Quality System Self Evaluation - January 5, 2021

Company name: **Address:**	Anodyne Electronics Manufacturing Corp. (AEM) #15 - 1925 Kirschner Road Kelowna, BC CANADA V1Y 4N7		
Phone:	1-250-763-1088	**Company Website:**	www.aem-corp.com
Starting Business Year:	2009	**TAX ID Number:**	85600 7893
DUNS Number:	243884199	**NCAGE Code:**	L9015
Company Email:	info@aem-corp.com		
North American Industry Classification System:	NAICS Codes 334290, 334220, 336413, 811213, 334511, 334310, 333314		
Quality System:	ISO9001 and AS9100 Registered by SAI Global, File Number 1613177 Workmanship Certified to IPC-A-610, J-STD-001 & IPC-7711/21		
Approvals held:	Transport Canada Manufacturing Approval Certificate #91-09. Transport Canada Approved Maintenance Organization Certificate #91-09. European Aviation Safety Agency EASA.145.7222 Maintenance Approval.		
Key Personnel:	Brian Wall – CEO – mailto:brian.wall@aem-corp.com Tony Weller – Director of Sales & Marketing – mailto:tony.weller@aem-corp.com Royal Smith – QA Manager – mailto:royal.smith@aem-corp.com Taylor Wylie – Operations Manager – mailto:taylor.wylie@aem-corp.com		
Contact Personnel:	Quality – Frank Vivent, Quality Engineer – mailto:frank.vivent@aem-corp.com Product Support – Tom Betzelt, Support Lead – mailto:tom.betzelt@aem-corp.com Accounts – Darlene Arbez, Account Clerk – mailto:darlene.arbez@aem-corp.com		
Facility Size:	1 Building, 32,000-sq.ft. (3000 sq.m.)		
Employees:	Total: 105 Quality: 10		
Product:	Design, development, manufacture and maintenance of airborne communication equipment, PA systems, illuminated panels, integrated keyboards, caution/warning panels, structural monitoring systems and other electronic devices.		
FAA Anti-Drug Program:	Under FAR 120.123(b), contractors located outside the United States are excluded from the requirements of the FAA Anti-Drug Program.		
Shipping Terms:	FCA Kelowna in accordance with ATA 300, best commercial practices. Certificate of Conformance provided with all shipments. Transport Canada Form One (FAA 8130-3 equivalent) is provided if applicable. Payment Terms are Net 30, unless otherwise specified.		

Oversight Inspection Agency: Transport Canada (TC)

I certify that this "Quality System Self Evaluation" is correct to the best of my ability and knowledge.

Date: January 5, 2021 **Title: QA Manager**

Name: Royal Smith **Signature**

CERTIFICATE OF REGISTRATION

This is to certify that

Anodyne Electronics Manufacturing Corp. (AEM)

#15 -1925 Kirschner Road, Kelowna, British Columbia, V1Y 4N7, Canada

The above organization has been audited in accordance with the requirements of AS9104/1:2012. QMI-SAI Canada Limited (SAI Global) located in Toronto, Ontario, Canada is accredited under the Industry Controlled Other Party (ICOP) scheme. The certificate is issued at the accreditation location in Toronto, Canada.

operates a

Quality Management System

which complies with the requirements of

ISO 9001:2015 + AS9100D

for the following scope of certification

Design, development, manufacture and maintenance of airborne communication equipment, PA systems, illuminated panels, integrated keyboards, caution/warning panels, structural monitoring systems and other electronic devices.

Certificate No.:	CERT-0133272	Original Certification Date:	November 5, 2010
File No.:	1613177	Certification Effective Date:	November 12, 2019
Issue Date:	November 13, 2019	Certification Expiry Date:	November 11, 2022

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

AS9100D

Registered by:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the **SAI Global** Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, **SAI Global** accepts responsibility only for proven negligence. This certificate remains the property of **SAI Global** and must be returned to them upon request.
To verify that this certificate is current, please refer to the **SAI Global** On-Line Certification Register:
https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_registry/

SAI GLOBAL
INFORM. INSPIRE. IMPROVE.

