for management of quality system, implementation, adherence and validation of the effectiveness/metrics as applicable.
- c. All applicable farm personnel are responsible for adhering to this procedure to assure that controlled documents are appropriately used, updated and distributed in accordance with this procedure.
- d. Transportation/hauling company is responsible for approval and hiring of hauler/ sampler, training and certification, product maintenance and sanitizing.
- e. Anyone who is approved and trained on the use of the QualiTru Inline Sampling System to collect a milk sample is responsible for understanding the content of this SOP. Training in the proper installation of the stainless steel QualiTru Sanitary Inspection Fittings, QualiTru Sterile Septa and general knowledge of aseptic technique is required before a person is qualified to perform this procedure.

4. Related Materials Requirements:

- a. Required equipment and supplies from QualiTru:
 - i. Bevel Seat Stainless Steel Sanitary Port designed and manufactured by QualiTru to connect into the Bulk Tank or Silo outlet line and hold the QualiTru Sterile Septa.
 - ii. Appropriate QualiTru Sterile Collection Bags.
 - iii. Appropriate QualiTru Sterile Septa. QualiTru can advise which Sterile Septa will work best for your application.
 - iv. Dust Cover (Blue).



- v. Wrench to tighten the nut used that holds the Sterile Septum in the stainless fitting.
 - vi. Portable Peristaltic Pump.
- b. Required items NOT supplied from QualiTru:
- i. Pre-installation items.
 - ii. Refrigerator requirements.
 - iii. System installation.
 - iv. System operation:
 1. Pre-sample collection.
 2. Collecting the producer sample.
 3. Splitting the producer sample.
 4. Sample storage requirements.
- c. Pre-Installation Items:
- i. If applicable, application to install the QualiTru Aseptic Sampling System shall be filed with the state regulatory agency and the person responsible for your operations regulatory oversight.
 - ii. Application shall be approved before the sampling equipment is installed.
 - iii. Guidelines for the approval application can be found in FDA issued MI-12-4 or contact your state regulatory agency or use Form A (see attached).
- d. System Installation:
- i. Install the QualiTru Sanitary Bevel Seat Fitting at the outlet valve of the bulk tank that connects the tube to the milk hauling truck. Locate the fitting where it is convenient to insert the needle, attached to the tubing of the sterile sampling bag, into the sterile septum.
 - ii. Location of the septum should be in a place that allows for easy changing of the septum and cleaning/sanitizing the Bevel Seat Fitting.
- e. Peristaltic Pump:
- i. The peristaltic pump comes with a clam shell head.
 - ii. Open the clam shell head by pulling up on the front of the head.
 - iii. Place the peristaltic section (larger "soft" portion) of the sterile sampling bag tubing over the rollers of the pump and close the clam shell head. (Make sure the peristaltic section is centered on the shell rollers)
 - iv. Make sure that the rotation of the pump rollers are correct so that it is pulling the milk from the milk line into the sterile sampling bag.
 - v. Verify the number on the pump dial or keypad matches the speed at which it was calculated to give the appropriate sample size.
 - vi. It is suggested the pump keypad be locked if possible. That will prevent any inadvertent changing of speed or pump roller rotation on the pump.
5. Related Material:
- a. PMO 2015 Revision.
 - b. QualiTru SOP related to use of QualiTru Inline Sterile Sampling System.



6. Procedures:

a. Pre-Sample Collection Requirements:

- i. Sample collection container must meet NCIMS, PMO and state regulatory agency approval. The QualiTru Sterile Collection Bag is shipped sterile and must be maintained in sanitary conditions.
- ii. Size of the sample needs to be determined with cooperation of the state milk regulatory agency.
- iii. Sample size obtained is to be kept to $\frac{3}{4}$ (three quarters or 1500cc) or less of the total volume of the sample container being used.
- iv. Person(s) performing the following steps must possess a valid milk receiver or bulk milk hauler/sampler license as defined in the current edition of the NCIMS, PMO and issued by the state regulatory agency.
- v. Person(s) performing the following these steps must wash and sanitize their hands before handling the equipment used to collect the milk sample.

