NONMANDATORY APPENDIX Z
QUALITY MANAGEMENT SYSTEM

Z-1 SCOPE AND PURPOSE

This Appendix identifies the elements that shall be addressed in a Quality Management System (QMS) for ASME BPE component manufacturers. These elements identify the procedures, describe the processes, and list the resources necessary to implement the QMS. The QMS shall identify and describe the authority of the individuals responsible for ensuring that the quality activities necessary for the manufacture of ASME BPE-compliant components are done in a consistent and controlled manner. These activities shall ensure that the requirements of the ASME BPE Standard are met through quality planning, quality assurance, and quality improvement.

A QMS established by a manufacturer that intends to meet the requirements of the ASME BPE Standard shall be suitable for the types of components being manufactured and the types of activities performed in the manufacture of those components.

Z-2 GENERAL

The manufacturer shall establish and maintain a QMS that ensures conformance to all applicable requirements of the current ASME BPE Standard. Upon the issuance of a revised ASME BPE Standard, the Certificate Holder shall review his QMS and, where required, revise it to be in conformance with the revised Standard. Implementation of the revised QMS shall be within 6 months of the date of issue of the revised Standard.

Z-3 QUALITY MANAGEMENT SYSTEM MANUAL

The QMS shall be documented in a written QMS manual. There is no specific format or particular arrangement required for the manual, as long as all applicable elements have been addressed and the various topics are arranged in a logical and easy-to-interpret manner. The elements identified in Z-3.1 through Z-3.15, as applicable to the manufacturer’s scope of work, shall be addressed in the manual. The manual shall be ASME’s guide for surveying and auditing the manufacturer’s activities and documentation for conformance to its QMS. The manual shall be an auditable document that identifies the controls and processes used to ensure that the activities performed in the manufacture of ASME BPE components will be in conformance with the ASME BPE Standard. The manual shall not be a reiteration of the ASME BPE Standard, but shall, instead, describe or identify what, when, where, and how processes are conducted.

Z-3.1 Quality Management System

(a) Management personnel shall establish objectives for measuring effective implementation of the QMS and are responsible for obtaining the desired results. A policy statement indicating management authority and responsibility shall be included.

(b) A description of the components being manufactured in accordance with the ASME BPE Standard shall be provided.

(c) The authority and duties of those responsible for implementing the QMS shall be clearly established. Individuals performing quality assurance and quality control functions shall not be under the direct supervision of those in charge of areas being evaluated. They shall also have sufficient and well-defined responsibility, authority, and organizational freedom to

1. identify quality-related problems
2. initiate, recommend, and provide solutions to quality-related problems
3. verify implementation of those solutions
4. assure that further processing, delivery, or use of a suspect material or product is halted until proper disposition of any potentially nonconforming, deficient, or unsatisfactory condition has occurred

(d) Activities required to be performed by qualified personnel shall be identified. Minimum qualifications for such personnel shall be established. Controls shall be established to ensure that only those personnel who have the specified qualifications are permitted to perform those activities.

(e) Auditing activities shall be performed by trained and qualified auditors. The qualification, experience, and training requirements for auditors shall be specified in the QMS manual. Auditing competence includes, at a minimum, demonstrated knowledge and understanding of

1. the ASME BPE Standard
2. applicable regulations
3. the QMS program
(c) Nondestructive Examination (NDE). Measures shall be established to ensure that NDE is performed by personnel whose qualifications meet the requirements of the ASME BPE Standard. These measures shall also ensure that all NDE activities are conducted in accordance with procedures as specified in the ASME BPE Standard.

(d) Surface Finish/Treatment. Measures shall be established to ensure that surface finish treatments and the procedures used to apply them conform to the requirements of the ASME BPE Standard.

(e) Special Controlled Environments. Provisions shall be enacted to identify activities that require special controlled environments, and appropriate measures are established to achieve and maintain the desired conditions.

Z-3.7 Control of Equipment and Tooling

Provisions shall be established for the safe storage of equipment and tooling that are not in service.

Z-3.8 Control of Outsourced Items and Services

(a) Controls shall be established to ensure that outsourced items and services meet the specified requirements of the ASME BPE Standard. Provisions shall be established for the qualification and approval of suppliers and for the correction or elimination of nonconformances in outsourced items and services.

(b) The method used to qualify, approve, and monitor the performance of suppliers shall be described.

(1) When the supplier is an ASME BPE Certificate Holder and the supplied items bear the ASME Certification Mark, the method employed shall be one of the following:

(-a) a review of the certificate’s scope, the QMS manual, or both, to determine the Certificate Holder’s capability of supplying the item.

(-b) receipt of the supplied item with documentation certifying that the work was performed in accordance with the ASME Certificate of Authorization with the certificate number identified.

(2) For items and services supplied by an organization that does not hold an ASME BPE Certificate of Authorization or for items supplied by an ASME BPE Certificate Holder when the items do not bear the ASME Certification Mark, the method employed shall be based on one or more of the following:

(-a) The supplier’s history of providing items or services that conform to specified requirements or that perform satisfactorily in service. This can be based on past performance or a current third-party certification from a recognized accreditation body. Additionally, when qualification and approval are based on third-party certification, the scope of that certification must be verified to be appropriate for the item or service being supplied.

