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1.0 Purpose

This SOP describes the procedure for documenting sanitary welding performed on equipment, tanks, and piping used in the manufacture of biopharmaceuticals.

2.0 Scope

This procedure applies to BDP staff involved in procurement, modification, or repair of equipment that contains sanitary welding and for staff reviewing documentation for welding on BDP equipment, tanks, and piping.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 The Manager, Quality Engineering and Validation, is responsible for the implementation of this procedure and for inspecting records pertaining to this procedure.

3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Craftsman Qualifications

4.1 Each craftsman performing the welding must be a certified welder with current credentials in high-purity welding.

5.0 General Guidelines

5.1 Orbital welding must be used whenever possible for joining sanitary piping. This technique offers superior results over manual welding.

5.2 Equipment vendors and contractors involved in sanitary welding should be made aware of the requirements of this SOP prior to their performing any welding work.

5.3 Each weld must be performed following the specific procedures set forth by their company. In general welds require the following documentation. Exception to these criteria will require BQA approval prior to the start of work.

- 5.3.1 Welding Equipment Specifics.
  - 5.3.1.1 Manufacturer
  - 5.3.1.2 Model
  - 5.3.1.3 Type
  - 5.3.1.4 Serial number
- 5.3.2 Welding Method
  - 5.3.2.1 Purge gas
  - 5.3.2.2 Diameter and wall thickness
  - 5.3.2.3 Weld head
- 5.3.3 Welding Parameters
  - 5.3.3.1 Peak Weld Currents
  - 5.3.3.2 Background Current
  - 5.3.3.3 Pulse Width/Rate
  - 5.3.3.4 Upslope/Downslope
  - 5.3.3.5 Pre/Post-flows
  - 5.3.3.6 Travel Speed
  - 5.3.3.7 Heat
- 5.3.4 Craftsman
  - 5.3.4.1 Name
  - 5.3.4.2 Signature
  - 5.3.4.3 Date/Time of Weld
- 5.3.5 Other
  - 5.3.5.1 Specific Weld Location
  - 5.3.5.2 Equipment or System Name
  - 5.3.5.3 Equipment or System ID Number
- 5.3.6 Weld Identification Number

5.3.6.1 The weld shall be given a unique identification number.

5.3.6.1.1 When a vendor does not have their own convention for identification, they will use the following guidance. The first five digits will be a code identifying the system the weld belongs to. The second portion will be a unique number, consecutively assigned.

5.3.6.1.2 Repair or modification welds will use the code guidance and must take care not to duplicate a number already in the system.

5.3.6.2 Test welds shall be numbered.

5.3.6.3 Etch each weld ID number on the exterior surface of the pipe or equipment near the weld.

5.3.6.4 Weld ID numbers must also appear on the P&ID drawings where applicable.

6.0 Test Weld (Coupon) Requirements

6.1 The welder must “coupon in” before beginning production welding using the exact same material that is to be installed.

6.2 The welder must “coupon out” before ending his/her shift.

6.3 A coupon must be created whenever there is a change in power source, a loss of power, a change in purge setup, a change in head, a change in tip (electrode), a change in pipe size or type, or a change in operator (see Steps 6.1 and 6.2).

6.4 A coupon must be created whenever a weld is rejected before proceeding with production welding.

6.5 Every coupon, good or bad, must be logged.

6.6 Coupons are to be retained by the BDP. Note that welding work that does not occur on site may not include coupons.

7.0 Weld Inspection

7.1 A qualified person, who has adequate training, knowledge, and credentials in high purity (sanitary) welding practices, will inspect welds. The BPE Standard requires 100% visual inspection of the outside of the weld and a minimum of 20% visual inspection of the inside or product contact side of the weld. Welds are inspected for the following:

7.1.1 cracks;

7.1.2 arc strikes;

7.1.3 oxidation;

7.1.4 burn through;

7.1.5 overlap;

7.1.6 incomplete fusion;

7.1.7 inadequate penetration;

7.1.8 smoothness;

7.1.9 polishing.

7.2 Any welds found to be inadequate by the criteria outlined above must be removed and given a new weld number. The new weld will be assigned a new identification number and documentation of the new weld must be traceable to the original weld documentation.

7.3 In some cases, inspection may include boroscope images or video. These must be saved as documentation of the inspection.

8.0 Documentation and Control

8.1 Documentation of sanitary welding will be collected and reviewed by BDP Engineering for each applicable weld project.

8.2 Documentation will be maintained in the MEF of the relevant system or piece of equipment.

9.0 References and Related Documents

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10.0 Change Summary