

Guidelines for sampling and maintenance of the QualiTru Side Mount Truck Sampler



1. Purpose

In an effort to increase the security, health and safety to haulers or transporters and mitigate the risk of physical, microbial and chemical adulteration to over the road transported fluid milk products, QualiTru in conjunction with its partner has developed the QualiTru Truck Mounted Recessed Port. (See Appendix A). Historically, sampling from a tanker truck involved the hauler or employee of the processor climbing the ladder located on the side of truck to the top, opening a top hatch, which exposes the product to the ambient environment and utilizing a dipper directing into the raw product. This poses a number of inefficient, unsanitary, and possibly harmful areas of opportunity that are corrected by installing a QualiTru Truck Mounted Recessed Port with security door, onto the side of the truck. By removing or avoiding the use of the top hatch on the top of the truck and installing the QualiTru Truck Mounted Recessed Port along the side, the product can no longer be accessed by anyone other than authorized personnel. Additionally, the product itself can no longer be exposed to the environment, nor exposed to possible unsanitary utensils, thus ensuring the integrity of the product. Further, the personnel responsible for taking the sample, will no longer be in danger of slips or falls as the sample is taken from the ground.

2. Scope

These guidelines and SOPs apply to the QualiTru Truck Mounted Recessed Port used to obtain the NCIMS required sample, for Grade "A" milk or food grade liquid being transported from the registered producer to a processing facility.

For further questions, please feel free to 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 processor 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, training and sanitizing.
- e. Anyone who is approved and trained on the use of the QualiTru Truck Mounted Recessed Port to collect a milk sample is responsible for understanding the content of this SOP. Training in the proper installation of the stainless QualiTru Truck Mounted Recessed Port, 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. Stainless Steel (S.S.) Side Mount Aseptic Sampler designed and manufactured for QualiTru to be mounted on the side of the tanker truck and hold the QualiTru Sterile Septa.
 - ii. 7 Port QualiTru Sterile Septa, Pn: 110011 or 110021.
 - iii. Septa cover (blue).
 - iv. Wrench to tighten the nut used to hold the septa in the S.S. fitting.
 - v. Assemble necessary items: needle, syringe, or QualiTru TruDraw Single Sampler.
- b. Required items NOT supplied from QualiTru.
 - i. Alcohol used to swab the front of the QualiTru Sterile Septum, prior to needle insertion.
 - ii. Cotton swab used to sanitize front of QualiTru Sterile Septum prior to needle insertion.
 - iii. Bottle of hand sanitizer or hand sanitizer wipes.
 - iv. State approved regulatory 2, 3 or 4-ounce sample bottles used to contain the milk collected from the QualiTru Sterile Septum.
- c. Pre-installation items.
 - i. Application to install the QualiTru Sampling System equipment 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.
- d. System Installation.
 - i. Installation of the QualiTru Truck Mounted Recessed Port should be completed by a welding and fabricating company that recognizes 3A and PMO standards, must be installed according to the recommendations of QualiTru engineers in a manner that is compatible with its intended use, as approved with your state regulator.
- e. System Operation.
 - i. Pre-Sample Collection Requirements.
 - ii. Collecting the producer sample.
 - iii. Sample storage requirements.

5. Related Material

- a. PMO 2015 Revision.
- b. QualiTru SOP related to use of Sterile Sampler, and QualiTru Truck Mounted Recessed Port.

6. Procedures

- a. General QualiTru Sampler Procedure.
 - i. Remove security seal from exterior of closed lid to gain access to the QualiTru Sterile Septum.
 - ii. Pull latch on exterior security lid, exposing the QualiTru Sterile Septum.
 - iii. Wash hands thoroughly.