Transport Canada Transports Canada

Certificate of Approval

This is to certify that

Anodyne Electronics Manufacturing Corp.

of

Kelowna, BC

Approved Maintenance Organization

91-09

is approved pursuant to CAR 573.02 for the maintenance of aeronautical products, and holds ratings in the following categories:

Avionics

The scope of privileges applicable to each category is limited to that specified in the respective rating documents that accompany this certificate, and is conditional upon compliance with the approved procedures and limitations specified in the organization's maintenance policy manual.

Signed: _____

B. Boechler
For the Minister of Transport

Dated: 2009-09-25

Supersedes certificate dated: _____

This Certificate is not transferable. The approval is valid until surrendered, suspended or canceled.

Canada

Transport Canada Transports Canada

Approved Maintenance Organization Ratings

– Avionics Category –

Anodyne Electronics Manufacturing Corp.

Approved Maintenance Organization 91-09

is authorized to perform maintenance, on avionics systems and equipment of the kinds listed below, within the scope of work shown and subject to any further limitations specified in the maintenance policy manual.

Rating	Scope of work	Effective Date
Radio systems	As specified in company manual	2009-09-25

Issued: 2009-09-25 Signed: B Boechler

B Boechler
For the Minister of Transport

Supersedes certificate dated: _____

Canada

European Aviation Safety Agency

APPROVAL CERTIFICATE

REFERENCE EASA.145.7222

Taking into account the provisions of Article 12 (2) of Regulation (EC) 216/2008 of the European Parliament and of the Council and the Technical Arrangements for maintenance currently in force between the European Aviation Safety Agency and TCCA, the European Aviation Safety Agency (EASA) hereby certifies:

Anodyne Electronics Manufacturing Corp.
TCCA AIRCRAFT MAINTENANCE ORGANISATION NUMBER: TCA AMO 91-09
15 – 1925 Kirschner Road
Kelowna, B.C. V1Y 4N7
Canada

as a Part-145 maintenance organisation approved to maintain the products listed in the TCCA Approval Certificate and associated Category Limitations Document and to issue related certificates of release to service using the above reference, subject to the following conditions:

1. The scope of the approval is limited to that specified on the TCCA Approval Certificate, and the associated category limitations documents for work carried out in Canada. (Unless otherwise agreed in a particular case by EASA).
2. This approval requires continued compliance with CAR 573 and the differences as specified in the Technical Arrangement for Maintenance, including the use of the TCCA Form 24-0078 for release/return to service of components up to and including powerplants.
3. Certificates of return to service must quote the EASA Part 145 approval reference number quoted above and the TCCA AMO number.
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited duration until the approval is surrendered, superseded, suspended or revoked.

Date of issue: 01 June 2010

Signed

For EASA

Certificate of Approval

This is to certify that

Anodyne Electronics Manufacturing Corp.

whose place of business is located at

#15-1925 Kirschner Road, Kelowna, BC

Approved Organization

91-09

is approved pursuant to CAR 561 for the

MANUFACTURE and **CERTIFICATION** of:

Aeronautical Products

specified in the respective Approval Limitation Records
that accompany this certificate

Signed: _____
B. Boechler
For the Minister of Transport

Dated: 2010-07-26

Supersedes certificate dated: _____

This Certificate is not transferable. The approval is valid until surrendered, suspended or canceled.

Transport Canada Transports Canada

Approval Limitation Record
– Aeronautical Product –
– Sub Assemblies and Parts –

Anodyne Electronics Manufacturing Corp.

the holder of Certificate of Approval Number: **91-09**

is limited to the manufacture and certification of the following Aeronautical Products :

Product	Model / Part Number	Approval Number	Effective Date
Communication and Navigation Equipment	As shown on the current approved AEM QPF 410-9 Approval Limitation Record	As shown on the current approved AEM QPF 410-9 Approval Limitation Record	2010-07-26

