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Weld Map Requirements

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(From a letter dated November 23, 2001 in response to a question as to whether or not weld maps were required.)

ASME Boiler and Pressure Vessel Code, Section IX, and ASME B31.3 require that each qualified welder and welder operator be assigned an identification symbol. That symbol shall be marked at each pressure containing weld, or an adjacent area to the weld.

In lieu of marking the actual weld, ASME B31.3 allows that appropriate records shall be filed. ASME does not define what appropriate records are. However, without marking each specific weld, at or adjacent to the weld, the only other means of identifying and locating each weld is through the use of a weld map. From an ASME standpoint, while there is not a specific requirement for a weld map it is implied.

A weld map depicts the physical aspects of a piping system, with some proportionality, and identifies each weld with a number. That identifying number provides reference on a Welders Log Sheet, which profiles each weld.

Aside from the above paraphrased implied requirement of ASME B31.3, Para. 328.5.1, *(b)*, the only time a weld map is actually mentioned, with regard to required documentation, is in the ASME Bioprocessing Equipment (BPE) standard.

ASME BPE Part MJ-10 – Documentation Requirements state:

> The following documentation shall be presented to the Owner/User or his designee, as a minimum:
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> *(a)* *Welding Documentation.* Welding Procedure Specifications (WPS) used, their respective Procedure Qualification Records (PQR), and welder Welding Procedure Qualifications (WPQ); weld maps of bioprocessing components; weld inspection logs of bioprocessing components (including type and date of inspection); welder identification of each weld shall be provided either on the weld map or on the inspection log.
>
> *(b)* ...
>
> *(c)* ...

ASME BPE requirements apply to all parts that contact either the product, raw materials, or product intermediates during manufacturing, process development, or scale-up; and all equipment or systems that are a critical part of product manufacture, such as Water-For-Injection (WFI), clean steam, ultrafiltration, intermediate product storage, and centrifuges.

The weld map can be created utilizing fabrication isometrics (spool drawings), or by creating a system isometric. In using fabrication isometrics the fabricator would use as-built fabrication isometrics, renumber them and identify them as weld maps. In creating a system isometric, an entire, as-built, piping system would be drawn on one large drawing or continued on multiple drawings if necessary. This type of drawing can fulfill two requirements. One requirement is to provide a weld map. The second requirement is to provide documentation of the system configuration. While this is not a Code requirement it is certainly documentation the FDA indicates in their "Guide to Inspection of High Purity Water Systems" as being necessary to perform a proper validation.

FDA's "Guide to Inspection of High Purity Water Systems" is a document used as a guideline by investigators and other FDA personnel in their review and evaluation of high purity (hygienic) water systems. While not all inclusive, it does provide the essence of expectation requirements for the FDA investigator, and should be considered an added resource for design, construction and validation requirements.

In it the guideline states, in part, under Section II-System Validation: "*In the review of a validation report, or in the validation of a high purity water system, there are several aspects that should be considered. Documentation should include a description of the system along with a print. The drawing needs to show all equipment in the system from the water feed to points of use. It should also show all sampling points and their designations. If a system has no print, it is usually considered an objectionable condition. The thinking is, if there is no print, then how can the system be validated? How can a quality control manager or microbiologist know where to sample? In those facilities observed without updated prints, serious problems were identified in these systems. The print should be compared to the actual system annually to insure its accuracy, to detect unreported changes and confirm reported changes to the system*".

Points made in this letter:

1. With non-hygienic piping the choice can be made in ASME to either place a mark at each weld identifying the welder or welder operator, or provide a weld map. While a weld map is not specifically required, it is implied as an alternative.

2. With piping that falls within the scope of ASME BPE, as described above, weld maps are required.

3. While not stipulated in either Title 29 CFR Part 210 – "Current good manufacturing practice in manufacturing, processing, packing, or holding of drugs; general", or Part 211 – "Current good manufacturing practice for finished pharmaceuticals", FDA inspectors expect system drawings to be available for review depicting all equipment, piping and sample points. These same drawings can be utilized as weld maps.

Weld map documentation should be considered applicable for all hygienic piping, ASME B31.3 Category M piping, high-pressure piping, and severe cyclic piping.

END OF LETTER