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INFORMATION AND PROCEDURES FOR OBTAINING AN ASME BPE CERTIFICATE OF AUTHORIZATION

An organization seeking to certify components manufactured in accordance with the ASME Standard for Bioprocessing Equipment, BPE, may have its Quality Management System surveyed by ASME. Currently, ASME's BPE Certification Program applies only to the manufacture of tubing and fittings.

The standard requires that the ASME Certification Mark be applied by an organization in possession of a valid ASME Certificate of Authorization. In order to obtain and maintain an ASME Certificate of Authorization, the Applicant must comply with requirements given in the current edition of ASME BPE Standard in effect. The "effective date" is the date when the requirements of the BPE Standard become effective 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 Quality Management System 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 to be reviewed by ASME, which either authorizes issuance of the Certificate or requests additional action by the Applicant. Two additional unannounced audits will be performed by ASME over the five year life of the certificate.

Surveys are performed at all locations where the activities as described in the Quality Management System Manual are being performed by the Applicant. The Survey Team will not be surveying organizations performing subcontracted activities for the Applicant.

The Quality Management System Manual and documentation which support understanding of the program must be in English. The Applicant is not prohibited from having a Quality Management System Manual in its native language; however, the English version shall govern when there is a discrepancy.

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 BPE Standard.

Quality Management Systems vary in complexity, detail and structure as to 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 your 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 an advanced deposit prior to establishment of survey dates. This will be applied to the cost of the Survey. If the Applicant withdraws their application after the remittance is received by ASME, there is an administrative fee which will be deducted from the original remittance as outlined in the [Price Guide](#).

The Applicant must complete the following steps in order to start the Certification Process to obtain a Certificate of Authorization to use the ASME Certification Mark with the BPE designator:

- Application Forms: Application Form along with Supplemental Application for ASME BPE Certification *Form P* shall be completed and submitted through [CAconnect](#)
- [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 CAconnect under the company profile
- Quality Management System Manual: A controlled and approved copy of the Quality Management System Manual shall be uploaded into CAconnect under the company profile
- Quality Management System Manual Checklist: A completed "BPE Quality Management System Manual Checklist" shall be uploaded into CAconnect under the company profile. The Checklist can be downloaded from our [Bioprocessing Equipment Certification web page](#);
- Fees/Payments: Applicant must remit the required Survey deposit and fees (refer to [Price Guide](#) for applicable deposits 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. If the Applicant withdraws their application after remittance is received by ASME, there is an administrative fee which will be deducted from the original remittance. Cancellation of survey dates is subject to a monetary penalty, deducted from the advance deposit in accordance with the Price Guide.

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 fee if the recommendation of the Survey Team is to issue the Certificate and for initial issuance the ASME Certification Mark stamp fee, in addition to the fees and expenses of the ASME Survey Team and the ASME administrative fees. 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 the refund be done electronically, please provide banking particulars in CAconnect. At the conclusion of each audit (unannounced or announced), 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 usual 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 show on the Certificate.

ASME can accept no liability for any consequences to the Applicant, which may be the result of a survey, audit or subsequent ASME actions.

If you have any questions, please contact the ASME Conformity Assessment Department via email at ca@asme.org