Issued: 2010-07-26 Signed: B. Boechler
For the Minister of Transport

Supersedes certificate dated: _____

Canada

QUALITY SYSTEM QUESTIONNAIRE

Quality Management System

General requirements	Yes	NO
01 A QMS has been established, documented, implemented and maintained with evidence of continual effectiveness improvement.	✓	
02 The QMS addresses customer, statutory, and regulatory requirements.	✓	
03 QMS processes have been determined and applied.	✓	
04 Sequence and interaction determined for QMS processes.	✓	
05 Criteria and methods determined to effectively operate and control QMS processes.	✓	
06 Availability of resources and information necessary to support the operation and monitoring available for QMS processes.	✓	
07 QMS processes are monitored, measured, and analyzed.	✓	
08 Actions implemented to continually improve planned results.	✓	
09 Processes are managed in accordance with applicable Aerospace Quality Management Systems (AQMS) standards.	✓	
10 Outsourced processes are defined and controlled.	✓	
Documentation requirements		
11 Documented statement of a quality policy.	✓	
12 Documented quality objectives.	✓	
13 Documented quality manual.	✓	
14 Documented procedures required by 9100-series standards.	✓	
15 Documented records required by 9100-series standards.	✓	
16 Necessary documents and records as per 9100-series standards.	✓	
17 Accessibility and awareness of personnel of relevant QMS documentation and changes.	✓	
Quality manual		
18 Quality manual established and maintained.	✓	
19 Includes the scope of the QMS.	✓	
20 Includes justification of exclusions.	None	
21 Includes QMS documented procedures or reference to them.	✓	
22 Includes a description of the QMS processes and interactions.	✓	
Control of documents		
23 Documents required by the QMS are controlled.	✓	
24 Are records controlled according to the requirements in Control of Records?	✓	
25 Documented **PROCEDURE** exists and includes: a) approval process; b) review, update, and re-approval process; c) identification of changes and current revision status; d) documents are legible, identifiable and available where needed; e) external documents are identified and controlled; and f) obsolete documents are identified and controlled.	✓	
Control of records		
26 Records are established and controlled	✓	
27 A documented **PROCEDURE** exists that includes controls for: a) identification; b) storage and protection; c) retrieval; d) retention; and e) disposition.	✓	
28 Supplier Created Records are legible, identifiable and retrievable	✓	

Management commitment	Yes	No
29 Evidence of top management commitment includes: a) communicating importance of meeting customer, statutory, and regulatory requirements; b) establishing a quality policy; c) establishing quality objectives; d) conducting management reviews; and e) ensuring availability of resources.	✓	
Customer focus		
30 Top management ensures: a) customer requirements are determined and met; b) product conformity is measured; c) on-time delivery (OTD) performance is measured; and d) actions are taken, if planned results are not or will not be achieved.	✓	
Quality policy		
31 Top management ensures that the quality policy: a) is appropriate; b) includes a commitment to comply with requirements and continually improve the effectiveness of the QMS; c) provides a framework to establish and review its quality objectives; d) is communicated and understood; and e) is reviewed for suitability.	✓	
Quality objectives		
32 Top management ensures that quality objectives are: a) established; b) measurable; and c) consistent with the quality policy.	✓	
Quality management system planning		
33 Has top management ensured that: a) the planning of the quality management system is carried out in order to meet the requirements given, as well as the quality objectives? and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	✓	
Responsibility, authority and communication		
34 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization?	✓	
Management representative		
35 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are established, implemented and maintained? b) reporting to top management on the performance of the quality management system and any need for improvement? c) ensuring the promotion of awareness of customer requirements throughout the organization? and d) the organizational freedom to resolve matters pertaining to quality?	✓	
Internal communication		
36 Has top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system?	✓	
Management review		
37 Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?	✓	
38 Are records from management reviews maintained?	✓	

Review input	Yes	No
39 Does the input to management review include information on: a) results of audits; b) customer feedback; c) process performance and product conformity; d) status of preventive and corrective actions; e) follow-up actions from previous management reviews; f) changes that could affect the quality management system; and g) recommendations for improvement.	✓	
Review output		
40 Does the output from the management review include any decisions and actions related to: a) improvement of the effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; and c) resource needs.	✓	
Provision of resources		
41 Has the organization determined and provided the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness? And b) to enhance customer satisfaction by meeting customer requirements?	✓	
Human resources		
42 Are personnel performing work affecting product quality competent based on appropriate education, training, skills and experience?	✓	
Competence, awareness and training		
43 Does the organization: a) determine the necessary competence for personnel performing work affecting product quality? b) provide training or take other actions to satisfy these needs? c) evaluate the effectiveness of the actions taken? d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? and e) maintain appropriate records of education, training, skills and experience?	✓	
Infrastructure		
44 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements which includes the following: a) buildings, workspace and associated utilities? b) process equipment (both hardware and software)? And c) supporting services (such as transport or communication)?	✓	
Work environment		
45 Does the organization determine and manage the work environment needed to achieve conformity to product requirements?	✓	
Planning of product realization		
46 Does the organization plan and develop the processes needed for product realization?	✓	
47 In planning product realization, does the organization determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirement? e) configuration of the product; and f) the identification of resources to support operation and maintenance of the product.	✓	
48 Is the output of this planning in a form suitable for the organization's method of operations?	✓	
Project management		
49 Product realization is planned and managed in a structured and controlled manner to meet requirements at acceptable risk.	✓	

