This article explores current trends in process piping technology including orbital welding SOPs, fabrication techniques, weld documentation, and passivation of stainless steel tubing systems.

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Installation of Pharmaceutical Process Piping - A Case Study

Part 2 - Orbital Welding, Weld Inspection, Weld Documentation, Passivation

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Installation

During the installation of process piping systems, it is critical for orbital welding personnel to work closely with Quality Assurance inspectors. The inspectors must be on site at the time of welding and inspect the welds as they are completed. Otherwise, the system would be welded together and it would not be possible to reach all of the welds with the fiberscope for inspection.

Figure 4. Orbital field welding of clean steam line to supply panel with a weld head. Welding operator is wearing gloves in compliance with contractor's SOP. The I.D. purge to this weld was twice the usual rate to compensate for a branch in the piping system. Photo courtesy of Sicor Inc.

Welds on product contact surfaces must meet the visual weld criteria of the Materials Joining part of ASME BPE-2000 Standards figure MJ-1 shown in Figure 5. The ASME BPE visual criteria for orbital welds were developed to assure that welded joints do not provide a surface which would favor the growth of microorganisms that would contaminate the system. For example, an unpenetrated weld is a crevice where bacteria can grow and escape the cleaning process. ID concavity or misalignment of weld components could interfere with drainability and make cleaning problematic. Owners and contractors must decide prior to the job on an acceptance level for discoloration of orbital welds from the color chart shown in AWS D18.1/D18.2.[8] Discoloration of the weld and heat-affected zone from oxidation resulting from poor purging during the weld sequence would reduce the corrosion resistance of the system.[9] Any undetected weld failures that lead to system contamination would violate 21 CFR 211(a) and be very costly to correct.

When a certified welder begins work at the start of his shift he connects his orbital welding power supply to a dedicated circuit. He will determine the size of tubing and/or fittings or other components to be welded. The welder selects the appropriate weld head, installs the proper size tube clamp inserts (collets), and a tungsten electrode of

