

CCE COORDINATION BULLETIN

BULLETIN NUMBER 2016-1

Proper use and reference to the General Requirements Standard, Number 00- in the application of the Replacement Parts and System Component Qualification Certificate Program (RPSCQC)

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 RPSCQC provision 3 states, "The TPV shall be based on a specific declared base standard or Accepted Practice (i.e., pumps, fillers, compression valves, instantizing systems). In the case of a replacement part or system component that can cover multiple standards or accepted practices, all standards and accepted practices must be declared and the replacement part or system component shall meet the most restrictive criteria applicable from the base standard(s). For example, a replacement pump impeller would be linked directly to the pump standard, 02-, or a replacement rising stem valve plug would be directly linked to the appropriate valve standards.

The publication of the 3-A Sanitary Standards for General Requirements, ANSI/3-A 00- requires some additional guidance as to how this standard may be utilized within the RPSCQC.

- 1. Provision 3 remains the primary focus of the program. Any replacement part or qualified component that can be linked directly to a single standard or group of closely related standards shall be evaluated against those standards and <u>not</u> the General Requirements Standard.
- 2. A generic replacement part or qualified component that would apply to all or a "significant majority" of individual equipment standards may be evaluated against and list the General Requirements Standard. A "significant majority" shall be interpreted the same as used in the development of the General Requirements Standard. An example of this type of component would be a control box conforming to all of the nonproduct contact surface requirements of the General Requirements Standard which can be mounted on multiple individual types of equipment (packaging machines, tanks, processing vessels, etc.).

It is not necessary to initial all of the sections of the General Requirements Standard when conducting a TPV using this option. The numbers of the General Requirements Standard sections used for the TPV are to be listed in the "Observations and Findings" section of the TPV Report cover page as documentation of the evaluation.