



**Quality System Self Evaluation – October 1, 2024**

**Company Name:** Anodyne Electronics Manufacturing Corp. (AEM)  
**Address:** #100 – 966 Crowley Avenue  
Kelowna, BC CANADA V1Y 0L1

**Phone:** 1-250-763-1088      **Company Website:** [www.aem-corp.com](http://www.aem-corp.com)

**Starting Business Year:** 2009      **TAX ID Number:** 85600 7893

**DUNS Number:** 243884199      **GST Number:** 856-007-893 RT0001

**NCAGE Code:** L9015      **PST Number:** 1001-2450

**Company Email:** [info@aem-corp.com](mailto: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 / Intertek, CERT-0148536. Workmanship Certified to J-STD-001, IPC-A-610, and IPC-7711/21.

**Approvals Held:** Transport Canada Manufacturing Approval Certificate #91-09.  
Transport Canada Approved Maintenance Organization Certificate #91-09.  
Japan Civil Aviation Bureau (JCAB) Approval.  
Controlled Goods (Canadian ITAR Equivalent) Certificate #25649.

**Key Personnel:** Taylor Wylie – COO – [taylor.wylie@aem-corp.com](mailto:taylor.wylie@aem-corp.com)  
Tony Weller – Sales & Marketing Director – [tony.weller@aem-corp.com](mailto:tony.weller@aem-corp.com)  
Monty McEwen – QA Director – [monty.mcewen@aem-corp.com](mailto:monty.mcewen@aem-corp.com)  
Omar Mwangari – Manufacturing Director – [omar.mwangari@aem-corp.com](mailto:omar.mwangari@aem-corp.com)

**Contact Personnel:** Quality – Frank Vivent – [frank.vivent@aem-corp.com](mailto:frank.vivent@aem-corp.com)  
Technical Support – Nathan Meade – [nathan.meade@aem-corp.com](mailto:nathan.meade@aem-corp.com)  
Accounts – Darlene Arbez – [darlene.arbez@aem-corp.com](mailto:darlene.arbez@aem-corp.com)

**Facility Size:** 1 Building, 35,000-sq.ft. (3250 sq.m.)

**Employees:** Total: 120    Quality: 10

**Product:** Design, development, manufacture and maintenance of airborne communication equipment, PA systems, illuminated panels, integrated keyboards, caution / warning panels, and structural monitoring systems.

**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.

Monty McEwen, QA Director  
Anodyne Electronics Manufacturing (AEM)

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Anodyne Electronics Manufacturing Corp. (AEM)

Main Site: #100-966 Crowley Ave.; Kelowna; British Columbia (Colombie-Britannique) V1Y 0L1; Canada

Has been audited and registered by Intertek as meeting the requirements of the standard:

## AS9100:D and ISO 9001:2015

The management system is applicable to:

Site Scope: Design, development, manufacture, and maintenance of airborne communication equipment, PA systems, illuminated panels, integrated keyboards, caution/warning panels, and structural monitoring systems.

**Certificate Number**

CERT-0148536

**Initial Certification Date**

05 November 2010

**Certificate Issue Date**

12 November 2022

**Certificate Reissue Date**

30 September 2024

**Certificate Expiry Date**

11 November 2025



intertek

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc. dba Intertek  
4700 Broadmoor Avenue S.E.,  
Kentwood, MI, USA



The assessment was performed in accordance with the requirements of AS9104/1:2012-01. Intertek is accredited under the Aerospace Registrar Management Program and IAQG ICOT scheme. In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-AS9100\_2009-AS9104\_1-ANAB-EN-LT-P-01.jul.17





## Certificate of Approval / Certificat d'agrément

This is to certify that / Nous certifions que l'organisme

**Anodyne Electronics Manufacturing Corp.**

*whose place of business is located at / dont le lieu d'affaires se trouve*

**#100 - 966 Crowley Avenue, Kelowna, BC**

## Approved Organization / Organisme agréé

**91-09**


is approved pursuant to CAR 561 for the / est agréé en vertu de la  
sous-partie 561 du RAC, en ce qui a trait à la

**MANUFACTURE and CERTIFICATION of /  
CONSTRUCTION et la CERTIFICATION de:**

**Aeronautical Products / Produits aéronautiques**

specified in the respective Approval Limitation Records that accompany  
this certificate / tel qu'il est spécifié dans la fiche de restriction d'agrément  
qui accompagne ce certificat.

