

BRANCH LEG STUDY FOR BIOPROCESSING EQUIPMENT



Currently in preview, click buy full version

STP-PT-065

BRANCH LEG STUDY FOR BIOPROCESSING EQUIPMENT

Contributing Authors and Editors:

Ethan Babcock, URI Mechanical Engineering Graduate
Mallory Corbin, Stevens Institute, Applied Chemistry Graduate
Randy Cotter, Cotter Brothers Corporation
Matthew Deane, URI Environmental Science Graduate Student
Bo Børge Husk Jensen, Ph.D., Alfa Laval
Dennis Mathen, Behringer Corporation
Phil Paquette, P.E.
Marc Pelletier, CRB Engineering
Joe Serdakowski, AutoSoft Systems
James Dean Vogel, P.E. The BioProcess Institute
Deborah Botham, Cotter Brothers Corporation
Jay Ankers, M+W U.S., Inc.

ASME STANDARDS
TECHNOLOGY, LLC

Date of Issuance: December 19, 2013

This report was prepared as an account of work sponsored by ASME Pressure Technology Codes & Standards and the ASME Standards Technology, LLC (ASME ST-LLC).

Neither ASME, ASME ST-LLC, the author, nor others involved in the preparation or review of this report, nor any of their respective employees, members or persons acting on their behalf, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe upon privately owned rights.

Reference herein to any specific commercial product, process or service by trade name, trademark, manufacturer or otherwise does not necessarily constitute or imply its endorsement, recommendation or favoring by ASME ST-LLC or others involved in the preparation or review of this report, or any agency thereof. The views and opinions of the authors, contributors and reviewers of the report expressed herein do not necessarily reflect those of ASME ST-LLC or others involved in the preparation or review of the report, or any agency thereof.

ASME ST-LLC does not take any position with respect to the validity of any patent rights asserted in connection with any items mentioned in this document, and does not undertake to insure anyone utilizing a publication against liability for infringement of any applicable Letters Patent, nor assumes any such liability. Users of a publication are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, is entirely their own responsibility.

Participation by federal agency representative(s) or person(s) affiliated with industry is not to be interpreted as government or industry endorsement of this publication.

ASME is the registered trademark of the American Society of Mechanical Engineers.

No part of this document may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

ASME Standards Technology, LLC
Two Park Avenue, New York, NY 10016-5990

ISBN No. 978-0-7918-6916-1

Copyright © 2013 by
ASME Standards Technology, LLC
All Rights Reserved

TABLE OF CONTENTS

Foreword.....	v
Acknowledgments.....	vi
1 PURPOSE AND USE.....	1
2 INTRODUCTION.....	3
2.1 Dead Leg.....	3
2.2 Standard and Short Outlet Tee.....	4
3 LITERATURE REVIEW.....	5
4 EXPERIMENT.....	6
4.1 System Description.....	6
4.2 Testing Procedure.....	7
4.3 Experimental Technique.....	8
4.3.1 Flow Rate Increase (FRI) Test.....	8
4.3.2 Flow Rate Maintain (FRM) Test.....	8
4.3.3 Pressure Increase (PI) Test.....	8
4.3.4 Pressure Maintain (PM) Test.....	9
4.4 Explanation of Rotation/Slope.....	9
4.5 Data Collected.....	9
4.6 Evaluation Method.....	9
5 THE FITTING TEST SPECIMEN.....	12
5.1 Variables Evaluated.....	14
5.1.1 Pipe Style.....	14
5.1.2 Flow Direction.....	16
5.1.3 Pipe Slope.....	16
5.1.4 Branch Rotation.....	16
5.1.5 Back Pressure.....	17
5.1.6 Temperature.....	17
6 RESULTS AND DISCUSSION.....	18
6.1 Variables Evaluated.....	18
6.2 Impact of L/D Ratio on Flow Rate Required to Achieve Air Removal State.....	18
6.2.1 Impact of Rotation Angle on Flow Rate Required to Achieve Air Removal State.....	18
6.2.2 Parameters for Predicting Air Removal States.....	18
6.2.3 Influence Flow Startup.....	19
6.2.4 Horizontal T-pieces Straight Through (L/D = 2).....	19
6.2.5 Vertical T-pieces Straight Through (L/D = 2).....	20
6.2.6 Horizontal T-pieces Straight Through (Short Outlet Tee).....	20
6.2.7 Influence of Rotation on the Wall.....	20
6.2.8 Influence of Temperature.....	22
6.2.9 Influence of Back Pressure.....	22
7 CONCLUSIONS & RECOMMENDATIONS.....	23
7.1 Considerations When Evaluating Existing Designs.....	23
References.....	25
Appendices	
Appendix A: Test Schematic	
Appendix B: Properties for PP-R Pipe	
Appendix C: Measure data for PP-R Pipes used in Experiments	
Appendix D: Flow Rate, Velocity and Reynolds Numbers	