Risk management	Yes	No
50 Establish, implement, and maintain a process for managing risk.	✓	
51 Risk management includes, as appropriate: a) responsibilities for risk management; b) definition of risk criteria; c) identification, assessment, and communication of risks; d) identification, implementation, and management of actions to mitigate risks that exceed defined risk acceptance; and e) acceptance of remaining risks after implementation of mitigating actions.	✓	
Determination of requirements related to the product		
52 Does the organization determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities? b) requirements not stated by the customer but necessary for specified or intended use, where known? c) statutory and regulatory requirements related to the product? and d) any additional requirements determined by the organization?	✓	
Review of requirements related to the product		
53 Does the organization review the requirements related to the product?	✓	
54 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that: a) product requirements are defined? b) contract or order requirements differing from those previously expressed are resolved? c) the organization has the ability to meet the defined requirements? d) special product requirements are determined? And e) risks have been identified?	✓	
55 Are records of the results of the review and actions arising from the review maintained?	✓	
56 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?	✓	
57 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	✓	
Customer communication		
58 Does the organization determine and implement effective arrangements for communicating with customers in relation to: a) product information? b) enquiries, contracts or order handling, including amendments? and c) customer feedback, including customer complaints?	✓	
Design and development planning		
59 Does the organization plan and control the design and development of product?	✓	
60 During the design and development planning, does the organization determine: a) the design and development stages? b) the review, verification and validation that are appropriate to each design and development stage? and c) the responsibilities and authorities for design and development?	✓	
61 Where appropriate, the organization divides the design and development effort into distinct activities and defines the tasks, resources, responsibilities, design content, input/output data, and design constraints.	✓	
62 Design and development tasks are based on the safety and functional objectives of the product to customer, statutory, and regulatory requirements.	✓	
63 Design and development planning considers the ability to produce, inspect, test, and maintain the product.	✓	
64 Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?	✓	
65 Is planning output updated, as appropriate, as the design and development progresses?	✓	
Design and development inputs		
66 Are inputs relating to product requirements determined and are records maintained?	✓	
67 Design and development inputs include: a) functional and performance requirements? b) applicable statutory and regulatory requirements? c) where applicable, information derived from previous similar designs? and d) other requirements essential for design and development?	✓	
68 Are these inputs reviewed for adequacy?	✓	

Design and development outputs	Yes	No
69 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release?	✓	
70 Do the design and development outputs: a) meet the input requirements for design and development? b) provide appropriate information for purchasing, production and for service provision? c) contain or reference product acceptance criteria? d) specify the characteristics of the product that are essential for its safe and proper use? And e) identify key characteristics, when applicable, in accordance with design or contract requirements?	✓	
71 Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization including: a.) drawings, part lists, specifications? b.) a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product? and c.) information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product?	✓	
72 At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements to: a) evaluate the ability of the results of design and development to meet requirements? b) identify any problems and propose necessary actions? and c) authorize progression to the next stage?	✓	
73 Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed?	✓	
74 Are records of the results of the reviews and any necessary actions maintained?	✓	
75 Is verification performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements?	✓	
76 Are records of the results of the reviews and any necessary actions maintained?	✓	
Design and development validation		
77 Is design and development validation performed in accordance with planned arrangements to ensure that the resulting product can meet the requirements for the specified application or intended use, where known?	✓	
78 Are records of the results of validation and any necessary actions maintained?	✓	
79 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following: a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria? b) test procedures describe the method of operation, the performance of the test, and the recording of the results? c) the correct configuration standard of the product is submitted for the test? d) the requirements of the test plan and the test procedures are observed? And e) the acceptance criteria are met?	✓	
80 Reports, calculations, test results, etc. demonstrate product definition meets the specified requirements for all operational conditions.	✓	
Control of design and development changes		
81 Are design and development changes identified and records maintained?	✓	
82 Are the changes reviewed, verified and validated, as appropriate, and approved before implementation?	✓	
83 Records of the change reviews and any actions are maintained.	✓	
84 Design and development changes are controlled in accordance with the configuration management process.	✓	
Purchasing process		
85 Does the organization ensure that purchased product conforms to specified purchase requirements?	✓	
86 Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources?	✓	
87 Are criteria for selection, evaluation and re-evaluation established?	✓	
88 Are records of the results of evaluations and any necessary actions arising from the evaluation maintained?	✓	
89 Does the organization: a) maintain a register of approved suppliers that includes the scope of the approval? b) periodically review supplier performance? c) define the necessary actions to take when dealing with suppliers that do not meet requirements? d) ensure that the organization and all suppliers use customer-approved special process sources? e) determine and manage risk when selecting and using suppliers? and f) determine the process, responsibilities and authority for the approval status decision, changes and conditions?	✓	

