SELF - AUDIT QUESTIONNAIRE

COMPANY NAME | PHONE NO. | FAX NO.

COMPANY ADDRESS

CITY | STATE | ZIP CODE | EMAIL ADDRESS

QUESTIONNAIRE COMPLETED BY | TITLE

SIGNATURE | DATE

ARE YOU CURRENTLY REGISTERED TO ONE OF THE FOLLOWING QUALITY MANAGEMENT SYSTEMS?
(check applicable registration):

☐ ISO9001 ☐ ISO/TS16949 ☐ AS9100

REGISTRAR | REGISTRATION NO.: | REG. DATE

PRODUCT MANUFACTURED AND/OR SUPPLIED

OF EMPLOYEES | # OF QA/QC PERSONNEL | LABORATORY/TEST FACILITIES:

If your company is not registered to ISO 9001, ISO/TS16949 or AS9100, please complete the following questionnaire by answering with a YES, NO or N/A (Not Applicable) in the appropriate spaces. Any comments you may wish to make, can be recorded at the end of the questionnaire.

Please return this page and the completed questionnaire to:
John Smith (jsmith@ambac.net)

**** If your company is ISO9001, ISO/TS16949 or AS9100 Registered you may stop here.
Return a copy of this page and a copy of your Registration Certificate(s) to:
John Smith (jsmith@ambac.net)**

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Page #1 and Certificates Reviewed By | Date | ☐ Approved ☐ Rejected

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A. MANAGEMENT RESPONSIBILITY

1. Are your organization's policies and Objectives, with regard to quality, clearly defined, documented and understood? (e.g. Quality Manual) — A1

2. Are the authorities and responsibilities of a persons function affecting quality clearly defined and documented? — A2

3. Do you have adequate verification resources and personnel to ensure product/service quality and quality systems conformance? — A3

4. Has management appointed a representative with defined authority and responsibility for ensuring that your quality management system is functioning correctly and effectively? — A4

5. Is the quality management system reviewed by management at regular and defined intervals to insure its continuing suitability and effectiveness, and are records of such reviews maintained? — A5

B. QUALITY SYSTEM

1. Does your organization have documented procedures that detail the functions of the quality management system, and are the procedures approved by management? — B1

2. Are the quality system procedures available to all relevant personnel? — B2

3. Are the procedures backed up by documented work and inspection instructions, product drawings product/process specifications etc.? — B3

C. DOCUMENT CONTROL

1. Are documents pertinent to the quality system (procedures/specifications/drawings or instructions etc) approved for adequacy by authorized personnel prior to issue? — C1

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2. Are the documents referred to in section C.1 above issued, controlled, and identified in accordance with defined document control procedures? C2

3. Are obsolete documents promptly removed from all points of issue or use? C3

4. Are changed or modified documents reviewed and approved by the authorized personnel prior to issue? C4

5. Do you suitably identify and control copies of drawings and /or specifications sent to suppliers? C5

D. PURCHASING

1. Does your organization qualify suppliers and sub-contractors by means of quality system audits, supplier self-audit questionnaire and/or review of product quality performance? D1

2. Do you maintain records of such audits and reviews? D2

3. Do your purchase orders clearly define product or service requirements such as type, class, style, grade etc.? D3

4. Do the purchase orders make reference to applicable technical data such as product drawings and specifications including the revisions thereof? D4

5. Do you request certificates of test/analysis when required and are such certificates reviewed for acceptability? D5

6. Do you encourage your suppliers to use statistical process control (SPC)? D6

E. PURCHASER SUPPLIED PRODUCT

1. Do you have documented procedures for verifying, storing and maintaining purchaser supplied product? E1

2. Do you report back to the purchaser such product which is incorrect, damaged or lost? E2

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F. PRODUCT IDENTIFICATION AND TRACEABILITY

1. Does your organization, when appropriate, identify lots/batches of products during and after manufacture?	F1	
2. Are drawings, specifications and other relevant documents available at verification points?	F2	
3. Are the batches of raw material or component parts identified in the records relating to the finished product?	F3	

G. PROCESS CONTROL

1. Do you have, and use, specific written procedures and/or work instructions for special and/or critical manufacturing processes?	G1	
2. Does your organization have, and use, documented product/process inspection and test instructions?	G2	
3. Are your manufacturing machines and/or production processes assessed for capability as part of product/process approval?	G3	
4. Do you use statistical process control (SPC) to monitor relevant product and process characteristics?	G4	
5. Is management informed of out of control conditions on significant product and process characteristics?	G5	
6. Are manufacturing, inspection and test environments suitable for maintaining adequate product and/or process control and are they in accordance with the standards applicable to your industry?	G6	

H. INSPECTION AND TESTING

1. Are incoming raw material and products inspected or otherwise verified prior to being put into storage or use and are records of such inspections/verification maintained?	H1	