Appendix E: Overview of Combinations of Configurations, Slopes and Rotations Tested for Straight Through Flow and Elbow Flow
 Appendix F: Test Results
 Appendix G: Representative Test Graphs
 Appendix H: Literature

LIST OF FIGURES

Figure 1-1: Cotter’s Test Fixture Used in the Pre-Study 2
 Figure 2-1: Principle Sketch of Branches 3
 Figure 4-1: Test Schematic for Horizontal Runs 7
 Figure 4-2: Example Images of a Visual Air Grade 10
 Figure 4-3: Example Image of Air Grade 1 10
 Figure 4-4: Evaluation Scheme for Including Time for Clearing Air into the Evaluation of Data-Developed During the Project 11
 Figure 5-1: Justification of the Designation Given to the Polypropylene (PP-R) and PVC Piping 12
 Figure 5-2: Principle Sketches of Manufactured Test Pieces 13
 Figure 5-3: T- designation, the True L/D and for Reference the L/D Achieved by the Dimension of ASME BPE Tees 14
 Figure 5-4: BPE Hygienic Clamp Joint: Short Outlet Tee (BPE 2012 Table DT-4.1.2-5) and Straight Tee (Table DT-4.1.2-4 BPE 2012) 14
 Figure 5-5: PP-2 Inch Straight Geometry L/D = Short (left) and L/D = 2 (right) 15
 Figure 5-6: PP-2 Inch Elbow Geometry L/D = 2 (left) and L/D = Short (right) 15
 Figure 5-7: Branch Rotation Designation 17
 Figure 6-1: Data for Upward Pointing Branch (0°) on a Horizontal Line at Ambient Temperature Plotted with Reynolds Number, Velocity and Flow Rate 19
 Figure 6-2: Velocity Required to Reach Certain State 20
 Figure 6-3: Results from the Elbows Configuration Test for L/D =2 21
 Figure 6-4: Results from the Elbow Configuration Test for SO tee 22

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.

Established in 1880, the American Society of Mechanical Engineers (ASME) is a professional not-for-profit organization with more than 135000 members and volunteers promoting the art, science and practice of mechanical and multidisciplinary engineering and allied sciences. ASME develops codes and standards that enhance public safety, and provides lifelong learning and technical exchange opportunities benefiting the engineering and technology community. Visit www.asme.org for more information.

The ASME Standards Technology, LLC (ASME ST-LLC) is a not-for-profit Limited Liability Company, with ASME as the sole member, formed in 2004 to carry out work related to new and developing technology. The ASME ST-LLC mission includes meeting the needs of industry and government by providing new standards-related products and services, which advance the application of emerging and newly commercialized science and technology and providing the research and technology development needed to establish and maintain the technical relevance of codes and standards. Visit www.stllc.asme.org for more information.

ACKNOWLEDGMENTS

ASME greatly appreciates the many contributors from the ASME BioProcess Equipment Standards Committee who participated in this study. They are named below, along with their role in this study. Special thanks go to Randy Cotter Sr. and Cotter Brothers Corporation, for their efforts in preparing the final report.

- 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*
- Dan Mathien, Behringer Corporation - *Contributor*
- Phil Paquette, P.E. - *Design Review*
- Marc Pelletier, CRB Engineering - *Contributor*
- Joe Serdakowski, AutoSoft Systems - *Data Analysis*
- James Dean Vogel, P.E. The BioProcess Institute - *Project Director*
- Deborah Botham, Cotter Brothers Corporation – *Contributing Editor*
- Jay Ankers, M+W U.S., Inc. – *ASME BPE Committee Chair*

Additionally, the following companies provided goods and services to support this study:

- Polypropylene Test Pieces - Arkema (through George Fisher)
- Hoses - AdvantaPure
- Valves - ITT, Gemu, Crane/Caulder, PBM
- Instruments - Anderson
- Fittings - VNE
- Seals - Parker
- Hangers - Behringer
- Pump - Fristam
- Special 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 $L/D \leq 6$ 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 $L/D \leq 2$ 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.