STP-PT-065

BRANCH LEG STUDY FOR BIOPROCESSING EQUIPMENT

ASME STANDARDS TECHNOLOGY, LLC

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FOREWORD

Industry standards for dead legs in biopharmaceutical processing equipment have been in place for over a decade. A dead leg is defined as an area of entrapment in a vessel or piping run that could lead to contamination of the product (ASME BPE 2012 GR-8). While an L/D (ratio of length leg over diameter of leg) of six may have been the historical maximum acceptable ratio, multiple studies promote designing to an L/D less than two. The drivers for reducing the L/D ratio are cleanability and the fact that today's technology renders the L/D target of two or less achievable.

The prevailing opinion was that optimum cleaning of process piping was achieved with a tangential turbulent flow rate of 5 feet/sec, and that solution passing through a pipe at this velocity would be sufficient to clean-un-place the piping with branches having an L/D less than two.

The purpose of this document is to provide information on the flow conditions required to displace air from piping branches in a timely manner. When air is displaced from the branched fitting, the cleaning solution comes in contact with the branched piping components being cleaned-in-place (CIP'ed) and effective cleaning can occur. Without contact of CIP solutions, there is no cleaning. This document is a study on the flow conditions required to ensure contact of the cleaning solution with the branched fittings – a key requirement for cleaning.

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- Ethan Babcock, URI Mechanical Engineering Graduate – *Experiments*
- Mallory Corbin, Stevens Institute, Applied Chemistry Graduate – *Data Analysis*
- Randy Cotter, Sr., Cotter Brothers Corporation - *Contributor*
- Matthew Deane, URI Environmental Science Graduate Student – *Experiments*
- Bo Boye Busk Jensen, Ph.D., Alfa Laval - *Contributor*
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- Deborah Botham, Cotter Brothers Corporation – *Contributing Editor*
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- Fittings - VNE
- Seals - Parker
- Hangers - Behringer
- Pump - Fristam
- Spool Pieces - Cotter Brothers

1 PURPOSE AND USE

Industry standards for dead legs in biopharmaceutical processing equipment have been in place for over a decade. A dead leg is defined as an area of entrapment in a vessel or piping run that could lead to contamination of the product (ASME BPE 2012 GR-8). While an L/D (ratio of length leg over diameter of leg) of six may have been the historical maximum acceptable ratio, multiple studies promote designing to an L/D of less than two. The drivers for reducing the L/D ratio to less than two, are cleanability and the fact that today's technology renders the L/D target of two or less achievable.

The prevailing opinion was that optimum cleaning of process piping was achieved with a tangential turbulent flow rate of 5 feet/sec, and that solution passing through a pipe at this velocity would be sufficient to clean-in-place the piping with branches having an L/D of less than two.

The purpose of this document is to provide information on the flow conditions required to displace air from piping branches in a timely manner. When air is displaced from the branched fitting, the cleaning solution comes in contact with the branched piping components being cleaned-in-place (CIP'ed) and effective cleaning can occur. Without contact of CIP solutions, there is no cleaning. Note: The actual cleaning of process piping is more complicated than simply supplying an adequate flow rate (it involves many other factors such as the reagent concentration, temperature, contact time, etc.) and cleaning processes are outside of the scope of this document. The focus of this document is on the flow conditions required to ensure contact of the cleaning solution with the branched fittings – a key requirement for cleaning.

The desire to minimize the L/D of branches in piping systems to facilitate cleaning is intuitive. The original L/D ≤ 6 specification was driven mostly by technology limitations in the pre-1997 (1st edition of the ASME BPE) era. As fabrication methods improved making smaller L/D ratios achievable, the L/D ≤ 2 became the standard. This requirement for L/D of ≤ 2 created new challenges in equipment, components, and process piping design; however Mr. Randy Cotter Sr. questioned whether the L/D of ≤ 2 target was valid. Until now, there was no scientific basis for the new standard.

In 2010, Cotter fabricated a serpentine test fixture from 1½ inch Sch. 40 clear PVC tubing with a 1.610 inch ID (see next page for Figure 4-1) to model a typical biopharmaceutical piping system and typical CIP conditions. The test fixture incorporated various branch connections with different L/D ratios (L/D =1, 2, 3, 4, and 6), oriented 90° vertical upward, 45° upward, and 90° vertical downward. Testing was performed with water at ambient temperature with flow rates ranging from 10 to 80 gpm, and back pressure ranging from 5 to 80 psig.

Initial test results indicated that for both the 45° and 90° vertical upward tee installations, regardless of flow or pressure, entrapped air could not be fully expelled from the branches. Further testing performed using red dye indicated that the turbulence created by the tangential flow of water across a downward oriented branch (L/D ratio of > 4) was insufficient to evacuate the red solution in a timely manner. The tests were performed at a variety of flow rates.

Cotter also had a series of discussions with collaborators who had developed CFD models. The CRD models had not included the presence of air in their evaluation.

Cotter Brothers Corporation presented their data complete with videos of the tests to the ASME BPE Committee. The Committee decided that further research was required. The ASME BPE commissioned a study that was executed in 2011-2012. This report provides the data from the study and includes conclusions and recommendations.