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2. Are controls adequate to prevent the use of nonconforming raw material or products except when authorized by the responsible personnel?	H2	
3. Are first-piece inspections conducted and recorded in accordance with documented procedures prior to machine or process start-up?	H3	
4. Are manufacturing personnel responsible for the quality of the work that they perform?	H4	
5. Are inspection sample sizes and frequencies during manufacture adequate to maintain product and/or process control and are the records of such inspection and test maintained?	H5	
6. Do you conduct final inspections and test in accordance with documented procedures and are records of such inspections and test maintained?	H6	
7. Does your final inspection include an audit of the relevant inspection/test documentation (including raw material) prior to final release?	H7	

I. INSPECTION. MEASURING AND TEST EQUIPMENT

1. Is all inspection and test equipment (including process monitoring equipment) calibrated in accordance with documented procedures?	I1	
2. Is such equipment individually identified and it's calibration status clearly identified?	I2	
3. Are persons conducting in-house calibrations suitably qualified?	I3	
4. Are calibrations conducted at prescribed intervals against equipment having a known valid relationship to nationally recognized standards?	I4	
5. Are records of calibrations, in-house and by outside organizations, maintained?	I5	

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J. INSPECTION AND TEST STATUS

1. Do you clearly identify the inspection and test status of products at all stages of storage and/or manufacture (e.g. accepted, rejected, hold and awaiting test)?	J1	
2. Does such identification, when relevant, refer to reject or inspection reports (nonconformance reports, customer complaints etc)?	J2	

K. CONTROL OF NONCONFORMING PRODUCT

1. Do you have, and use, documented procedures for the controlling of nonconforming product including the reworking of such products?	K1	
2. Are nonconforming products clearly identified as such and quarantined or segregated from good products?	K2	
3. Do you have a nominated responsible person, with the necessary authority, to review and disposition nonconforming product?	K3	
4. Do you maintain records of nonconforming products which identify the deficiencies and subsequent disposition?	K4	

L. CORRECTIVE ACTION

1. Does your organization take documented corrective action when significant product, process or quality system deficiencies are highlighted?	L1	
2. Are customer complaints registered and acted on in a timely manner?	L2	
3. Do you review and monitor the actions taken against a documented corrective action request for effectiveness and are the reviews recorded?	L3	
4. Do you maintain records of concessions granted to suppliers and in-house operations and are such records analyzed in order to determine trends?	L4	

5. Are reports of corrective action requests and concessions circulated to senior management for information and action? L5

M. HANDLING. STORAGE. PACKAGING AND DELIVERY.

1. Do you have, and use, documented procedures which cover the handling, storage, packaging and delivery of product? M1

2. Are stored raw materials and products assessed for damage and deterioration on a regular basis and are such assessments recorded? M2

3. Are packaging operations conducted in accordance with clearly defined procedures and/or packaging instructions? M3

4. Are packaged goods clearly identified in respect to part/product description, grade, type, batch number (when applicable) and quantity or mass? M4

5. Are products, especially those with a limited shelf-life, delivered on a basis of first-in, first-out (FIFO)? M5

N. QUALITY RECORDS

1. Are all documents categorized as quality records clearly defined as such in relevant procedures? N1

2. Are quality records legible and are they stored in a suitable location in a manner that makes them readily retrievable? N2

3. Are the retention periods of quality records established in writing? N3

O. INTERNAL QUALITY AUDITS

1. Do you compile an annual audit schedule and is it approved by the head of your organization? O1

2. Are the audits conducted by persons suitably qualified and/or experienced to do so? O2

3. Are the results of such audits recorded and are corrective actions taken on reported deficiencies?	O3	
4. Are the audits conducted in accordance with documented procedures?	O4	
5. Does senior management review the audit results and prescribe corrective actions or system modifications as and when they are deemed necessary?	O5	

P. TRAINING

1. Does your organization conduct a training needs analysis on a regular basis?	P1	
2. Does quality awareness training form part of the overall training plan?	P2	
3. Are job specifications available for all levels of management and staff whose job functions have some bearing on the quality of the product or service?	P3	
4. Are persons performing specific assigned tasks qualified on the basis of education, training and/or experience?	P4	
5. Do you maintain records of training (in-house and external) and qualifications/certification?	P5	

Q. STATISTICAL TECHNIQUES

1. Does your organization use sampling plans during Inspection?	Q1	
2. Do your sampling plans represent zero defects?	Q2	
3. Do you conduct failure modes and effects analysis (FMEA) in order to determine quality levels and control points?	Q3	
4. Have senior and middle management received any training in the application and benefits of statistical process control (SPC)?	Q4	

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COMMENTS / REMARKS

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Self-Audit Questionnaire Reviewed By

Approved

Rejected

Date

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SQA-95-20 Record of Change

Rev Level	Rev Date	Nature of Change	Reviewed and approved by
J	8/2/2018	Placed signature box on 1st page. Added names and e-mail addresses to return completed form. Added Record of Change page.	J. Smith
K	02/11/2019	Removed Drew Shearer (dshearer@ambac.net) as a point of contact.	J. Smith