1.0 Purpose

Definition: *Aseptic* means “without microorganisms”. Aseptic Sampling as defined by QMI is sampling with a sterile needle and septum using Aseptic Techniques. *Aseptic Technique* refers to practices that help reduce the risk of contamination.

The following procedures suggest an *Aseptic Technique*.

This procedure describes the proper installation and use of the QMI ® Aseptic Sampling System by manufacturing and quality control technicians.

2.0 Scope

This procedure applies to the general use of the QMI ® Aseptic Sampling System for Tanker Trucks.

3.0 Responsibility

Anyone who uses the QMI ® Aseptic Sampling System to transfer materials across the aseptic barrier of a tanker truck is responsible for understanding the content of this SOP. Training in the proper installation of the fittings and septums and general knowledge of aseptic technique is required before a person is qualified to perform this procedure.

4.0 Procedure

The QMI ® Aseptic Sampling System for material transfer (sampling) is used to achieve aseptic transfer of materials into and out of the aseptic barrier of tanker trucks. It is most suitable for use in applications involving the transfer of low viscosity, low particulate liquids at flow rates compatible with the size of the hypodermic needle used in the procedure.

4.1 Installation of the QMI Aseptic Sampling System fitting

4.1.1. The QMI ® Aseptic Sampling System fitting must be installed according to the recommendations of QMI engineers and in a manner that is compatible with its intended use. Drawings are available from QMI.
For example: A fitting may be welded into the cabinet or other locked location on the tanker truck. In this case, all qualification procedures for welded joints must be observed.

4.2 Installation of the QMI Aseptic Sampling System cartridge (Sampler)

4.2.1. The QMI ® Aseptic Sampling System septum (QMI Sampler) must be installed according to the instructions from QMI accompanying the package.

For example: A seven port sampling septum would be removed from its sterile wrapping and placed in the open fitting. The retaining collar (nut) is then hand tightened on to the fitting and the sampling septum is checked for even seating in the fitting. Finally, the retaining collar (nut) is tightened one eighth to one quarter turn using a wrench which can be purchased from QMI.

4.3 Penetration of the QMI Aseptic Sampling System and transfer of milk or other material

4.3.1. Penetration of the QMI ® Aseptic Sampling System for transfer of materials is achieved by using a hypodermic needle to pierce the septum. Material used in the QMI Aseptic Sampling System septum is non-coring when penetrated by any commercially available hypodermic needle. The practical limitation of needle size is 16, 18 or 23 gauge. Hypodermic needles used must be sterile and appropriately packaged to maintain sterility until the moment of use.

4.3.2. An appropriate device must be attached to the hypodermic needle to effect the transfer of material (sampling).

For example: The needle may be attached to an appropriately sized sterile syringe that can be used to withdraw material.

4.3.3. Step-wise procedure for penetration of the QMI ® Aseptic Sampling System and material transfer (sampling):

1. Assemble necessary materials: needle set-up, sterile swabs, sanitizing agent.

2. Swab the smooth plastic surface of the QMI ® Aseptic Sampling System septum with a sanitizing agent for an appropriate time period (typically 15-20 seconds).

3. Use proper sterile techniques to remove the needle from its sterile packaging.
4. 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 sampling material below it into the interior of the vessel. Penetrate the Aseptic Sampler with a slight angle when sampling from the outer channel guides.

5. Carry out the transfer of material (sampling).

6. 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.

5.0 The Sample must be recorded with appropriate regulatory procedure.
Quality Management, Incorporated (dba QMI ®)  
QMI ® Aseptic Sampling System  
Standard Operating Procedures  
For Tanker Trucks  
SOP XX02PP, Revision 02PP (20050218)

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