

Guidelines for QualiTru Line Sampling

1. Purpose:

Following these Standard Operating Procedures, farms and processing plants may use the QualiTru aseptic sampling method to obtain a sample of their liquid product. This process can be used to draw samples for microbiological, regulatory, analytical or other component testing for any liquid product. Additionally, this sampling method can be used for string sampling and mastitis management by drawing a sample over an extended period of time.

2. Scope:

These guidelines and SOPs apply to sampling from any line through-out a fluid system, and can be used in conjunction with the Diagnostic SOP.

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 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. Farm or processing plant 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 Aseptic Sampling System to collect a milk sample is responsible for understanding the content of this SOP. Training in the proper installation of the stainless QualiTru fittings, 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 Sanitary Port designed and manufactured for QualiTru to be mounted at any point through-out a system.
 1. Contact QualiTru for your specific application.
 - ii. 7 Port QualiTru Sterile Septum, Pn: 110011 or 110021.
 - iii. Septa cover (blue).
 - iv. Wrench to tighten the nut used to hold the septa in the stainless fitting.
 - v. Assemble necessary items: needle, syringe, or TruDraw Single Sampler.





- b. Required items NOT supplied from QualiTru:
 - i. Alcohol used to swab the front of the QualiTru Septum, prior to needle insertion.
 - ii. Cotton swab used to sanitize front of QualiTru Septum, prior to needle insertion.
 - iii. Bottle of hand sanitizer or hand sanitizer wipes.
 - iv. State approved regulatory sample container.

- c. Pre-installation items:
 - i. Application to install the QualiTru Aseptic Sampling equipment shall be filed with the state regulatory agency and the person responsible for your operations regulatory oversight, if applicable.
 - ii. Application shall be approved before the sampling equipment is installed.

- d. System Installation:
 - i. Installation of the QualiTru stainless steel components should be completed by a welding or fabricating company that recognizes 3-A and PMO standards. They 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 requirement.

5. Related Material:

- a. Most current approved PMO Revision.
- b. QualiTru SOP related to use of sterile septa, and QualiTru stainless steel components.

6. Procedures:

- a. General QualiTru Sterile Septum Installation:
 - i. Install QualiTru stainless steel components according to manufacturer's recommendations for location and function and remove nut. (see Appendix A)
 - ii. Wash hands thoroughly prior to putting on personal protective gear and disposable gloves.
 - iii. With an alcohol swab, clean out the interior housing of the stainless steel components, and verify they are clean of contaminants.
 - iv. Remove the Sterile Septum from its packaging, using caution to NOT touch the food contact surface of the Septa.
 - v. Place the Sterile Septum into the sanitary stainless steel components with channels exposed outwardly.
 - vi. Hand tighten the nut around the Sterile Septum.
 - vii. Use a wrench to tighten additional 1/8 of a turn, ****Do no overtighten****, as this can damage the Septum.



- viii. Place blue dust cover over the stainless nut to protect Septum from particles, dust and other environmental contaminants, when not in use.
- b. General QualiTru Sampler Procedure:
 - i. Wash hands thoroughly prior to putting on personal protective gear and disposable gloves.
 - ii. Gain access to surface of septum by removing blue dust cover.
 - iii. With an alcohol saturated swab or alcohol wipe, clean the surface of the septum being sampled. (Typically 15-20 seconds).
 - iv. Sterile Collection Bag or syringe:
 - 1. Line the needle up with one of the penetration channels and push the needle gently through the surface and all the way through the rubbery septum material below it into the interior of the vessel or line. (See Appendix B).
 - 2. Penetrate the Septum with a slight angle when sampling from the outer channels. (See Appendix B).
 - 3. Carry out the transfer of material (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.
 - a. If you are using a bag, you can adjust the rate of flow with a flow clamp, different size needle or a peristaltic pump.
 - 4. 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.
 - 5. Place the blue dust cover over the nut.
 - v. QualiTru TruDraw Single Sampler:
 - 1. Open Package containing the TruDraw Single Sampler.
 - 2. Remove TruDraw Single Sampler from package by only touching the body of the Sampler.
 - 3. Apply Sampler identification to body of Sampler, or prepare sticker with date, time and location of sample taken.
 - 4. While holding Sampler, rotate the cap counter-clockwise until it stops and firmly press cap down onto top of Sampler. Verify that the spikes under the cap have completely pierced the top lid of the Sampler.
 - 5. While holding cap against top of Sampler, remove cover from the hypodermic needle by pulling it off. Keep cover so it may be re-installed after taking sample.
 - 6. While holding Sampler, push needle into unused channel of the septum, to fill Sampler with fluid.
 - 7. Pull container to remove needle from septum and carefully replace cover of needle.
 - 8. Firmly pull on cap and remove it from Sampler. Safely discard cap and needle in a container for sharps.



