



ASME Standards Technology, LLC
Request for Proposals
RFP-ASMEST-11-01
BPE #1 – ASME BPE Deadleg Study

Date Posted: April 23, 2010
Proposal Due Date: May 24, 2010

1. Summary

ASME Standards Technology, LLC is soliciting proposals for a Deadleg Study. This project will confirm, with data, the effectiveness of typical cleaning and sterilizing methods on process piping that is designed per the ASME BPE standard requirements. If deadleg areas are present and cannot be effectively cleaned or sterilized, then this study will provide useful information to the industry. It also can provide the impetus to change the BPE standard towards a best practice. This may force a change in system design practices or cleaning protocol or both in all systems employed in the industry for years to come.

This project resulted from ASME Pressure Technology Codes and Standards (PTCS) Standards Committee requests to identify, prioritize, and address technology gaps in PTCS Codes, Standards, and Guidelines. This project is one of several included for ASME FY2011 funding and is intended to establish and maintain the technical relevance of ASME codes and standards products. An overview of the annual ASME PTCS project selection process is provided at <http://files.asme.org/STLLC/10192.pdf>.

2. Discussion

The scope of this project entails a test method to measure how effectively process components are cleaned, air is removed, and /or how effective bioburden reduction is at different flow rates versus deadleg ratios. In the BPE Standard, “Dead leg” is defined as “an area of entrapment in a vessel or piping run that could lead to contamination of the product”. In Part SD-3.11, deadleg is measured by the term L/D, where “L” is the leg extension from the ID wall normal to the flow pattern or direction and “D” is the ID of the extension or leg of a tubing fitting or the nominal dimension of a valve or instrument. The current target ratio identified in the BPE Standard is a 2:1 deadleg ratio. This study will show the effectiveness of design at different deadleg ratios at various positions and velocities to perform effective cleaning and to deliver a robust BioProcess.

The deliverable is a Technical Report containing: Design Analysis, Computational Fluid Dynamics Analysis, Experimental Results including, Flow and Cleanability (Riboflavin) test results, Performance Videos, and Recommendations for incorporation into the ASME BPE Standard. These recommendations may include Piping Configuration, Operational Methods, and Novel Equipment Designs.

Currently, there has been a great deal of resistance to using the ASME BPE Standard in Japan and Europe. The resistance stems from the perceived additional costs to hold design to a 2:1 Deadleg target. The 3-A standard currently only requires a 6:1 ratio (measured differently than BPE). This has been a huge obstacle in gaining global acceptance of the BPE Standard.

As the topic of cleanability and bioburden control has been on the forefront of discussion in the industry for some time, there was an initial investment made by Randy Cotter, Sr. of Cotter Brothers Corporation to develop a test rig to get a closer view of these deadlegs and how they respond to different flow velocities. The preliminary test results have shown some surprising results. This was the impetus to validate these initial results with further testing and analysis under proper, robust, and independent scientific scrutiny.

There have been several related studies conducted in recent years which proved informative, but none clearly address the cleanability of a deadleg, nor provide any specific data to support a position on design criteria. Studies based on different line sizes sometimes result in differing conclusions.

Young, J.H, Ferko, B.L., Gaber, R.P. “*Parameters Governing Steam Sterilization of Deadlegs*”, *J Pharm Sci Technol.* 1994 May-Jun; 48(3):140-7.

Habib, M.A., Badr, H. M., Said, S.A.M., Mokheimer, E.M.A., Hussaini, E.M.A., Al-Sanaa, M “*Characteristics of flow field and water concentration in a horizontal Deadleg*”, *Heat Mass Transfer* (2005) 41: 315–326.

Cotter, R “*Weld hold-up volume*”, *Cotter Brothers, Correspondence to the ASME, BPE, 2004.*

3. Scope of Work

a. Scope Description

The goal is to produce the data necessary to support the sale of the ASME BPE Standard to the rest of the world and achieve global acceptance.