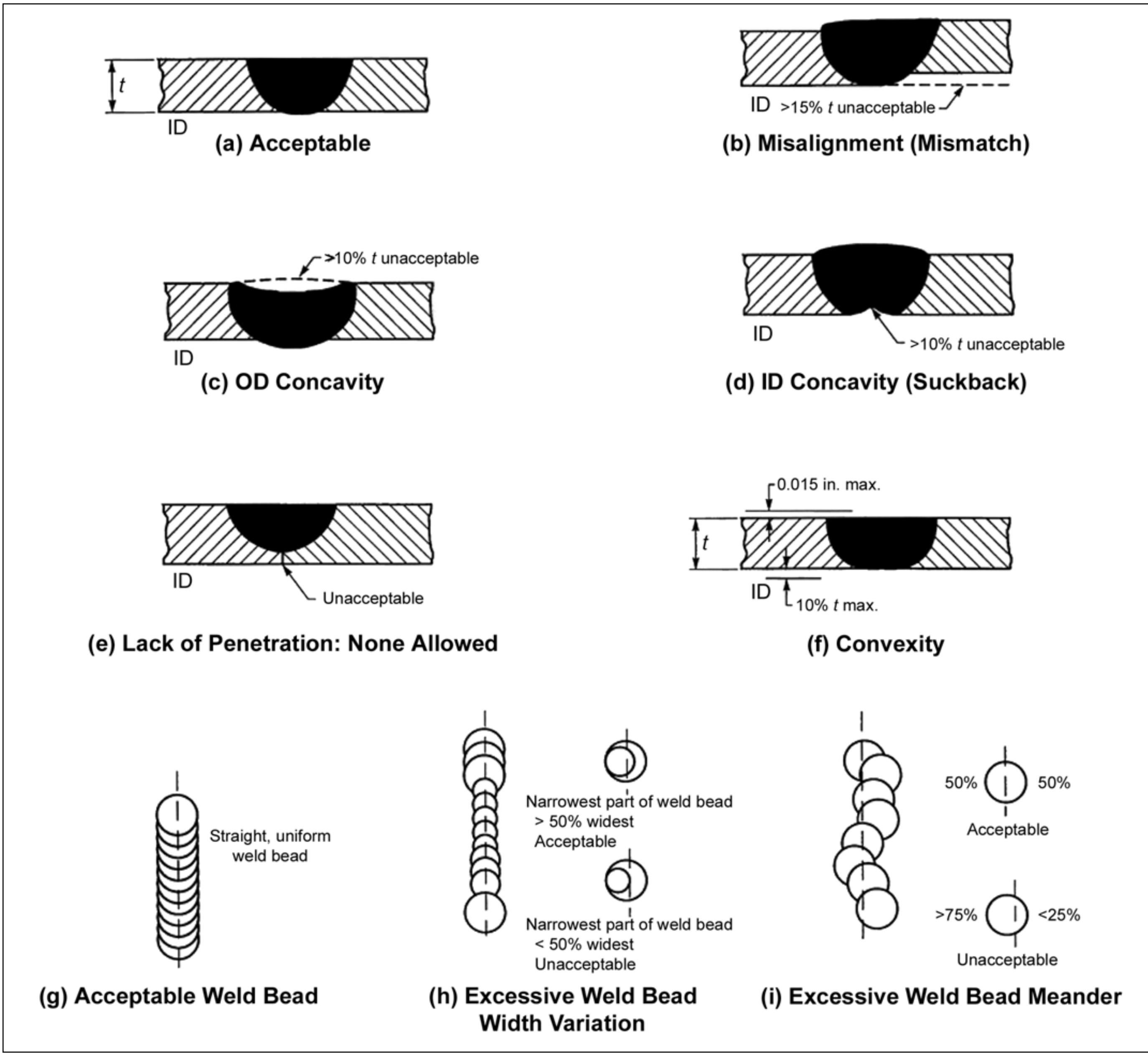

Figure 5. ASME BPE-2002 Figure MJ-1. Acceptance criteria for orbital tube welds. These visual weld criteria are intended to minimize the growth of microorganisms in biopharmaceutical tubing systems. *Reprinted with permission from the ASME.*

the correct length. He then calibrates the weld head for rotational speed to the power supply. A certified argon source is used for the weld head purge which protects the outside (OD) of the weld as well as for purging the ID of the part to be welded.

Opening Coupon

Before he can begin production welding, the welder must "coupon in" or perform a sample weld on the exact same material heat which is to be installed. Even with the restricted BPE sulfur range for 316L stainless steel, there is still some variability in weld penetration from heat-to-heat and schedules for different heats may vary by several amperes. A successful coupon demonstrates to the inspector that the machine is set up properly, the purge is adequate, and the welding operator knows how to operate the equipment.

The first coupon of the day is referred to as the "opening coupon" and welders refer to this as "burning a coupon." Coupon welds must be done on an actual weld joint, not just a "bead on pipe" (which is a weld made directly on a tube without a joint) to assure that the equipment and the operator can properly align the components. When the weld is completed, the welder brushes the outside (OD) with a stainless steel brush to remove weld oxidation, removes any burrs or sharp edges from the ends of the coupon, and gives it to the inspector. A flow chart showing the sequence of welding, weld inspection, and weld documentation is shown in Figure 6.

Coupon Log

Every coupon, good or bad, must be recorded in a coupon log. The weld is identified by the machine used, in this case labelled A or B, with a sample weld number, for example SWA 001, the date, and the welder's ID number. The time of day, date, and material heat number, argon certification, orbital weld head, and power supply serial numbers also are recorded, and the entry is initialled by the inspector. All of this is cross-referenced to the installing contractor's weld procedure documentation. Test coupons are performed routinely if there is a change in power source, a loss of power, a change in purge set-up, or a change of welding operator. Test welds also are performed 100% of the time after a weld has been rejected before proceeding with production welding.

Bench Welding

Once the coupon has been approved, the welder prepares for production welding. He decides whether he will be doing bench welds or field welds and connects the ID purge to the system or components to be welded. Bench welding is done in a protected area where spool pieces up to 20 feet long can be prefabricated prior to installation in the field. Spool pieces can include up to three bends totalling 180° or two bends of 90° each to allow for borescopic inspection. 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. The type of borescope used for weld inspection is flexible and more properly referred to as a fiberscope.

The installing contractor is responsible for knowing what length to cut tubing so that the finished spool piece will fit into the exact location in the field shown on the isometric (iso) drawing. The weld ends are cut and prepared in a square butt joint for welding. The components are held in a vise and a pipe stand to achieve the required slope of 0.6° according to the iso diagram. They are manually tack-welded together prior to welding. An ID purge must be used during tack-welding to prevent oxidation since an oxidized tack may prevent full joint penetration of the orbital weld. Unconsumed tack welds are a major source of weld rejection.

All of the welds in a spool piece may be performed before handing the assembly over to the inspector providing all of the welds are accessible to the fiberscope. Water-cooled weld heads used on this site permit high duty cycle welding and improved productivity. Welds were brushed on the OD prior to inspection. As an SOP, the ID purge remains connected to the spool piece until it is cool to the touch.

