



CCE COORDINATION BULLETIN

BULLETIN NUMBER 2006-2

Standard 02-10, Milk Pumps, Interpretation of Clause D11.2.2.5 Enclosed Threads

Background: On October 16, 2006 3-A SSI received from a Certified Conformance Evaluator (CCE) a Request for Interpretation of Clause D11.2.2.5 appearing in 3-A Standard 02-10. He specifically asks:

"I request that the following three items be interpreted as to their meaning to allow for TPVs to be properly completed. Or to declare that paragraph D11.2.2.5 can not be met as written.

1. What does "cleanable" mean with respect to a sharp cut thread?
2. What does "drainable" mean with respect to a sharp cut thread?
3. What does "validated" mean with respect to a cleaning procedure?"

3-A SSI procedures state:

"The 3-A SSI Secretariat shall attempt to resolve the ambiguity informally with the requester and Chair of the appropriate Working Group or the Chair of the Steering Committee. In the event that the ambiguity cannot be resolved informally, the issue shall be sent to the Interpretations Committee (IC) for an official interpretation."

The Chair of the relevant Work Group (4) and the Chair of the Steering Committee met with staff on October 17, 2006 via phone conference and concluded the following, which if accepted by the person requesting the Interpretation, will be come the official interpretation of the clause. The CCE submitter has accepted the following interpretation.

Interpretation of Clause D11.2.2.5, which states "D11.2.2.5: Enclosed threads shall be cleanable and drainable. The manufacturer will also provide validated cleaning procedures, should the area behind the seal become soiled."

- A. Interpretation of "Cleanable" as it relates to a sharp cut thread (in a non-product contact area).
"Cleanable" means the same as does the 3-A *Style and Format Manual* definition of this term: "Cleanable: The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed from soil." This definition applies. There is some method available to remove residual soil. This can be scrubbing with a bottle brush, cleaning using a steam hose, or some other effective method. Visual inspection can then be used. If the thread area looks clean after cleaning, it is considered "clean".
- B. Interpretation of "Drainable" as it as it relates to a sharp cut thread (in a non-product contact area). The 3-A *Style and Format Manual* section 6.1 on Draining applies. It states:

"Surfaces shall be self-draining except for typical clingage or adherence.

Alternate Paragraph

Surfaces shall be drainable and provided with sufficient drain points so the equipment can be drained.

Alternate Paragraph 2

Surfaces shall be self-draining except for typical clingage or adherence and {List all Application(s)} may be made to be drainable with sufficient drain points so the equipment can be drained.”

If the threads can drain, they are “drainable”. This may include the removal of a plug to effect the draining of the thread area. Then some residue will remain, which is “typical clingage” and is to be expected. This is a normal occurrence. Complete dryness is not required. In addition, drainable means “not self-draining”. If a nut or bolt is removed, then this area must drain except for “normal clingage”. If the pump is horizontally mounted, only a small portion of the bottom of the thread will retain liquid and should be considered as normal clingage.

- C. Interpretation of “validated” with respect to a cleaning procedure. “Validated” simply means that the manufacturer needs to demonstrate that they can clean the component with the stipulated cleaning procedure or method. The selection of the method is at the discretion of the manufacturer. For example, this may be by scrubbing in the direction of the threads with a bottle brush, or by steam cleaning. Validating the stated cleaning procedure (which must be supplied by the manufacturer and may appear in the owners’ manual) can be done by any effective means available to the manufacturer. This can include before and after photos of the item being cleaned or by swab test results.

Validation of the cleaning procedure can also be done during the TPV inspection. An example of this would be the CCE flooding the component with milk (or some other substance that will soil the component) and then following the manufacturer’s cleaning procedure and then ascertaining whether or not the component is “clean” based on the CCE’s experience. Note that this is a product non-contact surface. The goal is to be able to clean the interior surfaces. It is not necessary to obtain a sterile, dry surface after cleaning. This should be evaluated in the same way as one would evaluate the cleaning of any other non-product contact surface on the machine.