b. Collect the Producer Sample:

- i. Wash hands thoroughly and put on all applicable Personal Protection Equipment (PPE).
- ii. Connect the QualiTru Bevel Seat Sanitary Fitting to the outlet valve of the Bulk Tank or Silo and connection hose leading into the milk hauling truck.
- iii. At the start of the unload, prior to starting the pump, place a QualiTru Sterile Collection Bag in an ice bath.
- iv. Place the peristaltic section (larger "soft" portion) of the bag tubing into the clam shell pump roller head.
- v. Align the tubing with the rollers and close the clam shell head.
- vi. Remove the QualiTru dust cover protecting the QualiTru Sterile Septum. Place cover in refrigerator.
- vii. Swab the smooth surface of the QualiTru Sterile Septum with an approved sanitizing agent for the appropriate time following sanitizer instructions or recommendations (typically 15-20 seconds).
- viii. Make sure the white covering over the septum remains in place until all channels are used.
- ix. Using proper aseptic technique, remove the needle from its sterile packaging or cover.
- x. Place the needle cover in a sterile milk vial sample container and place in the refrigerator.
- xi. Line the needle up with one of the unused septum needle channels, with the bevel of the needle facing outwards from the center, and gently push the needle in until the shoulder of the needle is pressing against the white septum covering. (See Appendix B)
- xii. When using the outer Septum Channels, insert the needle with a slight angle, with the bevel of the needle slanted outwards from the center. (See Appendix B).
- xiii. Start the peristaltic pump, double check the speed and roller rotation are at the pre-determined settings.
- xiv. Start the pump and begin loading the truck.
- xv. At the completion of the unload or when the tanker truck or bulk tank is full, turn off the peristaltic pump. Remove the needle from the septum and put the needle cover back on the needle. Place the QualiTru dust cover back on the nut of the QualiTru Sanitary Inspection Fitting.
- xvi. See "Splitting the Producer Sample" below.



- xvii. If the tanker truck is not full and requires subsequent farms to fill, follow the exact procedures as stated above starting from "Collecting the Producer Sample" until the milk tanker truck or bulk tank is full.
 - xviii. The opening where the QualiTru Sterile Septum seats in the QualiTru Sanitary Inspection Fitting must be hand cleaned after all the ports have been used.
- c. Splitting the Producer Sample:
- i. Check and record the refrigerator temperatures using the certified thermometers supplied in the refrigerator on the upper and lower areas of the unit.
 - ii. Remove the QualiTru Sterile Collection Bag containing the producer sample from the ice bath.
 - iii. Properly agitate the QualiTru Sterile Collection Bag sufficiently to obtain a representative sample. Holding the bag in a vertical position with the sample tubing on the top side of the bag, semi-rapidly invert the QualiTru Sterile Collection Bag top side to the bottom while still in a vertical position, then back to its vertical position. Perform this motion semi-rapidly 25 times. Be sure to visually verify the butter fat is cascading upwards after each inversion and mixing thoroughly and evenly.
 - iv. After the 25th inversion and the bag's tubing is at the top vertical position, continue to hold the bag in the vertical position and take the sanitized scissors and cut off approximately 6 inches from the bag.
 - v. Prepare the sample vials you are going to use to transfer the milk from the QualiTru Sterile Collection Bag.
 - vi. Invert the QualiTru Sterile Collection Bag and let the milk run out the tubing for a few seconds.
(NOT INTO YOUR VIAL)
 - vii. Open the tops of the sample vials you have prepared and let the milk flow into the sample vials until the vials are no more than $\frac{3}{4}$ (three fourths) full.
 - viii. Close the cap on the sample vials and place the sample vials in the sample refrigerator or cooler, in a float. The cooler should have a water, ice mixture to keep the samples at the required temperature.
 - ix. The transfer of the milk from the QualiTru Sterile Collection Bag to the sample vials needs to be completed within 3 minutes after the final agitation of the QualiTru Sterile Collection Bag.
 - x. Consult a representative of the Co-op, state, or hauler to find out the appropriate information that needs to be put on the QualiTru Sterile Collection Bags and the sample vials.
- d. Storage of Samples:
- i. Store the samples in the sample collection refrigerator or another state milk regulatory agency approved storage location until the tanker leaves the dairy farm.
 - ii. The samples shall accompany the loaded milk tanker truck to the milk plant, receiving station or transfer station receiving the milk.
 - iii. Duplicate samples may be taken for pick-up and tested by the producer's milk handling company or State Milk Regulatory Agency.