7. Quality Records:

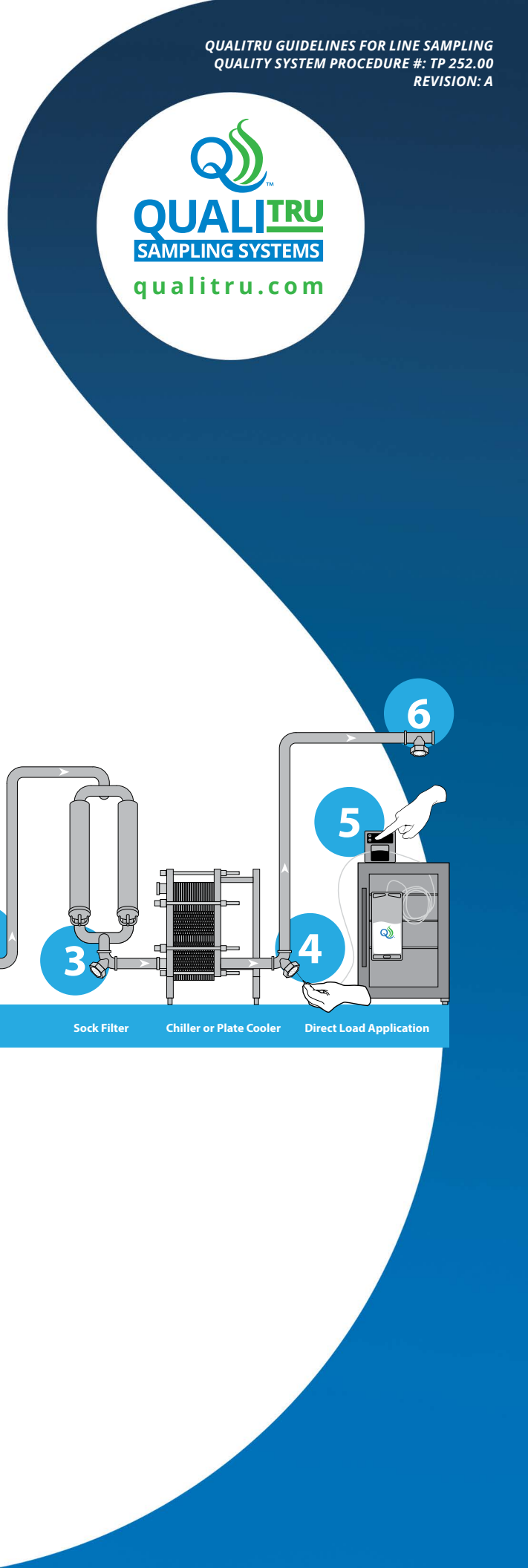
- a. Associated company manuals, and SOP.
- b. Records of education, training, skills and experience.
- c. Records related to the review of customer requirements.
- d. Supplier evaluation records.
- e. Product identification records.
- f. Product conformity records.
- g. Nonconformities and Corrective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