Signed / Signature: \_\_\_\_\_

  
C. Taylor  
For the Minister of Transport / Pour le Ministre des transports

Dated / Daté: 2022-07-27

Supersedes certificate dated / Remplace le certificat daté du: 2010-07-26

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

**Canada**

26-0761 (1003-01)



Approval Limitation Record / Fiche de restriction d'agrément
- Aeronautical Product / Produit aéronautique -
- Sub Assemblies and Parts / Sous-ensembles et pièces -

Anodyne Electronics Manufacturing Corp.

the holder of Certificate of Approval Number / Le titulaire du certificat d'agrément n°: 91-09

is limited to the manufacture and certification of the following Aeronautical Products /
peut construire et certifier uniquement les produits aéronautiques énumérés ci-dessous:

Table with 4 columns: Product / Produit, Model / Part Number / Modèle / Pièce n°, Approval Number / N° d'homologation, Effective Date / Mise en vigueur. Row 1: 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

Date of Issue / Date de délivrance: 2022-07-27

Signed / Signature: [Handwritten Signature]

Supersedes certificate dated / Remplace la liste datée du:

C. Taylor
For the Minister of Transport / Pour le Ministre des transports





## Certificate of Approval / Certificat d'agrément

This is to certify that / Nous certifions que

**Anodyne Electronics Manufacturing Corp.**

Of / de

**Kelowna, BC**

### Approved Maintenance Organization /

### Organisme de maintenance agréé

**91-09**

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

est autorisé en vertu du RAC 573.02 à effectuer la maintenance des produits aéronautiques, et possède des spécialités dans les catégories suivantes:

**Avionics / Avionique**

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.

L'étendue des avantages applicables à chaque catégorie se limite à ce qui est indiqué dans les documents pertinents aux spécialités qui accompagnent le présent certificat; et est conditionnelle au respect des procédures et des limites agréés énoncées dans le manuel de politiques de maintenance de l'organisme.

Date of Issue /  
Date de délivrance: 2022-07-27

Signed/  
Signature:   
C. Taylor

Supersedes certificate dated/  
Remplace la liste datée du: 2022-06-30

For the Minister of Transport/Pour le Ministre des transports

**Canada**

26-0761 (1003-01)



Approved Maintenance Organization Ratings /  
Spécialités d'organisme de maintenance agréé

– Avionics Category / Catégorie avionique –

*Anodyne Electronics Manufacturing Corp.*

Approved Maintenance Organization / Organisme de maintenance agréé

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.

est autorisé à effectuer des travaux de maintenance, sur des systèmes et de l'équipement avioniques appartenant aux types énumérés ci-dessous, pourvu que les travaux se limitent à la portée des travaux indiqués et sous réserve de toute limite additionnelle énoncée dans le manuel de politiques de maintenance.

Rating / Spécialité	Scope of work / Portée des travaux	Effective Date / Mise en vigueur
Radio systems / Systèmes radio	As specified in company manual / Selon ce qui est prévu dans le manuel de la compagnie	2009-09-25

Date of Issue /  
Date de délivrance: 2022-06-30

Signed/  
Signature:   
C. Taylor

Supersedes certificate dated/  
Remplace la liste datée du: 2017-06-08

For the Minister of Transport/Pour le Ministre des transports







UNCLASSIFIED / NON CLASSIFIÉ



Transport Canada Transports Canada



Transport Canada Civil Aviation  
Standards Branch (AARTM)  
330 Sparks Street  
Ottawa, ON K1A 0N5  
Canada

Company File  
5015 – 17219  
AMO Number  
91-09

2023-03-14

Monty McEwen  
Anodyne Electronics Manufacturing Corp  
Electronics Manufacturing Corp. (AEM)  
#100 - 966 Crowley Avenue  
Kelowna, British Columbia, CANADA  
V1Y 0L1

**Civil Aviation Bureau, Ministry of Land, Infrastructure, Transport and Tourism of Japan  
Supplement Approval (JCAB) in accordance with the Technical Arrangement for  
Maintenance**

Dear Mr. McEwen,

Following review of the elements contained in the JCAB supplement to your organization's approved Maintenance Policy Manual (MPM), and in accordance with the current Technical Arrangement for Maintenance (TA-M) between Transport Canada Civil Aviation (TCCA) and the JCAB, TCCA hereby confirms the initial approval of the JCAB supplement for the performance of maintenance on civilian aeronautical components under the regulatory control of JCAB.