7. Quality Records:

- a. Associated company manuals, and SOP.
- b. Records of education, training, skills and experience.
- c. Records related to the review of customer requirements.
- d. Supplier evaluation records.
- e. Product identification records.
- f. Product conformity records
- g. Nonconformities and Corrective Action, CAPA, SCAR, NCMR records.
- h. Results of Preventative Actions taken.
- i. Wash and Sanitation records.
- j. Related forms that address PMO Appendix B requirements.

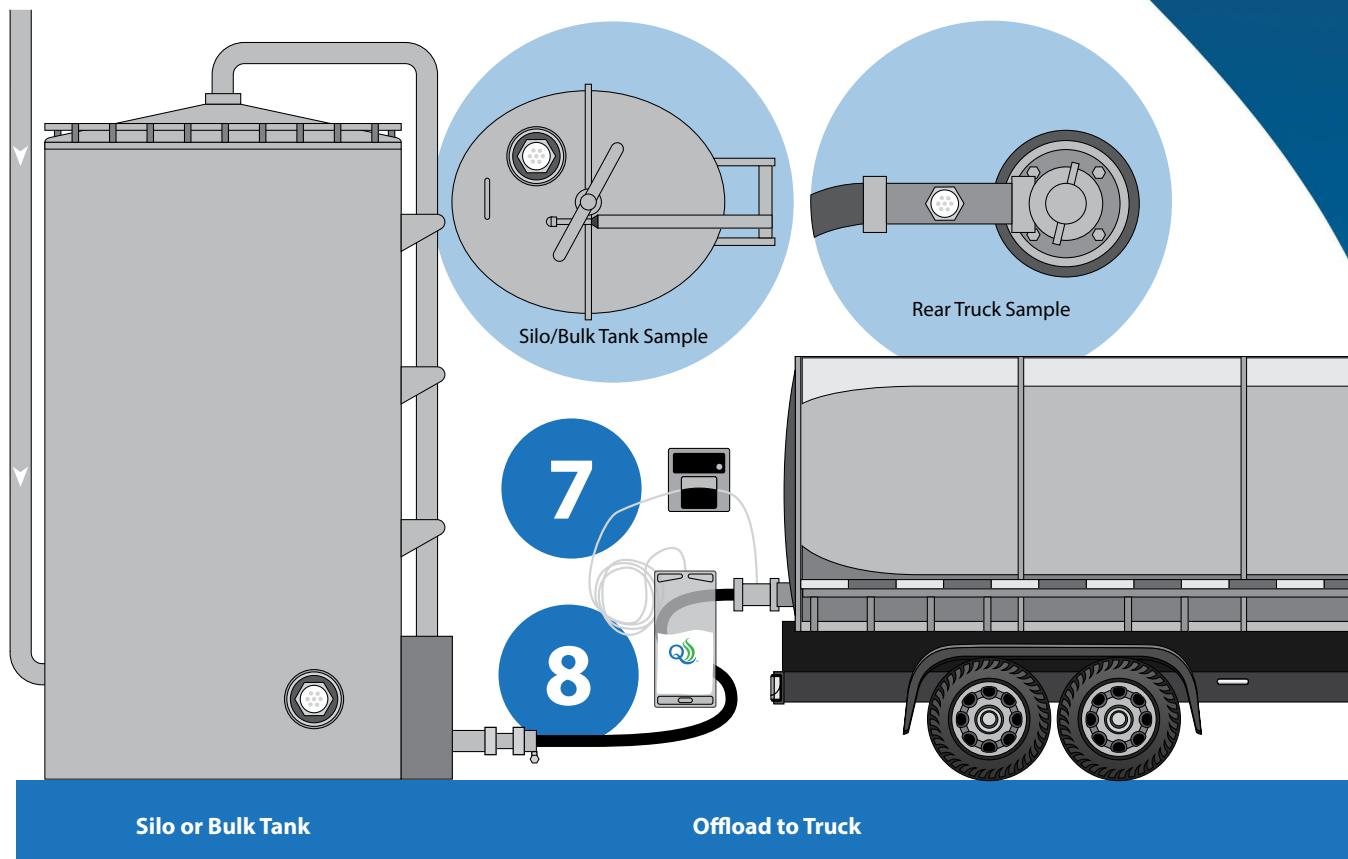
8. Forms:

- a. All internal forms used for track and trace compliance to ISO, FSMA, SQF, HACCP, PMO and all others not mentioned that are applicable to the traceability of use, cleaning and sanitizing of the QualiTru product.

Rev	Description of Change	Revision Date	DCO#
A	Initial Release	27APR2017	NA

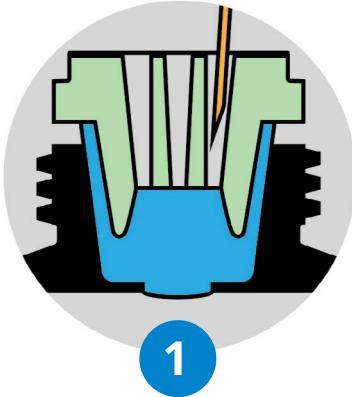
Appendix A.

***Diagram is a representation and may not reflect the exact final configuration of purchased product.

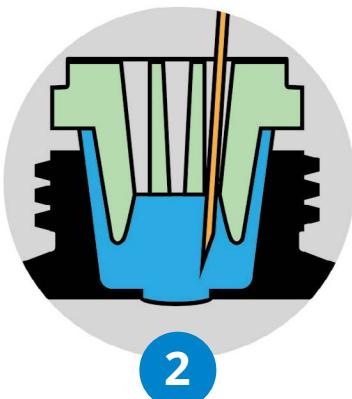


Appendix B.

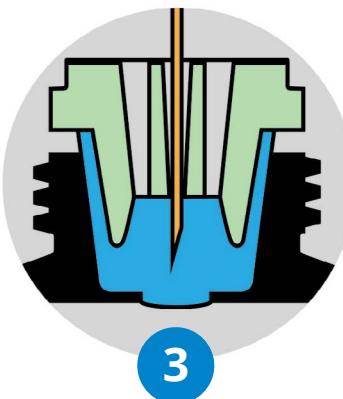
Proper Needle Insertion into QualiTru™ Septum



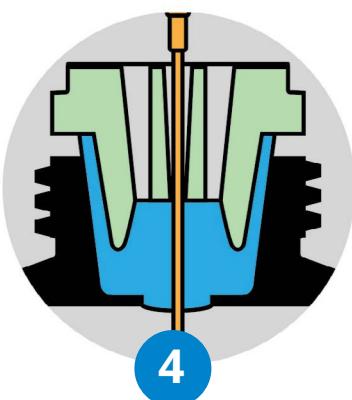
Line the hypodermic needle up with the channel you plan to use.



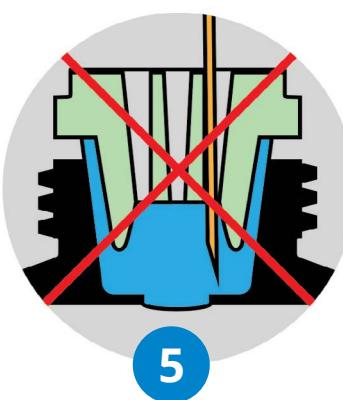
Face the bevel of the needle outward, or toward the outer ring.



Slowly push the hypodermic needle until you meet resistance.



Gently continue through the rubber until you can push no further.



Do not spin or twist on the way through, as you could core the rubber.