- Develop a detailed testing objective and plan, capture all data generated from the various tests, and generate a report on findings for the committee to evaluate.

b. Deliverable

The project deliverable shall be a technical report detailing the findings as per the Scope Description above. The report must be provided as a MS Word .doc file that is formatted in accordance with the ASME ST-LLC template, located here: <http://files.asme.org/STLLC/18396.doc>. One peer review cycle is anticipated and modifications required to the report, as a result of the review cycle, are the responsibility of the contractor awarded the contract.

c. Schedule

Investigators shall submit a schedule with their proposal that provides major milestones and a reporting schedule. ASME ST-LLC desires that the final deliverable be provided no later than June 30, 2011.

d. Reporting

A brief status report shall be provided monthly, via email, to the ASME ST-LLC project manager. Progress reports shall be presented at ASME BPE Standards committee meetings.

e. Travel Requirements

Travel requirements are to present project results to ASME BPE at their meetings. Travel expenses shall be reimbursed, within the project budget, per the project Travel Policy.

f. Budget

The total budget is approximately \$40,000.

4. Applicant Eligibility Requirements

ASME ST-LLC is seeking proposals from all qualified organizations including, but not limited to, engineering firms, consultants, academic institutions, and Federally Funded Research and Development Centers. In addition to relevant technical qualifications and experience, applicants must possess an understanding of relevant ASME codes and standards.

5. Basis for Selection and Award

ASME ST-LLC will select the winning proposal by evaluating and comparing the merits of each applicant's complete proposal. This process reflects ASME ST-LLC's desire to select an application based on its potential to achieve program objectives, rather than solely on evaluated technical merit or cost. Evaluation criteria include, but are not limited to, the following:

- Technical capabilities
- Experience
- Price
- Schedule
- Agreement with Terms and Conditions

ASME ST-LLC reserves the right to award, in whole or in part, any, all, or none of the applications submitted in response to this solicitation.

6. Contract Terms and Conditions

A fixed-price contract is preferred, but labor hour and expenses-type proposals will also be considered. Draft terms and conditions are located here <http://files.asme.org/STLLC/13937.pdf>. The final contractual terms and conditions will be negotiated between ASME ST-LLC and the winning applicant.

ASME ST-LLC will provide access to the required codes, standards, and other technical references.

7. Submission Requirements

a. Proposal Due Date

Proposals and amendments of proposals must be received by May 24, 2010. Applicants are encouraged to transmit their proposal well before this deadline.

b. Anticipated Selection and Award Date

ASME ST-LLC plans to select the winning proposal within two weeks of the proposal deadline.

c. Application Preparation Costs

This solicitation does not obligate ASME ST-LLC to pay any costs incurred in the preparation and submission of proposals, in making necessary studies or designs for the preparation thereof, or to acquire, or contract for any services.

d. Application Clarification

ASME ST-LLC reserves the right to request clarification of proposals and/or supplemental information. The award may be made after few or no exchanges, discussions, or negotiations. Therefore, all applicants are advised to submit their most favorable application to ASME ST-LLC. ASME ST-LLC reserves the right, without qualification, to reject any or all proposals received in response to this solicitation and to select any proposal, in whole or in part, as a basis for negotiation and/or award. ASME ST-LLC reserves the right to modify or cancel this solicitation. All questions relating to the solicitation must be submitted to the contact below. Any amendments to the solicitation will be posted on the ASME ST-LLC web site (http://stllc.asme.org/Requests_Proposals_RFPs.cfm).

e. Treatment of Proprietary Information

A proposal may include technical and/or other data, including trade secrets and/or privileged, confidential commercial or financial information, which the applicant does not want disclosed to the public or used by ASME ST-LLC for any purpose other than proposal evaluation. To protect such data, the applicant should specifically identify the data to be protected.

f. Proposal Preparation and Submittal Instructions

ASME ST-LLC may form a committee of subject matter experts to evaluate the technical qualifications of applicants. To help facilitate this evaluation, responses should include two separate documents, a Technical Proposal, and a Financial Proposal.

(1) Technical Proposal

- (a) Provide organization name and contact information.
- (b) Provide evidence of technical capabilities: credentials, qualifications, capabilities, and experience of individuals and the organization.
- (c) Describe approach to accomplish the Scope of Work.
- (d) Confirm agreement with the Scope of Work for the specified task(s)

(2) Financial Proposal

- (a) Provide a fixed price quotation or an hourly billing rate quotation and estimated project maximum.
- (b) Confirm agreement with the draft Terms and Conditions, or state any specific exceptions.

(3) Submit Technical and Financial Proposals via e-mail to the ASME ST-LLC contact below.

(4) Responses must be received on or before the deadline.

8. ASME Standards Technology, LLC Contact Information

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