The maintenance of the civilian aeronautical components under the regulatory control of JCAB will not exceed the organization's CAR 573 AMO certificate scope of ratings and limitations.

Your JCAB supplement dated 11-October 2022 at Revision 1.00, is hereby approved and is valid until 14-March 2025.

You are reminded that you will be required to submit your next application for continuance in accordance with the TA-M which is available on the Transport Canada website at:

<http://www.tc.gc.ca/eng/civilaviation/standards/technical-arrangement-maintenance-between-civil-aviation-bureau-ministry-land-infrastructure-transport-tourism-japan-transport-canada-civil-aviation.html>

Best Regards,

Craig Dennis  
Civil Aviation Safety Inspector, Operational Airworthiness  
Approved Organization Standards / Standards Branch



 Travaux publics et Services gouvernementaux Canada

Public Works and Government Services Canada



Controlled Goods Program

Programme des marchandises contrôlées



# Certificat *d'inscription accordé à*

# Certificate *of Registration issued to*

## ANODYNE ELECTRONICS MANUFACTURING CORP.

*Exercent ses activités sous le nom / Carrying on business as*

Le présent certificat confirme votre inscription au Programme des marchandises contrôlées. Votre inscription est assujettie à des conditions réglementaires et aux conditions énoncées par le ministre dans le document "Conditions de l'inscription".

This certificate confirms your registration with the Controlled Goods Program subject to conditions prescribed by regulations and any other conditions set out by the Minister in the "Conditions of Registration" document.

N° de certificat / Certificate No. 25649

Entrée en vigueur / Issued 2021/06/14

Date d'expiration / Expires 2026/03/14

Émis par le ministre en vertu de la Loi sur la production de défense  
Issued by the Minister pursuant to the Defence Production Act

  
Gestionaire / Manager







**QUALITY SYSTEM QUESTIONNAIRE**

**Quality Management System**

		Yes	No
<b>GENERAL REQUIREMENTS</b>			
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.	✓	
<b>DOCUMENTATION REQUIREMENTS</b>			
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.	✓	
<b>QUALITY MANUAL</b>			
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.	✓	
<b>CONTROL OF DOCUMENTS</b>			
23	Documents required by the QMS are controlled.	✓	
24	Are records controlled according to the requirements in Control of Records?	✓	
25	Documented <b>PROCEDURE</b> 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.	✓	



		Yes	No
<b>CONTROL OF RECORDS</b>			
26	Records are established and controlled	✓	
27	A documented <b>PROCEDURE</b> 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	✓	
<b>MANAGEMENT COMMITMENT</b>			
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.	✓	
<b>CUSTOMER FOCUS</b>			
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.	✓	
<b>QUALITY POLICY</b>			
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.	✓	
<b>QUALITY OBJECTIVES</b>			
32	Top management ensures that quality objectives are: a) established; b) measurable; and c) consistent with the quality policy.	✓	
<b>QUALITY MANAGEMENT SYSTEM PLANNING</b>			
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?	✓	
<b>RESPONSIBILITY, AUTHORITY AND COMMUNICATION</b>			
34	Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization?	✓	



		Yes	No
<b>MANAGEMENT REPRESENTATIVE</b>			
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?	✓	
<b>INTERNAL COMMUNICATION</b>			
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?	✓	
<b>MANAGEMENT REVIEW</b>			
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?	✓	
<b>REVIEW INPUT</b>			
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.	✓	
<b>REVIEW OUTPUT</b>			
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.	✓	
<b>PROVISION OF RESOURCES</b>			
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?	✓	
<b>HUMAN RESOURCES</b>			
42	Are personnel performing work affecting product quality competent based on appropriate education, training, skills and experience?	✓	
<b>COMPETENCE, AWARENESS AND TRAINING</b>			
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?	✓	