Purchasing information	Yes	No
90 Does purchasing information describe the product to be purchased, including where appropriate: a) requirements for approval of product, procedures, processes and equipment? b) requirements for qualification of personnel? c) quality management system requirements? d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data? e) requirements for design, test, inspection, verification, use of statistical techniques, and related instructions for acceptance (including critical items and key characteristics)? f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing? g) requirements relative to the supplier to: - notify the organization of nonconforming product? - receive nonconforming product disposition approvals? - notify of changes to product, processes, suppliers and facilities? And - adhere to flow down requirements? h) requirements to retain records? and i) right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records?	✓	
91 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier?	✓	
Verification of purchased product		
92 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements?	✓	
93 Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure?	✓	
94 Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained?	✓	
95 Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?	✓	
Control of production and service provision		
96 Does the organization plan and carry out production and service provision under controlled conditions? Do these controlled conditions include, as applicable: a) the availability of information that describes the characteristics of the product? b) the availability of work instructions, as necessary? c) the use of suitable equipment? d) the availability and use of monitoring and measuring devices? e) the implementation of monitoring and measurement? f) the implementation of release, delivery and post-delivery activities? g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)? h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized? i) provision for the prevention, detection, and removal of foreign objects? j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality? and k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)?	✓	
97 Planning appropriately considers: a) managing critical items and key characteristics; b) measurement tooling; c) identifying in-process verification points; and d) special processes.	✓	
98 Does validation of product include verification of the first article produced to the design data/specification? (FAI)	✓	
Post-delivery support		
99 Post-delivery support includes: a) a method of collecting and analyzing in-service data? b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements? c) the control and updating of technical documentation? d) the approval, control, and use of repair schemes? and e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities)?	✓	

Validation of processes for production and service provision	Yes	No
Note:These processes are frequently referred to as special processes.		
100 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, including any processes where deficiencies become apparent only after the product is in use or the service has been delivered)?	✓	
101 Does validation demonstrate the ability of these processes to achieve planned results?	✓	
102 Has the organization established arrangements for these processes including, as applicable: a) defined criteria for review and approval of the processes? b) approval of equipment and qualification of personnel? c) use of specific methods and procedures? d) requirements for records? and e) revalidation?	✓	
Identification and traceability		
103 Where appropriate, has the organization identified the product by suitable means throughout product realization?	✓	
104 Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration?	✓	
105 Has the organization identified the product status throughout product realization?	✓	
106 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media?	✓	
107 Where traceability is a requirement, does the organization control and record the unique identification of the product?	✓	
Customer property		
108 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product?	✓	
109 Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer?	✓	
Preservation of product		
110 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?	✓	
111 Does the preservation include identification, handling, packaging, storage and protection?	✓	
112 Does preservation also apply to the constituent parts of a product?	✓	
113 Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for: a) cleaning? b) prevention, detection and removal of foreign objects? c) special handling for sensitive products? d) marking and labeling including safety warnings? e) shelf life control and stock rotation? and f) special handling for hazardous materials?	✓	
Control of monitoring and measuring devices		
114 Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements?	✓	
115 Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria?	✓	
116 Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?	✓	
117 Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out?	✓	
118 Where necessary to ensure valid results, is measuring equipment: a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded? b) adjusted or re-adjusted as necessary? c) identified to enable the calibration status to be determined? d) safeguarded from adjustments that would invalidate the measurement result? and e) protected from damage and deterioration during handling, maintenance and storage?	✓	
119 Monitoring and measurement equipment calibration (and/or verification) recall process exists.	✓	
120 Previous results are assessed, recorded, and acted upon when M&M equipment is found out-of-conformance.	✓	
121 Are records of the results of calibration and verification maintained?	✓	
122 Software used for monitoring and measurement is confirmed before initial use and reconfirmed, as necessary.	✓	

