CCE COORDINATION BULLETIN 2022-3

Information for CCEs Regarding Various Scenarios for Conducting 3-A TPV Inspections for a 3-A Symbol Authorization, Replacement Parts Mark or Process Certificate

Background: As the 3-A TPV program enters its twentieth year of operation, it is important that the program clarify how to address various situations which have become more common with the consolidation of the equipment manufacturing industry. The following scenarios were not contemplated by the original authors of the 3-A TPV Manual for a 3-A Symbol Authorization under the TPV program back in 1999 – 2001. This CCE Bulletin is intended to provide information to CCEs on how to address these situations, which are summarized in the three (3) scenarios below.

- Scenario #1: The Original Equipment Manufacturer (OEM) with a 3-A Symbol is "Private Labeling" a piece of equipment with an existing 3-A Symbol for a distributor. In this scenario, the OEM is based in North America and has engaged a European distributor. The distributor manufactures nothing. They have a shelf in a warehouse where the equipment is received, placed on a shelf and shipped when an order is received from the Distributor's customer. It is common practice for OEM's to "Private Label" for Distributors and for Distributors not to identify the source of their product to the public for competitive and business reasons. This is a common practice in the equipment industry today. **Is the Distributor eligible for 3-A Symbol Authorization or Replacement Parts Mark?**

- Scenario #2: A Distributor is purchasing equipment from an OEM (Authorized 3-A Symbol Holder) with a current 3-A Symbol for that specific piece of equipment. The Distributor contracts with the 3-A Authorized Symbol Holder to "Private Label" for them. The distributor contacts a CCE for the CCE to conduct a TPV inspection, however the CCE contacted by the distributor is not the CCE of record for the OEM. **Is the Distributor eligible for 3-A Symbol Authorization or Replacement Parts Mark and if so, how should the CCE contacted by the distributor, but not the CCE of the OEM proceed?**

- Scenario #3: The same manufacturer is fabricating the same piece of equipment with the same model number or identification at different locations and requests a TPV inspection for 3-A Symbol Authorization for this piece of equipment. **Does 3-A SSIs TPV Program require:**
  - **one (1) 3-A Symbol Authorization or Replacement Parts Mark based on only one TPV inspection at one chosen fabrication location to cover all fabrication locations for the same piece of equipment, or**
  - **separate 3-A Symbol Authorizations with separate TPV inspections for each fabrication location where the same piece of equipment is being fabricated, or**
  - **some other solution to address this issue?**

Current 3-A References: The TPV Manual states:

- C2.3.1 Each cover page and supporting page(s) shall refer to only one (1) Symbol Authorization. If a TPV inspection encompasses multiple equipment or machinery type(s) which are maintained under different 3-A Sanitary Standards, a separate TPV report shall be prepared for each separate Authorization.
- C2.3.2.2 Verification Location: Record the location address where the verification was conducted. If the verification is conducted at the same location as the applicant's address, please use the phrase "Same as Applicant."
- C3.6.4.5 Engineering Design and Technical Construction File (EDTCF) (Appendix 4). This information, which may be assembled from multiple sources, is to be used by the CCE as a primary source of verification details. Since each EDTCF is unique to the equipment type manufactured, the amount and types of information present will vary widely. The CCE shall review the EDTCF carefully, and utilizing his/her expertise, determines if the file is complete. In order to mark this item with an "X" in the "Yes" column at least the following sections, as listed in the 3-A Sanitary Standards Format and Style Manual document, shall be present in the EDTCF:
- C3.2 The CCE shall use his/her knowledge and experience to conduct a detailed physical evaluation of the equipment, engineering drawings, and documentation associated with the equipment to be verified for conformance to the 3-A Sanitary Standard(s). This may include general assembly drawings and drawings of individual equipment components and sub-assemblies. The CCE shall conduct the verification at a pace to assure all components are carefully evaluated against the 3-A Sanitary Standard's criteria. If the equipment offered for evaluation can be configured using multiple optional components or accessories, all of the optional features must be presented for evaluation. The CCE shall be diligent in asking sufficient questions to determine such items as the identification of all materials of construction, options, or add-on features offered with the equipment, methods of fabrication, etc. are in conformance to the 3-A Sanitary Standard. The CCE shall request and review all certifications for components fabricated from rubber or rubber-like materials, plastic materials, adhesives, or metal alloys not identified by the applicable 3-A Sanitary Standard(s). Throughout the evaluation, the CCE shall exercise critical observation/critical analysis (as in careful judgment and scholarly recommendations) at all times.
- C3.6.4.5 Engineering Design and Technical Construction File (EDTCF) (Appendix 4). This information, which may be assembled from multiple sources, is to be used by the CCE as a primary source of verification details. Since each EDTCF is unique to the equipment type manufactured, the amount and types of information present will vary widely. The CCE shall review the EDTCF carefully, and utilizing his/her expertise, determines if the file is complete. In order to mark this item with an "X" in the "Yes" column at least the following sections, as listed in the 3-A Sanitary Standards Format and Style Manual document, shall be present in the EDTCF:
- C3.6.4.5.1 Required EDTCF documentation:
  a) Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
  b) A copy of the 3-A Sanitary Standard to be applied to the subject equipment;
  c) An overall drawing or general arrangement drawing of the subject equipment;
  d) Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard;
  e) If essential, any technical report or certificate obtained from a competent testing body or laboratory;
  f) Instructions for cleaning of the subject equipment or item referenced by the Standard (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items. (Example: silo tank door gasket);
  g) Material certifications for all materials of construction included in the equipment;
  h) For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standard;
  i) Change records; and
  j) Copy of the 3-A Symbol Authorization, if applicable.

CCE Guidance:

1. **Scenario #1:** When a Distributor is receiving "Private Labeled" equipment from an OEM and wants their own 3-A Symbol Authorization or Replacement Parts Mark for that equipment, the distributor may apply for 3-A Symbol Authorization or Replacement Parts Mark and have the CCE of record for the OEM prepare a TPV report based on the TPV inspection completed for the OEM which lists the OEM's facility as the fabrication location and the Distributor as the "Applicant." Distributors usually assign their own model numbers to the "Private Labeled" equipment. These model numbers must be listed in the TPV report submitted to 3-A SSI by the CCE along with the equivalent OEM model numbers for traceability purposes. Under this scenario, the CCE is not required to visit the distributor's location or warehouse where the equipment is received, stored and shipped. All of the information needed for completing a TPV report is available at the OEM site including the EDTCF.

   NOTE #1: If the Distributor, un-packs, repacks, inspects, re-labels or otherwise modifies the equipment in any way, then an on-site 3-A TPV inspection at the Distributor's location or warehouse is required.

   NOTE #2: Since Distributors have the right to keep their equipment supplier confidential, the CCE's TPV Report must be kept confidential, between the Distributor, the CCE, and 3-A SSI. 3-A SSI may share a 3-A TPV Report, when necessary, with designated 3-A staff, the Chair of the 3-A Steering Committee and/or the Chair of the TPVCC if a Report of Alleged Non-Compliance (RAN) is filed or there is another compelling reason for sharing this information with these parties. The 3-A TPV Report connects the Distributor to the supplier for internal 3-A SSI traceability purposes only.

2. **Scenario #2**: When a Distributor is purchasing equipment with an existing and current 3-A Symbol Authorization from an OEM and the OEM is the 3-A Symbol Holder or Replacement Parts Mark Holder for this equipment, but the CCE contacted by the distributor is not the same CCE that conducts the TPV inspection for the OEM, the CCE contacted by the Distributor is required, at a minimum to:
   - Confirm with 3-A SSI that the OEM has a current 3-A Symbol Authorization for the equipment of interest to the Distributor.
   - That the equipment the Distributor is requesting a 3-A Symbol or Replacement Parts Mark for, is covered by a current 3-A Symbol by the OEM, and
   - Ensure that the equipment to be covered by a 3-A Symbol or Replacement Parts Mark authorized by 3-A SSI to the Distributor has not been modified in any way from the same piece of equipment fabricated by and sent to the Distributor by the OEM that has a 3-A Symbol for that piece of equipment.