On a given spool piece, only one or two of the welds may be selected for inspection. On this job, 20% of the accessible welds had to be inspected, but in the process of getting the fiberscope to a particular weld, the QA inspector would see welds that were not scheduled for inspection. The weld inspectors estimated that they looked at about 90% of the welds although only 20% inspection was recorded. If the inspector saw a defect in a weld that was not listed for inspection, the defect would be reported and cut out. At that point, the inspection contractor would work with welding personnel to try to find the cause of the defect, eliminate the cause, and the welder would reweld the joint. All rewelded joints are borescope-inspected and the results indicated on the iso drawing as shown in Figure 7. In making rewelds, the welds must be kept far enough apart to avoid a second weld in the HAZ of the first since any detrimental changes to the metal from welding would be additive. A "pup piece" of the appropriate length may be used to keep the spool piece in conformance with the original dimensions.

Field Welding

Much of the field or "position" welding involves welding together the spool pieces or connecting spool pieces to longer piping runs. Purging is critical for all welds, but particularly for field welds since purge gas of the required purity must be present at the weld joint to avoid oxidation, while the ID purge pressure must be adequate to deliver the gas to the joint without creating excessive pressurization. Excessive pressure on the liquid weld pool results in ID concavity or can even blow out the weld. The flowrate required to achieve the correct ID pressure varies in the field with the tube diameter with the distance from the source and with any restrictions upstream. It also changes if the system has branches such as the weld on the steam line shown in Figure 4. In that case, the flow rate was doubled from what it would have been without a branch in the system. One of the branches was capped off while the other had a restrictor on the exit orifice to help in achieving the correct ID pressure. An oxygen meter was used to monitor the ID purge gas to determine when it was safe to weld.

Field welds must be planned for inspection. Some of the field welds in the mezzanine were inspected with the fiberscope from the floor below. The slope was checked for every change of direction. For this job, the required slope was 0.6° or 1% which is approximately 1/8 inch per foot. The amount of slope varies with the job and the length of the piping run, but the system must be drainable.

Weld numbers are assigned by QA and are recorded in the weld log, on the iso drawing, and etched on the pipe. The weld log and information on the pipe contain the same type of information as was recorded on the coupon log. All of the bench and field welds were recorded in the weld log whether or not they had been inspected. Only inspected welds are recorded in the borescope log.

Weld quality cannot be inspected into the system, but is only as good as the welding equipment, weld procedures (SOPs), materials and surface finish, gas quality, cutting, cleaning, fit-up, and operator experience allow. Third-party QA assures that the welding equipment is functioning properly and that the installing contractor follows his own SOPs. A quality standard such as BPE-2002 fosters understanding between the owner, the installing contractor, and the inspection contractor as to the quality level to be expected in a finished system. Orbital welding has made it possible to achieve high quality welds on a repeatable basis resulting in more cleanable piping systems. This is essential for the successful production of biopharmaceutical products.