MEASUREMENT, ANALYSIS AND IMPROVEMENT	Yes	No
123 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed: a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system? and c) to continually improve the effectiveness of the quality management system?	✓	
124 Does this include determination of applicable methods, including statistical techniques, and the extent of their use?	✓	
Customer satisfaction		
125 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements?	✓	
126 Customer satisfaction information includes product conformity, on-time delivery (OTD), customer complaints, and corrective action requests.	✓	
127 Improvement plans to address customer satisfaction deficiencies are in place.	✓	
Internal audit		
128 Does the organization conduct internal audits at planned intervals to determine whether the QMS: a) conforms to the planned arrangements, to the requirements of applicable International Standards and to the quality management system requirements established by the organization? and b) is effectively implemented and maintained?	✓	
129 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?	✓	
130 Is the audit criteria, scope, frequency and methods defined?	✓	
131 Does the organization ensure internal auditors do not audit their own work?	✓	
132 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in a documented procedure?	✓	
133 Audit records are maintained.	✓	
134 Does the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?	✓	
135 Do follow-up activities include the verification of the actions taken and the reporting of verification results?	✓	
Monitoring and measurement of processes		
136 Does the organization apply suitable methods for monitoring and measurement of the QMS processes?	✓	
137 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?	✓	
138 In the event of process nonconformity, does the organization: a) take appropriate action to correct the nonconforming process? b) evaluate whether the process nonconformity has resulted in product nonconformity? c) determine the effect on other processes or products? and d) identify and control the nonconforming product?	✓	
Monitoring and measurement of product		
139 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?	✓	
140 Acceptance measurement requirements are documented and include: a) criteria for acceptance and/or rejection; b) where in the sequence measurement and testing operations are performed; c) a record of the measurement results; and d) type of measurement instruments required and any specific instructions associated with their use.	✓	
141 When key characteristics have been identified, are they monitored and controlled?	✓	
142 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use?	✓	
143 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities?	✓	
144 Do records indicate the person(s) authorizing release of product?	✓	
145 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements?	✓	
146 Is product release and service delivery held until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?	✓	
147 Documents required to accompany the product are present at delivery.	✓	

Control of nonconforming product	Yes	No
148 Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery?	✓	
149 Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure?	✓	
150 Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions?	✓	
151 The process for approving personnel making these decisions is defined.	✓	
152 Does the organization deal with nonconforming product in one or more of the following ways by: a) taking action to eliminate the detected nonconformity? b) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer? c) taking action to preclude its original intended use or application? and d) taking action to contain the nonconformity effect on other processes or products.	✓	
153 Dispositions of use-as-is (UAI) or repair is used only after approval from design responsible organizations.	✓	
154 Dispositions of UAI or repair are not used without customer authorization.	✓	
155 Is product disposition for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable?	✓	
156 When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements?	✓	
157 Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained?	✓	
Analysis of data		
158 Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made?	✓	
159 Does the analysis of data provide information relating to: a) customer satisfaction? b) conformity to product requirements? c) characteristics and trends of processes and products including opportunities for preventive action? and d) suppliers?	✓	
Continual improvement		
160 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	✓	
161 Improvements and the evaluation of effectiveness are monitored.	✓	
Corrective action		
162 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?	✓	
163 Is a documented procedure established to define requirements for: a) reviewing nonconformities (including customer complaints)? b) determining the causes of nonconformities? c) evaluating the need for action to ensure that nonconformities do not recur? d) determining and implementing action needed? e) recording of the results of the action taken? f) reviewing corrective action taken? g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause? h) specific actions where timely and/or effective corrective actions are not achieved? And i) determining if additional nonconforming product exists.	✓	