		Yes	No
<b>INFRASTRUCTURE</b>			
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)?	✓	
<b>WORK ENVIRONMENT</b>			
45	Does the organization determine and manage the work environment needed to achieve conformity to product requirements?	✓	
<b>PLANNING OF PRODUCT REALIZATION</b>			
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?	✓	
<b>PROJECT MANAGEMENT</b>			
49	Product realization is planned and managed in a structured and controlled manner to meet requirements at acceptable risk.	✓	
<b>RISK MANAGEMENT</b>			
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.	✓	
<b>DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT</b>			
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?	✓	
<b>REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT</b>			
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?	✓	



		Yes	No
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?	✓	
<b>CUSTOMER COMMUNICATION</b>			
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?	✓	
<b>DESIGN AND DEVELOPMENT PLANNING</b>			
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?	✓	
<b>DESIGN AND DEVELOPMENT INPUTS</b>			
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?	✓	
<b>DESIGN AND DEVELOPMENT OUTPUTS</b>			
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?	✓	





		Yes	No
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?	✓	
<b>DESIGN AND DEVELOPMENT VALIDATION</b>			
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.	✓	
<b>CONTROL OF DESIGN AND DEVELOPMENT CHANGES</b>			
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.	✓	
<b>PURCHASING PROCESS</b>			
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?	✓	



		Yes	No
<b>PURCHASING INFORMATION</b>			
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?	✓	
<b>VERIFICATION OF PURCHASED PRODUCT</b>			
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?	✓	
<b>CONTROL OF PRODUCTION AND SERVICE PROVISION</b>			
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.	✓	



	Yes	No
98 Does validation of product include verification of the first article produced to the design data/specification? (FAI)	✓	
<b>POST-DELIVERY SUPPORT</b>		
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) e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities)?	✓	
<b>VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION</b>		
<b>Note:</b> 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?	✓	
<b>IDENTIFICATION AND TRACEABILITY</b>		
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?	✓	
<b>CUSTOMER PROPERTY</b>		
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?	✓	
<b>PRESERVATION OF PRODUCT</b>		
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?	✓	



	Yes	No
<b>CONTROL OF MONITORING AND MEASURING DEVICES</b>		
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: <ul style="list-style-type: none"> <li>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?</li> <li>b) adjusted or re-adjusted as necessary?</li> <li>c) identified to enable the calibration status to be determined?</li> <li>d) safeguarded from adjustments that would invalidate the measurement result? and</li> <li>e) protected from damage and deterioration during handling, maintenance and storage?</li> </ul>	✓	
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.	✓	
<b>MEASUREMENT, ANALYSIS AND IMPROVEMENT</b>		
123 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed: <ul style="list-style-type: none"> <li>a) to demonstrate conformity of the product?</li> <li>b) to ensure conformity of the quality management system? and</li> <li>c) to continually improve the effectiveness of the quality management system?</li> </ul>	✓	
124 Does this include determination of applicable methods, including statistical techniques, and the extent of their use?	✓	
<b>CUSTOMER SATISFACTION</b>		
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.	✓	
<b>INTERNAL AUDIT</b>		
128 Does the organization conduct internal audits at planned intervals to determine whether the QMS: <ul style="list-style-type: none"> <li>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</li> <li>b) is effectively implemented and maintained?</li> </ul>	✓	
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.	✓	



	Yes	No
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?	✓	
<b>MONITORING AND MEASUREMENT OF PROCESSES</b>		
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?	✓	
<b>MONITORING AND MEASUREMENT OF PRODUCT</b>		
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.	✓	
<b>CONTROL OF NONCONFORMING PRODUCT</b>		
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.	✓	





	Yes	No
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?	✓	
<b>ANALYSIS OF DATA</b>		
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?	✓	
<b>CONTINUAL IMPROVEMENT</b>		
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.	✓	
<b>CORRECTIVE ACTION</b>		
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.	✓	