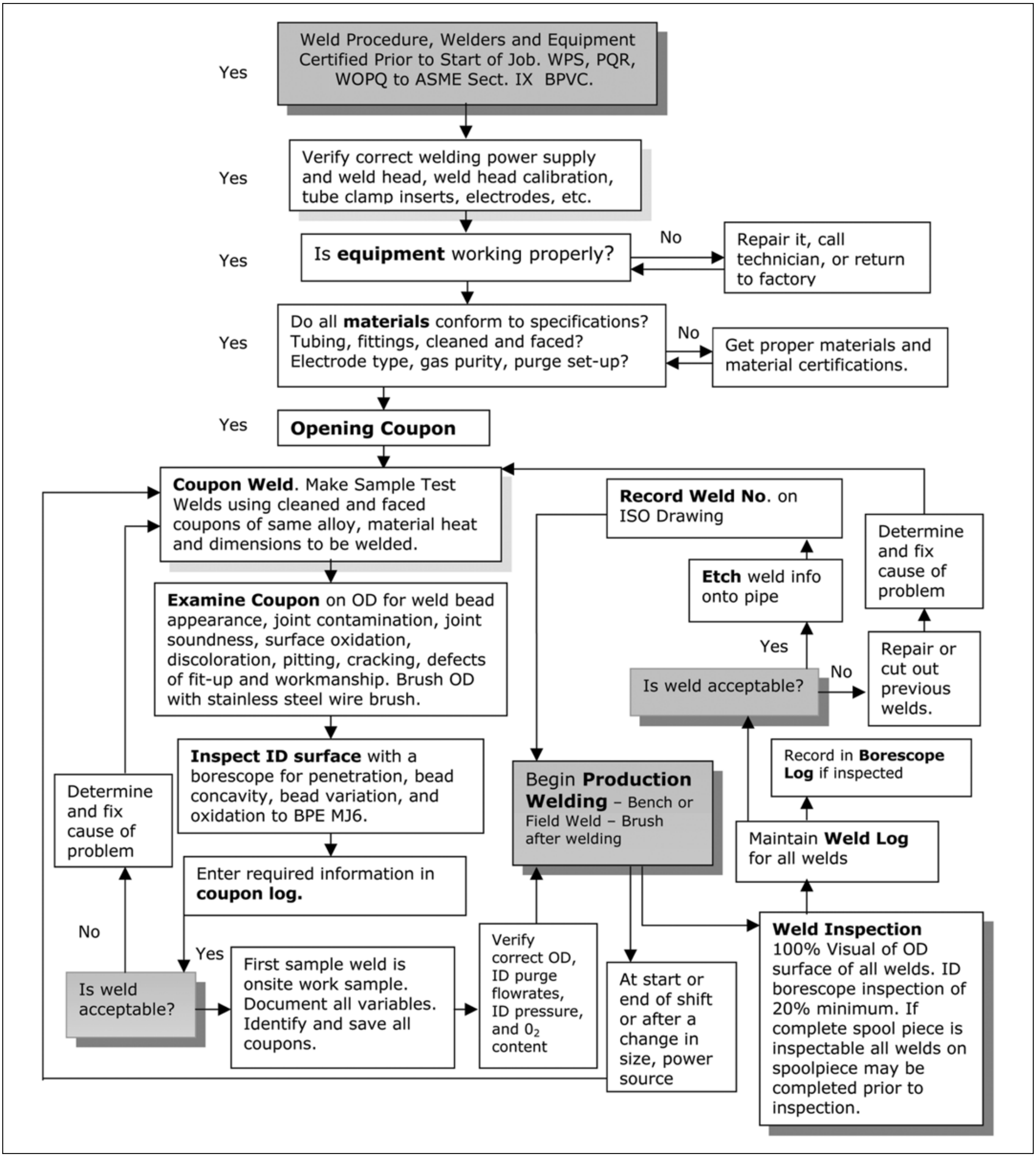

Figure 6. Flow chart for orbital welding/inspection/documentation of stainless steel welds.

Orbital Welding of Skids

Orbital welding is used extensively in the manufacture of equipment skids such as CIP skids or skids with stills for producing WFI. A considerable amount of stainless steel tubing is used to connect the various components on the skids. The skids are assembled by orbital welding at the vendor and brought to the pharmaceutical plant for installation. All of these welds and the field welds done when installing the skid on site must meet the same welding QA requirements. Welds done during skid manufacture are inspected at the vendor.

Isometric Drawings put on CAD

At the end of the job, all of the iso drawings are entered on a computer. Using "plant North," the separate iso drawings can be "clicked" together to combine them in a single document which is then stored on CD as a permanent record.

Pressure Testing

After installation and before passivation, the piping systems are pressure tested. The pressure testing operation is overseen by the Inspection Contractor. This consists of filling the piping system with clean air, nitrogen, or argon at 150% of the design pressure or 150 psi, whichever is greater, and then monitoring the pressure decay for four hours. If there is zero drop in pressure, the system passes. This must be done with a calibrated gauge with certifications.

Passivation

The annealing portion of the stainless steel production process results in a chromium oxide surface film that is enriched with chromium and reduced in iron when compared to the base metal. During the welding process, the passive or unreactive layer is disrupted so that in the weld and in the HAZ, the distribution of elements that comprise the surface may no longer be considered as being passive. During the welding process, the iron concentration at the surface of the weld becomes elevated while the amount of chromium is sharply reduced.[9] Unless a chemical passivation process is conducted before operating the system, the corrosion resistance of the system will be compromised and rouging will occur, especially at welded sites. The purpose of a chemical passivation is to remove free iron or other anodic contaminants from the surfaces of the stainless steel such that a more uniform formation of the passive surface is obtained.

Heat tint-containing oxides of both chromium and iron are formed on the stainless steel surface during welding and must be removed or prevented. Passivation cannot completely remove even relatively light heat tint because, while passivation affects only the outer 50 Å of surface, heat tint can extend to a depth of 400 Å or more.[10] Although the pitting potential of a weld with heat tint may be raised by passivation, suggesting that passivation restores the corrosion resistance lost by welding, when corrosion does occur on a heat-tinted passivated sample it is likely to occur preferentially in the HAZ.[10]

Mechanical grinding and pickling with a solution or paste containing a combination of nitric and hydrofluoric acid may be used to remove heat tint from the welds and HAZs. This treatment removes metal including the area beneath the heat tint which may be reduced in chromium.[11] This treatment, while effective in restoring corrosion resistance, roughens the stainless steel surface and is only suitable for use on surfaces that will be polished and passivated after treatment. Hand-held electrocleaning devices may accomplish the heat tint removal without roughening, but removes metal so dimensional tolerances may be compromised.