   Once these items are confirmed, the CCE contacted by the distributor may accept the 3-A Symbol Use Authorization or Replacement Parts Mark already obtained by the OEM. The CCE contacted by the Distributor is required to record all pertinent information about the equipment at the distributor location, listing model number(s) equivalent to the OEM's model number(s) for the purpose of traceability and submit this along with other required information to 3-A SSI as part of the documentation for recommending a 3-A Symbol for the Distributor for this specific piece of equipment.

   NOTE 1: If the Distributor un-packs, repacks, inspects, re-labels or modifies the equipment in any way, then the CCE contacted by the Distributor is required to conduct an on-site TPV conformance evaluation at the Distributor's location.

NOTE #2: Since Distributors have the right to keep their equipment supplier confidential, the CCE's TPV Report must be kept confidential, between the Distributor, the CCE, and 3-A SSI. 3-A SSI may share a 3-A TPV Report, when necessary, with designated 3-A staff, the Chair of the 3-A Steering Committee and/or the Chair of the TPVCC if a Report of Alleged Non-Compliance (RAN) is filed or there is another compelling reason for sharing this information with these parties. The 3-A TPV Report connects the Distributor to the supplier for internal 3-A SSI traceability purposes only.

Scenario #3: A company owning multiple or satellite manufacturing locations where the same piece of equipment with the same model number is fabricated at multiple locations, may apply for one 3-A Symbol Authorization or Replacement Parts Mark for the same equipment with the same model number, regardless of fabrication location, provided, at a minimum, the CCE must:

- Identify via mailing address, a contact person for each location and contact information for each location where the same equipment with the same model number is being manufactured
- Includes as part of the CCE's TPV inspection, a thorough review of the EDTCF for each manufacturing location
- Conducts an on-site conformance evaluation of at least one manufacturing location, preferably the site where the largest volume of equipment is being manufactured. Other manufacturing locations, different from the site where the onsite conformance evaluation is being conducted may be included in the onsite TPV inspection, if the CCE determines through a thorough review of the EDTCFs for each manufacturing location or by other methods, that manufacturing or quality assurance processes at different locations have enough differences that an onsite TPV inspection is needed.

Complete documentation of the CCE's TPV Report for all manufacturing locations must be submitted to 3-A SSI in order to be considered for 3-A Symbol Authorization, Replacement Parts Mark, Process Certificate or 5-year TPV renewal of the said 3-A TPV Programs.

The company's multiple manufacturing locations including mailing address, contact person and contact information for each location are required to be submitted by the CCE to 3-A SSI as well as the location(s) where the onsite TPV inspection was conducted.

The TPV Report submitted by the CCE to 3-A SSI is required to include applicable "Country of Origin" labeling information for those fabrication locations located outside the US.

NOTE #1: If the equipment type fabricated at more than one site is not identical to equipment fabricated with the same model number at different locations or if this equipment differs in any hygienically or functional way from the equipment type fabricated at a different location, then separate 3-A Symbol Authorizations will be required along with a separate TPV inspection for each 3-A Symbol Authorization or Replacement Parts Mark.

NOTE #2: Regardless of the specific scenario, the CCE always has the option of conducting an on-site TPV inspection at each fabrication location where the same equipment with the same model number is being fabricated if the CCE believes the fabrication conditions are or could be different at different locations and could impact the conformance of that piece of equipment and/or equipment type with the applicable 3-A Standard(s) or Accepted Practice(s).