(-b) Verification upon receipt inspection that the item or service conforms to specified requirements. Inspections shall be performed by qualified personnel using an inspection plan that details the characteristics to be inspected, the method of inspection, and the acceptance criteria. The results of the inspection shall be documented.

(-c) Verification during fabrication that the item or service performs satisfactorily in service. When adequate service performance cannot be verified through inspection activities on the completed component, hold points shall be established to evaluate the conformity of the supplied item or service. Work shall not proceed until the inspector has verified that the work performed is in conformance with the specified requirements.

(-d) On-site surveillance of the supplier by a qualified technical expert or an auditor to verify the conformance of the supplied item or service.

(e) Approving Suppliers Through Surveys and Audits. Surveys and audits shall be documented and conducted by qualified lead auditors and auditors using a checklist. The frequency of the surveys and audits shall be commensurate with the schedule of production or procurement, but shall be, at a minimum, commensurate with the surveys and audits conducted by ASME performed on BPE Certificate Holders.

(c) Controls shall be established for the segregation of outsourced items that are determined to be nonconforming.

Z-3.9 Control of Measurement and Test Equipment

Controls shall be established to ensure that tools, gauges, instruments, and other measuring and testing devices used in quality control activities.

(a) Procedures. Procedures shall be established to ensure that tools, gauges, instruments, and other measuring and testing devices used to verify conformance to the specified requirements are calibrated at regular intervals. Periodic checks on these devices shall be performed to determine that calibration is current. These periodic checks shall be documented.

(b) Calibration. Calibration shall be conducted using certified samples having documented traceability to primary standards, where such standards exist. If no primary standard exists, the standard or basis for calibration shall be documented.

(c) Control Measures. Control measures shall include provisions for identification of these devices and for determining calibration status by either equipment marking or records traceable to the equipment.

(d) Out-of-Tolerance Devices

(1) When a device fails to calibrate during a planned periodic calibration, provisions shall be established to ensure that appropriate corrective action shall be
taken. These provisions shall include a method for reviewing all measurements or tests performed with that device since the last successful periodic calibration to determine if applicable requirements have been met.

(2) When a device fails to calibrate during a periodic check, provisions need only address measurements or tests performed since the last successful periodic check provided the method and frequency used for the periodic check are described in calibration procedures.

Z-3.10 Nonconformances and Corrective Actions

(a) Items and services that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall address identification, documentation, evaluation, segregation, and disposition of nonconforming items, as well as the notification of affected organizations.

(b) Measures shall be established to ensure that conditions that do not conform to specified requirements, such as failures, malfunctions, deviations, defective material, or equipment, nonconformances, and other quality system deficiencies, are identified, reported to appropriate levels of management, and promptly corrected. These measures shall also ensure that the root cause(s) responsible for these nonconformances be determined and corrected.

(c) The identification of conditions causing recurring nonconformances, the cause of these conditions, and the corrective action taken shall be documented and reported to appropriate levels of management.

Z-3.11 Storage, Shipping, Handling, and Packaging

Controls shall be established for the cleaning, preservation, packaging, storage, and shipping of finished components.

Z-3.12 Control of Documents and Record Retention

(a) Provisions shall be established to ensure that documents that are to be maintained throughout the design and manufacture of the component are identified. A minimum retention period of 3 yr from the date the component is shipped shall be established.

(b) These provisions shall also require that manufacturer’s Data Reports, MTRs, and C of Cs shall be retained for a minimum period of 5 yr from the date the component is shipped.

(c) Document retention requirements shall extend to records of personnel training, qualification, and certification, for which the minimum retention time shall be 5 yr after their employment ceases. For personnel providing outsourced services in accordance with Z-3.1(f), provisions shall be established for the Certificate Holder to have access to their personnel records, as needed.

Z-3.13 Sample Forms

The use of forms shall be described. Typical examples, referred to as “exhibits” shall be included and marked “Sample.” These samples should be completed in a manner typical of that expected for actual production documents.

Z-3.14 Internal Audits

Requirements shall be established for internal audits. Those requirements should address the following, as a minimum:

(a) The frequency of internal audits shall be specified. These audits shall be conducted in accordance with a written procedure by qualified auditors not having direct responsibility for the areas being audited. All elements in the QMS shall be internally audited at least once during each certification period.

(b) Audit results shall be documented by auditing personnel and reviewed by management having responsibility over the areas being audited. This documentation shall bear the signatures of the responsible management personnel.

(c) Corrective actions taken in response to deficiencies or nonconformances shall be documented. Follow-up actions shall be required after corrective actions have been taken to ensure the problem has been corrected. These follow-up actions may include a re-audit of deficient areas.

Z-3.15 Management Performance Assessments

Management personnel with assigned responsibility shall review the organization’s QMS at least annually to ensure its continued suitability, adequacy, and effectiveness. The input from management review shall include information on the results of audits, process performance and product conformity, the status of preventive and corrective actions, and customer feedback, as appropriate.