



CCE COORDINATION BULLETIN

Guidance on Materials Acceptability Criteria

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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.

The guidance is provided to establish uniformity of interpretation during the phase-in period of the TPV Program.

1. Silicon carbide is considered to be a ceramic material and shall be deemed as acceptable when used as a seal component when the carbon and ceramic criteria paragraph is included in the materials section. To be used, silicon carbide does not have to be specifically listed.
2. 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces, Number 20-
 - 2.1. When the plastics criteria paragraph is listed in the materials section of a standard, all plastic materials must conform to the requirements of the standard unless exempted in an individual document as in Standard 45-01, section C1.a. If a plastic is not listed as one of the generic classes of plastic, the material may not be used. The applicant wishing to use such a plastic must petition the Steering Committee for an amendment to 20- to include the new generic class.
 - 2.2. Standard 20- is not a finished product standard. Therefore, certifications will be for the base resin not the completed or fabricated part.
 - 2.3. Certifications should verify that the plastic materials comply with both the appropriate FDA (21 CFR parts 177-199) citation and compliance with Standard 20-. The plastic supplier does not have to display a 3-A Symbol for the plastic to be used.

- 2.4. Basic information of the certifications, such as, material identification, supplier, and certifying body is to be recorded in the comment section of the TPV report. Alternatively, copies of the certifications can be attached to the report.
- 2.5. It is not necessary to review laboratory results as part of the certification review. However, the CCE should verify the tests results exist if the applicant is the party that had the testing performed.
3. Appurtenances on a piece of equipment for which there is a referenced 3-A Sanitary Standard must comply with the criteria of the referenced standard (including plastic and rubber materials). These items do not have to display the 3-A Symbol. The display of the symbol on these items is optional.
4. During a TPV evaluation, the appropriate parts, as listed in the TPV Manual, of the EDTCF are to be reviewed. If asked by the applicant, only the Table of Contents of the EDTCF must be submitted with their application. The EDTCF is an additional requirement for the 3-A Symbol Authorization program even though the information is routinely listed in the Appendix section of the 3-A Standards.