8. Forms:

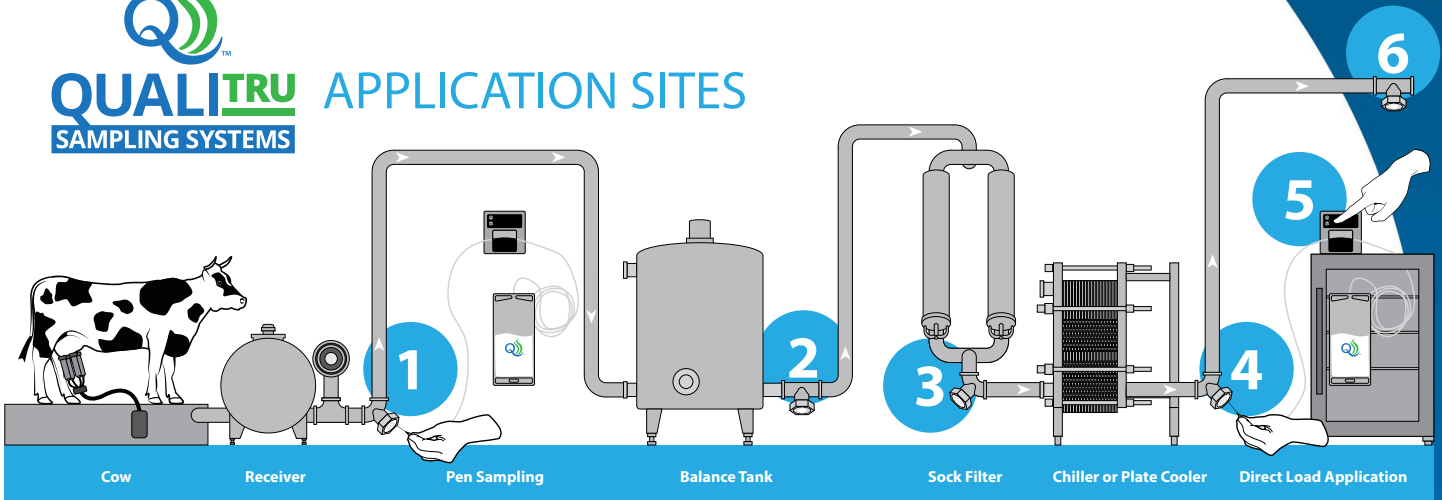
- a. All internal forms used for track and trace compliance to ISO, FSMA, SQF, HACCP, PMO and all others not mentioned that are applicable to the traceability of use, cleaning, and sanitizing of the QualiTru product.

Rev	Description of Change	Revision Date	DCO#
A	Initial Release	04/26/2017	NA

Appendix A.

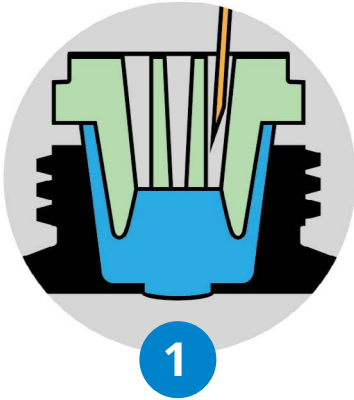


 **QUALITRU** APPLICATION SITES
SAMPLING SYSTEMS

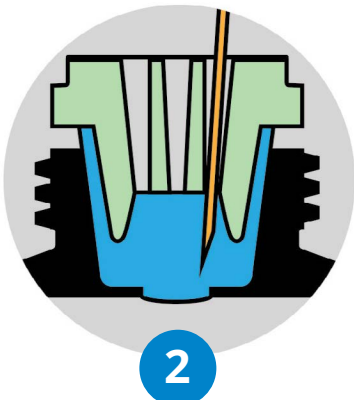


Appendix B.

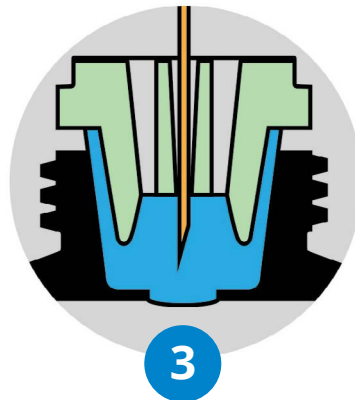
Proper Needle Insertion into QualiTru™ Septum



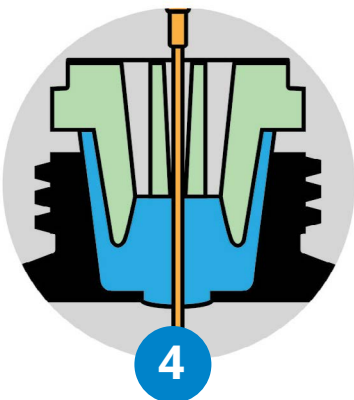
1
Line the hypodermic needle up with the channel you plan to use.



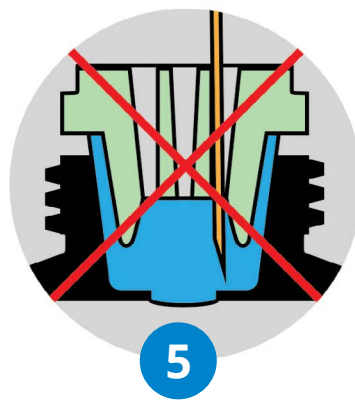
2
Face the bevel of the needle outward, or toward the outer ring.



3
Slowly push the hypodermic needle until you meet resistance.



4
Gently continue through the rubber until you can push no further.



5
Do not spin or twist on the way through, as you could core the rubber.