- iv. Remove blue dust cover.
- v. Swab the smooth plastic surface of the QualiTru Sterile Septum with sanitizing agent for an appropriate time period (typically 15-20 seconds),
- vi. Use proper sterile technique to remove the needle from its sterile packaging,
- vii. Line the needle up with one of the penetration channels and push the needle gently through the smooth plastic surface and all the way through the rubbery septum material below it into the interior of the vessel or line. (See Appendix B). Penetrate the Septum with a slight angle when sampling from the outer channels. (See Appendix B).
- viii. Carry out the transfer of material (QualiTru Single Sampler, Sterile Collection Bag or syringe). Fill the syringe or bag with the liquid sample. If you are using a syringe, the liquid sample may be transferred to a sterile sample container. If you are using a bag, you can adjust the rate of flow with a flow clamp, different size needle or a peristaltic pump.
- ix. After the material transfer is completed, withdraw the needle and cover it to prevent accidental needle sticks. Discard the needle properly in a container for sharps.
- x. Place the blue dust cover over the nut.
- xi. Replace the QualiTru Septa after each channel has been penetrated. Do not reuse the channels.
- xii. Close lid, verifying that the latch is engaged and will not open while in transit.
- xiii. The QualiTru Sterile Septum can be left in place during the CIP cycle and has been validated at a combined 250°F, 150psi for 100 hours.
- xiv. For an application outside these guidelines, please contact QualiTru.

b. General Security Seal Guidelines

- i. After a milk tanker is unloaded and washed, the wash station/plant seals all potential points of access to the interior of the tank with an appropriate sealing device such as a plastic tie or wire with a pressed metal seal. Each seal should have an identification number for traceability purposes. Access points that require sealing include inlet/outlet valves, manhole cover, vent tube, CIP connections, security lid of QualiTru Truck Mount Recessed Port, and any other point at which one could access the inside of the tank.
- ii. After washing the interior of the tanker and installation of seals, each seal is inspected and its number is recorded in an appropriate place. For example, numbers may be recorded on the wash tag, on the manifest, or on a log specifically carried by the driver for this purpose. The instrument used to record seal numbers will be referred to in this document as the "seal record."
- iii. If wash tags are used as the seal record, they should be printed with unique identifiers (company logo, plant I.D. number, etc.). Wash tags should be accounted for and kept in a secure place by receiving personnel as required by the PMO.
- iv. When the driver is preparing to leave on his collection route, he checks to verify that the numbers on the seals correspond to the numbers that were entered in the seal record. If the numbers match, the driver writes his initials on the seal record.
- v. If at any time the driver finds that a seal has been broken without his knowledge or that a seal is missing, he should immediately notify the plant or cooperative.



- vi. When the tanker arrives at the first farm pickup, the driver checks all seals to be sure that none are broken. The driver then breaks and removes the seals on the rear door and the outlet valve. The numbers on the broken seals are recorded.
- vii. At the last farm pick up the driver attaches a numbered seal to the inlet/outlet valve, the rear door, or any other point of access that has been opened. The seal numbers are recorded in the seal record. A padlock may be used instead of a seal to secure the rear door.
- viii. Any time the tanker is not under direct supervision of the driver, all openings on the tanker are secured with a seal or lock.
- ix. When the tanker arrives at the receiving plant, authorized receiving personnel compare the numbers on all seals to the numbers in the seal record. It is recommended that the receiving plant maintain a seal verification log.
- x. If the seal numbers match, the milk is eligible to be evaluated for unload based on the product quality.
- xi. If any seals do not correspond to the seal verification entries, or if any seal is inexplicably broken, the receiving plant does not unload the milk until a further investigation reveals the cause.
- xii. If a tanker delivers milk to a receiving plant more than once a day and is not washed until the last load is delivered, the procedure outlined above is utilized each time the tanker exits the plant. At the end of the day, after the plant has unloaded and washed the tanker, those points of access listed above are sealed with the seal numbers entered on the seal record. The cycle for the tanker begins again the following day or the next scheduled use.

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.

