

INFORMATION AND PROCEDURES FOR OBTAINING AN ASME BPE CERTIFICATE OF AUTHORIZATION OR QUALITY SYSTEM CERTIFICATE

An organization seeking to certify components or equipment manufactured in accordance with the ASME Bioprocessing Equipment (BPE) Standard will have its Quality Management System (QMS) surveyed by ASME. Currently, ASME's BPE Certification Program applies to the manufacture of metallic tubing, fittings, and valves, and polymeric static seals.

For metallic tubing, fittings, and valve manufacturers, use of the ASME Single Certification Mark is authorized under an ASME Certificate of Authorization. For polymeric static seals, a Quality System Certificate is issued to recognize the manufacturer's Quality Management System. In order to obtain and maintain an ASME Certificate of Authorization or Quality System Certificate, the Applicant must conform to the requirements identified in the current edition of the ASME BPE Standard in effect at the time the application is made. The "effective date" is the date when the requirements of the BPE Standard become mandatory, which is 6 months after its date of issuance. The Applicant or Certificate Holder is not precluded from implementing the latest published Standard earlier than the effective date.

ASME, by using Survey Teams, reviews the Applicant's QMS Manual and its implementation. Any findings noted during the survey are discussed between the Applicant and the Team and a written report of the survey is submitted to ASME. This report is reviewed by ASME, which either authorizes issuance of the Certificate or requests additional action by the Applicant. Two additional program audits will be performed by ASME over the five year life of the certificate. QMS Manual reviews are not conducted during the interim audits.

Surveys are performed at all locations where the activities, as described in the QMS Manual, are being performed by the Applicant. The Survey Team will not survey organizations performing subcontracted activities for the Applicant.

The QMS Manual and supporting documentation must be in English. The Applicant is not prohibited from having a QMS Manual in its native language; however, the English version shall govern.

The Survey Team is a two-person team and consists of a Team Leader and a Team Member. The Audit Team is a one-person team. The teams are experienced in the field of quality assurance and have been trained in understanding the technical and quality requirements of the ASME BPE Standard.

QMSs vary in complexity, detail and structure depending on an Applicant's size, scope and range of products manufactured. An estimated cost of the survey can be provided upon request when the

application form is completed and returned. The estimate provided is not a firm quotation. If the facility requires an extended survey because of its complexity, the estimate could be exceeded. The Survey Team will make every effort to conclude its work in a timely and efficient manner.

ASME requires a deposit prior to the establishment of survey dates. This will be applied to the cost of the Survey. If the Applicant withdraws their application after the deposit is received by ASME, the deposit will be returned, but there is an administrative fee which will be deducted from the refund as outlined in the [Price Guide](#). Cancellation of survey dates is also subject to a monetary penalty, deducted from the refund in accordance with the [Price Guide](#).

The Applicant must complete the following steps in order to start the certification process to obtain a Certificate of Authorization or a Quality System Certificate:

- CA Connect Account: New applicants will need to create a CA Connect account.
- Application Forms: An Application Form along with Supplemental Application for ASME BPE Certification (**Form P**) shall be completed and submitted through CA Connect.
- ASME Accreditation/Certification Agreement Form: Applicant shall complete the ASME Accreditation/Certification Form and e-mail it to ca@asme.org or upload it into CA Connect under the company profile.
- QMS Manual: A controlled and approved copy of the QMS Manual shall be uploaded into CA Connect under the company profile.
- QMS Manual Checklist: A completed "BPE Quality Management System Manual shall be uploaded into CA Connect under the company profile. The Checklist can be downloaded from the Bioprocessing Equipment Certification web-page.
- Fees/Payments: Applicant must remit the required Survey deposit and fees.

Please refer to the ASME [Price Guide](#) for applicable Survey deposits and fees. Prices are based on USD and are subject to change.

At the conclusion or termination of a survey, an invoice will be rendered or an Applicant may be entitled to a refund of the excess deposit. The invoice will include the BPE Certificate of Authorization or Quality System Certificate fee if the recommendation of the Survey Team is to issue the Certificate and for initial issuance of the ASME Certification Mark stamp fee, in addition to the fees and expenses of the ASME Survey Team and the ASME administrative fees. The advance deposit will be applied to the final invoice covering the cost of the certificate, the Certification Mark, and expense of the ASME Team conducting the survey. For the cost of the ASME Certification Mark for either a metal stamp or rubber stamp refer to the [Price Guide](#). If it is preferred that a refund be done electronically, please provide banking particulars in CA Connect. At the conclusion of each audit, an invoice will be rendered for the fees and expenses of the ASME Consultant and the ASME administrative fees. ASME will take action to withhold or withdraw the Certificate of Authorization for any nonpayment of invoices which are past due.

ASME will make every effort to conduct an evaluation of an Applicant's program at the earliest possible date after receipt of the application forms and deposit. However, it should be expected that a lead time of four to six months is typical because of scheduled surveys of other companies.

For renewals, to assure continuity of the certificate, the application form and advanced deposit must be submitted at least 6 months prior to the expiration date shown on the currently active Certificate.

ASME can accept no liability for any consequences to the Applicant resulting from of a survey, audit or subsequent ASME actions.

For questions, please contact the ASME Conformity Assessment Department via email at ca@asme.org