Interim Guidance on Mechanical Force Seals in 3-A SSI Valve Standards

The following guidance shall be used by the CCE when performing TPV evaluations. This guidance is effective immediately upon receipt and shall be used until revoked or included in an up-date of the TPV Manual.

The 3-A Format and Style Manual 00-01 includes the following definitions.

C1 Bond: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

C1.1 Mechanical Force Seal: The seal established between a flexible rubber, rubber-like, or plastic material when pressed into a special groove in a metal or glass component using a combination of compression, pressure, and the unique geometrical shapes of the joined materials to create a tight seal at the interface of the materials joined during conditions of intended use, including processing, cleaning, sanitizing, or sterilization. A mechanical force seal is not intended for routine disassembly for cleaning.

The definition for Mechanical Force Seal was added to the 3-A Format and Style Manual as a clarification of a fabrication technique, which has been used successfully for affixing the valve “plug” or seat seal on multiple valve designs for many years. The definition differentiates this seal attachment design from a Bond. The Mechanical Force Seal is not considered a Bond as it does not include the use of adhesive or cohesive forces to hold materials together. The technique produces a nonpermanent joint suitable for extended use without the removal of the elastomer. However, the seal can be removed for inspection or replacement as necessary.

Until such time as the various 3-A SSI Valve Standards are amended to incorporate the paragraphs relating to Mechanical Force Seals cited above, CCEs are instructed to accept the use of Mechanical Force Seals as a design and fabrication technique for 3-A Valve Standards only in the stem seat seal area. This acceptance requires that the seal is sound, properly fabricated and will result in cleanable surfaces and joints.

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