Guidelines for System Diagnostic Sampling and Process Verification

1. Purpose

With the integration of FSMA nearing completion and third party quality system requirements becoming more stringent, food producers and processors need to adjust accordingly to continue to be competitive in the market. The QualiTru Sampling System diagnostic functionality can be an integral part of a producer or processor quality system for regulatory and internal quality system process verification or system contamination identification.

2. Scope

This SOP will outline general guidelines for proper installation and use of the QualiTru Sampling System components required for process sampling. These samples can be used to verify the quality of the existing CIP cycle throughout the entirety of the process, or identify key sources of contamination for analysis.

For specific questions, please feel free to contact QualiTru Sampling Systems directly.

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 Sampling System to collect a fluid sample is responsible for understanding the content of this SOP. Training in the proper installation of the QualiTru Sanitary Port, 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. Sanitary Port: QualiTru Sanitary Port, designed and manufactured by QualiTru, and 3A certified, holds the QualiTru Sterile Septa and is installed at specific points throughout the process. Contact QualiTru for your specific application.
    ii. 7 or 12 Channel QualiTru Sterile Septa
    iii. Sterile Septa cover (blue)
    iv. Wrench to tighten the nut used to hold the Sterile Septum in the Sanitary Port
    v. Assemble necessary items: TruDraw Single Sampler, QualiTru Sterile Collection Bags or needle and syringe

c. Required items NOT supplied by 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 Septum prior to needle insertion
   iii. Bottle of hand sanitizer or sanitizer wipes
   iv. Disposable gloves and other PPE
   v. State approved regulatory 2, 3 or 4-ounce sample bottles used to contain the fluid collected from the QualiTru Septum

d. Pre-installation items
   i. If applicable, the 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 must be approved before the sampling equipment may be installed.

e. System Installation
   i. Installation of all QualiTru Sampling System components should be completed by a welding and fabricating company that recognizes 3A and/or PMO standards. Each component must be installed according to the recommendations of QualiTru engineers in a manner that is compatible with its intended use as approved by your state regulator.

f. System Operation
   i. Pre-Sample Collection Requirements
   ii. Collecting the processor sample
   iii. Sample storage requirements

5. Related Material

a. All applicable Processor quality system specifications, i.e.: SQF 7.2, HACCP, etc.
b. Pasteurized Milk Ordinance- PMO (most current revision)
c. QMI SOP related to use of QualiTru Sterile Sampler

6. Procedures

a. General Port Installation Site Identification (Farm)

Contamination within farming equipment can jeopardize milk production, jeopardize membership in the producer's co-op, limit whether a producer's milk will be accepted and jeopardize associated producer premium. Developing an On-The-Farm quality system with a Mastitis Control will allow the producer to identify potential areas of contamination or assist with their farm's overall quality management.

   i. The first step is to identify critical control locations throughout the milking process for sampling. These sampling locations are where potential contamination could appear in equipment.
      1. Potential locations may include: after the sanitary trap, before or after the balance tank, sock filters, chiller, or before loading into bulk tank or truck.

ii. After locations have been identified, evaluate the risk of contamination from high, medium to low at each location.
iii. Install QualiTru ports or fittings at select sampling points to break the system into separate and segregated portions for analysis. Start by breaking the system into thirds with three locations. Further breakdowns can be completed after initial evaluation, if needed.
iv. At a bare minimum, samples should be taken from each site in the beginning, middle and end of milking. It is highly recommended that samples be taken every two hours, from each site, until that milking is concluded.
v. Evaluate the results. Once all results have been compiled, look for trends. If a more detailed sample plan needs to be evaluated, use the data to either further isolate specific sections of the system or, correct the contamination issue.

b. General Port Installation Site Identification (Processor)

Whether you are implementing the QualiTru Sampling System throughout your processing systems as part of an increased level of compliance to regulatory requirements, increased awareness of specific portions of your system, or tracking down a possible contamination of finished goods, the installation is identical.

i. Begin with a complete system gap analysis from receiving to finished goods. Identify the key locations where a contamination could occur, all significant pieces of processing equipment and all critical control points.
ii. Evaluate the risk of contamination, organic build up and physical security of each site identified and label each based on high, medium or low risk.
iii. Once key sites throughout the process have been identified as high, medium or low risk, determine a testing schedule for each site.
iv. Install a QualiTru Port at the point either before, after or before and after the site identified.
    1. If a piece of equipment is being evaluated, QualiTru suggests installing the Sanitary Port 12-36 inches before and after the piece to validate the material going in versus what is coming out.
v. Create a master schedule of testing and create a spreadsheet with all results to track and trend results.
vi. In the event of a possible contamination, take a sample from all sites to narrow down the specific area of concern.

c. General Sterile Septa Installation Procedure

i. Install QualiTru Sanitary Port according to manufacturer's recommendations for location and function, then remove nut.
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 port, and verify it is clean of contaminants.
iv. Remove the QualiTru Sterile Septum from its packaging using caution to NOT touch the food contact surface of the Septa.

v. Place the QualiTru Sterile Septum into the QualiTru Sanitary Port with channels exposed outwardly.
vi. Hand tighten the nut around the QualiTru Sterile Septum.
vii. Use wrench provided to tighten additional 1/8 of a turn, ****Do not overtighten****, as this can damage the septum.
viii. When not in use, place blue dust cover over the stainless nut to protect QualiTru Sterile Septum from particles, dust and other environmental contaminants.

d. General QualiTru Sampler Procedure
i. Wash hands thoroughly
ii. Remove blue dust cover
iii. Swab the smooth plastic surface of the QualiTru Sterile Septum with sanitizing agent for an appropriate time period (typically 15-20 seconds)
iv. Use proper sterile technique to remove the needle from its sterile packaging
v. 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, 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).
vi. Carry out the transfer of material (TruDraw Single Sample, Sterile Collection Bag or filling 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.
vii. 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.
viii. Place the blue dust cover over the nut
ix. Replace the QualiTru Sterile Septa after each channel has been penetrated. Do not reuse the channels.
x. The QualiTru Sterile Septa can be left in place during the CIP cycle and has been validated at a combined 250°F, 150psi for 200 hours.
xi. For an application outside these guidelines, please contact QualiTru.