The most effective and practical way of retaining the corrosion resistance of a piping system during installation is to be very careful with the purging during the orbital welding operation so as to prevent the formation of visible heat tint to avoid contaminating the system especially with carbon steel tools or any other type of iron contamination, and then complete the process with chemical passivation.

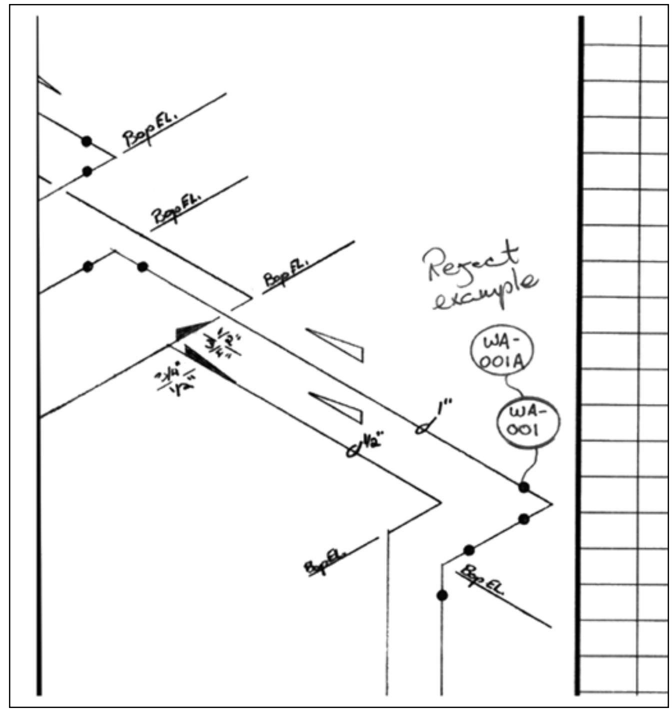

Figure 7. Example of how a rejected weld would be documented on an "iso" drawing. The first weld "window" shows the weld number which is recorded for every weld and the second window indicates that the first weld was cut out, replaced, and the number changed. *Courtesy of Pro-Tech Process, Inc.*

Preoperational passivation is an essential step in bringing a system on line. This is especially important for preventing corrosion of stainless steel systems operating at higher temperatures, subjected to service environments where harsh chemicals such as chlorides are used, or ultrapure water. At the Sicor site, a phosphate based alkaline cleaning solution was used to remove construction debris, organic films, and surface inclusions, i.e., aluminum, sulfides, and others. Citric acid, with a reducing agent and EDTA chelant system, was used for passivating the systems that had been installed with orbital welding. In addition to removing free iron (as with nitric or other mineral acids), citric based chelant systems dissolve surface contaminants and most types of inclusions that contribute to pitting corrosion. Chelants prevent the iron from adhering to the surface so it can be readily flushed from the system. The use of citric acid chelant systems results in an excellent chrome to iron (Cr/Fe) ratio on the surface[12] and is much less problematic from an environmental and safety standpoint than nitric or other mineral acids. However, passivation cannot overcome damage done by improper purging during the welding process.

Validation

Sicor Inc. has its own validation group which has a master plan for validation. There is a separate validation protocol for each system such as WFI, CIP, clean steam, etc. The validation group does a spot check during the installation and they hire third-party QA who works directly for Sicor. The owner is responsible for working with the FDA to assure them that everything is being done according to current Good Manufacturing Practices (cGMP) and that they have the documentation to prove it.

Risk of Change

When the facility is done, the user starts using it. Once he begins using the system, an operator may find a better way to do his job. This may involve moving piping. Such changes are typical. In the four to five years that it takes to make the vision a reality, the requirements for the facility may change. FDA approval for the drug for which the system at Sicor was built is expected in 2004, but there is always the risk that it won't be approved; then the facility would have to be modified to produce a different drug. They may need to switch a system for the production of a new drug or, if the current drug becomes a big seller, they may need to increase the system capacity to make larger quantities. This might require an adjustment of the flow rate of a water system or a change in the operating temperature. Unexpected changes put a strain on all utilities, water, and infrastructure. Steve Muehlberger likes to make his systems "robust" so they can change directions as demands on the system evolve.

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