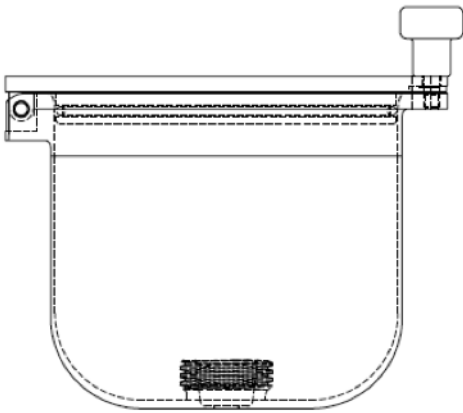
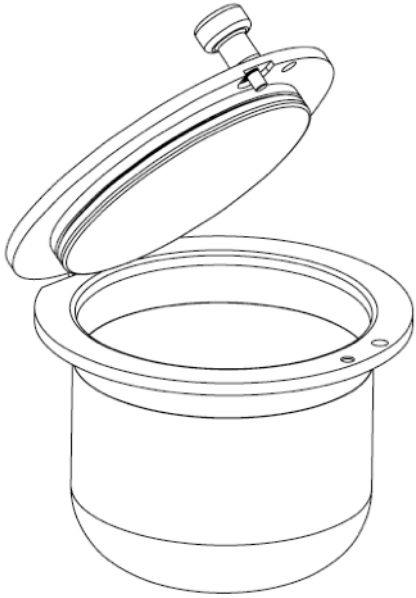
8. Forms

- 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		

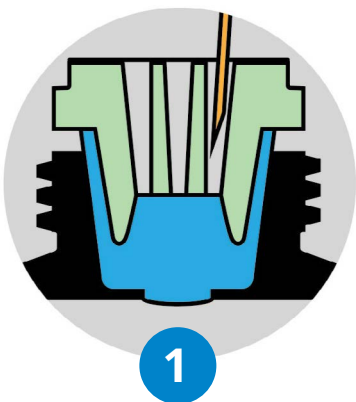
Appendix A.

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

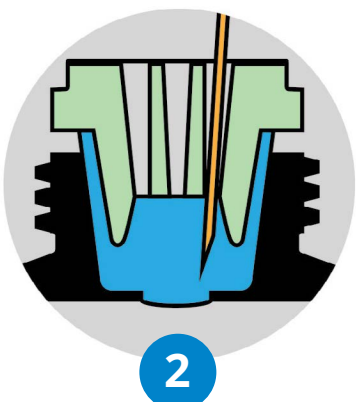


Appendix B

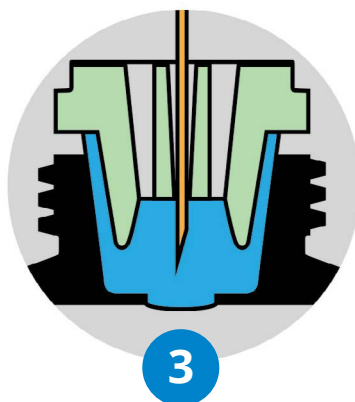
Proper Needle Insertion into QualiTru Sterile Septum



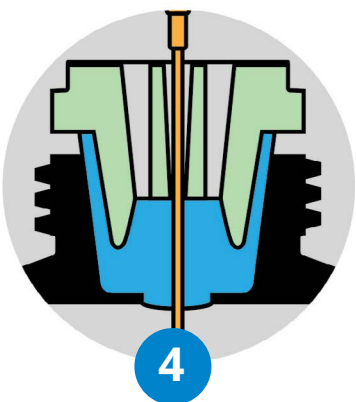
Line the hypodermic needle up with the channel you plan to use.



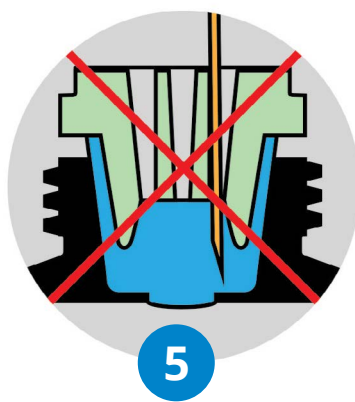
Face the bevel of the needle outward, or toward the outer ring.



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.