



3-A THIRD PARTY VERIFICATION... WHAT HAVE WE LEARNED ?

CERTIFIED CONFORMANCE
EVALUATOR VIEWS

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CCE's HAVE BEEN BUSY

- 3-A TPV Program Began in 2002 and Inspections Started in late 2003
- 57 Equipment Groups Contain Over 500 3-A Symbol Authorizations
- We are Nearly Through the Second 5 Year Cycle
- CCE's Have Visited Companies in 23 Countries

The TPV Report...Base Questions

1. Is the 3-A Standard No. displayed within Symbol (XX-XX) ?

Example...



02-10

2. Are Manual(s) Available for the Equipment?

The TPV Report...Base Questions

3. Is the Engineering Design and Technical Construction File (EDTCF) available and correct?
4. Is a copy of the current 3-A Sanitary Standard(s) for the Equipment on file?
5. Is A Quality Control Program or System In-Place and is it Verified?

The TPV Report...Base Questions

6. Are Rubber certificates reviewed for all rubber parts?
7. Are Plastic certificates reviewed for all plastic parts?

Then each paragraph of the standard must be referenced...the equipment evaluated for conformance... and the TPV Report Completed.

Frequent Issues & The EDTCF

- A Table of Contents is Essential
- In the event of a RAN, the Table of Contents is a Useful Tool to Reference for Supporting Data
- The EDTCF Table of Contents may simply indicate where supporting documents are located in files rather than duplicating data
- 3-A Materials Standards contain requirements for 21CFR177 conformity...not vice versa

Frequent Issues & The EDTCF

- Drawing and Design Practices frequently use symbols requiring evaluators to obtain supporting legend data.
- Equipment Documentation should provide guidance to the user for suggested cleaning methods.
- While 3-A does not describe Quality Program requirements, documentation showing Change Control and Change Records is essential to assure 3-A criteria is being met.

Frequent Issues & The EDTCF

- Multiple Seals are often lacking intermediate leakage paths.
- Leakage paths are only useful if they allow for visual leak detection.
- Adhesives are often used as crevice fillers.
- It is often difficult to document 21CFR175 conformity for Adhesives used as fillers.
- Don't forget to look upward for surfaces that may allow liquids to drop onto product contact areas or containers for product.

Standards Development Needs

- When standards are being written...Is the criteria able to be evaluated clearly?
- Will an evaluator be able to answer the question...Yes or No or Not Applicable?
- Standards criteria describing equipment installation details are beyond the fabricator's control.
- Equipment fabricators can only provide features to be used by an installer or integrator.

The On-Site Visit

A walk through the warehouse can reveal inventory that would not meet the standards.