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	04/18/17	N/A

QUALITRU SAMPLING SYSTEMS
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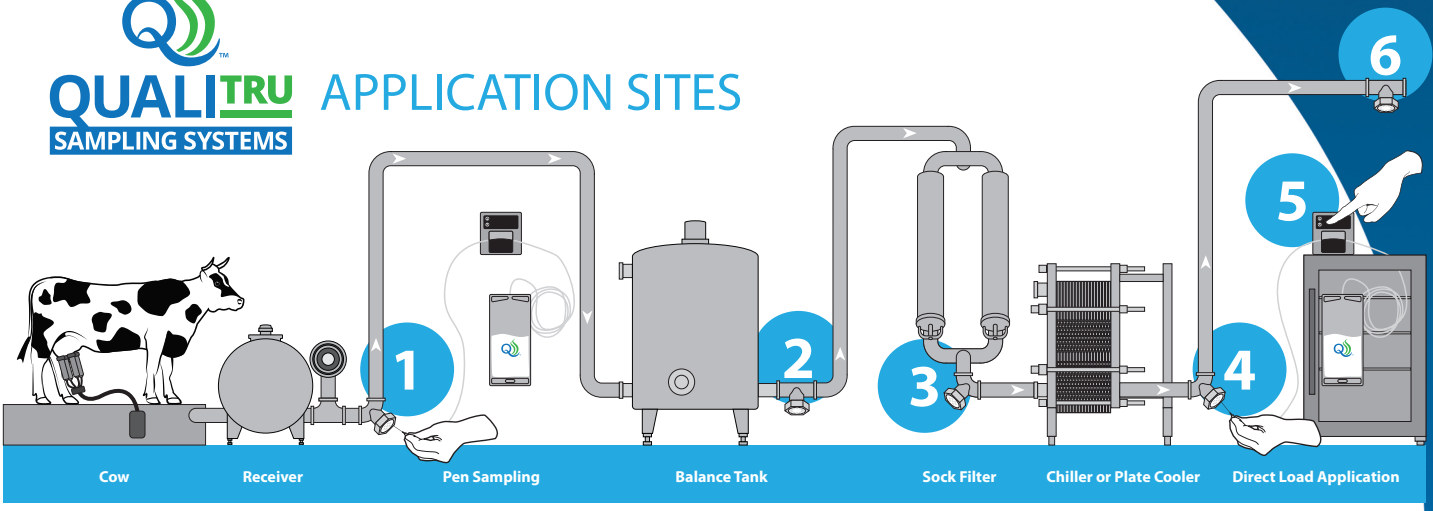
Appendix A.

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

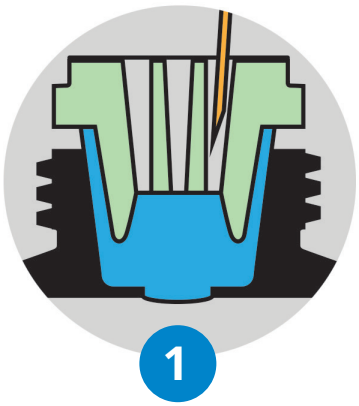
QUALITRU SAMPLING SYSTEMS

APPLICATION SITES



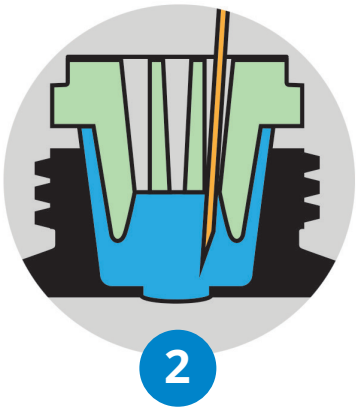
Appendix B

Proper Needle Insertion into QualiTru Sterile Septum



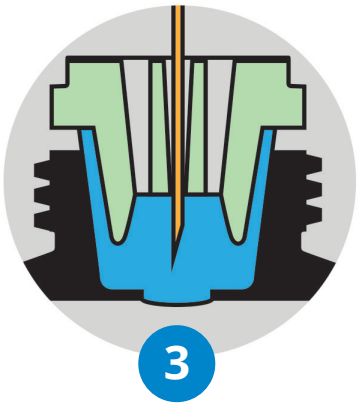
1

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



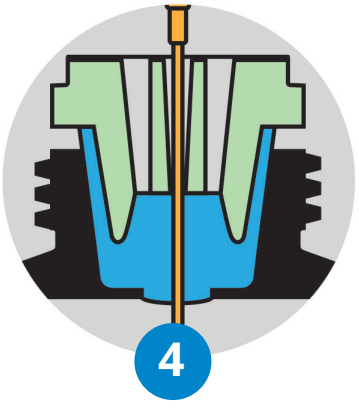
2

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



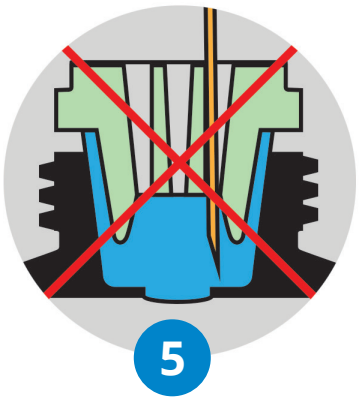
3

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.