Barbed Slip Joint
For Hose Connection

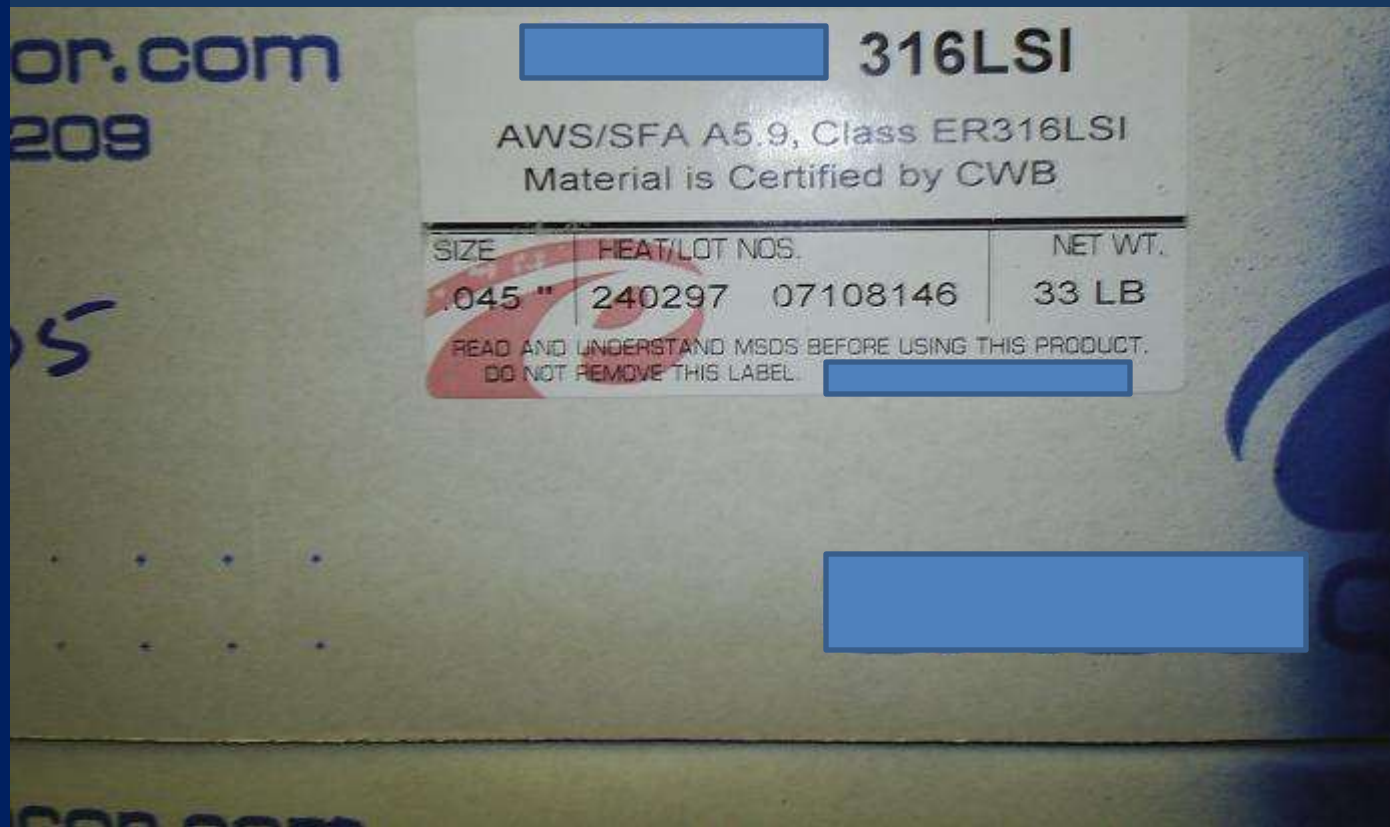
The On-Site Visit

Component parts that carry the 3-A Symbol need no additional follow-up?



The On-Site Visit

Are welding materials such as filler materials compatible?



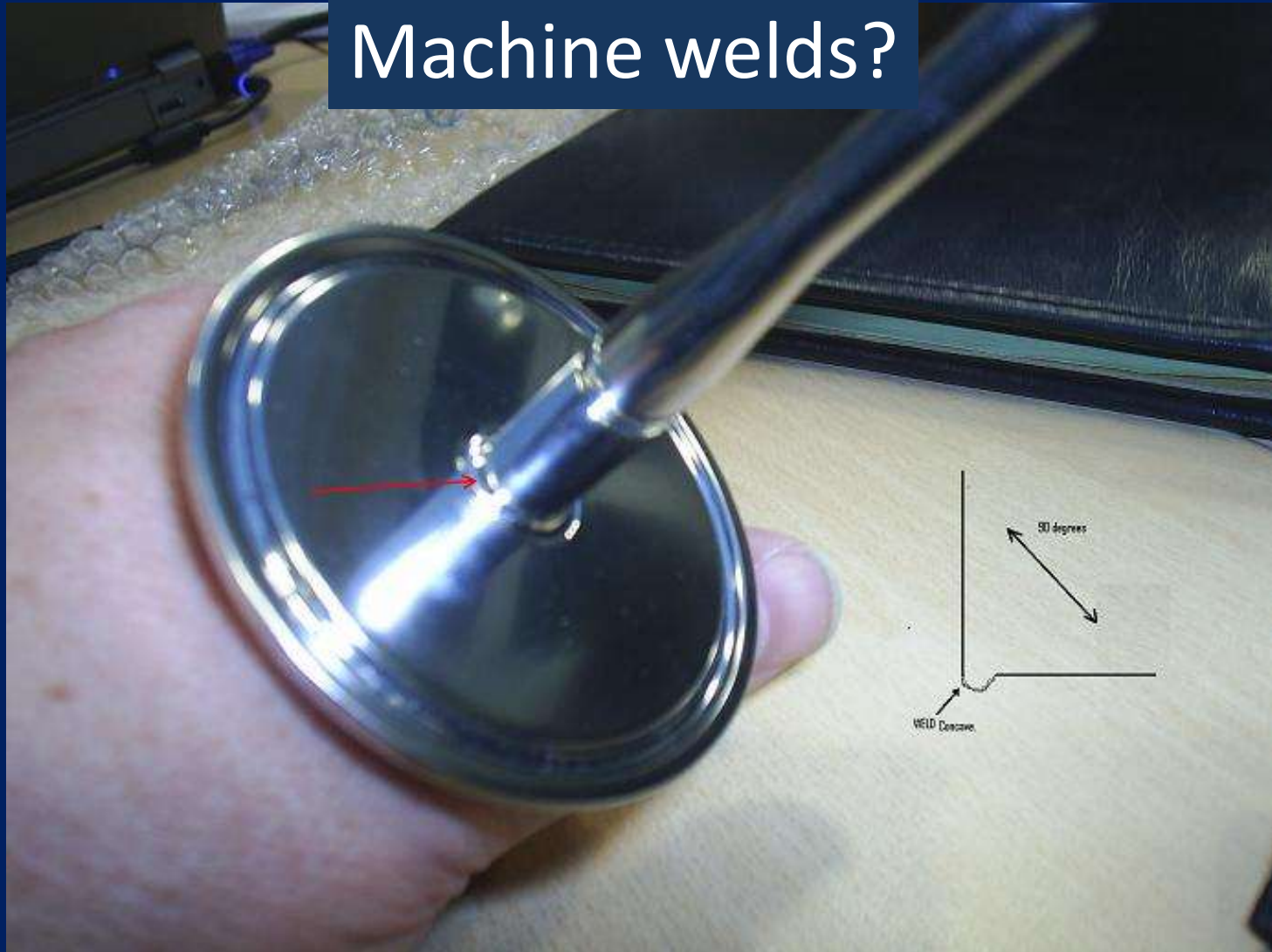
The On-Site Visit

Are welders properly trained
and/or certified?



The On-Site Visit

Machine welds?



The On-Site Visit

Use of simple hand tools?



The On-Site Visit

- Grinding and Polishing.
- Completed in an area separate from areas where metals other than Stainless Steel are fabricated?
- Grinding and polishing tools used for finishing stainless steel not used on mild steel or other alloys.

The On-Site Visit

Angles and Radii.



The On-Site Visit



Tools of the trade.

The On-Site Visit



Looks like square corners to us!

Thank You...



Questions